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(54) **CERTIFICATION APPARATUS AND METHOD FOR A MEDICAL DEVICE COMPUTER**

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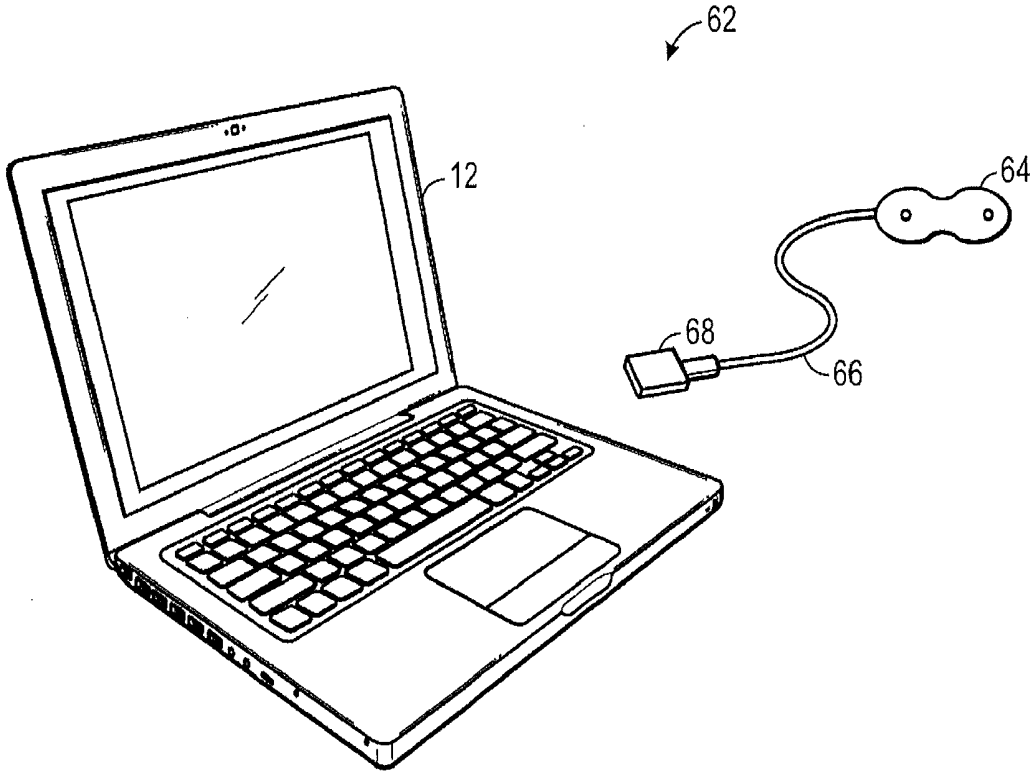
(57) **ABSTRACT**

Provided herein are methods and apparatuses for certifying computers for use in conjunction with medical devices. These methods may be used in conjunction with a computer that includes software for operating the medical device. To certify a particular computer, one or more testing algorithms or routines for processing data, e.g., data representative of a typical output generated by use of the medical device on a patient, may be executed and the results may be compared to an expected result. In particular embodiments, the certification process may use data stored on the device itself to determine certification or may use data stored with or bundled with the software for operating the device.



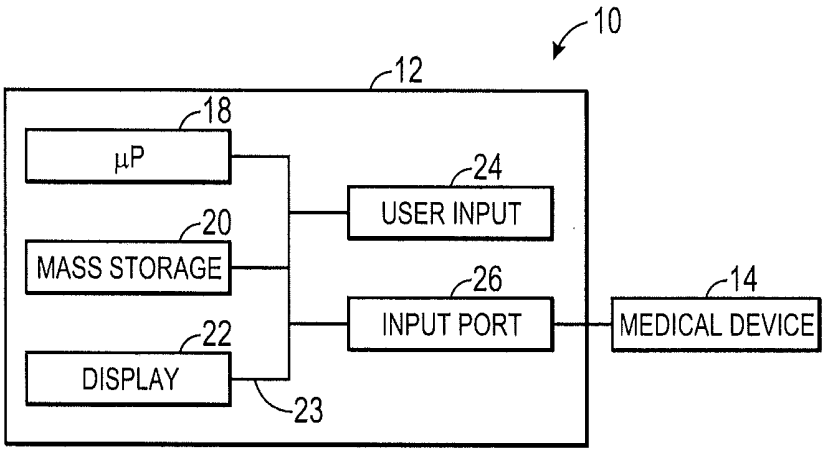

10
12
18
µP
20
MASS STORAGE
22
DISPLAY
23
24
USER INPUT
26
INPUT PORT
14
MEDICAL DEVICE

FIG. 1

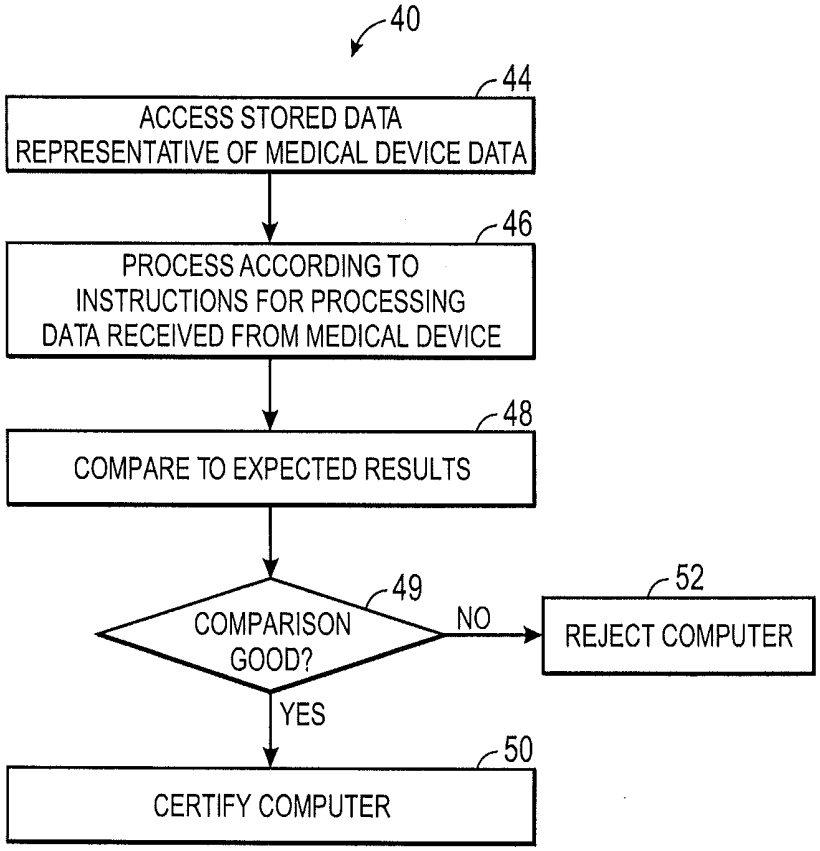

40
44
ACCESS STORED DATA REPRESENTATIVE OF MEDICAL DEVICE DATA
46
PROCESS ACCORDING TO INSTRUCTIONS FOR PROCESSING DATA RECEIVED FROM MEDICAL DEVICE
48
COMPARE TO EXPECTED RESULTS
49
COMPARISON GOOD?
NO
52
REJECT COMPUTER
YES
50
CERTIFY COMPUTER

FIG. 2

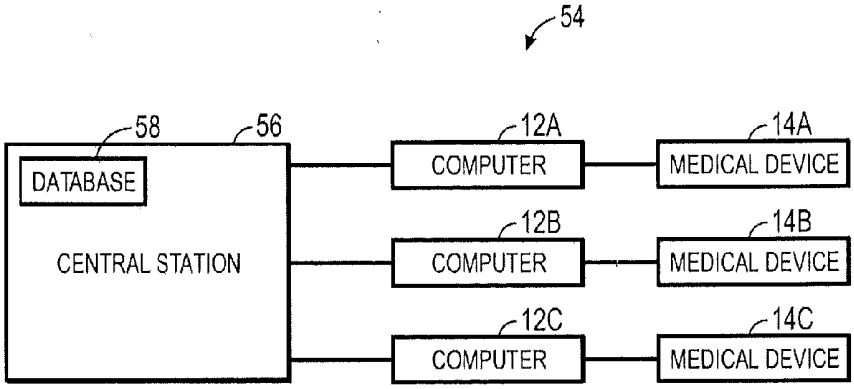

54
58
56
12A
14A
DATABASE
CENTRAL STATION
COMPUTER
MEDICAL DEVICE
12B
14B
COMPUTER
MEDICAL DEVICE
12C
14C
COMPUTER
MEDICAL DEVICE

FIG. 3

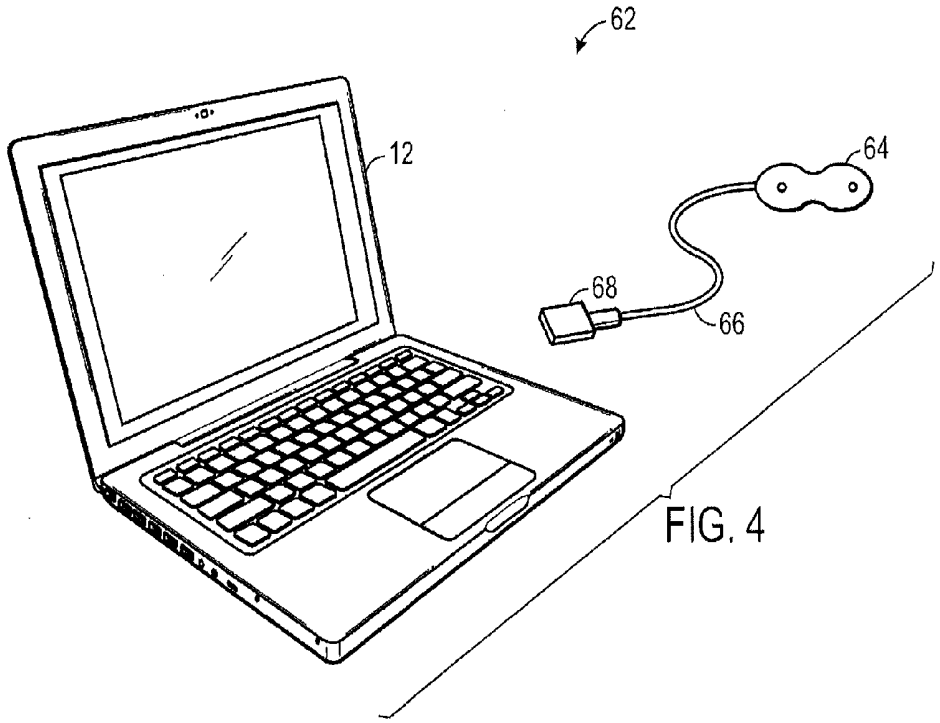

62
12
64
68
66

FIG. 4

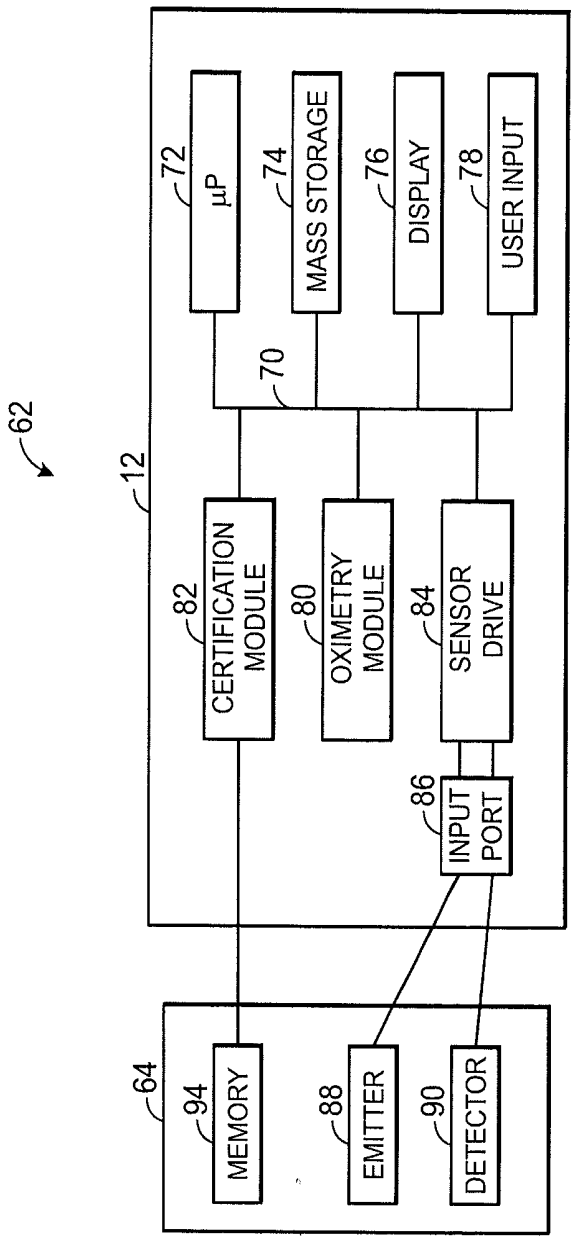

62
12
72
µP
74
MASS STORAGE
76
DISPLAY
78
USER INPUT
70
82
CERTIFICATION MODULE
80
OXIMETRY MODULE
84
SENSOR DRIVE
86
INPUT PORT
64
94
MEMORY
88
EMITTER
90
DETECTOR

FIG. 5

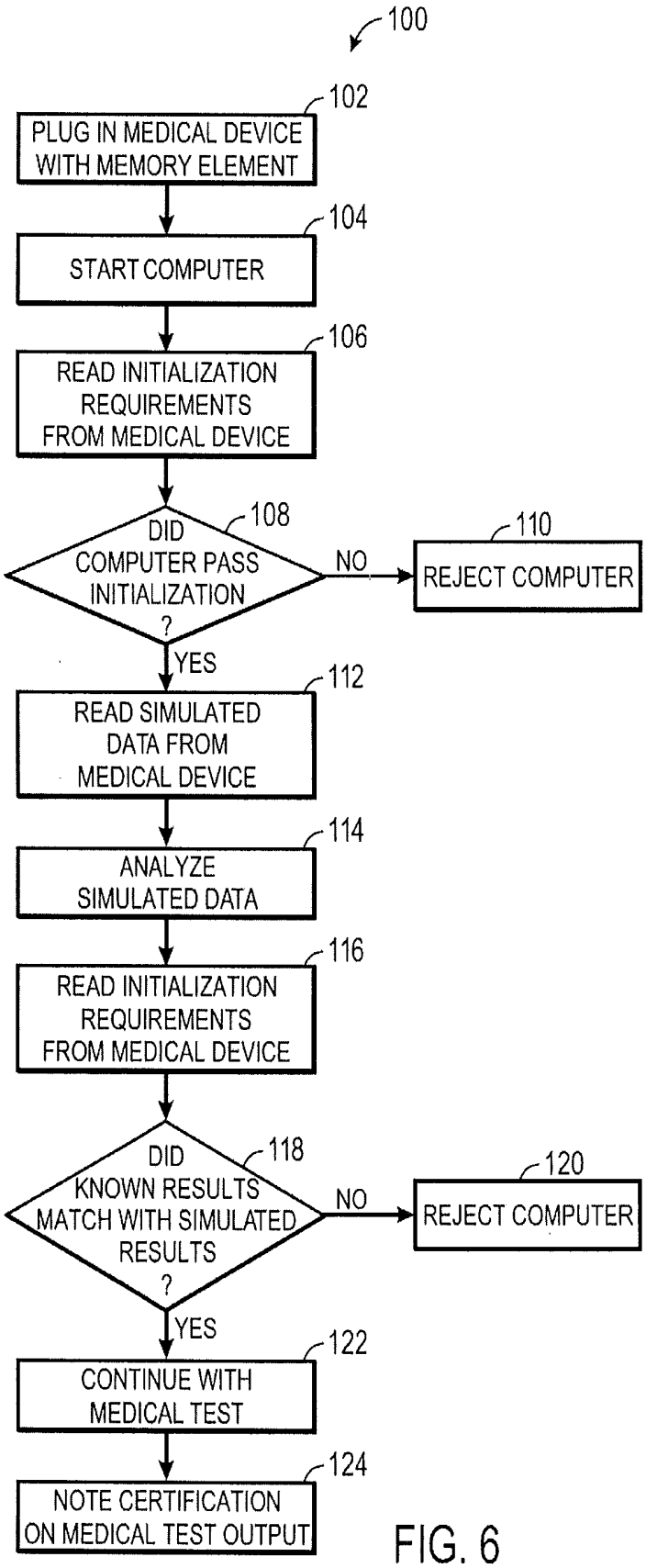

100
102
PLUG IN MEDICAL DEVICE WITH MEMORY ELEMENT
104
START COMPUTER
106
READ INITIALIZATION REQUIREMENTS FROM MEDICAL DEVICE
108
DID COMPUTER PASS INITIALIZATION ?
NO
110
REJECT COMPUTER
YES
112
READ SIMULATED DATA FROM MEDICAL DEVICE
114
ANALYZE SIMULATED DATA
116
READ INITIALIZATION REQUIREMENTS FROM MEDICAL DEVICE
118
DID KNOWN RESULTS MATCH WITH SIMULATED RESULTS ?
NO
120
REJECT COMPUTER
YES
122
CONTINUE WITH MEDICAL TEST
124
NOTE CERTIFICATION ON MEDICAL TEST OUTPUT

FIG. 6

CERTIFICATION APPARATUS AND METHOD FOR A MEDICAL DEVICE COMPUTER

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims priority to U.S. patent application Ser. No. 12/980,971, filed Dec. 29, 2010, the teachings of which are incorporated herein by reference for all purposes.

BACKGROUND

[0002] The present disclosure relates generally to medical monitors and, more particularly, to certification of computers that are used in conjunction with medical devices.

[0003] 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.

[0004] In the field of healthcare, caregivers (e.g., doctors and other healthcare professionals) often desire to monitor certain physiological characteristics of their patients. Accordingly, a wide variety of devices have been developed for monitoring many such characteristics of a patient. Such devices provide doctors and other healthcare personnel with the information they need to provide the best possible healthcare for their patients. As a result, such monitoring devices have become an indispensable part of modern medicine.

[0005] Monitoring devices are often configured as dedicated monitoring units (e.g., a stand-alone pulse oximetry monitor) with integral processing circuitry for receiving measurements from medical devices and converting these measurements into medical information that is meaningful to a clinician. However, certain types of medical devices are capable of being used with configurable personal computers that are loaded with software that communicates with the medical device. For example, a medical sensor may be capable of communicating directly with a personal computer, which, with the appropriate software, is able to receive the sensor measurements and process and display information related to the sensed data. In this manner, an off-the shelf computer may act as a medical monitor.

[0006] In contrast to dedicated monitoring devices, which are limited-purpose machines, a personal computer (e.g., a general purpose computer) may be used for a variety of tasks and, as such, may run a variety of different software programs. Different end users may select different brands and/or computer models depending on their own needs. Accordingly, different types of computers may have differing levels of compatibility with particular medical devices. Further, an individual computer may be frequently upgraded or changed from its factory condition according to the needs of the user, and these updates often occur automatically in response software or operating system changes. In certain instances, these changes may cause certain incompatibilities with installed software for receiving medical device information.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Advantages of the disclosed techniques may become apparent upon reading the following detailed description and upon reference to the drawings in which:

[0008] FIG. **1** illustrates a block diagram of a certification system for a computer to be used in conjunction with a medical device, in accordance with an embodiment of the present technique;

[0009] FIG. **2** illustrates a flow diagram of a certification method in accordance with an embodiment of the present technique;

[0010] FIG. **3** illustrates a perspective view of a central certification system for a medical facility;

[0011] FIG. **4** illustrates a perspective view of a certification system to be used in conjunction with a medical sensor;

[0012] FIG. **5** illustrates a block diagram of a certification system, in accordance with an embodiment of the present technique; and

[0013] FIG. **6** illustrates a flow diagram of a certification method in accordance with an embodiment of the present technique.

DETAILED DESCRIPTION

[0014] One or more 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.

[0015] Medical monitors are built according to FDA or other regulatory specifications and undergo quality testing by the manufacturer. However, in the case of medical devices that may be used with personal or off-the-shelf computers, while the medical devices themselves are subjected to quality testing by the manufacturer, the computers may be purchased by an end user and, thus, are not necessarily tested by the medical device manufacturer for compatibility with the medical device. In such cases, a particular model of computer may be certified by a technician as being compatible with a particular type of medical device and the device's associated software for processing data or measurements. This certification may involve having a technician run diagnostic tests on an individual model of a computer to verify that the device and installed software are compatible and that accurate readings and data processing are performed. Such certifications are time-consuming and involve skilled personnel. In addition, the certification must be repeated for different brands and different models of computers. Because computer vendors frequently change their offerings as technology changes and improves, a particular computer model that has been certified for use with a particular medical device may become obsolete and no longer available on the market. In addition, end users may change the functionality of their own computers, which may introduce device incompatibilities.

[0016] Provided herein is an automatic certification technique for a computer configured to be used in conjunction with a medical device. In addition, provided herein are systems and computers that include certification functionality (e.g., a certification module). The certification may involve using the computer to process stored data representative of

data collected by the medical device and comparing the processed results to an expected result. In this manner, the computer may be certified as performing according to expectations. In certain embodiments, the certification module as well as the data representative of the medical device may be installed directly on the computer (e.g., bundled with software for receiving and processing the medical device signal) so that the certification may take place without any outside input from the medical device. In other embodiments, an input from an associated device may trigger the certification process.

[0017] It should be understood that the certification techniques may be used in conjunction with medical devices for diagnosis and/or therapy. Such devices may include devices for sensing physiological parameters, collecting medical data (e.g., imaging data), delivering therapy, and performing procedures. The devices may include blood or tissue constituent sensors (e.g., pulse oximetry sensors, carbon dioxide sensors, or aquametry sensors), patient temperature sensors, transvascular fluid exchange sensors, blood flow, cardiovascular effort, glucose levels, total hematocrit, electrocardiography, electroencephalograpy, airway products and ventilation devices, infusion pumps, blood pressure devices, apnea masks, ultrasound transducers, and cardiac defibrillators. In addition, the certification techniques may be used with computers having installed software for receiving and processing signals from a medical device to generate medical information. Such computers may include personal computers, off-the-shelf computers, multi-purpose computers, laptops, desktop computers, notebooks, mobile communication devices, or any suitable computing device.

[0018] Turning now to the figures, FIG. **1** depicts an embodiment of a computer certification system **10** that includes a computer **12** configured to be used on conjunction with a medical device **14**. The computer **12** includes a processor **18** for executing routines or instructions stored in mass storage **20**, such as instructions for implementing the techniques discussed herein and instructions associated with medical device operating software. Additionally, the computer **12** may include a display **22** coupled to the processor **18** via internal bus **23** and configured to display information regarding the output generated by the medical device, such as physiological parameters and/or alarm or operating indications. In certain embodiments, the computer **12** is a multi-purpose computer that is configured to run any number of software programs, such as word processing, database programs, and internet access. While installation of the medical device operating software may disable or prevent operation of particular types of programs, other maintenance programs may be configured to operate in the background. As such, the display **22** may also be used for display of other information, e.g., in addition to medical device information, according to the inputs provided by the user, and the computer **12** may include various input components **24**, such as knobs, switches, keys and keypads, buttons, etc., to provide for operation and configuration of the computer **12**. The computer **12** may also include an input port **26** for coupling to the medical device **14**. For example, the computer may include a USB port for coupling to an external device. In other embodiments, the computer **12** may include a transceiver for coupling to wireless medical devices.

[0019] FIG. **2** is a process flow diagram illustrating a method **40** for certifying the computer **12**. The method may be performed as an automated procedure by a system, such as a system **10** that includes the computer **12** and the medical device **14**, or by the computer **12** without an associated medical device **14**. In addition, certain steps of the method may be performed by a processor, e.g., processor **18**, that executes stored instructions for implementing certain steps of the method **40**.

[0020] According to a particular embodiment, instructions for certification stored on the computer **12** access stored data that is representative of data generated by the medical device **14** at step **44**. It is envisioned that, in the depicted embodiment, the stored data may be stored in computer memory **20** or a portable memory device (e.g., a flash memory device). Accordingly, the stored data may be accessed when the computer **12** is not coupled to the medical device **14**. The certification instructions may be part of medical device software for receiving signals from the medical device **14** and generating medical information. In particular implementations, installation of the medical device software is accompanied by executing the method **40** to complete the installation. For example, the installation and/or certification may be performed by an end user. In other embodiments, the installation and certification may be performed by a vendor of the software and medical device. The vendor may purchase an off-the-shelf computer, install the software, and initiate the steps of the method **40** to certify the computer **12**. In other embodiments, the certification process **40** may begin upon computer startup or when the medical device software is accessed. That is, regardless of whether the initial certification was initiated by a vendor or the end user, additional certifications may be completed during the operation of the computer **12**.

[0021] At step **46**, the stored data is processed according to the instructions installed on the computer **12** for processing incoming signals from the medical device **14**. The processed output of the medical device operating software is compared to an expected result at step **48**. At decision step **49**, if the processed output is within an acceptable deviation from the expected result, the method **40** proceeds to step **50**, and the computer is certified to be used with the medical device **14**. If the processed output is outside of an acceptable deviation from the expected result, the method **40** proceeds to step **52**, and the computer is not certified or is rejected. Optionally, the method **40** may prevent incoming signals from the medical device **14** and/or coupling of the medical device **14** to the computer **12** if the computer **12** is rejected. In other embodiments, the medical device software may be prevented from completing installation if the computer **12** is rejected.

[0022] The stored data is representative of a typical medical device output when the medical device **14** is in operation (e.g., coupled to a patient). In particular embodiments, the stored data may be historical data that has been collected (e.g., recorded or stored) from a test device and that provides sufficient information for generating medical information about a patient. A test device may be a version of the medical device **14** that has been verified to generate a representative signal for a particular physiological parameter or other medical data. In other embodiments, the stored data may be simulated data that simulates the incoming signal of the medical device **14**. By using data from a test device or simulated data, the certification process may provide information about the functionality of the computer **12** and its installed software that is isolated from any variations or irregularities in a particular medical device **14**. That is, because the stored data is not generated by the medical device **14** itself, the certification may be specific to the computer **12**. In other implementations,

it may be advantageous to provide stored data that has been collected by the medical device **14** in question. For example, if the medical device **14** has been customized for a particular end use, the stored data may be generated from the medical device **14** for use in certification.

[0023] In certain embodiments, the medical device **14** may be configured to generate an analog signal or a digital signal that is further processed via hardware and/or software to condition the signal and generate an output representative of medical information. For example, if the medical device **14** is a temperature sensor, the stored data representative of the medical device signal may be stored in the form of an analog signal in which the voltage varies according to the sensed temperature. In other embodiments, the data representative of an analog signal may be converted to a digital signal, and the certification process may include a digital-to-analog conversion step. The analog signal or digital signal may be processed according to instructions encoded in the installed software, which may include correlating particular voltages to particular temperature readings and providing an indication of the sensed temperatures. The calculated temperatures may be compared to the expected results, e.g., results from a test run or results that were independently confirmed, to determine if the computer **12** is compatible with the medical device **14**. If the calculated temperatures deviate from the expected temperatures by less than a predetermined amount (e.g., less than a standard deviation), the computer **12** may be certified.

[0024] Certification or rejection of the computer **12** may trigger one or more audible or visual indicators. For example, the display of an indicator or text message may be triggered upon certification of the computer **12**. The indicator may be a green light, a check mark, and/or a message that refers to successful certification. Rejection of the computer **12** (e.g., a failure to be certified) may trigger an alarm, a red light, a message related to unsuccessful certification, and/or an inability to open or access the medical device software.

[0025] The certification information may be provided to a regulatory agency, such as the Food and Drug Administration (FDA), as part of the certification process. Computer certification, such as certification via method **40**, may be provided as part of the guidelines for approval of the medical device **14**. In addition, all or part of a certification process may form part of text-based instructions or other training materials for the medical device **14**. The device manufacturer may designate particular computer hardware specifications, including processor specifications, (manufacturer, speed, and features), RAM (memory size), hard disk size, other storage, communications, display, etc., and software specifications, such as operating system, drivers, utilities, etc as being compatible with the medical device software in question. These specifications may be provided as part of a software requirements specifications (SRS) document. As part of this or other submitted documentation for approval, the device manufacturer may specify how the use of the medical device software by an end user may be regulated or monitored, including any certification of the computer **12** to be used with the medical device **14**. For example, the specifications may include guidelines for the frequency of the certification, such as every time the computer **12** is booted or after every update to the computer **12**. In one embodiment, installation of new software or computer updates will trigger certification, such as via method **40**, either automatically or through a pop-up window or reminder on the computer display

[0026] Certification information for the computer **12** may be automatically provided to the FDA, or may be stored in the computer's memory **20** for later review or submission. FIG. **3** illustrates a block diagram of a system **54** for assembling certification information. The system **54** includes a central station **56** completion of certification of the computer **12** may be accompanied by entry of the certification date, time, or other information in a log file or database **58**. The database **58** may compile certification information from several computers (e.g., computers **12***a*, **12***b*, and **12***c*) that are configured to couple to medical devices (e.g., medical devices **14***a*, **14***b*, and **14***c*). The central station **56** may store certification information to be accessed during an audit or review of a medical facility.

[0027] In a specific embodiment, the certification techniques may be used in conjunction with a pulse oximetry system. FIG. **4** is a perspective view of a pulse oximetry system **62** with the computer **12** that may couple to a pulse oximetry sensor **64**. The sensor **64** may include optical components such as a light emitter (e.g., a light emitting diode) and a light detector (e.g., a photodetector) that are applied to a patient and may be used to generate a plethysmographic waveform, which may be further processed by the computer **12**. The sensor **64** may be coupled to the computer **12** wirelessly, or via a cable **66** that terminates in a connector **68** that is configured to couple to the computer. In a specific embodiment, the sensor **64** may be pulse oximetry sensor available from Nellcor-Puritan Bennett LLC, including a clip-type sensor suitable for placement on an appendage of a patient, e.g., a digit, an ear, etc. In other embodiments, the sensor **64** may be a bandage-type sensor having a generally flexible sensor body to enable conformable application of the sensor to a sensor site on a patient. In yet other embodiments, the sensor **64** may be secured to a patient via adhesive (e.g., in an embodiment having an electrode sensor) on the underside of the sensor body or by an external device, such as headband or other elastic tension device. In yet other embodiments, the sensor **64** may be configurable sensors capable of being configured or modified for placement at different sites (e.g., multiple tissue sites, such as a digit, a forehead of a patient, etc.). In embodiments in which the sensor **64** is wireless, wireless communication with the computer **12** may be accomplished using any suitable wireless standard, such as the ZigBee standard, WirelessHART standard, Bluetooth standard, IEEE 802.11x standards, or MiWi standard.

[0028] FIG. **5** is a block diagram of the system **62**. The computer **12** includes microprocessor **70** coupled to an internal bus **72**. Also connected to the bus **72** may be a mass storage device **74**, a display **76**, and a user input **78**. As depicted, the computer **12** may include functional modules, such as an oximetry module **80** and a certification module **82**. In other embodiments, the functionality of the oximetry module **80** and certification module **82** may be achieved via the microprocessor **70** executing routines stored in the mass storage device **74**. In addition, the computer **12** includes a sensor drive **84** coupled to a sensor input port **86**.

[0029] The sensor drive **84** may include a time processing unit (TPU) to provide timing control signals to light drive circuitry, which controls when the optical components of the sensor **64**, such as light emitter **88** and light detector **90**, are activated, and, if multiple light sources are used, the multiplexed timing for the different light sources. The sensor drive **84** may also control the gating-in of signals from sensor **64** through one or more switching circuits. The received signal

from the pulse oximetry sensor **64** may be passed to the oximetry module **80**, which may include one or more signal conditioning elements that may be hardware or software-enabled, including an amplifier, a low pass filter, and an analog-to-digital converter. Based at least in part upon the received signals, the oximetry module **80** may calculate the oxygen saturation and/or heart rate using various algorithms, such as those employed by the Nellcor™ N-600x™ pulse oximetry monitor, which may be used in conjunction with various Nellcor™ pulse oximetry sensors, such as OxiMax™ sensors. These algorithms may employ certain coefficients, which may be empirically determined, and may correspond to the wavelengths of light used. In one embodiment, the correction coefficients may be provided as a lookup table.

[0030] In the depicted embodiment, a memory element **94** associated with the sensor **64** is configured to store certain information that is accessed by the certification module **82**, such as stored data representative of output by the detector **90**. The memory element **94** may also store calibration and identification information, including compatibility information for the computer **12**. For example, the memory element **94** may store compatible medical device software version information that may be accessed by the calibration module **82** as part of the certification process. The memory element **94** may be associated with the sensor body, the cable **66**, or the connector **68**. In other embodiments, data representative of detector output may be stored on the computer **12** as part of the certification module **82**.

[0031] The computer **12** is capable of reading the information from the memory element **94** to as part of the certification process. FIG. **6** is a process flow diagram illustrating a method **100** for certifying the computer **12** in conjunction with the sensor **64**, on which data representative of sensor data is stored. According to an embodiment, the method **100** begins at step **102** by coupling the pulse oximetry sensor **64** to the computer **12** and starting the computer **12** (e.g., booting the computer or opening the medical device software installed on the computer) at step **104**.

[0032] The computer **12** reads the initialization requirements based on information stored in the memory element **94** at step **106** to determine if the computer **12** passes an initialization test at step **108**. The initialization requirements may include software and sensor compatibility requirements (e.g., if the sensor is from a manufacturer that is supported by the software), software and hardware specifications, and software version specifications. The stored information may include explicit initialization information, or may include identification information for the sensor that may be further analyzed by the certification module **82** to determine compatibility. If the computer **12** is not compatible with the medical device (e.g., sensor **64**), the computer **12** is rejected at step **110**. If the computer **12** passes the initialization requirements, the method **100** moves to step **112** to read simulated data stored on the memory element **94**. The simulated data may be processed by the oximetry module **80** at step **114** and the results compared with expected results at step **116**. If the results do not match, the computer is rejected at step **120**. If the results match expected results, the computer **12** is certified and the software may continue operating at step **122**. An indication of successful certification may be provided at step **124**.

[0033] The embodiments described above have been shown by way of example, and it should be understood that these embodiments may be susceptible to various modifications and alternative forms. It should be further understood that the claims are not intended to be limited to the particular forms disclosed, but rather to cover all modifications, equivalents, and alternatives falling within the spirit and scope of this disclosure.

What is claimed is:

1. A physiological sensor, comprising:
- a light emitter;
- a light detector;
- a memory element storing information representative of a measurement data output of the light detector and information related to one or more computer compatibility specifications; and
- a cable coupled to the light emitter and the light detector and configured to couple to a general purpose computer.

2. The physiological sensor of claim **1**, wherein the information representative of the measurement data output is stored as an analog signal.

3. The physiological sensor of claim **1**, wherein the sensor comprises a pulse oximetry sensor.

4. The physiological sensor of claim **1**, wherein the memory element is disposed on or in the cable.

5. The physiological sensor of claim **1**, wherein the information representative of the measurement data output is generated by a second detector not associated with the physiological sensor.

6. The physiological sensor of claim **1**, wherein the information related to one or more computer compatibility specifications comprises software version information.

7. The physiological sensor of claim **1**, wherein the cable is configured to couple to the general purpose computer via a USB connector.

8. A system, comprising:
- a sensor comprising a memory element storing first information related to one or more computer compatibility specifications and second information representative of a measurement data output of the sensor; and
- a computer configured to couple to the sensor and comprising a processor configured to execute routines for:
- accessing the first information from the memory element determining if the computer is compatible with the sensor based on the first information;
- accessing the second information only when the computer is compatible with the sensor;
- generating simulated medical information from the second information;
- comparing the simulated medical information to an expected result; and
- determining a certification of the computer to generate medical information from the sensor based on the comparison.

9. The system of claim **8**, comprising determining one or more physiological parameters from a measurement signal generated by the sensor only if the computer is certified to generate medical information.

10. The system of claim **8**, comprising stopping or exiting routines for processing a measurement signal from the medical device if the simulated medical information deviates from the expected result.

11. The system of claim **8**, comprising displaying an indication related to the certification on a display.

12. The system of claim **8**, wherein the sensor comprises a pulse oximetry sensor.

13. The system of claim **8**, wherein the simulated medical information comprises a plethysmographic waveform, a heart rate, or an oxygen saturation value.

14. The system of claim **8**, wherein the second information is stored as an analog signal.

15. The system of claim **8**, wherein the second information is data collected from a test device.

16. The system of claim **8**, wherein the second information is simulated data.

17. A method, comprising:

using a computer coupled to a sensor comprising a memory element storing first information related to one or more computer compatibility specifications and second information representative of a measurement data output of the sensor to:

access the first information from the memory element;

determine if the computer is compatible with the sensor based on the first information;

access the second information only when the computer is compatible with the sensor;

generate simulated medical information from the second information;

compare the simulated medical information to an expected result; and

determine a certification of the computer to generate medical information from the medical device based on the comparison.

18. The method of claim **17**, comprising using the computer to determine one or more physiological parameters from a measurement signal generated by the sensor only if the computer is certified to generate medical information.

19. The method of claim **17**, comprising using the computer to stop or exit routines for processing a measurement signal from the medical device if the simulated medical information deviates from the expected result.

20. The method of claim **17**, comprising using the computer to generate an output that the computer is not compatible with the sensor if the specification requirements do not match the specifications of the computer.

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摘要(译)

本文提供了用于认证与医疗设备结合使用的计算机的方法和设备。这些方法可以与包括用于操作医疗设备的软件的计算机结合使用。为了证明特定计算机，可以执行用于处理数据的一个或多个测试算法或例程，例如代表通过在患者身上使用医疗设备而产生的典型输出的数据，并且可以将结果与预期结果进行比较。在特定实施例中，认证过程可以使用存储在设备自身上的数据来确定认证，或者可以使用与软件一起存储或与软件捆绑在一起的数据来操作设备。