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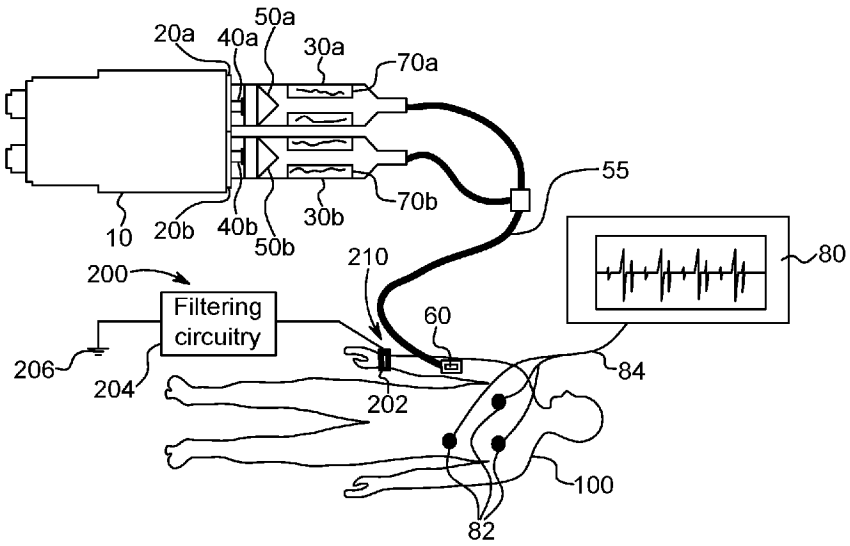

FIG. 2

(57) Abstract: A system for suppressing electrical noise in an electrocardiogram (ECG) signal displayed on an ECG monitor includes: a conductive material provided in contact with a surface of a patient; and filtering circuitry connected in series between the conductive material and ground. The filtering circuitry may be configured to filter to ground the electrical noise present within the patient.

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[Continued on next page]

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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SYSTEM AND METHOD FOR SUPPRESSING NOISE FROM ELECTROCARDIOGRAPHIC (ECG) SIGNALS

BACKGROUND

Field

[0001] The present disclosure relates to systems and methods for suppressing noise generated in an electrocardiographic (ECG) signal displayed on an ECG monitor due to external electrical equipment and, more particularly, to the suppression of noise generated in an ECG signal due to the presence of a powered injector in the vicinity of a patient.

Description of Related Art

[0002] Angiography is used generally in the detection and treatment of abnormalities or restrictions in blood vessels. In an angiographic procedure, one obtains a radiographic image of vascular structure with the assistance of a radiographic contrast medium (sometimes referred to simply as contrast) injected through a catheter. The vascular structures in fluid connection with the vein or artery in which the contrast is injected are filled with contrast. X-rays passing through the region of interest are absorbed by the contrast, causing a radiographic outline or image of blood vessels containing the contrast. The resulting images can be displayed on, for example, a monitor and recorded.

[0003] With reference to **FIG. 1**, in a typical medical imaging environment, a patient **100** is positioned in a room that includes an imaging system (not shown) as well as an injection system for injecting contrast and/or saline into the patient. One example of the injection system can include an injector **10** such as the MEDRAD® Stellant® CT Injection System available from the Radiology business of the Pharmaceutical Division of Bayer AG of Indianola, Pennsylvania, U.S.A. The injector **10** includes two syringe interfaces **20a** and **20b** to which two syringes **30a** and **30b** are removably attachable. Two drive members or pistons **40a** and **40b** operatively connect to plungers **50a** and **50b** slidably disposed in syringes **30a** and **30b**, respectively, to pressurize and inject the fluid therefrom into the patient **100** via a catheter **60** in fluid connection with syringes **30a** and **30b**. In addition, heater jackets **70a** and **70b** may be provided to maintain the fluid within the syringes **30a** and **30b** at a predetermined temperature. As shown in **FIG. 1**, such heater jackets **70a** and **70b** may each include an arcuate resistance heater portion configured to snap over the cylindrical body of the syringes **30a** and **30b**.

[0004] Further details of such injectors, control systems therefor, and injector protocols used therewith are described, for example, in United States Patent Nos. 5,494,036, 6,339,718, 6,643,537, and 6,958,053, the disclosures of which are incorporated herein by reference.

[0005] In many instances, a patient scheduled for a scanning procedure may also be connected to a vital signs monitoring system, such as an ECG monitor **80**, via a plurality of electrodes **82** attached to the skin of the patient. Each electrode **82** is connected via a lead **84** to the ECG monitor **80**. Electrical noise/disturbance(s) are generated as a result of the use of the injector **10** and related equipment. For instance, electrical noise may be generated when the heater jackets **70a** and **70b** are turned on and off or due to an electrical disturbance (i.e., an ESD field) that may develop during the delivery of a fluid by the injector **10** due to the dissimilarities between the materials used for the barrels of the syringes **30a** and **30b** (e.g., plastic) and the plungers **50a** and **50b** (e.g., rubber). This electrical noise can be conveyed from the injector **10** and related equipment to the patient **100** via, for example, a fluid path **55** connecting the injector **10** to the catheter **60**, which is conductive by virtue of the contrast medium or saline therein.

[0006] Unless this noise is safely routed to earth (low impedance), the noise will be picked up by the electrodes **82** of the ECG monitor **80**. The noise/electrical disturbance then causes a distortion **86** of the ECG signals displayed on the ECG monitor **80**. This is because the noise that is generated by the injector **10** and related equipment occupies the same part of the electromagnetic/frequency spectrum as the electrical (cardiac) signals generated by the heart of the patient **100**.

[0007] Accordingly, a need exists for a system to safely route to ground noise generated by external electrical equipment, such as a powered injector system, positioned in proximity to a patient connected to an ECG monitor such that this noise is prevented from causing distortions in the ECG signals that are displayed on an ECG monitor.

SUMMARY

[0008] The present disclosure describes examples of filtering circuitry that, when in use, will be connected in series between ground and a non-magnetic, yet metallic, element, such as a wrist strap, configured to be positioned in contact with a patient. The filtering circuitry, which may employ an array of selected capacitors, allows the system to filter to ground the electrical noise generated by the injector and related equipment while the cardiac signals generated by the heart are still picked up by the electrodes of an ECG monitor and conveyed to the ECG monitor for display free of such noise.

[0009] Accordingly, provided is a system for suppressing electrical noise in an electrocardiogram (ECG) signal displayed on an ECG monitor. The system comprises: a conductive material provided in contact with a surface of a patient; and filtering circuitry connected in series between the conductive material and ground. The filtering circuitry is configured to filter to ground the electrical noise present within the patient.

[0010] In one example, the electrical noise may be generated by at least one electrical device located near the patient. In the examples described hereinafter, the at least one electrical device may be a powered injector and associated devices. However, this is not to be construed as limiting the present disclosure as the electrical noise may be generated by other electrical devices located near the patient such as a heating device, anesthesiology equipment, or electrosurgical equipment.

[0011] In an example of the present disclosure, the conductive material may be provided as a bracelet configured to be worn on a wrist of the patient. The conductive material may be provided on an interior surface of the bracelet with an exterior surface of the bracelet is made from an insulated material. In addition, the conductive material is desirably non-magnetic so as not to interfere with medical imaging equipment.

[0012] In one example, the filtering circuitry may be configured as an array of capacitors. The array of capacitors may include four capacitors, each of which having a capacitance of about 0.0047 μF.

[0013] A specific example of the system comprises a wrist strap positioned around the wrist of a patient and comprising a conductive material provided in contact with a surface of the patient; and filtering circuitry comprising an array of capacitors connected in series between the conductive material of the wrist strap and ground. The filtering circuitry is configured to filter to ground the electrical noise present within the patient that is generated by at least one electrical device located near the patient.

[0014] Also provided is a method for suppressing electrical noise in an electrocardiogram (ECG) signal displayed on an ECG monitor. The method comprises: providing a conductive material in contact with a surface of a patient; providing filtering circuitry connected in series between the conductive material and ground; and filtering to ground, with the filtering circuitry, electrical noise present within the patient.

[0015] These and other features and characteristics of the device of the present disclosure, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the

accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the device of the present disclosure. As used in the specification and the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] **FIG. 1** is a schematic diagram of a conventional arrangement for delivering a fluid to a patient with an injector system during an imaging procedure;

[0017] **FIG. 2** is a schematic diagram of an arrangement for delivering a fluid to a patient with an injector system during an imaging procedure that includes a system for suppressing electrical noise in an ECG signal displayed on an ECG monitor in accordance with the present disclosure;

[0018] **FIG. 3** is a schematic diagram of an example of the system for suppressing electrical noise in an ECG signal displayed on an ECG monitor in accordance with the present disclosure;

[0019] **FIG. 4** is a waveform obtained that illustrates the noise generated when a heater jacket is turned on and off;

[0020] **FIG. 5** is a waveform obtained that illustrates the manner in which the noise generated by the heating jacket is suppressed utilizing the system of the present disclosure;

[0021] **FIG. 6** is a waveform obtained that illustrates the noise generated due to an electrical disturbance that develops during the delivery of a fluid by the injector system due to the dissimilarities between the materials used for the barrels of the syringes and the plungers; and

[0022] **FIG. 7** is a waveform obtained that illustrates the manner in which the noise generated by the dissimilarities between the materials of the barrels of the syringes and the plungers is suppressed utilizing the system of the present disclosure.

DETAILED DESCRIPTION

[0023] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives

thereof, shall relate to the device of the present disclosure as it is oriented in the drawing figures. However, it is to be understood that the device of the present disclosure may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the device of the present disclosure. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0024] A system is disclosed herein to prevent the noise generated by a powered injector or other electrical equipment located in an operating room from being conducted via the patient (and then the ECG leads) to an ECG monitor. The system routes that noise from the patient through the filtering circuitry discussed hereinafter to ground. By filtering the noise before it reaches the ECG leads/monitor, the circuitry essentially suppresses the noise upon its appearance on the patient (i.e., immediately routes that noise from the patient to ground) and prevents it from reaching, and being received by, the ECG leads, and thus prevents the noise from distorting the ECG waveforms that are displayed on the monitor.

[0025] With specific reference to **FIG. 2**, a patient **100** undergoing a medical imaging procedure is positioned in a room that includes an imaging system (not shown) and an injection system for injecting contrast and/or saline into the patient. As discussed hereinabove, the injection system can include an injector **10**, such as the MEDRAD® STELLANT® injector, that includes two syringe interfaces **20a** and **20b** to which two syringes **30a** and **30b** are removably attachable. Two drive members or pistons **40a** and **40b** operatively connect to plungers **50a** and **50b** slidably disposed in syringes **30a** and **30b**, respectively, to pressurize and inject the fluid therefrom into the patient **100** via a catheter **60** in fluid connection with syringes **30a** and **30b**. In addition, heater jackets **70a** and **70b** may be provided to maintain the fluid within the syringes **30a** and **30b** at a predetermined temperature. As shown in **FIG. 2**, such heater jackets **70a** and **70b** may each include an arcuate resistance heater portion configured to snap over the cylindrical body of the syringes **30a** and **30b**.

[0026] In many instances, a patient scheduled for a scanning procedure may also be connected to a vital signs monitoring system, such as an ECG monitor **80**, via a plurality of electrodes **82** attached to the skin of the patient. Each electrode **82** is connected via a lead **84** to the ECG monitor **80**. As discussed hereinabove, electrical noise/disturbance(s) are generated as a result of the use of the injector **10** and related equipment. For instance, electrical noise may be generated when the heater jackets **70a** and **70b** are turned on and off

or due to an electrical disturbance (i.e., an ESD field) that may develop during the delivery of a fluid by the injector **10** due to the dissimilarities between the materials used for the barrels of the syringes **30a** and **30b** (e.g., plastic) and the plungers **50a** and **50b** (e.g., rubber). This electrical noise can be conveyed from the injector **10** and related equipment to the patient **100** via, for example, the fluid path **55** connecting the injector **10** to the catheter **60**, which is conductive by virtue of the contrast medium or saline therein.

[0027] This noise will be picked up by the electrodes **82** of the ECG monitor **80** and cause a distortion of the ECG signal displayed on the ECG monitor **80** as shown in **FIG. 1** unless the noise is routed to ground. Directly grounding the patient would allow for the greatest noise suppression. However, doing so could cause a hazardous condition of an electrical shock if the patient comes into contact with a high current conductor line in the vicinity of the patient. Accordingly, the system of the present disclosure suppresses noise by preventing DC currents from flowing while also providing an impedance to ground that limits the patient leakage current to under a maximum patient leakage current of 500 microamps, which is the maximum allowable current during a single fault under the IEC/EN 60601-1 standard.

[0028] With reference to **FIG. 3** and continued reference to **FIG. 2**, illustrated is a system, denoted generally as reference numeral **200**, for suppressing electrical noise in an electrocardiogram (ECG) signal displayed on an ECG monitor **80**. The system **200** includes a conductive material **202** provided in contact with a surface of the patient **100**; and filtering circuitry **204** connected in series between the conductive material **202** and ground **206**.

[0029] The filtering circuitry **204** is configured to filter to ground **206** the electrical noise present within the patient **100** that is generated by the injector **10** and associated equipment located near the patient **100**. As can be seen from the output displayed on ECG monitor **80** in **FIG. 2**, the distortion **86** of the ECG signals displayed on the ECG monitor as shown in **FIG. 1** have been removed because the noise generated by the injector **10** and the associated equipment has been effectively filtered to ground **206** by the filtering circuitry **204**.

[0030] While the injector **10** and associated equipment is discussed herein as generating the electrical noise within the patient **100**, this is not to be construed as limiting the present disclosure as the electrical noise may be generated by other electrical devices located near the patient **100** such as anesthesiology equipment or electrosurgical equipment. As can be seen from the output displayed on ECG monitor **80**, the distortion **86** of the ECG signals displayed on the ECG monitor as shown in **FIG. 1** have been removed because the noise generated by the injector **10** and the associated equipment has been effectively filtered to ground **206** by the filtering circuitry **204**.

[0031] The filtering circuitry **204** may be configured as an array of capacitors **208**. For instance, the array of capacitors **208** may include four capacitors arranged as shown in **FIG. 3**. The size of the capacitors **208** is chosen such that the capacitance is high enough to effectively filter the noise generated by the injector **10** while also maintaining an impedance that is high enough to limit the patient leakage current to under the maximum patient leakage current of 500 microamps. An exemplary value of the capacitance for each of the capacitors of the array of capacitors **208** is about 0.0047 μF. In addition, the configuration of the array of capacitors **208** shown in **FIG. 3** was chosen to provide redundancy to the system. More specifically, by utilizing the configuration for the array of capacitors **208** shown in **FIG. 3**, if any one of the capacitors **208** fails, the filtering circuitry **204** will continue to function properly to filter noise.

[0032] While one example of the filtering circuitry **204** is specifically illustrated in **FIG. 3**, this is not to be construed as limiting the present disclosure as other arrangements for the filtering circuitry have been contemplated. For example, the filtering circuitry **204** may be configured as multiple strings of series capacitors, with those strings connected together in parallel.

[0033] With continued reference to **FIGS. 2** and **3**, the conductive material **202** of the system **200** may be provided as a bracelet or wrist strap, denoted generally as reference numeral **210**, configured to be worn on a wrist of the patient **100**. The conductive material **202** may be provided on an interior surface **212** of the bracelet **210** with an exterior surface **214** of the bracelet **210** made from an insulated material **216**. The insulated material **216** may take the form of any suitable insulated material such as, but not limited to, plastics, paints, anodization, or other non-conductive surface treatments. While the use of a bracelet or wrist strap has been described hereinabove as providing a connection for the conductive material **202** to the patient **100**, this is not to be construed as limiting the present disclosure as any suitable manner for providing a resistive connection between the conductive material **202** to the patient **100** may be utilized. For instance, the patient **100** may be required to wear a conductive gown that is operatively connected to the filtering circuitry **204**.

[0034] The conductive material **202** may be manufactured from any suitable metallic material. In addition, the conductive material **202** is desirably non-magnetic so as not to interfere with medical imaging equipment such as that found within a Magnetic Resonance Imaging (MRI) suite. Examples of materials that can be utilized as conductive material **202** include, but are not limited to, non-magnetic austenitic stainless steel, aluminum or aluminum alloy with an anti-corrosive but electrically conductive surface treatment, copper with an anti-

corrosive but electrically conductive surface treatment, a gold plating on a non-magnetic material, titanium or any other suitable material.

EXAMPLES

[0035] As discussed hereinabove, one of the elements of the injection system that may generate electrical noise are the heater jackets **70a** and **70b** when they turn on and off. **FIG. 4** is a waveform that illustrates the noise generated when a heater jacket is turned on and off (i.e., cycled). This noise is clearly shown by the spike **250** generated when the heater jackets **70a** and **70b** are turned on and the spike **252** generated when the heater jackets **70a** and **70b** are turned off. With reference to **FIG. 5**, another waveform was obtained when the heater jackets **70a** and **70b** were turned on and off. However, when this waveform was obtained, the patient **100** was connected to ground **206** via the filtering circuitry **204**. As can be seen in the waveform illustrated in **FIG. 5**, the spikes **250** and **252** have been eliminated from the signal represented on the waveform.

[0036] Another element of the injection system that may generate electrical noise is an electrical disturbance that develops during the delivery of a fluid by the injector system due to the dissimilarities between the materials used for the barrels of the syringes **30a** and **30b** and the plungers **50a** and **50b**. **FIG. 6** is a waveform that illustrates the noise generated during fluid delivery by the injection system due to the dissimilarities between the materials used for the barrels of the syringes **30a** and **30b** and the plungers **50a** and **50b**. This noise is clearly shown by the spikes **254** illustrated on the waveform. With reference to **FIG. 7**, another waveform was obtained during a fluid injection procedure with the injection system. However, when this waveform was obtained, the patient **100** was connected to ground **206** via the filtering circuitry **204**. As can be seen in the waveform illustrated in **FIG. 7**, the spikes **254** have been eliminated from the signal represented on the waveform.

[0037] While specific embodiments of the device of the present disclosure have been described in detail, it will be appreciated by those skilled in the art that various modifications and alternatives to those details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of the device of the present disclosure which is to be given the full breadth of the claims appended and any and all equivalents thereof.

THE INVENTION CLAIMED IS:

1. A system for suppressing electrical noise in an electrocardiogram (ECG) signal displayed on an ECG monitor, the system comprising:

a conductive material provided in contact with a surface of a patient; and

filtering circuitry connected in series between the conductive material and ground,

wherein the filtering circuitry is configured to filter to ground the electrical noise present within the patient.

2. The system of claim 1, wherein the electrical noise is generated by at least one electrical device located near the patient.

3. The system of claim 2, wherein the at least one electrical device is at least one of a powered injector, a heating device, anesthesiology equipment, and electrosurgical equipment.

4. The system of claim 1, wherein the conductive material is provided as a bracelet configured to be worn on a wrist of the patient.

5. The system of claim 4, wherein the conductive material is provided on an interior surface of the bracelet and an exterior surface of the bracelet is made from an insulated material.

6. The system of claim 1, wherein the conductive material is non-magnetic.

7. The system of claim 1, wherein the filtering circuitry is configured as an array of capacitors.

8. The system of claim 7, wherein the array of capacitors includes four capacitors.

9. The system of claim 8, wherein each of the capacitors of the array of capacitors has a capacitance of about 0.0047 μF.

10. A method for suppressing electrical noise in an electrocardiogram (ECG) signal displayed on an ECG monitor, the method comprising:

providing a conductive material in contact with a surface of a patient;

providing filtering circuitry connected in series between the conductive material and ground; and

filtering to ground, with the filtering circuitry, electrical noise present within the patient.

11. The method of claim 10, wherein the electrical noise is generated by at least one electrical device located near the patient.

12. The method of claim 11, wherein the at least one electrical device is at least one of a powered injector, a heating device, anesthesiology equipment, and electrosurgical equipment.

13. The method of claim 10, wherein the conductive material is provided as a bracelet configured to be worn on a wrist of the patient.

14. The method of claim 13, wherein the conductive material is provided on an interior surface of the bracelet and an exterior surface of the bracelet is made from an insulated material.

15. The method of claim 10, wherein the conductive material is non-magnetic.

16. The method of claim 10, wherein the filtering circuitry is configured as an array of capacitors.

17. The method of claim 16, wherein the array of capacitors includes four capacitors.

18. The method of claim 17, wherein each of the capacitors of the array of capacitors has a capacitance of about 0.0047 μF.

19. A system for suppressing electrical noise in an electrocardiogram (ECG) signal displayed on an ECG monitor, the system comprising:

a wrist strap positioned around the wrist of a patient and comprising a conductive material provided in contact with a surface of the patient; and

filtering circuitry comprising an array of capacitors connected in series between the conductive material of the wrist strap and ground,

wherein the filtering circuitry is configured to filter to ground the electrical noise present within the patient that is generated by at least one electrical device located near the patient.

20. The system of claim 19, wherein the at least one electrical device is at least one of a powered injector, a heating device, anesthesiology equipment, and electrosurgical equipment.

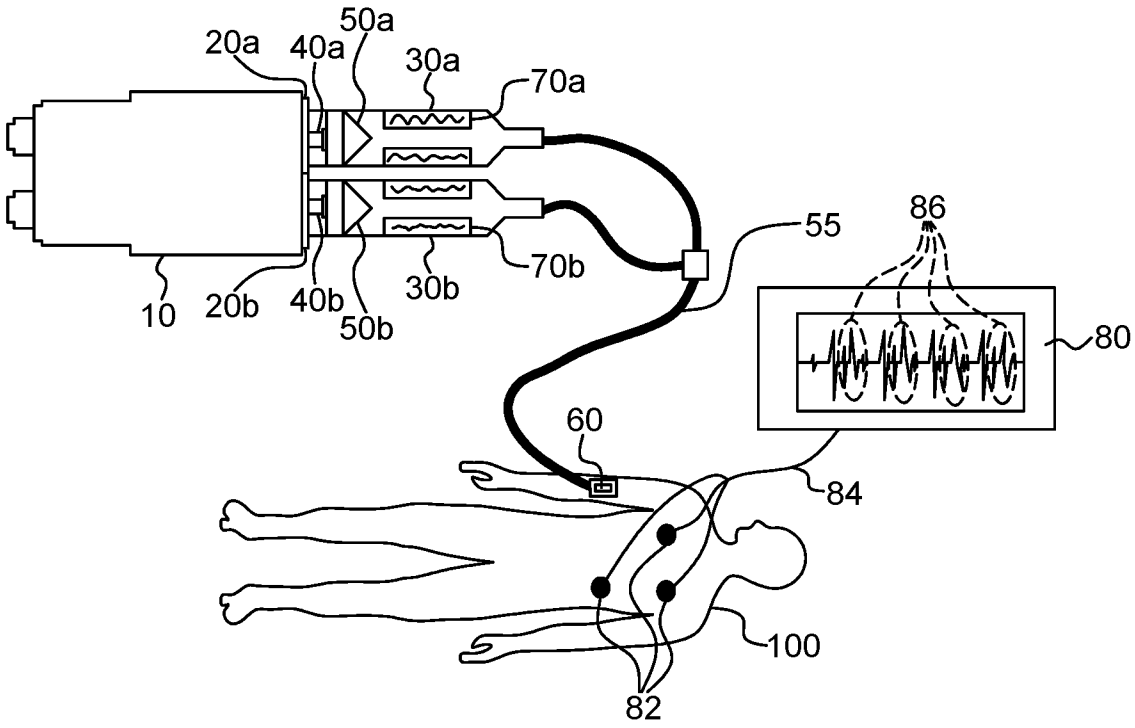


FIG. 1
PRIOR ART

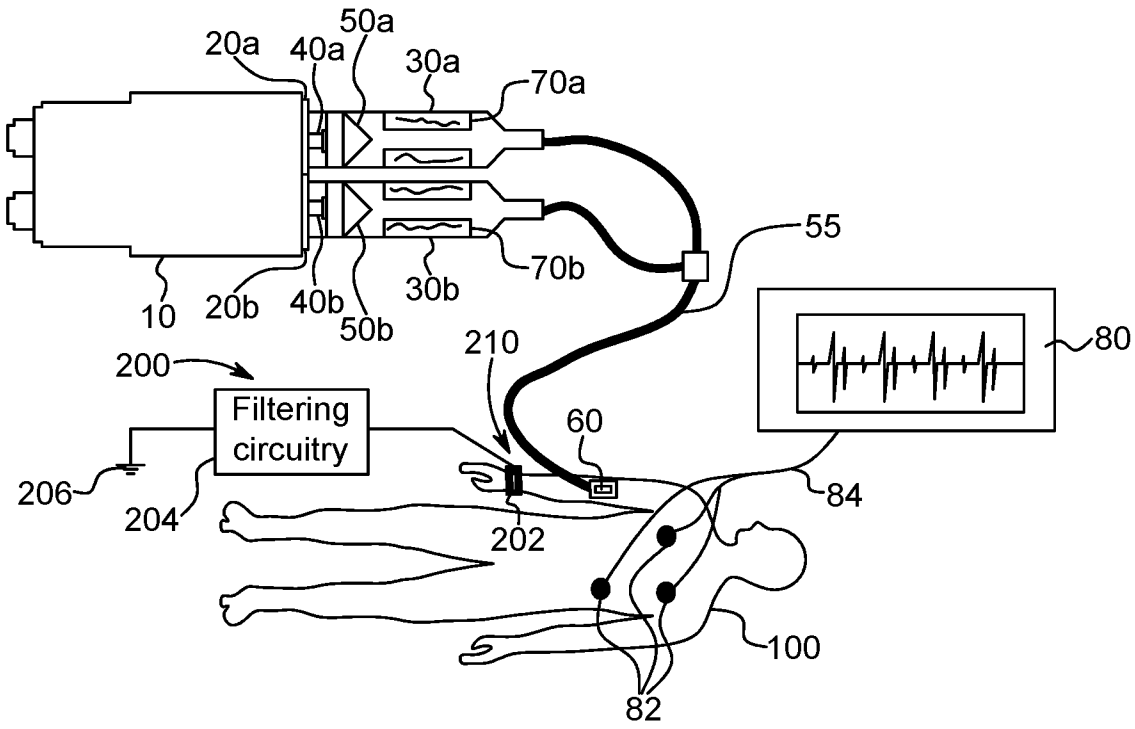


FIG. 2

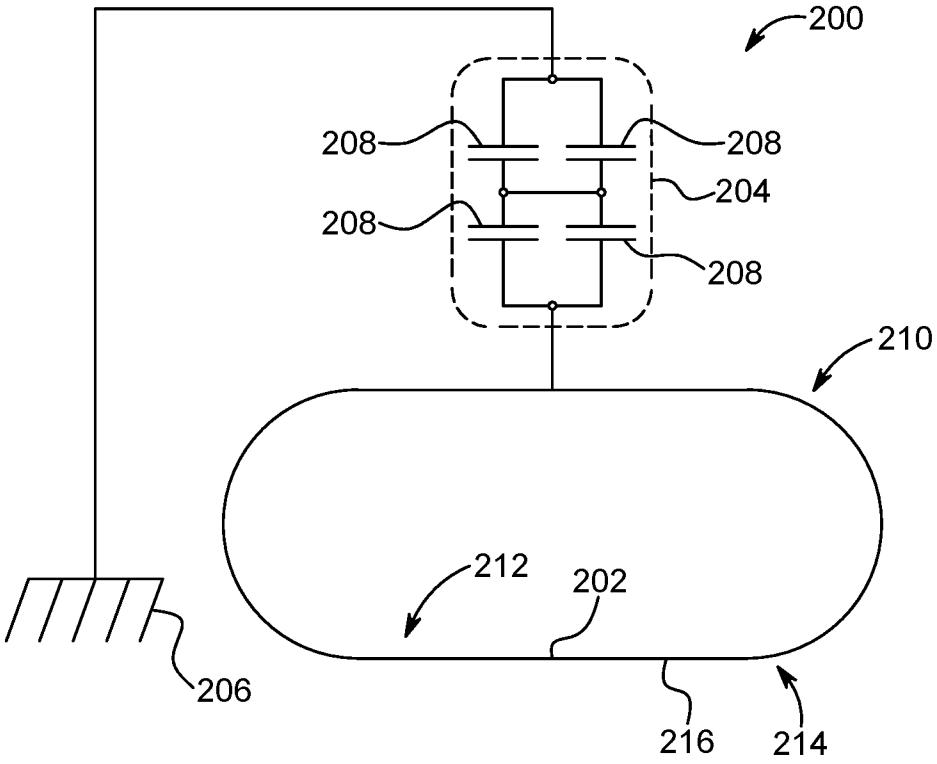
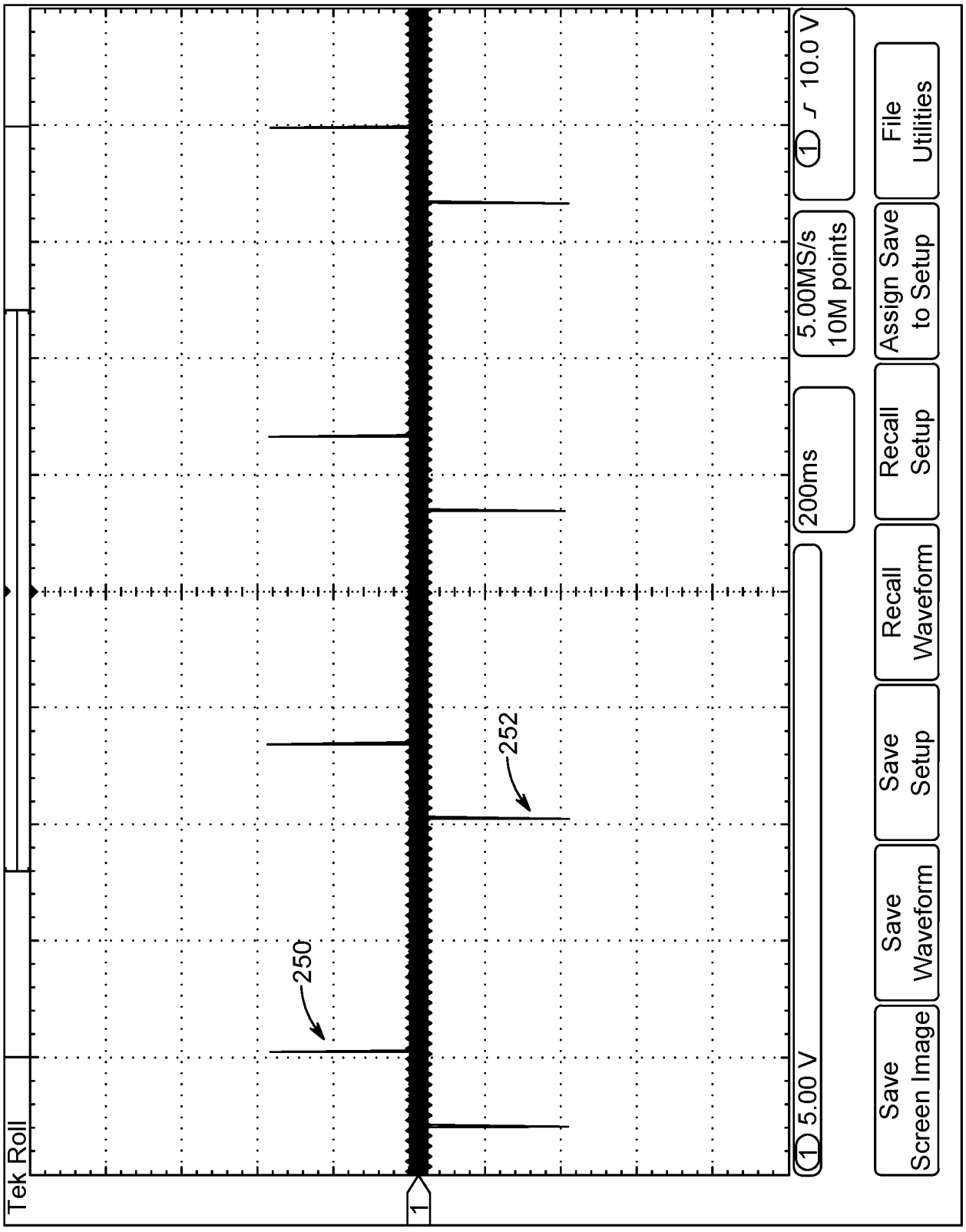


FIG. 3

FIG. 4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Utilities

FIG. 5

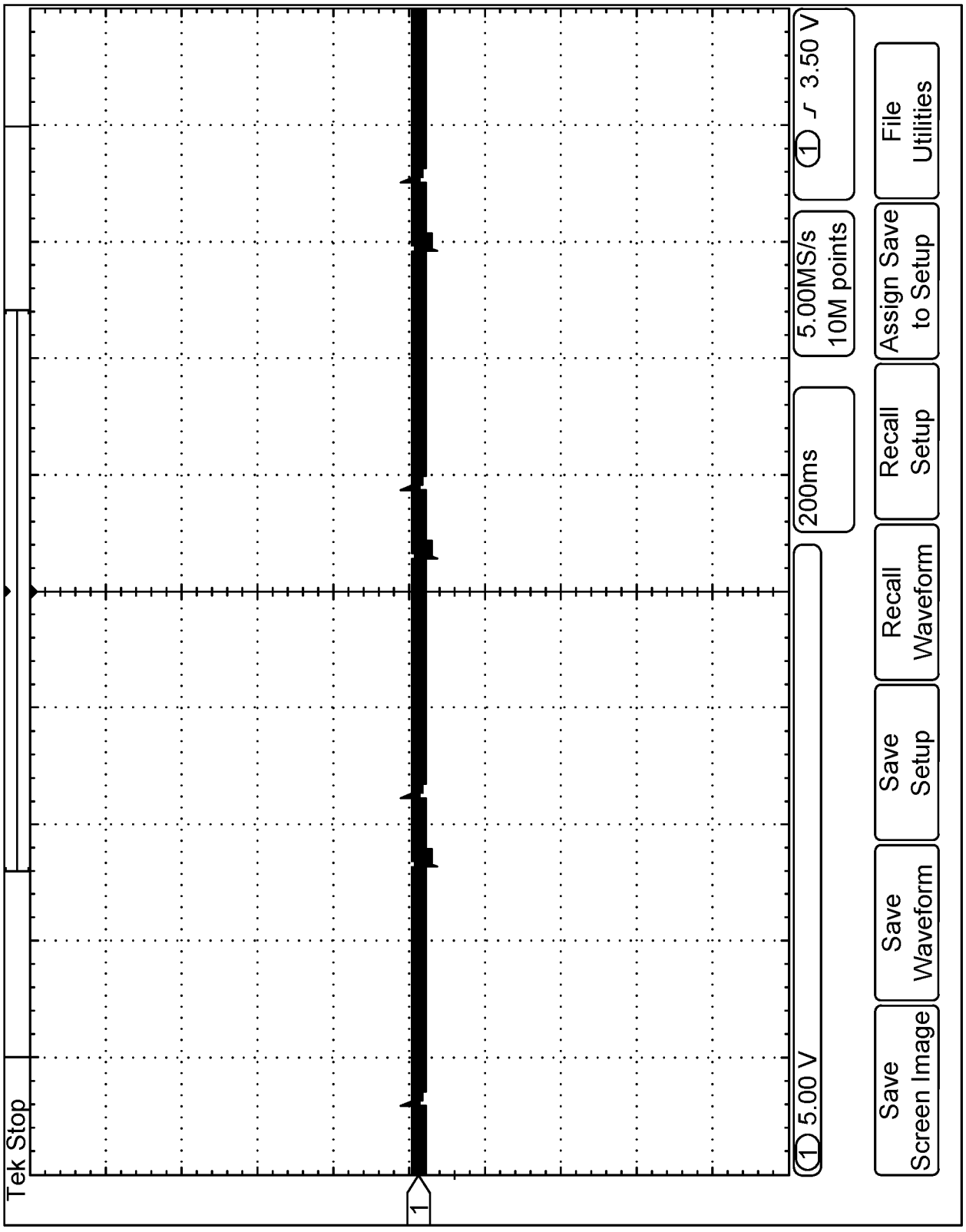
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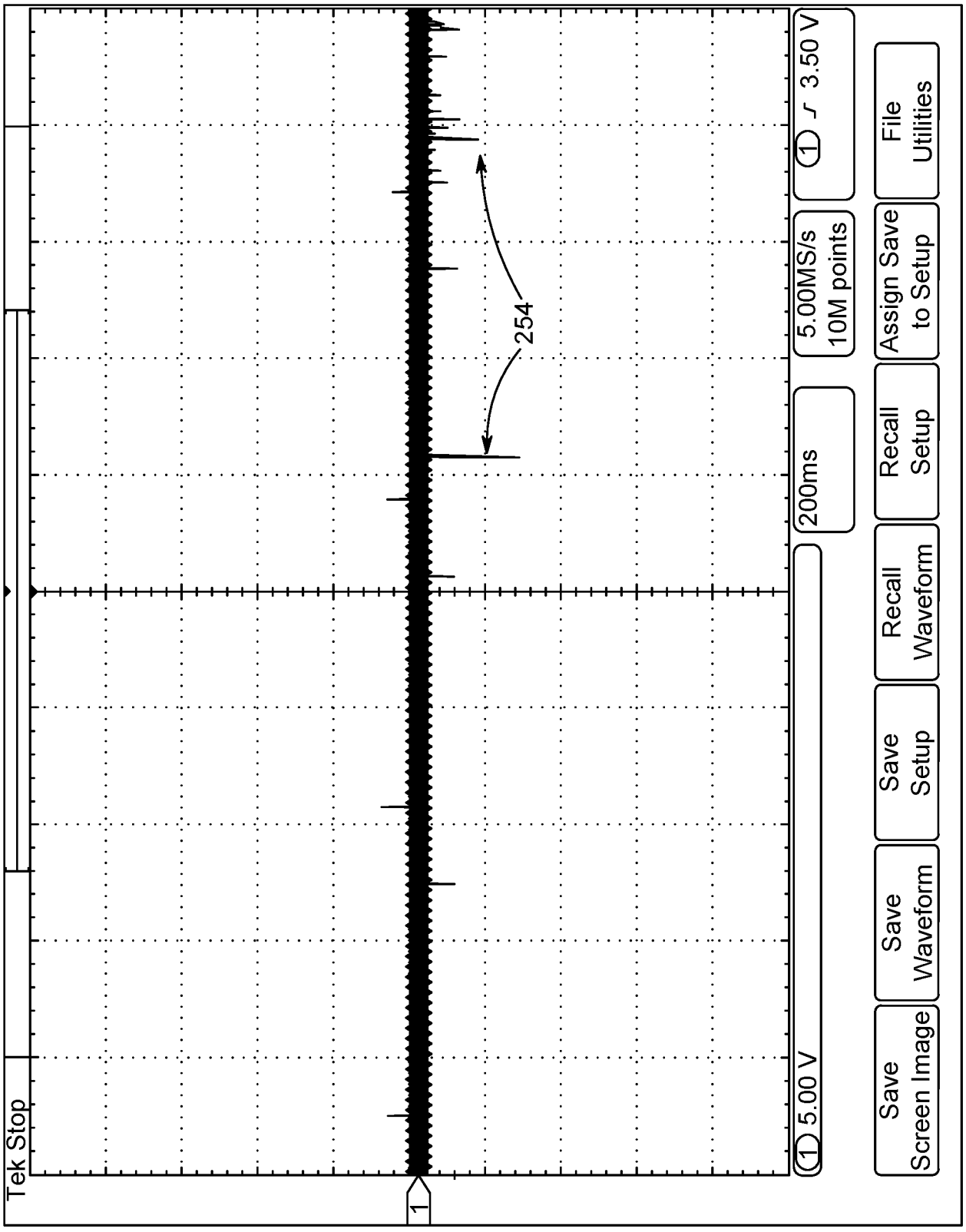
FIG. 6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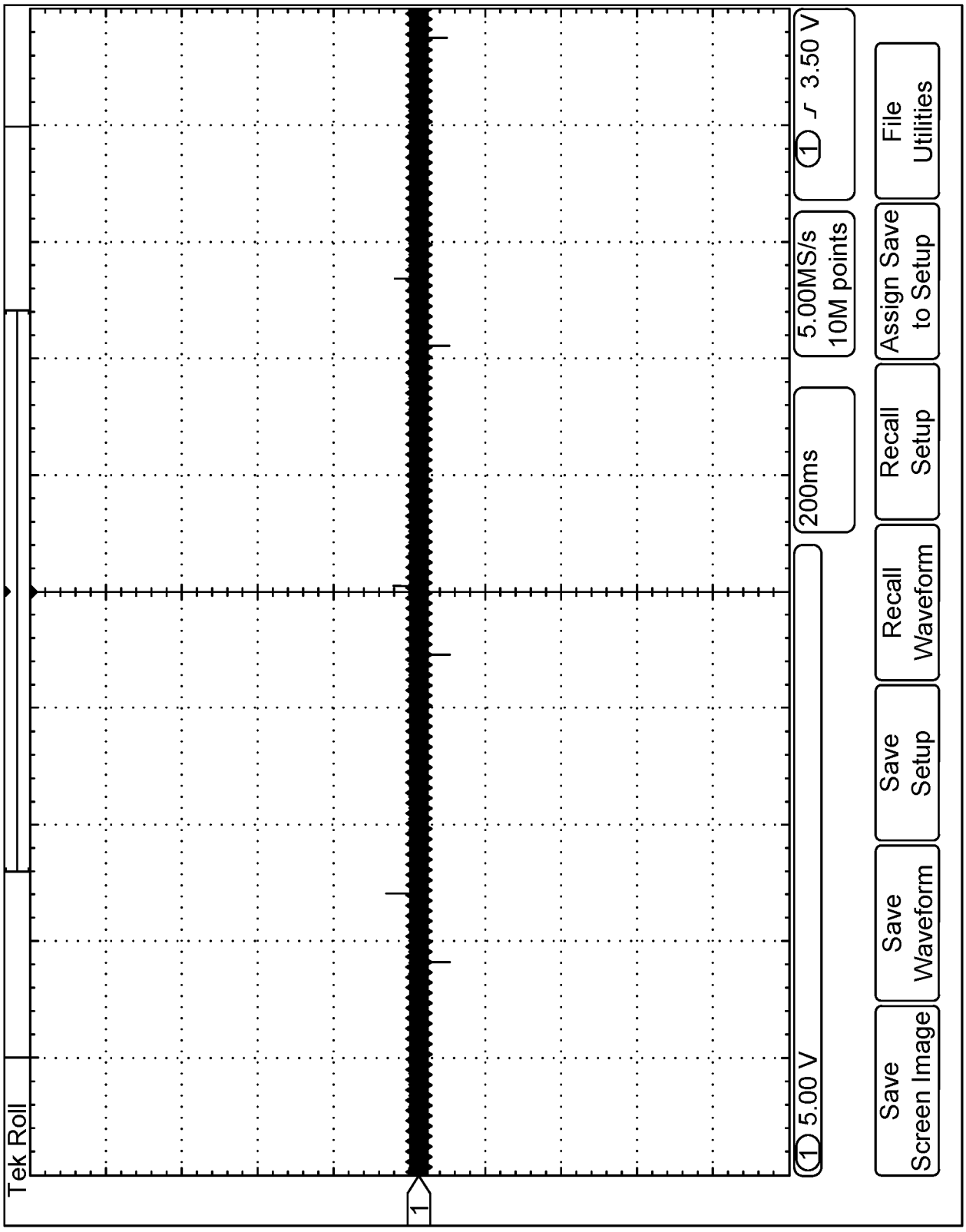
Utilities

FIG. 7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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/029770

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/0402
ADD. A61M5/145

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/313305 A1 (RANTALA BOERJE [FI]) 22 December 2011 (2011-12-22) paragraphs [0015], [0020] - [0025] -----	1-3, 6-12, 15-20
X	EP 2 823 757 A1 (BIOSENSE WEBSTER ISRAEL LTD [IL]) 14 January 2015 (2015-01-14) paragraphs [0030] - [0039] -----	1-3, 10-12, 19,20
X	US 2014/249430 A1 (SIMS NATHANIEL M [US] ET AL) 4 September 2014 (2014-09-04) abstract paragraphs [0174], [0202], [0224] -----	1,4,5, 10,13, 14,19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 2017	04/08/2017

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kowalczyk, Szczepan

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/029770

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011313305 A1	22-12-2011	CN 102283646 A	21-12-2011
		US 2011313305 A1	22-12-2011
EP 2823757 A1	14-01-2015	AU 2014203391 A1	22-01-2015
		CA 2855166 A1	25-12-2014
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		US 2009131759 A1	21-05-2009
		US 2014249430 A1	04-09-2014
		WO 2005044090 A2	19-05-2005
		WO 2005046433 A2	26-05-2005

专利名称(译)	用于抑制来自心电图（ECG）信号的噪声的系统和方法		
公开(公告)号	EP3448242A1	公开(公告)日	2019-03-06
申请号	EP2017722602	申请日	2017-04-27
[标]申请(专利权)人(译)	拜尔健康护理有限责任公司		
申请(专利权)人(译)	拜耳医药保健有限责任公司		
当前申请(专利权)人(译)	拜耳医药保健有限责任公司		
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IPC分类号	A61B5/00 A61B5/0402 A61M5/145		
CPC分类号	A61B5/0402 A61B5/6831 A61B5/7217 A61B5/7225 A61M5/14546 A61B5/044 A61B5/6804 A61B5/7203 H03H7/004 H03H7/0138		
代理机构(译)	BIP专利		
优先权	15/142737 2016-04-29 US		
外部链接	Espacenet		

摘要(译)

一种用于抑制ECG监视器上显示的心电图（ECG）信号中的电噪声的系统包括：设置成与患者表面接触的导电材料;以及在导电材料和地之间串联连接的滤波电路。滤波电路可以被配置为过滤以将患者体内存在的电噪声接地。