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(54) **DEVICE AND SYSTEM FOR GENERATING ULTRASONIC WAVES IN A TARGET REGION OF A SOFT SOLID AND METHOD FOR LOCALLY TREATING A TISSUE**

VORRICHTUNG UND SYSTEM ZUR ERZEUGUNG VON ULTRASCHALLWELLEN IN EINER ZIELREGION EINES WEICHEN FESTSTOFFES

DISPOSITIF ET SYSTÈME POUR GÉNÉRER DES ONDES ULTRASONORES DANS UNE RÉGION CIBLE D'UN SOLIDE MOU

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EP-A1- 1 795 131 **WO-A1-02/09813**
US-A1- 2005 154 382 **US-A1- 2015 065 916**

Description

TECHNICAL FIELD OF THE INVENTION

[0001] This invention relates to a device for generating ultrasonic waves in a target region of a soft solid. The invention also relates to a system for generating ultrasonic waves, which includes such a device. Finally, this invention also relates to a method for locally treating a tissue of a subject with ultrasonic waves.

[0002] In the meaning of the present invention, a soft solid is an organic tissue which can have an animal or vegetal origin. For instance, such a soft solid can be an organ of a human body, of an animal body or of a vegetable.

BACKGROUND OF THE INVENTION

[0003] As mentioned in WO-A-2006/021651, ultrasounds can be used for the treatment of varicose veins. In such a case, a thermal effect of high-intensity ultrasound waves is used in order to shrink a vein wall.

[0004] A cavitation phenomenon can also be used. For instance, for the treatment of varicose veins, cavitation bubbles are created in order to generate local shock waves when they collapse. This allows destroying the endothelium of a given vein or vessel. In order to obtain a significant cavitation phenomenon, ultrasonic waves must be generated and focused at the right location. To this end, crossed ultrasonic beams can be used, as mentioned in EP-A-2 636 428.

[0005] Spider veins, that are close to the skin of a subject, are sometimes visible or partially visible. It is known to treat a vein at several points along its length in order to increase the efficiency of a treatment. However, when one places a treatment device on the skin of a subject or patient, this device hides the vein, so that the practitioner cannot accurately orientate and/or move the device in order to precisely focus ultrasonic waves on the venin, along its path.

[0006] As mentioned in WO-A-2014/160964, one can use an ultrasound imaging probe in order to detect a target within a soft body, this being based on an ultrasound technology. However, such an ultrasonic probe is expensive and hardly detects a vein with a small diameter, where blood flows with a low flow rate. Actually, a vein where blood has a low flow rate is difficult, and sometimes impossible, to detect via Doppler or B-mode ultrasound technology. Actually, the smaller a vein is and the lower the blood flow rate in a vein is, the more difficult and the more costly the detection is.

[0007] On the other hand, WO-A-2009/112969 and WO-A-2012/156863 rely on the application of high intensity focused ultrasound (HIFU) with different types of ultrasound sources. They do not allow precisely controlling where the ultrasonic waves are applied.

[0008] EP-A-1 795 131 discloses a HIFU system which includes a treatment head with a light source illuminating the skin of a patient. Such a construction does not allow obtaining a clear image of an object located below the skin, such as a vein. Moreover, a single ultrasound transducer is used, which implies that the cavitation zone obtained at its focal point might be unstable. In addition, as visible for instance on figure 3 of this document, the light source is radially offset from an imaging unit, which does not allow precise enlightening of an object to be viewed.

[0009] WO-A-02/09813 discloses a method and a device for epilation where a single intrinsically focused transducer is used, with the same inconvenients as above with regards to the stability of the cavitation zone. Some lighting means are provided in the form of a low intensity laser, for aiming the ultrasonic beam, and a light source, for illuminating an area to be viewed. These items are not mounted on a body of the device but connected to it via light guides, which is cumbersome. Moreover, the light is directed towards the skin, which is satisfactory for seeing a hair for epilation, but does not allow clearly seeing an object located below the skin, such as a vein. The light coming from the laser or the light source arrives in a central axial zone of the device, in the same zone as the boresight of a video camera. Thus, only direct illumination of the skin is possible.

[0010] In another technical field, that is in the field of laser treatment, it is known from US-A-2005/154382 to use several light sources with an offset camera. It is also known from US- A-2015/065916 to use several light emitting diodes and several detectors is a vascular imaging system. These devices are expensive, cumbersome and difficult to use.

[0011] Similar issues of potential hiding of a zone to be treated occur for the treatment of acne, wrinkles, cellulitis, tattoos, melanoma and lentigines.

SUMMARY OF THE INVENTION

[0012] This invention aims at solving the problems of the known techniques with a new device which is efficient to generate ultrasonic waves in a target region of a soft solid and allows a practitioner to precisely choose where ultrasonic waves focus, in particular for obtaining a cavitation phenomenon at one or several given points, below the skin surface of a patient.

[0013] To this end, the invention relates to a device for generating ultrasonic waves in a target region of a soft solid according to claim 1.

[0014] Thanks to the invention, the light sources allow enlightening or illuminating a zone of the soft solid, in contact with the device, in particular the skin of a subject. These light sources also allow illuminating, by sub surface scattering (SSS), also known as subsurface light transport (SSLT), a portion of a muscle or tissue below the skin, which enables detection of spider veins and similar irregularities within a tissue such as acne, wrinkles, cellulitis, tattoos, melanoma and lentigines. In particular, in comparison to the teachings of EP-A-1 795 131 or WO-A-02/09813, operation of the device is not limited to seeing the skin of a patient. This derives from the fact that the different light sources distributed around the central axis have light beams that penetrate into the target region at several locations around the central axis, which induces a good illumination of the common focal point from different directions. Such an approach cannot be implemented if one uses a single light source, either centered on a central axis, as in WO-A-02/03813, or offset with respect to such an axis, as in EP-A-1 795 131. In addition, using at least two ultrasonic sources allows stabilizing the cavitation zone at their common focal point, which makes the device of the invention much easier to use than prior art systems. Thanks to the lighting means and embedded video camera of the invention, which are oriented towards the common focal point of the ultrasound sources, it is not necessary to use expansive pieces of equipment such as ultrasonic sensors or a Doppler camera, in order to efficiently position the device with respect to the soft solid. For instance, once the camera detects a vein or another irregularity in a tissue, the practitioner can use this detection to properly locate and/or move the device with respect to the tissue, in order to apply focused ultrasonic waves in the target region.

[0015] According to further aspects of the invention which are advantageous but not compulsory, the device might incorporate one or several of the following features, taken in any technically admissible configuration:

- A cavity, located in front of the or all ultrasonic source(s), is filled with a coupling medium and, in case this coupling medium is liquid, obturated by a membrane which belongs to an end surface of the device, is flexible, acoustically and optically transparent, has parallel main surfaces and a thickness below 100 μm, preferably below 50 μm, more preferably equal to about 35 μm.
- The coupling medium has an acoustic impedance between 1,45 and 1,65 10^6.kg.$s^{-1} \cdot m^{-2}$, more preferably equal to about 1.54 10^6.kg$\cdot s^{-1} \cdot m^{-2}$, and is optically transparent.
- The light sources are distributed around the cavity.
- The light sources are mounted within a series or holes provided on said body or on a ring mounted around said body, said holes being distributed around the central axis in such a way that light beams emitted by the light sources do not cross the cavity.
- The boresight of the video camera crosses a transparent part, also mounted on the body and which separates the video camera from the cavity.
- The light source are made of LEDs.
- The wavelength of the light emitted by the LEDs is selected between 586 and 605 nm, in particular in the yellow and/or orange spectrum.
- The video camera has automatic gain control.
- The device includes detection means for detecting ultrasonic waves in the target region and means for providing a user with a signal representative of the level of scattered ultrasonic waves. The detection means advantageously include some ultrasonic transducers which also constitute the ultrasonic sources.
- The lighting means are mounted on a support member adapted to come into contact with and to bear against a surface of the soft solid.
- The body of the device is designed and configured to be held in one hand,
- The position and/or orientation of the video camera within the body of the device is adjustable.

[0016] The invention also relates to a system for generating ultrasonic waves in a target region of a soft solid, this system including a device as mentioned here-above and a screen for displaying images captured by the video camera.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The invention will be better understood on the basis of the following description which is given in correspondence with the appended figures and as an illustrative example, without restricting the object of the invention. In the annexed figures:

- figure 1 is a perspective exploded view of a device according to a first embodiment of the invention;
- figure 2 is a perspective view of the device of figure 1 at a smaller scale ;
- figure 3 is a cut view along plane III on figure 2 at a larger scale ;
- figure 4 is a schematic representation of the use of a system including the device of figures 1 to 3;
- figure 5 is a perspective exploded view, similar to figure 1, for a device according to a second embodiment of the invention;
- figure 6 is a perspective view of the device of figure 1 at a smaller scale ;
- figure 7 is a cut view along plane VII on figure 6 at a larger scale;
- figure 8 is a bloc diagram of a method for using the device of figures 1 to 3 or the device of figures 5 to 7.

DETAILED DESCRIPTION OF SOME EMBODIMENTS

[0018] The device 2 represented on figures 1 to 3 constitutes a probe which belongs to a system schematically represented on figure 4.

[0019] Figures 1 to 3 show the structure of device 2, whereas figure 4 includes a functional representation of this device.

[0020] Device 2 includes a rigid body 20 made of a synthetic material such as plastic ABS or Nylon (registered trademark). This body 20 is centered on a longitudinal axis X2 and extends between a front end 22 and a rear end 24.

[0021] Next to front end 22, body 20 defines an opened cavity 26 which is obturated by a flexible membrane 28 made of an elastomer material, such as silicon, polyester, poly(methyl) methacrylate or PMMA. Membrane 28 is optically transparent in the visible range.

[0022] Membrane 28 is held in position on front end 22 of body 20 by a retaining ring 30 which is mounted around a front portion 20A of body 20 and pinches membrane 28 around an outer radial surface S20 of this front portion.

[0023] Three piezoelectric ceramic transducers 32 are mounted within front portion 20A of body 20 with their active faces 322 oriented towards membrane 28 and towards axis X2. Transducers 32 are regularly distributed around axis X2. These three transducers 32 are designed and mounted onto body 20 in such a way that the ultrasonic waves respectively originating from these three ultrasound sources are focused and converge to a common focal point P which is located on axis X2, beyond membrane 28 with respect to transducers 32. Ultrasound sources formed by transducers 32 can also be said to be confocal at point P.

[0024] Transducers 32 work at a frequency between 0,1 and 10 MHz, preferably between 500 kHz and 3 MHZ and more preferably equal to about 1,6 MHz. Each time, a transducer 32 is actuated for a duration between 5 and 20 seconds.

[0025] Membrane 28 is also acoustically transparent in the frequency working range of transducers 32.

[0026] When it is mounted on body 20, ring 30 has an end face 302 which is flush with a terminal edge 202 of front portion 20A. Thus, edge 202 and end face 302 together define an end surface S2 of device 2 which is perpendicular to axis X2. Focal point P is beyond surface S2 with respect to the three ultrasound sources formed by transducers 32.

[0027] The active surface 322 of each transducer 32 is in the form of a portion of the sphere centered on this focal point. Actually, the wall of body 20 which defines cavity 26 may also be in the form of a portion of a sphere centered on this focal point P, which makes the assembly of device 2 easier. However, another shape is also possible for this cavity. Each transducer 32 is mounted within a housing formed by a hole 206 which extends through front portion 20A. When transducers 32 are mounted within their respective housings 206, their active surfaces 322 define, together with an inner surface of front portion 20A and membrane 28, cavity 26.

[0028] As visible on figure 3, ring 30 is provided, next to end face 302, with a reduced diameter inner radial surface S30 whose diameter is adjusted to the diameter of outer radial surface S20, so that membrane 28 is efficiently pinched between surfaces S30 and S20. Ring 30 also includes a skirt 306 which has an axial length, measured along axis X2, selected so that ring 30 bears against an annular outer collar 20D of body 20 when ring 30 is mounted around body 20. In this configuration, surface 302 is flush with edge 202, as mentioned here-above.

[0029] Actually, collar 20D separates front portion 20A and rear portion 20B of body 20.

[0030] Skirt 306 extends at a slight radial distance of surface S20, which avoids a risk of wedging ring 30 when it is mounted onto body 20.

[0031] On figure 1, membrane 28 is represented on the left of ring 30, that is in front of it. Actually, when it is mounted on body 20, membrane 28 is located at the level of surface 302 along axis X2 and radially between surfaces S20 and S30, where it is pinched. Thus, when it is mounted on body 20, membrane 28 belongs to end surface S2.

[0032] Cavity 26 is filled with a coupling medium, more particularly a coupling fluid, which allows ultrasonic waves originating from transducers 32 to propagate within cavity 26. The coupling fluid is selected in order not to attenuate, or to attenuate as little as possible, ultrasound waves coming from transducers 32. For instance, it can be made of water cleared of gases. Alternatively, the coupling medium can be made of a gel.

[0033] This coupling medium is selected in order to minimize reflection and refraction of ultrasounds on membrane 28 and in order to maximize ultrasound transmission through this membrane. This coupling medium is identified with reference 34 on figures 3 and 4. It is optically transparent, at least in the visible range. Hereafter, Z_1 denotes the acoustic impedance of a tissue to be treated with system 4 and c_1 denotes the ultrasound waves velocity within this tissue. Similarly, Z_{34} and c_{34} denote the acoustic impedance and ultrasound wave's velocity of medium 34. Considering the case where device 2 is used to treat varicose veins in a human body, and considering that transmission is optimal when Z_{34} equals Z_1 and c_{34} equals c_1, one chooses a coupling medium with an acoustic impedance between 1,35 and 1,65 $10^6.kg \cdot s^{-1} \cdot m^{-2}$, more preferably equal to about 1.54 $10^6.kg \cdot s^{-1} \cdot m^{-2}$. Thus, coupling medium 34 is acoustically transparent for the ultrasonic waves emitted by transducers 32, i.e. in the frequency working range of transducers 32.

[0034] Moreover, in order not to alter the acoustic waves coming out of transducers 32, membrane 28 is chosen with parallel main surfaces, at least in its portion perpendicular to axis X2. In other words, its main surfaces perpendicular to axis X2 are parallel to each other. Its thickness is below 100 micrometers (μm), preferably below 50 μm, more preferably equal to about 35 μm. The material of membrane 28 is preferably transparent to ultrasound waves.

[0035] A series of light sources formed by some LEDs 40 is mounted within ring 30. Actually, ring 30 is provided with twenty through-holes 304 and one LED 40 is installed within each through-hole. Through-holes 304 are regularly distributed around axis X2 when ring 30 is mounted on body 20. Through-holes are each aligned on an axis A304 and all axes A 304 converge on a point Q which belongs to axis X2. As visible on figure 3, point Q is further away from membrane 28 and surface S2 than focal point P.

[0036] A target zone Z_1 is defined, which includes points P and Q and is centered on axis X2. Transducers

32 and LEDs 40 are oriented towards target zone Z_1. Target zone Z_1 is identified with hatches on figures 3 and 4. Its actual shape depends on the structure and control of transducers 32 and LEDs 40.

[0037] LEDs 40 are oriented towards axis X2 and their respective light beams B40 converge to the front, towards this axis, with an angle of convergence α between 45 and 60°. In other words, these light beams B40 make an angle between 30 and 45° with the skin of a patient when device 2 is in use. This angle with the skin of a patient is also the angle between beams B40 and end face 302.

[0038] LEDs 40 are mounted on body 20 via ring 30.

[0039] LEDs 40 are used to enlighten or illuminate the skin of a subject or patient when device 2 is in use. Actually, LEDs 40 enlighten or illuminate not only the outer surface of the skin of the subject but also a portion of the tissue located below the skin, via sub surface scattering.

[0040] Device 2 also includes a video camera 50 which is mounted within body 20. In other words, video camera 50 is embedded in body 20. More precisely, body 20 has an inner cylindrical wall 20C which defines a recess, centered on axis X2 for accommodating video camera 50. An elastomeric gasket 52 is mounted within wall 20C and holds video camera 50 within the recess. Video camera works in the visible range. In practice, video camera 50 is a micro video camera, that is a camera with a length smaller than or equal to 20 mm, preferably 15 mm, and a diameter smaller than or equal to 25 mm, preferably 15 mm.

[0041] Video camera 50 is arranged within body 20 in such a way that its boresight is aligned with axis X2. The boresight of camera 50 is oriented towards membrane 28, in the direction of arrow A50 on figure 3. Thus, camera 50 is also oriented towards target zone Z_1. Camera 50 is separated from cavity 26 by a transparent part 54, more precisely a cylindrical part centered on axis X2 and made of poly(methyl) methacrylate or PMMA, also known as Plexiglas (registered trademark). This part 54 allows camera 50 capturing pictures through cavity 26 and membrane 28.

[0042] The low thickness of membrane 28 avoids perturbating waves going through this membrane, including ultrasonic waves coming from transducers 32 and images captured by video camera 50. In other words, no significant visual interference or sound attenuation is generated by membrane 28.

[0043] Device 2 also includes a printed circuit board or PCB 60 which is received within its rear portion 20B and which is used to control transducer 32 and camera 50 and to connect them to other parts of system 4.

[0044] Body 20 also includes a cover 20E which is adapted to be mounted on rear portion 20B once items 50 and 60 have been immobilized on body 20. A control switch 70 is mounted on cover 20E and is used by a practitioner in order to activate transducers 32 via PCB 60, when appropriate.

[0045] A rear cap 80 is mounted on rear end 24 and a rear portion of cover 20E. Rear cap 80 holds cover 20E in position with respect to the remaining portions of body 20. Apart from cover 20E, body 20 is integral. Rear cap 80 is provided with holes or connectors to allow electrical connection of device 2 to other parts of system 4 via electric lines which are not represented on figures 1 to 3. One such hole is visible on figure 3. Actually, on figures 1 to 3, no electric cable is represented, for the sake of clarity.

[0046] As shown on figures 1 to 3, the general cylindrical shape of device 2 allows it to be held in one hand, with one finger pressing on switch 70 when necessary.

[0047] Body 20 is provided, in its surface defining cavity 26, with non represented recesses to accommodate bubbles potentially formed within medium 34 during use of device 2. Moreover, a channel is formed through body 20 in order to fill cavity 26 with coupling medium 34, the outlet of this channel is visible on figure 3, with reference 38.

[0048] In the use configuration shown on figure 4, PCB 60 is used to match the impedance in order to drive transducers 32 which generate acoustic waves focused on point P. On figure 4, arrows S60 represent the control of transducers 32 by PCB 60.

[0049] In the example of figure 4, a varicose vein V of a subject's tissue T is to be treated for destruction of its endothelium.

[0050] Camera 50 is used to efficiently locate or "place" device 2 with respect to tissue T, more particularly to its skin S, in order for this point P to coincide with varicose vein V or similar irregularities. When using system 4, the practitioner starts, in a first step a) represented on figure 8, by placing device 2 in contact with a primary zone of the patient's skin S where veins V to be treated are likely to be located. Identification of this primary zone can be performed with unaided eye.

[0051] The method also includes a step b) where transducers 32 are actuated, in order to generate cavitation bubbles within the patient's body, as mentioned hereabove.

[0052] A step c) is also implemented, where an image feedback of the tissue is obtained via camera 50.

[0053] In order for steps b) and c) to be realized efficiently, a step d) is implemented where LEDs 40 are actuated. During step b), the light beams B40 coming out of diodes 40 enlighten the portion of tissue T immediately adjacent to membrane 28 and to front end surface S2 of device 2, which allows camera 50 to capture images within a cone C_{50} which represents its visibility zone. In other words, a zone Z_2 of tissue T, which is identified in grey on figure 4, is targeted or enlightened via diffusion of light by beams B40. This zone Z_2 includes a disc of skin S and a layer of tissue T below this disc. This allows video camera 50, which is a relatively simple and inexpensive device, to efficiently capture images allowing visualizing vein V.

[0054] Illumination of zone Z_2 by LEDs 40 occurs as long as camera 50 captures images. In other words, step c) occurs only when step d) is implemented.

[0055] Advantageously, step b) also occurs only when step d) is implemented.

[0056] System 4 also includes a screen 6 which is connected to video camera 50 via a connecting line L6 and where an image V' of vein V, captured by video camera 50, can be shown in a further step e) of the method. A user of system 4 who has device 2 in hand and watches screen 6 can thus adapt the position of device 2 with respect to tissue T, in a further step f), in order to efficiently treat vein V by focusing beams B40 on this part of tissue T. In other words, step f) is implemented by the practitioner using device 2 to adapt the placement of device 2 with respect to the patient's skin S and tissue T. During steps e) and f), steps b), c) and d) are still implemented. In particular, the user can move device 2 along vein V in order to make point P coincident with vein V on several locations, for treating this vein along its path within tissue T.

[0057] In order to take into account possible variations of the ambient lighting and possible variations of the response of the tissue T to the light emitted by LEDs 40, video camera 50 preferably has automatic gain control. This allows optimizing the contrast of the images to display the veins or irregularities on screen 6.

[0058] System 4 also includes a signal coupler 8, an electronic control unit 10 for acquiring and treating a signal S8 coming out of signal coupler 8, a signal generator 12 controlled by unit 10 via a control signal S10 and an amplifier 14 which delivers to coupler 8 an amplified signal S14.

[0059] According to an advantageous aspect of the invention, transducers 32 can also be used in order to control cavitation by monitoring ultrasonic waves within tissue T. In such a case, an output signal S32 of each transducer 32, which corresponds to the level of scattered ultrasonic waves, is delivered to PCB 60 which provides it to signal coupler 8 and electronic control unit 10. An output device, such as a loudspeaker 16, is used to inform the practitioner or user of system 4 of the efficiency of the cavitation level within tissue T. For instance, the level and/or frequency of the sound emitted by loudspeaker 16 can be based on the output signal S32 of transducers 32, thus be representative of the level of scattered ultrasonic waves.

[0060] Alternatively, instead of loudspeaker 16, other means can be used to inform the practitioner about the detected ultrasonic waves, such as a dedicated screen, a subscreen of screen 6 or a LED or lamp visible by the practitioner which blinks when cavitation takes place, etc...

[0061] According to an alternative embodiment of the invention, sensors different from transducers 32 can be used in order to provide information to electronic control unit 10 with respect to the cavitation level within tissue T.

[0062] From a practical point of view, it appears that the wavelength of the light emitted by LEDs 40, which is in the visible range, can be selected between 586 and 605 nanometers (nm), in particular in the yellow and/orange spectrum, which allows an efficient illumination of zone Z_2, including by sub surface scattering or SSS.

[0063] As shown on figure 3, rear portion 20BA body 20 is provided with slides 20F for holding PCB 60 in position. These slides can also be used to house one or several tubes for feeding cavity 26 with coupling medium 34. In such a case, these tubes are connected to the channel whose outlet is visible with reference 38 on figure 3.

[0064] Ring 30 has a beveled surface 303 which converges towards end face 302. This allows surface 302, which defines the interface between device 2 and skin S during use of device 2, having a diameter D302 substantially smaller than the outer diameter D30 of ring 30 which cannot be reduced since LEDs 40 are accommodated within this ring. This enables reducing the friction surface on the skin S of the subject or patient to a disc of diameter D302. In practice, beveled surface 303 is dimensioned and oriented so that an angle β between surfaces 302 and 303 is between 30 and 45°.

[0065] Device 2 is easy to manipulate, with one hand, by a practitioner who can watch screen 6 as explained here-above. Device 2 is used as a big pen or probe, which is consistent with its ergonomics. Actually, depending on the habits of a practitioner, he/she might grip body 20 with different fingers so that the placement and displacement of device 2 with respect to tissue T might be different from one user to the other. In order to take this into account, and according to a non-represented aspect of the invention, the position and/or orientation of video camera 50 within body 20 is adjustable.

[0066] Since LEDs 40 are mounted within ring 30 which comes into contact with the skin S of a patient when the practitioner starts using device 2 and bears against skin S when lighting means are activated, the quantity of light transferred from LEDs 40 to enlightened zone Z_2 is maximal. This improves the quality of the images captured by video camera 50.

[0067] In the second embodiment of the invention represented on figures 5 to 7, the portions of device 2 of the second embodiment which are similar to the ones of the first embodiment have the same references. This second device or probe 2 can also be used as a part of the system of figure 4 and works substantially as device 2 of the first embodiment. Here-after, only the differences with the first embodiment are explained.

[0068] The rear cap 80 is formed of two halves 80A and 80B which are clipped together by elastic tongues 80C and corresponding recesses 80D. In this embodiment, the LEDs 40 are received within through holes 204 evenly distributed around axis X2 and provided within collar 20D.

[0069] Figure 7 shows one slide 20F of body 20 aligned with a channel 20G which has an outlet 38 connected to cavity 26. A non represented tube can be installed within slide 20F in order to feed channel 20G and cavity 26. This cavity is made within a front portion 20A of body 20 surrounded by three rings, namely an inner ring 31, an intermediate ring 33 and an outer ring 35. A holding member 53 is provided at the interface between rings 33 and 35. Ring 35 is aligned, along a direction parallel to axis X2, with light sources constituted by LEDs 40 and forms a wave guide for the light emitted by these LEDs, towards an end surface S2 of device 2.

[0070] This second embodiment has been designed to be compatible with an adjustment of the axial distance defined between focal point P and membrane 28, allowing the practitioner to adjust depth of penetration of the cavitation into tissue T. This is to treat more or less deep veins. For that purpose ring 31 is designed with an external thread which fits with an internal thread provided on ring 33. This ring 33 is also equipped with a circumferential groove 51 in which a non-represented O-ring is inserted. Ring 31 is hermetically bonded on front portion 20A of body 20. Ring 33 is screwed on ring 31 and membrane 28 is pinched by holding member 53 on ring 33 or bonded directly on the holding member 53. This assembly can be filled with coupling liquid and remains hermetic whatever the position of the ring 33 along axis X2 is, thanks to O-ring located in groove 51. Ring 35 is made of a transparent material, like PMMA or another transparent plastics. It is inserted on ring 33 and insures conduction of the light emitted by the LEDs 40.

[0071] The front edge 352 of outer ring 35 is beveled rearwardly towards axis X2 and membrane 28 is pinched between rings 35 and 33.

[0072] A ring 37 is mounted around rear portion 20B and collar 20D of body 20 and protects LEDs 40 and their wiring against contact with the user. As in the first embodiment, transducers 32 which form ultrasound wave sources, LEDs 40 and video camera 50 are mounted on body 20. In this case, LEDs 40 are directly mounted within holes 204 formed in body 20, whereas in the first embodiment, LEDs 40 are mounted on body 20 via ring 30 which is immobilized onto this body.

[0073] In this second embodiment, transducers 32, LEDs 40 and camera 50 are also oriented towards a target zone Z_1 visible on figure 6, which includes focal point P of transducers 32 and convergence point Q of LEDs 40.

[0074] Device 2 of this second embodiment can be used to implement the method of figure 8.

[0075] In both embodiments, the use of LEDs as lighting means is advantageous in terms of life time and because of the relatively low temperature of a diode, as compared to an incandescent bulb, which avoids burning the skin of a patient. Moreover, the lighting power of LEDs can be easily adjusted.

[0076] In both embodiments, the fact that the boresight of video camera 50 is aligned on central axis X2 induces that this boresight is globally perpendicular to the skin 5 of the patient when device 2 is in use. This makes it more intuitive to use.

[0077] In both embodiments, since LEDs 40 are located around transducers 32, light beams B40 do not have to cross cavity 26. This avoids reflection issues with respect to light beams B40 crossing coupling medium 34, whereas such a reflection could alter the quality of the images captured by video camera 50.

[0078] The invention is explained here above in case device 2 includes three ultrasound sources formed by transducers 32. However, it can also work with a single ultrasound source, with two such sources or with four such sources or more. With a single transducer used as an ultrasound source, the bubbles can be pushed away by a radiation force. This is why, in such a case, one should prefer a highly focalized ultrasound source. The interest of using several ultrasound sources is to create a network of interferences in a focal zone, where the cavitation bubbles can be trapped. Another interest of this approach is to reduce the size of the focal volume for improving treatment spatial resolution.

[0079] The invention is explained here-above in case video camera works in the visible range. Alternatively, an infra-red (IR) video camera can be used. In such a case, membrane 28 and coupling medium 34 are optically transparent in the IR range and the light used to enlighten zone Z_2 is adapted.

[0080] According to another approach, a lighting light with a different wavelength, e.g. ultraviolet, might be used to highlight a specific target. This could be coupled to the injection of a fluorescent agent.

[0081] The invention is explained here above in case it is used for treating a varicose vein. It can also be used for the treatment of acne, wrinkles, cellulites, tattoos, melanoma and/or lentigines. It can also be used for generating ultrasonic waves in a human or animal body.

[0082] According to a non represented alternative embodiment of the invention, the coupling medium which fills cavity 26 can be solid. In such a case, membrane 28 can be omitted.

Claims

1. Device (2) for generating ultrasonic waves in a target region (V) of a soft solid (T), this device including at least one ultrasound source (32) for generating ultrasonic waves in the soft solid, lighting means, for enlightening a zone (Z2) of the soft solid (T), and a video camera (50), for capturing images (V') in the zone (Z2) enlightened by the lighting means, wherein:

   - the device includes at least two ultrasound sources (32), preferably three ultrasound sources, mounted on a body (20) of the device and focused at a common focal point (P) in a target zone (Z_1), beyond an end surface (52) of the device with respect to the ultrasound sources,
   - the lighting means include several light sources (40) for enlightening the zone (Z_2) of the soft solid (T) via subsurface scattering, the light sources being distributed around a central axis (X2) of the device that includes a focal point (P)

of all the ultrasound sources (32),
- the ultrasound sources (32), the lighting sources (40) and the video camera (50) are mounted on the body (20) of the device and oriented toward the common focal point (P) in the target zone (Z_1),
- a boresight (A50) of the video camera (50) is aligned on the central axis (X2) of the device (2).

2. A device according to claim 1, **characterized in that** a cavity (26) located in front of all ultrasound source(s) (32) is filled with a coupling medium (34) and, in case this coupling medium is liquid, obturated by a membrane (28) which belongs to an end surface (32) of the device (2), is flexible, acoustically and optically transparent, has parallel main surfaces and a thickness below 100 μm, preferably below 50 μm, more preferably equal to about 35 μm.

3. A device according to claim 2, **characterized in that** the coupling medium (34) has an acoustic impedance between 1,45 and 1,65 $10^6.kg \cdot s^{-1} \cdot m^{-2}$, more preferably equal to about 1.54 $10^6.kg \cdot s^{-1} \cdot m^{-2}$, and is optically transparent.

4. A device according to one of claims 2 or 3, **characterized in that** the light sources (40) are distributed around the cavity (26).

5. A device according to one of claims 2 to 4, **characterized in that** the light sources (40) are mounted within a series of holes (204; 304) provided on said body (20) or on a ring (30) mounted around said body, said holes being distributed around the central axis (X2) in such a way that light beams (B40) emitted by the light sources (40) do not cross the cavity (26).

6. A device according to one of claims 2 to 5, **characterized in that** the boresight (A50) of the video camera (50) crosses a transparent part (54), also mounted on the body (20) and which separates the video camera from the cavity (26).

7. A device according to any preceding claims, **characterized in that** the lighting means (40) are located around the ultrasound source (32).

8. A device according to any preceding claim, **characterized in that** the light sources are made of LEDs (40).

9. A device according to claim 8, **characterized in that** the wavelength of the light emitted by the LEDs (40) is selected between 586 and 605 nm, in particular in the yellow and/or orange spectrum.

10. A device according to any preceding claim, **characterized in that** the video camera (50) has automatic gain control.

11. A device according to any preceding claim, **characterized in that** it includes detection means (32), in particular some ultrasonic transducers (32) which also constitute the ultrasound sources, for detecting ultrasonic waves in the target region (V) and means (16) for providing a user with a signal representative of the level of scattered ultrasonic waves.

12. A device according to any preceding claim, **characterized in that** the lighting means (40) are mounted on a support member (30) adapted to come into contact with and to bear against a surface (S) of the soft solid (T).

13. A device according to any preceding claim, **characterized in that** the body (20) is designed and configured to be held in one hand.

14. A device according to any preceding claim, **characterized in that** the position and/or orientation of the video camera (50) within the body of the device is adjustable.

15. A system (4) for generating ultrasonic waves in a target region (V) of a soft solid (T), this system including:

- a device (2) according to any preceding claim,
- a screen (6) for displaying images captured by the video camera (50) of the device.

Patentansprüche

1. Vorrichtung (2) zum Erzeugen von Ultraschallwellen in einer Zielregion (V) eines weichen Feststoffes (T), wobei diese Vorrichtung mindestens eine Ultraschallquelle (32) zum Erzeugen von Ultraschallwellen in dem weichen Feststoff, Beleuchtungsmittel zum Beleuchten einer Zone (Z2) des weichen Feststoffes (T) und eine Videokamera (50) zum Aufnehmen von Bildern (V') in der von den Beleuchtungsmitteln beleuchteten Zone (Z2) umfasst, wobei:

- die Vorrichtung mindestens zwei Ultraschallquellen (32), vorzugsweise drei Ultraschallquellen umfasst, die an einem Körper (20) der Vorrichtung montiert sind und zu einem gemeinsamen Brennpunkt (P) in einer Zielzone (Z_1)außerhalb einer Stirnfläche (52) der Vorrichtung in Bezug auf die Ultraschallquellen fokussiert sind,
- die Beleuchtungsmittel einige Lichtquellen (40) zum Beleuchten der Zone (Z_2) des weichen Feststoffs (T) über eine Volumenstreuung umfassen, wobei die Lichtquellen um eine Mittelachse (X2) der Vorrichtung, die einen Brenn-

punkt (P) aller Ultraschallquellen (32) enthält, verteilt sind,
- die Ultraschallquellen (32), die Lichtquellen (40) und die Videokamera (50) an dem Körper (20) der Vorrichtung montiert sind und zu dem gemeinsamen Brennpunkt (P) in der Zielzone (Z_1) gerichtet sind,
- eine Ziellinie (A50) der Videokamera (50) auf die Mittelachse (X2) der Vorrichtung (2) ausgerichtet ist.

2. Vorrichtung nach Anspruch 1, **dadurch gekennzeichnet, dass** eine Kavität (26), die vor allen Ultraschallquellen (32) liegt, mit einem Koppelmedium (34) gefüllt ist und im Fall, dass dieses Koppelmedium Flüssigkeit ist, durch eine Membran (28) verschlossen ist, die zu einer Stirnfläche (32) der Vorrichtung (2) gehört, flexibel, akustisch und optisch transparent ist, parallele Hauptflächen und eine Dicke unter 100 μm, vorzugsweise unter 50 μm, noch bevorzugter gleich ungefähr 35 μm aufweist.

3. Vorrichtung nach Anspruch 2, **dadurch gekennzeichnet, dass** das Koppelmedium (34) eine akustische Impedanz zwischen 1,45 und 1,65 10^6 $kg.s^{-1}.m^{-2}$, vorzugsweise gleich ungefähr 1,54 10^6 $kg.s^{-1}.m^{-2}$ aufweist und optisch transparent ist.

4. Vorrichtung nach einem der Ansprüche 2 oder 3, **dadurch gekennzeichnet, dass** die Lichtquellen (40) um die Kavität (26) herum verteilt sind.

5. Vorrichtung nach einem der Ansprüche 2 bis 4, **dadurch gekennzeichnet, dass** die Lichtquellen (40) in einer Reihe von Löchern (204; 304), die an dem Körper (20) vorgesehen sind, oder an einem Ring (30) montiert sind, der um den Körper herum montiert ist, wobei die Löcher um die Mittelachse (X2) herum derart verteilt sind, dass die von den Lichtquellen (40) abgegebenen Lichtstrahlen (B40) nicht die Kavität (26) kreuzen.

6. Vorrichtung nach einem der Ansprüche 2 bis 5, **dadurch gekennzeichnet, dass** die Ziellinie (A50) der Videokamera (50) ein transparentes Teil (54) durchquert, das ebenfalls an dem Körper (20) montiert ist und das die Videokamera von der Kavität (26) trennt.

7. Vorrichtung nach irgendeinem vorhergehenden Anspruch, **dadurch gekennzeichnet, dass** die Beleuchtungsmittel (40) um die Ultraschallquelle (32) herum angeordnet sind.

8. Vorrichtung nach Anspruch 8, **dadurch gekennzeichnet, dass** die Lichtquellen aus LEDs (40) bestehen.

9. Vorrichtung nach Anspruch 8, **dadurch gekennzeichnet, dass** die Wellenlänge des von den LEDs (40) abgegebenen Lichts zwischen 586 und 605nm ausgewählt ist, insbesondere in dem gelben und/oder orangefarbenem Spektrum liegt.

10. Vorrichtung nach irgendeinem vorhergehenden Anspruch, **dadurch gekennzeichnet, dass** die Videokamera (50) eine automatische Verstärkungsregelung aufweist.

11. Vorrichtung nach irgendeinem vorhergehenden Anspruch, **dadurch gekennzeichnet, dass** sie Detektionsmittel (32), insbesondere einige Ultraschallwandler (32), die auch die Ultraschallquellen bilden, zum Erfassen von Ultraschallwellen in der Zielregion (V) und Mittel (16) zum Liefern eines Signals an einen Benutzer umfasst, das repräsentativ für den Pegel der gestreuten Ultraschallwellen ist.

12. Vorrichtung nach irgendeinem vorhergehenden Anspruch, **dadurch gekennzeichnet, dass** die Beleuchtungsmittel (40) an einem Trägerelement (30) montiert sind, das angepasst ist, in Kontakt mit und abstützend an einer Fläche (S) des weichen Feststoffs (T) zu kommen.

13. Vorrichtung nach irgendeinem vorhergehenden Anspruch, **dadurch gekennzeichnet, dass** der Körper (20) so entworfen und konfiguriert ist, dass er in einer Hand gehalten wird.

14. Vorrichtung nach irgendeinem vorhergehenden Anspruch, **dadurch gekennzeichnet, dass** die Position und/oder Ausrichtung der Videokamera (50) in dem Körper der Vorrichtung einstellbar ist

15. System (4) zum Erzeugen von Ultraschallwellen in einer Zielregion (V) eines weichen Feststoffs (T), wobei dieses System umfasst:

- eine Vorrichtung (2) nach irgendeinem vorhergehenden Anspruch,
- einen Bildschirm (6) zum Anzeigen von Bildern, die von der Videokamera (50) der Vorrichtung aufgenommen sind.

Revendications

1. Dispositif (2) pour générer des ondes ultrasonores dans une région cible (V) d'un solide mou (T), ce dispositif comprenant au moins une source d'ultrasons (32) pour générer des ondes ultrasonores dans le solide mou, des moyens d'éclairage pour éclairer une zone (Z2) du solide mou (T) et une caméra vidéo (50) pour prendre des images (V') dans la zone (Z2) éclairée par les moyens d'éclairage, dans lequel :

le dispositif comprend au moins deux sources d'ultrasons (32), de préférence trois sources d'ultrasons, montées sur un corps (20) du dispositif et concentrées sur un point focal commun (P) dans une zone cible (Z_1), au-delà d'une surface d'extrémité (52) du dispositif par rapport aux sources d'ultrasons,
les moyens d'éclairage comprennent plusieurs sources de lumière (40) pour éclairer la zone (Z_2) du solide mou (T) via la transluminescence, les sources de lumière étant réparties autour d'un axe central (X2) du dispositif qui comprend un point focal (P) de toutes les sources d'ultrasons (32),
les sources d'ultrasons (32), les sources d'éclairage (40) et la caméra vidéo (50) sont montées sur le corps (20) du dispositif et orientées vers le point focal commun (P) dans la zone cible (Z_1), une ligne de visée (A50) de la caméra vidéo (50) est alignée sur l'axe central (X2) du dispositif (2).

2. Dispositif selon la revendication 1, **caractérisé en ce qu'**une cavité (26) positionnée en face de toutes les sources d'ultrasons (32) est remplie avec un milieu de couplage (34) et, dans le cas où ledit milieu de couplage est liquide, obturée par une membrane (28) qui appartient à une surface d'extrémité (32) du dispositif (2), est flexible, transparent du point de vue acoustique et optique, a des surfaces principales parallèles et une épaisseur inférieure à 100 μm, de préférence inférieure à 50 μm, encore de préférence égale à environ 35 μm.

3. Dispositif selon la revendication 2, **caractérisé en ce que** le milieu de couplage (34) a une impédance acoustique comprise entre 1,45 et 1,65 10^1.kg.s^{-1}·m^{-2}, encore de préférence égale à environ 1,54 10^6.kg.s^{-1}·m^{-2} et est optiquement transparent.

4. Dispositif selon l'une des revendications 2 ou 3, **caractérisé en ce que** les sources de lumière (40) sont réparties autour de la cavité (26).

5. Dispositif selon l'une des revendications 2 à 4, **caractérisé en ce que** les sources de lumière (40) sont montées dans une série de trous (204 ; 304) prévus sur ledit corps (20) ou sur une bague (30) montée autour dudit corps, lesdits trous étant répartis autour de l'axe central (X2) de sorte que des faisceaux lumineux (B40) émis par les sources de lumière (40) ne traversent pas la cavité (26).

6. Dispositif selon l'une des revendications 2 à 5, **caractérisé en ce que** la ligne de visée (A50) de la caméra vidéo (50) traverse une partie transparente (54), également montée sur le corps (20) et qui sépare la caméra vidéo de la cavité (26).

7. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les moyens d'éclairage (40) sont positionnés autour de la source d'ultrasons (32).

8. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les sources de lumière sont composées de LED (40).

9. Dispositif selon la revendication 8, **caractérisé en ce que** la longueur d'onde de la lumière émise par les LED (40) est sélectionnée entre 586 et 605 nm, en particulier dans le spectre jaune et/ou orange.

10. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** la caméra vidéo (50) a un contrôle de gain automatique.

11. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce qu'**il comprend des moyens de détection (32), en particulier certains transducteurs ultrasonores (32) qui constituent également les sources d'ultrasons, pour détecter les ondes ultrasonores dans la région cible (V) et des moyens (16) pour fournir, à un utilisateur, un signal représentatif du niveau d'ondes ultrasonores diffusées.

12. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les moyens d'éclairage (40) sont montés sur un élément de support (30) adapté pour venir en contact avec et s'appuyer contre une surface (S) du solide mou (T).

13. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le corps (20) est conçu et configuré pour être tenu à une main.

14. Dispositif selon l'une quelconque des revendications précédentes, **caractérisé en ce que** la position et/ou l'orientation de la caméra vidéo (50) à l'intérieur du corps du dispositif est ajustable.

15. Système (4) pour générer des ondes ultrasonores dans une région cible (V) d'un solide mou (T), ce système comprenant :

un dispositif (2) selon l'une quelconque des revendications précédentes,
un écran (6) pour afficher les images prises par la caméra vidéo (50) du dispositif.

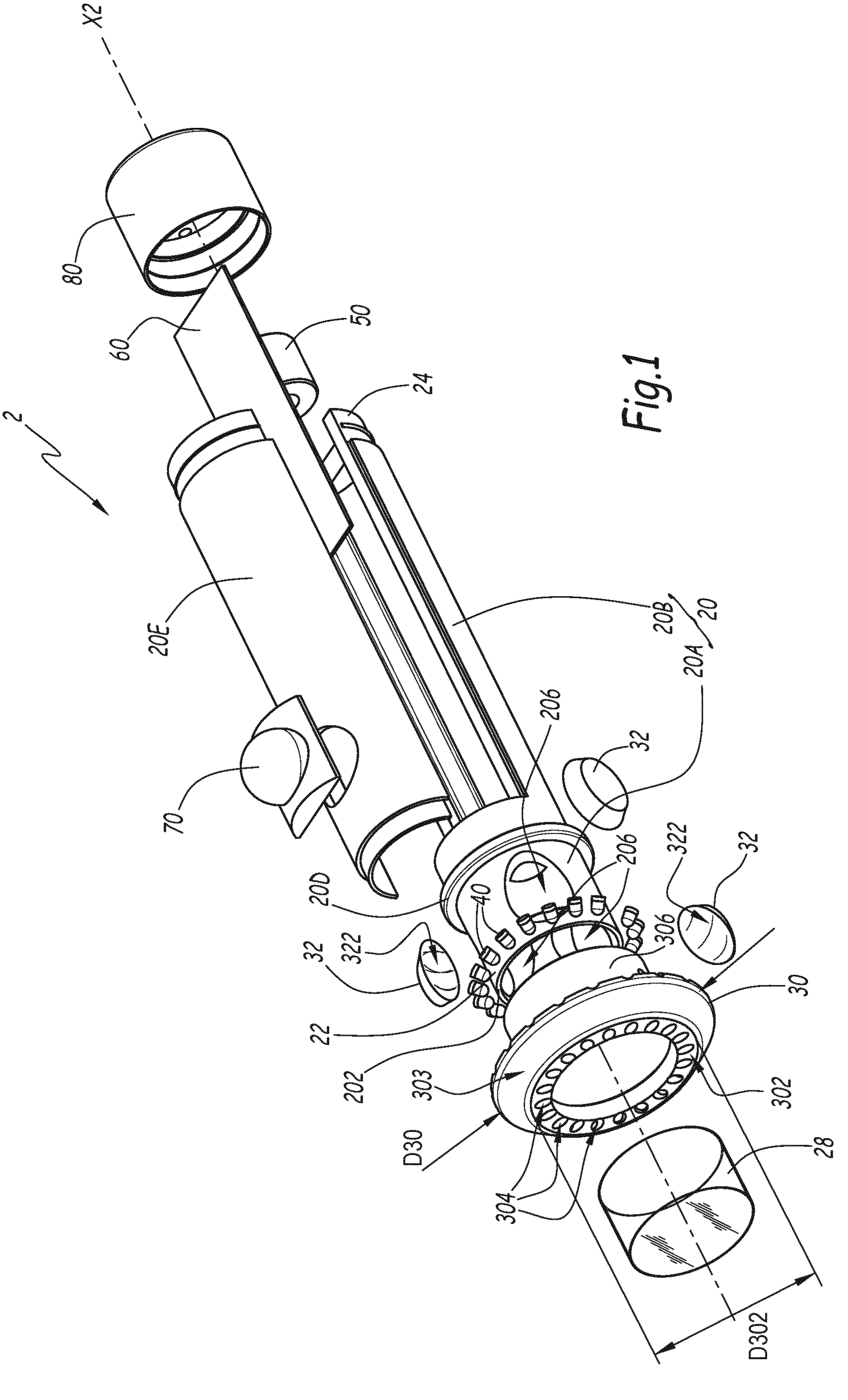

X2
80
60
50
24
2
20E
20B
20
20A
70
206
32
20D
40
206
322
32
306
322
32
22
30
202
303
302
D30
304
28
D302

Fig.1

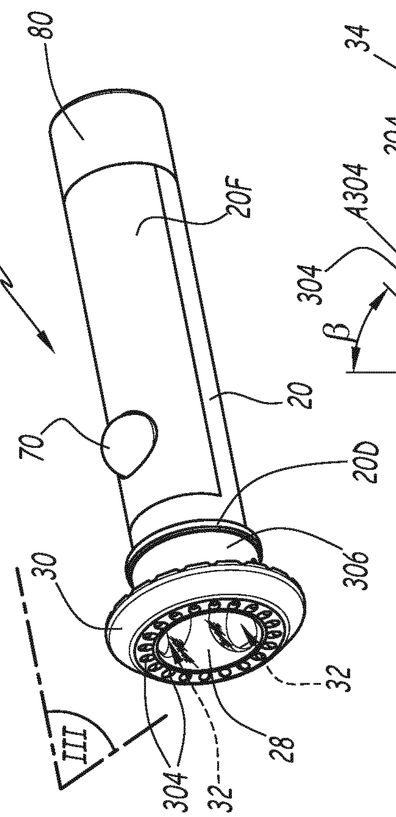
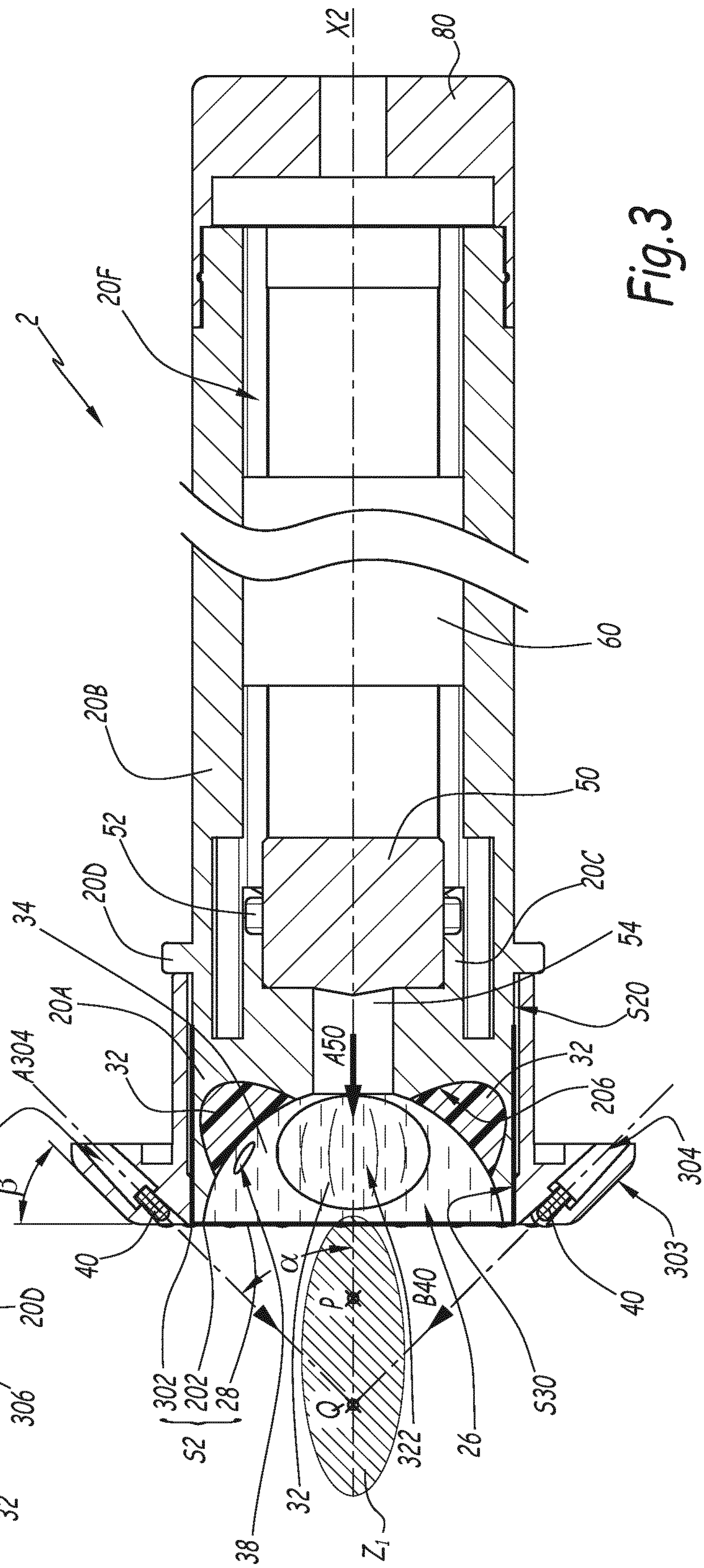

2
80
20F
20
70
20D
306
30
32
28
304
III

Fig. 2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2
20F
60
20B
50
52
20D
34
20C
54
20A
A304
S20
32
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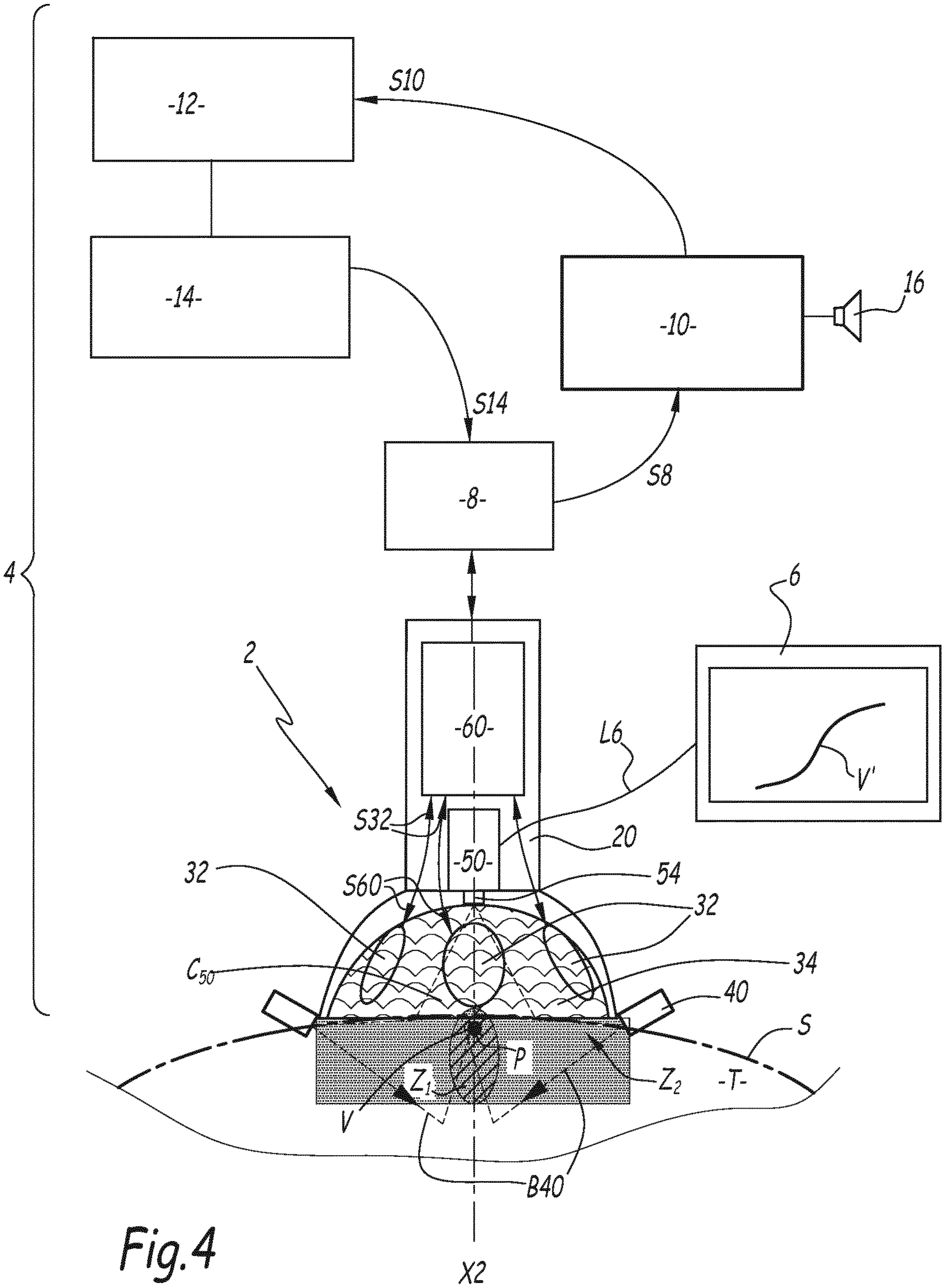
32
206
304
β
304
303
40
40
α
P
B40
Q
302
202
28
S2
38
32
322
26
S30
Z1

Fig.3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S10
-14-
-10-
16
S14
-8-
S8
4
6
2
-60-
L6
V'
S32
20
-50-
32
S60
54
32
C50
34
40
S
P
Z1
Z2
-T-
V
B40
X2

Fig.4

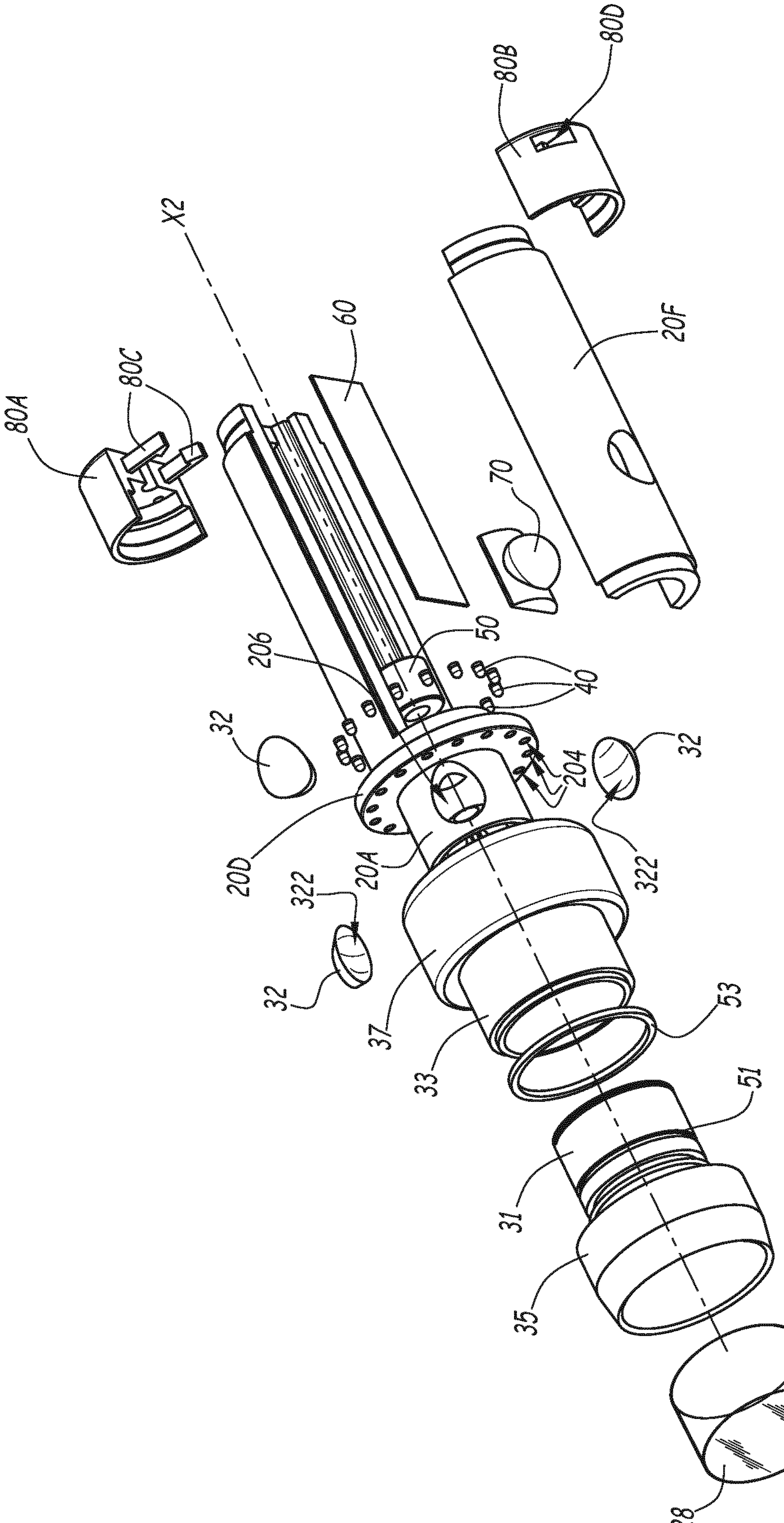
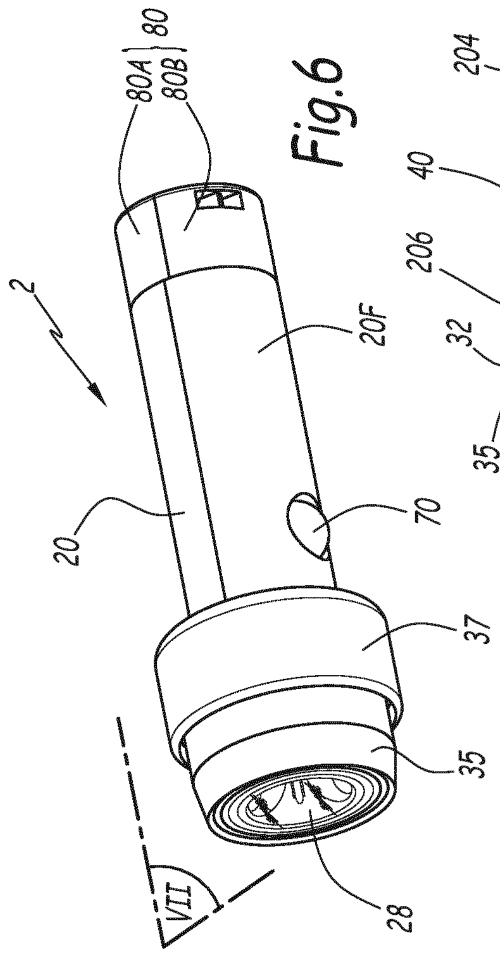

80A
80C
80B
80D
X2
60
20F
70
50
206
40
32
204
20D
20A
322
37
33
53
51
31
35
28

Fig.5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20
20F
70
37
35
28
80A
80B
80
VII

Fig.6

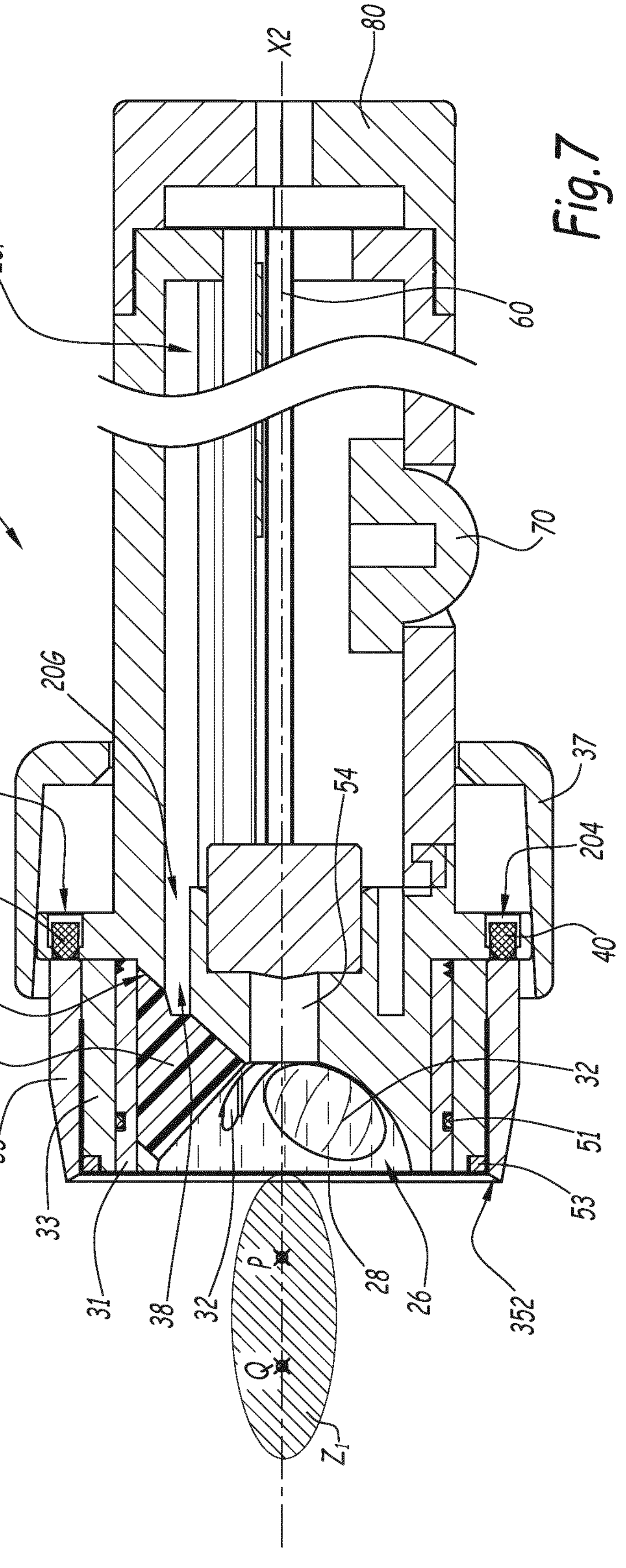
X2
80
20F
60
2
70
20G
204
40
206
32
35
33
31
38
32
28
26
352
53
51
32
54
37
204
40
P
Q
Z1

Fig.7

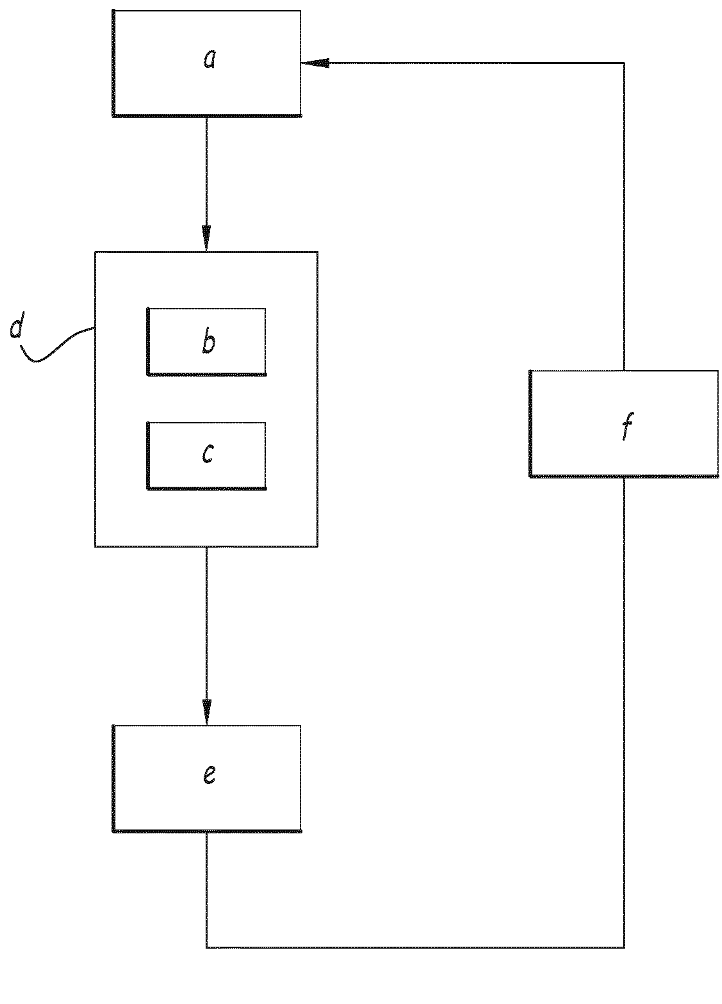

Fig.8

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于在软固体的目标区域中产生超声波的装置和系统以及用于局部治疗组织的方法		
公开(公告)号	EP3355795B1	公开(公告)日	2019-07-31
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发明人	CHAPELON, JEAN-YVES MESTAS, JEAN-LOUIS LAFON, CYRIL GREILLIER, BERNARD MILLERET, RENÉ		
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CPC分类号	A61B8/4483 A61B2017/22008 A61N7/02 A61N2007/0078 A61B90/36 A61B90/37 A61B2090/378		
代理机构(译)	LAVOIX		
优先权	2015306525 2015-09-29 EP		
其他公开文献	EP3355795A1		
外部链接	Espacenet		

摘要(译)

该装置（2）用于在软固体的目标区域中产生超声波，包括至少两个超声源（32），围绕装置（2）的中心轴（X2）分布的光源（40），用于启发通过次表面散射的软固体区域和摄像机（50），用于捕获由发光装置启发的区域的图像。超声源（32），光源（40）和摄像机（50）安装在装置（20）的主体上并朝向包括超声源（32）的焦点的共同目标区域定向。。摄像机的视轴在中心轴（X2）上对齐。