(54) Title: ULTRASOUND TRANSDUCER FOR CONTINUOUS BODY ORGAN IMAGING

(57) Abstract: This invention is an ultrasound transducer device (10) used for continuous imaging of the heart (and other body organs), and comprehensive evaluation of left ventricular wall motion. The device consists of a hemispherical transducer assembly (21, 23) which is attached to the body surface of the patient by an adhesive patch (20). The transducer permits sequential imaging of two orthogonal views of the heart by mechanical rotation of the transducer or with the use of two arrays arranged perpendicular to each other.
BACKGROUND OF INVENTION

1. Field of Invention

This invention relates to devices incorporating ultrasound transducers and more particularly to an ultrasound transducer device for the continuous imaging of multiple segments of the heart.

2. Description of Prior Art

Echocardiograms are normally performed by placing an ultrasound transducer on the chest wall. More recently, transesophageal echocardiography has been performed by mounting a transducer at the tip of a gastroscope and introducing it into the esophagus. Transesophageal echocardiography can be used for prolonged monitoring of the left heart ventricular function. However, the inconvenience of swallowing the probe, the potential for complications, poor tolerance of the probe during prolonged monitoring (except in a heavily sedated or intubated patient), inability to eat or drink while the probe is in the esophagus, as well as its expense limits its use. The standard transthoracic ultrasound probe is designed to make a specific diagnosis at a point in time and not for prolonged monitoring of patients. The narrow, long, shape of the transducer precludes proper motion-free positioning for long term use. Furthermore, patient motion is restricted by the transducer probe, i.e. the patient will not be able to turn to his/her left when a long transducer probe is placed below the left nipple (cardiac apex). Because of the limitations
of currently available ultrasound transducers, a low profile transducer that permits continuous imaging will be an important advance in transducer technology.

Currently available ultrasound transducers are hand-held devices which permit recording of cardiac structures and Doppler blood flow velocity signals at a fixed point in time. Changes in the clinical or hemodynamic status of the patient may be accompanied by left ventricular wall motion abnormalities and changes in cardiac output and pulmonary artery diastolic pressure. Thus, a repeat echocardiogram may be required to reevaluate the patient. Performance of serial echocardiograms within a short period of time is inconvenient, expensive and often impractical. Moreover, a hand-held transducer cannot be used for certain clinical applications of echocardiography such as intraoperative monitoring of left ventricular function in patients with coronary artery disease undergoing noncardiac surgery.

An ultrasound transducer for continuous imaging of the heart and other body parts is disclosed in U.S. Patent No. 5,598,845. The device disclosed therein permits continuous imaging of the left ventricular short axis from a parasternal position, or the four chamber view or two chamber view from apical placement of the transducer. A disadvantage of this transducer is that only an apical four chamber or a two chamber view can be imaged at a given time. The apical four chamber view displays the posterolateral wall which is supplied by the circumflex coronary artery, and the posterior septum which is supplied by the right coronary artery in
its proximal part and by the left anterior descending artery (LAD) in its distal part. The blood supply to the apex is from the left anterior descending artery. The apical two chamber view displays the anterior wall supplied by the LAD, and the inferior wall whose blood supply is from the right coronary artery. Thus, both the apical four chamber and two chamber views (orthogonal) are required for a comprehensive evaluation of left ventricular wall motion in patients with myocardial ischemia or myocardial infarction, and for monitoring of stress echocardiography.

**SUMMARY OF THE INVENTION**

The present invention provides an ultrasound transducer mounted inside a semispherical enclosure having a bottom surface conforming to the chest wall and attached to the skin with an adhesive to permit continuous imaging of orthogonal views of the heart and Doppler flow velocity profiles. In patients with loose skin, a strap is used to firmly attached the transducer to the chest wall.

The transducer will be automatically switched by means of a motor between an apical four chamber view and a two chamber view (i.e. 90° rotation along the long axis) every 10-30 seconds (or at a preset time interval) to permit continuous imaging of left ventricular wall motion (Figure 1). Alternatively, the transducer will have two arrays perpendicular to each other, one array or the other or both simultaneously being electronically activated so that the apical four chamber and two chamber view can be imaged in
sequence or simultaneously. Alternatively, a two dimensional array of transducer elements could be electronically steered to scan in one or more scan planes. This permits comprehensive evaluation of wall motion and it may also be used for myocardial contrast echocardiography and for continuous measurement of intracardiac pressures using contrast agents.

The present invention thus provides a simple, efficient, patient friendly and inexpensive device that permits continuous imaging of the heart in more than one plane, preferably orthogonal planes, and evaluation of left ventricular wall motion. In addition the present invention provides Doppler data.

DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention as well as other objects and further features thereof, reference is made to the following description which is to be read in conjunction with the accompanying drawing wherein:

Figure 1 illustrates the ultrasound transducer device of the present invention fixed to the patient’s chest;

Figure 2 is a simplified perspective view of a preferred configuration of the invention;

Figure 3 is a partial cross-sectional view of the invention;

Figure 4 is a top view of a disposable adhesive pad;

Figures 5A and 5B are simplified views of the transducer viewed from below and illustrated in two positions;

Figure 6 shows two and four chamber views of the heart;
Figure 7 illustrates a simplified version of an array;
Figure 8 illustrates a sectional view of a preferred embodiment of the rotatable transducer of the present invention;
Figure 9 is a top view of the rotatable transducer shown in Figure 8;
Figure 10 illustrates four transducers coupled to a single imaging monitor using multiplexing; and
Figure 11 shows an alternate configuration wherein the transducer is automatically steered, or tilted, to obtain multiple short axis views of the heart.

DESCRIPTION OF THE INVENTION

Figure 1 is a simplified view showing the transducer 10 of the present invention affixed to the chest wall of a patient 12 using an adhesive pad (see Figure 4).

Figure 2 is a perspective view of the transducer 10 of the present invention showing conducting wires 14 and 16 and a hook member 17, member 17 being adapted to receive a strap to additionally secure the transducer to the patient's chest.

Figure 3 is a sectional view of the transducer shown in Figure 2 illustrating the internal structure of transducer 10, and, in particular, shows an inner assembly 21, outer assembly 23 and knob 25 attached to inner assembly 21, rotation of knob 25 in turn rotating inner assembly 21. A plurality of knobs 31 extend around the circumference of the transducer base 33.

Figure 4 is a top view of a disposable adhesive pad 20 having
an adhesive layer 27 formed on the bottom surface and a plurality of holes 29 formed therein to receive corresponding knobs 31 formed on the base 33 of transducer 10. Pad 20 is attached to the bottom surface of transducer 10.

Figure 5A schematically illustrates the transducer at a baseline position and Figure 5B illustrates transducer 10 rotated 90° from the baseline initial position shown in Figure 5A, the transducer rotation occurring approximately every 10-20 seconds (the rotation is shown referenced to baseline array 72).

Figure 6A shows a view of the left ventricle and left atrium heart chamber (inferior wall 31 and anterior wall 33 are shown) that is produced by transducer 10 of the present invention and Figure 6B shows a chamber view of the left ventricle and left atrium heart chamber (posterior septum 35 and posterolateral wall 37 shown) after the transducer 10 is rotated approximately 90 degrees.

Figure 7 shows a bottom view of an alternate configuration of the transducer of the present invention. In particular, two conventional scanning semiconductor arrays 80 and 82 are mounted perpendicular to each other and each array semiconductor is alternately activated every 10-20 seconds to provide orthogonal views of the heart.

Figure 8 is a cross-sectional view of the preferred embodiment of transducer 10 of the present invention. In particular, transducer 10 comprises an outer assembly 80, inner assembly 82, ultrasound transducer 84 attached to the inner shell of inner
assembly 82, outer shell 86 of inner assembly 82, motor 88 for rotating the inner shell of the inner assembly 82 (and thus transducer 84) around the axis 90 of the direction of ultrasound propagation and detent latch 92 (three provided as shown in Figure 8). The direction of the ultrasound propagation is illustrated by the reference numeral 94. Motor 88 can be commanded to automatically rotate the inner shell of the inner assembly 82 by 90 degrees, causing the view to switch from short axis to long axis or form a four chamber to a two chamber view. In an alternate embodiment, a knurled knob can be used for manually rotating the inner shell of the inner assembly.

Figure 9 is a top view of the rotatable transducer 10 and illustrates the first imaging plane 96 and the second imaging plane 98, plane 98 being approximately 90 degrees from plane 96.

Figure 10 is a block diagram showing four transducers 10 connected to electronic modules 100, 102, 104 and 106. Device 110 comprises a video display 112 and illustrates an ultrasound image 114 thereon.

In the embodiment illustrated, four separate patients are hooked up with transducers 10, the output of transducers 10 being coupled to separate modules 100, 102, 104 and 106. The modules have the capability of transmitting the electronic signals from transducers 10 to central electronic unit 110, for example via conventional multiplexing techniques. The electronic modules, in turn, transmit image data to device 110, the images thereon being displayed on monitor 114 and then transmitted to a network (not
shown) via lead 116 if required. Information from the network can also be coupled back to device 110.

Figures 11A and 11B show in simplified form, transducer 10 being tilted relative to patient chest wall to obtain two short axis views of the ventricle, the lower left view showing the heart valve 13.

As noted hereinafore, U.S. Patent No. 5,598,845 describes a low profile ultrasound transducer designed to be attached to the skin surface to allow hands free continuous imaging of the heart and to allow positioning of the transducer to obtain a desired view. The present invention modifies the device disclosed in the '845 patent of the transducer to obtain continuous 2-chamber and 4-chamber orthogonal views (the teachings of Patent No. 5,598,845 necessary for an understanding of the present invention is hereby incorporated by reference).

The low profile transducer 10 is designed with an inner assembly 82 (Figure 8) that is essentially a ball and socket type joint so that the inner assembly can be moved freely to be positioned to achieve the desired image orientation. Once this is done, it remains in place due to friction between the inner assembly 82 and outer assembly 80. The inner assembly 82 consists of two concentric spherical shells, the outer shell 86 of the inner assembly being free to move in all directions within the outer assembly 80. The outer shell 86 of inner assembly 82 is constrained to rotate only about an axis that coincides with the direction of the ultrasound beam.
Detents 92 (Figure 9) limit this motion to within two 90 degree sectors, the center point of the two 90 degree sectors having a detent which is the nominal operating position.

In use, the inner shell of the inner assembly 82 is set in the nominal position and held there by a detent 92. When the health provider obtains the desired images by positioning the transducer 10 by mechanically or manually moving the inner assembly 82 with respect to the outer assembly 80, one view, either a 2 chamber of 4 chamber, is obtained. To go from one view to another, the inner shell of the inner assembly is rotated to one or the other 90 degree stops or detents. Since this rotation is occurring around the direction of propagation of the ultrasound beam, the imaging sector is rotated by 90 degrees and the alternate, desired view is obtained.

Other variations are available that can accomplish the same objective and are considered to be within the scope of the present invention. For example, other means can be used to facilitate the rotation by 90 degrees around the direction of propagation including the use of motors or actuating wires controlled by electromechanical means. In an alternate embodiment, two transducers or arrays of transducers for a phased array could be prepositioned at 90 degrees relative to one another and image rotation would be accomplished by electronic switching means or simultaneous image data acquisition (see Figure 7). Alternately, a two-dimensional array of transducer elements could be electronically steered to scan one or more scan planes. This would
allow unattended acquisition of 2 and 4 chamber views according to some preset time sequence, the images being recorded for later review by the clinician. When the transducer 10 is placed at the left sternal border, a short axis view of the left ventricle is obtained. The transducer is mechanically scanned inferiolaterally to obtain multiple short axis views of the heart. This provides a comprehensive evaluation of left ventricular wall motion. Ultrasound images are typically taken in a hospital environment with a single ultrasound machine and transducer dedicated as one system. This system is typically portable and is moved from patient to patient as required to perform studies. If it is desired to perform either intermittent or continuous imaging over a period of several hours, it is necessary to dedicate a single machine to each patient, or to continually move a single machine around. If it is desirable to be able to be imaging when certain events, for example chest pain, occurs, moving a single machine is not practical. In addition, it is expensive to dedicate a single machine to each patient. Typically, limited space is available in intensive care or cardiac care units, so the amount of space required to have multiple ultrasound imaging machines present presents a problem.

The present invention is capable of providing a system for performing ultrasound examinations on multiple patients substantially simultaneously, for monitoring applications. It is designed to be able to either perform continuous imaging on a single patient, to be used intermittently in a multiplexed manner
on several patients, and to allow for event recording, for example when an abnormal electrocardiogram is detected, or when a patient experiences chest pain.

In the preferred mode, each patient has an ultrasound transducer dedicated to imaging that patient. The common electronics required for imaging is present in a single central imaging unit, while each transducer will have a dedicated "satellite" electronics module. This partitioning of the system into a central unit and satellite units provides both economic advantages as well as more efficient use of available floor space.

In one version, all of the electronic subsystems required to generate and receive ultrasound signals are in the central unit. This includes the electronics subsystems that generate transmit pulses, the electronic subsystem to receive, amplify and detect received ultrasound echos, and all the electronic subsystems required to convert detected signals into an image (scan converter, video display, etc.). The transducers are driven over fairly long cables using line drivers and line receivers. The central unit simply switches between the different transducers in order to create images from the multiplexing of transducers that are attached thereto. In a second mode, the satellite electronics modules have preamplifiers to first amplify the relatively weak received ultrasound signals before they are sent down the long cable back to the central electronics module. This requires a preamplifier subsystem for each transducer which increases the overall system costs. However, this mode may provide improved image
quality that could be degraded by noise if signals that were not amplified were transmitted down the relatively long cables from the transducers to the central unit. In a third mode, the satellite electronics modules have all of the transmit and receive electronic subsystems and only digital communication of commands and data are sent between the satellite units and the central unit. Although this system mode may be the most expensive mode of operation. It is the system architecture that provides the highest quality images and is the most flexible in terms of expansion capabilities and other features. In any given application, one of these modes may be preferred from a cost/benefit analysis standpoint. Other partitionings of the electronic subsystems between the central unit and satellite units can be utilized and are within the scope of the present invention.

The imaging data will typically be recorded in digital form and may be archived or sent via a network to a central nursing station or other area for remote viewing and diagnosis. Another embodiment of the invention is a single echo machine which is multiplexed to, for example, four transducers attached to four different patients, each transducer being activated approximately every 30 seconds (Figure 10).

To obtain cardiac hemodynamics, the transducer is placed at the left sternal border to obtain a short axis view to obtain a pulmonary artery systolic signal to calculate cardiac output continuously, and the pulmonary regurgitant signal to calculate the pulmonary artery diastolic pressure continuously.
A first transducer is positioned at the left sternal border to obtain hemodynamic data (cardiac output and pulmonary artery diastolic pressure) and a second transducer is positioned at the cardiac apex to assess left ventricular function. The two transducers are then activated every 30 seconds, providing both hemodynamic and wall motion data.

A lower frequency transducer can be attached to the chest wall to provide continuous ultrasound delivery for therapeutic applications such as ultrasound induced thrombolysis.

While the invention has been described with reference to its preferred embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teaching of the invention without departing from its essential teachings.
WHAT IS CLAIMED IS:

1. An ultrasound transducer system for attachment to a surface of the body of a patient for providing continuous diagnostic information on a body organ function and comprising:

   a transducer assembly including a transducer enclosure, supporting means for mounting an ultrasound transducer means inside said enclosure, ultrasound transducer means mounted on said supporting means for transmitting and receiving ultrasound beams whereby information on the heart muscle inside said body surface can be obtained;

   conductor means for providing electrical signal connections between said transducer scanner and display equipment;

   an inner assembly positioned between said enclosure and said transducer mounting means; and

   a member attached to said supporting means, rotation of said member rotating said transducer means about the propagation direction of said ultrasound wave to provide a multi-plane image of the organ.

2. The transducer system of claim 1 further including detent latch means mounted to the inner shell of said inner assembly and cooperating with detents formed on the outer shell of said inner assembly to limit the rotational motion to a predetermined angular sector.
3. The transducer system of claim 1 wherein a motor means is utilized to rotate said member.

4. The transducer system of claim 1 wherein said ultrasound transducer means is configured in a two-dimensional array.

5. The device of claim 1 wherein the rotation of said member provides orthogonal views of the organ.

6. An ultrasound transducer device for attachment to a surface of the body of a patient for providing continuous imaging of the heart inside said body surface comprising:

   a transducer assembly including a transducer enclosure, supporting means for mounting an ultrasound transducer means inside said enclosure, ultrasound transducer means mounted on said supporting means for transmitting and receiving ultrasound beams whereby an image of an organ inside said body is provided, and;

   means for providing electrical signals between said transducer means and an externally located transducer scanner and display equipment, said transducer means comprising first and second arrays of transducers attached to said supporting means, said electrical providing means being sequentially activated in a manner whereby the ultrasound waves generated by said transducer arrays are propagated within a predetermined angular sector.

7. The device of claim 6 wherein the sequential actuation of said
transducer arrays provides orthogonal views of the left heart ventricle.

8. A method for providing continuous imaging of an organ inside the body of a patient comprising the steps of:
   providing a transducer assembly including a transducer enclosure, supporting means for mounting an ultrasound transducer means inside said enclosure, ultrasound transducer means mounted on said supporting means for transmitting and receiving ultrasound beams and mounting said transducer assembly to said patient whereby an image of the heart inside said body surface is produced;
   providing electrical signal connections between said transducer means and an externally located display; and
   directing the ultrasound beams over a predetermined angular sector whereby orthogonal views of the organ are provided.

9. The method of claim 8 wherein three dimensional images of the heart are provided.

10. The method of claim 8 wherein continuous three dimensional images of the organ are provided.

11. The method of claim 8 wherein said orthogonal images are displayed on said display.

12. The method of claim 8 wherein a plurality of transducers are
mounted to a like number of patients, the organ images produced by each patient being coupled to said display equipment in sequence.
**INTERNATIONAL SEARCH REPORT**

**International application No.**
PCT/US00/19742

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### A. CLASSIFICATION OF SUBJECT MATTER

- **IPC(7) :** A61B 8/00
- **US CL :** 600/459

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

### B. FIELDS SEARCHED

**Minimum documentation searched (classification system followed by classification symbols)**

- **U.S. :** 600/391, 392, 437, 438, 444-446, 450-454, 459

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

- **NONE**

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

- **EAST**
  - Search Terms: echocardiogra$, echosonogra$, support, holder, pad, adhesive

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tr>
<td>Y</td>
<td>US 5,598,845 A (CHANDRARATNA et al.) 04 February 1997, col. 4 lines 13-59.</td>
<td>1, 5, 8, 11</td>
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<td>X</td>
<td>US 5,381,794 A (TEI et al.) 17 January 1995, col. 1 lines 6-11, col. 3 lines 25-30, and col. 11 lines 10-14.</td>
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<td>Y</td>
<td>US 5,479,929 A (COOPER et al.) 02 January 1996, col. 3 lines 7-18.</td>
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<td>US 5,320,104 A (FEARNSIDE et al.) 14 June 1994, cols. 3 and 4.</td>
<td>4, 6-8, 11, 12</td>
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<td>Y</td>
<td>US 5,211,168 A (MASON et al.) 18 May 1993, col. 2 lines 26-37, and col. 4 lines 44-52.</td>
<td>4, 6-12</td>
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[X] Further documents are listed in the continuation of Box C.

- **A** - Special categories of cited documents
  - **Y** - Further document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  - **E** - Earlier document published on or after the international filing date
  - **U** - Document which may throw doubts on priority claims or which is cited to establish the publication date of another citation or other special reason (as specified)
  - **O** - Document referring to an oral disclosure, use, exhibition or other means
  - **P** - Document published prior to the international filing date but later than the priority date claimed

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**Date of the actual completion of the international search**

04 SEPTEMBER 2000

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**Date of mailing of the international search report**

26 OCT 2000

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**Name and mailing address of the ISA/US Commissioner of Patents and Trademarks**

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<td>Y</td>
<td>US 4,640,291 A (THOEN) 03 February 1987, col. 1 lines 53-57.</td>
<td>4, 6-12</td>
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<td>Y</td>
<td>US 5,720,285 A (PETERSEN) 24 February 1998, col. 18 lines 19-36.</td>
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