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(54) **AUTOMATED LONGITUDINAL POSITION TRANSLATOR FOR ULTRASONIC IMAGING PROBES, AND METHODS OF USING SAME**

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This patent is subject to a terminal disclaimer.

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**Related U.S. Application Data**

(63) Continuation of application No. 09/397,836, filed on Sep. 16, 1999, now Pat. No. 6,193,736, which is a continuation of application No. 09/040,058, filed on Mar. 17, 1998, now Pat. No. 6,013,030, which is a continuation of application No. 08/747,773, filed on Nov. 13, 1996, now Pat. No. 5,759,153, which is a continuation of application No. 08/573,507, filed on Dec. 12, 1995, now Pat. No. 5,592,942, which is a continuation of application No. 08/285,969, filed on Aug. 4, 1994, now Pat. No. 5,485,846, which is a continuation of application No. 07/906,311, filed on Jun. 30, 1992, now Pat. No. 5,361,768.

(51) **Int. Cl.**$^{7}$ .................... **A61B 8/12**

(52) **U.S. Cl.** .................... **600/463**

(58) **Field of Search** .................... 600/437, 439, 600/445–446, 462–463, 466–467, 471; 128/916; 606/159, 169, 170, 171, 180

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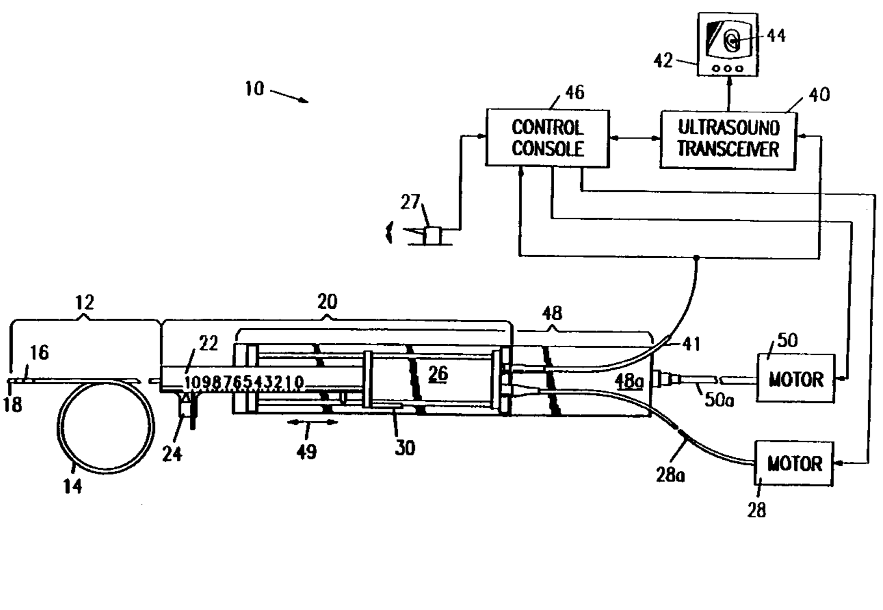
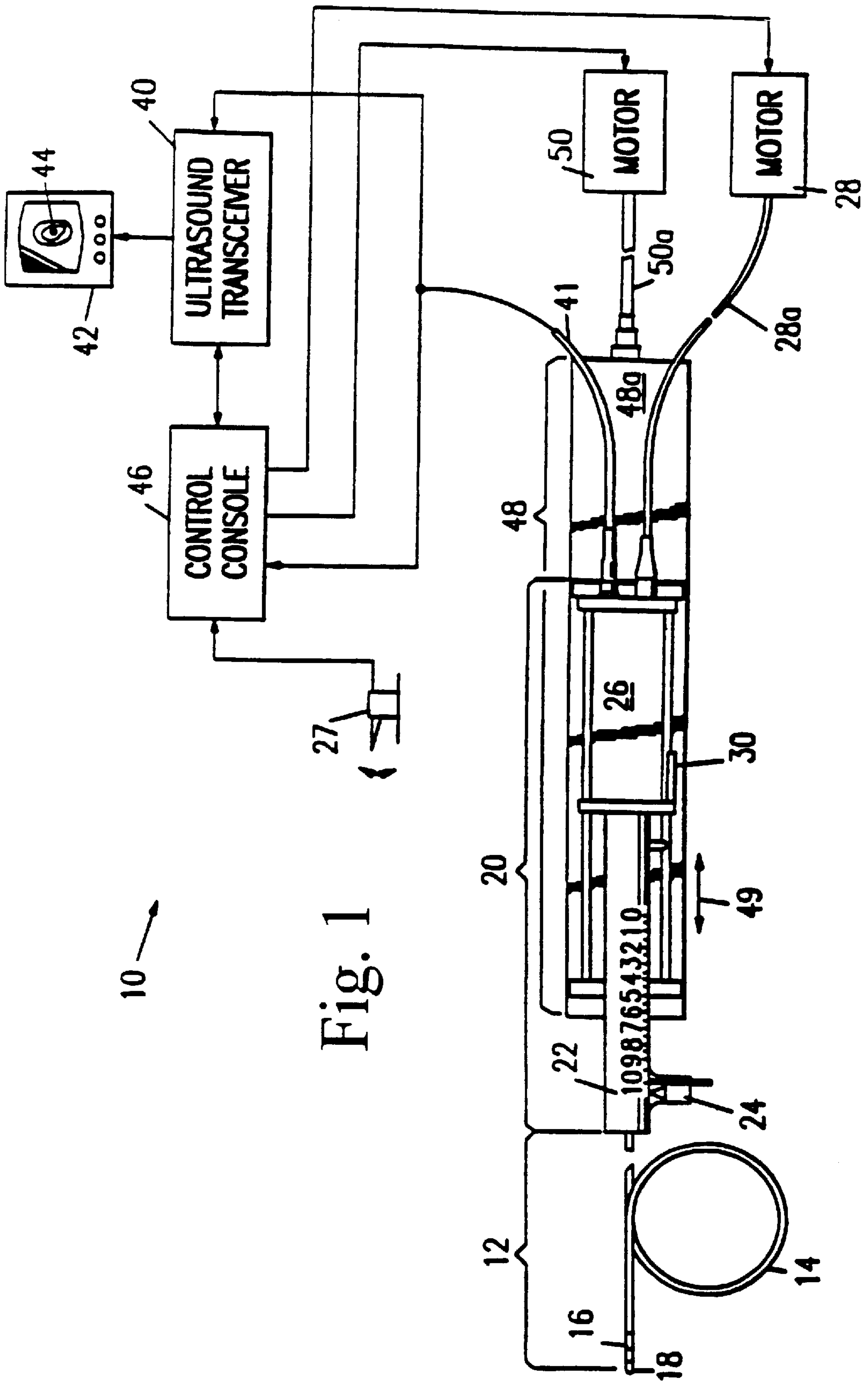
(57) **ABSTRACT**

A longitudinal position translator includes a probe drive module and a linear translation module. The probe drive module is coupled operatively to an ultrasonic imaging probe assembly having a distally located ultrasound transducer subassembly in such a manner that longitudinal shifting of the transducer subassembly may be effected. The probe drive module is preferably mounted to the linear translation unit so as to be moveable between a condition whereby longitudinal shifting of the transducer subassembly can be conducted either manually or automatically. When in the automatically-operable condition, the probe drive module will be engaged with a motor-driven screw associated with the linear translation module so as to cause the probe drive module to be longitudinally displaced at a constant motor-driven rate. In this manner, the distally located ultrasound transducer is longitudinally shifted during an ultrasound scan of surrounding intravascular (or other) tissue to thereby allow axially-spaced 360 data sample "slices" of the surrounding tissue to be obtained. The data samples may then be reconstructed into a three-dimensional or other two-dimensional representations of the scanned vessel to assist in diagnosis.

**13 Claims, 6 Drawing Sheets**

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CONTROL CONSOLE
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48a
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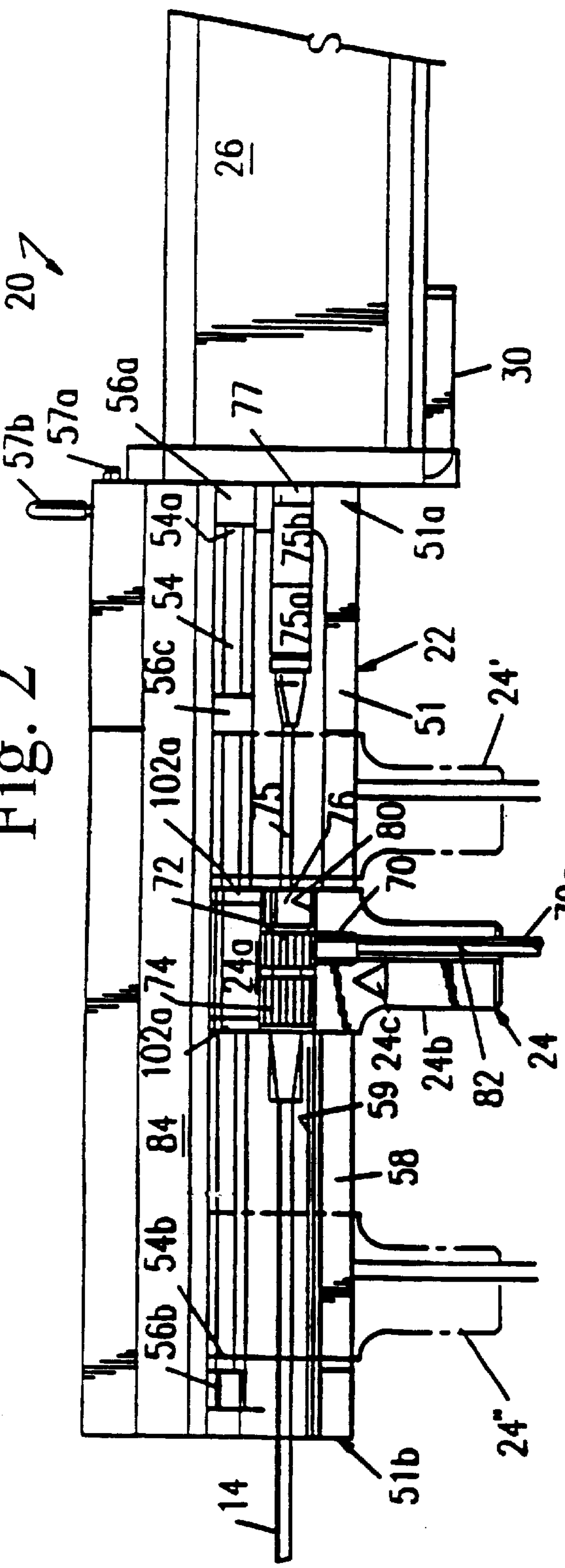
50a
10 9 8 7 6 5 4 3 2 1 0

Fig. 1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14

Fig. 2

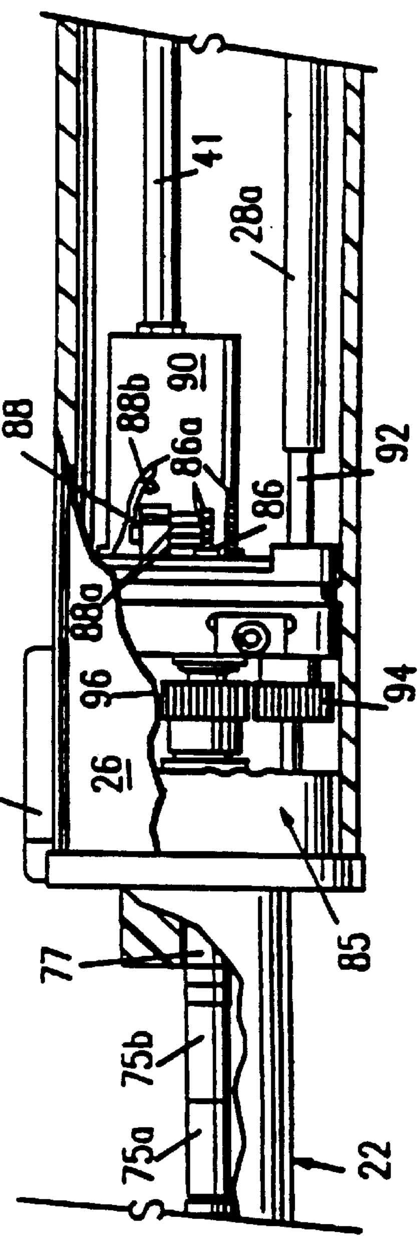
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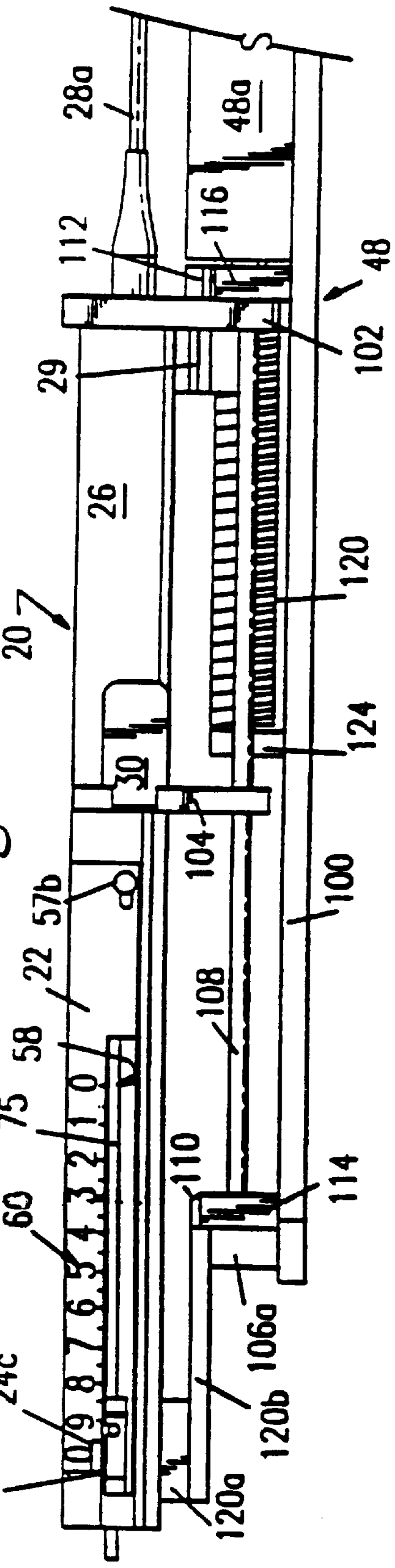
Fig. 3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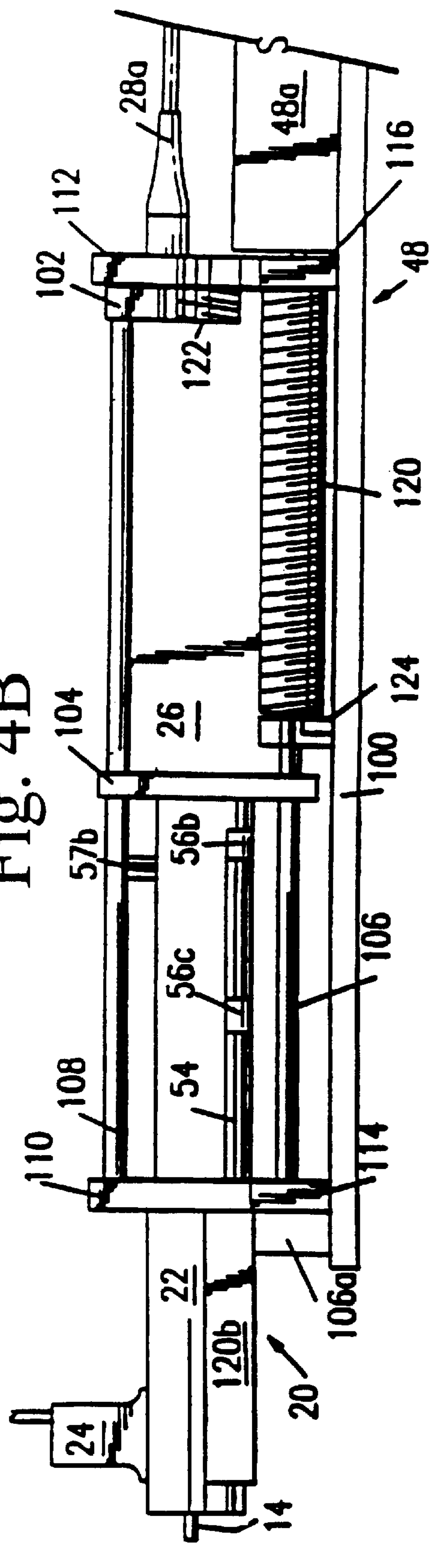
114
60
106a
24c
120b
24
120a

Fig. 4A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22
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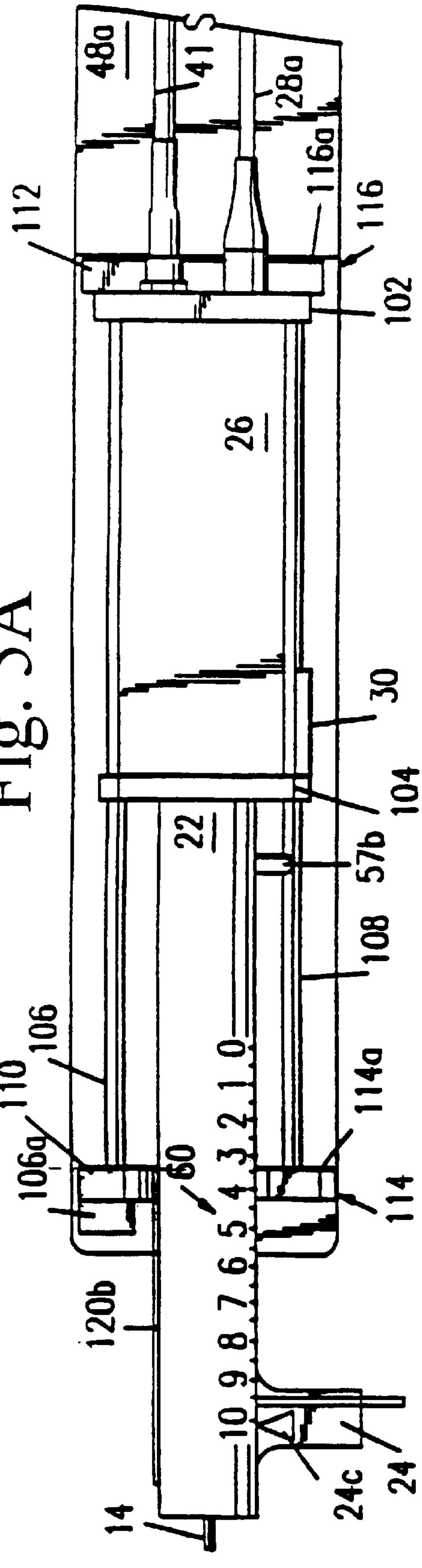
106a
20
24
14

Fig. 4B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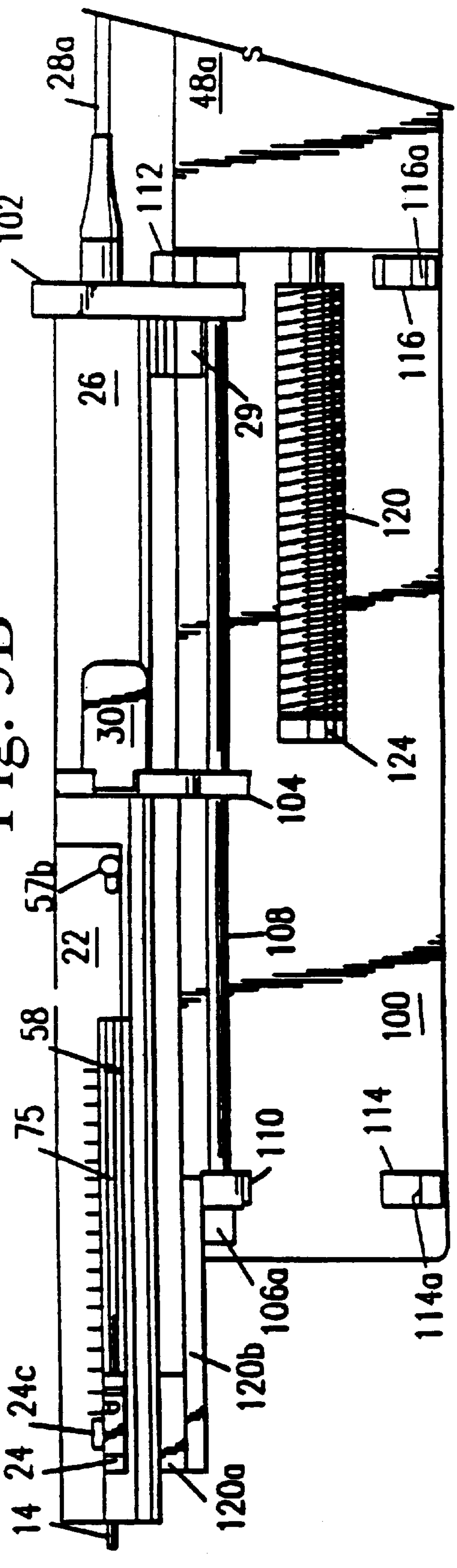
120b
24c
24
14

Fig. 5A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120a

Fig. 5B

Fig. 6B

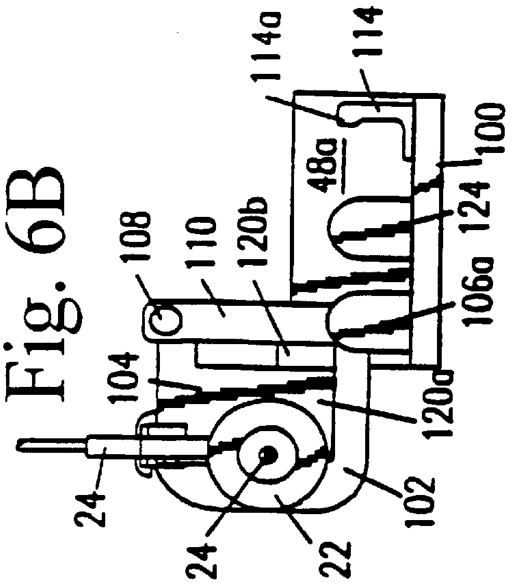



Fig. 6A

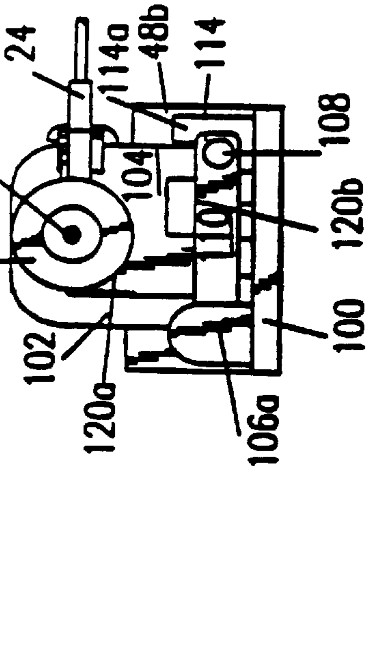
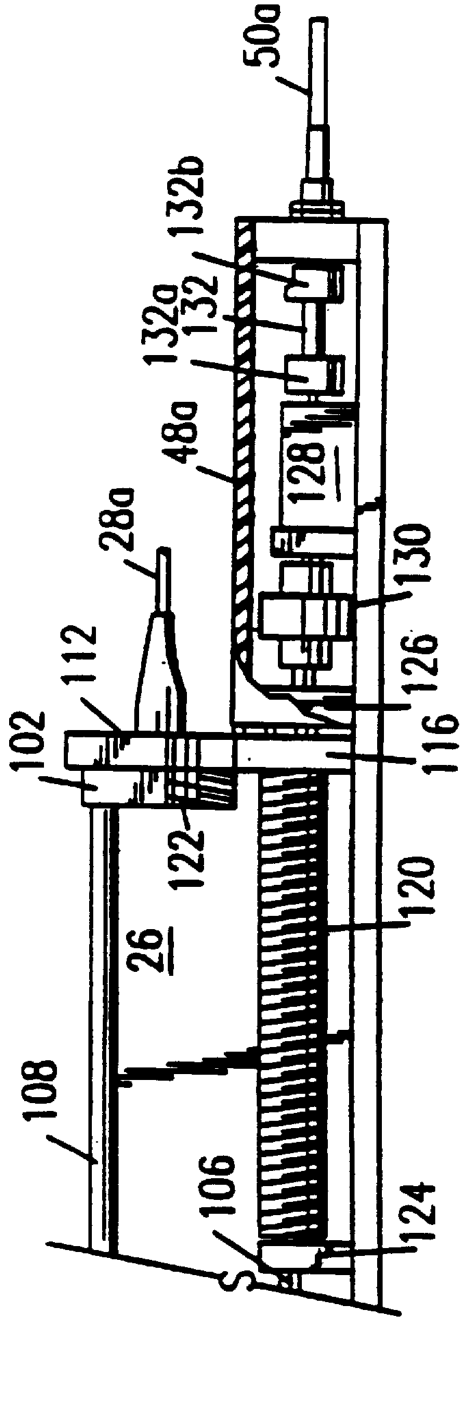



Fig. 7



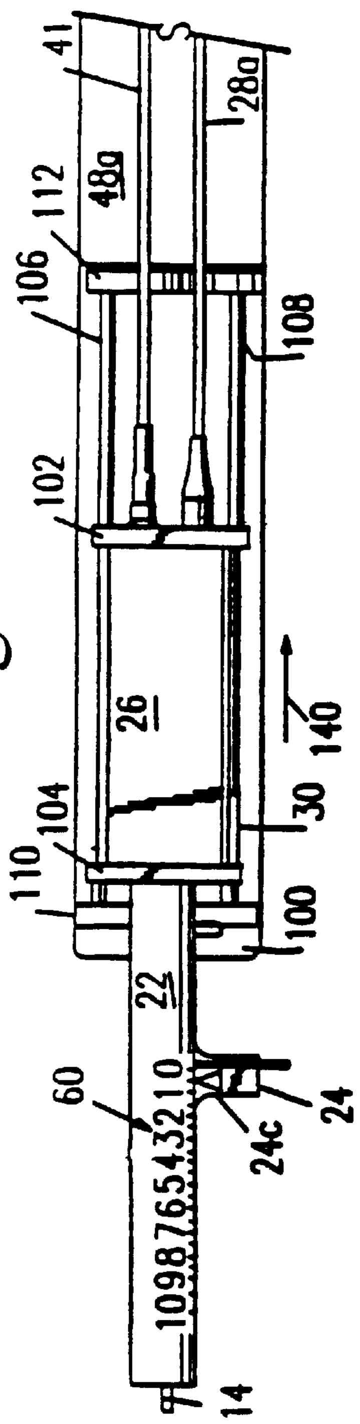



Fig. 8A

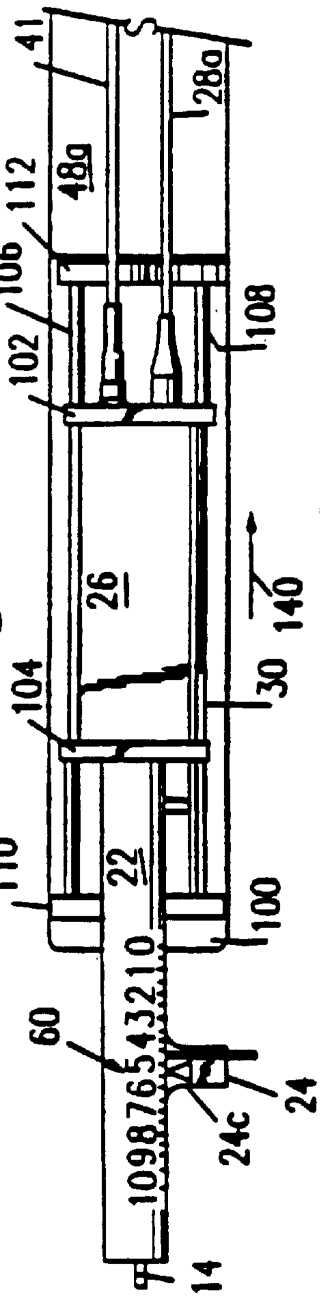



Fig. 8B

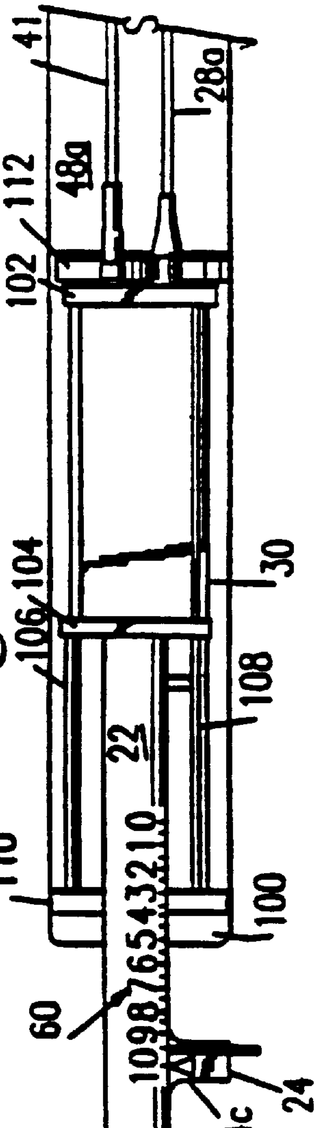



Fig. 8C

# AUTOMATED LONGITUDINAL POSITION TRANSLATOR FOR ULTRASONIC IMAGING PROBES, AND METHODS OF USING SAME

This is a continuation of U.S. application Ser. No. 09/397,836, filed Sep. 16, 1999 now U.S. Pat. No. 6,193, 736, which is a continuation of U.S. application Ser. No. 09/040,058, filed Mar. 17, 1998, now U.S. Pat. No. 6,013, 030, which is a continuation of U.S. application Ser. No. 08/747,773, filed Nov. 13, 1996 now U.S. Pat. No. 5,759, 153, which is a continuation of U.S. application Ser. No. 08/573,507, filed Dec. 12, 1995, now U.S. Pat. No. 5,592, 942, which is a continuation of U.S. application Ser. No. 08/285,969, filed Aug. 4, 1994, now U.S. Pat. No. 5,485, 846, which is a continuation of U.S. application Ser. No. 7/906,311, filed Jun. 30, 1992, now U.S. Pat. No. 5,361,768, which are expressly incorporated herein by reference in their entirety.

## CROSS-REFERENCE TO RELATED PATENTS AND APPLICATIONS

This application is related to commonly owned U.S. Pat. No. 5,115,814 issuing on May 26, 1992 to James M. Griffith et al, and entitled "Intravascular Ultrasonic Imaging Probe and Methods of Using Same", which is the parent of commonly owned and copending U.S. patent application Ser. No. 07/840,134 filed on Feb. 24, 1992, the entire content of each being expressly incorporated hereinto by reference.

## FIELD OF INVENTION

The present invention generally relates to elongate probe assemblies of sufficiently miniaturized dimensions so as to be capable of navigating tortuous paths within a patient's organs and/or vessels. In preferred forms, the present invention is embodied in automated units which are connectable to a probe assembly having a distally located ultrasound transducer subassembly which enables the transducer subassembly to be positioned accurately by an attending physician and then translated longitudinally (relative to the axis of the elongate probe assembly) within the patient under automated control.

## BACKGROUND OF THE INVENTION

### I. Introductory Background Information

Probe assemblies having therapeutic and/or diagnostic capabilities are being increasingly utilized by the medical community as an aid to treatment and/or diagnosis of intravascular and other organ ailments. In this regard, U.S. Pat. No. 5, 115, 814 discloses an intravascular probe assembly with a distally located ultrasonic imaging probe element which is positionable relative to intravascular sites. Operation of the ultrasonic element in conjunction with associated electronic components generates visible images that aid an attending physician in his or her treatment of a patient's vascular ailments. Thus, a physician may view in real (or essentially near real) time intravascular images generated by the ultrasonic imaging probe element to locate and identify intravascular abnormalities that may be present and thereby prescribe the appropriate treatment and/or therapy.

The need to position accurately a distally located operative probe element relative to an intravascular site using any therapeutic and/or diagnostic probe assembly is important so that the attending physician can confidently determine the location of any abnormalities within the patient's intravascular system. Accurate intravascular position information for the probe assembly will also enable the physician to later replicate probe positions that may be needed for subsequent therapeutic and/or diagnostic procedures. For example, to enable the physician to administer a prescribed treatment regimen over time and/or to later monitor the effects of earlier therapeutic procedures.

Recently ultrasonic imaging using computer-assisted reconstruction algorithms has enabled physicians to view a representation of the patient's interior intravascular structures in two or three dimensions (i.e., so-called three dimensional or longitudinal view reconstruction). In this connection, the current image reconstruction algorithms employ data-averaging techniques which assume that the intravascular structure between an adjacent pair of data samples will simply be an average of each such data sample. Thus, the algorithms use graphical "fill in" techniques to depict a selected section of a patient's vascular system under investigation. Of course, if data samples are not sufficiently closely spaced, then lesions and/or other vessel abnormalities may in fact remain undetected (i.e., since they might lie between a pair of data samples and thereby be "masked" by the image reconstruction algorithms mentioned previously).

In practice, it is quite difficult for conventional ultrasonic imaging probes to obtain sufficiently closely spaced data sample=of a section of a patient's vascular system under investigation since the reconstruction algorithms currently available depend upon the software's ability to process precisely longitudinally separated data samples. In this regard, conventional intravascular imaging systems depend upon manual longitudinal translation of the distally located ultrasound imaging probe element by an attending physician. Even with the, most skilled physician, it is practically impossible manually to exercise constant rate longitudinal translation of the ultrasound imaging probe (which thereby provides for a precisely known separation distance between adjacent data samples). In addition, with manual translation, the physician must manipulate the translation device while observing the conventional two dimensional sectional images. This division of the physician's attention and difficulty in providing a sufficiently slow constant translation rate can result in some diagnostic information being missed. In order to minimize the risk that diagnostic information is missed, then it is necessary to devote more time to conducting the actual imaging scan which may be stressful to the patient.

Thus, what has been needed in this art, is an ultrasound imaging probe assembly which is capable of being translated longitudinally within a section of a patient's vascular system at a precise constant rate. Such an ability would enable a series of corresponding precisely separated data samples to be obtained thereby minimizing (if not eliminating) distorted and/or inaccurate reconstructions of the ultrasonically scanned vessel section (i.e., since a greater number of more closely spaced data samples could reliably be obtained). Also, such an assembly could be operated in a "hands-off" manner which would then allow the physician to devote his attention entirely to the real time images with the assurance that all sections of the vessel were displayed. In terms of reconstruction, the ultrasound imaging probe could be removed immediately and the physician could interrogate the images or their alternative reconstructions on a near real time basis. Such a feature is especially important during coronary diagnostic imaging since minimal time would be needed to obtain reliable imaging while the blood flow through the vessel is blocked by the probe assembly. It is therefore towards fulfilling such needs that the present invention is directed.

II. Information Disclosure Statement

One prior proposal for effecting longitudinal movements of a distally located operative element associated with an elongate probe assembly is disclosed in U.S. Pat. No. 4,771,774 issued to John B. Simpson et al on Sep. 20, 1988 (hereinafter "Simpson et al '774"). The device disclosed in Simpson et al '774 includes a self-contained motor drive unit for rotating a distally located cutter element via a flexible drive cable with manual means to effect relative longitudinal movements' of the rotating cutter element.

More specifically, in Simpson et al '774, the proximal end of a flexible drive cable is slidably coupled to a hollow extension rotary drive shaft with a splined shaft. The hollow extension drive shaft is, in turn, coupled to a motor, whereas the splined shaft cooperates with a manually operated slide member. Sliding movements of the slide member relative to the motor drive unit housing translate into direct longitudinal movements of the flexible drive cable, and hence the distally located cutter element. In brief, this arrangement does not appear to allow for automated longitudinal movements of the distally located probe element.

## SUMMARY OF THE INVENTION

The longitudinal position translator of the present invention is especially adapted for use with an intravascular probe assembly of type disclosed in the above-mentioned U.S. Pat. No. 5,115,814 (incorporated fully by reference hereinto). That is, the preferred intravascular probe assembly with which the position translator of the present invention may be used will include a flexible guide sheath introduced along a tortuous path of a patient's vascular system, and a rotatable probe element (preferably an ultrasonic imaging probe) which is operatively introduced into the lumen of the guide sheath. Of course, the position translator of the present invention may be modified easily to accommodate less complex one-piece ultrasonic probe assemblies. Rotational movements supplied by a patient-external motor are transferred to a distally located transducer subassembly by means of a flexible torque cable which extends through the guide sheath.

As is described more completely in U.S. Pat. No. 5,115,814, the interior of the guide sheath provides a bearing surface against which the probe element rotates. This bearing surface supports the probe element during its rotation so that virtually no "play" is present—that is, so that the probe element rotates essentially coaxially relative to the vascular vessel undergoing therapy and/or investigation. The probe element is also longitudinally (i.e. axially) movable so that axial-spaced 360.degree. data sample "slices" of the patient's vascular vessel wall can be imaged.

The automated longitudinal position translator of the present invention generally includes a probe drive module and a linear translation module. The probe drive module is most preferably embodied in an elongate barrel-shaped housing structure having a manual positioning lever capable of reciprocal movements between advanced and retracted positions. The lever captures a proximal end of the guide sheath within which a probe element is disposed. A flexible torque cable connects the transducer subassembly at the distal end of the probe element to a drive shaft which is driven, in the preferred embodiment, by a precision rate-controlled motor located in a separate fixed base unit. Preferably, the housing is hinged in a "clamshell" fashion to more easily facilitate electrical and mechanical coupling of the intravascular probe assembly. The lever may be eliminated when using less complex one-piece ultrasonic probe assemblies or modified so as to capture the guide catheter or introducer.

The linear translation module supports the probe drive module. In addition, the linear translation module is coupled operatively to the probe drive module so as to allow for relative hinged movements thereby and thus permit the probe drive module to be moved between a manually-operable condition (whereby the probe drive module is disengaged from the longitudinal drive subassembly associated with the linear translation module to thereby allow a Physician to exercise manual control over the longitudinal positioning of the probe element) and an automated condition (whereby the probe drive module is operatively engaged with the linear translation module so that automated longitudinal position control over the probe element can be exercised)

In use, the ultrasound imaging probe will be physically positioned by an attending physician within a section of a patient's vascular system under investigation using conventional fluoroscopic positioning techniques. Thereafter, the proximal portion of the probe and guide sheath assembly will be coupled to the probe drive module. The probe drive module can then be employed to either manually or automatically translate the imaging probe element longitudinally within the section of the patient's vascular system under investigation during an ultrasonic imaging scan of the same as may be desired by the attending physician by moving the probe drive module between its manual and automated conditions, respectively. The present invention thus allows the distally located probe element to be rotated, while simultaneously providing the attending physician with the capability of longitudinally translating the probe element at a constant automated translation rate to thereby obtain reliable data samples representative of longitudinally spaced-apart data "slices" of the patient's vascular section under investigation. These data "slices" may then be reconstructed using conventional computer-assisted algorithms to present the entire section of the patient's vascular system under investigation in a more informative "two-dimensional" longitudinal or "three-dimensional" image display on a CRT (or other) monitor. The physician can thus manipulate the image orientation or two-dimensional sectional plane of the vascular section electronically and thereby achieve a more informative representation of the condition of the patient's vascular section under investigation.

In its preferred embodiment, the linear position translator provides for automated translation of the imaging probe from a distal location to a proximal location only. Thus, the imaging probe would not be advanced under automated control into the guide sheath. Such a preferred functional attribute eliminates the need for sophisticated sensor and control systems to sense and stop probe advancement should it encounter a "kink" or non-negotiable sharp bend in the guiding sheath. Furthermore, during probe withdrawal (i.e., distal to proximal motion), the guide sheath is supported by the probe and may not "kink". Also, since the probe has already negotiated all bends during its initial manual distal advancement, the attending physician is assured that the bends are in fact negotiable by the probe upon its withdrawal through that same path. Thus, although the preferred embodiment contemplates automated longitudinal translation in a proximal direction, it is likewise preferred that the attending physician advance the probe in a distal direction manually so that the physician may use his or her experience with the catheters and the tactile sensations to judge when an obstruction has been encountered.

Further features and advantages of the present invention will become more clear after careful consideration is given to the following detailed description of presently preferred exemplary embodiments.

## BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Reference will hereinafter be made to the accompanying drawings wherein like reference numerals throughout the various FIGURES denote like structural elements, and wherein;

FIG. **1** is a schematic view of an ultrasonic imaging system that includes an automated longitudinal position translator according to the present invention;

FIG. **2** is a top plan view of the probe drive module employed with the longitudinal position translator according to the present invention showing the housing thereof in an opened state;

FIG. **3** is a side elevation view, partly in section, of the probe drive module shown in FIG. **2**;

FIGS. **4**A and **4**B are each side elevation views of the longitudinal position translator according to the present invention in its automated and manual conditions, respectively;

FIGS. **5**A and **5**B are each top plan views of the longitudinal position translator according to the present invention in its automated and manual conditions, respectively;

FIGS. **6**A and **6**B are each front end elevational views of the longitudinal position translator according to the present invention in its automated and manual conditions, respectively;

FIG. **7** is a partial side elevational view which is also partly in section of the longitudinal position translator according to the present invention; and

FIGS. **8**A–**8**C are top plan views of the longitudinal position translator according to this invention which schematically depict a preferred mode of automated operation.

## DETAILED DESCRIPTION OF THE PREFERRED EXEMPLARY EMBODIMENTS

A schematic diagram of an exemplary ultrasound imaging system **10** is shown in accompanying FIG. **1**. System **10** generally includes an ultrasound imaging probe assembly **12** having a guide sheath **14** and a distally located ultrasound imaging probe element **16** inserted into the lumen of guide sheath **14**, the probe element **16** being depicted in FIG. **1** as being visible through the guide sheath's transparent wall. The ultrasonic imaging probe assembly **12** preferably embodies those features more fully described in the above-identified U.S. Pat. No. 5,115,814.

The overall length of the imaging probe assembly **12** is suitable for the desired diagnostic and/or therapeutic intravascular procedure. For example, the overall length of the probe assembly **12** may be shorter for direct (e.g., arteriotomy) insertions as compared to the length of the probe assembly **12** needed for percutaneous distal insertions (e.g., via the femoral artery). A representative length of the imaging probe assembly **12** is therefore shown in the accompanying drawings for clarity of presentation.

The terminal end of the guide sheath **14** preferably carries a radiopaque marker band **18** formed of gold or other fluoroscopically visible material. The marker band **18** allows the attending physician to monitor the progress and position of the guide sheath **14** during intravascular insertions using standard fluoroscopic imaging techniques.

The proximal end of the imaging probe assembly **12** is received within a probe drive module **20**. In essence, the probe drive module. includes a distally open-ended and longitudinally barrel-shaped housing **22**, and a positioning lever **24** which captures the proximal end of the guide sheath **14**. The proximal end of the ultrasound imaging probe element **16** is mechanically and electrically connected to the probe drive module **20**. Longitudinal reciprocal movements of the positioning lever **24** relative to the housing **22** will thus in turn effect relative longitudinal displacements of the distal end of the probe element **16** within the guide sheath **14** relative to the longitudinal axis of the probe assembly **12**.

The probe drive module **20** also includes a drive unit **26** fixedly connected proximal to the housing **22** and contains the structures which supply mechanical rotation and electrical signals to the probe element **16**. In the preferred embodiment, mechanical rotation of the probe element **16** is provided by a separate precision motor **28** associated with a base unit (not shown) and operatively coupled to the probe drive module **20** via a flexible drive cable **28***a*. It is entirely conceivable, however, that the drive unit **26** could be sized so as to accommodate the motor **28**.

The drive unit **26** is most preferably configured so that the attending physician may comfortable grasp its exterior with one hand while the probe drive module **20** is in its manual condition. The drive unit **26** thus forms a handle which allows the physician to manually manipulate the relative position between the housing **22** and the positioning lever **24** thereby responsively permitting manual longitudinal movements to be imparted to the probe element **16**. A thumb/finger switch **30** may thus be manually depressed to allow the physician to selectively operate the drive unit **26** and thereby rotate the ultrasonic imaging probe element **16** when it is desired to conduct an ultrasonic imaging scan. Electrical connection between the switch **30** and the control console **46** is made via I/O cabling **41**.

During rotation, electrical communication is established between the transducer subassembly in the distal end of the ultrasonic imaging probe element **16** and the ultrasound transceiver **40** via patient-internal electrical coaxial cabling (not shown) within the probe element **16**, drive unit **26** and electrical patient-external I/O cabling **41**. The ultrasound transceiver **40** produces a pulse signal (of desired magnitude and shape) which is applied via the electrical cabling **41** to an electroacoustic transducer associated with the distal end of the probe element **16**. The transceiver **40** also performs conventional signal processing operations (e.g., amplification, noise reduction and the like) on electrical signals generated by the electro-mechanical excitation of the transducer within the probe element **16** (i.e., signals generated by the transducer in response to receiving acoustic echo waves).

These signals are further processed digitally via known display algorithms (e.g., conventional PPI (radar) algorithms) and are then supplied as input to a CRT monitor **42** (or any other equivalent display device) so as to generate an ultrasound image **44** of desired format representative of the vascular structures reflecting ultrasonic energy toward the transducer within the distal end of the probe element **16**. A control console **46** may be employed by the attending physician so as to select the desired operational parameters of the ultrasound transceiver **40** and/or the display format of the image **44** on the CRT **42**, for example.

The probe drive module **20** is operatively coupled to and supported by the linear translation module **48** so as to allow for reciprocal rectilinear movements of the housing **22**/drive unit **26** relative to both the linear translation module **48** and the positioning arm **24** which collectively remain in a fixed position as will be described in greater detail below. As will also be described in greater detail below, the probe drive module **20** is mounted for hinged movements relative to the linear translation module **48** between a manually-operable condition (whereby the probe drive module **20** is operatively disengaged from the motor driven translator associated with the linear translation module **48**) and a automatically-operable condition (whereby the probe drive module **20** is operatively engaged with the motor driven translator associated with the linear translation module **48**).

The linear translation module **48** includes a proximal housing **48***a* which contains appropriate speed-reducers, drive shafts and associated couplings to be described below in connection with FIG. **7**. Suffice it to say here, however, that driven power is provided to the structures internally of housing **48***a* by a separated precision motor So associated with a system base unit (not shown) which is coupled operatively to the structures internally of housing **48***a* via a flexible drive shaft **50***a*. Again, it is entirely conceivable that the housing **48***a* of the linear translation module **48** could be sized and configured so as to accommodate the motor **50**. Automated operation of the motor **50** (and hence the linear translation module **48**) may be accomplished through the selection of appropriate operation parameters by the attending physician via control console **46**. Operation of both the linear translation module **48** and the probe drive module **20** may be initiated by depressing the foot-switch **27**.

The exemplary probe drive module **20** which is employed in the present invention is perhaps more clearly depicted in accompanying FIGS. **2** and **3**. As is seen, the housing **22** is collectively formed a pair of elongate lower and upper housing sections **51, 52**, respectively, which are coupled to one another along adjacent longitudinal edges in a clamshell-hinged arrangement via hinge pin **54**.

It will be noticed with particular reference to FIG. **2** that the proximal and distal ends **54***a*, **54***b* of pin **54** are rigidly fixed to the proximal and distal ends **51***a*, **51***b* of housing section **51**, respectively, while the housing section **52** is pivotally coupled to the pin **54** (and hence the housing section **51**) by means of proximal and distal and intermediate pivot sleeves **56***a*, **56***b* and **56***c*, respectively. The housing sections **51, 52** are maintained in their closed state (i.e., as shown in FIGS. **4**A through **5**B) by means of a spring-loaded detent **57***a* (see FIG. **2**) which may be moved into and out of an aperture (not shown) formed in the housing section **51** via operating lever **57***b*.

The positioning lever **24** is oriented transversely relative to the elongate axis of housing **22**. In this regard, the lever **24** includes a sleeve end **24***a* which is coupled to the pivot pin **54** to allow reciprocal longitudinal and pivotal movements of the lever **24** to occur relative to the longitudinal axis of pin **54**. The opposite end **24***b* of lever **24** extends radially outwardly from the housing **22**.

The housing **22** defines an elongate slot **58** when the housing sections **51, 52** are in a closed state (i.e., as depicted in FIG. **1**. The slot **58** allows the positioning lever **24** to be manually moved along the longitudinal axis of pin **54** during use (i.e., when the housing sections **51, 52** are in a closed state) between retracted and extended positions (shown respectively by phantom line representations **24**' and **24**" in FIG. **2**). The retracted position **24**' of lever **24** is established by a distal face of a pivot sleeve **56***c* integral with the housing section **52** and pivotally coupled to pin **54** in a manner similar to pivot sleeves **56***a* and **56***b*. On the other hand, the extended position **24**" of lever **24** is established by a proximal face of pivot sleeve **56***b*.

The lever **24** is supported by a concave inner surface **59** formed in the housing section **51** when the housing sections **51** and **52** are in a closed state. The inner surface **59** provides a bearing surface against which the lever **24** slides during the latter's movement between its retracted and extended positions **24**' and **24**", respectively.

A scale **60** (see FIGS. **4**A and **5**A) preferably is provided on the housing **22**. A pointer **24***c* associated with the lever **24** may be aligned with the scale **60** to provide an attending physician with information regarding the position of probe element **16** relative to its most distal position within the guide sheath **14**. That is, longitudinal movement of lever **24** an incremental distance (as measured by pointer **24***c* and the scale **60**) will effect movement of the probe element **16** relative to its most distal position within the guide sheath's distal end by that same incremental dimension.

Accompanying FIG. **2** also more clearly shows the cooperative engagement between positioning lever **24** and the proximal end of guide sheath **14**. In this regard, it will be noted that the proximal end of guide sheath **14** includes a side-arm port **70** which extends generally transverse to the longitudinal axis of guide sheath **14**. Side-arm port **70** includes a conventional Leur-type locking cap **72** that is coupled coaxially to a similar locking cap **74** associated with the proximal end of guide sheath **14**. Side-arm port **70** is thus in fluid-communication with the lumen of guide **14** so that saline solution, for example, may be introduced via side arm tubing **70***a*.

A shaft extension **75** of probe element **16** and electrical cabling coaxially carried thereby are mechanically and electrically coupled to the output shaft **77** of the probe drive module **20** via coaxial cable couplings **75***a* and **75***b*. It will be appreciated that coaxial cabling within the flexible torque cable portion of probe element **16** (not shown) will rotate with it as a unit during operation, but that the electrical I/O signals will be transferred to transceiver **40** by means of couplings **75***a* and **75***b*. The manner in which the separate electrical I/O path (represented by cable **41**—see FIG. **1**) and mechanical input path (represented by the flexible drive shaft **28***a* —see FIG. **1**) are combined into a common electrical/mechanical output path (represented by output shaft **77**) will be explained in greater detail with reference to FIG. **3**.

The shaft extension **75** is preferably fabricated from a length of conventional stainless steel hypodermic tube and is rigidly coupled at its distal end to a flexible torque cable (not shown). As mentioned briefly above, the torque cable extends the length of the guide sheath **14** and is connected at its distal end to a transducer subassembly in the distal end of the probe element **16**. The torque cable thereby transfers the rotational motion imparted via the motor to shaft extension **75** of the probe element **16** causing the transducer subassembly to similarly rotate within the lumen of the guide sheath **14** near the guide sheath's distal end, as well as to be longitudinally shifted within guide sheath **14** via manipulation of the relative position of the arm **24**.

The shaft extension **75** extends through an end cap **76** which is coupled coaxially to locking caps **72** and **74**. End cap **76** houses a synthetic resin bearing element (not shown) which serves as a proximal rotational bearing for the shaft **75**, and also serves to seal the proximal end of guide sheath **14** against fluid (e.g., saline liquid) leakage.

Lever **24** defines a pair of mutually transverse concave cradle surfaces **80** and **82**. The longitudinal dimension of cradle surface **80** is oriented parallel to the longitudinal dimension of housing **22**, whereas cradle surface **82** (which is joined at one of its ends to the cradle surface **80**) is oriented transverse to the longitudinal dimension of housing **22** (i.e., since it is traverse to cradle surface **80**).

Cradle surface **80** is sized and configured so as to accommodate an exterior surface portion of coaxially locked caps **72, 74** and **76**. Cradle surface **82**, on the other hand, is sized and configured to accept side-arm port **70** and side-arm tubing **70***a* extending therefrom. An axially extending inner concave surface **84** is defined in housing section **52** and, like cradle surface **82**, is sized and configured so as to accept an exterior portion of locking caps **72, 74** and **76**.

When housing sections **51** and **52** are in a closed state, caps **72, 74** and **76** will be enveloped by housing **22**. More specifically, inner concave surface **84** will positionally restrain caps **72, 74** and **76** within cradle surface **80** when housing sections **51** and **52** are closed. Since side-arm port **70** will likewise be positionally restrained within cradle surface **82** when housing sections **51, 52** are closed, caps **72, 74** and **76** will be moved longitudinally as a unit with position lever **24**. That is, longitudinal movements of lever arm **24** between its retracted and extended positions will cause the proximal end of guide sheath **14** (i.e., coaxially mounted caps **72, 74** and **76**) to be longitudinally moved relative to the longitudinally stationary (but axially rotatable) shaft extension **75**. In such a manner, the proximal end of guide sheath **14** will be moved closer to and farther from the open distal end of housing **22**.

As can be seen in FIG. **3**, the interior of the drive unit **26** is hollow to house electrical/mechanical coupling assembly **85**. Electrical/mechanical coupling **85** combines an electrical input path—represented by coaxial I/O cable **41** which establishes electrical communication with transceiver **40**—and a mechanical input path— represented by flexible drive shaft **28***a* associated with motor **28** (see FIG. **1**) into a common coaxial output shaft **77**.

Output shaft **77** is rotatably held within bearing block **86** and includes a rearwardly extending rotatable tail portion carrying a number of electrical slip-rings **86***a*. Electrical communication between the slip-rings **86***a* and, coupling **75***b* is established by a length of coaxial cable (not shown) housed within the output shaft **77**. Stationary brushes **88***a* in sliding electrical contact with respective ones of the slip-rings **86***a* are associated with a brush block **88**. Lead wires **88***b* are, in turn, coupled electrically at one end to brush block **88** (and hence to coaxial connector **75***a* via brushes **88***a* and slip-rings **86***a*), and at the other end to coaxial I/O cable **41** via a ferrite coil transformer (not shown). Slip-rings **86***a*, brush **88***a*, brush block **88**, lead wires **88***b*, and ferrite core transformer (not shown) are housed within a common electrically shielded enclosure **90**.

The mechanical input path generally represented by flexible drive shaft **28***a* is coupled operatively to one end of a rigid rotatable drive shaft **92** carrying a drive gear **94** at its other end. Drive gear **94** is, in turn, meshed with a gear **96** carried by output shaft **77**. Upon rotation of drive shaft **92**, meshed gears **94, 96** will cause shaft **77** to responsively rotate. Preferably, gears **94** and **96** are in a 1:1 ratio, but other gear sizes (and hence ratios) may be provided if desired.

The probe drive unit **20** is mounted for reciprocal rectilinear movements to the linear translation module **48** as is shown in accompanying FIGS. **4**A through **6**B. In this regard, the linear translation module includes a base plate **100** which supports the housing **48***a* and its internal structures (to be described below with reference to FIG. **7**). The probe drive module **20** itself includes a longitudinally spaced-apart pair of support flanges **102, 104**, each of which is slidably mounted onto a pair of parallel guide rails **106, 108**.

The proximal end of guide rail **106** is pivotally connected to the housing **48***a* while its distal terminal end is pivotally connected to an upright support block **106***a*. A forward and rearward pair of transverse support arms **110, 112** each having one end rigidly coupled to guide rail **106** and an opposite end rigidly coupled to the guide rail **108**. Thus, the support arms **110, 112** are capable of pivoting between a lowered position (e.g., as shown in FIGS. **4**A, **5**A and **6**A) and a raised position (e.g., as shown in FIGS. **4**B, **5**B and **6**B) by virtue of the pivotal guide rail **106** so as to, in turn, pivotally move the probe drive module **20** between its automatically-operable condition and its manually-operable condition, respectively, due to its attachment to the guide rails **106, 108** via support flanges **102, 104**.

The ends of each transverse support arm **110, 112** between which the guide rail **108** is fixed are removably captured by upright restraining posts **114, 116**, respectively. As is perhaps more clearly shown in FIGS. **6**A and **6**B, the restraining posts **114, 116** (only restraining post **114** being visible in FIGS. **6**A and **6**B) are rigidly supported by the base plate **100** and include an inwardly projecting lip **114***a*, **116***a* which provide an interference fit with the terminal ends of support arms **110, 112**, respectively. In this connection, it is preferred that the restraining posts **114, 116** be formed of a relatively stiff, but resilient plastics material (e.g., nylon, polyacetal or the like) so that when the probe drive unit is moved between its automatically-operable and manually-operable conditions, the posts **114, 116** are capable of yielding somewhat to allow such movement.

The positioning arm **24** of the probe drive unit **20** is fixedly tied to the forward transverse support arm **110** by an upright connector **120***a* on a longitudinal connector **120***b*. In this regard, the upper end of upright connector **120***a* extends through a longitudinal slot on the side of the housing **22** opposite slot **58** and positionally captures the ends of the positioning arm **24** around pin **54**. The lower end of the upright connector **120***a* is connected to the distal end of the horizontally disposed longitudinal connector **120***b*. The proximal end of longitudinal connector **120***b* is, in turn, rigidly fixed to the transverse support arm **110** by any suitable means (e.g., screws). It will be understood, therefore, that the position of the positioning arm **24** (and hence the guide sheath **14**) remains fixed relative to the base **100** of the linear translation module **48** during longitudinal movements of the probe drive module **20** along the guide rails **106** and **108**. Thus, the relative position of the patient-internal transducer subassembly at the distal end of the probe element **16** will correspondingly shift the same distance as the probe drive module **20** relative to the patient internal distal end of the guide sheath **14**.

Automated longitudinal shifting of the probe drive module **20** (and hence the ultrasonic transducer at the distal end of the probe element **16**) is permitted by the coaction between a longitudinally extending drive screw **120** and a threaded collar portion **122** (see FIGS. **4**B and **7**) associated with the support flange **102** of the probe drive module **20**. The distal and proximal ends of the drive screw **120** are rotatably supported by an upright distal bearing block **124** and an upright proximal bearing block **126** (see FIG. **7**), respectively.

As can be seen in FIGS. **4**B, **5**B, **6**B and **7**, the threaded collar portion **122** is disengaged from the threads of drive screw **120** when the probe drive module **20** is in its manually-operable condition. As a result, the attending physician may simply manually shift the probe drive module **20** longitudinally along the guide rails **106, 108**. When the probe drive module **20** is pivoted into its automatically-operable condition as shown in FIGS. **4**A, **5**A and **6**A, the threads associated with the threaded collar portion **122** will be mateably engaged with the threads of the drive screw **120**. As a result, rotation of the drive screw **120** about its longitudinal axis will translate into longitudinal displacement of the probe drive module **20**. The threads of the drive screw **120** and the threaded collar portion **122** as well as the rotation direction of the drive screw **120** are most preferably selected so as to effect longitudinal shifting of the probe drive module from the distal end of the drive screw towards the proximal end thereof—i.e., a distal to proximal displacement. However, these parameters could be changed so as to effect a reverse (proximal to distal) displacement of the probe drive unit, if necessary or desired.

The drive screw **120** is coupled operatively to the flexible drive shaft **50***a* (and hence to the driven output of motor **50**) by the structures contained within housing **48***a*. In this regard, the proximal end of the drive screw is coupled to the output shaft of a speed reducer **128** via a shaft coupling **130**. The input to the speed reducer **128** is, in turn, coupled to the flexible drive shaft **50***a* from a rigid shaft extension member **132** and its associated shaft couplings **132***a* and **132***b*. The speed reducer **128** is of a conventional variety which provides a predetermined reduced rotational speed output based on the rotational speed input. Preferably, the motor **50**, speed reducer **128** and drive screw **120** are designed so as to effect longitudinal translation of the probe drive unit **20** at a rate of between about 0.25 to 1.0 mm/sec. Of course, other longitudinal translation rates may be provided by varying the parameters of the motor **50**, speed reducer **128** and/or drive screw **120**.

In use, the attending physician will preposition the guide sheath **14** and imaging probe element **16** associated with the ultrasound imaging probe assembly **12** within the vessel of the patient to be examined using standard fluoroscopic techniques and/or the techniques disclosed in the above-mentioned U.S. Pat. No. 5,115,814. Once the guide sheath **14**/imaging probe element **16** have been prepositioned in a region of the patient's vessel which the physician desires to observe, the proximal end of the probe assembly **12** will be coupled to the probe drive module **20** in the manner described above. Thereafter, the physician may conduct an ultrasound scan of the patient's vessel by operatinq switch **30** to cause high-speed rotation of the transducer subassembly on the distal end of the probe element **16** within the guide sheath **14**. Data samples associated with different transverse sections of patient's vessel may then be obtained by the physician manually shifting the probe drive module **20** along the guide rails **106**, **108** in the manner described above.

Alternatively, the physician may elect to pivot the probe drive module **20** into its automatically-operable condition and then select automated operation of the same via the control console **46** and foot-switch **27**. In such a situation, the probe drive module (and hence the transducer subassembly at the distal end of the probe element **16**) will be shifted longitudinally at a constant rate simultaneously with high-speed rotation of the transducer subassembly. In this manner, data samples representing longitudinally spaced-apart 360.degree. slices" of the patient's interior vessel walls will be accumulated which can then be reconstructed using known algorithms and displayed in "two-dimensional" or "three-dimensional" formats on the monitor **42**.

Accompanying FIGS. **8**A–**8**C schematically depict the longitudinal translator according to this invention being operated in an automated manner. In this connection, and as was noted briefly above, the probe drive module **20** is most preferably translated in a distal to proximal direction by means of the linear translation module **48** (i.e., in the direction of arrows **140** in FIGS. **8**A and **8**B). In FIG. **8**A, the probe drive module is shown in a position at the beginning of an automated ultrasonic imaging scan, it being noted that the pointer **24***c* associated with the positioning arm **24** registers with the zero marking on the scale **60**. The physician will then initiate automated ultrasonic scanning via the foot-switch **27** which causes the probe drive unit **20** to be displaced proximally (arrow **140**) at a constant rate as shown in FIG. **8**B. This proximal displacement of the probe drive module **20** will, in turn, cause the transducer subassembly on the distal end of the probe element **16** to be longitudinally displaced proximally (i.e., pulled back away from) the distal-most end of the guide sheath **14**.

The ultrasonic imaging scan is automatically terminated (e.g., by use of suitable limit switches and/or position transducers) when the probe drive unit reaches its most proximal position as shown in FIG. **8**C. In this connection, the present invention most preferably is provided with a limit switch (not shown) enclosed within a limit switch housing **29** (see FIGS. **4***a* and **5**B) which is mechanically actuated when support flange **102** contacts support arm **112** (i.e., when the probe drive module **20** is in its most proximal position). The limit switch in housing **29** communicates electrically with the control console **46** via cabling **41**. Virtually any suitable equivalent position-sensing devices could be employed in place of the limit switch. For example, the housing **29** could be sized and configured to accommodate an absolute position transducer so as to communicate absolute position to the control console **46**. The information provided by such an absolute position transducer could be employed in conjunction with modified reconstruction algorithms for image reconstruction, even during manual operation of the probe drive module **20**.

Upon the probe drive module **20** reaching its most proximal position, the pointer **24***c* associated with the positioning arm **24** registers with the marking "10" on the scale **60** of housing **22**. Of course, the ultrasonic imaging scan need not necessarily be conducted over the entire range of 0–10 marked on the scale **60** and thus could be terminated at any time by the physician simply releasing the foot-switch **27** or by simply pivoting the probe drive module **20** into its manually-operable condition.

Those skilled in this art will recognize that a number of equivalent mechanical and/or electrical means could be employed. For example, locking slides, latches and quarter-turn screws could be used to allow engagement and disengagement of the probe drive module with the linear translation module. A flexible drive shaft connects the linear translation module to a rate-controlled motor which controls the automatic linear translation rate. The motor is most preferably located in a separate fixed base unit, but could be provided as in an integral part of the linear translation module, if desired.

Furthermore, various translation rates associated with the motor may be selected for various purposes. For example, slow rates give ample time for the physician to examine the real-time images in cases where time is not a limiting factor. The rate upper limit is governed by the probe rotation rate and the effective thickness of the imaging data slices generated by the probe, such that there is no (or an acceptable) gap between successive imaging data slices. This would prevent missing discernible features during vascular imaging with automatic Translation. The effective thickness is governed by the ultrasonic beam characteristics of the probe. For some applications, the translation may be discontinuous (i.e., gated to an electrocardiogram) for use with modified algorithms or programmed to translate a fixed distance discontinuously.

Thus, while the invention has been described in connection with what is presently considered to be the most practical and preferred embodiment, it is to be understood that the invention is not to be limited to the disclosed embodiment, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims.

What is claimed is:

**1**. A catheter system for detecting abnormalities within an anatomical structure of a patient, the system comprising:

a cable having proximal and distal ends, said cable comprising an imaging instrument coupled to a distal portion of said cable;

a position translator comprising a motor, said position translator in connection with the proximal end of said cable, wherein said position translator is adapted for manual linear translation of the cable relative to the catheter, and wherein said motor is adapted to effect automatic motor-driven linear translation of the cable relative to the catheter.

**2**. The catheter system of claim **1**, wherein the imaging instrument is an ultrasound transducer.

**3**. The catheter system of claim **2**, further comprising an ultrasound transceiver in electrical communication with the imaging instrument.

**4**. The catheter system of claim **3**, further comprising a control console in electrical communication with the motor and the ultrasound transceiver, wherein the control console is adapted for controlling the operational parameters of the ultrasound transceiver and the motor.

**5**. The catheter system of claim **1**, wherein a proximal portion of the cable is positioned within a drive module, said drive module comprising a distally open-ended and longtudinally barrel-shaped housing and a positioning lever which captures the proximal end of the cable.

**6**. A method for imaging a patient's body cavity, comprising the steps of:

providing a catheter having a sheath and a cable at least partially housed within the sheath, the cable operatively coupled to a position translator, said position translator comprising a motor, wherein said position translator is adapted for manual linear translation of the cable relative to the catheter, and wherein the motor is adapted to effect automatic motor-driven linear translation of the cable relative to the catheter;

positioning the catheter within a region of interest within the patient's body cavity; and translating the cable relative to the catheter.

**7**. The method of claim **6**, wherein the imaging instrument is an ultrasound transducer and the cable is electrically and mechanically coupled to a second motor capable of radially rotating the cable and thus the ultrasound transducer, and wherein the method further comprises the step of activating the second motor to radially rotate the ultrasound transducer.

**8**. The method of claim **7**, wherein the ultrasound transducer is in electrical communication with an ultrasound transceiver, said transceiver being in electrical communication with a monitor, and wherein the method further comprises the steps of:

receiving a signal transmitted by the ultrasound transducer, said signal being representative of the region of interest;

processing the signal by applying a display algorithm to said signal;

transmitting the processed signal to the monitor; and

displaying an ultrasound image on the monitor, said image representative of the region of interest.

**9**. The method claim **7**, wherein the ultrasound transducer is in electrical communication with an ultrasound transceiver, said ultrasound transceiver being in electrical communication with a control console, wherein the method further comprises the step of using the control console to select operational parameters of the ultrasound transceiver.

**10**. The method of claim **6**, wherein a control console is in electrical communication with the motor, and wherein the method further comprises the step of using the control console to select the linear translation speed of the motor.

**11**. The method of claim **6**, wherein the step of translating the cable relative to the catheter is performed by actuating the motor to effect automatic motor-driven linear translation of the cable relative to the catheter.

**12**. The method of claim **6**, wherein the step of translating the cable relative to the catheter is performed by manually translating the cable linearly relative to the catheter using the position translator.

**13**. A method of performing an ultrasonic imaging scan comprising the steps of:

providing a catheter, said catheter comprising a cable having proximal and distal portions, said cable comprising an ultrasound transducer coupled to its distal portion;

providing a position translator coupled to a motor, said position translator in connection with the proximal portion of the cable, wherein said position translator is adapted for manual linear translation of the cable relative to the catheter, and wherein the motor is adapted to effect automatic motor-driven linear translation of the cable relative to the catheter;

positioning the ultrasound transducer in a region of interest within an anatomical structure of a patient;

providing an ultrasound transceiver in electrical communication with the ultrasound transducer;

activating the ultrasound transceiver to generate a pulse signal transmitted to the ultrasound transducer;

radially rotating the cable thus rotating the ultrasound transducer; and activating the motor to effect an automatically controlled linear translation of the ultrasound transducer.

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摘要(译)

纵向位置转换器包括探针驱动模块和线性转换模块。探针驱动模块可操作地耦合到超声成像探针组件，该超声成像探针组件具有位于远端的超声换能器子组件，使得可以实现换能器子组件的纵向移动。探头驱动模块优选地安装在线性平移单元上，以便可以在一个条件下移动，从而可以手动或自动地进行换能器子组件的纵向移动。当处于可自动操作状态时，探针驱动模块将与与线性平移模块相关联的电机驱动螺钉接合，以使得探针驱动模块以恒定的电机驱动速率纵向移位。以这种方式，远侧定位的超声换能器在周围血管内（或其他）组织的超声扫描期间纵向移位，从而允许获得周围组织的轴向间隔的360个数据样本“切片”。然后可以将数据样本重建为扫描血管的三维或其他二维表示以辅助诊断。