



US009161722B2

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

(10) **Patent No.:** **US 9,161,722 B2**
(45) **Date of Patent:** **Oct. 20, 2015**

(54) **TECHNIQUE FOR REMANUFACTURING A MEDICAL SENSOR**

(75) Inventors: **David P. Besko**, Thornton, CO (US);
Donald R. Sandmore, Lyons, CO (US)

(73) Assignee: **COVIDIEN LP**, Mansfield, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 673 days.

(21) Appl. No.: **13/226,714**

(22) Filed: **Sep. 7, 2011**

(65) **Prior Publication Data**

US 2013/0060109 A1 Mar. 7, 2013

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
CPC **A61B 5/6832** (2013.01); **A61B 5/14552** (2013.01); **A61B 2560/028** (2013.01); **A61B 2562/0233** (2013.01); **A61B 2562/08** (2013.01); **A61B 2562/12** (2013.01); **Y10T 29/4973** (2015.01)

(58) **Field of Classification Search**
CPC A61B 5/1455; B29C 73/10; Y10T 29/49726; Y10T 29/4973; B32B 2556/00
USPC 600/310-344
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,964,408 A 10/1990 Hink et al.
5,090,410 A 2/1992 Saper et al.
5,170,786 A 12/1992 Thomas et al.

5,209,230 A 5/1993 Swedlow et al.
5,337,744 A 8/1994 Branigan
5,452,717 A 9/1995 Branigan et al.
5,660,567 A 8/1997 Nierlich et al.
5,673,693 A 10/1997 Solenberger
5,697,367 A 12/1997 Lewis et al.
5,797,841 A * 8/1998 Delonzor et al. 600/323
5,810,724 A 9/1998 Gronvall
RE36,000 E 12/1998 Swedlow et al.
5,851,178 A 12/1998 Aronow
5,891,026 A 4/1999 Wang et al.
5,910,108 A 6/1999 Solenberger
5,919,133 A 7/1999 Taylor et al.
5,999,834 A 12/1999 Wang et al.
6,073,038 A 6/2000 Wang et al.
6,144,868 A 11/2000 Parker
6,149,481 A 11/2000 Wang et al.
6,173,196 B1 1/2001 Delonzor et al.

(Continued)

FOREIGN PATENT DOCUMENTS

AU 2120892 A1 4/1993
EP 1945099 7/2008

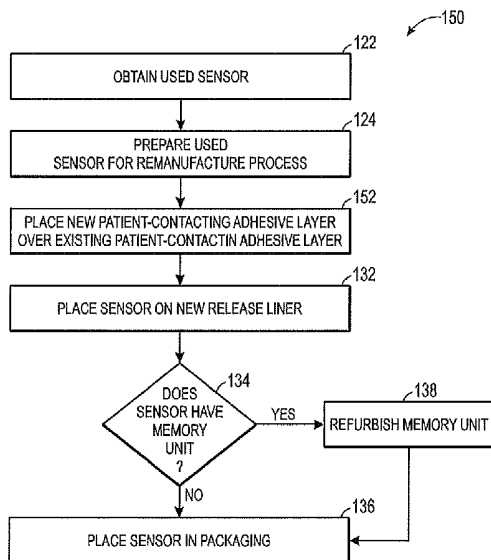
(Continued)

Primary Examiner — Eric Winakur
Assistant Examiner — Marjan Fardanesh
(74) *Attorney, Agent, or Firm* — Fletcher Yoder PC

(57) **ABSTRACT**

Remanufactured medical sensors and methods for remanufacturing used medical sensors are provided. Such a remanufactured sensor may include certain components from a used medical sensor and certain new components. For example, a remanufactured regional oximetry sensor may include a padding layer, an emitter and a pair of detectors, a flexible circuit coupled to the emitter and detectors, and a patient-contacting adhesive layer. The flexible circuit, the emitter, the first detector, the second detector, or any combination thereof, are from a used medical sensor, and the padding layer, the patient-contacting adhesive layer, or a combination thereof, are new.

3 Claims, 9 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

6,253,098 B1 6/2001 Walker et al.
 6,256,523 B1 7/2001 Diab et al.
 6,321,100 B1 11/2001 Parker
 6,343,224 B1 1/2002 Parker
 6,377,829 B1 4/2002 Al-Ali
 6,430,423 B2 8/2002 Delonzor et al.
 6,519,487 B1 2/2003 Parker
 6,671,531 B2 12/2003 Al-Ali et al.
 6,675,031 B1* 1/2004 Porges et al. 600/322
 6,678,543 B2 1/2004 Diab et al.
 6,681,126 B2 1/2004 Solenberger
 6,684,091 B2 1/2004 Parker
 6,725,075 B2 4/2004 Al-Ali
 6,735,459 B2 5/2004 Parker
 6,745,061 B1 6/2004 Hicks et al.
 6,748,254 B2 6/2004 O'Neil et al.
 6,763,255 B2 7/2004 Delonzor et al.
 6,792,300 B1 9/2004 Diab et al.
 6,813,511 B2 11/2004 Diab et al.
 6,920,345 B2 7/2005 Al-Ali et al.
 6,950,687 B2 9/2005 Al-Ali
 7,039,449 B2 5/2006 Al-Ali
 7,048,687 B1 5/2006 Reuss et al.
 7,190,984 B1 3/2007 Delonzor et al.
 7,225,007 B2 5/2007 Al-Ali et al.
 7,245,953 B1 7/2007 Parker
 7,248,910 B2 7/2007 Li et al.
 7,272,425 B2 9/2007 Al-Ali
 7,321,790 B2 1/2008 Delonzor et al.
 7,369,886 B2 5/2008 Delonzor et al.
 7,373,188 B2 5/2008 Delonzor et al.
 7,373,189 B2 5/2008 Delonzor et al.
 7,373,190 B2 5/2008 Delonzor et al.
 7,373,191 B2 5/2008 Delonzor et al.
 7,386,334 B2 6/2008 Delonzor et al.
 7,389,130 B2 6/2008 Delonzor et al.
 7,418,284 B2 8/2008 Delonzor et al.
 7,440,788 B2 10/2008 Jenkins et al.
 7,561,905 B2 7/2009 Delonzor et al.
 7,684,842 B2 3/2010 Ollerdessen
 2003/0109775 A1* 6/2003 O'Neil et al. 600/323

2003/0171662 A1 9/2003 O'Connor et al.
 2004/0133088 A1 7/2004 Al-Ali
 2004/0147822 A1 7/2004 Al-Ali et al.
 2005/0043600 A1 2/2005 Diab et al.
 2006/0161054 A1 7/2006 Reuss et al.
 2006/0200018 A1 9/2006 Al-Ali
 2007/0021659 A1 1/2007 Delonzor et al.
 2007/0021660 A1 1/2007 Delonzor et al.
 2007/0021662 A1 1/2007 Delonzor et al.
 2007/0027378 A1 2/2007 Delonzor et al.
 2007/0027379 A1 2/2007 Delonzor et al.
 2007/0027380 A1 2/2007 Delonzor et al.
 2007/0078311 A1 4/2007 Al-Ali et al.
 2007/0123763 A1 5/2007 Al-Ali et al.
 2007/0244378 A1 10/2007 Al-Ali et al.
 2008/0009691 A1 1/2008 Parker
 2008/0033267 A1 2/2008 Al-Ali
 2008/0081971 A1 4/2008 Ollerdessen
 2008/0088467 A1 4/2008 Al-Ali
 2008/0091089 A1 4/2008 Guillory et al.
 2008/0091090 A1 4/2008 Guillory et al.
 2008/0208023 A1 8/2008 Gruvac et al.
 2008/0228053 A1 9/2008 Wang et al.
 2009/0259114 A1* 10/2009 Johnson et al. 600/310
 2009/0323267 A1 12/2009 Besko et al.
 2010/0076282 A1 3/2010 Sandmore
 2010/0081902 A1 4/2010 McKenna et al.
 2010/0249554 A1 9/2010 McKenna et al.
 2010/0249557 A1 9/2010 Besko et al.
 2010/0331638 A1 12/2010 Besko et al.
 2012/0071739 A1 3/2012 Chen et al.
 2012/0071742 A1 3/2012 Medina et al.
 2012/0136223 A1 5/2012 Hodge et al.
 2012/0136257 A1 5/2012 Krishnan et al.
 2012/0216335 A1 8/2012 McKenna, Jr. et al.
 2012/0253148 A1 10/2012 Haisley et al.
 2012/0253152 A1 10/2012 Haisley et al.
 2012/0253159 A1 10/2012 Medina et al.

FOREIGN PATENT DOCUMENTS

JP 27195816 A2 8/2007
 WO WO2006092624 A1 9/2006

* cited by examiner

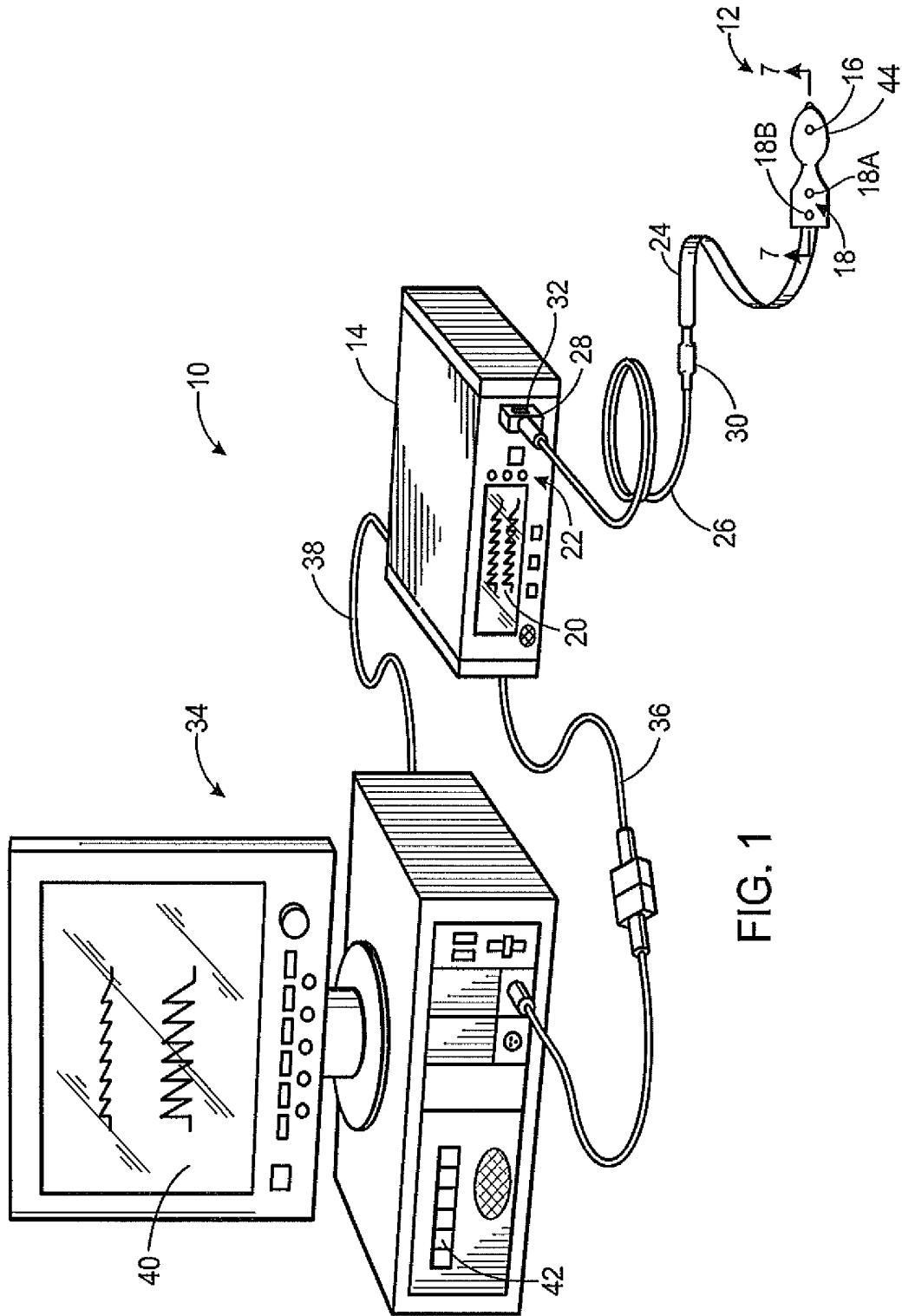
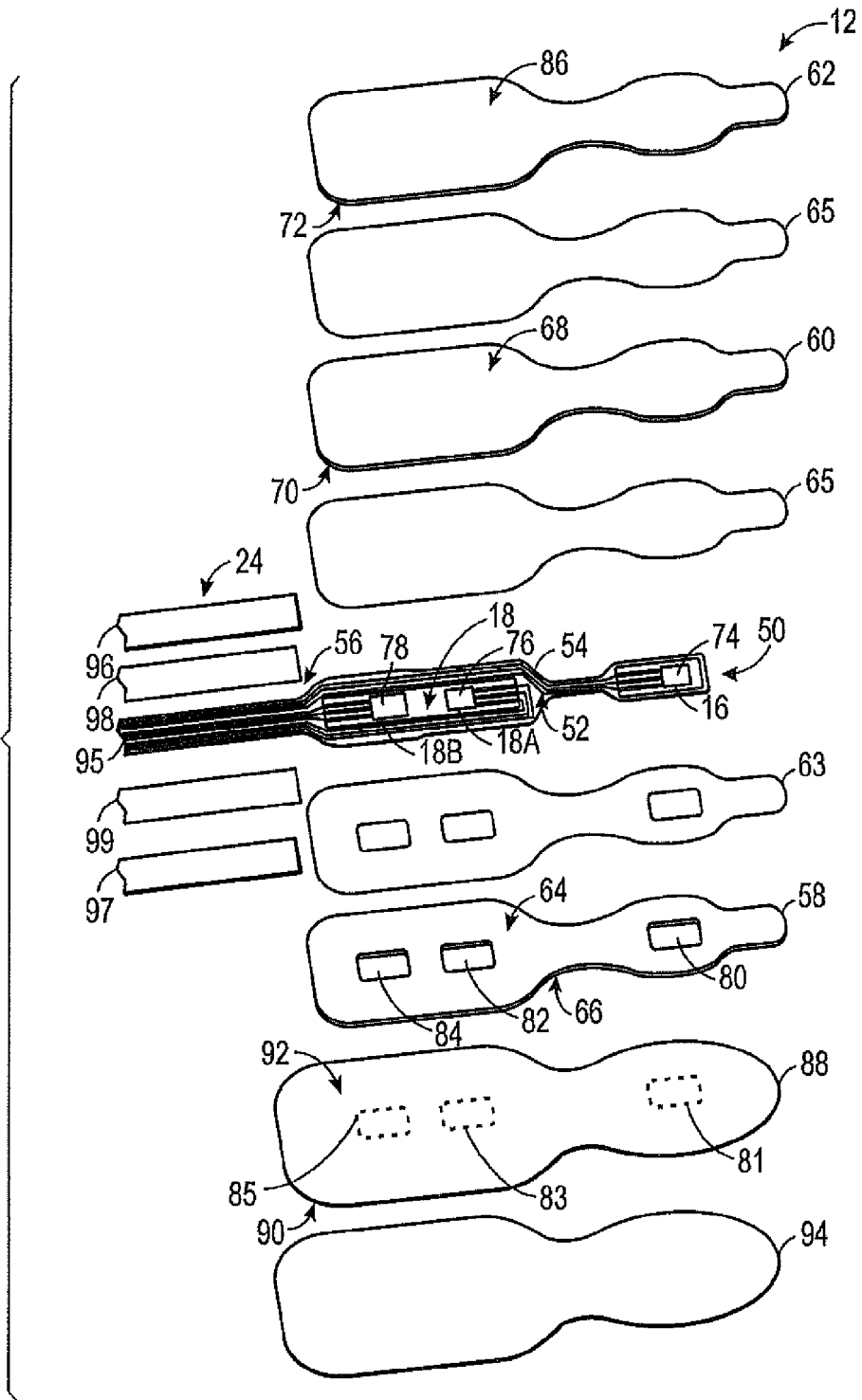


FIG. 1

FIG. 2



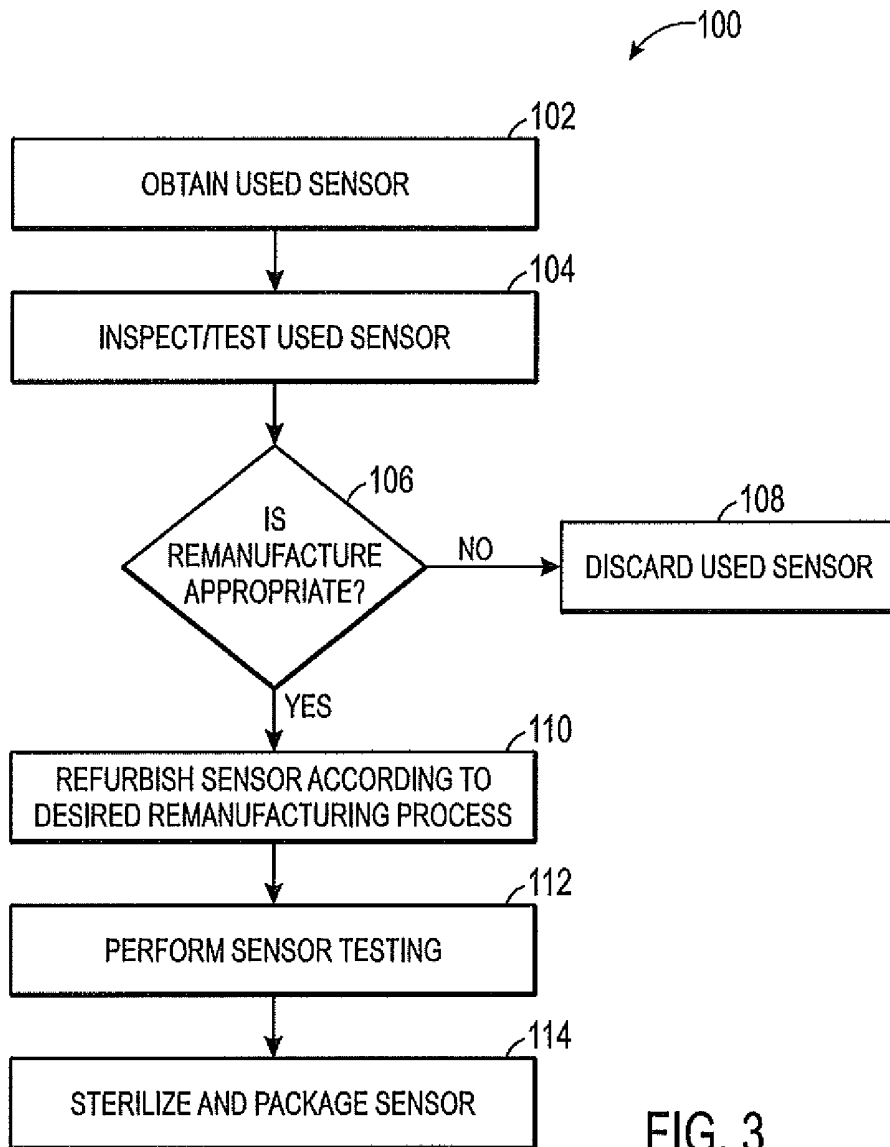


FIG. 3

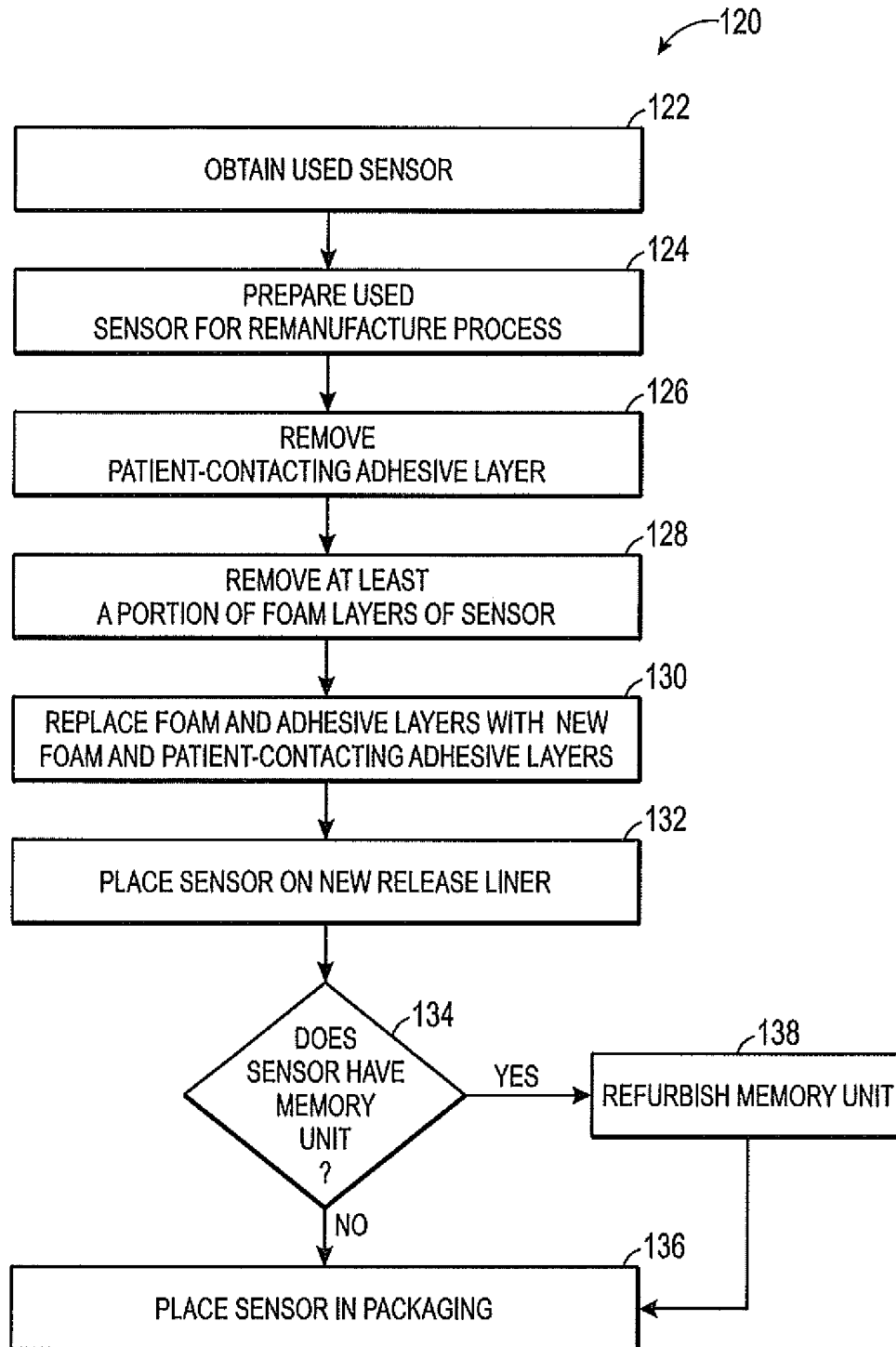


FIG. 4

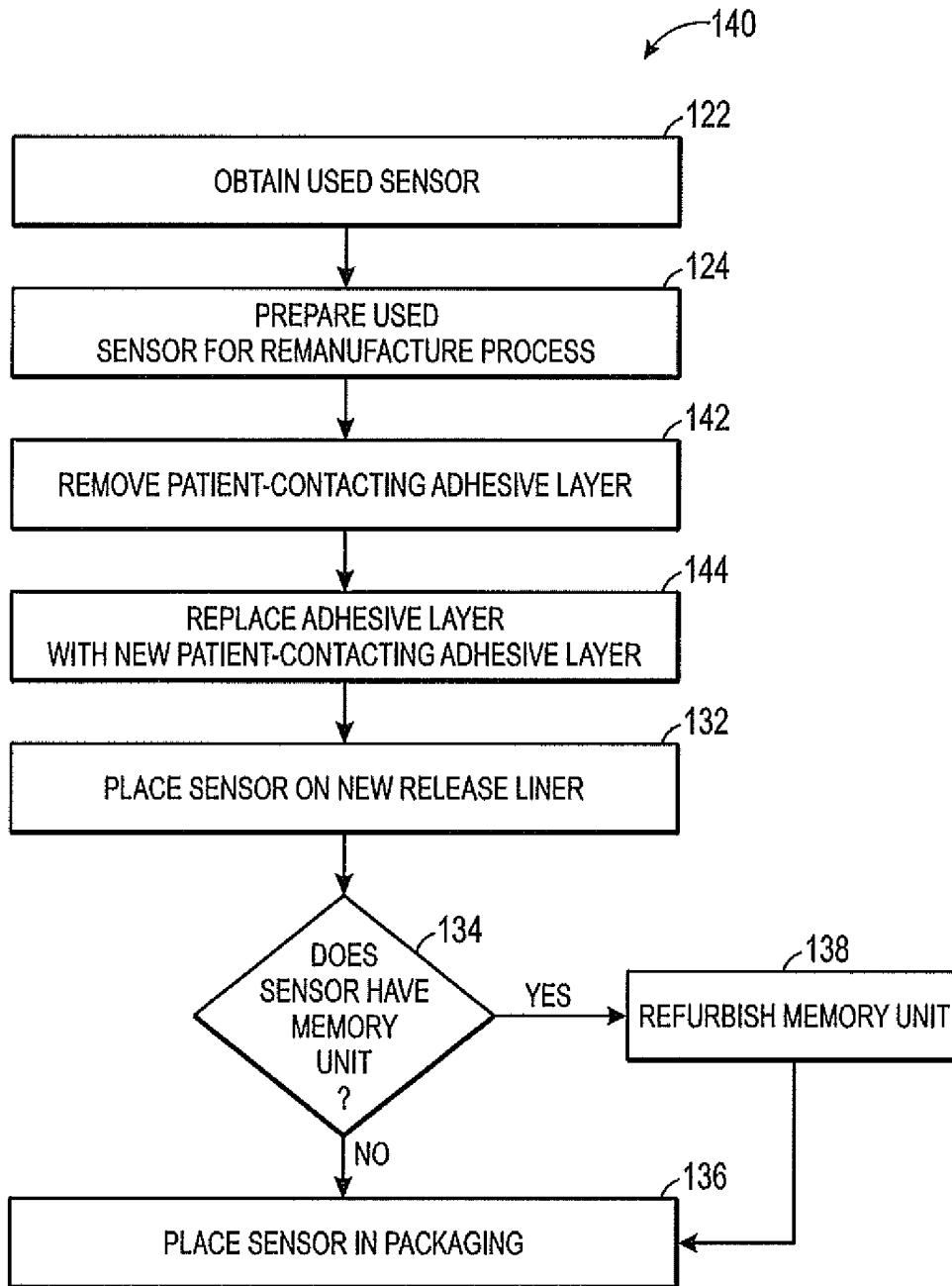
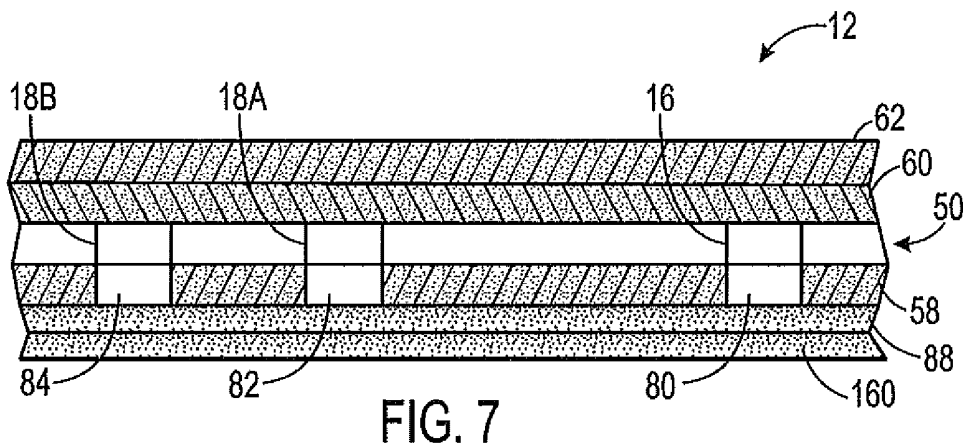
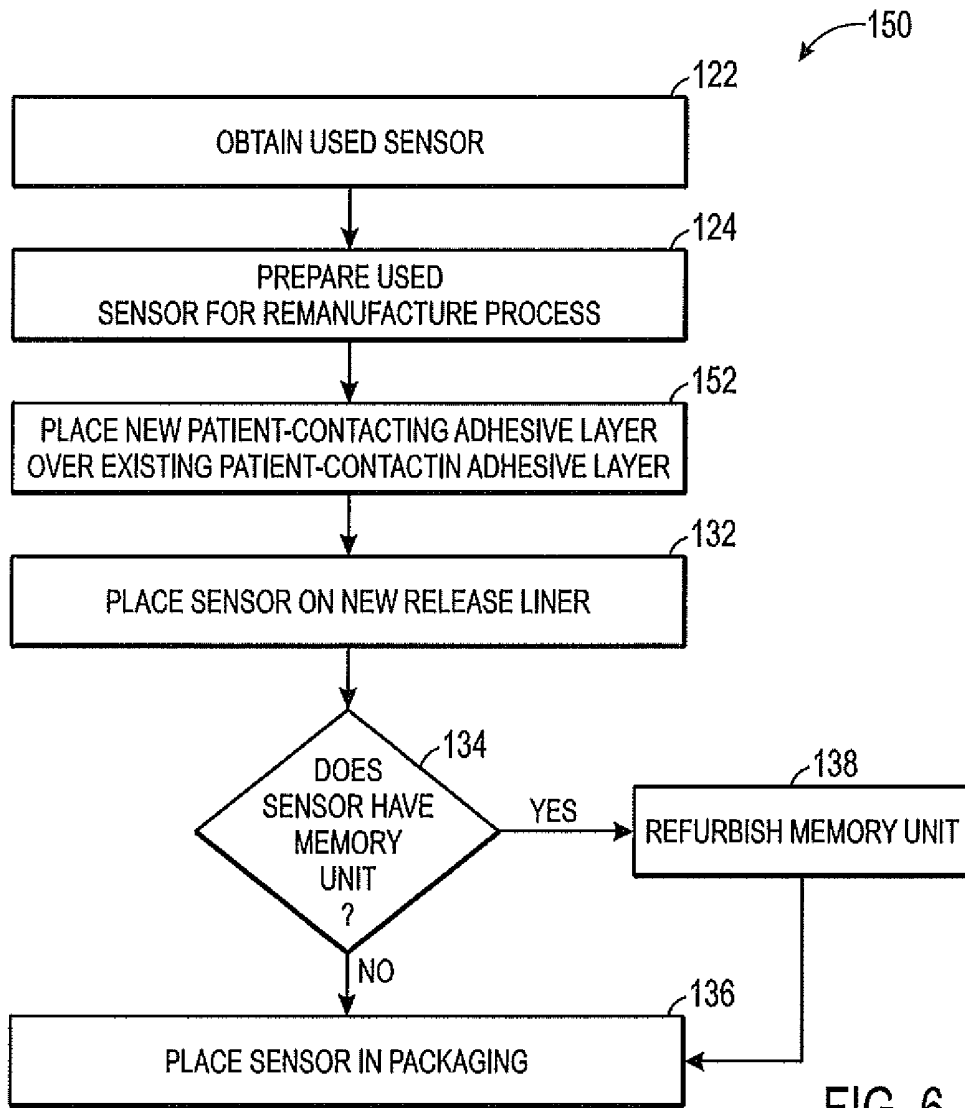


FIG. 5



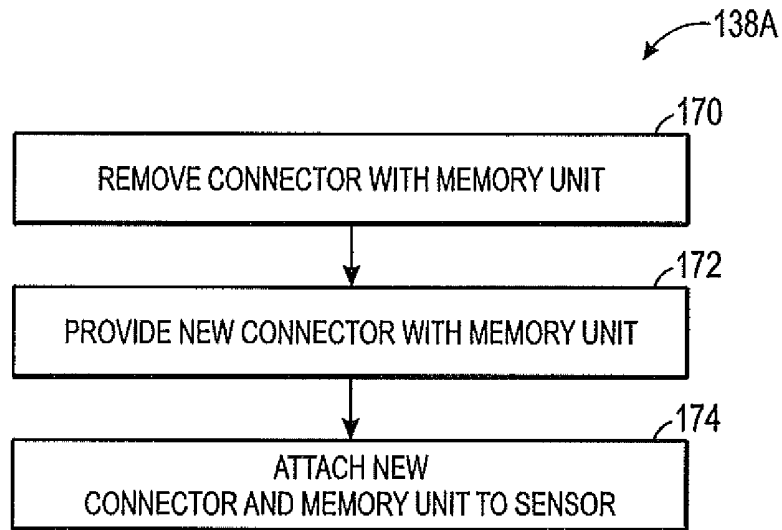


FIG. 8

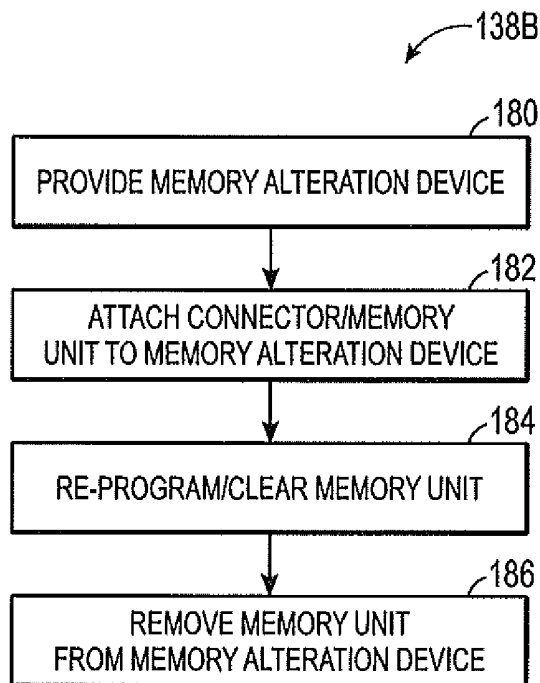


FIG. 9

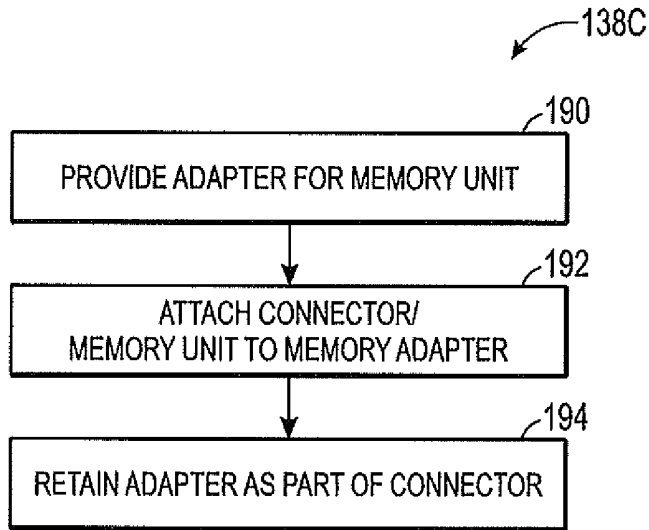


FIG. 10

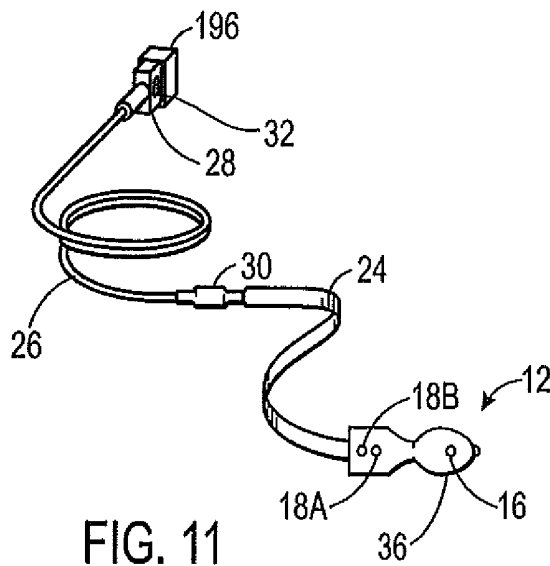


FIG. 11

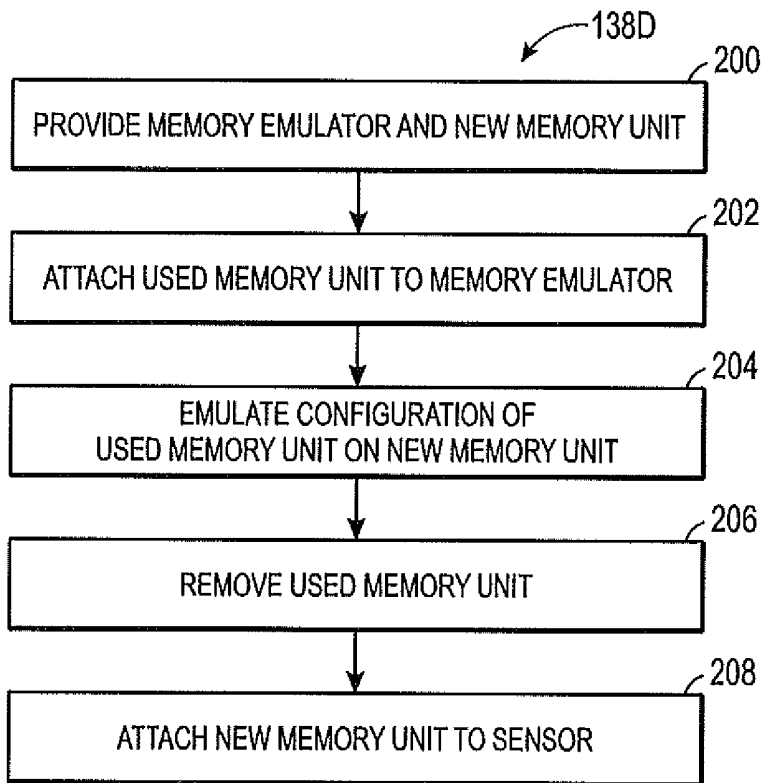


FIG. 12

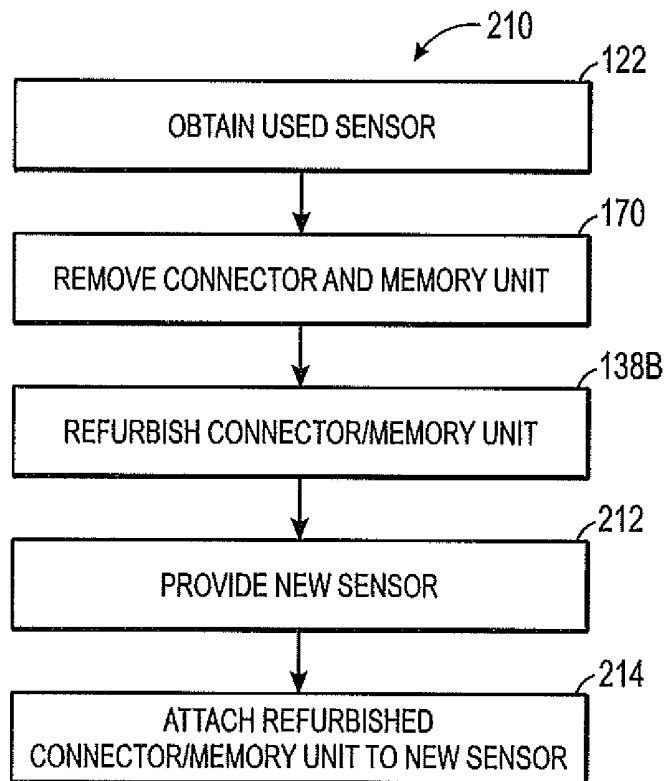


FIG. 13

TECHNIQUE FOR REMANUFACTURING A MEDICAL SENSOR

BACKGROUND

The present disclosure relates generally to remanufacturing disposable medical sensors and, more particularly, to remanufacturing, i.e., reconstructing, used medical sensors.

This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

A wide variety of devices have been developed for non-invasively monitoring physiological characteristics of patients. For example, a pulse oximetry sensor system may non-invasively detect various patient blood characteristics, such as the blood-oxygen saturation of hemoglobin in arterial blood, the volume of individual blood pulsations supply the tissue, and/or the rate of blood pulsations corresponding to each heart beat of a patient. During operation, the pulse oximeter sensor emits light and photoelectrically senses the absorption and/or scattering of the light after passage through the perfused tissue. A photo-plethysmographic waveform, which corresponds to the cyclic attenuation of optical energy through the patient's tissue, may be generated from the detected light. Additionally, one or more physiological characteristics may be calculated based upon the amount of light absorbed or scattered. More specifically, the light passed through the tissue may be selected to be of one or more wavelengths that may be absorbed or scattered by the blood in an amount correlative to the amount of the blood constituent present in the blood. The amount of light absorbed and/or scattered may then be used to estimate the amount of blood constituent in the tissue using various algorithms.

For example, a reflectance-type sensor placed on a patient's forehead may emit light into the site and detect the light that is "reflected" back after being transmitted through the forehead region. A transmission-type sensor having a bandage configuration may be placed on a finger, wherein the light waves are emitted through and detected on the opposite side of the finger. In either case, the amount of light detected may provide information that corresponds to valuable physiological patient data. The data collected by the sensor may be used to calculate one or more of the above physiological characteristics based upon the absorption or scattering of the light. For instance, the emitted light is typically selected to be of one or more wavelengths that are absorbed or scattered in an amount related to the presence of oxygenated versus deoxygenated hemoglobin in the blood. The amount of light absorbed and/or scattered may be used to estimate the amount of the oxygen in the tissue using various algorithms.

The sensors generally include one or more emitters that emit the light and one or more detectors that detect the light. During use, the emitter and detector may be held against the patient's skin to facilitate the transmission of light through the skin of the patient. Because these sensors come into contact with patient tissues, and possibly fluids, they are either sanitized for re-use or they are discarded after use. Indeed, many pulse oximeter medical sensors may be disposable and originally intended for use on a single patient. However, even

disposable sensors often include relatively expensive components that may be reused if the sensor could be refurbished.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the disclosed techniques may become apparent upon reading the following detailed description and upon reference to the drawings in which:

FIG. 1 is a front view of an embodiment of a monitoring system configured to be used with a sensor for oximetry and regional saturation, in accordance with an aspect of the present disclosure;

FIG. 2 is an exploded perspective view of an embodiment of the sensor of FIG. 1, in accordance with an aspect of the present disclosure;

FIG. 3 is a process flow diagram of an embodiment of a general method for remanufacturing the sensor of FIG. 1, in accordance with an aspect of the present disclosure;

FIG. 4 is a process flow diagram of an embodiment of a method for remanufacturing the sensor of FIG. 1 including removing at least a portion of one or more foam layers and the patient-contacting adhesive layer of the sensor, in accordance with an aspect of the present disclosure;

FIG. 5 is a process flow diagram of an embodiment of a method for remanufacturing the sensor of FIG. 1 including replacing the patient-contacting adhesive layer of the sensor, in accordance with an aspect of the present disclosure;

FIG. 6 is a process flow diagram of an embodiment of a method for remanufacturing the sensor of FIG. 1 including placing a new patient-contacting adhesive layer over the used patient-contacting adhesive layer of the sensor, in accordance with an aspect of the present disclosure;

FIG. 7 is a cross-sectional view taken along section 7-7 of FIG. 1 and illustrating an embodiment of the sensor of FIG. 1 having a new patient-contacting adhesive layer disposed over the used patient-contacting adhesive layer of the sensor, in accordance with an aspect of the present disclosure;

FIG. 8 is a process flow diagram of an embodiment of a method for refurbishing the time-out feature in accordance with the methods of FIGS. 3-6, including replacing the connector of the sensor of FIG. 1, in accordance with an aspect of the present disclosure;

FIG. 9 is a process flow diagram of an embodiment of a method for refurbishing the time-out feature in accordance with the methods of FIGS. 3-6, including re-programming the time-out feature contained within the connector of the sensor of FIG. 1, in accordance with an aspect of the present disclosure;

FIG. 10 is a process flow diagram of an embodiment of a method for refurbishing the time-out feature in accordance with the methods of FIGS. 3-6, including providing an adaptor for the time-out feature contained within the connector of the sensor of FIG. 1, in accordance with an aspect of the present disclosure;

FIG. 11 is a front view of an embodiment of a sensor resulting from the process of FIG. 10, wherein the sensor includes an adaptor coupled to the connector for altering the operability of the time-out feature, in accordance with an aspect of the present disclosure;

FIG. 12 is a process flow diagram of an embodiment of a method for refurbishing the time-out feature in accordance with the methods of FIGS. 3-6, including emulating the time-out feature contained within the connector of the sensor of FIG. 1 on a new memory unit, in accordance with an aspect of the present disclosure; and

FIG. 13 is a process flow diagram of an embodiment of a method for remanufacturing the sensor of FIG. 1 including

retaining only the connector and memory unit and replacing the used sensor with a new sensor, in accordance with an aspect of the present disclosure.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

One or more specific embodiments of the present techniques will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

When introducing elements of various embodiments of the present disclosure, the articles "a," "an," and "the" are intended to mean that there are one or more of the elements. The terms "comprising," "including," and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements. Additionally, it should be understood that references to "one embodiment" or "an embodiment" of the present disclosure are not intended to be interpreted as excluding the existence of additional embodiments that also incorporate the recited features. Also, as used herein, the term "over" or "above" refers to a component location on a sensor that is closer to patient tissue when the sensor is applied to the patient.

As noted above, the present embodiments relate to remanufacturing sensors that may be used to determine regional oxygen saturation. For example, the sensors described herein may incorporate one or more emitters and one or more detectors for determining the level of blood oxygen saturation in a particular region, such as a cerebral or somatic region. The sensors described herein may be constructed using a combination of new materials (i.e., materials that have not been incorporated into a medical sensor) and components taken from one or more used sensors. For example, a sensor may include a plurality of padding (e.g., foam, sponge, gel, or fiber) layers disposed on either side of a flexible electronic circuit, and an adhesive layer for attaching to a patient, such as to the patient's forehead, stomach, back, or another somatic region. Sensors constructed using the remanufacturing techniques described herein may incorporate used padding layers, flexible circuits, emitters, detectors, and, in certain embodiments, used adhesive layers, or any combination thereof.

By way of example, an INVOS® cerebral/somatic sensor, such as an OxyAlert™ NIR sensor or a SomaSensor® by Somanetics Corporation, which may include one or more emitters and a pair of detectors for determining site-specific oxygen levels, represents such sensors. Moreover, other types of sensors, such as those used for measuring water fraction, hematocrit, bispectral index (BIS), etc., may benefit from the techniques disclosed herein as well. An example system incorporating a sensor capable of performing regional oximetry is discussed with respect to FIG. 1, with various features of the sensor, such as a flexible circuit, foam layers, adhesive layers, and connector being discussed with respect to FIGS. 2, 7, and 11. As noted above, these sensors are generally known

to be one-time-use medical sensors that may be disposed after use by one patient. Though disposable, some components of these used sensors, such as the cables, connectors, and memory units associated therewith, may be employed in the construction of remanufactured sensors. Reusing these components to reconstruct a sensor may reduce waste, consequently reducing an impact on the environment, while accordingly reducing costs. Example methods for remanufacturing these and other sensors from new and/or used components are discussed with respect to FIGS. 3-6, 8-10, 12, and 13.

With this in mind, FIG. 1 depicts an embodiment of a patient monitoring system 10 that may be used in conjunction with a medical sensor 12. Although the depicted embodiments relate to sensors for use on a patient's head, it should be understood that, in certain embodiments, the features of the sensor 12 as provided herein may be incorporated into sensors for use on other tissue locations, such as the back, the stomach, the heel, the ear, an arm, a leg, or any other appropriate measurement site. In addition, although the embodiment of the patient monitoring system 10 illustrated in FIG. 1 relates to photoplethysmography or pulse oximetry, the system 10 may be configured to obtain a variety of medical measurements with a suitable medical sensor. For example, the system 10 may additionally be configured to determine patient electroencephalography (e.g., a bispectral index), or any other desired physiological parameter such as water fraction or hematocrit.

As noted, the system 10 includes the sensor 12 that is communicatively coupled to a patient monitor 14. The illustrated sensor 12 includes an emitter 16 and a pair of detectors 18. The emitter 16 and detectors 18 of the sensor 12 are coupled to the monitor 14 via first and second cables 24, 26 through a connector 28 coupled to a sensor port of the monitor 14. The first cable 24 may interface directly with the sensor 12 and may include a relatively flat, flexible cable having a plurality of printed conductors on a dielectric substrate. The first cable 24 may provide enhanced comfort for a patient due to its soft feel and flexibility, which may enable the patient to move about freely. However, other cables having a plurality of conductors (e.g., wires) may be directly coupled to the sensor 12 in other embodiments. For example, in certain embodiments, a cable such as the second cable 26 may couple directly to the sensor 12. The materials of the first cable 24 are discussed in detail with respect to FIG. 2. The first cable 24 may couple to the second cable 26, which may include a plurality of conductors disposed within an insulating material, via a cable adapter 30. As illustrated, the second cable 26 couples to the monitor 14 via the connector 28. It should be noted that in some embodiments, however, the sensor 12 and associated cables 24, 26 may couple to a pre-amplifier (not shown) configured to amplify signals collected by the detectors 18. For example, the pre-amplifier may have a cable that couples to the second cable 26 and additional cable that couples to the monitor 14. However, in the illustrated embodiment, the pre-amplifier may be provided as a part of the monitor 14. The connector 28, in certain embodiments, may include a memory unit 32 that may be configured to store patient historical data, such as historical regional oximetry data. The memory unit 32, alternatively or additionally, may be configured to store sensor-related information and time-out functionality to facilitate the operability of the sensor 12 with the monitor 14. In some embodiments, the memory unit 32 may be an erasable programmable read-only memory (EPROM) having code configured to execute a time-out routine that disables the operability of the sensor 12 with the

monitor **14** after a predetermined number of connections and/or uses, or after a predetermined amount of time.

The monitor **14** includes a monitor display **20** configured to display information regarding the physiological parameters monitored by the sensor **12**, information about the system, and/or alarm indications. The monitor **14** may include various input components **22**, such as knobs, switches, keys and keypads, buttons, etc., to provide for operation and configuration of the monitor. The monitor **14** also includes a processor that may be used to execute code such as code for implementing various monitoring functionalities enabled by the sensor **12**. As discussed below, for example, the monitor **14** may be configured to process signals generated by the detectors **18** to estimate the amount of oxygenated vs. de-oxygenated hemoglobin in a monitored region of the patient.

The monitor **14** may be any suitable monitor, such as a pulse oximetry monitor available from Nellcor Puritan Bennett LLC or an INVOS® System monitor available from Somanetics Corporation. Furthermore, to upgrade conventional operation provided by the monitor **14** to provide additional functions, the monitor **14** may be coupled to a multi-parameter patient monitor **34** via a cable **36** connected to a sensor input port or via a cable **38** connected to a digital communication port. In addition to the monitor **14**, or alternatively, the multi-parameter patient monitor **34** may be configured to calculate physiological parameters and to provide a central display **40** for the visualization of information from the monitor **14** and from other medical monitoring devices or systems. The multi-parameter monitor **34** includes a processor that may be configured to execute code. The multi-parameter monitor **34** may also include various input components **42**, such as knobs, switches, keys and keypads, buttons, etc., to provide for operation and configuration of the a multi-parameter monitor **34**. In addition, the monitor **14** and/or the multi-parameter monitor **34** may be connected to a network to enable the sharing of information with servers or other workstations.

The sensor **12**, illustrated as operatively connected to the monitor **14**, may include a sensor body **44** that houses the emitter **16** for emitting light at certain wavelengths into a tissue of a patient and the detectors **18** for detecting the light after it is reflected and/or absorbed by the blood and/or tissue of the patient. The sensor body **44** may be formed from any suitable material, including rigid or conformable materials, such as fabric, paper, rubber or elastomeric compositions (including acrylic elastomers, polyimide, silicones, silicone rubber, celluloid, PMDS elastomer, polyurethane, polypropylene, acrylics, nitrile, PVC films, acetates, and latex). One embodiment is discussed in detail below with respect to FIG. 2.

In certain embodiments, the sensor **12** may be a wireless sensor **12**. Accordingly, the wireless sensor **12** may establish a wireless communication with the patient monitor **14** and/or the multi-parameter patient monitor **34** using any suitable wireless standard. By way of example, the wireless module may be capable of communicating using one or more of the ZigBee standard, WirelessHART standard, Bluetooth standard, IEEE 802.11x standards, or MiWi standard.

As provided herein, the sensor **12** may be configured to perform regional oximetry. Indeed, in one embodiment, the sensor **12** may be an INVOS® cerebral/somatic sensor available from Somanetics Corporation. In regional oximetry, by comparing the relative intensities of light received at two or more detectors, it is possible to estimate the blood oxygen saturation of hemoglobin in a region of a body. For example, a regional oximeter may include a sensor to be placed on a patient's forehead and may be used to calculate the oxygen

saturation of a patient's blood within the venous, arterial and capillary systems of a region underlying the patient's forehead (e.g., in the cerebral cortex). As illustrated in FIGS. 1 and 2, the sensor **12** may include the emitter **16** and the two detectors **18**: one detector **18A** that is relatively "close" to the emitter **16** and another detector **18B** that is relatively "far" from the emitter **16**. Light intensity of one or more wavelengths may be received at both the "close" and the "far" detectors. Thus, the detector **18A** may receive a first portion of light and the detector **18B** may receive a second portion of light. Each of the detectors **18** may generate signals indicative of their respective portions of light. For example, the resulting signals may be contrasted to arrive at a regional saturation value that pertains to additional tissue through which the light received at the "far" detector passed (tissue in addition to the tissue through which the light received by the "close" detector passed, e.g., the brain tissue) when it was transmitted through a region of a patient (e.g., a patient's cranium). Surface data from the skin and skull is subtracted out to produce an rSO₂ value for deeper tissues.

To provide conformance to these or other patient tissues that are monitored by the sensor **12**, the sensor **12** may include a flexible (flex) circuit **50** operatively connected to the emitter **16** and the detectors **18**, as illustrated in FIG. 2. FIG. 2 depicts one embodiment of the manner in which the flex circuit **50** may be integrated into various used and/or new components to form the sensor **12**. Thus, in certain embodiments, the sensor **12** of FIG. 2 may be a remanufactured sensor constructed from a combination of new and used sensor materials. In this way, various materials forming the sensor **12** of FIGS. 1 and 2 discussed herein may be new or from a used medical sensor (e.g., a used regional oximeter). As illustrated, the emitter **16** and the detectors **18** are operatively connected to the flex circuit **50**. The flex circuit **50** may include various features for providing power to and carrying signals to and from the emitter **16** and the detectors **18**, such as a plurality of conductors **52** disposed (e.g., printed) on a main flexible substrate **54**. The main flexible substrate **54** may include any suitable flexible dielectric substrate. For example, the main flexible substrate **54** may include organic polymers such as polyimides, one example of which is KAPTON® polyimide film available from DuPont™. The plurality of conductors **52** may be formed from any suitable conductive material, such as gold (Au), silver (Ag), copper (Cu), or any combination thereof. The conductors **52** may be disposed on the main flexible substrate **54** using any suitable technique known in the art, such as photolithographic methods. As illustrated, the conductors **52** lead into a tapered section **56** of the flexible circuit **50**, where they become a part of the first cable **24**.

In FIG. 2, the flexible circuit **50** is disposed between a plurality of laminated layers including an inner foam layer **58** (i.e., between the flexible circuit **50** and the patient) and first and second outer foam layers **60**, **62**. It should be noted that while the present embodiments are discussed in the context of including foam layers, any suitable padding materials may be used in accordance with the disclosed embodiments. Therefore, as discussed herein, other medically-suitable padding materials that are compressible and capable of providing a degree of cushioning may be used in place of the foam layers. By way of example, padding materials may generally include foam, sponge, gel cushioning, fiber (e.g., woven fiber), or the like. Indeed, in certain of the remanufacturing embodiments discussed below, such as when any one or a combination of the foam layers **58**, **60**, **62** may be replaced, it may be desirable to use the same or different padding materials in the remanufactured version of the sensor **12**.

Generally, the foam layers **58**, **60**, **62** may be provided to protect the emitter **16** and the detectors **18** from damage, and also to enhance patient comfort. Thus, any number of padding layers may be suitably provided depending on the desired end use of the sensor **12**. Indeed, in certain embodiments, such as in embodiments where the sensor **12** may be used on an adult or in certain pediatric uses, the sensor **12** may not include the inner foam layer **58**. For example, in the SAFB-SM disposable adult SOMASENSOR® or the SPFB disposable pediatric SOMASENSOR®, the inner foam layer **58** may not be present. Each of the foam layers **58**, **60**, **62** may include any natural or synthetic foam material that is suitable for medical applications, such as medical-grade urethane foam. As an example, the foam layers **58**, **60**, **62** may include PORON® urethane foam available from Rogers Corporation.

To adhere the foam layers **58**, **60**, **62** to one another, and, in the case of the inner foam layer **58** and the first outer foam layer **60**, to the flexible circuit **50**, an adhesive may be provided on or between each layer. For example, in the illustrated embodiment, an adhesive **63** (e.g., an adhesive layer) may be applied directly to a top surface **64** and, in some embodiments, a bottom surface **66** of the inner foam layer **58**. Similarly, as illustrated, one or more adhesives, such as an adhesive **65**, may be applied to the top and/or bottom surfaces **68**, **70** of the first outer foam layer **60**, and to a bottom surface **72** of the second outer foam layer **62**. The adhesives **63**, **65** used for each of the surfaces **64**, **66**, **68**, **70**, **72** may be the same or different, and may include any suitable adhesive capable of securing the foam layers to one another and/or to the flexible circuit **50**. For example, the adhesives **63**, **65** may be an acrylic adhesive that is applied to each surface, a supported or unsupported transfer tape layer disposed on and/or between the surfaces, or any similar adhesive material applied directly to and/or between each of the surfaces **64**, **66**, **68**, **70**, **72**. The adhesives **63**, **65** may also be configured to block the ingress of light and other interfering signals into the sensor **12**.

For example, in certain embodiments, any one or a combination of the surfaces **64**, **66**, **68**, **70**, **72** may be coated with a layer or backing that includes a conductive adhesive, for example to shield the flexible circuit **50**, the emitter **16**, the detectors **18**, or any combination thereof from light and/or other electromagnetic interference (EMI). Indeed, the conductive adhesive may be colored (e.g., black) so as to filter all or a portion of light entering into the sensor **12**, and the conductive portions of the adhesive may act as a Faraday shield to dissipate EMI from the sensor **12**. Conductive adhesive materials employed in the construction and/or remanufacturing embodiments described herein may include intrinsically conductive polymers that are adhesive, nonconductive polymers that are adhesive, or any combination thereof. As an example, the adhesive material of the conductive adhesive may include a pressure-sensitive adhesive such as an acrylic adhesive. The intrinsically conductive polymers and nonconductive polymers may be combined with other conductive materials, such as metallic foil backing (e.g., copper foil backing), conductive fillers (e.g., conductive particles, tubes, rods, or fibers), and the like. By way of example, any one or a combination of the surfaces **64**, **66**, **68**, **70**, **72** may be coated with an ARCARE® electrically conductive adhesive available from Adhesives Research, Inc of Glen Rock, Pa. In certain embodiments, the conductive adhesives may also shield the flexible circuit **50**, the emitter **16**, the detectors **18**, or any combination thereof, from patient noise. Thus, it should be noted that in any of the remanufacturing methods described herein, any of the surfaces **64**, **66**, **68**, **70**, **72** may be remanufactured to include these conductive adhesives, and in embodiments where any of the surfaces **64**, **66**, **68**, **70**, **72**

have these conductive adhesives, the conductive adhesive may be replenished or otherwise replaced as appropriate.

As noted above, the flexible circuit **50** is disposed between the inner foam layer **58** and the first outer foam layer **60**, which are also attached to each other at the extents surrounding the flexible circuit **50**. However, as noted above, in other embodiments, the inner foam layer **58** may not be present. In the illustrated embodiment, the flexible circuit **50** is secured to the top surface **64** of the inner foam layer **58** and the bottom surface **70** of the first outer foam layer **60**, and the portion of these surfaces **64**, **70** that are not attached to the flexible circuit **50** are attached to one another. The inner foam layer **58**, which is disposed between an active face **74** of the emitter **16**, an active face **76** of the “close” detector **18A**, an active face **78** of the “far” detector **18B**, and the patient tissue to be monitored, includes a first optical window **80**, a second optical window **82**, and a third optical window **84**. The first optical window **80** enables the active face **76** of the emitter **16** to transmit unimpeded light toward the patient tissue, and the second and third optical windows **82**, **84** enable the active faces **76**, **78**, respectively, of the detectors **18** to receive the transmitted light from the patient (i.e., respective first and second portions of light). It should be noted that while the illustrated embodiment depicts the inner foam layer **58** as having the optical windows **80**, **82**, **84**, the inner foam layer **58** may not have the optical windows, such as in embodiments where the inner foam layer **58** and any adhesive secured thereto does not absorb or scatter the wavelengths of light used by the emitter **16** and the detectors **18**. In such embodiments, the sensor **12** may include an opaque perimeter material to prevent the ingress of light into the sensor **12**. Further, an opaque material may be provided between the emitter **16** and the detectors **18** to prevent an optical shunt from occurring between the emitter **16** and detectors **18**.

Conversely, the first and second outer foam layers **60**, **62** may be configured to prevent the ingress of light, which may interfere with oximetry measurements, into the sensor **12**. Indeed, an opaque paint, thin polymeric layer, or similar covering may be applied to a top surface **86** of the second outer foam layer **62** to prevent the ingress of light into the sensor **12**. Moreover, because the top surface **86** of the second outer foam layer **62** may be the outermost layer of the sensor **12**, various indications may be provided thereon, such as decorative markings, placement instructions, trade names, indications for use (e.g., indications for adult or neonate use), and so forth.

The opposite side of the sensor **12** (i.e., the patient side) includes a patient-contacting adhesive layer **88** laminated on the bottom surface **66** of the inner foam layer **58** in some embodiments, and laminated on the flexible circuit **50** or the adhesive **63** in other embodiments. The patient-contacting adhesive layer **88** may include any adhesive material suitable for integration into medical devices (e.g., a hypoallergenic adhesive material). In some embodiments, the adhesive material may be substantially transparent with respect to the wavelengths of light used for the oximetry measurements performed by the sensor **12**. In other embodiments where the patient-contacting adhesive layer **88** is not transparent with respect to the wavelengths of light used for the oximetry measurements, the patient-contacting adhesive layer **88** may include first, second, and third optical windows **81**, **83**, **85** (e.g., openings), illustrated as dashed lines, corresponding to the respective positions of the emitter **16** and the first and second detectors **18A**, **18B**. By way of example, the patient-contacting adhesive layer **88** may include an acrylic adhesive or a hydrocolloid adhesive. Generally, hydrocolloid adhesives may provide enhanced comfort for the patient and avoid

damage to the patient's skin when the sensor **12** is removed or repositioned. Further, the patient-contacting adhesive layer **88** may be a transfer adhesive or may be a single-sided adhesive. Thus, a patient-contacting surface **90** of the patient-contacting adhesive layer **88** will generally be provided as an adhesive surface, but a top surface **92** of the patient-contacting adhesive layer **88** may or may not be adhesive, depending on whether the bottom surface **66** of the inner foam layer **58** is adhesive or if the adhesive **63** is provided. Generally, the patient-contacting adhesive layer **88** may be a transfer adhesive where the patient-contacting surface **90** and the top surface **92** are both adhesive. In embodiments where the patient-contacting adhesive layer **88** is a hydrocolloid layer, both surfaces **90, 92** may be adhesive. In certain embodiments, the surface area of the hydrocolloid adhesive may be greater than the surface area of the foam layers (e.g., layer **58**), which may leave an outer perimeter of the adhesive surface **92** exposed once the sensor **12** is assembled. Accordingly, a film or other non-adhesive material may be applied to the surface **92** to render it non-adhesive. Indeed, it may be desirable to render the surface **92** non-adhesive because the exposed portion of the surface **92**, once the sensor **12** is assembled and in use, may undesirably adhere to clothing or other contaminants. Accordingly, in embodiments where the patient-contacting adhesive layer **88** includes a hydrocolloid layer, the non-adhesive film or coating may be used to render all or a portion of the surface **92** non-adhesive during remanufacture.

A release liner **94** may also be provided to prevent the inadvertent attachment of the patient-contacting layer **88** to a surface before the intended use of the sensor **12**. The release liner may include any liner having a release material suitable for use with the patient-contacting adhesive layer **88**, such as a coated release paper or a release plastic film. Example release materials include polyolefins (e.g., polypropylene, high- and low-density polyethylene), polyesters (e.g., biaxially-oriented polyethylene terephthalate), polyvinyl alcohol, Kraft paper, polystyrene, or the like.

As illustrated, the flexible circuit **50** tapers into a tail region **95**, which may serve as the inner portion of the first cable **24**. However, in other embodiments the flexible circuit **50** may not taper into a cable, and may instead directly interface with a cable, such as the second cable **26**. The tail region **95** may be surrounded by a padding material, such as first and second foam wrap layers **96, 97**. As an example, the first and second foam wrap layers **96, 97** may include a polyethylene foam, and may adhere to the tail region **95** via first and second adhesives **98, 99**. Because the first and second foam wrap layers **96, 97** are exposed and may encounter patient tissue and fluids or otherwise become contaminated, they may be remanufactured in accordance with the disclosed techniques.

As noted above, the sensor **12** discussed with respect to FIGS. **1** and **2** may be manufactured from a combination of new, refurbished, and/or used materials. Indeed, the present embodiments provide various methods for remanufacturing regional oximetry sensors in accordance with the embodiments discussed above. For example, FIG. **3** illustrates a generalized sensor remanufacturing method, FIGS. **4-6** illustrate sensor remanufacturing methods for replacing and/or refurbishing various features of the sensor **12**, and FIGS. **8-10** and **12** each illustrate a connector/memory unit remanufacturing method that can be performed in conjunction with or independently of the methods of FIGS. **4-6**.

Referring now to FIG. **3**, an embodiment of a method **100** for remanufacturing a medical sensor (e.g., an TWOS® sensor), such as the sensor **12**, is illustrated. The method begins with obtaining a used version of the sensor **12** (block **102**). The used version of the sensor **12** may be a single-use medical

sensor (i.e., for use on a single patient) or may be a reusable sensor. The sensor **12** may be obtained, as an example, by a technician or similar manufacturing personnel. The sensor **12** may be sterilized before or after the acts represented by block **102** such that the sensor **12** is suitable for handling by a technician or similar worker. The sensor **12** may also undergo inspection and/or testing to determine the operability of the sensor **12** (block **104**). As an example, in embodiments where the sensor **12** is a pulse oximetry sensor, the testing may include testing the operation and accuracy of the emitter(s) **16**, the detector(s) **18**, the sensor cable **24**, the cable connector **28**, and any other electronic features of the sensor **12**, such as the memory unit **32**.

After the sensor **12** has been inspected and tested, it may be determined whether it is appropriate to remanufacture the sensor (query **106**). For example, it may be determined whether the sensor **12** includes suitable components for remanufacture (e.g., by reviewing the results of the sensor testing acts of block **104** and/or visual inspection). Alternatively or additionally, it may be determined whether the sensor **12** has undergone previous iterations of remanufacturing. Accordingly, the sensor **12** may include one or more indications as to whether the sensor **12** has been previously remanufactured, such as an external mark on the sensor **12** or a counter stored on the memory unit **32**.

In embodiments where remanufacture is not appropriate, the used version of the sensor **12** may be discarded (block **108**). For example, one or more features of the used version of the sensor **12** may be inoperative, such as the emitter **16** and detectors **18** (e.g., FIG. **2**), the cable **24**, and so on. Depending on the degree to which the sensor **12** may be inoperative, it may no longer be cost-effective to remanufacture, and the sensor **12** may be discarded. In other embodiments, as mentioned above, the sensor **12** may have an external mark or a stored counter that indicates that the sensor **12** is not suitable for remanufacture. Indeed, as discussed herein, the external markings and/or the counter on the memory unit **32** may be incremented with each remanufacturing procedure.

Conversely, in embodiments where it is determined that at least a portion of the sensor **12** is suitable for remanufacturing, the sensor **12** may be remanufactured according to certain remanufacturing processes (block **110**). For example, in embodiments where the sensor **12** includes at least some operable components (e.g., an operable emitter and/or detector), or has one or more indications via the memory unit **32** and/or external marks that remanufacturing is suitable, the sensor **12** may be remanufactured. Embodiments of certain remanufacturing processes are discussed below. Indeed, while the remanufacturing processes discussed below are presented in the context of replacing all or a part of the sensor body **44**, connector **28**, memory unit **32**, or a combination, it should be noted that the processes described below may be performed independently or in conjunction with other steps, such as replacing the emitter **16** and/or the detectors **18**.

After the sensor **12** has been remanufactured, the sensor **12** is then tested to ensure that it is within certain operational tolerances (block **112**). For example, the sensor **12** may be attached or otherwise coupled to a test rig, which may determine and, if suitable, adjust varying operational parameters of the sensor **12**. For example, various sensor-specific information may be stored on the memory unit **32**, such as light emitting diode (LED)-related calibration data if the emitter **16** and/or detectors **18** are replaced, information pertaining to the sensor **12** (e.g., the name of the sensor **12**, a model code for the sensor **12**), or the like. The sensor **12** may then be packaged and sterilized (block **114**), and sent to a medical facility for use.

Certain sensor remanufacturing processes that may be performed in conjunction with or independent of the method 100 set forth above may include replacing some of all of the foam and/or adhesive layers of the sensor 12 (FIG. 2) with new foam and/or adhesive layers. FIG. 4 depicts an embodiment of one such method 120. The method 120 begins with obtaining the used version of the sensor 12 (block 122), which may include receiving the sensor 12 from a testing facility (e.g., in embodiments where method 120 is performed in conjunction with method 100), or obtaining the used sensor from a medical facility (e.g., in embodiments where method 120 is not performed in conjunction with method 100). For example, the sensor 12 may be obtained after the sensing components have been tested, or after the sensor 12 has been used to monitor a patient.

After the sensor 12 is obtained, the sensor 12 may be prepared for remanufacturing (block 124). For example, the preparation may include cleaning the sensor 12, such as by removing debris or other material away from the optics of the sensor 12, and may also include sterilizing the sensor 12. For example, the acts according to block 124 may include sterilizing the sensor 12 using ethylene oxide (EtO) gas, gamma irradiation, autoclaving, Pasteurization, chemical antiseptics, or other such materials and methods. Sterilization may be performed at the same facility as other remanufacturing steps, or may be performed at a separate facility.

Once the sensor has been prepared for remanufacturing, the patient-contacting adhesive layer (e.g., layer 88 of FIG. 2) may be removed (block 126). Specifically, the patient-contacting adhesive layer 88 may be removed before removing any of the foam layers 58, 60, 62, after removing the foam layers 58, 60, 62, or as the foam layers 58, 60, 62 are removed, as discussed below. Referring to the embodiment illustrated in FIG. 2 for example, as the inner foam layer 58 is removed, the patient-contacting adhesive layer 88, which is laminated against the inner foam layer 58, may also be removed. Further, it should be noted that in embodiments where the sensor 12 does not include the inner foam layer 58, removing the patient-contacting adhesive layer 88 may expose at least a portion of the flexible circuit 50 for remanufacture.

At least a portion of the foam layers 58, 60, 62 and/or the foam wrap layers 96, 97 may be removed from the sensor 12 (block 128). For example, referring to the embodiment illustrated in FIG. 2, all or a portion of the second outer foam layer 62, the first outer foam layer 60, the inner foam layer 58, the first foam wrap layer 96, the second foam wrap layer 97, or any combination thereof, may be partially or completely removed by cutting or pulling all or a portion of each layer away from the flexible circuit 50/tail region 95. It will be appreciated that during removal, the adhesives associated with each layer may also be removed. For example, it may be desirable to remove the second outer foam layer 62 and the first and second foam wrap layers 96, 97 due to their increased level of exposure to the environment during use. Accordingly, adhesives 65, 98, 99 may also be removed. In embodiments where the inner foam layer 58 is present, it may be desirable to remove the inner foam layer 58 and associated adhesive 63 to expose at least a portion of the flexible circuit 50 or due to its proximity to patient tissue. Furthermore, any one or a combination of the foam layers may be shaved (e.g., along its length) to expose a clean foam surface that can be attached to a new or used foam or adhesive layer. In embodiments where the sensor 12 does not include the inner foam layer 58, no foam layers may be removed from the body 44 of the sensor 12.

Once the foam 58, 60, 62, 96, 97 and adhesive layers 63, 65, 88, 98, 99 have been removed as appropriate, they may be

replaced with new foam 58, 60, 62, 96, 97 and adhesive 63, 65, 88, 98, 99 (block 130). Indeed, any one or a combination of the inner foam layer 58, first outer foam layer 60, and second outer foam layer 62 may be replaced along with the patient-contacting adhesive layer 88. The foam layers 58, 60, 62, 96, 97 may be replaced with the same or different foam materials than those originally used, and the patient-contacting adhesive layer 88 may be replaced with the same or a different adhesive. For example, the patient-contacting adhesive layer 88 may originally (i.e., before remanufacture) include an acrylic adhesive, and may be replaced with a hydrocolloid layer. Conversely, a hydrocolloid patient-contacting adhesive layer 88 may be replaced with an acrylic adhesive layer, or any suitable adhesive layer.

After the new foam layers 58, 60, 62, 96, 97 and new adhesive layers 63, 65, 88, 98, 99 have been integrated into the remanufactured version of the sensor 12, the sensor 12 may be placed on a new release liner 94 (block 132). The new release liner 94 may include any liner having a release material suitable for use with the patient-contacting adhesive layer 88, such as a coated release paper or a release plastic film. Example release materials include polyolefins (e.g., polypropylene, high- and low-density polyethylene), polyesters (e.g., biaxially-oriented polyethylene terephthalate), polyvinyl alcohol, Kraft paper, polystyrene or the like.

Before, during, or after the steps described above, it may be determined whether the used sensor has a memory unit (e.g., a memory unit having a time-out feature) (query 134). For example, a technician may inspect the connector 28 (FIG. 2) to identify whether the connector 28 houses a memory unit, or this may be done automatically during testing. The connector 28 may include markings, a particular shape, a color code, or similar feature to indicate the presence of a memory unit. In embodiments where the sensor 12 does not include a memory unit, the sensor 12 may be packaged (block 136). However, in embodiments where the sensor 12 does include a memory unit, the memory unit 32 (block 138) may be refurbished before packaging the sensor 12. For example, the memory unit 32 may be cleared of historical and/or programming data, may be re-programmed, may be cleaned, or a combination. In some embodiments, the memory unit 32 may be replaced. However, because the connector 28 and associated memory unit 32 may represent a significant portion of the overall cost for each sensor 12, it may be desirable to retain the connector 28 and memory unit 32 and simply re-program the memory unit 32. Accordingly, the acts represented by block 138 may include re-programming the memory unit 32. Certain embodiments of the manner in which the acts represented by block 138 may be performed are discussed in further detail below with respect to FIGS. 8-10 and 12.

While the method 120 described above may be performed in situations where it is desirable to replace one or more of the foam layers 58, 60, 62 of the sensor 12, it may be desirable to retain the foam layers 58, 60, 62 and only replace the patient-contacting adhesive layer 88 of the sensor 12. For example, during inspection (e.g., in method 100) to determine whether the sensor 12 should be remanufactured, it may be determined that the foam layers 58, 60, 62 do not need replacing. Accordingly, FIG. 5 depicts an embodiment of a method 140 that includes replacing the patient-contacting adhesive layer 88 while retaining the used foam layers 58, 60, 62. It will be appreciated that method 140 may include certain steps that are similar or the same steps as those described above with respect to method 120. Accordingly, those steps are referenced using the same reference numerals throughout the remainder of the present disclosure where the steps are the same. As with method 120, method 140 includes obtaining

the used version of the sensor **12** (block **122**). For example, the sensor **12** may be obtained from a sterilization facility, a third party that collects the used sensors **12**, or directly from the medical facility. The sensor **12** may also be prepared for the remanufacturing process (block **124**) by performing sterilization, re-painting used cables and/or outer layers, as discussed above

After the sensor **12** has been suitably prepared, the patient-contacting adhesive layer **88** may be removed without removing any foam layers **58**, **60**, **62** (block **142**). For example, referring to the embodiment illustrated in FIG. 2, the patient-contacting adhesive layer **88** may be pulled and/or cut away from the bottom surface **66** of the inner foam layer **58**. The used patient-contacting adhesive layer **88** may then be replaced with a new patient-contacting adhesive layer **88** (block **144**). For example, as set forth above with respect to certain of the acts represented by block **130**, the patient-contacting adhesive layer **88** may originally (i.e., before remanufacture) include an acrylic adhesive, and may be replaced with a hydrocolloid layer. Conversely, a hydrocolloid-containing patient-contacting adhesive layer **88** may be replaced with an acrylic adhesive layer, or any suitable adhesive layer. Further, the patient-contacting adhesive layer **88** may simply be replaced with the same type of adhesive layer.

After the adhesive layer has been replaced, the sensor may be placed on a new release liner (block **132**). It may also be determined whether the sensor has a memory unit (query **134**). As set forth above, in embodiments where the sensor **12** does not have the memory unit **32**, the sensor **12** may be placed in its packaging (block **136**). Conversely, in embodiments where the sensor **12** does include the memory unit **32**, the memory unit **32** may be refurbished before the sensor is placed in its packaging (block **138**), as discussed above.

Although the patient-contacting adhesive layer **88** is removed in the methods **120**, **140** described above, in certain embodiments, it may be desirable to place a new patient-contacting adhesive layer **88** over the used patient-contacting adhesive layer **88**. For example, referring to the embodiment illustrated in FIG. 2, removal of the used patient-contacting adhesive layer **88** may cause at least a portion of the inner foam layer **58** to be removed. Such situations may be undesirable, as the beneficial cushioning and protection for the flexible circuit **50**, as well as the enhanced patient comfort provided by the inner foam layer **58**, may be disrupted. Accordingly, the present disclosure also provides a method **150**, illustrated in FIG. 6, for remanufacturing the sensor **12** by placing a new patient-contacting adhesive layer **88** over the used patient-contacting adhesive layer **88**.

The method **150** includes obtaining the used version of the sensor **12** (block **122**) and preparing the used version of the sensor **12** for remanufacturing (block **124**), as described above with respect to methods **120** and **140**. In method **150**, the preparation of the sensor **12** may include trimming away a portion of the used patient-contacting adhesive layer **88** to fit within the extents of a new adhesive layer. Thereafter, the new patient-contacting adhesive layer **88** may be placed on top of the used patient-contacting adhesive layer **88** (block **152**). Again, the new patient-contacting adhesive layer **88** may be the same or different than the used patient-contacting adhesive layer **88**. Thus, a cross-section taken along line 7-7 of the sensor **12**, an embodiment of which is illustrated in FIG. 7, may reveal two distinct patient-contacting layers: the used patient-contacting adhesive layer **88** and a new patient-contacting adhesive layer **160** disposed over the used patient-contacting adhesive layer **88**. However, it should be noted that in certain embodiments, there may be no discernable difference between the used patient-contacting adhesive layer **88**

and the new patient-contacting adhesive layer **160**, such as in configurations where the adhesive layers **88**, **160** are the same, or where one or both include an unsupported transfer tape layer.

Returning to the method **150** illustrated in FIG. 6, after the new patient-contacting adhesive layer has been laminated over the used patient-contacting adhesive layer, the acts represented by blocks **132-138**, as described above, may be performed. Thus, the sensor may be placed on a new release liner (block **132**). It may also be determined whether the sensor **12** has the memory unit **32** (query **134**). In embodiments where the sensor **12** does not have the memory unit **32**, the sensor **12** may be placed in its packaging (block **136**). Conversely, in embodiments where the sensor **12** does include the memory unit **32**, the memory unit **32** may be refurbished before the sensor **12** is placed in its packaging (block **138**) as discussed above.

As noted above, FIGS. 8-10 and **12** illustrate embodiments of methods for refurbishing the memory unit **32** of the sensor **12**. Specifically, FIG. 8 illustrates a method **138A** that includes replacing the used connector **28** having the memory unit **32** with a new connector **28** having a new memory unit **32**. Specifically, method **138A** includes removing the connector **28**, which houses the memory unit **32**, from the sensor **12** (block **170**). For example, referring to the embodiment illustrated in FIG. 1, the connector **28** may be removed from the second sensor cable **26**, the connector **28** and the second sensor cable **26** may be removed from the first sensor cable **24**, or the connector **28**, the second sensor cable **26**, and the first sensor cable **24** may be removed from the sensor **12**. Because the first sensor cable **24** may be integral with the flexible circuit **50** (FIG. 2), in certain embodiments it may be desirable to only remove the connector **28** or the connector **28** and the second sensor cable **26**.

Once the connector **28** and associated memory unit **32** have been detached from the sensor **12**, a new connector **28** having the new memory unit **32** may be provided (block **172**). The connector **28** and/or new memory unit **32** may have the same or a similar configuration compared to the used memory unit **32**. In some embodiments, the new memory unit **32** may include stored code that enables new or enhanced functionality for the sensor **12** (e.g., when connected to the monitor **14**), such as increased patient history functionality and/or updated operational information that reflects any updates, upgrades, or other changes that have been made to the sensor **12**. For example, in embodiments where the emitter **16** and/or detectors **18** are replaced, new calibration data may be written to the memory unit **32**. The new connector **28** and memory unit **32** may then be attached to the sensor **12** (block **174**).

Because the connector **28** and associated memory unit **32** may represent a significant portion of the overall cost for each sensor **12**, it may be desirable to retain the connector **28** and memory unit **32** and simply re-program the memory unit **32**. FIG. 9 illustrates an embodiment of a method **138B** for re-programming the memory unit **32**. The method **138B** includes providing a memory alteration device (not shown) (block **180**), which may include a computer or other processor-based device that is capable of accessing and deleting at least a portion of the data stored on the memory unit. Indeed, the memory alteration device may be an application-specific or a general-purpose computer having code configured to re-program the memory unit contained within the connector. Furthermore, the memory alteration device may include one or more ports for coupling to the connector or to the memory unit, or both.

After the memory alteration device is provided, the connector **28** and/or memory unit **32** may be coupled to the

alteration device (block 182). As noted above, the memory alteration device may include a port that couples to the connector 28 through which the memory alteration device is able to access and re-program the memory unit 32. Alternatively or additionally, the memory alteration device may include a port that specifically receives the memory unit 32, such that the memory unit 32 may be removed from the connector 28 and coupled directly to the memory alteration device for re-programming.

Once the memory unit 32 is directly or indirectly coupled to the memory alteration device, the memory unit 32 may be cleared or otherwise re-programmed (block 184). For example, in embodiments where the memory unit 32 has time-out functionality that causes the sensor to become non-functional after a given number of connections, uses, or after a certain amount of time in operation, the memory alteration device may re-set the number of connections, uses, or time in operation to zero or another lower threshold value. Alternatively or additionally, in embodiments where the memory unit 32 contains stored patient or other historical data, the memory alteration device may clear the historical data. As noted above, in embodiments where the emitter 16 and/or the detectors 18 are replaced, new or updated calibration data may be written to the memory unit 32. In certain embodiments, sensor-related information may be written to the memory unit 32, which may be displayed on the display of a monitor to which the sensor 12 may attach (e.g., the display 20 of the patient monitor 14). For example, the memory unit 32 may be programmed such that the type of sensor is displayed (e.g., the name or model number of the sensor). An indication that the sensor 12 has been remanufactured, and in some embodiments, the number of remanufacturing iterations that the sensor 12 has undergone, may be provided along with the type of sensor. The indication may include, by way of example, a combination of alphanumeric characters or a combination of ASCII characters, or both. For example, for a disposable adult SomaSensor® from Somanetics Corporation (e.g., model SAFB-SM), the display 20 may read “SAFB-SM-R2,” with “SAFB-SM” indicating the model of the sensor 12 and “-R2” indicating that the sensor 12 is a sensor that has been remanufactured twice.

After the memory unit 32 is cleared and/or re-programmed, the memory unit 32 may be removed from the memory alteration device (block 186) and may be suitable for use in conjunction with a remanufactured sensor (i.e., sensor 12). However, rather than re-programming or replacing the memory unit 32 as set forth above, it may be desirable to use an adapter that is configured to manipulate a data stream to and/or from the memory unit 32 to enable continued operation of the sensor 12, even after a predetermined number of connections, uses, and/or time has been exceeded. FIG. 10 illustrates an embodiment of a method 138C that includes providing an adapter for the memory unit 32 (block 190). For example, referring to the embodiment depicted in FIG. 1, the adapter may be attached to the connector 28 (block 192). The adapter may be configured to manipulate data transmitted to the memory unit 32 such that the memory unit 32 receives data indicative of a reduced number of connections, a reduced operation time, and/or a reduced number of uses. Alternatively or additionally, the adapter may manipulate data transmitted from the memory unit 32 to the monitor 14 such that the memory unit 32 transmits data indicative of a reduced number of connections, a reduced operation time, and/or a reduced number of uses to the monitor 14. In either scenario, the adapter may enable the continued use, and therefore the

retention, of the electronic components of the sensor 12 after remanufacturing, including the flexible circuit 50, the emitter 16, and the detectors 18.

Due to its mode of operation, the adapter may be retained as a part of, or integral with, the connector 28 (block 194). An embodiment of such a configuration is illustrated in FIG. 11. Specifically, FIG. 11 depicts an embodiment of the sensor 12 where the connector 28 having the memory unit 32 is connected to an adapter unit 196. In some embodiments, as set forth above, the memory unit 32 may include time-out functionality, which causes the sensor 12 to become inactive after the sensor 12 has been in operation after a predetermined amount of time. As noted, because the connector 28, memory unit 32, and other electrical components of the sensor 12 may be retained in the manufacturing process, it may be desirable to increase the amount of time that these components may be placed in operation. Thus, the adapter unit 196 may be configured to disable or otherwise manipulate the time-out functionality to enable the continued use of the sensor 12. For example, the adapter unit 196 may provide data to the memory unit 32 that is indicative of a reduced amount of use compared to the actual amount of use of the sensor 12. Alternatively or additionally, the adapter unit 196 may manipulate the data that is transmitted from the memory unit 32 to the monitor 14 (FIG. 1) to enable the continued use of the sensor 12. Thus, the adapter unit 196, as illustrated, may be coupled to the connector 28 and may have the same or a similar pin-out configuration to the connector 28 for coupling to the monitor 14.

While the embodiments described above relate to situations where the original memory unit 32 or original memory unit programming is available, in situations where the memory unit components and/or the programming are not available, it may be desirable to emulate the original memory unit 32. For example, it may be desirable to emulate the original memory unit 32 using a replacement memory unit that has been programmed to mimic the function of the original memory unit. FIG. 12 illustrates an embodiment of such a method 138D, which may be performed in conjunction with certain of the sensor remanufacturing methods described above, or may be performed independently.

The method 138D includes providing a memory emulator (not shown) and a replacement memory unit 32 (block 200). For example, a memory emulator may include an application-specific or general purpose processor-based device (e.g., a computer) that is configured to interface with the original memory unit 32 and/or the connector 28 that includes the memory unit 32. The new memory unit 32 may include a memory device that is capable of being programmed in a similar manner to the original memory unit 32, such as an EPROM. The replacement or new memory unit 32 may also interface with the memory emulator such that the new memory unit 32 may be suitably programmed by the memory emulator to mimic the output of the original memory unit 32.

The used memory unit 32, or the used connector 28 having the memory unit 32, may then be attached to the memory emulator (block 202). For example, the memory emulator may have a connection port that is similar to the connection port of the monitor 14 of FIG. 1. In other embodiments, the memory emulator may include a memory interface, such that the used memory unit 32 is removed from the connector 28 before coupling to the memory emulator.

Once the used memory unit 32 is directly or indirectly connected to the memory emulator, the memory emulator may attempt to automatically, or in conjunction with a technician, emulate the operation of the used memory unit 32. For example, the output of the used memory unit 32 may be

analyzed, and the memory emulator may attempt to mimic or otherwise simulate the output of the used memory unit 32. Once the memory emulator has produced one or more routines that are able to suitably match the output of the used memory unit 32, the new memory unit 32 may be programmed to emulate the configuration of the used memory unit 32 (block 204).

After the operation of the used memory unit 32 is suitably emulated, the used memory unit 32 may be removed from the used/remanufactured sensor 12 (block 206). For example, the memory unit 32 may be removed from the connector 28, or the connector 28 may be removed from the sensor 12. In embodiments where the memory unit 32 has already been removed from the connector 28 during the emulation process, the connector 28 may be removed from the sensor 12. Indeed, once the used memory unit 32 has been removed, the new memory unit 32, which emulates the operation of the used memory unit 32, may be attached to the sensor 12 (block 208). For example, in embodiments where the used memory unit 32 has been removed from the connector 28, the new memory unit 32 may be integrated into the connector 28. However, in embodiments where the used connector 28 has been removed, a new connector 28 may be provided that includes the new memory unit 32.

Again, the connector 28 and memory unit 32 may represent a considerable amount of the total cost of the sensors described herein. Indeed, while it may be cost-effective to remanufacture various portions of the sensor 12 including the flexible circuit 50 and foam layers 58, 60, 62 of FIG. 2, it may be desirable to incorporate the used memory unit 32 and, in some embodiments, the connector 28, into a new sensor, such as the sensor 12 or another type of sensor. With this in mind, FIG. 13 illustrates an embodiment of a method 210 for integrating a used connector 28 and associated memory unit 32 with a new sensor.

Method 210 includes obtaining the used version of the sensor 12 (block 122) as described above with respect to FIGS. 3-6. For example, the sensor 12 may be obtained after the sensing and memory components have been tested (e.g., from a testing facility), after the sensor 12 has been sterilized (e.g., from a sterilization facility), or after the sensor 12 has been used to monitor a patient (e.g., from a medical facility). The connector 28 and memory unit 32 may then be removed (block 170) as described above with respect to FIG. 8. For example, the connector 28 having the memory unit 32 may be removed from the sensor cable or the connector 28 having the memory unit 32 and at least a portion of the sensor cable may be removed from the sensor 12.

Before or after removal of the connector 28 from the sensor 12, the memory unit 32 may be remanufactured according to method 138B described above with respect to FIG. 9, which includes re-programming the used memory unit 32. A new sensor may also be provided (block 212), such as a sensor having new electrical components and new layers disposed about the electrical components (e.g., flexible circuit 50 including emitter 16 and detectors 18 of FIG. 2). It may be appreciated that in embodiments where the memory unit 32 is remanufactured after being removed from the connector 28,

that the new sensor may also include a new connector 28. The remanufactured memory unit 32, or remanufactured memory unit 32 and connector 28, may then be attached to the new sensor (block 214).

While the disclosure may be susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the embodiments provided herein are not intended to be limited to the particular forms disclosed. Rather, the various embodiments may cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure as defined by the following appended claims.

What is claimed is:

1. A method of remanufacturing a used medical sensor, comprising:

obtaining the used medical sensor, the used medical sensor comprising:

a used padding layer;

a used flexible circuit secured to the used padding layer and comprising a plurality of conductors disposed on a flexible substrate;

a used emitter electrically coupled to the flexible circuit and adapted to transmit light into a patient tissue;

a used first detector coupled to the used flexible circuit and configured to detect a first portion of light passing through the patient tissue;

a used second detector coupled to the used flexible circuit and configured to detect a second portion of light passing through the patient tissue; and

a used patient-contacting adhesive layer attached to the used padding layer;

removing the used patient-contacting adhesive layer from the used padding layer by trimming away a portion of the used padding layer, the used padding layer comprising a used interior foam layer disposed between the used flexible circuit and the used patient-contacting adhesive layer;

retaining a remaining portion of the used interior foam layer;

laminating a new patient-contacting adhesive layer against the remaining portion of the used interior foam layer; and

packaging a remanufactured version of the used medical sensor.

2. The method of claim 1, comprising replacing a used memory unit disposed within a used connector of the used medical sensor with a new memory unit, wherein the new memory unit has substantially the same programming as the used medical sensor, or is configured to emulate the operation of the used memory unit.

3. The method of claim 1, comprising coupling a used memory unit disposed within a used connector of the used medical sensor with an adapter configured to manipulate a time-out functionality of the used memory unit to enable the continued operation of the sensor.

* * * * *

专利名称(译)	再制造医疗传感器的技术		
公开(公告)号	US9161722	公开(公告)日	2015-10-20
申请号	US13/226714	申请日	2011-09-07
[标]申请(专利权)人(译)	BESKO DAVID P SANDMORE DONALD - [R		
申请(专利权)人(译)	BESKO , DAVID P. SANDMORE , DONALD R.		
当前申请(专利权)人(译)	COVIDIEN LP		
[标]发明人	BESKO DAVID P SANDMORE DONALD R		
发明人	BESKO, DAVID P. SANDMORE, DONALD R.		
IPC分类号	A61B5/1455 A61B5/00		
CPC分类号	A61B5/14552 A61B5/6832 A61B2560/028 A61B2562/0233 A61B2562/08 A61B2562/12 Y10T29/4973 A61B5/14546 A61B5/6833 A61B5/68335 A61B2560/0443 A61B2560/0475 A61B2562/0238 A61B2562 /164 A61B2562/222 A61B2562/242		
其他公开文献	US20130060109A1		
外部链接	Espacenet USPTO		

摘要(译)

提供了再制造医疗传感器和用于再制造使用过的医疗传感器的方法。这种再制造的传感器可以包括来自使用过的医疗传感器和某些新部件的某些部件。例如，再制造的区域血氧测定传感器可包括填充层，发射器和一对检测器，耦合到发射器和检测器的柔性电路，以及患者接触的粘合剂层。柔性电路，发射器，第一检测器，第二检测器或其任何组合来自使用过的医疗传感器，并且衬垫层，患者接触粘合剂层或其组合是新的。

