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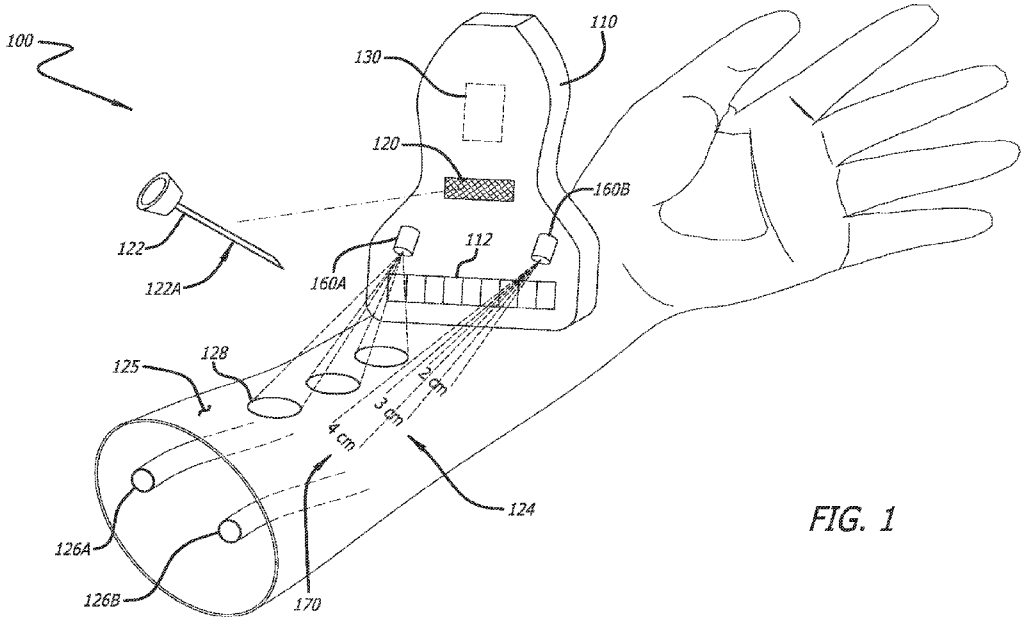

FIG. 1

(57) Abstract: Disclosed herein is an ultrasound imaging system configured to guide medical device insertion. The ultrasound imaging system includes an ultrasound probe having an ultrasound generation device configured to detect one or more anatomical targets within a target area, and one or more projectors configured to project one or more icons within the target area. The ultrasound imaging system can also include a console configured to generate the one or more icons. The console can be coupled to the ultrasound probe, and be in communication with each of the ultrasound generation device and the one or more projectors.

[Continued on next page]

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ULTRASOUND DETECTION SYSTEM

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 63/213,576, filed June 22, 2021, which is incorporated by reference in its entirety into this application.

BACKGROUND

[0002] Readily detecting and accessing a blood vessel using an ultrasound detection system can require a user to detect and access the blood vessel in a target area but view the detection of the blood vessel on a screen in another area. Having the user focusing their attention on two separate locations can lead to confusion on where to access the blood vessel and additional time needed to confirm the proper location for blood vessel access. It would be advantageous to have an ultrasound detection system that allowed a user to detect a blood vessel, view the detection of the blood vessel, confirm the access location for the blood vessel, and access the blood vessel all within the target area. Disclosed herein is an ultrasound detection system and method of use that address the foregoing.

SUMMARY

[0003] Disclosed herein is an ultrasound imaging system configured to guide medical device insertion. The system, according to some embodiments, includes: an ultrasound probe having an ultrasound generation device configured to detect one or more anatomical targets within a target area; one or more projectors configured to project one or more icons within the target area; and a console coupled to the ultrasound probe and in communication with each of the ultrasound generation device and the one or more projectors, where the console is configured to generate the one or more icons.

[0004] In some embodiments, the ultrasound probe includes one or more sensors configured to detect and track the location and orientation of a medical device within the target area, where the one or more sensors are in communication with the console.

[0005] In some embodiments, the one or more sensors are configured to detect and track the location and orientation of the medical device using a magnetic signature of the medical device.

[0006] In some embodiments, the orientation of the medical device includes the angle of trajectory of the medical device in relation to the ultrasound probe.

[0007] In some embodiments, the console includes one or more processors, an energy source, non-transitory computer readable medium and a plurality of logic modules.

[0008] In some embodiments, the plurality of logic modules, when executed by the processor, are configured to perform operations including (i) receiving ultrasound signals from the ultrasound probe, (ii) detecting the one or more anatomical targets within the target area, (iii) detecting and tracking the location and orientation of the medical device within the target area, (iv) determining one or more insertion sites within the target area to access the one or more anatomical targets, (v) calculating the insertion depth from the one or more insertion sites to the one or more anatomical targets along an angle of trajectory of the medical device, generating one or more icons, and (vi) projecting the one or more icons on a skin surface within the target area.

[0009] In some embodiments, the one or more projectors include one or more lasers.

[0010] In some embodiments, the one or more icons include icons having a shape, a size, a color, and an orientation in relation to either the ultrasound probe or the user.

[0011] In some embodiments, the one or more icons correspond to (i) the one or more insertion sites and (ii) the calculated insertion depth from the one or more insertion sites to the one or more anatomical targets along the angle of trajectory of the medical device.

[0012] In some embodiments, the one or more insertion sites are determined at specific locations within the target area relative to the ultrasound probe.

[0013] In some embodiments, the one or more insertion sites are determined based on predefined insertion depths within the target area.

[0014] In some embodiments, the one or more insertion sites are determined using one or more pre-determined angles of trajectory of the medical device.

[0015] In some embodiments, the medical device is a needle.

[0016] In some embodiments, the one or more anatomical targets include one or more blood vessels within the target area.

[0017] Also disclosed herein is a method of detecting and accessing an anatomical target. According to some embodiments, the method includes: detecting the anatomical target within a target area; detecting a medical device within the target area; determining one or more insertion sites within the target area to access the anatomical target; calculating the insertion depth to the anatomical target at any of the insertion sites; generating one or more icons corresponding to (i) the one or more insertion sites and (ii) the insertion depth to the anatomical target; projecting the one or more icons on the target area; and accessing the anatomical target at the insertion site.

[0018] In some embodiments of the method, detecting the anatomical target within the target area includes detecting the anatomical target with an ultrasound probe having an ultrasound generation device configured to generate and detect ultrasound signals, where the ultrasound probe is in communication with a console configured to receive the ultrasound signals.

[0019] In some embodiments of the method, detecting the medical device within the target area includes one or more sensors that are in communication with the console and that are coupled to the ultrasound probe, where the one or more sensors detect the location and orientation of the medical device.

[0020] In some embodiments of the method, the one or more sensors detect a magnetic signature of the medical device, and in further embodiments, the magnetic signature of the medical device is unique.

[0021] In some embodiments of the method, the one or more sensors detect an angle of trajectory of the medical device in relation to the one or more sensors.

[0022] In some embodiments of the method, determining the one or more insertion sites within the target area includes the console determining the one or more insertion sites.

[0023] In some embodiments of the method, the console determines the one or more insertion sites at specific locations relative to the ultrasound probe.

[0024] In some embodiments of the method, the console determines the one or more insertion sites by using pre-determined angles of trajectory of the medical device to determine the one or more insertion sites.

[0025] In some embodiments of the method, the console determines the one or more insertion sites based on predefined insertion depths within the target area.

[0026] In some embodiments of the method, calculating the insertion depth to the anatomical target at any of the insertion sites includes the console calculating the insertion depth to the anatomical target along the angle of trajectory of the medical device at any of the insertion sites.

[0027] In some embodiments of the method, the console calculates the insertion depth to the anatomical target along either the detected angle of trajectory of the medical device or a pre-determined angle of trajectory of the medical device.

[0028] In some embodiments of the method, generating one or more icons corresponding to the one or more insertion sites and the insertion depth to the anatomical target includes generating a first icon having a shape and a color corresponding to the insertion site and a second icon having text corresponding to the insertion depth to the anatomical target along the angle of trajectory of the medical device.

[0029] In some embodiments of the method, generating one or more icons includes generating one or more new icons when the angle of trajectory of the medical device changes.

[0030] In some embodiments of the method, generating one or more new icons when the angle of trajectory of the medical device changes includes generating one or more new icons configured to indicate to the user when the angle of trajectory of the medical device is in line with the pre-determined angle of trajectory.

[0031] In some embodiments of the method, projecting the one or more icons on the target area includes one or more projectors projecting the one or more icons on the target area, where the one or more projectors are in communication with the console and are coupled to the ultrasound probe.

[0032] In some embodiments of the method, projecting the one or more icons on the target area includes the one or more projectors projecting the one or more icons on a skin surface of the target area.

[0033] In some embodiments of the method, the one or more projectors include one or more lasers.

[0034] In some embodiments of the method, accessing the anatomical target at the insertion site includes the medical device accessing the anatomical target.

[0035] In some embodiments of the method, accessing the anatomical target at the insertion site includes inserting the medical device into the insertion site along a pre-determined angle of trajectory or the detected angle of trajectory.

[0036] In some embodiments of the method, accessing the anatomical target includes inserting the medical device through the one or more icons to access the target blood vessel.

[0037] In some embodiments of the method, the anatomical target includes one or more blood vessels within the target area.

[0038] 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

[0039] A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0040] FIG. 1 illustrates a perspective view of an ultrasound detection system, in accordance with some embodiments.

[0041] FIG. 2 illustrates a block diagram of some components of the ultrasound detection system including a console, in accordance with some embodiments.

[0042] FIG. 3A illustrates a cross sectional side view of the ultrasound detection system detecting an anatomical target within the target area and calculating the insertion depth to the anatomical target along an angle of trajectory of a medical device, in accordance with some embodiments.

[0043] FIG. 3B illustrates a plan view of the ultrasound detection system detecting an anatomical target within the target area and projecting one or more icons on the target area, in accordance with some embodiments.

[0044] FIG. 3C illustrates a cross sectional side view of the ultrasound detection system detecting an anatomical target within the target area and calculating the insertion depth to the anatomical target along an angle of trajectory of a medical device, in accordance with some embodiments.

[0045] FIG. 3D illustrates a plan view of the ultrasound detection system detecting an anatomical target within the target area and projecting one or more icons on the target area, in accordance with some embodiments.

[0046] FIG. 4 illustrates a flow chart of an exemplary method of detecting and accessing an anatomical target within a target area, in accordance with some embodiments.

DESCRIPTION

[0047] 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.

[0048] 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.

[0049] The term "logic" may be representative of hardware, firmware or software that is configured to perform one or more functions. As hardware, the term logic may refer to or include circuitry having data processing and/or storage functionality. Examples of such circuitry may include, but are not limited or restricted to a hardware processor (e.g., microprocessor, one or more processor cores, a digital signal processor, a programmable gate array, a microcontroller, an application specific integrated circuit "ASIC", etc.), a semiconductor memory, or combinatorial elements.

[0050] Additionally, or in the alternative, the term logic may refer to or include software such as one or more processes, one or more instances, Application Programming Interface(s) (API), subroutine(s), function(s), applet(s), servlet(s), routine(s), source code, object code, shared library/dynamic link library (dll), or even one or more instructions. This software may be stored in any type of a suitable non-transitory storage medium, or transitory storage medium (e.g., electrical, optical, acoustical or other form of propagated signals such as carrier waves, infrared signals, or digital signals). Examples of a non-transitory storage medium may include, but are not limited or restricted to a programmable circuit; non-persistent storage such as volatile memory (e.g., any type of random access memory "RAM"); or persistent storage such as non-volatile memory (e.g., read-only memory "ROM", power-backed RAM, flash memory, phase-change memory, etc.), a solid-state drive, hard disk drive, an optical disc drive, or a portable memory device. As firmware, the logic may be stored in persistent storage.

[0051] 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.

[0052] FIG. 1 illustrates a perspective view of an ultrasound imaging system 100 including an ultrasound probe 110 having one or more projectors 160A–160B thereon, in accordance with some embodiments. In some embodiments, the ultrasound imaging system 100 may be configured to guide medical device insertion. The ultrasound probe 110 may be configured to detect one or more anatomical targets within a target area 124 by contacting a skin surface within the target area 124. In some embodiments, the ultrasound probe 110 may include an ultrasound generation device 112 including an ultrasound acoustic stack or other various modalities of ultrasound generation. The ultrasound generation device 112 may be

configured to direct ultrasound waves into the target area 124 and detect reflections of the ultrasound waves. In some embodiments, the target area 124 may include one or more anatomical targets 126A–126B to be accessed by a medical device 122. Although the illustrated one or more anatomical targets 126A–126B include two anatomical targets, in other embodiments, the one or more anatomical targets may include 1, 3, 4, or more anatomical targets. In the illustrated embodiment, the one or more anatomical targets 126A–126B include blood vessels and as such the anatomical targets may be referred to as blood vessels herein below. However, in other embodiments the anatomical targets may include anatomical elements other than blood vessels. In some embodiments, the medical device 122 may include a vascular access device including a catheter, peripherally inserted central catheter ("PICC"), peripheral intravenous line ("PIV"), central venous catheter ("CVC"), midline catheter, a needle, or the like. In some embodiments, the medical device 122 may include ferrous elements configured to contain a magnetic signature 122A imprinted therein or otherwise coupled with the medical device 122, the magnetic signature 122A configured to be detected and tracked in three-dimensional space by one or more sensors 120 coupled to the ultrasound probe 110. In some embodiments, the one or more sensors 120 may be configured to detect and track the location of the medical device 122 in relation to the one or more sensors 120 (or the ultrasound probe 110 as a whole) and the orientation including the angle of trajectory of the medical device 122 in relation to the one or more sensors 120 (or the ultrasound probe 110 as a whole). Examples of magnetic tracking of a needle by an ultrasound probe can be found, for example, in U.S. Patent No. 9,456,766; U.S. Patent No. 9,492,097; U.S. Patent No. 9,554,716; U.S. Patent No. 10,449,330; U.S. Patent No. 10,524,691; and US 2018/0116551, each of which is incorporated by reference in its entirety into this application.

[0053] The magnetic signature 122A may include differentiating information/data regarding the medical device 122 such that a first subset of a plurality of the medical devices 122 includes a magnetic signature that is different from the magnetic signature 122A of a second subset of the plurality of the medical devices 122. In some embodiments, the differentiating information may include model information for the medical device 122, such as a module name or model number, for example. In some embodiments, the differentiating information may include dimensional information of the medical device 122, such as a length or diameter, for example. In some embodiments, the differentiating information may include manufacturing information for the medical device 122, such as a manufacturing date or lot number, for example. In some embodiments, the differentiating information may include

unique information pertaining to the medical device 122, such as a serial number, for example. As such, in some embodiments, the magnetic signature 122A for any one medical device 122 may be unique with respect to (i.e., be different from) the magnetic signature for every other medical device 122.

[0054] In some embodiments, the ultrasound probe 110 may further include a console 130 in communication with the ultrasound generation device 112. The console 130 may be configured to receive detected ultrasound signals from the ultrasound generation device 112. The ultrasound probe 110 may include the one or more sensors 120 coupled to the ultrasound probe 110, the sensors 120 configured to detect the medical device 122. The ultrasound probe 110 may also include one or more projectors 160A–160B coupled to the ultrasound probe 110, the one or more projectors 160A–160B configured to depict one or more icons 170 onto a skin surface 125 the target area 124. In some embodiments, the one or more projectors 160A–160B may be (i) in communication with the console 130 and (ii) configured to project the one or more icons 170 onto the skin surface 125 of the target area 124. In some embodiments, the one or more projectors 160A–160B may include one or more lasers. In some embodiments, the ultrasound generation device 112, the one or more sensors 120 and the one or more projectors 160A–160B may be wired to the console 130 or in wireless communication with the console 130. Exemplary wireless communication modalities can include WiFi, Bluetooth, Near Field Communications (NFC), cellular Global System for Mobile Communication ("GSM"), electromagnetic (EM), radio frequency (RF), combinations thereof, or the like.

[0055] As illustrated in FIG. 1, the ultrasound probe 110 may be configured to detect one or more anatomical targets, including one or more anatomical targets 126A–126B within the target area 124. The console 130 may be configured to detect and track the medical device 122 as the medical device 122 is moved within the target area 124. The console 130 may be configured to detect the angle of trajectory (see angle of trajectory 123 of FIG. 3A) of the medical device 122 as the medical device 122 is brought into the target area 124 to access the one or more blood vessels 126A–126B. The console 130 may be configured to determine one or more insertion sites 128 and calculate the insertion depth (see insertion depth 127 of FIG. 3A) to the one or more blood vessels 126A–126B at the insertion sites 128 along the current angle of trajectory of the medical device 122. The console 130 may be configured to generate one or more icons 170 configured to identify the insertion sites 128 to the user and the insertion depth to the one or more blood vessels 126A–126B at the insertion sites 128. In some

embodiments, the one or more projectors 160A–160B may be coupled to the ultrasound probe 110 or may be formed integrally with the ultrasound probe 110. Advantageously, the one or more projectors 160A–160B may be configured to depict the one or more icons 170 corresponding to the insertion site 128 and insertion depth to the one or more blood vessels 126A–126B onto the target area 124 to help guide a user during medical device insertion. Furthermore, the one or more icons 170 allow the user to focus their full attention on the target area 124 while the one or more projectors 160A–160B depict information to guide the insertion of the medical device 122.

[0056] FIG. 2 illustrates a block diagram of some components of the ultrasound imaging system 100 including the console 130 in accordance with some embodiments. In some embodiments, the console 130 includes one or more processors 132, an energy source 134, non-transitory computer readable medium ("memory") 136 and a plurality of logic modules. In some embodiments, the energy source 134 may be configured to provide power to the one or more projectors 160A–160B, the one or more sensors 120, and the ultrasound generation device 112. In some embodiments, the plurality of logic modules may include one or more of: an ultrasound probe receiving logic 138, a vessel detecting activation logic 140, a vessel detection logic 142, a medical device tracking activation logic 144, a medical device tracking detection logic 146, an insertion site determination logic 148, a medical device trajectory determination logic 150, an icon generation logic 152, a projector activation logic 154, and a projector depiction logic 156. In some embodiments, the ultrasound probe receiving logic 138 may be configured to receive the detected ultrasound signals from the ultrasound generation device 112.

[0057] In some embodiments, the vessel detecting activation logic 140 may be configured to activate detection of the one or more anatomical targets 126A–126B within the target area 124 from the detected ultrasound signals. In some embodiments, the vessel detecting activation logic 140 may be activated immediately upon the console 130 receiving detected ultrasound signals.

[0058] In some embodiments, the vessel detection logic 142 may be configured to detect the one or more anatomical targets 126A–126B including one or more blood vessels within the target area 124 from the detected ultrasound signals. In some embodiments, the vessel detection logic 142 may be configured to detect the orientation of the ultrasound probe 110 in in relation to the one or more blood vessels 126A–126B within the target area 124.

[0059] In some embodiments, the medical device tracking activation logic 144 may be configured to activate the one or more sensors 120 to track the medical device 122 moving through the target area 124. In some embodiments, the medical device tracking detection logic 146 may be configured to detect and track the medical device 122, as the medical device 122 moves through the target area 124 using the one or more sensors 120. In some embodiments, the medical device tracking detection logic 146 may detect the magnetic signature 122A of the medical device 122. In some embodiments, the medical device tracking detection logic 146 may be configured to detect and track the location of the medical device 122 and the orientation of the medical device 122 including the angle of trajectory of the medical device 122 in relation to the one or more sensors 120 or the ultrasound probe 110 as whole.

[0060] In some embodiments, the insertion site determination logic 148 may be configured to determine one or more insertion sites 128 within the target area 124 for accessing the one or more blood vessels 126A–126B. The insertion sites 128 may be the one or more locations on the skin surface 125 of the target area 124 wherein the medical device 122 may access the one or more blood vessels 126A–126B along an angle of trajectory. In some embodiments, the one or more insertion sites 128 may be determined using pre-determined angles of trajectory for the medical device 122. For example, pre-determined angles of trajectory in relation to the blood vessels 126A–126B of 35° or 45° of the medical device 122 accessing the one or more blood vessels 126A–126B may be used to determine the location of the insertion sites 128 within the target area 124. In some embodiments, the insertion site determination logic 148 may be configured to determine the one or more insertion sites 128 relative to the ultrasound probe 110. In some embodiments, the insertion site determination logic 148 may be configured to determine the one or more insertion sites 128 at pre-defined insertion depths. In some embodiments, the insertion site determination logic 148 may be configured to determine the one or more insertion sites 128 within the target area 124 for accessing the one or more blood vessels 126A–126B using information about the medical device 122 (e.g., the make and model of the medical device, the length of the medical device, or the like) to determine the one or more insertion sites 128.

[0061] In some embodiments, the medical device trajectory determination logic 150 may be configured to determine the angle of trajectory of the medical device 122 in relation to a target one of the blood vessels 126A–126B (i.e. the target blood vessel 126A), and calculate the insertion depth to which the medical device 122 needs be inserted into the target area 124

to access the target blood vessel 126A along the detected angle of trajectory of the medical device 122 at the one or more insertion sites 128. As the current angle of trajectory of the medical device 122 changes, the medical device trajectory determination logic 150 may be configured to determine a new insertion depth to which the medical device 122 needs to be inserted into the target area 124 to access the target blood vessel 126A at the one or more insertion sites 128. In some embodiments, as the detected angle of trajectory changes, the insertion site determination logic 150 may determine one or more new insertion sites 128 to access the target blood vessel 126A. The medical device trajectory determination logic 150 may then determine the insertion the medical device 122 needs to be insertion into the target area 124 to access the target blood vessel 126A along the detected angle of trajectory of the medical device 122 at the one or more new insertion sites 128. In some embodiments, the medical device trajectory determination logic 150 may calculate the insertion depth the medical device 122 needs to be inserted into the target area 124 using user pre-determined angles of trajectory.

[0062] In some embodiments, the icon generation logic 152 may be configured to generate the one or more icons 170 configured to be depicted onto a skin surface 125 within the target area 124. In some embodiments, the one or more icons 170 may include (i) one or more insertion site location icons 170 configured to indicate the one or more insertion sites 128 and (ii) one or more vessel insertion icons 170 configured to indicate the calculated insertion depth to the target blood vessel 126A. In some embodiments, the one or more icons 170 may include various shapes (e.g., circle, square, rectangle, triangle, or the like), various sizes, various colors, various orientations, and various text. In some embodiments, the one or more icons 170 may be configured to flash, to flicker or scroll through the target area 124. In some embodiments, the various colors may correspond to type of target blood vessel 126A, the size and insertion depth of the target blood vessel 126A or the like. In some embodiments, the various text may correspond to the insertion depth in unit measurement (e.g., centimeters, inches, or the like) or may correspond to the pre-determined angle of trajectory (e.g., 120°, 65° or the like) of the medical device 122. In some embodiments, the orientation of the one or more icons 170 may be changed. For example, the one or more icons 170 may be depicted on the target area in a transverse view, a longitudinal view, or a combination thereof. In some embodiments, the orientation of the one or more icons 170 may be changed in relation to the ultrasound probe 110. In some embodiments, the user may determine the shape, size, color and orientation of the one or more icons 170.

[0063] In some embodiments, the projector activation logic 154 may be configured to activate the one or more projectors 160A-160B. In some embodiments, the projector activation logic 154 may activate the one or more projectors 160A-160B upon starting up the system 100. In some embodiments, the projector depiction logic 156 may be configured to project the one or more icons 170 onto the skin surface 125 in the target area 124. In some embodiments, user pre-determined angles of trajectory are used to (i) determine the one or more insertion sites 128 and (ii) calculate the insertion depth to the target blood vessel 126A. In some embodiments, the projector depiction logic 156 may be configured to change the shape, color, or size of the one or more icons 170 when the medical device 122 is angled at one or more predetermined angles of trajectory 123. In some embodiments, once the medical device 122 is confirmed to be inserted into the target blood vessel 126A, the projector depiction logic 156 may be configured to cease projecting the one or more icons 170 on the target area 124. In some embodiments, the projector depiction logic 156 may be configured to project the one or more icons 170 at different orientations in relation to the ultrasound probe 110 or the user.

[0064] FIG. 3A illustrates a cross sectional view of the system 100 detecting and calculating the insertion depth 127 to the anatomical target 126A–126B, in accordance with some embodiments. The ultrasound probe 110 is as described above. The ultrasound probe 110 detects the one or more blood vessels 126A–126B within the target area 124. The console 130 may be configured to track the medical device 122 within the target area 124 using the one or more sensors 120. The console 130 may be configured to (i) determine the one or more insertion sites 128 within the target area 124, (ii) generate the one or more icons 170 corresponding to the one or more insertion sites 128, and (iii) depict the one or more icons 170 on the target area 124 via the one or more projectors 160A–160B. As the medical device 122 is moved within the target area 124, the one or more sensors 120 may be configured to (i) determine the angle of trajectory 123 of the medical device 122 in relation to the one or more sensors 120 coupled to the ultrasound probe 110 and (ii) transmit the detected angle of trajectory 123 of the medical device 122 to the console 130. The console 130 may use the detected angle of trajectory 123 of the medical device 122 in relation to the target blood vessel 126A to determine the insertion depth 127 to which the medical device 122 needs to be inserted into the target area 124 at the insertion site 128 to access the target blood vessel 126A along the detected angle of trajectory 123 of the medical device 122. For example, an angle of trajectory 123 (e.g., the illustrated angle 123 of about 135 degrees in FIG. 3A for example) of the medical device 122 in relation to the target blood vessel 126A leads to a greater insertion

depth 127 to which the medical device 122 must travel through the target area 124 to access the target blood vessel 126A. The console 130 may be configured to update the one or more icons 170 depicted by the one or more projectors 160A–160B as the detected angle of trajectory 123 of the medical device 122 within the target area 124 changes.

[0065] FIG. 3B illustrates a plan view of the system 100 of FIG. 3A detecting the medical device 122 within the target area 124 and the one or more projectors 160A-160B depicting the one or more icons 170 on the skin surface 125 within the target area 124, in accordance with some embodiments. The ultrasound probe 110 is configured to detect the target blood vessel 126A within the target area 124 as described above. The medical device 122 is detected by the one or more sensors 120 coupled to the ultrasound probe 110 as the ultrasound probe 110 is within the target area 124 as described above. As illustrated in FIG. 3B, the console 130 is configured to generate the icon 170A corresponding to the one or more insertion sites 128 and the icon 170B corresponding to the insertion depth 127 of the target vessel 126A along the angle of trajectory 123 of the medical device 122 at that specific insertion site 128. The projectors 160A-160B may be configured to depict the icons 170A-170B within the target area 124. The icons 170A-170B may be configured in the target area 124 to be adjacent and longitudinally in line with each other to enable the user to quickly identify the insertion site 128 and the insertion depth 127 to the target blood vessel 126A.

[0066] FIG. 3C illustrates a cross sectional side view of the system 100 detecting and calculating the insertion depth 127 to the anatomical target 126, in accordance with some embodiments. As illustrated in FIG. 3C, the angle of trajectory 123 of the medical device 122 (e.g., the illustrated angle 123 of about 95 degrees in FIG. 3C for example) is more acute than the angle of trajectory 123 of the medical device 122 illustrated in FIG. 3A. Thus, the calculated insertion depth 127 that the medical device 122 needs to travels within the target area 124 in order to access the target blood vessel 126A in FIG. 3C is less than the calculated insertion depth 127 that the medical device 122 needed to travel in FIG. 3A.

[0067] FIG. 3D illustrates a plan view of the system 100 of FIG. 3C detecting the medical device 122 within the target area 124 and the one or more projectors 160A-160B depicting the icons 170A-170B within the target area 124, in accordance with some embodiments. The icon 170B may be configured to indicate the calculated insertion depth 127 in FIG. 3C. Furthermore, the projectors 160A-160B may depict the icon 170B oriented in the transverse direction, giving the user multiple viewing options of the icons 170A-170B.

[0068] FIG. 4 illustrates a flow chart of an exemplary method 200 of detecting and accessing an anatomical target such as the blood vessel 126A, in accordance with some embodiments. In some embodiments, the method 200 includes detecting the blood vessel 126A within the target area 124 (block 202). In some embodiments, detecting the blood vessel 126A within the target area 124 includes using the ultrasound probe 110 having the ultrasound generation device 112 to detect the blood vessel 126A. In some embodiments, detecting the blood vessel 126A within the target area 124 includes contacting the skin surface 125 of the target area 124 with the ultrasound probe 110.

[0069] The method 200 further includes detecting the medical device 122 within the target area 124 (block 204). In some embodiments, detecting the medical device 122 within the target area 124 includes the one or more sensors 120 detecting the medical device 122 within the target area 124. In some embodiments, the one or more sensors 120 may detect the magnetic signature 122A of the medical device 122. In some embodiments, the one or more sensors 120 may detect and communicate to the console 130 the location of the medical device 122 within the target area 124 and the orientation of the medical device 122 in relation to the one or more sensors 120 coupled to the ultrasound probe 110.

[0070] The method 200 further includes determining one or more insertions sites 128 within the target area 124 to access the blood vessel 126A (block 206). In some embodiments, determining the one or more insertion sites 128 includes the console 130 determining the one or more insertion sites 128. In some embodiments, the one or more insertion sites 128 may be determined by using pre-determined angles of trajectory to determine the one or more insertion sites 128 within the target area 124. In some embodiments, the one or more insertion sites 128 may be determined predefined insertion depths. In some embodiments, the one or more insertion sites 128 may be determined at specific locations relative to the ultrasound probe 110.

[0071] The method 200 further includes calculating the insertion depth 127 to the blood vessel 126A at the one or more insertion sites 128 (block 208). In some embodiments, the console 130 is configured to calculate the insertion depth 127 to the blood vessel 126A at the one or more insertion sites 128. In some embodiments, the console 130 calculates the insertion depth 127 to the blood vessel 126A using the detected angle of trajectory 123 of the medical device 122 to calculate the insertion depth 127 at the one or more insertion sites 128. In some embodiments, the console 130 uses pre-determined angles of trajectory of the medical device 122 to calculate the insertion depth 127 to the blood vessel 126A at the one or more insertion

sites 128. In some embodiments, the console 130 may use pre-determined insertion depths to define the one or more insertion sites. In other words, the insertion sites 128 may be defined to correspond with defined insertion depths 127, such as 2 cm, 3 cm, or 4 cm, for example.

[0072] The method 200 further includes generating (i) one or more icons 170, the one or more icons 170 corresponding to the one or more insertion sites 128 and (ii) the insertion depth 127 to the target blood vessel 126A at the one or more insertion sites 128 (block 210). In some embodiments, the console 130 may be configured to generate the one or more icons 170. In some embodiments, the one or more icons 170 may include a variety of shapes, colors, text, sizes, or the like. In some embodiments, a first icon 170 having a shape, a size and a color may correspond to the insertion site 128 and a second icon 170, having text, that may correspond to the insertion depth 127 to the blood vessel 126A at the insertion site 128 along the detected angle of trajectory 123 of the medical device 122. In an embodiment, a single icon 170 having a shape, a size, a color and text within the shape may correspond to both the insertion site 128 and the insertion depth 127 to the blood vessel 126A at the insertion site 128 along the detected angle of trajectory 123 of the medical device 122. In some embodiments, generating one or more icons 170 includes generating (i) one or more new icons 170 corresponding to the one or more insertion sites 128 and (ii) the insertion depth 127 to the anatomical target 126 at the one or more insertion sites 128 when the angle of trajectory 123 of the medical device 122 changes. In some embodiments, generating one or more new icons 170 includes generating one or more new icons 170 configured to indicate to the user that the angle of trajectory 123 of the medical device 122 is in line with one of the pre-determined angles of trajectory 123. In some embodiments, generating the one or more new icons 170 includes changing one or more of the size, the shape, or the color of the new icons 170 to indicate to the user that the angle of trajectory 123 of the medical device 122 is in line with one of the pre-determined angles of trajectory 123.

[0073] The method 200 further includes projecting the one or more icons 170 on the target area 124 (block 212). In some embodiments, projecting the one or more icons 170 on the target area 124 includes the one or more projectors 160A–160B projecting the one or more icons 170 on the skin surface 125 within the target area 124. In some embodiments, projecting the one or more icons 170 on the target area 124 includes the one or more projectors 160A–160B projecting the one or more icons 170 on the target area 124 in different orientations in relation to the ultrasound probe 110 or the user.

[0074] The method 200 further includes accessing the blood vessel 126A at the insertion site 128 (block 214). In some embodiments, accessing the blood vessel 126A at the insertion site 128 includes inserting the medical device 122 into the insertion site 128 along the detected angle of trajectory 123 to access the blood vessel 126A. In some embodiments, inserting the medical device 122 into the insertion site 128 includes inserting the medical device 122 through the icon 170 projected onto the target area 124 corresponding to the insertion site 128. In some embodiments, inserting the medical device 122 into the insertion site 128 includes inserting the medical device the calculated insertion depth 127 depicted by the icon 170 on the target area 124.

[0075] 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 configured to guide medical device insertion, comprising:

an ultrasound probe comprising:

an ultrasound generation device configured to detect one or more anatomical targets within a target area;

one or more projectors configured to project one or more icons onto a skin surface within the target area; and

a console coupled to the ultrasound probe and in communication with each of the ultrasound generation device and the one or more projectors, the console configured to generate the one or more icons.

2. The ultrasound imaging system according to claim 1, wherein the ultrasound probe includes one or more sensors configured to detect and track the location and orientation of a medical device within the target area, the one or more sensors in communication with the console.

3. The ultrasound imaging system according to claim 2, wherein the one or more sensors are configured to detect and track the location and orientation of the medical device using a magnetic signature of the medical device.

4. The ultrasound imaging system according to claim 3, wherein the orientation of the medical device includes the angle of trajectory of the medical device in relation to the ultrasound probe.

5. The ultrasound imaging system according to any of the preceding claims, wherein the console includes:

one or more processors;

an energy source;

a non-transitory computer readable medium; and

a plurality of logic modules.

6. The ultrasound imaging system according to claim 5, wherein the plurality of logic modules, when executed by the processor, are configured to perform operations including:

receiving ultrasound signals from the ultrasound probe;

detecting the one or more anatomical targets within the target area;

detecting and tracking the location and orientation of the medical device within the target area;

determining one or more insertion sites within the target area to access the one or more anatomical targets;

calculating an insertion depth extending from the one or more insertion sites to the one or more anatomical targets along an angle of trajectory of the medical device;

generating one or more icons; and

projecting the one or more icons onto the skin surface within the target area.

7. The ultrasound imaging system according to any of the preceding claims, wherein the one or more projectors include one or more lasers.

8. The ultrasound imaging system according to any of the preceding claims, wherein the one or more icons include icons having a shape, a size, a color and an orientation in relation to either the ultrasound probe or the user.

9. The ultrasound imaging system according to any of the preceding claims, wherein the one or more icons correspond to the one or more insertion sites and the calculated insertion depth from the one or more insertion sites to the one or more anatomical targets along the angle of trajectory of the medical device.

10. The ultrasound imaging system according to any of claims 6-9, wherein the one or more insertion sites are determined at specific locations within the target area relative to the ultrasound probe.

11. The ultrasound imaging system according to any of claims 6-10, wherein the one or more insertion sites are determined based on pre-defined insertion depths within the target area.

12. The ultrasound imaging system according to any of claims 6-11, wherein the one or more insertion sites are determined based on one or more pre-determined angles of trajectory of the medical device.

13. The ultrasound imaging system according to any of the preceding claims, wherein the medical device is a needle.

14. The ultrasound imaging system according to any of the preceding claims, wherein the one or more anatomical targets include one or more blood vessels within the target area.

15. A method of detecting and accessing an anatomical target, comprising:

detecting an anatomical target within a target area;

detecting a medical device within the target area;

determining one or more insertion sites within the target area to access the anatomical target;

calculating an insertion depth to the anatomical target at any of the insertion sites;

generating one or more icons corresponding to the one or more insertion sites, each of the one or more icons including the insertion depth to the anatomical target;

projecting the one or more icons on the target area; and

accessing the anatomical target at one of the one or more insertion sites.

16. The method according to claim 15, wherein detecting the anatomical target within the target area includes detecting the anatomical target with an ultrasound probe having an ultrasound generation device configured to generate and detect ultrasound signals, the ultrasound probe in communication with a console configured to receive the ultrasound signals.

17. The method according to claim 16, wherein detecting the medical device within the target area includes one or more sensors in communication with the console and coupled to the ultrasound probe, the one or more sensors detecting the location and orientation of the medical device with respect to the ultrasound probe.

18. The method according to claim 17, wherein the one or more sensors detect a unique magnetic signature of the medical device.

19. The method according to either claim 17 or 18, wherein the one or more sensors detect an angle of trajectory of the medical device in relation to the ultrasound probe.

20. The method according to any of claims 15-19, wherein determining the one or more insertion sites within the target area includes the console determining the one or more insertion sites.

21. The method according to any of claims 15-20, wherein the console determines the one or more insertion sites at specific locations relative to the ultrasound probe.

22. The method according to any of claims 15-20, wherein the console determines the one or more insertion sites based on pre-determined angles of trajectory of the medical device.

23. The method according to any of claims 15-20, wherein the console determines the one or more insertion sites based on pre-defined insertion depths within the target area.

24. The method according to any of claims 15-23, wherein calculating the insertion depth to the anatomical target at any of the insertion sites includes the console calculating the insertion depth to the anatomical target along the angle of trajectory of the medical device at any of the insertion sites.

25. The method according to any of claims 15-23, wherein the console calculates the insertion depth to the anatomical target along either the detected angle of trajectory of the medical device or a pre-determined angle of trajectory of the medical device.

26. The method according to any of claims 15-25, wherein generating one or more icons corresponding to the one or more insertion sites and the insertion depth to the anatomical target includes generating:

a first icon having a shape and/or a color corresponding to the insertion site, and

a second icon having text corresponding to the insertion depth to the anatomical target along the angle of trajectory of the medical device.

27. The method according to any of claims 15-26, wherein generating one or more icons includes generating one or more new icons when the angle of trajectory of the medical device changes.

28. The method according to claim 27, wherein generating one or more new icons when the angle of trajectory of the medical device changes includes generating one or more new icons configured to indicate to the user when the angle of trajectory of the medical device is in line with the pre-determined angle of trajectory.

29. The method according to any of claims 15-28, wherein projecting the one or more icons on the target area includes one or more projectors projecting the one or more icons on the target area, the one or more projectors in communication with the console and coupled to the ultrasound probe.

30. The method according to claim 29, wherein projecting the one or more icons on the target area includes the one or more projectors projecting the one or more icons onto a skin surface of the target area.

31. The method according to any of claims 29-30, wherein the one or more projectors include one or more lasers.

32. The method according to any of claims 15-31, wherein accessing the anatomical target at the insertion site includes the medical device accessing the anatomical target.

33. The method according to claim 32, wherein accessing the anatomical target at the insertion site includes inserting the medical device into the insertion site along a pre-determined angle of trajectory or the detected angle of trajectory.

34. The method according to any of claims 32-33, wherein accessing the anatomical target includes inserting the medical device through the one or more icons to access the anatomical target.

35. The method according to any of claims 15-34, wherein the anatomical target includes one or more blood vessels within the target area.

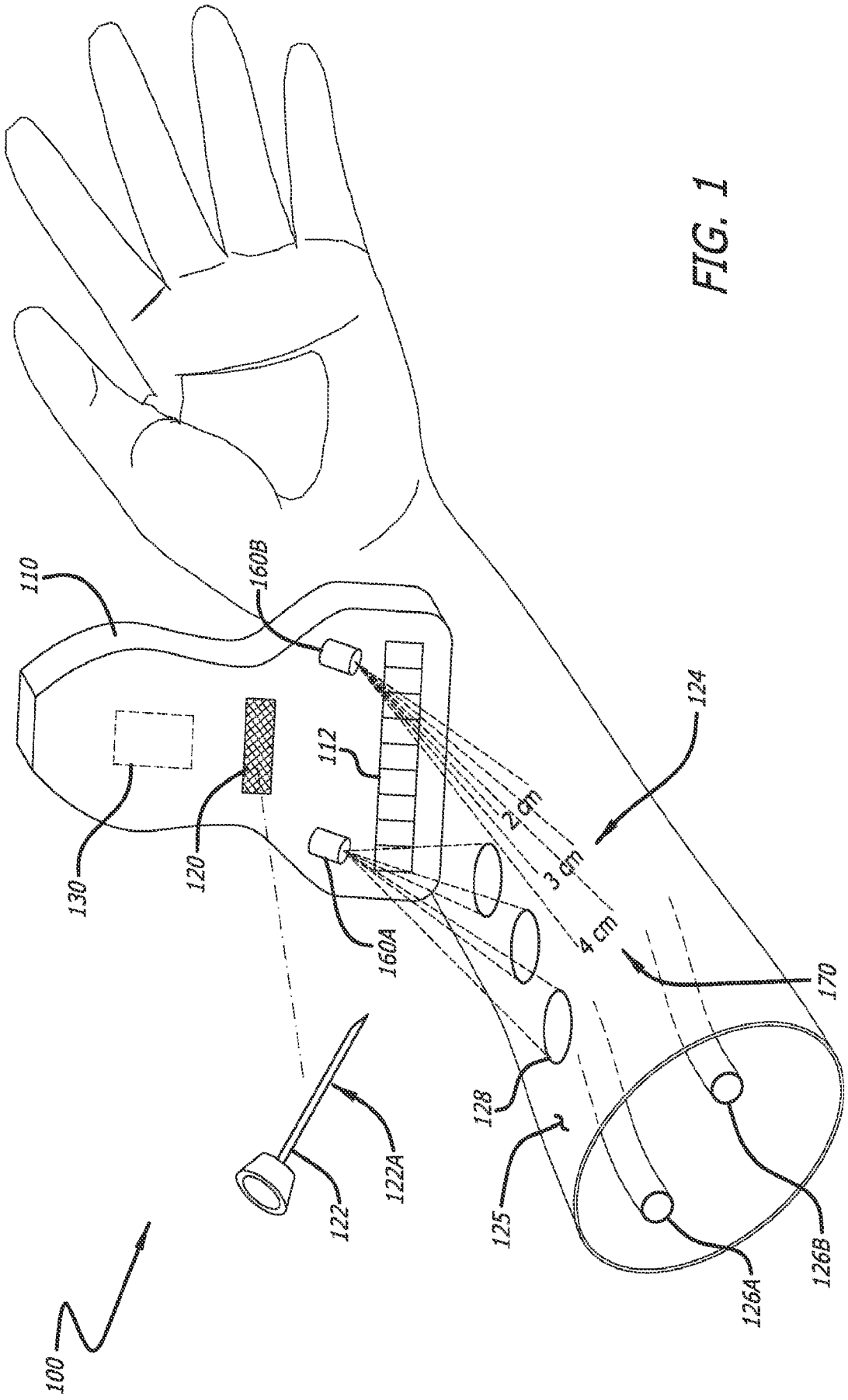

100
110
160B
112
120
130
160A
122
122A
124
2 cm
3 cm
4 cm
125
126A
126B
128
170

FIG. 1

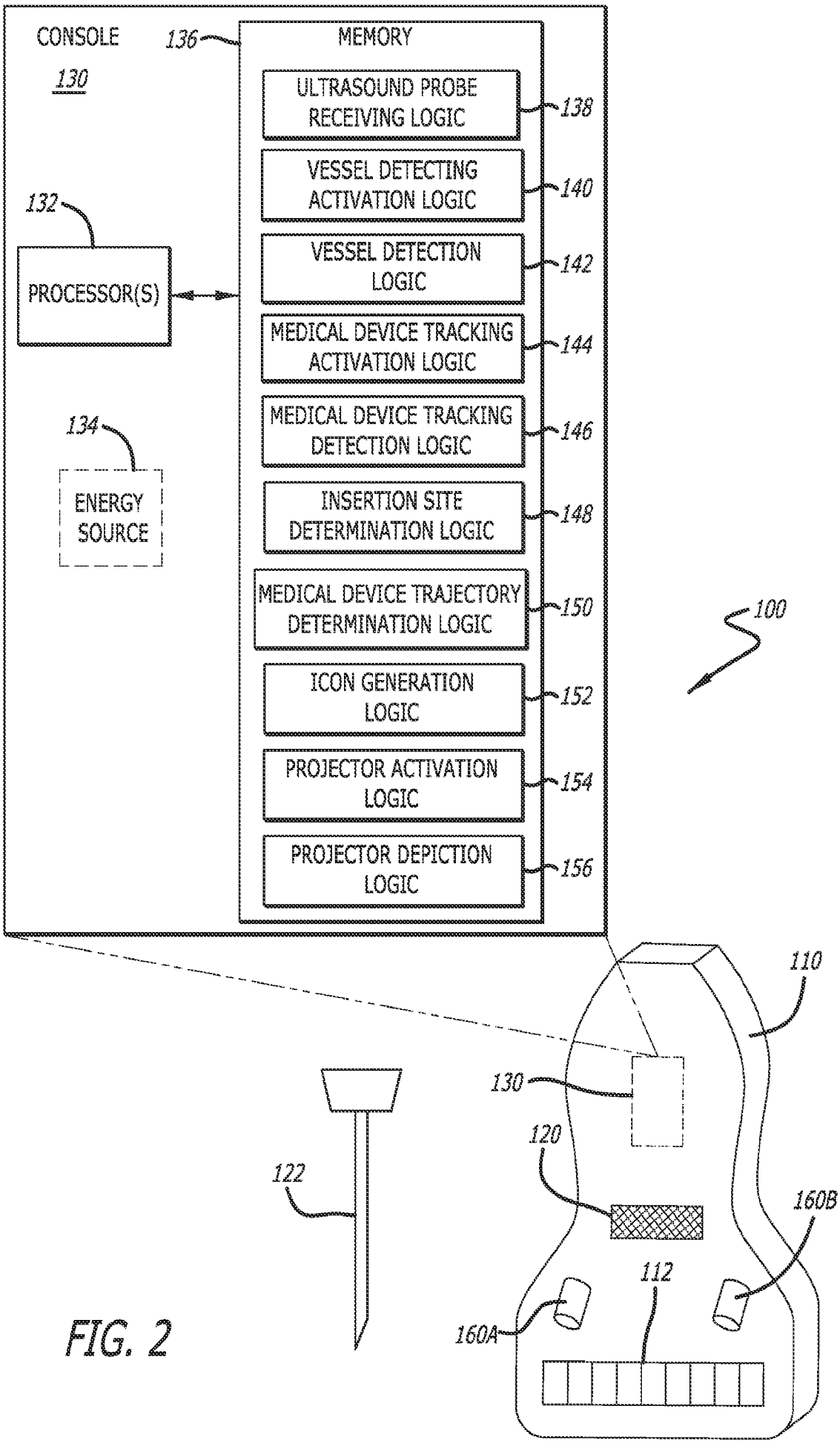
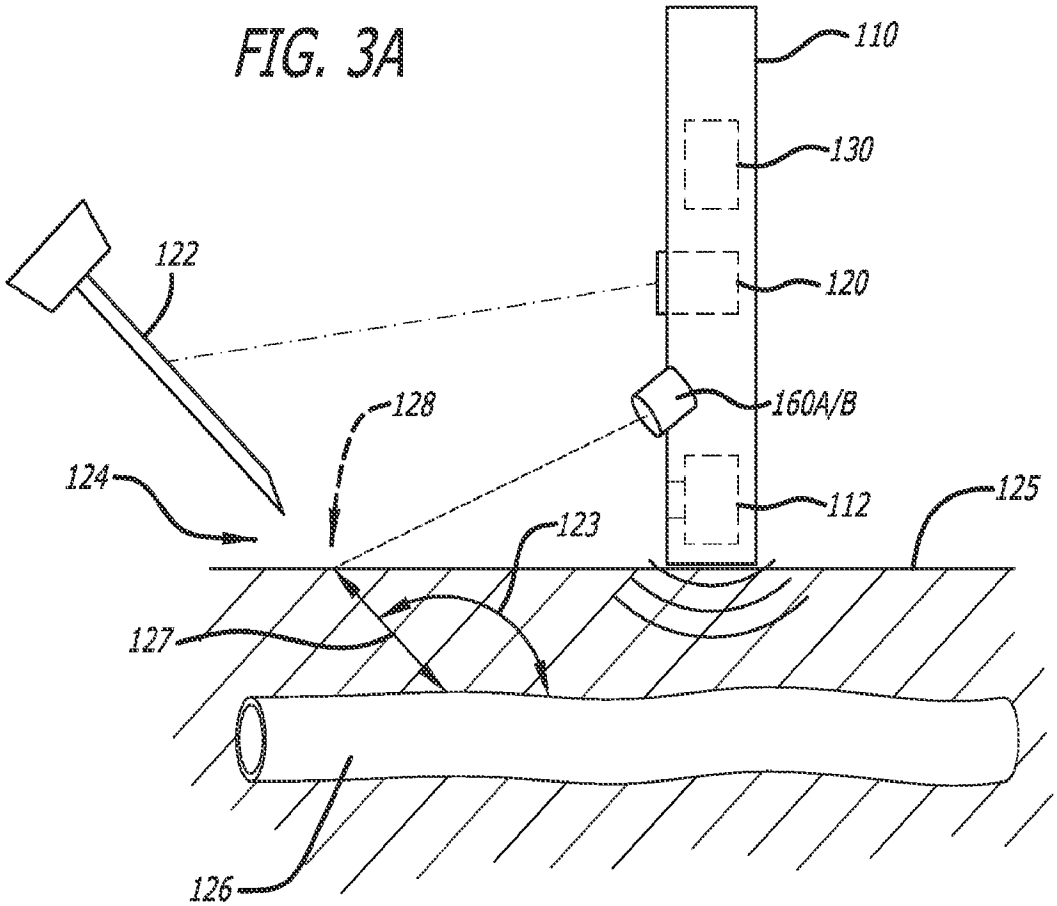

CONSOLE
130
136
MEMORY
ULTRASOUND PROBE RECEIVING LOGIC
138
VESSEL DETECTING ACTIVATION LOGIC
140
VESSEL DETECTION LOGIC
142
MEDICAL DEVICE TRACKING ACTIVATION LOGIC
144
MEDICAL DEVICE TRACKING DETECTION LOGIC
146
INSERTION SITE DETERMINATION LOGIC
148
MEDICAL DEVICE TRAJECTORY DETERMINATION LOGIC
150
ICON GENERATION LOGIC
152
PROJECTOR ACTIVATION LOGIC
154
PROJECTOR DEPICTION LOGIC
156
132
PROCESSOR(S)
134
ENERGY SOURCE
100
110
130
120
122
160B
112
160A

FIG. 2

FIG. 3A


110
130
122
120
160A/B
128
124
112
125
123
127
126

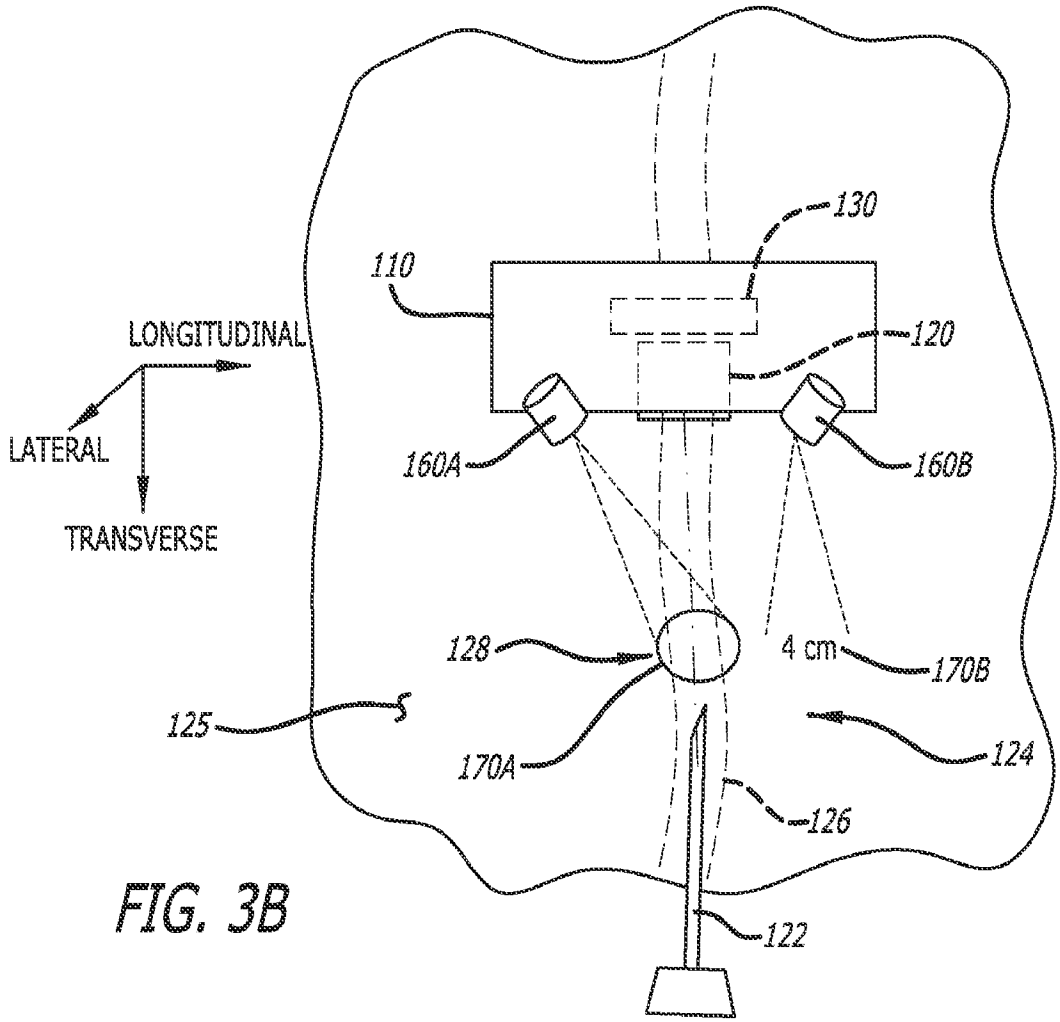
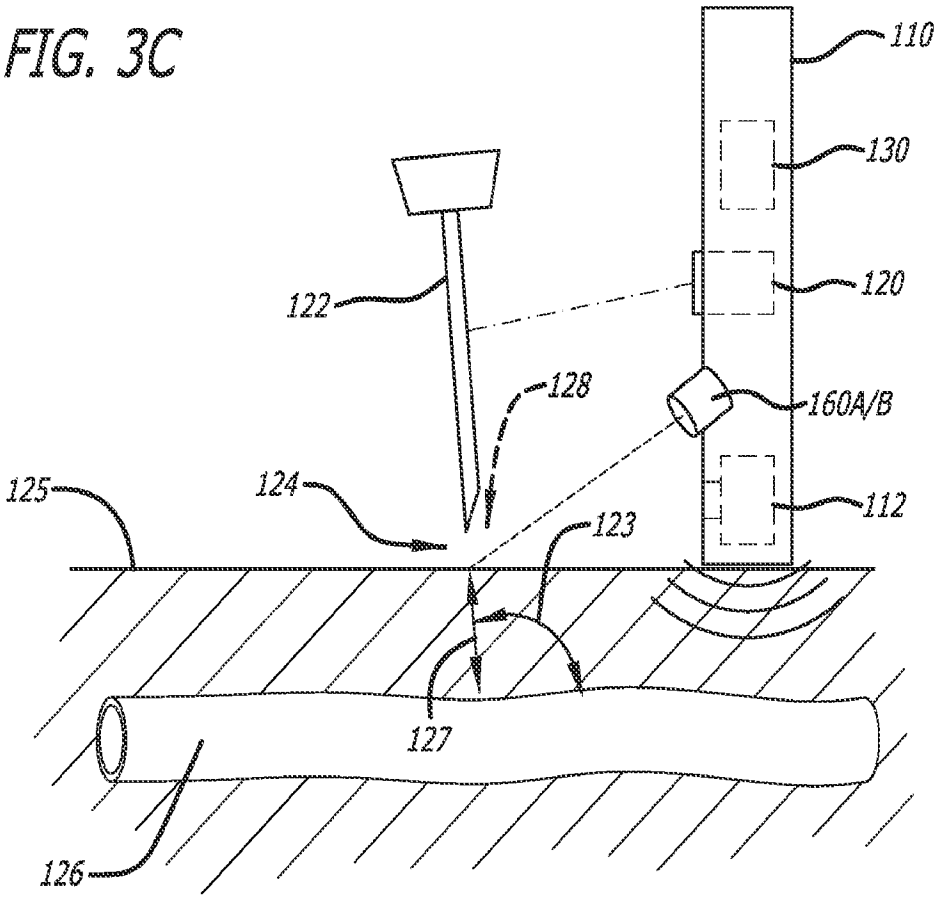

130
110
120
LONGITUDINAL
LATERAL
TRANSVERSE
160A
160B
128
4 cm
170B
125
170A
124
126
122

FIG. 3B

FIG. 3C


110
130
120
122
128
160A/B
125
124
112
123
127
126

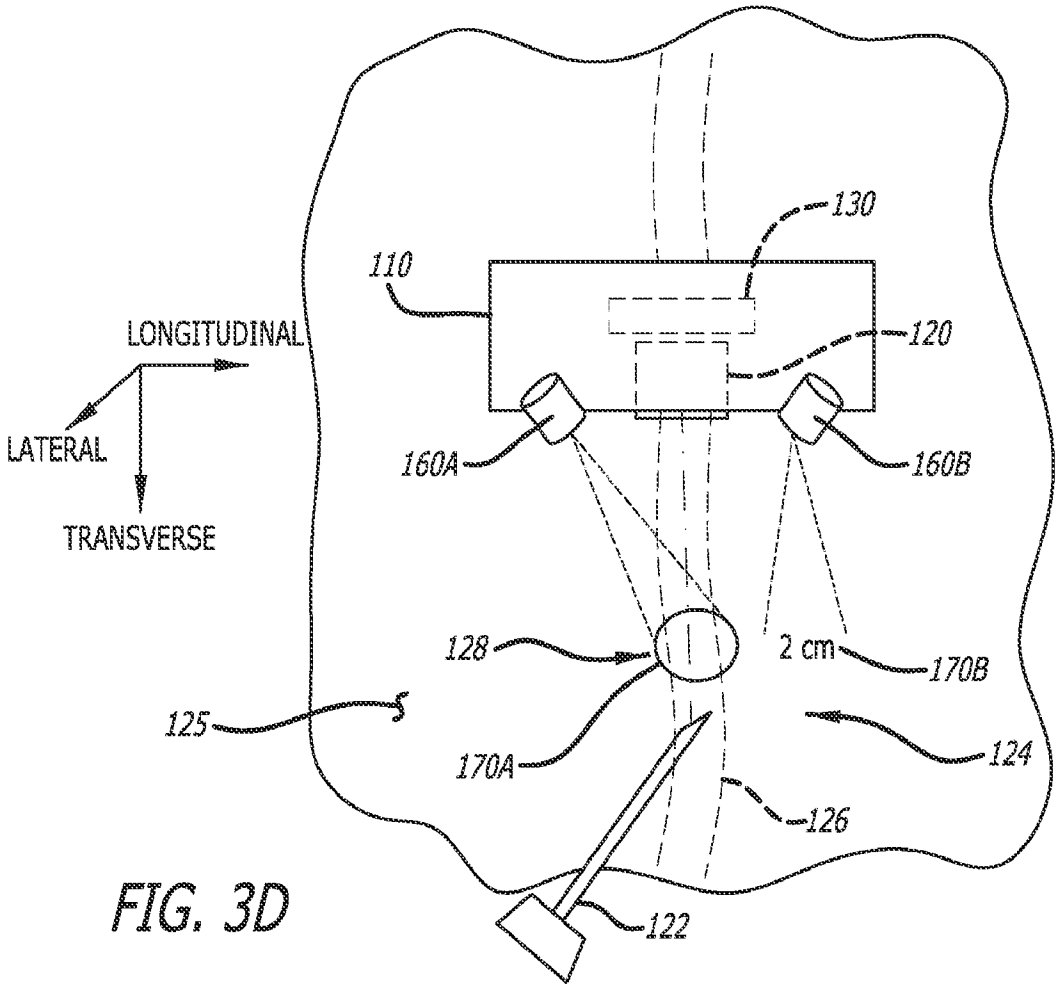
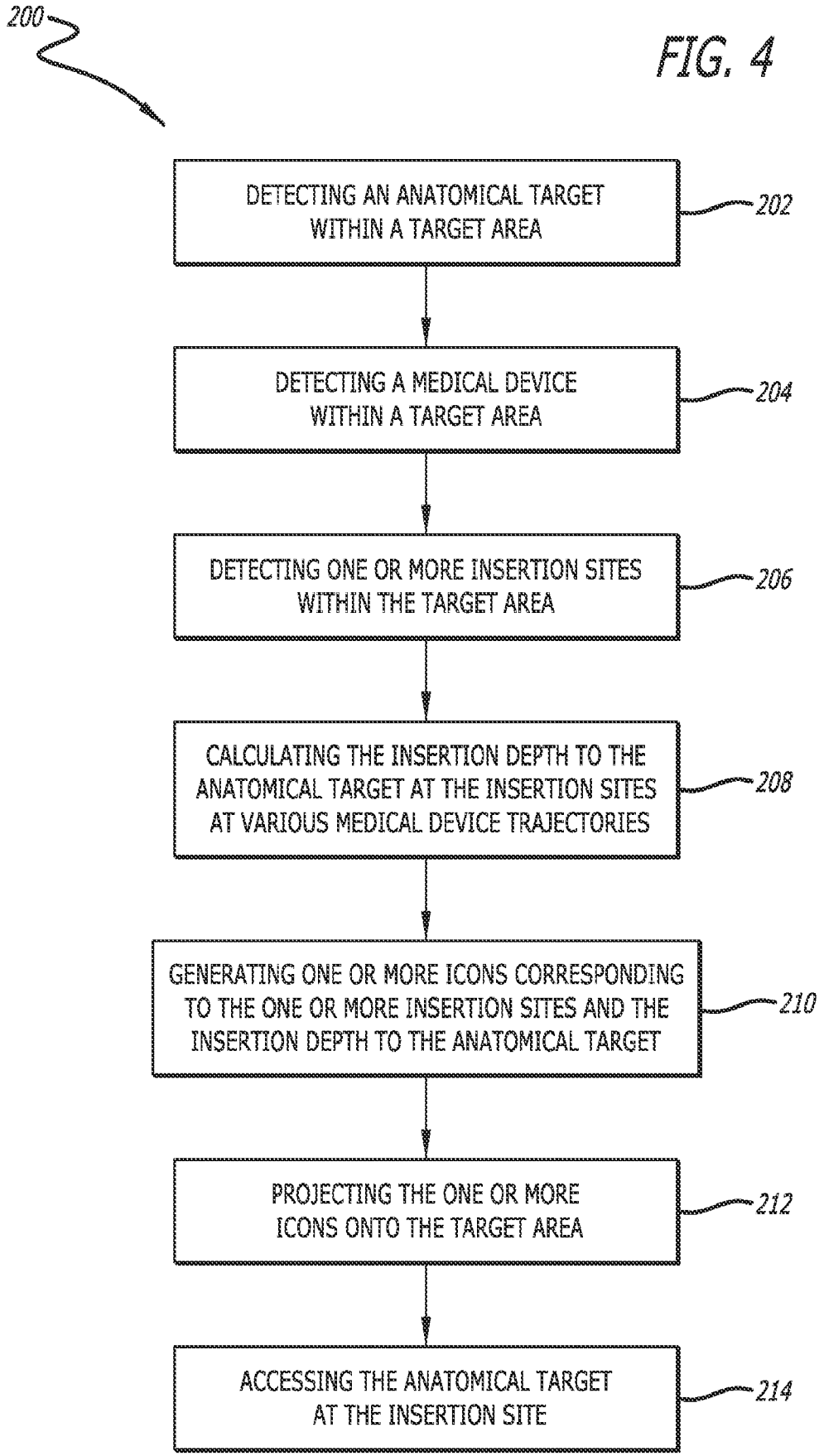

LONGITUDINAL
LATERAL
TRANSVERSE
130
110
120
160A
160B
128
2 cm
170B
125
170A
124
126
122

FIG. 3D

FIG. 4


200
DETECTING AN ANATOMICAL TARGET WITHIN A TARGET AREA
202
DETECTING A MEDICAL DEVICE WITHIN A TARGET AREA
204
DETECTING ONE OR MORE INSERTION SITES WITHIN THE TARGET AREA
206
CALCULATING THE INSERTION DEPTH TO THE ANATOMICAL TARGET AT THE INSERTION SITES AT VARIOUS MEDICAL DEVICE TRAJECTORIES
208
GENERATING ONE OR MORE ICONS CORRESPONDING TO THE ONE OR MORE INSERTION SITES AND THE INSERTION DEPTH TO THE ANATOMICAL TARGET
210
PROJECTING THE ONE OR MORE ICONS ONTO THE TARGET AREA
212
ACCESSING THE ANATOMICAL TARGET AT THE INSERTION SITE
214

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2022/034380

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/120154 A1 (SAUER FRANK [US] ET AL) 26 June 2003 (2003-06-26)	1,5-14
Y	abstract figures 1/8-8/8 paragraph [0011] - paragraph [0038]	2-4
X	US 2017/056062 A1 (BULJUBASIC NEDA [US]) 2 March 2017 (2017-03-02) abstract figures 1/17-17/17 paragraph [0006] - paragraph [0070]	1,14
Y	US 2013/006102 A1 (WILKES BRYSON G [US] ET AL) 3 January 2013 (2013-01-03) abstract figures 1-37 paragraph [0002] - paragraph [0180]	2-4

☐ 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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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
26 September 2022	05/10/2022

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	Moehrs, Sascha

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2022/034380

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15-35
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 15-35

Independent method claim 15 includes the step of accessing an anatomical target. From dependent claims 16 - 35 as well as from the description and the drawings, it is apparent that this step is related to the insertion of a medical device (needle, catheter, ecc.) into the human body (blood vessel, ecc.). Thus, independent method claim 15 corresponds to a method for the treatment of the human or animal body by surgery for which no search and no preliminary examination is carried out (Rules 39.1(iv), 67.1(iv) PCT). The same reasoning applies mutatis mutandis to dependent method claims 16 - 35.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2022/034380

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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