



US008562537B2

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

(10) **Patent No.:** **US 8,562,537 B2**
(45) **Date of Patent:** ***Oct. 22, 2013**

(54) **MULTIPURPOSE HOST SYSTEM FOR
INVASIVE CARDIOVASCULAR DIAGNOSTIC
MEASUREMENT ACQUISITION AND
DISPLAY**

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(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **13/410,099**

(22) Filed: **Mar. 1, 2012**

(65) **Prior Publication Data**

US 2012/0220837 A1 Aug. 30, 2012

Related U.S. Application Data

(60) Continuation of application No. 11/555,556, filed on
Nov. 1, 2006, which is a division of application No.
10/151,423, filed on May 20, 2002, now Pat. No.
7,134,994.

(51) **Int. Cl.**
A61B 5/02 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **600/485**; 600/301; 600/509

(58) **Field of Classification Search**
None
See application file for complete search history.

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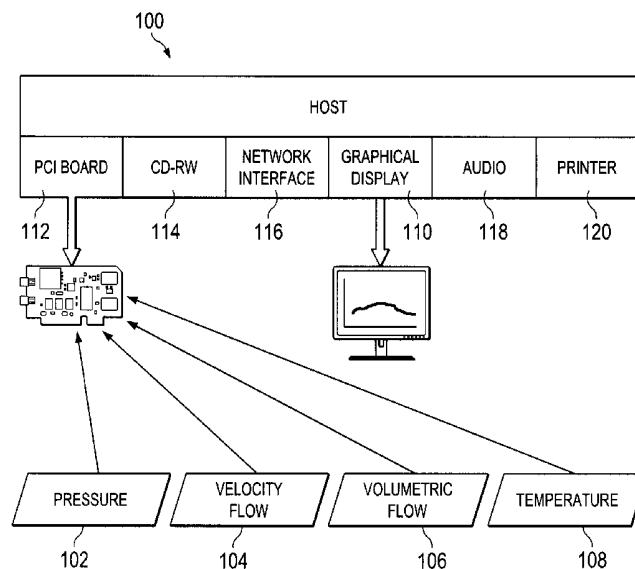
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(57) **ABSTRACT**

A multifunctional invasive cardiovascular diagnostic measurement host is disclosed that interfaces a variety of sensor devices, such as guide wire-mounted pressure sensors, flow sensors, temperature sensors, etc., and provides a multi-mode graphical user interface providing a plurality of displays in accordance with the various types of sensors and measurements rendered by the sensors.

30 Claims, 20 Drawing Sheets



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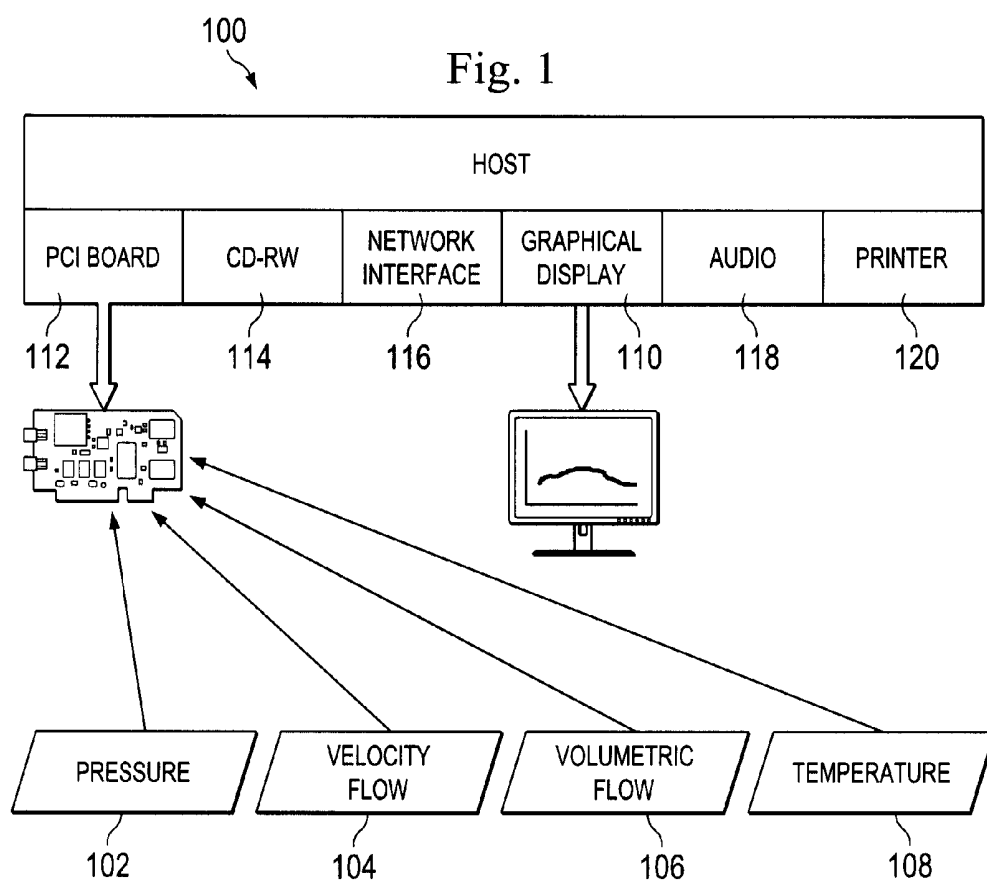
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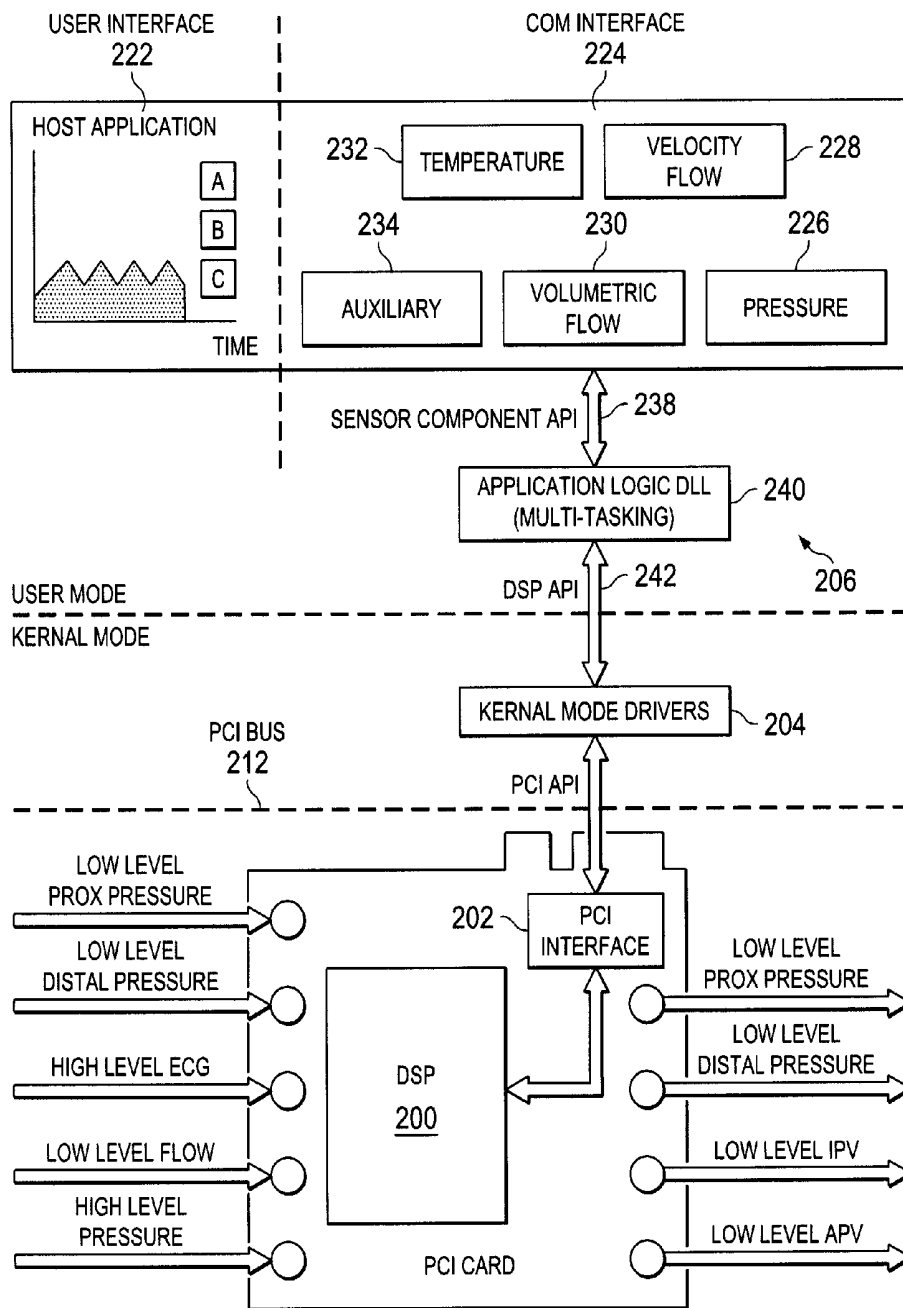


Fig. 2



Fig. 4

Patient	Last Name <input type="text"/>	First Name <input type="text"/>	MI <input type="text"/>
System	Patient ID <input type="text"/>	Physician <input type="text"/>	Gender <input type="text"/>
	Street 1 <input type="text"/>		
	Street 2 <input type="text"/>		
DICOM	City <input type="text"/>	State <input type="text"/>	Postal Code <input type="text"/>
Setup	Area Code <input type="text"/>	Phone Number <input type="text"/>	
			400 <input type="text"/> Keyboard

System	Pressure	Flow	Combo
--------	----------	------	-------

Fig. 5

Patient

System

DICOM

Setup

Last Name

First Name

MI ☐

Physician

Street 1

1 2 3 4 5 6 7 8 9 0 -

q w e r t y u i o p [

a s d f g h j k l ; '

z x c v b n m , . /

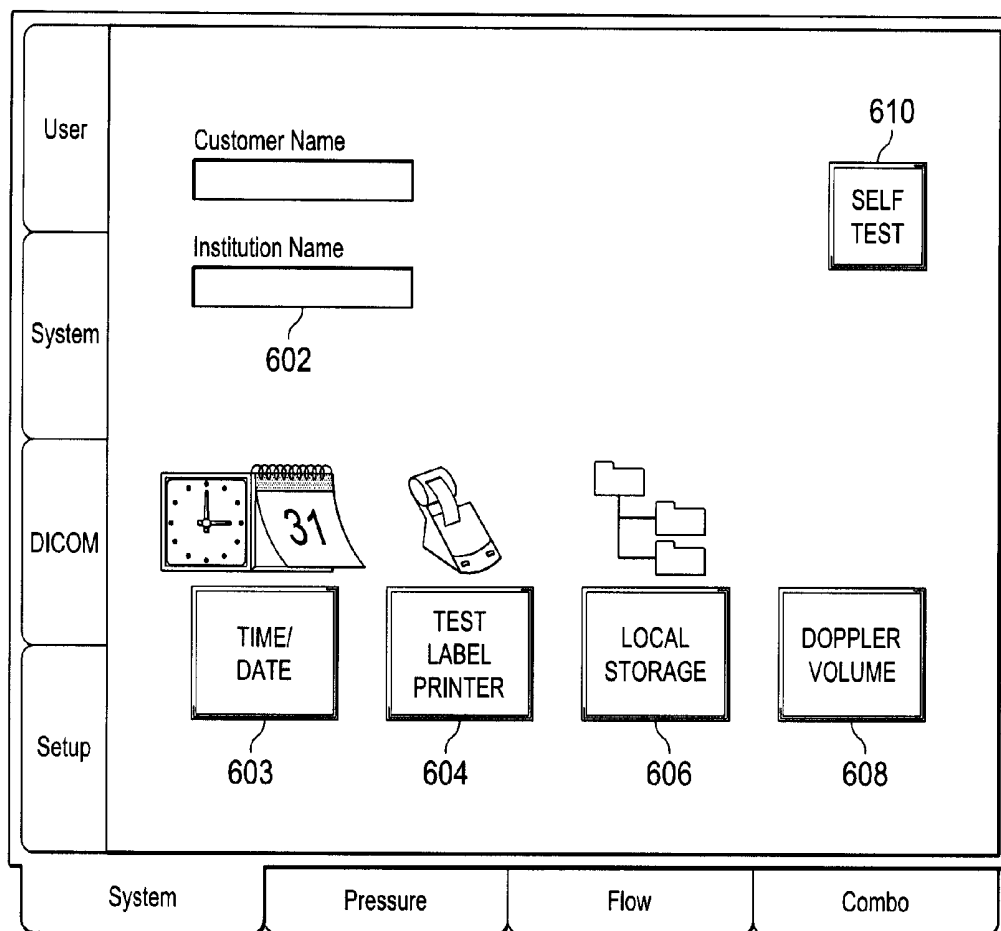
500

400

Keyboard

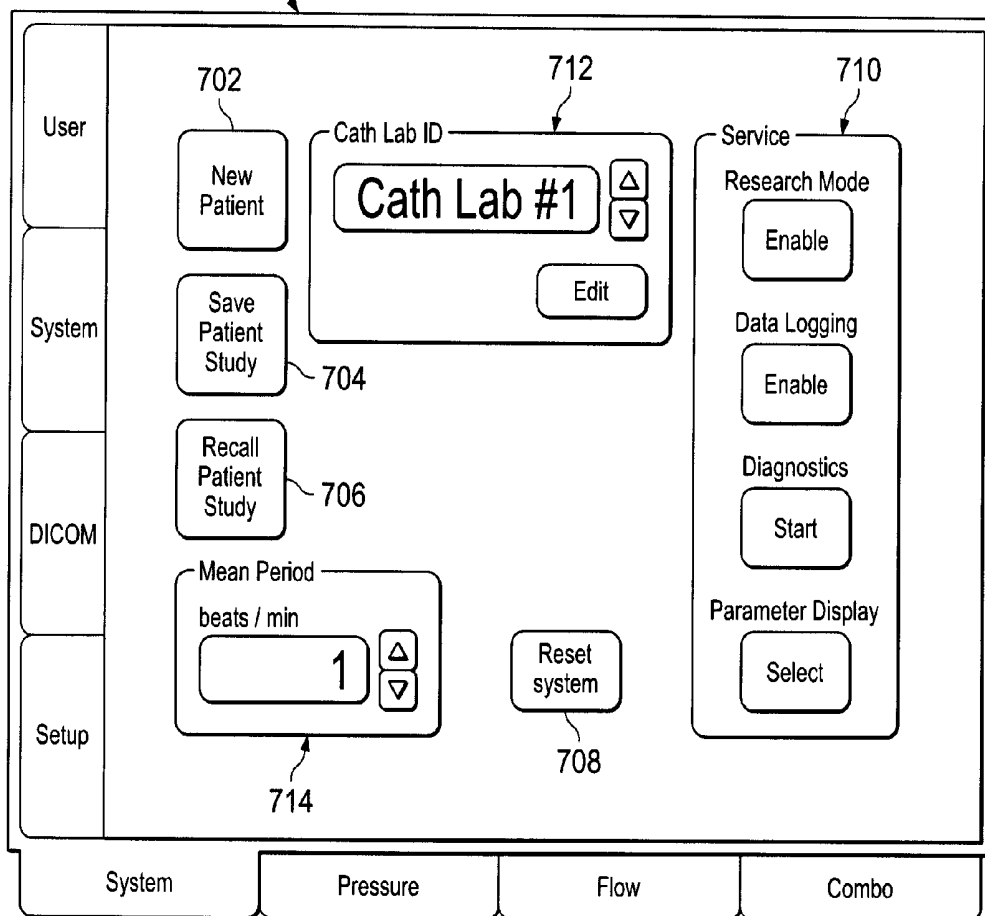
System Pressure Flow Combo

Fig. 6



700

Fig. 7



800

Fig. 8

User

802 Patient Name

804 Application Entity Title

System

805 TCP Port

806 IP Address

DICOM

808 Local DICOM Storage Location

810 Browse

812

Proprietary Format

DICOM Format

814 Configure

Setup

System Pressure Flow Combo

900

Fig. 9

Scale 908

Proximal

Auto Scaling: Off Adj

Maximum, mmHg: 50

Minimum, mmHg: 0

Distal

Auto Scaling: Off Adj

Maximum, mmHg: 100

Minimum, mmHg: 0

Analog Output

On

Offset Adjust: 30

Calibration Signal, mmHg: 100

Venous Pressure

Source: Preset

Assumed Value, mmHg: 20

Low Level Input Calibration 902a

Scale Value, mmHg: 100

Zero

Scale Value

Set

Distal Input 903

Zero

Normalize to Proximal

High Level Input Calibration 902b

Scale Value, mmHg: 100

Zero

Scale Value

Set

System Pressure Flow Combo

Fig. 10

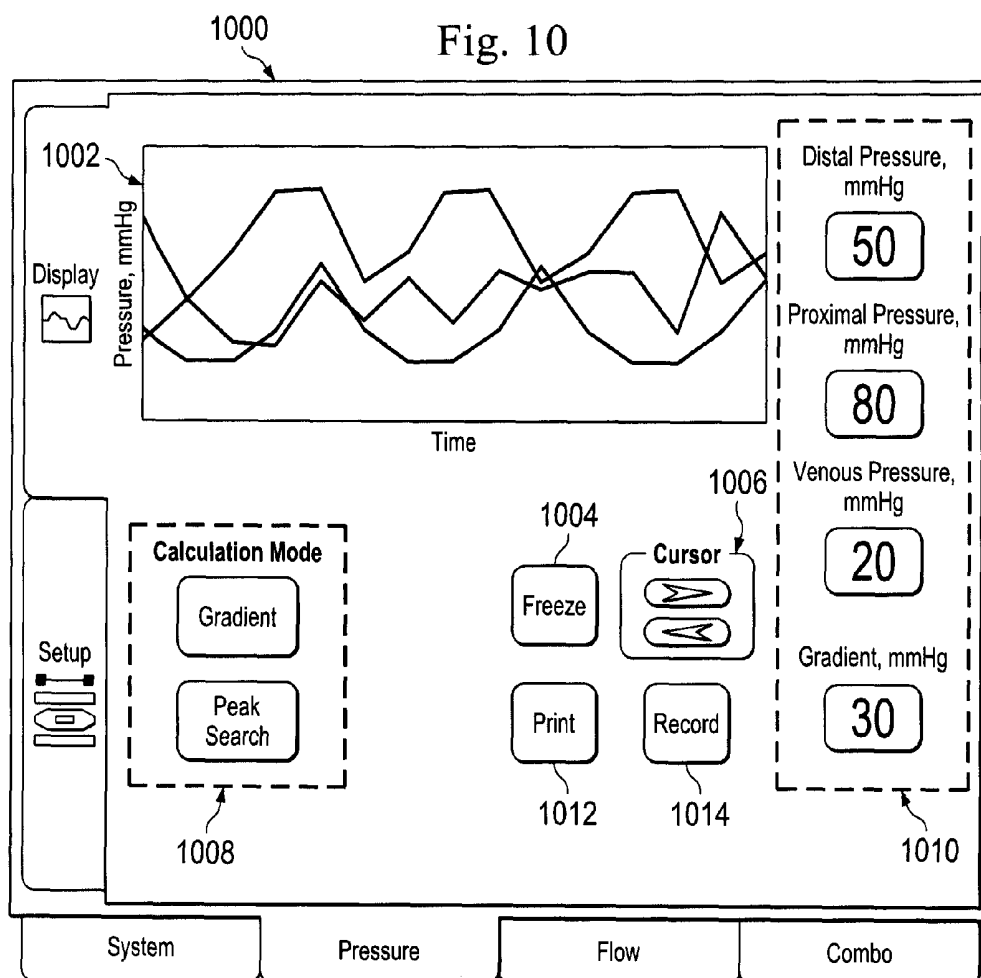
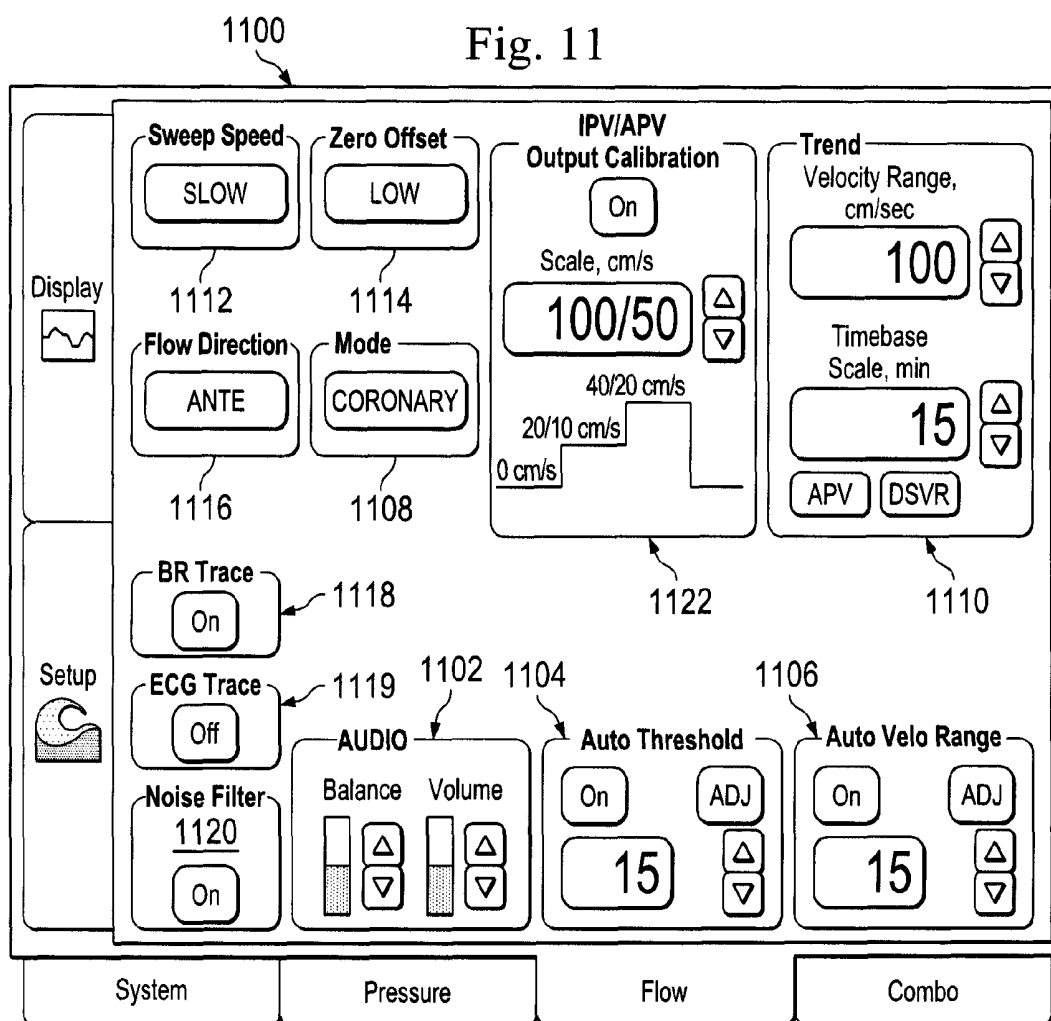
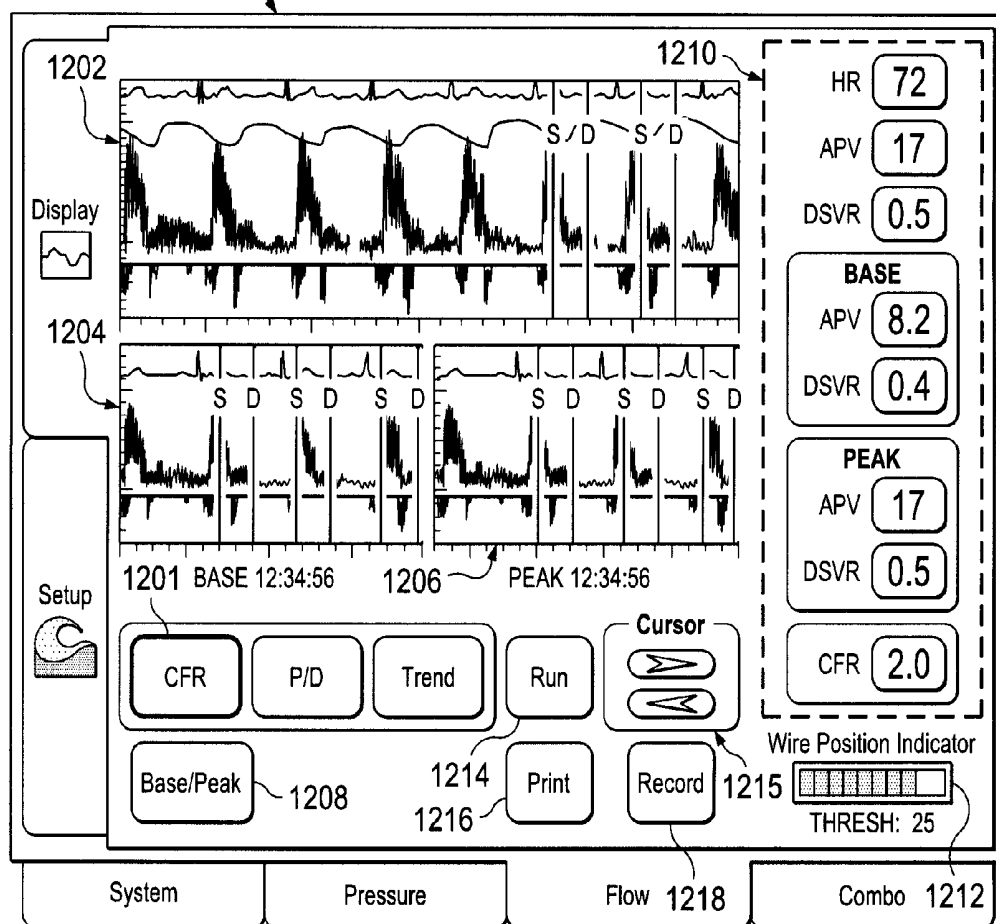


Fig. 11



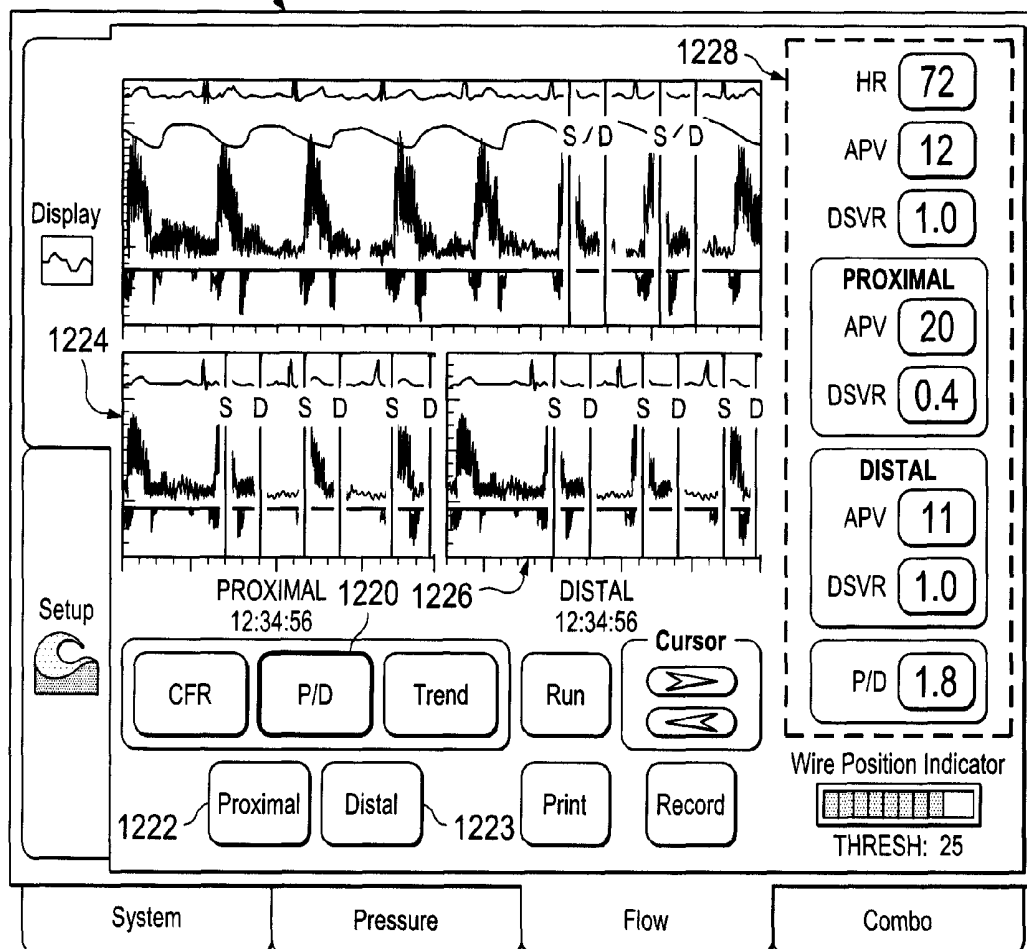
1200

Fig. 12a



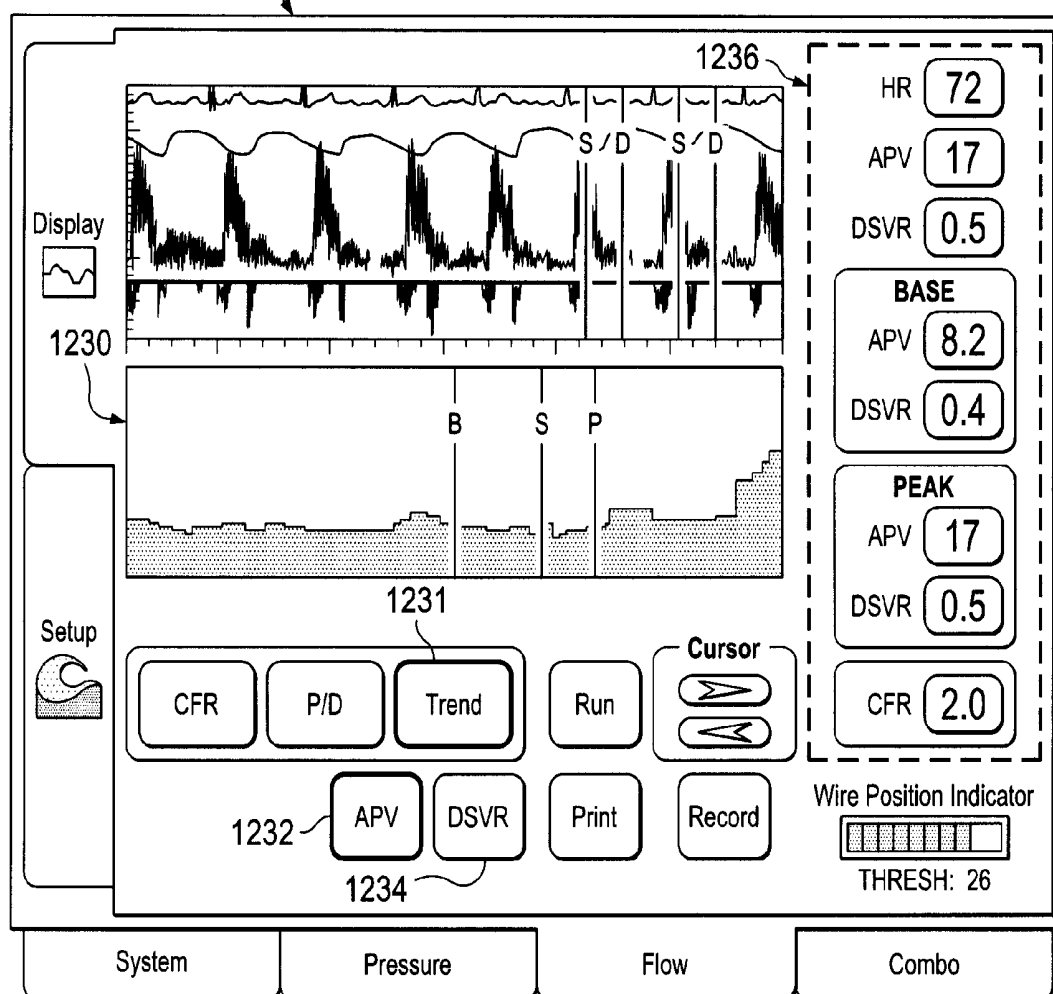
1200

Fig. 12b



1200

Fig. 12c



1200

Fig. 12d

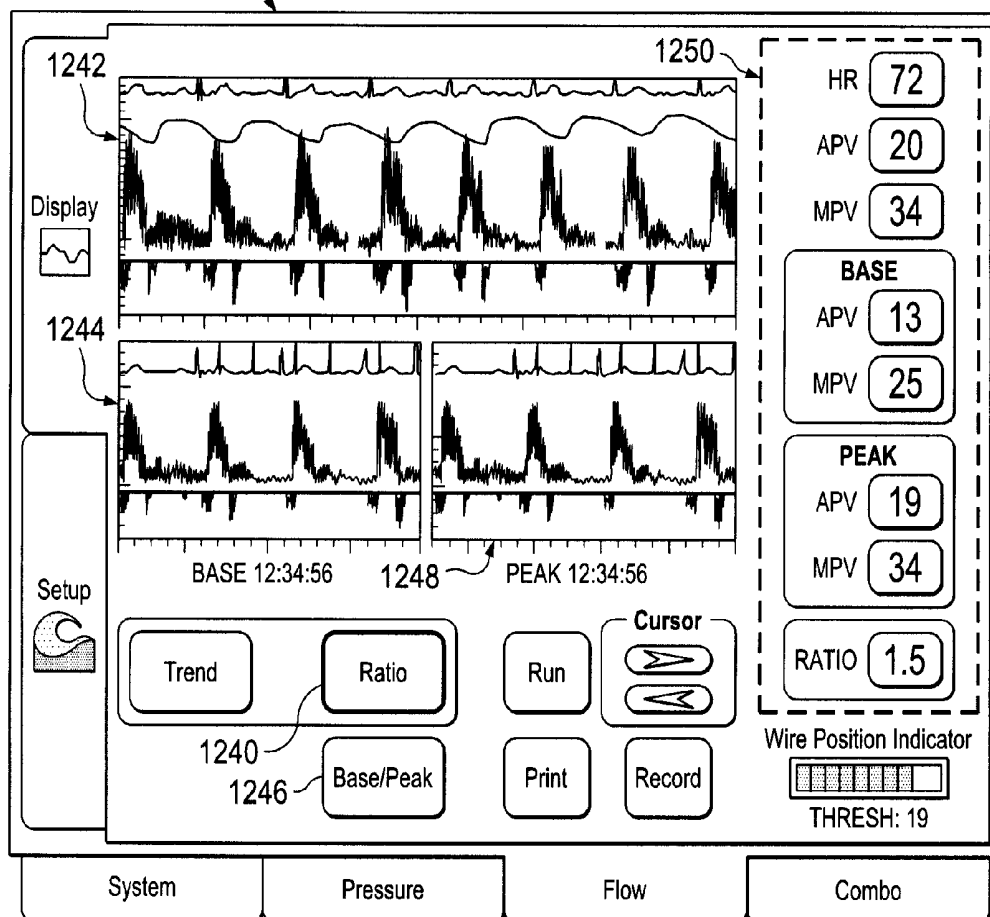
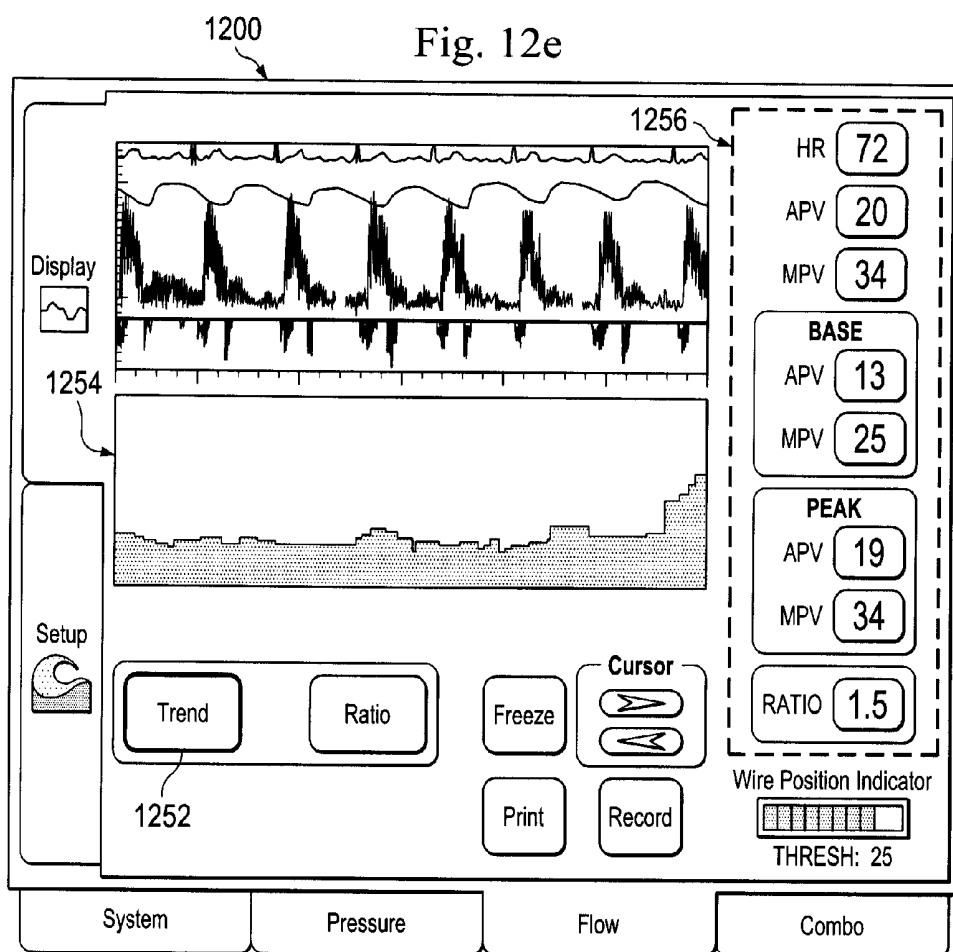
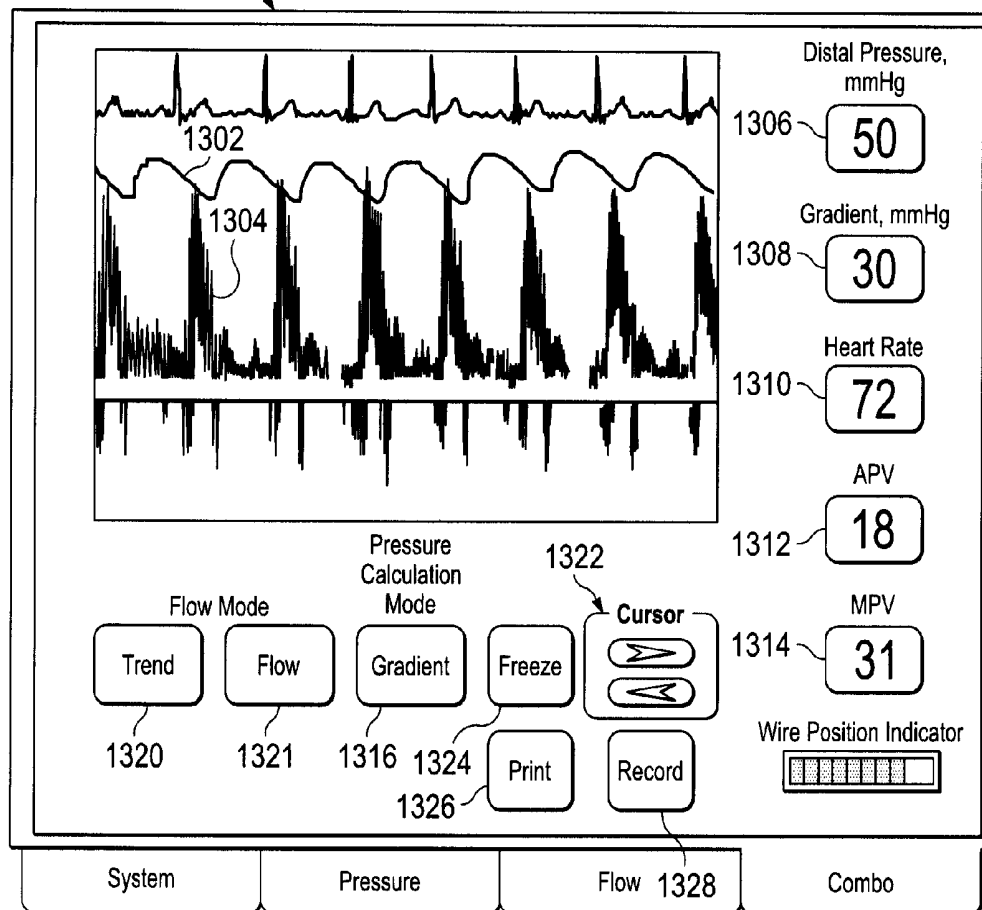


Fig. 12e



1300

Fig. 13



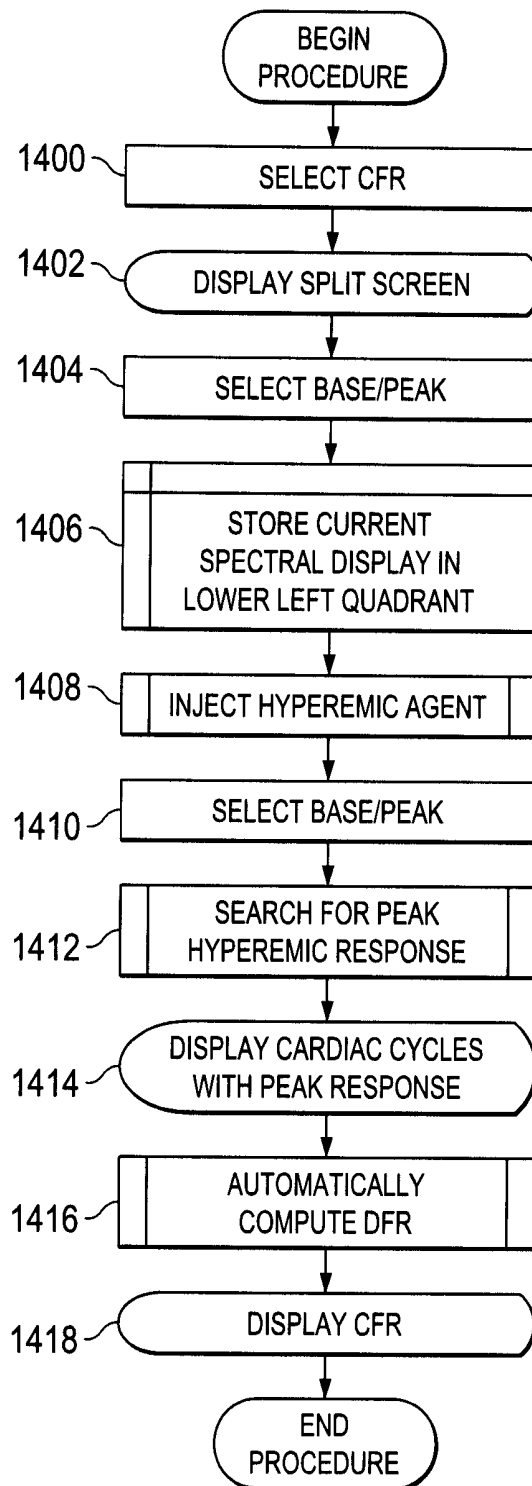


Fig. 14

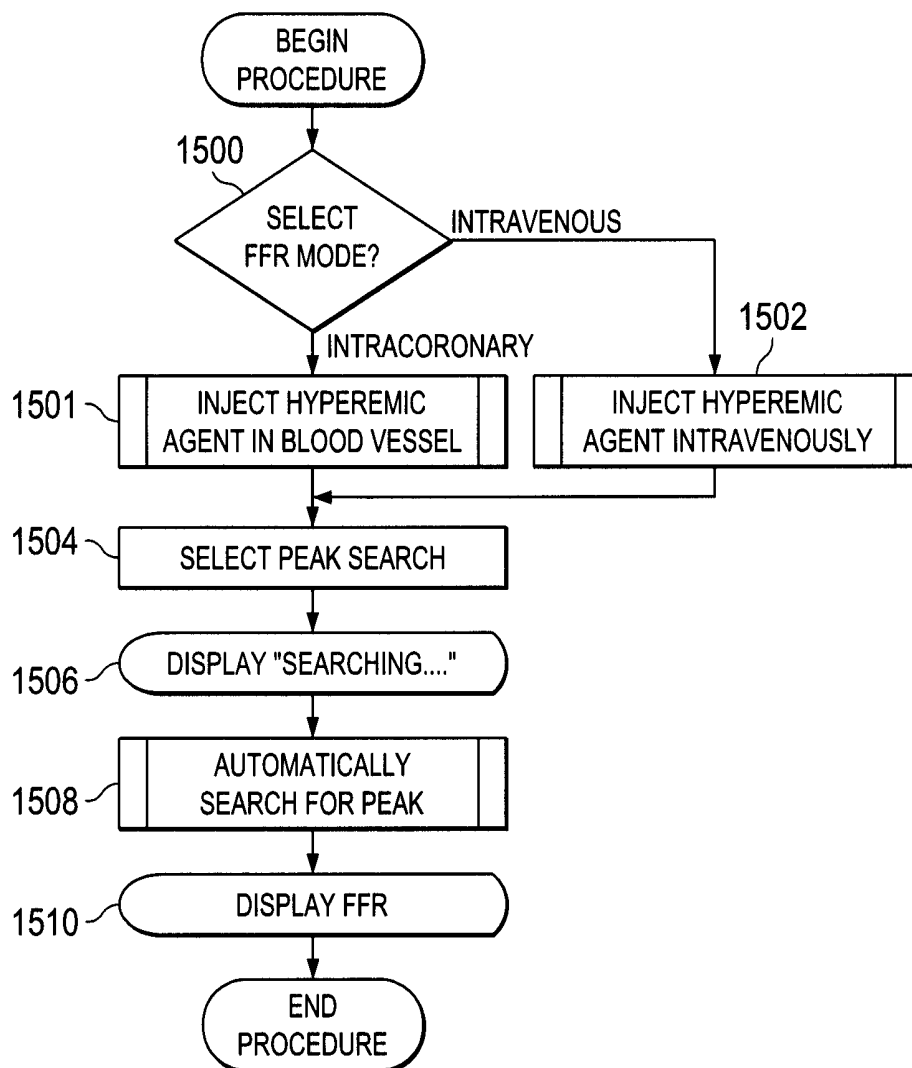


Fig. 15

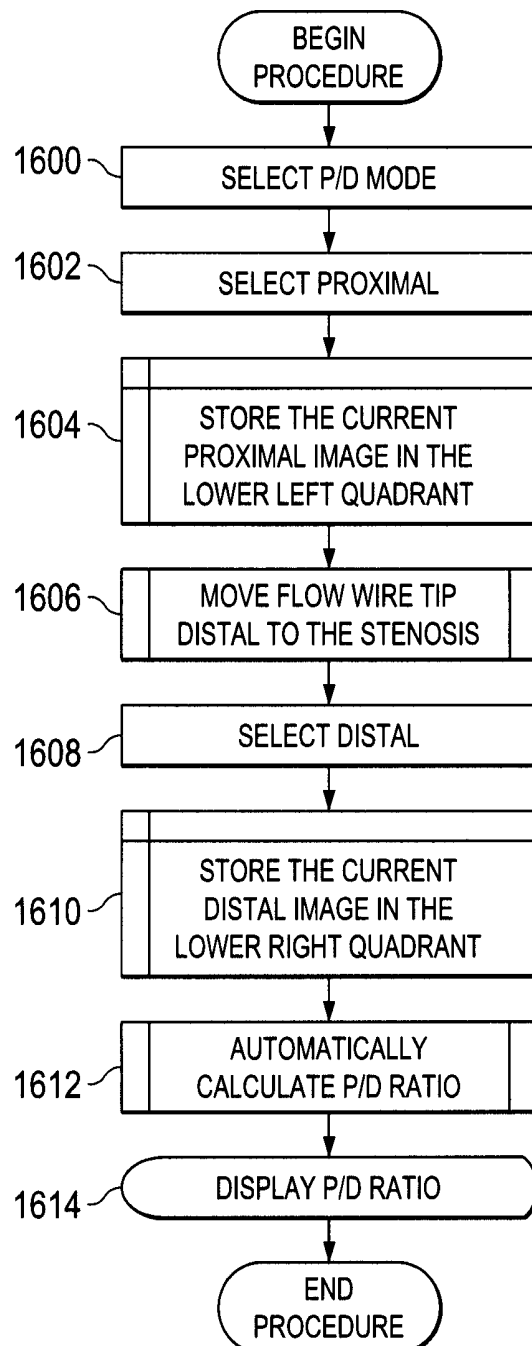


Fig. 16

MULTIPURPOSE HOST SYSTEM FOR INVASIVE CARDIOVASCULAR DIAGNOSTIC MEASUREMENT ACQUISITION AND DISPLAY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 11/555,556 filed on Nov. 1, 2006, which is a divisional of U.S. patent application Ser. No. 10/151,423 filed on May 20, 2002, now U.S. Pat. No. 7,134,994, each of which is hereby incorporated by reference in its entirety.

AREA OF THE INVENTION

The present invention generally relates to the area of diagnostic medical equipment, and more particularly to diagnostic devices for identifying and/or verifying efficacy of treatment of problematic blockages within coronary arteries by means of sensors mounted upon the end of a flexible elongate member such as a guide wire.

BACKGROUND OF THE INVENTION

Innovations in diagnosing and verifying the level of success of treatment of cardiovascular disease have migrated from external imaging processes to internal, catheterization-based, diagnostic processes. Diagnosis of cardiovascular disease has been performed through angiogram imaging wherein a radiopaque dye is injected into a vasculature and a live x-ray image is taken of the portions of the cardiovascular system of interest. Magnetic resonance imaging (MRI) has also been utilized to non-invasively detect cardiovascular disease. Diagnostic equipment and processes also have been developed for diagnosing vasculature blockages and other vasculature disease by means of ultra-miniature sensors placed upon a distal end of a flexible elongate member such as a catheter, or a guide wire used for catheterization procedures.

One such ultra-miniature sensor device is a pressure sensor mounted upon the distal end of a guide wire. An example of such a pressure sensor is provided in Corl et al. U.S. Pat. No. 6,106,476, the teachings of which are expressly incorporated herein by reference in their entirety. Such intravascular pressure sensor measures blood pressure at various points within the vasculature to facilitate locating and determining the severity of stenoses or other disruptors of blood flow within the vessels of the human body. Such devices are presently used to determine the need to perform an angioplasty procedure by measuring blood pressure within a vessel at multiple locations, including both upstream and downstream of a stenosis and measuring a pressure difference that indicates the severity of a partial blockage of the vessel.

In particular, a guide wire mounted pressure sensor is utilized to calculate fractional flow reserve (or "FFR"). In the coronary arteries, FFR is the maximum myocardial flow in the presence of stenosis divided by the normal maximum myocardial flow. This ratio is approximately equal to the mean hyperemic (i.e., dilated vessel) distal coronary pressure Pd divided by the mean arterial pressure Pa. Pd is measured with a pressure sensor mounted upon a distal portion of guide wire or other flexible elongate member after administering a hyperemic agent into the blood vessel causing it to dilate. Pa is measured using a variety of techniques in areas proximal of the stenosis, for example, in the aorta.

FFR provides a convenient, cost-effective way to assess the severity of coronary and peripheral lesions, especially inter-

mediate lesions. FFR provides an index of stenosis severity that allows rapid determination of whether an arterial blockage is significant enough to limit blood flow within the artery, thereby requiring treatment. The normal value of FFR is about 1.0. Values less than about 0.75 are deemed significant and require treatment. Treatment options include angioplasty and stenting.

Another such known ultra-miniature sensor device is a Doppler blood flow velocity sensor mounted upon the end of a guide wire. Such device emits ultrasonic waves along the axis of a blood vessel and observes a Doppler-shift in reflected echo waves to determine an approximation of instantaneous blood flow velocity. A Doppler transducer is shown in Corl et al. U.S. Pat. No. 6,106,476 on a guide wire that also carries a pressure transducer. Such devices are presently used to determine the success of a treatment to lessen the severity of a vessel blockage.

In particular, a Doppler transducer sensor is utilized to measure Coronary Flow Reserve (or "CFR"). CFR is a measure for determining whether a stenosis is functionally significant after treatment (e.g., post-angioplasty). CFR comprises a ratio of the hyperemic average peak velocity of blood flow to the baseline (resting) average peak velocity. Instantaneous peak velocity (IPV) is the peak observed velocity for an instantaneous Doppler spectrum provided by a Doppler transducer. An exemplary method of calculating an average peak velocity (APV) comprises averaging a set of IPV's over a cardiac cycle.

A known technique for determining whether an angioplasty was effective was to perform angioplasty, wait a few days, then perform thallium scintigraphy (imaging). If the angioplasty procedure was not effective, then re-intervention was performed and the lesion was again treated via angioplasty. On the other hand, using CFR, a flow measurement is taken immediately after angioplasty or stenting. The flow measurement is utilized to determine whether adequate flow has been restored to the vessel. If not, the balloon is inflated without the need for secondary re-intervention. A normal CFR is greater than about 2 and indicates that a lesion is not significant. Lower values may require additional intervention. In addition to being used post-treatment to determine the efficacy of treatment, CFR may be measured prior to treatment to determine if treatment is required.

A guide wire combination device, comprising a pressure sensor and a flow sensor having substantially different operational characteristics, was disclosed in the Corl et al. U.S. Pat. No. 6,106,476. While it has been proposed within the Corl et al. U.S. Pat. No. 6,106,476 to combine pressure and flow sensors on a single flexible elongate member, the prior art does not address how such a combination sensor is coupled to consoles that display an output corresponding to the signals provided by the flexible elongate member corresponding to the sensed pressure and flow within a vessel. Indeed, the relevant art comprises special-purpose monitors having static display interfaces that display a static set of parameters corresponding to a particular fixed set of diagnostic measurements (e.g., an aortic pressure and a pressure taken from a location proximate a stenosis). Thus, one type of monitor is utilized to process and display sensed pressure within a blood vessel. Another type of monitor provides output relating to blood flow within a vessel. As new intravascular diagnostic devices are developed, yet other special-purpose monitors/consoles are developed to display to a physician the sensed parameters.

There is substantial interest in simplifying every aspect of the operating room to reduce the incidence of errors. As one can imagine, the aforementioned intravascular pressure sen-

sors are utilized in operating room environments including many types of sensors and equipment for diagnosing and treating cardiovascular disease. Clearly, the room for error is very limited when performing such activities. Notwithstanding the interest to keep equipment and operations simple, there exists a variety of different sensors that are potentially inserted within a human vasculature to diagnose arterial disease (e.g., blockages) and/or monitor vital signs during a medical procedure. The approach taken in the field of interventional cardiac imaging has been to provide multiple, special-purpose monitor consoles. Each monitor type is linked to a particular type of sensor device.

In a known prior intravascular pressure sensor-to-physiological monitor interface arrangement, marketed by JOMED Inc. of Rancho Cordova, Calif., a physiology monitor receives and displays, on a permanently configured display interface, a set of pressure values corresponding to two distinct pressure signals that are received by the monitor. A first pressure signal is provided by an aortic pressure sensor, and a second pressure signal corresponds to a pressure sensed by a distally mounted solid-state pressure sensor mounted upon a guide wire. The display interface of the monitor is permanently configured to output parameter values corresponding to those two signals. Thus, if display of, for example, a flow signal value is desired, then a separate monitor, such as JOMED Inc.'s FloMap, is used.

SUMMARY OF THE INVENTION

The present invention provides addresses a need to provide a flexible, multipurpose host system for processing and displaying signals rendered by invasive cardiovascular sensors to reduce the amount of equipment and complexity of procedures for diagnosing and determining the efficacy of treatment of cardiovascular stenoses.

In particular, the present invention comprises a multipurpose host system that facilitates invasive cardiovascular diagnostic measurement acquisition and display. The host system includes a number of modularized components. The host system includes an external input signal bus interface for receiving data arising from cardiovascular diagnostic measurement sensors such as, for example, pressure transducers, Doppler flow transducers, temperature sensors, pH sensors, optical sensors, etc.

The host system also includes a plurality of measurement processing components for receiving data of particular sensor types. The processing components render diagnostic measurement parameter values according to the received data arising from various types of attached sensors. In a particular embodiment, the processing components are instantiated at startup time from component modules that are dynamically integrated into the host system. This allows the functionality of the host system to be extended to include new types of sensors without requiring an overhaul of the existing system software.

The host system also includes a multi-mode graphical user interface host. The interface host comprises a set of diagnostic measurement user interfaces. The output interfaces are integrated with the processing components and carry out displaying, on a graphical user interface a set of output values corresponding to parameter values rendered by the processing components.

BRIEF DESCRIPTION OF THE DRAWINGS

While the appended claims set forth the features of the present invention with particularity, the invention, together

with its objects and advantages, may be best understood from the following detailed description taken in conjunction with the accompanying drawings of which:

FIG. 1 is a schematic drawing depicting a system for conducting invasive cardiovascular diagnoses including an external input signal interface for receiving diagnostic parameter values of multiple types and a multimode graphical user interface for presenting the values according to a user-selected one of the multiple display modes;

FIG. 2 is a schematic drawing depicting an exemplary architecture of the system depicted in FIG. 1;

FIG. 3 depicts an exemplary generic graphical user interface specification upon which a set of graphical displays are based in accordance with the various graphical user interface modes supported by a host system embodying the present invention;

FIG. 4 depicts an exemplary graphical user interface for a patient data entry sub-screen of a system display mode of the host system;

FIG. 5 depicts an exemplary graphical user interface for a user/patient data entry sub-screen of a system display mode of the host system that includes a keyboard;

FIG. 6 depicts an exemplary graphical user interface for a system configuration sub-screen of a system display mode of the host system;

FIG. 7 depicts an exemplary graphical user interface for a setup sub-screen of a system display mode of the host system;

FIG. 8 depicts an exemplary graphical user interface for a communications sub-screen of a system display mode of the host system;

FIG. 9 depicts an exemplary graphical user interface for a setup sub-screen of a pressure display mode of the host system;

FIG. 10 depicts an exemplary graphical user interface for a display sub-screen of a pressure display mode of the host system;

FIG. 11 depicts an exemplary graphical user interface for a setup sub-screen of a flow display mode of the host system;

FIGS. 12a-e depict an exemplary graphical user interface for a display sub-screen of a flow display mode of the host system;

FIG. 13 depicts an exemplary graphical user interface for a combination flow and pressure display mode of operation of the host system;

FIG. 14 is a flowchart summarizing a set of steps for carrying out a coronary flow reserve measurement using the multipurpose host system described herein;

FIG. 15 is a flowchart summarizing a set of steps for carrying out a fractional flow reserve measurement using the multipurpose host system described herein; and

FIG. 16 is a flowchart summarizing a set of steps for carrying out a proximal/distal pressure ratio measurement using the multipurpose host system described herein.

DETAILED DESCRIPTION OF THE DRAWINGS

A multipurpose host system for invasive cardiovascular diagnostic measurement acquisition and display provides an advantage of the prior known systems in regard to its ability to present multiple user display interfaces. Each of the display interfaces corresponds to a particular purpose for which the multipurpose host is currently configured based, for example, upon one or more sensor devices communicatively coupled to its external signal interface. The host system is used, for example, in conjunction with interventional cardiology, e.g., angiography, or interventional procedures, e.g., angioplasty, to evaluate the hemodynamic status of an arterial blockage.

With reference to FIG. 1, a multipurpose host system 100 is, by way of example, a personal computer architecture-based system for assessing real-time invasive cardiovascular parameters from within a blood vessel (e.g., blood pressure and flow measurements). The multipurpose host processes input signals from multiple micro-miniature guide wire-mounted sensors (e.g., Doppler and pressure transducers) to produce real-time measurements, display various waveforms and derived parameters, and output high-level voltages proportional to calculated parameter values. The devices that supply the various data input signals are represented by pressure input 102, velocity flow input 104, volume flow 106, and temperature input 108. In an embodiment of the invention, the devices that provide the input to the host system 110 are presently used in existing, special-purpose processing boxes. This set is exemplary, as those skilled in the art will readily appreciate in view of this disclosure that alternative systems advantageously receive and process such diagnostic inputs as pH, ultrasound and light-based cross-sectional images of a vessel, biochemical markers, light spectrometry for tissue characterization, etc. It is further noted that the displayed output of the host system 100 is not limited to producing the measured parameters. Rather, the various modes of the host system 100 are capable of synthesizing generalized measures of physiological status (e.g., whether a blockage is severe and needs treatment) based upon the input parameter values.

The host system 100 operates in a plurality of modes, and each mode includes its own distinct graphical interface (rendered on graphical output display 110) and input parameter values (provided via a peripheral component interconnect (PCI) card 112) corresponding to particular sensor types. The PCI card 112 includes, by way of example, a digital signal processor (DSP) that samples data provided by the communicatively coupled input sensors and processes the sampled data to render digital data in a format expected by higher level components of the host system 100. Exemplary processes performed by the DSP include: A/D and D/A conversions, FFTs, level shifting, normalizing, and scaling. After processing the data, it is stored in a dual port RAM accessed, via the PCI bus of the host 100, by higher level application processes executing on the host system 100.

In the exemplary embodiment, input sensor types driving the output displays include pressure, flow, and temperature sensors mounted upon a flexible elongate member including combinations thereof placed, for example, upon a single guide wire or catheter. In fact, the flexible module-based architecture (see, FIG. 2) of the exemplary host system 110, which supports simultaneous display of multiple distinct types of input signals on a single graphical user interface, is particularly well suited for such combination devices since their output can be simultaneously monitored on a single interface even though modules that process the sensor inputs execute independently within the host system 100.

The exemplary host system 100 operates in pressure, flow, and combination (pressure/flow) modes. Though not essential to the invention, operation of each mode is preferably independent of the other modes, and each diagnostic display mode is driven by a designated set of parameter generation modules associated with particular input signals received by the host system from a communicatively coupled sensor. The pressure mode provides the user with a selection of calculated/derived parameters such as for example: proximal-distal pressure gradient, distal/proximal pressure ratio, normalized pressure ratio, and fractional flow reserve (normalized pressure ratio under hyperemic conditions). In an exemplary embodiment, the flow mode is divided into three operational modes: peripheral, coronary, and research. The peripheral

mode acquires measurements in the cerebral or peripheral vasculature. The coronary mode acquires measurements in the coronary arteries. The research mode provides a superset of peripheral and coronary modes plus additional parameters that may be of interest in a clinical research environment. The combination mode allows parameters associated with pressure and flow modes to be displayed simultaneously on a single graphical display.

In the illustrative embodiment of the invention, the graphical display interface 110 depicts calculated pressure and flow information on a strip chart graph on a graphical user interface display. The current values are, for example, displayed numerically as well. The graph scrolls as new information is calculated and added. A graphically displayed control enables a user to freeze the scrolling graphs and scroll backwards to view previously displayed portions of the scrolling graph. Additional display methods and techniques will be apparent to those skilled in the art.

The host system 100 embodies an extensible, component-based architecture, and thus the host system 100 supports a virtually limitless number of operating modes for processing and rendering graphical display output corresponding to an extensible set of input signals provided by sensors measuring a variety of types and combinations thereof. The host system 100 is modularized to support receiving and processing signals in a variety of formats from a variety of instruments. In a particular exemplary embodiment of the invention, the host system 100 relies on transducers and external diagnostic instrumentation to: (1) process the raw sensor information rendered by transducers/sensors inserted within a patient and (2) provide the information to the host 100 in particular digital or analog formats. The host system 100's capabilities are extendable, by way of example through enhancements to a currently installed peripheral component interconnect (PCI) board 110 or the addition of new PCI boards, to include additional signal processing capabilities. In an exemplary embodiment, transducers on the guide wire (patient isolated) provide low-level signals for blood velocity, flow, and pressure. A standard external pressure transducer (patient isolated) may be integrated with the host system to provide low-level aortic pressure. A high-level ECG signal input to the host provides synchronization for calculations (not patient isolated).

The interface of the host system 100 comprises a number of additional interfaces supporting the transfer and storage of information relating to the operation of the host system. Data storage device 114, for example, a CD-RW or a DVD-RW drive, is utilized to upload new software and store patient data processed and displayed during a diagnostic/treatment procedure. A network interface 116 provides remote access for performing functions similar to those provided by the data storage device 114. An audio input 118 enables annotation of input records by a user. A printer 120 facilitates printing out labels and/or compiled data from a diagnostic/treatment procedure. The set of peripheral/interface components identified in FIG. 1 is exemplary. As those skilled in the art will readily appreciate there exist a vast variety of I/O devices that can be advantageously incorporated into the host system 100 to enhance its utility.

Having described the peripheral components and external interfaces of an exemplary host system 100, attention is now directed to FIG. 2 that depicts an exemplary internal architecture of the host system 100 that facilitates operation of the host 100 in a variety of display modes associated with a variety of sensed invasive cardiovascular parameters such as temperature, pressure and blood flow within an artery. The PCI card 112 represents a highly flexible component of the

host system **100** architecture. The PCI card **112** includes a set of external sensor interface circuits for transmitting power and excitation signals to sensor devices and receiving sensed parameter values illustratively depicted in FIG. 2. In the illustrative example, the PCI card **112** includes both analog and digital input and output signals. Analog output signals are driven by the PCI card **112** output circuitry according to control commands supplied by high level user mode processes executing on the host system **100**.

It is noted that a wide variety of sensor types are known and the host system **100** is not limited to any particular type of sensor input. To the contrary, the present host system **100** is intended to provide a broad, extensible, multipurpose platform upon which a wide variety of application-specific modules are capable of processing and displaying sensor data rendered by a variety of sensor types and combinations of the sensor types including those described, by way of example herein.

The PCI card **112** includes a digital signal processor (or DSP) **200** that operates as a special purpose co-processor on the host system **100**. The DSP **200** receives digital samples corresponding to signals received via external inputs to the PCI card **112**, and carries out appropriate processing (e.g., FFT, filtering, scaling, normalizing, etc.) on the digital/digitized data samples. Thereafter, the processed data is placed into a dual port RAM within the PCI bus interface **202**.

Kernel mode drivers **204** executing on the host **100** facilitate communicating commands and data between the PCI card **112** and a set of user mode processes **206** that drive input parameter values for the multiple graphical user interface modes supported by the host system **100**. The kernel mode drivers **204** communicate with the PCI bus interface **202** according to a set of methods defined by a PCI Application Program Interface (API) **212**. The kernel mode drivers **204** access PCI registers and ports on the PCI bus interface **202** to extract processed sensor data and to issue control commands to the PCI card **112**. The kernel mode driver **204** carries out other desired driver functionality including issuing startup and diagnostic commands to the PCI card **112** and enabling and disabling particular inputs and outputs of the PCI card **112**. In an embodiment of the invention, the PCI API **212** are sufficiently generalized such that the PCI card **112** can be replaced by a different PCI card that includes a different set of input/output interfaces without requiring replacement of the presently installed kernel mode drivers **204**—though reconfiguration may be required to set up new connections between the kernel mode drivers **204** and sources and recipients of data and commands in the PCI interface **202**.

The kernel mode drivers **204** also includes functional components that respond to interrupts generated by the PCI card **112** (e.g., data ready, hardware errors, etc.). Other exemplary functions performed by the functional components of the kernel mode drivers **204** include detecting PCI installed devices, retrieving information about installed devices, read/write data from/to PCI configuration registers, execute a single read/write operation to an I/O port or memory on the PCI interface **202**, set up interrupt handling, allocate resources, and store sensor device-specific data. The functional driver module **214** responds to new data available for submission to user mode processes (described herein below) responsible for rendering input data that drives the user mode graphical user interface (e.g., graphs, instantaneous parameter values for pressure and flow velocity, etc.).

The user mode level of the host **100** embodies a modular/component based architecture. The modular architecture provides a high degree of flexibility in developing and incorporating new sensor types, and corresponding graphical user

interfaces, into the multimode host user interface. The user mode processes **206** include an extensible COM-based host application **222** that is responsible for presentation of a multiple interface mode graphical user interface (preferably with touch screen functionality). At startup, the host application **222** instantiates a set of user interface mode objects from a registry of available user interface mode object classes. Examples of such user interface mode objects include Pressure, Flow, and Combination. Extension of a base set of graphical user interfaces to include new user interface modes, such as Temperature and pH, is achieved by installing one or more new DLLs containing a user interface mode class objects corresponding to new user interface modes. In an embodiment of the invention, a separate user interface mode component object is provided for each distinct user interface mode supported by the host application **222**.

The set of user mode processes **206** also include a set of measurement processing components **224**. In an embodiment of the invention, each measurement processing component corresponds to a particular sensor. The measurement processing components **224** are instantiated from a set of sensor-specific component object model (COM) objects provided by one or more dynamically linked library (DLL) files. Each sensor-specific component is executed as a thread within a same process, or alternatively, as a separate process. Thus, a malfunction in one sensor-specific component will not affect the operation of properly operating sensor-specific components. The above-described COM approach to sensor data handling at the user mode level **206** also enables the set of input sensors and corresponding displayed interfaces to be readily extended by installing new DLLs from which the host system **100** instantiates COM objects corresponding to the new sensor input types. The illustrative host system **100** depicted in FIG. 2 includes the following sensor-specific components: pressure **226**, flow velocity **228**, flow volume **230**, temperature **232**, and auxiliary **234**. An exemplary input processed by the auxiliary component **234** is a position signal rendered by one or more displacement sensors (e.g., a rotational position, a lengthwise position along a vessel). The sensor-specific components are described further herein below. Additional component types of components in the set of measurement processing components **224** (e.g., temperature, pH, etc.) in accordance with alternative embodiments of the host system **100**.

In the illustrative embodiment of the invention, the set of sensor-specific components is extensible. Thus, when a new sensor type of sensor is developed for the host system **100**, the set of measurement processing components **224** is extended by developing and dynamically incorporating a new sensor-specific component object.

Thereafter, integration of the new sensor-specific component object is achieved by properly identifying the object as a member of the class of sensor-specific measurement processing components **224** that are instantiated when the system **100** starts up.

The set of measurement processing components **224** receive sensor data retrieved from the PCI interface **202** and drive inputs to particular ones of the graphical user interface display modes supported by the host application **222**. The communications with the kernel mode processes **204** are carried out via a sensor component API **238** which enables the measurement processing components **224** to communicate with an application logic component **240**. The sensor component API **238** methods are function oriented. An exemplary set of such methods in the sensor component API **238** include: setting operational states of the sensors, extracting sensor data, issuing control commands to the PCI card **112** config-

uring/controlling operation of the sensors. The application logic component 240 translates calls issued by ones of the set of measurement processing components 224 into calls to the kernel mode drivers 204. The application logic component 240 passes sensor data (originating from the PCI interface 202) from the kernel mode drivers 204 to the measurement processing components 224. Communications between the application logic component 240 and the kernel mode drivers 204 accessing the DSP 200 and the PCI interface 202 are carried out in accordance with a digital signal processing (DSP) API 242. The methods of the API 242 are hardware oriented, and include, by way of example: handling an interrupt, writing DRAM, writing DRAM, starting and stopping particular DSP functions relating to particular sensors and/or interfaces.

Having described the general architecture of the host system 100, attention is now directed to the multi-mode graphical user interface supported by the host application 222. It is further noted that the user interfaces preferably are augmented by touch screen functionality. The various display interface modes, while different, preferably share a common look and feel based upon a generic graphical user interface specification. FIG. 3 depicts an exemplary generic graphical user interface specification upon which a set of graphical displays are based in accordance with the various graphical user interface modes supported by the host application 222.

The exemplary graphical user interface architecture consists of three dedicated data display regions. A first region 300 is reserved for display of system and patient information. A second region 302 is reserved for system messages. A third region contains a set of hierarchical screens including a set of functionally related display and interactive components accessed, by way of example, by selection of one of a set of tabs 306.

The first region 300 is persistent and is displayed during all modes of operation of the host application 222. In an embodiment of the invention, the first region 300 includes one or more of the following fields relating to a patient/session: Patient Name, Patient ID—customer specific identification number, Physician—name of the attending physician, Institution—name of the client institution using the system, Date/Time—current date and time, and a branding logo.

The second region 302 of the exemplary graphical user interface general layout is reserved to display system messages. The second region 302 also persists for all modes of operation. The second region 302 includes, by way of example, the following fields relating to the display of messages generated by the host system: Current status—a message indicating the current operation state or status of the unit; Warning events—a message advising the user of a potential problem and possible remedy; Error events—a message notifying the user of a system error and possible corrective action; and System Mode—a message notifying a user of the current mode of operation of the host 100.

A third region 304, by way of example, is reserved to display parameters and input/output data fields according to a current mode of operation of the host 100 and display mode of the host application 222. The third region 304 is not persistent. Rather, the content of the third region 304 is determined by a particular use mode within which the host application is operating. In an embodiment of the invention, the third region 304 operates in one or more of the following modes: System, Pressure, Flow, and Combo (Combination). Additional modes are supported/displayed by the host application 222 in to accordance with alternative embodiments of the host 100. Such additional modes accommodate, for example, displaying additional sensor-provided/derived output parameters

(e.g., temperature, pH, etc.) or new sets/combinations of previously existing output parameters display elements. Each mode includes at least a second level of screens once the mode is selected by means of the tabs 306.

Turning now to FIG. 4, an exemplary graphical user interface is displayed that is suitable for entry of patient information in accordance with the System mode of operation of the host application 222. In particular, the displayed graphical display corresponds to a user (patient) data entry sub-screen under the System mode. While the host 100 supports input of data using traditional keyboard, in an embodiment of the invention, the user enters, edits, and/or deletes patient information via a touch screen keyboard called up by selecting the keyboard button 400. Turning briefly to FIG. 5, in response to a user selecting the keyboard button 400, the graphical user interface depicted in FIG. 4 is modified to include a touch screen keyboard 500. Alternatively, keyboard 500 is provided automatically. The information entered will persist for the duration of the current session. The Patient/System Information Display area (the first region 300) reflects changes in corresponding fields.

FIG. 6 comprises an exemplary system sub-screen under the System mode. The user enters relevant system information, e.g., customer/institution name 602, time/data 603, printer 604, LAN connection, local data storage 606, and/or a Doppler audio volume 608. The system sub-screen depicted in FIG. 6 preferably also includes a button/control 610 enabling a user to initiate a system self-test. The user specified information/configuration persists indefinitely and spans multiple patient sessions. The Patient/System Information Area (the first region 300) reflects changes entered via this interface.

FIG. 7 comprises an exemplary system setup sub-screen 700 under the System mode of the host application 222. While the system setup interface enables a user to modify default settings, the new default settings are stored in a non-volatile file, persist indefinitely, and span multiple patient sessions. The default settings are applied on system startup and reapplied via a reset button. As depicted in FIG. 7, the system setup sub-screen includes a new patient button 702 that invokes an interface enabling a user to enter new default setting for a new patient. A save patient study button 704 enables a user to store a session to a persistent device. A recall button 706 invokes an interface enabling a user to review and recall stored sessions. A reset system button 708 when selected, resets system information to default settings. A series of service selection buttons 710 enable a research mode of operation of the host system 100, enable data logging, commence diagnostics on the host 100, and enable selection of parameters displayed. A Cath Lab ID 712 allows the specification of a previously stored particular configuration/setup based, for example, upon a particular catheter lab within which the host 100 is to be used. However, the Cath Lab ID 712 field can be used to recall settings of any particular previously stored configuration/set up of the host 100. A mean period field 714 allows an operator to designate the number of cardiac cycles that are used to calculate a single average value (e.g., Average Peak Velocity).

FIG. 8 comprises an exemplary network communications setup sub-screen 800. In the exemplary embodiment, the sub-screen enables a user to provide information regarding report storage and transfer, connectivity, and format. In the exemplary embodiment a user interfaces to a DICOM (Digital Imaging and Communication in Medicine, an exemplary format for data exchange between two different systems) compliant information management system via the DICOM sub-screen 800 interface of the system mode of the host

application **222**. Other services provided by the DICOM sub-screen interface include transferring images to a remote DICOM archive and recalling images from the remote DICOM archive. The fields of the sub-screen **800** include a patient name **802**, an application entity title **804** for specifying the DICOM nodes with which the host **100** communicates, a TCP port field **805** specifies a port through which communications will take place, an Internet protocol address **806** identifying the address of the computer on the network with which the host **100** communicates, local DICOM storage location **808** specifies the local directory where the host **100** stores DICOM files, a browse button **810** launches a well known utility to search within the host **100**'s directory structure or create a new directory, storage file format **812** enables a user to select a file storage format (e.g., DICOM, proprietary, etc.), and a configure button **814** launches configuration of the communications based upon the specified field data.

An exemplary set of interfaces associated with the system (administrative) mode of operation of the host system **100** including the host application **222** has been described. Attention is now directed to a set of diagnostic modes of operation of the host system **100**, and more particularly the display interfaces associated with illustrative pressure, flow and combination modes of operation. With reference to FIG. 9, the host application **222** includes a pressure mode setup sub-screen **900** that enables a user to specify particular display attributes associated with a display sub-screen (see FIG. 10). The pressure setup sub-screen **900** preferably provides the user with input features to customize the operation of the pressure mode.

The illustrative pressure mode setup sub-screen **900** includes a set of low and high level input calibration controls **902a** and **902b** enabling a user to calibrate a pressure sensor in a variety of ways. The zero button in the calibration control displays **902a** and **902b** facilitates establishing a zero reference for the pressure sensor and a zero output level reference for any external instruments. Zero level calibration is performed by applying a zero pressure (ambient) and selecting the zero button on the calibration controls **902a** and **902b**. By way of example, low level input calibration is achieved through the low level input calibration control **902a** by applying a low pressure input, setting adjusting the scale value to the input pressure, and then pressing the set button. A high level input calibration is achieved through the high level input calibration control **902b** by applying a high pressure input, setting adjusting the scale value to the input pressure, and then pressing the set button.

Though not shown in FIG. 9, the low and high pressure calibration is alternatively performed by pressing the button labeled "scale value" to enable calibration by establishing a zero pressure and providing a "slope" or calibration factor defining the relationship between changes to the input pressure and the input signal. The button labeled "scale value" actually toggles the calibration mode, and in response the calibration display **902a** or **902b** converts to a calibration factor mode. Rather than supplying an actual pressure, instead a calibration factor expressed in terms of micro-volts per mmHg is entered by adjusting a displayed value and then pressing the set button.

The pressure mode setup sub-screen **900** also includes a distal input normalization control **903** for normalizing input pressure measurements from a distal pressure sensor via touch screen button controls. Normalization is the matching of the guide wire pressure sensor reading with an aortic pressure. Normalization is achieved by bringing the pressure sensor to an appropriate location and selecting the normalization button. This establishes a new value for the aortic pressure

that is used to determine various calculated/displayed output parameter values, including FFR. A distal sensor zero reference is established by selecting the zero button in the distal input normalization control **903** while applying a zero pressure reference.

The pressure mode setup sub-screen **900** also includes a set of venous pressure controls **904** including a venous pressure source control and venous pressure adjust (up/down) controls. A mean venous pressure value enables computing an FFR. The mean venous pressure may be input from a transducer via an external monitor or by a user preset value. Selecting the venous pressure source button on the setup sub-screen **900** toggles the source. Selecting 'External' designates the venous pressure source as a patient-applied transducer through an external monitor. Selecting 'Preset' allows the user to enter an assumed value. Selecting the up/down controls increases/decreases the preset value accordingly. The preferred range of values for the venous pressure is about 0-50 mmHg.

An analog output offset adjust **906** provides an interface for a user to adjust the offset and the pressure high level analog output of the host system **100**. The user can increase or decrease the output via the user interface. The output displays the current output adjustment level via the user interface. The analog output is modified accordingly. Change is effected by selecting the Up/Down arrow buttons adjacent to the Offset Adjust display to increase/decrease the value accordingly. The value will change, for example, in steps of 1 mmHg. The preferred range of values is about -30 to 330 mmHg.

The setup sub-screen **900** also includes maximum/minimum scaling presets **908** for both distal and proximal pressures. An on/off button enables/disables an autoscaling feature of the host graphical output display for the proximal and distal pressures. When autoscaling is activated, the scale of the output display expands as needed to handle an increased range of output pressures. A toggle button displayed in the "adjust" state for both proximal and distal scaling, enables manual adjustment of the maximum, and minimum scale values using the up/down arrow buttons. The pressure graph depicted in FIG. 10 in the display sub-screen for the pressure mode reflects the designated scales.

Turning to FIG. 10, an exemplary pressure mode display sub-screen **1000** displays data and pressure mode controls. The data driving the pressure display is supplied by the pressure component **226** of the set of Measurement processing components **224** identified in FIG. 2. The exemplary pressure mode display sub-screen **1000** includes a pressure waveform graph **1002** including multiple pressure waveforms including distal, venous, and aortic pressure waveforms. A run/freeze control **1004** stops and starts scrolling. A cursor/position control **1006** facilitates searching a waveform. A calculation mode control **1008** includes a first button for selecting a pressure calculation mode (e.g., distal/proximal gradient, distal/proximal ratio, normalized pressure ratio (NPR), and fractional flow reserve (FFR)) and a second button to search for peaks (visible only in FFR mode and used to detect peak hyperemic response after injecting a hyperemic agent). When the calculation mode control **1008** is selected, it changes to a next one of the available types of calculation modes. The exemplary pressure display sub-screen **1000** also includes a set of instantaneous/current measurement digital displays **1010** including: distal pressure, aortic pressure, venous pressure, and a selected calculated value (e.g., distal-to-proximal gradient, distal-to-proximal ratio, NPR, FFR). A print button **1012** initiates printing a set waveforms recorded during a session. Recording of the waveforms is toggled on/off by means of the record button **1014**.

In the illustrated display, gradient calculation mode has been selected. In an exemplary embodiment, a gradient output is measured by taking a difference between pressures before (e.g., aortic) and after a partially blocked vessel. The distal-to-proximal ratio is calculated by dividing the distal pressure by the proximal pressure. The normalized pressure ratio is calculated by subtracting the venous pressure from the distal and proximal pressures and then taking their ratio. The FFR value is calculated by taking the normalized pressure ratio at the peak hyperemic response. Pressure gradients/ratios across a heart valve are also provided in association with yet another potential calculated value rendered by the host **100**.

Next, an exemplary set of user interfaces are shown depicted that are associated with a flow mode of operation of the host **100** and host application **222**. The flow mode graphical user interface is subdivided into a number of sub-screens illustratively depicted by way of example herein. With reference to FIG. 11, a setup screen **1100** provides the user with interface setup features to select and customize the operation of the flow mode of operation of the host **100**. The flow setup includes controls to set for example: Doppler audio volume and balance **1102**—for a set of stereo speakers, a signal threshold **1104**—via an on/off button and a threshold adjust, and velocity range **1106**—similar to pressure in that a user can select either auto ranging or manually adjust the maximum on the scale in the case where the auto ranging is shut off. A configuration button **1108** toggles between coronary and peripheral artery configurations to take into consideration the delay of velocity changes in relation to an ECG signal.

Trend setup controls **1110** set velocity scale and time base scale for a trend output. Furthermore, the trended parameter, average peak velocity or diastolic/systolic velocity ratio, is selected via the trend setup controls **1110**. Other exemplary controls for the flow display mode include a sweep speed **1112** (selects the scrolling speed of the spectral display from 3 speeds: slow, medium, or fast), zero offset **1114** (selects the zero velocity baseline position from 3 locations: low, medium, or high), and a flow direction **1116** (select the direction of flow to be displayed above the baseline from 2 bearings: antegrade or retrograde). A user can also optionally designate whether to display a blood pressure trace **1118**, ECG trace **1119**. A user also selectively activates a noise filter **1120**. A calibration section **1122** allows a user to enable/disable an output calibration signal and select the particular waveform for performing the calibration.

With reference to FIGS. 12a-e, a set of illustrative examples of a flow display are provided in accordance with two primary flow sensing configurations, coronary and peripheral—as designated by the configuration button **1108** on the flow setup sub-screen depicted in FIG. 11. A flow operation sub-screen **1200** is displayed in its depicted state when a CFR operation button **1201** button is selected. In response, a multi-partitioned waveform display depicts a full wave form graph **1202** as well as two smaller waveform display output segment graphs **1204** and **1206** corresponding to the base waveform and peak wave form (under hyperemic conditions). The designation of the time frame in which data is gathered and displayed within the graphs **1204** and **1206** is determined by pressing the base/peak button **1208** a first time to acquire the base readings and then pressing the base/peak button **1208** a second time to acquire the peak readings.

The graphs **1202**, **1204** and **1206** display flow velocity (based upon flow velocity input data in the form of Doppler spectral arrays), measured in a variety of ways (e.g., average peak velocity, mean peak velocity and flow velocity). At each point in time, a set of grayscale values are assigned to each

representative frequency component of the display. Intensity is assigned to points along a same time slice on the graph based upon prevalence of the frequency indicative of blood flow velocity. The display generates a set of markers associated with particular sensed events. For example, the “S” represents the systolic pressure reading while the “D” represents the diastolic pressure reading in a cardiac cycle. A user can limit the displayed spectra by adjusting the threshold background **1104** to exclude low level frequency components. Simultaneous with the velocity spectra, an instantaneous peak velocity tracking the blood flow velocity envelope’s peak may also be displayed.

In the illustrative embodiment, instantaneous/current calculated values for graphed parameters are digitally displayed as well in field **1210**. In particular, field **1210** displays the instantaneous heart rate, average peak velocity (APV), and diastolic/systolic velocity ratio (DSVR). Additional sub-fields of field **1210** depict the APV and DSVR determined during a designated base time span and peak time span. Field **1210** also displays the CFR calculated from the base and peak values. An optimal wire position indicator **1212** visually prompts a user to move the wire to obtain optimal placement positioning. A run/freeze button **1214** starts and stops scrolling of the displayed waveforms, and a cursor **1215** allows scrolling within the previously displayed sections of the waveforms. A print button **1216** enables the printing of the waveforms. A record button **1218** toggles a data/waveform recorder between an active/inactive logging state.

Having described an exemplary interface associated with the CFR flow mode, attention is briefly directed to other coronary modes supported by the exemplary host system **100**. FIG. 12b depicts the display of the host system **100** when a user selects the proximal/distal button **1220** while in the coronary flow configuration. Instead of the base/peak button **1201**, a proximal button **1222** and a distal button **1223** are displayed.

The proximal button **1222** is selected to invoke pressure input processing by the host system **100** corresponding to a pressure observed proximal (before) a stenosis. The corresponding waveform is displayed upon a graph **1224**. The distal button **1223** is selected to invoke pressure input processing corresponding to a pressure observed distal (after) a stenosis. The corresponding waveform is displayed upon a graph **1226**.

The output display depicted in FIG. 12b includes instantaneous/current calculated values for graphed parameters in field **1228**. In particular, field **1228** displays the instantaneous heart rate, average peak velocity (APV), and diastolic/systolic velocity ratio (DSVR). Additional sub-fields of field **1228** depict the APV and DSVR determined for proximal and distal pressure readings. Field **1228** also displays the proximal/distal ratio calculated by the host **100** from the observed proximal and distal pressures.

FIG. 12c depicts a graphical output display rendered in accordance with trend calculations supported by the host system **100**. When the trend operation is selected, the host system **100** calculates an average flow velocity value (e.g., APV, DSVR, etc.) over a period of time (e.g., a cardiac cycle) and visually renders the value in the form of a graph **1230**. The trend mode is entered when a user selects a trend button **1231**. In response, an APV button **1232** and a DSVR button **1234** are displayed. Based upon a user’s selection, the calculated and displayed average is either an APV or a DSVR. It is noted that the above two trend parameters are merely exemplary as those skilled in the art will readily appreciate that other input/calculated are suitable for trend calculation, display and analysis.

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With continued reference to FIG. 12c a set of instantaneous/current calculated values for graphed parameters are digitally displayed in field 1236. The output parameters displayed in field 1236 are the same as the ones depicted in field 1210 in FIG. 12a. However, the BASE, Peak and CFR parameters are not calculated by the host 100 while trend analysis is occurring. Rather, these parameters are retrieved, if they exist, from previous calculations rendered when the user selects the CFR button 1201. The base value is marked in the trend graph 1230 with a "B", the peak value with a "P", and the starting point of the peak search with an "S". The time scale of the trend graph 1230 is on the order of one or multiple minutes. The time scale of the ECG graph above the trend graph is on the order of seconds.

Turning now to FIGS. 12d and 12e, graphical display outputs are illustratively depicted for two exemplary peripheral operations supported by the host 100. These two sub-screens of the flow mode graphical display 1200 are entered by selecting the peripheral configuration through the coronary/peripheral configuration button 1108 on the flow setup sub-screen depicted in FIG. 11. The peripheral configuration takes into account that, in peripheral arteries, a flow velocity signal lags an ECG signal, and therefore the peripheral configuration introduces a time shift to account for the lag.

FIG. 12d illustratively depicts the display 1200 when the ratio button 1240 is selected while the host system 100 is in the peripheral flow configuration. A graph 1242 displays a continuous graph depicting calculated flow velocity. A base flow velocity graph 1244 is rendered from data collected by the host system 100 after a base/peak button 1246 is selected a first time. A peak flow velocity graph 1248 is rendered from data obtained after the base/peak button 1246 is selected a second time.

In the illustrative embodiment, instantaneous/current calculated values for graphed parameters are digitally displayed as well in field 1250. In particular, field 1250 displays the instantaneous heart rate, APV, and mean peak velocity (MPV). Additional sub-fields of field 1250 depict the APV and MPV determined during a designated base time span and peak time span. Field 1250 also displays a ratio calculated from the base and peak values.

FIG. 12e illustratively depicts the display 1200 when the trend button 1252 is selected while the host system 100 is in the peripheral flow configuration. The two snapshot graphs 1244 and 1248 are replaced by a single trend graph 1254. In the illustrative embodiment, instantaneous/current calculated values for graphed parameters are digitally displayed as well in field 1256. In particular, field 1256 displays the instantaneous heart rate, APV, and mean peak velocity (MPV). Additional sub-fields of field 1256 depict the APV and MPV determined during a designated base time span and peak time span. Field 1256 also displays a ratio calculated from the base and peak values. However, the displayed Base, Peak and ratio values in field 1256, are provided from the previously described ratio operation described with reference to FIG. 12e.

Yet another exemplary mode of the multiple interface modes is a combination mode that provides data from multiple sensors in a single graphical interface. In the illustrative example, no new signal input types are needed to carry out the illustrative combination type of graphical display interface. In alternative embodiments, the combination mode includes additional sensor input types such as, for example, a temperature input or a position sensor. FIG. 13 provides an exemplary combination mode display in which flow and pressure measurements are combined to render two side-by-side scrolling graphs depicting sensed flow and pressure parameters during

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an invasive diagnostic procedure wherein a flexible elongate member such as a guide wire, configured as a combination device (in this particular case including both a pressure sensor and a Doppler flow sensor) is inserted into a patient. Such combination devices, used in association with the combination output provide a desirable environment in which to calculate fractional flow reserve (FFR) using pressure readings, and coronary flow reserve (CFR) using flow readings. However, it is possible to utilize the present system to make CFR and FFR measurements using non-combination devices, i.e. using multiple known single sensor devices.

Referring now to FIG. 13, the combination mode display screen 1300 includes a first graph 1302 of sensed pressure and a second graph 1304 of flow output parameters such as, for example, Doppler spectral arrays, average peak velocity and flow volume. Digital displays are provided that illustratively indicate instantaneous measurements for distal pressure 1306, a pressure calculation (based upon selected calculation via button 1316) such as gradient pressure 1308 (but also displays FFR or other calculated pressures), heart rate 1310, average peak flow velocity 1312 and mean peak flow velocity 1314.

A CFR/Trend button 1320 provided a user the capability of selecting a CFR operation or trend operation in association with the acquisition of flow data. A flow velocity button 1321 enables selection of a flow velocity output mode. As disclosed previously in FIGS. 10 and 12a-e the screen 1300, in an embodiment of the invention, reconfigures in association with a user's selection of the various selectable operations and calculations supported by the combination mode of the host 100.

The combination screen 1300 also preferably includes scroll controls in the form of scrolling arrows 1322 that enable a user to scroll forward and back along the graphical output. A freeze/run toggle button 1324 enables/disables scrolling of the graphs 1302 and 1304. A print button 1326 initiates printing a session (or portion thereof). A record button 1328 commences and halts recording session data in a toggling manner.

In addition to the touch screen controls, the host 100 preferably supports interactive remote control/selection of the various display components depicted in the exemplary graphical user interface displays described herein above.

Having described a set of exemplary graphical user interfaces associated with a host system 100 embodying the present invention, attention is directed to FIG. 14 which depicts a flowchart summarizing an exemplary set of steps for carrying out a coronary flow reserve (CFR) measurement. Initially, a user selects the flow interface mode of the host application 222. Thereafter, during step 1400 the user presses the CFR button 1201 on the display screen to measure CFR. In response during step 1402 the graph area of the screen 1200 vertically partitions into upper and lower halves. The upper half graph 1202 displays the real-time velocity spectra presently measured by the Doppler sensor. The lower half of the graph display area is divided horizontally into two sections for displaying snapshots of the spectral display taken from the upper partition. The lower left area contains baseline graph 1204, and the lower right area is reserve for a peak response graph 1206.

During step 1404, a user presses the BASE/PEAK button 1208 on the display 1200 to save the baseline spectral display. A snapshot of the real-time spectral display is transferred to the lower left (baseline) graph 1204 of the display during step 1406.

Next, at step 1408 a hyperemic agent is injected into the patient. At step 1410 the BASE/PEAK button 1208 is selected

a second time. In response, at step **1412** the host application **222** automatically begins a search for a peak hyperemic response (maximum average peak velocity (APV)—where the APV is determined by averaging the instantaneous peak velocity (IPV) over a cardiac cycle). During step **1414** a snapshot of the real-time spectral display is transferred to the lower right (peak) area on the graph **1202**. During steps **1416** and **1418** the CFR ratio is periodically recalculated based upon the maximum APV found during the search and the current maximum ratio is displayed digitally in field **1210**. Pressing the BASE/PEAK button **1208** a third time manually terminates the search. The search is automatically terminated if 5 consecutive seconds have elapsed and the maximum APV has not changed. The last CFR ratio value is held in the display as the process for determining the CFR ratio ends.

Turning now to FIG. **15**, an exemplary set of steps for carrying out a fractional flow reserve (FFR) determination using the host system **100** in a pressure mode and a guide wire including a pressure transducer is summarized. Initially, during step **1500** the FFR mode is selected via the calculation mode button of the calculation mode control **1008**. A blood pressure sensor is placed in position to measure distal pressure within a vessel. Aortic pressure is simultaneously monitored using an aortic pressure sensor. Thereafter, during step **1501** or **1502** (based upon the specifically selected FFR mode—intracoronary or intravenous) the hyperemic agent is either injected in the blood vessel under investigation or administered intravenously. The peak search button of the calculation mode control **1008** (displayed only for FFR mode) is selected to observe the hyperemic response of the vessel during step **1504**. The host application **222** displays a “searching” prompt at step **1506** until it locates a peak response while carrying out a search during step **1508**. When the peak is detected, the FFR value is displayed during step **1510** on the display **1000**.

The pressure mode of operation of the host application **222** preferably also supports determination of a proximal/distal ratio. The set of exemplary steps for such a procedure are depicted in FIG. **16**. Initially during step **1600** the P/D mode is selected via the calculation mode button of the calculation mode control **1008**. This results in a split screen similar to the one described above for the CFR ratio determination process summarized in FIG. **14**. Next, at step **1602** after moving a pressure sensor to a proper location within a vessel to obtain a proximal pressure reading, a user selects a proximal button that is displayed when the ratio calculation operation is selected. In response, during step **1604** the host application **222** stores the current proximal image in the lower left quadrant of the graph **1002** (in a split screen similar to the one displayed for CRF operations). Next, a pressure sensor of the guide wire is moved to a point beyond (distal to) a stenosis during step **1606**. At step **1608** a distal display button rendered within the calculation mode control **1008** area is selected on the graphical display screen **1000**. In response, during step **1610** the host application **222** stores the current distal image in the lower right quadrant of the graph **1002**. At step **1612** the proximal/distal pressure ratio is calculated based upon the stored inputs at steps **1604** and **1610**, and during step **1614** the P/D ratio is displayed on the display **1000**. It is noted that the ordering of taking the proximal and distal readings is not important to carry out the P/D ratio determination. In fact, in a system wherein two pressure sensors are simultaneously placed in proper locations to take the proximal and distal readings, the readings are taken at substantially the same time.

Having described a number of exemplary applications of the host system **100** and its multipurpose, multimode archi-

ture the breadth of potential configurations/applications of this architecture is demonstrated through two additional uses that involve the incorporation of a sensor orientation/displacement signal and a temperature sensor signal received by the PCI card **112** of the host system **100**. The host system **100**, for example, receives pressure sensor signals and a sensor displacement signal enabling the host system **100** to render a map of pressure variations along a vessel. The resulting substantially real-time graphical display can be used, for example, to locate a stenosis or guide optimal placement of treatment of a vessel blockage. In yet another application supported by the host system **100**, a position sensors identifying angular displacement as well as displacement along the length of a vessel are integrated, by the host system, with a temperature sensor mounted upon a flexible elongate member to provide a temperature map for the walls of a vessel to identify lesions. Such map is created by the host system **100** by rotating a temperature sensor placed against the vessel wall and drawing the temperature sensor back along the vessel. The host system **100** receives and integrates the signals provided by the temperature and position sensors and renders a corresponding map.

Illustrative embodiments of the present invention and certain variations thereof have been provided in the Figures and accompanying written description. Those skilled in the art will readily appreciate from the above disclosure that many variations to the disclosed embodiment are possible in alternative embodiments of the invention. Such modifications include, by way of example, modifications to the form and/or content of the disclosed functions and functional blocks of the disclosed architecture, the measurements processed by the host system, the calculations arising from the measurements, the methods for setting modes and acquiring the measurements. Additionally, imaging data, such as Intravascular Ultrasound, Magnetic Resonance Imaging, Optical Coherence Tomography, etc., may be obtained, analyzed, and/or displayed upon the multipurpose application interface supported by the host system described hereinabove. The present invention is not intended to be limited to the disclosed embodiments. Rather the present invention is intended to cover the disclosed embodiments as well as others falling within the scope and spirit of the invention to the fullest extent permitted in view of this disclosure and the inventions defined by the claims appended herein below.

What is claimed is:

1. A method of performing an invasive cardiovascular procedure using multiple invasive sensor types, the method comprising:

communicatively coupling a first invasive cardiovascular sensing component to a multi-purpose host system;
communicatively coupling a second invasive cardiovascular sensing component to the multi-purpose host system;
positioning at least a portion of the first invasive cardiovascular sensing component within a vessel of a patient;
positioning at least a portion of the second invasive cardiovascular sensing component within the vessel of the patient;

utilizing a user interface of the multi-purpose host system to control operation of the first invasive cardiovascular sensing component to cause the first invasive cardiovascular sensing component to obtain data related to a first invasive cardiovascular parameter while positioned within the vessel of the patient;

utilizing the user interface of the multi-purpose host system to control operation of the second invasive cardiovascular sensing component to cause the second invasive cardiovascular sensing component to obtain data

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related to a second invasive cardiovascular parameter while positioned within the vessel of the patient, the second invasive cardiovascular parameter being different than the first invasive cardiovascular parameter; utilizing a first processing component of the multi-purpose host system to process the data related to the first invasive cardiovascular parameter to produce values associated with the first invasive cardiovascular parameter for display on the user interface of the multi-purpose host system; and utilizing a second processing component of the multi-purpose host system to process the data related to the second invasive cardiovascular parameter to produce values associated with the second invasive cardiovascular parameter for display on the user interface of the multi-purpose host system.

2. The method of claim 1, wherein the data related to the first invasive cardiovascular parameter is processed by the first processing component independently from the data related to the second invasive cardiovascular parameter being processed by the second processing component.

3. The method of claim 1, wherein the first and second invasive cardiovascular parameters are selected from the group of parameters consisting of: pressure, flow velocity, flow volume, pH, ultrasound images, light-based images, and tissue characterization.

4. The method of claim 1, wherein the first invasive cardiovascular sensing component is secured to a first flexible elongate member and wherein positioning the first invasive cardiovascular sensing component within the vessel of the patient includes positioning the first flexible elongate member within the vessel of the patient.

5. The method of claim 4, wherein the second invasive cardiovascular sensing component is secured to the first flexible elongate member and wherein positioning the second invasive cardiovascular sensing component within the vessel of the patient includes positioning the first flexible elongate member within the vessel of the patient.

6. The method of claim 4, wherein the second invasive cardiovascular sensing component is secured to a second flexible elongate member and wherein positioning the second invasive cardiovascular sensing component within the vessel of the patient includes positioning the second flexible elongate member within the vessel of the patient.

7. The method of claim 1, wherein the first invasive cardiovascular parameter is a pressure within the vessel.

8. The method of claim 7, wherein the second invasive cardiovascular parameter is imaging data representative of the vessel.

9. The method of claim 8, wherein the second invasive cardiovascular parameter is ultrasound imaging data representative of the vessel.

10. The method of claim 8, wherein the second invasive cardiovascular parameter is OCT imaging data representative of the vessel.

11. The method of claim 7, wherein processing the data related to the first invasive cardiovascular parameter includes calculating a fractional flow reserve (FFR).

12. A method of performing an intravascular procedure using multiple invasive sensor types, the method comprising: obtaining a first elongate intravascular device sized and shaped for positioning within a vessel of a patient, the first elongate intravascular device including a first intravascular sensing element configured to obtain data related to a first intravascular parameter; obtaining a second elongate intravascular device sized and shaped for positioning within the vessel of the patient,

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the second elongate intravascular device including a second intravascular sensing element configured to obtain data related to a second intravascular parameter, the second intravascular parameter being different than the first intravascular parameter;

coupling the first and second elongate intravascular devices to a multi-purpose host system such that the first and second intravascular sensing components are in communication with a processing system of the multi-purpose host system, wherein the multi-purpose host system is configured to control operation of the first and second intravascular sensing components based on input to a user interface of the multi-purpose host system and wherein the processing system is configured to process the data related to the first and second intravascular parameters obtained by the first and second intravascular sensing elements.

13. The method of claim 12, wherein the first intravascular parameter is a pressure within the vessel and the second intravascular parameter is imaging data representative of the vessel.

14. A method of performing an intravascular procedure utilizing a pressure sensor and an imaging element to obtain pressure data and imaging data within a vessel of a patient, the method comprising:

obtaining a first elongate intravascular device sized and shaped for positioning within the vessel of the patient, the first elongate intravascular device including a pressure sensor configured to obtain data related to a pressure within the vessel of the patient;

obtaining a second elongate intravascular device sized and shaped for positioning within the vessel of the patient, the second elongate intravascular device including an imaging element configured to obtain imaging data representative of the vessel of the patient;

coupling the first elongate intravascular device to an external interface of a multi-purpose host system such that the pressure sensor is in communication with a processing system of the multi-purpose host system, wherein the multi-purpose host system is configured to control operation of the pressure sensor by transmitting signals through the external interface to obtain data related to the pressure within the vessel of the patient and wherein the processing system is configured to process the data related to the pressure within the vessel received through the external interface to produce values associated with the pressure within the vessel for display on a user interface of the multi-purpose host system; and

coupling the second elongate intravascular device to the external interface of the multi-purpose host system such that the imaging element is in communication with the processing system of the multi-purpose host system, wherein the multi-purpose host system is configured to control operation of the imaging element by transmitting signals through the external interface to obtain imaging data representative of the vessel of the patient and wherein the processing system is configured to process the imaging data representative of the vessel received through the external interface to produce images of the vessel for display on the user interface of the multi-purpose host system.

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15. The method of claim 14, further comprising:
 positioning the first elongate intravascular device within
 the vessel of the patient;
 obtaining data related to the pressure within the vessel of
 the patient with the pressure sensor while the first elongate
 intravascular device is positioned within the vessel
 of the patient;
 positioning the second elongate intravascular device
 within the vessel of the patient; and
 obtaining imaging data representative of the vessel of the
 patient with the imaging element while the second elongate
 intravascular device is positioned within the vessel
 of the patient.

16. A method of performing an invasive cardiovascular
 procedure using multiple sensor types, the method comprising:
 positioning portions of first and second invasive cardiovas-
 cular sensing components within a patient;
 communicatively coupling the first and second invasive
 cardiovascular sensing components to a control system;
 utilizing a user interface of the control system to control
 operation of the first and second invasive cardiovascular
 sensing components to cause the first invasive cardiovas-
 cular sensing component to obtain data related to a
 first invasive cardiovascular parameter and to cause the
 second invasive cardiovascular sensing component to
 obtain data related to a second invasive cardiovascular
 parameter, the second invasive cardiovascular parameter
 being different than the first invasive cardiovascular
 parameter; and
 utilizing a processing system associated with the control
 system to process the data related to the first and second
 invasive cardiovascular parameters to produce values
 associated with the first and second invasive cardiovas-
 cular parameters for display on the user interface of the
 control system.

17. The method of claim 16, wherein processing the data
 related to the first and second invasive cardiovascular param-
 eters includes processing the data related to the first invasive
 cardiovascular parameter independently from the data related
 to the second invasive cardiovascular parameter.

18. The method of claim 16, wherein the first and second
 invasive cardiovascular parameters are selected from the
 group of parameters consisting of: pressure, flow velocity,
 flow volume, pH, ultrasound images, light-based images, and
 tissue characterization.

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19. The method of claim 16, wherein the first invasive
 cardiovascular sensing component is secured to a first inva-
 sive cardiovascular device and wherein positioning the first
 invasive cardiovascular sensing component within the patient
 includes positioning the first invasive cardiovascular device
 within a vessel of the patient.

20. The method of claim 19, wherein the second invasive
 cardiovascular sensing component is secured to the first inva-
 sive cardiovascular device and wherein positioning the sec-
 ond invasive cardiovascular sensing component within the
 patient includes positioning the first invasive cardiovascular
 device within the vessel of the patient.

21. The method of claim 19, wherein the second invasive
 cardiovascular sensing component is secured to a second
 invasive cardiovascular device and wherein positioning the
 second invasive cardiovascular sensing component within the
 patient includes positioning the second invasive cardiovascu-
 lar device within the vessel of the patient.

22. The method of claim 21, wherein the first invasive
 cardiovascular parameter is a pressure within the vessel.

23. The method of claim 22, wherein the second invasive
 cardiovascular parameter is imaging data representative of
 the vessel.

24. The method of claim 23, wherein the second invasive
 cardiovascular parameter is ultrasound imaging data repre-
 sentative of the vessel.

25. The method of claim 23, wherein the second invasive
 cardiovascular parameter is OCT imaging data representative
 of the vessel.

26. The method of claim 23, wherein processing the data
 related to the first invasive cardiovascular parameter includes
 calculating a fractional flow reserve (FFR).

27. The method of claim 26, wherein the imaging data
 representative of the vessel is generated by a light-based
 imaging technique.

28. The method of claim 26, wherein the imaging data
 representative of the vessel is generated by optical coherence
 tomography (OCT).

29. The method of claim 26, wherein the imaging data
 representative of the vessel is suitable for characterizing a
 tissue of the vessel.

30. The method of claim 16, further comprising guiding
 placement of a treatment based on a display of the user inter-
 face.

* * * * *

专利名称(译)	多用途主机系统，用于侵入性心血管诊断测量采集和显示		
公开(公告)号	US8562537	公开(公告)日	2013-10-22
申请号	US13/410099	申请日	2012-03-01
[标]申请(专利权)人(译)	火山公司		
申请(专利权)人(译)	火山CORPORATION		
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IPC分类号	A61B5/02 A61B5/00 A61B5/0215 A61B5/027 A61B8/06		
CPC分类号	A61B5/0215 A61B5/027 A61B5/7435 A61B8/06 A61B8/12 G06F19/3406 A61B5/743 A61B5/6851 A61B5/1473 A61B5/14539 A61B5/026 A61B5/02055 A61B5/01 A61B8/468 A61B5/0066 A61B5/0035 A61B5/7475 A61B5/72 A61B5/6852 A61B5/0084 A61B2560/045 G06F19/3418 A61B8/488 G16H40/63		
代理机构(译)	海恩斯和布恩，LLP		
其他公开文献	US20120220837A1		
外部链接	Espacenet USPTO		

摘要(译)

公开了一种多功能侵入式心血管诊断测量主机，其连接各种传感器装置，例如安装有导线的压力传感器，流量传感器，温度传感器等，并提供多模式图形用户界面，其提供多个显示器。与传感器呈现的各种类型的传感器和测量。

