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SEARCH ROOM

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United States

[11] **3,587,561**

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[73] Assignee **Hoffmann-La Roche Inc.**
Nutley, N.J.

[54] **ULTRASONIC TRANSDUCER ASSEMBLY FOR BIOLOGICAL MONITORING**
9 Claims, 12 Drawing Figs.

[52] **U.S. Cl.** **128/2.05,** 310/8.1, 310/8.6, 310/9.1, 310/9.6
[51] **Int. Cl.** **A61b 5/02**
[50] **Field of Search** .... 128/2.05 (AF), (P), (R), (S), 24 (A); 310/8.1, 8.3, 8.6, 8.8, 9.1, 9.4, 9.6; 73/67.5, 67.6, 67.7, 67.8, 194 (A)

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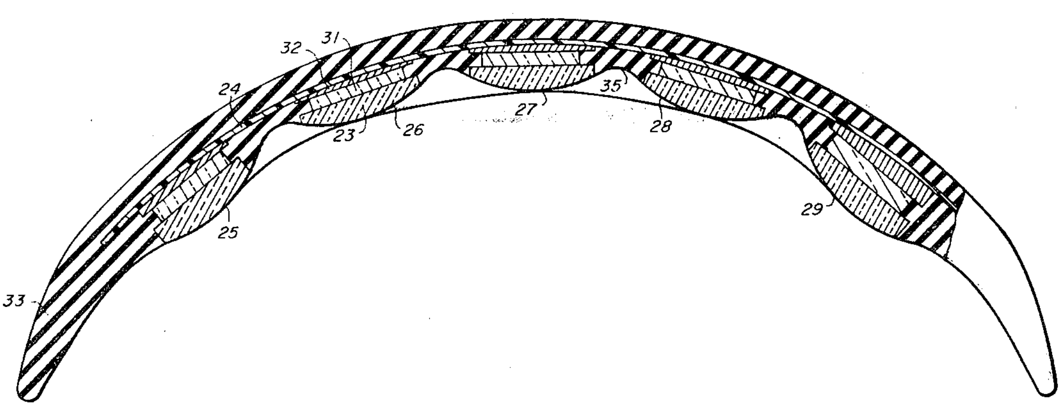
Attorneys—Samuel L. Welt, Jon S. Saxe, Bernard S. Leon and Jacob Frank

ABSTRACT: An ultrasonic transducer assembly for use with a human or an animal body, comprising a flexible printed circuit means having a preset curvature, for supporting an array of ultrasonic transducer units electrically connected to the printed circuit for irradiating a selected section of a body with ultrasonic energy and focusing the reflected transmitted ultrasonic energy. The transducer assembly is usable for blood pressure monitoring by placement with an inflatable cuff about a body limb for detection of arterial wall motion induced by cuff pressure variations.



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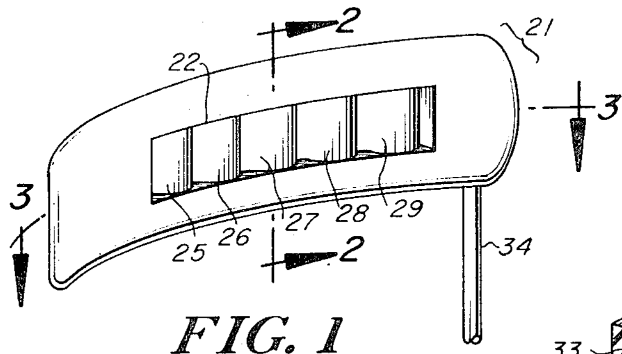

FIG. 1

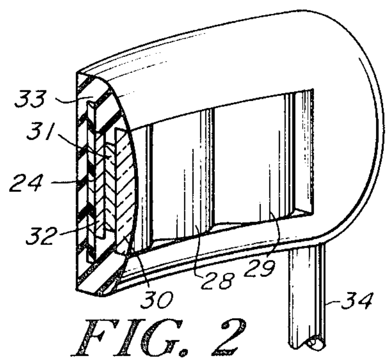

FIG. 2

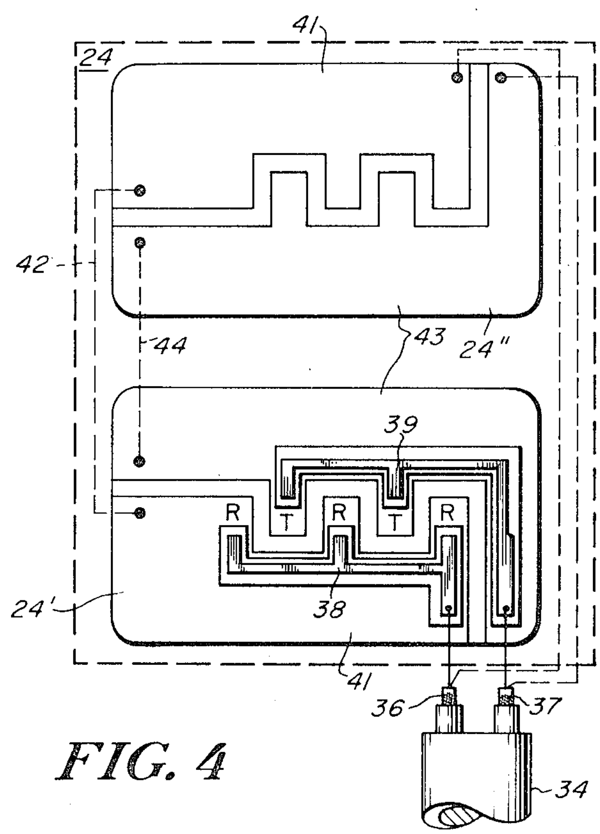

FIG. 4

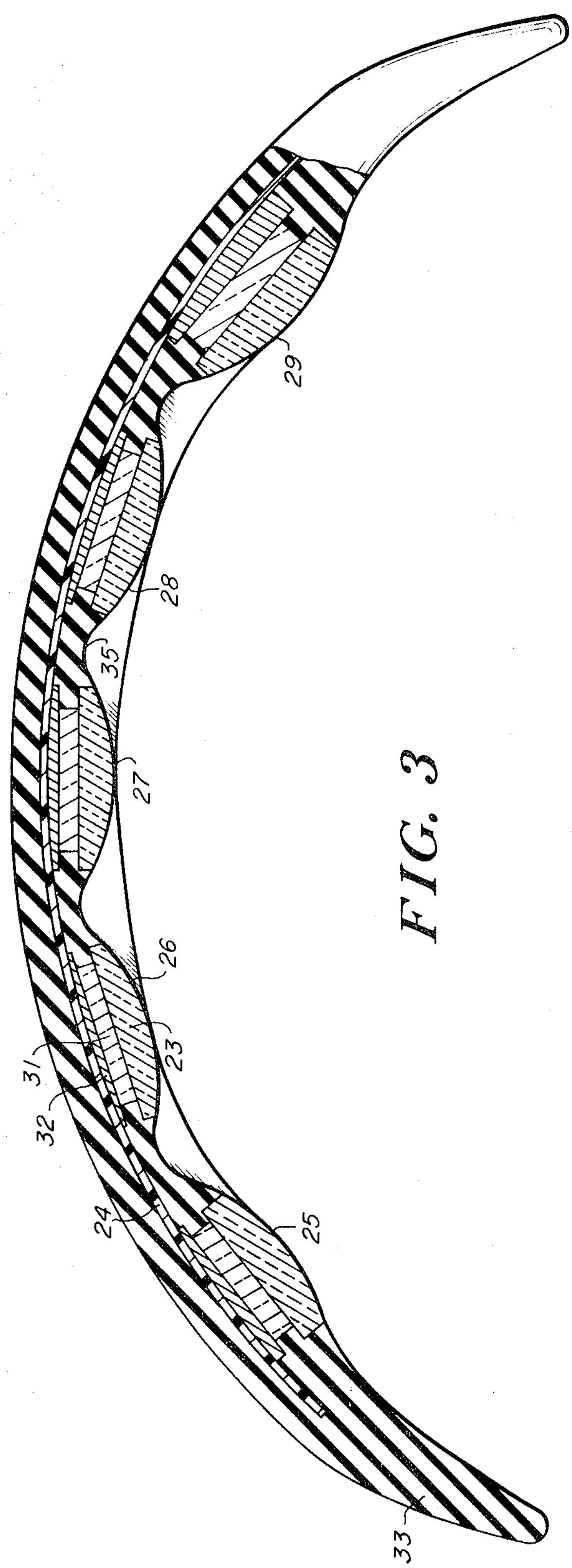

FIG. 3

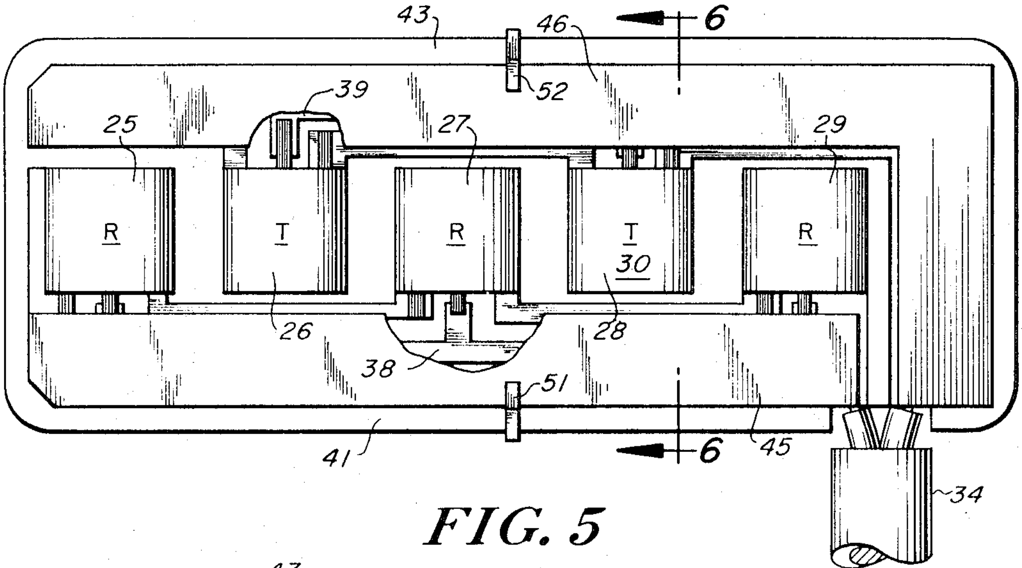

FIG. 5

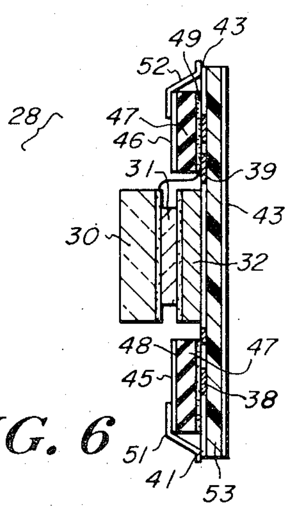

FIG. 6

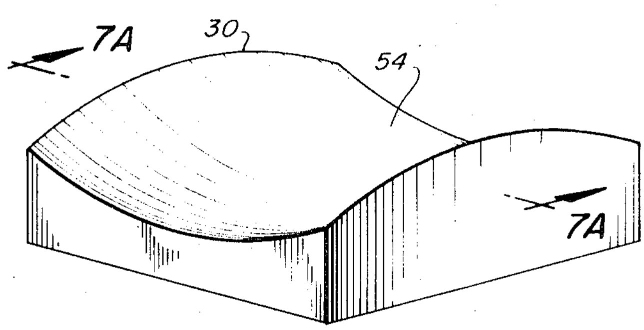

FIG. 7

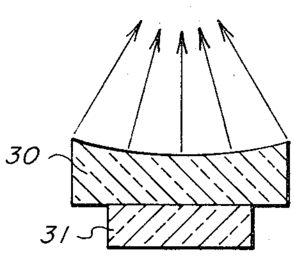

FIG. 7A

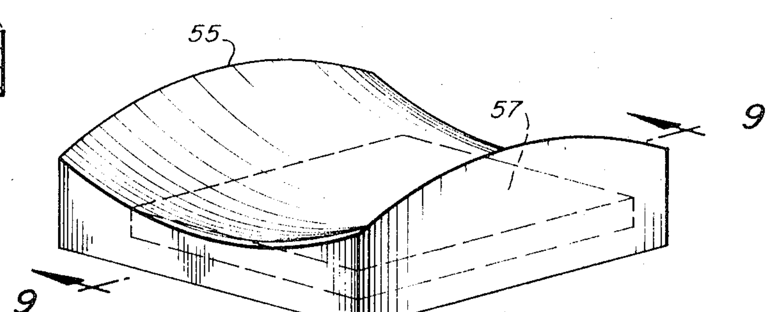

FIG. 8

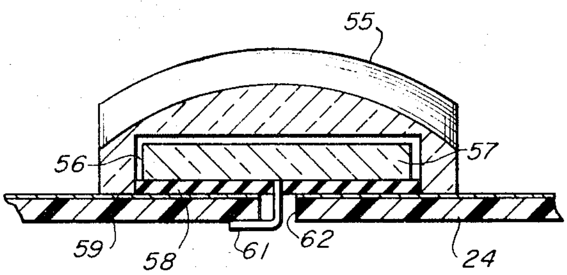

FIG. 9

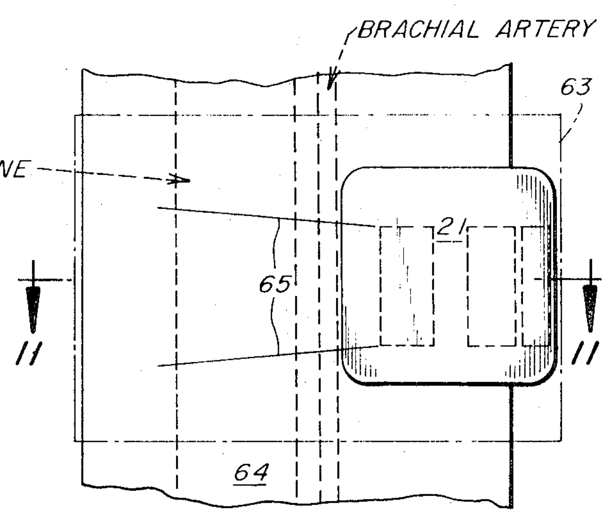

FIG. 10

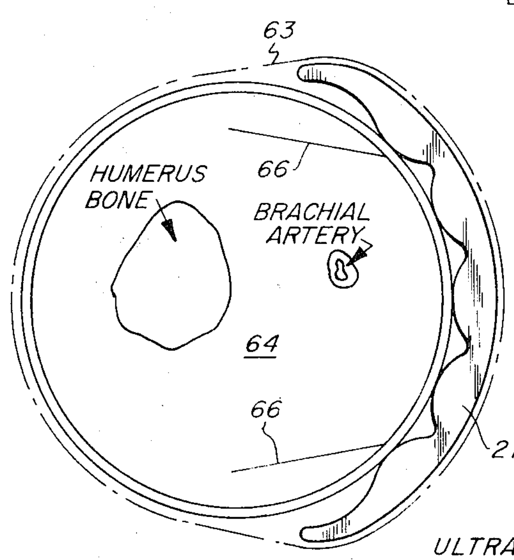

FIG. 11

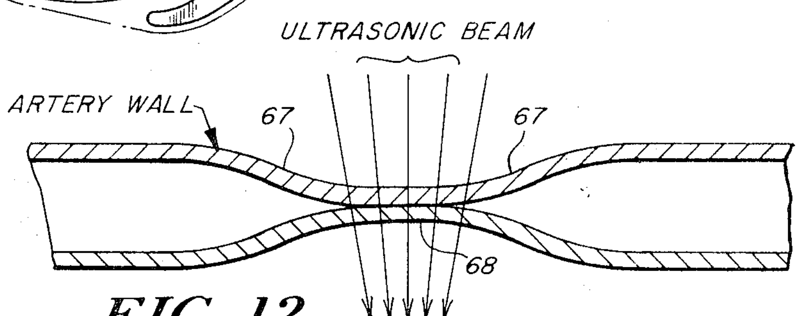

FIG. 12

ULTRASONIC TRANSDUCER ASSEMBLY FOR BIOLOGICAL MONITORING

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates in general to transducers, and, more particularly, to ultrasonic transducer apparatus for use in biological investigations.

2. Description of the Prior Art

In utilizing ultrasonic techniques for biological investigations several types of search units have been made available. Most of these units are of the type which are manually held against the body, are of bulky construction, and are not readily accommodated for body curvature.

Most of these devices were found to be unsuitable for use with a pneumatic cuff or similar mechanism for determining indirect movement of blood pressure values, by way of ultrasonics. In brief, this technique involves detecting motion of the wall of any artery constrictable under external occlusive pressure, by means such as an inflatable cuff, during the phase of rapid transition of the arterial wall between open and closed configurations. An ultrasonic transducer is employed under the cuff in close proximity to the skin surface for transmitting to and receiving ultrasonic energy from within a body limb. In implementation of this technique, systolic blood pressure can be observed from the external cuff or bladder pressure at the moment that the initially occluded artery first begins to momentarily change its shape from a closed to open configuration, and the diastolic pressure can be observed from the cuff or bladder pressure at the moment the artery ceases to be occluded during any part of the cardiac cycle. Such changes in arterial wall position are determined preferably by use of a Doppler ultrasonic technique, where the frequency of the reflected sound wave will deviate from the fixed frequency of the transmitted wave in proportion to the velocity of a movable surface which in the instant case is the arterial wall. The reflected sound wave, thus, is a wave frequency modulated in accordance with the velocity of the arterial wall.

After considerable study it was found that by merely placing an ultrasonic transducer under the cuff is not sufficient to provide data for reliably investigating arterial wall motion, for the reason that the lengthwise and lateral extension and size of an artery, such as the brachial artery within a human arm, varies from one person to another. In addition, arm diameter sizes varied from patient to patient.

Summary

The purpose of the present invention is to provide an ultrasonic transducer assembly for assuring reliable measurement of blood pressure values over a wide range of bodily variations, such as arm diameter. To attain this, the present invention contemplates an ultrasonic assembly including a flexible printed circuit board having a preset curved configuration and which board simultaneously serves to support on and provide an electrical connection with an array of transducer elements. The entire assembly, including lenses for the transducer elements, is electrically insulated to prevent any transfer of current to a patient. Other provisions of the present invention call for a recessed lens arrangement and a ceramic lens material which has physical characteristics similar to those of the transducer elements.

BRIEF DESCRIPTION OF THE DRAWINGS

Other advantages and capabilities of the invention will become apparent from the following description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a perspective view of the transducer assembly.

FIG. 2 is a cross-sectional view of the transducer assembly taken along line 2–2 of FIG. 1.

FIG. 3 is a cross-sectional view of the transducer assembly taken along line 3–3 of FIG. 1.

FIG. 4 is a schematic wiring diagram disclosing electrical hookup of the printed circuit board.

FIG. 5 is a top plan view of the transducer assembly with the potting compound removed.

FIG. 6 is a cross-sectional view of the transducer assembly taken along line 6–6 of FIG. 5.

FIG. 7 illustrates an alternate design for the lens portion of a transducer unit.

FIG. 7*a* shows a cross-sectional view of the alternate design taken along line 7*a*–7*a* of FIG. 7.

FIG. 8 depicts a perspective view of another form of transducer unit construction.

FIG. 9 is of cross-sectional view taken along line 9–9 of FIG. 8.

FIG. 10 is a schematic plan view of the transducer assembly and an occlusive cuff applied to an arm of a human subject.

FIG. 11 is a schematic cross-sectional view taken along line 11–11 of FIG. 10.

FIG. 12 is a schematic longitudinal cross-sectional view of a artery subjected to external occlusive pressure.

DESCRIPTION

There is illustrated in FIGS. 1, 2 and 3 a preferred embodiment of the present invention concerning an ultrasonic transducer assembly **21** having a surface defining a cavity **22** containing a plurality of exposed lenses representative of transducer units **25—29** arranged at equally spaced intervals between one another and adapted for dispersing a guided beam of ultrasonic energy and receiving reflected ultrasonic energy, as will be more fully described hereinafter.

As depicted in FIGS. 2 and 3 the transducer assembly basically includes a flexible printed circuit board **24** to the plurality of ultrasonic units **25—29** each comprising a transducer element **31**, such as a piezoelectric crystal, by way of individual transducer support boards **32**. The lens **30** of each transducer unit is secured to the crystal **31**. A flexible or semiflexible potting compound **33** serves to cover or encapsulate the printed circuit board and ultrasonic transducer units, as shown, except for leaving lenses **30** exposed. The top planar surface defined by he potting compound lays flush with the uppermost surfaces of lenses **30**. A cable **34** is electrically connected to the transducer assembly for delivering electrical energy to and/or deriving electrical energy from crystals **31**.

FIG. 3 depicts the normal preset curved configuration given to the transducer assembly, prior to crystal mounting, to assure minimum flexing of the assembly for utilization with a curved portion of a body surface. The absence of such a preset curved configuration would, upon application to the body with pressure, require the assembly to change from a flat to curved shape to conform with the curvature of the body area to which the assembly is applied, thereby materially changing the positioning of transducer units **25—29** to alter the effective energy transfer pattern thus reducing the reliability of the assembly as an input device to any particular system.

Also illustrated in FIG. 3 are a series of opening or recesses **35** in the potting compound between adjacent transducer units. Such a physical arrangement serves a threefold purpose including: reduction of ultrasonic cross-coupling; minimizing stress on bonding between lenses **30** and the potting compound; and enabling space **35** as well as cavity **22** to retain an ultrasonic coupling paste, which pastes are normally used as an intermediate medium when ultrasonic energy is applied to or derived from a patient.

A schematic circuit diagram of the transducer assembly is depicted in FIG. 4, wherein a cable **34**, including a pair of individually shielded wires **36**, **37**, or a single coaxial cable (common ground) are electrically connected to printed circuit board **24** having a subdivided circuit pattern on each the front and back portions **24'** and **24''** respectively. On the printed circuit board front face **24'**, the positioning of the receiver and transmitter crystals are respectively denoted as R and T for convenience. Also, at the front face **24'** are formed hot potential signal lines **38** and **39** to which are respectively connected in series the receiver (R) crystals of transducer units **25**, **27**, **29** and the transmitter (T) crystals of transducer units 26, 28. The subdivided pattern is such that the receiving and transmitting crystals are separated, having ground return signal lines 41 and 43, respectively or common ground, located at each side of the circuit board. The ground signal lines 41 at each side are connected via lead 42 whereas the ground signal lines 43 at each side are connected via lead 44. Cable wire 36 is tied to the receiver hot line 38 while its shield is connected to the associated ground line 41, whereby in similar fashion, cable wire 37 is tied to transmitter hot line 39 while its shield is connected to the associated ground line 43.

Although separate transmitting and receiving units are shown in an alternating arrangement along a longitudinal axis in the present embodiment, it should be understood that it might be expedient to have common transmitting and receiving units. In such a case, of course, only one hot potential line would be needed on the circuit board surface.

FIGS. 5 and 6 represent views of the transducer assembly less the encapsulating potting compound 33, wherein the receiver and transmitter hot lines 38 and 39, are shielded by RF shielding members 45 and 46 respectively each including a layer of insulation 47, such as fiberglass, clad with a copper coating 48. The RF shielding members are secured, by bonding agent 49, to the printed circuit board and are shown to overlap the adjacent ground lines 41, 43. The RF shield 45 is grounded to ground line 41 by way of a conductive band 51, whereas in a similar manner RF shield 46 is grounded to ground line 43 via a conductive band 52.

The printed circuit board basically, is a nonconductive flexible member 53 fabricated of fiberglass or other suitable material, and clad at each side with a thin layer of conductive material such as copper. As may be observed, the printed circuit board enables good electrical contact to be made with the crystal even with substantial flexing of the board enhancing its reliability. Prior to mounting the transducers, predetermined mechanical stresses are applied to shape the printed circuit board for altering the copper bonded at each side thereof, enabling the circuit board to normally present a precurved configuration. Potting compound 33 when applied aids to maintain said configuration.

Each of the transducer units as previously discussed, is similarly constructed with a piezoelectric crystal such as of lead zirconate titanate having the desired frequency resonance. The crystal is plated at each side (not shown) with a fine deposite of silver for purposes of making electrical contact to the transducers and electrical grounding. The underside of crystal 31 is bonded to a backing or transducer support board 32 to assure that the crystal is protected from any possibility of electrical shorting. For this reason the transducer support board is made of a nonconductive material like fiberglass, with a thin layer metallized surface at its underside enabling the support board to readily be soldered to the printed circuit board.

The type of lens selected for use with the crystal has been found to play an important role in the overall operation of the transducer assembly. The lens material selected must be such to: have similar physical characteristics to that of the crystal (piezoelectric materials) to reduce the effects of external stress and strain including thermal expansion; have a high ultrasonic velocity to maintain proper beam deflection from the crystal; and act as a good electrical insulator. The need for a relatively similar thermal expansion is necessary to prevent excessive strain on the crystal with varying temperatures, so that a good bond may be maintained intermediate the two members. A high ultrasonic velocity in the lens with respect to body tissue enables achievement of the desired maximum beam spread at the lens interface with body tissue. After extensive research, lenses of ceramic material and glass were found to best serve the desired functions, for example, alumina (Al_2O_3) was found to be highly desirable. Advantages of the alumina type lenses include such features as being mechanically strong, capable of being metallized, and being chemically inert so as not to be susceptible to ultrasonic coupling gels and alcohol or similar cleaning agents.

The overall transducer assembly, when applied about an arm and energized, will spread a pie-shaped like beam of ultrasonic energy as will be explained in greater detail hereinafter. A lens configuration selected to accomplish this end, may be best observed with respect to FIGS. 1, 3 and 5, wherein there is depicted a convex curvature across the lens 30 width for dispersing ultrasonic energy generated from the crystal by refraction at the lens-skin interface. In addition the convex curvature focuses reflections of the dispersed energy for reception purposes. Since the nature of flat ultrasonic transducers is that they generate a collimated ultrasonic beam and since the lenses have either flat surface or concave curvature in the length dimension, dispersion of ultrasonic energy in directions perpendicular to the longitudinal axis of the transducer assembly will be limited to a narrow section of the arm.

Another lens configuration especially conceived for this purpose is shown in FIGS. 7 and 7*a* where both convex and concave curvatures are designed within a depressed face 54 of the lens. An advantage of the latter embodiment is to narrow down the ultrasonic energy in the length dimension even more, so that the width of the ultrasonic beam falling on the artery would be reduced with an enchanced energy concentration allowing for a more accurate reading of artery motion.

An alternate approach in mounting the crystal with the lens is illustrated in FIGS. 8 and 9 where the electrically nonconductive lens 55 is provided with a rectangular cavity 56 at its backside. The lens 55 serves as a housing for the crystal 57 which is recessed within the housing allowing it to be spaced from the circuit board by an insulating member 58 such as silicone, epoxy or other suitable material. The peripheral surface about the bottom edge 59 of the housing is soldered to the printed circuit board 24. Electrical contact of crystal 57 with the board wiring is achieved by conductive straps 61 extending through apertures 62 in the printed circuit board and connected to the positive potential of the circuit.

In FIGS. 10 and 11 it is illustrated how the transducer assembly 21 is employed in combination with a conventional inflatable pneumatic cuff 63 (shown in phantom) placed about an arm 64 for utilizing an ultrasonic technique to measure blood pressure values. As previously noted, this technique involves use of the Doppler effect for detection of wall motion of an artery, such as the brachial artery, constrictable under external occlusive pressure during the phase of rapid transition of the arterial wall between open and closed configurations. The opening and closing arterial wall motion made mention to, will occur within that portion of the arm subject to the pneumatic cuff. Accordingly, the preset curved transducer assembly 21 is positioned between the cuff and arm, so that its lengthwise dimension is wrapped about the arm to partially environ its outer circumference.

As a result of the preset curved configuration and flexibility of the printed circuit support board, the transducer assembly will, with minimum flexing, readily conform with the arcuate surface of the arm about which it is placed with minimum strain between the printed circuit board and the transducer units or the bonded encapsulating insulation material, thus enhancing the reliability of the unit as a whole. The flexibility of the printed circuit boards allows for changes in its curvature when it is used on different arm diameter sizes. In addition, as a consequence of obviating the protrusion of directly in the arm by containing the transducing units within cavity or pocket 22 of the transducer assembly, the occlusive properties of the cuff will not be materially affected. At the same time, the pocket will retain an ultrasonic coupling gel inserted therein to maintain good contact with the arm, thus obviating any concern over the gel being squeezed out with the application of cuff pressure.

By way of the safety design concepts incorporated in the transducer assembly, the crystal upperside is insulated from the patient by the ceramic lens which may comprise of the special housing configuration shown in FIGS. 8 and 9, whereas the remainder of the transducer assembly is potted in the nonconductive potting compound, assuring that no electrical components will come in contact with a patient. Also, the support board protects the crystal underside from electrical shorting.

OPERATION

In operation, the transducer assembly, is applied about an arm under a pneumatic cuff **63** as depicted in FIGS. **10** and **11**. As pressure within the cuff is increased only a minimum flexing of the transducer assembly will occur in use with any one of a large range of arm sizes due to the initial preset curved configuration of the assembly.

Excitation of crystals **31** of transmitting units **26** and **28** by a suitable oscillating source via cable **34** will cause a generation of ultrasonic energy which, by way of lenses **30**, is guided to irradiate across the arm of beam of predetermined design, as illustrated in FIGS. **10** and **11**, that is narrow **65** along a first plane and spread **66** along a second plane perpendicular to the first. With such a beam configuration it is probable that with an initial placement of the transducer assembly on the arm the beam coverage will easily include the artery, thereby minimizing critical transducer placement. Spacing between the individual transducer units **25—29** is selected on the bases of available beam spread to assure proper beam overlap near the surface of the lenses. Reflections of the ultrasonic energy illuminating the artery will then be detected by the receiving units **25, 27** and **29**.

The advantage of the narrow beam configuration may be readily realized with reference to FIG. **12**, wherein it is shown that the arrangement reduces the error in sensing the motion of the artery from the partly occluded wall **67** as opposed to the occluded portion **68** which moves with a relatively faster velocity, thus, enabling more distinct Doppler signals to be detected.

Of course, as to the actual number of transducer units employed, it should be understood that the number of units to be used depends on the relative size of the crystals and the area of the arm to be covered. For the particular embodiment discussed above, it was found that a minimum coverage of three-quarters of the internal area of an average arm to be quite satisfactory.

I claim:

1. An ultrasonic transducer assembly for use on a human or animal body comprising:

printed circuit means resilient about a transverse axis and extending longitudinally to define a longitudinal axis perpendicular to said transverse axis,

said printed circuit means shaped to normally present a curved configuration to minimize flexing of the transducer assembly with varying shaped body surfaces;

a plurality of ultrasonic transducer means; and

means for electrically connecting and supporting each one of said transducer means on said printed circuit means in spaced relation along its longitudinal axis.

2. An ultrasonic transducer assembly according to claim **1** whereby each of said ultrasonic transducer means includes:

an ultrasonic transducer element; and

separate electrically insulating lens means secured to said transducer element.

3. An ultrasonic assembly according to claim **2** whereby said printed circuit means includes:

flexible electrically insulting compound means for encapsulating said printed circuit means and said ultrasonic transducer elements; and

an elongated cavity defined by said compound means in which said lens means are exposed.

4. An ultrasonic transducer assembly according to claim **3** whereby,

said compound means forms a top planar surface about said cavity and the upper surface of said lens means is substantially flush with said top planar surface.

5. An ultrasonic transducer assembly according to claim **2** whereby,

said ultrasonic element is of piezoelectric material; and

said lens means is of ceramic having a similar thermal expansion as its related ultrasonic element and a relatively high ultrasonic velocity with respect to body tissue.

6. An ultrasonic transducer assembly according to claim **5** whereby:

said ceramic lens is fabricated of alumina (Al_2O_3).

7. An ultrasonic transducer assembly according to claim **5** whereby,

said ceramic lens means defines a housing having an aperture in which said ultrasonic element is contained.

8. An ultrasonic transducer assembly according to claim **2** whereby said supporting means includes:

electrically insulating means bonded to said printed circuit means for supporting said transducer element.

9. An ultrasonic transducer assembly according to claim **2** whereby:

said lens means has a convex shape about an axis parallel with said transverse axis and a concave shape about an axis parallel with said longitudinal axis.