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REVIVANT CORPORATION

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BZ

REVIVANT CORPORATION, a Delaware corporation,

Plaintiff,

v.

THOMAS J. FOGARTY, M.D. and FOGARTY ENGINEERING,

Defendants.

C 05 01247

Case No.:

COMPLAINT FOR DECLARATORY RELIEF;

CERTIFICATION OF INTERESTED ENTITIES OR PERSONS

Plaintiff Revivant Corporation ("Revivant") alleges against Defendant Thomas J. Fogarty, M.D. and Defendant Fogarty Engineering (collectively "Defendants") as follows:

NATURE OF THE ACTION

1. This is an action for declaratory judgment under 28 U.S.C. § 2201 as to patent inventorship under 35 U.S.C. §§ 116 and 256. Revivant seeks declaratory relief as a result of Defendants wrongful and deliberate acts in violation of the above laws.

JURISDICTION

2. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a), as this Complaint includes a claim for declaratory relief pursuant to the patent laws of the United States, 35 U.S.C. §§ 116 and 256.

VENUE

3. Venue is proper in the Northern District of California pursuant to 28 U.S.C. § 1391(b) because Defendants reside in this District, a substantial part of the events or omissions giving rise to Revivant's claims occurred in this District, and a substantial part of the property in controversy is located in this District.

INTRADISTRICT ASSIGNMENT

4. This is an Intellectual Property Action, which is an excepted category pursuant to Civil Local Rule 3-2(c), and will be assigned on a district-wide basis.

THE PARTIES

5. Revivant is a corporation organized under the laws of Delaware with its principal place of business in Sunnyvale, California.

6. On information and belief, Defendant Fogarty is an individual residing in Portola Valley, California.

7. On information and belief, Defendant Fogarty Engineering is a sole proprietorship owned by Defendant Fogarty with its principal place of business in Portola Valley, California.

FACTUAL BACKGROUND

8. Originally named Emergency Medical Systems, Inc., Revivant was founded in 1997 by Defendants and Three Arch Partners, a venture capital investment company, to develop and market proprietary technology to treat sudden cardiac arrest both in and out of the hospital. As a launching point for the company's research and development, Defendants agreed to transfer to Revivant all right, title and interest in all of their assets, contracts or property rights in a field defined generally as resuscitation devices, and devices for vascular access and airway management. Revivant and Defendants entered into an Assignment and

Royalty Agreement (the "Assignment Agreement"), attached hereto as Exhibit A, whereby Defendants specifically agreed to assign and transfer existing patent applications within the field that named Defendant Fogarty and/or Defendant Fogarty Engineering's employees as inventors during their employment at Defendant Fogarty Engineering, as well as invention disclosures by the same, in return for a substantial amount of equity in Revivant. Three Arch Partners, of which Defendant Fogarty was a principle at that time, provided the funding needed to launch the new company, and received a similar amount of equity in Revivant in return.

9. The Assignment Agreement also provided for the payment of royalties to Defendants should any of the transferred intellectual property prove useful, novel and non-obvious, and result in patents whose claims cover one or more products sold by Revivant. The Assignment Agreement granted Revivant the right—in its sole discretion—to file, prosecute and maintain any patents based on the intellectual property transferred by Defendants.

10. In the seven years after its founding, Revivant engineers worked on a variety of concepts and products in the area of cardiac arrest. As a result of the extensive research and development activity at Revivant, the company finished development of its first product in 2003, which it currently manufactures and sells. That product is known as the AutoPulse™ Resuscitation System—a comprehensive resuscitation platform. The AutoPulse™ pumps a patient's chest with an external chest belt to circulate blood to the heart, brain and other vital organs during cardiac arrest treatment, thus allowing medics to focus on complementary interventions such as drugs, ventilation and defibrillation.

11. Revivant also has prosecuted and/or acquired patents to protect its intellectual property, and is the rightful assignee and owner of United States patents, including United States Patent No. 6,142,962 ("the '962 patent"), entitled "Resuscitation device having a motor driven belt to constrict/compress the chest," attached hereto as Exhibit B.

12. Since Revivant's inception and until the sale of the company to ZOLL Medical Corporation ("ZOLL") in October 2004, Defendant Fogarty was a significant

stockholder in Revivant and served as a member of Revivant's board of directors, along with representatives of Three Arch Partners and subsequent investors in the company. As an active board member and a stockholder, Defendant Fogarty was constantly apprised and approved of Revivant's development of resuscitation devices, including the development of the AutoPulse™ based on methods and technology different from that transferred by Defendants, and was also apprised and approved of Revivant's prosecution of patents to protect its intellectual property.

13. In the course of obtaining additional funding by new investors, including a financing in August 2003 in which ZOLL acquired an option to purchase Revivant in its entirety, and in the course of forecasting revenues, costs and profits associated with the AutoPulse™ and with Revivant as a whole, Revivant reasonably relied on affirmative acts and/or omissions by Defendant Fogarty, as a board member, who represented expressly or impliedly that Revivant's first commercial product was unencumbered by royalty obligations and that Revivant's intellectual property, including its patents and patent applications, was unencumbered by any known claims regarding inventorship.

14. In the Summer of 2004, more than seven years after the signing of the Assignment Agreement, and more than one year after the first commercial sale of the AutoPulse™, Defendants asserted for the first time that they were owed royalties for the sale of the AutoPulse™. In particular, Defendants have alleged that:

(a) one or more of Revivant's patents, such as the '962 patent, include patentable inventive contributions made by Defendant Fogarty and/or made by Defendant Fogarty Engineering's employees during their employment at Defendant Fogarty Engineering, but that these patents erroneously fail to name these inventors; and

(b) Revivant has breached the Assignment Agreement because the AutoPulse™ is covered by the claims of one or more issued patents that include patentable contributions made by Defendant Fogarty and/or made by Defendant Fogarty Engineering's employees during their employment at Defendant Fogarty Engineering, yet Revivant has failed to pay royalties to Defendants on sales of the AutoPulse™.

15. On December 10, 2004, Defendants filed an action in the Superior Court of California for the County of Santa Clara alleging breach of contract by Revivant for its failure to pay royalties on sales of the AutoPulse™, and asserting related claims that impliedly and necessarily dispute the inventorship of one or more Revivant patents.

16. Because of Defendants' unreasonable delay in making these allegations, Revivant has been prejudiced by the unavailability of documents and witnesses necessary to defend against these allegations. Moreover, Revivant will be harmed if Defendants are permitted to assert these allegations, which are inconsistent with their earlier conduct.

CAUSE OF ACTION
(Declaratory Judgment Pursuant To 35 U.S.C. §§ 116 & 256)

17. Revivant realleges and incorporate by reference the allegations contained in paragraphs 1 - 16.

18. Defendants have alleged that Defendant Fogarty and/or Defendant Fogarty Engineering's employees, during their employment at Defendant Fogarty Engineering, made inventive contributions to the '962 patent and other Revivant patents, and thus are erroneously omitted as inventors of one or more of Revivant's patents. Consequently, there is now an actual controversy over the inventorship of one or more of Revivant's issued patents.

19. Revivant's interest in these patents could be adversely affected by an action brought by Defendants to correct inventorship pursuant to 35 U.S.C. § 256, and Defendants have created in Revivant a reasonable apprehension that Defendants will do so.

20. Revivant seeks a judicial declaration that Defendant Fogarty and Defendant Fogarty Engineering's employees, during their employment at Defendant Fogarty Engineering, did not make inventive contributions to Revivant's Patents for which they are not currently named as inventors, and are not inventors of Revivant patents for which they are not currently named as inventors.

21. Alternatively, Revivant seeks a judicial declaration that Defendants are equitably estopped from asserting claims to correct inventorship of Revivant's patents.

22. Alternatively, Revivant seeks a judicial declaration that Defendants' laches bars them from asserting claims to correct inventorship of Revivant's patents.

23. Alternatively, Revivant seeks a judicial declaration that Defendants' unclean hands bar them from asserting claims to correct inventorship of Revivant's patents.

PRAYER FOR RELIEF

WHEREFORE, Revivant demands judgment in its favor and prays for:

A. a judicial declaration that Defendant Fogarty and Defendant Fogarty Engineering's employees are not inventors of Revivant patents for which they are not named as inventors or, in the alternative, a judicial declaration that Defendants are equitably estopped, barred by their laches, or barred by their unclean hands from asserting such inventorship.

B. a judicial declaration that this case is exceptional, and an award to Revivant of attorneys' fees, costs, and expenses it has incurred in this action pursuant to 35 U.S.C. § 285; and

C. such other and further relief as the Court deems appropriate pursuant to 28 U.S.C. § 2202.

Dated: January 7, 2005

Respectfully submitted,

HELLER EHRMAN WHITE & MCAULIFFE LLP

By M. Patricia Thayer
M. Patricia Thayer
Attorney for Plaintiff
REVIVANT CORPORATION

CERTIFICATION OF INTERESTED ENTITIES OR PERSONS

Pursuant to Civil Local Rule 3-16, the undersigned certifies that the following listed persons, associations of persons, firms, partnerships, corporations (including parent corporations) or other entities (i) have a financial interest in the subject matter in controversy or in a party to the proceeding, or (ii) have a non-financial interest in that subject matter or in a party that could be substantially affected by the outcome of this proceeding:

Adams Street Partners, LLC – former stockholder of Revivant Corporation

Bystrom, Steven R. (deceased) – former stockholder of Revivant Corporation

Canaan Partners – former stockholder of Revivant Corporation

CHL Medical Partners, L.P. / Collinson Howe & Lennox, LLC – former stockholder of Revivant Corporation

CLS Holdings, LLC – former stockholder of Revivant Corporation

Fogarty, Thomas J. – former stockholder of Revivant Corporation

Fogarty Family Revocable Trust – former stockholder of Revivant Corporation

Fogarty Separate Property Trust – former stockholder of Revivant Corporation

Ludlum, Kenneth – former stockholder of Revivant Corporation

MedVenture Associates – former stockholder of Revivant Corporation

Three Arch Partners, L.P. – former stockholder of Revivant Corporation

ZOLL Medical Corporation – parent company of Revivant Corporation

(a list of other former stockholders, each of whom held less than 1% of Revivant Corporation stock, can be provided upon the Court's request)

Dated: January 7, 2005

Respectfully submitted,

HELLER EHRMAN WHITE & MCAULIFFE LLP

By M. Patricia Thayer
M. Patricia Thayer
Attorneys for Plaintiff
REVIVANT CORPORATION

EXHIBIT A

ASSIGNMENT AND ROYALTY AGREEMENT

This Assignment and Royalty Agreement (the "Agreement") is made this 31st day of May, 1997 by and between Thomas J. Fogarty, an individual ("Fogarty") and Fogarty Engineering, a sole proprietorship of Fogarty ("Fogarty Engineering") (Each of Fogarty and Fogarty Engineering is a "Transferor" and, collectively, the "Transferors") and Emergency Medical Systems, Inc., a Delaware corporation (the "Company").

RECITALS

WHEREAS, Fogarty is the founder of the Company,

WHEREAS, as consideration for the issuance of shares of Common Stock of the Company to Thomas J. Fogarty, Trustee of the Fogarty Family Revocable Trust, Transferors desire to assign all of their right, title and interest in the Assets (as defined below) to the Company, subject to the terms hereof; and

WHEREAS, subject to the terms and conditions hereof, Company desires to make certain Royalty payments to Transferors.

AGREEMENT

1. Definitions. The following capitalized terms shall have the following definitions herein:

"Copyrights" shall mean all copyrights, and all other literary property and authorship rights, and all right, title, and interest in all copyrights, copyright registrations, certificates of copyright and copyrighted interests throughout the world.

"Field" shall mean (i) resuscitation devices with or without defibrillator capability for cardiac resuscitation; (ii) devices for vascular access intended for fluid or drug delivery or blood drawing, and/or (iii) airway management, including but not limited to, drug delivery.

"Intellectual Property Rights" shall mean, collectively, worldwide Patents, Trade Secrets, Copyrights, Trademarks, mask work rights, moral rights and all other intellectual property rights and proprietary rights, whether arising under the laws of the United States or any other state, country or jurisdiction, including all rights or causes of action for infringement or misappropriation of any of the foregoing, and within the Field, provided, however, that Intellectual Property Rights shall not include the issued patents and patent applications listed on Attachment A hereto.

"Net Sales" shall mean the actual amounts received by Transferee (defined below) for any sale of Products worldwide by Transferee, after the deduction of the following direct costs of sale of the Products: (i) refunds, replacements and credits for returns; (ii) trade, quantity or cash discounts, and commissions; (iii) shipping and insurance costs on the Products; and

(iv) taxes and duties on the Products; provided, however, that the Net Sales will not include the price of any ancillary product bundled and/or sold with the Products.

"Patents" shall mean all patents and patent applications and substitutions, extensions, reissues, reexaminations, renewals, provisionals, divisions, continuations, or continuations-in-part anywhere in the world, within the Field, and filed by or on behalf of Fogarty, Fogarty Engineering, or any employee, consultant or other inventor of Fogarty Engineering, both: (i) as of the date hereof, including without limitation, the patent applications and disclosures set forth in Attachment B attached hereto (the "Existing Patent Applications"), and (ii) at any time in the future during the Assignment Period (defined below), provided, however, that the term "Patents" shall not include the patents and patent applications listed on Attachment A.

"Products" shall mean any product developed and sold commercially by Transferee that, but for the existence of this Agreement, would infringe a Patent that issues from the Existing Patent Applications or any other patent applications filed by any of the Transferors and assigned to Transferee within six months after the date hereof.

"Trademarks" shall mean all right, title, and interest in all trademark, service mark, trade name, and trade dress rights arising under the common law, state law, federal law, and laws of foreign countries, and all right, title, and interest in all trademark, service mark, trade name, and trade dress applications and registrations throughout the world.

"Trade Secrets" shall mean all right, title, and interest in all trade secrets and trade secret rights arising under common law, state law, federal law, or laws of foreign countries.

"Valid Claim" shall mean: (i) a claim of an issued Patent; or (ii) a claim of a pending patent application. Notwithstanding the foregoing, the term "Valid Claim" will not include: (x) any claims that have been declared or rendered invalid or otherwise become unenforceable by reissue, disclaimer or a decision or judgment of a court of competent jurisdiction; or (y) any claims of Patents that have expired, lapsed or become abandoned.

2. Assignment of Intellectual Property Rights. Transferors hereby sell, transfer, assign and convey to the Company and its successors and assigns ("Transferee"), all right, title and interest in all assets and contract or property rights within the Field (the "Assets") that any of the Transferors owns as of the date hereof, including but not limited to the Existing Patent Applications, and including but not limited to all Intellectual Property Rights in all of the Assets, provided, however, that the Assets shall not include the patents and patent applications listed on Attachment A. In addition, each of Transferors agrees to assign all Assets (including all Intellectual Property Rights therein) that any of the Transferors may develop, acquire and/or otherwise own in the future from the date hereof until the later of: (i) four years after the date of this Agreement, or (ii) the date on which Fogarty ceases to serve as a member of the Board of Directors of the Company (the "Assignment Period").

3. Appointment of Transferee as Attorney in Fact. Transferors hereby appoint Transferee the attorney in fact of Transferors, with full power of substitution on behalf of Transferee to

demand and receive any of the Assets and to give receipts and releases for the same, to institute and prosecute in the name of Transferors, but for the benefit of Transferee, any legal or equitable proceedings Transferee deems proper in order to enforce any rights in the Assets and to defend or compromise any legal or equitable proceedings relating to the Assets as Transferee shall deem advisable. Transferors hereby declare that the appointment made and powers granted hereby are coupled with an interest and shall be irrevocable by Transferors.

4. Further Acts. Transferors hereby agree that Transferors and Transferors' successors and assigns will do, execute, acknowledge and deliver, or will cause to be done, executed, acknowledged and delivered such further acts, documents, or instruments confirming the conveyance of any of the Assets to Transferee as Transferee shall reasonably deem necessary, provided that Transferee shall provide all necessary documentation to Transferors. Fogarty and Fogarty Engineering agree to cause employees, consultants and/or inventors of Fogarty Engineering to execute, acknowledge and deliver such further acts, documents or instruments in order to convey any and/or all of the Assets, which exist now or may be created during the Assignment Period to Transferee as Transferee shall reasonably deem necessary, provided that Transferee shall provide all necessary documentation to Transferors.

5. Royalty. In consideration for the sale, transfer and assignment of all right, title and interest in the Assets contained in Section 2, Transferee will pay to Fogarty a royalty equal to four percent (4%) of the Net Sales in each country (the "Royalty"). Such Royalty shall be payable, for each country, for the period extending from the date of first sale by Transferee of a Product in such country until the expiration or termination of all Patents with a Valid Claim in such country. Notwithstanding anything in this Agreement to the contrary, the payment of and obligation to pay any and all Royalties herein with respect to each country will cease upon the first to occur of: (x) the expiration, lapse or termination of all Patents in such country; or (y) the determination by Transferee, at its sole discretion, and the notification of Transferors of such determination, that a Patent with a Valid Claim will not issue in such country.

(a) Bundled Products. In the event that a Product under this Agreement is sold in a combination package or bundled with other products, then Net Sales for purposes of determining the Royalty on the bundled product shall be calculated by multiplying the net selling price of that bundled product by the fraction A/A+B, where "A" is the published list price during the royalty-paying period in question of the Product sold separately, and "B" is the published list price during the royalty period in question of the other products sold separately. In the event that the products are not sold separately, then the fair market value of such other products, as determined by Transferee in good faith, shall be used in place of the published list price.

(b) Payment Terms; Reports. All payments under this Section 5.0 shall be payable by Transferee to Transferor on a quarterly basis, based on Net Sales of the preceding quarter. Payments shall be due and payable within ninety (90) days after the end of each fiscal quarter. On a quarterly basis, Transferee shall submit to Transferor a detailed report, showing all sales of Products in the Field by item and supporting the basis for the Royalty payments for that preceding quarter, including the Net Sales.

(c) Records and Audit. Transferor shall have the right, at its own expense, to direct an independent certified public accounting firm of his choosing (and which is also reasonably acceptable to Transferee), to audit the relevant accounting records of Transferee solely with regard to the amount payable by Transferee to Transferor hereunder; provided, however, that: (i) any such audit shall be conducted during regular business hours in such a manner as not to interfere with normal business activities; and (ii) in no event shall audits be made hereunder more frequently than once each calendar year. Such independent certified public accounting firm shall be under an obligation of confidentiality with respect to any and all information disclosed to it during an audit. In the event that the audit reveals amounts underpaid by Transferee to Transferor hereunder then, Transferee shall immediately pay to Transferor the amount of such underpayment plus interest at ten percent (10%) per annum, compounded per annum from the date of underpayment. In the event that the audit reveals an underpayment of ten percent (10%) or more, then Transferee shall also reimburse Transferor any reasonable costs, including but not limited to accountant's fees, associated with such audit. Transferee agrees to make its relevant books and records available to Transferor during normal business hours for any audit.

(d) Foreign Sales. For purposes of computing Net Sales on sales made in a currency other than United States dollars, Net Sales will be determined on the basis of the foreign currency for the country in which the Products are sold, and then converted into equivalent United States dollars at the rate of exchange for selling such foreign currency as published by the Wall Street Journal (U.S., Western Edition) for the last business day of each quarter.

(e) Currency and Withholding of Taxes. Transferee may withhold any taxes imposed upon Transferor or Transferee or its agents on account of Royalty payments under this Agreement. Transferor will not be entitled to reimbursement for taxes on its net income in consequence of such required Royalty payments. In the event Transferee makes Royalty payments on Products sold in a country in which provision is made by law or regulation for the withholding of taxes due by the royalty recipient and Transferee makes such deduction for the account of Transferor, Transferee will promptly furnish Transferor with such evidence of the withholding of any taxes. Transferee will also provide Transferor with a tax certificate or receipt from the competent tax authority of the withholding country, or such other supporting data, as may be required to establish that the tax has been withheld by Transferee and paid to the appropriate governmental entity on behalf of Transferor.

(f) No Set-Off. Any present or future law to the contrary notwithstanding, Transferee's obligation to pay Fogarty all amounts due hereunder is absolutely unconditional. Transferee shall not be entitled to any abatement, reduction, set-off, counterclaim, defense, interruptions, deferment, recoupment or deduction with respect to any royalty amount or any other sum payable hereunder, no matter how, when or against whom asserted, arising or claimed, nor shall any obligations of Transferee hereunder be affected for any reasons whatsoever. Transferee shall furnish to Fogarty, upon request, such certificates, acknowledgments, consent, estoppel letters, opinions of counsel, and other documents and instruments, all in form and substance reasonably satisfactory to Fogarty, which Fogarty reasonably determines to be necessary or proper to confirm any or all of the representations and agreements made by Transferee pursuant to this subsection (f).

6. Patent Filings. Transferee has the right to file, prosecute and maintain, at its expense, any Patents relating to Products in any and all countries and in Transferee's sole discretion, including prosecution and maintenance of the Patents listed in Attachment B attached hereto. Transferors will cooperate fully with Transferee in connection with all filings, prosecution and maintenance, including but not limited to with regard to the Patents listed in Attachment B. Within ten (10) days after the date of this Agreement, Transferors will transfer, or have transferred, all files relating to the Patents listed in Attachment B, and shall cooperate fully in the prosecution and maintenance of such Patents, including without limitation, timely executing any documents related thereto that Transferee reasonably requests.

7. Warranties.

(a) By All Parties. Each of the Transferors represents and warrants to Transferee and Transferee represents and warrants to each of the Transferors that: (i) it has full power and authority to execute, deliver and perform this Agreement; (ii) to such party's knowledge, the execution, delivery and performance by such party of the Agreement do not contravene any law, regulation, treaties, rules or order binding on such party and do not contravene the provisions of or constitute a default under any contract or other agreement binding on such party; and (iii) such party has the rights to grant and the ability to perform its obligations hereunder.

(b) Intellectual Property. Transferors represent and warrant that the Assets transferred hereunder do not infringe any Patent or other Intellectual Property Rights of any third party and that no person or entity has any valid claim or rights under any of the Assets. In no event will Transferee be deemed to have any Royalty obligations to Transferors with respect to any Products that: (i) have infringed, are deemed to infringe, or are alleged to infringe the Intellectual Property Rights of a third party; or (ii) have been or are alleged to have been misappropriated from a third party. In the event that Transferee cannot exercise its rights in any country due to infringement or threatened infringement of any third party Intellectual Property Rights by any Products in such country, then Transferee shall be relieved of all of its obligations under Section 5 of this Agreement solely with respect to such Product in such country, and Transferor shall fully indemnify and hold harmless Transferee for any and all such claims or actions. TRANSFEROR MAKES NO REPRESENTATION OR WARRANTY (EXPRESS OR IMPLIED) OF QUALITY OR FITNESS OF PURPOSE FOR ANY USE OR OF ANY RESULTS TO BE ACHIEVED BY THE USE OF ANY OF THE ASSETS TRANSFERRED HEREUNDER.

8. Miscellaneous.

(a) Amendment. This Agreement may not be amended or modified except by written instrument signed by the parties hereto.

(b) Assignment. This Agreement will bind and inure to the benefit of the parties and their respective successors and assigns. None of the Transferors nor Transferee may assign any of their rights or obligations under this Agreement without prior written consent of the other

parties, the granting or withholding and terms and conditions of which shall be in the sole and uncontrolled discretion of the party requesting to consent. Notwithstanding anything to the contrary, Transferee shall have the right to assign its rights and privileges hereunder to a successor in business, an acquirer of all or substantially all of its business or assets, a spin-off, a subsidiary or affiliate, a joint venture, or any other strategic alliances, without obtaining the consent of any of the Transferors, if and only if such assignment contains an express assumption by assignee of all obligations owed to Transferor hereunder, including Royalty payments and audit rights.

(c) Counterparts. This Agreement may be signed in counterparts.

(d) Governing Law. The validity and performance and construction of the terms and conditions of this Agreement shall be governed by the laws of the State of California.

(e) Modification and Waiver. No delay in enforcing any rights under this Agreement will be deemed a waiver of such rights. No actual waiver of a breach by either party of any covenant or condition of this Agreement will be deemed to constitute a waiver of any other or subsequent breach of that, or any other, covenant or condition.

(f) Notices. Any required notices hereunder will be given in writing at the address of each party set forth below, or to such other address as either party may substitute by written notice to the other in the manner contemplated herein, and will be deemed delivered: (i) upon receipt, if by personal service, by overnight express courier (as evidenced by such courier's confirmation of delivery), or by facsimile transmission (as evidenced by sender's confirmation receipt), or (ii) three business days after deposit in the U.S. mail, if by registered or certified mail, sent with return receipt requested.

(g) Severability. In the event that any provision of this Agreement becomes or is declared by a court or other tribunal of competent jurisdiction to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision; provided, however, the parties will negotiate in good faith to replace any ineffective, unenforceable or illegal provision with an effective replacement as soon as practical, such that the economic benefit of this Agreement to Transferors and Transferee remains the same.

(h) Entire Agreement. This Agreement constitutes the entire and exclusive Agreement between the parties hereto with respect to the subject matter hereof and supersedes and cancels all previous registrations, agreements, commitments and writings in respect thereof.

(i) No Agency. The status of the parties under this Agreement shall be as assignor and assignee and neither party shall be deemed or construed to be an employee, agent, partner, or other legal representative of the other party for any purpose whatsoever except as specifically set forth herein. Neither party shall have the right or authority to assume or otherwise create any obligation or responsibility, express or implied on behalf of the other party or to bind the other party in any matter or any thing whatsoever, except as specifically set forth herein.

The parties hereto have caused this Assignment and Royalty Agreement to be executed by their respective authorized representatives as of the date above written.

TRANSFERORS:

Thomas J. Fogarty

FOGARTY ENGINEERING

By: Thomas J. Fogarty
Name:
Title: Owner

TRANSFEREE:

EMERGENCY MEDICAL SERVICES, INC.

By: Thomas J. F
Name:
Title:

The parties hereto have caused this Assignment and Royalty Agreement to be executed by their respective authorized representatives as of the date above written.

TRANSFERORS:

_____
Thomas J. Fogarty

FOGARTY ENGINEERING

By:_____
Name:_____
Title:_____

TRANSFEREE:

EMERGENCY MEDICAL SERVICES, INC.

By:_____
Name:_____
Title:_____

ATTACHMENT B TO ASSIGNMENT AGREEMENT

- Patent Application No. 691042 (dated 8/1/96) - Minimally Invasive Direct Cardiac Massage Device & Method, regarding balloon device for cardiac resuscitation.
- Crocket & Fish File No. 212/041 - Cardiac Massage Pump with Electrodes.
- Crocket & Fish File No. 212/082 - Mechanical CPR Vest.

EXHIBIT B

US006142962A

United States Patent [19]

Mollenauer et al.

[11] Patent Number: 6,142,962

[45] Date of Patent: Nov. 7, 2000

[54] RESUSCITATION DEVICE HAVING A MOTOR DRIVEN BELT TO CONSTRICT/ COMPRESS THE CHEST

[75] Inventors: Kenneth H. Mollenauer; Darren R. Sherman; Steven R. Bystrom; Cameron Miner, all of Portola Valley, Calif.

[73] Assignee: Emergency Medical Systems, Inc., Sunnyvale, Calif.

[21] Appl. No.: 08/922,723

[22] Filed: Aug. 27, 1997

[51] Int. Cl.[7] A61H 31/00

[52] U.S. Cl. 601/41; 601/44

[58] Field of Search 601/1, 41–44, 601/134, 135, 89, 93, 97, 101, 105–107, 143, 144

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Primary Examiner—Danton D. DeMille

Attorney, Agent, or Firm—K. David Crockett, Esq.; Crockett & Crockett

[57] ABSTRACT

A resuscitation device for automatic compression of victim's chest using a compression belt which exerts force evenly over the entire thoracic cavity. The belt is constricted and relaxed through a motorized spool assembly which repeatedly tightens the belt and relaxes the belt to provide repeated and rapid chest compression. An assembly includes various resuscitation devices including chest compression devices, defibrillation devices, and airway management devices, along with communications devices and senses with initiate communications with emergency medical personnel automatically upon use of the device.

6 Claims, 14 Drawing Sheets

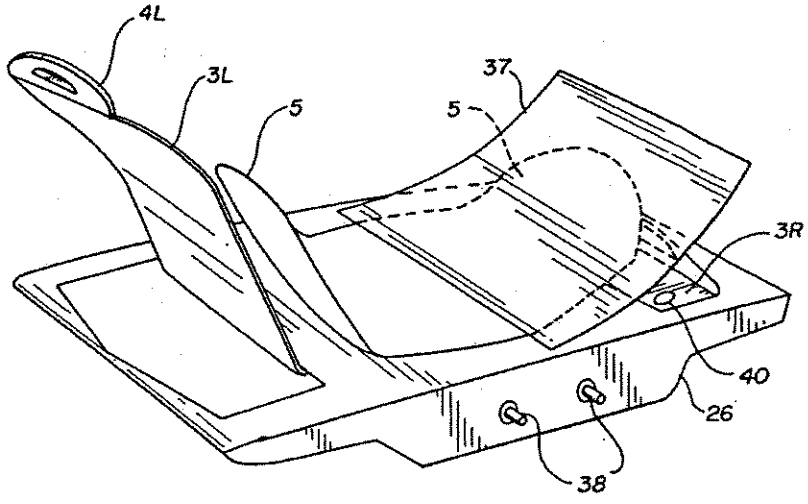


FIG. 1

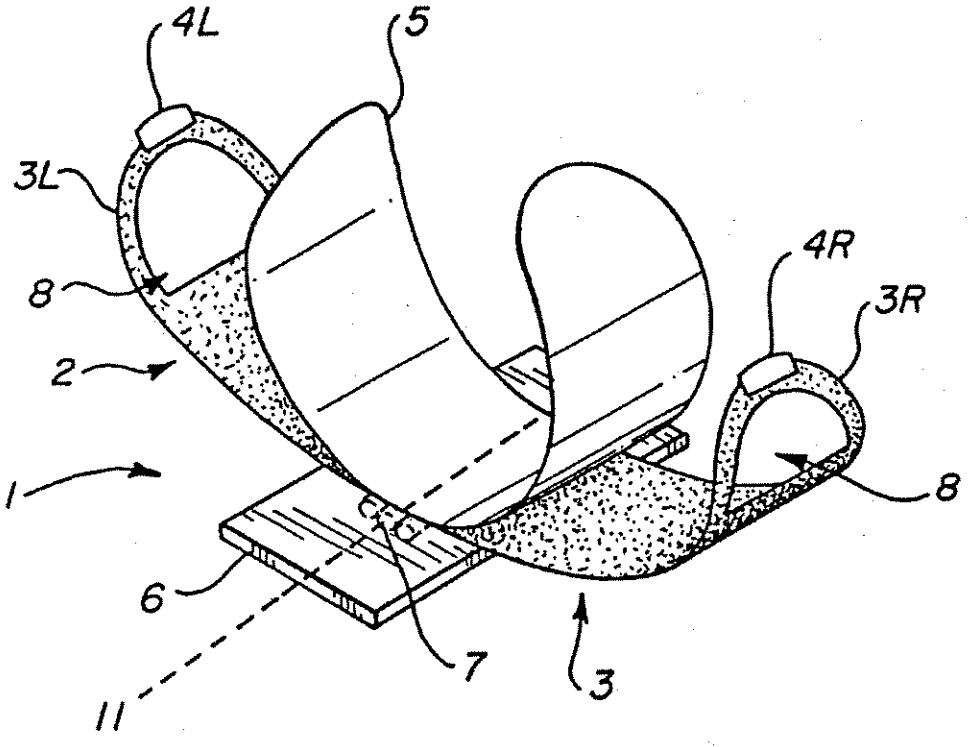


FIG. 2

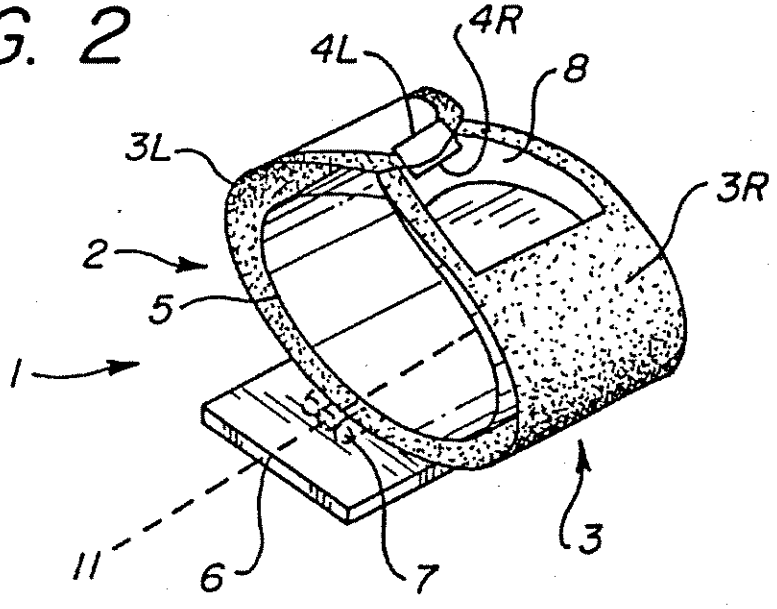
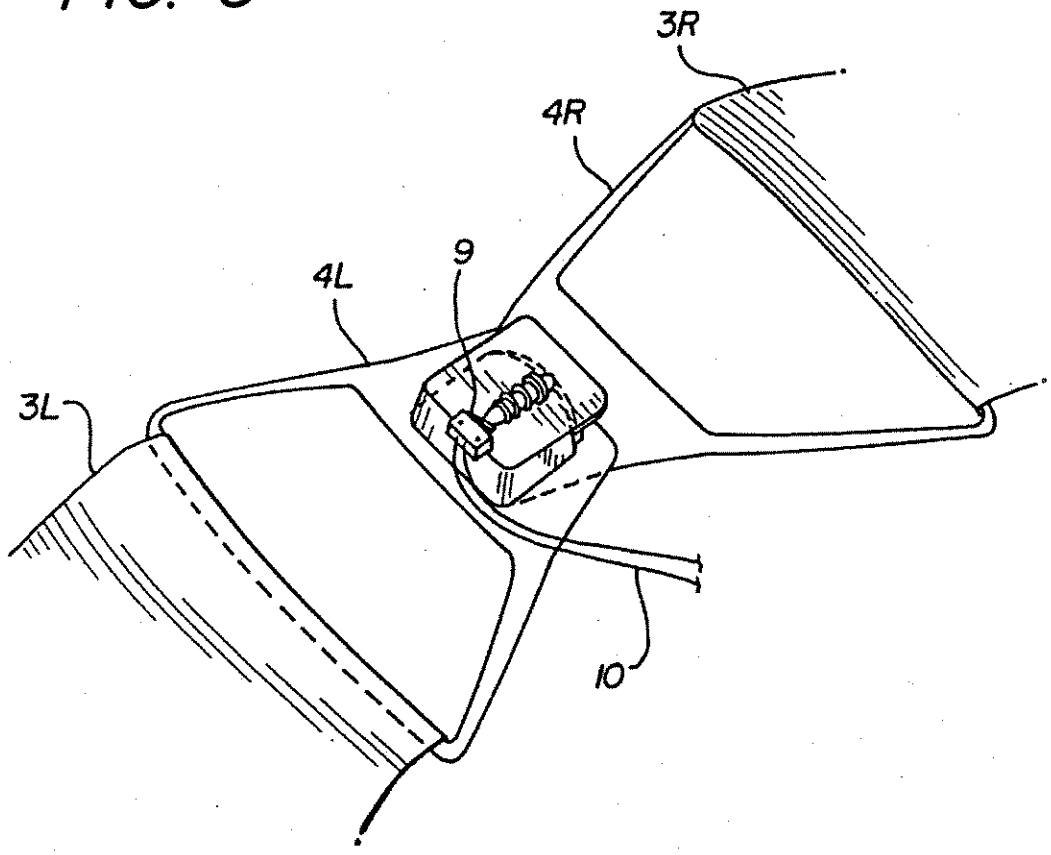


FIG. 3



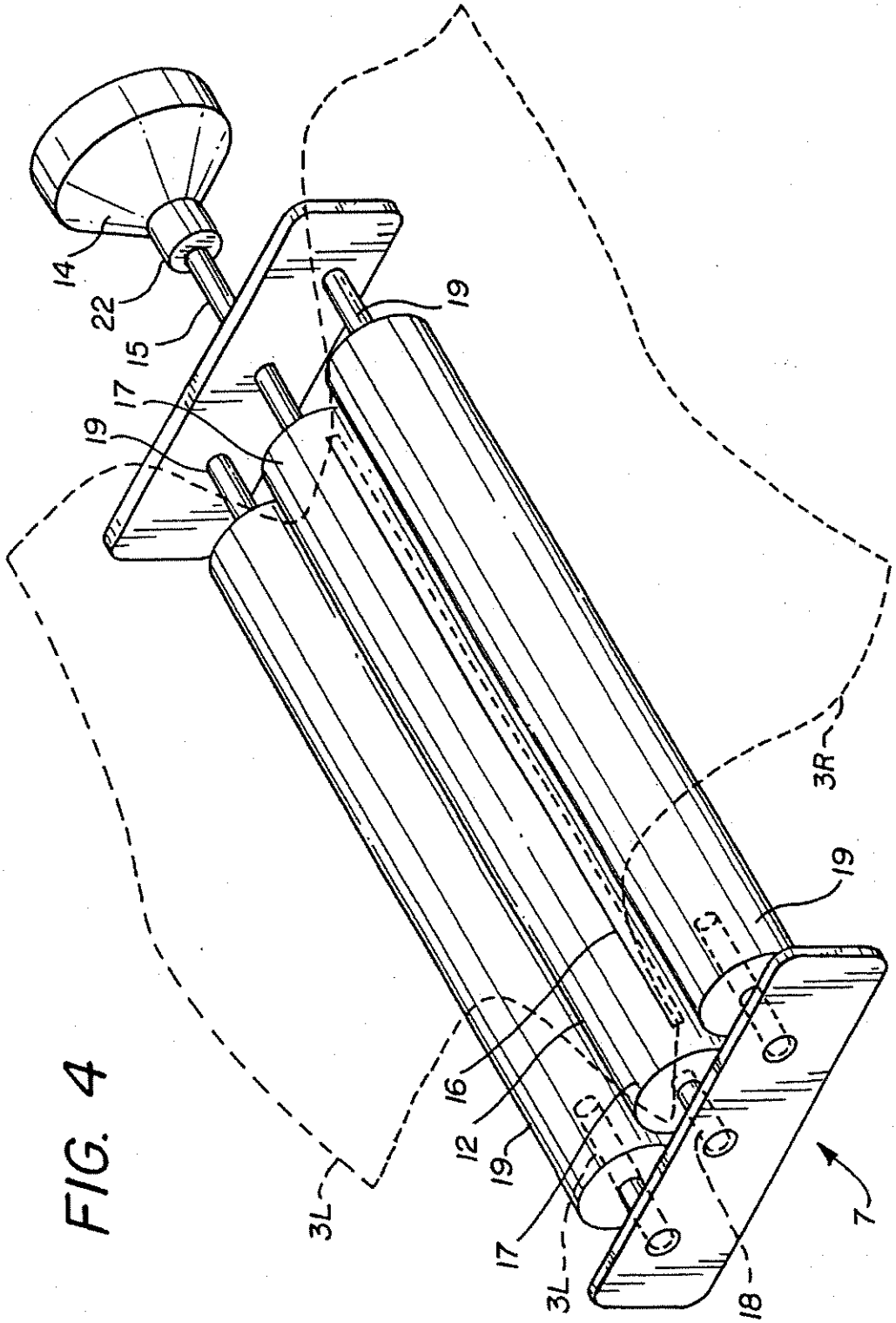


FIG. 4

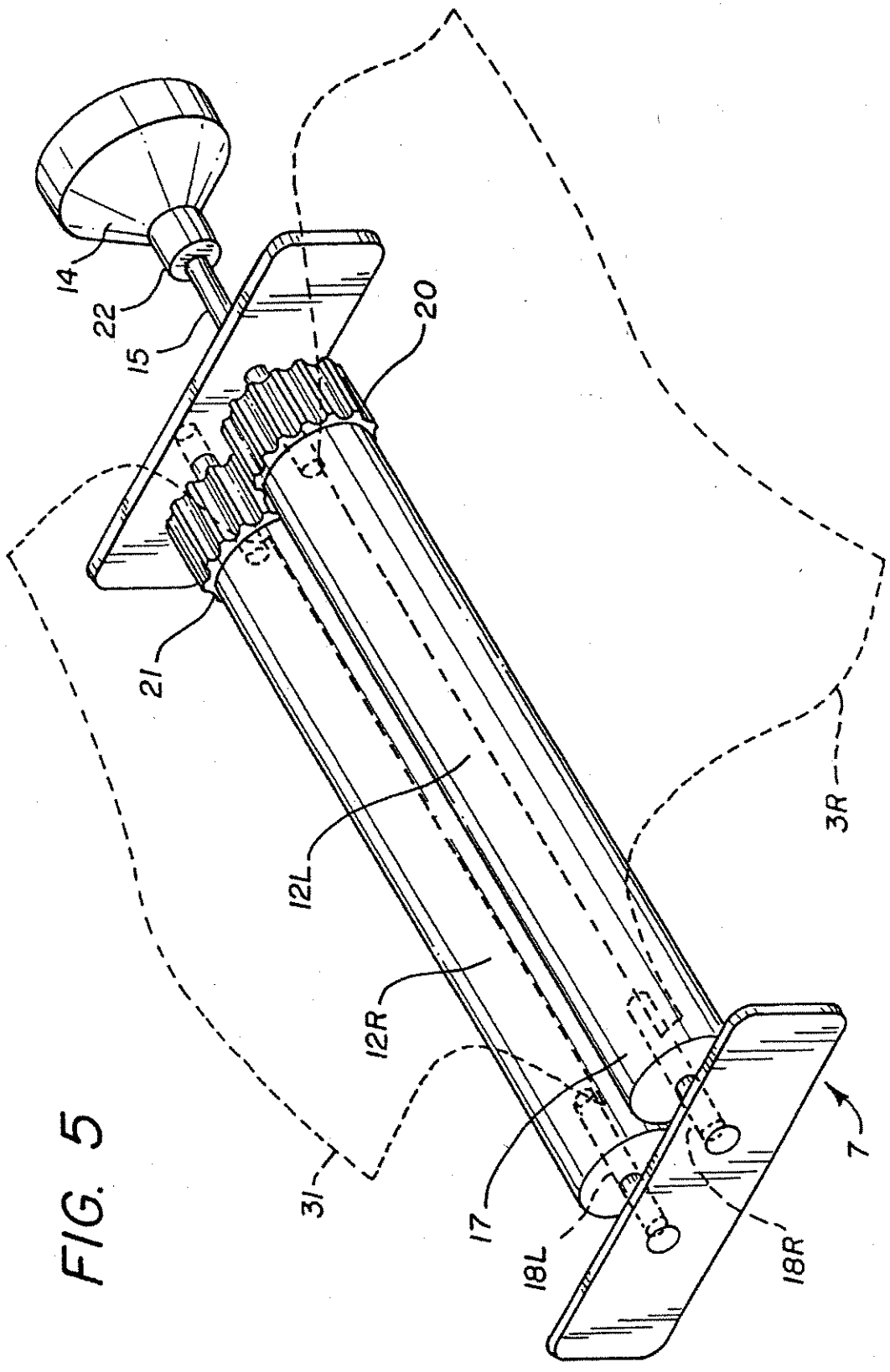


FIG. 5

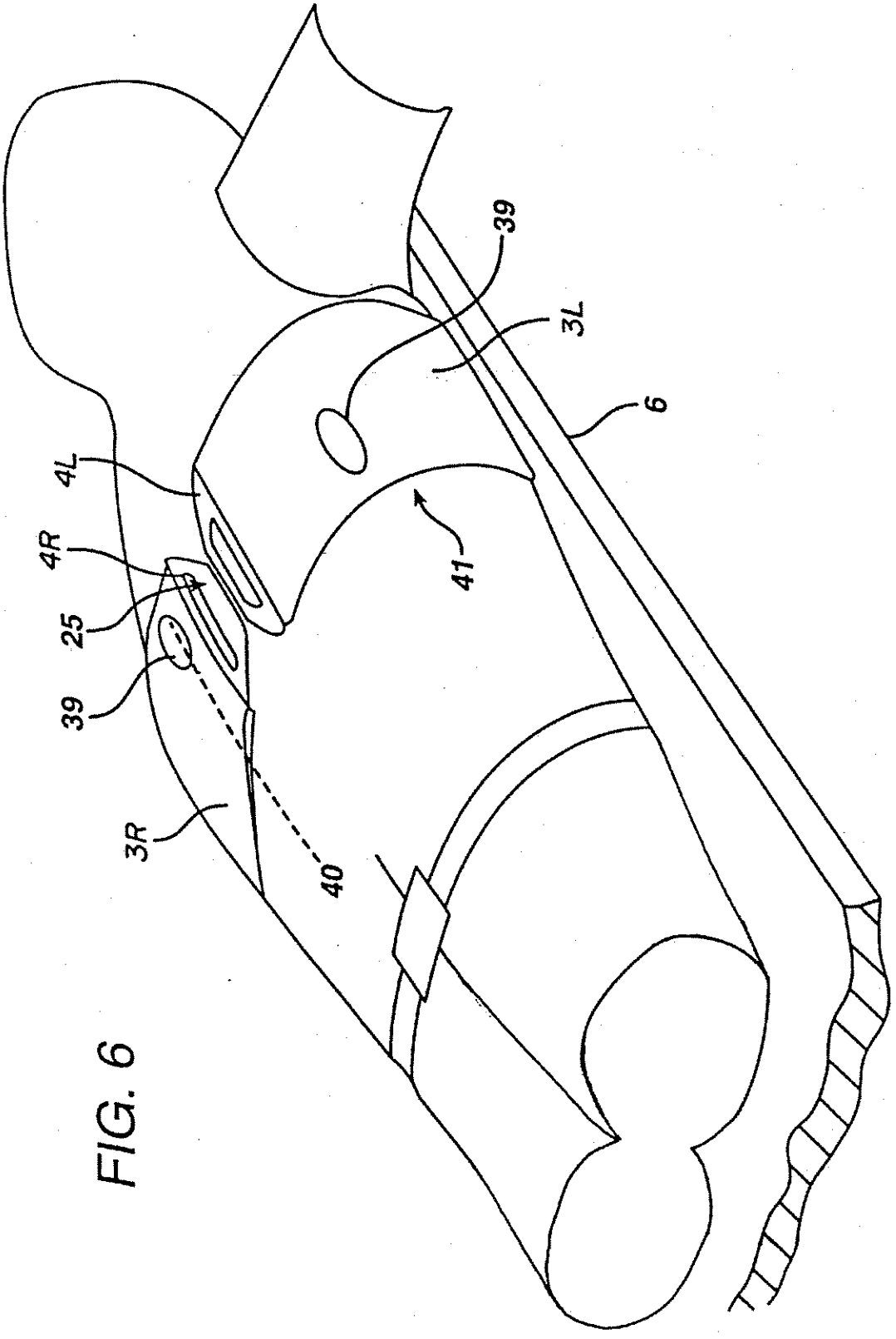


FIG. 6

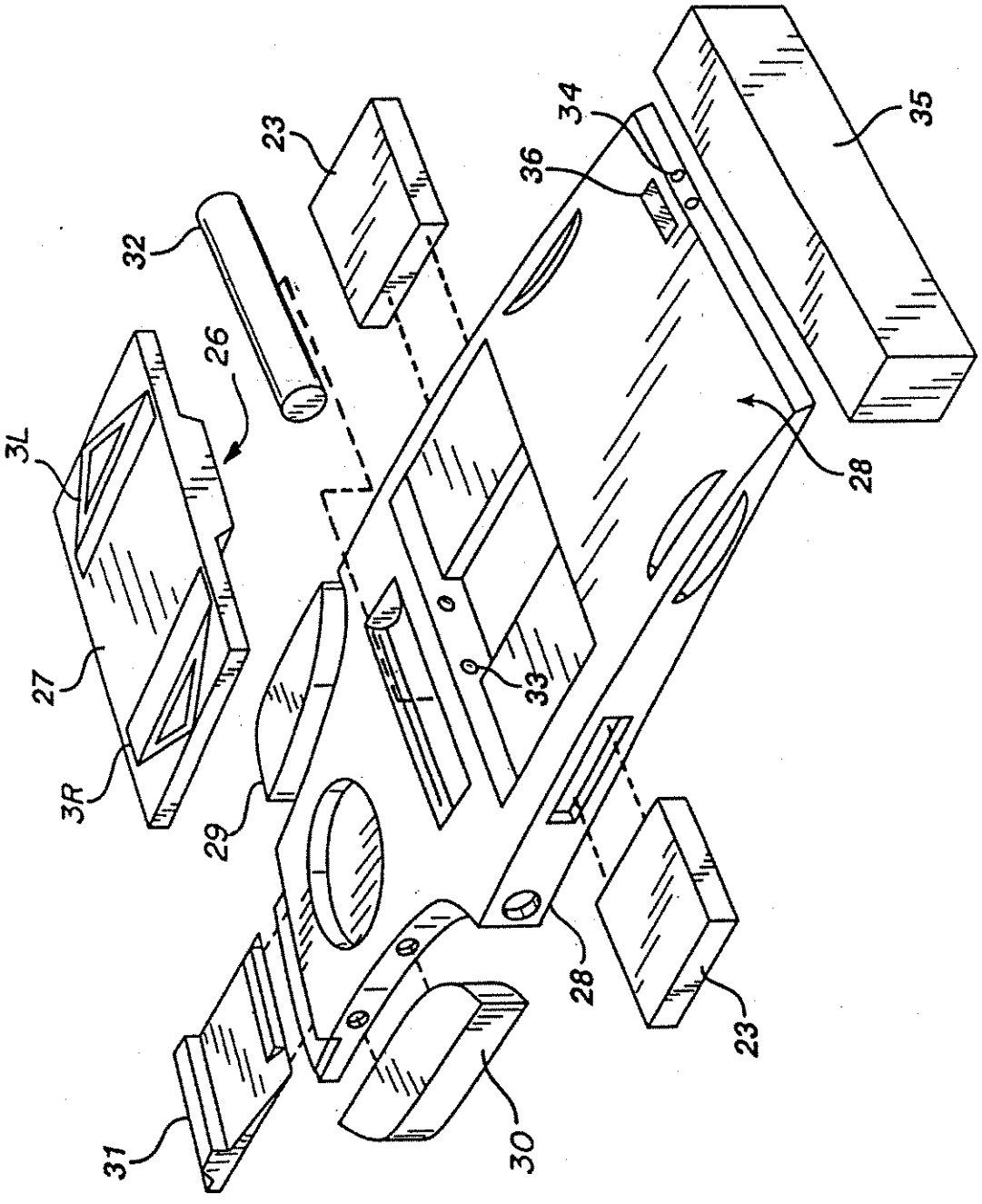


FIG. 7

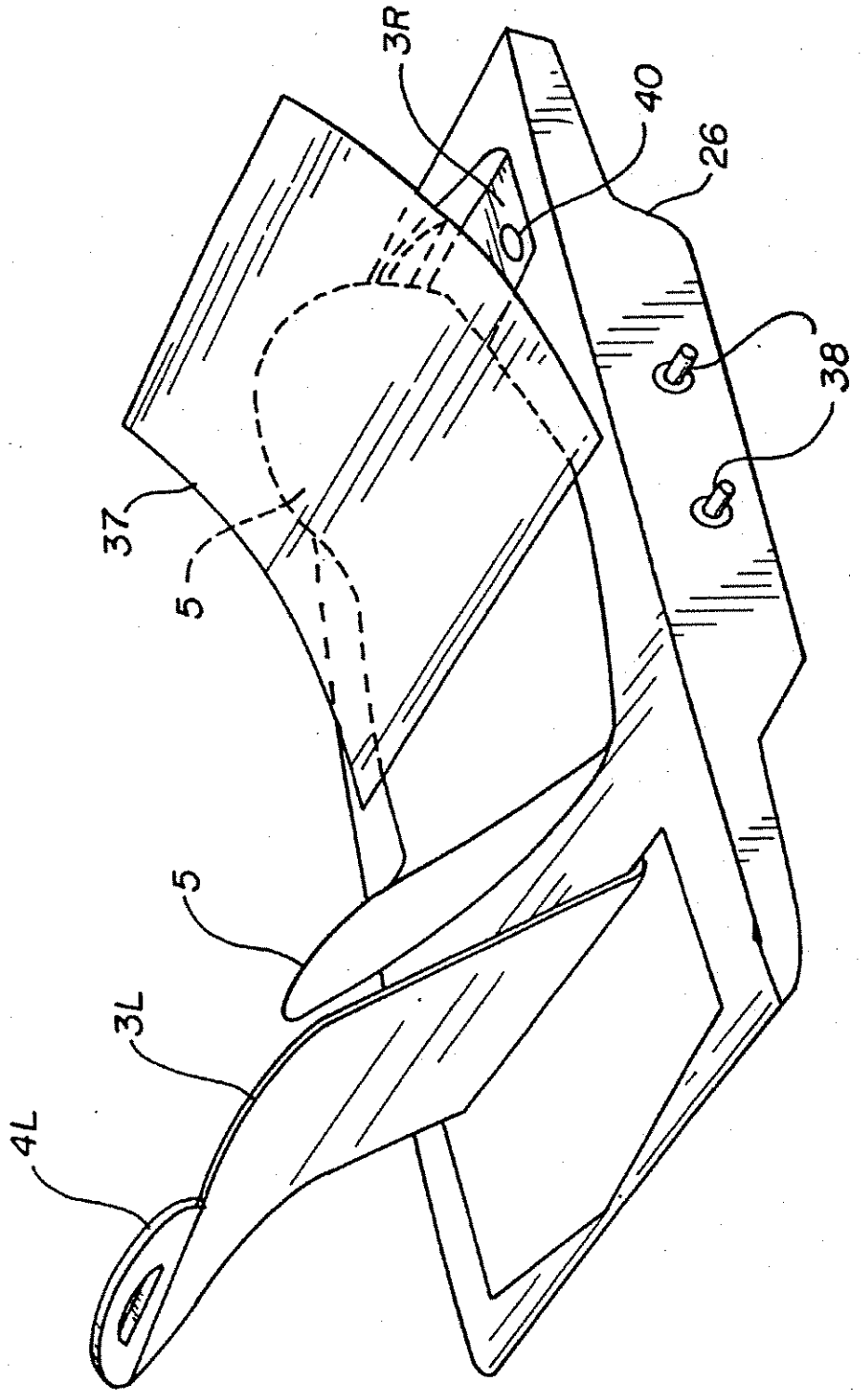


FIG. 8

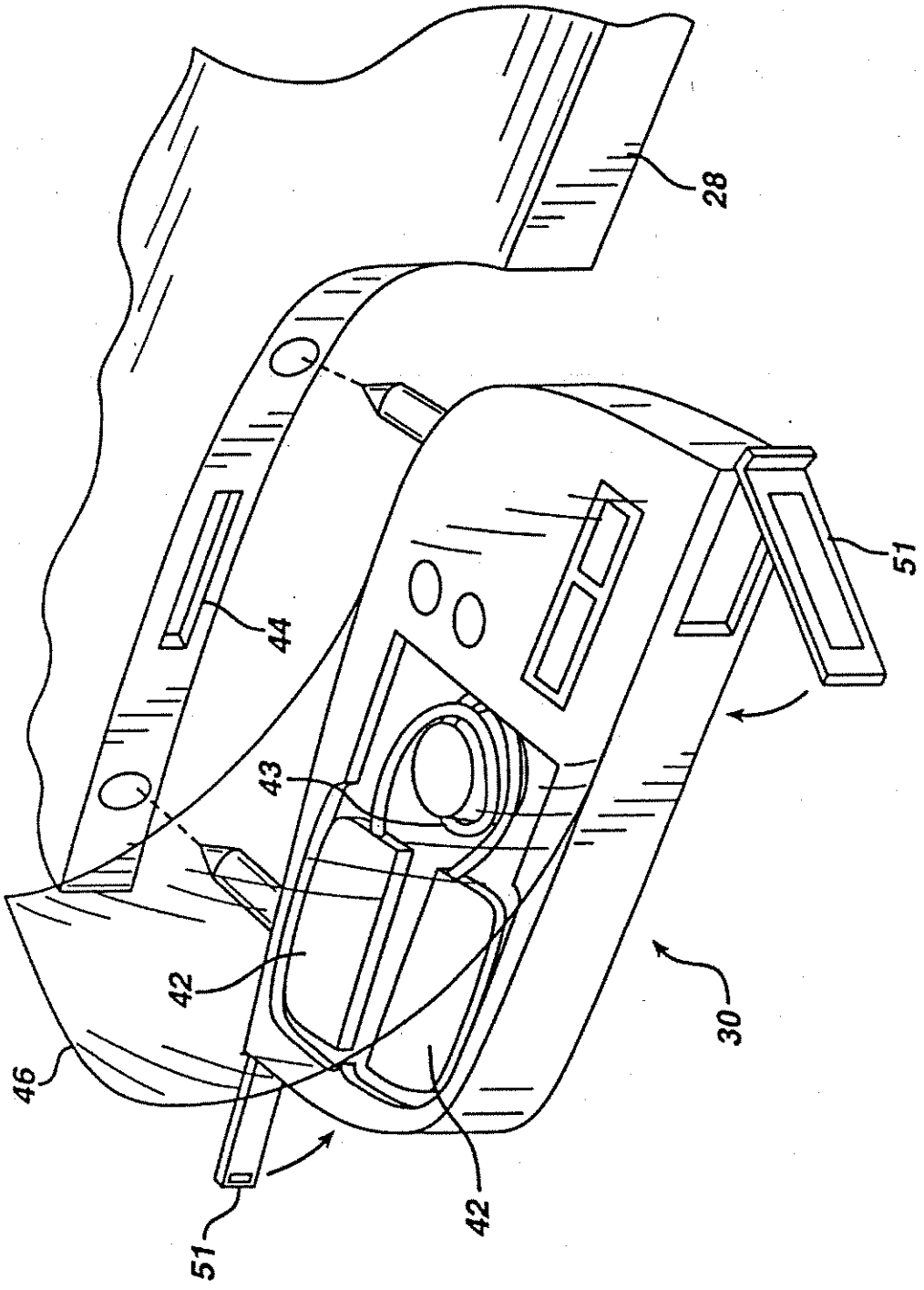


FIG. 9

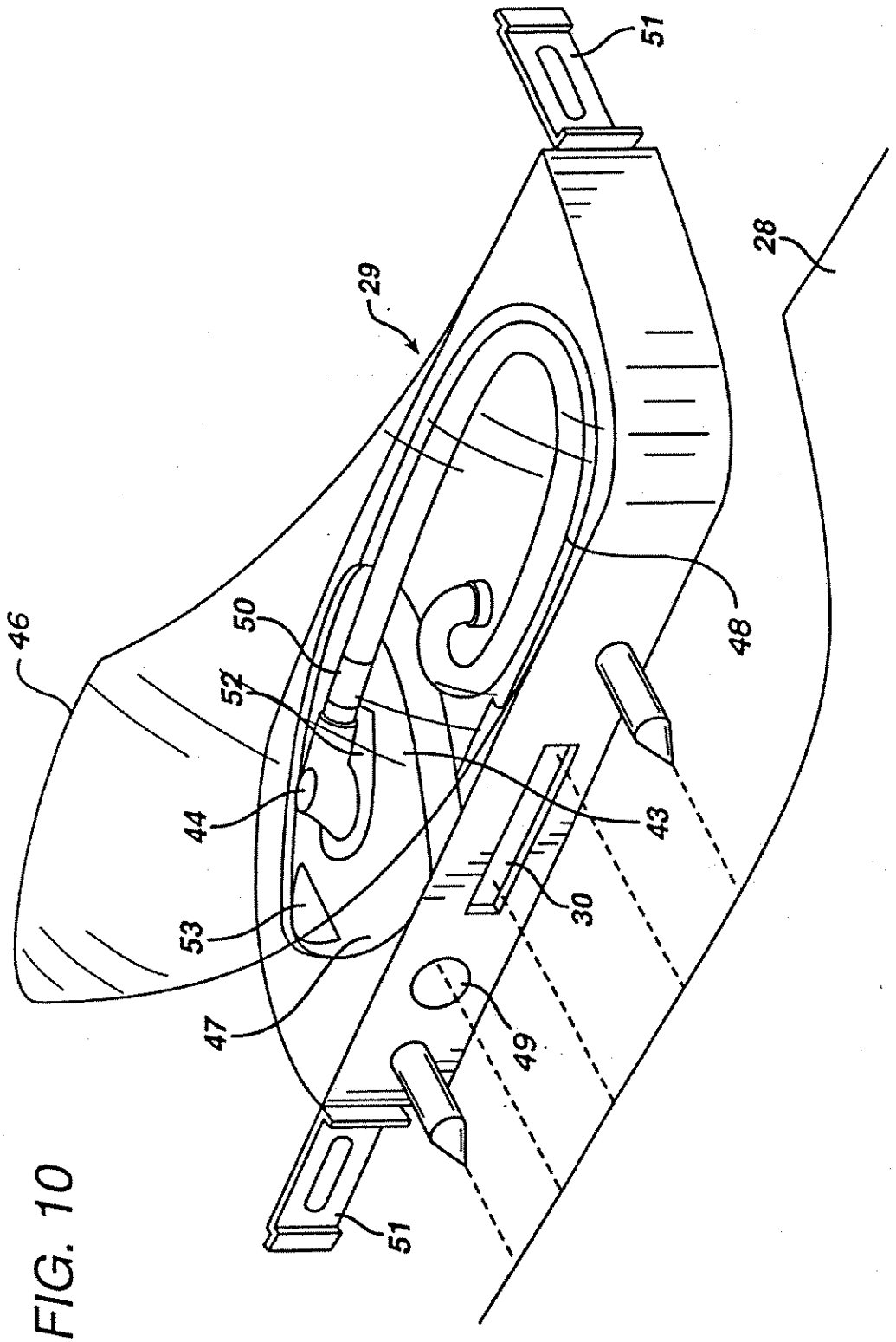


FIG. 10

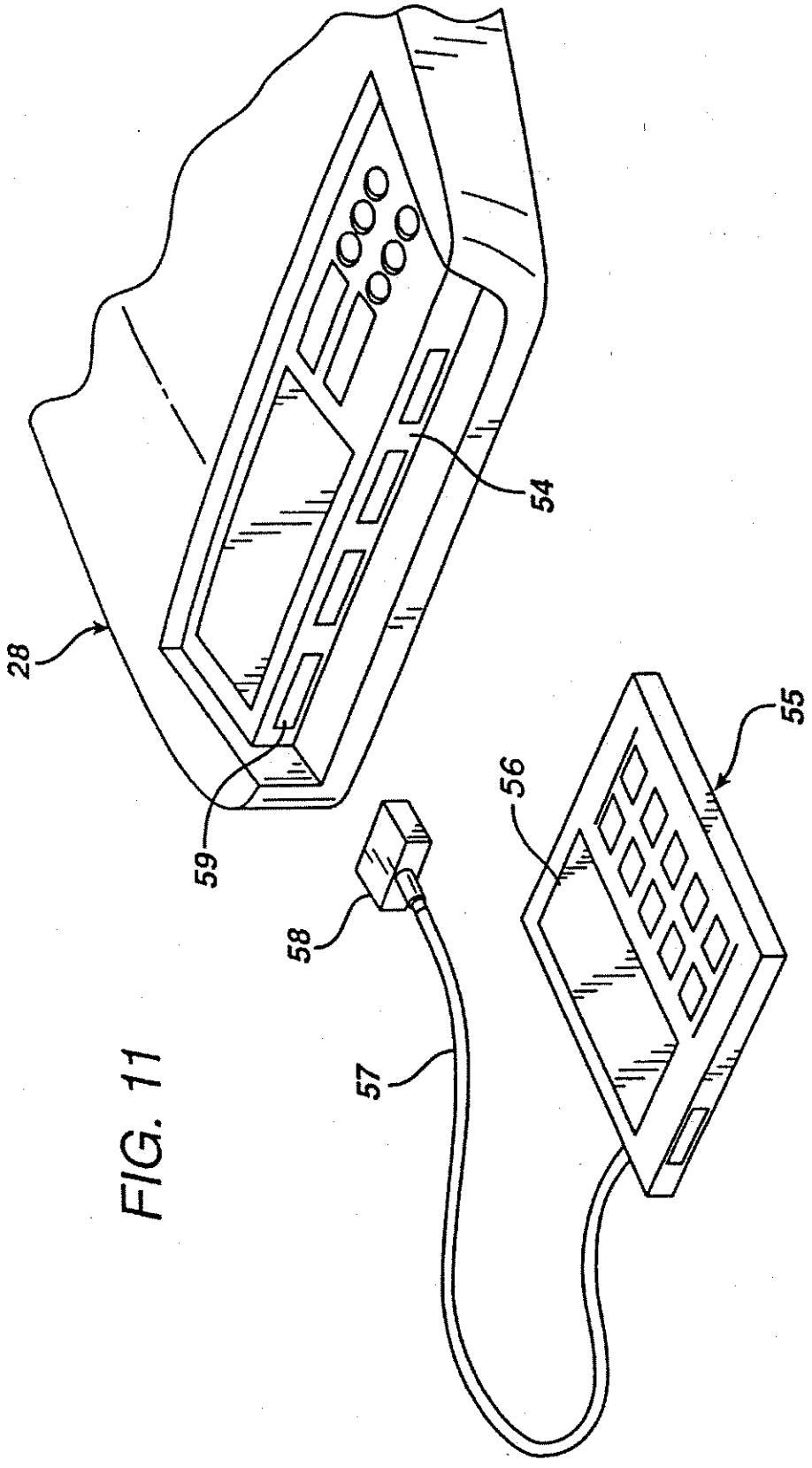


FIG. 11

FIG. 12A

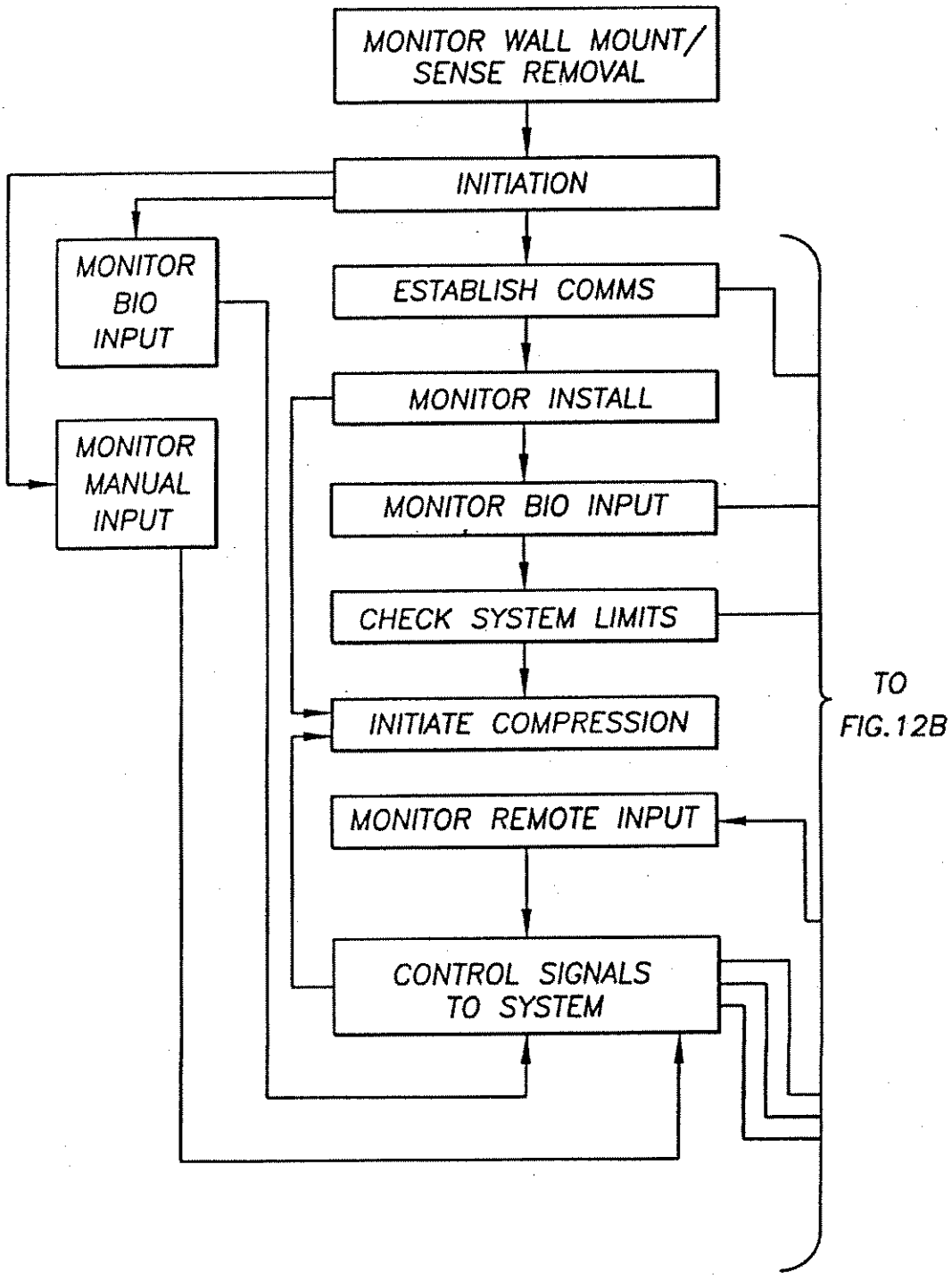

MONITOR WALL MOUNT/ SENSE REMOVAL
INITIATION
MONITOR BIO INPUT
MONITOR MANUAL INPUT
ESTABLISH COMMS
MONITOR INSTALL
MONITOR BIO INPUT
CHECK SYSTEM LIMITS
INITIATE COMPRESSION
MONITOR REMOTE INPUT
CONTROL SIGNALS TO SYSTEM
TO FIG. 12B

FIG. 12B

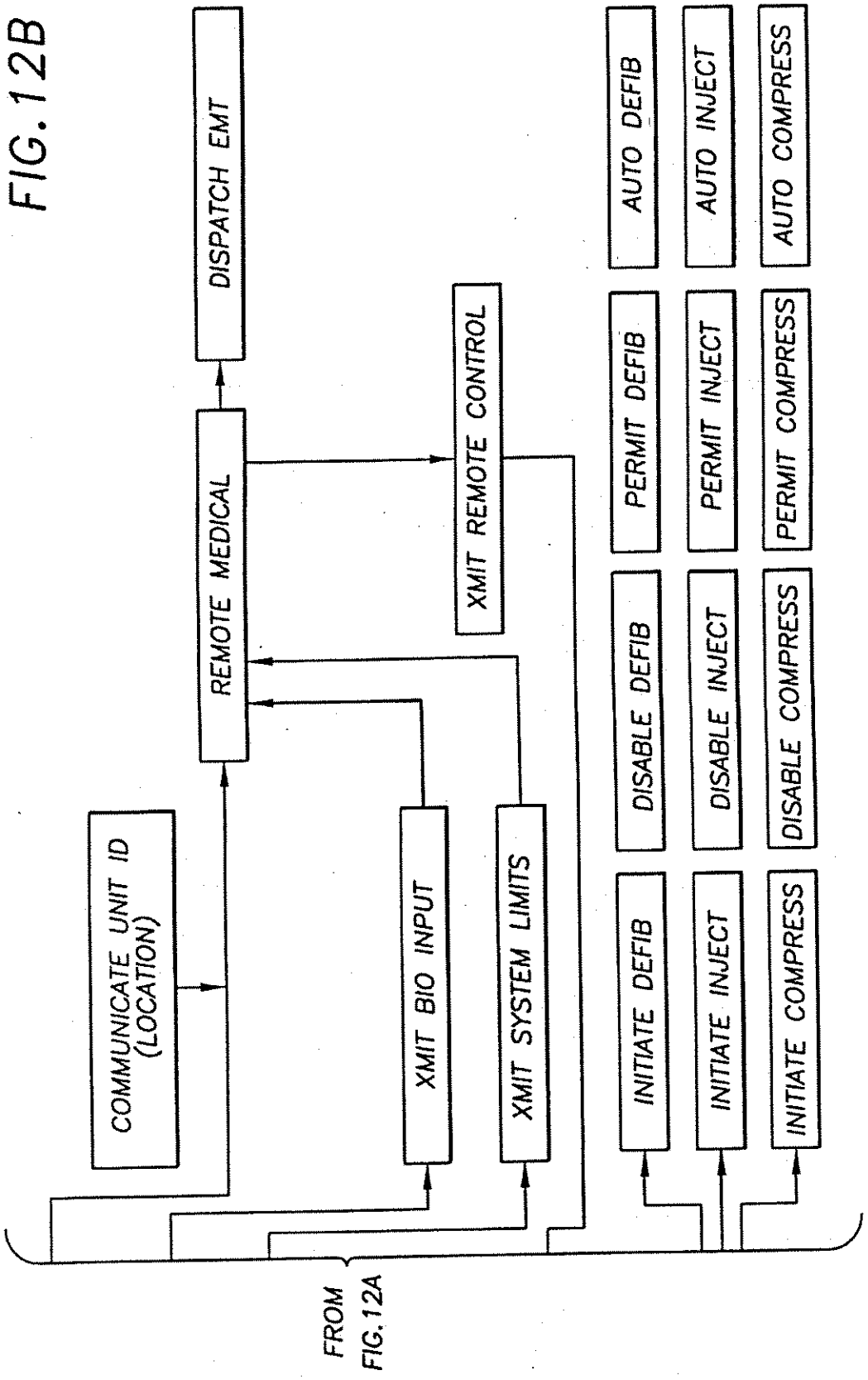

DISPATCH EMT
REMOTE MEDICAL
XMIT REMOTE CONTROL
AUTO DEFIB
AUTO INJECT
AUTO COMPRESS
PERMIT DEFIB
PERMIT INJECT
PERMIT COMPRESS
DISABLE DEFIB
DISABLE INJECT
DISABLE COMPRESS
INITIATE DEFIB
INITIATE INJECT
INITIATE COMPRESS
COMMUNICATE UNIT ID (LOCATION)
XMIT BIO INPUT
XMIT SYSTEM LIMITS
FROM FIG. 12A

FIG. 13A

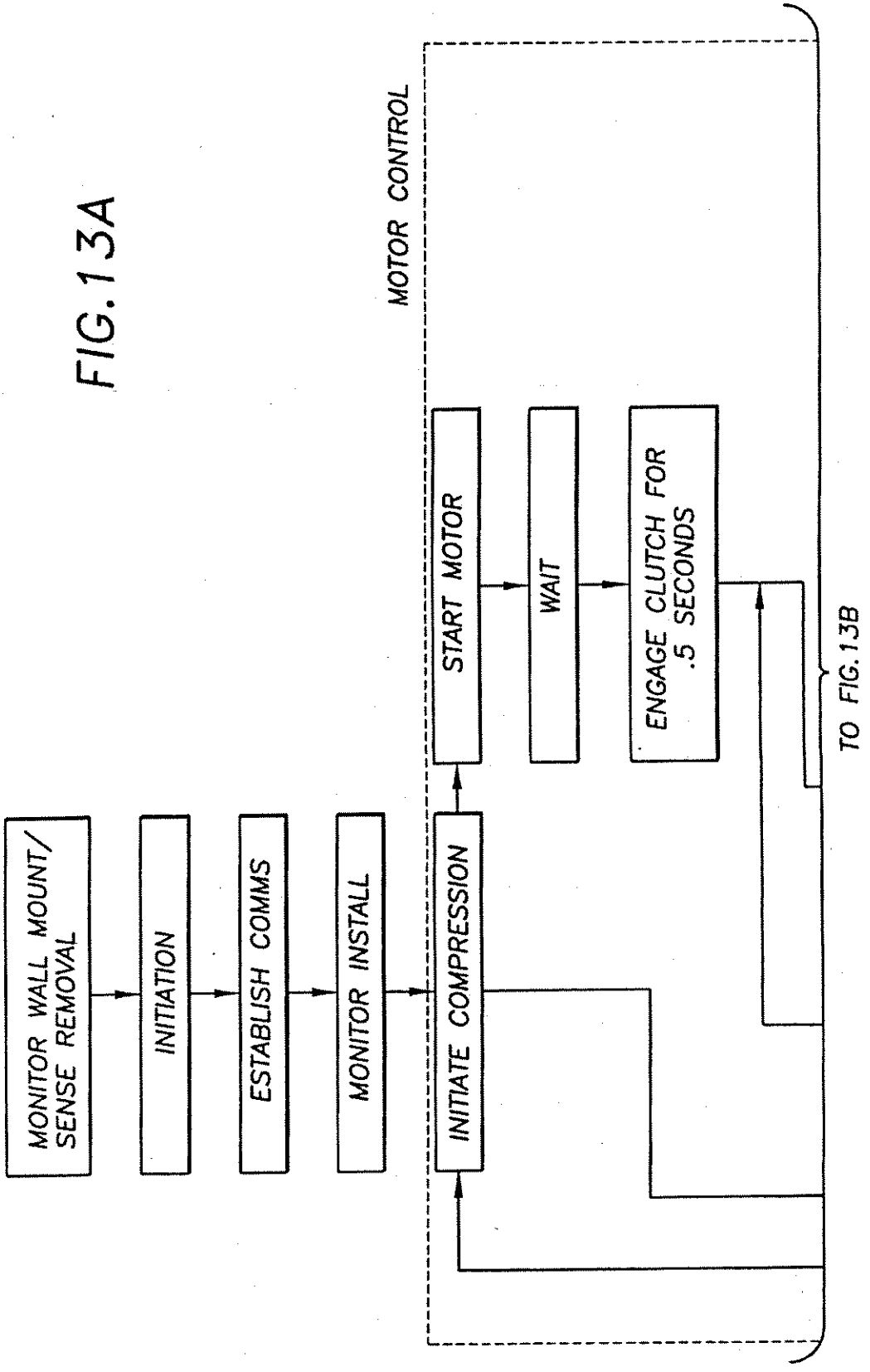
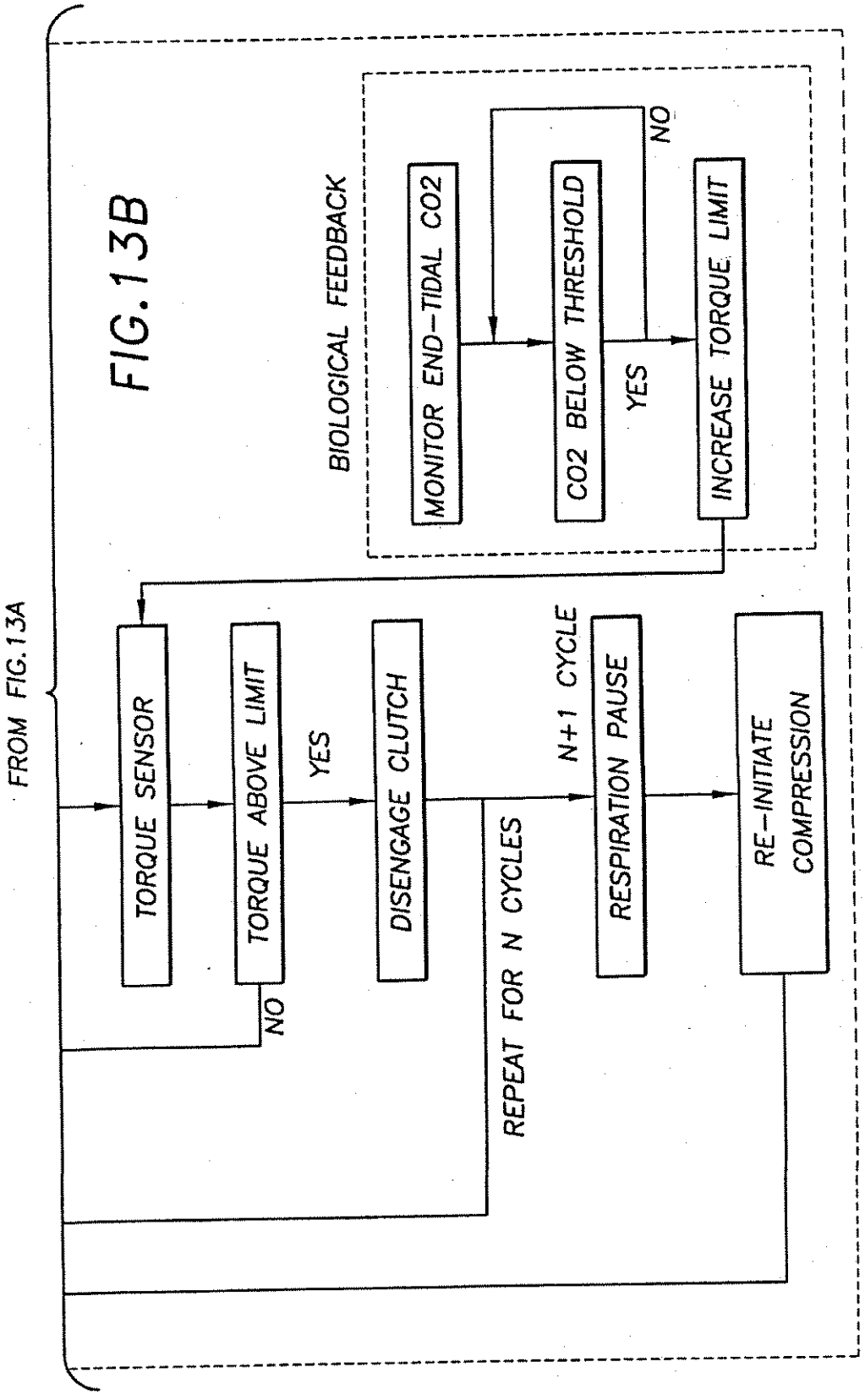

MOTOR CONTROL
MONITOR WALL MOUNT/ SENSE REMOVAL
INITIATION
ESTABLISH COMMS
MONITOR INSTALL
INITIATE COMPRESSION
START MOTOR
WAIT
ENGAGE CLUTCH FOR .5 SECONDS
TO FIG. 13B

FIG. 13B


FROM FIG. 13A
TORQUE SENSOR
TORQUE ABOVE LIMIT
YES
NO
DISENGAGE CLUTCH
REPEAT FOR N CYCLES
N+1 CYCLE
RESPIRATION PAUSE
RE-INITIATE COMPRESSION
BIOLOGICAL FEEDBACK
MONITOR END-TIDAL CO2
CO2 BELOW THRESHOLD
NO
YES
INCREASE TORQUE LIMIT

RESUSCITATION DEVICE HAVING A MOTOR DRIVEN BELT TO CONSTRICT/ COMPRESS THE CHEST

FIELD OF THE INVENTION

This invention relates to emergency medical devices and methods.

BACKGROUND OF THE INVENTION

Cardiopulmonary resuscitation (CPR) is a well known and valuable method of first aid. CPR is used to resuscitate people who have suffered from cardiac arrest after heart attack, electric shock, chest injury and many other causes. During cardiac arrest, the heart stops pumping blood, and a person suffering cardiac arrest will soon suffer brain damage from lack of blood supply to the brain. Thus, CPR requires repetitive chest compression to squeeze the heart and the thoracic cavity to pump blood through the body. Very often, the victim is not breathing, and mouth to mouth artificial respiration or a bag valve mask is used to supply air to the lungs while the chest compression pumps blood through the body.

It has been widely noted that CPR and chest compression can save cardiac arrest victims, especially when applied immediately after cardiac arrest. Chest compression requires that the person providing chest compression repetitively push down on the sternum of the victim at 80–100 compressions per minute. CPR and closed chest compression can be used anywhere, wherever the cardiac arrest victim is stricken. In the field, away from the hospital, it may be accomplished by ill-trained by-standers or highly trained paramedics and ambulance personnel.

When a first aid provider performs chest compression well, blood flow in the body is typically about 25–30% of normal blood flow. This is enough blood flow to prevent brain damage. However, when chest compression is required for long periods of time, it is difficult if not impossible to maintain adequate compression of the heart and rib cage. Even experienced paramedics cannot maintain adequate chest compression for more than a few minutes. Hightower, et al., Decay In Quality Of Chest Compressions Over Time, 26 Ann. Emerg. Med. 300 (September 1995). Thus, long periods of CPR, when required, are not often successful at sustaining or reviving the victim. At the same time, it appears that, if chest compression could be adequately maintained, cardiac arrest victims could be sustained for extended periods of time. Occasional reports of extended CPR efforts (45–90 minutes) have been reported, with the victims eventually being saved by coronary bypass surgery. See Tovar, et al., Successful Myocardial Revascularization and Neurologic Recovery, 22 Texas Heart J. 271 (1995).

In efforts to provide better blood flow and increase the effectiveness of bystander resuscitation efforts, modifications of the basic CPR procedure have been proposed and used. Of primary concern in relation to the devices and methods set forth below are the various mechanical devices proposed for use in main operative activity of CPR, namely repetitive compression of the thoracic cavity.

The device shown in Barkolow, Cardiopulmonary resuscitator Massager Pad, U.S. Pat. No. 4,570,615 (Feb. 18, 1986), the commercially available Thumper device, and other such devices, provide continuous automatic closed chest compression. Barkolow and others provide a piston which is placed over the chest cavity and supported by an arrangement of beams. The piston is placed over the sternum of a patient and set to repeatedly push downward on the chest under pneumatic power. The victim must first be installed into the device, and the height and stroke length of the piston must be adjusted for the patient before use, leading to delay in chest compression. Other analogous devices provide for hand operated piston action on the sternum. Everette, External Cardiac Compression Device, U.S. Pat. No. 5,257,619 (Nov. 2, 1993), for example, provides a simple chest pad mounted on a pivoting arm supported over a patient, which can be used to compress the chest by pushing down on the pivoting arm. These devices are not clinically more successful than manual chest compression. See Taylor, et al., External Cardiac Compression, A Randomized Comparison of Mechanical and Manual Techniques, 240 JAMA 644 (August 1978). Other devices for mechanical compression of the chest provide a compressing piston which is secured in place over the sternum via vests or straps around the chest. Woudenberg, Cardiopulmonary Resuscitator, U.S. Pat. No. 4,664,098 (May 12, 1987) shows such a device which is powered with an air cylinder. Waide, et al., External Cardiac Massage Device, U.S. Pat. No. 5,399,148 (Mar. 21, 1995) shows another such device which is manually operated. In another variation of such devices, a vest or belt designed for placement around the chest is provided with pneumatic bladders which are filled to exert compressive forces on the chest. Scarberry, Apparatus for Application of Pressure to a Human Body, U.S. Pat. No. 5,222,478 (Jun. 29, 1993) and Halperin, Cardiopulmonary Resuscitation and Assisted Circulation System, U.S. Pat. No. 4,928,674 (May 29, 1990) show examples of such devices.

Several operating parameters must be met in a successful resuscitation device. Chest compression must be accomplished vigorously if it is to be effective. Very little of the effort exerted in chest compression actually compresses the heart and large arteries of the thorax and most of the effort goes into deforming the chest and rib cage. The force needed to provide effective chest compression creates risk of other injuries. It is well known that placement of the hands over the sternum is required to avoid puncture of the heart during CPR. Numerous other injuries have been caused by chest compression. See Jones and Fletter, Complications After Cardiopulmonary Resuscitation, 12 AM. J. Emerg. Med. 687 (November 1994), which indicates that lacerations of the heart, coronary arteries, aortic aneurysm and rupture, fractured ribs, lung herniation, stomach and liver lacerations have been caused by CPR. Thus the risk of injury attendant to chest compression is high, and clearly may reduce the chances of survival of the victim vis-à-vis a resuscitation technique that could avoid those injuries. Chest compression will be completely ineffective for very large or obese cardiac arrest victims because the chest cannot be compressed enough to cause blood flow. Chest compression via pneumatic devices is hampered in its application to females due to the lack of provision for protecting the breasts from injury and applying compressive force to deformation of the thoracic cavity rather than the breasts.

CPR and chest compression should be initiated as quickly as possible after cardiac arrest to maximize its effectiveness and avoid neurologic damage due to lack of blood flow to the brain. Hypoxia sets in about two minutes after cardiac arrest, and brain damage is likely after about four minutes without blood flow to the brain, and the severity of neurologic defect increases rapidly with time. A delay of two or three minutes significantly lowers the chance of survival and increases the probability and severity of brain damage. However, CPR and ACLS are unlikely to be provided within this time frame. Response to cardiac arrest is generally

considered to occur in four phases, including action by Bystander CPR, Basic Life Support, Advanced Life Support, and the Emergency Room. By-stander CPR occurs, if at all, within the first few minutes after cardiac arrest. Basic Life Support is provided by First Responders who arrive on scene about 4–6 minutes after being dispatched to the scene. First responders include ambulance personnel, emergency medical technicians, firemen and police. They are generally capable of providing CPR but cannot provide drugs or intravascular access, defibrillation or intubation. Advanced Life Support is provided by paramedics or nurse practitioners who generally follow the first responders and arrive about 8–15 minutes after dispatch. ALCS is provided by paramedics, nurse practitioners or emergency medical doctors who are generally capable of providing CPR, drug therapy including intravenous drug delivery, defibrillation and intubation. The ALS providers may work with a victim for twenty to thirty minutes on scene before transporting the victim to a nearby hospital. Though defibrillation and drug therapy is often successful in reviving and sustaining the victim, CPR is often ineffective even when performed by well trained first responders and ALS personnel because chest compression becomes ineffective when the providers become fatigued. Thus, the initiation of CPR before arrival of first responders is critical to successful life support. Moreover, the assistance of a mechanical chest compression device during the Basic Life Support and Advanced Life Support stages is needed to maintain the effectiveness of CPR.

SUMMARY

The devices described below provide for circumferential chest compression with a device which is compact, portable or transportable, self-powered with a small power source, and easy to use by by-standers with little or no training. Additional features may also be provided in the device to take advantage of the power source and the structural support board contemplated for a commercial embodiment of the device.

In its simplest form, the device includes a broad belt which wraps around the chest and is buckled in the front of the cardiac arrest victim. The belt is repeatedly tightened around the chest to cause the chest compression necessary for CPR. The buckles and/or front portion of the belt are anatomically accommodating for the female breast, or for the obese person, so that the device is effective for women as well as men. The buckle may include an interlock which must be activated by proper attachment before the device will activate, thus preventing futile belt cycles. The operating mechanism for repeatedly tightening the belt is provided in a support board, and comprises a rolling mechanism which takes up the intermediate length of the belt to cause constriction around the chest. The roller is powered by a small electric motor, and the motor powered by batteries and/or standard electrical power supplies such as 120V household electrical sockets or 12V DC automobile power sockets (car cigarette lighter sockets). (An initial prototype used a power drill with a single 9.6V rechargeable battery, and provided powerful chest compression for about ten minutes.) The batteries and any necessary transformers may be housed in the support board, and the support board may be made in sizes useful for supporting the victim's head, adequate for storing batteries and other accessories, and convenient for mounting within office buildings, factories, airplanes and other areas of potential need. Thus, numerous inventions are incorporated into the portable resuscitation device described below.

The portable resuscitation device may incorporate a number of features and accessories that aid in the administration of CPR and other therapy. By-standers may be unable to confidently determine if chest compression is needed, or when it should be stopped. Accordingly, the device may be combined with an interlock system including a heart monitor or EKG which diagnoses the condition of the patient, and circuitry or a computer which initiates, permits or forbids belt operation accordingly. The power supply provided for belt constriction may also be used to provide power for defibrillation (an appropriate treatment for many cardiac arrests). Again, bystanders will most likely not be capable of determining when defibrillation is appropriate, and the defibrillation portion of the device may be provided with an interlock system including the heart monitor or EKG which diagnoses the condition of the patient and circuitry which initiates, permits, or forbids defibrillation. Expert systems implemented through the circuitry or computer modules can accomplish these functions.

Automatic, computer driven therapy of this nature may provide early and appropriate life saving response to many cardiac arrest patients who would otherwise die. However, some situations in which the device might be used may call for expert supervision of the CPR process by emergency medical technicians, emergency room doctors, or cardiologists. To this end, the expert systems mentioned above may be replaced with the expert diagnosis and decision-making of medical personnel through a telemetry system housed within the support board of the device. The support board can include a telemetry system which automatically dials medical personnel in a nearby hospital, emergency medical crew, ambulance, or even a central diagnostic and control facility. Interlocks, limit switches and other typical sensors can be used to sense the proper position and closure of the belt about the chest of the patient. Heart monitors and EKG electrodes can sense the heart rate and EKG of the victim. Using communication equipment within the device, this information can be communicated from the device to medical personnel remote from the victim. Through the same system, the medical personnel can communicate the device to initiate, permit or prohibit belt constriction or defibrillation, as dictated by preferred medical procedures. Communication can be established through normal telephone lines and a cordless telephone, or through a cellular telephone system, paging system, internet or any other communications system. The device can be programmed with location information, or provided with GPS capabilities to determine the location of the device, and this information can be automatically transmitted to an emergency response system such as the 911 system when the system is placed in use.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an overview of the resuscitation device, showing the inner and outer vests partially open.

FIG. 2 is an overview of the resuscitation device in the buckled configuration.

FIG. 3 is an detail view of the buckle used to close the device about a victim.

FIG. 4 shows the spool assembly used to operate the compression belt.

FIG. 5 shows an alternative embodiment of the spool assembly used to operate the compression belt.

FIG. 6 is a view of the resuscitation device properly positioned on a victim.

FIG. 7 shows the resuscitation device fitted with a number of additional devices for use during resuscitation.

FIG. 8 shows a detail view of the CRP module of FIG. 7.

FIG. 9 shows a detail view of the defibrillation module of FIG. 7.

FIG. 10 shows a detail view of the airway management module of FIG. 7.

FIG. 11 shows a detail view of the control and communications module of FIG. 7.

FIGS. 12A and 12B show a block diagram of the communications system.

FIGS. 13A and 13B show a block diagram of the motor control system.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows a simplified version of the resuscitation device 1. The mechanisms used for compressing the chest includes compression assembly 2 which includes a chest compression belt 3 with buckles 4*l* and 4R, a friction liner 5, a support board 6 and a motor driven spool assembly 7. The support board 6 is placed under a cardiac arrest victim, and the compression belt 3 and friction liner 5 are wrapped around the victim's chest. The chest compression belt, having a left side 3L and a right side 3R, is buckled over the victims chest by latching the buckles 4L and 4R together. In this configuration, the friction liner 5 will fit between the chest compression belt 3 and the victim and any clothes worn by the victim. The compression belt may be made of any strong material, and sail cloth has proven adequate for use. The compression belt may also be referred to as a vest, corset, girdle, strap or band. The friction liner may be made of Teflon®, tyvek™ or any other low friction material (by low friction, we mean a material that will permit sliding of the compression belt with less friction than expected between the belt and the victims clothing or bare skin). The friction liner may be made with any suitable lining material, as its purpose is to protect the victim from rubbing injury caused by the compression belt, and it may also serve to limit frictional forces impeding the compression belt operation. The friction liner can be provided in the form of a belt, vest, corset, girdle, strap or band, and may partially or completely encircle the chest.

The front of the compression belt 3, including the buckles 4L and 4R, are configured to provide a broad pressure point over the sternum of the victim. This is illustrated in FIG. 2. Large openings 8 may be provided to accommodate female breasts and obese male breasts. The underside of the buckles 4L and 4R are smooth and broad, to distribute compressive force evenly over a wide area of the chest corresponding to the sternum. The point at which the buckle attaches to the chest compression belt may vary considerably, from the front of the chest to the back of the compression assembly, and the openings 8 may be provided in the buckles rather than the belt itself. FIG. 3 shows a detail of the buckles 4L and 4R used to fasten the compression belt about the chest of the victim. The buckle may be of any type, and preferably includes a latch sensing switch 9 operably connected through wire 10 the motor control system (see FIG. 13) to indicate that the device has been buckled about the victims chest and is ready for the initiation of compression cycles. The buckles shown in FIG. 3 are D-ring shaped buckles with large openings 8, attached to the compression belt 3. Other fasteners and fastening means may be used.

The chest compression belt 3 is repeatedly tightened about the chest of a victim through the action of one or more tightening spools which make up the spool assembly 7 located within the support board 6. The spool assembly, illustrated in FIG. 4, includes at least one spool or reel connected to the compression belt 3 at the back of the belt, preferably near the center or saggital line 11 of the compression belt (although it may be located on the front or side of compression belt). FIG. 4 shows a view of the spool assembly and its attachment to the compression belt. A spool assembly includes a single drive spool 12 operably connected to the motor 14 through drive shaft 15. The compression belt is secured to the drive spool in any suitable manner. In this case a longitudinal slot 16 provided in the drive spool 12. The slot extends radially or chordally through the drive spool, and extends axially for a length corresponding to the width of the compression belt, leaving the ends 17 solid for connection to the drive shaft 15 and journal shaft 18. The belt is slipped through the slot to created a secure connection between the belt and the drive spool. When secured in this manner, the rotation of the drive spool 12 will take up the right side of the compression belt 3R and the left side of the compression belt 3L and roll them up onto the spool, thus tightening the compression belt about the chest of the victim wearing the device. Spindles or alignment rollers 19 provide for alignment and low friction feed of the belt onto the roll created by operation of the drive shaft.

Many alternative embodiments can be envisioned for the rolling mechanism, and one such alternative is illustrated in FIG. 5. Spools 12R and 12R are aligned in parallel and interconnected by a transmission gear 20 and planetary gear 21 and journaled upon shafts 18L and 18R. The drive shaft 15 is attached to spool 12R (or spool 12L) and operably attached to motor 14. The motor turns the shaft 15R and spool 12R in a counterclockwise direction to pull the right side of the compression belt 3R to the left and roll onto the spool. The transmission gear 20 acts upon the planetary gear 21 to cause clockwise rotation of spool 12R, which in turn pulls and wraps the left side of the compression belt 31 onto the spool 121.

Thus, many embodiments of mechanisms which can cause repeated cyclic tightening of the compression vest about the chest of the victim may be envisioned. The compression belt serves to radially compress the chest through the cooperative action of the belt, board, and buckle, and to disperse the compressive force around the chest.

The motor is energized to rotate the spools and cause the compression belt to constrict around the chest of a victim. A motor such as a battery operated hand drill motor provides adequate chest compression for the purposes of CPR. To cause repetitive constriction of the compression belt 3, the motor 14 must be attached via a clutch 22 or other such mechanism. The motor 14 may be attached to the drive shaft 15 through a torque slipping clutching mechanism which engages the drive shaft until a high torque is achieved (indicating great resistance to further constriction, and thus indicating that the victim's chest has been compressed), and releases automatically upon such high torque, only to re-engage after the belt has been expanded in response to the normal elastic expansion of the victim's chest. In this manner, repetitive compression is achieved without need to repeatedly energize and de-energize the motor, thereby extending the length of operating time for any given battery supply. Alternatively, the motor may be repeatedly energized and de-energized, with the spools spinning freely during periods in which the belt is de-energized, wherein the clutch mechanism 22 will be similar to clutch mechanisms used on electric drills (which engage during operation of the drill but spin freely when the drill is de-energized). While the natural elastic expansion of the chest should make it unnecessary to

drive the belt toward a loose condition, positive loosening may be achieved by reversing the motor or reversing the action of the motor through appropriate clutch or gear mechanisms. Timing of compressions is regulated through a computer module or a simple relay (windshield wiper style relays), and preferably will conform to standard of the Advanced Cardiac Life Support guidelines or Cardiopulmonary Resuscitation guidelines, or any other medically acceptable resuscitation regime. Current guidelines put forth by the American Heart Association call for 60–100 chest compressions per minute.

The motor is preferably battery powered, with provisions for taking power from any available power source. Batteries **23** may be stored within the support board **6**. Three volt batteries of convenient size, already available for use with numerous power tools, provide about five minutes of compression per battery, while twelve volt batteries (1700 mA-h per battery) have provided about ten minutes of compression per battery. A thirty minute total battery capacity is desirable (corresponding to the estimated average time between cardiac arrest and transport to the hospital). Accordingly, several batteries may be installed within the support board and electrically connected to the motor and its controller. The batteries are provided with a trickle charge through a charger socket and charger plugged into 120V AC power when the device is not in use. (It is intended that the device be installed in factories, office buildings, airplanes and other facilities with relatively stable sources of power, and that the unit remain plugged in and charging when not in use.) If AC power is readily available at the site of use, the device may continue to run on AC power to preserve the batteries for later use. The unit may also be plugged into an automobile power jack with an appropriate auto adapter, thus providing for use where an automobile is the only source of power, and for extended use in an ambulance.

FIG. **6** shows the resuscitation device installed on a cardiac arrest victim. The support board is placed under the victim, and the right and left portions of the compression belt are wrapped around the victim's chest and buckled over the front of the chest, indicated by arrow **25**. Once in place, the system may be put into operation by manually starting the motors or by automatic initiation given the proper feedback from sensors located on the device, including the buckle latch sensors.

A number of features may be combined with the basic system described above. The structure necessary for housing the operating mechanism for the belt, referred to as the support board above, can serve also as storage for additional devices used during resuscitation. FIG. **7** illustrates the resuscitation device **1** in a potential commercial embodiment. The support board **6** is sized to reach approximately from the lower lumbar region to the shoulders of a victim. The compression module **26** is separable from the support board **6**, and includes the compression belt and friction vest stored within the compression module. The spool assembly and motor are also stored within the compression module, although the motor may also be installed in the support board. In this figure, the compression module comprises a small support board **27** which fits into the larger system support board **28**.

Taking advantage of available space in the system support board, a compartment **29** for storage of airway management devices (bag masks, oxygen masks, etc.), and a compartment **30** for storage of defibrillation equipment (electrodes and paddles, etc.) are included with the support board. A control and communication module **31** may also be incorporated into the support board. A small oxygen bottle **32** may be included, along with hoses routed to an accessible point on the board, and any connector desired for connection between the oxygen bottle and devices provided in the airway management compartment. Batteries **23** are stored within the support board (the number of the batteries chosen according the desired operating time, and the placement of the batteries dictated by available space). Batteries are operably connected to the motor in the compression module through electrical connectors **33** and appropriate wiring throughout the support board. The batteries can also be operably connected to the defibrillation module and control and communications module. Although long life batteries can be used, rechargeable batteries may be preferred. Accordingly, charging connection **34** on the support board is provided for charging the batteries or operating the device through outside power supplies.

The device is intended to be stored for long periods of time between uses, and storage holder **35** is provide for this purpose. The storage holder can include such necessities as power supply connectors, power plug, a charging transformer. A removal sensor **36** is included in the support board to sense when the support board is removed from the storage holder (which, as described below, can be used as a condition indicating use of the device, and therefore the need to alert emergency medical personnel). The removal sensor can comprise a simple limit switch which senses physical removal of the system, and the limit switch can be used as a power switch or awaken switch which starts initiation of the system. The removal sensor can comprise a current sensor on the charging lines which treat cessation of charging current, increase in current draw through the charging system, or motor current as an indication of use. The choice of sensor may be made with many practical considerations in mind, such as the desire to avoid treating power outages as indications of use and other such unintended initiations. The state in which the device is deemed to be "in use" can be chosen according to the practical considerations, and in most instances it is expected that mere removal of the resuscitation device from the holder will constitute a clear signal someone has determined that a victim requires its use, and that emergency medical personnel should be dispatched to the location of the device. There are some environments in which later conditions will be used to indicate that the device is "in use," such as when installed in ambulances, airplanes, hospitals or other environments where it might be advisable to remove the device from its storage holder as a precaution or preparatory measure, and delay initiation of communications until the device is deployed or installed on the victim. In such cases, the buckle latch shown in FIG. **3** can be used as the sensor that indicates that the resuscitation device is in use.

FIG. **8** shows the details of the compression module **26**. When not in use, the module is covered with a tear sheet **37** which protects the compression belt from wear. The buckles are readily visible under the tear sheet. The electrical connectors **38** connect the batteries in the support board with the motor inside the compression module. The inside of the compression belt is fitted with penetrating electrodes **39** in the right sternum parasaggital location **40** and left rib medial location **41** for establishing the electrode contact needed for EKG sensing. These electrodes may be dispensed in environments where proper placement of the defibrillation electrodes can be assumed due to a high level of training amongst likely bystanders and first responders. The friction vest **5** is secured to the compression module above the spool assembly location.

FIG. **9** shows a detail view of the defibrillation module in the compartment **30**. The defibrillation module includes a

pair of defibrillation electrodes **42** connected to the batteries through the power connections **43**. The defibrillation electrodes will be controlled by circuitry housed within the defibrillation module, and may be connected to the control module through the data port **44**. The defibrillation module is releasably attached to the support board **28** with quick release latches **51**. Tear sheet **46** protects the components of the defibrillation module during storage and provides ready access for use. FIG. **10** shows the detail view of the airway management module in the compartment **29**, which includes an oxygen mask **47**, a length of tubing **48** and an air fitting **49** connecting the oxygen mask to the oxygen bottle within the support board. The oxygen mask serves as a blood gas exchange means, supplying oxygen to the lungs for exchange with blood gas such as CO_2. Optional medicine injectors **50** may be operably connected to the masks or hose to provide for automatic injection of ACLS medications into the airway. The defibrillation module is releasably attached to the support board **28** with quick release latches **51**. Tear sheet **46** protects the components of the airway management module during storage and provides ready access for use. An end-tidal CO_2 monitor **52** can be included in the mask to provide for biological feedback and monitoring of the success of the CPR. A skin mounted blood oxygen level monitor **53** can also be mounted on the mask for the same purpose (fingertip blood oxygen sensors may also be used, and supplied in the overall assembly to be readily available). The biological data obtained by the sensors is transmitted to the control module via appropriate wiring in the mask and support board.

FIG. **11** shows a detail view of the control and communications module. The control unit **54** is connected to the compression module, defibrillation module and the airway management module through appropriate wiring through the support board. The control unit is optionally connected to the communications unit **55**. The communications unit includes means for communicating the EKG and other measured medical parameters sensed on the board to the screen **56** and via telephone to remote medical personnel. The communications unit can include a telephone handset or speaker phone. Because the device is most likely to be used at a location separate from the storage holder, the communications module preferably includes a wireless communication device, such as wireless telephone, radio telephone or cellular, and any necessary telephone base will be installed in the storage holder.

The communications unit and control unit are set up to operate in the following manner, also illustrated in the block diagram of FIG. **12**. The device may remain mounted in a charging unit for months between use, and will be removed from the charging unit for use. Upon removal of the device from its storage location, a sensor in the control unit senses the removal (through limit switches, magnetic switches, or motion sensors, current sensors in the charging system, or otherwise) and initiates the system, checking functions, energizing a display unit and accomplishing other typical warm-up functions. As a first step, the system initiates a telephone communication with a medical facility through the communications unit. The communication may use any communication medium, whether it be standard telephone lines, cellular telephone system, paging system or radio transmitter. The system may be set up to initiate communications with central medical facility, such as a local 911 emergency system, a nearby hospital or ambulance service, or a central facility staffed with medical personnel trained specifically on the remote use of the device (all generally referred to as medical personnel). Upon establishing communication, the communications unit informs medical personnel of the location or identification of the device (which may be stored in computer memory in the communications unit, or determined through GPS or other such system), and this information can be used to dispatch an emergency medical team to the location of the device. In a simple embodiment which does not require a computer to control the actions of the alert feature, the removal sensor may comprise a limit switch, while the communications module may comprise a simple telephone unit installed in the storage holder together with a tape recorded message, where the operation of the relay in response to removal of the resuscitation device includes initiation of the telephone call to 911 and playback of an alert message providing alert information such as the location of the board. The communications unit may also be provided with an alert button which may be operated by a bystander regardless of the use of the board to summon an emergency team to the location regardless of the condition of the resuscitation device.

Before the emergency medical team arrives, a bystander will place the board under the victim, buckle the compression belt around the victim and apply defibrillation and/or sensing electrodes (or vice versa)(alternatively, sensing electrodes can be included on the inner surface of the compression belt). The system monitors the installation of the belt through signals provided through latching sensors in the buckle. The system monitors biological input, which can comprise monitoring of EKG signals from the EKG electrode patches of the defibrillation module, monitoring EKG signals belt mounted electrodes, monitoring signals from an end-tidal CO_2 monitor from the airway management module, and any other biological signal sensor incorporated into the device. The system can also monitor or respond to manually inputted instruction from the control unit, in order to provide on-site emergency medical personnel with control of the device when they arrive on scene. During operation, the system transmits all available biological information, including EKG signals, blood pressure, end-tidal CO_2 and any other monitored biological parameter to the remote medical facility, and it can also transmit information regarding the configuration of the device, including battery life, system operating limit settings (i.e., whether the system is set for automatic operation, permissive operation, or disabled in any function) so that medical personnel can ensure that the appropriate configuration is in effect.

Communication with the medical facility will allow emergency medical personnel to diagnose the condition of the patient and, through signals sent from the medical personnel to the communications unit, permit, initiate or prohibit certain additional therapeutic ACLS actions. For example, upon diagnosing the EKG conditions which indicate the need for defibrillation, the medical personnel can send a signal to the communications unit which acts upon the control unit to permit manual operation of the defibrillation electrodes by the bystander. The system also provides for application of a defibrillation shock via remote signal from the medical personnel. The device can incorporate the expert system such as the Automatic External Defibrillator. The medical personnel can also communicate other actions, and ensure that certain acts are undertaken by the bystander through the communication system. For example, the medical personnel may communicate verbally with the bystander to ascertain the cause of the cardiac arrest, the proper placement of the oxygen mask, appropriate clearing of the airway, and other information. Where the airway management module is provided with medication such as epinephrine, lidocaine, bretylium or other drugs called for in

the ACLS guidelines (or newly proposed drugs such as T3), the medical personnel can instruct by-standers to inject appropriate medication through the airway. Where automatic injectors such as those described in Kramer, Interactive External Defibrillation and Drug Injection System, U.S. Pat. No. 5,405,362 (Apr. 11, 1995) are provided, or similar system with non-osseous injectors are provided, the medical personnel can instruct by-standers to inject appropriate medication through these injectors. Where the injectors are provided with means for automatic operation based on measured EKG signals, blood pressure and end-tidal CO2, the medical personnel can send signals to the system to initiate injection by remote control of the medical personnel, permit injection by local control as determined by the expert system, permit injection by by-standers, or prohibit injection by the system or bystanders. For example, the system can be initially set up to forbid any injection. Medical personnel, having diagnosed ventricular fibrillation through the information provided by the communications unit, can send an appropriate signal to permit or initiate injection of epinephrine, and also send a signal to prohibit injection of atropine until called for under the ACLS guidelines. A newly proposed drug T3 can be administered through the airway, into the lungs, as a therapy for cardiac arrest. Controlled injection into the airway can be initiated or prohibited in the same manner. Thus, all actions in the ACLS, including compression, defibrillation, drug injection can be accomplished through the system under the guidance of medical personnel from a remote location, or they may be accomplished through expert systems installed in the control module. Each of these functions in incorporated in a system that automatically initiates communication with medical personnel and informs medical personnel of the location of the device so that emergency medical personnel my be dispatched to the location.

The repeated compression will be initiated upon buckling of the compression belt (automatically) or a switch can be provided for the bystander to initiate compression. The system will continue compression cycles, until de-activated, according the motor control block diagram of FIG. 13. Upon initiation of the system, the control unit will monitor installation of the belt via appropriate sensors in the buckles or through other sensors. When the motor control **57** receives the initiate compression signal from the control unit, the motor is started. The motor is preferably run continuously, rather than stopped and started, to avoid repeated application of startup current and thus conserve battery power. When the motor is up to speed, the clutch is engaged. As a baseline, the clutch is engaged every second for one-half second. This cyclic engagement of the clutch continues repeatedly for five cycles, as recommended by current CPR guidelines, and then is interrupted for a respiration pause, if desired. To avoid excessive drain on the batteries, the motor controller includes a torque sensor (sensing current supply to the motor, for example), and monitors the torque or load on the motor. A threshold is established above which further compression is not desired or useful, and if this occurs during the half second of clutch engagement, then the clutch is disengaged and the cycle continues. The system can monitor the effectiveness of the compression stroke by monitoring the CO2 content of the victim's exhalant. Where CO_2 content is low, indicating inadequate circulation, the control system increases the torque limit until the CO_2 levels are acceptable (or until the maximum torque of the motor is achieved.) This is another example of the device's use of biological signals to control operation of the system. The cycle time and period, number of cycles between respiration pauses, and the torque limit, can be set according to current guidelines, and can also be varied by the remote medical personnel via the remote control capabilities of the control unit.

Thus, while the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims.

We claim:

1. A chest compression device comprising;

a belt which is adapted to extend at least partially around the chest of a human;

a rotating member operatively connected to the belt to constrict the belt about the chest;

an electric motor for rotating the rotating member;

a clutch for operatively connecting the motor to the rotating member;

a controller for repeatedly engaging and disengaging the clutch;

a torque sensor operatively connected to the motor to sense the torque applied by the motor;

wherein the controller is capable of disengaging the clutch when the torque sensed by the torque sensor reaches a specified limit.

2. The device of claim **1** wherein the torque sensor is a current sensor which senses current supplied to the electric motor.

3. The chest compression device of claim **1** further comprising:

a biological parameter sensor for sensing a biological parameter of the human and transmitting a corresponding signal to the controller; and

wherein the controller is capable of adjusting the torque at which the clutch disengages based upon the signal corresponding to the sensed biological parameter.

4. The chest compression device of claim **3** wherein:

the biological parameter sensor is an end-tidal CO_2 sensor which senses CO_2 in the human's exhalant which transmits a signal corresponding to the level of CO_2 in the exhalant to the controller.

5. The chest compression device of claim **3** wherein:

the biological parameter sensor is a blood oxygen sensor which senses the level of blood oxygen in the human's blood and which transmits a signal corresponding to the level of blood oxygen to the controller.

6. A chest compression device comprising:

a belt which is adapted to extend at least partially around the chest of a human;

a rotating spool connected to the belt whereby rotation of the spool takes up the belt to pull the belt tightly about the chest;

an electric motor for rotating the rotating spool;

a clutch for operatively connecting the motor to the rotating spool;

a controller for repeatedly engaging and disengaging the clutch;

a torque sensor operatively connected to the motor to sense the torque applied by the motor; and

wherein the controller is capable of disengaging the clutch when the torque sensed by the torque sensor reaches a specified limit.

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