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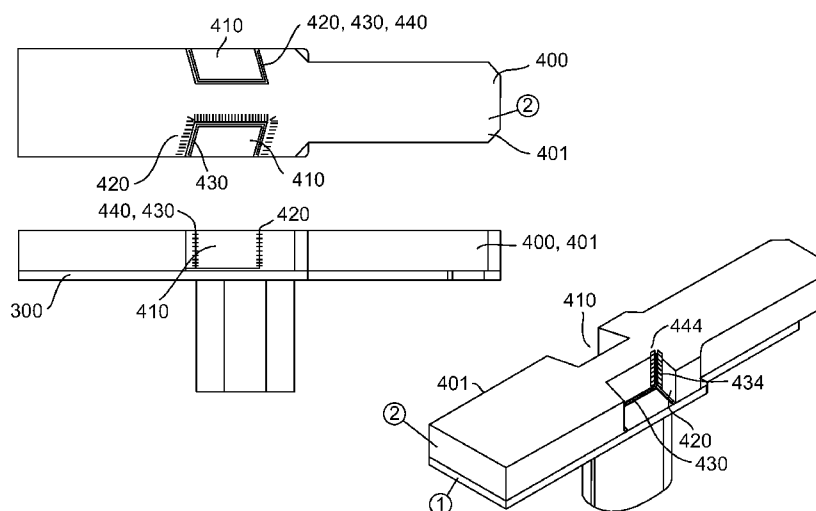


FIG. 4

(57) Abstract: Methods and devices are presented which enable to determine the location in a body of an area of interest using a visualization modality, and then position and aim a treatment tool with respect to that area of interest without using that visualization modality. An intermediate object such as a mattress comprises a set of spaced dimensional markings visible under the modality and a set of markings (the same markings or other markings) which are optically visible to a user. Positions are determined with respect to the first set of markings, then the optically visible markings may be used to position and aim the treatment tool. Some embodiments are useful for HIFU treatment following catheterization guided by fluoroscopic monitoring.



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CATH LAB SYSTEM FOR AIMING ULTRASOUND ENERGY

FIELD AND BACKGROUND OF THE INVENTION

5 The present invention, in some embodiments thereof, relates to a system and method for aiming projected energy in a catheterization laboratory or similar context, and more particularly, but not exclusively, to a system and method for aiming High Intensity Focused Ultrasound energy in a catheterization laboratory equipped with a fluoroscope.

10 Modern surgery often comprises operations using catheterization. The present invention is relevant to any context in which placement of a catheter is followed by treatment involving the catheter and extra-catheter energy sources, and to other contexts.

 A difficulty is sometimes encountered in the use of known systems, when apparatus used for visualization (e.g. during positioning of the catheter within the body, or to locate a treatment target or other object of interest) is incompatible with tools used for treatment of the catheterized patient. This is a familiar phenomenon: a surgeon may be prevented from using useful tools when working in an MRI environment because the tools are responsive to the MRI magnetic field, for example, or a surgeon may have difficulty approaching his patient when the patient is in a CT environment.

15 Embodiments of the present invention solve this kind of problem in the context of various treatments which may be undertaken in a cath lab.

 Applicant's PCT Application IB2012/054524 and Applicant's PCT Application IB2012/054525, both of which were filed on September 2, 2012, provide relevant background to some embodiments of inventions described below. Both these PCT applications are incorporated herein by reference in their entirety.

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SUMMARY OF THE INVENTION

 The general problem of incompatibility between visualization modality equipment and treatment equipment described in the background section is felt *inter alia* in the cath lab, where fluoroscopy is used to monitor the positioning of catheters, but cannot easily be used during treatment by, for example, by High Intensity Focused Ultrasound (HIFU). HIFU projectors known today are somewhat bulky and radio-

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opaque, so HIFU systems and fluoroscopy systems may be physically incompatible and hard or impossible to use simultaneously in some clinical situations.

Some embodiments of the present invention solve these and similar problems by providing an intermediate object (e.g., a support surface for supporting a patient, such as a mattress) having a spatially stable relationship with a patient during at least part of an operation procedure, and which comprises dimensional markings visible under an imaging modality (e.g. fluoroscope). According to some embodiments, areas of interest in a patient, detected by an imaging modality, can be measured with respect to a spatial relationship between those areas of interest and those dimensional markings of the intermediate object, since both markings and areas of interest are together visible on images created by the imaging modality.

In some embodiments, these dimensional markings are either optically visible or have a known spatial relationship to a second set of markings which is optically visible. In some embodiments, such optically visible markings can be used to position a treatment tool (e.g. a HIFU projector) in a position appropriate for treating an area of interest, without requiring use of the visualization modality during the positioning. Similarly, in some embodiments the optically visible markings can be used to aim the treatment tool, also without requiring use of the visualization modality during the aiming. In some embodiments, a sensor positioned by an interventional device, (e.g. by catheter) may be used to further position and/or aim a treatment which was initially aimed and/or positioned according to the optically visible markings.

In some embodiments, an intermediate object embodied as a flat or non-flat mattress comprises one or more open areas. In some embodiments the open areas are sized to accept a portion of a HIFU projector, enabling contact between a portion of a recumbent patient's body and a portion of a HIFU projector positioned to treat an area of interest. In some embodiments the markings are positioned adjacent to a border of the open areas, so that if a patient is positioned with an open area below an area of interest in the body, that area and markings are visible under the imaging modality when the area is empty of objects, and an operator may position and/or aim an energy projector in a open area according to markings surrounding the open area.

According to an aspect of some embodiments of the present invention there is provided a method for treating a target tissue using an extrabody High Intensity Focused Ultrasound (HIFU) projector, comprising:

- a) providing a support having a surface for stably supporting a patient, the support having an indentation sized to receive at least a portion of a HIFU projector;
- b) using a fluoroscopic imaging modality to detect a location of the target tissue while said patient is in a stable position supported by the support and the HIFU projector is absent from the indentation;
- c) introducing the HIFU projector into the indentation and positioning and orienting the projector with respect to the detected location of the target tissue while the patient remains in the stable position; and
- d) using the HIFU projector to treat the target tissue.

According to some embodiments of the invention, the method further comprises using a servomechanism to position and orient the projector with reference to the detected target tissue location.

According to some embodiments of the invention, the method further comprises defining the detected target tissue location with respect to radio-opaque markings stably positioned with respect to the surface, and positioning the projector with reference to the stably positioned markings.

According to some embodiments of the invention, the target tissue is a renal blood vessel.

According to an aspect of some embodiments of the present invention there is provided a method using a visualization modality and an intermediate object to positioning a surgical tool with respect to a region of interest in a body of a patient, the method comprising:

- a) positioning the patient in a stable spatial relationship with an intermediate object which comprises a first set of spaced dimensional markings, the first set of markings being visible under the visualization modality;
- b) using the visualization modality to determine a spatial relationship between the region of interest and the first set of markings; and

- c) positioning the treatment tool with respect to the region of interest by positioning the tool with respect to the first set of markings.

According to some embodiments of the invention, the method further comprises positioning the treatment tool with respect to the region of interest by positioning the treatment tool with respect to optically visible markings comprised in the intermediate object, the optically visible markings having a known spatial relationship to the first set of markings.

According to some embodiments of the invention, the method comprises positioning the treatment tool with respect to the region of interest by using a position sensor to report a position of the treatment tool with reference to a spatial coordinate system having a known relationship to the first set of markings.

According to some embodiments of the invention, the method comprises using a servo-mechanism to displace or aim the treatment tool.

According to some embodiments of the invention, the intermediate object is a mattress.

According to some embodiments of the invention, the mattress comprises at least one open area such that it is possible to position a portion of the patient's body over the open area when the patient's body is lying on the mattress.

According to some embodiments of the invention, the mattress is so shaped that a kidney-related organ of the patient may be positioned over the open area when the patient is centrally positioned on the mattress.

According to some embodiments of the invention, the mattress comprises at least two such open areas, the open areas being shaped as indentations in the two long sides of the mattress.

According to some embodiments of the invention, at least some markings of the first set of markings are positioned around at least a portion of a periphery of the open area.

According to some embodiments of the invention, the first set of markings and the optically visible markings are same markings, and are visible by direct optical observation and also by use of the visualization modality.

According to some embodiments of the invention, markings of the first set of markings are radio-opaque.

According to some embodiments of the invention, the optically visible markings are distinct from, and have a known spatial relationship to, the first set of markings.

According to some embodiments of the invention, the treatment tool is an energy projector.

5 According to some embodiments of the invention, the energy projector is a projector of acoustic energy.

According to some embodiments of the invention, the energy projector is a High Intensity Focused Ultrasound (HIFU) projector.

10 According to some embodiments of the invention, the visualization modality comprises an x-ray.

According to some embodiments of the invention, the visualization modality is a fluoroscope.

According to some embodiments of the invention, the method further comprises:

15 d) introducing into a body lumen of a patient a catheter which comprises a sensor sensitive to projected energy; and
e) using an energy projector to project energy detectable by the sensor, and calculating at least one of:

i) an improvement in positioning of the treatment tool; and
ii) an improvement of aiming of the treatment tool,
20 the calculating using information received from the sensor.

According to some embodiments of the invention, the information received from the sensor comprises a response to energy projected by the treatment tool.

According to some embodiments of the invention, the intermediate object is a mattress.

25 According to some embodiments of the invention, the intermediate object is a mattress and the treatment tool is a HIFU projector.

According to some embodiments of the invention, the treatment tool is a HIFU projector.

30 According to some embodiments of the invention, the mattress comprises at least one open area allowing contact with at least a portion of the body from underneath the mattress, when the patient is lying on the mattress.

According to some embodiments of the invention, the open area is formed as an indentation in a longitudinal side of the mattress.

According to some embodiments of the invention, the indentation is sized to receive therein at least a portion of the HIFU projector.

5 According to some embodiments of the invention, the open area is sized and positioned to enable to introduce a treatment portion of a HIFU projector under a portion of a body of a patient lying on the mattress, enabling direct contact between a component of the HIFU projector and the body.

10 According to some embodiments of the invention, the open area is sized and positioned to enable to introduce a HIFU projector under at least a portion of a renal area of a patient.

According to some embodiments of the invention, the open area is sized and positioned to enable to introduce a HIFU projector to a position under a kidney-related organ of a patient.

15 According to some embodiments of the invention, the method further comprises calculating aiming parameters of a HIFU projector.

According to some embodiments of the invention, the method further comprises calculating aiming parameters of a phased array projector.

20 According to some embodiments of the invention, at least some of the first set of markings is positioned adjacent to a border of the open area.

According to some embodiments of the invention, the optically visible markings are positioned adjacent to a border of the open area.

According to some embodiments of the invention, the method further comprises using a fluoroscope to monitor catheterization of the patient.

25 According to some embodiments of the invention, the body lumen is a renal blood vessel.

According to some embodiments of the invention, the body lumen is a urethra.

30 According to an aspect of some embodiments of the present invention there is provided a mattress which comprises spaced dimensional markings visible under an imaging modality.

According to some embodiments of the invention, the spaced dimensional markings are visible under x-ray imaging.

According to some embodiments of the invention, the spaced dimensional markings are visible under fluoroscopic imaging.

According to some embodiments of the invention, at least some of the spaced dimensional markings are also optically visible to a user.

5 According to some embodiments of the invention, the mattress further comprises an optically visible set of spaced dimensional markings distinct from the spaced dimensional markings visible under an imaging modality, and having a known spatial relationship thereto.

10 According to some embodiments of the invention, the mattress comprises at least one open region.

According to some embodiments of the invention, at least some of the spaced dimensional markings are positioned in proximity to a border of the at least one open region.

15 According to some embodiments of the invention, the at least one open region is sized to accommodate therein a HIFU projector.

According to some embodiments of the invention, the at least one open region is positioned where it can be beneath a kidney-related organ of a patient when the patient lies on his back on the mattress.

20 According to some embodiments of the invention, the mattress comprises two such openings, one on each longitudinal side of the mattress.

According to some embodiments of the invention, the spaced dimensional markings visible under an imaging modality are also optically visible to a viewer.

25 According to some embodiments of the invention, additional spaced dimensional markings distinct from the spaced dimensional markings visible under an imaging modality, the additional spaced dimensional markings being optically visible to a viewer and having a known spatial relationship to the spaced dimensional markings visible under an imaging modality.

According to an aspect of some embodiments of the present invention there is provided a mattress which comprises:

- 30 a) a surface for supporting the body of a patient; and
b) an indentation in the surface forming an open area which does not support any part of the body of a patient, yet which will be below a portion of a patient's

body when the patient is lying on the mattress the patient's body is being supported by the surface.

According to some embodiments of the invention, the open area is formed as an indentation in a long side of the mattress.

5 According to an aspect of some embodiments of the present invention there is provided a method of treating a recumbent patient which comprises:

- a) positioning the patient on a mattress which comprises:
 - i) a surface for supporting the body of a patient; and
 - ii) an indentation in the surface forming an open area which
- 10 does not support any part of the body of a patient, yet which will be below a portion of a patient's body when the patient is lying on the mattress the patient's body is being supported by the surface, the patient being so positioned that a region of interest in the patient's body is positioned above the open area;
- 15 b) introducing a treatment tool into the open area while the patient's body is being supported by the mattress; and
 - c) using the treatment tool to treat the area of interest from underneath the patient while the patient is supported on the mattress.

According to an aspect of some embodiments of the present invention there is provided a catheterization laboratory system which comprises:

- a) a catheter insertable in a patient;
- b) a table for positioning a support surface and a patient thereon;
- c) a support surface having an indentation sized to accommodate at least a portion of a HIFU projector therein;
- 25 d) a fluoroscopic imaging system; and
- e) a HIFU projector having a projecting portion sized to fit within the indentation.

According to some embodiments of the invention, the catheter comprises a sensor sensitive to projected energy.

30 According to some embodiments of the invention, the system further comprises a servomechanism for positioning the HIFU projector according to a target tissue position detected by the fluoroscope.

According to some embodiments of the invention, the system further comprises a set of radio-opaque ruler-like spatial distance markings having a stable positional relationship with the support surface.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

Implementation of the method and/or system of embodiments of the invention can involve performing or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware or by a combination thereof using an operating system.

For example, hardware for performing selected tasks according to embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

BRIEF DESCRIPTION OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the

drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

5 In the drawings:

FIG. 1 is a schematic overview of a cath lab system, according to some embodiments of the present invention;

FIG. 2 is a perspective view of the cath lab arrangement of Figure 1, according to some embodiments of the present invention;

10 FIG. 3 presents schematic views of a HIFU projector, according to some embodiments of the present invention;

FIG. 4 presents views of an intermediate object which is a mattress, according to some embodiments of the present invention;

15 FIG. 5 is a simplified flowchart of a method for positioning and/or aiming a treatment tool, according to some embodiments of the present invention;

FIG. 6 is a simplified schematic of an embodiment using a catheter sensor to further position and/or aim a treatment tool, according to some embodiments of the present invention;

20 FIG. 7 is a flowchart of a method for treating a patient according to some embodiments of the present invention; and

FIG. 8 is a simplified schematic of a mattress comprising one or more open areas, according to some embodiments of the present invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

25 The present invention, in some embodiments thereof, relates to a system and method for positioning and/or aiming a treatment tool to treat a patient, and more particularly, but not exclusively, to using projected High Intensity Focused Ultrasound energy to treat a patient in a catheterization laboratory.

30 The term "High Intensity Focused Ultrasound" is sometimes abbreviated "HIFU" herein.

A "catheterization laboratory" is sometimes referred to as a "cath lab" herein.

The term "mattress" is used herein. In an embodiment shown in figures discussed below, a flat mattress shape is presented, however it is to be understood that the term "mattress" is used herein to refer to any padded surface on which a patient may lie, sit, or lean, or on which he may repose a portion of his body, and the term "flat mattress" is used to refer to a mattress appropriate for supporting the recumbent body of a patient on a bed or table.

GENERALITY

For clarity and for simplicity of exposition, and because the cath lab context is of particular interest to the Applicant, the present invention is explained largely in terms of examples drawn from treatment in a cath lab, and in many cases the examples relate treatment by HIFU in a cath lab equipped with a fluoroscope used to monitor the catheterization process. It is to be understood that these examples are exemplary and not limiting. The invention is capable of being practiced in many contexts and in relation to many types of treatment equipment and/or visualization modalities, and the invention is conceived with respect to all such contexts. Therefore it should be understood that references to fluoroscopy are intended to refer to fluoroscopy as an exemplary visualization modality, but other visualization modalities (for example, but not limited to, CT, MRI, ultrasound imaging, portable x-ray machines and other forms of x-ray visualization) are also considered within the scope of the invention. Similarly, references to HIFU projection are exemplary, and other types of aimed energy beams (e.g. radiation treatment, microwave treatment) and also other types of treatment (e.g. cancer ablation, uterine fibroid treatment, essential tremor treatment, or a diagnostics procedure such as ultrasound imaging and the taking of biopsy samples) are also to be considered as within the scope of the invention. In general, the terms "surgical tool" and "treatment tool" are used herein to refer to any surgical apparatus and/or energy projector and/or biopsy tool and/or other type of diagnostic tool, and that references to a HIFU projector in exemplary embodiments comprised herein should also be understood as referring generally, in exemplary fashion, to any surgical tool. In other words, to simplify the disclosure, much of the description herein refers to an exemplary context, namely HIFU projection in a fluoroscopy-equipped cath lab, but these exemplary descriptions should be understood as being generalized to include other visualization modalities in general and surgical tools in general.

CATH LAB

Fluoroscopy is often used in a cath lab to monitor a catheterization process and/or to determine the location of treatment targets or other objects of interest in a patient's body. HIFU is often used to treat such treatment targets. However, the bulky and radio-opaque HIFU projectors currently available interfere with fluoroscopic imaging when the HIFU projectors are optimally positioned for treating a patient in some clinical scenarios, for example in using HIFU to modulate renal nerves to reduce blood pressure. This is a problem of the sort described in more general terms in the background section above, an incompatibility between the physical characteristics and requirements of a visualization modality and the physical characteristics and requirements of a treatment tool.

To alleviate this problem with respect to use of HIFU in a cath lab and in various other contexts, in some embodiments of the present invention an "intermediate object" (e.g. a mattress) having a stable spatial relationship with a patient during treatment, comprises a first set of spaced markings which are visible under a visualization modality such as a fluoroscope. The intermediate object also comprises spaced markings which are optically visible (e.g. to an operator or to an automated system which comprises a camera and image interpretation software). Optionally, these optically visible markings and these visible-under-a-visualization-modality markings are the same markings, visible both optically and by means of the imaging modality. For example, they may be radio-opaque optically visible lines and/or numerals. Alternatively, these optically visible markings may be a second set of markings having a known spatial relationship to the first set of markings.

In some embodiments, under fluoroscopy or another imaging modality the position of an object of interest in a body is determined with respect to the first set of (e.g. fluoroscopically visible) markings. Then, the optically visible markings are used to position and/or aim an energy projector such as a HIFU transmitter. In this manner, in some embodiments a HIFU projector or other treatment tool may be positioned and/or aimed toward a treatment target located by use of a visualization modality, yet the positioning and/or aiming may be done with reference to optically visible markings and without requiring use of the visualization modality during this positioning and aiming. In some alternative embodiments, positioning and/or aiming of a HIFU projector or

other treatment tools is accomplished using one or more sensors or sensing systems which report position of the treatment tool with respect to a coordinate system having a known relationship to the first set of markings.

Some embodiments of the present invention therefore overcome a problem mentioned above and in the background section, namely that in some clinical circumstances treatment equipment and visualization equipment are incompatible and cannot easily be used at the same time. Using embodiments of the invention a user or a processor or controller can position and/or aim a treatment tool such as a HIFU projector, by

a) use a visualization modality to note the location of a region of interest in a body of a patient with respect to spaced markings of an intermediate object such as a mattress (because body anatomy and the spaced markings are both visible in images produced by the imaging modality), and

b) use this noted information to position and/or aim (manually or servo-mechanically) a treatment tool such as a HIFU projector, the positioning and aiming optionally taking place in the absence of an active imaging modality such as fluoroscopy.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

FIGS. 1–3: CATH LAB ARRANGEMENT

Referring now to the drawings, Figures 1 and 2 are simplified overviews of a cath lab arrangement 100, and Figure 3 provides further detail of an energy projector which is an optional part of that arrangement, according to some embodiments of the present invention. As shown in Figure 1, arrangement 100 comprises:

a) a visualization modality 200, in this exemplary embodiment an x-ray projector 210 of a fluoroscope 220;

b) a treatment tool 500, in this exemplary embodiment an energy projector 510 such as a HIFU projector 520;

- c) a cath lab table 300;
- d) a support 400, optionally a mattress (also labeled 400), which will be described below with reference to more detailed figures;
- e) optionally, a fluoroscope sensor array 240 either on or in or under table 300; and
- f) optionally, a servo-mechanical placement system 505 optionally comprising a position sensor 506.

Figure 2 presents a perspective view of an embodiment of a cath lab arrangement presented in Figure 1. In Figure 2 some parts of visualization modality 200 are not shown. Table 300, optionally with a variable-height base 310, supports an intermediate object 400, such as a mattress 401. As will be discussed below, mattress 401 optionally comprises one or more open areas 410. Treatment tool 500, in this exemplary embodiment a HIFU projector 520 which is an energy projector 510, has a treatment portion 540 (the portion which is in contact with or most closely positioned to a patient during treatment) positioned in open area 410, an area optionally strategically positioned to enable contact or proximity between treatment portion 540 and a region of interest in the patient's body. In some embodiments servo-mechanical placement system 505 optionally comprising a position sensor 506 is used to position tool 500 with respect to object 400. In some embodiments position sensor 506 is used to detect the position of tool 500 with respect to object 400, and positioning of tool 500 is done manually.

In some embodiments a fluoroscope detector array 240 is positioned on or under or is embedded within table 300. A typical cath lab fluoroscope comprises an x-ray sensor positioned at one extremity of an arm shaped like a letter "C". Such arrangements are often called "C-Arm" x-rays. In typical use x-rays emanate from the top part of the "C" and pass through the patient and through his bed or table on the way to the sensor array located on the bottom arm of the "C". C-Arm x-rays are typically rotatable, so that coronal and sagittal images and images from other angles may be taken. In some embodiments an x-ray sensor may be attached to or embedded in a patient table 300.

To facilitate understanding of Figure 2, Figure 3 has been provided to show exemplary HIFU projector 520 in greater detail.

FIG. 4: INTERMEDIATE OBJECT EMBODIED AS MATTRESS

Attention is now drawn to Figure 4, which presents simplified views of an intermediate object 400, according to some embodiments of the present invention. Optionally, intermediate object 400 is a support having a surface which may be used to support all or part of a body of a patient. Optionally, intermediate object 400 is embodied as a mattress 401.

Mattress 401 comprises spaced dimensional markings 420, which are visible under an imaging modality 200. For example, markings 420 may be radio-opaque markings which are visible to an imaging modality 200 which is a fluoroscope 220. Markings 420 may be expressed in any spatial measures and in any coordinate system. For example, markings 420 may comprise markings expressed in millimeters in a Cartesian coordinate system, e.g. comprising 'x' and/or 'y' and/or 'z' coordinates. In some embodiments, some or all of markings 420 may be detachable from mattress 401 yet stably positionable with mattress 401, as for example a vertical rod 444 shown in Figure 4, and which in this exemplary embodiment comprises vertical spatial coordinate markings 420 and is optionally stably positionable with relation to (as an alternative to being embedded on or in) mattress 401.

In some embodiments, markings 420 are be optically visible as well as being radio-opaque (or otherwise visible under an imaging modality). Markings which are optically visible (that is, which can be seen optically by an operator such as a surgeon or medical technician and/or by image recognition software analyzing images provided by a camera such as a camera of a servo-mechanical device) are labeled markings 430 in the figure. Markings which are both optically visible and are radio-opaque or otherwise visible under an imaging modality are labeled markings 440 in the figure.

In some embodiments, intermediate object 400 (mattress 401 in this exemplary embodiment) comprises a first set of markings 420 which are visible under an imaging modality, and an additional set of spaced dimensional markings 430 which are optically visible, and there exists a known spatial relationship between markings 420 and markings 430. These embodiments enable placement of optically visible markings 430 in a position convenient for viewing by an operator while placing modality-visible markings 420 at another position, for example in a position more convenient for

construction or for maintenance or more convenient to use under the fluoroscope or other imaging modality.

In an embodiment shown in Figure 4, markings 440 are positioned adjacent to a border of open space 410. Optionally, open space 410 is an indentation in a support surface such as a mattress 401, the indentation being sized to receive at least a portion of an energy projector such as a HIFU projector, enabling a projection portion of the HIFU projector to be positioned within that indentation and beneath a portion of a body of a patient, to treat the patient.

In some embodiments, some or all of markings 440 may be detachable from mattress 401 yet are stably positionable with respect to mattress 401 and/or with respect to detachable marking objects such as rod 444. For example, a vertical rod 434 shown in Figure 4 comprises optically visible vertical spatial coordinate markings and is stably positioned in relation to (and is optionally attached to) mattress 401 and/or relative to marking rod 444.

FIGS. 5-7, SOME METHOD EMBODIMENTS

Attention is now drawn to Figure 5, which is a simplified flowchart showing some surgical methods, according to some embodiments of the present invention.

Figure 5 summarizes a method 700 using devices described herein. At 710 a patient is caused to have an at least temporarily stable physical relationship with an intermediate object 400. For example, a patient may be immobilized (or simply caused to lie quietly) on a mattress 401 positioned above a fluoroscope sensor array 240 which is on or in or under a supporting surface such as a cath lab table 300. In an exemplary and non-limiting embodiment here described, mattress 401 comprises open areas 410, and optionally the patient is positioned on mattress 401 so that an area of interest in the body is positioned over an open area 410. For example, in an operation to modulate renal nerves using HIFU energy, the kidney may be positioned over an open area 410. Alternatively, a kidney-related organ, such as for example a kidney and/or a renal artery and/or a renal vein may be positioned over an open area 410.

In an optional process shown at 720, a catheter 600 is inserted into the body and guided to a desired position, optionally under fluoroscopic monitoring. In some embodiments catheter 600 comprises a sensor 610 operable to detect projected energy, which may be HIFU energy or any other kind of projected energies used in clinical

contexts. During process 720 open areas 410 may be empty of treatment tools and therefore do not interfere with fluoroscopy.

At 730, note is taken of the location of objects of interest in the body. Since the fluoroscope images show markings 420, a user and/or an automated or partially automated system may note the position of objects of interest in the body in terms of the modality-visible markings 420. In embodiments where markings 420 are also optically visible (markings 440), the position of these objects of interest are thereby known with respect to these optically visible markings. In embodiments where optically visible markings 430 are distinct from markings 420, their relative positions are taken into account, so that the fluoroscopically detected positions of regions of interest are known in terms of optically visible markings 430. In optional embodiments the position of catheter 600 and/or of sensor 610 with respect to objects of interest in the body are also noted.

In embodiments which comprise a mattress 401 similar to that shown in Figure 4, the position of a treatment target or other object of interest in the body with respect to markings 420 may be seen directly, under fluoroscopy, because mattress 401 may comprise markings showing a coordinate system such a Cartesian coordinate system with, for example, x and y coordinates marked around three sides of open area 410, and optionally also having z coordinates indicating height and positioned vertically along sides or corners of area 410, as shown in Figure 4.

At 740, fluoroscopic imaging is optionally turned off, and a treatment tool 500 such as a HIFU projector 520 is introduced into open area 410 of mattress 401. Note that approaching projector 520 to the patient, and even touching the body of the patient with a treatment portion 540 of projector 520 does not require moving the patient, who is catheterized and therefore should be moved as little as possible. Fine positioning of projector 520 within open area 410 can then be accomplished by referring to visual markings 430, since the positions of objects of interest (such as treatment targets) are known in relation to the positions of visible markings 430.

In optional alternative implementations, mechanical placement system 505 may be used to position and aim projector 520 instead of or in addition to use of visible markings 430. Well-known servo-mechanical techniques can be used by system 505 to position and aim projector 520, once the position of a treatment target is known with

respect to a coordinate system based on markings in intermediate object 400, and the position of projector 520 with respect to that intermediate object 400 is also known. For example, in some embodiments a sensing device 506 such as an electric sensor and/or a laser measurement device and/or an electromagnetic object-tracking and control system
5 may be used to measure positions in space of projector 520 with reference to intermediate object 400, whose spatial relationship to an object of interest is also known through spatial markings of intermediate object 400 visible in an imaging modality.

HIFU transmitter 520 may be positioned directly under (or at any other desired position with respect to) a treatment target, simply by positioning it appropriately in
10 terms of the visible markings 440 which surround once it is introduced into open area 410. Optionally, spaced markings 550 or variably positionable markers 560 may be supplied on energy projector 520, to facilitate aligning this projector with respect to markings on the mattress.

Attention is now drawn to Figure 6, which is a simplified schematic of a system
15 including a catheter with an energy sensor, according to some embodiments of the present invention. Figure 6 is useful in explaining an additional optional process described at 750 of Figure 5.

Figure 6 shows optional embodiments wherein a catheter 600 inserted in a body of a patient 20 comprises a sensor 610. Sensor 610 is operable to detect projected
20 energy. Energy detected and reported by sensor 610 may be the therapeutic energies (e.g. HIFU) projected during treatment, and/or may be other energies (e.g. low-energy ultrasound or other types of energy projected by projector 520 and/or by an additional energy projector 580 comprised in or associated with projector 520).

Methods by which information from such a sensor can be used to position and/or
25 aim an energy projection device are taught in Applicant's PCT Application IB2012/054524 and Applicant's PCT Application IB2012/054525, which were mentioned in the Background section above. Using these or similar methods, after projector 520 has been positioned and aimed as described with reference to 740 of Figure 5, in optional embodiments, aiming and/or positioning of projector 520 may be
30 further refined in view of information gleaned by a controller 900 (Figure 6), operable to receive data from sensor 610 and calculate optimal aiming and/or positioning of projector 520 accordingly. In some embodiments, aiming and/or positioning of projector

520, in processes described at 740 and/or processes described at 750, may optionally use an actuator 910 controlled by controller 900 to move or modify projector 520.

Attention is now drawn to Figure 7, which is an additional flow chart providing additional details of an embodiment for treating a patient, according to embodiments of the present invention. Note the dotted horizontal line 902 in Figure 7. Processes above line 902 may be visible under x-ray visualization, whereas processes below line 902 may take place when equipment configurations would cause fluoroscope or other visualizations to be obscured or ineffective. Use of intermediate object 400, as taught herein, enables to complete these processes accurately and effectively in the absence of an operating visualization modality.

To summarize some aspects of some embodiments:

In some exemplary embodiments, a patient is stably positioned with respect to an intermediate object which comprises markings visible under a visualization modality, the visualization modality is used to determine a spatial relationship between a region of interest in the body and markings visible under the visualization modality. A treatment tool may then be positioned with respect to that region of interest. In some embodiments, this is done by positioning and/or aiming the treatment tool according to a set of optically visible markings comprised in the intermediate object and having a known spatial relationship to the markings visible under a visualization modality. In some embodiments this is done by using a position-sensing system to position and/or aim a treatment tool with reference to a coordinate system defined in terms of an intermediate object, using position-sensing sensors to sense the position and/or aiming of the treatment tool with respect to a coordinate system defined in terms of an intermediate object, thereby determining the treatment tool with reference to the region of interest. In some embodiments a servo-mechanism is used to accomplish this positioning and/or aiming, guided by feedback from the position-sensing system.

According to some embodiments, in a first phase of operation an operator uses an imaging modality such as a fluoroscope to observe positions of objects of interest in a body. Markings on the intermediate object are visible by means of the imaging modality, and enable a human operator or an automated system using image interpretation algorithms to record the observed positions of objects of interest in the body terms of their position relative to these intermediate object markings. Then in a second phase of

operation which can optionally take place in the absence of use of fluoroscopy or other imaging modalities, intermediate object markings visible to an operator may be used by the operator and/or by an automatic positioning system optionally using a camera and image interpretation software, or other measurement sensors, to position a HIFU projector or other projector with respect to the previously observed positions of objects of interest in the body. Physical positioning of a HIFU projector and/or control commands delivered to the HIFU projector, both optionally based on positioning information received in the first phase of operation, can thereby aim a HIFU beam at or near an intended target. In some embodiments, this aiming of the HIFU beam is sufficiently accurate to accomplish a surgeon's therapeutic purpose. In some embodiments, once the beam is approximately aimed, addition methods may be used to 'fine tune' the beam aim. For example, PCT Applications IB2012/054524 and IB2012/054525 *op cit.* teach devices and methods for accurately finely aiming such beam using feedback from a beam-sensitive sensor positioned near a therapeutic target. Using methods and devices disclosed herein, approximate aiming of a HIFU beam or other energy beam may be accomplished as described above and further described below, and then may optionally be further supplemented (i.e. made more accurate, or made to follow a desired pattern within an area of interest) using methods described in these PCT applications.

Example: treatment of high blood pressure:

For example, high blood pressure resistant to drug treatment may be treated by a HIFU beam used to modulate nervous tissue of afferent and efferent renal nerves, which procedure is known to reduce blood pressure in many cases. Therefore in an exemplary method of treatment in a first phase of operation fluoroscopy may be used to catheterize a patient, using a catheter which comprises a sensor sensitive to ultrasound. In exemplary embodiments the catheter is positioned within a renal blood vessel in proximity to a renal nerve. During this first phase of operation position of the catheter with respect to the intermediate object markings (e.g. markings on a mattress) are observed and optionally recorded, optionally in multiple angles of view such as coronal and sagittal). In a second phase of operation fluoroscopy is discontinued and a HIFU projector is positioned near target tissues, positioning being done with reference to the optically visible intermediate markings. In a third and optional phase of operation, the

fine aiming of a HIFU beam towards an intended target may be accomplished using feedback from an ultrasound sensor in the catheter, as taught in PCT Applications IB2012/054524 and IB2012/054525 *op cit*.

Attention is now drawn to Figure 8, which is a simplified schematic of a mattress 490 comprising one or more open areas 410, according to some embodiments of the present invention. Mattress shapes discussed above with reference to mattress 401 have additional utility, with or without embedded markings of any kind. In many clinical situations it is desired to have access to the body of a patient from underneath the patient, while the patient is recumbent on a bed or table. In many such situations, for example in an operation room, a cath-lab, a CT room, an MRI room, it is not desirable to alter the setup of the room, and beds and treatment tables in such rooms typically do not have holes within the table surface that enable medical personnel to have access to the patient's body from underneath the table. Figure 8 shows a mattress 490 which comprises open areas 410 similar to those discussed above with reference to mattress 401. Mattress 490 presents a large surface able to stably support the weight of a recumbent patient (or a leaning patient, mattress 490 need not necessarily be horizontal). Mattress 490 supports the patient's body in general, yet comprises open areas 410 which do not support a portion of a patient's body positioned above them. Rather, portions of a patient's body above an open area 410 are not directly supported by mattress 490, but rather are unsupported may be open to observation and/or contact and/or manipulation and/or treatment by medical personnel. In an optional method of treatment, a patient is positioned on a mattress 490 with an area of interest in the patient's body positioned above an open area 410, and that area of interest is then treated from underneath the patient by a medical tool or medical practitioner who accesses the area of interest from underneath the patient, yet from above the bed or table or other platform on which mattress 490 is positioned.

In some embodiments, a method of treatment comprises positioning a patient on a mattress 490 in such a way that an area of interest in the body of the patient is positioned above an open area 410, introducing a treatment tool into open area 410 while the patient's body is being supported by mattress 490, and using the treatment tool to treat the area of interest from underneath the patient, while the patient is supported on the mattress.

It is expected that during the life of a patent maturing from this application many relevant treatment tools will be developed and the scope of the terms “surgical tool” and “treatment tool” is intended to include all such new technologies *a priori*. Similarly, it is expected that during the life of a patent maturing from this application many relevant intermediate objects fulfilling the descriptions of object 400 above will be developed and the scope of the term “intermediate object” is intended to include all such new technologies *a priori*.

The terms "comprises", "comprising", "includes", "including", “having” and their conjugates mean "including but not limited to".

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

WHAT IS CLAIMED IS:

1. A method for treating a target tissue using an extrabody High Intensity Focused Ultrasound (HIFU) projector, comprising:
 - a) providing a support having a surface for stably supporting a patient, said support having an indentation sized to receive at least a portion of a HIFU projector;
 - b) using a fluoroscopic imaging modality to detect a location of said target tissue while said patient is in a stable position supported by said support and said HIFU projector is absent from said indentation;
 - c) introducing said HIFU projector into said indentation and positioning and orienting said projector with respect to said detected location of said target tissue while said patient remains in said stable position; and
 - d) using said HIFU projector to treat said target tissue.
2. The method of claim 1, further comprising using a servomechanism to position and orient said projector with reference to said detected target tissue location.
3. The method of claim 1, further comprising defining said detected target tissue location with respect to radio-opaque markings stably positioned with respect to said surface, and positioning said projector with reference to said stably positioned markings.
4. The method of claim 1, wherein said target tissue is a renal blood vessel.
5. A method using a visualization modality and an intermediate object to positioning a surgical tool with respect to a region of interest in a body of a patient, the method comprising:
 - a) providing an intermediate object which comprises:
 - i) a surface for positioning a patient in a stable physical relationship to said intermediate object;
 - ii) a set of spaced dimensional markings visible under said visualization modality; and

- iii) a set of optically visible spaced dimensional markings having a known spatial relationship to said markings visible under said visualization modality;
 - b) using said visualization modality to determine a spatial relationship between said region of interest and said markings visible under said visualization modality; and
 - c) positioning said treatment tool with respect to said region of interest by positioning said tool with respect to said optically visible markings.
6. The method of claim 5, wherein said intermediate object is a mattress.
7. The method of claim 6, wherein said mattress comprises at least one open area such that it is possible to position a portion of said patient's body over said open area when said patient's body is lying on said mattress.
8. The method of claim 7, wherein said mattress is so shaped that a kidney-related organ of said patient may be positioned over said open area when said patient is centrally positioned on said mattress.
9. The method of claim 7, wherein said mattress comprises at least two such open areas, said open areas being shaped as indentations in the two long sides of said mattress.
10. The method of claim 7, wherein at least some of said markings visible under said visualization modality are positioned around at least a portion of a periphery of said open area.
11. The method of claim 5, wherein said markings visible under said visualization modality and said optically visible markings are same markings, and are visible both by direct optical observation and also by use of said visualization modality.

12. The method of claim 11, wherein markings of said markings visible under said visualization modality are radio-opaque.
13. The method of claim 5, wherein said optically visible markings are distinct from, and have a known spatial relationship to, said markings visible under said visualization modality.
14. The method of claim 5, wherein said treatment tool is an energy projector.
15. The method of claim 14, wherein said energy projector is a projector of acoustic energy.
16. The method of claim 5, wherein said energy projector is a High Intensity Focused Ultrasound (HIFU) projector.
17. The method of claim 5, wherein said visualization modality comprises an x-ray.
18. The method of claim 17, wherein said visualization modality is a fluoroscope.
19. The method of claim 5, further comprising:
 - d) introducing into a body lumen of a patient a catheter which comprises a sensor sensitive to projected energy; and
 - e) using an energy projector to project energy detectable by said sensor, and calculating at least one of:
 - i) an improvement in positioning of said treatment tool; and
 - ii) an improvement of aiming of said treatment tool,said calculating using information received from said sensor.
20. The method of claim 19, wherein said information received from said sensor comprises a response to energy projected by said treatment tool.
21. The method of claim 19, wherein said intermediate object is a mattress.

22. The method of claim 21, wherein said intermediate object is a mattress and said treatment tool is a HIFU projector.
23. The method of claim 19, wherein said treatment tool is a HIFU projector.
24. The method of claim 21, wherein said mattress comprises at least one open area allowing contact with at least a portion of said body from underneath said mattress, when said patient is lying on said mattress.
25. The method of claim 24, wherein said open area is formed as an indentation in a longitudinal side of said mattress.
26. The method of claim 25, wherein said indentation is sized to receive therein at least a portion of said HIFU projector.
27. The method of claim 24, wherein said open area is sized and positioned to enable to introduce a treatment portion of a HIFU projector under a portion of a body of a patient lying on said mattress, enabling direct contact between a component of said HIFU projector and said body.
28. The method of claim 27, wherein said open area is sized and positioned to enable to introduce a HIFU projector under at least a portion of a renal area of a patient.
29. The method of claim 28, wherein said open area is sized and positioned to enable to introduce a HIFU projector to a position under a renal blood vessel of a patient.
30. The method of claim 19, further comprising calculating aiming parameters of a HIFU projector.
31. The method of claim 19, further comprising calculating aiming parameters of a phased array projector.

32. The method of claim 24, wherein at least some of said markings visible under said visualization modality are positioned adjacent to a border of said open area.
33. The method of claim 32, wherein said optically visible markings are positioned adjacent to a border of said open area.
34. The method of claim 19, further comprising using a fluoroscope to monitor catheterization of said patient.
35. The method of claim 19, wherein said body lumen is a renal blood vessel.
36. The method of claim 19, wherein said body lumen is a urethra.
37. A method using a visualization modality and an intermediate object to positioning a surgical tool with respect to a region of interest in a body of a patient, the method comprising:
- a) providing an intermediate object which comprises:
 - i) a surface for positioning a patient in a stable physical relationship to said intermediate object; and
 - ii) a set of spaced dimensional markings visible under said visualization modality;
 - b) using said visualization modality to determine a spatial relationship between said region of interest and said markings visible under said visualization modality; and
 - c) positioning said treatment tool with respect to said region of interest by using a position sensor to report a position of said treatment tool with reference to a spatial coordinate system having a known relationship to said markings visible under said visualization modality.
38. The method of claim 37, further comprising using a servo-mechanism to displace or aim said treatment tool.

39. A method of treating a recumbent patient which comprises:
- a) positioning said patient on a mattress which comprises:
 - i) a surface for supporting the body of a patient; and
 - ii) an indentation in said surface forming an open area which does not support any part of the body of a patient, yet which will be below a portion of a patient's body when said patient is lying on said mattress said patient's body is being supported by said surface,
said patient being so positioned that a region of interest in the patient's body is positioned above said open area;
 - b) introducing a treatment tool into said open area while said patient's body is being supported by said mattress; and
 - c) using said treatment tool to treat said area of interest from underneath said patient while said patient is supported on said mattress.
40. A mattress which comprises:
- a) a surface for supporting the body of a patient; and
 - b) an indentation in said surface forming an open area which does not support any part of the body of a patient, yet which will be below a portion of a patient's body when said patient is lying on said mattress said patient's body is being supported by said surface.
41. The mattress of claim 40, wherein said open area is formed as an indentation in a long side of said mattress.
42. A mattress which comprises spaced dimensional markings visible under an imaging modality.
43. The mattress of claim 42, wherein said spaced dimensional markings are visible under x-ray imaging.

44. The mattress of claim 42, wherein said spaced dimensional markings are visible under fluoroscopic imaging.

45. The mattress of claim 42, wherein at least some of said spaced dimensional markings are also optically visible to a user.

46. The mattress of claim 42, further comprising an optically visible set of spaced dimensional markings distinct from said spaced dimensional markings visible under an imaging modality, and having a known spatial relationship thereto.

47. The mattress of claim 42, comprising at least one open region.

48. The mattress of claim 47, wherein at least some of said spaced dimensional markings are positioned in proximity to a border of said at least one open region.

49. The mattress of claim 47, wherein said at least one open region is sized to accommodate therein a HIFU projector.

50. The mattress of claim 47, wherein said at least one open region is positioned where it can be beneath a kidney-related organ of a patient when said patient lies on his back on said mattress.

51. The mattress of claim 50, comprising two such openings, one on each longitudinal side of said mattress.

52. The mattress of claim 42, wherein said spaced dimensional markings visible under an imaging modality are also optically visible to a viewer.

53. The mattress of claim 42, further comprising additional spaced dimensional markings distinct from said spaced dimensional markings visible under an imaging modality, said additional spaced dimensional markings being optically visible to a

viewer and having a known spatial relationship to said spaced dimensional markings visible under an imaging modality.

54. A catheterization laboratory system which comprises:

- a) a catheter insertable in a patient;
- b) a table for positioning a support surface and a patient thereon;
- c) a support surface having an indentation sized to accommodate at least a portion of a HIFU projector therein;
- d) a fluoroscopic imaging system; and
- e) a HIFU projector having a projecting portion sized to fit within said indentation.

55. The system of claim 54, wherein said catheter comprises a sensor sensitive to projected energy.

56. The system of claim 54, further comprising a servomechanism for positioning said HIFU projector according to a target tissue position detected by said fluoroscope.

57. The system of claim 54, further comprising a set of radio-opaque ruler-like spatial distance markings having a stable positional relationship with said support surface.

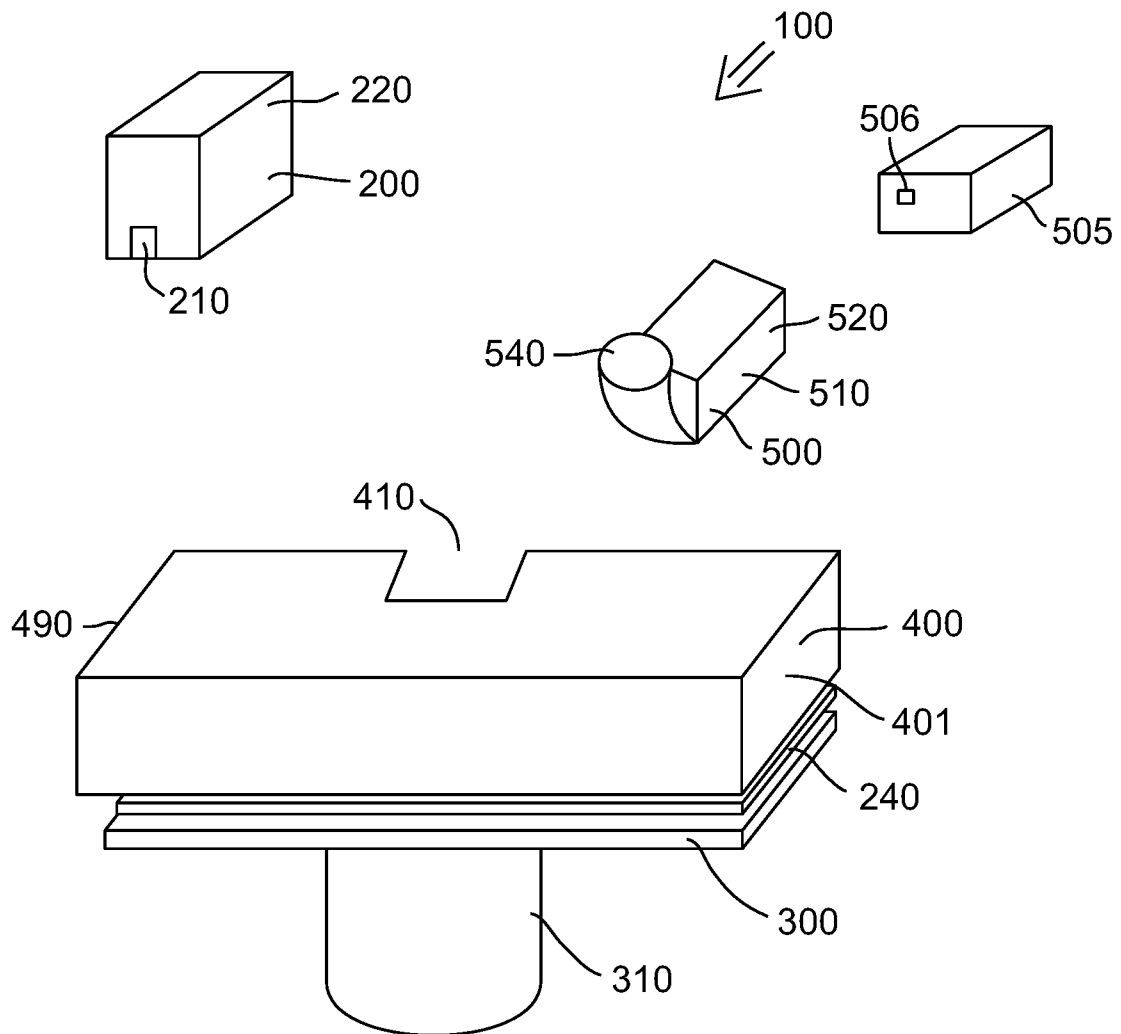


FIG. 1

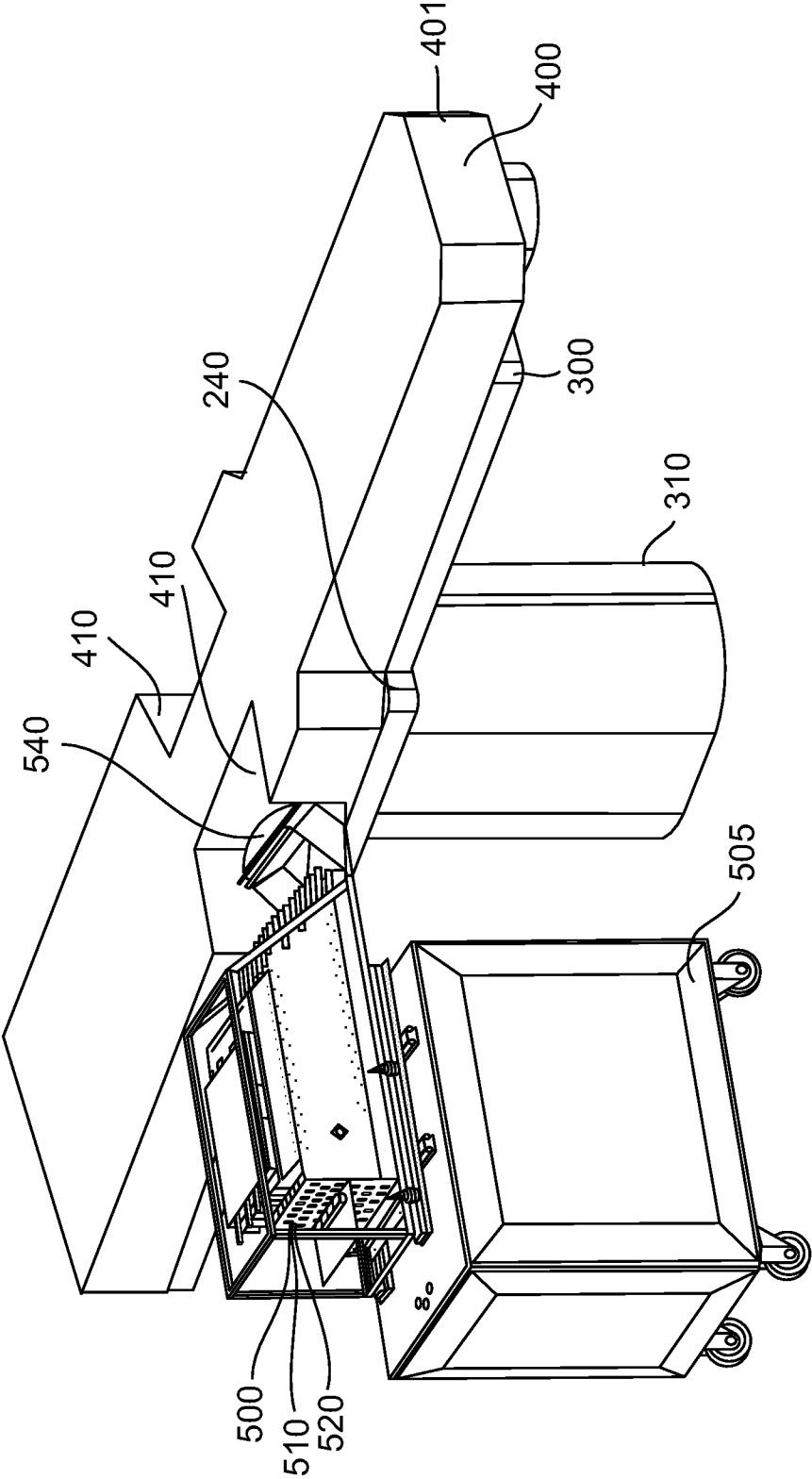
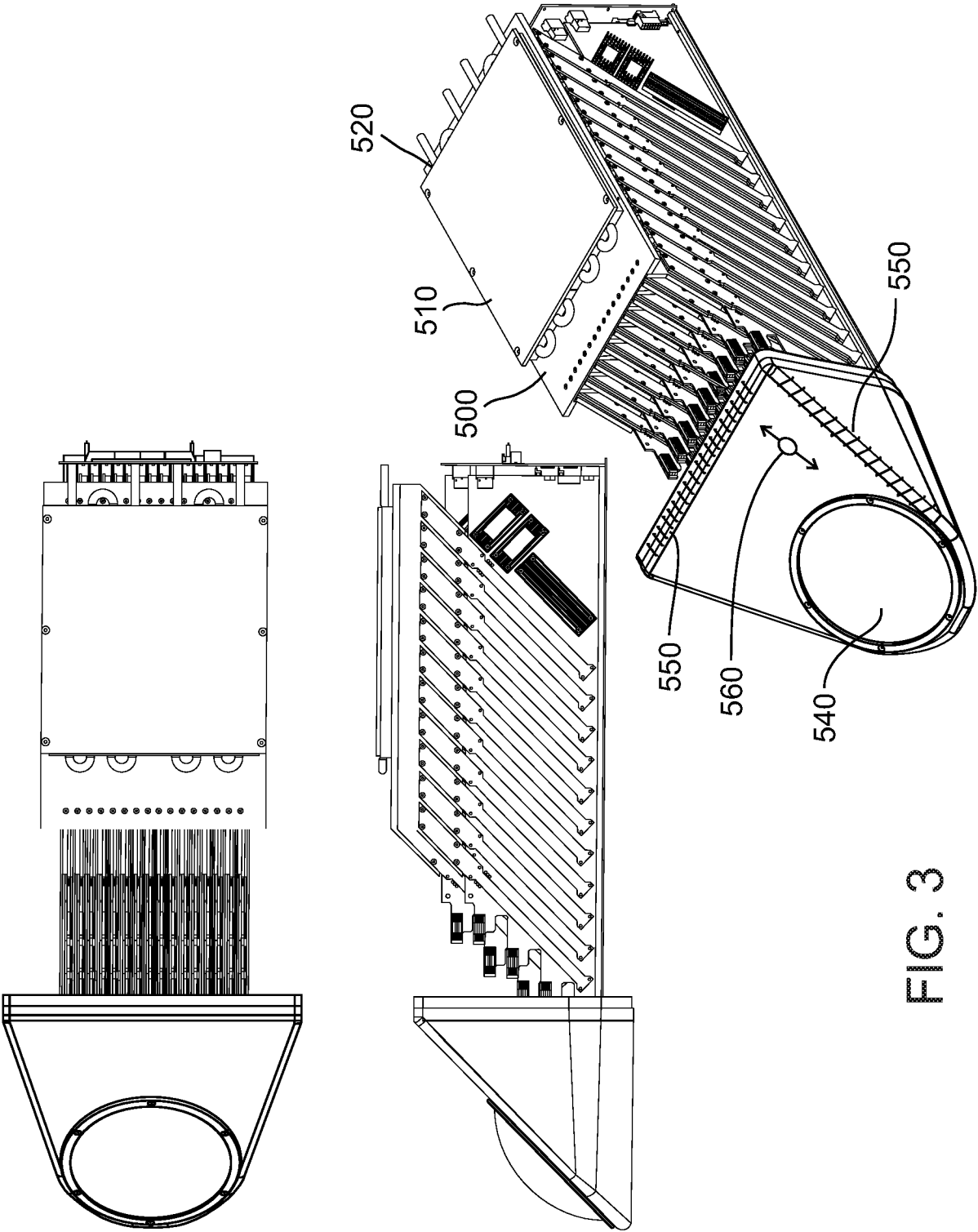


FIG. 2



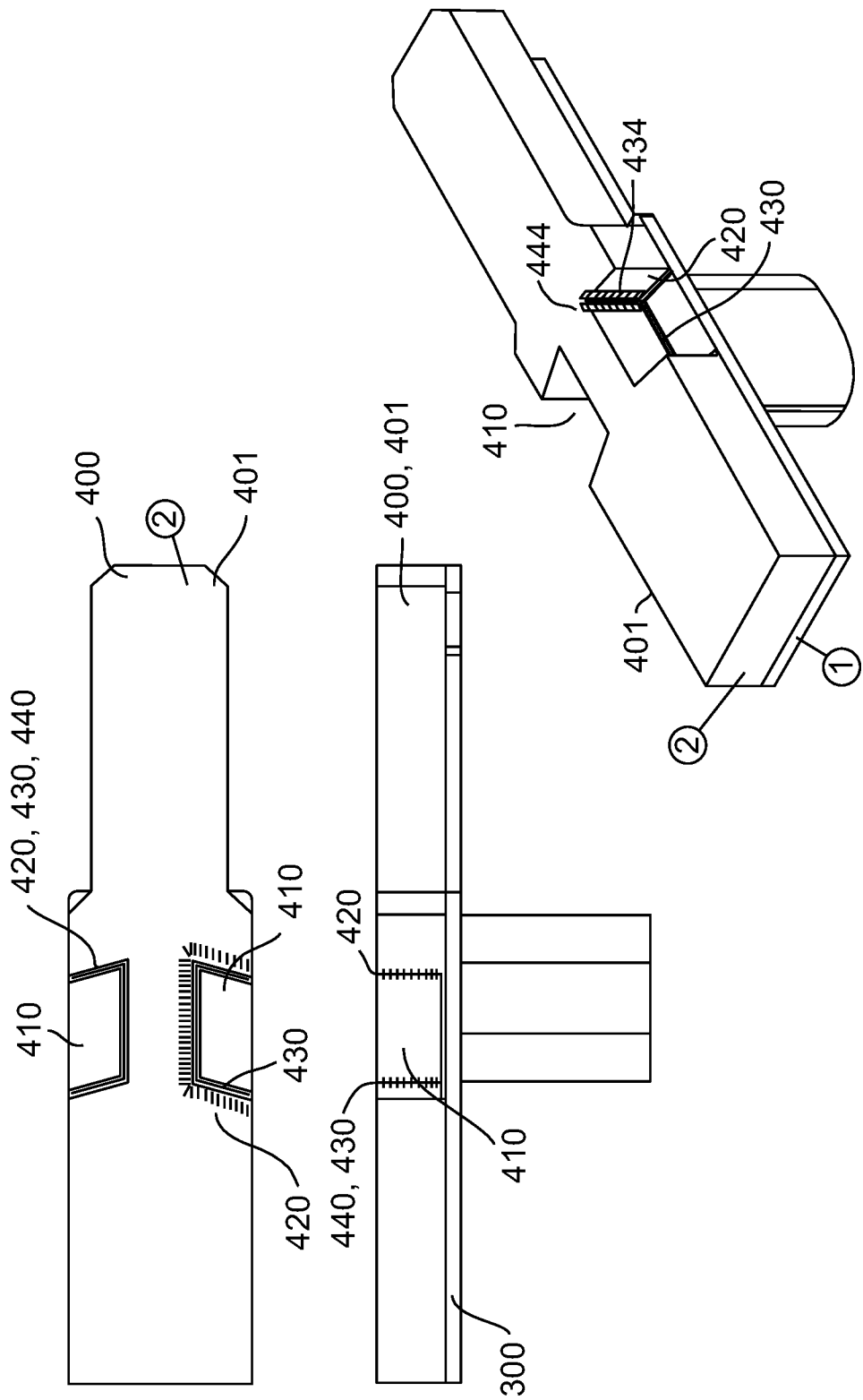


FIG. 4

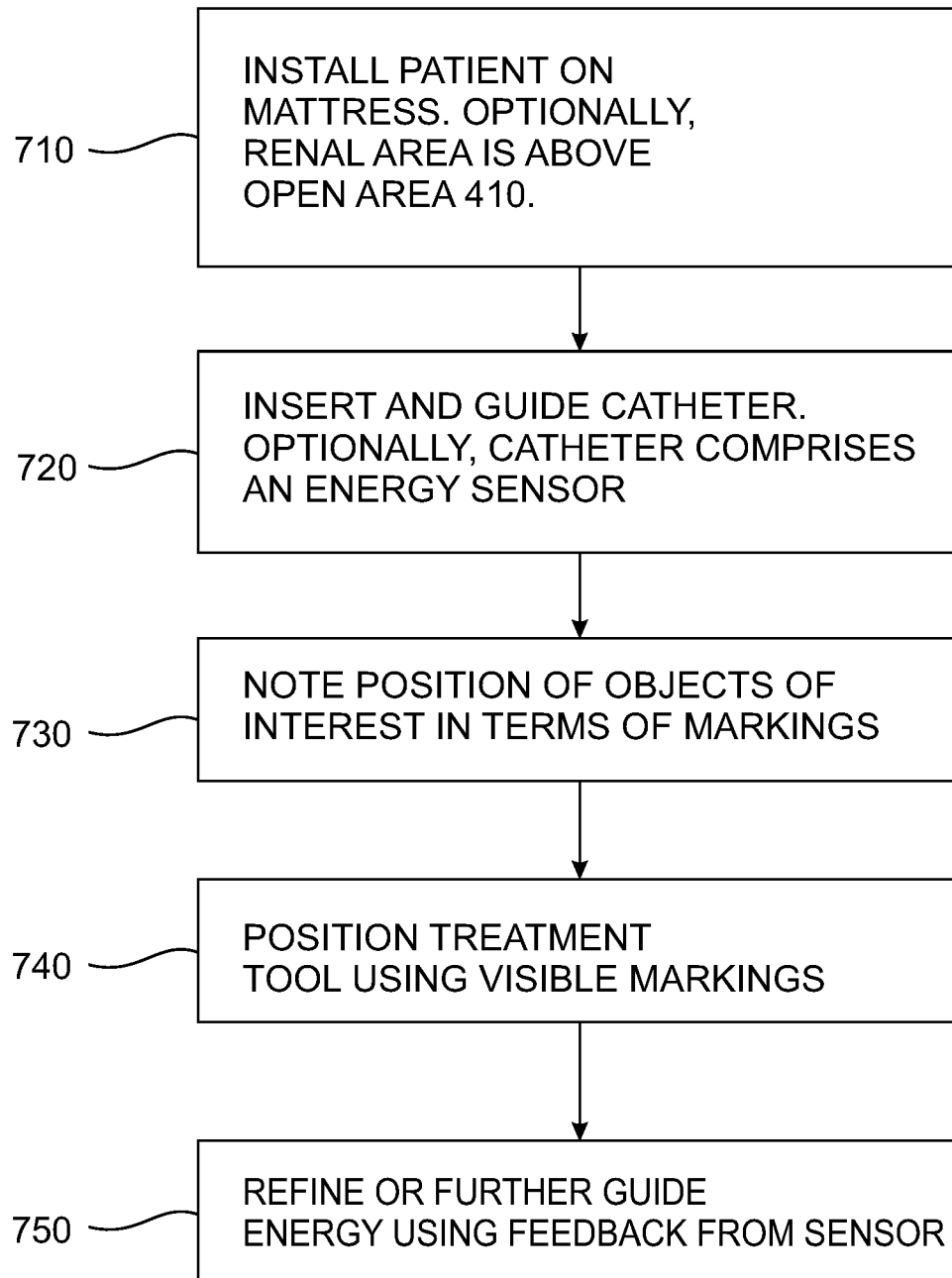


FIG. 5

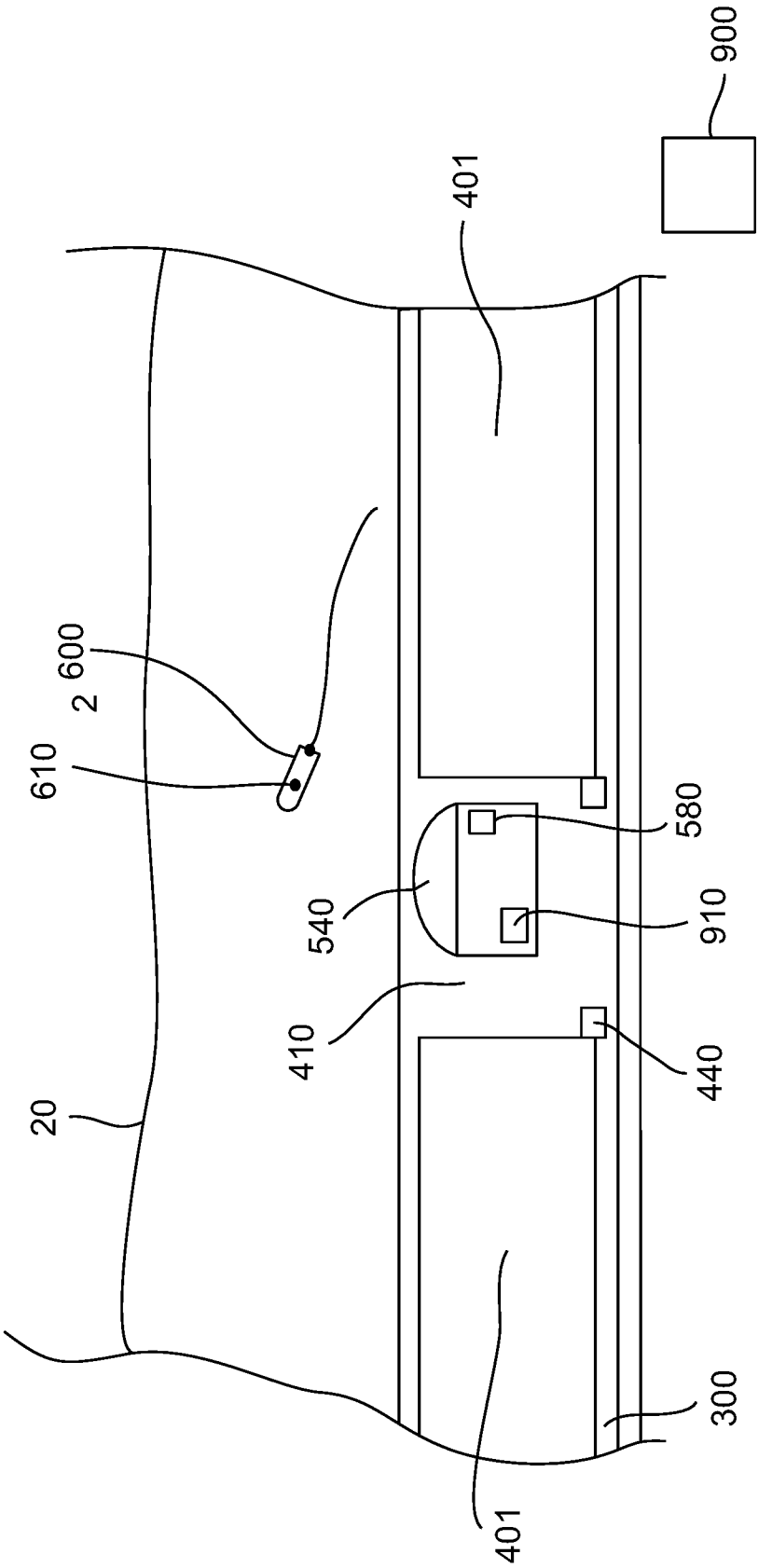


FIG. 6

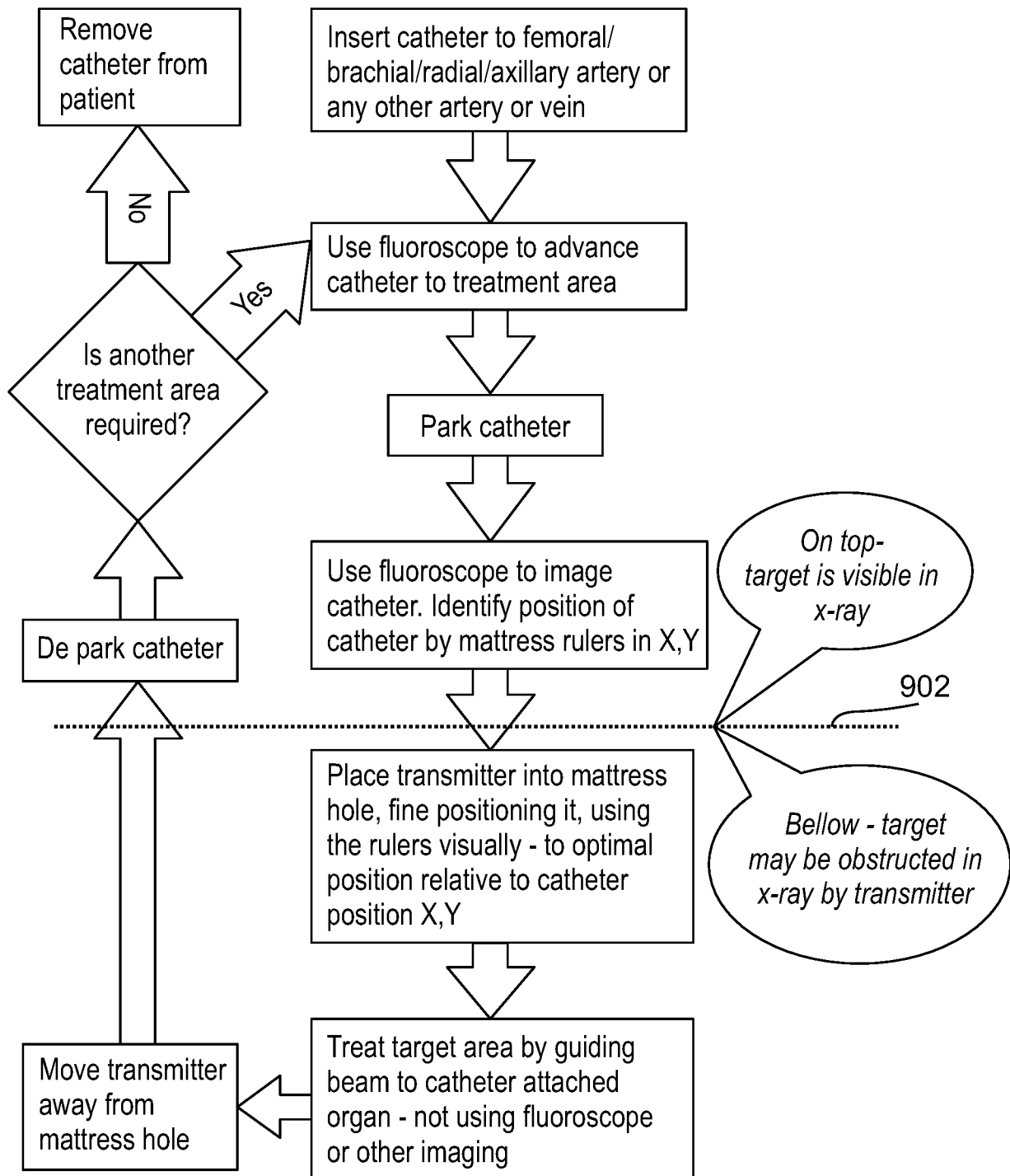


FIG. 7

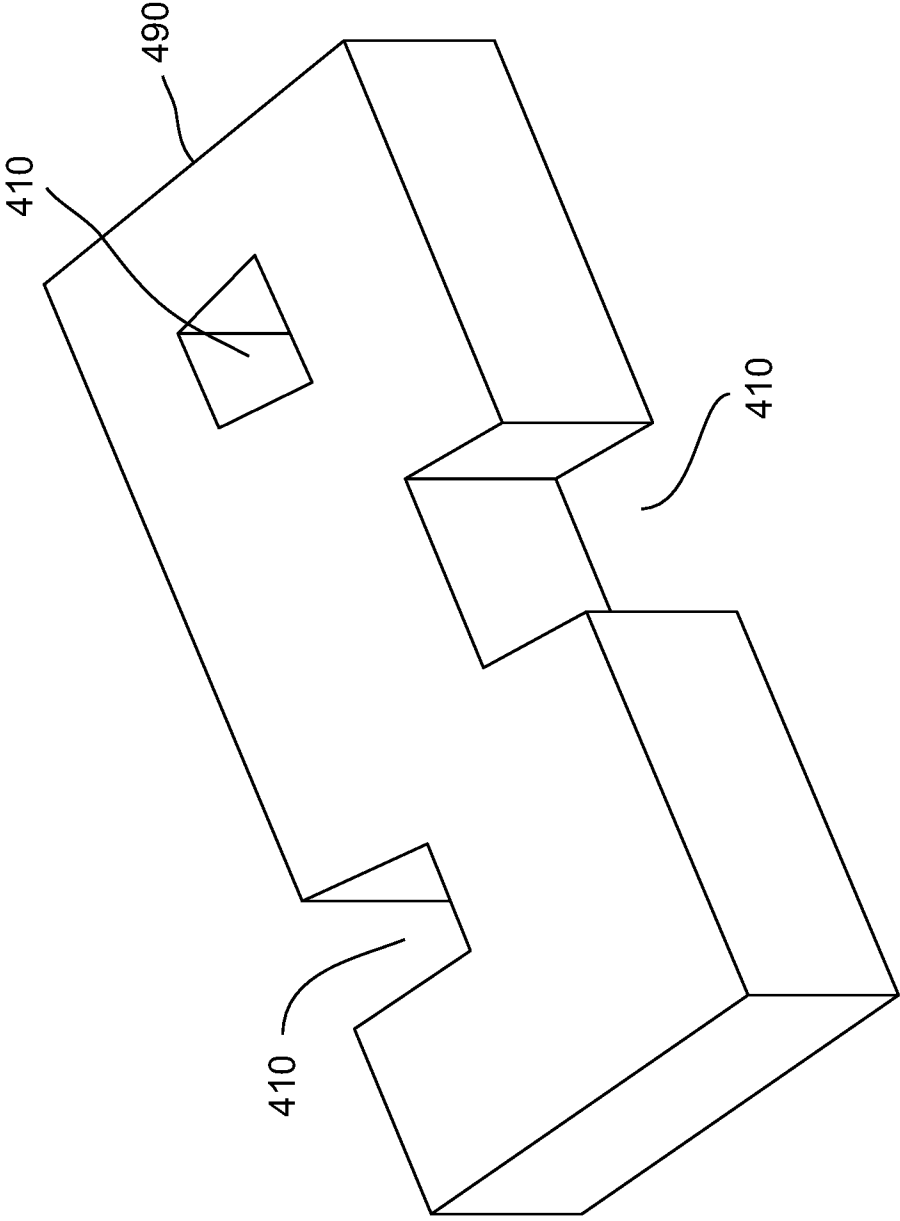


FIG. 8