IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BAXTER HEALTHCARE CORPORATION and GAMBRO LUNDIA AB, Plaintiffs, v. B. BRAUN MEDICAL INC. and B. BRAUN AVITUM AG, Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Baxter Healthcare Corporation and Gambro Lundia AB (collectively "Baxter") file this complaint for patent infringement against Defendants B. Braun Medical Inc. and B. Braun Avitum AG (collectively "B.Braun"), and in support thereof alleges and avers as follows:

THE PARTIES

1. Plaintiff Baxter Healthcare Corporation is a Delaware corporation with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

2. Plaintiff Gambro Lundia AB is a Swedish corporation headquartered at Magistratsvägen 16 226 43 Lund, Sweden, and doing business through its subsidiary Gambro Renal Products, Inc., located at One Baxter Parkway, Deerfield, Illinois 60015.

3. On information and belief, Defendant B. Braun Medical Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 824 Twelfth Avenue, Bethlehem, Pennsylvania 18018.

4. On information and belief, Defendant B. Braun Avitum AG is a German corporation headquartered at Schwarzenberger Weg 73 – 79, 34212 Melsungen, Germany, and doing business through its subsidiary B. Braun Medical Inc. located at 901 Marcon Boulevard, Allentown, Pennsylvania 18109.

NATURE OF THE ACTION

5. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271, based on B.Braun's infringement of U.S. Patent No. 6,887,214 (Exhibit A); U.S. Patent No. 7,232,418 (Exhibit B); U.S. Patent No. 7,314,554 (Exhibit C); U.S. Patent No. 7,727,391 (Exhibit D); U.S. Patent No. 7,867,393 (Exhibit E); U.S. Patent No. 8,267,308 (Exhibit F); and U.S. Patent No. 8,459,543 (Exhibit G) (collectively, the "Patents-in-Suit").

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because the claims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271.

7. This Court has personal jurisdiction over B.Braun because B.Braun has continuous and systematic contacts with the Commonwealth of Pennsylvania.

8. In particular, B. Braun Medical Inc. maintains its principal place of business in Bethlehem, Pennsylvania, and thereby has purposefully availed itself of the benefits and protections of the laws of the Commonwealth of Pennsylvania.

9. Additionally, B. Braun Avitum AG is doing business through its subsidiary B.Braun Medical Inc. in Allentown, Pennsylvania, and thereby has purposefully availed itself of the benefits and protections of the laws of the Commonwealth of Pennsylvania.

10. Venue is proper in this district under 28 U.S.C. § 1400(b).

11. In particular, B. Braun Medical Inc., through its principal place of business in Bethlehem, has a regular and established place of business in the Eastern District of Pennsylvania.

12. Additionally, B. Braun Avitum AG, has a regular and established place of business in the Eastern District of Pennsylvania through its subsidiary B. Braun Medical Inc.

13. The accused infringing product is B.Braun's OMNI® system.

14. On information and belief, B.Braun has imported OMNI® into the United States.

15. On information and belief, B.Braun has used OMNI® in the United States.

THE PATENTS-IN-SUIT

16. U.S. Patent No. 6,887,214 ("'214 Patent"), titled "Blood pump having a disposable blood passage cartridge with integrated pressure sensors," was issued by the United States Patent and Trademark Office ("USPTO") on May 3, 2005. Gambro Lundia AB is the lawful owner by assignment of the '214 Patent. Baxter Healthcare Corporation holds an implied exclusive license to the '214 Patent. Collectively, Baxter holds all right, title and interest in the '214 Patent, including the right to sue for patent infringement and damages, including past damages. A true and correct copy of the '214 Patent is attached hereto as Exhibit A.

17. U.S. Patent No. 7,232,418 ("'418 Patent"), titled "Support element, an integrated module for extracorporeal blood treatment comprising the support element, an apparatus for extracorporeal blood treatment equipped with the integrated module, and an assembly process for an integrated module for extracorporeal blood treatment," was issued by the USPTO on June 19, 2007. Gambro Lundia AB is the lawful owner by assignment of the '418 Patent. Baxter Healthcare Corporation holds an implied exclusive license to the '418 Patent. Collectively, Baxter holds all right, title and interest in the '418 Patent, including the right to sue for patent

infringement and damages, including past damages. A true and correct copy of the ‘418 Patent is attached hereto as Exhibit B.

18. U.S. Patent No. 7,314,554 (“‘554 Patent”), titled “Extracorporeal blood treatment machine,” was issued by the USPTO on January 1, 2008. Gambro Lundia AB is the lawful owner by assignment of the ‘554 Patent. Baxter Healthcare Corporation holds an implied exclusive license to the ‘554 Patent. Collectively, Baxter holds all right, title and interest in the ‘554 Patent, including the right to sue for patent infringement and damages, including past damages. A true and correct copy of the ‘554 Patent is attached hereto as Exhibit C.

19. U.S. Patent No. 7,727,391 (“‘391 Patent”), titled “Extracorporeal blood treatment machine,” was issued by the USPTO on June 1, 2010. Gambro Lundia AB is the lawful owner by assignment of the ‘391 Patent. Baxter Healthcare Corporation holds an implied exclusive license to the ‘391 Patent. Collectively, Baxter holds all right, title and interest in the ‘391 Patent, including the right to sue for patent infringement and damages, including past damages. A true and correct copy of the ‘391 Patent is attached hereto as Exhibit D.

20. U.S. Patent No. 7,867,393 (“‘393 Patent”), titled “Integrated module for blood treatment,” was issued by the USPTO on January 11, 2011. Gambro Lundia AB is the lawful owner by assignment of the ‘393 Patent. Baxter Healthcare Corporation holds an implied exclusive license to the ‘393 Patent. Collectively, Baxter holds all right, title and interest in the ‘393 Patent, including the right to sue for patent infringement and damages, including past damages. A true and correct copy of the ‘393 Patent is attached hereto as Exhibit E.

21. U.S. Patent No. 8,267,308 (“‘308 Patent”), titled “Fluid processing medical apparatus and method for setting-up a fluid processing medical apparatus,” was issued by the USPTO on September 18, 2012. Gambro Lundia AB is the lawful owner by assignment of the

‘308 Patent. Baxter Healthcare Corporation holds an implied exclusive license to the ‘308 Patent. Collectively, Baxter holds all right, title and interest in the ‘308 Patent, including the right to sue for patent infringement and damages, including past damages. A true and correct copy of the ‘308 Patent is attached hereto as Exhibit F.

22. U.S. Patent No. 8,459,543 (“‘543 Patent”), titled “Fluid processing medical apparatus and method for setting-up a fluid processing medical apparatus,” was issued by the USPTO on June 11, 2013. Gambro Lundia AB is the lawful owner by assignment of the ‘543 Patent. Baxter Healthcare Corporation holds an implied exclusive license to the ‘543 Patent. Collectively, Baxter holds all right, title and interest in the ‘543 Patent, including the right to sue for patent infringement and damages, including past damages. A true and correct copy of the ‘543 Patent is attached hereto as Exhibit G.

FACTUAL BACKGROUND

23. Acute kidney injury (“AKI”) is an abrupt or rapid decline in renal filtration function. It can range from minor loss of kidney function to complete kidney failure. Unlike chronic kidney disease, which occurs slowly over time, AKI often occurs in hospitalized patients treated in an intensive care environment, and it typically occurs over a few hours to a few days.

24. AKI generally occurs because of decreased kidney blood flow (kidney ischemia) which causes damage to the kidney tissue. Kidney ischemia can result from low blood pressure, exposure to substances harmful to the kidney, an inflammatory process in the kidney, or an obstruction of the urinary tract that impedes the flow of urine.

25. AKI causes a build-up of waste products in the blood and makes it hard for the kidneys to keep the right balance of fluid in the body. Without quick treatment, abnormal levels of salts and chemicals can build up in the body, which affects the ability of other body organs to

work properly. If the kidneys shut down completely, this may require temporary support from a dialysis machine, and may lead to death.

26. AKI may lead to a number of complications, including metabolic acidosis, high potassium levels, uremia, changes in body fluid balance, effects on other organ systems, and death. People who have experienced AKI may have an increased risk of chronic kidney disease in the future.

27. AKI is diagnosed on the basis of characteristic laboratory findings, such as elevated blood urea nitrogen and creatinine, or inability of the kidneys to produce sufficient amounts of urine. Management includes treatment of the underlying cause and supportive care, such as renal replacement therapy.

28. Acute renal therapy is a term that covers multiple therapy types.

29. The goals of acute renal treatments are the removal of waste products, restoration of acid-base balance, correction of electrolyte imbalances (e.g., hyperkalemia), patient fluid balance, nutritional support, and other conditions in which fluid removal is needed.

30. Two of the most common types of acute renal therapy are (1) continuous renal replacement therapy ("CRRT") and (2) therapeutic plasma exchange ("TPE").

31. CRRT is a dialysis modality used to treat critically ill, hospitalized patients in the intensive care unit who develop AKI. CRRT is a slow form of hemodialysis where the patient's blood is removed and pumped through a hemofilter, which resembles a dialyzer.

32. TPE is a treatment that removes plasma from the blood. The removed plasma is then replaced with a substitute.

Baxter's CRRT Solution

33. Baxter is a leading manufacturer of products for CRRT.

34. Baxter's PRISMAFLEX® System is a flexible, filter-based solution that meets the demands of multiple therapies with a versatile platform that can be customized to specific patient needs.

35. The PRISMAFLEX® System pumps blood from the patient through a filter and back into the patient's circulatory system. As the blood passes through the filter, the desired treatment processes take place. Depending on the therapy, the processes can include fluid removal, hemofiltration or plasma exchange.

36. The PRISMAFLEX® System delivers slow, continuous 24-hour treatment for, among other things, metabolic control; fluid removal; acid/base control; and electrolyte balance.

37. The PRISMAFLEX® System offers four CRRT options: Continuous Veno-Venous Hemodiafiltration ("CVVHDF"); Continuous Veno-Venous Hemodialysis ("CVVHD"); Continuous Veno-Venous Hemofiltration ("CVVH"); and Slow Continuous Ultrafiltration ("SCUF").

38. The PRISMAFLEX® System also can be used for TPE without additional equipment. During TPE, plasma is removed and pumped through the large-pore membrane of the plasma filter, while a colloid solution, such as albumin and/or plasma, or a combination of crystalloid/colloid solution is infused post-plasma filter to replace the removed plasma.

39. The PRISMAFLEX® System provides automated and integrated anticoagulation options through the fifth fluid pump (pre-blood pump) and syringe pump.

40. The PRISMAFLEX® System eliminates the need for manual dose programming of ancillary pumps outside the system. The PRISMAFLEX® System also allows for easier dose tracking.

41. The PRISMAFLEX® System features a highly accurate, scale-based fluid management system and provides fluid removal accuracy through algorithms and self-calibrating fluid scales.

42. The PRISMAFLEX® System monitors accumulated fluid balance/imbalance and adjusts accordingly to help reduce risk of patient injury.

43. PrisMAX® is Baxter's next generation CRRT platform. Baxter's 510(k) to market PrisMAX® was approved by the FDA on May 3, 2017.

44. Baxter Healthcare Corporation has an implied exclusive sublicense under the Patents-in-Suit to distribute the PRISMAFLEX® and PrisMAX® systems in the United States.

B.Braun's Infringing Products

45. The B.Braun Avitum Division handles products and services related to extracorporeal blood treatment, including those relating to acute blood purification.

46. B.Braun currently offers two machines for CRRT: OMNI® and Diapact® CRRT.

47. B.Braun imported into the United States at least one OMNI® device manufactured in Germany, which was then displayed in operation, showing the use thereof, at the American Society of Nephrology Kidney Week trade show on November 3, 2017, in New Orleans, Louisiana.

48. OMNI® has a full spectrum of therapy, dilution and anticoagulation modes.

(OMNI: The Reinvention of Acute Blood Purification, B.Braun, *available at* https://www.bbraun.com/content/dam/catalog/bbraun/bbraunProductCatalog/S/AEM2015/en-01/b3/omni.pdf.bb-.19724193/omni.pdf (last visited 1/10/2018) ("OMNI® Brochure") at 5).

49. OMNI® can perform four CRRT options: CVVHDF, CVVHD, CVVH, and SCUF. (*Id.*).

50. OMNI® can also perform TPE. (*Id.*).

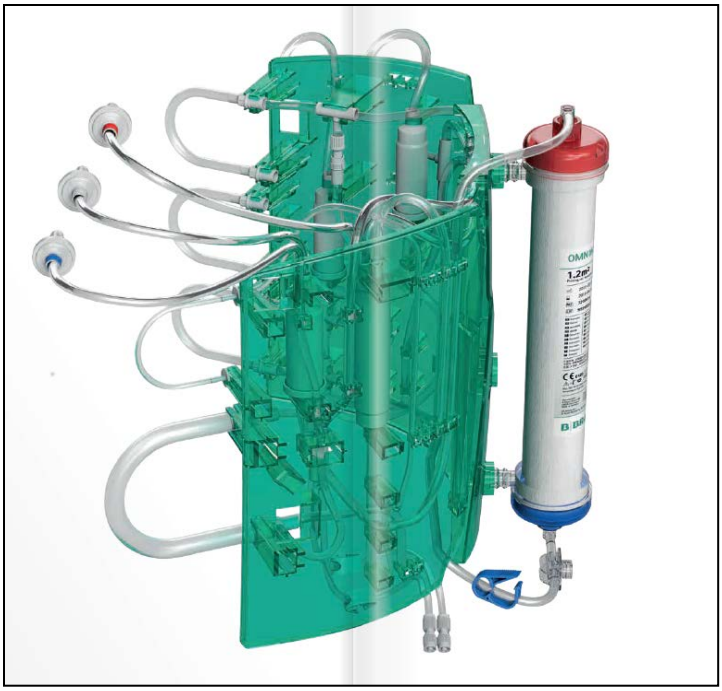
51. OMNI® includes a fully preconnected OMNIset®. (*Id.*).

52. OMNIset® can be scanned by the barcode scanner; snapped into OMNI®; and then loaded and primed automatically:

(*Id.*).

53. OMNI® also includes a fully, preconnected OMNIfilter®. (*Id.*).

54. OMNIfilter® is designed to reduce setup, loading and priming workloads:

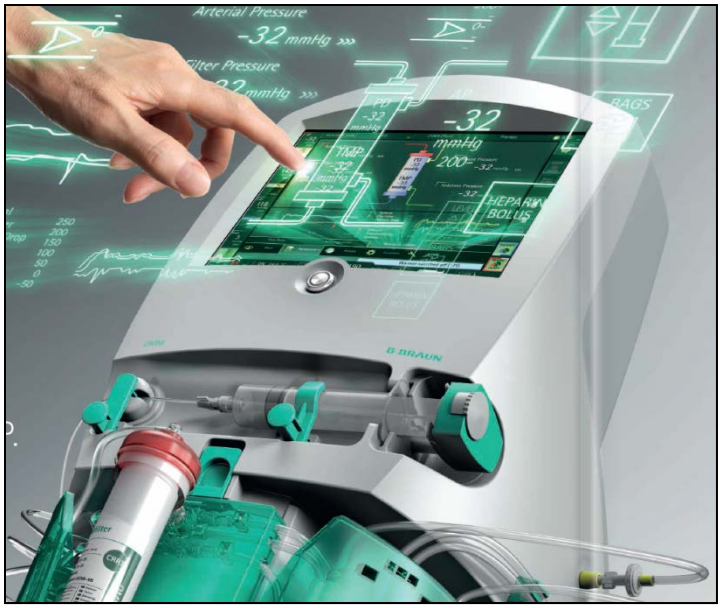


(*Id.*).

55. OMNI® includes a 12" touchscreen that provides a user interface. (*Id.* at 6).

56. OMNI® sounds audible alarms that help the user safely follow treatment, change the bag, or troubleshoot. (*Id.*).

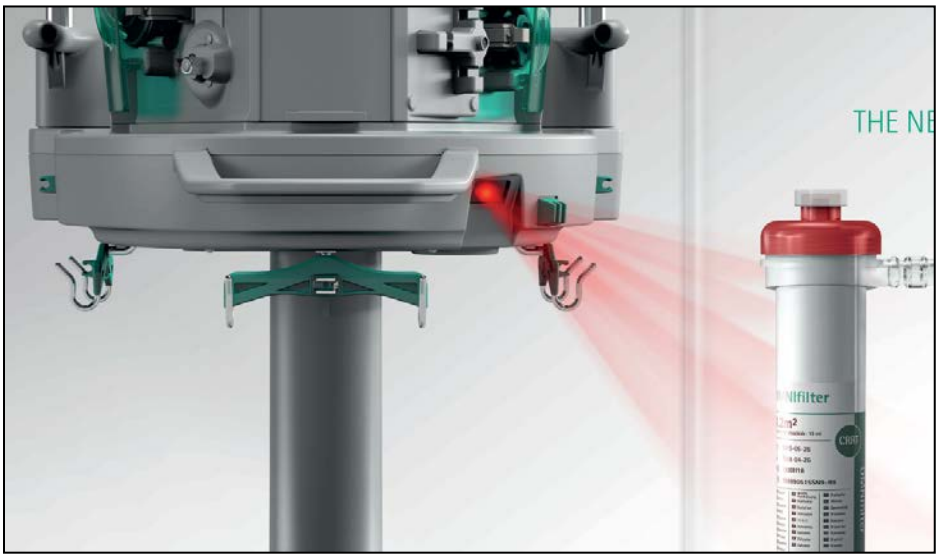
57. OMNI® can communicate with the ICU's patient monitoring system to enable rapid response if any alarms occur:



(*Id.*).

58. OMNI® includes a barcode scanner. (*Id.* at 8).

59. The OMNI® barcode scanner is designed for use when setting up and replacing the filters to ensure that setup errors are avoided and expired filters are not introduced into the system:



(*Id.*).

COUNT I
INFRINGEMENT OF THE ‘214 PATENT

60. Baxter incorporates by reference the allegations in Paragraphs 1 through 59 above.

61. The ‘214 Patent is directed to an “integrated disposable cartridge for dialysis or ultrafiltration treatment of blood . . . that includes integral miniature pressure sensors.” (Ex. A, ‘214 Patent at Abstract). The integrated disposable cartridge contains a blood cartridge housing and a separate filtrate cartridge housing where the blood filter is integrated with the blood path tubing to and from the patient. (*Id*. at 5:4–5).

62. B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed at least claim 25 of the ‘214 Patent, either literally or under the doctrine of equivalents, by using and/or importing OMNI® in the United States.

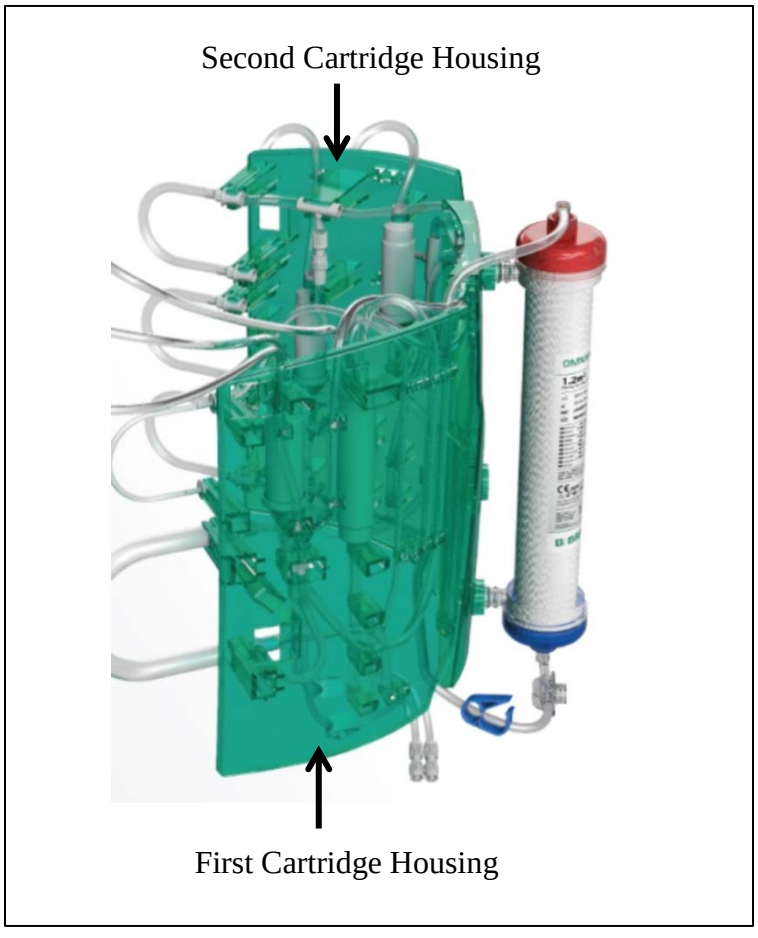
63. For example, B.Braun has infringed claim 25 of the ‘214 Patent, which recites as follows:

> 25. A disposable extracorporeal blood circuit for processing blood from a mammal and attachable to a blood treatment device having a blood pump and a filtrate pump, said blood circuit comprising:
>
> a blood passage having a blood withdrawal port connectable to a vascular system of the mammal, a blood return port connectable to the vascular system, and a blood passage between the withdrawal port and the return port through which blood flows wherein the blood passage has a smooth and continuous wall throughout the passage;
>
> a blood filter having a blood inlet and a blood outlet coupled to said blood passage such that the blood flows through said filter, and said filter further comprising a filtrate output coupled to a filtrate line,
>
> a first cartridge housing to which is attached a blood loop of the blood passage and the pressure sensor, wherein the blood passage is mounted to an inside surface of the first cartridge housing such that the blood loop extends outwardly of the cartridge housing, and said first cartridge housing is detachably mountable to the blood treatment device to

engage the blood loop to the blood pump when the first cartridge housing is mounted on the device, and

a second cartridge housing to which is attached a filtrate loop of the filtrate line, wherein the filtrate line is mounted to an inside surface of the second cartridge housing such that said filtrate loop extends outwardly of the second cartridge housing, said second cartridge housing is distinct and separate from the first cartridge housing, and said second cartridge housing is detachably mountable to the device to engage the filtrate loop to the filtrate pump of the blood treatment device.

64. As shown in the image below, OMNI® includes a first cartridge housing attached to a blood loop of the blood passage and a second cartridge housing attached to a filtrate loop of the filtrate line that extends outwardly from the housing:



(OMNI® Brochure at 5 (annotated)).

65. In view of the foregoing, B.Braun's use and/or importation of OMNI® has directly infringed the '214 Patent in violation of 35 U.S.C. § 271(a).

66. B.Braun's infringement of the '214 Patent will cause Baxter Healthcare Corporation and Gambro Lundia AB to suffer substantial and irreparable harm.

67. B.Braun's infringement of the '214 Patent will result in loss of market leadership and loss of market share for Baxter's PRISMAFLEX® System and PrisMAX®. Such losses cannot be adequately compensated by money damages.

68. B.Braun's infringement of the '214 Patent will expose Baxter to loss of pricing discretion for the PRISMAFLEX® System and PrisMAX® and price erosion the magnitude and adverse effects of which cannot be adequately compensated by money damages.

69. B.Braun's infringement of the '214 Patent will disrupt Baxter's customer relationships. Such disruption will result in the formation of customer relationships between B.Braun and Baxter's existing customers, the adverse effects of which cannot be adequately compensated by money damages.

COUNT II
INFRINGEMENT OF THE '418 PATENT

70. Baxter incorporates by reference the allegations in Paragraphs 1 through 59 above.

71. The '418 Patent is directed to an "integrated module for extracorporeal blood treatment [that] has a flat-shaped support element which exhibits on an internal face thereof a complex of fluid distribution lines and on an external face thereof a high-flow dialyzer." (Ex. B, '418 Patent at Abstract). The support element simplifies the "operations for assembly of the integrated module, reduces the scope for error in positioning the distribution lines on the support element, improves precision in the couplings between the U-segments of the distribution lines

and the peristaltic pumps of the blood treatment apparatus, enables, after use, a simple and practical separation of the support element from the fluid distribution lines, reduces assembly costs and times of the integrated module." (*Id*. at 2:56–64).

72. B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed at least claim 1 of the '418 Patent, either literally or under the doctrine of equivalents, by using and/or importing OMNI® in the United States.

73. For example, B.Braun has infringed claim 1 of the '418 Patent, which recites as follows:

> 1. A support element for an integrated module for extracorporeal blood treatment, comprising:
>
> a base body:
>
> at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line;
>
> an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line, said at least one axial locator having an undercut surface, said undercut surface being positioned in an axial direction of the axially extended tract of a fluid distribution line.

74. As shown in the image below, the OMNI® cassette comes equipped with features allowing the tubing to be held axially in place with a fixture seating that has an undercut surface:

(OMNI® Brochure at 5 (annotated)).

75. In view of the foregoing, B.Braun's use and/or importation of OMNI® has directly infringed the '418 Patent in violation of 35 U.S.C. § 271(a).

76. B.Braun's infringement of the '418 Patent will cause Baxter Healthcare Corporation and Gambro Lundia AB to suffer substantial and irreparable harm.

77. B.Braun's infringement of the '418 Patent will result in loss of market leadership and loss of market share for Baxter's PRISMAFLEX® System and PrisMAX®. Such losses cannot be adequately compensated by money damages.

78. B.Braun's infringement of the '418 Patent will expose Baxter to loss of pricing discretion for the PRISMAFLEX® System and PrisMAX® and price erosion whose magnitude and adverse effects cannot be adequately compensated by money damages.

79. B.Braun's infringement of the '418 Patent will disrupt Baxter's customer relationships. Such disruption will result in the formation of customer relationships between B.Braun and Baxter's existing customers, the adverse effects of which cannot be adequately compensated by money damages.

COUNT III
INFRINGEMENT OF THE '554 PATENT

80. Baxter incorporates by reference the allegations in Paragraphs 1 through 59 above.

81. The '554 Patent is directed to "an extracorporeal blood treatment machine." (Ex. C, '590 Patent at Abstract). The blood circuit is equipped with an inlet line leading to a filtration unit and with an outlet line from the filtration unit. (*Id*.). The fluid circuit has an inlet line leading to the filtration unit and an outlet line from the filtration unit so the fluid taken from the primary container can circulate within the filtration unit. (*Id*.). There is also an infusion line at the outlet line of the blood circuit. (*Id*.). The inlet line of the fluid circuit has an infusion branch at the outlet line of the blood circuit. (*Id*.).

82. B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed at least claim 1 of the '554 Patent, either literally or under the doctrine of equivalents, by using and/or importing OMNI® in the United States.

83. For example, B.Braun has infringed claim 1 of the '554 Patent, which recites as follows:

> 1. An extracorporeal blood treatment machine comprising:
>
> at least one filtration unit;
>
> a blood circuit having an inlet line leading to the filtration unit and an outlet line from the filtration unit;

a fluid circuit having at least one inlet line leading to the filtration unit and one outlet line from the filtration unit;

at least one infusion line comprising at least a pre-infusion branch connected to the inlet line of the blood circuit and a post-infusion branch connected to the outlet line of the blood circuit;

an auxiliary pre-infusion line connected to the inlet line of the blood circuit

at least one primary fluid container connected so as to supply the inlet line of the fluid circuit;

at least a secondary fluid container for supplying said auxiliary pre-infusion line;

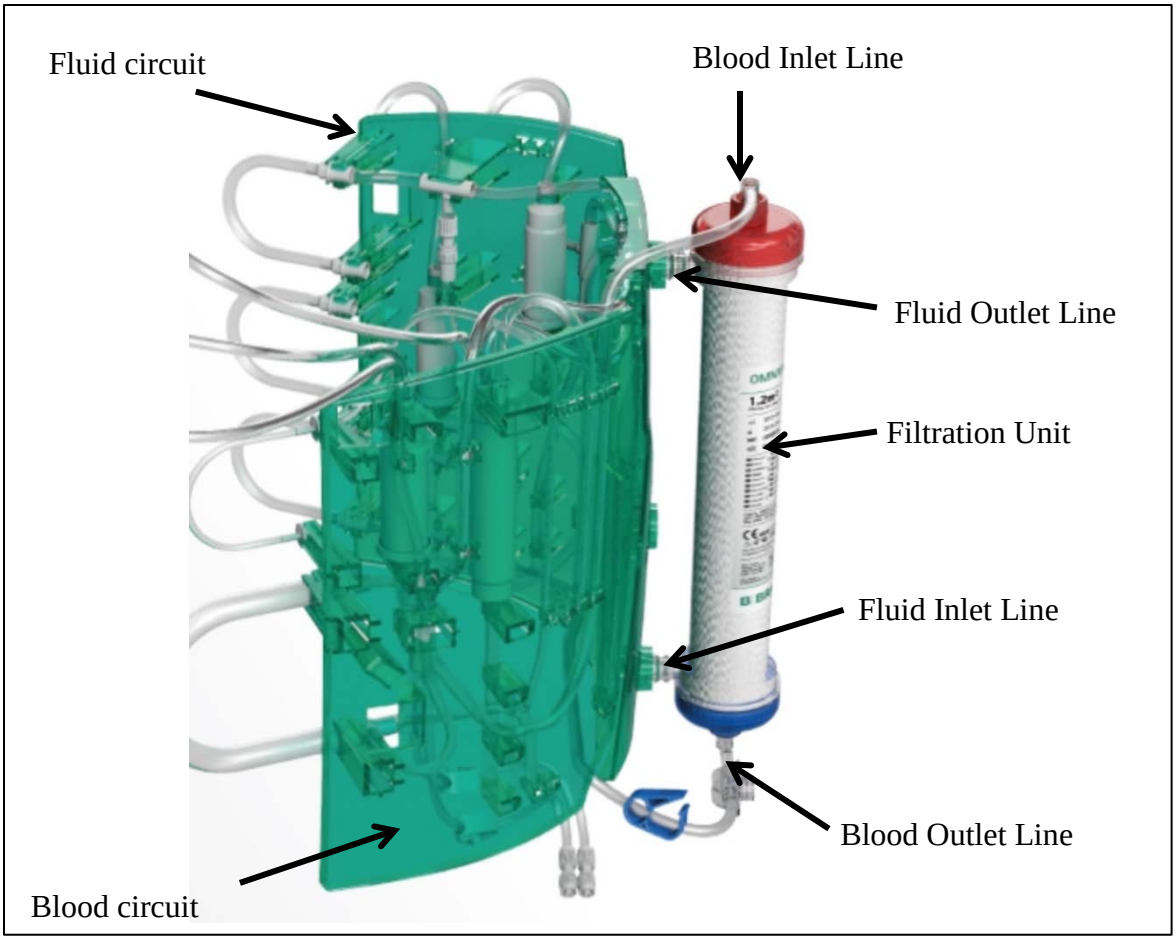
at least one auxiliary fluid container for supplying said at least one infusion line,

wherein the inlet line of the fluid circuit comprises an intake branch leading to the filtration unit and at least one infusion branch connected to the outlet line of the blood circuit, wherein said at least one infusion branch of the fluid circuit line has at least a length which is separate from said post-infusion branch of the at least one infusion line;

said fluid circuit further comprising selecting means for determining percentages of a flow of a fluid within said length of the infusion branch and the intake branch,

said at least one infusion line further comprising other selecting means for determining the percentage of flow within the post-infusion branch and the pre-infusion branch.

84. As shown in the image below, the OMNI® cassette has a blood circuit with an inlet/outlet line leading to/from a filtration unit; a fluid circuit with an inlet/outlet line leading to/from a filtration unit:



(OMNI® Brochure at 5 (annotated)).

85. OMNI® also has an infusion line off the fluid circuit that has a pre-infusion line that is connected to the inlet line of the blood circuit.

86. OMNI® also has an infusion line off the fluid circuit that has a post-infusion branch connected to the outlet line of the blood circuit

87. In view of the foregoing, B.Braun's use and/or importation of OMNI® has directly infringed the '554 Patent in violation of 35 U.S.C. § 271(a).

88. B.Braun's infringement of the '554 Patent will cause Baxter Healthcare Corporation and Gambro Lundia AB to suffer substantial and irreparable harm.

89. B.Braun's infringement of the '554 Patent will result in loss of market leadership and loss of market share for Baxter's PRISMAFLEX® System and PrisMAX®. Such losses cannot be adequately compensated by money damages.

90. B.Braun's infringement of the '554 Patent will expose Baxter to loss of pricing discretion for the PRISMAFLEX® System and PrisMAX® and price erosion whose magnitude and adverse effects cannot be adequately compensated by money damages.

91. B.Braun's infringement of the '554 Patent will disrupt Baxter's customer relationships. Such disruption will result in the formation of customer relationships between B.Braun and Baxter's existing customers, the adverse effects of which cannot be adequately compensated by money damages.

COUNT IV
INFRINGEMENT OF THE '391 PATENT

92. Baxter incorporates by reference the allegations in Paragraphs 1 through 59 above.

93. The '391 Patent is directed to "an extracorporeal blood treatment machine." (Ex. D, '391 Patent at Abstract). The blood circuit is equipped with an inlet line leading to a filtration unit and with an outlet line from the filtration unit. (*Id*.). The fluid circuit has an inlet line leading to the filtration unit and an outlet line from the filtration unit so the fluid taken from the primary container can circulate within the filtration unit. (*Id*.). There is also an infusion line at the outlet line of the blood circuit. (*Id*.). The inlet line of the fluid circuit has an infusion branch at the outlet line of the blood circuit. (*Id*.).

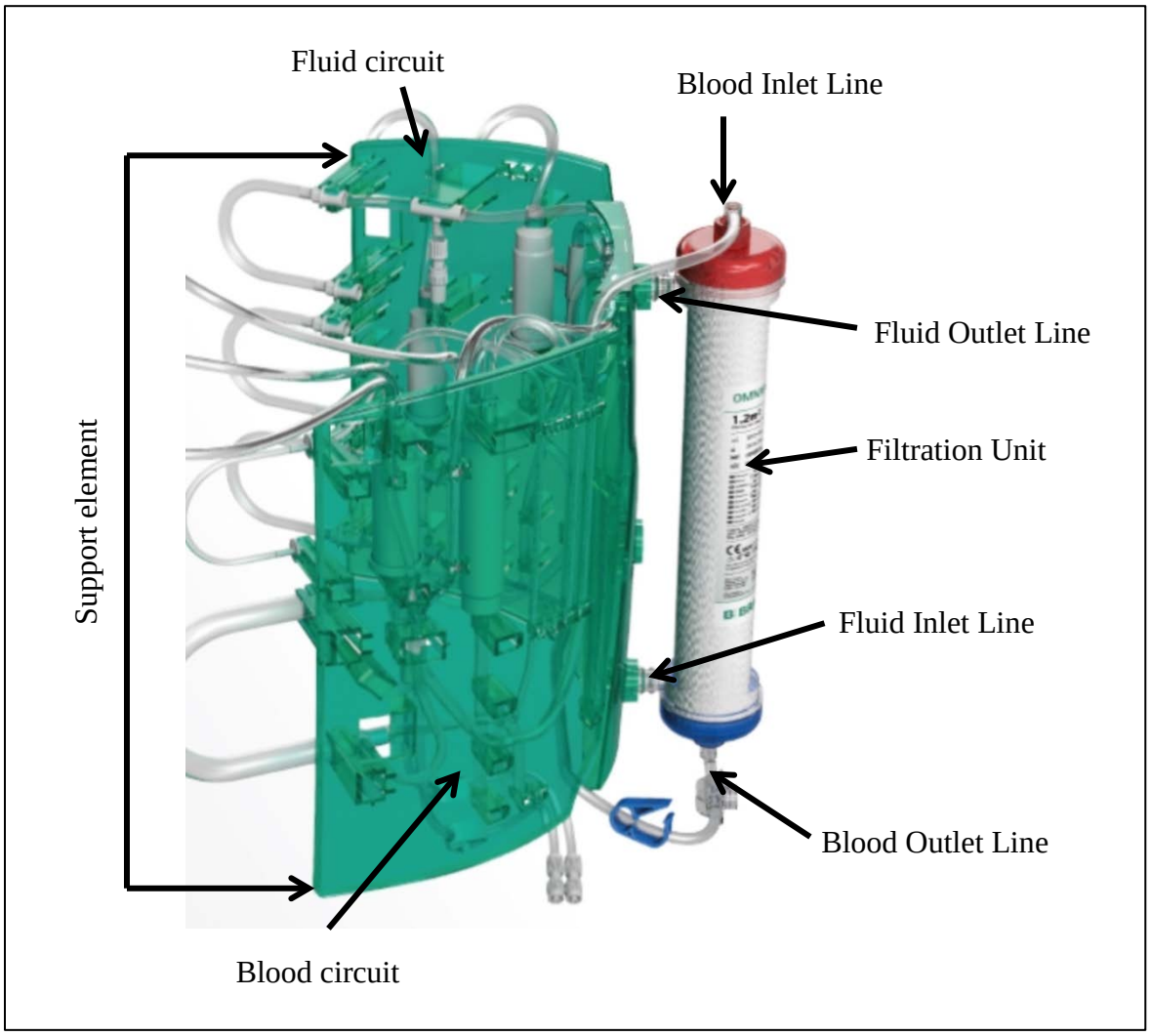
94. B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed at least claim 1 of the '391 Patent, either literally or under the doctrine of equivalents, by using and/or importing OMNI® in the United States.

95. For example, B.Braun has infringed claim 1 of the ‘391 Patent, which recites as follows:

> 1. An integrated module for blood treatment, comprising:
>
> a support element;
>
> at least one filtration unit engaged to the support element; and
>
> a fluid distribution circuitry associated to the support element and cooperating with the filtration unit, said fluid distribution circuitry including:
>
> a plurality of tubes;
>
> a blood circuit having at least an inlet line connected to the filtration unit, and an outlet line connected to said filtration unit;
>
> a fluid circuit having at least an inlet line connected to the filtration unit, and an outlet line connected to the filtration unit, the inlet line of the fluid circuit being designed to be connected to at least a primary fluid container; and
>
> at least an infusion line acting on the outlet line of the blood circuit, said infusion line being designed to be supplied by at least an auxiliary fluid container, and the infusion line being fastened to the support element so as to define at least a U-arranged tube length with respect to said support element, at least an outlet length of the infusion line having a branching splitting up into pre-infusion branch conveying fluid to the inlet line of the blood circuit, and into post-infusion branch conveying fluid to the outlet line of the blood circuit;
>
> wherein the inlet line of the fluid circuit comprises at least an infusion branch connected to the outlet line of the blood circuit, the inlet line of the fluid circuit being fastened to the support element so as to define at least a U-arranged tube length with respect to said support element, at least an outlet length of the inlet line of the fluid circuit having a branching splitting up into intake branch conveying the fluid to the filtration unit, and into the infusion branch, separate from the post-infusion branch of the infusion line, conveying the fluid to a blood circuit.

96. As shown in the image below, the OMNI® cassette has an integrated blood module with a support element, where the filtration unit is engaged to the support unit; a fluid

circuit with an inlet/outlet line leading to/from a filtration unit; and a blood circuit with an inlet/outlet line leading to/from a filtration unit:



(OMNI® Brochure at 5 (annotated)).

97. OMNI® also has an infusion line off the fluid circuit that is connected to the outlet of the blood circuit.

98. In view of the foregoing, B.Braun's use and/or importation of OMNI® has directly infringed the '391 Patent in violation of 35 U.S.C. § 271(a).

99. B.Braun's infringement of the '554 Patent will cause Baxter Healthcare Corporation and Gambro Lundia AB to suffer substantial and irreparable harm.

100. B.Braun's infringement of the '391 Patent will result in loss of market leadership and loss of market share for Baxter's PRISMAFLEX® System and PrisMAX®. Such losses cannot be adequately compensated by money damages.

101. B.Braun's infringement of the '391 Patent will expose Baxter to loss of pricing discretion for the PRISMAFLEX® System and PrisMAX® and price erosion whose magnitude and adverse effects cannot be adequately compensated by money damages.

102. B.Braun's infringement of the '391 Patent will disrupt Baxter's customer relationships. Such disruption will result in the formation of customer relationships between B.Braun and Baxter's existing customers, the adverse effects of which cannot be adequately compensated by money damages.

COUNT V
INFRINGEMENT OF THE '393 PATENT

103. Baxter incorporates by reference the allegations in Paragraphs 1 through 59 above.

104. The '393 Patent is directed to a "support element [] with a plurality of connectors [] which receive corresponding counter-connectors of a blood treatment device." (Ex. E, '393 Patent at Abstract). The support element will easily connect with the blood treatment device. (*Id.* at 2:45–50).

105. B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed at least claim 1 of the '393 Patent, either literally or under the doctrine of equivalents, by using and/or importing OMNI® in the United States.

106. For example, B.Braun has infringed claim 1 of the '393 Patent, which recites as follows:

1. An integrated module for fluid treatment, comprising:

a support element having:

a base body;

at least a first and at a least a second connector associated with the base body and distanced one from another;

at least an intermediate connector interposed between said first and second connectors, distanced from said first connector and from said second connector and directly constrained to the base body, said first, second, and intermediate connectors defining pairs of connectors having differentiated interaxes there-between for engaging to corresponding pairs of counter-connectors associated with various blood treatment devices which are mountable on the support element;

at least one blood treatment device engaged on the support element and having:

a containment body presenting a main development axis and including a lateral surface and first and second end surfaces;

at least one semi-permeable membrane operating internally of the containment body and defining a first chamber and a second chamber;

a first counter-connector and a second counter-connector, both emerging from the lateral surface of the containment body and being fixed to a pair of connectors selected from the first, second, and intermediate connectors associated with the base body, at least one of the first counter-connector and the second counter-connector being placed in fluid communication with the second chamber of the blood treatment device and with respective first end portions of said pair of connectors, wherein the intermediate connector is not connected to a counter-connector of the blood treatment device;

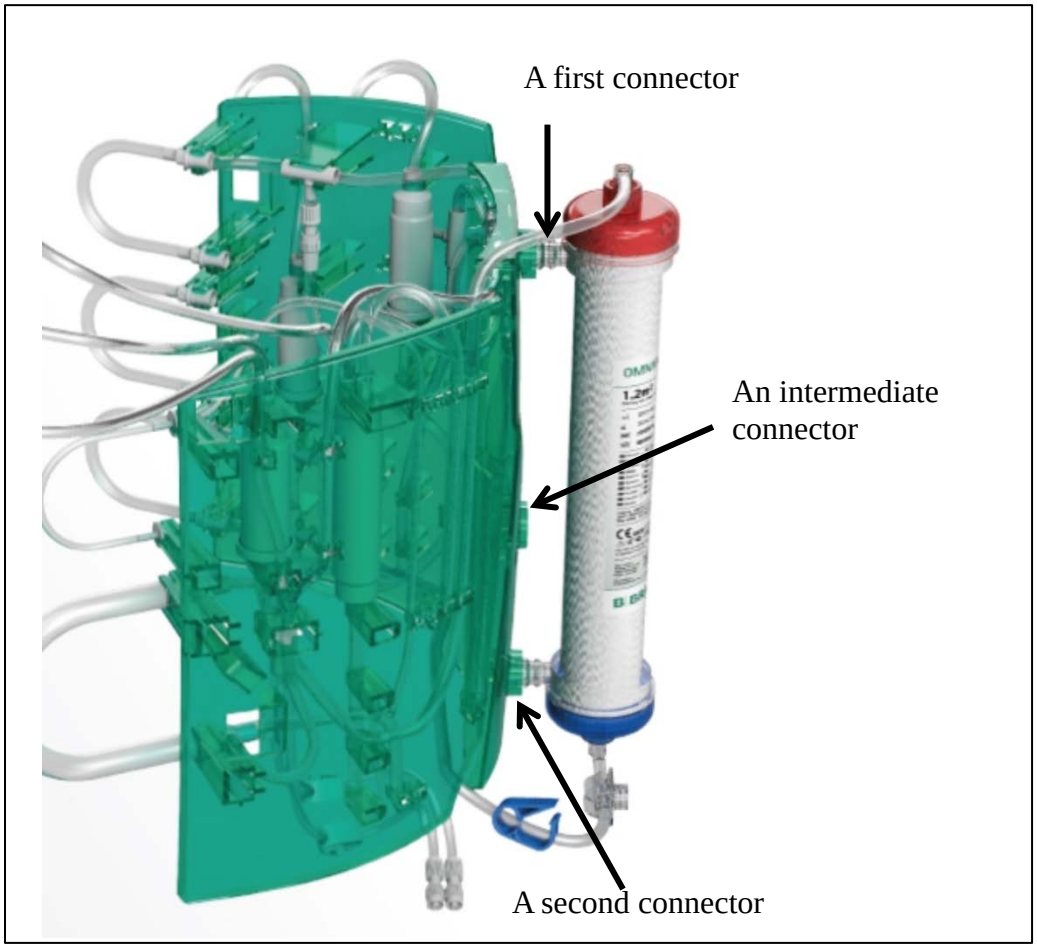
at least one inlet port to the first chamber associated with the first end surface and emerging axially along the development axis; and

at least one outlet port from the first chamber associated with the second end surface and emerging axially along the development axis;

a fluid distribution circuitry associated with the support element and cooperating with the blood treatment device, each of said pair of

connectors presenting a fluid passage having a first end portion in fluid communication with a corresponding channel in a respective counter-connector on the blood treatment device and a second end portion in fluid communication with the fluid distribution circuitry the fluid distribution circuitry presenting at least one blood line having a blood withdrawal branch placed in fluid communication with the inlet port of the first chamber and emerging axially from the first end surface along the development axis and at least one blood return branch placed in fluid communication with the outlet port of the first chamber and emerging axially from the second end surface along the development axis.

107. As shown in the image below, OMNI® includes three ports on its cassette which are each compatible to connect with a dialyzer male luer lock:



(OMNI® Brochure at 5 (annotated)).

108. In view of the foregoing, B.Braun's use and/or importation of OMNI® has directly infringed the '393 Patent in violation of 35 U.S.C. § 271(a).

109. B.Braun's infringement of the '393 Patent will cause Baxter Healthcare Corporation and Gambro Lundia AB to suffer substantial and irreparable harm.

110. B.Braun's infringement of the '393 Patent will result in loss of market leadership and loss of market share for Baxter's PRISMAFLEX® System and PrisMAX®. Such losses cannot be adequately compensated by money damages.

111. B.Braun's infringement of the '393 Patent will expose Baxter to loss of pricing discretion for the PRISMAFLEX® System and PrisMAX® and price erosion whose magnitude and adverse effects cannot be adequately compensated by money damages.

112. B.Braun's infringement of the '393 Patent will disrupt Baxter's customer relationships. Such disruption will result in the formation of customer relationships between B.Braun and Baxter's existing customers, the adverse effects of which cannot be adequately compensated by money damages.

COUNT VI
INFRINGEMENT OF THE '308 PATENT

113. Baxter incorporates by reference the allegations in Paragraphs 1 through 59 above.

114. The '308 Patent is directed to "a method for setting up a fluid treatment apparatus using a single, and always accessible, reader of information relating to replaceable components which are to be mounted on the apparatus to perform the fluid treatment." (Ex. F, '308 Patent at Abstract). The reader is used to ensure proper machine setup and data entry of information when replaceable components are used. (*Id*. at 3:53–56).

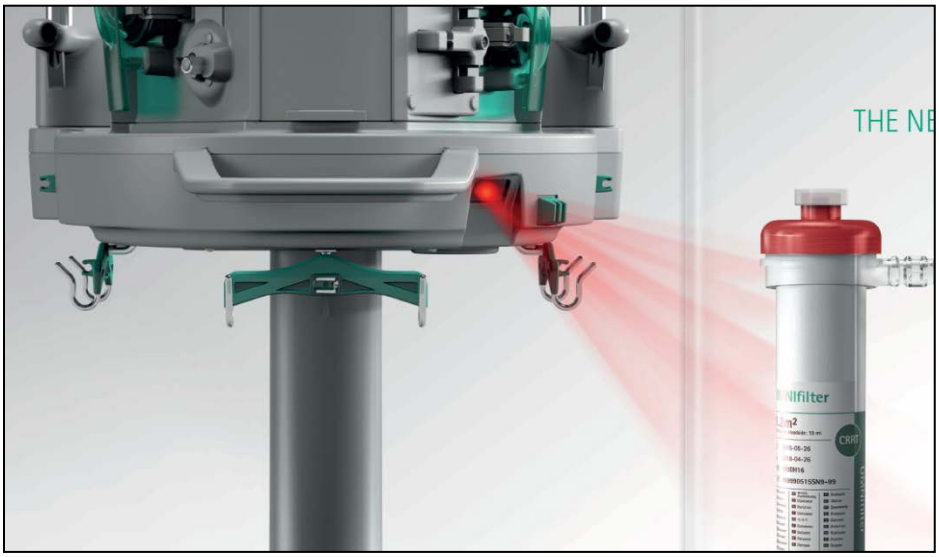
115. B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed at least claim 1 of the '308 Patent, either literally or under the doctrine of equivalents, by using and/or importing OMNI® in the United States.

116. For example, B.Braun has infringed claim 1 of the ‘308 Patent, which recites as follows:

> 1. Method for setting-up a fluid processing medical apparatus, the apparatus being of the type comprising:
>
> a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus,
>
> at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,
>
> the method comprising the following steps:
>
> providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,
>
> reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,
>
> coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information,
>
> the method further comprising the steps of:
>
> selecting a desired treatment procedure,
>
> checking if the new component fits with the selected treatment procedure,
>
> signaling if the new component does not fit with the selected treatment procedure.

117. OMNI® has a barcode scanner for use when setting up the filters.

118. The OMNI® barcode scanner ensures that setup errors are avoided and expired filters are not introduced into the system:



(OMNI® Brochure at 8).

119. In view of the foregoing, B.Braun's use and/or importation of OMNI® has directly infringed the '308 Patent in violation of 35 U.S.C. § 271(a).

120. B.Braun's infringement of the '308 Patent will cause one or more of Plaintiffs Baxter Healthcare Corporation and Gambro Lundia AB to suffer substantial and irreparable harm.

121. B.Braun's infringement of the '308 Patent will result in loss of market leadership and loss of market share for Baxter's PRISMAFLEX® System and PrisMAX®. Such losses cannot be adequately compensated by money damages.

122. B.Braun's infringement of the '308 Patent will expose Baxter to loss of pricing discretion for the PRISMAFLEX® System and PrisMAX® and price erosion whose magnitude and adverse effects cannot be adequately compensated by money damages.

123. B.Braun's infringement of the '308 Patent will disrupt Baxter's customer relationships. Such disruption will result in the formation of customer relationships between

B.Braun and Baxter's existing customers, the adverse effects of which cannot be adequately compensated by money damages.

COUNT VII
INFRINGEMENT OF THE '543 PATENT

124. Baxter incorporates by reference the allegations in Paragraphs 1 through 59 above.

125. The '543 Patent is directed to "a method for setting up a fluid treatment apparatus using a single, and always accessible, reader of information relating to replaceable components which are to be mounted on the apparatus to perform the fluid treatment." (Ex. G, '543 Patent at Abstract). The reader is used to ensure proper machine setup and data entry of information when replaceable components are used. (*Id*. at 3:53–56).

126. B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed at least claim 1 of the '543 Patent, either literally or under the doctrine of equivalents, by using and/or importing OMNI® in the United States.

127. For example, B.Braun has infringed claim 1 of the '543 Patent, which recites as follows:

> 1. Method for setting-up an extracorporeal blood treatment apparatus, the apparatus being of the type comprising:
>
> > a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus, said components comprising a plurality of components of different categories, each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories, and
> >
> > wherein said apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only,

at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

the method comprising the following steps:

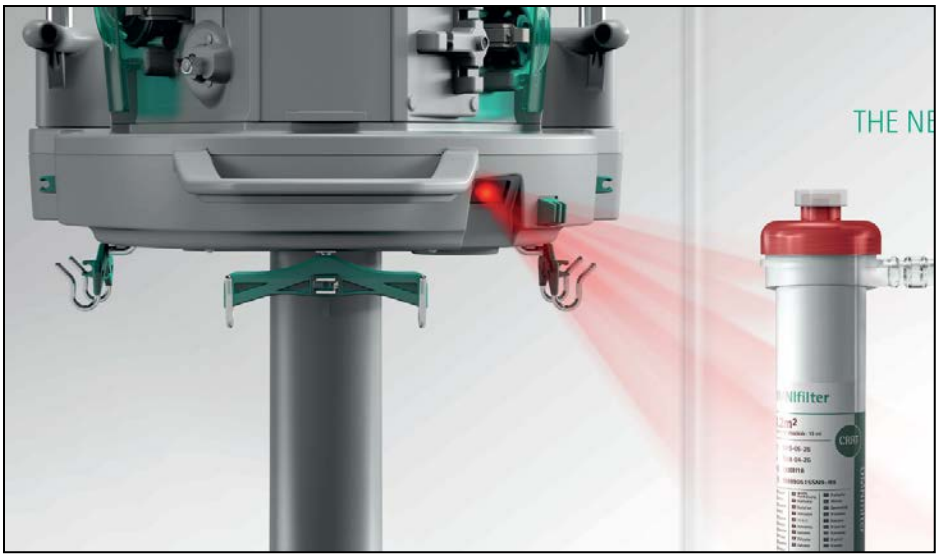
providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,

reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

128. OMNI® has a barcode scanner for use when setting up the filters.

129. The OMNI® barcode scanner ensures that setup errors are avoided and expired filters are not introduced into the system:



(OMNI® Brochure at 8).

130. In view of the foregoing, B.Braun's use and/or importation of OMNI® has directly infringed the '543 Patent in violation of 35 U.S.C. § 271(a).

131. B.Braun's infringement of the '543 Patent will cause Baxter Healthcare Corporation and Gambro Lundia AB to suffer substantial and irreparable harm.

132. B.Braun's infringement of the '543 Patent will result in loss of market leadership and loss of market share for Baxter's PRISMAFLEX® System and PrisMAX®. Such losses cannot be adequately compensated by money damages.

133. B.Braun's infringement of the '543 Patent will expose Baxter to loss of pricing discretion for the PRISMAFLEX® System and PrisMAX® and price erosion whose magnitude and adverse effects cannot be adequately compensated by money damages.

134. B.Braun's infringement of the '543 Patent will disrupt Baxter's customer relationships. Such disruption will result in the formation of customer relationships between B.Braun and Baxter's existing customers, the adverse effects of which cannot be adequately compensated by money damages.

CONCLUSION AND PRAYER FOR RELIEF

WHEREFORE, Baxter respectfully requests that:

A. The Court find that B.Braun has directly infringed, induced others to infringe, and/or contributorily infringed the Patents-in-Suit and hold B.Braun liable for such infringement;

B. The Court issue an order pursuant to 35 U.S.C. § 283 permanently enjoining B.Braun, and anyone acting or participating by, through or in concert with B.Braun, from infringing, contributing to, and/or inducing infringement of Patents-in-Suit;

C. The Court declare that this is an exceptional case entitling Baxter to its reasonable attorneys' fees under 35 U.S.C. § 285;

D. The Court award Baxter its costs and reasonable attorneys' fees; and

E. The Court award such other relief as the court may deem just and proper.

Dated: January 11, 2018

K&L GATES LLP

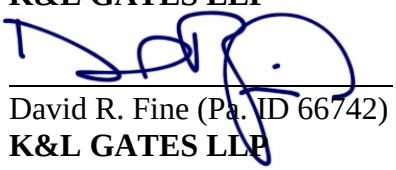


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EXHIBIT A

US006887214B1

(12) **United States Patent**
Levin et al.

(10) **Patent No.: US 6,887,214 B1**
(45) **Date of Patent: May 3, 2005**

(54) **BLOOD PUMP HAVING A DISPOSABLE BLOOD PASSAGE CARTRIDGE WITH INTEGRATED PRESSURE SENSORS**

(75) Inventors: **Howard R. Levin**, Teaneck, NJ (US); **Mark Gelfand**, New York, NY (US); **Steven Bernard**, Yonkers, NY (US)

(73) Assignee: **CHF Solutions, Inc.**, New York, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 220 days.

(21) Appl. No.: **09/660,195**

(22) Filed: **Sep. 12, 2000**

(51) **Int. Cl.**[7] **A61M 37/00**; C02F 1/44

(52) **U.S. Cl.** **604/6.11**; 604/6.09; 604/4.01; 210/645

(58) **Field of Search** 604/5.01, 6.09, 604/6.11, 65–67; 210/90, 94, 409, 461, 418, 428, 435, 645–647, 252, 258–260; 422/44–48

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Primary Examiner—Angela D. Sykes
Assistant Examiner—Leslie R. Deak
(74) *Attorney, Agent, or Firm*—Nixon & Vanderhye, P.C.

(57) **ABSTRACT**

An integrated disposable cartridge for dialysis or ultrafiltration treatment of blood is disclosed that includes integral miniature pressure sensors. Sensors are embedded in the tubing of the cartridge to measure pressure of blood or other fluids. Cartridge elements form a continuous smooth bore passage for blood that reduces probability of clotting.

31 Claims, 7 Drawing Sheets

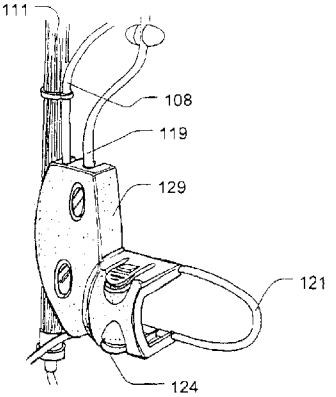

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Figure 1

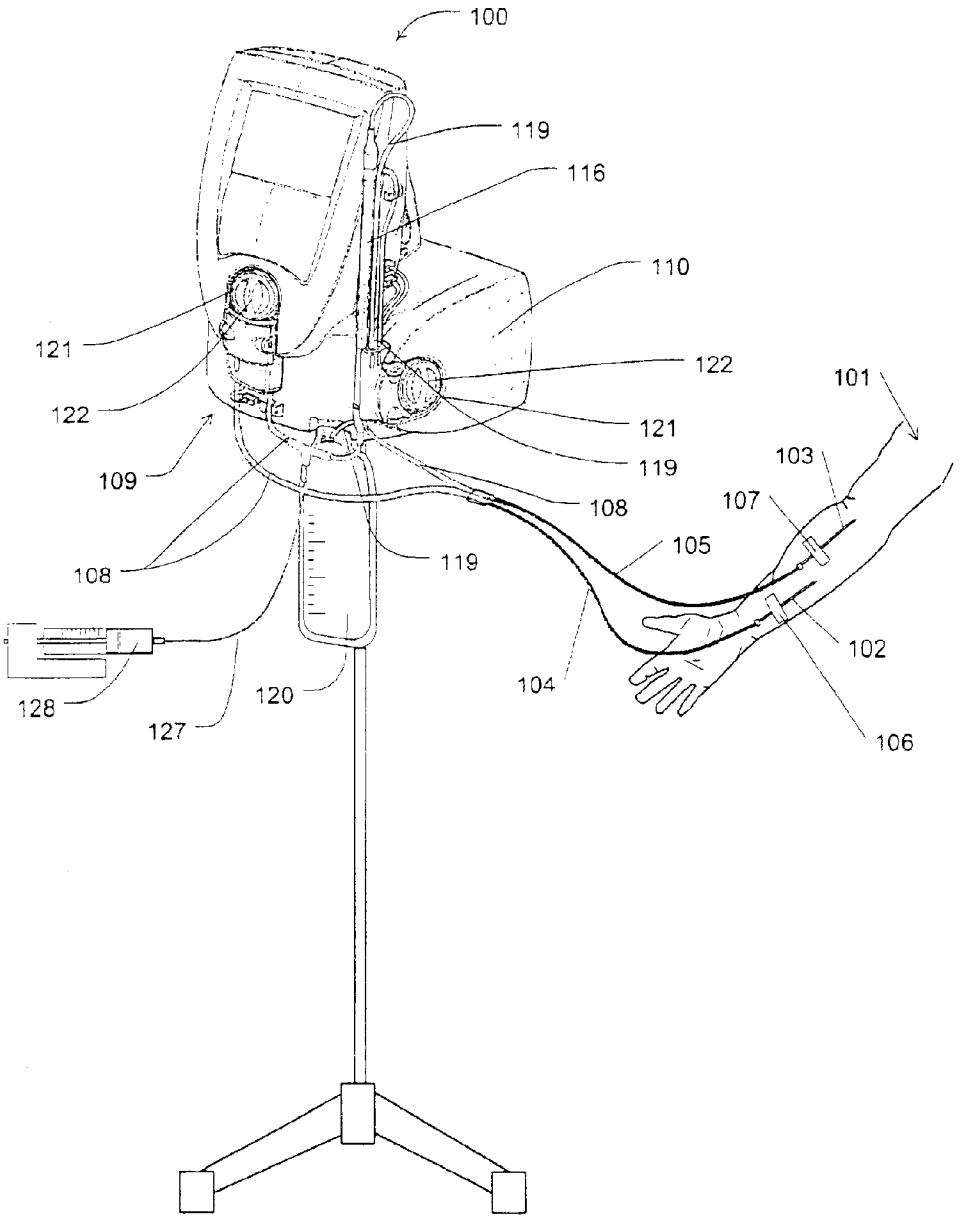
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Figure 2

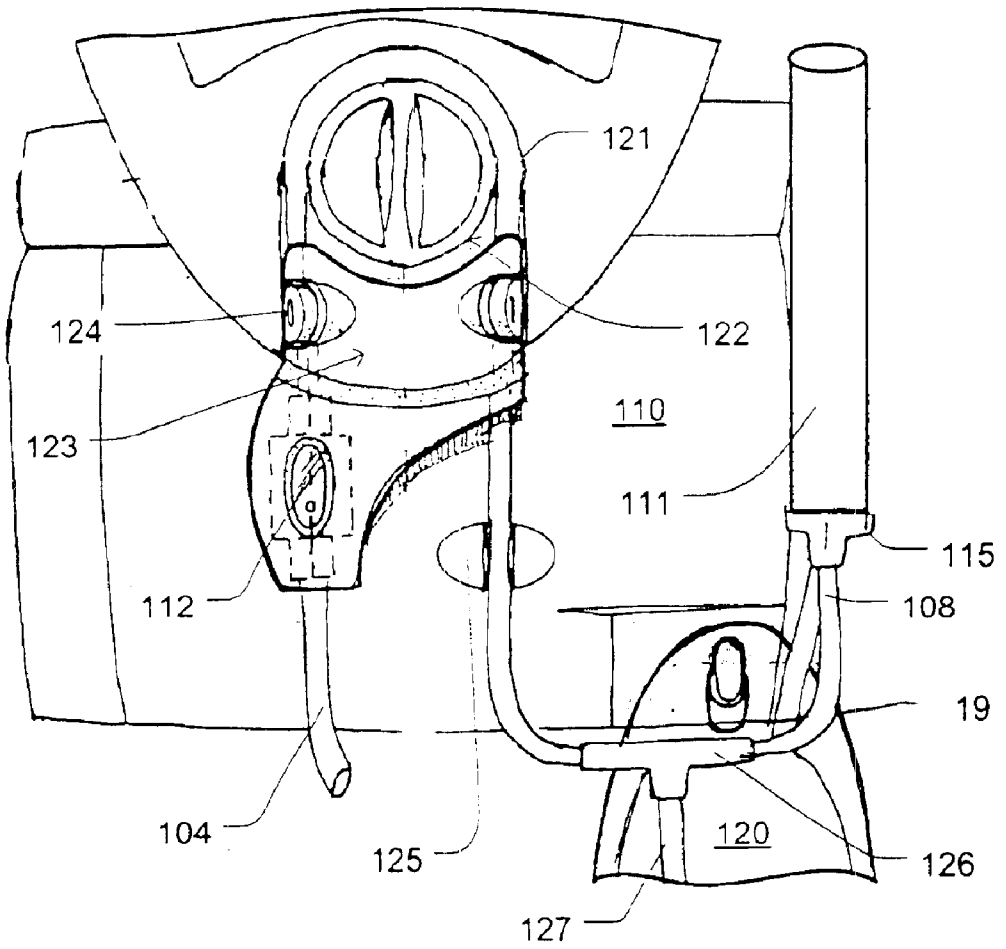
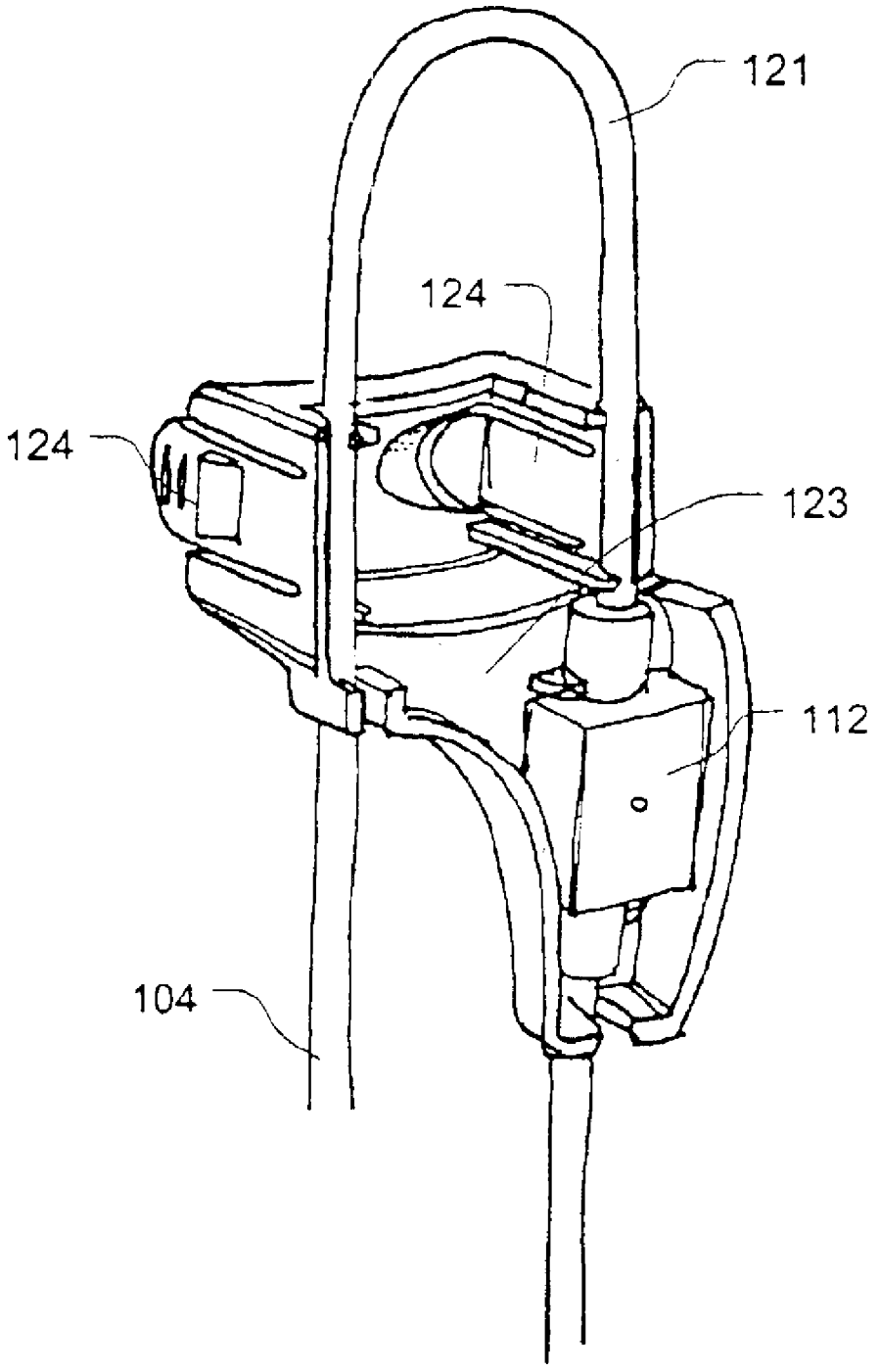


Figure 3



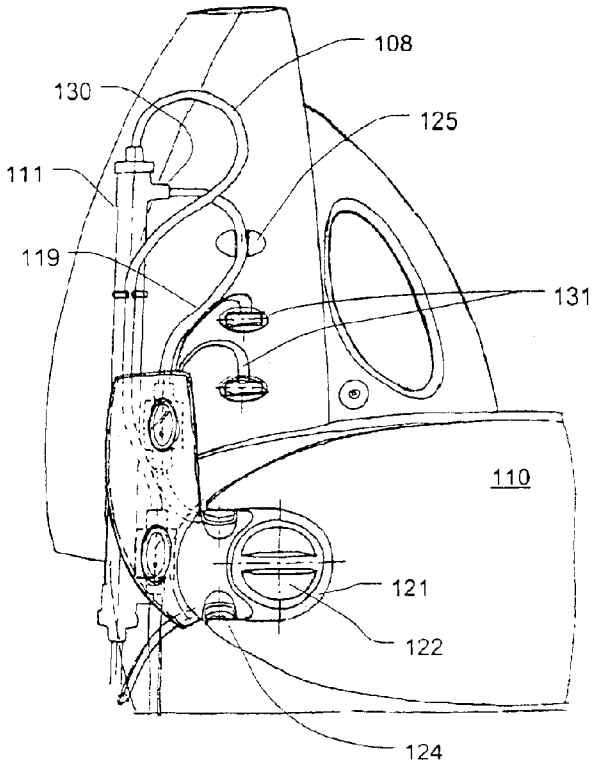


Fig. 4

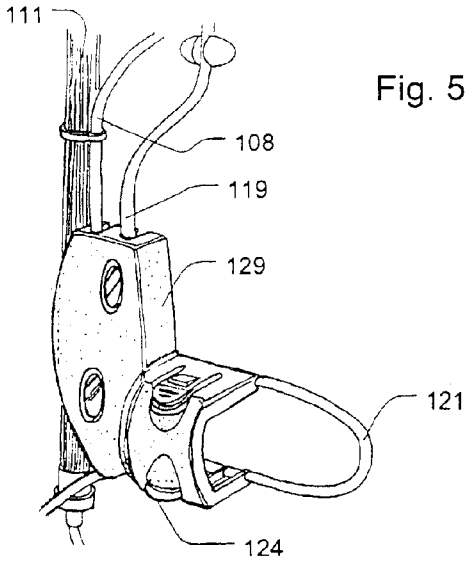


Fig. 5

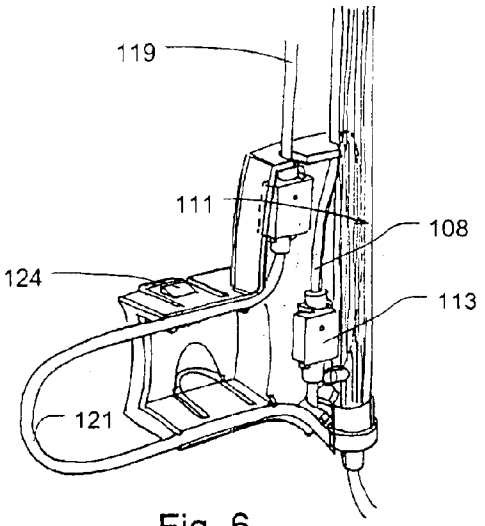


Fig. 6

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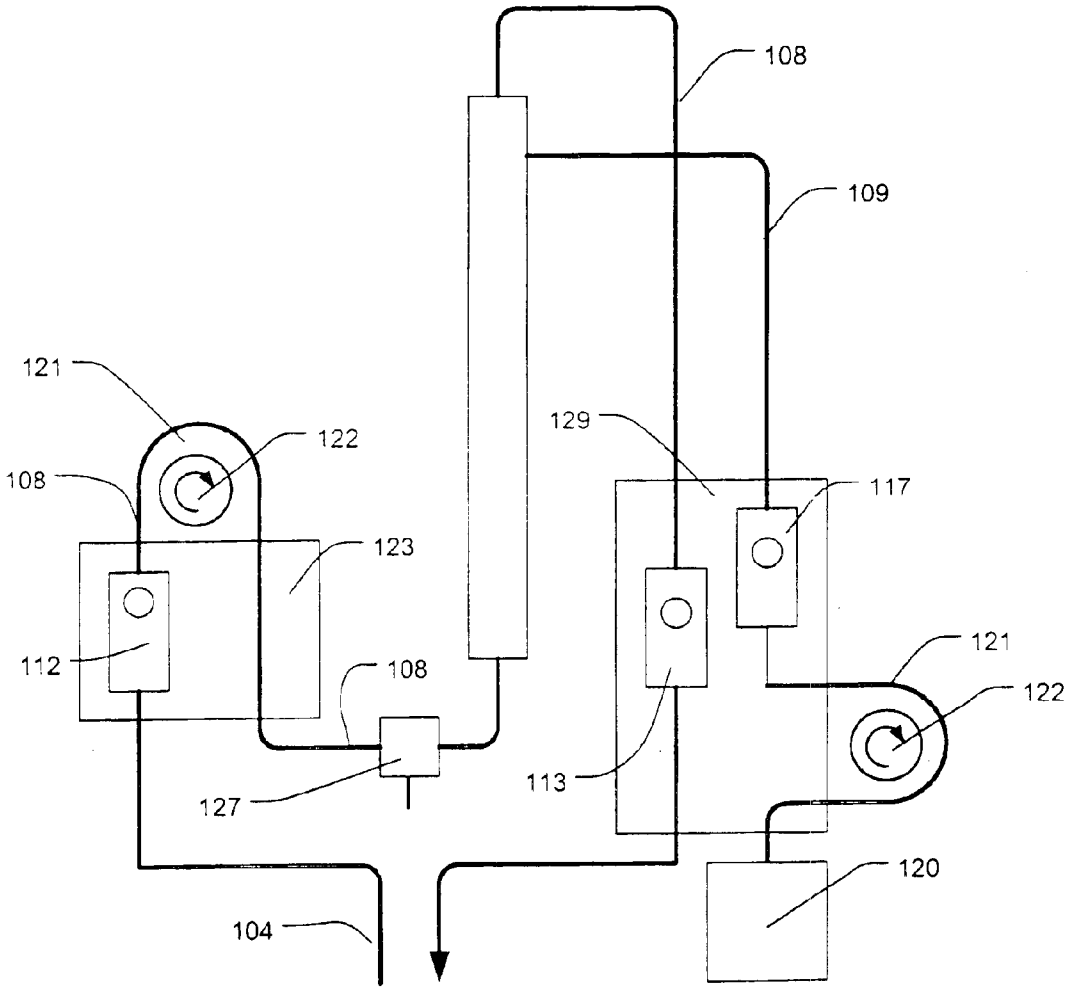

Figure 8

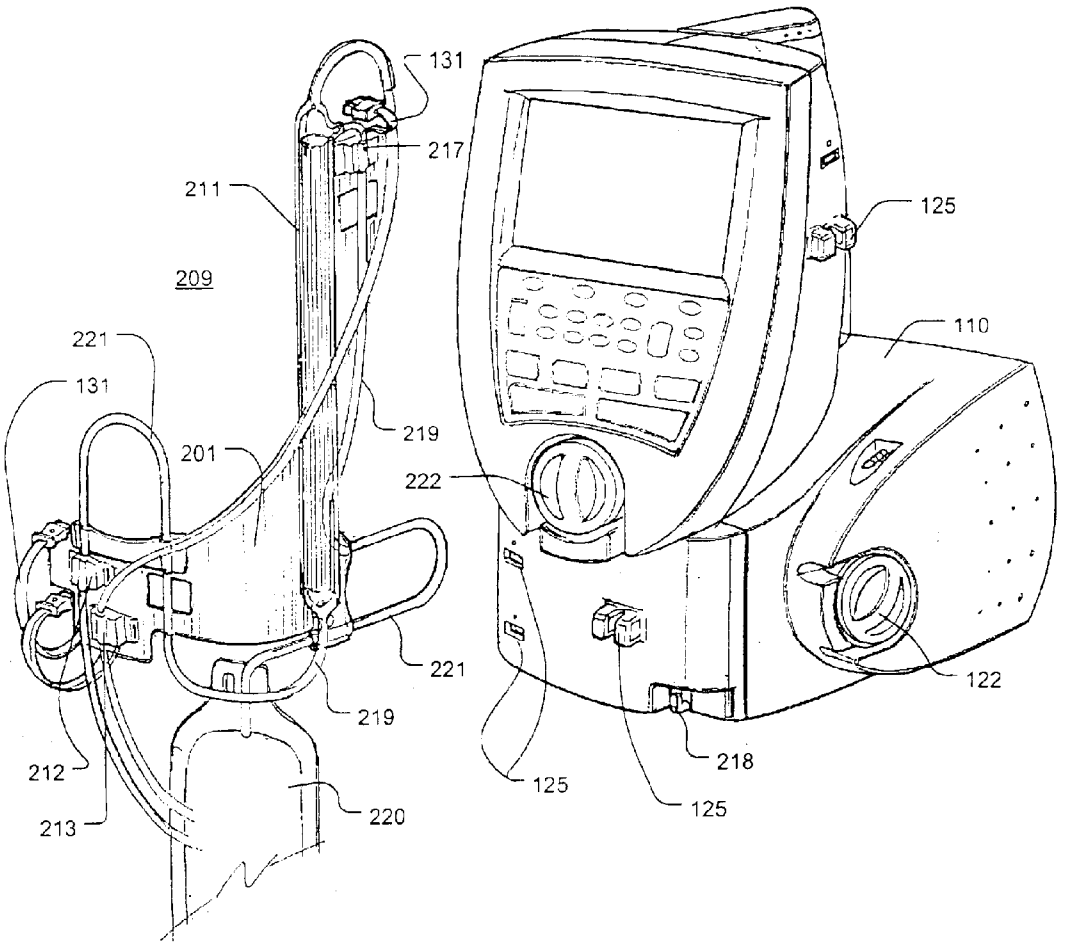
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Figure 9

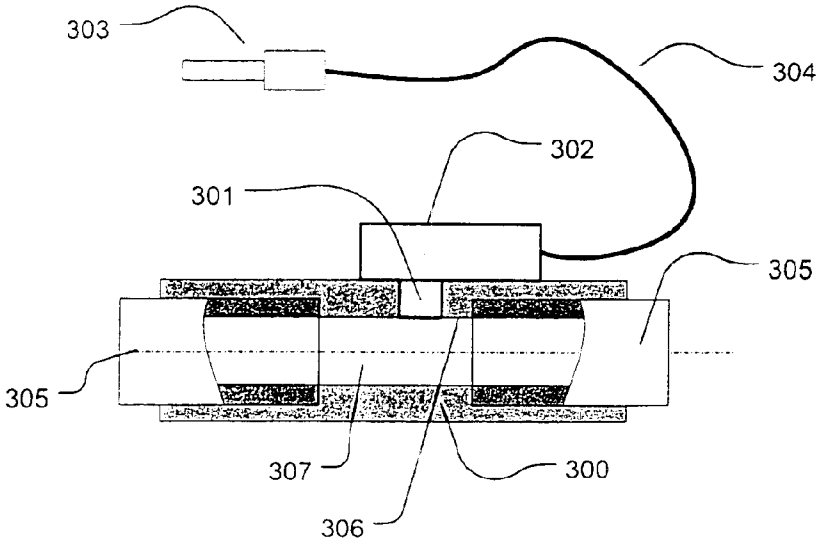
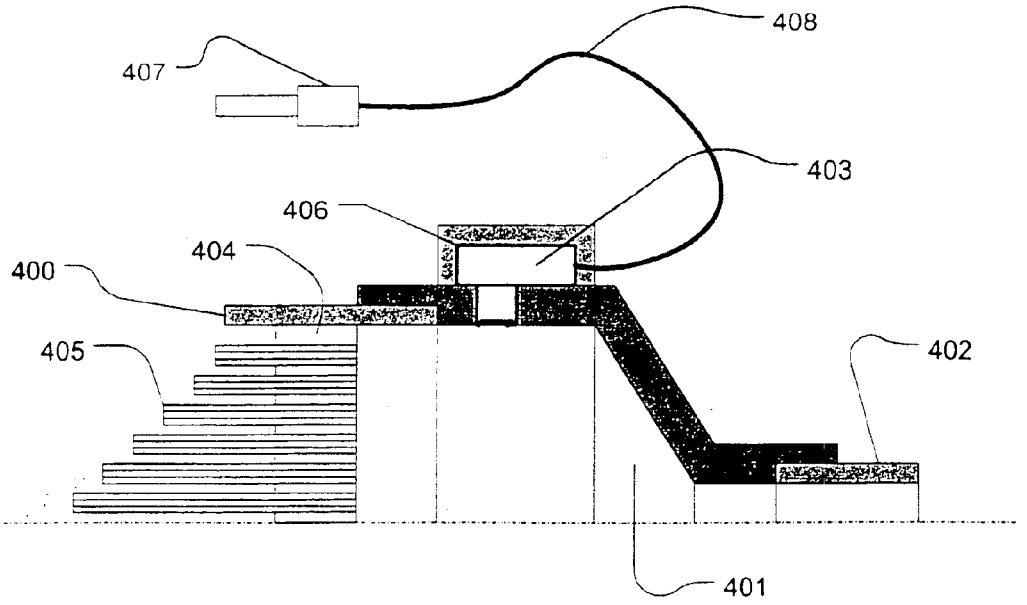


Figure 10



BLOOD PUMP HAVING A DISPOSABLE BLOOD PASSAGE CARTRIDGE WITH INTEGRATED PRESSURE SENSORS

FIELD OF THE INVENTION

This invention relates to an apparatus for the extracorporeal treatment of blood. More specifically, the invention relates an apparatus to treat patients by removing excessive fluids, such as water, from the blood of patients suffering from fluid overload.

BACKGROUND OF THE INVENTION

1. Mechanical Fluid Removal Therapies

Patients that exhibit symptoms of body fluid overload retain excessive amounts of fluid in the abdomen, legs and lungs. For example, excessive fluid in the lungs, referred to as edema, can cause patients to have difficulty breathing. Moreover, edema in the lungs leads to poor blood oxygenation. Poor oxygenation leads to acidosis and deleterious neurological and hormonal phenomena that increases vasoconstriction and load on the heart. In addition, vasoconstriction leads to reduced blood flow to the kidneys and diminishes the effectiveness of the main pharmacological means of fluid removal—diuretic treatment. The reduced blood flow can result in kidney failure.

Different modalities of Continuous Renal Replacement Therapy (CRRT) have been used to treat patients suffering from excess fluid overload and acute renal failure. In the acute condition, CRRT has been performed using standard methods of hemodialysis and continuous arterio-venous hemofiltration (CAVH). More recently, continuous veno-venous hemofiltration (CVVH) has been used to reduce the complications associated with such issues as hemodynamic instability and need for arterial access.

Hemodialysis and hemofiltration can be used to remove excess fluid from a patient, especially in patients whose kidneys have failed. The term "Renal Replacement Therapy" generally refers to all forms of dialysis, solute and fluid balancing therapy. Another category of patients affected by fluid overload are those with congestive heart failure (CHF). Patients suffering from CHF have weakened hearts that are unable to provide normal blood flow to the kidney and organs of the body. CHF patients may have normal kidneys, but lack sufficient blood flow to maintain proper kidney functions of removing excess fluid, e.g., water, from the body. The build-up of excessive fluids due to inadequate kidney functions further increases the blood pumping load on the heart, which is already suffering from CHF.

Renal replacement therapy performs two primary functions: ultrafiltration (removal of water from blood plasma), and solute clearance (removal of different molecular weight solid substances from blood plasma). The filter utilized, also called hemofilter or "dialyzer", can be set up to perform either or both of these functions simultaneously, with or without fluid replacement. Similarly, the various modes of renal replacement therapy relate to whether fluids, solutes or both are removed and whether fluids are replaced. "Clearance" describes the removal of substances, both normal and waste product, from the blood whether by kidney function or during renal replacement therapy.

Dialysis is the diffusive transfer of small solutes out of a blood plasma compartment by diffusion across the membrane itself. It occurs as a result of a concentration gradient, with diffusion occurring from the compartment with higher concentration (typically the blood compartment) to the compartment with lower concentration (typically the dialysate compartment). Since the concentration of solutes in the plasma decreases, clearance is obtained, but fluid may not be removed. Ultrafiltration can be combined with dialysis.

Hemofiltration is the combination of ultrafiltration and fluid replacement, typically in much larger volumes than needed for fluid control. The replacement fluid contains electrolytes, but not other small molecules. Since the net effect of replacing fluid without small solutes and ultrafiltration of fluid with small solutes results in net removal of small solutes, clearance is obtained.

Existing renal replacement therapy machines and specifically those used in acute setting to perform (Slow Continuous Ultrafiltration) SCUF and CVVH therapy were designed to primarily perform hemofiltration and hemodialysis, not merely fluid removal. Blood is composed of cellular components suspended in the fluid component called plasma. Water is the primary constituent of plasma in which physiological solutes such as sodium and potassium are dissolved. Also, in plasma, larger molecules, such as proteins and blood cells, are suspended. Hemofiltration and hemodialysis remove solutes (and some larger molecules) in addition to fluid removal. Ultrafiltration relates to fluid removal from blood, and does not remove solutes or larger molecules.

Ultrafiltration and hemofiltration operate primarily by convection. In hemofiltration, a solute molecule is swept through a filter membrane by a moving stream of ultrafiltrate. Proteins and blood cells are retained in the blood by the membrane. In patients with renal failure, renal replacement therapy, such as hemofiltration or dialysis, removes undesired solutes. In renal replacement therapy, vital elements such as electrolytes are also removed from the blood and need to be replaced to maintain electrolyte balance. Thus, hemofiltration and dialysis treatments usually require fluid replacement. In contrast, ultrafiltation does not remove substantial amounts of electrolytes and solutes.

During hemofiltration solute removal is entirely dependent on convective transport. Hemofiltration is relatively inefficient for solute removal, as compared to dialysis. Hemodialysis allows the removal of water and solutes by diffusion across a membrane in the direction of the concentration gradient. Diffusion transfers solute molecules across the membrane in the direction of the lower solute concentration at the rate inversely proportional to the molecular weight.

Hemodialysis requires a large filter membrane surface to enable effective solute clearance by diffusion. Hemofiltration requires large amount of ultrafiltrate to be transferred across the membrane to remove a relatively small amount of solute. This is a consequence of convection being an inefficient method of solute transport. Large amounts of fluid such as 1 to 4 liters per hour (L/hour) are continuously being removed during CVVH. The resulting loss of water and electrolytes are immediately dangerous to the patient. To maintain fluid and electrolyte balance, equally large or slightly lower amount of replacement fluid is infused into the patient. Replacement fluid is thus added into the extracorporeal blood circuit before or after the filter.

Ultrafiltration utilizes extracorporal blood filters to remove fluids from blood, where the filter generally includes a blood passage having input and output ports, a filtered fluid discharge port and a finely porous membrane separating the blood passage and the ultrafiltrate of filtrate discharge port. Ultrafiltration involves the convective transfer of excessive

fluid out of the blood plasma from the blood passage, through pores in the membrane, and to the discharge port of the filter. The pores filter electrolytes and small and middle sized molecules (up to 20,000 to 30,000 daltons) from the blood plasma. Importantly, since the concentration of small solutes is the same in the ultrafiltrate as in the plasma, effectively, no clearance of solutes from the blood plasma occurs during ultrafiltration. Accordingly, the ultrafiltrate output from the filter is substantially all fluids, e.g., water, and is relatively free of solutes.

2. Limitations of Existing Devices for Ultrafiltration

Dialysis machines historically used sets of disposable components that are assembled of various parts from different manufacturers. This allowed flexibility but had certain disadvantages. Joints between component parts may leak, allow ingress of air and facilitate blood clotting. High skill was required from hospital nurses and technicians to assemble tubes, connectors, filters and accessories and then load them correctly into pumps, bubble detectors, pressure sensors and other interface elements of a dialysis machine. In the setting of a chronic dialysis center such practice was acceptable. However, in an acute setting, such as an Intensive Care Unit (ICU) of a hospital, the complexities of dialysis machines became an impediment.

As a result, use of mechanical fluid removal in the ICU, Emergency Rooms and general floors of a hospital has been limited. One United States manufacturer recently released sophisticated apparatus marketed under the tradename "Prisma"™ by Hospal-Gambro. It uses an integrated set of disposable dialysis components in which tubing, filter and accessories are bonded together and no assembly is required. The filter, sensor interfaces and four dedicated pump segments (for blood, dialysate, replacement solution and effluent) are mounted on a flat plastic cartridge to simplify the loading of the dialysis pumps. The Prisma™ machine is advertised as "an integrated system for continuous fluid management and automated renal replacement therapy blood."

While Prisma™ has been a significant advancement in the state of the art and has enjoyed wide adoption, it has its deficiencies. One deficiency is that, although the Prisma™ set of disposable dialysis components is continuous and bonded together, it does not present a smooth blood path but incorporates elements that create stagnant and slow moving blood zones. In such zones blood clots are likely to form. It also employs an interface to pressure sensors that is relatively inaccurate, unreliable and requires maintenance. There is a need for an improved design of the blood flow dialysis set that is simple to use, requires no maintenance or special training, and has improved performance over the existing set of disposable components for the Prisma™ machine.

In addition, the Prisma™ set does not integrate pressure sensors. Instead it integrates pressure "pods" shaped as domes. The interface surface of a pod is made out of silicon membrane approximately one inch in diameter. When mounted on the Prisma™ machine pods interface with the permanently installed pressure sensors that are the part of the machine. The interface is sealed by a rubber gasket so that the pod membrane serves as a lid on the pressure transducer cavity. When in operation, blood and other fluids flow through pods and come in contact with the membrane.

Pressure pods provide a means to measure the pressure of blood and other fluids flowing outside an interface surface. When the pressure inside the pod is increased the diaphragm stretches and thereby compresses the air inside a transducer cavity. As a result pressure in the bloodline or a fluid line is measured. The pod membrane serves as a barrier between the blood and potential contamination from environment, as is similar to the clinical invasive vascular blood pressure measurements. This method, although functional, has several deficiencies:

1. To be accurate pods have to be positioned perfectly when the pressure inside is atmospheric. Over time, if there is even a miniscule leak on the transducer side of the membrane, pod will creep and gradually stop transmitting pressure accurately because of the tension in the membrane.
2. Stretchable membranes and air filled transducer cavities add compliance to the circuit. Compliance is a delay in a pressure measurement due to the time required to stretch the pods and compress the air inside the pod cavity. Compliance is not desired since it makes the system less responsive to controls.
3. Pods filled with blood increase the blood-plastic contact surface and create stagnant zones with low blood flow velocity that facilitate clot formation. Because clots may form in the pods, the use of pods also necessitates the use of clot capture devices.
4. Pod domes have significant volume that increases the total extracorporeal volume of blood. This increased volume also increases the time that blood spends in contact with foreign materials. Altogether this increases risks of blood loss, hypotension and clotting.

SUMMARY OF THE INVENTION

To better address the needs of fluid removal and dialysis in the acute and emergency setting and to eliminate significant limitations of existing designs, applicants have developed a device that integrates all elements needed for successful blood treatment for ultrafiltration in one disposable set of components. This component set includes the tubing and filter that forms a blood path from the patient through the ultrafiltration machine and a return to the patient. The set also includes the pressure sensors apparatus for various types of blood treatments.

Extracorporeal blood treatments are known in the prior art where blood is continuously withdrawn from, processed and returned into the same or different vein in the patient's arm. For example, such methodology is commonly used in blood apheresis treatment. Examples of apparatus for plasma apheresis are marketed by Spectra™ or Trima™ from Gambro. However, extracorporeal blood treatment that draws blood solely from peripheral veins, e.g., the arms, has been limited. The major limitation of peripheral access is the relatively modest amount of blood that can be withdrawn per unit of time. It is accepted that in almost all patients the blood flow of 40–60 mL/min can be established. In some cases, blood flow of up to 100 mL/min can be achieved. Blood flow available from a peripheral vein is a great deal lower than the blood flow of 100–400 mL/min that is required to operate current renal replacement therapy machines, such as the Prisma™ system in an adult patient.

The apparently insufficient blood flow from a peripheral vein was perceived by the engineering and medical community as a prohibitive factor in using peripheral access for renal replacement therapy. In spite of an apparent clinical need, the peripheral vein ultrafiltration was never developed or actively investigated. Contrary to the conventional wisdom regarding the blood flow requirement, applicants analyzed the medical and engineering considerations behind the requirement for blood flow for renal replacement therapy.

They developed a clinically useful method and apparatus for fluid removal that can operate at blood flows of less than 100 ml/min and preferably of 40 to 60 ml/min.

The invention integrates the filter with the blood path tubing to and from the patient. The present invention has several distinguishing features that constitute an improvement over the state of the art. It incorporates an intravenous extracoraporal circuit that is disclosed in commonly owned (U.S. patent application Ser. No. 09/618,759, filed Jul. 18, 2000) and is hereby incorporated by reference. This extracorporal circuit provides blood flows of 10 to 60 ml/min, which is sufficient to remove excessive fluids from the blood via ultrafiltration. A straightforward dependency exists between the amount of ultrafiltrate removed from the blood and the flow (volume per unit time) of blood that passes through the filter. Blood condenses in the filter. In practice approximately 20% to 30% of the ultrafiltrate volume can be safely removed from the blood as filtrate. If more is removed, the blood becomes too dense with red blood cells and protein and will flow sluggishly. By removing 20% to 30% as ultrafiltrate, sufficient excess fluid may be removed by filtering just 2% or less of the total cardiac output of the patient. This 2% of cardiac output T can be removed through peripheral veins. Thus, an ultrafiltrate system has been a developed that requires only peripheral vein access.

The proposed invention integrates single use pressure sensors with the single use blood set. After being used on one patient, the entire set including the pressure sensors is discarded. Disposable pressure sensors are a part of the disposable blood circuit. The integrated sensors do not disturb the laminar blood flow inside the bloodline since the internal diameter of the sensor element is the same as of the blood tubing (3.2 mm or 4.5 mm). The sensing element is less than 5 mun in diameter and is embedded flush in the wall of the sensor housing. The housing is bonded flush with the internal wall of the blood line tube to form a continuous channel. Although similar disposable blood pressure sensors (such as ones made by Merit Medical of Utah) are used widely for invasive blood pressure measurement this design has never been previously used in an apparatus for fluid removal or as an integral part of a extracorporeal blood treatment set.

Pressure sensors are included as the integral elements of the blood circuit. The pressure sensor component includes a blood passageway coaxial to and integral with the passageway of the lumen of the blood circuit. For example common blood tubing internal diameters of 3.2 and 4.5 mm can be used for the blood passageway in the pressure sensor. A small silicone or other flexible material filled window in the wall of the tubing separates blood from the pressure sensitive element. This way there is no disturbance to the smooth flow of blood to facilitate clotting. There is no stagnant zone where blood is not moving. There is no added compliance since there is virtually no compressible gas in the system and the silicone filled window can be made as small as 1 to 5 mm^2. In addition, if the sensing element of the sensor is compatible with blood there is no loss of accuracy associated with the transmission of pressure through the diaphragm. The frequency response of the sensor is also vastly improved since there is no significant compliance in the measuring element.

SUMMARY OF THE DRAWINGS

A preferred embodiment and best mode of the invention is illustrated in the attached drawings that are described as follows:

FIG. **1** is a perspective view of a intravenous blood ultrafiltration system having a first embodiment of a disposable blood circuit cartridge with an integrated pressure sensor.

FIG. **2** is a font view of a first portion of the blood circuit cartridge.

FIG. **3** is a rear view of the first portion of the blood circuit cartridge shown in FIG. **2**.

FIG. **4** is a side view of a second portion of the blood circuit cartridge.

FIG. **5** is a perspective view of the second portion of the blood circuit cartridge.

FIG. **6** is a rear view of the second portion of the blood circuit.

FIG. **7** is a schematic diagram showing a fluid path of blood and removed fluids for the blood cartridge.

FIG. **8** is a view of a second embodiment of a disposable blood circuit cartridge, where the cartridge is shown separately from an associated pump console.

FIG. **9** is a partial cross-sectional view of an integral disposable pressure sensor in a tube section of a blood circuit cartridge.

FIG. **10** is partial cross-sectional view of an integral disposable pressure sensor in a filter section of a blood circuit cartridge.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **1** shows an intravenous blood ultrafiltration system **100** for treating a patient suffering from fluid overload. The patient **101**, e.g., a human or other mammal, can undergo ultrafiltration treatment to remove fluid, e.g., water, from his blood while lying in bed or sitting in a chair. The patient can be in a physician's office, outpatient clinic, hospital emergency room or other medical treatment center. The center need not be an ICU or other intensive treatment unit.

To initiate ultrafiltration treatment, two standard 18G IV needles **102** and **103** are introduced into suitable peripheral veins (on the same or different arms) for the withdrawal and return of the blood. The needles are attached to withdrawal tubing **104** and return tubing **105**, and secured to skin with attachments, such as adhesive strips **106** and **107**. The withdrawal and return tubing form portions of a continuous blood fluid passage **108** that extends through a disposable blood circuit cartridge **109**.

The disposable blood circuit cartridge **109** is attached to a pumping console **110**. The cartridge may be detached from the console, as is shown in FIG. **7**. The cartridge **109** includes the continuous blood passage **108** through which flows blood withdrawn from the patient. After flowing the cartridge, the blood is returned to the patient via return tubing **105**.

The blood passage **108** through the cartridge **109** supports a continual flow of blood, and is substantially free of stagnation areas in which blood might pool and coagulate. In addition, the blood passage is generally free of air interfaces so that the blood while in the cartridge does not encounter blood-air interfaces. If the blood were permitted to be exposed to air, the blood would begin to coagulate and the coagulated blood could form occlusions in the passage or flow back into the blood vessel of the patient.

The blood passage **108** includes the blood tubing **104** leading from and blood tubing **105** leading to the patient for withdrawing and reintroducing blood into the patient. Simi-

lar tubing sections extend through the cartridge and form additional links in the passage **108**. These tubing links are coupled to a blood filter **111** and pressure sensors **112**, **113**, that are contiguous with the tubing and form sections of the blood passage **108**. All sections of the blood passage, including the filter and sensors, are continues flow sections, such as formed by a hollow tube with smooth cylindrical sides. The pressure sensors have hollow straight-tube blood passages with a small pressure sensor mounted flush with the wall of the sensor tube so as to avoid obstructing the blood flow. Similarly, the filter has continuous blood flow passages that avoid areas of stagnate blood.

The blood filter **111** may be a cylindrical tube **400** having a conical blood inlet **401** and a conical blood outlet, each coupled to the tubing of the blood passage **108**, as is shown in FIG. **10**. The hollow tube **400** of the filter **111** includes an open cylindrical filter entrance **401** having a pressure sensor **403** mounted on the wall of the inlet. A pressure sensor on the filter is optional and is now shown in FIG. **1**. The filter is packed with porous hollow fibers **405** arranged in parallel with each other and the axis of the filter. These fibers **405** are each open to blood flow at the inlet **401** of the filter and discharge blood at their outlets in an outlet section of the filter. The filter fibers have cylindrical walls that are formed of a porous membrane. Blood cells and proteins does not pass through the walls of the filter fibers, but filtrate solution, e.g., water, ions and small molecules, does pass through the porous fiber walls. The membrane in the walls of the filter fibers **405** separates the blood flowing through the fiber into a blood component (which flows through the fiber, via the outlet section of the filter and the blood return tubing, and back into the patient) and a filtrate component (which is discharged through filtrate line **119** into the ultrafiltrate bag **120**). The filtrate disposable blood circuit cartridge **109** is supplied separate from the console and packaged in a sterile package (not shown). See FIG. **8**. The cartridge is intended to be used for one single treatment, and not to be reused. The cartridge is inserted into the pump console **110** by threading the tubing loops **121** in the blood passage **108**, and ultrafiltrate discharge tubing **119** over the rims of roller pumps **121** and **122**. As the pumps rotate, they slidably engage the tubing and force blood and ultrafiltrate fluids to move through the cartridge fluid passages. The microprocessor pump drivers control the flow rate of the blood and ultrafiltrate through the cartridge. The pump drivers are part of the console and are controlled by a computer system within the console. However, the console and its pumps are not part of the present invention. The present invention is embodied in the disposable blood circuit cartridge. Once the cartridge is installed to the console (as shown in FIG. **1**), the system is primed with a sterile priming solution. The needles for the withdrawal tube **104** and the return **105** tube are inserted into a peripheral blood vessel(s) of the patient **101**. Tubes can be connected to the needles and blood displaces the priming solution. Treatment can begin as common in fluid removal or dialysis.

FIG. **2** is a close-up front view of a portion of the cartridge **108** fitted on the pump **122**. FIG. **3** is a close-up rear view of the same portion of the cartridge, but removed from the console. The tubing of the cartridge may be mounted in a molded-plastic housing **123** that fits into a recess in the surface of the console and snaps into the console with latches **124**. A blood withdrawal pressure sensor **112** is mounted to an inside surface of the cartridge housing **123**. The console may include clips **125** to hold the tubing in place, in addition to the recess and latch coupling between console and the cartridge housing **123**. The clips **125** on the housing may incorporate a bubble detector to sense bubbles flowing in the blood passage of the cartridge.

The blood passage **108** may include a T-connector **126** so that medicines and drugs can be introduced into the blood flowing through the passage. These medicines and drugs would flow through a tube line **127** from an injection pump **128** to the connector **126** and into the blood passage.

FIGS. **4** to **6** show a second cartridge housing **129** for supporting the filter **111** and the tubing loop **121** that is threaded into the rim "raceway" of the pump **122** that moves filtrate from the filtrate output **130** of the filter through the filtrate line **119** to the bag **120**. The filter may snap into or be bonded to the second cartridge housing. The filter is mounted vertically in the console. The blood inlet is at the lower end of the filter and the outlets for the blood and filtrate are at the top. The pressure sensor **132** for the filtrate tube, and a sensor **113** for the blood return tube **105** are mounted to an inside surface of the second cartridge housing **129**. The pressure sensors **112**, **113** and **117** may include transducers that convert pressures into electrical signals carried by signal wires **131** that are connected to a computer controller in the console.

During operation, the ultrafiltration system **100** (including pump console and disposable blood circuit cartridge) requires minimal intervention from user. User sets the maximum rate at which fluid is to be removed from the patient using a control panel on the console. Blood circulates through the blood passage in the cartridge. As the blood passes through the filter **111**, ultrafiltrate is removed from the blood and is discharged from the filter into the ultrafiltrate tubing **119** and is collected into a graduated collection bag **120**. When the bag is full (as detected by a bag weight sensor in the console), the console issues an alarm and ultrafiltration stops until the bag is emptied.

FIG. **7** is a schematic diagram of the blood and filtrate flow through the ultrafiltration system **100**. Blood is withdrawn from the patient through an 18 Gage withdrawal needle **102**, flows into the withdrawal tubing **104** and enters the blood passage **108** of the cartridge **123**. The needle is inserted into a suitable peripheral vein in the patient's arm or any other suitable peripheral vein. Blood flow through the withdrawal tubing is controlled by the speed of the roller pumps **122**. Before entering the pump, blood passes through approximately two meters of plastic withdrawal tubing **104**. This tubing may be formed of medical PVC of the kind used for IV lines and has internal diameter (ID) of 3 mm. The tubing for the pump loop **121** has the same ID as do other portions the tubing in the blood passage. During operation, the pump rollers compress the pump segment tubing. The rotational speed (RPM) of the pump governs the fluid flow rate through the tubing. The pump may rotated by a DC motor in the console, and is under microprocessor control. The system may pump approximately 1 ml (milliliter) of blood for each full rotation of the pump **122** and, for example, a pump speed of 60 RPM provides a flow rate of 60 ml/m (milliliters/minute).

Pressure sensors **112**, **113** are integral to the blood passage **108** in the cartridges **123** and **129**. These sensors are disposed in the passage **108** such that a diaphragm of the sensor, which is the device that is in fluid contact with the load and directly responds to the blood pressure, is adjacent the blood passage. The diaphragm does not form stagnant areas in the passage. Similarly, a pressure sensor **117** (which also includes a diaphragm in fluid contact with the filtered fluid) for the ultrafiltrate is integrally formed in the filtrate tubing **119** between the filter **111** and the ultrafiltration bag

120. These pressure sensors are included in the disposable cartridge and are intended for one-time use. The pressure sensors each have a generally straight and hollow fluid passage that is coupled to the blood or filtrate tubing in the cartridge. The passages in the sensors are contiguous with the blood and ultrafiltrate passages of the cartridge.

The fluid flow passage in each sensor includes in a peripheral wall a pressure sensing diaphragm that is relatively small compared to the passage. As blood or ultrafiltrate flows across the diaphragm, the pressure of the flow displaces the diaphragm. This diaphragm displacement is converted by a mechanical-to-electrical transducer in the sensor to an electrical signal, e.g., a voltage level, that is indicative of the pressure of the flow. The electrical signal is output by the sensor to the pump console **110** through an electrical signal line, e.g. a wire **131**. A controller in the console receives the pressure signals via the lines **131** and determines the pressure level of the blood or ultrafiltrate in the blood or ultrafiltrate passage in which the associated sensor is positioned.

The advantages of the pressure sensors **111**, **112** and **117** include that the fluid passage within the sensor is a smooth hollow tube through which the blood or ultrafiltrate flows without obstruction or stagnation; the sensors do not introduce a blood-air interface to the blood flowing through the cartridge, and they provide a direct electrical signal output that reliably indicates the pressure in the sensor passage. These pressure sensors are an improvement over existing blood flow pressure sensors that have bubble traps or separation diaphragms, which are less accurate, and have areas of stagnant blood flow.

The pressure sensors **111**, **112** and **117** may be sufficiently sensitive to measure negative (suction) pressure to minus 400 mmHg (millimeter of mercury). The withdrawal pressure signal is used by the console to maintain the blood flow from the vein and through the withdrawal tube **104**. Typically, a peripheral vein can continuously supply 60–100 ml/min of blood. The sensor can be applied to confirm that an acceptable flow of blood is being withdrawn from the vein by sensing pressure in the withdrawal tube, by adjusting the pressure reading for any height difference between the sensor **111** and the peripheral vein, and by compensating for flow resistance in the tubing **104** from the vein to the sensor.

If the pressure reading indicates that the blood flow has dropped significantly from the withdrawal vein, then the console may determine that the vein has an occlusion (such as a vein collapse) and reduce the speed of the pump or stop it altogether accordingly. For example, blood flow can be temporarily impeded by the collapse of the vein caused by patient movement, a crimp or kink in the tubing, or occlusion by clotting. In other cases the vein of the patient may not be sufficient to supply the maximum desired flow of 60 ml/min. Such conditions obstruct the blood flow and are detected by the blood withdrawal pressure sensor. The software executed by the microprocessor of the pump console controls the pump speeds such that the rate of flow in the blood passage of the cartridge **109** slows the withdrawal of blood to prevent or recover from the collapse of the vein and reestablish the blood flow based on the signal from the withdrawal pressure sensor. Similarly, a pressure signal from the sensor **112** may also be used to detect a disconnection in the withdrawal bloodline **104** from the needle **103**. This condition is detected by the abrupt decrease of the withdrawal pressure generated by the pump. An occlusion in the withdrawal tube **104** may be caused by the collapse of a vein or a kink in the tube, and can result in a rapid decrease (more negative) of the pump suction pressure that is detected by the sensor **112** which signals a controller in the pump console. In response to this rapid pressure decrease, the controller may reduce the pump speed to slow the blood flow being withdrawn, or stop the pump and issue an alarm.

In addition, a pressure sensor **113** may be incorporated into blood passage of the cartridge **129** that is downstream of the pump **122** and filter **111**. This return sensor **113** detects the pressure of the blood being returned to a peripheral blood vessel of the patient, and provides a signal indicative of the pressure of the flow of the return blood. The sensor signal is processed by a controller in the console, and may be used to detect abnormal conditions in the return tubing **105**, such as an occlusion, an unacceptable clotting of the filter or a disconnection of the blood tubing with the pump, the filter **110**, the return line or the catheter needle in the patient. In addition, the blood return circuit pressure sensor **113** and the signal from the filtrate pressure sensor **117** may serve also to determine a rate of filtrate flow into the bag **120**. The ultrafiltrate sensor **117** may also to detect clotting or fouling of the filter **110** or the filtrate line **119**.

FIG. **8** shows an alternative embodiment of a disposable blood circuit cartridge **209**. This cartridge is similar in many respects to the first blood circuit cartridge **109**, but includes a substrate sheet **201** on which the blood passage **208**, filter **211**, pressure sensors **212**, **213** and **217**, and filtrate tube **219** are mounted. In addition, the cartridge **209** may include a filtrate bag **220** that is hung on a hook **218** on the console. This hook may be connected to a strain gage or pressure transducer to sense the weight of the bag and thereby provide a signal indicative of when the bag is full to a controller in the console. The substrate sheet is a molded plastic material formed to fit onto the console and align the loops **221** of the blood and filtrate passages with the roller pumps **122**. In addition, attachment clips (not shown) on an inside surface of the substrate may connect to clip-holders **222** on the console. Blood passage tubes **208** and filtrate tube **219** are positioned by the attachments to the substrate **201** to facilitate loading into slots of the air detector **125** and the blood leak detector **125**.

FIG. **9** is a cross section drawing of a pressure sensor **300**. The sensor includes a diaphragm **301** mounted flush with the inside surface of the wall **306** of the hollow tubular flow passage **307** in the sensor. The flow passage has a similar ID (Typically 3 or 4.5 mm) to that of the blood passage **305** which is coupled to is the inlet and outlet of the sensor. Accordingly, the flow passage **307** forms a contiguous section of the blood passage **305** with the tubing in the cartridge. The diaphragm **301** is deflected by the pressure of the blood flow through the passage **307**. This deflection is sensed by a pressure transducer **302**, e.g., a piezoelectric semiconductor, which generates an electrical signal indicative of the blood/filtrate pressure on the diaphragm. A signal wire **304** and a connector **303** transmits the sensor electrical signal to the controller in the pump console.

The sensors may be a flow-through type pressure sensor commonly used for blood pressure measurement. The sensor has a passage that is contiguous with the tubing for the blood passage or the ultrafiltrate tubing. The mechanical-to-electrical transducer of the sensor may be a strain gauge or capacitive circuit having a piezoresistive element implanted on an etched silicon diaphragm. The diaphragm is positioned at the periphery of the passage and flush with the wall of the passage so that blood or ultrafiltrate flows across the diaphragm without disturbing the flow. The pressure of the blood or ultrafiltrate acts on the diaphragm. The piezoresistive transducer element of the sensor is responsive to the stress induced on the diaphragm by an external pressure,

such as the flow of blood or ultrafiltrate. A piezoresistive transducer can provide linear output in the form of an analog voltage that is proportional to pressure input and ratiometric with a supply voltage. High sensitivity, frequency response and excellent long-term repeatability make these pressure sensors suitable for the blood cartridge application.

The pressure sensor housing incorporates a monolithic silicon piezoresistor, which generates a changing output voltage with variations in applied pressure. The resistive element, which constitutes a strain gauge, is ion implanted on a thin silicon diaphragm. Applying pressure to the diaphragm results in a resistance change in the strain gauge, which in turn causes a change in the output voltage directly proportional to the applied pressure. Applying a voltage supply across the piezoresistor transducer element will force an electric current to flow through the element. Pressure applied to the piezoresistor via the diaphragm produces a change in the element resistance and a corresponding change in the output voltage of the sensor. This output voltage can be converted by the pump console into a corresponding pressure of the fluid, e.g., blood or ultrafiltrate, applied to the pressure sensor. Small inexpensive pressure sensors that are suitable for blood pressure measurements are sold by Motorola under the tradename Digital DNA™ (Digital Blood Pressure Meter, AN 1571/D).

FIG. **10** illustrates a cross-sectional view of a pressure sensor embedded in the wall of a filter housing **400** of a hemofilter, dialyzer or hemoconcentrator. These filters have hollow fibers **405** coaxial with the device tubular body **400**. Filter fibers are embedded in the packing or potting material **404** in the cylinder of the filter. Blood tubing **402** is bonded or connected with a quick connector the filter header cap **401**. A disposable pressure sensor **403** is assembled with the cap **401** with the pressure sensitive element **408** protruding through the wall and in contact with blood. The pressure sensor **403** is covered by a housing cover **406**, and has electric wires **408** attached to the electric plug in connector **407**. A similar sensor can be attached or embedded in the wall of the filter housing **400** to measure ultrafiltrate pressure in the space formed by the outer wall of the fibers **405** packing material **404** and the inner wall of the housing **400**.

What is claimed is:

1. A disposable cartridge for mounting an extracorporeal blood passage on a pump device comprising:

a. a first cartridge housing supporting said blood passage, wherein said first cartridge housing is configured to seat in a first recess of the pump device, wherein said blood passage has a blood inlet connectable to a vascular system of a patient and a blood outlet connectable to the vascular system such that blood flows through the blood passage;

b. a blood pump coupling loop of the blood passage attached to the first cartridge housing and extending outwardly from said housing, wherein a blood pump of the device engages the pump coupling loop when said first cartridge housing is seated on the blood pump device;

c. a second cartridge housing supporting said blood passage and a filtrate passage, wherein said second cartridge housing is distinct and separate from said first cartridge housing, wherein said second cartridge housing is configured to seat in a second recess of the blood pump device, and

d. a filtrate pump coupling loop of the filtrate passage extending outwardly from said second cartridge housing, wherein a filtrate pump of the device engages the filtrate pump coupling loop when said cartridge housing is seat on the pump device, wherein through said filtrate passage flows filtrate withdraw from blood in the blood passage.

2. A cartridge as in claim **1** wherein said blood passage connects said first cartridge housing to said second cartridge housing.

3. A cartridge as in claim **1** wherein an electronic pressure sensor is fixed to the first cartridge housing and is arranged to sense a pressure of the blood flow through the blood passage, wherein said sensor outputs an electrical signal indicative of the blood flow pressure to the device.

4. A cartridge as in claim **3** where a second pressure sensor is to fixed to the second cartridge housing and said second pressure sensor is arranged to sense a pressure of filtrate flow through the filtrate passage, wherein said sensor outputs an electrical signal indicative of the filtrate flow pressure to the device.

5. A cartridge as in claim **4** where the second pressure sensor is embedded in the filter and is in fluid contact with the filtered fluid.

6. A cartridge as in claim **4** further comprising a third pressure sensor arranged to sense a blood pressure in return blood passage included with the disposable cartridge.

7. A cartridge as in claim **3**, where the pressure sensor and the pump coupling loop of the blood passage are rigidly fixed to an underside of the first cartridge housing and the first cartridge housing detachably attaches to the pump device adjacent to a raceway of the blood pump and said raceway receives the loop.

8. A cartridge as in claim **7** where the blood passage is formed of transparent material so that the blood flow is visible.

9. A cartridge as in claim **7** wherein the cartridge is discarded after treatment of the patient and after being released from the pump device.

10. A cartridge in claim **3** where the pressure sensor is in fluid contact with the blood.

11. A cartridge as claim **3** wherein the pressure sensor is sealed in a pressure sensor housing formed of a biocompatible and flexible material, and the sensor housing includes an integral and flexible membrane in contact with the blood and electronic sensors.

12. A cartridge as in claim **3** wherein the pressure sensor includes a pressure responsive diaphragm exposed to the blood flow and a mechanical-to-electric transducer coupled to the diaphragm and having an electrical signal output indicative of the pressure of the blood.

13. A cartridge as in claim **12** wherein the mechanical-to-electric transducer includes a strain gain bridge or capacitive element to convert displacement of the diaphragm to said electrical signal.

14. A cartridge as in claim **3** further comprising electrical signal connectors extending from the pressure sensor on the cartridge to a detachable electrical coupling on the blood pump device.

15. A cartridge as in claim **1** wherein the filtrate passage extending from the second cartridge housing discharges filtrate fluid to a filtrate collection container.

16. A cartridge as in claim **1** further comprising a pressure sensor housing affixed to the first cartridge housing for the pressure sensor, where the pressure sensor housing includes a smooth tubular channel contiguous with the blood passage fixed to the first cartridge housing and the pressure sensor is mounted flush with a wall of the first cartridge housing.

17. A cartridge as in claim **1** wherein blood pump coupling loop of said first cartridge housing extends substan-

tially vertical when attached to the pump device and the filtrate pump coupling loop of the second cartridge housing extends substantially vertical when attached to the filtrate pump.

18. A cartridge as in claim **1** wherein said first cartridge housing has an inside side surface facing the device when the first cartridge housing is seated on the device, and wherein said blood passage is attached to the inside surface of the first cartridge housing.

19. A cartridge as in claim **1** wherein said second cartridge housing has an inside side surface facing the device when the second cartridge housing is seated on the device, and wherein said filtrate passage and a filter are attached to the inside surface of the second cartridge housing.

20. A blood circuit as in claim **1** wherein said first cartridge housing is seated on a front of the device and the second cartridge housing is seated on a side of the device.

21. A blood circuit as in claim **1** further comprising a blood filter having an input and a blood output coupled to the blood passage and a filtrate outlet coupled to the filtrate line, wherein said filter is fixed to the second cartridge housing.

22. A cartridge as in claim **21** wherein the filter is of a group consisting of a hemodialyzer, hemofilter or hemoconcentrator, and the filter includes an integral pressure sensor embedded in a blood passage wall of the filter.

23. A cartridge as in claim **21** wherein the blood filter in the second cartridge housing is substantially vertical when said second cartridge housing is mounted in the device, and wherein said filter has a bottom filtered blood outlet to the blood passage.

24. A blood circuit as in claim **21** wherein said filter is oriented vertically on the second cartridge housing when said housing is mounted on the device, and said filter inlet is at a top of the filter.

25. A disposable extracorporeal blood circuit for processing blood from a mammal and attachable to a blood treatment device having a blood pump and a filtrate pump, said blood circuit comprising:

a blood passage having a blood withdrawal port connectable to a vascular system of the mammal, a blood return port connectable to the vascular system, and a blood passage between the withdrawal port and the return port through which blood flows wherein the blood passage has a smooth and continuous wall throughout the passage;

a blood filter having a blood inlet and a blood outlet coupled to said blood passage such that the blood flows through said filter, and said filter further comprising a filtrate output coupled to a filtrate line,

a first cartridge housing to which is attached a blood loop of the blood passage and the pressure sensor, wherein the blood passage is mounted to an inside surface of the first cartridge housing such that the blood loop extends outwardly of the cartridge housing, and said first cartridge housing is detachably mountable to the blood treatment device to engage the blood loop to the blood pump when the first cartridge housing is mounted on the device, and

a second cartridge housing to which is attached a filtrate loop of the filtrate line, wherein the filtrate line is mounted to an inside surface of the second cartridge housing such that said filtrate loop extends outwardly of the second cartridge housing, said second cartridge housing is distinct and separate from the first cartridge housing, and said second cartridge housing is detachably mountable to the device to engage the filtrate loop to the filtrate pump of the blood treatment device.

26. A disposable extracorporeal blood circuit as in claim **25** further comprising a pressure sensor fixed to the inside surface of the first cartridge housing and connected to the blood passage, wherein said pressure sensor outputs a signal indicative of a blood pressure in the blood passage.

27. A disposable extracorporeal blood circuit as in claim **25** wherein the tubular blood circuit line is connectable to a roller blood pump of the blood pump.

28. A disposable extracorporeal blood circuit as in claim **25** wherein the withdrawal and return blood vessels are the same blood vessel.

29. A disposable extracorporeal blood circuit as in claim **25** wherein the blood filter in the second cartridge housing is substantially vertical when said second cartridge housing is mounted in the device, and wherein said filter has a bottom filtered blood outlet to the blood passage.

30. A disposable extracorporeal blood circuit as in claim **25** wherein blood pump coupling loop of said first cartridge housing extends substantially vertical when attached to the pump device and the filtrate pump coupling loop of the second cartridge housing extends substantially vertical when attached to the filtrate pump.

31. A blood circuit as in claim **25** wherein said first cartridge housing is seated on a front of the device and the second cartridge housing is seated on a side of the device.

* * * * *

EXHIBIT B

US007232418B2

(12) **United States Patent**
Neri et al.

(10) **Patent No.: US 7,232,418 B2**
(45) **Date of Patent: *Jun. 19, 2007**

(54) **SUPPORT ELEMENT, AN INTEGRATED MODULE FOR EXTRACORPOREAL BLOOD TREATMENT COMPRISING THE SUPPORT ELEMENT, AN APPARATUS FOR EXTRACORPOREAL BLOOD TREATMENT EQUIPPED WITH THE INTEGRATED MODULE, AND AN ASSEMBLY PROCESS FOR AN INTEGRATED MODULE FOR EXTRACORPOREAL BLOOD TREATMENT**

(75) Inventors: **Roberto Neri**, Mirandola (IT); **Roberto Ribolzi**, Modena (IT); **Jacques Duchamp**, Bron (FR); **Aziz Aberkane**, Decines (FR); **Gabriel Meyssonnier**, Dizimieu (FR); **Dominique Pouchoulin**, Tramoyes (FR)

(73) Assignee: **Gambro Lundia AB**, Lund (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 420 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/771,415**

(22) Filed: **Feb. 5, 2004**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 60/470,442, filed on May 15, 2003.

(30) **Foreign Application Priority Data**

Feb. 7, 2003 (IT) MI2003A0215

(51) **Int. Cl.**

A61M 37/00	(2006.01)
A61M 1/16	(2006.01)
F04B 43/08	(2006.01)
B01D 63/00	(2006.01)
F16K 1/00	(2006.01)
C02F 1/44	(2006.01)

(52) **U.S. Cl.** **604/4.01**; 604/6.09; 604/6.11; 210/645; 210/321.6; 210/195.2; 417/477.2; 137/861

(58) **Field of Classification Search** 604/4.01, 604/5.01, 5.04, 6.09, 6.11, 6.16; 210/645–647, 210/90, 525, 232, 195.2; 422/44; 417/477.2, 417/237, 439, 472, 474; 137/861

See application file for complete search history.

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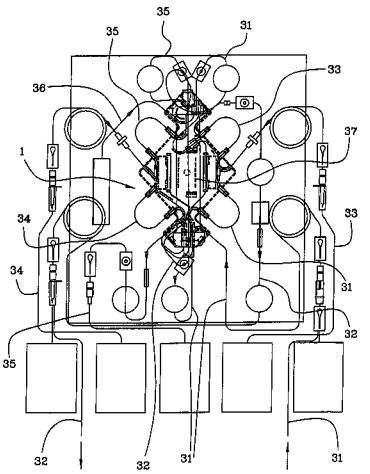

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(74) *Attorney, Agent, or Firm*—Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.

(57) **ABSTRACT**

An integrated module for extracorporeal blood treatment has a flat-shaped support element which exhibits on an internal face thereof a complex of fluid distribution lines and on an external face thereof a high-flow dialyzer. The support element has a base body which exhibits fixture seatings, each of which houses an axially extended tract of a fluid distribution line. The tract of the fluid distribution line, with respect to adjacent tracts, has an increased diameter due to the presence of a junction collar made of a rigid material. Each fixture seating exhibits two axial locators for positioning the axially extended tract of a fluid distribution line in a fixed position. The locators interact with the junction collar, and the distribution lines can be fixed to the base body by a resilient fixture of the junction collars in the seatings without gluing. The module is configured to be mounted on an apparatus for intensive treatment of renal insufficiency.

67 Claims, 14 Drawing Sheets

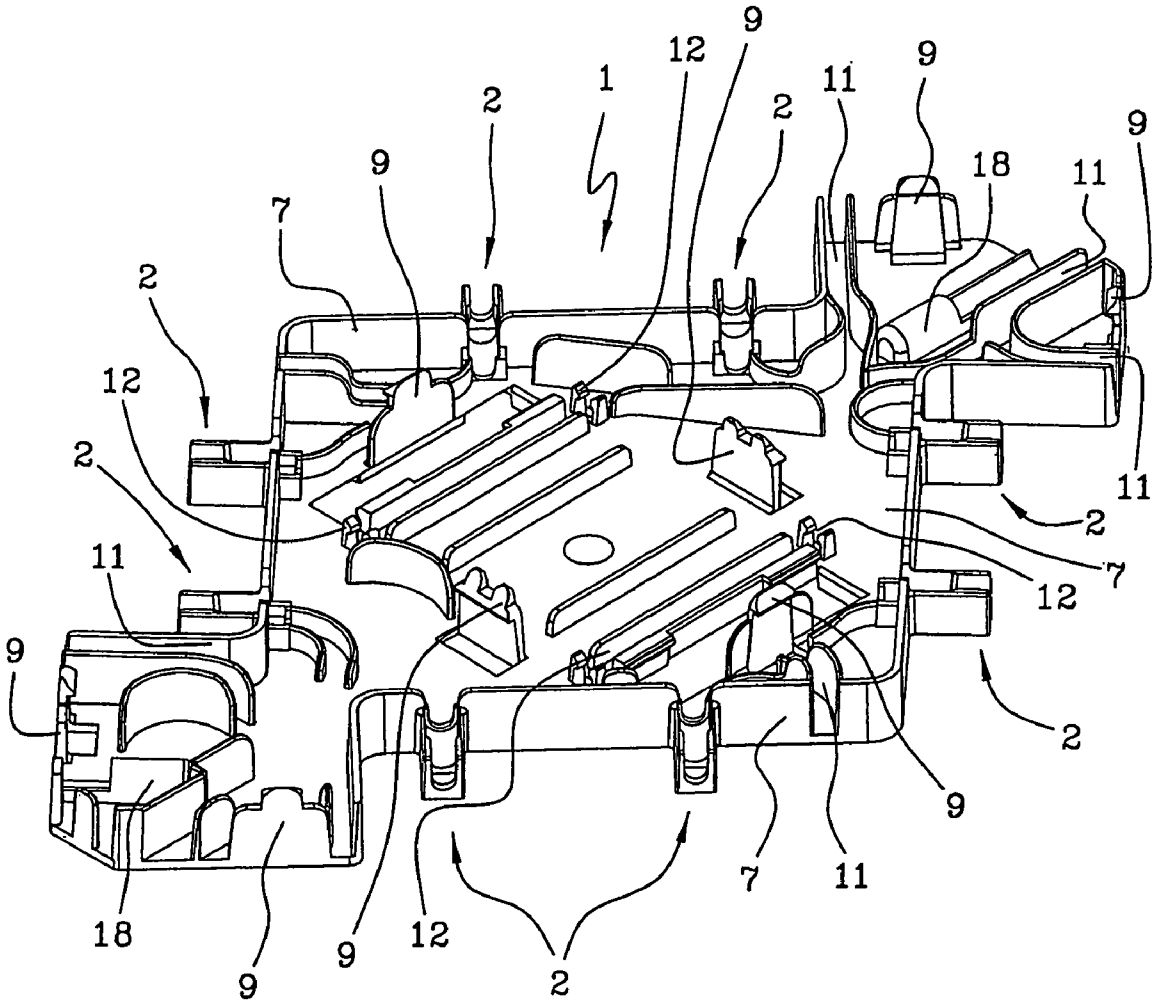


FIG 1

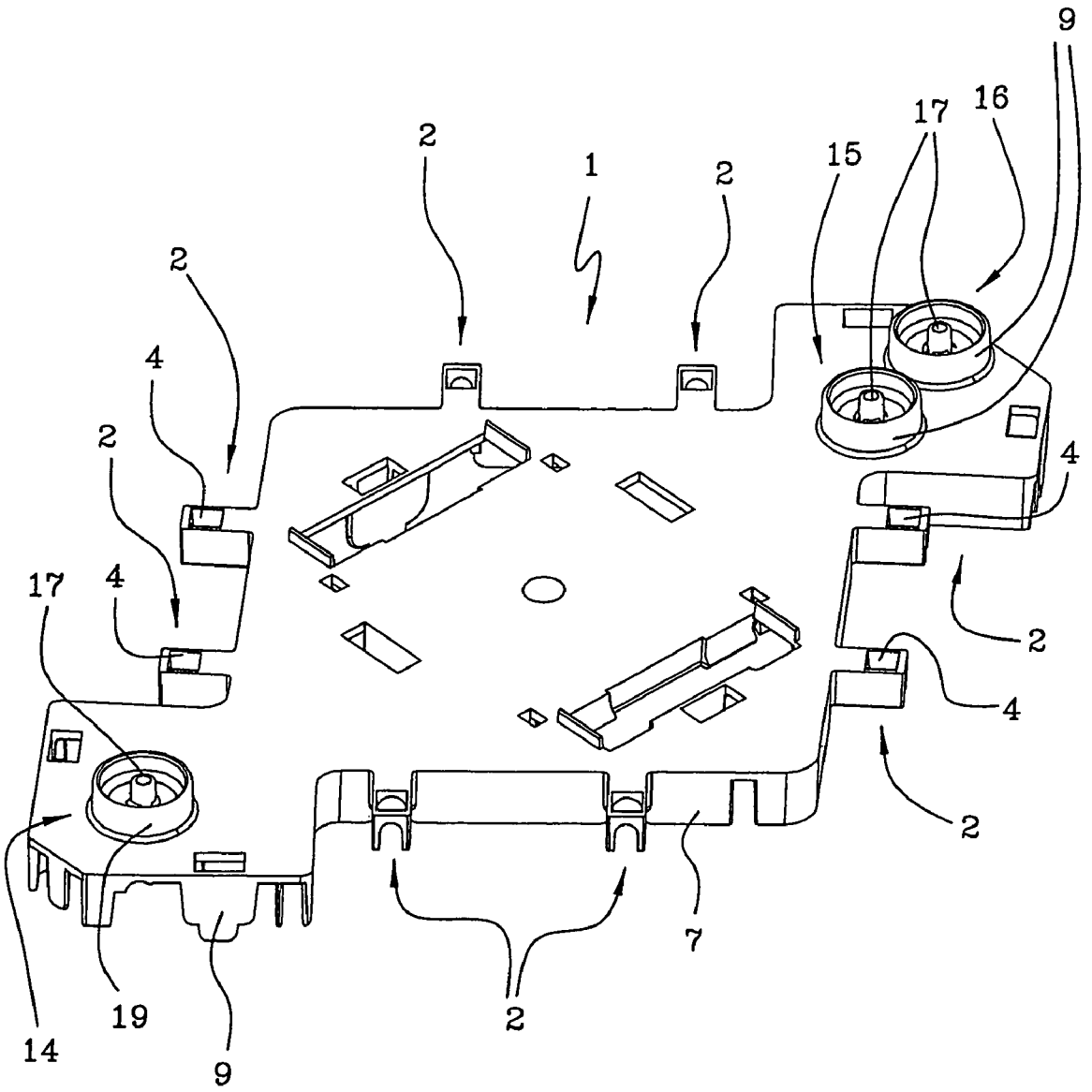
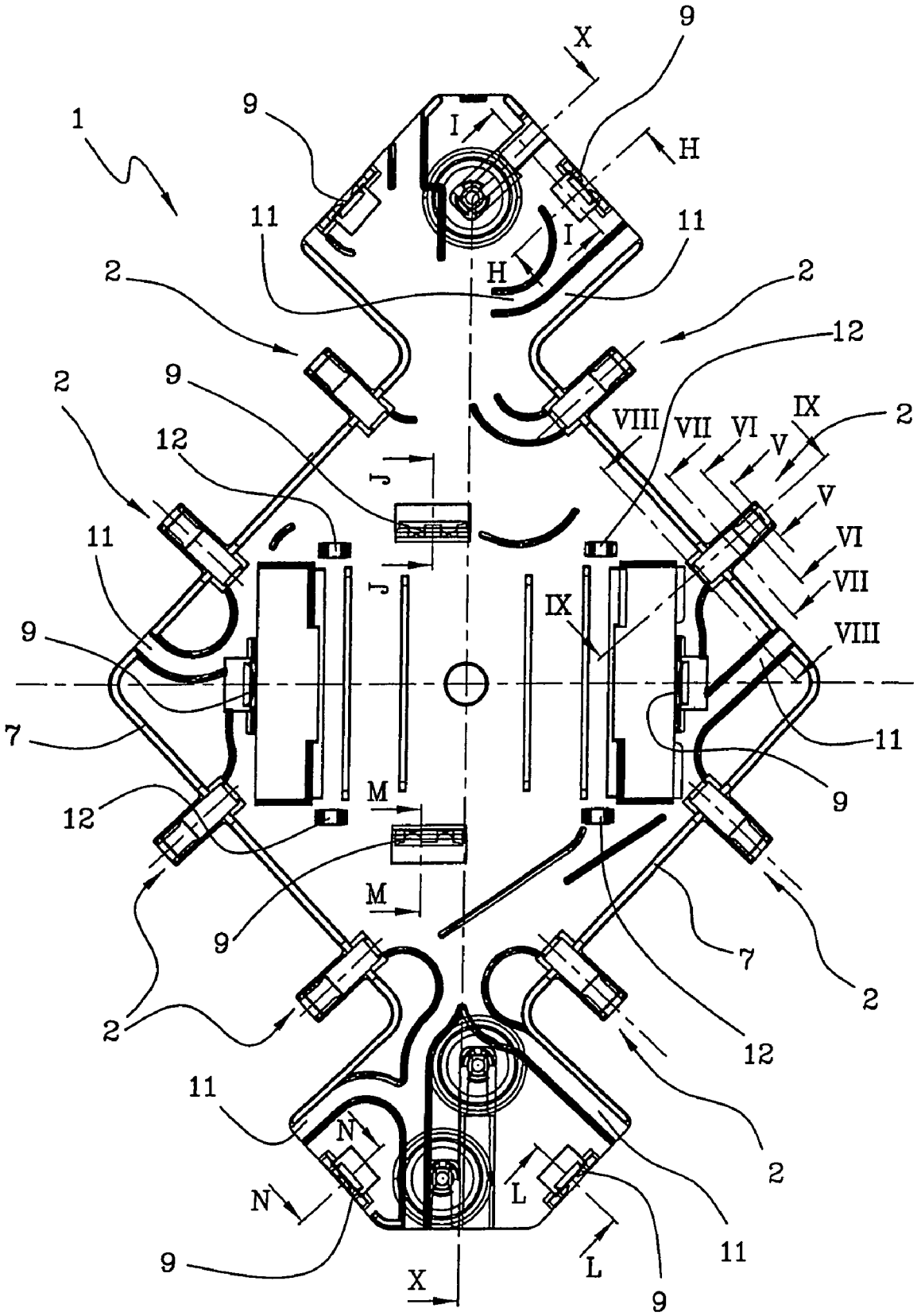


FIG 2

FIG 3



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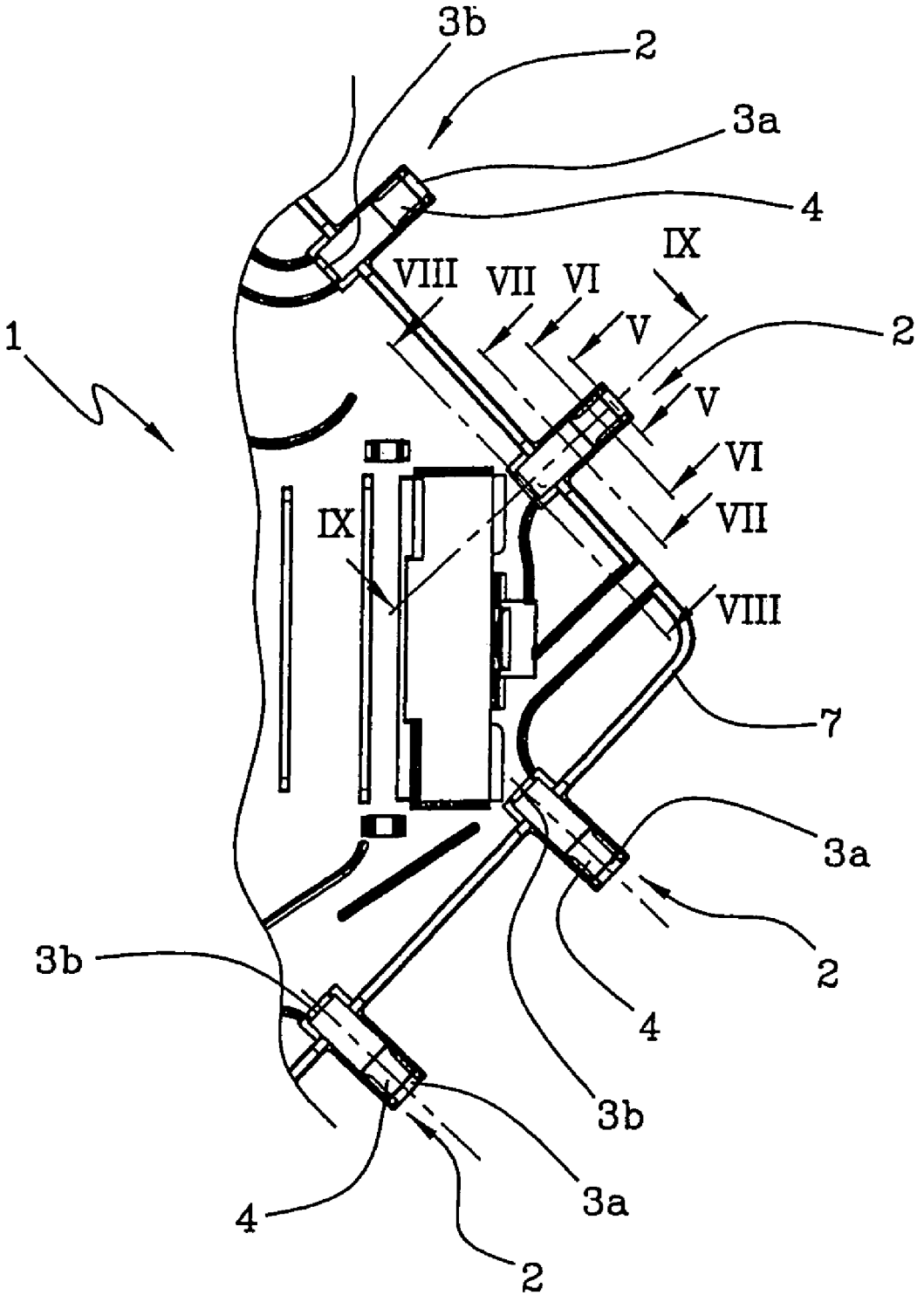


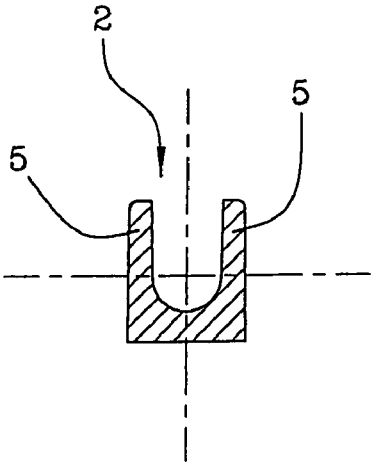


FIG 5

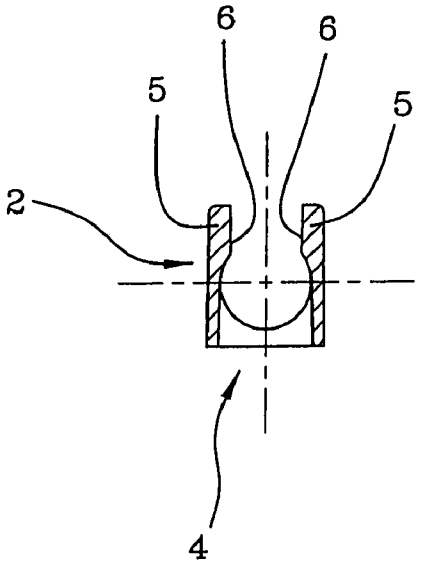


FIG 6

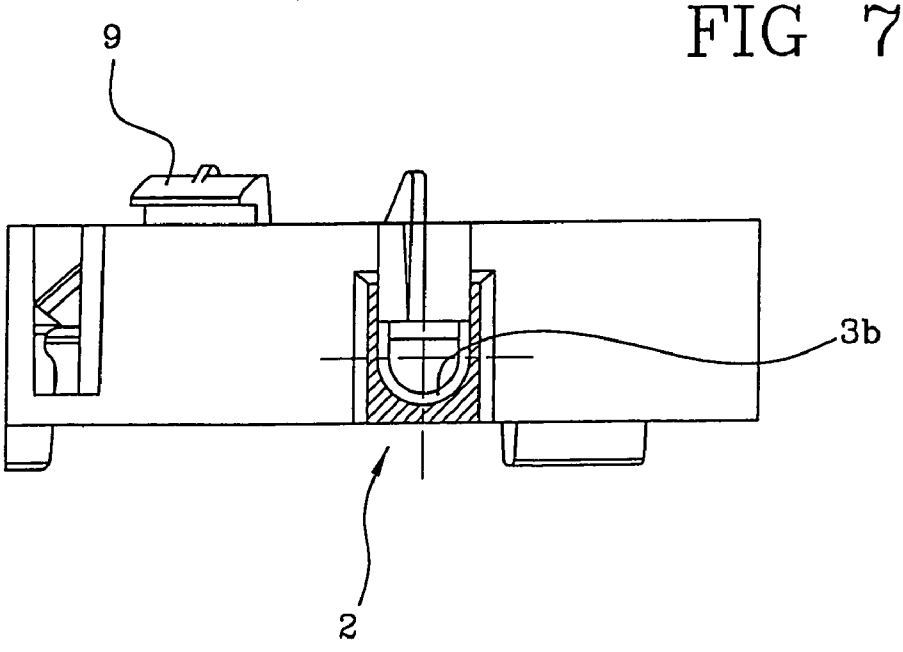


FIG 7

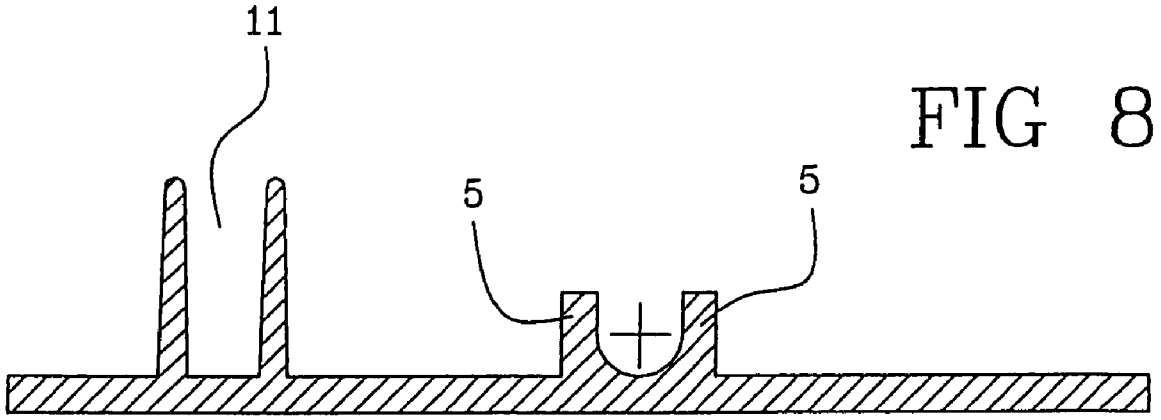


FIG 8

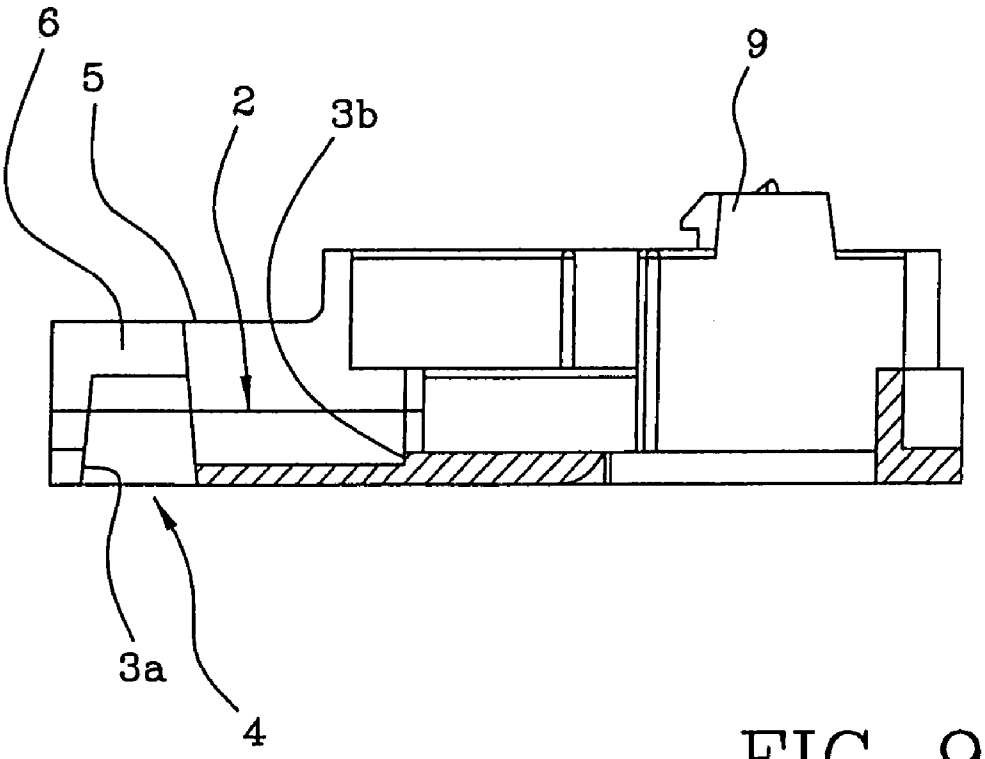


FIG 9

FIG 10

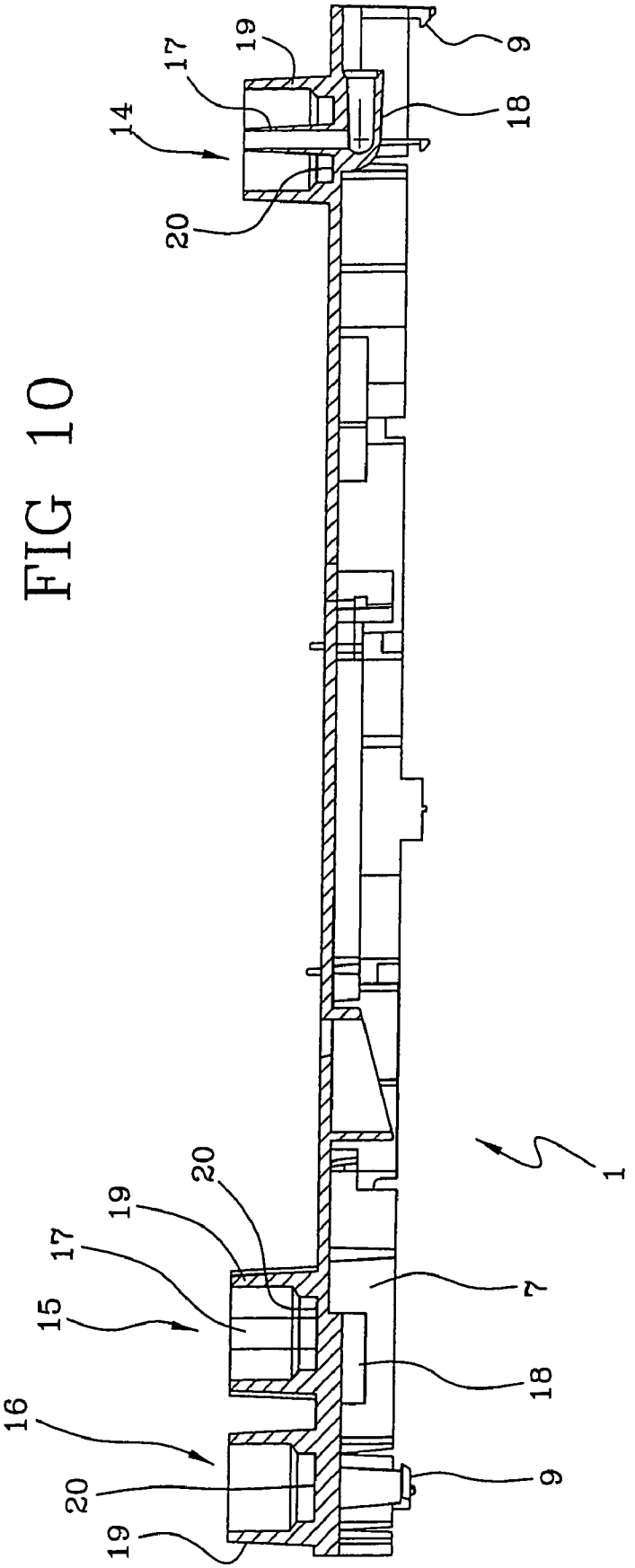
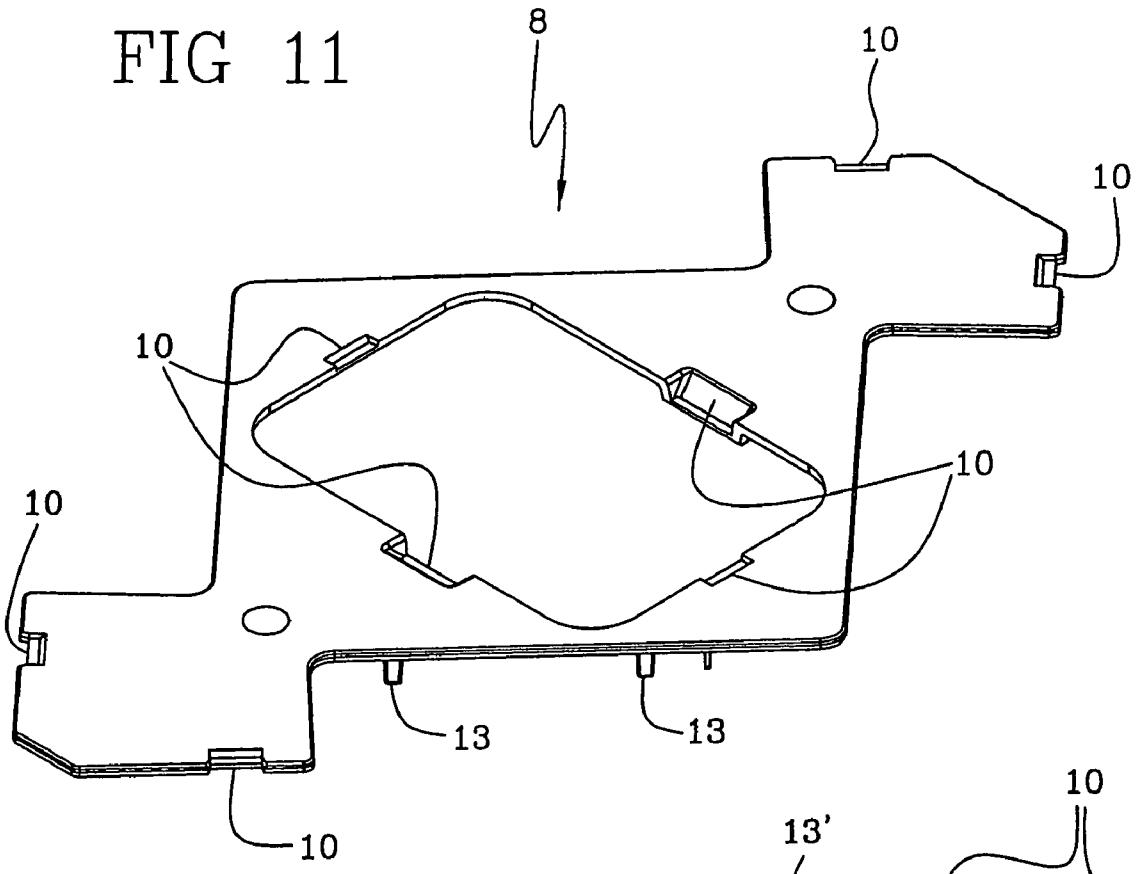


FIG 11



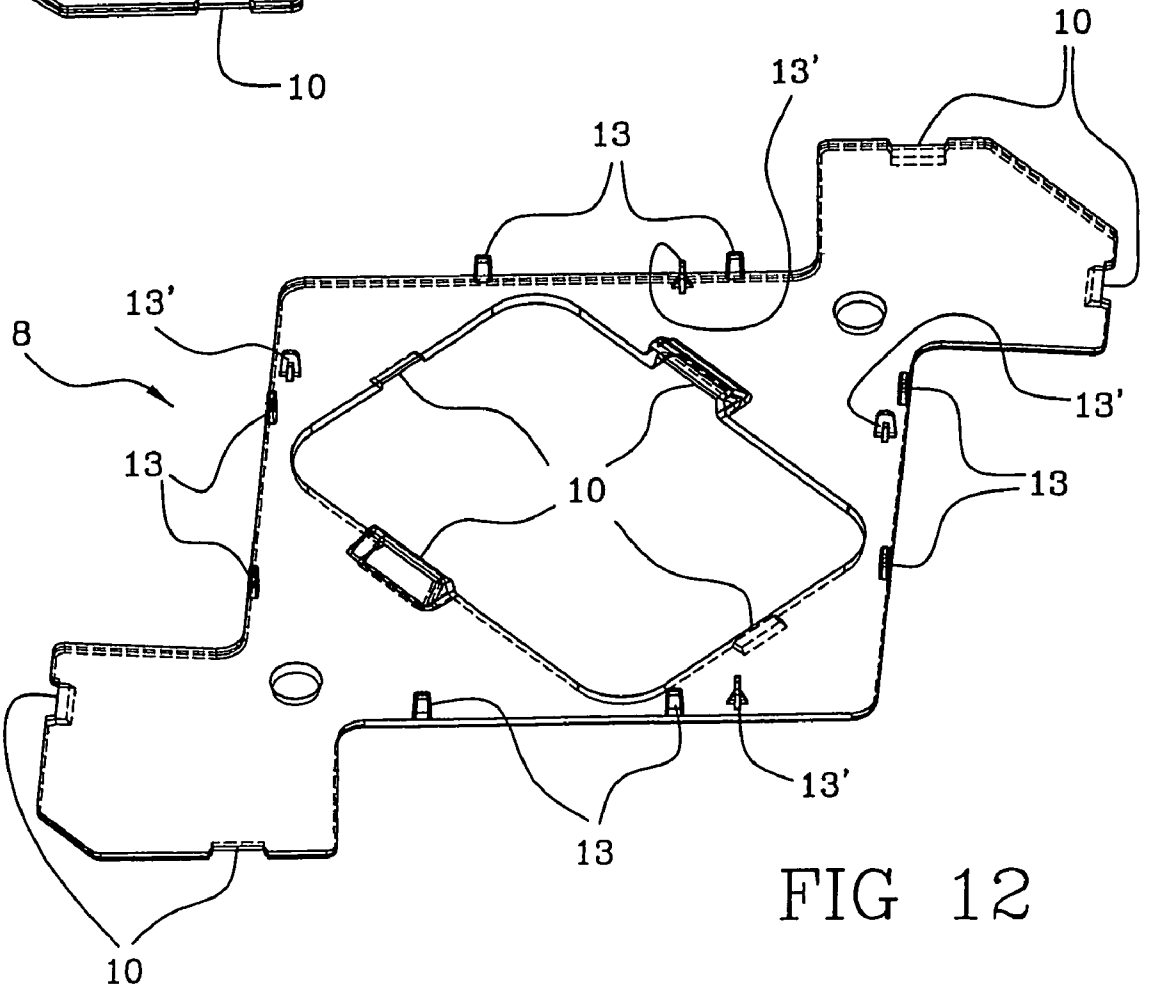


FIG 12

FIG 13

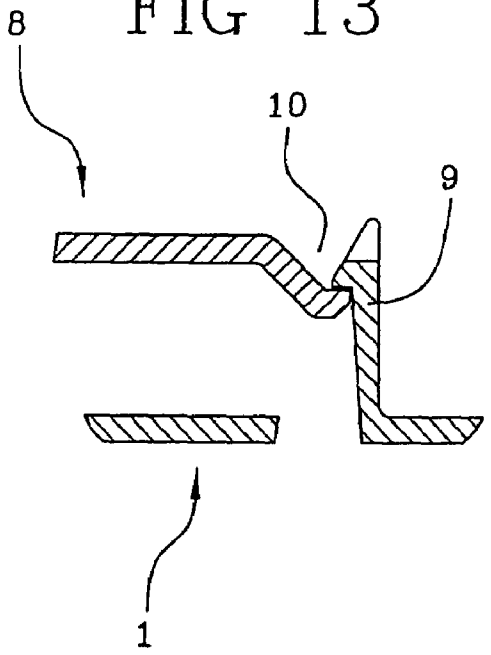


FIG 14

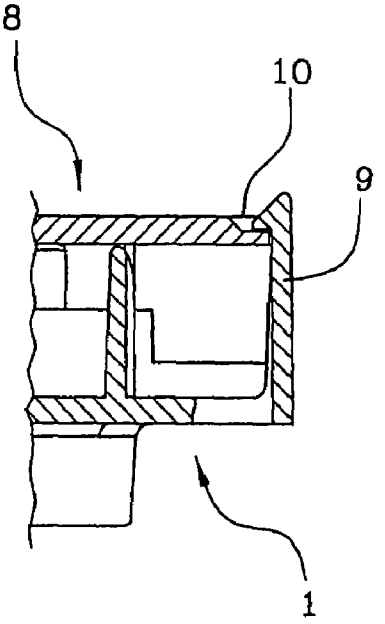


FIG 15

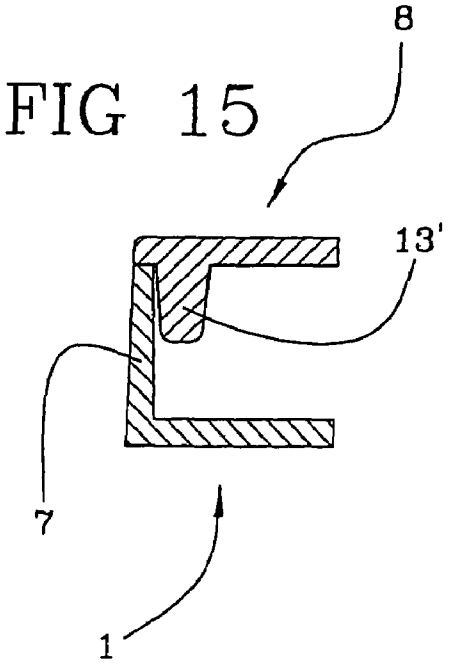
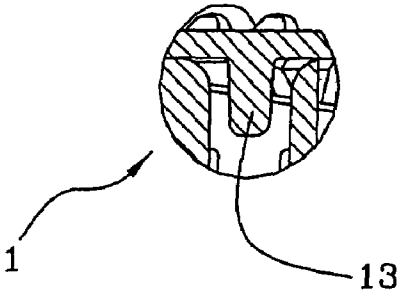


FIG 16



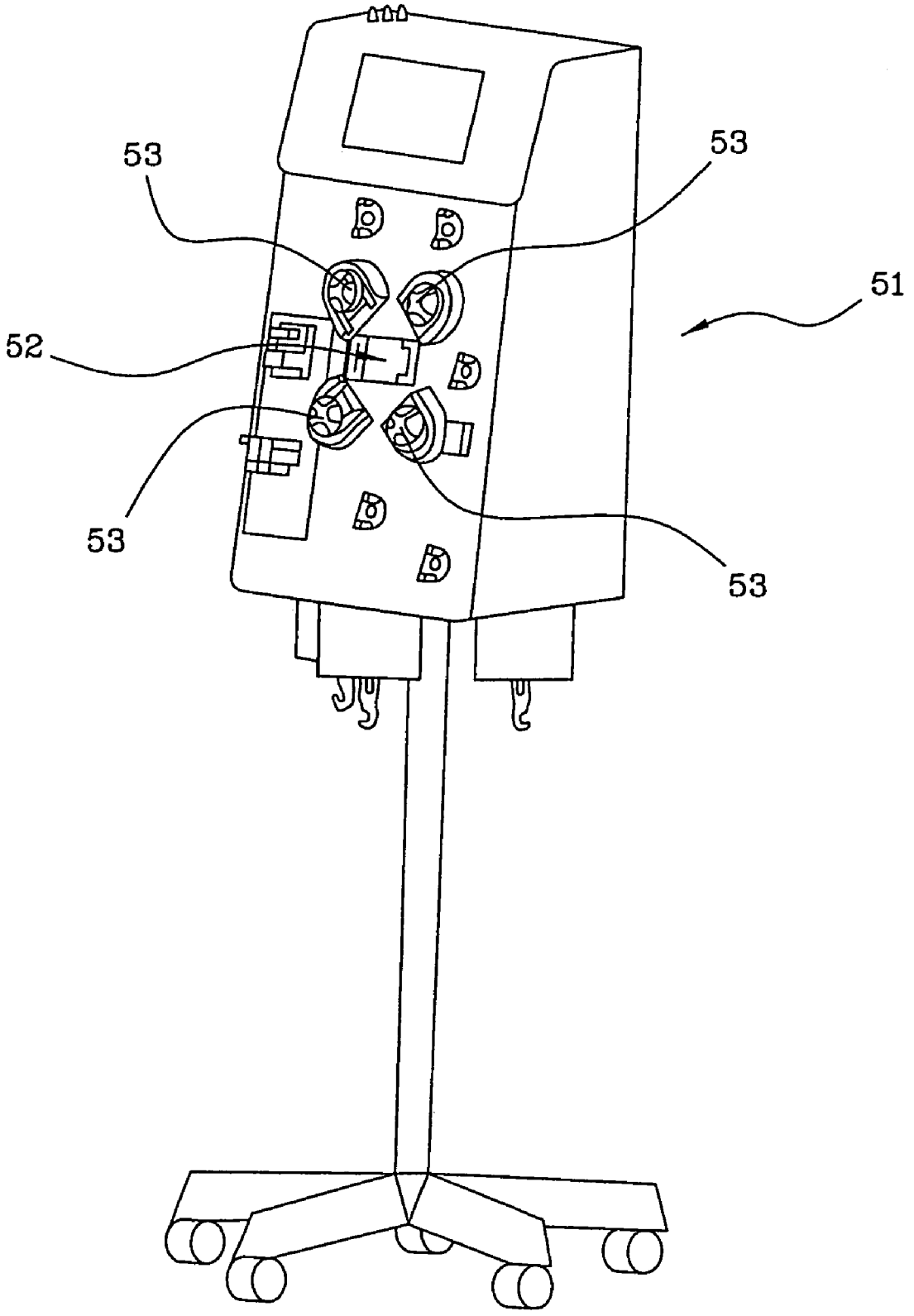


FIG 17

FIG 18

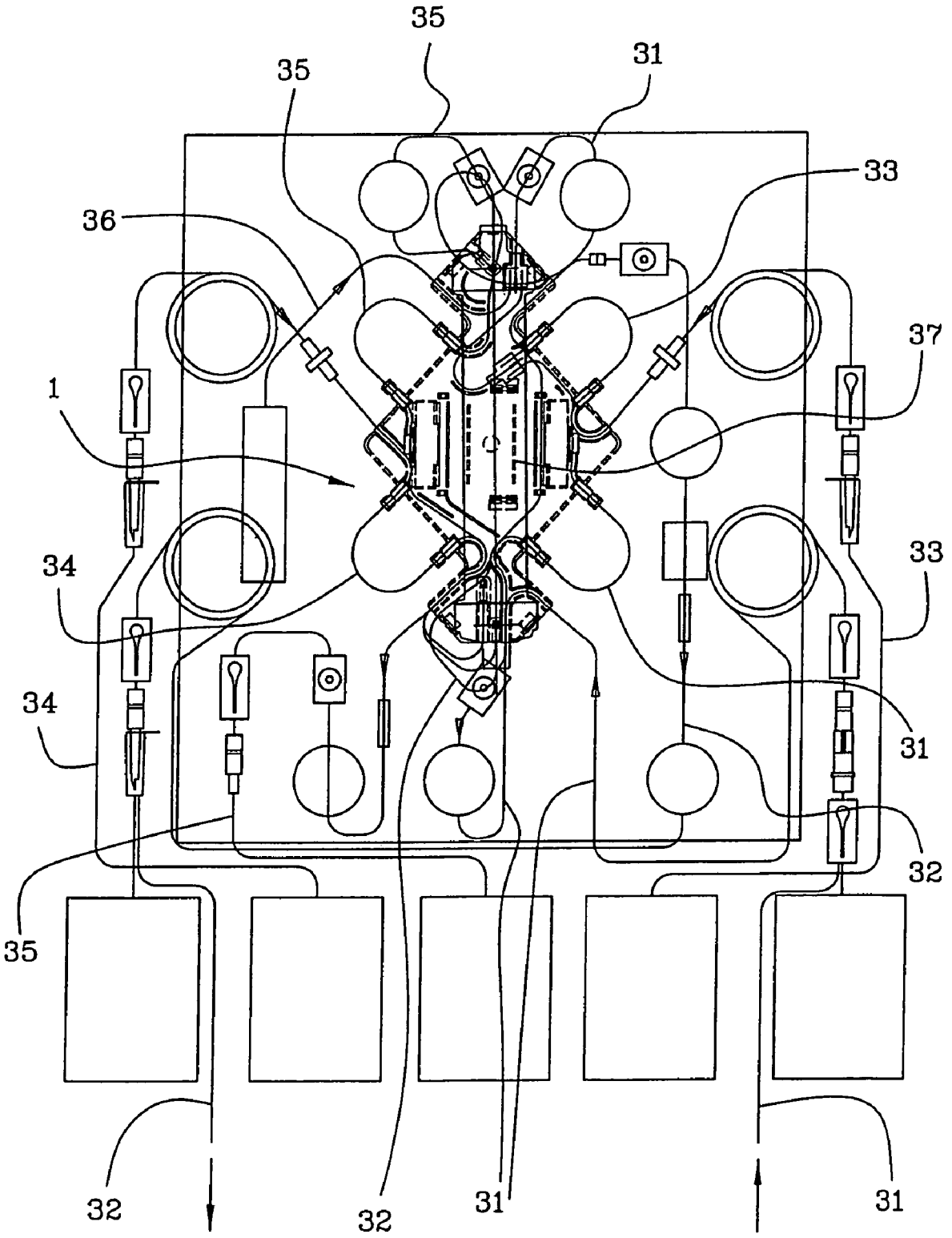


FIG 19

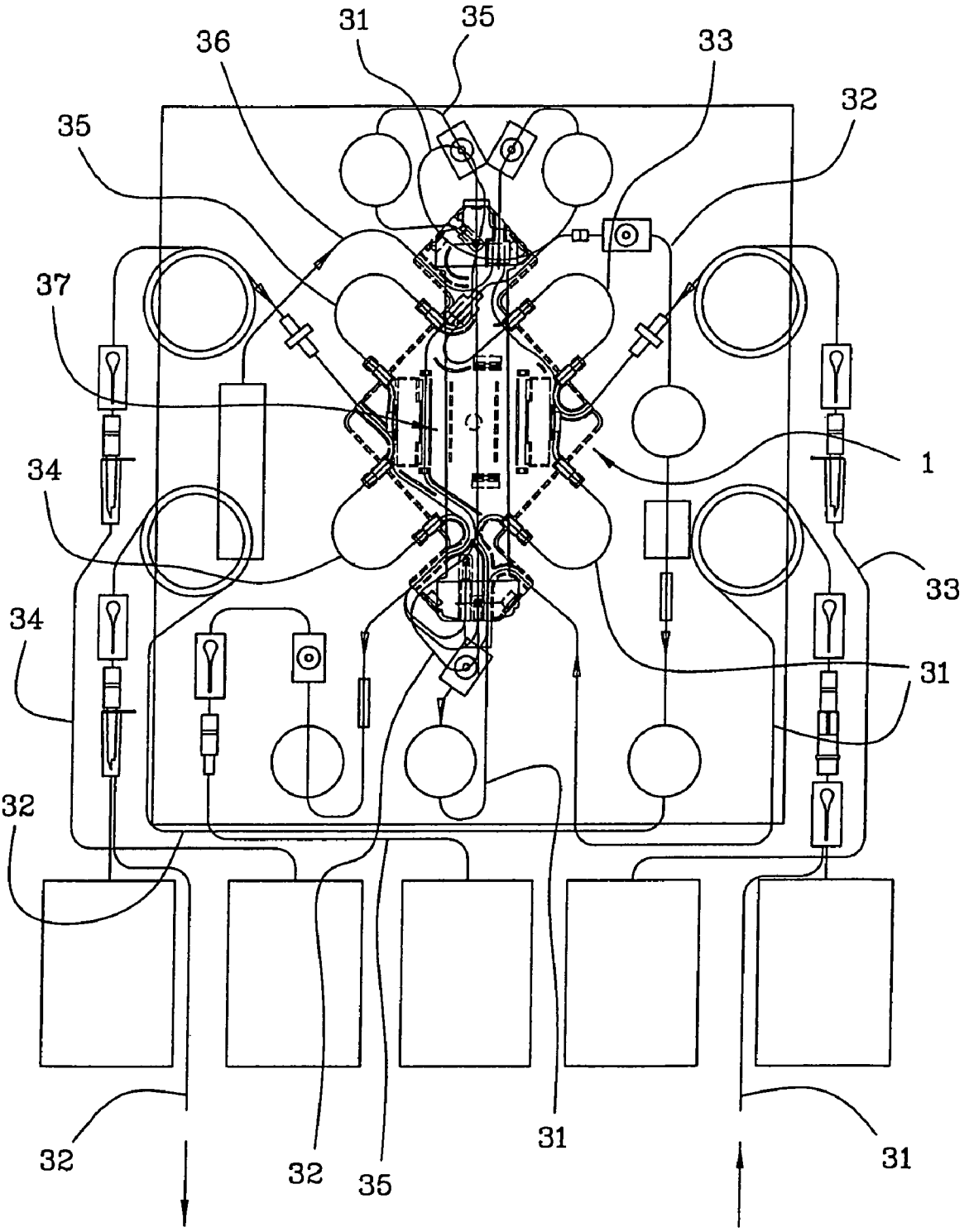
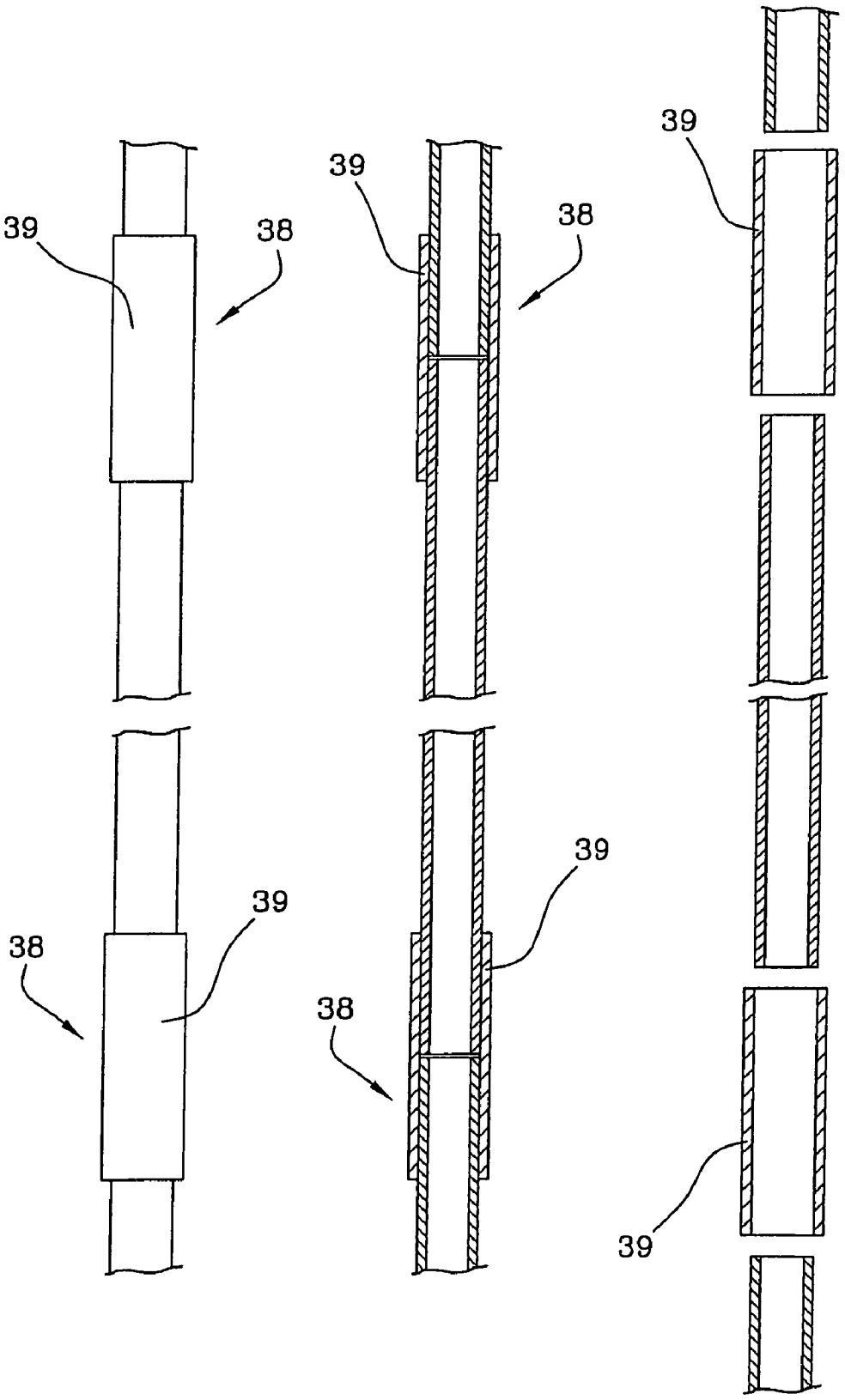


FIG 20 FIG 21 FIG 22



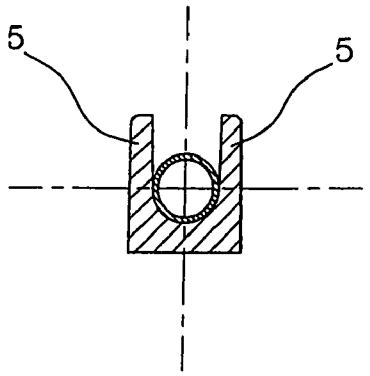


FIG 23

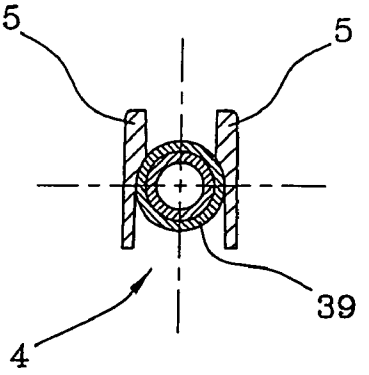


FIG 24

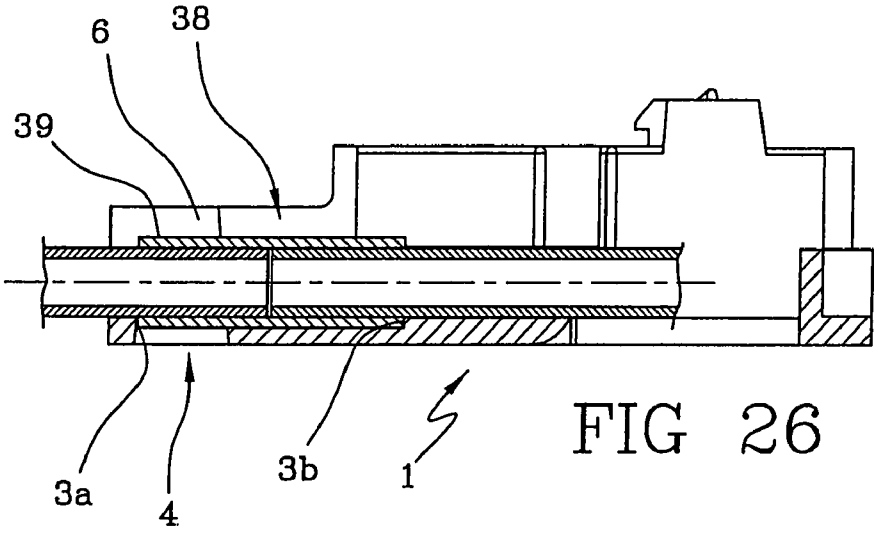


FIG 26

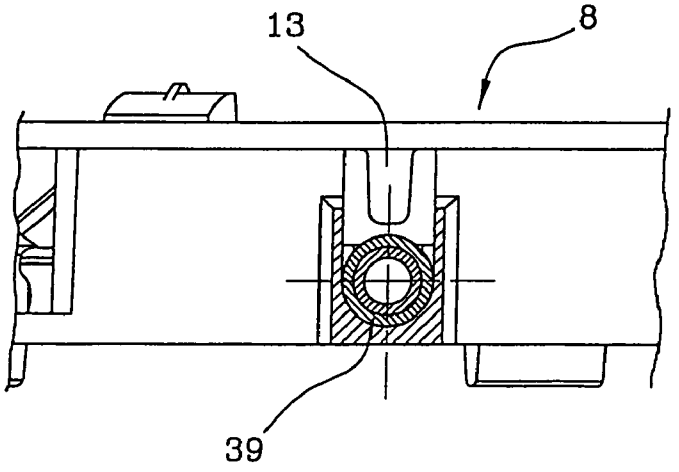


FIG 25

SUPPORT ELEMENT, AN INTEGRATED MODULE FOR EXTRACORPOREAL BLOOD TREATMENT COMPRISING THE SUPPORT ELEMENT, AN APPARATUS FOR EXTRACORPOREAL BLOOD TREATMENT EQUIPPED WITH THE INTEGRATED MODULE, AND AN ASSEMBLY PROCESS FOR AN INTEGRATED MODULE FOR EXTRACORPOREAL BLOOD TREATMENT

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of Italian Patent Application No. MI2003 A 000215, filed on Feb. 7, 2003, and the benefit of U.S. Provisional Application No. 60/470,442 filed May 15, 2003, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The invention relates to a support element, to an integrated module for extracorporeal treatment of blood comprising the support element, and to an apparatus for extracorporeal treatment of blood equipped with the integrated module. The invention further relates to an assembly process of an integrated module for extracorporeal treatment of blood.

Specifically, though not exclusively, the invention can be usefully applied to the field of extracorporeal treatment of blood for treatment of renal insufficiency.

The prior art teaches apparatus for blood treatment which remove blood from the patient in a line, carry out an extracorporeal treatment on the blood and then return the treated blood to the patient. Apparatus of this type are used for various treatments; for example therapeutic and non-therapeutic plasmapheresis, extracorporeal oxygenation of blood, purification of blood and removal of water in cases of renal insufficiency. The present invention will be described with particular reference to intensive treatment of renal insufficiency, without any limitation being placed on the ambit of the invention to this specific application thereof.

EP 0 611 227 teaches a multifunctional integrated module for application to a multifunction apparatus for intensive treatment of renal insufficiency, in particular for hemodialysis, hemofiltration and hemodiafiltration. The integrated module comprises a support element, a blood treatment device mounted on the support element and a complex of fluid distribution lines cooperating with the treatment device and associated to the support element. The blood treatment device comprises a semi-permeable membrane which separates two chambers. The distribution line complex comprises a blood withdrawal line from the patient (or arterial line) connected to an inlet of a first chamber of the treatment device, a return line (or venous line) of the treated blood to the patient, connected to an outlet of the first chamber, an infeed line of a treatment fluid (for example a dialysis liquid) connected to an inlet of the second chamber of the treatment device, a waste fluid discharge line connected to an outlet of the second chamber, an infusion line of a substitution liquid which is introduced into at least one of the blood lines, an anticoagulant infusion line which is introduced into the arterial line. The support element comprises a plate-shaped body made of press-formed plastic material. The complex of fluid distribution lines is fixed to the support element at gluing points and zones which are predefined on an internal face of the plate-shaped body, while the treatment device is mounted on the external face of the plate-shaped body itself.

During use, the integrated module is mounted on the blood treatment device and set up following a predefined and simple interconnection procedure so that the treatment device is connected, by the distribution lines, to the cardiovascular system of the patient as well as to suitable containers for access and collection to and of the fluids used in the process. Some distribution lines of the module are coupled with respective peristaltic pumps which the apparatus is equipped with. The pumps invoke circulation of the fluids in the lines; the lines are each provided with a U-shaped arched segment, preformed during assembly of the module and intended for coupling to a pump. On mounting the integrated module on the apparatus the various arched segments of the distribution lines are easily couplable about the peristaltic pumps, so that the latter are immediately operative.

The integrated module is of a disposable type, i.e. destined to be disposed of, usually after a first use, and substituted by another.

The above-described integrated module has the advantage of being easily and rapidly installed on the treatment device. The simple and rapid set-up of the module is particularly advantageous for renal insufficiency intensive treatments, in which the personnel at work is often not expert in the use of machines for blood treatment and where the urgent readying and application of the machine is often of vital importance. Similarly, the dismounting of the module is equally rapid and simple.

The prior art as described above is susceptible to improvement at various levels:

- firstly, the fact that the integrated module has to be totally eliminated after use, including parts such as, for example, the plastic support element, which does not come into direct contact with bodily fluids;
- secondly, the assembly of the integrated module, which is a rather delicate stage, as high precision of positioning of the U-segments of the distribution lines on the support element is required, so that correct coupling with the peristaltic pumps can be achieved;
- thirdly, in relation to the long set-up times and high costs of assembly of the integrated module, which must include a relatively complicated and laborious stage of precise positioning and gluing of the various distribution lines in predetermined gluing zones on the support element.

SUMMARY OF THE INVENTION

The present invention provides a support element for an integrated module for extracorporeal blood treatment thanks to which the module itself can be rapidly assembled and mounted on a blood treatment device.

The invention enables a simplification of the operations for assembly of the integrated module, reduces the scope for error in positioning the distribution lines on the support element, improves precision in the couplings between the U-segments of the distribution lines and the peristaltic pumps of the blood treatment apparatus, enables, after use, a simple and practical separation of the support element from the fluid distribution lines, reduces assembly costs and times of the integrated module.

The above objectives are all achieved by a support element made according to one or more of the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Further characteristics and advantages of the invention will better emerge from the detailed description of a preferred but non-exclusive embodiment of a support element according to the present invention. The description is made herein below with reference to the accompanying figures of the drawings, which are given by way of example and which are non-limiting.

FIG. **1** is a perspective view of the internal face of the base body of the support element.

FIG. **2** is a perspective view of the external face of the base body of FIG. **1**.

FIG. **3** is a plan view of the internal face of FIG. **1**.

FIG. **4** is an enlarged detail of FIG. **3**.

FIG. **5** is section V—V of FIG. **4**.

FIG. **6** is section VI—VI of FIG. **4**.

FIG. **7** is section VII—VII of FIG. **4**.

FIG. **8** is section VIII—VIII of FIG. **4**.

FIG. **9** is section IX—IX of FIG. **4**.

FIG. **10** is section X—X of FIG. **3**.

FIG. **11** is a perspective view of the upper face of the cover of the support element.

FIG. **12** is a perspective view of the lower face of the cover of FIG. **11**.

FIGS. from **13** to **16** show, in section, four coupling zones between the cover and the base body.

FIG. **17** is an apparatus for intensive treatment of renal insufficiency predisposed to receive an integrated module for blood treatment comprising the support element of the preceding figures.

FIG. **18** is a diagram of a multifunctional integrated module, able to perform treatments with a pre-infusion of liquid into the extracorporeal blood circuit, operatively connected to the apparatus of FIG. **17**.

FIG. **19** is a diagram of another multifunctional integrated module, able to perform a post-infusion, associated to the apparatus of FIG. **17**.

FIG. **20** is a tract of a distribution line including a pump segment comprised between two joint collars **39**.

FIG. **21** is a longitudinal section of FIG. **20**.

FIG. **22** is an exploded view of FIG. **21** in which some components of the distribution line are illustrated before assembly.

FIGS. **23**, **24**, **25** and **26** show FIGS. **5**, **6**, **7** and **9** with the joint collar **39** coupled in the fixture seating.

LEGEND

1 Base body of the integrated module for extracorporeal blood treatment

2 Fixture seatings for joint-fixture of line tracts **38**

3*a* Axial reference locator for positioning of a line tract **38** arranged in the fixture seating **2** in an external direction of the base body **1**

3*b* Axial reference locator cooperating with locator **3***a* and arranged in the fixture seating in an internal direction of the base body **1**

4 Through-hole located on the bottom of the seating **2** through which an extraction force can be applied from below on the tract of line **38** constrained in the fixture seating **2**

5 Lateral walls laterally defining the fixture seating **2**

6 Reliefs developing in an internal direction of the fixture seating **2** from the lateral walls **5**

7 Raised edge rising from the perimeter of the base body **1**

8 Cover of the integrated module couplable to the base body **1**

9 Flexible tabs associated to the base body **1** for fitting the cover **8**

10 Recesses on the cover **8** cooperating with the tabs **9**

11 Guide channels associated to the base body **1** for housing two superposed channels of the fluid distribution line

12 Joint elements associated to the base body **1** for receiving and constraining the fluid distribution lines

13 Teeth projecting downwards from the cover **8** for limiting the raising of the tracts of line **38** constrained in the fixture seatings **2**

13' Teeth projecting downwards from the cover **8** and situated in proximity or in contact with the internal side of the raised edge **7** for aiding fitting and positioning of the cover **8** on the base body **1**

14 First connector associated to the base body **1** for mounting the treatment device **37** to the base body **1**

15 Second connector for mounting the treatment device **37**

16 Third connector for mounting the treatment device **37**

17 First terminal portion of a connector for fluid connection with the treatment device **37**

18 Second terminal portion of a connector for fluid connection with a fluid distribution line

19 Sealing collar external of the first terminal portion **17**

20 Connection wall connecting the sealing collar **19** with the first portion **17**

31 Blood withdrawal line (arterial line)

32 Blood return line (venous line)

33 Substitution fluid infeed line (pre-infusion line and/or post-infusion line according to the type of integrated module)

34 Supply line of a treatment fluid (for example, a dialysis liquid)

35 Discharge line of a waste fluid

36 Supply line of an anticoagulant fluid

37 Blood treatment device (for example a dialysis filter)

38 Axial tracts of line with increased external diameter, destined for use in the fixture seatings **2** on the base body **1**

39 Joint collars causing the increase in diameter of line tracts **38**

51 Apparatus for extracorporeal blood treatment destined to receive the integrated module

52 Housing zone for the integrated module on the apparatus **51**

53 Peristaltic pumps predisposed on the apparatus **51**.

DETAILED DESCRIPTION

The support element is used as a component of a multifunctional integrated module for extracorporeal blood treatment, in which the integrated module is operatively associable to a multifunctional apparatus for treatment of renal insufficiency. The integrated module is used in particular for intensive treatment of renal insufficiency.

The integrated module comprises the support element, a blood treatment device mounted on the support element, and a complex of fluid distribution lines associated to the support element and cooperating with the treatment device. Each distribution line comprises at least one flexible tube.

The Support Element.

With reference to FIGS. from **1** to **16**, the following is a description of the support element. It comprises a base body

1 which in turn comprises a part consisting of a flat plate with a plurality of perimeter edges giving the body **1** a polygonal shape. In more detail, the flat plate has a rhomboid central part and two projecting parts, upper and lower, also rhomboid and extending along a common longitudinal axis.

The base body **1** exhibits means for connecting, for receiving and constraining the complex of fluid distribution lines. The means for connecting project from an internal face of the flat plate of the base body **1** and are made in a single piece there-with by press-forming (injection) of a plastic material.

The means for connecting the complex of lines comprise a plurality of fixture seatings **2** located on the periphery of the central rhomboid part of the base body **1**. In more detail, the base body **1** exhibits two fixture seatings **2**, paired and beside the other, for each side of the rhombus. Each fixture seating **2** is predisposed and configured for a resilient press-fitting and joint-fitting of a corresponding tract of a fluid distribution line, as will better emerge from the following description.

Each fixture seating **2** is axially elongate, in the shape of a superiorly-open channel, for receiving a corresponding axially elongate tract of a fluid distribution line. The housing channel is also open at opposite ends thereof. Each fixture seating **2** is provided with two axial reference locators **3***a*, **3***b*, respectively external and internal, axially distanced and opposite, between which the tract of line will be positioned and constrained. Each fixture seating **2** can be provided with a single reference locator **3***a* or **3***b* for the positioning of the tract of line in the fixed position.

Each axial locator **3***a*, **3***b*, is fashioned from a raised edge projecting towards the inside of the fixture seating **2** at an axial end opening of the fixture seating **2**. The raised edge cooperates contactingly with a corresponding projection, in the form of an annular abutment, predisposed externally of the tract of line destined to be engaged in the fixture seating **2**, as will be better explained herein below. The coupling between a projection on the tract of line and the corresponding internal raised edge determines a correct and precise positioning of the tract of line in the fixture seating **2**.

In more detail, the means for connecting the lines comprise a plurality of pairs of fixture seatings **2**; the fixture seatings of each pair are situated side-by-side on the periphery of the base body **1** and receive and constrain two tracts of end of a U-shaped arched segment of a line. Each pair of fixture seatings **2** is arranged on a different perimeter side of the rhomboid central part of the base body **1**, each pair having a different orientation with respect to the other pairs. The U-shaped segment cooperates with a peristaltic pump belonging to the treatment apparatus, as will be better explained herein below (the segment is known as the pump segment for this reason). The U-shaped pump segment projects externalwise beyond the periphery of the base body **1**.

In more detail, each fixture seating **2** extends axially in length, with a rounded-U-shaped transversal section, to receive an axial tract of a fluid distribution line, and exhibits at two opposite axial ends two undercut surfaces corresponding to two opposite axial directions of the tract of fluid distribution line in the longitudinal seating. The two axial undercut surfaces are fashioned from the two above-mentioned raised edges and result in axial locators **3***a* and **3***b* which, as mentioned above, determine the axial positioning of the tract of line in the constrained position thereof.

The upper opening for forced insertion of the tract of line has at least one end part, facing externalwise of the base body **1** (i.e. towards the U-shaped arched segment of the corresponding fluid distribution line), having a passage section which is narrower than the maximum width of the seating: that is, the upper entrance to the channel is narrower with respect to the "real" width of the seating, i.e. the part of the seating where the tract of line is housed when in the constrained position. The tract of line inserted into the channel of the seating has an external diameter which is greater than the minimum width of the passage section, so as to create a friction insertion, and has a diameter which is about equal to the maximum width of the fixture seating, so that the tract of line inserted and fixed in the seating is not crushed, or in any case only very lightly crushed by the walls of the seating.

Each fixture seating **2** inferiorly exhibits a through-hole **4**, facing the upper insertion opening, through which a pressure from below can be exerted on the tract of line constrained in the fixture seating in order to extract it (if this is envisaged after use of the integrated module) through the upper insertion opening.

Each fixture seating **2** exhibits an axial end tract which extends axially internally of the perimeter of the base body **1** and an axial end tract which extends externally.

As mentioned above, each fixture seating **2** comprises an upper opening for insertion of a tract of line predisposed for the insertion. At least a part of the length of the upper opening projects externally beyond the perimeter edge of the base body **1**. In more detail, the opening is laterally delimited by two lateral walls **5** located side-by-side, each of which walls **5** exhibits an upper edge. The upper opening of the channel is delimited by the upper edges of the two lateral walls **5**. In the part of the opening projecting beyond the base body **1**, the two upper edges of the lateral walls **5** are straight (and continuous) and parallel one to another, so that the upper opening of the seating extends in a same plane as the lie plane of the upper edges of the lateral walls **5**, which are conformed so that the upper opening is flat and extends throughout the length of the seating, or at least for the part thereof which extends beyond the perimeter edge of the base body **1**.

Each of the two lateral walls **5** internally exhibits a lateral relief **6** projecting from the wall **5** towards the inside of the opening to define an undercut surface with respect to an extraction direction of the tract of line through the upper opening of the seating: the two reliefs **6**, one for each lateral wall **5**, face towards and cooperate with each other in order to obstruct the extraction of the tract of line from the channel of the seating.

Each undercut surface, and the lateral relief **6** giving rise to the undercut surface, is predisposed inferiorly of the upper edge of the lateral wall **5**; in other words each lateral relief **6** emerges laterally from a side of the lateral wall **5**, without emerging upwards, i.e. beyond the upper edge of the wall **5** itself. Each lateral relief **6** is situated in a part of end of the seating facing towards the U-shaped line segment (the pump segment). Each undercut surface is inclined with respect to the extraction direction of the tract of line so that the line can be extracted by force; in effect, the undercut surface lends a certain stability to the positioning of the tract of line with respect to extraction, while the inclination of the undercut surface is such that, by acting with an appropriate extracting force, the tract of line can be removed from its fixture seating.

Each fixture seating **2** exhibits two series of undercut surfaces which operate in two reciprocally transversal directions of movement of the tract of line with respect to the seating: one of the directions is that of axial sliding (in this case the undercut surfaces are situated on the locators **3***a* and

3*b* and act in opposite directions) and the other direction is the extraction direction, through the upper opening for forced insertion. The combined action of these undercut surfaces determines the stable and precise positioning of the tract of line in the fixture seating **2**.

The internal face of the base body **1**, i.e. the face from which the means for connecting for the various lines emerge, exhibits a raised perimeter edge **7** for laterally containing at least a part of the complex of distribution lines.

In other words, the base body **1** comprises a vertical front wall (where front and vertical relate to the work position of the module on the blood treatment apparatus) which comprises the flat plate-shaped part, and a perimeter wall (i.e. the raised edge **7**) arranged on the back of the front wall (once more with reference to the work position of the integrated module when mounted on the apparatus). The perimeter wall in effect develops in a distancing direction from the posterior side of the front wall and defines a work seating in which at least a part of the complex of fluid distribution lines can be housed, which lines are destined to be associated to the support element. The height of the raised edge **7** is at least double that of the external diameter of a tube of a fluid distribution line; therefore the work seating can contain two tubes, one above another.

The support element further comprises a cover **8** coupled to the base body **1**, which cover **8** is provided for closing at least a part of the complex of distribution lines associated to the means for connecting. The cover **8** at least partially closes the work seating housing the lines. The cover **8** helps keep the fluid distribution lines in a stable position in the work seating. The cover **8**, with the module in the work position on the apparatus, is situated behind the front wall of the base body **1**.

The base body **1** comprises means for hooking for removably coupling the cover **8** to the base body **1**, made in a single piece with the base body **1** itself. A part of the means for hooking is predisposed on the perimeter of the base body **1**, while another part thereof is arranged internally of the perimeter. The means for hooking comprise a plurality of flexible tabs **9** which emerge from the base body **1** and which are each provided with an engaging tooth which couples with a recess **10** in the cover **8**. The cover **8** exhibits at its centre a through-hole on a rim of which some of the recesses **10** are afforded, while others of the recesses **10** are arranged on the external perimeter.

Various guide channels of the distribution lines emerge from the internal face of the base body **1**; these channels are both curved and straight and define pathways followed by the distribution lines. Each channel is defined by two lateral walls, side-by-side and parallel. The reciprocal distance of two side-by-side walls is about equal to an external diameter of the tubes. For some channels, indicated by **11**, the lateral walls are configured and arranged in such a way that a height of the channel is at least double a width thereof; these channels **11** are able to house or laterally contain two tracts of line, one above another.

The internal face of the base body **1** also exhibits some pairs of fixture elements **12** for resilient fixture of lines. The fixture elements **12** of each pair cooperate and are arranged one in front of another in a same pair; they hold the distribution lines firm and tight.

The cover **8** closes off at least a part of the internal face bearing the means for connecting the lines. The cover **8** extends in a sort of flat plate shape, with a perimeter that corresponds to the perimeter of the internal face of the base body **1**. Thus it comprises a rhomboid central part with two end parts, one upper and the other lower, also rhomboid and arranged along a median longitudinal axis of the cover **8**. At a centre thereof the central part of the cover **8** exhibits the above-cited through-hole, which is rectangular in shape. With the cover **8** coupled to the base body **1**, a containment space is defined between the internal face of the base body **1** and an internal face of the cover **8**, which closes at least a part of the complex of distribution lines.

On a periphery of the central part thereof, the cover **8** exhibits a plurality of teeth **13**, projecting downwards, each of which is associated to a fixture seating **2**. Each tooth **13**, when the cover **8** is coupled to the base body **1**, at least partially enters a respective fixture seating and thus limits a raising of the tract of line constrained in the fixture seating **2**. When the cover **8** is mounted on the base body **1**, the lower end of each tooth **13** is located slightly above the undercut surface on the relief **6** which prevents a raising of the tract of line constrained in the fixture seating **2**. Should the tract of line be raised beyond the undercut surface, the teeth **13** provide a guarantee against further raising thereof.

On an external face thereof located opposite to the internal face, the base body **1** also exhibits means for connecting, for attaching a blood treatment device (for example a high-flow dialyzer). The means for connecting are also made in a single piece with the base body **1**, by press-forming. The means for connecting the dialyzer comprise a first and a second connector, **14** and **15**, associated to the base body **1** and located at a distance one from the other; they are destined to receive and engage with corresponding seatings afforded on the blood treatment device which is mountable on the support element. The first and second connectors **14** and **15** are made in a single piece with the base body **1**. There is also a third connector **16**, distanced from the first and second connectors **14** and **15** and made in a single piece with the base body **1**. The three connectors **14**, **15** and **16** define, in combination one with another one, a plurality of pairs of connectors having differentiated interaxes for engaging with corresponding pairs of seatings associated to different blood treatment devices mountable on the support element. The three connectors **14**, **15** and **16**, are unaligned with one another.

Each connector **14**, **15** and **16** defines a fluid passage having a first terminal portion **17**, destined to be set in fluid communication with a corresponding channel in a respective seating on the blood treatment device, and a second terminal portion **18**, destined to be set in fluid communication with one of the fluid distribution lines associable to the base body **1**. The fluid passage is integrated in the connectors **14**, **15** and **16**, which are in turn made in a single piece with the base body **1**.

In more detail, each connector **14**, **15**, **16** comprises a tubular channel, which defines the first terminal portion **17**, a sealing collar **19**, located in a radially external position to the tubular channel, and a connecting wall **20** which develops continuously between an external lateral surface of the tubular channel and an internal lateral surface of the sealing collar **19**, defining an annular seating for engaging each seating. The tubular channel is coaxially arranged with respect to the sealing collar **19**. The annular seating exhibits a bottom which is delimited by the connecting wall **20**. The annular seating exhibits an increasing radial dimension as it progresses from the bottom connecting wall **18**; it comprises a first zone, adjacent to the bottom and having a constant radial dimension; a second zone, distal with respect to the bottom and having a constant radial dimension which is greater than the radial dimension of the first zone; and a third zone, which is a transit zone between the first and second

zones and which has a progressively growing radial dimension as it progresses away from the bottom connecting wall **20**.

Each connector **14**, **15** and **16**, is directly constrained to the base body **1**.

The tubular channel, i.e. the channel defining the first terminal portion **17**, and the sealing collar **19** of each seating **14**, **15** and **16**, are parallel to one another in the base body **1**, defining a single coupling direction with the corresponding connectors of a treatment device.

The base body **1** and the connectors **14**, **15** and **16** of the blood treatment device (located on the external face of the base body **1**) are made of a rigid material in order to offer a good mechanical support for the device.

The Complex of Fluid Distribution Lines.

The fluid distribution lines comprise flexible tubes having internal sections for fluid passage which internal sections are the same for all the tubes.

The complex of fluid distribution lines associated to the support element comprises: a blood withdrawal line **31**, a blood return line **32**, a substitute fluid infeed line **33**, a treatment fluid infeed line **34** (for example a dialysis liquid), a waste fluid discharge line **35**, and an anticoagulant infeed line **36**.

37 denotes a blood treatment device mounted on the support element and comprising a first and a second chamber, separated from each other by a semi-permeable membrane. The blood treatment device **37** is selected from a group comprising devices for: hemofiltration, hemodialysis, high-flow dialyzers and hemodiafiltration devices. In the illustrated embodiment the treatment device is a high-flow dialyzer.

The blood withdrawal line **31** is connected to the first chamber of the treatment device **37**. The blood return line **32** receives the treated blood exiting from the first chamber and returns it to the patient. The treatment fluid infeed line **34** is fluidly connected to an inlet of the second chamber of the blood treatment device **37**. The treatment fluid (dialysis liquid) is destined to receive, through the semi-permeable membrane, the impurities present in the patient's blood and the excess fluid which is to be removed from the blood. The waste fluid discharge line **35** is fluidly connected to an outlet of the second chamber and carries the waste fluid exiting from the blood treatment device **37** to a collection recipient.

The blood treatment device **37** comprises a blood withdrawal port, a blood return port, a treatment fluid inlet port and a waste fluid discharge port, in fluid connection (respectively) with the blood withdrawal line **31**, the blood return line **32**, the treatment fluid supply line **34** and the waste fluid discharge line **35**.

The substitution fluid infeed line **33** receives an infusion or substitution fluid from a source (for example a tank or bag) and feeds it through a Y connection to a blood circulation line; or to the blood withdrawal line **31** (pre-infusion upstream of the blood treatment device **37**, as in the example of FIG. **8**) or to the blood return line **32** (post-infusion downstream of the blood treatment device **37**, as in the example of FIG. **19**).

The anticoagulant supply line **36** infeeds an anticoagulant into the blood withdrawal line **31** through a Y connection.

The blood withdrawal line **31**, the substitution fluid infeed line **33**, the treatment fluid infeed line **34**, the waste fluid discharge line **35**, each exhibit at least two tracts **38** having a predetermined length and an increased external diameter with respect to adjacent tracts thereof. The two tracts **38** having increased external diameter are arranged on the respective line at a predetermined distance one from the other. Each axial tract **38** having an increased external diameter gives rise to two external abutments. Each axial tract **38** with increased external diameter comprised between the two abutments will be press-inserted in a corresponding fixture seating **2** arranged on the periphery of the base body **1**. When the complex of distribution lines is applied to the support element, each segment of line comprised between two axial tracts **38** having an increased external diameter (the pump segment) is arranged in a U-shaped arch, and is coupled to a peristaltic pump belonging to the treatment device, which pump invokes circulation of fluid in the line. The length of the segment of line comprised between the two tracts of line **38** (pump segment) is predetermined in order to guarantee a correct coupling with the peristaltic pump.

In more detail, each axial tract of line **38** with an increased external diameter comprises a joint collar **39** which contains and coaxially joins two end parts and two adjacent tracts of line: a part of an end of a tract of line is inserted into the collar **39** up to not more than half of the length of the collar **39** itself, through an axial opening in the collar **39**, while the part of end of the other tract of line is inserted into the axial hole at the other end of the collar **39**. A stable joint of the collar **39** with the end parts of the tracts of line can be achieved by known means, for example by hot-welding. The inter diameter of the joint collar **39** is about the same as the external diameter of the tubes forming the distribution lines. The U-shaped segment (pump segment) comprises a tube having two opposite ends inserted in two joint collars **39** and in fluid connection with two ends of two tubes, also inserted, but on the opposite side, in the same joint collars. The material used for making the arched segments of tube is suitable for operation with the peristaltic pumps and is different to the material used for the other two tubes coupled to the joint collar **39**, which undergo no interaction with the peristaltic pumps. Each joint collar **39** is made of a more rigid material that that of the tracts of line the collar **39** joins. During the assembly stage of the integrated module the collar **39** is inserted snugly into the fixture seating **2**. The axial length of the joint collar **39** is about the same as the axial distance between the axial locators **3***a* and **3***b* located in the fixture seating **2**. The collars **39** can be slightly longer or shorter, depending on whether the desired coupling between the collar **39** and the seating **2** is achieved by axial interference or with axial play. The external diameter of the collar **39** is about the same as or slightly smaller than the maximum width of the fixture seating **2**; the diameter is also greater than the minimum width of the upper insertion opening of the fixture seating **2**, so that the insertion of the joint collar **39** in the fixture seating **2** is achieved by resilient friction fitting.

As previously mentioned, the length of the segment of line comprised between two joint collars **39** (pump segment) is predefined in order to obtain, once the line is coupled to the support element, a U-shaped segment precisely positioned and shaped for interaction with the peristaltic pump.

The arrangement of the complex of distribution lines on the integrated module is described in more detail herein below.

The Integrated Module.

FIGS. **18** and **19** show two integrated modules which are different essentially because of the different configurations of the distribution lines. In more detail, in the first of the modules (FIG. **18**), the substitution fluid infeed line **33** is inserted into the blood withdrawal line **31** (pre-infusion), while in the second module (FIG. **19**) the substitution fluid

infeed line **33** (the same numbers are used in the two figures for the sake of simplicity) is inserted into the blood return line **32** (post-infusion).

The Extracorporeal Blood Treatment Apparatus.

The extracorporeal blood treatment apparatus, illustrated in FIG. **17** and indicated in its entirety by **51**, comprises a housing zone **52** predisposed for receiving the integrated module for extracorporeal blood treatment (selectively one of the two above-described modules); the four peristaltic pumps **53** are located by the side of the housing zone **52** and are operatively associated to the four U-shaped segments of the fluid distribution lines in the integrated module. The apparatus can be used to perform treatments requiring the use of fewer than four pumps, in cooperation with appropriate modules provided with fewer than four U-shaped segments. The apparatus **51** further comprises a central treatment control unit, of known type and not illustrated, which controls the various treatment procedures. No special explanation of these is necessary in the present description.

The axial locators **3***a* and **3***b* ensure the precision in position and stability of the U-shaped segment cooperating with the peristaltic pumps **53**. One locator alone, either external **3***a* or internal **3***b* according to the rotation direction of the corresponding pump **53**, can be provided for each fixture seating **2**; the locator will operate contrastingly to the action of the pump in relation to the tract of line constrained in the fixture seating **2**, which action can be drawing or thrusting according to the direction of the pump and the position of the fixture seating **2** (if the seating **2** is located upstream of the pump the tube housed in the seating is drawn by the pump, while if the seating **2** is located downstream of the pump the tube is thrust). Both locators **3***a* and **3***b* can be provided in one alone of the two fixture seatings **2** located at the ends of a U-shaped segment (pump segment); and one locator **3***a*, **3***b* alone can be provided in one alone of the two fixture seatings **2** located at an end of a U-shaped segment.

The lateral reliefs **6**, which define a narrow-section upper inlet of the fixture seating, are also undercuts which hold the tract of line engaged in the fixture seating **2** in position.

Integrated Module Assembly.

The assembly of the integrated module for fluid treatment comprises the following stages:

manufacture of the support element, for example by press-forming the plastic material of the two pieces which make up the element: the base body **1** and the cover **8**;

fixing the blood treatment device to the support element, in particular to the external face of the base body **1**;

associating the complex of distribution lines for the fluids to the support element and to the treatment device.

Fitting the treatment device to the support element includes the following stages:

Selecting a pair of connectors from connectors **14**, **15** and **16**, to which the seatings on the treatment device are to be fixed;

Depositing a predetermined quantity of glue on the annular seatings of each selected connector;

At least partially inserting each seating in the respective annular seating in order to achieve a mechanical lock and a liquid-sealed coupling; during the insertion stage, at least a portion of the predetermined quantity of glue enters the second zone of the annular seating, i.e. the upper broadened zone which is radially larger than the bottom zone of the annular seating; on conclusion of the insertion stage, the volume of the glue added to the volume of the portion of seating housed in the annular seating is lower than the overall volume of the annular seating, in order to avoid any glue exiting from the seating and occupying even minimally the fluid passage zone.

The coupling of the complex of fluid distribution lines to the support element comprises an insertion stage of the junction collars **39** internally of the fixture seatings **2**. This stage is performed by a simple pressure fit, taking care to make sure the abutments formed by each junction collar **39** meet with the locators **3***a* and **3***b* of the respective fixture seating **2**. The junction collar **39** is friction-fitted in the fixture seating **2** through the upper opening defined between the lateral walls **5**, which opening is narrower than the diameter of the junction collar **39**. The junction collar **39**, which externally identifies the axial tract of line engaged in the fixture seating **2**, is thus stably joint-coupled in the seating **2**, with no need for glues and with considerable precision of positioning thanks to the coupling between the locators **3***a* and **3***b* and the ends of the junction collar **39**.

The cover **8** is coupled to the base body **1** after the distribution lines have been engaged. The cover **8** at least partially closes off the lines engaged to the base body **1** and guarantees the lines' housed stability.

The integrated module is destined to be replaced by a new module. The support element can be easily separated from the distribution lines and the treatment device and re-used, after suitable washing and sterilizing procedures, as a support element for a new treatment module; or it can be disposed of suitably.

Detaching the distribution lines is done by removing the cover **8** and extracting the complex of lines from the housing zone on the base body **1**: the extraction procedure is made easier by the through-holes **4** which enable an extracting pressure to be exerted from the bottom on the collars **39**, causing the lines to exit through the upper openings of the fixture seatings **2**.

The invention claimed is:

1. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body:

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line;

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line, said at least one axial locator having an undercut surface, said undercut surface being positioned in an axial direction of the axially extended tract of a fluid distribution line.

2. The support element of claim **1**, wherein said axial locator is a first axial locator, said support element further comprising a second axial locator, said first and second axial locators being axially reciprocally separated, wherein the axially extended tract of a fluid distribution line is positioned in a fixed position between the first and second axial locators.

3. The support element of claim **1**, wherein the at least one fixture seating comprises a superiorly-open channel, said channel being configured to accept the axially extended tract of a fluid distribution line said axial locator having an edge projecting into the channel from a wall delimiting the channel.

4. The support element of claim 1, further comprising at least one pair of fixture seatings, said at least one pair having first and second fixture seatings being configured on a periphery of the base body, said at least one pair of fixture seatings being further configured to receive first and second ends of a U-shaped segment of at least one fluid distribution line, the U-shaped segment being configured to cooperate with a peristaltic pump.

5. The support element of claim 4, wherein the U-shaped segment projects outside the periphery of the base body.

6. The support element of claim 4, wherein the base body further comprises:

a flat plate-shaped part having a plurality of perimeter sides, said plurality of perimeter sides defining a polygonal shape of the base body;

a plurality of pairs of fixture seatings, each pair of fixture seatings including first and second fixture seatings, said first and second fixture seatings being provided on one of the plurality of perimeter sides, wherein said first and second fixture seatings being arranged adjacent and reciprocally parallel to one another.

7. The support element of claim 1, wherein the base body has at least one flat sheet-shaped part, said at least one flat sheet-shaped part having an internal face and an external face, said internal face having a raised, edge on a perimeter of the internal face, the support element further comprising:

a cover coupled to the base body, said cover being configured to cover at least a part of the internal face of the base body and having at least one flat plate-shaped part, said cover also having a cover perimeter corresponding to a perimeter of the internal face of the base body;

a containment space positioned between the internal face of the base body and an internal face of the cover, said containment space being configured to house a complex of fluid distribution lines; and

a connector positioned on the internal face of the base body configured to engage and constrain the complex of fluid distribution lines;

said raised edge on the perimeter of the internal face of the base body being configured to laterally delimit said containment space, said base body further comprising at least one hooking tab including a single piece and the base body, said hooking tab being configured to removably couple the cover to the base body.

8. The support element of claim 1, wherein the base body has at least one flat sheet-shaped part, said at least one flat sheet-shaped part having an internal face and an external face, the support element further comprising:

a cover coupled to the base body, configured to cover at least a part of the internal face of the base body, said cover having at least one flat plate-shaped part;

a containment space delimited by the internal face of the base body and an internal face of the cover, said containment space being configured to house a complex of fluid distribution lines; and

at least one guide channel positioned on the internal face of the base body, said at least one guide channel being configured to receive at least a first axial tract of a fluid distribution line and further configured to define a guided pathway for the first axially extended tract of the fluid distribution line, a height of the at least one guide channel being at least twice a width of the at least one guide channel, said at least one guide channel being configured to house and laterally contain at least first and second axial tracts of line, one of the first and second axial tracts of line being superposed on the other;

wherein the at least one guide channel is delimited by first and second lateral walls, said first and second lateral walls rising from the internal face of the base body.

9. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body:

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line, said at least one fixture seating being configured to accept a forced insertion and a resilient joint-coupling of the axially extended tract of a fluid distribution line, the at least one fixture seating having at least one opening configured to accept insertion of the axially extended tract of a fluid distribution line, the at least one opening having a passage section with a width, at least a portion of said width being smaller than a maximum width of the at least one fixture seating;

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line.

10. The support element of claim 9, wherein said axial locator is a first axial locator, said support element further comprising a second axial locator, said first and second axial locators being axially reciprocally separated, wherein the axially extended tract of a fluid distribution line is positioned in a fixed position between the first and second axial locators.

11. The support element of claim 9, wherein the at least one fixture seating comprises a superiorly-open channel, said channel being configured to accept the axially extended tract of a fluid distribution line said axial locator having an edge projecting into the channel from a wall delimiting the channel.

12. The support element of claim 9, further comprising at least one pair of fixture seatings, said at least one pair having first and second fixture seatings being configured on a periphery of the base body, said at least one pair of fixture seatings being further configured to receive first and second ends of a U-shaped segment of at least one fluid distribution line, the U-shaped segment being configured to cooperate with a peristaltic pump.

13. The support element of claim 12, wherein the U-shaped segment projects outside the periphery of the base body.

14. The support element of claim 12, wherein the base body further comprises:

a flat plate-shaped part having a plurality of perimeter sides, said plurality of perimeter sides defining a polygonal shape of the base body;

a plurality of pairs of fixture seatings, each pair of fixture seatings including first and second fixture seatings, said first and second fixture seatings being provided on one of the plurality of perimeter sides, wherein said first and second fixture seatings being arranged adjacent and reciprocally parallel to one another.

15. The support element of claim 9, wherein the base body has at least one flat sheet-shaped part, said at least one flat sheet-shaped part having an internal face and an external

face, said internal face having a raised edge on a perimeter of the internal face, the support element further comprising:

a cover coupled to the base body, said cover being configured to cover at least a part of the internal face of the base body and having at least one flat plate-shaped part, said cover also having a cover perimeter corresponding to a perimeter of the internal face of the base body;

a containment space positioned between the internal face of the base body and an internal face of the cover, said containment space being configured to house a complex of fluid distribution lines; and

a connector positioned on the internal face of the base body configured to engage and constrain the complex of fluid distribution lines;

said raised edge on the perimeter of the internal face of the base body being configured to laterally delimit said containment space, said base body further comprising at least one hooking tab including a single piece and the base body, said hooking tab being configured to removably couple the cover to the base body.

16. The support element of claim **9**, wherein the base body has at least one flat sheet-shaped part, said at least one flat sheet-shaped part having an internal face and an external face, the support element further comprising:

a cover coupled to the base body, configured to cover at least a part of the internal face of the base body, said cover having at least one flat plate-shaped part;

a containment space delimited by the internal face of the base body and an internal face of the cover, said containment space being configured to house a complex of fluid distribution lines; and

at least one guide channel positioned on the internal face of the base body, said at least one guide channel being configured to receive at least a first axial tract of a fluid distribution line and further configured to define a guided pathway for the first axially extended tract of the fluid distribution line, a height of the at least one guide channel being at least twice a width of the at least one guide channel, said at least one guide channel being configured to house and laterally contain at least first and second axial tracts of line, one of the first and second axial tracts of line being superposed on the other;

wherein the at least one guide channel is delimited by first and second lateral walls, said first and second lateral walls rising from the internal face of the base body.

17. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line, said at least one fixture seating further having a primary surface for receiving the axially extended tract of the fluid distribution line, said surface having at least two undercut surfaces, said at least two undercut surfaces being configured to obstruct at least a first and second displacement of the axially extended tract of the fluid distribution line, said first displacement being in an axial direction and said second displacement being in an upwards extraction direction passing through an upper insertion opening;

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line.

18. The support element of claim **17**, wherein said axial locator is a first axial locator, said support element further comprising a second axial locator, said first and second axial locators being axially reciprocally separated, wherein the axially extended tract of a fluid distribution line is positioned in a fixed position between the first and second axial locators.

19. The support element of claim **17**, wherein the at least one fixture seating comprises a superiorly-open channel, said channel being configured to accept the axially extended tract of a fluid distribution line said axial locator having an edge projecting into the channel from a wall delimiting the channel.

20. The support element of claim **17**, further comprising at least one pair of fixture seatings, said at least one pair having first and second fixture seatings being configured on a periphery of the base body, said at least one pair of fixture seatings being further configured to receive first and second ends of a U-shaped segment of at least one fluid distribution line, the U-shaped segment being configured to cooperate with a peristaltic pump.

21. The support element of claim **20**, wherein the U-shaped segment projects outside the periphery of the base body.

22. The support element of claim **20**, wherein the base body further comprises:

a flat plate-shaped part having a plurality of perimeter sides, said plurality of perimeter sides defining a polygonal shape of the base body;

a plurality of pairs of fixture seatings, each pair of fixture seatings including first and second fixture seatings, said first and second fixture seatings being provided on one of the plurality of perimeter sides, wherein said first and second fixture seatings being arranged adjacent and reciprocally parallel to one another.

23. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line, said at least one fixture seating further having at least one superior opening configured to accept a forced insertion of the axially extended tract of the fluid distribution line and at least one inferior through-hole facing the at least one superior opening, said at least one inferior through-hole being configured to allow an exertion of pressure onto the axially extended tract of a fluid distribution line through said at least one inferior through-hole, said axially extended tract of a fluid distribution line engaging the at least one fixture seating, wherein said exertion enables an extraction of the axially extended tract of a fluid distribution line through the superior opening;

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line.

24. The support element of claim **23**, wherein said axial locator is a first axial locator, said support element further comprising a second axial locator, said first and second axial locators being axially reciprocally separated, wherein the

axially extended tract of a fluid distribution line is positioned in a fixed position between the first and second axial locators.

25. The support element of claim **23**, wherein the at least one fixture seating comprises a superiorly-open channel, said channel being configured to accept the axially extended tract of a fluid distribution line said axial locator having an edge projecting into the channel from a wall delimiting the channel.

26. The support element of claim **23**, further comprising at least one pair of fixture seatings, said at least one pair having first and second fixture seatings being configured on a periphery of the base body, said at least one pair of fixture seatings being further configured to receive first and second ends of a U-shaped segment of at least one fluid distribution line, the U-shaped segment being configured to cooperate with a peristaltic pump.

27. The support element of claim **26**, wherein the U-shaped segment projects outside the periphery of the base body.

28. The support element of claim **26**, wherein the base body further comprises:

a flat plate-shaped part having a plurality of perimeter sides, said plurality of perimeter sides defining a polygonal shape of the base body;

a plurality of pairs of fixture seatings, each pair of fixture seatings including first and second fixture seatings, said first and second fixture seatings being provided on one of the plurality of perimeter sides, wherein said first and second fixture seatings being arranged adjacent and reciprocally parallel to one another.

29. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line;

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line; and

a lateral relief projecting inside the channel from at least one of the first and second lateral walls, the at least one lateral relief forming at least one undercut surface positioned in an extraction direction of the axially extended tract of a fluid distribution line through the superior opening of the channel, the at least undercut surface being configured inferior to the upper edge of the lateral wall wherein;

the at least one fixture seating comprises a channel having a superior opening configured to accept an insertion of the axially extended tract of the fluid distribution line,

the channel extending axially and at least partially projecting in an external direction, said channel projecting outside of a perimeter border of the base body, the channel having first and second lateral walls, said first and second lateral walls being adjacent to each other, said first lateral wall having a first upper edge and said second lateral wall having a second upper edge,

the superior opening being bounded by the first and second upper edges of the first and second lateral walls.

30. The support element of claim **29**, wherein said lateral relief is a first lateral relief, said support element comprising a second lateral relief, said first and second lateral reliefs being configured to face one another and cooperate to obstruct an extraction of the axially extended tract of the fluid distribution line.

31. The support element of claim **29**, wherein the channel is configured to constrain a tract of an end segment of U-shaped line, said lateral relief being provided in a part of end of the channel facing the segment of U-shaped line.

32. The support element of claim **29**, wherein the at least one undercut surface is configured to enable extraction of the axially extended tract of a fluid distribution line by a forcing movement.

33. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line;

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line;

a complex of distribution lines;

a cover removably couplable to the base body, said cover being configured to cover at least a part of the internal face of the base body;

a containment space between the internal face of the base body; and

an internal face of the cover, said containment space being configured to house at least a part of the complex of distribution lines, wherein the base body is flat-plate shaped and the at least one fixture seating extends over an internal face of the base body.

34. The support element of claim **33**, wherein the cover exhibits at least one tooth projecting downwards, said tooth entering at least partially into the at least one fixture seating, said tooth further limiting a raising movement of the axial tract line constrained in the at least one fixture seating.

35. The support element of claim **33**, wherein the internal face of the base body comprises a raised edge on a perimeter of the internal face of the base body, said raised edge being configured to laterally contain at least a part of the complex of distribution lines, the cover of the support element having a flat plate-shape and covering a perimeter substantially similar to the perimeter of the internal face of the base body.

36. The support element of claim **35**, wherein the base body comprises at least one hooking tab formed of a single piece along with the base body, said hooking tab being configured to removably couple the cover to the base body.

37. The support element of claim **33**, wherein the at least one fixture seating comprises an axial end tract extending axially and internally to a perimeter side of the base body and an end tract extending axially and external to the perimeter side of the base body.

38. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body;

at least one fixture seating configured on the base body to receive and constrain an axially extending tract of a fluid distribution line, the at least one fixture seating having a channel with an opening configured to accept a forced insertion of the axially extended tract of the fluid distribution line, the channel being axially extended and at least partially projecting axially outside

a perimeter edge of the base body, at least the part of the channel projecting axially outside a perimeter edge of the base body being laterally delimited by first and second walls, the first and second walls being adjacent to each other, each of said first and second walls having an upper edge delimiting the opening configured to accept a forced insertion; and

at least one lateral relief projecting into the channel from at least one of the first and second walls, the at least one lateral relief forming at least one undercut surface positioned in an extraction direction of the axially extended tract of the fluid distribution line through the superior opening of the channel, the at least one undercut surface being arranged inferior to a superior edge of at least one of the first and second walls.

39. A support element for an integrated module for extracorporeal blood treatment, comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line;

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line;

at least first, second, and third connectors being joined to the base body and separated from each other by a distance, said at least first, second, and third connectors being further configured to receive and constrain corresponding seatings of a blood treatment device, said blood treatment device being mountable on the support element, each of said first, second, and third connectors defining a fluid passage having a first terminal portion configured to be placed in fluid communication with a corresponding channel, said channel being present in a respective seating included in the blood treatment device, and a second terminal portion configured to be placed in fluid communication with a fluid distribution line being coupled to the base body.

40. The support element of claim **39**, wherein the first and the second connectors are formed of a single piece along with the base body.

41. The support element of claim **39**, wherein said third connector is formed of a single piece along with the base body, said first, second, and third connectors being configured in pairs, each pair having a different interaxes from another pair, the interaxes corresponding with interaxes of pairs of seatings associated with various blood treatment devices, said various blood treatment devices being mountable on the support element.

42. The support element of claim **39**, wherein each of the first, second, and third connectors comprises:

a tubular channel, defining the first terminal portion;

a sealing collar, provided in a position radially external to the tubular channel; and

a continuous connecting wall provided between a lateral external surface of the tubular channel and a lateral internal surface of the sealing collar, said continuous connecting wall defining an annular seating for each at least one fixture seating.

43. The support element of claim **39**, wherein the tubular channel defines the first terminal position, said tubular channel being arranged coaxial to the sealing collar, the annular seating having a bottom delimited by the connecting wall.

44. The support element of claim **42**, wherein the annular seating has a radius, said radius increasing in a distal direction from the bottom of the annular seating.

45. The support element of claim **44**, wherein the annular seating comprises:

a first zone having a constant radius, said first zone being adjacent to the bottom of the annular seating;

a second zone having a constant radius larger than the constant radius of the first zone; and

a transitional third zone positioned between the first zone and the second zone, said transitional third zone having a radius progressively increasing in a distal direction from the bottom of the annular seating.

46. The support element of claim **42**, wherein the tubular channel and the sealing collar of each of the first, second, and third connectors are parallel to each other, said tubular channels and sealing collars emerging from the base body and defining a single coupling direction with the corresponding seatings of a blood treatment device.

47. The support element of claim **42**, wherein the first, second, and third connectors and the base body are made of a rigid material, said material providing mechanical support to the blood treatment device.

48. The support element of claim **42**, wherein the first, second, and third connectors are not aligned with each other.

49. The support element of claim **42**, wherein the first, second, and third connectors are directly constrained to the base body.

50. The support element of claim **42**, wherein the first, second, and third connectors are each provided on a first face of the base body, said first face being opposite a second face of the base body, said base body bearing the at least one fixture seating.

51. A fluid distribution line for an integrated module for an extracorporeal blood treatment, comprising:

a first tract of line having a larger external diameter than adjacent tracts of line; and

first and second external abutments, the first tract of line is positioned between the first and second external abutments, said first tract of line being configured for insertion in the fixture seating configured on a support element comprising:

a base body;

at least one fixture seating located on the base body said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line; and

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line.

52. The distribution line of claim **51**, comprising:

a second tract of line, said first and second tracts of line being separated axially from each other; and

a segment of line being positioned between the first and second tracts of line, said segment of line being configured to form a U-shaped arched segment, said U-shaped arched segment being coupled to a peristaltic pump.

53. The distribution line of claim **51**, wherein the first tract of line comprises a junction collar, said junction collar

accepting and joining first and second end zones of first and second parts of a fluid-connected line.

54. The distribution line of claim **53**, wherein the junction collar is formed of a rigid material, said rigid material being more rigid than a material forming the first and second end zones of the first and second parts of fluid-connected line connected by the junction collar.

55. A series of elements configured to be coupled to each other, comprising:

a first element, said first element being the a support element comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line; and

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line;

a second element, said second element being a complex of fluid distribution lines, said fluid distribution lines comprising at least one tract of line; and

first and second external abutments, the at least one tract of line being positioned between the first and second external abutments, said at least one tract of line being configured for insertion in the fixture seating configured on the support element.

56. An assembly process of the series of elements of claim **55**, wherein the at least one tract of line having a larger external diameter being positioned between the first and second external abutments is inserted in the at least one fixture seating provided on the support element, the first and second abutments overlapping with the axial locator configured in the at least one fixture seating, the support element being provided with a cover, said cover being subsequently coupled to the base body to at least partially cover the at least one tract of line having a larger diameter.

57. An integrated module for extracorporeal blood treatment, comprising:

a support element comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line; and

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line;

at least one blood treatment device mounted on the support element, said at least one blood treatment device comprising at least first and second chambers, said first and second chambers being separated by at least one semi-permeable membrane;

a complex of fluid distribution lines associated to the support element and cooperating with the blood treatment device, said complex of fluid distribution lines comprising at least one line having a larger external diameter than adjacent tracts of line;

first and second external abutments, wherein the at least one tract of line with a larger external diameter is positioned between the first and second external abutments, said at least one tract of line with a larger external diameter being configured for insertion in the fixture seating provided on the support element.

58. The integrated module of claim **57**, for use in treatment of renal insufficiency, wherein the blood treatment device is selected from a group comprising hemofiltration, hemodialysis, high-flow filtration, and hemodiafiltration devices.

59. An apparatus for extracorporeal treatment of blood, comprising:

a housing zone for receiving an integrated module for extracorporeal blood treatment according to claim **57**; and

one or more pumps configured to circulate fluid and cooperate with the complex of fluid distribution lines of the integrated module.

60. An integrated module for extracorporeal blood treatment, having:

a support element comprising:

a base body;

at least one fixture seating located on the base body, said at least one fixture seating being axially extended and configured to house an axially extended tract of a fluid distribution line; and

an axial locator arranged in said seating fixture, said axial locator being configured to position said axially extended tract of a fluid distribution line in a fixed position, said axial locator being further configured to interact with a corresponding element predisposed on said axially extended tract of a fluid distribution line;

at least one blood treatment device mounted on the support element, said at least one blood treatment device comprising at least first and second chambers, said first and second chambers being separated by at least one semi-permeable membrane; and

a complex of fluid distribution lines associated to the support element and cooperating with the blood treatment device, said blood treatment device further comprising:

a containment body housing said first and second chambers being separated by said at least one semi-permeable membrane;

first and second counter-connectors associated to the containment body, said first and second counter-connectors being fixed to first, second, or third connectors associated with the base body, the first and second connectors being set in fluid connection with the second chamber of the blood treatment device and first terminal portions of the first and second connectors;

at least one inlet port to the first chamber; and

at least one outlet port from the first chamber, said blood treatment device being fixed to said base body by at least one pair of connectors from the group comprising said first, second, and third connectors.

61. The module of claim **60**, wherein the complex of fluid distribution lines further comprises at least one discharge line of waste fluid, said at least one discharge line being set in communication with the second terminal portion of one of the first, second, and third connectors.

62. The module of claim **61**, wherein the complex of fluid distribution lines further comprises at least one infeed line of a treatment fluid, said at least one infeed line being in

communication with the second terminal portion of another of the first, second, and third connectors.

63. The module of claim **61**, wherein at least one of the lines is attached to the support element, said at least one line defining at least one U-shaped arched segment on the support element and said at least one line being further configured to cooperate with a peristaltic pump.

64. The module of claim **63**, wherein the U-shaped segment extends outside of the perimeter wall of the support element.

65. The module of claim **60**, wherein the complex of fluid distribution lines further comprises: at least one blood withdrawal line, said at least one blood withdrawal line being in communication with the inlet port of the first chamber, and at least one blood return line, said at least one blood return line being in communication with the outlet port of the first chamber.

66. The integrated module of claim **60**, for use in treatment of renal insufficiency, wherein the blood treatment device is selected from a group comprising hemofiltration, hemodialysis, high-flow filtration, and hemodiafiltration devices.

67. An apparatus for extracorporeal treatment of blood, comprising:

a housing zone for receiving an integrated module for extracorporeal blood treatment according to claim **60**; and

one or more pumps configured to circulate fluid and cooperate with the complex of fluid distribution lines of the integrated module.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,232,418 B2
APPLICATION NO. : 10/771415
DATED : June 19, 2007
INVENTOR(S) : Neri et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, line 40, "body:" should read --body;--.

Column 13, line 26, "raised, edge" should read --raised edge--.

Column 14, line 9, "body:" should read --body;--.

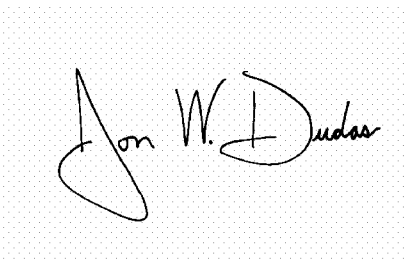
Column 17, line 53, "wherein;" should read --wherein:--.

Column 20, line 48, "body said" should read --body, said--.

Column 21, line 10, "being the a" should read --being a--.

Signed and Sealed this

Fourteenth Day of August, 2007



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT C

US007314554B2

(12) **United States Patent**
Delnevo et al.

(10) **Patent No.: US 7,314,554 B2**
(45) **Date of Patent: Jan. 1, 2008**

(54) **EXTRACORPOREAL BLOOD TREATMENT MACHINE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 383 days.

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(51) **Int. Cl.**

B01D 61/28	(2006.01)
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B01D 61/32	(2006.01)
A61M 1/14	(2006.01)

(52) **U.S. Cl.** **210/258**; 210/85; 210/87; 210/90; 210/96.1; 210/97; 210/134; 210/143; 210/252; 210/257.1; 210/258; 210/321.6; 210/321.65; 210/416.1; 210/436; 210/472; 604/4.01; 604/5.01; 604/6.07; 604/6.09; 604/6.1; 604/6.11; 604/65; 604/67

(58) **Field of Classification Search** 210/85, 210/87, 90, 96.1, 97, 134, 143, 252, 257.1, 210/257.2, 258, 321.6, 321.65, 321.71, 416.1, 210/433.1, 436, 472; 604/4.01, 5.01, 6.07, 604/6.09, 6.1, 6.11, 65, 66, 67
See application file for complete search history.

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(Continued)

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(57) **ABSTRACT**

The invention relates to an extracorporeal blood treatment machine in which a blood circuit (**3**) is equipped with an inlet line leading to a filtration unit (**2**) and with an outlet line (**3***b*) from the filtration unit; a fluid circuit comprises an inlet line (**4***a*) leading to the filtration unit and an outlet line (**4***b*) from the filtration unit so as to allow a fluid taken from a primary container (**5**) to circulate within the filtration unit, thus enabling the treatment of the patient's blood. There is further an infusion line (**6**) acting on the outlet line of the blood circuit, which is supplied by an auxiliary fluid container (**7**). The inlet line of the fluid circuit is equipped with at least an infusion branch (**8**) acting on the outlet line of the blood circuit so as to enable the intensive therapy machine to manage therapies with large exchange of fluids.

48 Claims, 3 Drawing Sheets

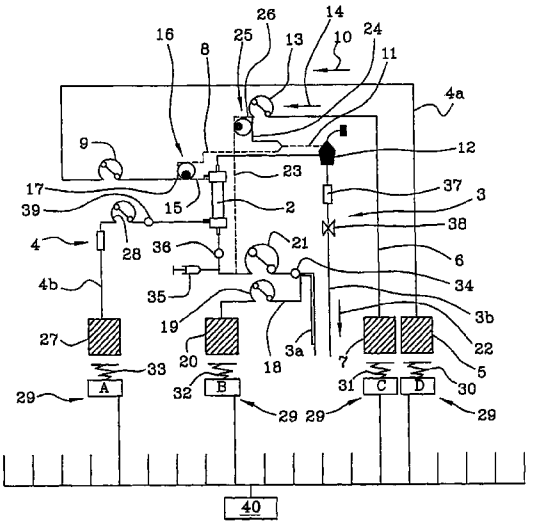

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FIG 1

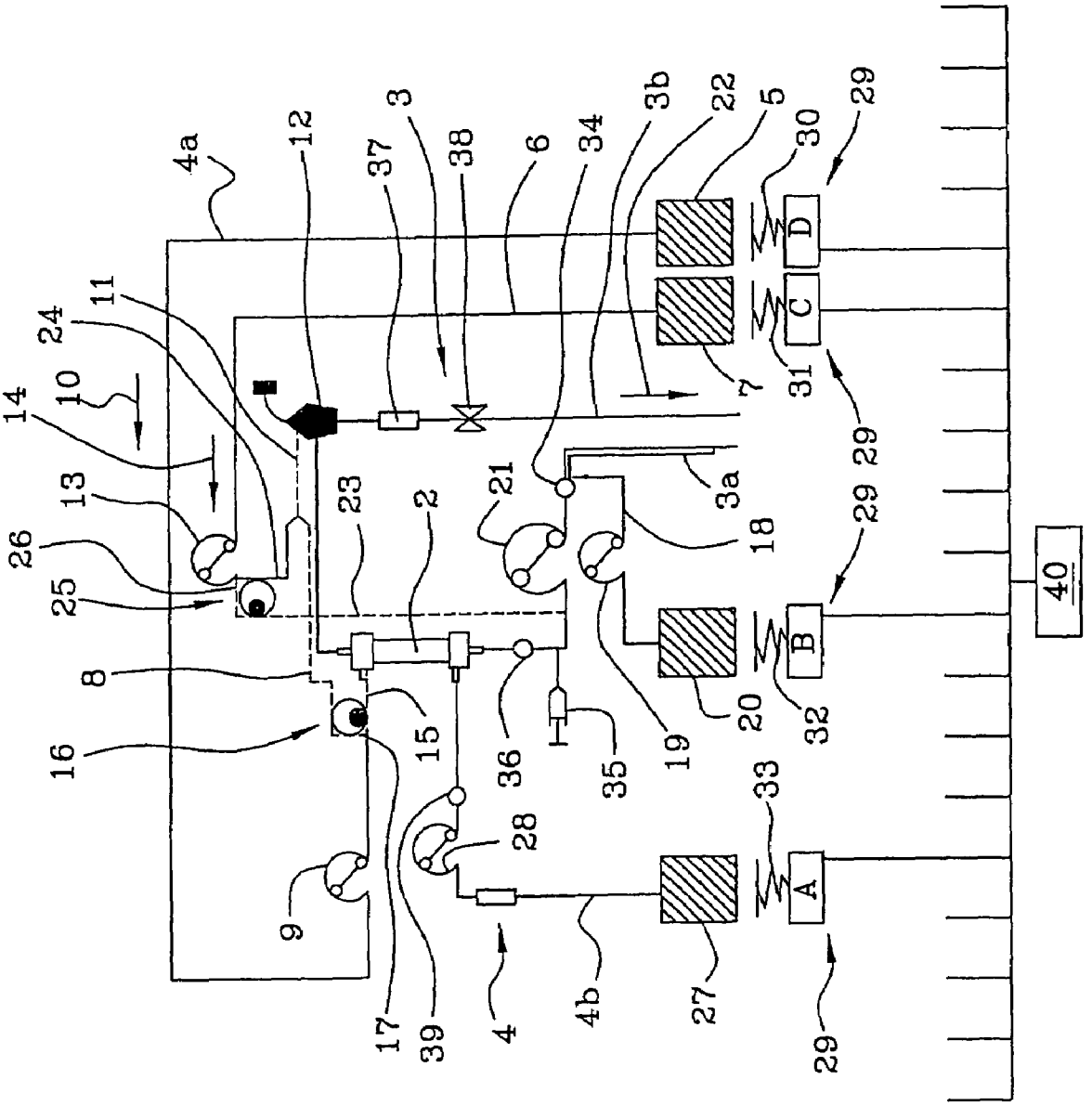
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FIG 2

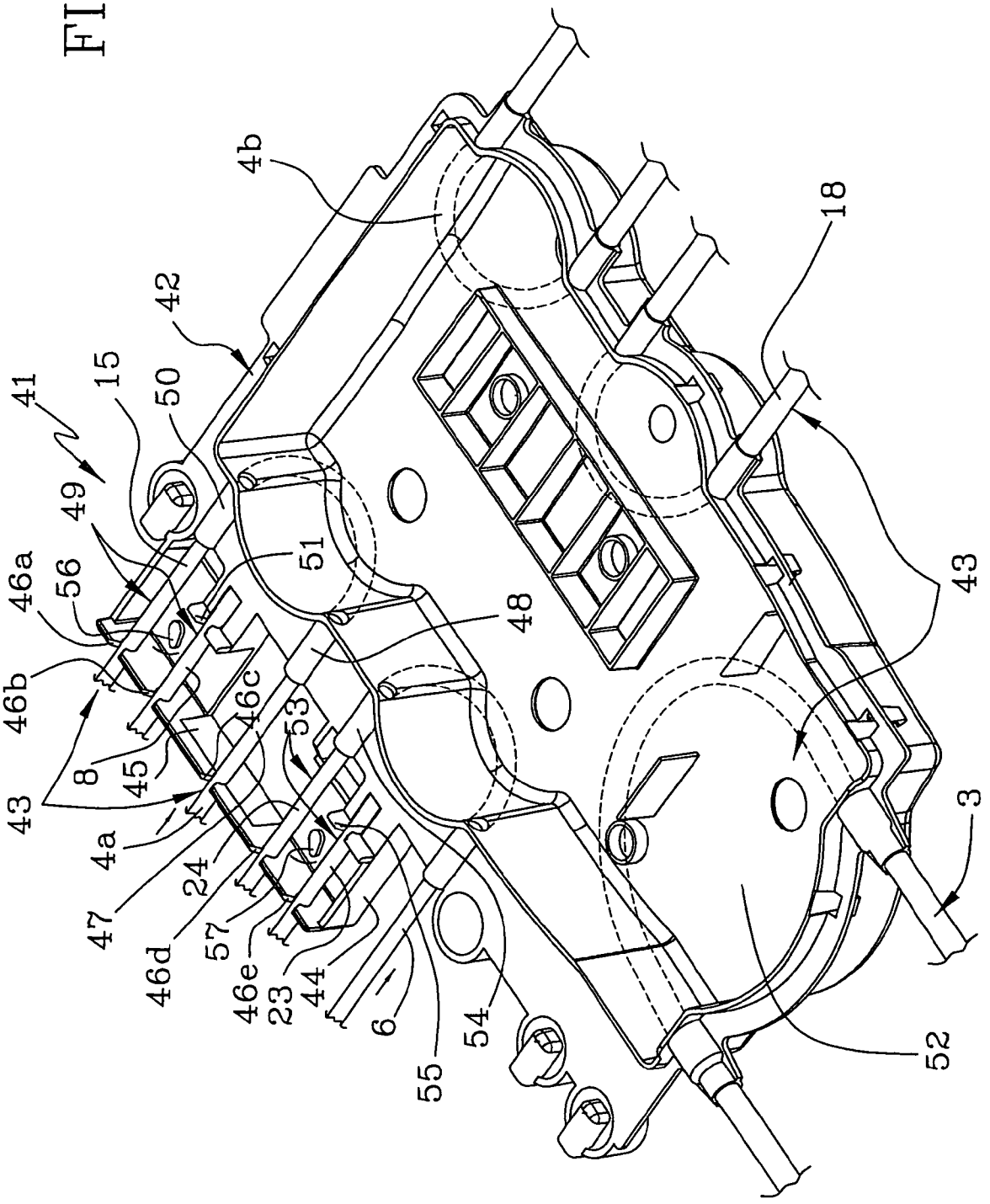
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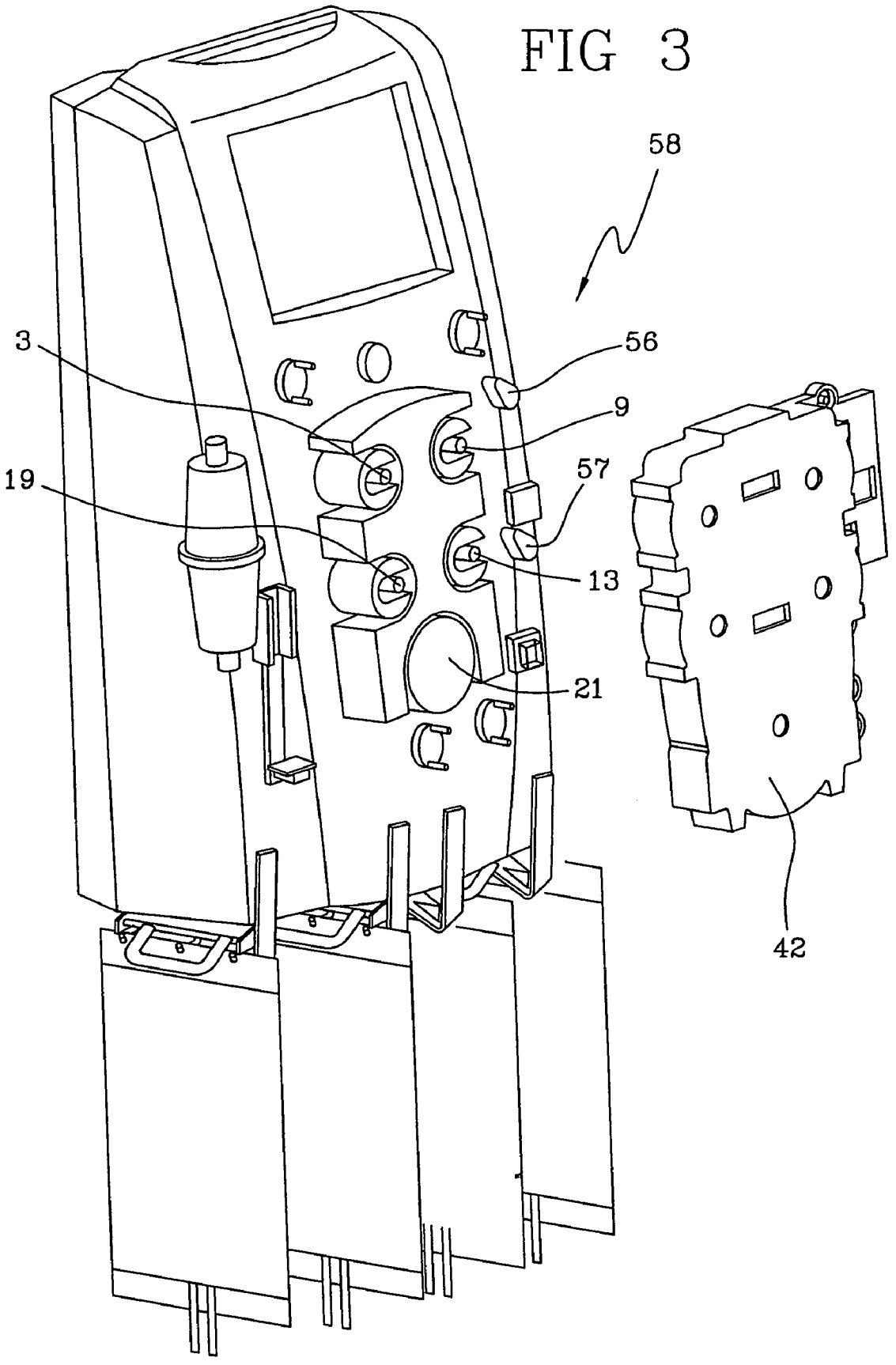
FIG 3



EXTRACORPOREAL BLOOD TREATMENT MACHINE

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of Italian Patent Application No. MI2003 A 000212, filed on Feb. 7, 2003, and the benefit of U.S. Provisional Application No. 60/469,839, filed May, 13, 2003, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to an extracorporeal blood treatment machine and to an integrated treatment module that can be used on said machine.

The object of the invention can be used for instance in intensive therapy machines which can carry out a plurality of different blood treatments.

Extracorporeal treatments generally consists in taking blood from the patient, in treating said blood when it is outside the patient's body and then in re-circulating the blood thus treated.

The treatment typically consists in removing from the blood unwanted and/or dangerous substances, as well as excess liquid in patients who cannot autonomously carry out said operations, such as for instances patients suffering from temporary or permanent kidney problems.

For instance, it may be necessary to add or remove substances from blood, to keep a correct acid/base ratio or also to remove fluid excess from the body.

The extracorporeal treatment is generally obtained by removing blood from the patient, by letting the blood flow within a filtration unit where a semipermeable membrane ensures the exchange of suitable substances, molecules and fluids.

Generally though not necessarily, said exchange is carried out by letting a given biological fluid ensuring the aforesaid exchanges pass in counter-current and within a secondary chamber of the filtration unit.

It should be noted that currently used machines can enable different types of blood treatment.

In the ultrafiltration treatment the substances and fluids to be eliminated are removed by convection from the blood, pass through the semipermeable membrane and are led towards the aforesaid secondary chamber.

In hemofiltration treatments part of the molecules, substances and fluids present in the blood pass through the membrane by convection as in the ultrafiltration treatment, although further necessary elements are added to the blood; typically a suitable fluid is infused directly into the blood before or after the latter passes through the filtration unit and anyhow before it is carried back into the patient.

In haemodialysis treatments a fluid containing material to be transferred into the blood is introduced into the secondary chamber of the filtration unit. The unwanted material flows through the semipermeable membrane from the blood into the secondary fluid and the desired substances/molecules from the secondary fluid can pass through the membrane as far as the blood.

In hemodiafiltration treatments the blood and the secondary fluid exchange their respective substances/molecules as in haemodialysis and, in addition, a fluid is infused into the blood as in haemofiltration treatments.

Obviously, in order to carry out each of said extracorporeal blood treatments, the blood has to be removed from a patient's vein or artery, suitably circulated in the machine and then re-introduced into the patient.

As is also known, blood treatment machines for intensive therapy have to be ready as fast as possible for an immediate use for any possible emergency.

Obviously, to this purpose the machine must not require either preliminary sanitizing operations or long pre-assembling operations of the various components for the various therapies.

As is known, intensive therapy machines are present on the market and are currently used, in which a blood circuit comprises a line for taking blood from the patient, which carries said blood to a filtration cartridge, and an outlet line from the filtration cartridge, which carries the treated blood back into the patient's body.

The machine is then equipped with a circuit for the passage of dialysis fluid; also said circuit has an intake line leading into the filtration unit, which is supplied by a sterile bag containing the dialysis liquid, and has also an outlet line enabling the passage of a fluid which has received by convection/diffusion the dangerous substances and molecules from the blood towards a collection bag for their subsequent removal.

Said machine is further equipped with an infusion line allowing with suitable doses—to transfer directly into the blood upstream from the filtration unit the content of another liquid bag, thus adding the necessary products into the blood.

A known intensive therapy machine is further equipped with a suitable syringe containing for instance heparin as blood anticoagulant, the latter being added to the blood taken from the patient so as to avoid the creation of dangerous clots within the circuit.

The structure and circuitry mentioned above are generally defined by a single integrated module attached to the machine body.

It is evident that in order to enable the immediate use of the machine, the fluid bags referred to above have to be present and already sterile, so as to be directly and easily connected to their respective tubes, the latter also being sterile and disposable.

The machine is further equipped with a suitable control unit managing the flow of fluids by means of suitable peristaltic pumps and respective sensors associated to the circuit.

It is evident that by suitably setting the control unit said machine can selectively carry out one or more of the extracorporeal blood treatments described above (i.e. ultrafiltration, haemofiltration, haemodialysis and haemodiafiltration).

The machine described above, though being today quite a vanguard device for extracorporeal blood treatments in intensive therapies, has proved to be susceptible of several improvements.

In particular, a first intrinsic drawback in intensive therapy machines is related to the limited availability of fluids for operations involving the exchange of substances by convection/diffusion within the filter and for pre- or post-infusions into the blood line.

Said limitation is obviously related to the necessary use of prepackaged sterile fluid bags typically containing 6 kg of dialysis liquid.

It is evident that the pre-established fluid amount to be used imposes some limitations, in particular in the case of therapies with large exchange of fluids, which would sometimes be extremely suitable in emergency cases.

On the other hand, it is not possible to use larger fluid amounts in intensive therapies since suitably treated water taken from the water network cannot be used as exchange fluid in short times; indeed, this would involve long operations for installing the devices for in-line preparation of sterile liquids; moreover, it is not possible to use bags with higher amounts of liquids due to the obvious problems involving transport and management of said containers by the personnel.

Another problem of known intensive therapy machines consists in achieving an optimal management of the administration of anticoagulant substances which are necessary for a good working of the machine.

In particular, today known intensive therapy machines cannot manage effectively the use of regional anticoagulation methods, such as for instance citrate-based methods, since the use of said techniques requires the administration of further solutions recovering the blood ion balance before carrying the treated blood back into the patient's body.

SUMMARY OF THE INVENTION

Under these circumstances the present invention aims at solving basically all the drawbacks referred to above.

A first technical aim of the invention is to provide physicians with the possibility to manage therapies with large exchange of fluids using an intensive therapy machine where, in any case, fluids are housed in small-size containers.

A further aim of the present invention is to be able to manage intensive therapies by using regional anticoagulation techniques, i.e. acting on the blood only in the extracorporeal circuit, without having to limit pre-infusion upstream from the filtration unit.

Moreover, an aim of the present invention is to enable the substantial separation of the use of regional anticoagulation techniques from the infusion of fluids for carrying out the necessary therapeutic exchange (by convection or diffusion).

Finally, an auxiliary aim of the present invention is to provide an machine ensuring quite simple and reliable loading and installing operations, further enabling the complete control of the therapy cycles that are carried out.

These and other aims, which shall be evident in the course of the present description, are basically achieved by an extracorporeal blood treatment machine as described in the appended claims.

Further characteristics and advantages will be clearer from the detailed description of a preferred though not exclusive embodiment of an extracorporeal blood treatment machine according to the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

This description will be given below with reference to the appended tables, which are provided as a mere guidance and are therefore not limiting, in which:

FIG. **1** shows schematically a hydraulic circuit to be used in an intensive therapy machine in accordance with the present invention;

FIG. **2** shows an integrated module comprising a support element and a portion of the fluid distribution circuitry, to be used in intensive therapy machines in accordance with the present invention; and

FIG. **3** shows an machine body in accordance with the invention.

DETAILED DESCRIPTION

With reference to the figures mentioned above, the numeral **1** globally refers to a machine for extracorporeal blood treatment, in particular for intensive therapies.

As can be inferred from the appended table **1**, the machine consists of a blood circuit **3**, which takes blood from a patient, for instance by means of a catheter introduced into a vein or artery of said patient, and through at least an inlet line **3***a* takes said blood, for instance continuously, to a filtration unit **2**.

Then the blood passes through a primary chamber of said filtration unit **2** and through an outlet line **3***b* the treated blood is carried back to the patient.

The connection with an auxiliary pre-infusion line **18** is provided immediately downstream from the blood collecting zone on the inlet line **3***a*.

In particular, the machine is equipped with at least a secondary fluid container or bag **20** for supplying the pre-infusion line **18**; by using corresponding means for conveying fluid, in the example shown comprising an auxiliary pre-infusion pump **19**, for instance a peristaltic pump, it is possible to control the fluid flow within said line by introducing said fluid directly into the blood by means of a direct connection to the inlet line **3***a*.

Generally, the secondary fluid container **20** can house a suitable biological fluid for a pre-infusion, however said bag **20** can also contain an anticoagulant, generally causing a regional anticoagulation so as to ensure a particular working of the machine as shall be explained below in further detail.

After defining a direction of blood circulation **22** from the inlet line **3***a* towards the filtration unit and from the latter through the outlet line **3***b* towards the patient, a known blood pressure sensor **34**, which shall not be described in further detail, is placed immediately downstream from the auxiliary pre-infusion line **18**.

The blood circuit **3** therefore comprises means for conveying fluid, i.e. in this particular case at least a blood pump **21** for controlling and managing the suitable blood flow in the circuit. Also the blood pump **21** is generally a peristaltic pump.

Following the direction of blood circulation **22**, there is then a device **35** for administering an anticoagulant, for instance a syringe containing suitable doses of heparin.

The blood then passes through another pressure sensor **36** controlling the correct flow within the blood circuit.

After passing through a main chamber of the filtration unit **2**, where the suitable exchanges of substances, molecules and fluids occur by means of a semipermeable membrane, the treated blood enters the outlet line **3***b* first passing though a gas separating device (generally air) **12** commonly known as "bubble trap", designed so as to ensure the detection and removal of substances or air bubbles present in the blood.

The treated blood getting out of the separating device **12** then passes through an air bubble sensor **37** verifying the absence of said dangerous formations within the treated blood that has to be re-introduced in the patient's blood circulation.

Immediately downstream from the bubble sensor **37** there is an element **38** which, in case of alarm, can block the blood flow towards the patient.

In particular, should the bubble sensor **37** detect the presence of anomalies in the blood flow, the machine through the element **38** (be it a tap, a clamp or similar) would be able to block immediately the passage of blood so as to avoid any consequence to the patient.

Downstream from said element **38** the treated blood is then carried back to the patient undergoing therapy.

The extracorporeal blood treatment machine shown above is then equipped with a fluid circuit **4**, which is also provided with at least an inlet line **4***a* leading into the filtration unit **2** and with an outlet line **4***b* from the filtration unit.

At least a primary fluid container **5** is designed to supply the inlet line **4***a* of the fluid circuit **4** (generally the primary fluid container **5** shall consist of a bag containing a suitable dialysis liquid).

The inlet line **4***a* then comprises means for conveying fluid such as at least a pump **9** (in the embodiment shown a peristaltic pump) for controlling the flow of liquid from the bag **5** and for defining a direction of circulation **10**.

Downstream from the pump **9** in the direction of circulation **10** there is a branching **17** splitting the fluid circuit **4** up into an intake branch **15** and an infusion branch **8**.

In particular, the infusion branch **8** is connected to the outlet line **3***b* of the blood circuit **3**.

In other words, by means of said infusion branch **8** it is possible to obtain a post-infusion directly in the blood line using the content of the primary fluid container **5**.

Conversely, the intake branch **15** conveys the fluid directly to the filtration unit and in particular to a secondary chamber of said unit.

The fluid circuit **4** is further equipped with selecting means **16** for determining the percentages of fluid flow within the infusion branch **8** and the intake branch **15**.

Generally said selecting means **16**, usually placed near the branching **17**, can be positioned at least between a first operating condition in which they allow the passage of fluid in the intake branch **15** and block the passage in the infusion branch **8**, and a second operating condition in which they allow the passage of fluid in the infusion branch **8** and block the passage in the intake branch **15**.

In other words, said selecting means **16** can consist of a valve element operating on the fluid circuit **4** by alternatively blocking the passage of fluid in either branch.

It is also evident that it might be provided for suitable selectors, which are able to establish a priori the amount of liquid that has to pass through both branches simultaneously.

It will also be possible to vary the percentages of fluid in either branch as a function of time and of the pre-established therapies.

The dialysis liquid through the intake branch **15** gets into a secondary chamber of the filtration unit **2**.

In particular, the primary chamber through which the blood flow passes is separated from the secondary chamber through which the dialysis liquid passes by means of a semipermeable membrane ensuring the suitable passage of the dangerous substances/molecules and of fluid from the blood towards the dialysis liquid mainly by means of convection and diffusion processes, and also ensuring through the same principles the passage of substances/molecules from the dialysis liquid towards the blood.

The dialysis fluid then gets into the outlet line **4***b* and passes through a suitable pressure sensor **39** whose function is to control the working of said line.

Then there are means for conveying fluid, for instance a suction pump **28** controlling the flow in the outlet line **4***b* within the fluid circuit **4**. Also said pump will generally be a peristaltic pump.

The fluid to be eliminated then passes through a blood detector and is conveyed into a collection container or bag **27**.

Further analyzing the particular circuit of the machine according to the invention, note the presence of at least another infusion line **6** acting on the outlet line **3***b* of the blood circuit **3**.

In particular, the infusion fluid is taken from at least an auxiliary container **7** and is sent directly to the outlet line **3***b* of the blood circuit **3** through means for conveying fluid, generally an infusion pump **13** controlling its flow (in the example a peristaltic pump).

In particular and as can be observed in the appended figure, the infusion liquid can be introduced directly into the gas separating device **12**.

As can also be inferred, the infusion branch **8** of the fluid circuit **4** and the infusion line **6** are equipped with a common end length **11** letting into the blood circuit **3**.

Said intake end length **11** is placed downstream from the infusion pump **13** with respect to a direction of infusion **14** and carries the fluid directly into the bubble trap device **12**.

Further referring to the diagram in FIG. **1**, one can notice the presence within the infusion line **6** of at least a pre-infusion branch **23** connected to an inlet line **3***a* of the blood circuit **3**.

In further detail, downstream from the infusion pump **13** with respect to the direction of infusion **14**, there is a branching **26** splitting the infusion line **6** up into pre-infusion branch **23** and post-infusion branch **24**.

The pre-infusion branch **23**, in particular, carries the fluid taken from the bag **7** on the inlet line **3***a* of the blood circuit downstream from the blood pump **21** with respect to the direction of circulation **22**.

Conversely, the post-infusion branch **24** is connected directly to the common end length **11**.

The infusion line **6** further comprises selecting means **25** for determining the percentage of liquid flow to be sent to the post-infusion branch **24** and to the pre-infusion branch **23**.

The selecting means **25** placed near the branching **26** can be positioned between at least a first operating condition in which they allow the passage of fluid in the pre-infusion branch **23** and block the passage in the post-infusion branch **24**, and at least a second operating condition in which they allow the passage of fluid in the post-infusion branch **24** and block the passage in the pre-infusion branch **23**.

Obviously, as in the case of the selecting means **16** present on the fluid circuit **4**, also the other selecting means **25** will be able to determine the percentage of fluid that has to pass in each of the two branches and to possibly vary it in time in accordance with the planned therapies. Moreover, the selecting means **16** and the other selecting means **25** will generally though not necessarily be of the same nature.

The machine is then equipped with means **29** for determining at least the weight of the primary fluid container **5** and/or of the auxiliary fluid container **7** and/or of the secondary fluid container **20** and/or of the collection container **27**.

In particular, said means **29** comprise weight sensors, for instance respective scales **30**, **31**, **32** and **33** (at least an independent one for each fluid bag associated to the machine).

In particular, there will be at least 4 of said scales, each pair being independent from the other, and each one measuring the respective weight of a bag.

It should then be pointed out that there is a processing unit or CPU **40** acting on the blood circuit **3** and in particular on the pressure sensor **34**, on the blood pump **21**, on the device **35** for heparin infusion, on the other pressure sensor **36**, and

on the device for detecting the presence of air bubbles **37** and on its respective closing element **38**.

Said CPU **40** has also to control the fluid circuit **4** and, in particular, shall be input with the data detected by the scales **30** and concerning the weight of the bag **5** and shall act on the pump **9**, on the selecting means **16**, on the pressure sensor **39**, then on the suction pump **28** and shall eventually receive the data detected by the scales **33** whose function is to determine the weight of the collection container **27**.

The CPU **40** shall also act on the infusion line **6** checking the weight of the auxiliary container **7** (checked by the scales **31**) and will be able to control both the infusion pump **13** and the other selecting means **26**.

Eventually, the CPU **40** shall also act on the auxiliary pre-infusion line **18** detecting the weight of the secondary fluid container **20** by means of the scales **32** and suitably controlling the pump **19** according to the treatments to be carried out.

Reminding that the above description has been made with the sole purpose of describing the whole of the hydraulic circuit of the extracorporeal blood treatment machine, here is a short description of the working of the device.

Once the whole hydraulic circuit and the filtering unit **2** have been correctly associated to the machine so that the various peristaltic pumps engage the respective lengths of tubes and that all the sensors have been suitably positioned, and the various bags containing the various fluids have been associated to the corresponding liquid supply/intake lines, and the blood circuit has been connected to a patient's artery/vein, the initial circulation of blood within its circuit is enabled.

Therefore, according to the kind of therapy that has been set, the extracorporeal blood treatment machine is automatically started and controlled by the processing unit **40**.

If the patient undergoes an ultrafiltration treatment, as well as the blood pump **21** the suction pump **28** connected to the outlet line of the fluid circuit **4** is started, so as to take by convection a fluid excess in the patient by means of the filtration unit.

Conversely, if the therapy that has been set comprises a haemofiltration treatment, as well as the blood pump **21** and the suction pump **28** for taking fluids by convection also the pump **9** on the inlet line of the fluid circuit **4** and the selecting means **16** placed so as to enable a post-infusion are started.

Also the infusion line **6** shall be used so as to enable a further addition of liquids to the post-infusion or to enable a suitable pre-infusion.

Conversely, if the treatment involves haemodialysis, the pumps **9** and **28** of the fluid circuit **4** shall be started and the selecting means **16** shall be positioned so as to ensure the passage of the dialysis liquid only towards the filtration unit **2** so as to take substances and/or molecules and/or liquids by diffusion and possibly by convection if the transmembrane pressure through the filtration unit is other than zero.

Eventually, if a haemodiafiltration treatment has to be carried out, beyond the blood pump **21** the fluid circuit and therefore the pumps **9** and **28** shall be started, so as to ensure a circulation of the liquid within the filtration unit **2** and also the pump **14** of the infusion line **6** shall be started so as to ensure a pre- or post-infusion.

It will be possible to set up therapies comprising one or more of the treatments referred to above.

In all the treatments described above, possibly except the ultrafiltration treatment, it will be possible to use the auxiliary pre-infusion line for introducing an anticoagulant and/or a suitable infusion liquid into the blood.

The anticoagulant can also be administered by means of the suitable device **35** designed for the introduction of heparin into blood.

Concerning this it should be pointed out that the machine according to the invention is designed to receive various kinds of syringes according to the amount of anticoagulant to be administered.

Obviously, it is the control unit **40** that, being connected to the various devices, sensors, pumps and being input with the data on weight from the scales, is able—once it is set—to control and automate the whole working of the machine.

In further detail, it is possible to set the flows of the various pumps present on the machine in accordance with the therapy or therapies to be started.

Obviously, the setting of said flows results in an amount of fluid taken from the patient (weight loss), which will generally be given by the difference between the weight of the liquid that has been collected in the bag **27** and of the liquid circulated in the circuit through the primary fluid container **5**, the auxiliary fluid container **7** and the secondary fluid container **20**.

In particular, in accordance with the data received by the control unit coming from the various scales (and the theoretical flow rates fixed on each pump of therapy/treatment carried out) the control unit **40** shall control the means for circulating fluid in the various lines by suitably varying the thrust exerted by the various pumps **9**, **13**, **19**, **21** and **28**.

In particular, the signals coming from the scales referred to above **30**, **31**, **32**, **33** are used by the control unit **40** for determining the weight of the particular fluid introduced into the line or collected.

In order to determine the amount of fluid released or collected in a particular bag or container the control unit **40** compares at regular intervals (the greater the flows the smaller the intervals) the actual weight of the container with the desired weight (which is a direct function of the desired flow for each pump and of the time interval between each control step $\Delta W = Q\,\Delta t$).

The desired weight can be calculated as a function of the required flow (stored in a suitable storage unit of the computer) and of the time elapsed from the beginning of the treatment.

If the actual weight and the desired weight differ from each other, the control unit acts on the corresponding pump so as to reduce, and possibly cancel, said difference. In other words, during each cycle not an absolute weight variation, but only the variation in the time interval is taken into consideration to correct the latter.

The control unit takes into consideration variations in the difference starting from the last comparison, so as to avoid oscillations of the actual flow around the desired flow.

Reminding that the above description has been carried out with the sole purpose of providing a general view of the blood treatment machine and of the hydraulic circuit thereto associated, it should be noted that generally the whole machine shall comprise a body **58** (see in particular FIG. **3**) designed to integrate all instruments and devices to be used several times in different treatments on one or more patients.

In particular, the machine body **58**, beyond the whole electronic control circuitry (processing unit **40**, data input and reading display, pressure sensors **34**, **36**, **39**, . . .) shall also have on its front surface the blood pump **21**, the fluid pump **9**, the infusion pump **13** and the auxiliary pre-infusion pump **19**.

Conversely, the parts of the machine that are designed to be used only once for each treatment on the patient, generally in the course of an intensive therapy, shall be housed in

a corresponding disposable integrated module **41** to be attached directly onto the machine body **58**.

As shown in FIG. **2**, the integrated module **41** for blood treatment has a support element **42** consisting of a main body **52** and of a supporting structure **44** associated, for instance as one piece, to the main body and placed laterally with respect to the latter.

Said integrated module further comprises a fluid distribution circuitry **43** (represented only partially in the appended FIG. **2**) associated to said support element **42** and cooperating with the filtration unit **2** so as to carry out the hydraulic circuit previously described.

In particular, it is possible to note how the main body **52** defines a housing compartment designed to receive the respective U-arranged lengths of tubes of the circuitry, which are kept in position so as to be ready to cooperate with the respective peristaltic pumps housed by the machine body **58**.

As can be observed, the blood circuit **3** and in general the inlet line **3***a* of the blood circuit **3** is fastened by means of connectors to a side wall of the main body **52**, in the same way as also the inlet line **4***a* of the fluid circuit **4** and the outlet line **4***b* of the fluid circuit **4** are secured to the main body **52**.

Also the infusion line **6** and the auxiliary pre-infusion line **18** are secured to the main body **52** (see again FIG. **2**).

All the portions of lines referred to above are secured to the support element **42** so as to define at least a corresponding U-arranged length of tube with respect to said support element **42** and so that each of said U-lengths can cooperate with the corresponding peristaltic pump housed in the machine body.

Going into further constructive details, it can be noted how the support structure **44** comprises a positioning fin **45** provided with a given number of main seats **46***a*, **46***b*, **46***c*, **46***d* and **46***e* suitably placed so that respective tubes of the fluid distribution circuit **43** associated to the support element can be engaged therein.

As can be further observed, the inlet line **4***a* of the fluid circuit **4** is fastened to the main body **52** on the support structure **44**.

As a matter of fact, at least an inlet length **47** is kept in position by the support structure **44** by means of a main seat **46***c* of the positioning fin **45** and by a corresponding connector **48** defined on the main body.

The outlet length **49** of the fluid circuit **4** is engaged in its turn with the respective engagement connector **50** and with the main seat **46***a* of the positioning fin **45**.

As can be noted from the arrangement shown, the inlet and outlet lengths **47** and **49** engaged to their respective connectors **48**, **50** and with the main seats **46***c* and **46***a* are placed in a substantially rectilinear arrangement and are parallel one to the other.

It should then be pointed out that the outlet length **49** has a branching **17** splitting up into intake branch **15** designed to convey the fluid to the filtration unit, and infusion branch **8** designed to convey the fluid to the blood circuit **3**.

Said branching **17** cannot be seen in FIG. **2** since it is defined by the engagement connector **50** on the opposite side with respect to the one shown in said figure.

In other words, the connector **50** has a basically T shape, whose two outlets are connected to the intake branch **15** and to the infusion branch **8**.

The infusion branch **8** is further secured to an auxiliary seat **51** of the support structure and to another main seat **46***b*.

When engaged the infusion branch **8** and the intake branch **15** are placed in a rectilinear arrangement and are parallel one to the other.

Also the infusion line **6** is fastened to the main body **52** on the support structure **44**.

At least an outlet length **53** of the infusion line **6** is engaged to a main seat **46***d* of the positioning fin and to a respective engagement connector **54**.

Analogously to the above description, also the outlet length **53** of the infusion line **6** has a branching **26** splitting up into pre-infusion branch **23** designed to convey the fluid to the inlet line **3***a* of the blood circuit **3**, and post-infusion branch designed to convey the fluid to the outlet line **3***b* of the blood circuit **3**.

Here again the branching **26** is not shown in FIG. **2** since it is defined by the T-shaped connector **54**, one of whose outlets can be seen only on the opposite side with respect to the one shown.

The pre-infusion branch **23** is secured to an auxiliary seat **55** of the support structure and to another main seat **46***e* of the fin **45**.

Said arrangement enables to have pre-infusion branch **23** and post-infusion branch **24** in rectilinear configuration and parallel one to the other.

It should now be observed that the selecting means **16** previously defined act by enabling or blocking the passage of fluid in the infusion branch **8** and/or in the intake branch **15** exactly on the rectilinear lengths defined on the support structure **44**.

In particular, said selecting means **16** can be defined by suitable cams or clamps.

The example of embodiment shown provides for a moving element **56**, which as a result of its movement blocks either the infusion branch **8** or the intake branch **15**.

Said moving element **56** is generally mounted directly onto the machine body **58** and has been shown with a mere explicative purpose and with a hatched line in the appended FIG. **2**.

Wholly similarly, the other selecting means **25** can comprise a moving element **57** acting on the pre-infusion branch **23** or on the post-infusion branch **24** for selectively blocking or enabling the passage of fluid.

Here again said moving element **57** has been shown by way of example in FIG. **2**; however, it should be noted that generally said element is mounted directly onto the machine body **58**.

The invention has important advantages.

It is obvious that the use of a hydraulic circuit enabling a passage of the dialysis fluid within the filtration unit or selectively towards a post-infusion by using the same liquid coming from the primary fluid bag **5**, allows to manage therapies with a large volume of fluids, particularly in intensive therapy machines where anyhow said fluids are housed in small bags.

As a matter of fact, it will be possible to carry out a pre- and/or post-infusion into the blood line using the fluid of the primary container **5** and of the auxiliary container **7**, thus carrying out for instance a more intense ultrafiltration.

Moreover, the presence of a branching also on the infusion line allows to manage therapies with regional anticoagulation techniques without limiting the possibilities of dialysis pre-filter infusion in any way.

When regional anticoagulation techniques are used, such as for instances the use of citrates, it is always necessary, before carrying the treated blood back into the patient, to administer to the latter suitable substances (for instance calcium) for recovering the ion balance in the blood.

It is obvious that the elimination/balance of the anticoagulant substances should be carried out downstream from the filtration unit, for instance by means of the post-infusion line.

In the machine according to the invention, however, in order to balance the ions in the returned blood it will be possible to use directly the fluid circuit by introducing a suitable reagent into the primary fluid bag **5** and by using the inlet line **4***a* for carrying out the post-infusion through the infusion branch **8**.

The infusion line **6** shall thus enable to carry out pre-infusions, ensuring the optimal working of the machine also during this kind of treatments.

Therefore, the particular arrangement of the pre- and post-infusion lines and of the dialysis lines enables—also in intensive therapy machines where all the various fluids are contained in small bags—to carry out all the necessary therapies/treatments, thus eliminating the operational limits present in known machines.

The invention claimed is:

1. An extracorporeal blood treatment machine comprising:

at least one filtration unit;

a blood circuit having an inlet line leading to the filtration unit and an outlet line from the filtration unit;

a fluid circuit having at least one inlet line leading to the filtration unit and one outlet line from the filtration unit;

at least one infusion line comprising at least a pre-infusion branch connected to the inlet line of the blood circuit and a post-infusion branch connected to the outlet line of the blood circuit;

an auxiliary pre-infusion line connected to the inlet line of the blood circuit

at least one primary fluid container connected so as to supply the inlet line of the fluid circuit;

at least a secondary fluid container for supplying said auxiliary pre-infusion line;

at least one auxiliary fluid container for supplying said at least one infusion line,

wherein the inlet line of the fluid circuit comprises an intake branch leading to the filtration unit and at least one infusion branch connected to the outlet line of the blood circuit, wherein said at least one infusion branch of the fluid circuit line has at least a length which is separate from said post-infusion branch of the at least one infusion line;

said fluid circuit further comprising selecting means for determining percentages of a flow of a fluid within said length of the infusion branch and the intake branch,

said at least one infusion line further comprising other selecting means for determining the percentage of flow within the post-infusion branch and the pre-infusion branch.

2. A machine according to claim **1**, wherein the inlet line of the fluid circuit comprises means for conveying fluid, said means for conveying fluid including at least one inlet line pump, for controlling the fluid flow.

3. A machine according to claim **2**, wherein the infusion branch of the fluid circuit is placed downstream from said inlet line pump with respect to a direction of circulation of the fluid.

4. A machine according to claim **1**, wherein the infusion branch of the fluid circuit and the infusion line are equipped with a common end length letting into the blood circuit.

5. A machine according to claim **4**, further comprising a gas separating device engaged on the outlet line of the blood circuit.

6. A machine according to claim **5**, wherein the common end length infuses the fluid directly into said gas separating device.

7. A machine according to claim **1**, further comprising means for conveying the fluid, said means for conveying fluid including an infusion pump, for controlling the fluid flow in the infusion line.

8. A machine according to claim **4**, wherein the common end length is placed downstream from the infusion pump with respect to a direction of infusion.

9. A machine according to claim **1**, wherein the selecting means are placed near a branching of the fluid circuit splitting into the intake branch and the infusion branch.

10. A machine according to claim **1**, wherein the selecting means is positioned at least between a first operation condition in which said selecting means allow the passage of fluid in the intake branch and block the passage in the infusion branch, and a second operating condition in which said selecting means allow the passage of fluid in the infusion branch and block the passage in the intake branch.

11. A machine according to claim **1**, wherein the auxiliary pre-infusion line comprises means for conveying fluid, said pre-infusion line including at least one auxiliary pre-infusion pump, for controlling the fluid flow.

12. A machine according to claim **1**, wherein the blood circuit comprises means for conveying fluid, said blood circuit including at least one blood pump, for controlling the flow of blood in the circuit.

13. A machine according to claim **12**, wherein the auxiliary pre-infusion line operates upstream from the blood pump with respect to a direction of blood circulation.

14. A machine according to claim **1**, wherein the secondary fluid container supplying the auxiliary pre-infusion line is configured to contain an anticoagulant.

15. A machine according to claim **12**, wherein the pre-infusion branch operates downstream from the blood pump with respect to a direction of blood circulation.

16. A machine according to claim **7**, wherein the pre-infusion branch is placed downstream from the infusion pump with respect to a direction of infusion.

17. A machine according to claim **1**, wherein the other selecting means are placed near a branching of the infusion line splitting up into the pre-infusion branch and the post-infusion branch.

18. A machine according to claim **1**, wherein the other selecting means can be positioned at least between a first operation condition in which said selecting means allow the passage of fluid in the pre-infusion branch and block the passage in the post-infusion branch, and at least a second operating condition in which said selecting means allow the passage of fluid in the post-infusion branch and block the passage in the pre-infusion branch.

19. A machine according to claim **4**, wherein the pre-infusion branch starts from the post-infusion branch upstream from the common end length with respect to a direction of infusion.

20. A machine according to claim **1**, further comprising a collection container engaged to the outlet line of the fluid circuit.

21. A machine according to claim **1**, wherein the outlet line of the fluid circuit further comprises means for circulating fluid, said outlet line of the fluid circuit including an outlet line pump, for controlling a flow within the fluid circuit.

22. A machine according to claim **1**, further comprising means for determining a weight of at least said primary fluid container.

23. A machine according to claim 22, further comprising means for determining a weight of at least said auxiliary fluid container.

24. A machine according to claim 23, further comprising means for determining a weight of at least said secondary fluid container.

25. A machine according to claim 24, further comprising means for determining a weight of at least a collection container engaged to the outlet line of the fluid circuit.

26. A machine according to claim 25, wherein said means for determining the weight of at least said primary fluid container, of at least said auxiliary fluid container, of at least said secondary fluid container, and of at least said collection container each comprise at least a respective scale for each one of said collection container, said primary fluid container, said secondary fluid container, and said auxiliary fluid container.

27. A machine according to claim 26, further comprising a processing unit acting on the blood circuit, on the fluid circuit, and on the infusion line, thus allowing respective flows of the blood circuit, fluid circuit, and infusion line to be controlled.

28. A machine according to claim 27, wherein the processing unit acts on the auxiliary pre-infusion line.

29. A machine according to claim 27, wherein the processing unit acts by controlling an inlet line pump operating on the inlet line of the fluid circuit, an infusion pump operating on the infusion line, a blood pump operating on the blood circuit, an outlet line pump operating on the outlet line of the fluid circuit, or the auxiliary pre-infusion pump operating on the auxiliary pre-infusion line.

30. A machine according to claim 27, wherein the processing unit acts on the selecting means, or on the other selecting means.

31. A machine according to claim 27, wherein the processing unit is input with a signal concerning weights detected by the means for determining the weight.

32. A machine according to claim 1, incorporating an integrated module for blood treatment comprising:

a support element carrying the filtration unit; and

a fluid distribution circuit associated to the support element and cooperating with the filtration unit, the fluid distribution circuit including the blood circuit, the fluid circuit, the infusion line, and the auxiliary pre-infusion line, wherein the selecting means comprises a moving element acting on the infusion branch or on the intake branch on a support structure connected to a main body for selectively blocking or allowing a passage of said fluid in said infusion branch or intake branch.

33. A machine according to claim 32, wherein said moving element is mounted directly onto a machine body.

34. A machine according to claim 32, wherein the other selecting means comprises a moving element acting on said pre-infusion branch and/or on said post-infusion branch for selectively blocking or enabling the passage of said fluid in said pre-infusion branch or in said post-infusion branch.

35. A machine according to claim 34, wherein said moving element is mounted directly onto a machine body.

36. A machine according to claim 32, wherein the support element comprises a main body and a support structure associated to the main body, said support structure being placed laterally with respect to the main body.

37. A machine according to claim 36, wherein the support structure comprises a positioning fin having at least one main seat configured to connect to respective tubes of the fluid distribution circuit to be associated to the support element.

38. A machine according to claim 37, wherein the inlet line of the fluid circuit is fastened to the support element so as to define at least a U-shaped tube length with respect to said support element, said U-shaped tube length being configured to cooperate operationally with a respective pump.

39. A machine according to claim 38, wherein the inlet line is fastened to the main body on the support structure, at least an inlet length of the fluid circuit being connected to a first main seat of the positioning fin and to a first respective engagement connector, at least an outlet length of the fluid circuit being connected to a second main seat of the positioning fin and to a second respective engagement connector.

40. A machine according to claim 39, wherein the inlet and outlet lengths connected to the first and second engagement connectors and to the first and second main seats are placed in a rectilinear arrangement and are parallel to one another.

41. A machine according to claim 39, wherein the outlet length has a branching splitting into the intake branch conveying the fluid to the filtration unit, and into the infusion branch conveying the fluid to the blood circuit.

42. A machine according to claim 41, wherein said branching, splitting into the intake branch and the infusion branch, is defined on an engagement connector.

43. A machine according to claim 40, wherein the infusion branch and the intake branch, when engaged to the support structure, are placed in a rectilinear arrangement and are parallel to one another.

44. A machine according to claim 37, wherein the infusion line is secured to the support element so as to define at least one U-shaped tube length with respect to said support element, said at least one U-shaped tube length being configured to cooperate operationally with a respective pump.

45. A machine according to claim 44, wherein the infusion line is fastened to the main body on the support structure, at least an outlet length of the infusion line being connected to a main seat of the positioning fin and to a respective engagement connector.

46. A machine according to claim 45, wherein the outlet length has a branching splitting up into the pre-infusion branch conveying fluid to an inlet line of the blood circuit, and into the post-infusion branch conveying fluid to an outlet line of the blood circuit.

47. A machine according to claim 46, wherein the branching, splitting into the pre-infusion branch and the post-infusion branch, is defined on an engagement connector.

48. A machine according to claim 46, wherein the pre-infusion branch and the post-infusion branch, when connected to the support structure, are placed in a rectilinear arrangement and are parallel to one another.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

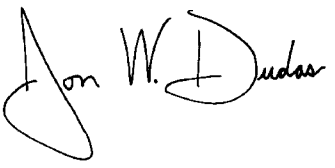
PATENT NO. : 7,314,554 B2
APPLICATION NO. : 10/771377
DATED : January 1, 2008
INVENTOR(S) : Annalisa Delnevo et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 1, column 11, line 33, “circuit” should read --circuit;--.

Signed and Sealed this

Twenty-ninth Day of April, 2008



JON W. DUDAS
Director of the United States Patent and Trademark Office

EXHIBIT D

US007727391B2

(12) **United States Patent**
Delnevo et al.

(10) **Patent No.: US 7,727,391 B2**
(45) **Date of Patent: *Jun. 1, 2010**

(54) **EXTRACORPOREAL BLOOD TREATMENT MACHINE**

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(73) Assignee: **Gambro Lundia AB** (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 277 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: **Nov. 13, 2007**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(60) Provisional application No. 60/469,839, filed on May 13, 2003.

(30) **Foreign Application Priority Data**

Feb. 7, 2003 (IT) MI2003A0212

(51) **Int. Cl.**

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B01D 61/30	(2006.01)
B01D 61/32	(2006.01)
A61M 37/00	(2006.01)
A61M 1/16	(2006.01)

(52) **U.S. Cl.** **210/252**; 210/258; 210/321.6; 210/416.1; 210/433.1; 604/4.01; 604/6.09; 604/6.11

(58) **Field of Classification Search** 210/252, 210/253, 257.1, 257.2, 258, 321.6, 321.65, 210/321.71, 416.1, 433.1, 436, 472; 604/4.01, 604/5.01, 6.07, 6.09, 6.1, 6.11, 65, 66, 67

See application file for complete search history.

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Primary Examiner—John Kim

(74) *Attorney, Agent, or Firm*—Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

(57) **ABSTRACT**

The invention relates to an extracorporeal blood treatment machine in which a blood circuit (**3**) is equipped with an inlet line leading to a filtration unit (**2**) and with an outlet line (**3***b*) from the filtration unit; a fluid circuit comprises an inlet line (**4***a*) leading to the filtration unit and an outlet line (**4***b*) from the filtration unit so as to allow a fluid taken from a primary container (**5**) to circulate within the filtration unit, thus enabling the treatment of the patient's blood. There is further an infusion line (**6**) acting on the outlet line of the blood circuit, which is supplied by an auxiliary fluid container (**7**). The inlet line of the fluid circuit is equipped with at least an infusion branch (**8**) acting on the outlet line of the blood circuit so as to enable the intensive therapy machine to manage therapies with large exchange of fluids.

19 Claims, 3 Drawing Sheets

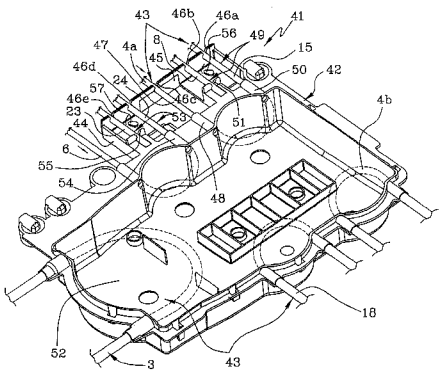

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FIG 1

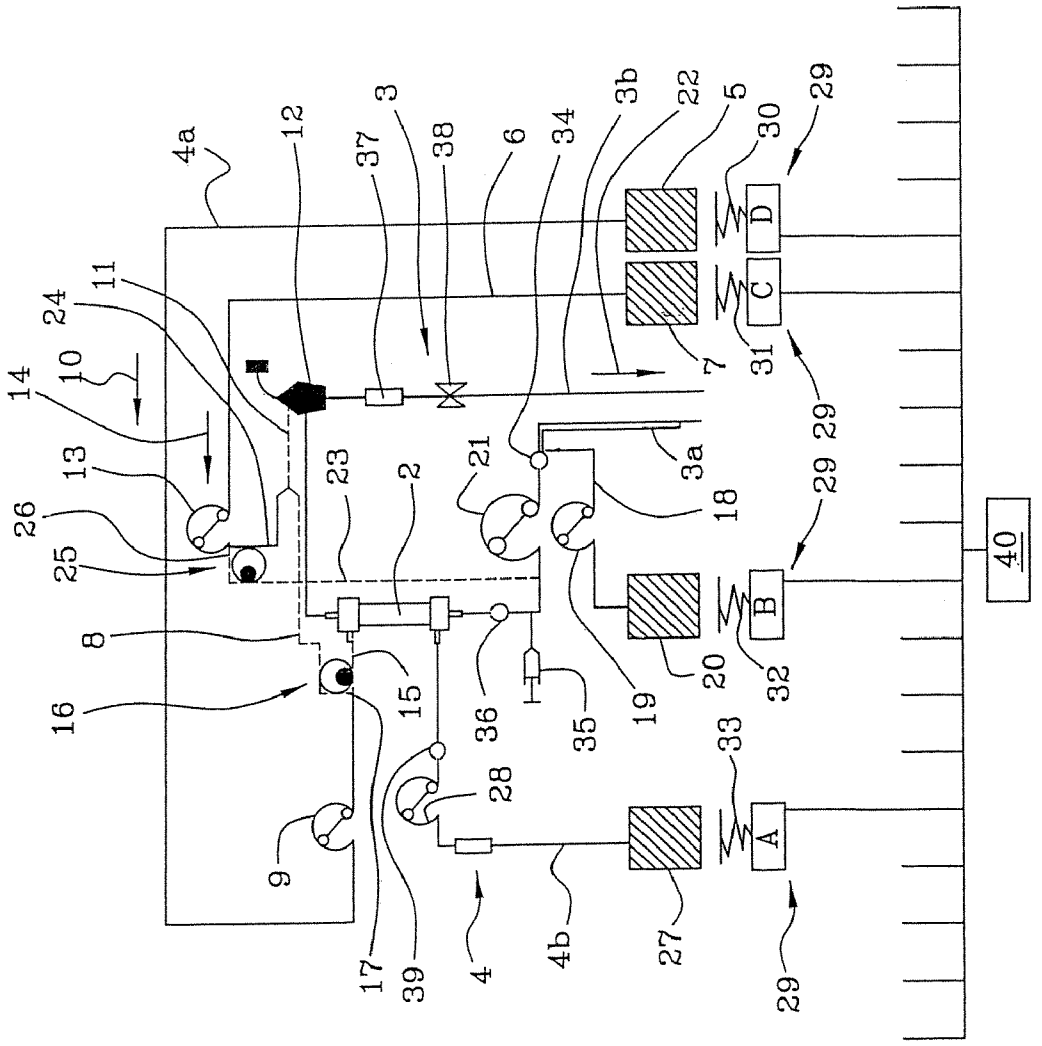
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FIG 2

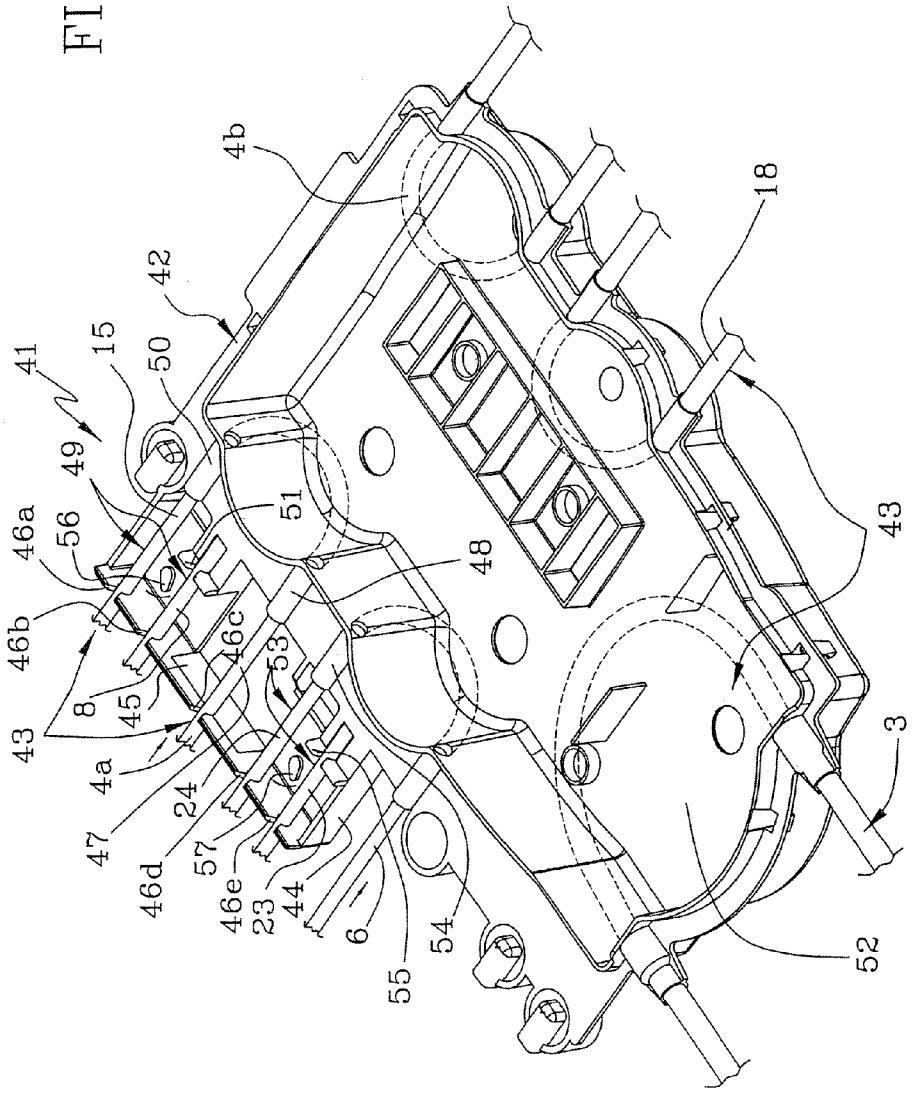
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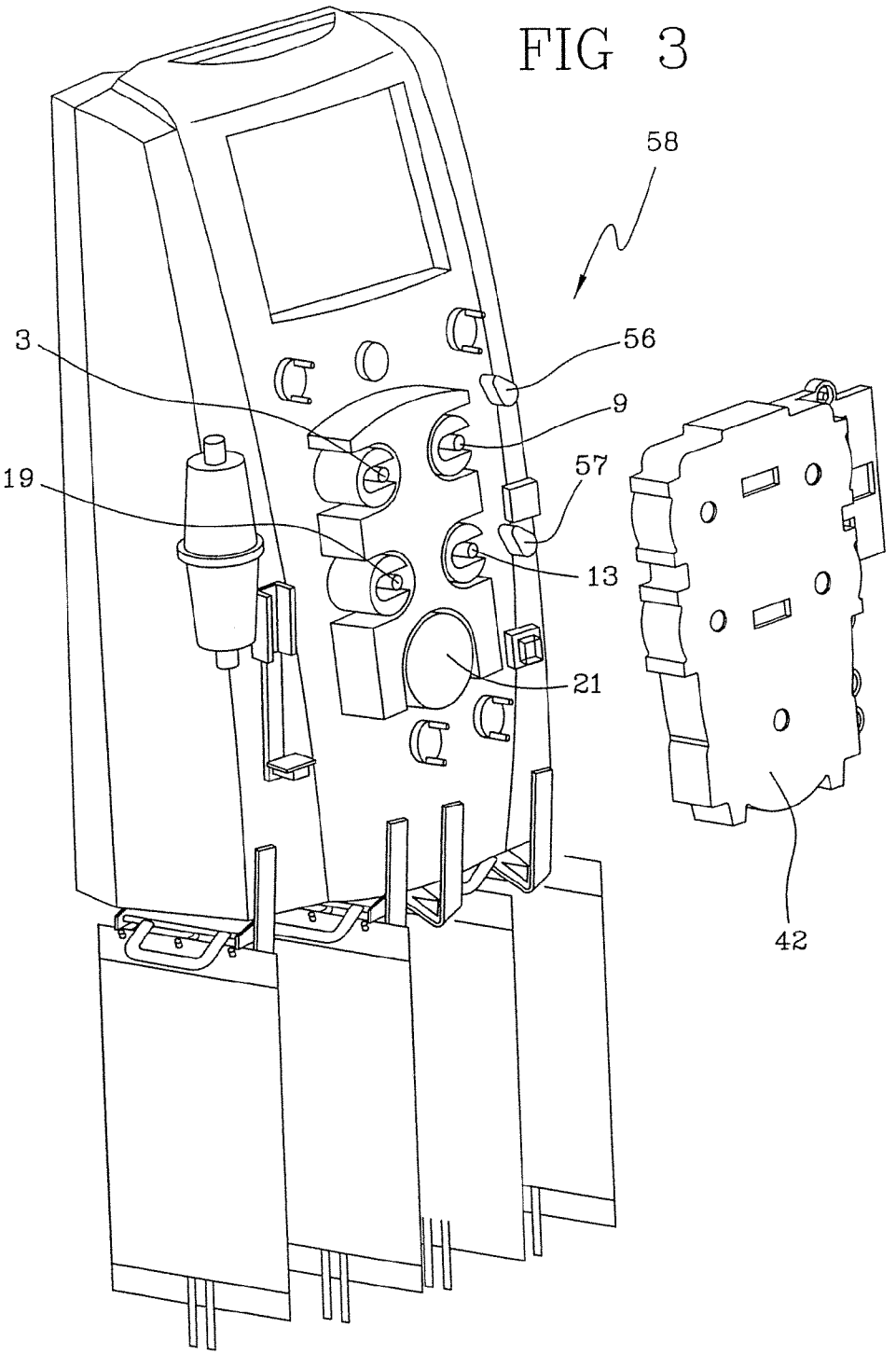
FIG 3



EXTRACORPOREAL BLOOD TREATMENT MACHINE

CROSS REFERENCE TO RELATED APPLICATIONS

This is a division of application Ser. No. 10/771,377, filed Feb. 5, 2004, now U.S. Pat. No. 7,314,554, issued on Jan. 1, 2008, and claims the priority of Italian Patent Application No. MI2003 A 000212, filed on Feb. 7, 2003, and the benefit of U.S. Provisional Application No. 60/469,839, filed May 13, 2003, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to an extracorporeal blood treatment machine and to an integrated treatment module that can be used on said machine.

The object of the invention can be used for instance in intensive therapy machines which can carry out a plurality of different blood treatments.

Extracorporeal treatments generally consists in taking blood from the patient, in treating said blood when it is outside the patient's body and then in re-circulating the blood thus treated.

The treatment typically consists in removing from the blood unwanted and/or dangerous substances, as well as excess liquid in patients who cannot autonomously carry out said operations, such as for instances patients suffering from temporary or permanent kidney problems.

For instance, it may be necessary to add or remove substances from blood, to keep a correct acid/base ratio or also to remove fluid excess from the body.

The extracorporeal treatment is generally obtained by removing blood from the patient, by letting the blood flow within a filtration unit where a semipermeable membrane ensures the exchange of suitable substances, molecules and fluids.

Generally though not necessarily, said exchange is carried out by letting a given biological fluid ensuring the aforesaid exchanges pass in counter-current and within a secondary chamber of the filtration unit.

It should be noted that currently used machines can enable different types of blood treatment.

In the ultrafiltration treatment the substances and fluids to be eliminated are removed by convection from the blood, pass through the semipermeable membrane and are led towards the aforesaid secondary chamber.

In hemofiltration treatments part of the molecules, substances and fluids present in the blood pass through the membrane by convection as in the ultrafiltration treatment, although further necessary elements are added to the blood; typically a suitable fluid is infused directly into the blood before or after the latter passes through the filtration unit and anyhow before it is carried back into the patient.

In haemodialysis treatments a fluid containing material to be transferred into the blood is introduced into the secondary chamber of the filtration unit. The unwanted material flows through the semipermeable membrane from the blood into the secondary fluid and the desired substances/molecules from the secondary fluid can pass through the membrane as far as the blood.

In hemodiafiltration treatments the blood and the secondary fluid exchange their respective substances/molecules as in haemodialysis and, in addition, a fluid is infused into the blood as in haemofiltration treatments.

Obviously, in order to carry out each of said extracorporeal blood treatments, the blood has to be removed from a patient's vein or artery, suitably circulated in the machine and then re-introduced into the patient.

As is also known, blood treatment machines for intensive therapy have to be ready as fast as possible for an immediate use for any possible emergency.

Obviously, to this purpose the machine must not require either preliminary sanitizing operations or long pre-assembling operations of the various components for the various therapies.

As is known, intensive therapy machines are present on the market and are currently used, in which a blood circuit comprises a line for taking blood from the patient, which carries said blood to a filtration cartridge, and an outlet line from the filtration cartridge, which carries the treated blood back into the patient's body.

The machine is then equipped with a circuit for the passage of dialysis fluid; also said circuit has an intake line leading into the filtration unit, which is supplied by a sterile bag containing the dialysis liquid, and has also an outlet line enabling the passage of a fluid which has received by convection/diffusion the dangerous substances and molecules from the blood towards a collection bag for their subsequent removal.

Said machine is further equipped with an infusion line allowing—with suitable doses—to transfer directly into the blood upstream from the filtration unit the content of another liquid bag, thus adding the necessary products into the blood.

A known intensive therapy machine is further equipped with a suitable syringe containing for instance heparin as blood anticoagulant, the latter being added to the blood taken from the patient so as to avoid the creation of dangerous clots within the circuit.

The structure and circuitry mentioned above are generally defined by a single integrated module attached to the machine body.

It is evident that in order to enable the immediate use of the machine, the fluid bags referred to above have to be present and already sterile, so as to be directly and easily connected to their respective tubes, the latter also being sterile and disposable.

The machine is further equipped with a suitable control unit managing the flow of fluids by means of suitable peristaltic pumps and respective sensors associated to the circuit.

It is evident that by suitably setting the control unit said machine can selectively carry out one or more of the extracorporeal blood treatments described above (i.e. ultrafiltration, haemofiltration, haemodialysis and haemodiafiltration).

The machine described above, though being today quite a vanguard device for extracorporeal blood treatments in intensive therapies, has proved to be susceptible of several improvements.

In particular, a first intrinsic drawback in intensive therapy machines is related to the limited availability of fluids for operations involving the exchange of substances by convection/diffusion within the filter and for pre- or post-infusions into the blood line.

Said limitation is obviously related to the necessary use of pre-packaged sterile fluid bags typically containing 6 kg of dialysis liquid.

It is evident that the pre-established fluid amount to be used imposes some limitations, in particular in the case of therapies with large exchange of fluids, which would sometimes be extremely suitable in emergency cases.

On the other hand, it is not possible to use larger fluid amounts in intensive therapies since suitably treated water

taken from the water network cannot be used as exchange fluid in short times; indeed, this would involve long operations for installing the devices for in-line preparation of sterile liquids; moreover, it is not possible to use bags with higher amounts of liquids due to the obvious problems involving transport and management of said containers by the personnel.

Another problem of known intensive therapy machines consists in achieving an optimal management of the administration of anticoagulant substances which are necessary for a good working of the machine.

In particular, today known intensive therapy machines cannot manage effectively the use of regional anticoagulation methods, such as for instance citrate-based methods, since the use of said techniques requires the administration of further solutions recovering the blood ion balance before carrying the treated blood back into the patient's body.

SUMMARY OF THE INVENTION

Under these circumstances the present invention aims at solving basically all the drawbacks referred to above.

A first technical aim of the invention is to provide physicians with the possibility to manage therapies with large exchange of fluids using an intensive therapy machine where, in any case, fluids are housed in small-size containers.

A further aim of the present invention is to be able to manage intensive therapies by using regional anticoagulation techniques, i.e. acting on the blood only in the extracorporeal circuit, without having to limit pre-infusion upstream from the filtration unit.

Moreover, an aim of the present invention is to enable the substantial separation of the use of regional anticoagulation techniques from the infusion of fluids for carrying out the necessary therapeutic exchange (by convection or diffusion).

Finally, an auxiliary aim of the present invention is to provide an machine ensuring quite simple and reliable loading and installing operations, further enabling the complete control of the therapy cycles that are carried out.

These and other aims, which shall be evident in the course of the present description, are basically achieved by an extracorporeal blood treatment machine as described in the appended claims.

Further characteristics and advantages will be clearer from the detailed description of a preferred though not exclusive embodiment of an extracorporeal blood treatment machine according to the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

This description will be given below with reference to the appended tables, which are provided as a mere guidance and are therefore not limiting, in which:

FIG. **1** shows schematically a hydraulic circuit to be used in an intensive therapy machine in accordance with the present invention;

FIG. **2** shows an integrated module comprising a support element and a portion of the fluid distribution circuitry, to be used in intensive therapy machines in accordance with the pre-sent invention; and

FIG. **3** shows an machine body in accordance with the invention.

DETAILED DESCRIPTION

With reference to the figures mentioned above, the numeral **1** globally refers to a machine for extracorporeal blood treatment, in particular for intensive therapies.

As can be inferred from the appended table **1**, the machine consists of a blood circuit **3**, which takes blood from a patient, for instance by means of a catheter introduced into a vein or artery of said patient, and through at least an inlet line **3***a* takes said blood, for instance continuously, to a filtration unit **2**.

Then the blood passes through a primary chamber of said filtration unit **2** and through an outlet line **3***b* the treated blood is carried back to the patient.

The connection with an auxiliary pre-infusion line **18** is provided immediately downstream from the blood collecting zone on the inlet line **3***a*.

In particular, the machine is equipped with at least a secondary fluid container or bag **20** for supplying the pre-infusion line **18**; by using corresponding means for conveying fluid, in the example shown comprising an auxiliary pre-infusion pump **19**, for instance a peristaltic pump, it is possible to control the fluid flow within said line by introducing said fluid directly into the blood by means of a direct connection to the inlet line **3***a*.

Generally, the secondary fluid container **20** can house a suitable biological fluid for a pre-infusion, however said bag **20** can also contain an anticoagulant, generally causing a regional anticoagulation so as to ensure a particular working of the machine as shall be explained below in further detail.

After defining a direction of blood circulation **22** from the inlet line **3***a* towards the filtration unit and from the latter through the outlet line **3***b* towards the patient, a known blood pressure sensor **34**, which shall not be described in further detail, is placed immediately downstream from the auxiliary pre-infusion line **18**.

The blood circuit **3** therefore comprises means for conveying fluid, i.e. in this particular case at least a blood pump **21** for controlling and managing the suitable blood flow in the circuit. Also the blood pump **21** is generally a peristaltic pump.

Following the direction of blood circulation **22**, there is then a device **35** for administering an anticoagulant, for instance a syringe containing suitable doses of heparin.

The blood then passes through another pressure sensor **36** controlling the correct flow within the blood circuit.

After passing through a main chamber of the filtration unit **2**, where the suitable exchanges of substances, molecules and fluids occur by means of a semipermeable membrane, the treated blood enters the outlet line **3***b* first passing though a gas separating device (generally air) **12** commonly known as "bubble trap", designed so as to ensure the detection and removal of substances or air bubbles present in the blood.

The treated blood getting out of the separating device **12** then passes through an air bubble sensor **37** verifying the absence of said dangerous formations within the treated blood that has to be re-introduced in the patient's blood circulation.

Immediately downstream from the bubble sensor **37** there is an element **38** which, in case of alarm, can block the blood flow towards the patient.

In particular, should the bubble sensor **37** detect the presence of anomalies in the blood flow, the machine through the element **38** (be it a tap, a clamp or similar) would be able to block immediately the passage of blood so as to avoid any consequence to the patient.

Downstream from said element **38** the treated blood is then carried back to the patient undergoing therapy.

The extracorporeal blood treatment machine shown above is then equipped with a fluid circuit **4**, which is also provided with at least an inlet line **4***a* leading into the filtration unit **2** and with an outlet line **4***b* from the filtration unit.

At least a primary fluid container **5** is designed to supply the inlet line **4***a* of the fluid circuit **4** (generally the primary fluid container **5** shall consist of a bag containing a suitable dialysis liquid).

The inlet line **4***a* then comprises means for conveying fluid such as at least a pump **9** (in the embodiment shown a peristaltic pump) for controlling the flow of liquid from the bag **5** and for defining a direction of circulation **10**.

Downstream from the pump **9** in the direction of circulation **10** there is a branching **17** splitting the fluid circuit **4** up into an intake branch **15** and an infusion branch **8**.

In particular, the infusion branch **8** is connected to the outlet line **3***b* of the blood circuit **3**.

In other words, by means of said infusion branch **8** it is possible to obtain a post-infusion directly in the blood line using the content of the primary fluid container **5**.

Conversely, the intake branch **15** conveys the fluid directly to the filtration unit and in particular to a secondary chamber of said unit.

The fluid circuit **4** is further equipped with selecting means **16** for determining the percentages of fluid flow within the infusion branch **8** and the intake branch **15**.

Generally said selecting means **16**, usually placed near the branching **17**, can be positioned at least between a first operating condition in which they allow the passage of fluid in the intake branch **15** and block the passage in the infusion branch **8**, and a second operating condition in which they allow the passage of fluid in the infusion branch **8** and block the passage in the intake branch **15**.

In other words, said selecting means **16** can consist of a valve element operating on the fluid circuit **4** by alternatively blocking the passage of fluid in either branch.

It is also evident that it might be provided for suitable selectors, which are able to establish a priori the amount of liquid that has to pass through both branches simultaneously.

It will also be possible to vary the percentages of fluid in either branch as a function of time and of the pre-established therapies.

The dialysis liquid through the intake branch **15** gets into a secondary chamber of the filtration unit **2**.

In particular, the primary chamber through which the blood flow passes is separated from the secondary chamber through which the dialysis liquid passes by means of a semipermeable membrane ensuring the suitable passage of the dangerous substances/molecules and of fluid from the blood towards the dialysis liquid mainly by means of convection and diffusion processes, and also ensuring through the same principles the passage of substances/molecules from the dialysis liquid towards the blood.

The dialysis fluid then gets into the outlet line **4***b* and passes through a suitable pressure sensor **39** whose function is to control the working of said line.

Then there are means for conveying fluid, for instance a suction pump **28** controlling the flow in the outlet line **4***b* within the fluid circuit **4**. Also said pump will generally be a peristaltic pump.

The fluid to be eliminated then passes through a blood detector and is conveyed into a collection container or bag **27**.

Further analyzing the particular circuit of the machine according to the invention, note the presence of at least another infusion line **6** acting on the outlet line **3***b* of the blood circuit **3**.

In particular, the infusion fluid is taken from at least an auxiliary container **7** and is sent directly to the outlet line **3***b* of the blood circuit **3** through means for conveying fluid, generally an infusion pump **13** controlling its flow (in the example a peristaltic pump).

In particular and as can be observed in the appended figure, the infusion liquid can be introduced directly into the gas separating device **12**.

As can also be inferred, the infusion branch **8** of the fluid circuit **4** and the infusion line **6** are equipped with a common end length **11** letting into the blood circuit **3**.

Said intake end length **11** is placed downstream from the infusion pump **13** with respect to a direction of infusion **14** and carries the fluid directly into the bubble trap device **12**.

Further referring to the diagram in FIG. **1**, one can notice the presence within the infusion line **6** of at least a pre-infusion branch **23** connected to an inlet line **3***a* of the blood circuit **3**.

In further detail, downstream from the infusion pump **13** with respect to the direction of infusion **14**, there is a branching **26** splitting the infusion line **6** up into pre-infusion branch **23** and post-infusion branch **24**.

The pre-infusion branch **23**, in particular, carries the fluid taken from the bag **7** on the inlet line **3***a* of the blood circuit down-stream from the blood pump **21** with respect to the direction of circulation **22**.

Conversely, the post-infusion branch **24** is connected directly to the common end length **11**.

The infusion line **6** further comprises selecting means **25** for determining the percentage of liquid flow to be sent to the post-infusion branch **24** and to the pre-infusion branch **23**.

The selecting means **25** placed near the branching **26** can be positioned between at least a first operating condition in which they allow the passage of fluid in the pre-infusion branch **23** and block the passage in the post-infusion branch **24**, and at least a second operating condition in which they allow the passage of fluid in the post-infusion branch **24** and block the passage in the pre-infusion branch **23**.

Obviously, as in the case of the selecting means **16** present on the fluid circuit **4**, also the other selecting means **25** will be able to determine the percentage of fluid that has to pass in each of the two branches and to possibly vary it in time in accordance with the planned therapies. Moreover, the selecting means **16** and the other selecting means **25** will generally though not necessarily be of the same nature.

The machine is then equipped with means **29** for determining at least the weight of the primary fluid container **5** and/or of the auxiliary fluid container **7** and/or of the secondary fluid container **20** and/or of the collection container **27**.

In particular, said means **29** comprise weight sensors, for instance respective scales **30**, **31**, **32** and **33** (at least an independent one for each fluid bag associated to the machine).

In particular, there will be at least 4 of said scales, each pair being independent from the other, and each one measuring the respective weight of a bag.

It should then be pointed out that there is a processing unit or CPU **40** acting on the blood circuit **3** and in particular on the pressure sensor **34**, on the blood pump **21**, on the device **35** for heparin infusion, on the other pressure sensor **36**, and on the device for detecting the presence of air bubbles **37** and on its respective closing element **38**.

Said CPU **40** has also to control the fluid circuit **4** and, in particular, shall be input with the data detected by the scales **30** and concerning the weight of the bag **5** and shall act on the pump **9**, on the selecting means **16**, on the pressure sensor **39**, then on the suction pump **28** and shall eventually receive the data detected by the scales **33** whose function is to determine the weight of the collection container **27**.

The CPU **40** shall also act on the infusion line **6** checking the weight of the auxiliary container **7** (checked by the scales **31**) and will be able to control both the infusion pump **13** and the other selecting means **26**.

Eventually, the CPU **40** shall also act on the auxiliary pre-infusion line **18** detecting the weight of the secondary fluid container **20** by means of the scales **32** and suitably controlling the pump **19** according to the treatments to be carried out.

Reminding that the above description has been made with the sole purpose of describing the whole of the hydraulic circuit of the extracorporeal blood treatment machine, here is a short description of the working of the device.

Once the whole hydraulic circuit and the filtering unit **2** have been correctly associated to the machine so that the various peristaltic pumps engage the respective lengths of tubes and that all the sensors have been suitably positioned, and the various bags containing the various fluids have been associated to the corresponding liquid supply/intake lines, and the blood circuit has been connected to a patient's artery/vein, the initial circulation of blood within its circuit is enabled.

Therefore, according to the kind of therapy that has been set, the extracorporeal blood treatment machine is automatically started and controlled by the processing unit **40**.

If the patient undergoes an ultrafiltration treatment, as well as the blood pump **21** the suction pump **28** connected to the outlet line of the fluid circuit **4** is started, so as to take by convection a fluid excess in the patient by means of the filtration unit.

Conversely, if the therapy that has been set comprises a haemofiltration treatment, as well as the blood pump **21** and the suction pump **28** for taking fluids by convection also the pump **9** on the inlet line of the fluid circuit **4** and the selecting means **16** placed so as to enable a post-infusion are started.

Also the infusion line **6** shall be used so as to enable a further addition of liquids to the post-infusion or to enable a suitable pre-infusion.

Conversely, if the treatment involves haemodialysis, the pumps **9** and **28** of the fluid circuit **4** shall be started and the selecting means **16** shall be positioned so as to ensure the passage of the dialysis liquid only towards the filtration unit **2** so as to take substances and/or molecules and/or liquids by diffusion and possibly by convection if the transmembrane pressure through the filtration unit is other than zero.

Eventually, if a haemodiafiltration treatment has to be carried out, beyond the blood pump **21** the fluid circuit and therefore the pumps **9** and **28** shall be started, so as to ensure a circulation of the liquid within the filtration unit **2** and also the pump **14** of the infusion line **6** shall be started so as to ensure a pre- or post-infusion.

It will be possible to set up therapies comprising one or more of the treatments referred to above.

In all the treatments described above, possibly except the ultrafiltration treatment, it will be possible to use the auxiliary pre-infusion line for introducing an anticoagulant and/or a suitable infusion liquid into the blood.

The anticoagulant can also be administered by means of the suitable device **35** designed for the introduction of heparin into blood.

Concerning this it should be pointed out that the machine according to the invention is designed to receive various kinds of syringes according to the amount of anticoagulant to be administered.

Obviously, it is the control unit **40** that, being connected to the various devices, sensors, pumps and being input with the data on weight from the scales, is able—once it is set—to control and automate the whole working of the machine.

In further detail, it is possible to set the flows of the various pumps present on the machine in accordance with the therapy or therapies to be started.

Obviously, the setting of said flows results in an amount of fluid taken from the patient (weight loss), which will generally be given by the difference between the weight of the liquid that has been collected in the bag **27** and of the liquid circulated in the circuit through the primary fluid container **5**, the auxiliary fluid container **7** and the secondary fluid container **20**.

In particular, in accordance with the data received by the control unit coming from the various scales (and the theoretical flow rates fixed on each pump of therapy/treatment carried out) the control unit **40** shall control the means for circulating fluid in the various lines by suitably varying the thrust exerted by the various pumps **9**, **13**, **19**, **21** and **28**.

In particular, the signals coming from the scales referred to above **30**, **31**, **32**, **33** are used by the control unit **40** for determining the weight of the particular fluid introduced into the line or collected.

In order to determine the amount of fluid released or collected in a particular bag or container the control unit **40** compares at regular intervals (the greater the flows the smaller the intervals) the actual weight of the container with the desired weight (which is a direct function of the desired flow for each pump and of the time interval between each control step $\Delta W = Q\,\Delta t$).

The desired weight can be calculated as a function of the required flow (stored in a suitable storage unit of the computer) and of the time elapsed from the beginning of the treatment.

If the actual weight and the desired weight differ from each other, the control unit acts on the corresponding pump so as to reduce, and possibly cancel, said difference. In other words, during each cycle not an absolute weight variation, but only the variation in the time interval is taken into consideration to correct the latter.

The control unit takes into consideration variations in the difference starting from the last comparison, so as to avoid oscillations of the actual flow around the desired flow.

Reminding that the above description has been carried out with the sole purpose of providing a general view of the blood treatment machine and of the hydraulic circuit thereto associated, it should be noted that generally the whole machine shall comprise a body **58** (see in particular FIG. **3**) designed to integrate all instruments and devices to be used several times in different treatments on one or more patients.

In particular, the machine body **58**, beyond the whole electronic control circuitry (processing unit **40**, data input and reading display, pressure sensors **34**, **36**, **39**, . . .) shall also have on its front surface the blood pump **21**, the fluid pump **9**, the infusion pump **13** and the auxiliary pre-infusion pump **19**.

Conversely, the parts of the machine that are designed to be used only once for each treatment on the patient, generally in the course of an intensive therapy, shall be housed in a corresponding disposable integrated module **41** to be attached directly onto the machine body **58**.

As shown in FIG. **2**, the integrated module **41** for blood treatment has a support element **42** consisting of a main body **52** and of a supporting structure **44** associated, for instance as one piece, to the main body and placed laterally with respect to the latter.

Said integrated module further comprises a fluid distribution circuitry **43** (represented only partially in the appended FIG. **2**) associated to said support element **42** and cooperating with the filtration unit **2** so as to carry out the hydraulic circuit previously described.

In particular, it is possible to note how the main body **52** defines a housing compartment designed to receive the respective U-arranged lengths of tubes of the circuitry, which

are kept in position so as to be ready to cooperate with the respective peristaltic pumps housed by the machine body **58**.

As can be observed, the blood circuit **3** and in general the inlet line **3***a* of the blood circuit **3** is fastened by means of connectors to a side wall of the main body **52**, in the same way as also the inlet line **4***a* of the fluid circuit **4** and the outlet line **4***b* of the fluid circuit **4** are secured to the main body **52**.

Also the infusion line **6** and the auxiliary pre-infusion line **18** are secured to the main body **52** (see again FIG. **2**).

All the portions of lines referred to above are secured to the support element **42** so as to define at least a corresponding U-arranged length of tube with respect to said support element **42** and so that each of said U-lengths can cooperate with the corresponding peristaltic pump housed in the machine body.

Going into further constructive details, it can be noted how the support structure **44** comprises a positioning fin **45** provided with a given number of main seats **46***a*, **46***b*, **46***c*, **46***d* and **46***e* suitably placed so that respective tubes of the fluid distribution circuit **43** associated to the support element can be engaged therein.

As can be further observed, the inlet line **4***a* of the fluid circuit **4** is fastened to the main body **52** on the support structure **44**.

As a matter of fact, at least an inlet length **47** is kept in position by the support structure **44** by means of a main seat **46***c* of the positioning fin **45** and by a corresponding connector **48** defined on the main body.

The outlet length **49** of the fluid circuit **4** is engaged in its turn with the respective engagement connector **50** and with the main seat **46***a* of the positioning fin **45**.

As can be noted from the arrangement shown, the inlet and outlet lengths **47** and **49** engaged to their respective connectors **48**, **50** and with the main seats **46***c* and **46***a* are placed in a substantially rectilinear arrangement and are parallel one to the other.

It should then be pointed out that the outlet length **49** has a branching **17** splitting up into intake branch **15** designed to convey the fluid to the filtration unit, and infusion branch **8** designed to convey the fluid to the blood circuit **3**.

Said branching **17** cannot be seen in FIG. **2** since it is defined by the engagement connector **50** on the opposite side with respect to the one shown in said figure.

In other words, the connector **50** has a basically T shape, whose two outlets are connected to the intake branch **15** and to the infusion branch **8**.

The infusion branch **8** is further secured to an auxiliary seat **51** of the support structure and to another main seat **46***b*.

When engaged the infusion branch **8** and the intake branch **15** are placed in a rectilinear arrangement and are parallel one to the other.

Also the infusion line **6** is fastened to the main body **52** on the support structure **44**.

At least an outlet length **53** of the infusion line **6** is engaged to a main seat **46***d* of the positioning fin and to a respective engagement connector **54**.

Analogously to the above description, also the outlet length **53** of the infusion line **6** has a branching **26** splitting up into pre-infusion branch **23** designed to convey the fluid to the inlet line **3***a* of the blood circuit **3**, and post-infusion branch designed to convey the fluid to the outlet line **3***b* of the blood circuit **3**.

Here again the branching **26** is not shown in FIG. **2** since it is defined by the T-shaped connector **54**, one of whose outlets can be seen only on the opposite side with respect to the one shown.

The pre-infusion branch **23** is secured to an auxiliary seat **55** of the support structure and to another main seat **46***e* of the fin **45**.

Said arrangement enables to have pre-infusion branch **23** and post-infusion branch **24** in rectilinear configuration and parallel one to the other.

It should now be observed that the selecting means **16** previously defined act by enabling or blocking the passage of fluid in the infusion branch **8** and/or in the intake branch **15** exactly on the rectilinear lengths defined on the support structure **44**.

In particular, said selecting means **16** can be defined by suitable cams or clamps.

The example of embodiment shown provides for a moving element **56**, which as a result of its movement blocks either the infusion branch **8** or the intake branch **15**.

Said moving element **56** is generally mounted directly onto the machine body **58** and has been shown with a mere explicative purpose and with a hatched line in the appended FIG. **2**.

Wholly similarly, the other selecting means **25** can comprise a moving element **57** acting on the pre-infusion branch **23** or on the post-infusion branch **24** for selectively blocking or enabling the passage of fluid.

Here again said moving element **57** has been shown by way of example in FIG. **2**; however, it should be noted that generally said element is mounted directly onto the machine body **58**.

The invention has important advantages.

It is obvious that the use of a hydraulic circuit enabling a passage of the dialysis fluid within the filtration unit or selectively towards a post-infusion by using the same liquid coming from the primary fluid bag **5**, allows to manage therapies with a large volume of fluids, particularly in intensive therapy machines where anyhow said fluids are housed in small bags.

As a matter of fact, it will be possible to carry out a pre- and/or post-infusion into the blood line using the fluid of the primary container **5** and of the auxiliary container **7**, thus carrying out for instance a more intense ultrafiltration.

Moreover, the presence of a branching also on the infusion line allows to manage therapies with regional anticoagulation techniques without limiting the possibilities of dialysis prefilter infusion in any way.

When regional anticoagulation techniques are used, such as for instances the use of citrates, it is always necessary, before carrying the treated blood back into the patient, to administer to the latter suitable substances (for instance calcium) for recovering the ion balance in the blood.

It is obvious that the elimination/balance of the anticoagulant substances should be carried out downstream from the filtration unit, for instance by means of the post-infusion line.

In the machine according to the invention, however, in order to balance the ions in the returned blood it will be possible to use directly the fluid circuit by introducing a suitable reagent into the primary fluid bag **5** and by using the inlet line **4***a* for carrying out the post-infusion through the infusion branch **8**.

The infusion line **6** shall thus enable to carry out pre-infusions, ensuring the optimal working of the machine also during this kind of treatments.

Therefore, the particular arrangement of the pre- and post-infusion lines and of the dialysis lines enables—also in intensive therapy machines where all the various fluids are contained in small bags—to carry out all the necessary therapies/treatments, thus eliminating the operational limits present in known machines.

The invention claimed is:

1. An integrated module for blood treatment, comprising:

a support element;

at least one filtration unit engaged to the support element; and

a fluid distribution circuitry associated to the support element and cooperating with the filtration unit, said fluid distribution circuitry including:

a plurality of tubes;

a blood circuit having at least an inlet line connected to the filtration unit, and an outlet line connected to said filtration unit;

a fluid circuit having at least an inlet line connected to the filtration unit, and an outlet line connected to the filtration unit, the inlet line of the fluid circuit being designed to be connected to at least a primary fluid container; and

at least an infusion line acting on the outlet line of the blood circuit, said infusion line being designed to be supplied by at least an auxiliary fluid container, and the infusion line being fastened to the support element so as to define at least a U-arranged tube length with respect to said support element, at least an outlet length of the infusion line having a branching splitting up into pre-infusion branch conveying fluid to the inlet line of the blood circuit, and into post-infusion branch conveying fluid to the outlet line of the blood circuit;

wherein the inlet line of the fluid circuit comprises at least an infusion branch connected to the outlet line of the blood circuit, the inlet line of the fluid circuit being fastened to the support element so as to define at least a U-arranged tube length with respect to said support element, at least an outlet length of the inlet line of the fluid circuit having a branching splitting up into intake branch conveying the fluid to the filtration unit, and into the infusion branch, separate from the post-infusion branch of the infusion line, conveying the fluid to a blood circuit.

2. A module according to claim 1, wherein the support element comprises a main body and a support structure associated to the main body and placed laterally with respect to the latter.

3. A module according to claim 2, wherein the support structure comprises a positioning fin having a given number of main seats in which each of the tubes of the fluid distribution circuit are respectively engaged.

4. A module according to claim 1, wherein the inlet line of the fluid circuit is fastened to the support element so as to define at least a U-arranged tube length with respect to said support element, which shall cooperate operationally with a respective pump.

5. A module according to claim 3, wherein the inlet line of the fluid circuit is fastened to the main body on the support structure so as to define at least a U-arranged tube length with respect to said support structure, which shall cooperate operationally with a respective pump, at least an inlet length of the inlet line of the fluid circuit being engaged in a main seat of the positioning fin and to a respective engagement connector on the main body, at least an outlet length of the inlet line of the fluid circuit being engaged in a main seat of the positioning fin and to the respective engagement connector.

6. A module according to claim 5, wherein the inlet and outlet lengths engaged to the connectors and to the main seats are placed in a rectilinear arrangement and are parallel one to the other.

7. A module according to claim 5, wherein the outlet length has a branching splitting up into intake branch conveying the fluid to the filtration unit, and into infusion branch conveying the fluid to a blood circuit.

8. A module according to claim 7, wherein the branching splitting up into infusion branch and intake branch is defined on an engagement connector.

9. A module according to claim 7, wherein the infusion branch is secured to an auxiliary seat and to another main seat.

10. A module according to claim 7, wherein the infusion branch and the intake branch are placed in a rectilinear arrangement and are parallel one to the other.

11. A module according to claim 1, wherein the infusion line is secured to the support element so as to define at least a U-arranged tube length with respect to said support element, said tube length being designed to cooperate operationally with a respective pump.

12. A module according to claim 3, wherein the infusion line is fastened to the main body on the support structure so as to define at least a U-arranged tube length with respect to said support element, at least an outlet length of the infusion line being engaged to a main seat of the positioning fin and to a respective engagement connector on the main body.

13. A module according to claim 12, wherein the outlet length has a branching splitting up into pre-infusion branch conveying fluid to the inlet line of the blood circuit, and into post-infusion branch conveying fluid to the outlet line of the blood circuit.

14. A module according to claim 13, wherein the branching splitting up into pre-infusion branch and post-infusion branch is defined on an engagement connector.

15. A module according to claim 13, wherein the pre-infusion branch is secured to an auxiliary seat and to another main seat.

16. A module according to claim 14, wherein the pre-infusion branch and the post-infusion branch are placed in a rectilinear arrangement and are parallel one to the other.

17. A module according to claim 1, further comprising an auxiliary pre-infusion line acting on the inlet line of the blood circuit and having at least a pre-infusion branch connected to the inlet line of the blood circuit.

18. An integrated module for blood treatment, comprising:

a support element presenting a main body and a support structure associated to the main body and placed laterally with respect to the latter, the support structure comprising a positioning fin having a given number of main seats;

at least one filtration unit engaged to the support element; and

a fluid distribution circuitry associated to the support element and cooperating with the filtration unit, said fluid distribution circuitry including:

a blood circuit having at least an inlet line connected to the filtration unit, and an outlet line connected to said filtration unit;

a fluid circuit having at least an inlet line connected to the filtration unit, and an outlet line connected to the filtration unit, the inlet line of the fluid circuit being designed to be connected to at least a primary fluid container, the inlet line of the fluid circuit comprises at least an infusion branch connected to the outlet line of the blood circuit, an inlet length of the inlet line is engaged on a main seat of the positioning fin and to a connector of the main body, an outlet length of the inlet line is engaged with a connector on the main

body and with a main seat on the positioning fin, the infusion branch being in engagement with a main seat of the positioning fin; and

at least an infusion line fastened to the main body and acting on the outlet line of the blood circuit, said infusion line being designed to be supplied by at least an auxiliary fluid container, at least an outlet length of the infusion line having a branching splitting up into pre-infusion branch conveying fluid to the inlet line of the blood circuit, and into post-infusion branch conveying fluid to the outlet line of the blood circuit, the outlet length of the infusion line being engaged to a main seat of the positioning fin and to an engagement connector of the main body, the pre-infusion branch is secured to another main seat of the positioning fin.

19. The module according to claim **18**, wherein the inlet and outlet lengths engaged to the connectors and to the main seats are placed in a rectilinear arrangement and are parallel one to the other.

* * * * *

EXHIBIT E

US007867393B2

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Duchamp et al.

(10) **Patent No.: US 7,867,393 B2**
(45) **Date of Patent: *Jan. 11, 2011**

(54) **INTEGRATED MODULE FOR BLOOD TREATMENT**

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(73) Assignee: **Gambro Lundia AB** (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 687 days.

This patent is subject to a terminal disclaimer.

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(22) Filed: **Apr. 13, 2007**

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Related U.S. Application Data

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(60) Provisional application No. 60/470,451, filed on May 15, 2003.

(30) **Foreign Application Priority Data**

Feb. 7, 2003 (IT) MI2003A0214

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B01D 61/30 (2006.01)
B01D 61/28 (2006.01)
B01D 63/00 (2006.01)

(52) **U.S. Cl.** **210/232**; 210/195.2; 210/240; 210/258; 210/321.6; 137/861; 248/274.1; 248/295.11; 248/309.1; 248/560; 248/576; 312/209; 604/4.01; 604/6.09; 604/6.11

(58) **Field of Classification Search** 210/195.2, 210/232, 239, 240, 249, 258, 321.6, 416.1; 604/4.01, 6.09, 6.11; 137/111, 269, 861; 138/111, 115, 118; 284/274.1, 295.11, 309.1, 284/560, 576; 312/209
See application file for complete search history.

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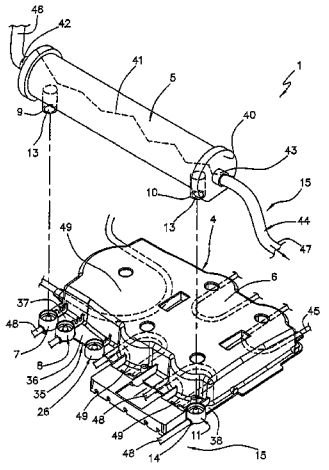
Primary Examiner—John Kim
(74) *Attorney, Agent, or Firm*—Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

(57) **ABSTRACT**

The support element (**4**) is provided with a plurality of connectors (**7**), (**8**), (**11**) which receive corresponding counter-connectors of a blood treatment device. The support element is also predisposed to include a fluid distribution circuitry cooperating with the blood treatment device in order to provide an integrated module for blood treatment. An assembly process of the integrated module for blood treatment is also described.

30 Claims, 9 Drawing Sheets



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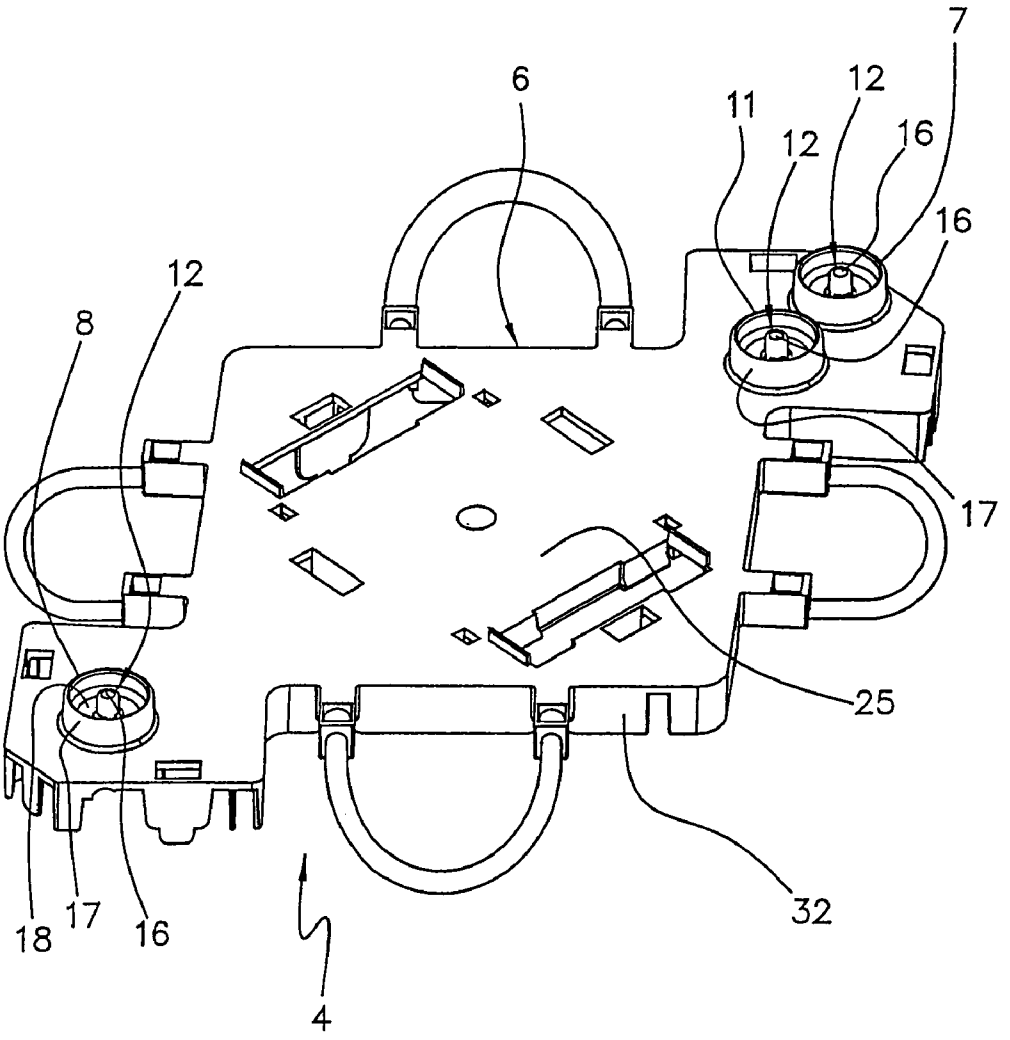

Fig. 1

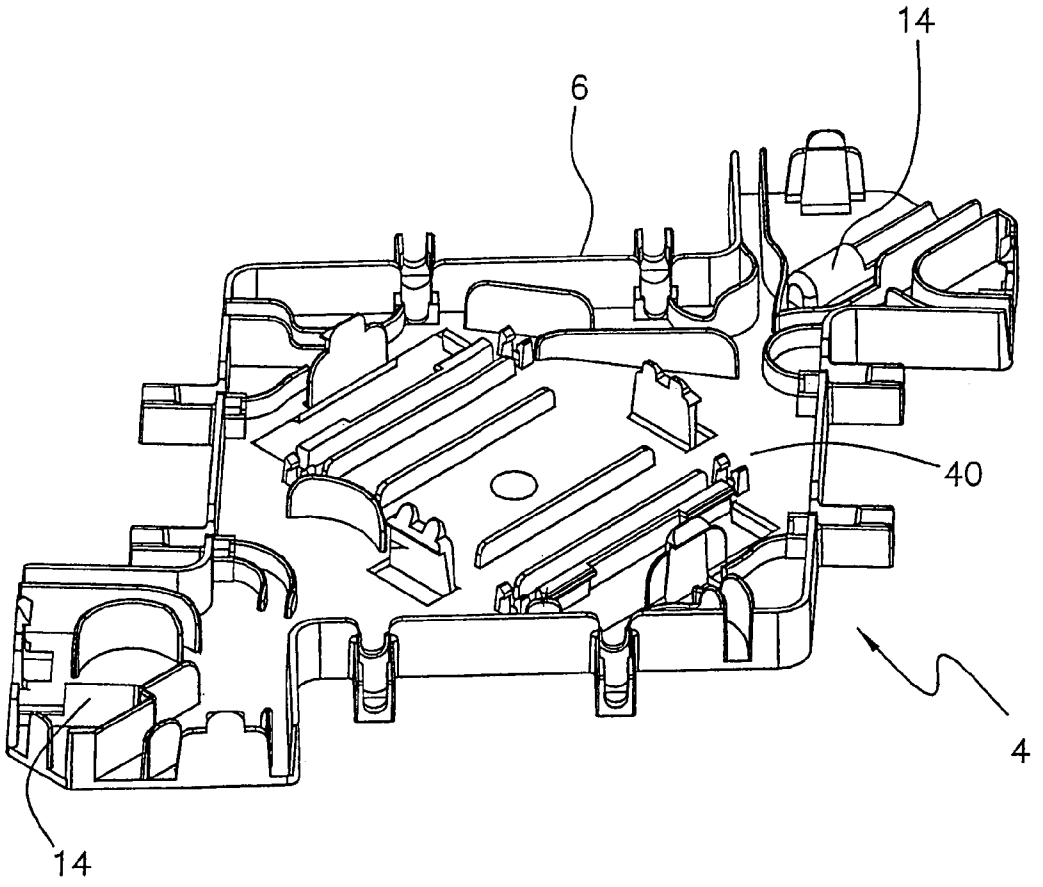

Fig. 2

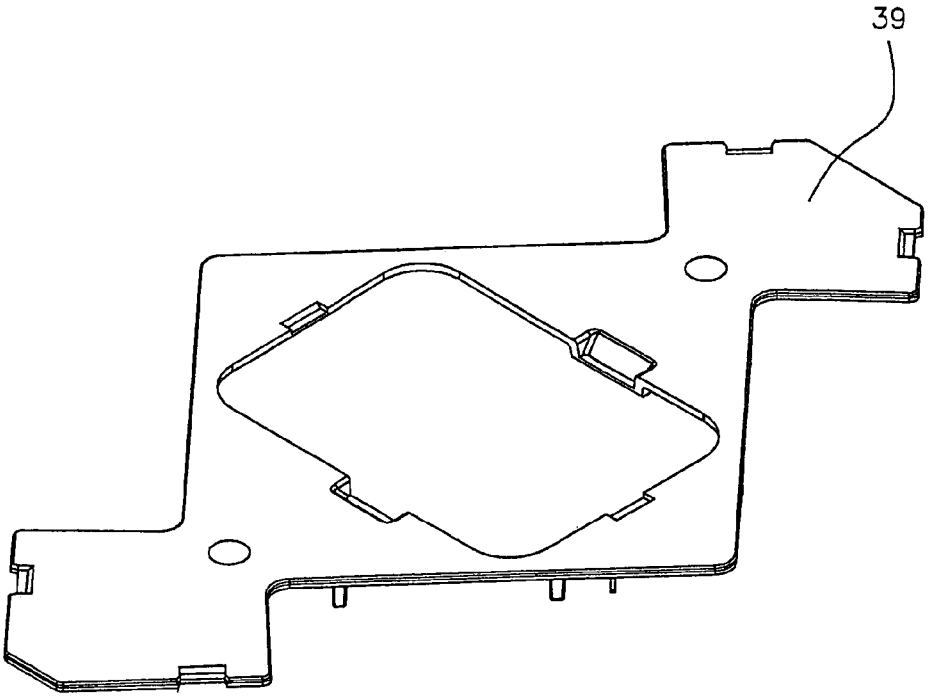

Fig. 3

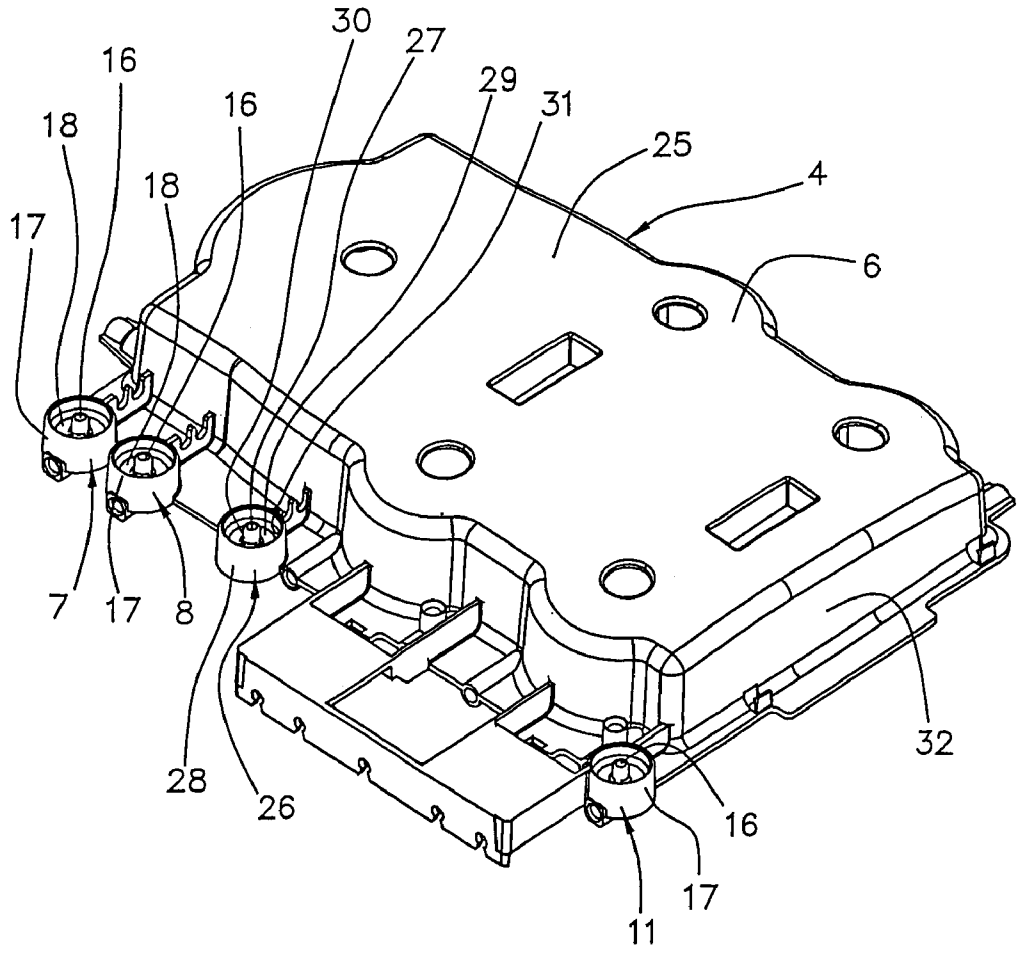

Fig. 4

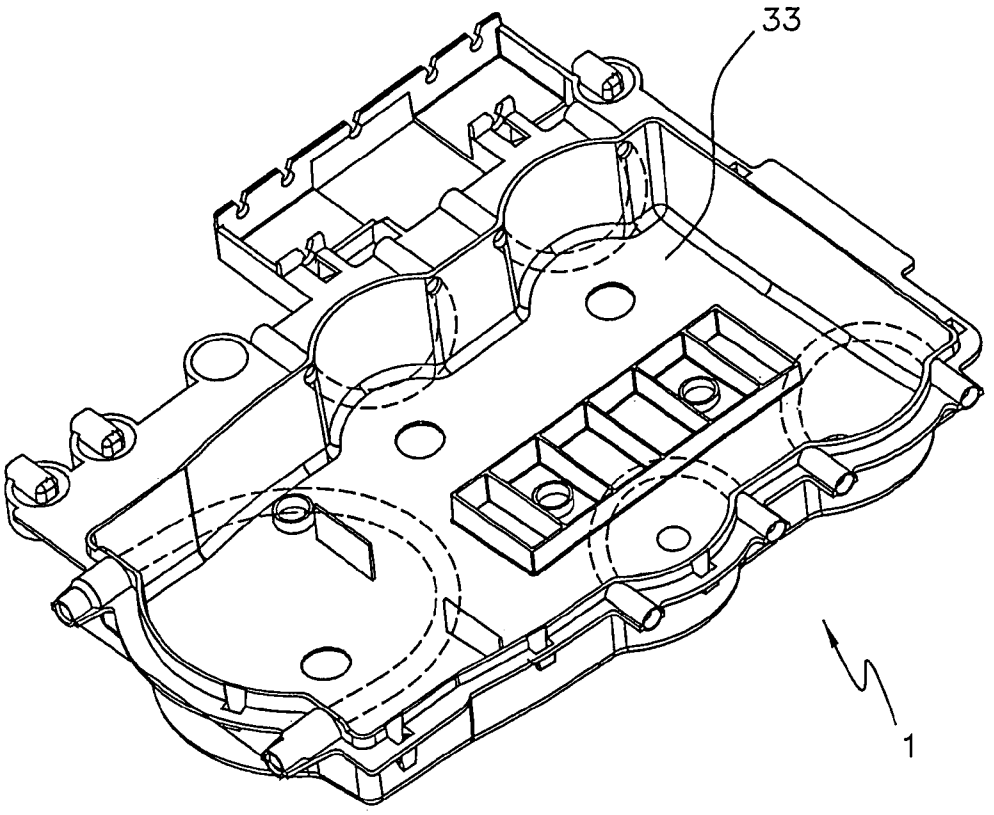

Fig. 5

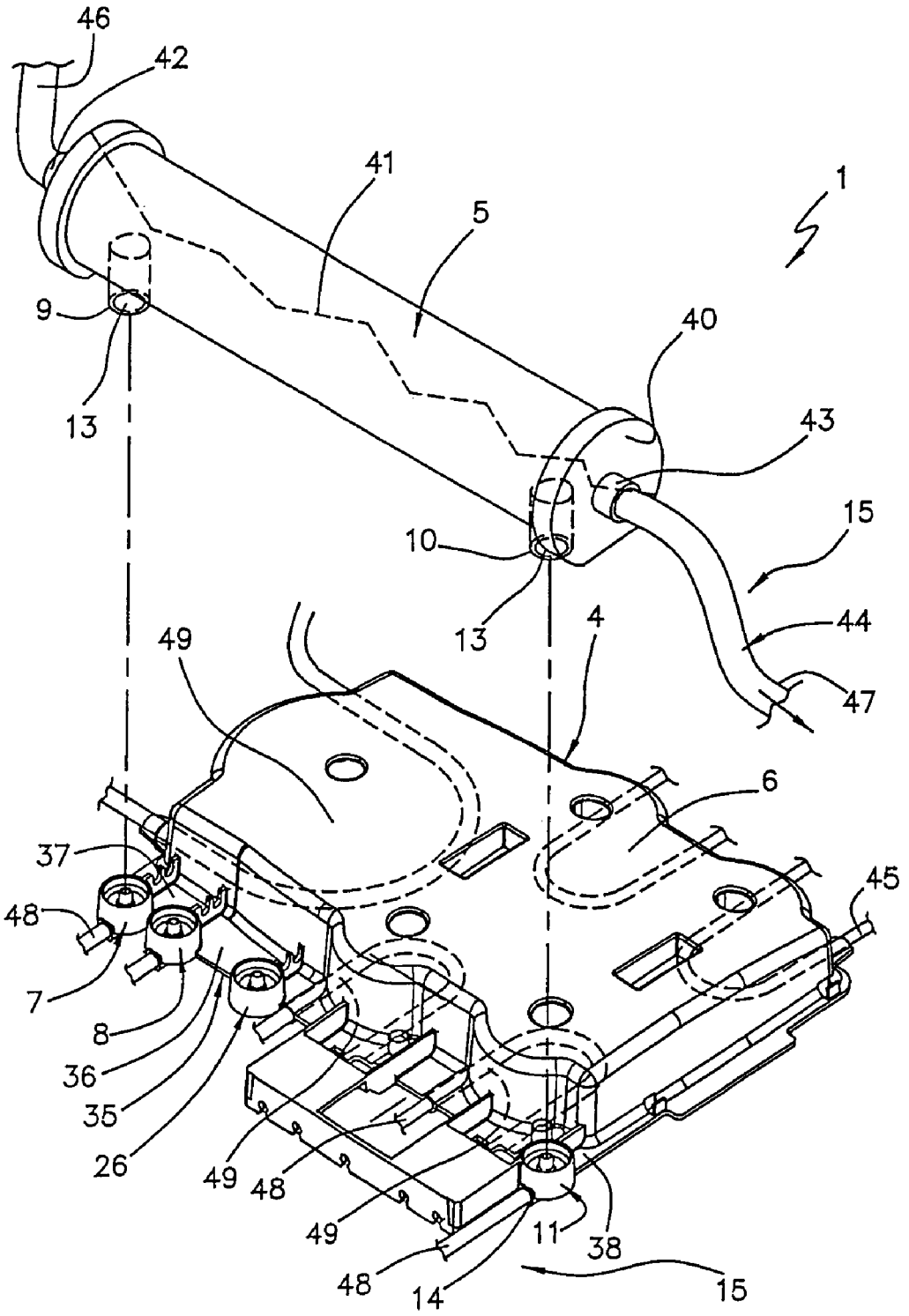
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Fig. 6

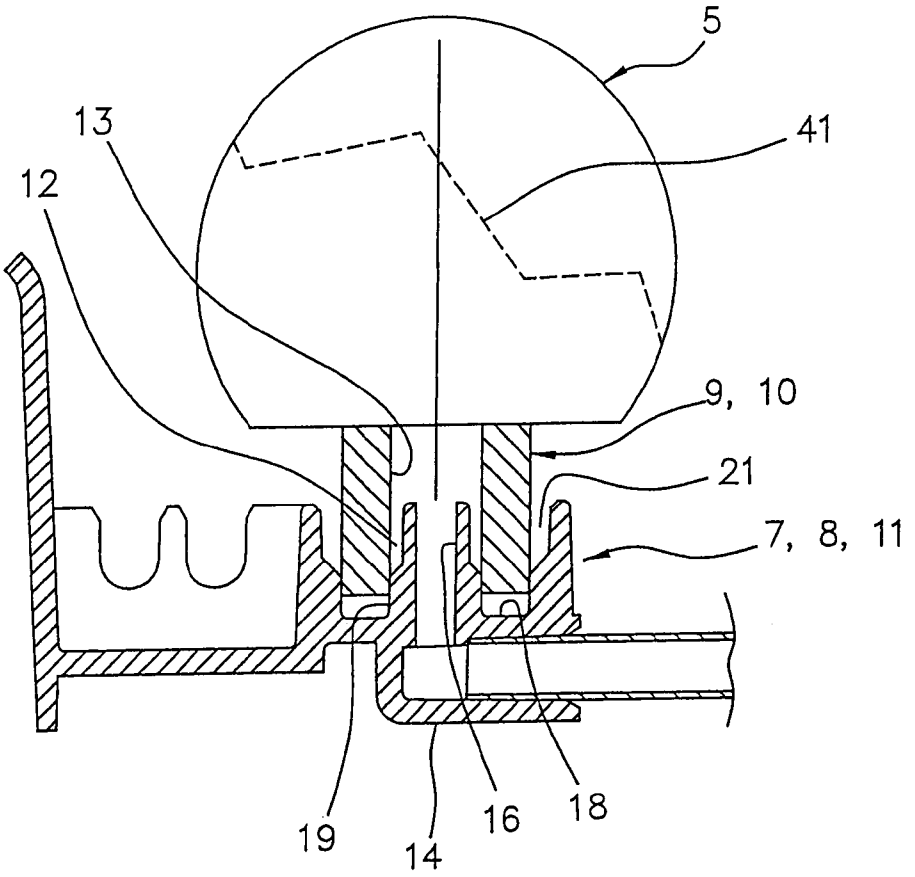
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Fig. 7a

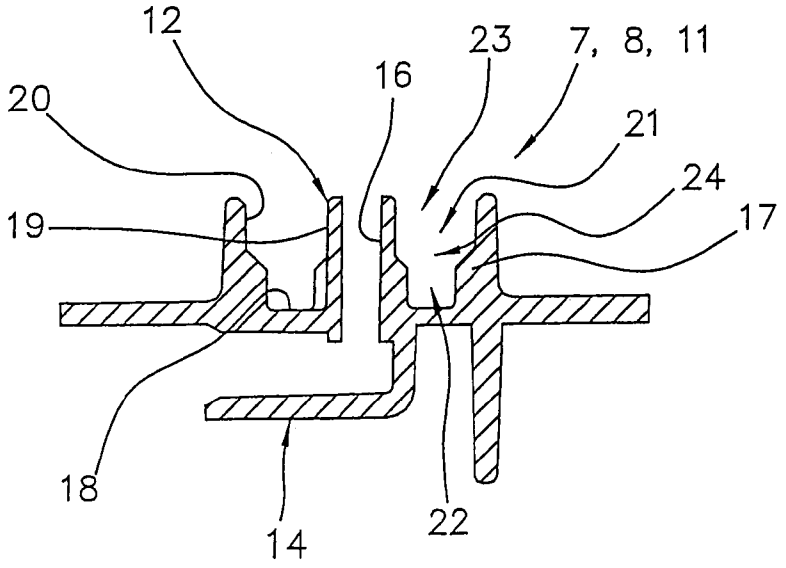
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Fig. 7b

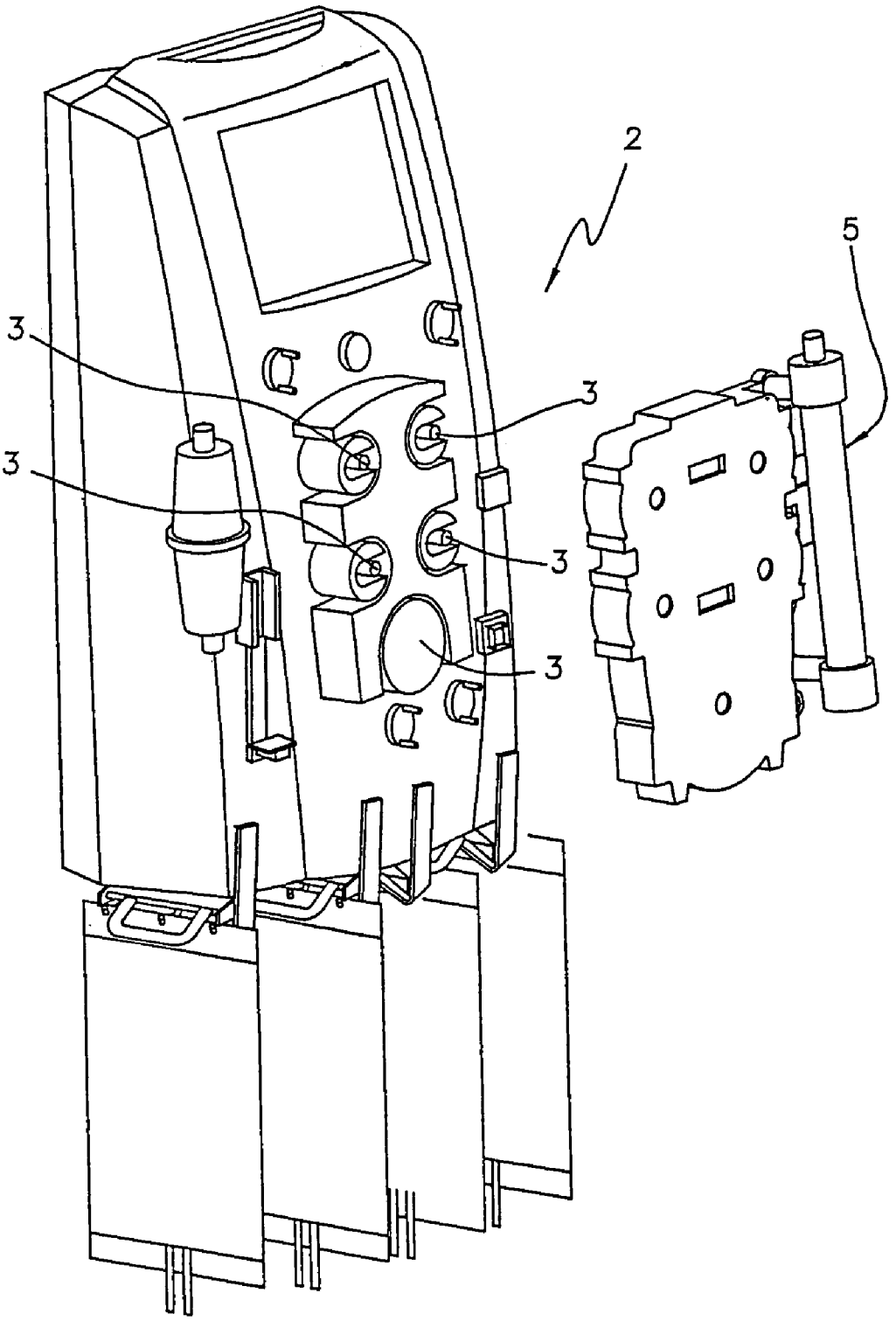

Fig. 8

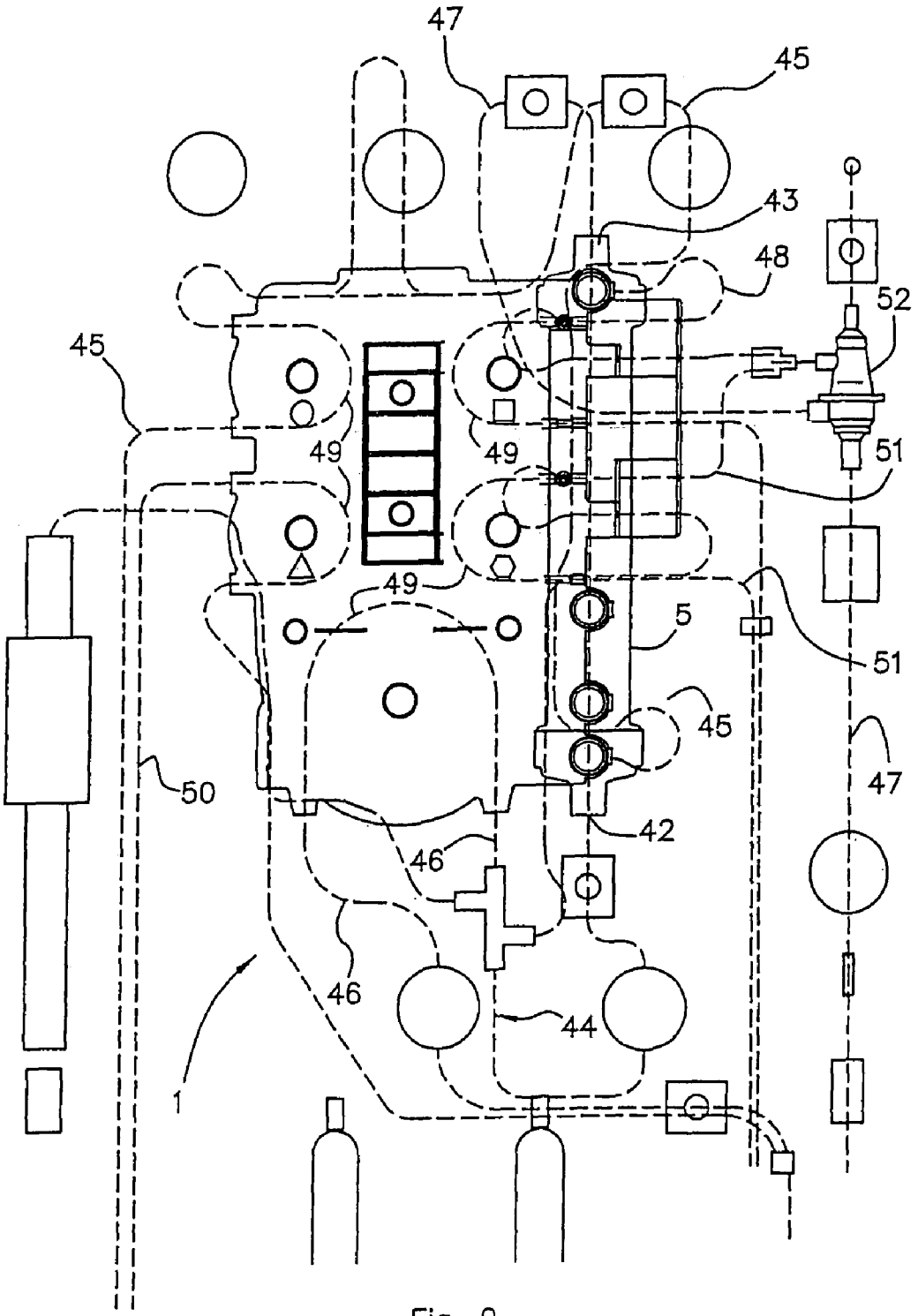

Fig. 9

INTEGRATED MODULE FOR BLOOD TREATMENT

This is a division of application Ser. No. 10/771,536, filed Feb. 5, 2004, now U.S. Pat. No. 7,223,338, which claims the benefit of priority of Italian Patent Application No. MI2003A000214, filed on Feb. 7, 2003, and claims the benefit of U.S. Provisional Application No. 60/470,451, filed May 15, 2003, the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The invention relates to a support element, to an integrated module for blood treatment comprising the support element, and to an apparatus for extracorporeal treatment of blood equipped with the integrated module. The invention also relates to a manufacturing process for an integrated module for blood treatment.

As is known, for carrying out extracorporeal blood treatments, such as, for example, hemodialysis, hemofiltration, hemodiafiltration, plasmapheresis, extracorporeal blood oxygenation, extracorporeal blood filtration or other treatments, there must be present at least one extracorporeal circuit through which the blood is made to circulate in order to be transported towards a treatment device. The treated blood is then returned to the patient's cardiovascular system.

With reference, by way of example, to a dialysis treatment, the extracorporeal circuit used comprises: a dialysis filter constituted by a container body including at least a first and a second chamber, separated from each other by a semipermeable membrane, a blood withdrawal line leading to the first chamber of the dialyzer filter and a blood return line destined to receive blood outletting from the first chamber and to return it to the patient. The second chamber of the dialyzer filter is connected to a dialysis liquid circulation circuit destined to receive the impurities present in the blood, as well as the excess fluid which is to be removed from the patient's blood.

At present, in extracorporeal blood treatment apparatus, the totality of lines destined for dialysis liquid circulation is housed inside the dialysis machine, while the lines forming the extracorporeal blood circuit are changed after each single treatment and are connected to the dialyzer filter, which can be changed either at each treatment or periodically, according to needs.

From the structural point of view, the dialyzer filter, the dialysis liquid circulation lines and the lines forming the patient's blood withdrawal and return branches are constituted by separate parts which are connected up and cooperate operatively following assembly.

The market offers apparatus, in particular destined for intensive kidney failure treatment, which are advantageously provided with integrated modules comprising a support structure, a dialyzer filter constrained to the support structure by means of a support element emerging from the support structure, as well as a hydraulic circuit comprising the tubing necessary for defining the withdrawal branch and the return branch of the blood from and to the patient, the lines (if present) for infusion of anticoagulant, or of substitution liquids, the dialysis liquid supply line, the discharge line for discharge liquid outletting from the dialysis filter second chamber.

The above-described integrated modules enable an easy and immediate attachment of the lines on the treatment apparatus and do not need any connection between the treatment device, for example a dialyzer filter, and the various tubes or

lines destined to carry blood and other fluids. Further, the integrated modules enable removal both of the tubes carrying the blood and those carrying other fluids once the treatment has been concluded. In other words, with a simple loading operation and a connecting-up of the terminals and the fluid transport lines to the relative sources, i.e. bags or other, the user can start up the dialysis apparatus.

Similarly, once the treatment has been concluded, a small number of disconnecting operations and dismounting of the integrated module from the blood treatment machine will enable the operator to completely remove the extracorporeal circuit, the blood treatment device, any tubing for circulation of infusion liquids as well as for the dialysis liquid.

The ease with which the module can be set up guarantees efficiency and speed, much to be appreciated in the case of intensive treatment, where the personnel involved, not necessarily expert in the use of blood treatment machines, can operate quickly and extremely reliably.

Though the above-described integrated modules have had a notable market success, they have shown themselves to be susceptible to improvement in various aspects.

Firstly, in the prior art, the connection between the support body and the blood treatment device includes an additional support interpositioned between the body of the treatment device and the support element, considerably complicating the overall structure of the integrated model.

The presence of an intermediate support structure between the support body and the dialyzer body causes the integrated module to be considerably unwieldy.

Additionally, the need to connect the dialyzer filter or another treatment device used with the extracorporeal blood circuit lines and the treatment fluid lines constitutes a further difficulty, as the connecting-up operations have to be performed in a zone which is difficult to access.

The above has obviously hampered the possibility of automating the assembly stages, considerably increasing production costs of the integrated modules at present on the market.

SUMMARY OF THE INVENTION

A main aim of the present invention is to make available a support element for an integrated module for blood treatment, and an integrated module for blood treatment comprising the support element, which overcome all of the above-described limitations and drawbacks.

In particular, an aim of the present invention is to provide a new support element which is easily and automatically assemblable with a blood treatment device, consequently reducing the overall costs for realization of an integrated module for extracorporeal blood treatment.

These aims and more besides will better emerge from the detailed description that follows, of a support element and an integrated module for blood treatment, comprising the support element as characterized in one or more of the appended claims.

Further characteristics and advantages will better emerge from the detailed description that follows of some preferred embodiments of a support element and an integrated module incorporating the support element of the present invention.

The following detailed description will also illustrate a manufacturing process of an integrated module for blood treatment, according to the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description will now be made with reference to the accompanying figures of the drawings, provided as a non-limiting example, in which:

FIG. **1** is a perspective view of a support element for an integrated module according to a first embodiment of the invention;

FIG. **2** shows the support element of FIG. **1** in an upturned position relative to the position of FIG. **1**;

FIG. **3** is a perspective view of a cover for closing an open side of the support element of FIG. **1**;

FIG. **4** is a perspective view of a support element for an integrated module in a second embodiment of the invention;

FIG. **5** shows the support element of FIG. **4** in an upturned position relative to the position of FIG. **4**;

FIG. **6** is a perspective view of an integrated module for extracorporeal treatment of blood with the support element of FIG.**5**;

FIG. **7***a* shows a detail of the module of FIG. **6**, relating to a coupling between a seating of the support element and a corresponding connector of a blood treatment device;

FIG. **7***b* shows a detail of FIG. **1**;

FIG. **8** schematically illustrates the module of FIG. **6** constrained on a frontal operative wall of a machine for extracorporeal blood treatment;

FIG. **9** is a schematic representation of the module of FIG. **6** in CRRT (continuous renal replacement therapy) configuration.

DETAILED DESCRIPTION

With reference to the accompanying figures of the drawings, **1** denotes in its entirety an integrated module for blood treatment in accordance with the present invention. The module **1** can be engaged to a machine for extracorporeal blood treatment **2**, provided with one or more pumps **3** destined to cooperate with the module **1**. The module **1** comprises a support element **4** to which a blood treatment device **5**, for example a plasma-filter, a hemodialysis filter, a hemofiltration filter, a filter for hemodiafiltration or a different unit.

In greater detail, the support element **4** comprises a base body **6** exhibiting at least a first and at least a second connector **7** and **8**, distanced one from another, destined to receive and connect with corresponding counter-connectors **9** and **10** of the blood treatment device **5**. The first and second connectors **7** and **8** are directly constrained to the base body **6**; in the illustrated embodiments the connectors **7** and **8** are made of a rigid plastic material and in a single piece with the base body **6**.

The support element **4** exhibits a third connector **11**, distanced from the connectors **7**, **8** and directly constrained on the base body **6**; in the illustrated embodiments the third connector **11** is made of rigid plastic material and in a single piece with the base body **6**; the three connectors define pairs of connectors having differentiated interaxes for engaging with corresponding pairs of counter-connectors associated to different blood treatment devices which are mountable on the support element **4**. This is so that a single base body **6** can be used to realize integrated modules having different characteristics, thanks to the possibility of engaging treatment devices **5** which are not only different as regards the membrane, but also in terms of overall size and therefore interaxes of the relative counter-connectors.

Each of the connectors **7**, **8**, **11** constitutes a rigid support and defines a fluid passage having a first end portion **12**, destined to be placed in fluid communication with a corresponding channel **13** present in a respective counter-connector **9**, **10** exhibited by the blood treatment device **5**; each connector **7**, **8**, **11** also exhibits a second end portion **14**, destined to be placed in fluid communication with a fluid distribution circuitry **15** associable to the base body **6**. In a further structural detail, each of the connectors **7**, **8**, **11** comprises a tubular channel **16**, defining the first end portion **12**, a sealing collar **17**, in a position which is radially external to the tubular channel **16**, and a connecting wall **18**, which develops continuously between an external lateral surface **19** of the tubular channel **16** and an internal lateral surface **20** of the sealing collar **17**.

The external lateral surface **19** of the tubular channel **16**, the internal lateral surface **20** of the sealing collar **17** and the connecting wall **18** together define an annular seating **21**, a bottom of which is delimited by the connecting wall **18**, shaped in order to receive and engage a corresponding counter-connector of the blood treatment device.

The tubular channel **16** is coaxially arranged with respect to the sealing collar **17**, and has geometry of revolution therewith, with a common axis of symmetry. The annular seating **21** exhibits an increasing radial dimension as it progresses from the bottom connecting wall **18**; it comprises a first zone **22**, adjacent to the bottom and having a constant radial dimension; a second zone **23**, distal with respect to the bottom and having a constant radial dimension which is greater than the radial dimension of the first zone **22**; and a third zone **24**, which is a transit zone between the first and second zones **22** and **23** and which has a progressively growing radial dimension as it progresses away from the bottom connecting wall **18**.

The tubular channel **16** and the sealing collar **17** of each connector **7**, **8**, **11** are parallel to one another in the base body **6**, defining a single coupling direction with the corresponding counter-connectors of a treatment device **5**.

In the illustrated embodiments, the various counter-connectors and connectors exhibit axes of symmetry which are perpendicular to a frontal wall **25** of the support element **4**.

The support element **4** shown in FIGS. **4**-**7** further comprises a fourth connector **26** which is distanced from the first, second and third connectors **7**, **8** and **11**. The fourth connector **26** is also directly connected to the support element **4**.

In the embodiment of FIGS. **4**-**7** the fourth connector **26** is made of rigid plastic in a single piece with the base body **6** and defines, with at least one of the other connectors **7**, **8** and **11** a further pair of connectors which can be engaged to a corresponding pair of counter-connectors associated to a blood treatment device mountable to the support element **4**.

The fourth connector **26** comprises a central cylindrical body **27** for positioning, a sealing collar **28** located in a radially external position with respect to the central cylindrical body **27**, and a bottom connecting wall **29** which develops continuously between an external lateral surface **30** of the central cylindrical body **27** and an internal lateral surface **31** of the collar **28**. The fourth connector **26** defines a connecting and sealing site for a counter-connector of the blood treatment device **5**.

As shown in FIGS. **6**, **7***a* (and the same goes for the support elements of FIGS. **1**-**3**, **7***b*), the various connectors are made of rigid material in order to offer a mechanical support to the blood treatment device and, according to each individual case, to define a passage or an obstruction for fluid passing through the counter-connectors **9**, **10**.

In the support element of FIGS. **4**-**6** the four connectors are aligned and arranged on one side of the base body **6**. More precisely, the base body **6** of the element illustrated in FIGS. **4**-**6** and **7***a* comprises a frontal wall **25** and a perimeter wall **32** connected around an edge thereof to the frontal wall **25**, which together define a works housing area **33** which can house at least a portion of the works of the support element, i.e. a fluid distribution circuitry **15** destined to be associated to the support element **4**.

The works housing area **33** exhibits an open side **34** which enables the integrated module **1** to be correctly positioned and adequately locked onto the machine, as will be better described herein below.

The support element **4** exhibits an auxiliary structure **35** which extends laterally and externally with respect to the works housing area **33** from a base zone **36** of the perimeter wall **32**. The four connectors emerge from the auxiliary structure **35**: the first, second and fourth connector **7**, **8**, **26** are adjacently situated, and arranged at a first end zone **37** of the auxiliary structure **35**, while the third connector **11** is located at a second end zone **38**, opposite the first end zone **37**.

In the illustrated embodiment of FIGS. **1-3**, the base body **6** comprises a frontal wall **25** and a perimeter wall **32** joined at an edge thereof to the frontal wall **25**, defining a works housing area **33** which can house at least a portion of the fluid distribution circuitry **15** destined to be associated to the support element **4**.

In this embodiment, however, the connectors **7**, **8** and **11** are not aligned and emerge directly from the frontal wall **25**. Further, a cover **39** is associated to the perimeter wall **32** on an opposite edge thereof with respect to the frontal wall **25**.

A support element according to the invention can advantageously be used for realizing an integrated module, such as for example the module illustrated in FIG. **6**, where by way of example the support element **4** of FIGS. **4** and **5** is used.

As can be observed, the blood treatment device **5** is fixed to the support element **4** by at least one pair of connectors; the blood treatment device comprises a body **40**, at least one semipermeable membrane **41** (for example a parallel hollow fiber membrane or a plate membrane) operating internally of the body **40** and defining a first chamber and a second chamber; a first and a second connector are associated to the body **40** and fixed to the respective connectors on the base body **6**.

The first and second counter-connectors **9**, **10**, are tubular and are in fluid communication with the second chamber of the treatment device and with respective first end portions **12** of the connectors.

The treatment device exhibits an inlet port **42** to the first chamber, and at least one outlet port **43** from the first chamber, for connection of an extracorporeal blood circuit line **44** or another physiological fluid.

A fluid distribution circuitry **15** is attached to the support element **4** and cooperates with the treatment device **5**. In more detail, the circuitry comprises:

- at least one discharge line **45** of discharge fluid, in communication with the second terminal portion **14** of one of the connectors;
- at least one blood line **44** having a blood withdrawal branch **46**, placed in communication with the inlet **42** of the first chamber, and at least one branch **47** of a blood return line, placed in communication with the outlet **43** of the first chamber;
- at least one supply line **48** of fresh dialysis liquid, placed in communication with the second end portion **14** of another of the connectors.

Each of the lines is constrained to the support element **4**, defining at least one tract of tubing **49** which is arranged in a U-shape, in relation to the support element **4**.

During operation the U-shaped tracts are destined to cooperate with the respective peristaltic pumps **3** located on a panel of a machine for extracorporeal blood treatment. Each tract of U-shaped tubing extends internally or externally (FIG. **7**) with respect to the perimeter wall **32** of the support element **4**.

FIG. **9** is a diagram of the integrated module **1** in the CRRT configuration. As can be observed, the module **1** also has lines **50** and **51** for respective pre and post blood pump infusions (pre-dilution and/or post-dilution).

An air separator device **52** operates on the branch **47** of the blood line **44** and receives an infusion line **51**.

The invention also relates to an assembly procedure for an integrated module for fluid treatment which comprises the stages of predisposing a support element **4**, for example such as in FIGS. **1-3** or in FIGS. **4-6**, as well as a treatment device **5** which is intended for coupling to the support element **4**. The blood treatment device **5** is then fixed to the support element **4**. Finally a fluid distribution circuitry **15** is associated to the support element **4** and to the blood treatment device **5** so as to create the necessary blood circulation lines, the discharge lines, the infusion lines for any liquid substitution lines, and dialysis lines.

The connection of the distribution circuitry to the blood treatment device can be done before, at the same time as or after the circuitry fixing stage to the support element **4**.

The fixing stage of the blood treatment device to the support element **4** comprises the sub-stages of selecting a pair of connectors to which the counter-connectors **9**, **10** on the blood treatment device are to be connected, applying a predetermined quantity of glue, normally polymer-resin based, in the annular seatings **21** of each chosen connector, at least partially inserting each counter-connector in the respective annular seating in order to obtain a mechanical bond and a liquid-proof seal coupling.

During the insertion stage, at least a portion of the glue applied in the annular seating actually settles in the second zone **23** of the annular seating. On completion of the counter-connector insertion stage in the annular seating, the volume of the quantity of glue previously applied added to the volume of the portion of counter-connector housed in the annular seating is less than the overall volume of the annular seating. This prevents any glue material from migrating towards the tubular channel **16** and causing a partial or total occlusion.

The stage of associating a fluid distribution circuitry **15** to the support element **4** and the blood treatment device **5** comprises the sub-stages of liquid-proof sealing of an end portion of a discharge fluid discharge line **45** with the second end portion **14** of one of the connectors, and of sealedly fixing an end portion of a fresh dialysis liquid supply line **48** to the second end portion of a further of the connectors.

The stage of associating the blood distribution circuitry also includes sealedly fixing an end portion of a blood withdrawal branch **46** to an inlet port of the first chamber, and an end portion of a blood return branch **47** to an outlet port of the first chamber.

The fixing of the various above-mentioned end portions can be achieved by gluing, friction fitting or hot-coupling.

The invention provides important advantages.

Firstly, the direct fixing of the blood treatment device to the selected connectors of the support element does not require the use of other support elements of the same device.

Further, the connectors receive on one side the counter-connectors of the blood treatment device and on the other side the end portions of distribution circuitry lines, realizing a contemporaneous mechanical and hydraulic connection between the fluid distribution circuitry and the blood treatment device.

The presence of various connectors means the treatment device can be used with connectors having different inter-axes.

The special fixing modality of the blood treatment device and the various fluid lines to the support element considerably facilitates the assembly process of an integrated module according to the invention.

The specific structure of the integrated module and the support element minimizes the length of fluid line needed to realize the connections with the blood treatment device.

The invention claimed is:

1. An integrated module for fluid treatment, comprising:

a support element having:

a base body;

at least a first and at a least a second connector associated with the base body and distanced one from another;

at least an intermediate connector interposed between said first and second connectors, distanced from said first connector and from said second connector and directly constrained to the base body, said first, second, and intermediate connectors defining pairs of connectors having differentiated interaxes there-between for engaging to corresponding pairs of counter-connectors associated with various blood treatment devices which are mountable on the support element;

at least one blood treatment device engaged on the support element and having:

a containment body presenting a main development axis and including a lateral surface and first and second end surfaces;

at least one semi-permeable membrane operating internally of the containment body and defining a first chamber and a second chamber;

a first counter-connector and a second counter-connector, both emerging from the lateral surface of the containment body and being fixed to a pair of connectors selected from the first, second, and intermediate connectors associated with the base body, at least one of the first counter-connector and the second counter-connector being placed in fluid communication with the second chamber of the blood treatment device and with respective first end portions of said pair of connectors, wherein the intermediate connector is not connected to a counter-connector of the blood treatment device;

at least one inlet port to the first chamber associated with the first end surface and emerging axially along the development axis; and

at least one outlet port from the first chamber associated with the second end surface and emerging axially along the development axis;

a fluid distribution circuitry associated with the support element and cooperating with the blood treatment device, each of said pair of connectors presenting a fluid passage having a first end portion in fluid communication with a corresponding channel in a respective counter-connector on the blood treatment device and a second end portion in fluid communication with the fluid distribution circuitry the fluid distribution circuitry presenting at least one blood line having a blood withdrawal branch placed in fluid communication with the inlet port of the first chamber and emerging axially from the first end surface along the development axis and at least one blood return branch placed in fluid communication with the outlet port of the first chamber and emerging axially from the second end surface along the development axis.

2. The integrated module of claim **1**, wherein the pair of second connectors are directly constrained to the base body.

3. The integrated module of claim **2**, wherein the pair of connectors are made in a single piece with the base body.

4. The integrated module of claim **1**, wherein the intermediate connector is made in a single piece with the base body.

5. The integrated module of claim **1**, wherein each of said pair of connectors comprises:

a tubular channel defining said first end portion;

a sealing collar set in a radially external position with respect to the tubular channel; and

a connecting wall developing continuously between an external lateral surface of said tubular channel and an internal lateral surface of said sealing collar to define an annular seating for engagement of each counter-connector.

6. The integrated module of claim **5**, wherein the tubular channel defining said first end portion is coaxially arranged with respect to the sealing collar, said annular seating exhibiting a bottom delimited by said connecting wall.

7. The integrated module of claim **6**, wherein said annular seating exhibits a radial dimension that increases progressively in a direction moving away from a bottom wall.

8. The integrated module of claim **7**, wherein said annular seating exhibits:

a first zone, adjacent to said bottom wall and having a constant radial dimension;

a second zone, distal of said bottom wall and having a constant radial dimension greater than the radial dimension of the first zone; and

a third transition zone configured between the first zone and the second zone, said third transition zone having a progressively increasing dimension in a distancing direction from said bottom wall.

9. The integrated module of claim **5**, wherein the tubular channel and the sealing collar of each connector are parallel to one another as they emerge from the base body, defining a single coupling direction for coupling with corresponding counter-connectors of a blood treatment device.

10. The integrated module of claim **1**, comprising a fourth connector, distanced from said first, second, and intermediate connectors, said fourth connector being made as a single piece with the base body and defining, with at least one of said first, second, and intermediate connectors, a further pair of connectors which can be engaged to a corresponding pair of counter-connectors associated with a blood treatment device which is mountable on the support element.

11. The integrated module of claim **10**, wherein the fourth connector comprises:

a central cylindrical positioning body;

a sealing collar, set in a radially external position to the cylindrical positioning body; and

a connecting wall, developing continuously between an external lateral surface of said cylindrical positioning body and an internal lateral surface of said cylindrical positioning body and an internal lateral surface of said sealing collar;

said fourth connector defining a connecting and sealing site for a counter-connector of the blood treatment device.

12. The integrated module of claim **2**, wherein said pair of connectors and said base body are made of a rigid material in order to offer a mechanical support for the blood treatment device.

13. The integrated module of claim **1**, wherein said first, second, and intermediate connectors are aligned one next to another.

14. The integrated module of claim **2**, wherein said pair of connectors are arranged on a side of the base body.

15. The integrated module of claim **1**, wherein said base body comprises a frontal wall and a perimeter wall, which perimeter wall is connected by a side thereof to the frontal wall and defines a works area within which at least a portion of a fluid distribution circuitry configured to be associated with the support element can be housed.

16. The integrated module of claim **15**, comprising an auxiliary structure extending laterally and externally with

respect to said works area from a base zone of the perimeter wall, said pair of connectors emerging from said auxiliary structure.

17. The integrated module of claim **1**, wherein said first, second, and intermediate connectors are not aligned one next to another.

18. The integrated module of claim **1**, wherein the base body comprises a frontal wall, from which said pair of connectors directly project, and a cover associated with a perimeter wall at an opposite edge thereof with respect to the frontal wall.

19. The integrated module of claim **1**, wherein said blood treatment device is fixed to the base body by at least the pair of said connectors.

20. The integrated module of claim **19**, wherein said pair of connectors is interpositioned between the counter-connectors and a portion of the fluid distribution circuitry.

21. The integrated module of claim **1**, wherein the fluid distribution circuitry comprises at least one discharge line of a discharge fluid in communication with the second end portion of one of said pair of connectors.

22. The integrated module of claim **21**, wherein the fluid distribution circuitry comprises at least one fresh dialysis liquid supply line in communication with the second end portion of another of said pair of connectors.

23. The integrated module of claim **22**, wherein the fluid distribution circuitry comprises at least one blood circuit line having a blood withdrawal branch in communication with the inlet port of the first chamber, and at least one blood return branch in communication with the outlet port of the first chamber.

24. The integrated module of claim **21**, wherein at least one of said at least one distribution lines is constrained to the support element and defines at least one tract of tubing configured in a U-shape in relation to the support element, said at least one tract of tubing being destined during operation to cooperate with a peristaltic pump.

25. The integrated module of claim **24**, wherein the at least one tract of tubing configured in a U-shape extends internally or externally with respect to the perimeter wall of the support element.

26. The integrated module of claim **1**, wherein the counter-connectors of the blood treatment device are fixed to the pair of said connectors by a prefixed quantity of glue in the annular seatings of each of said connectors, each of said counter-connectors being partially inserted into a respective annular seating in order to obtain a mechanical lock and a liquid-proof seal.

27. The integrated module of claim **26**, wherein at least a portion of the prefixed quantity of glue is configured in a second zone of the respective annular seating, and wherein a volume of said prefixed quantity of glue, added to a volume of a portion of each counter-connector housed in the annular seating, is less than a total volume of the annular seating.

28. The integrated module of claim **23**, wherein the end portion of the discharge line is liquid-proof fixed to the second end portion of one of said connectors, the end portion of the fresh dialysis liquid supply line is liquid-proof fixed to the second end portion of another of said connectors, the end portion of the blood withdrawal branch is liquid-proof fixed to the inlet port of the first chamber, and the end portion of the blood return branch is liquid-proof fixed to the outlet port of the first chamber.

29. An integrated module for fluid treatment, comprising:

a support element having:

a base body;

a first and a second connector associated with the base body and distanced one from another;

at least an intermediate connector interposed between said first and second connectors, distanced from said first connector and from said second connector and directly constrained to the base body, said first and said second connectors being the outermost connectors, said first, second, and intermediate connectors defining pairs of connectors having differentiated interaxes therebetween for engaging to corresponding pairs of counter-connectors associated with various blood treatment devices which are mountable on the support element;

at least one blood treatment device engaged on the support element and having:

a containment body presenting a main development axis and including a lateral surface and first and second end surfaces;

at least one semi-permeable membrane operating internally of the containment body and defining a first chamber and a second chamber;

a first counter-connector and a second counter-connector, both emerging from the lateral surface of the containment body and being fixed to a pair of connectors selected from the first, second, and intermediate connectors associated with the base body, at least one of the first counter-connector and the second counter-connector being placed in fluid communication with the second chamber of the blood treatment device and with respective first end portions of said pair of connectors, wherein the remaining connector of the first, second and intermediate connectors is not connected to a counter-connector of the blood treatment device;

at least one inlet port to the first chamber associated with the first end surface and emerging axially along the development axis; and

at least one outlet port from the first chamber associated with the second end surface and emerging axially along the development axis;

a fluid distribution circuitry associated with the support element and cooperating with the blood treatment device, each of said first and second connectors presenting a fluid passage having a first end portion in fluid communication with a corresponding channel in a respective counter-connector on the blood treatment device and a second end portion in fluid communication with the fluid distribution circuitry, the fluid distribution circuit presenting at least one blood line having a blood withdrawal branch placed in fluid communication with the inlet port of the first chamber and emerging axially from the first end surface along the development axis and at least one blood return branch placed in fluid communication with the outlet port of the first chamber and emerging axially from the second end surface along the development axis.

30. An integrated module for fluid treatment, comprising:

a support element having:

a base body;

at least a first and at a least a second connector associated with the base body and

distanced one from another;

at least an intermediate connector, distanced from said first connector and from said second connector, said first, second and intermediate connectors defining pairs of connectors having differentiated interaxes therebetween for engaging to corresponding pairs of counter-connectors associated with various blood treatment devices which are mountable on the support element,

wherein the first, the second and the intermediate connectors are directly constrained to the base body and the first, the second and the intermediate connectors are made in a single piece with the base body;

at least one blood treatment device engaged on the support element and having:

a containment body presenting a main development axis and including a lateral surface and first and second end surfaces;

at least one semi-permeable membrane operating internally of the containment body and defining a first chamber and a second chamber;

a first counter-connector and a second counter-connector, both emerging from the lateral surface of the containment body and being fixed to a pair of the three connectors associated with the base body, at least one of the first counter-connector and the second counter-connector being placed in fluid communication with the second chamber of the blood treatment device and with respective first end portions of said pair of connectors, wherein the remaining connector of the first, second and intermediate connectors is not connected to a counter-connector of the blood treatment device;

at least one inlet port to the first chamber associated with the first end surface and emerging axially along the development axis; and

at least one outlet port from the first chamber associated with the second end surface and emerging axially along the development axis;

a fluid distribution circuitry associated with the support element and cooperating with the blood treatment device, each of said first and second connectors presenting a fluid passage having a first end portion in fluid communication with a corresponding channel in a respective counter-connector on the blood treatment device and a second end portion in fluid communication with the fluid distribution circuitry, the fluid distribution circuit presenting at least one blood line having a blood withdrawal branch placed in fluid communication with the inlet port of the first chamber and emerging axially from the first end surface along the development axis and at least one blood return branch placed in fluid communication with the outlet port of the first chamber and emerging axially from the second end surface along the development axis.

* * * * *

EXHIBIT F

US008267308B2

(12) **United States Patent**
Devergne et al.

(10) **Patent No.: US 8,267,308 B2**
(45) **Date of Patent: Sep. 18, 2012**

(54) **FLUID PROCESSING MEDICAL APPARATUS AND METHOD FOR SETTING-UP A FLUID PROCESSING MEDICAL APPARATUS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 233 days.

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§ 371 (c)(1),
(2), (4) Date: **Apr. 20, 2010**

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PCT Pub. Date: **Oct. 30, 2008**

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(51) **Int. Cl.**
G06F 17/00 (2006.01)

(52) **U.S. Cl.** **235/375**; 235/435

(58) **Field of Classification Search** 235/375, 235/382, 376, 435; 715/744

See application file for complete search history.

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Primary Examiner — Edwyn Labaze
(74) *Attorney, Agent, or Firm* — Pearne & Gordon LLP

(57) **ABSTRACT**

The invention relates to a method for setting up a fluid treatment apparatus using a single, and always accessible, reader of information relating to replaceable components which are to be mounted on the apparatus to perform the fluid treatment. It is also disclosed a fluid treatment apparatus having the always accessible reader. The reader can also be relied on to enter information other that those relating to the replaceable components, such as commands for the apparatus, patients' related information, etcetera.

50 Claims, 15 Drawing Sheets

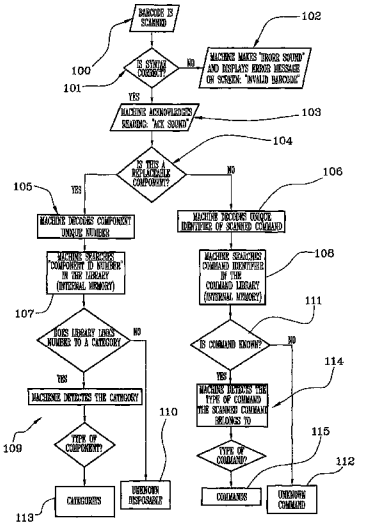

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FIG 1

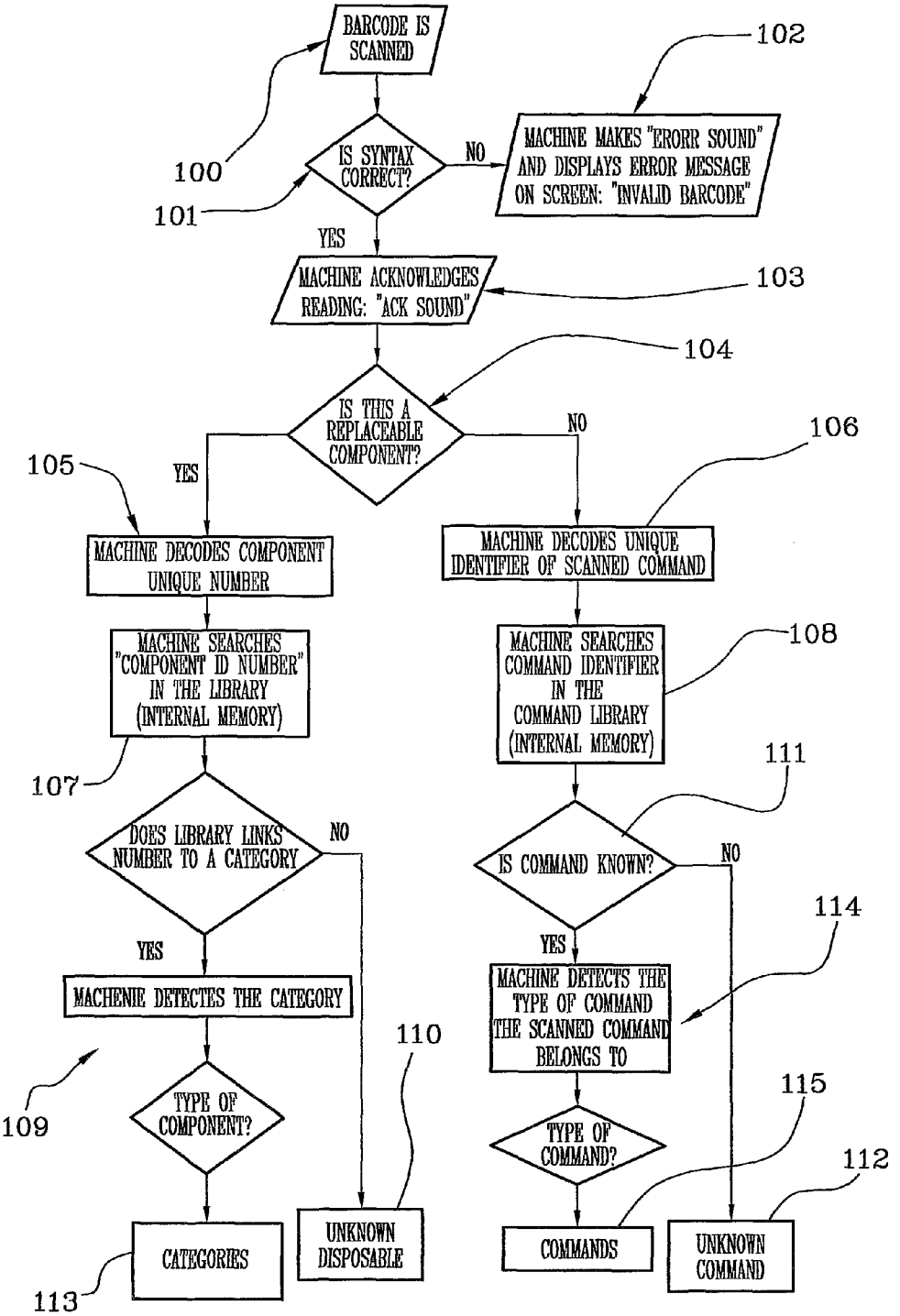

BARCODE IS SCANNED
100
IS SYNTAX CORRECT?
101
NO
MACHINE MAKES "ERORR SOUND" AND DISPLAYS ERROR MESSAGE ON SCREEN: "INVALID BARCODE"
102
YES
MACHINE ACKNOWLEDGES READING: "ACK SOUND"
103
IS THIS A REPLACEABLE COMPONENT?
104
YES
NO
105
106
MACHINE DECODES COMPONENT UNIQUE NUMBER
MACHINE DECODES UNIQUE IDENTIFIER OF SCANNED COMMAND
MACHINE SEARCHES "COMPONENT ID NUMBER" IN THE LIBRARY (INTERNAL MEMORY)
MACHINE SEARCHES COMMAND IDENTIFIER IN THE COMMAND LIBRARY (INTERNAL MEMORY)
108
107
111
DOES LIBRARY LINKS NUMBER TO A CATEGORY
NO
IS COMMAND KNOWN?
NO
YES
YES
114
MACHENIE DETECTES THE CATEGORY
MACHINE DETECTS THE TYPE OF COMMAND THE SCANNED COMMAND BELONGS TO
110
109
TYPE OF COMPONENT?
TYPE OF COMMAND?
115
112
CATEGORIES
UNKNOWN DISPOSABLE
COMMANDS
UNKNOWN COMMAND
113

FIG 2

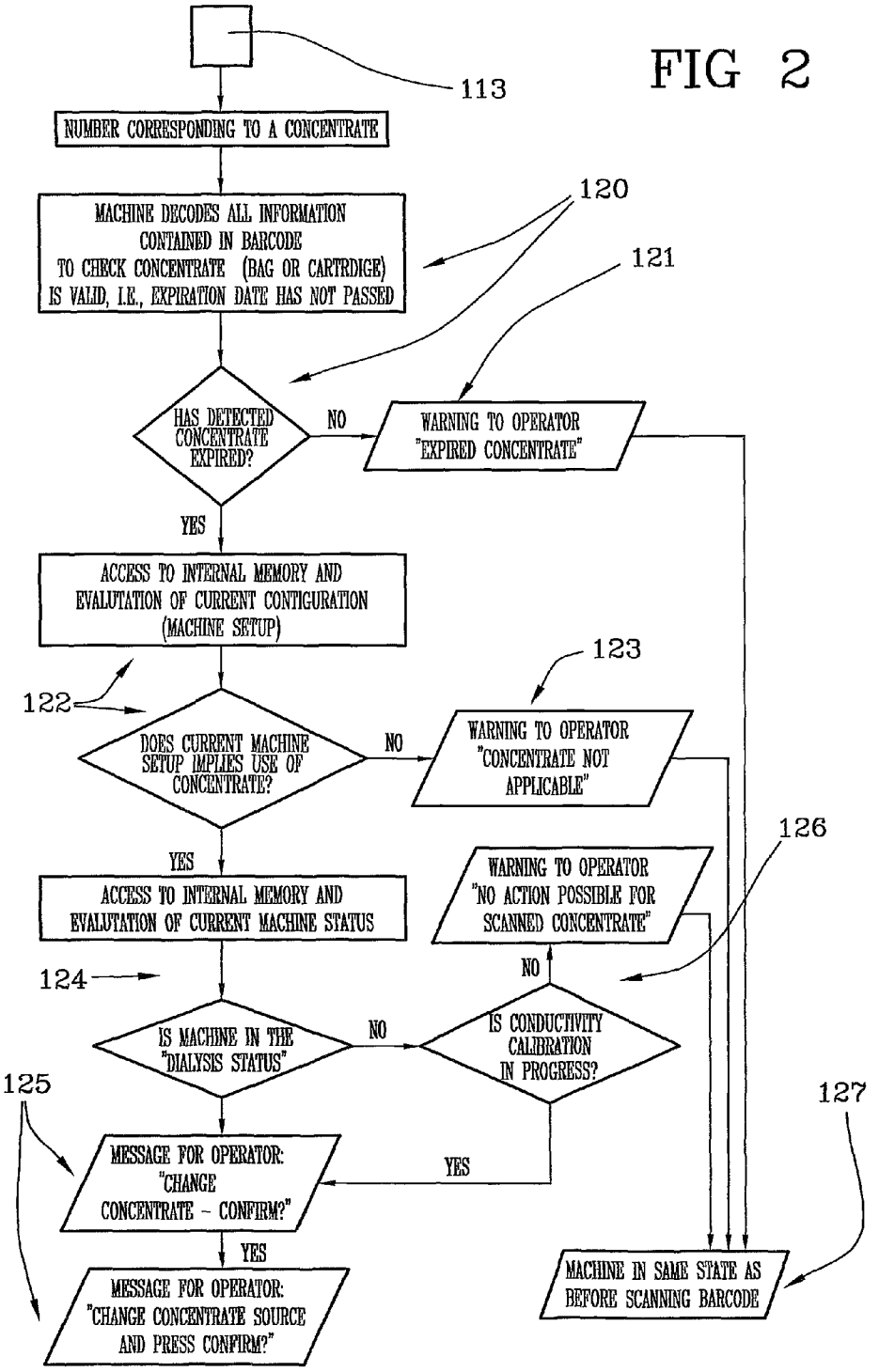

113
NUMBER CORRESPONDING TO A CONCENTRATE
120
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK CONCENTRATE (BAG OR CARTRIDGE) IS VALID, I.E., EXPIRATION DATE HAS NOT PASSED
121
HAS DETECTED CONCENTRATE EXPIRED?
NO
WARNING TO OPERATOR "EXPIRED CONCENTRATE"
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT CONTIGURATION (MACHINE SETUP)
122
123
DOES CURRENT MACHINE SETUP IMPLIES USE OF CONCENTRATE?
NO
WARNING TO OPERATOR "CONCENTRATE NOT APPLICABLE"
126
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
WARNING TO OPERATOR "NO ACTION POSSIBLE FOR SCANNED CONCENTRATE"
NO
124
IS MACHINE IN THE "DIALYSIS STATUS"
NO
IS CONDUCTIVITY CALIBRATION IN PROGRESS?
125
127
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE - CONFIRM?"
YES
YES
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE SOURCE AND PRESS CONFIRM?"
MACHINE IN SAME STATE AS BEFORE SCANNING BARCODE

FIG 3

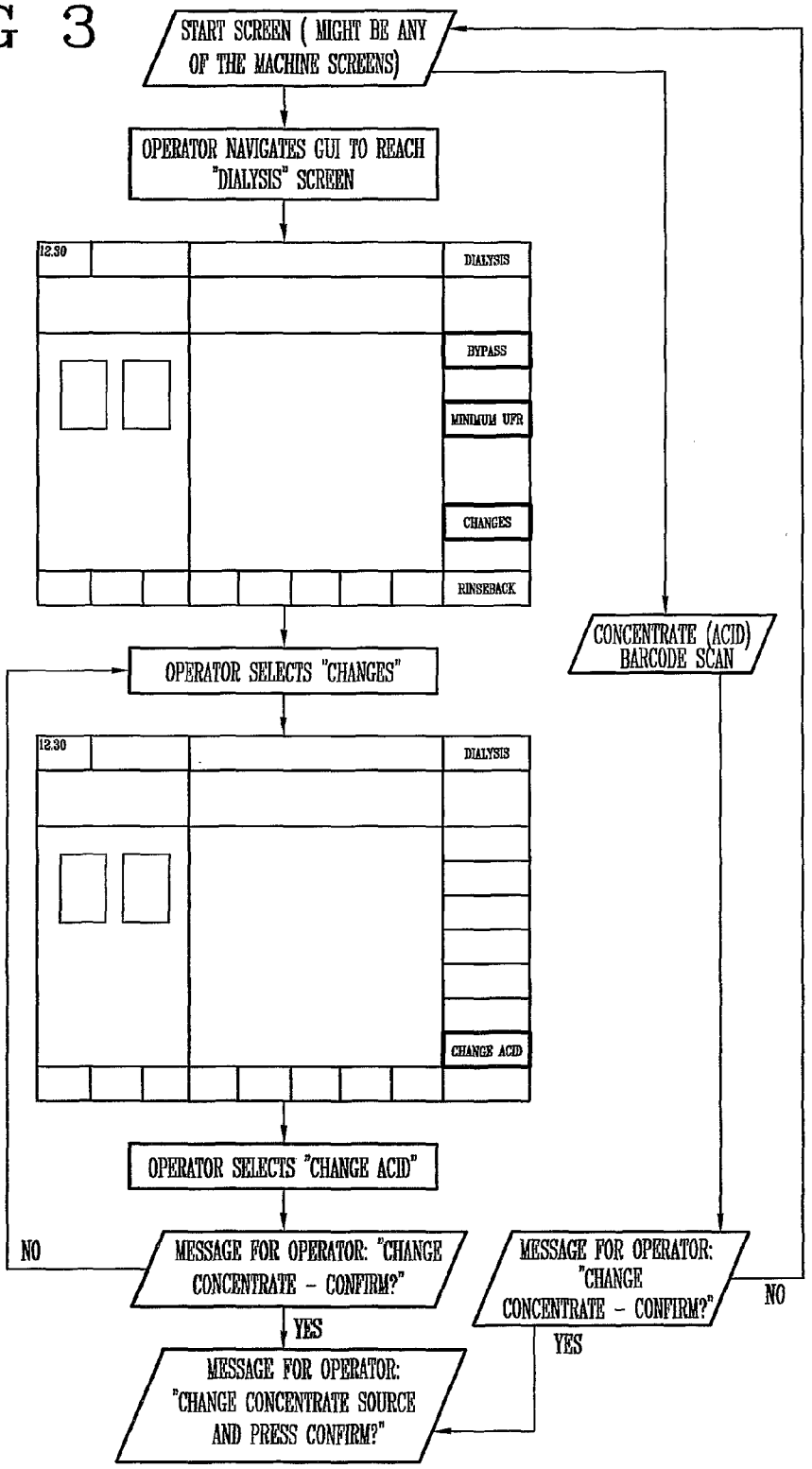

START SCREEN (MIGHT BE ANY OF THE MACHINE SCREENS)
OPERATOR NAVIGATES GUI TO REACH "DIALYSIS" SCREEN
12.30
DIALYSIS
BYPASS
MINIMUM UFR
CHANGES
RINSEBACK
CONCENTRATE (ACID) BARCODE SCAN
OPERATOR SELECTS "CHANGES"
12.30
DIALYSIS
CHANGE ACID
OPERATOR SELECTS "CHANGE ACID"
NO
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE - CONFIRM?"
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE - CONFIRM?"
NO
YES
YES
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE SOURCE AND PRESS CONFIRM?"

FIG 4

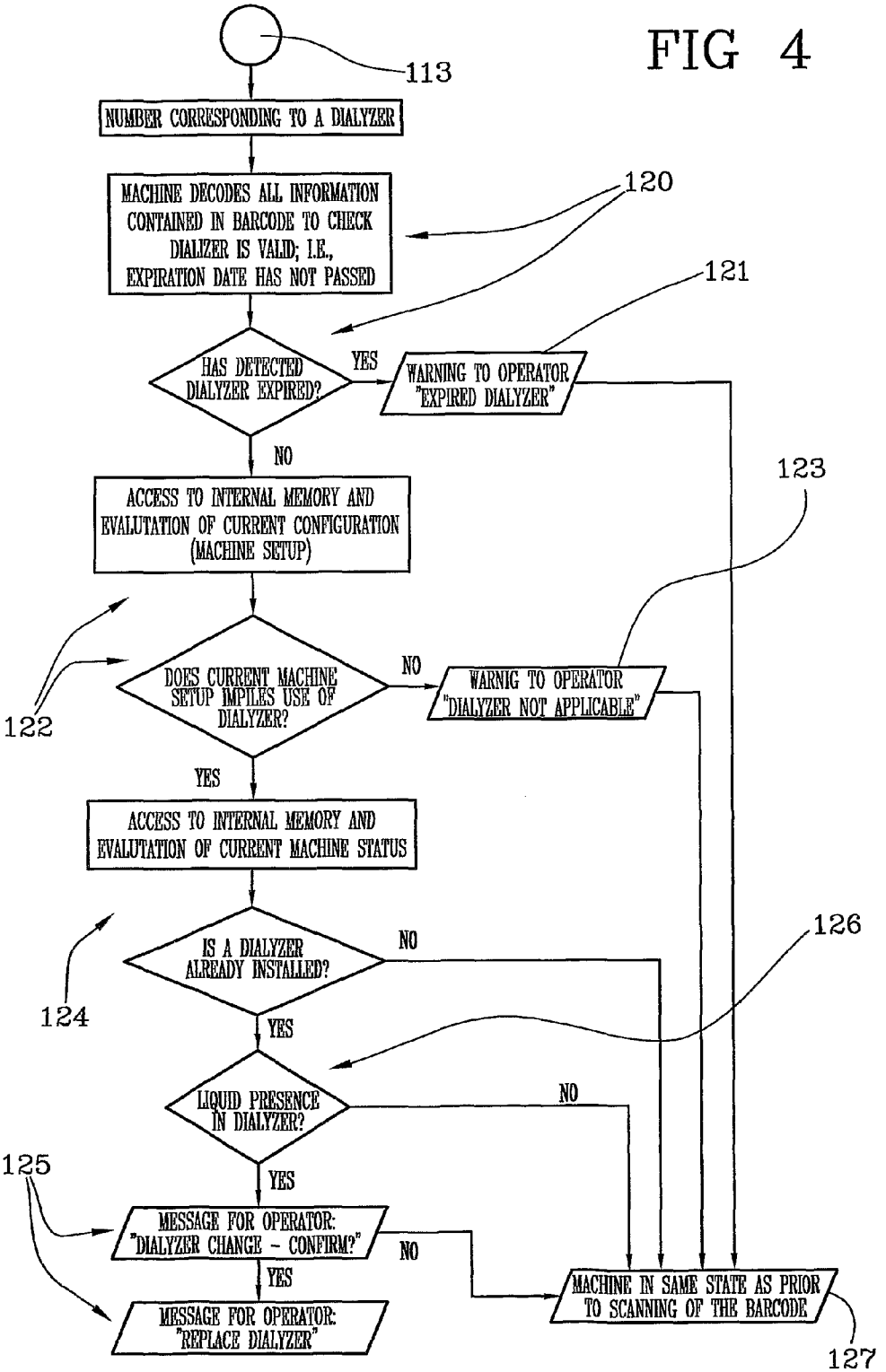

113
NUMBER CORRESPONDING TO A DIALYZER
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK DIALIZER IS VALID; I.E., EXPIRATION DATE HAS NOT PASSED
120
121
HAS DETECTED DIALYZER EXPIRED?
YES
WARNING TO OPERATOR "EXPIRED DIALYZER"
NO
123
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT CONFIGURATION (MACHINE SETUP)
DOES CURRENT MACHINE SETUP IMPILES USE OF DIALYZER?
NO
WARNIG TO OPERATOR "DIALYZER NOT APPLICABLE"
122
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
IS A DIALYZER ALREADY INSTALLED?
NO
126
124
YES
LIQUID PRESENCE IN DIALYZER?
NO
125
YES
MESSAGE FOR OPERATOR: "DIALYZER CHANGE - CONFIRM?"
NO
YES
MESSAGE FOR OPERATOR: "REPLACE DIALYZER"
MACHINE IN SAME STATE AS PRIOR TO SCANNING OF THE BARCODE
127

FIG 5

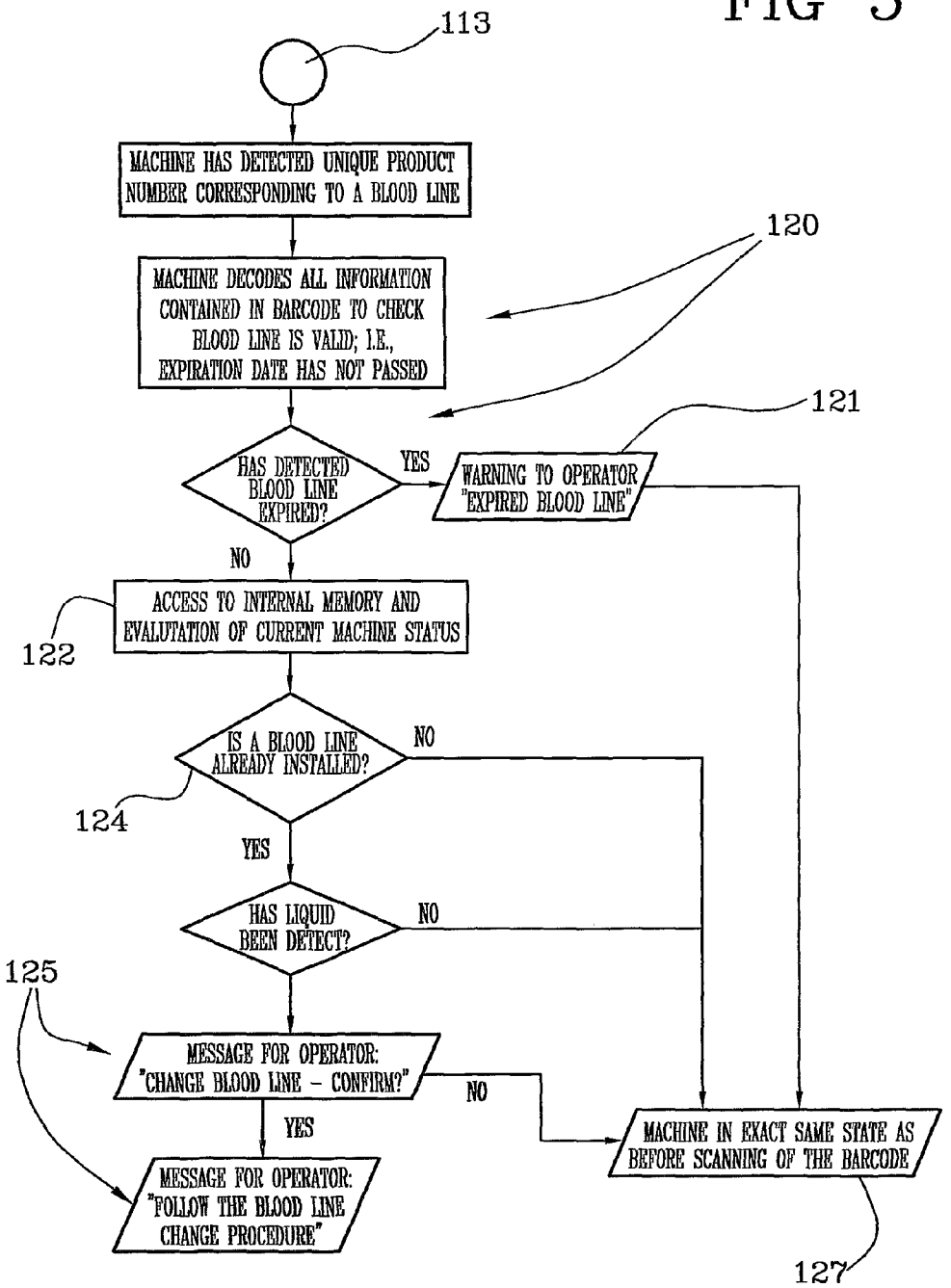

113
MACHINE HAS DETECTED UNIQUE PRODUCT NUMBER CORRESPONDING TO A BLOOD LINE
120
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK BLOOD LINE IS VALID; I.E., EXPIRATION DATE HAS NOT PASSED
121
HAS DETECTED BLOOD LINE EXPIRED?
YES
WARNING TO OPERATOR "EXPIRED BLOOD LINE"
NO
122
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
IS A BLOOD LINE ALREADY INSTALLED?
NO
124
YES
HAS LIQUID BEEN DETECT?
NO
125
MESSAGE FOR OPERATOR: "CHANGE BLOOD LINE - CONFIRM?"
NO
YES
MESSAGE FOR OPERATOR: "FOLLOW THE BLOOD LINE CHANGE PROCEDURE"
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE
127

FIG 6

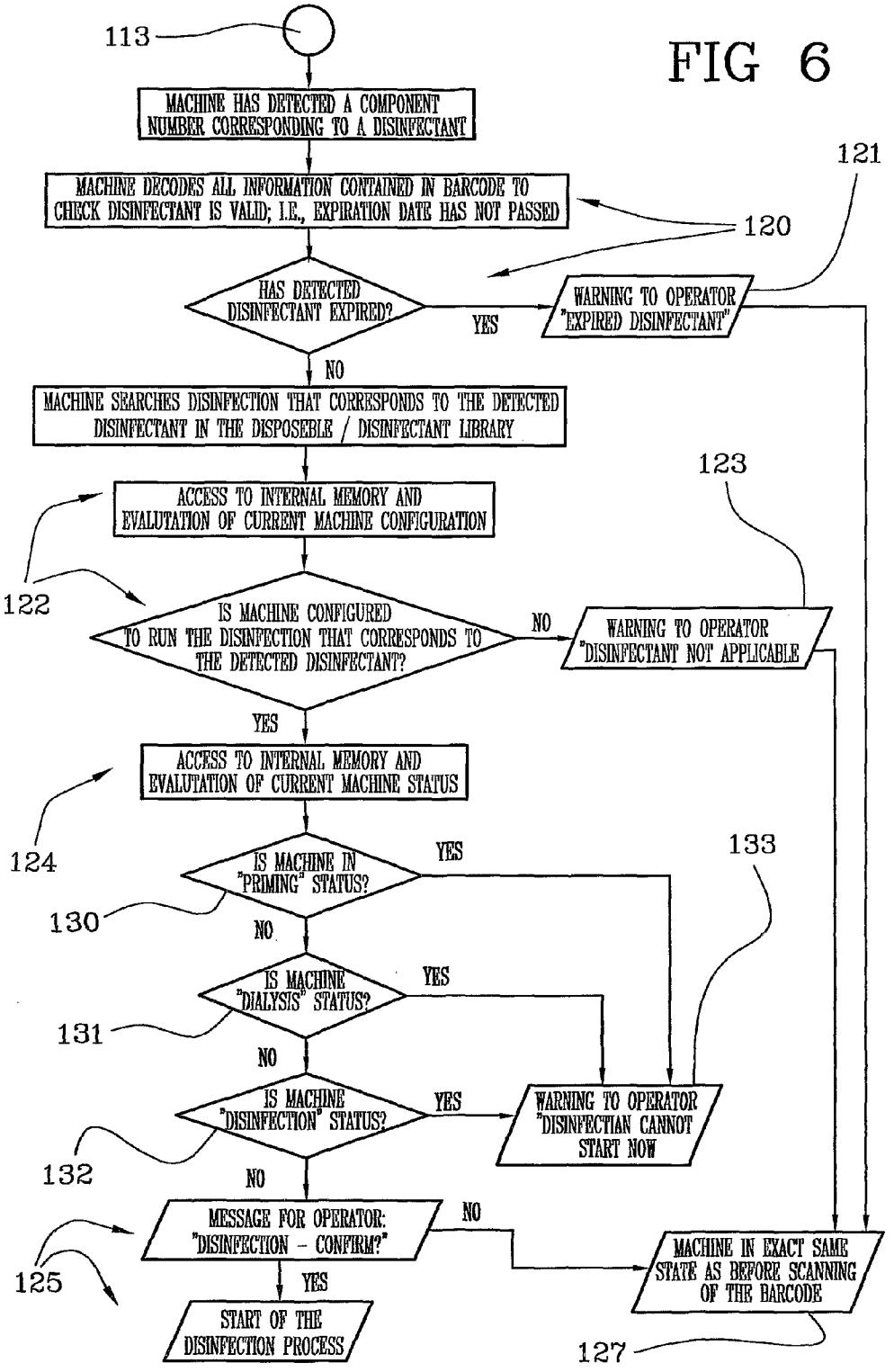

113
MACHINE HAS DETECTED A COMPONENT NUMBER CORRESPONDING TO A DISINFECTANT
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK DISINFECTANT IS VALID; I.E., EXPIRATION DATE HAS NOT PASSED
120
121
HAS DETECTED DISINFECTANT EXPIRED?
YES
WARNING TO OPERATOR "EXPIRED DISINFECTANT"
NO
MACHINE SEARCHES DISINFECTION THAT CORRESPONDS TO THE DETECTED DISINFECTANT IN THE DISPOSEBLE / DISINFECTANT LIBRARY
123
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
122
IS MACHINE CONFIGURED TO RUN THE DISINFECTION THAT CORRESPONDS TO THE DETECTED DISINFECTANT?
NO
WARNING TO OPERATOR "DISINFECTANT NOT APPLICABLE
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
124
IS MACHINE IN "PRIMING" STATUS?
YES
133
130
NO
IS MACHINE "DIALYSIS" STATUS?
YES
131
NO
IS MACHINE "DISINFECTION" STATUS?
YES
WARNING TO OPERATOR "DISINFECTIAN CANNOT START NOW
132
NO
MESSAGE FOR OPERATOR: "DISINFECTION - CONFIRM?"
NO
125
YES
START OF THE DISINFECTION PROCESS
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE
127

FIG 7

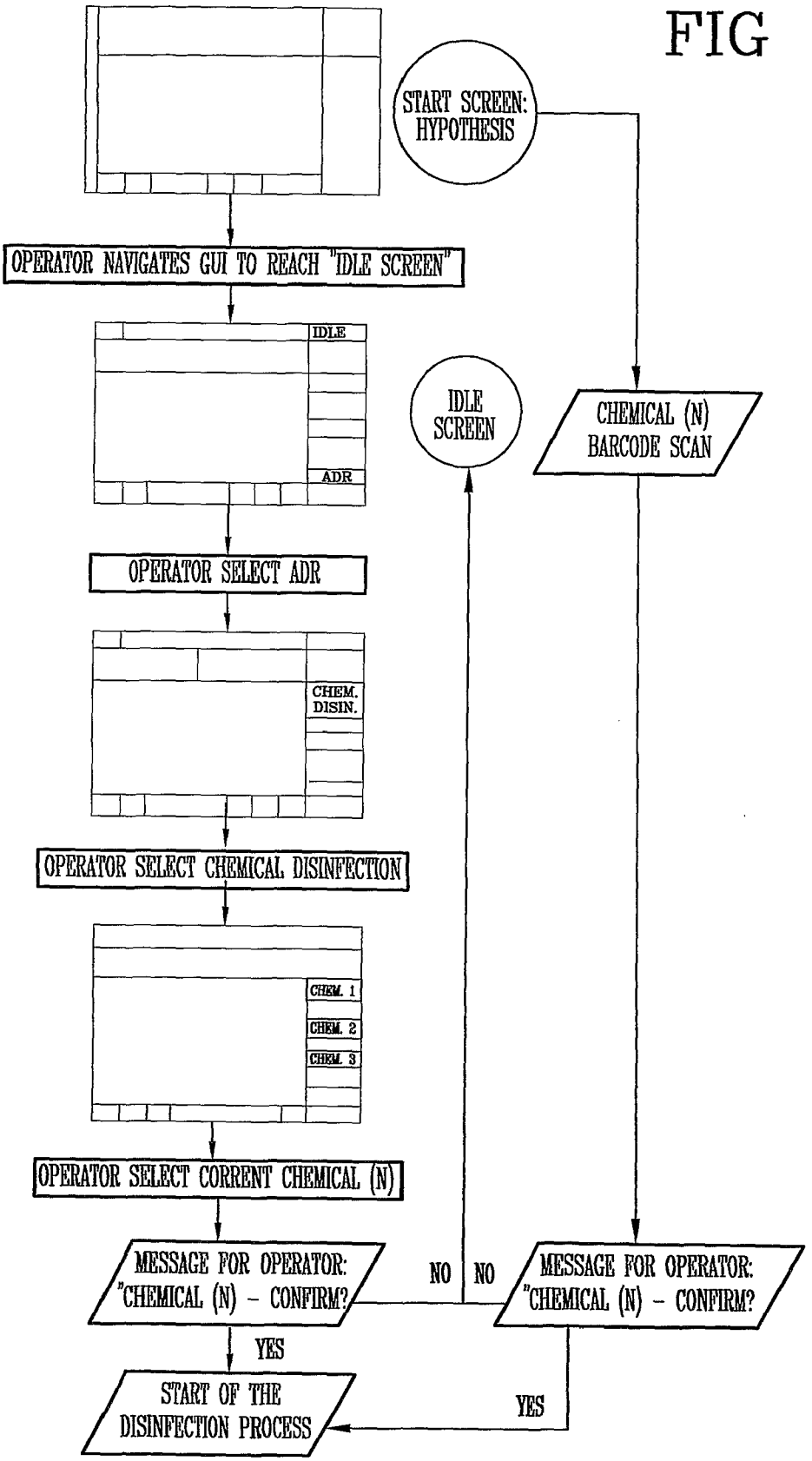

START SCREEN: HYPOTHESIS
OPERATOR NAVIGATES GUI TO REACH "IDLE SCREEN"
IDLE
ADR
IDLE SCREEN
CHEMICAL (N) BARCODE SCAN
OPERATOR SELECT ADR
CHEM. DISIN.
OPERATOR SELECT CHEMICAL DISINFECTION
CHEM. 1
CHEM. 2
CHEM. 3
OPERATOR SELECT CORRENT CHEMICAL (N)
MESSAGE FOR OPERATOR: "CHEMICAL (N) - CONFIRM?
NO
NO
MESSAGE FOR OPERATOR: "CHEMICAL (N) - CONFIRM?
YES
YES
START OF THE DISINFECTION PROCESS

FIG 8

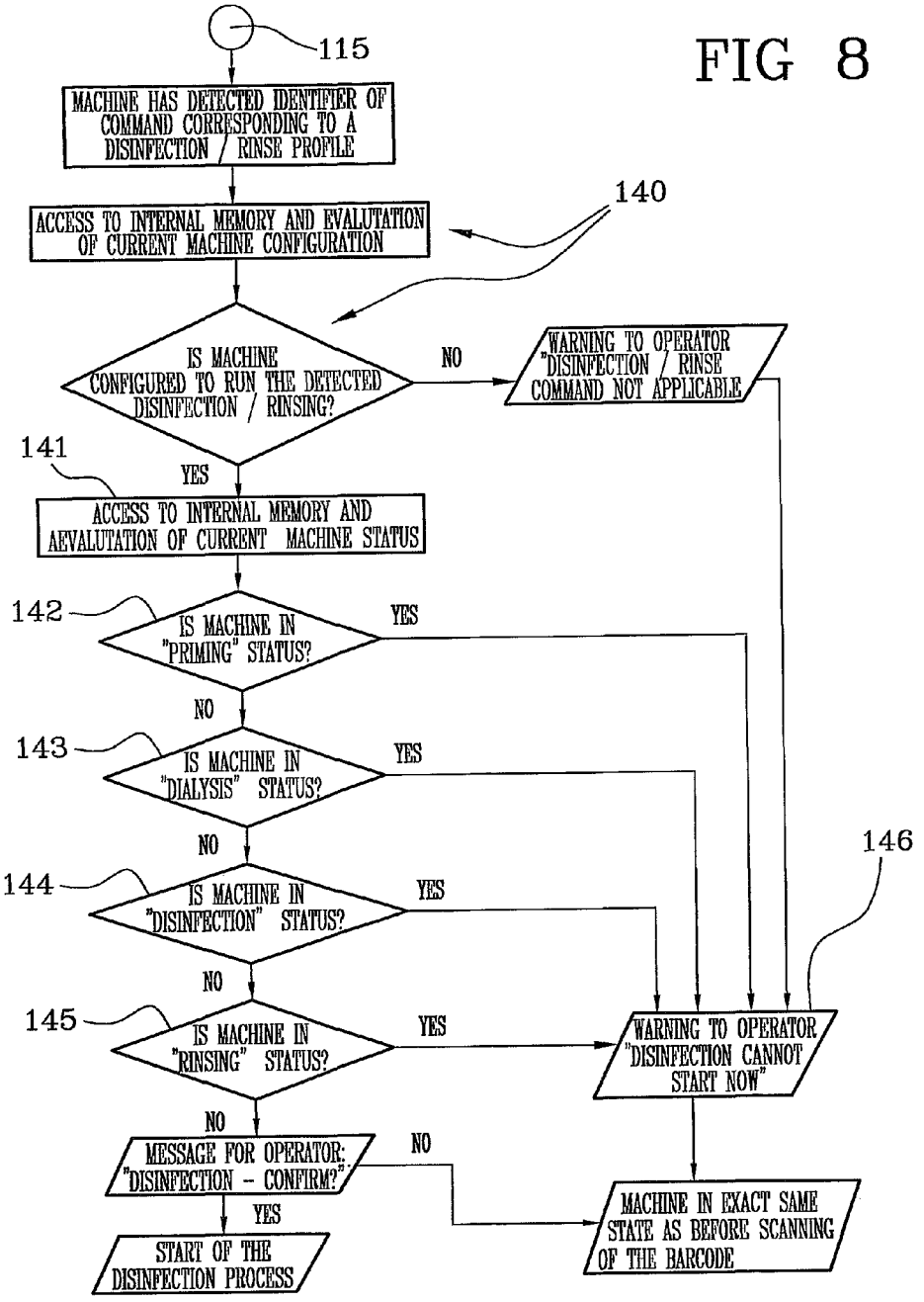

115
MACHINE HAS DETECTED IDENTIFIER OF COMMAND CORRESPONDING TO A DISINFECTION / RINSE PROFILE
140
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
IS MACHINE CONFIGURED TO RUN THE DETECTED DISINFECTION / RINSING?
NO
WARNING TO OPERATOR "DISINFECTION / RINSE COMMAND NOT APPLICABLE
141
YES
ACCESS TO INTERNAL MEMORY AND AEVALUTATION OF CURRENT MACHINE STATUS
142
IS MACHINE IN "PRIMING" STATUS?
YES
NO
143
IS MACHINE IN "DIALYSIS" STATUS?
YES
NO
144
IS MACHINE IN "DISINFECTION" STATUS?
YES
NO
146
145
IS MACHINE IN "RINSING" STATUS?
YES
WARNING TO OPERATOR "DISINFECTION CANNOT START NOW"
NO
MESSAGE FOR OPERATOR: "DISINFECTION - CONFIRM?"
NO
YES
START OF THE DISINFECTION PROCESS
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE

FIG 9

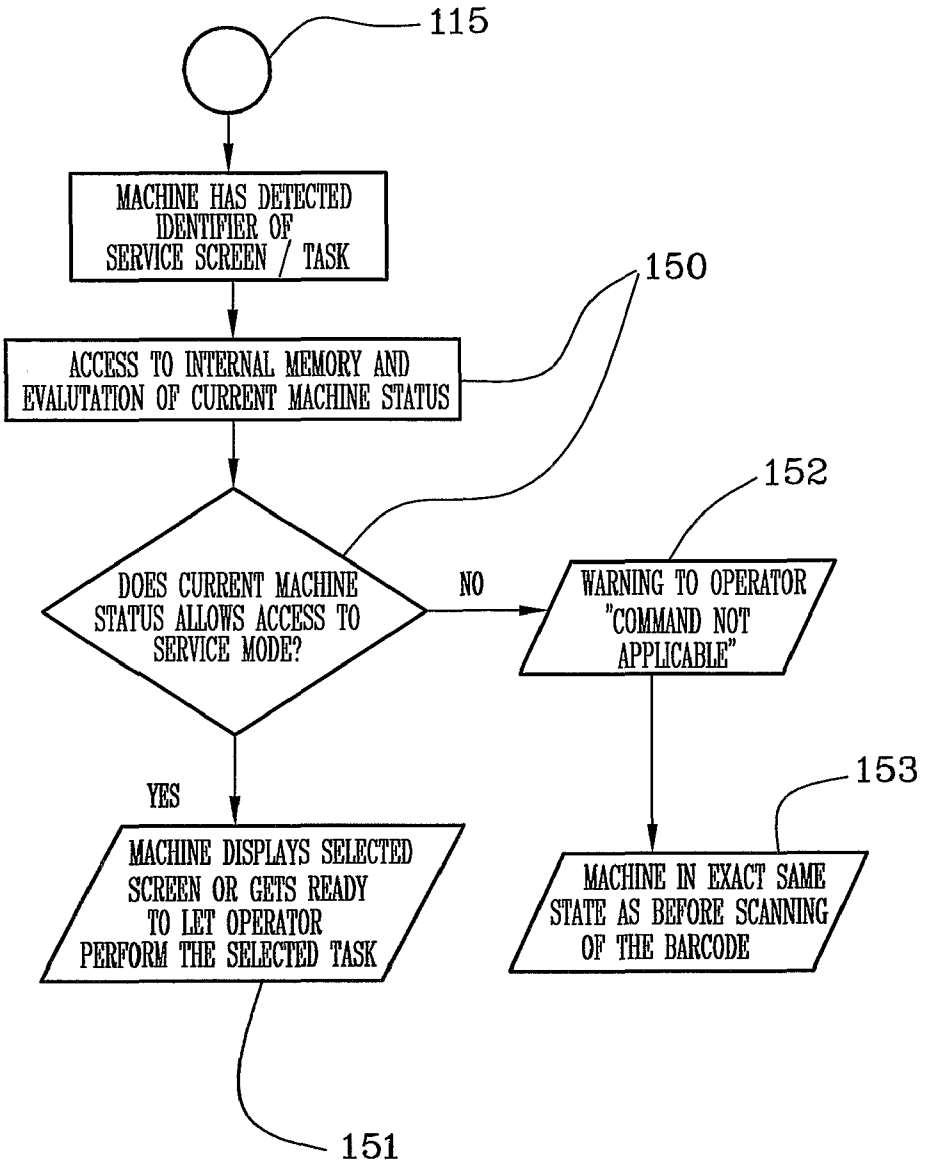

115
MACHINE HAS DETECTED IDENTIFIER OF SERVICE SCREEN / TASK
150
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
152
DOES CURRENT MACHINE STATUS ALLOWS ACCESS TO SERVICE MODE?
NO
WARNING TO OPERATOR "COMMAND NOT APPLICABLE"
153
YES
MACHINE DISPLAYS SELECTED SCREEN OR GETS READY TO LET OPERATOR PERFORM THE SELECTED TASK
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE
151

FIG 10

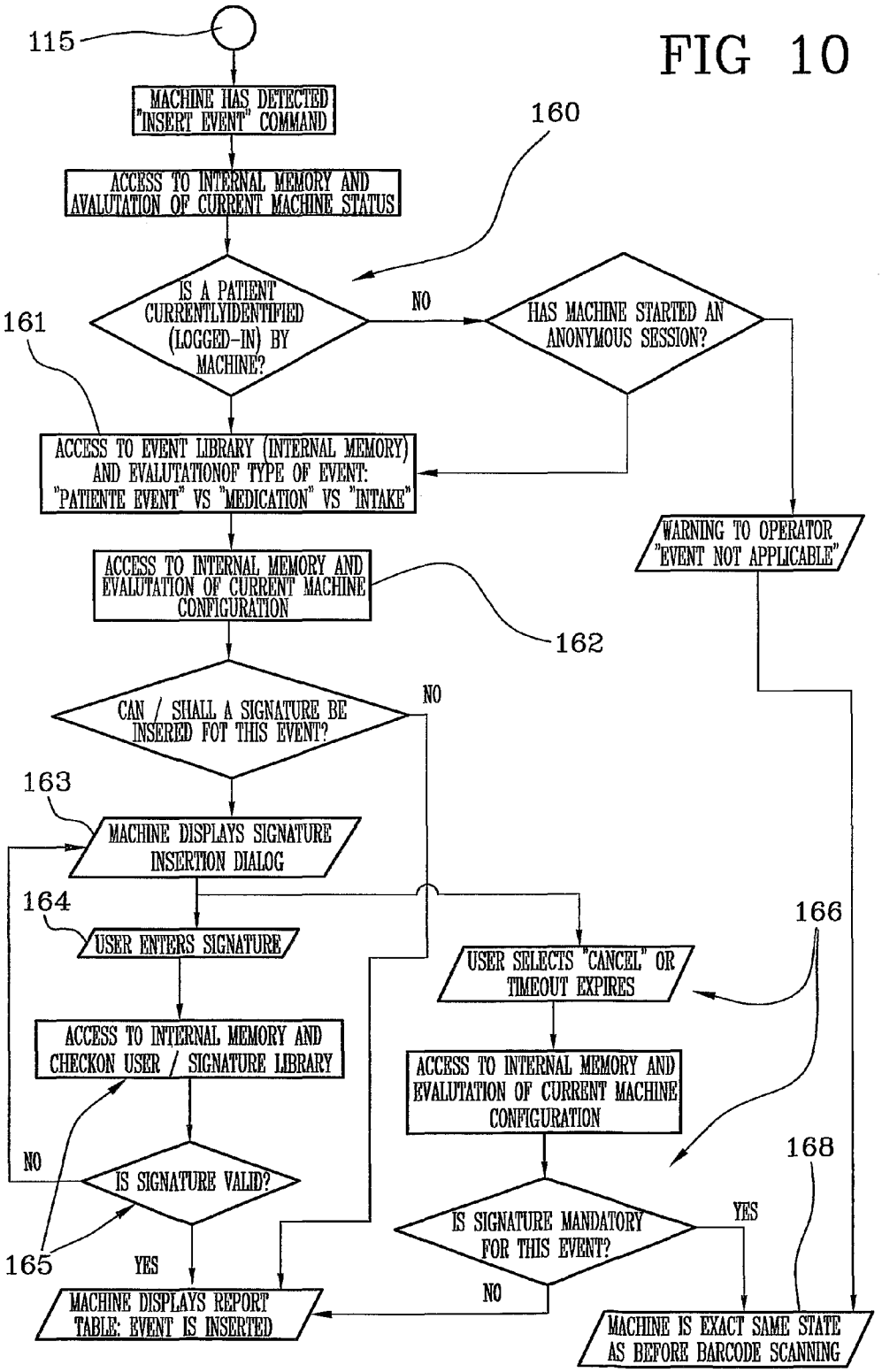

115
MACHINE HAS DETECTED "INSERT EVENT" COMMAND
ACCESS TO INTERNAL MEMORY AND AVALUTATION OF CURRENT MACHINE STATUS
160
IS A PATIENT CURRENTLYIDENTIFIED (LOGGED-IN) BY MACHINE?
NO
HAS MACHINE STARTED AN ANONYMOUS SESSION?
161
ACCESS TO EVENT LIBRARY (INTERNAL MEMORY) AND EVALUTATIONOF TYPE OF EVENT: "PATIENTE EVENT" VS "MEDICATION" VS "INTAKE"
WARNING TO OPERATOR "EVENT NOT APPLICABLE"
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
162
CAN / SHALL A SIGNATURE BE INSERED FOT THIS EVENT?
NO
163
MACHINE DISPLAYS SIGNATURE INSERTION DIALOG
164
USER ENTERS SIGNATURE
166
USER SELECTS "CANCEL" OR TIMEOUT EXPIRES
ACCESS TO INTERNAL MEMORY AND CHECKON USER / SIGNATURE LIBRARY
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
168
NO
IS SIGNATURE VALID?
IS SIGNATURE MANDATORY FOR THIS EVENT?
YES
165
YES
NO
MACHINE DISPLAYS REPORT TABLE: EVENT IS INSERTED
MACHINE IS EXACT SAME STATE AS BEFORE BARCODE SCANNING

FIG 11

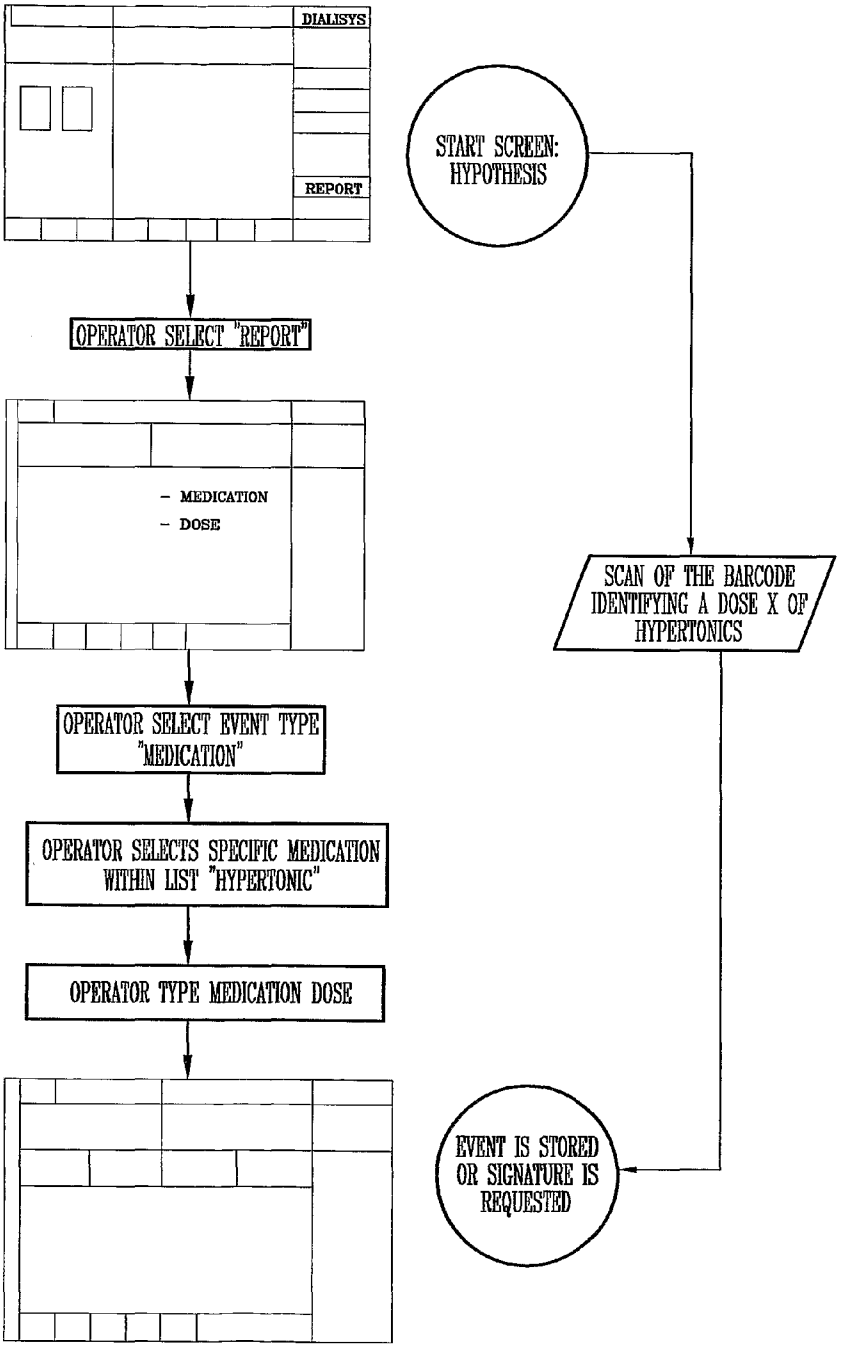

DIALISYS
REPORT
START SCREEN: HYPOTHESIS
OPERATOR SELECT "REPORT"
- MEDICATION
- DOSE
SCAN OF THE BARCODE IDENTIFYING A DOSE X OF HYPERTONICS
OPERATOR SELECT EVENT TYPE "MEDICATION"
OPERATOR SELECTS SPECIFIC MEDICATION WITHIN LIST "HYPERTONIC"
OPERATOR TYPE MEDICATION DOSE
EVENT IS STORED OR SIGNATURE IS REQUESTED

FIG 12

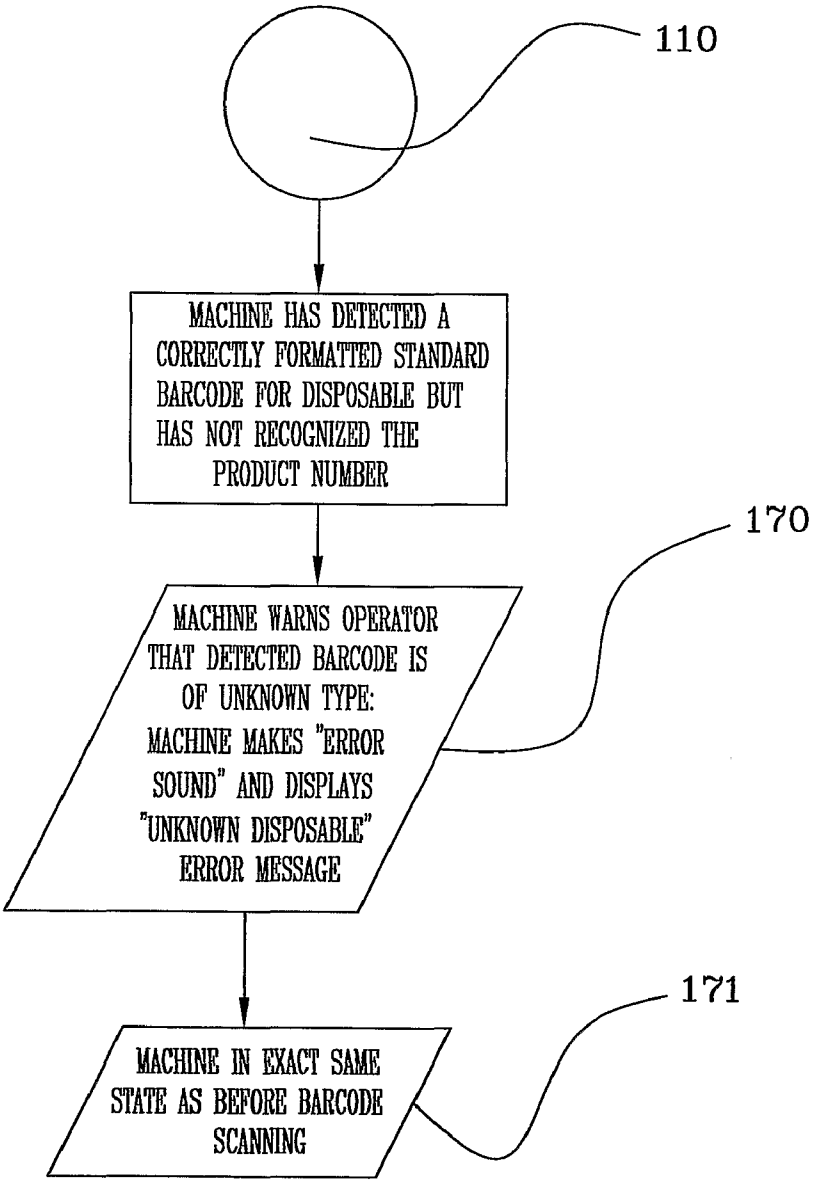
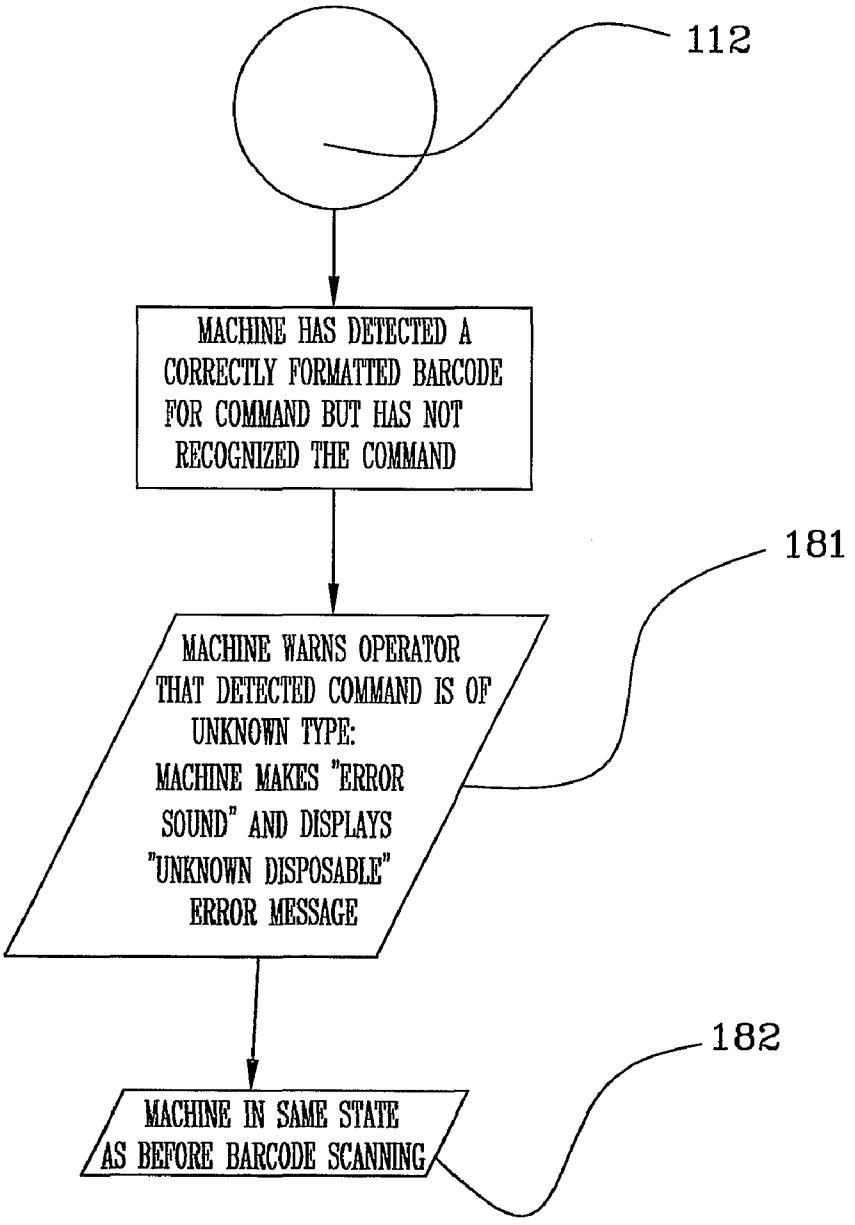
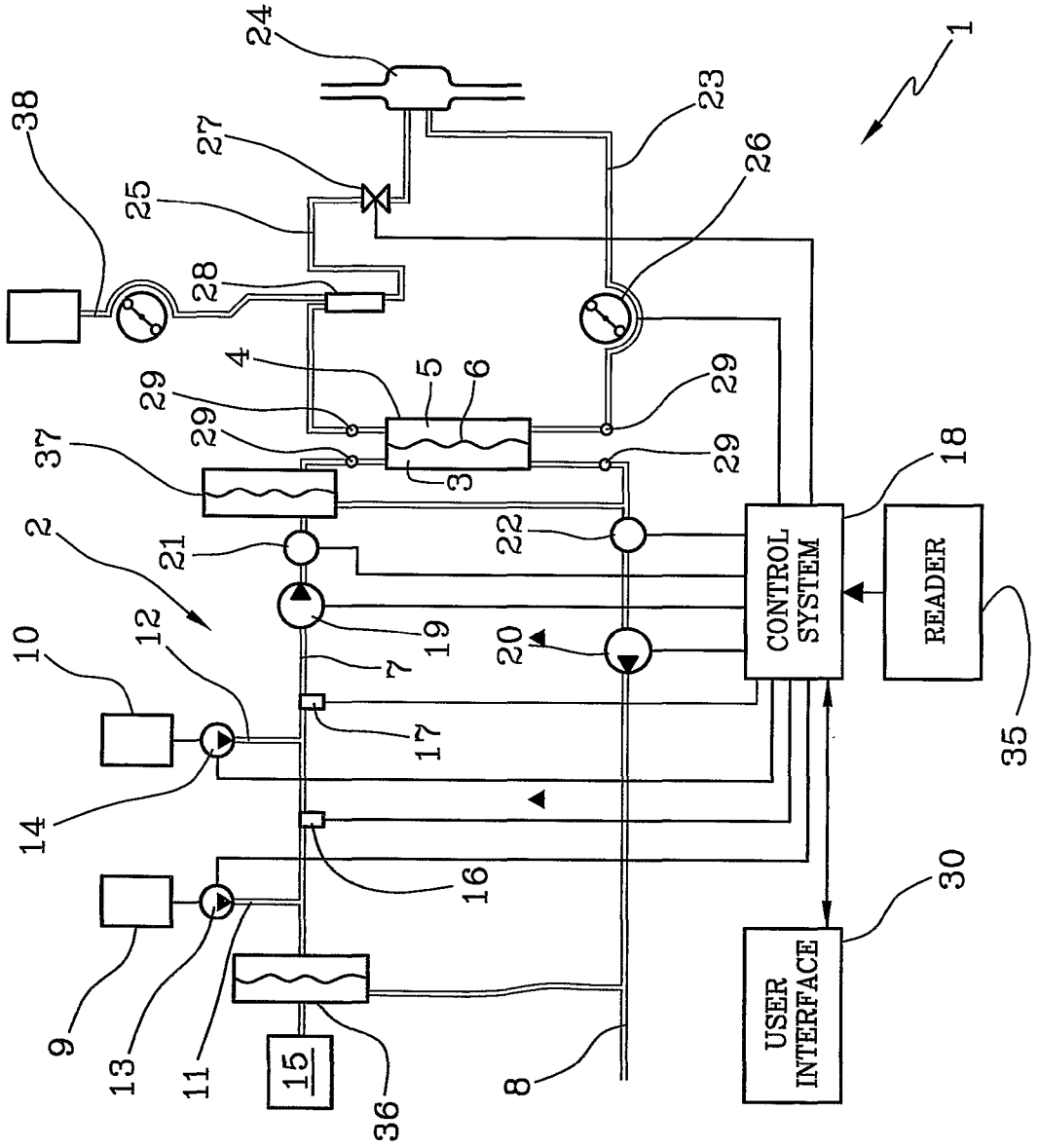

110
MACHINE HAS DETECTED A CORRECTLY FORMATTED STANDARD BARCODE FOR DISPOSABLE BUT HAS NOT RECOGNIZED THE PRODUCT NUMBER
170
MACHINE WARNS OPERATOR THAT DETECTED BARCODE IS OF UNKNOWN TYPE: MACHINE MAKES "ERROR SOUND" AND DISPLAYS "UNKNOWN DISPOSABLE" ERROR MESSAGE
171
MACHINE IN EXACT SAME STATE AS BEFORE BARCODE SCANNING

FIG 13


112
MACHINE HAS DETECTED A CORRECTLY FORMATTED BARCODE FOR COMMAND BUT HAS NOT RECOGNIZED THE COMMAND
181
MACHINE WARNS OPERATOR THAT DETECTED COMMAND IS OF UNKNOWN TYPE: MACHINE MAKES "ERROR SOUND" AND DISPLAYS "UNKNOWN DISPOSABLE" ERROR MESSAGE
182
MACHINE IN SAME STATE AS BEFORE BARCODE SCANNING


1
2
3
4
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7
8
9
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11
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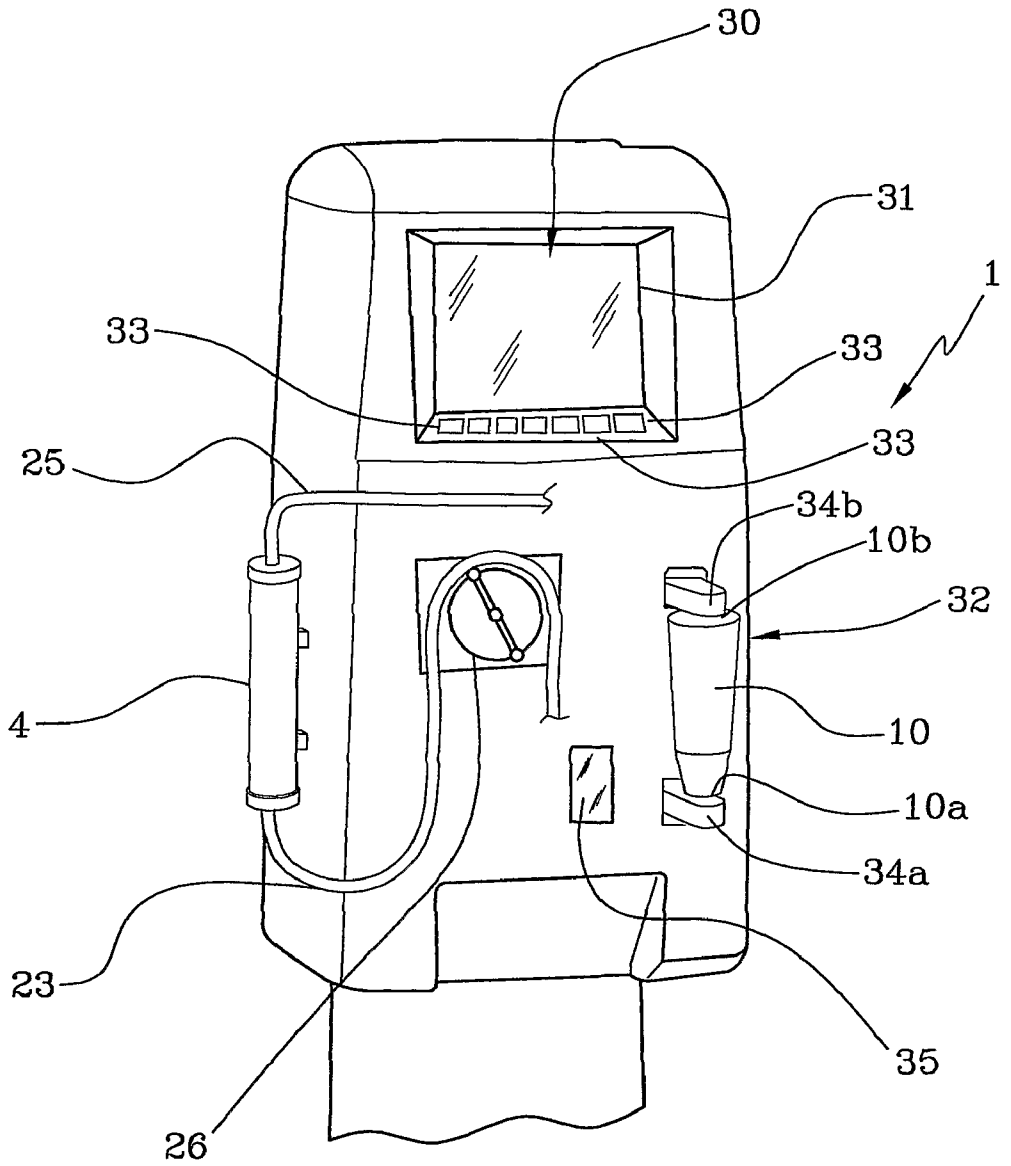
29
30
35
36
37
38
CONTROL SYSTEM
READER
USER INTERFACE

FIG 14

FIG 15



FLUID PROCESSING MEDICAL APPARATUS AND METHOD FOR SETTING-UP A FLUID PROCESSING MEDICAL APPARATUS

FIELD OF THE INVENTION

The invention relates to a fluid processing medical apparatus such as an extracorporeal blood treatment apparatus for performing one or more of the following treatments: ultrafiltration, hemodialysis, hemodiafiltration, hemofiltration, plasmapheresis, oxygenation, or other procedures on whole blood or on blood components, such as separation or collection of blood or blood components. The invention also concerns a method for setting-up a fluid processing medical apparatus.

BACKGROUND OF THE INVENTION

Blood processing apparatus such as extracorporeal blood treatment machines comprise a number of components which have a use limited in time or in the number of use cycles. In the present specification, the following definitions assume the meaning below indicated:

- disposables are those components which can be associate to the processing apparatus for the duration of a single procedure or treatment (i.e. single use components)
- semi-disposables are those components which can be associate to the processing apparatus for the duration of a limited number of procedures or treatments (i.e. components designed to be used a limited number of times).

Depending upon the situations, components such as filters (hemo-dialyzers, hemo-filters, ultrafilters and the like), solutions bags, containers hosting liquids or powders for preparation of treatment liquids, tubing sets, extracorporeal blood circuits, integrated modules including a number of the components just mentioned could be used as disposables or semi-disposables.

Before the medical apparatus, e.g. a blood treatment machine, has to execute a treatment session, the operator shall setup the machine and install all appropriate disposable components suitable for running the selected treatment procedure. The operator also checks if one or more semi-disposable components need to be changed.

Referring for instance to a blood treatment for treating patients suffering from kidney failure, before any procedure starts the operator should normally install the filter, the bloodlines, the access devices adequate for the treatment session. The operator also installs the appropriate concentrates and solutions to be used during the treatment, checks and/or changes the ultrafilters in the liquid preparation circuit (in case on-line liquid preparation is selected).

For the purpose of disclosure of the present invention disposables and semi-disposable components are hereinafter globally referred to as replaceable components.

As it can be easily understood the blood treatment apparatus shall be properly instructed as to which specific replaceable components are installed because each component has specific properties which may affect the working of the apparatus and the direct or indirect delivery to the patient of substances.

During the past years, in order to facilitate setup procedures, those replaceable components to be mounted on the treatment apparatus have been provided with indicia (such as bar codes, color codes, microchips, RFID devices, mechanical keys, etcetera) secured to the component and detectable by a respective appropriate reader associated to the treatment apparatus to provide the apparatus at least with an information relating to the identity of the same component.

Here below the technical solutions which the applicant regards as relevant are described.

A first solution is disclosed in WO80-02376 which describes a hemodialysis system using disposables tubing and filter having optical or magnetic coding indicia on a strip. The strip can be coded to match a specific program or procedure, and the system can be constructed or programmed to generate a signal should the module and the program in the system not correspond.

U.S. Pat. No. 5,769,811 shows a blood processing machine and disposable units for use therewith. The disposable units generally comprise a centrifuge bowl for separating whole blood into blood constituents, an inlet tube for conveying blood into the bowl, an outlet tube for conveying the blood constituents away from the bowl, and a manifold for placing the inlet tube and the outlet tube in fluid communication with a tube from a donor. The manifold has a machine-readable bar-code label for identifying to the blood processing machine which type of disposable unit is being coupled to it. The machine itself comprises a central processing unit that controls overall operation, a first computer memory containing safety-monitoring instructions that cause the central processing unit to monitor various state parameters in order to ensure donor safety, and a second computer memory containing instructions that define at least one apheresis or blood-processing protocol. In some implementations, the second computer memory is removable from and insertable into the blood processing machine by an operator.

U.S. Pat. No. 6,626,355 discloses a medical apparatus comprising an accessory port and at least one accessory piece comprising a connection element complementary to said accessory port; the connection element includes a storage unit where coded and/or un-coded information is stored, is read by means of a readout unit disposed in the section of said accessory port, and is compared to identification information stored in readout unit; the medical device is activated when the identification information match the desired identification information, and is blocked when the identification information do not match. Coded identification information is decodable by means of a proprietary key.

EP1170023 concerns a hemodialysis machine comprising at least one semi-permanent component, such as an ultrafilter for use in the online preparation of dialysis liquid. The component is changed periodically after being used for several consecutive dialysis treatments; the machine comprises a bar-code reader for identifying the semi-permanent components thus unequivocally identifying the semi-permanent component mounted on the machine, and communicating its presence and identity to said control unit in the machine.

U.S. Pat. No. 6,685,831 discloses a dialysis machine with a device for preparing dialysis solutions. Preparation of dialysis fluids of different concentrations is achieved by the fact that the device has a detector device, at least two connections and at least two interchangeable storage containers to hold the solution ingredients to be metered. Each container is connected to at least one connector, and the connectors are connectable to the connections; the connectors or the areas of a connecting tube near the connectors have identification means which can be detected by the detector device. It is also disclosed a connector for connecting a storage container with solution ingredients to a medical apparatus, where the connector or areas of a connecting tube near the connector has identification means. Detecting a connection of a solution ingredient storage container is guaranteed by the fact that the connector is provided with identification means and is attached to a matching component, and a reader unit determines the type and position of the connector.

WO01/41831 discloses a hemofiltration machine including a chassis, at least one flow controlling element on the chassis, and a controller for the hemofiltration machine to operate the flow controlling element to carry out a processing task in response to a control program, the controller including an input on the chassis for reading coded indicia, an extracorporeal circuit for circulating blood from an individual through a hemofilter, and a fluid processing cartridge holding the extracorporeal circuit for mounting as an integrated unit on the chassis in operating engagement with the flow controlling element and for removal as an integrated unit from the chassis, the fluid processing cartridge carrying coded indicia incorporating a control program for the controller, the coded indicia being readable by the input in response to mounting the fluid processing cartridge on the chassis, to thereby transfer the control program to the controller for execution. Document WO2004033024 shows a medical-technical identification device for identifying a sterile product for example a product intended for one-time-use only, when connected to a piece of medical equipment. The sterile product includes a fixedly mounted information carrier which is adapted to deliver or to offer specific product information in a contactless fashion to a reading element connected to the equipment.

U.S. Pat. No. 5,658,456 describes a dialysis apparatus having a dialysate preparation module and a tank for storing a dialysate solution, for performing automatic verification of dialysate chemicals prior to adding said chemicals to said dialysate preparation module so as to insure correct preparation of said dialysate solution, comprising: an electronic reader of a machine-readable indicator, said electronic reader incorporated into said dialysis machine; a bottle containing a unit batch of dialysate chemicals for treatment of a medical condition of a patient to be treated by said dialysis machine, said bottle adapted to be installed on an opening apparatus in said machine such that, when said bottle is opened, said dialysate chemicals are placed in fluid communication with said tank for delivery of said unit batch of dialysate chemicals automatically into said tank; and a machine-readable indicator containing coded information (ID,LOT,DATE) as to said dialysate chemicals contained in said bottle, said machine-readable indicator applied to said bottle in a manner for permitting machine identification of the contents of said bottle by said electronic reader prior to operating the opening apparatus to open said bottle and adding said dialysate chemicals to said tank, whereby machine identification of said dialysate chemicals contained in said bottle may occur prior to introduction of said chemicals into said tank.

SUMMARY OF THE INVENTION

While numerous solutions have been provided, the applicant has envisaged a new method and a new apparatus which are suitable for further improving machine setup and data entry of information when replaceable components are used.

Indeed, according to the technical solutions of the prior art, the treatment apparatus had a respective reader located in correspondence of the position where the disposable or semi-disposable article is expected to be mounted on.

This situation renders impossible accessing the reader while a disposable or semi-disposable is already installed.

Moreover in case a plurality of disposable or semi-disposable components have to be installed in different locations of the apparatus, then a corresponding number of readers would be required.

Furthermore the reader of replaceable devices ID according to the prior art is only used for a single purpose and cannot be relied on for entering commands or other data into the medical apparatus.

In view of this situation it is a goal of the present invention to provide a fluid processing medical apparatus and method for transferring data to a fluid processing medical apparatus capable of enhancing setup procedures and, more in general, transfer of data to the medical apparatus.

It is a further object of the invention to reduce the number of readers to be present on the medical apparatus side without impairing on the ease and data entry reliability.

The above aims are reached by a method for setting-up a fluid processing medical apparatus, the apparatus being of the type comprising:

a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus, at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen, the method comprising the following steps:

- providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,
- reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,
- coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

According to an aspect of the invention, after the reading step it is provided a step of verifying if the new component is of the same category of a component already installed on the machine. In other words if for instance the new component is a concentrate container, such as a bicarbonate cartridge, the method provides for checking if a bicarbonate cartridge was already installed on the apparatus. In practice the verifying step can be done by checking if a component having the same category of the new component has been already read before and/or by checking if a component is engaged with the engaging means of the type adapted to receive the new component.

The steps of reading and verifying can be repeated every time a new component is to be coupled to the apparatus.

The replaceable components are a plurality of components of different categories (by way of non limiting example a plurality of filters, a plurality of concentrate cartridges, a plurality of bloodlines, etcetera), where each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories. The medical apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only.

In an embodiment, the method includes the sequential steps of:

- signaling that a component of the same category is already installed on the apparatus
- requesting for confirmation to substitute the installed component with the new component,

initiating a procedure for substitution of the installed component with the new component.

According to a further aspect of the invention, for instance before coupling each new component to the apparatus, the method provides for:

selecting a desired treatment procedure (for instance in case the apparatus is a blood treatment machine, the method provides for selecting among a plurality of treatments such as hemofiltration, ultrafiltration, hemodiafiltration, hemodialysis etcetera),

checking if the new component fits with the selected treatment procedure,

signaling if the new component does not fit with the selected treatment procedure.

While in one embodiment the information is fixed to the replaceable component, the information carrier could also be the packaging of the component or a card associated with the component.

According to a further aspect the reader can be relied on for entering commands into the apparatus by associating command information to a readable information carrier, relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus, initiating a treatment procedure complying with the entered command.

According to another embodiment the reader can be relied on for entering commands into the apparatus by associating patient data information to a readable information carrier, relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus.

In addition to the above way of entering component related information and initiating a substitution procedure of a replaceable component, the method of the invention provides for an additional and parallel procedure for installing a new replaceable component on the apparatus without interacting with said reader.

This additional procedure includes the following steps:

entering the information of a new component to be installed on the apparatus by acting on said user interface,

verifying if the new component is of the same category of a component already installed on the machine,

displaying on said screen a message informing if a component of the same category is already installed,

in case a component of the same category is already installed asking for confirmation to proceed with the substitution thereof,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

In case a component of the same category is already present the method can also provide for the following steps: moving the installed component from an operating condition to a non-operating condition where it can be safely disengaged from the apparatus, and then disengaging said component before installing the new one.

The step of entering information by acting on the user interface comprises the steps of:

Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component (this can be done with a navigation keyboard or keypad either part of the screen or external, which allows the user to navigate through various displays stored in the memory of the user interface control system),

Selecting the desired display of the user interface,

Selecting the new component to be installed by acting on said selected display.

The user interface can also be used to enter commands without acting on said reader and/or to enter patient related information again without acting on said reader.

The above specified aims are also reached by a fluid processing medical apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus.

In practice the control system includes means for controlling the apparatus operation (a network of sensors, actuators and connections not further detailed as their nature is not relevant for the purpose of present invention), means for receiving and storing information coming from and/or going to the user interface and means for receiving and storing information coming from the reader (i.e. wired or wireless connections to the reader, a control processing unit of digital or analogical type and a memory).

In one embodiment the control system is programmed (i.e. comprises means in the form of an analogical circuit portion or in the form of a suitably programmed digital processor) for verifying if the new component is of the same category of a component already installed on the apparatus. The above steps of reading and verifying can be automatically repeated anytime the reader reads information of a new component to be installed. In one embodiment the step of verifying includes determining the category of the new component, and/or checking if a component of the same category was detected before, and/or checking if a component is engaged with the engaging means of the type adapted to receive the components of the category of the new component.

The replaceable components are a plurality of components of different categories (by way of non limiting example a plurality of filters, a plurality of concentrate cartridges, a plurality of bloodlines, etcetera), where each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories. The medical apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only.

According to one aspect of the invention, the control system is also programmed (i.e. comprises means in the form of

an analogical circuit portion or in the form of a suitably programmed digital processor) for sequentially executing the following steps:

- signaling that a component of the same category is already installed on the apparatus,
- requesting for confirmation to substitute the installed component with the new component,
- initiating a procedure for substitution of the installed component with the new component.

In accordance with a further aspect of the invention, the control system is programmed for executing the following steps:

- receiving selection of a desired treatment procedure,
- checking if the new component fits with the selected treatment procedure,
- signaling if the new component does not fit with the selected treatment procedure,
- allowing the step of coupling the new component with the apparatus only after the step of checking if the new component fits with the selected treatment procedure.

According to an embodiment of the invention, the information comprises one or more selected in the group including:

- Identity of the component,
- Identity of a series of identical components (this can happen in case a series of component shares same identical characteristics),
- Expiration date of the component,
- Manufacturer,
- One or more commands for programming the apparatus to execute a procedure on said fluid,
- Data concerning a patient (pressure measures made before treatment, prescription, personal information)

The information carrier is one selected in the group comprising: a surface of the component, a packaging of the component, a card associated with the component.

The apparatus of the invention can also have the control system programmed for receiving commands for carrying out a corresponding procedure on said fluid and/or patient data by reading corresponding information associated to a readable information carrier which is approached to the reading portion.

In addition to the reader, the control system can also be programmed for executing an additional procedure for installing a new replaceable component on the apparatus without interacting with said reader, the additional procedure comprising the steps of:

- allowing to enter information of a new component to be installed on the apparatus by acting on said user interface,
- verifying if the new component is of the same category of a component already installed on the machine,
- displaying on said screen a message informing if a component of the same category is already installed,
- coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

The step of allowing entering information by acting on the user interface can comprise the steps of:

- Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component,
- Allowing selecting the desired display of the user interface,
- Allowing selecting the new component to be installed by acting on said selected display.

In practice the reader used in the invention can be any optical reader (bar code reader, or color code reader, or reader of any optically detectable shape and/or pattern) or a radio-frequency reader (RFID reader) or magnetic reader (reader of magnetic strips) or any other equivalent reader adapted to detect said information when the component and the reading portion are approached one another (in contact or in proximity).

Further characteristics and advantages will better emerge from the following description in relation to some preferred but non-limiting embodiments of the invention.

SHORT DESCRIPTION OF THE DRAWINGS

Referring now to the enclosed figures several methods and corresponding apparatus will be described with reference, again by way of non limiting example, to replaceable components adopted in blood treatment apparatus.

The description will be made with reference to the figures of the accompanying drawings, also provided by way of non-limiting example, in which:

FIG. **1** is a block diagram showing the steps of the main flow of process executed by the control system of the apparatus of FIG. **14** when the reader of the apparatus of FIG. **14** reads information concerning a replaceable component or concerning a command;

FIG. **2** a block diagram showing the process followed after the steps of FIG. **1** by the control system of the apparatus of FIG. **14** when reading a concentrate related information via the reader;

FIG. **3** is a block diagram showing the steps performed by a user for changing a concentrate container using the apparatus of FIGS. **1**, **2** and **14**;

FIGS. **4** and **5** show the process followed after the main flow of FIG. **1** by the control unit of the apparatus of FIG. **14** when respectively a dialyzer or a bloodlines code;

FIG. **6** is a block diagram showing the process followed control system **18**, after the main flow steps of FIG. **1**, when a disinfection procedure is initiated upon a code of a disinfectant is read;

FIG. **7** is a block diagram showing the steps performed by a user for initiating a disinfection procedure;

FIGS. **8-10** show the procedure followed by the control system **18** of apparatus of the invention when using the reader for entering commands, such as by way of non limiting examples: DISINFECTION, RINSE or SERVICE COMMAND;

FIG. **11** a block diagram showing the steps performed by a user for inserting an event command when using the reader and when using the user interface **30**, and

FIGS. **12** and **13** are block diagrams showing the steps performed by the control system after the main flow of FIG. **1** if respectively the code is neither recognized as a known replaceable component nor as a known command;

FIG. **14** is a schematic view of the circuits of a blood treatment apparatus provided with a reader for reading information relating to replaceable components, according to the invention;

FIG. **15** is a schematic elevation of the blood treatment machine of FIG. **14**.

DETAILED DESCRIPTION OF NON-LIMITING EMBODIMENTS

With reference to the enclosed figures, reference numeral **1** indicates a fluid processing medical apparatus according to an embodiment of the present invention.

The apparatus **1** of the non limiting embodiments herein described is an extracorporeal blood treatment machine for the treatment of pathologies such as kidney failure, liver failure, or congestive heart failure. While for sake of clarity and conciseness, the invention will be explained in detail with reference to an extracorporeal blood treatment machine, the invention could find application in other fluid processing apparatuses such as machines for processing whole blood or blood components coming from a donor or from a source (such as one or more containers), machines for blood oxygenation, machines for the cleaning or purification of water for medical use, machines for the preparation of medical fluids, machines for the delivery of medical fluids (infusion devices or drug administration machines), etcetera.

Going back to the embodiment of the attached figures, the apparatus **1** is an extracorporeal blood treatment machine able to perform one or more of the following extracorporeal blood treatments: ultrafiltration, dialysis, hemofiltration, and hemodiafiltration.

The apparatus **1** according to the embodiment of the drawings mainly comprises:

- A hydraulic circuit **2** for fresh treatment liquid, such as dialysis liquid, which in use is to be sent into a first chamber **3** of a blood treatment unit, **4** and/or infusion liquid, which in use is to be sent into the patient. The hydraulic circuit is responsible for bringing the treatment liquid to the treatment unit and/or directly to the patient with appropriate chemical and physical properties. The hydraulic circuit is also responsible for evacuating waste fluid from the blood treatment unit.
- A blood treatment unit **4** comprising at least a casing defining at least two chambers **3**, **5** separated by a semipermeable membrane **6**.
- Bloodlines **23**, **25** connected to the second chamber of the blood treatment unit.
- A cabinet structure **32** housing the hydraulic circuit **2** and supporting, during treatment, the treatment unit **4** and the bloodlines **23**, **25**.
- A user interface **30** which is typically mounted on a front panel of the cabinet structure, but which could alternatively be in the form of an independent unit, separate from the cabinet.

The circuit **2** includes at least a supply conduit **7**, bringing dialysis liquid to the first chamber inlet, and a waste conduit **8**, receiving spent liquid exiting via an outlet of the first chamber. One or more concentrate sources of concentrates could be present. The concentrate sources could be designed to include containers for housing concentrated solutions or dry concentrates. In the enclosed embodiment containers **9**, **10** deliver concentrated solutions, via respective lines **11**, **12** and upon the action of respective concentrate pumps **13**, **14**, into the conduit **7** thereby properly mixing water coming from a source **15** with said concentrates and obtaining the dialysis liquid. In the machine of the enclosed embodiment one of the two containers, for instance container **10**, is a dry concentrate cartridge. While not shown in the drawings, cartridge **10** is also connected, upstream line **12**, to a source of water or of solution directly or indirectly coming from source **15**. Conductivity or concentration sensors **16**, **17** can be provided on conduit **7** downstream each respective concentrate line. Said sensors provide control signals to a control system **18** which is responsible to act on the concentrate pumps based on desired concentration settings and on said control signals. Sensors (not shown) detecting conductivity or concentration of electrolytes can also be present on the waste conduit **8**. A pump **19** is generally operating on supply conduit **7** and a pump **20** on the waste conduit **8**. Of course different alternative embodiments can be envisaged to bring dialysis liquid to the treatment unit with appropriate chemical and physical properties. For instance pre-prepared dialysis liquid bags or containers could be used, with no need of online preparation of liquid from concentrates and water.

Fluid balance sensors, for instance a first and a second flow-meter **21**, **22**, operating on the supply conduit **7** and on waste conduit **8** respectively, are used and are connected to the control system to provide signals necessary for regulating at least one of pumps **19**, **20**. Of course other fluid balance systems can be used: scales for instance or balance chambers or any other volumetric or mass or flow-rate based system available to the skilled man.

One or more ultrafilters could operate in the hydraulic circuit, upstream the treatment unit **4**. For instance in the enclosed embodiment one ultrafilter **36** is present upstream concentrate line **11** and one ultrafilter **37** is placed downstream all concentrate lines **11** and **12**.

The blood treatment unit **4** comprises at least a casing defining at least two chambers **3**, **5** separated by a semipermeable membrane **6**. The properties and type of membrane can vary depending upon the patient's needs and type of treatment to be executed: in particular the treatment unit could be an ultrafilter, an hemofilter, a dialyzer, an hemodiafilter, a plasmafilter etcetera.

The bloodlines **23**, **25** connected to the second chamber of the blood treatment unit comprise an arterial branch **23**, which in use serves to withdraw patient's blood to be treated, and a venous branch **25**, which in uses serves to return treated blood to the patient.

The user interface **30** herein disclosed is connected with and part of the medical apparatus **1**; however the user interface could be a self powered unit with wired or wireless connection to the control unit of the medical apparatus.

The user interface **30** of the embodiment shown includes a screen **31**, for instance a touch screen, which allows interaction with the user interface, for instance selection of certain parameters, visualization, either in analogical or in digital form, of values of said parameters and display of other information; of course depending upon the case the user interface could include also buttons, knobs, or other hardware means **31** positioned off the screen and operable to introduce entries into the control system.

The activity of the user interface is determined by control system **18**, which is connected to the user interface, is responsive to actions by a user on said user interface, and controls operations of the medical apparatus **1** by acting on a plurality of actuators (such as pumps **12**, **13**, **19**, **20**, **27**, valve **27** and others) and by receiving signals from a plurality of sensors (such as for instance sensors **12**, **13**, **21**, **22**, **29** etc.).

The control system of presently shown embodiment includes a main control unit, connected to the user interface **30**, and at least a memory connected to the main control unit. From a technical point of view the main control unit includes at least a microprocessor, while the above-mentioned memory can be in a single physical memory or in physically separated memory devices. Of course other alternative could be equivalently adopted, such as a control system partly or totally of analogical type.

In extracorporeal blood treatment apparatus, as the one just described, as well in other medical apparatus some components are replaceable, in the sense that they are replaced more or less frequently during the life of the apparatus, according to criteria which could vary depending upon the patient, the specific component, the market where the component is used, etcetera. By way of non limiting example, referring to a dialysis machine for chronic treatment as the one just

described, the dialyzer, the blood tubing set, the access devices, the infusion lines and bags are replaced at the end of each treatment session or procedure. If a rinsing and/or priming procedure is activated using fresh liquid coming from a bag the empty bag is typically disposed of at the end of the procedure. The ultrafilters and concentrate containers used for the preparation of treatment liquid can be changed at the end of each treatment session, or after a number of sessions, or after a number of working hours.

In conclusion, with reference to the blood treatment apparatus just described, a number of components are replaceable components: the concentrate containers **10**, **11** (which can be in the form of deformable bags or rigid containers, containing concentrated either in liquid or in solid form), the bloodlines **23**, **25**, the blood treatment unit **4**, the ultrafilters **36**, **37** in the dialysis preparation circuit, any infusion lines **38**, the bags or other containers for the injection of fluids into the blood circuit or into the blood lines, the access devices (needles, catheters, or the like).

As can be easily understood, the apparatus of the type described can host and use a plurality of components of the same category: for instance the same blood treatment apparatus can alternatively use a number of different blood treatment units, or a number of alternative bloodlines, or a number of alternative concentrate containers etcetera. Typically before each treatment, an operator selects the needles, bloodlines, bags, dialyzer or other blood treatment unit, as well as other replaceable components ideal for that specific treatment. The apparatus has engaging means differentiated per type of component: for instance the ultrafilters located in the fluid preparation section of the hydraulic circuit present connectors positioned and shaped so that they cannot be engaged in place of the dialyzer; each component of the same category presents respective mechanical connections to the apparatus different from those of the components of other categories, so that each replaceable component fits with the respective connections on the machine and setup mistakes on the part of the operator are minimized.

More precisely, the means for engaging replaceable components of different categories comprises a plurality of different types of engaging means, each type of engaging means being designed for engaging, in a respective operating area, respective components of one corresponding category only. Practically all concentrate containers of the same category (for instance all bicarbonate containers) have identical connectors and engage with corresponding ports suitably shaped on the apparatus: the cartridge **10** has for instance two opposed connectors or ports **10***a*, **10***b* receivable in corresponding ports or connectors **34***a*, **34***b* of the apparatus **1**. Analogously all bloodlines are designed to engage corresponding seats on the apparatus, seats which are not suitable for hosting the concentrate containers or other components. In the same manner all blood treatment units (hemofilters, dialyzers, hemodiafilters, etcetera) form another category and have connector or ports designed to couple with a corresponding engaging means (which can include tubular ports and or counter-connectors other support mechanisms to hold in place the unit **4**) on the support structure of the apparatus.

Before using the described apparatus, a user should prepare it for the specific treatment to be delivered. The user should install all replaceable components: put in place the bloodlines, the treatment unit, the various concentrate containers, substitute the ultrafilters if necessary, install all necessary bags and infusion lines. Then a priming process is started to clean, rinse and to remove air from all components which are expected to enter in contact with blood or with treatment liquid.

In view of this situation it is fundamental when setting the machine to inform the machine about the specific components that have been mounted as the procedures or treatments that the machine can deliver are in general related to the components used. In order to enter setup information, the user can enter data of any kind relying on the user interface: for instance, prescription data, treatment selection information, and of course data relating to the components installed on the machine.

As it will be explained in detail the user can navigate through the various levels or menus of the user interface **30** and select or enter the information corresponding to each replaceable component installed on the machine.

In order to facilitate the data entry process, a reader **35** is provided operatively connected with the control system **18** and having a reading portion for reading information concerning the components. Each replaceable component is associated to a respective information; the information is borne by the respective component (i.e. on a label or directly on the component) or by the respective component packaging or by a card or other support; the nature of the reader is such that to read the information it is necessary approaching to one another the component and the reading portion (depending upon the nature of the reader, which could be an optical reader such as a linear or bi-dimensional bar code reader, an radio based reader such as RFID reader, a mechanical reader, or a reader of other nature, the user will need to approach more or less the information support to the reading portion or even put reader and information support into contact). In accordance with one aspect of the invention the information carrier and the reading portion should either be put into reciprocal contact or relatively approached at a distance in the range of 30 cm or less.

The reader can be fixed to the apparatus support structure or be in the form of a movable reader connected to the apparatus control unit via wires or wireless.

In any case the reading portion of the reader is always operating in a position distinct and spaced from said operating areas where the replaceable components are expected to operate in use conditions. In this way, the reading portion is accessible for reading the information irrespective of the components being engaged or not to the apparatus.

Going now to the specific embodiments of the attached figures, FIG. **1** discloses in form of block diagram the steps followed by the control system. As mentioned the control system can include a microprocessor based control unit which is suitably programmed to execute the steps here below disclosed. Alternatively the control system can be an analogical system which is designed to carry out the steps as below described. In any case the control system by way of intrinsic design or by way of a suitable program includes means for performing the steps below described.

While it will not be repeated for each step in below description it is intended that the control system is programmed for, or includes means for, performing each one of below steps. These means included in the control systems can be suitably designed analogical circuit portions or programmed digital circuits of a control processing unit.

Referring to FIG. **1** the control system receives the scanned code, for instance a barcode, from the reader **1** (step **100**). The control system communicating with the reader is programmed for receiving the information concerning the components: in practice, every time a new component is approached to the reader (or the reader to support bearing the component information) sufficiently for the reader to read information concerning a component to be installed on the apparatus, then said read out information is transferred to the

control system **18**. The control system then verifies if the syntax of the scanned code satisfies predefined criteria (step **101**) and in the negative generates and error signal (which can be audible and/or displayed on the screen **31**), as per step **102**.

The control system can also generate an acknowledgement message and/or sound, when on the other hand the barcode syntax is correct (step **103**).

Then the control system verifies if the scanned code corresponds to a code of replaceable component (step **104**) and in the affirmative decodes the product number (step **105**), for instance by comparing it with a list of numbers stored in the control system memory (step **107**).

In the negative, the control system decodes the command number (step **106**), for instance by comparing it with a list of numbers stored in the control system memory (step **108**). In practice, depending as to whether the code corresponds to a component or to a command the control system follows one of the two branches of the diagram of FIG. **1**.

If the control system has detected a code of a component, then the identity of said component is searched in the library present in the control system memory and first the category of the component is identified (step **109**) and a corresponding procedure initiated (step **113**); if a component category, is not identified a corresponding audible and/or displayable signal is generated (step **110**).

If the control system detects a command code, in step **111** the control system verifies if the command is known or not. In the latter case a audible and/or displayable signal is generated (step **112**). If the command code is recognized as one of the known commands, the type of command is detected (step **114**) and a corresponding procedure initiated (step **115**).

In case for instance the control system has detected a component code corresponding to a concentrate, then the procedure and steps of FIG. **2** is followed. If the control system has detected a component code corresponding to a dialyzer, then the procedure and steps of FIG. **4** is followed. If the control system has detected a component code corresponding to a bloodline, then the procedure and steps of FIG. **5** is followed. Of course component of other categories could be encompassed with slightly different procedures followed by the control system depending upon the category of the component.

In FIG. **2**, after the step **113**, the control system verifies that the number is that of a concentrate, checks expiration date or other validity parameters (step **120**), and warns accordingly the operator through audible and/or visual signals (step **121**). The control system verifies then if the machine setup or configuration requires the detected type of concentrate (step **122**) and in the negative warns accordingly the operator through audible and/or visual signals (step **123**)

The control system also verifies the status of the apparatus in order to detect if the new component the code of which has been just read is of the same category of a component (same dry concentrate for instance) already installed on the machine (step **124**). In the affirmative the control unit is also programmed for signaling that a component of the same category is already installed on the apparatus. If the control unit verifies that a component of the same category as the one read by the reader, then the control unit is programmed for requesting for confirmation to substitute the installed component with the new component (step **125**). In case a conductivity calibration procedure is ongoing the control system informs that it is not possible to take any action for the scanned concentrate (step **126**). In case the concentrate is not valid, or not applicable in view of the apparatus selected treatment, or if a calibration or other momentary procedure preventing substitution of the specific component is ongoing, then the control system returns to a condition where it is ready to receive a new bar code reading (step **127**).

FIG. **4** and FIG. **5** flow diagrams are very similar to the above described diagram and procedure of FIG. **2**, so the steps **120**, **121**, **122**, **123** executed by the control system will not be described again as the only difference is that in FIG. **4** a dialyzer code is detected and in FIG. **5** a bloodlines code is detected. As to FIG. **4** it is however to be noted that in case a dialyzer code is detected the control system verifies the status of the treatment procedure and if a dialyzer is already installed (step **124**). Then it also verified if priming of the dialyzer currently installed is still running and if it has been completed or not (step **126**). Steps **125** and **127** are similar again to those of FIG. **2** for the concentrate code. As to FIG. **5**, after step **122** the control system verifies if a bloodline is already installed on the machine and also if blood has been already sensed by use for instance of a sensor (a sensor associated with the bloodline and able to detect blood presence such as an optical sensor or a conductivity sensor or an electromagnetic sensor or a capacity sensor can be alternatively used. The sensor is in communication with the control system). Steps **125** and **127** are similar again to those of FIG. **2** for the concentrate code.

FIG. **6** diagram shows the procedure followed by the control system when a the code of a disinfectant replaceable component is detected. FIG. **6** flow diagram is very similar to the above described diagram and procedure of FIG. **2**, so the steps **120**, **121**, **122**, **123** executed by the control system will not be described again as the only difference is that in FIG. **6** a disinfectant code is detected. In FIG. **6** flow, after step **122** the step **124** of verifying the machine status includes verifying if the blood treatment apparatus **1** is in one of the following operating conditions:

- priming status (step **130**), i.e. a status where lines are washed and rinsed before the treatment.
- dialysis status (step **131**), i.e. the true blood treatment,
- disinfection status (step **132**), i.e. disinfection of the circuit **2** after treatment.

If the apparatus is in one of the above conditions, then a step **133** is executed where the control systems generates a visible and/or audible signal warning the operator that a disinfection procedure of the blood treatment apparatus cannot be started.

Steps **125** and **127** of FIG. **6** are similar to those of FIG. **2**, but for the fact that a disinfection confirmation is required and that after confirmation a disinfection procedure will start.

FIG. **8** diagram shows the procedure followed by the control system when a code of a command corresponding to a disinfection rinse profile is detected a disinfectant replaceable component is detected. The control system then verifies if the configuration of the machine is adapted to run the command (step **140**). In the affirmative the control system verifies if the machine status (step **141**), which includes verifying if the blood treatment apparatus **1** is in one of the following operating conditions:

- priming status (step **142**), i.e. a status where lines are washed before the treatment.
- dialysis status (step **143**), i.e. the true blood treatment,
- disinfection status (step **144**), i.e. disinfection of the circuit **2** after treatment,
- rinsing status (step **145**), i.e. when the lines are rinsed after a treatment.

If the apparatus is in one of the above conditions, then a step **146** is executed where the control systems generates a

visible and/or audible signal warning the operator that a disinfection procedure of the blood treatment apparatus cannot be started.

Steps **125** and **127** of FIG. **8** are similar to those of FIG. **6**.

FIG. **9** diagram shows the procedure followed by the control system when a code of a command corresponding to a request to go to a service screen or to perform a task is detected. The control system then verifies if the status of the machine is adapted to allow the command, i.e. to access to the status screen (step **150**). In the affirmative the control system loads on the user interface screen **31** the service screen and allows the operator to interact with it (step **151**). If the command is a task, after step **150** the control system will let the operator to perform the task in question. If the check of step **150** is negative, then control systems generates a visible and/or audible signal warning the operator that the command is not applicable (step **152**) and then the control system returns to a condition where it is ready to receive a new bar code reading (step **127**).

FIG. **10** diagram shows the procedure followed by the control system when a code of a command corresponding to an event that needs to be inserted is detected (events can be for instance: a medication given to the patient, a patient problem that has been detected and so on). The control system then verifies if the status of the machine is adapted to receive the event command (step **160**). Then the control system compares the event command with a list of events stored in a library (step **161**) and also checks the apparatus configuration (step **162**). The control system then verifies if for the entered event command a signature is necessary or not (step **163**). In the affirmative the signature is allowed to be entered (step **164**) via an appropriate means (a touch screen portion can be used) and validated by comparing it with a signatures library (step **165**). In case of no validation the control system returns to step **163**. In case the signature is not mandatory (steps **166**) or if the signature has been validated the control system moves to step **167** where the event is recorded and inserted in a report table. In case a signature has not been inserted, but it is required for the event, then the control system returns to a condition where it is ready to receive a new bar code reading (step **168**).

FIG. **12** diagram shows the procedure followed by the control system when a correctly formatted unknown code of a replaceable component is read. The control systems generates a visible and/or audible signal warning the operator that the code is unknown (step **171**) and then the control system returns to a condition where it is ready to receive a new bar code reading (step **172**).

FIG. **13** diagram shows the procedure followed by the control system when a correctly formatted unknown code of a command is read. The control systems generates a visible and/or audible signal warning the operator that the code is unknown (step **181**) and then the control system returns to a condition where it is ready to receive a new bar code reading (step **182**).

Going now to FIGS. **3**, **7** and **11** comparatively showing the steps performed by a user when using the reader (right side of each figure) and when using the user interface **30** (left side), it is clear how advantageous id the reader for entering commands and components identities. Of course the presence of the user interface which also allows to manually enter the same commands and information in the control system gives redundancy and consequently high reliability.

The above steps subsequent to reading of a code can be basically repeated by the control system every time the reader reads information concerning a component to be installed on the apparatus or a command to be executed.

The above apparatus and method have been described assuming that the reading portion is always active, i.e. in a status where it is able to read information. While this could be the case, it is also alternatively possible to have activation and de-activation of the reader and of the reading portion depending upon the following circumstances.

In particular, the control system of the apparatus **1** could be programmed for receiving a information concerning a fluid treatment procedure selected by a user (by acting on the user interface for instance), and then verifying if the selected fluid treatment procedure requires or not use of the reading portion. For instance in case of a blood treatment machine after set up of the machine the machine can start the extracorporeal blood treatment. During such a treatment it is normally not necessary to enter data using the reader and this latter can be conveniently turned off. The de-activation of the reading portion, when the selected treatment procedure does not require use of the reading portion, can be automatic (i.e. upon detection of the selection or of the start of the specific procedure) or commanded by the user acting on the user interface (which can have an appropriate key or dedicated area). The control system can also be programmed for de-activating said reading portion, when the reading portion reads no information during a prefixed timeout period.

The control system can also be programmed for verifying if the selected fluid treatment procedure requires or not use of the reading portion and for activating said reading portion, when the selected treatment procedure does require use of the reading portion.

In accordance with one embodiment the control system is programmed for activating said reading portion, when the apparatus is turned on.

With the reference to the example of the enclosed drawings where the apparatus **1** is an extracorporeal treatment machine, the control system can be programmed—and thereby includes means—for executing one or more of the following steps of detecting that:

a) a setup procedure has been selected or initiated (which could include one or more steps of setting a prescription, preparing the machine for treatment by engaging any replaceable components with the machine, etcetera),

b) a blood treatment session has been initiated or that a command to initiate a blood treatment procedure has been entered through the user interface,

c) a blood treatment session has been concluded or that a command to stop a blood treatment procedure has been entered through the user interface,

d) a rinse back procedure has been initiated or that a command to initiate a rinse back procedure has been entered through the user interface.

The control system can be programmed—and thereby define means—for turning the reader on upon detection of a) or of c) or of d) and for turning the reader off, upon detection of b).

The medical apparatus **1** above described represents a non-limiting example, which the present invention can be applied to. The apparatus can of course include other components, which are not herein disclosed, as they are not relevant for the purpose of the understanding of present invention.

For instance when verifying the compliance of a component with a selected treatment procedure, this can be done in practice by relying on appropriate sensors of presence, such as mechanical switches or electromagnetic sensors or optical sensors or equivalents thereof (operative in correspondence of the operating areas of the various components), or by means of indirect tests on the fluids interested or affected by the presence of said components (for instance if a concentrate

container is present, then conductivity in the treatment liquid is affected, if a dialyzer is present pressures in several parts of the circuit **2** and bloodlines are affected, if an ultrafilter is present again pressure sensing can be used).

The invention claimed is:

1. Method for setting-up a fluid processing medical apparatus, the apparatus being of the type comprising:

a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus,

at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

the method comprising the following steps:

providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,

reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information,

the method further comprising the steps of:

selecting a desired treatment procedure,

checking if the new component fits with the selected treatment procedure,

signaling if the new component does not fit with the selected treatment procedure.

2. Method according to claim **1**, wherein after the reading step it is provided a step of verifying if the new component is of the same category of a component already installed on the apparatus.

3. Method according to claim **2**, comprising the step of signaling that a component of the same category is already installed on the apparatus.

4. Method according to claim **3**, herein after the signaling step, the following steps are provided:

requesting for confirmation to substitute the installed component with the new component,

initiating a procedure for substitution of the installed component with the new component.

5. Method according to claim **4**, wherein the above steps of selecting a desired treatment procedure, checking if the new component fits with the selected treatment procedure, and signaling if the new component does not fit with the selected treatment procedure are performed before the step of coupling the new component with the apparatus.

6. Method according to claim **2**, the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component of the same category was detected before,

checking if a component is engaged with the engaging means of the type adapted to

receive the components of the category of the new component.

7. Method according to claim **2**, the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component is engaged with the engaging means of the type adapted to

receive the components of the category of the new component.

8. Method according to claim **1**, wherein said components comprise a plurality of components of different categories, each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories.

9. Method according to claim **8**, wherein said apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only.

10. Method according to claim **1**, wherein the above steps of reading and verifying are repeated for any new component to be installed.

11. Method according to claim **1**, wherein the information comprises one or more selected in the group including:

Identity of the component,

Identity of a series of identical components,

Expiration date of the component,

Manufacturer,

One or more commands for programming the apparatus to execute a procedure on said fluid,

Data concerning a patient.

12. Method according to claim **1**, wherein the information carrier is one selected in the group comprising: a surface of the component, a packaging of the component, a card associated with the component.

13. Method according to claim **1**, comprising the step of entering commands into the apparatus for carrying out a corresponding procedure on said fluid, said step of entering commands including the following sub-steps:

Associating a command information to a readable information carrier,

Relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus,

Initiating a treatment procedure complying with the entered command.

14. Method according to claim **1**, comprising the step of entering patient data into the apparatus, said step of entering patient data including the following sub-steps:

Associating patient data information to a readable information carrier,

Relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus.

15. Method according to claim **1**, comprising an additional procedure for installing a new replaceable component on the apparatus without interacting with said reader, said additional procedure including the following steps:

entering the information of a new component to be installed on the apparatus by acting on said user interface,

verifying if the new component is of the same category of a component already installed on the machine,

displaying on said screen a message informing if a component of the same category is already installed,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

16. Method according to claim **15**, wherein said step of entering information by acting on the user interface comprises the steps of:

a. Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component,

b. Selecting the desired display of the user interface,

c. Selecting the new component to be installed by acting on said selected display.

17. Method according to claim **15**, comprising a step of entering commands using said user interface and without acting on said reader.

18. Method according to claim **15**, comprising a step of entering patient related information using said user interface and without acting on said reader.

19. Method according to claim **1**, wherein for reading the information, the carrier of said information is and the reading portion are approached to a distance less then 30 cm.

20. Method according to claim **1**, before the reading portion can read any information, a step is provided for activation of said reading portion.

21. Method according to claim **1**, after the reading portion has read any information, a step is provided for de-activation of said reading portion.

22. Method according to claim **1**, wherein the reading portion is deactivated when at least one of the following circumstances occurs:

the reading portion reads no information for a prefixed timeout period,

a user turns the reading portion off by acting of the user interface,

a specific procedure not requiring use of the reading portion is selected by the user,

a specific procedure not requiring use of the reading portion is initiated by the apparatus.

23. Method according to claim **1**, wherein the reading portion is activated when at least one of the following circumstances occurs:

the apparatus is turned on,

a user turns the reading portion on by acting on the user interface,

a specific procedure requiring use of the reading portion is selected by the user,

a specific procedure requiring use of the reading portion is initiated by the apparatus.

24. Fluid processing medical apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus, wherein the control system is programmed for verifying if the new component is of the same category of a component already installed on the machine, and wherein the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component of the same category was detected before,

checking if a component is engaged with the engaging means of the type adapted to

receive the components of the category of the new component.

25. Apparatus according to claim **24**, wherein said components comprise a plurality of components of different categories, each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories.

26. Apparatus according to claim **25**, wherein said apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only.

27. Apparatus according to claim **24**, wherein the control system is also programmed for signaling that a component of the same category is already installed on the apparatus.

28. Apparatus according to claim **27**, wherein the control system is programmed for executing the following steps, after the signaling step:

requesting for confirmation to substitute the installed component with the new component,

initiating a procedure for substitution of the installed component with the new component.

29. Apparatus according to claim **24**, wherein the control system is programmed for executing the following steps:

receiving selection of a desired treatment procedure,

checking if the new component fits with the selected treatment procedure,

signaling if the new component does not fit with the selected treatment procedure.

30. Apparatus according to claim **24**, wherein the control system is programmed for repeating the above steps of reading and verifying anytime the reader reads information of a new component to be installed.

31. Apparatus according to claim **24**, wherein the information comprises one or more selected in the group including:

Identity of the component,

Identity of a series of identical components,

Expiration date of the component,

Manufacturer,

One or more commands for programming the apparatus to execute a procedure on said fluid,

Data concerning a patient.

32. Apparatus according to claim **24**, wherein the information carrier is one selected in the group comprising: a surface of the component, a packaging of the component, a card associated with the component.

33. Apparatus according to claim **24**, wherein the control system is programmed for receiving commands for carrying out a corresponding procedure on said fluid by reading a command information associated to a readable information carrier which is approached to the reading portion.

34. Apparatus according to claim **24**, wherein the reader comprises an optical reader or a radio-frequency reader adapted to detect said information when the component and the reading portion are approached one another at a distance less then 30 cm.

35. Apparatus according to claim 24, wherein the user interface comprises a means for receiving an entry addressed to turn on or off the reading portion, said control system being programmed for:

receiving said entry, and

respectively turning on or off the reading portion depending upon the entry.

36. Apparatus according to claim 24, wherein the control system is programmed for:

receiving a information concerning a fluid treatment procedure selected by a user,

verifying if the selected fluid treatment procedure requires or not use of the reading portion de-activating said reading portion, when the selected treatment procedure does not require use of the reading portion.

37. Apparatus according to claim 24, wherein the control system is programmed for de-activating said reading portion, when the reading portion reads no information during a prefixed timeout period.

38. Apparatus according to claim 24, wherein the control system is programmed for:

receiving a information concerning a fluid treatment procedure selected by a user,

verifying if the selected fluid treatment procedure requires or not use of the reading portion activating said reading portion, when the selected treatment procedure does require use of the reading portion.

39. Apparatus according to claim 24, wherein the control system is programmed for activating said reading portion, when the apparatus is turned on.

40. Method for setting-up a fluid processing medical apparatus, the apparatus being of the type comprising:

a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus,

at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

the method comprising the following steps:

providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,

reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information, wherein after the reading step it is provided a step of verifying if the new component is of the same category of a component already installed on the apparatus, and wherein the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component of the same category was detected before,

checking if a component is engaged with the engaging means of the type adapted to

receive the components of the category of the new component.

41. Method for setting-up a fluid processing medical apparatus, the apparatus being of the type comprising:

a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus,

at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

the method comprising the following steps:

providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,

reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information, the method further comprising the step of entering commands into the apparatus for carrying out a corresponding procedure on said fluid, said step of entering commands including the following sub-steps:

Associating a command information to a readable information carrier,

Relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus,

Initiating a treatment procedure complying with the entered command.

42. Method for setting-up a fluid processing medical apparatus, the apparatus being of the type comprising:

a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus,

at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

the method comprising the following steps:

providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,

reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information, the method further comprising the step of entering patient data into the apparatus, said step of entering patient data including the following sub-steps:

Associating patient data information to a readable information carrier,

Relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus.

43. Fluid processing medical apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus, wherein the control system is programmed for executing the following steps:

receiving selection of a desired treatment procedure,

checking if the new component fits with the selected treatment procedure,

signaling if the new component does not fit with the selected treatment procedure.

44. Apparatus according to claim **43**, wherein the control system is programmed for allowing the step of coupling the new component with the apparatus only after the step of checking if the new component fits with the selected treatment procedure.

45. Fluid processing medical apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus, wherein the control system is programmed for receiving commands for carrying out a corresponding procedure on said fluid by reading a command information associated to a readable information carrier which is approached to the reading portion.

46. Apparatus according to claim **45**, wherein the control system is programmed for receiving patient data by reading data carried by a readable information carrier which is approached to the reading portion.

47. Apparatus according to claim **46**, wherein the control system is programmed for executing an additional procedure for installing a new replaceable component on the apparatus without interacting with said reader, the additional procedure comprising the steps of:

allowing to enter information of a new component to be installed on the apparatus by acting on said user interface,

verifying if the new component is of the same category of a component already installed on the machine,

displaying on said screen a message informing if a component of the same category is already installed,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

48. Apparatus according to claim **47**, wherein said step of allowing entering information by acting on the user interface comprises the steps of:

Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component,

Allowing selecting the desired display of the user interface,

Allowing selecting the new component to be installed by acting on said selected display.

49. Fluid processing medical apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus, wherein the control system is programmed for:

receiving a information concerning a fluid treatment procedure selected by a user,

verifying if the selected fluid treatment procedure requires or not use of the reading portion de-activating said reading portion, when the selected treatment procedure does not require use of the reading portion.

50. Fluid processing medical apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said oper-

ating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus, wherein the control system is programmed for:

receiving a information concerning a fluid treatment procedure selected by a user,

verifying if the selected fluid treatment procedure requires or not use of the reading portion activating said reading portion, when the selected treatment procedure does require use of the reading portion.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 8,267,308 B2
APPLICATION NO.	: 12/596070
DATED	: September 18, 2012
INVENTOR(S)	: Jacky Devergne et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At column 17, line 42, claim 4, after “claim 3,”, please delete “herein” and insert therefor --wherein--.

Signed and Sealed this
Eleventh Day of December, 2012

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office

EXHIBIT G

US008459543B2

(12) **United States Patent**
Devergne et al.

(10) **Patent No.: US 8,459,543 B2**
(45) **Date of Patent: *Jun. 11, 2013**

(54) **FLUID PROCESSING MEDICAL APPARATUS AND METHOD FOR SETTING-UP A FLUID PROCESSING MEDICAL APPARATUS**

(75) Inventors: **Jacky Devergne**, Littleton, CO (US); **Nicolas Goux**, Craponne (FR); **David Nepote-Vesino**, Jonage (FR); **Michele Stefanini**, Mirandola (IT); **Giulio Guaitoli**, Carpi (IT); **Gianni Borsari**, Medolla (IT)

(73) Assignee: **Gambro Lundia AB**, Lund (SE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/616,819**

(22) Filed: **Sep. 14, 2012**

(65) **Prior Publication Data**

US 2013/0062404 A1 Mar. 14, 2013

Related U.S. Application Data

(63) Continuation of application No. 12/596,070, filed as application No. PCT/IB2007/001646 on Jun. 19, 2007, now Pat. No. 8,267,308.

(30) **Foreign Application Priority Data**

Apr. 19, 2007 (FR) 07 02823

(51) **Int. Cl.**
G06F 17/00 (2006.01)

(52) **U.S. Cl.**
USPC **235/375**; 235/435

(58) **Field of Classification Search**
USPC 235/375, 382, 376, 435; 715/744
See application file for complete search history.

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Primary Examiner — Edwyn Labaze
(74) *Attorney, Agent, or Firm* — Pearne & Gordon LLP

(57) **ABSTRACT**

The invention relates to a method for setting up a fluid treatment apparatus using a single, and always accessible, reader of information relating to replaceable components which are to be mounted on the apparatus to perform the fluid treatment. It is also disclosed a fluid treatment apparatus having the always accessible reader. The reader can also be relied on to enter information other that those relating to the replaceable components, such as commands for the apparatus, patients' related information, etcetera.

43 Claims, 15 Drawing Sheets

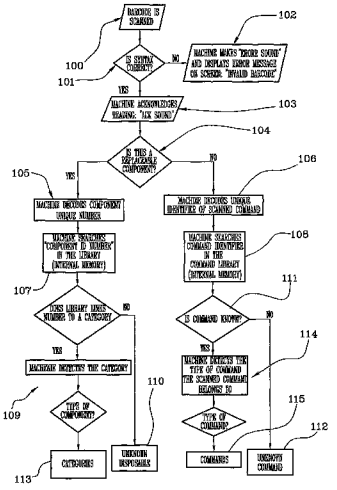

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FIG 1

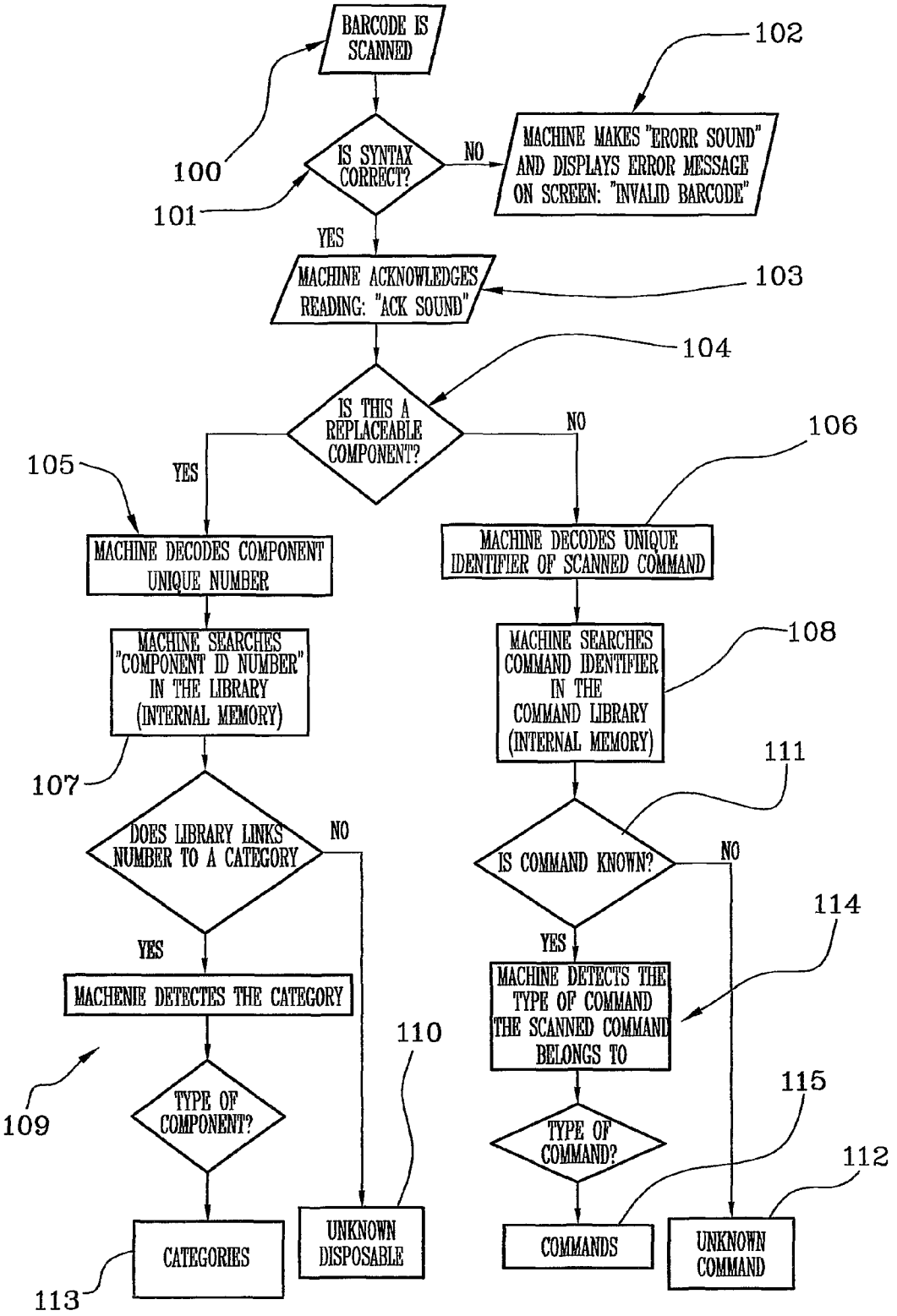

BARCODE IS SCANNED
100
IS SYNTAX CORRECT?
101
NO
MACHINE MAKES "ERORR SOUND" AND DISPLAYS ERROR MESSAGE ON SCREEN: "INVALID BARCODE"
102
YES
MACHINE ACKNOWLEDGES READING: "ACK SOUND"
103
IS THIS A REPLACEABLE COMPONENT?
104
YES
NO
105
106
MACHINE DECODES COMPONENT UNIQUE NUMBER
MACHINE DECODES UNIQUE IDENTIFIER OF SCANNED COMMAND
MACHINE SEARCHES "COMPONENT ID NUMBER" IN THE LIBRARY (INTERNAL MEMORY)
MACHINE SEARCHES COMMAND IDENTIFIER IN THE COMMAND LIBRARY (INTERNAL MEMORY)
108
107
111
DOES LIBRARY LINKS NUMBER TO A CATEGORY
NO
IS COMMAND KNOWN?
NO
YES
YES
114
MACHENIE DETECTES THE CATEGORY
MACHINE DETECTS THE TYPE OF COMMAND THE SCANNED COMMAND BELONGS TO
110
109
TYPE OF COMPONENT?
TYPE OF COMMAND?
115
112
CATEGORIES
UNKNOWN DISPOSABLE
COMMANDS
UNKNOWN COMMAND
113

FIG 2

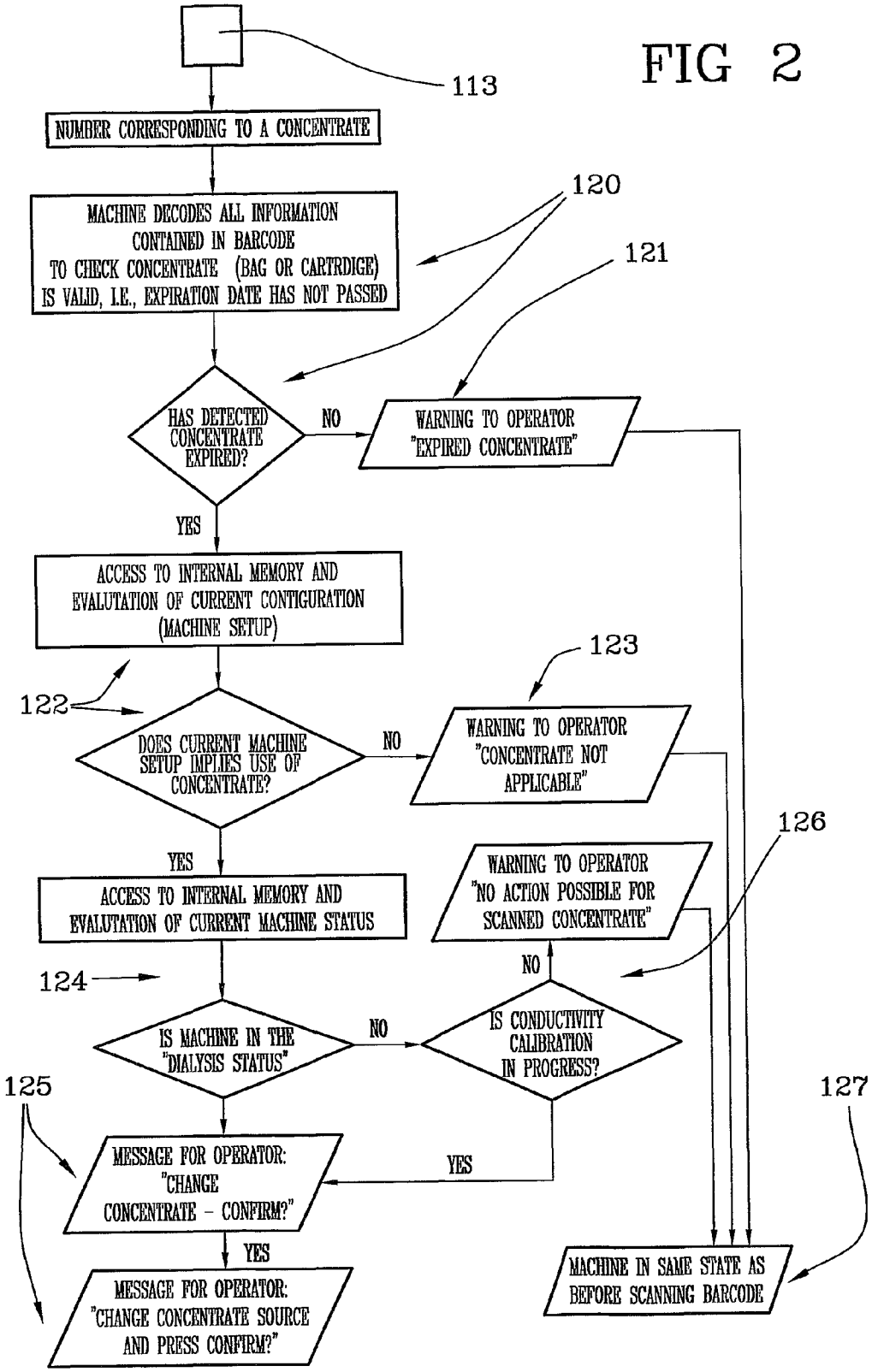

113
NUMBER CORRESPONDING TO A CONCENTRATE
120
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK CONCENTRATE (BAG OR CARTRDIGE) IS VALID, I.E., EXPIRATION DATE HAS NOT PASSED
121
HAS DETECTED CONCENTRATE EXPIRED?
NO
WARNING TO OPERATOR "EXPIRED CONCENTRATE"
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT CONTIGURATION (MACHINE SETUP)
123
122
DOES CURRENT MACHINE SETUP IMPLIES USE OF CONCENTRATE?
NO
WARNING TO OPERATOR "CONCENTRATE NOT APPLICABLE"
126
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
WARNING TO OPERATOR "NO ACTION POSSIBLE FOR SCANNED CONCENTRATE"
NO
124
IS MACHINE IN THE "DIALYSIS STATUS"
NO
IS CONDUCTIVITY CALIBRATION IN PROGRESS?
125
127
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE - CONFIRM?"
YES
YES
MACHINE IN SAME STATE AS BEFORE SCANNING BARCODE
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE SOURCE AND PRESS CONFIRM?"

FIG 3

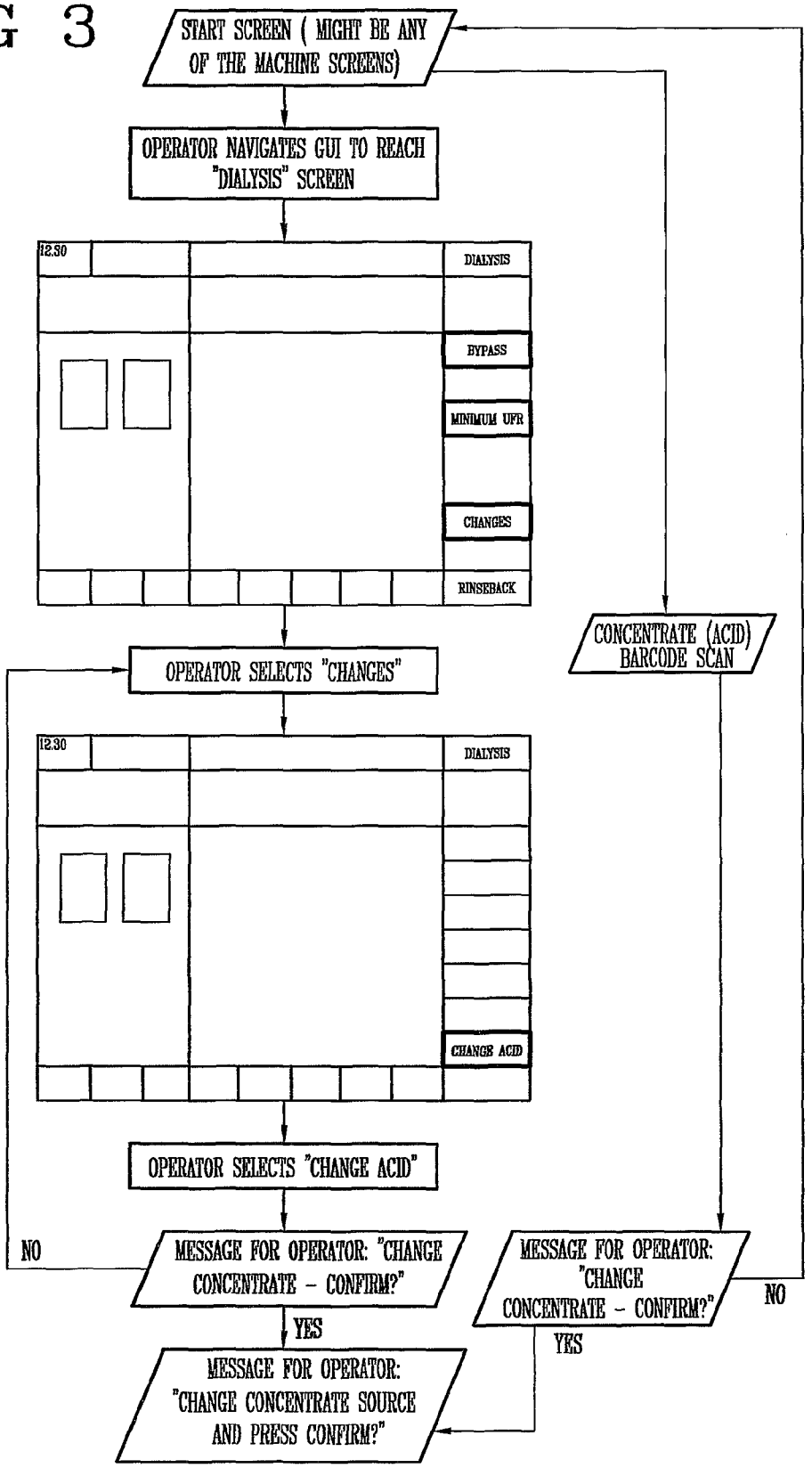

START SCREEN (MIGHT BE ANY OF THE MACHINE SCREENS)
OPERATOR NAVIGATES GUI TO REACH "DIALYSIS" SCREEN
12.30
DIALYSIS
BYPASS
MINIMUM UFR
CHANGES
RINSEBACK
CONCENTRATE (ACID) BARCODE SCAN
OPERATOR SELECTS "CHANGES"
12.30
DIALYSIS
CHANGE ACID
OPERATOR SELECTS "CHANGE ACID"
NO
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE - CONFIRM?"
YES
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE SOURCE AND PRESS CONFIRM?"
MESSAGE FOR OPERATOR: "CHANGE CONCENTRATE - CONFIRM?"
NO
YES

FIG 4

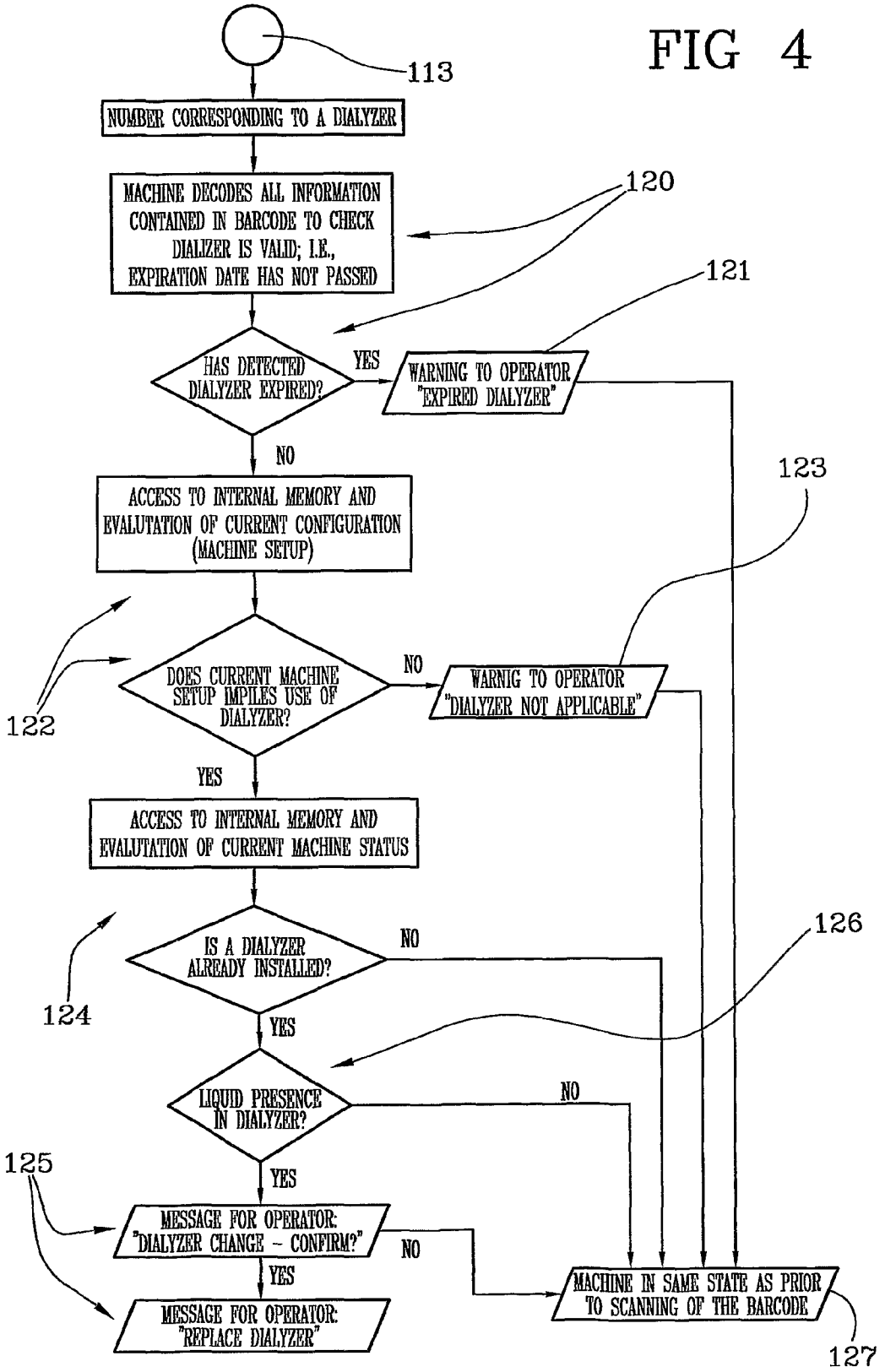

113
NUMBER CORRESPONDING TO A DIALYZER
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK DIALIZER IS VALID; I.E., EXPIRATION DATE HAS NOT PASSED
120
121
HAS DETECTED DIALYZER EXPIRED?
YES
WARNING TO OPERATOR "EXPIRED DIALYZER"
NO
123
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT CONFIGURATION (MACHINE SETUP)
122
DOES CURRENT MACHINE SETUP IMPILES USE OF DIALYZER?
NO
WARNIG TO OPERATOR "DIALYZER NOT APPLICABLE"
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
126
124
IS A DIALYZER ALREADY INSTALLED?
NO
YES
LIQUID PRESENCE IN DIALYZER?
NO
125
YES
MESSAGE FOR OPERATOR: "DIALYZER CHANGE - CONFIRM?"
NO
YES
MESSAGE FOR OPERATOR: "REPLACE DIALYZER"
MACHINE IN SAME STATE AS PRIOR TO SCANNING OF THE BARCODE
127

FIG 5

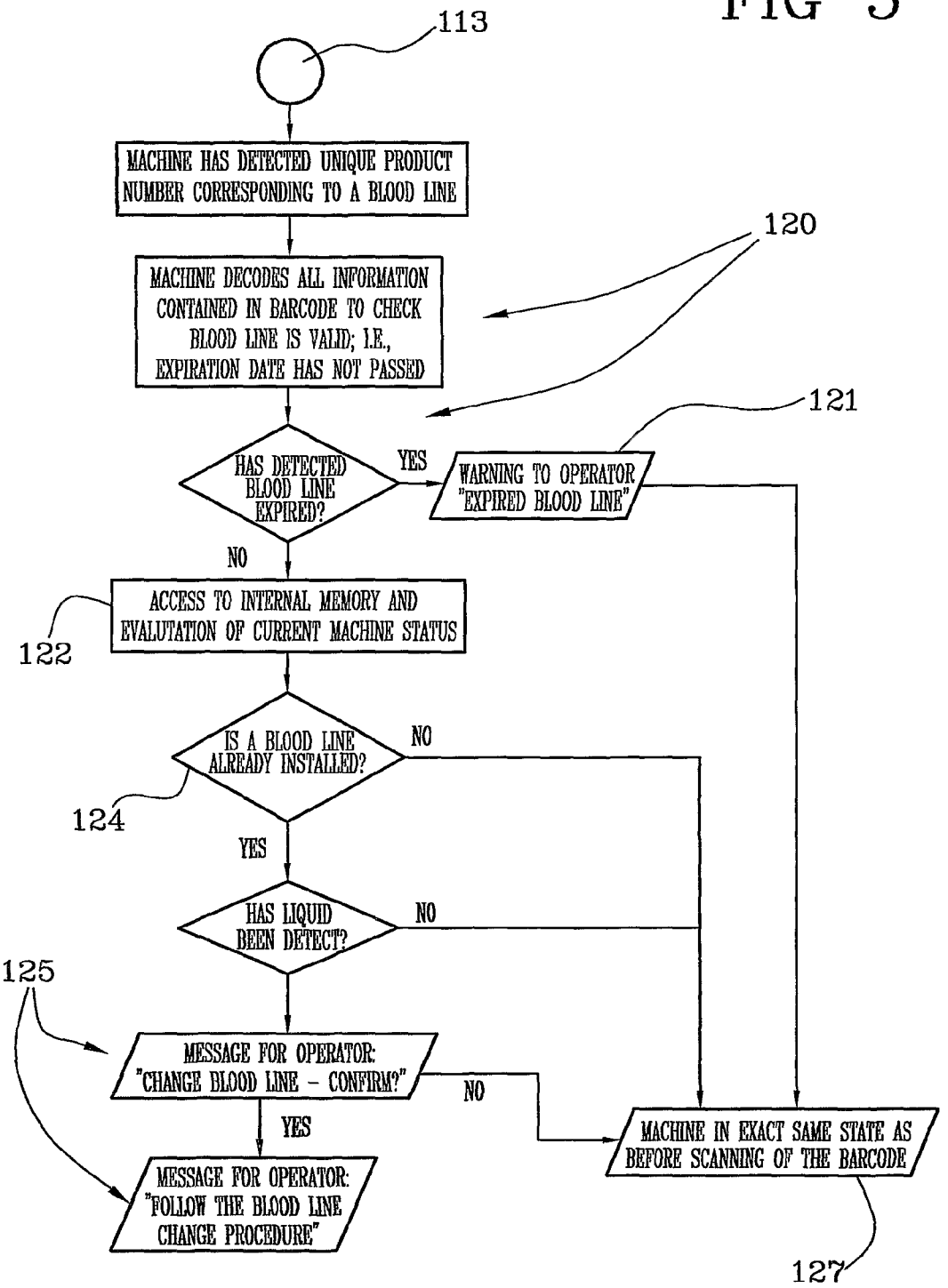

113
MACHINE HAS DETECTED UNIQUE PRODUCT NUMBER CORRESPONDING TO A BLOOD LINE
120
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK BLOOD LINE IS VALID; I.E., EXPIRATION DATE HAS NOT PASSED
121
HAS DETECTED BLOOD LINE EXPIRED?
YES
WARNING TO OPERATOR "EXPIRED BLOOD LINE"
NO
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
122
IS A BLOOD LINE ALREADY INSTALLED?
NO
124
YES
HAS LIQUID BEEN DETECT?
NO
125
MESSAGE FOR OPERATOR: "CHANGE BLOOD LINE - CONFIRM?"
NO
YES
MESSAGE FOR OPERATOR: "FOLLOW THE BLOOD LINE CHANGE PROCEDURE"
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE
127

FIG 6

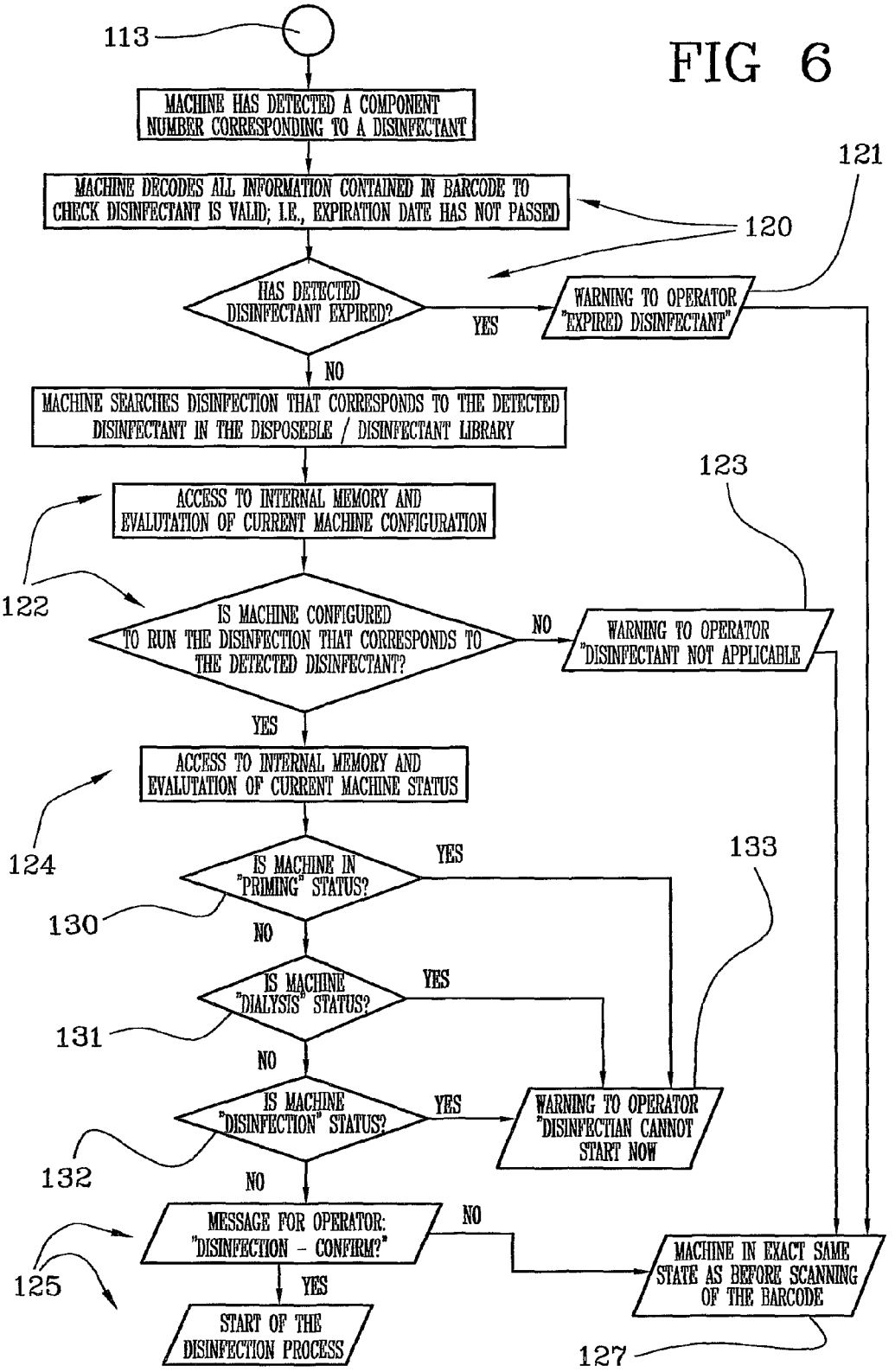

113
MACHINE HAS DETECTED A COMPONENT NUMBER CORRESPONDING TO A DISINFECTANT
MACHINE DECODES ALL INFORMATION CONTAINED IN BARCODE TO CHECK DISINFECTANT IS VALID; I.E., EXPIRATION DATE HAS NOT PASSED
120
121
HAS DETECTED DISINFECTANT EXPIRED?
YES
WARNING TO OPERATOR "EXPIRED DISINFECTANT"
NO
MACHINE SEARCHES DISINFECTION THAT CORRESPONDS TO THE DETECTED DISINFECTANT IN THE DISPOSEBLE / DISINFECTANT LIBRARY
123
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
122
IS MACHINE CONFIGURED TO RUN THE DISINFECTION THAT CORRESPONDS TO THE DETECTED DISINFECTANT?
NO
WARNING TO OPERATOR "DISINFECTANT NOT APPLICABLE
YES
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
124
IS MACHINE IN "PRIMING" STATUS?
YES
133
130
NO
IS MACHINE "DIALYSIS" STATUS?
YES
131
NO
IS MACHINE "DISINFECTION" STATUS?
YES
WARNING TO OPERATOR "DISINFECTIAN CANNOT START NOW
132
NO
MESSAGE FOR OPERATOR: "DISINFECTION - CONFIRM?"
NO
125
YES
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE
START OF THE DISINFECTION PROCESS
127

FIG 7

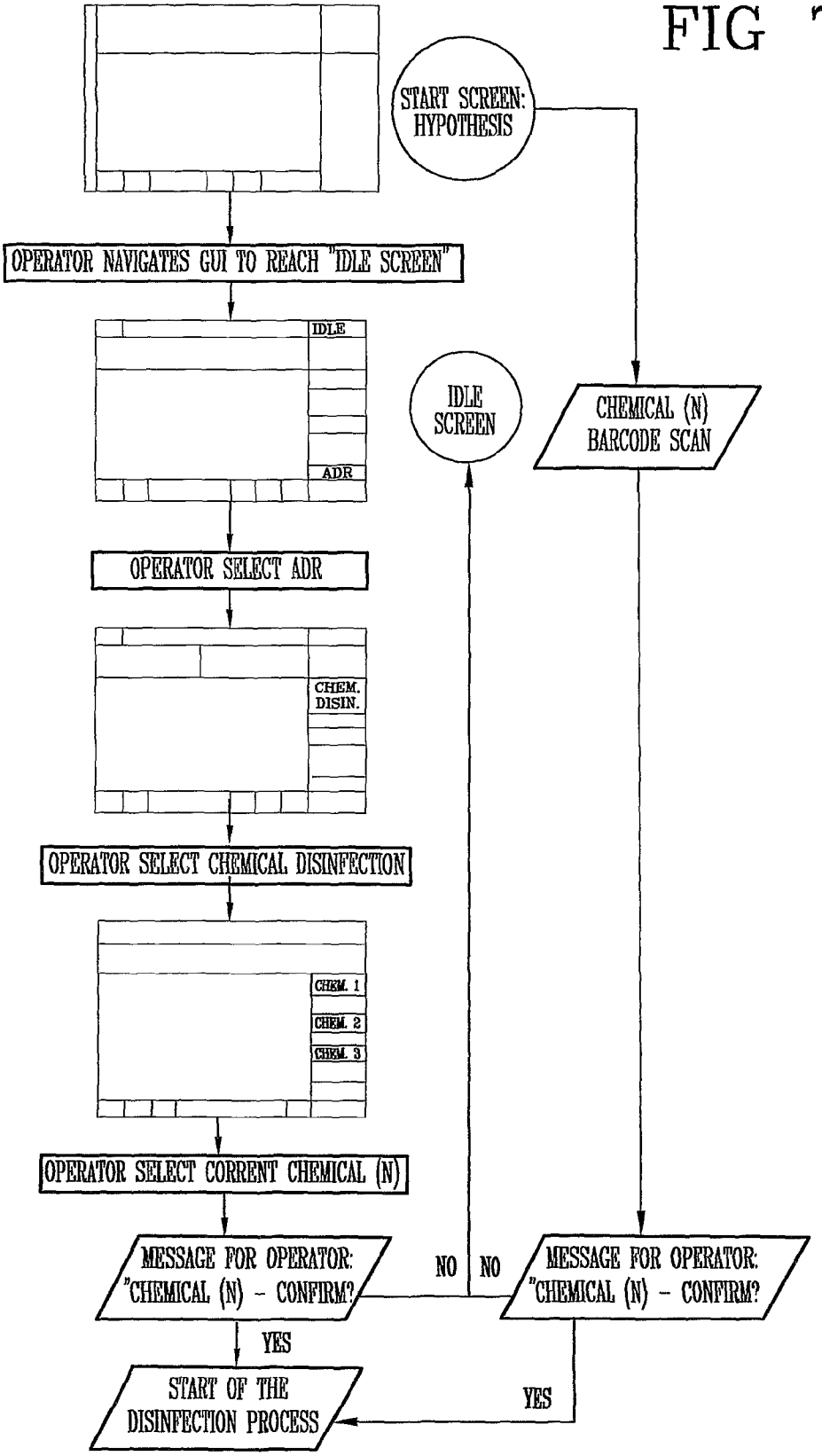

START SCREEN: HYPOTHESIS
OPERATOR NAVIGATES GUI TO REACH "IDLE SCREEN"
IDLE
ADR
IDLE SCREEN
CHEMICAL (N) BARCODE SCAN
OPERATOR SELECT ADR
CHEM. DISIN.
OPERATOR SELECT CHEMICAL DISINFECTION
CHEM. 1
CHEM. 2
CHEM. 3
OPERATOR SELECT CORRENT CHEMICAL (N)
MESSAGE FOR OPERATOR: "CHEMICAL (N) - CONFIRM?
NO
NO
MESSAGE FOR OPERATOR: "CHEMICAL (N) - CONFIRM?
YES
YES
START OF THE DISINFECTION PROCESS

FIG 8

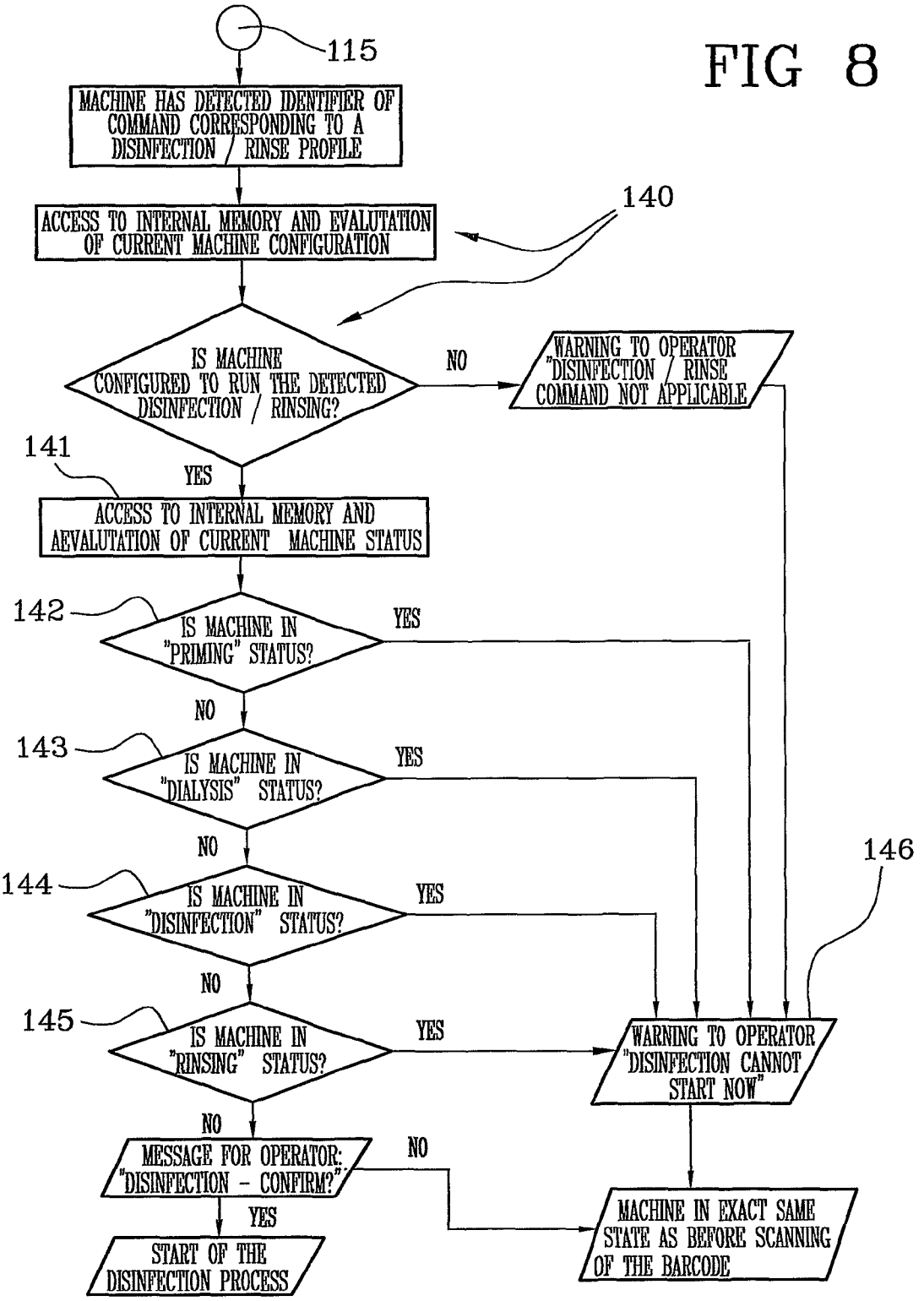

115
MACHINE HAS DETECTED IDENTIFIER OF COMMAND CORRESPONDING TO A DISINFECTION / RINSE PROFILE
140
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
IS MACHINE CONFIGURED TO RUN THE DETECTED DISINFECTION / RINSING?
NO
WARNING TO OPERATOR "DISINFECTION / RINSE COMMAND NOT APPLICABLE
141
YES
ACCESS TO INTERNAL MEMORY AND AEVALUTATION OF CURRENT MACHINE STATUS
142
IS MACHINE IN "PRIMING" STATUS?
YES
NO
143
IS MACHINE IN "DIALYSIS" STATUS?
YES
NO
144
IS MACHINE IN "DISINFECTION" STATUS?
YES
NO
146
145
IS MACHINE IN "RINSING" STATUS?
YES
WARNING TO OPERATOR "DISINFECTION CANNOT START NOW"
NO
MESSAGE FOR OPERATOR: "DISINFECTION - CONFIRM?"
NO
YES
START OF THE DISINFECTION PROCESS
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE

FIG 9

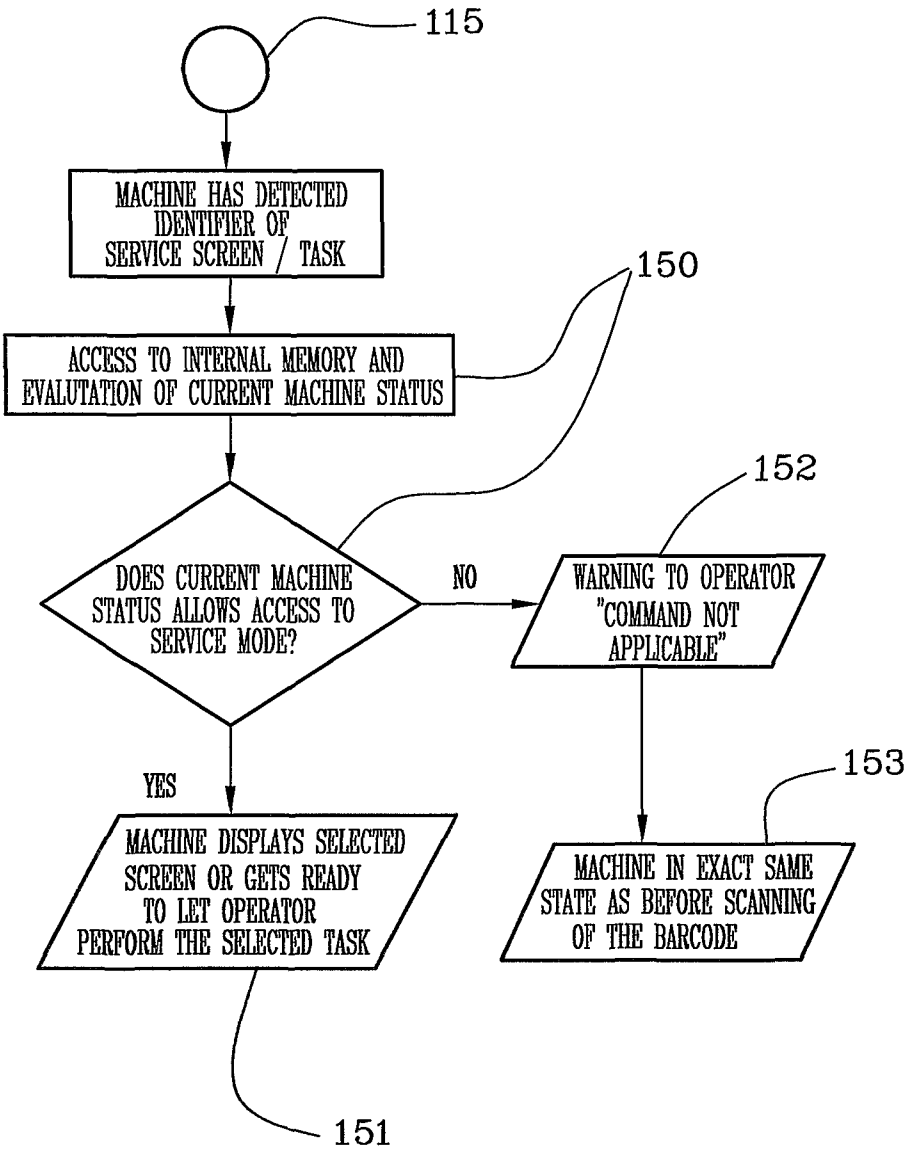

115
MACHINE HAS DETECTED IDENTIFIER OF SERVICE SCREEN / TASK
150
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE STATUS
152
DOES CURRENT MACHINE STATUS ALLOWS ACCESS TO SERVICE MODE?
NO
WARNING TO OPERATOR "COMMAND NOT APPLICABLE"
153
YES
MACHINE DISPLAYS SELECTED SCREEN OR GETS READY TO LET OPERATOR PERFORM THE SELECTED TASK
MACHINE IN EXACT SAME STATE AS BEFORE SCANNING OF THE BARCODE
151

FIG 10

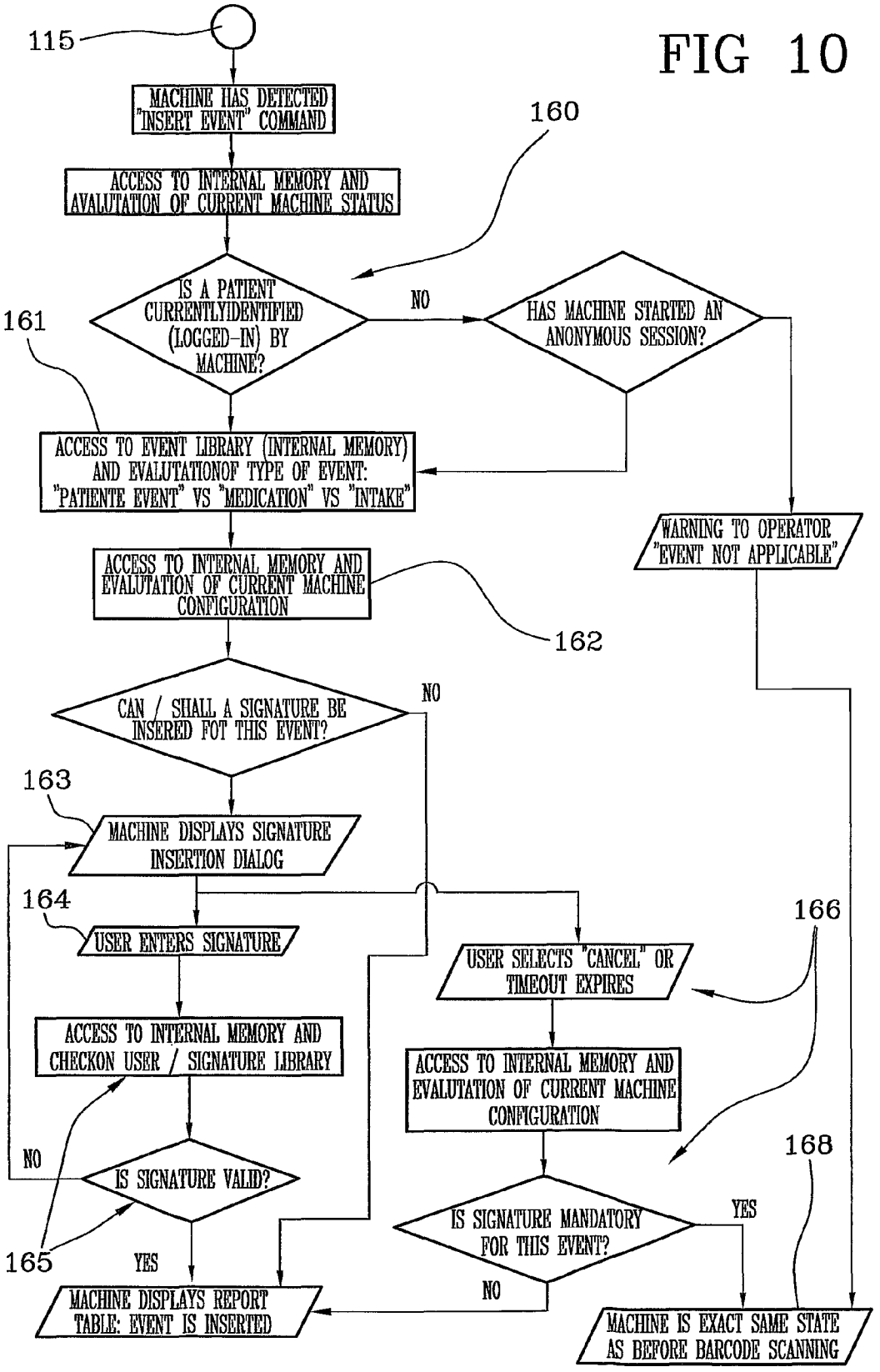

115
MACHINE HAS DETECTED "INSERT EVENT" COMMAND
ACCESS TO INTERNAL MEMORY AND AVALUTATION OF CURRENT MACHINE STATUS
160
IS A PATIENT CURRENTLYIDENTIFIED (LOGGED-IN) BY MACHINE?
NO
HAS MACHINE STARTED AN ANONYMOUS SESSION?
161
ACCESS TO EVENT LIBRARY (INTERNAL MEMORY) AND EVALUTATIONOF TYPE OF EVENT: "PATIENTE EVENT" VS "MEDICATION" VS "INTAKE"
WARNING TO OPERATOR "EVENT NOT APPLICABLE"
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
162
CAN / SHALL A SIGNATURE BE INSERED FOT THIS EVENT?
NO
163
MACHINE DISPLAYS SIGNATURE INSERTION DIALOG
164
USER ENTERS SIGNATURE
166
USER SELECTS "CANCEL" OR TIMEOUT EXPIRES
ACCESS TO INTERNAL MEMORY AND CHECKON USER / SIGNATURE LIBRARY
ACCESS TO INTERNAL MEMORY AND EVALUTATION OF CURRENT MACHINE CONFIGURATION
168
NO
IS SIGNATURE VALID?
IS SIGNATURE MANDATORY FOR THIS EVENT?
YES
165
YES
NO
MACHINE DISPLAYS REPORT TABLE: EVENT IS INSERTED
MACHINE IS EXACT SAME STATE AS BEFORE BARCODE SCANNING

FIG 11

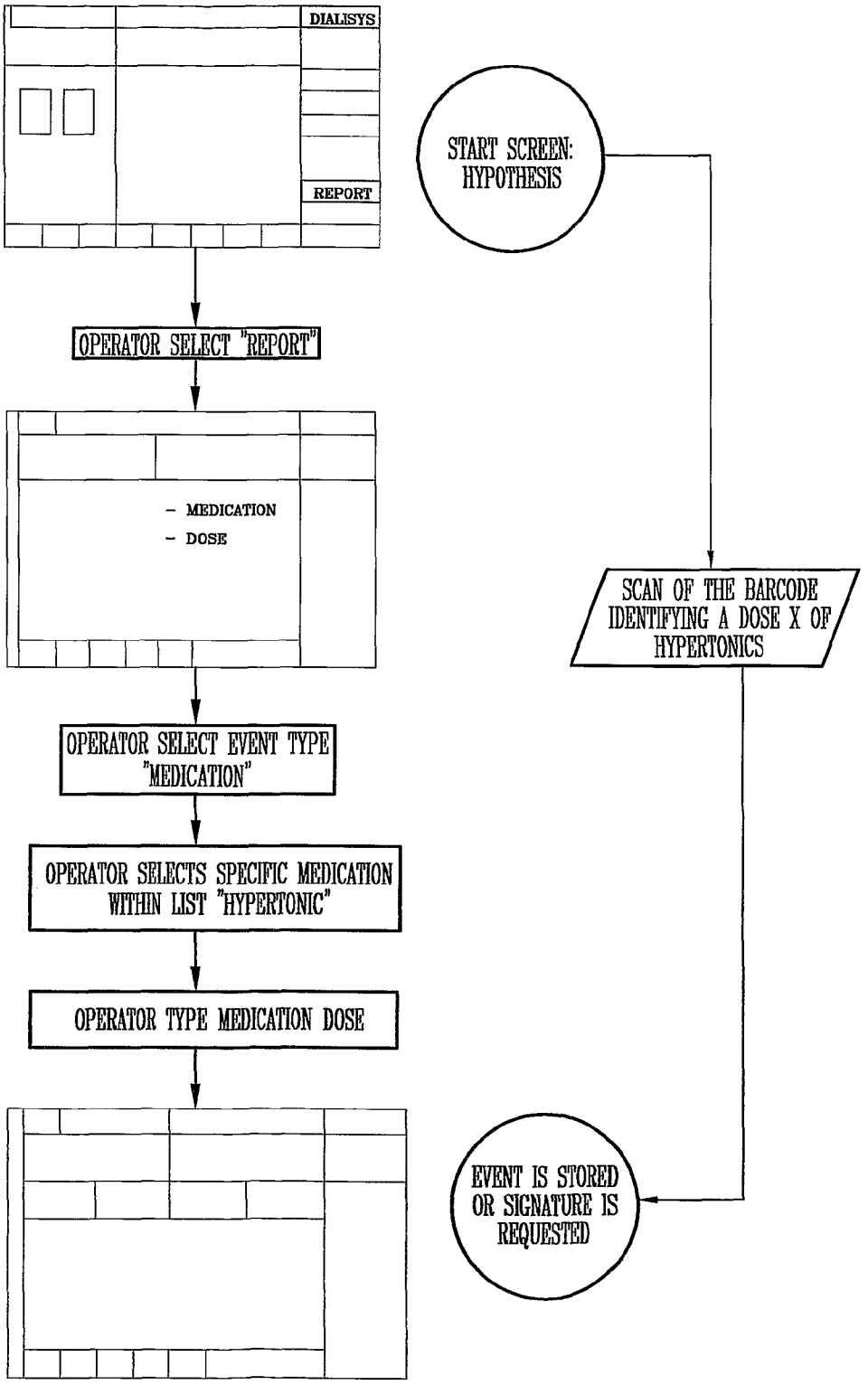

DIALISYS
REPORT
START SCREEN: HYPOTHESIS
OPERATOR SELECT "REPORT"
- MEDICATION
- DOSE
SCAN OF THE BARCODE IDENTIFYING A DOSE X OF HYPERTONICS
OPERATOR SELECT EVENT TYPE "MEDICATION"
OPERATOR SELECTS SPECIFIC MEDICATION WITHIN LIST "HYPERTONIC"
OPERATOR TYPE MEDICATION DOSE
EVENT IS STORED OR SIGNATURE IS REQUESTED

FIG 12

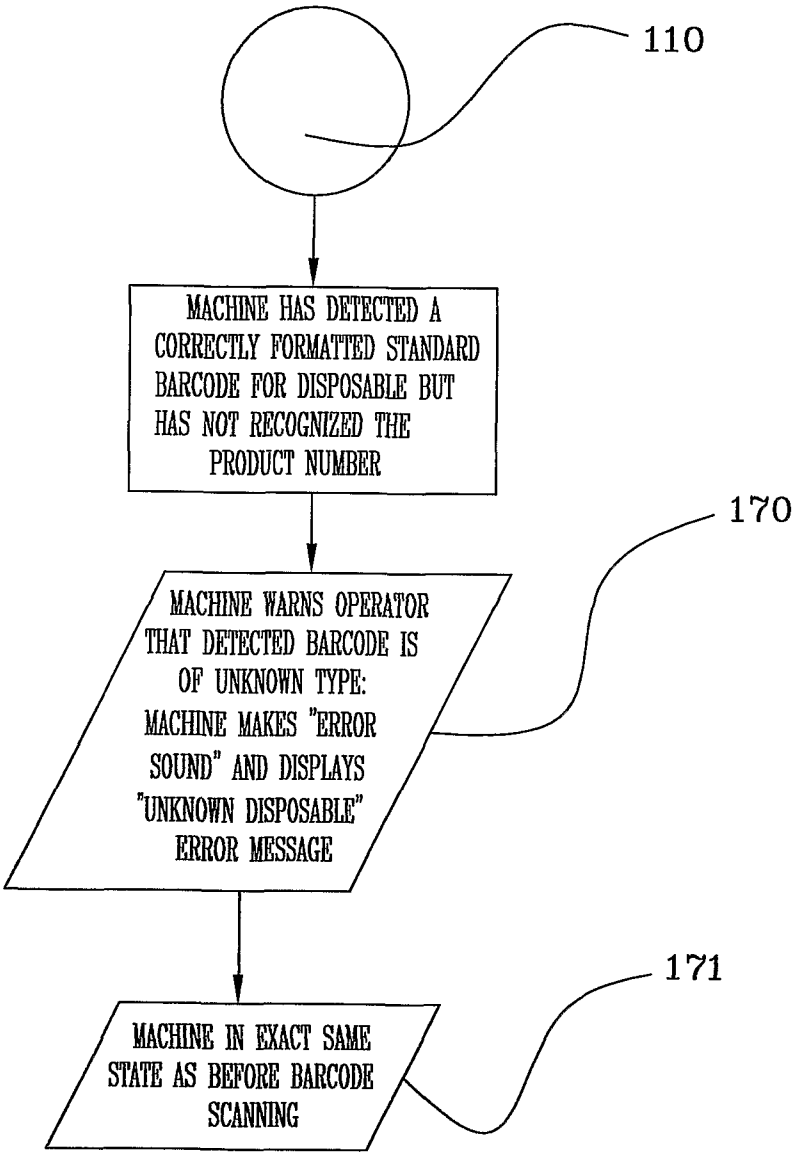
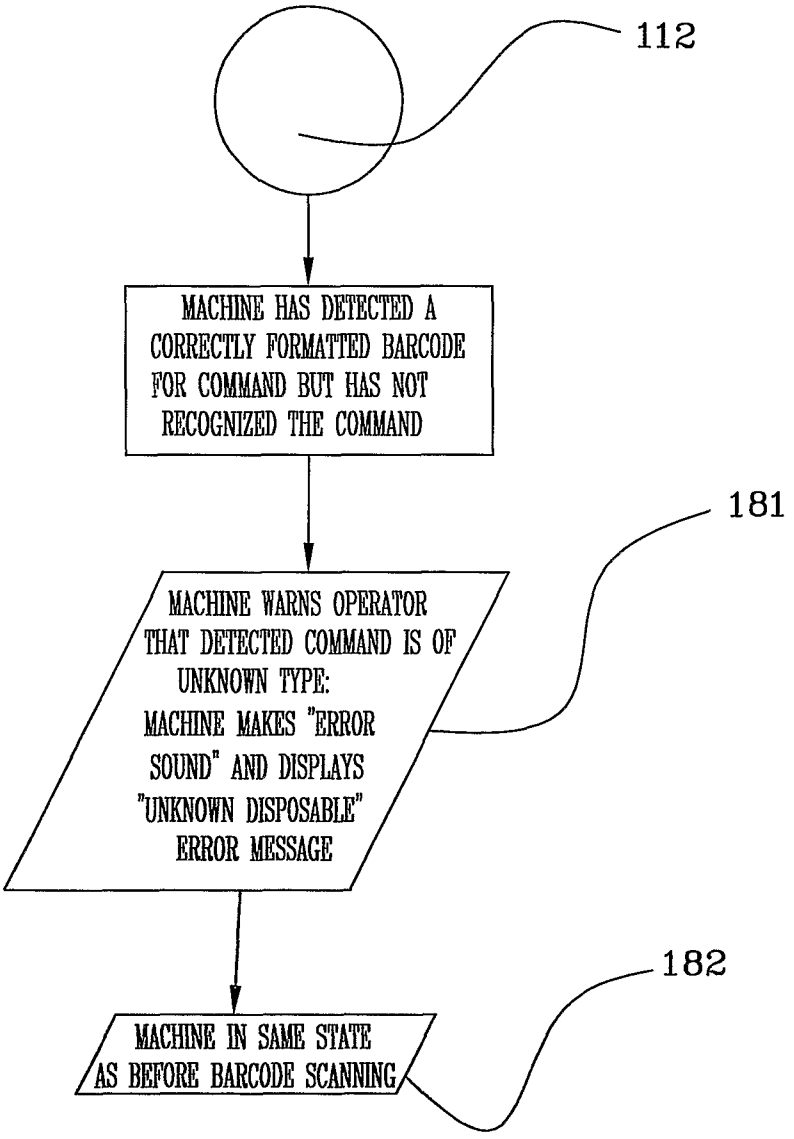

110
MACHINE HAS DETECTED A CORRECTLY FORMATTED STANDARD BARCODE FOR DISPOSABLE BUT HAS NOT RECOGNIZED THE PRODUCT NUMBER
170
MACHINE WARNS OPERATOR THAT DETECTED BARCODE IS OF UNKNOWN TYPE: MACHINE MAKES "ERROR SOUND" AND DISPLAYS "UNKNOWN DISPOSABLE" ERROR MESSAGE
171
MACHINE IN EXACT SAME STATE AS BEFORE BARCODE SCANNING

FIG 13


112
MACHINE HAS DETECTED A CORRECTLY FORMATTED BARCODE FOR COMMAND BUT HAS NOT RECOGNIZED THE COMMAND
181
MACHINE WARNS OPERATOR THAT DETECTED COMMAND IS OF UNKNOWN TYPE: MACHINE MAKES "ERROR SOUND" AND DISPLAYS "UNKNOWN DISPOSABLE" ERROR MESSAGE
182
MACHINE IN SAME STATE AS BEFORE BARCODE SCANNING

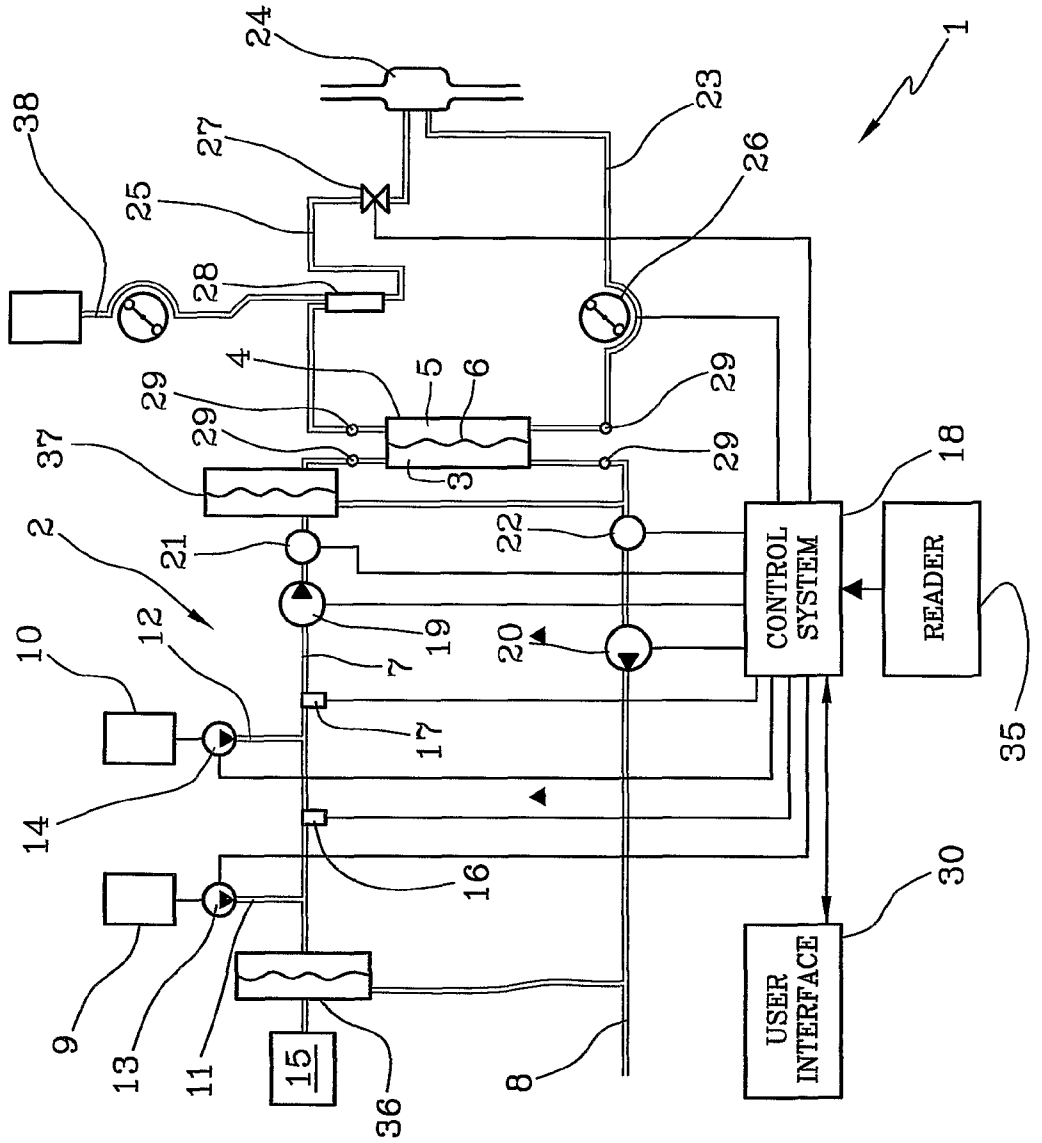
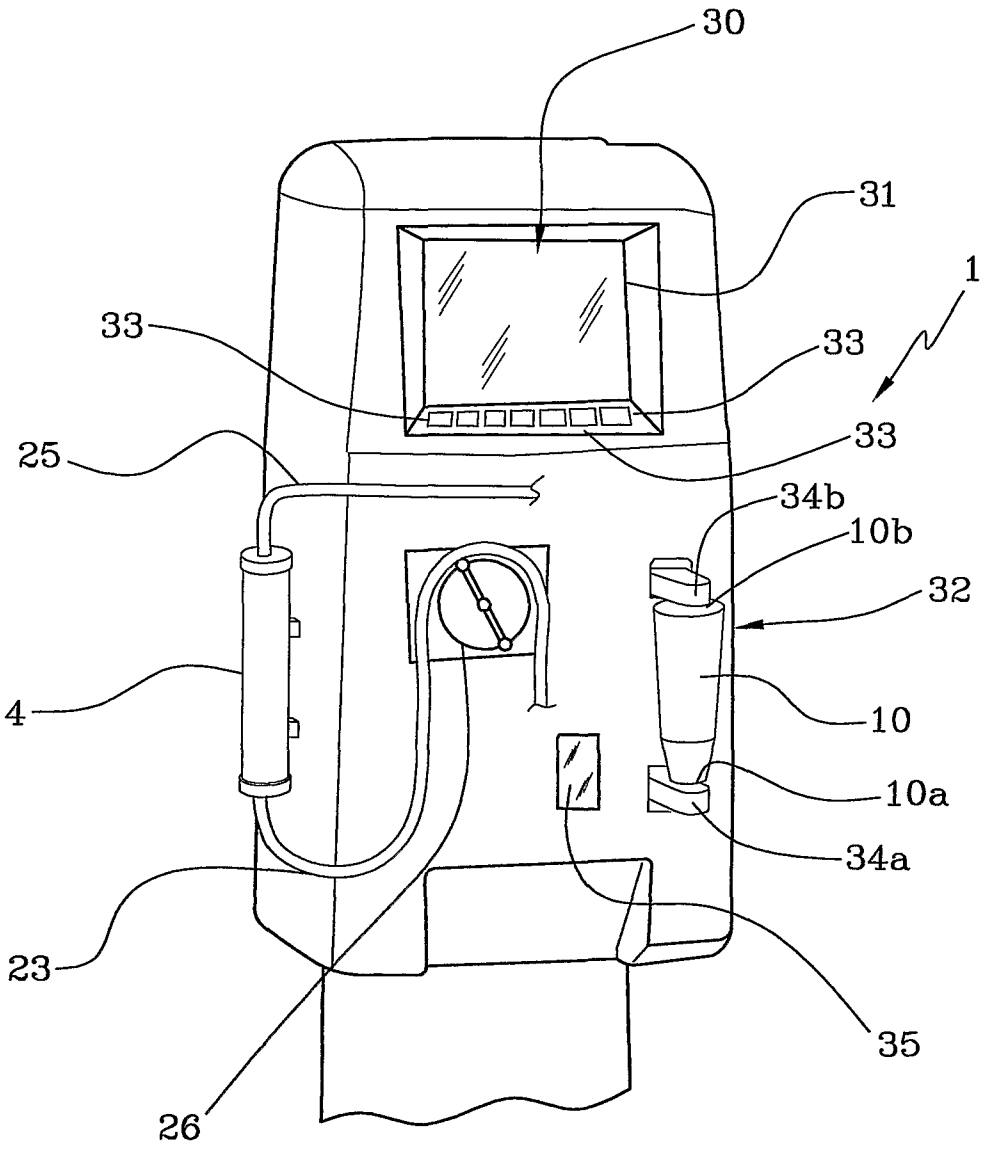

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
29
29
29
35
36
37
38
CONTROL SYSTEM
READER
USER INTERFACE
30

FIG 14

FIG 15



FLUID PROCESSING MEDICAL APPARATUS AND METHOD FOR SETTING-UP A FLUID PROCESSING MEDICAL APPARATUS

FIELD OF THE INVENTION

The invention relates to a fluid processing medical apparatus such as an extracorporeal blood treatment apparatus for performing one or more of the following treatments: ultrafiltration, hemodialysis, hemodiafiltration, hemofiltration, plasmapheresis, oxygenation, or other procedures on whole blood or on blood components, such as separation or collection of blood or blood components. The invention also concerns a method for setting-up a fluid processing medical apparatus.

BACKGROUND OF THE INVENTION

Blood processing apparatus such as extracorporeal blood treatment machines comprise a number of components which have a use limited in time or in the number of use cycles. In the present specification, the following definitions assume the meaning below indicated:

- disposables are those components which can be associate to the processing apparatus for the duration of a single procedure or treatment (i.e. single use components)
- semi-disposables are those components which can be associate to the processing apparatus for the duration of a limited number of procedures or treatments (i.e. components designed to be used a limited number of times).

Depending upon the situations, components such as filters (hemo-dialyzers, hemo-filters, ultrafilters and the like), solutions bags, containers hosting liquids or powders for preparation of treatment liquids, tubing sets, extracorporeal blood circuits, integrated modules including a number of the components just mentioned could be used as disposables or semi-disposables.

Before the medical apparatus, e.g. a blood treatment machine, has to execute a treatment session, the operator shall setup the machine and install all appropriate disposable components suitable for running the selected treatment procedure. The operator also checks if one or more semi-disposable components need to be changed.

Referring for instance to a blood treatment for treating patients suffering from kidney failure, before any procedure starts the operator should normally install the filter, the bloodlines, the access devices adequate for the treatment session. The operator also installs the appropriate concentrates and solutions to be used during the treatment, checks and/or changes the ultrafilters in the liquid preparation circuit (in case on-line liquid preparation is selected).

For the purpose of disclosure of the present invention disposables and semi-disposable components are hereinafter globally referred to as replaceable components.

As it can be easily understood the blood treatment apparatus shall be properly instructed as to which specific replaceable components are installed because each component has specific properties which may affect the working of the apparatus and the direct or indirect delivery to the patient of substances.

During the past years, in order to facilitate setup procedures, those replaceable components to be mounted on the treatment apparatus have been provided with indicia (such as bar codes, color codes, microchips, RFID devices, mechanical keys, etcetera) secured to the component and detectable by a respective appropriate reader associated to the treatment apparatus to provide the apparatus at least with an information relating to the identity of the same component.

Here below the technical solutions which the applicant regards as relevant are described.

A first solution is disclosed in WO80-02376 which describes a hemodialysis system using disposables tubing and filter having optical or magnetic coding indicia on a strip. The strip can be coded to match a specific program or procedure, and the system can be constructed or programmed to generate a signal should the module and the program in the system not correspond.

U.S. Pat. No. 5,769,811 shows a blood processing machine and disposable units for use therewith. The disposable units generally comprise a centrifuge bowl for separating whole blood into blood constituents, an inlet tube for conveying blood into the bowl, an outlet tube for conveying the blood constituents away from the bowl, and a manifold for placing the inlet tube and the outlet tube in fluid communication with a tube from a donor. The manifold has a machine-readable bar-code label for identifying to the blood processing machine which type of disposable unit is being coupled to it. The machine itself comprises a central processing unit that controls overall operation, a first computer memory containing safety-monitoring instructions that cause the central processing unit to monitor various state parameters in order to ensure donor safety, and a second computer memory containing instructions that define at least one apheresis or blood-processing protocol. In some implementations, the second computer memory is removable from and insertable into the blood processing machine by an operator.

U.S. Pat. No. 6,626,355 discloses a medical apparatus comprising an accessory port and at least one accessory piece comprising a connection element complementary to said accessory port; the connection element includes a storage unit where coded and/or un-coded information is stored, is read by means of a readout unit disposed in the section of said accessory port, and is compared to identification information stored in readout unit; the medical device is activated when the identification information match the desired identification information, and is blocked when the identification information do not match. Coded identification information is decodable by means of a proprietary key.

EP1170023 concerns a hemodialysis machine comprising at least one semi-permanent component, such as an ultrafilter for use in the online preparation of dialysis liquid. The component is changed periodically after being used for several consecutive dialysis treatments; the machine comprises a bar-code reader for identifying the semi-permanent components thus unequivocally identifying the semi-permanent component mounted on the machine, and communicating its presence and identity to said control unit in the machine.

U.S. Pat. No. 6,685,831 discloses a dialysis machine with a device for preparing dialysis solutions. Preparation of dialysis fluids of different concentrations is achieved by the fact that the device has a detector device, at least two connections and at least two interchangeable storage containers to hold the solution ingredients to be metered. Each container is connected to at least one connector, and the connectors are connectable to the connections; the connectors or the areas of a connecting tube near the connectors have identification means which can be detected by the detector device. It is also disclosed a connector for connecting a storage container with solution ingredients to a medical apparatus, where the connector or areas of a connecting tube near the connector has identification means. Detecting a connection of a solution ingredient storage container is guaranteed by the fact that the connector is provided with identification means and is attached to a matching component, and a reader unit determines the type and position of the connector.

WO01/41831 discloses a hemofiltration machine including a chassis, at least one flow controlling element on the chassis, and a controller for the hemofiltration machine to operate the flow controlling element to carry out a processing task in response to a control program, the controller including an input on the chassis for reading coded indicia, an extracorporeal circuit for circulating blood from an individual through a hemofilter, and a fluid processing cartridge holding the extracorporeal circuit for mounting as an integrated unit on the chassis in operating engagement with the flow controlling element and for removal as an integrated unit from the chassis, the fluid processing cartridge carrying coded indicia incorporating a control program for the controller, the coded indicia being readable by the input in response to mounting the fluid processing cartridge on the chassis, to thereby transfer the control program to the controller for execution. Document WO2004033024 shows a medical-technical identification device for identifying a sterile product for example a product intended for one-time-use only, when connected to a piece of medical equipment. The sterile product includes a fixedly mounted information carrier which is adapted to deliver or to offer specific product information in a contactless fashion to a reading element connected to the equipment.

U.S. Pat. No. 5,658,456 describes a dialysis apparatus having a dialysate preparation module and a tank for storing a dialysate solution, for performing automatic verification of dialysate chemicals prior to adding said chemicals to said dialysate preparation module so as to insure correct preparation of said dialysate solution, comprising: an electronic reader of a machine-readable indicator, said electronic reader incorporated into said dialysis machine; a bottle containing a unit batch of dialysate chemicals for treatment of a medical condition of a patient to be treated by said dialysis machine, said bottle adapted to be installed on an opening apparatus in said machine such that, when said bottle is opened, said dialysate chemicals are placed in fluid communication with said tank for delivery of said unit batch of dialysate chemicals automatically into said tank; and a machine-readable indicator containing coded information (ID,LOT,DATE) as to said dialysate chemicals contained in said bottle, said machine-readable indicator applied to said bottle in a manner for permitting machine identification of the contents of said bottle by said electronic reader prior to operating the opening apparatus to open said bottle and adding said dialysate chemicals to said tank, whereby machine identification of said dialysate chemicals contained in said bottle may occur prior to introduction of said chemicals into said tank.

SUMMARY OF THE INVENTION

While numerous solutions have been provided, the applicant has envisaged a new method and a new apparatus which are suitable for further improving machine setup and data entry of information when replaceable components are used.

Indeed, according to the technical solutions of the prior art, the treatment apparatus had a respective reader located in correspondence of the position where the disposable or semi-disposable article is expected to be mounted on.

This situation renders impossible accessing the reader while a disposable or semi-disposable is already installed.

Moreover in case a plurality of disposable or semi-disposable components have to be installed in different locations of the apparatus, then a corresponding number of readers would be required.

Furthermore the reader of replaceable devices ID according to the prior art is only used for a single purpose and cannot be relied on for entering commands or other data into the medical apparatus.

In view of this situation it is a goal of the present invention to provide a fluid processing medical apparatus and method for transferring data to a fluid processing medical apparatus capable of enhancing setup procedures and, more in general, transfer of data to the medical apparatus.

It is a further object of the invention to reduce the number of readers to be present on the medical apparatus side without impairing on the ease and data entry reliability.

The above aims are reached by a method for setting-up a fluid processing medical apparatus, the apparatus being of the type comprising:

- a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus,
- at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen, the method comprising the following steps:
  - providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,
  - reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,
  - coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

According to an aspect of the invention, after the reading step it is provided a step of verifying if the new component is of the same category of a component already installed on the machine. In other words if for instance the new component is a concentrate container, such as a bicarbonate cartridge, the method provides for checking if a bicarbonate cartridge was already installed on the apparatus. In practice the verifying step can be done by checking if a component having the same category of the new component has been already read before and/or by checking if a component is engaged with the engaging means of the type adapted to receive the new component.

The steps of reading and verifying can be repeated every time a new component is to be coupled to the apparatus.

The replaceable components are a plurality of components of different categories (by way of non limiting example a plurality of filters, a plurality of concentrate cartridges, a plurality of bloodlines, etcetera), where each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories. The medical apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only.

In an embodiment, the method includes the sequential steps of:

- signaling that a component of the same category is already installed on the apparatus
- requesting for confirmation to substitute the installed component with the new component,

initiating a procedure for substitution of the installed component with the new component.

According to a further aspect of the invention, for instance before coupling each new component to the apparatus, the method provides for:

selecting a desired treatment procedure (for instance in case the apparatus is a blood treatment machine, the method provides for selecting among a plurality of treatments such as hemofiltration, ultrafiltration, hemodiafiltration, hemodialysis etcetera),

checking if the new component fits with the selected treatment procedure,

signaling if the new component does not fit with the selected treatment procedure.

While in one embodiment the information is fixed to the replaceable component, the information carrier could also be the packaging of the component or a card associated with the component.

According to a further aspect the reader can be relied on for entering commands into the apparatus by associating command information to a readable information carrier, relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus, initiating a treatment procedure complying with the entered command.

According to another embodiment the reader can be relied on for entering commands into the apparatus by associating patient data information to a readable information carrier, relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus.

In addition to the above way of entering component related information and initiating a substitution procedure of a replaceable component, the method of the invention provides for an additional and parallel procedure for installing a new replaceable component on the apparatus without interacting with said reader. This additional procedure includes the following steps:

entering the information of a new component to be installed on the apparatus by acting on said user interface,

verifying if the new component is of the same category of a component already installed on the machine,

displaying on said screen a message informing if a component of the same category is already installed,

in case a component of the same category is already installed asking for confirmation to proceed with the substitution thereof,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

In case a component of the same category is already present the method can also provide for the following steps: moving the installed component from an operating condition to a non-operating condition where it can be safely disengaged from the apparatus, and then disengaging said component before installing the new one.

The step of entering information by acting on the user interface comprises the steps of:

Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component (this can be done with a navigation keyboard or keypad either part of the screen or external, which allows the user to navigate through various displays stored in the memory of the user interface control system),

Selecting the desired display of the user interface,

Selecting the new component to be installed by acting on said selected display.

The user interface can also be used to enter commands without acting on said reader and/or to enter patient related information again without acting on said reader.

The above specified aims are also reached by a fluid processing medical apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus.

In practice the control system includes means for controlling the apparatus operation (a network of sensors, actuators and connections not further detailed as their nature is not relevant for the purpose of present invention), means for receiving and storing information coming from and/or going to the user interface and means for receiving and storing information coming from the reader (i.e. wired or wireless connections to the reader, a control processing unit of digital or analogical type and a memory).

In one embodiment the control system is programmed (i.e. comprises means in the form of an analogical circuit portion or in the form of a suitably programmed digital processor) for verifying if the new component is of the same category of a component already installed on the apparatus. The above steps of reading and verifying can be automatically repeated anytime the reader reads information of a new component to be installed. In one embodiment the step of verifying includes determining the category of the new component, and/or checking if a component of the same category was detected before, and/or checking if a component is engaged with the engaging means of the type adapted to receive the components of the category of the new component.

The replaceable components are a plurality of components of different categories (by way of non limiting example a plurality of filters, a plurality of concentrate cartridges, a plurality of bloodlines, etcetera), where each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories. The medical apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only.

According to one aspect of the invention, the control system is also programmed (i.e. comprises means in the form of

an analogical circuit portion or in the form of a suitably programmed digital processor) for sequentially executing the following steps:

- signaling that a component of the same category is already installed on the apparatus,
- requesting for confirmation to substitute the installed component with the new component,
- initiating a procedure for substitution of the installed component with the new component.

In accordance with a further aspect of the invention, the control system is programmed for executing the following steps:

- receiving selection of a desired treatment procedure,
- checking if the new component fits with the selected treatment procedure,
- signaling if the new component does not fit with the selected treatment procedure,
- allowing the step of coupling the new component with the apparatus only after the step of checking if the new component fits with the selected treatment procedure.

According to an embodiment of the invention, the information comprises one or more selected in the group including:

- Identity of the component,
- Identity of a series of identical components (this can happen in case a series of component shares same identical characteristics),
- Expiration date of the component,
- Manufacturer,
- One or more commands for programming the apparatus to execute a procedure on said fluid,
- Data concerning a patient (pressure measures made before treatment, prescription, personal information)

The information carrier is one selected in the group comprising: a surface of the component, a packaging of the component, a card associated with the component.

The apparatus of the invention can also have the control system programmed for receiving commands for carrying out a corresponding procedure on said fluid and/or patient data by reading corresponding information associated to a readable information carrier which is approached to the reading portion.

In addition to the reader, the control system can also be programmed for executing an additional procedure for installing a new replaceable component on the apparatus without interacting with said reader, the additional procedure comprising the steps of:

- allowing to enter information of a new component to be installed on the apparatus by acting on said user interface,
- verifying if the new component is of the same category of a component already installed on the machine,
- displaying on said screen a message informing if a component of the same category is already installed,
- coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

The step of allowing entering information by acting on the user interface can comprise the steps of:

- Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component,
- Allowing selecting the desired display of the user interface,
- Allowing selecting the new component to be installed by acting on said selected display.

In practice the reader used in the invention can be any optical reader (bar code reader, or color code reader, or reader of any optically detectable shape and/or pattern) or a radio-frequency reader (RFID reader) or magnetic reader (reader of magnetic strips) or any other equivalent reader adapted to detect said information when the component and the reading portion are approached one another (in contact or in proximity).

Further characteristics and advantages will better emerge from the following description in relation to some preferred but non-limiting embodiments of the invention.

SHORT DESCRIPTION OF THE DRAWINGS

Referring now to the enclosed figures several methods and corresponding apparatus will be described with reference, again by way of non limiting example, to replaceable components adopted in blood treatment apparatus.

The description will be made with reference to the figures of the accompanying drawings, also provided by way of non-limiting example, in which:

FIG. **1** is a block diagram showing the steps of the main flow of process executed by the control system of the apparatus of FIG. **14** when the reader of the apparatus of FIG. **14** reads information concerning a replaceable component or concerning a command;

FIG. **2** a block diagram showing the process followed after the steps of FIG. **1** by the control system of the apparatus of FIG. **14** when reading a concentrate related information via the reader;

FIG. **3** is a block diagram showing the steps performed by a user for changing a concentrate container using the apparatus of FIGS. **1**, **2** and **14**;

FIGS. **4** and **5** show the process followed after the main flow of FIG. **1** by the control unit of the apparatus of FIG. **14** when respectively a dialyzer or a bloodlines code;

FIG. **6** is a block diagram showing the process followed control system **18**, after the main flow steps of FIG. **1**, when a disinfection procedure is initiated upon a code of a disinfectant is read;

FIG. **7** is a block diagram showing the steps performed by a user for initiating a disinfection procedure;

FIGS. **8-10** show the procedure followed by the control system **18** of apparatus of the invention when using the reader for entering commands, such as by way of non limiting examples: DISINFECTION, RINSE or SERVICE COMMAND;

FIG. **11** a block diagram showing the steps performed by a user for inserting an event command when using the reader and when using the user interface **30**, and

FIGS. **12** and **13** are block diagrams showing the steps performed by the control system after the main flow of FIG. **1** if respectively the code is neither recognized as a known replaceable component nor as a known command;

FIG. **14** is a schematic view of the circuits of a blood treatment apparatus provided with a reader for reading information relating to replaceable components, according to the invention;

FIG. **15** is a schematic elevation of the blood treatment machine of FIG. **14**.

DETAILED DESCRIPTION OF NON-LIMITING EMBODIMENTS

With reference to the enclosed figures, reference numeral **1** indicates a fluid processing medical apparatus according to an embodiment of the present invention.

The apparatus **1** of the non limiting embodiments herein described is an extracorporeal blood treatment machine for the treatment of pathologies such as kidney failure, liver failure, or congestive heart failure. While for sake of clarity and conciseness, the invention will be explained in detail with reference to an extracorporeal blood treatment machine, the invention could find application in other fluid processing apparatuses such as machines for processing whole blood or blood components coming from a donor or from a source (such as one or more containers), machines for blood oxygenation, machines for the cleaning or purification of water for medical use, machines for the preparation of medical fluids, machines for the delivery of medical fluids (infusion devices or drug administration machines), etcetera.

Going back to the embodiment of the attached figures, the apparatus **1** is an extracorporeal blood treatment machine able to perform one or more of the following extracorporeal blood treatments: ultrafiltration, dialysis, hemofiltration, and hemodiafiltration.

The apparatus **1** according to the embodiment of the drawings mainly comprises:

- A hydraulic circuit **2** for fresh treatment liquid, such as dialysis liquid, which in use is to be sent into a first chamber **3** of a blood treatment unit, 4 and/or infusion liquid, which in use is to be sent into the patient. The hydraulic circuit is responsible for bringing the treatment liquid to the treatment unit and/or directly to the patient with appropriate chemical and physical properties. The hydraulic circuit is also responsible for evacuating waste fluid from the blood treatment unit.
- A blood treatment unit **4** comprising at least a casing defining at least two chambers **3**, **5** separated by a semipermeable membrane **6**.
- Bloodlines **23**, **25** connected to the second chamber of the blood treatment unit.
- A cabinet structure **32** housing the hydraulic circuit **2** and supporting, during treatment, the treatment unit **4** and the bloodlines **23**, **25**.
- A user interface **30** which is typically mounted on a front panel of the cabinet structure, but which could alternatively be in the form of an independent unit, separate from the cabinet.

The circuit **2** includes at least a supply conduit **7**, bringing dialysis liquid to the first chamber inlet, and a waste conduit **8**, receiving spent liquid exiting via an outlet of the first chamber. One or more concentrate sources of concentrates could be present. The concentrate sources could be designed to include containers for housing concentrated solutions or dry concentrates. In the enclosed embodiment containers **9**, **10** deliver concentrated solutions, via respective lines **11**, **12** and upon the action of respective concentrate pumps **13**, **14**, into the conduit **7** thereby properly mixing water coming from a source **15** with said concentrates and obtaining the dialysis liquid. In the machine of the enclosed embodiment one of the two containers, for instance container **10**, is a dry concentrate cartridge. While not shown in the drawings, cartridge **10** is also connected, upstream line **12**, to a source of water or of solution directly or indirectly coming from source **15**. Conductivity or concentration sensors **16**, **17** can be provided on conduit **7** downstream each respective concentrate line. Said sensors provide control signals to a control system **18** which is responsible to act on the concentrate pumps based on desired concentration settings and on said control signals. Sensors (not shown) detecting conductivity or concentration of electrolytes can also be present on the waste conduit **8**. A pump **19** is generally operating on supply conduit **7** and a pump **20** on the waste conduit **8**. Of course different alternative embodiments can be envisaged to bring dialysis liquid to the treatment unit with appropriate chemical and physical properties. For instance pre-prepared dialysis liquid bags or containers could be used, with no need of online preparation of liquid from concentrates and water.

Fluid balance sensors, for instance a first and a second flow-meter **21**, **22**, operating on the supply conduit **7** and on waste conduit **8** respectively, are used and are connected to the control system to provide signals necessary for regulating at least one of pumps **19**, **20**. Of course other fluid balance systems can be used: scales for instance or balance chambers or any other volumetric or mass or flow-rate based system available to the skilled man.

One or more ultrafilters could operate in the hydraulic circuit, upstream the treatment unit **4**. For instance in the enclosed embodiment one ultrafilter **36** is present upstream concentrate line **11** and one ultrafilter **37** is placed downstream all concentrate lines **11** and **12**.

The blood treatment unit **4** comprises at least a casing defining at least two chambers **3**, **5** separated by a semipermeable membrane **6**. The properties and type of membrane can vary depending upon the patient's needs and type of treatment to be executed: in particular the treatment unit could be an ultrafilter, an hemofilter, a dialyzer, an hemodiafilter, a plasmafilter etcetera.

The bloodlines **23**, **25** connected to the second chamber of the blood treatment unit comprise an arterial branch **23**, which in use serves to withdraw patient's blood to be treated, and a venous branch **25**, which in uses serves to return treated blood to the patient.

The user interface **30** herein disclosed is connected with and part of the medical apparatus **1**; however the user interface could be a self powered unit with wired or wireless connection to the control unit of the medical apparatus.

The user interface **30** of the embodiment shown includes a screen **31**, for instance a touch screen, which allows interaction with the user interface, for instance selection of certain parameters, visualization, either in analogical or in digital form, of values of said parameters and display of other information; of course depending upon the case the user interface could include also buttons, knobs, or other hardware means **31** positioned off the screen and operable to introduce entries into the control system.

The activity of the user interface is determined by control system **18**, which is connected to the user interface, is responsive to actions by a user on said user interface, and controls operations of the medical apparatus **1** by acting on a plurality of actuators (such as pumps **12**, **13**, **19**, **20**, **27**, valve **27** and others) and by receiving signals from a plurality of sensors (such as for instance sensors **12**, **13**, **21**, **22**, **29** etc.).

The control system of presently shown embodiment includes a main control unit, connected to the user interface **30**, and at least a memory connected to the main control unit. From a technical point of view the main control unit includes at least a microprocessor, while the above-mentioned memory can be in a single physical memory or in physically separated memory devices. Of course other alternative could be equivalently adopted, such as a control system partly or totally of analogical type.

In extracorporeal blood treatment apparatus, as the one just described, as well in other medical apparatus some components are replaceable, in the sense that they are replaced more or less frequently during the life of the apparatus, according to criteria which could vary depending upon the patient, the specific component, the market where the component is used, etcetera. By way of non limiting example, referring to a dialysis machine for chronic treatment as the one just

described, the dialyzer, the blood tubing set, the access devices, the infusion lines and bags are replaced at the end of each treatment session or procedure. If a rinsing and/or priming procedure is activated using fresh liquid coming from a bag the empty bag is typically disposed of at the end of the procedure. The ultrafilters and concentrate containers used for the preparation of treatment liquid can be changed at the end of each treatment session, or after a number of sessions, or after a number of working hours.

In conclusion, with reference to the blood treatment apparatus just described, a number of components are replaceable components: the concentrate containers **10**, **11** (which can be in the form of deformable bags or rigid containers, containing concentrated either in liquid or in solid form), the bloodlines **23**, **25**, the blood treatment unit **4**, the ultrafilters **36**, **37** in the dialysis preparation circuit, any infusion lines **38**, the bags or other containers for the injection of fluids into the blood circuit or into the blood lines, the access devices (needles, catheters, or the like).

As can be easily understood, the apparatus of the type described can host and use a plurality of components of the same category: for instance the same blood treatment apparatus can alternatively use a number of different blood treatment units, or a number of alternative bloodlines, or a number of alternative concentrate containers etcetera. Typically before each treatment, an operator selects the needles, bloodlines, bags, dialyzer or other blood treatment unit, as well as other replaceable components ideal for that specific treatment. The apparatus has engaging means differentiated per type of component: for instance the ultrafilters located in the fluid preparation section of the hydraulic circuit present connectors positioned and shaped so that they cannot be engaged in place of the dialyzer; each component of the same category presents respective mechanical connections to the apparatus different from those of the components of other categories, so that each replaceable component fits with the respective connections on the machine and setup mistakes on the part of the operator are minimized.

More precisely, the means for engaging replaceable components of different categories comprises a plurality of different types of engaging means, each type of engaging means being designed for engaging, in a respective operating area, respective components of one corresponding category only. Practically all concentrate containers of the same category (for instance all bicarbonate containers) have identical connectors and engage with corresponding ports suitably shaped on the apparatus: the cartridge **10** has for instance two opposed connectors or ports **10***a*, **10***b* receivable in corresponding ports or connectors **34***a*, **34***b* of the apparatus **1**. Analogously all bloodlines are designed to engage corresponding seats on the apparatus, seats which are not suitable for hosting the concentrate containers or other components. In the same manner all blood treatment units (hemofilters, dialyzers, hemodiafilters, etcetera) form another category and have connector or ports designed to couple with a corresponding engaging means (which can include tubular ports and or counter-connectors other support mechanisms to hold in place the unit **4**) on the support structure of the apparatus.

Before using the described apparatus, a user should prepare it for the specific treatment to be delivered. The user should install all replaceable components: put in place the bloodlines, the treatment unit, the various concentrate containers, substitute the ultrafilters if necessary, install all necessary bags and infusion lines. Then a priming process is started to clean, rinse and to remove air from all components which are expected to enter in contact with blood or with treatment liquid.

In view of this situation it is fundamental when setting the machine to inform the machine about the specific components that have been mounted as the procedures or treatments that the machine can deliver are in general related to the components used. In order to enter setup information, the user can enter data of any kind relying on the user interface: for instance, prescription data, treatment selection information, and of course data relating to the components installed on the machine.

As it will be explained in detail the user can navigate through the various levels or menus of the user interface **30** and select or enter the information corresponding to each replaceable component installed on the machine.

In order to facilitate the data entry process, a reader **35** is provided operatively connected with the control system **18** and having a reading portion for reading information concerning the components. Each replaceable component is associated to a respective information; the information is borne by the respective component (i.e. on a label or directly on the component) or by the respective component packaging or by a card or other support; the nature of the reader is such that to read the information it is necessary approaching to one another the component and the reading portion (depending upon the nature of the reader, which could be an optical reader such as a linear or bi-dimensional bar code reader, an radio based reader such as RFID reader, a mechanical reader, or a reader of other nature, the user will need to approach more or less the information support to the reading portion or even put reader and information support into contact). In accordance with one aspect of the invention the information carrier and the reading portion should either be put into reciprocal contact or relatively approached at a distance in the range of 30 cm or less.

The reader can be fixed to the apparatus support structure or be in the form of a movable reader connected to the apparatus control unit via wires or wireless.

In any case the reading portion of the reader is always operating in a position distinct and spaced from said operating areas where the replaceable components are expected to operate in use conditions. In this way, the reading portion is accessible for reading the information irrespective of the components being engaged or not to the apparatus.

Going now to the specific embodiments of the attached figures, FIG. **1** discloses in form of block diagram the steps followed by the control system. As mentioned the control system can include a microprocessor based control unit which is suitably programmed to execute the steps here below disclosed. Alternatively the control system can be an analogical system which is designed to carry out the steps as below described. In any case the control system by way of intrinsic design or by way of a suitable program includes means for performing the steps below described.

While it will not be repeated for each step in below description it is intended that the control system is programmed for, or includes means for, performing each one of below steps. These means included in the control systems can be suitably designed analogical circuit portions or programmed digital circuits of a control processing unit.

Referring to FIG. **1** the control system receives the scanned code, for instance a barcode, from the reader **1** (step **100**). The control system communicating with the reader is programmed for receiving the information concerning the components: in practice, every time a new component is approached to the reader (or the reader to support bearing the component information) sufficiently for the reader to read

information concerning a component to be installed on the apparatus, then said read out information is transferred to the control system **18**.

The control system then verifies if the syntax of the scanned code satisfies predefined criteria (step **101**) and in the negative generates and error signal (which can be audible and/or displayed on the screen **31**), as per step **102**.

The control system can also generate an acknowledgement message and/or sound, when on the other hand the barcode syntax is correct (step**103**).

Then the control system verifies if the scanned code corresponds to a code of replaceable component (step **104**) and in the affirmative decodes the product number (step **105**), for instance by comparing it with a list of numbers stored in the control system memory (step **107**).

In the negative, the control system decodes the command number (step **106**), for instance by comparing it with a list of numbers stored in the control system memory (step **108**). In practice, depending as to whether the code corresponds to a component or to a command the control system follows one of the two branches of the diagram of FIG. **1**.

If the control system has detected a code of a component, then the identity of said component is searched in the library present in the control system memory and first the category of the component is identified (step **109**) and a corresponding procedure initiated (step **113**); if a component category, is not identified a corresponding audible and/or displayable signal is generated (step **110**).

If the control system detects a command code, in step **111** the control system verifies if the command is known or not. In the latter case a audible and/or displayable signal is generated (step **112**). If the command code is recognized as one of the known commands, the type of command is detected (step **114**) and a corresponding procedure initiated (step **115**).

In case for instance the control system has detected a component code corresponding to a concentrate, then the procedure and steps of FIG. **2** is followed. If the control system has detected a component code corresponding to a dialyzer, then the procedure and steps of FIG. **4** is followed. If the control system has detected a component code corresponding to a bloodline, then the procedure and steps of FIG. **5** is followed. Of course component of other categories could be encompassed with slightly different procedures followed by the control system depending upon the category of the component.

In FIG. **2**, after the step **113**, the control system verifies that the number is that of a concentrate, checks expiration date or other validity parameters (step **120**), and warns accordingly the operator through audible and/or visual signals (step **121**). The control system verifies then if the machine setup or configuration requires the detected type of concentrate (step **122**) and in the negative warns accordingly the operator through audible and/or visual signals (step **123**)

The control system also verifies the status of the apparatus in order to detect if the new component the code of which has been just read is of the same category of a component (same dry concentrate for instance) already installed on the machine (step **124**). In the affirmative the control unit is also programmed for signaling that a component of the same category is already installed on the apparatus. If the control unit verifies that a component of the same category as the one read by the reader, then the control unit is programmed for requesting for confirmation to substitute the installed component with the new component (step **125**). In case a conductivity calibration procedure is ongoing the control system informs that it is not possible to take any action for the scanned concentrate (step **126**). In case the concentrate is not valid, or not applicable in view of the apparatus selected treatment, or if a calibration or other momentary procedure preventing substitution of the specific component is ongoing, then the control system returns to a condition where it is ready to receive a new bar code reading (step **127**).

FIG. **4** and FIG. **5** flow diagrams are very similar to the above described diagram and procedure of FIG. **2**, so the steps **120**, **121**, **122**, **123** executed by the control system will not be described again as the only difference is that in FIG. **4** a dialyzer code is detected and in FIG. **5** a bloodlines code is detected. As to FIG. **4** it is however to be noted that in case a dialyzer code is detected the control system verifies the status of the treatment procedure and if a dialyzer is already installed (step **124**). Then it also verified if priming of the dialyzer currently installed is still running and if it has been completed or not (step **126**). Steps **125** and **127** are similar again to those of FIG. **2** for the concentrate code. As to FIG. **5**, after step **122** the control system verifies if a bloodline is already installed on the machine and also if blood has been already sensed by use for instance of a sensor (a sensor associated with the bloodline and able to detect blood presence such as an optical sensor or a conductivity sensor or an electromagnetic sensor or a capacity sensor can be alternatively used. The sensor is in communication with the control system). Steps **125** and **127** are similar again to those of FIG. **2** for the concentrate code.

FIG. **6** diagram shows the procedure followed by the control system when a the code of a disinfectant replaceable component is detected. FIG. **6** flow diagram is very similar to the above described diagram and procedure of FIG. **2**, so the steps **120**, **121**, **122**, **123** executed by the control system will not be described again as the only difference is that in FIG. **6** a disinfectant code is detected. In FIG. **6** flow, after step **122** the step **124** of verifying the machine status includes verifying if the blood treatment apparatus **1** is in one of the following operating conditions:

- priming status (step **130**), i.e. a status where lines are washed and rinsed before the treatment.
- dialysis status (step **131**), i.e. the true blood treatment,
- disinfection status (step **132**), i.e. disinfection of the circuit **2** after treatment.

If the apparatus is in one of the above conditions, then a step **133** is executed where the control systems generates a visible and/or audible signal warning the operator that a disinfection procedure of the blood treatment apparatus cannot be started.

Steps **125** and **127** of FIG. **6** are similar to those of FIG. **2**, but for the fact that a disinfection confirmation is required and that after confirmation a disinfection procedure will start.

FIG. **8** diagram shows the procedure followed by the control system when a code of a command corresponding to a disinfection rinse profile is detected a disinfectant replaceable component is detected. The control system then verifies if the configuration of the machine is adapted to run the command (step **140**). In the affirmative the control system verifies if the machine status (step **141**), which includes verifying if the blood treatment apparatus **1** is in one of the following operating conditions:

- priming status (step **142**), i.e. a status where lines are washed before the treatment.
- dialysis status (step **143**), i.e. the true blood treatment,
- disinfection status (step **144**), i.e. disinfection of the circuit **2** after treatment,
- rinsing status (step **145**), i.e. when the lines are rinsed after a treatment.

If the apparatus is in one of the above conditions, then a step **146** is executed where the control systems generates a

visible and/or audible signal warning the operator that a disinfection procedure of the blood treatment apparatus cannot be started.

Steps **125** and **127** of FIG. **8** are similar to those of FIG. **6**.

FIG. **9** diagram shows the procedure followed by the control system when a code of a command corresponding to a request to go to a service screen or to perform a task is detected. The control system then verifies if the status of the machine is adapted to allow the command, i.e. to access to the status screen (step **150**). In the affirmative the control system loads on the user interface screen **31** the service screen and allows the operator to interact with it (step **151**). If the command is a task, after step **150** the control system will let the operator to perform the task in question. If the check of step **150** is negative, then control systems generates a visible and/or audible signal warning the operator that the command is not applicable (step **152**) and then the control system returns to a condition where it is ready to receive a new bar code reading (step **127**).

FIG. **10** diagram shows the procedure followed by the control system when a code of a command corresponding to an event that needs to be inserted is detected (events can be for instance: a medication given to the patient, a patient problem that has been detected and so on). The control system then verifies if the status of the machine is adapted to receive the event command (step **160**). Then the control system compares the event command with a list of events stored in a library (step **161**) and also checks the apparatus configuration (step **162**). The control system then verifies if for the entered event command a signature is necessary or not (step **163**). In the affirmative the signature is allowed to be entered (step **164**) via an appropriate means (a touch screen portion can be used) and validated by comparing it with a signatures library (step **165**). In case of no validation the control system returns to step **163**. In case the signature is not mandatory (steps **166**) or if the signature has been validated the control system moves to step **167** where the event is recorded and inserted in a report table. In case a signature has not been inserted, but it is required for the event, then the control system returns to a condition where it is ready to receive a new bar code reading (step **168**).

FIG. **12** diagram shows the procedure followed by the control system when a correctly formatted unknown code of a replaceable component is read. The control systems generates a visible and/or audible signal warning the operator that the code is unknown (step **171**) and then the control system returns to a condition where it is ready to receive a new bar code reading (step **172**).

FIG. **13** diagram shows the procedure followed by the control system when a correctly formatted unknown code of a command is read. The control systems generates a visible and/or audible signal warning the operator that the code is unknown (step **181**) and then the control system returns to a condition where it is ready to receive a new bar code reading (step **182**).

Going now to FIGS. **3**, **7** and **11** comparatively showing the steps performed by a user when using the reader (right side of each figure) and when using the user interface **30** (left side), it is clear how advantageous id the reader for entering commands and components identities. Of course the presence of the user interface which also allows to manually enter the same commands and information in the control system gives redundancy and consequently high reliability.

The above steps subsequent to reading of a code can be basically repeated by the control system every time the reader reads information concerning a component to be installed on the apparatus or a command to be executed.

The above apparatus and method have been described assuming that the reading portion is always active, i.e. in a status where it is able to read information. While this could be the case, it is also alternatively possible to have activation and de-activation of the reader and of the reading portion depending upon the following circumstances.

In particular, the control system of the apparatus **1** could be programmed for receiving a information concerning a fluid treatment procedure selected by a user (by acting on the user interface for instance), and then verifying if the selected fluid treatment procedure requires or not use of the reading portion. For instance in case of a blood treatment machine after set up of the machine the machine can start the extracorporeal blood treatment. During such a treatment it is normally not necessary to enter data using the reader and this latter can be conveniently turned off. The de-activation of the reading portion, when the selected treatment procedure does not require use of the reading portion, can be automatic (i.e. upon detection of the selection or of the start of the specific procedure) or commanded by the user acting on the user interface (which can have an appropriate key or dedicated area). The control system can also be programmed for de-activating said reading portion, when the reading portion reads no information during a prefixed timeout period.

The control system can also be programmed for verifying if the selected fluid treatment procedure requires or not use of the reading portion and for activating said reading portion, when the selected treatment procedure does require use of the reading portion.

In accordance with one embodiment the control system is programmed for activating said reading portion, when the apparatus is turned on.

With the reference to the example of the enclosed drawings where the apparatus **1** is an extracorporeal treatment machine, the control system can be programmed—and thereby includes means—for executing one or more of the following steps of detecting that:

a) a setup procedure has been selected or initiated (which could include one or more steps of setting a prescription, preparing the machine for treatment by engaging any replaceable components with the machine, etcetera),

b) a blood treatment session has been initiated or that a command to initiate a blood treatment procedure has been entered through the user interface,

c) a blood treatment session has been concluded or that a command to stop a blood treatment procedure has been entered through the user interface,

d) a rinse back procedure has been initiated or that a command to initiate a rinse back procedure has been entered through the user interface.

The control system can be programmed—and thereby define means—for turning the reader on upon detection of a) or of c) or of d) and for turning the reader off, upon detection of b).

The medical apparatus **1** above described represents a non-limiting example, which the present invention can be applied to. The apparatus can of course include other components, which are not herein disclosed, as they are not relevant for the purpose of the understanding of present invention.

For instance when verifying the compliance of a component with a selected treatment procedure, this can be done in practice by relying on appropriate sensors of presence, such as mechanical switches or electromagnetic sensors or optical sensors or equivalents thereof (operative in correspondence of the operating areas of the various components), or by means of indirect tests on the fluids interested or affected by the presence of said components (for instance if a concentrate

container is present, then conductivity in the treatment liquid is affected, if a dialyzer is present pressures in several parts of the circuit **2** and bloodlines are affected, if an ultrafilter is present again pressure sensing can be used).

The invention claimed is:

1. Method for setting-up an extracorporeal blood treatment apparatus, the apparatus being of the type comprising:

a support structure for receiving a plurality of replaceable components of different categories in correspondence of respective operating areas of said apparatus, said components comprising a plurality of components of different categories, each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories, and

wherein said apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only,

at least a user interface for enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

the method comprising the following steps:

providing a reader having a reading portion for reading information concerning the components, the reading portion being distinct and spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not with apparatus,

reading the information of a new component to be installed on the apparatus by relatively approaching the reading portion to a carrier of said new component information,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

2. Method according to claim **1**, wherein after the reading step it is provided a step of verifying if the new component is of the same category of a component already installed on the apparatus.

3. Method according to claim **2**, comprising the step of signaling that a component of the same category is already installed on the apparatus.

4. Method according to claim **3**, wherein after the signaling step, the following steps are provided:

requesting for confirmation to substitute the installed component with the new component,

initiating a procedure for substitution of the installed component with the new component.

5. Method according to claim **2**, the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component of the same category was detected before,

checking if a component is engaged with the engaging means of the type adapted to receive the components of the category of the new component.

6. Method according to claim **2**, the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component is engaged with the engaging means of the type adapted to receive the components of the category of the new component.

7. Method according to claim **1**, comprising the steps of:

selecting a desired treatment procedure,

checking if the new component fits with the selected treatment procedure,

signaling if the new component does not fit with the selected treatment procedure.

8. Method according to claim **7**, wherein the steps of selecting a desired treatment procedure, checking if the new component fits with the selected treatment procedure, and signaling if the new component does not fit with the selected treatment procedure are performed before the step of coupling the new component with the apparatus.

9. Method according to claim **1**, wherein the above steps of reading and verifying are repeated for any new component to be installed.

10. Method according to claim **1**, wherein the information comprises one or more selected in the group including:

Identity of the component,

Identity of a series of identical components,

Expiration date of the component,

Manufacturer,

One or more commands for programming the apparatus to execute a procedure on said fluid,

Data concerning a patient,

11. Method according to claim **1**, wherein the information carrier is one selected in the group comprising: a surface of the component, a packaging of the component, a card associated with the component.

12. Method according to claim **1**, comprising the step of entering commands into the apparatus for carrying out a corresponding procedure on said fluid, said step of entering commands including the following sub-steps:

Associating a command information to a readable information carrier,

Relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus,

Initiating a treatment procedure complying with the entered command.

13. Method according to claim **1**, comprising the step of entering patient data into the apparatus, said step of entering patient data including the following sub-steps:

Associating patient data information to a readable information carrier,

Relatively approaching to one another the information carrier and the reading portion to enter the command in the apparatus.

14. Method according to claim **1**, comprising an additional procedure for installing a new replaceable component on the apparatus without interacting with said reader, said additional procedure including the following steps:

entering the information of a new component to be installed on the apparatus by acting on said user interface,

verifying if the new component is of the same category of a component already installed on the machine,

displaying on said screen a message informing if a component of the same category is already installed,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

15. Method according to claim **14**, wherein said step of entering information by acting on the user interface comprises the steps of:

a. Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component,

b. Selecting the desired display of the user interface,

c. Selecting the new component to be installed by acting on said selected display.

16. Method according to claim **14**, comprising a step of entering commands using said user interface and without acting on said reader.

17. Method according to claim **14**, comprising a step of entering patient related information using said user interface and without acting on said reader.

18. Method according to claim **1**, wherein for reading the information, the carrier of said information is and the reading portion are approached to a distance less then 30 cm.

19. Method according to claim **1**, before the reading portion can read any information, a step is provided for activation of said reading portion.

20. Method according to claim **1**, after the reading portion has read any information, a step is provided for de-activation of said reading portion.

21. Method according to claim **1**, wherein the reading portion is deactivated when at least one of the following circumstances occurs:

the reading portion reads no information for a prefixed timeout period,

a user turns the reading portion off by acting of the user interface,

a specific procedure not requiring use of the reading portion is selected by the user

a specific procedure not requiring use of the reading portion is initiated by the apparatus.

22. Method according to claim **1**, wherein the reading portion is activated when at least one of the following circumstances occurs:

the apparatus is turned on,

a user turns the reading portion on by acting on the user interface,

a specific procedure requiring use of the reading portion is selected by the user,

a specific procedure requiring use of the reading portion is initiated by the apparatus.

23. Extracorporeal blood treatment apparatus, comprising:

a support structure,

a plurality of replaceable components of different categories engaged to the support structure in correspondence of respective operating areas, said components comprising a plurality of components of different categories, each component of a same category having respective mechanical connection to a corresponding operating area on the apparatus, different from that of components of other categories, and wherein said apparatus includes a plurality of different types of engaging means, each type of engaging means being designed for mechanically engaging, in a respective operating area, a component of one corresponding category only,

at least a user interface enabling setting of a plurality of parameters pertinent to operation of said apparatus or pertinent to a process to be performed by said apparatus, the user interface including at least a screen,

a reader, distinct from said user interface, having a reading portion for reading information concerning the components, the reading portion being spaced from said operating areas and accessible for reading the information irrespective of the components being engaged or not to the support structure,

a control system for controlling operation of said medical apparatus and responsive to actions by a user on said user interface, said control system also communicating with the reader and being programmed for receiving and storing at least said information concerning the components every time the reader reads information concerning a new component to be installed on the apparatus.

24. Apparatus according to claim **23**, wherein the control system is programmed for verifying if the new component is of the same category of a component already installed on the machine.

25. Apparatus according to claim **24**, wherein the control system is programmed for repeating the above steps of reading and verifying anytime the reader reads information of a new component to be installed.

26. Apparatus according to claim **23**, wherein the control system is also programmed for signaling that a component of the same category is already installed on the apparatus.

27. Apparatus according to claim **26**, wherein the control system is programmed for executing the following steps, after the signaling step:

requesting for confirmation to substitute the installed component with the new component,

initiating a procedure for substitution of the installed component with the new component.

28. Apparatus according to claim **23**, wherein the control system is programmed for executing the following steps:

receiving selection of a desired treatment procedure,

checking if the new component fits with the selected treatment procedure,

signaling if the new component does not fit with the selected treatment procedure.

29. Apparatus according to claim **28**, wherein the control system is programmed for allowing the step of coupling the new component with the apparatus only after the step of checking if the new component fits with the selected treatment procedure.

30. Apparatus according to claim **23**, wherein the information comprises one or more selected in the group including:

Identity of the component,

Identity of a series of identical components,

Expiration date of the component,

Manufacturer,

One or more commands for programming the apparatus to execute a procedure on said fluid,

Data concerning a patient.

31. Apparatus according to claim **23**, wherein the information carrier is one selected in the group comprising: a surface of the component, a packaging of the component, a card associated with the component.

32. Apparatus according to claim **23**, wherein the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component of the same category was detected before,

checking if a component is engaged with the engaging means of the type adapted to receive the components of the category of the new component.

33. Apparatus according to claim **23**, wherein the step of verifying comprises the steps of:

determining the category of the new component,

checking if a component is engaged with the engaging means of the type adapted to receive the components of the category of the new component.

34. Apparatus according to claim **23**, wherein the control system is programmed for receiving commands for carrying out a corresponding procedure on said fluid by reading a command information associated to a readable information carrier which is approached to the reading portion.

35. Apparatus according to claim 34, wherein the control system is programmed for receiving patient data by reading data carried by a readable information carrier which is approached to the reading portion.

36. Apparatus according to claim 35, wherein the control system is programmed for executing an additional procedure for installing a new replaceable component on the apparatus without interacting with said reader, the additional procedure comprising the steps of:

allowing to enter information of a new component to be installed on the apparatus by acting on said user interface,

verifying if the new component is of the same category of a component already installed on the machine,

displaying on said screen a message informing if a component of the same category is already installed,

coupling the new component with the apparatus in correspondence of a respective of said operating areas, the component when coupled leaving the reading portion accessible for reading the information.

37. Apparatus according to claim 36, wherein said step of allowing entering information by acting on the user interface comprises the steps of:

Configuring the user interface as a plurality of displays, each display being accessible to the operator and including information corresponding to at least a respective replaceable component,

Allowing selecting the desired display of the user interface,

Allowing selecting the new component to be installed by acting on said selected display.

38. Apparatus according to claim 23, wherein the reader comprises an optical reader or a radio-frequency reader adapted to detect said information when the component and the reading portion are approached one another at a distance less then 30 cm.

39. Apparatus according to claim 23, wherein the user interface comprises a means for receiving an entry addressed to turn on or off the reading portion, said control system being programmed for:

receiving said entry, and

respectively turning on or off the reading portion depending upon the entry.

40. Apparatus according to claim 23, wherein the control system is programmed for:

receiving a information concerning a fluid treatment procedure selected by a user,

verifying if the selected fluid treatment procedure requires or not use of the reading portion de-activating said reading portion, when the selected treatment procedure does not require use of the reading portion.

41. Apparatus according to claim 23, wherein the control system is programmed for de-activating said reading portion, when the reading portion reads no information during a prefixed timeout period.

42. Apparatus according to claim 23, wherein the control system is programmed for:

receiving a information concerning a fluid treatment procedure selected by a user,

verifying if the selected fluid treatment procedure requires or not use of the reading portion activating said reading portion, when the selected treatment procedure does require use of the reading portion.

43. Apparatus according to claim 23, wherein the control system is programmed for activating said reading portion, when the apparatus is turned on.

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