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(54) **ULTRASONIC SCANNING APPARATUS**

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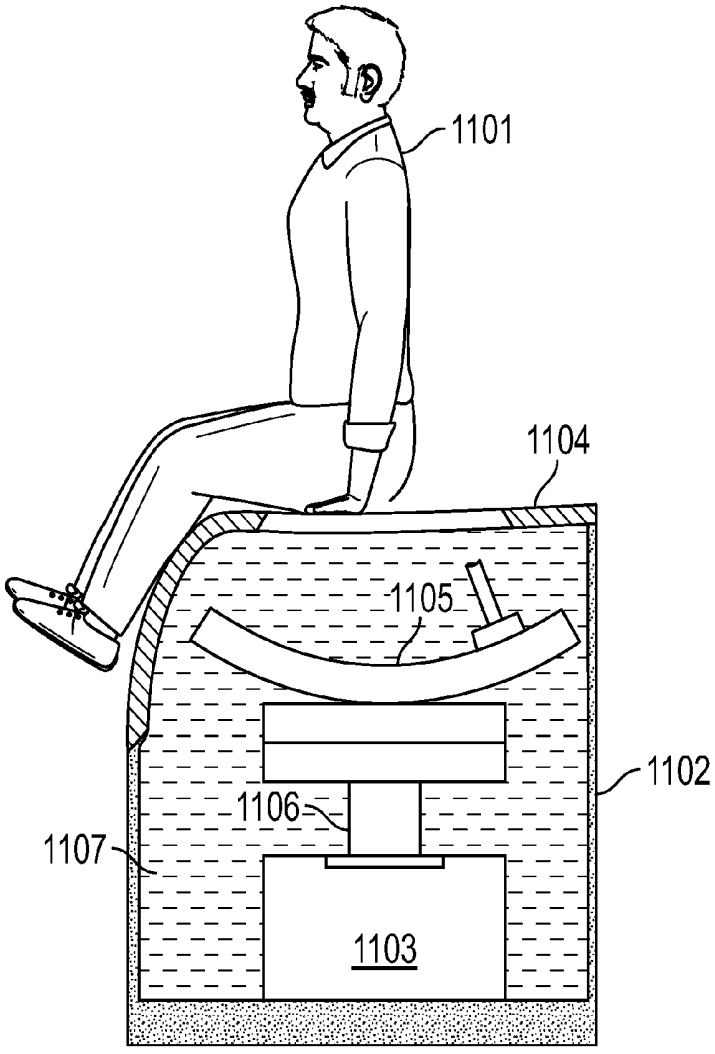
(52) **U.S. Cl.**

CPC ***A61B 8/40*** (2013.01); ***A61B 8/10*** (2013.01); ***A61B 8/44*** (2013.01)

(57) **ABSTRACT**

The present disclosure is directed to a precision ultrasound scanner for imaging, for example, the prostate in a way that produces a superior image of the prostate while removing the iatrogenic risk and patient discomfort associated with other methods of providing an ultrasound image of the prostate. The present disclosure describes an apparatus and method for forming a high precision image of the prostate from outside the patient's body wherein the resolution in sufficient to image, for example, cancerous lesions on the surface of the prostate. To achieve such images, coded excitation, tissue harmonic imaging, advanced transducers operating in the 10 MHz to 40 MHz range is used to achieve a useable signal-to-noise reflection while being able to position the imaging transducer as close as possible to the prostate without risk or discomfort to the patient.



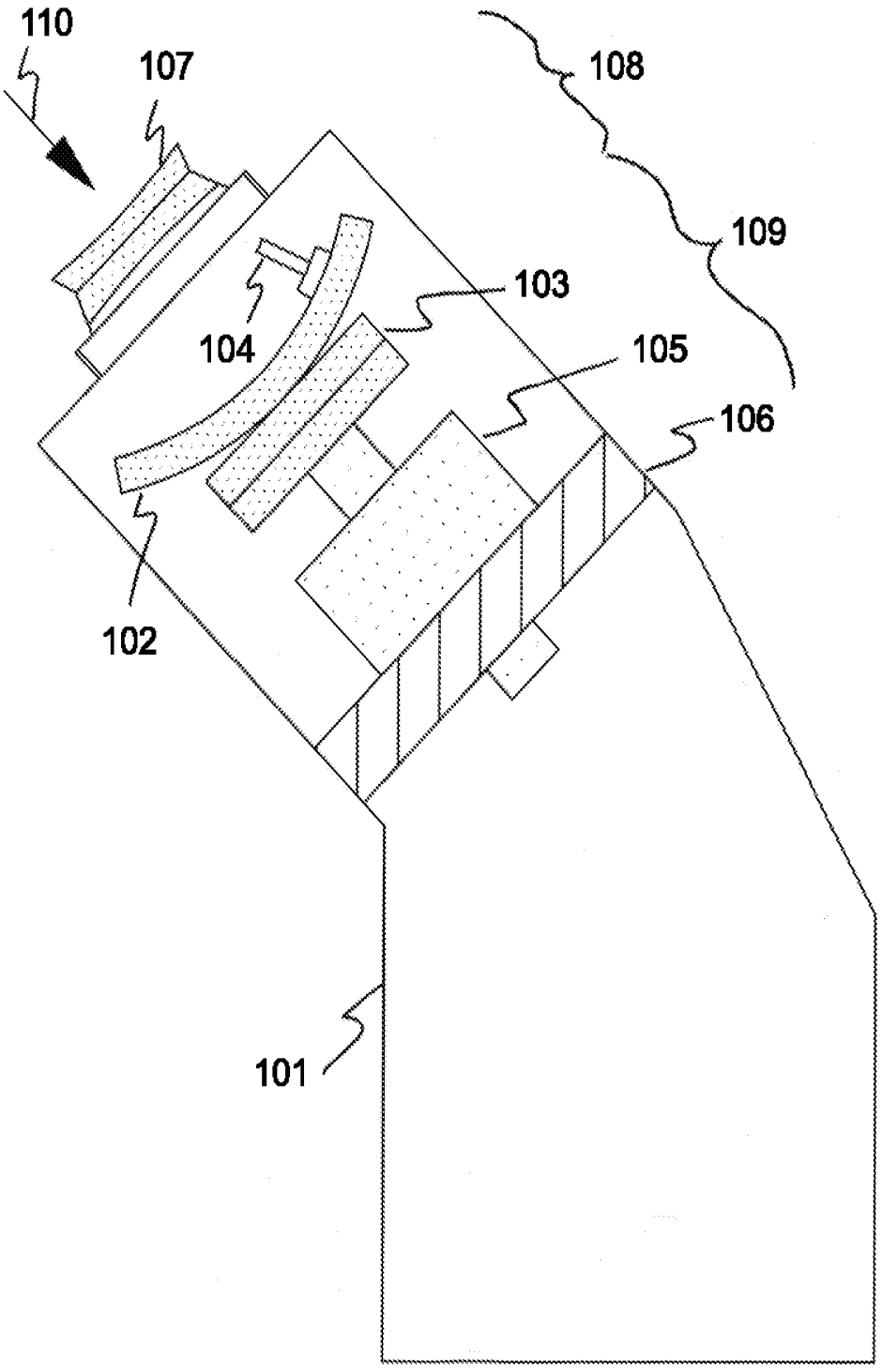


Figure 1 (Prior Art)

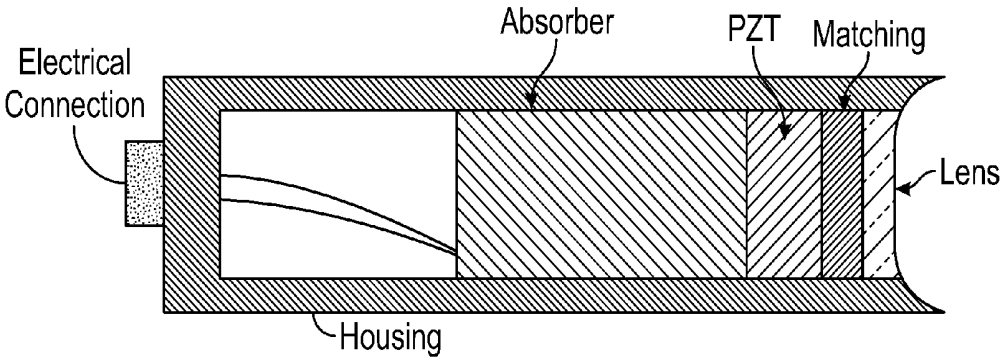


FIG. 2A
(Prior Art)

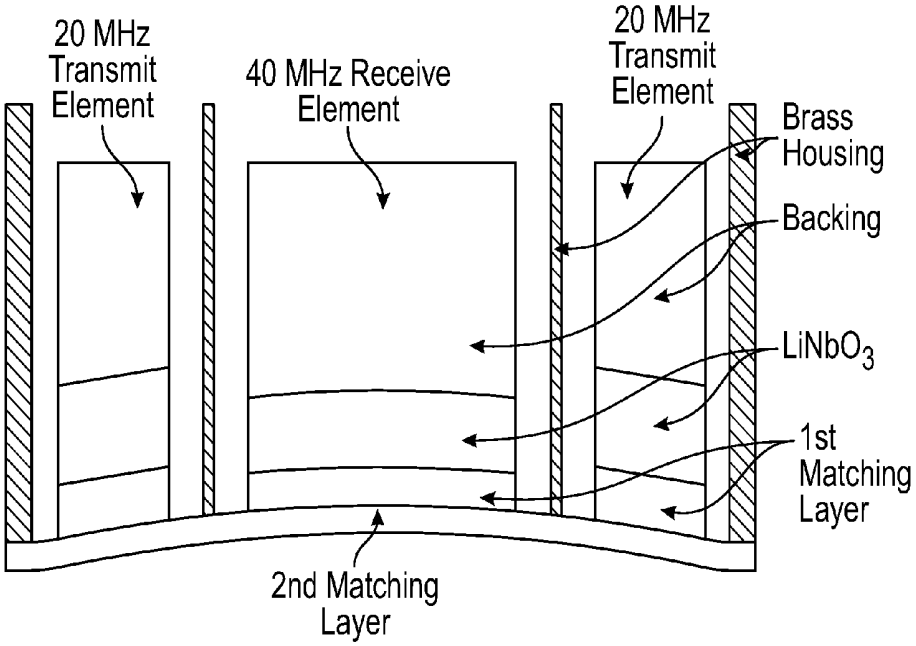


FIG. 2B
(Prior Art)

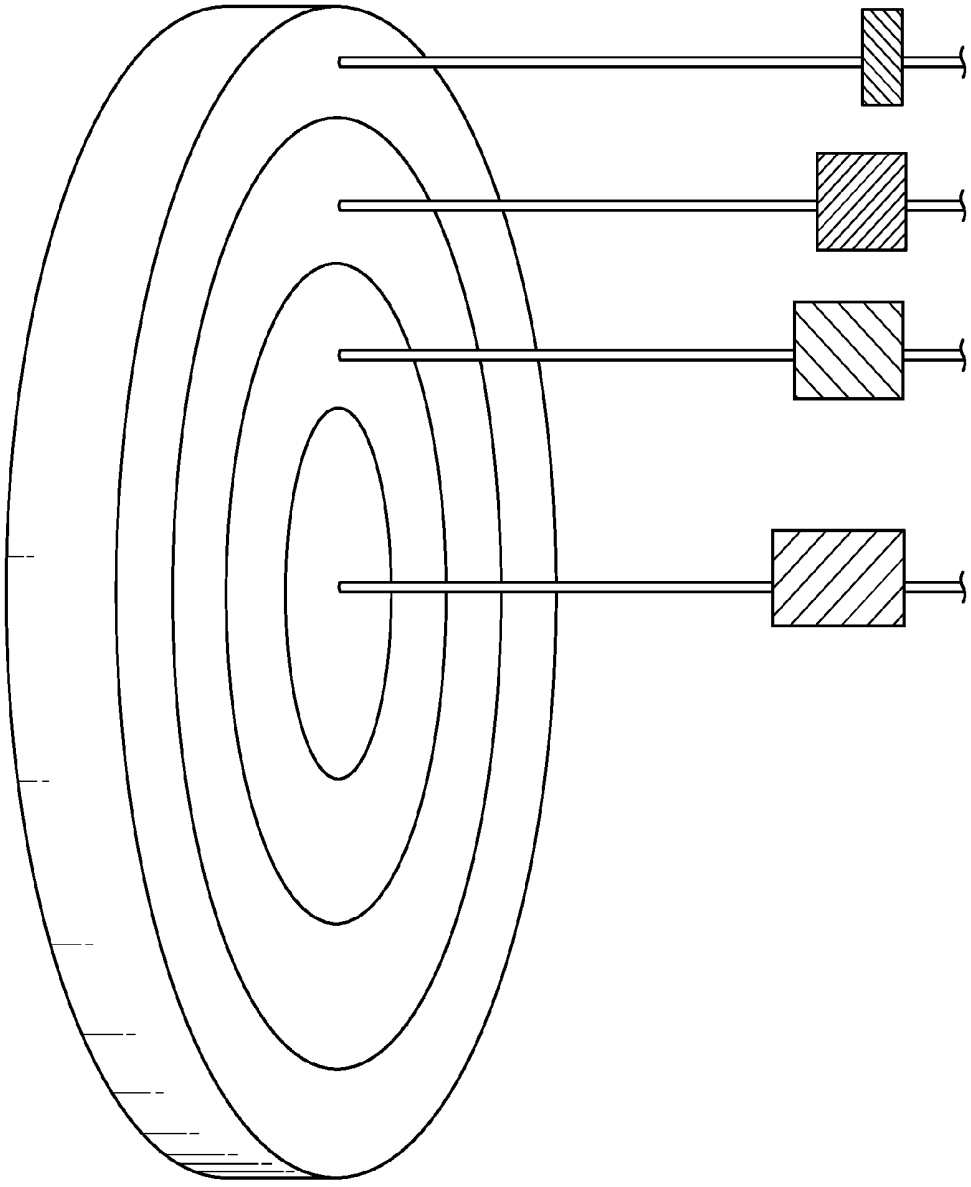


FIG. 3
(Prior Art)

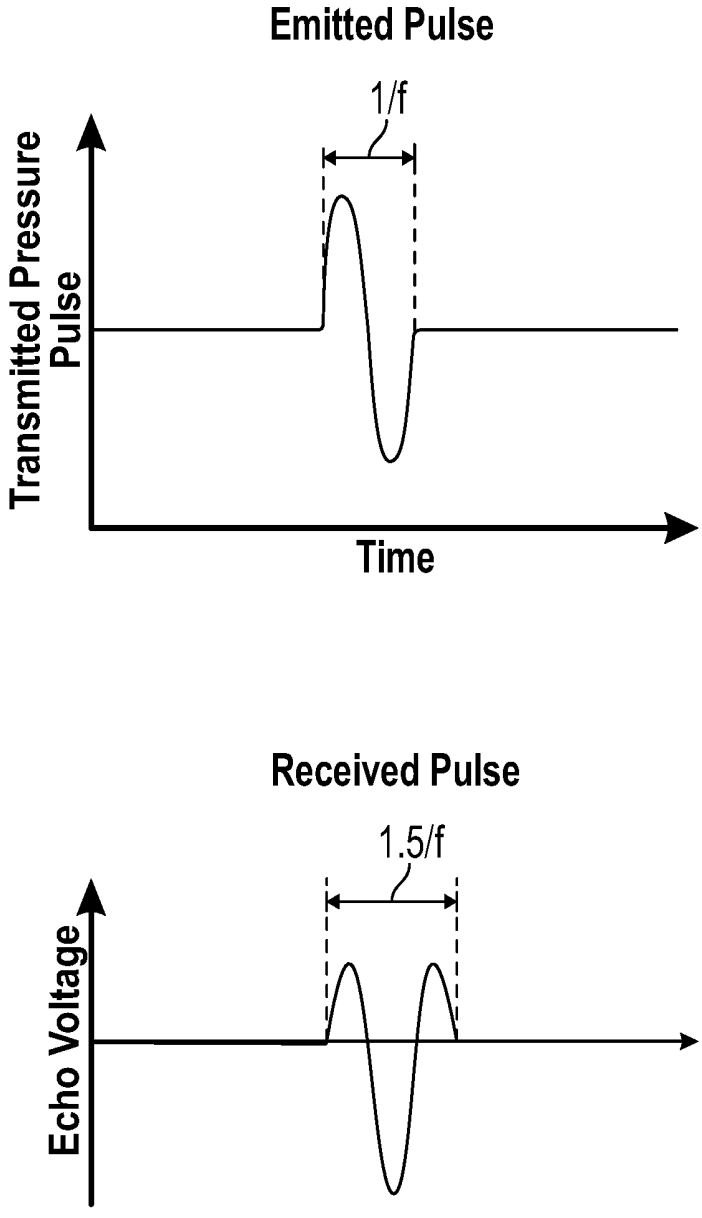


FIG. 4
(Prior Art)

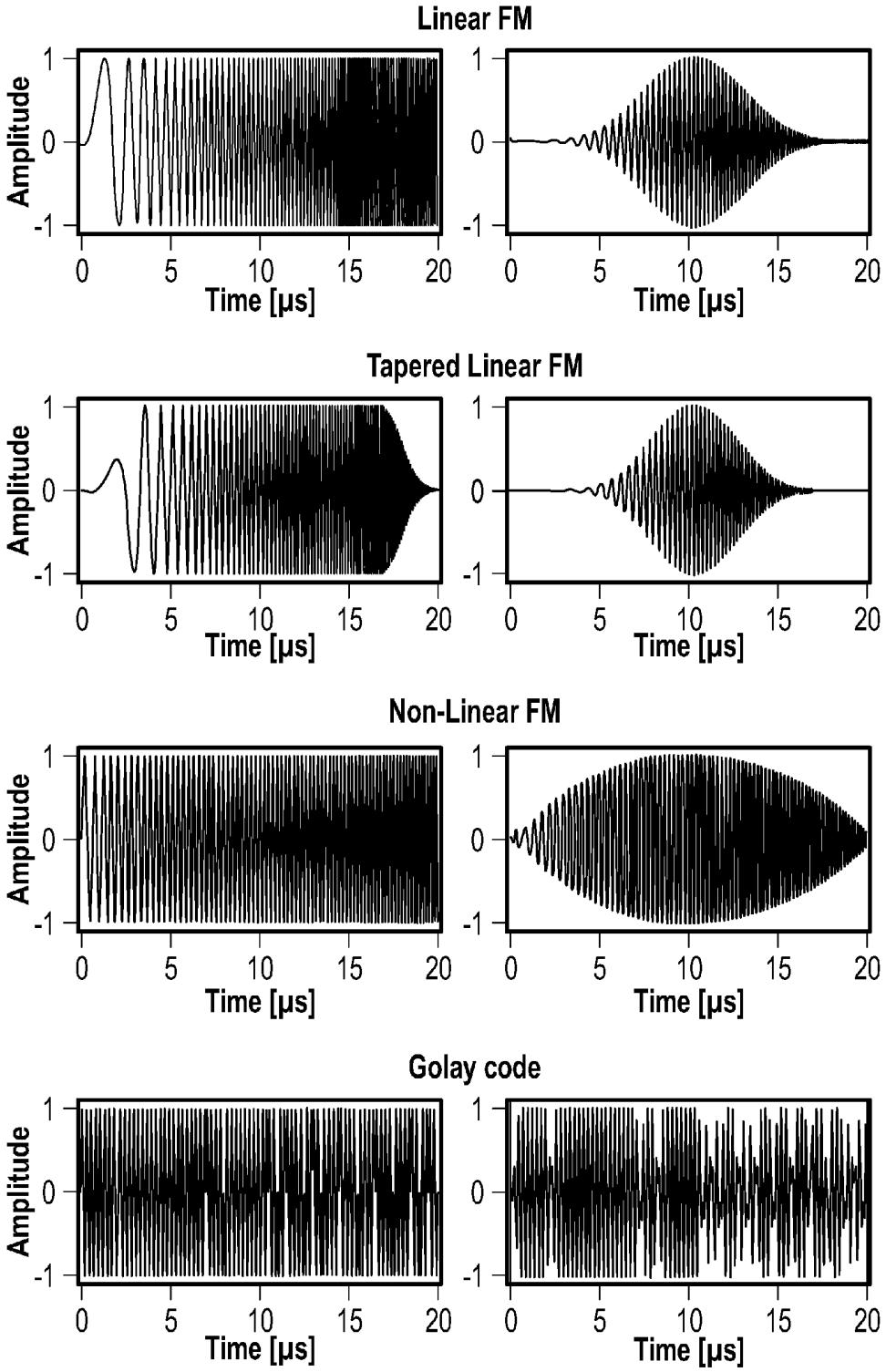


FIG. 5
(Prior Art)

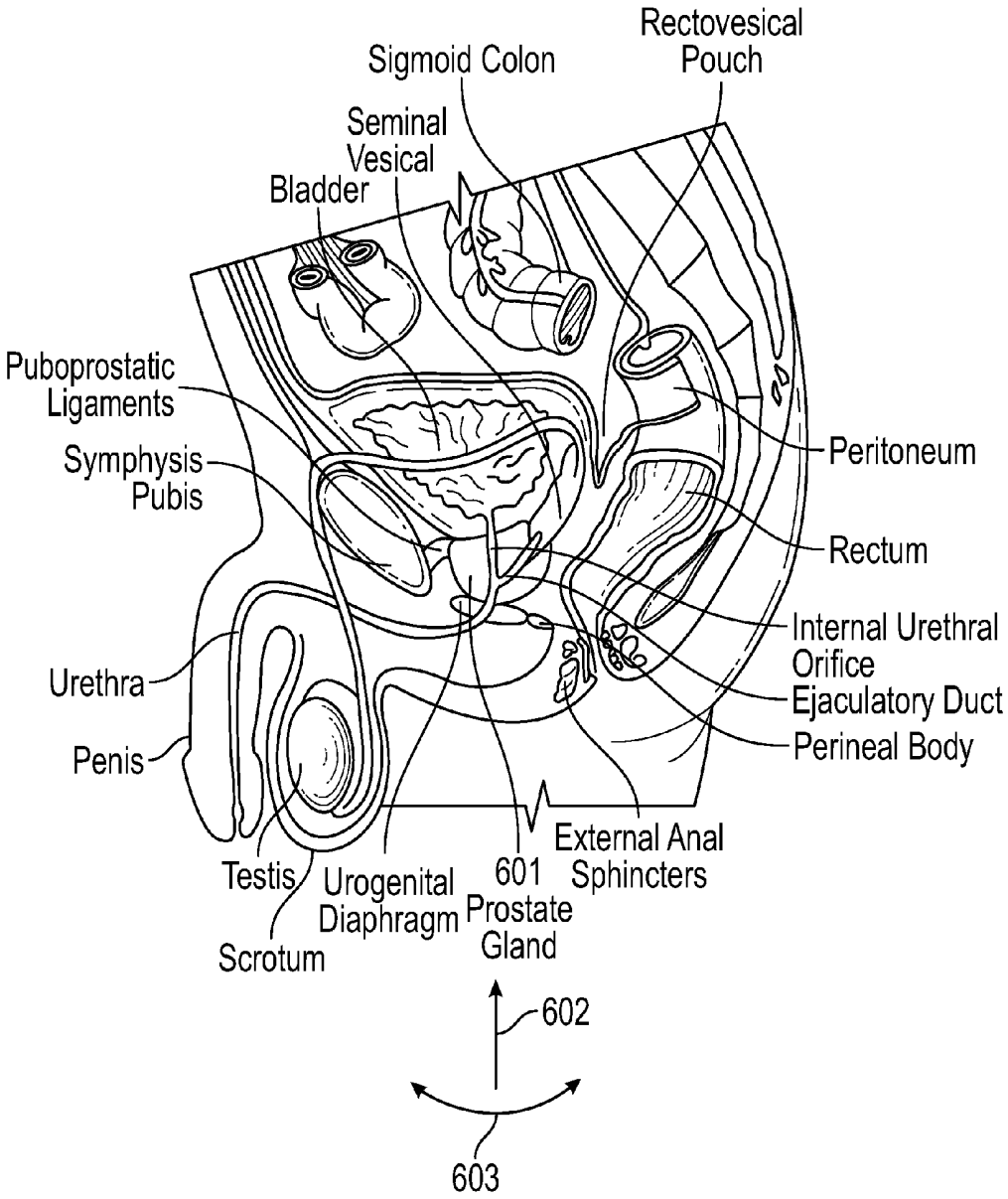
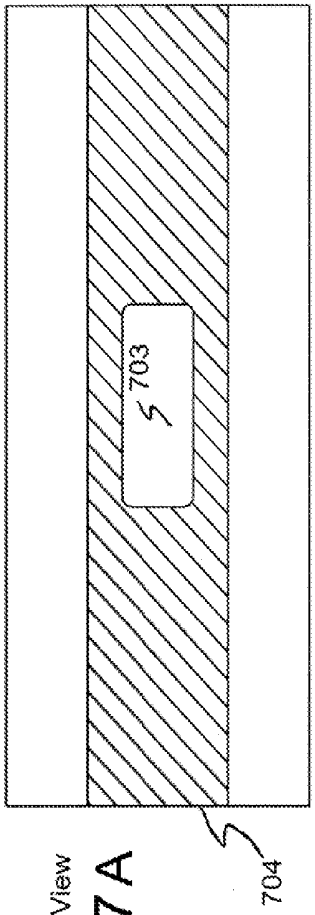
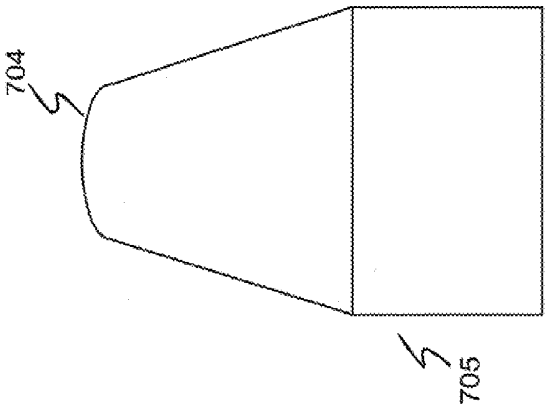

Rectovesical Pouch
Sigmoid Colon
Seminal Vesical
Bladder
Puboprostatic Ligaments
Symphysis Pubis
Peritoneum
Rectum
Internal Urethral Orifice
Ejaculatory Duct
Perineal Body
Urethra
Penis
External Anal Sphincters
Testis
Urogenital Diaphragm
601
Prostate Gland
Scrotum
602
603

FIG. 6



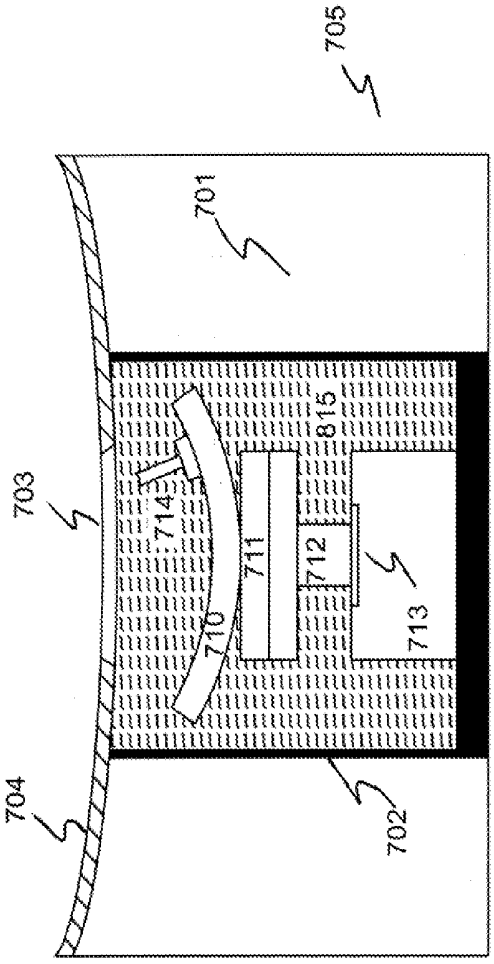
Top View

Figure 7A



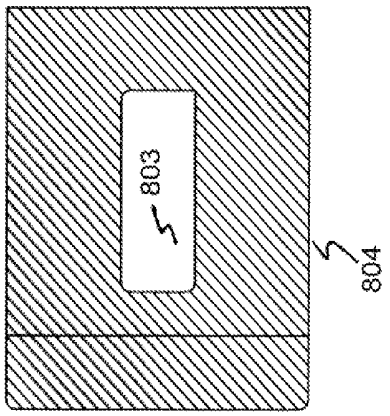
End View

Figure 7B



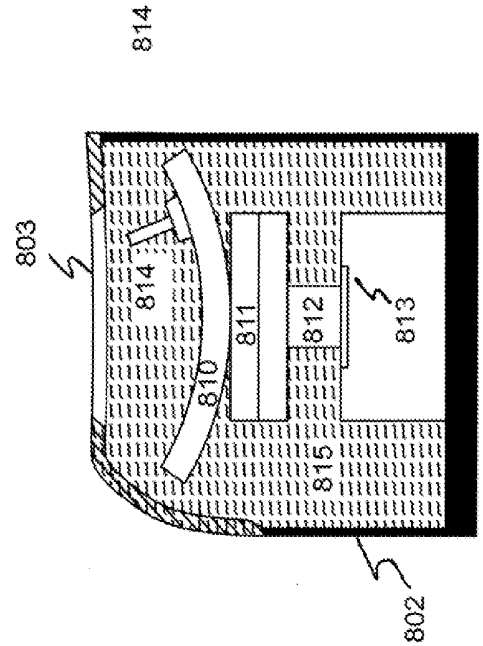
Side View

Figure 7C



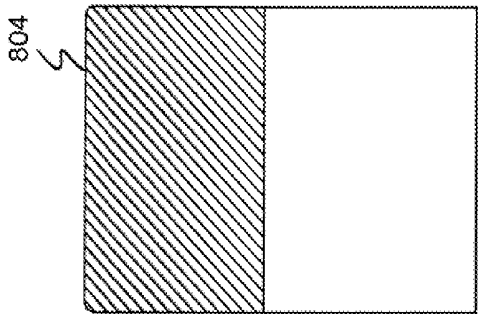
Top View

Figure 8A



Side View

Figure 8C



End View

Figure 8B

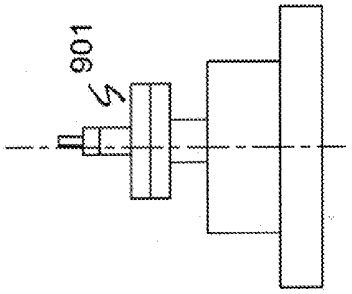


Fig. 9C

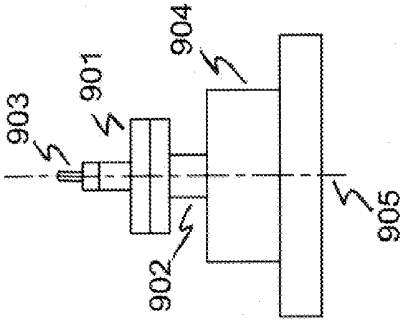


Fig. 9B

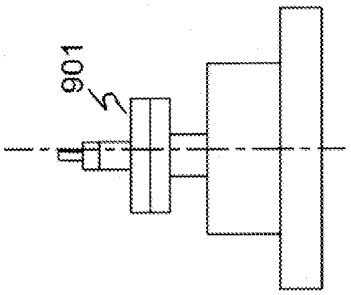


Fig. 9A

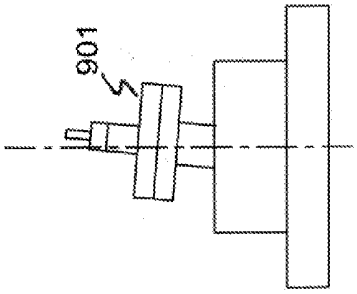


Fig. 9F

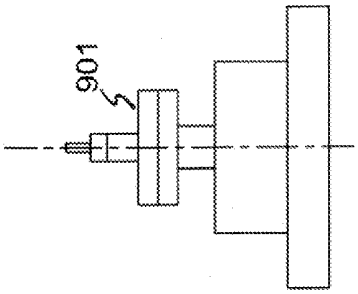


Fig. 9E

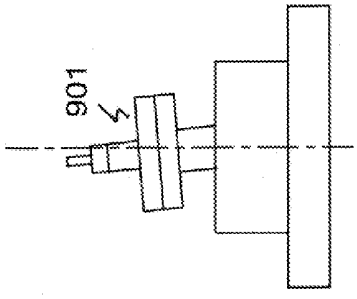


Fig. 9D

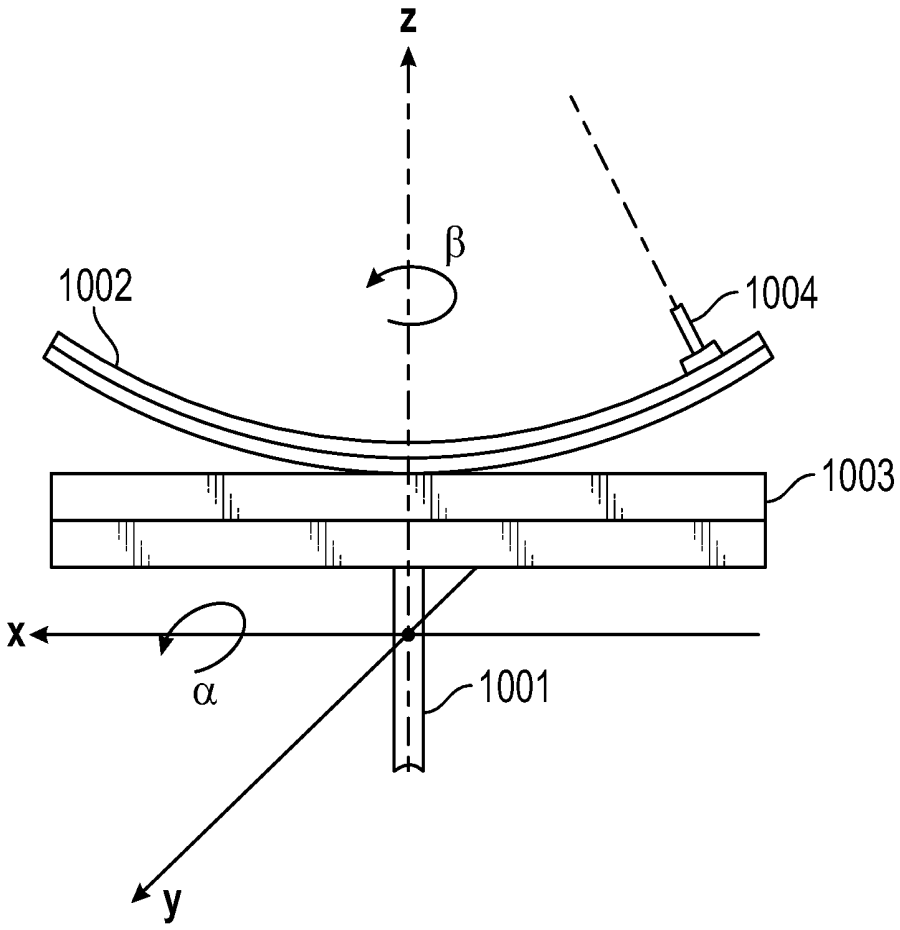


FIG. 10

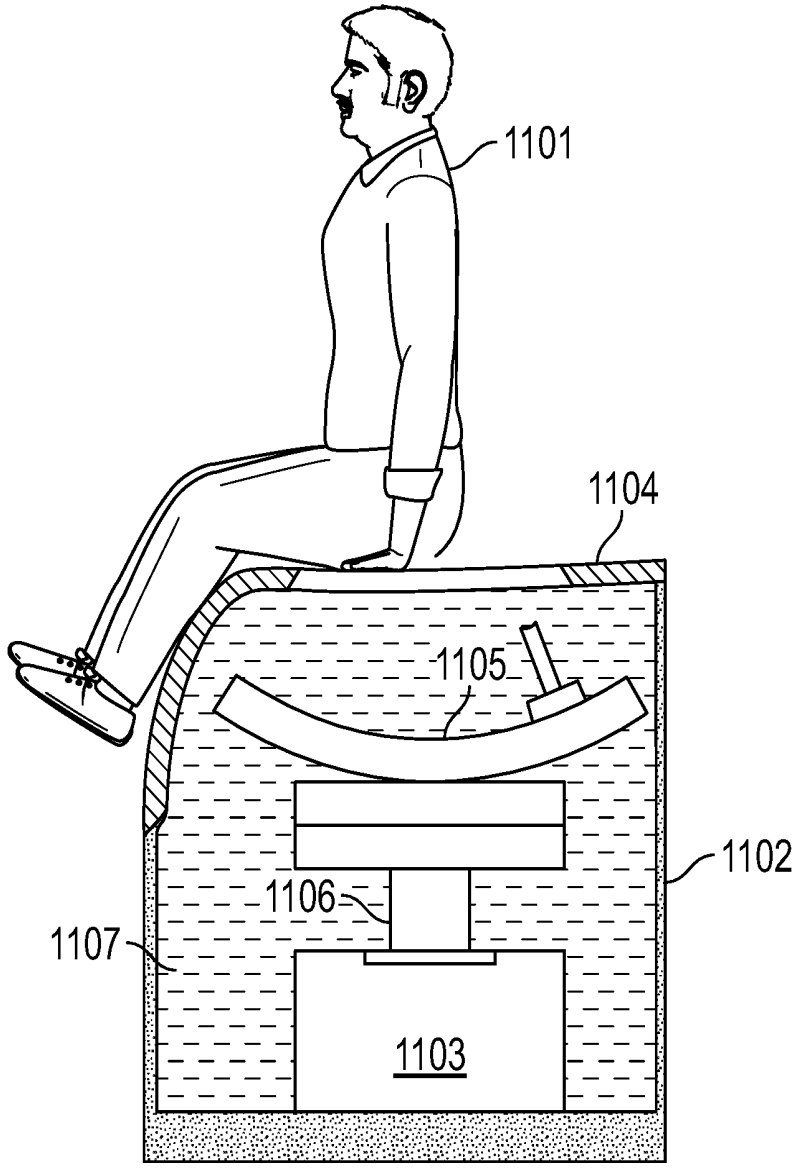


FIG. 11

ULTRASONIC SCANNING APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefits, under 35 U.S. C. §119(e), of U.S. Provisional Application Ser. No. 62/240,636 entitled "Ultrasound Scanning Apparatus" filed Oct. 13, 2015 which is incorporated herein by reference.

FIELD

[0002] The present disclosure relates to ultrasound imaging of biological materials such the heart, liver, spleen and prostate and in particular directed to an apparatus for a low iatrogenic risk, easily implemented method for precision ultrasound scanning of the prostate gland.

BACKGROUND

[0003] Ultrasound imaging of body parts, including the eye has been pursued for a number of years. Ultrasound Bio Microscopy (UBMs) are hand-held devices that have been available for years but are not suitable for precision measurements. An arc scanner, has been developed and tested for ultrasound scanning of the eye under the names of Artemis 1, Artemis 2, Artemis 3 and the ArcScan Insight 100. These devices have given improved ultrasound scans of the eye by using an eye seal to provide a continuous water (or water equivalent) path from the transducer to the eye (the eye has acoustic properties similar to water).

[0004] The ArcScan Insight 100 can make B-scans of an eye with a resolution of about 30 microns and a repeatability of about 2 to 5 microns using a single element transducer operating at a center frequency of about 40 MHz. Other workers in the field have used lower frequency transducers in the 5 to 10 MHz range to image the retina of an eye (the retina is on the order of 25 mm from the anterior surface of the cornea). Others have participated in work using annular array transducers and linear transducer arrays as well as coded excitation techniques for imaging the eye and other body parts with ultrasound.

[0005] Many of the ArcScan Insight 100 hardware innovations (such fluid bearings and arc scanning with variable radii of curvature) and many of the well-known ultrasound image enhancement techniques (such as annular array transducers, coded excitation, advanced data processing) can be combined to provide a precision ultrasound scanner for other body parts.

[0006] The prostate gland can be imaged by X-rays, MRI (magnetic resonance imaging) or ultrasound. Imaging by ultrasound is less risky than imaging by X-rays and is far more convenient than imaging by MRI.

[0007] Ultrasound imaging can be accomplished by a hand-held sector scanner device or by a trans-rectal ultrasound probe. The hand-held sector scanner can make a qualitative image of the prostate by imaging through the abdominal wall but resolution is typically poor. This is a low iatrogenic risk procedure and easily applied imaging technique but the image quality is too poor to make informed decisions, for example about cancer cell development. The trans-rectal ultrasound probe can make a better image than a hand-held sector scanner because the ultrasound transducer can be positioned within 10 or 20 millimeters of the prostate gland on the other side of the rectal wall from the prostate. The image is difficult to co-register successive B-scans and so is not quite precise and accurate enough to make informed decisions about, for example, cancer cell development. In addition, a trans-rectal probe causes some discomfort to the patient and has moderate iatrogenic risk. The procedure can lead to infections if the endoscope is improperly sterilized or more severe problems if the probe pierces the rectal wall, as occasionally happens.

[0008] There remains, therefore, a need for a low iatrogenic risk, easily implemented method of ultrasound imaging for the prostate that produces a superior image compared to a hand-held sector scanner or a trans-rectal probe that can be used as a screening tool for diseases of the prostate.

SUMMARY

[0009] These and other needs are addressed by the present disclosure. The various embodiments and configurations of the present disclosure are directed generally to ultrasound imaging of biological materials such the heart, liver, spleen and prostate and in particular directed to an apparatus for a precision ultrasound scanning of the prostate gland. The present disclosure describes a precision ultrasound scanner for imaging the prostate in a way that can produce a superior image of the prostate while removing the iatrogenic risk and patient discomfort associated with other methods of providing an ultrasound image of the prostate. Such a precision ultrasound scanner for imaging the prostate can also serve as a low-risk screening tool for prostate problems such as enlarged prostate (called benign prostatic hyperplasia or BPH) and prostate cancer because of its ease of use.

[0010] In the present disclosure, known techniques can be combined in some embodiments to achieve high resolution and tissue depths of 60 millimeters or more. These include the use of annular arrays of two or more independent transducer elements; coded excitation of transmitted ultrasound pulses; and detection of higher frequency harmonics in methods generally know as tissue harmonic imaging.

[0011] An innovation of the present disclosure is the use of different types of seating apparatuses that allow the use of a precision arc scanning instrument to be used while minimizing or eliminating iatrogenic risk and patient discomfort. This approach provides for imaging the prostate gland through the perineum so that the scanning transducer can get close to the prostate and avoid bony structures that would block ultrasound energy.

[0012] The elements of a precision ultrasound scanning apparatus for imaging a prostate can include:

[0013] 1. A scanning instrument container formed by a saddle (on which the patient sits) and an instrument body under the saddle. The instrument body contains the scanning apparatus and can be filled with a liquid such as distilled water. Alternately, the scanning instrument container can be formed by a bowl (on which the patient sits) and an instrument body within the bowl. The instrument body contains the scanning apparatus and wherein the instrument body can be filled with a liquid such as distilled water.

[0014] 2. The scanning instrument container formed by a saddle can house the scanning instrument and can also comprise stirrups for the patient's feet, and handle bars. The stirrups and handle bars can allow the patient to lean forward to assume an optimal position for scanning.

[0015] 3. A scanning apparatus contained within the scanning instrument container that can comprise an x-y-z-beta positioning mechanism; a scan head that can comprise an

arcuate guide track and/or a linear guide track; a transducer probe carriage that moves along one of the guide tracks; a transducer which can be a single element needle probe, an annular array probe or a linear transducer array. The scanning apparatus can include a video camera that can provide an optical image of the outside of the body part being scanned by the ultrasound probe. The positioning mechanism may be able to tilt the scan head. Tilting means changing the tilt angle of the positioner mechanism and scan head by rotating about the x-axis in the y-z plane. The arcuate guide track is aligned with the x-axis such that the transducer carriage moves back and forth in an arc aligned with the x-axis. A linear guide track would also be aligned with the x-axis such that the transducer carriage moves back and forth parallel to the x-axis.

[0016] 4. A computer, comprising input and/or output devices that controls the scanning apparatus (controls the positioning mechanism, the scan head motion, the transmitting and receiving of the ultrasound probe and the manipulation of A-scans to form a B-scan of the prostate gland).

[0017] 5. A detachable window connected to and embedded in the saddle or bowl of the scanning instrument container. The window is made from a material that can transmit optical and acoustic energy. The window may be round, elliptical or square with rounded corners such that the window can allow the scanner to scan the selected body part of the patient.

[0018] 6. A disposable and deformable container of clear gel that can conform to the detachable window in the saddle and to the body part being scanned by the ultrasound probe. For example, a disposable bag of gel can be placed over the window. The patient sits on the bag so that the gel is in contact with the window and with the patient's body. Alternately, the disposable and deformable container could, for example, be a pair of shorts with the disposable and deformable container of clear gel sewn into the crotch area of the shorts.

[0019] The configuration of the scanning instrument container formed by a saddle or bowl on which the patient sits can allow the scan to be conducted upwards through the patient's perineum thereby providing a short transmission/receiving path to the prostate while remaining a non-invasive procedure that minimizes patient discomfort and risk of infection. This configuration, as well as other configurations discussed, are designed to 1) provide a continuous fluid path of substantially similar acoustic transmission properties from the ultrasound transducer to the body part being scanned and 2) minimize the distance between the ultrasound transducer to the body part being scanned.

[0020] In the example of the prostate gland, the frequency characteristic of the ultrasound probe and the peak power of the transducer emissions are commonly selected so that an image of the prostate can be formed when the prostate is about 50 to 130 millimeters from the face of the transducer element. The center frequency of the probe may be in the range of about 10 MHz to about 40 MHz to provide the required image resolution.

[0021] The peak power output of the ultrasound probe will be within the limits established by the FDA or other regulatory body. For example, a spatial-peak pulse-average intensity of 94 mW/cm^2 and a spatial-peak temporal-average intensity of 190 W/cm^2 would be allowable under 2008 FDA guidelines (Publication Reference 4) for the prostate gland. This compares to a spatial-peak pulse-average intensity of 17 mW/cm^2 and a spatial-peak temporal-average intensity of 28 W/cm^2 allowable under current FDA guidelines for ophthalmic imaging. This represents a six-fold increase in transducer power over allowable ophthalmic imaging transducer power (a scan depth of about 6 to 7.5 mm for anterior segment scanning of the human eye and a scan depth of about 25 mm for retinal scanning of the human eye).

[0022] It is noted that attenuation of signal strength in body tissue is typically about 0.5 dB per cm per MHz.

[0023] The present disclosure can utilize annular array transducers to increase the depth of tissue that can be scanned since annular array transducers can transmit at its characteristic frequency and receive at the characteristic frequency or at twice the characteristic frequency.

[0024] The present disclosure can also utilize coded excitation techniques such as chirp-coded excitation or Golay code excitation, for example, and over-sampling techniques to increase signal-to-noise ratio thereby allowing deeper imaging capability. As in the ultrasound device described herein for scanning the eye, the noise floor of the data acquisition system is typically the noise figure associated with the amplifier input to the A/D device.

[0025] The method of the present disclosure using the above described saddle or bowl apparatus can include the following steps:

[0026] 1. The scanning instrument container is filled with distilled water

[0027] 2. The disposable and deformable container of clear gel is placed on the saddle and the patient sits on the container of clear gel in preparation for scanning. Alternately, the patient puts on the disposable shorts and sits on the saddle or bowl.

[0028] 3. When the probe is centered on the arcuate guide track, the video camera is used to position the ultrasound probe on the area of interest of the patient. In this operation, the positioner assembly moves the scan head into position for scanning.

[0029] 4. Scans are then made at different depths of focus and at different meridians by:

[0030] aligning the arcuate guide track by rotating the arcuate guide assembly about its beta axis

[0031] translating the scan head by small amounts

[0032] tilting the scan head assembly by small amounts

[0033] The above general procedure can be similar to that used for ultrasound scanning of an eye using an arc scanning device. The above scanning modes are discussed in further detail in FIGS. **9**A-**9**F.

[0034] The following definitions are used herein:

[0035] The phrases at least one, one or more, and and/or are open-ended expressions that are both conjunctive and disjunctive in operation. For example, each of the expressions "at least one of A, B and C", "at least one of A, B, or C", "one or more of A, B, and C", "one or more of A, B, or C" and "A, B, and/or C" means A alone, B alone, C alone, A and B together, A and C together, B and C together, or A, B and C together.

[0036] Acoustic impedance means the product of sound speed times density, pc, where p is the density (~993 kg/cu meter for water at 37 C) and c is the sound speed (1,520 meters per second at 37 C). Thus acoustic impedance of water at 37 C is about 1.509×10^6 kg/(sq meter-sec) or 1.509 Mrayls.

[0037] An acoustically reflective surface or interface is a surface or interface that has sufficient acoustic impedance difference across the interface to cause a measurable reflected acoustic signal. A specular surface is typically a very strong acoustically reflective surface.

[0038] Anterior means situated at the front part of a structure; anterior is the opposite of posterior.

[0039] An A-scan is a representation of a rectified, filtered reflected acoustic signal as a function of time, received by an ultrasonic transducer from acoustic pulses originally emitted by the ultrasonic transducer from a known fixed position relative to a body component.

[0040] Accuracy as used herein means substantially free from measurement error.

[0041] Aligning means positioning the acoustic transducer accurately and reproducibly in all three dimensions of space with respect to a feature of the body component of interest (such as the heart, liver, spleen and prostate, etcetera).

[0042] An arc scanner, as used herein, is an ultrasound eye scanning device where the ultrasound transducer moves back and forth along an arcuate guide track wherein the focal point of the ultrasound transducer is typically placed somewhere within the eye near the region of interest (i.e. the corneas, the lens etcetera). The scanner may also include a linear guide track which can move the arcuate guide track laterally such that the effective radius of curvature of the arcuate track is either increased or decreased. The scanner utilizes a transducer that both sends and receives pulses as it moves along 1) an arcuate guide track, which guide track has a center of curvature whose position can be moved to scan different curved surfaces; 2) a linear guide track; and 3) a combination of linear and arcuate guide tracks which can create a range of centers of curvature whose position can be moved to scan different curved surfaces.

[0043] Automatic refers to any process or operation done without material human input when the process or operation is performed. However, a process or operation can be automatic, even though performance of the process or operation uses material or immaterial human input, if the input is received before performance of the process or operation. Human input is deemed to be material if such input influences how the process or operation will be performed. Human input that consents to the performance of the process or operation is not deemed to be "material."

[0044] Auto-centering means automatically, typically under computer control, causing centration of the arc scanning transducer with the body component of interest.

[0045] Body habitus is somewhat redundant, since habitus by itself means "physique or body build.". Body size and habitus describe the physical characteristics of an individual and include such considerations as physique, general bearing, and body build.

[0046] A B-scan is a processed representation of A-scan data by either or both of converting it from a time to a distance using acoustic velocities and by using grayscales, which correspond to A-scan amplitudes, to highlight the features along the A-scan time history trace (the latter also referred to as an A-scan vector).

[0047] Centration means substantially aligning the center of curvature of the arc scanning transducer in all three dimensions of space with the center of curvature of the eye component of interest (such as the cornea, pupil, lens, retina, etcetera) such that rays from the transducer pass through both centers of curvature. A special case is when both centers of curvature are coincident.

[0048] Coded excitations are engineered excitation pulses that are capable of increasing the effective penetration depth of a transmitted signal in echo location imaging systems such as radar, sonar and ultrasound, by improving the signal-to-noise ratio (SNR).

[0049] Chirping is a coded excitation that can be thought of as a complex exponential sequence with linearly increasing frequency. A linear chirp is a coded signal that linearly spans a frequency bandwidth $B=f_2-f_1$, where f_1 and f_2 are the starting and ending frequencies, respectively. If the chirp sweeps from f_1 to f_2 over a time, then the chirp-coded excitation is described by: $s(t)=\omega(t)\cos(2\pi f_1 t+\pi bt^2)$.

[0050] Fiducial means a reference, marker or datum in the field of view of an imaging device.

[0051] Fixation means having the patient focus an eye on an optical target such that the eye's optical axis is in a known spatial relationship with the optical target. In fixation, the light source is axially aligned in the arc plane with the light source in the center of the arc so as to obtain maximum signal strength such that moving away from the center of the arc in either direction results in signal strength diminishing equally in either direction away from the center.

[0052] A guide is an apparatus for directing the motion of another apparatus.

[0053] Hand-held ultrasonic scanner See Ultrasound Bio Microscopy (UBM).

[0054] The home position of the imaging ultrasound transducer is its position during the registration process.

[0055] An iatrogenic risk is a risk due to the activity of a physician or therapy. For example, an iatrogenic illness is an illness that is caused by a medication or physician.

[0056] An imaging ultrasound transducer is the device that is responsible for creating the outgoing ultrasound pulse and detecting the reflected ultrasound signal that is used for creating the A-Scans and B-Scans.

[0057] As used herein, a meridian is a 2-dimensional plane section through the approximate center of a 3-dimensional eye and its angle is commonly expressed relative to a horizon defined by the nasal canthus and temporal canthus of the eye.

[0058] The perineum is the pelvic floor and associated structures occupying the pelvic outlet, bounded anteriorly by the pubic symphysis, laterally by the ischial tuberosities, and posteriorly by the coccyx. The region between the scrotum and the anus in males,

[0059] Positioner means the mechanism that positions a scan head relative to a selected part of an eye. In the present disclosure, the positioner can move back and forth along the x, y or z axes and rotate in the β direction about the z-axis. Normally the positioner does not move during a scan, only the scan head moves. In certain operations, such as measuring the thickness of a region, the positioner may move during a scan.

[0060] Position tracking sensors are a set of position sensors whose sole purpose is to monitor the movement of the eye or any other anatomical feature during the imaging scan so as to remove unwanted movement of the feature.

[0061] Posterior means situated at the back part of a structure; posterior is the opposite of anterior.

[0062] Precise as used herein means sharply defined and repeatable.

[0063] Precision means how close in value successive measurements fall when attempting to repeat the same measurement between two detectable features in the image field. In a normal distribution precision is characterized by the standard deviation of the set of repeated measurements. Precision is very similar to the definition of repeatability.

[0064] The prostate is a compound tubuloalveolar exocrine gland of the male reproductive system. The function of the prostate is to secrete a slightly alkaline fluid, milky or white in appearance, that in humans usually constitutes roughly 30% of the volume of the semen

[0065] The pulse transit time across a region of the eye is the time it takes a sound pulse to traverse the region.

[0066] Refractive means anything pertaining to the focusing of light rays by the various components of the eye, principally the cornea and lens.

[0067] Registration as used herein means aligning.

[0068] Scan head means the mechanism that comprises the ultrasound transducer, the transducer holder and carriage as well as any guide tracks that allow the transducer to be moved relative to the positioner. Guide tracks may be linear, arcuate or any other appropriate geometry. The guide tracks may be rigid or flexible. Normally, only the scan head is moved during a scan.

[0069] Sector scanner is an ultrasonic scanner that sweeps a sector like a radar. The swept area is pie-shaped with its central point typically located near the face of the ultrasound transducer.

[0070] A specular surface means a mirror-like surface that reflects either optical or acoustic waves. For example, an ultrasound beam emanating from a transducer will be reflected directly back to that transducer when the beam is aligned perpendicular to a specular surface.

[0071] Tissue means an aggregate of cells usually of a particular kind together with their intercellular substance that form one of the structural materials of a plant or an animal and that in animals include connective tissue, epithelium, muscle tissue, and nerve tissue.

[0072] A track or guide track is an apparatus along which another apparatus moves. In an ultrasound scanner or combined ultrasound and optical scanner, a guide track is an apparatus along which one or more ultrasound transducers and/or optical probes moves during a scan.

[0073] Trans-rectal ultrasound is used to create an image of organs in the pelvis by a probe inserted into the rectum. The most common usage for transrectal ultrasound is for the evaluation of the prostate gland in men with elevated prostate specific antigen or prostatic nodules on digital rectal exam.

[0074] Tissue harmonic imaging exploits non-linear propagation of ultrasound through the body tissues. The high pressure portion of the wave travels faster than low pressure resulting in distortion of the shape of the wave. This change in waveform leads to generation of harmonics (multiples of the fundamental or transmitted frequency) from tissue. Typically, the 2nd harmonic is used to produce the image as the subsequent harmonics are of decreasing amplitude and hence insufficient to generate a proper image. These harmonic waves that are generated within the tissue, increase with depth to a point of maximum intensity and then decrease with further depth due to attenuation. Hence the maximum intensity is achieved at an optimum depth below the surface. Advantages over conventional ultrasound include: decreased reverberation and side lobe artifacts; increased axial and lateral resolution; increased signal to noise ratio; and improved resolution in patients with large body habitus.

[0075] Ultrasonic or ultrasound means sound that is above the human ear's upper frequency limit. When used for imaging an object like the eye, the sound passes through a liquid medium, and its frequency is many orders of magnitude greater than can be detected by the human ear. For high-resolution acoustic imaging in the eye, the frequency is typically in the approximate range of about 5 to about 80 MHz.

[0076] Ultrasound Bio Microscopy (UBM) is an imaging technique using hand-held ultrasound device that can capture anterior segment images using a transducer to emit short acoustic pulses ranging from about 20 to about 80 MHz. This type of ultrasound scanner is also called a sector scanner. The UBM method is capable of making qualitative ultrasound images of the anterior segment of the eye but cannot unambiguously make accurate, precision, comprehensive, measurable images of the cornea, lens or other components of the eye.

[0077] A vector refers to a single acoustic pulse and its multiple reflections from various eye components. An A-scan is a representation of this data whose amplitude is typically rectified.

[0078] Water equivalent as used herein means a fluid or a gel having the approximate acoustic impedance of water.

BRIEF DESCRIPTION OF THE DRAWINGS

[0079] The present disclosure may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the disclosure. In the drawings, like reference numerals may refer to like or analogous components throughout the several views.

[0080] FIG. **1** is a schematic of a prior art arc scanner for imaging an eye using ultrasound.

[0081] FIGS. **2**A and **2**B are schematics of prior art single and dual element ultrasound transducer assemblies, respectively.

[0082] FIG. **3** is a schematic of the transducer face of a prior art multi-element ultrasound transducer configuration.

[0083] FIG. **4** is an example of a simple emitted and received ultrasound pulse waveform.

[0084] FIG. **5** shows examples of several known emitted chirp ultrasound pulse waveforms.

[0085] FIG. **6** illustrates the male perineum and the direction of the transducer pulse of the present disclosure.

[0086] FIGS. **7**A-**7**C are schematics of a saddle seating apparatus with an ultrasound scanner inside.

[0087] FIGS. **8**A-**8**C are schematics of a bowl seating apparatus with an ultrasound scanner inside.

[0088] FIGS. **9**A-**9**F illustrate modes of positioning a scan head with respect to a patient.

[0089] FIG. **10** illustrates the co-ordinate system used by the scanning devices of the present disclosure.

[0090] FIG. **11** is a schematic of a bowl seating apparatus with an ultrasound scanner inside and a patient in position for scanning the prostate.

DETAILED DESCRIPTION OF THE DRAWINGS

[0091] In this disclosure, an apparatus and a method are described that are the basis for a rapid screening device for non-invasive, high quality imaging of the prostate. This method can also be applied to other body parts. The apparatus and method combine several known ultrasound imaging components and techniques such as precision eye scanners, annular array transducers, coded excitation and biharmonic tissue imaging in an innovative way to ensure high quality imaging and patient comfort and safety. An important aspect of this disclosure is the apparatus and method to position the patient and the scanning apparatus in a way that minimizes the transducer distance to the prostate gland while preserving patient comfort and minimizing or eliminating patient risk.

Precision Eye Scanner

[0092] An ultra sound scanning apparatus, as described for example, in U.S. Pat. No. 8,317,709, which is incorporated herein by reference, is comprised of a positioning mechanism and a scan head. The positioning mechanism has x, y, z and beta (rotation about its z-axis) positioning mechanisms which make it possible to position the scan head relative to the eye component of interest. This operation is carried out while the patient's eye is positioned in contact with an eyepiece attached to the scanner and while the patient's head is fixed relative to the scanner by a head rest or by the eyepiece or by a combination of both. Once the positioning mechanism is set, the only moving part relative to the eye component of interest is the scan head. The scan head may be comprised of only an arcuate guide track which is typically used to produce an ultrasound scan of the cornea and/or much of the anterior segment of an eye. The scan head may be comprised of only a linear guide track. In another embodiment, the scan head may be comprised of an arcuate guide track and a linear guide track that can be moved in a combination of linear and arcuate motions to produce an ultrasound scan of the entire anterior segment including much of the posterior surface of the lens. The movement of the positioner and scan head relative to patient's eye socket is precisely known at all times by a system of magnetic encoder strips.

[0093] The movement of the scan head relative to the eye component of interest is therefore known with precision and accuracy as long as the patient does not move their eye during the scan. A single scan can take less than a second. A sequence of scans can take several seconds. A patient's eye can move significantly even during a single scan, thus degrading the precision and accuracy of the scan. The usual procedure, when this occurs, is to re-scan the patient. In US Publication No. 2013/0310692 entitled "Correcting for Unintended Motion for Ultrasonic Eye Scans", which is incorporated herein by reference, a device and method of tracking any movement of the patient's eye, relative to the positioning mechanism, during a scan is described.

Ultrasound Eye Scanning Apparatus

[0094] FIG. **1** is a schematic of the principal elements of a prior art ultrasound eye scanning device such as described in U.S. Pat. No. 8,510,883, which is incorporated herein by reference. The scanning apparatus **101** of this example is comprised of a scan head assembly **108** (shown here as an arcuate guide **102** with scanning transducer **104** on a transducer carriage which moves back and forth along the arcuate guide track, and a linear guide track **103** which moves the arcuate guide track back and forth as described in FIG. **4**), a positioning mechanism **109** comprised of an x-y-z and beta mechanisms **105** mounted on a base **106** which is rigidly attached to scanning apparatus **101**, and a disposable eyepiece **107**. The scanning machine **101** is typically connected to a computer (not shown) which includes a processor module, a memory module, and a video monitor. The patient is seated at the machine **101** with their eye engaged with disposable eyepiece **107**. The patient is typically looking downward during a scan sequence. The patient is fixed with respect to the scanning machine **101** by a headrest system and by the eyepiece **107**. The operator using, for example, a mouse and/or a keyboard and video screen inputs information into the computer selecting the type of scan and scan configurations as well as the desired type of output analyses. The operator, for example, again using a mouse and/or a keyboard, a video camera located in the scanning machine and video screen, then centers a reference marker such as, for example, a set of cross hairs displayed on a video screen on the desired component of the patient's eye which is also displayed on video screen. This is done by setting one of the cross hairs as the prime meridian for scanning. These steps are carried out using the positioning mechanism which can move the scan head in the x, y, z and beta space (three translational motions plus rotation about the z-axis). Once this is accomplished, the operator instructs computer using either a mouse and/or a keyboard to proceed with the scanning sequence. Now the computer processor takes over the procedure and issues instructions to the scan head **108** and the transducer **104** and receives positional and imaging data. The computer processor proceeds with a sequence of operations such as, for example: (1) with the transducer carriage substantially centered on the arcuate guide track, rough focusing of transducer **104** on a selected eye component; (2) accurately centering of the arcuate guide track with respect to the selected eye component; (3) accurately focusing transducer **104** on the selected feature of the selected eye component; (4) rotating the scan head through a substantial angle (including orthogonal) and repeating steps (1) through (3) on a second meridian; (5) rotating the scan head back to the prime meridian; (6) initiating a set of A-scans along each of the of selected scan meridians, storing this information in the memory module; (7) utilizing the processor, converting the A-scans for each meridian into a set of B-scans and then processing the B-scans to form an image associated with each meridian; (8) performing the selected analyses on the A-scans, B-scans and images associated with each or all of the meridians scanned; and (9) outputting the data in a preselected format to an output device such as storage disk drive or a printer. As can be appreciated, the patient's head must remain fixed with respect to the scanning machine **101** during the above operations when scanning is being carried out, which in a modern ultrasound scanning machine, can take several tens of seconds.

[0095] An eyepiece serves to complete a continuous acoustic path for ultrasonic scanning, that path extending in water from the transducer to the surface of the patient's eye. The eyepiece **107** also separates the water in which the patient's eye is immersed from the water in the chamber in which the transducer guide track assemblies are contained. The patient sits at the machine and looks down through the eyepiece **107** as shown by arrow **110**. Finally, the eyepiece

provides an additional steady rest for the patient and helps the patient to remain steady during a scan procedure.

[0096] As can be appreciated, the arcuate guide track used to image the eye has a radius of curvature similar to that of the cornea and anterior surface of the natural lens. If an arcuate guide track is used for imaging a prostate, for example, the radius of curvature can be appropriately adjusted by a combination of arcuate and linear motions such as described for example in U.S. Pat. No. 8,317,709. As can be further appreciated, the guide track can have another shape than arcuate or could, in principle, be made to flex in a precise way so as to custom fit a patient.

Annular Array Transducers and Coded Excitation

Single Element Ultrasound Transducer

[0097] A prior art single element or needle transducer is shown in FIG. **2**A (taken from a slide show entitled "Ultrasound transducers by Ravi Managuli). This type of transducer is currently used in precision arc scanners such as described in FIG. **1**, in the previous section and, for example, in U.S. Pat. No. 8,317,709 and U.S. Pat. No. 8,758,252, which is incorporated by reference herein. The single transducer element both transmits an ultrasound pulse and receives the echoed pulse.

Annular Array Ultrasound Transducers

[0098] FIG. **2**B is a schematic of a prior art dual element ultrasound transducer assembly as described in "20 MHz/40 MHz Dual Element Transducers for High Frequency Harmonic Imaging", Kim, Cannata, Liu, Chang, Silverman and Shung, IEEE Transactions on Ultrasonics, Ferroelectrics and Frequency Control, VOL. 55; NO. 12, December 2008. Both the annular element and the center element can transmit and receive ultrasound pulses independently. In another mode, the center element can transmit and receive a pulse at one frequency while the annular element can transmit and receive a separate pulse at a different frequency. In yet another mode, the annular element can transmit and receive a pulse at one frequency while the center element can receive the echoed pulse at a harmonic frequency of the transmitted pulse.

[0099] As discussed in the above reference, a concentric annular type dual element transducer was used for second harmonic imaging to improve spatial resolution and depth of penetration for ophthalmic imaging applications. The outer ring element was designed to transmit a 20 MHz signal and the inner circular element was designed to receive the 40 MHz second harmonic signal.

[0100] Tissue harmonic ultrasound imaging has been accepted as one of the standard imaging modalities in many applications since its introduction to medical ultrasound imaging in the 1990s. Especially in cardiac and abdominal studies, tissue harmonic imaging is very often used for diagnostics along with fundamental imaging. By utilizing the second harmonic component of the received signal, images can be improved by reducing near field reverberation, decreasing phase aberration error, and improving border delineation.

[0101] In ophthalmology, imaging of the posterior segment which includes the retina, require improved spatial resolution and depth of penetration for proper diagnosis of retinal disease. This same second harmonic imaging technique can be used to improve imaging of, for example, the prostate.

[0102] Recently, broad band single element transducers operating at about 20 MHz have been used for imaging the posterior segment of the eye, but were limited in spatial resolution at that frequency. Unfortunately, transducers operating at 20 MHz cannot provide the spatial resolution needed to adequately delineate layers on the posterior segment of the human eye. Those operating in the higher frequency range do not provide sufficient depth of penetration such that the reflected signal can be detected above the noise floor. A concentric annular type dual element transducer for second harmonic imaging of the posterior segment of the eye wherein the outer ring element is used for transmit and the inner circular element for receive. A ring-shaped outer element produces higher side lobes than does a circular element of the same diameter, but this is to some degree compensated for by inherently lower side lobes in the harmonic compared with the fundamental.

[0103] Harmonic imaging with 20 MHz transmit and 40 MHz receive showed capability superior to that of fundamental imaging at 20 MHz to diagnose retinal disease in the posterior segment of the eye. The center frequencies of transmit and receive elements of dual element transducers can be further optimized to match the designed center frequencies to support a larger dynamic range. The aperture size of transmit and receive elements can also be optimized with further experimentation to achieve the best combination of transmit and receive efficiency.

[0104] There is a need to form a high precision image of the prostate from outside the patient's body wherein the resolution in sufficient to image, for example, cancerous lesions on the surface of the prostate. To achieve such images, coded excitation, tissue harmonic imaging, advanced transducers operating in the 10 MHz to 20 MHz range will be required to achieve a useable signal-to-noise reflection while being able to position the imaging transducer as close as possible to the prostate without risk or discomfort to the patient.

[0105] FIG. **3** is a schematic of the transducer face of a prior art multi-element ultrasound transducer configuration (taken from a slide show entitled "Ultrasound transducers by Ravi Managuli).

[0106] As discussed in "High-Frequency Ultrasonic Imaging of the Anterior Segment Using an Annular Array Transducer" Ronald H. Silverman, Jeffrey A. Ketterling and D. Jackson Coleman, Ophthalmology. April 2007, very-high-frequency ultrasound (VHFU>35 MHz) allows imaging of anterior segment structures of the eye with a resolution of less than 40 microns. The low focal ratio of VHFU transducers, however, results in a depth-of-field of less than 1,000 microns (1,000 microns is equal to 1-mm). A dual element high-frequency annular array transducer for ocular imaging shows improved depth-of-field sensitivity and resolution compared to conventional single element transducers.

[0107] As also discussed in the preceding reference, a spherically curved multiple annular array ultrasound transducer was tested wherein the array consisted of five concentric rings of equal area, had an overall aperture of 6 mm and a geometric focus of 12 mm. The nominal center frequency of all array elements was 40 MHz. An experimental system was designed in which a single array element was pulsed and echo data recorded from all elements. By

sequentially pulsing each element, echo data were acquired for all 25 transmit/receive annular combinations. The echo data were then synthetically focused and composite images produced. This technology offers improved depth-of-field, sensitivity and lateral resolution compared to single element fixed focus transducers and dual element annular array transducers currently used for VHFU imaging of the eye.

[0108] Factors that impact upon the overall utility of ultrasound systems include resolution, penetration, speed (frames/second), sensitivity (signal/noise) and depth-of-field. Resolution generally improves (and penetration declines) with frequency. Very-high-frequency (>35 MHz) ultrasound (VHFU) provides an axial resolution of <40-μm, allowing exquisitely detailed depiction of anatomic structures. However, attenuation at this frequency is high, even in water, limiting clinical imaging in this frequency range to the anterior segment.

[0109] Annular arrays can be fabricated with no curvature (i.e., flat) with a spherical lens, or with a spherical geometry. While the principle of dynamic focusing is the same for all, spherically curved devices are advantageous compared to flat arrays because fewer elements are required to achieve the same improvement in depth of field. Spherical curvature also leads to better lateral resolution for two transducers of similar aperture and number of elements.

[0110] Current VHFU systems for evaluation of the anterior segment of the eye are constrained by their very limited depth of field. This results in reduced sensitivity and degraded resolution outside a focal zone that measures under one millimeter in axial extent. The performance of an annular array transducer operating in the same frequency range as current single-element UBM systems showed that this technology can provide a six-fold increase in depth of field. The improved resolution and sensitivity offered by annular array technology can therefore provide significant practical advantages in diagnostic imaging of anatomy and pathology. Furthermore, this technology can be readily extended to lower frequencies, such as 20-25 MHz, that would allow improved assessment of pathologies. In summary, a 40-MHz multiple annular array transducer for imaging of the anterior and posterior segments can be fabricated to achieve improved depth-of-field, sensitivity and lateral resolution.

[0111] Spatial resolution in an ultrasonic imaging system is dependent on beam and focal properties of the source, tissue attenuation, non-linearity of the medium, tissue inhomogeneity, and speed of sound speed in each tissue region.

[0112] In ultrasound, axial resolution is improved as the bandwidth of the transducer is increased, which typically occurs for higher center frequencies. However, the attenuation of sound typically increases as frequency increases, which results in a decrease in penetration depth. Therefore, there is an inherent tradeoff between spatial resolution and penetration in ultrasonic imaging.

[0113] One way to increase the penetration depth without reducing axial resolution is by increasing the excitation pulse amplitude. However, increased excitation amplitude results in increased pressure levels that could result in unwanted heating or damage to tissues. Therefore, increasing the excitation pulse amplitude is not always a viable solution, depending on the region being imaged. For example, regulations for ultrasound power and time duration are low for the eye relative to the heart for example.

Coded Excitation

[0114] Coded excitations are engineered excitation pulses that are capable of increasing the effective penetration depth of a transmitted signal in echo location imaging systems such as radar, sonar and ultrasound, by improving the signal-to-noise ratio (SNR).

[0115] An alternate solution to increase the penetration depth, as opposed to increasing the excitation pulse amplitude, would be to increase the excitation pulse duration by using coded excitation which increases the total transmitted energy and allows for the minimization of the transmitted peak power. However, increasing signal duration has the negative effect of decreasing the axial resolution of the ultrasonic imaging system.

[0116] In order to restore the axial resolution after excitation with a coded signal, pulse compression is used. Pulse compression can be realized by using one or more filtering methods. The main disadvantage of using coded excitation and pulse compression would be the introduction of range side lobes that can appear as false echoes in an image. The introduction of range side lobes is a detriment to ultrasonic image quality because it can reduce the contrast resolution. The main advantage for using coded excitation is that it is known to improve the echo signal-to-noise ratio by increasing the time/bandwidth product of the coded signal. This improvement in echo signal-to-noise results in greater depth of penetration in the range of a few centimeters for ultrasonic imaging and improved image quality. Furthermore, this increase in penetration depth allows the possibility of shifting to higher frequencies with larger bandwidths in order to increase the spatial resolution at depths where normally it would be difficult to image.

[0117] Ultrasound is a non-ionizing, non-invasive, real-time imaging method than other techniques such as magnetic resonance imaging. However, the finer resolution advantages offered by high frequency ultrasound are offset by limitations in penetration depth caused by frequency-dependent attenuation and limitations in depth-of-field when low f-number transducers are employed to improve cross-range resolution. Attenuation of ultrasound in tissue increases with frequency and, therefore, current uses of high frequency ultrasound are limited to applications that do not require deep penetration to image the tissue of interest. High frequency ultrasound image quality can be significantly improved by using two independent approaches.

[0118] The first approach uses synthetic focused annular arrays with overall apertures similar to typical spherically focused transducers to increase depth-of-field. The radial symmetry of annular arrays leads to a high-quality radiation pattern while employing fewer elements than linear or phased arrays. However, annular arrays need to be mechanically scanned to obtain a 2D image.

[0119] An annular array ultrasound transducer can consist of a two element array such as shown in FIG. **2**B or a multi-element array such as shown in FIG. **3**.

[0120] As an example, concentric annular type dual element transducers for second harmonic imaging at 20 MHz/40 MHz were designed to improve spatial resolution and depth of penetration for ophthalmic imaging applications. The outer ring element may be designed to transmit the 20 MHz signal and the inner circular element may be designed to receive the 40 MHz second harmonic signal. These types of annular arrays are described, for example, in "20 MHz/40 MHz Dual Element Transducers for High Frequency Har-

monic Imaging, Kim, Cannata, Liu, Chang, Silverman and Shung, IEEE Transactions on Ultrasonics, Ferroelectrics and Frequency Control, Vol. 55; NO. 12, December 2008.

[0121] A multi-annuli array transducer is described in "Chirp Coded Excitation Imaging with a High-frequency Ultrasound Annular Array", Mamou, Ketterling and Silverman, IEEE Trans Ultrasonics, Ferroelectrics and Frequency Control. 28 Feb. 2008. The array consists of five equal-area annuli with a 10-mm total aperture and a 31-mm geometric focus.

[0122] The second high frequency ultrasound imaging approach uses coded excitations (i.e., engineered excitation pulses) that are capable of increasing the effective penetration depth by improving the signal-to-noise ratio. Resolution and penetration depth are critically important for medical ultrasound imaging. Normally, these two properties present a tradeoff, in which one property can be improved only at the expense of the other. However, it has been demonstrated that coded excitation is capable of extending the limit associated with this tradeoff. Coded excitation permits the signal-to-noise ratio to be increased through appropriate encoding on transmit and decoding on receive. In a published study, linear chirp signals were used to excite an annular array transducer. The objectives of this study were to demonstrate that chirp annular array imaging can lead to better image quality than current state-of-the-art high frequency ultrasound images. The described methods are general and are applicable to a vast range of clinical applications, including ophthalmological, dermatological, and gastrointestinal imaging.

[0123] To appreciate how coded excitation can increase signal-to-noise ratio (SNR), white noise can be added to the received response. Typically, a response had an SNR of 45 dB, which is in the range of most ultrasound imaging systems. Chirp excitations led to an increase in SNR of greater than 14 dB.

[0124] FIG. **4** is an example of a simple emitted and received ultrasound pulse waveform that is used, for example, in the precision arc scanner described above which uses a single element transducer such as shown in FIG. **2**A taken from "Ultrasonography of the Eye and Orbit", Second Edition, Coleman et al, published by Lippincott Williams & Wilkins, 2006.

[0125] FIG. **5** shows examples of several emitted coded excitation ultrasound pulse waveforms. This figure was taken from "Use of Modulated Excitation Signals in Medical Ultrasound. Part I: Basic Concepts and Expected Benefits", Misaridis and Jensen, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, vol. 52, no. 2, February 2005.

Tissue Harmonic Imaging

[0126] Tissue harmonic imaging exploits non-linear propagation of ultrasound through body tissues. The high pressure portion of the wave travels faster than low pressure resulting in distortion of the shape of the wave. This change in waveform leads to generation of harmonics (multiples of the fundamental or transmitted frequency) from the tissue. Typically, the second harmonic is used to produce the image as the subsequent harmonics are of decreasing amplitude and hence insufficient to generate a proper image. These harmonic waves that are generated within the tissue, increase with depth to a point of maximum intensity and then decrease with further depth due to attenuation. Hence the maximum intensity is achieved at an optimum depth below the surface. Advantages over conventional ultrasound include: decreased reverberation and side lobe artifacts; increased axial and lateral resolution; increased signal-to-noise ratio; and improved resolution in patients with large body habitus.

[0127] Tissue harmonic ultrasound imaging has been accepted as one of the standard imaging modalities in many applications since its introduction to medical ultrasound imaging in the 1990s. Especially in cardiac and abdominal studies, tissue harmonic imaging is very often used for diagnostics along with fundamental imaging. By utilizing the second harmonic component of the received signal, images can be improved by reducing near field reverberation, decreasing phase aberration error, and improving border delineation.

[0128] Ultrasound tissue harmonic imaging utilizing non-linear distortion of the transmitted frequencies within the body is useful for producing a sharper, higher-contrast ultrasound image than that of the fundamental frequency. Due to its improved conspicuity (the property of being clearly discernible) and border definition, tissue harmonic imaging has been widely used for detecting subtle lesions in, for example, the thyroid and breast, and visualizing technically-challenging patients with high body mass index. However, compared to conventional ultrasound imaging, tissue harmonic imaging suffers from the low signal-to-noise ratio, resulting in limited penetration depth. The signal-to-noise ratio in tissue harmonic imaging can be substantially increased by utilizing coded excitation techniques, such as described previously in this disclosure. In coded tissue harmonic imaging, similar to conventional coded excitation, specially-encoded ultrasound signals (for example, Barker, Golay and chirp) are transmitted, and then back-scattered receive signals containing fundamental and harmonic frequencies are selectively decoded via pulse compression.

Tissue Harmonic Imaging and Coded Excitation Together

[0129] Tissue harmonic imaging allows one to obtain medical ultrasound images with higher signal-to-noise ratio and higher spatial resolution. Tissue harmonic imaging and coded excitation together have been applied to medical ultrasound imaging. Coded excitation can overcome the trade-off between spatial resolution and penetration, which occurs when using a conventional transmitted pulse. For example, a chirp signal is frequently used for medical ultrasound imaging. A combination of coded excitation and tissue harmonic imaging has been found to produce superior ultrasound images.

[0130] As discussed in "Use of Modulated Excitation Signals in Medical Ultrasound. Part I: Basic Concepts and Expected Benefits", Misaridis and Jensen, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, vol. 52, no. 2, February 2005, tissue harmonic imaging allows one to obtain medical ultrasound images with higher signal-to-noise ratio and higher spatial resolution. Tissue harmonic imaging and coded excitation applied to medical ultrasound imaging has been investigated. Coded excitation can overcome the trade-off between spatial resolution and penetration, which occurs when using a conventional transmitted pulse. For example, a chirp signal is frequently used for medical ultrasound imaging. A combination of coded

excitation and tissue harmonic imaging has been found to produce superior ultrasound images.

[0131] As discussed in "Coded Excitation for Ultrasound Tissue Harmonic Imaging", Song, Kim, Sohn, Song and Yoo. Received in revised form 18 Dec. 2009 Ultrasonics journal homepage: www.elsevier.com/locate/ultras, it is shown how coded signals, when processed with a matched filter, can be evaluated in the presence of ultrasonic attenuation using ambiguity functions. It is shown that if matched-filter receiver processing is used, the compressed output is not the autocorrelation function of the code, but a cross section of the ambiguity function for a certain frequency downshift. Therefore, the AF of the transmitted waveform ought to have desired properties in the entire delay-frequency shift plane. The criteria of selecting the appropriate coded waveforms and receiver processing filters have been discussed in detail. One of the main results is the conclusion that linear FM signals have the best and most robust features for ultrasound imaging. Other coded signals such as non-linear FM and binary complementary Golay codes also have been considered and characterized in terms of SNR and sensitivity to frequency shifts. These results have been demonstrated. It is found that, in the case of linear FM signals, a SNR improvement of 12 to 18 dB can be expected for large imaging depths of attenuating media, without any depth dependent filter compensation. In contrast, nonlinear FM modulation and binary codes are shown to give a SNR improvement of only 4 to 9 dB when processed with a matched filter. It was shown how the higher demands on the codes in medical ultrasound can be met by amplitude tapering of the emitted signal and by using a mismatched filter during receive processing to keep temporal side lobes below 60 to 100 dB.

Present Disclosure

[0132] The present disclosure, which uses features described above, illustrates two apparatuses for utilizing a precision ultrasound scanner to make an image of a prostate for a male patient without causing undue patient discomfort or health risk due to the activity of the physician or, for example, a device such as a trans-rectal probe. A feature of each apparatus is that the scanner positioning mechanism and scan head are completely immersed in water. The patient sits on the instrument with his rectal area over an acoustically transparent window (the window may also be optically transparent). The ultrasound transducer is positioned as close to the underside of the window as possible prior to initiating a sequence of scans. The ultrasound transducer is centered on the region closest to the patient's prostate, for example, using either ultrasound or optical means to center on the rectum such that the ultrasound pulses are aimed at the prostate through the perineum.

[0133] FIG. **6** illustrates the principal features of in the male perineum and the direction **602** from which the transducer pulse is emitted. The prostate gland **601** sits just below the bladder. The ultrasound transducer is moved along an arcuate or linear guide track. An arcuate guide track is preferred since the transducer can maintain an approximately constant distance from the prostate glands **601** by moving in a curved motion **603**. By imaging from below the patient through the perineum, the ultrasound emitted and reflected pulses do not pass through any bony structures that would severely attenuate ultrasound pulses.

[0134] The patient sits on a thin bag of acoustically transparent gel (the gel may also be optically transparent) so that the transmission path from the ultrasound transducer to the prostate is substantially of the same acoustic impedance (the gel bag conforms to the window over the scanner and to the patient's anatomy).

[0135] The male prostate is often described as the size of a walnut or golf ball. The prostate gland is approximately 40 mm by 30 mm by 20 mm. As described in the present disclosure, the positioning of the patient for scanning is designed to place the ultrasound transducer approximately 50 to 130 mm from the nearest surface of the prostate.

[0136] FIGS. **7**A-**7**C are schematics of a saddle seating apparatus **705** with an ultrasound scanner positioned inside the saddle apparatus. The patient is seated on saddle **704** with his rectal area over window **703**. The ultrasound scanner apparatus is contained within a water-tight enclosure **702** which is filled with water **715**. The other instrument volume **701** is open to the ambient air and may contain a computer, power supplies and fluidics modules.

[0137] The ultrasound scanner apparatus is comprised of a positioning mechanism **712** which can be moved vertically (along the z-axis) as well as in both lateral directions (x and y-axes) on slider **713**. The ultrasound scanner apparatus is also comprised of a scan head which is further comprised of either or both a linear guide track **711**, an arcuate guide track **710** on which the ultrasound transducer and its carriage **714** moves as discussed above. The ultrasound transducer can be a single element needle probe, an annular array probe, and/or a linear transducer array. The scanning apparatus can also include a video camera (not shown) that provides an optical image of the outside of the body part being scanned by the ultrasound probe. This can enable a healthcare professional to more accurately position the ultrasound transducer relative to the target to be imaged. The positioning mechanism may able to tilt. Tilting means changing the tilt angle of the positioner mechanism and scan head by rotating about the x-axis in the y-z plane. The arcuate guide track is aligned with the x-axis such that the transducer carriage moves back and forth in an arc aligned with the x-axis. A linear guide track would also be aligned with the x-axis such that the transducer carriage moves back and forth parallel to the x-axis.

[0138] FIGS. **8**A-**8**C are schematics of a bowl seating apparatus with an ultrasound scanner **803** inside. Functionally, this apparatus is similar to the apparatus of FIGS. **7**A-**7**C. Functionally, this apparatus is similar to the apparatus of FIGS. **7**A-**7**C. FIGS. **8**A-**8**C are schematics of a saddle seating apparatus **814** with an ultrasound scanner positioned inside the saddle apparatus. The patient is seated on saddle **804** with his rectal area over window **803**. The ultrasound scanner apparatus is contained within a water-tight enclosure **802** which is filled with water **815**. The other instrument volume **801** is open to the ambient air and may contain a computer, power supplies and fluidics modules.

[0139] The transparent window **703** or **803** can be detachable window and is connected to and embedded in the saddle of the scanning instrument container. The window is typically made from a material that can transmit optical and acoustic energy. The window may be round, elliptical or square with rounded corners such that the window can allow the scanner to scan the selected body part of the patient.

[0140] The ultrasound scanner apparatus is comprised of a positioning mechanism **812** which can be moved vertically

(along the z-axis) as well as in both lateral directions (x and y-axes) on slider **813**. The ultrasound scanner apparatus is also comprised of a scan head which is further comprised of either or both a linear guide track **811**, an arcuate guide track **810** on which the ultrasound transducer and its carriage **814** moves as discussed above.

[0141] As noted, the patient sits on a thin bag (not shown) of acoustically transparent gel (the gel may also be optically transparent) so that the transmission path from the ultrasound transducer to the prostate is substantially of the same acoustic impedance (the gel bag conforms to the window over the scanner and to the patient's anatomy). The thin bag is positioned between the seated patient (who is seated on the saddle **704** or **804**) and the acoustically transparent window **703** or **803** and conforms to the detachable window in the saddle and to the body part being scanned by the ultrasound probe to form the continuous acoustic transmission path to and from the target feature of the patient. The disposable bag of gel is typically placed over the window, and the patient commonly sits on the bag so that the gel is in contact with the window and with the patient's body. Alternately, the disposable and deformable container could, for example, be a pair of shorts with the disposable and deformable container of clear gel sewn into the crotch area of the shorts.

[0142] As will be appreciated, the saddle **704** or **804**, in other embodiments, can be bowl-shaped to act as a shallow reservoir for water in which the patent is seated. In this embodiment, no gel is required. A disadvantage of this approach is that the water will need to be removed by a pump and attached piping or by a stop cock with gravity flow through piping after each patient is imaged. The thin bag of acoustically transparent gel, on the other hand, can simply be removed and discarded by a health care professional after each patient is imaged.

[0143] The scanning instrument container formed by a saddle can comprise stirrups (not shown) for the patient's feet and handle bars (not shown) for the patient's hands. The stirrups and handle bars can allow the patient to lean forward to assume an optimal position for scanning and assist patients in sitting and standing.

[0144] A computer (not shown), comprising input and/or output devices, controls the scanning apparatus (controls the positioning mechanism, the scan head, the transmitting and receiving of the ultrasound probe and/or the manipulation of A-scans to form a B-scan of the prostate gland) as discussed above.

[0145] The configuration of the scanning instrument container formed by a saddle or bowl on which the patient sits can allow the scan to be conducted upwards through the patient's perineum thereby providing a short transmission/receiving path to the prostate while remaining a non-invasive procedure that minimizes patient discomfort and risk of infection. This configuration, can not only provide a continuous fluid path of substantially similar acoustic transmission properties from the ultrasound transducer to the body part being scanned but also substantially minimize the distance between the ultrasound transducer to the body part being scanned.

[0146] The frequency characteristic of the ultrasound probe and the peak power of the transducer emissions are commonly selected so that an image of the prostate can be formed when the prostate is about 50 to 130 millimeters from the face of the transducer element. The center frequency of the probe may be in the range of about 10 MHz to about 40 MHz to provide the required image resolution.

[0147] The peak power output of the ultrasound probe can be within the limits established by the FDA or other regulatory body. For example, a spatial-peak pulse-average intensity of 94 mW/cm^2 and a spatial-peak temporal-average intensity of 190 W/cm^2 would be allowable under 2008 FDA guidelines. This compares to a spatial-peak pulse-average intensity of 17 mW/cm^2 and a spatial-peak temporal-average intensity of 28 W/cm^2 allowable under current FDA guidelines for ophthalmic imaging. This represents a six-fold increase in transducer power over allowable ophthalmic imaging transducer power (a scan depth of about 6 to 7.5 mm for anterior segment scanning of the human eye and a scan depth of about 25 mm for retinal scanning of the human eye).

[0148] In operation, the scanning instrument container of the bowl seating apparatus is filled with distilled water; the disposable and deformable container of clear gel is placed on the saddle; the patient sits on the container of clear gel in preparation for scanning (or the patient puts on the disposable shorts and sits on the saddle or bowl); the probe is centered on the arcuate guide track; the video camera is used to position the ultrasound probe on the area of interest of the patient (such as by the positioner assembly moving the scan head into position for scanning); and scans are then made at different depths of focus and at different meridians (by rotating the arcuate guide assembly about its beta axis or by tilting the arcuate guide assembly). Scans may also be made through different sections of the prostate by translating the arcuate guide assembly with the positioner mechanism.

[0149] FIGS. **9**A-**9**F illustrate modes of positioning a scan head with respect to a patient. FIGS. **9**A-**9**F show a series of end views of the seating apparatus shown in FIGS. **7**A-**7**C, for example. FIGS. **9**A-**9**C illustrates a translational positioning of the scan head **901** with respect to the vertical centerline. This mode of scanning allows a series of images showing vertical cuts through the prostate gland. Using the positioning accuracy and resolution of the eye scanning instrument, lateral scan head movements of 5 to 10 microns (0.005 to 0.01 mm) are routinely used. Thus many closely spaced vertical cuts through the prostate gland can be made with the prostate scanning instrument moving in its translational mode. As noted previously, the prostate gland is approximately 40 mm by 30 mm by 20 mm. For example, if desired, vertical scans can be made at a lateral spacing of every 0.01 mm over a lateral range of about 5 to about 10 mm on either side of the vertical centerline.

[0150] FIGS. **9**D-**9**F illustrate a tilt positioning of the scan head **901** with respect to the vertical centerline. This mode of scanning allows a series of images showing cuts through the prostate gland that are at a slight angle to either side of the vertical centerline. Using the positioning accuracy and resolution of the eye scanning instrument, angular scan head movements of 1 degree are routinely used. Thus many closely spaced angular cuts through the prostate gland can be made with the prostate scanning instrument moving in its tilt mode. As noted previously, the prostate gland is approximately 40 mm by 30 mm by 20 mm. For example, if desired, vertical scans can be made at an angular spacing of every 1 degree over an included angular range of about 10 to about 25 degrees, depending on the size of the prostate gland and the distance from the ultrasound transducer to the prostate.

[0151] FIG. **10** illustrates the co-ordinate system used by the scanning devices of the present disclosure. The scanning device comprises a scan head positioning device, of which only a portion **1001** is shown in FIG. **10**, and a scan head further comprising a linear guide track **1003**, an arcuate guide track **1002** and a transducer carriage **1004** on which an ultrasound transducer is mounted. The ultrasound beam emitted by the transducer is aimed at the center of curvature of the arcuate guide track **1002**.

[0152] The linear guide track **1003** can be held stationary while the transducer carriage **1004** moves back and forth along the arcuate guide track **1002** to form an arc scan. The linear guide track **1003** can move back and forth along the x-axis to form to a linear scan. Both the arcuate and linear guide tracks can be moved to form more complex scanning motions.

[0153] The positioner mechanism **1001** can move the scan head in the x, y and z directions as well as rotate the scan head around the z-axis through an angle beta. These motions are typically used to position the scan head relative to the patient prior to scanning. The positioner mechanism includes the ability to move the scan head in the y-direction which allows types of scans described in FIGS. **9**A-**9**C.

[0154] As illustrated in FIG. **10**, the positioner mechanism can also be modified to include a tilting mechanism centered at the origin of the x-y-z co-ordinate system to allow the scan head to be tilted or rotated about the x-axis through an angle alpha. The ability to tilt the scan head allows types of scans described in FIGS. **9**D-**9**F.

[0155] The z-axis is aligned with the axis of the positioner mechanism **1001**. Positive motion along the z-axis moves the scan head towards the patient's prostate gland. The x and y directions are in a plane normal to the z-axis. The arcuate guide track **1002** is aligned with the x-axis such that the transducer carriage **1004** moves back and forth in the x-z plane along the arcuate guide track **1002**. The motion of the linear guide track **1003** is back and forth along the x-axis. The beta direction represents rotation of the positioner mechanism and scan head around the z-axis. The angle alpha represents the tilt angle of the positioner mechanism and scan head. The tilt angle is changed by rotating the scan head about the x-axis.

[0156] FIG. **11** is a schematic of a bowl seating apparatus with an ultrasound scanner inside and a patient **1101** in position for scanning the prostate. In a scanning operation, the patient **1101** remains immobile on the top wall **1104** of the enclosure as shown, for example in the bowl apparatus of FIG. **11**. Since the lower end of the positioning mechanism **1106** is fixed with respect to the support surface **1102**, the lower end of the positioning mechanism **1106** is also fixed with respect to the patient **1101**. Any prescribed movement of the top end of the positioning mechanism **1106** and any prescribed movement of the scan head **1105** is recorded by a magnetic or optical based positioning system.

[0157] An instrument volume **1103** is separate from the fluid (typically distilled water) in the interior volume **1107** of the enclosure. A computer and other equipment are contained in instrument volume **1103** while the scanning apparatus (top of the positioning mechanism and scan head) are contained in the interior volume **1107** of the enclosure.

[0158] The ability to precisely and accurately determine the location of the scan head at all times relative to the patient enables the system of the present disclosure to generate high resolution ultrasound images of a selected organ of a patient as long as the reflected ultrasound waveforms can be detected.

[0159] A number of variations and modifications of the disclosed subject matter can be used. As will be appreciated, it would be possible to provide for some features of the disclosure without providing others.

[0160] The present disclosure, in various embodiments, includes components, methods, processes, systems and/or apparatus substantially as depicted and described herein, including various embodiments, sub-combinations, and subsets thereof. Those of skill in the art will understand how to make and use the present disclosure after understanding the present disclosure. The present disclosure, in various embodiments, includes providing devices and processes in the absence of items not depicted and/or described herein or in various embodiments hereof, including in the absence of such items as may have been used in previous devices or processes, for example for improving performance, achieving ease and\or reducing cost of implementation.

[0161] The foregoing discussion of the disclosure has been presented for purposes of illustration and description. The foregoing is not intended to limit the disclosure to the form or forms disclosed herein. In the foregoing Detailed Description for example, various features of the disclosure are grouped together in one or more embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed disclosure requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the following claims are hereby incorporated into this Detailed Description, with each claim standing on its own as a separate preferred embodiment of the disclosure.

[0162] Moreover, though the description of the disclosure has included description of one or more embodiments and certain variations and modifications, other variations and modifications are within the scope of the disclosure, e.g., as may be within the skill and knowledge of those in the art, after understanding the present disclosure. It is intended to obtain rights which include alternative embodiments to the extent permitted, including alternate, interchangeable and/or equivalent structures, functions, ranges or steps to those claimed, whether or not such alternate, interchangeable and/or equivalent structures, functions, ranges or steps are disclosed herein, and without intending to publicly dedicate any patentable subject matter.

What is claimed:

1. A system for imaging a body part of a patient, comprising:

an enclosure positioned on a support surface, the enclosure having an interior volume and having a top wall to support a patient;

a window portion positioned in a top wall of the enclosure, a bottom surface of the window portion positioned a first distance above the support surface, the window portion being substantially acoustically transparent;

a fluid disposed in the interior volume of the enclosure, the fluid having a fluid level within the interior volume that is a second distance above the support surface, wherein the second distance is at least as large as the first distance; and

an ultrasound transducer imaging system positioned in the interior volume of the enclosure, the ultrasound transducer imaging system having an ultrasound transducer operably interconnected to a track, wherein the ultrasound transducer is configured to record a plurality of A-scan images of the body part of the patient while the patient is supported by the top wall.

2. The system of claim **1**, wherein the track is an arcuate track operably interconnected to a linear track that is substantially parallel to the support surface, wherein the linear track is operably interconnected to a positioning mechanism, and wherein the positioning mechanism moves the ultrasound transducer imaging system in a first horizontal direction, a second horizontal direction, a vertical direction, a rotational direction around the vertical direction and an angular direction with respect to the vertical direction.

3. The system of claim **1**, wherein the track is an arcuate track operably interconnected to a linear track that is substantially parallel to the support surface, wherein the linear track is operably interconnected to a positioning mechanism, and wherein the fluid is water.

4. The system of claim **1**, further comprising:

an acoustically transparent gel positioned between the window portion and the patient to provide a substantially continuous acoustic transmission path from the transducer to the patient body part, wherein the top wall of the enclosure has a saddle or curved or curvilinear shape.

5. The system of claim **1**, further comprising:

an instrument volume positioned adjacent the enclosure, wherein the instrument volume is filled with a gas.

6. The system of claim **1**, wherein the window portion is optically transparent.

7. The system of claim **1**, wherein the window portion is substantially parallel to the support surface and positioned above the ultrasound transducer.

8. A method for imaging a body part of a patient, comprising:

providing an enclosure on a support surface, the enclosure having a window portion on a top surface of the enclosure, the window portion is substantially acoustically transparent, and the enclosure is filled with a fluid;

providing an ultrasound transducer imaging system in the fluid in the enclosure, the ultrasound transducer imaging system having an ultrasound transducer operably interconnected to an arcuate track;

positioning a patient on the enclosure with a body part positioned over the window portion;

scanning the body part using the ultrasound transducer imaging system, wherein the ultrasound transducer records a plurality of A-scan images of the body part along the arcuate track; and

combining, by a computer, the plurality of A-scan images to form a B-scan image.

9. The method of claim **8**, further comprising:

providing a linear track of the ultrasound transducer system, wherein the arcuate track is operably interconnected to the linear track.

10. The method of claim **9**, further comprising:

providing a positioning mechanism of the ultrasound transducer imaging system, wherein the linear track is operably interconnected to the positioning mechanism, and wherein the positioning mechanism is configured to move the ultrasound transducer imaging system in a first horizontal direction, a second horizontal direction, a vertical direction, a rotational direction around the vertical direction and an angular direction with respect to the vertical direction.

11. The method of claim **8**, further comprising at least one of:

positioning the legs of the patient on either side of the enclosure, and

positioning the legs of the patient in front of the enclosure.

12. The method of claim **8**, further comprising:

providing a gel-filled interface positioned between the window portion and the patient, wherein the acoustic impedance of the gel-filled interface is substantially similar to the body part of the patient.

13. The method of claim **8**, wherein the fluid is water.

14. The method of claim **8**, wherein the window portion is substantially optically transparent and positioned between the body part of the patient and the ultrasound transducer system.

15. The method of claim **8**, wherein the window portion is substantially parallel to the support surface.

16. An ultrasound imaging device for a body part of a patient, comprising:

an enclosure positioned on a support surface, the enclosure having an interior volume;

a window portion positioned on a top surface of the enclosure, the window portion is substantially parallel to the support surface, the window portion is substantially acoustically transparent, wherein the top surface of the enclosure is configured to support a seated patient;

a fluid disposed in the interior volume of the enclosure;

an ultrasound transducer imaging system positioned in the fluid in the interior volume of the enclosure, the ultrasound transducer imaging system having an ultrasound transducer operably interconnected to at least one of an arcuate or linear track, wherein the ultrasound transducer is configured to record a plurality of A-scan images along the at least one of an arcuate or linear track.

17. The device of claim **16**, wherein the at least one of an arcuate or linear track is an arcuate track and wherein the arcuate track operably interconnected to a linear track that is substantially parallel to the support surface, and the linear track is operably interconnected to a positioning mechanism.

18. The device of claim **16**, wherein the top surface of the enclosure has a saddle shape, and a saddle point of the saddle shape is located on the window portion and wherein the window portion is optically transparent.

19. The device of claim **16**, further comprising:

a gel-filled interface positioned on the window portion, wherein the acoustic impedance of the gel-filled interface is substantially similar to the body part.

20. The device of claim **16**, wherein the positioning mechanism is configured to move the ultrasound transducer imaging system in a first horizontal direction, a second horizontal direction, a vertical direction, a rotational direction around the vertical direction and an angular direction with respect to the vertical direction.

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摘要(译)

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