

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ADVANTAGE MEDICAL ELECTRONICS, LLC &  
LIFESYNC CORPORATION  
Petitioners

v.

KPR U.S., LLC  
Patent Owner

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Patent 8,795,004

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**PETITION FOR *INTER PARTES* REVIEW**

**UNDER 35 U.S.C. § 311 *ET SEQ.* AND 37 C.F.R. § 42.100 *ET SEQ.*  
(CLAIMS 1-2, 4-11, 13-14 & 16-17) of U.S. PATENT NO. 8,795,004)**

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## I. INTRODUCTION

Advantage Medical Electronics, LLC known more commonly as “Advantage Medical Cables” (“AMC”) and LifeSync Corporation (“LifeSync”) petition for *inter partes* review, seeking cancellation of claims 1-2, 4-11, 13-14 and 16-17 of U.S. Patent No. 8,795,004 to Selvitelli et al. (“’004 patent,” Ex. 1001), purportedly owned by KPR U.S., LLC (“purported Patent Owner”).

The challenged claims are directed to ECG electrode connectors that allow a user to move a lever parallel to a patient’s skin or body (i.e., about an axis orthogonal to a contact plane extending through a contact member) or a lever where an actuating portion and engaging region of the lever are in a plane parallel to the contact plane to allow for a press stud of an electrode to be inserted therein. Once released, part of the lever will engage the press stud to cause the press stud to contact the electrical contact member. The ’004 patent purports to be predicated on the discovery of utilizing a lever that extends parallel to the contact plane defined by the contact member and thus pivots about an axis that is orthogonal to the contact plane. As evidenced by the prior art references cited in this Petition and the Declaration of Terry Layton, Ph.D., the use of levers that pivot about an axis orthogonal to the contact plane defined by the contact member or levers where the actuating portion and engaging region were in a lever plane parallel to the contact plane was well known in the art at the time of the invention.

In this Petition, Petitioners present several references that render obvious the challenged claims of the '004 patent. Section VII of this Petition summarizes the prosecution history of the '004 patent. Section VIII sets forth the state of the art relative to the '004 patent. Section IX sets forth the claim construction for the challenged claims of the '004 patent. Section X sets forth the detailed grounds for invalidity of the challenged claims. This showing is accompanied by the Declaration of Terry Layton, Ph.D. ("Layton Decl.," Ex. 1002.)

Petitioners are reasonably likely to prevail in showing that the challenged claims are not patentable. Therefore, *inter partes* review of the '004 patent should be instituted.

## **II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8**

### **A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))**

Petitioners certify that the following are real parties-in-interest: AMC and LifeSync.

### **B. Related Matters (37 C.F.R. § 42.8(b)(2))**

On March 1, 2022, the purported Patent Owner and Cardinal Health 200, LLC ("Cardinal Health") sued the Petitioners and 3M Company ("3M") in the U.S. District Court for the Southern District of Florida (civil action No. 0:22-cv-60468-RAR), alleging infringement of the '004 patent and U.S. Patent No, 8,038,484 (the

“’484 patent”). The earliest service date of the complaint served on the Petitioners identified above was March 9, 2022. This Petition has been filed within one year of Petitioners being served a complaint alleging infringement of the ’004 patent. 35 U.S.C. § 315(b); 37 C.F.R. § 42.101(b).

A petition has been concurrently filed on this day on the ‘484 patent.

**C. Lead and Back-Up Counsel and Service Information (37 C.F.R. § 42.8(b)(3-4))**

Petitioners appoint Scott W. Smilie (Reg. No. 44,341) of Patzik, Frank & Samotny Ltd. as lead counsel, and appoints Jeffrey A. Pine (Reg. No. 36,893) and Jordan Herzog (Reg. No. 38,182) of Patzik, Frank & Samotny Ltd. as back-up counsel. A Power of Attorney for each Petitioner identified in Section I is filed concurrently.

**D. Service Information Under 37 C.F.R. § 42.8(b)(4)**

Service of any documents to lead and back-up counsel can be made via hand delivery to Patzik, Frank & Samotny Ltd., Suite 2700, 200 S. Wacker Drive, Chicago, IL 60606. Petitioners consent to service by email at [jpine@pfs-law.com](mailto:jpine@pfs-law.com), [ssmilie@pfs-law.com](mailto:ssmilie@pfs-law.com), [jherzog@pfs-law.com](mailto:jherzog@pfs-law.com) and [ipdocket@pfs-law.com](mailto:ipdocket@pfs-law.com).

**III. GROUNDS FOR STANDING (§ 42.104(a))**

Petitioners certify that the ’004 patent is available for *inter partes* review and that the Petitioners are not barred or estopped from requesting *inter partes*

review challenging the claims of the '004 patent on the grounds identified in this Petition.

#### **IV. OVERVIEW OF CHALLENGE (§ 42.104(b))**

*Inter partes* review of the '004 patent's challenged claims is requested on the grounds for unpatentability listed in the index below.

<b>Ground</b>	<b>Basis</b>	<b>Index of References</b>	<b>Claims Challenged</b>
1	§ 103(a)	Fukuda, Christensson and Sessions	1-2, 4-8, 10-11, 13-14, 16-17
2	§ 103(a)	Fukuda, Christensson, Sessions and Powell	9

Fukuda and Sessions were not cited or relied upon by the examiner during prosecution of the '004 patent. At no time were these references submitted to the Patent and Trademark Office in association with the application for the '004 patent. Christensson and Powell were before the examiner but not relied upon. To support the proposed grounds of unpatentability, this Petition is accompanied by the declaration of technical expert Terry Layton, Ph.D. (Layton Decl., Ex. 1002.)

#### **V. OVERVIEW OF THE '004 PATENT**

The '004 patent was filed on September 30, 2013 and issued on August 5, 2014 and was filed as a continuation of U.S. patent application serial No. 13/785,713, filed on March 5, 2013, now U.S. patent No. 8,690,611 (the "'611 patent"), which was filed as a continuation of U.S. patent application serial No.

13/433,096, filed on April 10, 2012, now U.S. patent No. 8,408,948 (the “’948 patent”), which was filed as a continuation of U.S. patent application serial No. 13/182,656, filed on July 14, 2011, now U.S. patent No. 8,152,571 (the “’571 patent”), which was filed as a continuation of U.S. patent application serial No. 12/330,550, filed on December 9, 2008, now the ‘484 patent, which claims priority to U.S. provisional patent application serial No. 61/012,825, filed on December 11, 2007 (“Selvitelli ‘825 App.”) The ‘004 patent’s challenged claims are directed to an ECG connector assembly that allows a user to move a lever parallel to a patient’s skin or body (i.e., about an axis orthogonal to a contact plane extending through a contact member) or having an actuating portion and engaging region that are in a lever plan parallel to the contact plane to allow the lever to be moved to allow a press stud of an electrode to be inserted in the connector. Once released, part of the lever will engage the press stud to cause the press stud to contact the electrical contact member.

## **VI. PERSON OF ORDINARY SKILL IN THE RELEVANT FIELD AND THE RELEVANT TIMEFRAME**

The field of the ’004 patent is biomedical connectors and, more particularly, biomedical electrode connectors for attaching a lead wire to an ECG electrode placed on a patient’s body. (‘004 patent, Ex. 1001, Col. 1:22-26.) Within a field, the level of ordinary skill in the art is evidenced by the prior art references of record. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995.) A person of

ordinary skill in the art (“POSITA”) is a hypothetical person who is presumed to be aware of all pertinent art, thinks along conventional wisdom in the art, and is a person of ordinary creativity. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007); *see also* Layton Decl., Ex. 1002 ¶¶ 6, 13-22.

A POSITA of the ’004 patent would have had education and/or experience in the biological sciences, engineering, or medical device manufacturing and/or design along with knowledge of the scientific literature in the field. (*Id.* at ¶31.) Although education and experience levels may vary, a POSITA would have had at least a bachelor’s degree in bioengineering, biomedical engineering, or equivalent. (*Id.*)

As of the earliest effective filing date of the ’004 patent claims, a POSITA also would have had work experience in the field of medical devices or medical test instruments, including several years of experience designing connectors or attachment mechanisms for medical devices or medical test instruments. (*Id.* at ¶34.) A person holding only a bachelor’s degree would be required to have had three (3) years of relevant work experience to qualify as a POSITA, but a person with a more advanced degree, such as a master’s of science or doctorate, could qualify as a POSITA with fewer years of experience. (*Id.*)

## **VII. PROSECUTION HISTORY**

Application serial No. 14/041,471 (the “’471 patent application”), which issued as the ’004 patent, included 14 claims when originally filed. (’004 File

History, Ex. 1003, at 238-242.) In a preliminary amendment dated September 30, 2013, the applicant of the '471 patent application ("Applicant") cancelled claims 1-14 and introduced new claims 15-35. (*Id.* at 199-206.) In an Office Action dated March 31, 2014, the examiner rejected claims 15-35 on the ground of nonstatutory obviousness-type double patenting over claims 1-18 of the '948 patent, claims 1-17 of the '571 patent and claims 1-13 of the '484 patent. (*Id.* at 79-84.) The examiner also provisionally rejected claims 13-35 on the ground of nonstatutory obviousness-type double patenting over claims 15-34 of copending U.S. patent application serial No. 14/041,484<sup>1</sup> and claims 15-34 of copending U.S. patent application serial No. 13/785,713<sup>2</sup>. (*Id.*)

The Applicant filed a terminal disclaimer dated April 17, 2014, which led to a Notice of Allowance issuing on May 1, 2014. (*Id.* at 43-50 & 72-73.)

## **VIII. STATE OF THE ART RELATIVE TO THE '004 PATENT**

The '004 patent is broadly directed to an ECG electrode connector having a housing, an electrical contact member defining a contact plane and a lever coupled to the housing about an axis orthogonal to the contact plane. The '004 patent purports to overcome disadvantages well-known in the art of ECG electrode connectors, such as having to snap or press the connector onto the press stud of the

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<sup>1</sup> U.S. patent application serial No. 14/041,484 was abandoned.

<sup>2</sup> U.S. patent application serial No. 13/785,713 issued as the '611 patent.

electrode in a direction towards the patient, which can, among other things, cause pain and discomfort to the patient ('004 patent, Ex. 1001, Col. 1:41 to Col. 2:23.)

### **A. Technical Background**

The electrocardiogram (“ECG” or “EKG”) system is a common diagnostic tool that measures and records the electrical activity of the heart. (Layton Decl., Ex. 1002, ¶ 33.) An ECG system produces a graphic representation of electrical activity called an electrocardiograph, which records the electrical voltage in the heart in the form of a continuous strip graph or on a monitor screen. (*Id.*) An ECG is constructed by measuring electrical potential between various points of the body using a galvanometer or voltmeter. (*Id.*) A typical ECG system relies on electrodes placed on a patient in specific locations to detect electrical impulses generated by the heart during each beat. (*Id.*) Electrical impulses detected by the electrodes are communicated to an ECG monitor via a plurality of leadwires, each of which terminates with an electrically conductive electrode connector that is physically connected to one of the electrodes so as to be in electrical communication therewith. (*Id.*)

The electrodes include pads that are placed on and temporarily adhered to various locations of the skin of a patient using a conductive gel or adhesive. (*Id.* at ¶ 34.) A metal press stud can extend upwardly from the pad to allow the lead wire to be connected thereto. (*Id.*)

There are two primary ways in which electrode connectors attach to the studs of biomedical patient electrodes, namely by pinch connection or snap/press connection. (*Id.* at ¶ 35.) The pinch connection can be further broken down into open end or alligator pinch connections and closed end or plate pinch connections. (*Id.*)

“Snap” or “press” connectors snap onto the stud of the electrode by the application of a downward pressure. (*Id.* at ¶ 36.) An example of such an electrode connector is found in U.S. patent No. 4,671,591 issued to Archer. (Ex. 1005; Layton Decl., ¶ 36.)

An example of an open end pinch connector is found in U.S. patent No. 4,178,052 issued to Ekbom (Ex. 1004), which discloses an open ended electrode connector adapted to pinch the stud of a patient electrode between a pair of opposing jaws. (Layton Decl., Ex. 1002, ¶ 37.) Another example of an open end electrode connector is found in Japanese patent publication no. JPH09276239 (*Id.*; Fukuda, Ex. 1007.)

An example of a closed end pinch or plate connector is found in U.S. patent No. 3,740,703 to Sessions (Ex. 1006; Layton Decl., Ex. 1002, ¶ 38.) In these connectors, the stud of the electrode is passed through an aperture in a conductive plate, and a biasing member moves a lever to retain the stud in electrical contact with the conductive plate. (*Id.*)

The prior art demonstrates that those of ordinary skill in the art were aware of the problems with snap-on electrode connectors identified in the '004 patent since at least the early 1970s. (*Id.* at ¶ 39.) For example, Robert W. Sessions, in his application for a Terminal Clamp filed in 1971, noted that the use of snap-on or button connectors “will result in a considerable pressure on the terminal of the electrode tending to compress the adjacent flesh of the patient until the firmness thereof is greater than the pressure forces required to effect engagement of the two terminals.” (Sessions, Ex. 1006, Col. 1: 41-45; Layton Decl., Ex. 1002, ¶ 39.) When a conductive gel is used to facilitate the electrical connection between the terminal and the skin surface, the downward force applied to attach the connector to the press stud will spread the conductive gel used outwardly from the central terminus which can “effect a separation of the adhesively connected portions from the skin surface, thereby considerably reducing the effective attaching area and which, in some cases, could even result in a sufficient weakening of the adhesive bond between the electrode and the skin surface to a point where electrical conduction is impaired by the poor connection of the electrode structure to the skin surface.” (Sessions, Ex. 1006, Col. 1: 16-21; 34-64; Layton Decl., Ex. 1002, ¶ 39.) The spreading of the gel can also remove the conductive gel from in “between the inner face of the electrode terminal structure and the opposing skin surface, thus further reducing the efficiency of the conductive connection following release of

the applied pressure.” (Sessions, Ex. 1006, at Col. 1: 64 to Col. 2:5; Layton Decl., Ex. 1002, ¶ 39.)

Sessions solved this known problem by “the production of a terminal clip by means of which a conductor may be operatively connected to an electrode of the type described without the application of undesired pressure on the terminal in a direction towards the skin surface, i.e. by providing a structure in which the applying forces are laterally directed to portions of the terminal clip with substantially no force whatsoever being applied in a direction toward the electrode structure or the terminal thereof.” (Sessions, Ex. 1006, Col. 2: 13-22; Layton Decl., Ex. 1002, ¶ 40.)

It was also known in the prior art that open end or alligator pinch connectors were disfavored because they could come into contact with a ground or outlet terminal that could allow an unwanted current to pass through the connector and they “cannot provide desired electrical contact and stability with a snap style contact stud.”. (Layton Decl., Ex. 1002, ¶ 41; Christensson, Ex. 1008, Col.1:50-52.) In order to avoid the problem of coming into contact with a ground or outlet terminal, it was known to include the electrical contact member within an insulated or non-conductive housing. (Layton Decl., Ex. 1002, ¶ 42.) In view of the known issues, Fukuda teaches placing an electrical contact member of an ECG connector within an insulated housing that encloses the electrical contact member and

includes an opening to allow for an electrode stud to be inserted therein to engage the electrical contact member. (*Id.* at ¶ 43.)

## **B. Summary of the Prior Art**

The prior art references relied upon disclose an ECG electrode connector that meets all of the limitations recited in the challenged claims. The references comprise Exhibits 1006-1009.

### **1. Japanese Patent Publication No. JPH09276239A, (together with the English translation and Verification of Translation, “Fukuda”) (Ex. 1007)**

Fukuda was filed April 9, 1996 and published October 28, 1997, and is prior art under 35 U.S.C. § 102(b). Fukuda discloses an open end pinch type biomedical electrode connector having an insulated housing (Fukuda, Ex. 1007, ¶¶ [0011] – [0012]), an electrical contact member fixed to the housing (*Id.* at ¶ [0014]) and a lever that pivots about an axis orthogonal to a contact plane between a disengaged position and an engaged position where the engaging region of the lever operably engages the press stud to cause a portion of the press stud to contact the electrical contact member. (*Id.* at ¶ [0024].)

### **2. U.S. Patent No. 3,740,703 (“Sessions”) (Ex. 1006)**

Sessions was filed November 24, 1971 and issued June 19, 1973, and is prior art under 35 U.S.C. § 102(b). Sessions discloses a closed end pinch type biomedical electrode connector having an electrical contact member having a

contact opening and a lever that pivots about an axis orthogonal to a contact plane between a disengaged position and an engaged position where the engaging region of the lever operably engages the press stud to cause a portion of the press stud to contact the electrical contact member and retain it therein. (Sessions, Ex. 1006, Col. 4: 5-39; Col. 5:11-47.)

**3. U.S. Patent No. 5,944,562 (“Christensson”) (Ex. 1008)**

Christensson was filed April 28, 1997 and issued August 31, 1999, and is prior art under 35 U.S.C. § 102(b). Christensson discloses a closed end pinch type biomedical connector having an insulated housing, an electrical contact member fixed to the housing and a lever that pivots between a disengaged position and an engaged position. (Christensson, Ex. 1008, Col. 4: 36-40; Col. 5: 25-28; Col 6: 39-43.) Christensson further discloses that the contact opening is smaller than and substantially concentric with the opening in the housing. (*Id.* at Col 6: 34-39; Fig. 7.)

**4. U.S. Patent No. 7,214,107 (“Powell”) (Ex. 1009)**

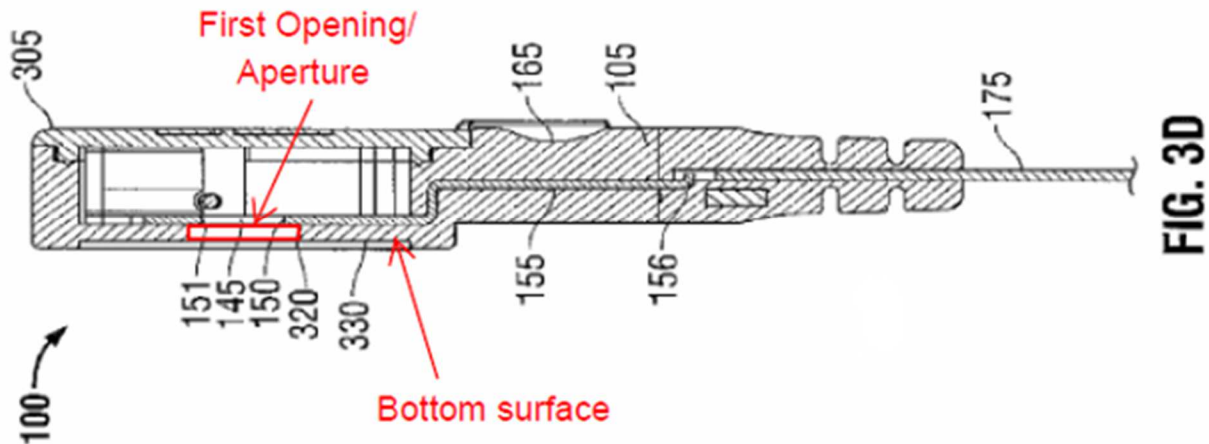
Powell was filed November 22, 2004 and published May 25, 2006 as U.S. patent publication no. 2006/0110962, and is prior art under 35 U.S.C. § 102(b). Powell discloses a biomedical electrode connector having insulated housing and actuating members. (Powell, Ex. 1009, Col. 1: 6-10; Col. 9: 14-25)

## **IX. CLAIM CONSTRUCTION PURSUANT TO 37 C.F.R. § 42.104(B)(3)**

In *inter partes* reviews filed after November 13, 2018, claims are construed according to the *Phillips* standard consistent with Article III federal courts. 83 Fed. Reg. 51340, 51340-41 (Oct. 11, 2018) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)). Claims are to be construed under the same standard as in federal court, in view of the specification and intrinsic record. *Id.* Petitioner propose that all claims should be entitled to their plain and ordinary meaning, except for the limitations addressed below.

### **A. First Opening**

The term “first opening” is used in independent claim 1, which states “a housing having a first opening dimensioned to receive a press stud of an ECG electrode pad.” (’004 patent, Ex. 1001, Col. 10: 27-28.) The specification identifies the “first opening” in the housing as the aperture 320, 620, 920 that starts at the bottom surface 330, 630 and 930 of the housing 105, 405, 705 extending upwardly through the width of the bottom portion of the housing as shown in Fig. 3D. (*Id.* at Col. 7: 3-7, Col. 7: 66 to Col. 8: 3; Col. 8: 62-65.)



For example, “the bottom surface 330 of housing 105 provides an aperture 320 disposed therein” (*Id.* at Col. 7: 3-7.) The term “first opening” is construed to mean the same as the aperture, or a hole extending through the bottom wall of the housing from the bottom surface of the housing to the inner surface of the bottom wall that is sized to allow a press stud to extend therethrough. (Layton Decl., Ex. 1002, ¶ 49.)

## **B. Electrical Contact Member**

The term “electrical contact member” is in independent claims 1 and 13. The specification states that “the spring member biases the press stud against a mating electrical contact member provided within the connector housing to electrically couple the press stud and the contact member, and to achieve positive mechanical coupling of the press stud and the connector housing.” (‘004 patent, Ex. 1001, Col. 2: 58-63.) The term “electrical contact member” is construed to

mean a conductive member that makes an electrical connection upon connection with another conductive article.

### **C. Fixed**

The term “fixed” is in independent claim 1, which states “an electrical contact member fixed to the housing . . . .” (‘004 patent, Ex. 1001, Col. 10: 29-32.) The term “fixed” is not otherwise used in the specification of the ‘004 patent other than to describe the fixed leg 131 and fixed end of spring 120. The term “fixed” was first introduced during the prosecution in Amendment “A” dated November 29, 2011 in connection with application serial No. 13/182,656, for which the ‘004 Patent claims benefit to. (Amendment A, Ex. 1010, at 2.) In particular, the Applicant amended the claims to change “an electrical contact member disposed on the inner surface of the housing” to “an electrical contact member fixed to the inner surface of the housing. (*Id.*) The term “fixed” is construed to mean to fasten securely in position. (Layton Decl., Ex. 1002, ¶ 51.)

### **D. Contact Plane**

The term “contact plane” is in independent claims 1 and 13, which states that the “electrical contact member fixed to the housing and defining a contact plane” (claim 1) and “electrical contact member defining a contact plane . . . .” (claim 13) (‘004 patent, Ex. 1001, Col. 10: 29-30; Col. 11:23.) The term “contact plane” is not otherwise used in the specification of the ‘004 patent. The term

“contact plane” was first introduced during the prosecution in Amendment “B” dated June 13, 2011 in connection with application serial No. 12/330,550, for which the ‘004 patent claims benefit to. (Amendment B, Ex. 1011, at 2-4, 7.) A plane is a two-dimensional flat surface that extends infinitely in those two dimensions. (Layton Decl., Ex. 1002, ¶ 52.) The term contact plane is construed to mean a two-dimensional flat surface that extends through at least part of the electrical contact member. (*Id.* at ¶¶ 52-53.)

#### **E. Second Opening**

The term “second opening” is in claim 1. The specification identifies the opening in the electrical contact member as being the contact opening. (‘004 patent, Ex. 1001, Col. 6: 63-65; Col. 7: 62-66; Col. 8: 57-63.) The term “second opening” is construed to mean the same as the contact opening, or a hole extending through the electrical contact member.

#### **F. At Least Partially Within the First Opening**

The term “at least partially within the first opening” is in claim 1, which states “a second opening smaller than and disposed at least partially within the first opening. (‘004 patent, Ex. 1001, Col. 10: 30-32.) The Applicant uses the term “within opening” in the specification to identify something that is positioned inside of an opening. (See e.g., *Id.* at Col. 7:12-15 (“A press stud may then be introduced into connector 100 by, for example, placing connector 100 over a press stud such

that the bulbous end press stud is positioned **within opening** 145, as shown in FIG. 10A.”) (emphasis added).) The term “at least partially within the first opening” is construed to mean that the opening in the electrical contact member is smaller than the opening in the housing and is positioned at least partially inside of the opening, between the inner and bottom surfaces of the bottom wall of the housing. (Layton Decl., Ex. 1002, ¶ 55.)

#### **G. Pivotal About an Axis Orthogonal to the Contact Plane**

The term “pivotal about an axis orthogonal to the contact plane” is in independent claim 1 and dependent claim 17. The term “orthogonal” means intersecting at right angles and the term “pivotal” means capable of being rotated about a pivot point. (Layton Decl. Ex. 1002, ¶ 56.) The term “pivotal about an axis orthogonal to the contact plane” is construed to mean the lever is pivotal about a pivot point defining an axis that extends perpendicularly to a contact plane defined by the electrical contact member. (Layton Decl., Ex. 1002, ¶ 56.)

#### **H. Engaged Position**

The term “engaged position” is used in claims 1 and 13 and is not otherwise used in the specification of the ‘004 patent other than the claims. The term “engaged” means to come together. (Layton Decl., Ex. 1002, ¶ 57.) The term “engaged position” is construed to mean the overall position of the lever where its engaged region contacts a press stud. (Layton Decl., Ex. 1002, ¶ 57.)

## **I. Disengaged Position**

The term “disengaged position” is used in claims 1 and 13 and is not otherwise used in the specification of the ‘004 patent other than the claims. The term “disengaged” means to be released from something. (Layton Decl., Ex. 1002, ¶ 58.) The term “disengaged position” is construed to mean the overall position of the lever when sufficient force is applied to its actuating portion of the lever to move its engaging portion away from a press stud to allow the electrode connector to be removed from the press stud. (Layton Decl., Ex. 1002, ¶ 58.)

## **J. Actuating Portion**

The term “actuating portion” is in independent claims 1 and 13. The term “actuating portion” is not otherwise used in the specification of the ‘004 patent. The ‘004 patent used the term “actuating end” 1336a as the portion of a lever where “a clinician may apply finger pressure . . . that is sufficient to overcome the biasing force of biasing member 1338, thereby causing engaging region 1336 to move to a second position as herein described.” (‘004 patent, Ex. 1001, Col. 9: 56-60.) The term “actuate” means to “put into mechanical action or motion.” (Merriam-Webster actuate definition, Ex. 1012.) The term “actuating portion” is construed to mean the portion of the lever that may be pressed or moved in order to move the lever between an engaged and a disengaged position. (Layton Decl., Ex. 1002, ¶ 59.)

### **K. Engaging Region**

The term “engaging region” is in independent claims 1 and 13. The ‘004 patent discloses, among other things, that “[e]ngaging region 716 of lever 710 includes an engaging surface 732 for coupling the connector 700 to a press stud . . . .” (‘004 patent, Ex. 1001, Col. 8: 48-50.) The ‘004 patent further discloses that “lever 1340, may be released so that biasing member 1338 moves engaging region 1336a of lever 1340 against the head of the male press stud (not explicitly shown) to push or force the lower portion of the press stud into a second contact opening portion 1334b of contact opening 1334.” (*Id.* at Col. 10: 6-11.) The term “engaging region” is construed to mean the portion of the lever that includes a surface that engages the press stud when the lever is in the engaged position. (Layton Decl., Ex. 1002, ¶ 60.)

### **L. Operably Engage**

The term “operably engage” is in claim 1. The term “engage” means to come together. (Layton Decl., Ex. 1002, ¶ 62.) The term “operably engage” is construed to mean to make contact with.

### **M. Disposed Substantially Concentrically**

The term “disposed substantially concentrically” is in dependent claims 4 and 16, which states that the “second opening disposed substantially concentrically with respect to the first opening [or aperture for claim 16].” (‘004 patent, Ex. 1001,

Col. 10: 47-49; Col. 11: 43-45.) The term “concentric” or “concentrically” is not otherwise used in the specification. The term “concentric” is defined as “having a common center” or “having a common axis.” (Merriam-Webster concentric definition, Ex. 1013.) The term “disposed substantially concentrically” is construed to mean that the second or contact opening is positioned such that the axis extending through its center is the same or close to the axis extending through the first opening or aperture. (Layton Decl., Ex. 1002, ¶ 62.)

#### **N. Contact Opening**

The term “contact opening” is in claim 13 and is construed to mean the same as the “second opening”, or a hole extending through the electrical contact member.

#### **O. At Least Partially Exposed Within the Aperture**

The term “at least partially exposed within the aperture” is in claim 13, which states “a contact opening that is at least partially exposed within the aperture.” (‘004 patent, Ex. 1001, Co. 11: 23-25.) The ‘004 patent uses the term “within opening” in the specification to identify something that is positioned inside of an opening. (See e.g., *id.* at Col. 7:12-15 (“A press stud may then be introduced into connector 100 by, for example, placing connector 100 over a press stud such that the bulbous end press stud is positioned within opening 145, as shown in FIG. 10A.”) (emphasis added).) The term “as least partially exposed within the

aperture” is construed to mean that the opening in the electrical contact member is positioned at least partially inside of the aperture, between the inner and bottom surfaces of the bottom wall of the housing. (Layton Decl., Ex. 1002, ¶ 64.)

#### **P. Lever Plane**

The term “lever plane” is in independent claim 13, which states that the “the actuating portion and the engaging region are positioned in a lever plane.” (‘004 patent, Ex. 1001, Col. 11: 32-34.) The term “lever plane” is not otherwise used in the specification of the ‘004 patent. The term “lever plane” was first introduced during the prosecution in a Preliminary Amendment dated September 30, 2013 in connection with application serial No. 14/041,471, which issued as the ‘004 patent. (‘004 patent file history, Ex. 1003, at 199-206.) A plane is a two-dimensional flat surface that extends infinitely in those two dimensions. (Layton Decl., Ex. 1002, ¶ 52.) The term lever plane is construed to mean a two-dimensional flat surface that extends through at least part of the actuating portion and the engaging region of the lever. (Layton Decl., Ex. 1002, ¶¶ 65-66.)

#### **X. UNPATENTABILITY GROUNDS**

The references reviewed below render the claimed subject unpatentable under 35 U.S.C. § 103. As detailed below, the Petitioners have a reasonable likelihood of prevailing as to each of the following grounds of unpatentability. Throughout the grounds, the figures have been annotated to identify elements of

the claim in the prior art and emphasis added to the evidence to support the challenge.

**A. Ground 1: Claims 1-2, 4-8, 10-11, 13-14 & 16-17 Are Rendered Obvious by Fukuda in View of Christensson and Sessions**

U.S. Patent No. 8,795,004	Fukuda in view of Christensson and Sessions
[1.0] An ECG connector assembly, comprising:	<p>“This invention is in regard to the bio contact electrode device used to transmit the cardiac action potential to a monitoring device such as an electrocardiograph.” (Fukuda, Ex. 1007, ¶ [0001].)</p> <p>(Layton Decl., Ex. 1002, ¶¶ 78-81.)</p>
[1.1] a housing having a first opening dimensioned to receive a press stud of an ECG electrode pad;	<p>Fukuda teaching a housing (base member 10 and cover member 11) having a first opening (receiving hole 20) disposed therein dimensioned to operably receive the press stud (terminal portion 5) of an ECG electrode pad (base pad 3).</p> <p>“As shown in FIG. 1, <b>the connecting tool 1 comprises: the insulating part that consists of base member 10, cover member 11 and holding member 12 . . .</b>” (Fukuda, Ex. 1007, ¶ [0011] (emphasis added).)</p> <p>“Further, <b>the base member 10 is provided with a support shaft protrusion 19 in the width direction at the near center area with the function described later, and receiving hole 20 in the length direction arranged in a row for receiving the terminal portion 5 of the contact electrode.</b>” (Fukuda, Ex. 1007, ¶ [0012] (emphasis added).)</p>

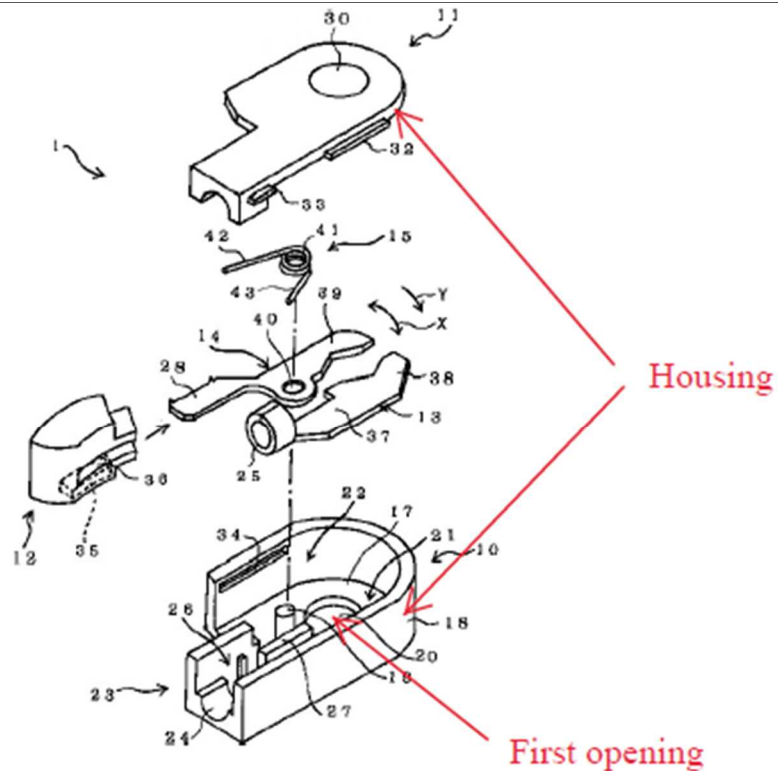


FIG. 1

Christensson also teaches an ECG connector assembly (clasp 20) having a housing (upper and lower portions 25 and 26) having a first opening (opening 26h) disposed therein dimensioned to operatively receive the press stud 17a of an ECG electrode pad.

Christensson teaches that “[t]he upper and lower portions 25 and 26 of the clasp 20 are of a molded material, preferably plastic resin which has electrical insulating properties, typically of nylon or poly carbonate plastic which is completely sterilizable.” (Christensson, Ex. 1008, Col. 5: 25-28 (emphasis added).)

“Near the center of the bottom portion 26 of the clasp 20 is an oblong opening 26h which is slightly larger at its forward end as shown in FIG. 7.” (Christensson, Ex. 1008, Col. 6: 34-36 (emphasis added).)

“When the stud 17a is introduced into the forward enlarged end of the opening 30h in the spring 30 through opening 26h, it can do so because the opening is large enough at its forward end to accommodate the stud 17a.” (Christensson, Ex. 1008, Col. 6: 48-

52 (emphasis added).)

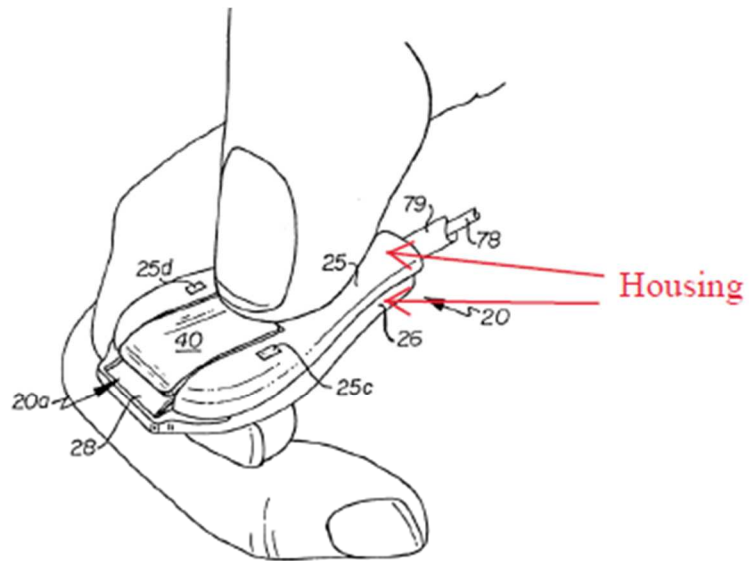


Fig. 2

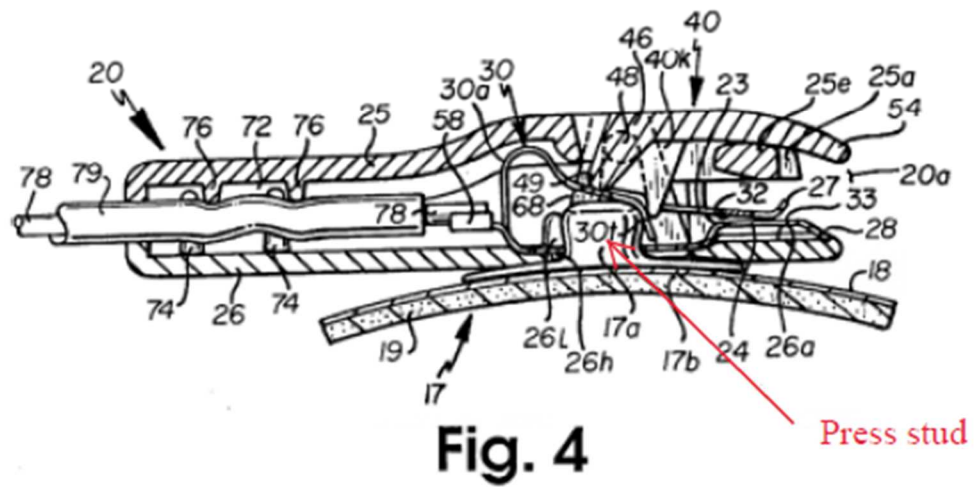
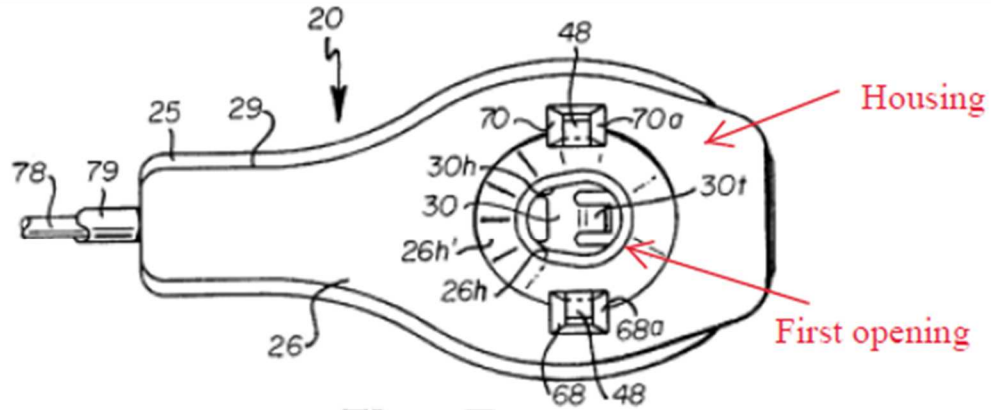


Fig. 4



**Fig. 7**

(Layton Decl., Ex. 1002, ¶¶ 82-85.)

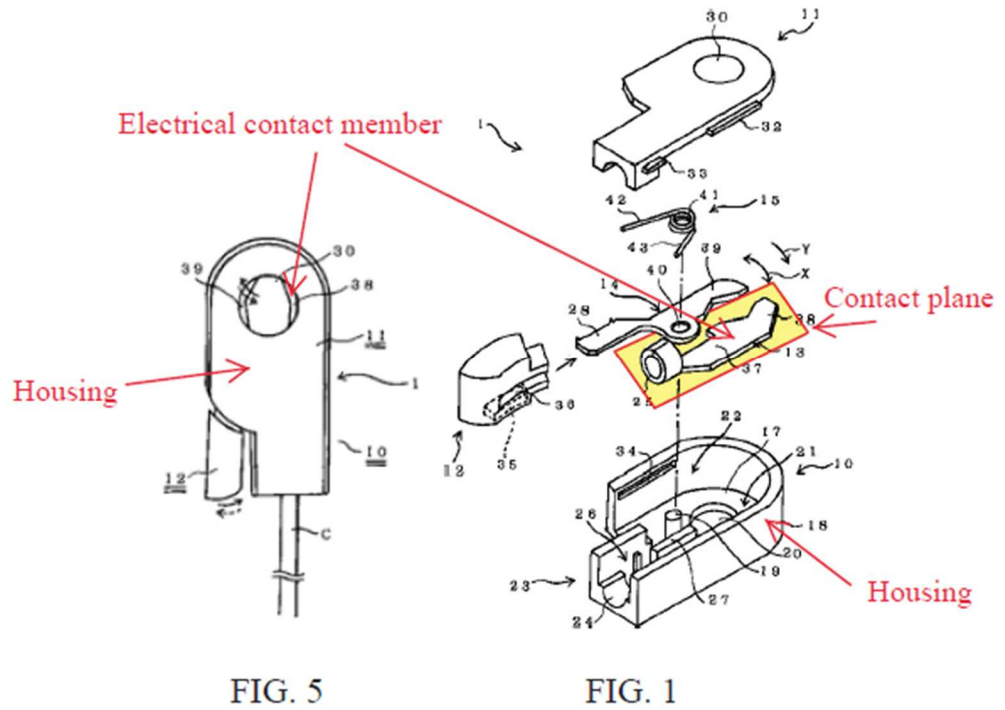
**[1.2]** an electrical contact member fixed to the housing and defining a contact plane

As noted above, “contact plane” is construed to mean “a two-dimensional flat surface that extends through at least a part of the electrical contact member.” The contact plane may extend through the contact member at any point along its height or thickness. (Layton Decl., Ex. 1002, ¶ 89.)

Fukuda teaches an electrical contact member 13 that is fixed to the housing (base member 10) and defining a contact plane (a plane extending through contact member 13).

“In addition, in the first assembly portion 21 a holding plate 27 is projected from the bottom surface 17 in order to clamp **and immobilize the first contact member 13 incorporated therein with the side wall 18.**” (Fukuda, Ex. 1007, ¶ [0014] (emphasis added).)

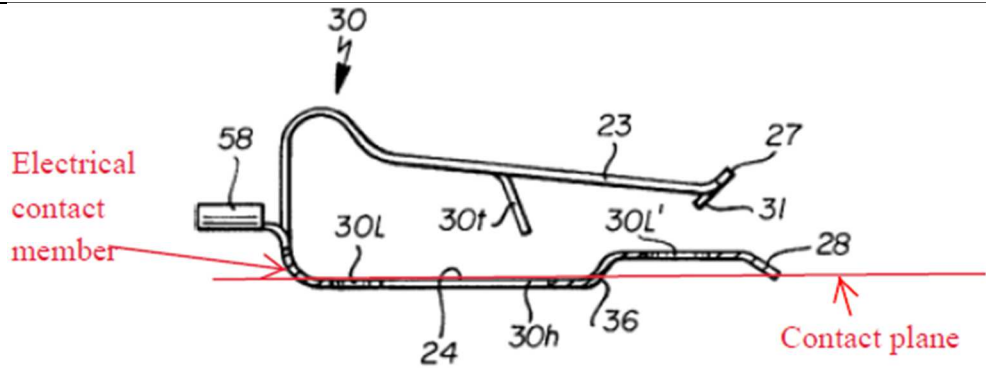
“The first contact member 13 with the lead cord C causes the compression ring 25 enter the compression ring receiving portion 26 of the first assembly portion 21, and the connecting member 37 is incorporated into the base member 10 so as to be sandwiched between the side wall 18 and the holding plate 27. By incorporating in this way, **the first contact member 13 becomes fixed** by the first assembly portion 21.” (Fukuda, Ex. 1007, ¶ [0019] (emphasis added).)



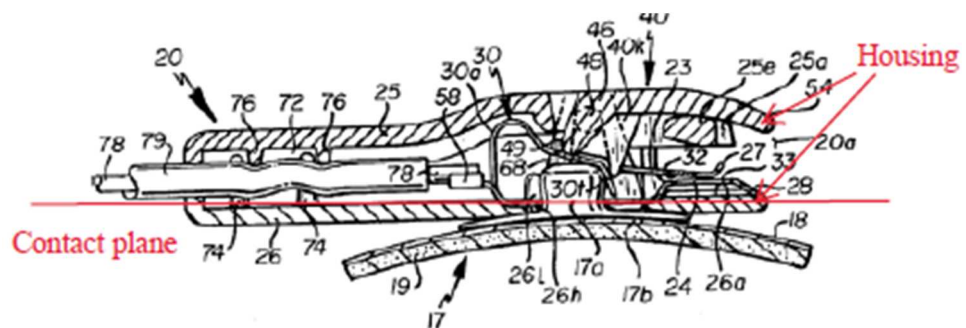
Christensson also teaches an ECG connector assembly (clasp 20) having an electrical contact member (spring 30) fixed to the housing (lower portion 25) and defining a contact plane (defined by a plane extending through clip arm 24).

**“Spring 30 is metallic for conductive purposes**, preferably being of plated, annealed spring steel (1050 grade, heat treated to Rockwell 45 hardness) or stainless steel and is completely sterilizable upon disconnection from the electrode 12 between uses.” (Christensson, Ex. 1008, Col. 4: 36-40 (emphasis added).)

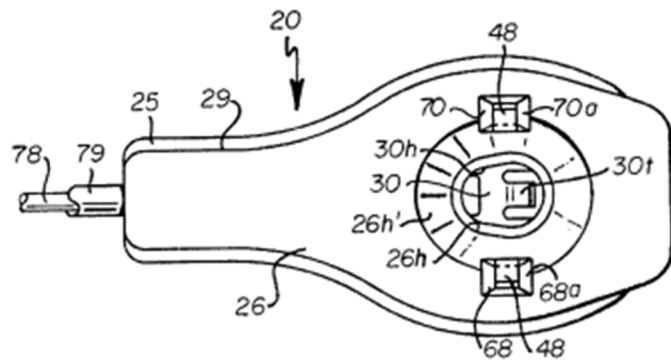
**“Near the center of the bottom portion 26 of the clasp 20 is an oblong opening 26h which is slightly larger at its forward end as shown in FIG. 7. Around the opening 26h is an upwardly and centrally tapered surface 26h'. Aligned above it is a similarly shaped opening 30h in the lower arm 24 of the spring 30. The spring 30 is also provided with two pairs of openings 30L and 30L' in the lower arm 24. The openings 30L [sic, 30L and 30L'] are placed over aligned locating pins that project upwardly from the lower surface of the lower portion 26 of the clasp 20 for holding the spring 30 in place.”** (Christensson, Ex. 1008, Col. 6: 34-43 (emphasis added).)



**Fig. 12**



**Fig. 4**



**Fig. 7**

(Layton Decl., Ex. 1002, ¶¶ 86-92.)

[1.3] and having a second opening

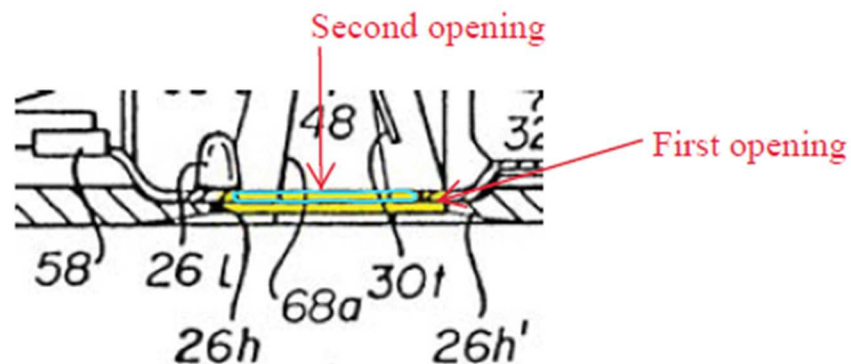
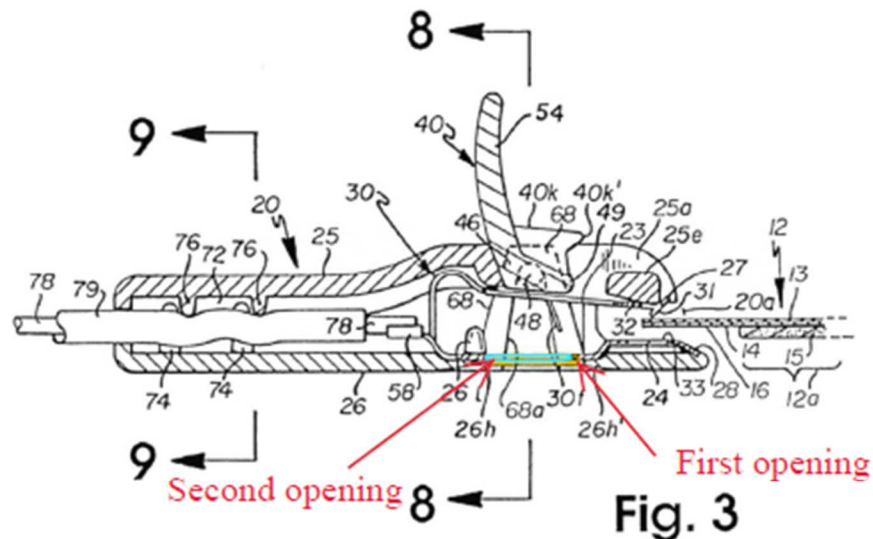
As noted above, the term “first opening” is construed to mean “a hole extending through the bottom wall of the housing from the bottom surface of the housing to the inner surface of the bottom wall that is sized to allow a press stud to extend therethrough.”

smaller than and disposed at least partially within the first opening; and

Christensson teaches an ECG connector assembly (clasp 20) having a second opening 30h smaller than and disposed at least partially within the first opening 26h (as shown in Fig. 3 and 7.)

**“Near the center of the bottom portion 26 of the clasp 20 is an oblong opening 26h which is slightly larger at its forward end as shown in FIG. 7. Around the opening 26h is an upwardly and centrally tapered surface 26h'. Aligned above it is a similarly shaped opening 30h in the lower arm 24 of the spring 30. ”**  
(Christensson, Ex. 1008, Col. 6: 34-39 (emphasis added).)

As shown in the annotated FIG.3 below, the first opening is highlighted in yellow and the second opening is defined by the light blue box and shown within the first opening. (Layton Decl., Ex. 1002, ¶ 94.)



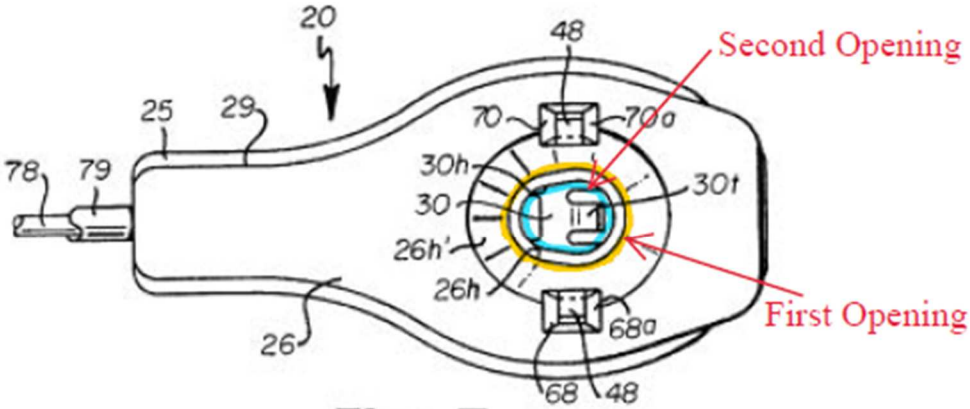
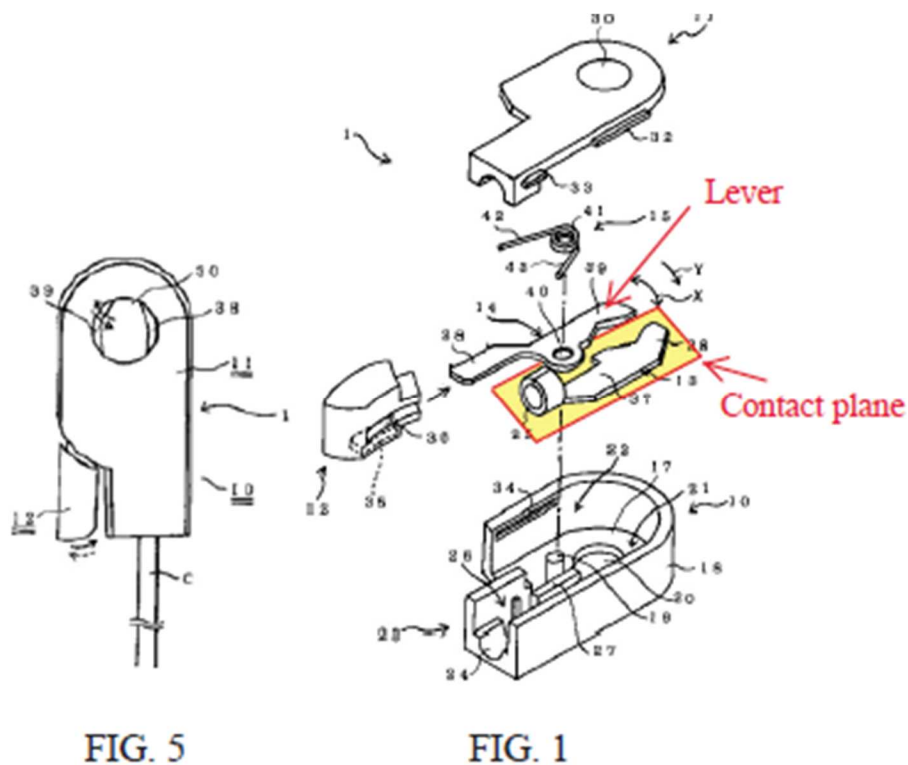
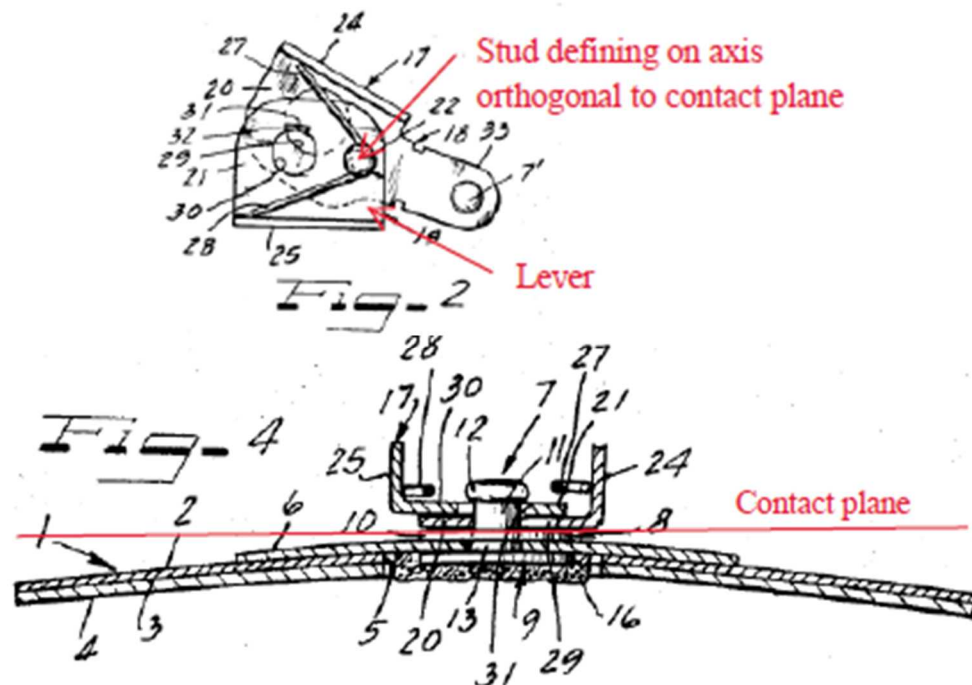
	<p style="text-align: center;">Enlarged partial view of Fig. 3</p>  <p style="text-align: center;"><b>Fig. 7</b></p> <p>(Layton Decl., Ex. 1002, ¶¶ 93-94.)</p>
<p><b>[1.4]</b> a lever pivotable about an axis orthogonal to the contact plane</p>	<p>Fukuda teaches a lever (contact member 14) pivotable about an axis (defined by pivot projection 19) orthogonal to the contact plane (defined by plane extending through contact member 13).</p> <p>Fukuda teaches a lever or contact member 14 wherein “[t]he second contact member 14 is the side that holds the terminal portion 5 of the contact electrode 2 as a pair with the first contact member 13 and operates to release the holding member, wherein an <b>operating part 28</b> for conducting the movement is provided on the proximal end; . . . and a <b>rotation fulcrum hole 40</b> is further provided at a middle position. . . . The second contact member 14 is incorporated into the second assembly portion 21 of the base member 10 so that the support shaft protrusion 19 of the base member 10 is inserted into the rotation fulcrum hole 40 thereof. By incorporating in this way, and in a state described later when the actuating force of the spring 15 is applied, a <b>rotational movement</b>, i.e. a motion of clamping or releasing the terminal portion 5 of the contact electrode 2 <b>can be performed by moving the operating part 28 with fingers as shown by arrow X in FIG. 1.</b>” (Fukuda, Ex. 1007, ¶¶ [0020]-[0021] (emphasis added).)</p> <p>“An external view of the connecting tool thus obtained is shown in FIG.5. The holding member 12 is usually in a position as shown in</p>

FIG.5. In this state, as shown in FIG. 5, a part of the < shaped holding members 38 and 39 is exposed in the internal space of the opening 30. Then, at the time of use, when the holding member 12 is pressed in as shown by the solid arrow, a part of the < shaped holding members 38 and 39 opens in conjunction with each other. In this state, the terminal portion 5 of FIG. 3 is inserted into the opening portion 30. At this time, the tip of the terminal portion 5 fits into the space of the opening 30 and does not protrude out of the opening. This status is shown by the dotted line 5A in FIG.7. With this inserted state, the holding member 12 is released from the hand. Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the < shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30.” (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)



Sessions teaches the use of a lever (member 19) that is pivotable about an axis (defined by stud 22) that is orthogonal to the contact plane (defined by plate 20).

“The terminal clip 17 comprises a pair of **members 18 and 19** illustrated as being formed from suitable sheet metal stock and formed to provide respective **base plates or portions 20 and 21**, **pivoted together by a stud member 22 . . .**” (Sessions, Ex. 1006, Col. 4: 10-28 (emphasis added).)



(Layton Decl., Ex. 1002, ¶¶ 95-98.)

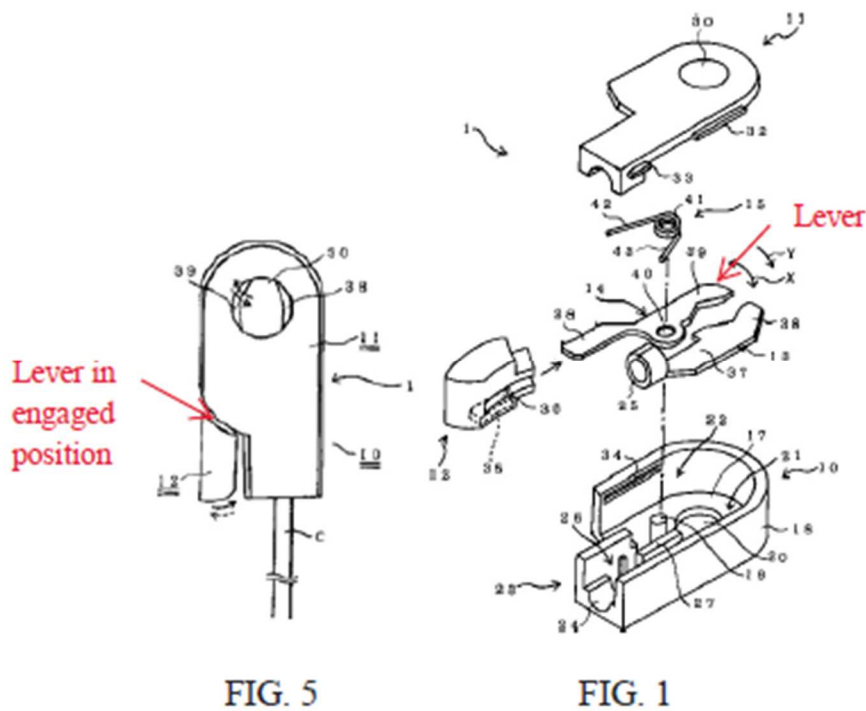
[1.5] and having at least an engaged position and a disengaged position,

Fukuda teaches a lever (contact member 14) having at least an engaged position (as shown in Fig. 5 without a press stud) and a disengaged position (when one moves the actuating portion of the lever inward). (Layton Decl., Ex. 1002, ¶ 99.)

Fukuda teaches a lever or contact member 14 wherein “[t]he second contact member 14 is the side that holds the terminal portion 5 of the contact electrode 2 as a pair with the first contact member 13 and operates to release the holding member . . . By

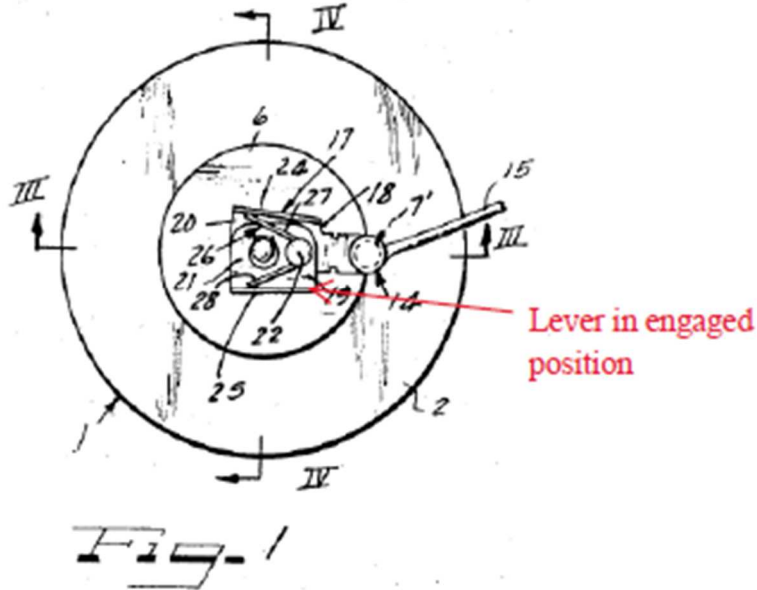
incorporating in this way, and in a state described later when the actuating force of the spring 15 is applied, **a rotational movement**, i.e. a motion of clamping or releasing the terminal portion 5 of the contact electrode 2 **can be performed by moving the operating part 28 with fingers as shown by arrow X in FIG. 1.**" (Fukuda, Ex. 1007, ¶¶ [0020]-[0021] (emphasis added).)

"An external view of the connecting tool thus obtained is shown in FIG.5. The holding member 12 is usually in a position as shown in FIG.5. In this state, as shown in FIG. 5, a part of the < shaped holding members 38 and 39 is exposed in the internal space of the opening 30. **Then, at the time of use, when the holding member 12 is pressed in as shown by the solid arrow, a part of the < shaped holding members 38 and 39 opens in conjunction with each other. In this state, the terminal portion 5 of FIG. 3 is inserted into the opening portion 30.** At this time, the tip of the terminal portion 5 fits into the space of the opening 30 and does not protrude out of the opening. This status is shown by the dotted line 5A in FIG.7. **With this inserted state, the holding member 12 is released from the hand. Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the < shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30.**" (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)



Sessions teaches the use of a lever (member 19) having at least an engaged position (see Fig. 1) and a disengaged position (when one squeezes the two members 18, 19 together). (Layton Decl., Ex. 1002, ¶ 100.)

**“The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and 25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening is engaged with the neck portion of the button terminal disposed below the head 12 while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7 substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal.”** (Sessions, Ex. 1006, Col. 5: 11-28 (emphasis added).)



(Layton Decl., Ex. 1002, ¶¶ 99-100.)

[1.6] wherein the lever comprises an actuating portion, an engaging region, and a pivot,

Fukuda teaches a lever (contact member 14) that comprises an actuating portion (operating part 28 with holding member 12 thereon), an engaging region (the ‘>’ shaped end of sandwiching portion 39), and a pivot (pivot projection 19).

Fukuda teaches a lever or contact member 14 wherein “[t]he second contact member 14 is the side that holds the terminal portion 5 of the contact electrode 2 as a pair with the first contact member 13 and operates to release the holding member, wherein an **operating part 28** for conducting the movement is provided on the proximal end; while **on the tip end a holding member 39 shaped as a <** that is paired with the holding member 38 of the first contact member 13 is provided, and a **rotation fulcrum hole 40** is further provided at a middle position. . . . The second contact member 14 is incorporated into the second assembly portion 21 of the base member 10 so that the support shaft protrusion 19 of the base member 10 is inserted into the rotation fulcrum hole 40 thereof. By incorporating in this way, and in a state described later when the actuating force of the spring 15 is applied, a **rotational movement**, i.e. a motion of clamping or releasing the terminal portion 5 of the contact electrode 2 **can be performed by moving**

	<p><b>the operating part 28 with fingers as shown by arrow X in FIG. 1.” (Fukuda, Ex. 1007, ¶ [0020]-[0021] (emphasis added).)</b></p> <p>“An external view of the connecting tool thus obtained is shown in FIG.5. The holding member 12 is usually in a position as shown in FIG.5. In this state, as shown in FIG. 5, a part of the &lt; shaped holding members 38 and 39 is exposed in the internal space of the opening 30. <b>Then, at the time of use, when the holding member 12 is pressed in as shown by the solid arrow, a part of the &lt; shaped holding members 38 and 39 opens in conjunction with each other. In this state, the terminal portion 5 of FIG. 3 is inserted into the opening portion 30.</b> At this time, the tip of the terminal portion 5 fits into the space of the opening 30 and does not protrude out of the opening. This status is shown by the dotted line 5A in FIG.7. <b>With this inserted state, the holding member 12 is released from the hand. Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the &lt; shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30.” (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)</b></p>
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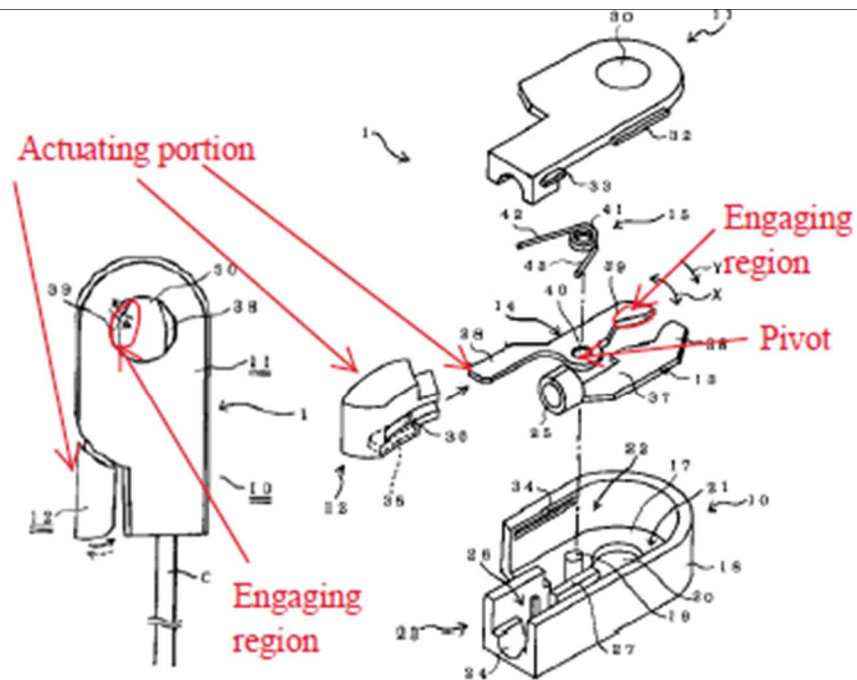


FIG. 5

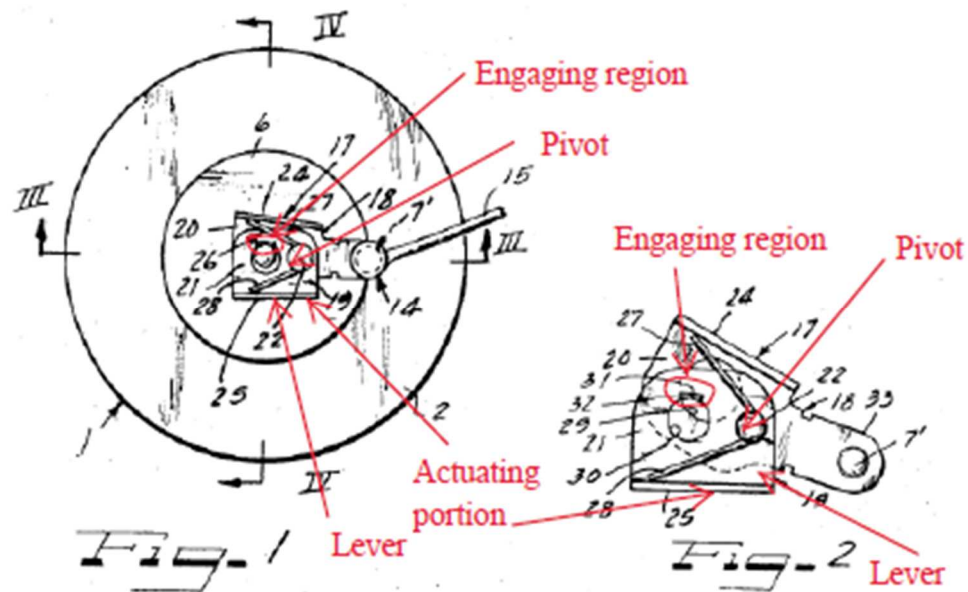
FIG. 1

Sessions teaches the use of a lever (member 19) that includes an actuating portion (side wall 25), an engaging region (the portion of member 19 that includes the interior of opening 30 that includes the engaging surface (projection 31)) and a pivot (stud 22).

“The terminal clip 17 comprises a pair of **members 18 and 19** illustrated as being formed from suitable sheet metal stock and formed to provide respective base plates or portions 20 and 21, **pivoted together by a stud member 22**, illustrated as having a shank 23 extending outwardly from the two base plates. Extending along an outer edge of the plate 20 is an outwardly or upwardly extending sidewall or flange 24, and in like manner **extending along an edge of the plate 21 is a similarly extending flange or sidewall 25**. Extending around the shank 23 of the stud 22 is the central portion 26' of a **torsion spring indicated generally by the numeral 26** having like oppositely disposed portions 27 and 28 adapted to bear respectively on the flanges 24 and 25 of the respective plates thereby tending to urge the plate 18 in a clockwise direction and the plate 19 in counter clockwise direction with respect to the axis of the stud 22, producing corresponding separating movement of the walls 24 and 25.” (Sessions, Ex. 1006, Col. 4: 10-28 (emphasis added).)

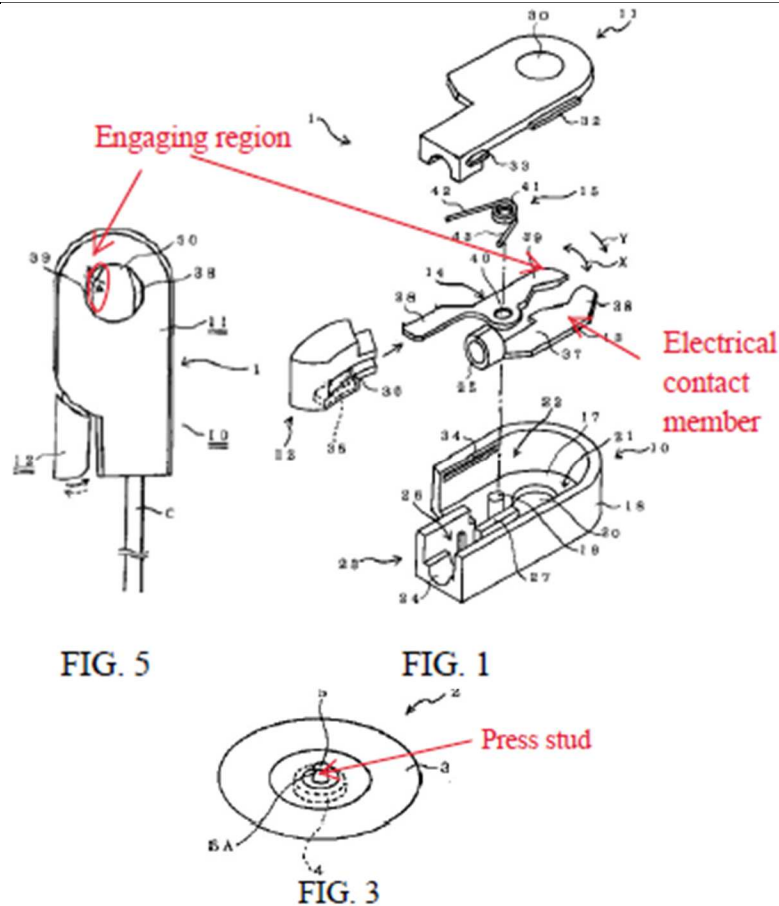
“As particularly illustrated in FIGS. 2 and 4, a **portion of the base plate 21 defining the periphery of the opening 30 is deformed downwardly into the opening 29, forming a projection 31**, the lower edge of which is defined by the adjacent peripheral edge of the opening 30 as illustrated in FIG. 2.” (Sessions, Ex. 1006, Col. 4: 34-39 (emphasis added).)

“The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and 25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening is engaged with the neck portion of the button terminal disposed below the head 12 while **the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7** substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal.” (Sessions, Ex. 1006 Col. 5: 11-28 (emphasis added).)



	(Layton Decl., Ex. 1002, ¶¶ 101-102.)
[1.7] the engaging region configured to operably engage the press stud to cause a portion of the press stud to contact the electrical contact member when the lever is in the engaged position. <sup>3</sup>	<p>Fukuda teaches a lever (member 14) having an engaging region (the &gt; shaped end of holding member 39) configured to operably engage the press stud (the narrow waist portion 5A of terminal portion 5) to cause a portion (the narrow waist portion 5A) of the press stud (terminal portion 5) to contact the electrical contact member (member 13) when the lever (member 14) is in the engaged position.</p> <p>“Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the &lt; shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way <b>that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30.</b>” (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)</p>

<sup>3</sup> This limitation refers to a manner of operating an apparatus and is entitled to no patentable weight. “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Petitioner has nevertheless included this limitation in its invalidity analysis.



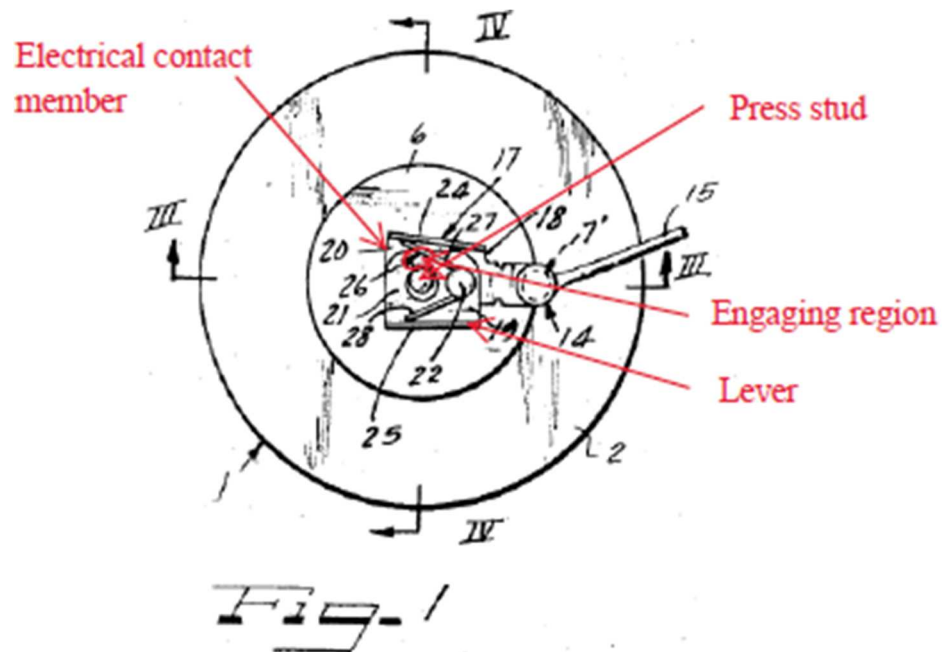
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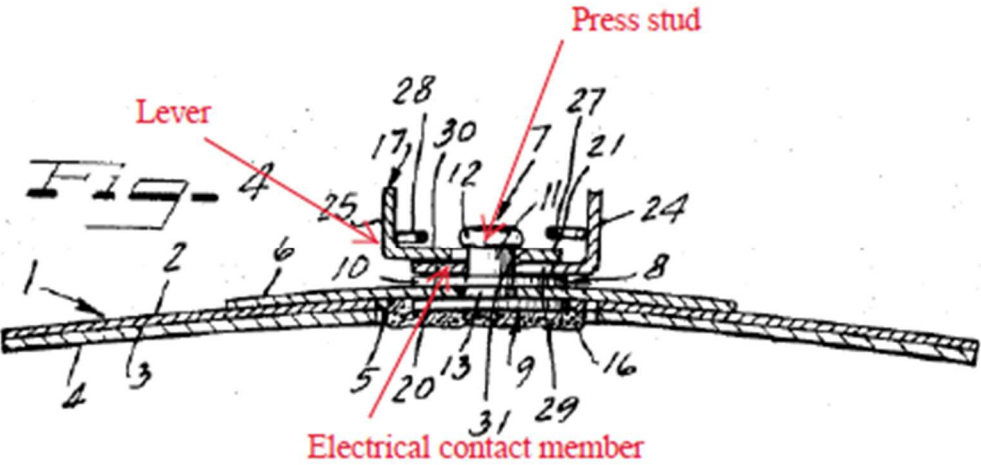
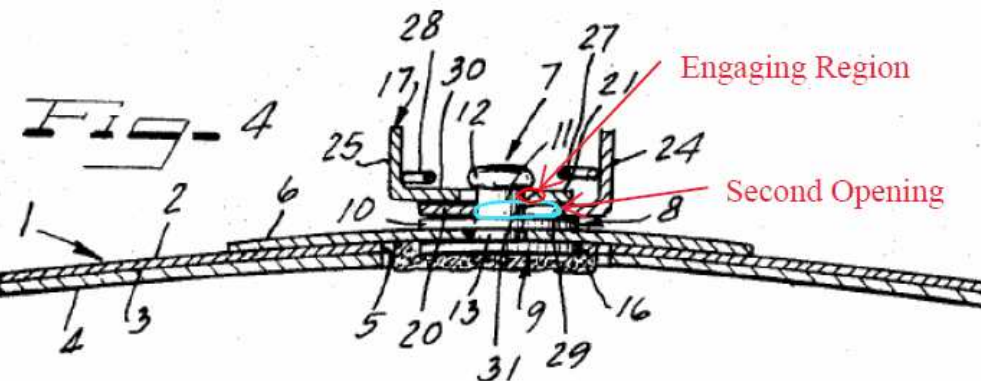
Sessions teaches a lever (clip member 19) having an engaging region (the portion of member 19 that includes the interior of opening 30 that includes the engaging surface (projection 31)) that is configured to operatively engage the press stud (terminal 7) to cause a portion (the narrow waist, see reference numeral 11 in Figs. 3 and 4) of the press stud (terminal 7) to contact the electrical contact member (member 18) when the lever is in the engaged position as illustrated in Figure 4.

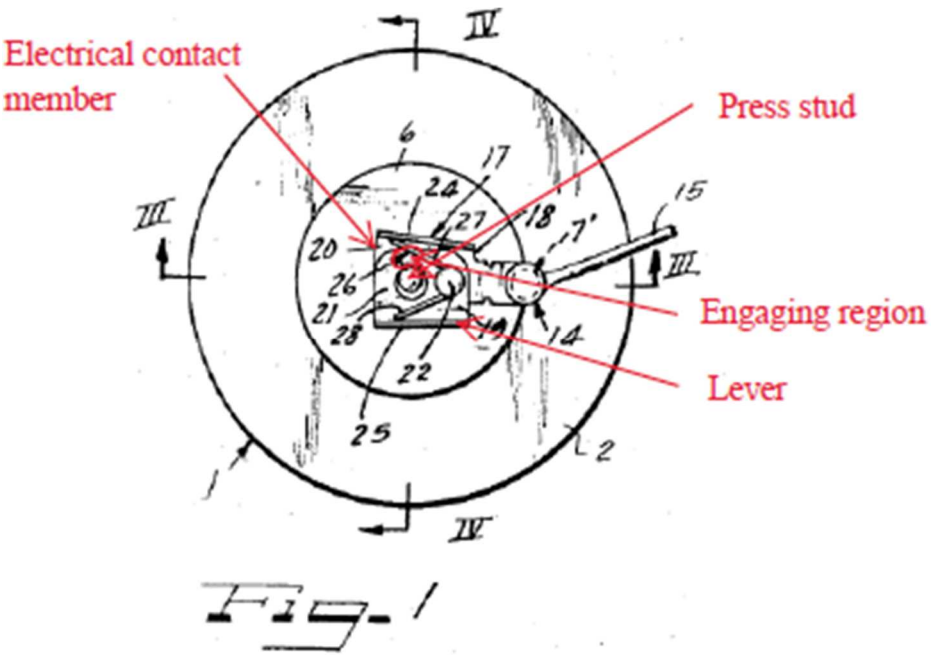
“As particularly illustrated in FIGS. 2 and 4, a portion of the base plate 21 defining the periphery of the opening 30 is deformed downwardly into the opening 29, forming a projection 31, the lower edge of which is defined by the adjacent peripheral edge of the opening 30 as illustrated in FIG. 2.” (Sessions, Ex. 1006, Col. 4: 34-39 (emphasis added).)

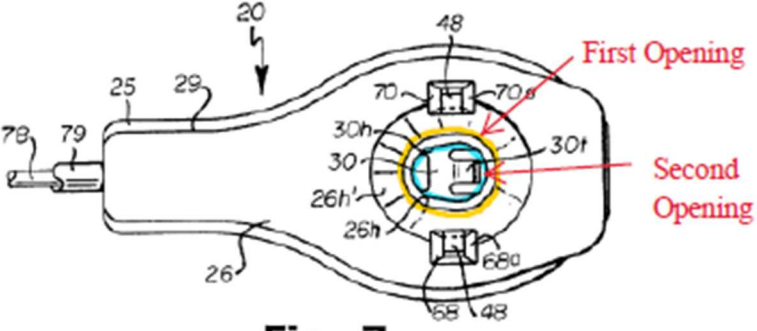
“The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and

25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening 20 [sic, 30] is engaged with the neck portion of the button terminal disposed below the head 12 **while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7** substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal.” (Sessions, Ex. 1006, Col. 5: 11-28 (emphasis added).)



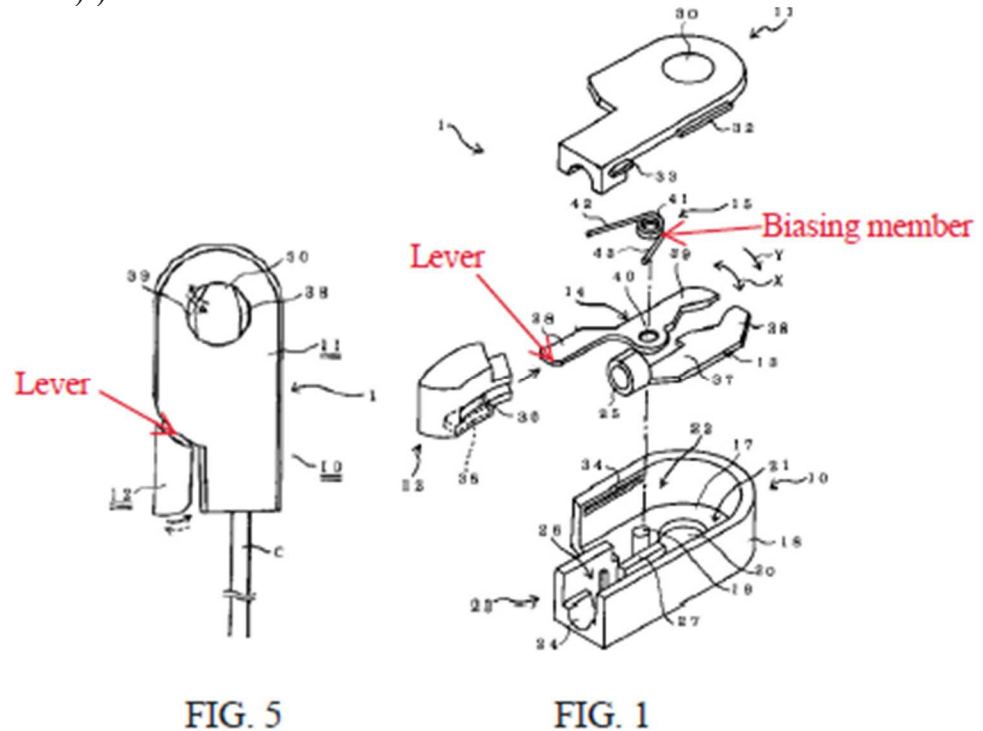
	 <p>(Layton Decl., Ex. 1002, ¶¶ 103-107.)</p>
<p>[2] The ECG connector assembly of claim 1 wherein the engaging region extends across the second opening when the lever is in the engaged position.</p>	<p>As shown in Fig. 4 of Sessions, the engaging region (the portion of member 19 that includes the interior of opening 30 that includes the engaging surface (projection 31)) extends across the second opening (circular opening 29) when the lever (member 19) is in the engaged position.</p> <p>“As clearly illustrated in FIG. 4, one peripheral edge defining the opening is engaged with the neck portion of the button terminal disposed below the head 12 while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7 substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal.” (Sessions, Ex. 1006, Col. 5: 20-28.)</p> 

	 <p>(Layton Decl., Ex. 1002, ¶¶ 108-111.)</p>
<p>[4] The ECG connector assembly of claim 1 wherein the second opening is disposed substantially concentrically with respect to the first opening.</p>	<p>Christensson teaches an ECG connector assembly (clasp 20) having a housing (upper and lower portions 25 and 26) having a first opening (opening 26h) and an electrical contact member (spring 30) that has a second opening (opening 30h) disposed substantially concentrically to the opening 26h (as shown in Fig. 7).</p> <p>“Near the center of the bottom portion 26 of the clasp 20 is an <b>oblong opening 26h</b> which is slightly larger at its forward end as shown in FIG. 7. Around the opening 26h is an upwardly and centrally tapered surface 26h'. Aligned above it is a <b>similarly shaped opening 30h in the lower arm 24 of the spring 30</b>. . . .” (Christensson, Ex. 1008, Col. 6: 34-39(emphasis added).)</p>

	 <p style="text-align: center;"><b>Fig. 7</b></p> <p>(Layton Decl., Ex. 1002, ¶¶ 112-115.)</p>
<p><b>[5]</b> The ECG connector assembly of claim 1 further comprising a biasing member configured<sup>4</sup> to bias the lever towards the engaged position.</p>	<p>Fukuda teaches a biasing member (spring 15) configured to bias the lever (contact member 14) towards the engaged position (where it contacts a press stud) as shown in Fig. 5 (without the press stud).</p> <p>“The connecting tool 1 is formed by a first and second contact members 13,14; a base member 10; an insulating member composed of a cover member 11 and a holding member 12; and a <b>spring 15 that actuates the second contact member 14 in the direction shown by the arrow.</b>” (Fukuda, Ex. 1007, [Abstract] (emphasis added).)</p> <p>“Also the holding member 12 functions <b>to provide an actuating force in order to sandwich the terminal portion 5 of the contact electrode 2 with the second contact member 14 by receiving the elastic contact of the spring 15</b> through the spring receiving groove 36 as described later.” (Fukuda, Ex. 1007, ¶ [0016] (emphasis added).)</p> <p>“The spring 15 utilizes a torsion coil spring, the coil member 41 thereof is fitted to the support shaft protrusion 19 to be incorporated into the base member 10. <b>Further one of the spring arms 43 is elastically contacted with the holding plate 27, and</b></p>

<sup>4</sup> To the extent this limitation refers to the configuration of a biasing member, it recites a manner of operating an apparatus and is entitled to no patentable weight. Petitioner has nevertheless included this limitation in its invalidity analysis.

the other spring arm 42 is elastically contacted to the holding member 12 fitted to the operating part 28 of the second contact member 14 through the spring receiving groove 36. By doing so, the second contact member 14 becomes actuated as shown by arrow Y in FIG. 1.” (Fukuda, Ex. 1007, ¶ [0022] (emphasis added).)



Sessions teaches a biasing member (torsion spring 26) configured to bias the lever (member 19) towards the engaged position as shown in Fig. 1.

“Extending around the shank 23 of the stud 22 is the central portion 26’ of a **torsion spring indicated generally by the numeral 26** having like oppositely disposed portions 27 and 28 adapted to bear respectively on the flanges 24 and 25 of the respective plates thereby tending to urge the plate 18 in a clockwise direction and the plate 19 in counter clockwise direction with respect to the axis of the stud 22, producing corresponding separating movement of the walls 24 and 25.” (Sessions, Ex. 1006, Col. 4: 20-28 (emphasis added).)

“The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and

25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening is engaged with the neck portion of the button terminal disposed below the head 12 while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7 substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal.” (Sessions, Ex. 1006, Col. 5:11-28 (emphasis added).)

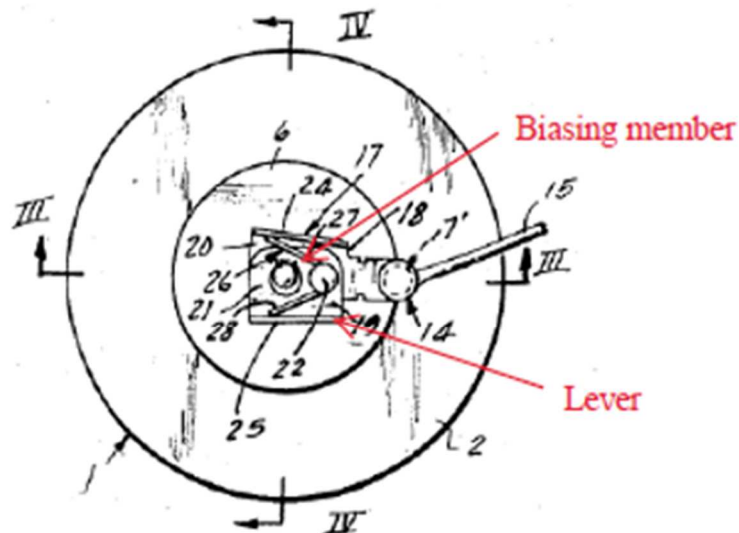


Fig. 1

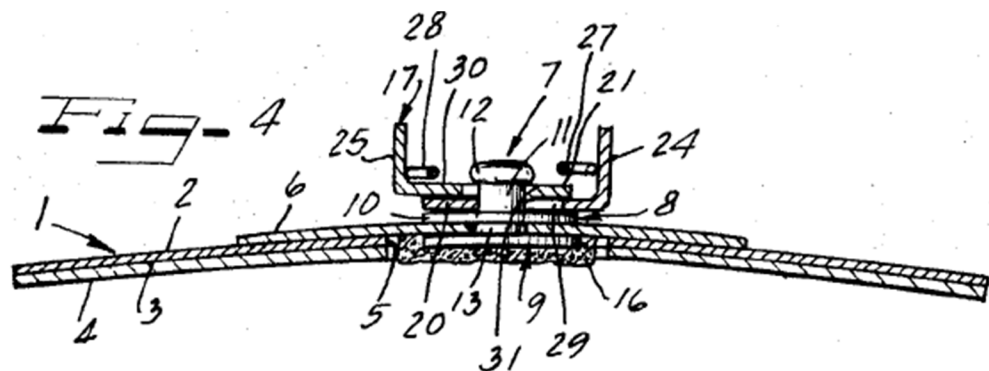
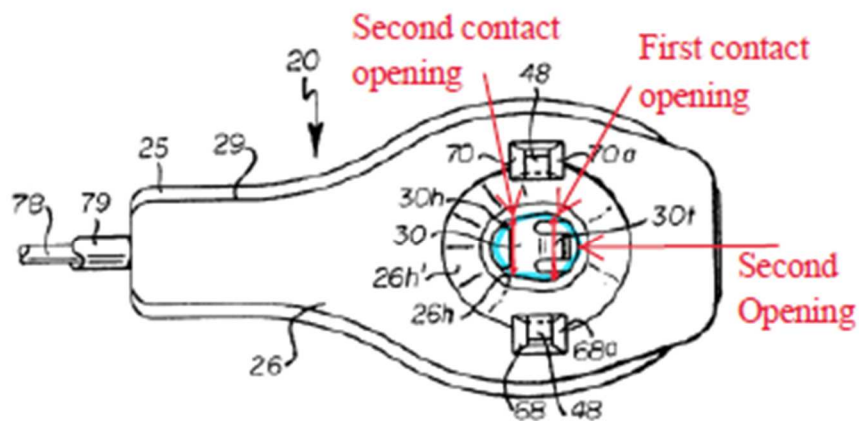


Fig. 4

	(Layton Decl., Ex. 1002, ¶¶ 116-118.)
<p>[6] The ECG connector assembly of claim 1 wherein the second opening includes a first contact opening portion and a second contact opening portion, wherein an internal dimension of the first contact opening portion is greater than a corresponding internal dimension of the second contact opening portion.</p>	<p>Christensson teaches an ECG connector assembly (clasp 20) where the second opening (opening 30h) in the lower arm 24 of the spring 30 is ovoid shaped as shown in Figure 7. This ovoid shape includes a first contact opening portion (the “forward end” of opening 30h) and a second contact opening portion (the opposing end of opening 30h). The first contact opening portion has a larger internal dimension than the second contact opening.</p> <p>“Near the center of the bottom portion 26 of the clasp 20 is an oblong opening 26h which is <b>slightly larger at its forward end as shown in FIG. 7</b>. Around the opening 26h is an upwardly and centrally tapered Surface 26h'. Aligned above it is a <b>similarly shaped opening 30h in the lower arm 24 of the spring 30</b>. . . . The forward portion of the opening 26h and the forward portion of the opening 30h of the spring 30 are large enough to accommodate the stud 17a of a snap-type electrode 18 shown in FIG. 4. When the stud 17a is introduced into the forward enlarged end of the opening 30h in the spring 30 through opening 26h, it can do So because the opening is large enough at its forward end to accommodate the stud 17a. However, when the lever 40 is thrown forwardly and downwardly to the operating position, a keel 40k provided as an integral part of the lever 40 exerts a rearward force on a downwardly projecting tab or finger 30T which extends downwardly from the upper spring arm 23, causing tab 30T to be deflected rearwardly so as to shift the lug or stud 17a of the snap-type electrode 18 rearwardly in the oblong opening 30h, thereby locking it in place.” (Christensson, Ex. 1008, Col. 6:34-39; 45-59 (emphasis added).)</p>



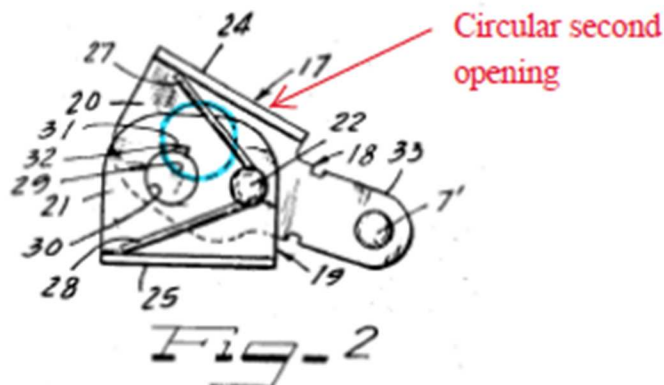
**Fig. 7**

(Layton Decl., Ex. 1002, ¶¶ 119-121.)

[7] The ECG connector assembly of claim 1 wherein the second opening has a shape selected from the group consisting of ovoid shaped, pear-shaped, keyhole-shaped, circular, and a shape described by the intersection of two partially-coincident circles.

Sessions teaches a connector assembly (terminal clip 17) where the second opening (circular opening 29) is circular.

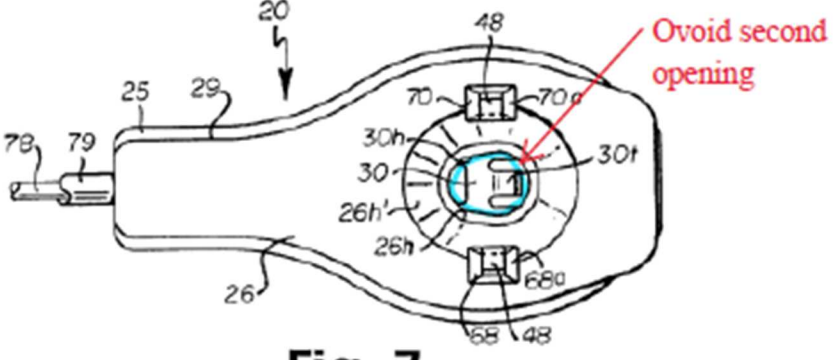
“As illustrated in FIG. 2, the base plate 20 is provided with a **circular opening 29** therein . . . .” (Sessions, Ex. 1006, Col 4: 28-30 (emphasis added).)



**Fig. 2**

Christensson teaches an ECG connector assembly (clasp 20) where the second opening 30h in the lower arm 24 of the spring 30 is ovoid shaped as shown in Figure 7.

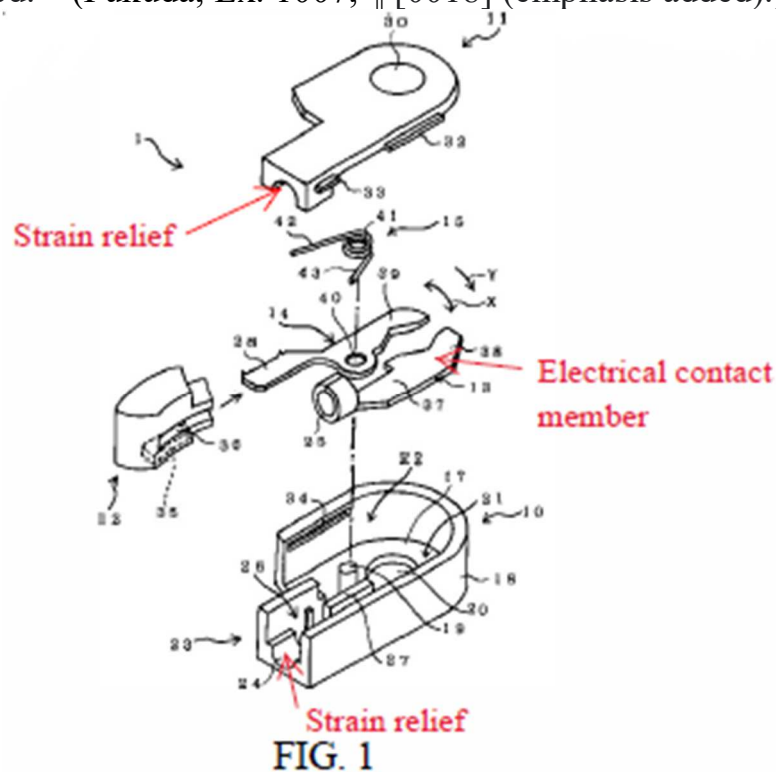
“Near the center of the bottom portion 26 of the clasp 20 is an oblong opening 26h which is **slightly larger at its forward end as shown in FIG. 7**. Around the opening 26h is an upwardly and centrally tapered Surface 26h'. Aligned above it is a **similarly shaped opening 30h in the lower arm 24 of the spring 30.**”

	<p>(Christensson, Ex. 1008, Col. 6:34-39 (emphasis added).)</p>  <p><b>Fig. 7</b></p> <p>(Layton Decl., Ex. 1002, ¶¶ 122-124.)</p>
<p><b>[8]</b> The ECG connector assembly of claim 1 wherein the electrical contact member is constructed from material selected from the group consisting of stainless steel and low-carbon steel.</p>	<p>Christensson teaches where the electrical contact member (spring 30) is constructed from stainless steel.</p> <p>Christensson teaches that “[s]pring 30 is metallic for conductive purposes, preferably being of plated, annealed spring steel (1050° grade, heat treated to Rockwell 45 hardness) or <b>stainless steel</b> and is completely sterilizable upon disconnection from the electrode 12 between uses.” (Christensson, Ex. 1008, Col. 4:37-41 (emphasis added).)</p> <p>(Layton Decl., Ex. 1002, ¶¶ 125-127.)</p>
<p><b>[10]</b> The ECG connector assembly of claim 1 further comprising: a lead wire coupled to the electrical</p>	<p>Fukuda teaches an ECG connector assembly (connecting tool 1) that comprises a lead wire (lead cord C) coupled to the electrical contact member (contact member 13); and a strain relief (semi-circular groove 31 along with semi-circular groove 24) and having at least part of the lead wire (lead cord C) disposed therethrough.</p> <p>Fukuda teaches “as seen from FIG. 2 showing the back side of the cover member 11, a pressing portion 29 is protruded, and in the part corresponds to the cord introducing portion 23 of the base member 10, <b>a semi-circular groove 31 is provided in pair with</b></p>

contact member; and a strain relief having at least a portion of the lead wire disposed therethrough.

**the semicircular groove 24 in the cord introducing portion to press down the lead cord.”** (Fukuda, Ex. 1007, ¶ [0015] (emphasis added).)

“FIG. 4 shows a state in which the **lead cord C is attached to the first contact member 13**. The tip of the lead cord C is passed through the compression ring 25 and guided to the connecting member 37, the insulating part at the tip of the cord C is peeled off, **core wire 50 is pulled out and soldered to the connecting member 37**. The soldered state is shown as 51. After that, the compression ring 25 is crimped and the lead cord C is tightened and fixed.” (Fukuda, Ex. 1007, ¶ [0018] (emphasis added).)

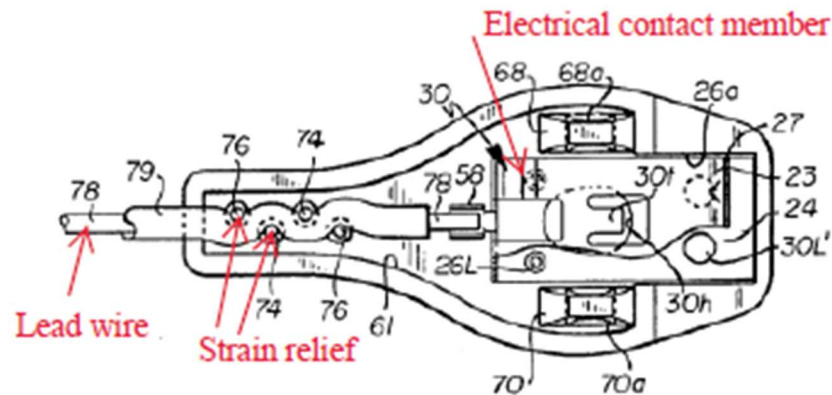


Christensson teaches an ECG connector assembly (clasp 20) having a lead wire (electrical lead 78) coupled to the electrical contact member (at lug 58 of spring 30); and a strain relief (pins 74, 76) having at least part of the lead wire (electrical lead 78) disposed therethrough.

Christensson teaches that “[t]he closed portion, i.e., the left end 30a of the spring 30 is also provided with a centrally-positioned, rearwardly extending, rigid, trough-shaped, electrically conductive lug 58. **An electrical lead 78 has its inner end contacting the**

**surface of the lug 58 and is preferably soldered to it.”**  
(Christensson, Ex. 1008, Col. 5:19-24 (emphasis added).)

“The lead 78, 79 is held in a serpentine passage between staggered pins including two upper retaining pins 76 and two lower retaining pins 74. **The pins 74, 76 act as a maze which serves as a strain relief function and are fabricated as a part of the upper and lower portions 25, 26 of the clasp 20.**” (Christensson, Ex. 1008, Col. 5:67 to Col. 6:5 (emphasis added).)



**Fig. 6**

(Layton Decl., Ex. 1002, ¶¶ 128-133.)

**[11]** The ECG connector assembly of claim 1 wherein the actuating portion of the lever protrudes through a lever recess defined in a side wall of the housing when the

Fukuda teaches the actuating portion (operating part 28 within holding member 12) of the lever (contact member 14) protrudes through a lever recess (as shown in Figs. 1 and 5) defined in a side wall of the housing (base member 10 and cover member 11) when the lever (member 14) is in the engaged position (see Fig. 5).

**“The second assembly portion 22 is formed in the way that the integrated second contact member 14 causes the operating part 28 to project out of the base member 10.”** (Fukuda, Ex. 1007, ¶ [0014] (emphasis added).)

“The holding member 12 is formed in a block shape with a fitting hole 35 and a spring receiving groove 36. This holding member 12 is fitted to the operating part 28 (described later) of the second contact member 14 through the fitting hole 35, and functions to cover the operating part 28 with insulation. Also the holding

lever is in the engaged position.

member 12 functions to provide an actuating force in order to sandwich the terminal portion 5 of the contact electrode 2 with the second contact member 14 by receiving the elastic contact of the spring 15 through the spring receiving groove 36 as described later.” (Fukuda, Ex. 1007, ¶ [0016].)

“An external view of the connecting tool thus obtained is shown in FIG.5. **The holding member 12 is usually in a position as shown in FIG. 5. . . .** Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the < shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5.” (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)

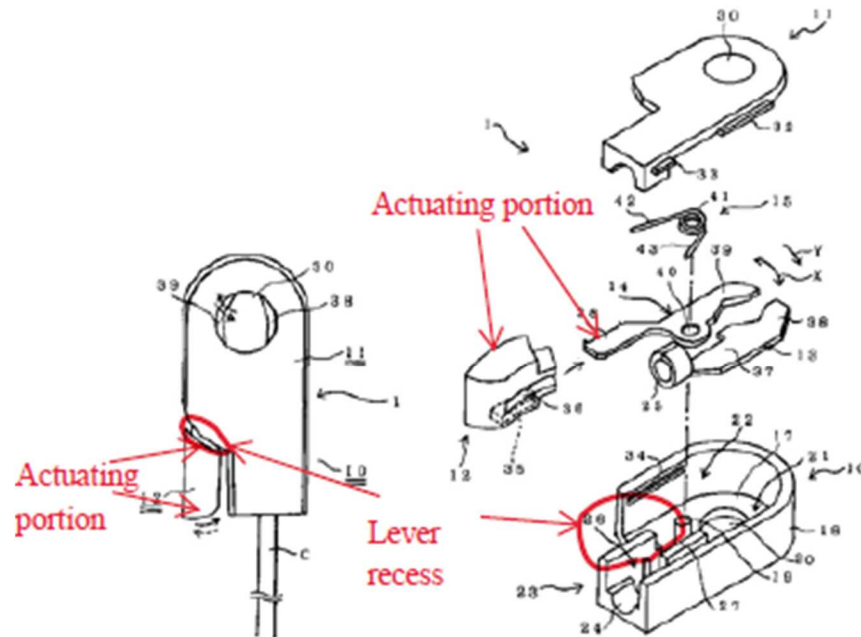


FIG. 5

FIG. 1

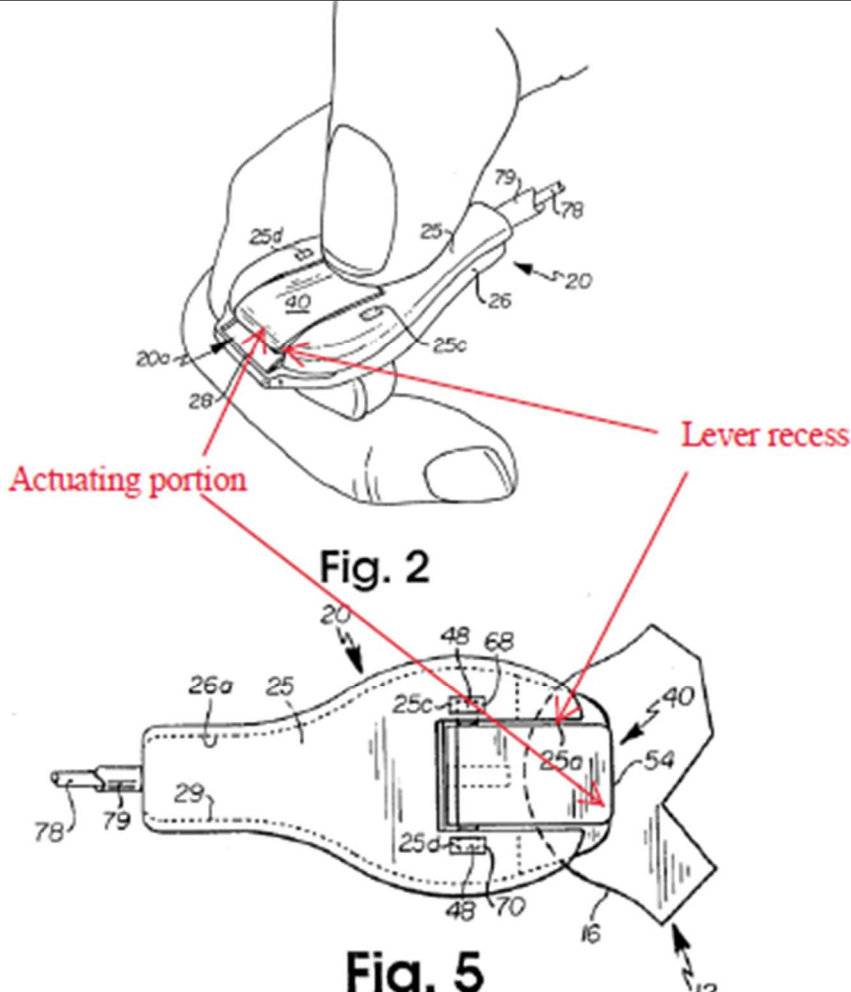
Christensson teaches the actuating portion (free end 54) of the lever 40 protrudes through a lever recess (central cavity 25a) defined in a wall of the housing (upper and lower member 25, 26) when the lever 40 is in the engaged position, as shown in Figures 2 and 5.

“Affixed above the intermediate portion of upper clip arm 23 is a thumb-length jaw operating lever 40 which rotates forwardly on

laterally extending aligned pivots 48 between a lever-up inoperative position (FIG. 3) and a **lever-down operating position (FIG. 4) in line with the clasp body**. . . . It should be noted that during the jaw closing operation, **the free end 54 of lever 40 swings forwardly toward the jaw opening 20a. This permits it to be easily operated with the finger or thumb**, tending to move the open clasp 20 toward engagement with the electrode 12 rather than away from it.” (Christensson, Ex. 1008, Col. 4:46-50; 52-57 (emphasis added).)

“The upper and lower portions 25 and 26 of the clasp 20 are of a molded material, preferably plastic resin which has electrical insulating properties, typically of nylon or poly carbonate plastic which is completely sterilizable. **The upper portion 25 has a forwardly facing, upwardly opening, central cavity 25a to receive the lever 40** (FIG. 5).” (Christensson, Ex. 1008, Col. 5: 25-30 (emphasis added).)

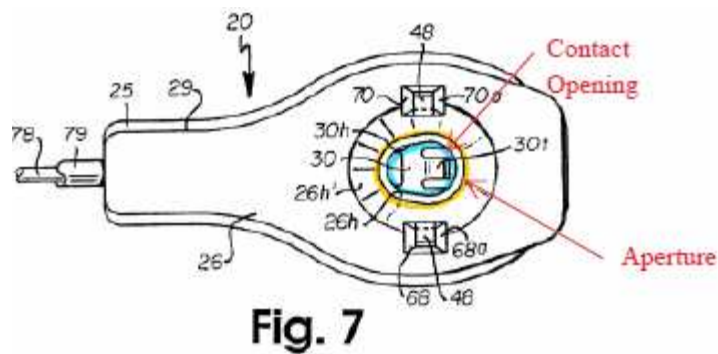
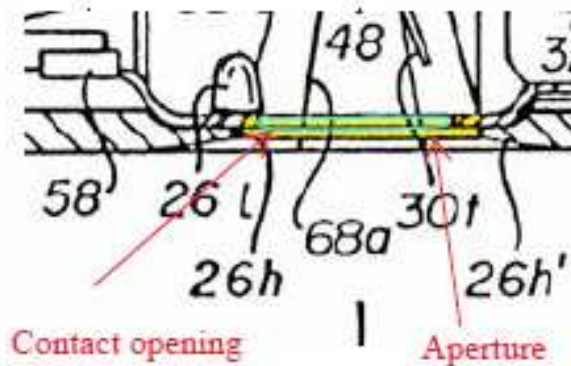
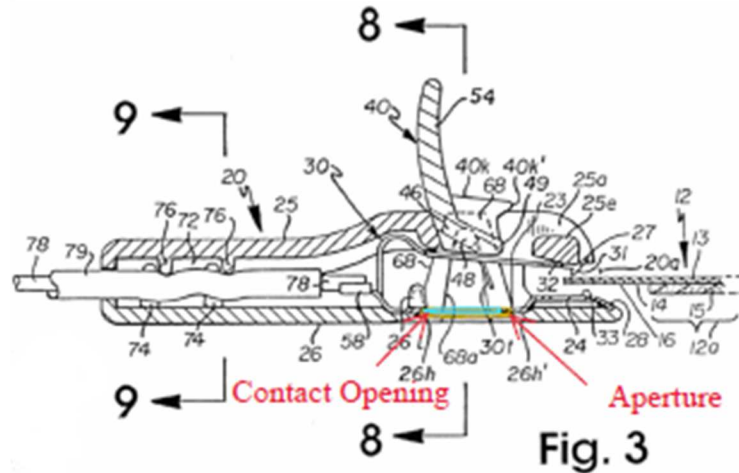
“In FIG. 5 is shown a top plan view of the clasp 20 with the lever 40 in the operating mode. In this mode **the lever 40 is thrown forwardly into the upwardly opening cavity 25a which receives the free end 54 of the lever 40, providing a clasp that is free of projections and has a smoothly contoured surface.**” (Christensson, Ex. 1008, Col. 6: 24-29 (emphasis added).)

	 <p>(Layton Decl., Ex. 1002, ¶¶ 134-137.)</p>
<p><b>[13.0]</b> An ECG connector assembly, comprising:</p>	<p>See claim element 1.0. (Layton Decl., Ex. 1002, ¶ 139.)</p>
<p><b>[13.1]</b> a housing having an aperture dimensioned</p>	<p>See claim element 1.1.<sup>5</sup> (Layton Decl., Ex. 1002, ¶¶ 140-142.)</p>

<sup>5</sup> While claim element 13.1 uses the term aperture and claim 1 uses the term first opening, these terms refer to the same element and are construed the same.

to operably receive a press stud;	
<b>[13.2]</b> an electrical contact member defining a contact plane	See claim element 1.2. <sup>6</sup> (Layton Decl., Ex. 1002, ¶ 143.)
<b>[13.3]</b> and having a contact opening that is at least partially exposed within the aperture;	<p>As shown in Figs. 3 and 7, Christensson teaches an ECG connector assembly (clasp 20) having an electrical contact member (spring 30) having a contact opening (opening 30h) that is at least partially exposed within the aperture (opening 26h).</p> <p><b>“Near the center of the bottom portion 26 of the clasp 20 is an oblong opening 26h which is slightly larger at its forward end as shown in FIG. 7. Around the opening 26h is an upwardly and centrally tapered surface 26h'. Aligned above it is a similarly shaped opening 30h in the lower arm 24 of the spring 30.”</b> (Christensson, Ex. 1008, Col. 6: 34-39 (emphasis added).)</p> <p><b>Fig. 12</b></p>

<sup>6</sup> It is noted that claim element 1.2 requires the additional limitation that the electrical contact member be fixed to the housing, which is not present in claim element 13.2.



(Layton Decl., Ex. 1002, ¶¶ 144-147.)

[13.4] a lever having an actuating portion, a pivot, and an engaging region,

See claim element 1.6. (Layton Decl., Ex. 1002, ¶ 148.)

<p><b>[13.5]</b> wherein the pivot is pivotable between an engaged position and a disengaged position,</p>	<p>See claim elements 1.4 and 1.5. (Layton Decl., Ex. 1002, ¶ 149.)</p>
<p><b>[13.6]</b> the engaging region configured to retain a press stud inserted into the aperture of the housing against at least a portion of the electrical contact member when the lever is in the engaged position<sup>7</sup> and</p>	<p>Fukuda teaches a lever (contact member 14) having an engaging region (the &gt; shaped end of holding member 39) configured to retain a press stud (terminal portion 5) inserted into the aperture (receiving hole 20) of the housing (base member 10) against at least a portion of the electrical contact member (the &lt; shaped end of holding member 38 of contact member 13) when the lever (contact member 14) is in the engaged position (as shown in Fig. 5 without the press stud).</p> <p>“Consequently, the holding member 12 returns as shown by the dotted arrow in FIG. 5, and the &lt; shaped holding portions 38 and 39 also return as shown by the dotted arrow in conjunction with the holding member 12, and sandwich the terminal portion 5. The terminal portion 5 is clamped in the way <b>that the neck portion 5A (FIG. 3) of the terminal portion 5 is sandwiched between the holding members 38 and 39 of the opening portion 30.</b>” (Fukuda, Ex. 1007, ¶ [0024] (emphasis added).)</p>

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<sup>7</sup> This limitation refers to a manner of operating an apparatus and is entitled to no patentable weight. Petitioner has nevertheless included this limitation in its invalidity analysis.

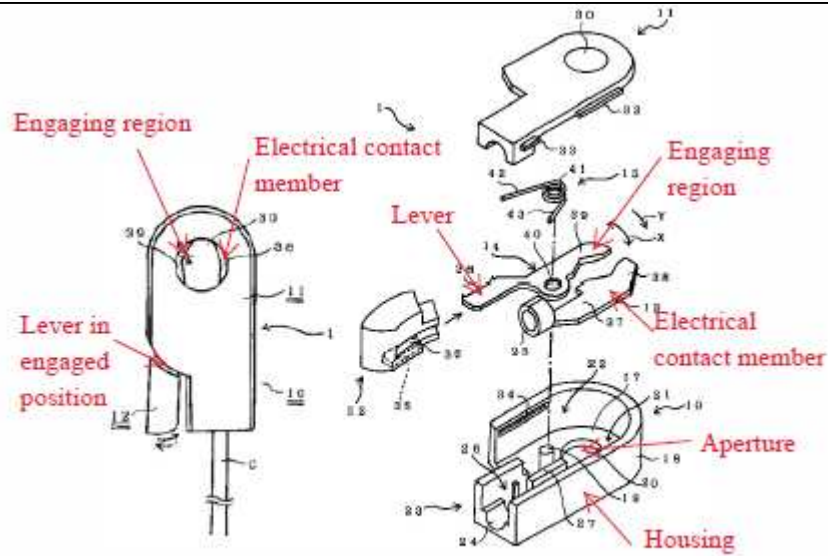


FIG. 5

FIG. 1

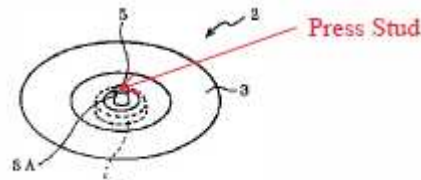


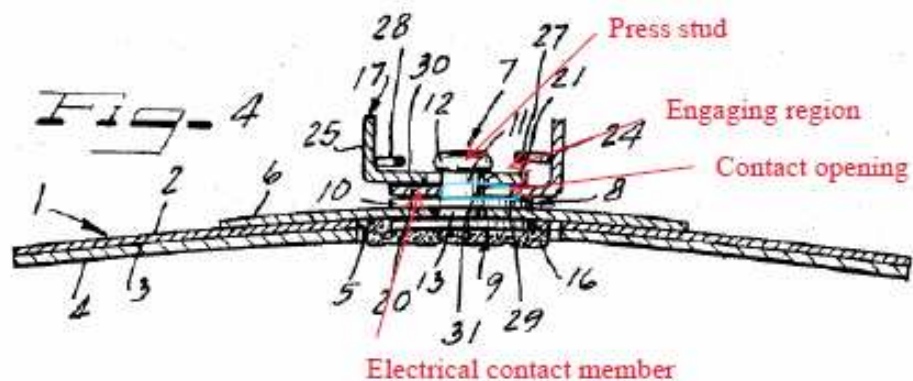
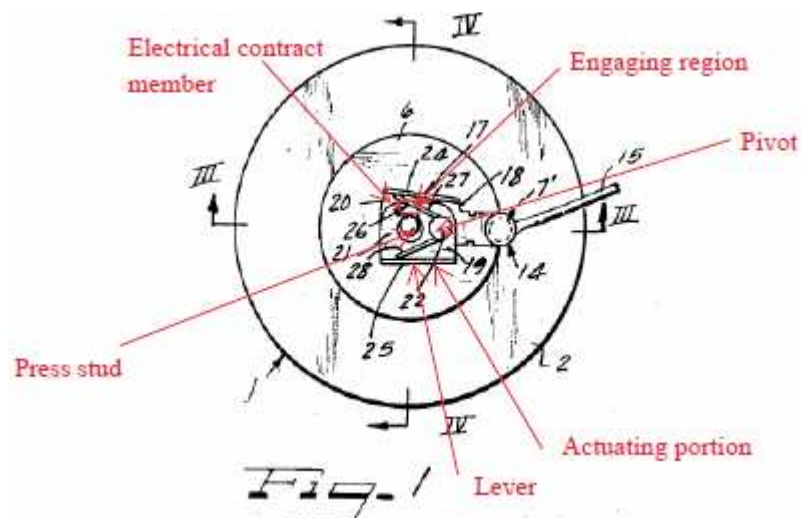
FIG. 3

Sessions discloses the engaging region (the portion of member 19 that includes the interior of opening 30 that includes the engaging surface (projection 31)) configured to retain a press stud (terminal portion 5) against a portion of the electrical contact member (the interior of opening 29) when the lever (clip member 19) is in the engaged position (see Fig. 1).

“As particularly illustrated in FIGS. 2 and 4, a **portion of the base plate 21 defining the periphery of the opening 30 is deformed downwardly into the opening 29, forming a projection 31**, the lower edge of which is defined by the adjacent peripheral edge of the opening 30 as illustrated in FIG. 2.” (Sessions, Ex. 1006, Col. 4: 34-39 (emphasis added).)

“The clip may then be taken between the thumb and forefinger grasping the same by the upwardly extending wall portions 24 and 25 and by this application of a squeezing pressure thereto, the members 18 and 19 may be pivoted in opposition to the action of the torsion spring, into a position in which the opening 30 is

sufficiently aligned with the opening 29 to permit reception of the button terminal 7 through both openings to a position substantially as illustrated in FIGS. 3 and 4. As clearly illustrated in FIG. 4, one peripheral edge defining the opening is engaged with the neck portion of the button terminal disposed below the head 12 **while the arcuate peripheral edge of the projection 31 engages such neck portion of the button 7** substantially diametrically opposite to the engagement of the peripheral edge of the opening 29 with the button terminal, whereby clamping forces are exerted by the respective members of the clip upon such button terminal.” (Sessions, Ex. 1006, Col. 5: 11-28 (emphasis added).)



(Layton Decl., Ex. 1002, ¶¶ 150-153.)

[13.7]  
wherein the

As noted above, the term “lever plane” is construed to mean “a two-dimensional flat surface that extends through at least part a



to bias the lever towards the engaged position.	
<b>[14.0]</b> The ECG connector assembly of claim 13 wherein the engaging region extends across the contact opening when the lever is in the engaged position.	See claim 2. <sup>9</sup> (Layton Decl., Ex. 1002, ¶¶ 159-162.)
<b>[16]</b> The ECG connector assembly of claim 13 wherein the contact opening is disposed substantially concentricall	See claim 4. <sup>10</sup> (Layton Decl., Ex. 1002, ¶¶ 163-168.)

weight. Petitioner has nevertheless included this limitation in its invalidity analysis.

<sup>9</sup> While Claim 14 uses the term contact opening and Claim 2 uses the term second opening, these terms refer to the same element and are construed the same.

<sup>10</sup> While claim 16 uses the term contact opening and claim 4 uses the term second opening, these terms refer to the same element and are construed the same.

y with respect to the aperture.	
[17] The ECG connector assembly of claim 13 wherein the lever is pivotable about an axis orthogonal to the contact plane.	See claim element 1.4. (Layton Decl., Ex. 1002, ¶ 169.)

**Rationale to Combine:** A POSITA would have been motivated to combine Fukuda with Christensson and Sessions, and such combination would have had a reasonable expectation of success. The references themselves provide a motivation to combine. In particular, Christensson discloses that the use of open end pinch clips, as taught by Fukuda, “has certain disadvantages and, in particular, cannot provide desired electrical contact and stability with a snap style contact stud.” (Christensson, Ex. 1008, Col. 1: 50-52.) In order to address that problem, Christensson teaches a closed end pinch type ECG connector having an electrical contact member with an oblong opening within the opening of the bottom wall of the housing that includes a larger first portion that allows the bulbous head of the stud through and a smaller second portion that locks the stud in place relative to the connector and prevent it from being withdrawn. (*Id.* at Col 6: 34-65.)

Christensson thus teaches that closed end pinch type ECG connectors provide a more secure physical connection to ECG electrodes than open end pinch type connectors (referred to as “alligator clip” connectors by Christensson), and thus Christensson provides a motivation to combine certain features of closed end pinch type connectors such those disclosed in Sessions and Christensson, into open end pinch type connectors such as Fukuda, in order to achieve a more secure connection between the connector and the press stud. (Christensson, Ex. 1008, Col. 1:50-59; *see also*, Layton Decl., Ex. 1002, ¶173-175.)

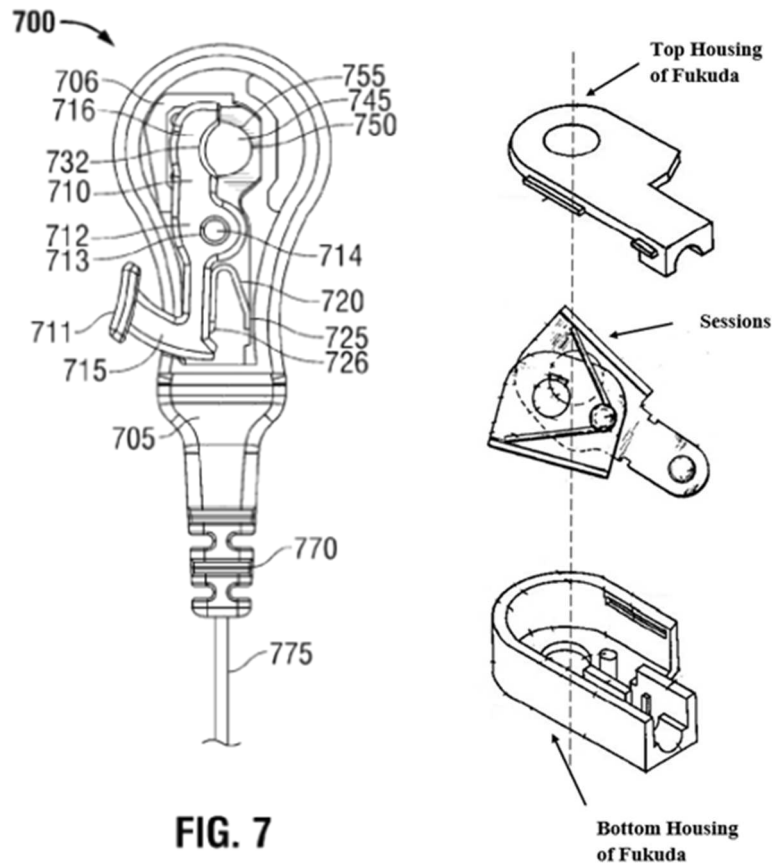
Fukuda teaches an open end pinch type ECG connector having all of the limitations of claim 1 except for the second opening of the electrical contact member, and its positioning and size relative to the first opening of the housing. (Layton, Decl., Ex. 1002, ¶¶ 171-172.) Christensson teaches a closed end pinch type ECG connector having an electrical contact member having a second opening smaller than and disposed at least partially within a first opening of the housing. (Christensson, Ex. 1008, Col. 6: 34-43.) While Fukuda teaches a lever pivotable about an axis orthogonal to a contact plane, this structure is also taught by Sessions, but in the context of a closed end pinch type ECG connector, rather than an open end pinch type connector. (Sessions, Ex. 1006, Col. 4: 10-28.) It would have been obvious for a POSITA to use the electrical contact member of Christensson or Sessions and the lever of Fukuda in order to achieve the more

secure physical connection afforded by closed end pinch type ECG connectors. (Layton Decl., Ex. 1002, ¶ 175.)

The combination of Fukuda, Sessions and Christensson as applied to claim 1 also renders obvious claims 2, 4-8, 10-11, 13-14 and 16-17 of the '004 patent, and the motivation of achieving the more secure physical connection afforded by closed end pinch ECG connectors also applies to the combination of Fukuda, Sessions and Christensson relative to these claims. (Layton Decl., Ex. 1002, ¶¶ 179-185.)

A POSITA would have had a reasonable expectation of success in combining Fukuda, Sessions and Christensson as applied to claims 1-2, 4-8, 10-11, 13-14 and 16-17 of the '004 patent because the electrical contact members of Fukuda (contact member 13), Sessions (plate 20) and Christensson (spring 30), and the levers of Fukuda (contact member 14) and Sessions (member 19), are highly analogous components. (Layton Decl., Ex. 1002, ¶ 185.) The electrical contact members of closed end pinch type ECG connectors of Christensson and Session are readily adaptable for placement within the housing (base member 10 and cover member 11) of Fukuda, in place of the open end pinch type electrical contact member of Fukuda. (*Id.* at ¶¶ 186-187.) For example, as shown in Fig. 7 of the '004 patent and the annotated Fig. below, the connector of Sessions may be readily

placed within the housing of Fukuda to obtain a closed end pinch type connector within a housing as disclosed in the '004 patent. (*Id.* at ¶ 187.)



**FIG. 7**

It would have been a routine matter for a manufacturer to modify the open end pinch connector taught in Fukuda to a closed end pinch connector taught by Sessions or Christensson. (*Id.* at ¶ 184.) It is well established that the combination of familiar elements according to known methods is likely to be obvious when it does no more than lead to a predictable result. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

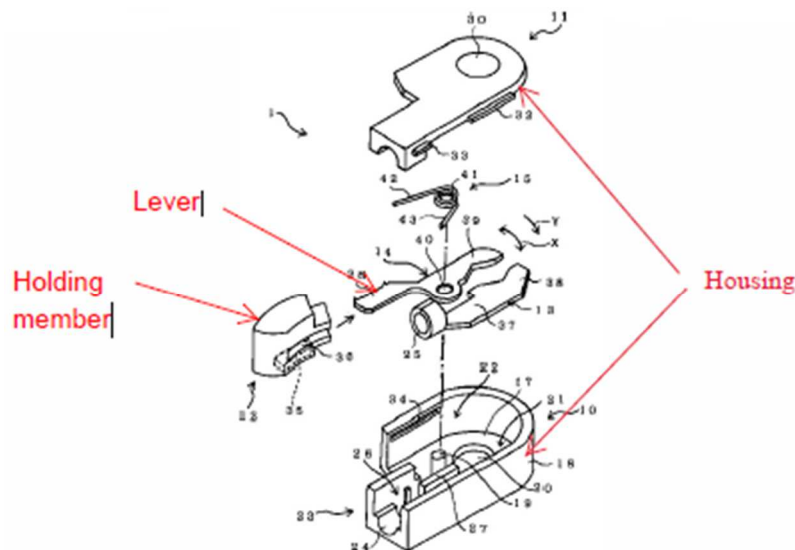
**B. Ground 2: Claim 9 Is Rendered Obvious by Fukuda in View of Christensson, Sessions and Powell**

U.S. Patent No. 8,795,004	Fukuda in view of Christensson, Sessions and Powell
<p>[9] The ECG connector assembly of claim 1 wherein the housing and the lever are constructed from an electrically non-conducting material.</p>	<p>Powell teaches that the housing (housing elements 102, 104) and the lever (opposed actuator elements 106) are constructed from an electrical non-conductive material.</p> <p>“The connector body comprises top and bottom connector housing elements <b>102, 104, as well as two opposed actuator elements 106</b> which are pivoted at their one end 107 so as to allow the opposing or distal end to move with respect to the housing elements 102, 104. <b>Each of these components comprise a molded polymer such as ABS (acrylonitrile butadine styrene), although other materials such as polyethylene, fluoropolymers (e.g., ETFE), and the like may be used.</b>” (Powell, Ex. 1009, Col. 9: 14-22 (emphasis added).)</p> <div data-bbox="532 1052 1317 1745"> <p>FIG. 1a</p> <p>FIG. 1b</p> </div> <p>Fukuda teaches that the housing (base member 10 and cover member 11) and part of lever (holding member 12) is insulated, or</p>

made from electrically non-conducting material.

**“The insulating part features: base member that is formed to allow the parts of the said contact members and the spring fitted in, a cover member constructed to cover the base assembly into which each part of the contactor member and the spring been incorporated, and a holding member that covers the operating part by fitting the operating part of the second contact member.”** (Fukuda, Ex. 1007, ¶ [0008] (emphasis added).)

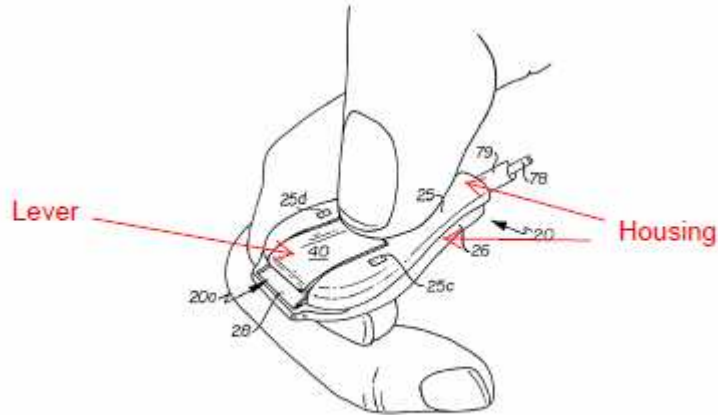
**“Each member of the insulating part is formed by plastic molding.”** (Fukuda, Ex. 1007, ¶ [0012] (emphasis added).)



Christensson teaches that the housing (upper and lower portions 25 and 26 of the clasp 20) is insulated, or made from electrically non-conducting material. Christensson does not expressly disclose what material the lever 40 is made out of, but would be obvious to one of ordinary skill in the art for it to be made out of the same non-conductive material as the housing. (Layton Decl., Ex. 1002, ¶ 192). The particular non-conductive materials were all well known in the art and would simply be a matter of design choice. (*Id.* at ¶193).

Christensson teaches that “[t]he upper and lower portions 25 and 26 of the clasp 20 are of a molded material, preferably plastic

**resin which has electrical insulating properties**, typically of nylon or polycarbonate plastic which is completely sterilizable.” (Christensson, Ex. 1008, Col. 5: 25-28 (emphasis added).)



**Fig. 2**

(Layton Decl., Ex. 1002, ¶¶ 188-196.)

**Rationale to Combine:** Regarding claim 9, Fukuda, Sessions and Christensson do not expressly disclose an entire lever constructed from an electrically non-conducting material. Fukuda discloses a conductive lever having a non-conducting cover surrounding an actuating portion of the lever. Should this lever cover accidentally separate from the remainder of the lever while in operation, a patient or treating medical professional is in danger of coming into electrical contact with the lead wire and ECG electrode. (Layton Decl., Ex. 1002, ¶ 192.) Powell disclosed an ECG connector having a lever constructed entirely from a non-conducting material. (Powell, Ex. 1009, Col. 9: 14-22.) It would have been obvious to a POSITA to modify the lever of Fukuda or Sessions to be constructed

entirely of a non-conductive material in order to better ensure electrical isolation of lead wires and ECG from patient and medical care providers. (Layton Decl., Ex. 1002, ¶ 193.)

Moreover, a POSITA would have had a reasonable expectation of success in combining Fukuda, Sessions, Christensson and Powell as applied to claim 9, as the use of a nonconductive material is an obvious matter of design choice and the types of materials used for the lever are readily interchangeable. (Layton Decl., Ex. 1002, ¶ 196.)

## **XI. CONCLUSION**

There is a reasonable likelihood that Petitioners will prevail on claims 1-2, 4-11, 13-14 and 16-17 of the 8,795,004 patent. *Inter partes* review should be instituted for each challenged claim.

## **XII. CERTIFICATE OF WORD COUNT**

Pursuant to 37 C.F.R. § 42.24, the undersigned attorney for the Petitioner, Petitioners declare that the argument section of this Petition (Sections I & III-XI) has a total of 13,765 words, according to the word count tool in Microsoft Word™.

Respectfully submitted,

**PATZIK, FRANK & SAMOTNY LTD.**

Dated: August 2, 2022

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### XIII. APPENDIX OF EXHIBITS

<b>Exhibit No.</b>	<b>Description</b>	<b>Identifier</b>
Ex. 1001	U.S. Patent No. 8,795,004	'004 patent
Ex. 1002	Declaration of Terry Layton, Ph.D.	Layton Decl.
Ex. 1003	File History of U.S. Patent No. 8,795,004	'004 patent file history
Ex. 1004	U.S. Patent No. 4,178,052	Ekborn
Ex. 1005	U.S. Patent No. 4,671,591	Archer
Ex. 1006	U.S. Patent No. 3,740,703	Sessions
Ex. 1007	Japanese Patent Publication No. JPH09276239A, English translation of Japanese Patent Publication No. JPH09276239A and Verification of Translation	Fukuda
Ex. 1008	U.S. Patent No. 5,944,562	Christensson
Ex. 1009	U.S. Patent No. 7,214,107	Powell
Ex. 1010	Amendment "A" dated November 29, 2011 in connection with application serial No. 13/182,656	Amendment A
Ex. 1011	Amendment "B" dated June 13, 2011 in connection with application serial No. 12/330,550	Amendment B
Ex. 1012	Merriam-Webster online dictionary, <a href="https://www.merriam-webster.com/dictionary/actuate">https://www.merriam-webster.com/dictionary/actuate</a>	Merriam-Webster actuate definition
Ex. 1013	Merriam-Webster online dictionary, <a href="https://www.merriam-webster.com/dictionary/concentric">https://www.merriam-webster.com/dictionary/concentric</a>	Merriam-Webster concentric definition

## CERTIFICATE OF SERVICE

Under 37 C.F.R. §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on August 2, 2022, a complete and entire copy of the PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,795,004 UNDER 35. U.S.C. § 311 ET SEQ. AND 37 CFR § 42.100 ET SEQ. encompassing all exhibits and Power of Attorney, were served on a flashdrive via FedEx Priority Overnight at the correspondence address of record for the patent owner of the subject patent and patent owner's litigation counsel as follows:

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