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(54) SYSTEMS AND METHODS FOR ULTRASOUND-BASED MEDICAL DEVICE ASSESSMENT

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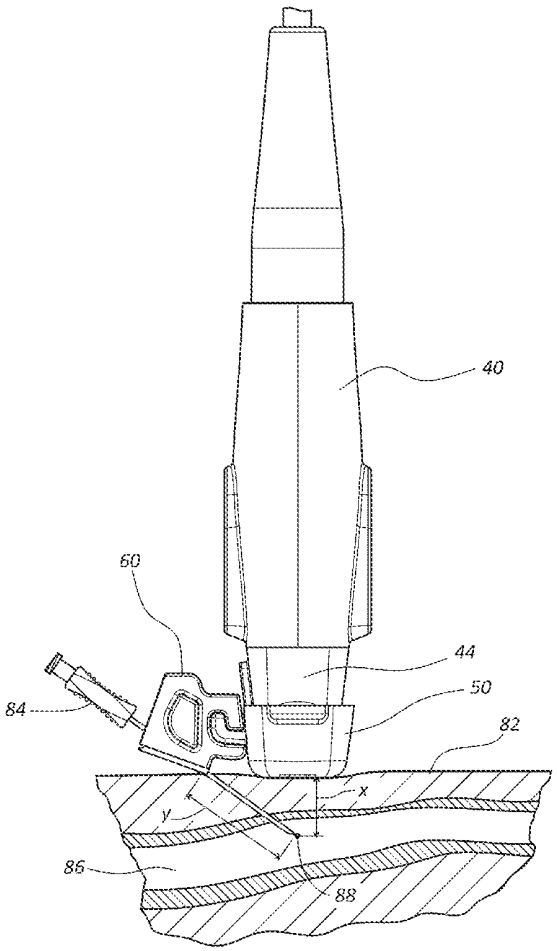
USPC **600/424**

(57) **ABSTRACT**

Systems and methods for assisting the placement of a catheter within the body of a patient through the use of an ultrasound imaging system are disclosed. In particular, the systems and methods described herein enable a clinician to determine, prior to insertion of the medical device, how much of the device will be disposed within the vessel, thus enabling the clinician to choose a catheter with suitable length. In one embodiment, an ultrasound imaging system for assisting with placement of the medical device comprises a console, a probe for producing an image of a target location, and a processor. The processor provides to a user proximity information relating to the anticipated proximity of the medical device to the target location prior to insertion of the medical device. A display is included for depicting the image, target location depth, and the proximity information of the medical device to the target location.



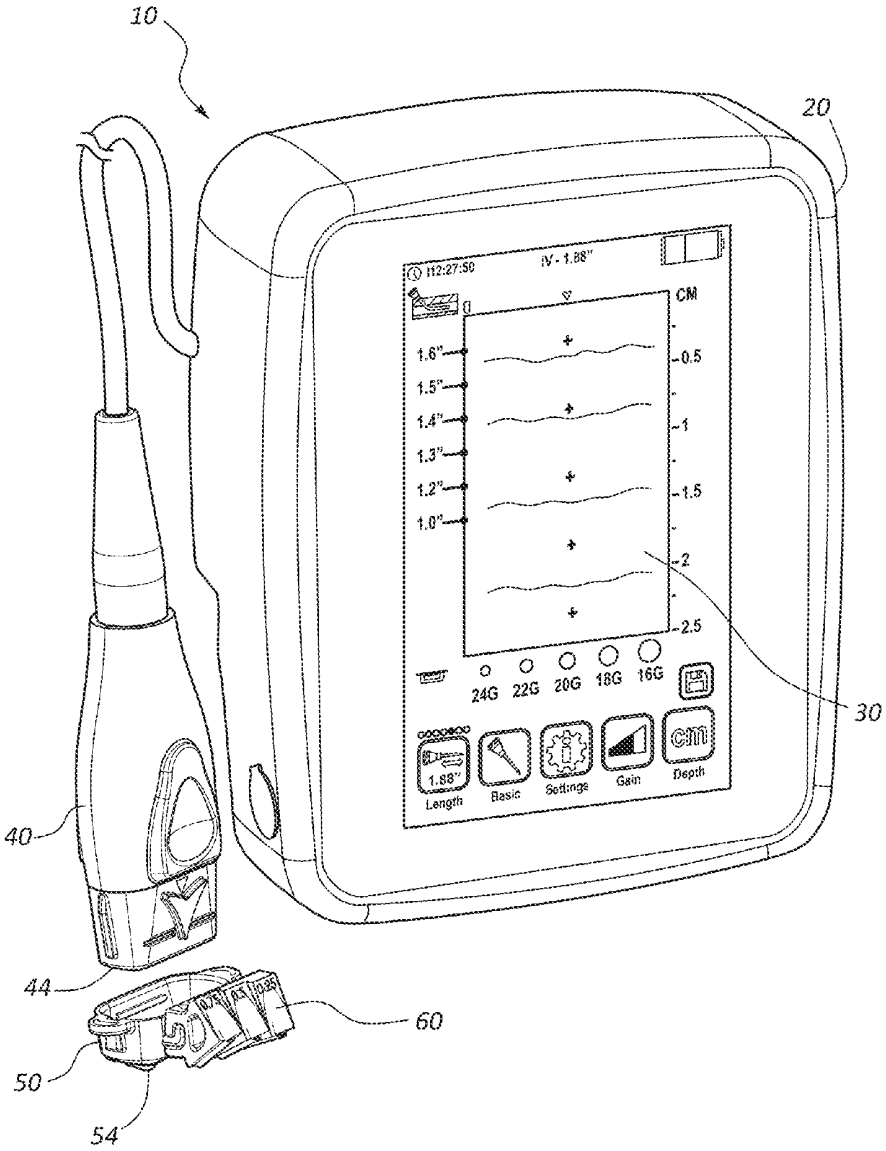

10
20
30
40
44
50
54
60
CM
1.6"
1.5"
1.4"
1.3"
1.2"
1.0"
0.5
1
1.5
2
2.5
24G
22G
20G
18G
16G
1.88"
Length
Basic
Settings
Gain
Depth
cm

FIG. 1

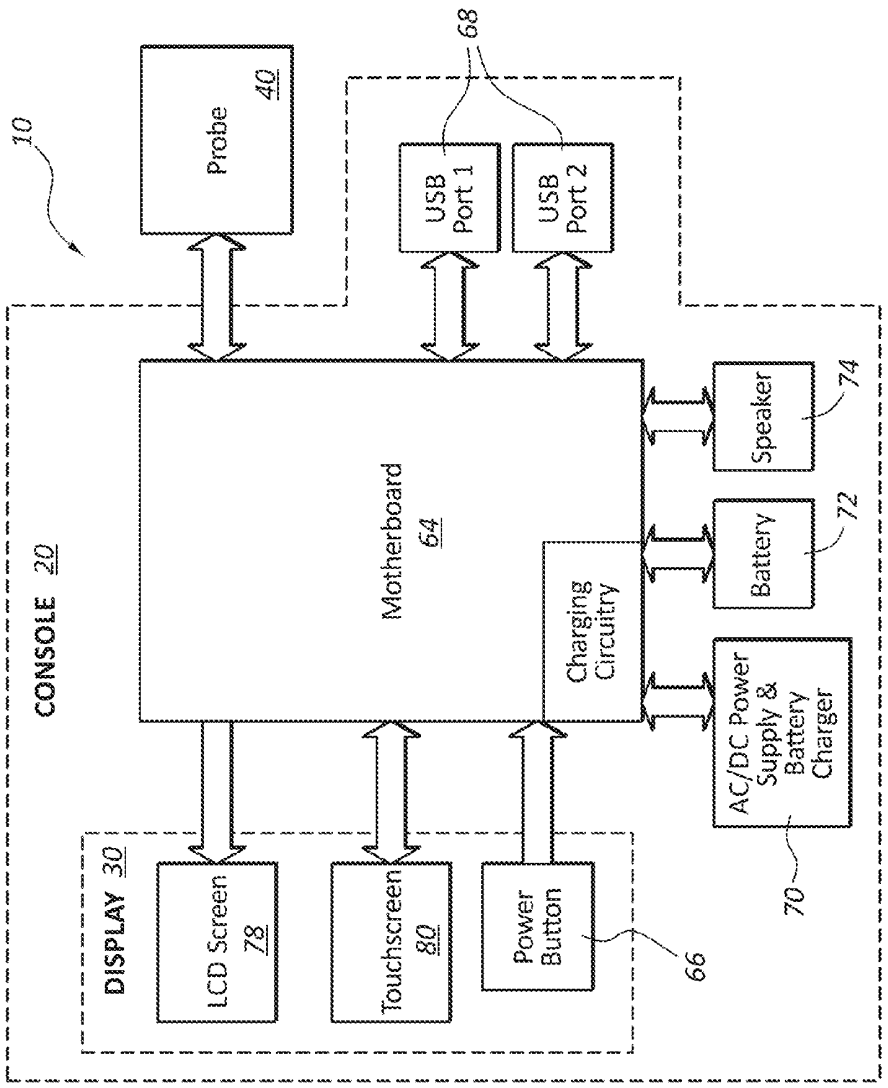

10
Probe
40
68
USB Port 1
USB Port 2
CONSOLE 20
Motherboard 64
Charging Circuitry
Speaker
74
Battery
72
AC/DC Power Supply & Battery Charger
70
DISPLAY 30
LCD Screen 78
Touchscreen 80
Power Button
66

FIG. 2

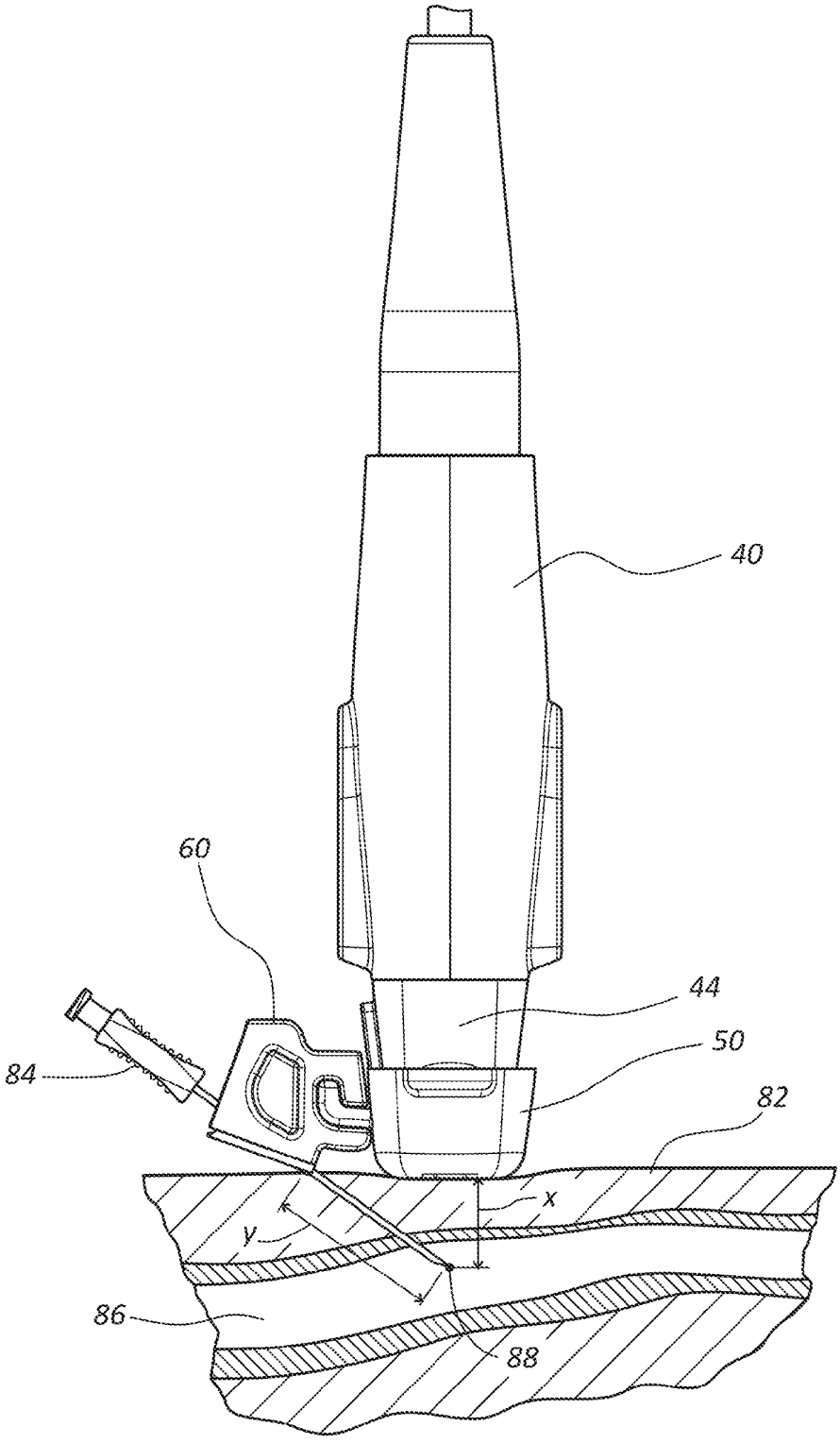


FIG. 3

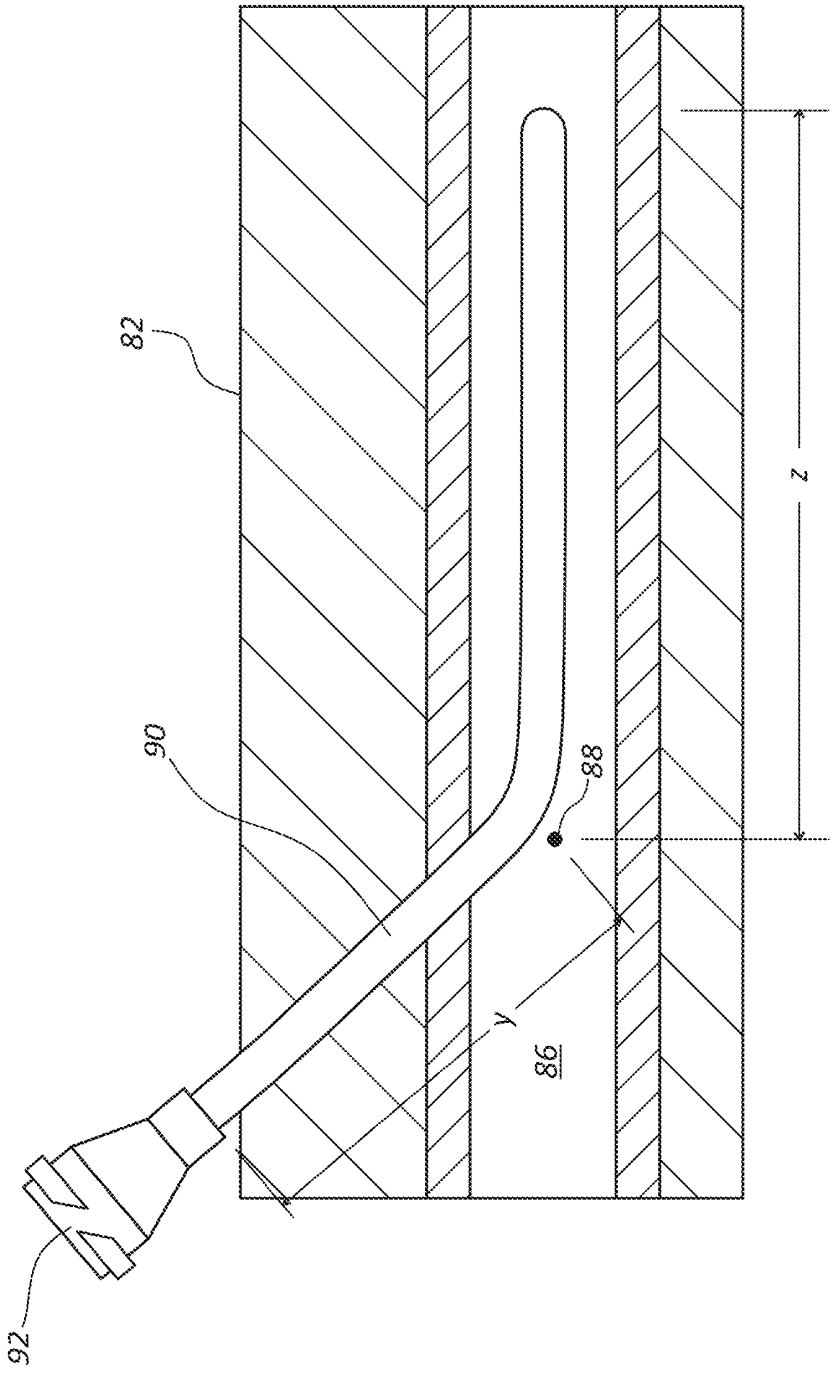


FIG. 4

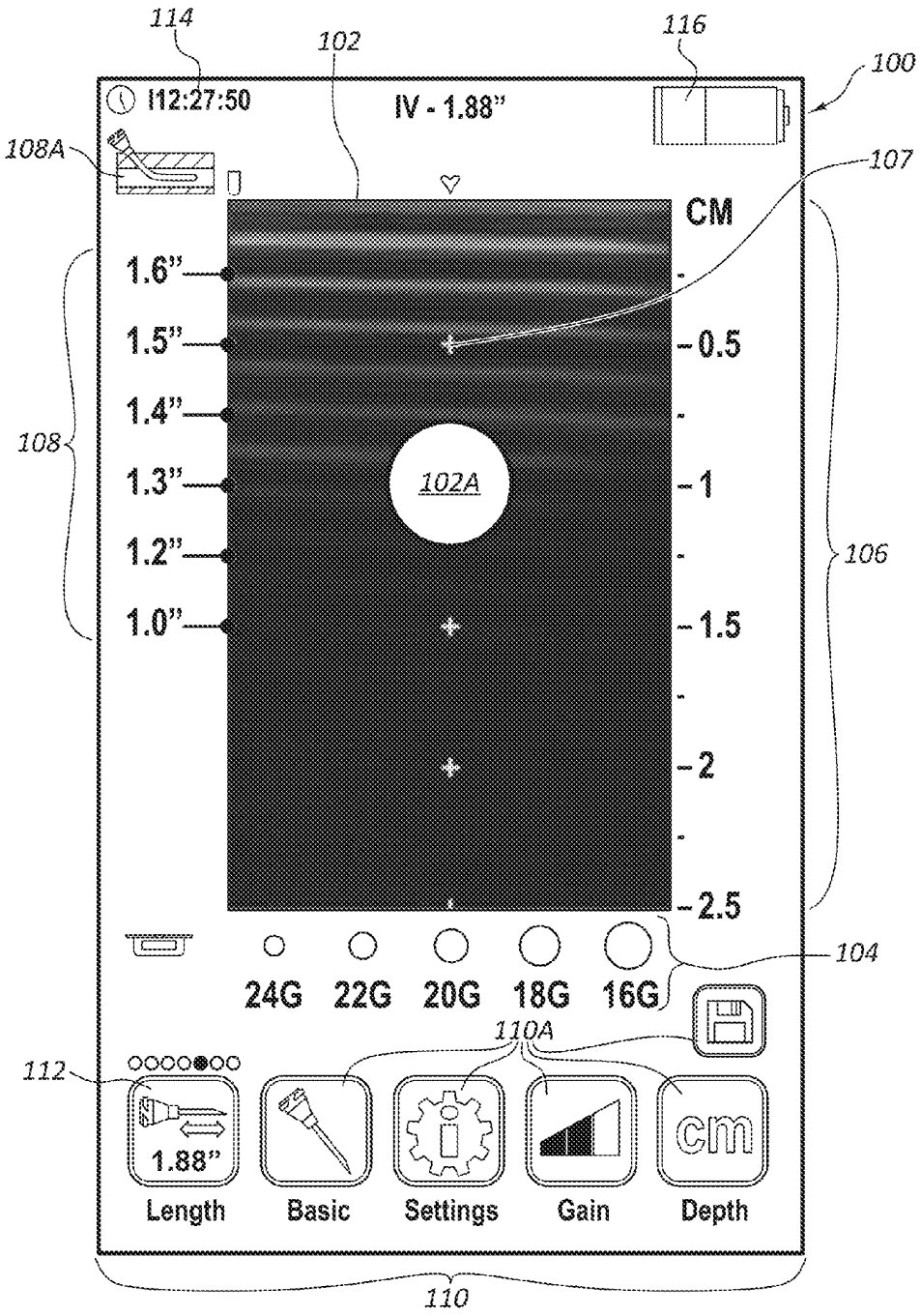

114
102
116
100
12:27:50
IV - 1.88"
108A
107
CM
1.6"
1.5"
1.4"
1.3"
1.2"
1.0"
0.5
1
1.5
2
2.5
108
102A
106
104
24G
22G
20G
18G
16G
110A
112
1.88"
Length
Basic
Settings
Gain
Depth
cm
110

FIG. 5

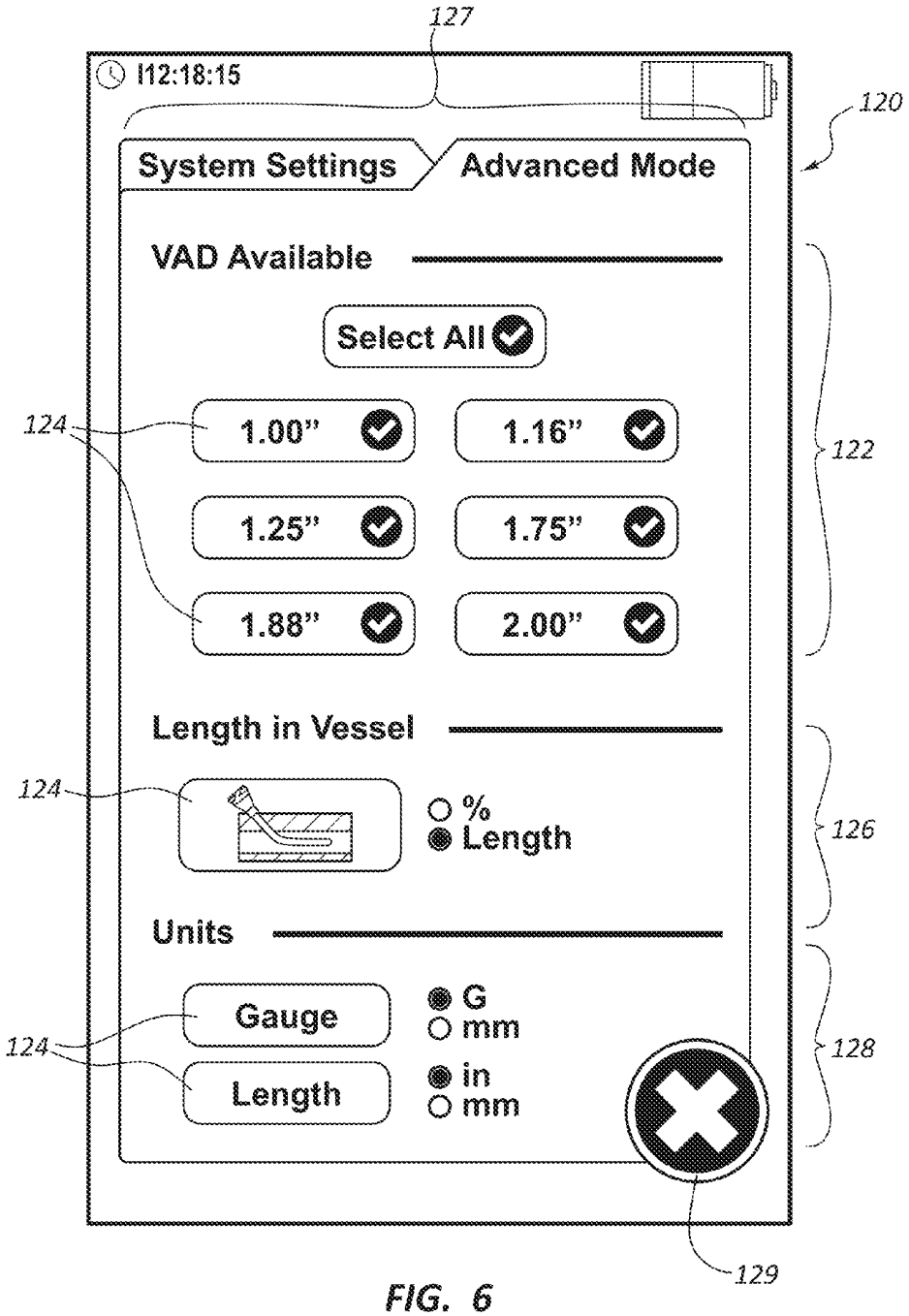

127
12:18:15
120
System Settings
Advanced Mode
VAD Available
Select All
124
1.00"
1.16"
1.25"
1.75"
1.88"
2.00"
122
Length in Vessel
124
%
Length
126
Units
Gauge
G
mm
124
Length
in
mm
128
129

FIG. 6

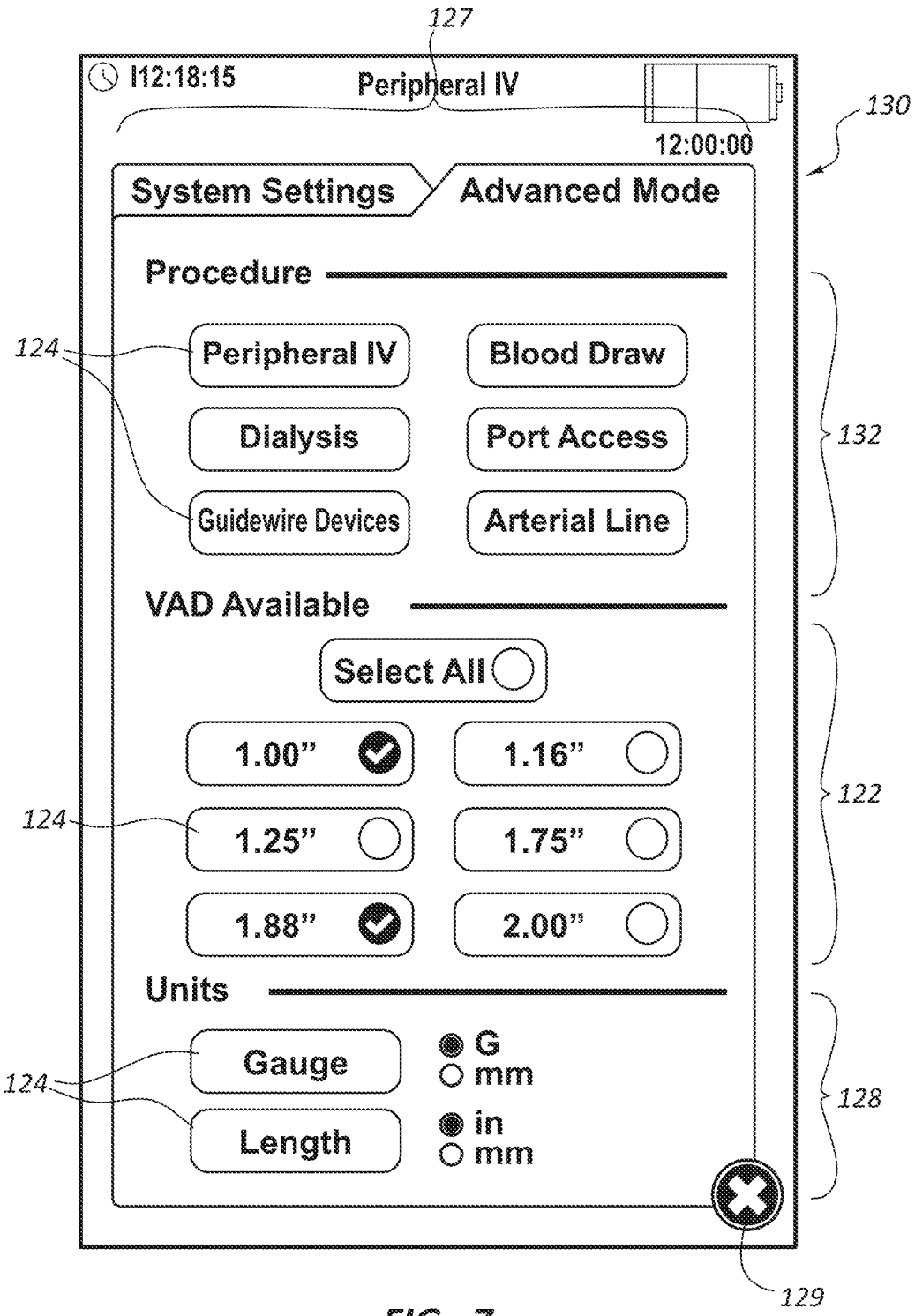

127
12:18:15
Peripheral IV
12:00:00
130
System Settings
Advanced Mode
Procedure
124
Peripheral IV
Blood Draw
Dialysis
Port Access
Guidewire Devices
Arterial Line
132
VAD Available
Select All
1.00”
1.16”
122
124
1.25”
1.75”
1.88”
2.00”
Units
Gauge
G
mm
124
Length
in
mm
128
129

FIG. 7

142 140

Needle Guide Depth (cm)	Catheter Length selected					
	1.00"	1.16"	1.25"	1.75"	1.88"	2.00"
	Length in vessel displayed					
	(in)	(in)	(in)	(in)	(in)	(in)
0.25	0.71	0.87	0.96	1.46	1.59	1.71
0.50	0.59	0.75	0.84	1.34	1.47	1.59
0.75	0.51	0.67	0.76	1.26	1.39	1.51
1.00	-	0.55	0.64	1.14	1.27	1.39
1.25	-	-	0.52	1.02	1.15	1.27
1.50	-	-	-	0.91	1.04	1.16

146

144

FIG. 8

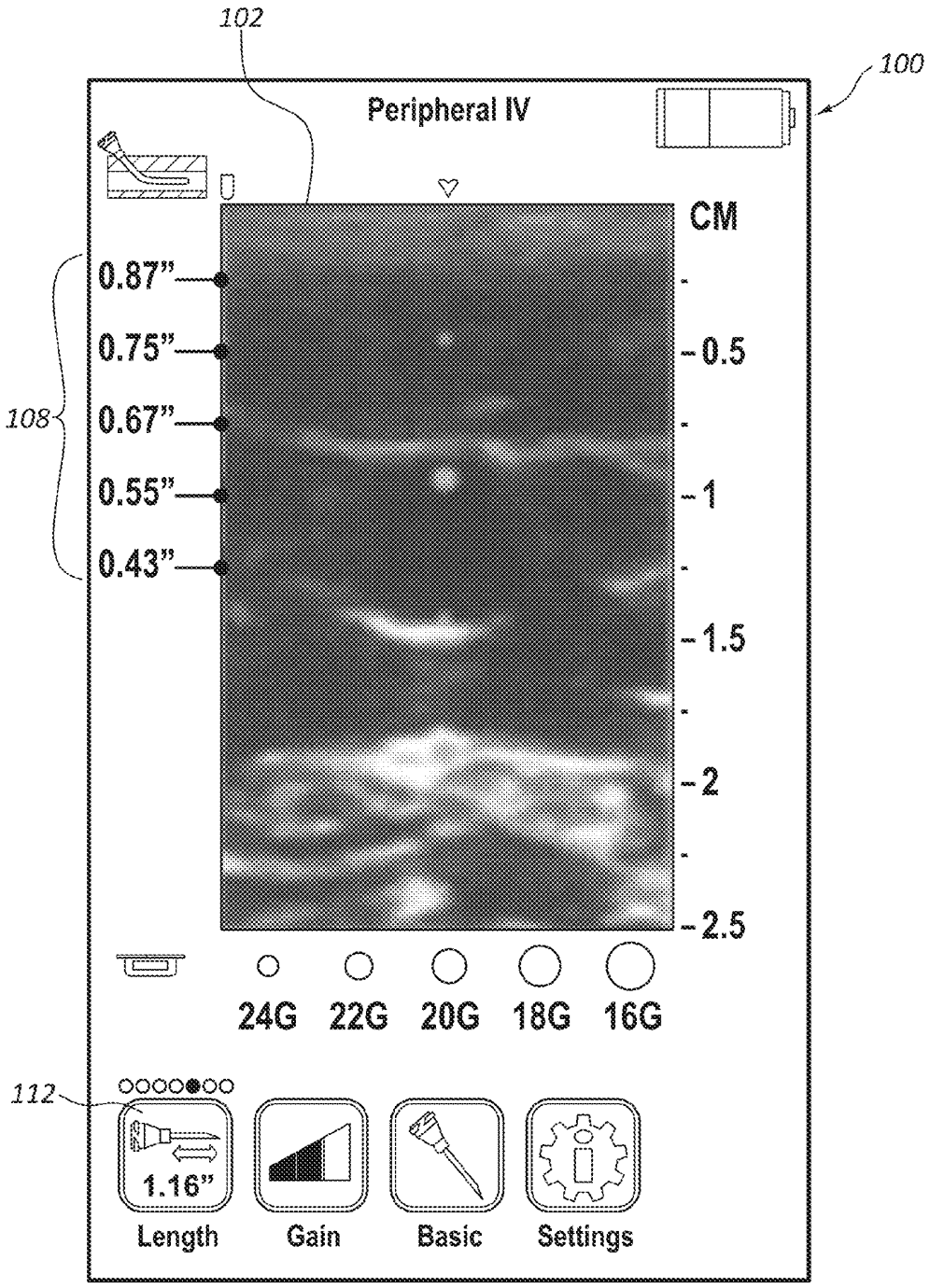

102
100
Peripheral IV
CM
0.87"
0.75"
0.67"
0.55"
0.43"
108
0.5
1
1.5
2
2.5
24G
22G
20G
18G
16G
112
1.16"
Length
Gain
Basic
Settings

FIG. 9A

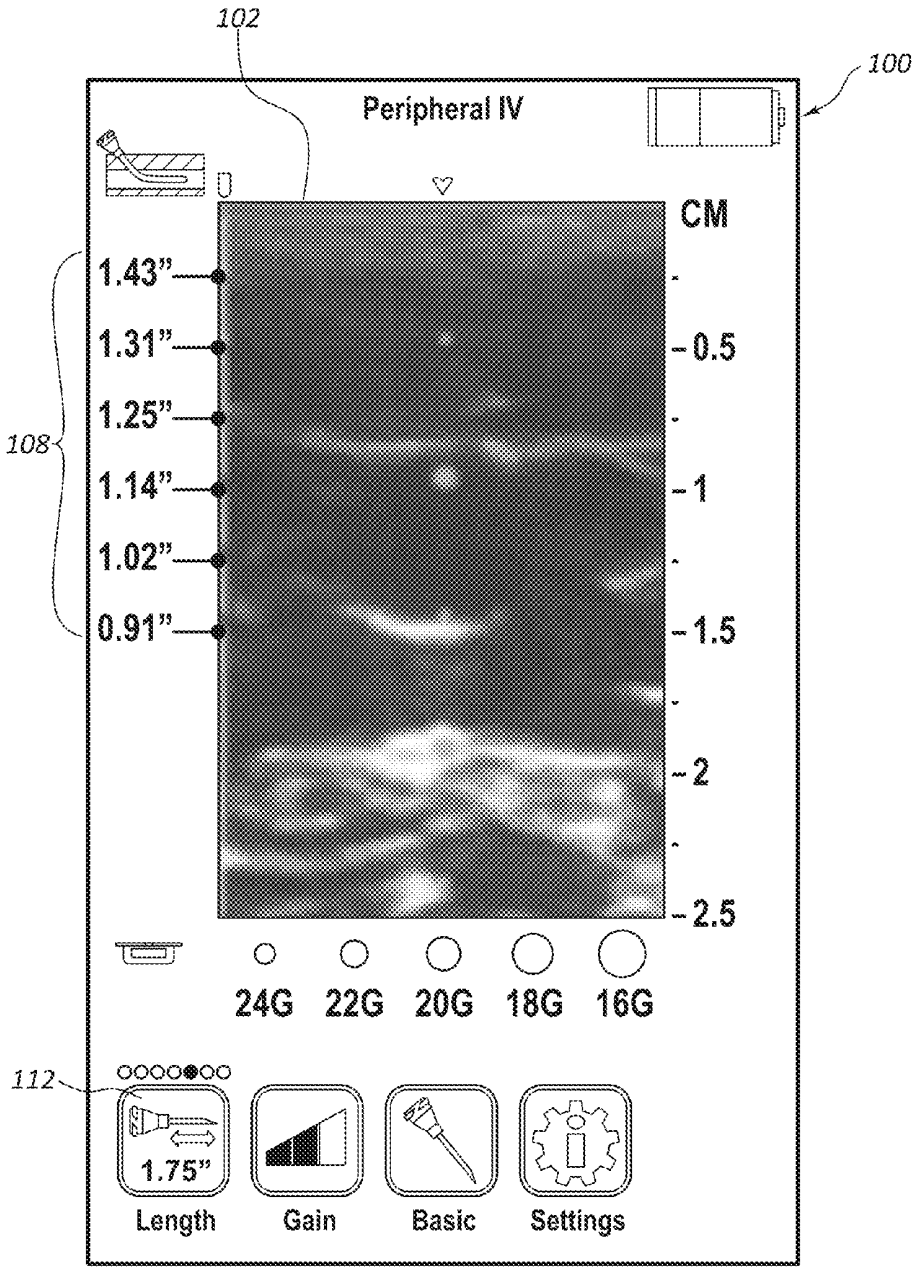

102
100
Peripheral IV
CM
1.43"
1.31"
1.25"
1.14"
1.02"
0.91"
108
0.5
1
1.5
2
2.5
24G
22G
20G
18G
16G
112
1.75"
Length
Gain
Basic
Settings

FIG. 9B

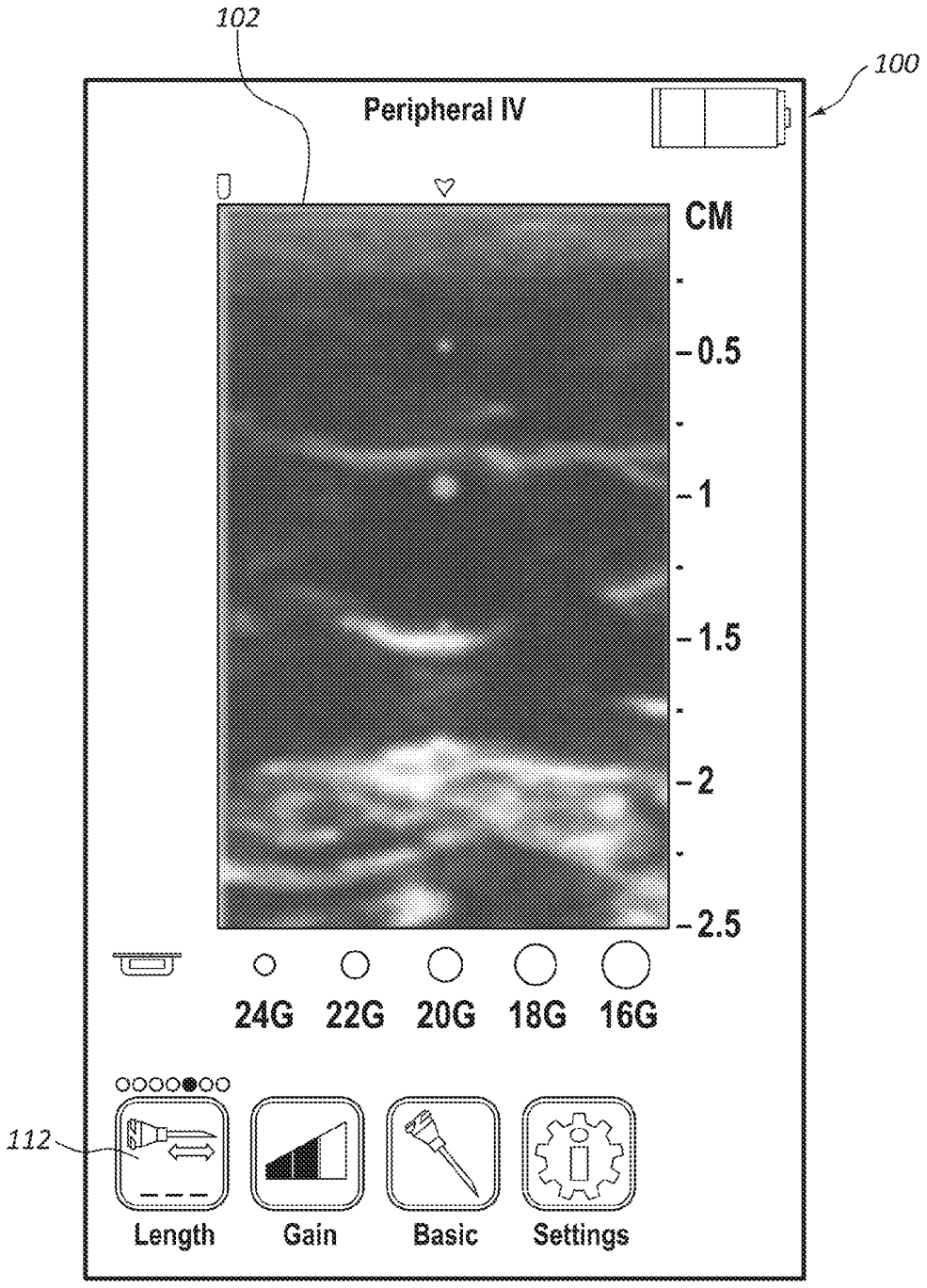

102
100
Peripheral IV
CM
0.5
1
1.5
2
2.5
24G
22G
20G
18G
16G
112
Length
Gain
Basic
Settings

FIG. 9C

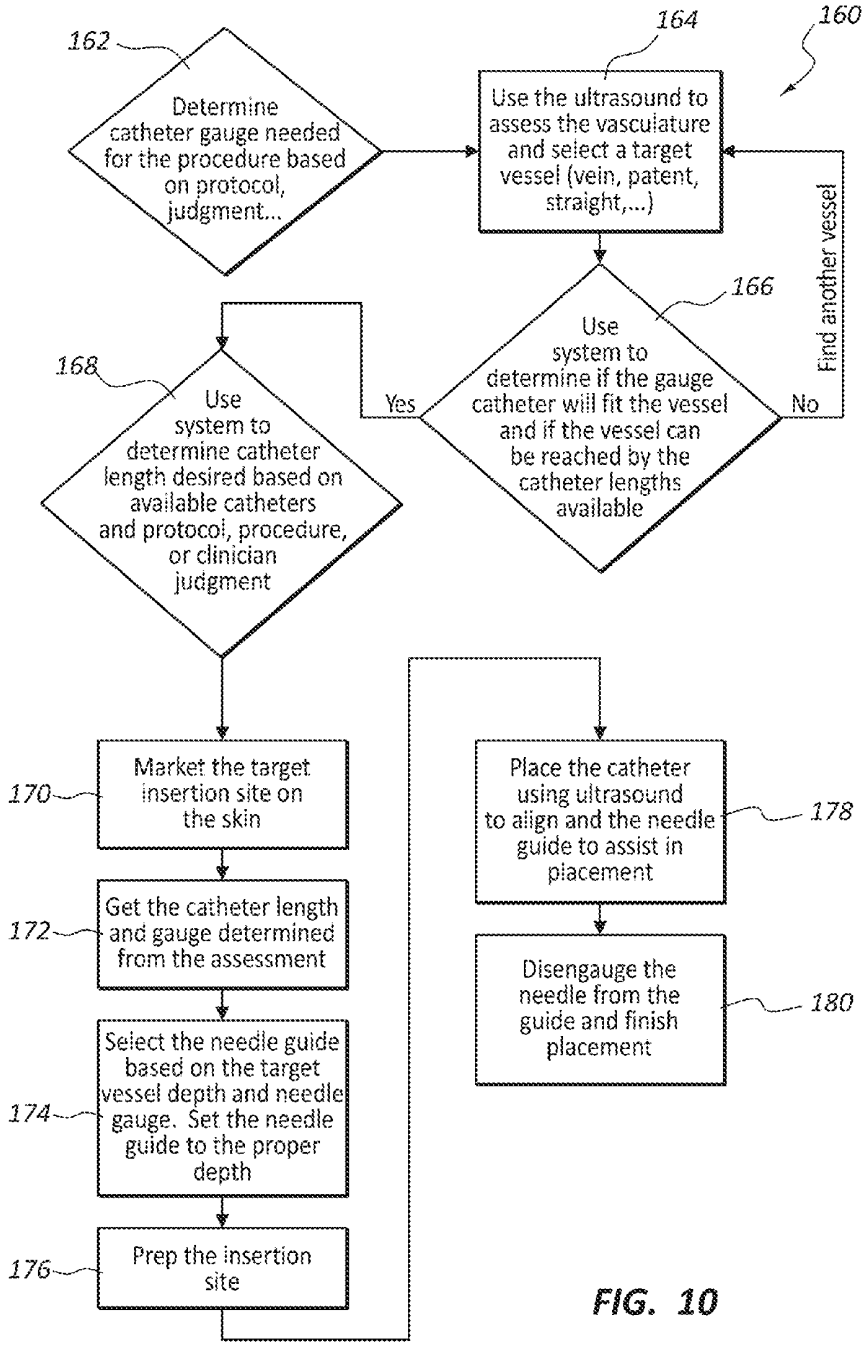

162
Determine catheter gauge needed for the procedure based on protocol, judgment...
164
160
Use the ultrasound to assess the vasculature and select a target vessel (vein, patent, straight,...)
166
Use system to determine if the gauge catheter will fit the vessel and if the vessel can be reached by the catheter lengths available
Yes
No
Find another vessel
168
Use system to determine catheter length desired based on available catheters and protocol, procedure, or clinician judgment
170
Market the target insertion site on the skin
172
Get the catheter length and gauge determined from the assessment
174
Select the needle guide based on the target vessel depth and needle gauge. Set the needle guide to the proper depth
176
Prep the insertion site
178
Place the catheter using ultrasound to align and the needle guide to assist in placement
180
Disengauge the needle from the guide and finish placement

FIG. 10

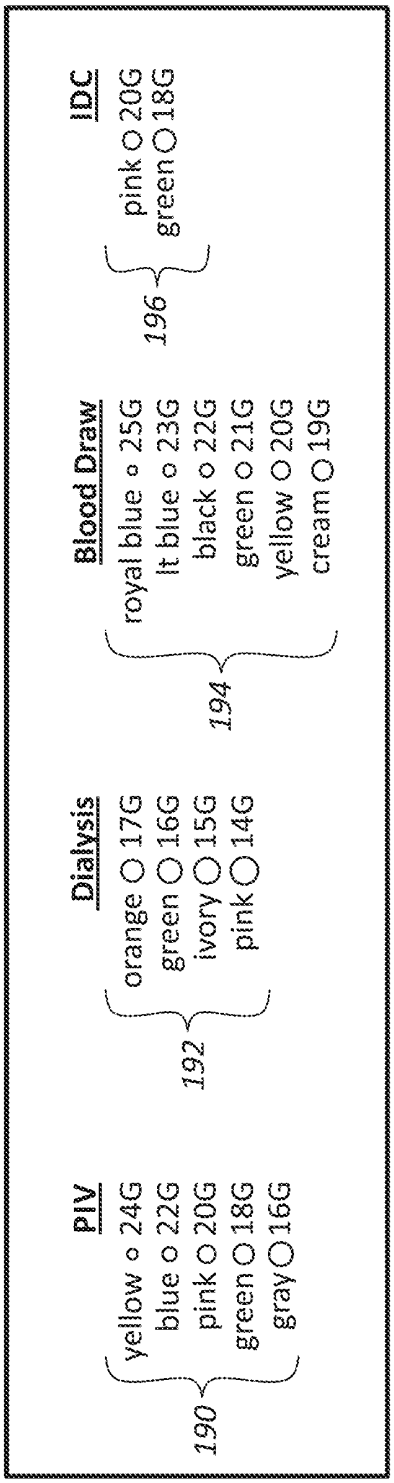

PIV
yellow ○ 24G
blue ○ 22G
pink ○ 20G
green ○ 18G
gray ○ 16G
190
Dialysis
orange ○ 17G
green ○ 16G
ivory ○ 15G
pink ○ 14G
192
Blood Draw
royal blue ○ 25G
lt blue ○ 23G
black ○ 22G
green ○ 21G
yellow ○ 20G
cream ○ 19G
194
IDC
pink ○ 20G
green ○ 18G
196

FIG. 11

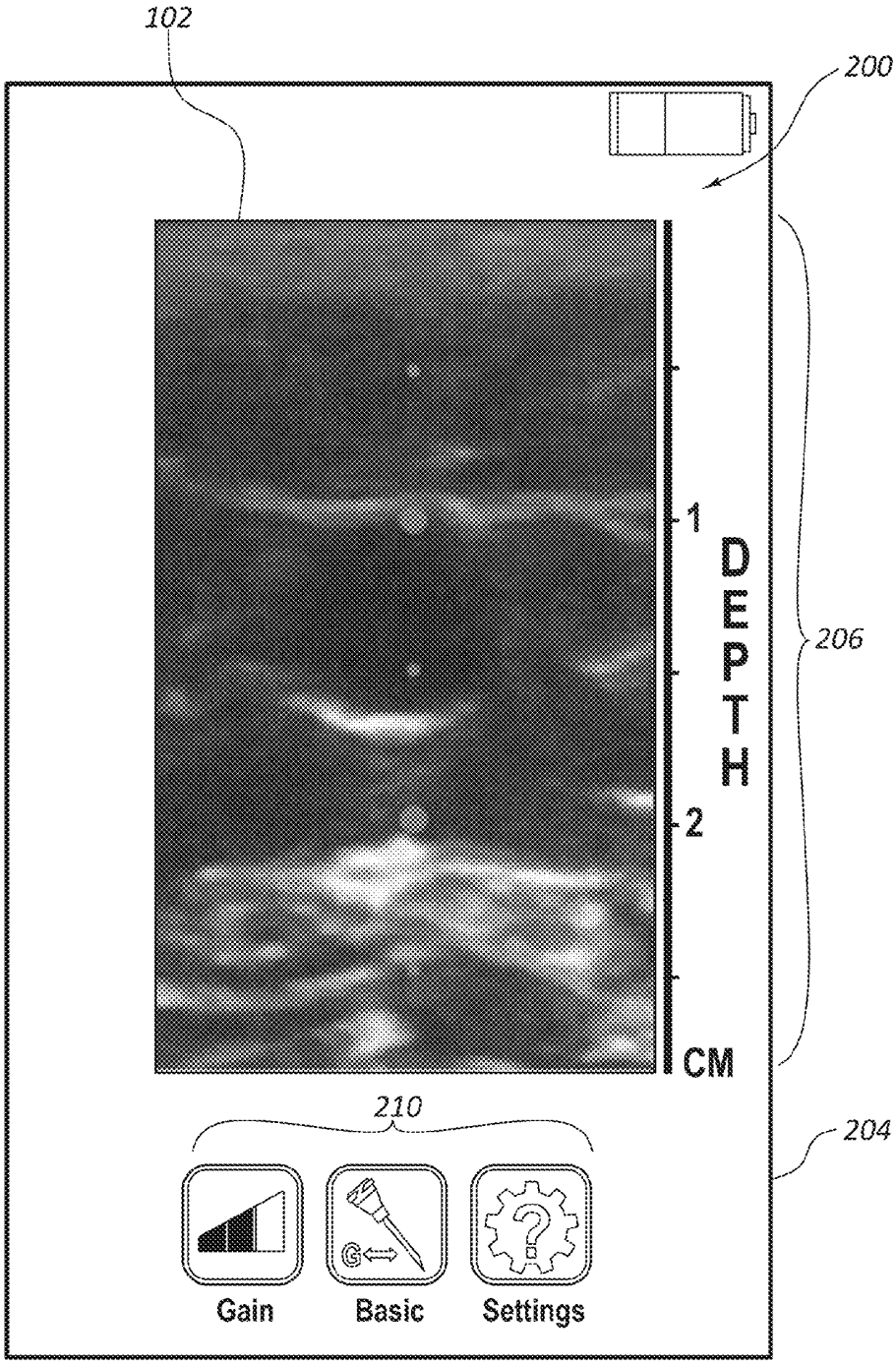


FIG. 12A

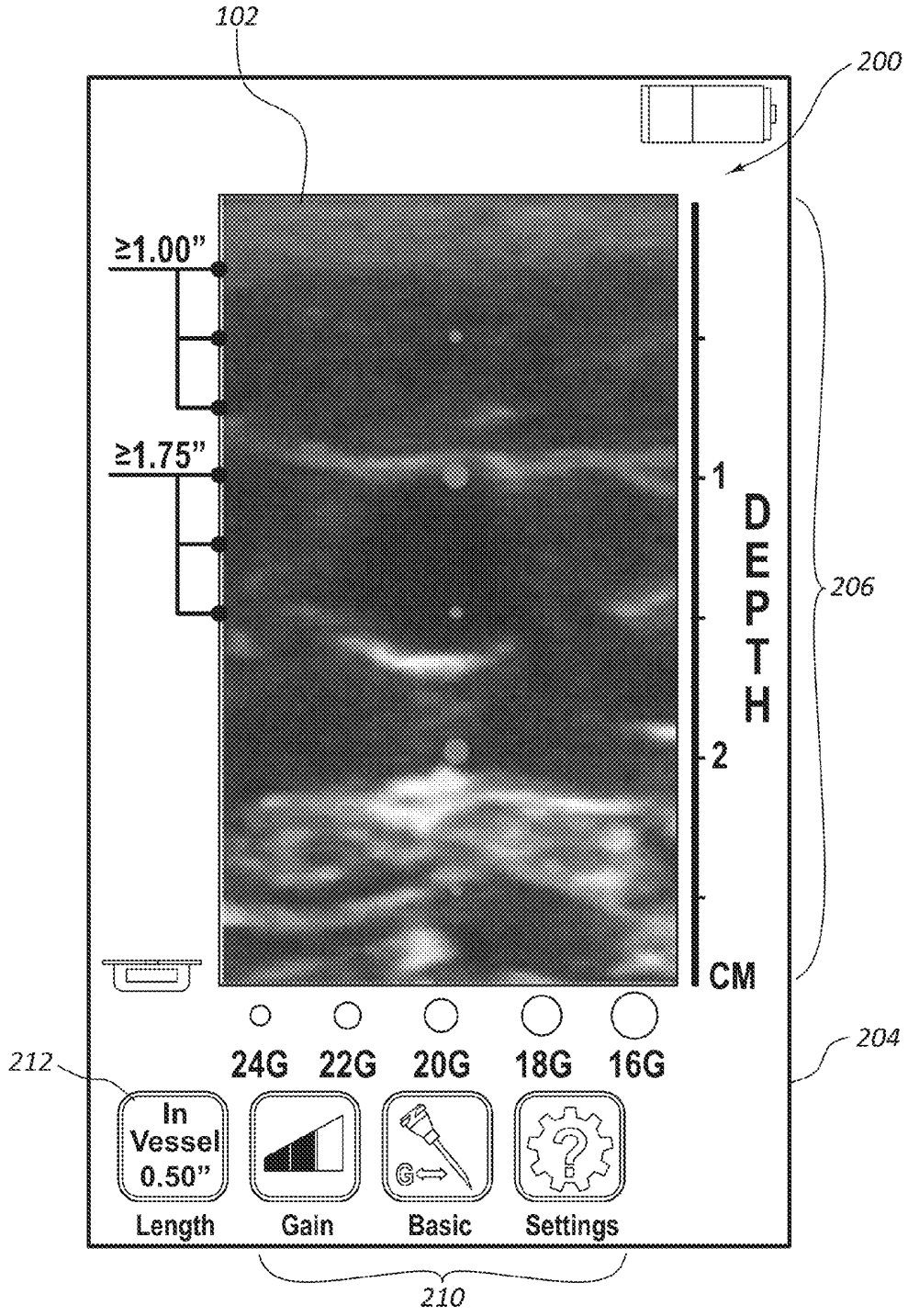

102
200
≥1.00"
≥1.75"
1
2
DEPTH
CM
206
24G
22G
20G
18G
16G
204
212
In Vessel 0.50"
Length
Gain
Basic
Settings
210

FIG. 12B

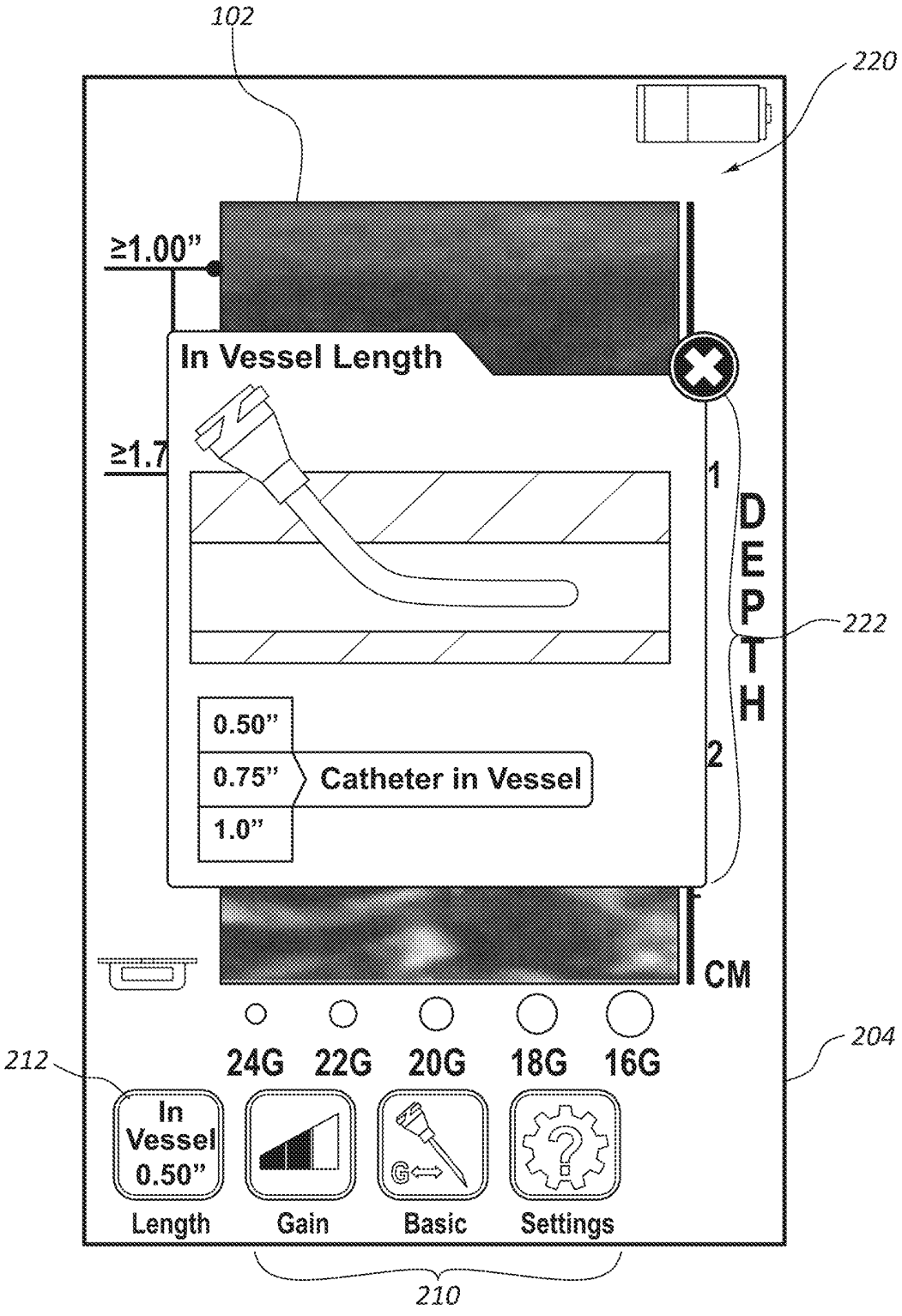

102
220
≥1.00"
In Vessel Length
≥1.7
1
DEPTH
222
2
0.50"
0.75"
Catheter in Vessel
1.0"
CM
24G
22G
20G
18G
16G
204
212
In Vessel 0.50"
Length
Gain
Basic
Settings
210

FIG. 12C

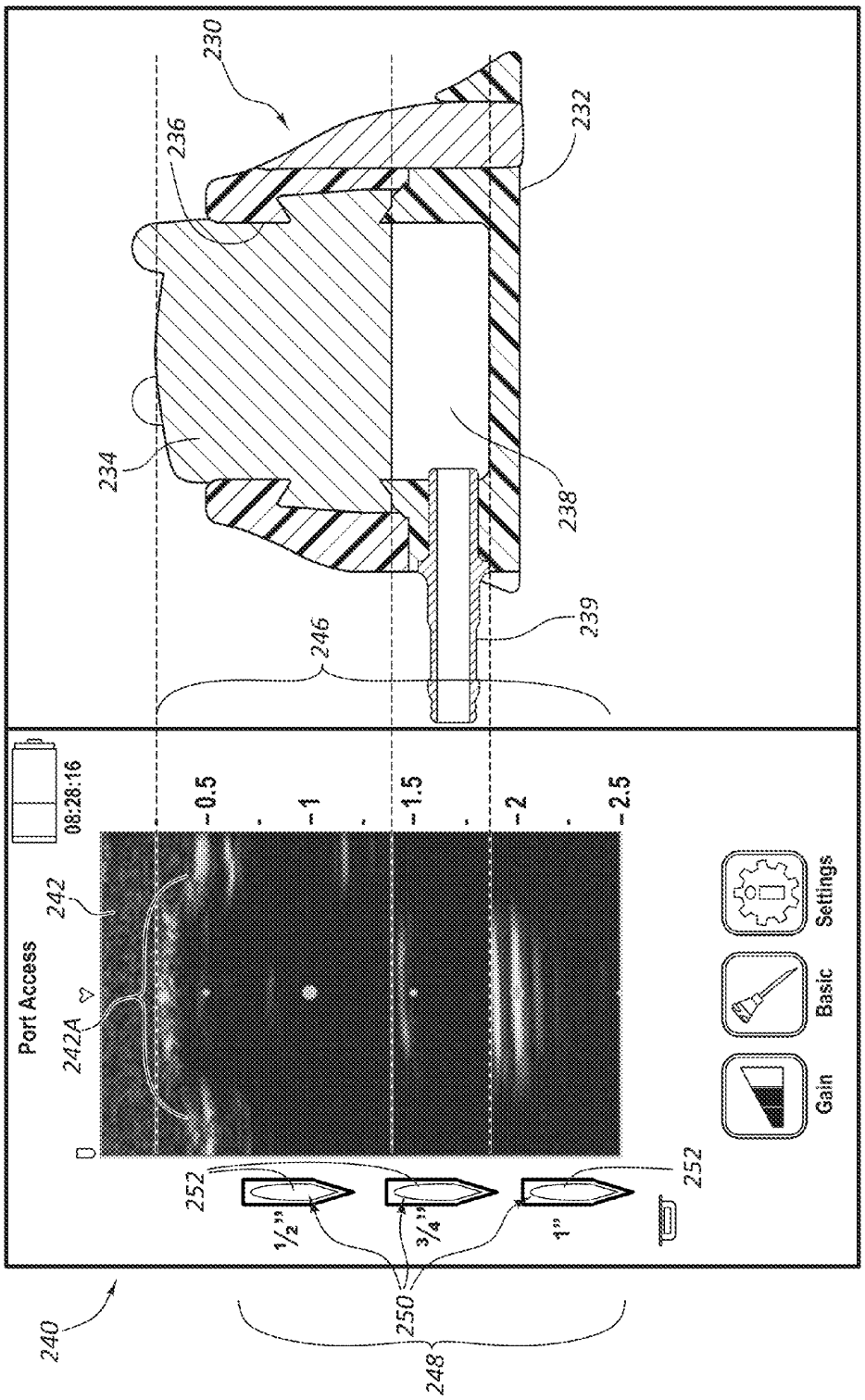

230
236
232
234
238
239
246
08:28:16
-0.5
-1
-1.5
-2
-2.5
Port Access
242
242A
0
252
252
1/2"
3/4"
1"
Gain
Basic
Settings
240
250
248

FIG. 13

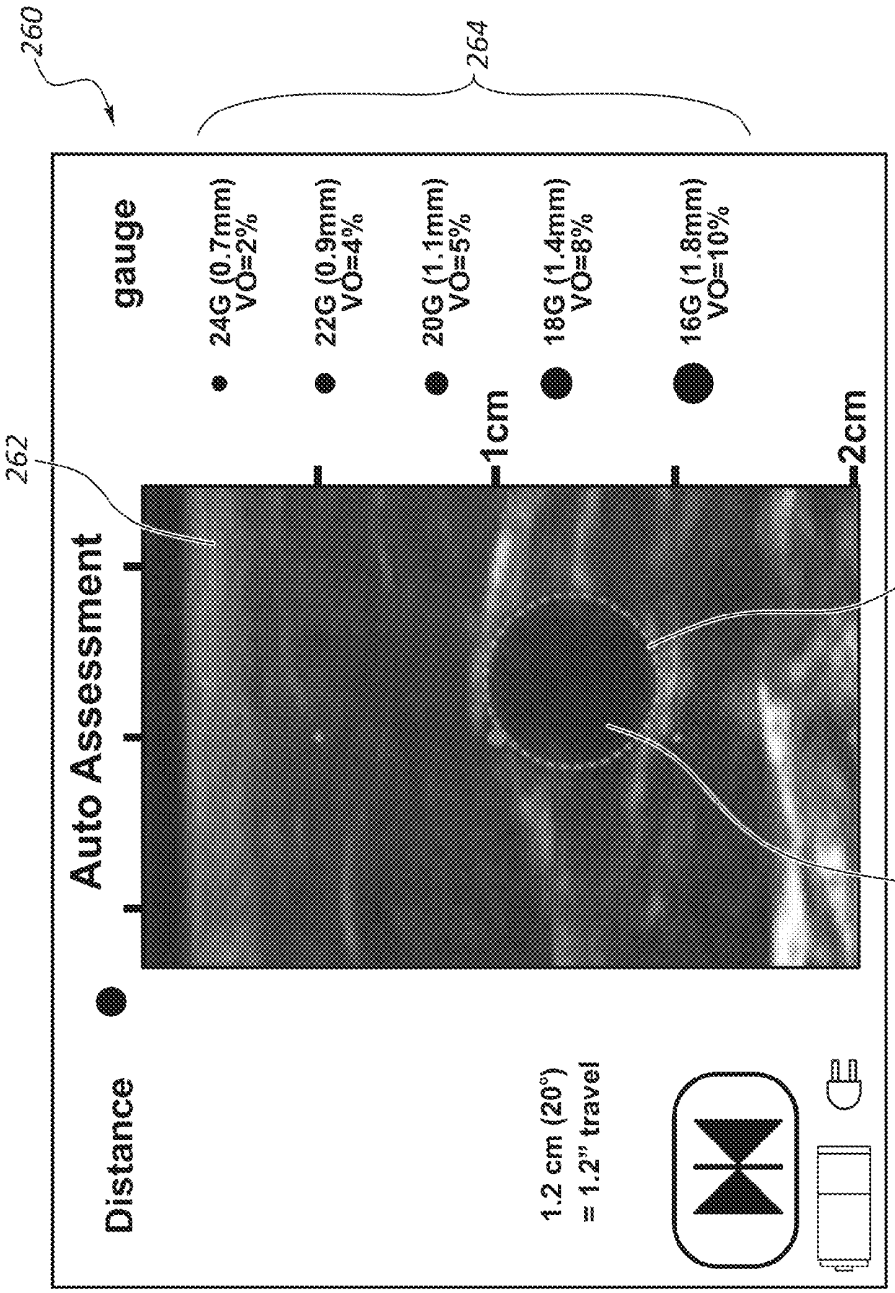

260
264
gauge
24G (0.7mm) VO=2%
22G (0.9mm) VO=4%
20G (1.1mm) VO=5%
18G (1.4mm) VO=8%
16G (1.8mm) VO=10%
1cm
2cm
262
Auto Assessment
268
262A
Distance
1.2 cm (20°) = 1.2" travel

FIG. 14

SYSTEMS AND METHODS FOR ULTRASOUND-BASED MEDICAL DEVICE ASSESSMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 61/550,332, filed Oct. 21, 2011, and titled "System and Method for Ultrasound-Based Medical Device Assessment," which is incorporated herein by reference in its entirety.

BRIEF SUMMARY

[0002] Briefly summarized, embodiments of the present invention are directed to systems and methods for assisting the placement of a medical device, such as a catheter, within a vessel or other suitable location within the body of a patient through the use of an ultrasound imaging system. In particular, the systems and methods described herein enable a clinician to determine, prior to insertion of the medical device, how much of the device will be disposed within the vessel, thus enabling the clinician to choose a catheter with suitable length so as to ensure a sufficient portion of the catheter is disposed within the vessel.

[0003] In one embodiment, an ultrasound imaging system for assisting with placement of a medical device near a target location within a body of a patient is disclosed. The system comprises a console, a probe including a needle guide that produces an ultrasound image of the target location, and a processor. The processor provides to a user proximity information relating to the anticipated proximity of the medical device to the target location prior to insertion of the medical device into the body. A display is also included for depicting the ultrasound image, depth information of the target location, and the proximity information of the medical device with respect to the target location. In one embodiment, the medical device is a catheter. In this case, the proximity information relates to the amount of a distal portion of the catheter that would be disposed within the vessel when the catheter is inserted into the body. In another embodiment, the proximity information relates to whether an access needle that is to be inserted into the body to access an implanted access port is sufficiently long as to adequately access a fluid reservoir of the port.

[0004] These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0006] FIG. **1** is a perspective view of a portable ultrasound imaging system that serves as one possible environment in which embodiments of the present invention can be practiced;

[0007] FIG. **2** is a block diagram showing various components of the ultrasound imaging system of FIG. **1**;

[0008] FIG. **3** is a cross sectional side view of an ultrasound probe of the system of FIG. **1** during use;

[0009] FIG. **4** is a cross sectional side view of a catheter disposed in a vessel;

[0010] FIG. **5** shows a depiction on the display of the system of FIG. **1** according to one embodiment;

[0011] FIG. **6** shows a depiction on the display of the system of FIG. **1** according to one embodiment;

[0012] FIG. **7** shows a depiction on the display of the system of FIG. **1** according to one embodiment;

[0013] FIG. **8** is a lookup table used by the system of FIG. **1** according to one embodiment;

[0014] FIGS. **9A-9C** show various depictions on the display of the system of FIG. **1** according to one embodiment; and

[0015] FIG. **10** shows a flowchart including various stages for the insertion of a medical device within the body of a patient, according to one embodiment.

[0016] FIG. **11** shows various gauge sizes for medical devices for use with the system of FIG. **1**;

[0017] FIGS. **12A-12C** shows various depictions on the display of the system of FIG. **1** according to one embodiment;

[0018] FIG. **13** shows a depiction on the display of the system of FIG. **1** together with a cross sectional view of an implantable access port according to one embodiment; and

[0019] FIG. **14** shows a depiction on the display of the system of FIG. **1** according to one embodiment.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

[0020] Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

[0021] For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

[0022] Embodiments of the present invention are generally directed to methods for assisting the placement of an elongate medical device, such as a catheter, within a vessel or other suitable location within the body of a patient through the use of an ultrasound imaging system. In particular, the systems and methods described herein enable a clinician to determine, prior to insertion of the medical device, how much of the device will be disposed within the vessel, thus enabling the clinician to choose a catheter with suitable length so as to ensure a sufficient portion of the catheter is disposed within the vessel.

[0023] In another embodiment, color-coded icons, each representing a cross sectional size of a corresponding catheter or other suitable device, are depicted on a display of the ultrasound imaging system, together with and in relation to an ultrasound image of the vessel to be accessed. The color-

coding of the catheter icons enables the clinician to readily identify which size of catheter will be most suitable for insertion into the imaged vessel.

[0024] In addition, in one embodiment, the color-coded icons are scalable in size according to scale of the accompanying ultrasound image so as to preserve a 1:1 relationship in size. As such, the clinician is able to discern the cross sectional size of one or more catheters represented by their corresponding icons in scalar relation to the cross sectional image of the vessel depicted on the display of the ultrasound imaging system, and thus choose a catheter of suitable gauge for subsequent insertion into the ultrasonically imaged vessel.

[0025] FIG. **1** shows various components of an ultrasound imaging system **10**, according to one embodiment. As shown, the system **10** includes a console **20** housing various electronic and other components necessary for processing and depicting ultrasonic images. The console **20** includes a touchscreen display **30** for depicting ultrasonic images and for enabling touch-based input by a clinician to control the device and its functionality. A probe **40**, containing one or more transducer elements in a head **44** thereof for emitting and receiving ultrasonic signals, is operably attached to the console **20** via a cable or other suitable interface.

[0026] An optional cap **50** is shown for removable attachment to the head **44** of the probe **40** so as to cover the transducer elements disposed therein. The cap in one embodiment includes a hydrogel insert for providing an ultrasonically transparent interface between the probe head **44** and the skin surface. A needle guide **60** is slidably attached to the cap **50** to assist with guiding needles through the patient's skin and into the vessel being imaged by the system **10**. Further details regarding the probe cap, hydrogel insert, and needle guide can be found in U.S. patent application Ser. No. 13/206,396, filed Aug. 9, 2011, and entitled "Support and Cover Structures for an Ultrasound Probe Head," and Ser. No. 13/531,406, filed Jun. 22, 2012, and entitled "Needle Guide with Selectable Aspects." Each of the foregoing applications is incorporated herein by reference in its entirety. Note that other ultrasound imaging devices and systems that differ from that shown here can also benefit from the embodiments described herein.

[0027] FIG. **2** shows a block diagram of the system **10** of FIG. **1**, according to one embodiment. In detail, the console **20**, display **30**, and probe **40** are represented, as in FIG. **1**. The console **20** includes therein a motherboard **64** for governing system functionality and includes a processor or other general or special purpose computer, memory, storage locations, and other components for system operation. A power button **66** is included, as are USB ports **68** for interfacing with other devices. An external power supply **70**, as well as a battery **72** and speaker **74**, are provided for operation. The display **30** in the present embodiment includes an LCD screen **78** or other suitable screen, and a touchscreen **80** to enable touch-based functionality via the display **30**. Note that the system **10** can include different, fewer, or more components than those listed here, including those components that enable the system to operate in a networked manner with other local or remote computing or network systems.

[0028] FIG. **3** shows use of the system **10** in accessing a vessel **86** with a needle **84** in preparation for inserting a catheter into the vessel. The probe **40**, equipped with the head-covering cap **50** and attached needle guide **60**, is placed against the skin so as to ultrasonically image a slice of internal body tissue of the patient below the surface of the skin **82**. Indeed, a target location **88** of the vessel **86** imaged by the probe **40** is disposed a substantially vertical depth x below the end of the probe, corresponding to the skin surface **82**. Though shown here as a central portion of the vessel **86**, the target location **88** can be any one of various subcutaneous locations within the body.

[0029] The needle **84**, disposed in the needle guide **60**, follows an angled catheter insertion path a distance y to intercept the target location **88**. This catheter insertion path, initially defined by the needle **84**, is the same path to be followed by the catheter in order to gain access to and enter into the vessel **86**. The vertical depth x from probe head **44** to the target location **88** can be calculated by a processor or other suitable component of the motherboard **64** of the system **10**. Further, the system **10** can be loaded with appropriate data to know the distance y of the catheter insertion path to reach a given target location **88** at a depth x. In the present embodiment, these data are known by virtue of the position of the needle guide with respect to the probe head **44** and the angles in which the needle **84** can be oriented in the needle guide **60** in order to enable the needle to intercept the target location **88**. As mentioned, such data can be loaded into the system memory for use by the processor during ultrasonic imaging, as will be described. In another embodiment, the system computes the distance y in real time based on the vertical depth x and other relevant factors.

[0030] FIG. **4** shows a catheter **90**, including a hub **92**, disposed along the catheter insertion path (FIG. **3**) of length y so that a distal portion of the catheter corresponding to a length z is disposed within the vessel **86**, approximately extending from the target location **88**. So disposed, the catheter hub **92** is positioned proximate the skin surface **82**. In accordance with one embodiment, the system **10** is configured to inform a user prior to catheter placement how much of a catheter of a given overall length will be disposed in the vessel **88** after placement is complete. The length of the catheter portion disposed within the vessel **88** is indicated in FIG. **4** by z. This in turn enables a user of the system **10** to choose an appropriate catheter length prior to actual insertion of the catheter into the patient so as to ensure that a sufficient portion of the catheter is disposed within the vessel. Note that while the following discussion focuses on placement of a catheter into a vessel, the principles described herein can be applied to the placement of other elongate and various medical devices, including various needles, catheters, access ports, etc.

[0031] FIG. **5** shows a depiction **100** as depicted on the display **30** of the ultrasound imaging system **10** (FIG. **1**) during operation thereof. An ultrasound image **102** is shown, including an image **102**A of a vessel in cross section. The imaged vessel **102**A shown here corresponds to the vessel **86** shown in FIG. **3**, for example, though it is appreciated that the imaged item can be one of a variety of types of subcutaneous body features. A gauge icon field **104** is disposed below the ultrasound image **102** and includes a plurality of icons that each represent a cross sectional size, in gauge, of a catheter of the indicated size that is commonly available for insertion into the vessel via a catheter placement procedure. This assists the user in ascertaining an appropriately gauged catheter for insertion into the vessel represented by the vessel image **102**A on the ultrasound image **102**. Also shown are depth demarcations **106** (in cm) arranged along the image right border and corresponding depth markers **107** superimposed on the image **102** itself to assist the clinician in determining the depth of the vessel image **102**A or other imaged

feature. Note that the motherboard **64** (FIG. **2**) or sub-component thereof determines the depth of the vessel image **102**A, indicated at x in FIG. **3** as discussed. The depth of the vessel represented by the image **102**A is readily seen by consulting the depth demarcations **106** to the right of the ultrasound image **102**

[0032] As mentioned, the icons of the gauge icon field **104** represent cross sectional gauge sizes of, in this embodiment, various peripheral IV ("PIV") catheters used for providing vascular access to a patient. The gauge icons are color coded in accordance with a standardized color coding scheme that indicates the particular size of various PIV catheters. As will be seen, however, the icon field **104** can include color-coded icons representative of other medical devices designed for insertion into the patient body, such as dialysis catheters, blood draw needles, guidewire devices, port access needles, arterial lines, etc. Thus, the size, shape, and color of the icons can vary according to the catheter or other medical device the icons are configured to represent. As such, the discussion here should not be understood to limit the present disclosure in any way. Also, the particular colors shown can vary according to need, desire, convention, device type, etc.

[0033] In one embodiment, it is appreciated that the size of the icons in the field **104** can vary according to the scale of the ultrasound image **102** as to preserve a 1:1 size ratio therebetween. For example, the user of the system **10** can selectively increase the magnification of the ultrasound image **102** to double its previous size. When this occurs, the system **10** includes functionality to correspondingly scale, or alter the size of, the icons in the field **104** such that the icon size as depicted corresponds with the size of the vessel image **102**A and other imaged features depicted on the display **30**.

[0034] In another embodiment, the system **10** is configured to change the depth markers **107** to a particular icon when that icon is touched or otherwise selected by the user on the display **30**. For instance, if the "**20**G" icon of the field **104** is pressed on the display **30** by the user, each of the four depth markers **107** that are overlaid atop the ultrasound image **102** will temporarily be replaced by a gauge icon of identical size and color as the "**20**G" icon of the icon field **104**. This places the corresponding gauge icon in close proximity to the vessel image **102**A and thus enables the user to more easily see how much of the vessel would be occupied by the selected catheter gauge size. The icon replacement of the depth markers **107** would last for a predetermined time, such as three seconds, in one embodiment, though this can be varied. In another embodiment, the icons can replace the depth markers indefinitely, or until user input deselects them.

[0035] In accordance with the present embodiment, FIG. **5** also gives details regarding the ability of the system **10** in one embodiment to provide information to the user regarding the amount of a catheter or other elongate medical device that can be disposed within the imaged vessel prior to actual catheter insertion into the vessel. As shown on the depiction **100** of FIG. **5**, an in-vessel catheter length field **108** is shown on the left border of the ultrasound image **102**, indicating the length of the portion of the catheter that would be disposed within an imaged vessel disposed at a plurality of discrete depths depicted in the image. When the system is in the in-vessel catheter length mode, an icon **108**A is displayed on the display **30** together with the in-vessel catheter length field **108**. Note that the display also depicts a clock icon **114** and a battery level indicator **116**, though other icons/information can be optionally depicted on the display.

[0036] The particular in-vessel lengths shown in the field **108** are dependent upon the total catheter length selected, which is shown in a catheter length selection button **112** residing in a control button field **110** below the gauge icon field **104**, though other locations are possible. The control button field **110** also contains additional control buttons **110**A to govern other system processes, such as system settings, saving the ultrasound image, etc. As shown in the present example of FIG. **5**, the total catheter length as indicated by the catheter length selection button **112** is 1.88 inches; thus, each of the depths marked in the in-vessel catheter length field **108** indicate the length of the portion of the 1.88 inch-long catheter that would be disposed in a vessel located at the below-skin depth as indicated by the depth demarcations **106**, i.e., the distance x on FIG. **3**.

[0037] For instance, as shown in the ultrasound image **102** of depiction **100** of FIG. **5**, the imaged vessel **102**A is shown at about **1** cm in depth, as indicated by the image depth demarcations **106** on the right side of the image. The catheter length selection button **112** indicates that a **1.88** inch total-length catheter has been selected. Thus, for a 1.88 inch total-length catheter, the user can see from the in-vessel catheter length field **108** disposed on the left side of the ultrasound image **102** that approximately 1.3 inches of the catheter would be disposed within the imaged vessel **102**A if the catheter were to be inserted therein. As seen in FIG. **4**, the remainder portion of the catheter would be taken up by the angled insertion path (indicated by y) between the skin surface **82** and the target location **88** where the catheter enters the vessel wall. Note that this information is provided before the catheter is inserted, thus enabling the clinician to select the proper catheter length before vascular access is attempted. As noted above in connection with FIG. **3**, the ability of the system **10** to calculate the depth x of the vessel, together with knowledge of the length y of the needle/catheter insertion path, enables the system to determine the amount of catheter length to be disposed within the vessel **86** beginning at the target location **88** for a catheter inserted along the insertion path, prior to actual catheter insertion.

[0038] The overall length of the catheter represented and depicted by the system **10** can be selected by the user, in the present embodiment. FIG. **6** shows a depiction **120** as one example of an interface that enables the user to select one or more possible catheter lengths that can be toggled through by the user in order to select a catheter having sufficient length to reside within the imaged vessel. In particular, the depiction **120** of FIG. **6** shows a touchscreen interface including a catheter length selection field **122** listing the available catheter lengths as buttons **124** that can be toggled on or off by the user. If a particular catheter length option is toggled off, the user will not be able to select that length as an option via the catheter length selection button **112** on the depiction **100** of FIG. **5**. Also shown in the depiction **120** is a length-in-vessel unit selection field **126** to show the amount of catheter in the vessel in either a length measurement or as a percentage of overall catheter length, and a unit selection field **128** to select the dimensional units for the gauge and catheter length. Thus, it is seen that the touch screen interface shown here enables a clinician to select which available catheter lengths can be used by the device **10** to calculate the length of the catheter residing within the vessel when the catheter is disposed therein. Once the present depiction is cancelled and the depiction **100** of FIG. **5** returns, the overall catheter length indicated in the catheter length selection button **112** defaults to

the smallest catheter length among those previously selected from the field **122** of FIG. **6**, in one embodiment.

[0039] FIG. **7** shows a depiction **130** disclosing another possible user interface for selecting operational aspects of the system **10**. In addition to the catheter length selection field **122** and units selection field **128** already discussed, the depiction **130** includes a procedure selection field **132**, where a user can select which type of procedure for which the system **10** will be used in assisting in the placement of a medical device into the body of the patient. Such procedures include PIV, dialysis, blood draw, etc., and employ catheters or needles. This enables the user to select the desired procedure, which then enables the system **10** to depict the procedure-specific gauge icon field **104** and to depict in the length selection field **122** the available lengths of catheters or needles to be used for the procedure, which lengths can be selected by the clinician, as just described. The selected lengths will then be available for call-up on the display **30** during the procedure via the length selection button **112** shown in FIG. **5** and used in a manner similar to that described above in connection with that figure. As such, the system **10** and associated methods described herein can be employed for a variety of procedures involving vascular access by a medical device, including devices not explicitly set forth herein.

[0040] Reference is now made to FIG. **8**, which depicts a lookup table **140** used by the system **10** in displaying the in-vessel catheter lengths shown in the in-vessel catheter length field **108** (FIG. **5**) in accordance with one embodiment. As shown, the table **140** includes a set of possible catheter length values **142**, which correspond with the available catheter lengths shown in the catheter length selection field **122** of FIGS. **6** and **7**. Note that in the embodiment of FIG. **6**, only one procedure, i.e., peripheral IV catheter insertion, is selectable on the system **10**; as such, only one lookup table, e.g., table **140** of FIG. **8** is included in the system. In the embodiment shown in FIG. **7**, multiple procedures are possible, as shown in the procedure selection field **132**; thus, one lookup table for each procedure may be included in the system **10** in this case. In one embodiment, the lookup table **140** is stored in a memory/storage location located on or in operable communication with the motherboard **64** (FIG. **2**).

[0041] The table **140** of FIG. **8** further includes a set of needle guide depth values **144** that indicate the angle and depth at which a catheter, such as the catheter **90** shown in FIG. **4**, will intercept a target location, such as a vessel as indicated by the target location **88** shown in FIG. **3**. The values **144** shown in FIG. **8** thus represent the target location depth x (FIG. **3**). As it assumes that the catheter will be inserted along the angled insertion path of length y, which path is first established via insertion of a needle through the needle guide **60**, the system **10** regards the depths listed in **144** as accurate.

[0042] Thus, when a user selects a particular overall catheter length via the catheter length selection button **112** (FIG. **5**) during imaging of a vessel, the system **10**, via its motherboard processor or other suitable component, can access the lookup table **140** for the selected catheter length. Then, for each of the listed target location depth values **144**, the system **10** can depict a corresponding column of the length-in-vessel values **146**, which each indicate the length of the portion of the catheter that would reside within the imaged vessel if the catheter having the selected overall length (set **142**) were placed in a vessel at the target location at the corresponding depth (set **144**). These length-in-vessel values are also referred to herein as proximity information or data.

[0043] These length-in-vessel values **146** for the selected overall catheter length are then depicted on the display **30** in the in-vessel catheter length field **108** as shown in FIG. **5**, or in some other suitable location. With this and the other information depicted on display **30** of FIG. **5**, the user can decide whether the currently selected catheter is long enough to suitable dwell in the imaged vessel **102**A. If not, the user can press the catheter length selection button **112** and change the selected catheter length while continuing to image the vessel **102**A. The system will then access the lookup table (FIG. **8**) and acquire the length-in-vessel values **146** that correspond to the newly selected overall catheter length from the possible lengths **142**. The display **30** will be refreshed to depict the new length-in-vessel values in the in-vessel catheter length field **108** for each of the depth values **144** of the table **140**. Note that the number of possible depth values **144**, overall catheter length values **142**, and corresponding length-in-vessel values **146** can vary according to type of procedure, size range of catheters, type of medical device to be inserted, etc.

[0044] As mentioned above, during use of the system **10** the user can toggle between the various catheter lengths, previously selected via the interface shown in the depictions of FIG. **6** or **7** for example, in order to determine the amount of catheter (or other suitable medical device) that will remain in the vessel after placement thereof. FIGS. **9**A-**9**C show one example of such toggling, wherein the catheter length is selected by the clinician via successive pressing of the catheter length selection button **112**, which toggles between the length selections of 1.16 inches (FIG. **9**A), 1.75 inches (FIG. **9**B), and no selected catheter length (FIG. **9**C). As further shown in FIGS. **9**A-**9**C, the amounts of catheter length in the vessel as seen in the in-vessel catheter length field **108** vary according to the particular catheter length selected, corresponding with the data in the lookup table **140** of FIG. **8**. Note that when no catheter length is selected in the selection button **112**, the in-vessel length field **108** is unpopulated. Note further that the particular units shown for vessel depth, catheter length, etc. can vary from what is shown and described herein.

[0045] FIG. **10** shows a flowchart **160** of a typical catheter insertion procedure using the system **10** and methods described herein. It is assumed here that a peripheral IV catheter insertion procedure will be performed. If more than one procedure can be assisted by use of the system **10**, an initial selection of the desired procedure via procedure selection field **132** would be performed by using the interface depicted in the depiction **130** of FIG. **7**. The selection of the desired units in which measurements are to be displayed (fields **126** and **128** in FIGS. **6** and **7**) can also be made at this point, if necessary.

[0046] At stage **162**, a user determines the catheter gauge needed for the catheter insertion procedure. At stage **164**, the ultrasound imaging system **10** (FIG. **1**) is employed to image a vessel or other subcutaneous object and determine a target location (FIG. **3**). At stage **166**, the system **10** is employed to determine whether the initially selected catheter gauge will fit in the imaged vessel and whether the vessel can be reached by any one of the available catheter lengths. If not, another vessel that meets these requirements is searched for.

[0047] If the answer to the inquiry at stage **166** is yes, stage **168** is executed wherein the system **10** is employed to determine an ideal overall catheter length that disposes a desirable portion of the catheter within the vessel, as has been described

above in connection with FIGS. **3**-**9**C and which conforms to any requirements or procedures of the user. At stage **170**, a skin insertion site is marked, after which a catheter of proper overall length and gauge as previously indicated by the system **10** is acquired in stage **172**. At stage **174**, the particular guide channel of the needle guide (such as needle guide **60** of FIG. **3** that includes three guide channels for accessing three unique target depths) is selected so as to guide a needle to the proper depth to intercept the targeted vessel. Any necessary adjustment of the needle guide can be performed at this stage.

[0048] The skin insertion site is prepped at stage **176**, and at stage **178** the peripheral IV catheter-equipped needle is inserted through the needle guide, into the patient's skin, and proceeds along the insertion path (FIG. **3**) to intercept the targeted vessel and insert the catheter the desired distance into the vessel, as was anticipated and planned for prior to inserted by use of the system **10**. The ultrasound imaging of the system **10** can be employed to help guide the needle into the vessel, in one embodiment. At stage **180**, the needle is removed from the needle guide and the placement procedure is completed according to protocol.

[0049] FIG. **11** shows some of the common catheter/needle gauge sizes for example procedures with which the system **10** can be employed to assist in device placement, including peripheral IV catheter gauge icons **190**, dialysis catheter gauge icons **192**, blood draw needle gauge icons **194**, an intermediate dwell catheter gauge icons **196**. These icons can be depicted in the gauge icon field **104** (FIG. **5**), as has been described. Note that many other catheters, needles, and other suitable medical devices can be placed using the system **10** as described herein.

[0050] Reference is now made to FIGS. **12**A-**12**C, which shows a depiction **200** of the present system according to another embodiment. The depiction is similar in various respects to previous depictions as shown in FIG. **12**A, including the ultrasound image **102**, an imaged vessel **102**A, a control button field **210**, depth demarcations **206**, and a gauge icon field **204**. In contrast to the above discussion in connection with FIGS. **3**-**9**C, however, in the present embodiment the system **10** can be configured such that the user inputs the desired amount of catheter length to be disposed within the imaged vessel. This can be done in the present embodiment by toggling the catheter length-in-vessel selection button **212** shown in FIG. **12**B. The system **10**, having calculated the depth of the vessel (x in FIG. **3**) and knowing the distance of the angled insertion path (y in FIG. **3**), can then inform the clinician as to the catheter(s) having overall lengths sufficient to provide at least the desired length of catheter within the vessel. This information is displayed to the left of the ultrasound image **102** in a suggested catheter length field **208**, as shown in FIG. **12**B. FIG. **12**C shows an optional depiction **220** wherein a catheter length-in-vessel selection field **222** is shown. Such a field would be employed by the user to select how much of a catheter to be placed would occupy the vessel interior. The selection made by the user from the selection field **222** would then be displayed in the catheter length-in-vessel selection button **212**. Of course, other selection and depiction schemes for such user selections can be employed. Optionally, the system **10** in one embodiment can recommend only a single catheter having the best fit for the desired amount of catheter to remain in the vessel.

[0051] Reference is made to FIG. **13**, which depicts use of the system **10** in inserting a needle into an implanted access port within the patient's body, according to one embodiment. An example access port **230** is shown on the right side of FIG. **13** and includes a body **232** and a septum **234** disposed in an opening **236** that is defined by the port body. The septum **234** provides needle-penetrable access to a reservoir **238**. A stem **239** provides a fluid outlet for the reservoir **238**. Thus, the access port **230** can be used in providing fluid medicaments to a patient by inserting a needle through the patient skin and into the septum **234** such that the distal opening of the needle resides within the reservoir. Fluid can then be passed from the needle distal opening into the reservoir **238**, where it can then exit the reservoir through the stem **239** and pass into the patient body via a catheter connected to the stem.

[0052] On the left side of FIG. **13** is a depiction **240** from the display **30** of the system **10** according to the present embodiment. As shown, an ultrasound image **242** is depicted, which includes an image of a port **242**A. The imaged port **242**A in the ultrasound image **242** corresponds with the port **230**, which is shown here for reference purposes. The various features of the port **230** can be seen ultrasonically in the ultrasonic port image **242**A as indicated by the horizontal dash lines extending between the actual and imaged port, including the top of the septum **234**, the bottom of the septum, and the bottom surface of the reservoir **238**.

[0053] The depiction **240** includes depth demarcations on the right side of the ultrasound image **242** for use in determining the depth of the imaged port **242**A under the patient skin. The depiction further includes a needle depth field **248** along the left side of the ultrasound image **242** that provides proximity information regarding possible needle lengths that may be used to access the implanted port. Particularly, the needle depth field **248** includes a plurality of needle depth icons **250** that can indicate to a user the depth to which select needles of different lengths would descend in accessing the imaged port **242**A. The needle depth icons **250** are aligned next to the ultrasound image **242** to show how deep a needle of the indicated length would reach in accessing the imaged port **242**A. Specifically, each needle depth icon **250** includes an image of a distal opening **252** of the needle which further assists the user in determining when the distal opening is sufficiently disposed within the port reservoir so as to suitably infuse fluids therethrough.

[0054] For instance, it is seen from the depiction **240** that a needle of length ½ inch piercing the skin and vertically pressed down into the imaged port **242**A would not descend sufficiently far to penetrate through the bottom of the port septum, while a of ¾ inch length would successfully pierce the entire septum. Thus, the user is able to determine the proper length of needle to use in accessing the implanted port prior to needle insertion. This functionality is enabled by virtue of the ability of the system **10** to determine the depth of the implanted port and to visually distinguish the port features of interest, including the septum and the reservoir. In the present embodiment, the size of the needle depth icons **250** are scalable with the ultrasound image **242** in a 1:1 ratio so as to preserve the ability to determine a suitable needle depth. This embodiment thus serves as but one example of where the system **10** can be employed in assisting with the insertion of medical devices other than catheters. Other examples are also contemplated.

[0055] Reference is made to FIG. **14**, which shows a depiction **260** by the display **30** of the system **10** according to one embodiment. As shown, the depiction includes an ultrasound image **262** and an imaged vessel **262**A. A gauge icon field **264** is disposed to the right of the ultrasound image **262**. In the

present embodiment it is appreciated that a processor or other suitable component of the motherboard **64** of system **10** (FIG. **2**) can execute one or more algorithms to automatically detect the presence of a vessel in the ultrasound image **262** captured by the system **10** during operation. These algorithms take advantage of the fact that blood vessels represent a rapid gradient change compared to surrounding tissue when viewed ultrasonically, due to the relative density difference between the two. Further, vessels are typically round and possess a relatively ultrasonically homogenous interior structure, which further assist algorithms in detecting vessels in an ultrasonic image.

[0056] In one embodiment vessel detection is an automated process. First, a data set represented by the ultrasonic image is presented for analysis. Vessel and tissue boundaries are detected via application of an edge detection filter, such as a Canny or Sobel filter. Convolution is then applied to the resultant data set of identified candidate vessels to map approximated centers of the vessels. Multiple circle kernels may be applied during convolution corresponding to known or likely vessel diameters.

[0057] Once the centers of the candidate vessels are determined, a radially expanding edge detection mapping process is performed to identify one or more maximum gradient transition points for each vessel. If the identified transition points are sufficiently close in proximity, a boundary will be established for the respective candidate vessel. The interior of the candidate vessel will then be analyzed to ensure sufficient image homogeneity exists therein. If so, the vessel is confirmed and the identified boundary thereof is highlighted or otherwise indicated. In the ultrasound image **262** of FIG. **14**, the boundary of the automatically identified vessel **262**A is indicated by highlighted perimeters **268**.

[0058] In another embodiment, a clinician can locate and touch the display **30** to indicate the approximate center of a vessel imaged by the system **10**. The system **10** can then execute the above edge detection mapping process and proceed from that point as described above.

[0059] The above examples of auto or user-assisted vessel/object detection can be used in one embodiment to provide further or more specific information to the user. For instance and as shown to the left of the ultrasound image **262** of FIG. **14**, the particular depth and/or distance to the detected vessel **268** can be identified and depicted. Also and as shown in the gauge icon field **264** on the right side of the ultrasound image **262**, the percentage amount of vessel occupation ("VO") for the detected vessel **268** can be displayed specific to the detected vessel. This further assists the user in choosing the properly-sized catheter/medical device to insert. These features can be employed on the embodiments described further above as well. For instance, in the embodiment described in connection with FIGS. **3-11**, depiction of the in-vessel catheter length field **108** could be limited to the in-vessel catheter length corresponding to a vessel (here, the vessel **102**A) that is automatically or semi-automatically identified in a manner similar to that described in connection with FIG. **14**.

[0060] It should be remembered that the ultrasound system disclosed herein is but one example of a system in which the present embodiments can be practiced; other devices and systems that produce and/or depict ultrasound images can also benefit from the principles described herein.

[0061] Embodiments described herein may comprise a special purpose or general-purpose computer including computer hardware, as discussed in greater detail below. Embodiments within the scope of the present disclosure also include computer-readable media for carrying or having computer-executable instructions or data structures stored thereon. Such computer-readable media can be any available media that can be accessed by a general purpose or special purpose computer. By way of example, and not limitation, computer-readable media can comprise physical (or recordable-type) computer-readable storage media, such as, RAM, ROM, EEPROM, CD-ROM or other optical disk storage, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store desired program code means in the form of computer-executable instructions or data structures and which can be accessed by a general purpose or special purpose computer.

[0062] A "network" is defined herein as one or more data links that enable the transport of electronic data between computer systems and/or modules. When information is transferred or provided over a network or another communications connection (either hardwired, wireless, or a combination of hardwired or wireless) to a computer, the computer properly views the connection as a computer-readable medium. Thus, by way of example, and not limitation, computer-readable media can also comprise a network or data links which can be used to carry or store desired program code means in the form of computer-executable instructions or data structures and which can be accessed by a general purpose or special purpose computer.

[0063] Computer-executable instructions comprise, for example, instructions and data which cause a general purpose computer, special purpose computer, or special purpose processing device to perform a certain function or group of functions. The computer executable instructions may be, for example, binaries, intermediate format instructions such as assembly language, or even source code. Although the subject matter has been described in language specific to structural features and/or methodological acts, it is to be understood that the subject matter defined in the appended claims is not necessarily limited to the described features or acts described above. Rather, the described features and acts are disclosed as example forms of implementing the claims.

[0064] Those skilled in the art will appreciate that the embodiments herein may be practiced in network computing environments with many types of computer system configurations, including, personal computers, desktop computers, laptop computers, message processors, hand-held devices, multi-processor systems, microprocessor-based or programmable consumer electronics, network PCs, minicomputers, mainframe computers, mobile telephones and devices, PDAs, pagers, and the like. The embodiments may also be practiced in distributed system environments where local and remote computer systems, which are linked (either by hardwired data links, wireless data links, or by a combination of hardwired and wireless data links) through a network, both perform tasks. In a distributed system environment, program modules may be located in both local and remote memory storage devices.

[0065] Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An ultrasound imaging system for assisting with placement of a medical device near a target location within a body of a patient, the system comprising:

a console;

a probe that produces an ultrasound image of the target location;

a processor that provides proximity information relating to anticipated proximity of the medical device to the target location prior to insertion of the medical device into the body; and

a display for depicting the ultrasound image and the proximity information of the medical device to the target location.

2. The system as defined in claim **1**, wherein the probe includes a needle guide, wherein the medical device includes an elongate device, and wherein the display further depicts depth information of the target location.

3. The system as defined in claim **2**, wherein the elongate medical device includes a catheter including an overall length, wherein the target location is a vessel, and wherein the proximity information relates to the amount of the overall length of the catheter that would be disposed within the vessel when the catheter is inserted into the body.

4. The system as defined in claim **3**, wherein a user can select different overall catheter lengths, and wherein the system calculates proximity information for each of the selected overall catheter lengths.

5. The system as defined in claim **4**, wherein, for each catheter length, the display depicts an in-vessel catheter length for each of a plurality of depths indicated for the ultrasound image.

6. The system as defined in claim **5**, wherein the display includes a touchscreen display, and wherein the display includes a button that enables toggling between the plurality of selected overall catheter lengths.

7. The system as defined in claim **6**, wherein the processor can access a storage location including a lookup table, the lookup table including an in-vessel catheter length for each of a plurality of depths of the ultrasound image.

8. The system as defined in claim **1**, further comprising a storage location where a lookup table is located, the lookup table including the proximity information for at least one medical device.

9. The system as defined in claim **1**, wherein the target location is a reservoir of an access port previously implanted within the body, wherein the medical device is an access needle for delivering fluids to the access port, and wherein the proximity information relates to the depth to which one or more needles of predetermined overall lengths will descend in relation to the depth of the access port.

10. The system as defined in claim **1**, wherein the medical device includes at least one of a catheter, an access needle, and an infusion needle.

11. The system as defined in claim **1**, wherein the ultrasound image is scalable in size and wherein the display includes a medical device size icon field that depicts various predetermined sizes of the medical device, the medical device size icon field being scalable so as to maintain a 1:1 ratio with the ultrasound image.

12. A method for conveying information from an ultrasound imaging system relating to insertion of a medical device into a patient body, the method comprising:

depicting an ultrasonic image of at least one target location within the patient body;

determining proximity information relating to anticipated proximity of the medical device to the target location prior to insertion of the medical device into the body; and

conveying the proximity information to a user.

13. The method for conveying as defined in claim **12**, wherein the medical device is an elongate medical device a portion of which is to reside within a vessel and wherein the proximity information includes vessel depth-dependant information relating to how much of the elongate medical device is to reside within the vessel.

14. The method for conveying as defined in claim **13**, wherein the elongate device is a catheter, and wherein the method further comprises determining proximity information for at least two catheters of differing overall lengths, the proximity information differing for each of the at least two catheters.

15. The method for conveying as defined in claim **14**, further comprising identifying the overall length of the at least two catheters via user input to the ultrasound imaging system.

16. The method for conveying as defined in claim **15**, wherein depicting the ultrasonic image of the at least one target further comprises:

automatically defining the vessel via an edge detection and convolution algorithm; and

visually highlighting the vessel on the depicted ultrasound image.

17. The method for conveying as defined in claim **15**, wherein depicting the ultrasonic image of the at least one target further comprises:

receiving user input to identify a central portion of the vessel; and

executing a convolution algorithm to define a boundary of the vessel.

18. The method for conveying as defined in claim **12**, wherein determining the proximity information further comprises:

accessing a lookup table disposed in a memory location to acquire the proximity information, the proximity information based on an assumed angled insertion path from a needle guide disposed on an ultrasound probe of the ultrasound imaging system.

19. The method for conveying as defined in claim **12**, wherein the proximity information is depicted on the display, and wherein determining the proximity information further comprises aligning the proximity information to depth information on the depiction of the ultrasound image.

20. The method for conveying as defined in claim **12**, wherein the medical device is a catheter a portion of which is to reside within a vessel and wherein the proximity information includes indications of overall lengths of catheters that are sufficiently long to access the depth of the target location when the catheter is inserted to the target location.

21. The method for conveying as defined in claim **20**, wherein the indications of overall catheter lengths are dependent upon user input regarding a desired amount of catheter length to de disposed within the vessel after insertion of the catheter is complete.

22. A computer-readable medium including computer executable code that, when executed, causes a general pur-

pose computer to perform the following in relation to the insertion of a medical device into a patient body:

depict on a display of an ultrasound imaging system an ultrasonic image of at least one target location within the patient body;

determine proximity information relating to anticipated proximity of the medical device to the target location prior to insertion of the medical device into the body; and

convey the proximity information to a user.

23. The computer-readable medium as defined in claim **22**, further including executable code to automatically execute an edge detection algorithm to detect a circular vessel in the ultrasound image.

24. The computer-readable medium as defined in claim **23**, further including executable code to perform the following:

calculate a depth of the detected vessel, and

determine the proximity information relating to anticipated proximity of the medical device to the detected vessel at the calculated depth prior to insertion of the medical device into the body.

25. The computer-readable medium as defined in claim **22**, further including executable code to perform the following:

receive user input to indicate a central portion of a vessel present in the ultrasound image; and

execute a vessel boundary detection algorithm to determine the boundary of the vessel present in the ultrasound image.

26. A method of using an ultrasonic imaging system in inserting a catheter into a vessel of a patient, the method comprising:

inputting into the ultrasound imaging system the overall length of the catheter to be inserted into the vessel;

ultrasonically imaging for depiction on a display the vessel with a probe of the ultrasound imaging device; and

observing information provided by the ultrasound imaging system prior to catheter insertion, the information relating to the length of a distal portion of the catheter that would be disposed within the vessel after catheter insertion.

27. The method of using as defined in claim **26**, wherein the information provided by the ultrasound imaging system is provided according to one or more depths indicated on the ultrasound image.

28. The method of using as defined in claim **26**, further comprising inputting a type of procedure for which the catheter is to be employed.

29. The method of using as defined in claim **26**, wherein inputting the overall length of the catheter further comprises selecting one or more possible catheter lengths from a list of available lengths presented by the ultrasound imaging system.

30. The method of using as defined in claim **26**, further comprising observing possible catheter gauges on the display to determine a desired gauge size for the imaged vessel.

31. The method of using as defined in claim **26**, further comprising:

inputting into the ultrasound imaging system the overall length of an alternate catheter to be inserted into the vessel; and

observing information provided by the ultrasound imaging system prior to alternate catheter insertion, the information relating to the length of a distal portion of the alternate catheter that would be disposed within the vessel after alternate catheter insertion.

32. The method of using as defined in claim **26**, wherein ultrasonically imaging further comprises identifying a depth of the vessel, and wherein observing information further comprises observing information provided by the ultrasound imaging system prior to catheter insertion, the information relating to the length of a distal portion of the catheter that would be disposed within the vessel at the identified depth after catheter insertion.

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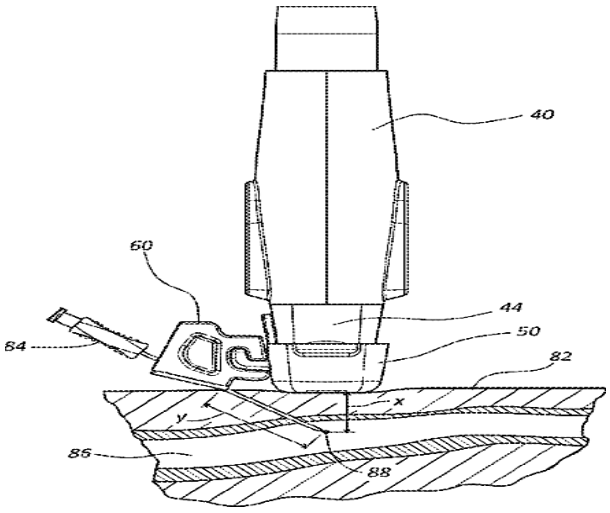
公开了通过使用超声成像系统来辅助将导管放置在患者体内的系统和方法。特别地，本文所述的系统和方法使临床医生能够在插入医疗装置之前确定将多少装置放置在血管内，从而使临床医生能够选择具有合适长度的导管。在一个实施例中，用于辅助放置医疗设备的超声成像系统包括控制台，用于产生目标位置的图像的探头，以及处理器。在插入医疗设备之前，处理器向用户提供与医疗设备与目标位置的预期接近度有关的接近度信息。包括显示器，用于描绘医疗设备到目标位置的图像，目标位置深度和接近度信息。