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(54) **ULTRASOUND SYSTEM AND METHOD TO DETERMINE MECHANICAL PROPERTIES OF A TARGET REGION**

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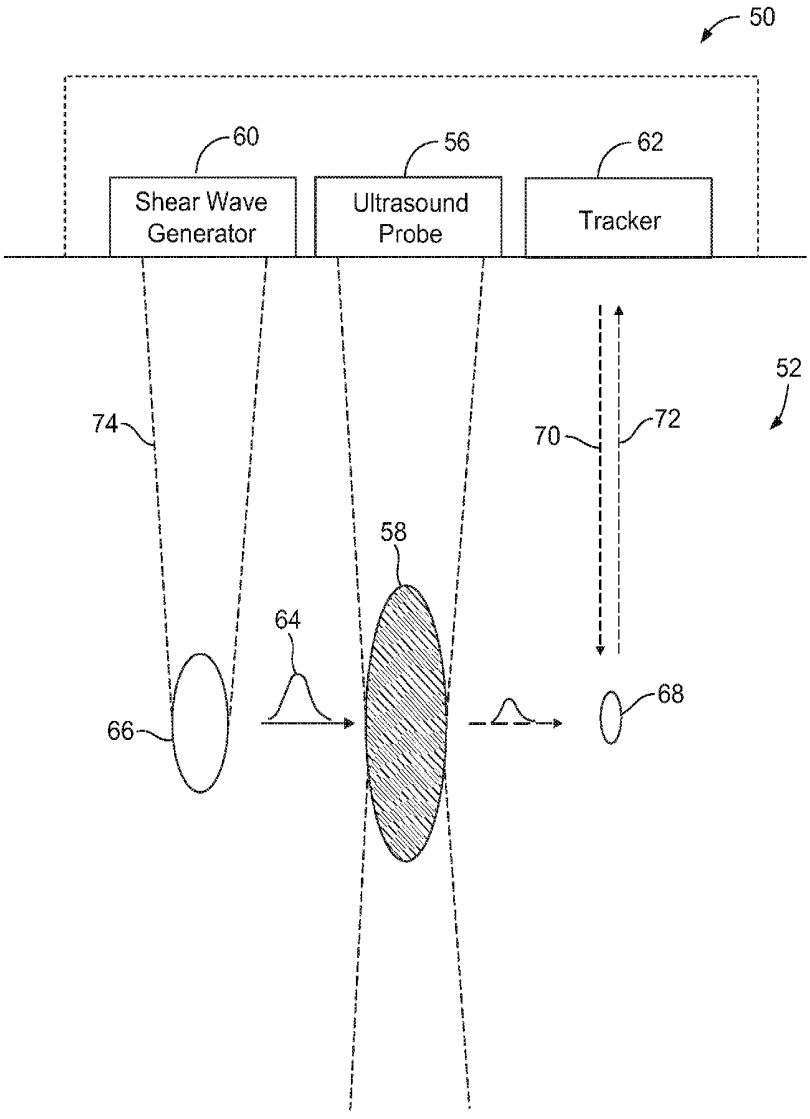
(57) **ABSTRACT**

An ultrasound system that is configured to determine whether adipose tissue of a patient received therapy at a treatment location. The system includes an ultrasound probe and a shear-wave-generating module to control the probe to provide a shear-wave beam that is configured to generate a shear wave at a first site within the patient. The shear wave is configured to propagate through the treatment location toward a second site within the patient. The system also includes a tracking module to control the probe to track the shear wave at the second site within the patient to determine if the treatment location received the therapy.



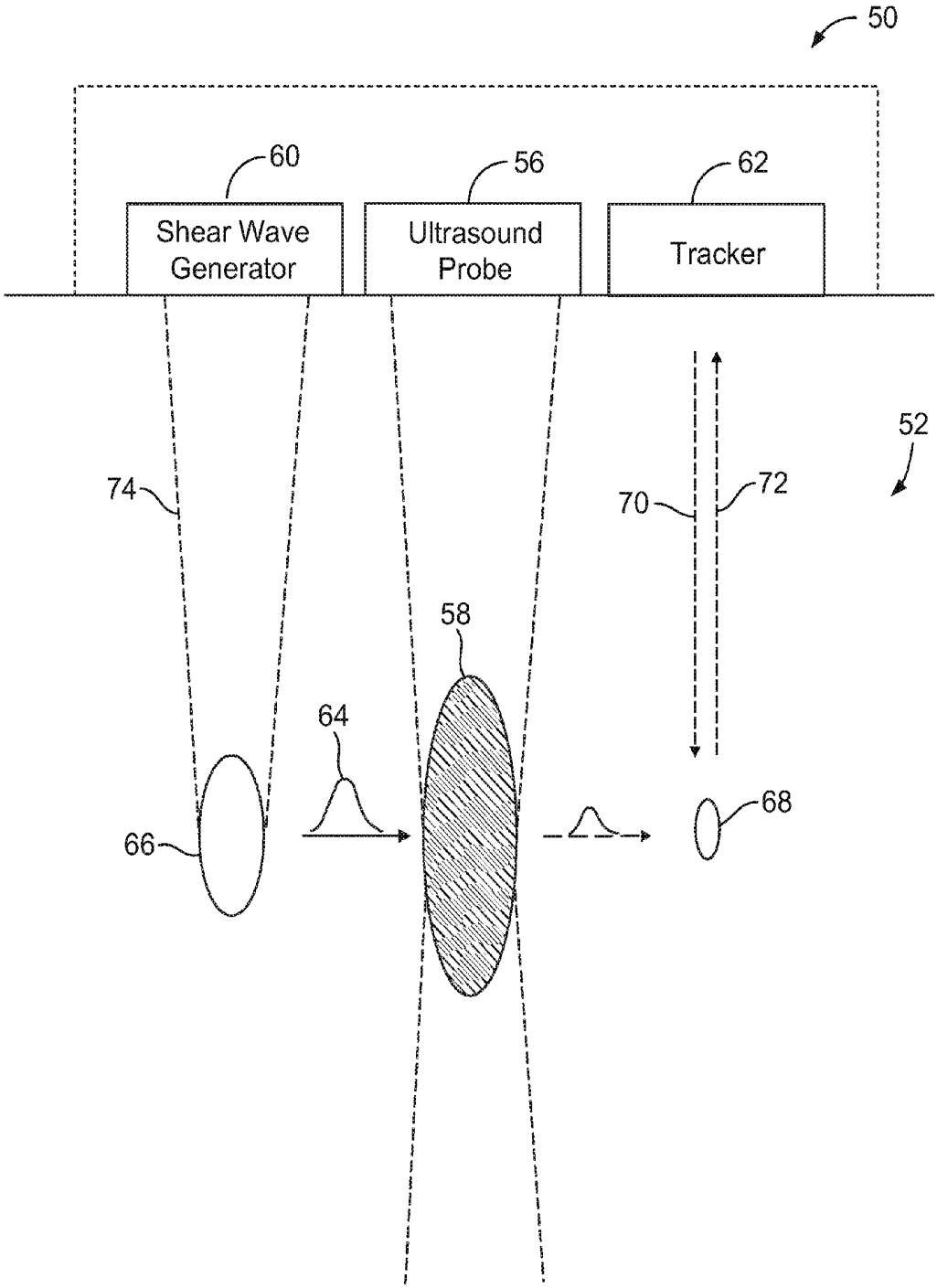

50
60
56
62
Shear Wave Generator
Ultrasound Probe
Tracker
52
74
70
72
58
64
66
68

FIG. 1

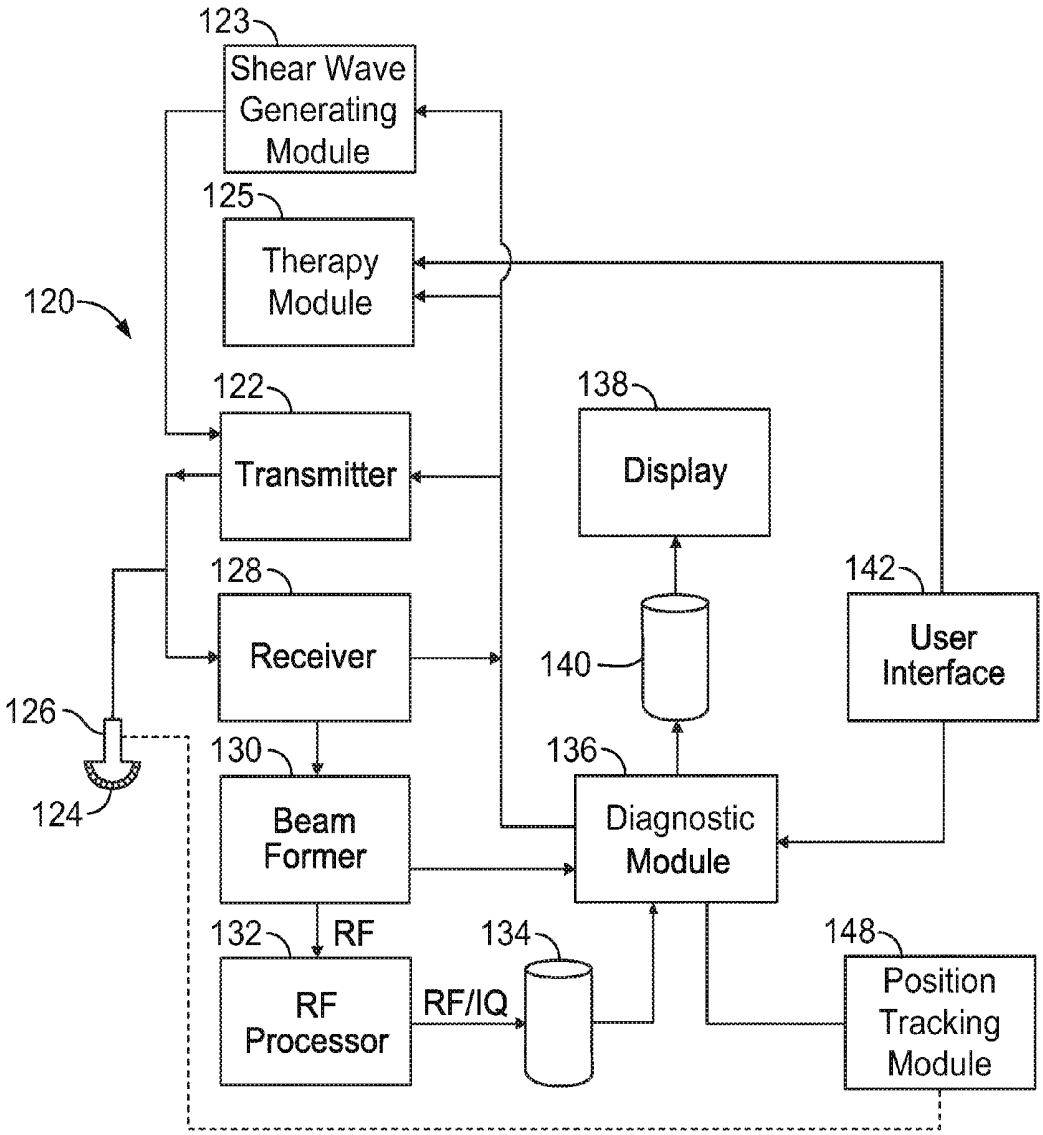

123
Shear Wave Generating Module
125
Therapy Module
120
122
Transmitter
138
Display
128
Receiver
140
142
User Interface
126
124
130
Beam Former
136
Diagnostic Module
132
RF
RF Processor
RF/IQ
134
148
Position Tracking Module

FIG. 2

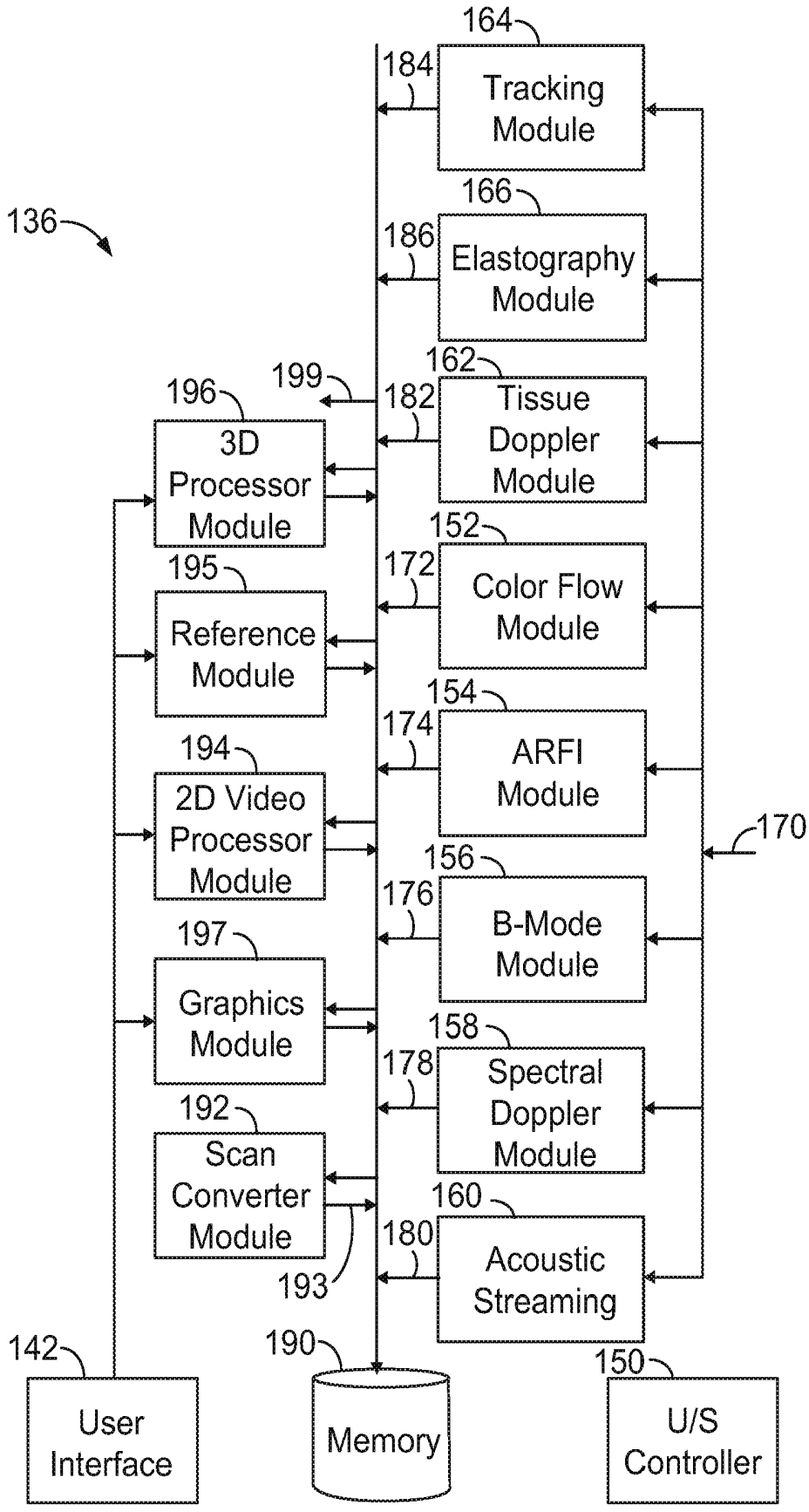

136
164
184
Tracking Module
166
186
Elastography Module
162
199
182
Tissue Doppler Module
196
3D Processor Module
152
172
Color Flow Module
195
Reference Module
154
174
ARFI Module
194
2D Video Processor Module
170
156
176
B-Mode Module
197
Graphics Module
158
178
Spectral Doppler Module
192
Scan Converter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

FIG. 3

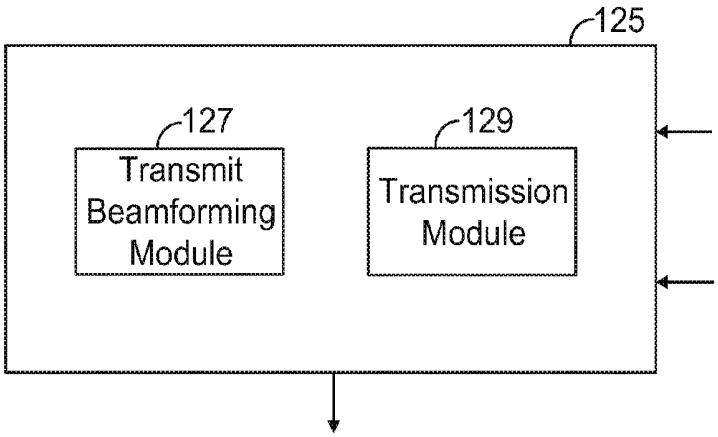

125
127
Transmit Beamforming Module
129
Transmission Module

FIG. 4

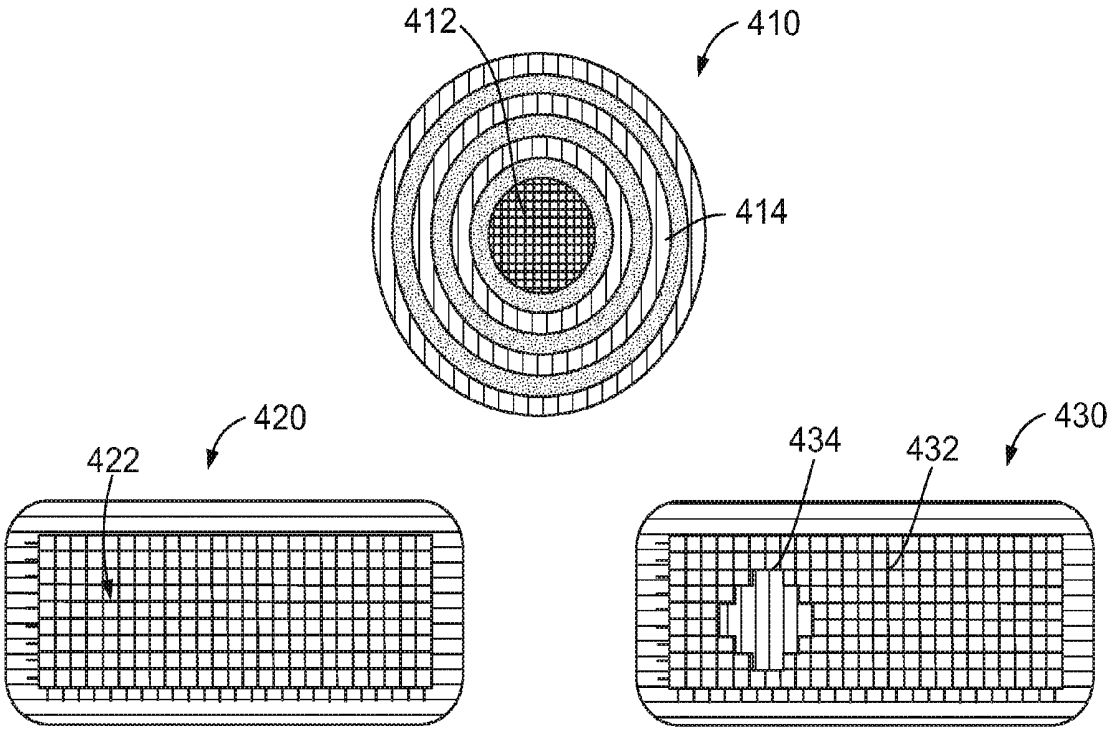

412
410
414
420
422
430
434
432

FIG. 5

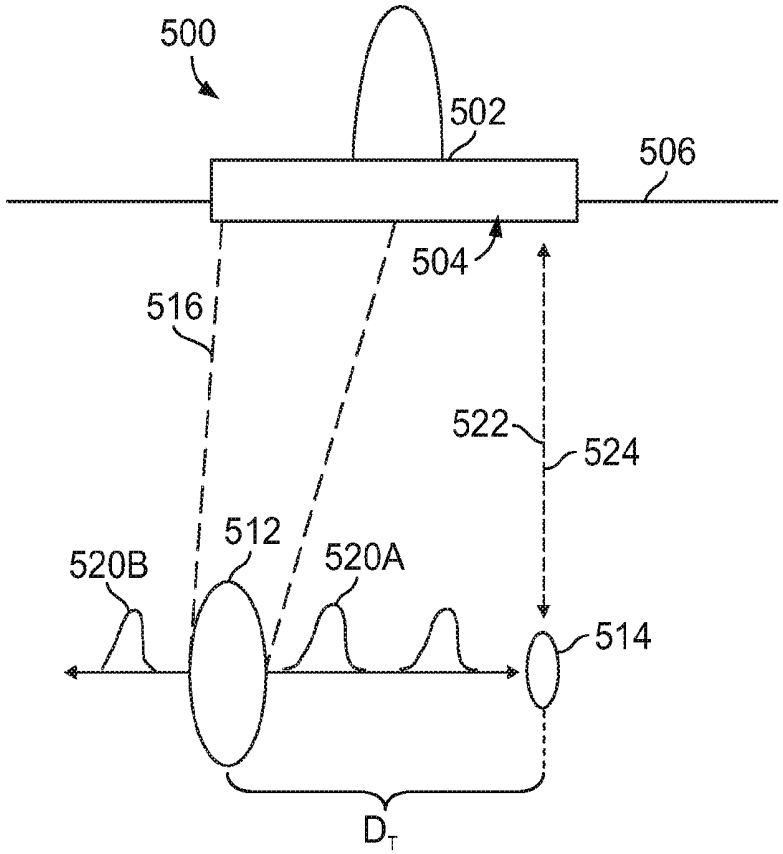

500
502
506
504
516
522
524
512
520B
520A
514
D_T

FIG. 6

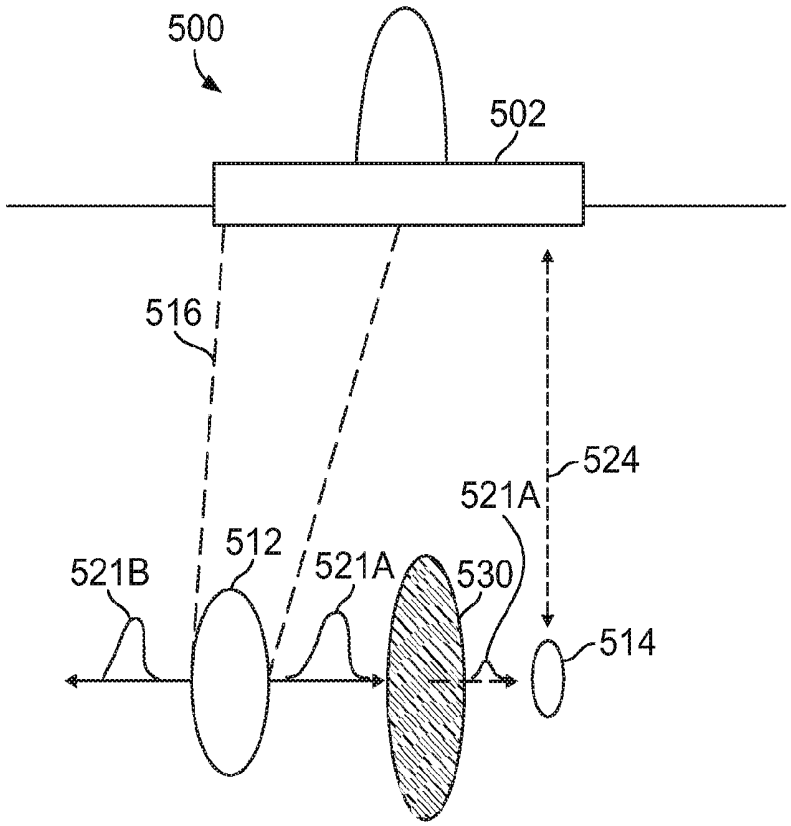

500
502
516
524
521A
512
521B
521A
530
514

FIG. 7

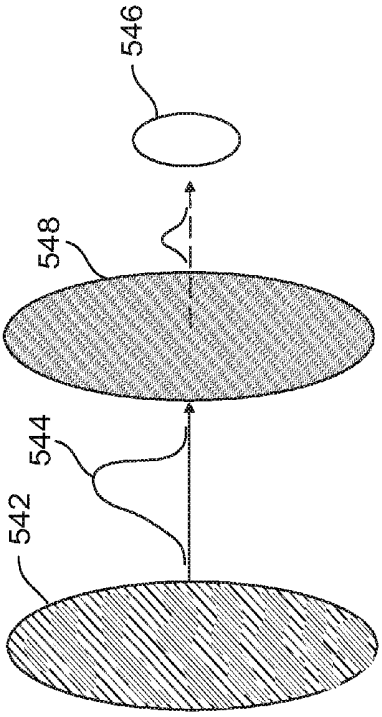


FIG. 8

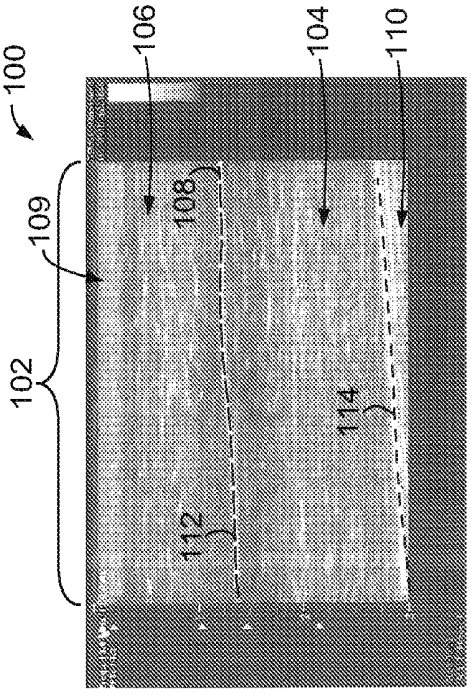


FIG. 10

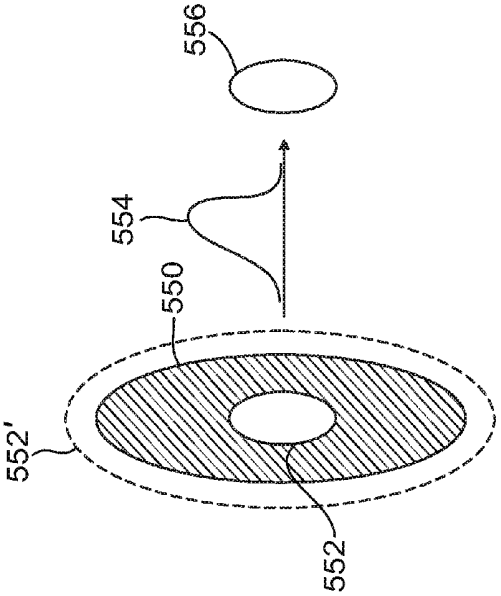


FIG. 9

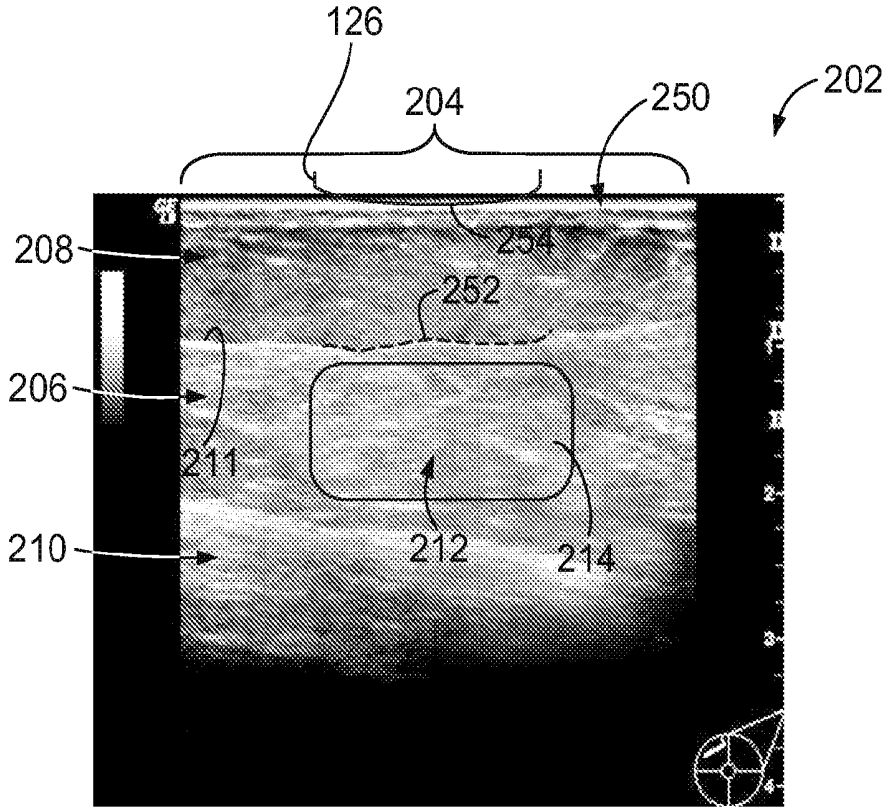

126
204
250
202
208
254
252
206
211
212
214
210

FIG. 11

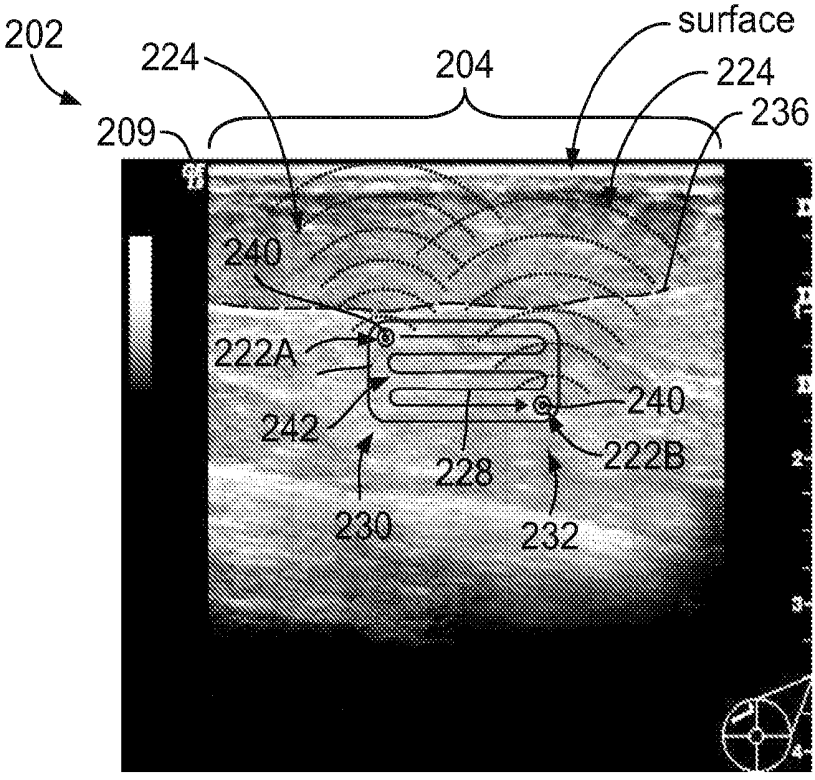

202
224
204
surface
224
236
209
240
222A
240
242
222B
228
230
232

FIG. 12

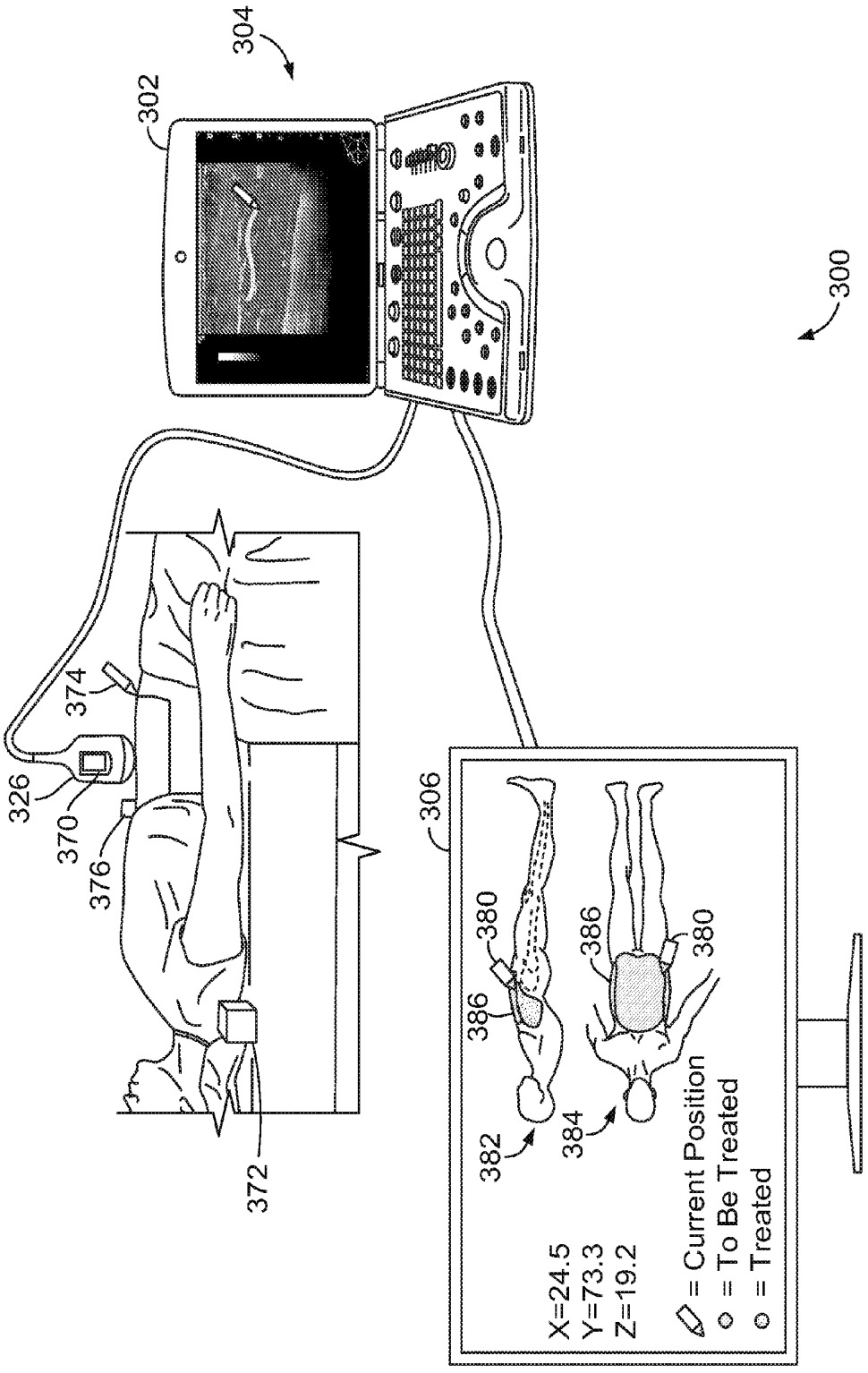

304
302
300
374
326
370
376
372
306
380
386
382
384
X=24.5
Y=73.3
Z=19.2
= Current Position
= To Be Treated
= Treated

FIG. 13

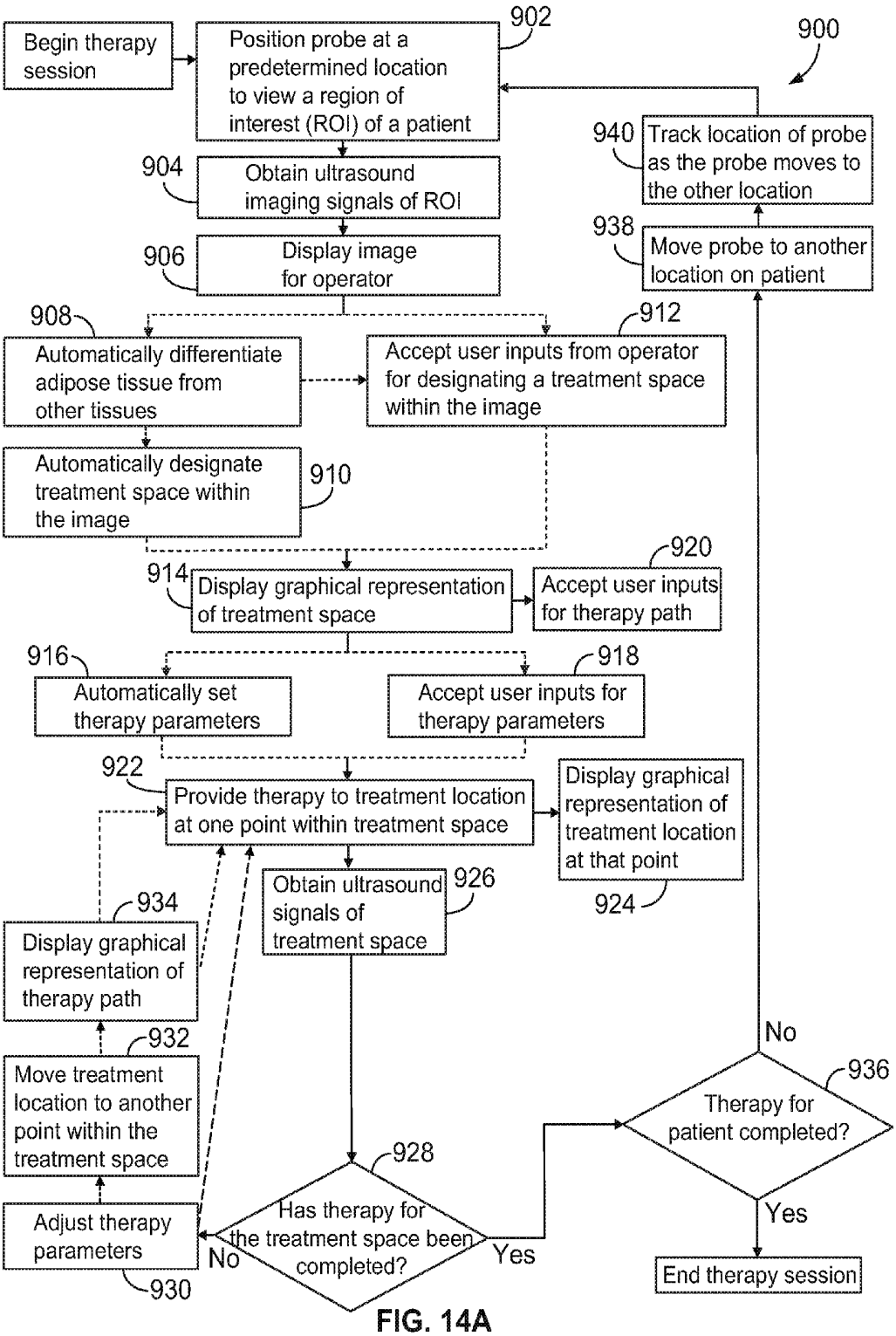

Begin therapy session
Position probe at a predetermined location to view a region of interest (ROI) of a patient
902
900
940
Track location of probe as the probe moves to the other location
904
Obtain ultrasound imaging signals of ROI
938
Move probe to another location on patient
906
Display image for operator
908
912
Automatically differentiate adipose tissue from other tissues
Accept user inputs from operator for designating a treatment space within the image
Automatically designate treatment space within the image
910
914
Display graphical representation of treatment space
920
Accept user inputs for therapy path
916
Automatically set therapy parameters
918
Accept user inputs for therapy parameters
922
Provide therapy to treatment location at one point within treatment space
Display graphical representation of treatment location at that point
924
926
Obtain ultrasound signals of treatment space
934
Display graphical representation of therapy path
932
Move treatment location to another point within the treatment space
928
Has therapy for the treatment space been completed?
No
Yes
Adjust therapy parameters
930
No
936
Therapy for patient completed?
Yes
End therapy session

FIG. 14A

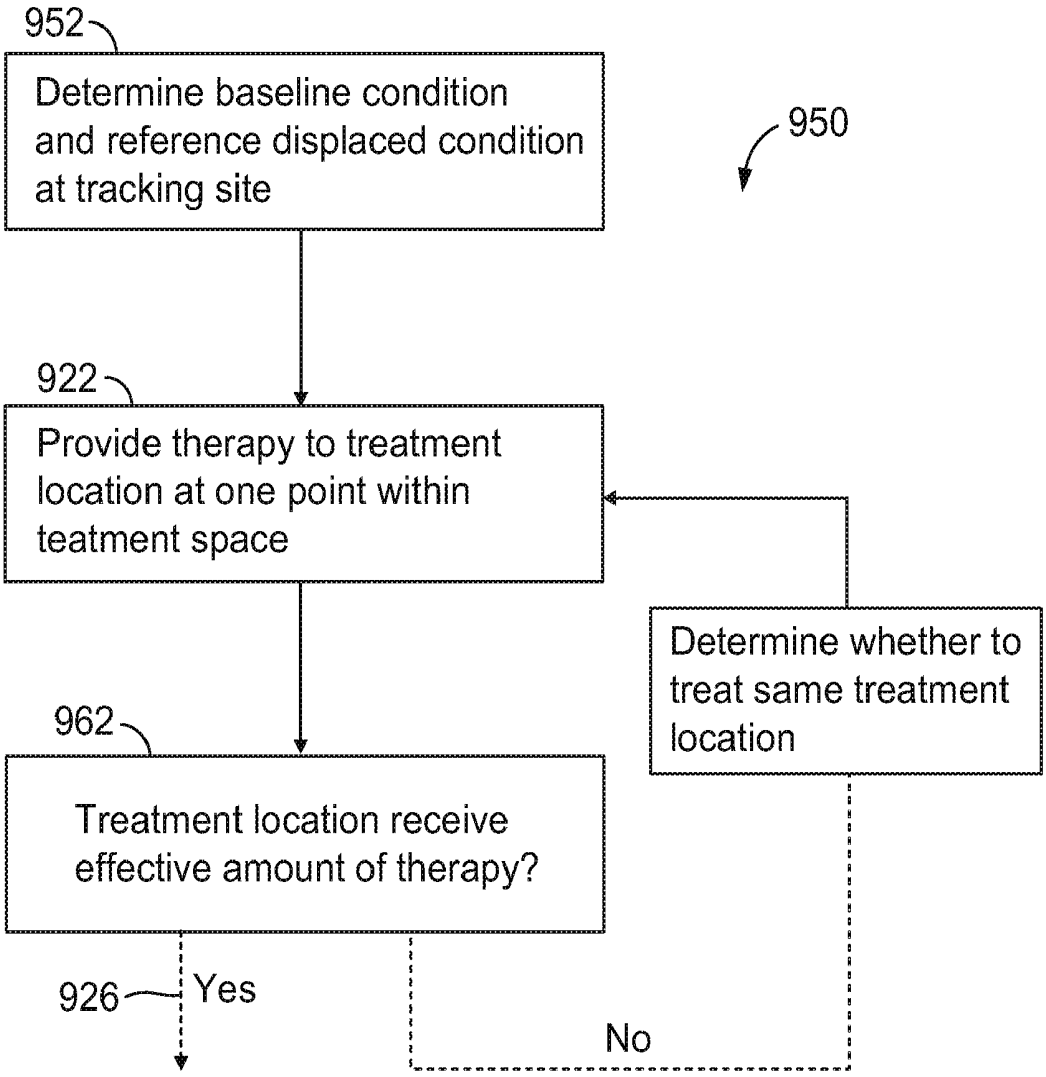

952
Determine baseline condition and reference displaced condition at tracking site
950
922
Provide therapy to treatment location at one point within teatment space
Determine whether to treat same treatment location
962
Treatment location receive effective amount of therapy?
926
Yes
No

FIG. 14B

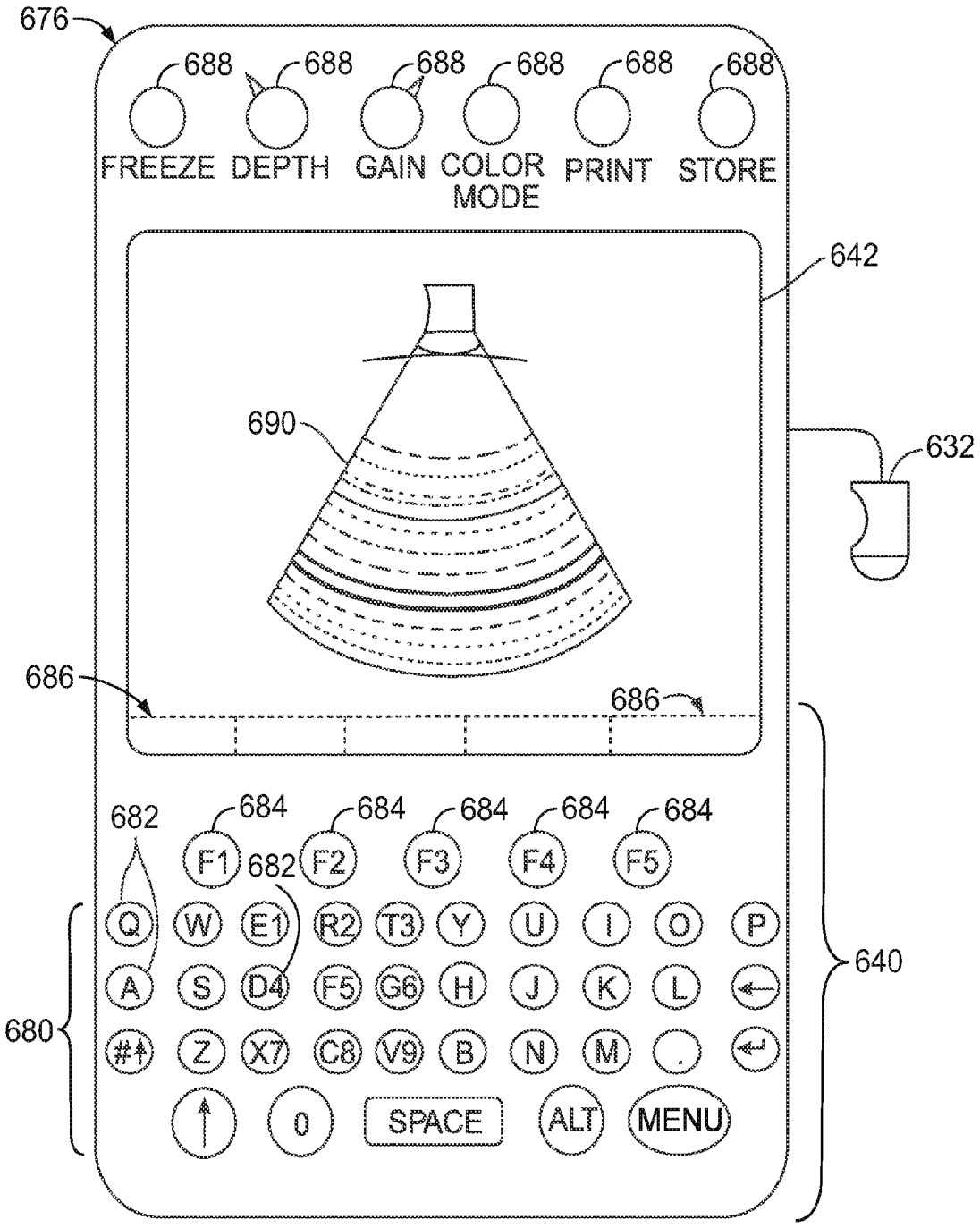

676
688
688
688
688
688
688
FREEZE
DEPTH
GAIN
COLOR MODE
PRINT
STORE
642
690
632
686
686
682
684
684
684
684
684
F1
F2
F3
F4
F5
682
Q
W
E1
R2
T3
Y
U
I
O
P
A
S
D4
F5
G6
H
J
K
L
Z
X7
C8
V9
B
N
M
0
SPACE
ALT
MENU
680
640

FIG. 15

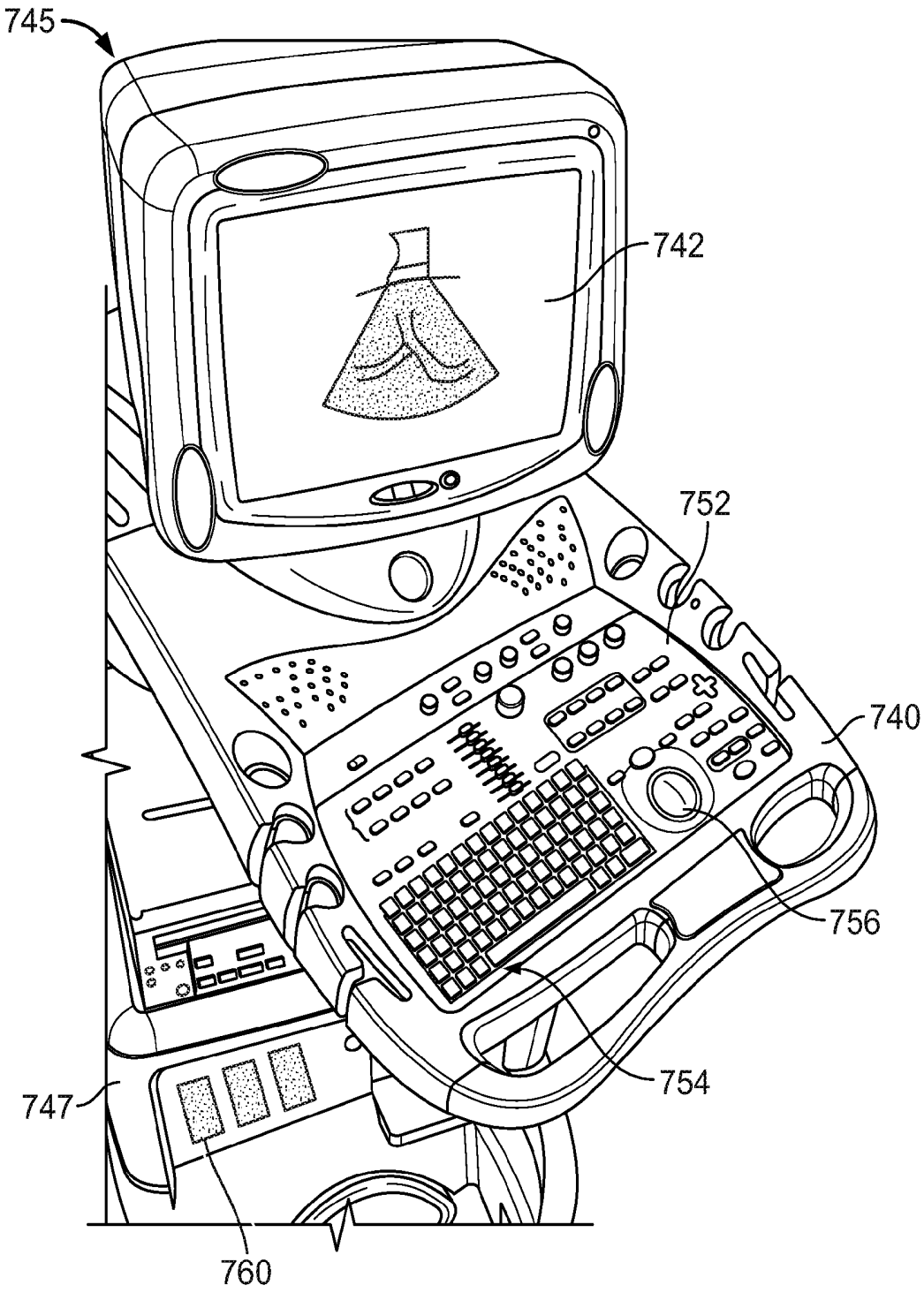


FIG. 16

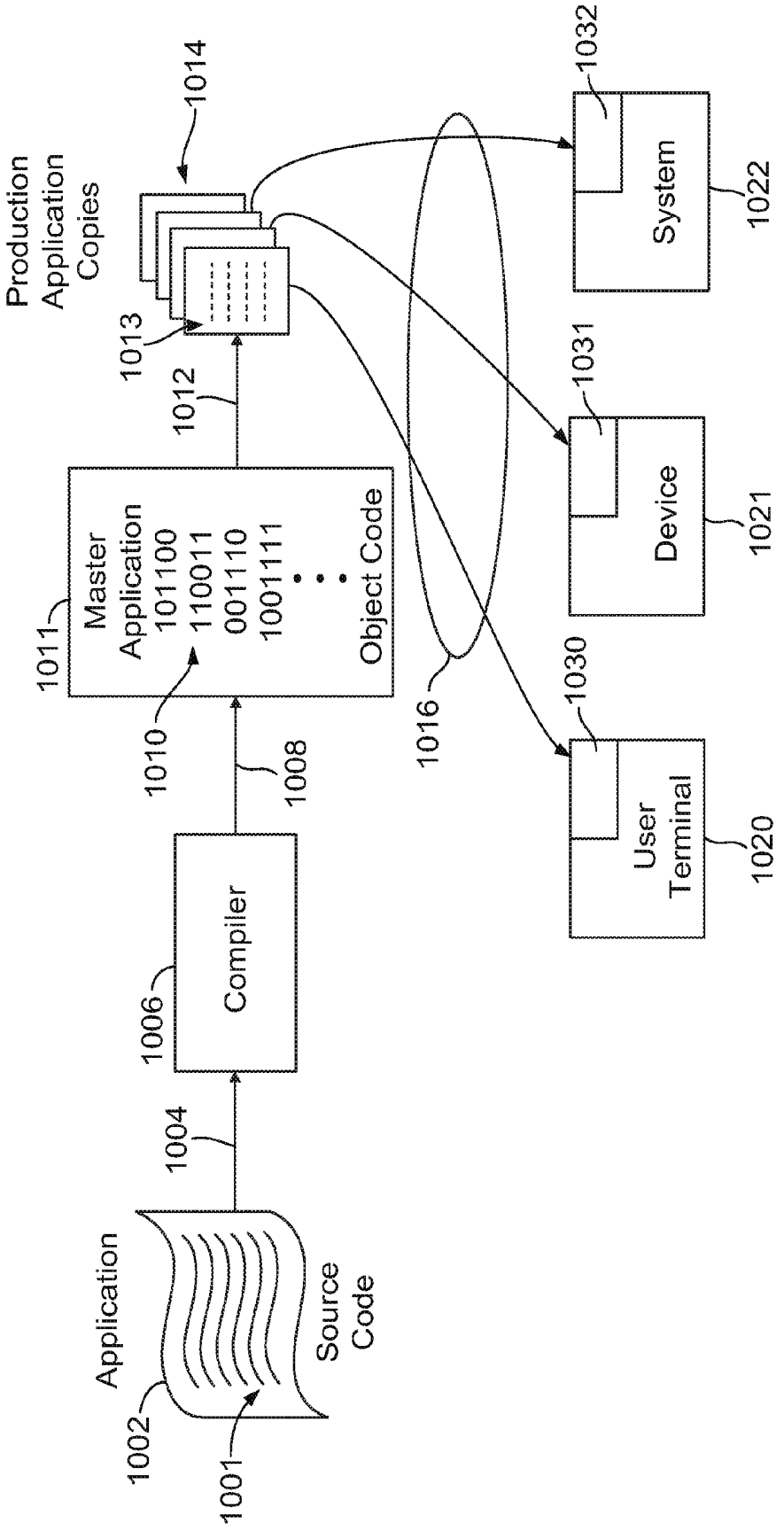

Application Source Code
1002
1001
1004
Compiler
1006
1008
Master Application
101100
110011
001110
1001111
Object Code
1011
1010
1012
1013
1014
Production Application Copies
1016
1030
User Terminal
1020
1031
Device
1021
1032
System
1022

FIG. 17

ULTRASOUND SYSTEM AND METHOD TO DETERMINE MECHANICAL PROPERTIES OF A TARGET REGION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application includes subject matter that is similar to the subject matter described in U.S. Patent Application having Attorney Docket No. 235594 (555-0003US), entitled "ULTRASOUND SYSTEM AND METHOD TO AUTOMATICALLY DELIVER THERAPY BASED ON USER DEFINED TREATMENT SPACES," and Attorney Docket No. 235615 (555-0004US), entitled "ULTRASOUND SYSTEM AND METHOD TO AUTOMATICALLY IDENTIFY AND TREAT ADIPOSE TISSUE," 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 ultrasound therapy systems that provide treatment of a region of interest in a patient, and more particularly, to ultrasound systems that 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 target region within the adipose tissue. The HIFU signals may at least partially liquefy the adipose tissue at the target region through lysis, cavitation, and/or thermal damage of the cells.

[0004] In some known HIFU systems, an operator typically directs several applications of therapy to separate locations within a region of the patient's body. When an operator moves the target from one location in the adipose tissue to a new location in the adipose tissue, the mechanical properties of the adipose tissue in the new location may be different from previous locations. As such, the therapy parameters for delivering the HIFU signals may need to be changed in light of the different mechanical properties. However, known HIFU systems have limited capabilities in identifying the mechanical properties of the target region. Furthermore, known HIFU systems may not be capable of determining whether the therapy delivered to one location was effective in at least partially liquefying the adipose tissue.

[0005] Accordingly, there is a need for an ultrasound therapy system that determines mechanical properties of a proposed target region. There is also a need for an ultrasound system that confirms that an effective amount of treatment was delivered to a location within a patient.

BRIEF DESCRIPTION OF THE INVENTION

[0006] In one embodiment, an ultrasound system is provided that is configured to determine whether adipose tissue of a patient received therapy at a treatment location. The system includes an ultrasound probe and a shear-wave-generating module to control the probe to provide a shear-wave beam that is configured to generate a shear wave at a first site within the patient. The shear wave is configured to propagate through the treatment location toward a second site within the patient. The system also includes a tracking module to control the probe to track the shear wave at the second site within the patient to determine if the treatment location received the therapy.

[0007] In another embodiment, a method to determine whether adipose tissue of a patient received therapy at a treatment location is provided. The method includes providing a shear-wave beam to generate a shear wave at a first site within the patient. The shear wave is configured to propagate through the treatment location toward a second site within the patient. The method also includes tracking the shear wave at the second site within the patient to determine if the treatment location received the therapy.

[0008] In yet another embodiment, a system configured to determine whether adipose tissue of a patient received therapy at a treatment location is provided. The system includes a shear-wave-generator that is configured to generate a shear wave at a first site within the patient. The shear wave is configured to propagate through the treatment location toward a second site within the patient. The system also includes a tracker that is configured to track the shear wave at the second site within the patient to determine if the treatment location received the therapy.

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

[0011] FIG. **3** is a block diagram of a diagnostic module in the ultrasound system of FIG. **2** formed in accordance with an embodiment of the invention.

[0012] FIG. **4** is a block diagram of a therapy module in the ultrasound system of FIG. **2** formed in accordance with an embodiment of the invention.

[0013] FIG. **5** illustrates transducer arrays that may be used with a probe in accordance with various embodiments.

[0014] FIG. **6** is a schematic diagram of a probe in accordance with an embodiment of the invention and a region-of-interest (ROI) within a patient.

[0015] FIG. **7** is a schematic diagram of the ROI in FIG. **6** after therapy has been applied by the probe.

[0016] FIG. **8** illustrates another method in accordance with an embodiment of the invention.

[0017] FIG. **9** illustrates another method in accordance with an embodiment of the invention.

[0018] FIG. **10** illustrates a window presented on a display that displays a treatment space of an ROI.

[0019] FIG. **11** illustrates another window presented on the display of FIG. **10** that displays a treatment space of an ROI.

[0020] FIG. **12** shows the window in FIG. **10** as the ultrasound system delivers therapy to the treatment space.

[0021] FIG. **13** illustrates an ultrasound system in accordance with one embodiment that includes a tracking system and a registering system.

[0022] FIG. **14**A is a flowchart illustrating a method in accordance with one embodiment.

[0023] FIG. **14**B is a flowchart illustrating another method in accordance with one embodiment.

[0024] FIG. **15** 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.

[0025] FIG. **16** 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.

[0026] FIG. **17** 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

[0027] Exemplary embodiments that are described in detail below include ultrasound systems and methods for treating a region of interest (ROI). The ROI may include at least one of adipose tissue and non-adipose tissue, such as a dermis layer, muscle tissue, bone, tissue of organs, and blood vessels. The system may also include a display or imaging device that displays 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. Furthermore, the display may also indicate those locations within the ROI that have been treated. Treatment of the ROI may include providing high-intensity focused ultrasound (HIFU) signals to treatment locations within the ROI. When therapy is delivered to a treatment location within adipose tissue, mechanical properties or characteristics of the adipose tissue may be affected. For example, HIFU signals may be directed to treatment locations within the adipose tissue to at least partially liquefy the adipose tissue.

[0028] Exemplary embodiments may also include methods and systems for determining whether an effective amount of therapy has been received at a treatment location. As an example, a treatment location within adipose tissue of a patient has received an "effective amount" of therapy if the adipose tissue at the treatment location has been at least partially liquefied for the purpose of body contouring and/or weight loss.

[0029] Also, methods and systems described herein may be configured to track a shear wave that propagates through a tissue in order to determine the mechanical properties of the tissue. In particular embodiments, the shear wave is configured to propagate through a treatment location that may or may not have already received therapy. As used herein, a shear wave or waves "propagating through" a site or location may include the shear wave being generated at that site or location or being generated at another adjacent site. More specifically, in some embodiments, therapy may be applied to a treatment location and shear waves may be generated at the treatment location (whether subsequent to or during the application of therapy). The shear waves may be tracked at another site to determine the mechanical properties of the adipose tissue at the treatment location. If the treatment location received an effective amount of therapy, the shear wave may not be detected at the other site or the shear wave may be substantially affected (i.e., if the waveform characteristics of the shear wave that are detected at the other site after therapy are significantly different from the waveform characteristics of the shear wave before therapy).

[0030] 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.

[0031] 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.

[0032] 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 imaging and therapy that are exclusively performed through ultrasound. 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. In addition, shear waves may be generated by an ultrasound probe or by another system or device. Further, the various embodiments may be implemented in other non-medical imaging systems, for example, non-destructive testing systems, such as airport screening systems.

[0033] A technical effect of the various embodiments of the systems and methods described herein include confirming or determining if a treatment location within adipose tissue has been at least partially liquefied. Another technical effect may include determining mechanical properties of adipose tissue at a target region or a treatment location. Another technical effect may include generating an image of an ROI and indicating to a user that a treatment location within the ROI has been at least partially liquefied. 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. Other technical effects may be provided by the embodiments described herein.

[0034] FIG. **1** is a diagram of an exemplary ultrasound system **50** formed in accordance with an embodiment. The system **50** is configured to treat adipose tissue **52** (or another tissue) within a region of interest (ROI) of a patient and/or determine mechanical properties of the adipose tissue **52** (or the other tissue) within the ROI. The system **50** may include an ultrasound probe **56**, a shear-wave generator **60**, and a tracker **62**. The probe **56** is configured to deliver, during a therapy session, a therapy to a treatment location **58** within the adipose tissue **52** of the ROI. For example, the probe **56** may be configured to deliver HIFU signals to the treatment location **58**. The therapy delivered to the treatment location **58** may affect mechanical properties of the adipose tissue **52** at the treatment location **58**. For instance, the adipose tissue **52** at the treatment location **58** may be lysed through cavitation or thermal treatment resulting in the adipose tissue **52** being at least partially liquefied. The liquefied adipose tissue **52** exhibits different mechanical properties than adipose tis-

sue **52** that has not received the therapy. The resulting change, if any, in the mechanical properties at the treatment location **58** may facilitate determining (a) whether the therapy was received by the adipose tissue at the treatment location **58**; (b) whether the therapy was effective for treating the adipose tissue **52**; and (c) information regarding the mechanical properties of the adipose tissue **52** at the treatment location **58**.

[0035] The system **50** may determine the mechanical properties of the treatment location **58** before and after treatment using elastographic methods and, particularly, using shear waves. Mechanical properties may include at least one of a shear elasticity modulus, Young's modulus, dynamic shear viscosity, and mechanical impedance of the target tissue. The mechanical properties may be calculated or determined using propagation parameters, such as a shear wave velocity, a shear wave attenuation coefficient, an amplitude and velocity of shear displacement of tissue particles in a propagating shear wave, and spatial and temporal dependencies of the amplitude and velocity of shear displacement of tissue particles. Another parameter that may be used is shear viscosity, which may be derived from changes in shear velocity as a function of frequency.

[0036] As shown, the treatment location **58** is located substantially between a generation site **66** (also called a first site or a shear-wave source) and a tracking site **68** (also called a second site). Prior to generating a shear wave, the tracker **62** may deliver one or more tracking pulses **70** toward the tracking site **68**. A reflection signal **72** from the adipose tissue **52** of the tracking site **68** may be indicative of the adipose tissue **52** at the second site **68** in a baseline condition (i.e., before any displacement caused by the shear wave).

[0037] After obtaining the reflection signal(s) **72** of the second site **68** before any displacement, the shear-wave generator **60** is configured to deliver a pushing or shear-wave-generating pulse **74** toward the first site **66** that is proximate to the treatment location **58**. The pushing pulse **74** generates a shear wave **64** at the first site **66** that propagates toward the treatment location **58** (also called target region) and toward the second site **68**. The shear-wave generator **60** may generate the shear wave **64** before therapy has been applied to the treatment location **58**. The tracker **62** is configured to track the shear wave **64** at the second site **68** by delivering one or more tracking pulses **70** toward the second site **68**. When the shear wave **64** propagates to the second site **68**, another reflection signal **72** of the tracking pulse **70** is provided. More specifically, the tracking pulses **70** are modified by the adipose tissue **52** at the second site **68** while experiencing the shear wave **64**. The reflection signal **72** from the second site **68** indicates a reference displaced condition of the adipose tissue **52** at the second site **68**. Reflection signals **72** of the reference displaced condition and the baseline condition of the second site **68** provide references that may be compared to by other conditions of the second site **68**.

[0038] After receiving the reflected signal **72** of the reference displaced condition, the probe **56** may deliver therapy (e.g., HIFU signals) to the treatment location **58**. During or subsequent to treatment, the shear-wave generator **60** may deliver one or more pushing or shear-wave-generating pulses **74** to the first site **66** to generate another shear wave **64**. If an effective amount of therapy was received by the adipose tissue **52** at the treatment location **58**, the mechanical properties of the adipose tissue **52** at the treatment location **58** should substantially affect propagation of the shear wave **64**. For example, if the treatment location **58** is substantially liquefied, the shear wave **64** may not propagate through the treatment location **58** or reach the second site **68**. If the shear wave **64** reaches the second site **68**, characteristics of the shear wave **64** (e.g., velocity and amplitude) may be significantly affected. More specifically, the velocity may be slower and the amplitude may be smaller as compared to a velocity and amplitude of the shear wave **64** when the treatment location **58** has not received therapy.

[0039] The pushing pulse **74** and the tracking pulse **70** may be delivered at different intensity levels. The pushing pulse **74** may be an intense pulse that generates an appreciable radiation force at the first site **66**. For example, the pushing pulse **74** may be an amplitude-modulated beam of focused ultrasound that provides a radiation force to generate the shear wave **64** at the first site **66**. A significant amount of acoustic energy may be delivered to the first site **66** to achieve a desired initial displacement at the first site **66**. The localized force generating the shear wave **64** causes tissue displacement along the wave path. In some embodiments, the shear waves may propagate from a point source. In other embodiments, the shear waves may be virtually extended shear waves extending along a plane.

[0040] The tracker **62** may use any imaging technique capable of detecting internal motion of tissue within the ROI. For example, tissue displacements at the first, second, or any other site may be determined using ultrasonic correlation based methods or other pattern matching methods. The tracker **62** may use any pulsed-echo imaging methods, B-mode imaging methods, and pulsed or continuous Doppler imaging methods. Furthermore, the tracker **62** may be a magnetic resonance imaging (MRI) system. Optical tracking may also be used to detect internal motion of the ROI.

[0041] Separate components or devices may be used for therapy, imaging, shear wave generation, and shear wave detection. Alternatively, one component or device (e.g., a transducer) may be used for any combination (or all) of therapy, imaging, shear-wave-generating, and detecting. Accordingly, as shown in FIG. **1**, the shear-wave generator **60**, the probe **56**, and the tracker **62** may all be incorporated into a single device or system, such as the system **120** described in detail below. More specifically, the functions of the shear-wave generator **60** and the tracker **62** may be performed by the probe **56**. However, in alternative embodiments, one or more of the shear-wave generator **60**, the probe **56**, and the tracker **62** operates separately from the other components. For example the shear-wave generator **60** and the tracker **62** may be separate ultrasound probes. Also, in alternative embodiments, the shear-wave generator may be made by a mechanical actuator or an audio speaker.

[0042] FIG. **2** is a block diagram of an exemplary ultrasound therapy system **120** in which various embodiments can provide therapy to and/or display a ROI during a therapy session for treating adipose tissue. 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/or for therapy of tile ROI. The pulsed ultrasonic signals may also be for generating and/or tracking shear waves. For example, the probe **126** may deliver low energy pulses during imaging and tracking, medium to high energy pulses to generate shear waves, and high energy pulses during therapy. A variety of array geometries and configurations may be used and the

array of transducer elements **124** may be provided as part of, for example, different types of ultrasound probes.

[0043] The imaging and tracking signals may be 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**.

[0044] 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.

[0045] 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 currently 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**.

[0046] The diagnostic module **136** is configured to analyze ultrasound signals for imaging the ROI and/or tracking shear waves propagating through the ROI. Furthermore, the diagnostic module **136** may also 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.

[0047] 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**.

[0048] The diagnostic module **136** may be configured to control the probe **126** to deliver and obtain diagnostic ultrasound signals from the ROI and to control the probe **126** to deliver a pushing pulse to generate a shear wave within the ROI. The therapy module **125** is configured to deliver a therapy to the treatment locations based within the ROI. The therapy module **125** may automatically move the treatment location between multiple points based on user inputs.

[0049] 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.

[0050] The system **120** also includes a shear-wave-generating module **123** that is operatively coupled to the diagnostic module **136** or a sub-module of the diagnostic module **136**. The shear-wave-generating module **123** is configured to control the probe **126** to generate a shear wave at a site within the ROI of the patient. The shear-wave-generating module **123** may control the probe **126** or, more particularly, the transducer elements **124** to direct a shear-wave-generating or pushing pulse(s) toward the predetermined site to generate the shear wave. Alternatively, the shear-wave-generating module **123** may control another device capable of generating shear waves. For example, the shear-wave-generating module **123** may control a therapy transducer, a mechanical actuator, or an audio device to generate the shear waves. The pushing pulse(s) may be configured to generate a desired shear wave and to direct the shear wave along a desired path or direction.

[0051] 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.

[0052] FIG. **3** is an exemplary block diagram of the diagnostic module **136**, and FIG. **4** is an exemplary block diagram

of the therapy module **125**. The therapy and diagnostic modules **125** (FIG. **4**) and **136** (FIG. **3**) 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. **3** and **4** 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. **3** and **4** 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**.

[0053] The operations of the modules illustrated in FIGS. **3** and **4** 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. **3**, 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 tracking module **164**, and an elastography module **166**. Other modules may be included, such as an M-mode module, power Doppler module, 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.

[0054] Each of modules **152-166** is 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**, tracking 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. **2**) 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.

[0055] 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. **2**) or the image memory **140** (FIG. **2**). 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).

[0056] 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. **2**). 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.

[0057] Referring again to FIG. **3**, 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. **2**). 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. **2**). 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.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] Referring to FIG. **4**, the therapy module **125** may be coupled to the diagnostic module **136** (FIG. **2**) and the user interface **142** (FIG. **2**) and include a transmit beamforming module **127** and a transmission module **129**. 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.

[0062] FIG. **5** 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. **2**) controls the probe **126** (FIG. **2**) to deliver imaging and/or tracking pulses, the shear-wave-generating module **123** (FIG. **2**) controls the probe to generate a shear wave, and the therapy module **125** (FIG. **2**) controls the probe to generate therapy pulses. Relative to one another, the imaging and tracking pulses may be low energy, the shear-wave-generating pulses may be medium to high energy, and the therapy pulses may be high energy.

[0063] 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 and shear-wave-generating pulses may also be 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** or to track a shear wave. Embodiments of 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.

[0064] The transducer **420** includes an array **422** where the entire array may be used for imaging, tracking, 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. Although not shown, the transducer **430** may also have tracking portion of the array **432** that includes a subset of transducer elements for tracking shear waves. The therapy portion, tracking portion, and an imaging portion may share transducer elements. Thus, the diagnostic module **136** and the therapy module **125** may deliver low energy imaging and/or tracking pulses and high energy therapy pulses, respectively, in an interspersed manner to an at least partially overlapping array of transducer elements.

[0065] 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, therapy, and tracking arrays into one transducer, therapy may be applied immediately after the transducer images the ROI and the shear wave may be immediately generated thereafter and before. As such, an accurate representation or identification of the adipose tissue may be provided immediately before the therapy is applied. However, in alternative embodiments, separate transducers may be used for therapy, imaging, and/or tracking.

[0066] FIGS. **6-9** are schematic diagrams illustrating an ultrasonic probe **500** or methods configured to deliver therapy to a treatment location and to confirm whether an amount of therapy received at the treatment location was sufficient for ablating or liquefying adipose tissue. In addition or alternatively, the ultrasonic probe **500** may be used to determine mechanical properties of the adipose tissue proximate to the treatment location.

[0067] FIG. **6** illustrates the probe **500** having a transducer **502** with an array **504** of transducer elements. As shown, the transducer **502** is located on a skin surface **506** on an ROI of a patient. The ROI includes adipose tissue at a depth beneath the surface **506**. In some embodiments, the probe **500** may deliver tracking pulses **522** to a tracking or second site **514** to receive reflection signals **524** indicative of a baseline condition of the adipose tissue. Also, before therapy is applied to a treatment location, the probe may generate shear waves **520** at a first or generation site **512** to determine a reference displaced condition of the adipose tissue at the second site **514**. The first and second sites **512** and **514** may be separated from each other a distance D_T. The transducer **502** may deliver a beam or a pulse **516** of focused ultrasound signals to a predetermined spatial volume at the first site **512** to generate the shear waves **520**. The resulting radiation force at the first site **512** generates the shear waves **520**A and **520**B that propagate away from the first site **512** in opposing directions that are substantially parallel to a surface of the transducer **502**. Furthermore, since the propagation of the shear waves **520**A and **520**B are directly related to mechanical properties of the adipose tissue within the ROI, the distance D_T may be configured so that the shear waves **520** are capable of crossing the distance D_T without being fully attenuated.

[0068] Although FIG. **6** only shows shear waves **520**A and **520**B traveling perpendicular to a direction of the beam, many shear waves may be generated at the first site **512** that propagate away from the first site in multiple directions. The shear waves may be spherically diverging, diverging from a plane, or diverging in some other configuration. Furthermore, in some embodiments, multiple pushing pulses may be used to create a shear wave directed in a particular direction. Such shear waves may be generated using methods similar to those used in supersonic shear wave imaging.

[0069] After delivering the beam **516** for generating the shear waves **520**, the transducer **502** may deliver a series of tracking pulses **522** toward the second site **514**. When the shear wave **520**A propagates through the second site **514**, the reflected signals **524** are modified from the baseline condition by the shear wave **520**A. The reflected signals **524** from the series of tracking pulses **522** represent various levels of dis-

placement of the adipose tissue as the shear wave **520**A or waves **520**A pass through the second site **514**. A relative motion of the adipose tissue at the second site **514** may be determined using correlations between the reflected signals **524** of the second site **514** in the baseline condition and displaced conditions. For example, a displacement as a function of time for the adipose tissue at the second site **514** may be determined. Accordingly, reference characteristics of the shear wave **520**A may be determined. These reference characteristics may later be compared to characteristics of shear waves propagating through treated adipose tissue.

[0070] More specifically, the baseline and displaced conditions of the second site **514** may facilitate determining mechanical properties of the adipose tissue at the region between the first and second sites **512** and **514**. Furthermore, the baseline and displaced conditions may facilitate determining whether therapy was received by a treatment location located between the first and second sites **512** and **514**. Also, a time for propagating the distance D_T may be calculated by measuring the time between shear wave generation and shear wave detection.

[0071] FIG. **7** illustrates the probe **500** at a time after therapy has been delivered to a treatment location **530**. After therapy has been delivered, the transducer **502** may deliver the beam **516** to the first site **512** to generate more shear waves **521**. The shear wave **521**A may be directed to propagate toward the second site **514** and the shear wave **521**B propagates in an opposite direction. When the shear wave **521**A propagates through the treatment location **530**, the mechanical properties of the adipose tissue at the treatment location **530** may affect the propagation of the shear wave **521**A. In particular, if the therapy received at the treatment location **530** has at least partially liquefied the adipose tissue, the propagation of the shear wave **521**A may be significantly affected.

[0072] The reflected signals **524** may indicate characteristics of the shear wave **521**A that are different from the characteristics of the shear wave **520**A (FIG. **6**) at the second site **514**. For example, at least one of the shear wave velocity, the shear wave amplitude, the shear wave viscosity, and the shear wave frequency may be noticeably different at the second site **514** (i.e., values or data of the reflected signals before and after treatment may be significantly different indicating a change in mechanical properties). Furthermore, in some instances, the shear wave **521**A may not reach the second site **514** or may not propagate through the treatment location **530** within a predetermined period of time. For example, the shear wave **520** may not propagate through the second site **514** within a predetermined time period that is greater than the time period calculated for a shear wave to propagate the distance D_T before treatment.

[0073] FIG. **8** illustrates another method for confirming that therapy was received at a treatment location. When therapy is applied to a treatment location **542**, shear waves **544** may be generated from the treatment location **542** and propagate in a direction toward a tracking site **546**. In some embodiments, the therapy system (not shown) may utilize the shear waves **544** generated at the treatment location **542** to determine the effectiveness of therapy applied to other treatment locations. More specifically, as shown, a treatment location **548** may be located substantially between the treatment location **542** and the tracking site **546**. The treatment location **548** receives therapy before the treatment location **542**. When the therapy is subsequently delivered to the treatment location **542**, the shear waves **544** may propagate toward the treatment location **548**. Mechanical properties of the adipose tissue at the treatment location **548** may affect the wave propagation of the shear waves **544** as described above. Accordingly, the tracking site **546** may be tracked after therapy is applied to the treatment location **542** to determine if ablation of the adipose tissue at the treatment location **548** was effective.

[0074] Alternatively, the shear waves **544** generated at the treatment location **548** may be tracked to determine characteristics or mechanical properties of the adipose tissue proximate to the treatment location **548**.

[0075] FIG. **9** illustrates another method for confirming that therapy was received at a treatment location. In some embodiments, shear-waves that are configured to be generated at the treatment location may be detected. For example, FIG. **9** shows a treatment location **550** and a first or generation site **552**. A first shear-wave generating beam may be directed toward the treatment location **550** before therapy has been applied to the treatment location **550**. The first shear-wave generating beam generates shear waves **554** at the first site **552** that at least partially overlaps the intended treatment location **550**. The shear waves **554** may be detected at an adjacent tracking site **556**. The detected shear waves **554**, prior to therapy being applied to the treatment location **550**, provide an initial or baseline condition of the tissue at the tracking site **556**. Subsequently, a therapy beam may be delivered to the treatment location **550**. A second shear-wave generating beam may then be directed toward the treatment location **550**. If the treatment location **550** had received an effective amount of therapy, the shear waves **554** will not be detected at the tracking site **556** or will be significantly weaker and/or slower.

[0076] As shown in FIG. **9**, in some embodiments, dimensions of the treatment location **550** (i.e., an area or volume within the adipose tissue) may be greater than dimensions of the first site **552** (i.e., dimensions of the generation pulse created by the shear-wave generating beam). More specifically, a focal region of the therapy beam may be greater than a focal region of the shear-wave generating beam. As one example, if the shear-wave generating beam has a higher frequency, such as a harmonic, a narrower shear-wave generating beam may be formed such that the generation site **552** is within the treatment location **550** as shown in FIG. **9**. In other embodiments, the shear-wave generating beam may have a focal region that is greater than the focal region of the therapy beam such that the first site (indicated by **552**') has larger dimensions than the treatment location **550**.

[0077] In other embodiments, shear waves may be used to determine a size, shape, or make-up of the treatment location after therapy has been delivered. For example, the shear waves may be separately generated at multiple generation sites on one side of the treatment location along a vertical axis. The shear waves may be detected at respective tracking sites along the vertical axis on the other side of the treatment location. At the center of the treatment location, the adipose tissue may be most affected by the therapy and any shear waves would not be able to propagate therethrough. However, at a periphery of the treatment location, the shear waves may pass through with some additional attenuation. Those shear waves with more attenuation indicate areas of the treatment location that received effectively more therapy. Accordingly, a size, shape, and make-up of the treatment location may be determined. Alternatively, the shear waves may be generated within the treatment location as discussed above, and the

shear waves may be detected to determine the mechanical properties of the tissue within the treatment location.

[0078] FIG. **10** illustrates a window **100** that may be presented on the display **138** (FIG. **2**). The display **138** communicates with the diagnostic module **136** (FIG. **2**) 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** or 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 treatment locations within the adipose tissue **104**. The system **120** may also confirm that an effective amount of therapy was received at the treatment locations by using, for example, the shear wave methods described above. Alternatively, the user of the system **120** may be able to recognize or identify through the image **102** the different layers of tissue and designate certain locations to receive therapy. The user may also be able to visually identify whether or not the therapy was effective.

[0079] In order to automatically differentiate the adipose tissue **104**, **106** from the non-adipose tissues and, more specifically, the dermis layer **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 layer **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. **2**) 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. **10**). 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. **10**.

[0080] 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 **104** and **106** 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. 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.

[0081] In addition to identifying the adipose tissue **104** and **106** by measuring for adipose characteristics, 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. Furthermore, techniques described above may be used to examine patterns in the image that are characteristic of different types of tissues (e.g., muscle tissue, connective tissue, bone tissue). For instance, a layered appearance characteristic of muscle tissue may be determined, or a cellular structure of adipose tissue caused by connective tissue boundaries could be determined.

[0082] 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. **10** illustrates a B-mode gray-scale image of the ROI. As shown, different tissues may have different brightness levels. The diagnostic module **136** 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 layer **109** and the adipose tissues **104** and **106** separated by the connective tissue **108**.

[0083] Also, the system **120** may use elastography processing methods alone or in addition to other processing methods to differentiate the adipose tissue **104** and **106**. 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. Other elastography techniques, such as inducing and measuring the shear waves as described above or vibro-acoustography may be used to differentiate adipose tissue from other tissue types.

[0084] In some embodiments, after the initial scan to obtain diagnostic ultrasound signals has been performed and the adipose tissues **104** and **106** have 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 **104**. Based on the thickness of the adipose tissue **104** 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 **104** decreases or increases as the adipose tissue **104** extends laterally across the ROI (e.g., across the image **102**), 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**.

[0085] 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, such as the shear-wave methods described above. After or while the adipose tissue **104** 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 **104** before treatment. In the second supplemental scan, the color, brightness, or density of the adipose tissue **104** may change where the adipose tissue **104** 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 **104**. 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 **104** by comparison of the images.

[0086] In addition or alternatively, the diagnostic module **136** may use other processing methods to facilitate determining whether a characteristic of the adipose tissue **104** 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.

[0087] FIGS. **11** and **12** 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. **11** illustrates a window **202** that may be presented on the display **138** (FIG. **2**). As shown in an image **204**, the ROI includes adipose tissue **206** and **208** and non-adipose tissues, such as dermis layer **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. **2**) 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 **211** 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.

[0088] The display **138** may indicate to the user or another viewer (e.g., the patient) 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**.

[0089] 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.

[0090] The outline **214** may be positioned with respect to reference points **250**, **252**, and **254**. The reference module **195** (FIG. **3**) 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 **216** are shown in FIG. **11**. However, the reference point **254** and the probe **216** 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.

[0091] 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.

[0092] Furthermore, the reference module **195** may use data gathered or determined by the diagnostic module **136** (FIG. **2**) to determine where to place the treatment space **212** within the ROI. For example, the reference module **195** may

use information or data regarding the tissue characterization discussed above. More specifically, 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.

[0093] 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.

[0094] FIG. **12** shows the window **202** as the system **120** (FIG. **2**) delivers therapy to the treatment space **212**. When therapy is applied, ultrasonic therapy signals (e.g., HIFU) from the probe **126** (FIG. **2**) are directed toward a treatment location **222** (indicated as dots **222**A and **222**B in FIG. **12**) 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 (e.g., 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., through lysing, thermal damage, and/or cavitation) the adipose tissue **206** within the focal region.

[0095] The therapy module **125** (FIG. **2**) 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 **222**A). 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 **222**B). 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. **12**.

[0096] Moreover, the therapy module **125** may operate in conjunction with the shear-wave-generating module **123** and the diagnostic module **136** to confirm that each treatment location **222** receives an effective amount of therapy. The system **120** may use the shear-wave methods described above. For example, after therapy has been applied to a first treatment location, the shear-wave-generating module **123** may automatically generate a shear wave at a generation site proximate to one side of the first treatment location. The diagnostic module may then automatically track a tracking site located on another side of the first treatment location to determine whether the treatment location received an effective amount of treatment. If the treatment location received an effective amount of treatment, the system **120** may then automatically move to a second treatment location.

[0097] The therapy path **228** may have various shapes and may be pre-programmed or, alternatively, drawn by the user. As shown in FIG. **12**, 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. **12**, 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 tissues **206** and **208**. The boundary **236** may or may not be shown to the viewer.

[0098] However, the therapy path **228** shown in FIG. **12** 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.

[0099] 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**. Other 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. 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 adjust the therapy parameters before applying therapy to the treatment space **212** again or another treatment space.

[0100] Returning to FIG. **12**, 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.

[0101] 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.

[0102] FIG. **13** illustrates an ultrasound system **300** formed in accordance with one embodiment. The system **300** may include similar features and components as described above with respect to FIGS. **1-11**. 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. **2**). 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. **2**. 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.

[0103] Also shown in FIG. **13**, 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. **13**, 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**.

[0104] 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.

[0105] FIG. **14**A is a flowchart illustrating a method **900** for delivering therapy to at least one ROI in a patient. The method **900** 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 **902** 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 **904**. 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.

[0106] An image of the ROI is generated and displayed to the operator and, optionally, patient at **906**. 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 **908** 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 **910** by overlaying a graphical presentation (e.g., line) that indicates a boundary between the layers of tissue.

[0107] However, the system may also accept user inputs at **912** 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 **914** a graphical representation (e.g., an outline) of the designated treatment space. The system may then automatically set therapy parameters at **916** and/or the system may accept user inputs for therapy parameters at **918**. For example, the system may determine mechanical properties of the treatment space by using the shear wave methods described above. Based upon the determined mechanical properties, the system may adjust the therapy parameters. Optionally, at **920**, the operator may designate a therapy path within the treatment space. Therapy is then provided to a treatment location at **922** within the designated treatment space. The system may optionally, at **924**, display a graphical representation (e.g., a marker) of the treatment location with the image.

[0108] After or while providing treatment to the treatment space, the system may obtain ultrasound signals of the treatment space at **926**. At **928**, 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 **930** and/or automatically move the treatment location at **932** 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 **934**. The system provides therapy to a new point and continues this process until the therapy for the corresponding treatment space is complete.

[0109] After therapy for the treatment space is completed, the system may determine (or ask the operator) at **936** 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 **938** to another location on the patient. In some embodiments, the system may also track at **940** 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.

[0110] Although the flowchart illustrates sequential steps in the method **900**, 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.

[0111] FIG. **14**B is a flowchart illustrating a sub-method **950** for confirming an effective amount of therapy was delivered to a treatment location within an ROI of a patient. Before therapy is provided to a treatment location at **922**, the system may automatically or may be commanded by the user to determine a baseline condition and a reference displaced condition at **952** of a tracking site located proximate to the treatment location. The baseline condition may be determined by tracking the tracking site when the adipose tissue is at rest. A shear wave may then be generated at a generation site that is proximate to the treatment location in which the treatment location is substantially between the generation and tracking sites. The reference displaced condition may be determined by tracking the tracking site when a shear wave propagates through the tracking site before the treatment location receives therapy. At **922**, therapy is provided to the treatment location. The method **950** also includes determining at **962** whether the treatment location received an effective amount of therapy by propagating a shear wave from the generation site to the tracking site. The treatment location received an effective amount of therapy if the shear wave is not detected at the tracking site. The treatment location did not receive an effective amount of therapy if the shear wave is detected at the tracking site and the shear wave has not been substantially affected by propagating through the treatment location. If the treatment location did not receive an effective amount of therapy at the treatment location, then the system determines whether the same treatment location should be treated or whether a different treatment location located near the original treatment location should be treated. The system then provides therapy at **922** to the chosen treatment location. The therapy may be the same as before or include a different set of therapy parameters that may be more effective in treatment. If the original treatment location did receive an effective amount of therapy, the system moves on to step **926**.

[0112] FIG. **15** 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.

[0113] Multi-function controls **684** may each be assigned functions in accordance with the mode of system operation. Therefore, each of the multi-function 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," "gain control," "color-mode," "print," and "store."

[0114] As another example shown in FIG. **16**, 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.

[0115] 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.

[0116] FIG. **17** 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. **17**, the "application" represents one or more of the methods and process operations discussed above.

[0117] As shown in FIG. **17**, 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. **17**, 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**).

[0118] 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.

[0119] 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**.

[0120] 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.

[0121] 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".

[0122] 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.

[0123] 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 soft-

ware. 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.

[0124] 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.

[0125] 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.

[0126] 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.

[0127] 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 system configured to determine whether adipose tissue of a patient received therapy at a treatment location, the system comprising:

an ultrasound probe;

a shear-wave-generating module to control the probe to provide a shear-wave beam that is configured to generate a shear wave at a first site within the patient the shear wave being configured to propagate through the treatment location toward a second site within the patient; and

a tracking module to control the probe to track the shear wave at the second site within the patient to determine if the treatment location received the therapy.

2. The system in accordance with claim **1** further comprising a therapy module to control the probe to deliver the therapy to the treatment location within the adipose tissue.

3. The system in accordance with claim **2** wherein the treatment location is a first treatment location located substantially between the first and second sites, the probe being controlled to deliver therapy to a second treatment location at the first site, the therapy at the second treatment location generating the shear wave that propagates toward the second site.

4. The system in accordance with claim **1** wherein the first site is located at the treatment location.

5. The system in accordance with claim **1** wherein the first site is located such that the treatment location is substantially between the first and second sites.

6. The system in accordance with claim **1** wherein the probe is configured to apply acoustic radiation force to the first site to generate the shear wave.

7. The system in accordance with claim **1** wherein the tracking module is configured to control the probe to deliver one or more tracking pulses to the second site.

8. The system in accordance with claim **1** further comprising a display to show a region-of-interest including the treatment location to an operator, the display displaying a graphical representation of the treatment location.

9. A method to determine whether adipose tissue of a patient received therapy at a treatment location, the method comprising:

providing a shear-wave beam to generate a shear wave at a first site within the patient, the shear wave being configured to propagate through the treatment location toward a second site within the patient; and

tracking the shear wave at the second site within the patient; and

determining whether the treatment location received the therapy.

10. The method in accordance with claim **9** wherein the determining includes determining that the treatment location had received an effective amount of the therapy if the shear wave has been substantially affected by propagating through the treatment location.

11. The method in accordance with claim **9** wherein the determining includes determining that the treatment location had not received an effective amount of the therapy if the

shear wave is detected at the second site and has not been substantially affected by propagating through the treatment location.

12. The method in accordance with claim **9** wherein the generating the shear wave includes applying acoustic radiation force to the first site using focused ultrasound.

13. The method in accordance with claim **9** wherein the first site is at the treatment location.

14. The method in accordance with claim **9** wherein the first site is located such that the treatment location is substantially between the first and second sites.

15. The method in accordance with claim **9** wherein the tracking the shear wave includes using ultrasonic imaging techniques.

16. The method in accordance with claim **9** wherein the shear wave is a second shear wave, the method further comprising:

generating a first shear wave at the first site before delivering therapy to the treatment location; and

tracking the first shear wave at the second site, the first shear wave providing a reflection signal of the tracking pulse at the second site that is representative of the second site in a displaced condition.

17. The method in accordance with claim **16** further comprising determining mechanical properties of the adipose tissue between the first and second sites based upon the reflected signal of the second site in the displaced condition.

18. The method in accordance with claim **9** wherein the generating the shear wave at the first site and the tracking the shear wave at the second site are performed by a common ultrasound probe.

19. The method in accordance with claim **9** further comprising determining a baseline condition of the second site.

20. A system configured to determine whether adipose tissue of a patient received therapy at a treatment location, the system comprising:

a shear-wave-generator configured to generate a shear wave at a first site within the patient, the shear wave being configured to propagate through the treatment location toward a second site within the patient; and

a tracker configured to track the shear wave at the second site within the patient to determine if the treatment location received the therapy.

21. The system in accordance with claim **20** further comprising an ultrasound probe configured to deliver therapy to the treatment location within the adipose tissue.

22. The system in accordance with claim **20** wherein the tracker uses medical imaging techniques to track the shear wave at the second site.

23. The system in accordance with claim **21** wherein the probe comprises the shear-wave generator and the tracker.

24. The system in accordance with claim **22** wherein the treatment location is located at one of (a) the first site and (b) substantially between the first and second sites.

* * * * *

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摘要(译)

一种超声系统，其被配置为确定患者的脂肪组织是否在治疗位置接受治疗。该系统包括超声探头和剪切波产生模块，以控制探头以提供剪切波束，该剪切波束被配置成在患者体内的第一部位处产生剪切波。剪切波被配置为通过治疗位置朝向患者体内的第二部位传播。该系统还包括跟踪模块，用于控制探针以跟踪患者体内第二部位的剪切波，以确定治疗部位是否接受治疗。