

William C. Baton
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
wbaton@saul.com
alexander.callo@saul.com

*Attorneys for Plaintiff
Prestan Products LLC*

Of Counsel:

John F. Bennett
ULMER & BERNE LLP
312 Walnut Street, Suite 1400
Cincinnati, OH 45202-4029
(513) 698-5000
jrbennett@ulmer.com

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

PRESTAN PRODUCTS LLC,

Plaintiff,

v.

**INNOSONIAN AMERICA, LLC and
INNOSONIAN, INC.,**

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

DEMAND FOR JURY TRIAL

(Filed Electronically)

COMPLAINT

Prestan Products LLC ("Prestan"), for its complaint against Defendants Innosonian America, LLC ("Innosonian America") and Innosonian, Inc. ("Innosonian Korea") (collectively, "Innosonian"), states as follows:

SUMMARY AND NATURE OF THE ACTION

1. This is an action for patent infringement. Prestan owns a patent directed to a unique CPR training manikin with real-time feedback, and Innosonian—without permission—has copied Prestan's patented technology and incorporated it into competitive products. Prestan files this lawsuit to put an end to Innosonian's willful infringement and to recover damages

resulting from Innosonian's misconduct.

PARTIES

2. Prestan is a Delaware limited liability company with a principal place of business at 5101 Naiman Parkway, Solon, OH 44139.

3. Defendant Innosonian America is a New Jersey limited liability company with a principal place of business at 5760 NC 96 Hwy W, Youngsville, NC 27596.

4. On information and belief, Defendant Innosonian Korea is a Korean corporation with a principal place of business at 62 Bangbae-ro, Bangbae-dong, Seocho-gu, Seoul, South Korea. On information and belief, Defendant Innosonian Korea owns and controls Defendant Innosonian America, and Defendant Innosonian America is acting as the agent of Defendant Innosonian Korea for purposes of conducting the business of Defendant Innosonian Korea in this jurisdiction and elsewhere throughout the United States.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, Title 35 of the United States Code, 35 U.S.C. § 271 et seq. Subject matter jurisdiction of this Court is conferred by 28 U.S.C. §§ 1331 and 1338.

6. Venue in this judicial district is proper under 28 U.S.C. § 1400(b) and 28 U.S.C. § 1391(c) at least because this Judicial District is where Defendant Innosonian America resides and where Defendants Innosonian America and Innosonian Korea have committed acts of infringement.

7. This Court likewise has personal jurisdiction over Defendants Innosonian America and Innosonian Korea at least because New Jersey is Defendant Innosonian America's state of organization, and Defendants Innosonian America and Innosonian Korea committed the

below-described tortious acts of infringement in New Jersey.

8. In the alternative, this Court has personal jurisdiction over Innosonian Korea because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Prestan's claims arise under federal law; (b) Innosonian Korea is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Innosonian Korea has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing, importing, offering to sell, and/or selling manikins that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Innosonian Korea satisfies due process.

9. On information and belief, Innosonian America and Innosonian Korea work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the manufacturing, use, importation, marketing, offer for sale, sale, and/or distribution of manikins throughout the United States, including in this Judicial District.

10. On information and belief, Innosonian America acts at the direction, and for the benefit, of Innosonian Korea, and is controlled and/or dominated by Innosonian Korea.

11. On information and belief, Innosonian America and Innosonian Korea act, operate, and/or hold themselves out to the public as a single integrated business.

PATENT-IN-SUIT

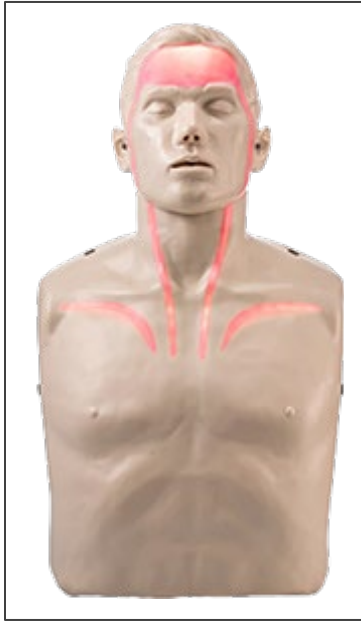
12. United States Patent No. 8,465,293 ("the '293 patent") is titled "Medical Training Device" and issued on June 18, 2013. Attached as Exhibit 1 is a copy of the '293 patent.

13. Prestan is the owner of the '293 patent by assignment.

14. In general, the '293 patent is directed to an improved CPR training manikin that provides real-time feedback.

BACKGROUND FACTS

15. Innosonian is in the business of making and commercializing training manikins that practice the '293 patent (the "Infringing Manikins"), including, but not limited to, the "Brayden" CPR training manikin, shown below from Defendant Innosonian Korea's website (<http://innosonian.com/eng/brayden-brayden.html>):



16. On or about January 7, 2020, Prestan wrote Innosonian concerning its infringement of the '293 patent.

17. On information and belief, prior to receiving the letter, Innosonian had already been aware of the '293 patent and its scope.

CLAIM FOR RELIEF **(Infringement of U.S. Patent No. 8,465,293)**

18. Prestan repeats and incorporates by reference the allegations set forth in the foregoing paragraphs.

19. Innosonian infringed and continues to infringe one or more claims of the '293 patent, including claim 13, in violation of 35 U.S.C. § 271, at least by selling and using within

the United States the Infringing Manikins.

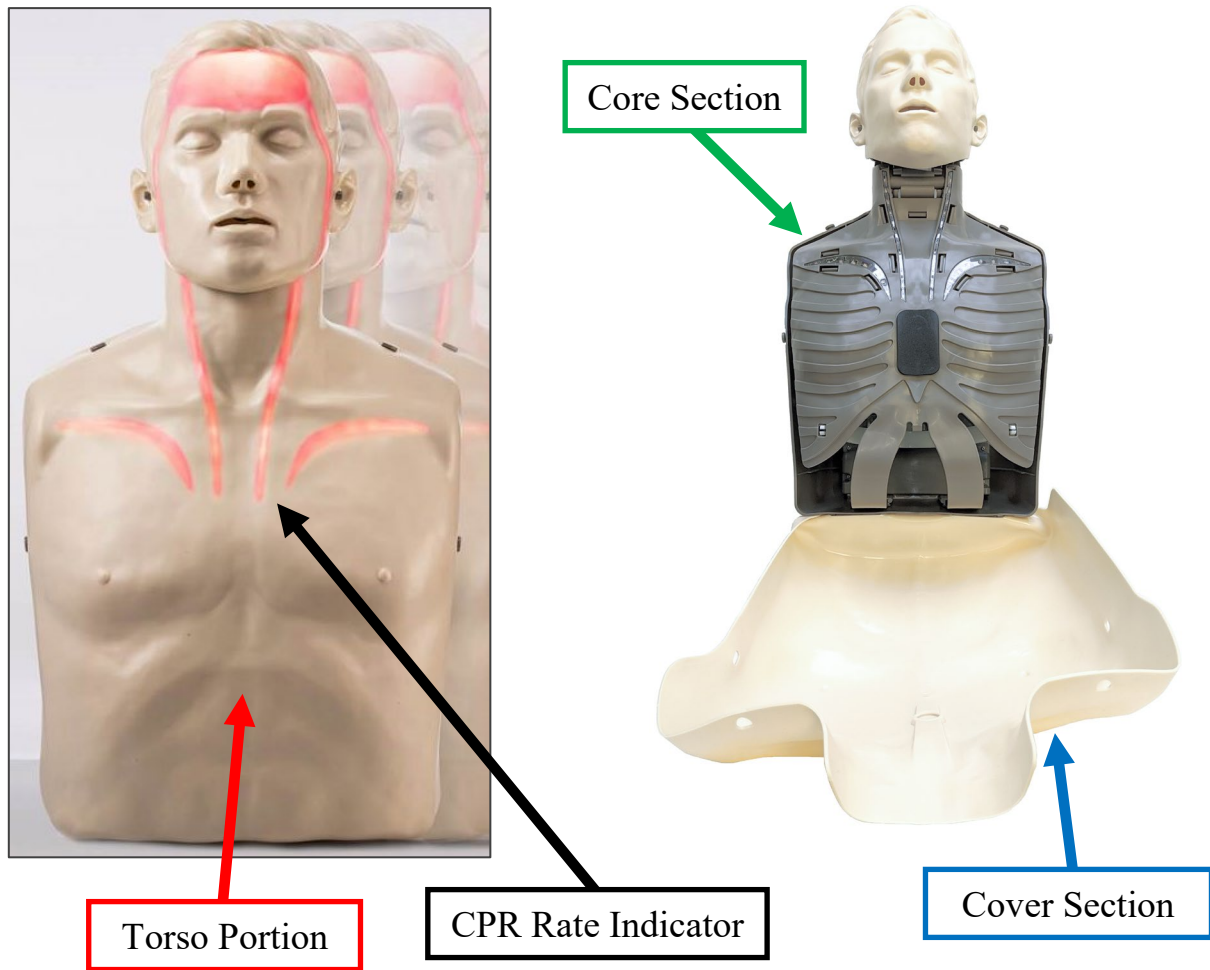
20. For example, claim 13 of the '293 patent recites:

An improved medical training device comprising,

- a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;*
- b) a CPR rate indicator integral with the torso portion and under the removable pliable cover section for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed; and*
- c) a portion of the removable pliable cover section adjacent the CPR rate indicator is configured to view the CPR rate indicator through the removable pliable cover section by the person being trained on the device.*

21. Innosonian's Infringing Manikins meet each limitation of claim 13.

22. For example, as shown in the following images of an Infringing Manikin, it has the claimed torso portion (indicated by red arrow), compressible core section (green arrow), removable pliable cover section (blue arrow), and CPR rate indicator (black arrow):



23. In addition, a portion of the cover section is both adjacent the CPR rate indicator and configured to view the CPR rate indicator through the cover section.

24. Further, as explained on Defendant Innosonian America's website (<https://www.innosonian.us/brayden>), the Brayden's CPR rate indicator provides "real time feedback of CPR performance," including at least with respect to the rate of CPR compressions being performed.

25. As further explained in the "Instructions for Use" published by Defendant Innosonian Korea and included in the packaging accompanying the Infringing Manikins, "[w]hen chest compressions with a fast speed (over 120 times per minute) are performed, all of

the 'blood circulation' indication lights will illuminate." An accurate copy of such instructions is available at <https://www.innosonian.eu/download/701/>.

26. Innosonian has infringed claim 13 of the '293 patent with full knowledge of the patent and both knowing and intending that Innosonian's conduct infringe at least claim 13 of the '293 patent.

27. Prestan has been and continues to be damaged and otherwise harmed by Innosonian's infringement.

28. Prestan will be irreparably harmed unless Innosonian's infringing activities are enjoined.

PRAYER FOR RELIEF

WHEREFORE, Prestan prays for judgment and relief against Defendants Innosonian America and Innosonian Korea, including:

- A. Adjudging that Defendants have infringed one or more claims of the '293 patent;
- B. Permanently enjoining each Defendant, its officers, agents, suppliers, distributors, servants, employees, successors, assigns, and all persons acting in concert or participation with each Defendant from continuing acts of infringement of the '293 patent;
- C. Awarding Prestan damages attributable to the infringement, including at least a reasonable royalty, together with pre-judgment and post-judgment interest;
- D. Awarding Prestan enhanced damages for Defendants' willful infringement under 35 U.S.C. § 284;
- E. Adjudging this case to be exceptional under 35 U.S.C. § 285;
- F. Awarding Prestan its costs and reasonable attorneys' fees; and
- G. Such other and further relief as this Court may deem just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Prestan demands trial by jury on all issues so triable as to this complaint.

Dated: January 26, 2023

Respectfully submitted,

s/ William C. Baton

William C. Baton

Alexander L. Callo

SAUL EWING LLP

One Riverfront Plaza, Suite 1520

Newark, NJ 07102-5426

(973) 286-6700

wbaton@saul.com

alexander.callo@saul.com

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Cincinnati, OH 45202-4029

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jbennett@ulmer.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: January 26, 2023

s/ William C. Baton
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Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
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EXHIBIT 1



US008465293B2

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

(10) **Patent No.:** **US 8,465,293 B2**
(45) **Date of Patent:** **Jun. 18, 2013**

(54) **MEDICAL TRAINING DEVICE**

(75) Inventors: **John J. Pastrick**, University Heights,
OH (US); **Mark E. Cook**, Stow, OH
(US); **Timothy E. Lint**, North Royalton,
OH (US); **Christopher E. Bryniarski**,
South Euclid, OH (US)

(73) Assignee: **Prestan Products LLC**, Mayfield
Village, OH (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

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(Continued)

(21) Appl. No.: **12/782,829**

(22) Filed: **May 19, 2010**

(65) **Prior Publication Data**

US 2010/0291522 A1 Nov. 18, 2010

Related U.S. Application Data

(63) Continuation-in-part of application No. 11/469,645,
filed on Sep. 1, 2006, now abandoned.

(60) Provisional application No. 60/713,276, filed on Sep.
1, 2005, provisional application No. 61/179,709, filed
on May 19, 2009.

(51) **Int. Cl.**
G09B 23/28 (2006.01)

(52) **U.S. Cl.**
USPC **434/265**

(58) **Field of Classification Search**
USPC 434/262, 265
See application file for complete search history.

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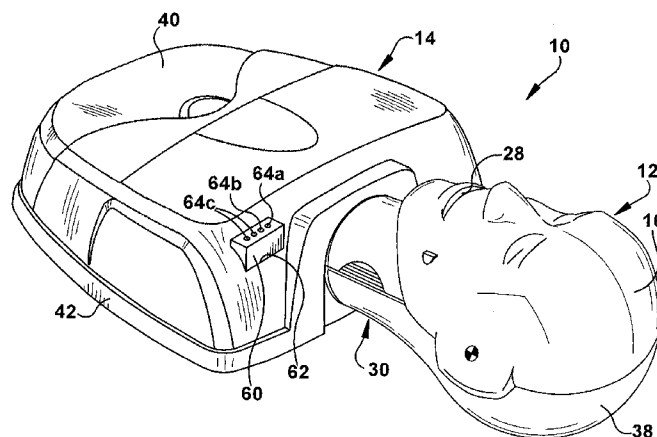
Primary Examiner — Xuan Thai

Assistant Examiner — Evan Page

(57) **ABSTRACT**

A medical training device with an improved clam shell type torso arrangement. An improved two-piece tiltable head feature, including mechanical mounting structure for secure attachment of an improved lung bag or face shield. The head also includes an improved nose feature to provide a more realistic representation of nasal cartilage, and an improved neck assembly. Additionally, an electro-mechanical indicator device is provided to show real time feedback of the CPR compression rate being administered by a student on the training manikin of the present application. The feedback by the device may be provided preferably by visual indicators, but may also have, or alternatively have, audio indicators or signals, such as words or sounds, to indicate whether or not the student is compressing within the preferred rate range, and/or the degree of variance in the student's compression sequences.

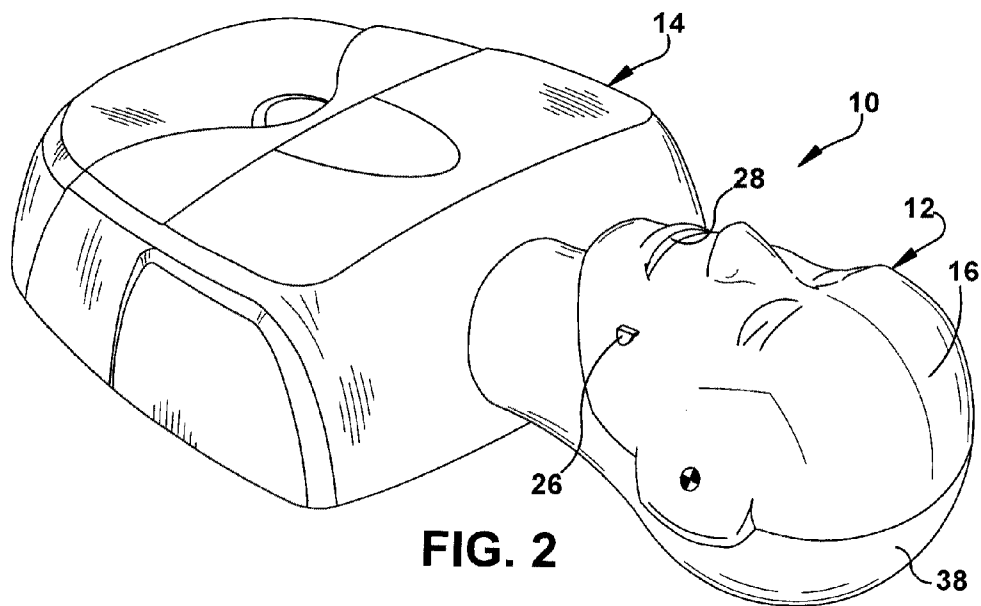
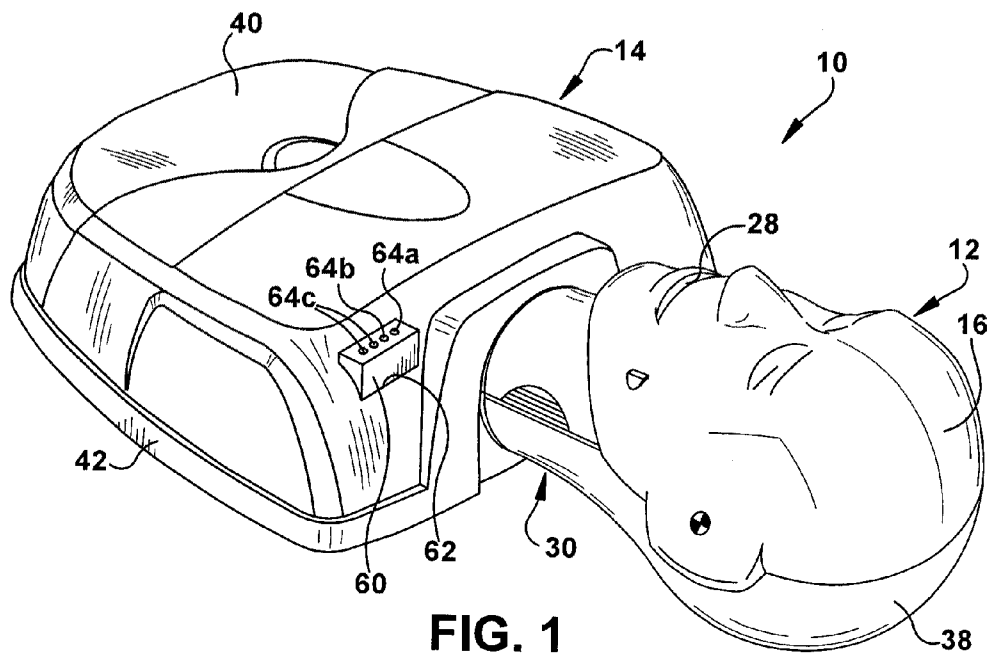
16 Claims, 13 Drawing Sheets

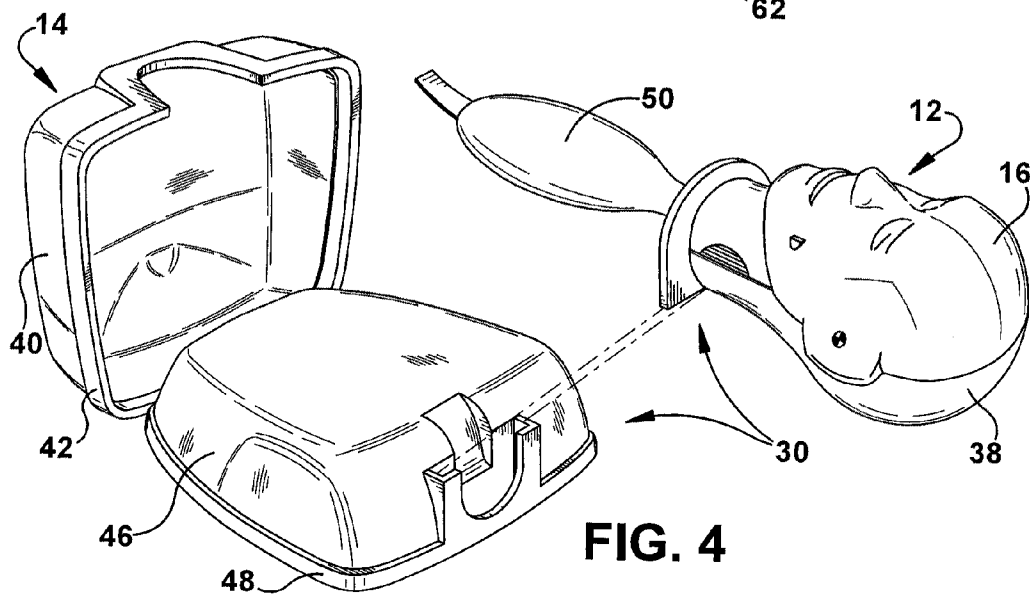
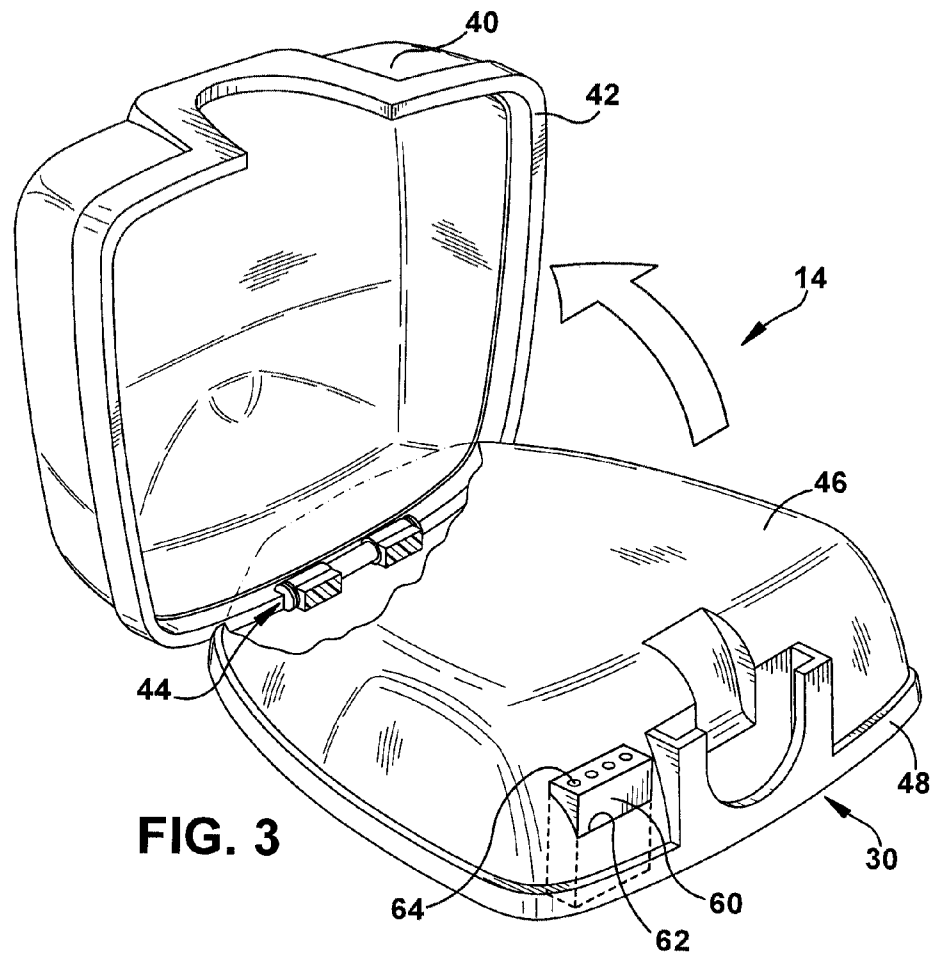


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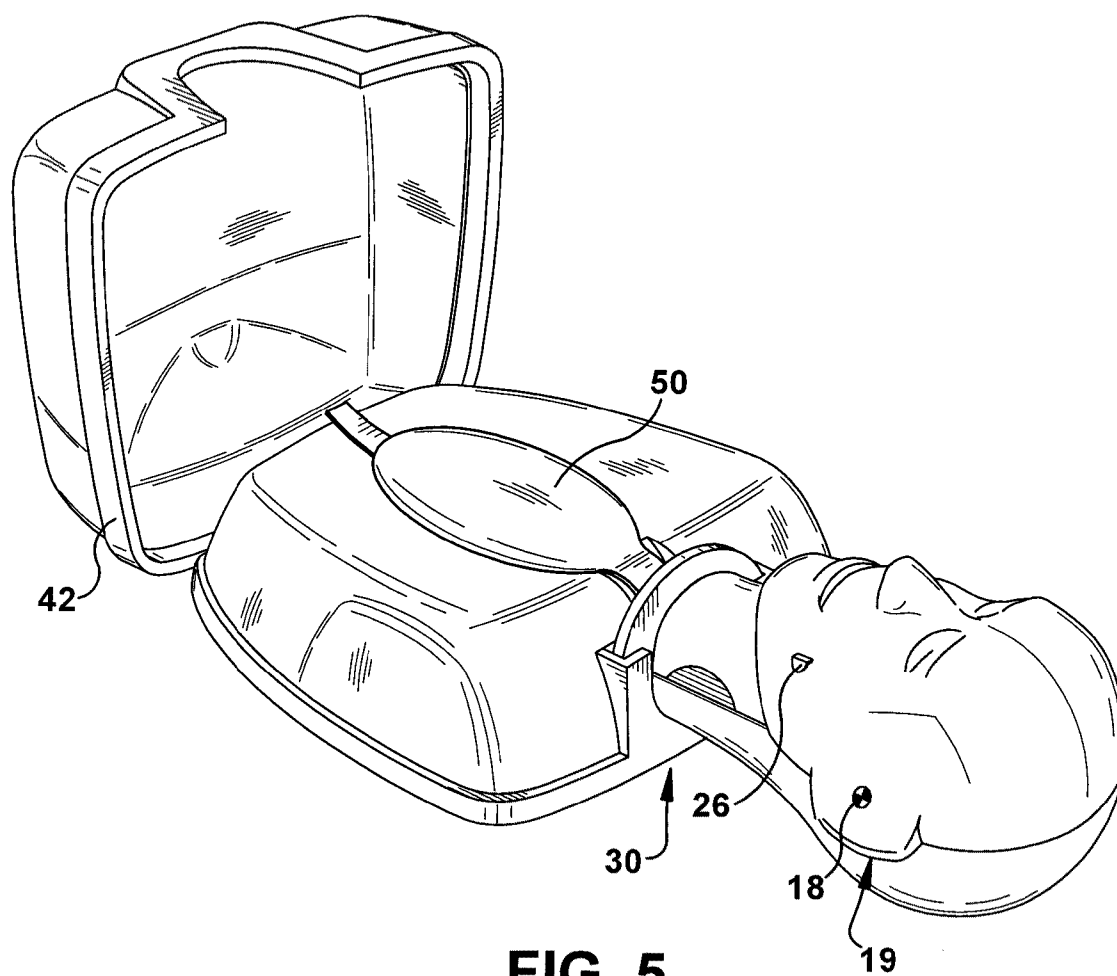


FIG. 5

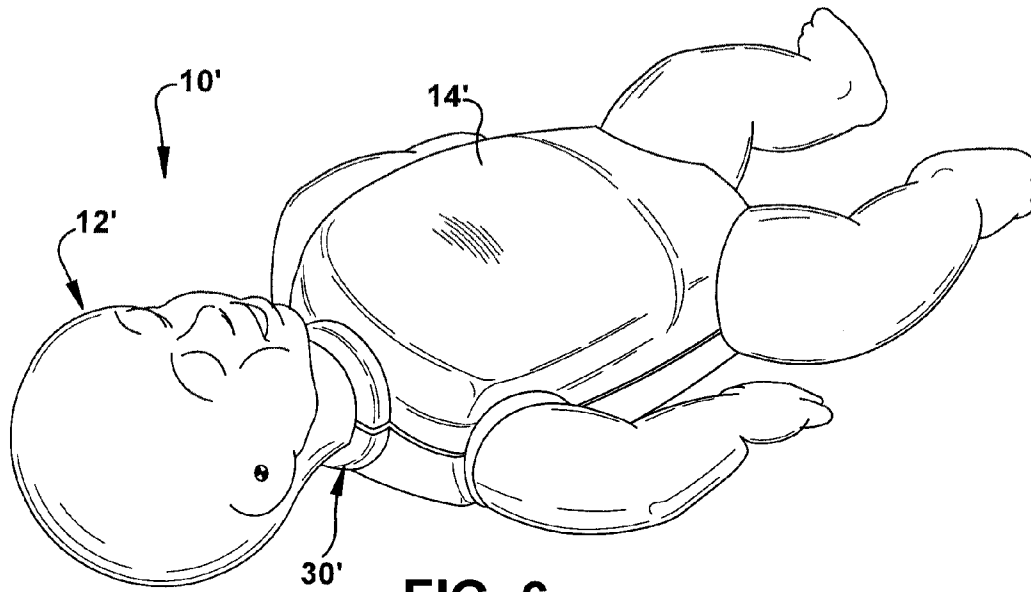


FIG. 6

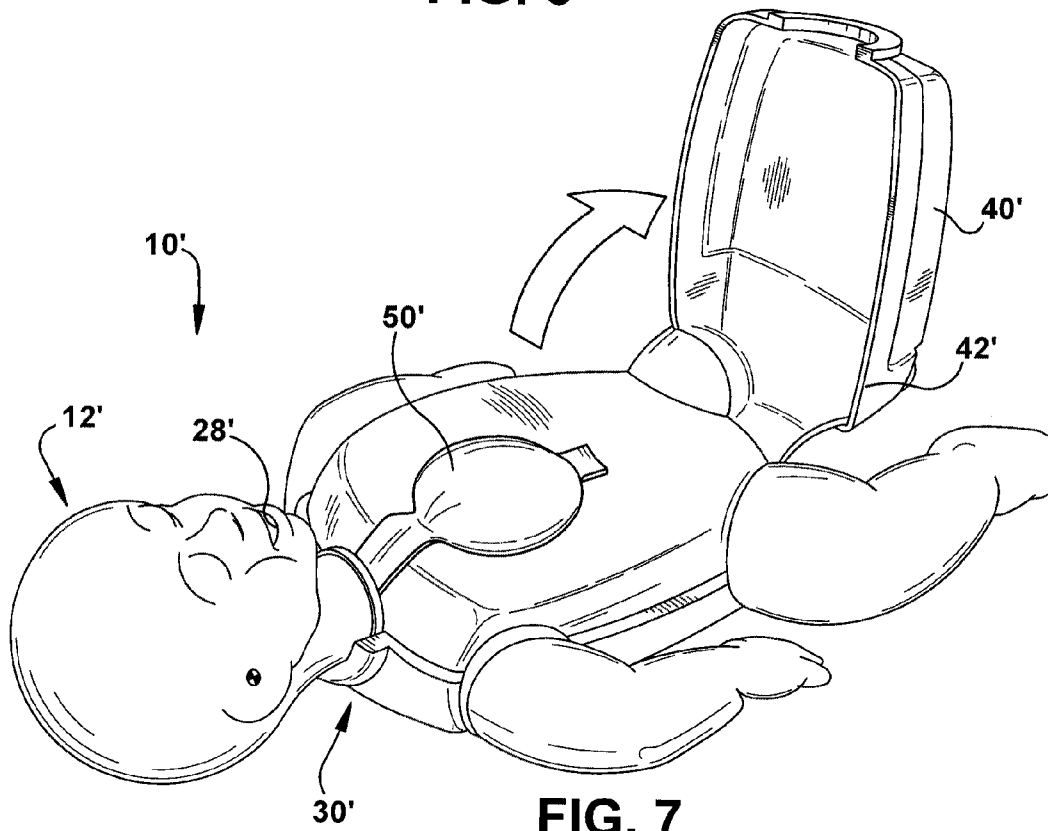
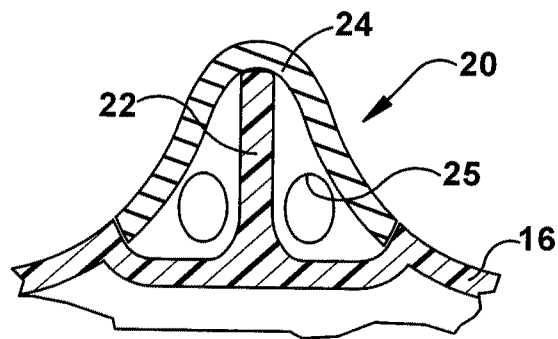
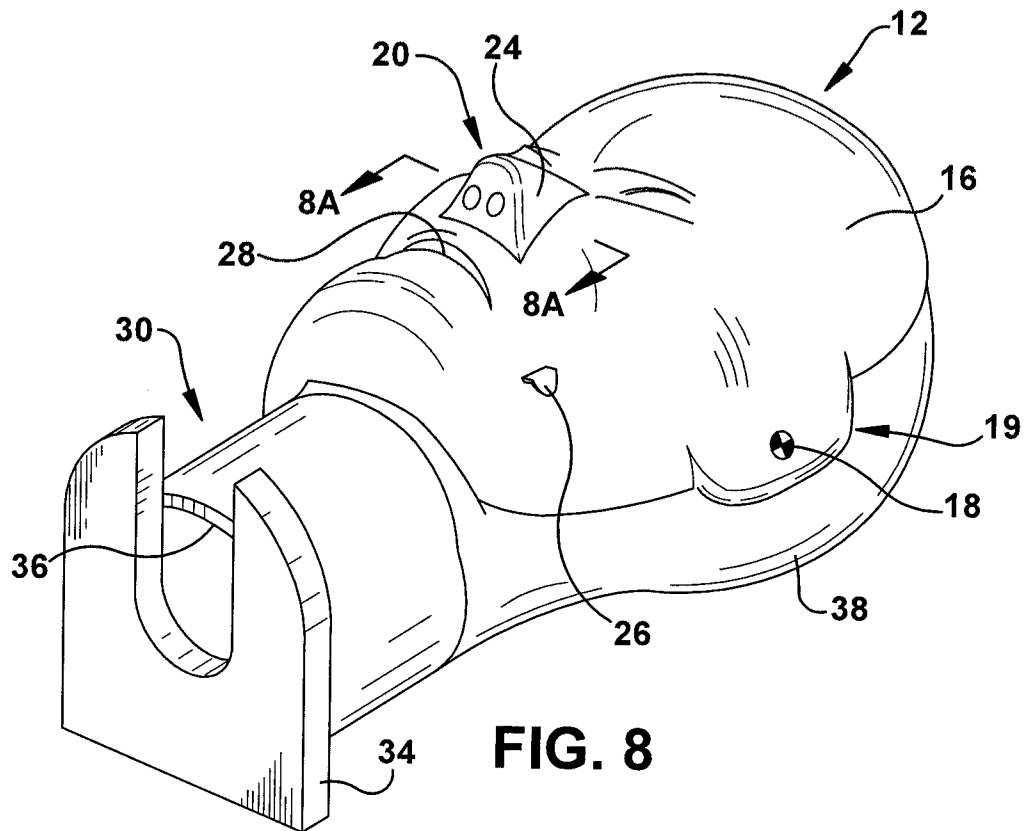
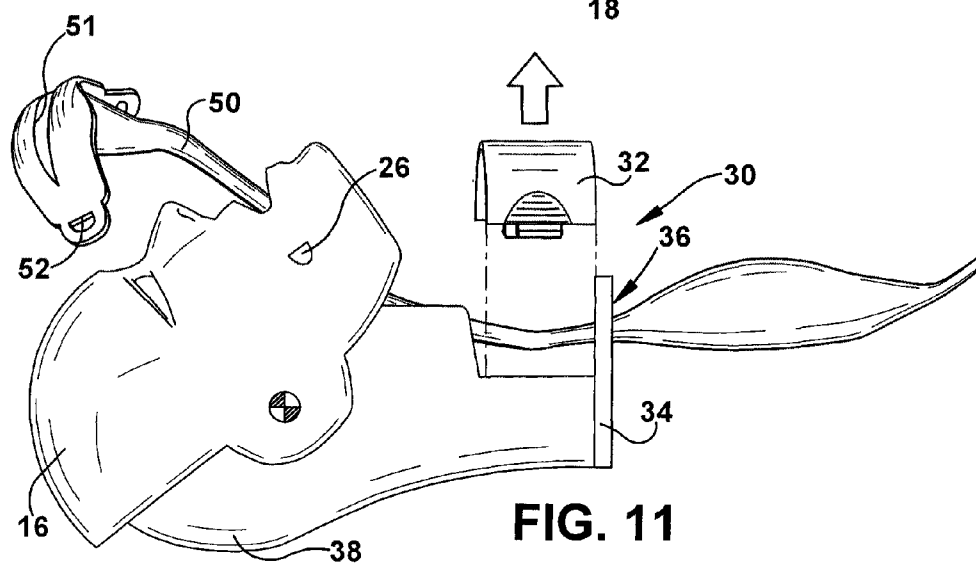
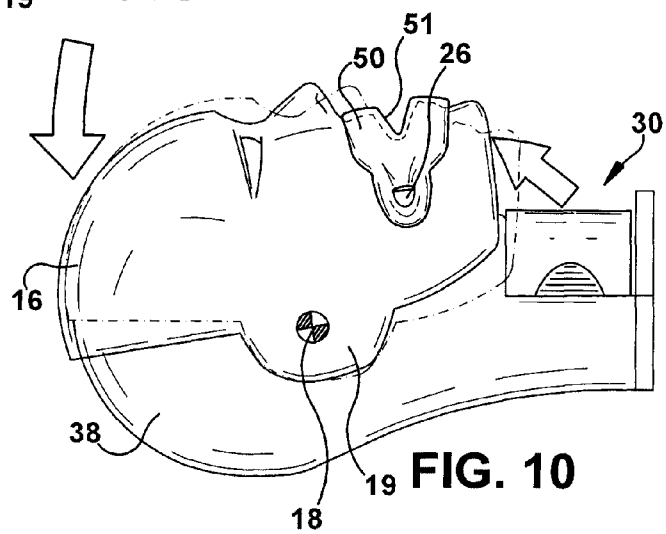
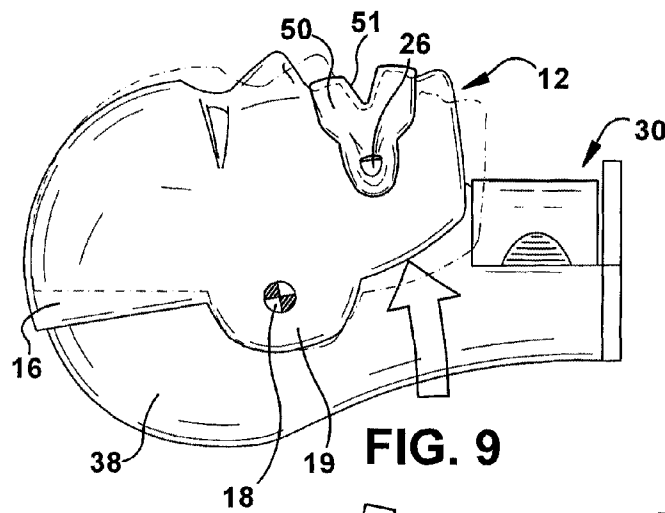
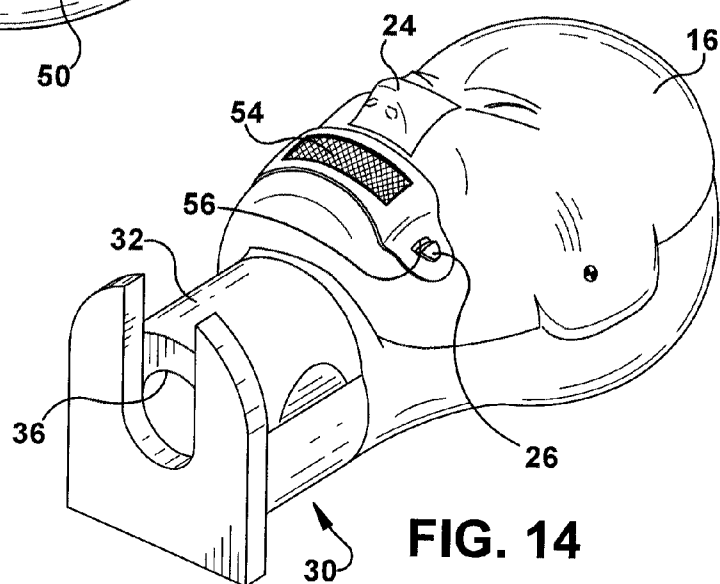
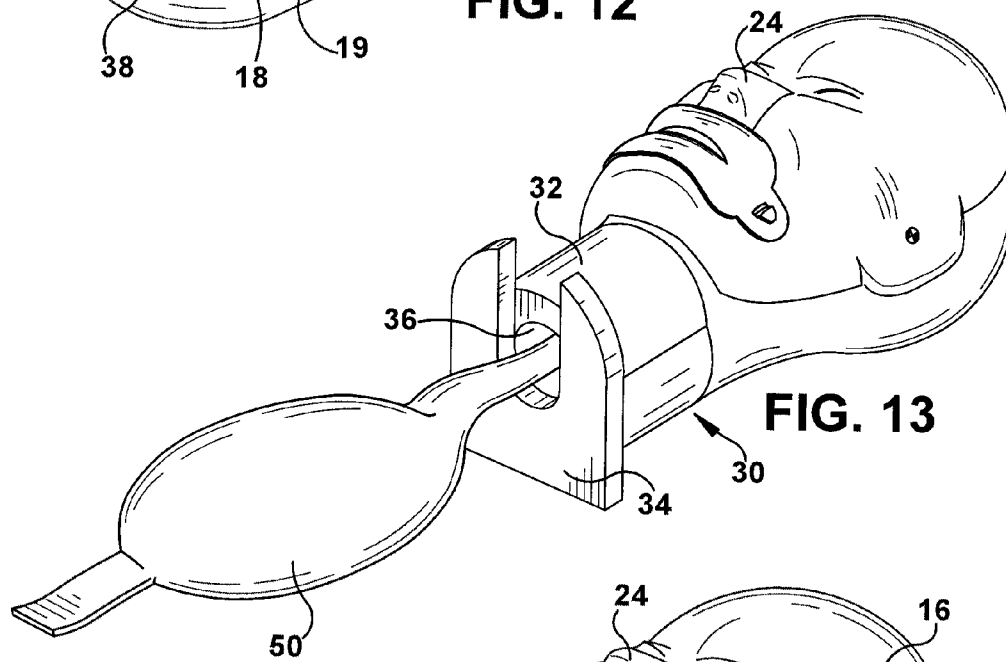
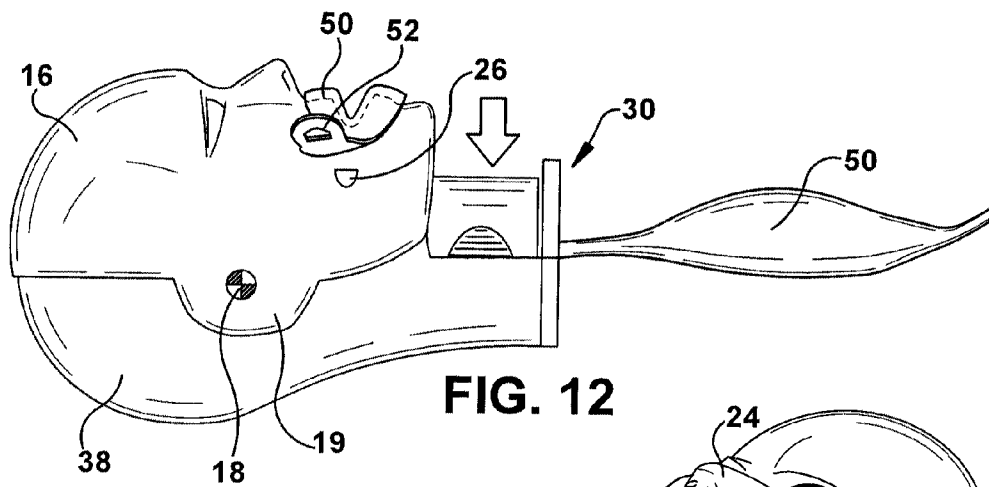
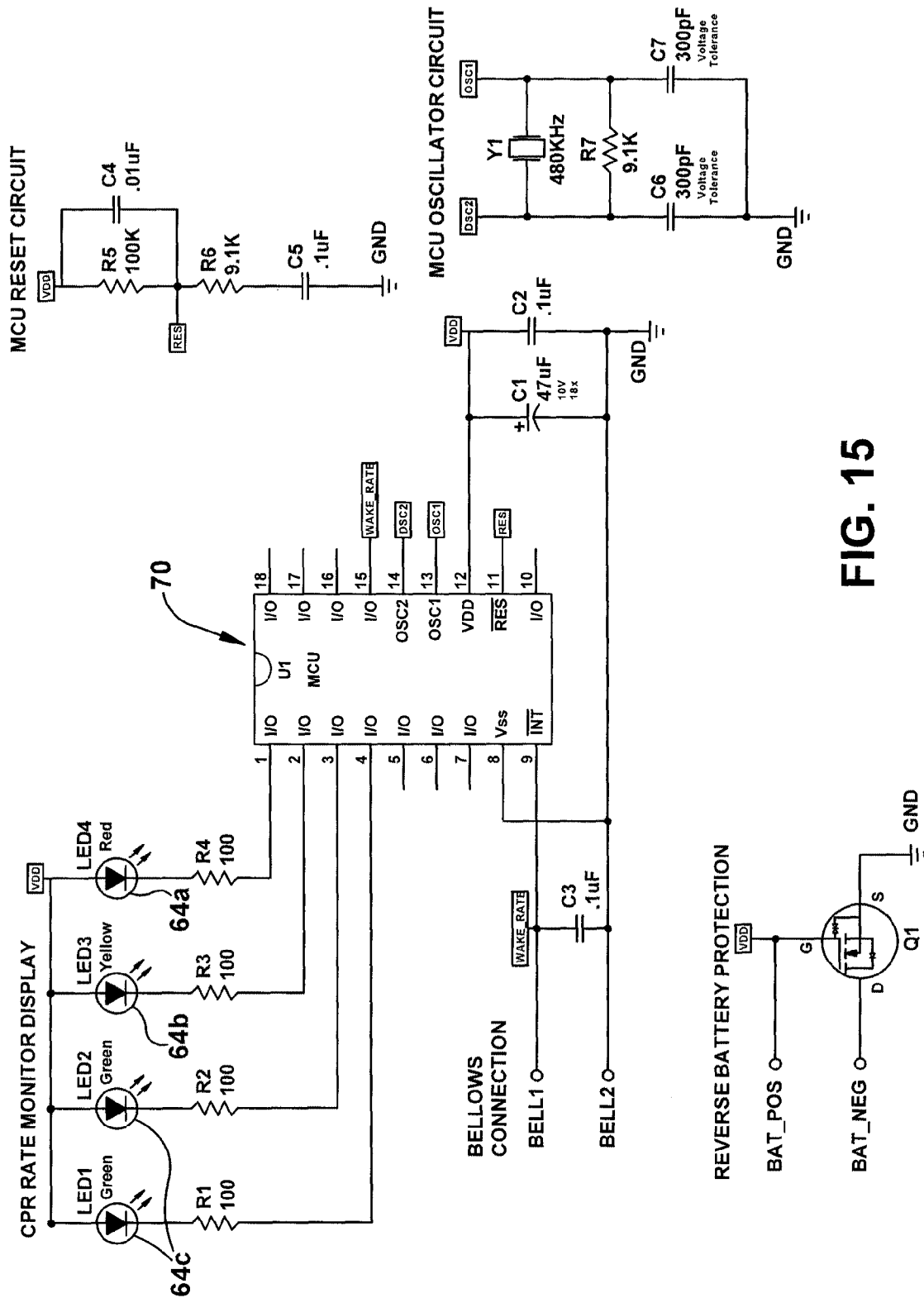


FIG. 7









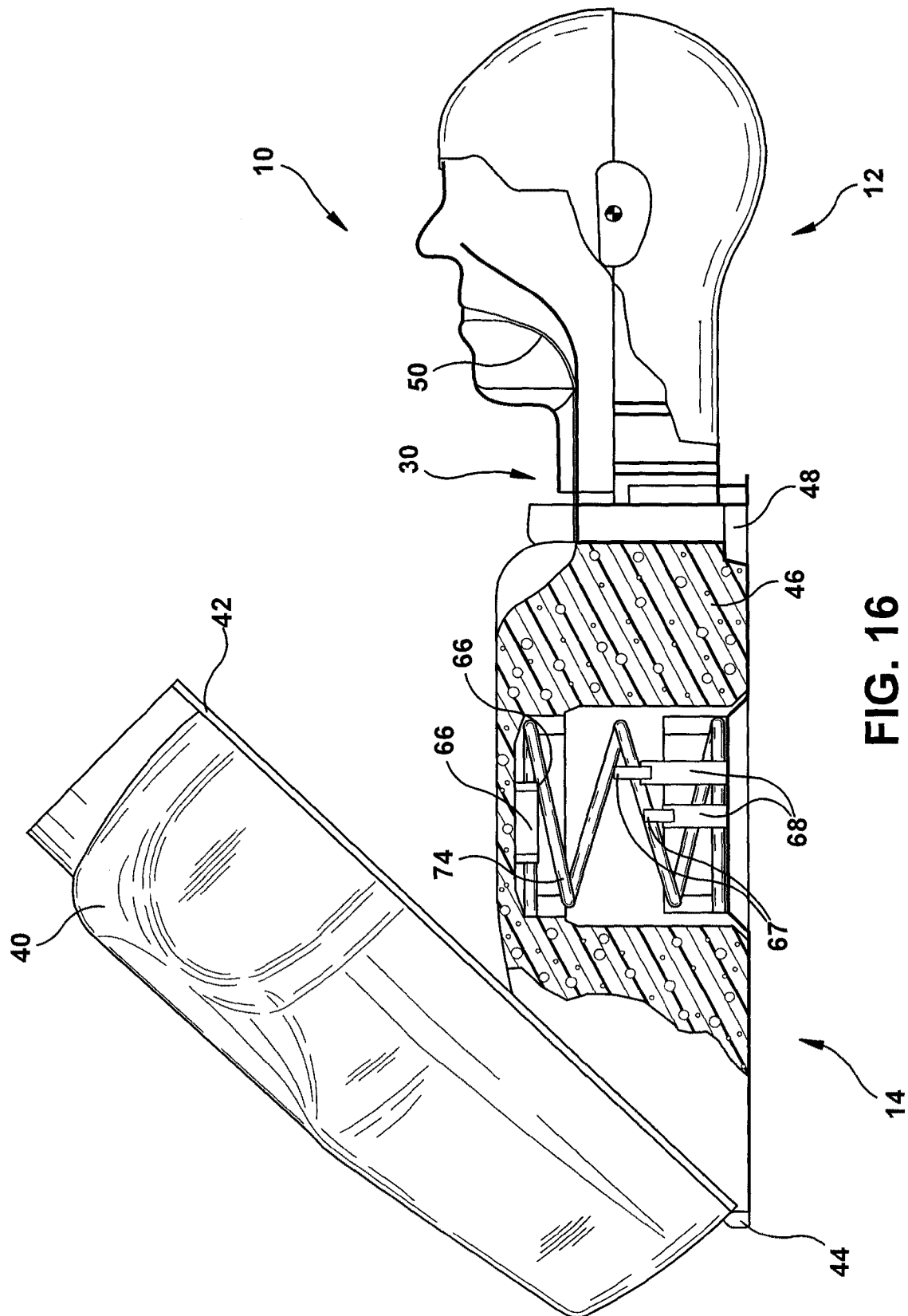


FIG. 16

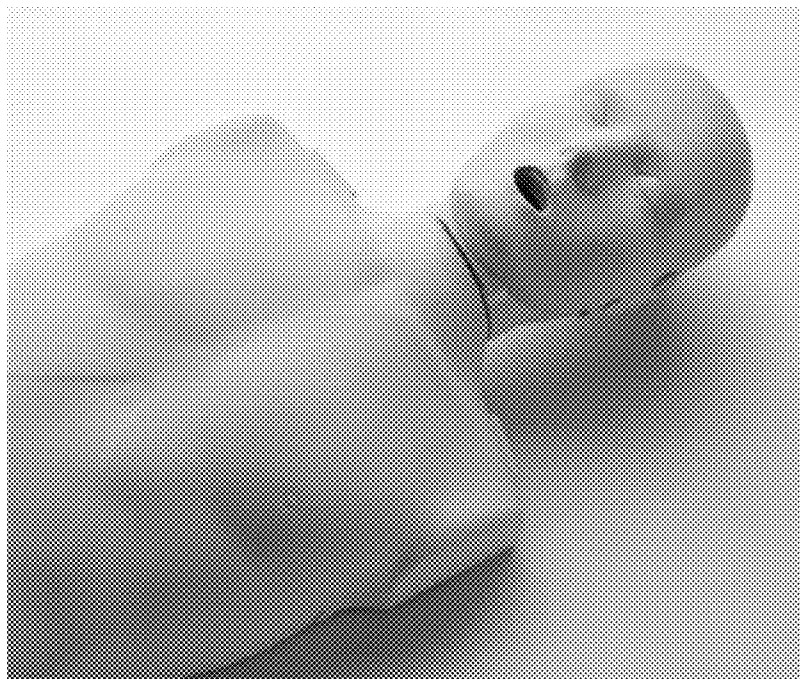


FIGURE 17

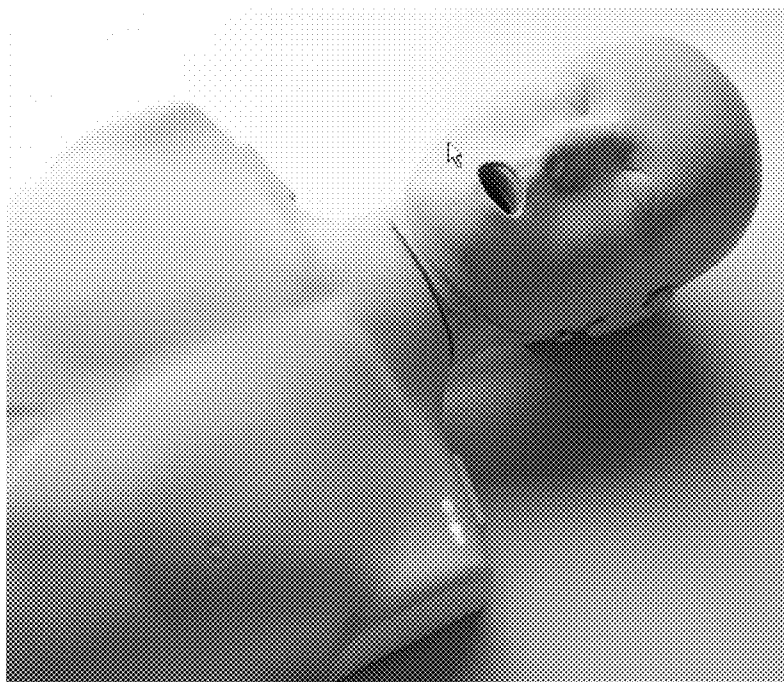


FIGURE 18

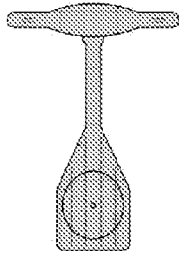


FIGURE 19

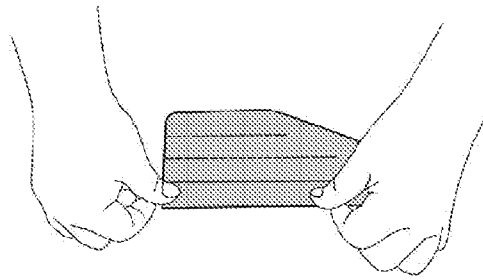


FIGURE 20

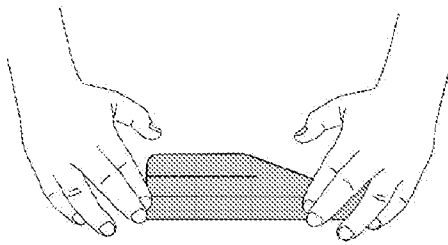


FIGURE 21

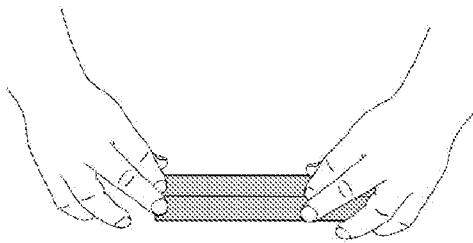


FIGURE 22

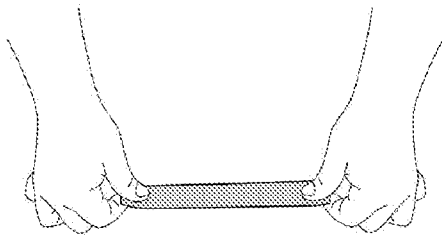


FIGURE 23

FIGURE 24

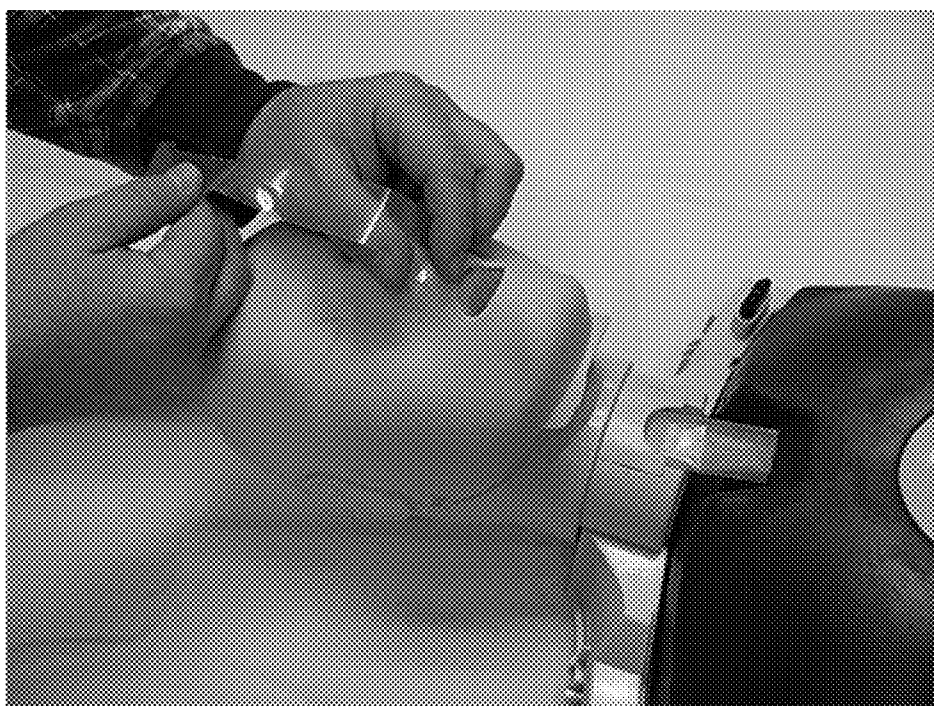


FIGURE 25

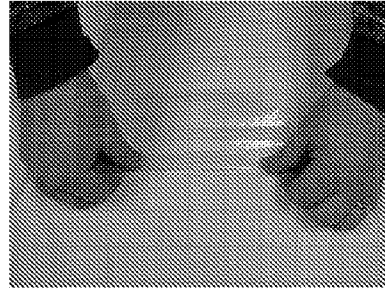


FIGURE 26

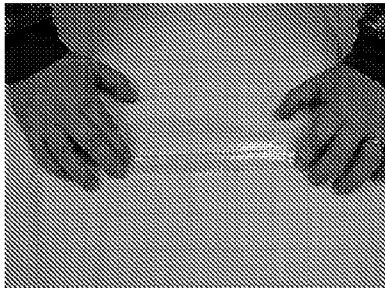


FIGURE 27

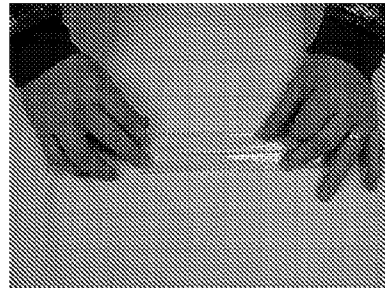


FIGURE 28

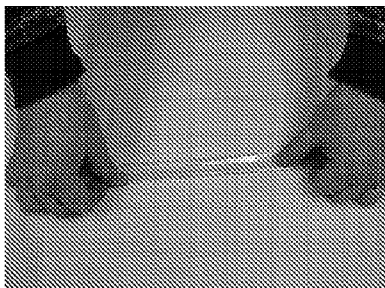
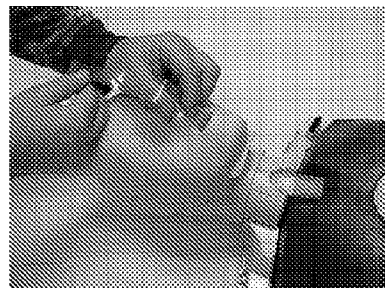


FIGURE 29



1

MEDICAL TRAINING DEVICE**FIELD OF INVENTION**

The present application is directed to an improved medical training device, and more particularly to a medical training manikin having improved features and accessories.

BACKGROUND

Numerous solutions have been offered in the past to provide an inexpensive medical training manikin which can be used in a training environment for either a group of trainees or a single individual. It is desired that such medical training manikins are lightweight for easy transportation to the training site, as well as simple and quick to assemble, readily able to be cleaned or otherwise maintained in a sanitary condition, easy to use, and capable of substantially simulating the functions and responses of a human patient.

Prior art devices which have attempted to provide solutions to the above include U.S. Pat. Nos. 6,500,009, 5,330,514, 5,468,151, 4,984,987 and 5,885,084.

SUMMARY OF THE INVENTION

The present medical training device provides a number of improved features over prior products. The present product has an improved clam shell type torso arrangement. An improved two-piece tiltable head feature is also provided. A head may include mechanical mounting structure for secure attachment of an improved lung bag or face shield. The head also includes an improved nose feature to provide a more realistic representation of nasal cartilage, and an improved neck assembly. Additionally, an electro-mechanical indicator device is provided to show real time feedback of the CPR compression rate being administered by a student on the training manikin of the present application. The feedback by the device may be provided preferably by visual indicators, but may also have, or alternatively have, audio indicators or signals, such as words or sounds, to indicate whether or not the student is compressing within the preferred rate range, and/or the degree of variance in the student's compression sequences. The indicator device also includes an automatic on/off sleep feature which is activated by use and non-use of the present training manikin.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the improved medical training device of the present application showing a feedback indicator device.

FIG. 2 is a perspective view of the improved medical training device having mechanical mounting structure on the head for securing a lung bag or face shield.

FIG. 3 is a schematic perspective view of the improved medical training device showing a two-piece clam shell style torso, where one piece is an outer skin portion made of thin pliable material supported by a substantially rigid frame, and a second piece is an inner compressible core material supporting a compression rate indicator device.

FIG. 4 illustrates a torso similar to FIG. 3, together with a schematic, perspective illustration of the head with a neck assembly and a lung bag prior to engagement with the torso.

FIG. 5 illustrates the engaged torso and head of the device of FIG. 4.

FIG. 6 is a schematic, perspective illustration of the improved medical training device in an infant embodiment.

2

FIG. 7 is a schematic, perspective illustration of the infant embodiment of FIG. 6 with the pliable cover in an open position with respect to the torso.

FIG. 8 is a schematic, perspective illustration of the head and neck assembly of the improved medical training device of the present application.

FIG. 8A is a cut-away view of an improved nose structure taken along the line 8A-8A in FIG. 8.

FIGS. 9 and 10 are schematic side views of the improved medical training device schematically illustrating the pivoting or tilting movement of the face portion of the head to enable training of the jaw thrust technique.

FIGS. 11, 12 and 13 are schematic side and perspective illustrations of the installation of a lung bag which is secured to the face portion of the improved medical training device at posts or hooks protruding from the face portion.

FIG. 14 schematically illustrates a face shield which is mechanically secured to the face portion of the improved medical training device, and may alternatively be secured over a lung bag.

FIG. 15 schematically illustrates an electrical circuit diagram for a CPR compression rate indicator of the present medical training device.

FIG. 16 is a partial side view, schematic cut-away illustrating the internal sensors, bellows and electrical contacts used in connection with the CPR compression rate indicator of the present medical training device.

FIG. 17 is a partial perspective view of an alternate embodiment of the improved medical training device of the present application with the feedback indicator device shown in the off position.

FIG. 18 is a partial perspective view of the embodiment of FIG. 17 with the feedback indicator device shown in the on position.

FIG. 19 is a schematic top view of a lung bag of the present application.

FIG. 20 is a schematic view of the lung bag of FIG. 19 being folded in a first step prior to insertion into the training device of the present application.

FIG. 21 is a schematic view of the lung bag of FIG. 19 being folded in a second step prior to insertion into the training device of the present application.

FIG. 22 is a schematic view of the lung bag of FIG. 19 being folded in a third step prior to insertion into the training device of the present application.

FIG. 23 is a schematic view of the lung bag of FIG. 19 being folded in a fourth step prior to insertion into the training device of the present application.

FIG. 29 is a schematic partial top view of the folded lung bag of FIG. 19 being inserted into the improved medical training device.

DETAILED DESCRIPTION

The present application provides an improved medical training device 10. A general view of the adult embodiment of the improved medical training product or device 10 is shown in FIGS. 1 to 5, and the infant embodiment is shown generally at reference 10' in FIGS. 6 and 7. Unless otherwise indicated, many features of the adult and infant embodiments are similar and will not be distinguished in detail, other than by the use of a prime designation in connection with the infant embodiment.

The improved device 10 includes a torso which is a two-piece clam shell style torso 14. The improved two-piece torso 14 is shown in a variety of positions in FIGS. 3 to 5. One piece of the torso 14 comprises an outer skin portion 40 made of

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thin pliable material, which is preferably a molded elastomeric material. In the illustrated embodiment of FIGS. 1, 3 to 5 and 7, the pliable skin material 40 is supported by a substantially rigid portion or frame 42. The rigid frame 42 is preferably manufactured of a rigid molded plastic material. The frame 42 and skin 40 may be secured together by molding the two pieces together, or may be mechanically secured together, such as by an adhesive.

The second torso piece is an inner core portion 46 which is covered by the outer pliable skin 40, as shown in FIGS. 1 and 6. The skin and core pieces of the torso 14 may be connected together at a hinge 44 located along one side of the frame 42. The core portion 46 is preferably of a compressible core material, such as a polyurethane foam material, to enable simulated CPR compressions. The second core torso piece 46 may likewise include a base frame 48 for supporting the core portion 46, which base frame 48 may be secured to the core 46 via adhesive. The frames 42, 48 may be connected together at the hinge 44 along one side of the rigid support portions or frames. As shown in FIG. 16, mechanical (such as posts 68, and a spring or bellows 74) and electrical components used to perform and measure compressions during operation of the manikin training device, are provided internally of the core 46.

The torso 14 may include a variety of additional features, such as openings for insertion of additional demonstration organs (not shown), such as for organ transplant trainings. Additional components, such as a simulated heart or lung to be compressed, are shown in FIGS. 6 and 7.

The use of a two-piece torso 14 allows for fast and easy opening and closing of outer skin 40 for quick installation of a lung bag 50 which enables simulation of lung and chest expansion, particularly through the pliable outer skin portion 40. As illustrated in the figures, the pliable outer skin portion 40 is molded to include simulated landmarks commonly found on the human torso for use during student training and CPR performance. Additionally, the torso 14 opens to capture and secure a head 12 at a neck assembly 30. The neck assembly 30 is illustrated in a position generally opposite the hinge 44. A neck assembly 30 of a variety of designs may be provided as shown in FIGS. 4-5 and 11-12.

The improved two-piece head 12 is provided with molded head pieces, where the front half or face portion 16 is movable/tiltable, and the back half or base head portion 38 is stationary. A pliable simulated skin cover (not shown) may also be added to the face portion 16 where desired for additional cleanliness or maintenance considerations. Additionally, an improved nose simulation is also provided as best shown in FIGS. 8 and 8A. The nose includes a simulated rigid nose cartilage portion 22 with a removable pliable cover portion 24 over said simulated rigid nose cartilage 24. The nose cartilage portion 22 is formed as a part of the rigid face portion 16, with the removable cover portion 24 formed of pliable material with openings 25 simulating nostrils. The cover portion 24 is snapped into place over the nose cartilage portion 22 to simulate skin.

Pivot points 18, forming a pivot axis, are provided to interconnect the head and face portions near simulated ears 19 located on opposing sides of the base head portion 38, which is similar to the natural pivot location of the human head generally at the top of the spine. The use of pivot points 18, and a single pivot axis, near the ears 19, eliminates the need for more complex multiple piece pivot designs that are often necessitated by movement of the back of the head.

The front half or face portion 16 of the present device pivots at the pivot points 18, which define the single pivot axis, or is tilted by either a tilt of the forehead (pressing

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against the forehead) and lifting the chin as shown by the arrows in FIG. 10, or by a jaw line lift illustrated by the arrows in FIG. 9, which enables the training of the jaw thrust technique. In particular, the two pieces of the head may be biased by a spring or weight positioned intermediate the two pieces of the head 12 and internally. The design is preferably such that the jaw of the front or face portion 16 must be moved to a certain level or position before the forehead may be tilted back as provided by the mechanical shape of the pivot mechanism.

The two-piece head pieces are shown in a variety of positions in FIGS. 11 to 16. In the illustrated embodiments, a neck assembly 30 for attachment to the fixed head portion 38 is also provided. The lung bag 50 also passes through the neck assembly 30 during engagement within the head 12 and torso 14 of the improved medical training device 10. In the embodiments of FIGS. 2 and 8, the neck assembly 30 is provided integrally with the back head portion 38 such that the lung bag 50 is threaded through a mouth opening 28 in the face portion 16, through a fixed neck assembly 30 and into the torso 14 positioned intermediate the skin 40 and core portion 46, as shown in FIG. 7.

In FIGS. 3 to 5 and 9 to 14, a base portion 34 of the neck assembly 30 is provided as part of the fixed base head portion 38, and a second portion is provided as a removable slider cover 32 having finger tabs 33, which snaps into engagement with the base portion 34 of the neck assembly 30. In either embodiment, the neck assembly 30 provides an opening 36 for passage of the lung bag 50 intermediate the head 12 and torso 14.

As shown in FIGS. 11 to 13, and 19-29, the lung bag 50 is made of thin-film polymer material. To make use of the present device, the lung bag 50 is inserted through the mouth opening 28 of the face portion 16 of the head 14, through any neck assembly 30, and laid on the compressible core portion 46 of the torso 14 while the outer skin 40 is in an open position, as shown in FIGS. 3 to 4 and 7.

FIGS. 19-23 and 29 demonstrate a method of folding the lung bag 50 for insertion of the lung bag into the mouth opening and engagement with the torso. The lung bag 50 is a sealed bag to be inflated for simulation of lung inflation, with a single opening formed as a mouth portion 51 of the lung bag 50, and having a single axis aligned with the single opening and along the length of the lung bag. To insert the lung bag into the training device 10, the lung bag, as specifically shown in FIG. 19, is positioned with the single axis transverse with respect to the person folding the lung bag. As shown, the lung bag may be divided into 5 sections. First, one edge of the lung bag is first folded inward toward the single central axis, as shown in FIG. 20, such that the lung bag is arranged in a 4 section width. Next, the 2 aligned folded sections are folded toward the single central axis, as shown in FIG. 21, such that the lung bag is arranged in a 3 aligned folded section width. Next, the other edge of the lung bag is folded inward toward the single central axis and aligned folded sections, as shown in FIG. 22, such that the lung bag is arranged in a 2 aligned folded section width. Finally, the 2 aligned folded section width is folded toward the 3 aligned folded section width, such that all 5 sections of the lung bag are aligned in a single width section aligned with the single central axis. The width of the section is preferably slightly narrower than the width of the mouth opening 28 in the face portion 16. Once that lung bag is folded to form a single strip, the lung bag is inserted into the mouth opening 28, through the head portion and fixed neck assembly 30, and into the torso 14, as shown in FIG. 29. Once an end of the lung bag passes through the fixed neck assembly onto the torso, the end portion may be pulled

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through such that the large bag portion of the lung bag is positioned over the torso to serve as a simulated lung, and the elongate section of the lung bag is engaged through the head portion and neck assembly.

Two openings **52** provided on the lung bag at the sides of the mouth portion **51**, which openings **52** are for attachment to protruding portions **26**, such as posts or hooks, extending from the face portion **16** of the head **14**. The lung bag **50** is secured to and held flush against the mouth area of face portion **16** by the mechanical means of the holes or cuts **52** in the thin-film lung bag material. Similar holes or cuts **56** may be provided in a face shield barrier **54** to secure the face shield **54** covering the mouth opening **28** in the face portion **16**, as shown in FIG. **15**, or secured over the lung bag **50** covering the mouth opening **51**, such that two layers of material are mechanically secured to the face portion **15** using the protruding posts **26**. With both the lung bags and face shields of the present design, the thin-film material is secured in place flush to the face portion of the manikin which improves training efficacy by reducing interference of the material, reducing the need for repositioning of the material, and improving the visual presence of the manikin during training.

Finally, the present device provides a novel CPR rate indicator **60**, which is an electro-mechanical device that provides real time feedback of CPR compression rate being administered by the student on the training manikin device **10**, **10'**. The feedback is provided directly by visual indicators and indicates whether or not the student is compressing within the preferred compression rate range. Also, the indicator **60** may inform the student concerning what degree of variance there is in the compressions being administered. Indications may be provided as colored illuminated indicators, a numeric readout, or other visual methods. The CPR rate indicator may be provided as an add on module which is integrated within or connected to an existing manikin product so as to be visually accessible to the student while CPR is being performed. As shown in FIGS. **1** and **3**, the CPR rate indicator **60** is provided integrally with the torso **14**. A window or opening **62** may be provided through the skin **40** and core portion **46** to enable viewing of the indicator **60** during use of the present training device. Alternatively, the indicator **60** may be provided as an original equipment feature to the manikin product **10**, **10'**. Where illuminated indicators **64** are provided, they may be color coded to convey the level of student performance, e.g. red **64a** is poor, for example, less than 60 compressions per minute; yellow **64b** is fair, for example, less than 80 but greater than 60 compressions per minute; green **64c** is acceptable, for example, less than 100 but greater than 80 compressions per minute; the illumination of both green lights **64c** is a preferred performance, for example, 100 or more compressions per minute; and if desired, illumination and flashing of both green lights may be a more preferred performance rate. The indication may be provided by colored/illuminated indicators **64a-c**, such as LED's, a numeric readout, or other visual method, as well as by audio signals, such as beeps or tonal sounds. Audio signals may be provided as negative sounds, more positive sounds, most positive sounds and double positive sounds, to convey the desired rate performance information. The indicator module **60** is preferably integrated within, or connected to, the manikin **10** to be visually accessible to the student while CPR is being performed on the manikin training device.

The CPR rate indicator **60** of the present application is preferably desired as a visual training feature, which is passive and, unlike audio feedback, does not interfere with the training exercise. However, it should be understood that audio feedback may have additional desirability under certain train-

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ing circumstances. Additionally, the visual feedback is preferred over prior art metronome type timing devices which the student attempts to follow and match repeating audible signals that represent the desired frequency of compression. By remaining a passive feature, the visual indicators can be ignored until it is desired by the student or instructor. Further, the real time feedback regarding the compression rate performed is believed superior to other methods which record the compression rate, but the record can only be reviewed after the training exercise is completed. With the present rate indicator device **60**, the student can view the visual indicators **64** while the compressions are in progress, and make concurrent adjustments and improve training performance during the exercise. Also, the CPR rate indicator **60** may be configured to respond with positive visual feedback only when both the compression rate being performed by the student and the depth of compression into the core portion **46** are properly achieved.

FIG. **15** provides a schematic illustration of the electrical circuit of the CPR rate indicator **60**, which includes a conventional microprocessor unit **70** for recording and calculating the desired measurements described, the desired visual indicators **64a-c**, audio indicators, controllers, such as automatic on and off controls, and a power supply. The device is battery operated, with an operating voltage range of between 2.20VDC and 5.5VDC, meaning that either 2 or 3 conventional batteries may optionally be designed for use. The indicator **60** is preferably provided as a series of LED or other lights which would be located at any position which is visible to the student during the application of compressions to the manikin, but preferably would be provided within a slot or window **62**, which may either be formed by providing an opening in the pliable skin **40** through which the lights may be visible or pass, or by a transparent or translucent skin or portion of the pliable skin **40**, which window or transparent/translucent skin may be positioned over or above the indicator lights, for example, near the shoulder of the manikin device **10** as shown in FIGS. **1** and **3**, **17** and **18**. As shown in FIG. **18**, the pliable skin **40** is provided over the indicator **60**, and the skin is provided of any thin or transparent or translucent pliable polymer material. Examples of such material include thermoplastic elastomers, or TPE, or regular elastics or rubber materials. The pliable skin may be of uniform thickness over the indicator **60**, or the window may be formed by providing an opening, or simply by thinning the skin polymer material in the area desired to form the window for viewing of the lighted indicator **60**.

Upon approaching the present manikin device having a CPR compression rate indicator **60**, the indicator may be in the off mode, as shown in FIG. **17**. Upon an initial compression such that the sensor **66** engages the electrical contacts **67**, **68**, the rate indicator is automatically moved to on mode of operation. During initial student compressions on the manikin device **10**, **10'**, the visual display would only provide a red light **64a**. The indicator **60** waits during the initial compressions until the student begins to perform at a regular compression speed. After a few data points are collected using sensors **66** interconnected with the indicator device **60**, a real time moving average of the speed of compressions is measured and calculated by the microprocessor unit **70**. Later during the compression exercise, a different number of points are collected for averaging. To collect such compression data, the electrical sensor **66** is provided as shown in FIG. **16** at the center of the manikin torso **14** with a wire contact **67** extending to the indicator module **60** for recording the number, speed and depth of compressions. The electrical sensors **66** may be provided for engagement with posts **68** supporting the

wire contact 67. The posts 68 are of a specific height such that engagement of the contact with the posts by the student ensures that the desired compression depth has been achieved by the student to simulate heart compression. After the last compression is sensed by the sensor 66, a timer within the indicator 60, generally shown within the microprocessor 70 in FIG. 15, is activated which may be customized to a desired time period. After the passage of the desired time, if no compressions are sensed, the indicator 60 is automatically moved to the off or sleep mode. In sleep mode, the device draws only about 1 micro Amp (μ A) of current. Thus, the use of such a novel timer and sleep mode in the indicator 60 enables the present manikin device 10, 10' to achieve longer battery life. The use of the timer is ideal in a teaching environment, since an instructor or student need not specifically turn the manikin device on or off, as the device 60 is able to wake itself up from a low power consumption sleep mode. In the illustrated preferred embodiment, the training device does not include an on/off switch.

The CPR indicator 60 must accurately display the rate of CPR compressions performed on the device 10, 10', thus a microcontroller (MCU) is preferred in the illustrated circuit of FIG. 15. Since the compression rate is a function of time, the clock source must be accurate and a resonator is preferable over a simple resistor/capacitor network, which has very wide tolerances and in many cases is also temperature dependent. An oscillator network is connected to pins 13 and 14 of the microcontroller as shown in FIG. 15. Because there is no on/off switch in the circuit, it is technically always powered by the batteries, and low power consumption of 1 μ A during sleep mode is essential. A metal-oxide semiconductor field-effect transistor or MOSFET is preferred in the current design for reverse battery protection, as in FIG. 15, since, unlike a diode, the MOSFET minimizes the voltage drop across it to maximize run time.

Once the device is in sleep mode, it is activated or reactivated when the bellows 74 is pressed at least one time. Pressing the bellows 74, closes a set of electrical contacts across the bell1 and bell2 connection points shown in FIG. 15, and the microcontroller is awakened from sleep mode using wakeup pin 15. Pin 9 is provided as an interrupt pin to measure the time between each compression (which is the closing of a switch). A minimum of two compressions are required to be made before a compression rate may be calculated. After the second compression, the rate will be displayed using the LED's, which is generally the red LED 64a. The LED's which are later illuminated depend on the very last two compressions which are received. When the compressions stop, the microcontroller detects that the rate has fallen out of range or specification, and the red LED 64a is illuminated. If no more compressions are made, the circuit moves to sleep mode and all visual indicators 64 are turned off.

Although the medical training device of the present application has been described in detail sufficient for one of ordinary skill in the art to practice the invention, it should be understood that various changes, substitutions and alterations may be made without departing from the spirit or scope of the device as defined in the attached claims. Moreover, the scope of the present device is not intended to be limited to the specific embodiments described here, which are provided by way of example. As one of ordinary skill in the art will readily appreciate from the disclosure of the present device and its embodiments, other components and means presently existing or later to be developed that perform substantially the same function to achieve substantially the same result as those of the corresponding embodiments described here, may be utilized according to the present application. Accordingly,

the appended claims are intended to include within their scope such other components or means.

We claim:

1. An improved medical training device comprising,
 - a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;
 - b) a head portion interconnected with said torso portion, and having a fixed, non-movable, back half section and a movable front half face section which are pivotably interconnected near simulated ear sections;
 - c) attachment portions located on said front face section and projecting therefrom for attachment of a lung bag or a face shield; and
 - d) a CPR rate indicator integral with the torso portion and under the removable pliable cover section for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed; and
 - e) the portion of the removable pliable cover section adjacent the CPR rate indicator is configured to view the CPR rate indicator through the removable pliable cover section by the person being trained on the device.

2. The improved medical training device of claim 1 wherein the removable pliable cover section adjacent the CPR rate indicator is translucent.

3. A CPR rate indicator module comprising a single unit mounted within a CPR medical training device and having at least two light emitting diode indicators for providing real time feedback to a student of their rate of CPR compressions during a training exercise.

4. The CPR rate indicator module of claim 3 further comprising at least three light emitting diode indicators having three different colors of indicators for providing real time feedback of CPR compression rates.

5. The CPR rate indicator module of claims 3 or 4 wherein additional indicators are provided for real time feedback of CPR compression rates which are audio indicators.

6. The CPR rate indicator module of claim 4 wherein said visual indicators are colored red, yellow and/or green lights.

7. A method for folding a lung bag for use in connection with a medical training manikin, said lung bag manufactured of a thin film polymer material and having a single inflation opening, an elongate portion and a bag portion, where the single inflation opening and the elongate portion are formed along a central axis extending the length of the lung bag, the single inflation opening for receiving air during simulation of lung inflation, and at least two attachment openings formed in the bag adjacent the single inflation opening for mechanical attachment to a head of a medical training manikin, the method comprising the steps of:

- a) positioning the lung bag in a flattened position;
- b) folding the lung bag in the same direction as the central axis to form flattened layers of the lung bag into a strip having a width which is substantially aligned with the elongate portion of the lung bag; and
- c) inserting the strip of the flattened layers of the lung bag into a medical training manikin.

8. The improved medical training device of claim 1 wherein the removable pliable cover section adjacent the CPR rate indicator includes an opening for viewing the CPR rate indicator.

9. The improved medical training device of claim 1 wherein the removable pliable cover section adjacent the CPR rate indicator is transparent.

10. A lung bag for use in connection with a medical training manikin, the lung bag manufactured of a thin film polymer

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material and having a single inflation opening, an elongate portion and a bag portion, where the single inflation opening and the elongate portion are formed along a central axis extending the length of the lung bag, the single inflation opening for receiving air during simulation of lung inflation, and two attachment openings positioned on opposite edges of the single inflation opening for mechanical attachment of the lung bag to a head of a medical training manikin.

11. An improved medical training device comprising,

a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;

b) a head and neck portion with attachment portions located on and projecting therefrom for attachment of a lung bag or a face shield; and

c) a CPR rate indicator integral with the torso portion and under the removable pliable cover section for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed; and

d) a portion of the removable pliable cover section adjacent the CPR rate indicator is configured to view the CPR rate indicator through the removable pliable cover section by the person being trained on the device.

12. An improved medical training device comprising,

a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;

b) a head portion interconnected with said torso portion, and having a fixed, non-movable, back half section and a movable front half face section which are pivotably interconnected near simulated ear sections;

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c) a CPR rate indicator integral with the torso portion and under the removable pliable cover section for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed; and

d) a portion of the removable pliable cover section adjacent the CPR rate indicator is configured to view the CPR rate indicator through the removable pliable cover section by the person being trained on the device.

13. An improved medical training device comprising,

a) a torso portion having a compressible core section and a removable pliable cover section, which core and cover sections are interconnected;

b) a CPR rate indicator integral with the torso portion and under the removable pliable cover section for directly providing real time feed back to a person being trained on said device of the rate of CPR compressions being performed; and

c) a portion of the removable pliable cover section adjacent the CPR rate indicator is configured to view the CPR rate indicator through the removable pliable cover section by the person being trained on the device.

14. The improved medical training device of claims **11**, **12** or **13** wherein the portion of the removable pliable cover section adjacent the CPR rate indicator is translucent.

15. The improved medical training device of claims **11**, **12** or **13** wherein the portion of the removable pliable cover section adjacent the CPR rate indicator includes an opening for viewing the CPR rate indicator.

16. The improved medical training device of claims **11**, **12** or **13** wherein the portion of the removable pliable cover section adjacent the CPR rate indicator is transparent.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 8,465,293 B2
APPLICATION NO. : 12/782829
DATED : June 18, 2013
INVENTOR(S) : John J. Pastrick et al.

Page 1 of 1

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

On the Title Page:

In Col. 1, under "Related U.S. Application Data" or item (63), the proper currently pending status of the parent application should be changed from "now abandoned" to read as follows:

Continuation-in-part of application No. 11/469,645, filed on Sep. 1, 2006, --currently pending--.

Signed and Sealed this
Sixth Day of August, 2013

A handwritten signature in cursive script, appearing to read "Teresa Stanek Rea".

Teresa Stanek Rea
Acting Director of the United States Patent and Trademark Office