US 20050101849A1

(19) United States
(12) Patent Application Publication (10) Pub. No.: US 2005/0101849 A1
Al-Ali et al. (43) Pub. Date: May 12, 2005

(54) PULSE OXIMETRY DATA CAPTURE SYSTEM

(76) Inventors: **Ammar Al-Ali**, Tustin, CA (US); **Bilal Muhsin**, Aliso Viejo, CA (US); **Michael Lee**, Aliso Viejo, CA (US)

Correspondence Address:
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614 (US)

(21) Appl. No.: 10/983,048

(22) Filed: Nov. 5, 2004

Related U.S. Application Data

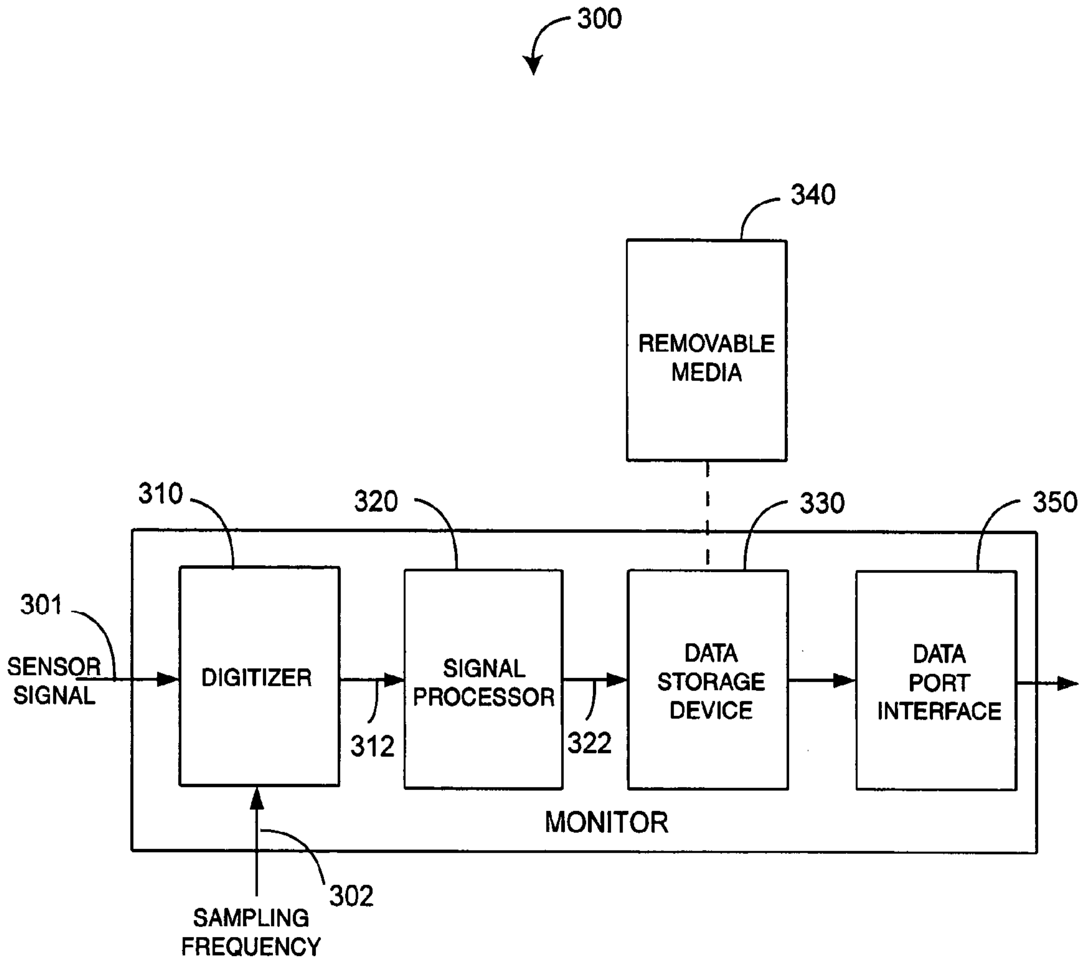
(60) Provisional application No. 60/518,051, filed on Nov. 7, 2003.

Publication Classification

(51) Int. Cl.[7] A61B 5/00
(52) U.S. Cl. 600/323; 600/481; 600/322

(57) **ABSTRACT**

A data capture system utilizes a sensor with emitters adapted to transmit light into a fleshy medium and a detector adapted to generate intensity signals in response to receiving light after absorption by the fleshy medium. A monitor is configured to input the intensity signals, generate digitized signals from the intensity signals at a sampling rate and compute at least one physiological parameter responsive to magnitudes of the digitized signals. A data storage device is integrated with the monitor and is adapted to record data derived from the digitized signals on a removable storage media at the sampling rate.



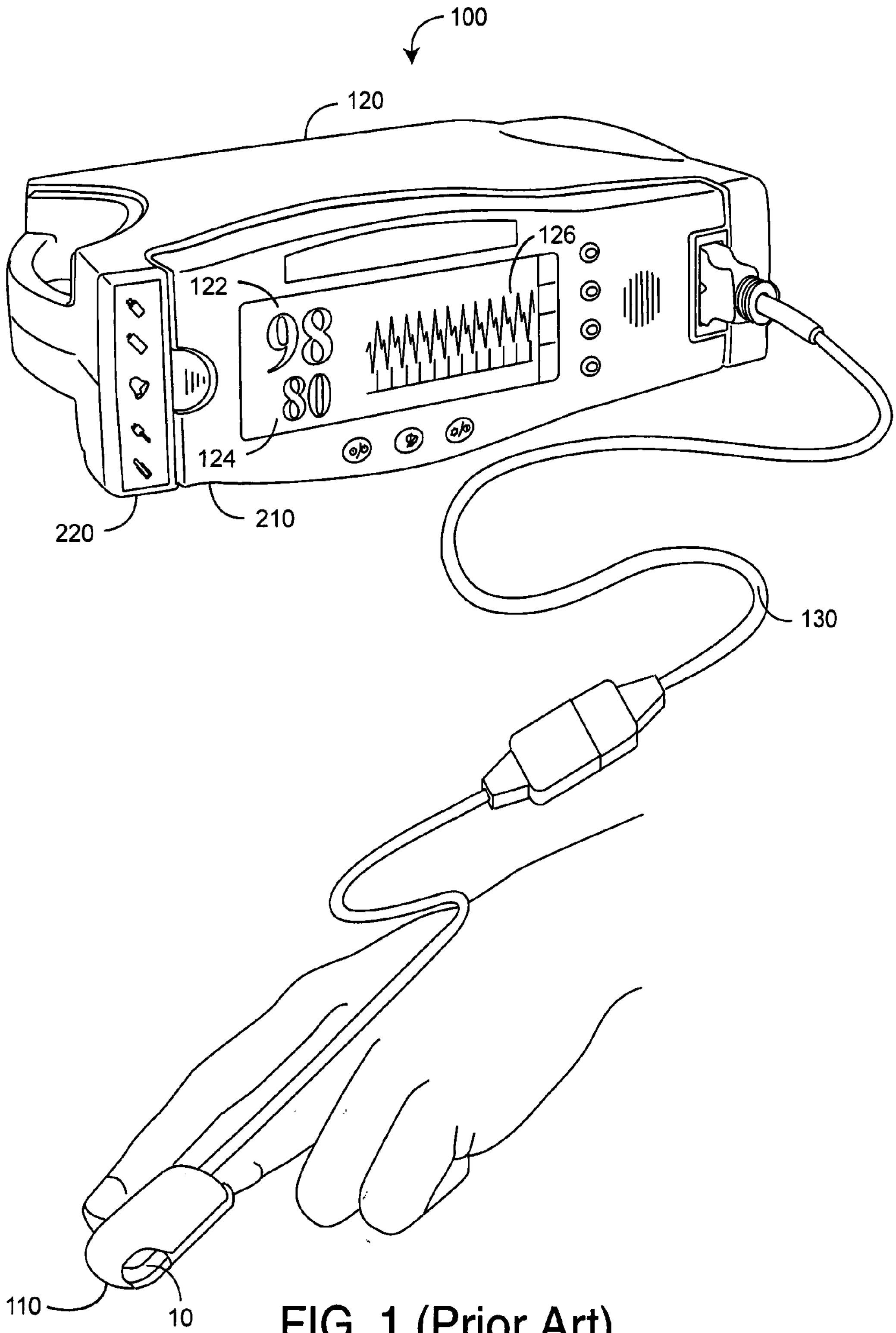


FIG. 1 (Prior Art)

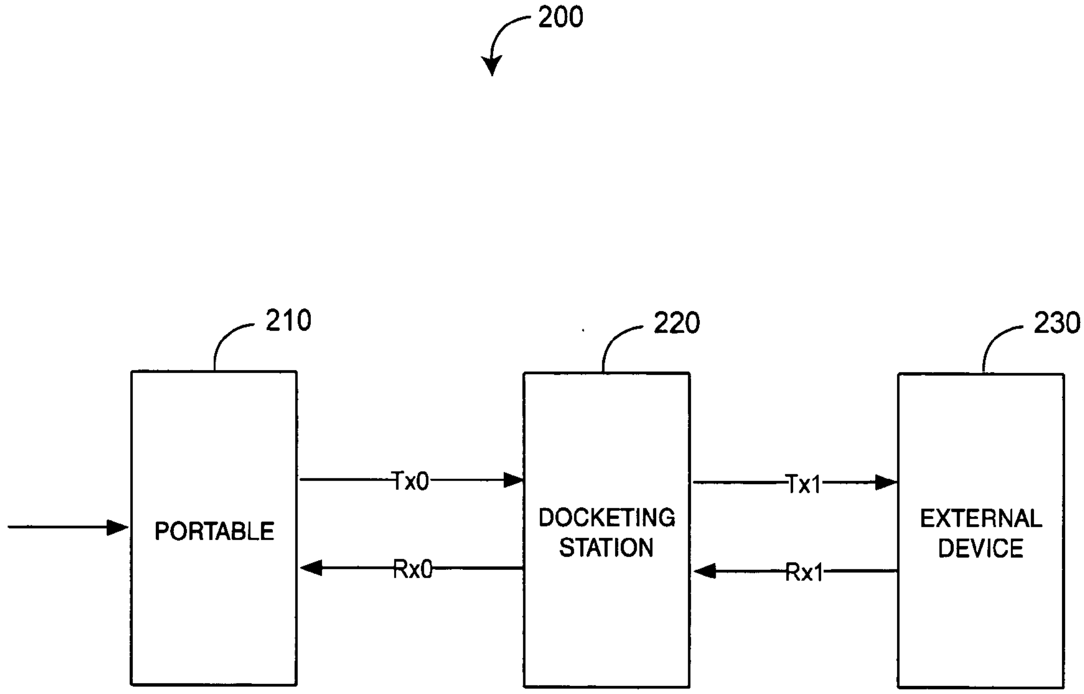


FIG. 2 (Prior Art)

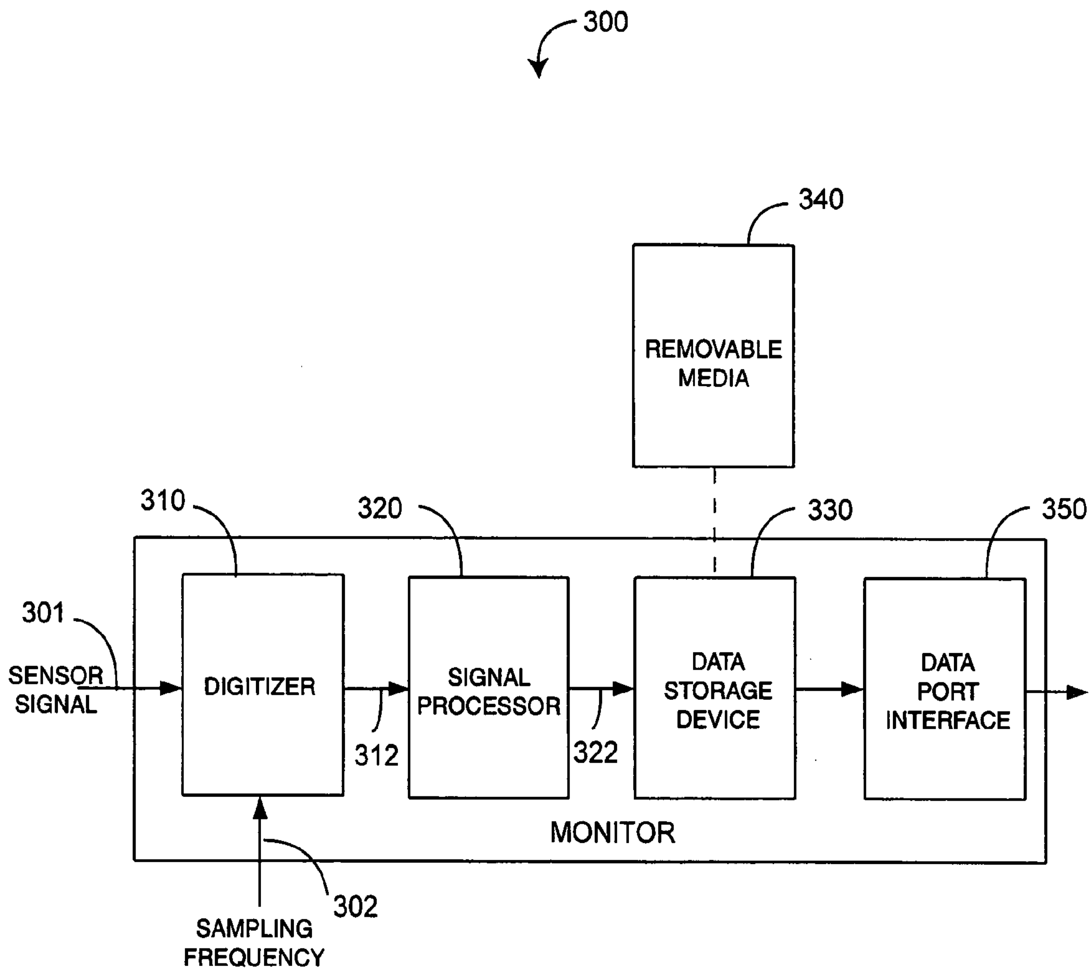

300
340
REMOVABLE MEDIA
310
320
330
350
301
SENSOR SIGNAL
DIGITIZER
SIGNAL PROCESSOR
DATA STORAGE DEVICE
DATA PORT INTERFACE
312
322
MONITOR
302
SAMPLING FREQUENCY

FIG. 3

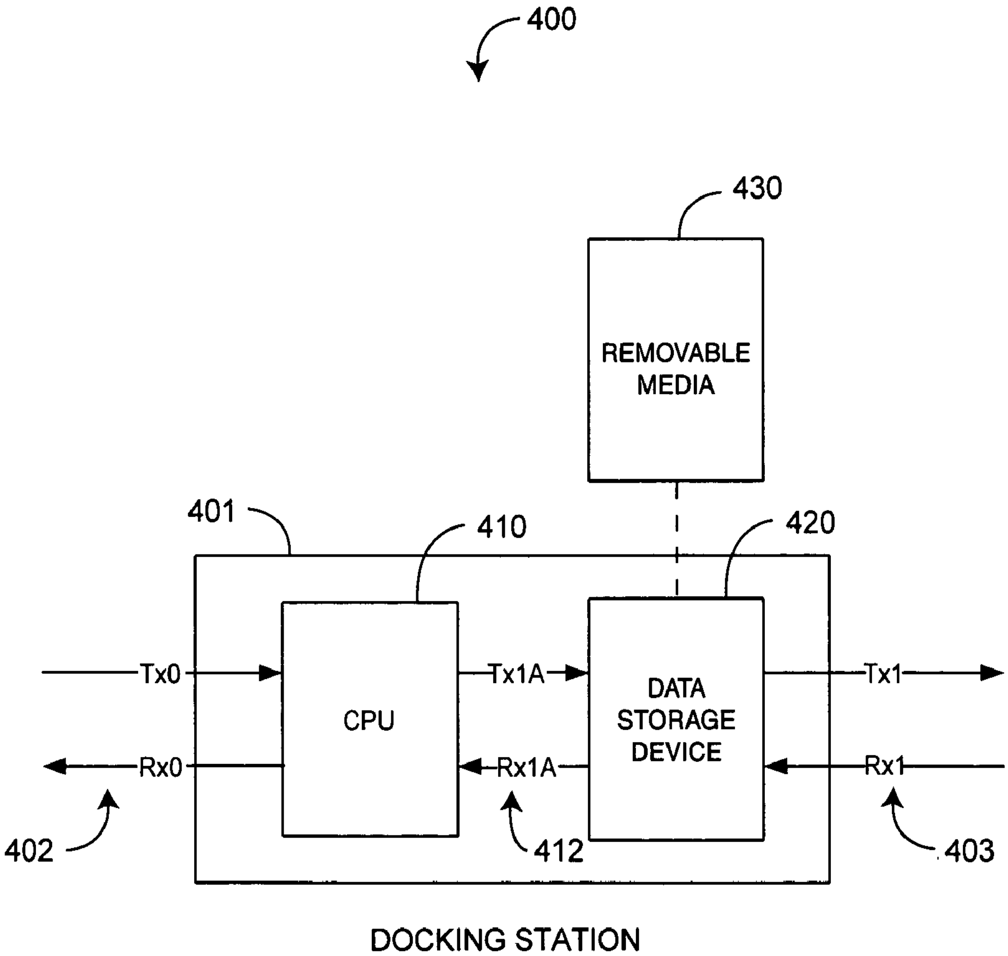

400
430
REMOVABLE MEDIA
401
410
420
Tx0
CPU
Tx1A
DATA STORAGE DEVICE
Tx1
Rx0
Rx1A
Rx1
402
412
403
DOCKING STATION

FIG. 4

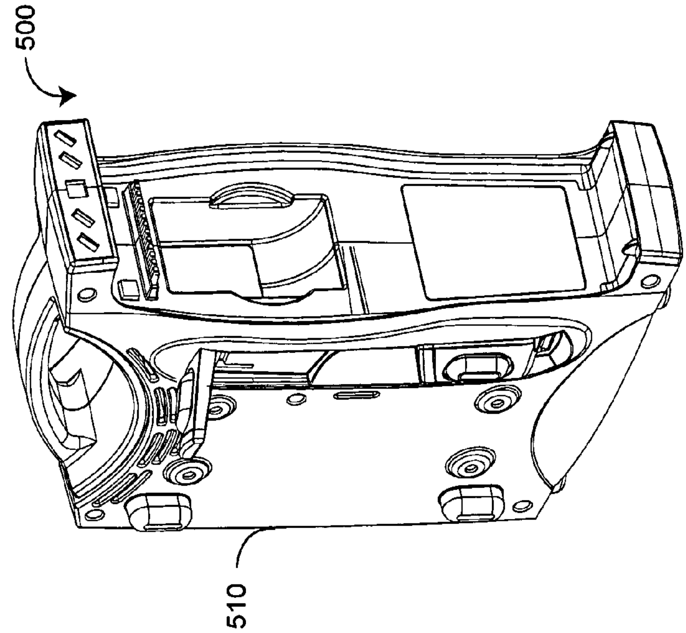


FIG. 5B

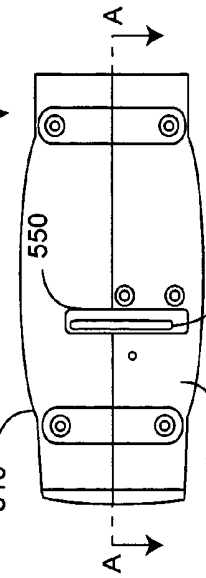


FIG. 5D

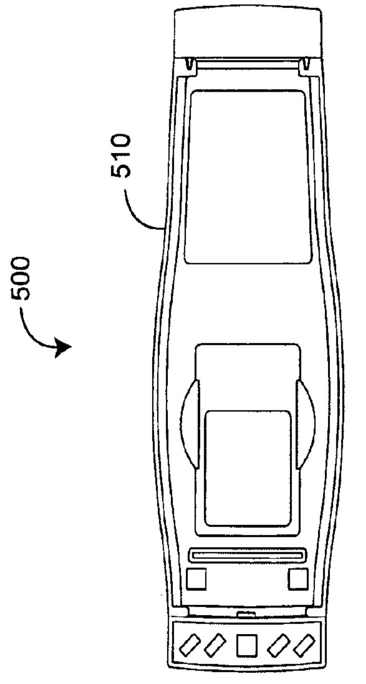


FIG. 5A

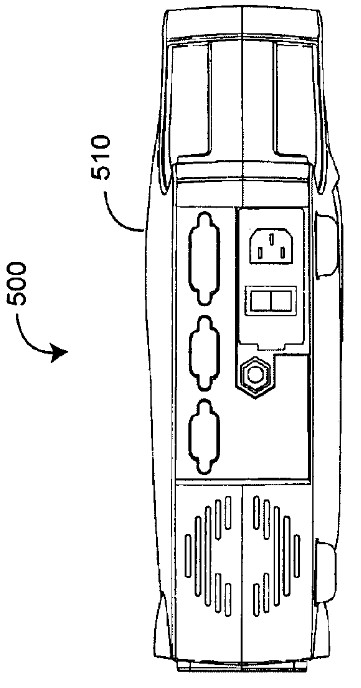
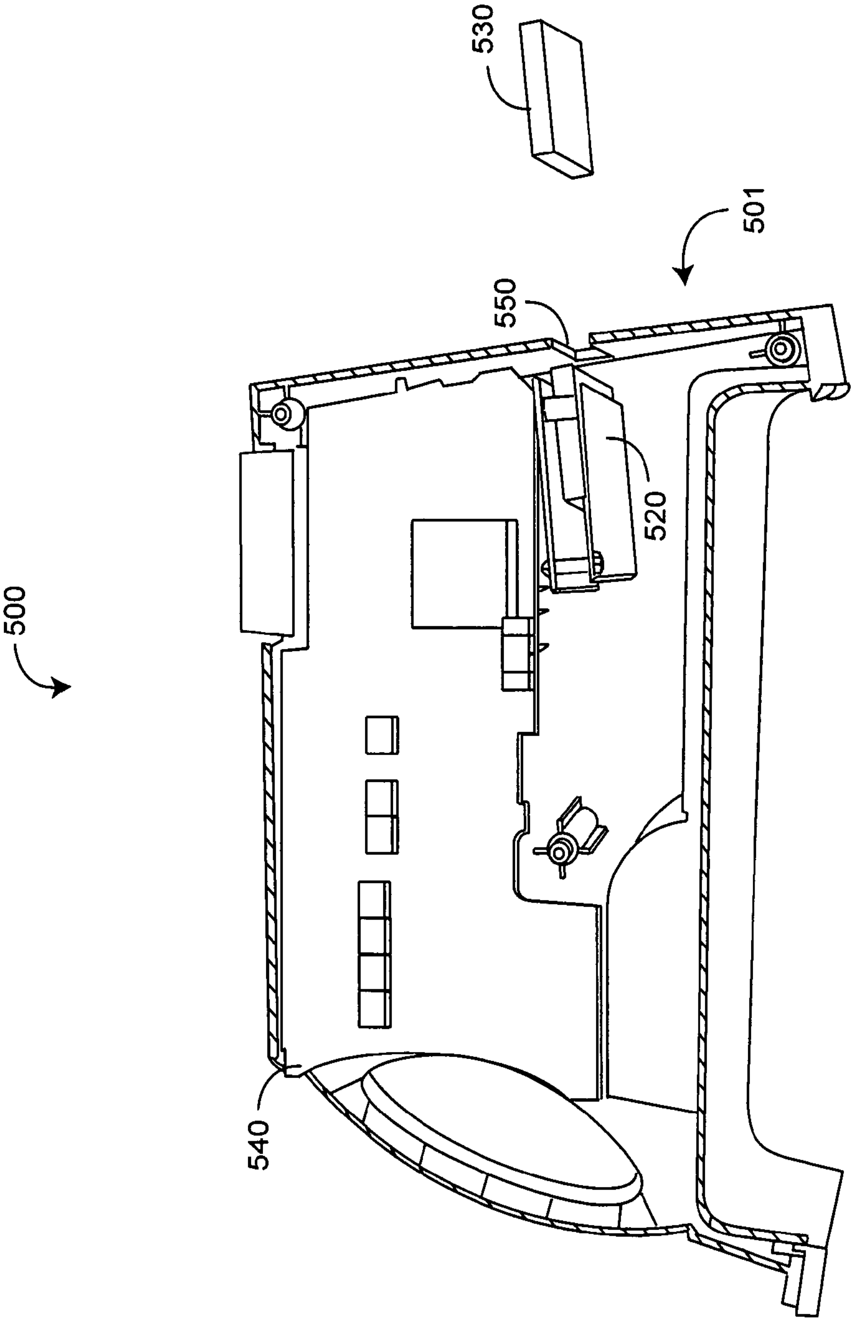


FIG. 5C



(SECTION A-A)

FIG. 5E

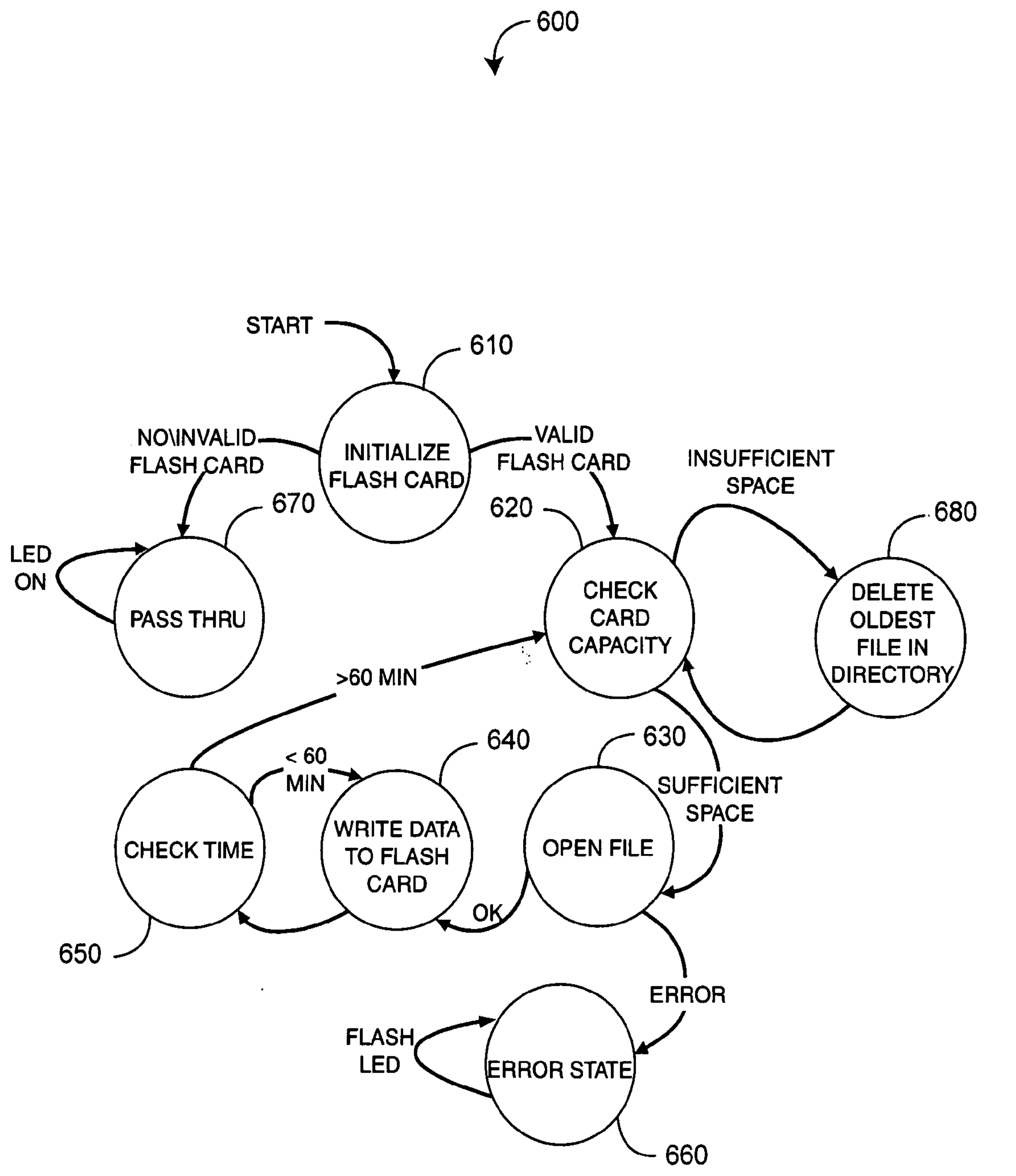

600
START
610
INITIALIZE FLASH CARD
NO\INVALID FLASH CARD
VALID FLASH CARD
INSUFFICIENT SPACE
670
620
680
LED ON
PASS THRU
CHECK CARD CAPACITY
DELETE OLDEST FILE IN DIRECTORY
>60 MIN
640
630
< 60 MIN
SUFFICIENT SPACE
CHECK TIME
WRITE DATA TO FLASH CARD
OPEN FILE
OK
650
ERROR
FLASH LED
ERROR STATE
660

FIG. 6

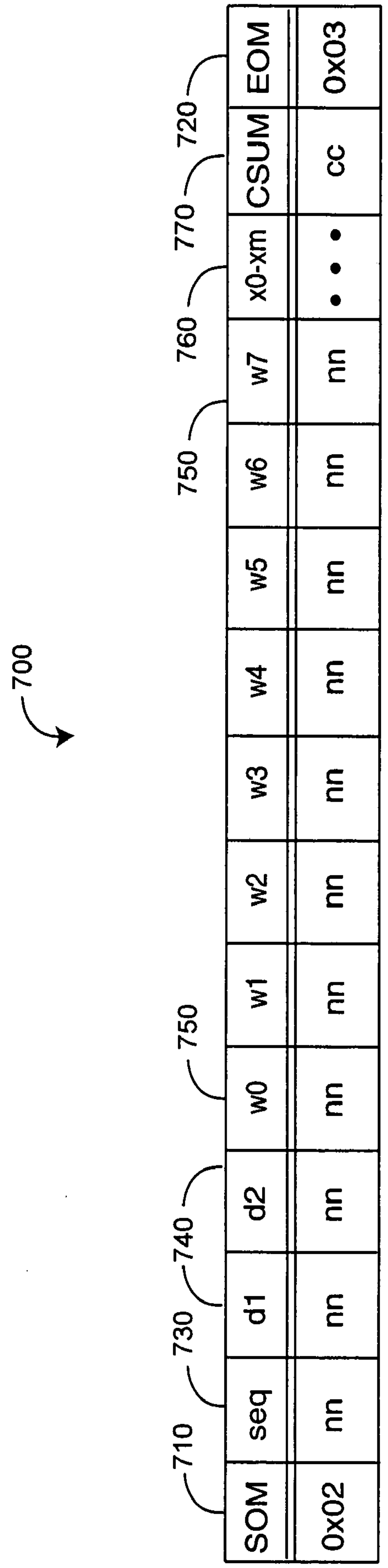

700
710
730
740
750
760
770
720
SOM
seq
d1
d2
w0
w1
w2
w3
w4
w5
w6
w7
x0-xm
CSUM
EOM
0x02
nn
cc
0x03

FIG. 7

PULSE OXIMETRY DATA CAPTURE SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application relates to and claims the benefit of prior U.S. Provisional Patent Application No. 60/518,051 entitled *Pulse Oximetry Trend Data Storage System*, filed Nov. 7, 2003 and incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Pulse oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care units, general wards and home care by providing early detection of decreases in the arterial oxygen supply, reducing the risk of accidental death and injury. **FIG. 1** illustrates a pulse oximetry system **100** having a sensor **110** applied to a patient, a monitor **120**, and a patient cable **130** connecting the sensor **110** and the monitor **120**. The sensor **110** has emitters (not shown) and a detector (not shown) and is attached to a patient at a selected fleshy medium site, such as a fingertip **10** as shown or an ear lobe. The emitters are positioned to project light of at least two wavelengths through the blood vessels and capillaries of the fleshy medium. The detector is positioned so as to detect the emitted light after absorption by the fleshy medium, including hemoglobin and other constituents of pulsatile blood flowing within the fleshy medium, generating at least first and second intensity signals in response. A pulse oximetry sensor is described in U.S. Pat. No. 6,256,523 entitled *Low Noise Optical Probes*, and a pulse oximetry monitor is described in U.S. Pat. No. 6,745,060 entitled *Signal Processing Apparatus*, both assigned to Masimo Corporation, Irvine, Calif. and both incorporated by reference herein.

[0003] The monitor **120**, which may be a standalone device or may be incorporated as a module or built-in portion of a multiparameter patient monitoring system, computes at least one physiological parameter responsive to magnitudes of the intensity signals. A monitor **120** typically provides a numerical readout of the patient's oxygen saturation **122**, a numerical readout of pulse rate **124**, and a display of the patient's plethysmograph **126**, which provides a visual display of the patient's pulse contour and pulse rate.

[0004] In one embodiment, the pulse oximetry system **100** has a portable instrument **210** and a docking station **220**, such as described in U.S. Pat. No. 6,584,336 entitled *Universal/Upgrading Pulse Oximeter*, assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. The portable **210** is a battery operated, fully functional, stand-alone pulse oximeter monitor, as described above, which can be installed into the docking station **220** to expand its functionality.

[0005] **FIG. 2** illustrates data communications for the portable **210** and docking station **220**. The portable **210** has bi-directional serial data communications with the docking station **220** using universal asynchronous receive, Rx**0**, and transmit, Tx**0**, (UART) signals, and the docking station **220** has bi-directional serial data communications with an external device **230** using Tx**1** and Rx**1** UART signals.

SUMMARY OF THE INVENTION

[0006] A conventional pulse oximeter may store trend data that consists of, for example, oxygen saturation and pulse rate. This data is recorded at a low rate, such as 1 Hz. Although the resolution afforded by a low data rate is fine for many patient diagnostic purposes, it is desirable to store the plethysmograph waveform, other pulse oximeter parameters and various internal data at a high rate, such as the sensor signal sampling rate. The resulting high resolution data advantageously assists and/or improves patient condition evaluation, pulse oximetry exception diagnosis and algorithm development. Further, pulse oximetry data is conventionally stored using an external computer or a laptop, which may not always be available or is otherwise cumbersome.

[0007] A pulse oximetry data capture system advantageously replaces an external computer with a small data storage device that utilizes removable storage media to hold many hours of high resolution data. In one embodiment, the data storage device is integrated into a docking station for a portable instrument. The removable storage media, having been written with data, can be easily shipped off-site from where the data is collected for later analysis.

[0008] One aspect of a pulse oximetry data capture system is a sensor having emitters adapted to transmit light of at least first and second wavelengths into a fleshy medium. A detector is adapted to generate at least first and second intensity signals in response to receiving light after absorption by constituents of pulsatile blood flowing within the fleshy medium. A monitor is configured to input the intensity signals, generate digitized signals from the intensity signals at a sampling rate and compute at least one physiological parameter responsive to magnitudes of the digitized signals. A data storage device is integrated with the monitor and is adapted to record data derived from the digitized signals on a removable storage media at the sampling rate.

[0009] Another aspect of a pulse oximetry data capture system is a method having the steps of emitting light of at least first and second wavelengths and detecting the light after absorption by a fleshy tissue site so as to generate a corresponding sensor signal. Additional steps are digitizing at a sampling rate, demodulating the sensor signal so as to generate a plethysmograph, and calculating at least oxygen saturation and pulse rate from the plethysmograph. A further step is writing data to the removable media. The data comprises the plethysmograph at the sampling frequency along with the oxygen saturation and the pulse rate at a sub-sampling frequency.

[0010] A further aspect of a data capture system has a sensor adapted to generate an intensity signal responsive to light absorption by constituents of pulsatile blood flowing within a fleshy medium. A digitizer inputs the intensity signal and generates a digital plethysmograph signal at a sampling rate. A signal processor inputs the plethysmograph and calculates an oxygen saturation and pulse rate. A storage media is configured to removably load into a data storage device. The data storage device inputs the plethysmograph, oxygen saturation and pulse rate and writes the plethymograph to the storage media at the sampling rate, along with the oxygen saturation and the pulse rate at a sub-sampling rate.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] **FIG. 1** is a perspective view of a prior art pulse oximetry system having a portable pulse oximeter and a docking station;

[0012] **FIG. 2** is a block diagram of portable and docking station data communications;

[0013] **FIG. 3** is a general block diagram of a pulse oximetry data capture system;

[0014] **FIG. 4** is a block diagram of a pulse oximetry docking station incorporating a data capture system;

[0015] FIGS. **5**A-E are front, front perspective, back, side and internal top views, respectively, of a pulse oximetry docking station incorporating a data capture system;

[0016] **FIG. 6** is a program flow diagram for a pulse oximetry data capture system; and

[0017] **FIG. 7** is a table illustrating a multiple byte message package.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0018] **FIG. 3** illustrates a pulse oximetry data capture system **300** having a digitizer **310**, signal processor **320**, a data storage device **330**, a removable media **340** and a data port interface **350**. The digitizer **310** samples the sensor signal **301** based upon a predetermined sampling frequency **302** and performs an analog-to-digital conversion of the sampled signal to generate a digitized sensor signal **312**. The signal processor **320** demodulates the red (RD) and IR components of the digitized sensor signal **312** into RD and IR plethysmograph signals and operates on those plethysmograph signals so as to calculate oxygen saturation and pulse rate. A pulse oximetry demodulator is described in U.S. Pat. No. 6,643,530 entitled *Method and Apparatus for Demodulating Signals in a Pulse Oximetry System*, assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. As a result, the signal processor **320** generates a data stream **322** comprising plethysmograph, oxygen saturation and pulse rate values among other data. The data storage device **330** inputs the data stream **322**, which is recorded on the removable media **340**. The data stream **322** may also be provided to an external device via the data port interface **350**. In various embodiments, the data storage device **330** may transparently "pass-through" the data stream **322** to other system components, such as the data port interface **350**, or it may otherwise tap the data stream **322** as it is utilized elsewhere in the system **300**. Alternatively, the signal processor **320** or other system components may provide the data storage device **330** with a dedicated data stream used solely for data recording purposes.

[0019] In one embodiment, the data stream **322** comprises raw, filtered and/or scaled plethysmograph waveform data; computed output data such as oxygen saturation, pulse rate, signal strength and signal quality; and other system data such as sensor status, monitor status, monitor settings, alarms, and internal algorithm parameters and variables. Pulse oximetry signal strength and signal quality or confidence data are described in U.S. Pat. No. 6,463,311 entitled *Plethysmograph Pulse Recognition Processor* and U.S. Pat. No. 6,684,090 entitled *Pulse Oximetry Data Confidence Indicator*, both assigned to Masimo Corporation, Irvine, Calif. and both incorporated by reference herein. Sensor status, monitor status and settings and alarms are described in U.S. Pat. No. 6,658,276 entitled *Pulse Oximeter User Interface*, also assigned to Masimo Corporation and incorporated by reference herein.

[0020] **FIG. 4** illustrates a docking station embodiment **400** of a data capture system **300** (**FIG. 3**). A docking station **401** has a CPU **410**, a data storage device **420** and an associated removable storage media **430**. The docking station communicates with a portable pulse oximeter via input UART signals **402** and with an external device via output UART signals **403**. The docking station CPU **410** communicates with the data storage device **420** using internal UART signals **412**. The CPU **410** receives pulse oximetry and related data from the portable via the input UART signals **402** and may generate additional data in response. The received portable data and/or the CPU generated data is transmitted to the data storage device **420** via the internal UART signals **412** and recorded on the removable media **430** accordingly, as described in further detail below.

[0021] FIGS. **5**A-E illustrate a particular docking station embodiment **500** of a pulse oximetry data capture system **400** (**FIG. 4**). The data storage device **520** (**FIG. 5E**) is a Flashcore-B available from TERN, Inc., Davis, Calif., and the removable storage media **530** (**FIG. 5E**) is a 256 MB Compact Flash card. The data storage device **520** is installed internally to the docking station **510** adjacent a circuit board **540** (**FIG. 5E**) and proximate the docking station bottom **501**. The docking station **510** supplies power to the data storage device **520**. The data storage device **520** transparently passes-through the internal UART signals **412** (**FIG. 4**) to the output UART signals **403** (**FIG. 4**). A slot **550** is created in the bottom of the docking station **510**, which allows insertion and removal of the storage media **530** into and out of the storage device **520**. One of ordinary skill will recognize that the data storage device **520** and associated removable media **530** can utilize various data storage technologies other than Compact Flash, such as Memory Stick, SmartMedia, Secure Digital Card, USB Flash Disk and MicroDrive to name just a few.

[0022] **FIG. 6** illustrates program flow **600** for the docking station CPU to control and write data to the data storage device **520** (**FIG. 5E**). To start, a flash card **530** (**FIG. 5E**) is validated and initialized **610**. If a valid flash card is in the data storage device, then the card capacity is checked **620**. If the card capacity is sufficient, then a file is opened **630** and data writing begins **640**. Data is advantageously written to the data storage device in multiple byte message packets at up to the IR and red signal sampling rate, as described with respect to **FIG. 7**, below. The writing time is checked **650**. After one hour of data is recorded, the card capacity is rechecked **620** and, if sufficient, another file is opened **630** and recording continues. If an error occurs in opening a file, an LED indicator is flashed **660**. If no valid flash card is detected, data is passed through to the external device signal lines and the LED indicator is turned on **670**. If there is insufficient flash card capacity, the oldest file is deleted **680**.

[0023] **FIG. 7** illustrates a multiple byte message packet having start of message (SOM) **710**, end of message (EOM) **720**, sequence (seq) **730** and check sum (CSUM) 770 bytes and one or more data segments d1-d**2740**, w**0**-w**7750** and x**0**-xm **760**. The SOM **710** and EOM **720** are fixed-value bytes that delineate each message packet. The seq 730 byte identifies specific message packets in a cyclical group of message packets, as described below. The data segments **740**-**760** are formatted so as to allow storage of the data stream **322** (**FIG. 3**) described above. The check sum **770** is for communications error detection and is the sum of the data bytes **740-760** modulo **256**. The message packets **700** are transmitted to the data storage device **420** (**FIG. 4**) and stored on the removable storage media **430** (**FIG. 4**) at about the IR and red (RD) signal sampling rate. In this manner, sufficient information with sufficient resolution is stored on the removable storage media for a thorough external data analysis.

[**0024**] In one embodiment, 32-bit IR waveform data can be stored in w**0**-w**3750**, **32**-bit RD waveform data can be stored in w**4**-w**7750**, and various 16-bit output data, such as oxygen saturation and pulse rate can be stored in d**1**-d**2740** as identified by the sequence byte **730**. In a particular embodiment, the sampling rate is 62.5 Hz, and **62** messages packets are stored in a specific sequence per second. The sequence byte (seq) **730** increments from 1 to 62 with each successive message packet **700** and then resets to 1, repeating so as to identify the specific data in, say, d**1**-d**2740**. For example, plethysmograph waveform data is stored in w**0**-w**7750** at a 62 Hz rate and oxygen saturation, corresponding to seq=1 and pulse rate, corresponding to seq=2, are stored in d**1**-d**2740** at a sub-sampling rate of 1 Hz.

[**0025**] A pulse oximetry data capture system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A data capture system comprising:

a sensor having emitters adapted to transmit light of at least first and second wavelengths into a fleshy medium and a detector adapted to generate at least first and second intensity signals in response to receiving light after absorption by constituents of pulsatile blood flowing within the fleshy medium;

a monitor configured to input said intensity signals, generate digitized signals from said intensity signals at a sampling rate and compute at least one physiological parameter responsive to magnitudes of said digitized signals; and

a data storage device integrated with said monitor,

said data storage device being adapted to record data derived from said digitized signals on a removable storage media at said sampling rate.

2. The data capture system according to claim 1 wherein said monitor comprises:

a portable instrument that functions as a stand-along pulse oximeter; and

a docking station configured to receive and expand the functionality of said portable instrument,

said data storage device being mounted internally to, and drawing power from, said docking station.

3. The data capture system according to claim 2 further comprising a data path within said docking station so as to provide communications with an external device, said data storage device installed along said data path so as to capture and transparently pass-through said communications.

4. The data capture system according to claim 3 further comprising:

a slot defined in a bottom wall of said docking station,

said data storage device mounted inside said docking station proximate said wall,

said slot providing removable storage media access to said storage device.

5. The data capture system according to claim 1 wherein said data comprises at least one of a raw, a filtered and a scaled plethysmograph.

6. The data capture system according to claim 5 wherein said data comprises oxygen saturation and pulse rate.

7. The data capture system according to claim 6 wherein said data comprises signal quality.

8. The data capture system according to claim 6 wherein said data comprises at least one of sensor status, monitor status, monitor settings and alarm data.

9. A data capture method comprising the steps of:

emitting light of at least first and second wavelengths;

detecting said light after absorption by a fleshy medium site so as to generate a corresponding sensor signal;

digitizing at a sampling rate;

demodulating said sensor signal so as to generate a plethysmograph;

calculating at least oxygen saturation and pulse rate from said plethysmograph; and

writing data to a removable storage media, said data comprising said plethysmograph at said sampling frequency along with said oxygen saturation and said pulse rate at a sub-sampling frequency.

10. The data capture method according to claim 9 further comprising the steps of:

creating a plurality of files on said removable storage media;

recording said data in each of said files;

checking capacity of said removable storage media; and

deleting an oldest one of said files if said removable storage media is over capacity.

11. The data capture method according to claim 10 further comprising the steps of:

removing said removable storage media from a patient site after said recording step;

reading said removable storage media at an off-site so as to process said data and remotely evaluate at least one of a patient, a monitor of said patient and an algorithm executing on said monitor.

12. A data capture system comprising:

a sensor adapted to generate an intensity signal responsive to light absorption by constituents of pulsatile blood flowing within a fleshy medium;

a digitizer inputting said intensity signal and generating a digital plethysmograph signal at a sampling rate;

a signal processor inputting said plethysmograph and calculating an oxygen saturation and pulse rate;

a data storage device inputting said plethysmograph, oxygen saturation and pulse rate;

a storage media configured to removably load into said data storage device,

said data storage device writing said plethymograph to said storage media at said sampling rate, along with said oxygen saturation and said pulse rate at a sub-sampling rate.

13. The data capture system according to claim 12 further comprising:

a data port adapted to communicate with an external device; and

a communications path between said signal processor and said data port configured to output said plethysmograph, oxygen saturation and pulse rate to said external device;

wherein said data storage device is installed along said communications path and configured to transparently capture and write said plethysmograph to said removable storage media.

14. The data capture system according to claim 13 further comprising:

a portable instrument having said digitizer;

a docking station configured to accept said portable instrument and housing said data storage device; and

a plurality of UART signals provided between said docking station and said data storage device along said communications path.

* * * * *

专利名称(译)	脉搏血氧仪数据采集系统		
公开(公告)号	US20050101849A1	公开(公告)日	2005-05-12
申请号	US10/983048	申请日	2004-11-05
[标]申请(专利权)人(译)	AL ALI AMMAR 穆赫辛BILAL LEE MICHAEL		
申请(专利权)人(译)	AL-ALI AMMAR 穆赫辛BILAL LEE MICHAEL		
当前申请(专利权)人(译)	摩根大通银行，NATIONAL ASSOCIATION		
[标]发明人	AL ALI AMMAR MUHSIN BILAL LEE MICHAEL		
发明人	AL-ALI, AMMAR MUHSIN, BILAL LEE, MICHAEL		
IPC分类号	A61B5/00		
CPC分类号	A61B5/0002 A61B2560/0475 A61B2560/0456 A61B5/14551		
优先权	60/518051 2003-11-07 US		
其他公开文献	US7373193		
外部链接	Espacenet USPTO		

摘要(译)

数据捕获系统利用具有适于将光传输到肉质介质中的发射器的传感器和适于响应于在被肉质介质吸收之后接收光而产生强度信号的检测器。监视器被配置为输入强度信号，以采样速率从强度信号生成数字化信号，并响应于数字化信号的大小计算至少一个生理参数。数据存储设备与监视器集成在一起，并且适于以采样速率将从数字化信号导出的数据记录在可移动存储介质上。