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(54) Method of pulse examination

(57) A method of pulse examination which is particularly easily carried out using a container (10). The method entails matching the impedance of a liquid couplant in the container (10), to the impedance of the tissue of an examined female breast. The time per unit distance taken for ultrasonic pulses to travel through breast tissue and a reference liquid respectively are found and the reference liquid mixed with a second liquid in a ratio dependent on the difference between those times to form a liquid couplant with an impedance similar to the impedance of the breast tissue. The method thus compensates simply but accurately for velocity variations in the breasts of different patients.

The liquid container (10) contains a liquid in contact with the top of a breast being ultrasonically scanned. The container comprises fluid-impervious material (20) and an opening (26) to be placed about the breasts of a female torso. Inflatable sealing means (28) seals the perimeter of the opening against the body. The method of use of the container (10) enables more rapid, accurate and meaningful scanning than was previously possible.

Fig_1

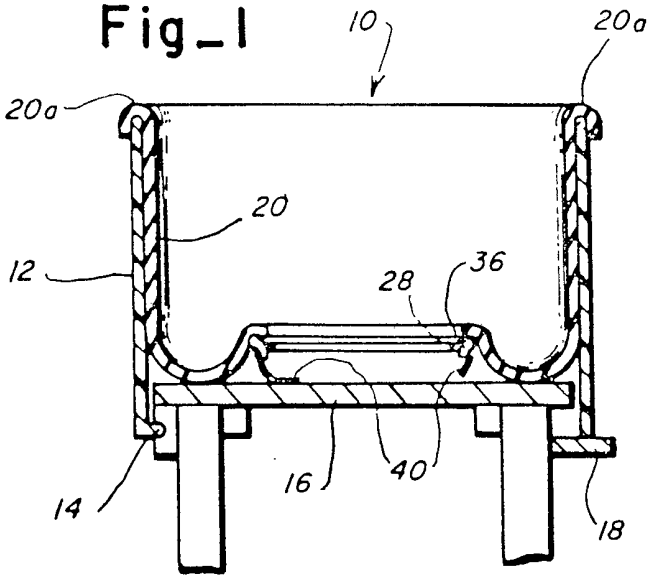

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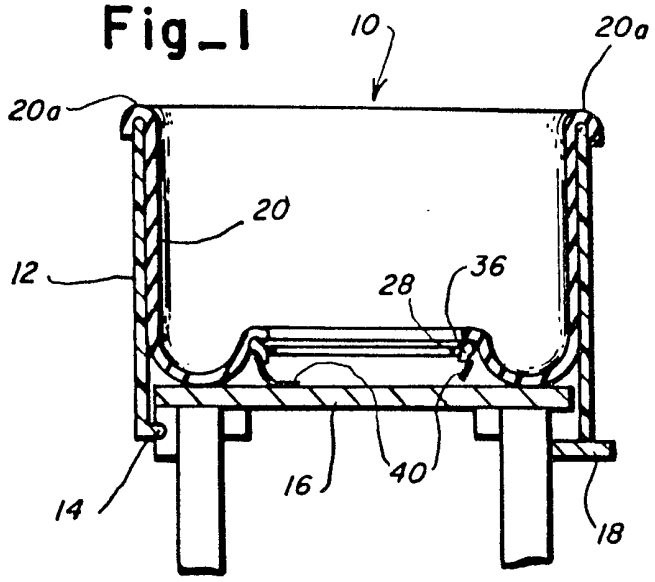
Fig_1



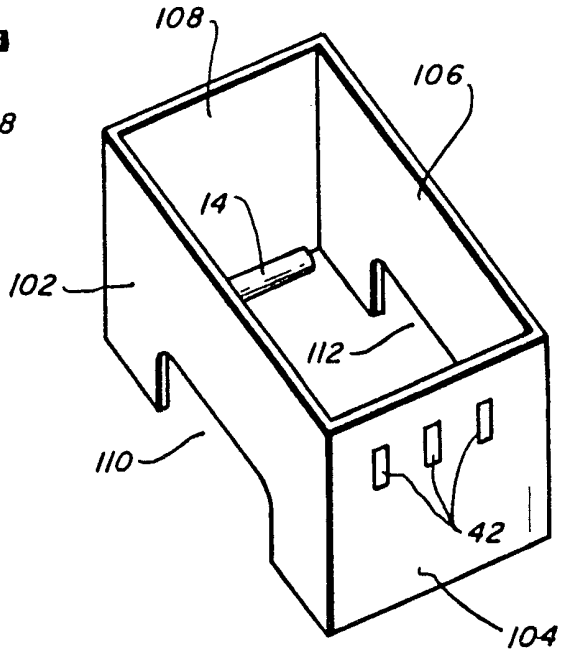


Fig_2

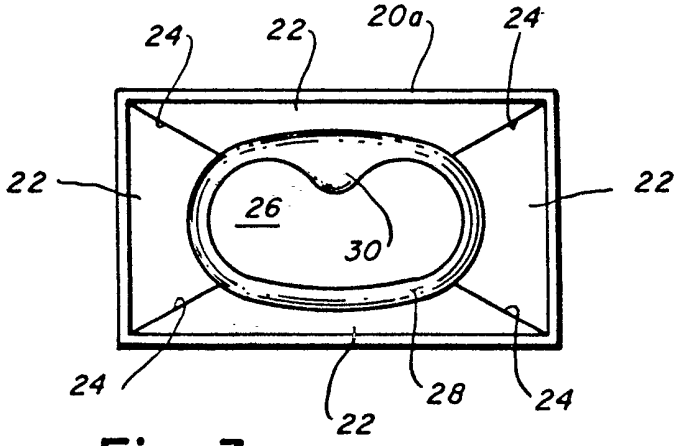


Fig_3

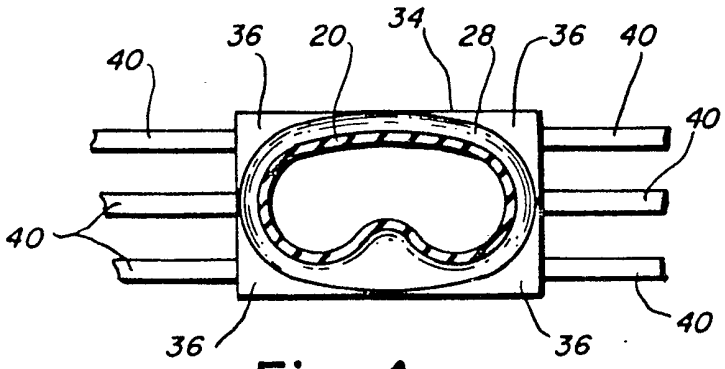


Fig_4

SPECIFICATION

Method of pulse examination

The present invention relates to a method of compensating for velocity variations in the various body members of different patients dealt with by pulse examination equipment of the type in which a body member is immersed in a liquid that thereby defines the propagation medium between the body member and a transmitting transducer. The amplitude of a reflected pulse in a pulse reflection imaging system used for ultrasonic examination is indicative of the magnitude of density changes represented by any discontinuity in the propagation path, while the return time of the reflected pulse indicates the distance from the transducer to the discontinuity.

Liquid couplants, such as water, are often used between the transducer and the examined region of a patient's body particularly when contact scanning—contact between the transducer and patient—would distort the region and render the acquired data meaningless. Coupling media are commonly used, for example in breast scanning, wherein difficulty is encountered in maintaining the breast steady when contact scanning is employed. The body region is immersed in the coupling medium, and the transducer scans the body from a non-contacting position. The medium provides the acoustical propagation path between the transducer and the region.

Known methods of employing a coupling medium in ultrasonic breast scanning include the following:

In "A Combined Clinical and Research Approach to the Problem of Ultrasound Visualization of the Breast" (E. Kelly-Frye, et al; *Ultrasound in Medicine;* Vol. 1, pp. 309—320; 1975) a technique is disclosed whereby the patient lies prone with the breast hanging in water and scanned from underneath.

In "Ultrasound Mammography" (G. Baum; *Ultrasound* in Medicine; Vol. 2, pp. 469—470; 1976) the patient sits with her breast through a circular hole in the side of a water tank which contains the transducer.

In "Differential Diagnosis of Breast Tumors" (T. Kobayashi; Cancer; Vol. 33, pp. 940—951; 1974) a plastic water bag containing the scanning probe is placed on the breast of the supine patient with a coupling gel between the bag and breast.

According to the present invention there is provided a method of compensating for velocity variations in the various body members of different patients dealt with by pulse examination equipment of the type in which a body member is immersed in a liquid that thereby defines the propagation medium between the body member and a transmitting transducer, the method comprising the steps of:

a) measuring the time taken for an energy impulse to travel a known distance through a reference liquid from the transmitting to a receiving transducer both in contact with the body;

b) measuring the time taken for an energy pulse to travel a known distance through a reference liquid from the transmitting transducer to the receiving transducer both immersed in said liquid;

c) mixing a quantity of said reference liquid with a quantity of a second liquid in a ratio dependent upon the difference in time per unit distance ascertained from the measurements of steps a) and b) so as to form a resultant liquid having an impedance to said energy impulses similar to the impedance of the body member, said resultant liquid then being suitable for use as a couplant in pulse examination of the body member.

A liquid container for use in a method according to the invention can be placed over one or both breasts of a supine patient. Preferably, the container covers the area of axilla to axilla. The perimeter of the opening of the container is contoured to fit the body but it need not provide an exact fit owing to the sealing means. The sealing means may be an expandable membrane which contours itself to the patient's body to provide a water-tight seal to the body being examined.

A container can be constructed so that, when water, brine or oil (as appropriate) is contained in it and the sealing means is inflated, the breast assumes a natural shape owing to the buoyance of breast tissue. Scanning accordingly generates accurate and meaningful data. In other words, the breast is substantially unhindered by the sealing means acting on the chest and not substantially on the breast.

A container can be constructed for use in a method according to the present invention to have the following advantages over known containers:

1. A larger portion of the breast can be examined.
2. Bubbles which adhere to the skin can easily be seen and dislodged.
3. There is no plastic between the water and the skin.
4. A fresh volume of water or other liquid can be used for each patient without significantly impeding the total examination time.
5. A relatively small volume of water or other liquid is required, thus speeding up total examination time.

Advantage 4, listed above, is of particular significance. The velocity of sound in breast tissue varies greatly from person to person; the velocity generally decreases significantly with tissue age. If no correction for the actual velocity is made, echoes can be mis-registered in the images, introducing range errors into the data.

As a fresh volume of liquid can be used for each patient, the present invention employs a compensation technique wherein the density of the water (or other contained medium), and the consequential sound velocity in the medium, can

be adjusted to match the sound velocity in the breast of each individual patient.

Hence it can be seen that a container may be constructed to be particularly well adapted for use with an ultrasonic breast-scanning system and to be particularly suited for mass screening programmes wherein time is of the essence.

For a better understanding of the present invention and to show how the same may be carried into effect reference will now be made, by way of example, to the accompanying drawings, in which:

Figure 1 is a cross-sectional view showing a liquid container for use in ultrasonic breast examinations employing a compensation method in accordance with the invention,

Figure 2 is an isometric view of the container support structure,

Figure 3 is a top plan view of the container, and

Figure 4 is a fragmentary bottom plan view of the container showing the arrangement for sealing to the patient's body.

Figure 1 is a cross-sectional view showing a container 10 constructed for use in a method in accordance with the invention which container 10 includes a rigid supporting structure 12 preferably formed from an acrylic plastic such as Plexiglas (Registered Trade Mark). The structure 12 is mounted for rotational movement at 14 about a table 16 and may accordingly be pivoted out of the way when a patient is to get on or off the table. A stop 18 limits the rotational movement of the support 12 and supports the container 10 when the container is pivoted into position over the patient, as explained hereinbelow.

As more clearly shown in Figure 2, the support 12 comprises walls 102, 104, 106, 108. The walls 102, 106 are provided with respective, generally concave, cutout regions 110, 112 which are sized to fit over the torso of a supine patient so that the patient's chest is under the area between the walls 102, 106.

As shown in Figure 1, a flexible, waterproof liner 20 is then placed within the confines of the support 12, with its top edge 20a draped over the top edge of the support. The liner 20 is preferably formed from 3/8" (10 mm) neoprene, owing to the durability of neoprene and the ease with which the liner may therefore be shaped and repaired. The shape and other features of the liner are more clearly shown in Figure 3.

Figure 3 is a top plan view of the lined container and shows the liner 20 draped over the edge of the support 12 at 20a. The liner is formed from four pieces 22 of neoprene which define a generally oval opening 26 that overlies the patient's chest so that the patient's breasts are within the lined container. The pieces 22 are cemented together along seams 24 by means of a sealing cement. The liner is formed in this manner to fit as flat as possible against the walls of the support 12 whereby the neoprene is not stressed when the container is subsequently filled with water. As will become more apparent, the stressing of the neoprene will tend adversely to affect the seal between the container and the patient's body.

Sealing contact between the patient's skin and the container is provided by a gas-expandable membrane or tube 28 which circumscribes the opening 26. The membrane may be conveniently formed from 1/8" (3 mm) neoprene. A relatively wider area 30 is located to contact the sternum of the patient to seal the area between the breasts by "ballooning" when the membrane is inflated. Further details concerning the membrane and its affiliation to the container are explained with reference to Figure 4.

Figure 4 shows that the expandable membrane 28 is affixed to a layer of neoprene 34. The neoprene layer 34 lies between the membrane 28 and the liner 20 and includes an opening which is aligned with those of the liner 20 and the membrane 28. The membrane 28 is cemented to the layer 34 which is, in turn, cemented to the liner 20. The outer periphery of the layer 34 is thereby unattached to the liner and forms a continuous perimetrical flap 36 which is deformable and has four large corner portions between which there are relatively narrow connecting portions.

A series of straps 40 (not shown fully in Figure 1) have their ends affixed to longitudinally spaced regions of two opposite sides of the flap 36. As shown in outline in Figure 1, the straps 40 are sized to pass under the patient so as to pull upon said two opposite sides of the flap 36 and exert a counter-pressure tending to produce a sealing force at the membrane/patient interface. The other ends of the straps are conveniently fastened to the opposite sides of the container 10 by means of a reusable fibrous contact fastening device, such as strips of Velcro (Registered Trade Mark), affixed to the container at 42 (Figure 2) and to the straps 40 themselves. The Velcro (Registered Trade Mark) strips provide for continuous adjustment of the effective length of each strap, and the consequent accommodation of a variety of body sizes.

Once the lined container 10 has been secured and the membrane 28 inflated with air *via* a valve, a small amount of water may be poured into the top of the container to permit an inspection for leaks between the membrane and patient, and the straps 40 may be accordingly adjusted.

As previously indicated, the container lends itself to a velocity compensation technique which yields more accurate images in spite of the variation in acoustic velocities from breast to breast.

The breast velocity is measured, prior to the examination, with a frame device adapted to hold a transmitting transducer and receiving transducer in an adjustably spaced relationship. The spacing is adjusted so that both transducer contact the breast. A jelly couplant may be used if desired.

The transducers are coupled to an A-trace imaging system, many of which are known in the art, so that the time lag between the launching of

the pulse and its reception by the receiving transducer is displayed on the CRT of the imaging system.

The delay of the ultrasound is measured by placing the leading edge of the A-trace of the transmitted signal in the centre of the CRT. Without further adjustment of the transducer spacing, the frame is immersed in a liquid of standard velocity (such as pure water at a constant temperature). The position of the echo left or right of centre (ΔT) is then recorded. The delay time (T) is recorded. The velocity of the sound in the breast is then

$$V_B = V_R\left(1 + \frac{\Delta T}{T}\right)$$

where V_R is the reference velocity. Note that the separation of the transducers need not be known. Furthermore the accuracy of the two measurements (T and ΔT) need not be great because they represent the deviation from a nominal velocity—not the velocity itself.

The equipment used for this measurement is independent of the B-scan equipment so these measurements can be made on one patient while another is being examined with the B-scan imager. Since both breasts can normally be measured with the same transducer spacing, only three measurements need be made —ΔT_L, ΔT_R, and T, where ΔT_L and ΔT_R are the delays for the left and right breasts, respectively.

The patient then lies on a gurney, and the container 10 is placed over one or both breasts. The container 10 is then filled with fresh water, or a solution, which is characterised by substantially the same acoustical velocity as the patient's breast. Since the acoustical velocity of salt water is higher than fresh water, the solution can conveniently be a combination of predetermined quantities of fresh water and salt water in proportions specified on a chart and related to the observed echo positions ΔT. Slower velocities than that of fresh water may be necessary for a small percentage of the patients and may be provided by the use of some oils.

Once the container 10 has been filled, so that the breasts are buoyant and retain their natural shape, scanning may be performed.

It should be noted that the system electronics must also be adjusted to compensate for the breast velocity. This may be provided by means of a knob adjustment which is calibrated in terms of either velocity or observed echo position on the A-trace.

Claims

1. A method of compensating for velocity variations in the various body members of different patients dealt with by pulse examination equipment of the type in which a body member is immersed in a liquid that thereby defines the propagation medium between the body member and a transmitting transducer, the method comprising the steps of:

a) measuring the time taken for an energy pulse to travel a known distance through a body member from the transmitting to a receiving transducer both in contact with the body;

b) measuring the time taken for an energy pulse to travel a known distance through a reference liquid from the transmitting transducer to the receiving transducer both immersed in said liquid;

c) mixing a quantity of said reference liquid with a quantity of a second liquid in a ratio dependent upon the difference in time per unit distance ascertained from the measurements of steps a) and b) so as to form a resultant liquid having an impedance to said energy pulses similar to the impedence of the body member, said resultant liquid then being suitable for use as a couplant in pulse examination of the body member.

2. The method of claim 1 wherein the reference liquid is either salt water or fresh water.

3. The method of claim 2, wherein the second liquid is either fresh water or salt water.

4. The method of claim 1 or 2, wherein the second liquid is an oil in which the velocity of sound is less than in fresh water.

5. The method of any preceding claim, wherein the time measured in step a) and the time measured in step b) are measured by producing respective A-trace displays.

6. A method substantially as hereinbefore described.

New claims or amendments to claims filed on 14th January 1983.
Superseded claims 1, 4, 5, 6.

New or amended claims:—

1. A method of compensating for velocity variations in the breasts of different female patients dealt with by pulse examination equipment of the type in which at last one breast is immersed in a liquid that thereby defines the propagation medium between the breast(s) and a transducer coupled to a B-trace imaging system, the method comprising the steps of:

a) measuring the time taken for an energy pulse to travel a known distance through breast tissue from a transmitting transducer coupled to an A-trace imaging system to a receiving transducer also coupled to the A-trace imaging system, both these transducers being in contact with the body of a patient;

b) measuring the time taken for an energy pulse to travel a known distance through a reference liquid from said transmitting transducer to said receiving transducer both immersed in said liquid;

c) mixing a quantity of said reference liquid with a quantity of a second liquid in a ratio dependent upon the difference in time per unit distance ascertained from the measurements of steps a) and b) so as to form a resultant liquid having an impedance to said energy pulses similar to the impedance of the breast(s) of the patient,

said resultant liquid then being suitable for use as a couplant in pulse examination of the breast(s).

4. The method of claim 1, wherein the second liquid is an oil in which the velocity of sound is less than in fresh water.

5. A method substantially as hereinbefore described.

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