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(54) **ACOUSTIC WINDOW FOR ULTRASOUND PROBES**

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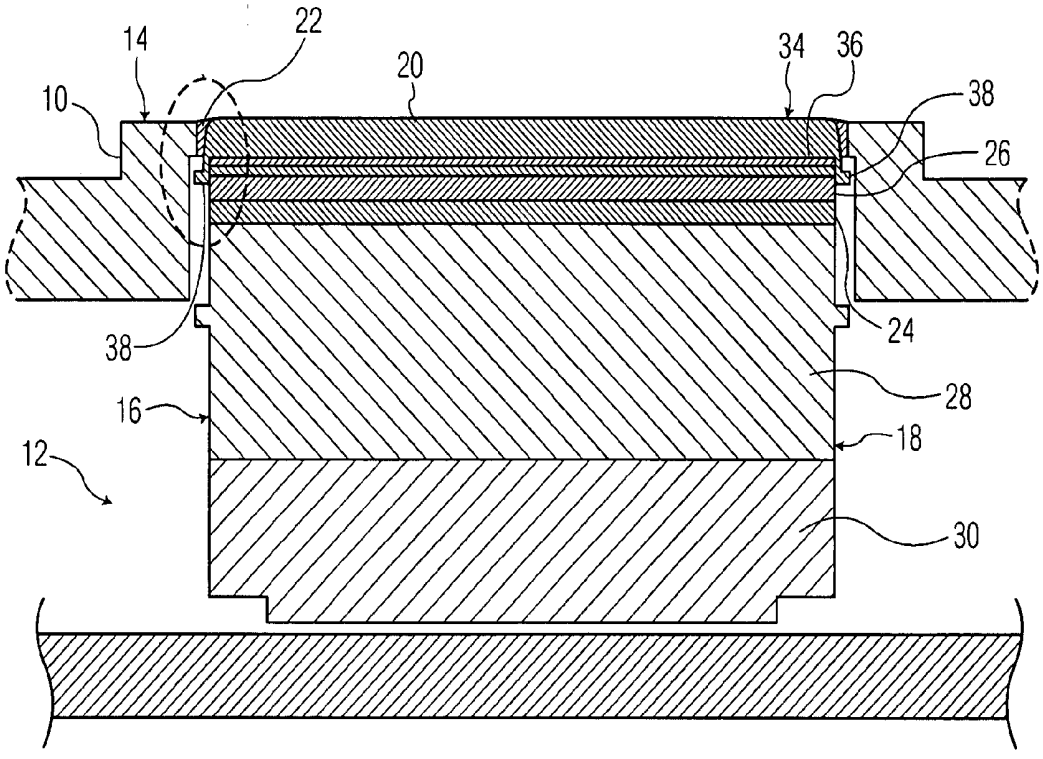
(57) **ABSTRACT**

Acoustic window for an ultrasound probe including a layer of PEBAX™ having a surface adapted to face a transducer array and an opposed surface adapted to face the object being examined and optionally impervious polymer layers arranged on one or both surfaces of the PEBAX™ layer. An outer polymer layer on the object-facing surface, when present, protects the PEBAX™ layer from chemicals while the inner polymer layer on the transducer array-facing surface, when present, is bonded to the transducer array of the probe. The polymer layers may each be made from an impervious polymer which has a negligible acoustic impact including, for example, polyethylene, Mylar™ and Kapton™. A method for manufacturing the acoustic window and an ultrasound probe including the same are also disclosed.



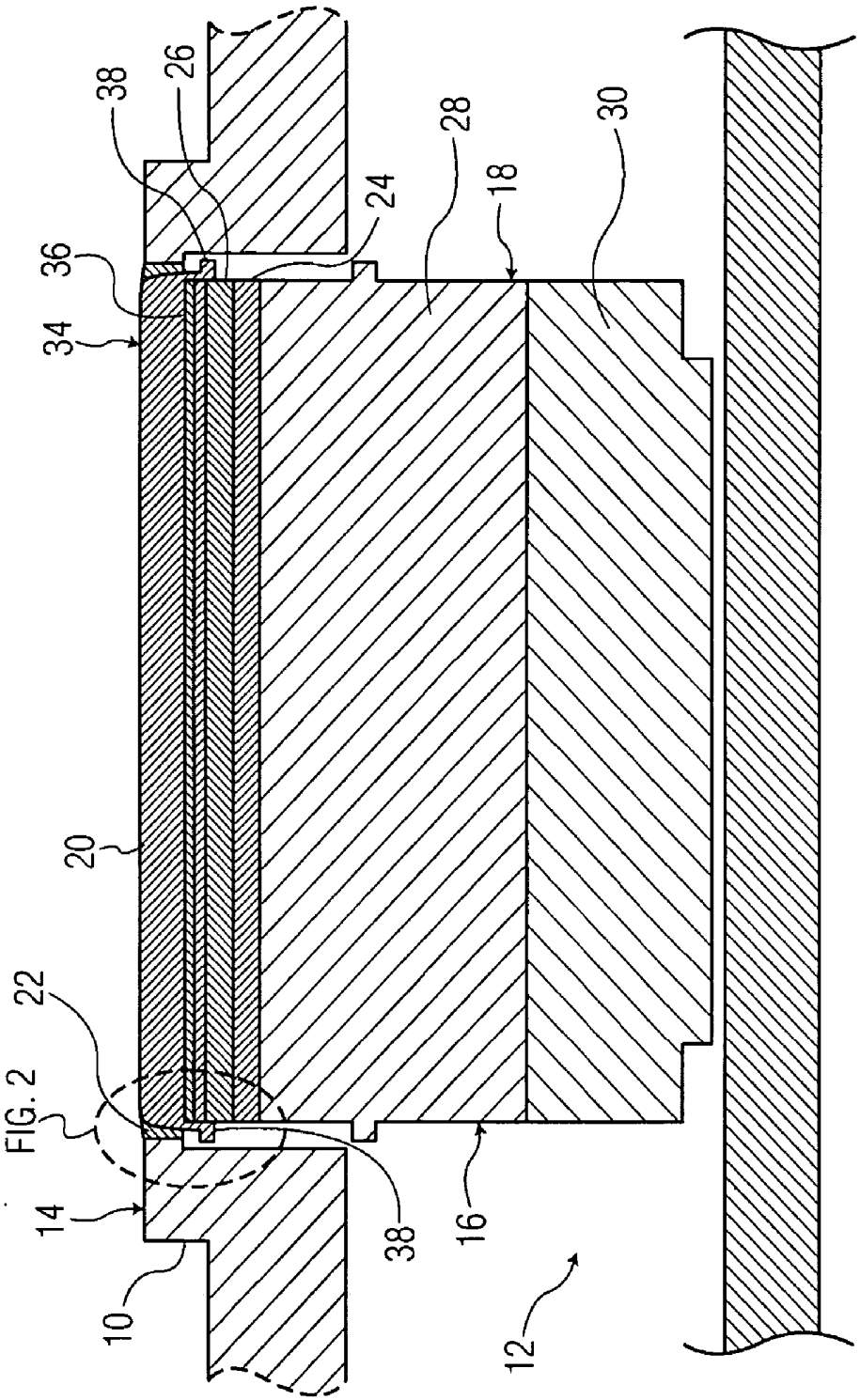


FIG. 1

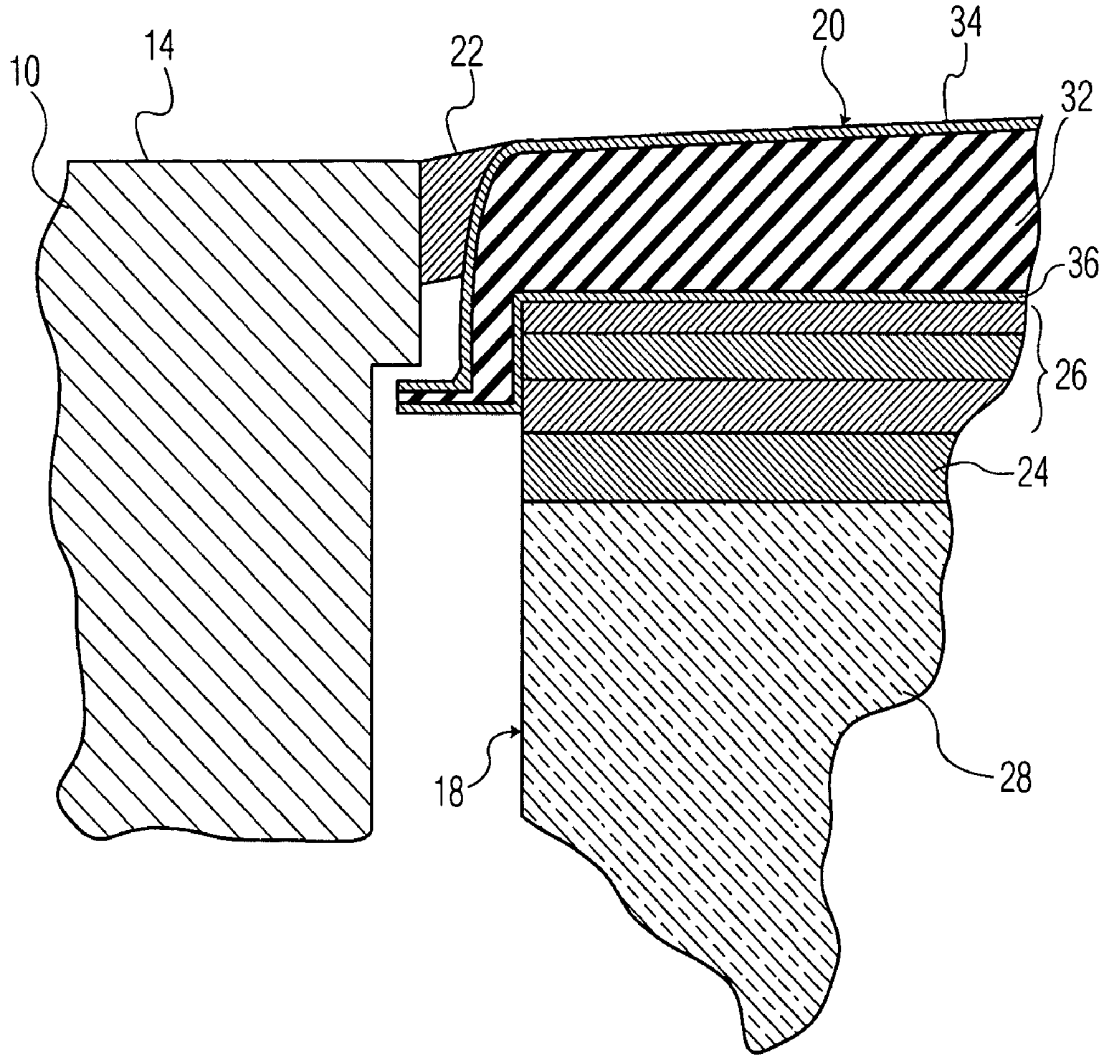


FIG. 2

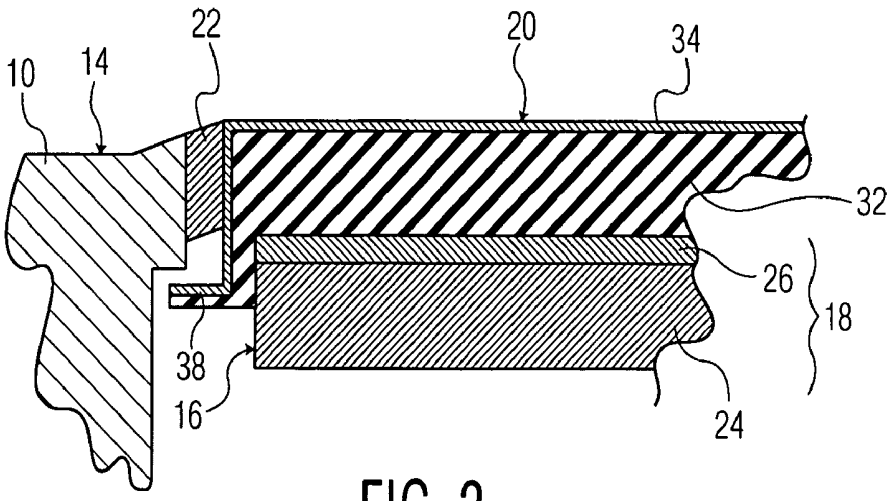


FIG. 3

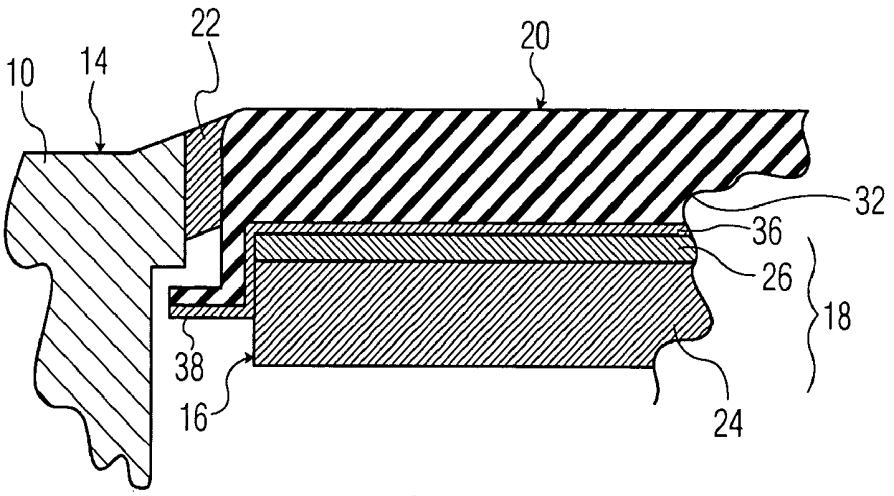


FIG. 4

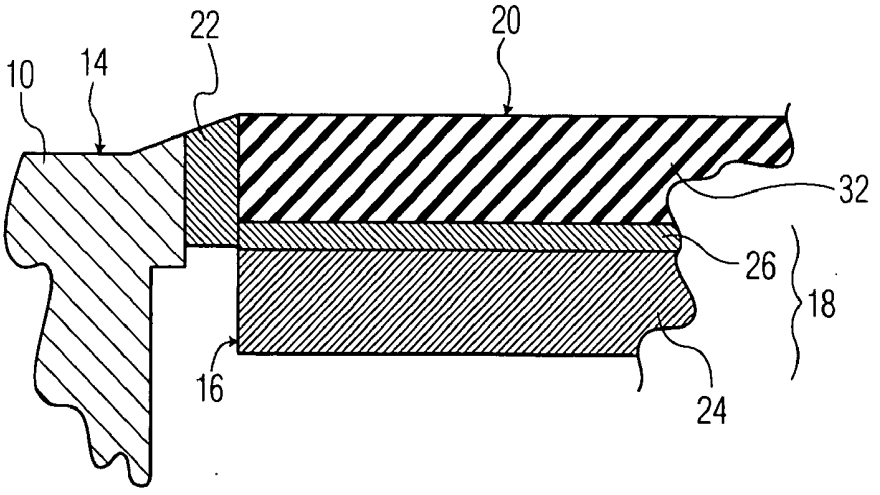


FIG. 5

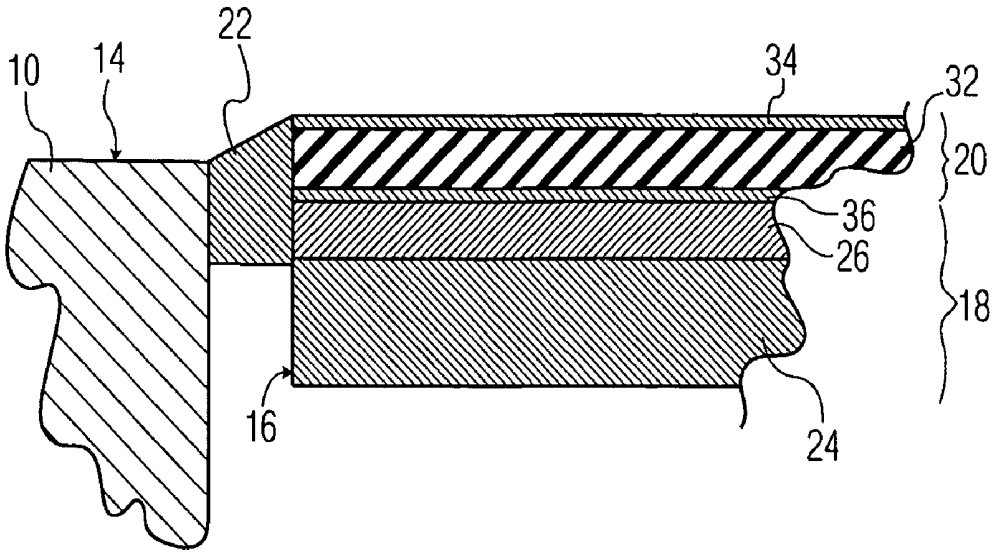


FIG. 6

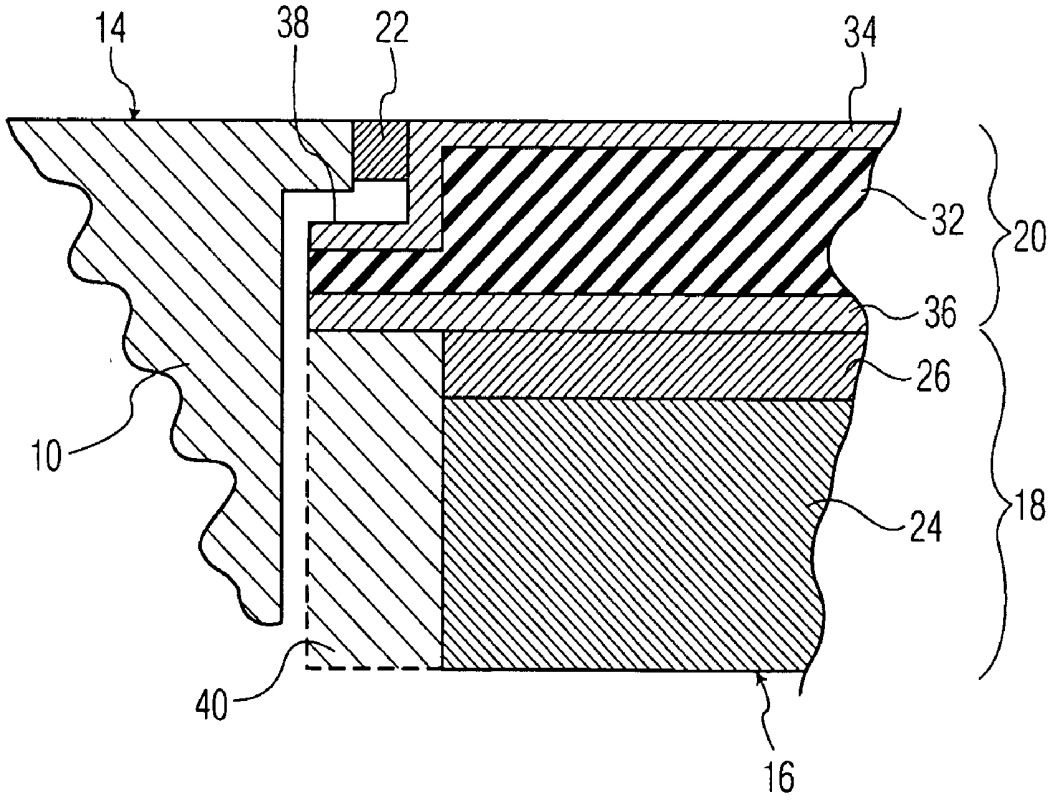


FIG. 7

ACOUSTIC WINDOW FOR ULTRASOUND PROBES

CROSS REFERENCE TO RELATED CASES

[0001] Applicants claim the benefit of Provisional Application Ser. No. 60/539,302, filed 26 Jan. 2004.

FIELD OF THE INVENTION

[0002] The present invention relates generally to ultrasound probes and more particularly to an acoustic window for ultrasound probes and a method for manufacturing the same.

BACKGROUND OF THE INVENTION

[0003] Ultrasound probes are commonly used for imaging internal body parts. Typically, an ultrasound probe includes an outer hard plastic body, usually referred to as a housing for transesophageal echocardiographic (TEE) probes and as a nose for transthoracic or intracavity probes, an acoustic window fixed to the housing/nose and a transducer array arranged in the housing/nose. The transducer array is sometimes referred to in the art as an acoustic stack assembly and usually includes a layer of piezoelectric material, one or more acoustic matching layers adjacent the active surface of the piezoelectric material and a backing layer on the reverse side of the piezoelectric material.

[0004] During use of all of these possible products, an outer surface of the acoustic window is exposed to the surrounding environment and thus the acoustic window serves as the interface between the transducer array and the surrounding environment. Ultrasonic waves generated by the transducer array pass through the acoustic window in their path toward and from the body parts being imaged. The acoustic window also contacts the patient to ensure optimal acoustic conditions.

[0005] Various factors are considered when selecting materials from which to construct the acoustic window of an ultrasound probe. It is desired that the acoustic window is formed from a material that has an acoustic impedance which matches, or at least closely approximates, that of the human body part being imaged, such as the tissue of the human body. Acoustic impedance is based on the elasticity, mass density and speed of sound of the material. Additional characteristics of the material include acceptable mechanical and electrical performance, biocompatibility, chemical resistance, low attenuation and stability to ultraviolet rays.

[0006] One particular material that has excellent mechanical and electrical performance, the desired impedance and velocity characteristics of the human body as well as low attenuation is a particular polymer block amide called PEBAX™ (sold by Autochem). However, an unfortunate property of PEBAX™ is its acute susceptibility to solvents, particularly isopropyl alcohol, which is a disinfectant commonly used to clean ultrasound probes after use. Disinfection of ultrasound probes should be performed after each use of the probe, especially for transesophageal echocardiographic (TEE) probes which are inserted into a patient's throat during the imaging procedure. Disinfection is also required for intracavity probes, which are usually highly contaminated, and for intraoperative probes, which must be high-level disinfected and used with a sterile sheath. In view of this susceptibility, PEBAX™ was not considered for use in an acoustic window of a reusable ultrasound probe.

OBJECTS AND SUMMARY OF THE INVENTION

[0007] It is an object of the present invention to provide a new and improved acoustic window for use in ultrasound probes, ultrasound probes including the same and a method for manufacturing the same.

[0008] It is still another object of the present invention to provide a new and improved acoustic window including PEBAX™ which overcomes the problem which prevented the use of PEBAX™ in prior art acoustic windows, and an ultrasound probe including the same.

[0009] It is yet another object of the present invention to provide a new and improved method for manufacturing an acoustic window including PEBAX™ for use in an ultrasound probe and an acoustic window manufactured thereby.

[0010] In order to achieve these objects and others, an acoustic window for an ultrasound probe in accordance with the invention includes a PEBAX™ layer having a first surface adapted to face a transducer array and an opposed surfaces adapted to face outward toward the object being examined, a first layer of an impervious polymer arranged on the first surface of the PEBAX™ layer and a second layer of an impervious polymer arranged on the second surface of the PEBAX™ layer. The PEBAX™ layer is thus sandwiched between the polymer layers. The polymer layers may be bonded to the PEBAX™ layer, e.g., by using heat and/or a primer, with the PEBAX™ itself acting as an adhesive, or by providing an adhesive between the polymer layers and the PEBAX™ layer.

[0011] The polymer layers may each be made from any type of impervious polymer which preferably has a negligible acoustic impact including, but not limited to, polyethylene, Mylar™ and Kapton™. A different polymer can be used for each polymer layer if desired or the same polymer can be used for both layers.

[0012] An alternative construction of the acoustic window includes a layer of PEBAX™ having opposed surfaces and only a layer of an impervious polymer arranged on an upper surface of the PEBAX™ layer which is designed to be exposed to the ambient atmosphere, i.e., come into contact with the patient. In this case, the PEBAX™ layer is attached directly to the upper surface of the transducer array, possibly by heat, pressure, primers and/or adhesives. Also, the polymer layer would preferably be sealed with an impervious seal to the housing of the probe into which the transducer assembly is installed in order to prevent ingress of solvent into the PEBAX or the probe.

[0013] Another alternative construction of the acoustic window would be to provide only a polymer layer between the PEBAX™ layer and the transducer array in which case the upper surface of the PEBAX™ layer is exposed. In yet another alternative construction, the acoustic window could consist of only the PEBAX™ layer, without any covering polymer layers. In both of these constructions, care would have to be taken to limit solvent exposure.

[0014] A method for manufacturing an acoustic window in accordance with the invention entails providing a layer of

PEBAX™ and sandwiching the PEBAX™ layer between a first impervious polymer layer and a second impervious polymer layer. The polymer layers are preferably bonded to the PEBAX™ layer to prevent separation therefrom.

[0015] An ultrasound probe in accordance with the invention includes a housing defining a cavity extending inward from a peripheral surface, a transducer array arranged in the cavity of the housing to produce ultrasound beams, and an acoustic window as described above attached or bonded directly to the transducer array. The transducer array may include independently-addressable transducer elements such that ultrasound beams in various planes and volumes can be generated thereby. The housing may be in the form of a housing for a transesophageal echocardiographic ultrasound probe or transnasal probe, or a nose for a transthoracic, intracavity or intraoperative probe. Thus, as used herein, a "housing" of an ultrasound probe may be either a housing per se or a nose depending on the type of probe.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The invention, together with further objects and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals identify like elements.

[0017] **FIG. 1** is a cross-sectional view of a portion of a first embodiment of a generic ultrasound probe taken through the transducer assembly.

[0018] **FIG. 2** is an enlarged view of the section designated A in **FIG. 1**.

[0019] **FIG. 3** is a cross-sectional view of a portion of a second embodiment of a generic ultrasound probe in accordance with the invention taken through the transducer assembly.

[0020] **FIG. 4** is a cross-sectional view of a portion of a third embodiment of a generic ultrasound probe in accordance with the invention taken through the transducer assembly.

[0021] **FIG. 5** is a cross-sectional view of a portion of a fourth embodiment of a generic ultrasound probe in accordance with the invention taken through the transducer assembly.

[0022] **FIG. 6** is a cross-sectional view of a portion of a fifth embodiment of a generic ultrasound probe in accordance with the invention taken through the transducer assembly.

[0023] **FIG. 7** is a cross-sectional view of a portion of a sixth embodiment of a generic ultrasound probe in accordance with the invention taken through the transducer assembly.

DETAILED DESCRIPTION OF THE INVENTION

[0024] Referring to the accompanying drawings wherein like reference numerals refer to the same or similar elements, an ultrasound probe in accordance with the invention includes an outer hard plastic body **10**, referred to herein as a housing, defining a cavity **12** extending inward from an opening in a peripheral surface **14** and a transducer assembly **16** arranged in the cavity **12**. Housing **10** can be shaped in the form of any type of transthoracic, intracavity, TEE, transnasal probe or any other type of ultrasound probe. Housing **10** and the transducer assembly **16** in accordance with the invention can also be used in any imaging device in the medical field.

[0025] Transducer assembly **16** includes a transducer array **18** and an acoustic window **20** fixed, attached or bonded directly to the transducer array **18** to thereby form a transducer assembly **16** with an integral acoustic window **20**. The direct fixing or attachment of the acoustic window **20** to the transducer array **18** may be accomplished through the use of an adhesive. The transducer array **18** includes a layer of piezoelectric material **24**, one or more acoustic matching layers **26** adjacent the active surface of the piezoelectric material **24** and a backing layer **28** on the reverse side of the piezoelectric material **24**.

[0026] To prevent fluids which come into contact with the acoustic window **20** from entering into the interior of the housing **10** during use of the ultrasound probe, a seal **22** is arranged between the housing **10** and the acoustic window **20**. The seal **22** is made of a flexible material and should be sufficiently impermeable to fluids and materials such as those used during an ultrasound examination which are known to those skilled in the art.

[0027] The flexible seal **22** may be matched with the durometer of the acoustic window **20** and will thus conform to the shape of the acoustic window **20** if the acoustic window **20** is impacted.

[0028] Transducer array **18** includes a layer of piezoelectric material **24**, an acoustic matching section **26** adjacent the active surface of the piezoelectric layer **24** and a backing layer **28** on the opposite side of the piezoelectric layer **24** from the acoustic matching section **26**. The acoustic matching section **26** may contain one or more acoustic matching layers. The acoustic window **20** is attached to the upper surface of the acoustic matching section **26**. Although a heatsink **30** is shown under the backing layer **28**, this is an optional feature and is used only in certain types of ultrasound probes.

[0029] The transducer array **18** is preferably constructed as a matrix array for which it is not necessary to provide lateral focus through the use of a lens. The transducer elements in the piezoelectric layer **24** are thus independently addressable and are connected to an integrated circuit which is connected in turn to a circuit board. The transducer elements may be segmented into (or designated as) transmit sub-arrays and receive sub-arrays. Each transmit sub-array may be connected to a respective intra-group transmit pre-processor which is connected to a respective transmit beamformer channel. Each receive sub-array may be connected to a respective intra-group receive pre-processor which is connected to a respective receive beamformer channel. Control of the sub-arrays is obtained by a control processor in a manner known in the art, for example, as disclosed in U.S. Pat. No. 6,572,547 incorporated by reference herein.

[0030] A matrix array will therefore be considered as a type of transducer array which is capable of generating multi-planar images on an object by appropriate electronic control of transducer elements of the transducer array.

[0031] Alternatively, a conventional two-dimensional array in which the transducer elements themselves are

curved to provide the focus could be used in combination with the acoustic window **20**. Furthermore, in another alternative use, the acoustic window **20** could be bonded on top of a conventional lens material to form a window or standoff.

[**0032**] Referring now to **FIG. 2**, in accordance with the invention, the acoustic window **20** includes an elastomer layer **32** sandwiched between upper and lower polymer layers **34**, **36**, respectively, with the upper polymer layer **34** defining an outer, exposed surface of the transducer assembly **16**. The lower polymer layer **36** is attached directly to the upper surface of the acoustic matching section **26** of the transducer array **18** without any gap therebetween.

[**0033**] The elastomer layer **32** is made of PEBAX™ which is sandwiched between the two polymer layers **34**,**36**, e.g.;, thin films of polymer, and the polymer layers **34**, **36** and PEBAX™ layer **32** are bonded to one another. The polymer layers **34**,**36** will therefore not separate from the PEBAX™ layer **32** during mechanical stress or environmental cycling.

[**0034**] Bonding of the polymer layers **34**,**36** to the PEBAX™ layer **32** can be accomplished in several ways. For example, the PEBAX™ layer **32** can be primed and/or heated, such that it acts as an adhesive to cause the polymer layers **34**,**36** to be bonded thereto. In addition to or instead of priming the PEBAX™ layer **32**, it is possible to provide adhesive between each polymer layer **34**,**36** and the PEBAX™ layer **32**.

[**0035**] Bonding of materials directly to PEBAX™ is often problematic. Thus, in the invention, by providing the lower polymer layer **36**, the transducer array **18** can be bonded more easily to the lower polymer layer **36** than to the PEBAX™ layer **32**. On the other hand, providing the upper polymer layer **34** protects the PEBAX™ layer **32** from scratches and other types of mechanical damage and also creates a barrier that eliminates chemical susceptibility.

[**0036**] PEBAX™ is a moldable material and therefore lends itself nicely to the production of acoustic windows having various shapes and sizes. PEBAX™ can also be blended with polyethylene or other materials to tailor its properties. It is available in a range of durometers, several of which are appropriate for use in an acoustic window.

[**0037**] The polymer layers **34**, **36** may each be made from any type of impervious polymer which preferably has a negligible acoustic impact including, but not limited to, polyethylene, Mylar™ and Kapton™. A different polymer can be used for each polymer layer **34**, **36** if desired or the same polymer can be used for both polymer layers **34**,**36**.

[**0038**] Although the embodiment of the acoustic window **20** shown in **FIG. 2** includes both an upper polymer layer **34** and a lower polymer layer **36**, it is possible to construct an acoustic window without the lower polymer layer **36**. In this embodiment, shown in **FIG. 3**, the PEBAX™ layer **32** is bonded directly to or formed directly on the upper surface of the transducer array **18**, i.e., the upper surface of the acoustic matching section **26** of the transducer array **18**.

[**0039**] The acoustic window **20** may have a larger cross-sectional area than the acoustic matching section **26** so that a portion of the acoustic window **20** is situated alongside the acoustic matching **26**. The lower polymer layer **36** is therefore bonded to the lateral edge of the acoustic matching section **26** (see **FIG. 2**) or may have a cross-sectional area which is substantially the same as the acoustic matching section **26** (see **FIGS. 5 and 6**). The acoustic window **20** has an extended section **38** alongside an upper portion of the transducer array **18** which serves to create a convoluted path (in combination with the peripheral surface of the cavity of the housing **10** into which the transducer assembly **16** is placed) to prevent fluids from entering into the interior of the housing **10**. This improves the electrical safety of the probe. Further, the presence of the upper polymer layer **34** provides an easy bonding of the acoustic window **20** to the seal **22**.

[**0040**] By covering at least the portion of the PEBAX™ layer **32** which would otherwise be exposed to the surrounding environment with the upper polymer layer **34**, the outer, exposed surface of the acoustic window **20** is defined by the upper polymer layer **34** and therefore disinfectants such as isopropyl alcohol can come into contact with the upper polymer layer **34** but do not come into contact with PEBAX™ layer **32**. This avoids the problems which arise when PEBAX™ layer **32** comes into contact with such disinfectants.

[**0041**] The acoustic window **20** described above can be used in various types of ultrasound probes having transducer arrays. For example, the acoustic window can be formed in a transesophageal echocardiographic (TEE) ultrasound probe, transnasal ultrasound probe, a transnasal echocardiographic ultrasound probe, an intra-operative ultrasound probe or an intracavity ultrasound probe.

[**0042**] It is also envisioned that the acoustic window **20** is formed without the upper polymer layer **36**, i.e., with only a single lower polymer layer **36** between the transducer array **18** and the acoustic window **20** (as shown in **FIG. 4**), or without both the upper and lower polymer layers **34**,**36** (as shown in **FIG. 5**) with the PEBAX™ layer **32** being formed directly on the transducer array **18** as discussed above. In this case, since the PEBAX™ layer **32** is exposed to the surrounding environment, the use of disinfectants which are not compatible with PEBAX™ would be prohibited. These designs could also be utilized for a single-use device.

[**0043**] **FIG. 6** shows an embodiment wherein the acoustic window **20** includes the PEBAX™ layer **32** and the upper and lower polymer layers **34**,**36**. In this embodiment, as well as in the embodiment shown in **FIG. 5**, the acoustic window **20** does not extend beyond the lateral edges of the transducer array **18**. Thus, the dimensions of the transducer array **18** and the acoustic window **20** are substantially the same. The seal **22** thus engages the acoustic window **20** and a part of the transducer array **18**.

[**0044**] **FIG. 7** shows another embodiment wherein the acoustic window **20** includes the PEBAX™ layer **32** and the upper and lower polymer layers **34**,**36**. In this embodiment, the acoustic window **20** does not have an extended portion **38** alongside the transducer array **18** and thus is entirely above the transducer array **18**. That is, as shown in **FIGS. 2-4**, a portion of the acoustic window **20** is alongside the acoustic matching section **26** of the transducer array **18**. By appropriate construction of the housing **10**, it is possible to create a convoluted path between the housing **10** and the acoustic window **20** to prevent fluids from entering into interior of the housing. To support the portion of the acoustic

window **20** extending laterally beyond the transducer array **18**, an optional support **40** (shown in dotted lines) may be provided.

[**0045**] Although illustrative embodiments of the present invention have been described herein with reference to the accompanying drawings, it is to be understood that the invention is not limited to these precise embodiments, and that various other changes and modifications may be effected therein by one of ordinary skill in the art without departing from the scope or spirit of the invention.

1. An acoustic window for an ultrasound probe, comprising:

a layer of PEBAX™ having a first surface adapted to face a transducer array and an opposed second surface adapted to face an object being examined;

an optional first layer of an impervious polymer arranged on said first surface of said PEBAX™ layer; and

an optional second layer of an impervious polymer arranged on said second surface of said PEBAX™ layer such that when said first and second polymer layers are present, said PEBAX™ layer is sandwiched between said first and second impervious polymer layers.

2. The acoustic window of claim 1, wherein the acoustic window includes said first and second polymer layers and said first and second polymer layers are bonded to said PEBAX™ layer.

3. The acoustic window of claim 2, further comprising an adhesive interposed between said first and second polymer layers and said PEBAX™ layer for bonding said first and second polymer layers to said PEBAX™ layer.

4. The acoustic window of claim 1, wherein said first and second polymer layers are each made from polyethylene, Mylar™ or Kapton™.

5. The acoustic window of claim 1, wherein the acoustic window includes said first and second polymer layers and said first and second polymer layers are made from a different impervious polymer.

6. The acoustic window of claim 1, wherein the acoustic window includes only said first polymer layer and not said second polymer layer.

7. The acoustic window of claim 1, wherein the acoustic window includes only said second polymer layer and not said first polymer layer.

8. The acoustic window of claim 1, wherein the acoustic window consists of only said PEBAX™ layer.

9. A method for manufacturing an acoustic window, comprising the steps of:

providing a PEBAX™ layer; and

sandwiching the PEBAX™ layer between a first layer of an impervious polymer and a second layer of an impervious polymer.

10. The method of claim 9, further comprising the step of bonding the first and second polymer layers directly to the PEBAX™ layer.

11. The method of claim 9, wherein the step of bonding the first and second polymer layers to the PEBAX™ layer comprises the step of at least one of priming and heating the PEBAX™ layer such that it acts as an adhesive.

12. The method of claim 9, wherein the step of bonding the first and second polymer layers to the PEBAX™ layer comprises the step of arranging an adhesive between each of the first and second polymer layers and the PEBAX™ layer.

13. An ultrasound probe, comprising:

a housing defining a cavity extending inward from an opening in a peripheral surface;

a transducer array arranged in said cavity of said housing to produce ultrasound beams, said transducer array comprising a plurality of independently-addressable transducer elements such that ultrasound beams in various planes and volumes are generateable by said transducer elements; and

an acoustic window attached to said transducer array, said acoustic window comprising a layer of PEBAX™ having a first surface arranged to face said transducer array and an opposed second surface arranged to face outward, an optional first layer of an impervious polymer arranged on said first surface of said PEBAX™ layer and an optional second layer of an impervious polymer arranged on said second surface of said PEBAX™ layer such that when said first and second polymer layers are present, said PEBAX™ layer is sandwiched between said first and second polymer layers.

14. The ultrasound probe of claim 13, wherein said housing is in the form of a housing of a transesophageal echocardiographic probe, a housing of a transnasal probe, a nose of a transthoracic probe, a nose of an intracavity probe or a nose of an intraoperative probe.

15. The ultrasound probe of claim 13, further comprising a flexible seal interposed between said acoustic window and said housing to seal said cavity.

16. The ultrasound probe of claim 13, wherein said acoustic window includes only said first polymer layer and not said second polymer layer.

17. The ultrasound probe of claim 13, wherein said acoustic window includes only said second polymer layer and not said first polymer layer.

18. The ultrasound probe of claim 13, wherein the acoustic window consists of only said PEBAX™ layer.

19. The ultrasound probe of claim 13, wherein said acoustic window includes said first and second polymer layers and said first and second polymer layers are each made from polyethylene, Mylar™ or Kapton™.

20. The ultrasound probe of claim 13, wherein said acoustic window includes said first and second polymer layers and said first and second polymer layers are made from a different impervious polymer.

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摘要(译)

用于超声探头的声窗，包括PEBAX TM层，其具有适于面向换能器阵列的表面和适于面对被检查物体的相对表面以及布置在PEBAX TM层的一个或两个表面上的可选的不可渗透聚合物层。当存在时，面向物体表面上的外聚合物层保护PEBAX TM层免受化学物质的影响，而当换能器阵列面对表面上的内聚合物层（当存在时）粘合到探针的换能器阵列上。聚合物层可各自由不可渗透的聚合物制成，其具有可忽略的声学影响，包括例如聚乙烯，Mylar TM和Kapton TM。还公开了一种用于制造声窗的方法和包括该方法的超声探头。