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(71) Applicant: NESA MEDTECH PRIVATE LIMITED

[IN/IN]; 15, 33 Main, 7th Block, Bhavani Colony, Banashankari 3rd Stage, Bangalore 560085 (IN).

(72) Inventors: KOTHAMACHU, Sreekar;

No. 15, Siri Nilayam, 33 Main, 7th Block, Bhavani Colony, Banashankari 3rd Stage, Karnataka, Bangalore 560085 (IN). SAM-NEKAR, Darshan Dayanand; 46/2, 2nd Main, AVK College Road, PJ extension, Karnataka, Davangere 577002 (IN). M, Sandeep P; 15, 8th Cross, Kamakya Layout, BSK 3rd Stage, Karnataka, Bangalore 560085 (IN). P, Lakshmi Bai; #659, 14th B Main, Gokula 1st stage, Mathikere, Karnataka, Bengaluru 560054 (IN).

(74) Agent: SINGH, Manisha;

LEXORBIS, 606-607, 6th Floor, Gamma Block, Sigma Soft Tech Park No. 7, Whitefield Main Road, Varthur Hobli, Karnataka, Bengaluru 560066 (IN).

(54) Title: A SYSTEM AND METHOD FOR GUIDING A USER IN NAVIGATING A DEVICE DURING A PROCEDURE

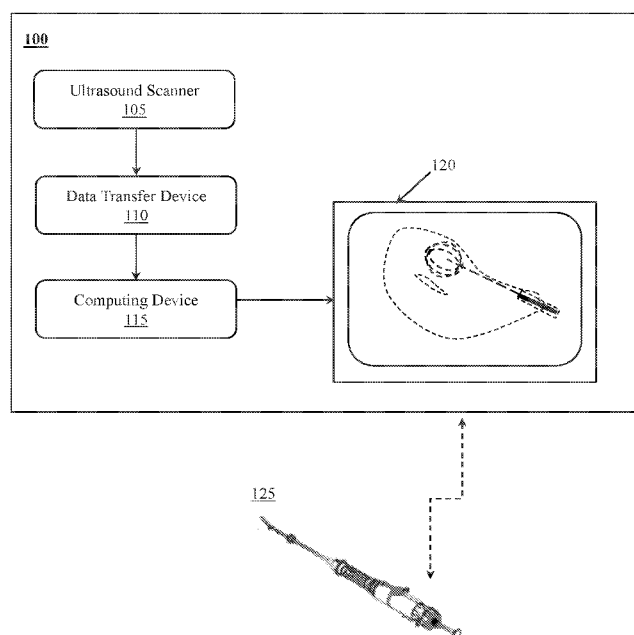


FIGURE 1

(57) Abstract: Disclosed in a system (100) for guiding a user in navigating an interventional device (125) during a procedure. The system (100) comprises, an ultrasound scanner (105) for capturing ultrasound images of a uterus of the subject, and a computing device (115), wherein the 5 computing device (115) generates a 3D representative model of the uterus using one or more annotated images, generates initial guidance parameters for moving a tip of the interventional device (125), from a reference point to reach a target point in a target region, generates treatment parameters using the three-dimensional representative model of the uterus, displays and during the procedure, the computing device (115) periodically updates the guidance parameters based 0 on a current position of the tip of the interventional device (125), real-time data of the interior of the uterus and the initial guidance parameters.

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A SYSTEM AND METHOD FOR GUIDING A USER IN NAVIGATING A DEVICE DURING A PROCEDURE

[001] This complete specification claims priority from the provisional application
5 numbered “202241041581”, titled “system and method for guidance and navigation
during interventional procedures”, filed on July 20, 2023, and the provisional application
numbered “202241041606”, titled “a system and method for guidance and estimation of
treatment zone during interventional procedures” filed on July 20, 2023.

10 TECHNICAL FIELD

[002] The present disclosure generally relates to systems and methods used in
interventional procedures and more particularly to a system and method for guiding a user in
navigating a device during a procedure.

15 BACKGROUND

[003] Interventional procedures are performed to diagnose or treat uterine fibroids. These
procedures may include, but are not limited to ablation, biopsy, drug delivery etc. These
20 procedures are required to reach the target location in the fibroid to perform diagnosis or
treat the fibroids.

[004] For instance, ablation which is one of the minimally invasive interventional
procedures that uses thermal energy to target fibroids to reduce the size of the fibroid
25 significantly. Typically, ablation is done through a laparoscopic or a transcervical procedure.
During the laparoscopic procedure, physicians make a small opening in the abdomen to
insert a laparoscope with a camera at the tip. Using the laparoscopic camera and a
laparoscopic ultrasound tool, the physicians locate the fibroids and deploy ablation needle
into the fibroids to treat the fibroids.

30 [005] During the transcervical procedure, an imaging device (a transcervical ultrasound
transducer for example) and a device having needle are inserted through the cervix to locate
and treat the fibroids.

[006] As described, the conventional systems and methods provide real-time two-dimensional images captured from an imaging device and the physicians need to visualize and characterize the fibroids, and orient, move, and operate the device to reach the target area of the fibroids. Hence the procedures using the conventional system are complex, and planning depends on the intuition and experience of the physicians. In addition, since the conventional procedures are subjective and skillful in nature, there are high chances of not reaching the target location and delivering optimal intervention leading to incomplete treatment, prolonged hospitalization and further surgical intervention. Further, the conventional procedure using the conventional device is subjective as the physician needs to locate and plan the procedure. Adapting to the devices and procedures is complex and requires additional training or a skilled person.

BRIEF SUMMARY

[007] This summary is provided to introduce a selection of concepts in a simple manner that is further described in the detailed description of the disclosure. This summary is not intended to identify key or essential inventive concepts of the subject matter nor is it intended for determining the scope of the disclosure.

[008] To overcome at least one of the problems mentioned above, there exists a need for a system and method for guiding a user in navigating an interventional device during an interventional procedure on a subject.

[009] A method for guiding a user in navigating an interventional device through the cervix uteri of a subject during an interventional procedure on the subject is disclosed. The method comprises, capturing a plurality of ultrasound images of a uterus of the subject using an ultrasound transducer, displaying the plurality of ultrasound images on a display unit for enabling the user to select one or more images from the plurality of ultrasound images, receiving annotations provided by the user on the one or more images selected by the user, the annotations indicating the uterus landmarks and one or more target regions inside the uterus, generating a three-dimensional representative model of the uterus using the annotated images, generating initial guidance parameters for moving a tip of the interventional device,

from a reference point to reach a target point in the target region, wherein the guidance parameters are generated using the three-dimensional representative model of the uterus, generating treatment parameters based on the one or more target regions inside the uterus, displaying the guidance parameters and the treatment parameters on the display unit, capturing real-time data of uterus, using the ultrasound transducer while the user moves the tip of the interventional device towards the target point, and periodically updating the guidance parameters based on current position of the tip of the interventional device, the real-time data, and the initial guidance parameters.

[0010] Further, a system for guiding a user in navigating an interventional device through the cervix uteri of a subject during an interventional procedure on the subject is disclosed. The system comprises, an ultrasound scanner configured for capturing a plurality of ultrasound images of a uterus of the subject using an ultrasound transducer, and a computing device configured for, displaying, on a display unit, the plurality of ultrasound images for enabling the user to select one or more images from the plurality of ultrasound images, receiving, through the display unit, annotations provided by the user on the one or more images selected by the user, the annotations indicating the uterus landmarks and one or more target regions inside the uterus, generating, by a three-dimensional model generation module, a three-dimensional representative model of the uterus using the annotated images, generating initial guidance parameters, by a guidance parameter generation module, for moving a tip of the interventional device, from a reference point to reach a target point in the target region, wherein the guidance parameters are generated using the three-dimensional representative model of the uterus, generating treatment parameters, by a treatment parameter generation module, using the three-dimensional representative model of the uterus, displaying, on the display unit, the guidance parameters and the treatment parameters on the display unit, capturing, through the ultrasound scanner, real-time data of uterus while the user moves the tip of the interventional device towards the target point, and periodically updating, by a processor, the guidance parameters based on a current position of the tip of the interventional device, and the initial guidance parameters.

[0011] To further clarify advantages and features of the present disclosure, a more particular description of the disclosure will be rendered by reference to specific embodiments

thereof, which is illustrated in the appended figures. It is to be appreciated that these figures depict only typical embodiments of the disclosure and are therefore not to be considered limiting of its scope. The disclosure will be described and explained with additional specificity and detail with the accompanying figures.

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BRIEF DESCRIPTION OF THE FIGURES

[0012] The disclosed method and system will be described and explained with additional specificity and detail with the accompanying figures in which:

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[0013] Figure 1 is block diagram of a system for guiding a user in navigating an interventional device during an interventional procedure on a subject in accordance with an embodiment of the present disclosure;

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[0014] Figure 2 is a block diagram of the computing device 115 in accordance with an embodiment of the present disclosure;

[0015] Figure 3 shows an exemplary image displayed by the computing device in accordance with an embodiment of the present disclosure;

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[0016] Figure 4 shows an exemplary interventional device for performing the interventional procedure;

[0017] Figure 5 illustrates an example method of generating a 3D model;

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[0018] Figure 6 shows a graph illustrating a method of determining a shortest distance between two points in a 3D space;

[0019] Figure 8 shows the image requirement in accordance with an embodiment of the present disclosure; and

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[0020] Figure 8 shows an exemplary interface displaying additional guidance parameters in accordance with an embodiment of the present disclosure.

[0021] Further, persons skilled in the art to which this disclosure belongs will appreciate that elements in the figures are illustrated for simplicity and may not have been necessarily drawn to scale. Furthermore, in terms of the construction of the joining ring and one or more components of the bearing assembly may have been represented in the figures by conventional symbols, and the figures may show only those specific details that are pertinent to understanding the embodiments of the present disclosure so as not to obscure the figures with details that will be readily apparent to those of ordinary skill in the art having benefit of the description herein.

DETAILED DESCRIPTION

[0022] For the purpose of promoting an understanding of the principles of the disclosure, reference will now be made to the embodiment illustrated in the figures and specific language will be used to describe them. It will nevertheless be understood that no limitation of the scope of the disclosure is thereby intended. Such alterations and further modifications to the disclosure, and such further applications of the principles of the disclosure as described herein being contemplated as would normally occur to one skilled in the art to which the disclosure relates are deemed to be a part of this disclosure.

[0023] It will be understood by those skilled in the art that the foregoing general description and the following detailed description are exemplary and explanatory of the disclosure and are not intended to be restrictive thereof.

[0024] In the present disclosure, relational terms such as first and second, and the like, may be used to distinguish one entity from the other, without necessarily implying any actual relationship or order between such entities.

[0025] The terms "comprises", "comprising", or any other variations thereof, are intended to cover a non-exclusive inclusion, such that a process or method that comprises a list of steps does not include only those steps but may include other steps not expressly listed or inherent to such a process or a method. Similarly, one or more elements or structures or components preceded by "comprises... a" does not, without more constraints, preclude the existence of

other elements, other structures, other components, additional devices, additional elements, additional structures, or additional components. Appearances of the phrase “in an embodiment”, “in another embodiment” and similar language throughout this specification may, but do not necessarily, all refer to the same embodiment.

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[0026] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. The components, methods, and examples provided herein are illustrative only and not intended to be limiting.

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[0027] Embodiments of the present disclosure will be described below in detail with reference to the accompanying figures.

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[0028] Embodiments of the present disclosure disclose a system and a method for guiding a user in navigating an interventional device through the cervix uteri of a subject during an interventional procedure on the subject. Initially, a plurality of ultrasound images of a uterus of the subject is captured through an ultrasound transducer. In a preferred embodiment, the plurality of ultrasound images of the uterus is captured by introducing the ultrasound transducer trans-vaginally proximal to the cervix uteri of the subject. Alternatively, the images may be captured using an abdominal ultrasound transducer. The plurality of ultrasound images are then displayed on a display unit for enabling a user to select one or more images from the plurality of ultrasound images and for annotating the selected images. Then the system receives the annotations provided by the user on the one or more images selected by the user, the annotations indicating the uterus landmarks and one or more target regions inside the uterus. The term uterus landmarks as described herein refers to anatomical features, structures, or reference points of the uterus that helps in defining its structure, function, or location. Then the system generates a three-dimensional representative model of the uterus using the annotated images. Further, using the three-dimensional representative model of the uterus, the system generates initial guidance parameters for moving a tip of the interventional device, from a reference point to reach a target point in the target region and generates treatment parameters based on the one or more target regions inside the uterus, and displays the guidance parameters and the treatment parameters on the display unit to guide the user during the interventional procedure on the subject. While performing the

interventional procedure, that is while navigating the tip of the interventional device, the system captures real-time data of the uterus, using the ultrasound transducer, and periodically updates the guidance parameters based on a current position of the tip of the interventional device, the real-time data of the interior of the uterus and the initial guidance parameters. It is to be noted that the target region may be a fibroid or any region in the uterus. In the present disclosure, fibroid is considered as an example target region and the target point may be any point in the fibroid.

[0029] Figure 1 is block diagram of a system for guiding a user in navigating an interventional device during an interventional procedure on a subject in accordance with an embodiment of the present disclosure. As shown, the system 100 comprises an ultrasound transducer 105, a data transfer device 110, a computing device 115 and a display device 120, wherein the said devices are communicatively connected through wired or wireless communication networks.

[0030] The ultrasound transducer 105 is a transvaginal ultrasound transducer used in the hospital for scanning human subjects. Alternatively, the ultrasound transducer 105 may be an abdominal ultrasound transducer. The ultrasound transducer 105 is communicatively connected to an ultrasound scanner (not shown) and the ultrasound transducer 105 radiates ultrasound and receives reflected ultrasound and thereby. The scanner then uses the reflected ultrasound to generate images. During the scanning procedure, the ultrasound transducer is introduced trans-vaginally proximal to the cervix uteri of the subject and a plurality of ultrasound images of a uterus of the subject is captured. In the case of the abdominal ultrasound transducer, the transducer is swept along the abdomen to acquire a volume scan of the entire uterus in different orientations and the images are captured. In one embodiment of the present disclosure, the plurality of ultrasound images of the uterus is obtained by scanning the uterus in two orthogonal planes and one or more images are captured in each of the two orthogonal planes.

[0031] The data transfer device 110 then transfers the plurality of ultrasound images to the computing device 115 for further processing. The data transfer device 110 may be a frame

grabber or a wired or wireless communication module or any other equipment capable of transferring digital image data from a source device to a destination device.

5 [0032] In one embodiment of the present disclosure, the computing device 115 is configured for guiding the user in navigating an interventional device 125 through the cervix uteri of the subject during an interventional procedure on the subject. The computing device 115 may include, for example, a computer server or a network of computers having communication and computational capabilities for processing high volume data. Hence, the computing device 115 may include one or more processors, associated processing modules, 10 interfaces and storage devices communicatively interconnected to one another through one or more communication means for communicating information. The storage associated with the computing device 115 may include volatile and non-volatile memory devices for storing information and instructions to be executed by the one or more processors and for storing temporary variables or other intermediate information during processing. In one embodiment 15 of the present disclosure, the computing device 115 comprises an input and output module 120 for receiving calibration data from the user and for guiding the user during the interventional procedure.

20 [0033] Figure 2 is a block diagram of the computing device 115 in accordance with an embodiment of the present disclosure. As shown, the computing device 115 comprises a network interface module 203 enabling communication with the data transfer device 110, a processor 204, a memory module 206 for storing temporary data during processing and for storing instructions to be executed by the processor 204. Further, the data transfer device 110 comprises a 3D model generation module 208, guidance parameter generation module 210 25 and a treatment parameter generation module 212.

[0034] As described, the plurality of ultrasound images of the uterus of the subject is captured by scanning the uterus in two orthogonal planes, and the captured images are communicated to computing device 115. That is, one or more images are captured in each of 30 the two orthogonal planes. In one embodiment of the present disclosure, the user may set a resolution for the incoming images and all the images will be converted to the resolution set by the user and stored in the memory for further processing.

[0035] Then the processor 204 displays the plurality of ultrasound images on the display unit 120 for enabling the user to select one or more images from the plurality of ultrasound images, the one or more images including at least one image obtained from scanning in each of the two orthogonal planes. That is, the computing device 115 displays all the ultrasound images and enables the user to browse through all the images to select one or more images in which the uterus and the target regions (one or more fibroids) are clearly visible. Further, the computing device 115 enables the user to annotate the one or more images selected by the user. In one embodiment of the present disclosure, the annotations include calibrating the selected images, marking the uterus landmarks, and marking the one or more fibroids in the uterus. In a preferred embodiment, the annotations further include marking target points in the one or more fibroids. However, the guidance parameter generation module 210 may be configured to determine the target point in the fibroid based on the maximum length, the maximum width, and the maximum depth of the fibroid, for example. In another embodiment, the computing device 115 is configured for automatically selecting and annotating the one or more images using trained machine learning models.

[0036] Figure 3 shows an exemplary image displayed by the computing device in accordance with an embodiment of the present disclosure. As shown, the computing device 115 displays the image on the display unit 120 and provides an image scale 303 for calibration by the user. Based on the calibration, the computing device 115 computes the length of each pixel. This value is used to get the coordinates of uterus and the one or more fibroids based on the annotation on the anatomical features of the uterus. That is, when the user annotates the uterus and the fibroids, the computing device 115 identifies the number of pixels in the annotations. Upon this calibration, the user annotates uterus and the one or more fibroids and its relevant orientation details in each of the selected images. That is, the user needs to annotate at least the uterus landmarks and the one or more fibroids in the one or more images in each of the orthogonal planes obtained from scanning in two orthogonal planes. Further, the user needs to annotate at least the uterus landmarks and the one or more fibroids in the one or more images obtained from scanning in the two orthogonal planes. The user may annotate the selected images in multiple ways using one or more tools provided by the computing device 115. For example, the user may mark the uterus and the one or more

fibroids inside the uterus by drawing circle(s), ellipse(s), dots, lines, etc. The annotated images are stored in the memory module 206 for further processing. As described, the computing device 115 may automatically select and annotate the one or more images using the trained machine learning models.

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[0037] Once the user annotates the uterus landmarks and the one or more fibroids, the plurality of ultrasound images and the one or more annotated images (that is the anatomical features) are post-processed by the computing device 115 to detect the coordinates in three dimensions (3D coordinates) of the uterus and one or more fibroids inside the uterus, and to generate a 3D representative model of the uterus. These 3D coordinates are used to generate the initial guidance parameters to the one or more fibroids, specifically, for guiding the user to navigate the tip of the interventional device from a reference point to a target point in the fibroid. If multiple fibroids are identified, the initial guidance parameters are generated for each fibroid. The initial guidance parameters may include, but not limited to, a profile, a length of the transcervical interventional device 125, angulation of the transcervical interventional device 125 and a length of insertion of the transcervical interventional device 125 from a reference point. In one embodiment, the reference point is an external orifice of the uterus. Figure 4 shows an exemplary interventional device for performing the interventional procedure. Referring to the Figure 4, the profile of the interventional device 125 defines and refers to the angled tip 408. That is, the interventional device 125 may work with different angled tip having different angles, which may vary between zero to forty-five degrees. Further, angulation of the transcervical interventional device 125 as described herein refers to an angle at which the interventional device 125 needs to be rotated during the procedure. The device comprises an adjustable stopper 409 which is adjustable based on the insertion length to prevent accidental insertion of the needle into the uterus.

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[0038] Referring to Figure 2, on receiving the annotations from the user, the 3D model generation module 208 generates a 3D representative model of the uterus. The term 3D representative model as described herein refers to a model of the uterus and may not be an exact 3D replica of the uterus. In other words, the 3D representative model of the uterus resembles a 3D model of the uterus. In one embodiment of the present disclosure, the 3D model generation module 208 uses the information such as uterus dimensions, one or more

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fibroid dimensions, one or more fibroid positions with respect to a reference point (external orifice of the uterus) for generating the 3D representative model of the uterus. In one embodiment of the present disclosure, the reference point is the cervix uteri. Such information is determined based on the user's annotations on the images obtained from scanning in the two orthogonal planes. That is, once the user annotates the uterus landmarks and the one or more fibroids in the one or more images, the 3D model generation module 208 processes the annotated images and generates the values required for the generating the 3D representative model of the uterus. That is, the 3D model generation module 208 derives the width and depth of the uterus and fibroids from the annotations on the images obtained through scanning in two orthogonal planes. Then the distance of a fibroid is derived using the annotated images of the uterus and the fibroid. Similarly, the length of the uterus and the fibroid are derived from the annotated images obtained through scanning in two orthogonal planes. The distance of the fibroid is derived from the annotated images of the uterus and the fibroid. Figure 5 illustrates an example method of generating a 3D representative model. As shown, the images annotated with uterus landmarks and the fibroid are used and the distances are measured using the calibration data. Then the plurality of ultrasound images is used to generate the 3D representative model of the uterus.

[0039] On generating the 3D representative model of the uterus, the guidance parameter generation module 210 generates the initial guidance parameters for guiding the user to reach the one or more fibroids during the interventional procedure on the subject. The initial guidance parameters may include, but not limited to, a profile, a length of the transcervical interventional device, angulation of the transcervical interventional device and a length of insertion of the transcervical interventional device from a reference point, wherein the reference point is the external orifice of the uterus. In one embodiment of the present disclosure, the guidance parameter generation module 210 uses the 3D representative model of the uterus for generating the initial guidance parameters. That is, one or more values for each of the guidance parameters are calculated based on the reference point and the target point in the 3D representative model, wherein the reference point is the external orifice of the uterus, and the target site point is preferably any location in the fibroid. For example, considering the guidance parameter generation module 210, on receiving the annotations on the fibroids, the guidance parameter generation module 210 computes the size of the fibroid

based on the number of pixels. Similarly, on identifying the reference point and the target point, the guidance parameter generation module 210 computes the distance between the reference point and the target point.

5 [0040] It is to be noted that a proprietary interventional device 125 (shown in Figure 1) for interventional procedures is compatible with different angled tips (hereafter referred as profile) that allows the extension of the device 125 in a range of its specified angles. These sets of angles help in covering the major parts of the uterus for the intervention. In addition, the device 125 comprises markings to determine extent of extension of an interventional
10 device, markings provided on a sheath to enable determination of extent of insertion of the angled tip into the uterine cavity and rotary markings provided on the device 125 to enable determination of rotational orientation of the sheath. The system and method disclosed in the present disclosure generates guidance parameters to assist in interventional procedure for fibroid using the device 125. In other words, the system and method provide values to select
15 and adjust various components of the device 125 to precisely reach the target point in the fibroid.

[0041] As described, the annotation data is used to get the coordinates of the reference point and the target point in the target region, that is a target point in the fibroid. Once the
20 coordinates of the reference point and the target point is generated, the guidance parameter generation module 210 generates the initial guidance parameters for guiding the user to reach the one or more target points in the fibroid during the interventional procedure on the subject. It is to be noted that the initial guidance parameters are generated to reach each of the one or more target points in the fibroid. In one embodiment, the guidance parameter generation
25 module 210 reads the target point in the fibroid and the reference point in the 3D representative model and determines the shortest distance between the two points. Figure 6 shows a graph illustrating a method of determining the shortest distance between two points in a 3D space. This distance is run through multiple combinations of the interventional device having different angulations, lengths of angled tip and the length of the interventional device.
30 As shown, the guidance parameter generation module 210 computes the distance between external orifice 604 (reference point) of the uterus and the target point 608 in the fibroids

based on the number of pixels covered and the angle is determined based on the reference point and the one or more fibroids.

[0042] The guidance parameter generation module 210 also computes an angle between the two points and converts the angle into a rotational value which will be common for all types of interventional device 120. On identifying the shortest distance and the angle between the reference point (external orifice of the uterus) and the target point in the fibroid, the guidance parameter generation module 210 generates guidance parameters by shortlisting the common intervention devices having different profiles and picks up the optimal one from that group, wherein the optimal one is the one having minimum variation (in distance) between a tip of the intervention device 125 and the target point in the fibroid. That is, based on the distance between the reference point and the target point, the guidance parameter generation module 210 selects the length of the interventional device 125, and based on the angle, it selects the profile of the interventional device 125. The variation in distance is computed using the 3D representative model of the uterus, coordinates of the reference point and the coordinates of the target point and the device profile, the length of the transcervical interventional device, angulation of the transcervical interventional device and a length of insertion of the transcervical interventional device. For example, the guidance parameter generation module 210 computes the required length of the interventional device 125 and the length of insertion of the 125 based on the Y distance between the reference point and the target point. As shown in Figure 6, the profile and the angulation of the interventional device 125 is calculated based on the target point of the fibroid. In any combination of the guidance parameters, the length of insertion of the interventional device 125 is preferably between 2cm and 5cm, however the insertion length may vary. Considering an interventional device 125 having five different profiles, for example, having different angulation and length, the guidance parameter generation module 210 shortlists one having minimum variation (in distance) between a tip of the intervention device 125 and the target point in the fibroid, wherein the variation is calculated based on the spatial co-ordinates. Below table explains the process of shortlisting the profile of the interventional device 125.

Iteration 1	Profile A = 5 mm variation	Considered profile is B
	Profile B = 4 mm variation	Variation is 4 mm

Iteration 2	Profile B = 4 mm variation	Considered profile is C
	Profile C = 3 mm variation	Variation is 3 mm
Iteration 3	Profile C = 3 mm variation	Considered profile is D
	Profile D = 2 mm variation	Variation is 2 mm
Iteration 4	Profile D = 2 mm variation	Considered profile is E
	Profile E = 1 mm variation	Variation is 1 mm

[0043] In the above example, the guidance parameter generation module 210 selects the interventional device 125 having profile E which has minimum variation among others. Further, the guidance parameter generation module 210 displays the profile along with the distance between the reference point and the target point in the fibroid.

[0044] As described, based on the 3D representative model of the uterus, the reference point (the external orifice of the uterus) and the target point in the fibroid, the guidance parameter generation module 210 generates the initial guidance parameters (values) to assists the user in navigating to the target point in the fibroid. The guidance parameters include but not limited to length of the interventional device 125, profile, type of the angled tip, length of the angled tip, and angle of rotation of the angled tip from the reference point on the intervention device. As described, the guidance parameters and their values are displayed on the display unit 120 of the computing device 115.

[0045] In one embodiment of the present disclosure, the treatment parameter generation module 212 generates the treatment parameters for treating the fibroids in the uterus of the subject. The treatment parameters as described herein may include but not limited to treatment power, temperature and treatment time, etc., wherein the treatment parameters are determined based on maximum length, maximum width, and the maximum depth, and the specification of the interventional device 125. The treatment parameter generation module 212 of the device 115 reads treatment parameters from a treatment chart stored in the proposed system which is obtained by the treatment device manufacturer that contains the estimated treatment area for a specific combination of parameter. Based on the maximum length, the maximum width, and the maximum depth of the fibroid and the device specification, the treatment parameter generation module 212 generates the treatment

parameters for treating the fibroids in the uterus. The treatment parameter can include the treatment power and the treatment time if the procedure us a radiofrequency ablation. The treatment options can also include microwave ablation, ultrasound ablation, cryoablation, or injecting drugs to the centre of the fibroid.

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[0046] Upon generating the guidance parameters and the treatment parameters, the computing device 115 displays the same on the display unit 120 along with the 3D representative model of the uterus. The 3D representative model displayed on display unit 120 is an interactive model which can be rotated by the user. In one embodiment, the display unit 120 displays the details of each fibroid when it is activated individually. The details of the fibroid, along with fibroid size, fibroid position also contains the guidance and the treatment parameters of the fibroid. Hence, the system provides the detailed information on the uterus and the fibroids along with the initial guidance parameters and the treatment parameters, thereby enabling the user to use the correct interventional device 125 during the interventional procedure.

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[0047] During the interventional procedure, once the user inserts the interventional device 125 through the cervix uteri of the subject and positions the transducer, the transducer scans both the target point in the fibroid region and the angulated tip in the same image. The image having both the target point in the fibroid region and the angulated tip is captured from the video using data transfer device 110 and is sent to the computing device 115 for further processing and guiding the user. The physician can perform this step of capturing image multiple times to capture the image as per the requirement. Alternatively, image may be captured using abdominal ultrasound transducers.

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[0048] On receiving the image, the processor 204 displays the image on the display unit 120 (preferably a touch screen display), wherein the image comprises the image of the angulated tip, the target point in the fibroid to which the tip of the interventional device 125 device should reach, and a reference scale of the captured image. In one embodiment of the present disclosure, the image of the angulated tip, the target point in the fibroid to which the tip of the interventional device 125 device should reach is displayed as an overlay on the 3D

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representative model of the uterus. The processor 204 further displays an image scale using which the user may calibrate the image.

[0049] Figure 7 shows the image requirement in accordance with an embodiment of the present disclosure. As shown, the image should include the target region (the fibroid region) 704, and the angulated tip 708 of the interventional device 125. The user then needs to identify the points on the captured image's reference scale 712 and indicate the displayed scale length and needs to click on the top and bottom point to indicate the annotation reference scale value. Preceding this, the user needs to detect the angulated tip 708 and click on them, with a cursor on the screen, respectively. This annotated frame is saved to display an overlay of the path with which the interventional device 125 projects with its specified length, along with an estimation of the treatment zone and its safety region. The manner in which the system 100 guides the user during the procedure is described in detail further below.

[0050] As described, an image (of both the fibroid region and the angulated tip inclusive) is captured from the ultrasound transducer for processing by the computing device 115. The computing device 115 displays the image for annotation by the user. This annotation is used by the computing device 115 for calculating the pixel dimensions. Further, the user annotates the angulated tip, using an angulated tip annotation marker, as shown in Figure 7. Alternatively, one or more machine learning model is trained for identifying the rear end and the front tip of the angulated tip. The computing device 115 then stores the annotated image for further processing. With such annotation, the computing device 115 may guide the user to move the interventional device 115 to the target point. When the user moves the interventional device 125 during the procedure, the real-time data is captured and processed in real-time or near real-time, the position of the tip of the interventional device 125 is computed and the processor 204 updates the guidance parameters in real-time based on a current position of the tip of the interventional device 125, and the initial guidance parameters.

[0051] In one embodiment of the present disclosure, the computing device 115 is further configured for computing and displaying an estimated safety zone for assisting the user. The

estimated safety zone is displayed as an overlay on the 3D representative model of the uterus. Figure 8 shows an exemplary interface displaying additional guidance parameters in accordance with an embodiment of the present disclosure. As shown, during the interventional procedure, the ultrasound transducer captures the image, the image including the fibroid region 802 and the tip 708 of the interventional device 125. Then the data transfer device 110 transfers the captured image to the computing device 120 for further processing. On receiving the image, the computing device 115 identifies the angulated tip 708 of the interventional device 125 and projects treatment trajectory 804 to reach the target point 806 based on the co-ordinates of the target point 804 and the co-ordinates the angulated tip 708. As shown, the tip 708 of the interventional device 125 and the trajectory is displayed as an overlay on the 3D representative model of the uterus. In one embodiment of the present disclosure, the computing device 115 further computes and displays the estimated safety zone (outer ellipsoid 808) by adding a length (5 mm for example) to the fibroid region's 802 (inner ellipsoid) length and width. For example, estimated safety zone (outer ellipsoid) length = 5 mm + estimated treatment zone (inner ellipsoid) length, and estimated safety zone (outer ellipsoid) width = 5 mm + estimated treatment zone (inner ellipsoid) width.

[0052] As described, the system and method disclosed in the present disclosure guides the user in navigating the interventional device through the cervix uteri of the subject during the interventional procedure on the subject by providing data on the profile, the length of the interventional device required to reach the target point (distance between the front end of the angulated tip and the target point), angle between the front end of the angulated tip and the target point and the treatment zone. Whenever the user modifies the treatment device length or treatment parameters, the system assigns the value to the corresponding variable, and this value from the variable is taken for calculating the length accordingly.

[0053] The proposed system and method may be implemented for interventional procedures including but not limited to ablation procedures, biopsy procedures or drug delivery to the target location.

[0054] While specific language has been used to describe the disclosure, any limitations arising on account of the same are not intended. As would be apparent to a person skilled in

the art, various working modifications may be made to the method in order to implement the inventive concept as taught herein.

5 [0055] The figures and the foregoing description give examples of embodiments. Those skilled in the art will appreciate that one or more of the described elements may well be combined into a single functional element. Alternatively, certain elements may be split into multiple functional elements. Elements from one embodiment may be added to another embodiment. For example, orders of processes described herein may be changed and are not limited to the manner described herein. Moreover, the actions of any flow diagram need not be implemented in the order shown; nor do all of the acts necessarily need to be performed. 10 Also, those acts that are not dependent on other acts may be performed in parallel with the other acts. The scope of embodiments is by no means limited by these specific examples. Numerous variations, whether explicitly given in the specification or not, such as differences in structure, dimension, and use of material, are possible. The scope of embodiments is at least as broad as given by the following claims. 15

We Claim:

1. A method for guiding a user in navigating an interventional device through the cervix
uteri of a subject during an interventional procedure on the subject, the method
5 comprising:
 - capturing a plurality of ultrasound images of a uterus of the subject using an
ultrasound transducer;
 - displaying the plurality of ultrasound images on a display unit for enabling the
user to select one or more images from the plurality of ultrasound images;
 - 10 receiving annotations provided by the user on the one or more images selected by
the user, the annotations indicating the uterus landmarks and one or more target regions
inside the uterus;
 - generating a three-dimensional representative model of the uterus using the
annotated images;
 - 15 generating initial guidance parameters for moving a tip of the interventional
device, from a reference point to reach a target point in the target region, wherein the
guidance parameters are generated using the three-dimensional representative model of
the uterus;
 - generating treatment parameters based on the one or more target regions inside
20 the uterus;
 - displaying the guidance parameters and the treatment parameters on the display
unit;
 - capturing real-time data of uterus, using the ultrasound transducer while the user
moves the tip of the interventional device towards the target point; and
 - 25 periodically updating the guidance parameters based on current position of the tip
of the interventional device, the real-time data, and the initial guidance parameters.
2. The method as claimed in claim 1, wherein the ultrasound transducer is introduced trans-
vaginally proximal to the cervix uteri of the subject for capturing the plurality of
30 ultrasound images of the uterus of the subject.

The method as claimed in claim 1, wherein the plurality of ultrasound images includes images obtained from scanning in two orthogonal planes.

3. The method as claimed in claim 1, wherein the one or more images selected by the user include at least one image obtained from scanning in the two orthogonal planes.

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4. The method as claimed in claim 1, wherein the three-dimensional representative model is created using the one or more annotated images and one or more images from the plurality of ultrasound images.

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5. The method as claimed in claim 1, wherein the guidance parameters comprise a profile, a length of the transcervical interventional device, angulation of the transcervical interventional device and a length of insertion of the interventional device.

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6. The method as claimed in claim 1, wherein the treatment parameters are generated for each of the one or more target regions based on maximum length, maximum width, and the maximum depth of the one or more target regions of each of the one or more target regions.

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7. A system (100) for guiding a user in navigating an interventional device (125) through the cervix uteri of a subject during an interventional procedure on the subject, the system (100) comprises:

an ultrasound scanner (105) configured for capturing a plurality of ultrasound images of a uterus of the subject using an ultrasound transducer; and

a computing device (115) configured for:

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displaying, on a display unit (120), the plurality of ultrasound images for enabling the user to select one or more images from the plurality of ultrasound images;

receiving, through the display unit (120), annotations provided by the user on the one or more images selected by the user, the annotations indicating the uterus landmarks and one or more target regions inside the uterus;

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generating, by a three-dimensional model generation module (208), a three-dimensional representative model of the uterus using the annotated images;

- generating initial guidance parameters, by a guidance parameter generation module (210), for moving a tip of the interventional device (125), from a reference point to reach a target point in the target region, wherein the guidance parameters are generated using the three-dimensional representative model of the uterus;
- generating treatment parameters, by a treatment parameter generation module (212), using the three-dimensional representative model of the uterus;
- displaying, on the display unit (120), the guidance parameters and the treatment parameters on the display unit;
- capturing, through the ultrasound scanner (105), real-time data of uterus while the user moves the tip of the interventional device (125) towards the target point; and
- periodically updating, by a processor (204), the guidance parameters based on a current position of the tip of the interventional device (125), and the initial guidance parameters.
8. The system (100) as claimed in claim 7, wherein the computing device (115) is configured for determining for displaying optimal intervention on real-time data as the intervention device reaches to the target region, a treatment trajectory (804) and a safety zone (808) based on co-ordinates of the angulated tip (808), the target point (806) and the 3D representative model of the uterus.
9. The system (100) as claimed in claim 8, wherein the computing device (115) displays the optimal intervention, the treatment trajectory (804) and the safety zone (808) as an overlay on the 3D representative model of the uterus.

1/8

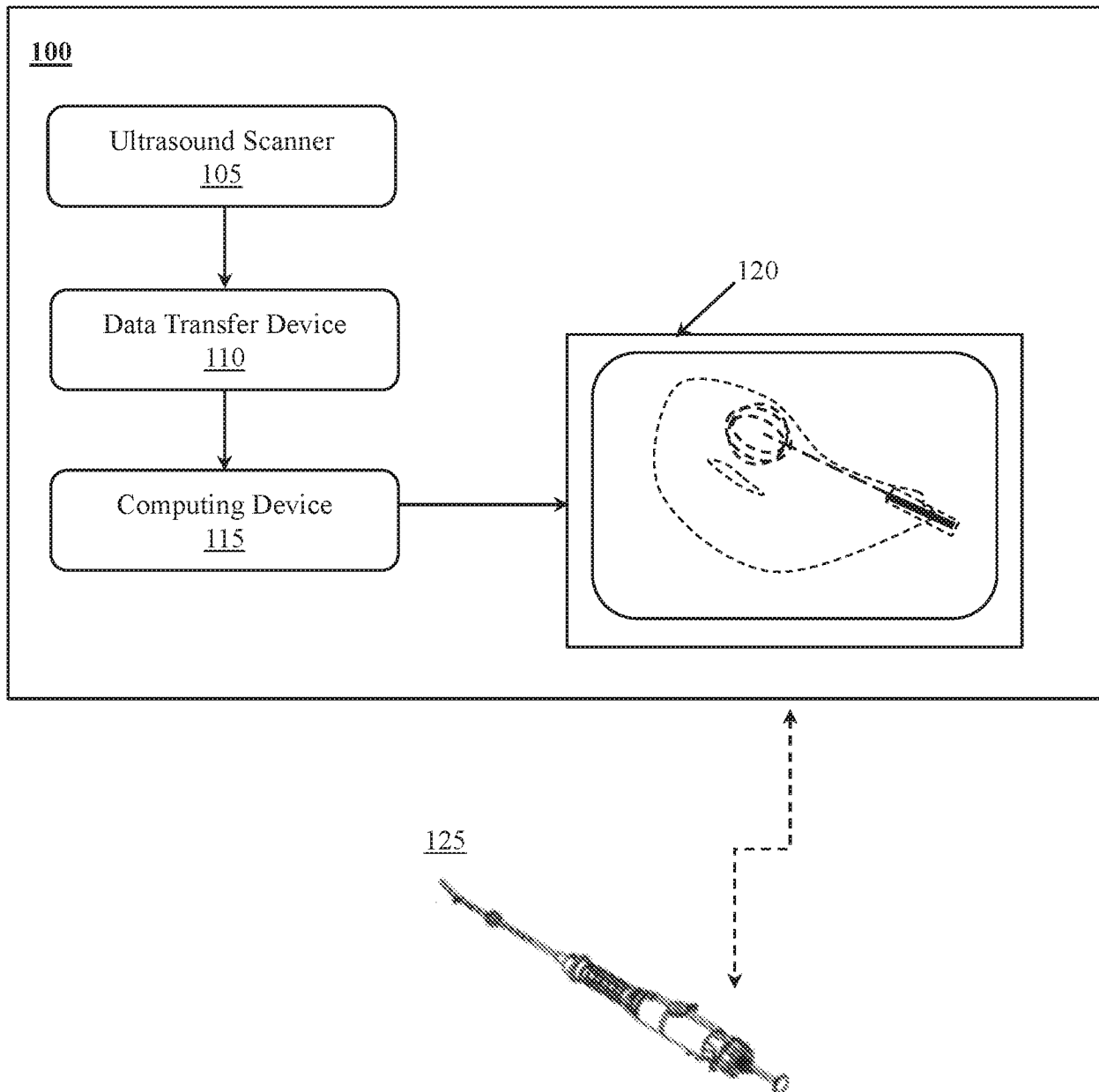


FIGURE 1

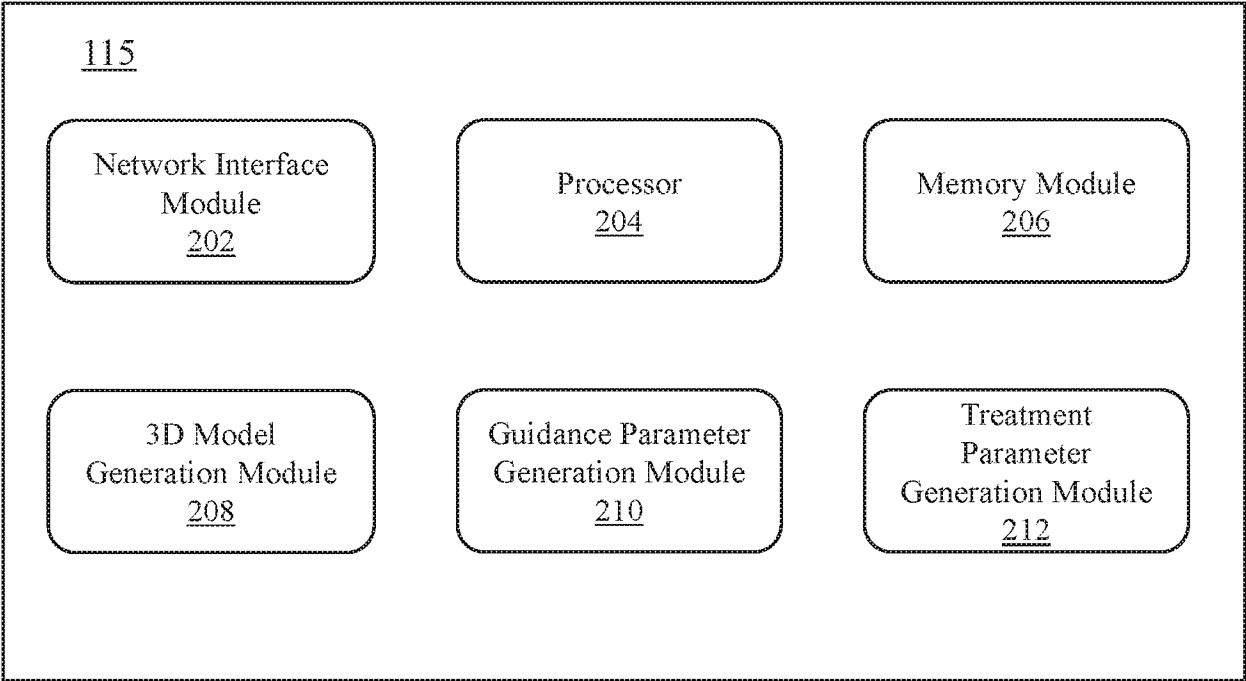


FIGURE 2

3/8

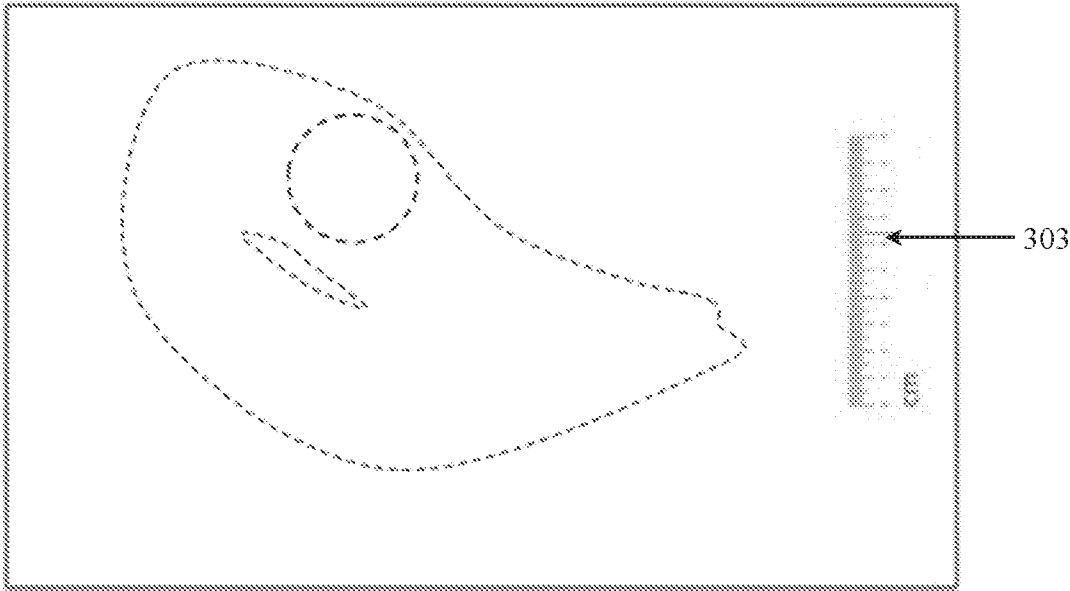


FIGURE 3

4/8

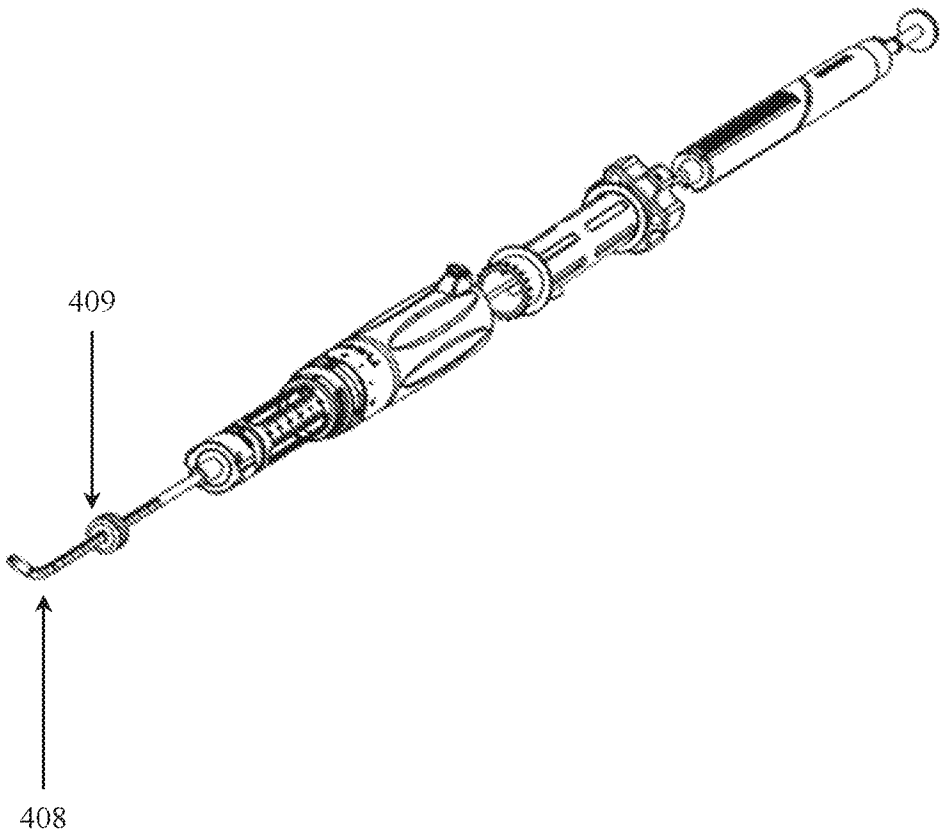


FIGURE 4

5/8

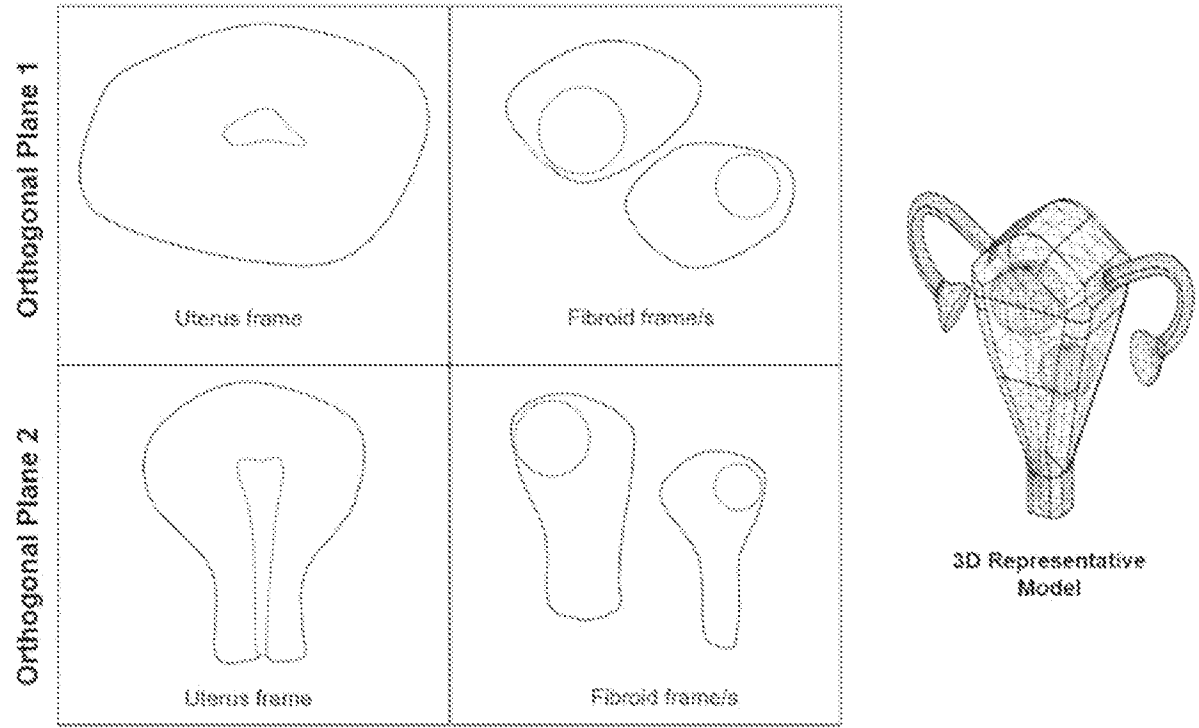


FIGURE 5

6/8

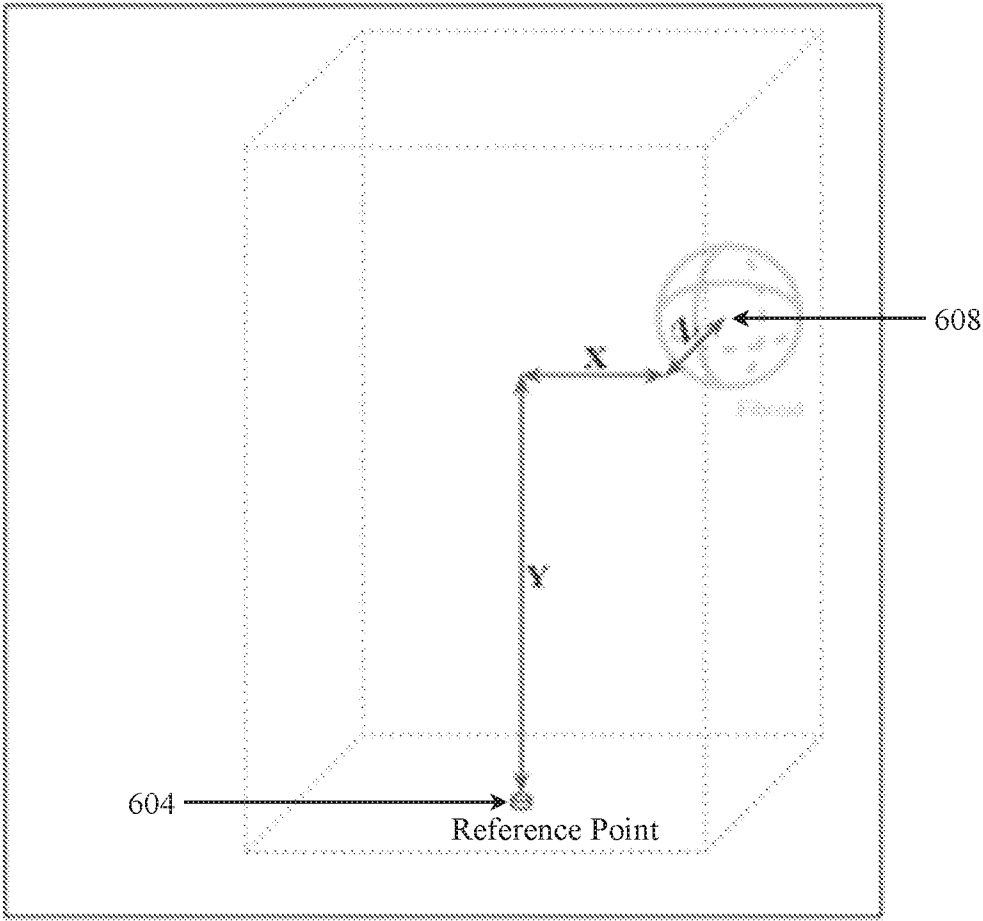


FIGURE 6

7/8

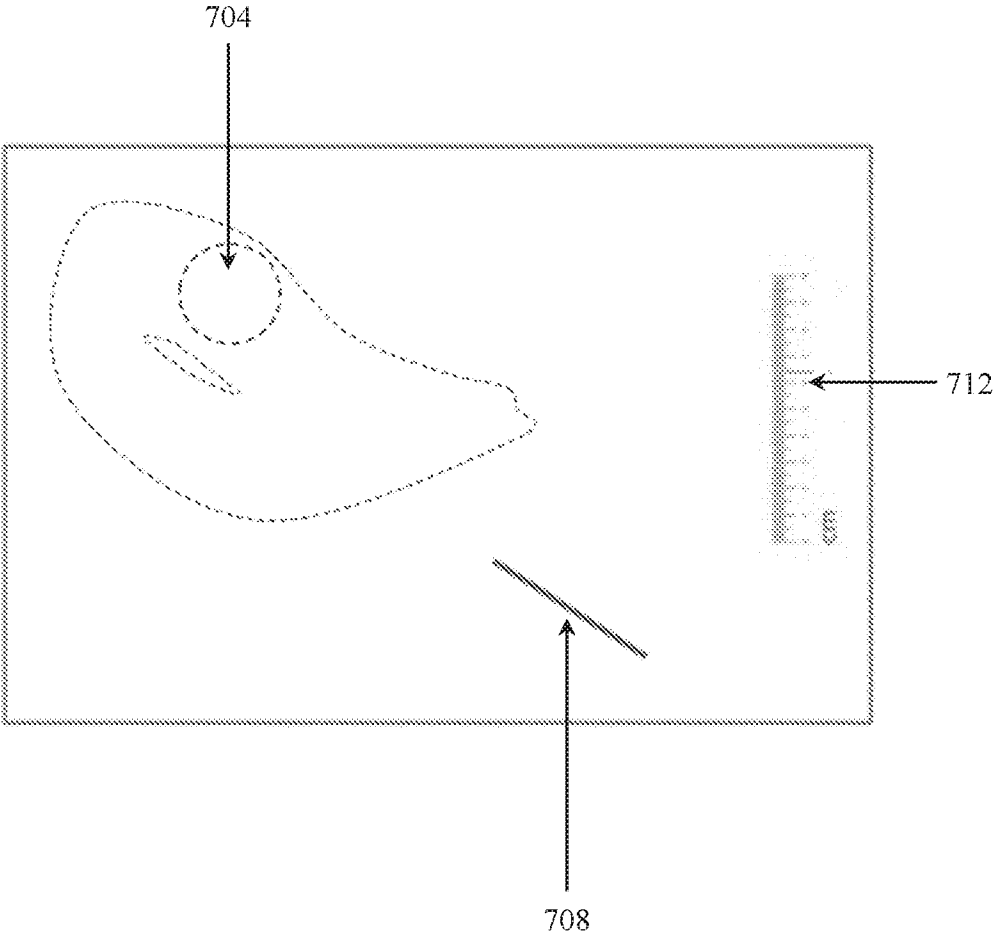


FIGURE 7

8/8

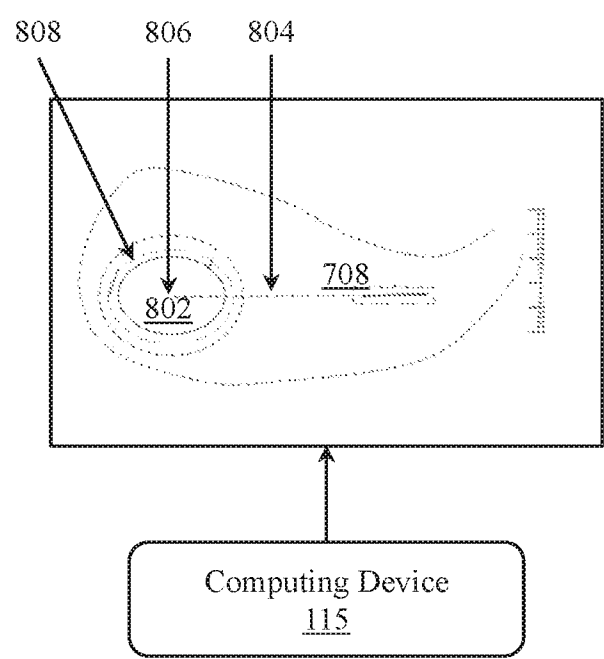


FIGURE 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2023/051072

A. CLASSIFICATION OF SUBJECT MATTER

A61B1/01, A61B1/045, A61B1/303 Version=2024.01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

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

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

Search Databases: PatSeer, IPO Internal Database

Keywords: Ultrasound, navigation, uterus, guidance parameter

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20210322092 A1 (NESA MEDTECH (IN)) 21 October 2021 (21.10.2021) Abstract, Description	1-9
X	US 20170236272 A1 (VERAN MEDICAL TECHNOLOGIES INC (US)) 17 August 2017 (17.08.2017) Abstract, Description	1-9



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

20-03-2024

Date of mailing of the international search report

20-03-2024

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Facsimile No.

Authorized officer

Pritish Ranjan Pal

Telephone No. +91-1125300200

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IN2023/051072

Citation	Pub.Date	Family	Pub.Date
US 20210322092 A1	21-10-2021	WO 2020044227 A1	05-03-2020
		EP 3843650 A4	18-05-2022
		CN 112638302 A	09-04-2021