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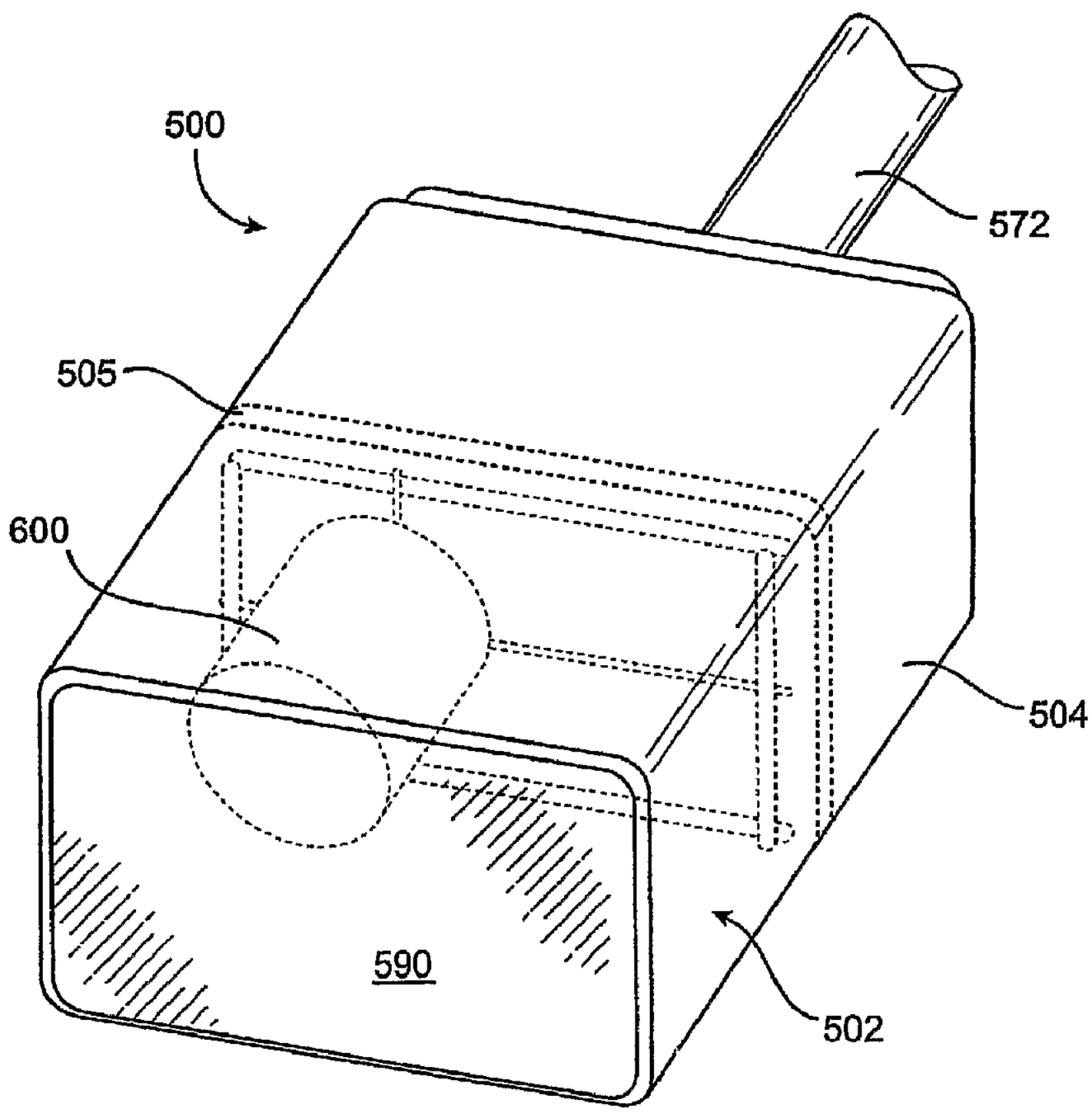

(57) Abrégé/Abstract:
A therapy head for use in HIFU procedures is described. The therapy head has an enclosure with a window, an energy applicator and a means of moving the energy applicator within the enclosure. The therapy head uses motors and actuators to move the

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(57) Abrégé(suite)/Abstract(continued):
energy applicator, usually an ultrasound transducer, inside the enclosure. A controller is provided either internally or externally that allows the therapy head to identify and distinguish locations where the therapy head should be to radiate energy into a patient. The controller uses the motors and actuators to move the energy applicator into the desired locations.

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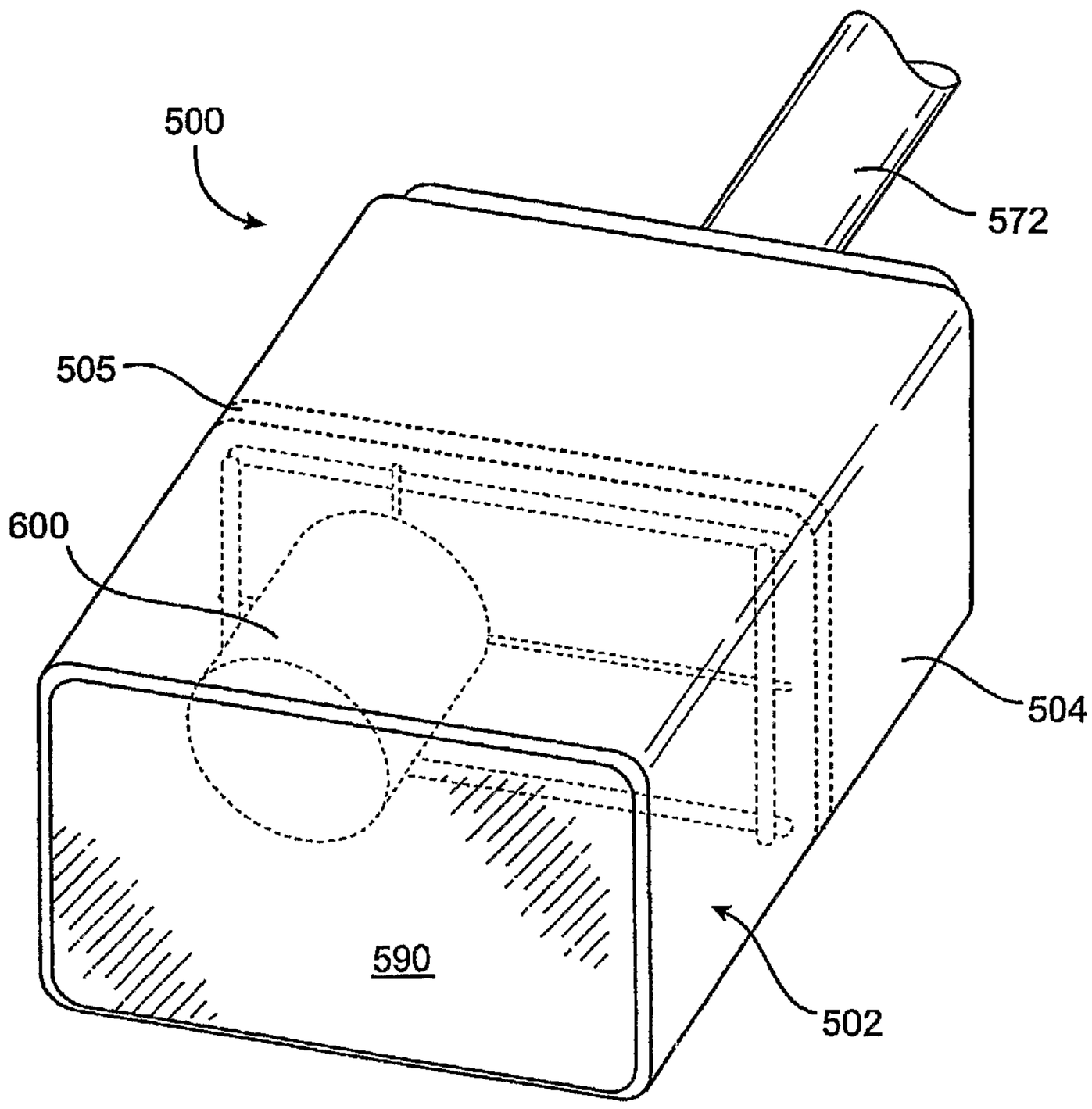
(54) Title: ULTRASOUND THERAPY HEAD WITH MOVEMENT CONTROL



(57) Abstract: A therapy head for use in HIFU procedures is described. The therapy head has an enclosure with a window, an energy applicator and a means of moving the energy applicator within the enclosure. The therapy head uses motors and actuators to move the energy applicator, usually an ultrasound transducer, inside the enclosure. A controller is provided either internally or externally that allows the therapy head to identify and distinguish locations where the therapy head should be to radiate energy into a patient. The controller uses the motors and actuators to move the energy applicator into the desired locations.

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ULTRASOUND THERAPY HEAD WITH MOVEMENT CONTROL

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims the benefit of provisional application no. 60/534,036 (Attorney Docket No. 021356-001100US), filed on December 30, 2003, the full disclosure of which is incorporated herein by reference.

[0002] The subject matter of the present application is related to that of the following applications: 10/750,370, entitled "Medical Device Inline Degasser" (Attorney Docket No. 02356-000500US); 10/751,344, entitled "Articulating Arm for Medical Procedures" (Attorney Docket No. 02356-000600US); 10/750,369, entitled "Disposable Transducer Seal" (Attorney Docket No. 02356-000700US); 60/533,528, entitled "Position Tracking Device" (Attorney Docket No. 021356-000900US); 60/533,988, entitled "Method for Planning and Performing Ultrasound Therapy" (Attorney Docket No. 021356-001000US); 60/533,958, entitled "Systems and Methods for the Destruction of Adipose Tissue" (Attorney Docket No. 021356-001200US); 60/534,034, entitled "Component Ultrasound Transducer" (Attorney Docket No. 021356-001300US); the full disclosure of each of these applications are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention. The present invention relates to a handheld medical device for delivering energy in precise locations into the human body. The device is principally for non-invasive therapies.

[0004] 2. Background of the present invention. A general problem in the application of high intensity focused ultrasound (HIFU) for therapeutic purposes is that it is often necessary to hold the therapeutic means stationary for some significant amount of time over the tissue to be treated. Alternatively, it may be necessary to scan the therapy beam at a slow, constant rate through the tissue to be treated. Both of these requirements present a barrier to a hand-held therapeutic device, as it is often difficult or impossible for a person to either hold the device steady, or to scan at an acceptably slow and steady rate for the desired therapeutic effect.

[0005] A HIFU procedure may require that the ultrasound beam be scanned over the treatment volume at a constant rate (e.g. 5mm/sec +/- 1mm/sec) to achieve the desired therapeutic effect. Additionally, the treatment volume must be scanned so that there is never more than a 2mm spacing between adjacent focal lines of treatment. These requirements are beyond the capabilities of human beings. The solution in the past has been to incorporate a computer controlled motion device rigidly mounted to something that is stationary with respect to the patient (e.g. the floor, wall or bed). Such a device is either absolutely stationary, or is able to scan at a precise rate in a precise pattern without any human intervention. Such an arrangement has the disadvantages of size and bulk, complexity and reliability of the overall device.

[0006] Thus there remains a need in the art for a HIFU applicator that can be easily manipulated by a user while still providing reliable and uniform treatment.

[0007] There is also a need for a HIFU transducer that can keep track of the tissue volumes treated so as to prevent re-treatment of those same volumes.

[0008] There is still further a need for a therapy device that can assist the operator in identifying regions of tissue to be treated.

BRIEF SUMMARY OF THE INVENTION

[0009] It is an objective of the present invention to provide for a therapy head usable in HIFU procedures that can be easily manipulated and provide reliable and uniform treatment.

[0010] It is another object of the presenting invention to track tissue in a library or map of the tissue to be treated.

[0011] It is still further an objective of the present invention to provide a means for alerting a physician to any problems or difficulties associated with a procedure using a HIFU generator of the present invention.

[0012] At least some of the objectives of the present invention are realized through an ultrasound therapy head comprising an enclosure having a window, at least one energy applicator suspended within the enclosure and a means for maneuvering the energy applicator within the enclosure such that the energy applicator radiates energy through the window.

[0013] Preferably the energy applicator is an ultrasound transducer however a variety of other energy applicator may be used in combination with an ultrasound transducer.

[0014] The means for maneuvering the energy applicator preferably includes a means for determining the position of the energy applicator within the enclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Figure 1 illustrates a therapy head.

[0016] Figure 2 shows a therapy head on an articulating arm with external control elements.

[0017] Figures 3A-3B show internal views of actuators and motors in the therapy head.

[0018] Figure 4 provides a schematic of the elements of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0019] Described herein is a device for use primarily in high intensity ultrasound procedures. A therapy head is disclosed having an enclosure with a window. The enclosure contains one or more energy applicators, and a means of moving the energy applicators within the enclosure. The energy applicators are positioned so the radiant energy passes through the window to a patient.

[0020] The enclosure is preferably small enough to be manipulated by hand. It can be operated by itself with a physician carrying the load of the therapy head, or it can be supported by an articulating arm or other mechanical device. The enclosure has a window that is oriented toward a patient. The window may be made from any material so long as it is essentially transparent to the energy applicator. The window may be incorporated into the enclosure, or it may be a removable device. If the window is a removable device, then the window will cover an access port through which the interior components of the enclosure may be accessed. The window may also be a disposable device, such as a disposable transducer seal.

[0021] Within the enclosure is at least one energy applicator. Preferably this energy applicator is an ultrasound transducer. More preferably the ultrasound transducer is a high intensity focused ultrasound transducer. However the transducer may be a component transducer assembly, or a device that incorporates multiple energy applicators, some of which may not be ultrasound transducers.

[0022] There is a means for maneuvering the energy applicator within the enclosure. The means for maneuvering the energy applicator requires two components. A first component is one or more actuators. The energy applicator is attached to the actuators. The attachment may be a slidable engagement, rotational engagement or through a series of traveler rods. The actuators are driven by a force generating device, like an electric motor or the equivalent. Electric motors are preferred for their small size and reliability. One or more position sensing devices, such as rotational or optical encoders, are built into either the motor assembly, or the actuators, so the movement of the energy applicator within the enclosure is known. Alternatively the energy applicator may also contain a miniature location device (e.g. like mini-GPS system) that an external sensor can identify to determine the location of the energy applicator within the enclosure.

[0023] The second component of the maneuvering means is a driver or controller. The driver or controller directs the movement of the motors, and thus the movement of the actuators and the maneuvering of the energy applicator. The controller may be a medical appliance, a computer, or a specialized medical procedure controller. The controller may be positioned within the enclosure, or it may be a device outside the enclosure providing signal to the motors.

[0024] In operation, the controller has a library of data used to coordinate the movement of the energy applicator and the dosage of the radiant energy into the patient. By controlling the movement of the energy applicator while radiant energy is emitted through the window, a precise energy dosage may be delivered into the patient. The controller can be programmed with the parameters needed to perform the task. Parameters may include the type of therapy to be administered and the maximum safe dosage that may be applied to a patient for a given area, volume or mass of tissue.

[0025] Once the therapy head has been completely prepared for a procedure, a physician can place the therapy head on a patient. The therapy head can move the energy applicator within the enclosure to treat the patient according to the procedure parameters programmed into the controller. If the procedure area is small, then the controller can move and activate the energy emitter without any additional input from a user.

[0026] If the treatment area exceeds the window of the enclosure, or exceeds the range of motion of the energy applicator within the enclosure, the therapy head must be moved to cover as much area as needed. Movement of the therapy head can be done manually, or

through a mechanical device. Data from the encoders is relayed to the controller so that the controller can identify the position of the energy applicator within the confines of the enclosure. This position information can be combined with a Position Tracking Device (Co-pending application, serial number unassigned), and an Articulating Arm (Co-pending application, serial number un-assigned). The controller can utilize position data from the present invention, combined with the data derived from the two aforementioned co-pending applications, to produce precise position data for the energy applicator with respect to the enclosure, the patient and a fixed external reference point. During the procedure if the controller reads the position or motion information from the encoders and other sensors and determines the energy applicator is not in the proper position, the controller can use the means for maneuvering the applicator, to correct the energy applicator's position.

[0027] Similarly the controller can identify the dosage of energy delivered with great precision to any particular area. The controller can track the amount of energy transmitted into the patient through out the treatment area and can cause the energy applicator to radiate or not radiate depending on the amount of energy already deposited into the patient at the particular place in the procedure.

[0028] Turning now to the drawings, in Figure 1 there is a therapy head 50 having an energy applicator 600 within an enclosure 500. The enclosure has a window 590 for allowing radiant energy to pass from the enclosure to a patient. The therapy head 50 is preferably small and light enough for a physician to move it comfortably with one hand. The therapy head 50 may increase in both size and weight if the physician is assisted by an articulating arm 200 in bearing the weight of the therapy head 50. There is a data link 572 extending between the therapy head 50 and an external computer 400 or a therapy controller 450.

[0029] The therapy head 50 may be mounted (Fig. 2) on an articulated arm 200 supported by a base 100. The articulating arm 200 would also have its movements and functions monitored or controlled by a computer 400 or therapy controller 450.

[0030] The enclosure 500 contains motor drives 508, 510 for moving the energy applicator 600 within the enclosure (Fig. 3A). The motor drives are connected directly, or through a gear assembly, to a pair of traveler rods 520, 528. The traveler rods in turn move a pair of slotted actuators 520', 528'. The slotted actuators travel along the traveler rods carrying the energy applicator at the intersection of the two slotted actuators. As the traveler rods rotate in response to movement from the motors, the slotted actuators carry the energy applicator

throughout the range of motion of the slotted traveler rods. Rotational encoders 530 are positioned on the traveler rods 520, 528 so that the movement of the energy applicator can be accurately measured.

[0031] Alternatively, the motor drives 508, 510 can directly drive rotational actuators 514, 516 to move the energy applicator 600 within the enclosure (Fig 3B). In this embodiment there is no need for a gear mechanism. As the motor drives move the axis of the motor assemblies back and forth, the actuators 514, 516 move in direct correlation to the motors. The sensitivity of the positioning of the energy applicator can be controlled through the motor drives, or the actuators used in response to the energy applicator. Three motors (not shown) may also be used to drive three articulating arms.

[0032] Figure 4 illustrates a schematic of the present invention. The therapy head 50 is shown in cross section with a partition 504 separating an upper enclosure from a lower enclosure. The partition is water tight so that fluid in the lower partition does not seep into the upper enclosure. There are a pair of motor drive units 508, 510 within the upper enclosure. The motor drive units pass rotational energy to the energy applicator 600 through a series of mechanical actuators 514, 516, 518. The actuators extend through the water tight partition 504 and are themselves water resistant. An acoustic window 590 is displaced at the bottom of the enclosure.

WHAT IS CLAIMED IS:

1. An ultrasound head comprising:

an enclosure having a window;

at least one directional energy applicator suspended within said enclosure; and

a positioner within said enclosure for maneuvering the energy applicator such that said energy applicator radiates energy through said window.

2. The therapy head of claim 1, wherein said window is a transmissible window for said energy applicator.

3. The therapy head of claim 1, wherein said energy applicator is an ultrasound transducer.

4. The energy applicator of claim 3, wherein said ultrasound transducer is an imaging transducer.

5. The energy applicator of claim 3, wherein said ultrasound transducer is a high intensity focused ultrasound transducer.

6. The therapy head of claim 1, wherein the energy applicator is a component ultrasound transducer.

7. The therapy head of claim 1, wherein the means for maneuvering said energy applicator includes a one or more position sensors.

8. The therapy head of claim 1, wherein said window is a disposable transducer seal.

9. The therapy head of claim 1, wherein said positioner comprises a plurality of actuators driven by one or more motors, wherein said energy applicator is movably attached to said actuators.

10. The means for maneuvering said energy applicator as described in claim 9, further comprising a plurality of encoders for measuring movement within said enclosure.

11. The means for maneuvering said energy applicator as described in claim 10, wherein said motors are electrical motors.

12. The therapy head of claim 1, wherein said energy applicator is removable and interchangeable within the enclosure.

13. The therapy head of claim 1, wherein said positioner further comprises a plurality of encoders.

14. The therapy head of claim 1, wherein said enclosure further comprises a horizontal water tight partition defining an upper enclosure and a lower enclosure, said upper enclosure containing said means for maneuvering and said lower enclosure containing said energy applicator, said window being in said lower enclosure.

15. The therapy head of claim 14, further comprising a fluid circulation system for circulating a coupling fluid through said lower enclosure.

16. A method for delivering ultrasound energy to a body surface, said method comprising:

engaging an enclosure against the body structure; and

positioning and activating an ultrasound transducer within the enclosure so that ultrasound energy is scanned over the body surface through a window in the enclosure which remains stationary relative to the body surface.

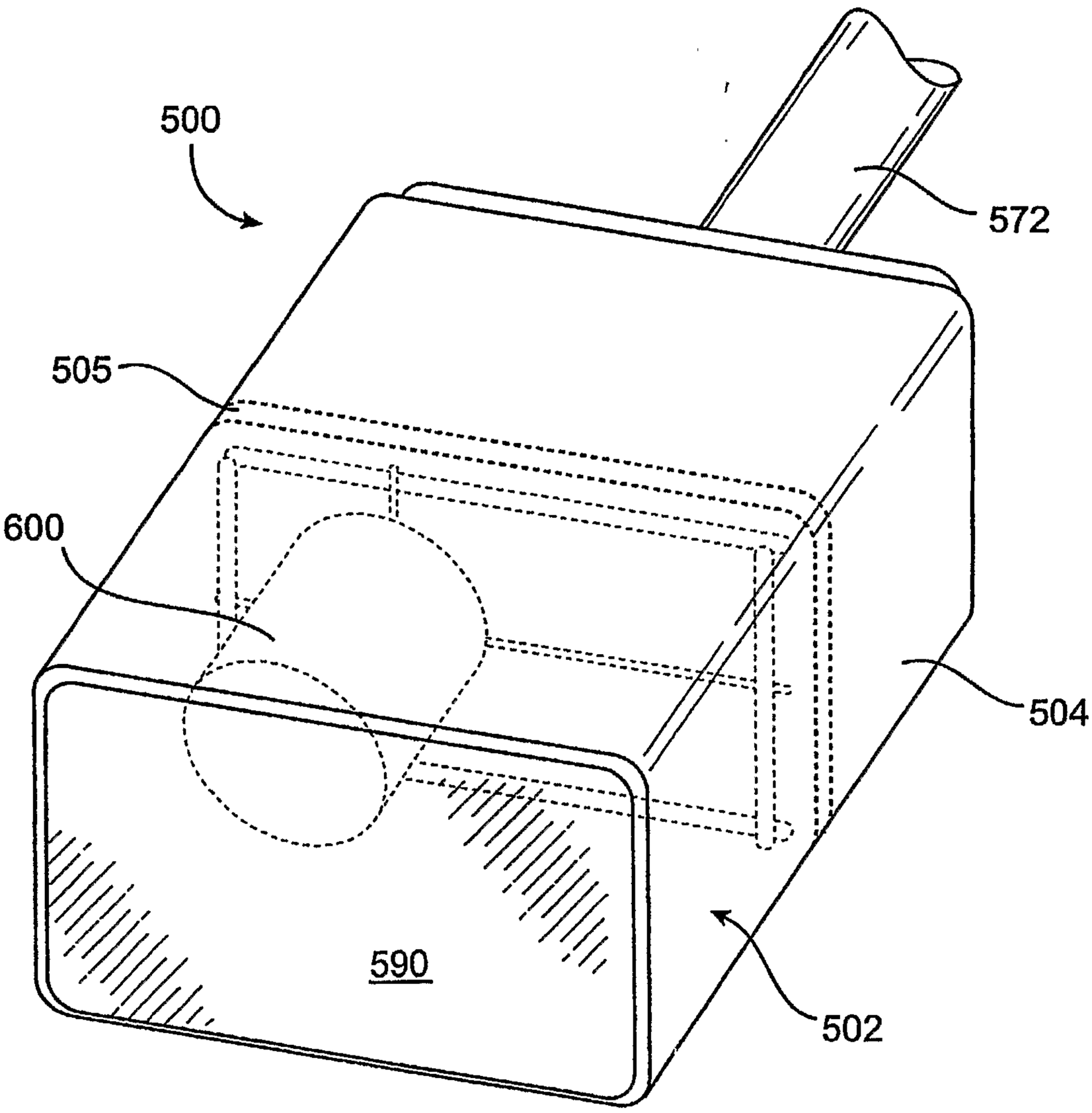


FIG. 1

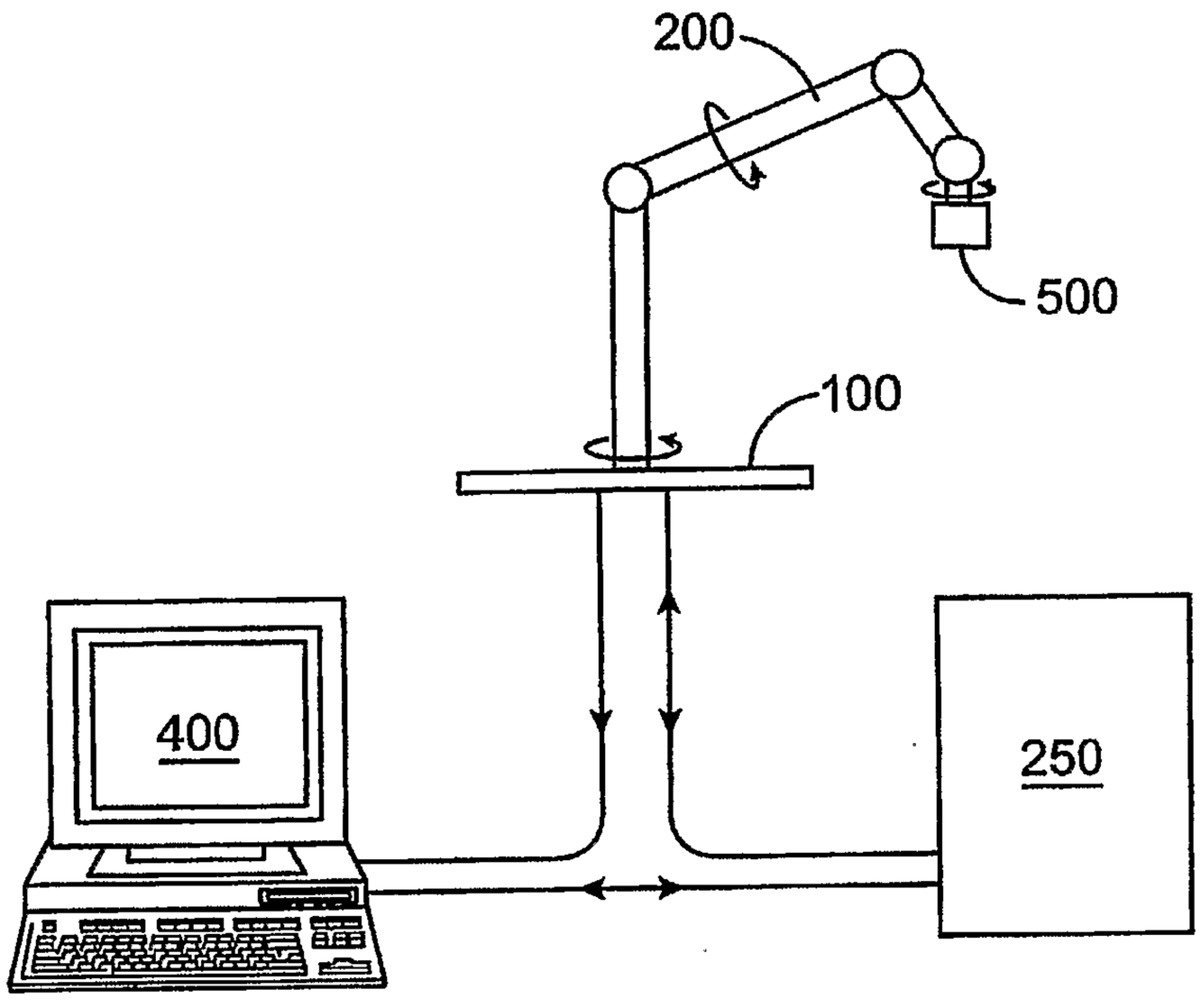


FIG. 2

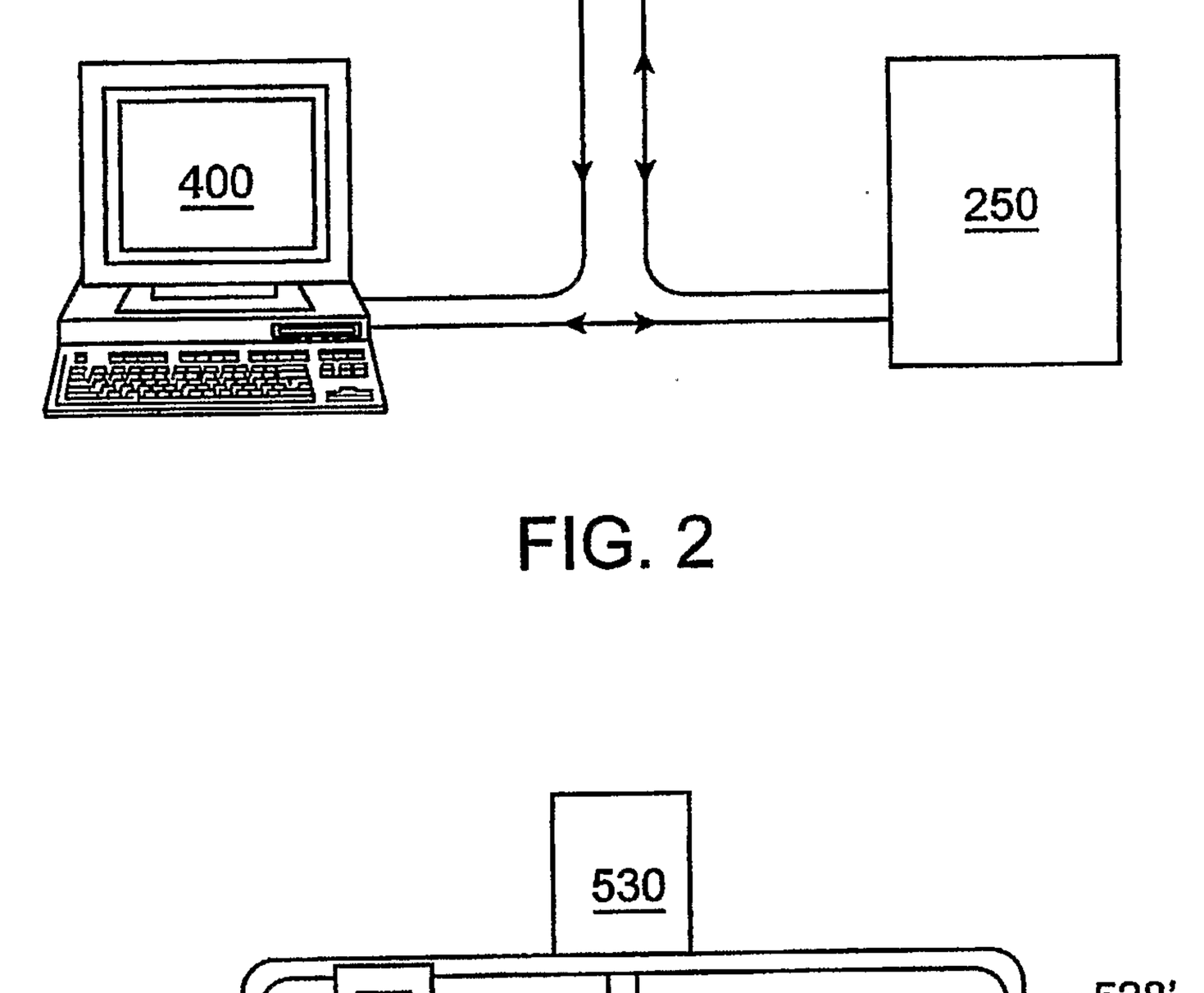


FIG. 3A

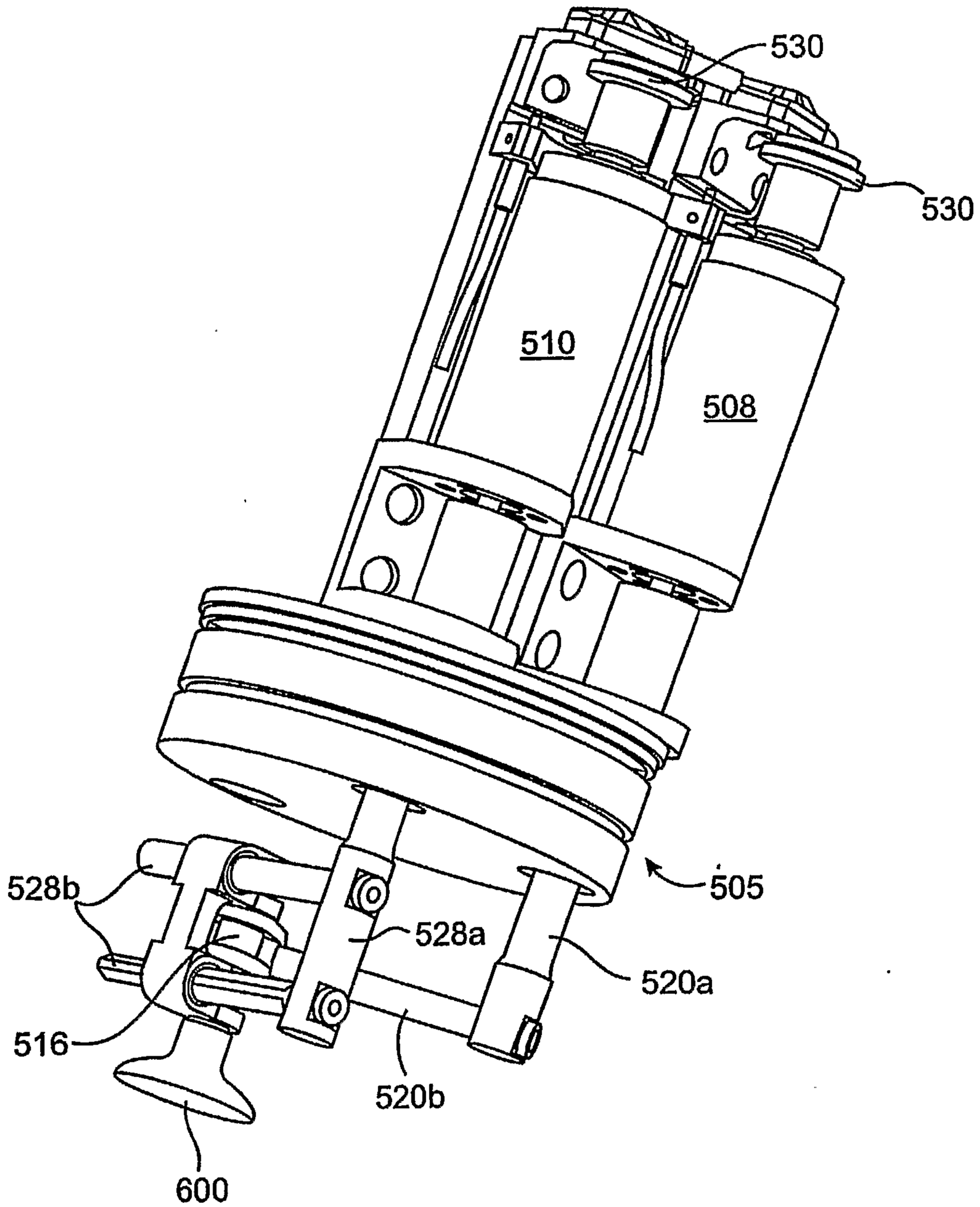


FIG. 3B

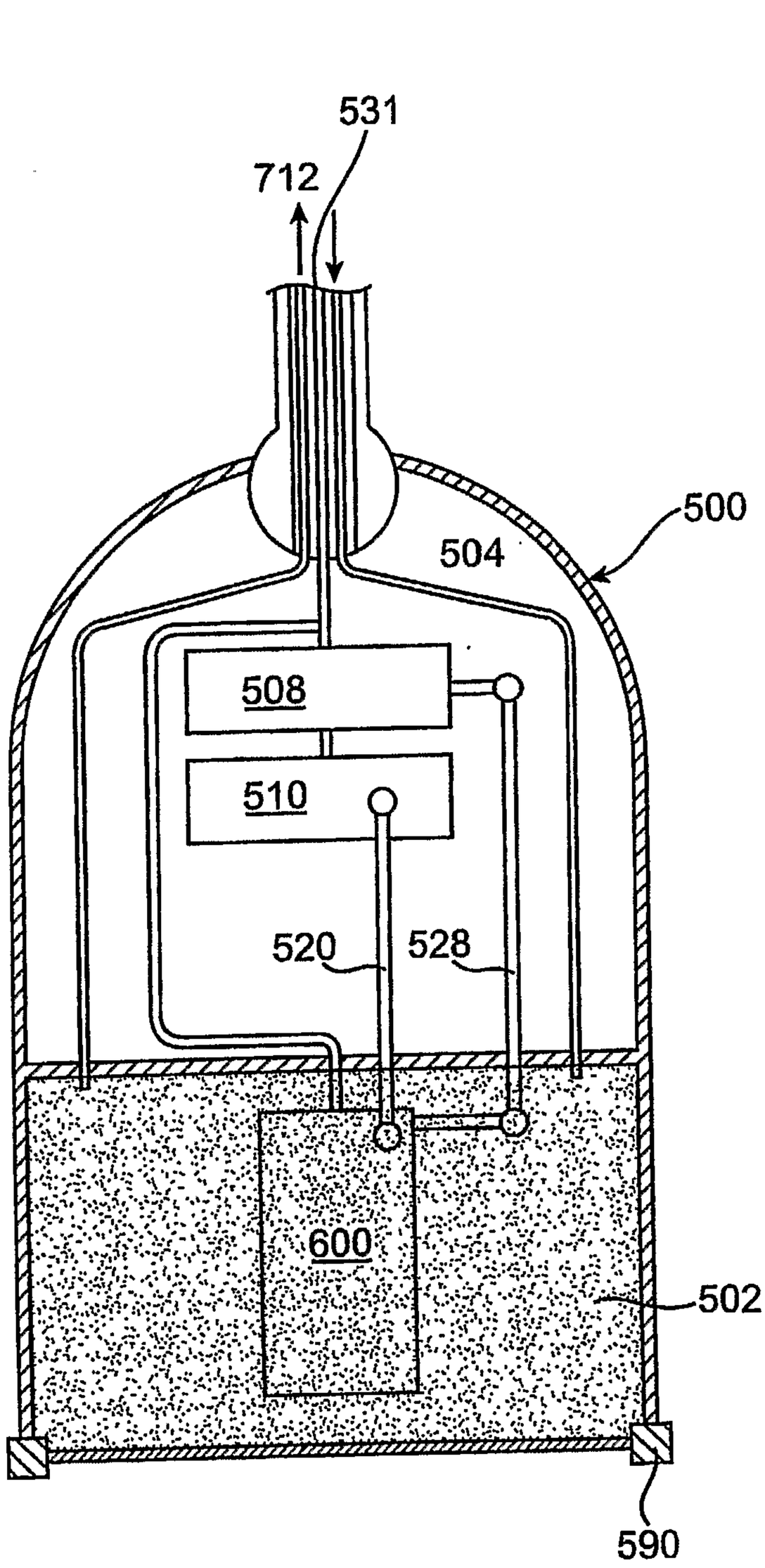
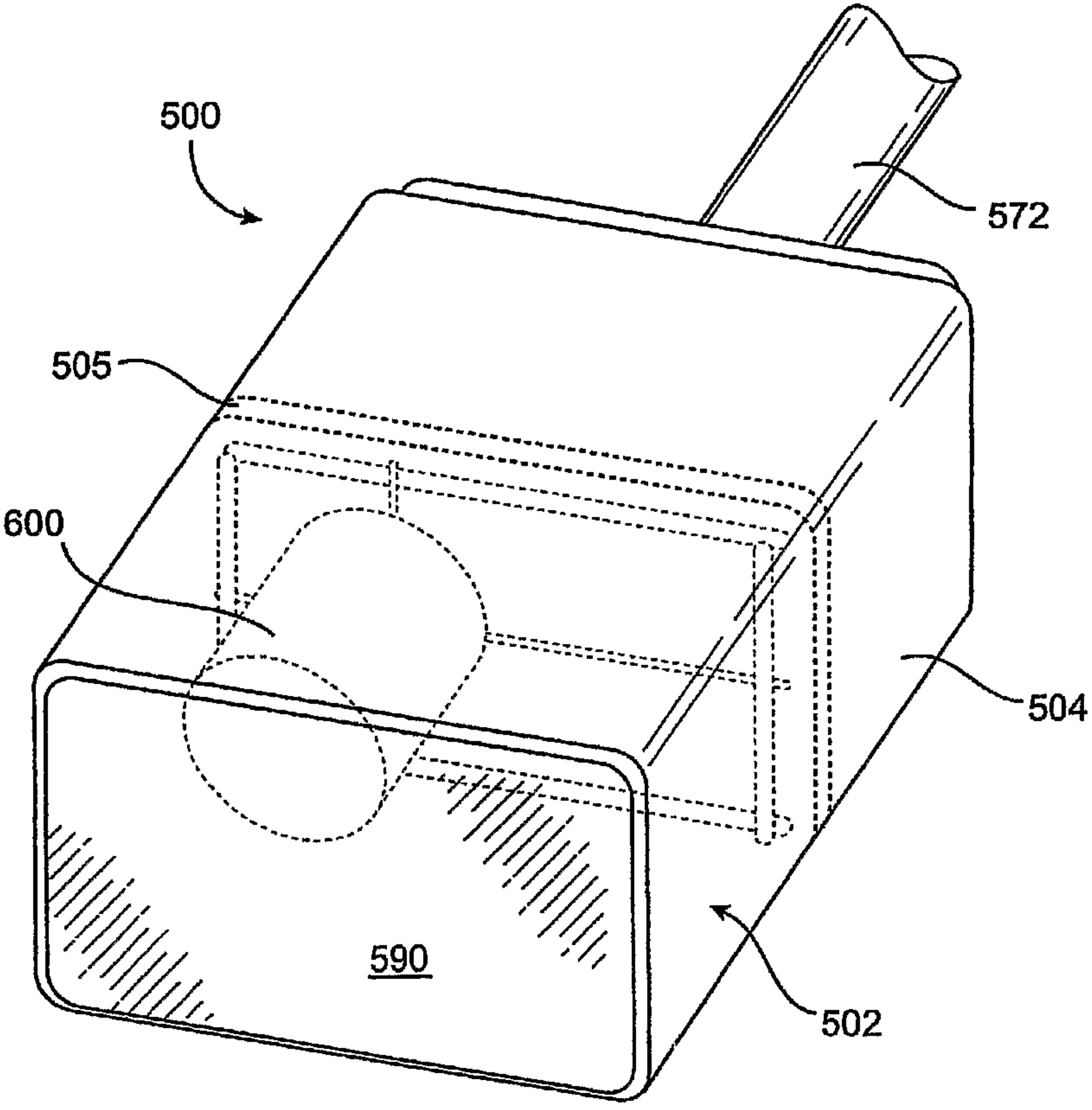


FIG. 4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