US 20160302772A1

(19) **United States**
(12) **Patent Application Publication**
Cummins et al.
(10) **Pub. No.: US 2016/0302772 A1**
(43) **Pub. Date: Oct. 20, 2016**

(54) **ULTRASOUND DEVICES AND METHODS FOR NEEDLE PROCEDURES**

(71) Applicants: **Thomas Cummins**, Santa Monica, CA (US); **Jay C Mung**, Los Angeles, CA (US)

(72) Inventors: **Thomas Cummins**, Santa Monica, CA (US); **Jay C Mung**, Los Angeles, CA (US)

(21) Appl. No.: **14/688,428**

(22) Filed: **Apr. 16, 2015**

Publication Classification

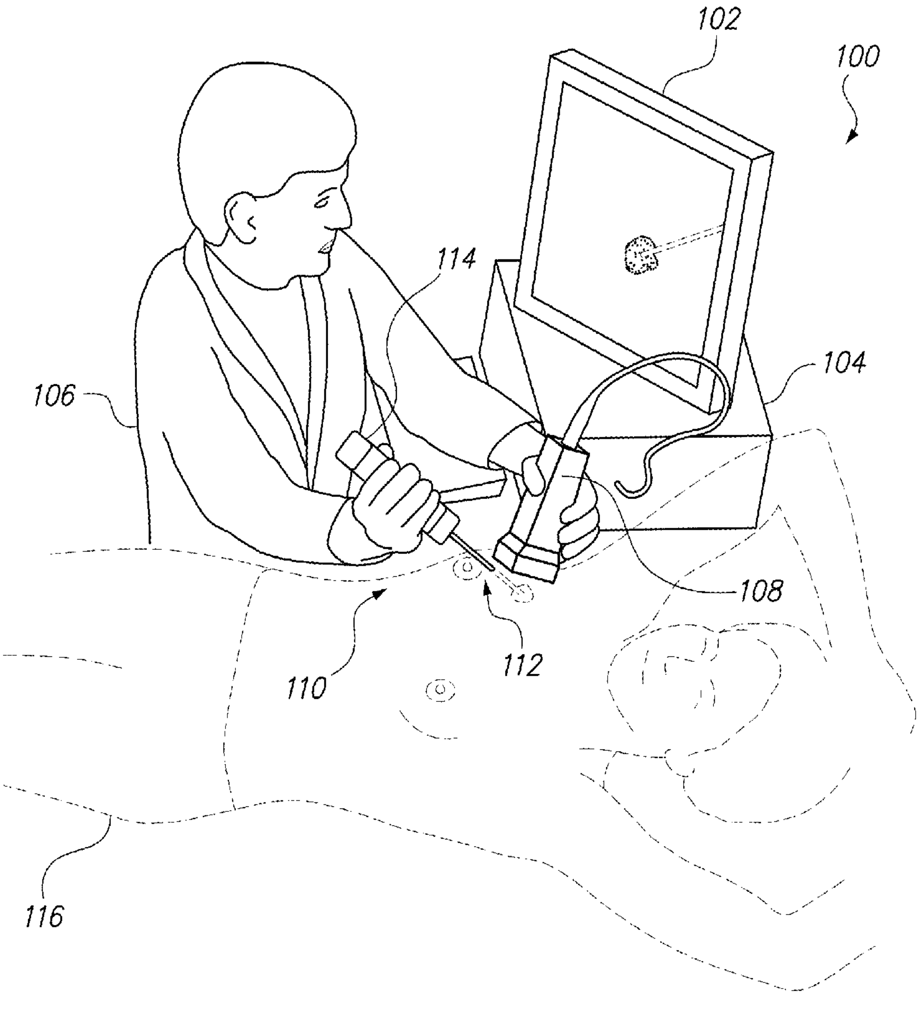
(51) **Int. Cl.**

A61B 8/00	(2006.01)
A61B 90/00	(2006.01)
A61B 8/08	(2006.01)

(52) **U.S. Cl.**
CPC *A61B 8/54* (2013.01); *A61B 8/0841* (2013.01); *A61B 90/39* (2016.02); *A61B 2090/3929* (2016.02)

(57) **ABSTRACT**

A technique of controlling a transducer. The method includes transmitting signals to the transducer, receiving signals from the transducer, and automatically adjusting the signals transmitted to the transducer based on characteristic of the signals received from the transducer. The transducer may be an ultrasound transducer. The adjustment of the signal may be performed at least in part by dynamically updating a signal threshold, for example via a proportional-integral-derivative or other type of control loop implemented at least in part by a field programmable gate array. One or more visual, audio, and haptic feedback to a user based on the signals received from the transducer. The signal may be also included a coded excitation communication and/or a Doppler signal. Automatically adjusting the signals transmitted to the transducer may achieve synchronization with an external imaging system. Also, systems that perform the technique.



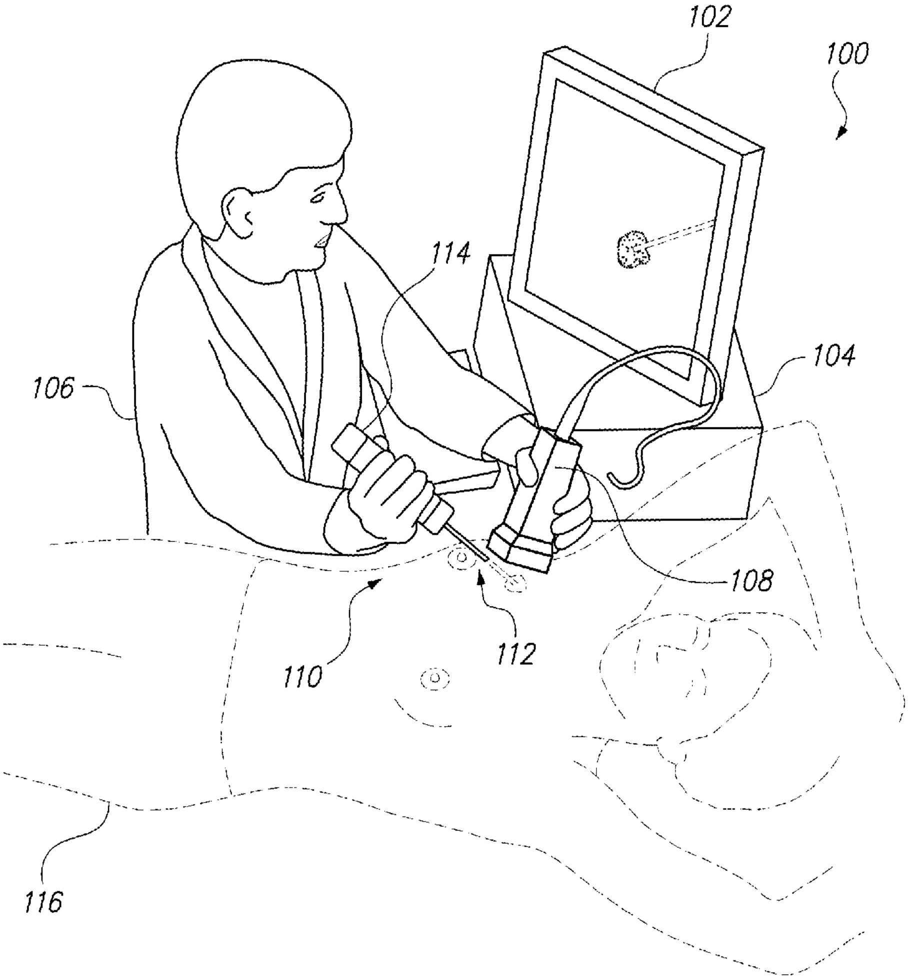


FIG. 1

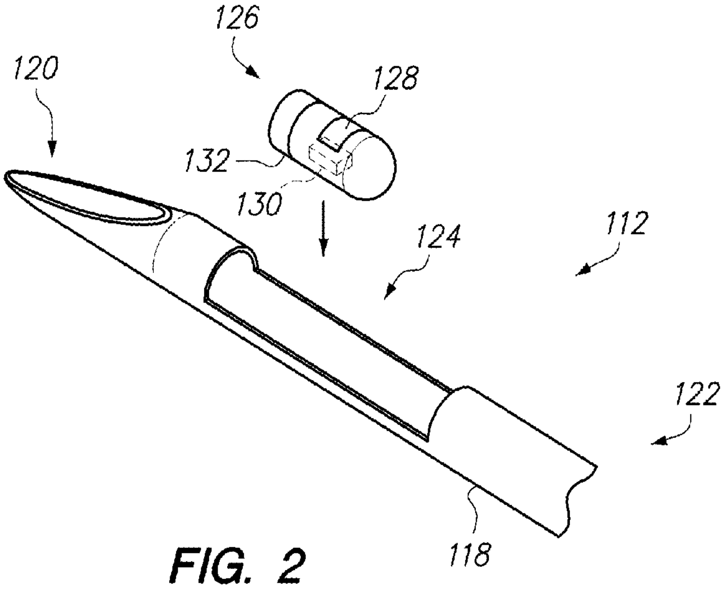


FIG. 2

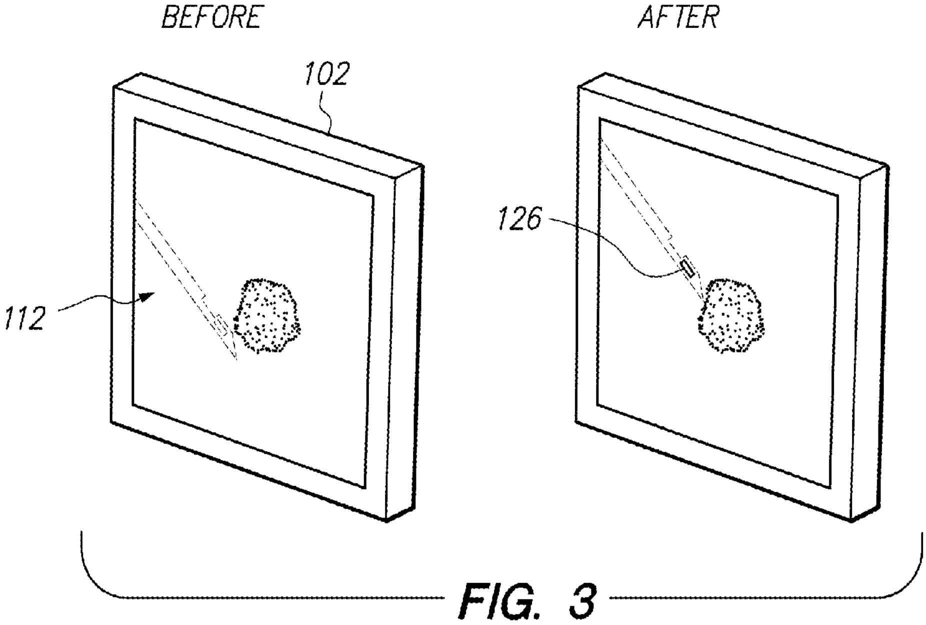


FIG. 3

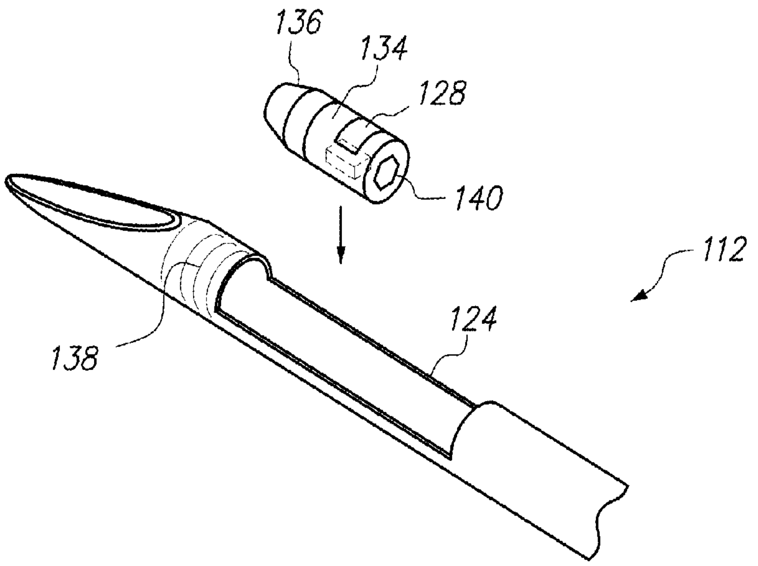


FIG. 4

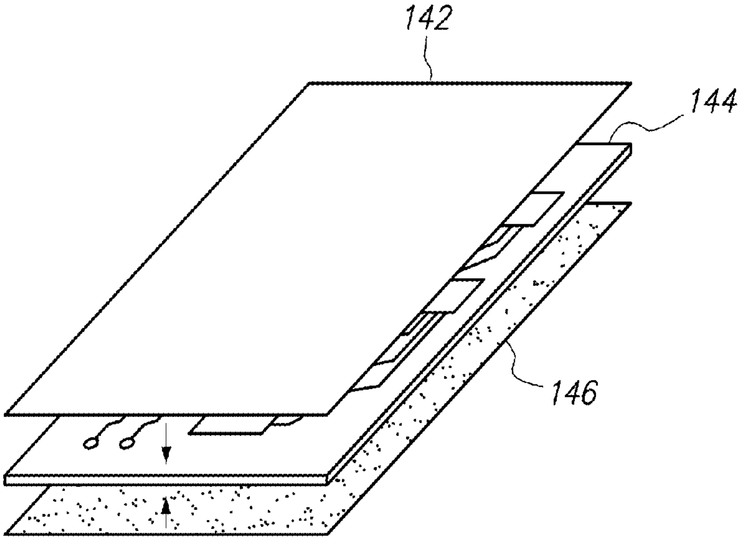


FIG. 5

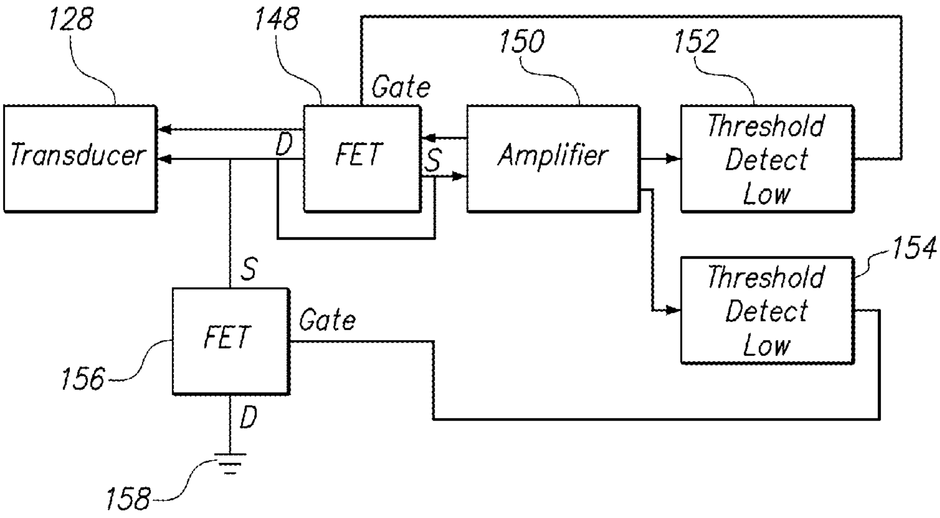

128
148
150
152
Gate
Transducer
D
FET
S
Amplifier
Threshold Detect Low
154
Threshold Detect Low
S
FET
Gate
156
D
158

FIG. 6

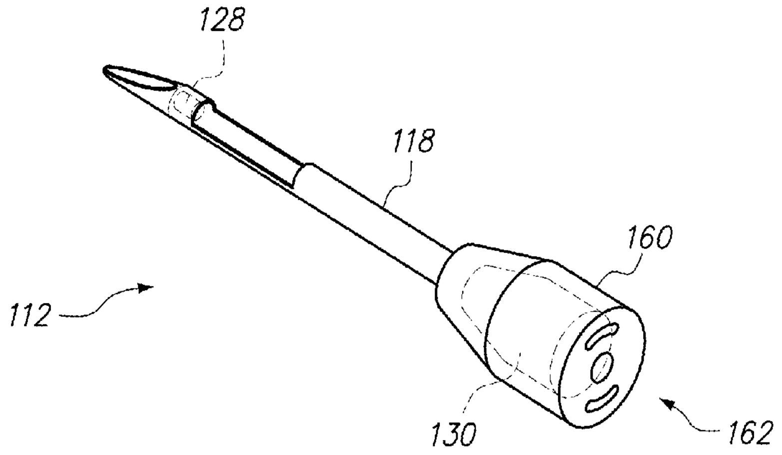


FIG. 7

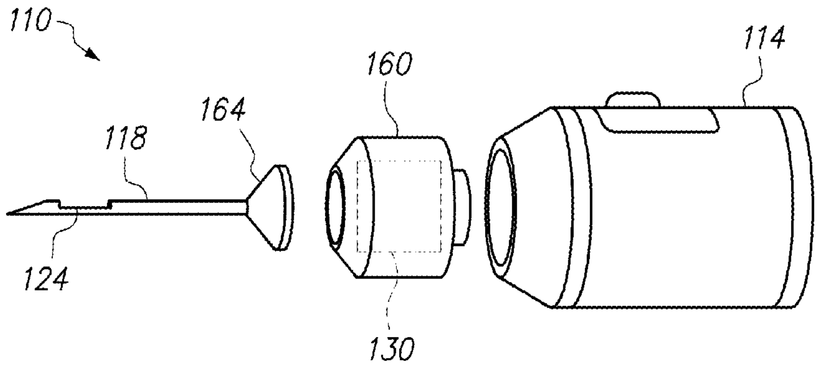


FIG. 8

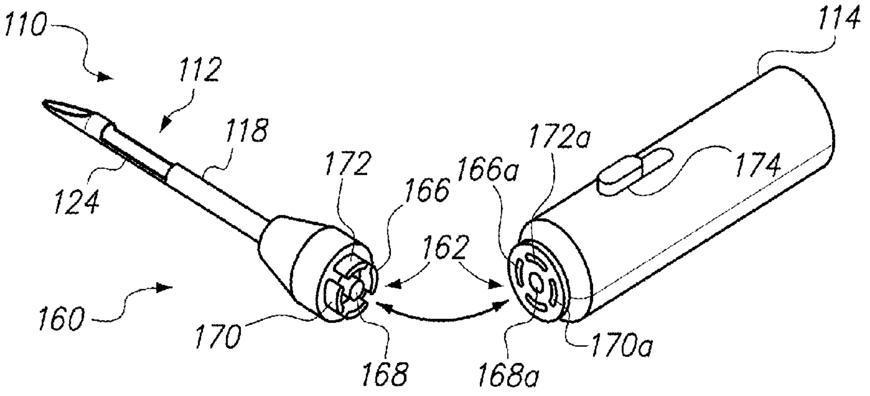


FIG. 9

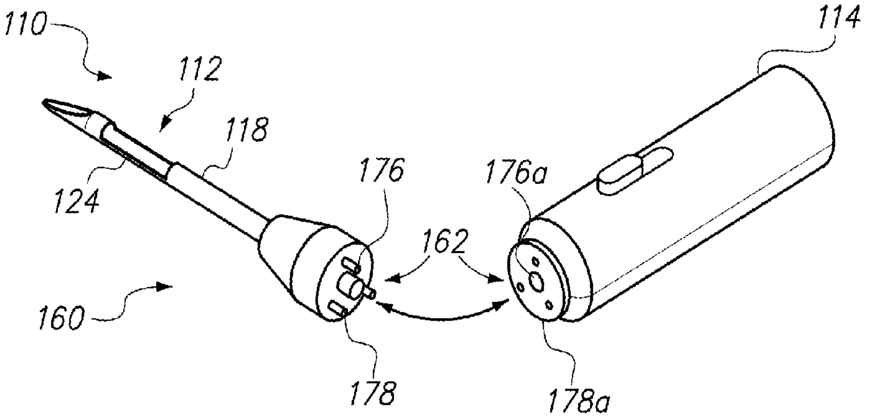


FIG. 10

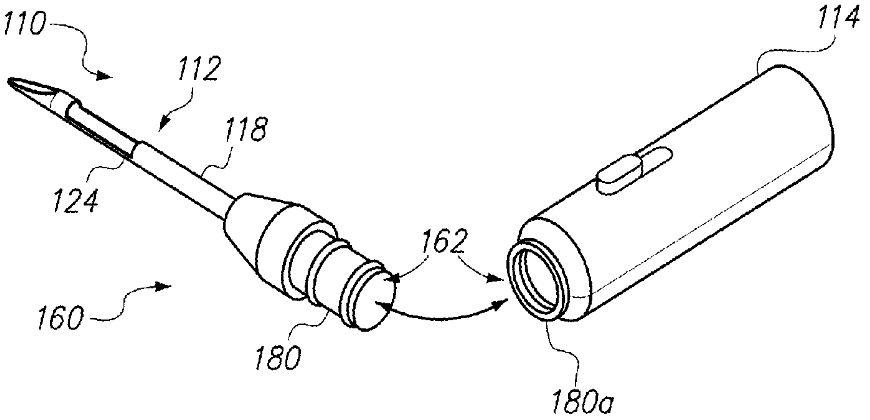


FIG. 11

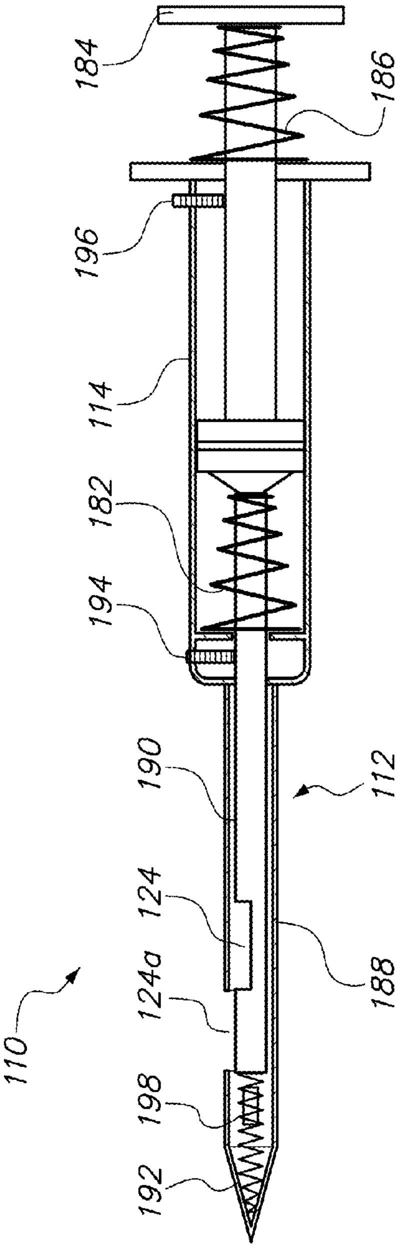

110
184
186
196
114
182
194
190
112
124
124a
188
198
192

FIG. 12

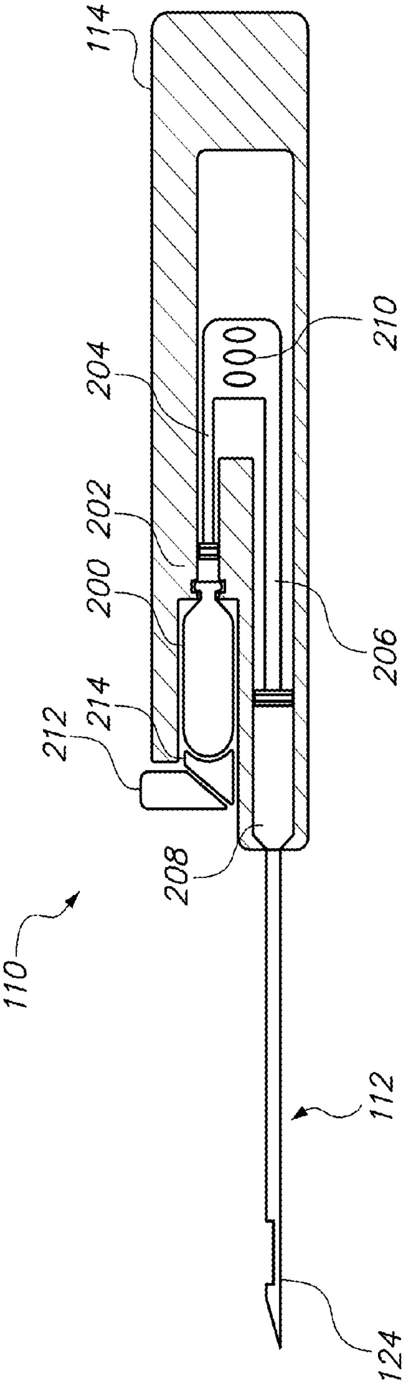

114
210
204
202
200
206
214
212
208
110
112
124

FIG. 13

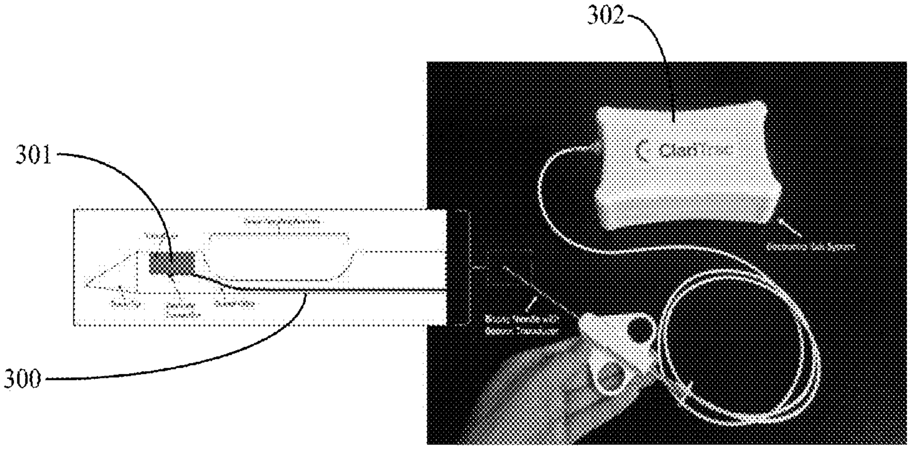

302
301
300

Fig. 14

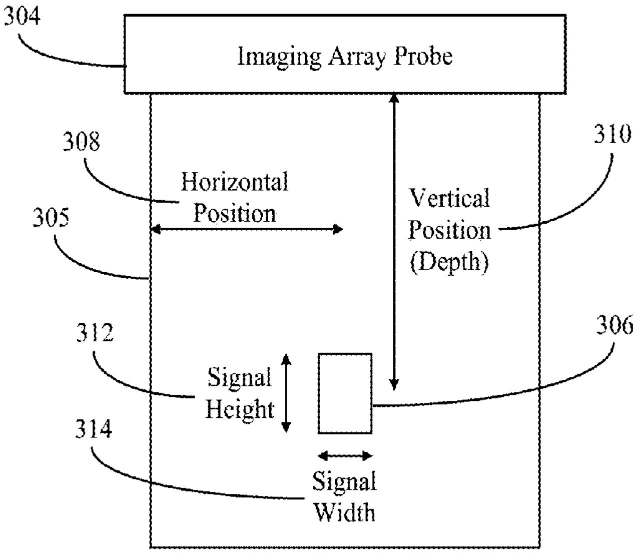

304
Imaging Array Probe
308
Horizontal Position
310
Vertical Position (Depth)
305
312
Signal Height
306
314
Signal Width

Fig. 15

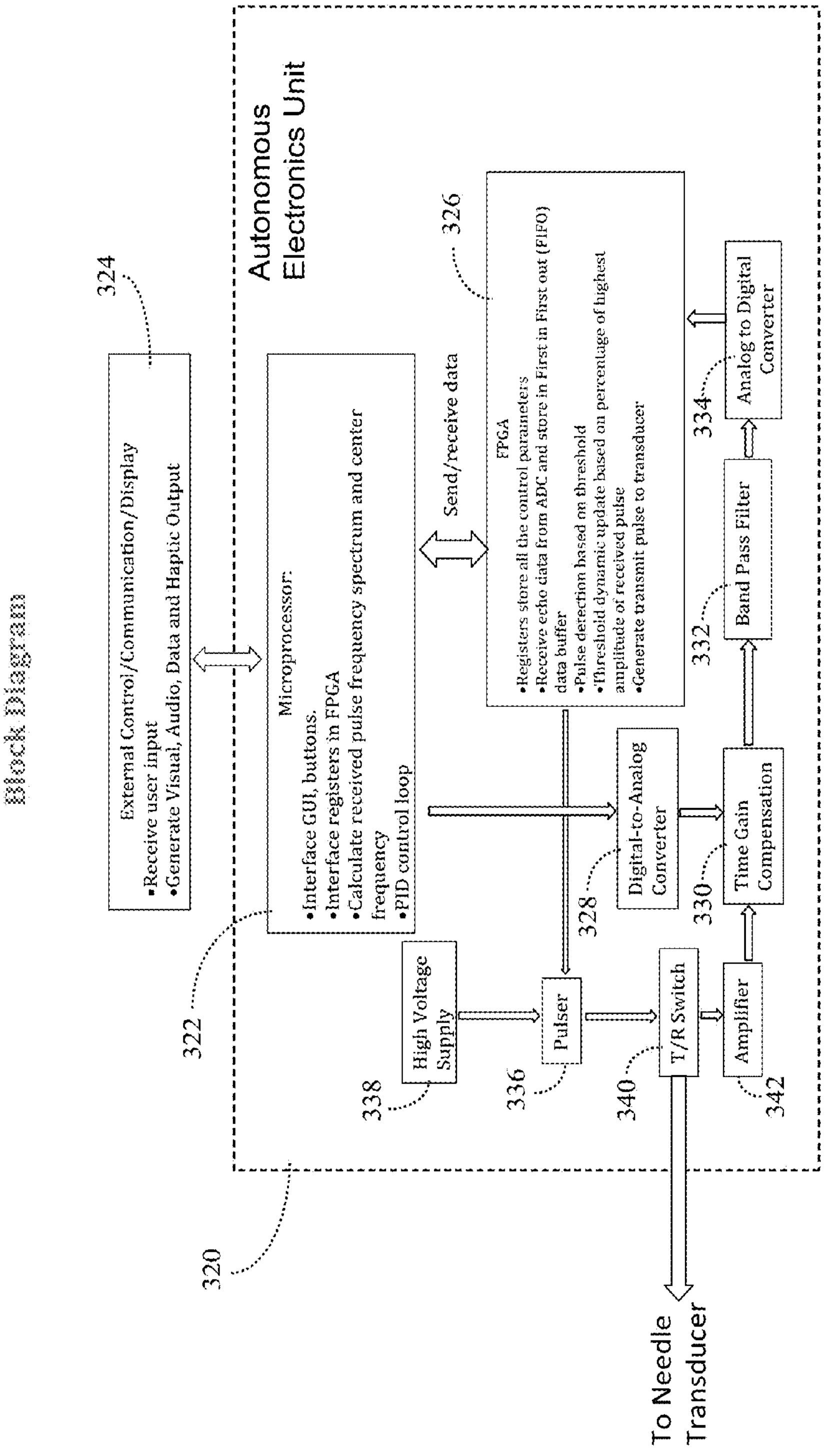

Block Diagram

Fig. 16

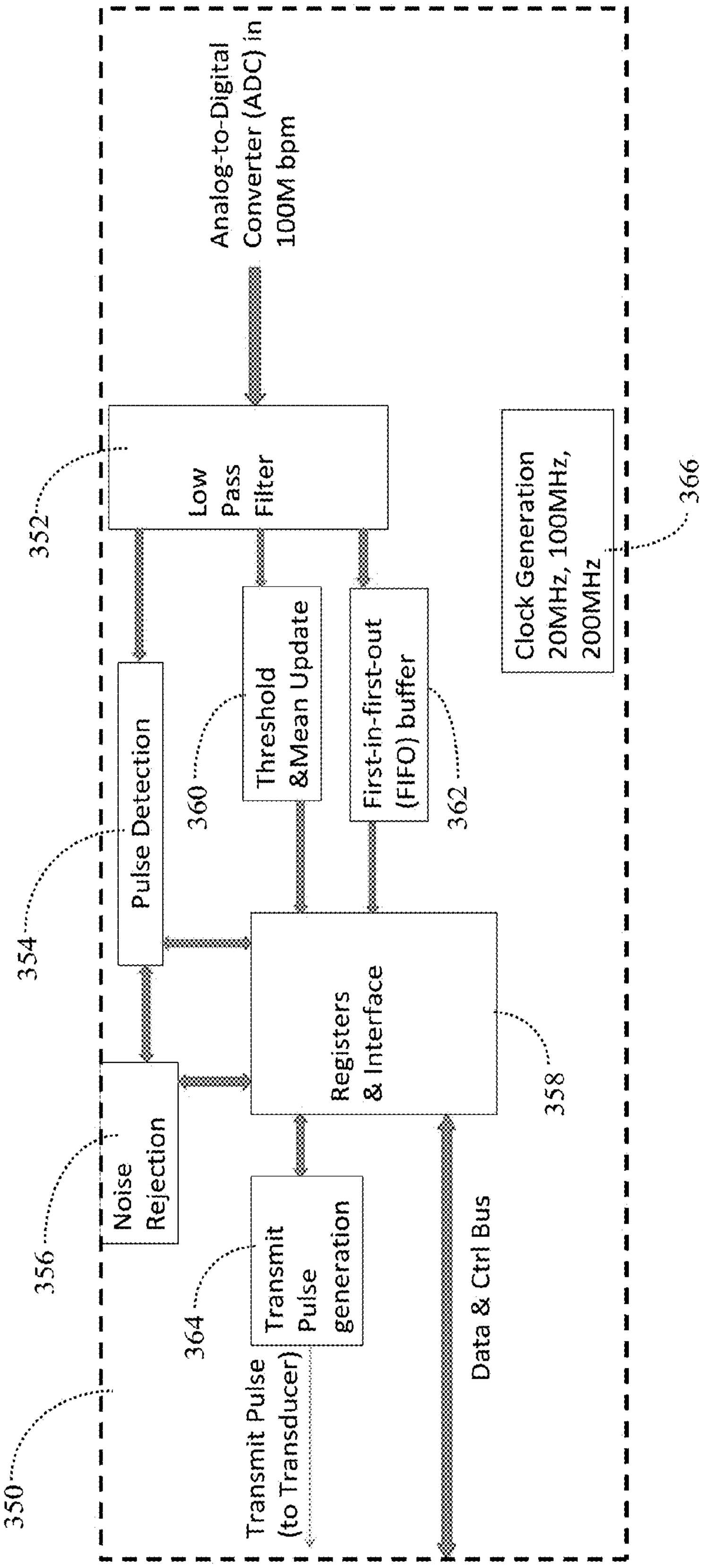

Analog-to-Digital Converter (ADC) in 100M bpm
Low Pass Filter
352
Clock Generation 20MHz, 100MHz, 200MHz
366
Pulse Detection
354
Threshold &Mean Update
360
First-in-first-out (FIFO) buffer
362
Registers & Interface
358
Noise Rejection
356
Transmit Pulse generation
364
Data & Ctrl Bus
Transmit Pulse (to Transducer)
350

Fig. 17

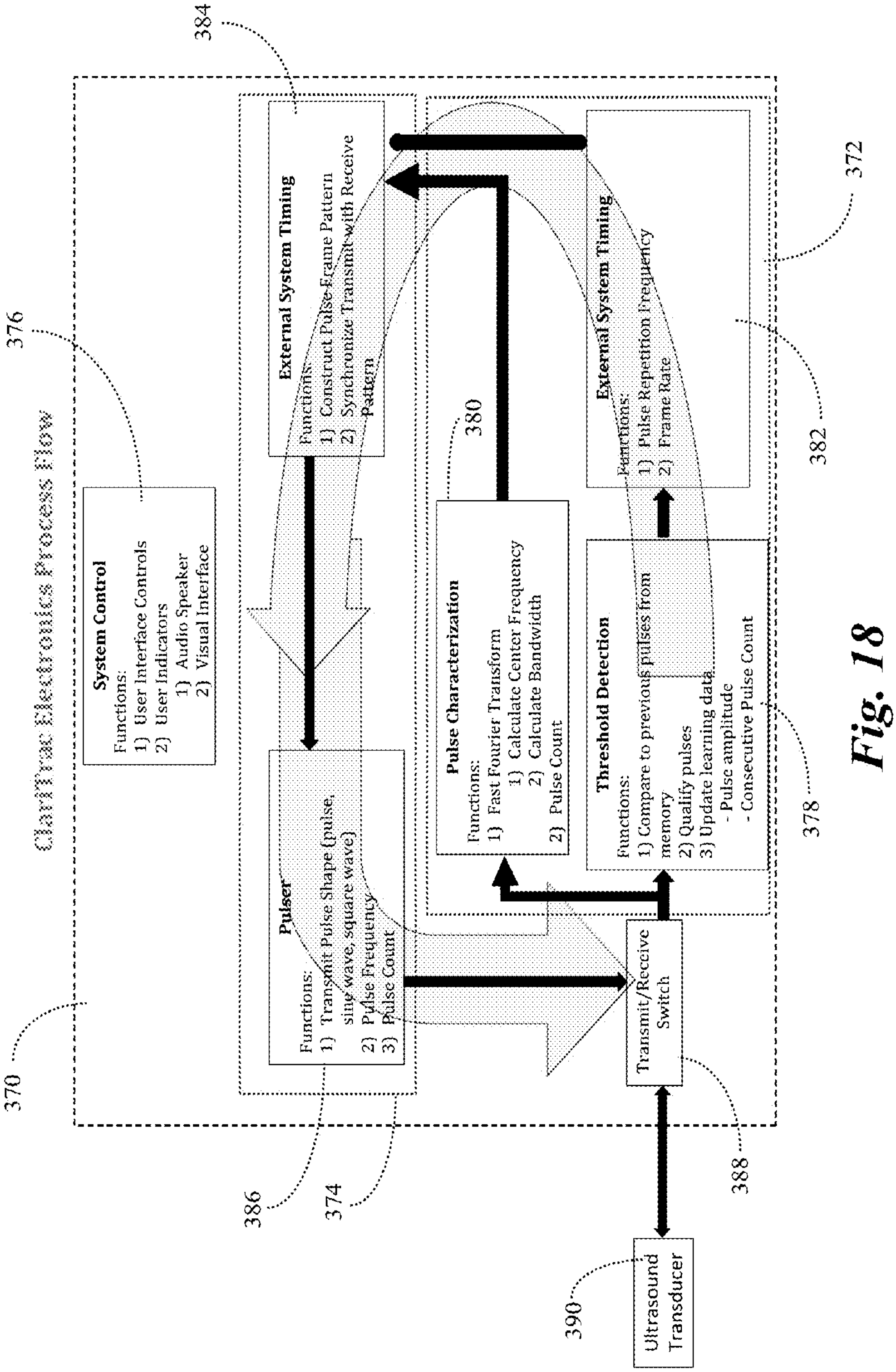
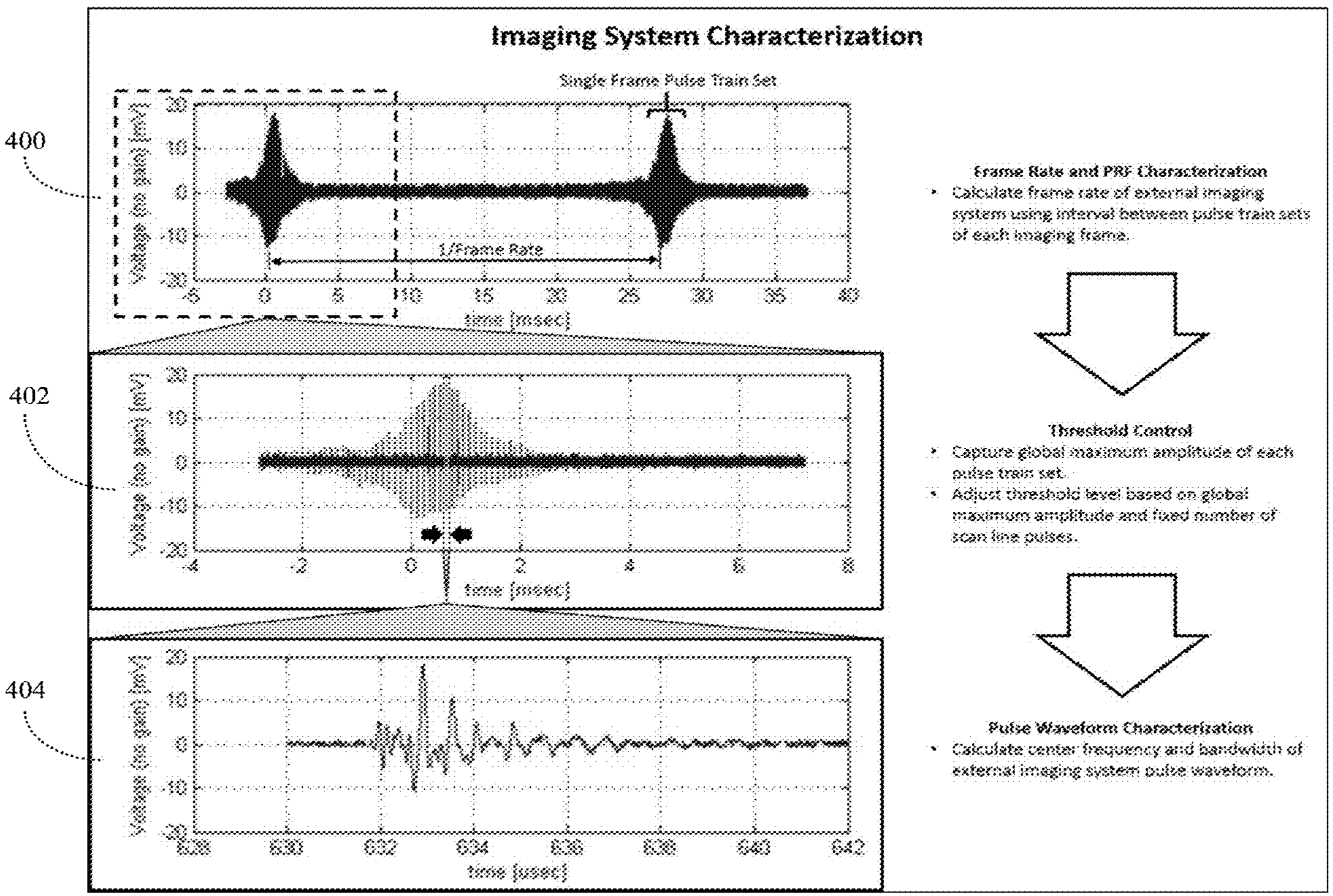

ClariTrac Electronics Process Flow
System Control
Functions:
1) User Interface Controls
2) User Indicators
1) Audio Speaker
2) Visual Interface
External System Timing
Functions:
1) Construct Pulse Frame Pattern
2) Synchronize Transmit with Receive Pattern
Pulser
Functions:
1) Transmit Pulse Shape (pulse, sine wave, square wave)
2) Pulse Frequency
3) Pulse Count
Pulse Characterization
Functions:
1) Fast Fourier Transform
1) Calculate Center Frequency
2) Calculate Bandwidth
2) Pulse Count
External System Timing
Functions:
1) Pulse Repetition Frequency
2) Frame Rate
Threshold Detection
Functions:
1) Compare to previous pulses from memory
2) Qualify pulses
3) Update learning data
- Pulse amplitude
- Consecutive Pulse Count
Transmit/Receive Switch
Ultrasound Transducer
370
372
374
376
378
380
382
384
386
388
390

Fig. 18



Imaging System Characterization

Frame Rate and PRF Characterization
- Calculate frame rate of external imaging system using interval between pulse train sets of each imaging frame.

Threshold Control
- Capture global maximum amplitude of each pulse train set.
- Adjust threshold level based on global maximum amplitude and fixed number of scan line pulses.

Pulse Waveform Characterization
- Calculate center frequency and bandwidth of external imaging system pulse waveform.

Fig. 19

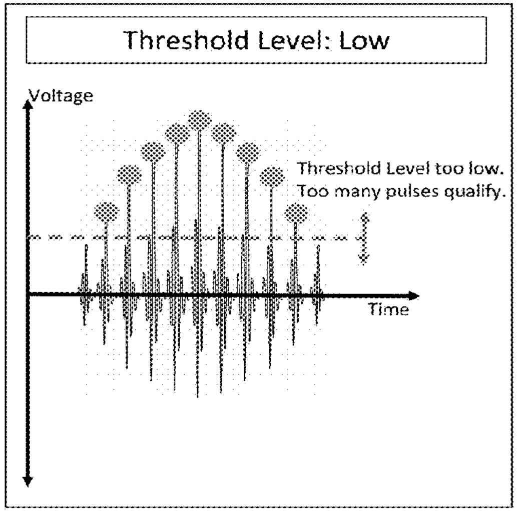


Fig. 20

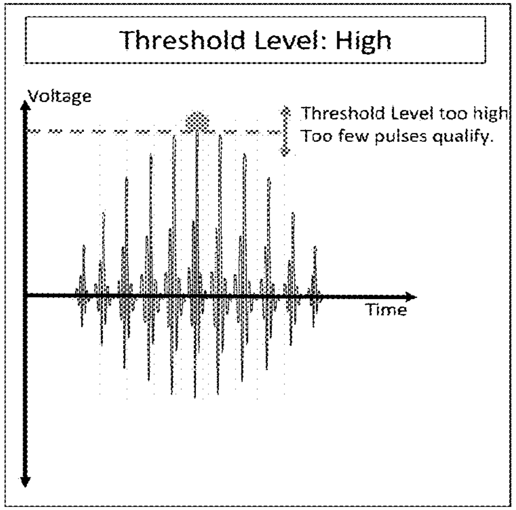


Fig. 21

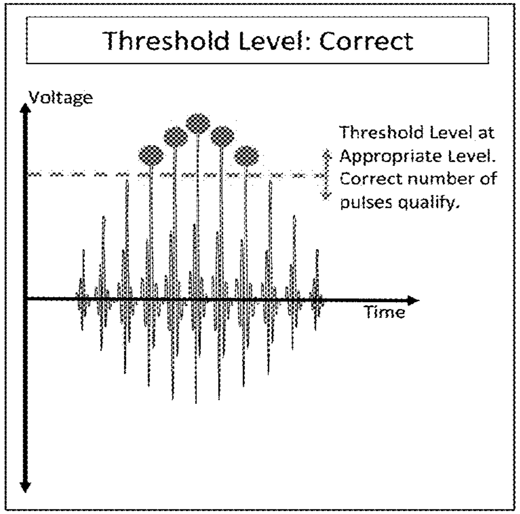


Fig. 22

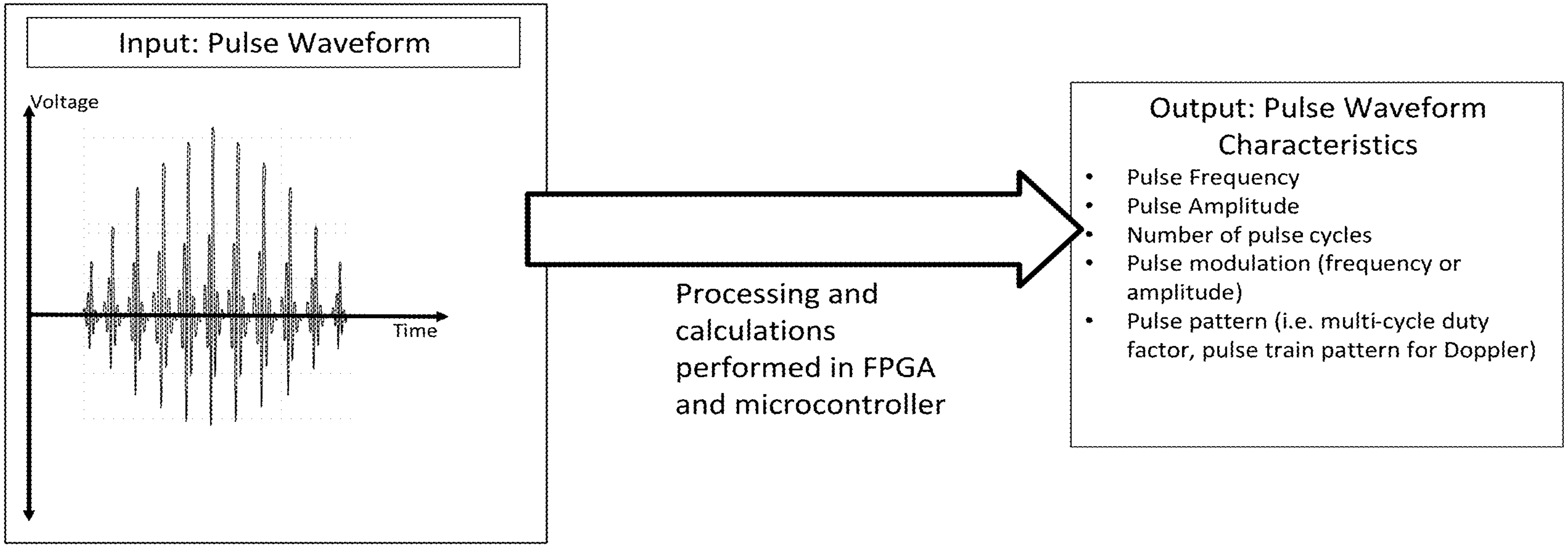

Input: Pulse Waveform
Voltage
Time
Processing and calculations performed in FPGA and microcontroller
Output: Pulse Waveform Characteristics
• Pulse Frequency
• Pulse Amplitude
• Number of pulse cycles
• Pulse modulation (frequency or amplitude)
• Pulse pattern (i.e. multi-cycle duty factor, pulse train pattern for Doppler)

Fig. 23

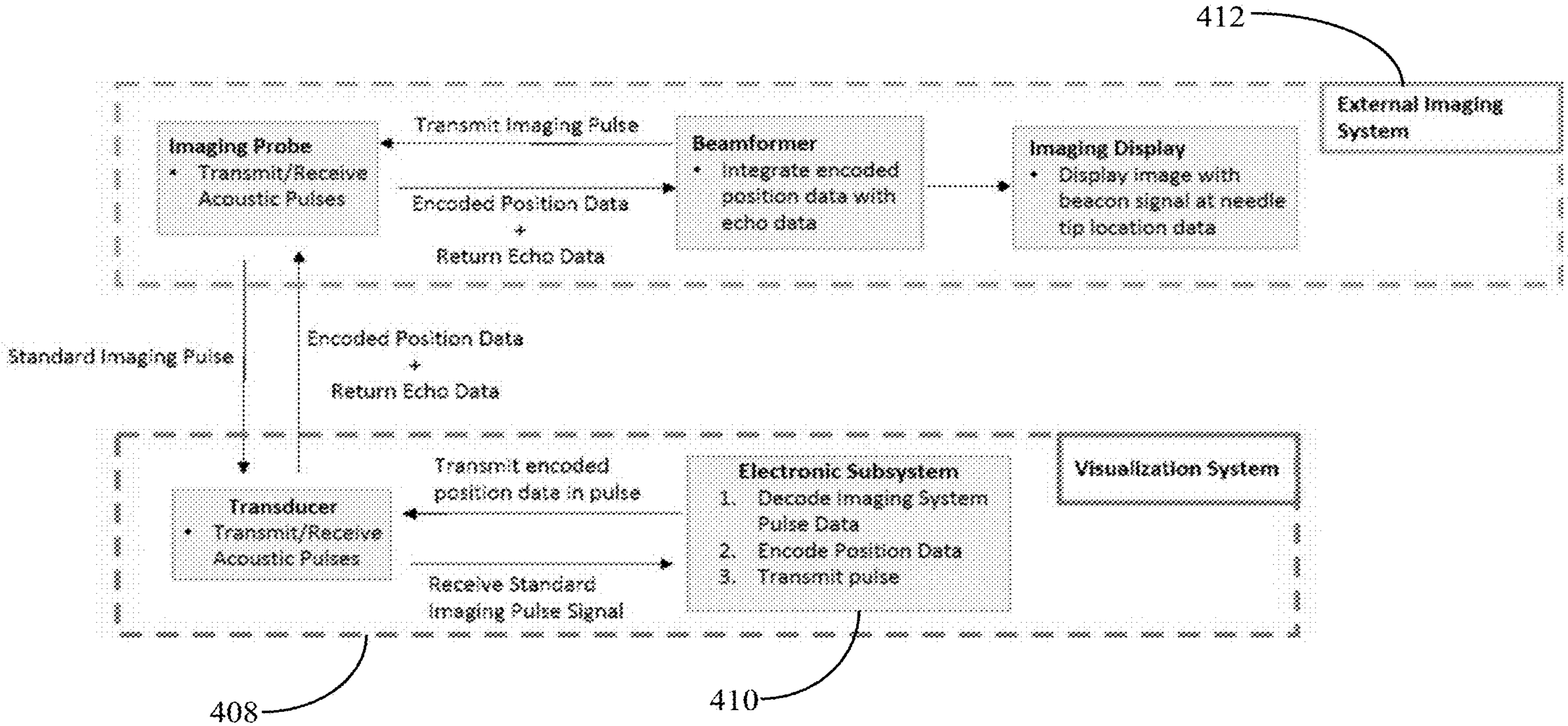

412
External Imaging System
Imaging Probe
• Transmit/Receive Acoustic Pulses
Transmit Imaging Pulse
Encoded Position Data + Return Echo Data
Beamformer
• Integrate encoded position data with echo data
Imaging Display
• Display image with beacon signal at needle tip location data
Standard Imaging Pulse
Encoded Position Data + Return Echo Data
Visualization System
Transducer
• Transmit/Receive Acoustic Pulses
Transmit encoded position data in pulse
Receive Standard Imaging Pulse Signal
Electronic Subsystem
1. Decode Imaging System Pulse Data
2. Encode Position Data
3. Transmit pulse
408
410

Fig. 24

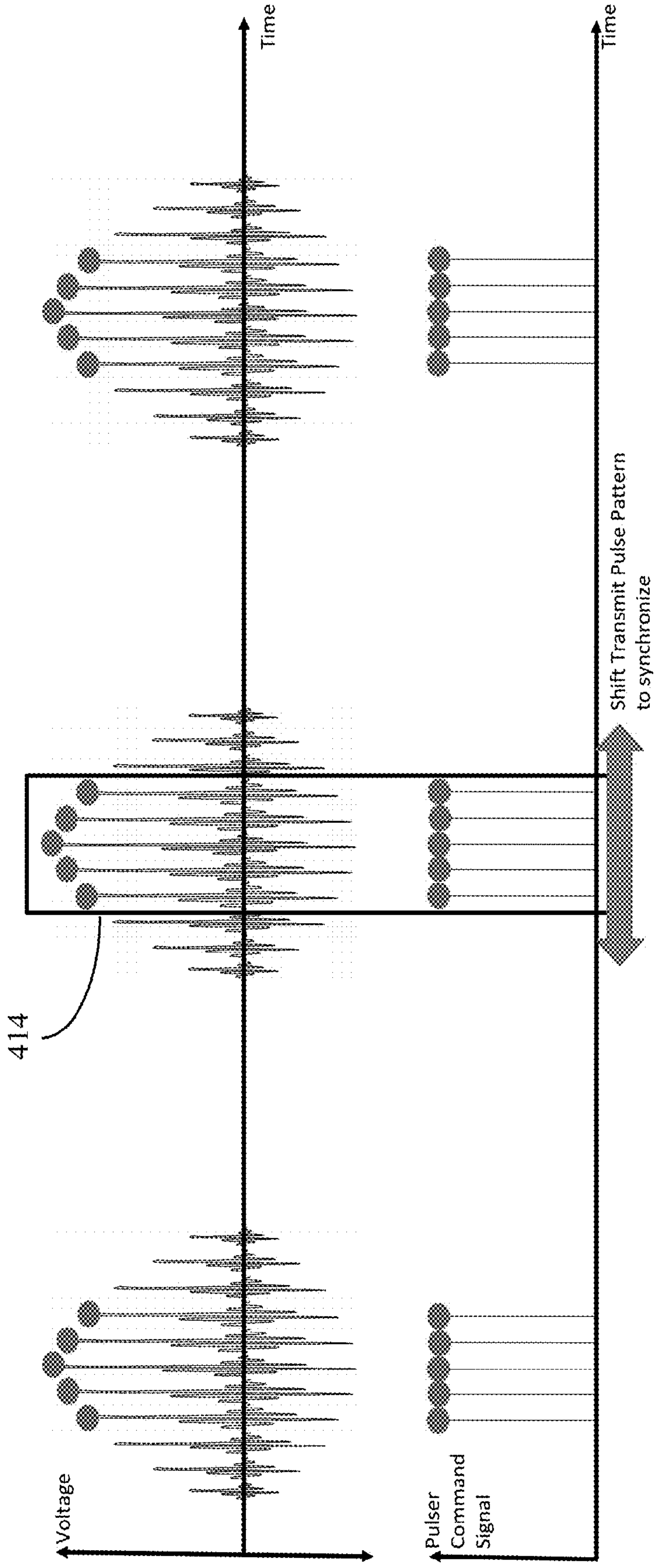

Time
Time
Shift Transmit Pulse Pattern to synchronize
414
Voltage
Pulser Command Signal

Fig. 25

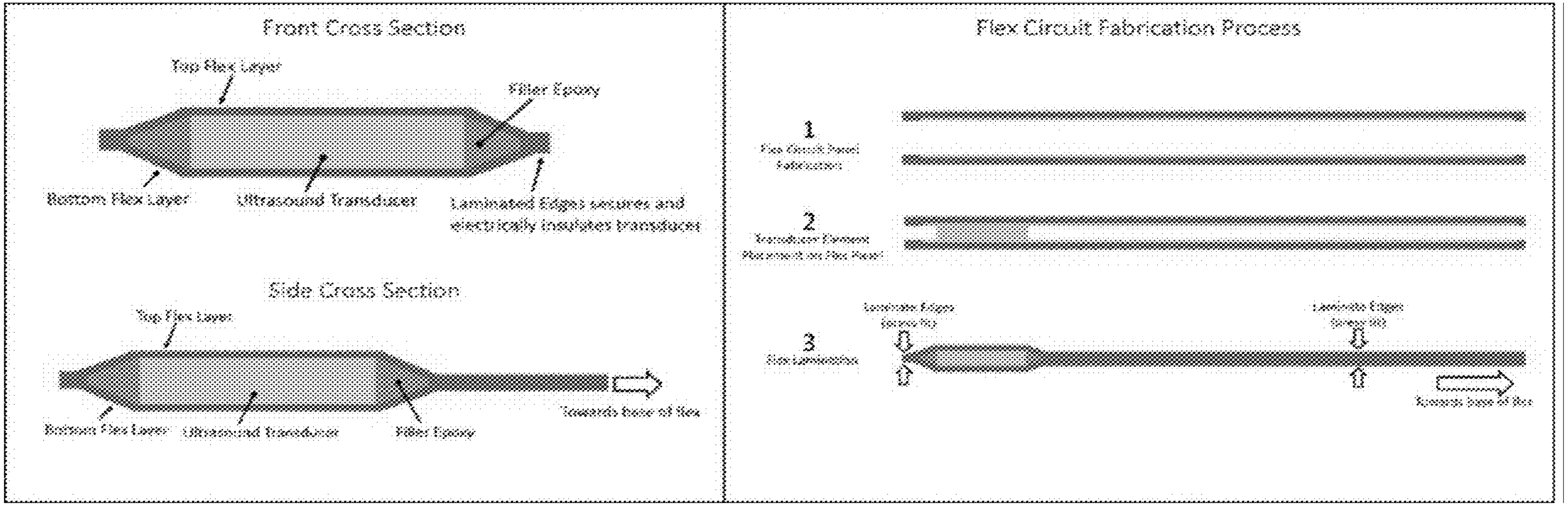

Front Cross Section
Top Flex Layer
Filler Epoxy
Bottom Flex Layer
Ultrasound Transducer
Laminated Edges secures and electrically insulates transducer
Side Cross Section
Top Flex Layer
Bottom Flex Layer
Ultrasound Transducer
Filler Epoxy
Towards base of flex
Flex Circuit Fabrication Process
1
Flex Circuit Panel Fabrication
2
Transducer Element Placement on Flex Panel
3
Flex Lamination
Laminate Edges
Laminate Edges
Towards base of flex

Fig. 26

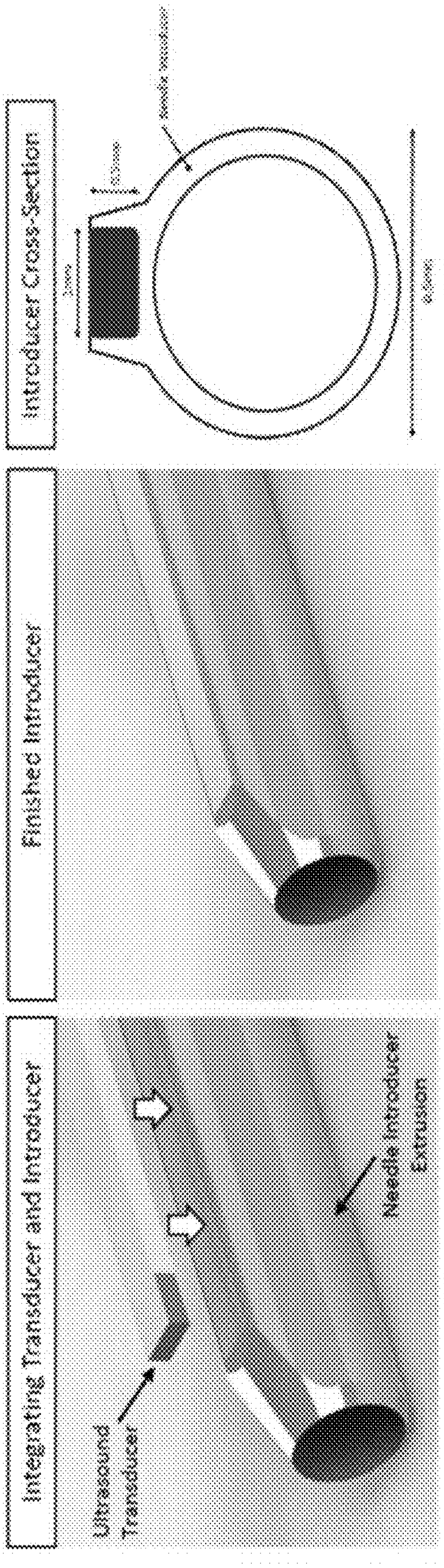

Integrating Transducer and Introducer
Ultrasound Transducer
Needle Introducer Extrusion
A)
Finished Introducer
B)
Introducer Cross-Section
Needle Introducer
C)

Fig. 27

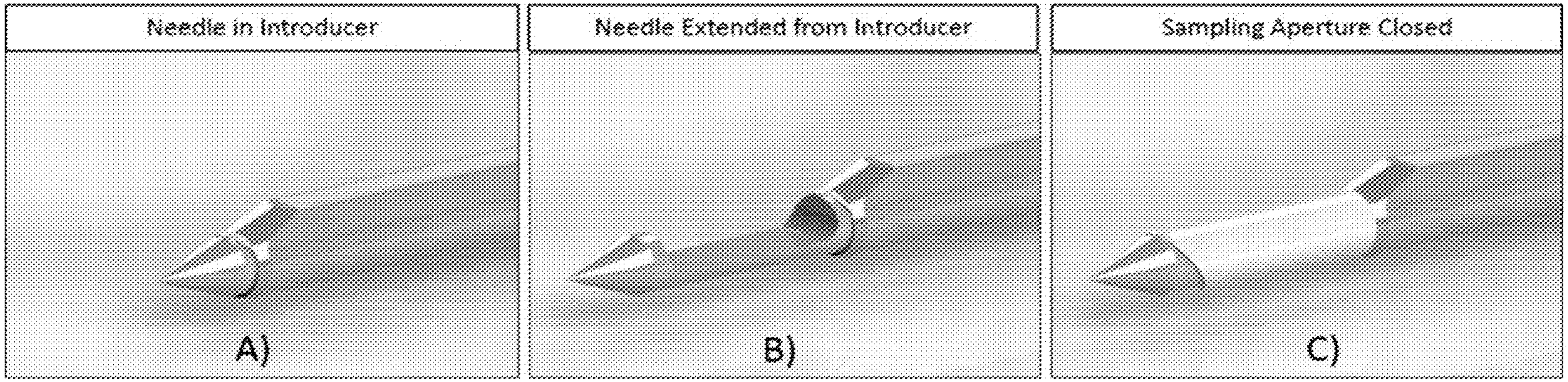

Needle in Introducer
A)
Needle Extended from Introducer
B)
Sampling Aperture Closed
C)

Fig. 28

ULTRASOUND DEVICES AND METHODS FOR NEEDLE PROCEDURES

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application claims benefit of and priority to U.S. Provisional Patent Application Ser. No. 61/674,818 filed on Jul. 23, 2012 entitled "Ultrasound Device for Needle Procedures," the entire contents of which are hereby incorporated by reference herein. The present application is a continuation-in-part of U.S. patent application Ser. No. 13/769,146 filed on Feb. 15, 2013 entitled "Ultrasound Device for Needle Procedures," the entire contents of where are also hereby incorporated by reference herein.

BACKGROUND

[0002] The present disclosure generally relates to ultrasound imaging systems and medical devices and more particularly to the use of such systems and devices for needle procedures such as biopsies, nerve blocks, and vascular access.

[0003] Ultrasound is the most common medical imaging modality after X-ray imaging. The benefits of ultrasound are clear: it is safe, relatively affordable, and fast. Given these benefits, it is no surprise that ultrasound usage is increasing.

[0004] Doctors commonly use ultrasound to guide needle placement in patients. For example, where there is a suspicion of breast cancer, a practitioner will use ultrasound on a patient to visualize a suspicious lesion and subsequently guide a needle to acquire a tissue sample from that lesion for testing. Such needle procedures are typically difficult for a number of reasons. First, ultrasound image-guided procedures require expert hand-eye coordination. Second, even under optimal imaging conditions, ultrasound can be difficult for a number of reasons. The resulting ultrasound image does not accurately depict the exact location of tools, such as needles or catheters, due to the specular reflector nature of the materials of the tools. Furthermore, ultrasound images can be colorless, speckled, and difficult to interpret. These factors add to time and complexity of ultrasound-guided procedures while decreasing precision and confidence.

[0005] Myriad approaches try to address these and other issues. For example, U.S. Pat. No. 5,329,927 describes a vibrating mechanism coupled to a cannula or needle for Doppler enhanced visualization. Such an arrangement unfortunately requires additional workflow steps including having to sterilize and then attach the vibrating mechanism. Furthermore, smaller ultrasound units may not have Doppler capability required for functionality.

[0006] Several needle manufacturers have used echogenic or texturing methods to enhance needle visibility such as that described in U.S. Patent Application Publication 2012/0059247. The texture is generally a dimpling or scoring of a typically smooth surface to reduce the specular reflector properties. Results show that these textured needles only provide slight benefit in ideal conditions.

[0007] Another approach to try to effect accurate needle guidance is to restrict the motion of the needle within the ultrasound imaging plane. For example, U.S. Pat. No. 6,485,426 describes a frame that clips onto the ultrasound imaging probe and biopsy needle to direct the needle. Such an arrangement unfortunately also adds steps to workflow and sterilization. Furthermore, the arrangement severely limits the important aspect of range of motion for needle manipulation.

[0008] Yet another attempt to improve ultrasound guidance is by way of an electromagnetic ("EM") position sensing system to detect the needle tip in relation to the ultrasound imaging probe and then annotate the ultrasound image accordingly. Such a system is made by Ultrasonix. However, this system is a proprietary one that requires specific compatibility between the needles and the imaging system and therefore limits the range of procedures. Furthermore EM sensing is costly, requires a calibration step, and is prone to registration error with the ultrasound image.

[0009] Ultrasonix also released a spatial compounding feature for enhanced needle visualization. This feature relies on enhancing straight line features in the image, and therefore requires the needle to be in the imaging plane to be useful.

[0010] A further attempt to improve ultrasound guidance involves a stylet having an ultrasound transducer associated therewith, wherein the stylet is carried within a hollow biopsy needle. Such an arrangement is described in U.S. Pat. Nos. 5,158,088; 4,407,294; and 4,249,539. In particular, the stylet is a wired, non-disposable device that signals acoustically and/or electronically between the tool in question and the ultrasound imaging device for ultrasound image enhancement. Unfortunately, this attempt also introduces a number of additional steps into the clinical workflow. For example, using the stylet requires an additional step of placing the stylet into the hollow needle. Moreover, as the stylet is nondisposable, it must be sterilized before each use. In addition, because the stylet must be used along with other tools, only certain types of tools are compatible with the system.

[0011] Accordingly, an ultrasound device for needle procedures that is simple to use, wireless, disposable, accurate, and compatible with pre-existing ultrasonic diagnostic imaging systems and devices is therefore desired.

SUMMARY

[0012] One exemplary embodiment of the disclosed subject matter includes techniques of controlling a transducer. In some aspects, the technique includes transmitting signals to the transducer, receiving signals from the transducer, and automatically adjusting the signals transmitted to the transducer based on characteristic of the signals received from the transducer. The transducer may be an ultrasound transducer. The adjustment of the signal may be performed at least in part by dynamically updating a signal threshold, for example via a proportional-integral-derivative or other type of control loop implemented at least in part by a field programmable gate array. One or more visual, audio, and haptic feedback to a user based on the signals received from the transducer. The signal may be also included a coded excitation communication and/or a Doppler signal. Automatically adjusting the signals transmitted to the transducer may achieve synchronization with an external imaging system. Also, systems that perform the techniques.

[0013] This brief summary has been provided so that the nature of the invention may be understood quickly. Additional steps and/or different steps than those set forth in this summary may be used. A more complete understanding of the invention may be obtained by reference to the following description in connection with the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Some non-limiting exemplary embodiments of the disclosed subject matter are illustrated in the following drawings. Identical or duplicate or equivalent or similar structures, elements, or parts that appear in one or more drawings are generally labeled with the same reference numeral, optionally with an additional letter or letters to distinguish between similar objects or variants of objects, and may not be repeatedly labeled and/or described. Dimensions of components and features shown in the figures are chosen for convenience or clarity of presentation. For convenience or clarity, some elements or structures are not shown or shown only partially and/or with different perspective or from different point of views.

[0015] FIG. **1** is a perspective view of an embodiment of the inventions disclosed herein being used by a medical practitioner to help perform a biopsy;

[0016] FIG. **2** illustrates aspects of an embodiment of the inventions disclosed herein and particularly the aspect of a drop-in beacon transducer unit;

[0017] FIG. **3** illustrates "before and after" ultrasound images wherein the exact location of the needle tip of an embodiment of the inventions disclosed herein may be seen on the "after" ultrasound image once a drop-in beacon transducer unit is activated;

[0018] FIG. **4** illustrates a threaded housing aspect of a drop-in beacon transducer unit;

[0019] FIG. **5** illustrates another aspect and particularly an integrated circuit disposed between a transducer film and an adhesive layer;

[0020] FIG. **6** illustrates a schematic of an exemplary electrical subsystem;

[0021] FIG. **7** illustrates another aspect and particularly a needle device with a transducer and an adapter with electrical subsystem;

[0022] FIG. **8** illustrates another aspect of the inventions disclosed herein and particularly a needle device with a transducer and a removable adapter with electrical subsystem, wherein the adapter is in turn coupled to a handle;

[0023] FIG. **9** illustrates a bayonet-mount aspect of the disclosed inventions;

[0024] FIG. **10** illustrates a slide-and-click aspect of the disclosed inventions;

[0025] FIG. **11** illustrates a cartridge-mount aspect of the inventions disclosed herein;

[0026] FIG. **12** illustrates a mechanically powered vacuum aspect; and

[0027] FIG. **13** illustrates a gas-powered vacuum aspect of the disclosed inventions.

[0028] FIG. **14** illustrates a needle visualization system aspect of the disclosed inventions.

[0029] FIG. **15** illustrates forming a square shaped beacon signal according to aspects of the disclosed inventions.

[0030] FIG. **16** illustrates a block diagram of an electronic system that shapes beacon signals according to aspects of the disclosed inventions.

[0031] FIG. **17** illustrates a block diagram of a part of an electronic system according to aspects of the disclosed inventions.

[0032] FIG. **18** illustrates a process flow according to aspects of the disclosed inventions.

[0033] FIG. **19** illustrates data captured from a beacon transducer according to aspects of the disclosed inventions.

[0034] FIGS. **20** to **22** illustrate threshold detection according to aspects of the disclosed inventions.

[0035] FIG. **23** illustrates pulse waveform characterization according to as aspect of the disclosed inventions.

[0036] FIG. **24** illustrates synchronization with an external system according to aspects of the disclosed inventions.

[0037] FIG. **25** illustrates external system timing according to aspects of the disclosed inventions.

[0038] FIG. **26** illustrates a modular flex circuit transducer and fabrication thereof according to aspects of the disclosed inventions.

[0039] FIG. **27** illustrates integration of a modular flex transducer component into a needle introducer according to aspects of the disclosed inventions.

[0040] FIG. **28** illustrates use of aspects of the disclosed inventions with a biopsy needle device.

DETAILED DESCRIPTION

[0041] A general problem in the field of needle devices using ultrasound to guide the needle during a needle procedure is an inaccurate representation on an ultrasound imaging display of the actual locale of the needle tip within a patient's body. A general solution is an ultrasound needle device comprising a needle shaft and a transducer integrated within a distal end of the needle shaft.

[0042] A technical problem in the field of biopsy devices is accurate tissue sampling. A technical solution implementing the spirit of the disclosed inventions is a needle shaft adapted to cut tissue and a transducer disposed about the distal end of the needle shaft. The transducer may be part of a drop-in, self-contained beacon unit that fits within the needle shaft. The transducer may alternatively include electrical leads connectable to an electrical subsystem housed within an adapter that is connectable to a handle. Alternatively, the electrical subsystem may be housed within a handle connectable to the needle shaft by a bayonet mount configuration, a slide-and-click configuration, or a cartridge configuration. The electrical subsystem is preferably configured to control when the transducer emits an ultrasound pulse. The handle may include all or part of a vacuum means for suctioning in tissue disposed at or near a tissue sampling aperture of the needle shaft.

[0043] Potential benefits of the general and technical solutions provided by the disclosed subject matter include a "plug and play" disposable transducer beacon unit designed for use with a needle shaft. Other potential benefits include a disposable needle and transducer unit easily mountable to an adapter that is in turn easily attachable to a handle. Further potential benefits include a biopsy device quickly attachable to a handle that may include efficient mechanical or pneumatic structures for pulling tissue into the device.

[0044] A general nonlimiting overview of practicing the present disclosure is presented below. The overview outlines exemplary practice of embodiments of the present disclosure, providing a constructive basis for variant and/or alternative and/or divergent embodiments, some of which are subsequently described.

[0045] FIG. **1** is a perspective view of an embodiment of the inventions disclosed herein being used by a medical practitioner to help perform a biopsy. The disclosed inventions need not be limited to use for a biopsy but may instead be used in a variety of needle procedures, including but not limited to nerve blocks, vascular access, and ultrasound-guided catheter diagnostic and therapeutic procedures such as ultrasound-guided ablation. As seen in FIG. **1**, a practitioner **106** is using an ultrasound imaging system **100** to extract a tissue sample from a patient **116**. The system **100** may include a display **102**, computer **104**, ultrasound imaging probe **108**, and novel needle device **110** according to one or more aspects of the inventions disclosed herein.

[0046] The display **102** of the ultrasound imaging system **100** displays the real-time sonogram of the tissue. The practitioner uses this display **102** to visualize, for example, a suspected lesion and needle for guidance. It is here where the needle shaft of the needle device **110** is supposed to be visualized going into the suspected lesion. The probe **108** is used to image the suspected lesion located inside the body of the patient **116**.

[0047] The needle device **110** includes a handle **114** attachable to a needle **112** that is adapted to cut tissue and an ultrasound transducer integrated with the needle **112**. The needle **112** is preferably a hollow shaft having a tissue sampling aperture with one or more sharp surfaces for cutting tissue. The transducer is preferably integrated near or about one end of the needle shaft. "Integrated" means affixed permanently or temporarily inside or outside the needle shaft, or alternatively a part of the needle shaft **118**.

[0048] In use, the practitioner uses the imaging probe **108** (in one hand) to guide the needle device **110** (in the other hand) by viewing the ultrasound display **102**. The needle device **110** may be vacuum assisted to draw tissue into the tissue sampling aperture. Exemplary vacuum assist mechanisms are illustrated in FIGS. **12** and **13**. The needle device **110** may be a 20 completely disposable or modular device with disposable needle and transducer.

[0049] FIG. **2** illustrates aspects of an embodiment of needle device **110** and particularly a needle **112** having a needle shaft **118** with a distal end **120** and a proximate end **122**. The shaft **118** is preferably a hollow cylinder formed by walls having a cut-out to create a tissue sampling aperture **124** disposed between the distal and proximate ends **120**, **122**. The walls of the tissue sampling aperture **124** are preferably sharp for cutting tissue during a biopsy procedure. A drop-in beacon transducer unit **126** is integrated with the needle shaft **118** at or about the distal end **120** near the tip of the shaft **118**. The beacon unit **126** contains an ultrasound transducer **128** and optionally the supporting electronic subsystem **130** and/or power supply **132**. In this manner, the beacon unit **126** may advantageously be a "plug and play" disposable component meant for integration with existing needle devices.

[0050] FIG. **3** illustrates "before and after" ultrasound images wherein the exact location of the tip of a needle of an embodiment of the inventions disclosed herein may be seen on the "after" ultrasound image once a drop-in beacon transducer unit **126** is activated. Such an invention is clearly highly valuable to those skilled in the art.

[0051] The beacon unit **126** may be bonded, threaded, or otherwise attached or fitted to or within some component of the needle shaft **118** being used during the needle procedure. FIG. **4** illustrates a threaded housing aspect of a drop-in unit **126**. In particular, FIG. **4** shows that the beacon unit **126** may comprise a housing **134** with external threading **136** and the needle shaft **118** may have internal threading **138** wherein the beacon unit may be screw-fit within the needle shaft **118** or similar arrangement. The housing **134** of the beacon unit **126** may have a hex slot **140** or the like for screwing the unit **126** into the walls of the shaft **118**. Alternatively, the housing **134** may also be the needle shaft **118** itself or a sub-component of the needle assembly, as in the case of biopsy needles that have multiple components.

[0052] A drop-in beacon unit such as that illustrated in FIGS. **2** through **4** may be fabricated by way of one or more of the following steps. Start with a hollow tube with outer diameter of approximately 3 millimeters and length of approximately 5 to 10 millimeters. Add an integrated circuit for the electrical subsystem, such as system **130** illustrated in FIG. **2**. Drill a hole in the side of the tube to accommodate wiring (not shown) and transducer (such as that shown in FIG. **2**). Run a wire from the integrated circuit to an electrical interconnect and to the hole and also to an optional power supply. The power supply may be a small, high voltage battery **132** that may fit within the self-contained beacon unit **126** or in the handle **114**. Alternatively, the beacon unit **126** may be wirelessly powered by the use of wireless power technology disclosed by one or more of the following United States patents, each of which is incorporated by reference as if fully disclosed herein: U.S. Pat. Nos. 6,289,237; 6,615,074; 6,856,291; 7,027,311; 7,057,514; 7,084,605; 7,373,133; 7,383,064; 7,403,803; 7,440,780; 7,567,824; 7,639,994; and 7,643,312. Next, fill the hollow tube with non-conductive acoustic backing material (not shown) and cure. If a battery is to be used, add the battery **132**. Then place piezoelectric material in the hole, completing electrical connection with wiring. Finally, create the acoustic bond and coat the unit **126** with parylene.

[0053] Instead of a drop-in beacon unit arrangement such as that illustrated in FIGS. **2** through **4**, the beacon transponder unit **126** may comprise a film or flex circuit that is wrapped or bonded onto the needle shaft **118** or needle sub-component. FIG. **5** depicts an integrated film embodiment of a self-contained beacon unit **126**. Turning in detail to FIG. **5**, transducer **128** may comprise a piezoelectric ultrasound transducer film or material. This film material **142** may either be rigid or flexible with electrodes (not shown) on both the top and bottom surfaces to receive and apply a voltage potential across the transducer **128**. An integrated circuit **144** may be fabricated on either a substrate such as a silicon wafer or printed circuit board and be connected to both electrodes of the piezoelectric transducer film **142**. The integrated circuit **144** may be coupled with a logic and/or power source to comprise in whole or in part the electrical subsystem **130** for the beacon unit **126**. An adhesive layer or patch **146** may serve as a coupling interface between the needle shaft **118** and beacon unit **126**. If the beacon unit **126** is not a self-contained or self-powered unit, electrical leads (not shown) may be in communication with the film **142**. In such case, when the transducer **128** receives and sends acoustic pulses from and to the imaging probe **108**, the leads will be used to conduct the electrical signals to and from the transducer **128** to the electrical subsystem **130**.

[0054] FIG. **6** illustrates a schematic of an exemplary electrical subsystem of the disclosed inventions, such as electrical subsystem **130** depicted in FIG. **2**. The electrical subsystem **130** may particularly be designed such that it is built to receive and send ultrasound pulses automatically through the transducer **128**. The electrical subsystem **130** preferably and advantageously is configured to control when an ultrasound pulse from the transducer **128** is to be emitted.

[0055] Turning in detail to FIG. **6**, a signal from transducer **128** is amplified by amplifier **150** and then sent to a high threshold detector **154** and a low threshold detector **152**. If the signal is above the low threshold, the field effect transistor **148** is closed and the amplified signal is sent back to the transducer **128**. However, once the amplified signal reaches above the high threshold, the field effect transistor **156** closes and connects the transmitting line to ground **158** to stop the transmission of the signal. In this manner, the system **100** sends back ultrasound pulses to achieve the desired end result, such as the bright beacon-like image on the ultrasound imaging monitor depicted in the "after" version of FIG. **3**. Further details of an exemplary electrical subsystem of the disclosed inventions are discussed below with respect to FIGS. **14** to **24**.

[0056] FIG. **7** illustrates another aspect of an embodiment of the inventions disclosed herein and particularly a needle **112** with a transducer **128** integrated at a distal end of a needle shaft **118**. At the opposite end thereof is an adapter **160** with electrical subsystem **130**. The adapter **160** has electrical/mechanical connection means **162** for connection to a handle such as that shown in FIG. **1**. The integrated unit illustrated in FIG. **7** is advantageously disposable.

[0057] FIG. **8** illustrates another aspect of an embodiment of the inventions disclosed herein and particularly a needle device **110** with a transducer **128** integrated at a distal end of a needle shaft **118**. At the opposite end thereof is a connector **164** that is attachable to a removable adapter **160** with electrical subsystem **130**. The adapter **160** is attachable to a handle **114**.

[0058] FIG. **9** illustrates a bayonet-mount aspect of the disclosed inventions. As shown in FIG. **9**, needle device **110** comprises a needle **112** with needle shaft **118** including a tissue sampling aperture **124**, transducer (not shown) disposed at or about aperture **124**, adapter **160** with electrical/mechanical connection means **162** and particularly a bayonet configuration thereof, and handle **114** with button **174** for actuating the device **110**. In association with adapter **160**, the connection means **162** may comprise one or more of the following: a male mechanical interconnect locking mechanism **166**, a vacuum channel **168**, an electrical (+) lead connect **170**, and an electrical (−) lead connect **172**. In association with handle **114**, the connection means **162** may comprise one or more of the following: a female mechanical interconnect locking mechanism **166***a*, a vacuum channel **168***a*, an electrical (+) lead connect **170***a*, and an electrical (−) lead connect **172***a*.

[0059] FIG. **10** illustrates a slide-and-click aspect of the disclosed inventions. As shown in FIG. **10**, needle device **110** comprises a needle **112**, adapter **160** with electrical/mechanical connection means **162**, and handle **114**. Connection means **162** may comprise complementary mechanical and electrical interconnects **178**, **178***a* that slide and click into one another. A vacuum port **176**, **176***a* enables negative pressure to be applied to tissue at or about the distal end of needle **112**.

[0060] FIG. **11** illustrates a cartridge-mount aspect of the inventions disclosed herein. As shown in FIG. **11**, needle device **110** comprises a needle **112**, adapter **160** with electrical/mechanical connection means **162**, and handle **114**. Connection means **162** may comprise a male cartridge insert **180** at the end of needle **112** opposite tissue sampling aperture **124** and a female component **180***a* in handle **114**. The cartridge insert **180** may contain the electrical contacts so the electrical subsystem **130** (not shown) in the handle **114** may be connected to the transducer **128** (not shown) at the distal tip of the needle shaft **118**. FIG. **12** illustrates a cross-sectional view of another aspect of an embodiment of the inventions disclosed herein and particularly a mechanically powered vacuum aspect. The integrated tissue-cutting needle device **110** includes a vacuum means in the form of a needle syringe arrangement. In particular, as seen in FIG. **12**, a plunger barrel or handle **114** contains a spring **182** so when plunger **184** is depressed (barrel is in "empty" position), the spring **182** resists and applies force to push the plunger **184** back into the "full" position. The tendency of the plunger **184** to return to the "full" position creates negative air pressure in the barrel chamber. The spring **182** need not be within the barrel chamber, as the same force may be achieved from a spring **186** between the plunger shaft and the outside of the chamber.

[0061] The needle device **110** illustrated in FIG. **12** may comprise a cutting mechanism that may include two nested, concentric thin-walled tubes **188**, **190**. The outer tube **188** ends in a sharp cone-tip **192**. A spring **198** inside the tip of the outer tube **188** pushes against the inner tube **190**. Both tubes **188**, **190** may include sampling notches **124**, **124***a* in the tube walls **188**, **190**, positioned so when the inner tube **190** fully compresses the tip-spring **198**, both sampling notches **124**, **124***a* line up and the cutter is considered in the "open" position. The edges of the sampling notches **124**, **124***a* are sharp so when the inner tube **190** slides and the sampling notches **124**, **124***a* becomes "shut," the action is like a guillotine, cutting whatever tissue is within the notches **124**, **124***a*.

[0062] To initiate the vacuum and cutting mechanisms, the user must first depress the plunger **184** to the "empty position." The air-tight plunger **184**, in addition to displacing air from the barrel and compressing the plunger spring **182** or **186**, also pushes against the inner needle tube **190**, which compresses the needle spring **192**. With the plunger **184** in the fully depressed position, cams **194**, **196** activate to cock each spring **182**, **186** in their compressed position. One cam **196** engages the plunger shaft to hold the plunger **184** in the "empty" position. The other cam **194** engages the inner needle tube **190** to hold the cutter window **124** in the "open" position.

[0063] With the needle vacuum and cutter cocked, the user then inserts and guides the needle **112** to the appropriate location within the body of the patient **116**. Upon identifying the suspicious lesion, the user engages the vacuum by disrupting the plunger-cam **196**. This disruption allows the spring **182** to decompress until the next cam-engagement point on the plunger shaft to create negative pressure in the barrel chamber. This negative pressure is continuous to the sampling notch **124** in the needle **112**, which pulls tissue into the notch **124**. If the vacuum pressure is not sufficient, the user can disrupt the plunger-cam several more times until the spring is fully decompressed.

[0064] Once sufficient tissue is pulled into the sampling notch **124**, the user then disrupts the cutter-cam **194**. This releases the spring action on the inner cutting tube **190**, closing the "guillotine." With the tissue sample cut, the user removes the needle **112** from the patient **116** and then removes the sample from the needle **112**.

[0065] FIG. **13** illustrates a cross-sectional view of a gas-powered vacuum aspect of an embodiment of the disclosed inventions. In particular, FIG. **13** depicts a gas-powered vacuum assisted device sub-component of ultrasound device **110** that may be integrated within the handle

114. As seen in FIG. **13**, handle **114** may contain a high-pressure gas canister **200** that may contain liquid carbon dioxide, compressed air, or the like. The pressure from the gas in this canister **200** is released when a sharp pin **202** pierces the canister **202**, releasing the gas to press up against the positive pressure piston **204** coupled to the negative pressure piston **206** via the physical connection **210**. When the negative pressure piston **206** is forced to the right side of FIG. **13**, a vacuum is created in the vacuum cylinder **208**. This vacuum cylinder **208** extends into the needle **112** via a needle vacuum cylinder attachment on the needle **112** where it terminates at the sampling aperture **124**. Thus, when the gas canister **200** is forced into the pin **202** via the canister button cam **214** upon actuation of button **212**, a vacuum is applied to the vacuum cylinder **208** in the needle **112**. Tissue is then pulled into the sampling aperture **124** where a cutting mechanism, such as sharp walls forming the sample aperture **124**, may excise the tissue.

[0066] Transducer and Electronic Subsystem

[0067] Conventional 2D ultrasound images (B-mode) can be considered a linear or swept raster ensemble of 1D scan lines (A-mode). Basically each scan line is created when the ultrasound imaging probe transmits a focused pulse of ultrasound energy into the patient and then captures the echoed energy. The timing and amplitude of the echoes form a single column of an image of the patient's anatomy. Multiple sequential scan lines cover the field-of-view to form, column by column, a 2D image. Ultrasound works well to image soft tissue. However, needles and other surgical tools are difficult to image reliably because they behave as specular reflectors. This makes the ultrasound-guided procedure more difficult.

[0068] Aspects of the disclosed inventions attempt to enhance ultrasound needle visualization by selectively triggering return ultrasound pulses directed towards the imaging probe upon receiving incident transmit energy from the appropriate scan lines. The external imaging system's receiving beamformer treats these generated pulses as it does all return echo energy and the end result is a bright, clear "beacon" signal appearing on the imaging system's display. Since the process of beamforming in the external imaging system is understood, an electronic subsystem according to aspects of the disclosed inventions generates a transmit waveform and precisely controlled time points so that the pulses are received by an external imaging system at the appropriate time and converted into a useful signal that shows the position of the ultrasound transducer. For example, the signal may be used to generate a position "beacon" signal on an external ultrasound or other system's imaging display.

[0069] FIG. **14** illustrates a needle visualization system design in an effort to achieve the foregoing. The system includes biopsy needle **300** with beacon transducer **301** and electronic subsystem **302**. Transducer **301** and electronic subsystem **302** preferably form a disposable "plug-and-play" package that can be integrated with existing disposable interventional tools.

[0070] Beacon transducer **301** is mounted in or on needle **300**. The transducer (e.g., an acoustic stack and electrical connectors) should be compact in order to fit into the form factor of the needle. For example, if the transducer is to fit into a 14 AWG core biopsy needle, all components including the transducer and connecting cable must be housed inside the inner trocar shaft so as not to interfere with the biopsy needle's tissue sampling mechanism.

[0071] More generally, any type of transducer may be used, for example a transducer incorporated into, part of, or otherwise attached to an instrument used to perform a procedure. For example, the transducer may be mounted in or on a needle shaft, introducer, dilator, catheter or any other tool that can be inserted inside the body and guided with ultrasound imaging. Aspects of the disclosed inventions may also be used with multiple transducers, for example to show two separate locations on a needle (i.e. biopsy needle tip and biopsy needle cutting sheath) or other tool.

[0072] An exemplary design and fabrication method for transducer **301** is discussed below with respect to FIGS. **25** to **27**.

[0073] Electronic subsystem **302** receives incoming electrical signals from the transducer when ultrasonic pulses transmitted by the imaging probe array through the tissue are received. This imaging probe array may be any type of linear, phase, curved-linear, 2D array, mechanically swept imaging probe, or other imaging probe device. Using this technique, a bright marker may be introduced into the B-mode ultrasound image to indicate the tip or other positions of the needle or interventional tool.

[0074] This image enhancement preferably is achieved through purely acoustic energy transmission techniques without the need to modify the software or hardware of the external ultrasound imaging system. As one possible result, aspects of the disclosed inventions preferably can work with nearly all ultrasound imaging systems universally. Possible benefits of such broad-ranging applicability include but are not limited to the ability to use this beacon visualization system with any external ultrasound imaging system, the ability to use this beacon visualization system with existing devices such as biopsy needles, having more freedom to update external systems without having to update other components, flexibility in choice of imaging systems, and simplified stock control (e.g., of transducers and other equipment). The system furthermore preferably results in real-time or near real-time imaging, allowing the user to perform procedures such biopsies and other procedures without interruption to the clinical workflow. In addition, less experienced technicians may be able to use the system because they may not have to learn how to compensate for "lag" in generated images.

[0075] User outputs from or driven by the electronic subsystem may include imaging information, characteristics about signals sent to and/or received from one or more transducers, information derived from some or all of those characteristics, visual display data, audio feedback, haptic feedback, and/or some combination thereof. In some aspects, data for the outputs may be provided via one or more data output ports such as GPIB and/or USB ports. Output data may be formatted or otherwise applicable to generating a heads-up and/or virtual reality display (e.g., via smartglasses or some other headset) that corresponds with transducer position relative to an external imaging probe. For example, an indicator light or signal appearing in the user's field of view may instruct the user when the transducer(s) and therefore associated needle or other tool is within the imaging plane, thus helping the user guide the tool throughout a procedure.

[0076] In an attempt to achieve the foregoing, the electronic subsystem uses received ultrasound pulses to "learn" what type of scanner it is being used with and then to "pair" with that system by synchronizing a pulse pattern and transmitting a pulse waveform that matches that of the imaging system. Part of the learning process according to aspects of the disclosed inventions include dynamic threshold detection. Threshold detection according to aspects of the disclosed inventions includes detecting depth and position in the azimuth and elevation direction relative to an imaging probe:

[0077] Depth Position:

[0078] The needle transducer should have sufficient sensitivity to detect imaging pulse trains up to a depth of 20 centimeters from the probe, the generally accepted maximum realistic depth for most applications of the subject technology. Different maximum depths may be used.

[0079] Azimuthal Plane Position:

[0080] Aspects of the disclosed invention capture a signal from each scan line pulse within the pulse train of each imaging frame. Within only 1 frame, the pulse repetition frequency (PRF) of the external imaging system preferably may be calculated by measuring the time between adjacent pulse trains. With each imaging plane, a threshold may be applied to determine how many scan line pulses are above a threshold. This number may be used as an error value for a proportional-integral-derivative (PID) controller. A set point may be establish for the number of scan lines that should be above the fixed threshold, and the error value may be used to modulate the gain applied to the incoming signal. This feedback control mechanisms preferably ensures that system only transmits an excitation pulse to the transducer when the imaging probes scan lines are most directly lined up with the needle transducer. The intended result is that the imaging probe receives pulses from the transducer beacon system only when the scan lines are generated when the imaging aperture is centered directly above the needle transducer. Thus, the imaging screen should display a bright beacon signal in the azimuthal plane precisely at the transducer's location.

[0081] Elevation Direction:

[0082] From a user perspective it is preferably not to see a beacon signal on the imaging screen when the needle tip itself is not within the imaging plane of the transducer array. Not transmitting a pulse from the needle transducer when the transducer is outside the imaging plane is therefore preferable. One technique for doing so according to aspects of the disclosed inventions is to use a fixed amplitude threshold and variable gain modulated by the error of the PID controller.

[0083] Some aspects of the disclosed inventions attempt to precisely control the critical characteristics of the beacon signal in order to maintain a uniform signal at the prices location of the needle tip. These characteristics and their control mechanisms illustrated in FIG. **15**. In the figure, block **304** represents an imaging array probe and area **305** represents an imaging field for the probe. Beacon signal **306** in the imaging field is characterized by horizontal position **308**, vertical position (depth) **310**, signal height **312**, and signal width **314**. The signal also may be characterized by signal brightness and "blinking" frequency. Audio feedback may also be used to provide real-time information to a user about the beacon signal. Control mechanisms associated with these factors according to aspects of the disclosed inventions include the following:

Beacon Signal Characteristic	Control Mechanism
Horizontal Position	Select pulses from within a pulse train set of a single imaging frame to center a signal on the actual position of the needle transducer.
Vertical Position (Depth)	Send transmit pulses so external imaging array pulse(s) reach a needle transducer at precisely the same time.
Signal Width	Select a discrete number of scan lines within an imaging frame to which the system responds.
Signal Height	Select a number of transmit waveform cycles. The transmit signal pulse length and number of cycles determines the total signal height.
Signal Brightness	Vary a transmit signal amplitude. In some aspects, signal brightness may be pure white on B-mode imaging if the transmit signal is at the top most of the dynamic range of the receive beamformer of the external imaging system.
Blinking Frequency	Transmit the pulses at calculated intervals, which may cause the signal to appear to "blink." A blinking signal may be more conspicuous and therefore more useful for identifying a position of a needle tip that includes a transducer. These intervals can be determined based on the frame rate of the external imaging system. For example, by transmitting for 10 consecutive frames and then not transmitting for 10 consecutive frames with a frame rate of 20 Hz the beacon signal will appear to blink at frequency of 1 Hz.
Audio Feedback	Emit an audio signal, for example from the electronics subsystem, when the transducer (and therefore needle) is within the imaging plane, thereby helping the user to keep the needle within the plain throughout a procedure.

[0084] The foregoing control mechanisms were successfully tested in conjunction with commercial ultrasound scanners. The Appendix to the Specification shows the results of one such test using a Phillips iu22 scanner with linear array probe. The various image tiles in the Appendix show that these mechanisms have the ability to manipulate a beacon signal in the depth position as well as the height and width of the signal. The Appendix forms a part of this disclosure and is hereby incorporated as if fully set forth herein.

[0085] Doppler signals may be sent by the electrical subsystem in some aspects of the disclosed inventions. These signals may be interpreted by the external imaging system as echo signals from tissue. The signals may be coded to a certain frequency shift, which may be translated by the external imaging system to a velocity and be displayed in an imaging mode such as color Doppler as a red or blue signal, providing enhanced beacon signal contrast to the user. This doppler signal waveform may be interpreted by the electric subsystem, which in turn may trigger a visual, auditory, or other cue. Examples of such cues include but are not limited to particular colors, sounds, haptic outputs, and the like. The cue(s) may provide an enhanced indication of transducer position during a procedure.

[0086] In some aspects, the electrical subsystem may also transmit coded excitation pulses in order to send communication signals other than the ones used to form a beacon signal. These coded excitation pulses could communicate information such as commands, position and orientation information, and/or Doppler signal information.

[0087] Aspects of the disclosed inventions adapt to different brands and/or models of external imaging systems and respond with a suitable pulse sequence. FIG. **16** illustrates a block diagram of an electronic system that may be used to perform such operations. System **320** includes microprocessor **322** that communicates with external control/communications/display unit **324**. The microprocessor preferably performs the following functions:

- **[0088]** Control interface GUI and buttons.
- **[0089]** Interface with registers in FPGA
- **[0090]** Calculate received pulse frequency spectrum and center frequency
- **[0091]** Control Proportional-integral-derivative (PID) loop

The external control/communications/display unit preferable provides the following functions:

- **[0092]** External Control/Communication/Display
- **[0093]** Receive user input
- **[0094]** Generate Visual, Audio, Data and Haptic Output

[0095] The microprocessor sends and receives data to/from FPGA (Field Programmable Gate Array) **326**. The FPGA preferably performs the following functions:

- **[0096]** Store control parameters in registers
- **[0097]** Receive echo data from an analog to digital converter for storage in a first-in-first-out (FIFO) data buffer
- **[0098]** Detect pulses based on a threshold
- **[0099]** Dynamically update the threshold based on percentage of highest amplitude of received pulse
- **[0100]** Generate transmit pulse to transducer

[0101] The PID control loop includes digital to analog converter **328**, time gain compensation unit **330**, band pass filter **332**, and analog to digital converter **334**. The FPGA uses information from the control loop under control of the microprocessor to control pulser **336**, which is provided power by supply **338**. The pulser feeds transmit/receive switch **340** or another interface for transmission of pulses to a needle or other type of transducer. Received signals from the switch are sent to amplifier **342**, which in turn are sent to time gain compensation unit **330** in the PID control loop. Thus, feedback is provided to the FPGA for implementation of the control mechanisms discussed above.

[0102] While a PID control loop is illustrated in FIG. **16**, aspects of the disclosed inventions are not limited to a PID control loop. Rather, the subject technology encompasses medical imaging systems and/or subsystems that use learning in order to adapt to different external systems and/or to provide more accurate or real-time imaging information.

[0103] Likewise, while FIG. **16** shows use of a microprocessor and FPGA, other types of processors may be used. In addition, various of the elements shown in FIG. **16** may be combined, and certain functions may be divided among various elements in different ways from those depicted and described.

[0104] Further details of one possible arrangement of FPGA **326** are illustrated in FIG. **17**. FPGA **350** includes low pass filter **352**, pulse detection unit **354**, noise rejection unit **356**, registers and interface unit **358**, threshold and mean update unit **360**, FIFO buffer **362**, transmit pulse generation unit **364**, and clock **366**. In some aspects, these elements interact as depicted in FIG. **17** to perform the functions of FPGA **326** discussed above with respect to FIG. **16**. Details of some possible techniques for performing these operations are described below.

[0105] FIG. **18** illustrates a process flow according to aspects of the disclosed inventions. Flow **370** includes learning processes **372**, system response **374**, and system control **376**. Learning process **372** attempt to learn the pulsing pattern of an external imaging system. System response **374** attempts to generate pulse formation and synchronization. System control **376** handles user interface controls and user indicators, for example interfaces to audio and visual indicators.

[0106] As depicted, learning process **372** includes threshold detection **378**, pulse characterization **380**, and external system timing **382**. Threshold detection includes the following:

- **[0107]** Compare current pulse(s) to previous pulse(s) from memory
- **[0108]** Update learning data
- **[0109]** Control pulse amplitude
- **[0110]** Control pulse count

Pulse characterization includes the following:

- **[0111]** Fast Fourier Transform
  - **[0112]** Calculate center frequency
  - **[0113]** Calculate bandwidth
- **[0114]** Pulse count

External system timing includes the following:

- **[0115]** Pulse repetition frequency
- **[0116]** Frame rate

[0117] As depicted, system response **374** includes external system timing **384** and pulser **386**. External system timing includes the following:

- **[0118]** Construct pulse frame pattern
- **[0119]** Synchronize transmit with receive pattern

Pulser includes the following:

- **[0120]** Transmit pulse shape (pulse, sine wave, square wave)
- **[0121]** Generate pulse with learned pulse frequency
- **[0122]** Generate pulse with learned pulse count

[0123] Transmit/receive switch **388** controls whether pulses are transmitted to or received from transducer **390**. In operation, pulses are transmitted and received, information about the received pulses are used during flow **370** to determine how to modify the pulses to adapt a particular external imaging system, pulse characteristics are modified, and pulses are again transmitted/received.

[0124] In more detail, the processing algorithm preferably uses several characterization steps to learn about an external imaging system. FIG. **19** shows plots **400**, **402**, and **404** at three times scales for a signal received at a needle transducer from an ultrasound imaging probe. In plot **400**, the signal exhibits a periodicity of ~27 milliseconds. This demonstrates two successive scan line ensemble frames for an imaging rate of ~35 frames per second. Plot **402** zooms in on a single frame and the individual scan line transmit events can be resolved. The amplitudes are based on the spatial focusing of each scan line. Energy directly focused at the needle transducer will yield a higher amplitude signal than transmit energy focused elsewhere. These raster scan lines create one 2D image frame. Plot **404** zooms in on a single scan line, thereby showing that the received pulse is approximately 1 microsecond in half-max duration. The pulse yields a strong primary spike at 633 microseconds but reverberations characteristic of “ring-down” are likely caused by narrow bandwidths. This type of analysis may be used to characterize signals to/from a beacon transducer according to aspects of the disclosed inventions.

[0125] FIGS. **20** to **22** illustrate threshold detection according to aspects of the disclosed inventions, for example as may be performed by threshold detection **378** in FIG. **18**. The input to threshold detection may include pulse waveform data, and the output may include qualifying pulse pattern and timing. In some aspects, the threshold level is variable and is automatically raised and lowered in order to have a fixed number of pulses PASS above the threshold level. By setting a fixed number of pulses to "Qualify", the width of the beacon signal may be controlled. FIG. **20** illustrates a threshold level that is too low: too many pulses qualify. FIG. **21** illustrates a threshold level that is too high: too few pulses qualify. FIG. **22** illustrates an appropriate threshold level: an appropriate number of pulses qualify.

[0126] FIG. **23** illustrates pulse waveform characterization according to aspects of the disclosed inventions, for example as may be performed by pulse characterization **380** in FIG. **18**. The input to pulse waveform characterization may include pulse waveform data, and the output may include pulse waveform characteristics. In some aspects, the threshold level is variable and is automatically raised and lowered in order to have a fixed number of pulses PASS above the threshold level. By setting a fixed number of pulses to "Qualify", the width of the beacon signal may be controlled. Processing and calculations preferably are performed in an FPGA and/or microprocessor (e.g., microcontroller). The output pulse waveform characteristics may include, for example, pulse frequency, pulse amplitude, number of pulse cycles, pulse modulation (frequency or amplitude), and pulse pattern (i.e. multi-cycle duty factor, pulse train pattern for Doppler).

[0127] FIG. **24** illustrates synchronization with an external imaging system according to aspects of the disclosed inventions. System **408** in FIG. **24** includes electronic subsystem **410** according to aspects of the disclosed inventions, for example including features described above. According to some aspects, the electronic subsystem creates a communications link with external visualization system **412** by synchronizing with the external system.

[0128] For example, by establishing a method of echo data decoding and encoding, the electronics sub-system may be able to encode position data into its transmitted pulses. These transmitted pulses may be sent by the needle transducer, received by the external imaging probe, and then integrated with the received echo data in the imaging system's beamforming process. This technique may be used to transmit data for the purpose of needle (or other instrument) visualization. In some aspects, the data transfer format is essentially analog acoustic energy pulses traveling between the ClariTrac transducer and the external ultrasound probe.

[0129] In more detail, the automated nature of the signal processing depicted in FIG. **24**, including the decoding and encoding processes, may permit pairing (i.e., synchronization) with many if not all external imaging systems. To achieve this pairing, the electronic subsystem according to some aspects (1) receives and characterize pulses from the external imaging system probe, (2) generates a transmit pulse waveform, for example as described above, and (3) transmits it in a pattern synchronized with that of the external imaging system probe. The synchronization processes attempts to facilitate production of a clear, stable, and precisely located beacon signal on the external ultrasound system's imaging display. Pairing preferably is possible with external systems that use various arrays such as linear and phase arrays operating in various modes such as B-Mode and Doppler-Mode.

[0130] FIG. **25** illustrates external system timing according to aspects of the disclosed inventions, for example as may be performed by external timing **382** in FIG. **18**. The input to external timing may include pulse waveform data, and the output may include an external system pulse pattern. In some aspects, a new pulser pattern set is created based on the received pulse pattern, and techniques according to the subject technology (e.g., learning and response) continuously adjust the time position of the pulse command signal pattern to synchronize with the external imaging system. Box **414** in FIG. **25** illustrates successful shifting of a pulse pattern to synchronize with an external system.

[0131] Modular Flex Circuit Transducer

[0132] Aspects of the disclosed inventions include a batch fabrication process that combines flex circuit interconnect technologies with needle fabrication techniques, creating an inexpensive modular solution for ultrasound transducer production that may work with a broad range of existing needle designs including those currently used by medical device companies FIG. **26** illustrates a modular flex circuit transducer and fabrication thereof according to aspects of the disclosed inventions. As shown, piezoelectrical (PZT) elements may be laminated in a single flex circuit panel and subsequently separated to form discrete, modular transducer components. These components may have the electrodes already connected and may be ready for integration with a needle assembly.

[0133] FIG. **27** illustrates integration of a modular flex transducer component into a needle introducer according to aspects of the disclosed inventions. In the figure, individual ultrasound transducer (A) is integrated into the polymer needle introducer extrusion to form the (B) finished Introducer. The cross section of an 11 AWG polymer extrusion is shown in (C). The introducer's circular inner lumen may accommodate a large core biopsy needle. This design is intended to allow introducers of various gauges to be made by only changing the polymer extrusion sub-component of the introducer.

[0134] FIG. **28** illustrates use of aspects of the disclosed inventions with a biopsy needle device. During a biopsy procedure, the needle and introducer (A) is advanced to a lesion under the guidance of the beacon transducer. Once the lesion is reached as confirmed by the beacon signal on the imaging screen, the needle core may be (B) extended from the introducer. To sample the tissue, the (C) sampling aperture may be shut rapidly under the force of a spring loaded mechanism in the biopsy handle. The needle then may be extracted from the introducer to collect the tissue sample. The introducer may remain at the lesion location throughout the procedure, enabling multiple passes to be performed with the beacon signal confirming the precise location from where the samples are taken.

[0135] Generality of Invention

[0136] While certain embodiments have been described, the embodiments have been presented by way of example only and are not intended to limit the scope of the inventions. Indeed, the novel devices and methods described herein may be embodied in a variety of other forms; furthermore, various omissions, substitutions, and changes in the form of the devices and methods described herein may be made without departing from the spirit of the inventions. For example, the terms “aspect,” “example,” “preferably,” and the like denote features that may be preferable but not essential to include in some embodiments of the invention. In addition, details illustrated or disclosed with respect to any one aspect of the invention may be used with other aspects of the invention. Additional elements and/or steps may be added to various aspects of the invention and/or some disclosed elements and/or steps may be subtracted from various aspects of the invention without departing from the scope of the invention. Singular elements/steps (e.g., “unit,” “element,” and “structure”) imply plural elements/steps and vice versa. Some steps may be performed serially, in parallel, in a pipelined manner, or in different orders than disclosed herein. Many other variations are possible which remain within the content, scope, and spirit of the invention, and these variations would become clear to those skilled in the art after perusal of this application. The accompanying claims and their equivalents are intended to cover such forms or modifications as would fall within the scope and spirit of the inventions.

1. A method of controlling a transducer, comprising:
transmitting signals to the transducer;
receiving signals from the transducer; and
automatically adjusting the signals transmitted to the transducer based on characteristic of the signals received from the transducer.

2. A method as in claim **1**, wherein the transducer comprises an ultrasound transducer.

3. A method as in claim **1**, wherein the step of automatically adjusting the signals transmitted to the transducer is performed at least in part at least in part by dynamically updating a signal threshold.

4. A method as in claim **1**, wherein the step of automatically adjusting the signals transmitted to the transducer is performed at least in part by a proportional-integral-derivative control loop.

5. A method as in claim **4**, wherein the proportional-integral-derivative control loop is performed at least in part by a field programmable gate array.

6. A method as in claim **1**, further comprising providing one or more visual, audio, and haptic feedback to a user based on the signals received from the transducer.

7. A method as in claim **6**, wherein the visual feedback further comprises virtual reality data.

8. A method as in claim **1**, wherein the signal further comprises a coded excitation communication or a Doppler signal.

9. A method as in claim **1**, wherein the step of automatically adjusting the signals transmitted to the transducer further comprises synchronizing with an external imaging system.

10. A method as in claim **1**, wherein the transducer is mounted in or on a needle shaft, introducer, dilator, or catheter.

11. A control system for at least one imaging transducer, comprising:
at least one interface through which signals are transmitted to or received from the transducer;
at least an electronic subsystem including at least one tangible computing element that performs steps including:
receiving signals from the transducer; and
automatically adjusting the signals transmitted to the transducer based on characteristic of the signals received from the transducer.

12. A system as in claim **11**, wherein the transducer comprises an ultrasound transducer.

13. A system as in claim **11**, wherein the step of automatically adjusting the signals transmitted to the transducer is performed at least in part by dynamically updating a signal threshold.

14. A system as in claim **11**, wherein the step of automatically adjusting the signals transmitted to the transducer is performed at least in part by a proportional-integral-derivative control loop.

15. A system as in claim **14**, wherein the electronic subsystem includes at least a field programmable gate array that performs at least part of the proportional-integral-derivative control loop.

16. A system as in claim **11**, wherein the electronic subsystem further provides one or more visual, audio, and haptic feedback to a user based on the signals received from the transducer.

17. A system as in claim **16**, wherein the visual feedback further comprises virtual reality data.

18. A system as in claim **11**, wherein the signal further comprises a coded excitation communication or a Doppler signal.

19. A system as in claim **11**, wherein the step of automatically adjusting the signals transmitted to the transducer further comprises synchronizing with an external imaging system.

20. A system as in claim **11**, further comprising the transducer and a needle shaft, introducer, dilator, or catheter in or on which the transducer is mounted.

* * * * *

专利名称(译)	用于针头程序的超声装置和方法		
公开(公告)号	US20160302772A1	公开(公告)日	2016-10-20
申请号	US14/688428	申请日	2015-04-16
[标]申请(专利权)人(译)	康明斯THOMAS MUNG JAY C		
申请(专利权)人(译)	CUMMINS，THOMAS 绿豆，JAYÇ		
当前申请(专利权)人(译)	CLARITRAC INC.		
[标]发明人	CUMMINS THOMAS MUNG JAY C		
发明人	CUMMINS, THOMAS MUNG, JAY C		
IPC分类号	A61B8/00 A61B90/00 A61B8/08		
CPC分类号	A61B8/54 A61B2090/3929 A61B90/39 A61B8/0841 A61B8/13 A61B8/4254 A61B8/4263 A61B8/4472 A61B8/4483 A61B8/4494 A61B8/461 A61B10/0275 A61B10/0283 A61B2017/00106		
优先权	13/769146 2013-02-15 US 61/674818 2012-07-23 US		
外部链接	Espacenet USPTO		

摘要(译)

控制换能器的技术。该方法包括将信号发送到换能器，从换能器接收信号，以及基于从换能器接收的信号的特性来自动调节发送到换能器的信号。换能器可以是超声换能器。可以至少部分地通过动态地更新信号阈值，例如通过至少部分由现场可编程门阵列实现的比例积分微分或其他类型的控制回路来执行信号的调整。基于从换能器接收的信号向用户提供一个或多个视觉，音频和触觉反馈。该信号还可以包括编码激励通信和/或多普勒信号。自动调整传输到换能器的信号可以实现与外部成像系统的同步。此外，执行该技术的系统。