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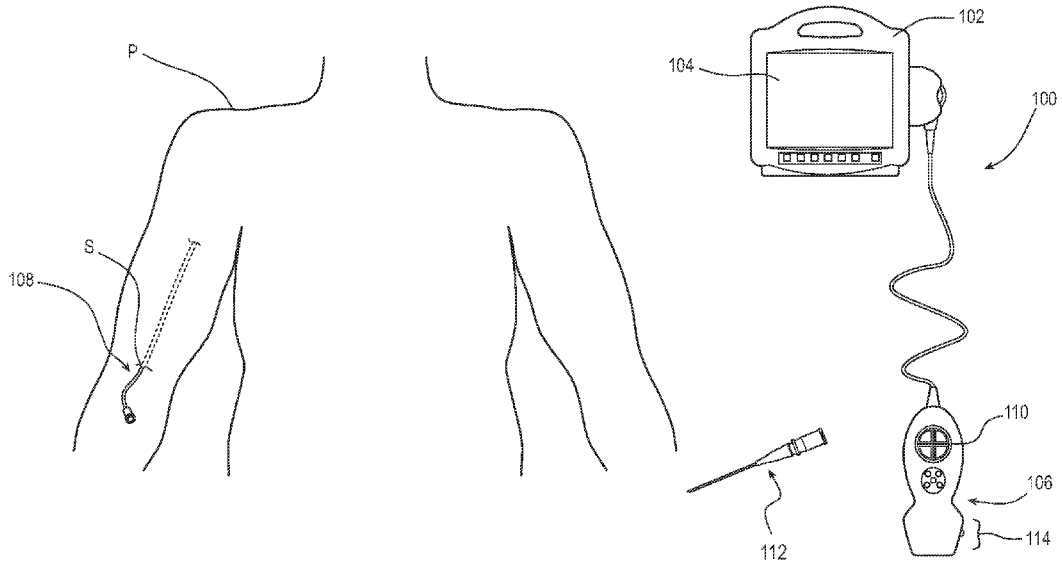

FIG. 1

(57) Abstract: Disclosed herein are dynamically adjusting ultrasound-imaging systems and methods thereof. For example, an ultrasound-imaging system can include an ultrasound probe, a console, and a display screen. The ultrasound probe includes an array of ultrasonic transducers that, when activated, emit generated ultrasound signals into a patient, receive reflected ultrasound signals from the patient, and convert the reflected ultrasound signals into corresponding electrical signals for processing into ultrasound images. The console is configured to execute instructions for dynamically adjusting a distance of activated ultrasonic transducers from a predefined target or area, an orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area. The display screen is configured to display a graphical user interface including the ultrasound images processed by the console from the corresponding electrical signals

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DYNAMICALLY ADJUSTING ULTRASOUND-IMAGING SYSTEMS AND METHODS THEREOF

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 63/075,707, filed September 8, 2020, which is incorporated by reference in its entirety into this application.

BACKGROUND

[0002] Ultrasound imaging is a widely accepted tool for guiding interventional instruments such as needles to targets such as blood vessels or organs in the human body. In order to successfully guide, for example, a needle to a blood vessel using ultrasound imaging, the needle is monitored in real-time both immediately before and after a percutaneous puncture in order to enable a clinician to determine the distance and the orientation of the needle to the blood vessel and ensure successful access thereto. However, through inadvertent movement of an ultrasound probe during the ultrasound imaging, the clinician can lose both the blood vessel and the needle, which can be difficult and time consuming to find again. In addition, it is often easier to monitor the distance and orientation of the needle immediately before the percutaneous puncture with a needle plane including the needle perpendicular to an image plane of the ultrasound probe. And it is often easier to monitor the distance and orientation of the needle immediately after the percutaneous puncture with the needle plane parallel to the image plane. As with inadvertently moving the ultrasound probe, the clinician can lose both the blood vessel and the needle when adjusting the image plane before and after the percutaneous puncture, which can be difficult and time consuming to find again. What is needed are ultrasound-imaging systems and methods thereof that can dynamically adjust the image plane to facilitate guiding interventional instruments to targets in at least the human body.

[0003] Disclosed herein are dynamically adjusting ultrasound-imaging systems and methods thereof.

SUMMARY

[0004] Disclosed herein is an ultrasound-imaging system including, in some embodiments, an ultrasound probe, a console, and a display screen. The ultrasound probe

includes an array of ultrasonic transducers. Activated ultrasonic transducers of the array of ultrasonic transducers are configured to emit generated ultrasound signals into a patient, receive reflected ultrasound signals from the patient, and convert the reflected ultrasound signals into corresponding electrical signals of the ultrasound signals for processing into ultrasound images. The console is configured to communicate with the ultrasound probe. The console includes memory with executable instructions and a processor configured to execute the instructions. The instructions are for dynamically adjusting a distance of the activated ultrasonic transducers from a predefined target or area, an orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area. The instructions are also for processing the corresponding electrical signals of the ultrasound signals into the ultrasound images. The display screen is configured to communicate with the console. The display screen is configured to display a graphical user interface ("GUI") including the ultrasound images.

[0005] In some embodiments, the ultrasound probe further includes an array of magnetic sensors. The magnetic sensors are configured to convert magnetic signals from a magnetized medical device into corresponding electrical signals of the magnetic signals. The electrical signals are processed by the console into distance and orientation information with respect to the predefined target or area for display of an iconographic representation of the medical device on the display screen.

[0006] In some embodiments, the distance and orientation of the activated ultrasonic transducers is adjusted with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe. An image plane is established by the activated ultrasonic transducers being perpendicular or parallel to a medical-device plane including the medical device for accessing the predefined target or area with the medical device.

[0007] In some embodiments, the distance and orientation of the activated ultrasonic transducers is adjusted with respect to a blood vessel as the predefined target. An image plane is established by the activated ultrasonic transducers being perpendicular or parallel to the blood vessel in accordance with an orientation of the blood vessel.

[0008] In some embodiments, the ultrasound-imaging system further includes a stand-alone optical interrogator communicatively coupled to the console or an integrated optical interrogator integrated into the console, as well as an optical-fiber stylet. The optical

interrogator is configured to emit input optical signals, receive reflected optical signals, and convert the reflected optical signals into corresponding electrical signals of the optical signals for processing by the console into distance and orientation information with respect to the predefined target or area for display of an iconographic representation of a medical device on the display. The optical-fiber stylet configured to be disposed in a lumen of the medical device. The optical-fiber stylet is configured to convey the input optical signals from the optical interrogator to a number of fiber Bragg grating ("FBG") sensors along a length of the optical-fiber stylet. The optical-fiber stylet is also configured to convey the reflected optical signals from the number of FBG sensors back to the optical interrogator.

[0009] In some embodiments, the distance and orientation of the activated ultrasonic transducers is adjusted with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe. An image plane is established by the activated ultrasonic transducers being perpendicular or parallel to a medical-device plane including the medical device for accessing the predefined target or area with the medical device.

[0010] In some embodiments, the distance and orientation of the activated ultrasonic transducers is adjusted with respect to a blood vessel as the predefined target. An image plane is established by the activated ultrasonic transducers being perpendicular or parallel to the blood vessel in accordance with an orientation of the blood vessel.

[0011] In some embodiments, the image plane includes a blood vessel as the predefined target or area and the medical device includes a needle, the image plane being perpendicular to the medical-device plane upon approach of the needle and parallel to the medical-device plane upon a percutaneous puncture with the needle.

[0012] In some embodiments, the array of ultrasonic transducers is a two-dimensional ("2-D") array of ultrasonic transducers. The activated ultrasonic transducers are an approximately linear subset of ultrasonic transducers of the 2-D array of ultrasonic transducers activated by the console at any given time.

[0013] In some embodiments, the array of ultrasonic transducers is a movable linear array of ultrasonic transducers. The activated ultrasonic transducers are a subset of the ultrasonic transducers up to all the ultrasonic transducers in the linear array of ultrasonic transducers activated by the console at any given time.

[0014] In some embodiments, the ultrasound probe further includes an accelerometer, a gyroscope, a magnetometer, or a combination thereof configured to provide positional-tracking data to the console. The processor is further configured to execute the instructions for processing the positional-tracking data for the adjusting of the distance of the activated ultrasonic transducers from the predefined target or area, the orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area.

[0015] In some embodiments, the distance and the orientation of the activated ultrasonic transducers is maintained with respect to the predefined target or area when the ultrasound probe is inadvertently moved with respect to the predefined target or area.

[0016] Also disclosed herein is a method of an ultrasound-imaging system including a non-transitory computer-readable medium ("CRM") having executable instructions that cause the ultrasound-imaging system to perform a set of operations for ultrasound imaging when the instructions are executed by a processor of a console of the ultrasound-imaging system. The method includes, in some embodiments, an activating operation, an adjusting operation, a first processing operation, and a first displaying operation. The activating operation includes activating ultrasonic transducers of an array of ultrasonic transducers of an ultrasound probe communicatively coupled to the console. With the activating operation, the ultrasonic transducers emit generated ultrasound signals into a patient, receive reflected ultrasound signals from the patient, and convert the reflected ultrasound signals into corresponding electrical signals of the ultrasound signals for processing into ultrasound images. The adjusting operation includes dynamically adjusting a distance of activated ultrasonic transducers from a predefined target or area, an orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area. The first processing operation includes processing the corresponding electrical signals of the ultrasound signals into the ultrasound images. The first displaying operation includes displaying on a display screen communicatively coupled to the console a GUI including the ultrasound images.

[0017] In some embodiments, the method further includes a converting operation, a second processing operation, and a second displaying operation. The converting operation includes converting magnetic signals from a magnetized medical device with an array of magnetic sensors of the ultrasound probe into corresponding electrical signals of the magnetic

signals. The second processing operation includes processing the corresponding electrical signals of the magnetic signals with the processor into distance and orientation information with respect to the predefined target or area. The second displaying operation includes displaying an iconographic representation of the medical device on the display screen.

[0018] In some embodiments, the method further includes an adjusting operation in response to the magnetic signals. The adjusting operation includes adjusting the distance and orientation of the activated ultrasonic transducers with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe. The adjusting operation establishes an image plane by the activated ultrasonic transducers perpendicular or parallel to a medical-device plane including the medical device for accessing the predefined target or area with the medical device.

[0019] In some embodiments, the method further includes an adjusting operation in response to an orientation of a blood vessel as the predefined target. The adjusting operation includes adjusting the distance and orientation of the activated ultrasonic transducers with respect to the orientation of the blood vessel. The adjusting operation establishes an image plane by the activated ultrasonic transducers perpendicular or parallel to the blood vessel.

[0020] In some embodiments, the method further include optical signal-related operations, as well as a third processing operation and a third displaying operation. The optical signal-related operations include emitting input optical signals, receiving reflected optical signals, and converting the reflected optical signals into corresponding electrical signals of the optical signals by a stand-alone optical interrogator communicatively coupled to the console or an integrated optical interrogator integrated into the console. The optical signal-related operations also include conveying the input optical signals from the optical interrogator to a number of FBG sensors along a length of an optical-fiber stylet, as well as conveying the reflected optical signals from the number of FBG sensors back to the optical interrogator with the optical-fiber stylet disposed in a lumen of the medical device. The third processing operation includes processing the corresponding electrical signals of the optical signals with the processor into distance and orientation information with respect to the predefined target or area. The third displaying operation includes displaying an iconographic representation of a medical device on the display screen.

[0021] In some embodiments, the method further includes an adjusting operation in response to the optical signals. The adjusting operation includes adjusting the distance and orientation of the activated ultrasonic transducers with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe. The adjusting operation establishes an image plane by the activated ultrasonic transducers perpendicular or parallel to a medical-device plane including the medical device for accessing the predefined target or area with the medical device.

[0022] In some embodiments, the method further includes an adjusting operation in response to an orientation of a blood vessel as the predefined target. The adjusting operation includes adjusting the distance and orientation of the activated ultrasonic transducers with respect to the orientation of the blood vessel. The adjusting operation establishes an image plane by the activated ultrasonic transducers perpendicular or parallel to the blood vessel.

[0023] In some embodiments, the establishing of the image plane is perpendicular to the medical-device plane upon approach of the medical device and parallel to the medical-device plane upon insertion of the medical device. The image plane includes a blood vessel as the predefined target or area and the medical-device plane includes a needle as the medical device.

[0024] In some embodiments, the activating operation includes activating an approximately linear subset of ultrasonic transducers of a 2-D array of ultrasonic transducers.

[0025] In some embodiments, the activating operation includes activating a subset of the ultrasonic transducers up to all the ultrasonic transducers in a movable linear array of ultrasonic transducers.

[0026] In some embodiments, the method further includes a data-providing operation and a fourth processing operation. The data providing operation includes providing positional-tracking data to the console from an accelerometer, a gyroscope, a magnetometer, or a combination thereof of the ultrasound probe. The fourth processing operation includes processing the positional-tracking data with the processor for the adjusting operation.

[0027] In some embodiments, the method further includes a maintaining operation. The maintaining operation includes maintaining the distance and the orientation of the activated

ultrasonic transducers with respect to the predefined target or area when the ultrasound probe is inadvertently moved with respect to the predefined target or area.

[0028] These and other features of the concepts provided herein will become more apparent to those of skill in the art in view of the accompanying drawings and following description, which describe particular embodiments of such concepts in greater detail.

DRAWINGS

[0029] FIG. 1 illustrates an ultrasound-imaging system and a patient in accordance with some embodiments.

[0030] FIG. 2 illustrates a block diagram of the ultrasound-imaging system in accordance with some embodiments.

[0031] FIG. 3A illustrates an ultrasound probe of the ultrasound-imaging system imaging a blood vessel in accordance with some embodiments.

[0032] FIG. 3B illustrates an ultrasound image of the blood vessel of FIG. 3A on a display screen of the ultrasound-imaging system in accordance with some embodiments.

[0033] FIG. 4 illustrates the ultrasound probe of the ultrasound-imaging system configured as a 2-D ultrasound probe in accordance with some embodiments.

[0034] FIG. 5A illustrates activated ultrasonic transducers of an array of ultrasonic transducers of the ultrasound probe in accordance with some embodiments.

[0035] FIG. 5B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 5A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0036] FIG. 6A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 5A upon rotating the ultrasound probe without dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0037] FIG. 6B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 6A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0038] FIG. 7A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 5A upon rotating the ultrasound probe with dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0039] FIG. 7B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 7A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0040] FIG. 8A illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe in accordance with some embodiments.

[0041] FIG. 8B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 8A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0042] FIG. 9A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 8A upon translating the ultrasound probe without dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0043] FIG. 9B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 9A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0044] FIG. 10A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 10A upon translating the ultrasound probe with dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0045] FIG. 10B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 10A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0046] FIG. 11 illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe perpendicular to a medical-device plane of a magnetized medical device in accordance with some embodiments.

[0047] FIG. 12 illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe perpendicular to the medical-device plane of the

magnetized medical device after yawing the medical device and dynamically adjusting the activated ultrasonic transducers in accordance with some embodiments.

[0048] FIG. 13 illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe perpendicular to the medical-device plane of the magnetized medical device after yawing the medical device and dynamically adjusting the activated ultrasonic transducers in accordance with some embodiments.

[0049] FIG. 14 illustrates the ultrasound probe of the ultrasound-imaging system configured as a linear ultrasound probe in accordance with some embodiments.

[0050] FIG. 15A illustrates activated ultrasonic transducers of an array of ultrasonic transducers of the ultrasound probe in accordance with some embodiments.

[0051] FIG. 15B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 15A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0052] FIG. 16A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 15A upon rotating the ultrasound probe without dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0053] FIG. 16B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 16A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0054] FIG. 17A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 15A upon rotating the ultrasound probe with dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0055] FIG. 17B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 17A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0056] FIG. 18A illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe in accordance with some embodiments.

[0057] FIG. 18B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 18A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0058] FIG. 19A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 18A upon translating the ultrasound probe without dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0059] FIG. 19B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 19A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0060] FIG. 20A illustrates the activated ultrasonic transducers of the ultrasound probe of FIG. 20A upon translating the ultrasound probe with dynamic adjusting of the activated ultrasonic transducers in accordance with some embodiments.

[0061] FIG. 20B illustrates the ultrasound image of the blood vessel of FIG. 3A obtained with the activated ultrasonic transducers of FIG. 20A on the display screen of the ultrasound-imaging system in accordance with some embodiments.

[0062] FIG. 21 illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe perpendicular to the medical-device plane of the magnetized medical device in accordance with some embodiments.

[0063] FIG. 22 illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe perpendicular to the medical-device plane of the magnetized medical device after yawing the medical device and dynamically adjusting the activated ultrasonic transducers in accordance with some embodiments.

[0064] FIG. 23 illustrates the activated ultrasonic transducers of the array of ultrasonic transducers of the ultrasound probe perpendicular to the medical-device plane of the magnetized medical device after yawing the medical device and dynamically adjusting the activated ultrasonic transducers in accordance with some embodiments.

DESCRIPTION

[0065] Before some particular embodiments are disclosed in greater detail, it should be understood that the particular embodiments disclosed herein do not limit the scope of the

concepts provided herein. It should also be understood that a particular embodiment disclosed herein can have features that can be readily separated from the particular embodiment and optionally combined with or substituted for features of any of a number of other embodiments disclosed herein.

[0066] Regarding terms used herein, it should also be understood the terms are for the purpose of describing some particular embodiments, and the terms do not limit the scope of the concepts provided herein. Ordinal numbers (e.g., first, second, third, etc.) are generally used to distinguish or identify different features or steps in a group of features or steps, and do not supply a serial or numerical limitation. For example, "first," "second," and "third" features or steps need not necessarily appear in that order, and the particular embodiments including such features or steps need not necessarily be limited to the three features or steps. Labels such as "left," "right," "top," "bottom," "front," "back," and the like are used for convenience and are not intended to imply, for example, any particular fixed location, orientation, or direction. Instead, such labels are used to reflect, for example, relative location, orientation, or directions. Singular forms of "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

[0067] With respect to "proximal," a "proximal portion" or a "proximal-end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near a clinician when the catheter is used on a patient. Likewise, a "proximal length" of, for example, the catheter includes a length of the catheter intended to be near the clinician when the catheter is used on the patient. A "proximal end" of, for example, the catheter includes an end of the catheter intended to be near the clinician when the catheter is used on the patient. The proximal portion, the proximal-end portion, or the proximal length of the catheter can include the proximal end of the catheter; however, the proximal portion, the proximal-end portion, or the proximal length of the catheter need not include the proximal end of the catheter. That is, unless context suggests otherwise, the proximal portion, the proximal-end portion, or the proximal length of the catheter is not a terminal portion or terminal length of the catheter.

[0068] With respect to "distal," a "distal portion" or a "distal-end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near or in a patient when the catheter is used on the patient. Likewise, a "distal length" of, for example, the catheter includes a length of the catheter intended to be near or in the patient when the catheter is used on the patient. A "distal end" of, for example, the catheter includes an end of

the catheter intended to be near or in the patient when the catheter is used on the patient. The distal portion, the distal-end portion, or the distal length of the catheter can include the distal end of the catheter; however, the distal portion, the distal-end portion, or the distal length of the catheter need not include the distal end of the catheter. That is, unless context suggests otherwise, the distal portion, the distal-end portion, or the distal length of the catheter is not a terminal portion or terminal length of the catheter.

[0069] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by those of ordinary skill in the art.

[0070] As set forth above, ultrasound-imaging systems and methods thereof are needed that can dynamically adjust the image plane to facilitate guiding interventional instruments to targets in at least the human body. Disclosed herein are dynamically adjusting ultrasound-imaging systems and methods thereof.

Ultrasound-imaging systems

[0071] FIG. 1 illustrates an ultrasound-imaging system 100, a needle 112, and a patient *P* in accordance with some embodiments. FIG. 2 illustrates a block diagram of the ultrasound-imaging system 100 in accordance with some embodiments. FIG. 3A illustrates an ultrasound probe 106 of the ultrasound-imaging system 100 imaging a blood vessel of the patient *P* prior to accessing the blood vessel in accordance with some embodiments. FIG. 3B illustrates an ultrasound image of the blood vessel of FIG. 3A on a display screen 104 of the ultrasound-imaging system 100 with an iconographic representation of the needle 112 in accordance with some embodiments.

[0072] As shown, the ultrasound-imaging system 100 includes a console 102, the display screen 104, and the ultrasound probe 106. The ultrasound-imaging system 100 is useful for imaging a target such as a blood vessel or an organ within a body of the patient *P* prior to a percutaneous puncture with the needle 112 for inserting the needle 112 or another medical device into the target and accessing the target. Indeed, the ultrasound-imaging system 100 is shown in FIG. 1 in a general relationship to the patient *P* during an ultrasound-based medical procedure to place a catheter 108 into the vasculature of the patient *P* through a skin insertion site *S* created by a percutaneous puncture with the needle 112. It should be appreciated that the ultrasound-imaging system 100 can be useful in a variety of ultrasound-based medical

procedures other than catheterization. For example, the percutaneous puncture with the needle 112 can be performed to biopsy tissue of an organ of the patient *P*.

[0073] The console 102 houses a variety of components of the ultrasound-imaging system 100, and it is appreciated the console 102 can take any of a variety of forms. A processor 116 and memory 118 such as random-access memory ("RAM") or non-volatile memory (e.g., electrically erasable programmable read-only memory ["EEPROM"]) is included in the console 102 for controlling functions of the ultrasound-imaging system 100, as well as executing various logic operations or algorithms during operation of the ultrasound-imaging system 100 in accordance executable instructions 120 therefor stored in the memory 118 for execution by the processor 116. For example, the console 102 is configured to instantiate by way of the instructions 120 one or more processes for dynamically adjusting a distance of activated ultrasonic transducers 149 from a predefined target (e.g., blood vessel) or area, an orientation of the activated ultrasonic transducers 149 to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers 149 with respect to the predefined target or area, as well as process electrical signals from the ultrasound probe 106 into ultrasound images. Dynamically adjusting the activated ultrasonic transducers 149 uses ultrasound-imaging data, magnetic-field data, shape-sensing data, or a combination thereof received by the console 102 for activating certain ultrasonic transducers of a 2-D array of the ultrasonic transducers 148 or moving those already activated in a linear array of the ultrasonic transducers 148. A digital controller/analog interface 122 is also included with the console 102 and is in communication with both the processor 116 and other system components to govern interfacing between the ultrasound probe 106 and other system components set forth herein.

[0074] The ultrasound-imaging system 100 further includes ports 124 for connection with additional components such as optional components 126 including a printer, storage media, keyboard, etc. The ports 124 can be universal serial bus ("USB") ports, though other types of ports can be used for this connection or any other connections shown or described herein. A power connection 128 is included with the console 102 to enable operable connection to an external power supply 130. An internal power supply 132 (e.g., a battery) can also be employed either with or exclusive of the external power supply 130. Power management circuitry 134 is included with the digital controller/analog interface 122 of the console 102 to regulate power use and distribution.

[0075] Optionally, a stand-alone optical interrogator 154 can be communicatively coupled to the console 102 by way of one of the ports 124. Alternatively, the console 102 can include an integrated optical interrogator integrated into the console 102. Such an optical interrogator is configured to emit input optical signals into a companion optical-fiber stylet 156 for shape sensing with the ultrasound-imaging system 100, which optical-fiber stylet 156, in turn, is configured to be inserted into a lumen of a medical device such as the needle 112 and convey the input optical signals from the optical interrogator 154 to a number of FBG sensors along a length of the optical-fiber stylet 156. The optical interrogator 154 is also configured to receive reflected optical signals conveyed by the optical-fiber stylet 156 reflected from the number of FBG sensors, the reflected optical signals indicative of a shape of the optical-fiber stylet 156. The optical interrogator 154 is also configured to convert the reflected optical signals into corresponding electrical signals for processing by the console 102 into distance and orientation information with respect to the target for dynamically adjusting a distance of the activated ultrasonic transducers 149, an orientation of the activated ultrasonic transducers 149, or both the distance and the orientation of the activated ultrasonic transducers 149 with respect to the target or the medical device when it is brought into proximity of the target. For example, the distance and orientation of the activated ultrasonic transducers 149 can be adjusted with respect to a blood vessel as the target. Indeed, an image plane can be established by the activated ultrasonic transducers 149 being perpendicular or parallel to the blood vessel in accordance with an orientation of the blood vessel. In another example, when a medical device such as the needle 112 is brought into proximity of the ultrasound probe 106, an image plane can be established by the activated ultrasonic transducers 149 being perpendicular to a medical-device plane including the medical device as shown in FIGS. 11-13 and 21-23 or parallel to the medical-device plane including the medical device for accessing the target with the medical device. The image plane can be perpendicular to the medical-device plane upon approach of the medical device and parallel to the medical-device plane upon insertion of the medical device (e.g., percutaneous puncture with the needle 112). The distance and orientation information can also be used for displaying an iconographic representation of the medical device on the display.

[0076] The display screen 104 is integrated into the console 102 to provide a GUI and display information for a clinician during such as one-or-more ultrasound images of the target or the patient *P* attained by the ultrasound probe 106. In addition, the ultrasound-imaging system 100 enables the distance and orientation of a magnetized medical device such as the

needle 112 to be superimposed in real-time atop an ultrasound image of the target, thus enabling a clinician to accurately guide the magnetized medical device to the intended target. Notwithstanding the foregoing, the display screen 104 can alternatively be separate from the console 102 and communicatively coupled thereto. A console button interface 136 and control buttons 110 (*see* FIG. 1) included on the ultrasound probe 106 can be used to immediately call up a desired mode to the display screen 104 by the clinician for assistance in an ultrasound-based medical procedure. In some embodiments, the display screen 104 is an LCD device.

[0077] The ultrasound probe 106 is employed in connection with ultrasound-based visualization of a target such as a blood vessel (*see* FIG. 3A) in preparation for inserting the needle 112 or another medical device into the target. Such visualization gives real-time ultrasound guidance and assists in reducing complications typically associated with such insertion, including inadvertent arterial puncture, hematoma, pneumothorax, etc. As described in more detail below, the ultrasound probe 106 is configured to provide to the console 102 electrical signals corresponding to both the ultrasound-imaging data, the magnetic-field data, the shape-sensing data, or a combination thereof for the real-time ultrasound guidance.

[0078] FIG. 4 illustrates the ultrasound probe 106 of the ultrasound-imaging system 100 configured as a 2-D ultrasound probe in accordance with some embodiments. FIG. 14 illustrates the ultrasound probe 106 of the ultrasound-imaging system 100 configured as a linear ultrasound probe in accordance with some embodiments.

[0079] The ultrasound probe 106 includes a probe head 114 that houses a mounted and moveable (e.g., translatable or rotatable along a central axis) linear array of the ultrasonic transducers 148 or a 2-D array of the ultrasonic transducers 148, wherein the ultrasonic transducers 148 are piezoelectric transducers or capacitive micromachined ultrasonic transducers ("CMUTs"). When the ultrasound probe 106 is configured with the 2-D array of the ultrasonic transducers 148, a subset of the ultrasonic transducers 148 is linearly activated as needed for ultrasound imaging in accordance with ultrasound-imaging data, magnetic-field data, shape-sensing data, or a combination thereof to maintain the target in an image plane or switch to a different image plane (e.g., from perpendicular to a medical-device plane to parallel to the medical-device plane) including the target. (*See*, for example, the activated ultrasonic transducers 149 of FIGS. 5A, 7A, 10A, 12, or 13.) When the ultrasound probe 106 is configured with the moveable linear array of the ultrasonic transducers 148, the ultrasonic transducers 148 already activated for ultrasound imaging (e.g., a subset of the ultrasonic transducers 148 up to

all the ultrasonic transducers 148) are moved together on the moveable linear array as needed for ultrasound imaging in accordance with ultrasound-imaging data, magnetic-field data, shape-sensing data, or a combination thereof to maintain the target in an image plane established by the activated ultrasonic transducers 149 or switch to a different image plane including the target. (*See*, for example, the activated ultrasonic transducers 149 of FIGS. 15A, 17A, 20A, 22, or 23.)

[0080] The probe head 114 is configured for placement against skin of the patient *P* proximate a prospective needle-insertion site where the activated ultrasonic transducers 149 in the probe head 114 can generate and emit the generated ultrasound signals into the patient *P* in a number of pulses, receive reflected ultrasound signals or ultrasound echoes from the patient *P* by way of reflection of the generated ultrasonic pulses by the body of the patient *P*, and convert the reflected ultrasound signals into corresponding electrical signals for processing into ultrasound images by the console 102 to which the ultrasound probe 106 is communicatively coupled. In this way, a clinician can employ the ultrasound-imaging system 100 to determine a suitable insertion site and establish vascular access with the needle 112 or another medical device.

[0081] The ultrasound probe 106 further includes the control buttons 110 for controlling certain aspects of the ultrasound-imaging system 100 during an ultrasound-based medical procedure, thus eliminating the need for the clinician to reach out of a sterile field around the patient *P* to control the ultrasound-imaging system 100. For example, a control button of the control buttons 110 can be configured to select or lock onto the target (e.g., a blood vessel, an organ, etc.) when pressed for visualization of the target in preparation for inserting the needle 112 or another medical device into the target. Such a control button can also be configured to deselect the target, which is useful whether the target was selected by the control button or another means such as by holding the ultrasound probe 106 stationary over the target to select the target, issuing a voice command to select the target, or the like.

[0082] FIG. 2 shows that the ultrasound probe 106 further includes a button and memory controller 138 for governing button and ultrasound-probe operation. The button-and-memory controller 138 can include non-volatile memory (e.g., EEPROM). The button-and-memory controller 138 is in operable communication with a probe interface 140 of the console 102, which includes an input/output ("I/O") component 142 for interfacing with the ultrasonic

transducers 148 and a button and memory I/O component 144 for interfacing with the button-and-memory controller 138.

[0083] Also as seen in FIGS. 2 and 3A, the ultrasound probe 106 can include a magnetic-sensor array 146 for detecting a magnetized medical device such as the needle 112 during ultrasound-based medical procedures. The magnetic-sensor array 146 includes a number of magnetic sensors 150 embedded within or included on a housing of the ultrasound probe 106. The magnetic sensors 150 are configured to detect a magnetic field or a disturbance in a magnetic field as magnetic signals associated with the magnetized medical device when it is in proximity to the magnetic-sensor array 146. The magnetic sensors 150 are also configured to convert the magnetic signals from the magnetized medical device (e.g., the needle 112) into electrical signals for the console 102 to process into distance and orientation information for the magnetized medical device with respect to the predefined target, as well as for display of an iconographic representation of the magnetized medical device on the display screen 104. (*See* the magnetic field **B** of the needle 112 in FIG. 3A.) Thus, the magnetic-sensor array 146 enables the ultrasound-imaging system 100 to track the needle 112 or the like.

[0084] Though configured here as magnetic sensors, it is appreciated that the magnetic sensors 150 can be sensors of other types and configurations. Also, though they are described herein as included with the ultrasound probe 106, the magnetic sensors 150 of the magnetic-sensor array 146 can be included in a component separate from the ultrasound probe 106 such as a sleeve into which the ultrasound probe 106 is inserted or even a separate handheld device. The magnetic sensors 150 can be disposed in an annular configuration about the probe head 114 of the ultrasound probe 106, though it is appreciated that the magnetic sensors 150 can be arranged in other configurations, such as in an arched, planar, or semi-circular arrangement.

[0085] Each magnetic sensor of the magnetic sensors 150 includes three orthogonal sensor coils for enabling detection of a magnetic field in three spatial dimensions. Such 3-dimensional ("3-D") magnetic sensors can be purchased, for example, from Honeywell Sensing and Control of Morristown, NJ. Further, the magnetic sensors 150 are configured as Hall-effect sensors, though other types of magnetic sensors could be employed. Further, instead of 3-D sensors, a plurality of 1-dimensional ("1-D") magnetic sensors can be included and arranged as desired to achieve 1-, 2-, or 3-D detection capability.

[0086] Five magnetic sensors for the magnetic sensors 150 are included in the magnetic-sensor array 146 so as to enable detection of a magnetized medical device such as the needle 112 in three spatial dimensions (e.g., X, Y, Z coordinate space), as well as the pitch and yaw orientation of the magnetized medical device itself. Detection of the magnetized medical device in accordance with the foregoing when the magnetized medical device is brought into proximity of the ultrasound probe 106 allows for dynamically adjusting a distance of the activated ultrasonic transducers 149, an orientation of the activated ultrasonic transducers 149, or both the distance and the orientation of the activated ultrasonic transducers 149 with respect to the target or the magnetized medical device. For example, the distance and orientation of the activated ultrasonic transducers 149 can be adjusted with respect to a blood vessel as the target. Indeed, an image plane can be established by the activated ultrasonic transducers 149 being perpendicular or parallel to the blood vessel in accordance with an orientation of the blood vessel. In another example, as shown among FIGS. 11-13 and 21-23, when the magnetized medical device is brought into proximity of the ultrasound probe 106, an image plane can be established by the activated ultrasonic transducers 149 being perpendicular to a medical-device plane including the magnetized medical device for accessing the target with the magnetized medical device. While not shown, the image plane can also be established by the activated ultrasonic transducers 149 being parallel to the medical-device plane including the magnetized medical device for accessing the target with the magnetized medical device such as after insertion of the medical device into the patient. Note that in some embodiments, orthogonal sensing components of two or more of the magnetic sensors 150 enable the pitch and yaw attitude of the magnetized medical device to be determined, which enables tracking with relatively high accuracy. In other embodiments, fewer than five or more than five magnetic sensors of the magnetic sensors 150 can be employed in the magnetic-sensor array 146. More generally, it is appreciated that the number, size, type, and placement of the magnetic sensors 150 of the magnetic-sensor array 146 can vary from what is explicitly shown here.

[0087] As shown in FIG. 2, the ultrasound probe 106 can further include an inertial measurement unit ("IMU") 158 or any one or more components thereof for inertial measurement selected from an accelerometer 160, a gyroscope 162, and a magnetometer 164 configured to provide positional-tracking data of the ultrasound probe 106 to the console 102 for stabilization of an image plane. The processor 116 is further configured to execute the instructions 120 for processing the positional-tracking data for adjusting the distance of the activated ultrasonic transducers 149 from the target, the orientation of the activated ultrasonic

transducers 149 to the target, or both the distance and the orientation of the activated ultrasonic transducers 149 with respect to the target to maintain the distance and the orientation of the activated ultrasonic transducers 149 with respect to the target when the ultrasound probe 106 is inadvertently moved with respect to the target.

[0088] It is appreciated that a medical device of a magnetizable material enables the medical device (e.g., the needle 112) to be magnetized by a magnetizer, if not already magnetized, and tracked by the ultrasound-imaging system 100 when the magnetized medical device is brought into proximity of the magnetic sensors 150 of the magnetic-sensor array 146 or inserted into the body of the patient *P* during an ultrasound-based medical procedure. Such magnetic-based tracking of the magnetized medical device assists the clinician in placing a distal tip thereof in a desired location, such as in a lumen of a blood vessel, by superimposing a simulated needle image representing the real-time distance and orientation of the needle 112 over an ultrasound image of the body of the patient *P* being accessed by the magnetized medical device. Such a medical device can be stainless steel such as SS 304 stainless steel; however, other suitable needle materials that are capable of being magnetized can be employed. So configured, the needle 112 or the like can produce a magnetic field or create a magnetic disturbance in a magnetic field detectable as magnetic signals by the magnetic-sensor array 146 of the ultrasound probe 106 so as to enable the distance and orientation of the magnetized medical device to be tracked by the ultrasound-imaging system 100 for dynamically adjusting the distance of the activated ultrasonic transducers 149, an orientation of the activated ultrasonic transducers 149, or both the distance and the orientation of the activated ultrasonic transducers 149 with respect to the magnetized medical device.

[0089] During operation of the ultrasound-imaging system 100, the probe head 114 of the ultrasound probe 106 is placed against skin of the patient *P*. An ultrasound beam 152 is produced so as to ultrasonically image a portion of a target such as a blood vessel beneath a surface of the skin of the patient *P*. (*See* FIG. 3A.) The ultrasonic image of the blood vessel can be depicted and stabilized on the display screen 104 of the ultrasound-imaging system 100 as shown in FIG. 3B despite inadvertent movements of the ultrasound probe 106. Indeed, this is shown among FIGS. 5A, 5B, 7A, 7B, 8A, 8B, 10A, and 10B for the ultrasound probe 106 configured with the 2-D array of the ultrasonic transducers 148 and FIGS. 15A, 15B, 17A, 17B, 18A, 18B, 20A, and 20B for the ultrasound probe 106 configured with the moveable linear array of the ultrasonic transducers 148.

[0090] FIGS. 5A and 5B illustrate the activated ultrasonic transducers 149 of the 2-D array of the ultrasonic transducers 148 of the ultrasound probe 106 in accordance with some embodiments. FIGS. 15A and 15B illustrate the activated ultrasonic transducers 149 of the moveable linear array of the ultrasonic transducers 148 of the ultrasound probe 106 in accordance with some embodiments. As shown in FIG. 7A, upon rotating the ultrasound probe 106 as might occur with an inadvertent movement of the ultrasound probe 106, dynamic adjustment of the activated ultrasonic transducers 149 occurs to maintain the target in the image plane. Such dynamic adjustment includes deactivating certain ultrasonic transducers and activating certain other ultrasonic transducers to maintain a distance and orientation of the activated ultrasonic transducers 149 to the target, which stabilizes the ultrasound image as shown in FIG. 7B. (*Compare* FIG. 7B *with* 5B.) Without such dynamic adjustment as shown by FIG. 6A, the distance and orientation of the activated ultrasonic transducers 149 to the target is not maintained, which results in a different ultrasound image as shown in FIG. 6B. (*Compare* FIG. 6B *with* 5B.) Likewise, as shown in FIG. 17A, upon rotating the ultrasound probe 106 as might occur with an inadvertent movement of the ultrasound probe 106, dynamic adjustment of the activated ultrasonic transducers 149 occurs to maintain the target in the image plane. Such dynamic adjustment includes automatically rotating the moveable linear array of the ultrasonic transducers 148 (within the probe head 114) to maintain a distance and orientation of the activated ultrasonic transducers 149 to the target, which stabilizes the ultrasound image as shown in FIG. 17B. (*Compare* FIG. 17B *with* 15B.) Without such dynamic adjustment as shown by FIG. 16A, the distance and orientation of the activated ultrasonic transducers 149 to the target is not maintained, which results in a different ultrasound image as shown in FIG. 16B. (*Compare* FIG. 16B *with* 15B.)

[0091] FIGS. 8A and 8B illustrate the activated ultrasonic transducers 149 of the 2-D array of the ultrasonic transducers 148 of the ultrasound probe 106 in accordance with some embodiments. FIGS. 18A and 18B illustrate the activated ultrasonic transducers 149 of the moveable linear array of the ultrasonic transducers 148 of the ultrasound probe 106 in accordance with some embodiments. As shown in FIG. 10A, upon translating the ultrasound probe 106 as might occur with an inadvertence movement of the ultrasound probe 106, dynamic adjustment of the activated ultrasonic transducers 149 occurs to maintain the target in the image plane. Such dynamic adjustment includes deactivating certain ultrasonic transducers and activating certain other ultrasonic transducers to maintain a distance and orientation of the activated ultrasonic transducers 149 to the target, which stabilizes the ultrasound image as

shown in FIG. 10B. (*Compare* FIG. 10B *with* 8B.) Without such dynamic adjustment as shown by FIG. 9A, the distance and orientation of the activated ultrasonic transducers 149 to the target is not maintained, which results in a different ultrasound image as shown in FIG. 9B. (*Compare* FIG. 9B *with* 8B.) Likewise, as shown in FIG. 20A, upon translating the ultrasound probe 106 as might occur with an inadvertent movement of the ultrasound probe 106, dynamic adjustment of the activated ultrasonic transducers 149 occurs to maintain the target in the image plane. Such dynamic adjustment includes automatically translating the moveable linear array of the ultrasonic transducers 148 (within the probe head 114) to maintain a distance and orientation of the activated ultrasonic transducers 149 to the target, which stabilizes the ultrasound image as shown in FIG. 20B. (*Compare* FIG. 20B *with* 18B.) Without such dynamic adjustment as shown by FIG. 19A, the distance and orientation of the activated ultrasonic transducers 149 to the target is not maintained, which results in a different ultrasound image as shown in FIG. 19B. (*Compare* FIG. 19B *with* 18B.)

[0092] The ultrasound-imaging system 100 is configured to detect the distance and orientation of a medical device by way of the magnetic sensors 150 or shape-sensing optical-fiber stylet 156. By way of example, the magnetic-sensor array 146 of the ultrasound probe 106 is configured to detect a magnetic field of the magnetized medical device or a disturbance in a magnetic field due to the magnetized magnetic device. Each magnetic sensor of the magnetic sensors 150 in the magnetic-sensor array 146 is configured to spatially detect the needle 112 in 3-dimensional space. (*See* FIG. 3A.) Thus, during operation of the ultrasound-imaging system 100, magnetic field strength data of the medical device's magnetic field sensed by each magnetic sensor of the magnetic sensors 150 is forwarded to the processor 116 of the console 102, which computes in real-time the distance and orientation of the magnetized medical device useful for dynamically adjusting a distance of the activated ultrasonic transducers 149, an orientation of the activated ultrasonic transducers 149, or both the distance and the orientation of the activated ultrasonic transducers 149 with respect to the magnetized medical device. Again, the distance and orientation of the magnetized medical device is also for graphical display on the display screen 104.

[0093] The distance or orientation of any point along an entire length of the magnetized medical device in a coordinate space with respect to the magnetic-sensor array 146 can be determined by the ultrasound-imaging system 100 using the magnetic-field strength data sensed by the magnetic sensors 150. Moreover, a pitch and yaw of the needle 112 can also be

determined. Suitable circuitry of the ultrasound probe 106, the console 102, or other components of the ultrasound-imaging system 100 can provide the calculations necessary for such distance or orientation. In some embodiments, the needle 112 can be tracked using the teachings of one or more patents of U.S. Patent Nos.: 5,775,322; 5,879,297; 6,129,668; 6,216,028; and 6,263,230, each of which is incorporated by reference in its entirety into this application.

[0094] The distance and orientation information determined by the ultrasound-imaging system 100, together with an entire length of the magnetized medical device, as known by or input into the ultrasound-imaging system 100, enables the ultrasound-imaging system 100 to accurately determine the distance and orientation of the entire length of the magnetized medical device, including a distal tip thereof, with respect to the magnetic-sensor array 146. This, in turn, enables the ultrasound-imaging system 100 to superimpose an image of the needle 112 on an ultrasound image produced by the ultrasound beam 152 of the ultrasound probe 106 on the display screen 104, as well as dynamically adjusting the activated ultrasonic transducers 149. For example, the ultrasound image depicted on the display screen 104 can include depiction of the surface of the skin of the patient *P* and a subcutaneous blood vessel thereunder to be accessed by the needle 112, as well as a depiction of the magnetized medical device as detected by the ultrasound-imaging system 100 and its orientation to the vessel. The ultrasound image corresponds to an image acquired by the ultrasound beam 152 of the ultrasound probe 106. It should be appreciated that only a portion of an entire length of the magnetized medical device is magnetized and, thus, tracked by the ultrasound-imaging system 100.

[0095] Note that further details regarding structure and operation of the ultrasound-imaging system 100 can be found in U.S. Patent No. 9,456,766, titled "Apparatus for Use with Needle Insertion Guidance System," which is incorporated by reference in its entirety into this application.

Methods

[0096] Methods of the foregoing ultrasound-imaging systems include methods implemented in the ultrasound-imaging systems. For example, a method of the ultrasound-imaging system 100 includes a non-transitory CRM (e.g., EEPROM) having the instructions 120 stored thereon that cause the ultrasound-imaging system 100 to perform a set of operations for ultrasound imaging when the instructions 120 are executed by the processor 116 of the

console 102. Such a method includes an activating operation, an adjusting operation, a first processing operation, and a first displaying operation.

[0097] The activating operation includes activating the ultrasonic transducers of the array of the ultrasonic transducers 148 of the ultrasound probe 106 communicatively coupled to the console 102. With the activating operation, the ultrasonic transducers 148 emit generated ultrasound signals into the patient *P*, receive reflected ultrasound signals from the patient *P*, and convert the reflected ultrasound signals into corresponding electrical signals for processing into ultrasound images. The activating operation can include activating an approximately linear subset of the ultrasonic transducers 148 of a 2-D array of the ultrasonic transducers 148. Alternatively, the activating operation can include activating a subset of the ultrasonic transducers 148 up to all the ultrasonic transducers 148 in the movable linear array of the ultrasonic transducers 148.

[0098] The adjusting operation includes dynamically adjusting a distance of the activated ultrasonic transducers 149 from a predefined target or area, an orientation of the activated ultrasonic transducers 149 to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers 149 with respect to the predefined target or area. For example, the adjusting operation can be in response to an orientation of a blood vessel as the predefined target. The adjusting operation includes adjusting the distance and orientation of the activated ultrasonic transducers 149 with respect to the orientation of the blood vessel so as to establish an image plane by the activated ultrasonic transducers 149 perpendicular or parallel to the blood vessel.

[0099] The first processing operation includes processing the corresponding electrical signals of the ultrasound signals into the ultrasound images.

[0100] The first displaying operation includes displaying on the display screen 104 communicatively coupled to the console 102 the GUI including the ultrasound images.

[0101] As to magnetic signal-related operations, the method can include a converting operation, a second processing operation, and a second displaying operation. The converting operation includes converting magnetic signals from a magnetized medical device (e.g., the needle 112) with the magnetic-sensor array 146 of the ultrasound probe 106 into corresponding electrical signals. The second processing operation includes processing the corresponding electrical signals of the magnetic signals with the processor 116 into distance and orientation

information with respect to the predefined target or area. The second displaying operation includes displaying an iconographic representation of the medical device on the display screen 104.

[0102] The method further includes an adjusting operation in response to the magnetic signals. The adjusting operation includes adjusting the distance and orientation of the activated ultrasonic transducers 149 with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe 106. The adjusting operation establishes an image plane by the activated ultrasonic transducers 149 perpendicular or parallel to the medical-device plane including the medical device for accessing the predefined target or area with the medical device. The establishing of the image plane can be perpendicular to the medical-device plane upon approach of the medical device and parallel to the medical-device plane upon insertion of the medical device. The image plane can include a blood vessel as the predefined target or area and the medical-device plane can include the needle 112 as the medical device.

[0103] As to optical signal-related operations, the method can include a number of optical signal-related operations, as well as a third processing operation and a third displaying operation. The optical signal-related operations include emitting input optical signals, receiving reflected optical signals, and converting the reflected optical signals into corresponding electrical signals of the optical signals by the optical interrogator 154. The optical signal-related operations also include conveying the input optical signals from the optical interrogator 154 to the number of FBG sensors along the length of the optical-fiber stylet 156, as well as conveying the reflected optical signals from the number of FBG sensors back to the optical interrogator 154 with the optical-fiber stylet 156 disposed in a lumen of the medical device. The third processing operation includes processing the corresponding electrical signals of the optical signals with the processor 116 into distance and orientation information with respect to the predefined target or area. The third displaying operation includes displaying an iconographic representation of a medical device on the display screen 104.

[0104] The method further includes an adjusting operation in response to the optical signals. The adjusting operation includes adjusting the distance and orientation of the activated ultrasonic transducers 149 with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe 106. The adjusting operation establishes an image plane by the activated ultrasonic transducers 149 perpendicular or parallel to the

medical-device plane including the medical device for accessing the predefined target or area with the medical device. Again, the establishing of the image plane is perpendicular to the medical-device plane upon approach of the medical device and parallel to the medical-device plane upon insertion of the medical device. The image plane includes a blood vessel as the predefined target or area and the medical-device plane includes the needle 112 as the medical device.

[0105] The method can further include a data-providing operation and a fourth processing operation. The data-providing operation includes providing positional-tracking data to the console 102 from the accelerometer 160, the gyroscope 162, the magnetometer 164, or a combination thereof of the ultrasound probe 106. The fourth processing operation includes processing the positional-tracking data with the processor 116 for the adjusting operation.

[0106] The method can further include a maintaining operation. The maintaining operation includes maintaining the distance and the orientation of the activated ultrasonic transducers 149 with respect to the predefined target or area when the ultrasound probe 106 is inadvertently moved with respect to the predefined target or area.

[0107] While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.

CLAIMS

What is claimed is:

1. An ultrasound-imaging system, comprising:

an ultrasound probe including an array of ultrasonic transducers, activated ultrasonic transducers of the array of ultrasonic transducers configured to emit generated ultrasound signals into a patient, receive reflected ultrasound signals from the patient, and convert the reflected ultrasound signals into corresponding electrical signals of the ultrasound signals for processing into ultrasound images;

a console configured to communicate with the ultrasound probe, the console including memory with executable instructions and a processor configured to execute the instructions for:

dynamically adjusting a distance of the activated ultrasonic transducers from a predefined target or area, an orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area; and

processing the corresponding electrical signals of the ultrasound signals into the ultrasound images; and

a display screen configured to communicate with the console, the display screen configured to display a graphical user interface ("GUI") including the ultrasound images.

2. The ultrasound-imaging system of claim 1, the ultrasound probe further comprising: an array of magnetic sensors configured to convert magnetic signals from a magnetized medical device into corresponding electrical signals of the magnetic signals for processing by the processor into distance and orientation information with respect to the predefined target or area for display of an iconographic representation of the medical device on the display screen.

3. The ultrasound-imaging system of claim 2, wherein the distance and orientation of the activated ultrasonic transducers is adjusted with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe, an image plane

established by the activated ultrasonic transducers being perpendicular or parallel to a medical-device plane including the medical device for accessing the predefined target or area with the medical device.

4. The ultrasound-imaging system of claim 2, wherein the distance and orientation of the activated ultrasonic transducers is adjusted with respect to a blood vessel as the predefined target, an image plane established by the activated ultrasonic transducers being perpendicular or parallel to the blood vessel in accordance with an orientation of the blood vessel.

5. The ultrasound-imaging system of any of claims 1-4, further comprising:

a stand-alone optical interrogator communicatively coupled to the console or an integrated optical interrogator integrated into the console, the optical interrogator configured to emit input optical signals, receive reflected optical signals, and convert the reflected optical signals into corresponding electrical signals of the optical signals for processing by the processor into distance and orientation information with respect to the predefined target or area for display of an iconographic representation of a medical device on the display; and

an optical-fiber stylet configured to convey the input optical signals from the optical interrogator to a number of fiber Bragg grating ("FBG") sensors along a length of the optical-fiber stylet and the reflected optical signals from the number of FBG sensors back to the optical interrogator, the optical-fiber stylet configured to be disposed in a lumen of the medical device.

6. The ultrasound-imaging system of claim 5, wherein the distance and orientation of the activated ultrasonic transducers is adjusted with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe, an image plane established by the activated ultrasonic transducers being perpendicular or parallel to a medical-device plane including the medical device for accessing the predefined target or area with the medical device.

7. The ultrasound-imaging system of claim 5, wherein the distance and orientation of the activated ultrasonic transducers is adjusted with respect to a blood vessel as the predefined target, an image plane established by the activated ultrasonic transducers being

perpendicular or parallel to the blood vessel in accordance with an orientation of the blood vessel.

8. The ultrasound-imaging system of claim 3, wherein the image plane includes a blood vessel as the predefined target and the medical device includes a needle, the image plane being perpendicular to the medical-device plane upon approach of the needle and parallel to the medical-device plane upon a percutaneous puncture with the needle.

9. The ultrasound-imaging system of any of claims 1-8, wherein the array of ultrasonic transducers is a two-dimensional array of ultrasonic transducers, the activated ultrasonic transducers being an approximately linear subset of ultrasonic transducers of the two-dimensional array of ultrasonic transducers activated by the console at any given time.

10. The ultrasound-imaging system of any of claims 1-8, wherein the array of ultrasonic transducers is a movable linear array of ultrasonic transducers, the activated ultrasonic transducers being a subset of the ultrasonic transducers up to all the ultrasonic transducers in the linear array of ultrasonic transducers activated by the console at any given time.

11. The ultrasound-imaging system of claim 9, the ultrasound probe further comprising an accelerometer, a gyroscope, a magnetometer, or a combination thereof configured to provide positional-tracking data to the console, the processor further configured to execute the instructions for processing the positional-tracking data for the adjusting of the distance of the activated ultrasonic transducers from the predefined target or area, the orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area.

12. The ultrasound-imaging system of claim 9, wherein the distance and the orientation of the activated ultrasonic transducers is maintained with respect to the predefined target or area when the ultrasound probe is inadvertently moved with respect to the predefined target or area.

13. A method of an ultrasound-imaging system including a non-transitory computer-readable medium ("CRM") having executable instructions that cause the ultrasound-imaging system to perform a set of operations for ultrasound imaging when the instructions are executed by a processor of a console of the ultrasound-imaging system, the method comprising:

activating ultrasonic transducers of an array of ultrasonic transducers of an ultrasound probe communicatively coupled to the console, whereby the ultrasonic transducers emit generated ultrasound signals into a patient, receive reflected ultrasound signals from the patient, and convert the reflected ultrasound signals into corresponding electrical signals of the ultrasound signals for processing into ultrasound images;

dynamically adjusting a distance of activated ultrasonic transducers from a predefined target or area, an orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area;

processing the corresponding electrical signals of the ultrasound signals into the ultrasound images; and

displaying on a display screen communicatively coupled to the console a graphical user interface ("GUI") including the ultrasound images.

14. The method of claim 13, further comprising:

converting magnetic signals from a magnetized medical device with an array of magnetic sensors of the ultrasound probe into corresponding electrical signals of the magnetic signals; and

processing the corresponding electrical signals of the magnetic signals with the processor into distance and orientation information with respect to the predefined target or area; and

displaying an iconographic representation of the medical device on the display screen.

15. The method of claim 14, further comprising adjusting the distance and orientation of the activated ultrasonic transducers with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe, thereby establishing an image plane by the activated ultrasonic transducers perpendicular or parallel to a medical-

device plane including the medical device for accessing the predefined target or area with the medical device.

16. The method of claim 14, further comprising adjusting the distance and orientation of the activated ultrasonic transducers with respect to an orientation of a blood vessel as the predefined target, thereby establishing an image plane by the activated ultrasonic transducers perpendicular or parallel to the blood vessel.

17. The method of any of claims 13-16, further comprising:

emitting input optical signals, receiving reflected optical signals, and converting the reflected optical signals into corresponding electrical signals of the optical signals by a stand-alone optical interrogator communicatively coupled to the console or an integrated optical interrogator integrated into the console;

conveying the input optical signals from the optical interrogator to a number of fiber Bragg grating ("FBG") sensors along a length of an optical-fiber stylet and the reflected optical signals from the number of FBG sensors back to the optical interrogator with the optical-fiber stylet disposed in a lumen of the medical device;

processing the corresponding electrical signals of the optical signals with the processor into distance and orientation information with respect to the predefined target or area; and

displaying an iconographic representation of a medical device on the display screen.

18. The method of claim 17, further comprising adjusting the distance and orientation of the activated ultrasonic transducers with respect to the predefined target or area when the medical device is brought into proximity of the ultrasound probe, thereby establishing an image plane by the activated ultrasonic transducers perpendicular or parallel to a medical-device plane including the medical device for accessing the predefined target or area with the medical device.

19. The method of claim 17, further comprising adjusting the distance and orientation of the activated ultrasonic transducers with respect to an orientation of a blood

vessel as the predefined target, thereby establishing an image plane by the activated ultrasonic transducers perpendicular or parallel to the blood vessel.

20. The method of claim 15, wherein the establishing of the image plane is perpendicular to the medical-device plane upon approach of the medical device and parallel to the medical-device plane upon insertion of the needle, the image plane including a blood vessel as the predefined target and the medical-device plane including a needle as the medical device.

21. The method of any of claims 13-20, wherein the activating of the ultrasonic transducers of the array of ultrasonic transducers includes activating an approximately linear subset of ultrasonic transducers of a two-dimensional array of ultrasonic transducers.

22. The method of any of claims 13-20, wherein the activating of the ultrasonic transducers of the array of ultrasonic transducers includes activating a subset of the ultrasonic transducers up to all the ultrasonic transducers in a movable linear array of ultrasonic transducers.

23. The method of claim 21, further comprising:

providing positional-tracking data to the console from an accelerometer, a gyroscope, a magnetometer, or a combination thereof of the ultrasound probe ; and

processing the positional-tracking data with the processor for the adjusting of the distance of the activated ultrasonic transducers from the predefined target or area or area, the orientation of the activated ultrasonic transducers to the predefined target or area, or both the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area or area.

24. The method of claim 21, further comprising maintaining the distance and the orientation of the activated ultrasonic transducers with respect to the predefined target or area when the ultrasound probe is inadvertently moved with respect to the predefined target or area.

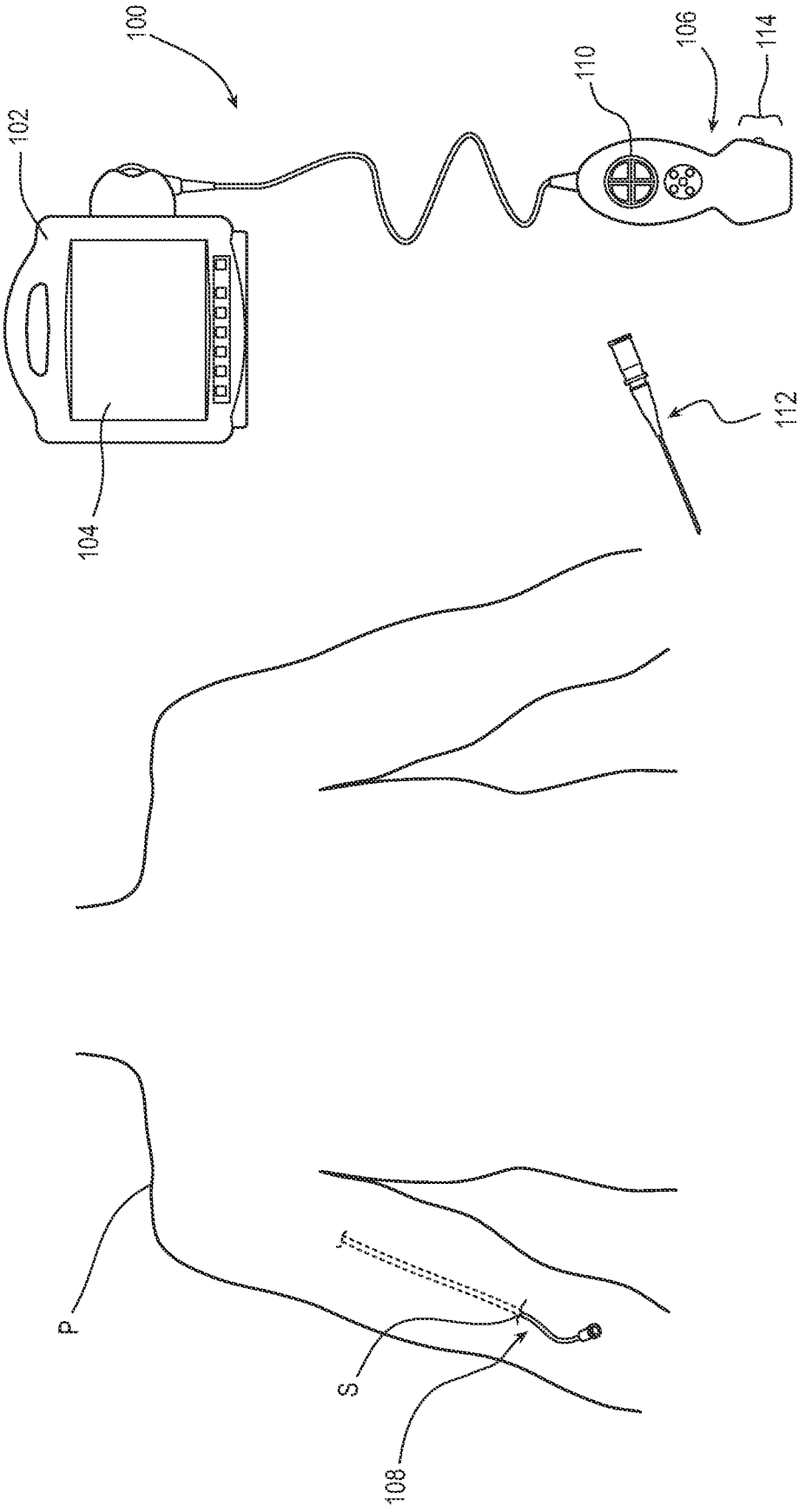
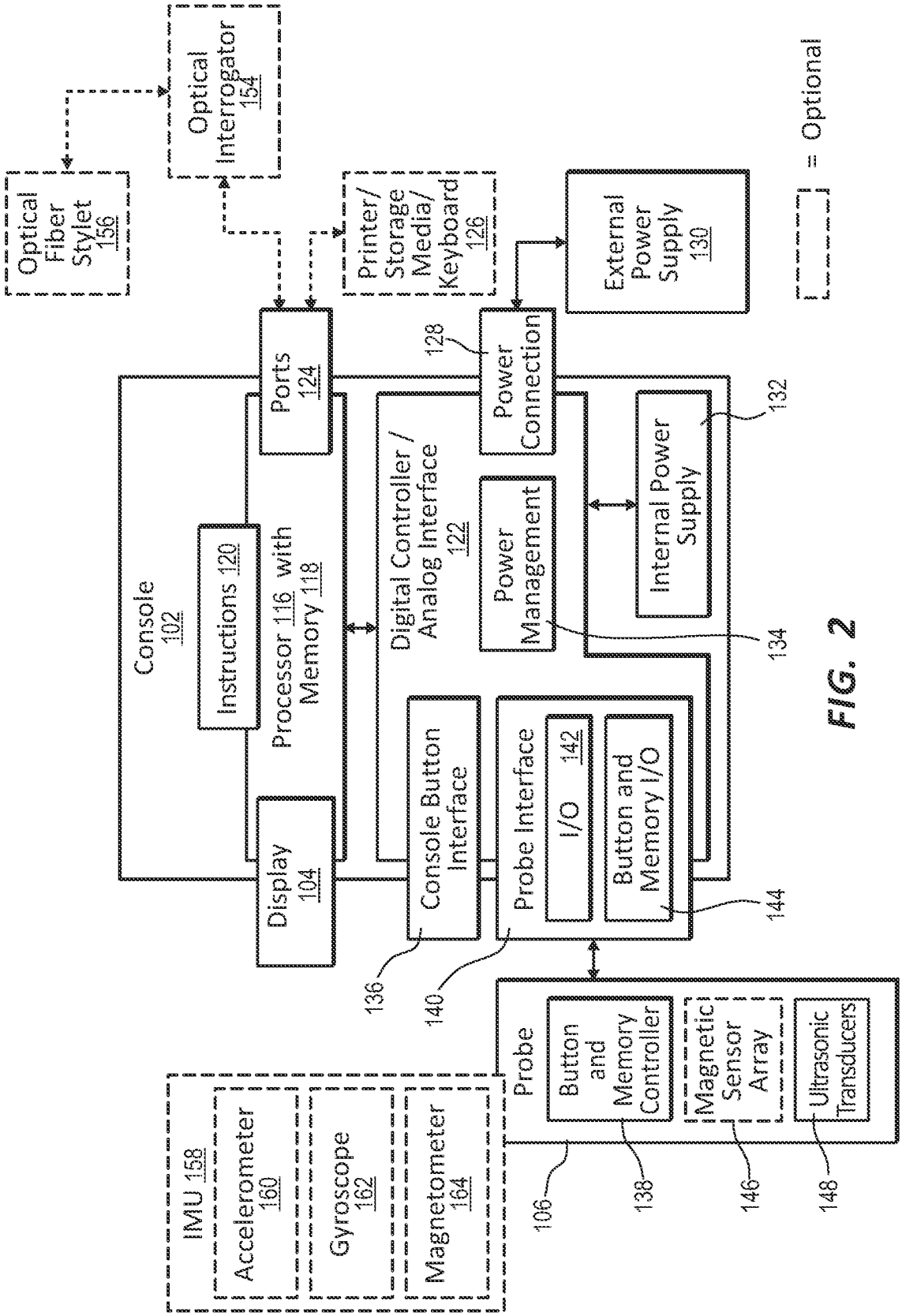


FIG. 1


Optical Fiber Stylet 156
Optical Interrogator 154
Printer/ Storage Media/ Keyboard 126
External Power Supply 130
= Optional
Console 102
Instructions 120
Processor 116 with Memory 118
Ports 124
Digital Controller / Analog Interface 122
Power Connection
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Power Management
Internal Power Supply
132
134
Display 104
Console Button Interface
Probe Interface
I/O 142
Button and Memory I/O
144
136
140
IMU 158
Accelerometer 160
Gyroscope 162
Magnetometer 164
Probe
Button and Memory Controller
Magnetic Sensor Array
Ultrasonic Transducers
106
138
146
148

FIG. 2

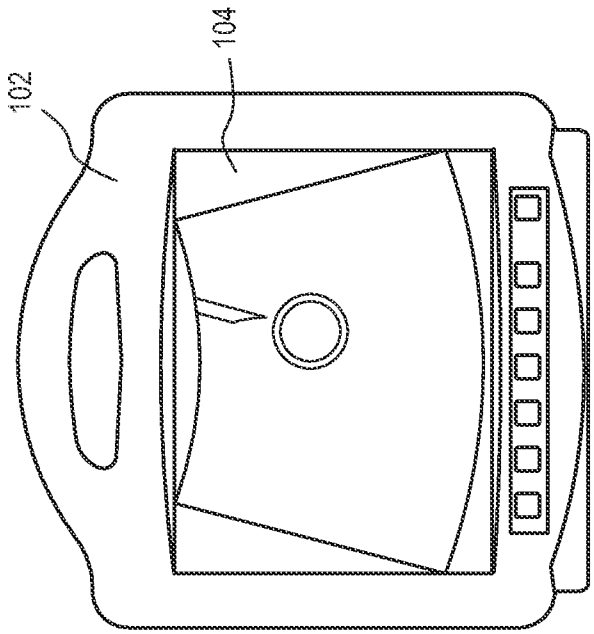


FIG. 3B

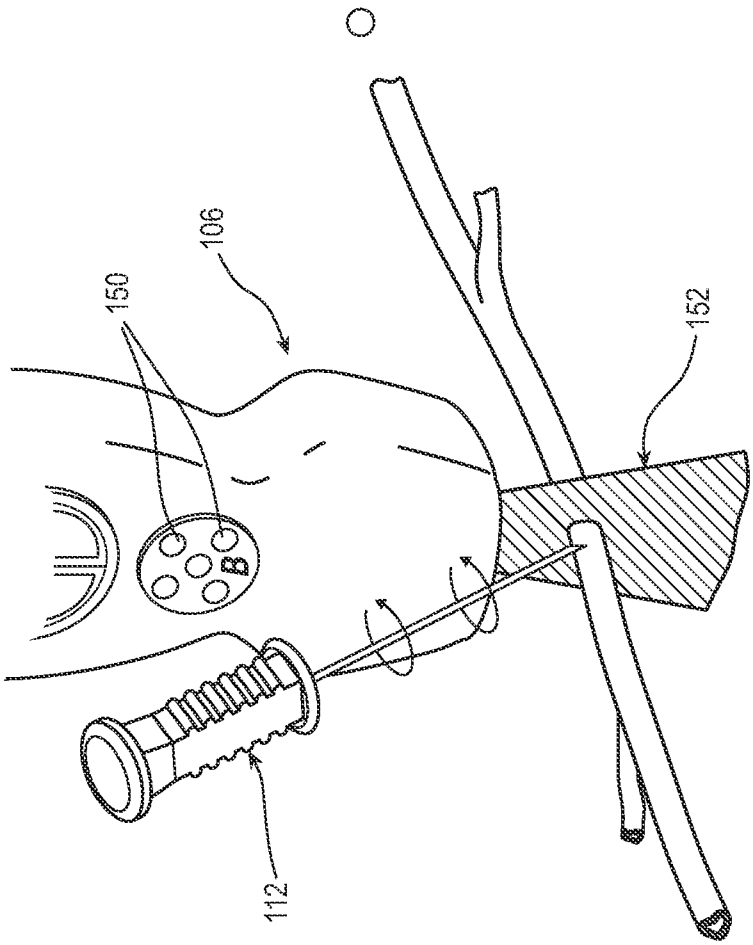


FIG. 3A

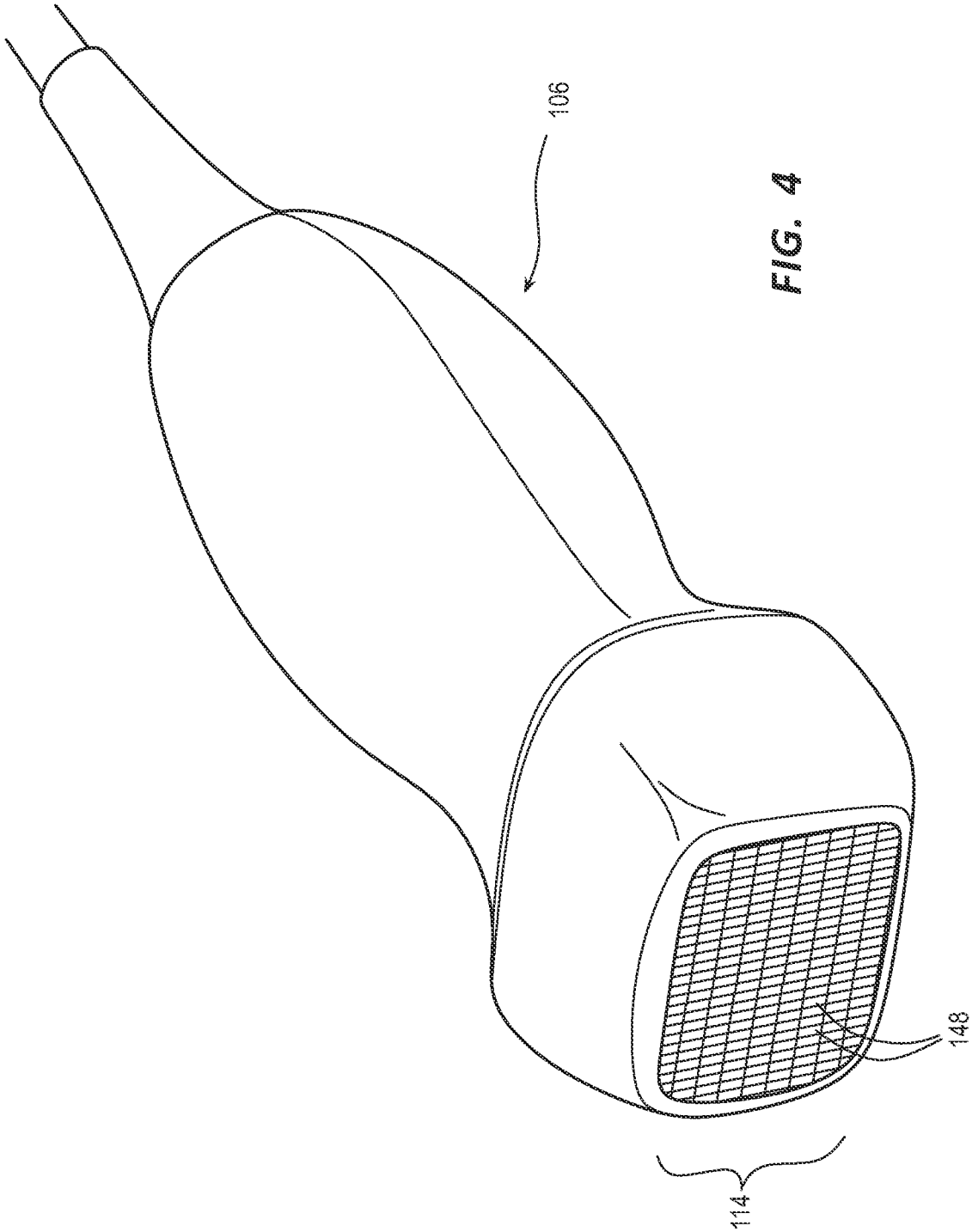


FIG. 4

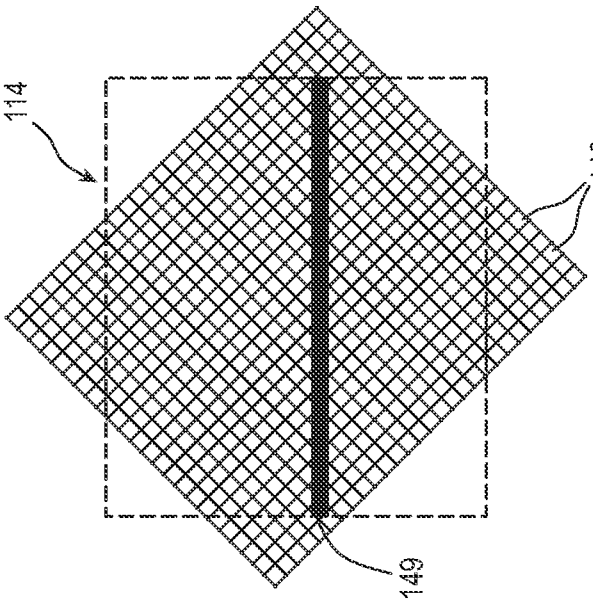


FIG. 7A

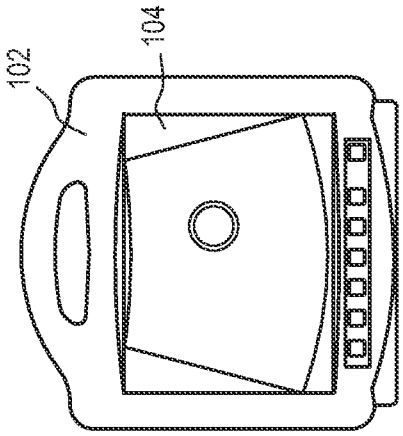


FIG. 7B

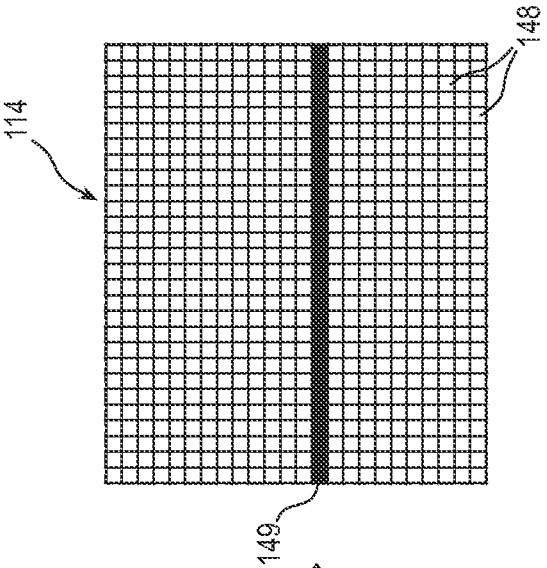


FIG. 5A

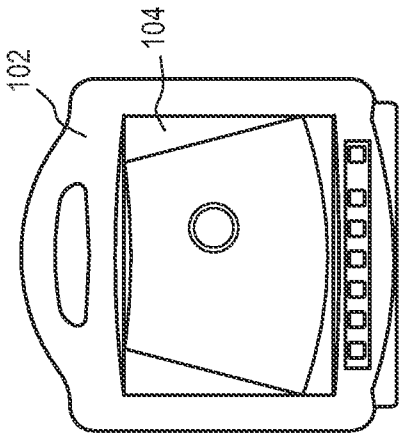


FIG. 5B

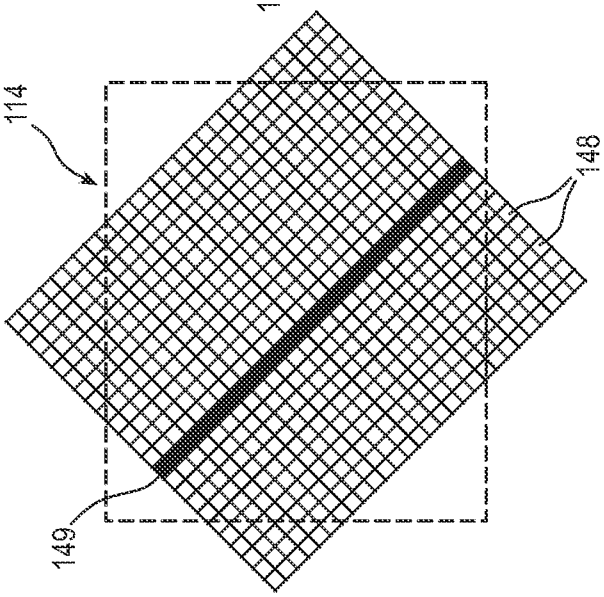


FIG. 6A

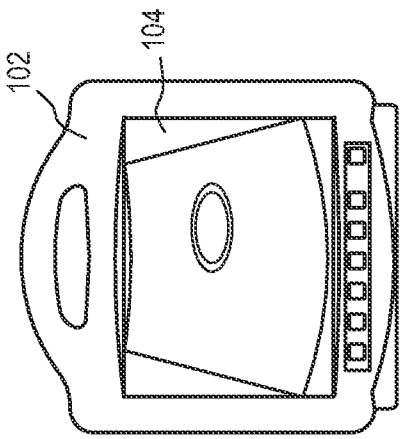


FIG. 6B

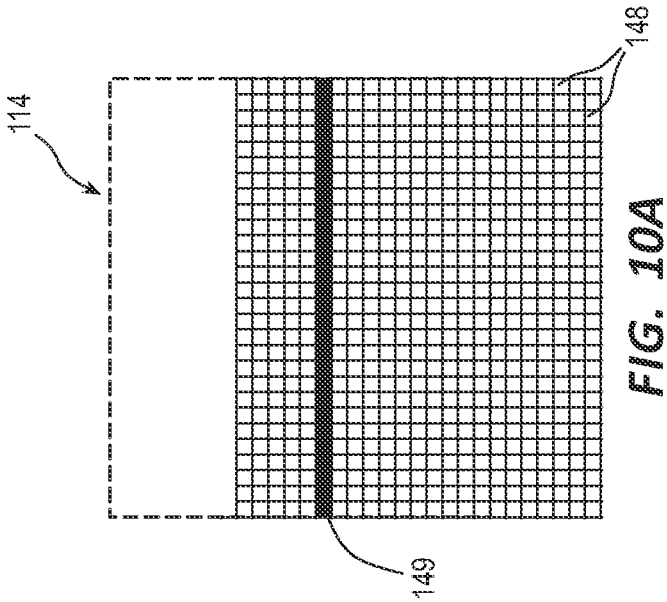


FIG. 10A

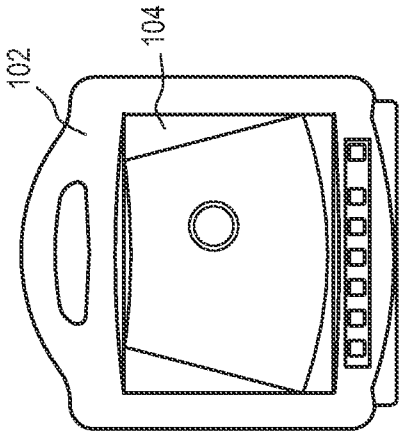


FIG. 10B

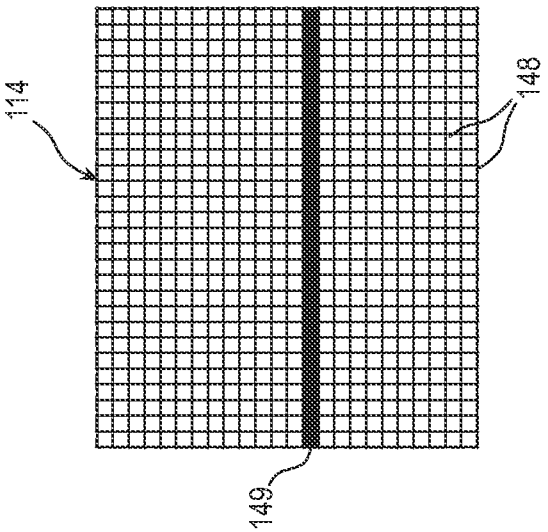


FIG. 8A

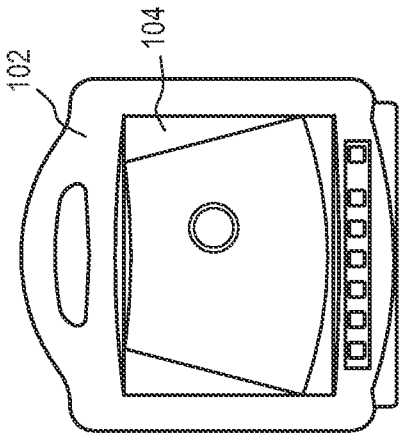


FIG. 8B

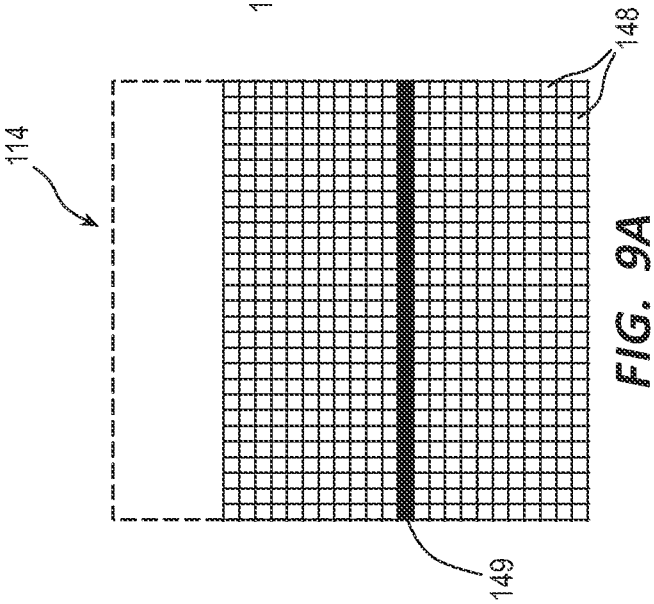


FIG. 9A

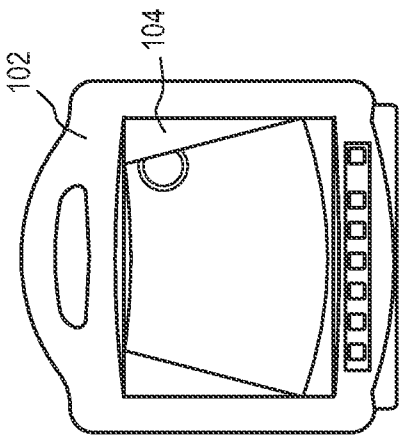
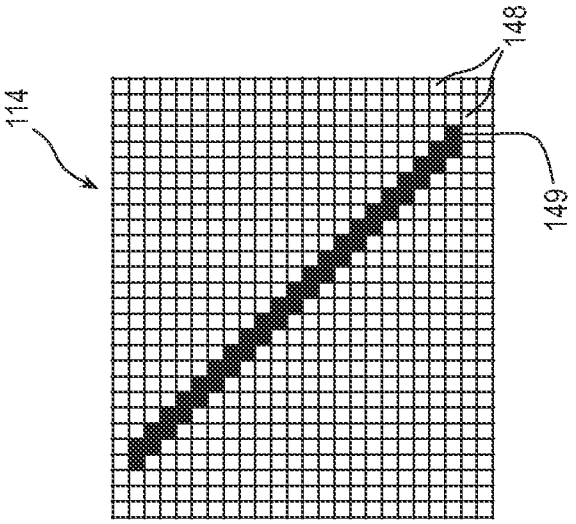


FIG. 9B



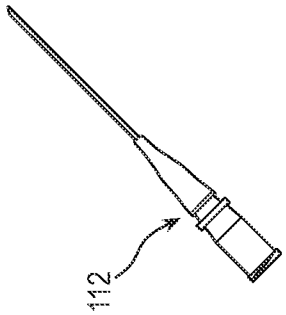
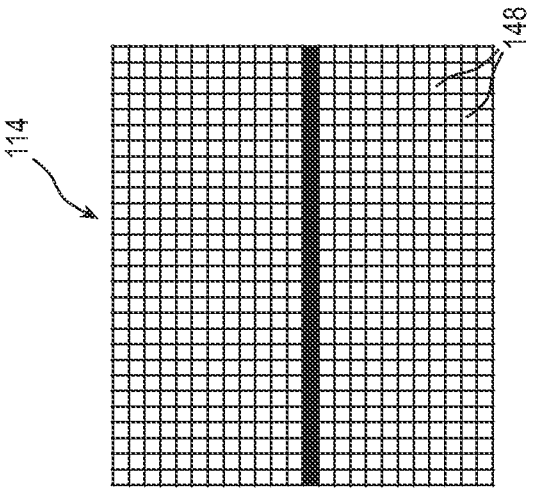


FIG. 13



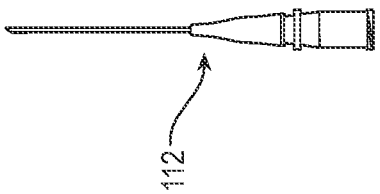
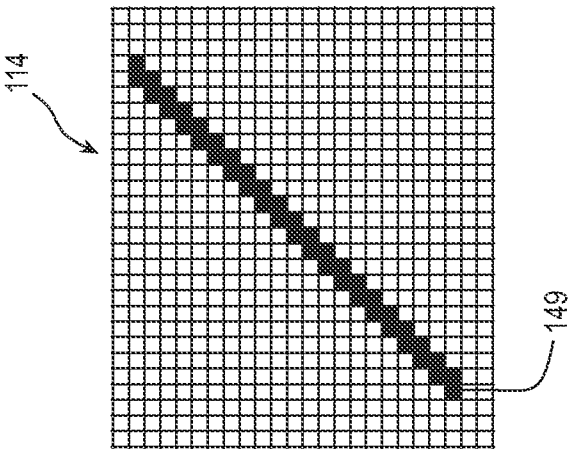


FIG. 11



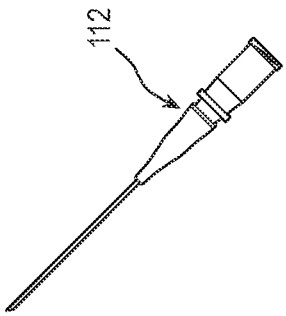


FIG. 12

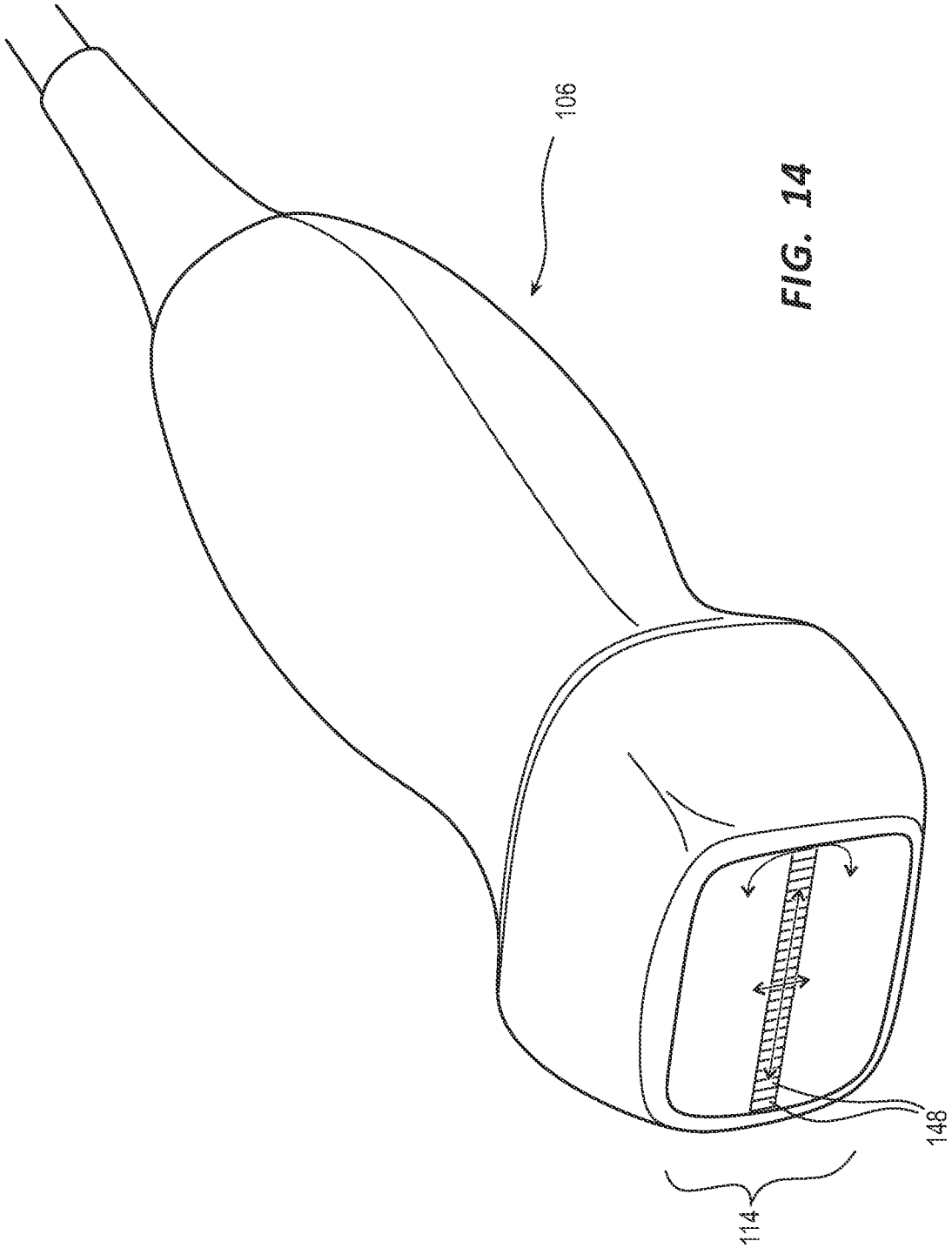


FIG. 14

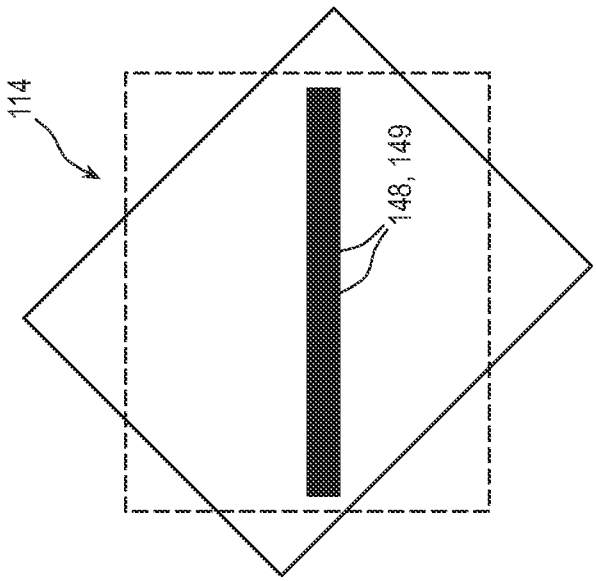


FIG. 17A

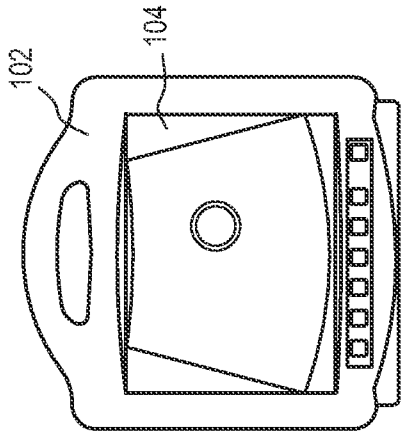


FIG. 17B

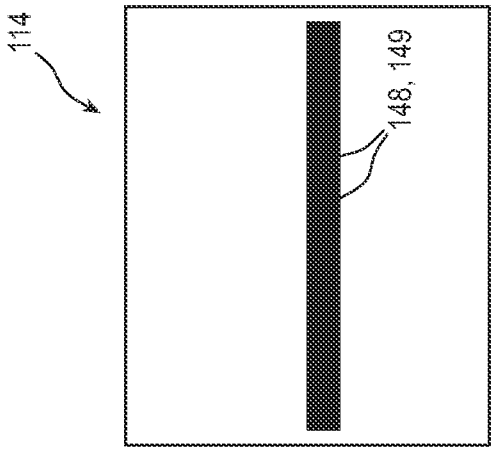


FIG. 15A

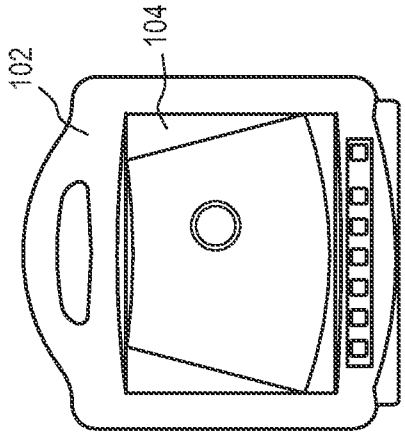


FIG. 15B

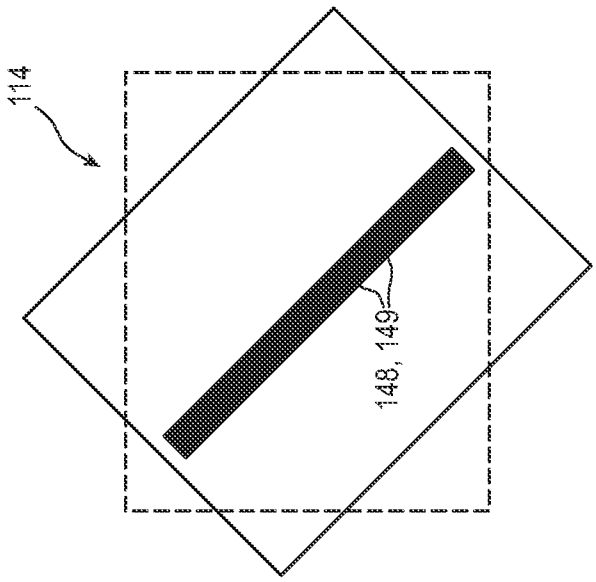


FIG. 16A

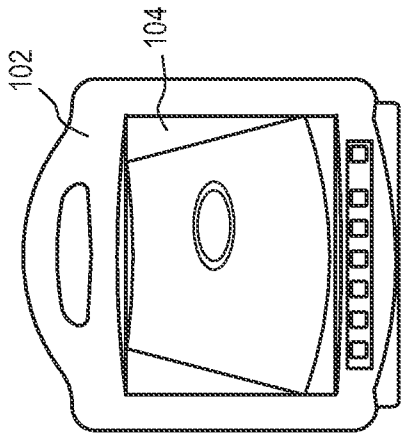


FIG. 16B

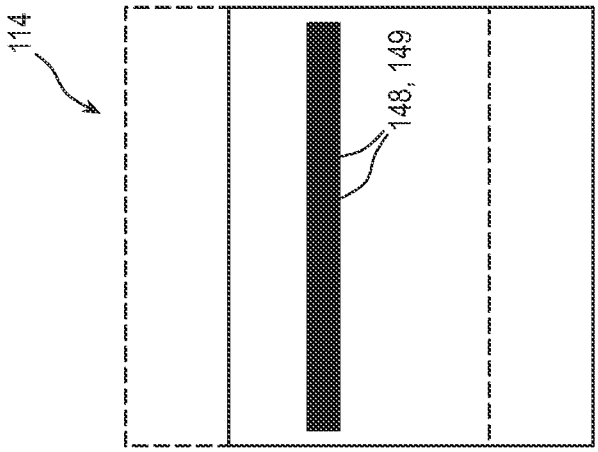


FIG. 20A

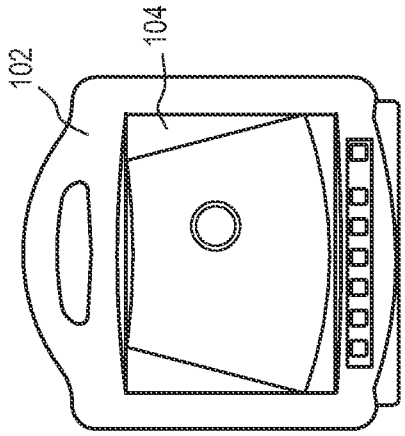


FIG. 20B

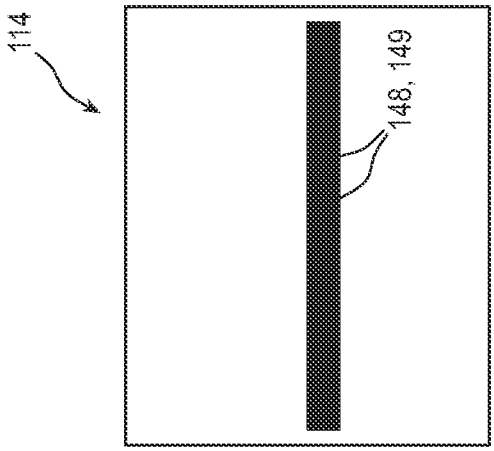


FIG. 18A

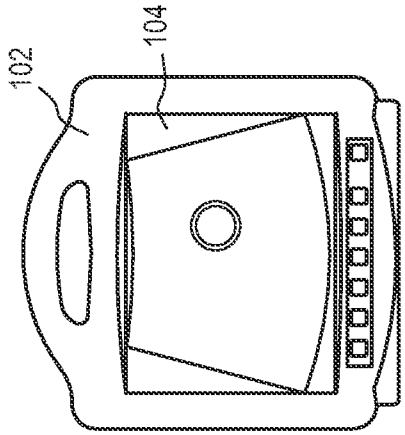


FIG. 18B

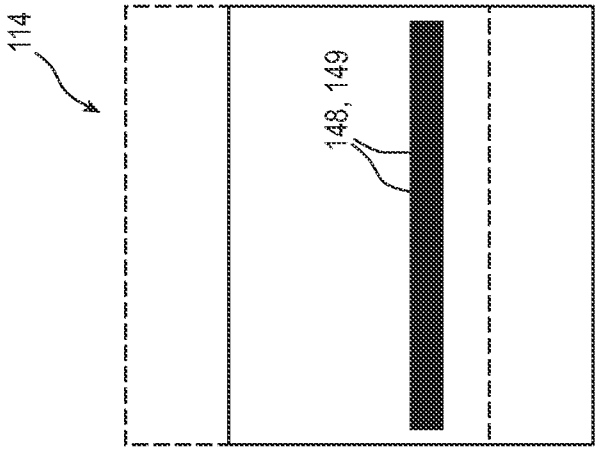


FIG. 19A

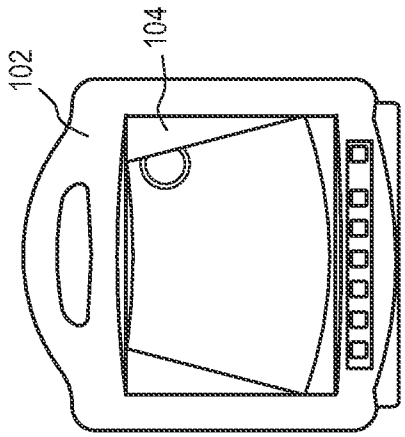
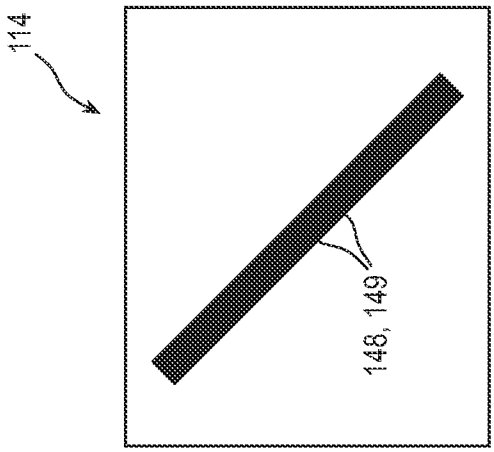


FIG. 19B



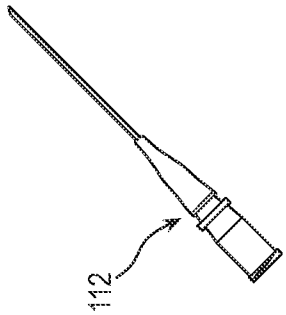
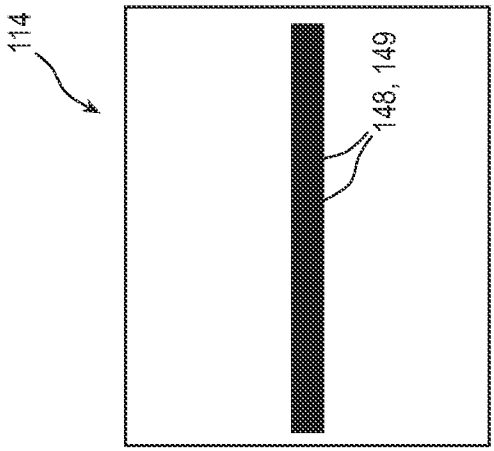


FIG. 23



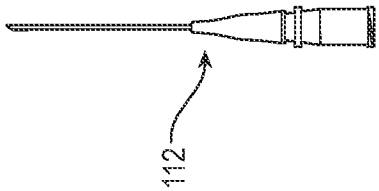
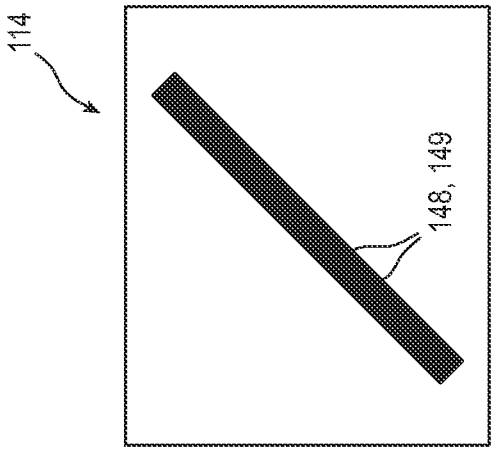


FIG. 21



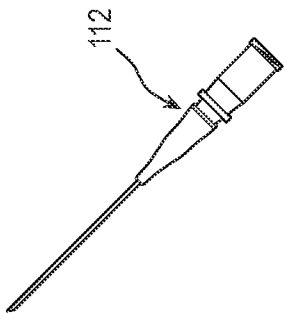


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2021/049294

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/08 A61B8/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2019/365348 A1 (TOUME SAMER [IL] ET AL) 5 December 2019 (2019-12-05) paragraphs [0106], [0107], [0108], [0110] - [0112], [0124], [0168], [0186] - [0190], [0193] figure 1	1,8-13, 20-24 2-7, 14-19
Y	US 2015/359991 A1 (DUNBAR ALLAN [DE] ET AL) 17 December 2015 (2015-12-17) paragraphs [0042] - [0043]	2-4, 14-16
Y	US 2006/013523 A1 (CHILDLERS BROOKS A [US] ET AL) 19 January 2006 (2006-01-19) paragraphs [0016], [0017], [0031]	5-7, 17-19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 November 2021	08/12/2021

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Willig, Hendrik

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2021/049294

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2019365348 A1	05-12-2019	NONE	
US 2015359991 A1	17-12-2015	CN 105025787 A	04-11-2015
		DK 2996556 T3	31-05-2021
		EP 2996556 A1	23-03-2016
		ES 2871063 T3	28-10-2021
		JP 6549992 B2	24-07-2019
		JP 2016509884 A	04-04-2016
		KR 20150123233 A	03-11-2015
		PL 2996556 T3	02-11-2021
		US 2015359991 A1	17-12-2015
		WO 2014135592 A1	12-09-2014
US 2006013523 A1	19-01-2006	NONE	