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(54) **ULTRASOUND SYSTEM AND METHOD TO AUTOMATICALLY IDENTIFY AND TREAT ADIPOSE TISSUE**

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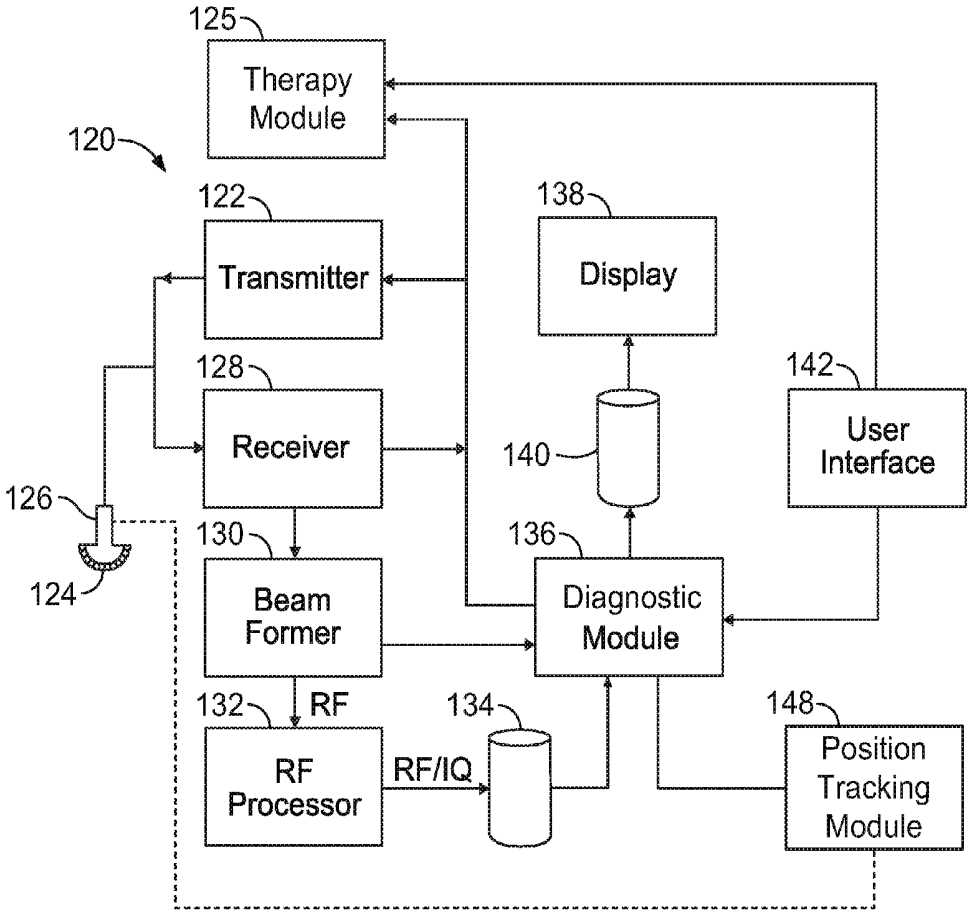
(57) **ABSTRACT**

An ultrasound imaging and therapy system that includes an ultrasound probe and an ultrasound diagnostic module to control the probe to obtain diagnostic ultrasound signals from a region of interest (ROI). The ROI includes adipose tissue and non-adipose tissue. The diagnostic module analyzes the diagnostic ultrasound signals and automatically differentiates adipose tissue from non-adipose tissue. The system also includes an ultrasound therapy module to control the probe to deliver, during a therapy session, a therapy at a treatment location based on a therapy parameter to the adipose tissue differentiated by the ultrasound diagnostic module. A method for delivering therapy to a region of interest (ROI) in a patient is also provided.



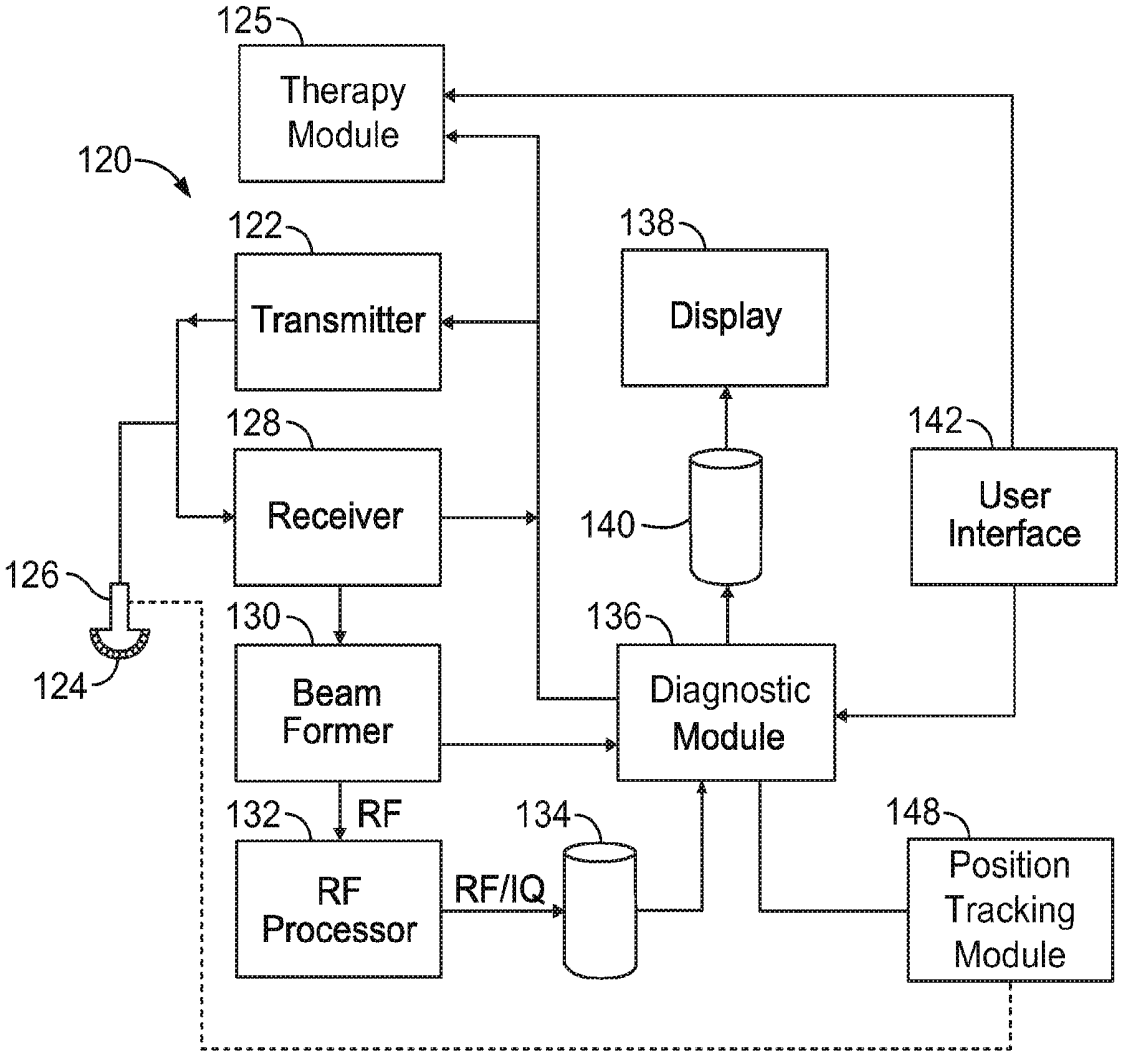

125
Therapy Module
120
122
Transmitter
138
Display
128
Receiver
142
User Interface
140
126
124
130
Beam Former
136
Diagnostic Module
132
RF
134
148
RF Processor
RF/IQ
Position Tracking Module

FIG. 1

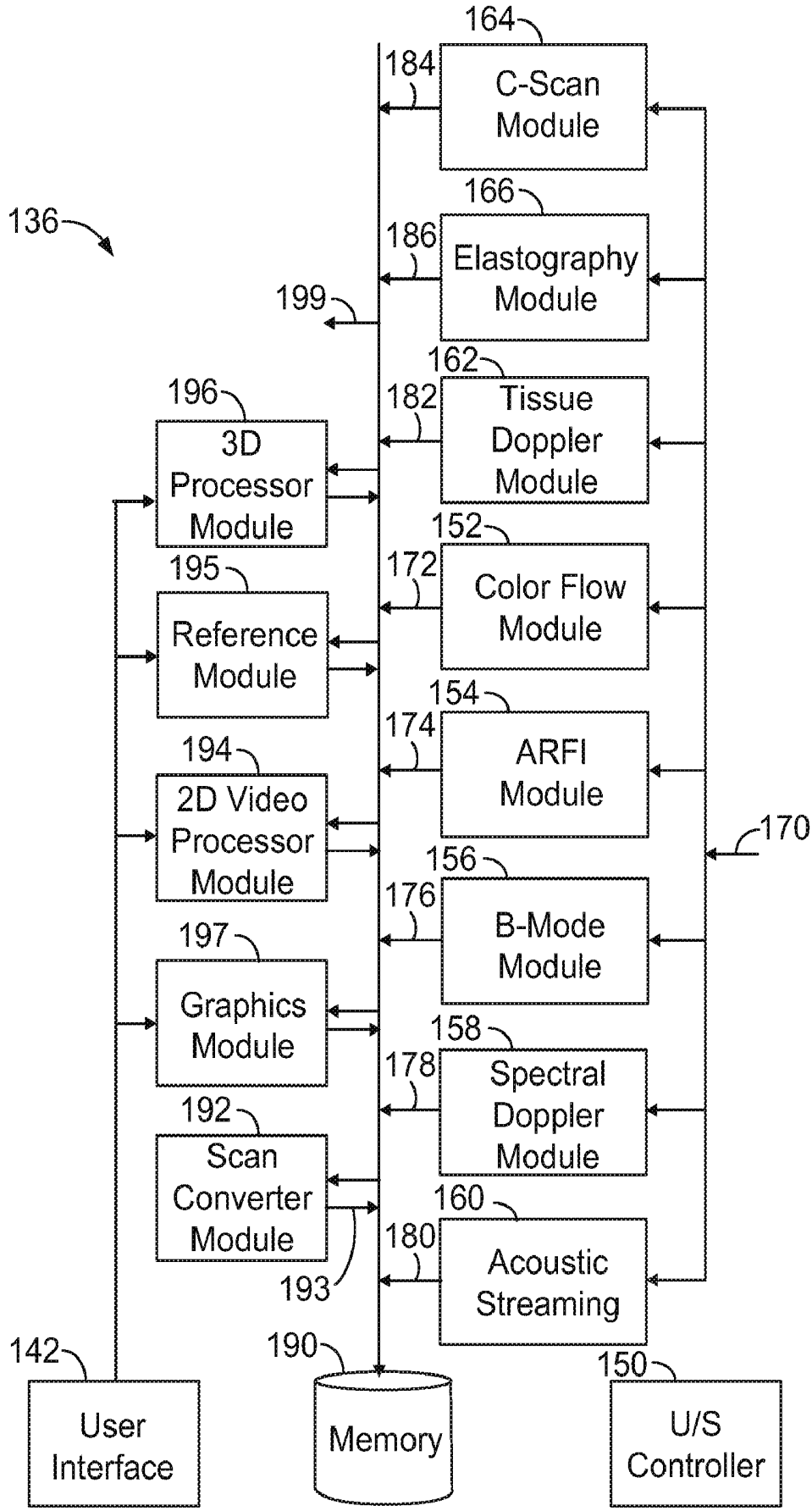

136
164
184
C-Scan Module
166
186
Elastography Module
199
162
182
Tissue Doppler Module
196
3D Processor Module
152
172
Color Flow Module
195
Reference Module
154
174
ARFI Module
194
2D Video Processor Module
170
156
176
B-Mode Module
197
Graphics Module
158
178
Spectral Doppler Module
192
Scan Converter Module
160
180
Acoustic Streaming
193
142
User Interface
190
Memory
150
U/S Controller

FIG. 2

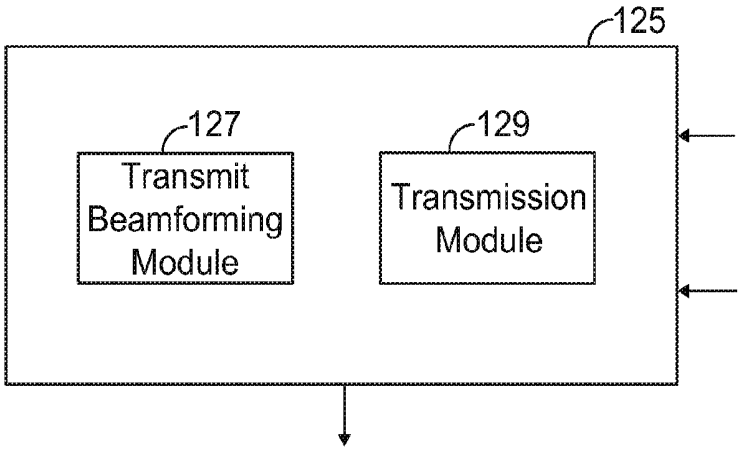

125
127
Transmit Beamforming Module
129
Transmission Module

FIG. 3

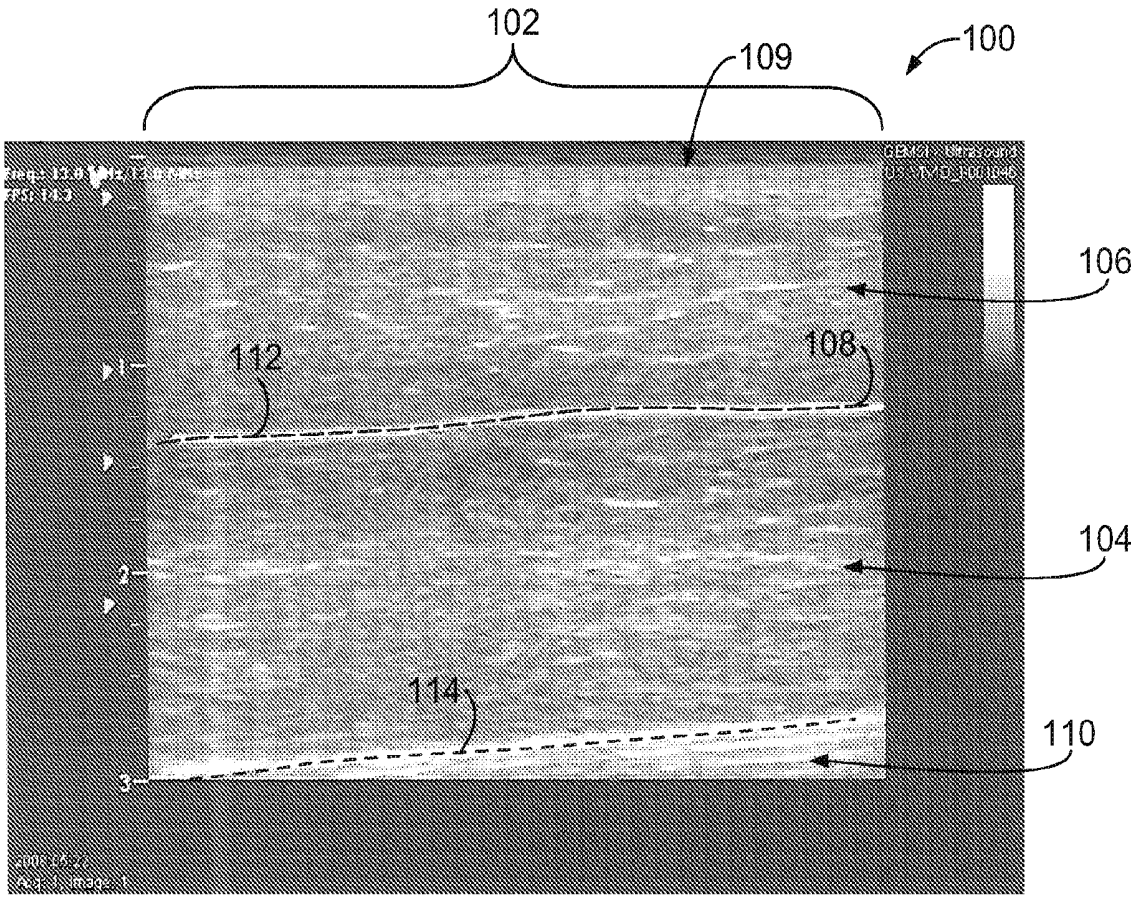

102
109
100
106
112
108
104
114
110

FIG. 4

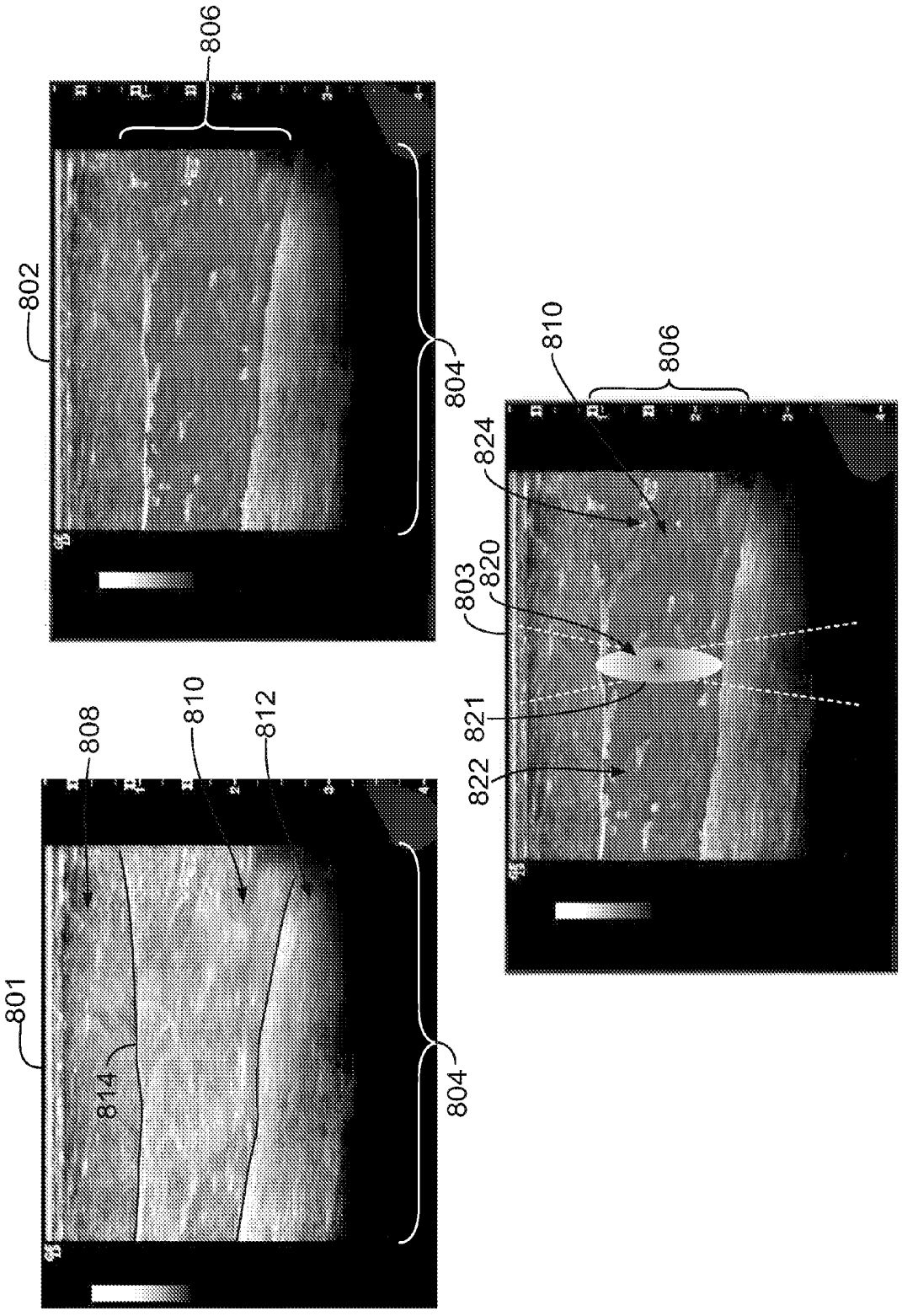


FIG. 5

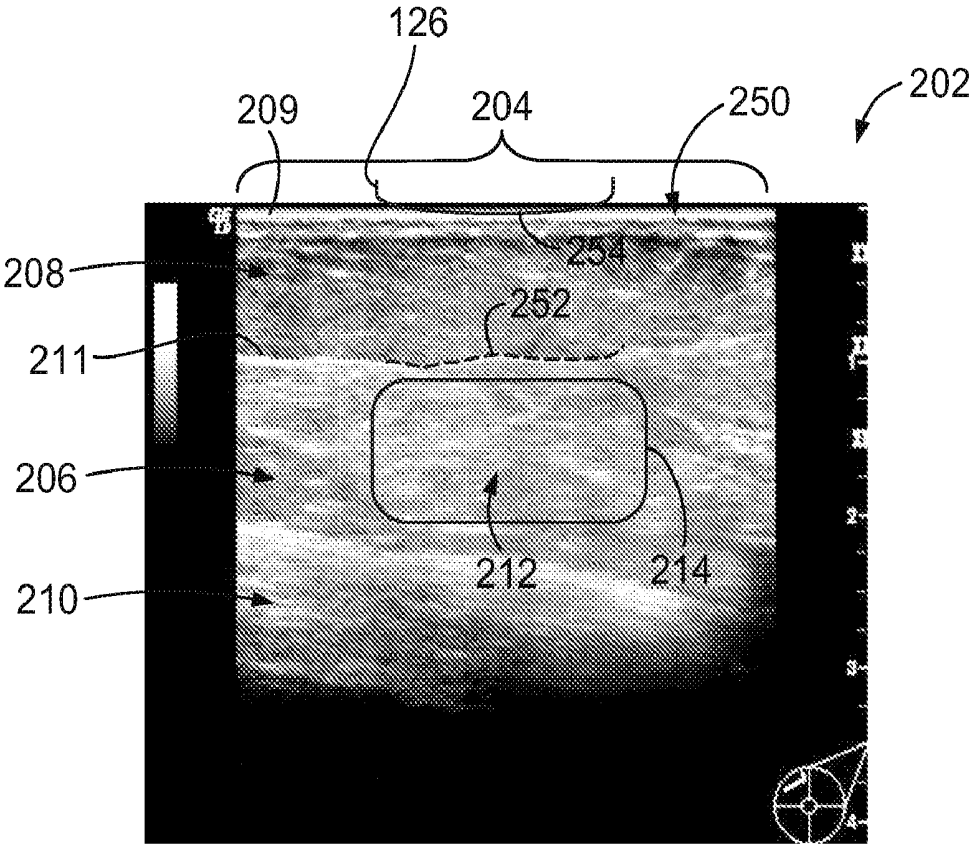

126
209
204
250
202
254
208
252
211
206
212
214
210

FIG. 6

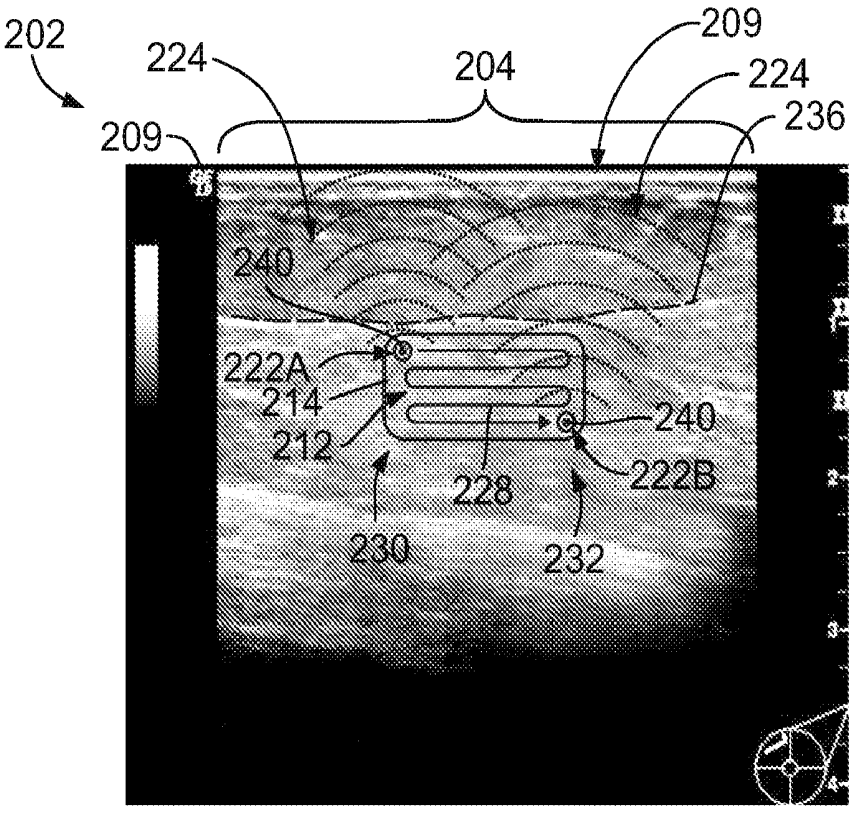

202
224
204
209
224
209
236
240
222A
214
212
240
222B
228
230
232

FIG. 7

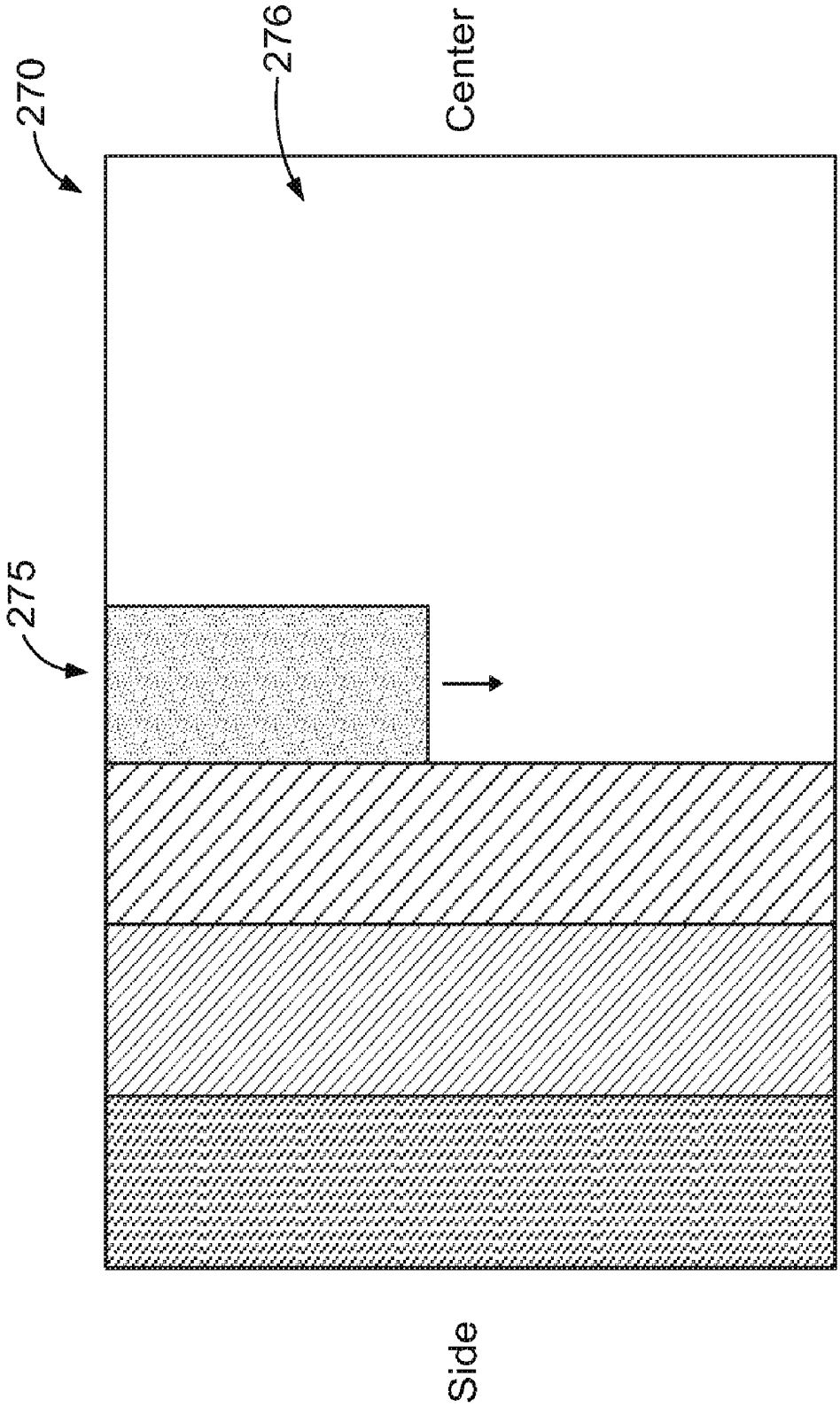


FIG. 8

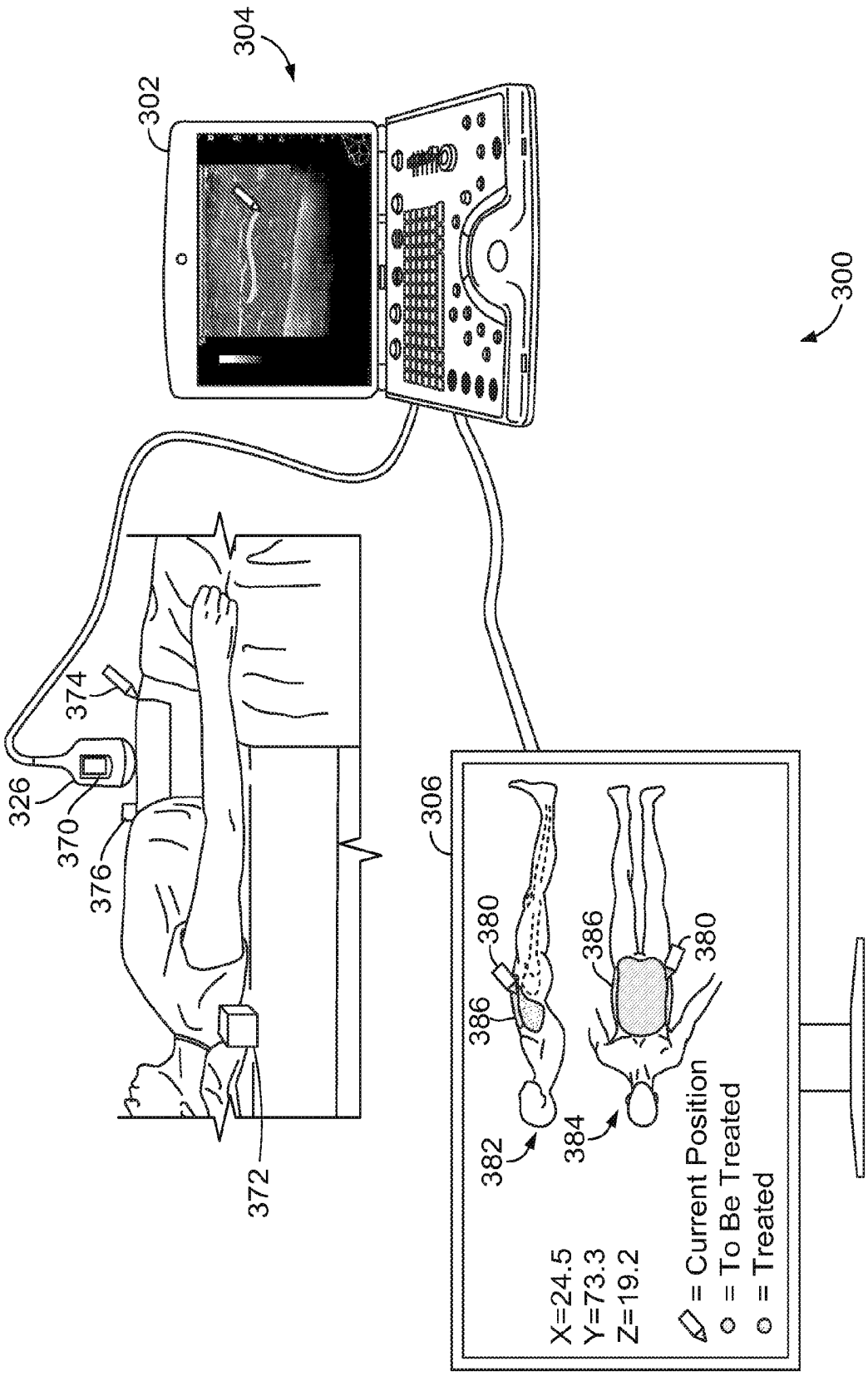

304
302
300
374
326
370
376
372
306
380
386
382
384
X=24.5
Y=73.3
Z=19.2
= Current Position
= To Be Treated
= Treated

FIG. 9

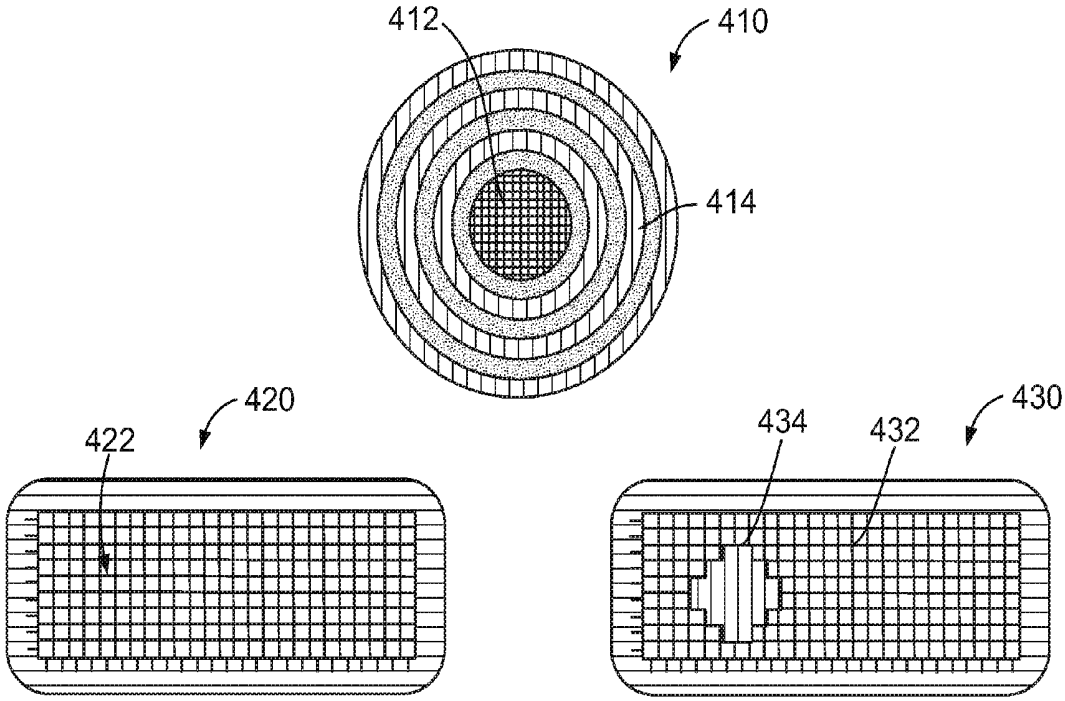


FIG. 10

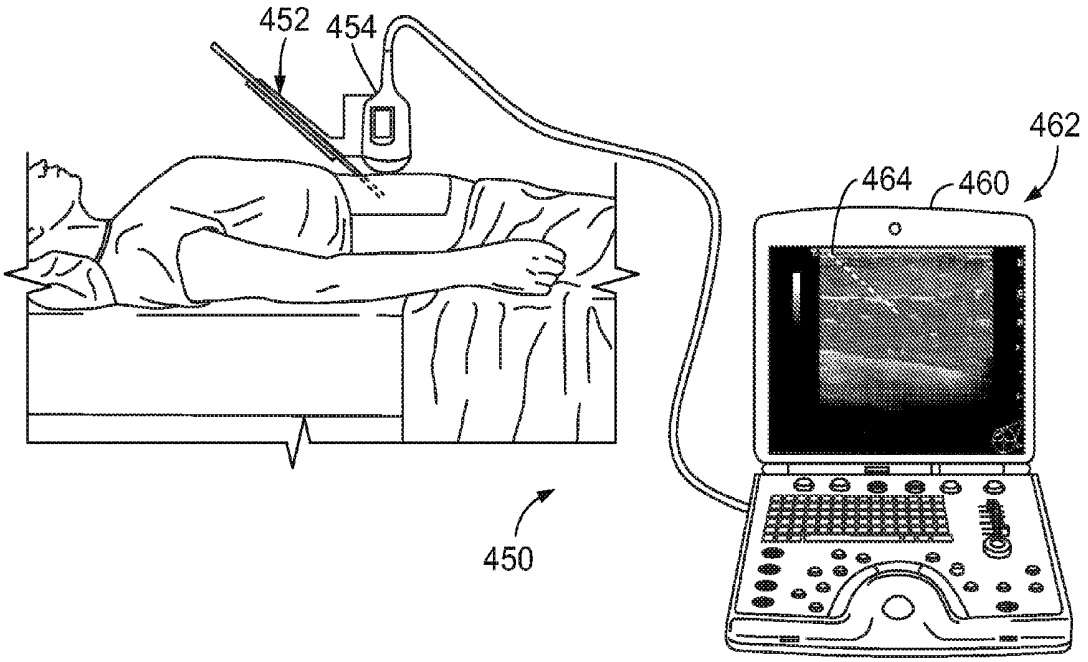


FIG. 11

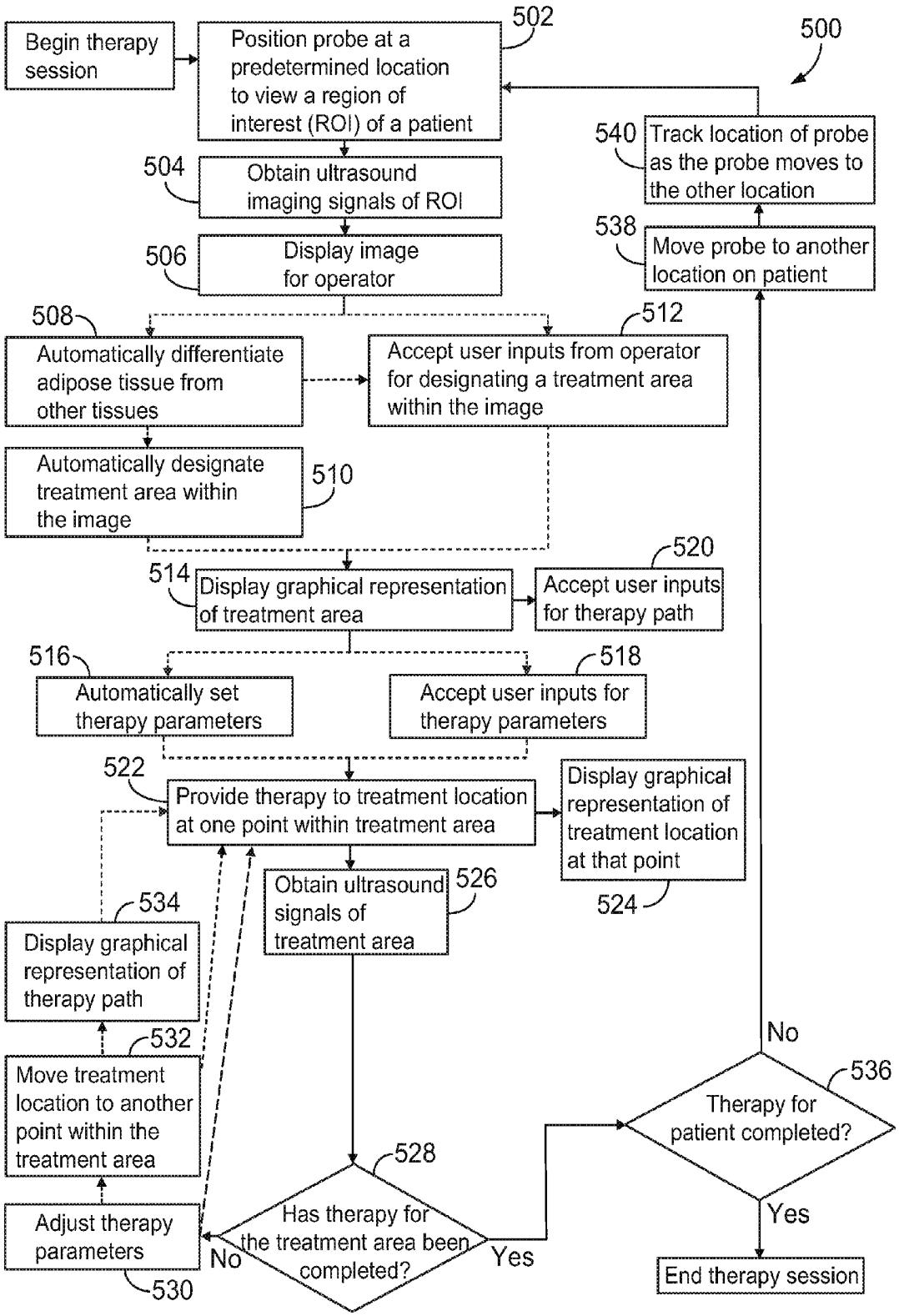

Begin therapy session
Position probe at a predetermined location to view a region of interest (ROI) of a patient
502
500
Track location of probe as the probe moves to the other location
540
Obtain ultrasound imaging signals of ROI
504
Display image for operator
506
Move probe to another location on patient
538
508
Automatically differentiate adipose tissue from other tissues
512
Accept user inputs from operator for designating a treatment area within the image
Automatically designate treatment area within the image
510
514
Display graphical representation of treatment area
520
Accept user inputs for therapy path
516
Automatically set therapy parameters
518
Accept user inputs for therapy parameters
522
Provide therapy to treatment location at one point within treatment area
Display graphical representation of treatment location at that point
524
Obtain ultrasound signals of treatment area
526
534
Display graphical representation of therapy path
532
Move treatment location to another point within the treatment area
No
536
Therapy for patient completed?
528
Has therapy for the treatment area been completed?
No
Yes
Yes
Adjust therapy parameters
530
End therapy session

FIG. 12

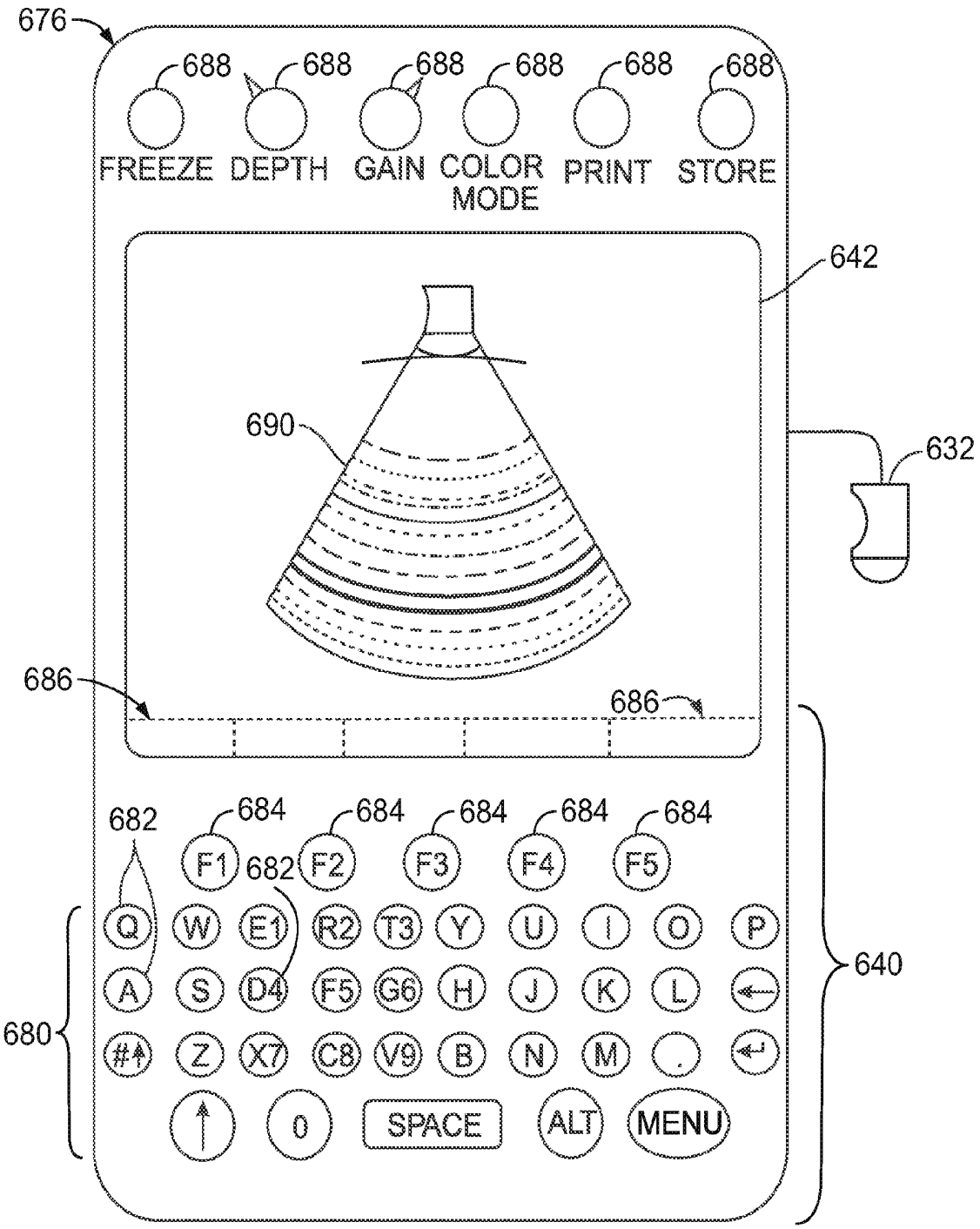

676
688
688
688
688
688
688
FREEZE
DEPTH
GAIN
COLOR MODE
PRINT
STORE
642
690
632
686
686
682
684
684
684
684
684
F1
F2
F3
F4
F5
682
Q
W
E1
R2
T3
Y
U
I
O
P
A
S
D4
F5
G6
H
J
K
L
#
Z
X7
C8
V9
B
N
M
.
0
SPACE
ALT
MENU
680
640

FIG. 13

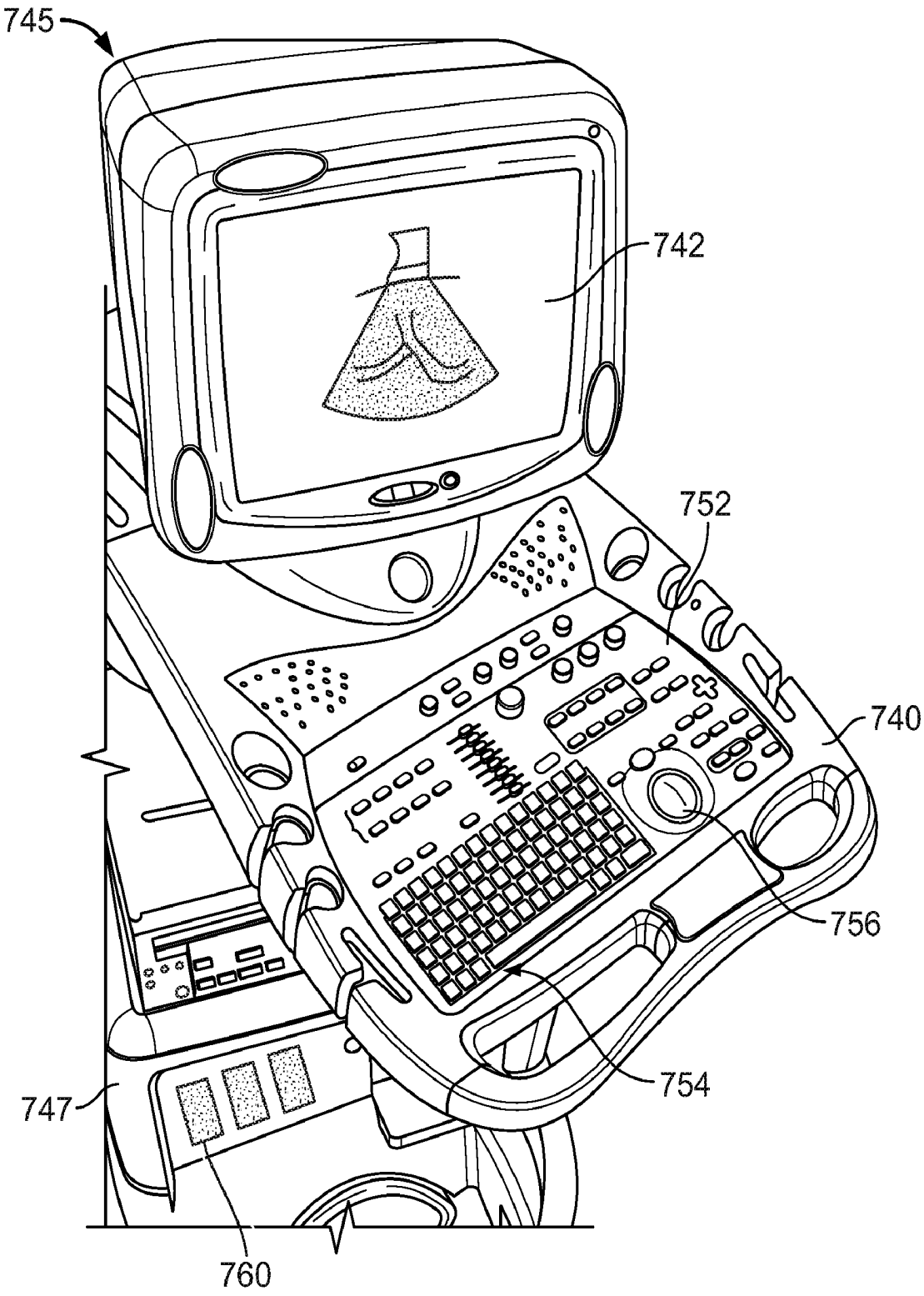


FIG. 14

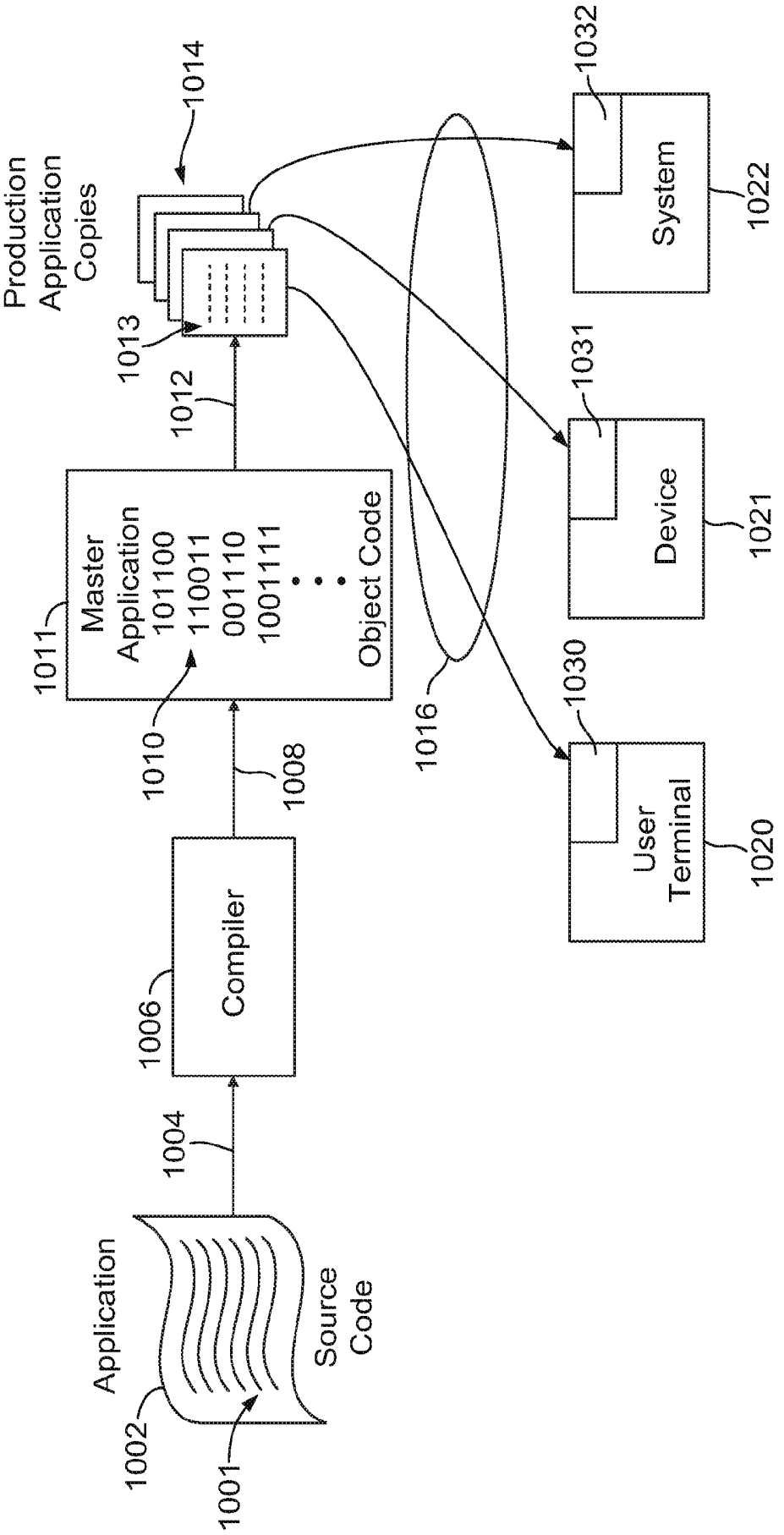

Application Source Code
1002
1001
1004
Compiler
1006
1008
Master Application
101100
110011
001110
1001111
Object Code
1011
1010
1012
1013
Production Application Copies
1014
1016
1030
User Terminal
1020
1031
Device
1021
1032
System
1022

FIG. 15

ULTRASOUND SYSTEM AND METHOD TO AUTOMATICALLY IDENTIFY AND TREAT ADIPOSE TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application includes subject matter that is similar to the subject matter described in U.S. Patent Applications having Attorney Docket No. 235594 (555-0003US), entitled "ULTRASOUND SYSTEM AND METHOD TO DELIVER THERAPY BASED ON USER DEFINED TREATMENT SPACES," and Attorney Docket No. 235610 (555-0005US), entitled "ULTRASOUND SYSTEM AND METHOD TO DETERMINE MECHANICAL PROPERTIES OF A TARGET REGION," both of which are filed contemporaneously herewith and are incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

[0002] The subject matter herein relates generally to diagnostic imaging and therapy systems that provide diagnostic imaging and treatment of a region of interest in a patient, and more particularly, to ultrasound systems that image and treat adipose tissue.

[0003] Various body contouring systems exist today that attempt to remove or destroy fatty tissue (or adipose tissue) from a person's body. Some systems may be invasive, such as liposuction, where a device is inserted into the body and physically removes adipose tissue through suction. Other systems may be non-invasive. For example, in one non-invasive system high-intensity focused ultrasound (HIFU) signals are directed toward a region within the adipose tissue. The HIFU signals may at least partially liquefy the adipose tissue through lysing or causing cavitation or thermal damage of the cells within the adipose tissue.

[0004] However, since the ultrasound signals may have a harmful effect on the non-adipose tissue, it is important for a user of a HIFU system to know and control where treatment has been provided within the body of a patient. In one known system, a user draws an outline of a region on a surface of the body where treatment will be provided and also applies markers to the surface around or within the outline on the body of the patient. A video camera is positioned over the body and oriented to view the surface of the patient's skin where therapy is applied. The HIFU system tracks the progress of the therapy based upon the location of the outline on the body and the markers.

[0005] The HIFU system described above has certain limitations. For example, the HIFU system may only display the surface of the patient's skin and does not provide a visual representation or image of the volume of the body under the surface. Consequently, the above HIFU system does not provide control for localizing therapy to certain regions under the surface of the skin. Further, the above conventional HIFU system also does not know or determine where non-adipose tissue may be located with respect to the adipose tissue. Therefore, the HIFU system does not automatically differentiate the tissues. The HIFU system may also not confirm that therapy has been delivered to the desired regions.

[0006] Accordingly, there is a need for ultrasound imaging and therapy systems that indicate where, within a volume of the patient, therapy has been provided or will be provided. Furthermore, there is a need for systems that facilitate a user of the system in identifying a treatment space of a region of interest beneath the surface and applying treatment to the space.

BRIEF DESCRIPTION OF THE INVENTION

[0007] In one embodiment, an ultrasound imaging and therapy system that includes an ultrasound probe and an ultrasound diagnostic module to control the probe to obtain diagnostic ultrasound signals from a region of interest (ROI). The ROI includes adipose tissue and non-adipose tissue. The diagnostic module analyzes the diagnostic ultrasound signals and automatically differentiates adipose tissue from non-adipose tissue. The system also includes an ultrasound therapy module to control the probe to deliver, during a therapy session, a therapy at a treatment location based on a therapy parameter to the adipose tissue differentiated by the ultrasound diagnostic module.

[0008] In another embodiment, a method for delivering therapy to a region of interest (ROI) in a patient is provided. The method includes obtaining diagnostic ultrasound signals from a region of interest (ROI). The ROI includes adipose tissue and non-adipose tissue. The method also includes analyzing the diagnostic ultrasound signals and automatically differentiating adipose tissue from non-adipose tissue. Also, the method includes delivering therapy, during a therapy session, at a treatment location based on a therapy parameter to the adipose tissue differentiated by the ultrasound diagnostic module.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. **1** is a block diagram of an ultrasound system formed in accordance with an embodiment of the invention.

[0010] FIG. **2** is a block diagram of a diagnostic module in the ultrasound system of FIG. **1** formed in accordance with an embodiment of the invention.

[0011] FIG. **3** is a block diagram of a therapy module in the ultrasound system of FIG. **1** formed in accordance with an embodiment of the invention.

[0012] FIG. **4** illustrates a window presented on a display of FIG. **1** that displays a treatment space of a region of interest.

[0013] FIG. **5** illustrates windows that may be presented on the display of FIG. **1**.

[0014] FIG. **6** illustrates another window presented on a display of FIG. **1** that displays a treatment space of a region of interest.

[0015] FIG. **7** shows the window in FIG. **6** as the ultrasound system delivers therapy to the treatment space.

[0016] FIG. **8** is an image of a C-plane view of a region of interest.

[0017] FIG. **9** illustrates an ultrasound system in accordance with one embodiment that includes a tracking system and a registering system.

[0018] FIG. **10** illustrates transducer arrays that may be used with a probe in accordance with various embodiments.

[0019] FIG. **11** illustrates an ultrasound system in accordance with one embodiment that includes a device for removing adipose tissue from a patient during a therapy session.

[0020] FIG. **12** is a flowchart illustrating a method in accordance with one embodiment.

[0021] FIG. **13** illustrates a hand carried or pocket-sized ultrasound imaging system that may be configured to display a region of interest during a therapy session in accordance with various embodiments.

[0022] FIG. **14** illustrates a console-based ultrasound imaging system provided on a movable base that may be configured to display a region of interest during a therapy session in accordance with various embodiments.

[0023] FIG. **15** is a block diagram of exemplary manners in which embodiments of the invention may be stored, distributed, and installed on computer readable medium.

DETAILED DESCRIPTION OF THE INVENTION

[0024] Exemplary embodiments that are described in detail below include ultrasound systems and methods for imaging and treating a region of interest (ROI). The ROI may include adipose tissue and/or non-adipose tissue, such as muscle tissue, bone, tissue of organs, and blood vessels. The system may display the ROI so that an operator or user of the system can distinguish the adipose tissue and the non-adipose tissue and/or the system may automatically differentiate the adipose tissue and the non-adipose tissue prior to treating. Treatment of the ROI may include providing high-intensity focused ultrasound (HIFU) signals to treatment locations within the ROI. For example, HIFU signals may be directed to treatment locations within the adipose tissue to at least partially liquefy the adipose tissue. Liquefication may occur through cell lysis, cavitation, and/or thermal damage in the adipose tissue.

[0025] The following detailed description of certain embodiments will be better understood when read in conjunction with the appended drawings. To the extent that the figures illustrate diagrams of the functional blocks of various embodiments, the functional blocks are not necessarily indicative of the division between hardware circuitry. Thus, for example, one or more of the functional blocks (e.g., processors or memories) may be implemented in a single piece of hardware (e.g., a general purpose signal processor or random access memory, hard disk, or the like). Similarly, the programs may be stand alone programs, may be incorporated as subroutines in an operating system, may be functions in an installed software package, and the like. It should be understood that the various embodiments are not limited to the arrangements and instrumentality shown in the drawings.

[0026] As used herein, an element or step recited in the singular and proceeded with the word "a" or "an" should be understood as not excluding plural of said elements or steps, unless such exclusion is explicitly stated. Furthermore, references to "one embodiment" are not intended to be interpreted as excluding the existence of additional embodiments that also incorporate the recited features. Moreover, unless explicitly stated to the contrary, embodiments "comprising" or "having" an element or a plurality of elements having a particular property may include additional such elements not having that property.

[0027] It should be noted that although the various embodiments may be described in connection with an ultrasound system, the methods and systems described herein are not limited to ultrasound imaging. In particular, the various embodiments may be implemented in connection with different types of medical imaging, including, for example, magnetic resonance imaging (MRI) and computed-tomography (CT) imaging. Further, the various embodiments may be implemented in other non-medical imaging systems, for example, non-destructive testing systems, such as airport screening systems.

[0028] A technical effect of the various embodiments of the systems and methods described herein include generating an image of a ROI and accepting user inputs to designate a treatment space within the ROI that corresponds to adipose tissue. Another technical effect may include providing therapy to treatment locations and automatically moving the treatment location between multiple points (or treatment sites) within the treatment. In some embodiments, another technical effect includes analyzing the diagnostic ultrasound signals and automatically differentiating adipose tissue from non-adipose tissue. Other technical effects may be provided by the embodiments described herein.

[0029] FIG. **1** is a block diagram of an exemplary ultrasound imaging and therapy system **120** in which the various embodiments can display and provide therapy to a ROI as described in more detail below. The ultrasound system **120** includes a transmitter **122** that drives an array of transducer elements **124** (e.g., piezoelectric crystals) within a probe **126** to emit pulsed ultrasonic signals into a body or volume. The pulsed ultrasonic signals may be for imaging and for therapy of the ROI. For example, the probe **126** may deliver low energy pulses during imaging and high energy pulses during therapy. A variety of geometries may be used and the array of transducer elements **124** may be provided as part of, for example, different types of ultrasound probes.

[0030] The imaging signals are back-scattered from structures in the body, for example, adipose tissue, muscular tissue, connective tissue, blood cells, veins or objects within the body (e.g., a catheter or needle) to produce echoes that return to the elements **124**. The echoes are received by a receiver **128**. The received echoes are provided to a beamformer **130** that performs beamforming and outputs an RF signal. The RF signal is then provided to an RF processor **132** that processes the RF signal. Alternatively, the RF processor **132** may include a complex demodulator (not shown) that demodulates the RF signal to form IQ data pairs representative of the echo signals. The RF or IQ signal data may then be provided directly to a memory **134** for storage (e.g., temporary storage). Optionally, the output of the beamformer **130** may be passed directly to the diagnostic module **136**.

[0031] The ultrasound system **120** also includes a processor or diagnostic module **136** to process the acquired ultrasound information (e.g., RF signal data or IQ data pairs) and prepare frames of ultrasound information for display on a display **138**. The diagnostic module **136** is adapted to perform one or more processing operations according to a plurality of selectable ultrasound modalities on the acquired ultrasound information. Acquired ultrasound information may be processed in real-time during a scanning or therapy session as the echo signals are received. Additionally or alternatively, the ultrasound information may be stored temporarily in the memory **134** during a scanning session and processed in less than real-time in a live or off-line operation. An image memory **140** is included for storing processed frames of acquired ultrasound information that are not scheduled to be displayed immediately. The image memory **140** may comprise any known data storage medium, for example, a permanent storage medium, removable storage medium, etc.

[0032] The diagnostic module **136** is connected to a user interface **142** that controls operation of the diagnostic module **136** as explained below in more detail and is configured to receive inputs from a user. The display **138** includes one or more monitors that present patient information, including diagnostic and therapeutic ultrasound images to the user for review, diagnosis, analysis, and treatment. The display **138** may automatically display, for example, a 2D, 3D, or 4D ultrasound data set stored in the memory **134** or **140** or cur-

rently being acquired, which data set is also displayed with a graphical representation (e.g., an outline of a treatment space or a marker within the treatment space). One or both of the memory **134** and the memory **140** may store 3D data sets of the ultrasound data, where such 3D data sets are accessed to present 2D and 3D images. For example, a 3D ultrasound data set may be mapped into the corresponding memory **134** or **140**, as well as one or more reference planes. The processing of the data, including the data sets, may be based in part on user inputs, for example, user selections received at the user interface **142**.

[0033] The diagnostic module **136** is configured to analyze ultrasound signals and automatically differentiate adipose tissue from non-adipose tissue (e.g., muscle tissue., bone, connective tissue, organs). The diagnostic module **136** may also be configured to receive user imaging commands for outlining or otherwise providing an overlay that indicates a treatment space within the ROI. The diagnostic module **136** may also receive user therapy commands (e.g., through the user interface **142**) regarding how to apply therapy to treatment locations within the ROI. The therapy commands may relate to therapy parameters and the like.

[0034] The diagnostic module **136** communicates with a therapy module **125** that is configured to control the probe **126** during a therapy session. A "therapy session," as used herein, is a period of time in which a patient receives therapy. For example, a therapy session may include a single application of ultrasounds signals to liquefy adipose tissue at a single treatment location or within a single treatment space within the body. A therapy session may also include an extended period of time in which a patient receives multiple applications of ultrasound signals within a treatment space of one region of the body or within multiple regions of the body. A therapy session may also include one visit by a patient to an operator of the system **120**.

[0035] The diagnostic module **136** is configured to control the probe **126** to obtain diagnostic ultrasound signals from the ROI, and the therapy module **125** is configured to deliver a therapy to the treatment locations based on one or more therapy parameters. The therapy module **125** may automatically move the treatment location between multiple points based on user inputs.

[0036] In operation, the system **120** acquires data, for example, volumetric data sets by various techniques (e.g., 3D scanning, real-time 3D imaging, volume scanning, 2D scanning with transducers having positioning sensors, freehand scanning using a voxel correlation technique, scanning using 2D or matrix array transducers, etc.). The data may be acquired by moving the probe **126**, such as along a linear or curvilinear path, while scanning the ROI. At each linear or arcuate position, the probe **126** obtains scan planes that are stored in the memory **134**. The probe **126** also may be mechanically moveable within the ultrasound probe.

[0037] Optionally, the system **120** may include a position tracking module **148** that tracks a position of the probe **126** and communicates the position to the diagnostic module **136**. A position of the probe **126** may be tracked relative to a reference point on or near the patient, a marker, and the like. As will be described in greater detail below, the position of the probe **126** may be used to indicate, to the user, regions of the patient that have already been treated, are being treated, or have yet to be treated.

[0038] FIG. **2** is an exemplary block diagram of the diagnostic module **136**, and FIG. **3** is an exemplary block diagram of the therapy module **125**. The therapy and diagnostic modules **125** (FIG. **3**) and **136** (FIG. **2**) are illustrated conceptually as a collection of modules, but may be implemented utilizing any combination of dedicated hardware boards, DSPs, processors, etc. Alternatively, the modules of FIGS. **2** and **3** may be implemented utilizing an off-the-shelf PC with a single processor or multiple processors, with the functional operations distributed between the processors. As a further option, the modules of FIGS. **2** and **3** may be implemented utilizing a hybrid configuration in which certain modular functions are performed utilizing dedicated hardware, while the remaining modular functions are performed utilizing an off-the-shelf PC and the like. The modules also may be implemented as software modules within a processing unit. Furthermore, the diagnostic module **136** may include the therapy module **125**, or the therapy module **125** may include the diagnostic module **136**.

[0039] The operations of the modules illustrated in FIGS. **2** and **3** may be controlled by a local ultrasound controller **150** or by the diagnostic module **136**. The modules **152-166** perform mid-processor operations. The diagnostic module **136** may receive ultrasound data **170** in one of several forms. In the embodiment of FIG. **2**, the received ultrasound data **170** constitutes IQ data pairs representing the real and imaginary components associated with each data sample. The IQ data pairs are provided to one or more modules, for example, a color-flow module **152**, an acoustic radiation force imaging (ARFI) module **154**, a B-mode module **156**, a spectral Doppler module **158**, an acoustic streaming module **160**, a tissue Doppler module **162**, a C-scan module **164**, and an elastography module **166**. Other modules may be included, such as an M-mode module, power Doppler module., harmonic tissue strain imaging, among others. However, embodiments described herein are not limited to processing IQ data pairs. For example, processing may be done with RF data and/or using other methods. Furthermore, data may be processed through multiple modules.

[0040] Each of modules **152-166** are configured to process the IQ data pairs in a corresponding manner to generate, respectively, color-flow data **172**, ARFI data **174**, B-mode data **176**, spectral Doppler data **178**, acoustic streaming data **180**, tissue Doppler data **182**, C-scan data **184**, elastography data **186**, among others, all of which may be stored in a memory **190** (or memory **134** or image memory **140** shown in FIG. **1**) temporarily before subsequent processing. The data **172-186** may be stored, for example, as sets of vector data values, where each set defines an individual ultrasound image frame. The vector data values are generally organized based on the polar coordinate system.

[0041] A scan converter module **192** accesses and obtains from the memory **190** the vector data values associated with an image frame and converts the set of vector data values to Cartesian coordinates to generate an ultrasound image frame **193** formatted for display. The ultrasound image frames **193** generated by the scan converter module **192** may be provided back to the memory **190** for subsequent processing or may be provided to the memory **134** (FIG. **1**) or the image memory **140** (FIG. **1**). Once the scan converter module **192** generates the ultrasound image frames **193** associated with the data, the image frames may be restored in the memory **190** or communicated over a bus **199** to a database (not shown), the memory **134**, the image memory **140** and/or to other processors (not shown).

[0042] As an example, it may be desired to view different ultrasound images relating to a therapy session in real-time on the display **138** (FIG. **1**). To do so, the scan converter module **192** obtains data sets for images stored in the memory **190** of that are currently being acquired. The vector data is interpolated where necessary and converted into an X, Y format for video display to produce ultrasound image frames. The scan converted ultrasound image frames are provided to a display controller (not shown) that may include a video processor that maps the video to a gray-scale mapping for video display. The gray-scale map may represent a transfer function of the raw image data to displayed gray levels. Once the video data is mapped to the gray-scale values, the display controller controls the display **138**, which may include one or more monitors or windows of the display, to display the image frame. The image displayed in the display **138** is produced from an image frame of data in which each datum indicates the intensity or brightness of a respective pixel in the display.

[0043] Referring again to FIG. **2**, a 2D video processor module **194** may be used to combine one or more of the frames generated from the different types of ultrasound information. For example, the 2D video processor module **194** may combine different image frames by mapping one type of data to a gray map and mapping the other type of data to a color map for video display. In the final displayed image, the color pixel data is superimposed on the gray scale pixel data to form a single multi-mode image frame that is again restored in the memory **190** or communicated over the bus **199**. Successive frames of images may be stored as a cine loop (4D images) in the memory **190** or memory **140** (FIG. **1**). The cine loop represents a first in, first out circular image buffer to capture image data that is displayed in real-time to the user. The user may freeze the cine loop by entering a freeze command at the user interface **142**. The user interface **142** may include, for example, a keyboard and mouse and all other input controls associated with inputting information into the ultrasound system **120** (FIG. **1**). In one embodiment, the user interface **142** includes the display **138** that may be touch-sensitive or configured to interact with a stylus. The user interface **142** may also receive user inputs through voice-recognition or activation.

[0044] A 3D processor module **196** is also controlled by the user interface **142** and accesses the memory **190** to obtain spatially consecutive groups of ultrasound image frames and to generate three-dimensional image representations thereof, such as through volume rendering or surface rendering algorithms as are known. The three-dimensional images may be generated utilizing various imaging techniques, such as ray-casting, maximum intensity pixel projection and the like.

[0045] A graphic module **197** may also be controlled by the system **120** and may access the memory **190** to obtain groups of ultrasound image frames that have been stored or that are currently being acquired. The graphic module **197** may generate images that include the images of the ROI and a graphical representation positioned (e.g., overlaid) onto the images of the ROI. The graphical representation may represent an outline of a treatment space, the focal point or region of the therapy beam, a path taken by the focal region within the treatment space, a probe used during the session, and the like. Graphical representations may also be used to indicate the progress of the therapy session. The graphical representations may be generated using a saved graphical image or drawing (e.g., computer graphic generated drawing), or the graphical representation may be directly drawn by the user onto the image using a pointing device, e.g., an electronic stylus or mouse, or another interface device.

[0046] Also shown, a reference module **195** may be used to identify a reference point on or near the patient during the therapy session. For example, a reference point may be an anatomical element or structure of the body that is determined by the system **120** or by the user. The reference point may also be an element or marker positioned on the surface of the body of the patient. As will be described in greater detail below, the reference module **195** may use the imaging data to determine a relation of the treatment space with respect to a reference point.

[0047] Referring to FIG. **3**, the therapy module **125** may be coupled to the diagnostic module **136** (FIG. **2**) and the user interface **142** (FIG. **1**) and include a transmit beamforming module **127** and a transmission module **129**. The therapy module **125** and the diagnostic module **136** may also be a common module or processor. The transmit beamforming module **127** is configured to control the location and movement of a focal point or region generated by the transducer elements **124**. For example, the transmit beamforming module **127** may control electronic or mechanical steering of the probe to move the focal region of a therapy beam within the treatment spaces or between different treatment spaces. The transmission module **129** is configured to drive the transducer elements **124** (or only a portion or subset of the transducer elements **124**) in delivering energy pulses to the ROI for imaging and therapy.

[0048] FIG. **4** illustrates a window **100** that may be presented on the display **138** (FIG. **1**). The display **138** communicates with the diagnostic module **136** (FIG. **1**) to display an image **102** of the ROI of the patient within the window **100**. As shown in the image **102**, the ROI may include adipose layers or tissues **104** and **106** and non-adipose layers or tissues, such as dermis layer **109**, connective tissue **108**, and muscle tissue **110**. The image **102** of the ROI may also include other anatomical structures such as bone, organs, cartilage, and others. As will be discussed in greater detail, the system **120** may be able to automatically identify or differentiate between the layers. After differentiating the adipose tissue **104** from other tissues, the system **120** may deliver therapy pulses (e.g., HIFU) to at least one of the adipose tissue **104** and **106**. Alternatively, the user of the system **120** may be able to recognize or identify through the image **102** the different layers of tissue. The user may then enter user inputs for designating spaces within at least one of the adipose tissue **104** and **106** for receiving therapy.

[0049] In order to automatically differentiate the adipose tissue **104**, **106** from the non-adipose tissues and, more specifically, the dermis tissue **109**, connective tissue **108**, and muscle tissue **110**, the diagnostic module **136** may analyze ultrasound signals received from the ROI. For instance, the diagnostic module **136** may use data obtained through one or more processing methods (e.g., B-mode, elastography, color-flow). In some embodiments, the diagnostic module **136** automatically differentiates the adipose tissue **104** from the non-adipose tissues by at least identifying barriers or boundaries **112** and **114** (indicated as hashed lines) between the adipose tissues **104** and **106** and/or an adjacent non-adipose tissue, such as the dermis tissue **109** and the muscle tissue **110**. For example, the diagnostic module **136** may identify the connective tissue **108** that extends between the adipose tissues **104** and **106**. The system **120** (FIG. **1**) may use stored information regarding general human anatomy at the ROI to

identify a location of the adipose tissue **104** in relation to the boundary **112** (i.e., the connective tissue **108** shown in FIG. **4**). More specifically, the system **120** may identify the adipose tissue **104** as the tissue or layer extending directly beneath the connective tissue **108**. Optionally, the system **120** may indicate to the operator the different layers and tissues within the ROI by illustrating graphical representations of the barriers or boundaries **112** and **114**, such as overlaying hashed lines onto the image **102** as shown in FIG. **4**.

[0050] The system **120** may automatically differentiate tissues within the ROI using other methods separately or in conjunction with identifying barriers or boundaries. As another example, the diagnostic module **136** may automatically differentiate the adipose tissue from other tissues by at least directly measuring a plurality of points within the ROI for an adipose characteristic. The adipose characteristic may include a measure of the tissue mechanical properties at one or more points, such as a tissue stiffness, a shear wave velocity between points, a longitudinal wave velocity between points, and a density of the tissue at one or more points. The adipose characteristic may also relate to thermal properties, including thermal conductivity and specific heat. Another adipose characteristic may be cavitation inducibility provided that non-adipose tissue would not be damaged under the conditions that produced cavitation in adipose tissue.

[0051] In addition to identifying the adipose tissue **104** by measuring for an adipose characteristic, the diagnostic module **136** may identify other tissues by measuring for non-adipose characteristics. For example, the diagnostic module **136** may identify the connective tissue **108** and the muscle tissue **110** by measuring tissue mechanical properties at one or more points within the ROI, such as a tissue stiffness, a shear wave velocity between points, a longitudinal wave velocity between points, and a density of the tissue at one or more points. The non-adipose characteristic may also relate to thermal properties.

[0052] Furthermore, techniques using one or more modules **152-166** (FIG. **2**) and/or the methods described above may be used to examine patterns in the image that are characteristic of different types of tissues (e.g., adipose tissue, muscle tissue, connective tissue, bone tissue). For instance, a layered appearance that is characteristic of muscle tissue may be determined, or a cellular structure of adipose tissue caused by connective tissue boundaries could be determined.

[0053] As a more specific example, in some embodiments, the diagnostic module **136** may analyze images obtained through B-mode processing. A B-mode image is an image that may be gray-scale or colored showing a cross-section of the ROI along a scanning plane. The B-mode image relates to acoustic backscatter energy from different tissues within the ROI. FIG. **4** illustrates a B-mode gray-scale image of the ROI. As shown, different tissues may have different brightness levels. The diagnostic module **120** may measure a brightness level of a plurality of points within the image **102** to differentiate the adipose tissue **104** relative to other tissues. Furthermore, the diagnostic module **136** may use stored information, such as the expected anatomical structures for a particular ROI, in addition to the measured brightness levels to determine the adipose tissue **104**. As one example, if the ROI is of the abdomen, the diagnostic module **136** may expect the image **102** to include the dermis tissue **106** and the adipose tissue **104** separated by the connective tissue **108**.

[0054] Also, the system **120** may use elastography processing methods alone or in addition to other processing methods to differentiate the adipose tissue **104**. In one type of ultrasound elastography, a compression is applied to the ROI (e.g., along the skin surface) and strain images of the tissues in response to the compression may be obtained. For example, speckle tracking techniques may use data obtained before and after the applied compression to calculate the relative motion of different types of tissues due to their different mechanical properties (e.g., tissue strain or stiffness). As such, the images obtained through elastography, also called elastograms, relate to elastic properties of the tissues. Moreover, other techniques may be used to examine the mechanical properties of different tissues. For example, other elastography techniques, such as inducing and measuring the shear waves or vibro-acoustography, may be used to differentiate adipose tissue from other tissue types.

[0055] FIG. **5** shows three windows **801-803** that may be shown together or separately on the display **138** (FIG. **1**). More specifically, FIG. **5** illustrates an embodiment where the diagnostic module **136** (FIG. **1**) uses data obtained through a B-mode processing method and data obtained through an elastographic processing method. The window **801** includes a B-mode image **804** of a ROI. As discussed above, the diagnostic module **136** may use data from the B-mode processing method and/or the elastographic processing method to automatically differentiate adipose tissue **808** and **810** from non-adipose tissues **812** and **814**. The window **802** illustrates the B-mode image **804** and an elastographic image **806** (also referred to as an elastogram) that overlay one another or are integrated with each other. (Although not shown in FIG. **5**, the elastogram **806** may be colored (e.g., red) and overlay the black-and-white or gray-scale B-mode image **804** so as to provide a reddish tinge or shading.) The window **802** may represent the ROI before applying therapy.

[0056] The window **803** is an example of a window that an operator may see on the display **138** (FIG. **1**) during a therapy session. As shown, a treatment location **820** may be indicated by a graphical representation **821**, such as an elongated oval. The window **803** shows a treated space **822** to the left of the treatment location **820** that has already received therapy and an untreated space **824** to the right of the treatment location **820** that has not received therapy. When therapy is applied and HIFU signals are directed to the treatment location **820**, the adipose tissue **810** may be at least partially liquefied at or proximate to the treatment location **820**. Accordingly, mechanical properties of the adipose tissue **810** corresponding to the treated space **822** will be different than mechanical properties of the adipose tissue **810** corresponding to the untreated space **824**. During treatment of the adipose tissue **810**, the elastogram **806** may be updated. Spaces having different mechanical properties may be visually different in the elastogram **806** and, consequently, the window **803**. For example, a portion of the elastogram **806** corresponding to the treated space **822** may have a greenish color or shading. A portion of the elastogram **806** corresponding to the untreated space **824** may have a reddish color or shading. Accordingly, the window **803** may indicate to the operator the spaces or areas of the ROI in the patient that have been treated, that are being treated, or that have not been treated.

[0057] Furthermore, the elastogram **806** is not limited to showing two colors where one is for the treated space and the other is for the untreated space. The elastogram **806** may show a spectrum of colors that are indicative of the mechanical properties of the adipose tissue **810**. For example, if the therapy applied to the treatment location **820** does not liquefy

the adipose tissue **810** at the treatment location **820**, the color (or some other visual indication) in the elastogram **806** may indicate to the operator that the treatment only partially liquefied the adipose tissue **810**.

[0058] In some embodiments, after the initial scan to obtain diagnostic ultrasound signals has been performed and the adipose tissue has been identified, the diagnostic module **136** may automatically set a therapy parameter before therapy is applied to the ROI. For example, the diagnostic module **136** may identify a thickness of a layer of the adipose tissue. Based on the thickness of the adipose tissue and/or other factors, the diagnostic module **136** may automatically set a focal region depth, a focal region size, an ablation time for each point within the ROI that receives therapy, an energy level of the therapy signals, and a rate of focal region movement within the ROI during the therapy session. Other parameters may be automatically set, including a peak negative pressure, a pulse repetition rate, a duty cycle, a dwell time, and pulse sequences. Also, if the thickness, depth, or density of the layer of the adipose tissue(s) decreases or increases as the adipose tissue extends laterally across the ROI (e.g., across the image **102** (FIG. **4**)), the therapy parameters may change in accordance with the thickness, density, or depth of the layer as the therapy is applied. For example, if the thickness is decreasing, then the focal region size may also decrease or the energy level of the therapy signals may decrease as the therapy moves along the adipose tissue **104**.

[0059] After or while therapy is applied within the ROI, the diagnostic module **136** may analyze ultrasound signals from a second supplemental scan to confirm treatment of the ROI. For example, the diagnostic module **136** may obtain images from the second scan that include data processed through elastography methods. After or while the adipose tissue receives therapy, images obtained through elastography methods may indicate a change in tissue stiffness at a location that has received or is receiving therapy. More specifically, an initial image may have a color, brightness, or density that indicates a tissue stiffness of the adipose tissue before treatment. In the second supplemental scan, the color, brightness, or density of the adipose tissue may change where the adipose tissue received therapy. The images from the initial and supplemental scans may be used by the system **120** to confirm that treatment was received within the adipose tissue. For example, the images from the initial and supplemental scans may be superimposed with each other or shown side-by-side on the display **138**. The operator may confirm that treatment was received within the adipose tissue by comparison of the images.

[0060] In addition or alternatively, the diagnostic module **136** may use other processing methods to facilitate determining whether a characteristic of the adipose tissue or another tissue has changed due to therapy. Also, after evaluating the ROI in the second supplemental scan, the therapy parameters may be adjusted if therapy is to be applied again to the ROI or if the focal region moves to another location within the ROI.

[0061] FIGS. **6** and **7** also illustrate features of the system **120** that may be used by an operator during a therapy session to facilitate delivering therapy to the ROI. FIG. **6** illustrates a window **202** that may be presented on the display **138** (FIG. **1**). As shown in an image **204**, the ROI includes adipose tissue **206** and **208** and non-adipose tissues, such as dermis tissue **209**, muscle tissue **210**, and connective tissue **211**. In some embodiments, the system **120** automatically designates a treatment space **212** or the user interface **142** (FIG. **1**) accepts user inputs for designating the treatment space **212** within the ROI. The treatment space **212** represents a space that will be treated during a therapy session and is generally located within an adipose tissue, such as the adipose tissue **206**. The designated treatment space **212** may correspond to a portion of the adipose tissue **206** within the image **204** or the treatment space **212** may correspond to all of the adipose tissue **206** within the ROI. By way of example, the treatment space **212** may be located and shaped so that the treatment space **212** is a distance away from the non-adipose tissues **208** and **210**. As such, a probability of therapy being inadvertently applied to spaces outside of the treatment space **212**, such as the non-adipose tissues **211** and **210**, may be decreased.

[0062] The display **138** may indicate to the user or another viewer (e.g., the patient or a person in a remote location) the treatment space **212** designated by the user inputs. A graphical representation, such as an outline **214**, may be overlaid upon the image **204**. The outline **214** designates boundaries of the treatment space **212** to indicate to a viewer where the therapy will be applied. The outline **214** may be determined by parameters entered by the user. For example, the user may select pre-programmed outlines **214** or may enter coordinates or dimensions for the treatment space **212** to form the outline **214**. The outline **214** may indicate an enclosed region within the treatment space **212**. The outline **214** may have various shapes including a rounded rectangular shape (as shown), a parallelogram shape, another geometric shape, and the like, or a shape determined by the system **120**.

[0063] The user may also enter a drawing notation to indicate where the outline **214** should be located. The drawing notation may be entered through a keyboard, a mouse, or another pointing device. As an example, the user may use a stylus pen and directly contact a touch-sensitive screen of the display **138** or a pad that is communicatively coupled to the user interface **142** to draw the drawing notation onto the image **204**. As another example, the user interface **142** may recognize touches from a finger to the screen of the display **138**. Furthermore, the user interface **142** may have a voice-activation module that receives voice commands from the user for entering user inputs including the drawing notation.

[0064] The outline **214** may be positioned with respect to reference points **250**, **252**, and **254**. The reference module **195** (FIG. **2**) may be configured to automatically identify the reference points **250**, **252**, or **254** on the patient or receive user inputs that identify the reference points. For instance, the reference point **250** may be a surface of the patient's skin or the dermis layer **209**, the reference point **252** may be a particular point of or a portion of a boundary between the adipose tissues **206** and **208**, and the reference point **254** may be a point along a surface of the probe **126**. (For illustrative purposes, the reference point **254** and the probe **126** are shown in FIG. **6**. However, the reference point **254** and the probe **126** may or may not be shown to the viewer in the image **204**.) Reference points may also be other points within the ROI, such as bone, other artifacts, or a reference element such as a metallic sticker placed on a patient's skin.

[0065] After identifying a reference point, the reference module **195** may determine a relation of the treatment space **212** with respect to the identified reference point using ultrasound signal processing methods (e.g., speckle tracking). The reference module **195** may position the outline **214** of the treatment space **212** on the image **204** based on the relation of the treatment space **212** with respect to the identified reference point. As a more specific example, the reference module

195 may establish a positional relation between the adipose tissue 206 and the reference point 254 that represents a surface of the probe 126. Based on the positional relation, the reference module 195 may adjust a position of the treatment space 212 on the image 204. In other words, as the probe 126 moves along the surface of the skin or is pressed into the patient, the outline 214 on the image 204 may also move.

[0066] Furthermore, the reference module 195 may use data gathered or determined by the diagnostic module 136 (FIG. 1) to determine where to place the treatment space 212 within the ROI. More specifically, the reference module 195 may use information or data regarding the tissue characterization discussed above. For example, the reference module 195 may use the plurality of points within the ROI that were analyzed for adipose or non-adipose characteristics. Using this data, the reference module 195 may automatically locate or determine the position of the treatment space 212 within the ROI.

[0067] In some embodiments, the diagnostic module 136 may be configured to acquire the diagnostic ultrasound signals at different frame rates. A frame rate is the number of frames or images taken per second. More specifically, the diagnostic module 136 may be configured to acquire diagnostic ultrasound signals associated with different imaging spaces within the ROI at different frame rates. For example, signals from the treatment space 212 may be acquired at one frame rate while signals from other spaces outside of the treatment space 212 may be acquired at another frame rate. In one embodiment, the diagnostic module 136 is configured to acquire diagnostic ultrasound signals at a first rate in an imaging space that includes the treatment space 212 and at a slower second rate in an imaging space that excludes the treatment space 212. Alternatively, the first rate may be slower than the second rate.

[0068] FIG. 7 shows the window 202 as the system 120 (FIG. 1) delivers therapy to the treatment space 212. When therapy is applied, ultrasonic therapy signals (e.g., HIFU) from the probe 126 (FIG. 1) are directed toward a treatment location 222 (indicated as dots 222A and 222B in FIG. 7) within the treatment space 212. A treatment location 222 includes a region where a therapy beam 224 formed by ultrasound signals from the transducer elements 124 is focused (i.e., the treatment location 222 includes a focal region of the transducer elements 124) within a body of a patient. The therapy beam 224 is shaped and directed by a selected configuration and operation of the transducer elements 124. As such, the focal region of the therapy beam 224 and, consequently, the treatment location 222 may vary in size and shape within a single therapy session. When the adipose tissue 206 is treated, the therapy beam 224 that is delivered to the treatment location 222 at least partially liquefies (e.g., lyses, causes cavitation and/or thermal damage) the adipose tissue 206 within the focal region. Adipose tissue within a space that immediately surrounds the focal region may also be affected.

[0069] The therapy module 125 (FIG. 1) is configured to move the treatment location 222 throughout the treatment space 212 between multiple points or treatment sites. As used herein, "moving the treatment location between multiple points" includes moving the treatment location 222 along a therapy path 228 between a first point and an end point and also includes moving the treatment location 222 to separate and distinct points within the treatment space 212 that may or may not be adjacent to one another along a path. The therapy path 228 may be formed by separate points where therapy is applied. For example, therapy may first be applied to a first point (indicated as the treatment location 222A). After therapy has been applied to the first point, the focal region may be readjusted onto a second point along the therapy path 228 that is separate and remotely spaced from the first point. Therapy may then be applied to the second point. The process may continue along the therapy path 228 until the therapy session is concluded at an end point (indicated as the treatment location 222B). In other embodiments, the therapy may be continuously applied as the focal region is moved along the therapy path 228 in a sweeping manner. For example, therapy may be continuously applied as the treatment location 222 is moved between the first point and the end point in FIG. 7.

[0070] The therapy path 228 may have various shapes and may be pre-programmed or, alternatively, drawn by the user. As shown in FIG. 7, the therapy module 125 may direct the treatment location 222 in a sweeping manner within the treatment space 212. More specifically, the treatment location 222 may move from a first lateral location 230 proximate one side of the image 204 or outline 214 to a second lateral location that 232 is proximate an opposing side of the image 204 or the outline 214. The treatment location 222 may maintain a predetermined depth within the adipose tissue 206 as the treatment location 222 moves between the first and second lateral locations 230 and 232. In some embodiments, after the treatment location 222 is moved from the first lateral location 230 to the second lateral location 232, the depth of the treatment location 222 may be increased or decreased. As shown in FIG. 7, the treatment location 222 moves back and forth between the first and second lateral locations 230 and 232 and increases a depth of the treatment location 222 after each crossing of the treatment space 212. As such, portions of the adipose tissue 206 may avoid sustaining multiple periods of therapy. Alternatively, the depth of the treatment location 222 may gradually change as the treatment location 222 is moved in a sweeping manner. As an example, the depth of the treatment location 222 within the adipose tissue 206 may move parallel to a boundary 236 (indicated as a dashed line) between the adipose tissue 206 and the non-adipose tissue 208. The boundary 236 may or may not be shown to the viewer.

[0071] However, the therapy path 228 shown in FIG. 7 is just one example of applying therapy to multiple points within the treatment space 212. Many other therapy paths may be taken by the treatment location 222. For example, the therapy module 125 may direct the treatment location 222 in a sweeping manner between two vertical locations while changing a lateral position within the treatment space 212 after the vertical locations have been traversed. Furthermore, the treatment location 222 is not required to move between adjacent points along the therapy path 228, but may be moved to predetermined or random points within the treatment space 212 that are not adjacent to each other. For example, therapy may be applied to one corner of a treatment space 212. Subsequently, the focal region may then be readjusted to another corner and therapy may be applied.

[0072] As described above, the delivery of therapy may be based upon a therapy parameter. A therapy parameter includes any factor or value that may be determined by the system 120 or any input that may be entered by the user that affects the therapy applied to the ROI. For example, a therapy parameter may include a transducer parameter that relates to the configuration or operation of the transducer elements 124 or probe 126. Examples of a transducer parameter include a

focal region depth, a focal region size, an ablation time for each point within the ROI that receives therapy, an energy level of the therapy signals, and a rate of focal region movement within the ROI during the therapy session. The transducer parameters may also include a frequency or intensity of the therapy ultrasound signals, power, peak rarefactional pressure, pulse repetition frequency and length, duty cycle, depth of field, wave form used, speed of beam movement, density of beam, cavitation priming pulse, and general pulse sequence parameters. Also, therapy parameters may include anatomical parameters, such as the location, shape, thickness, and orientation of the adipose tissue **206** and the non-adipose tissues. An anatomical parameter may also include a density of the adipose tissue **206** and the non-adipose tissues. Furthermore, therapy parameters include the type of probe **126** used during the therapy session. The age, gender, weight, ethnicity, genetics, or medical history of the patient may also be therapy parameters. After therapy has been applied to the treatment space **212**, the system **120** or the operator may ad just the therapy parameters before applying therapy to the treatment space **212** again or another treatment space.

[0073] Returning to FIG. **7**, in some embodiments, the display **138** may overlay another graphical representation, such as a marker **240**, onto the image **204** that designates the treatment location or locations **222**. The size and shape of the marker **240** may correspond to a size and shape of the focal region of the probe **126**. As the therapy beam **224** moves the treatment location **222** within the treatment space **212**, the display **138** may continuously update the marker **240** to cover new points within the treatment space **212** as the new points are receiving the therapy. In some embodiments, the marker **240** may only correspond to the point or points within the treatment space that are currently receiving treatment.

[0074] However, in other embodiments, the marker **240** or another graphical representation may also indicate a path within the treatment space **212** that has received therapy. For example, if the treatment location **222** is applied continuously and moved within the treatment space **212**, the path may be indicated by a thick line (e.g., like a paint stroke) along the path. If the therapy is applied at separate and distinct points, a graphical representation, such as the marker **240**, may be left on each point. As such, at an end of the therapy session, the image **204** may have multiple markers **240** overlaid upon the image **204** that indicate where therapy has been applied. In some embodiments, the graphical representations that indicate past therapy may remain on the image **204** indefinitely (i.e., until removed by the user or until the therapy session has concluded). In other embodiments, the graphical representations indicating past therapy may change as time progresses. Such graphical representations may indicate a time since therapy was applied, a fluidity of the tissue, a temperature, tissue stiffness, or some other characteristic of the tissue that may change with time. As an example, when therapy is first applied to a point, the graphical representation may be red to indicate that the point has recently received therapy. As time progresses, the graphical representation may fade or change into another color (e.g., blue) to indicate a predetermined amount of time has passed since therapy was applied to the point.

[0075] FIG. **8** is an image **270** of a C-plane view of the ROI at a predetermined depth. A C-plane view extends along a plane that does not intersect the probe **126** or the transducer elements **124**. The C-plane view may be perpendicular to the view of the image **204** shown in FIGS. **6** and **7**. In some embodiments, the C-plane view of the ROI is used in conjunction with the image **204**. The image **270** may be provided in a window (not shown) on the display **138** concurrently with the window **202** or separately. The image **270** may also be presented on a separate display (not shown). In alternative embodiments, the image **270** is used exclusively during a therapy session (i.e., without the images **102** and **204**).

[0076] The C-plane view in FIG. **8** shows an ultrasound image **270** along the C-plane at a predetermined depth. The following is with respect to one depth with the ROI. However, alter therapy has been applied to one depth of the ROI, the user of the system **120** (FIG. **1**) may change depths and obtain a new C-plane view at the new depth. As shown, the image **270** illustrates sections **272**-**275** that indicate those spaces within the view of the image **270** that have completed treatment or a portion of treatment. Section **276** has not received any treatment. As an example, the image **270** may be of a patient's abdomen region. Section **272** may be proximate to a side of the patient and section **276** may be proximate to a center (e.g., navel) of the patient. During a therapy session, a user may apply therapy to section **272** near the patient's side.

[0077] As similarly described above, the image **270** may indicate to the user those spaces of the abdomen region that have already completed treatment. The system **120** may determine that the adipose tissue has characteristics that are different before, during, and after treatment in sections **272**-**275** through ultrasound signal processing methods. The characteristics may relate to, for example, a tissue stiffness or a temperature of the corresponding section. The characteristics may correlate to different or contrasting colors in the image of FIG. **8** depending upon the measured value of the characteristics. More specifically, the section **275** may have a color that indicates therapy is being currently provided or was recently provided. The section **272** may have a color that indicates therapy was applied therein a period of time ago.

[0078] FIG. **9** illustrates an ultrasound system **300** formed in accordance with one embodiment. The system **300** may include or use similar features, components, processes, and windows as described above with respect to FIGS. **1**-**8**. More specifically, the system **300** includes a portable computer **302** that has a primary display **304** and that is communicatively coupled to a secondary display **306**. The computer **302** may also include software and internal circuitry configured to perform as described above with respect to the system **120** (FIG. **1**). The system **300** includes a probe **326** that is coupled to the computer **302** and has a probe position device **370**. The system also includes a reference position device **372** that may be located near the patient or may be attached to the patient. The position devices **370** and **372** may have transmitters and/or receivers that communicate with each other and/or with the computer **302**. For example, the position devices **370** and **372** may communicate with a position tracking module (not shown), such as the position tracking module **148** shown in FIG. **1**. The position tracking module may receive signals from the position devices **370** and/or **372**. In one particular embodiment, the position device **372** has a pair of coils that creates an electromagnetic field. The position tracking module receives data (e.g., positional information) from the position devices **370** and **372** regarding a location of the probe **326**. As the probe **326** applies therapy to the patient and is moved along the patient, the display **304** and/or **306** may show the movement of the probe **326** with respect to the patient.

[0079] Also shown in FIG. **9**, the system **300** may be configured to register where therapy will be applied during the therapy session. The system **300** may include an electronic pen **374** and fiducial element **376** attached to the body of the patient. The fiducial element **376** is attached near the sternum of the patient in FIG. **9**, but may be attached to other spaces. A user desiring to outline or delineate where therapy will be applied may use the electronic pen **374** to draw on the body of the patient. First, the electronic pen **374** may register with the fiducial element **376** so that the location of the electronic pen **374** with respect to the body of the patient is known. After registering, the electronic pen **374** moves along the surface of the body and communicates with the computer **302** a current position of the electronic pen **374**. Also, the electronic pen **374** may mark the patient's body (e.g., through ink, resin, or another substance) where therapy will be applied. The computer **302** uses the data received by the electronic pen **374** and the position device **372** to indicate on the display **306** where therapy is to be applied. As shown, the display **306** may show a graphical representation **382** of a side-view of the body and a graphical representation **384** of an anterior view of the body. The computer **302** uses the information from the electronic pen **374** to outline a region **386** of the body to be treated. The region **386** may be colored green prior to treatment. In an alternative embodiment, a single element or device may perform the functions of the fiducial element **376** and the reference position device **372**.

[0080] As one example, the graphical representations **382** and **384** may be digital photographs of the patient's body. When therapy is applied to the body, the computer **302** tracks the position of the probe **326**. As therapy is applied, the display **306** indicates an overall progress of the therapy session. For example, the display **306** may show the user the region of the body that is currently receiving therapy, the regions of the body that have already received therapy, and the regions of the body that have yet to receive therapy. For example, the regions that have received therapy may be colored red and the regions that have not received therapy may be colored green. Also, a graphical representation **380** of the probe **326** may be shown on the display **306** to indicate a current position of the probe **326** with respect to the body.

[0081] FIG. **10** illustrates transducers **410**, **420**, and **430** that may be used with a probe (not shown) in accordance with various embodiments. The transducers **410**, **420**, and **430** may include reconfigurable arrays. In some embodiments, the diagnostic module **136** (FIG. **1**) and the therapy module **125** (FIG. **1**) control the probe **126** (FIG. **1**) to deliver low energy imaging pulses and high energy therapy pulses, respectively. The transducer **410** has an imaging array **412** and a separate therapy array **414** that surrounds the imaging array **412**. The imaging array **412** and the therapy array **414** may be in a fixed relationship with respect to each other. The imaging pulses and the therapy pulses may be delivered separately or in an overlapping or interleaved manner. In some embodiments, low energy imaging pulses may also by transmitted by the therapy array **414**. The reflections of these low energy imaging pulses may be received by the imaging array **412** to form an image of the focal region of the therapy array **414**. Embodiments of such a dual therapy and imaging system are described in more detail in U.S. Pat. No. 5.769,790, which is incorporated by reference in the entirety.

[0082] When imaging or applying therapy to a patient, the pressure applied by the transducer to the patient's body may alter the thickness or other characteristics of the ROI, such as tissue stiffness. By combining the imaging and therapy arrays into one transducer, therapy may be applied immediately after the transducer images the ROI. As such, an accurate representation or identification of the adipose tissue may be provided immediately before the therapy is applied.

[0083] The transducer **420** includes an array **422** where the entire array may be used for both imaging and therapy. However, the transducer **430** has an array **432** of transducer elements where a therapy portion **434** of the array **432** may be activated to provide therapy. As such, the therapy module **125** may drive a subset (e.g., the therapy portion **434**) of the transducer elements of the array **432** based on the user inputs designating the treatment space. Thus, the diagnostic module **136** and the therapy module **125** may deliver low energy imaging pulses and high energy therapy pulses in an interspersed manner to an at least partially overlapping array of transducer elements.

[0084] FIG. **11** illustrates an ultrasound system **450** in accordance with one embodiment that includes a device **452** for removing tissue or liquid from a patient during a therapy session. The device **452** may include a hollow tube that is inserted into the body of the patient (i.e., beneath the skin of the patient proximate to where therapy is being received). The device **452** may also include a suction device (not shown) for removing the tissue or liquid from within the ROI through the tube. The probe **454** is communicatively coupled to a computer **460** having a display **462**. The display **462** may show the tube or provide a graphical representation **464** of the tube during a therapy session. The display **462** may show images of the ROI as the tissue is removed from the patient. In one embodiment, an image of the ROI before treatment may be shown side-by-side with an image of the ROI as treatment is being applied. As such, the operator of the system **450** may visually identify an amount of tissue that has been removed from the patient during the therapy session. In addition, the system **450** may incorporate other imaging, therapy, user interface, tracking, and registering features as described above with respect to system **120** and **300**.

[0085] FIG. **12** is a flowchart illustrating a method **500** for delivering therapy to at least one ROI in a patient. The method **500** may be performed by a user or an operator of an imaging and therapy system. For example, the system used may be the systems **120**, **300**, or **450** (discussed above) or other systems described below. The therapy session may begin at **502** when the operator positions a probe at a predetermined location on the body of the patient to view an ROI. The ROI may be one of many that will be viewed during the therapy session. Ultrasound imaging signals of the ROI are obtained at **504**. The signals may be processed into data via different ultrasound sub-modules, such as the modules **152-166** described above with reference to FIG. **2**. In one embodiment, the signals are processed into data through at least one of B-mode and elastography processing.

[0086] An image of the ROI is generated and displayed to the operator and, optionally, patient at **506**. The image may be, for example, a B-mode image in gray-scale and/or color. The image may also be a combination of images that are superimposed or arranged side-by-side with each other on a display. For example, the image may be formed from data obtained through B-mode processing and data obtained through elastography. Optionally, the system may automatically differentiate adipose tissue from other tissues at **508** and indicate to the operator the different layers of tissue within the image. The system may indicate the differentiation of tissues

within the image to the user through lines, color, brightness, or other visual indications. Also, the system may automatically designate a treatment space at **510** by overlaying a graphical presentation (e.g., line) that indicates a boundary between the layers of tissue.

[0087] However, the system may also accept user inputs at **512** from the operator after a simple image (i.e., an image without graphical representations or other indications) of the ROI is displayed or after an image is displayed that automatically differentiates the tissues and indicates the different tissues to the operator. The user inputs may designate a treatment space. The system may display at **514** a graphical representation (e.g., an outline) of the designated treatment space. The system may then automatically set therapy parameters at **516** and/or the system may accept user inputs for therapy parameters at **518**. Optionally, at **520**, the operator may designate a therapy path within the treatment space. Therapy is then provided to a treatment location at **522** within the designated treatment space. The system may optionally, at **524**, display a graphical representation (e.g., a marker) of the treatment location with the image.

[0088] After or while providing treatment to the treatment space, the system may obtain ultrasound signals of the treatment space at **526**. At **528**, the system determines whether treatment is complete. If treatment for the corresponding treatment space is not complete, the system may automatically adjust the therapy parameters at **530** and/or automatically move the treatment location at **532** to another point within the treatment space. The treatment location may move while providing treatment or after treatment has ended for a particular point. Furthermore, the therapy parameters may be adjusted while the treatment location is moving. Optionally, the system may display a graphical representation that indicates the path taken by the treatment location within the treatment space at **534**. The system provides therapy to a new point and continues this process until the therapy for the corresponding treatment space is complete.

[0089] After therapy for the treatment space is completed, the system may determine (or ask the operator) at **536** whether therapy for the patient is complete. If therapy for the patient is complete, then the therapy session has ended. However, if the therapy session is not complete, then the system or the operator may move the probe at **538** to another location on the patient. In some embodiments, the system may also track at **540** a location of the probe as the probe moves to another location. The system may also display to the operator those regions that have already received treatment and those regions that have not received treatment.

[0090] Although the flowchart illustrates sequential steps in the method **500**, embodiments herein include methods that perform fewer steps and also methods that perform the steps in different orders or may perform steps simultaneously. For example, the system may display an image of the ROI after the system has automatically differentiated the adipose tissue from other tissues. The system may also provide therapy to a treatment location within the ROI and simultaneously obtain imaging signals and display an image of the ROI during the therapy.

[0091] FIG. **13** shows another example of an ultrasound system and, in particular, a hand carried or pocket-sized ultrasound imaging system **676**. In the system **676**, a display **642** and a user interface **640** form a single unit. By way of example, the pocket-sized ultrasound imaging system **676** may be a pocket-sized or hand-sized ultrasound system approximately 2 inches wide, approximately 4 inches in length, and approximately 0.5 inches in depth and weighs less than 3 ounces. The display **642** may be, for example, a 320× 320 pixel color LCD display (on which a medical image **690** may be displayed in combination with a graphical representation(s) as described above). A typewriter-like keyboard **680** of buttons **682** may optionally be included in the user interface **640**. It should be noted that the various embodiments may be implemented in connection with a pocket-sized ultrasound system **676** having different dimensions, weights, and power consumption.

[0092] Multi-function controls **684** may each be assigned functions in accordance with the mode of system operation. Therefore, each of the multifunction controls **684** may be configured to provide a plurality of different actions. Label display spaces **686** associated with the multi-function controls **684** may be included as necessary on the display **642**. The system **676** may also have additional keys and/or controls **688** for special purpose functions, which may include, but are not limited to "freeze," "depth control," "again control," "color-mode," "print," and "store."

[0093] As another example shown in FIG. **14**, a console-based ultrasound system **745** may be provided on a movable base **747** that may be configured to display the region of interest during a therapy session. The system **745** may also be referred to as a cart-based system. A display **742** and user interface **740** are provided and it should be understood that the display **742** may be separate or separable from the user interface **740**. The user interface **740** may optionally be a touchscreen, allowing the operator to select options by touching displayed graphics, icons, and the like.

[0094] The user interface **740** also includes control buttons **752** that may be used to control the portable ultrasound imaging system **745** as desired or needed, and/or as typically provided. The user interface **740** provides multiple interface options that the user may physically manipulate to interact with ultrasound data and other data that may be displayed, as well as to enter user inputs and set and change imaging or therapy parameters. The interface options may be used for specific inputs, programmable inputs, contextual inputs, and the like. For example, a keyboard **754** and track ball **756** may be provided. The system **745** has at least one probe port **760** for accepting probes.

[0095] FIG. **15** is a block diagram of exemplary manners in which various embodiments described herein may be stored, distributed and installed on computer readable medium. In FIG. **15**, the "application" represents one or more of the methods and process operations discussed above.

[0096] As shown in FIG. **15**, the application is initially generated and stored as source code **1001** on a source computer readable medium **1002**. The source code **1001** is then conveyed over path **1004** and processed by a compiler **1006** to produce object code **1010**. The object code **1010** is conveyed over path **1008** and saved as one or more application masters on a master computer readable medium **1011**. The object code **1010** is then copied numerous times, as denoted by path **1012**, to produce production application copies **1013** that are saved on separate production computer readable medium **1014**. The production computer readable medium **1014** is then conveyed, as denoted by path **1016**, to various systems, devices, terminals and the like. In the example of FIG. **15**, a user terminal **1020**, a device **1021** and a system **1022** are shown as examples of hardware components, on which the

production computer readable medium **1014** are installed as applications (as denoted by **1030-1032**).

[0097] The source code may be written as scripts, or in any high-level or low-level language. Examples of the source, master, and production computer readable medium **1002**, **1011** and **1014** include, but are not limited to, CDROM, RAM, ROM, Flash memory, RAID drives, memory on a computer system and the like. Examples of the paths **1004**, **1008**, **1012**, and **1016** include, but are not limited to, network paths, the internet, Bluetooth, GSM, infrared wireless LANs, HIPERLAN, 3G, satellite, and the like. The paths **1004**, **1008**, **1012**, and **1016** may also represent public or private carrier services that transport one or more physical copies of the source, master, or production computer readable medium **1002**, **1011**, or **1014** between two geographic locations. The paths **1004**, **1008**, **1012**, and **1016** may represent threads carried out by one or more processors in parallel. For example, one computer may hold the source code **1001**, compiler **1006** and object code **1010**. Multiple computers may operate in parallel to produce the production application copies **1013**. The paths **1004**, **1008**, **1012**, and **1016** may be intra-state, inter-state, intra-country, inter-country, intra-continental, inter-continental and the like.

[0098] As used throughout the specification and claims, the phrases "computer readable medium" and "instructions configured to" shall refer to any one or all of i) the source computer readable medium **1002** and source code **1001**, ii) the master computer readable medium and object code **1010**, iii) the production computer readable medium **1014** and production application copies **1013** and/or iv) the applications **1030-1032** saved in memory in the terminal **1020**, device **1021** and system **1022**.

[0099] The various embodiments and/or components, for example, the monitor or display, or components and controllers therein, also may be implemented as part of one or more computers or processors. The computer or processor may include a computing device, an input device, a display unit, and an interface, for example, for accessing the Internet. The computer or processor may include a microprocessor. The microprocessor may be connected to a communication bus. The computer or processor may also include a memory. The memory may include Random Access Memory (RAM) and Read Only Memory (ROM). The computer or processor further may include a storage device, which may be a hard disk drive or a removable storage drive such as a floppy disk drive, optical disk drive, and the like. The storage device may also be other similar means for loading computer programs or other instructions into the computer or processor.

[0100] As used herein, the term "computer" may include any processor-based or microprocessor-based system including systems using microcontrollers, reduced instruction set computers (RISC), application specific integrated circuits (ASICs), logic circuits, and any other circuit or processor capable of executing the functions described herein. The above examples are exemplary only, and are thus not intended to limit in any way the definition and/or meaning of the term "computer".

[0101] The computer or processor executes a set of instructions that are stored in one or more storage elements, in order to process input data. The storage elements may also store data or other information as desired or needed. The storage element may be in the form of an information source or a physical memory element within a processing machine.

[0102] The set of instructions may include various commands that instruct the computer or processor as a processing machine to perform specific operations such as the methods and processes described herein. The set of instructions may be in the form of a software program. The software may be in various forms such as system software or application software. Further, the software may be in the form of a collection of separate programs, a program module within a larger program or a portion of a program module. The software also may include modular programming in the form of object-oriented programming. The processing of input data by the processing machine may be in response to user commands, or in response to results of previous processing, or in response to a request made by another processing machine.

[0103] As used herein, the terms "software" and "firmware" are interchangeable, and include any computer program stored in memory for execution by a computer, including RAM memory, ROM memory, EPROM memory, EEPROM memory, and non-volatile RAM (NVRAM) memory. The above memory types are exemplary only, and are thus not limiting as to the types of memory usable for storage of a computer program.

[0104] Although the embodiments described above are illustrated as treating adipose tissue, alternative embodiments may be used to treat other tissues within the body. For example, the above described embodiments may be used to image and treat a tumor within a region of interest. As described above with respect to adipose tissue, embodiments may be used to automatically identify the tumor and/or to allow user inputs to identify treatment spaces within a region of interest and to set therapy parameters for the treatment. Furthermore, embodiments described herein may be used for palliative treatments for cancer, thermal treatment of muscles, or ultrasonically activating drugs, proteins, stem cells, vaccines, DNA, and gene delivery.

[0105] It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described embodiments (and/or aspects thereof) may be used in combination with each other. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from its scope. Dimensions, types of materials, orientations of the various components, and the number and positions of the various components described herein are intended to define parameters of certain embodiments, and are by no means limiting and are merely exemplary embodiments. Many other embodiments and modifications within the spirit and scope of the claims will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects. Further, the limitations of the following claims are not written in means—plus-function format and are not intended to be interpreted based on 35 U.S.C. §112, sixth paragraph, unless and until such claim limitations expressly use the phrase "means for" followed by a statement of function void of further structure.

[0106] This written description uses examples to disclose the invention, including the best mode, and also to enable any person skilled in the art to practice the invention, including making and using any devices or systems and performing any incorporated methods. The patentable scope of the invention is defined by the claims, and may include other examples that occur to those skilled in the art. Such other examples are intended to be within the scope of the claims if they have structural elements that do not differ from the literal language of the claims, or if they include equivalent structural elements with insubstantial differences from the literal languages of the claims.

What is claimed is:

1. An ultrasound imaging and therapy system, comprising:
an ultrasound probe;
an ultrasound diagnostic module to control the probe to obtain diagnostic ultrasound signals from a region of interest (ROI), the ROI including adipose tissue and non-adipose tissue, the diagnostic module analyzing the diagnostic ultrasound signals and automatically differentiating adipose tissue from non-adipose tissue; and
an ultrasound therapy module to control the probe to deliver, during a therapy session, a therapy at a treatment location based on a therapy parameter to the adipose tissue differentiated by the ultrasound diagnostic module.

2. The system in accordance with claim **1** wherein the diagnostic module differentiates the adipose tissue by identifying a barrier between the adipose and non-adipose tissue.

3. The system in accordance with claim **1** wherein the diagnostic module differentiates the adipose tissue by directly measuring a plurality of points within the ROI for an adipose characteristic.

4. The system in accordance with claim **3** wherein the adipose characteristic constitutes one of a measure of tissue stiffness, longitudinal or shear wave velocity, density, cavitation inducibility, thermal conductivity, and specific heat.

5. The system in accordance with claim **1** wherein the diagnostic module differentiates the adipose tissue based on one of elastography and B-mode analysis of the diagnostic ultrasound signals.

6. The system in accordance with claim **1** wherein the diagnostic module obtains a first set of diagnostic ultrasound signals during an initial scan before the therapy module begins to deliver the therapy to the ROI and obtains a second set of diagnostic ultrasound signals during a supplemental scan during the therapy session, the therapy module adjusting the therapy parameter based on the second set of diagnostic ultrasound signals.

7. The system in accordance with claim **1** wherein the diagnostic module automatically sets the therapy parameter based on the diagnostic ultrasound signal obtained by the diagnostic module.

8. The system in accordance with claim **7** wherein the therapy parameter represents at least one of a focal region depth, a focal region size, an ablation time for each point, an energy level of the therapy, and a rate of focal region movement within the ROI during the therapy session.

9. The system in accordance with claim **1** wherein the diagnostic module identifies a thickness of a layer of the adipose tissue and the therapy module adjusts the therapy parameter based on the thickness.

10. The system in accordance with claim **1** wherein the diagnostic module analyzes the diagnostic ultrasound signals to confirm a location of the adipose tissue prior to delivering the therapy.

11. The system in accordance with claim **1** wherein the diagnostic module analyzes the diagnostic ultrasound signals to confirm the treatment of the treatment location.

12. A method for delivering therapy to a region of interest (ROI) in a patient, the method comprising:
obtaining diagnostic ultrasound signals from a region of interest (ROI), the ROI including adipose tissue and non-adipose tissue:
analyzing the diagnostic ultrasound signals and automatically differentiating adipose tissue from non-adipose tissue; and
delivering therapy, during a therapy session, at a treatment location based on a therapy parameter to the adipose tissue differentiated by the ultrasound diagnostic module.

13. The method in accordance with claim **12** wherein the automatically differentiating includes identifying a barrier between the adipose and non-adipose tissue.

14. The method in accordance with claim **12** wherein the automatically differentiating includes directly measuring a plurality of points within the ROI for an adipose characteristic.

15. The method in accordance with claim **14** wherein the adipose characteristic constitutes one of, a measure of tissue stiffness, longitudinal or shear wave velocity, density, cavitation inducibility, thermal conductivity and specific heat

16. The method in accordance with claim **12** wherein the automatically differentiating includes using one of elastography and B-mode analysis of the diagnostic ultrasound signals to automatically differentiate the adipose tissue from the non-adipose tissue.

17. The method in accordance with claim **12** wherein the obtaining diagnostic ultrasound signals from the ROI includes obtaining a first set of diagnostic ultrasound signals during an initial scan before delivering the therapy to the ROI and obtaining a second set of diagnostic ultrasound signals during a supplemental scan during the therapy session, the method further comprising adjusting the therapy parameter based on the second set of diagnostic ultrasound signals.

18. The method in accordance with claim **12** further comprising automatically setting the therapy parameter based on the diagnostic ultrasound signals obtained.

19. The method in accordance with claim **18** wherein the therapy parameter represents at least one of a focal region depth, a focal region size, an ablation time for each point, an energy level of the therapy, and a rate of focal region movement within the ROI during the therapy session.

20. The method in accordance with claim **12** further comprising identifying a thickness of a layer of the adipose tissue and adjusting the therapy parameter based on the thickness.

21. The method in accordance with claim **12** further comprising analyzing the diagnostic ultrasound signals to confirm a location of the adipose tissue prior to delivering the therapy.

22. The method in accordance with claim **12** further comprising analyzing the diagnostic ultrasound signals to confirm the treatment of the treatment location.

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专利名称(译)	超声系统和自动识别和治疗脂肪组织的方法		
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摘要(译)

一种超声成像和治疗系统，包括超声探头和超声诊断模块，以控制探头以从感兴趣区域（ROI）获得诊断超声信号。 ROI包括脂肪组织和非脂肪组织。诊断模块分析诊断超声信号并自动区分脂肪组织和非脂肪组织。该系统还包括超声治疗模块，用于控制探头在治疗期间基于对超声诊断模块区分的脂肪组织的治疗参数在治疗位置输送治疗。还提供了一种用于将治疗递送到患者的感兴趣区域（ROI）的方法。