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(54) **ADAPTOR TO ALLOW ELECTROGRAM VISUALIZATION AND PACING FROM TEMPORARY EPICARDIAL WIRES**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

4,149,527 A * 4/1979 Naylor A61B 5/7217 600/510
4,832,041 A * 5/1989 Wang A61B 5/0428 600/510

(Continued)

OTHER PUBLICATIONS

Hodam and Starr. "Temporary postoperative epicardial pacing electrodes. Their value and management after open-heart surgery." Ann Thorac Surg. Dec. 1969;8(6):506-10. (Year: 1969).*

(Continued)

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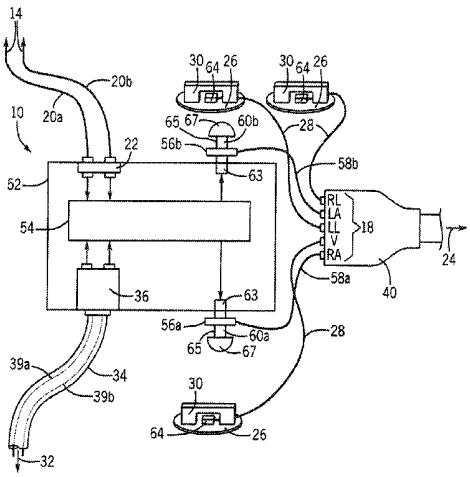
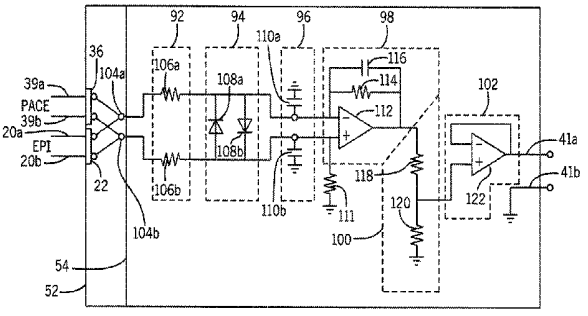
(57) **ABSTRACT**

A connector block that permits simultaneous and continuous interconnection of the three leads of the epicardial pacing wires, the pacemaker, and the ECG monitor on clear separately labeled connectors is provided. Circuitry is provided that allows the display of epicardial signals on the telemetry unit, while still preserving the ability to pace the heart from the pacemaker. When pacing the connector block prevents excessive loading of the pacer signals by the ECG monitor and/or damage to the monitor by the high-voltage pacer signals. The connector block may be used universally on all monitors without the need for sophisticated understanding of the electrical characteristics of the ECG monitor or concern for damage or improper signal loading.

20 Claims, 3 Drawing Sheets





(51) **Int. Cl.**

A61N 1/05	(2006.01)
A61B 5/00	(2006.01)
A61B 5/044	(2006.01)
A61N 1/365	(2006.01)

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CPC ... A61B 5/7203; A61B 5/7217; A61B 5/7225; A61N 1/0587; A61N 1/0595; A61N 1/36014; A61N 1/36017; A61N 1/362; A61N 1/3625; A61N 1/375; A61N 1/3752

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,666,958	A *	9/1997	Rothenberg	A61N 1/056 439/909
5,682,902	A *	11/1997	Herleikson	A61B 5/0452 128/901
6,246,902	B1 *	6/2001	Naylor	A61B 5/0428 128/901
87,558,851		6/2014	Deno et al.	
2003/0040784	A1 *	2/2003	Pasternak	A61N 1/3752 607/116
2008/0058656	A1	3/2008	Costello et al.	

OTHER PUBLICATIONS

Anjan S Batra et al.; "Post operative temporary epicardial pacing: When, how and why?." Annals of pediatric cardiology 1, No. 2 (2008): pp. 120-126, US.

Kurt Piggott et al.; "Intra-operative arrhythmia predicts post-operative arrhythmia and the need for temporary pacing wires." Cardiology in the Young 25, No. 03 (2014) pp. 1-5; US.

Bart Maesen et al.; "Post-operative atrial fibrillation; a maze of mechanisms." Europace 14, No. 2 (2012): pp. 159-174. Europe.

M.C. Reade; "Temporary epicardial pacing after cardiac surgery: a practical review." Anaesthesia 62, No. 3 (2007): pp. 264-271. US.

Yartsev, A.; "Anatomy of the Temporary Pacemaker Circuit" retrieved from web-site: http:/www.derangedphysiology.com/main/core-topics-intensive-care/mechanical-haemodynamic-support, Chapter 2.5.2 / anatomy-temporary-pacemaker-circuit; pp. 1-4; US.

A. Kerkoff; "Definitions of Anatomy & Physiology [Online]". web-site: http://www.(livestrong.com/article/1 37578-definitions-anatomy-physiology); (Jan. 15, 2014). pp. 1-4; US.

J. Mon, "Anatomy, and Physiology of the Cardiovascular System," in Anatomy and Physiology for Health Professionals, 2nd ed. Burlington. MA: Jones and Bartlett Publisher, 2016, ch. 5. sec. The Heart, pp. 37-40.; US.

Openstax College; "Cardiac Muscle and Electrical Activity". OpenStax-CNX module: m46664; (Mar. 20, 2013). web-site: https://cnx.org/content/m46664/1.3/; US.

Barbara J. Drew et al.; "Practice Standards for Electrocardiographic Monitoring in Hospital Settings an american heart association scientific statement from the councils on cardiovascular nursing, clinical cardiology, and cardiovascular disease in the young: Endorsed by the international society of computerized electrocardiology and the american association of critical-care nurses." Circulation 110, No. 17 (2004): pp. 2721-2746. US.

Allison V. Rosen et al.; "Common ECG lead placement errors. Part I: Limb lead reversals." International Journal of Medical Students 2, No. 3 (2014): pp. 92-98. US.

B.T. Bethea et al.; "Determining the utility of temporary pacing wires after coronary artery bypass surgery."The Annals of thoracic surgery 79, No. 1 (2005): pp. 104-107. US.

Yasir Abu-Omar et al., "Indications and positioning of temporary pacing wires." Multimedia Manual of Cardio-Thoracic Surgery 2006, No. 0512 (2006); pp. 1-4: mmcts-2005. EP.

M. Manning; "Switch and Multiplexer Design Considerations for Hostile Environments" web-site: www.analog.com/analogdialogue Analog Dialogue 45-05, (May 2011). pp. 1-7; US.

"What is an Ideal Diode?"(n.d.),Retrieved Feb. 22. 2016, from http://www.learningaboutelectronics.com/Articles/Ideal-diode.php; pp. 1-8; US.

"Lessons in Electric Circuits"—vol. III. (n.d.). Retrieved Feb. 22, 2016, from https://www.ibiblio.org/kuphaldt/electricCircuits/Seini/SEMI - 3 .html; pp. 1-69; US.

"Analog Devices", (n.d.), Retrieved Feb. 24, 2016, from http ://www. analog. com/en/products/amplifiers/adc-drivers/full y-differential-arnplifiers/ad8476.html; pp. 1-10; US.

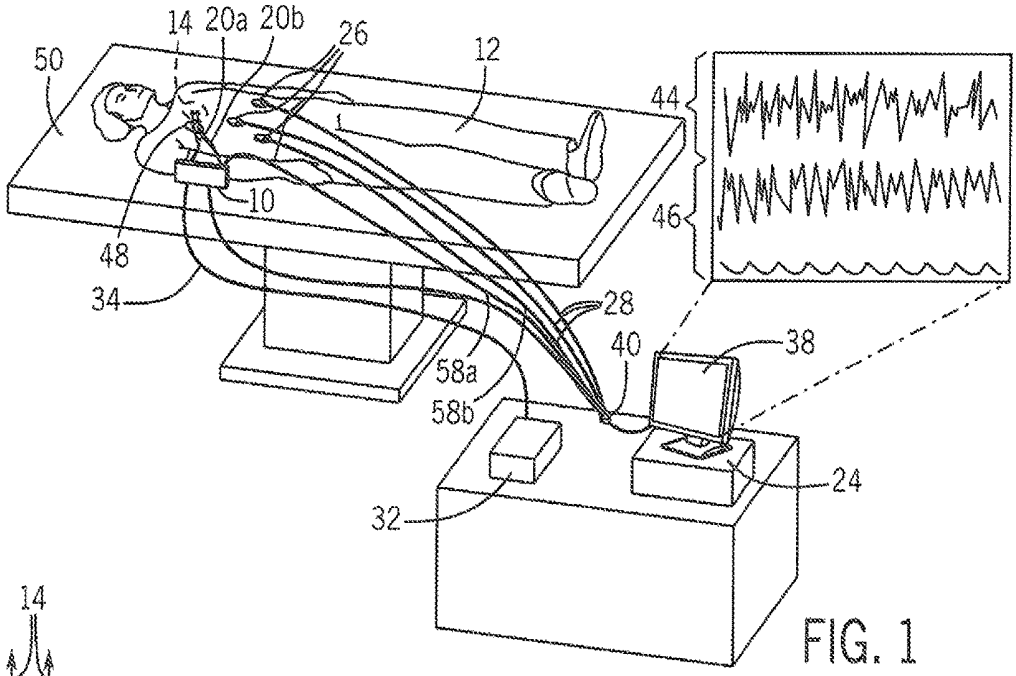
Yueh-Tze Lan et al.; Postoperative arrhythmia. Current Opinion in Cardiology. 18(2), pp. 73-78; 2003; US.

Johann Auer et al.; Risk factors of postoperative atrial fibrillation after cardiac surgery. Journal of cardiac surgery, 20(5), pp. 425-431; 2005, Austria.

Bill Laumeister; Lightning Bolts, Defibrillators, and Protection Circuitry Save Lives; Webpage—Application Note 5724: http://www.maximintegrated.com/en/an5724; 2014 Maxim Integrated; pp. 1-7; US.

Adel S. Sedra et al.;"Microelectronic Circuits"; Book; Oxford University Press; pp. 1-8; 2015; US.

* cited by examiner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20a
20b
26
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44
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58b
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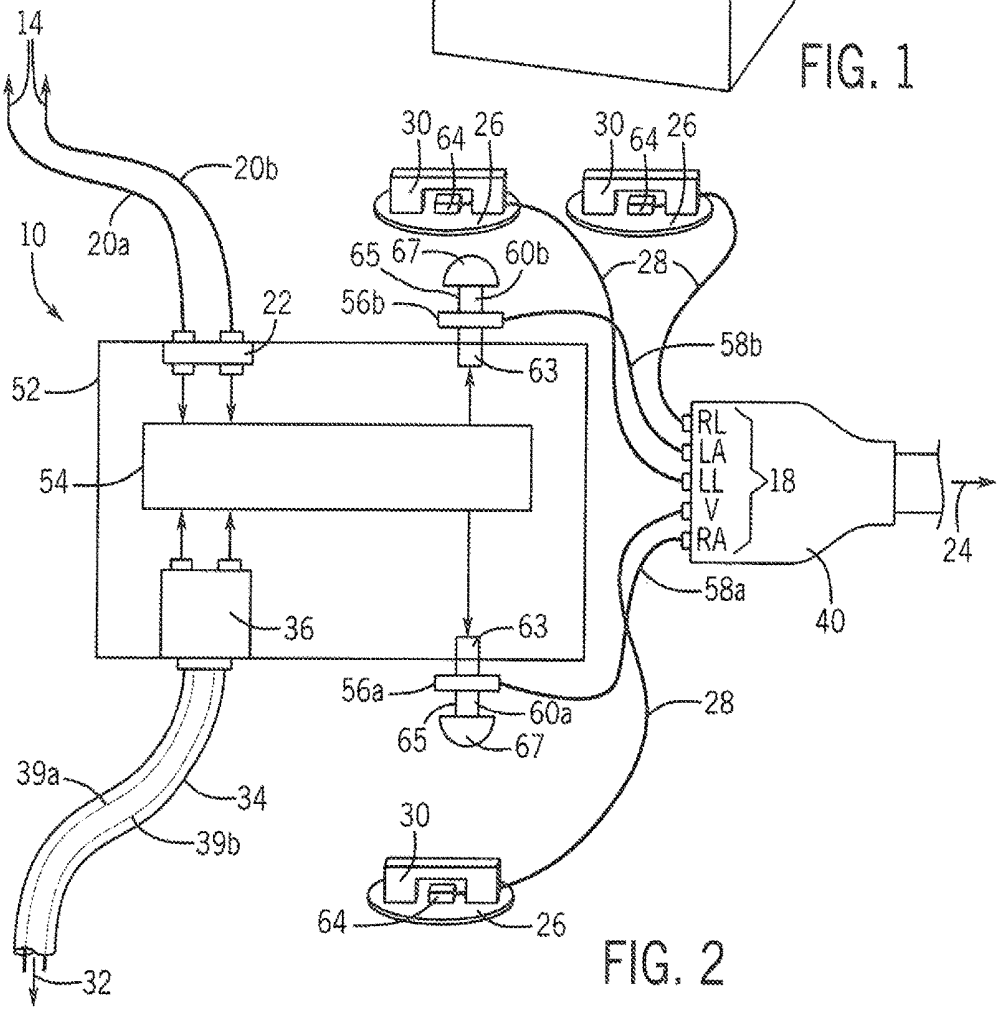
32

FIG. 1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22
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64
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60b
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28
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63
52
54
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58a
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36
56a
60a
39a
34
39b
32

FIG. 2

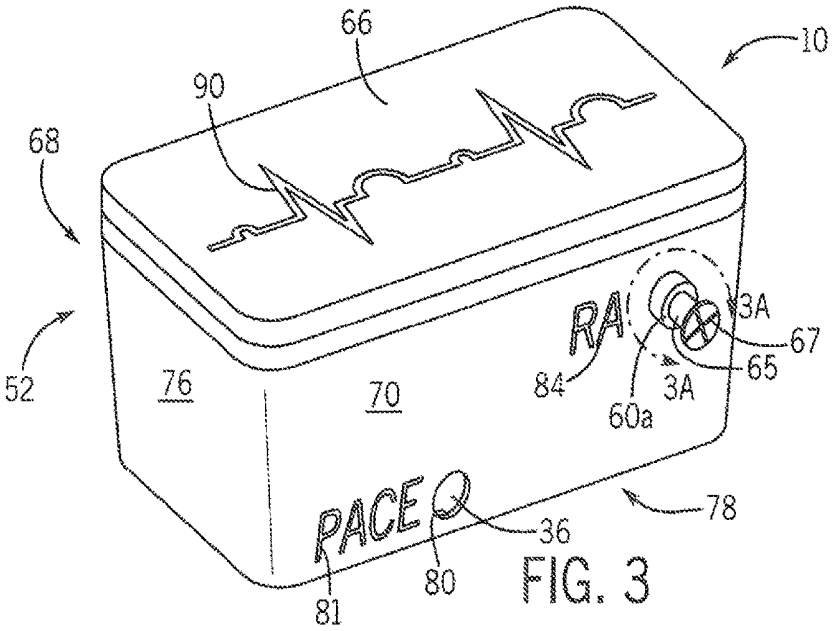

FIG. 3

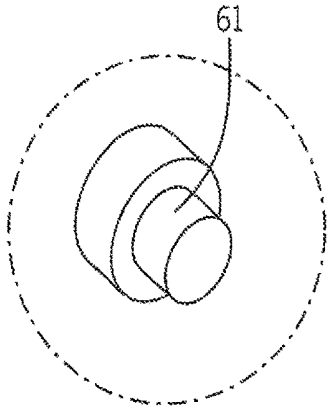

FIG. 3A

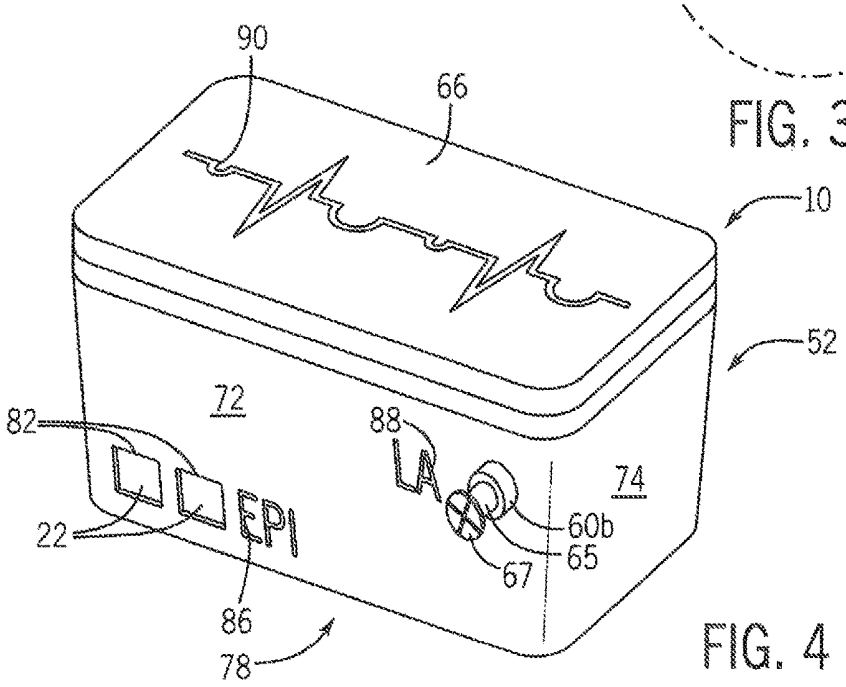

FIG. 4

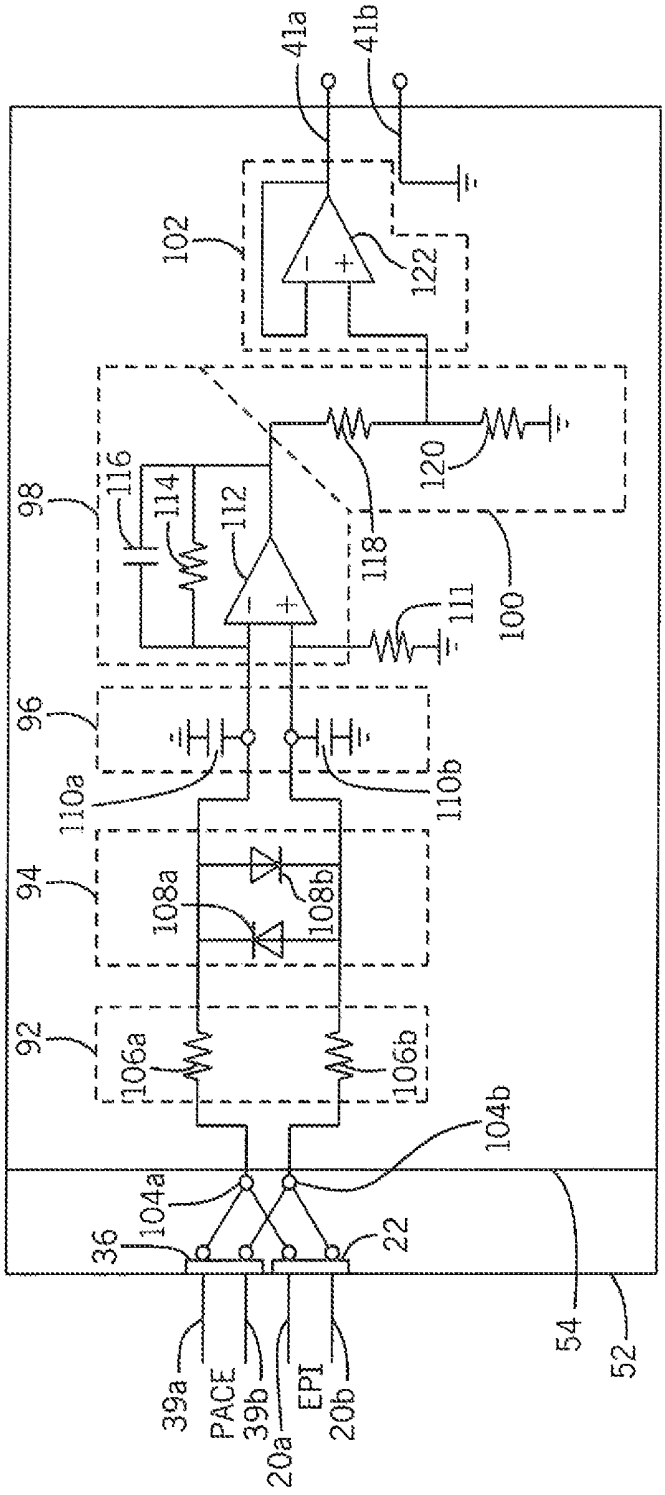
41a
41b
102
122
120
98
116
114
112
118
100
111
96
110a
110b
94
108a
108b
92
106a
106b
104b
104a
36
22
54
52
39a
PACE
39b
20a
EPI
20b

FIG. 5

ADAPTOR TO ALLOW ELECTROGRAM VISUALIZATION AND PACING FROM TEMPORARY EPICARDIAL WIRES

CROSS REFERENCE TO RELATED APPLICATIONS

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

BACKGROUND OF THE INVENTION

The present invention relates to electrocardiographic (ECG) monitoring systems and, more specifically, to ECG monitoring systems that allow simultaneous pacing during electrogram visualization using epicardial pacing leads.

Telemetry monitoring allows medical professionals to monitor electrical activity of the heart in real time and for extended periods of time. Telemetry monitoring is often utilized after cardiac surgery, when patients are most at risk for arrhythmias. Abnormally slow or fast heart rhythms can cause increased morbidity and mortality in the patient. Atrial fibrillation is a common arrhythmia encountered postoperatively, although ventricular arrhythmias and conduction disturbances can also occur.

Atrial arrhythmias can be difficult for medical professionals to differentiate when monitoring surface ECG leads.

Due to this risk of postoperative arrhythmias, many patients have temporary epicardial pacing wires placed on the outside of their heart epicardium (outer layer of heart muscle) to permit pacing of the heart (via an artificial temporary pacemaker). The proximal ends of the epicardial pacing wires are normally wrapped and taped to the outer chest wall until needed for arrhythmia treatment.

Normally, cardiac rhythms are obtained from surface ECG electrodes placed on the patient's chest and viewed on bedside monitors. However, since atrial signals are not easily visualized using surface ECG electrodes, if the medical professional detects an irregularity, an ECG technician may be called to connect the epicardial pacing wires to an ECG monitor so that a medical professional can interpret the ECG signals with more accuracy (since the proximity of the recording wires to the atrial impulses greatly enhances atrial waveforms). If an arrhythmia is detected and the medical professional wishes to pace the heart, the epicardial pacing wires are detached from the ECG monitor and reconnected to a temporary pacemaker for pacing.

The process of connecting the epicardial pacing wires is time-consuming, and may need to be repeated for successive rounds of visualization and pacing. This also carries with it a risk of misconnection of three sets of wires from the ECG monitor, the pacemaker, and the epicardial connections.

SUMMARY OF THE INVENTION

The present invention provides a connector block that permits simultaneous and continuous interconnection of the three sets of wires of the epicardial pacing wires, the pacemaker, and the ECG monitor on clear, separately labeled connectors. As such, the connector block provides an intuitive and rapid interconnection system easily used in a hospital environment reducing procedure times and the chance of misconnection. By including circuitry to prevent excessive loading of the high-voltage pacer signals by the ECG monitor, the connector block may be used universally on all monitors without the need for sophisticated understanding of the electrical characteristics of the ECG monitor or concern for damage or improper signal loading.

Specifically, in one embodiment, the invention provides a connector box for connecting epicardial pacing leads of a patient to: (a) a pace generator which can analyze the rhythm and potentially deliver a pacing signal through the epicardial pacing leads to the heart of the patient and (b) a telemetry monitor receiving cardiac signals through the epicardial pacing leads from the heart of the patient, simultaneously to allow epicardial signals to be displayed on the monitor. The connector box includes first terminals for transmitting electrical cardiac signals to and from the epicardial pacing leads connected to the heart of the patient; second terminals for transmitting the epicardial signal to the pace generator and transmitting an electrical impulse to and from the pace generator; third terminals outputting a conditioned electrical signal to the telemetry monitor, and electrical circuitry connected with the first, second, and third terminals, which presents current division so the pacing current is propagated almost completely to the heart while the circuitry is receiving and conditioning the voltage potentials induced by the heart signal and the pacing signal with a clipper that limits the voltage sent to the monitor at at least one predetermined voltage level.

It is thus a feature of at least one embodiment of the invention to allow for simultaneous and continuous interconnection of epicardial pacing wires for pacing and diagnosis thus avoiding the cumbersome process of alternating the epicardial wires between pacemaker and telemetry.

The first, second, and third terminal may be labeled with an indicia identifying the epicardial leads, pacer generator, and telemetry monitor.

It is thus a feature of at least one embodiment of the invention to allow for intuitive and rapid connection of the appropriate connector to each terminal in the challenging environment of medical care.

In one embodiment, the connector box has a weight and a size adapted to be supported on the body of the patient.

It is thus a feature of at least one embodiment of the invention to reduce the risk of the wires from becoming dislodged from the epicardium due to pulling and maneuvering of the epicardial pacing wires. It is a further object of at least one embodiment of the invention to eliminate the need for extension leads on the epicardial wires.

Skin electrodes may be positioned on the body of the patient and received by the telemetry monitor to display both cardiac signals from the epicardial pacing leads and body electrodes.

It is thus a feature of at least one embodiment of the invention to permit simultaneous real-time monitoring of ventricular or atrial cardiac signals for improved rhythm discrimination and immediate analysis and feedback after pacing.

The first, second and third terminals may be mechanically releasable electrical connectors. The third terminals may have connectors matching those of skin electrodes positioned on the body. The connectors of the third terminals may be snaps providing attachment of the connector box to the telemetry monitor. It is thus a feature of at least one embodiment of the invention to use similar connectors (such as alligator clips or snaps) as used to connect surface electrodes to the telemetry monitor for increased adaptability.

The clipper may be an active clipping circuit using an operational amplifier. The active clipping circuit may provide a first gain multiplying circuit and a second dividing circuit and operates to clip by boosting the signal at the first

gain multiplying circuit beyond the output voltage range of the first gain multiplying circuit. The clipping circuit may provide a first and second clipping voltage level and clips the current limited combination signal if it exceeds the first clipping voltage level or is less than the second voltage clipping level.

It is thus a feature of at least one embodiment of the invention to maintain the scale necessary to monitor the ECG signals from becoming skewed by the pacing spikes and to protect the monitor from high voltage damage.

A passive clipping circuit may provide back-to-back diodes shunting the current limited combination signal. A low pass filter may filter high-frequency signals from the current limited combined signal.

It is thus a feature of at least one embodiment of the invention to condition the voltage potentials induced by the combined heart signal and pacing signal to limit the current entering the clipping circuit while preserving the battery life.

The present invention also facilitates a telemetry monitoring system to read the signals from the connecting epicardial leads of a patient, while also connecting to a pace generator adapted to allow a pacing signal through the epicardial pacing leads to a heart of the patient if needed. The system includes a telemetry monitor receiving cardiac signals through the epicardial pacing leads from the heart of the patient simultaneous with delivery of the pacing signal; and a connector box having first terminals for transmitting electrical cardiac signals to and from the epicardial pacing leads connected to the heart of the patient; second terminals for transmitting the electrical cardiac signals to the pace generator and transmitting an electrical impulse to and from the pace generator; third terminals outputting a conditioned electrical signal to the telemetry monitor; and electrical circuitry communicating with the first, second, and third terminals and providing a current limiter steering the electrical impulse predominantly to the heart of the patient and not to the electrical circuitry and receiving voltage signals induced by the heart; and a clipper limiting the voltage signals sent to the telemetry monitor at at least one predetermined voltage level.

The telemetry monitor has two connectors to the device, currently labeled as (LA) position input and a right arm (RA) position input, though other electrode position inputs could be utilized depending on the monitor. These connectors attach to the appropriate telemetry leads to transfer the conditioned electrical signal into the LA and RA telemetry inputs, or other electrode position inputs as necessary.

It is thus a feature of at least one embodiment of the invention to adopt the connector box for use with any telemetry monitor system to display an atrial electrogram (AEG) using atrial epicardial connections on the telemetry.

The epicardial pacing leads are connected to the atrium or ventricle of the patient.

It is thus a feature of at least one embodiment of the invention to provide improved atrial signals for differentiating atrial and junctional arrhythmias when P waves are not clearly visible from the surface electrode ECG.

The present invention also provides a method of delivering cardiac signals to a telemetry monitor and delivering pacing signals to a patient simultaneously utilizing a connector box with a first terminal for transmitting electrical signals to and from epicardial pacing leads connected to an epicardium of the heart; a second terminal for transmitting the electrical cardiac signals to the pace generator and transmitting an electrical impulse to and from a pace generator, a third terminal outputting a conditioned electrical signal to the telemetry monitor, and electrical circuitry communicating with the first, second, and third terminal and providing a current limiter steering the electrical impulse predominantly to the heart of the patient and not to the electrical circuitry and receiving voltage signals induced by the heart; and a clipper limiting the voltage sent to the telemetry monitor at at least one predetermined voltage level, the method including the steps of: connecting epicardial pacing leads to the first terminal; connecting a pacemaker connector to the second terminal; and connecting the telemetry monitor to the third terminal.

These particular objects and advantages may apply to only some embodiments falling within the claims and thus do not define the scope of the invention.

BRIEF DESCRIPTION OF THE FIGURES

FIG. **1** is a perspective view of an adaptor of the present invention positioned between epicardial pacing wires sutured to the patient and medical devices requiring access to those epicardial pacing wires;

FIG. **2** is a simplified block diagram of one embodiment of the present invention showing the adaptor communicating between the epicardial pacing wires, a pacemaker and a 5-electrode telemetry monitor;

FIG. **3** is a perspective view of a right side of the adaptor showing a labeled terminal for connecting a pacemaker and a labeled terminal for connecting a right arm (RA) lead to a telemetry monitor cable:

FIG. **3**A is a perspective view of an alternative connector of the terminal connecting the RA lead;

FIG. **4** is a perspective view of a left side of the adaptor showing labeled terminals for connecting epicardial leads and a labeled screw terminal for connecting a left arm (LA) lead of the telemetry monitor cable; and

FIG. **5** is a schematic of the conditioning circuitry of the adaptor used to allow pacing output and to eliminate pacing artifact.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. **1**, the connector block **10** of the present invention may provide a hub between a patient **12** and multiple medical devices including a pulse generator **32** delivering pacing signals to the patient **12** and a telemetry monitoring system **24** for visualizing cardiac signals **44**, **46** of a heart **14** of the patient **12**.

The patient **12** may be supported on a patient bed or table **50** in a hospital environment, for example, in a surgical room following cardiac surgical procedure. The connector block **10** may be conveniently positioned near the patient **12**, such as mounted to the patient bed or table **50** to provide a stable connection point in close proximity to the patient **12**. Alternatively, and preferably, the connector block **10** may have a size and weight, which allows it to be taped or otherwise adhered to the patient's chest or body to avoid dislodgement or accidental removal of the patient connections. For example, the connector block **10** may have an adhesive backing, which it stuck directly onto the patient's chest or body.

Referring now also to FIG. **2**, a first connection is made to the patient **12** by placing epicardial pacing wires **20***a*, **20***b* directly on an epicardium of the heart **14** of the patient **12**. The epicardial pacing wires **20***a*, **20***b* are typically installed during surgery, with small electrode needle tips on one end sutured into the atrial epicardium of the heart **14** and larger needles on the other end penetrating the body wall and

exiting the skin at puncture wound **48** in the chest, bringing the epicardial pacing wires **20***a*, **20***b* to the surface of the skin. For example, in a bipolar circuit a positive electrode and negative electrode may be placed in each chamber of the heart **14**, typically the right atrium and/or right ventricle. The positive electrode and negative electrode may be found on two separate wires or on a single wire with the electrodes typically placed about 8 mm apart (for example, Medtronic Bipolar Coaxial 6495).

In the exemplary embodiment, the positive and negative electrodes are epicardial pacing wires **20***a* and **20***b*, respectively, placed at the right atrium of the heart **14** to serve the dual purpose of atrial pacing and atrial visualization as described below. The epicardial pacing wires **20** then extend from the patient **12** and connect to the external connector block **10** to allow for these dual functions to operate simultaneously.

During pacing, the epicardial pacing wires **20***a*, **20***b* are used to deliver a small electrical current from the negative electrode to the positive electrode to activate myocardial cells of the heart **14**. A pulse generator **32** may be connected to the connector block **10** to thereby deliver this electrical current to the epicardial pacing wires **20***a*, **20***b*. For example, the pulse generator **32** may deliver a ventricular pacing impulse to the ventricle of the heart or deliver an atrial pacing impulse to the right atrium of the heart. The source of the pacing energy is typically a rechargeable or replaceable battery in the pulse generator **32**. In the exemplary embodiment, the pulse generator **32** delivers an atrial pacing impulse to the connector box **10** which in turn is delivered to the epicardial pacing wires **20***a*, **20***b* connected to the right atrium of the heart **14**. Atrial signals from the heart **14** may return through the epicardial pacing wires **20***a*, **20***b* and be delivered to the pulse generator **32** which then applies processing algorithms to the atrial signals to determine a proper pacing prescription. The pulse generator **32** may be, for example, Medtronic 5392, 5391, 5348, 5388 Dual Chamber Temporary Pacemakers.

During visualization, the epicardial pacing wires **20***a*, **20***b* are able to transmit changes in electric potential between the positive and negative electrodes during cardiac rhythm. In the exemplary embodiment, the connector block **10** receives these electrical heart signals and conditions these signals, which is in turn delivered to the telemetry monitoring system **24** for atrial visualization as further described below.

A second connection is made to the patient **12** by placing multiple surface ECG electrodes **26** on a body of the patient **12**. The surface ECG electrodes **26** are used to detect the electrical changes on the skin that arise from the heart's depolarization during cardiac rhythm. For example, the surface ECG electrodes **26** are placed at known body positions for a 3-electrode system (3-lead ECG), 5-electrode system (5-lead ECG) and 10-electrode system (12-lead ECG).

Referring still to FIG. **2**, in the illustrated embodiment, three ECG electrodes **26** are attached to the patient **12**. The surface ECG electrodes **26** may provide conductive gel pads that are adhered to the body of the patient **12** with outwardly protruding buttons **64** that "snap on" to fasteners **30** of three ECG cables **28**, respectively, which can deliver the surface ECG signals directly to the telemetry monitoring system **24**.

The telemetry monitoring system **24** may allow for real time visualization of the cardiac signals from the patient **12** by displaying the signals on a monitor **38** for analysis by the medical professional. The signals from the multiple surface ECG electrodes **26** are delivered through the multiple ECG cables **28** directly to the telemetry monitoring system **24**, which receives the ECG cardiac signals and displays them on the monitor **38**. In contrast, the leads from the epicardial pacing wires **20***a*, **20***b* may connect through the connector block **10** which may then deliver the conditioned epicardial signals to the telemetry monitoring system **24**. In this manner the telemetry monitoring system **24** may allow both the surface ECG electrode waveforms **46** and epicardial waveforms **44** to be viewed simultaneously on the monitor **38**. It is understood that other patient parameters may be displayed on the monitor **38** or be monitored by the telemetry monitoring system **24**, such as peripheral pulse oximetry, blood pressure, respiratory rate, body temperature, etc.

Referring now to FIGS. **3** and **4**, the multi-device connector block **10** may provide a housing **52**, for example, having outer walls defining a rectangular inner volume **68** sealed from contamination. The housing **52** includes a bottom wall **78** joined on its right and left edges by upwardly extending right **70** and left **72** sidewalls, respectively, and joined on its top and bottom edges by upwardly extending top **74** and bottom **76** sidewalls, respectively. A top cover **66** is attachable over the inner volume **68** and may be permanently sealed, such as glued shut, to enclose the volume **68** or may be removable to allow access to the volume **68** containing the conditioning circuitry **54** therein. The top cover **66** may include a label **90**, such as an ECG signal graphic or text label clearly denoting the function of the connector block **10** as an epicardial/pacer/monitor interconnection box. Different iterations of the device will allow variable designs of the block **10**, such as a low profile device which can attach to the chest.

Referring now to FIGS. **2** and **4**, the left sidewall **72** may include a pair of small openings **82** providing access to epicardial terminals **22** therein for connection of the epicardial pacing wires **20***a*, **20***b*. The epicardial terminals **22** may be a spring-loaded terminal allowing the wires to be engaged and disengaged by sliding into and out of the epicardial terminals **22**. The epicardial terminals **22** are stabilized within the housing **52** for connection of the epicardial pacing wires **20***a*, **20***b* to the connector block **10**. The epicardial terminals **22** are adapted to receive and grip the epicardial pacing wires **20***a*, **20***b* extending into the openings **82** and connect the wires to the conditioning circuitry **54** within the housing **52**. It is understood that the epicardial terminals **22** may be any suitable wire connector such as terminal blocks, posts, crimp on connectors, insulation displacement connector, etc. connecting the epicardial pacing wires **20***a*, **20***b* to the internal conditioning circuitry **54**.

The openings **82** for the epicardial pacing wires **20***a*, **20***b* may be labeled on the left sidewall **72** of the housing **52** with a label **86** to clearly indicate connection of epicardial pacing wires **20** to the epicardial terminals **22**. The label **86** may use the term "EPI" or "EPICARDIAL" or another clearly recognizable term or abbreviation, representing connection of epicardial pacing wires **20***a*, **20***b*. Generally the label **86** may be any of a sticker, a decal, a label printed directly on the housing **52** or molded into the housing **52**.

Referring now to FIGS. **2** and **3**, the right sidewall **70** may include a small opening **80** allowing attachment therethrough of a pacemaker cable **34** (connecting the pulse generator **32**) to pace terminals **36** of the connector block **10**. The pace terminals **36** are stabilized within the housing **52** for connection of the pacemaker cable **34** to the connector block **10**. The pacemaker cable **34** may be an industry standard connector, for example, Medtronic 5433 (Atrial) Cable, connecting the pulse generator **32** on one end to epicardial pacing wires **20** or electrodes on the other end. In the exemplary embodiment, the pacemaker cable **34** pro-

vides both positive wire **39***a* and negative wire **39***b* therein. The pace terminals **36** receive the wires **39***a*, **39***b* of the pacemaker cable **34** and separately conducts positive **39***a* and negative **39***b* wires to electrically couple the wires **39***a*, **39***b* to the internal conditioning circuitry **54** of the connector block **10** for delivery of the current pulse to the epicardial pacing wires **20***a*, **20***b* for pacing.

Generally, during bipolar pacing, a small electrical current is delivered by the pulse generator **32** to the negative pacing wire **39***b*, which travels through the connector block **10** to the negative epicardial pacing wire **20***b*, which delivers the current pulse to the heart **14**. The returning current travels through the positive epicardial pacing wire **20***a* through the connector block **10** to the positive pacing wire **39***a*, which finally returns to the pulse generator **32** to complete the circuit. The pacemaker cable **34** may also receive atrial signals from the heart **14** (via epicardial pacing wires **20***a*, **20***b* placed on the heart **14** and delivering the atrial signals to the connector box **10**), and deliver the atrial signals to the pulse generator **32** for analysis to determine a proper pacing prescription.

The opening **80** for the pacemaker cable **34** may be labeled on the right sidewall **70** of the housing **52** with a label **81** to clearly indicate connection of the pacemaker cable **34**. The label **81** may use the term "PACE" or another clearly recognizable term representing connection of the pacemaker cable **34**/pulse generator **32** and may be fabricated as discussed above.

Referring now to FIGS. **2**, **3** and **4**, in one embodiment, the sidewalls **70**, **72** of the housing **52** also include electrically conductive bolts or screws **60***a*, **60***b*, respectively, threaded into the sidewalls **70**, **72** with a tip **63** of the screws **60***a*, **60***b* extending into the housing **52** and a shank **65** and head **67** of the screw **60***a*, **60***b* extending outwardly from the housing sidewalls **72**, **70**. The screws **60***a*, **60***b* are electrically coupled to the internal conditioning circuitry **54**, for example by soldering conductive wire between the internal conditioning circuitry **54** and the tips **63** of the screws **60***a*, **60***b*.

Electrical conductors **58***a*, **58***b* may be used to connect the screws **60***a*, **60***b* to a multichannel ECG monitor cable **40** of the telemetry monitoring system **24** allowing the conditioned epicardial signals to be viewed on the monitor **38**. The electrical conductors **58***a*, **58***b* connecting the screws **60***a*, **60***b* to the multichannel monitor cable **40** may include conductive clips **56***a*, **56***b*, such as alligator clips, on theirs first ends allowing the electrical conductors **58***a*, **58***b* to clip onto the screws **60***a*, **60***b*. The second opposite ends of the electrical conductors **58***a*, **58***b* are connected to the multichannel monitor cable **40**.

In an alternative embodiment, as seen in FIG. **3***a*, the screws **60***a*, **60***b* may be replaced with snaps **61**, similar to buttons **64** found on surface electrodes **26**, extending between an interior of the housing **52** and exterior of the housing **52** to conduct the conditioned epicardial signal through the snaps **61**. The snaps **61** are attachable to the fasteners **30** of normal ECG cables **28** (see FIG. **2**) allowing the standard ECG cables **28** to be used instead of the electrical conductors **58***a*, **58***b*.

Referring now to FIG. **2**, in the exemplary embodiment, the telemetry monitoring system **24** is a multichannel system that accepts a 5-electrode input with electrode positions at the IRA, RL, LA, LL and chest positions. In this respect, the ECG monitor cable **40** of the telemetry monitoring system **24** includes a plurality of terminals **18** for receiving each of the 5-electrode inputs, i.e., RA, RL, LA, LL and chest. Typically, the respective surface ECG electrodes **26** are connected to each of the 5-electrode inputs. However, the variable surface electrode positions, such as the RA or LA, may be omitted and replaced by the electrical conductors **58***a*, **58***b*, respectively. In this iteration, the electrical conductor **58***a* delivers a signal output from the screw **60***a* to the RA surface electrode position and the electrical conductor **58***b* is attached to screw **60***b*, which is connected to ground, and connected at the LA surface electrode position. Thus, RA and LA terminals **18** of the ECG monitor cable **40** receive connections from the epicardial pacing wires **20***a*, **20***b* (via connector block **10**) and the RL, LL and chest terminals **18** are connected directly to the respective surface ECG electrodes **26**. It is understood that other surface electrode inputs could be utilized depending on the telemetry unit. For example, instead of RA or LA inputs, the chest terminal input may be used instead.

The right screw **60***a* extending outwardly from the right sidewall **70** may be labeled with a label **84** to clearly indicate that it may replace the RA connection of the multichannel monitor cable **40**, such as with the letters "RA", and the left screw **60***b* extending outwardly from the left sidewall **72** may be labeled with a decal **88** to clearly indicate that it may replace the LA connection of the multichannel monitor cable **40**, such as with the letters "LA".

It is understood that the telemetry monitoring system **24** may also accept 3-electrode and 12-electrode systems and similarly replace the RA and LA electrode positions with the epicardial pacing wires **20** (via connector block **10**) and still simultaneously display the surface ECG electrodes **26** heart signals. For example, in a 3-electrode system the electrical conductors **58***a*, **58***b* representing epicardial pacing wires **20***a*, **20***b* are attached to the RA and LA electrode positions, respectively, and a surface ECG electrode **26** is connected to a LL electrode position on the patient **12**.

Referring now to FIG. **5**, when atrial pacing and atrial visualization are performed simultaneously, pacing artifact can be seen on the monitor **38** as high magnitude pacing stimuli or spikes. In order to maintain the scale necessary to view the smaller atrial epicardial signals (in the lower mV range) compared to the much large pacing artifact (10-20 V range) the internal conditioning circuitry **54** of the connector block **10** processes the incoming epicardial signals before delivering them to the telemetry monitoring system **24**. By reducing the pacing artifact, the monitor **38** is also protected from distortion, noise, and damage. The internal conditioning circuitry **54** attempts to preserve the incoming atrial epicardial signals as close to their original signal levels as possible.

As mentioned above, the positive **39***a* and negative **39***b* wires of the pacemaker cable **34** from the pulse generator **32** may be received at terminal **36** exposed through the housing **52** and connect respectively to junction points **104***a* and **104***b* on the circuitry **54** held within the housing **52**. The same junction points **104***a* and **104***b* may also connect to epicardial terminals **22** exposed through the housing **52** and communicating with the epicardial pacing wires **20***a* and **20***b*.

Junction points **104***a* and **104***b* may connect to passive current limiting circuitry **92**. For example, junction **104***a* connects to a first terminal of resistor **106***a* and junction **104***b* connects to a first terminal of resistor **106***b*. The resistors **106***a*, **106***b* are sized for example to be 10 kilo-ohms or larger to prevent undue loading on the pacer signals by the circuitry **54** thus providing input current limiting circuitry **92**.

Following the current limiting circuitry **92**, the signal is received by a first passive clipping circuit **94** that provides

voltage protection of the internal conditioning circuitry **54** against high voltages of the pacing signal. Specifically, the remaining lead of resistor **106***a* provides a common juncture point with a cathode of diode **108***a*, an anode of diode **108***b*, one terminal of filter capacitor **110***a*, and a negative (inverting) input of operational amplifier **112**. The remaining terminal of capacitor **110***a* connects to ground. Similarly the remaining lead of resistor **106***b* connects to an anode of diode **108***a*, a cathode of diode **108***b*, one terminal of filter capacitor **110***b*, and the positive (noninverting) input of operational amplifier **112**. The remaining terminal of capacitor **110***b* connects to ground. The diodes **108***a* and **108***b*, thus connected back-to-back, provides a first passive clipping circuit **94** limiting the voltage to approximately the 0.7 volt conduction threshold of the diodes **108**.

Following the first protective clipping circuit **94**, a low pass filter **96** reduces the high voltage spikes of the pacer signal that occur before conduction of the diodes **108** before being passed onto the active clipping stage. For example, capacitors **110***a*, **110***b* together with the resistance of resistors **106***a*, **106***b* provide a low pass filter **96** having a frequency cut off of approximately 50 kilohertz.

Following the low pass filter **96**, an active clipping circuit provides a gain block **98** that "clips" the high voltage spikes by boosting the gain of the incoming signal. Since the system supply reference voltage limits the overall signal amplitude to slightly below the supply reference voltage (e.g. approximately plus and minus 1.5 volts), the high voltage pacing artifact is cut off or "clipped" above the supply reference voltage. For example, the operational amplifier **112** has its noninverting input connected through resistor **111** to ground. The inverting input also connects to the output of the operational amplifier **112** through parallel connected resistor **114** and capacitor **116**. These components are connected to provide a voltage stable gain of approximately 100 by the operational amplifier **112** providing gain block **98**.

The amplifiers remain "saturated" so the top of the signal flattens out and remains flattened until the signal amplitude is decreased to below the supply reference voltage. The added gain provided by the operational amplifier **112** for the purpose of clipping is then removed for the purpose of restoring the signals to their proper level by using a division block **100** to divide the signal by a factor of 100 and bring it back down to its original value. For example, operational amplifier **112** is followed by a divider circuit comprised of series connected resistors **118** and **120** leading to ground. The junction of these resistors provides a divided voltage of approximately 100. These resistors **118** and **120** provide division block **100**.

As noted, the effect of the successive application of gain block **98** and divider block **100** is to return the voltage received at the gain block back to the same voltage output from the divider block **100**. The purpose of the successive operations is to boost the signal received by operational amplifier **112** beyond a compliance voltage range of that amplifier causing the amplifiers' fundamental limitations resulting from the voltage limits of its power rail to effectively clip the pacemaker signal at a desired voltage. For this purpose operational amplifier may be TLV **272** operational amplifier commercially available from Texas Instruments and having rapid recovery from clipping. Together gain block **98** and divider block **100** provide an active clipping circuit of high precision operating at a low voltage (the diodes below the level of 108 suitable for use with the present invention. The clipping provided by these blocks prevents the signal from the pacemaker from overwhelming the monitor **38** such as may provide a distorted signal, signal noise, or even monitor damage.

Following the voltage divider **100**, an isolation amplifier **102** buffers the load provided by the monitor **38** for example preventing undue current from being diverted from the voltage divider **100**. Specifically, a voltage at the junction of resistors **118** and **120** may be received by the noninverting input of operational amplifier **122** configured with its inverting input connected to its output to provide a unity gain buffer amplifier. The output of amplifier **122** provides leads **41***a* accessible through screw **60***a* to the monitor **38** with lead **41***b* accessible through screw **60***b* being reference to ground also provided to monitor **38**.

The operational amplifiers **112** and **122** may be provided with electrical power from a contained battery or an appropriately isolated power supply as is generally understood in the art. The voltage provided to the operational amplifier **112** will desirably be regulated so as to provide an accurate clipping level for the circuit.

In operation, the connector box **10** is installed on or near the patient **12**. The epicardial pacing wires **20***a*, **20***b* emerging from the puncture wound **48** in the chest of the patient **12** are inserted into the openings **82** of the left sidewall **72** of housing **52**, labeled "EPI", providing access to the epicardial terminals **22**. The wires **20***a*, **20***b* are attached to the epicardial terminals **22** coupling the wires **20***a*, **20***b* to the connector box **10**. Then, the pacemaker cable **34** attached to the pulse generator **32** on one end is inserted into the opening **80** of the right sidewall **70** of the housing **52**, labeled "PACE", providing access to the pace terminals **36**. The pacemaker cable **34** is attached to the pace terminals **36** coupling the pacemaker cable **34** to the connector box **10**. Finally, electrical conductors **58***a*, **58***b* are clipped or snapped onto screws **60***a*, **60***b* of the left **72** and right **70** sidewalls of the housing **52**, labeled "RA" and "LA". The other end of the electrical conductors **58***a*, **58***b* are inserted into the RA and LA terminals **18**, respectively, of the multichannel monitor cable **40** coupling the connector box **10** to the telemetry monitoring system **24**. The medical professional may also install surface ECG electrodes **26** on the patient **12** at known ECG electrode positions on the body. ECG cables **28** may then be clipped or snapped onto the buttons **64** of the surface ECG electrodes **26** on one end and inserted into the respective terminals **18** (e.g., RL, LL, chest) of the monitor cable **40** on the other end.

Once the three connections are made to the connector box **10** of the epicardial paving wires **20***a*, **20***b*, pulse generator **32**, and telemetry monitoring system **24**, the medical professional may view the patient's cardiac signals on the monitor **38** of the telemetry monitoring system **24** to view the epicardial waveforms **44**. If surface ECG electrodes **26** are coupled to the telemetry monitoring system **24**, the medical professional may view the surface ECG electrode waveforms **46** and epicardial waveforms **44** simultaneously. During cardiac visualization, the medical professional may deliver pacing pulses to the patient **12** through the epicardial pacing wires **20***a*, **20***b* by initiating the appropriate prompts on the pulse generator **32**. Simultaneous with and immediately after pacing, the medical professional may view the surface ECG electrode waveforms **46** and epicardial waveforms **44** on the monitor **38** to determine if additional pacing is needed in a quick and convenient manner.

Certain terminology is used herein for purposes of reference only, and thus is not intended to be limiting. For example, terms such as "upper", "lower", "above", and "below" refer to directions in the drawings to which reference is made. Terms such as "front", "back", "rear", "bot-

tom" and "side", describe the orientation of portions of the component within a consistent but arbitrary frame of reference, which is made clear by reference to the text and the associated drawings describing the component under discussion. Such terminology may include the words specifically mentioned above, derivatives thereof, and words of similar import. Similarly, the terms "first", "second" and other such numerical terms referring to structures do not imply a sequence or order unless clearly indicated by the context. When elements are indicated to be electrically connected, that connection may be direct or through an intervening conductive element.

When introducing elements or features of the present disclosure and the exemplary embodiments, the articles "a", "an", "the" and "said" are intended to mean that there are one or more of such elements or features. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements or features other than those specifically noted. It is further to be understood that the method steps, processes, and operations described herein are not to be construed as necessarily requiring their performance in the particular order discussed or illustrated, unless specifically identified as an order of performance. It is also to be understood that additional or alternative steps may be employed.

It is specifically intended that the present invention not be limited to the embodiments and illustrations contained herein and the claims should be understood to include modified forms of those embodiments including portions of the embodiments and combinations of elements of different embodiments as come within the scope of the following claims. All of the publications described herein, including patents and non-patent publications, are hereby incorporated herein by reference in their entireties.

The invention claimed is:

1. A method of delivering cardiac signals to a telemetry monitor and delivering pacing signals to a patient simultaneously, the method comprising the steps of:

providing a connector box with a first terminal for transmitting electrical signals to and from epicardial pacing leads connected to an epicardium of a heart; a second terminal for transmitting the electrical cardiac signals to the pace generator and transmitting an electrical impulse to and from a pace generator; a third terminal outputting a conditioned electrical signal to the telemetry monitor; and electrical circuitry communicating with the first, second, and third terminal and providing a current limiter steering the electrical impulse predominantly to the heart of the patient and not to the electrical circuitry and receiving voltage signals induced by the heart; and a clipper limiting the voltage signal sent to the telemetry monitor at at least one predetermined voltage level;

connecting the epicardial pacing leads to the first terminal;

connecting a pacemaker connector connecting the pace generator to the second terminal; and

connecting the telemetry monitor to the third terminal.

2. The method of claim **1** further comprising the step of displaying the conditioned electrical signal on the telemetry monitor.

3. The method of claim **2** further comprising the step of placing surface electrodes on a chest of the patient.

4. The method of claim **3** further comprising the step of electrically connecting the surface electrodes to the telemetry monitor and displaying a cardiac signal from the surface electrodes on the telemetry monitor.

5. The method of claim **1** further comprising the step of adhering the connector box to the chest of the patient.

6. The method of claim **1** further comprising the step of connecting the epicardial pacing leads to a right atrium of a patient's heart.

7. A connector box for connecting epicardial pacing leads of a patient to: (a) a pace generator delivering a pacing signal through the epicardial pacing leads to a heart of the patient and (b) a telemetry monitor receiving cardiac signals through the epicardial pacing leads from the heart of the patient, simultaneously, comprising:

first terminals configured to transmit electrical cardiac signals to and from the epicardial pacing leads connected to the heart of the patient;

second terminals configured to transmit the electrical cardiac signals to the pace generator and transmitting an electrical impulse to and from the pace generator;

third terminals configured to output a conditioned electrical signal to the telemetry monitor; and

electrical circuitry configured to communicate with the first, second, and third terminals and comprising

a current limiter configured to steer the electrical impulse predominantly to the heart of the patient and not to the electrical circuitry and configured to receive voltage signals induced by the heart; and

a clipper configured to limit the voltage signals sent to the telemetry monitor at at least one predetermined voltage level.

8. The connector box of claim **7** wherein the clipper is an active clipping circuit using an operational amplifier.

9. The connector box of claim **8** wherein the active clipping circuit provides a first gain multiplying circuit and a second dividing circuit and operates to clip by boosting the signal at the first gain multiplying circuit beyond an output voltage range of the first gain multiplying circuit and then attenuating the signal back to a cardiac signal voltage range suitable to be displayed by the associated telemetry monitor.

10. The connector box of claim **9** wherein the active clipping circuit provides a first and second clipping voltage level and clips a current limited combination signal if it exceeds the first positive clipping voltage level or is less than the second negative voltage clipping level.

11. The connector box of claim **7** further comprising a passive clipping circuit providing back-to-back diodes shunting the current limited combination signal.

12. The connector box of claim **7** further including a low pass filter filtering high-frequency signals from the current limited combined signal.

13. The connector box of claim **7** wherein the first, second, and third terminals are labeled with an indicia identifying a one of the epicardial leads, pacer generator, and telemetry monitor.

14. The connector box of claim **13** wherein the connector box has a weight and a size adapted to be supported on the body of the patient.

15. The connector box of claim **13** further including skin electrodes configured to be positioned on a body of the patient and configured to communicate with the telemetry monitor to display both cardiac signals from the epicardial pacing leads and body electrodes.

16. The connector box of claim **13** wherein the third terminals have connectors matching those of skin electrodes positionable on the body.

17. The connector box of claim **7** wherein the connectors of the third terminals are snaps providing attachment of the connector box to the telemetry monitor.

18. The connector box of claim 7 wherein the first, second and third terminals are mechanically releasable electrical connectors.

19. A telemetry monitoring system for connecting epicardial pacing leads of a patient to a pace generator adapted to deliver a pacing signal through the epicardial pacing leads to a heart of the patient, comprising:

a telemetry monitor configured to receive cardiac signals through the epicardial pacing leads from the heart of the patient; and

a connector box having

first terminals configured to transmit electrical cardiac signals to and from the epicardial pacing leads connected to the heart of the patient;

second terminals configured to transmit the electrical cardiac signals to the pace generator and configured to transmit an electrical impulse to and from the pace generator;

third terminals configured to output a conditioned electrical signal to the telemetry monitor; and

electrical circuitry configured to communicate with the first, second, and third terminals and comprising

a current limiter configured to steer the electrical impulse predominantly to the heart of the patient and not to the electrical circuitry and receiving voltage signals induced by the heart; and

a clipper configured to limit the voltage signals sent to the telemetry monitor at at least one predetermined voltage level

wherein the telemetry monitor simultaneously receives cardiac signals with the delivery of pacing signals by the pace generator.

20. The system of claim 19 wherein the telemetry monitor has a connector having two monitoring electrode position inputs and is configured to receive the conditioned electrical signal into the two monitoring electrode position inputs.

* * * * *

专利名称(译)	适配器，可通过临时心外膜导线进行电描记图观察和起搏		
公开(公告)号	US10471261	公开(公告)日	2019-11-12
申请号	US15/229371	申请日	2016-08-05
[标]申请(专利权)人(译)	威斯康星校友研究基金会		
申请(专利权)人(译)	威斯康星校友研究基金会		
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外部链接	Espacenet		

摘要(译)

提供了一个连接器块，该块允许在透明且单独标记的连接器上同时连续连接心外膜起搏线，起搏器和ECG监护仪的三根导线。提供的电路允许在遥测单元上显示心外膜信号，同时仍保留起搏器对心脏起搏的能力。在起搏时，连接器块可防止ECG监护仪过度加载起搏器信号和/或防止高压起搏器信号损坏监护仪。该连接器块可普遍用于所有监视器，而无需对ECG监视器的电气特性有深入的了解，也无需担心损坏或信号加载不当。