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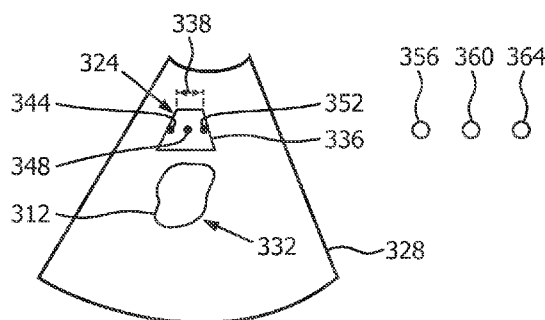
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(54) **Title:** ULTRASOUND SHEAR WAVE ELASTOGRAPHY FEATURING THERAPY MONITORING**FIG. 3B**

(57) **Abstract:** In a diagnostic scanner for shear wave elastography imaging an ultrasound exposure safety processor is configured for spatially relating respective definitions of an imaging zone (324), and an extended dead-tissue zone (312) that includes both a dead-tissue zone and a surrounding margin. Based on whether a push pulse focus (344, 348, 352) is to be within the extended dead-tissue zone, the processor automatically decides as to a level of acoustic power with which the pulse is to be produced. If it is to be within, the pulse may be produced with a mechanical index, a thermal index, and/or a spatial-peak-temporal-average intensity that exceeds respectively 1.9, 6.0 and 720 milliwatts per square centimeter. The imaging zone may be definable interactively so as to dynamically trigger the deciding and the producing, with optimal push pulse settings being dynamically derived automatically, without the need for user intervention. A display of multiple push pulse sites (344-352) allows user manipulation of spatial definition indicia (336) to dynamically control displacement tracking.

Ultrasound Shear Wave Elastography Featuring Therapy Monitoring

5 FIELD OF THE INVENTION

The present invention relates to medical ultrasound push pulse generation and, more specifically, to applications that involve dead body-tissue.

BACKGROUND OF THE INVENTION

10 Radio-frequency ablation (RFA) is gaining widespread use in minimally invasive treatment of unresectable malignant hepatic tumors. The clinical problem associated with RFA procedures is the high local recurrence rate in treated patients: ranging from 1.7% to 41% for hepatocellular carcinoma. A primary reason is that inaccurate identification of the ablation zone, especially errors in size measurement, leads to undertreatment. The standard
15 of success by which ablation is currently measured is complete destruction of all malignant cells along with a safe margin of normal tissue. It is therefore important for physicians to be able to identify the ablation region and assess therapy success while the patient is still in surgery. A variety of imaging modalities have been attempted to visualize the ablation zone including conventional B-mode ultrasound (US), contrast-enhanced US (CEUS), contrast-
20 enhanced computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET). All of these modalities are of limited use, because they carry certain disadvantages. Specifically, US does not provide adequate brightness contrast between ablated and surrounding tissue; the use of CEUS for liver imaging has not been approved by Food and Drug Administration (FDA), and the other modalities lack the
25 capability of real-time evaluation and dynamic monitoring of the effects of therapy. The above drawbacks likewise apply to other thermal based therapy options for treating a tumor, include high-intensity focused ultrasound (HIFU) and microwave ablation.

During RFA procedures tissue stiffness is elevated due to thermal necrosis. The high stiffness contrast between treated and non-treated tissue has led to the development
30 and use of ultrasound elastography for visualizing the coagulation zone during liver RFA. Acoustic radiation force based ultrasound shear wave elastography has been proposed to monitor and assess the ablation region for therapy guidance by quantitatively measuring tissue mechanical properties such as shear modulus (or the similar “Young’s modulus”) and shear viscosity.

In acoustic radiation force based ultrasound shear wave elastography, the dedicated pulse sequence consists of one or more long push pulses (typically hundreds of microseconds long each) and a series of interleaved tracking pulses. Due to the effect of acoustic radiation force, the push pulse causes tissue in the focal area to move away from the probe surface, simultaneously establishing a shear wave propagating away from the focal region in a direction perpendicular to the push beam.

For each lateral position along the shear wave pathway at the focal depth, the tissue motion induced by the shear wave will be mainly in the same direction as the push beam. Consequently, the tracking pulses can monitor such dynamic response for each position and derive, position-by-position, a displacement waveform representing the magnitude of tissue movement as a function of time.

By tracking displacements at multiple locations along the shear wave propagation path, one can estimate shear wave speed and further determine absolute values of tissue mechanical properties.

The speed at which a shear wave propagates inside tissue is governed, according to some mechanical models, by shear modulus, shear viscosity, tissue density and shear wave frequency.

The stiffer the tissue is, the faster the waves move -- however with lower shear wave vibration amplitude.

In one study, ex vivo porcine liver stiffness was found to be significantly greater for those areas that had undergone RFA than areas not treated. See H. Xie, S. Zhou, J. Robert and V. Shamdasani, "Quantitative Assessment of Thermal Lesion Stiffness in the Liver: Initial ex vivo Results", 2011 IEEE International Ultrasonics Symposium Proceedings, pp. 2098-2011.

The study notes that a combination of factors, including shear wave displacement signal-to-noise ratio (SNR), collectively amount to an upper limit in the accuracy of shear elasticity estimation, and that the SNR is bounded by FDA thermal and mechanical index limits applied to diagnostic ultrasound imaging.

In another in vivo study of acoustic radiation force impulse (ARFI) imaging of the heart, ARFI-induced displacements were found to rise with transmit power level. See D. Bradway, P. Hollender, et. al, "Feasibility and Safety of Transthoracic Cardiac Acoustic Radiation Force Impulse Imaging Methods", 2012 IEEE International Ultrasonics Symposium Proceedings, pp.2027-2030.

This included emissions with a mechanical index (MI) exceeding the FDA exposure limit for diagnostic ultrasound imaging of 1.9, although heat dissipation from physiological motion, and blood perfusion, of the heart diminished any potential bioeffects from temperature rise.

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SUMMARY OF THE INVENTION

What is proposed herein below addresses one or more of the above concerns.

For the application of liver RFA visualization and assessment, it is important to delineate the ablation zone with high accuracy. During the procedure, the stiffness will increase to approximately, by either measure, i.e., Young's modulus or the shear modulus (in soft tissues Young's modulus is about 3 times shear modulus), 50-200 kilopascals (kPa), leading to significant reduction in shear wave amplitude and poor shear wave SNR. If the displacement drops below the level of ultrasound motion tracking accuracy ($<1\mu\text{m}$), erroneous estimation, or even failure to yield a stiffness reading, will occur and result in inaccurate ablation zone visualization and potentially incomplete ablation treatment.

Visualizing and predicting the progress of a developing ablation region is important in guiding the therapy procedure and evaluating its effectiveness. To reliably distinguish surrounding non-treated normal tissue, the transition zone and the necrosis zone, shear wave elastography should have the capability of accurately and robustly quantifying a stiffness range from 5 kPa to potentially 200 kPa or even higher.

In accordance with what is proposed herein, incorporated into a diagnostic scanner is a specialized shear wave elastography feature. The feature can excite push pulses with higher driving voltage and/or longer push duration to enhance shear wave signal amplitude for targeted tumor ablation regions. Considering the invasive nature of liver RFA therapy, slightly exceeding diagnostic mechanical index (MI), thermal index (TI) and spatial-peak-temporal-average intensity (I_{SPTA}) safety limits should not pose the potential for more severe tissue damage than coagulation necrosis by thermal based therapy. Limited clinical trials have been carried out in vivo using shear wave elastography with acoustic output moderately elevated above the regulatory limits, just for diagnostic imaging purposes. In one study, push pulses with mechanical indices of 1.9, 2.5 and 3.0 were used on volunteers. As anticipated, no clinical evidence of adverse events has been reported. The advantages of what is proposed herein for therapy monitoring include more accurate tissue stiffness quantification, more robust measurement, and better imaging reproducibility than the shear

wave elastography feature currently designed for diagnostic imaging. To protect the patient's safety, multiple safety mechanisms are also proposed.

In one aspect of what is proposed herein, an ultrasound exposure safety processor is configured for spatially relating respective definitions of: a) an extended dead-tissue zone that includes both a dead-tissue zone and a surrounding margin; and b) an imaging zone. Based on whether a focus of a push pulse is to be within the extended dead-tissue zone, the processor automatically decides as to a level of acoustic power with which the pulse is to be produced, and causes the pulse to be produced with the decided upon level.

As a sub-aspect, the processor is configured for the producing, if the pulse focus is to be within the extended dead-tissue zone, with an MI, a TI, and/or an I_{SPTA} that exceeds respectively 1.9, 6.0 and 720 milliwatts per square centimeter.

Details of the novel, therapy specific ultrasound shear-wave-elastography exposure-safety facility are set forth further below, with the aid of the following drawings, which are not drawn to scale.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of one example of a system that features a therapy specific ultrasound shear-wave-elastography exposure-safety facility, in accordance with the present invention;

FIG. 2 is a conceptual and schematic diagram exemplary of user controls and irradiation levels, in accordance with the present invention;

FIGs. 3A, 3B, 3C, and 3D are conceptual and schematic diagrams of possible screens and possible body tissue regions, in accordance with the present invention; and

FIG. 4 consists of flow diagrams serving as examples of how the therapy specific ultrasound shear-wave-elastography exposure-safety facility operates.

DETAILED DESCRIPTION OF EMBODIMENTS

FIG. 1 depicts, by way of illustrative and non-limitative example, an ultrasound scanner 100 which incorporates a therapy specific ultrasound shear-wave-elastography exposure-safety facility. In effect, the facility is implementable on a conventional diagnostic ultrasound system. The scanner 100 includes an ultrasound imaging probe 102 that incorporates an ultrasound transducer 104, an ultrasound beamformer 108, an ultrasound exposure safety processor 112, and a user interface 116. The user interface 116

includes a display 118 having a screen 120, and a user control section 124 that includes a facility enablement switch 128 and a fingerprint scanner 132.

The transducer 104 is configured for conventional ultrasound imaging modes, e.g., A-mode, two-dimensional (or “B-mode”) imaging, Doppler, contrast imaging and etc. It is further configured for producing, i.e., forming and emitting, acoustic-radiation-force-based push pulses 136 for shear wave elastography imaging. Alternatively, separate transducers may be provided. For example, one can be designed for generating the push pulses 136 with foci 138. The other can be designed for generating tracking pulses along multiple beam directions, and for the B-mode imaging. The two types of transducer may be concentrically arranged. A dot 139 appears as a broken line in FIG. 1, and, as discussed further herein below, corresponds to an onscreen displayed symbol representative of the site of the focus 138.

Activation of the facility may be accomplished via the fingerprint scanner 132, as a safety measure. Alternatively, or in addition, it may be required that a password be entered.

The facility enablement switch 128, and its arrangement in the user control section 124, constitute an additional safety measure.

Referring to FIG. 2 which constitutes an example scenario, the user control section 124 includes multiple user-actuable buttons. The user control section 124 may be a system touch panel, keyboard, or part of the display screen 120. The buttons may be mechanical buttons or soft buttons on the display screen 120. More generally, they may be any types of user-actuable switches or other controls. Two of the buttons are specialized for activating respective modes of operation that both involve producing ultrasound push pulses, as in shear wave elastography applications. One of the modes may be a typical diagnostic mode for shear wave elastography. The other mode, the “therapy mode”, is specific to the exposure-safety facility. The two buttons 204, 208 are disposed at opposite ends 212, 216 of the control section 124. The diagnostic mode button 204 is colored green; whereas, the therapy mode button 208 for the exposure-safety facility is colored red. Also, the therapy mode button 208 has a label 209, icon 210 such as a cartoon, or both, representative of therapy. A cartoon, for example, may show the the multiple tips of an RFA electrode. By contrast, the diagnostic mode button 204 has no such label or icon. In the current example, the diagnostic mode button is provided with a visible label 211 representative of diagnostic imaging, such as “diagnosis.” The therapy mode button 208 is, in addition, considerably larger than the diagnostic mode button 204. Due to the above-

described design of the two buttons 204, 208, an operator is unlikely to inadvertently press one of the two buttons when the other one was intended. Moreover, even if the therapy mode button 208 were to be pressed in error, the operator would then be prompted for password or biometric activation of the exposure-safety facility.

5 In therapy mode for the example scenario of FIG. 2, push pulses 136 emitted to a region being treated are produced with an acoustic power that slightly exceeds FDA exposure limits for diagnostic ultrasound imaging. The larger acoustic power results in larger body tissue displacements and consequently greater SNR. Advantageously, what allows for this slight departure from FDA diagnostic safety standards is the fact that the push pulse 136
10 is placed at a site of thermal ablation, and any possible bioeffects of the push pulse, mainly thermal, would not negatively impact that site.

Acoustic power varies with a number of factors, such as pulse duration, transmit voltage and aperture size. Acoustic power can be assessed as an average acoustic power 220 over a predetermined time period 224, less than 100 milliseconds for example.

15 Acoustic power 220 beyond a predetermined power threshold 228 for a push pulse 136 is only enabled in therapy mode, and only if the focus 138 of the pulse is within the extended dead-tissue zone. The latter is a zone within the body tissue that includes a dead-tissue zone, such as an ablation zone, and a surrounding margin that can be planned and defined by the physician. The margin, which is at least partially surrounding, serves as a transition between
20 normal, untreated tissue and the ablation zone. An acoustic power 232 of X milliwatts (mW), which is equal to or below the threshold 228, might not, and at least typically would not, be used in therapy mode in the extended dead-tissue zone; whereas, an acoustic power 236 of Y mW which exceeds the threshold can only be produced in therapy mode and only if the focus 138 of the pulse 136 is in the extended dead-tissue zone. More particularly, by default, if not
25 always, therapy mode push pulses 136 whose foci 138 are in the extended dead-tissue zone are produced with an acoustic power that exceeds the threshold 228. Pulse 240 produced with acoustic power Y is, by virtue of the fact that Y exceeds the threshold 228, produced with at least one of a mechanical index (MI) 244, a thermal index (TI) 248, and a spatial-peak-temporal-average intensity (I_{SPTA}) 252 exceeding respectively 1.9, 6.0 and 720
30 milliwatts per square centimeter. Although pulses 136 can be produced with two levels of acoustic power, they can alternatively be produced with multiple levels. For example, the relatively high-powered pulse 240 may be produced with one level of acoustic power when focused in the dead-tissue zone and with another, possibly lower, level when focused in the margin, albeit at a level that still exceeds the power threshold 228.

FIG. 3A shows a dead-tissue zone 304 in which ablation occurs, surrounded by a margin 308. The zone 304 and its margin 308 collectively are referred to as an “extended dead-tissue zone” 312. The latter exists within body tissue 316 under skin 320 of a human or animal patient or within an ex vivo sample. The dead-tissue zone 304 may correspond to, or include, a tumor treated by ablation, such as RFA, HIFU and microwave ablation.

Like the two zones 304, 312 above, an elastography imaging zone is defined in a preliminary step in the therapy mode. It is within the imaging zone (illustrated in the examples below) where the foci 138 of therapy mode push pulses 136 are located; although, it is noted that a push pulse may be partially, or even totally albeit slightly, outside the imaging zone, and depicted as such by the placement of its corresponding symbol onscreen. In particular, an imaging zone exists, like the foci 138, within body tissue. Some of the foci 138 are outside the extended dead-tissue zone 312, so that stiffness readings from inside the zone can be compared to those from outside so as to localize a current border of the zone. The border between the margin 308 and the dead-tissue zone 304 is also monitored.

Although ablation, in the examples discussed herein, is the cause of death of the tissue in the dead-tissue zone 304, the intended scope of what is discussed herein is not limited to ablation. The cause of death may, for instance, be natural. In some of such cases, the slightly elevated power level of ultrasound exposure would not have any negative impact. In this scenario, elastography, shear wave or otherwise, may be performed for purposes other than determining borders. Such purposes may include staging, or fibrosis quantification, before surgery.

At least both the extended dead-tissue zone 312 and the imaging zone are depicted on the screen 120 of the display 118. A few examples reflecting particular user interactions are seen in FIGs. 3B, 3C, and 3D. B-mode images are shown, adhering to the convention that the fan-out narrows toward the top of the depiction, leading toward where the imaging probe 102 is located.

In Figure 3B, over a B-mode image 328, a definition 332 of the extended dead-tissue zone 312 is shown. An elastography imaging box 336 has a span 338 which is matched against a criterion in launching the push pulses 136 and intervening body-tissue displacement tracking, as discussed further below. The imaging box 336, a screen graphic, corresponds to an imaging zone 324 which exists within body tissue. In the current example, it can be seen that the imaging zone 324 is disjoint from or non-overlapping 340 with the extended dead-tissue zone 312. Accordingly, no relatively high power pulse 136 such as the

above-mentioned pulse 240 issues. Thus, the three pulse focus sites 344, 348, 352, appropriately are in the imaging zone 324 and are, as ordinarily would be this case, not in the extended dead-tissue zone 312. The three sites 344-352 are accordingly green, indicating that the respective pulses 136 are produced with a lower, diagnostic-mode type of acoustic power 232 such as that decided upon for a pulse 136 whose focus 138 is not within the
 5 extended dead-tissue zone 312. The three pulse focus sites 344-352 are depicted onscreen, overlaid onto the B-mode image 328, as symbols 356, 360, 364, such as dots.

For a second B-mode image 368 seen in FIG. 3C, the two zones 312, 324 overlap 370. The three dots 372, 376, 380 are red, since they are seen onscreen as
 10 superimposed on and therefore “in” the extended dead-tissue zone 312, implying that the respective pulse sites correspond to pulses 136 whose foci 138 are within the extended dead-tissue zone.

For a third B-mode image 384 as shown in FIG. 3D, the two zones 312, 324 again overlap. However, in perhaps a more typical scenario, the imaging zone 324
 15 overextends the extended dead-tissue zone 312 to form a non-overlapping portion 386. Four of the dots 387, 390, 391 and 394 are green, and four of the dots 388, 389, 392 and 393 are red. The elastography imaging zone 324 can be extended to match any targeted extent of the B-mode image 384 underlying the superimposed graphics such as the imaging box 336. In Figs. 3A-3D, the number of push foci 138 is selected just for illustration purposes. The
 20 actual number of push foci 138 in the lateral and axial directions is intelligently determined by the system depending on information of the push pulse acoustic characteristics, underlying tissue properties and the size of the elastography imaging box 336. “Axial” is in the imaging depth direction of the ultrasound probe 102. “Lateral” is in the azimuthal direction. As discussed in more detail below, whenever dots 387-394 are seen onscreen and the imaging
 25 box 336 meets a sufficient-size criterion, body tissue displacement tracking is ongoing for the respective sites. The tracking can be serial, site by site, or in parallel, as via multiline acquisition. The tracking entails, for each site 344, firing tracking pulses repeatedly, at a pulse repetition frequency (PRF) such as 2 kilohertz (kHz).

Operationally and as seen in FIG. 4, in a diagnostic mode subprocedure 410,
 30 the green button 204 is pressed (step S402). A mode leading to push pulse operation is thereby enabled (step S404). Any firing of a push pulse 136 is with its acoustic power not exceeding the power threshold 228.

When, in a main subprocedure 420, the red button 208 is pressed (step S412). The user is prompted to enter a password or input a biometric identifier, as by swiping a

finger over a fingerprint scanner (step S414). If the password/identifier is not accepted (step S416), the user is re-prompted (step S418) and return is made to step S414. The extended dead-tissue zone 312 is spatially defined (step S420). The definition 332 can be done either manually by the physician based on tumor appearance on real-time ultrasound imaging, or automatically by tumor segmentation through registering pre-surgery images captured by MRI, CT or other imaging modalities and real-time ultrasound images. In the first case, the system user interface will provide a simple tool to define shapes such as circle, ellipse, rectangle, square, and free-form polygons. Next, the ultrasound exposure safety processor 112 sets a box-span threshold T_{BS} , based on the size or an extent of the just-defined extended dead-tissue zone 312 (step S422). The larger the zone 312, the larger the span 338 of the imaging box 336 will tend to be. Launching and maintaining body-tissue displacement tracking is dependent of the span 338 being sufficiently large. The just-defined extended dead-tissue zone 312 is displayed on the screen 120 (step S424). At this point in the processing, a site visualizing subprocedure 430 and a displacement tracking subprocedure 440 are launched for concurrent execution with the next, i.e., imaging box manipulation, step of the instant subprocedure 420, with the displacement tracking subprocedure being “placed in a holding pattern” until the user sufficiently enlarges the imaging box 336. Next in the main subprocedure 420, the user control section 124 is utilized to manipulate (e.g., drag, expand, contract) the imaging box 336 based on location and size of the tumor in the B-mode image 328 and on what location is to be currently imaged by the tracking (step S426). The pulses 136 of a series may be focused on a particular site 344, or on a group 344-352 of sites, and may be repetitive over that group. Any push pulse site 344 added for the series by the manipulation of the imaging box 336 dynamically produces the pulses of the added site as part of the series. When it is detected, from the user control section 124, that the manipulation has ended (step S428) but has later resumed (step S430), return is made to the box manipulation step S426).

Concurrently with step S426 of the main subprocedure 420, the site visualizing subprocedure 430 visualizes the pulse sites 344. First, the ultrasound exposure safety processor 112 spatially relates the spatial definition 332 of the extended dead-tissue zone 312 to the spatial definition of the imaging zone 324 (step S432). The user may have provided the latter definition by the positions, and orientations, of the polygonal sides of the imaging box 336 or, in the case of a curved boundary, its position and, if applicable, orientation. With regard to the relating of the definitions and by way of example, if there is no overlap 370 between the imaging zone 324 and the extended dead-tissue zone 312 (step

S434), then, extending adjacently to, rather than toward or away from, the extended dead-tissue zone 312, there is formed a single linear array of foci 138 to be produced with acoustic power not exceeding the power threshold 228, as seen herein above for the three pulse focus sites 344-352 (step S436). Otherwise, if there is overlap 370 (step S434), the processing

5 choice depends on whether the imaging box 336 is fully within the extended dead-tissue zone 312 (step S438). If the imaging box 336 is fully within the extended dead-tissue zone 312 (step S438), then, within the extended dead-tissue zone 312, there is formed a single linear array of foci 138 to be produced with acoustic power 236 that exceeds the power threshold 228 (step S440). If, on the other hand, the imaging box 336 is not fully within the extended

10 dead-tissue zone 312 (step S438), the processing choice depends on whether the extended dead-tissue zone 312 is fully within the imaging box 336 (step S442). If the extended dead-tissue zone 312 is fully within the imaging box 336 (step S442), then, within the imaging box 336, a planar array of foci 138 in the axial and lateral directions is formed (step S444). Push pulses with foci 138 in the extended dead-tissue zone 312 are to be produced with acoustic

15 power 236 that exceeds the power threshold 228. Push pulses 136 with foci 138 not in the extended dead-tissue zone 312 are to be produced with acoustic power 232 that does not exceed the power threshold 228. An amount, or amounts, by which the imaging box 336 overextends the extended dead-tissue zone 312 can be taken into account. The automatic push pulse setting can, for example, create one or more push pulses outside the extended

20 dead-tissue zone 312 in correspondence with the determined amount, or amounts, of overextension. On the other hand, if the extended dead-tissue zone 312 is not fully within the imaging box 336 (step S442), other relation-based rules are applicable (step S446). For example, a partial overlap implies higher-powered pulses in the overlap portion and lower-powered pulses in the remaining imaging box portion. This approach could be potentially

25 used iteratively in ablating the entire tumor. In any event, regardless of the relation, symbols at the sites 344 of the respective foci 138 are displayed onscreen, e.g., as green or red dots 387-394 correspondingly (step S448). If imaging is complete (step S450), the subprocedure halts. Otherwise, if the adjusting is still being made (step S450), return is made to step S432.

Also concurrently with step S426 of subprocedure main 420, the displacement

30 tracking subprocedure 440 checks for when the box-span threshold T_{BS} is met (step S452). Upon being met (step S452), an ablation monitoring subprocedure 450 is launched, and, in the current subprocedure 440, each of a series of push pulses 136 is produced (step S454). The pulses 136 of the series may be focused on a particular site 344, or on a group of sites, and may be repetitive over that group. Each push pulse 136 generates a respective shear

wave originating from the site of the pulse (step S456). The consequent body tissue displacement, for each push pulse 136, is tracked by lateral location, and the tracking results are stored (step S458). If tracking is to continue (step S460), return is made to the threshold checking step S452.

5 Subprocedure 450 updates a stiffness map and, based on the map, distinguishes zones 304, 312 in real time. In particular, the tissue displacements stored in step S458 are utilized to derive a shear stiffness map of the imaging zone 324 (step S460). The map is used to spatially identify the current borders between ablated body tissue and a transition zone, and between the transition zone and normal, non-treated body tissue (step 10 S462). If this real-time monitoring is to continue (step S464), return is made to step S460.

 These borders can be visually monitored by the physician in controlling, or stopping, the ablation procedure, thereby enabling sufficient ablation without excess damage to body tissue 316. Lines representing the borders can be graphically depicted onscreen, or the borders can be surmised by the physician based on a displayed, dynamically-updated 15 color-coded rendition of the stiffness values in the map.

 An ultrasound exposure safety processor is configured for spatially relating respective definitions of an imaging zone, and an extended dead-tissue zone that includes both a dead-tissue zone and a surrounding margin. Based on whether a push pulse focus is to be within the extended dead-tissue zone, the processor automatically decides as to a level of 20 acoustic power with which the pulse is to be produced. If the pulse focus is to be within the extended dead-tissue zone, the pulse may be produced with an MI, a TI, and/or an I_{SPTA} that exceeds respectively 1.9, 6.0 and 720 milliwatts per square centimeter. The imaging zone may be definable interactively so as to dynamically trigger the deciding and the producing, with optimal push pulse settings being dynamically derived automatically, without the need 25 for user intervention. A display of multiple push pulse sites allows user manipulation of spatial definition indicia to dynamically control displacement tracking.

 The proposed methodology can advantageously be applied clinically in cardiac and non-cardiac treatment or examination. Clinical application can be made to examination or monitoring of bodily tissue such as the liver, prostate, and myocardium, 30 where local tissue stiffness will be elevated by therapy treatment, such as heat based RF ablation, HIFU and microwave ablation, or for staging a tumor pre-surgery.

 While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered

illustrative or exemplary and not restrictive; the invention is not limited to the disclosed embodiments.

For example, the shear stiffness map may be displayed as an overlay on the B-mode image supplemented with push pulse sites, or may be displayed separately, alongside, 5 overlaying a separate B-mode image. As another example, the visualization of extended dead-tissue zone, the imaging zone, pulse site symbols, and ultrasound image may be implemented as three-dimensional.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, 10 the disclosure, and the appended claims. In the claims, the word "comprising" does not exclude other elements or steps, and the indefinite article "a" or "an" does not exclude a plurality. Any reference signs in the claims should not be construed as limiting the scope.

A computer program can be stored momentarily, temporarily or for a longer period of time on a suitable computer-readable medium, such as an optical storage medium 15 or a solid-state medium. Such a medium is non-transitory only in the sense of not being a transitory, propagating signal, but includes other forms of computer-readable media such as register memory, processor cache and RAM.

A single processor or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different 20 dependent claims does not indicate that a combination of these measures cannot be used to advantage.

CLAIMS:

What is claimed is:

1. A medical ultrasound apparatus comprising:
 - an ultrasound exposure safety processor (112) configured for:
 - spatially relating respective definitions of: a) an extended dead-tissue zone that includes both a dead-tissue zone and a surrounding margin; and b) an imaging zone;
 - based on whether a focus of a push pulse is to be within said extended dead-tissue zone, automatically deciding as to a level of acoustic power with which said pulse is to be produced; and
 - causing said pulse to be produced with the decided upon level of acoustic power.
2. The apparatus of claim 1, further comprising a user interface (116) for the defining of said imaging zone interactively, said apparatus being configured for dynamically triggering said deciding responsive to said defining of said imaging zone.
3. The apparatus of claim 2, said defining, to which said triggering is responsive, comprising resizing an imaging box (336) sufficiently to achieve a predetermined span.
4. The apparatus of claim 1, said processor being configured for automatically, without need for user intervention, based on the relation, determining optimal push pulse settings.
5. The apparatus of claim 4, said settings being for forming a shear stiffness map based on a shear wave generated by said pulse (136), said determining being based on said forming.
6. The apparatus of claim 4, said apparatus being configured for the producing of said pulse dynamically taking into account a result of said determining (S434, S438, S442, S450, S454, S460).
7. The apparatus of claim 4, said determining comprising taking into account an amount of coverage, if any, by said imaging zone (324) over said extended dead-tissue zone.
8. The apparatus of claim 1, the causing being dynamically responsive to the defining of said imaging zone (S452).
9. The apparatus of claim 1, said pulse being one of a series of push pulses said processor causes to being produced with a respective decided upon level of acoustic power, said apparatus further comprising a display (118), said apparatus being configured for, via said display, spatially depicting concurrently two types of push pulses, in an instance in which said series of said pulses includes, as one of the types, at least one push pulse whose focus is in said extended dead-tissue zone and, as the other type, at least one other push pulse whose

focus is outside said extended dead-tissue zone, said display respectively indicating push pulse by push pulse, via their individual depictions, the type of the push pulse.

10. The apparatus of claim 1, said pulse being one of a series of push pulses said processor causes to being produced with a respective decided upon level of acoustic power, said apparatus further comprising a user interface and configured for visualizing, on said interface, sites (344-352) corresponding to the foci, said visualizing being dynamically responsive to said deciding.

11. The apparatus of claim 10, said visualizing comprising depicting symbols (356-364) correspondingly for said sites.

12. The apparatus of claim 11, said depicting being operative for a push pulse of said series whose focus is placed outside said extended dead-tissue zone (312).

13. The apparatus of claim 12, said depicting being operative for any push pulse of said series whose focus is placed outside said extended dead-tissue zone, both in cases in which the two definitions overlap (370) and in cases in which the two definitions do not overlap.

14. The apparatus of claim 11, further configured for depicting, via said user interface, concurrently with said symbols, spatial indicia of the two definitions (S426, S448).

15. The apparatus of claim 1, further comprising a user interface and configured for visual outlining of said imaging zone, on said interface, via an imaging box.

16. The apparatus of claim 15, further configured for, dynamically responsive to manipulation of said box (S426), updating said deciding (S432).

17. The apparatus of claim 16, said pulse being one of a series of push pulses said processor causes to being produced with a respective decided upon level of acoustic power (232, 236), said apparatus being further configured for dynamically producing, as part of said series, any push pulse added to said series by said manipulation.

18. The apparatus of claim 1, said margin (308) serving as a transition between non-treated, normal tissue and said dead-tissue zone, said apparatus being configured for, via shear wave elastography using said pulse, measuring stiffness of body tissue in said imaging zone so as to monitor, in real time, for spatially distinguishing among said normal tissue, said margin and said dead-tissue zone.

19. The apparatus of claim 1, said acoustic power being an average acoustic power (220) assessable over a period of predetermined duration not exceeding 100 milliseconds.

20. The apparatus of claim 1, said processor being configured such that the producing, if said focus (138) is to be within said extended dead-tissue zone, is, at least by default, with at least

one of a mechanical index (MI), a thermal index (TI), and a spatial-peak-temporal-average intensity (I_{SPTA}) exceeding respectively 1.9, 6.0 and 720 milliwatts per square centimeter.

21. The apparatus of claim 1, further comprising a user interface that includes a section (124) with manually-actuatable controls, said section having opposite ends, said apparatus being configured such that at least one of:

a) a first control from among said controls is located at one of said ends, a second control from among said controls is located at the other end; and

b) a first (208) of said controls is colored red and has at least one of a label, or icon, correspondingly representative of therapy, and a second of said controls is colored green and does not have such a label or icon,

said apparatus being further configured such that, in case said level exceeds a predetermined threshold, actuation of said first switch is required for activating the producing and such that actuation of said second switch, although leading to an operational mode for push pulses, does not activate any producing at a level exceeding said threshold.

22. The apparatus of claim 1, said deciding occurring in a given mode of operation, said apparatus having another mode of operation (S404) for producing push pulses in which said apparatus is incapable of producing any push pulse with an acoustic power as high as said level is enabled for in case said focus is, in said given mode, within said extended dead-tissue zone.

23. The apparatus of claim 1, said processor being further configured for subjecting, to password, or biometric identifier, protected activation, enablement of the producing, if said level exceeds a predetermined threshold (S228).

24. A computer readable medium embodying a computer program for ultrasound exposure safety, said program having instructions executable by a processor for performing a plurality of acts, among said plurality there being the acts of:

spatially relating (S432) respective definitions of: a) an extended dead-tissue zone that includes both a dead-tissue zone and a surrounding margin; and b) an imaging zone; and

based on whether a focus of a push pulse is to be within said extended dead-tissue zone, automatically deciding as to a level of acoustic power with which said pulse is to be produced.

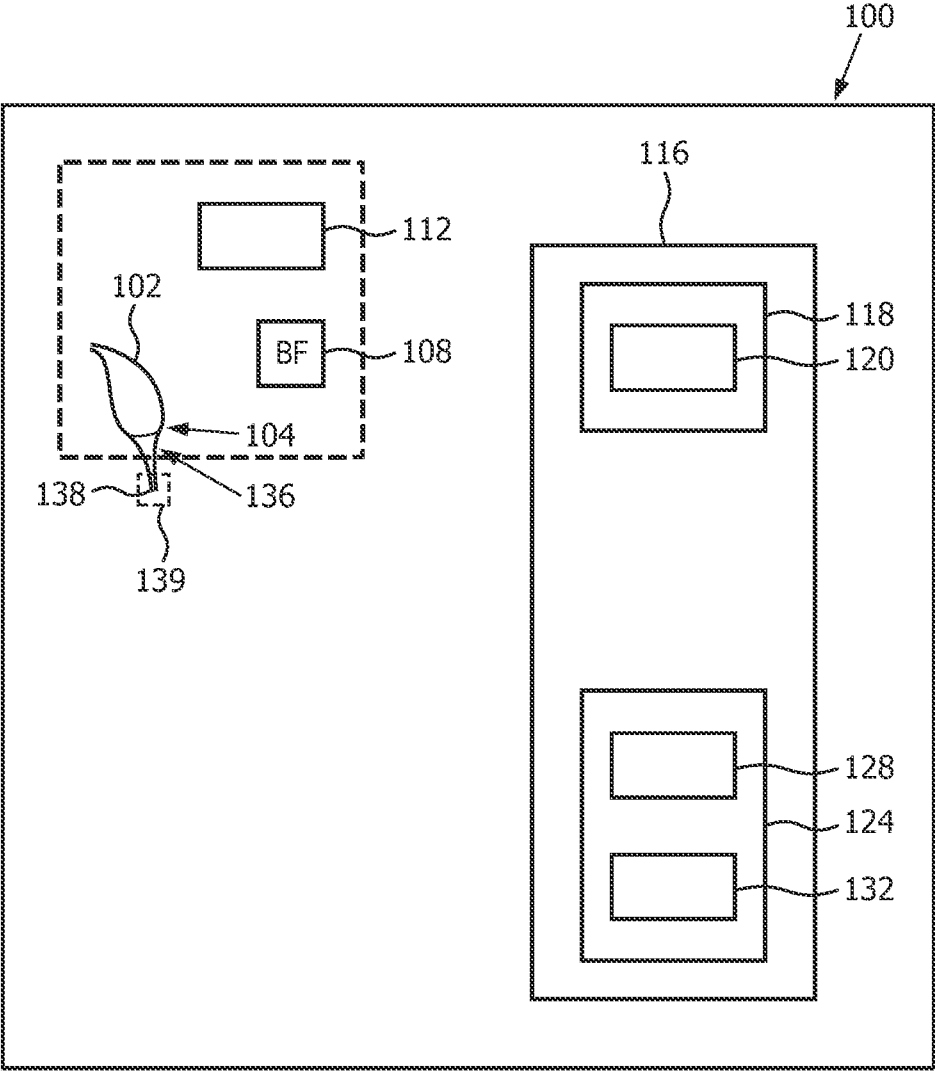


FIG. 1

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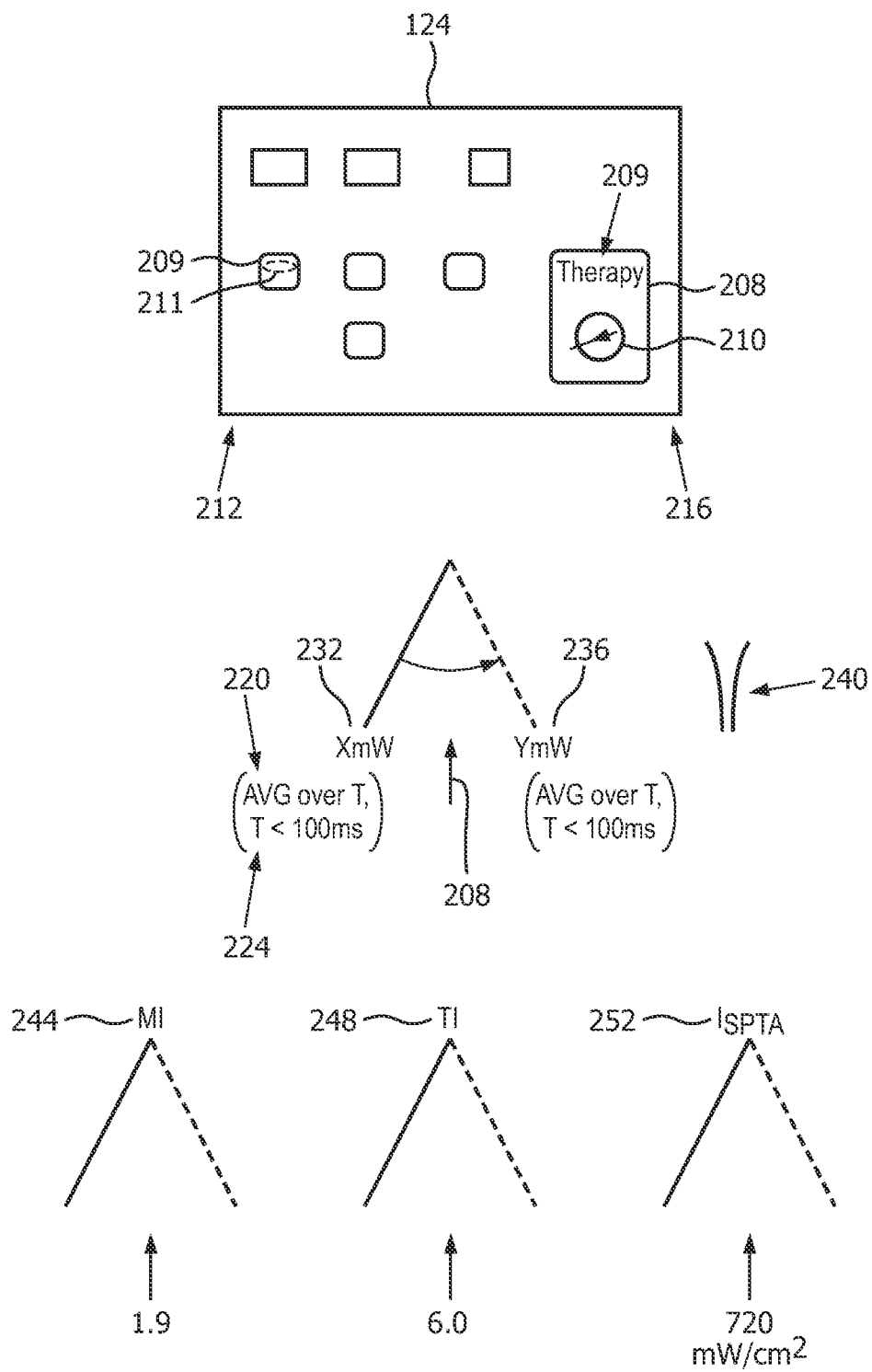


FIG. 2

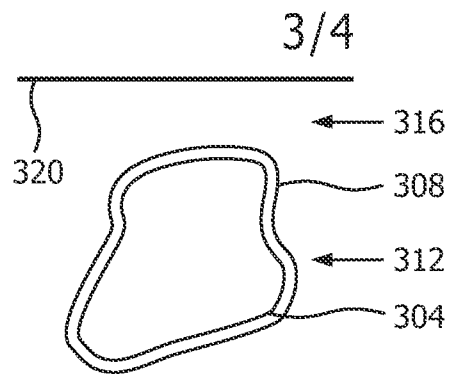


FIG. 3A

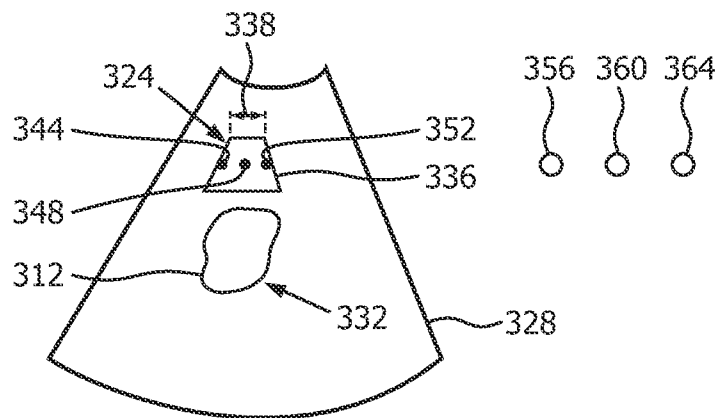


FIG. 3B

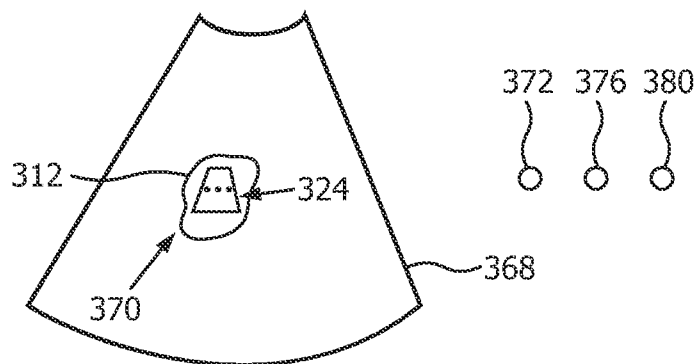


FIG. 3C

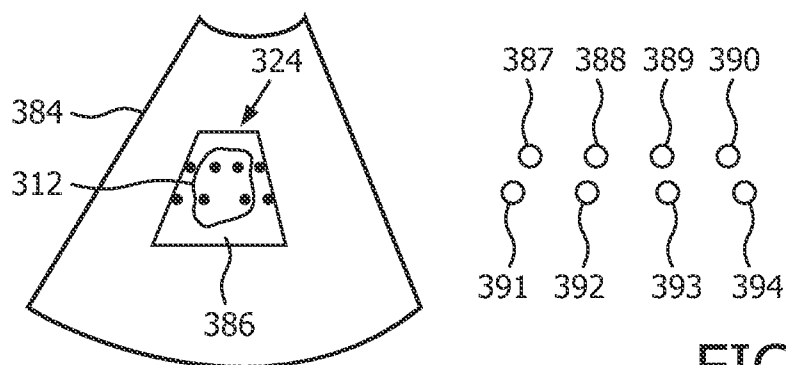


FIG. 3D

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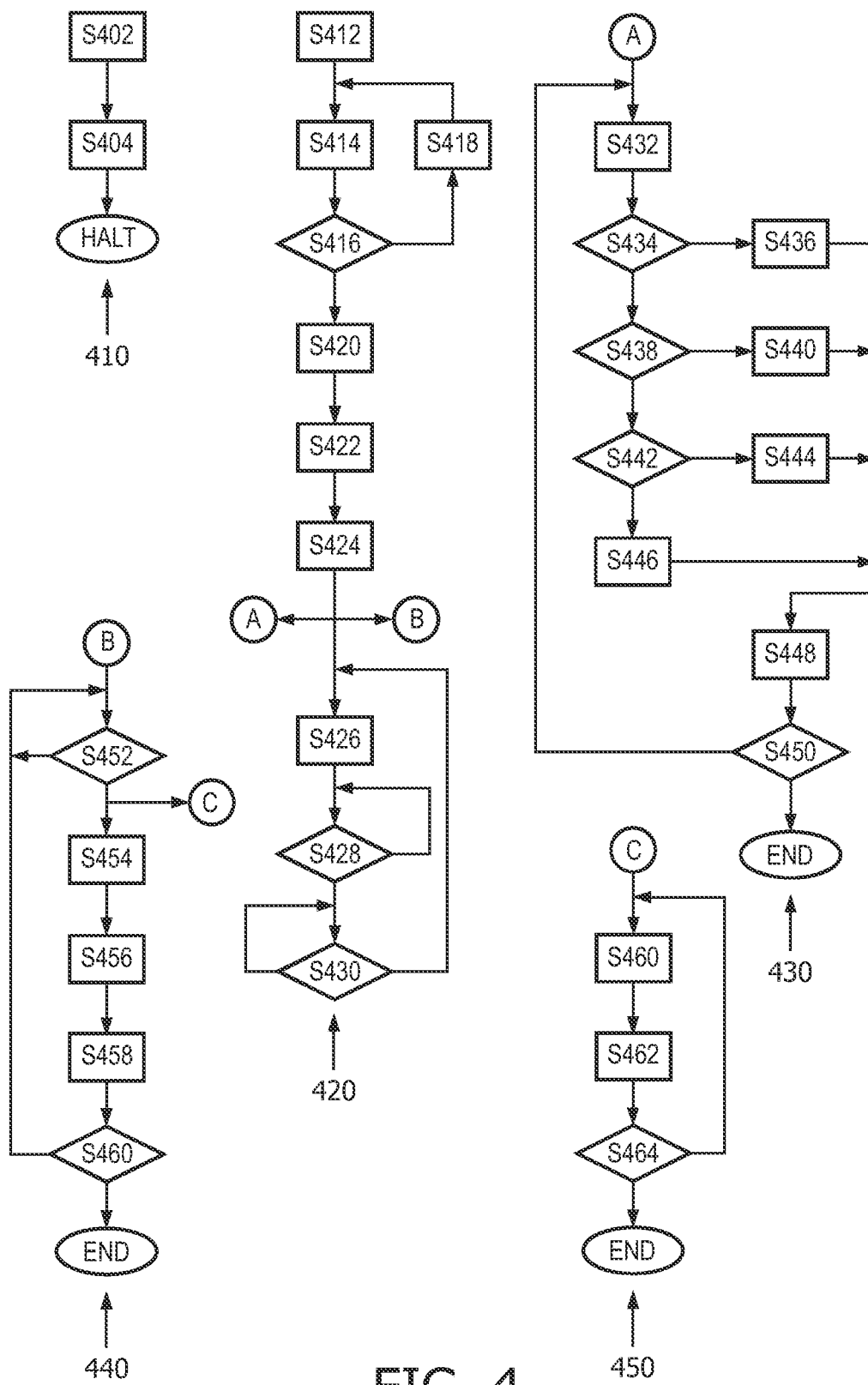


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2015/054498

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

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

B. FIELDS SEARCHED

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

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/215899 A1 (TRAHEY GREGG E [US] ET AL) 29 September 2005 (2005-09-29)	1-4, 6-20,22, 24
A	paragraphs [0004] - [0008], [0046] - [0085], [0088] - [0092]; figures	21,23
Y	US 2010/016719 A1 (FREIBURGER PAUL [US] ET AL) 21 January 2010 (2010-01-21) the whole document	1-4, 6-20,22, 24



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search

28 September 2015

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Küster, Gunilla

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2015/054498

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	LIZZI F L ET AL: "Radiation-force technique to monitor lesions during ultrasonic therapy", ULTRASOUND IN MEDICINE AND BIOLOGY, NEW YORK, NY, US, vol. 29, no. 11, 1 November 2003 (2003-11-01), pages 1593-1605, XP004477172, ISSN: 0301-5629, DOI: 10.1016/S0301-5629(03)01052-4 the whole document -----	1,24
A	FAHEY B J ET AL: "Acoustic radiation force impulse imaging of myocardial radiofrequency ablation: initial in vivo results", IEEE TRANSACTIONS ON ULTRASONICS, FERROELECTRICS AND FREQUENCY CONTROL, IEEE, US, vol. 52, no. 4, 1 April 2005 (2005-04-01), pages 631-641, XP011367382, ISSN: 0885-3010, DOI: 10.1109/TUFFC.2005.1428046 the whole document -----	1,24
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2015/054498

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US 2010016719	A1	21-01-2010	NONE
US 2012302883	A1	29-11-2012	KR 20120131552 A 05-12-2012 US 2012302883 A1 29-11-2012