FORM 2

THE PATENTS ACT, 1970

(39 of 1970)

The patent Rule, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

TITLE OF THE INVENTION

A system for automatic ultrasound scanning and the method thereof

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Preamble to the Description

[0001] The following specification describes the invention and the manner in which is to be performed:

DESCRIPTION OF THE INVENTION

5 **Technical field of the invention**

[0002] The field of the invention generally relates to automatic ultrasound scanning using a novel design to minimize the scanning time, improvise the precision in sonological diagnosis, relieve sonologist pain due to repeated stress injury in arm due to scanning and performing virtual scanning.

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Background of the invention

[0003] Ultrasonography (USG) uses sound waves to produce images of the inside of the body. Ultrasound modality for imaging is not only inexpensive but also does not use ionizing radiation like X-rays or Computed Tomography (CT). It can be

- 5 used in any age group and noninvasive. It also can capture images of soft tissues, which are difficult for X-rays. Magnetic Resonance Imaging (MRI) is radiation free but few patients are claustrophobic and contraindicated in patients with implants, and in developing countries its affordability is of concern. Even if MRI machines are available, the cost and regular availability of various coils are difficult to procure
- 10 especially in government hospitals, which are the major contributors to healthcare delivery system in developing countries.

[0004] Recent developments have paved way for the ability of USG to diagnose a myriad of Musculoskeletal (MSK) problems with enhanced resolution. The diagnostic USG also can examine wide zones with extended Field of View (FOV) imaging.

[0005] USG can be widely used in abdomen and pelvis for diagnosing and differentiating benign from malignant lesions in liver, kidney, spleen, pancreas, prostate, gall bladder, uterus, endometrium, cervix. Doppler study plays important role in understanding vascularity of lesions. USG can be used in follow-up cases of

- 20 post chemotherapy and radiation therapy for early detection of secondaries. USG can be used for studying arteries and veins of upper and lower limbs, small parts, MSK and Neurosonogram (NSG) in infants. It also contributes in the field of fetal medicine where USG is the topmost modality for detection of fetal anomalies and differentiating between normal and abnormal fetuses whereas CT Scan is
- 25 contraindicated due to radiation and MRI has limited accuracy due to fetal movements.

[0006] According to a market Analysis, USG market expected to exceed \$7 billion by 2019. With 0.3 million babies born daily, 7 million newborns die in the perinatal period annually in developing countries and 8 million children die during their first

year of life, which can be significantly reduced with prenatal follow-up. USG has wide spectrum of applications including tumour detection in abdomen, pelvis and small parts.

- [0007] The patent document US20160367216 titled "Zone visualization for ultrasound guided procedures" discloses a system for automatic zone visualization employing an USG probe and an USG imaging workstation. In operation, USG probe scans an anatomical region, and the USG imaging workstation tracks a generation of an USG volume of an anatomical structure within a patient space responsive to the scan of the anatomical region by the USG probe. The USG imaging workstation further tracks a labeling of procedurally defined zones of the anatomical structure within the USG volume derived from an USG volume model of the anatomical structure labeled with the procedurally defined zones to thereby facilitate an USG-guided visualization of the anatomical structures. However, the device does not mention including a modified design of a platform with USG probe
- 15 moving as programmed automatically.

[0008] The Patent document **US20130090600** titled "*Device, system and method of automatic vessel access based on real time volumetric ultrasound*" relates to an automatic vessel access device based on real time volumetric USG is provided. The automatic vessel access device comprises a probe configured to generate a VOI

- 20 image of a candidate vessel in a real time volume USG scan mode, a control device coupled to the probe, and at least one motor coupled to the control device. The control device comprises at least one processing module configured to determine at least one control parameter based on the VOI image, and a driver module coupled with the at least one processing module and configured to drive the at least one
- 25 motor to automatically access the candidate vessel according to the at least one control parameter. The invention described in the patent is not a general one and cannot be used in other anatomical regions. Additionally, automatic ultrasound scanning is not mentioned.

[0009] The Patent document **US20110172532** titled "Automatic adjustment of scan angle, scan depth and scan speed in an ultrasound system" discloses an USG system includes an USG data acquisition unit, which is responsive to predetermined scan angle, scan depth and scan speed, configured to repeatedly transmit an USG

- 5 signal to a target object and receive an USG echo reflected from the target object to form a plurality of USG frame data sets. It also includes a processing unit configured to form a plurality of volume data sets each having a plurality of frames based on the plurality of USG frame data sets and form at least two 2-dimensional USG images based on the volume data sets. The processing unit is further
- 10 configured to detect contours of the target object from the 2-dimensional USG images and adjust the predetermined scan angle, scan depth and scan speed based on the detected contours. Though the patent discusses about the predetermined scan angle, scan depth and scan speed, configured in a particular way or changing the configuration, it does not discuss about automatic scanning, which will relieve the
- 15 pain of the sonologist, who examines the patient using USG machine.

[0010] Thus, there is a need to design an USG system in which probe moves automatically as programmed so that a list of anatomical parameters can be measured and 3D or 4D volumetric data are collected without any manual intervention by minimizing the scanning time, improving the precision in 20 sonological diagnosis, relieving sonologist pain due to repeated stress injury in arm due to scanning and to perform virtual scanning. In the entire document, organism includes human beings.

Summary of the invention

- 25 **[0011]** The present invention provides an automatic program-controlled ultrasound scanning system for collecting images including 3D and 4D models for region of interest in an organism including a human being to be examined having a probe. It has an arch, a movable holder sliding over a groove, a motion controller to move, push, rotate and tilt the probe, a processor to send commands to motion controller
- 30 and a storage unit. The automatic scanning first starts fixing the arch and moving

the probe to the region of interest in the organism using motion controller with commands from the processor as programmed for scanning, collecting, displaying the signals and images of the region of interest in the organism collected from the probe on screen or display units. It can be used for scanning of fetus, abdomen,

5 pelvis, small parts, MSK of the region of interest in the organism and in NSG and doppler studies.

[0012] The system can also be used for wide variety of applications such as diagnosing fetal abnormalities such as cardiac anomalies, any structural defects and

differentiating between normal and abnormal fetus, early detection of neoplasm, differentiating benign from malignant lesions and also in follow up investigations (post cancerous) for early detection of secondaries. Along with diagnostic area, USG plays an important role in therapeutic area such as USG guided biopsy, Fine Needle Aspiration Cytology (FNAC), Percutaneous Nephrostomy (PCN),
 Amniocentesis and Chorionic Villus Sampling (CVS).

Brief description of the drawings

[0013] The foregoing and other features of embodiments will become more apparent from the following detailed description of embodiments when read in conjunction with the accompanying drawings.

[0014] Figure 1 is a block diagram illustrating an automatic program-controlled ultrasound scanning system (100) for collecting images including 3D and 4D models (101) of region of interest (ROI) in an organism (102) to be examined

having a probe according to an embodiment of the present invention.

[0015] Figure 2 explains how the proposed arch (104) can be used at different regions of interest in an organism (102).

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[0016] Figure 3 depicts various movements such as moving along an axis and titling the arch (104).

[0017] Figure 4 portrays how the radius of the arch (**104**) can be varied with radial mechanical structure (**114**).

5 [0018] Figure 5 deals with plurality of arches (104) independently moving along an axis and titling the arch (104)

[0019] Figure 6 explains single or plurality of grooves (106) in the arch (104).

10 **[0020] Figure 7** depicts how the force sensor **(111)** and proximity sensor **(113)** are positioned in one of the embodiments.

[0021] Figure 8 shows plurality of probes (103) in one or more grooves (106) in the arch (104).

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[0022] Figure 9 shows plurality of probes (**103**) in one or more grooves (**106**) in the arch (**104**) where the probes operate independently.

[0023] Figure 10 shows a method to use one embodiment of the present invention,which is general in nature and suitable for applying in any ROI in an organism.

Detailed description of the invention

[0024] The embodiments of the present invention will now be described in detail with reference to the accompanying drawings. However, the present invention is not limited to the embodiments. The present invention can be modified in various forms. Thus, the embodiments of the present invention are only provided to explain more clearly the present invention to the ordinarily skilled in the art of the present invention. In the accompanying drawings, like reference numerals are used to

30 indicate like components.

[0025] The specification may refer to "an", "one" or "some" embodiment(s) in several locations. This does not necessarily imply that each such reference is to the same embodiment(s), or that the feature only applies to a single embodiment. Single

features of different embodiments may also be combined to provide other embodiments.

- [0026] As used herein, the singular forms "a", "an" and "the" are intended to
 include the plural forms as well, unless expressly stated otherwise. It will be further understood that the terms "includes", "comprises", "including" and/or "comprising" when used in this specification, specify the presence of stated features, integers, steps, operations, elements and/or components, but do not preclude the presence or addition of one or more other features integers, steps, operations, elements, and/or groups thereof. As used herein, the term
- "and/or" includes any and all combinations and arrangements of one or more of the associated listed items.
- [0027] Unless otherwise defined, all terms (including 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 pertains. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and will not be interpreted in an idealized or overly formal
- 20 sense unless expressly so defined herein.

[0028] The present invention as a system depicted in Figure 1 is an automatic program-controlled ultrasound scanning system (100) for collecting the signals and images including 3D and 4D models (101) of a ROI in an organism (102) to be

- 25 examined having a probe (103) comprising an arch (104) having at least one arch end (105) with one or more grooves (106), a movable holder (107) operably coupled with the probe (103) sliding over the groove (106) of the arch (104), a motion controller (108) to move, push, rotate and tilt the probe (103) with the moveable holder (107), a processor (109) to send commands to the motion controller (108) to
- change a pose of the probe (103) with the moveable holder (107) and a storage unit(110) operably coupled with the processor (109) to collect the signals and images

including 3D and 4D models (101) of the ROI in the organism (102) examined from the probe (103).

- [0029] Figure 2 explains how the proposed arch (104) can be used at different regions of interest in an organism (102). This is made possible as in one of embodiments, the arch end (105) has a fixing structure including screw and nut/bolt mechanism to tighten the arch (104) over a particular ROI in the organism (102). Thus, the movement of the arch (104) is along an axis parallel to the table or the side of longitudinal axis of the organism. In another embodiment, the arch end (105)
- 10 slips along a rail fixed to the table and can be fixed at any point. As these are not the core of the invention and many such possibilities are allowed.

[0030] Figure 3 depicts various movements such as moving along an axis and titling the arch (104). The top portion of the figure 3 explains the movement along an axis and bottom portion of the figure 3 explains the tilting movement of the arch (104). In one of the embodiments, where automatic programming is used, the processor (109) instructs the motion controller (108) to move the arch (104) in a particular way as desired. It is presumed that the motion controller (108) includes any servo controller, Personalized Computer (PC) based controller, specialized microprocessor, Programmable Logic Controllers (PLC) and Programmable Automation Controllers (PAC). It is also implied that sufficient motorized unit, which is controlled by the motion controller (108) provides sufficient movement of the arch (104). It must be recalled that tilting movement of the arch (104) is also

25 movement along an axis and tilting of the arch (104) in sequence get effect as programmed.

[0031] Figure 4 portrays how the radius of the arch (**104**) can be varied with radial mechanical structure (**114**). Changing the radius can also be done manually. In one

affected by the motion controller (108). Additionally, any combination of

30 of the embodiments, the arch (104) includes a radial mechanical structure (114) consisting of three collapsible subunits such that any subset of the subunits can expand in order to increase the radius of the arch (104). The radial mechanical

structure (114) is any mechanical structure, which can increase the radius of the arch (104) without restriction.

[0032] Figure 5 deals with plurality of arches (104) independently moving along
an axis and titling the arch (104). In order to minimize the scanning time, which is one of the objectives of the invention, in one of the embodiments, there are plurality of arches (104) as shown depending upon the requirement. It must be recalled, each such arch (104) can operate independently meaning one of the arches (104) tilts while the rest of the arches (104) are kept in the usual or any desired position as shown in the figure 5. It is obvious that each such arch (104) is provided with same

- or similar probe (103). It is also assumed that the standard USG system (100) is capable of handling multiple probes (103) simultaneously. In a possible embodiment, the storage unit (110) stores the signals and images generated by each probe (103) at the suitable positions such that as if it were done by a single probe
- 15 (**103**).

[0033] Figure 6 explains single or plurality of grooves (106) in the arch (104). This is basically a design change incorporated to handle multiple probes (103) instead of each arch (104) having one probe (103), an arch can have multiple grooves (106)

- 20 so that there can be multiple probes (103). It must be recalled that the probes (103) operate independently. Additionally, in one of the embodiments the plurality of grooves (106) are interconnected in a particular pattern to make the scanning cover all the zones and all the angles to get the signals and images including 3D and 4D (101) of the ROI in the organism (102).
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[0034] Figure 7 depicts how a force sensor (111) and a proximity sensor (113) are positioned in one of the embodiments. In one of the embodiments, the force sensor (111) is operably coupled with the moveable holder (107), which holds the probe (103) so that under any circumstances, the applied force does not exceed the predefined limits (112). In the unfortunate event of more force applied than the

30 predefined limits (112). In the unfortunate event of more force applied than the predefined limits (112), the force sensor (111) will force the USG system (100) to halt immediately. In addition to one force sensor (111) per probe (103), in other

embodiments, a proximity sensor (113) is also present so that it gives feedback to the motion controller (108) appropriately. This also provides additional safety to the patients. The placement of the force sensor (111) and the proximity sensor (113) shown in Fig.7 is only illustrative in nature and other useful positions are also the

5 choices for the force sensor (111) and the proximity sensor (113).

[0035] Figure 8 shows plurality of probes (103) in one or more grooves (106) in the arch (104). The primary objective is to reduce the scanning time. At the same time, the coverage of the ROI in the organism (102) should be sufficient to get the size rad = rad =

- 10 signals and images including 3D and 4D (101) of the ROI in the organism (102). The extended configuration involves plurality of probes (104) in one or more grooves (106) in each arch (104) to minimize the scanning time. During scanning, as larger zone can be covered in shorter time, sonologists can be effectively relieved off from their pains due to stress injury in arm.
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[0036] Figure 9 shows plurality of probes (103) in one or more grooves (106) in the arch (104) where the probes operate independently. Such configuration is difficult to operate manually due to less number of hands of sonologists. This indirectly demand programmable system comprising a processor (109) and a storage unit (110). As defined in the program, the processor (109) will issue commands to the motion controller (108). The motion controller (108) will move the moveable holder (107), which will eventually move the probe (103) on a ROI in the organism (102). The movement of probe (103) can be along the axis and/or tilted. Thus, the movement of probe can be programmatically decided.

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[0037] The present invention as a method depicted in Figure 10 include steps comprising, fixing (118) the arch (104) over the ROI in the organism to be examined, moving (119) the probe (103) to the ROI in the organism to be examined automatically using the motion controller (108) using the commands from the

30 processor (109) as programmed, scanning (120) the ROI in the organism to be examined automatically using the probe (103), collecting (121) the signals and images of ROI in the organism to be examined automatically using the probe (103)

and displaying (**122**) the signals and images of ROI in the organism to be examined automatically collected from the probe (**103**) on a screen or display units.

- [0038] All equivalent relationships to those illustrated in the drawings and described in the application are intended to be encompassed by the present invention. The examples used to illustrate the embodiments of the present invention, in no way limit the applicability of the present invention to them. It is to be noted that those with ordinary skill in the art will appreciate that various modifications and alternatives to the details could be developed in the light of the
- 10 overall teachings of the disclosure, without departing from the scope of the invention.

Use case example 1:

- 15 As per one of the embodiments, a patient for example a pregnant lady opting for fetus scan is asked to lay down on an examination table. The arch (104) will be fixed (118) around the abdomen of the patient (102). As per the preprogramed manner, the probe (103) moves (119) over the abdomen of the patient (102) to examine automatically using the motion controller (108) using the commands from
- 20 the processor (109). The system (100) scans (120), collects (121) and stores (123) the images of the fetus of the patient (102) examined automatically using the probe (103). Care is taken using the force sensor (111) and the proximity sensor (113) such that the patient is not hurt in anyway beyond predefined limits (112). The 3D and 4D models (101) of the abdomen of the patient (102) examined automatically
- for medical anomaly (125) in the fetus are analyzed (124) using machine learning algorithm (126) pretrained for detecting the anomaly and differentiating between normal and abnormal fetus. Moreover, the USG system (100) measures (127) a list of anatomical parameters (128) using 3D and 4D models (101) of the fetus (102) using another machine learning algorithm (129) pretrained for detecting a list of
- anatomical parameters (128).

Claims:

We Claim:

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- 5 1. An automatic program-controlled ultrasound scanning system (100) for collecting one or more signals and images including 3D and 4D models (101) of a region of interest in an organism (102) to be examined having a probe (103) comprising:
 - a) an arch (104) having at least one arch end (105) with one or more grooves (106);
 - b) a movable holder (107) operably coupled with the probe (103) sliding over the groove (106) of the arch (104);
 - c) a motion controller (108) to move, push, rotate and tilt the probe (103) with the moveable holder (107);

d) a processor (109) to send commands to the motion controller (108) to change a pose of the probe (103) with the moveable holder (107); and

- e) a storage unit (110) operably coupled with the processor (109) to collect the signals and images including 3D and 4D models (101) of the region of interest in the organism (102) examined from the probe (103).
- The system (100) as claimed in claim 1, wherein the system (100) further comprises a force sensor (111) operably coupled with the movable holder (107) and the processor (109) to avoid pushing the probe (103) beyond predefined limits (112).
- The system (100) as claimed in claim 1, wherein the system (100) further comprises a proximity sensor (113) operably coupled with the probe (103) and the processor (109) to scan the region of interest in the organism (102) within predefined limits (112).
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- The system (100) as claimed in claim 1, wherein the system (100) further comprises radial mechanical structure (114) to change the radius of the arch (104).
- 5. The system (100) as claimed in claim 1, wherein the arch (104) is any combination of a movable arch (115) with one or more fixtures to move the arch (104) in a specified manner and titling the arch (116) with one or more fixtures to tilt the arch (104) in a specified manner.
- 6. The system (100) as claimed in any of the above claims, wherein the system (100) is used for scanning human fetus for detecting structural abnormalities, differentiating features of benign and malignant lesions in abdomen and pelvis, small parts, vessel abnormalities in upper and lower limbs such as deep vein thrombosis, diagnosing plaque in carotid artery in atherosclerotic condition.
- 7. A method (117) of scanning using an automatic program-controlled ultrasound scanning system (100) for collecting the signals and images including 3D and 4D models (101) of a region of interest in an organism (102) to be examined having a probe (103) comprising:
 - an arch (104) having at least one arch end (105) with one or more grooves (106);
 - ii) a movable holder (107) operably coupled with the probe (103) sliding over the groove (106) of the arch (104);
 - iii) a motion controller (108) to move, push, rotate and tilt the probe(103) with the moveable holder (107);
 - iv) a processor (109) to send one or more commands to the motion controller (108) to change a pose of the probe (103) with the moveable holder (107); and

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- v) a storage unit (110) operably coupled with the processor (109) to collect one or more signals and images including 3D and 4D models (101) of the region of interest in the organism (102) examined from the probe (103).
- a) fixing (118) the arch (104) over the region of interest in the organism to be examined;
 - b) moving (119) the probe (103) to the region of interest in the organism (102) to be examined automatically using the motion controller (108) using the commands from the processor (109) as programmed;
- c) scanning (120) the region of interest in the organism to be examined automatically using the probe (103);
 - d) collecting (121) the signals and images of the region of interest in the organism to be examined automatically using the probe (103); and
 - e) displaying (122) the signals and images of the region of interest in the organism to be examined automatically collected from the probe (103) on a screen or a display unit.
- The method (117) as claimed in claim 7, wherein the method (117) further comprises storing (123) the signals and images of the region of interest in the organism to be examined automatically collected from the probe (103) in the storage unit (110) including 3D and 4D models (101) of the region of interest in the organism (102).
- 9. The method (117) as claimed in claim 7, wherein the method (117) further
 25 comprises analyzing (124) 3D and 4D models (101) of the region of interest in the organism (102) to be examined automatically collected from the probe (103) by the processor (109) for medical anomaly (125) using pretrained machine learning algorithm (126).

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10. The method (117) as claimed in claim 7, wherein the method (117) further comprises measuring (127) a list of anatomical parameters (128) using 3D and 4D models (101) of the region of interest in the organism (102) using another machine learning algorithm (129) pretrained for detecting a list of anatomical parameters (128).

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Bindu Sharma Agent for the applicant Regn no: IN/PA 1055 Dated: 13th November 2019

Abstract

A system for automatic ultrasound scanning and the method thereof

[0040] The invention discloses an automatic program-controlled ultrasound scanning system (100) for collecting images including 3D and 4D models (101) of region of interest (ROI) in an organism (102) to be examined having a probe (103)

- 5 comprising an arch (104), movable holder (107) sliding over groove (106), motion controller (108) to move, push, rotate and tilt the probe (103), processor (109) to send commands to motion controller (108) and storage unit (110). The scanning starts by fixing (118) the arch (104), moving (119) the probe (103) to ROI using motion controller (108) with commands from processor (109) as programmed for
- 10 scanning (120), collecting (121) displaying (122) the signals and images of ROI in the organism (102) on display units. It is used for scanning of fetus, abdomen, pelvis, small parts, MSK of ROI and in NSG and doppler studies.

(Figure 1)

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