US Patent & Trademark Office
Patent Public Search | Text View

United States Patent	12383228
Kind Code	B2
Date of Patent	August 12, 2025
Inventor(s)	Fleischman; Aaron

High resolution intravascular ultrasound (H-IVUS)

Abstract

High-resolution intravascular ultrasound (H-IVUS) operates under a large acoustic bandwidth, provides high resolution while maintaining good depth penetration, and exhibits other favorable characteristics like focused imaging. A H-IVUS transducer assembly can be manufactured at a low cost using conventional methods commonly utilized in the microelectronics industry. The H-IVUS transducer assembly can include a printed circuit having one or more electrical signal conditioners. One or more convertors made of a polymer and configured to convert electrical energy to acoustic energy and acoustic energy to electrical energy can be formed in place away from the printed circuit. After construction, the one or more formed in place convertors are interfaced to the printed circuit with at least a conductive material.

Inventors:	**Fleischman; Aaron (Beachwood, OH)**
Applicant:	**THE CLEVELAND CLINIC FOUNDATION** (Cleveland, OH)
Family ID:	**1000008750786**
Assignee:	**THE CLEVELAND CLINIC FOUNDATION (Cleveland, OH)**
Appl. No.:	**17/715556**
Filed:	**April 07, 2022**

Prior Publication Data

Document Identifier	Publication Date
US 20220330913 A1	Oct. 20, 2022

Related U.S. Application Data

us-provisional-application US 63176388 20210419

Publication Classification

Int. Cl.: **A61B8/00** (20060101); **B06B1/06** (20060101); **H04R31/00** (20060101)

U.S. Cl.:

CPC   **A61B8/4483** (20130101); **B06B1/0688** (20130101); **H04R31/00** (20130101);

Field of Classification Search

CPC: A61B (8/4483); B06B (1/0688); B06B (1/0207); B06B (1/0215); B06B (2201/76); B06B (1/0622); B06B (1/0644); B06B (2201/56); H04R (31/00); H10N (30/084); H10N (30/857)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
5635784	12/1996	Seale	310/40MM	F16C 32/0493
6641540	12/2002	Fleischman	600/459	B06B 1/0651
7927275	12/2010	Kuban	600/437	G06T 7/0012
8864674	12/2013	Corl	600/462	B06B 1/0215
9259206	12/2015	Degertekin	N/A	B06B 1/0292
9408588	12/2015	Huang	N/A	B06B 1/0292
9700280	12/2016	Courtney	N/A	G10K 11/352
2002/0077551	12/2001	Fleischman	600/459	B06B 1/0688
2004/0039286	12/2003	Kuban	600/467	A61B 8/543
2004/0054289	12/2003	Eberle	600/459	A61B 8/12
2005/0197574	12/2004	Eberle	600/437	B06B 1/0622
2011/0021924	12/2010	Sethuraman	600/463	A61B 5/02007
2011/0034809	12/2010	Eberle	600/467	B06B 1/0633
2012/0206014	12/2011	Bibl	310/330	G10K 11/32
2014/0257107	12/2013	Rice	600/459	A61B 8/12
2016/0008067	12/2015	Hadjicostis	600/439	A61B 8/445
2016/0058414	12/2015	Corl	600/463	A61B 8/4444
2018/0035891	12/2017	Van Soest et al.	N/A	N/A
2020/0037985	12/2019	Stigall	N/A	A61B 8/445
2021/0113195	12/2020	van Rens	N/A	B06B 1/0292

OTHER PUBLICATIONS

Janjic et.al., A 2-D Ultrasound Transducer With Front-End ASIC and Low Cable Count for 3-D Forward-Looking Intravascular Imaging: Performance and Characterization, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, vol. 65, Issue 10, Oct. 2018. (Year: 2018). cited by examiner

Chen et.al., A Single-Cable PVDF Transducer Readout IC for Intravascular Photoacoustic Imaging, 2015 IEEE International Ultrasonics Symposium Proceedings, 2015 (Year: 2015). cited by examiner

Chen, Chao, et al. "A single-cable PVDF transducer readout IC for intravascular photoacoustic imaging." 2015 IEEE International Ultrasonics Symposium (IUS). IEEE, 2015. cited by applicant

Fleischman, Aaron, et al. "Miniature high frequency focused ultrasonic transducers for minimally invasive imaging procedures." Sensors and Actuators A: Physical 103.1-2 (2003): 76-82. cited by applicant

Lockwood, G. R., and C. R. Hazzard. "Development of small aperture polymer transducers for high frequency imaging." 1997 IEEE Ultrasonics Symposium Proceedings. An International Symposium (Cat. No. 97CH36118). vol. 2. IEEE, 1997. cited by applicant

Ketterling, Jeffrey A., et al. "Design and fabrication of a 40-MHz annular array transducer." IEEE transactions on ultrasonics, ferroelectrics, and frequency control 52.4 (2005): 672-681. cited by applicant

Primary Examiner: Carley; Jeffrey T

Assistant Examiner: Abraham; Jose K

Attorney, Agent or Firm: Tarolli, Sundheim, Covell & Tummino LLP

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS (1) This application claims the benefit of U.S. Provisional Application Ser. No. 63/176,388, filed 19 Apr. 2021, entitled "HIGH RESOLUTION INTRAVASCULAR ULTRASOUND", the entirety of which is incorporated by reference for all purposes.

TECHNICAL FIELD
(1) The present disclosure relates generally to intravascular ultrasound (IVUS) and, more specifically, to a transducer assembly that enables high resolution IVUS (H-IVUS) imaging and methods for constructing the H-IVUS transducer assembly.

BACKGROUND
(2) Intravascular ultrasound (IVUS) imaging is a technique for imaging central and peripheral blood vessels using sound waves, not ionizing radiation. IVUS can provide images with good depth penetration for identification and classification of stent deployment, identification of stent tissue coverage, identification of Thin-Cap Fibroatheromas (TCFAs), assessment of plaque erosion, assessment of soft plaque burden, real-time classification of plaques for treatment planning, and more. However, IVUS generally has poor resolution that is significantly worse than other techniques such as intravascular optical coherence tomography (IVOCT). One solution to improve resolution is combined IVOCT-IVUS, but such a combined approach has limitations in terms of cost, complexity, and technical constraints.

SUMMARY
(3) High-resolution intravascular ultrasound (H-IVUS) can provide focused imaging with a high (near optical coherence tomography (OCT)-level) resolution that maintains the good depth penetration characteristic of traditional IVUS and provides other favorable characteristics at a low cost (less expensive than current IVUS catheters), while being manufactured using conventional methods commonly utilized in the microelectronics industry. Notably, H-IVUS does not require the use of intravascular OCT to reach this favorable spatial resolution.

(4) In an aspect, the present disclosure includes a transducer assembly that can be used for H-IVUS. The transducer assembly can include a printed circuit having one or more electrical signal conditioners; and one or more formed in place convertors made of a polymer and configured to convert electrical energy to acoustic energy and acoustic energy to electrical energy. The one or more formed in place convertors are interfaced to the printed circuit with at least a conductive

material.

(5) In another aspect, the present disclosure includes a method for constructing the transducer assembly that can be used for H-IVUS. The method includes transferring convertor material to a precise location on a printed circuit using a shaped end effector; applying one or more of pressure, heat, and vibration to the convertor material using the shaped end effector to irreversibly deform the convertor material to match a shape of the shaped end effector; and interfacing the deformed convertor material to the printed circuit via a connection mechanism. The connection mechanism includes at least a conductive material.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The foregoing and other features of the present disclosure will become apparent to those skilled in the art to which the present disclosure relates upon reading the following description with reference to the accompanying drawings, in which:

(2) FIG. **1** is an illustration of a fabricated high-resolution intravascular ultrasound (H-IVUS) transducer assembly;

(3) FIGS. **2** and **3** are illustrations of different ways the H-IVUS transducer assembly of FIG. **1** can be fabricated;

(4) FIG. **4** is an illustration of a cross-section of a multiplicity of focused H-IVUS transducers;

(5) FIGS. **5-7** are process flow diagrams of methods for assembling a H-IVUS transducer;

(6) FIG. **8** is an image of a miniaturized printed circuit board (PCB) that was developed for flip-chip bonding of an analog front end (AFE) application specific integrated circuit (ASIC) next to an integrated high bandwidth piezoelectric micro-machined ultrasonic transducer-poly[vinylidenefluoride-co-trifluoroethylene] (PMUT-TrFE) used in the experiment described below;

(7) FIG. **9** shows graphs of the pulse voltage and edge rate of the H-IVUS pulser from the experiment described below;

(8) FIG. **10** is a diagram of a shunt duplicator (a) and a series duplicator (b), both using an active limiter from the experiment described below;

(9) FIG. **11** is a parasitic model of the coupling capacitor from the experiment described below;

(10) FIG. **12** is a diagram of the low noise amplifier (LNA) implemented using a self-biased push-pull topology with resistive feedback from the experiment described below;

(11) FIG. **13** is a plot showing total AFE signal-to-noise ratio (SNR) and LNA NMOS width vs. $C.sub.HV$ value from the experiment described below;

(12) FIG. **14** is a die photograph of the fabricated AFE ASIC from the experiment described below;

(13) FIG. **15** is a photograph of the AFE-ASIC and PMUT-TrFE integrated on a miniaturized PCB that was mounted on the tip of a standard 1 mm catheter from the experiment described below;

(14) FIG. **16** is shows plots the AFE input (a) and output (b) voltage recovery during a pulsing cycle from the experiment described below;

(15) FIG. **17** is a plot of the gain of different chips over a wide frequency range from the experiment described below;

(16) FIGS. **18** and **19** are examples of the test setup from the experiment described below;

(17) FIG. **20** is an example shaping technique that can be used to create a H-IVUS dielectric;

(18) FIGS. **21** and **22** show theoretical radiation patterns produced by the H-IVUS dielectric of FIG. **20**;

(19) FIG. **23** shows fundamental and harmonic images from a MEMS phantom; and

(20) FIG. **24** is an example of resolving thin membranes with magnetic resonance angiography (MRA).

DETAILED DESCRIPTION

I. Definitions

(21) In the context of the present disclosure, the singular forms "a," "an" and "the" can also include the plural forms, unless the context clearly indicates otherwise.

(22) The terms "comprises" and/or "comprising," as used herein, can specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups.

(23) As used herein, the term "and/or" can include any and all combinations of one or more of the associated listed items.

(24) Additionally, although the terms "first," "second," etc. may be used herein to describe various elements, these elements should not be limited by these terms. These terms are only used to distinguish one element from another. Thus, a "first" element discussed below could also be termed a "second" element without departing from the teachings of the present disclosure. The sequence of operations (or acts/steps) is not limited to the order presented in the claims or figures unless specifically indicated otherwise.

(25) As used herein, the term "intra vascular ultrasound (IVUS)" refers to a medical imaging methodology specifically using a specially designed catheter with a miniaturized ultrasound transducer attached to the distal end of the catheter. High-resolution IVUS (H-IVUS) refers to an IVUS system configured for high spatial resolution and other favorable advantages.

(26) As used herein, the term "spatial resolution" includes both axial resolution and lateral resolution.

(27) As used herein, the term "axial resolution" refers to the depth of penetration of sound waves. Generally, IVUS and H-IVUS exhibit good axial resolution. Axial resolution (Rax) can be expressed as

(28) $R_{ax} = \frac{1}{2}\frac{c}{BW}$,
where BW is bandwidth.

(29) As used herein, the term "lateral resolution" refers to the width across a section of anatomy. The term "resolution" can be used interchangeably with "lateral resolution". Generally, IVUS exhibits a lateral resolution/resolution that is significantly worse than other techniques such as intravascular optical coherence tomography (IVOCT), but H-IVUS has a lateral resolution that is the same or better than other techniques. Lateral resolution (Rlat) can be expressed as

(30) $R_{lat} = \overline{\lambda}(\frac{focallength}{diameter}) = \overline{\lambda} \times (f\text{ - number})$.

(31) As used herein, the term "transducer" refers to a device that can send and receive energy and convert this energy to another form (e.g., an ultrasound transducer converts electrical energy to acoustic energy and acoustic energy to electrical energy) and may have to send information along a distance. For example, an H-IVUS ultrasound transducer can include a convertor that facilitates the energy conversion and an electrical signal conditioner (ESC), which may include an amplifier.

(32) As used herein, the term "printed circuit board (PCB)" refers to at least one layer of nonconductive substrate that mechanically supports and electronically connects electrical or electronic components using conductive tracks, pads, and other features etched from a layer fixed to the nonconductive substrate.

(33) As used herein, the term "electrical signal conditioner (ESC)" relates to a device that can manipulate a signal to meet requirements necessary for further processing. In one example, an electrical signal conditioner can include an amplifier.

(34) As used herein, the term "application specific integrated circuit (ASIC)" refers to an integrated circuit (IC) chip customized for a particular use, rather than intended for a general-purpose use.

(35) As used herein, the term "convertor" refers to a device that converts one from of energy to another form of energy. The convertor can be formed in place and later interfaced with a PCB.

(36) As used herein, the term "piezo" refers to a material that exhibits piezoelectricity (an electric charge that accumulates in certain solid materials in response to applied mechanical stress). One

type of material that exhibits piezoelectricity is a piezopolymer.

(37) As used herein, the term "patient" refers to any warm-blooded organism (e.g., a human being, a primate, a cat, a dog, a rabbit, a mouse, etc.).

II. Overview

(38) Intravascular ultrasound (IVUS) can be used to provide images of central and peripheral blood vessels that have a good depth penetration, but poor resolution. High-resolution intravascular ultrasound (H-IVUS) expands the acoustic bandwidth of traditional IVUS, provides high resolution (at near optical coherence tomography (OCT) levels), and maintains the good depth penetration characteristic of traditional IVUS. H-IVUS also provides other favorable characteristics like focused imaging and a low cost of manufacturing by using conventional methods commonly utilized in the microelectronics industry. Specific technological improvements include: (1) manufacture of focused piezopolymer transducers to improve lateral resolution; (2) wide-bandwidth transducers to enable improved axial resolution (e.g., of ˜18 μm); (3) a flexible broadband transducer design to enable imaging over a wide frequency range (e.g., from 20 MHz to 80 MHz) using different excitation pulse frequencies and pulse inversion to obtain harmonic data; (4) focusing transducers to produce peak harmonic responses within the target vessel unlike unfocussed transducers, which produce peak harmonic responses at the Raleigh length, beyond the target vessel; (5) H-IVUS transducers and electronics can be assembled using standard printed circuit board (PCB) assembly methods to create H-IVUS PCBs and can be tested prior to catheter assembly to greatly decrease manufacturing costs compared to standard IVUS, which is typically tested only after the catheter is built; and (6) broadband fundamental and harmonic bands can be obtained with pulse inversion, providing additional scattering information from tissues that enables machine learning plaque classification.

(39) H-IVUS can be used in the diagnosis and treatment of coronary artery disease and peripheral artery disease, assessment of stent placement, forward looking needle guidance, high resolution tissue imaging for minimally invasive surgery, and the like. H-IVUS can meet needs of clinicians and clinical researchers; several examples of the way H-IVUS can meet these needs include: characterization of stent deployment; identification of stent tissue coverage; identification of TCFAs; assessment of plaque erosion; assessment of soft plaque burden; full pullback, real time classification of plaques for treatment planning; and more. Additionally, H-IVUS is superior to combined IVOCT-IVUS, which is limited in terms of cost, complexity, and technical constraints. For example, in simultaneous IVOCT-IVUS acquisitions, one must accommodate IVUS, the slower imaging modality, limiting pullback length or requiring a longer duration contrast agent flush to clear blood, both options being clinically undesirable.

III. Systems

(40) An aspect of the present disclosure can include a system that includes a high-resolution intravascular ultrasound (H-IVUS) transducer assembly **10** (shown in FIG. **1**) that enables H-IVUS imaging. The system can also include a catheter (e.g., of a size traditionally used for IVUS) that the H-IVUS transducer assembly **10** can reside on or within. For example, the H-IVUS transducer assembly **10** can be mounted at or near an open portion of the catheter (see, e.g., FIG. **15**) to provide a superior spatial resolution to traditional IVUS systems while being significantly less expensive. A catheter with a H-IVUS transducer assembly **10** can be used in the diagnosis and treatment of coronary artery disease and peripheral artery disease, assessment of stent placement, forward looking needle guidance, high resolution tissue imaging for minimally invasive surgery, and the like. It should be noted that the elements of the figures are not drawn to scale. For example, the convertor material may be thinner than is illustrated in the figures.

(41) In a H-IVUS transducer assembly **10**, a convertor **16** (e.g., especially when made of a Piezo polymer) provides a generally weak signal and requires an electrical signal conditioner (ESC) **14** that includes at least an amplifier so that the signal can be transmitted across a distance. The amplifier must interface with the convertor **16** to enable strong signal transmission down the length

of the catheter. Accordingly, the convertor **16** and the ESC **14** including the amplifier can be co-located on a printed circuit **12**. Notably, a Piezo polymer material generally has a high output impedance, which results in signal attenuation when coupled into a 50 ohm coaxial cable. While Piezo polymers have lower piezo response than ceramics (like lead zirconate titanate (PZT)), the dominant signal degradation is this mismatch. Further, even small area ceramic materials suffer from this effect as the output impedance is inversely proportional to the area of the transducer. This issue is exacerbated for Piezo polymer transducer as they have a significantly lower dielectric constants than ceramics.

(42) An example of the H-IVUS transducer assembly **10** is shown in FIG. **1**. The H-IVUS transducer assembly can be formed on a printed circuit board (PCB) having a printed circuit **12** thereon or therein. The printed circuit **12** can have one or more ESCs **14** thereon. Although only a single ESC **14** is shown in FIG. **1**, this is only for ease of illustration and explanation. It will be understood that any number of ESCs can exist on the printed circuit **12** based on requirements of the intended application/use. In one example, the ESC **14** can be embodied on or in one or more application specific integrated circuits (ASICs) that is formed on/mounted to the printed circuit **12**.

(43) One or more ESC **14** can interface with one or more convertors **16** on the printed circuit **12** (for example, the ESC **14** can be configured to interface with one or more convertors **16**). The interface between the ESC **14** and the one or more convertors **16** can be an electrical and/or mechanical coupling. Although only a single convertor **16** is shown in FIG. **1**, this is only for ease of illustration and explanation. It will be understood that any number of convertors can exist on the printed circuit **12** based on requirements of the intended application/use.

(44) The convertor **16** can be configured to convert electrical energy to acoustic energy and acoustic energy to electrical energy. The convertor **16** can include one or more piezoelectric materials. At least one of the one or more piezoelectric materials can be a polymer (e.g., a piezoelectric polymer). The piezoelectric polymer (also referred to as a "Piezo polymer") can be a thermoplastic, which may include polyvinylidene difluoride (PVDF) and/or trifluoroethylene (TrFE). For example, the piezoelectric polymer may be PVDF or PVDF-TrFE. The convertor **16** can have a shape that can facilitate at least a portion of the conversion of electrical energy to acoustic energy and acoustic energy to electrical energy. The shape of the convertor **16** (e.g., shape of an emitter of the convertor **16**) can be designed to compensate for aberration of the ultrasound beam by the catheter. Example shapes include generally parabolic, generally concave, or any arbitrary shape. When the shape is generally concave or parabolic, it should be understood that the shapes of each convertor **16**, if there are multiple convertors **16**, can be different (e.g., between different convertors **16** on the same printed circuit **12** or between different printed circuits **12**) enabling different depths of energy focus.

(45) The convertor **16** can be interfaced to the printed circuit **12** with at least a conductive material (at interface **18**). In some instances, the conductive material can be ductile. As an example, the conductive material can be a curable conductive fluid. As another example, the interface **18** can be created by a non-conductive epoxy and the conductive material can be already within the printed circuit **12**.

(46) The H-IVUS transducer assembly **10** can be manufactured using conventional methods commonly utilized in the microelectronics industry. The H-IVUS transducer assembly **10** can include the printed circuit **12** on a PCB, at least one ESC **14** formed on the printed circuit **12**, and one or more convertors **16** that can interface to be printed circuit at interface **18**. In one example, the convertor **16** can be made inside of or from a PCB. In another example, the H-IVUS transducer assembly **10** can include a PCB hybrid where at least the convertor **16** is manufactured separately from the PCB and then placed onto a PCB; in this case, the convertor **16** can be constructed on one or more external substrates where it is then singulated and mated to a PCB using pick and place technology. The convertor **16** can be shaped either via application of a uniform pressure or by using a mandrel (either before or after being mated to the PCB). In the example where the convertor **16** is

a Piezo polymer film, this approach to shaping maximizes the number of transducers per unit area of the Piezo polymer film.

(47) FIG. **2** shows an example **20** where the ESC **14** is formed on the printed circuit **12** (or PCB), while the convertor **16** is formed in a separate place. The convertor **16** in this example can be referred to as a "formed in place" convertor **16**. It should be noted that the convertor **16** can be shaped either before or after it mates/interfaces with the printed circuit **12** or PCB. In some instances, the printed circuit **12** or PCB can include a pre-shaped receiving area for the convertor **16** that is configured to accept the convertor **16**. In other instances, the printed circuit **12** or PCB can include and/or be formed of a material that is permanently deformable under pressure and/or heat (e.g., pressure and/or heat that is due to placement of the formed in place convertor **16**). The material can also have at least one acoustic property, which can be complementary to the acoustic properties provided by the material of the convertor **16** (e.g., the Piezo polymer).

(48) Although the convertor **16** can be formed on/in the PCB, it is often preferable to form the convertor **16** independently from the PCB. The rationale for forming the convertor **16** separately from the PCB is as follows: (1) custom electronics in the form of an Application Specific Integrated Circuit (ASIC or computer chips) can be readily designed and fabricated at low costs; (2) chip on board technology where the ASIC is directly attached to the PCB by a process called flip chip bonding is a high yield standard electronics fabrication process; (3) high performance ASICs and PCBs with suitable form factors for placement within a 3 F catheter have been demonstrated; (4) methods for forming shaped piezo polymer transducers in PCBs compatible with flip chip bonding have been demonstrated creating a hybrid PCB transducer package; (5) these hybrids can be attached to fine wire cables using standard electronic fabrication methods; (6) the hybrid PCB transducer package can be functionally tested before making an IVUS catheter demonstrating significant cost avoidance in comparison to building catheters with only functioning transducers.

(49) FIG. **3** shows a way for the convertor **16**, formed outside the PCB, to be placed within the PCB. The convertor **16** can be mated with a backing **32** (e.g., a material that is non-conductive and/or conductive with appropriate acoustic properties for the transducer) to become a focused transistor **36**. In some instances, the backing **32** material can include an epoxy material. In other instances, a bottom electrode patterned on the polymer film or on top of the backing material before applying the polymer film and adhering it with conductive spray.

(50) The focused transistor **36** can be placed within an empty space **34** within a printed circuit **12** (e.g., using pick and place technology). In the example shown in FIG. **3**, the ESC **14** can be formed on the PCB **12**. Air pressure can be used to shape the convertor **16** either before placing in the PCB **12** or after placement in the PCB. An example of a multiplicity (e.g., 2 or more) of shaped focused transistors is shown in FIG. **4**. Each of the multiplicity of shaped focused transistors can have a convertor **16** mated with a backing **32**.

IV. Methods

(51) Another aspect of the present disclosure can include methods **50-70** (FIGS. **5-7**) for assembling a high-resolution intravascular ultrasound (H-IVUS) transducer (like the H-IVUS transducer shown in FIGS. **1-4**). The methods are illustrated as process flow diagrams with flowchart illustrations. For purposes of simplicity, the methods are shown and described as being executed serially; however, it is to be understood and appreciated that the present disclosure is not limited by the illustrated order as some steps could occur in different orders and/or concurrently with other steps shown and described herein. Moreover, not all illustrated aspects may be required to implement the methods **50-70**.

(52) As noted above, the H-IVUS transducer assembly (e.g., element **10** of FIG. **1**) can be manufactured using conventional methods commonly utilized in the microelectronics industry. The H-IVUS transducer assembly can include the printed circuit on a PCB, at least one ESC formed on the printed circuit, and one or more convertors that can interface to the printed circuit at an

interface. In one example, the convertor can be made inside of or from a PCB. In another example, the H-IVUS transducer assembly can include a PCB hybrid where at least the convertor is manufactured separately from the PCB and then placed onto a PCB; in this case, the convertor can be constructed on one or more external substrates where it is then singulated and mated to a PCB using pick and place technology. The convertor can be shaped either via application of a uniform pressure (e.g., by applying air) or by using a mandrel (either before or after being mated to the PCB). In the example where the convertor **16** is a Piezo polymer film, this approach to shaping maximizes the number of transducers per unit area of the Piezo polymer film.

(53) The material of the convertor (e.g., a Piezo polymer) is easy to shape to improve lateral resolution, which enables superior axial resolution and optimized signal excitation. The convertor requires at least an amplifier in conjunction therewith in order to enable strong signal transmission down a length of catheter (in an IVUS catheter application). Thus, the convertor and the electronics must be co-located. Using pick and place technology, the transducer can be mated to a PCB to co-locate the transducer and the electronics.

(54) FIG. **5** illustrates a method **40** for assembling a H-IVUS transducer assembly. At Step **52** one or more electrical signal conditioners (ESC **14**) can be formed on a printed circuit (or PCB) (printed circuit **12**). At Step **54**, one or more convertors (e.g., Piezo polymer transducers) (convertor **16**) can be formed in place (away from the printed circuit). At Step **56**, the one or more formed in place convertors can be interfaced to the printed circuit (at interface **18**).

(55) FIG. **6** illustrates another method **50** for assembling a H-IVUS transducer assembly. At Step **62**, a convertor material can be transferred to a precise location on a printed circuit (or PCB) using a shaped end effector (e.g., a mandrel). The shaped end effector can include a contoured shape in two dimensions or three dimensions and, in some instances, can include a non-stick coating, a polished surface, a micro-patterned surface, or the like. The shaped end effector can include one or more sensors (e.g., one or more of a pressure sensor, a displacement sensor, a rotation sensor, a temperature sensor, or the like). The one or more sensors can provide feedback and control the shaped end effector as the convertor material is irreversibly deformed and may help to reduce friction and/or improve surface finish during the manufacturing/forming process. It should be noted that at least one of the one or more convertors and/or one or more additional components can be applied to one or both sides of the printed circuit. In some instances, the shaped end effector can be attached to an automation machine that controls movement of the shaped end effector along one or more motion axes.

(56) At Step **64**, one or more of pressure, heat, and vibration can be applied to the convertor material using the shaped end effector to irreversibly deform the convertor material to match a shape of the shaped end effector. The pressure, heat, and vibration can also irreversibly deform the printed circuit. Alternatively, the printed circuit can be pre-formed with an area (or a deformation) to accept the convertor (e.g., a preshaped receiving area). An electric field can be applied to the formed convertor material. For example, the shaped end effector can be configured to be used as an electrode to generate an electrical field.

(57) At Step **66**, the shaped convertor material can be interfaced to the printed circuit via a connection mechanism. The connection mechanism can include a conductive material, like a curable conductive fluid (e.g., a conductive adhesive that is applied to one or both surfaces of the printed circuit and the deformed convertor material). The connection mechanism can also include a non-conductive epoxy and the conductive aspects can be within the printed circuit. It should be noted that a shape of the printed circuit and the convertor when attached compensates for one or more dimensional changes due to shaping recoil, stress relieving, or the like.

(58) FIG. **7** illustrates another method **70** for making a H-IVUS transducer. In this example, the convertor, which can be a polymer with dielectric properties, can be formed outside the PCB. At **72**, an amount of a convertor material can be singulated with a backing material (e.g., focused transistor **36**) for placement within a hole (e.g., empty space **34**) of a printed circuit. For example,

the backing material can include epoxy. At **74**, the backing material singulated with the convertor material can be placed into the hole of the printed circuit using a pick and place method. At **76**, the convertor material can be shaped, either between steps **72** and **74** or after step **74**. The shaping can be done by applying air pressure to the convertor material to shape the convertor material. For example, after shaping, the convertor material comprises a spherically shaped aperture section with a depth into the backing material controlled by the air pressure. This method can work for a plurality of backing materials singulated with the convertor material (focused transducers **36**) that are placed in a plurality of holes of printed circuits using the pick and place method; the focused transducers can be shaped using air pressure on a form with circular apertures before mating, after mating, but before placement, or after placement.

V. Experimental

(59) This experiment shows an example high resolution Intravascular Ultrasound (H-IVUS) Transducer, which is manufactured at a low cost using conventional methods commonly utilized in the microelectronics industry and improves spatial resolution of traditional IVUS. The H-IVUS transducer has one or more high-bandwidth piezoelectric micro-machined ultrasound transducers (PMUTs) and one or more front-end interface amplifiers (analog front ends (AFEs)) on a printed circuit. The one or more PMUTs are interfaced with the printed circuit.

(60) Piezoelectric Micro-Machined Ultrasonic Transducer (PMUT)

(61) The H-IVUS transducer has one or more high-bandwidth PMUTs. PMUTs provide superior resolution to image small critical structures while still having high soft tissue penetration for soft plaque evaluation.

(62) PMUTs are generally fabricated from piezoelectric films, such as poly[(vinylidenefluoride-co-trifluoroethylene] (PMUT-TrFE). The thickness of a PMUT-TrFE film was chosen to resonate at 40 MHz (sufficient bandwidth exists to capture the 2.sup.nd harmonic at 80 MHz and a sub-harmonic at 20 MHz). This wide bandwidth allows echo data collection at the harmonic frequencies for image sharpening.

(63) The transducer was spherically focused using a custom forming tool to define the focal length. The transducer impedance was measured and modeled as a 2.2 pF capacitor with 30 kΩ leakage resistance at 40 MHz. Acoustic modeling estimated the transducer SNR to be 88 dB, however, due to the high impedance, this SNR would be reduced by 19 dB in a 50Ω system.

(64) PMUT-TrFE, compared to conventional ceramic transducers and capacitive micro-machined ultrasonic transducers (CMUT), has higher bandwidth and output impedance. Hence, PMUT-TrFE transducers cannot be directly connected to the conventional, 500 coaxial cable without significant insertion loss.

(65) Analog Front End (AFE) Interface

(66) To buffer the high impedance transducer signal and improve SNR, an Analog Front End (AFE) Application Specific Integrated Circuit (ASIC) was designed to interface with a PMUT-TrFE transducer. The AFE ASIC was developed to withstand high-voltage pulses during imaging, while retaining low noise amplification of acoustic echoes from tissue targets.

(67) The ASIC had a width of 0.85 mm allowing for flip-chip bonding. The ASIC was twice as long as needed to include test circuits. Preliminary bench characterization data is presented that the ASIC can interface with the PMUT-TrFE transducer, withstand a 100V pulse, pre-amplify, and buffer the echo signal with appropriate post-high-voltage-pulse recovery time. It is also shown that the fabricated silicon could be integrated with a PMUT-TrFE transducer on a miniaturized PCB that fits within a standard 1 mm catheter (FIG. **8**).

(68) The AFE duplexes the high voltage pulses and amplifies and buffers the echo signals. A shunt/series-duplexer topology was considered because modern integrated fabrication processes do not provide high voltage FETs to withstand the pulsing voltage. Instead, an active limiter clamps the input voltage under the allowable voltage level of 7V peak (drain-source breakdown voltage of the process). This topology allowed the ASIC to be fabricated with standard low-voltage processes

with high breakdown voltage metal-insulator-metal capacitors.

(69) The active limiter was designed based on the current flow into the low voltage part of the circuit, namely the amplifier and buffer. The pulse shape of a commercial IVUS device (Avtech AVB1-3-C, Avtech Electrosystems) was used to model the current surge during transducer excitation. The pulse had a maximum pulsing voltage V_p of 101V and a maximum edge rate of 74 GV/s (FIG. **9**). Maximum edge rate determined the maximum current that could flow into the amplifiers and hence the active limiter performance requirement.

(70) In the fabricated design, a series-duplexer topology was chosen over the shunt-duplexer topology (FIG. **10**) because shunt duplexers require an IVUS pulser to provide low noise ground during receiving; this is uncommon since the IVUS pulser is normally high impedance for safety reasons. The series duplexer has a significantly lower clamping current, minimizing the size of the limiter parasitic impedance.

(71) High Voltage Coupling Capacitor

(72) The AFE circuit was designed to have two high voltage coupling capacitors C_{HV} in series, an LNA, and an active limiter to implement the series-duplexer topology. The design was optimized for signal chain gain and noise of the series-duplexer circuit. The optimized design variable was the size of the high voltage coupling capacitor C_{HV}, which was sized to present enough input impedance to limit current during high voltage pulsing without overly loading the transducer during echo recovery.

(73) A bigger coupling capacitor reduces insertion loss and presents higher signal amplitude at the low noise amplifier A_V input. However, a bigger coupling capacitor also results in higher clamping current during pulsing cycles. This increases the size of limiter transistors, which increases the parasitic capacitance of the amplifier, and reduces signal gain. Therefore, this amplifier topology has a process-dependent optimum C_{HV} based on the transducer capacitance.

(74) The AFE was designed for the OnSemi I3T80 process, which offers metal-insulator-metal (MIM) capacitors rated to 50V. Two high voltage capacitors were put in series to implement the coupling capacitor with 100V pulse voltage tolerance. Because the MIM capacitor had low capacitance per area, it introduced non-negligible substrate-coupled parasitic capacitance (FIG. **11**). The ratio of substrate-coupled parasitic capacitance to high voltage capacitor was modeled as $\kappa = C_{HV}/C_{HVpar}$. The process dependent parameter κ is an essential parameter in the optimization. For the I3T80 process κ=15%.

(75) Active Limiter

(76) The active limiter clamps the voltage below the FET gate breakdown voltage during the pulsing period. The active limiter used two transistors with gates tied to the output of the LNA. During high voltage pulsing, as the input voltage of LNA approaches threshold (hysteretic and set by the output voltage of the LNA), the comparator will turn on either the NMOS or PMOS to source or sink the incoming current.

(77) Active limiter transistors contribute significant input parasitic capacitance to the LNA due to their large size. The minimum size of active limiter transistors was related to coupling capacitor size and maximum edge rate by a process dependent parameter γ,

(78) $\gamma = C_{LIM} / \frac{1}{2}C_{HV} = \alpha(\frac{dV_p}{dt})_{max}$

(79) where α is the ratio of parasitic capacitance to limiter transistor current capability. α=9.3 pF/A and γ=6.9 were calculated for the I3T80 process using simulations. These values were used for SNR optimization of the amplifier.

(80) The active limiter size also affects the amplifier's post-pulse-recovery time because a large limiter induces more parasitic capacitance that holds more charge after pulsing.

(81) Low Noise Amplifier (LNA) and Buffer

(82) The LNA pre-amplifies and sets the bandwidth of the echo signal. It was implemented using a

self-biased push-pull topology with resistive feedback (FIG. **12**). Feedback resistance R.sub.f sets the amplifier's gain. The combination of feedback capacitance C.sub.f (the sum of C.sub.gd of the two amplifier transistors) and R.sub.f, sets the LNA bandwidth.

(83) With process dependent parameter κ and γ, C.sub.HV was selected by optimizing the trade-off between input signal amplitude and amplifier gain (FIG. **13**). With a constraint of minimum signal chain gain of 3 V/V, the SNR was maximized with C.sub.HV=2-5 pF. The design used C.sub.HV=3.45 pF to account for fabrication tolerance.

(84) Results

(85) The AFE ASIC was fabricated using the OnSemi I3T80 0.35-μm process (FIG. **14**). Each chip had a fully integrated analog front end, an isolated high voltage capacitor, an isolated low noise amplifier and limiter, and an isolated buffer. This allowed the analog front end to be tested as a whole or in parts. The integrated circuits were wirebonded into SO-20 packages for bench test. The fabricated chip (including test circuits) was small enough to be integrated with the PMUT-TrFE transducer on a PCB within a standard 1 mm diameter catheter (FIG. **15**).

(86) High Voltage Capacitor Testing

(87) Using an impedance analyzer (Agilent 4395A, Agilent Technology), the coupling capacitor (C.sub.HV) for two chips were measured. The values of 3.46 pF and 3.66 pF were close to the designed value and well within the optimized range.

(88) During imaging, the 100-V high voltage pulses could potentially stress the capacitors. To determine capacitor stability, an unpulsed coupling capacitor was subjected to 100-V pulses and the capacitor value was measured over 2M pulse cycles (Table I). Recorded data showed no degradation of the coupling capacitors under high voltage pulses.

(89) TABLE-US-00001 TABLE I CHV MEASURED AFTER 100-V PULSING Cycles 10 k 100 k 500 k 1 M 2 M Pulsed C.sub.HV 3.46 3.40 3.46 3.44 3.46 Measured (pF)

Pulse Recovery

(90) IVUS imaging requires the amplifier to recover quickly post-pulsing to receive the small signal echo from tissue. To image blood vessel walls only 0.5 mm away from the tip of the catheter, the amplifier must recover within 667 ns after pulsing, based on the speed of sound in blood.

(91) The LNA recovery time was tested with a commercial pulser (Avtech AVB1-3-C, Avtech Electrosystems). A 100V high voltage, 40-MHz monocycle pulse was applied to the input of the AFE to test the clamping ability of the active limiter and the post-pulse-recovery time of the amplifier. As a result, the amplifier's output voltage was kept well below breakdown voltage, and the amplifier recovered ˜500 ns after pulsing (FIG. **16**). The measured recovery time was significantly less than 667 ns and suitable for IVUS imaging.

(92) Signal Amplifier Testing

(93) The AFE had an unloaded gain of 15 dB (Agilent 4395A, Agilent Technology) and a −3 dB bandwidth of 110 MHz. When loaded with 50Ω, the AFE had a −3 dB bandwidth of 92 MHz, and a unity-gain bandwidth of 225 MHz (FIG. **17**).

(94) To calculate the total signal chain gain, which includes the insertion loss (IL) between the PMUT-TrFE and AFE, IL was modeled and applied to the S21 measurement. Given that PMUT-TrFE was modeled as a capacitor with 2.2 pF capacitance with 30 kΩ leakage resistance at 40 MHz, and the coupling capacitor was 3.45 pF, IL≅5.2 dB at 40 MHz. As a result, the loaded total signal chain was 9.8 dB at 40 MHz.

(95) The analog front end was tested to have an SNR of 20.1 dB at the output assuming a transducer-referred input signal amplitude of 1 mV. The noise performance was significantly better than this baseline.

(96) The output impedance of the buffer at the end of the signal chain was well matched to 50Ω. The output impedance of the AFE was measured with an impedance analyzer (Agilent 4395A, Agilent Technology) to be 53.7Ω and 51.7Ω for the two chips tested.

(97) Pulse-Echo Testing

(98) To demonstrate the AFE ASIC's ability to work with the PMUT-TrFE transducer in an integrated IVUS system, a test system was set up for a pulse-echo test (FIGS. **18** and **19**). A test PMUT-TrFE was mounted on a small PCB and immersed in water in a beaker. The test PMUT-TrFE was positioned so that the bottom of beaker was one focal length away. The test PMUT-TrFE board was connected to the input of the AFE. A commercial IVUS pulser was connected to the input of the AFE and PMUT to provide a high voltage 40 MHz monocycle pulse. Measurements were taken with a fast oscilloscope at the input of AFE (attenuated by 48 dB to protect the oscilloscope from direct pulsing) and the output of AFE.

(99) The test successfully demonstrated that the AFE ASIC interfaces well with the PMUT. The AFE ASIC duplexed high voltage pulses and echo signals and amplified and buffered the echo signal into a 50Ω system. This basic test demonstrated pulse-echo transmission and reception with a received signal amplitude of about 100 mV.

(100) Alternate Shaping Technique

(101) Air pressure can be used to create spherically shaped sections, with f=r/A, the aperture is fixed by the size of the hole, the f value can be controlled by controlling the diameter (2r), and diameter can be controlled by air pressure. Shown in FIG. **20** is an example shaping technique that can be used to create a H-IVUS dielectric. This shaping technique can be used to create a multiplicity of focus transistors (greater than 2) using air pressure of a form with circular perforations. Devices can be singulated and placed into holes in a printed circuit board with circuitry using a pick and place method (an example of the multiplicity is shown in FIG. **4**). FIGS. **21** and **22** show theoretical radiation patterns produced by the H-IVUS dielectric of FIG. **20**; The theoretical radiation patterns have a long focal region with a narrow beam width.

(102) Harmonic Imaging

(103) Tissue is an acoustically non-linear material. Sound propagating though tissue will produce harmonic overtones of the fundamental transmit frequency. Such harmonic overtones can be used to produce images with higher contrast and resolution. Additionally, these harmonic overtones can possibly yield additional information about tissue based on non-linear tissue properties. However, any imaging exploiting the harmonic overtones requires a broad band high frequency ultrasonic transistor. FIG. **23** shows fundamental and harmonic images from a MEMS phantom with fixed lines and spaces micromachined into a silicon wafer.

(104) This can be very useful when imaging thin membranes, such as those of blood vessels and/or stents. FIG. **24** is an example of resolving thin membranes with magnetic resonance angiography (MRA).

(105) From the above description, those skilled in the art will perceive improvements, changes, and modifications. Such improvements, changes and modifications are within the skill of one in the art and are intended to be covered by the appended claims.

Claims

1. A high-resolution intravascular ultrasound (H-IVUS) transducer assembly comprising: a printed circuit having one or more electrical signal conditioners, each of the one or more electrical signal conditioners comprising one or more front-end interface amplifiers and dual high voltage coupling capacitors in series; and one or more convertors made of a polymer and configured to convert electrical energy to acoustic energy and acoustic energy to electrical energy, wherein the one or more convertors are interfaced to a pre-shaped receiving area of the printed circuit with at least a conductive material and shaped into a generally concave shape after being placed on the printed circuit, wherein the pre-shaped receiving area comprises a material that is permanently deformable under pressure and/or heat, wherein the material has at least one acoustic property that is complementary to at least one acoustic property of the polymer of the one or more convertors to convert electrical energy to acoustic energy and acoustic energy to electrical energy.

2. The H-IVUS transducer assembly of claim 1, wherein the polymer comprises a piezoelectric polymer that is thermoplastic.

3. The H-IVUS transducer assembly of claim 2, wherein the thermoplastic comprises polyvinylidene difluoride (PVDF) and/or polyvinylidene difluoride trifluoroethylene (PVDF-TrFE).

4. The H-IVUS transducer assembly of claim 1, wherein the one or more electrical signal conditioners are embodied on one or more application specific integrated circuits (ASICs).

5. The H-IVUS transducer assembly of claim 1, wherein at least one of the one or more electrical signal conditioners is configured to interface with the one or more convertors.

6. The H-IVUS transducer assembly of claim 1, wherein at least a portion of the conductive material comprises a curable conductive fluid, and/or wherein the one or more convertors are interfaced to the printed circuit with a non-conductive epoxy.