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(54) **WEARABLE ULTRASOUND DEVICE**

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H01L 41/047	(2006.01)
H01L 41/08	(2006.01)
H01L 41/25	(2006.01)
G01F 22/00	(2006.01)
G01N 29/24	(2006.01)

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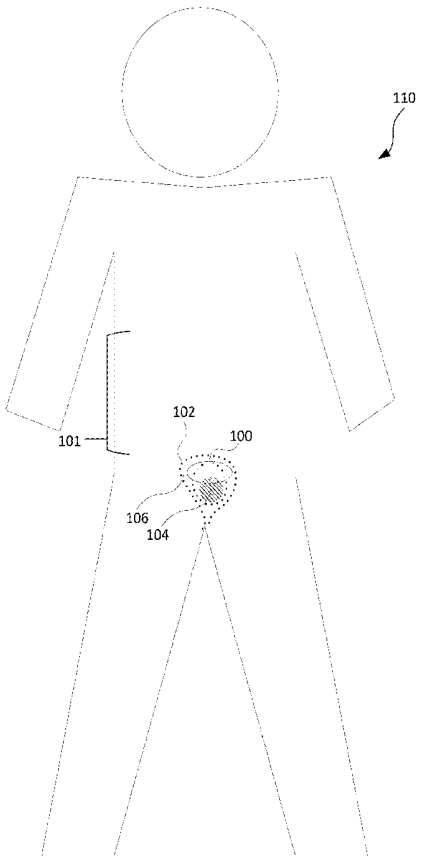
(57) **ABSTRACT**

Systems, methods, and apparatuses for non-invasively measuring volumes of a body cavity by a wearable ultrasonic device are provided. The wearable ultrasonic device can collect data related to the body cavity perform diagnostic measurements associated with the body cavity to provide alerts to user. The wearable ultrasonic device can be affixed to the skin of a user's body. The wearable ultrasonic device can include an ultrasonic transducer that transmits and receives ultrasonic signals directed toward the body cavity such as a user's urinary bladder. The device can include processing electronics coupled to the ultrasonic transducer to process the ultrasonic signals to determine the volume of the body cavity and transmit alerts to the user when the volume reaches a particular threshold. The processing electronics can be integrated with the ultrasonic transducer to operate at low voltages and be battery powered.



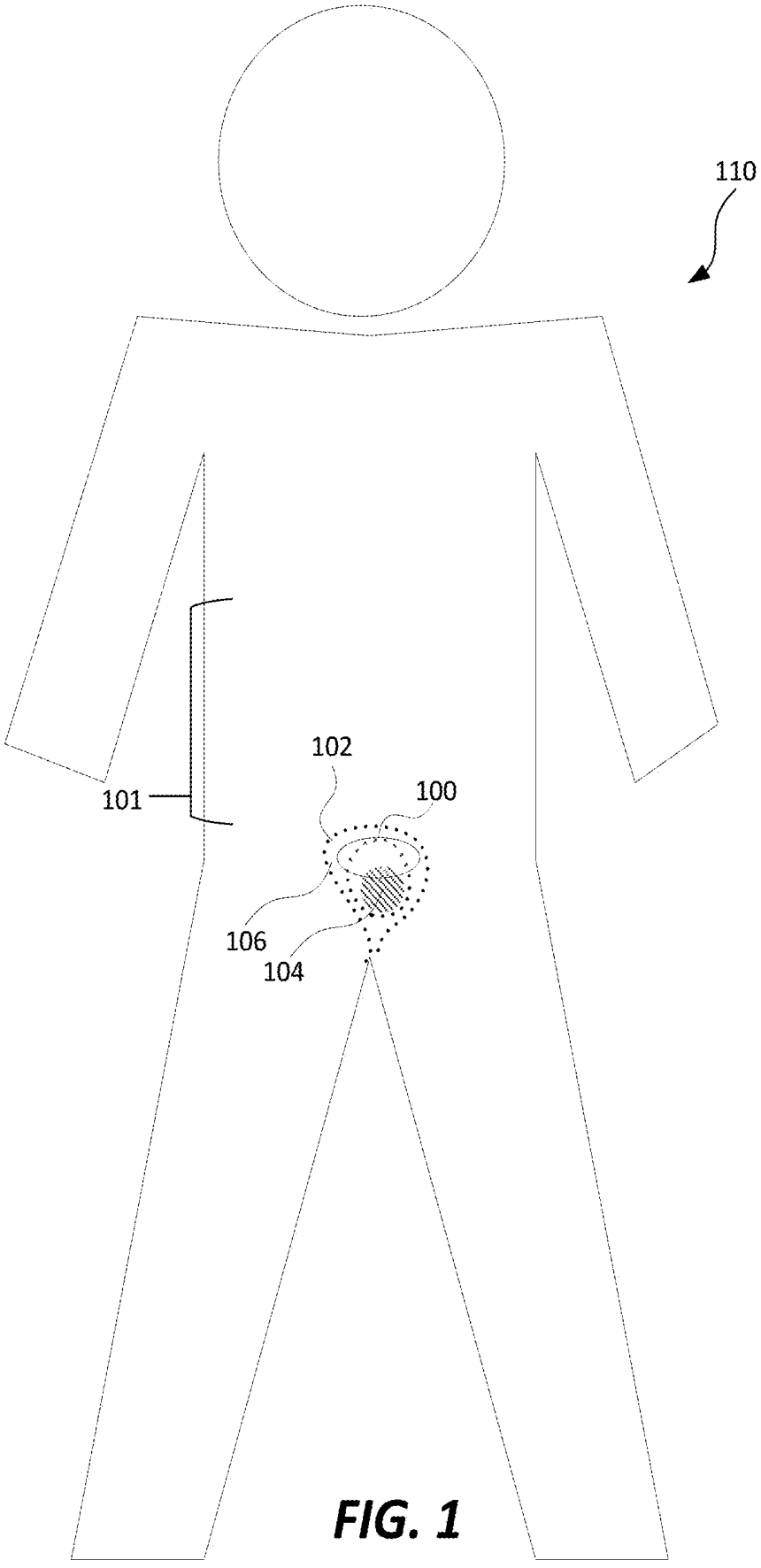


FIG. 1

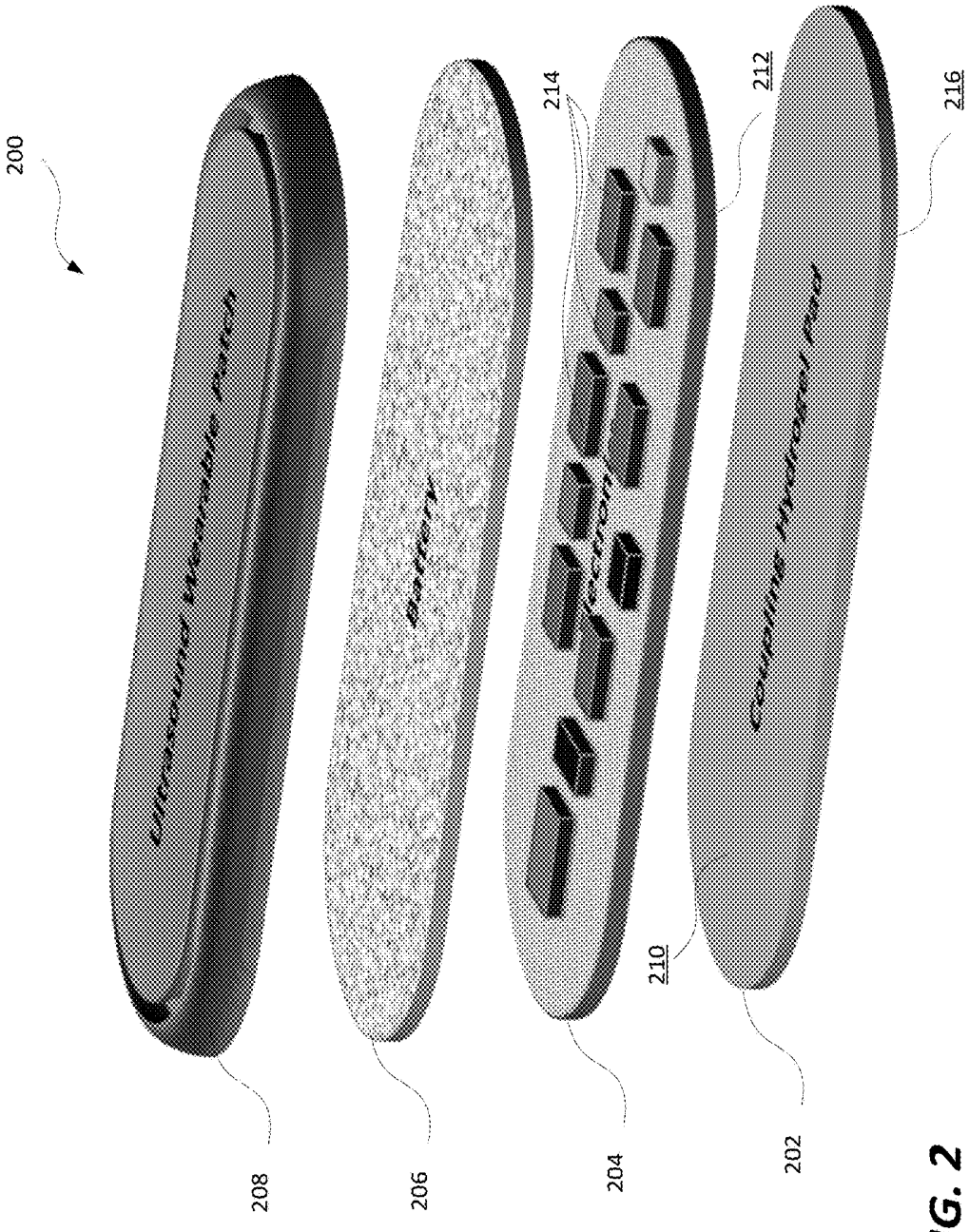


FIG. 2

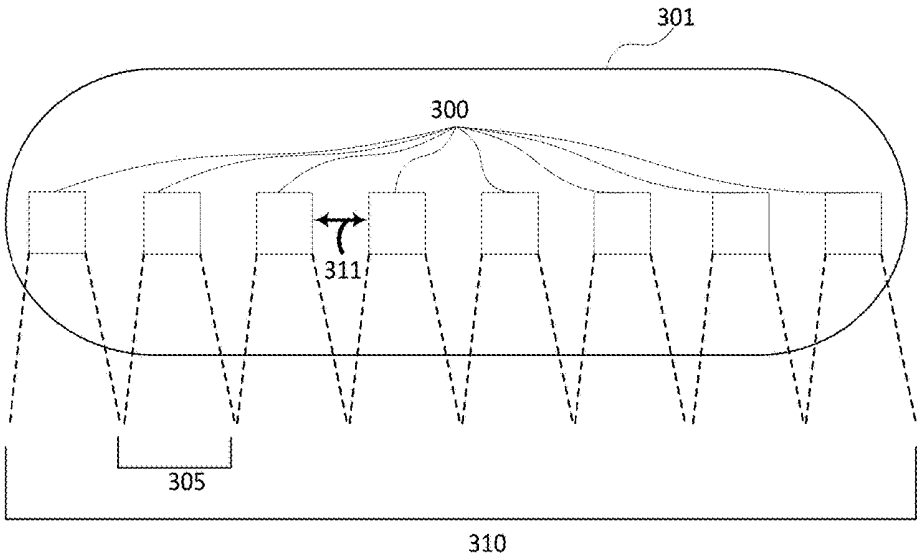


FIG. 3A

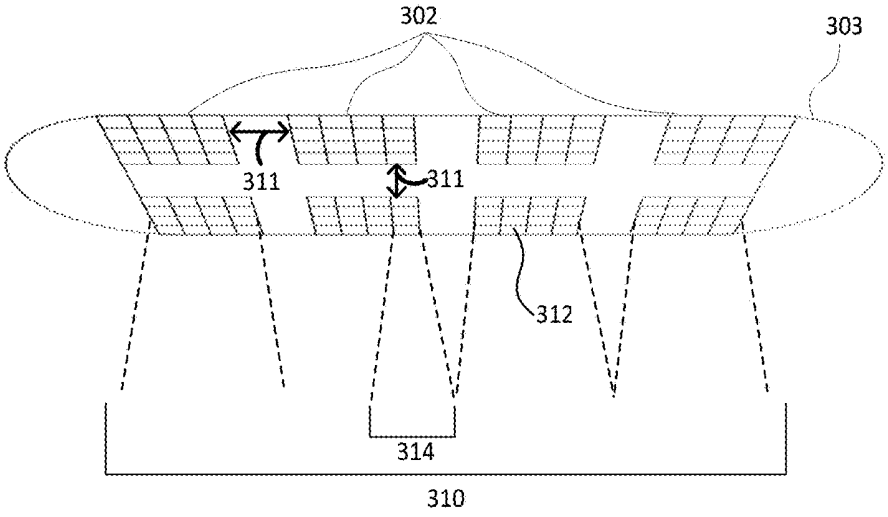


FIG. 3B

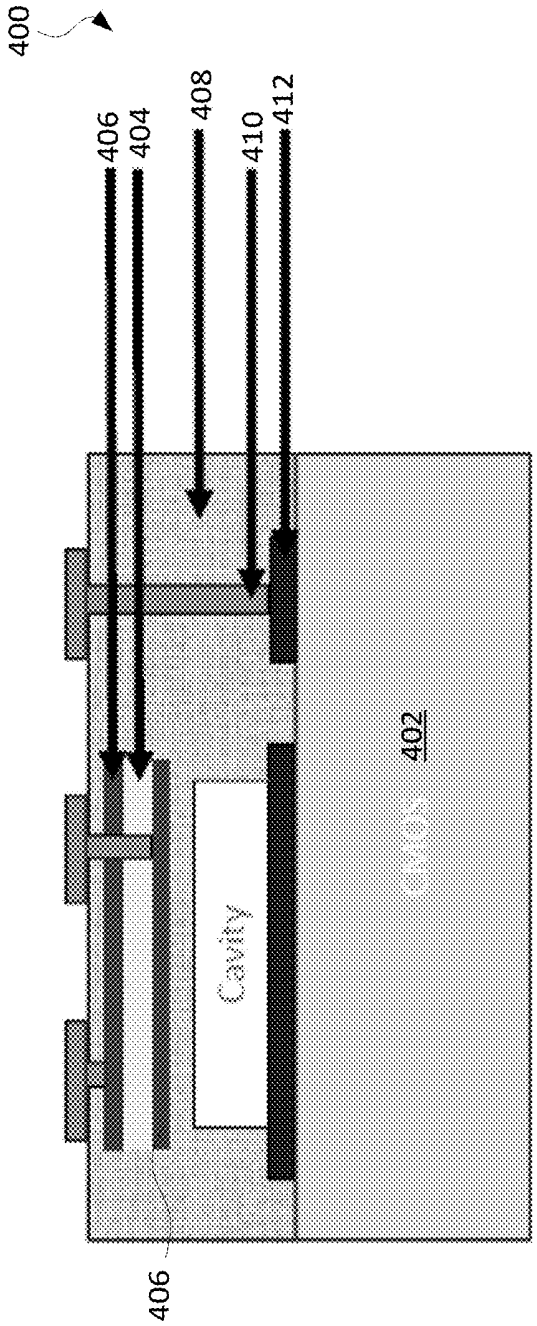


FIG. 4

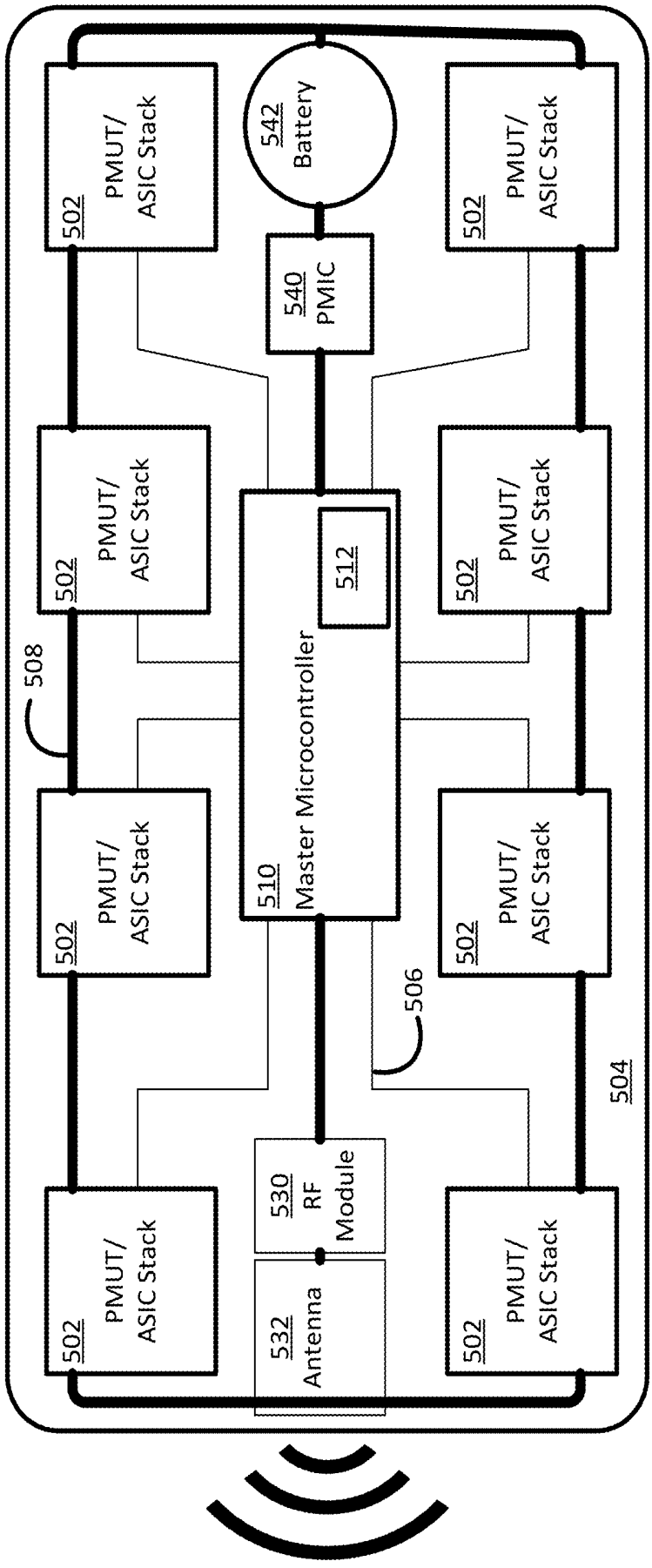

502
PMUT/
ASIC Stack
542
Battery
502
PMUT/
ASIC Stack
540
PMIC
502
PMUT/
ASIC Stack
512
502
PMUT/
ASIC Stack
508
510
Master Microcontroller
502
PMUT/
ASIC Stack
502
PMUT/
ASIC Stack
506
504
530
RF
Module
532
Antenna
502
PMUT/
ASIC Stack
502
PMUT/
ASIC Stack

FIG. 5A

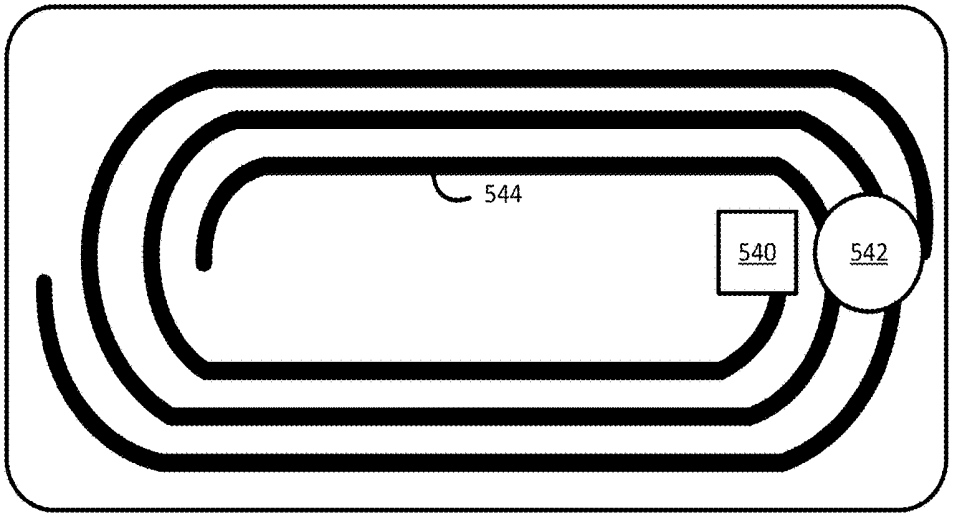


FIG. 5B

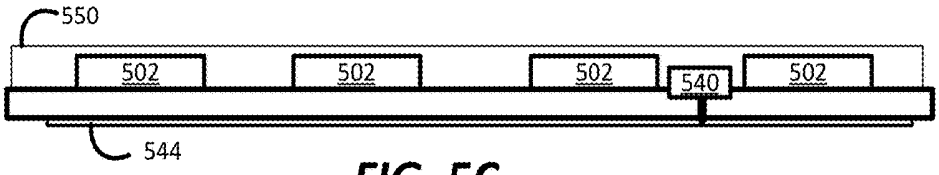


FIG. 5C

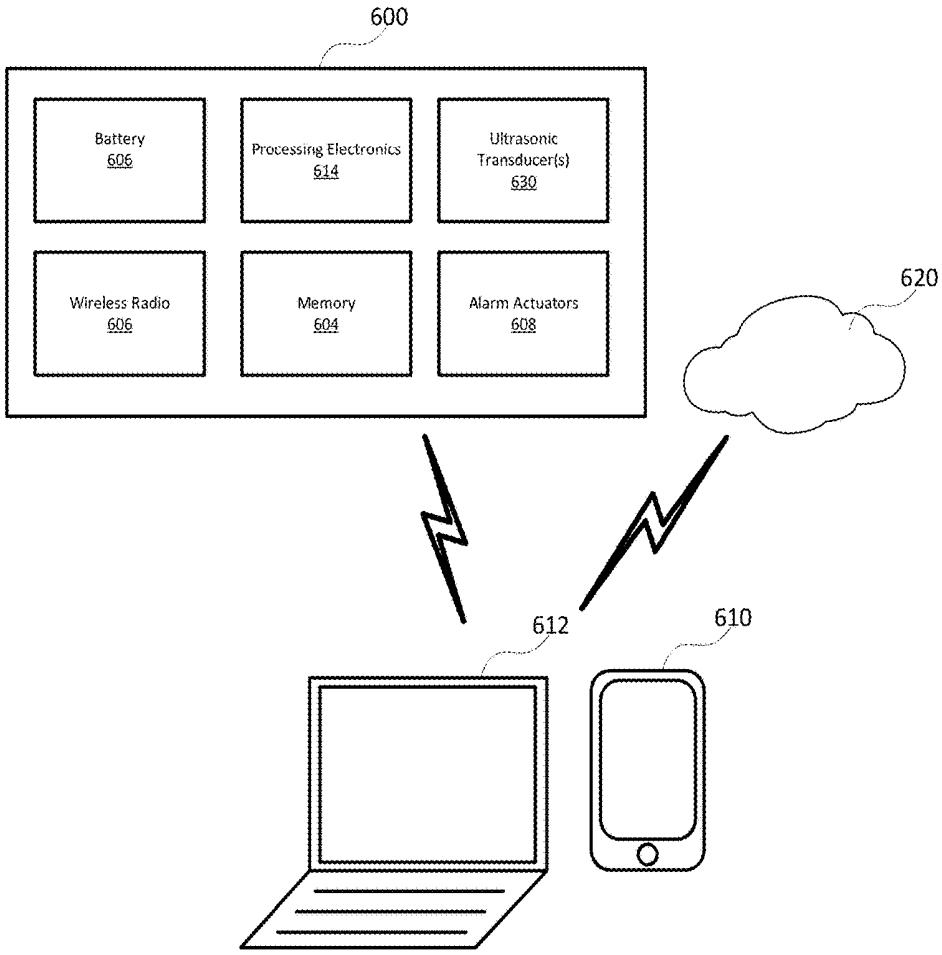

600
Battery
606
Processing Electronics
614
Ultrasonic
Transducer(s)
630
Wireless Radio
606
Memory
604
Alarm Actuators
608
620
612
610

FIG. 6

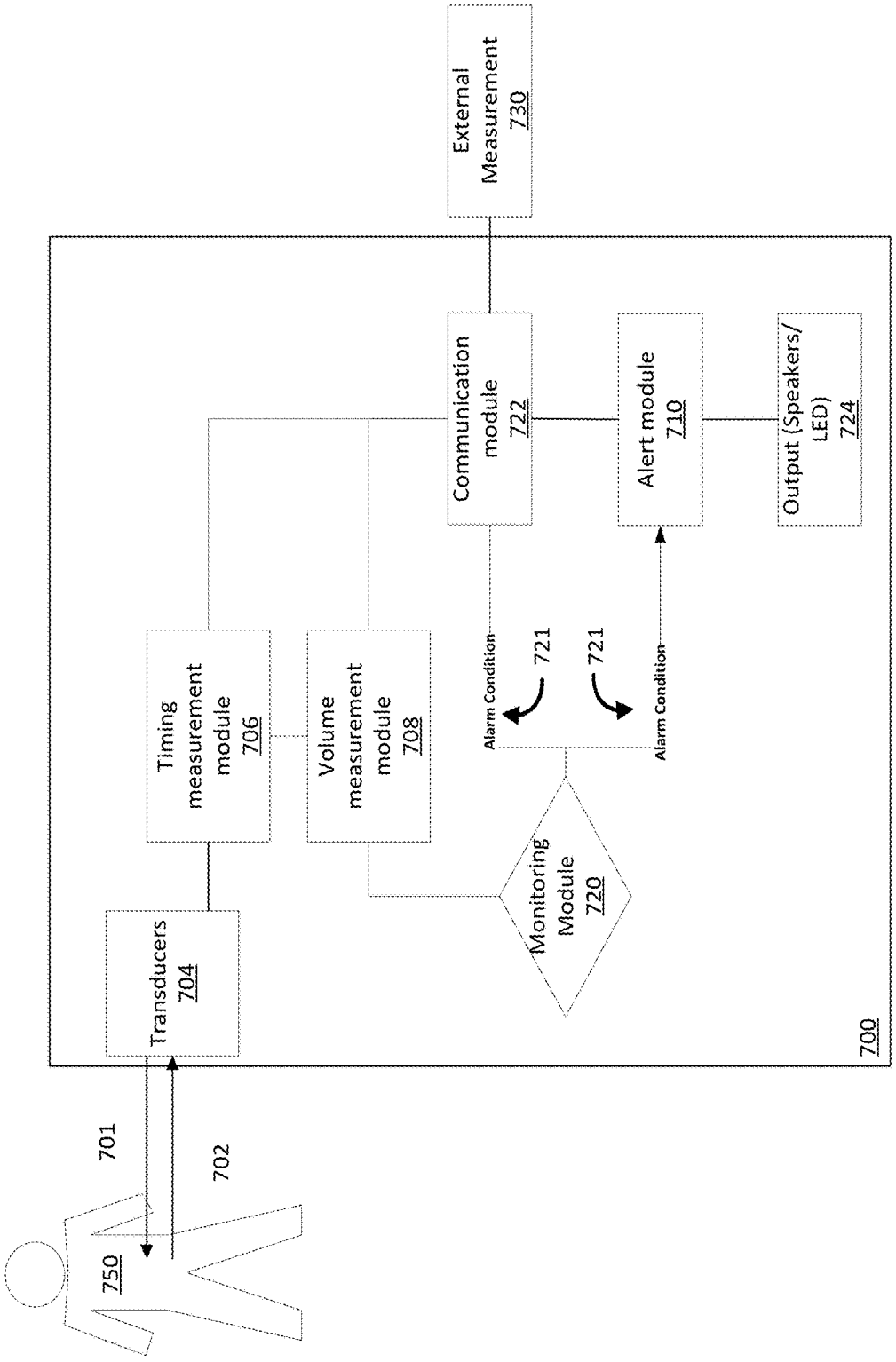

External Measurement 730
Communication module 722
Alert module 710
Output (Speakers/ LED) 724
Timing measurement module 706
Volume measurement module 708
Alarm Condition
721
721
Alarm Condition
Monitoring Module 720
Transducers 704
700
701
702
750

FIG. 7

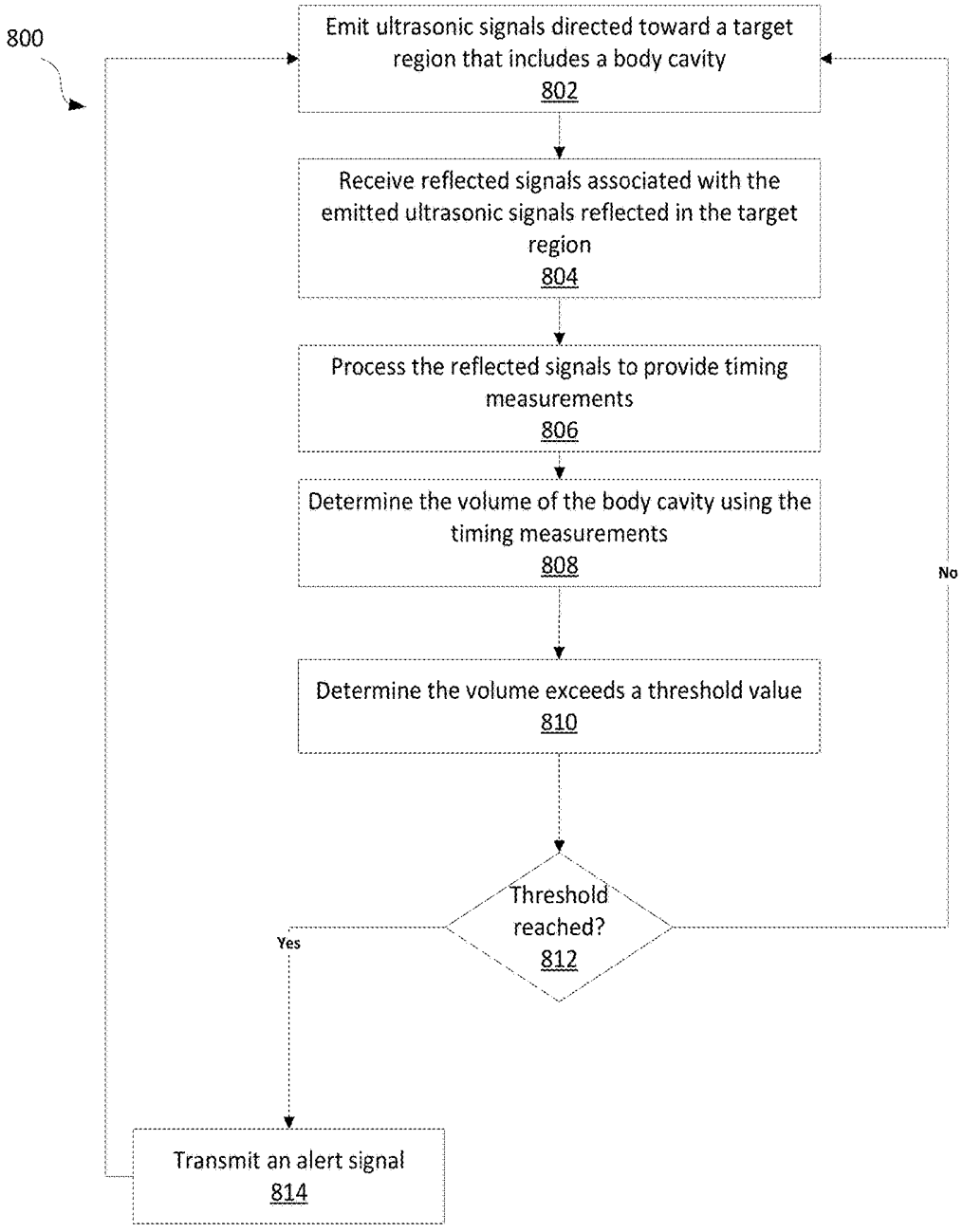

800
Emit ultrasonic signals directed toward a target region that includes a body cavity
802
Receive reflected signals associated with the emitted ultrasonic signals reflected in the target region
804
Process the reflected signals to provide timing measurements
806
Determine the volume of the body cavity using the timing measurements
808
Determine the volume exceeds a threshold value
810
Threshold reached?
812
Yes
No
Transmit an alert signal
814

FIG. 8

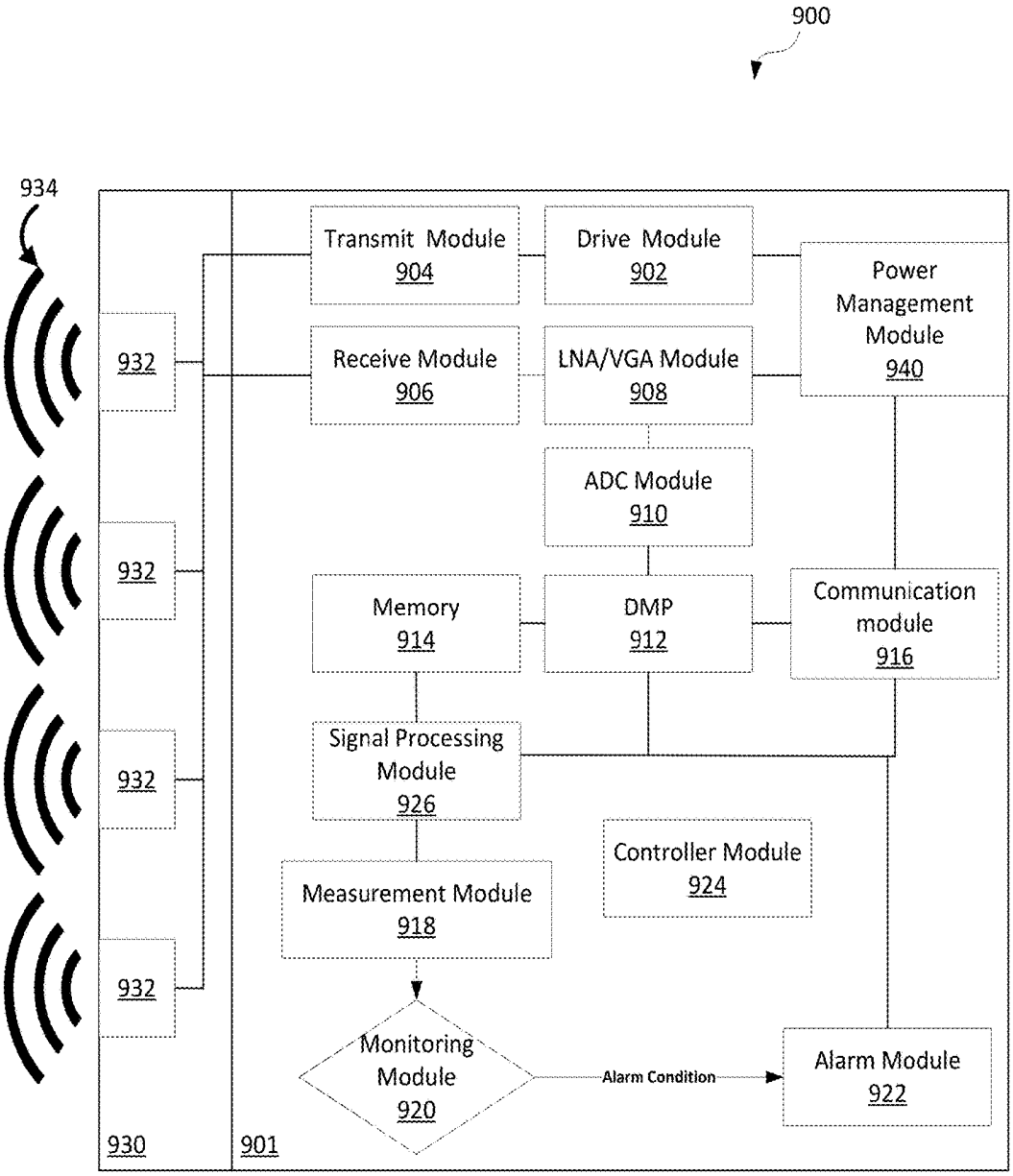

900
934
932
932
932
932
Transmit Module
904
Drive Module
902
Power
Management
Module
940
Receive Module
906
LNA/VGA Module
908
ADC Module
910
Memory
914
DMP
912
Communication
module
916
Signal Processing
Module
926
Controller Module
924
Measurement Module
918
Monitoring
Module
920
Alarm Condition
Alarm Module
922
930
901

FIG. 9

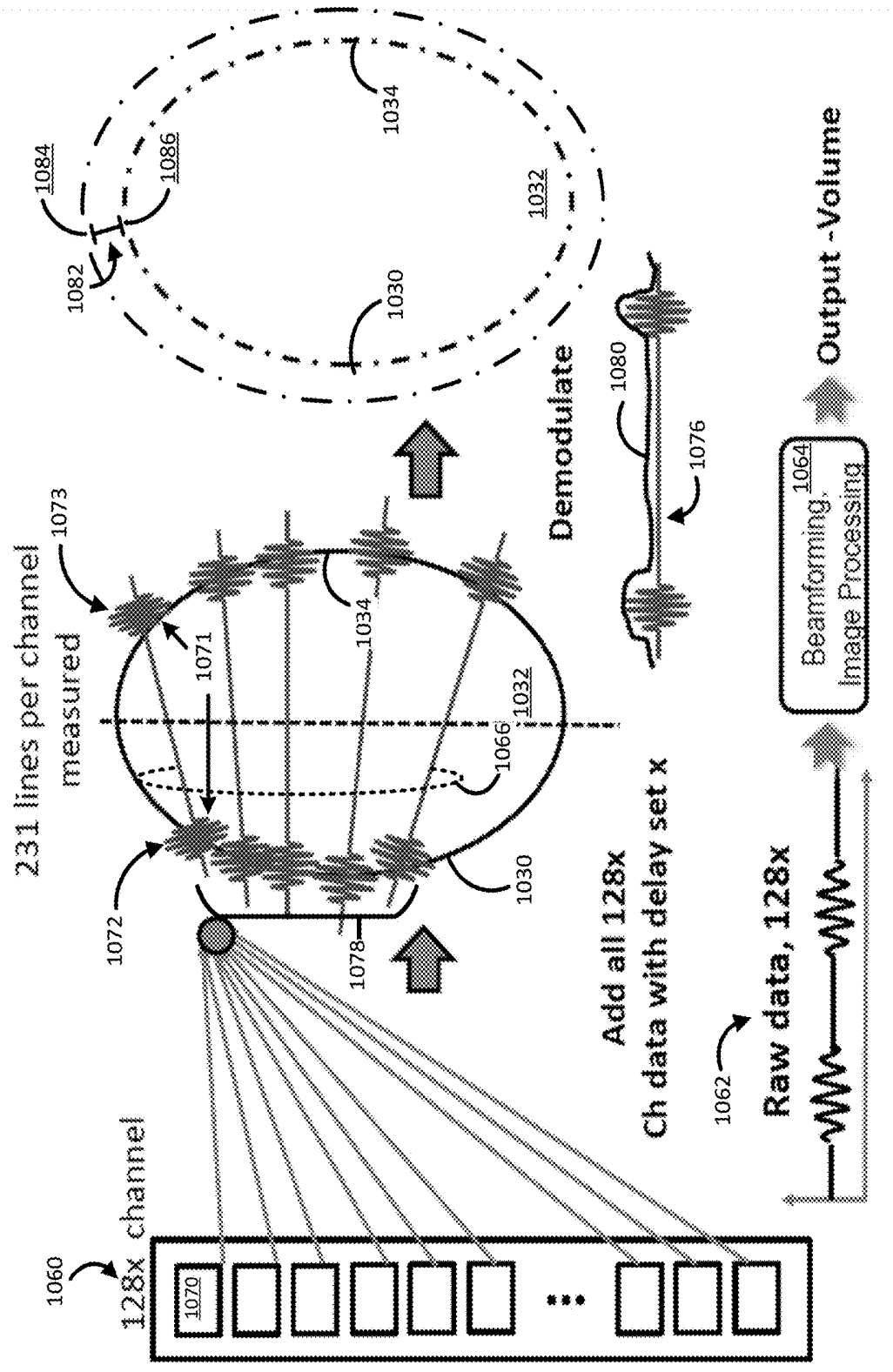

1084
1086
1034
1032
1082
1030
1080
1076
Demodulate
Output -Volume
Beamforming, 1064
Image Processing
231 lines per channel measured
1073
1071
1034
1032
1066
1030
1072
1078
Add all 128x
Ch data with delay set x
1062
Raw data, 128x
1060
128x channel
1070

FIG. 10A

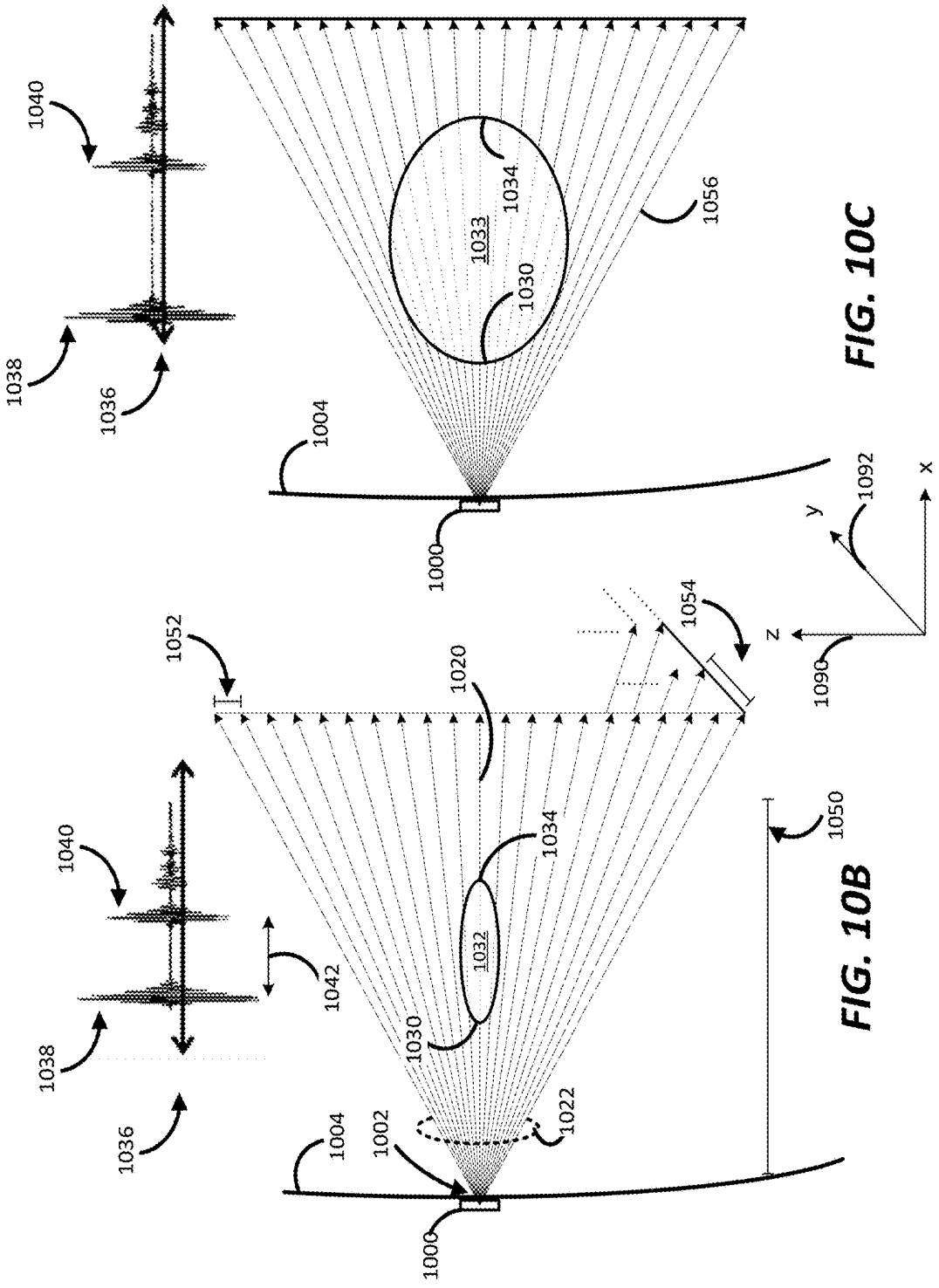


FIG. 10C

FIG. 10B

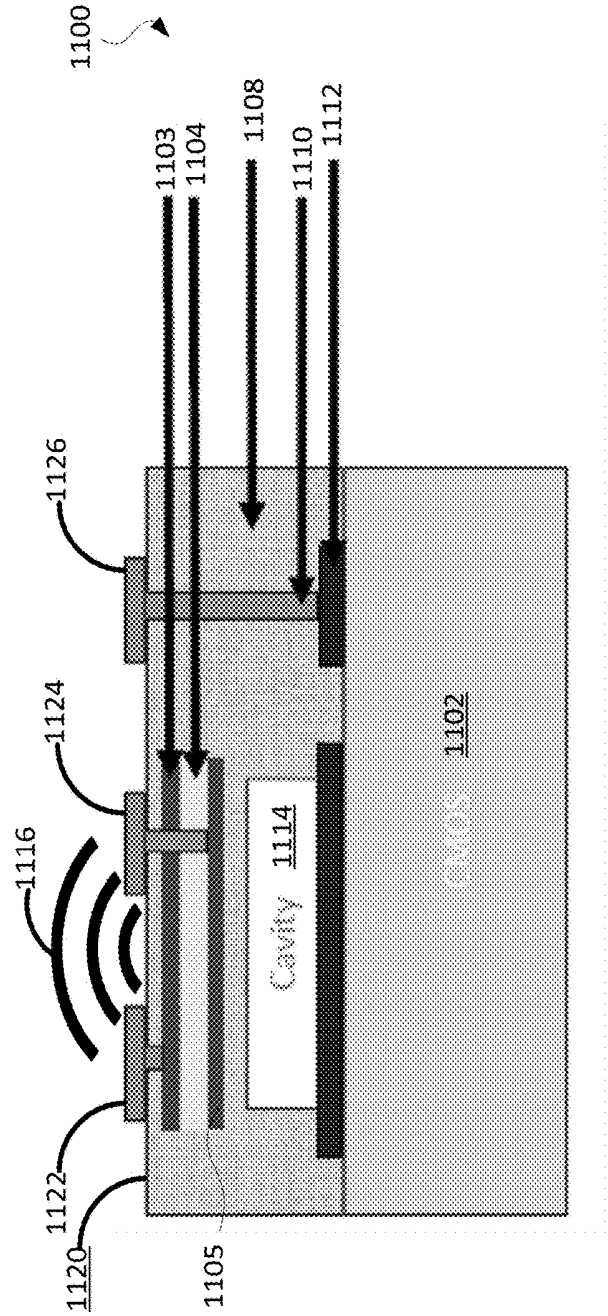

1100
1103
1104
1108
1110
1112
1126
1124
1116
1122
1120
1105
Cavity 1114
1102

FIG. 11

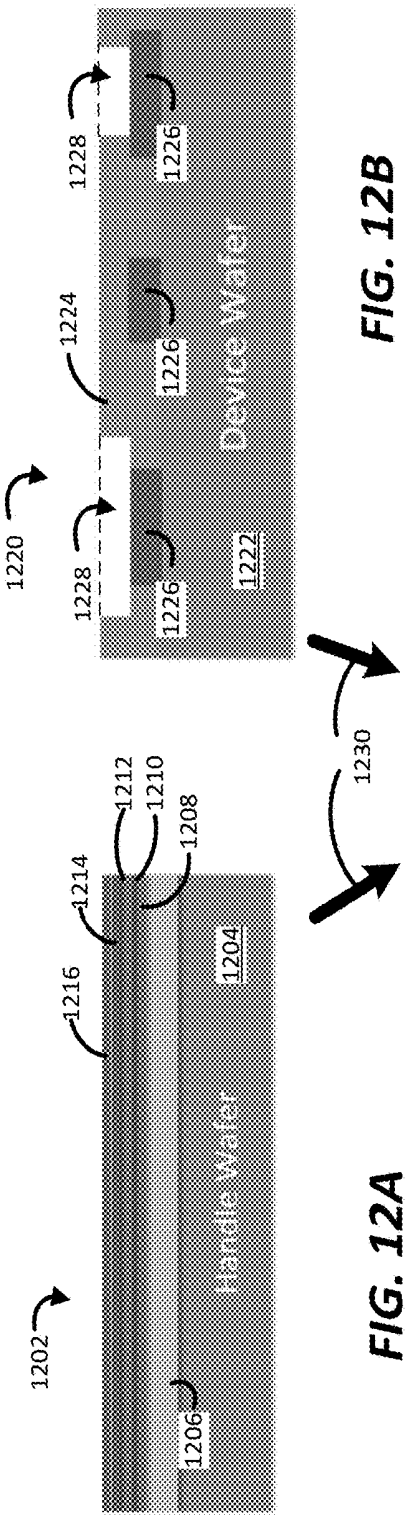


FIG. 12A

FIG. 12B

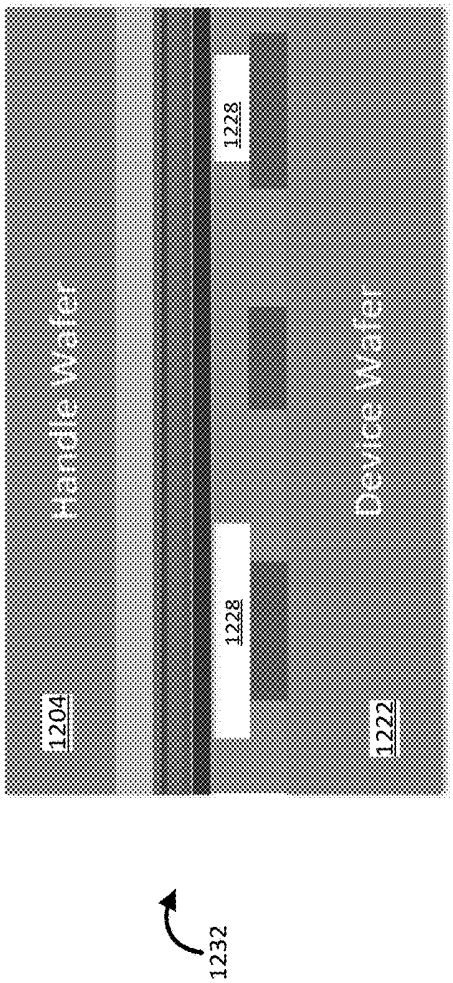


FIG. 12C

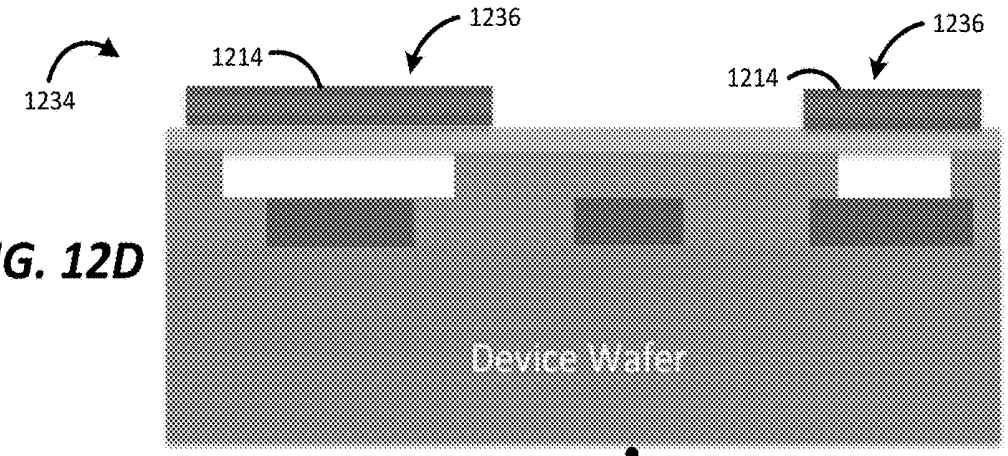


FIG. 12D

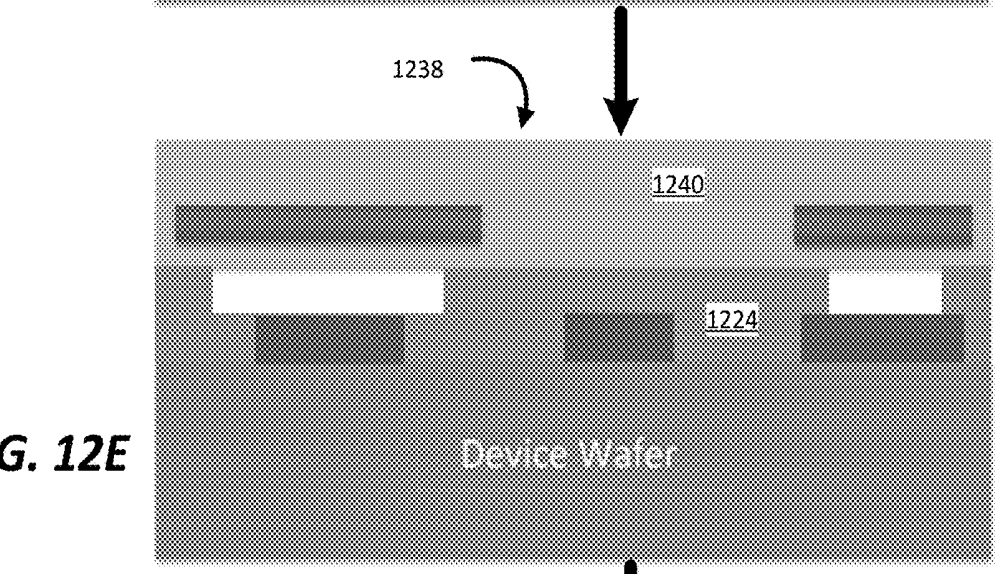


FIG. 12E

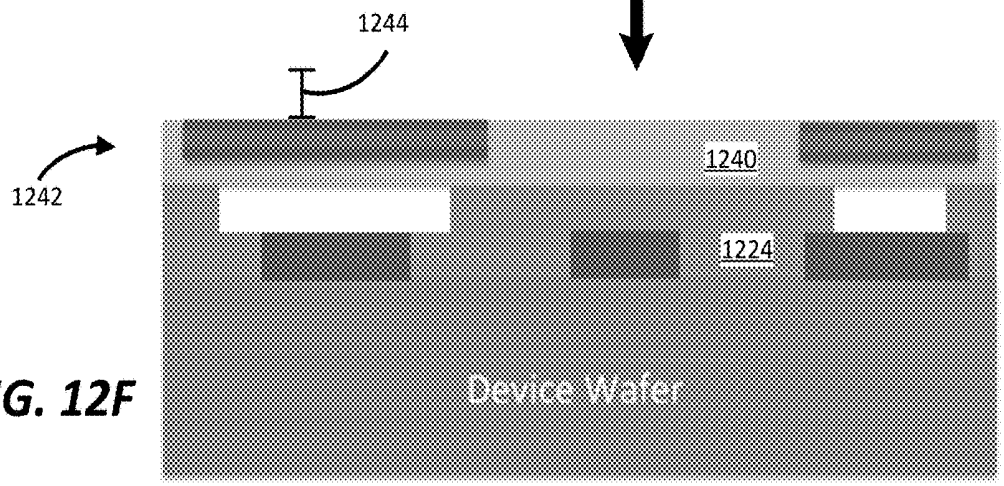


FIG. 12F

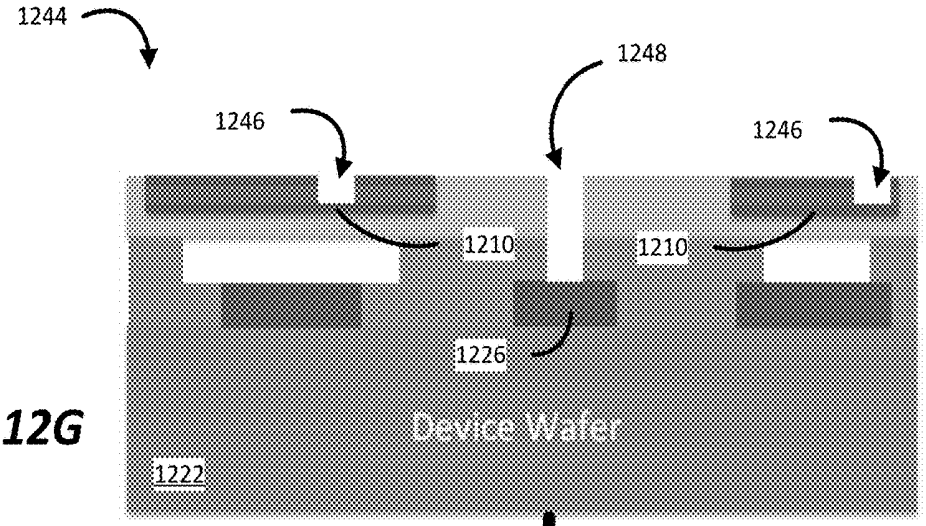


FIG. 12G

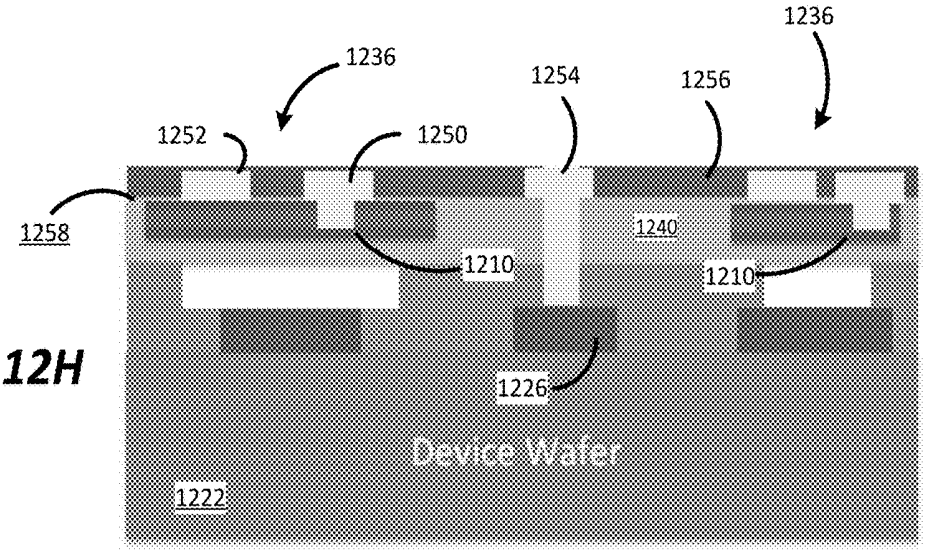


FIG. 12H

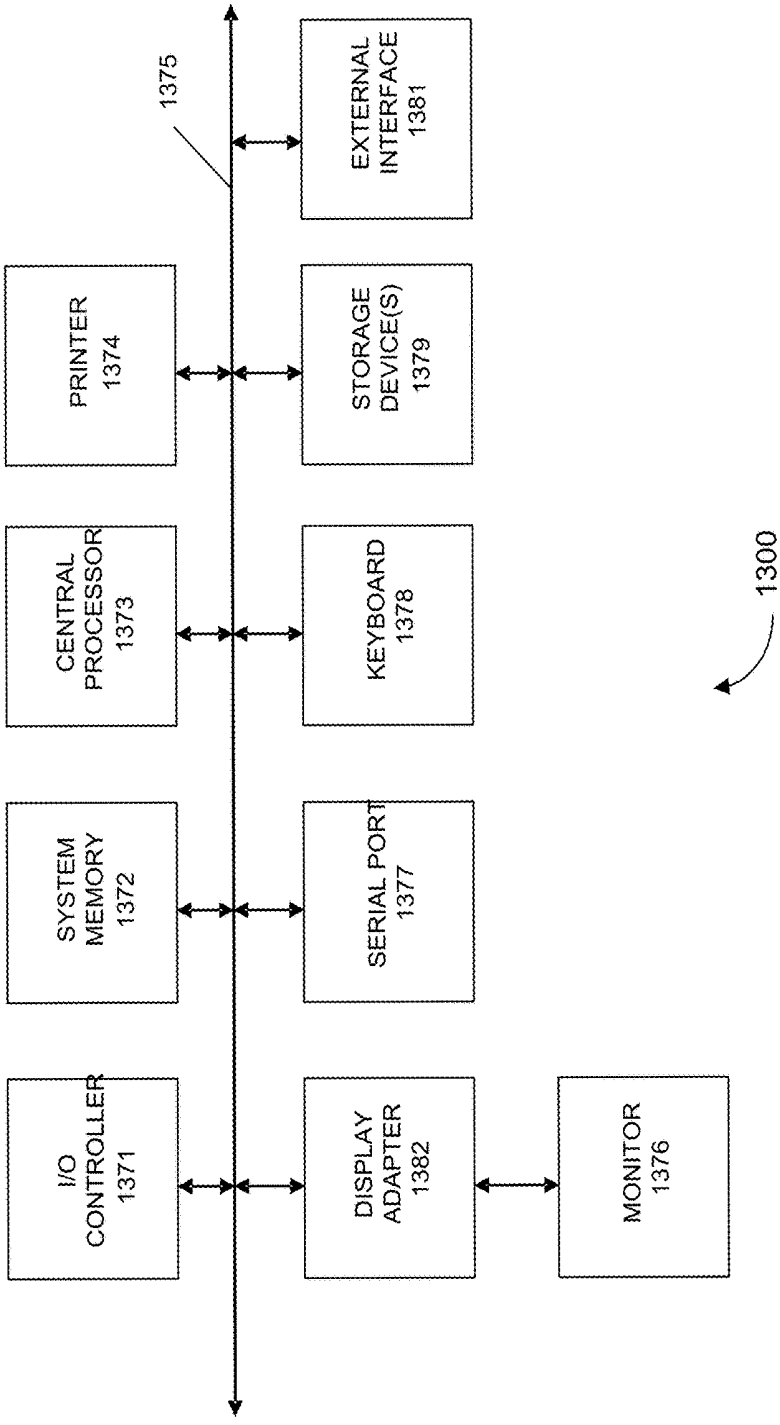

1375
EXTERNAL INTERFACE 1381
PRINTER 1374
STORAGE DEVICE(S) 1379
CENTRAL PROCESSOR 1373
KEYBOARD 1378
SYSTEM MEMORY 1372
SERIAL PORT 1377
I/O CONTROLLER 1371
DISPLAY ADAPTER 1382
MONITOR 1376
1300

FIG. 13

WEARABLE ULTRASOUND DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a non-provisional application claiming priority to U.S. Provisional Patent Application No. 62/455,763 entitled "Wearable Ultrasound Device" filed on Feb. 7, 2017.

FIELD

[0002] The present disclosure relates generally to systems and methods of monitoring internal organs using an ultrasonic wearable device, and more particularly to wearable ultrasound devices for non-invasively measuring the volume of fluid in a body cavity such as a urinary bladder. Methods and systems used for a wearable ultrasonic transducer are also described.

BACKGROUND

[0003] Urinary incontinence affects millions of people all over the world. Such incontinence causes discomfort and embarrassment, sometimes to the point of social isolation. Generally, incontinence occurs when bladder sphincter muscles are not capable of retaining urine within the bladder as bladder pressure and distension increases. Urinary incontinence often results, for example, from weakened pelvic muscles that are unable to suppress the flow of urine when a common occurrence such as coughing, laughing, or mild physical exertion causes an increase in abdominal (and bladder) pressure. In many cases, incontinence consistently occurs when the bladder volume reaches a maximum volume threshold for a given individual. Additionally, millions of children suffer from nocturnal enuresis. Nocturnal enuresis results in the involuntary loss of urine during sleep in children 0-12 years old. Children with nocturnal enuresis are more likely to have behavioral disorders and low self-esteem than their non-wetting peers. Also, diabetic autonomic neuropathy causes the nerves of the bladder to no longer respond to pressure as the bladder fills with urine. Diabetic autonomic neuropathy can lead to increased risk of urinary tract infections and involuntary loss of urine. Thus, real-time non-invasive measurement of bladder volume and notification of approaching an individual's particular threshold volume may help to prevent incontinence and treat nocturnal enuresis.

[0004] While conventional image-based ultrasound devices can be used to measure bladder volume, such devices are large, expensive, require extensive electronics, and have high operating voltages, such that they are not sufficiently mobile for everyday use outside of a hospital or clinical setting. Further, conventional devices require a device operator to manually define a cavity area on a two-dimensional image, from which the conventional ultrasound device can determine a cross-section measurement of the defined area. Because of the conventional device size and voltage limitations and the requirements for input from a trained operator, bladder measurements are typically only performed periodically in a hospital or clinical setting. Moreover, because conventional devices are used in hospital or clinical settings, they often do not include connectivity needed to notify users of monitored parameters.

[0005] Accordingly, wearable ultrasound devices that address the foregoing problems are desirable.

SUMMARY

[0006] Embodiments provide systems, methods, and apparatuses for non-invasively measuring volumes of fluids in a body cavity by a wearable ultrasonic device are provided. The wearable ultrasonic device may collect data related to the body cavity and provide a user alerts to improve the management a variety of bladder ailments such as diabetic autonomic neuropathy, nocturnal enuresis, and urinary incontinence. For example, a portable ultrasound device can be affixed to the skin of an user's body. An ultrasonic transducer incorporated in the device may transmit and receive ultrasonic signals directed towards a body cavity such as a user's urinary bladder. The device may include processing electronics coupled to the ultrasonic transducer to process the ultrasonic signals to determine the volume of the body cavity. If the body cavity is the user's urinary bladder, the device may determine the volume of fluid in the urinary bladder in real time and may generate alerts when the volume reaches a particular threshold so that the individual can manage evacuation and prevent incontinence. The wearable device with processing electronics coupled to the ultrasonic transducer can operate at low voltages and, as a result, be battery powered.

[0007] In some embodiments, the device may non-invasively measure a volume of a body cavity as the volume of the body varies over time. For example, the processing electronics may be configured to receive reflected signals associated with emitted ultrasonic signals reflected from a target region associated with the wearable device. The processing electronics may digitize the reflected signals. In some embodiments, the processing electronics may transmit the digital reflected signals to measurement circuitry to analyze the signal information, and determine the volume of the fluid in the body cavity based on the received reflected signals. The processing electronics may be further configured to store digital reflected signals, compare the determined volume of the fluid with a threshold volume and output an alert when the determined volume reaches or exceeds the threshold volume. The threshold volume may be user-specific, and the alert may include a haptic alert generated by an actuator, an audible alert generated by a speaker or a light emitting diode coupled to the processing electronics. By determining the volume of fluid in the body cavity such as the urinary bladder and/or alerting the user as described above, the device may help the user or a supervising medical professional manage voiding of the urinary bladder and avoid incontinence.

[0008] According to other embodiments, a method of measuring a volume of a body cavity is provided. The volume of the body cavity may be determined using an ultrasonic signal emitted from an array of transducers. The ultrasonic signal can be emitted along different lines through the body cavity in a target region. The reflections from the front wall of the body cavity (e.g., a bladder) may be measured first, and reflections from the back wall measured second. The measurements for each line can provide a pair a peaks: one peak for the echo from the front side of the body cavity and another peak for the echo from the backside of the body cavity. The volume of the body cavity can be determined using a time difference between the respective peaks for each of a plurality of lines. The peaks may be identified in specified time windows, which may be determined during a calibration phase using machine learning to identify a best fit for the times associated with the first peak and the second

peak when the body cavity is at different volumes (e.g., empty and full). Thus, different time windows of different models may be used to search for the peaks corresponding to different lines. Additional channels may be used, each potentially having a delay between received signals from a same point on the body cavity.

[0009] The wearable electronic device may include transducer circuitry coupled to processing circuitry in a combined device. The transducer circuitry may include one or more piezoelectric micromachined ultrasonic transducers (PMUTs). The transducer circuitry may be provided on a first substrate and the processing circuitry may be formed on a device wafer. One or more of cavities may be formed on the device wafer to isolate the processing circuitry from ultrasonic signals generated by the transducer circuitry. The combined device may be formed by bonding a device oxide layer of the processing circuitry to a bonding oxide layer of the transducer circuitry. The combined device may be further processed to form vias and contacts coupled the processing circuitry and transducer circuitry. The combined device may operate at lower voltages than existing ultrasonic devices.

[0010] A better understanding of the nature and advantages of embodiments of the present invention may be gained with reference to the following detailed description and the accompanying drawings. In the drawings, like reference numerals represent like parts throughout similar views.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. **1** shows an illustration of wearable device positioned on a user's body for non-invasively measuring a volume of a fluid in a body cavity according to an embodiment of the present invention.

[0012] FIG. **2** shows an exploded view of a wearable device for non-invasively measuring a volume of a fluid in a body cavity according to an embodiment of the present invention.

[0013] FIG. **3**A shows an array of piezoelectric micromachined ultrasonic transducers used in a wearable device as described above according to an embodiment of the present invention.

[0014] FIG. **3**B shows a simplified illustration of a two-dimensional array of piezoelectric micromachined ultrasonic transducers used in a wearable device according to an embodiment of the present invention.

[0015] FIG. **4** shows a cross-sectional view of a single piezoelectric micromachined ultrasonic transducer bonded to a CMOS wafer used in a wearable device according to an embodiment of the present invention.

[0016] FIG. **5**A shows a block diagram of the processing electronics board according to an embodiment of the present invention.

[0017] FIG. **5**B shows a simplified illustration of a receiving coil configured to receive wireless energy according to an embodiment of the invention.

[0018] FIG. **5**C shows a simplified elevation view of the processing electronics board according to an embodiment of the present invention.

[0019] FIG. **6** shows a simplified schematic of a wearable device in communication with other devices according to an embodiment of the present invention.

[0020] FIG. **7** shows a device for volume measurement and monitoring of a body cavity according to an embodiment of the present invention.

[0021] FIG. **8** shows a flowchart illustrating the operation of a wearable ultrasonic device according to an embodiment of the present invention.

[0022] FIG. **9** shows a simplified block diagram of a PMUT/ASIC stack according to an embodiment of the present invention.

[0023] FIG. **10**A shows a simplified diagram of processing the signal received on a plurality of channels according to an embodiment of the present invention.

[0024] FIGS. **10**B and **10**C illustrate return echoes associated with various sized body cavities disposed in the range of coverage of a channel according to an embodiment of the present invention.

[0025] FIG. **11** shows a cross-sectional view of a single piezoelectric micromachined ultrasonic transducer bonded to a CMOS wafer used in an ultrasonic wearable device according to an embodiment of the present invention.

[0026] FIGS. **12**A-**12**H illustrate a device stack corresponding to process steps used to fabricate piezoelectric micromachined ultrasonic transducers bonded to an application specific integrated circuit according to an embodiment of the present invention.

[0027] FIG. **13** shows a block diagram of an example computer system usable with system and methods according to embodiments of the present invention.

DETAILED DESCRIPTION

[0028] In contrast with conventional ultrasound devices, methods and systems for a wearable ultrasonic device are provided. As examples, wearable devices can be worn on the body, such as affixed to a user's skin (potentially with an intervening membrane) or as part of material used in clothing. A wearable device may maintain approximate contact with a user's body, e.g., throughout daily activities. Wearables can include devices that collect data using various electronic circuits and sensors to generate data related a user's health. In addition to portability, wearable devices described herein can determine body cavity information without requiring inputs from a trained operator, e.g., just the user. Also, wearable devices described herein may integrate transducer and signal processing circuitry to reduce the necessary transducer bias voltage.

[0029] A wearable ultrasonic device can include a coupling hydrogel pad for affixing the device to a surface of the body and providing acoustic coupling interface between the device and the body. The device can include at least one ultrasonic transducer coupled to the coupling pad interface and configured to emit ultrasonic signals directed towards a target region and receive returning ultrasonic echo signals associated with the emitted ultrasonic signals. The device can further include processing electronics coupled to at least one ultrasonic transducer and a battery coupled to and configured to power at least one ultrasonic transducer and the processing electronics.

[0030] In many embodiments, the device may determine parameters associated with a cavity of the body. For example, the device may non-invasively measure a volume of a fluid in a body cavity. In some embodiments, the processing electronics may determine the parameters associated with the body cavity. For example, the processing electronics may be configured to store information associ-

ated with the returning signals, analyze the signal information, and determine the volume of the fluid in the body cavity based on the stored information. In particular, the body cavity may be a cavity in a urinary bladder. The processing electronics may thus be configured to determine a volume of a fluid in the urinary bladder. The processing electronics may be further configured to compare the determined volume of the fluid with a threshold volume and output an alert when the determined volume reaches or exceeds the threshold volume. The threshold volume may be user-specific, and the alert may include a haptic alert generated by an actuator coupled to the processing electronics. By determining the volume of fluid in the body cavity such as the urinary bladder and/or alerting the user as described above, the device may help the user or a supervising medical professional manage voiding of the urinary bladder and avoid incontinence.

[0031] The device may also be helpful to identify irregularities in voiding. For example, the processing electronics may be configured to determine the volume of a fluid in the urinary bladder after voiding by the user. The processing electronics may be further configured to identify voiding dysfunction based on the determined volume after voiding. By tracking the determined volume after voiding and/or comparing it to normal values, the user, a medical professional, or the device's processing electronics itself may be able to identify irregular or dysfunctional voiding so that it can be addressed and treated appropriately.

[0032] The device may also be helpful to determine other parameters, in addition to volume of fluid in the body cavity. For example, the processing electronics may be configured to determine a volume of the structure surrounding the body cavity, such as the total urinary bladder volume (i.e. the capacity of the bladder), based on the stored information associated with the returning signals. Since the total urinary bladder volume may be different for an individual, this may help to determine an appropriate user-specific threshold volume of fluid therein that warrants notification or alerting of the user. As another example, the processing electronics may be configured to determine a thickness of a wall of the urinary bladder. The thickness of the wall may also vary for individuals, and may also aid in determining the appropriate user-specific threshold volume.

[0033] In many embodiments, the device may further include a wireless radio coupled to the processing electronics. For example, the wireless radio may be configured to transmit stored information associated with the return signals to a remote computing device. The remote computing device may thus be configured to determine the volume of the fluid in the body cavity based on the stored information. Determination of the volume or other parameters by a remote computing device may help to reduce the size, complexity, and power requirements of the processing electronics. As another example, the processing electronics may be configured to transmit alerts or other stored information as described above to a remote device (such as a smart phone) via the wireless radio. The processing electronics may also be configured to receive information from a remote device via the wireless radio. For example, the processing electronics may be configured to receive control signals configured to calibrate the device and/or modify alerts via the wireless radio. As another example, the processing electronics may be configured to receive user-specific data from a remote device via the wireless radio. Such user-specific data may help in determining the parameters and/or threshold values described above.

[0034] In many embodiments, the battery may be a rechargeable battery so that the device may be used on a prolonged basis. In some cases, the device may include receiving coils that are electrically coupled to the rechargeable battery. The receiving coils may be configured to receive energy form an external energy source wirelessly and transmit the energy to recharge the rechargeable battery. For example, the receiving coils may be configured to receive energy from an external energy source via radio frequency transmission.

[0035] The coupling interface may also aid in transmission of ultrasonic signals. For example, the coupling interface may include an adhesive hydrogel layer configured to adhere to the skin surface of a user. The hydrogel may thus act as a conductive medium that improves the bond between the skin and the transducers, thus ensuring more efficient transmission of the ultrasonic signals between the body and the transducers.

[0036] The device may be designed to minimize the size and required operating voltage while maintaining the required functionality. To achieve such size and operability, at least one ultrasonic transducer may include an array of piezoelectric micromachined ultrasonic transducers (PMUT). The array of PMUTs may be formed on a microelectromechanical system (MEMS) wafer that is bonded to a CMOS wafer containing the processing electronics. The interconnect between the CMOS and the PMUTs may be a thru-silicon-via (TSV). In some embodiments, each PMUT may include an active piezoelectric layer including aluminum nitride, a passive elastic layer including single-crystal Silicon, and top and bottom electrodes including Molybdenum. The active piezoelectric layer may include scandium doped aluminum nitride. In some embodiments, the array of PMUTs may be configured to have a driving voltage of less than 4 Volts. For example, the array may be configured to generate a maximum acoustic intensity of up to 80 mW/cm2 at a depth of up to 3 cm with an AC input driving voltage of 3.3 Volts. The array may be configured to have a frequency response of 800 KHz to 1.0 MHz.

[0037] The device's size may be minimized to allow for easy and non-invasive wearing by the patient. For example, the device may have a cross section that measures 2 cm by 4 cm and may have a thickness of 0.5 cm or less. This way, the device may be easily secured to a user's skin and may be easily hidden from view by the user's clothing without losing functionality.

[0038] The arrangement of the PMUTs on the device may allow for capturing particular features of the user's body. In many embodiments, the PMUTs may be spaced apart a predetermined distance so as to form an aperture that encompasses a particular body cavity for which information is desired. For example, the PMUTs may be spaced apart a distance so that a resulting aperture encompasses the urinary bladder of a user. In some cases, the PMUTs may be spaced apart roughly 5-6 mm.

[0039] In addition to identifying tissue structures and characteristics thereof, the device may be used therapeutically. In many embodiments, the array of PMUTs may be configured to emit ultrasonic signals that release therapeutic compositions within a targeted region of the user's body. For example, the PMUTs may be used to non-invasively rupture

microbubbles containing therapeutic compositions when the microbubbles are in a targeted region.

I. Wearable Device

[0040] Aspects of the present disclosure relate to wearable devices for non-invasively measuring volumes of fluids in a body cavity. In particular, a portable wearable ultrasound device may be provided that can be affixed to the skin of an user's body. An array of ultrasonic transducers incorporated in the device may transmit and receive ultrasonic signals directed towards a body cavity such as the user's urinary bladder. The device may process the ultrasonic signals to determine the volume of fluid in the urinary bladder in real time and may generate alerts when the volume reaches a particular threshold so that the individual can manage evacuation and prevent incontinence.

[0041] A. Example Placement of Wearable Device

[0042] Embodiments of a wearable ultrasonic device are provided herein. The wearable ultrasonic device may be positioned by a user to continuously monitor a portion of the user's body. In some embodiments, the user may position the wearable ultrasonic device to monitor bladder function. The wearable ultrasonic device may emit ultrasonic pulses receive echoes to collect data related to bladder function. The collected data may be processed to provide the user bladder information and alerts to assist with managing a variety of bladder issues such as diabetic autonomic neuropathy, nocturnal enuresis, and urinary incontinence. The collected data, bladder information, and alerts may be transmitted to a user's mobile device, to an electronic device of a treating physician, and/or a cloud data server for further analysis and alerts.

[0043] FIG. **1** shows an illustration of wearable device positioned on a user's body for non-invasively measuring a volume of a fluid in a body cavity according to an embodiment of the present invention. As shown in FIG. **1** a user **110** may affix a wearable device **100** under the abdomen **101** in order to position the transducers above so that the sub-apertures capture the user's bladder **102**. As described below, device **100** may be adhered directly to the user's skin using an adhesive coupling interface (not shown in FIG. **1**), which may only require applying the adhesive coupling interface to the user's skin with moderate force. Once it is secured in place, device **100** may be operable to analyze various features of the user's bladder **102** to aid in managing urinary incontinence. This may include, but is not limited to, the volume of fluid **104** disposed in bladder **102** at any given time, the thickness of the bladder wall **106**, the shape of the bladder **102**, any other feature of bladder **102**, and/or any combination thereof. In other embodiments, the device **100** may be positioned to monitor another area of the user **110**. Device **100** may be configured to monitor another body cavity or function such as the heart, vascular system, and the like.

[0044] B. Example Layers of Wearable Device

[0045] The wearable device may be constructed of various layers. Each layer may provide different functionality. As described above, the wearable device can be attached to the skin of a person. One layer can help with such attachment, or such a coupling layer can be considered as an addition to the wearable device, as opposed to an integrated part.

[0046] FIG. **2** shows an exploded view of the wearable device **200** for non-invasively measuring a volume of a fluid in a body cavity according to an embodiment of the present invention. Device **200** (e.g. **100** from FIG. **1**) may include a coupling interface **202**, a processing electronics board **204**, a battery **206**, and a cover **208**. As will be described in further detail below, device **200** may include one or more ultrasonic transducers (not shown in detail in FIG. **2**) that enable it to insonify and thus interrogate a volume of tissue in a user's body, such as for the purpose of non-invasively measuring a volume of fluid in a body cavity, such as a urinary bladder. In particular, the ultrasonic transducers are integrated into the processing electronics board **204**. While any suitable ultrasound techniques may be used to obtain the requisite information for determining the volume, in some embodiments, the transducers may direct ultrasonic signals towards the body cavity (such as the bladder) at a fundamental frequency, receive returning echoes of the ultrasonic signals, convert these echoes into digital form and store this digital information in memory on the device.

[0047] The transducers may be coupled to and/or integrated with the processing electronics board **204**, which may have additional processing electronics **214** that are configured to control the transducers, receive information from the transducers, process the information to determine the volume, store the information in memory, and/or transmit any of the information to a remote device for further processing or output as will be described in further detail below. In some embodiments, the processing electronics **214** may be implemented using field programmable gate array. Battery **206** may be electrically coupled to the processing electronics board **204** to power the processing electronics **214** and the ultrasonic transducers. In some embodiments, battery **206** may be a rechargeable battery. In other embodiments, battery **206** can integrated with the processing electronics board **204**. For convenient charging, although not shown in FIG. **2**, device **200** may include a charging spiral that allows the battery to be recharged inductively. Alternatively, battery **206** may be removed for charging and/or replacement.

[0048] Although shown in an exploded view in FIG. **2**, processing electronics board **204**, battery **206**, and cover **208** may be assembled to form a single assembly for use in operation. In order to allow convenient replacement of any of coupling interface **202**, processing electronics board **204**, battery **206**, and cover **208**, some or all of these components may be removably coupled to one another by any suitable means. For example, coupling interface **202** may have an adhesive on a top surface **210** that interfaces with bottom surface **212** of the processing electronics **214** which incorporate the ultrasonic transducers (as will be described in further detail with respect to FIGS. **7** and **9** below). The adhesive may allow coupling interface **202** to remain affixed to processing electronics **214** under normal operation, but also allow removal of coupling interface **202** upon a moderate pulling force by a user. This may allow a user to replace coupling interface **202** as it becomes less effective and/or worn out. Similarly, battery **206** may be removably coupled to processing electronics by any suitable mechanism, including a snap fit connection, adhesive, or any other removable coupling. This may allow battery **206** to be removed so that it can be charged and/or replaced with another battery. In other embodiments, the battery **206** may be non-removably fixed to the processing electronics board **204** to reduce device size and complexity. Finally, cover **208** may be removably coupled to the remaining portion of device by any suitable mechanism, such as a snap fit mechanical connection, an adhesive, or any other removable

coupling. For example, cover **208** may be snap fit to the perimeter surface of processing electronics board **204** so as to protect the battery **206** and processing electronics **214** mounted on processing electronics board **204** in operation while allowing access to said components when needed.

[0049] Coupling interface **202** may be configured to affix device **200** to a surface of a user's body while also acting as a conductive medium that improves the bond between the skin and the ultrasonic transducers (described in further detail below), thus ensuring more efficient transmission of ultrasonic signals between the body and the transducers. For example, coupling interface **202** may be an adhesive hydrogel pad that improves the bond between a user's skin and the ultrasonic transducers of device **200** that are coupled to processing electronics board **204**. As described above, coupling interface **202** may be removably coupled to device **200** via top surface **210** so that it can be replaced when worn out or otherwise as desired by the user. Similarly, bottom surface **216** of coupling interface **202** may include an adhesive layer or adhesive portions so that it can adhere to a user's skin at a desired location for several hours to keep the device in place during daily activity, but still be removed from a user's skin without causing excessive discomfort. In some embodiments, coupling interface **202** may include any suitable components and arrangement thereof for both wearable device **200** to the user's body and conducting ultrasonic signals between the body and transducers. For example, coupling interface **202** may include an adhesive portion along its perimeter with an ultrasound hydrogel or other conductive medium housed in its perimeter.

[0050] As described above, device **200** may include ultrasonic transducers that may be used to non-invasively measure a volume of a fluid in a body cavity. While conventional ultrasound imaging devices can be used to measure the volume of fluids in body cavities, these devices are not sufficiently portable or wearable. Indeed, because such devices have high operating voltages (sometimes requiring as much as 100 V) and require extensive electronics, they are limited to imaging systems used onsite at medical centers, and cannot be incorporated in a portable, wearable device for real-time monitoring during daily use. The design of the individual ultrasonic transducers, as incorporated in the processing electronics, and the arrangement of the array of transducers allow device **200** to operate on significantly less voltage while still providing the requisite ultrasonic emission and sensing capabilities needed for accurately measuring volumes of fluid in body cavities non-invasively in real time. Specifically, the device **200** may be designed so that the dimensions are approximately 2 cm×4 cm, with a thickness of 0.5 cm or less. This way, the device may be easily wearable without interrupting the daily activity of the user and easily covered by the user's clothing when in operation.

[0051] C. Transducer Array and Stack

[0052] In order to achieve the aforementioned functionality and geometry, device **200** may include an array of piezoelectric micromachined ultrasonic transducers (PMUTs) formed on a microelectromechanical system (MEMS) wafer. The MEMS wafer may be bonded to a complementary metal-oxide-semiconductor (CMOS) wafer, which may include the processing electronics needed to control the PMUT and process the signals received therefrom to monitor the volume of fluid in the relevant body cavity. A process used to form the MEMS wafer will be described below with reference to FIGS. **12**A-**12**H.

[0053] FIG. **3**A shows an array of piezoelectric micromachined ultrasonic transducers used in a wearable device as described above, in accordance with many embodiments. As noted above, rather than a single ultrasonic transducer, device **301** may incorporate an array of PMUTs **300** that may operate at a lower voltage than bulk PZT ceramic transducers and capacitive micromachined transducers, and allow device **301** to be portable and wearable. As shown in the simplified view of FIG. **3**A, each PMUT **300** may have a range of coverage, or sub-aperture **305**, across which it may transmit and receive ultrasonic signals in operation. While these sub-apertures **305** may be smaller than the relevant body cavity to be analyzed, it will be understood that the PMUTs **300** can be arranged so that the information from the set of sub-apertures can be used to effectively generate an aperture **310** to analyze a particular target area. The arrangement of the PMUTs **300** may correspond to a predetermined distance **311** that forms a desired aperture **310**. Aperture **310** may form a cone that encompasses the body cavity. For example, if device is used to measure the volume of fluid in a urinary bladder, it may be desirable to have eight PMUTs **300** or "sup aperture tiles" spaced apart approximately 5-6 mm. In some cases, each sub-aperture tile may include 16 PMUT elements, such that each tile generates **16** channels, for a total of 128 channels. This arrangement may provide a suitable aperture with the sufficient number of channels to measure features of a bladder of a user with sufficient resolution. It will be understood that while a linear array of PMUTs **300** is shown in FIG. **3**A for illustrative purposes, other suitable arrangements may be used depending on the desired body cavity to be measured.

[0054] FIG. **3**B shows a simplified illustration of a two-dimensional array of piezoelectric micromachined ultrasonic transducers used in a wearable device **303** according to an embodiment of the present invention. Rather than a single ultrasonic transducer, each sub-aperture tile **302** may include 16 elements **312**. The 16 elements **312** may be arranged in an array. For example, sub-aperture tile **302** may be a 4×4 array of the 16 elements **312**. Each element **312** may correspond to a channel. In some embodiments, each channel can be made of an array of transducers. In a particular embodiment, each element **312** may include 49 PMUTs. Integrating multiple elements **312** into a single sub-aperture tile **302** can reduce overall size of the transducer array allowing a reduced operating voltage, and facilitating a portable and wearable device **303**. As shown in the simplified view of FIG. **3**B, each element **312** may have a range of coverage, or sub-aperture **314**, across which it may transmit and receive ultrasonic signals in operation. While these sub-apertures **314** may be smaller than the relevant body cavity to be analyzed, it will be understood that each element **312** can be arranged so that the information from the set of sub-apertures **314** can be used to effectively generate an aperture **310** to analyze a particular target area. The aperture size must be large enough to cover the target area.

[0055] For example, if device **303** is used to measure the volume of fluid in a urinary bladder, it may be desirable to have eight sub-aperture tiles **302** arranged in a 4×2 rectangular array. Each sub-aperture tile **302** tile can be approximately 7.2 mm by 7.2 mm. Each sub-aperture tile **302** can be spaced apart approximately 3-4 mm. In some cases, the 16 elements **312**, for each of the sub-aperture tiles **302**

generates **16** channels, for a total of 128 channels. In some embodiments, each element **312** can be 1.8 mm by 1.8 mm. This arrangement may provide a suitable aperture with the sufficient number of channels to measure features of a bladder of a user with sufficient resolution. It will be understood that while a rectangular array of sub-aperture tiles **302** is shown in FIG. **3**B for illustrative purposes, other suitable arrangements may be used depending on the desired body cavity to be measured.

[0056] In some embodiments, device **303** may include a single-chip containing 8 PMUT sub-aperture tiles with 16 elements each as described above. As will be understood by those skilled in the art, the number of transmit/receive channels of such a device may be tuned to obtain the desired resolution for a given application. For example, it may be desirable, in the case of measuring bladder features as described herein, to provide a single-chip, 8 sub-aperture tiles by 16 elements per tile device with 128 channels. The device may provide 128 emission channels and 128 receiving channels.

[0057] The design and arrangement described above may allow device **303** to produce enough acoustic intensity while operating with a significantly lower voltage than traditional ultrasound equipment. It will be understood that this allows the device to meet the size and battery constraints needed for a wearable device. Specifically, a device **303** as described may run on 4 Volts or less (e.g. 3.3 V), and may generate an acoustic intensity of as much as 80 mW/cm^2 as many as 3 cm below the contact point with a user's skin. This particular intensity and depth may be suitable for monitoring a user's bladder. While described herein primarily for the purpose of monitoring a user's bladder, it will be understood that the principles described herein may apply to monitoring or otherwise measuring features of other tissues as well.

[0058] FIG. **4** shows a cross-sectional view of a single piezoelectric micromachined ultrasonic transducer **400** bonded to a CMOS wafer **402** used in a wearable device, as described above, in accordance with many embodiments. As described above, and as shown in FIG. **4**, each PMUT **400** may be formed on a MEMS wafer that is bonded to a CMOS wafer **402**. In this way, PMUT **400** may be coupled to the requisite processing electronics of the CMOS. It will be understood that each PMUT may have an active piezoelectric layer **404** along with top and bottom electrodes **406**. The passive elastic layer **408** may comprise SiO_2 or any other suitable passive layer. The active piezoelectric layer **404** may be approximately 1 μm thick Aluminum Nitride, and the passive elastic layer may be approximately 1 μm thick single-crystal Silicon. In some embodiments, the active piezoelectric layer **404** may be Scandium-doped Aluminum Nitride. Alternatively, the active piezoelectric layer **404** may be another suitable piezoelectric ceramic such as PZT. Both the top and bottom electrodes **406** may comprise Molybdenum. In order to bond the PMUT **400** to the top metal **412** of CMOS wafer **402**, fusion bonding via thru-silicon-via (TSV) as shown at **410** may be used. This methodology results in significant parasitic reduction which in turn results in generation of increased acoustic intensity in operation.

[0059] In some embodiments, device **303** may include a single-chip containing 8 PMUT sup-aperture tiles with 16 elements each as described above. As will be understood by those skilled in the art, the number of transmit/receive channels of such a device may be tuned to obtain the desired resolution for a given application. For example, it may be desirable, in the case of measuring bladder features as described herein, to provide a single-chip, 8 sub-aperture tiles×16 element PMUT device with 128 channels.

[0060] The design and arrangement described above may allow device **100** to produce enough acoustic intensity while operating with a significantly lower voltage than traditional ultrasound equipment. It will be understood that this allows the device to meet the size and battery constraints needed for a wearable device. Specifically, a device **100** as described may run on 4 Volts or less (e.g. 3.3 V), and may generate an acoustic intensity of as much as 80 mW/cm^2 as many as 3 cm below the contact point with a user's skin. This particular intensity and depth may be suitable for monitoring a user's bladder.

[0061] D. Example Circuitry

[0062] FIGS. **5**A-**5**C show views of the processing electronics board and transducer array. FIG. **5**A shows a block diagram of the processing electronics board **204** according to an embodiment of the present invention. The processing electronics board **204** can include PMUT/ASIC integrated stacks **502**, a flexible printed circuit board **504**, data interconnects **506**, power interconnects **508**, a master microcontroller **510**, a Radio Frequency (RF) module **530**, an antenna **532**, a battery **542**, and a power management integrated circuit (PMIC) **540**. In some embodiments, the PMUT/ASIC integrated stacks **502** can comprise a plurality of transducers coupled to an application specific integrated circuit (ASIC). The ASIC can include processing and measurement circuitry. The PMUT/ASIC integrated stacks **502** can include 16 channels per chip. The ASIC can provide multi-channel control with no connection parasitics because the processing and measurement circuitry is coupled directly to the transducer. The ASIC can include voltage drivers to drive the transducers. The processing circuitry can access on-chip memory to perform on-chip beam forming. For the purpose of the description of FIG. **5**A, the processing electronics board **204** may be positioned on a user's abdomen to measure the volume of the user's bladder.

[0063] In some embodiments, the master microcontroller **510** can be configured to operate the board in a plurality of modes. The plurality of modes includes, standby, startup, transmit, receive, processing. In standby mode, the master microcontroller **510** puts all elements of the processing electronics board **204** in a sleep mode to conserve power. Upon receiving a command or input from the user, the master microcontroller **510** may enter startup mode. In startup mode the master microcontroller may send commands to startup each of the slave ASICs at each PMUT/ASIC integrated stacks **502** and the PMIC **540**. The PMIC **540** may generate a voltage to power the devices on the processing electronics board. In some embodiments, the voltage may be approximately 24 V. In transmit mode, the microcontroller may send commands to each of the ASICs coupled to the PMUT/ASIC integrated stacks **502** to fire pulses on all channels. The pulses may be fired at 24 V. After transmitting a pulse, the master microcontroller may send commands to enter receive mode. In receive mode, the transducers in the PMUT/ASIC integrated stacks **502** will generate a signal in response to a receiving echo associated with the previous pulse. As used herein, with reference to the receiving echo, returning signal, reflected signal, and received signal may also be used to describe the receiving echo. The PMUT/ASIC integrated stacks **502** may use processing circuitry in the ASIC to digitize the signal and

store the digital reflected signal data in an on-chip memory. In some embodiments, the ASIC includes one or more analog-to-digital converters and an SRAM to store the digital signal data.

[0064] The master microcontroller **510** can send a command to enter data processing mode. In this mode, the circuitry in the slave ASICs may be powered off except for memory. The master microcontroller **510** may receive the digital reflected signal data from the on-chip memory of each ASIC. The master microcontroller **510** can further process the digital reflected signal data and perform received data beam-forming. Using the processed data, the master microcontroller **510** may determine a bladder's size. During the data processing mode, the master microcontroller may send commands to the RF module **530** to initiate wireless communication with a remote device. The master microcontroller **510** can send and receive data and commands with the RF module **530**. The data can include ultrasound data, digital reflected signal data, bladder size data, and alerts. The RF module **530** may be operable to perform wireless transmission using antenna **532** using a variety of frequencies such as WiFi, Bluetooth, and the like. After transmitting data, the master microcontroller **510** can continuously record data, go into a standby mode and record data at predetermined intervals, or go into a standby mode and record data upon receiving a command from a user.

[0065] In some embodiments, the processing electronics may include a beamforming engine. The master microcontroller **510** can include a beamforming module **512** that include circuits, instructions, or the like. The beamforming module **512** may process digital signal data associated with a return echo from one or more of the PMUT/ASIC integrated stacks **502** to reconstruct a far field beam pattern associated with aperture **310**. Beamforming module **512** can also focus and steer an ultrasound beam associated with the transducer array, e.g., by providing control signal to PMUT/ASIC integrated stacks **502**. When performing a signal analysis, beamforming module **512** may time delay one or more digital signals associated with a return echo according to a delay profile for a target point to focus and steer the beam. The beamforming module **512** may control the directionality, sensitivity, resolution, and signal-to-noise ratio of the system. In some embodiments, the beamforming module can use the digital signal data to determine data associated with 231 beamforming lines that pass through target points.

[0066] FIG. **5**B shows a simplified illustration of a receiving coil configured to receive wireless energy according to an embodiment of the invention. In some embodiments, the battery **542** may be a rechargeable battery so that the device may be used on a prolonged basis. In some cases, the device may include receiving coils **544** that are electrically coupled to the rechargeable battery **542** and or the PMIC **540**. The receiving coils **544** may be configured to receive energy form an external energy source wirelessly and transmit the energy to recharge the rechargeable battery **542**. For example, the receiving coils **544** may be configured to receive energy from an external energy source via radio frequency transmission. The receiving coils **544** and PMIC **540** may be configured to support, for example, one of Qi, Power Matters Association, or Association for wireless power standards, and may operate at different frequencies. In some embodiments, the device processing electronics board may include a port for wired charging/wired power.

[0067] FIG. **5**C shows a simplified elevation view of the processing electronics board according to an embodiments of the present invention. In some embodiments, the processing electronics board **204** may include a cap **550**. The cap **550** may provide electrical isolation from the surrounding environment and a smooth surface for the coupling interface **202**. The cap **550** may be configured to be transparent to ultrasound. The PMUT/ASIC integrated stacks **502**, charging coil **544**, and PMIC **540** are also illustrated in FIG. **5**C.

[0068] E. Communication System Involving Wearable Device

[0069] FIG. **6** shows a simplified schematic of a wearable device **600** in communication with other devices, in accordance with many embodiments. In some embodiments, wearable device **600** can be wearable device **100** described in FIGS. **1-5**. Wearable device **600** may include a battery that provides power to all of the device components, ultrasonic transducers **630** that send and ultrasonic signals towards the bladder for analysis thereof, and processing electronics **614** which are configured to control the transducers **630**, receive the information from the ultrasonic transducers **630**, process the information to determine the volume, store the information in memory **604**, and/or transmit any of the information to a remote device such as a remote device **610** or a personal computer **612** for further processing or output. In some embodiments, the processing electronics **614** generate digital ultrasound data from the 128 channels at a 10 MHz data rate. The processing electronics **614** may be configured to transmit data using a general purpose serial interface such as a 7-wire interface. Memory **604** may be used to store data received from transducers, patient-specific data used for processing such data, processing algorithms themselves, bladder information calculated using the processing algorithms, bladder information threshold related data, operating parameters for components of device **600**, and/or any other data needed for operation of device **600**. In some embodiments, the remote device **610** may be any portable mobile electronic device such as a PDA, a smart phone, a tablet, a smartwatch, or the like.

[0070] In order to transmit information to a remote device, device **600** may also include a wireless radio **606**. Wireless radio **606** may be any suitable radio that can wirelessly transmit information to remote devices, including radios that employ short range, low power communication protocols such as Bluetooth, low power Bluetooth, or other protocols. As further depicted in FIG. **6**, information may also be transmitted to and from a data cloud **620** which may include a number of remote servers and/or databases. For example, device **100** may transmit information to the data cloud **620** via remote devices **610** and/or **612**, which can be accessed by authorized users and/or authorized third parties such as healthcare providers, drug makers, researchers, and the like. It will be understood that information relating to the bladder monitoring may help to update bladder monitoring algorithms used by device **600**, remote devices **610**, **612**, or data cloud **620** remote servers, may aid healthcare providers and researchers in identifying and diagnosing conditions of a user, and may aid drug makers in assessing whether drugs used while monitoring a user's bladder are effectively treating conditions that cause frequent urination.

[0071] As described above, device **600** may be used to alert a patient of conditions related to their bladder, including when the volume of fluid in the bladder reaches a threshold volume. Accordingly, device **600** may include one

or more alarm actuators **608**. These alarm actuators **608** may provide haptic, visual, and/or audible alarms to the user upon the occurrence of an event, as will be described in further detail below. For example, alarm actuators **608** may vibrate, sound an audible alarm tone, and/or emit a visible light when a user's bladder volume reaches a threshold value. It will be understood that alarm actuators **608** may be configured to provide different notifications for different types of events, including more intense alerts for more serious events. Additionally, it will be understood that alarm actuators **608** may be customized for a particular user to meet his or her specific needs.

II. Continuous Measurement of Volume and Alerts

[0072] Non-invasively measuring and monitoring volume of a fluid in a subject's body cavity (e.g., a urinary bladder) will now be described. As described above, monitoring the volume of fluid in a user's urinary bladder may help the user manage urinary incontinence, nocturnal enuresis, diabetes autonomic neuropathy, and the like. Continuous measurement provided by methods and systems described herein can improve management and treatment of bladder dysfunction compared to conventional devices that offer limited monitoring only in a hospital or clinical setting with a trained operator. Although some examples are described in relation to a bladder, other embodiments can involve other body cavities such as a heart, a kidney, a portion of a vascular system, and the like.

[0073] A. Device for Volume Measurement and Alert

[0074] FIG. **7** shows a device for volume measurement and monitoring of a body cavity according to an embodiment of the present invention. The device **700** may include one or more ultrasonic transducers **704**, a timing measurement module **706**, a volume measurement module **708**, a monitoring module **720**, an alert module **710**, a communication module **722**, and an output module **724**. In some embodiments, communication module **722** may be coupled to an external measurement module **730**.

[0075] In the example shown, the ultrasonic transducers **704** emit ultrasonic signals **701** toward a body cavity of a user **750**. The ultrasonic transducers **704** receive a returning ultrasonic signal **702** associated with the emitted ultrasonic signals **701**. The device **700** can convert the returning ultrasonic signals **702** to digital signals and transmit the signals to the timing measurement module **706**. In other embodiments, the signals stay analog. The conversion can involve analog-to-digital converters (ADCs) that may be in timing measurement module **706** The timing measurement module **706** may be configured to process the digital signals associated with the returning ultrasonic signal **702**. The processing can include aligning digital signals associated with the returning ultrasonic signal, identifying peaks in the digital signal, e.g., by searching specified time windows in the signal. In some embodiments, the timing measurement module **706** may coherently sum the digital signals to form a composite digital signal integrating the digital signals associated with each channel. Device **700** can transmit the timing data to volume measurement module **708** or to the external measurement module **730**, via communication module **722**, for further processing.

[0076] The volume measurement module **708**, and/or the external measurement module **730**, can determine, based on the received times of the peaks, a roundtrip time for an emitted ultrasonic signal from the first wall to a second wall of a body cavity. Pairs of peaks can be identified as corresponding to a same emission line, where one peak corresponds to a front wall (side) and a second peak corresponds to a back wall (side). A time difference between a pair of peaks can provide the roundtrip time between the front wall and the back wall.

[0077] The roundtrip time can be used to determine a volume of the body cavity. The device **700** can route the volume of the body cavity to the monitoring module **720**. The monitoring module **720** can determine whether the volume exceeds a threshold value. The threshold value can include a minimum/maximum volume, a rate of change of the volume, and the like. The threshold value may be a percentage of the minimum/maximum volume, and thus the threshold value may be user-specific. The monitoring module **720** can detect an alarm condition **721** based on the threshold value and transmit the alarm condition **721** to one or more of the communication module **722** and an alert module **710**. The alert module **710** can include alert circuitry and/or instructions to process the alarm condition **721** and transmit a signal to output module **724** or an external device to trigger an alert for the user. In some embodiments, the alert module **710** and the monitoring module **720** may be combined in a single module. The output module **724** can be at least one or speakers, an LED, a haptic motor, and the like.

[0078] B. Method of Performing Emitting Pulses and Performing Measurement

[0079] FIG. **8** is a flowchart **800** illustrating the operation of a wearable ultrasonic device, in accordance with many embodiments. It will be understood by those skilled in the art that the order of the steps may be switched, some of the steps may be combined, and/or some of the steps may be optional. The flowchart of FIG. **8** is one example of the method and is not intended to be limiting. Thus, it will be understood by those skilled in the art that various other operation(s) disclosed in this application may be used instead of those shown in FIG. **8**. Method **800** may be performed by any or all of the devices and components described above. For example, method **800** may be performed by a wearable device, such as device **100**, including transducers processing electronics, associated components thereof and/or any suitable combination thereof. The steps of method **800** will now be described with reference to FIG. **8**.

[0080] At step **802**, a transmit phase may case the transducers of the wearable device to emit ultrasonic signals directed toward a target region that may include a body cavity. In some embodiments, wearable device may transmit ultrasound pulses towards a bladder. As described above, in order to measure a user's bladder volume and related characteristics, the transducers may be configured to generate an acoustic intensity of as much as 80 mW/cm^2 up to 3 cm below the contact point with a user's skin. As also described above, ultrasound pulses are transmitted towards the bladder at a fundamental frequency. The transmission of the ultrasound pulses may occur for a predetermined period, which period may be referred to as a transmission phase. For example, the transmission phase may last for up to 10 microseconds (i.e. 5 cycles at 0.5 MHz). This may be sufficient to reach the maximum output pressure amplitude from the transducers. Ultrasonic frequencies emitted at step **802** may vary from 20 KHz to 20 MHz depending on a variety of factors such as a wave speed of a fluid associated with the body cavity, desired resolution, the depth and size of a target, and the like.

[0081] At step **804**, a receive phase, after the transmission phase is completed, may cause the transducers to be configured to receive reflected signals associated with the emitted ultrasonic signals reflected in the target region. Configuring the transducers may include entering a receiving phase, during which returning echoes of the transmitted pulses are received by the transducers. In some cases, there may be a predetermined delay period between the transmission phase and the receiving phase to allow time for the signals to travel through the tissue. As with the transmission phase, the receiving phase may occur for a predetermined period, which may last for up to 500 microseconds. The predetermined period may depend on an expected distance from the transducers to a body cavity in the target region. The predetermined period may allow a range of 35 cm of travel, which may ensure that the device is able to capture signals so as to accurately measure bladder features for a wide range of potential users. The transducers may receive the returning echoes on the sub-apertures as described above with respect to FIG. **3**A. The transducers may generate a return voltage corresponding to the returning echoes.

[0082] In some embodiments, the returning echoes may be received by the transducers using beamforming techniques. It will be understood by those skilled in the art that using beamforming techniques may better analyze the received signals and increase the accuracy of the data received and in turn, increase the accuracy of the monitoring process described herein. As the echoes are received by transducers, they may be processed by processing electronics and stored in memory of the device. Specifically, the returning echoes may be converted to digital form by the transducers and/or processing electronics, and stored in this digital form in memory. The returning echoes may be associated with a plurality of channels. The returning echoes associated with each channel may be delayed to align, or focus, the returning echoes associated the plurality of channels and summed to form a coherently summed signal. Alternatively, or additionally, the returning echoes may be transmitted to a remote device or data cloud for further processing.

[0083] At step **806**, the received reflected signals may be processed to provide timing measurements associated with the body cavity. The timing measurements, or reflected echoes, may be further processed to determine bladder information. In many embodiments, the timing measurements, or the stored returning echoes, may be processed by processing electronics using signal processing algorithms to determine the bladder information. The bladder information may include the volume of fluid in the bladder, the thickness of bladder walls, the shape of the bladder, any other bladder features and/or any suitable combination thereof. As an example, the signal processing algorithms performed by processing electronics may find a distance to the front and back wall of a user's bladder along a plurality of beam directions and thus calculate the shape and volume of the bladder. In some embodiments, the processing of the returning echoes to determine bladder information may be done remotely, rather than using the processing electronics of wearable device. In this way, the processing electronics may be simplified and more powerful processors of remote devices may be utilized.

[0084] At step **808**, the volume of the body cavity may be determined using the timing measurements. The volume the body cavity may be stored in memory, along with any other information measured. The determined information (e.g., bladder information) may be transmitted via wireless radio to a remote device to be stored thereon, or to be transmitted for storage on data cloud. In some embodiments, determined information may be stored temporarily and transmitted periodically to a remote device, so that space can be periodically cleared on memory for future returning echo data to be stored.

[0085] In some embodiments, the stored data may be used to visually display an indication of a user's bladder status on a remote device. For example, a mobile application may be installed on a user's remote device that may provide a user interface for the user to track bladder volume. The mobile application may provide a visual indicator of the user's bladder status, which may include the current volume in the bladder as well as an indication of a relevant threshold volume (as will be described below). In this way, the user may be able to visualize if they are coming close to a threshold amount of fluid, so that they can better manage incontinence.

[0086] In some embodiments, the mobile app may be configured to notify the user whenever the bladder status has a significant change, which may be defined as a particular percent of change in volume of the fluid in the bladder. Further, the mobile application may allow a user to look at historical data, input any additional information (such as tracking voiding events and/or cases of incontinence), and cause any of this data to be transmitted to third parties for analysis. For example, a user may want to provide historical data regarding his or her bladder status to a healthcare provider for a medical diagnosis. The mobile application may also provide a convenient way for a user to manage the device settings. For example, the user may access settings in the mobile application that determine how the alerts (described below) function, input information related to the patient that may be used in processing algorithms and threshold determination (as described below) and generally customize the operation of the device and mobile application itself.

[0087] At step **810**, the volume of the body cavity is compared to one or more threshold values. For example, if the volume of the body cavity corresponds to a volume of urine in a bladder, it may be compared to a threshold volume. The threshold volume may be a volume predictive of incontinence of an individual. This may be a threshold above which an individual's ability to retain urine within the bladder is impaired. While a default threshold volume based on generally known principles may be used, in some cases, the threshold volume is unique to an individual, based on any number of factors. Accordingly, the threshold volume may be determined based upon factors such as a patient's physiological or demographic data.

[0088] Since the wearable device also collects and stores (to the device memory or the data cloud) data related to the user's bladder, this historical data, gathered using the wearable device (or other related devices), may also be used to determine the threshold volume for a given individual. For example, voiding events may be detected by the wearable device to determine a best fit volume from the bladder size associated with the voiding events. The wearable device may implement one or more machine learning algorithms, such as linear regression, to determine threshold values. Thus, the threshold volume may be dynamically changing as additional data is collected for an individual. Upon comparison of the bladder information with the threshold at step

810, it is determined whether any threshold is reached at step **812**. If a threshold is not reached, the process may repeat, starting at the transmission phase described with respect to step **802**.

[0089] At step **814**, if it is determined that a threshold bladder volume is reached, the user may be alerted. As described above, the user may be alerted directly by the wearable device with alarm actuators, which may provide haptic alerts, visual alerts, and/or audible alerts. For example, wearable device may vibrate, may have LED indicators that flash, and/or may emit an audible tone to alert the user when a threshold bladder volume is reached. In some embodiments, wearable device may transmit an alert signal wirelessly to remote device and cause the remote device to alert the user (or a third party) as to the bladder status. For example, the wearable device may transmit a Bluetooth signal to a remote device that causes the remote device to vibrate, make a noise, flash lights, and/or display a text notification on the remote device. Once alerted, the user may be able to better manage and otherwise avoid incontinence. Upon alerting the user, the process may repeat, starting at the transmission phase described with respect to step **802**. Although described herein in terms of alerting based on reaching a threshold volume, it will be understood that alerts may be customized for and by a user as described above, for example, by using the mobile application interface.

[0090] In addition to the periodic determination of bladder volume or other information described above, a wearable device may also be configured to make determinations based on other conditions. For example, in some cases, bladder volume after voiding by the user may be of particular significance. Thus, the wearable device may be able to detect a voiding event automatically (based on a decrease in fluid volume, for example) and/or receive an input from a user as to a voiding event, and the volumes before and after may be stored and marked as pre and post voiding volumes. As with the data above, this data may be stored in the device memory or remotely, and may be used to identify irregularities in voiding. For example, the processing electronics may track the determined volume after voiding and the user, medical professional, or the device itself may be able to identify irregular or dysfunctional voiding so that it can be addressed and treated appropriately.

[0091] In some embodiments, the wearable device may continuously monitor and record data associated with bladder size. The data may provide bladder information to determine how fast the bladder fills, how fast the bladder drains, and the like. Continuous activity data may be stored in the device memory or transmitted to the remoted device. In some embodiments, the device can prepare and transmit a report of bladder activity to the remote device. In other embodiments, the remote device may be configured to receive raw continuous activity data, such as volume measurements associated with the bladder, and prepare an activity report. The activity report may include information useful to the user, such as whether the bladder is full or empty. The activity report may include additional information for a physician such as fill/drain rates, volume measurements, and the like.

[0092] The wearable device may be configurable to one or more modes. For example, the wearable device can be configured to receive instructions from the remote device to begin monitoring the bladder or associated body cavity. The remote device can be configured to operate in multiple modes depending on a category of bladder dysfunction. For example, a urinary tract infection mode can configure the device to increase a number of scans during bladder activity such as urinating. The activity may be identified by an increased rate of change of the bladder volume. Another mode may be a positioning mode. In a positioning mode, the processing electronics may determine the device is positioned in a suitable location and transmit feedback to a user via alarm actuators, the remote device, and/or the personal computer.

[0093] Although devices and methods described herein illustratively refer primarily to monitoring of bladder volume in order to manage urinary incontinence, it will be understood that the devices and methods described herein are not so limited in scope. In some embodiments, the wearable device may be used as a tool to help "potty train" young children. In this case, the children may wear the device as described above, and a supervising adult may receive alerts (via a smartphone or computer as described above) when the volume of the child's bladder reaches a threshold value. The adult may then use this prediction to guide the child to void his bladder at the correct time, allowing the child to learn from these instances.

[0094] In some embodiments, the wearable device may also be used as a therapeutic device. In many medical applications, it is desirable to treat a patient with microbubbles that contain therapeutic contents. However, it is often difficult to non-invasively and precisely cause the microbubbles to release their therapeutic contents in a particular target region. Since such microbubbles may be precisely burst by ultrasonic signals as would be generated by the PMUTs described above, it will be understood that the PMUTs of the wearable device may be used to effectively release the therapeutic contents of one or more microbubbles in a desired area. Specifically, the wearable device may be positioned so that the PMUTs are aimed at a target region, and once the microbubbles reach this region, the device may be activated to burst the microbubbles and release the therapeutic contents thereof. In some embodiments, the microbubbles may be configured to act as contrast agents. The wearable device may be configured for microbubble contrast agent destruction.

III. Volume Measurement

[0095] When using a wearable ultrasonic device to measure bladder volume, typical techniques for measuring volume are not available. Currently, imaging is done by large machines and a trained operator can identify the bladder. The machine can then determine a volume of that region from the images and input by the trained operator. A wearable ultrasonic device is provided with a small form factor, a transducer array, and processing electronics integrated with the transducer array. The integrated processing electronics and a lower resolution less than the resolution required for an image enable volume measurements to be calculated by a battery powered wearable device.

[0096] A. Device for Volume Measurement

[0097] FIG. **9** shows a simplified block diagram of a PMUT/ASIC stack according to an embodiment of the present invention. The PMUT/ASIC Stack **900** may include a PMUT stack **930** and an ASIC stack **901**. The PMUT stack **930** may include a plurality of transducer channels **932**. The ASIC stack may include a drive module **902**, a transmit

module **904**, a receive module **906**, a Low-Noise Amplifier/Variable Gain Amplifier (LNA/VGA) module **908**, an analog-to-digital (ADC) module **910**, a digital multiplexer **912**, a memory **914**, a signal processing module **926**, a measurement module **918**, a monitoring module **920**, an alarm module **922**, a communication module **916**, a controller module **924**, and a power management module **940**. Some of the elements in FIG. **9** may be implement on a different chip, e.g., a master microcontroller. The elements described in FIG. **9**, alone or in combination with a master microcontroller, may detect a set of peak pairs in a reflected ultrasonic signal. The elements may identify that the set of peak pairs corresponds to a set of time differences that may be used to determine the volume of a body cavity.

[0098] PMUT stack **930** shows an embodiment with four transducer channels **932**, each of which may include one or more transducers. The transducer channels **932** may correspond to the elements **312** shown in FIG. **3**. Each transducer channel **932** may emit ultrasonic signals toward a target region. In some embodiments, each transducer channel **932** may receive reflected signals associated with the emitted signals reflected in the target region. Each of the four transducer channels **932** may be coupled to a transmit module **904** and a receive module **906**. The transmit module **904** may be configured to cause the transducers **934** to emit ultrasonic signals automatically according to a timing schedule specified in the transmit module **904** or according to commands received from the communication module **916**, the controller module **924**, or another device communicatively coupled to the transmit module **904**. The transmit module **904** may be coupled to the drive module **902**. The transmit module may include instructions that, when executed, cause the drive module to supply power to the transducer channels **932** to emit ultrasonic signals.

[0099] In some embodiments, the transmit module **904** may be configured to include a steering module. The steering module may shift the transmitted pulses to steer the ultrasonic beam emitted from the transducer channels **932**. The transmit module **904** may steer the emitted pulses in the elevation direction and the azimuth direction.

[0100] The combined signal generated from transducer channels **932** can form beams (lines), e.g., due to the constructive and destructive effects of the difference wave patterns of the individual transducers. The lines can be defined based on the positions of transducer channels **932**.

[0101] After emitting an ultrasonic signal, the receive module **906** may begin receiving an analog signal in response to the reflected ultrasonic signals received at the one or more transducer channels **932**. In some embodiments, the transducer channels **932** may correspond to a plurality of channels. Each transducer channel **932** can receive echoes from different points of the body cavity, e.g., corresponding to the different beams (lines) that are emitted. Each echo can correspond to a peak in the reflected signal, and the echoes from a given point of the body cavity will reach the different channels at different times. Accordingly, the receive module **906** may include a steering module to introduce a delay in the received analog signal.

[0102] The receive module **906** may transmit the analog signal to the an amplifier module such as LNA/VGA Module **908**. The LNA/VGA module **908** may amplify the analog signal and transmit an amplified analog signal to the ADC module **910**. The receive module **906** and LNA/VGA module **908** may be operable to boost the signal to noise ration of the received analog signal. The ADC module **910** uniformly samples the amplified analog signal and transmits the digital signal to the memory module **914**. In other embodiments, the ADC module may transmit the digital signal to the digital multiplexer **912**. The digital multiplexer **912** may transmit the digital signal to one or more of the signal processing module **926**, the communication module **916**, and the memory **914**. In some embodiments, memory module **914** is a FIFO memory. Data signals for a plurality of channels stored in the memory module **914** may correspond to a selected focal point. The memory module **914** may include a 256 KB internal buffer.

[0103] The signal processing module **926** may receive digital signals for each channel from at least one of memory module **914**, digital multiplexer **912**, and communication module **916**. The signal processing module **926** may receive or include data or circuitry to implement a delay profile (which may be predetermined) for the incoming digital signals, where the delay profile is used align the data signals for a given line. For greater accuracy, multiple channels can be used to measure a same point on a body cavity. To combine the measurements, delays can be used to align the signals to provide a single measurement. The alignment is needed since the channels are at different positions, and thus the echo from a point will reach the different channels at different times, hence the delays. Further details are described with respect to FIGS. **10**A-**10**C.

[0104] The delayed signals or measured values from the delayed signals (e.g., timing values) may be summed to form an average measurement, e.g., as digital data. In some embodiments, the signal processing module **926** may detect an envelope of a waveform associated with the digital data. The envelope may be logarithmically compressed and processed to improve the signal to noise ratio of the digital data. The digital data may include peaks with a reception time that may be used to determine a time of flight of the ultrasonic signal to various points on the body cavity. Envelope detection may simplify peak detection. The signal processing module **926** may transmit the digital data to the measurement module **918** to determine properties related to a body cavity in the target region. The digital data can include an averaged time measurement for echoes from each of a plurality of points along emitted lines.

[0105] The measurement module **918** may include instructions and/or circuitry to determine one or more of the presence of a body cavity in the target region, the dimensions of the body cavity, the volume of the body cavity and the like. In some embodiments, the measurement module may be configured to determine the rate of change of various physical properties related to the body cavity. In some embodiments, the cavity is a user's bladder.

[0106] To perform such measurements, measurement module **918** can identify a pair of peaks (e.g., by analyzing times associated with the peaks) that correspond to a same line. The pairs of peaks can be determined based on an expected timing relationship. For example, the peak (pulse) times can form two sets, with the first set being received first and associated with a front wall. A second set of times can correspond to a back wall and be received later. Further details are described with respect to FIGS. **10**A-**10**C.

[0107] The measurement module may transmit body cavity measurements to a monitoring module **920**. The monitoring module **920** may monitor body cavity properties to determine if a particular property crosses a threshold value.

Examples of threshold values can include a minimum volume, a warning volume, a maximum volume, a maximum rate of change value, and the like. The monitoring module **920** may determine one of the threshold values has been reached or passed and transmit an alarm condition to alarm module **922**. The alarm module **922** may activate an alarm system coupled to the processing board of the wearable device. For example, the alarm module **922** may activate a speaker, an LED, or a haptic feedback module to alert the user of an alarm condition. In some embodiments, the alarm module **922** may be coupled to the communication module **916** and be configured to cause an alarm condition on a connected mobile device such as a smart watch, mobile phone, tablet, laptop computer, and the like.

[0108] In some embodiments, the monitoring module **920** may detect conditions bladder dysfunction. For example, if the minimum volume threshold is not reach, the alarm module **922** may notify the user of an incomplete evacuation of the bladder and the user is at an increased risk of a urinary tract infection. In another example, if the warning volume is reached, the alarm module **922** may transmit an alert to notify a user suffering from urinary incontinence of a pending enuresis. In yet another example, if the maximum rate of change value is exceeded, the alarm module **922** may notify the user may be alerted of ongoing enuresis. In some embodiments, the thickness of a wall of the bladder may be determined.

[0109] The ASIC **901** may further include a power management module **940**. The power management module **940** may interface with the battery on the processing electronics board. The power management module **940** may include various output voltages depending on the requirements of the modules coupled to one or more outputs. In some embodiments the power management module operates at 24 V. The power management module **940** may provide a 24 V signal to the drive module **902** in order to drive the transducer channels **932** in the PMUT stack **930**. The drive module **902** may drive the transducers at a voltage less than approximately 4 V.

[0110] In some embodiments, the ASIC **901** may include a controller module **924**. The controller module **924** may include instructions to execute one or more of the modules implemented in the ASIC **901**. In some embodiments, one or more of the modules, such as the signal processing module **926**, the measurement module **918**, the monitoring module **920**, the alarm module **922**, and the like may be implemented in the master microcontroller **510** described in FIG. **5**A. The communication module **916** may be configured to transmit data using a general purpose serial interface, such as a 7-wire communications interface. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

[0111] B. Beamshaping Using Transducer Array

[0112] In some embodiments, a method is provided to measure a volume using timing measurements corresponding to different lines through the bladder. Specifically, a transducer can emit an ultrasonic signal, which expands as a wave pattern in the body. The reflections (echoes) from the front wall of the bladder may be measured first, and reflections from the back wall second. Each line may provide two measurements: one for the front side of the bladder and one for the backside of the bladder. The lines can be generated by an array of transducers.

[0113] FIG. **10**A shows a simplified diagram of processing a reflected ultrasound wave **1036** on a plurality of channels according to an embodiment of the present invention. In some embodiments, an array of transducer channels **1060** receive raw data **1062** associated with a reflected ultrasound wave **1036**. The raw data is processed using the signal processing module **1064** to determine a plurality of scan lines **1066**. The signal processing module uses one or more delay profiles to determine the plurality of scan lines **1066** from the raw data **1062**. The scan lines **1066** may be processed to discard any unsatisfactory readings. The scan lines may be compared to a threshold value prior to being considered for the volume calculation.

[0114] An emitted pulse can be generated using the array of channels **1060**. Each channel **1070** may comprise 49 transducers. The array of channels **1060** may be excited at the same time to emit a pulse directed toward a target area. The aperture size may correspond to the size of the array of channels **1060**. In some embodiments, a device may include 16 channels on a tile and 8 tiles in the device resulting in 128 channels. For example, when a plurality of transducers are used, the resulting wave patterns of the array combine to provide linear signals. The wave patterns essentially cancel out except along the lines (e.g., 231 lines). The exact position and number of transducers affects the number of lines and their position. Thus, each of the detected pulses **1072** correspond to one of the lines. The received signal **1074** can be analyzed using a signal processing module **1064** to identify the times of the pulses **1072**, and match pulses as corresponding to a same line. This matching can be done based on an expected range of reception times for a given line. The signal processing module **1064** can include a delay set for each channel, e.g., where these delays correspond to different time windows in which the peak for a particular point (front or back wall) of a line is expected to be found. The delay profile may include delays (time windows) associated with each line. In some embodiments, the delay (time window) profile may include 231 different delays (time windows) per channel. These delays for different peaks (pulses) that correspond to different points along beam lines through the body cavity should not be confused with the delays associated with echoes from a single point to multiple channels, where such other delays are used for aligning signals to obtain an averaged timing value for that point. Thus there are delays between lines for a given channel (corresponding to time windows), and delays between channels for a given point on a line.

[0115] The reflected signal can include a first set of separate pulses **1078** corresponding to different point on the first wall **1030**. Each of the first set of separate pulses **1078** corresponds to a different delay time relative to emission, where a longer time delay corresponds to a front wall point farther from the transducer and a shorter time delay corresponds to a front wall point closer to the transducer.

[0116] The delay between emission and receiving the pulses for a given point (pixel) of a bladder wall can be determined by the device, e.g., by analyzing a channel signal over a time window corresponding to an expected time. The time window can be updated, if a peak is not identified. For example, the distance to the closest front wall point can be a fixed proportion relative to the distance from the transducer to that closest point.

[0117] Further, the time measurement for a given point can be averaged over multiple channels. Each channel will

receive the echo from a point at a different time. But, an expected delay (i.e., between channel, not between lines) can be determined based on the distance between channels. After this compensation (aligning) a single time measurement **1076** can be obtained as an average of the time measurements for channels having an appreciable peak in a time window corresponding to that channel. The single time measurement can be determined by coherently summing the aligned raw data. Summation of the aligned raw data can focus the returning echoes and improve the signal to noise ratio by eliminating the noise that may appear on an individual line. Using the raw data **1062** or the single time measurement **1076**, the wearable device can detect an envelope **1080** associated with the peaks. The envelope **1080** may be detected using various signal processing techniques such as an analytic signal detector, and the like. Envelope **1080** may simplify peak detection to determine a peak pair **1071**. The peak pair **1071** may comprise a peak associated with a front echo that corresponds to pulses **1072**, and a second peak associated with a back echo **1073**. The received echoes may be further processed to determine a first side **1084** and a second side **1086** of the bladder wall. The wall thickness **1082** may be determined using the first side **1084** and the second side **1086**. The wall thickness may be stored in memory or transmitted to a remote device.

[0118] C. Emission Lines Per Channel

[0119] FIGS. **10**B and **10**C illustrate return echoes associated with a body cavity disposed in a target area, or range of coverage, for a channel. FIG. **10**B illustrates a return echo associated with a first body cavity disposed in the range of coverage of a channel according to an embodiment of the present invention. FIG. **10**B shows a channel **1000** at a contact point **1002** with a user's skin **1004**. The user's skin **1004** may be at the abdominal surface near a user's bladder **1032**. The channel **1000** may transmit a single pulse ultrasound wave. The ultrasound wave may be characterized by both a pulse duration and a pulse frequency. A reflected ultrasound wave **1036** may be received at the channel. The channel **1000** can monitor the reflection coming off of a first wall **1030** of the bladder **1032** and a second wall **1034** of the bladder **1032**. The reflected ultrasound wave **1036** may include a first peak **1038** and a second peak **1040** corresponding to the first wall **1030** and the second wall **1034** respectively. The peaks of the reflected ultrasound wave **1036** may correspond to a time of flight of an ultrasound pulse emitted from the channel **1000** to the first wall **1030** and the second wall **1034**. A time of flight between the first wall and the second wall **1042** may be used to determine the volume of the bladder. The time of flight between the first wall and the second wall **1042** can correspond to the first peak **1038** and the second peak **1040** and be used to determine a distance between the first wall **1030** and to the second wall **1034** of the bladder **1032**. In other embodiments, a first distance from the channel **1000** to the first wall **1030** and a second distance from the channel **1000** to the second wall **1034** may be determined to calculate the volume of the bladder.

[0120] In some embodiments, the reflected ultrasound wave **1036** may be received by a plurality of channels. The reflected ultrasound wave **1036** may be sampled at each channel by an analog-to-digital converter and stored in a first-in-first-out (FIFO) memory. The measurement and processing circuitry may select data from the FIFO memory that corresponds to a focal point. In some embodiments data from a plurality of channels may be selected and summed for reflected ultrasound wave **1036** beamforming. Beamforming can be used to form a plurality of lines **1022**. The reflected ultrasound wave **1036** beamforming may be performed by a signal processing module. The signal processing module may receive digitized echoes for each channel. The digitized echoes may be delayed based on a pre-determined delay profile and coherently summed to form digital scanline data, or, put simply, lines.

[0121] While a volume for the body cavity may be determined using a single line, to enhance the accuracy the plurality of lines **1022** may be used. The plurality of lines **1022** can be formed using digitized echoes for each channel and adjusting the delay profile to form a different line. The echo arrives at each channel at different times depending on the location of a target point in the target area and the channel position on the transducer. The center channel receives the echo from the target point at a reference time different from the off-center channels. The pre-determined delay profile may include channel delays corresponding to a time delay for each channel relative to the center channel. For example, the delay for a specific target point in the target area for the center channel may be $\text{delay}_{point\ n}$. The delay for each off-center channel may be the delay for the specific target point plus an additional delay associated with the off-center channel, $\text{delay}_{point\ n}+\text{delay}_{off\text{-}center\ channel\ n}$. By applying the proper time delay to each channel, the received echoes may be aligned before being coherently summed. Aligning the received echoes may provide a focused reflected signal. In some embodiments, a resolution of the number of lines used to determine the volume of the bladder **1032** may be less than the resolution required for a visual image. The lower resolution may be associated with a lower device voltage. The lower device voltage may improve the battery life of the wearable device. In some embodiments, a plurality of lines can be spaced according to a focal distance.

[0122] In some embodiments, to resolve the size of a body cavity, a particular resolution is necessary. The particular resolution may be lower than a resolution required to image the bladder **1032**. Ultrasound resolution depends on the size of the active aperture of the transducer or transducer array, the frequency and bandwidth of the transducer, and the selected transmit focal distance. the range of coverage can be determined by the aperture size. A synthetic aperture can be produced using a multi-channel ultrasound transducer with digital beamforming. The aperture may be larger than an object of interest in the range of coverage. The range of coverage can be characterized by a focal distance **1050**, elevation line spacing **1052**, and azimuth line spacing **1054**. In some embodiments, the bladder **1032** is disposed in the range of coverage. FIG. **10**B illustrates a voided bladder **1032** in the range of coverage. The voided bladder can be approximately 1.5 cm tall by 4 cm wide by 5 cm deep. The distance from the user's skin to the voided bladder may be 5 cm to the first wall **1030** and 10 cm to the second wall **1034**.

[0123] In some embodiments, the focal distance **1050** may be 10 cm. In the z-direction **1090**, the elevation line spacing **1052** may be approximately 0.5 cm at the focal distance **1050**. In some embodiments, a target area of 10 cm in the z-direction **1090** may be used. With an elevation line spacing of approximately 0.5 cm, 21 lines may be used to cover the target area. In the y-direction **1092**, the azimuth line spacing **1054** may be 1 cm at the focal distance. In some embodi-

ments, a target area of 10 cm in the y-direction may be used. With an azimuth line spacing in the y-direction of approximately 1 cm, 11 lines may be used to cover the target area of 10 cm in the y-direction. In with the elevation and azimuth spacing described, 231 total lines may be used. The max steer angle for a system with 231 lines may be 26.6°. Beamforming and signal processing may generate an approximately 10 nanosecond resolution. In some embodiments, lateral resolution requirements at a focal distance of 10 cm may include $\lambda/D \leq 0.5$ in elevation and 0.1 in azimuth, where D is the focal distance in cm and λ is the wavelength in MHz. In some embodiments, using 231 lines, the volume of a body cavity may be determined within a standard deviation of 5 cc.

[0124] FIG. **10**C illustrates a return echo associated with a second body cavity disposed in the range of coverage of a channel according to an embodiment of the present invention. In FIG. **10**C, the second body cavity is a full bladder **1033**. An average full bladder **1033** may be 7 cm tall by 8 cm wide by 11 cm deep. The distance from user's skin **1004** may be 2.5 cm to the first wall **1030** and 13.5 cm to the second wall.

[0125] As shown in FIG. **10**C, the position of the front wall and the second wall can change relative to the position of the channel **1000**. To address changes in target position, a calibration phase may be implemented by the a controller module and a signal processing module. The focal distance **1050** may be adjusted to improve the detection of the peaks at a particular distance from the channel **1000**. The focal distance may correspond to a time window in the received digital data. For example, the calibration phase may begin with a focal distance at a first distance. The reflected ultrasound wave associated with the first distance may be processed by the signal processing module and determine if a suitable echo is present. If a suitable echo is not detected, the controller module may shift the focal distance to a second distance. A ultrasound wave is transmitted and received. The second reflected ultrasound wave associated with the second distance may be processed by the signal processing module. If a suitable echo is present, the signal processing module may begin the volume measurement processing and calculation using the second reflected ultrasound wave. The signal processing module and the controller module can be configured to continue shifting the focal distance until a suitable echo is received. The wearable device can customize the calibration phase for a particular user based on the data collected during continuous measurement. The calibration phase can update the delay profile with delays associated with the lines for each channel.

[0126] In some embodiments, the calibration phase can detect lines not directed at the target. Line **1056** in FIG. **10**C does not scatter off the full bladder **1033** in any body cavity state, e.g., when the bladder is full or empty. The calibration phase may determine, based on an estimated center of the cavity, missed lines and discard the data from time and volume calculations. In some embodiments a channel may be positioned such that no lines associated with the channel intersect the target. In these cases, the wearable device may discard all data associated with the channel. In addition to missing the target, the calibration phase may determine data from a channel or line is erroneous and discard the associated data.

IV. Composition of Transducer/Processing Device

[0127] The wearable electronic device may include transducer circuitry coupled to processing circuitry in a combined device. The transducer circuitry may include one or more piezoelectric micromachined ultrasonic transducers (PMUTs). The transducer circuitry may be provided on a first substrate and the processing circuitry may be formed on a device wafer. A plurality of cavities may be formed on the device wafer to isolate the processing circuitry from ultrasonic signals generated by the transducer circuitry. The device wafer may be formed using standard CMOS processes. The stacked CMOS device may be formed by bonding the first substrate to the device wafer and forming contacts thereon. The stacked CMOS device may operate at lower voltages.

[0128] A. Transducer Device Components

[0129] FIG. **11** shows a cross-sectional view of a single piezoelectric micromachined ultrasonic transducer **1100** bonded to a CMOS wafer **1102** used in a wearable device as described above, in accordance with many embodiments. As described above, and as shown in FIG. **11**, each piezoelectric micromachined ultrasonic transducers (PMUT) **1100** may be formed on a MEMS wafer that is bonded to a CMOS wafer **1102**. In this way, PMUT **1100** may be coupled to the requisite processing electronics of the CMOS wafer **1102**. It will be understood that each PMUT may have an active piezoelectric layer **1104** along with a first electrode **1103** and a second electrode **1105**. The first electrode **1103** and the second electrode can be electrically coupled to the piezoelectric layer **1104**.

[0130] In some embodiments, the PMUT **1100** may include a first contact **1122** electrically coupled to the first electrode **1103**, a second contact **1124** electrically coupled to the second electrode **1105**, and a third electrode electrically coupled to the CMOS wafer **1102**. In some embodiments, a bias may be introduced between the first electrode **1103** and the second electrode **1105** to cause stress in the piezoelectric layer **1104**. Alternating the bias at a predetermined frequency may cause the piezoelectric layer **1104** to generate sound waves. One or more vias **1110** may be formed to in the PMUT **1100**. Each of the contacts may be wire bonded outside PMUT **1100** to an electronics board. In some embodiments, PMUT **1100** may include a passivation layer formed on a surface **1120** and the contacts. Referring to FIG. **1**, the top surface **210** of an adhesive coupling interface may be coupled to the surface **1120** of the PMUT **1100**.

[0131] In some embodiments, the passive elastic layer **1108** may comprise SiO_2 or any other suitable passive layer. The active piezoelectric layer **1104** may be approximately 1 μm thick Aluminum Nitride, and the passive elastic layer may be approximately 1 μm thick single-crystal Silicon. In some embodiments, the active piezoelectric layer **1104** may be Scandium-doped Aluminum Nitride. Alternatively, the active piezoelectric layer **1104** may be another suitable piezoelectric ceramic such as PZT. Both the top and bottom electrodes **1106** may comprise Molybdenum. In order to bond the PMUT **1100** to the top metal **1112** of CMOS wafer **1102**, fusion bonding via thru-silicon-via (TSV) as shown at **1110** may be used. This methodology results in significant parasitic reduction which in turn results in generation of increased acoustic intensity in operation.

[0132] In some embodiments, cavity **1114** may be formed with a vacuum or near vacuum to isolate the transducer from the processing electronics in the CMOS wafer **1102**. The

sound generated by PMUT will not travel through the cavity **1114** minimizing reflection and interference that may be caused by material interfaces with the CMOS wafer **1102**. The cavity **1114** may cause ultrasound **1116** to travel away from the PMUT **1100**. Ultrasound **1116** may travel through the adhesive coupling interface and into the body of a user. The body, and the bladder, may reflect ultrasound **1116** causing a return echo to reflect back to the PMUT **1100**. The return echo travels through the adhesive coupling interface and is received by the PMUT **1100**.

[0133] After transmitting ultrasound **1116**, the bias between the first electrode **1103** and the second electrode **1105** can be removed. The return echo may cause stress in the piezoelectric layer **1104**. The stress causes an electric charge to accumulate in the piezoelectric layer **1104**. In some embodiments, the first electrode **1103** and the second electrode may measure the electric charge that accumulates in the piezoelectric layer.

[0134] In some embodiments, the CMOS wafer **1102** may be an application specific integrated circuit (ASIC) that includes one or more devices necessary to drive the transducer. The drive voltage for an array of PMUTs may be less than 4 volts. The ASIC can be manufactured to meet size requirements associated with the size of an associated PMUT. In some embodiments, the ASIC may include one or more modules to receive measured signals. The ASIC may be configured to further process the signal. For example, the ASIC may include one or more analog to digital converters to convert the returning echoes to a digital signal. In some embodiments, the ASIC may transmit the digital signal to at least one or more of a memory, a processor, and a remote device. In other embodiments, the ASIC may include one or more signal processing modules.

[0135] B. Manufacturing Process to Create Transducer, Layers and Materials.

[0136] FIGS. **12**A-**12**H illustrate a device stack corresponding to the process steps used to fabricate a piezoelectric micromachined ultrasonic transducers (PMUTs) bonded to an application specific integrated circuit (ASIC) according to an embodiment of the present invention. Bonding the plurality of PMUTs to an ASIC reduces parasitics and the bonded PMUTs can be driven at a low voltage, for example, less than 4 volts. The ASIC may include circuitry and/or instructions to execute one or more of the modules shown in FIG. **9**. To form an integrated PMUT/ASIC stack, several steps may be performed. FIG. **12**A shows a transducer device **1202**. The transducer device **1202** may comprise a first wafer **1204**, an oxide layer **1206**, a seed layer **1208**, a first electrode layer **1210**, a piezoelectric layer **1212**, a second electrode layer **1214**, and a bonding oxide layer **1216**. The first wafer **1204** may be referred to as a handle wafer, a first substrate, and the like. In some embodiments, the first wafer **1204** is a silicon wafer that may be removed during one or more processing steps. An oxide layer **1206** may be formed on the first wafer **1204**. In some embodiments, the oxide layer **1206** may be a 500 Å thermal oxide layer. In some embodiments, the first wafer **1204** may be a first substrate and provided with an oxide layer **1206** formed on a handle wafer. Next, a seed layer **1208** is formed on oxide layer **1206**. The seed layer **1208** may be aluminum nitride (AlN). The seed layer **1208** may be used to influence the crystal structure of layers deposited thereon. In some embodiments, the first substrate may include the seed layer **1208**.

[0137] The transducer device **1202** may include a plurality of PMUT device layers. The first PMUT device layer may include a first electrode layer **1210** coupled to the seed layer **1208**. In some embodiments, the thickness of the first electrode layer **1210** deposited on the seed layer **1208** may be approximately 200 Å. The first electrode layer **1210** may be molybdenum. The crystal structure of the first electrode layer **1210** may be determined by the grain boundary with the seed layer **1208**. The grain boundary may depend on the crystal structure of the seed layer **1208**.

[0138] A piezoelectric layer **1212** may be coupled to the first electrode layer **1210**. The piezoelectric layer **1212** may include one or more of AlN, Scandium-doped AlN, Lead Zirconate Titanate (PZT), and the like. In some embodiments, the thickness of the piezoelectric layer **1212** deposited on the first electrode layer **1210** may be approximately 1 μm. In other embodiments, the piezoelectric layer **1212** can comprise a plurality of layers such as a first platinum layer, a PZT seed layer, a PZT layer, and a second platinum layer. The thickness of each of the first platinum layer and the second platinum layer may be approximately 200 Å, the thickness of the PZT seed layer may be approximately 30 Å, and the thickness of the PZT layer may be approximately 2 μm. The crystal structure of the piezoelectric layer **1212** may be determined by the crystal structure of the seed layer **1208**. In some embodiments, the first electrode layer **1210** crystal structure may approximately align with the crystal structure of the seed layer **1208**. The grain boundary between the first electrode layer **1210** and the piezoelectric layer **1212** may determine the crystal structure of the piezoelectric layer **1212**.

[0139] The PMUT device layers may further include a second electrode layer **1214** coupled to the piezoelectric layer **1212**. In some embodiments, the thickness of the second electrode layer **1214** deposited on the piezoelectric layer **1212** may be approximately 200 Å. The second electrode layer **1214** may be molybdenum. The crystal structure of the second electrode layer **1214** may be determined by the grain boundary with the piezoelectric layer **1212**. The grain boundary may depend on the crystal structure of the piezoelectric layer **1212**. After forming the PMUT device layers, a bonding oxide layer **1216** may be formed on the second electrode layer **1214**. The bonding oxide layer can be a high density plasma (HDP) oxide. In some embodiments, the thickness of the bonding oxide layer deposited on the second electrode layer **1214** can be approximately 500 Å.

[0140] FIG. **12**B shows a second portion of the integrated PMUT/ASIC stack may include a processing device comprising a device wafer **1220**. The device wafer **1220** may include a "system-on-a-chip" ASIC **1222**. The ASIC **1222** may be built using standard semiconductor processing steps, such as 0.18 μm CMOS. The ASIC **1222** may include general and signal processing circuitry, measurement circuitry, alert circuitry, memory, and the like. The ASIC may include one or more contacts **1226** coupled to the electrical circuits of the ASIC **1222**. The contacts **1226** may be a conducting material, for example, aluminum, copper, gold, and the like. In some embodiments the contacts **1226** may be bond pads associated with the circuitry of the ASIC **1222**. A device oxide layer **1224** can be formed on the ASIC **1222** and the contacts **1226**. The device oxide layer **1224** may form a passivation layer for the ASIC **1222** and contacts **1226**. The thickness of the device oxide layer **1224** depos-

ited on the ASIC **1222** and contacts may be 5000 Å. The device oxide layer **1224** may be an oxide layer. In some embodiments, the passivation layer may be deposited using Plasma Enhanced Chemical Vapor Deposition (PECVD). After depositing the device oxide layer **1224**, device wafer **1220** may be patterned using well known semiconductor techniques. The device oxide layer **1224** may be patterned to produce vias to access the contacts **1226** or form one or more cavities **1228** where the transducers are to be formed.

[0141] FIG. **12**C shows the transducer device **1202** bonded to the device wafer **1220**. To form the integrated PMUT/ASIC stack **1232** the transducer device **1202** may be bonded to the device wafer **1220**. The bonding oxide layer **1216** of the transducer device **1202** may be fusion bonded with the device oxide layer **1224** of the device oxide layer **1224** of the device wafer **1220**. The surfaces may be prepared for fusion bonding by dry cleaning or wet cleaning to remove any impurities. In some embodiments, the transducer device **1202** and the device wafer **1220** may be fusion bonded by annealing the integrated PMUT/ASIC stack **1232** at approximately 300° C. for 3 hours. The fusion bonding may be performed at low pressure or near vacuum to form a vacuum in the one or more cavities **1228**. The vacuum may facilitate directing sound waves generated by the PMUT away from the ASIC **1222**.

[0142] After forming the PMUT/ASIC stack **1232**, the first wafer **1204**, the oxide layer **1206**, and the seed layer **1208** may be removed from the stack **1234** as shown in FIG. **12**D. The layers may be removed by back grinding until the PMUT device layers are exposed. Back grinding may be used to expose the second electrode layer **1214**. The remaining PMUT device layers may be patterned to form one or more transducer areas **1236**. A patterned PMUT/ASIC stack **1238** may have an oxide layer **1240** formed thereon as illustrated in FIG. **12**E. The oxide layer **1240** may electrically isolate the one or more transducers **1236**. In some embodiments, the oxide layer **1240** may be deposited using PECVD. The oxide layer **1240** may be approximately 3000 Å. FIG. **12**F shows the PMUT/ASIC stack after a portion of the oxide layer **1240** is removed. After depositing oxide layer **1240**, the second electrode layer **1214** may be exposed on PMUT/ASIC stack **1242** by removing a portion **1248** of oxide layer **1240**. The oxide layer **1240** may be removed using chemical mechanical polishing.

[0143] FIG. **12**G illustrates a PMUT/ASIC stack **1244** with one or more vias. After exposing the second electrode layer **1214**, one or more vias may be formed in the PMUT/ASIC stack **1244**. A first set of vias **1246** may be patterned to provide contact with the first electrode layer **1210**. The first set of vias **1246** may be formed by etching through the second electrode layer and the piezoelectric layer to expose the first electrode layer. A second set of vias **1248** may be patterned to provide contact with the one or more contacts **1226** coupled to the electric circuitry of the ASIC **1222**. The second set of vias **1248** may be formed by etching through the oxide layers **1240**, **1224**.

[0144] FIG. **12**H illustrates a finished PMUT/ASIC stack. The stack can include device contacts and a passivation layer. To finish the device, conductor channels may be formed by depositing conductive material in the one or more vias formed in PMUT/ASIC stack **1244**. The conductive material may be one or more of Ti/TiN, Al, Au, Ag, and the like. In some embodiments, 200 Å of Ti/TiN may be deposited, followed by the deposition of 9000 Å of Al. The deposited conductive material may be patterned to form the one or more device contacts. The device contacts may be patterned to form one or more bond pads at surface **1258**. A first electrode device contact **1250** and a second electrode device contact **1252** may be formed for each transducer area **1236** by the conductor channels. One or more ASIC device contacts **1254** may also be formed by depositing and patterning the conductive material. After patterning the conductive material, a passivation layer **1256** may be formed on surface **1258** of the oxide layer **1240** to electrically isolate the device contacts. In some embodiments, the passivation layer **1256** may be SiO_2. In some embodiments, the thickness of the passivation layer **1256** may be approximately The passivation layer **1256** may be etched to expose the one or more device contacts.

[0145] The dimensions of the cavity may be determined to produce echoes at a particular frequency. In some embodiments, the PMUT may transmit at a frequency of for example, 2 MHz, 3.5 MHz, 5 MHz, or higher to produce data suitable for image formation. In some embodiments, the PMUT can transmit at frequencies less than 1 MHz to produce data suitable to determine the depth of a bladder wall. The PMUT may be configured to transmit at a range of ultrasound frequencies from 20 KHz to 20 MHz.

[0146] The methods and techniques described herein may be used to form a variety of PMUT arrays compatible with CMOS semiconductor processes. In some embodiments, PMUT materials and dimensions can be compliant with Semiconductor Equipment and Materials International (SEMI) standard specifications. Because PMUTs can be compliant with SEMI specifications, the transducer arrays can be used with existing CMOS semiconductor fabrication tools and methods. For example, in some embodiments, photolithography may be used to form one or more PMUTs. In contrast, current piezoelectric ultrasound transducer arrays are formed using a die saw that cannot match the precision of photolithography. As a result, PMUTs can be smaller, operate at lower voltages, and have lower parasitics.

V. Example Computer System

[0147] Any of the computer systems mentioned herein may utilize any suitable number of subsystems. Examples of such subsystems are shown in FIG. **13** in computer apparatus **1300**. In some embodiments, a computer system may include a single computer apparatus, where the subsystems can be the components of the computer apparatus. In other embodiments, a computer system can include multiple computer apparatuses, each being a subsystem, with internal components. Aspects of the computer system may be used as part of the wearable device, the processing electronics, and the application specific integrated circuit described above.

[0148] The subsystems shown in FIG. **13** are interconnected via a system bus **1375**. Additional subsystems such as a printer **1374**, keyboard **1378**, storage device(s) **1379**, monitor **1376**, which is coupled to display adapter **1382**, and others are shown. Peripherals and input/output (I/O) devices, which couple to I/O controller **1371**, can be connected to the computer system by any number of means known in the art such as input/output (I/O) port **1377** (e.g., USB, FireWire®). For example, I/O port **1377** or external interface **81** (e.g. Ethernet, WiFi, etc.) can be used to connect computer system **1300** to a wide area network such as the Internet, a mouse input device, or a scanner. The interconnection via system bus **1375** allows the central processor **1373** to

communicate with each subsystem and to control the execution of a plurality of instructions from system memory **1372** or the storage device(s) **1379** (e.g., a fixed disk, such as a hard drive, or optical disk), as well as the exchange of information between subsystems. The system memory **1372** and/or the storage device(s) **1379** may embody a computer readable medium. Another subsystem is a data collection device **1385**, such as a camera, microphone, accelerometer, and the like. Any of the data mentioned herein can be output from one component to another component and can be output to the user.

[0149] A computer system can include a plurality of the same components or subsystems, e.g., connected together by external interface **1381**, by an internal interface, or via removable storage devices that can be connected and removed from one component to another component. In some embodiments, computer systems, subsystem, or apparatuses can communicate over a network. In such instances, one computer can be considered a client and another computer a server, where each can be part of a same computer system. A client and a server can each include multiple systems, subsystems, or components.

[0150] Aspects of embodiments can be implemented in the form of control logic using hardware circuitry (e.g. an application specific integrated circuit or field programmable gate array) and/or using computer software with a generally programmable processor in a modular or integrated manner. As used herein, a processor can include a single-core processor, multi-core processor on a same integrated chip, or multiple processing units on a single circuit board or networked, as well as dedicated hardware. Based on the disclosure and teachings provided herein, a person of ordinary skill in the art will know and appreciate other ways and/or methods to implement embodiments of the present invention using hardware and a combination of hardware and software.

[0151] Any of the software components or functions described in this application may be implemented as software code to be executed by a processor using any suitable computer language such as, for example, Java, C, C++, C#, Objective-C, Swift, or scripting language such as Perl or Python using, for example, conventional or object-oriented techniques. The software code may be stored as a series of instructions or commands on a computer readable medium for storage and/or transmission. A suitable non-transitory computer readable medium can include random access memory (RAM), a read only memory (ROM), a magnetic medium such as a hard-drive or a floppy disk, or an optical medium such as a compact disk (CD) or DVD (digital versatile disk), flash memory, and the like. The computer readable medium may be any combination of such storage or transmission devices.

[0152] Such programs may also be encoded and transmitted using carrier signals adapted for transmission via wired, optical, and/or wireless networks conforming to a variety of protocols, including the Internet. As such, a computer readable medium according to an embodiment of the present invention may be created using a data signal encoded with such programs. Computer readable media encoded with the program code may be packaged with a compatible device or provided separately from other devices (e.g., via Internet download). Any such computer readable medium may reside on or within a single computer program product (e.g. a hard drive, a CD, or an entire computer system), and may be present on or within different computer program products within a system or network. A computer system may include a monitor, printer, or other suitable display for providing any of the results mentioned herein to a user.

[0153] Any of the methods described herein may be totally or partially performed with a computer system including one or more processors, which can be configured to perform the steps. Thus, embodiments can be directed to computer systems configured to perform the steps of any of the methods described herein, potentially with different components performing a respective step or a respective group of steps. Although presented as numbered steps, steps of methods herein can be performed at a same time or at different times or in a different order. Additionally, portions of these steps may be used with portions of other steps from other methods. Also, all or portions of a step may be optional. Additionally, any of the steps of any of the methods can be performed with modules, units, circuits, or other means of a system for performing these steps.

[0154] Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

[0155] The use of the terms "a" and "an" and "the" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected" is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening.

[0156] Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0157] Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all

modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0158] The above description of example embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form described, and many modifications and variations are possible in light of the teaching above.

[0159] All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

1. A wearable ultrasonic device, the device comprising:
- a coupling pad interface for affixing the device to a surface of a user's body and providing acoustic coupling;
- at least one ultrasonic transducer coupled to the coupling interface and configured to:
  - emit ultrasonic signals directed towards a target region, and
  - receive returning ultrasonic signals associated with the emitted ultrasonic signals;
- processing electronics coupled to the at least one ultrasonic transducer; and
- a battery coupled to and configured to power the ultrasonic transducer and processing electronics.

2. The wearable ultrasonic device of claim **1**, wherein the processing electronics are further configured for use in a non-invasive determination of a volume of a fluid in a body cavity associated with the returning ultrasonic signals.

3-4. (canceled)

5. The wearable ultrasonic device of claim **1**, further comprising a wireless radio coupled to the processing electronics and configured to transmit stored information associated with the returning ultrasonic signals to a remote computing device, the remote computing device being configured to determine a volume of a fluid in a body cavity based on the stored information.

6. The wearable ultrasonic device of claim **1**, wherein the processing electronics are configured to store information associated with the returning ultrasonic signals and determine a volume of a fluid in a body cavity based on the stored information.

7. The wearable ultrasonic device of claim **2**, wherein the processing electronics are configured to compare the determined volume of the fluid with a threshold volume and output an alert when the determined volume exceeds the threshold volume.

8-11. (canceled)

12. The wearable ultrasonic device of claim **5**, wherein the processing electronics are configured to receive control signals, user-specific data, or both from a remote device via the wireless radio.

13-21. (canceled)

22. The wearable ultrasonic device of claim **1**, wherein the at least one ultrasonic transducer comprises an array of piezoelectric micromachined ultrasonic transducers (PMUTs).

23-30. (canceled)

31. The wearable ultrasonic device of claim **1**, wherein the at least one ultrasonic transducer is configured to emit and receive the ultrasonic signals sequentially, the at least one ultrasonic transducer being configured with a transmit phase for transmitting and a receive phase for receiving the returning ultrasonic signals, and wherein the at least one ultrasonic transducer is configured to receive the returning ultrasonic signals using time delays, summations, or both to focus the returning ultrasonic signals.

32. A method of monitoring a volume of a body cavity of a subject, wherein the volume of the body cavity varies over time, the method comprising:
- emitting, by a transducer of a device attached to the subject, ultrasonic signals directed toward a target region that includes the body cavity, the emitted ultrasonic signals being emitted automatically at different times according to a timing schedule specified by the device;
- receiving, by the transducer, reflected signals associated with the emitted ultrasonic signals reflected in the target region, each of the reflected signals corresponding to a respective emitted ultrasonic signal;
- for each reflected signal of the reflected signals:
  - processing, by measurement circuitry of the device, the reflected signal to provide timing measurements of when reflected pulses are received;
  - determining, by the measurement circuitry, the volume of the body cavity using the timing measurements;
  - determining, by the measurement circuitry, whether the volume exceeds a threshold value; and
  - when the volume exceeds the threshold value for a given measurement, transmitting an alert signal from the measurement circuitry to alert circuitry, thereby causing an alert to be provided to the subject.

33. The method of claim **32**, wherein the measurement circuitry includes one or more of an amplifier module, an analog to digital converter module, a digital multiplexer, a signal processing module, a measurement module, a monitoring module, an alarm module, a controller module, a communication module, and a memory.

34. The method of claim **32**, wherein determining the volume exceeds the threshold value includes the volume increasing above the threshold value, the volume decreasing below the threshold value, or both.

35. The method of claim **32**, further comprising determining, using the timing measurements, a distance between a first wall of the body cavity and a second wall of the body cavity along an emission line.

36. The method of claim **32**, further comprising transmitting the timing measurements to a remote device configured to determine the volume of the body cavity.

37. (canceled)

38. The method of claim **32** further comprising detecting, by the measurement circuitry, a rate of change of the volume of the body cavity exceeds a rate of change threshold associated with a voiding of the body cavity.

39-48. (canceled)

49. A method comprising:
- providing a transducer device comprising:
  - a first substrate;
  - a first electrode layer coupled to the first substrate;
  - a piezoelectric layer coupled to the first electrode layer;
  - a second electrode layer coupled to the piezoelectric layer;

a bonding oxide layer coupled to the second electrode layer;

providing a processing device comprising:

a device wafer;

one or more device wafer contacts coupled to the device wafer;

a device oxide layer coupled to the device wafer, the device oxide layer including one or more cavities;

bonding the bonding oxide layer to the device oxide layer;

after the bonding, removing the first substrate;

patterning a transducer area in the first electrode layer, the piezoelectric layer, and the second electrode layer;

creating a first via by etching the second electrode layer and the piezoelectric layer to expose the first electrode layer;

creating a second via by etching to expose the one or more device wafer contacts coupled; and

forming conductor channels in the first via and the second via.

50. The method of claim **49** further comprising patterning a plurality of transducer areas in the first electrode layer, the piezoelectric layer, and the second electrode layer.

51. The method of claim **49**, wherein the device wafer includes processing electronics operable to supply a drive voltage to the transducer area.

52-54. (canceled)

55. The method of claim **49**, wherein the device wafer includes processing electronics operable to measure a return voltage associated with the transducer area.

56-57. (canceled)

58. The method of claim **49**, wherein providing the transducer device further comprises:

providing a handle wafer;

forming a first oxide layer coupled to the handle wafer;

forming a seed layer coupled to the first oxide layer;

forming the first electrode layer coupled to the seed layer;

forming the piezoelectric layer coupled to the first electrode layer;

forming the second electrode layer coupled to the piezoelectric layer; and

forming the bonding oxide layer coupled to the second electrode layer.

59. The method of claim **49**, wherein providing the processing device further comprises:

providing the device wafer;

forming the device oxide layer coupled to the device wafer; and

forming a cavity in the device oxide layer.

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摘要(译)

提供了用于通过可穿戴超声装置非侵入地测量体腔体积的系统，方法和设备。可穿戴超声装置可收集与体腔相关的数据，执行与体腔相关的诊断测量，以向用户提供警报。可穿戴超声装置可以固定在使用者身体的皮肤上。可穿戴超声装置可包括超声换能器，其发送和接收指向体腔的超声信号，例如使用者的膀胱。该装置可包括耦合到超声换能器的处理电子器件，以处理超声信号以确定体腔的体积，并在体积达到特定阈值时将警报传送给用户。处理电子器件可以与超声换能器集成以在低电压下操作并且由电池供电。