



US 20160278869A1

(19) **United States**

(12) **Patent Application Publication**
Grunwald

(10) **Pub. No.: US 2016/0278869 A1**

(43) **Pub. Date: Sep. 29, 2016**

(54) **DEVICE AND METHOD FOR VASCULAR ACCESS**

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(21) Appl. No.: **14/996,247**

(22) Filed: **Jan. 15, 2016**

Related U.S. Application Data

(60) Provisional application No. 62/104,895, filed on Jan. 19, 2015.

Publication Classification

(51) **Int. Cl.**

<i>A61B 34/20</i>	(2006.01)
<i>A61B 5/042</i>	(2006.01)
<i>A61B 5/0456</i>	(2006.01)
<i>A61B 5/00</i>	(2006.01)
<i>A61B 5/0404</i>	(2006.01)
<i>A61B 8/08</i>	(2006.01)
<i>A61B 8/00</i>	(2006.01)

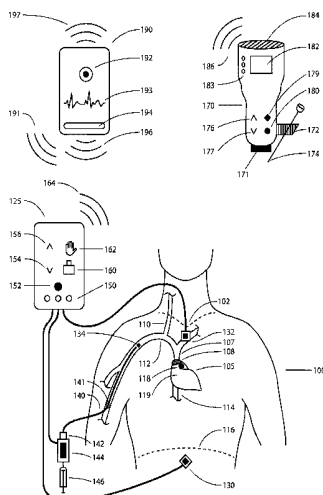
(52) **U.S. Cl.**

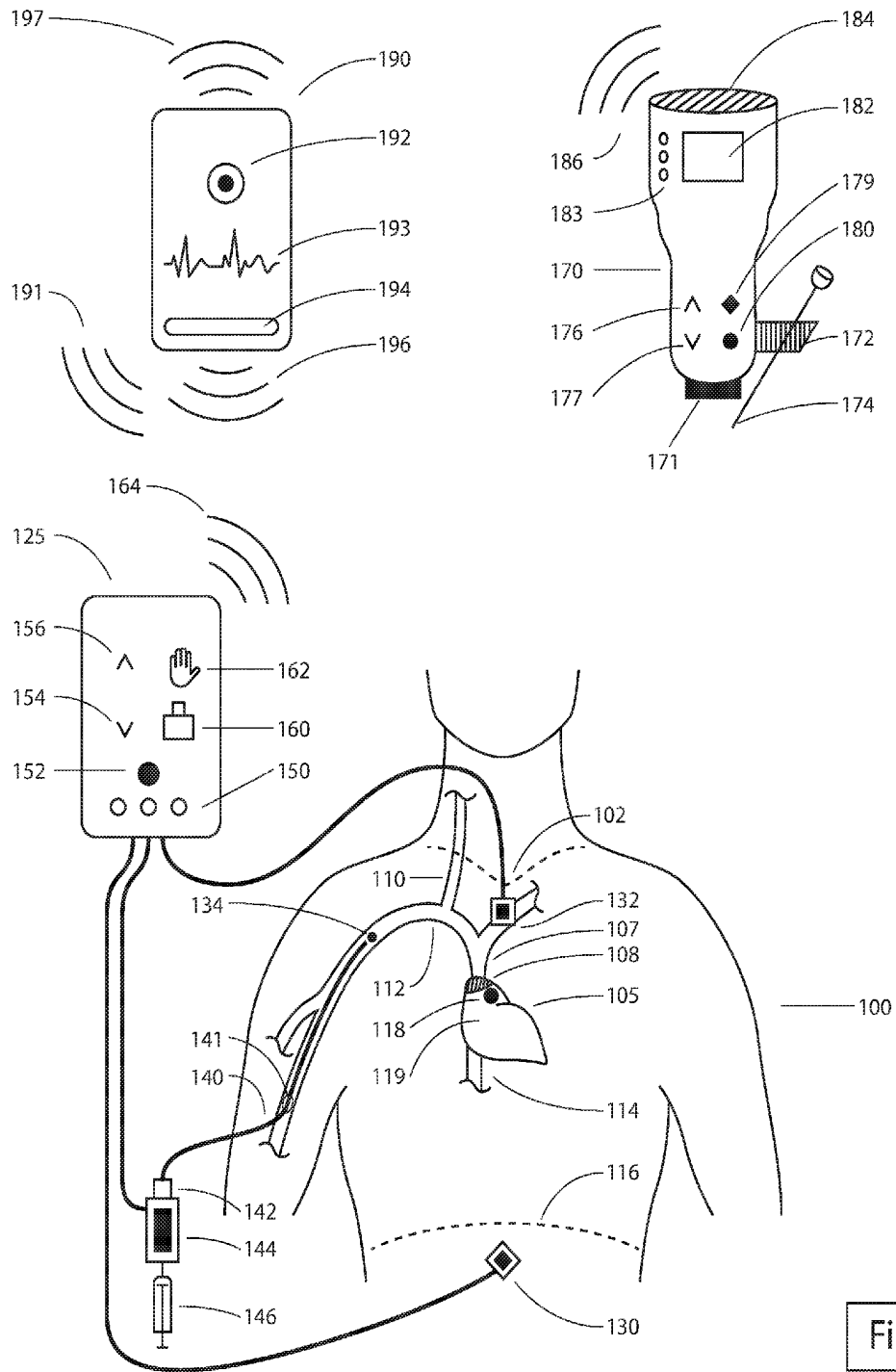
CPC *A61B 34/20* (2016.02); *A61B 8/0841* (2013.01); *A61B 5/042* (2013.01); *A61B 8/463* (2013.01); *A61B 5/743* (2013.01); *A61B 8/5223* (2013.01); *A61B 8/565* (2013.01); *A61B 8/4427* (2013.01); *A61B 5/0404* (2013.01); *A61B 5/7475* (2013.01); *A61B 5/0006* (2013.01); *A61B 5/7445* (2013.01); *A61B 8/4472* (2013.01); *A61B 8/4494* (2013.01); *A61B 8/5207* (2013.01); *A61B 8/546* (2013.01); *A61B 5/0456* (2013.01); *A61B 2034/2051* (2016.02); *A61B 2034/2063* (2016.02)

(57) **ABSTRACT**

A new device and method are introduced herein to facilitate vascular access in general and the placement of central venous access devices in particular. In one embodiment, the

device consists of the following components: a wireless ultrasound imaging handheld scanner, a Bluetooth ECG (electrocardiography) data acquisition module with patient ECG cable and sterile adaptor, and a mobile medical application running on a mobile platform (device), e.g., a tablet, smartphone or smart watch. Ultrasound imaging and/or ECG-based catheter guidance provided by the device disclosed herein can be used to independently or simultaneously visualize the catheter in the vasculature and/or guide its placement at the desired location. In another embodiment of the present invention, ultrasound imaging of the blood vessel targeted for vascular access can be used for assessing the blood vessel size prior to cannulating the blood vessel, for guiding an access needle into the targeted blood vessel, and for visualizing the catheter in the vasculature after the introduction of the catheter. In another embodiment of the present invention, ECG-based navigation of an intravascular catheter can be used for tracking such intravascular catheter in the vasculature and positioning such intravascular catheter at a desired location. In one aspect of the present invention, the ultrasound imaging handheld scanner contains all the electronics required to acquire and process ultrasound images and to transfer them wirelessly to a mobile platform device, e.g., a tablet or a smartphone. In another aspect of the present invention, the ECG data acquisition module contains all the electronics required to acquire and process tracking and positioning information for ECG-based catheter guidance and to transfer such information wirelessly to a mobile platform device, e.g., a tablet or a smartphone. In another aspect of the present invention, algorithms are introduced for processing and synchronization of ultrasound images and ECG signals. In another aspect of the present invention, user interfaces for the handheld ultrasound imaging scanner, the ECG data acquisition module, and the mobile medical application running on a mobile platform are introduced in order to simplify the use of ultrasound imaging and/or ECG-based guidance for catheter placement on mobile platforms. In another aspect of the present invention, a new vascular access method is introduced using simultaneous ultrasound imaging and ECG-based catheter guidance. According to the present invention, using ultrasound imaging of a catheter in the vasculature simultaneously with detecting ECG signals at the tip of the catheter provide accurate and reliable catheter location information in adult and pediatric population for most of patients conditions and clinical environments.





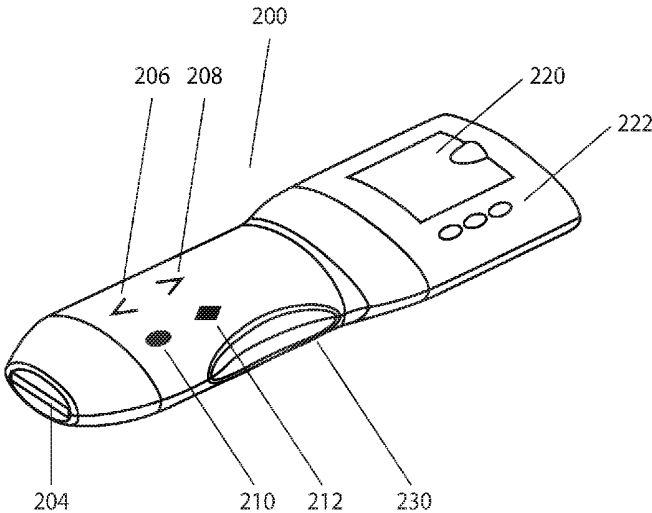


Fig. 2

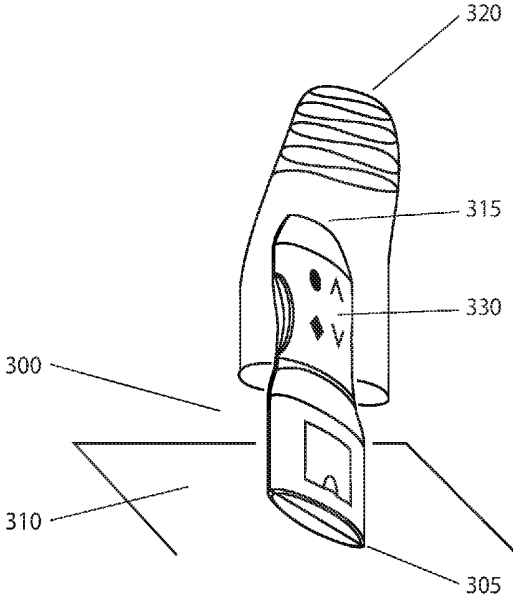


Fig. 3

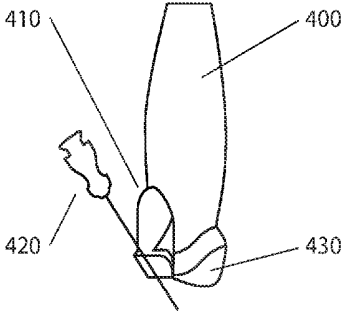


Fig. 4

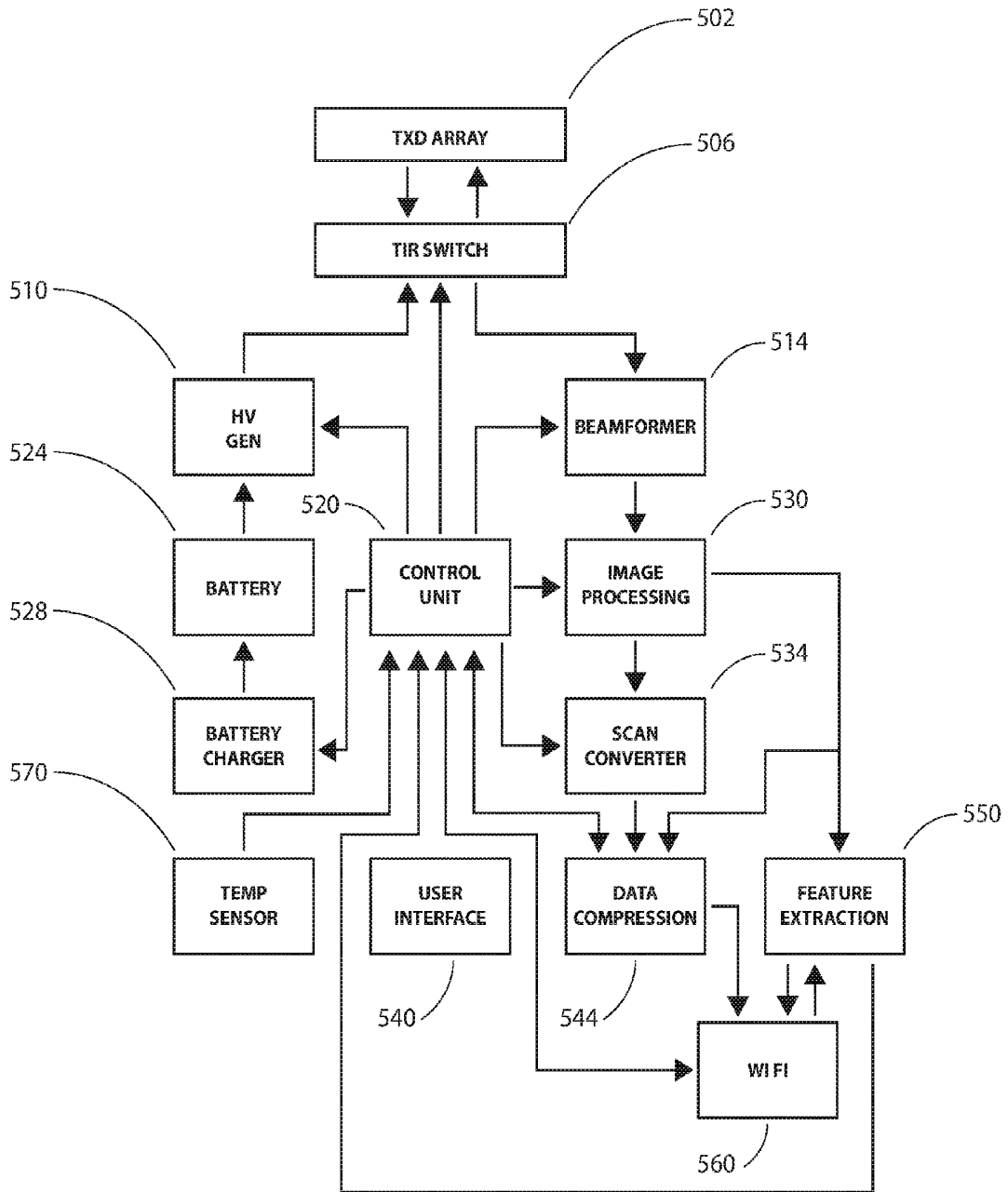


Fig. 5

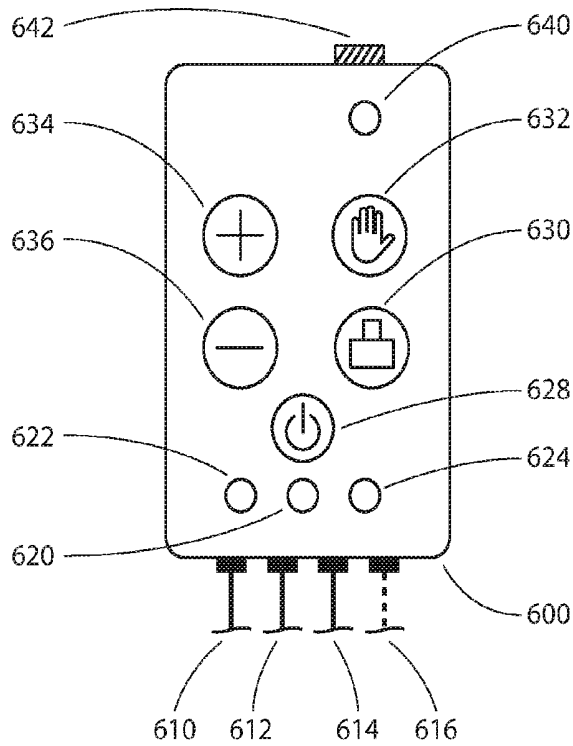


Fig. 6

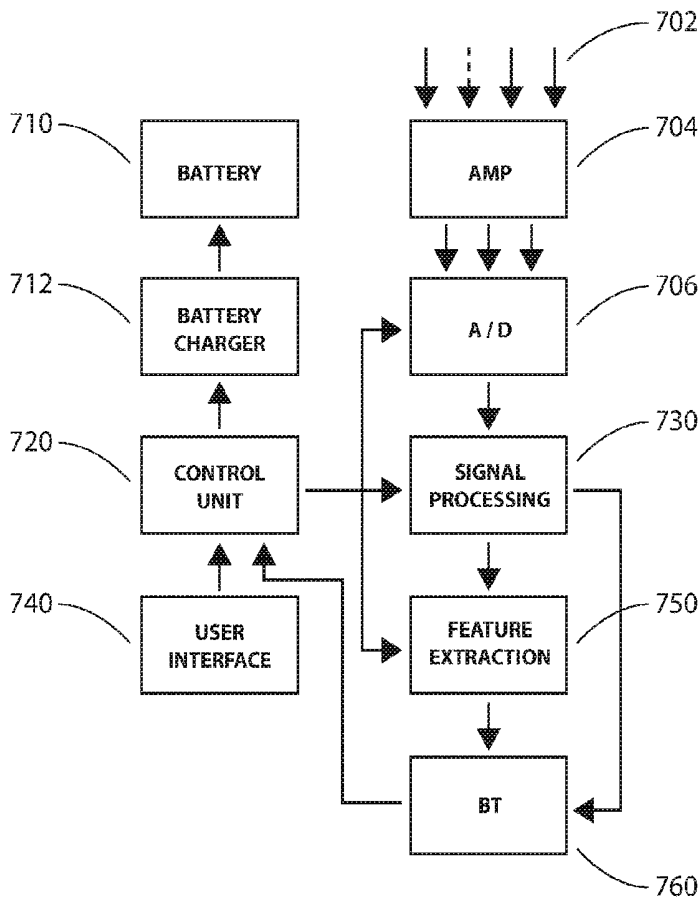


Fig. 7

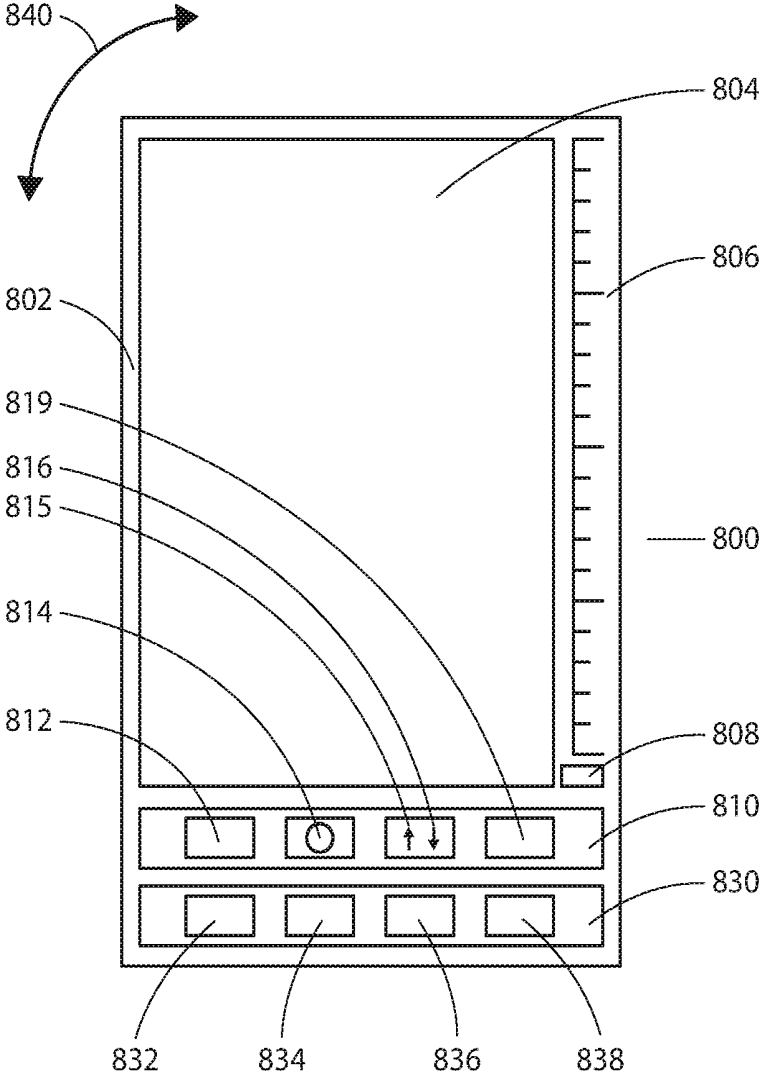


Fig. 8

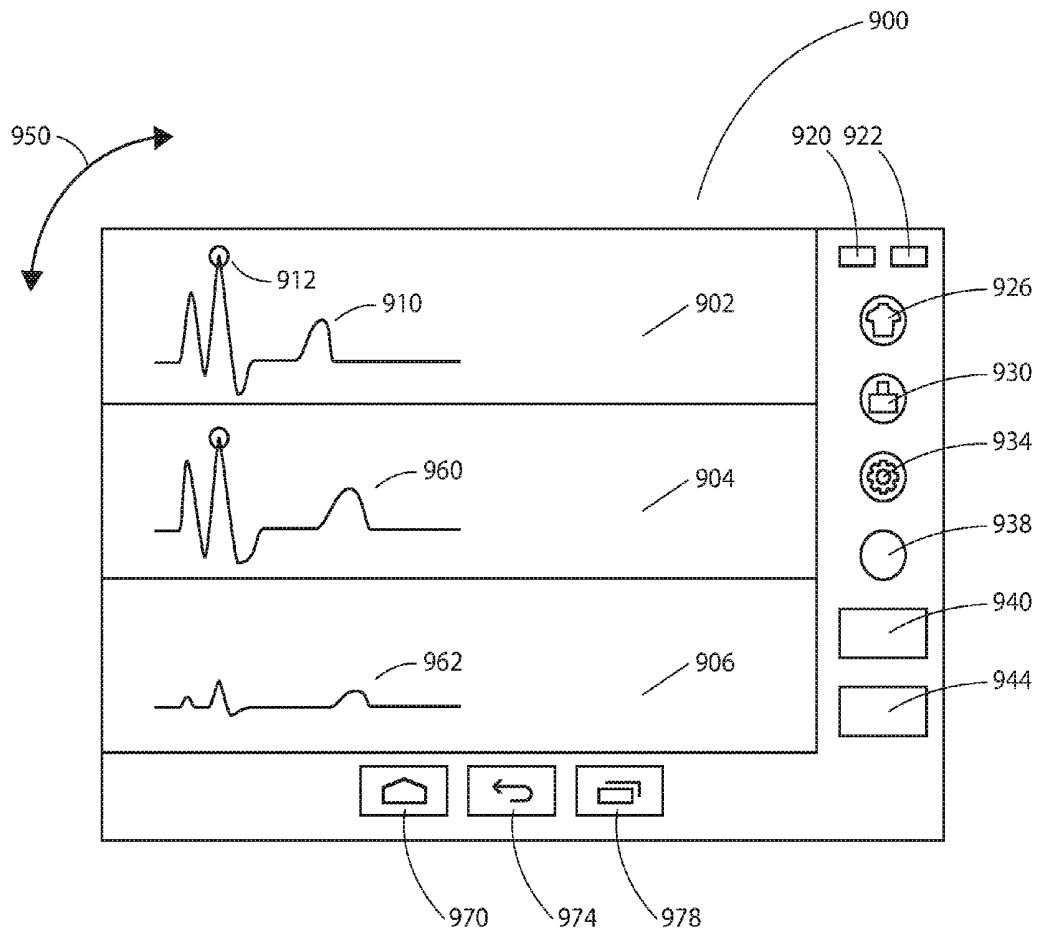


Fig. 9

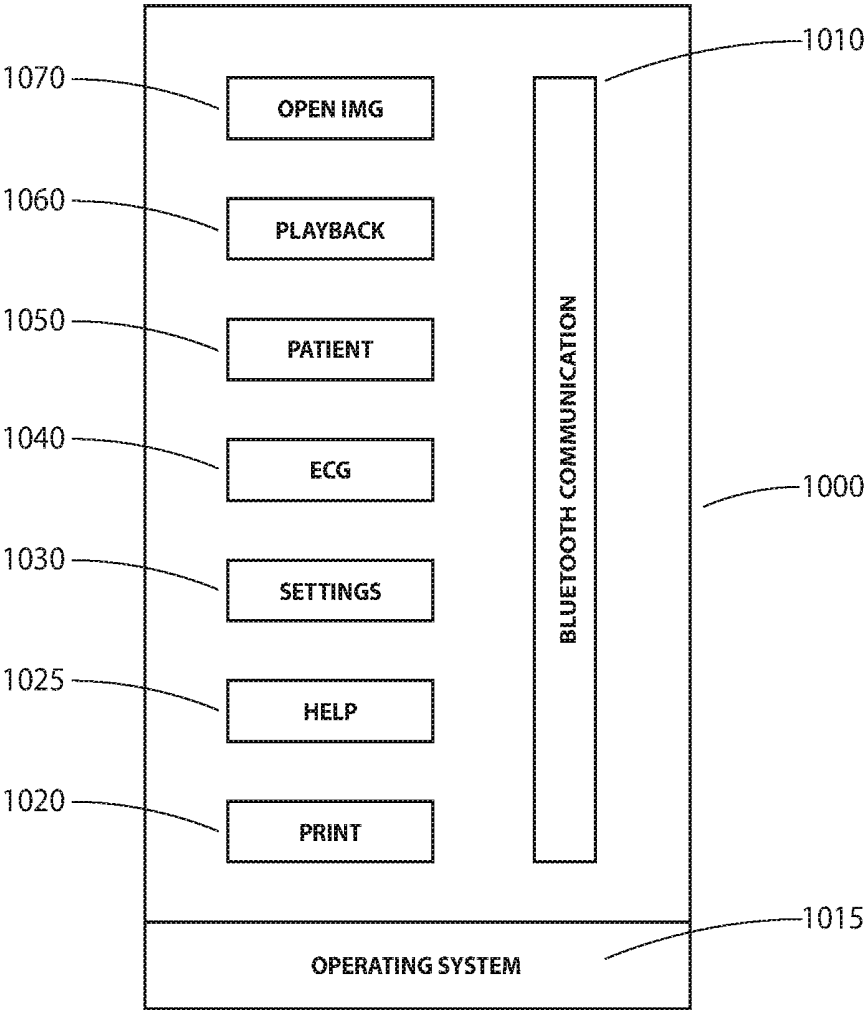


Fig. 10

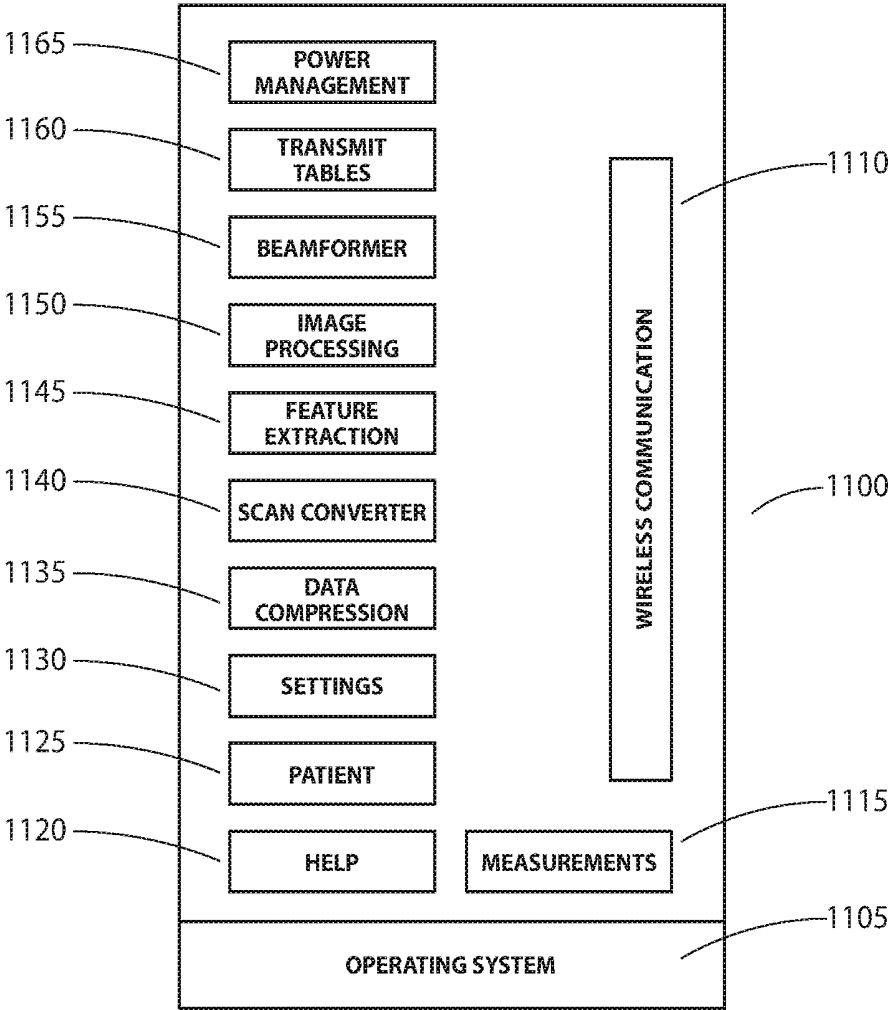


Fig. 11

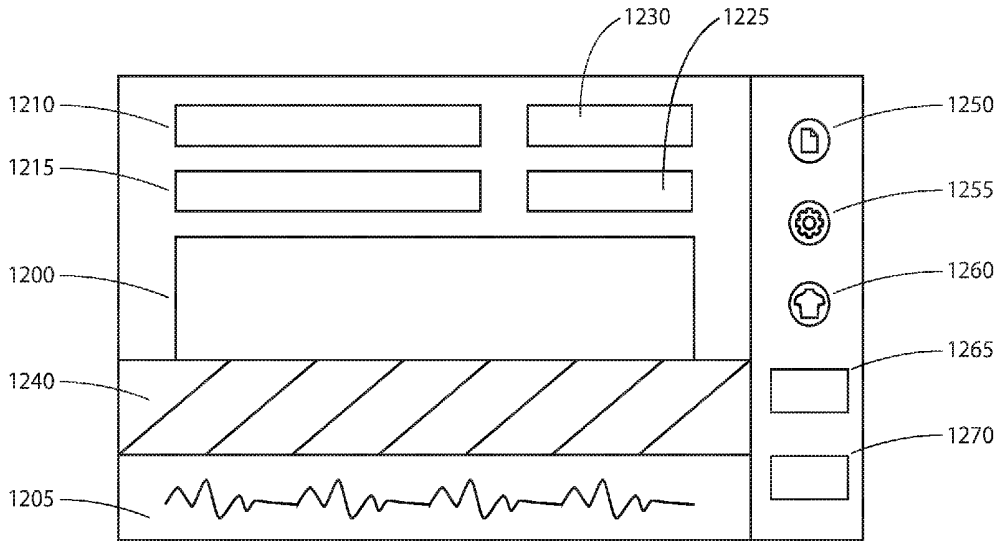


Fig. 12

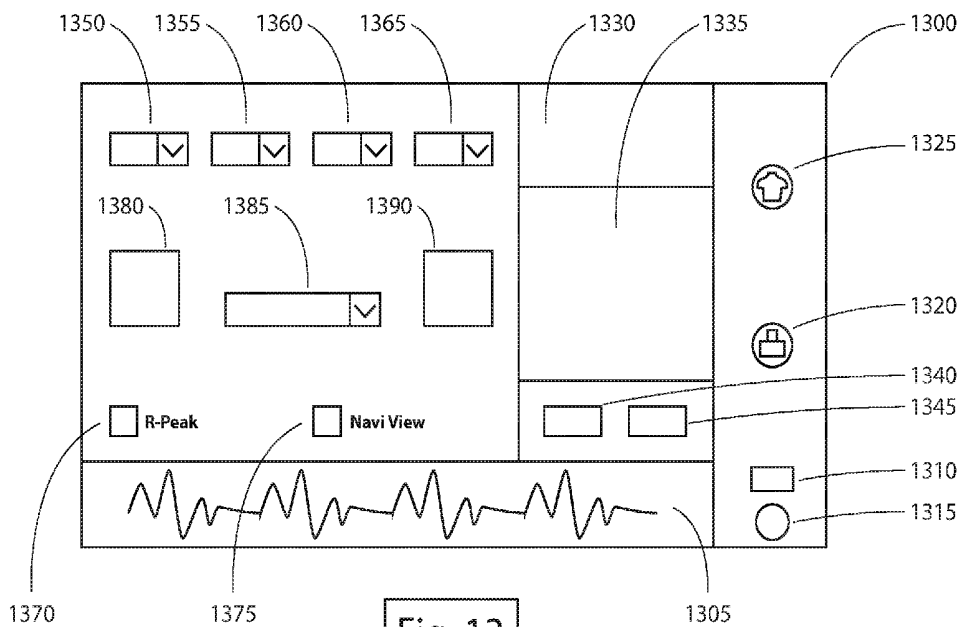


Fig. 13

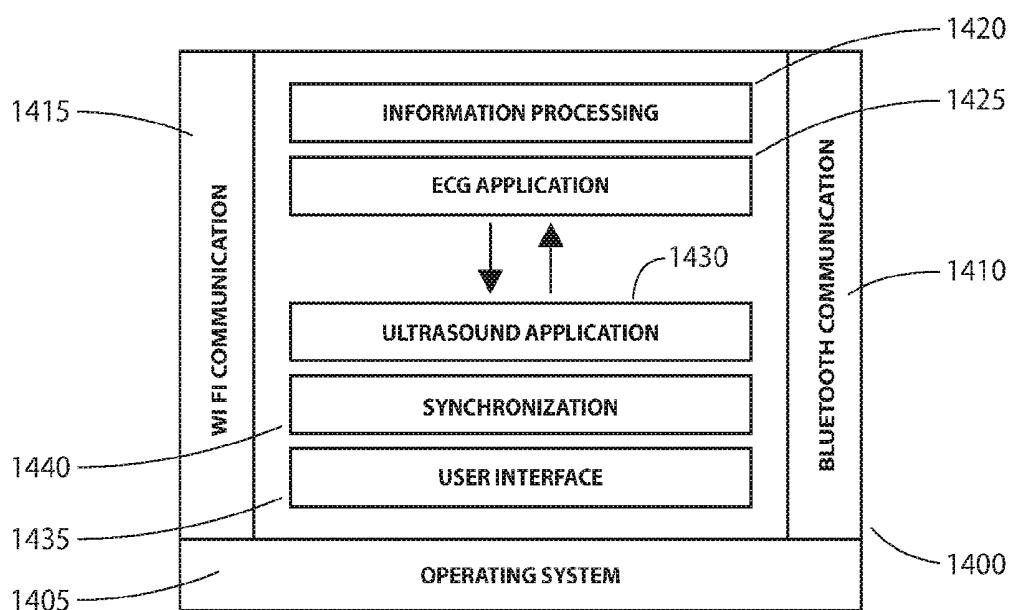


Fig. 14

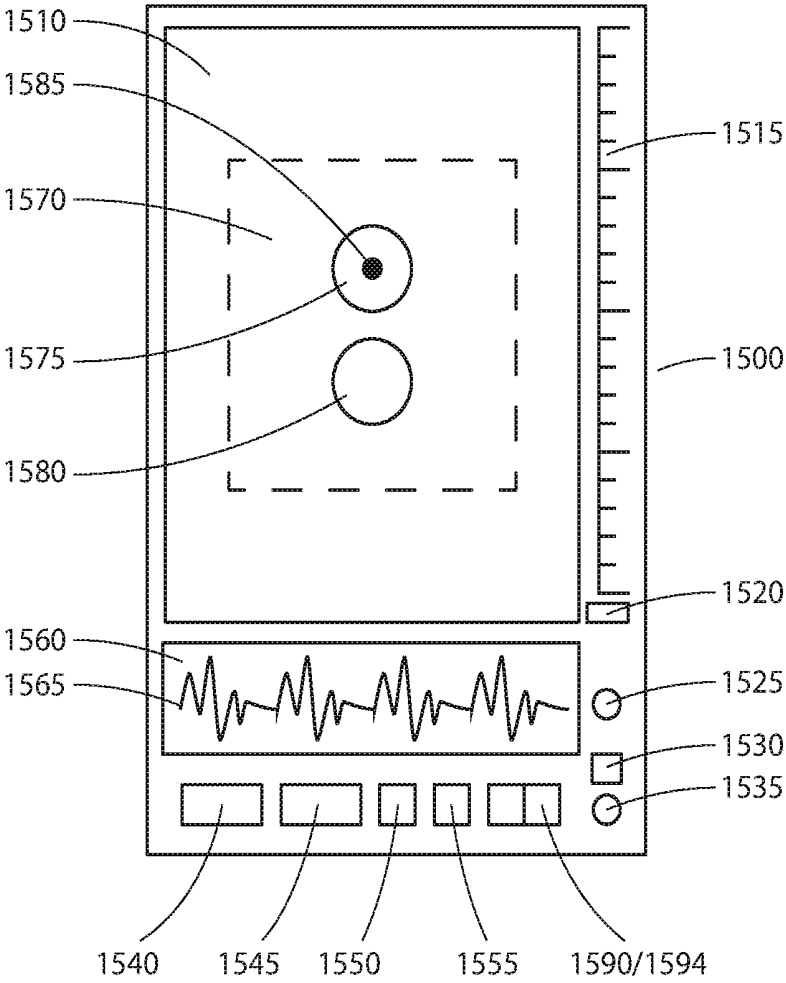


Fig. 15

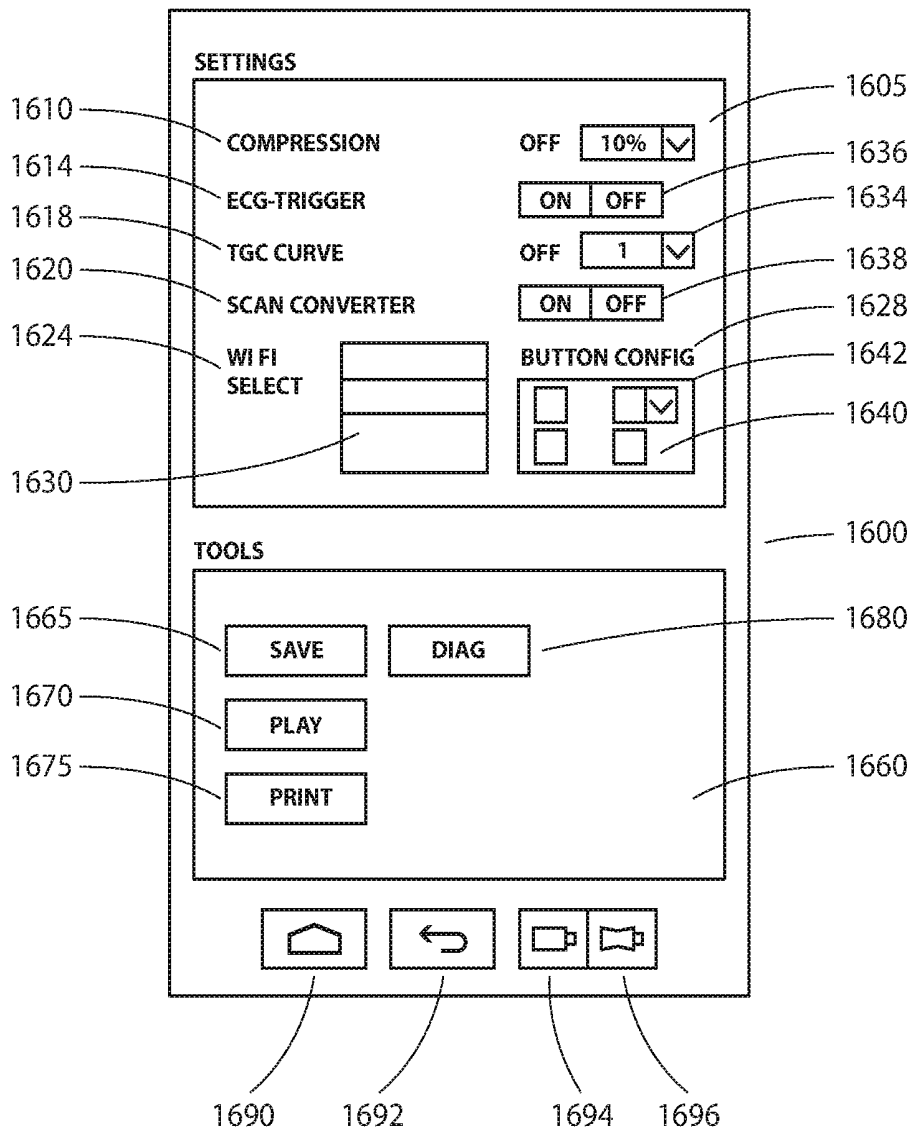


Fig. 16

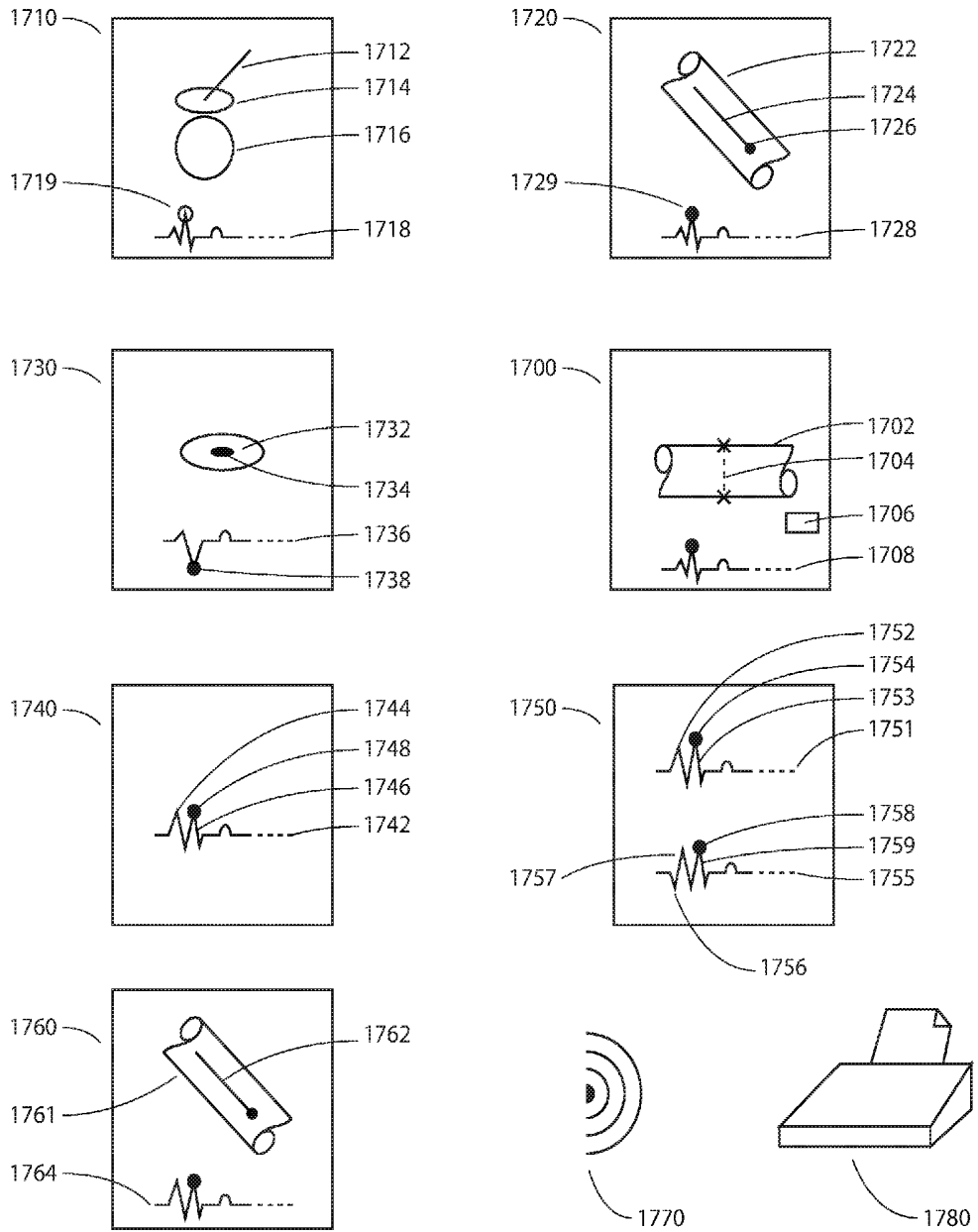


Fig. 17

DEVICE AND METHOD FOR VASCULAR ACCESS

[0001] This application claims priority to U.S. Provisional Patent Application No. 62/104,895 filed on Jan. 19, 2015, the disclosure of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The invention relates to the field of vascular access, in particular to the placement of vascular access devices, e.g., peripherally and centrally inserted central catheters, implantable ports, etc. Currently, ultrasound imaging is used to guide venipuncture and the insertion of a catheter in a vein and ECG-based guidance is used to confirm the tip location of the catheter at the cavo-atrial junction. Electromagnetic tracking, Doppler and ECG are used to track (navigate) the intravascular catheter from the insertion point towards the cavo-atrial junction and chest X-rays, ECG, and fluoroscopy are used to place the catheter tip at the cavo-atrial junction. Transcutaneous ultrasound imaging is currently used to visualize the catheter in the vasculature after insertion and to check if the catheter has accidentally moved to an undesired location wherever ultrasound imaging is available at that location. Transesophageal ultrasound imaging can also be used to accurately place the catheter tip at the cavo-atrial junction. The purpose of the present invention is to provide a single easy-to-use, wireless device which combines ultrasound imaging and ECG-based tracking in order to guide a needle and a catheter for vascular access and to help position the catheter at the desired location in the vasculature.

BACKGROUND OF THE INVENTION

Clinical Need

[0003] Vascular access is an important element of any minimally invasive clinical procedure and of clinical procedures needing access to the central venous system, e.g., chemotherapy, parenteral nutrition, etc. The access of the patient's vasculatures involves gaining access to the vasculature through an insertion or access point, inserting a catheter into the vasculature (cannulation) and advancing the catheter through the vasculature to the desired end location of the catheter tip. In different clinical situations the desired location of the catheter tip may be different for each of the situations. Due to the patient's anatomy, the catheter may not always go the desired route in the vasculature from the insertion to the end point. In many clinical situations accessing the patient's veins or arteries at the desired access point may be challenging because of the patient's anatomy or because of the blood vessel size and patency. For these reasons, devices and methods are needed to guide the insertion of a catheter into a blood vessel, the navigation of the catheter through the vasculature on the desired path, and the placement of the catheter at the desired location.

PRIOR ART

[0004] Currently, ultrasound imaging is used to guide venipuncture and the insertion of a catheter in a vein and ECG-based guidance is used to confirm the tip location of the catheter at the cavo-atrial junction. Electromagnetic tracking, Doppler, ECG, and fluoroscopy are used to track (navigate) the intravascular catheter from the insertion point towards the cavo-atrial junction and chest X-rays, fluoroscopy, and ECG

are used to place the catheter tip at the cavo-atrial junction. Further, transcutaneous ultrasound imaging is currently used to visualize the catheter in the vasculature after insertion and to check if the catheter has accidentally moved to an undesired location wherever ultrasound imaging is available at that location. Transesophageal ultrasound imaging can also be used to accurately place the catheter tip at the cavo-atrial junction.

Contributions of the Present Invention

[0005] The purpose of the present invention is to provide a single easy-to-use, wireless device which combines ultrasound imaging and ECG-based tracking in order to guide a needle and a catheter for vascular access and to help position the catheter at the desired location in the vasculature.

SUMMARY OF THE INVENTION

[0006] A new device and method are introduced herein to facilitate vascular access in general and the placement of central venous access devices in particular. In one embodiment, the device consists of the following components: a wireless ultrasound imaging handheld scanner, a Bluetooth ECG (electrocardiography) data acquisition module with patient ECG cable and sterile adaptor, and a mobile medical application running on a mobile platform (device), e.g., a tablet, smartphone or smart watch. Ultrasound imaging and/or ECG-based catheter guidance provided by the device disclosed herein can be used to independently or simultaneously visualize the catheter in the vasculature and/or guide its placement at the desired location.

[0007] In another embodiment of the present invention, ultrasound imaging of the blood vessel targeted for vascular access can be used for assessing the blood vessel size prior to cannulating the blood vessel, for guiding an access needle into the targeted blood vessel, and for visualizing the catheter in the vasculature after the introduction of the catheter.

[0008] In another embodiment of the present invention, ECG-based navigation of an intravascular catheter can be used for tracking such intravascular catheter in the vasculature and positioning such intravascular catheter at a desired location.

[0009] In one aspect of the present invention, the ultrasound imaging handheld scanner contains all the electronics required to acquire and process ultrasound images and to transfer them wirelessly to a mobile platform device, e.g., a tablet or a smartphone.

[0010] In another aspect of the present invention, the ECG data acquisition module contains all the electronics required to acquire and process tracking and positioning information for ECG-based catheter guidance and to transfer such information wirelessly to a mobile platform device, e.g., a tablet or a smartphone.

[0011] In another aspect of the present invention, algorithms are introduced for processing and synchronization of ultrasound images and ECG signals.

[0012] In another aspect of the present invention, user interfaces for the handheld ultrasound imaging scanner, the ECG data acquisition module, and the mobile medical application running on a mobile platform are introduced in order to simplify the use of ultrasound imaging and/or ECG-based guidance for catheter placement on mobile platforms.

[0013] In another aspect of the present invention, a new vascular access method is introduced using simultaneous ultrasound imaging and ECG-based catheter guidance.

According to the present invention, using ultrasound imaging of a catheter in the vasculature simultaneously with detecting ECG signals at the tip of the catheter provide accurate and reliable catheter location information in adult and pediatric population for most of patients conditions and clinical environments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1: Overview of the device and method for vascular access according to the present invention

[0015] FIG. 2: Wireless hand held ultrasound imaging device according to the present invention

[0016] FIG. 3: Method of use of the ultrasound imaging device according to the present invention

[0017] FIG. 4: Needle guide for the ultrasound imaging device according to the present invention

[0018] FIG. 5: Block diagram of the ultrasound imaging device according to the present invention

[0019] FIG. 6: ECG device according to the present invention

[0020] FIG. 7: Block diagram of the ECG device according to the present invention

[0021] FIG. 8: User interface for ultrasound imaging according to the present invention

[0022] FIG. 9: User interface for the ECG device according to the present invention

[0023] FIG. 10: Block diagram of the software application for the ECG device according to the present invention

[0024] FIG. 11: Block diagram of the software application for ultrasound imaging according to the present invention

[0025] FIG. 12: User interface for patient information input according to the present invention

[0026] FIG. 13: User interface for ECG device settings according to the present invention

[0027] FIG. 14: Block diagram of the software application for the vascular access device according to the present invention

[0028] FIG. 15: User interface for the vascular access device according to the present invention

[0029] FIG. 16: User interface for ultrasound imaging settings according to the present invention

[0030] FIG. 17: Method for guiding the placement of catheters according to the present invention

DETAILED DESCRIPTION OF THE INVENTION

[0031] FIG. 1 illustrates the device and the method for vascular access according to the present invention. The patient **100** is subject to a vascular access procedure, whereby the catheter **140** is inserted in the vasculature, e.g., in the venous system at the access point **141**. The catheter **140** is pushed such that the catheter tip **134** navigates from the access point **140** towards a desired location in the vasculature, e.g., at the cavo-atrial junction (CAJ) **108** near the sino-atrial node **118** of the patient's heart **105**. On the way towards the cavo-atrial junction, the catheter tip reaches the subclavian vein **112** and the superior vena cava **107** and can inadvertently reach the internal jugular vein **110**, the right atrium **119** or the inferior vena cava **114**. The catheter **140** is inserted into the vein through a needle, which punctures the vein at the insertion point **141**, and which is removed after the insertion of the catheter.

[0032] The hand held ultrasound imaging device **170** is used during the vascular access procedure in order to:

[0033] a) Assess blood vessel size and select the appropriate catheter size of approximately $\frac{1}{3}$ of the blood vessel size.

[0034] b) Verify blood vessel patency to see if there are potential obstacles along the catheter path

[0035] c) Guide the insertion of the needle into the right blood vessel and avoid injuring nerves or other relevant tissue.

[0036] d) Verify if the catheter is on the desired path or has reached an undesired location wherever such path and/or location can be visualized by ultrasound imaging.

[0037] The ultrasound imaging device **170** has an ergonomic hand-held enclosure and communicates wirelessly with the mobile platform device **190** through a wireless communication channel **186** and **196**. The housing of the hand held imaging scanner **170** has a flat and wide surface **184** in order to allow for placing the housing on a flat surface, e.g., on a table. The wireless ultrasound imaging device **170** further comprises a linear transducer array **171** to transmit and receive ultrasound energy. A pair of buttons on the housing allows for the increase **177** and the decrease **176** of the field of view of the ultrasound image. The button **179** allows for stopping and starting ultrasound imaging in order to conserve power. The button **180** allows for switching between the ultrasound imaging mode, the ECG-based navigation mode and the combined ultrasound imaging—ECG-based navigation mode of the device **190**. A mechanical needle guide **172** can be mounted on the housing of the device **170** in order to allow for accurate guidance of a needle **174** in the field of view of the transducer array **171**. The cover **182** can be opened in order to allow for the exchange of rechargeable batteries. The LEDs **183** indicate: a) the status of the wireless connection, the battery status, and the on/off imaging status of the device **170**.

[0038] The Bluetooth ECG data acquisition device **125** provides ECG signals from the patient's body and from the tip of the catheter to the device **190** via the Bluetooth communication channel **164-191**. The ECG signals are acquired by the device **125** from the patient via three leads: a reference lead **130** placed on the patient's abdomen right below the diaphragm **116**, a control lead **132** placed on the patient's skin over the jugular notch **102**, and catheter lead via the sterile adaptor (connector) **144**. The connector **144** can be an alligator clip which is connected to a stylet or to a guidewire inserted in the catheter **140**. The connector **144** can also be a saline solution adaptor which makes an electrical connection to saline solution flowing from a syringe **146** through the catheter hub **142** to the catheter tip **134**. Using the connector **144**, the device **125** can obtain ECG information from the tip **134** of the catheter **140**. The LEDs **150** indicate: the status of the Bluetooth communication, the battery status, and the on/off status of the device **125**. The ON/OFF button **152** is used to switch the device **125** on and off. Buttons **154** and **156** are used to increase and respectively decrease the scale on the display of the device **190** and/or the amplification of the ECG signal in the device **125**. The button **162** is used to create a reference ECG waveform on the display of the device **190**. The button **160** is used to save and print patient information and ECG waveforms in the memory of the device **190** and on an optional Bluetooth printer connected to the device **190**, respectively.

[0039] The device **190** is a mobile platform, e.g., a tablet or a smartphone which runs a mobile application described in the present invention. On the display of the device **190** ultra-

sound images 192 and ECG waveforms 193 are displayed according to the present invention. Control buttons 194 are used to control the device 190 and to remotely control the ultrasound imaging device 170 and the ECG data acquisition device 125. Ultrasound images, ECG waveforms, other patient information and voice can be transferred via the wireless communication channel 197 to other mobile devices in real time.

[0040] FIG. 2 illustrates the wireless hand held ultrasound imaging device 200 according to the present invention. The ultrasound imaging device 200 consists of an ergonomic housing 230 which allows for the user to easily hold the housing in one hand and to perform all hand movements necessary for ultrasound imaging required by vascular access and needle puncture. A linear transducer array and the associated electronics are used to provide ultrasound images of appropriate resolution, penetration depth (field of view), and frame rate. Several buttons on the housing 230 allow an operator to access the most frequently used functions during ultrasound imaging with only one hand: decrease field of view (208) (shallower) and increase field of view (206) (deeper), switch between ECG-based guidance, combined ultrasound-ECG guidance, and ultrasound only operating modes (210) and starting and stopping ultrasound imaging in order to conserve power (212). The cover 220 can be opened in order to allow for the exchange of rechargeable batteries. The LEDs 222 indicate: a) the status of the wireless connection, the battery status, and the on/off imaging status of the device.

[0041] FIG. 3 illustrates a method of use of the ultrasound imaging device according to the present invention. The ultrasound imaging device 300 is placed in a stable position with the flat surface of the housing 305 on a flat surface like a table or a cart or other flat surfaces 310 and with the transducer array 315 facing up. In this position of the scanner 300, a single sterile operator can place a sterile bag 320 over the housing 300 and handle the scanner in such a way as not to compromise the sterile field while using the scanner 300 and operating its buttons 330.

[0042] FIG. 4 illustrates a needle guide for the ultrasound imaging device according to the present invention. The hand held scanner according to the present invention 400 can be fitted with a device 410 on either side or laterally in order to allow for guiding a needle 420 in the field of view of the transducer array 430 in-plane or out of plane. A sterile needle guide 410 can also be attached to the housing 400 after a sterile bag has been placed over the housing as described in FIG. 3.

[0043] FIG. 5 illustrates a block diagram of the ultrasound imaging device according to the present invention. The linear transducer array of 16 to 256 transducer elements 502 is powered by the high voltage generator 510. The transmit-receive switch 506 alternates between powering the transducer array 502 using the high voltage generator 510 during the transmit time and receiving the incoming signals generated by the incoming ultrasound echoes during receive time. The incoming signals generated by the incoming ultrasound echoes is processed by the beamformer 514 to form a focused ultrasound beam out of the 16 to 256 individual signals generated by the transducer array 502. The high voltage generator 510, the transmit-receive switch 506 and the beamformer 514 are synchronized, set up, and controlled by the control unit 520.

[0044] The image processing block 530 generates a raw ultrasound image out of the individual ultrasound beams provided by the beamformer 514 and processes the received individual beams and the raw ultrasound image in order to improve signal-to-noise ratio, contrast, and gain, and to reduce image speckles amongst others. The image processed by the image processing block 530 is then transferred to the scan converter 534, which performs linear or bi-linear weighted interpolation and converts the image into a format that can be visualized on a display.

[0045] The same processed image is also transferred to a feature extraction block 550 which extracts certain useful relevant features from the image which can serve for automatic control and adjustments of system settings. One such extracted relevant feature is the computed difference between subsequent images. In the case that such differences between subsequent images are not relevant for a certain period of time, it is assumed that the device is not in clinical use and the high voltage generator will automatically be turned off by the control unit 520 in order to conserve battery power.

[0046] Other extracted relevant features are the average, the minimum and the maximum amplitudes in an image or in a certain area of an image. These features and their changes in time allow for performing automatic adjustment of the signal gain in order to optimize overall gain compensation and image contrast.

[0047] Another extracted relevant feature is the offset or the delay from the image origin to the first returning ultrasound echo. This offset (delay) is used to compute typical initial internal ultrasound echoes in the transducer housing and to the patient skin. These initial echoes are very strong and are eliminated from the image display in order to not influence the display of the weaker ultrasound echoes coming from real targets in the patient's body. This offset (delay) is also used to compute the reference position for the image display in order to optimize the presentation of the useful ultrasound image on the display and not to waste display space for unwanted ultrasound echoes or delays.

[0048] The image scan converted by 534 is compressed (lossy or lossless) by the data compression module 544 in order to decrease the data throughput through the WiFi communication channel 560. The image processed by the block 530 can alternatively be sent to the data compression block 544 in the case that no scan converting of the image is needed to be performed in the hand held device 170. The data compression module 544 can alternatively be set to no compression, i.e., it does not perform any compression on the ultrasound images.

[0049] The ultrasound images scan converted or not and compressed or uncompressed, as well as the features extracted by the feature extraction module 550 are transmitted by the WiFi communication module 560 in real time to the display and receiving device 190 in FIG. 1. The extracted features by module 550 are also sent to the control unit 520 for automatic adaptive adjustments.

[0050] The WiFi communication module 560 also receives commands and messages from the device 190 in FIG. 1. These commands and messages are interpreted and directed to the control unit 520 for execution. The hand held device 170 in FIG. 1 has an user interface consisting of several buttons. The inputs from these buttons are processed by the user interface module 540 and directed to the control unit 520 for execution. The control unit 520 also controls the battery charger 528 and transmits status information about the status

of the battery and of the hand-held device to the device 190 in FIG. 1 through the WiFi communication channel 560.

[0051] The temperature sensor 570 measures the internal temperature in the housing of the hand held ultrasound imaging device. The control unit transmits this value over the WiFi communication channel 560 and takes appropriate power management measures to keep the internal temperature under the designated threshold, e.g., by turning off the high voltage generator or the battery charger 528. The battery charger 528 charges the internal battery 524 which provides power for all the electronics of the device including for the high voltage generator 510.

[0052] FIG. 6 illustrates an ECG device according to the present invention. The device 600 is an ECG data acquisition and processing device with a wireless Bluetooth connection to the device 190 in FIG. 1. The device 600 has several connectors for connecting ECG leads: the connector and lead 610 can be connected to a control electrode, e.g., 132 in FIG. 1, the connector and the lead 612 can be connected to a reference electrode, e.g., 130 in FIG. 1, the connector and lead 614 can be connected to catheter, e.g., 144 in FIG. 1, the connectors and the lead 616 can be connected to an active, noise-reduction electrode.

[0053] The LED 622 indicates the status of the Bluetooth connection, the LED 620 indicates if the device 600 is on or off, the LED 624 indicates the internal battery status. The button 628 is used to turn on and off the device 600. Pressing the button 630 sends a "Print/Save" command to the device 190 in FIG. 1. Pressing the button 632 sends a "Freeze" command to the device 190 in FIG. 1. Pressing the button 634 sends a command to increase the scale of the ECG signal to the device 190 in FIG. 1. Pressing the button 636 sends a command to decrease the scale of the ECG signal to the device 190 in FIG. 1.

[0054] The LED 640 is on when the device 600 is charging. The micro USB connector 642 allows for charging the rechargeable battery of the device 600 via an USB cable. The device 600 transmits ECG and status information to the device 190 in FIG. 1 via Bluetooth. ECG information includes raw ECG data, processed signals, and relevant features extracted from the ECG signal.

[0055] The communication protocol over the Bluetooth communication channel between the device 600 and the device 190 in FIG. 1 is structured as to allow the bidirectional transmission of multiple ECG signals, relevant features, and messages in real time. Each signal can be sampled and transmitted with up to 1000 samples per second per signal. The Bluetooth communication channel of the device 600 can also receive messages, commands, and settings from the device 190 in FIG. 1.

[0056] FIG. 7 illustrates a block diagram of the ECG device according to the present invention. ECG signals 702 as described for example by 610, 612, and 614 in FIG. 6 are input to the input optically isolated amplifier 704 which are then analog-to-digital converted by the A/D converter 706. The digital signals are processed by the signal processing module 730.

[0057] The signal processing performed by module 730 includes notch filtering of unwanted frequencies, high pass filtering for base line fluctuations reduction, common mode rejection and averaging. The signal processing performed by module 730 further includes synchronization between several ECG signals and the computation of signals using weighted averages of the input raw ECG signals.

[0058] The feature extraction block 750 detects the R peaks of the ECG waveforms, marks the location of the ECG R-peak on the ECG signal and computes the heart rate using instantaneous and averaged computations. The feature extraction block 750 further detects ECG lead-off conditions, i.e., the conditions in which a lead is not connected to the patient. The signal processing results and the extracted relevant features of the signals are transmitted over the Bluetooth communication channel to the device 190 in FIG. 1 using the Bluetooth module 760.

[0059] The Bluetooth module 760 also receives messages from the device 190 in FIG. 1 and transmits commands to the control unit 720. The control unit 720 also receives commands directly from the buttons situated on the housing of device as illustrated in FIG. 6, buttons 630, 632, 634, 636. The control unit 720 controls the status of the LEDs 620, 622 and 624 illustrated in FIG. 6.

[0060] The control unit 720 also controls the status and settings of the battery charger 712, of the A/D converter 706, of the signal processing block 730 and of the feature extraction block 750. The battery charger 712 charges the internal battery 710.

[0061] FIG. 8 illustrates a user interface for ultrasound imaging according to the present invention. The user interface 800 is displayed on the touchscreen 802 of the device 190 in FIG. 1. Display window 804 is used to display ultrasound images received from the device 170 in FIG. 1. The depth scale 806 shows target mm markers and can be used to assess the sizes of objects visualized on the ultrasound images and their distance from the face of the transducer linear array.

[0062] The field of view indicator 808 is a number indicating the maximum depth (distance from transducer face) which can be visualized at the current system settings. The field of view value can be changed by touching the screen over the display window 804 of the ultrasound image and by moving the finger up and down on the touch screen. Moving the finger up decreases the field of view and moving the finger down increases the field of view. Moving the finger up while touching the screen has the same effect of decreasing the field of view as pressing the button 208 in FIG. 2. Moving the finger down while touching the screen has the same effect of increasing the field of view as pressing the button 206 in FIG. 2.

[0063] Tapping on the display window 804 when the ultrasound image is displayed in real time freezes the ultrasound image and tapping on the display window 804 when the ultrasound image is frozen unfreezes the ultrasound image and switches back to the real-time display mode. A frozen image can be displayed in a small window on the bottom of the display 804 for reference purposes.

[0064] The touch button 812 is used to start the measurements mode. Touching the button 812 while in the measurements mode exits the measurements mode. The measurements mode can be used to assess the size of the objects visualized on the ultrasound image. When in measurements mode, when tapping a first time on the display window 804, a first marker is drawn at the tapping location. When tapping a second time on the display window 804, a second marker is drawn at the tapping location, a dotted line is drawn between the two markers and the distance in mm between the two markers is displayed close to the dotted line or in one of the corners of the display window 804. In order to move the location of one marker, the user has to drag and drop it to a new location by using a finger and touching the touch screen.

A new dotted line is drawn and the new distance is calculated and displayed after the marker was dropped at a new location.

[0065] The buttons **810** provide real-time control for ultrasound imaging. Touching the button **812** when in measurements mode, erases all graphics related to measurements and exits the measurement mode. Touching the button **814** switches the display mode to a combined displayed mode, in which ultrasound images and ECG signals are displayed at the same time on the display **802** as illustrated in FIG. 15.

[0066] Turning the device **800** with 90 degrees in either direction (**840**) switches the display mode from ultrasound imaging (in portrait orientation) to the ECG mode and display (in landscape orientation) as illustrated in FIG. 9. If an ECG mode and display are not available, the action switches the ultrasound imaging display from a portrait mode to a landscape mode.

[0067] The buttons **815** and **816** are used to change the overall gain setting of the ultrasound image: touching the button **815** increases the overall gain and touching the button **816** decreases the overall gain of the ultrasound image.

[0068] Touching the button **819** enters a “Tools” menu as illustrated in FIG. 16. The field **830** of the graphical user interface provides general controls and additional functions for the ultrasound imaging device **170** in FIG. 1.

[0069] The button **832** is divided into a left and a right button. The left button **832** provides a “Home” function, i.e., the mobile device **190** in FIG. 1 goes to its home page without exiting the ultrasound imaging application described by the user interface **800**. The right button **832** provides a “Back” function, i.e., when touching this button, the menu navigation goes one step back to a previous state.

[0070] Button **834** switches the display **802** to a “Patient” display illustrated in FIG. 12. Touching the button **836** switches to the Setting menu and user interface illustrated in FIG. 16. The display window **838** shows the battery levels of the batteries of the devices **170** and **190** from FIG. 1.

[0071] FIG. 9 illustrates a user interface for the ECG device according to the present invention. The graphical user interface **900** is displayed on the touchscreen display of the device **190** in FIG. 1. The display window **902** displays a reference (frozen) ECG waveform **910** with a marker marking the R-peak of the ECG waveform. Display window **904** displays a real-time signal **960**, which can be an ECG waveform or a computed signal. The R-peak of the ECG waveform or a certain location in the computed signal is marked with a marker similar to the marker **912**. Display window **906** displays a real time ECG waveform from a skin (surface, control) ECG electrode.

[0072] The ECG signals displayed in windows **904** and **906** are acquired and/or computed by the device **125** in FIG. 1 and transmitted to the device **190** in FIG. 1 over the Bluetooth communication channel **164-191** in FIG. 1. The signal scale of the signal displayed in display windows **904** can be increased or decreased using two-finger zoom over the touchscreen in the display area **904** to zoom out (increase signal scale) or zoom in (decrease signal scale).

[0073] When tapping once on the display window **904** the signal in the display window **904** is copied and frozen as a reference signal in the display window **902**. When tapping on the display window **902**, the reference signal **910** is erased. The baseline of the signal **960** can be moved up and down in the display window **904** by touching the display window **904** and dragging up and down the ECG signal. The baseline of the signal **962** can be moved up and down in the display

window **906** by touching the display window **906** and dragging up and down the ECG signal. The indicator **920** indicates the battery level of device **125** in FIG. 1 and the indicator **922** indicates the battery level of device **190** in FIG. 1.

[0074] Touching the button **926** switches to the patient information screen illustrated in FIG. 12. Touching button **930** prints the waveform displayed in window **902** together with patient information input as described in FIG. 12 on a Bluetooth printer connected to the device **190** in FIG. 1 as described in FIG. 13. Touching the button **930** also saves the printed image as an image file in jpg format in the memory (internal or removable) of the device **190** in FIG. 1. Touching the button **930** also saves the ECG waveforms for a patient in a file in the memory (internal or removable) of the device **190** in FIG. 1. The file names containing printed images or case data are automatically generated. Touching the button **934** switches the graphical user interface to the display illustrated in FIG. 13.

[0075] If an ultrasound imaging device **170** in FIG. 1 is connected to the device **190** in FIG. 1, touching the button **938** or rotating the device **190** in FIG. 1 with 90 degrees from landscape to portrait view switches the user interface to the one illustrated in FIG. 8. The field **940** displays the heart rate computed by device **125** in FIG. 1 and transmitted in real time to the device **190** in FIG. 1.

[0076] Field **944** shows the logo of the device and also serves as start/pause button for the real time display of the ECG waveform in display window **904**. The button **970** provides a “Home” function, i.e., the mobile device **190** in FIG. 1 goes to its home page without exiting the ultrasound imaging application described by the user interface **900**. The button **974** provides a “Back” function, i.e., when touching this button, the menu navigation goes one step back to a previous state. The button **978** is a shortcut to Settings screen illustrated in FIG. 13.

[0077] FIG. 10 illustrates a block diagram of the software application **1000** for the ECG device according to the present invention. The software application **1000** can run on any mobile platform fulfilling minimum requirements, e.g., tablets, smartphones, smart watches and other smart wearable and head-mounted technology. The application **1000** is built on a real-time multi-tasking operating system **1015** and structured into several threads of execution with appropriate execution priorities and computing and memory resources.

[0078] The Bluetooth communication thread **1010** ensures the communication over the Bluetooth communication channel **164-191** in FIG. 1 between the devices **125** and **190** in FIG. 1 and between the device **190** in FIG. 1 and a connected Bluetooth printer. Upon user request, the “Print” thread **1020** prints ECG waveforms and patient information on a Bluetooth printer, when such a printer is connected to the device **190** in FIG. 1. The “Print” thread **1020** also saves data files to the storage medium available in the device **190** in FIG. 1. The “Print” thread **1020** performs the functions described in FIG. 9 for button **930**. The “Print” thread **1020** continuously saves in real-time the data received from the device **125** in FIG. 1 in a memory buffer.

[0079] Upon touching the button **930** in FIG. 9, the data from the internal memory buffer is converted into an optimized file format and also transferred to a permanent storage medium. The thread “Help” **1025** is responsible for all real-time and off-line activities related to providing real time context dependent, educational, and on line help to the user.

[0080] The user can obtain real time context dependent help regarding the system functionality by touching a question mark drawn on the user interface, dragging and dropping it on the region of interest on the graphical user interface, about which the user wants to obtain help.

[0081] Educational help is provided in the form of pictures, text, and movies which the user can select from a list of available choices.

[0082] On line help can be obtained by connecting to available remote help tools, e.g., clinical information database.

[0083] Additionally, the user can obtain help using the phone or the wireless communication capabilities of the mobile platform device 190 in FIG. 1. The user can dial a number and can share in real time the information displayed on the graphical user interface, for example on the display in FIG. 9, with the person answering the phone call.

[0084] The thread "Settings" 1030 is responsible for activities related to setting and maintaining the system status, including setting and maintaining the status of devices 125 and 190 in FIG. 1 through appropriate communication.

[0085] The thread "ECG" 1040 is responsible for maintaining the Bluetooth communication and for receiving and transmitting messages from and to the device 125 in FIG. 1, for displaying signals and information, including relevant features on the display of device 190 in FIG. 1 as illustrated in FIG. 9 and for the user interface interaction related to the display illustrated and described in FIG. 9.

[0086] The thread "Patient" 1050 is responsible for implementing the activities related to the "Patient" button 926 in FIG. 9. A user interface corresponding to thread 1050 is illustrated in FIG. 12.

[0087] The "Playback" thread 1060 is responsible for activities related to playing back patient data saved to file. When a case data file is opened using the "Open Img" thread 1070, the thread "Playback" 1060 reads the contents of the file and post processes it as if the data was real time data. I.e., the data can be modified through the user interface as it is displayed on the display illustrated in FIG. 9 using all real time controls as if the data was real time data. For example, the user can change the signal scale using a finger zoom function over the display 904, modify the baseline of the signals by touching, dragging and dropping the signals, freezing the signal in display window 902, or modifying the signal scale of the signal displayed in display window 906. The thread "Open Img" 1070 is responsible for activities related to finding and opening a saved file. A file can be saved either as an image file containing the printout of the information printed to a Bluetooth printer or as a case data file containing the signals and information for a patient received from the device 125 in FIG. 1.

[0088] FIG. 11 illustrates a block diagram of the software application 1100 for ultrasound imaging according to the present invention. The software application 1100 can run on any mobile platform fulfilling minimum requirements, e.g., tablets, smartphones, smart watches and other smart wearable and head-mounted technology. The application 1100 is built on a real-time multi-tasking operating system 1105 and structured into several threads of execution with appropriate execution priorities and computing and memory resources.

[0089] The wireless communication thread 1110 ensures wireless communication over the communication channel 186-196 in FIG. 1 between the devices 170 and 190 in FIG. 1 and between the device 190 in FIG. 1 and a Bluetooth or other wireless printer connected to the device 190 in FIG. 1. In

another embodiment of the present invention, the thread 1110 can ensure real-time communication with other wireless devices and the real-time broadcasting over the communication channel 197 of the ultrasound images received from the device 170 in FIG. 1.

[0090] The "Measurements" thread 1115 is responsible for activities related to measurements of object on the ultrasound image as described in FIG. 8.

[0091] The thread "Help" 1120 is responsible for all real-time and off-line activities related to providing real time context dependent, educational, and on line help to the user. The user can obtain real time context dependent help regarding the system functionality by touching a question mark drawn on the user interface, dragging and dropping it on the region of interest on the graphical user interface, about which the user wants to obtain help.

[0092] Educational help is provided in the form of pictures, text, and movies which the user can select from a list of available choices.

[0093] On line help can be obtained by connecting to available remote help tools, e.g., clinical information database.

[0094] Additionally, the user can obtain help using the phone or the wireless communication capabilities of the mobile platform device 190 in FIG. 1. The user can dial a number and can share in real time the information displayed on the graphical user interface, for example on the display in FIG. 9, with the person answering the phone call.

[0095] The thread "Patient" 1125 is responsible for implementing the activities related to the "Patient" button 834 in FIG. 8. A user interface corresponding to thread 1125 is illustrated in FIG. 12.

[0096] The thread "Settings" 1130 is responsible for activities related to setting and maintaining the system status, including setting and maintaining the status of devices 170 and 190 in FIG. 1 through appropriate communication.

[0097] The thread "Data Compression" 1135 performs data decompression on the ultrasound imaging data received from device 170 in FIG. 1, if the device was set to performed data compression as described in FIG. 5.

[0098] The thread "Scan Converter" 1140 performs scan conversion operations on the ultrasound imaging data received from device 170 in FIG. 1 if the device 170 does not perform such scan conversion operations. A scan conversion operation is defined as a conversion between the data structures of ultrasound images as acquired by the beamformer 514 in FIG. 5 and the data structures of the corresponding ultrasound images as displayed on the display 804 in FIG. 8.

[0099] The thread "Feature Extraction" extracts relevant features from the ultrasound image received from the device 170 in FIG. 1. Such relevant features may include averages, gray scale distributions, recognition of active the field of view, recognition of idle states of the device 170 in FIG. 1, the computation of the image attenuation as a function of imaging depth, and the recognition of the boundaries and of the characteristics of certain objects in the ultrasound image.

[0100] The thread "Image processing" 1150 is responsible for image stabilization and enhancement, e.g., low pass, high pass, band pass and selective filtering, time gain compensation, rescaling, and reorientation of ultrasound images.

[0101] The thread "Beamformer" 1155 is responsible for setting and controlling the module beamformer 514 in FIG. 5. Such setting and controlling include selecting beamforming tables computed by thread 1160, setting the field of view, the amplification scale, and the power management of the device

170 in FIG. 1 determined by thread **1165** as a function of overall system settings and imaging parameters. Such setting and controlling may result from user input or automatically from computations by the threads **1135**, **1140**, **1145**, or **1150** and are transmitted to the device **170** in FIG. 1 over the wireless communication channel **196-186** in FIG. 1.

[**0102**] FIG. 12 illustrates a user interface for patient information input according to the present invention. The display window **1205** displays a real-time ECG waveform from the control electrode **132** in FIG. 1 connected to the patient's skin. The heart rate displayed in field **1265** in real time is computed by the device **125** in FIG. 1 based on the ECG waveform acquired from the control electrode **132** in FIG. 1.

[**0103**] The field **1240** displays an alphanumeric keyboard which can be used by touching the touchscreen of the device **190** in FIG. 1. The soft alphanumeric keyboard **1240** is automatically displayed if any of the input fields **1210**, **1215**, **1200**, **1225** or **1230** are touched. The field **1200** labeled "Notes" is a general text input field. The field **1215** is labeled "Device Type" and the user can input information about the vascular access device (VAD) used in the clinical procedure. The field **1210** is labeled "Patient" and the user can input the name and/or the ID of the patient undergoing the vascular access device placement procedure. The field **1230** is labeled "Institution" and the user can input the name of the clinical institution and/or the name of the clinician performing the VAD placement procedure. Field **1225** is labeled "Inserted Length" and the user can input the insertion length of the VAD at the end of the VAD placement procedure.

[**0104**] The information input in the alphanumeric fields is stored in the patient's file and printed on paper on the Bluetooth printer, if such a printer is connected, when the user touches the button **930** in FIG. 9. Touching the button **1250** opens a dialog box and a display window allowing the user to select for visualization archived images or to select a file to playback archived patient data.

[**0105**] The button **1255** switches the screen to the "Settings" display illustrated in FIG. 13. The button **1260** is labeled "New Patient". When touching this button, all input fields of the display **1200** are cleared and the memory used for temporary storage of patient information and case data is reinitialized. Field **1270** shows the logo of the device.

[**0106**] FIG. 13 illustrates a user interface for ECG device settings **1300** according to the present invention. The display window **1305** displays an ECG waveform of the patient from the electrodes connected to the skin as a control electrode. The heart rate displayed in field **1310** in real time is computed based on the ECG waveform displayed in display window **1305**. Field **1315** shows the logo of the device.

[**0107**] Touching the button **1320** switches the display to a display window allowing for setting up a Bluetooth printer. Touching the button **1325** switches the display to the display illustrated in FIG. 12. The display window **1330** displays messages related to the Bluetooth communication between the devices **190** and **125** in FIG. 1 and between the device **190** in FIG. 1 and a Bluetooth printer. The display window **1330** also displays messages related to the wireless communication between the devices **190** and **170** in FIG. 1, if a device **170** is connected. The display window **1335** lists all discovered Bluetooth devices including the device **125** in FIG. 1 and a Bluetooth printer and allows for the selection of desired devices. The button **1340** is labeled "Refresh". Touching this button restarts the discovery of Bluetooth devices displayed in window **1335**. The button **1345** is labeled "Connect".

[**0108**] Touching the button **1345** allows for establishing Bluetooth communication between the device **190** in FIG. 1 and the device selected in window **1335**, i.e., a particular device **125** in FIG. 1. One or more devices **125** in FIG. 1 can be discovered but only one such device can be connected at any one time.

[**0109**] The drop-down selection box **1350** is labeled "ECG rate" and allows for the selection of the rate for the A/D sampling of the ECG signals performed by device **125** in FIG. 1. The drop-down selection box **1355** is labeled "IV Gain" and allows for the selection of the acquisition amplification and/or display scale of the intravascular ECG signal acquired by device **125** in FIG. 1. The drop-down selection box **1360** is labeled "CE Gain" and allows for the selection of the acquisition amplification and/or display scale of the ECG control signal acquired by device **125** in FIG. 1. The drop-down selection box **1365** allows for the selection of a notch filter implemented by the device **125** in FIG. 1. The parameters selected using the selection boxes **1350**, **1355**, **1360**, and **1365** are sent by the device **190** to the device **125** in FIG. 1 upon selection over the Bluetooth communication channel **191-164**.

[**0110**] Touching the button **1380** labeled "SW Version" displays the version of the mobile application running on the device **190** in FIG. 1 and of the firmware of devices **125** and **170** in FIG. 1.

[**0111**] The drop-down selection box **1385** allows for the selection of the display scale and/or attenuation coefficient for the ECG control signal displayed in window **1305**. The signal attenuation for display purposes is performed by the application running on the device **190** in FIG. 1 and by the thread **1040** shown in FIG. 10. Touching the button **1390** resets the settings of the devices **125**, **170**, and **190** in FIG. 1 to factory defaults.

[**0112**] The check box **1370** is labeled "R-Peak". The user can check and uncheck the box **1370** by touching it. When checked, the device **125** in FIG. 1 computes the location of the R-peak in the ECG waveform and the device **190** in FIG. 1 displays a marker over the R-peak of the ECG waveform on the display illustrated in FIG. 9. The user can check and uncheck the box **1375** by touching it. When checked, the device **125** in FIG. 1 computes another specific signal related to the tip of the catheter of the vascular access device and the device **190** in FIG. 1 displays this signal in the display window **904** illustrated in FIG. 9.

[**0113**] FIG. 14 illustrates a block diagram of the software application for the vascular access device according to the present invention. The software application **1400** runs on the device **190** in FIG. 1 on top of a real-time multitasking operating system **1405**. The software module **1410** ensures Bluetooth communication with the device **125** over the communication channel **191-164** in FIG. 1 and with a Bluetooth printer. Software module **1415** ensures wireless communication over a wireless channel using a wireless protocol between the devices **190** and **170** over the communication channel **196-186** in FIG. 1. Software module **1415** further ensures wireless communication over a wireless channel using a wireless protocol between the device **190** and another wireless device for the purpose of broadcasting in real time patient information, signals and images acquired from the patient by the device according to the present invention.

[**0114**] In another embodiment of the present invention, the software module **1415** also includes capabilities to transfer

patient information, signals and images in real time to another device over a wireless phone and/or smartphone connection.

[0115] The ECG application module 1425 has the functions and the block diagram illustrated in FIG. 10. The ultrasound imaging application module 1430 has the functions and the block diagram illustrated in FIG. 11. The synchronization module 1440 performs synchronization between the ECG application 1425 and the ultrasound imaging application 1430. The synchronization performed by the module 1440 includes synchronization between the resources of the device 190 in FIG. 1 allocated to the two applications 1425 and 1430, timing synchronization between applications 1425 and 1430.

[0116] One method of timing synchronization according to the present invention is ECG-triggered ultrasound imaging and information processing. In such ECG-triggered timing synchronization, the ECG signals and the ultrasound images are processed based on a trigger in the ECG waveform, for example based on the occurrence of an R-peak in the control ECG signal. When such a trigger occurs, certain parameters of the ultrasound image received from the device 170 in FIG. 1 and certain parameters of the signals received from device 125 in FIG. 1 are computed by the information processing block 1420.

[0117] Examples of such computed parameters include blood vessel sizes. Since the blood vessel diameter changes during the heart cycle, determining the blood vessel size at the same moment in time in each heart cycle leads to a more accurate determination of the vessel size. The determination of the blood vessel size triggered by ECG can be computed or determined with user interaction through the user interface illustrated in FIG. 15. Accurate estimation of blood vessel size is important for the determination of the size of the vascular access device catheter.

[0118] Another type of synchronization and processing performed by modules 1440 and 1420 is the correlation of the ultrasound image with the ECG signal at the tip of the catheter at certain locations in the vasculature, for example in the internal jugular vein. The user interface module 1435 is controlling the user interface illustrated in FIGS. 8, 9, 12, 13, 15, and 16.

[0119] The user interface module 1435 together with the synchronization module 1440 are responsible for switching between the ultrasound imaging interface illustrated in FIG. 8 and the ECG interface illustrated in FIG. 9 when the device 190 in FIG. 1 rotated by 90 degrees as explained in FIGS. 8 (840) and 9 (950).

[0120] FIG. 15 illustrates a user interface for the vascular access device according to the present invention. The graphical user interface 1500 is displayed on the touch screen of a mobile device 190 in FIG. 1, e.g., a tablet or a smartphone. A simplified version of this interface can be displayed on a smart watch or on head mounted device. The display window 1510 display ultrasound images acquired and processed by the device 170 in FIG. 1 and transmitted to device 190 in FIG. 1 over a wireless communication channel.

[0121] An ultrasound image 1570 is presented on the display window 1510 with the origin of the image 1570 on the top of the screen and with the deepest field of view of the image on the bottom of the image 1570. The display scale in mm 1515 is displayed to the right of the display window 1510. Objects closer to the skin 1575 are displayed closer to the origin of the ultrasound image 1570, i.e., closer to the top of the image 1570. Deeper objects 1580 are displayed closer to the bottom of the image 1570. The devices 170 and 190 in

FIG. 1 ensure good enough resolution and contrast in order to clearly depict in the ultrasound image 1570 veins (1575), arteries (1580) and catheters of at least 3 Fr in size 1585 positioned inside blood vessels 1575.

[0122] The devices 170 and 190, as well as the communication channel 196-186 in FIG. 1 ensures communication speed and data throughput high enough in order to display real time ultrasound images at minimum 10 images per second. The display window 1520 displays the field of view, i.e., the maximum target depth for which ultrasound images can be acquired for a specific setting of the device 170 in FIG. 1. The display window 1510 for ultrasound images ensures the user interface functionality described in FIG. 8 for the display window 804.

[0123] The display window 1560 displays ECG and other signals 1565 acquired and processed by the device 125 in FIG. 1 and transmitted to the device 190 in FIG. 1 over a Bluetooth communication channel (164-191 in FIG. 1). The display window 1560 ensures the user interface functionality described in FIG. 9 for display window 904. Touching the button 1540 switches the graphical user interface to the user interface described in FIG. 16. Touching the button 1545 enables printing to a wireless printer. Depending on the system settings, either the ultrasound image 1570 or the signal 1565 or both can be printed on one or two different printers. For example, the ultrasound image 1570 can be printed on wireless printer using Direct WiFi and the signal 1565 can be printed on a Bluetooth printer.

[0124] Touching the button 1545 also enables saving of patient information, ECG signals and frozen ultrasound images in dedicated files on the selected storage medium of the device 190 in FIG. 1. Touching the button 1550 switches the user interface of the device 190 in FIG. 1 to the user interface presented in FIG. 8. Touching the button 1555 switches the user interface of the device 190 in FIG. 1 to the user interface presented in FIG. 9.

[0125] Buttons 1590 and 1594 provide a “Home” and a “Back” function respectively, as described in FIG. 9, buttons 970 and 974 respectively. The field 1530 displays the heart rate computed by the device 125 in FIG. 1. The field 1535 displays the logo of the device. The field 1535 also serves as a toggle button for the selection of the signal 1565 displayed in display window 1560. One out of two or more signals acquired and/or computed by the device 125 in FIG. 1 can be selected to be displayed in window 1560. The button 1525 is a toggle button. Touching the button 1525 enables or disables synchronization function between the ECG signal and the ultrasound image as described in FIG. 14.

[0126] FIG. 16 illustrates a user interface for ultrasound imaging settings and tools according to the present invention. The display window 1600 is displayed on the screen of the device 190 in FIG. 1 and is divided into a “Settings” section 1605 and a “Tools” Section 1660. The setting called “Compression” 1610 allows for the selection of the compression ratio for the ultrasound images transferred from the device 170 to the device 190 over the communication channel 196-186 in FIG. 1 through a drop down selection box. When the compression is set to off, ultrasound images are transferred uncompressed.

[0127] Touching the button 1636 toggles on and off the ECG trigger 1614. When turned on, the ECG trigger works as described in FIG. 14. The setting TGC curve 1618 allows for the selection of a time-gain compensation (TGC) curve used to optimized image quality by compensating ultrasound

attenuation due to depth. The TGC can be switched off, in which case the blocks 530 in FIG. 5 and 1150 in FIG. 11 do not perform any attenuation compensation on the ultrasound image. One TGC curve can be selected out of a set of predefined TGC curves by using the drop box 1634. The predefined set of TGC curves allows for choosing the optimal ultrasound attenuation compensation in a typical clinical situation, e.g., when working on neonates, when placing peripherally inserted central lines (PICC), when placing implantable ports, when accessing the blood vessels by femoral access.

[0128] The “Scan Converter” setting 1620 allows for turning on and off with the help of the selection button 1638 the scan converter function performed by block 534 in FIG. 5. When the scan converter function performed by block 534 in FIG. 5 is turned off, then automatically the scan converter function 1140 in FIG. 11 is turned on and reciprocally, such that only one scan converter function is active at one time.

[0129] The WiFi select field 1624 displays a list of available WiFi devices in the display window 1630. By touching the appropriate name listed in display window 1630, the device 170 can be wirelessly connected, e.g., through a direct wireless connection to the device 190 in FIG. 1. The Button Configuration field 1628 allows the user to configure the buttons 1640 of device 170 in FIG. 1 to perform functions selected from the drop down list 1642. The user touches one of the buttons 1640 to select it and the selects the desired function for that button from the drop down list 1642. Touching the selected button again allocated the selected function to that button.

[0130] The “Tools” menu displayed in display window 1660 allows for performing certain less frequently used functions. Touching the button “Save” 1665 saves patient case data to a file on the storage medium of the device 190 in FIG. 1. Touching the button “Play” 1670 allows for selecting a stored patient file and playing it back on a display window for ultrasound images on the device 190 in FIG. 1. Touching the “Print” button 1675 allows for printing an ultrasound image including measurements to a connected wireless printer. Touching the “Diag” button brings up a number of diagnostics options used to verify the functionality of the devices 170 and 190 in FIG. 1. Buttons 1690 and 1692 provide a “Home” and a “Back” function respectively, as described in FIG. 9, buttons 970 and 974 respectively. Display window 1694 indicates the battery level of device 170 in FIG. 1 and display window 1696 indicates the battery level of device 190 in FIG. 1.

[0131] FIG. 17 illustrates a method for vascular access according to the present invention consisting of the steps described herein below. The displays illustrated by 1700, 1710, 1720, 1730, 1740, 1750, and 1760 are simplified forms of the display illustrated and described in FIG. 15 displayed on the device 190 in FIG. 1. The ultrasound images illustrated in FIG. 17 are acquired by the device 170 in FIG. 1 and transmitted to the device 190 in FIG. 1 according to the present invention. The ECG signals illustrated in FIG. 17 are acquired by the device 125 in FIG. 1 and transmitted to the device 190 in FIG. 1 according to the present invention. The method for vascular access according to the present invention consists of the following steps:

[0132] 1. Estimation of the blood vessel size considered for vascular access illustrated by the display 1700. The targeted blood vessel for vascular access 1702 is visualized on the ultrasound image in FIG. 15. The skin (surface, control) ECG

signal 1708 is selected to be displayed as described in FIG. 15. In order to increase measurement accuracy on the ultrasound image, ECG-triggered ultrasound imaging described in FIG. 14 is enabled by using the button 1525 in FIG. 15. The blood vessel diameter 1704 is measured as described in FIG. 8 and displayed in the field 1706. Thus, the user can estimate the size of the vascular access device which is recommended to be approximately one third of the blood vessel diameter. The patency of the targeted blood vessel is also evaluated at this step using ultrasound imaging along the blood vessel and visualizing differences in the blood vessel diameter along the blood vessel. The diameter of the blood vessel may decrease due to obstructions such as blood clots, tumors, or other causes. In general, the size of the access device catheter should be one third of the minimum diameter of the targeted blood vessel on the desired catheter path.

[0133] 2. Puncture and access of the targeted blood vessel illustrated by the display 1710. In display 1710 an uncompressible artery 1716 and a compressible vein 1714 are illustrated, displayed by ultrasound imaging in case of peripheral access. In the ultrasound image, the access needle 1712 is also illustrated. The access needle can be inserted in the targeted blood vessel under ultrasound guidance freehanded or by using the needle guide described in FIG. 4. The skin (surface, control) ECG signal 1718 displayed simultaneously with the ultrasound image is used to monitor the patient’s heart rate and the presence of any heart rhythm abnormalities, e.g., extra systoles. The heart rate and heart rhythm abnormalities are computed using the detection of the R-peak 1719 of the ECG waveform as described in FIG. 9 and displayed in the field 1530 in FIG. 15.

[0134] 3. Checking the catheter path within the blood vessels illustrated by the display 1720. Wherever accessible to ultrasound imaging, the targeted blood vessel path for the catheter placement is visualized, for example in a longitudinal view 1722. If the catheter 1724 is in the targeted blood vessel, the catheter can be visualized on the ultrasound image, as well as the catheter tip 1726. An ECG signal 1728 is displayed simultaneously with the ultrasound image. A skin (surface, control) ECG signal is selected for the display 1728 and used to monitor the patient’s heart rate and the presence of any heart rhythm abnormalities, e.g., extra systoles, for example when the catheter touches the wall of the right atrium. The heart rate and rhythm abnormalities are computed using the detection of the R-peak 1729 of the ECG waveform as described in FIG. 9 and displayed in the field 1530 in FIG. 15. An intravascular ECG signal at the tip of the catheter is selected for the display 1728 and used to correlate in real time the position of the tip of the catheter 1726 visualized on the ultrasound image with the ECG waveform from the tip of the catheter at that location. Checking the catheter path within the blood vessels illustrated by the display 1720 can be performed either by longitudinal ultrasound imaging, i.e., along a blood vessel or by transversal ultrasound imaging, i.e., perpendicular on a blood vessel.

[0135] 4. Checking abnormal catheter locations as illustrated in Figure 1730. If the catheter did not follow the desired path through the vasculature and could not be visualized in step 2, abnormal positions of the catheter within the vasculature are checked as illustrated by 1730. Wherever accessible to ultrasound imaging, the possible abnormal catheter locations, e.g., in the internal jugular vein are visualized. A catheter 1734 can be identified in a blood vessel in a transversal view 1732. Checking the catheter path within the blood ves-

sels illustrated by the display 1730 can be performed either by longitudinal ultrasound imaging, i.e., along a blood vessel or by transversal ultrasound imaging, i.e., perpendicular on a blood vessel. A skin (surface, control) ECG signal is selected for the display 1736 and used to monitor the patient's heart rate and the presence of any heart rhythm abnormalities, e.g., extra systoles, for example when the catheter touches the wall of the right atrium. The heart rate is computed using the detection of the R-peak 1738 of the ECG waveform as described in FIG. 9 and displayed in the field 1530 in FIG. 15. An intravascular ECG signal at the tip of the catheter is alternatively selected for the display 1736 and used to correlate in real time the position of the tip of the catheter visualized on the ultrasound image 1734 with the ECG waveform from the tip of the catheter at that location. Checking the catheter path within the blood vessels illustrated by the display 1730 can be performed either by longitudinal ultrasound imaging, i.e., along a blood vessel or by transversal ultrasound imaging, i.e., perpendicular on a blood vessel.

[0136] 5. Approaching the cavo-atrial junction as illustrated in 1740. As described in the literature, as the catheter tip of the vascular access device approaches the cavo-atrial junction the P-wave 1744 of the ECG waveform 1742 increases. The P-wave can be easily identified as being the predominant waveform to the left of the R-peak 1748 of the QRS complex 1746 of the ECG-waveform 1742.

[0137] 6. In order to place the catheter tip at the cavo-atrial junction, the catheter is first advanced beyond the cavo-atrial junction until the P-wave of the ECG waveform 1755 situated to the left of the marker 1758 indicating the peak of the R-wave 1759 starts to decrease or becomes biphasic with a negative first peak 1756 and a predominant second positive peak 1757. Then, the catheter is pulled back to the cavo-atrial junction until the P-wave 1752 situated to the left of the marker 1754 of the R-peak of the R-wave 1753 of the ECG waveform 1751 reaches its maximum positive amplitude without presenting the biphasic aspect identified by 1756 and 1757.

[0138] 7. The ultrasound image showing a blood vessel of interest 1761 and the catheter 1762 inside that vessel, as well as the ECG waveform 1764 corresponding to the catheter tip location at the target location are frozen on display 1760 and saved to the patient file using the user interface described in FIG. 15. The information is printed wirelessly (1770) to a wireless printer 1780 for documentation purposes.

What is claimed is:

1. A method for vascular access, the method comprising:
 - obtaining an ultrasound image of a blood vessel,
 - obtaining an ECG signal from a skin electrode,
 - obtaining an ECG signal from the tip of a vascular devices in the said blood vessel,
 - analyzing the said ultrasound image and the said ECG signals, and
 - providing information helpful to vascular access in real time as a result of said analysis.
2. The method as defined in claim 1, wherein acquisition of the ultrasound images is synchronized with the ECG signal obtained from the skin electrode.
3. The method as defined in claim 2, wherein the synchronization of the ultrasound image acquisition with the ECG signal is used for a more accurate assessment of the blood vessel size in view of vascular access.
4. The method as defined in claim 2, wherein the synchronization of the ultrasound image acquisition with the ECG

signal is used for a more accurate assessment of the blood vessel patency in view of vascular access.

5. The method as defined in claim 1, wherein the ultrasound image of a vascular device in a blood vessel is displayed simultaneously with the ECG signal at the tip of the vascular device on the same display.

6. The method as defined in claim 5, wherein the location of the catheter tip in the blood vessel is estimated based on the correlation between the ultrasound image and the ECG signal.

7. A device for vascular access, the device comprising:

- an ultrasound image acquisition and processing unit
- an ECG signal acquisition and processing unit
- a display and graphical user interface unit

8. The device as defined in claim 7, wherein the ultrasound image acquisition and processing unit comprises a module to perform ultrasound image acquisition and processing on a trigger.

9. The device as defined in claim 7, wherein the ultrasound image acquisition and processing unit comprises software to perform data compression.

10. The device as defined in claim 7, wherein the ultrasound image acquisition and processing unit comprises software to perform pattern recognition.

11. The device as defined in claim 7, wherein the ultrasound image acquisition and processing unit comprises software to perform scan conversion.

12. The device as defined in claim 7, wherein the ultrasound image acquisition and processing unit comprises software to perform time gain compensation.

13. The device as defined in claim 7, wherein the ultrasound image acquisition and processing unit comprises software and hardware for wireless transmission of ultrasound images.

14. The device as defined in claim 7, wherein the ultrasound image acquisition and processing unit is handheld.

15. The device as defined in claim 7, wherein the ECG signal acquisition and processing unit comprises:

- a module to extract certain features from the skin ECG signal
- a module to generate a trigger based on certain features of the skin ECG signal

16. The device as defined in claim 7, wherein the ECG signal acquisition and processing unit comprises software and hardware for wireless transmission of ECG signals.

17. The device as defined in claim 7, wherein the ECG signal acquisition and processing unit is handheld.

18. The device as defined in claim 7, wherein the display and graphical user interface unit comprises:

- A graphical layout to simultaneously display ultrasound images and ECG signals at the tip of the vascular device;
- A graphical user interface to allow for control and synchronization of ultrasound images and ECG signals.

19. The device as defined in claim 7, wherein the display and graphical user interface unit comprises software to perform data decompression.

20. The device as defined in claim 7, wherein the display and graphical user interface unit comprises software to perform pattern recognition.

21. The device as defined in claim 7, wherein the display and graphical user interface unit comprises software to perform scan conversion.

22. The device as defined in claim 7, wherein the display and graphical user interface unit comprises software to perform time gain compensation.

23. The device as defined in claim 7, wherein the display and graphical user interface unit comprises software and hardware for wireless transmission of ultrasound images and ECG signals.

24. The device as defined in claim 7, wherein the display and graphical user interface unit is handheld.

* * * * *

专利名称(译)	血管通路的装置和方法		
公开(公告)号	US20160278869A1	公开(公告)日	2016-09-29
申请号	US14/996247	申请日	2016-01-15
[标]申请(专利权)人(译)	巴德阿克塞斯系统股份有限公司		
申请(专利权)人(译)	BARD接入系统, INC.		
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[标]发明人	GRUNWALD SORIN		
发明人	GRUNWALD, SORIN		
IPC分类号	A61B34/20 A61B5/042 A61B5/0456 A61B5/00 A61B5/0404 A61B8/08 A61B8/00		
CPC分类号	A61B34/20 A61B2034/2063 A61B5/042 A61B8/463 A61B5/743 A61B8/5223 A61B8/565 A61B8/4427 A61B5/0404 A61B5/7475 A61B5/0006 A61B5/7445 A61B8/4472 A61B8/4494 A61B8/5207 A61B8/546 A61B5/0456 A61B2034/2051 A61B8/0841 A61B5/0017 A61B5/065 A61B2034/2065 A61B8/4416		
优先权	62/104895 2015-01-19 US		
外部链接	Espacenet	USPTO	

摘要(译)

本文介绍了一种新的装置和方法,以促进一般的血管通路和特别是中心静脉通路装置的放置。在一个实施例中,该设备包括以下组件:无线超声成像手持扫描仪,具有患者ECG电缆和无菌适配器的蓝牙ECG(心电图)数据采集模块,以及在移动平台(设备)上运行的移动医疗应用,例如,平板电脑,智能手机或智能手表。由本文公开的装置提供的超声成像和/或基于ECG的导管引导可用于独立地或同时使脉管系统中的导管可视化并引导其在所需位置处的放置。在本发明的另一个实施例中,用于血管通路的血管的超声成像可用于在插管血管之前评估血管尺寸,用于将进入针引导到目标血管中,以及用于可视化引导导管后导管在脉管系统中。在本发明的另一个实施例中,血管内导管的基于ECG的导航可用于跟踪脉管系统中的这种血管内导管并将这种血管内导管定位在所需位置。在本发明的一个方面,超声成像手持扫描仪包含获取和处理超声图像并将它们无线传输到移动平台设备(例如平板电脑或智能电话)所需的所有电子设备。在本发明的另一方面,ECG数据采集模块包含获取和处理基于ECG的导管引导的跟踪和定位信息以及将这些信息无线传输到移动平台设备(例如平板电脑或平板电脑)所需的所有电子设备。手机。在本发明的另一方面,引入了用于处理和同步超声图像的算法心电信号。在本发明的另一方面,引入了用于手持式超声成像扫描仪,ECG数据采集模块和在移动平台上运行的移动医疗应用的用户界面,以便简化超声成像和/或基于ECG的使用。在移动平台上放置导管的指南。在本发明的另一方面,使用同时超声成像和基于ECG的导管引导引入新的血管通路方法。根据本发明,在脉管系统中使用导管的超声成像同时检测导管尖端处的ECG信号,在成人和儿科人群中为大多数患者状况和临床环境提供准确且可靠的导管位置信息。

