



159159

APPARATUS AND METHOD FOR ULTRASOUND COUPLING

Field of the Invention

5 The invention relates to the use of ultrasound examination devices. In particular, the invention relates to the use of such devices for facilitating more efficient and high quality imagery from said examination.

Background

10

Ultrasound imaging is widely used in medicine. It is possible to perform diagnosis or therapeutic procedures with the guidance of ultrasonography (for instance biopsies or drainage of fluid collections). A hand-held probe (called a scan head) is placed directly on and moved over the patient to acquire the image. Acoustic gel is used to couple the
15 probe to the body, because the high frequency sound waves don't travel well through air.

Medical ultrasonography is used in:

- Cardiology/echocardiography/TEE
- Interventional pain
- 20 • Vascular access
- Endocrinology
- Gynecology/obstetrics
- Ophthalmology; A-scan ultrasonography, B-scan ultrasonography
- Urology, prostate scanning, bladder, testicular, brachytherapy (guidance of



G00002

- radioactive seed implants)

- Ultrasound images muscle and soft tissue very well and is particularly useful for delineating the interfaces between solid and fluid-filled spaces. It renders "live" images, where the operator can dynamically select the most useful section for diagnosing and documenting changes, often enabling rapid diagnoses. It has no known long-term side effects and rarely causes any discomfort to the patient, and is relatively inexpensive compared to other imaging modalities.
- 10 Ultrasound doesn't penetrate bone or air very well. Therefore, imaging the heart through the chest is difficult because the "acoustic window between the ribs is small, and the bones and air in the lungs degrade the image. A coupling gel is needed for good imaging.
- 15 Ultrasonography uses a probe containing one or more acoustic transducers to send pulses of sound into a material. The ultrasound system sends a voltage to a piezo-electric crystal (transducer), which converts the voltage into a mechanical shock (sound) wave.
- 20 A traditional transrectal prostate biopsy assembly used for prostate biopsy may include needles to extract samples of the tissue and an ultrasound probe which is wrapped around with a "condom" filled with ultrasound gel (acoustic gel). The ultrasound gel must always ensure that there is no air gap between the organ and the sensor array.

In the conventional methodology for the prostate biopsy, a large amount of ultrasound gel is typically required to ensure that gaps between the entire sensor array on the probe and the organ are filled. This is because the probe has to move along the longitudinal axis and rotate in the longitudinal axis to develop an ultrasound image for the doctor to
5 diagnosis.

In addition, there is also potential for “condom” breakage when the ultrasound probe moves in and out of the rectum many times. As frictional force build up between the condom and the wall of the rectum, condom breakage is more likely to happen in the
10 presence of large quantity of gel inside the condom. When the “condom” breaks, spillage of the gel will occur and the operation will have to be interrupted.

Another drawback of this methodology is that air bubbles may be present between the condom and the ultrasound probe due to the uneven distribution of gel over the sensor
15 array of the ultrasound probe. This will then affect the consistency and clarity of the ultrasound image.

Movement of the ultrasound probe in the rectum will cause the prostate to expand and shrink thus affecting the aim of the needle during the extraction of tissues from the
20 prostate.

Summary of Invention

In a first aspect the inventions provides a transmission device fixed to an ultrasound probe, said transmission device comprising: a projection; said projection arranged to
5 project from the probe, adjacent to a sensing end of said probe, when said device is mounted thereto; wherein said projection is further arranged to provide a signal path for said ultrasound waves.

In a second aspect, the invention provides an ultrasound probe assembly comprising: an
10 ultrasound probe; a probe sheath into which the probe is inserted and a transmission device according to the first aspect.

Accordingly, the use of the transmission device provides a transmission path from the sensor of the probe directly to the sheath without the need for an intervening gel or other
15 additive.

The transmission device may be integral with the probe, that is, integrally fixed to the probe at the time of manufacture.

20 Alternatively, the transmission device may be a separate device mountable to an existing probe. In this case, a surface in contact with the probe may be roughened, tacky or other high frictional layer to assist the adhesion of the transmission device to the probe.

In a still further embodiment, the transmission device may be part of a membranous sleeve arranged to be slid over the probe, and having the projection being a thickened portion of said sleeve.

- 5 In one embodiment, the projection may be made of medical grade silicone. It may be oval shape with the top filled up with silicone and bottom only a thin layer of silicone making it big enough for the air to escape when the probe is inserted fully. Also the resilient force from the elastic characteristics of the silicone is sufficient to hold the transmission device in position.

10

The transmission device may be arranged to fit over the sensor adjacent to the end of the probe. In this case, the localized area of the sensor array of the ultrasound probe is used to create the ultrasound image. Alternatively, the transmission device may fit over the entire end, or a portion thereof, of the probe.

15

This method may ensure that the interface between the ultrasound probe and the organ to be diagnosed will have uniform acoustic impedance throughout the operation, even when the ultrasound probe is required to move in and out of the orifices or along the contour of the body.

20

In one embodiment, the projection may have a low friction surface, such as a smooth surface or a surface layer to aid with reducing friction.

In a further embodiment, the transmission device may be of sufficient deformability to mold to the shape of the patient's body during examination. This may be particularly advantageous for examination of the body having significant variation in shape.

- 5 In a further embodiment, the projection may be made of medical grade silicone. This projection may have similar acoustic impedance to water. It may be oval shape with the top filled up with silicone and bottom only a thin layer of silicone making it big enough for the air to escape when the probe is inserted fully.
- 10 Alternatively, the projection may be of an elastomeric material such as any one or a combination of HDPE, latex and nitrile rubber.

In one embodiment, the device and/or projection may be a single use item, and so disposable after the first use. The materials of the disposable device may be such that
15 are adapted for a single use to discourage multiple use.

Alternatively, the device and/or projection, may be a multiple use device. In this case, materials may be selected to ensure such multiple use, with cleaning and disinfection processes after each use. In such a case, the thickness of the device may also be
20 increased so as to be more abrasion resistant, heat resistance or other such dimension and/or material variation so as to meet the cleaning/disinfection cycle.

Brief Description of Drawings

It will be convenient to further describe the present invention with respect to the accompanying drawings that illustrate possible arrangements of the invention. Other
5 arrangements of the invention are possible, and consequently the particularity of the accompanying drawings is not to be understood as superseding the generality of the preceding description of the invention.

Figure 1 is a schematic view of an ultrasound examination;

10 Figures 2A to 2C are various views of an ultrasound probe having a transmission device according to one embodiment of the present invention;

Figure 3A to 3C are various views of an ultrasound probe having a transmission device according to a further embodiment of the present invention.

15 **Detailed Description**

Figure 1 shows one application of an ultrasound examination whereby an ultrasound probe 45 is inserted in the rectum 40 so as to bring the probe proximate to the prostate 30. In this case the probe 45 is under control of an automated or semi-automated device
20 15.

The probe 45 produces harmless high-frequency sound waves, emanating from a sensor adjacent to the end of the probe. The sound waves are inaudible to the human ear, which bounce off the surface of the prostate. The sound waves are recorded and transformed into video or photographic images of the prostate gland.

The probe 45 is inserted into and moved reciprocally in a sheath 10, located in the rectum, which provides a guard against shifting of the organs during examination, which may otherwise occur as the probe 45 is moved.

5

The probe can provide images at different angles to help your doctor estimate the size of the prostate and detect any abnormal growths. A prostate biopsy uses transrectal ultrasound imaging to guide several small needles 35 through the rectum wall into areas of the prostate where abnormalities are detected. The needles remove a tiny amount of
10 tissue to be analyzed in a laboratory.

Figures 2A to 2C show one embodiment of the present invention whereby a transmission device 80 comprises a clip 60 which is arranged to engage the probe 65 but external to the membranous sleeve 70. In this case, the clip 60 may be a spring steel, or
15 stainless steel circular clip arranged to resiliently engage the probe 65. Alternatively, the clip 60 may be a silicone member of sufficient rigidity to remain fixed during examination. In a further alternative, the clip may be a steel reinforced silicone member, having the benefits of a silicone coating and the resilient rigidity of steel. Projecting from the clip 60 is a projection 55, positioned over the probe sensor, which in this case
20 is a flat elastomeric "bump". The projection 55 is arranged to contact the sheath 50 such that, in the clipped position, the projection 55 provides a transmission path from the probe sensor to the sheath to provide better ultrasonic imagery.

As discussed, prior art arrangements are noted to use an excessive quantity of gel in the interstitial space 75 between the sleeve 70 and the sheath 50. With insufficient, paths to flow out when the probe was inserted, the process is quite messy and inconvenient. Further, voids are known to form on extraction leading to a break in the signal path
5 between the sensor and sheath. The reciprocal motion of the probe within the sheath therefore presented significant difficulties in providing an efficient ultrasonic image. The intent of the present invention is to maintain the transmission device 80 in engagement with the probe 65 without the need for such gel, except as an entirely optional lubricant in limited circumstances. By providing an elastomeric projection 55
10 for the transmission path from the probe 65 to the sheath 50, optimum conditions for the transmission of the ultrasound are achieved.

The size of the projection 55, relative to the internal diameter of the sheath may provide an air gap 73, so as to allow the escape of air trapped during the reciprocal motion of the
15 probe 65 with the sheath 50.

The embodiment of Figure 2 provides significant advantages, including:

1. Prevention of air trapped in the gel and hence achieves improved imaging quality;
- 20 2. Less gel is required;
3. Gel overflow is eliminated.

Figures 3A to 3C show an alternative arrangement whereby the transmission device 90 is in fact an enlarged or thickened portion of the membranous sleeve 95. The thickened

portion 90 being of the same material as the sleeve 95 provides a resilient contact between the probe 105 and the sheath 85 so as to provide a transmission path from the sensor to the sheath 85. Thus, whereby a reciprocal motion of the probe may be inconvenient through excessive gel or produce poor imagery through excessive air gaps, the use of the transmission device provides for continuous contact and so a continuous transmission path for the ultrasound.

Similar to the embodiment of Figures 2A to 2C, the embodiment of Figure 3A to 3C also provides a gap 92 through which air can escape 93 during the reciprocal motion of the probe 105 within the sheath 85.

The embodiment of Figure 3 provides significant advantages, including:

1. Use of gel is not required and hence risk of infection is minimized;
2. More comfortable for patient since no direct contact/friction with relative movement;
3. No breakage of condom;
4. Low cost;
5. Faster and easier set up;
6. Interruption free operation;
7. Consistent imaging since no more air trapped in the gel;
8. Longer shelf life;
9. Less stringent in storage;
10. Provide clean operation.

For alternative ultrasound applications for the present invention, surface scan require doctors to use one hand on the control keyboard and one hand on the probe, therefore one-hand operation is the key idea for the use of our localized methodology.

- 5 The transmission device may be of a cylindrical shape and stretchable with several sizes to choose from, with sufficient resiliency to hold the device against the probe. This eliminates the use of gel while making sure that the coupler is always in position to the probe, doctors can rest assured that the imaging is consistent.
- 10 Besides one hand operation, the soft material may also be able to compensate the unevenness of the surface area, for example, human stomach, neck or hand, these are the area that require large amounts of gel. For the present invention, no gel is required. By way of example, during a prenatal ultrasound examination, it is often the case for that the examiner place the probe on the patient's back to receive a more optimum
- 15 image. Traditionally this involved an additional large smear of gel on the patient's back adding to the discomfort and mess. With an ultrasound probe according to the prior art, no gel whatsoever is required.

Other alternative applications for the present invention may include:

- 20 1. Abdominal ultrasound
2. Obstetric Ultrasound (Pregnancy)
3. Renal Ultrasound (Kidneys and Bladder)
4. Small parts Ultrasound (Thyroid, testes, etc)
5. Vascular ultrasound

6. Musculoskeletal Ultrasound

7. Interventional Ultrasound

Claims:

1. A transmission device fixed to an ultrasound probe, said transmission device comprising:
5 a projection;
said projection arranged to project from the probe, adjacent to a sensing end of said probe, when said device is mounted thereto;
wherein said projection is further arranged to provide a signal path for said ultrasound waves.
10
2. The transmission device according to claim 1, wherein the ultrasound probe is arranged to be inserted reciprocally into a sheath during examination, the transmission device arranged to provide the signal path from the sensor to said sheath.
15
3. The transmission device according to claim 1 or 2, wherein the device is integral with the probe.
4. The transmission device according to claim 1 or 2, wherein the device is
20 mountable to the probe.
5. The transmission device according to any one of claims 1 to 4, wherein said device includes a membranous sleeve, said projection being a thickened portion

of said membranous sleeve, said membranous sleeve arranged to slide over the probe.

6. The transmission device according to any one of claims 1 to 4, wherein the
5 device is a clip for engaging the probe, said projection fixed to said clip.
7. The transmission device according to any one of claims 1 to 6, wherein said projection comprises an elastomeric material.
- 10 8. The transmission device according to any one of claims 1 to 7, wherein said elastomeric material includes any one or a combination of silicone, HDPE, latex and nitrile rubber.
9. The transmission device according to any one of claims 1 to 8, wherein said
15 elastomeric material is of a deformable material capable of molding to the body of a patient under examination..
10. An ultrasound probe assembly comprising:
an ultrasound probe;
20 a probe sheath into which the probe is inserted and
a transmission device according to any one of claims 1 to 9.