US 20250255551A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2025/0255551 A1**

BICEK et al. (43) **Pub. Date: Aug. 14, 2025**

(54) **MONITORING AND MANAGEMENT OF WEARABLE DEVICES**

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(21) Appl. No.: **19/190,168**

(22) Filed: **Apr. 25, 2025**

Related U.S. Application Data

(63) Continuation of application No. 19/071,122, filed on Mar. 5, 2025, which is a continuation-in-part of application No. 18/096,441, filed on Jan. 12, 2023, now Pat. No. 12,254,165.

(60) Provisional application No. 63/300,971, filed on Jan. 19, 2022.

Publication Classification

(51) **Int. Cl.**

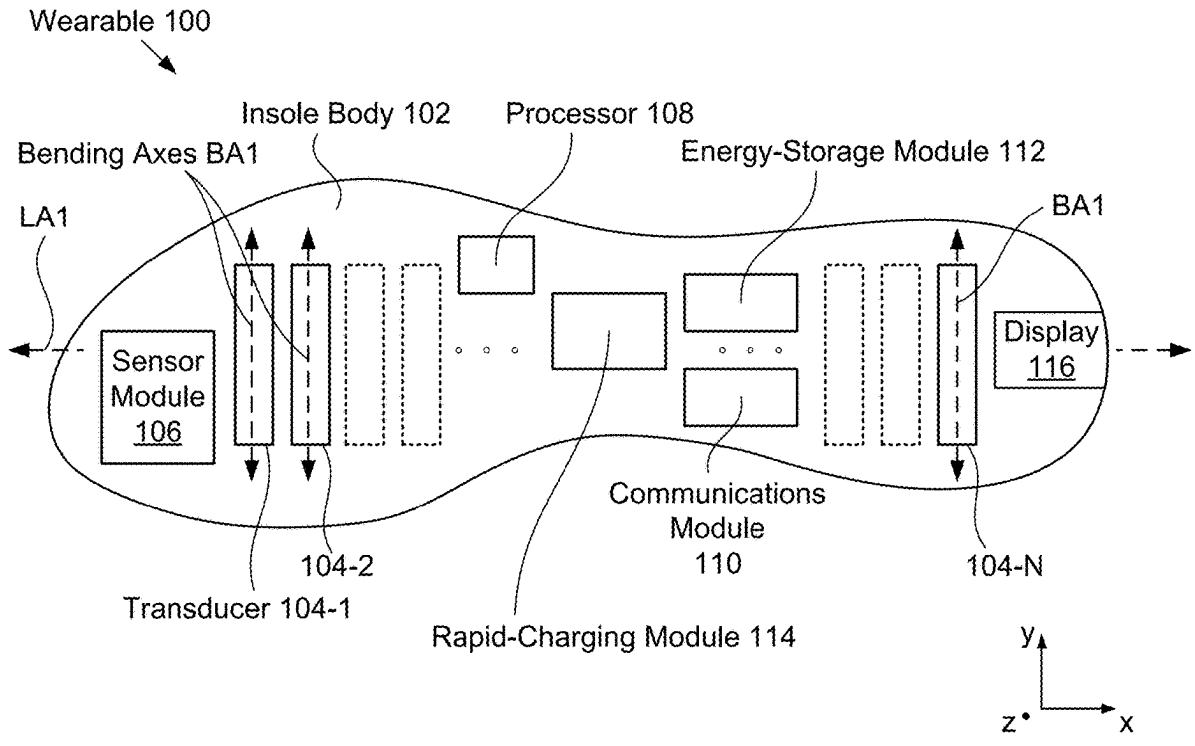
A61B 5/00	(2006.01)
A43B 3/46	(2022.01)
A61B 5/0205	(2006.01)
G06F 3/04817	(2022.01)
G06F 3/0488	(2022.01)
G16H 10/65	(2018.01)

(52) **U.S. Cl.**

CPC ***A61B 5/6829*** (2013.01); ***A43B 3/46*** (2022.01); ***A61B 5/02055*** (2013.01); ***A61B 5/7435*** (2013.01); ***G06F 3/04817*** (2013.01); ***G06F 3/0488*** (2013.01); ***G16H 10/65*** (2018.01)

(57) **ABSTRACT**

Aspects of the present disclosure describe systems and methods that enable a user of a computing device (e.g., a smartphone, tablet, etc.) to interact with a wearable device worn by the user. In one embodiment, the computing device provides a touchscreen-based graphical user interface (GUI). The GUI displays a plurality of icons, each associated with a respective health/fitness parameter (e.g., heart rate, blood oxygen saturation, etc.). The GUI enables the user to interact with the wearable device through the computing device, via presses of icons and press-and-holds of the icons.



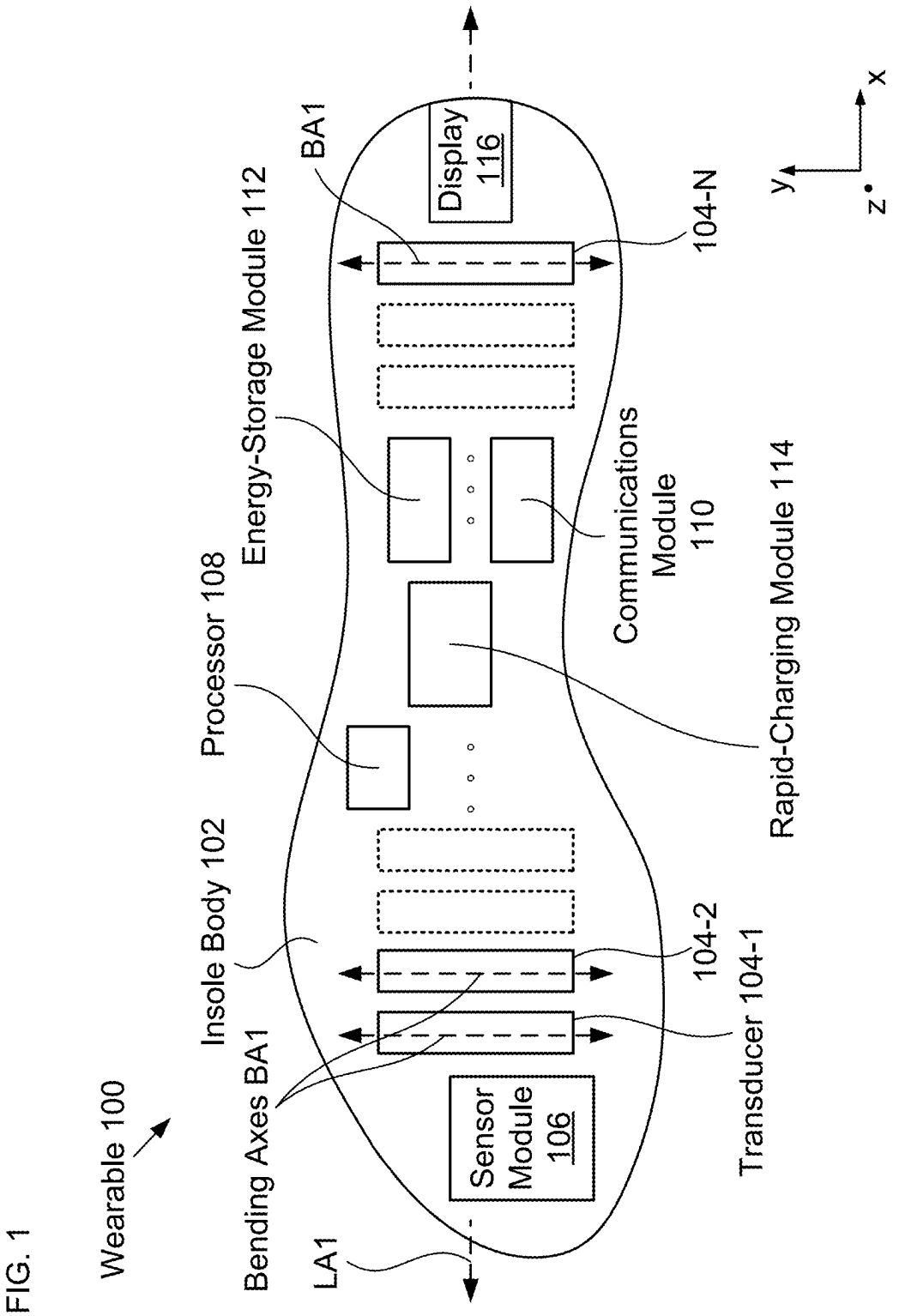

Wearable 100
Insole Body 102
Bending Axes BA1
LA1
BA1
Display 116
Energy-Storage Module 112
Processor 108
Sensor Module 106
Communications Module 110
Rapid-Charging Module 114
104-N
104-2
Transducer 104-1
y
x
z

FIG. 1

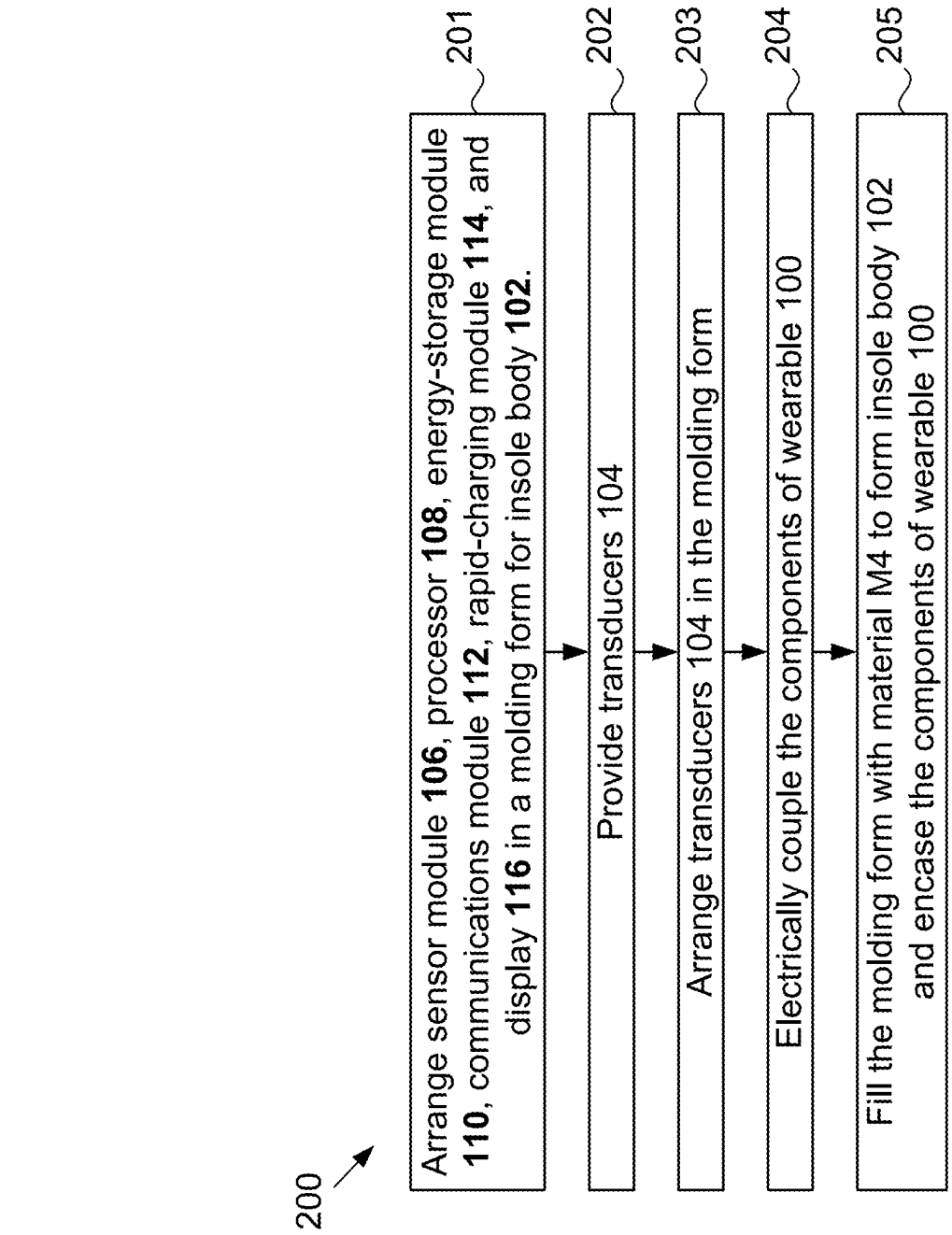

200
Arrange sensor module 106, processor 108, energy-storage module 110, communications module 112, rapid-charging module 114, and display 116 in a molding form for insole body 102.
201
Provide transducers 104
202
Arrange transducers 104 in the molding form
203
Electrically couple the components of wearable 100
204
Fill the molding form with material M4 to form insole body 102 and encase the components of wearable 100
205

FIG. 2

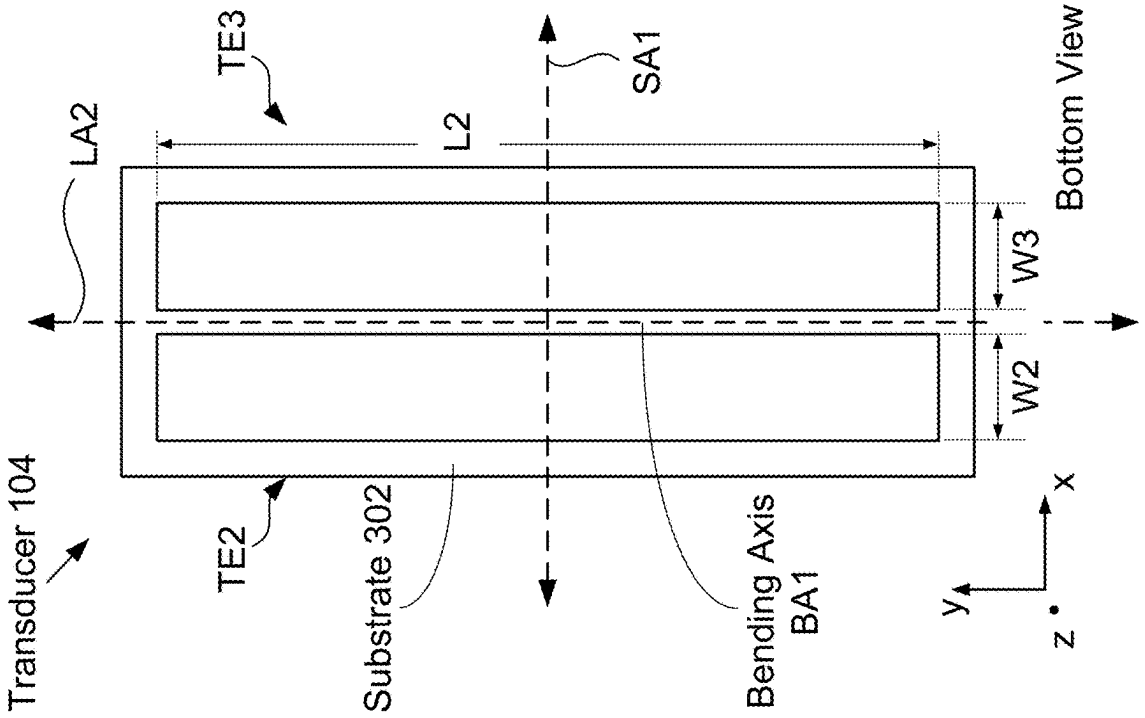

Transducer 104
TE2
Substrate 302
Bending Axis BA1
TE3
SA1
L2
LA2
W2
W3
Bottom View
x
y
z

FIG. 3B

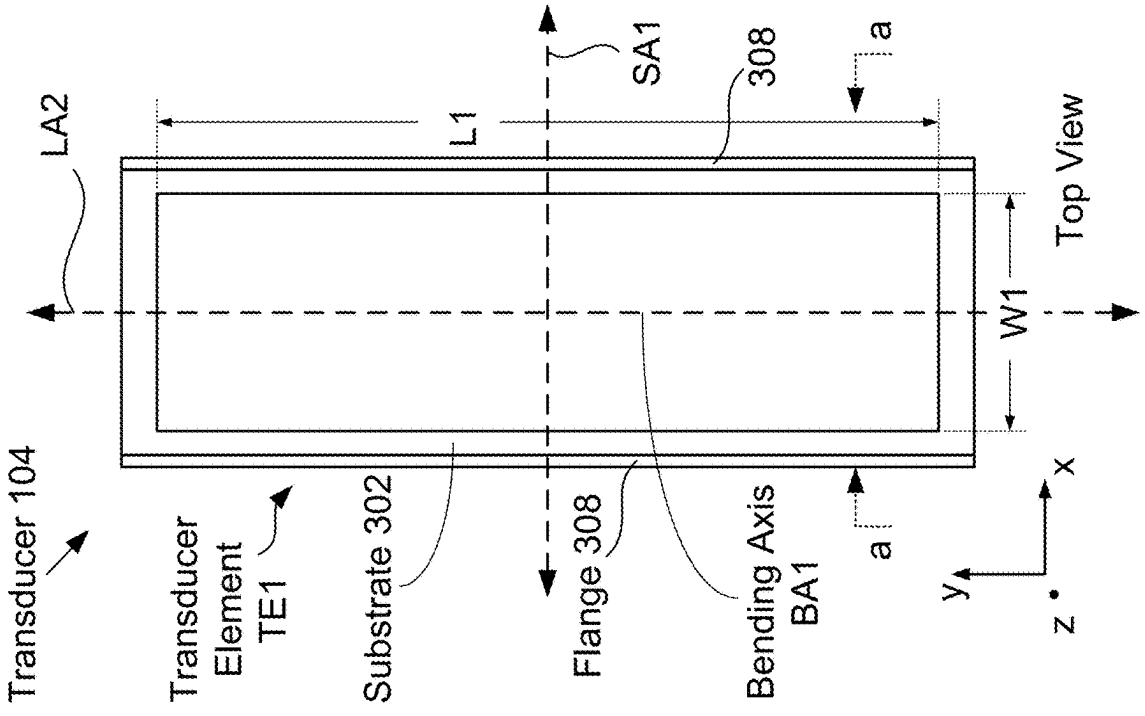
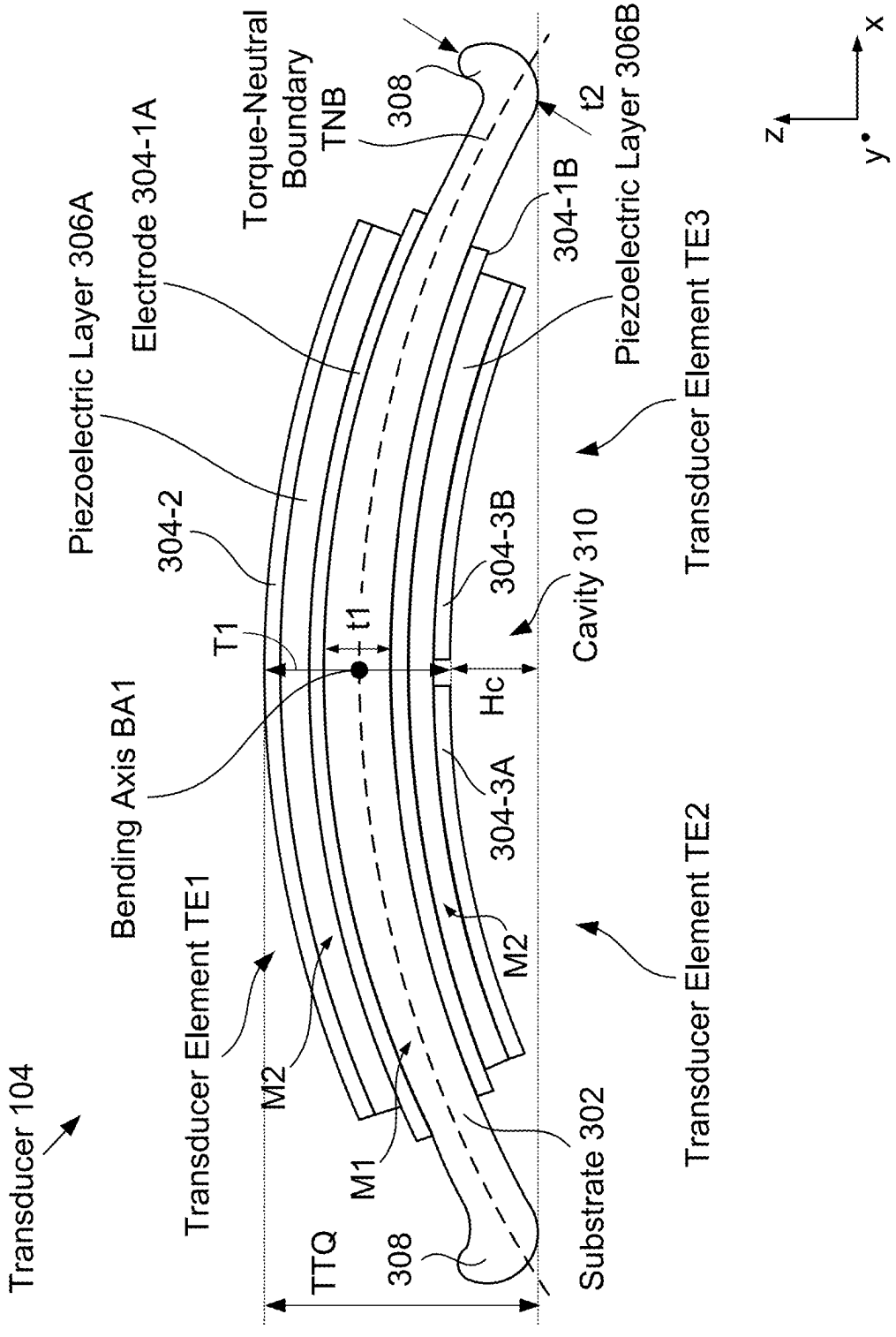

Transducer 104
Transducer Element TE1
Substrate 302
Flange 308
Bending Axis BA1
a
a
L1
SA1
308
LA2
W1
Top View
x
y
z

FIG. 3A

FIG. 3C


Transducer 104
Transducer Element TE1
Transducer Element TE2
Transducer Element TE3
Piezoelectric Layer 306A
Piezoelectric Layer 306B
Electrode 304-1A
304-1B
304-2
304-3A
304-3B
Torque-Neutral Boundary TNB
Bending Axis BA1
Cavity 310
Substrate 302
308
308
M1
M2
M2
T1
t1
t2
Hc
TTQ
x
y
z

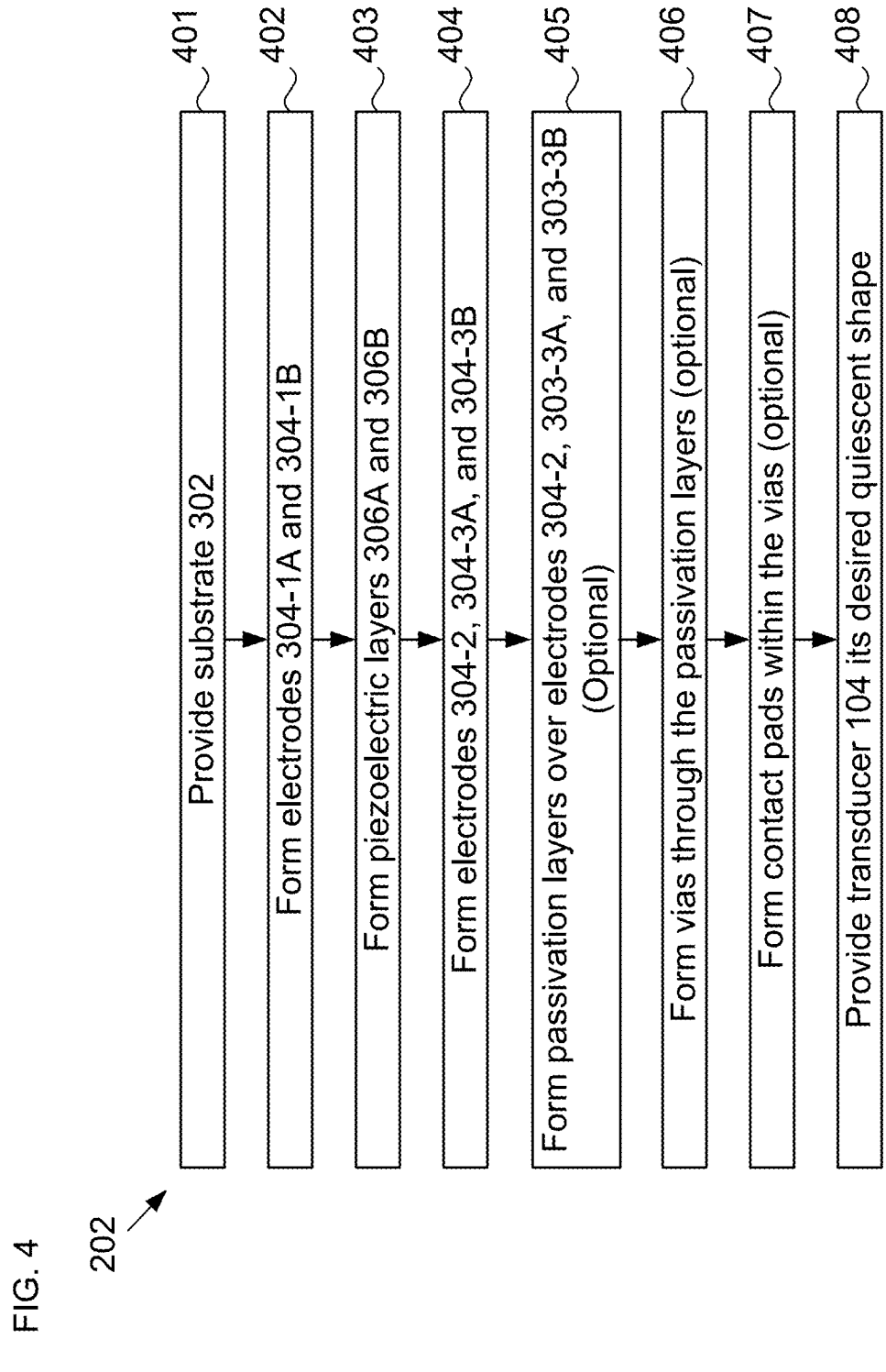

202
401
Provide substrate 302
402
Form electrodes 304-1A and 304-1B
403
Form piezoelectric layers 306A and 306B
404
Form electrodes 304-2, 304-3A, and 304-3B
405
Form passivation layers over electrodes 304-2, 303-3A, and 303-3B (Optional)
406
Form vias through the passivation layers (optional)
407
Form contact pads within the vias (optional)
408
Provide transducer 104 its desired quiescent shape

FIG. 4

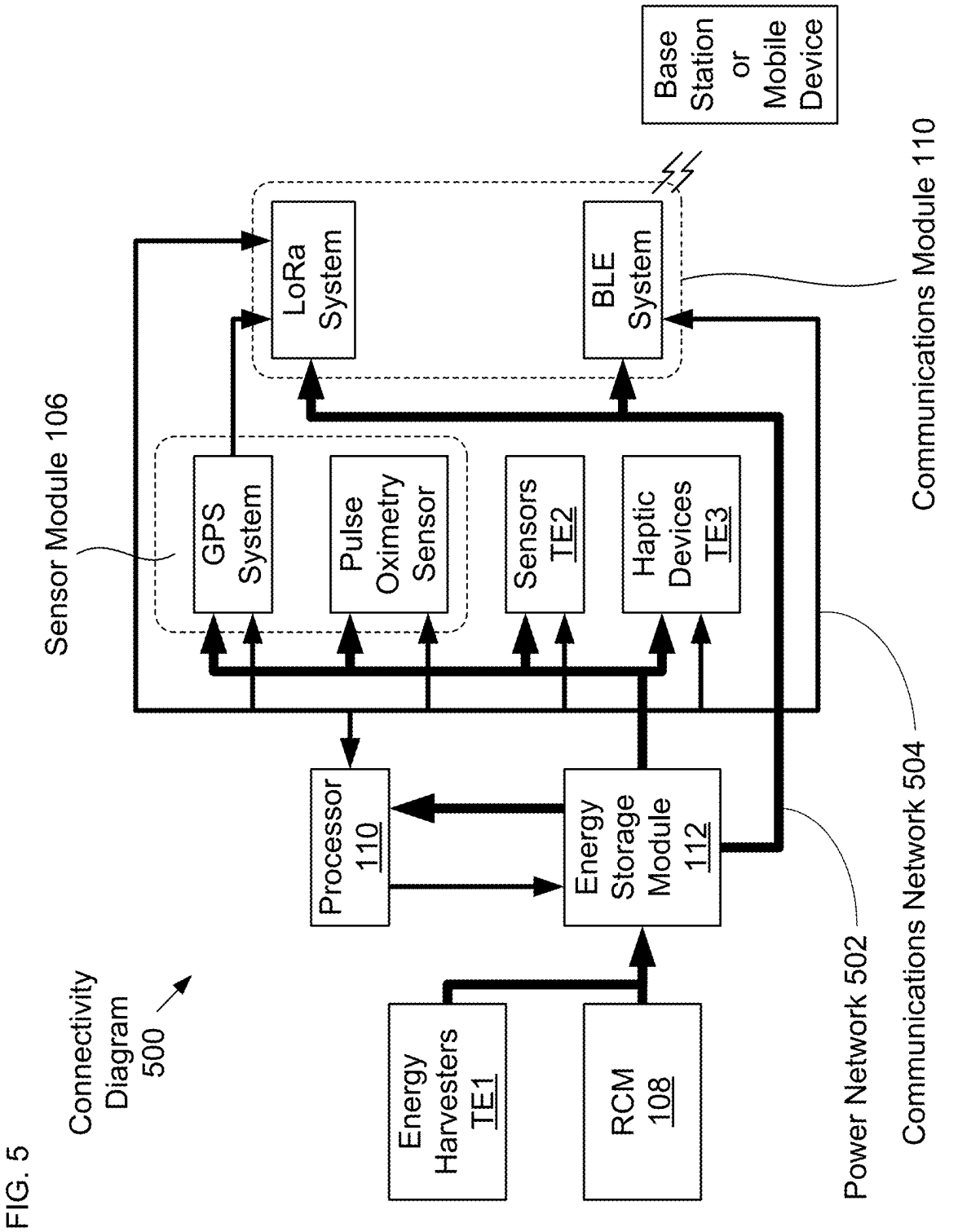

Base Station or Mobile Device
LoRa System
BLE System
Communications Module 110
Sensor Module 106
GPS System
Pulse Oximetry Sensor
Sensors TE2
Haptic Devices TE3
Processor 110
Energy Storage Module 112
Energy Harvesters TE1
RCM 108
Power Network 502
Communications Network 504
Connectivity Diagram 500

FIG. 5

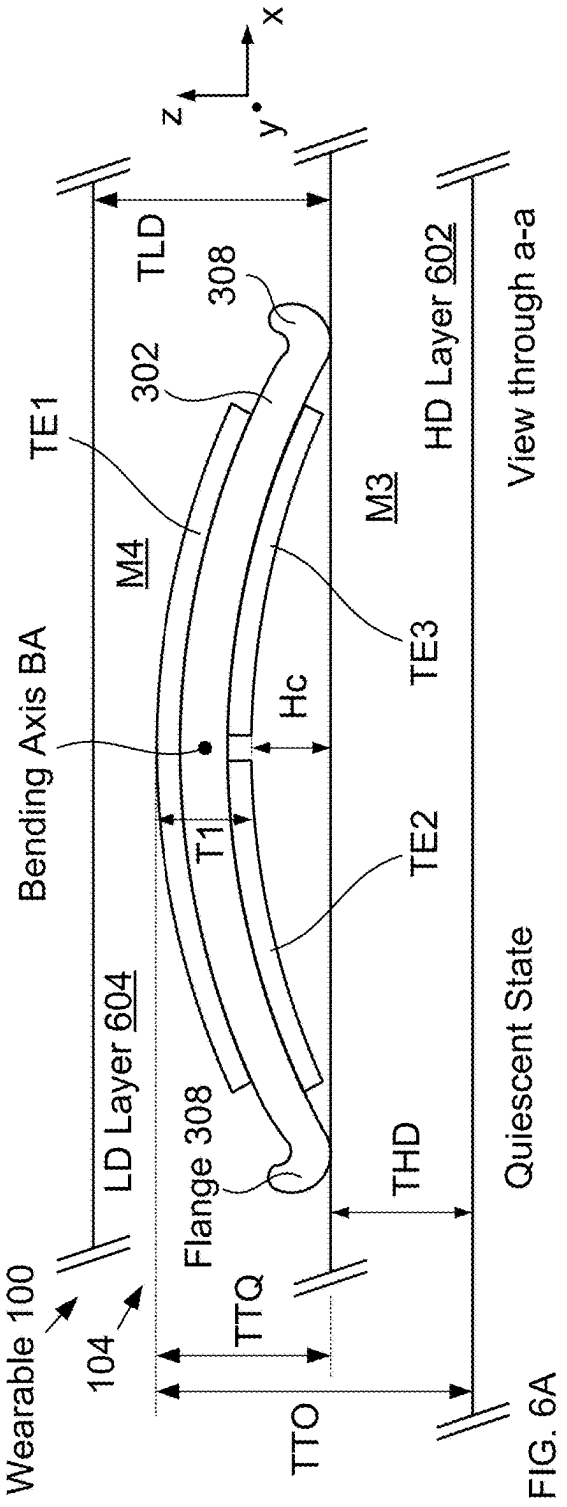

Wearable 100
104
LD Layer 604
Flange 308
TTQ
TTO
THD
Bending Axis BA
T1
Hc
TE1
TE2
TE3
M4
M3
302
308
TLD
HD Layer 602
Quiescent State
View through a-a
x
z
y

FIG. 6A

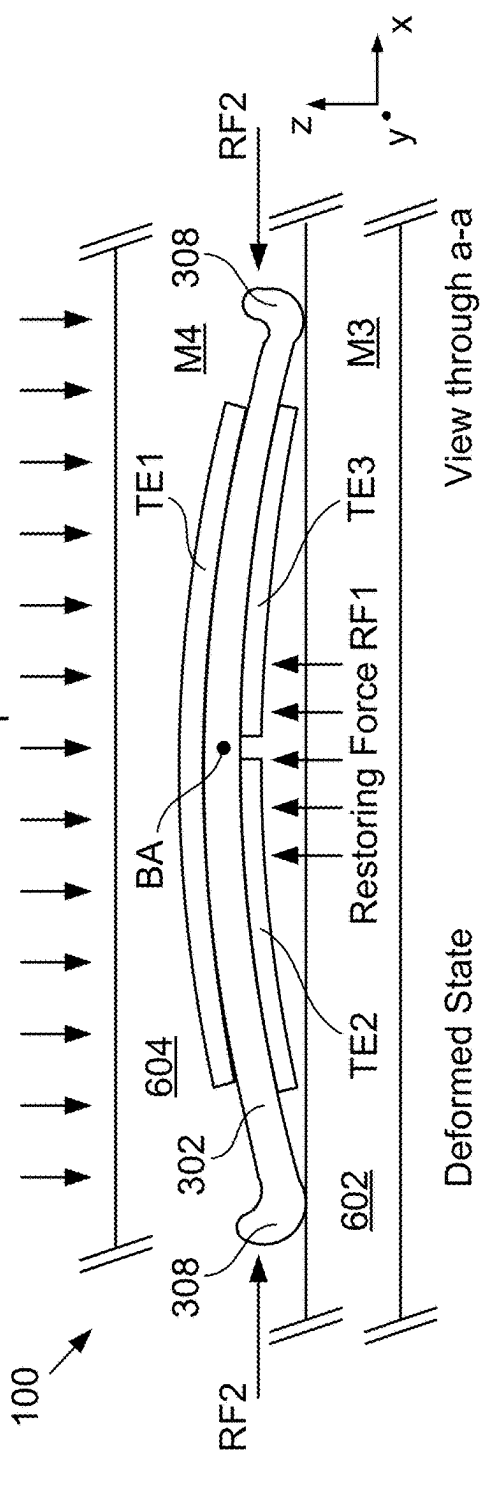

100
F
RF2
RF2
BA
TE1
TE2
TE3
M4
M3
302
308
604
602
Restoring Force RF1
Deformed State
View through a-a
x
z
y

FIG. 6B

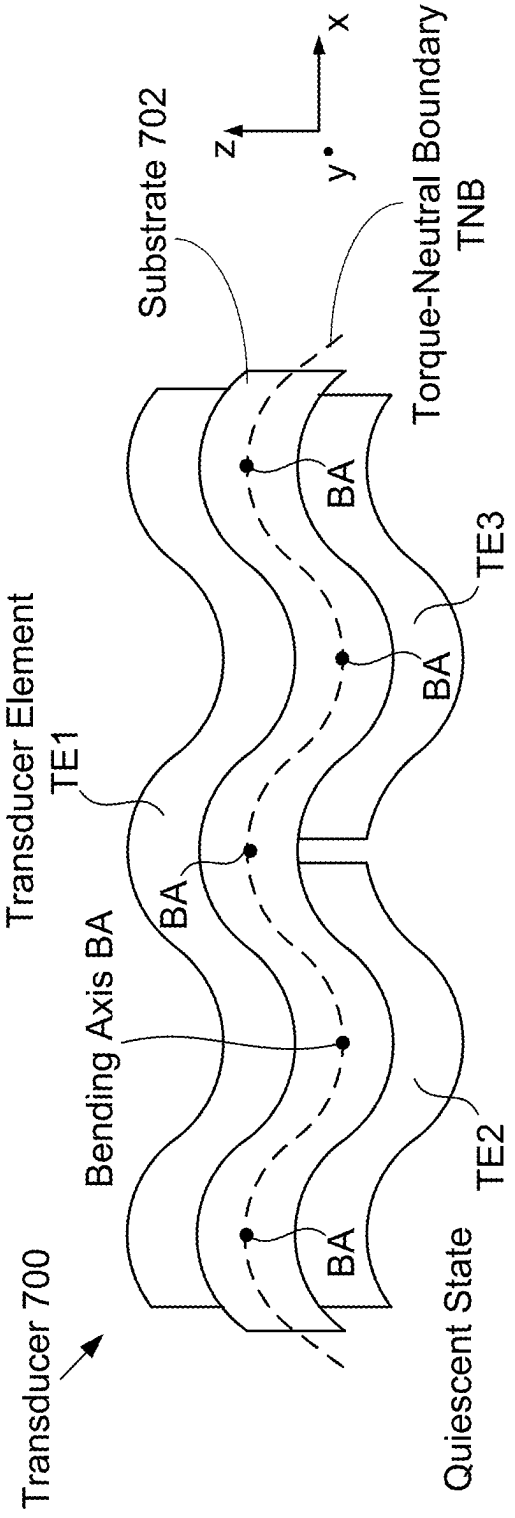

Transducer 700
Transducer Element
TE1
Bending Axis BA
BA
BA
BA
Substrate 702
z
x
y
Torque-Neutral Boundary
TNB
TE3
TE2
Quiescent State
View through a-a

FIG. 7A

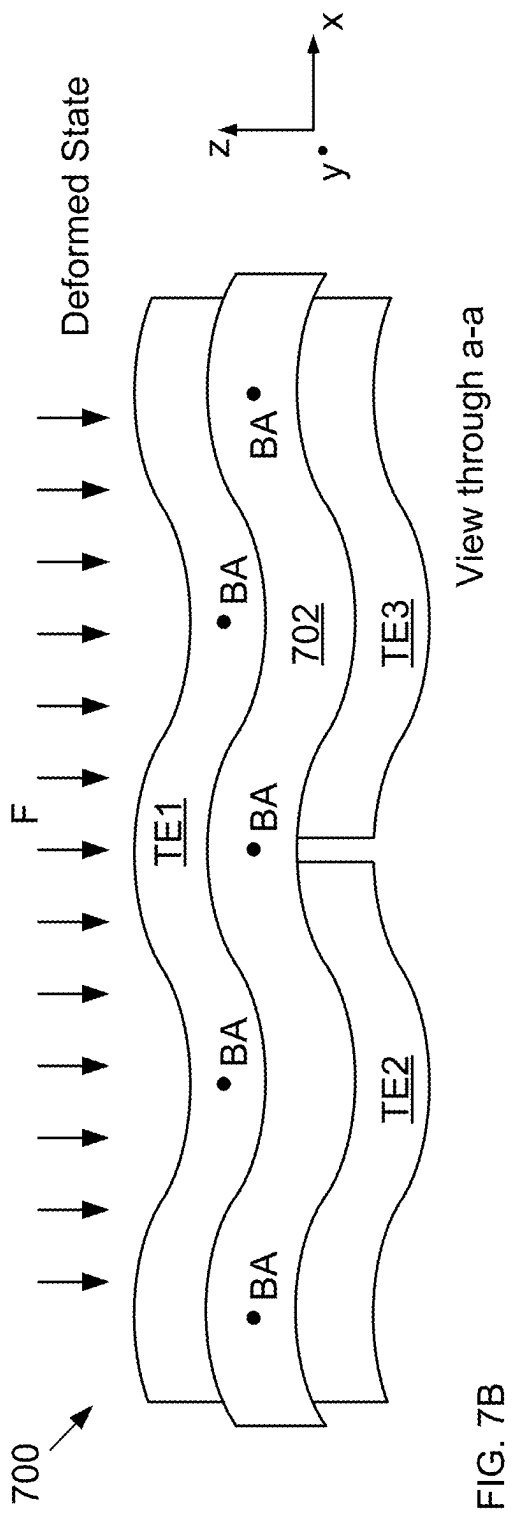

700
F
Deformed State
TE1
BA
BA
BA
BA
702
TE3
TE2
z
x
y
View through a-a

FIG. 7B

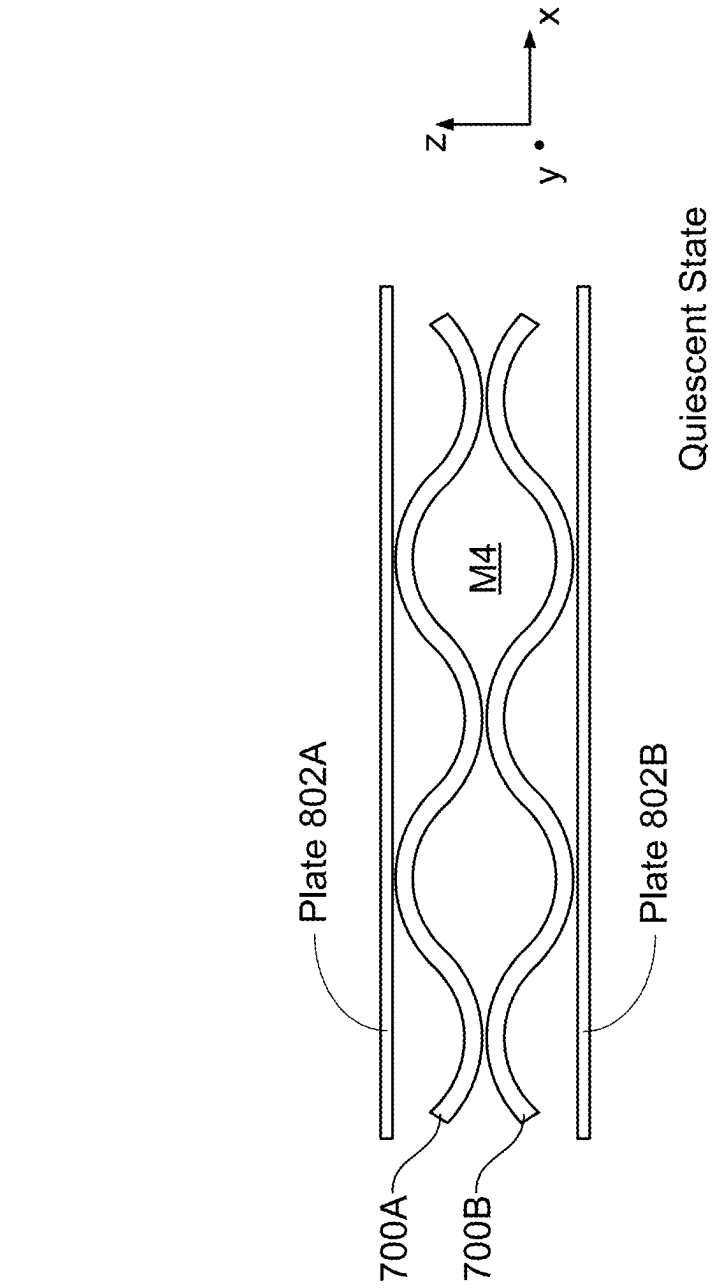


FIG. 8

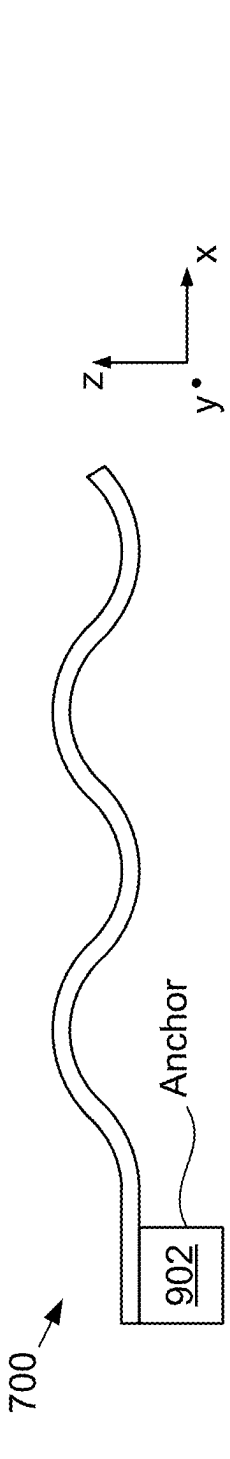


FIG. 9A

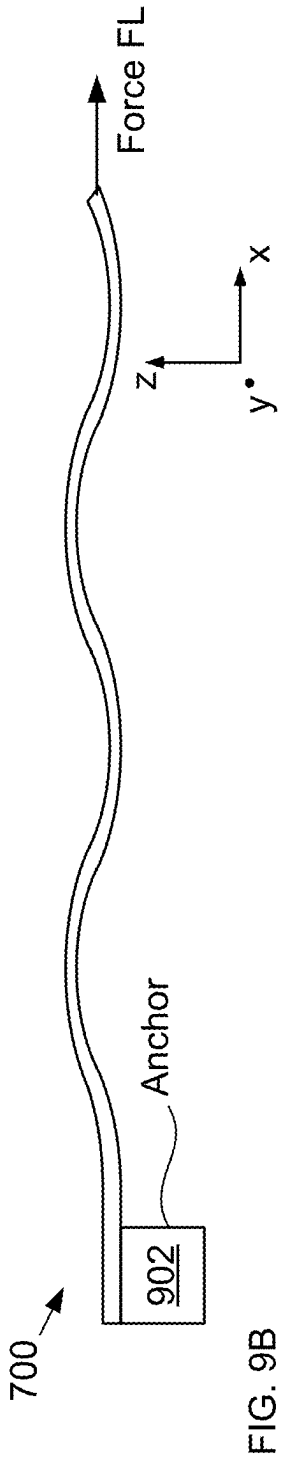


FIG. 9B

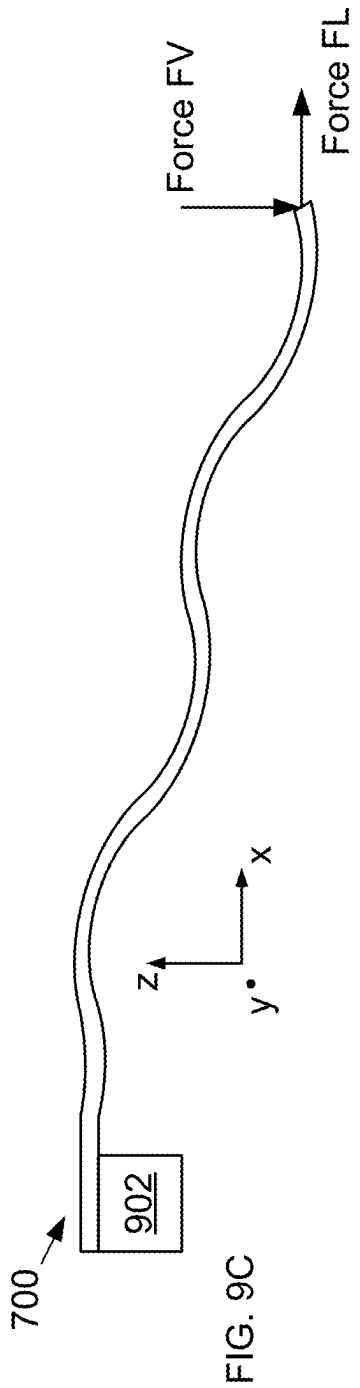


FIG. 9C

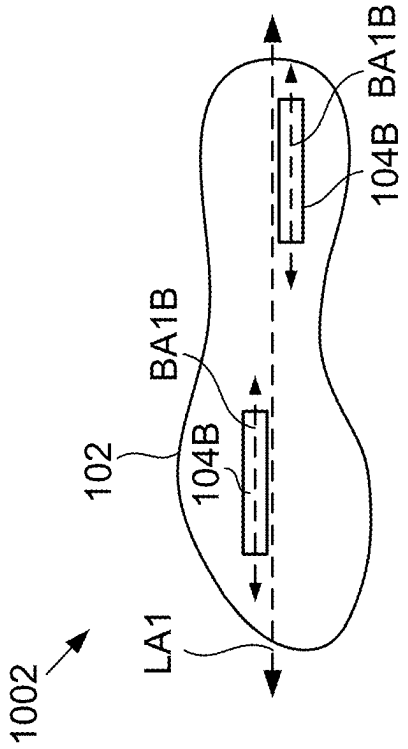


FIG. 10A

FIG. 10B

FIG. 10C

FIG. 10D

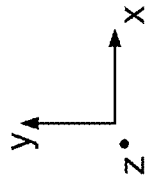


FIG. 11

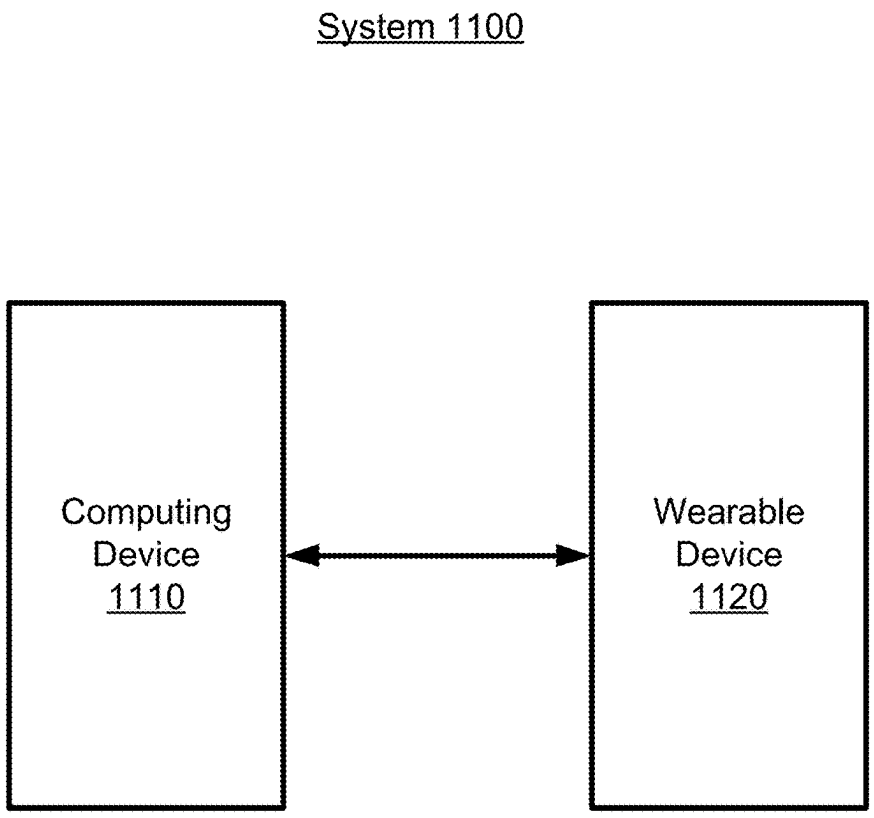


FIG. 12

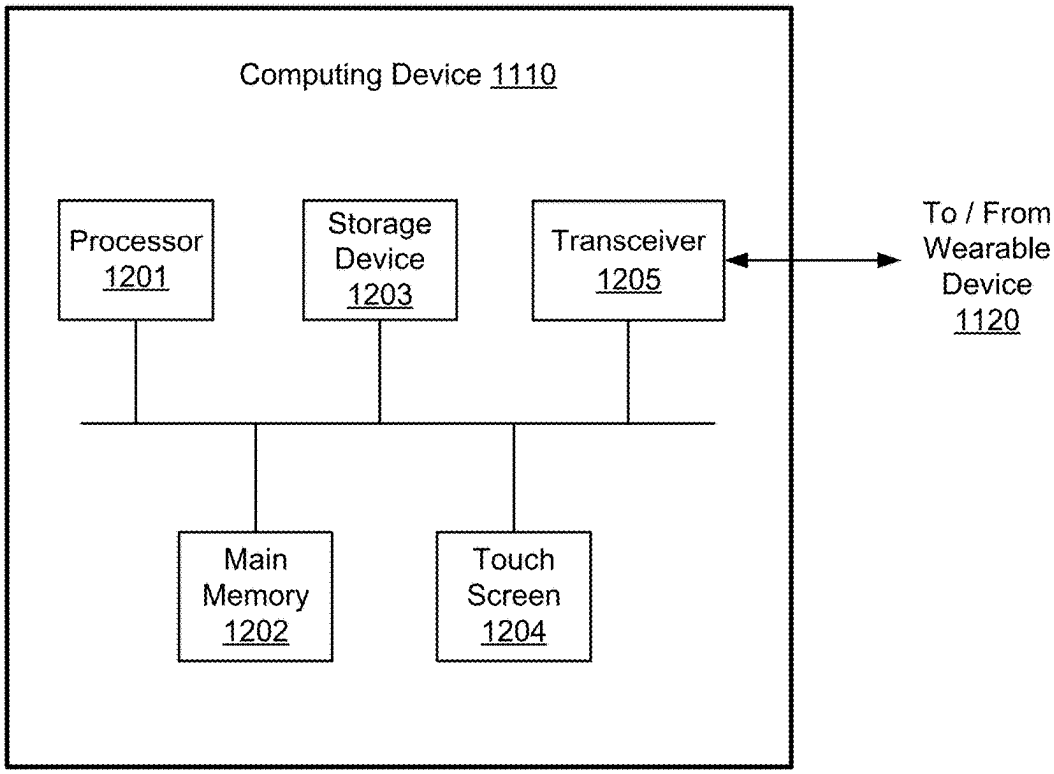

Computing Device 1110
Processor 1201
Storage Device 1203
Transceiver 1205
To / From Wearable Device 1120
Main Memory 1202
Touch Screen 1204

FIG. 13

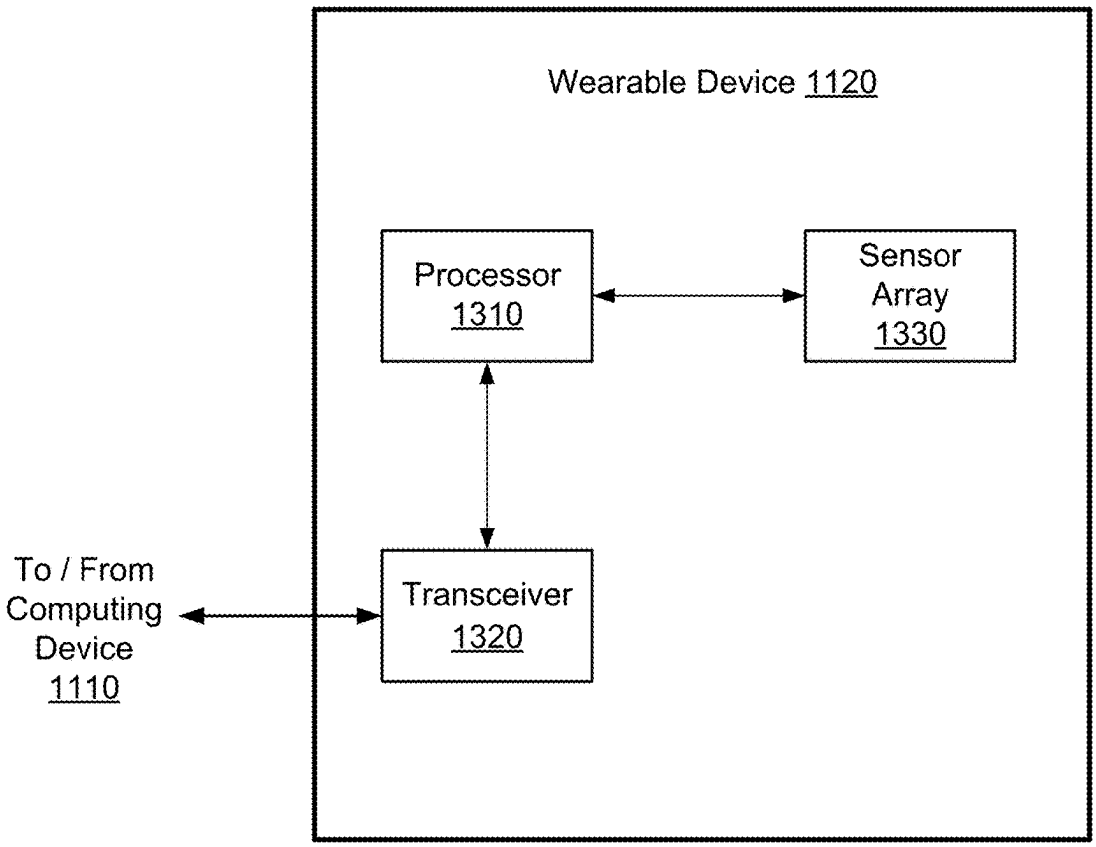

Wearable Device 1120
Processor 1310
Sensor Array 1330
Transceiver 1320
To / From Computing Device 1110

FIG. 14

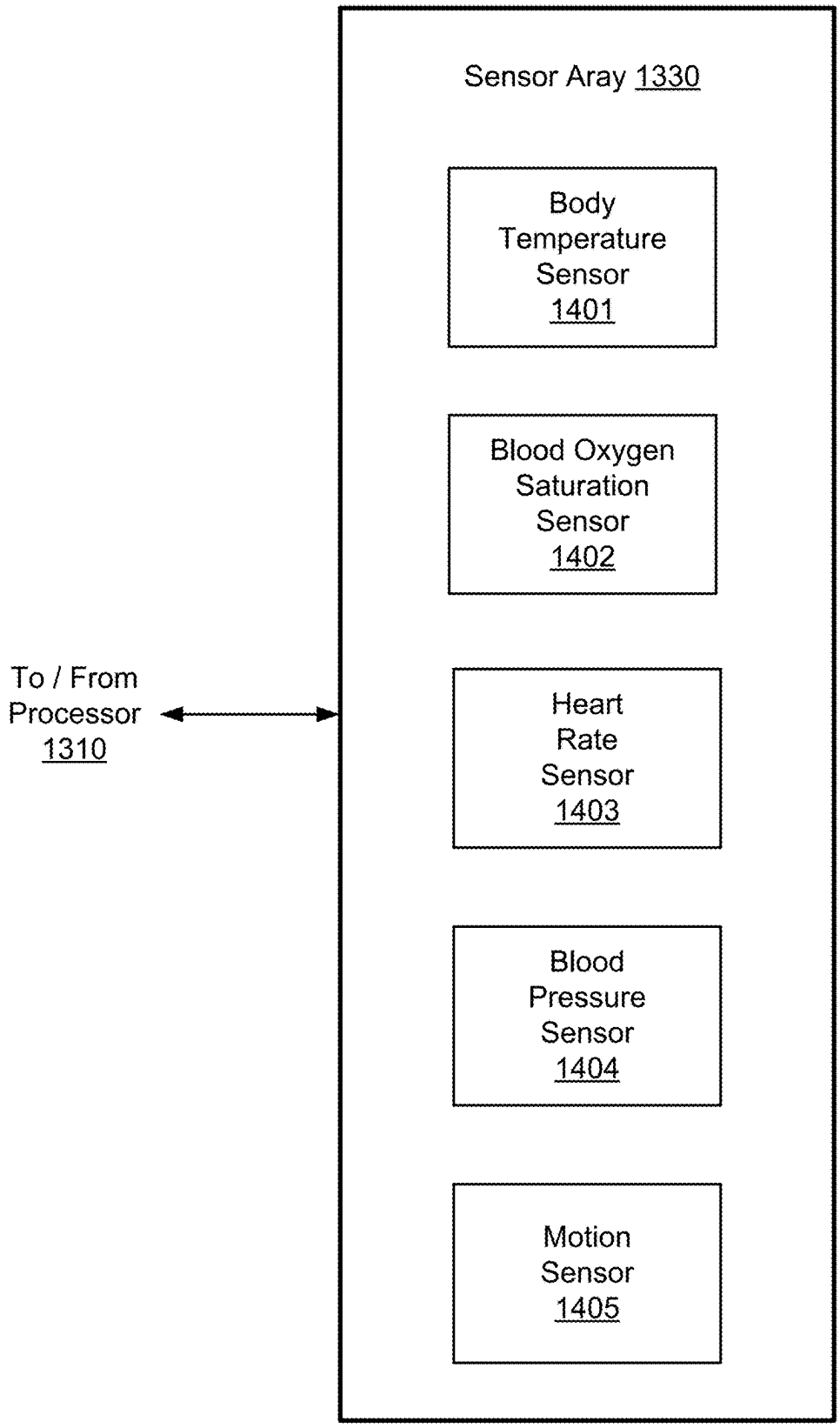

Sensor Aray 1330
Body Temperature Sensor 1401
Blood Oxygen Saturation Sensor 1402
Heart Rate Sensor 1403
Blood Pressure Sensor 1404
Motion Sensor 1405
To / From Processor 1310

FIG. 15

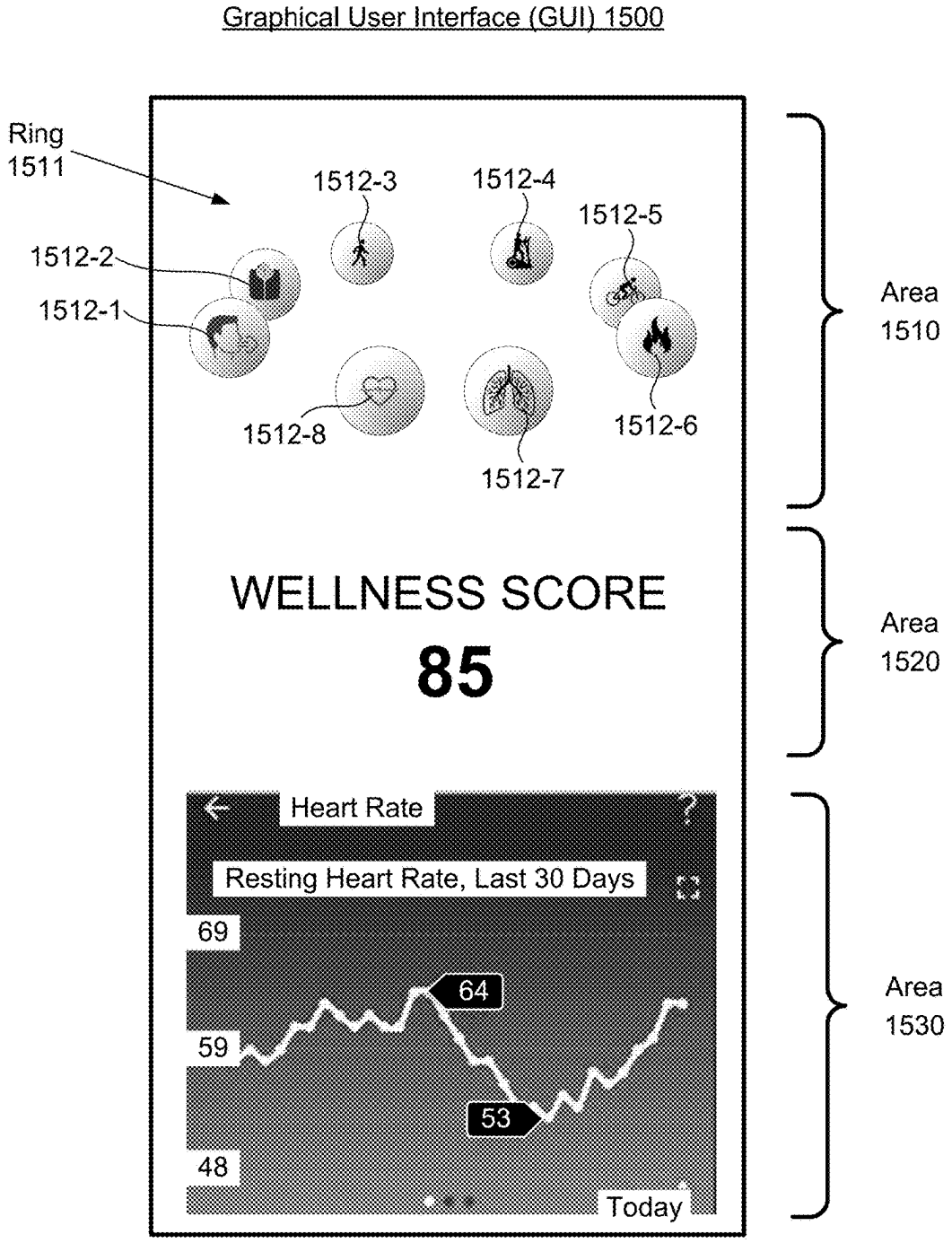

Graphical User Interface (GUI) 1500
Ring 1511
1512-1
1512-2
1512-3
1512-4
1512-5
1512-6
1512-7
1512-8
WELLNESS SCORE
85
Heart Rate
Resting Heart Rate, Last 30 Days
69
64
59
53
48
Today
Area 1510
Area 1520
Area 1530

FIG. 16

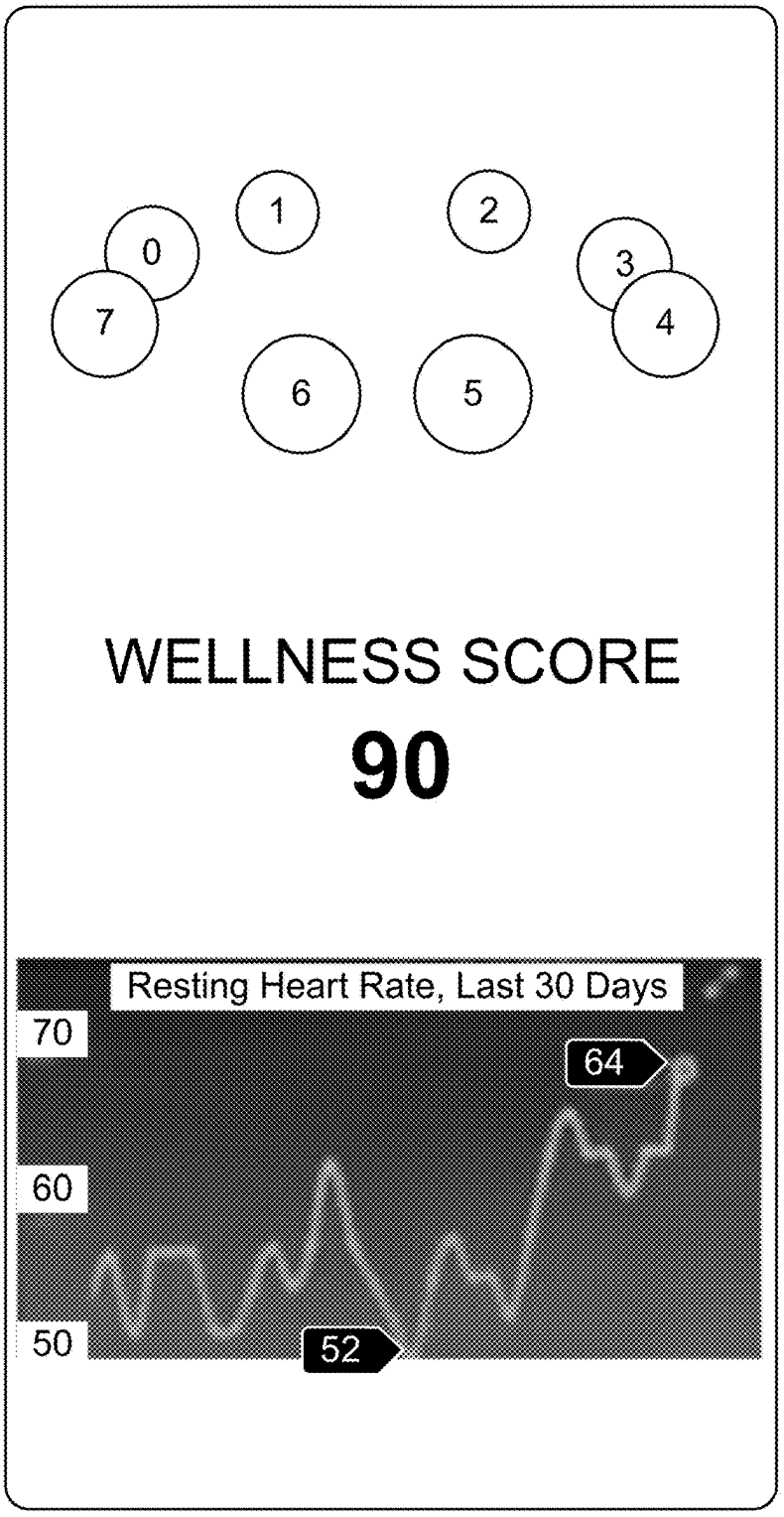
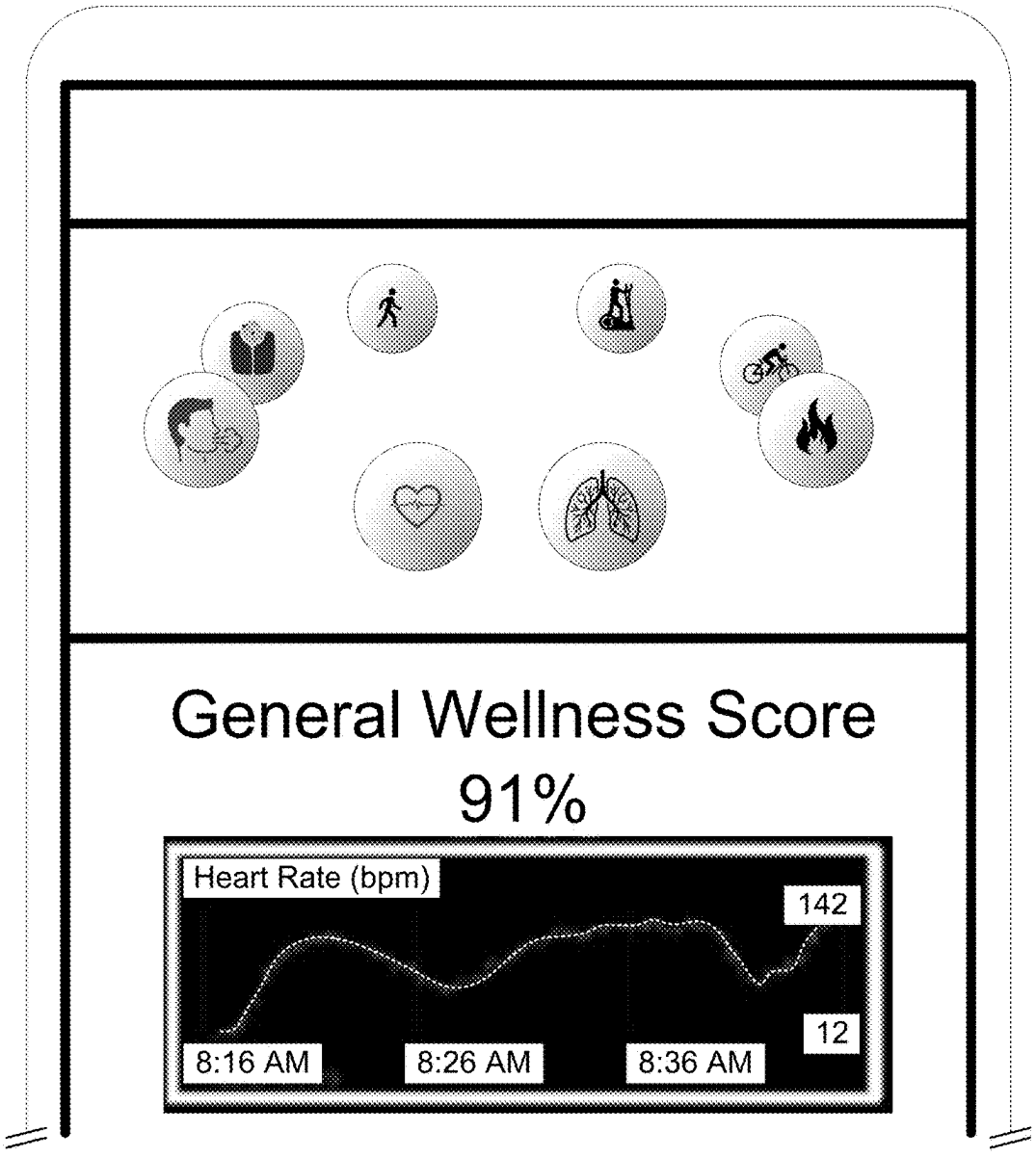

0
1
2
3
4
5
6
7
WELLNESS SCORE
90
Resting Heart Rate, Last 30 Days
70
60
50
64
52

FIG. 17


General Wellness Score
91%
Heart Rate (bpm)
142
12
8:16 AM
8:26 AM
8:36 AM

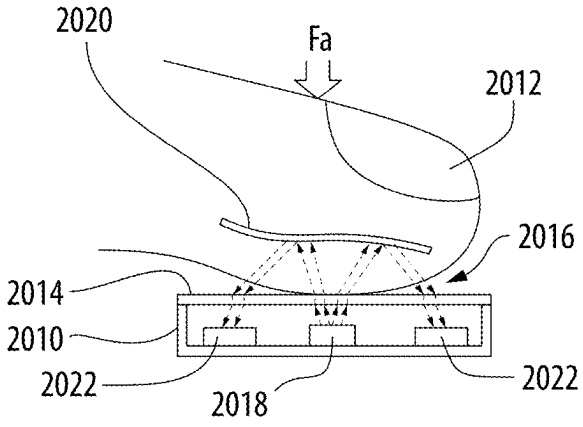


FIG. 18A

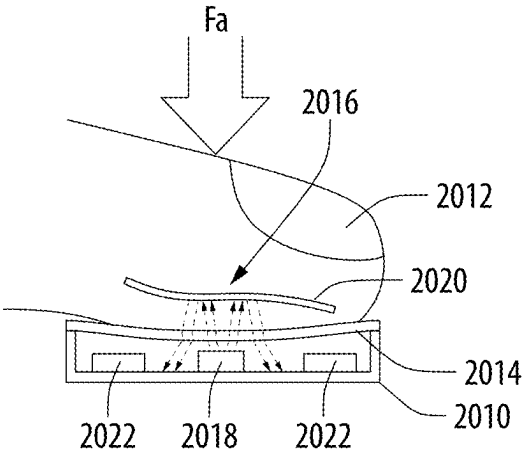


FIG. 18B

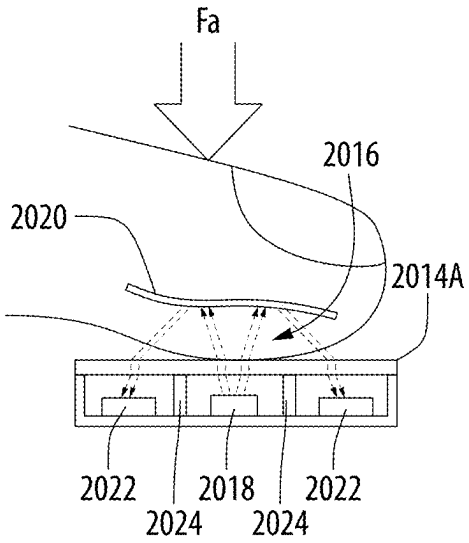


FIG. 19A

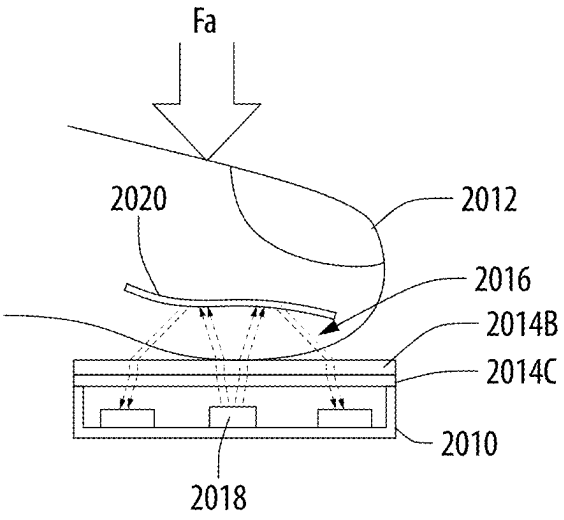


FIG. 19B

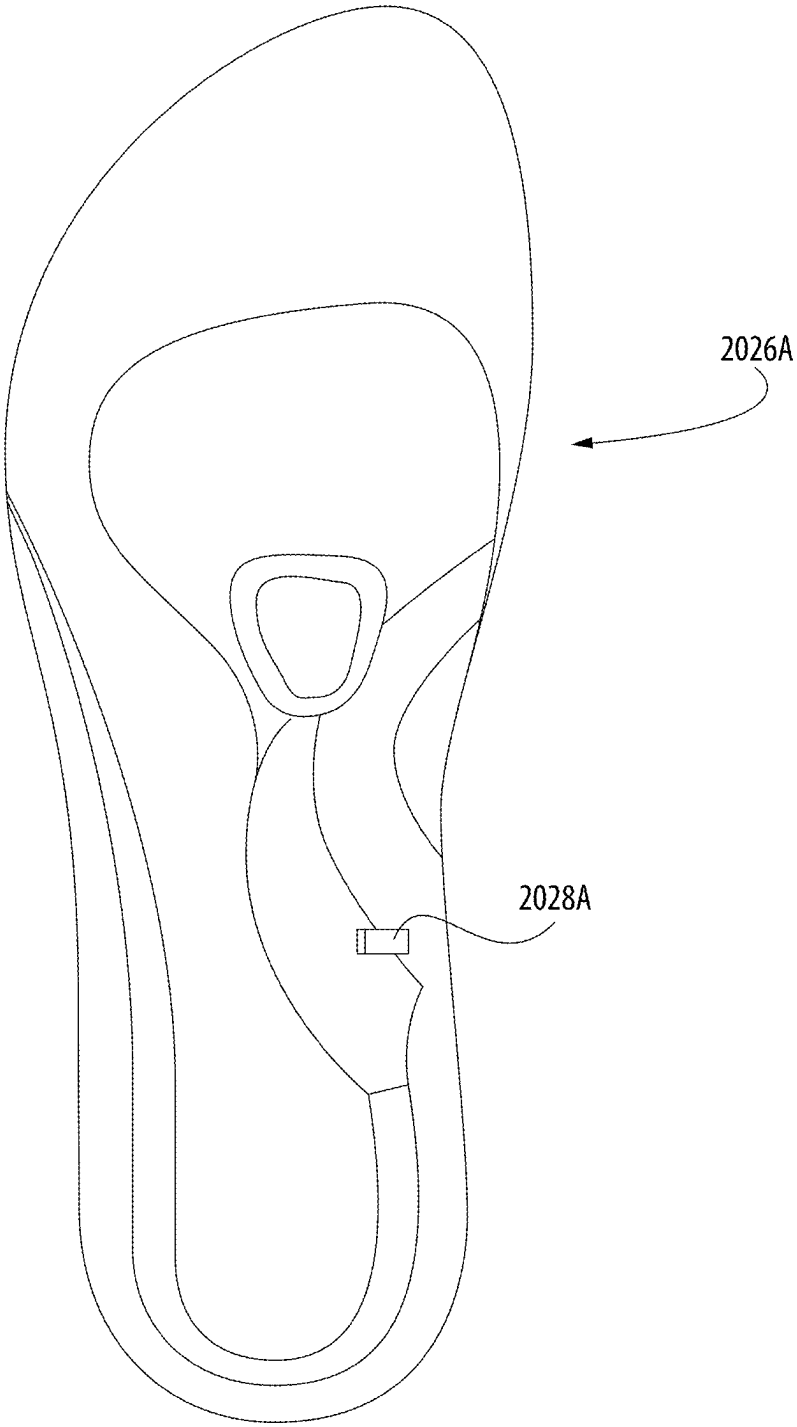


FIG. 20

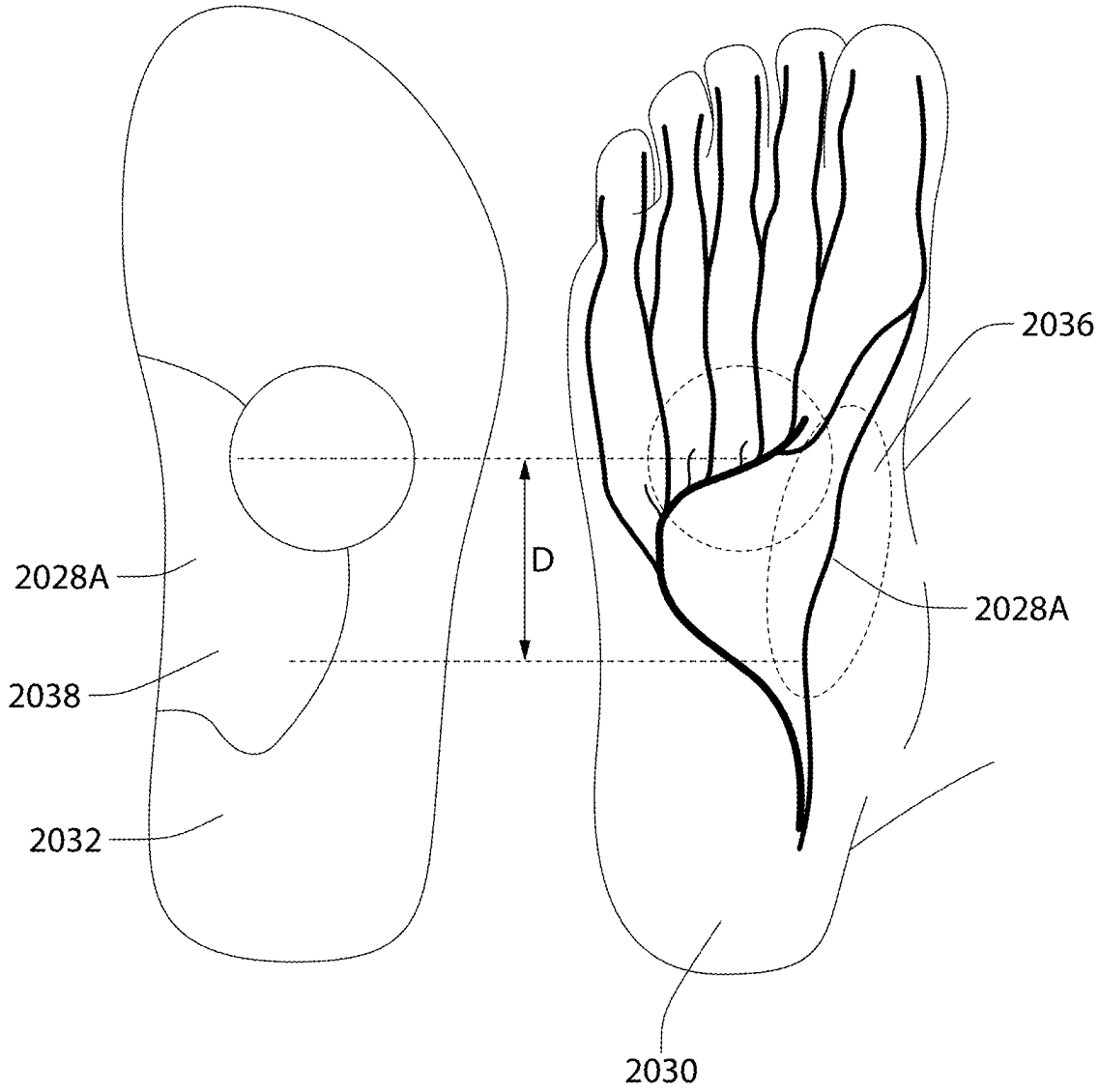


FIG. 21

FIG. 22

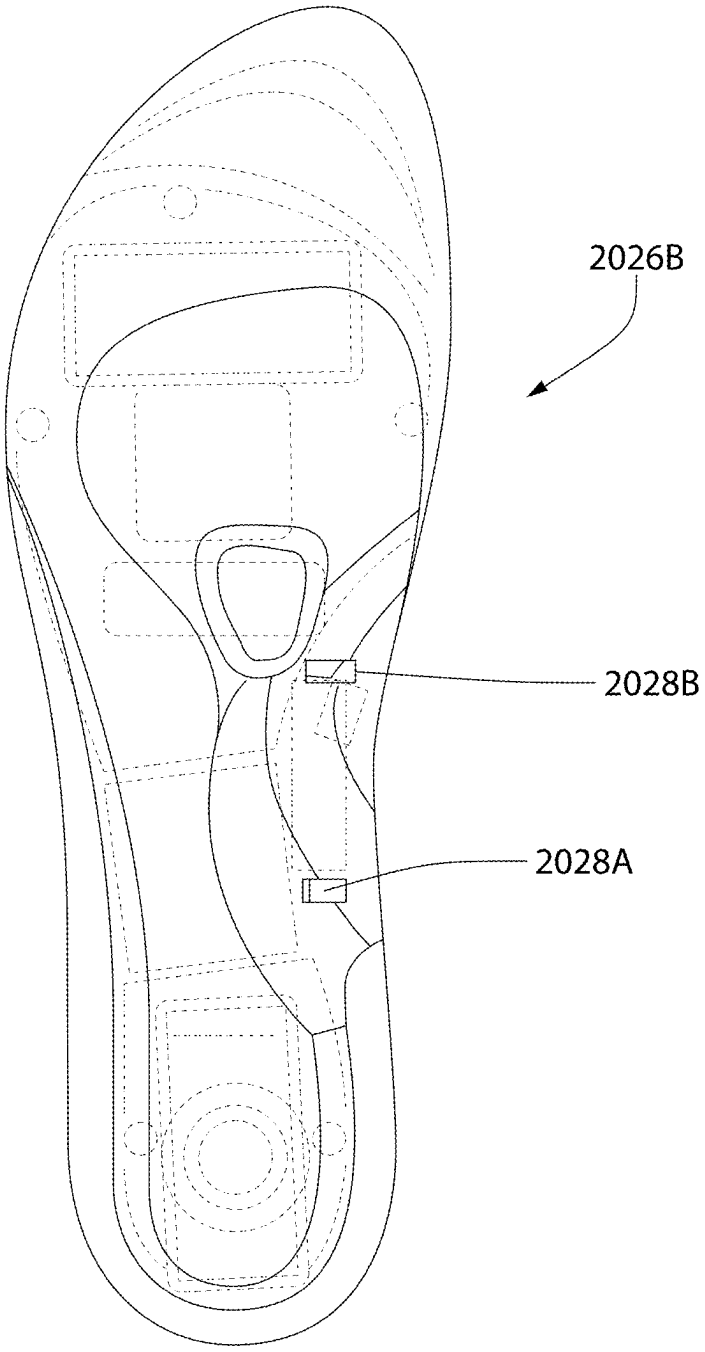


FIG. 23

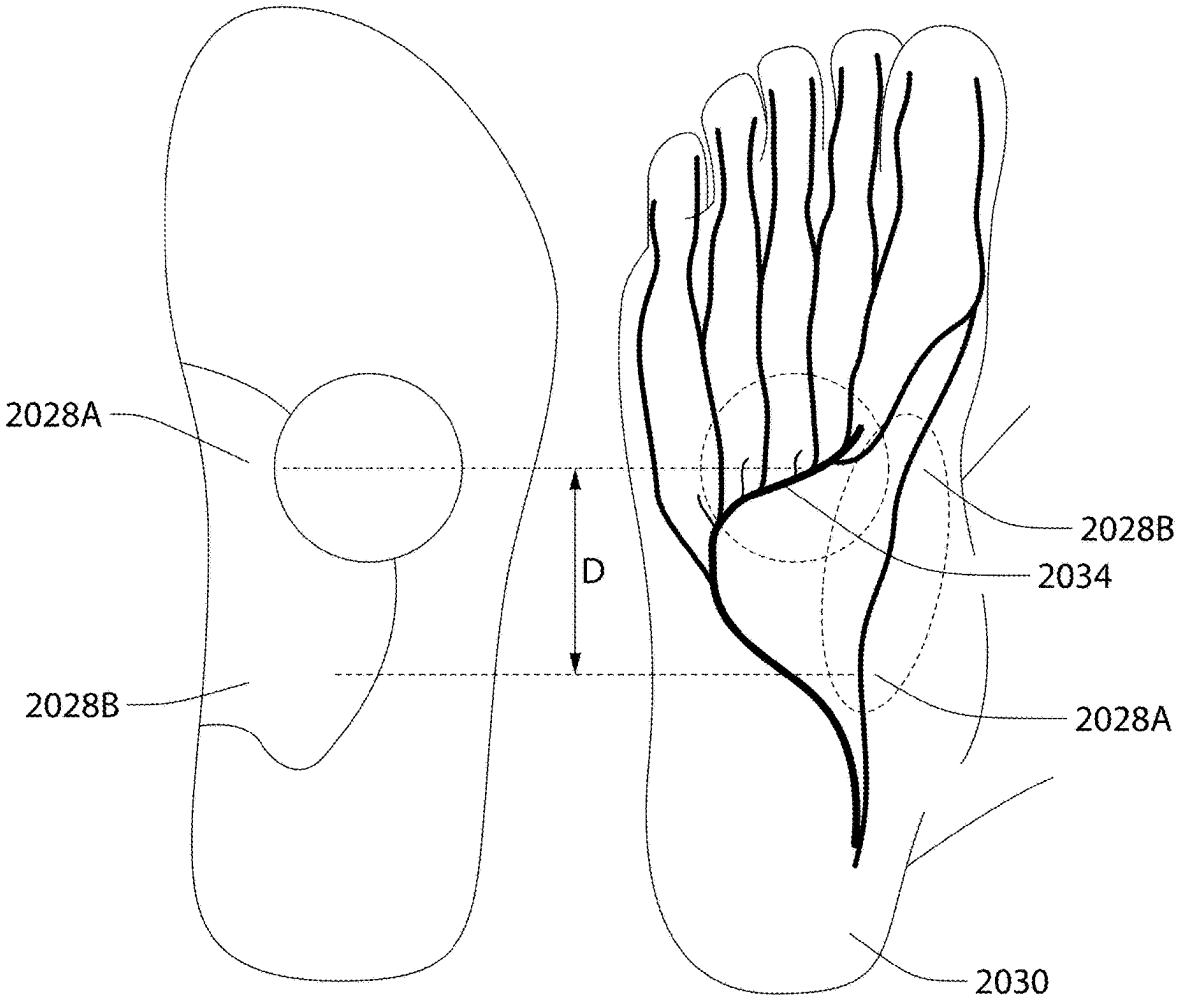


FIG. 24

FIG. 25

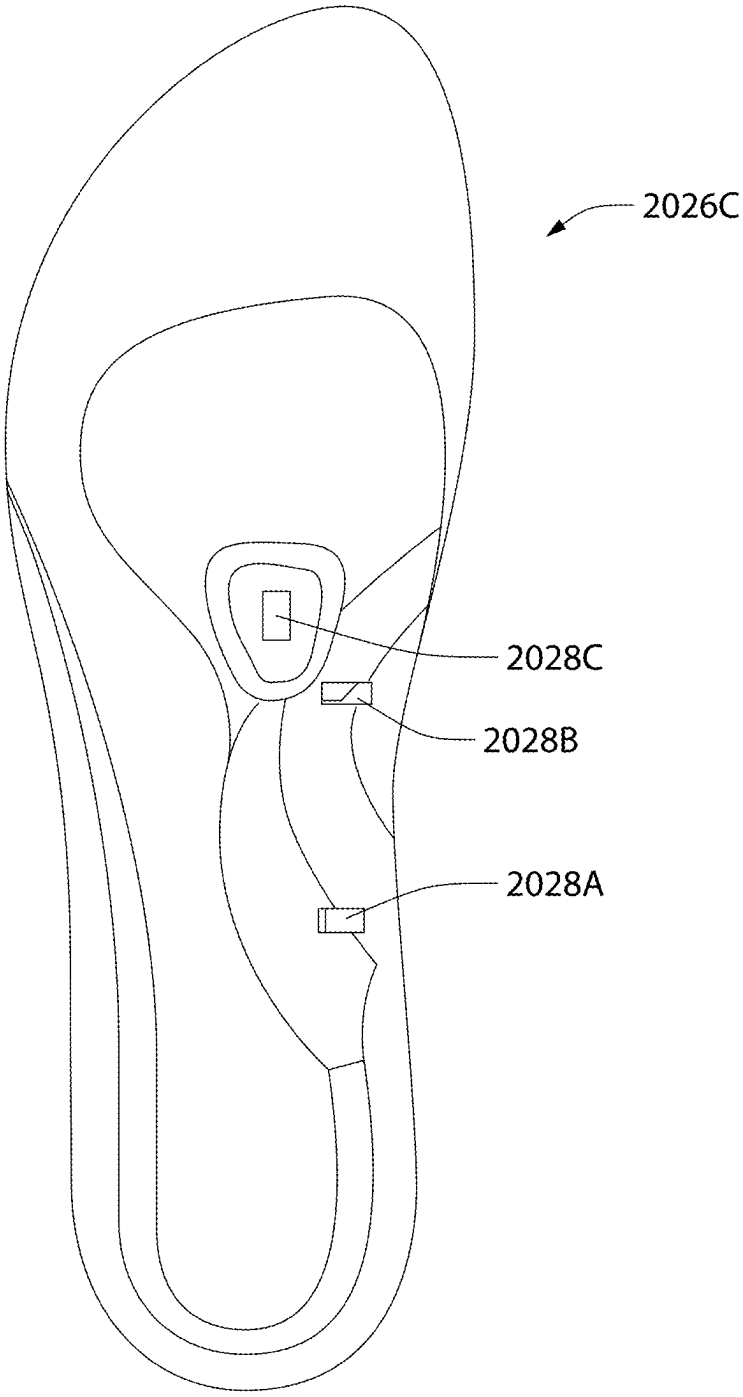


FIG. 26

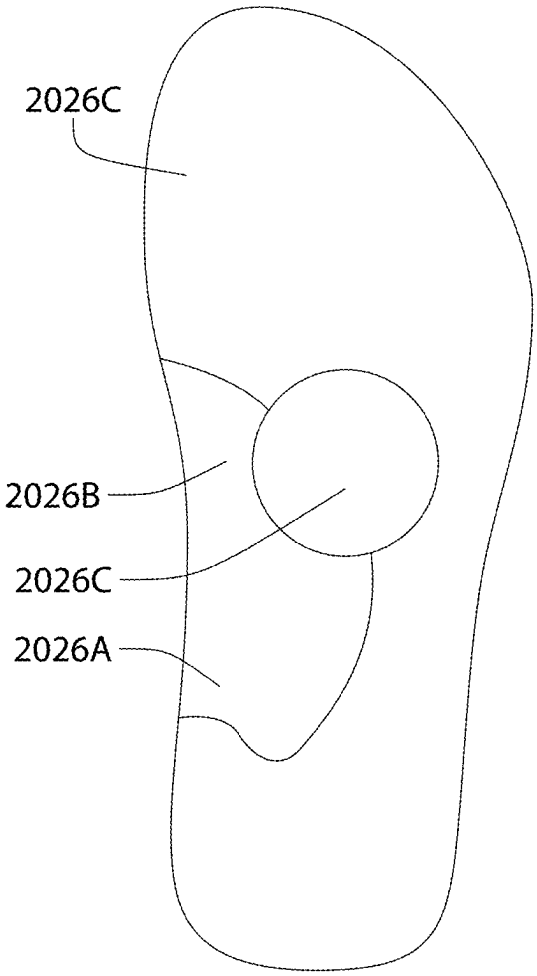


FIG. 27

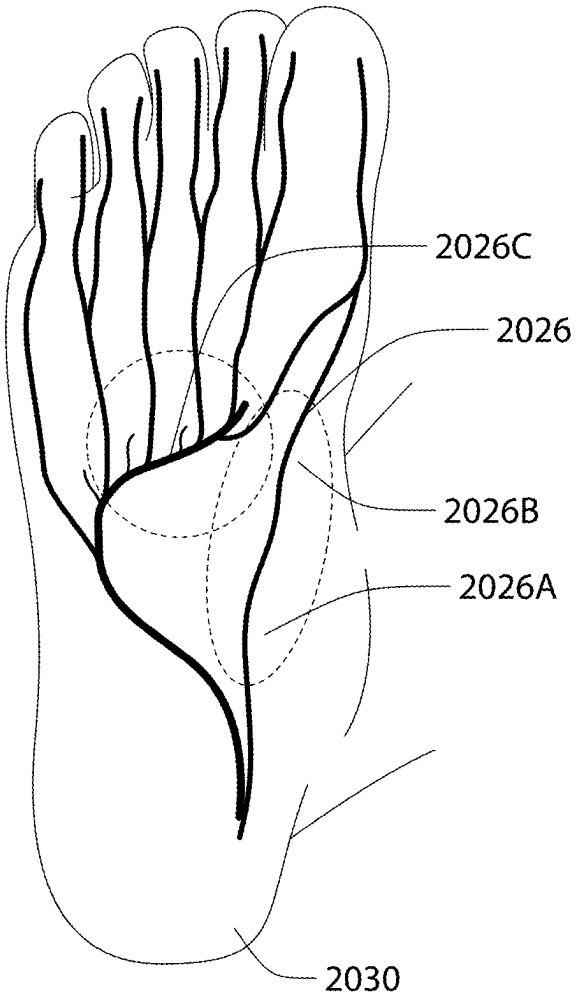


FIG. 28

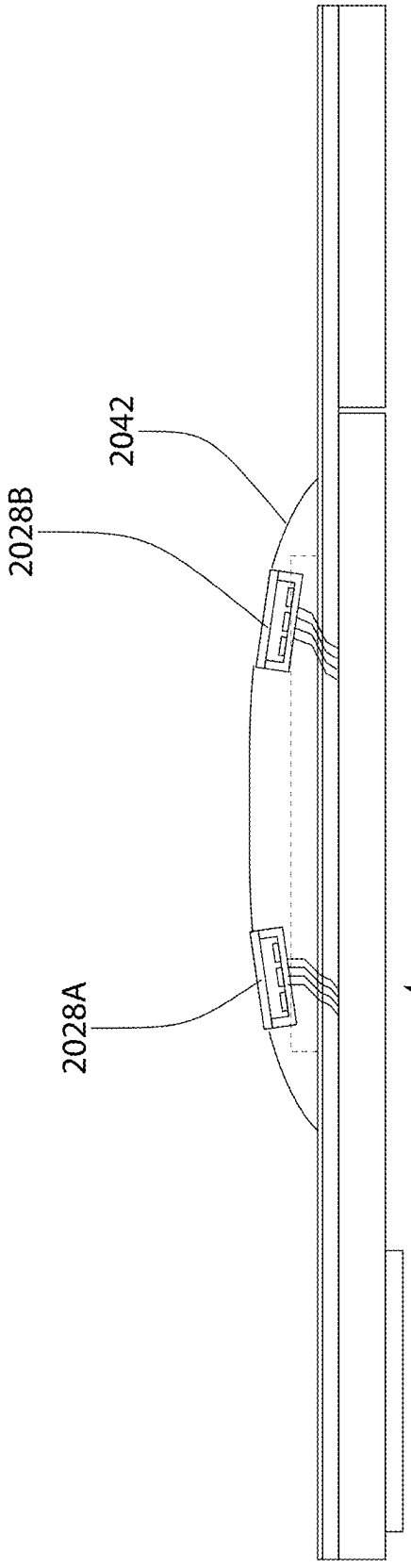


FIG. 29

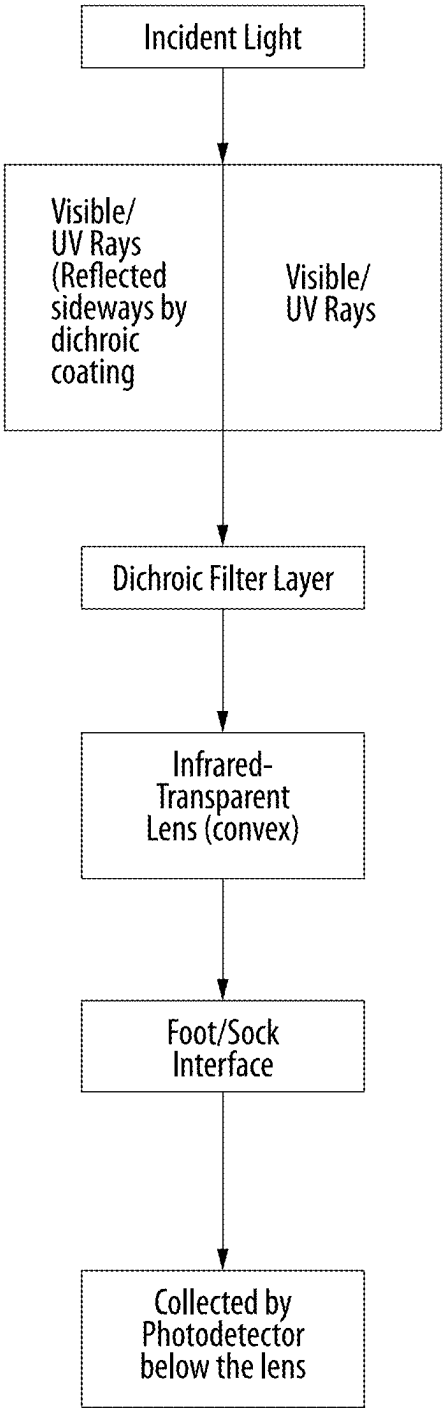

Incident Light
Visible/
UV Rays
(Reflected
sideways by
dichroic
coating
Visible/
UV Rays
Dichroic Filter Layer
Infrared-
Transparent
Lens (convex)
Foot/Sock
Interface
Collected by
Photodetector
below the lens

FIG. 30

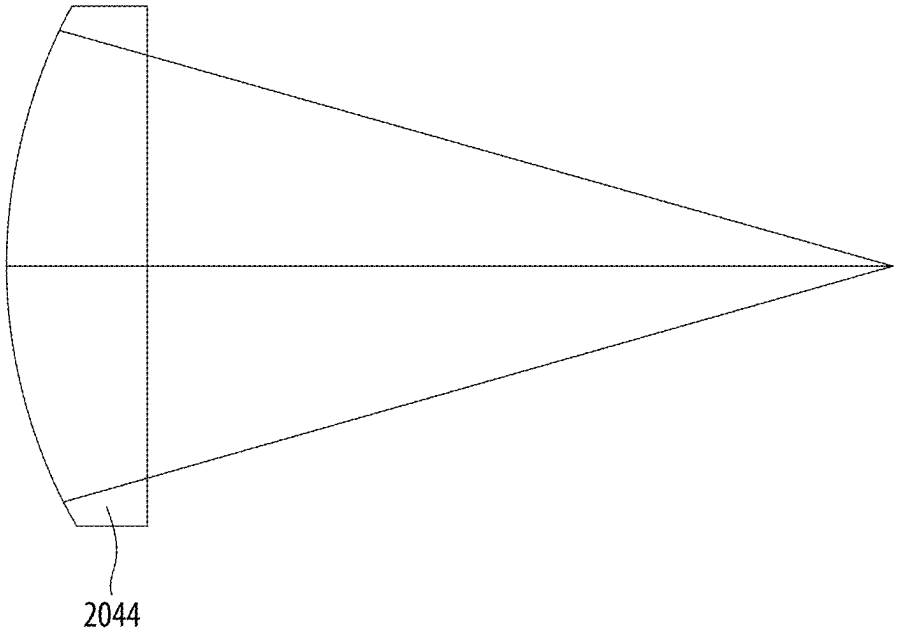


FIG. 31

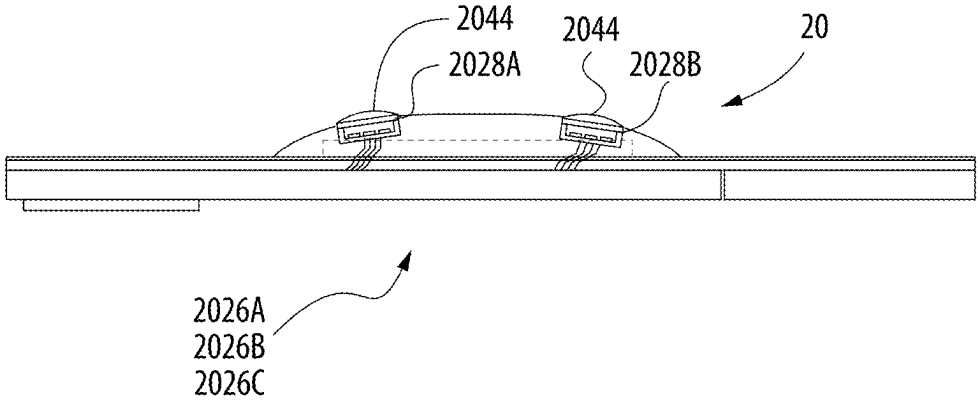


FIG. 32

Sensor	Purpose	Wavelengths	Sampling Rate	Photo-detector Sensitivity	Placement
"Single-PPG"	-Primarily for: HR & SpO2	-520 nm (green) - HR only; since it is lower in power consumption -660 nm (red) 940 nm (near IR "NIR") - SpO2 only HR can be measured too -All 3 LEDs can be inside a single PPG package to lower power consumption when measuring HR only turn "on" only 520 nm LED use only 660 and 940 nm LEDs when measuring only SpO2 (you obtain HR too) and BP -this is the lowest power configuration when all three LEDs are present inside the PPG package	500-1,000Hz	TBD (520nm) ≥0.6 Amps/ Watt(660nm) ≥0.4 Amps/ Watt(940nm)	Anywhere along the medial plantar artery within the foot's plantar arch
"Dual-PPG"	-Primarily for BP	-Only 660 and 940 nm LEDs are needed To measure BP only you need just 660 and 940 nm -You can obtain HR and SpO2 as well -This is the lowest power configuration to measure HR, SpO2 and BP together	500-1,000Hz for both PPGs	Same as Sensor 1	-Place 1st PPG behind the 1st met-head -Place the 2nd PPG 2.5 to 11cm away from the 1st PPG Both along the medial plantar artery within the foot's plantar arch
"Triple-PPG"	-Diabetes Detection -Cardiovascular disease detection	520nm, 660nm, 940nm	500-1,000Hz for 1st and 2nd PPGs 100-200 Hz for 3rd PPG	400-1,100nm spectral range	PPG 1 and 2 placement as with blood pressure along Medial Plantar Artery PPG 3 Center of Metatarsal arch on Lateral Plantar Artery (weight bearing, need thicker glass lid or condenser or lens)

FIG. 33

MONITORING AND MANAGEMENT OF WEARABLE DEVICES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuing application of U.S. patent application Ser. No. 19/071,122, filed Mar. 5, 2025, entitled "Smart Insole Having Optimized Optical Sensor Placement" (Attorney Docket 3226-006US2), which is a continuation-in-part application of U.S. patent application Ser. No. 18/096,441, filed Jan. 12, 2023, entitled "Monitoring and Management of Wearable Devices" (Attorney Docket 3226-006US1), which claims priority to U.S. Provisional Application Ser. No. 63/300,971, filed Jan. 19, 2022, entitled "Sensors for Smart Garments and Applications Thereof" (Attorney Docket 3226-006PR1), each of which is incorporated herein by reference. This application also incorporates by reference U.S. patent Ser. No. 17/373,690, entitled "Piezo-Elements for Wearable Devices," (Attorney Docket 3226-001US1). If there are any contradictions or inconsistencies in language between this application and one or more of the cases that have been incorporated by reference that might affect the interpretation of the claims in this case, the claims in this case should be interpreted to be consistent with the language in this case.

TECHNICAL FIELD

[0002] The present disclosure relates to wearable devices in general, and, more particularly, to: (1) self-powered sensors and actuators suitable for inclusion in a wearable, such as smart clothing for use by humans and/or animals such as, garments, footwear, accessories, and the like; and (2) optical sensor placement for accurate vital sign measurements for wearable insoles.

BACKGROUND

[0003] Wearables, such as fitness trackers and smart watches have become increasingly popular over the past few years. These devices and systems have evolved to the point at which they can connect with other devices, like computers and smartphones, thereby enhancing their overall capabilities.

[0004] Unfortunately, one area that remains a challenge is providing power to wearables-particularly as more systems and sub-systems are included to augment their capabilities. For example, many contemporary wearables include rechargeable batteries. Unfortunately, rechargeable batteries must be frequently connected to a charging station of some sort, during which time the wearable is typically out of service.

[0005] Furthermore, the capacity of many rechargeable batteries (e.g. Lithium ion "Li+" or Lithium polymer "LiPo," etc.) degrades over time to a point where the wearable becomes inoperative.

[0006] The need for a self-powered wearable that requires little or no downtime for recharging remains, as yet, unmet in the prior art. In addition, there is a need for an elegant graphical user interface (GUI) for computing devices (e.g., smartphones, tablets, laptop computers, desktop computers, etc.) through which a user can interact with wearables. Additionally, specifically for wearables such as insoles for shoes, there is a need for placement of certain sensors to provide as accurate precise and accurate readings as possible

SUMMARY

[0007] The present disclosure is directed toward self-powered wearables for users/subjects such as humans, animals, robotics, exoskeletons, and the like. Embodiments in accordance with the present disclosure are suitable for use in accessories and/or garments for humans, such as clothing, shoes, sandals, exercise equipment and clothing, cell phone cases, luggage (e.g., suitcases, backpacks, etc.), purses, undergarments (e.g., bras, socks, sole members (e.g., insoles, midsoles, outsoles, etc.), human-machine interfaces (e.g., joysticks, position-sensing-gloves, etc.), smart gloves, and the like, as well as garments and/or accessories for animals, such as horseshoes, leashes, collars, and the like.

[0008] Like the prior art, embodiments in accordance with the present disclosure include transducers that generate electrical energy in response to an applied force. In sharp contrast to the prior art, however, transducers disclosed herein have a quiescent shape that is curved (or "bent") about at least one bending axis. The transducers are configured to generate electrical energy when they are flattened relative to their bending axis (or axes) in response to the applied force, as well as when returning to their quiescent state upon removal of the applied force. Furthermore, transducers in accordance with the present disclosure are dimensioned and arranged to mitigate compression of their piezoelectric material by the applied force.

[0009] An advance over the prior art is realized by incorporating a transducer comprising a non-resonant energy harvester into a wearable to power one or more devices, such as sensors, haptic devices, wireless communication devices, and the like, such that the energy harvester generates electrical energy when it (1) "flattens" in response to the application of a force and/or returns to its non-flat quiescent state when the applied force is removed. By configuring the energy harvester such that it functions substantially as a bending-strain-based device, it can generate significantly more power than those known in the prior art. Furthermore, some energy harvesters in accordance with the present disclosure employ a low dielectric-constant (K) or "low-K" piezoelectric material, which enables high-voltage/power operation and/or a significantly thinner energy harvester or sensor transducer.

[0010] An illustrative embodiment in accordance with the present disclosure is a smart shoe insole comprising a processor, an energy storage unit, a wireless communications module, a geolocation module, and plurality of pre-bent, multi-function, bending-strain-based, bimorph transducers. Each bimorph transducer includes three pre-bent, low-K piezoelectric transducer elements configured as a piezoelectric bending-strain-based energy harvester, a pressure sensor, and a haptic device.

[0011] In each bimorph transducer, the energy harvester is disposed on the front side of a stainless-steel substrate and the pressure sensor and haptic device are disposed on the backside of the substrate. The bimorph transducer is configured such that it has a non-planar quiescent shape and can bend out of this quiescent shape in response to a force applied to the transducer. In some embodiments, the substrate of a transducer comprises a material other than stainless steel.

[0012] In the illustrative embodiment, the piezoelectric material of each transducer element is magnetron-sputter-deposited low-K aluminum nitride (AlN), which enables high-voltage operation using a very thin piezoelectric layer.

In some embodiments, at least one transducer element of a bimorph transducer comprises a different low-K piezoelectric material (e.g., scandium-doped AlN, undoped ZnO, doped zinc oxide (ZnO), polyvinylidene fluoride (PVDF), doped PVDF, lithium niobate ($LiNbO_3$), etc.). In some embodiments, the piezoelectric material is deposited by a suitable technique other than magnetron sputtering, such as non-magnetron sputtering, plasma-deposition technique, and the like.

[0013] In some embodiments, the piezoelectric material of at least one transducer element is a high-K material, such as Sol-gel lead-zirconate-titanate (PZT), thick doped Sol-gel PZT, and the like.

[0014] In some embodiments, a transducer is a monomorph that includes one or more transducer elements on only the top or bottom of a substrate.

[0015] In some embodiments, a transducer includes a substrate that comprises flanges at its ends, where the flanges are thicker than the thickness of the substrate outside of the flange region. The flanges are configured such that their larger surface area compresses a greater amount of resilient material surrounding the transducer when the transducer is flattened by an applied force. The compression of the resilient material develops a potential energy that gives rise to a restoring force on the transducer once the applied force is removed.

[0016] In some embodiments, the total operational thickness of a transducer in its quiescent state is within the range of approximately 1.5 mm to approximately 9 mm. In some embodiments, the total operational thickness of a transducer is less than or equal to 3.5 mm. In some embodiments, the total operational thickness of a transducer is within the range of 1.5 to 2.0 mm.

[0017] In some embodiments, a wearable includes one or more sensors that are external to the bimorph transducers, such as a pulse-oximetry sensor, an accelerometer, a gyroscopic sensor, a temperature sensor, a force, load, one or more pressure sensors, a haptic device, and the like.

[0018] An embodiment in accordance with the present disclosure is an apparatus comprising: a bending-strain-based transducer that includes: (i) a first transducer element disposed on a first surface of a substrate, the first transducer element being a non-resonant energy harvester; and (ii) a second transducer element disposed on a second surface of the substrate, the first and second surfaces being on opposite sides of the substrate, wherein the second transducer element is selected from the group consisting of a resonant energy harvester, a non-resonant energy harvester, a force sensor, a load sensor, a pressure sensor, and a haptic device; wherein the transducer has a quiescent shape that is non-planar.

[0019] Another embodiment in accordance with the present disclosure is an apparatus comprising a first bimorph transducer having a quiescent shape that is non-planar, wherein the first bimorph transducer includes a first transducer element disposed on a first surface of a substrate, the first transducer element being a non-resonant energy harvester, and wherein the first bimorph transducer is configured to bend in response to a first force.

[0020] Yet another embodiment in accordance with the present disclosure is a method comprising forming a first bending-strain-based transducer by operations that include: forming a first transducer element on a first surface of a substrate, the first transducer element including a first piezoelectric layer, wherein the first transducer element is configured as a non-resonant energy harvester; forming a second transducer element on a second surface of the substrate, the second transducer element including a first portion of a second piezoelectric layer and being selected from the group consisting of a non-resonant energy harvester, a sensor, and a haptic device; and providing the first bending-strain-based transducer with a quiescent shape that is non-planar.

[0021] Yet another embodiment in accordance with the present disclosure comprises systems and methods for providing a graphical user interface (GUI) on a computing device (e.g., a smartphone, a tablet, a laptop computer, a desktop computer, etc.) through which a user can interact with one or more wearable devices (e.g., embodiments of wearable devices described in this application; smart watches such as Apple Watch® or Google Pixel Watch®; fitness trackers such as Fitbit® or Amazon Halo View®; etc.).

[0022] Yet another embodiment in accordance with the present disclosure is directed to a wearable smart insole for a user having foot having a planter arch and a medial plantar artery (MPA) along the plantar arch. The wearable smart insole includes an optical sensor disposed in the insole along the MPA, a power handling circuit, and an energy storage module operatively coupled with the power handing circuit to provide power to the optical sensor. The optical sensor is disposed along the MPA in the insole and provides a signal for obtaining heart rate data and blood oxygen saturation data.

[0023] The optical sensor may also provide a signal for obtaining an estimation of blood pressure. The optical sensor may be a pulse-oximetry sensor that provides a photoplethysmography signal. The pulse-oximetry sensor may include at least one support wall to prevent bending of an upper glass surface of the pulse oximetry sensor. The pulse-oximetry sensor may include a double glass upper surface to prevent bending of the upper surface of the pulse-oximetry sensor. The pulse-oximetry sensor may include a glass upper surface that is greater than 2 mm thick to prevent bending of the upper surface of the pulse-oximetry sensor. The optical sensor, along with motion tracking technology, may be used to calculate VO_2 max. The insole may available in a plurality of sizes, each size having a different plantar arch height.

[0024] Another embodiment in accordance with the present disclosure is directed to a wearable smart insole for a user having foot having a planter arch and a medial plantar artery (MPA) along the plantar arch. The wearable smart insole includes a first optical sensor disposed in the insole along the MPA adjacent a toe end of the plantar arch, and a second optical sensor disposed in the insole along the MPA adjacent a heel end of the plantar arch. The wearable smart insole further includes a power handling circuit and an energy storage module operatively coupled with the power handing circuit to provide power to the optical sensor. At least one of the first optical sensor and the second optical sensor is disposed along the MPA in the insole provides a signal for obtaining heart rate data and blood oxygen saturation data. Both the first optical sensor and the second optical sensor disposed along the MPA in the insole, in combination, are used to calculate Pulse Transit Time (PTT) for use in calculating systolic blood pressure and diastolic blood pressure.

[0025] The two optical sensors may be pulse-oximetry sensors that provide photoplethysmography signals. The two

pulse-oximetry sensors may each include at least one support wall to prevent bending of an upper glass surface of the pulse oximetry sensor. The two pulse-oximetry sensors may each include a double glass upper surface to prevent bending of the upper surface of the pulse-oximetry sensor. The two pulse-oximetry sensors may each include a glass upper surface that is greater than 2 mm thick to prevent bending of the upper surface of the pulse-oximetry sensor.

[0026] Another embodiment in accordance with the present disclosure is directed to a wearable smart insole for a user having a foot having a planter arch, a medial plantar artery (MPA) along the planter arch, and a lateral plantar artery. The wearable smart insole includes a first optical sensor disposed in the insole along the MPA adjacent a toe end of the plantar arch, a second optical sensor disposed in the insole along the MPA adjacent a heel end of the plantar arch, and a third optical sensor disposed along the lateral plantar artery in the plantar arch. The wearable smart insole further includes a power handling circuit and an energy storage module operatively coupled with the power handing circuit to provide power to the optical sensor. At least one of the first optical sensor and the second optical sensor and the third optical sensor provides a signal for obtaining heart rate data and blood oxygen saturation data. At least two of the optical sensors are used, in combination, to calculate Pulse Transit Time (PTT) for use in calculating systolic blood pressure and diastolic blood pressure. All three of the optical sensors are used, in combination, to calculate pulse wave velocity (PWV) to detect at least one of diabetes and other cardiovascular issues.

[0027] The other cardiovascular issues noted above may be, for example, hypertension, arteriosclerosis, peripheral artery disease (PAD), affect arterial stiffness, blood flow, and pressure dynamics. The three optical sensors may be pulse-oximetry sensors that provide photoplethysmography signals. The three pulse-oximetry sensors may each include at least one support wall to prevent bending of an upper glass surface of the pulse oximetry sensor. The two pulse-oximetry sensors may each include a double glass upper surface to prevent bending of the upper surface of the pulse-oximetry sensor. The three pulse-oximetry sensors may each include a glass upper surface that is greater than 2 mm thick to prevent bending of the upper surface of the pulse-oximetry sensor.

[0028] In all embodiments, lenses may be included over the optical sensors, wherein the lens enhances the signal-to-noise ratio in a signal provided by the optical sensors. The lenses may be, for example, convex aspheric lenses.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] FIG. **1** depicts a schematic drawing of a plan view of an illustrative embodiment of a wearable in accordance with present disclosure.

[0030] FIG. **2** depicts operations of a method for forming a wearable in accordance with present disclosure.

[0031] FIGS. **3**A-C depict schematic drawings of top, bottom, and cross-sectional views, respectively, of a representative transducer **104** in accordance with the illustrative embodiment.

[0032] FIG. **4** depicts sub-operations suitable for forming a transducer in accordance with the present disclosure.

[0033] FIG. **5** depicts a block diagram showing component connectivity for a wearable in accordance with the present disclosure.

[0034] FIGS. **6**A-B depict schematic drawings of simplified sectional views of a region of completed wearable **100** in its quiescent and deformed states, respectively.

[0035] FIGS. **7**A-B depict schematic drawings of sectional views of an alternative embodiment of a transducer, in its quiescent and deformed states, in accordance with the present disclosure.

[0036] FIG. **8** depicts a schematic drawing of a sectional view of an alternative arrangement of transducers within a wearable in accordance with the present disclosure.

[0037] FIGS. **9**A-C depict schematic drawings of cross-sectional views of a cantilevered ruffled transducer under different force conditions in accordance with the present disclosure.

[0038] FIGS. **10**A-D depict schematic drawings of cross-sectional views of wearables having alternative arrangements of bimorph transducers within a wearable in accordance with the present disclosure.

[0039] FIG. **11** depicts a block diagram of a system comprising a computing device and a wearable device, in accordance with one embodiment of the present disclosure.

[0040] FIG. **12** depicts a block diagram of salient elements of computing device **1110**, as shown in FIG. **11**, in accordance with one embodiment of the present disclosure.

[0041] FIG. **13** depicts a block diagram of salient elements of wearable device **1120**, as shown in FIG. **11**, in accordance with one embodiment of the present disclosure.

[0042] FIG. **14** depicts a block diagram of salient elements of health/fitness sensor array **1330**, as shown in FIG. **13**, in accordance with one embodiment of the present disclosure.

[0043] FIG. **15** depicts a graphical user interface (GUI) in accordance with one embodiment of the present disclosure.

[0044] FIG. **16** depicts a first implementation of graphical user interface (GUI) **1500**, as shown in FIG. **15**, executing on a computing device, in accordance with one embodiment of the present disclosure.

[0045] FIG. **17** depicts a second implementation of GUI **1500** executing on a computing device, in accordance with one embodiment of the present disclosure.

[0046] FIG. **18**A depicts a simplified elevation view of the effect of a small applied force to an optical sensor.

[0047] FIG. **18**B depicts a simplified elevation view of the effect of a larger applied force to an optical sensor.

[0048] FIG. **19**A depicts a simplified elevation view of the effect of a larger applied force to an optical sensor having a thicker glass lid and added structural walls.

[0049] FIG. **19**B depicts a simplified elevation view of the effect of a larger applied force to an optical sensor having a double glass lid.

[0050] FIG. **20** depicts a top schematic view of a smart insole having optical sensor placement in accordance with an exemplary embodiment of the present invention, wherein the insole has a single optical sensor.

[0051] FIG. **21** depicts a top view of the smart insole of FIG. **20**.

[0052] FIG. **22** depicts a bottom view a foot of a user showing optical sensor placement for the smart insole of FIGS. **20** and **21**.

[0053] FIG. **23** depicts a top schematic view of a smart insole having optical sensor placement in accordance with another exemplary embodiment of the present invention, wherein the insole has dual optical sensors.

[0054] FIG. **24** depicts a top view of the smart insole of FIG. **23**.

[0055] FIG. **25** depicts a bottom view a foot of a user showing optical sensor placement for the smart insole of FIGS. **23** and **24**.

[0056] FIG. **26** depicts a top schematic view of a smart insole having optical sensor placement in accordance with another exemplary embodiment of the present invention, wherein the insole has triple optical sensors.

[0057] FIG. **27** depicts a top view of the smart insole of FIG. **26**.

[0058] FIG. **28** depicts a bottom view a foot of a user showing optical sensor placement for the smart insole of FIGS. **26** and **27**.

[0059] FIG. **29** depicts a simplified cross-sectional view of the insole of FIG. **26** showing optical sensors, ribbon cables connecting the optical sensors), and a fabric top.

[0060] FIG. **30** depicts a simplified cross-sectional diagram of an example of a lens for an optical sensor in accordance with the present invention.

[0061] FIG. **31** depicts an example of a convex aspheric curvature lens for an optical sensor in accordance with the present invention,

[0062] FIG. **32** depicts a simplified cross-sectional view of another example of an insole in accordance with the various embodiments of the present invention, including optical sensors having added convex aspheric lenses.

[0063] FIG. **33** depicts a summary table of optical sensor placement and additional information.

DETAILED DESCRIPTION

[0064] The following merely illustrates the principles of the disclosure. It will thus be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the disclosure and are included within its spirit and scope.

[0065] Furthermore, all examples and conditional language recited herein are principally intended expressly to be only for pedagogical purposes to aid the reader in understanding the principles of the disclosure and the concepts contributed by the inventor(s) to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions.

[0066] Moreover, all statements herein reciting principles, aspects, and embodiments of the disclosure, as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents as well as equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure.

[0067] Thus, for example, it will be appreciated by those skilled in the art that any block diagrams herein represent conceptual views of illustrative circuitry embodying the principles of the disclosure. Similarly, it will be appreciated that any flow charts, flow diagrams, state transition diagrams, pseudo code, and the like represent various processes which may be substantially represented in computer readable medium and so executed by a computer or processor, whether or not such computer or processor is explicitly shown.

[0068] The functions of the various elements shown in the Drawing, including any functional blocks that may be labeled as "processors", may be provided through the use of dedicated hardware as well as hardware capable of executing software in association with appropriate software. When provided by a processor, the functions may be provided by a single dedicated processor, by a single shared processor, or by a plurality of individual processors, some of which may be shared. Moreover, explicit use of the term "processor" or "controller" should not be construed to refer exclusively to hardware capable of executing software, and may implicitly include, without limitation, digital signal processor (DSP) hardware, network processor, application specific integrated circuit (ASIC), field programmable gate array (FPGA), read-only memory (ROM) for storing software, random access memory (RAM), and non-volatile storage. Other hardware, conventional and/or custom, may also be included.

[0069] Software modules, or simply modules which are implied to be software, may be represented herein as any combination of flowchart elements or other elements indicating performance of process steps and/or textual description. Such modules may be executed by hardware that is expressly or implicitly shown.

[0070] Unless otherwise explicitly specified herein, the figures comprising the drawing are not drawn to scale.

[0071] The following terms are defined for use in this Specification, including the appended claims:

[0072] "sole member" is defined as a portion of shoe sole and, as used herein, can mean at least one of a shoe insole, a shoe midsole, and a shoe outsole.

[0073] "wearable" is defined as an object meant to be worn, used, and/or carried by a user where the object includes at least one transducer, such as a sensor, haptic device, etc., and where the user can be a human or an animal. A wearable, as used herein, includes garments, undergarments (e.g., bras, shoe soles, etc.), shoes, fashion electronics (e.g., fitness trackers, smart watches, etc.), accessories (e.g., backpacks, cell phone cases, purses, wallets, etc.), sporting equipment (e.g., fitness bands, etc.), horseshoes, leashes, tethers, collars, and the like.

[0074] "bending-strain-based transducer" is defined as a transducer that is configured to bend about a bending axis located in a plane in response to a force applied at least partially along a direction normal to that plane. For example, a normally flat bending-strain-based transducer lies in a first plane when in its quiescent state but will bend out of the first plane in response to the force, while a normally curved bending-strain-based transducer will become flatter, or completely flat, in response to the force. Bending of a bending-strain-based transducer in accordance with the present disclosure can manifest as an induced curvature that is substantially uniform across at least one lateral dimension of the device or as a localized bend that occurs at one or more localized points of the device, such as at a point of support for a cantilevered or doubly-supported element.

[0075] "non-resonant energy harvester" is defined as an energy harvester that does not require a driving force at or near its natural resonant frequency to generate voltage and/or electrical power. For example, a non-resonant energy harvester can generate voltage and/or electrical power in response to an aperiodic stimulus or the application of a substantially constant force.

[0076] "aligned" is defined as being co-linear or parallel with. For example, two elements that are aligned can

either be arranged along the same axis or arranged such that they are parallel with one another.

[0077] "low-K piezoelectric material" is defined as a piezoelectric material having a dielectric constant that is less than or equal to 30 at room temperature.

[0078] "high-K piezoelectric material" is defined as a piezoelectric material having a dielectric constant that is greater than or equal to 100 at room temperature.

[0079] "optical sensor" is a sensor that optically obtains data that used to detect blood volume changes in the microvascular bed of tissue. For present purposes, the optical sensor provides a photoplethysmograph (PPG) obtained by using a pulse oximeter that measures peripheral oxygen saturation SpO_2 which illuminates the skin and measures changes in light absorption that monitors the perfusion of blood to the dermis and subcutaneous tissue of the skin. With each cardiac cycle the heart pumps blood to the periphery. Even though this pressure pulse is somewhat damped by the time it reaches the skin, it is enough to distend the arteries and arterioles in the subcutaneous tissue. The change in volume caused by the pressure pulse is detected by illuminating the skin with the light from a light-emitting diode (LED) and then measuring the amount of light either transmitted or reflected to a photodiode. Each cardiac cycle appears as a peak. Because blood flow to the skin can be modulated by multiple other physiological systems, the optical sensor can also be used to monitor breathing, hypovolemia, and other circulatory conditions. However, for purposes of the present invention, the term "optical sensor" is intended to be more broadly construed to include any type of optical sensor that provides appropriate data in the present context, and is not intended to be limited to sensors that provide a PPG.

[0080] FIG. **1** depicts a schematic drawing of a plan view of an illustrative embodiment of a wearable in accordance with present disclosure. Wearable **100** is an orthotic shoe insole that can be reversibly inserted into a shoe. In the depicted example, wearable **100** comprises insole body **102**, transducers **104-1** through **104**-N, sensor module **106**, processor **108**, energy-storage module **110**, communications module **112**, rapid-charging module **114**, and display **116**.

[0081] It should be noted that, although the illustrative embodiment comprises a wearable that is a shoe insole, the teachings of the present disclosure can be applied to virtually any wearable suitable for use by a human, an animal, a robot, or as part of an exoskeleton. Furthermore, the teachings of the present disclosure, when applied to footwear (e.g., shoes, sneakers, cleats, slippers, socks, etc.), are not limited to reversibly insertable insoles but, rather, can be applied to myriad sole members, such as shoe insoles that are permanently joined to a shoe, outsoles, mid-soles (e.g., for high heel shoes, etc.), or to footwear that is, itself, a wearable comprising removable or non-removable non-resonant energy harvesters, sensors, and the like.

[0082] FIG. **2** depicts operations of a method for forming a wearable in accordance with present disclosure. Method **200** begins with operation **201**, wherein sensor module **106**, processor **108**, energy-storage module **110**, communications module **112**, rapid-charging module **114**, and an optional display **116** are arranged in a molding form suitable for the formation of insole body **102**.

[0083] Insole body **102** is a conventional shoe insole comprising a resilient material suitable for providing cushioning to the user. Insole body **102** is a substantially "foot-shaped" body comprising material M**1**. Insole body **102** is characterized by longitudinal axis LA**1**, which is substantially aligned with the long dimension of the insole body (i.e., from the heel to the toes of the user, or vice versa).

[0084] Each of transducers **104-1** through **104**-N (referred to, collectively, as transducers **104**) is a multi-function bimorph transducer that includes a non-resonant energy harvester that is configured to operate in bending mode rather than compression. In the depicted example, each of transducers **104** includes a non-resonant energy harvester, a pressure sensor, and a haptic device for providing a sensory signal to the user. A representative transducer **104** is described in more detail below and with respect to FIGS. **3**A-C.

[0085] Sensor module **106** includes one or more sensors for measuring user-based and/or environmental parameters other than pressure. Examples of sensors suitable for inclusion in sensor module **106** include, without limitation, temperature sensors, chemical sensors (e.g., oxygen sensors, humidity sensors, salinity sensors, electrolyte sensors, ion sensors, etc.), volatile organic compound (VOC) sensors for measuring ambient concentrations of "reducing gases" associated with air quality—e.g. alcohols, aldehydes, ketones, organic acids, amines, organic chloramines, aliphatic and aromatic hydrocarbons (e.g. for detection of the onset of "athletes foot" or other ailments), GPS sensors, accelerometers, gyroscopes, inertial sensors, optical sensors, including but not limited to pulse-oximetry sensors (or photoplethysmography sensors), carbon dioxide sensors, blood-alcohol sensors, glucose sensors, infrared (IR) temperature sensors, and the like.

[0086] In the depicted example, sensor module **106** includes a GPS system, a pulse-oximetry sensor, and a multi-axis accelerometer. The GPS system provides location and elevation information to processor **108** and transmits and receives information to/from communications module **110**.

[0087] The pulse-oximetry sensor provides user-centric data to processor **108**, such as heart rate and blood oxygen level. Respiratory rate and burned calories can be calculated from heart rate. It is known that the respiratory rate calculation is accurate, yet the burned calories of contemporary wearable smart watches using this conversion technique are known to be inaccurate.

[0088] The multi-axis accelerometer enables wearable **100** to detect walking, running, skipping, etc., as well as calculation of burned calories by the human or animal body with an accuracy that greater exceeds the accuracy possible in the prior art. The aforementioned heartrate calculation method is used in combination with the multi-axis accelerometer to obtain these superior results via a computer software algorithm.

[0089] It is an aspect of the present disclosure that calorie burning can be determined with higher accuracy than possible in the prior art because transducer **100** enables measurement of the actual mechanical power expended, where P=(force F=mass m*acceleration $a_{x,\ y\ or\ z}$)*(speed S=$a_{x,\ y\ or\ z}$*time t), which can then be converted to human power (or animal power) using a known conversion factor to determine calories burned with less than 5% inaccuracy. Prior-art

systems use only the measured heart rate to calculate burned calories, which has been found to be 27% to 93% inaccurate.

[0090] The multi-axis accelerometer also enables wearable **100** to detect potentially catastrophic events, such as a fall by the user, as well as assess user behavior, such as after a fall has been detected. For example, the accelerometer enables detection of a lack of movement (potentially indicating a state of unconscious), rapid, random movements (potentially indicating onset of a seizure), movements indicative of crawling (e.g., to call for help, etc.), as well as other user-centric behavior, such as when the user is lying down, etc.

[0091] In some embodiments, a second, external multi-axis accelerometer (e.g., located in a wrist band, a chest band, a garment, a smart watch, a fitness tracker, etc.) is used in conjunction with wearable **100** to provide additional information regarding upper body movements. Such an arrangement enables better determination of the calories burned by the upper body, providing improved accuracy for overall calorie-burn calculations.

[0092] In some embodiments, the location of the pulse-oximetry sensor, IR temperature sensor or other optical sensor within wearable **100** is carefully selected relative to advantageously position it relative to the blood vessels (e.g., arteries carrying oxygen-laden red blood cells) in the body portion of the user with which it is to be operatively coupled.

[0093] Processor **108** includes processing circuitry, control circuitry, memory, and the like, that is configured to, among other things, send and receive signals to/from transducers **104** and sensor module **106**, execute instructions, analyze and store data, and transmit and receive signals to/from communications module **112**. In the depicted example, the processor is implemented as a single, discrete component within wearable **100**; however, in other embodiments, the processor can be distributed, at least in part, among multiple components in wearable **100**, implemented, in part or in full, in a remote or cloud-based computing system, or otherwise implemented in a suitable arrangement for carrying out the functions described herein. In some embodiments, some, or all of the capability of processor **108** is incorporated into communications module **110**.

[0094] Communications module **110** is configured to enable wireless communications to and from wearable **100**. In some embodiments, communications module **110** employs one or more communications systems, such as Bluetooth® low-energy (BLE) communications system, LoRa, long-range cellular, satellite, Bluetooth®, Wi-Fi, Zigbee, A-wave, radio frequency (RF), and the like. In the depicted example, communications module **110** includes a LoRa communications system and a Bluetooth® low-energy (BLE) communications system. The LoRa communications system is configured to transmit and receive GPS data to/from wearable **100** via cellular communications networks, while the BLE system is configured to communicate with processor **108** and other components within wearable **100**. In the depicted example, the BLE system is also configured to communicate with a base station, such as a dedicated base station or a mobile device running a dedicated app for interfacing to wearable **100**.

[0095] It should be noted that the relatively larger amount of space available in an insole than, for example, in a mobile phone, enables the communications antennae of communications module **110** to be designed to enable better reception and more consistent transmission to/from their respective paired devices.

[0096] It is an aspect of the present disclosure that the inclusion of a GPS system in sensor module **106** and a communications module that communicates with a mobile device, such as a cell phone, tablet, etc., enables high-level functionality, such as computer applications that enable location of a wearable at any time, or an alarm when a distance between the wearable and base station or mobile device exceeds a threshold. This is particularly useful for locating a user that might require assistance (e.g., a missing child, a "wandering" lost Alzheimer's patient, an intoxicated user, a missing camper/hiker/skier, a lost animal, a missing robot, etc.).

[0097] Energy-storage module **112** includes power-handling circuitry (e.g., AC to DC rectification, etc.) and one or more energy storage units. Energy-storage module **112** is operatively coupled with each of transducers **104** and configured to store energy generated by their respective non-resonant energy harvesters, as well as provide power to the transducers and the other electronics included in wearable **100**. In the depicted example, energy-storage module **112** includes a lithium-polymer battery suitable for storing enough charge for several hours/days of normal use. In some embodiments, energy-storage module **112** includes one or more super capacitors and/or a different energy-storage device, such as a rechargeable battery, a rechargeable standard capacitor, a hybrid-system of a primary battery and/or a rechargeable battery and/or a super capacitor and/or a capacitor, and the like.

[0098] Rapid-charging module **114** is optionally included in wearable **100** and includes an interface for electrically coupling to an external power source to rapidly charge the energy storage units of energy-storage module **112**. In the depicted example, rapid-charging module **114** includes an inductive-charging coil sub-system and associated circuitry. In some embodiments, the rapid-charging module includes a different interface that enables electrical connection to an external power source.

[0099] Display **116** is optionally included in wearable **100** to enable visual determination of the state of the wearable, such as charge level, etc. In the depicted example, display **116** includes a plurality of LEDs; however, other display elements can be used in display **116** without departing from the scope of the present disclosure.

[0100] At operation **202**, transducers **104** are provided.

[0101] FIGS. **3**A-B depict schematic drawings of simplified top and bottom views, respectively, of a representative transducer **104** in accordance with the illustrative embodiment.

[0102] FIG. **3**C depicts a schematic drawing of a detailed sectional view of the layer structure of transducer **104** in accordance with the illustrative embodiment. The sectional view shown in FIG. **3**C is taken through line a-a, as indicated in FIG. **3**A.

[0103] Transducer **104** includes substrate **302** and transducer elements TE**1**, TE**2**, and TE**3**. Transducer element TE**1** is disposed on the top surface of substrate **302**, and transducer elements TE**2** and TE**3** are disposed on the bottom surface of substrate **302**, collectively forming a bimorph-transducer structure. Because the physical configuration of transducer element TE**1** is substantially equivalent to that of the combination of transducer element TE**2** and TE**3**, the

structure is balanced about substrate **302** and transducer **104** is characterized by torque-neutral boundary TNB, which runs through the center of the substrate.

[0104] Transducer **104** is configured as a "ridge transducer" having a non-planar quiescent shape that curved along one dimension (the x-dimension in the depicted example), thereby forming a ridge along an orthogonal dimension (i.e., the y-dimension), as well as a cavity beneath the ridge. The ridge of transducer **104** is substantially aligned with bending axis BA. In some embodiments, transducer **104** has a cross-section along at least one dimension that is described by a known curved shape, such as sinusoidal, parabolic, catenary, and the like.

[0105] It is an aspect of the present disclosure that a piezoelectric transducer having a quiescent shape that is non-planar affords significant advantages over prior-art piezoelectric transducers, such as:

[0106] improved reliability due to inherent overstress limit; or

[0107] increased restoring force; or

[0108] increased energy generation for a given force; or

[0109] any combination of i, ii, and iii.

[0110] Although the illustrative embodiment includes rectangular piezoelectric transducers, in some embodiments, at least one piezoelectric transducer in a wearable has a non-rectangular shape. In some embodiments the non-rectangular shape (e.g. circular) piezoelectric transducers may be used as a force sensor (e.g. step-counter) or as a haptic device or both.

[0111] In some embodiments, transducer is configured as a concave (or convex disc) that is radially symmetric about its center point that defines a peak (or center of a valley).

[0112] In some embodiments, transducer **104** is a ruffled transducer having a series of ridges and furrows aligned with one dimension. In some embodiments, transducer **104** is shaped such that it is ruffled in two dimensions (i.e., has peaks and valleys along two dimensions (e.g., the x- and y-dimensions), thereby defining a "waffle-like" structure. In some such embodiments, the shape of transducer is defined such that strain is distributed substantially evenly along at least one dimension.

[0113] Transducer element TE**1** is configured as a non-resonant energy harvester and includes electrodes **304-1**A and **304-2** and piezoelectric layer **306**A. Transducer element TE**1** is configured to generate electrical energy in response to deformation of piezoelectric layer **306**A out of its quiescent shape due to an applied force.

[0114] Transducer element TE**2** is configured as a pressure sensor and includes electrodes **304-1**B, **304-3**A, and a first portion of piezoelectric layer **306**B. Transducer element TE**2** is configured to provide an electrical signal whose magnitude is based on the amount of strain induced in the region of piezoelectric layer **306**B between electrodes **304-1**B and **304-3**A by the bending of substrate **302** in response to the applied force. As a result, the electrical signal provided by transducer element TE**2** is indicative of the magnitude of applied force F.

[0115] Transducer element TE**3** is configured as a haptic device and includes electrodes **304-1**B, **304-3**B, and a second portion of piezoelectric layer **306**B. Transducer element TE**3** is configured to generate a vibration signal that is perceptible to the user of wearable **100** in response to a drive signal provided by processor **108**. As a result, transducer **100** can provide signals to the user in the case of potential foot slippage, a potential mis-step, detected body-balance issues, as part of behavioral retraining during, for example, physical therapy after a stroke, a wake-up alarm, and the like. In some embodiments, haptic devices are arranged around the perimeter of the foot to enable their use as directional stimuli for helping vision-impaired persons safely navigate through a landscape. In some embodiments, the haptic devices are operatively coupled with a voice-controlled handheld mobile device, or alarm to, for example, provide an audible warning if the user is about to walk into a street intersection with automobiles passing or across train tracks, and the like.

[0116] Although the illustrative embodiment includes a multi-function transducer having energy harvesting, sensing, and haptic feedback capabilities, in some embodiments, transducer **104** includes only non-resonant energy harvesters, only a non-resonant energy harvester and a sensor, or only a non-resonant energy harvester and a haptic device.

[0117] FIG. **4** depicts sub-operations suitable for forming a transducer in accordance with the present disclosure. Operation **202** begins with sub-operation **401**, wherein substrate **302** is provided.

[0118] Substrate **302** is a flexible substrate suitable for planar processing methods. Substrate **302** comprises a layer of material M**1** having thickness, t**1**.

[0119] Material M**1** is selected to provide a desired combination of flexibility, yield strength, and plastic-deformation point. As discussed below, in order to form a pre-bent transducer, such as transducer **104**, the plastic-deformation point of material M**1** must be less than or equal to the yield strength of the material included in piezoelectric layers **306**A and **306**B. As a result, the piezoelectric layers deposited on the substrate will not fracture when the substrate is deformed from its initial planar configuration into its quiescent non-planar shape. It is an aspect of the present disclosure that a transducer whose substrate has a plastic deformation point that is within the range of approximately 70% to approximately 80% of the fracture stress point of its piezoelectric material affords particular advantages over the prior art.

[0120] The thickness, t**1**, of substrate **302** depends on the choice of material M**1** and is typically within the range of approximately 10 microns to approximately 1.5 mm; however, a thickness within the range of approximately 200 microns to approximately 750 microns is preferable for many applications.

[0121] In the depicted example, material M**1** is sintered stainless steel having a Young's modulus (E_y) of approximately 190 MPa and a plastic-deformation point of approximately 1400 MPa. It should be noted that sintered stainless steel can have a plastic-deformation point of up to 1500 MPa depending on sintering temperature and time. As a result, in some embodiments, M**1** has a different plastic-deformation point that is less than or equal to 1500 MPa.

[0122] The choice of stainless steel and, in particular, sintered stainless steel as material M**1** enables the thickness of substrate **302** to be very thin compared to most alternative materials. The minimum value for t**1** is dictated by a need for substrate **302** to generate sufficient restoring force when deformed to enable it to return fully to its quiescent state once the applied force is removed. The maximum value of t**1** is dictated by a need to enable the substrate to deform fully in response to a reasonable amount of applied force. For a transducer that is intended for use in an insole and

whose substrate comprises sintered stainless steel, for example, a suitable value for t1 is typically within the range of 500 microns to approximately 1.5 mm. In the depicted example, t1 is equal to 600 microns.

[0123] In some embodiments, M1 comprises a different material and/or substrate **302** has a different thickness, t1. Materials suitable for use in substrate **302** include, without limitation, low-Young's modulus materials (e.g., polyimides, polydimethylsiloxane (PDMS), plastics, etc.), moderate-Young's modulus materials (e.g., flexible glasses, Corning Willow® glass, etc.), and high-Young's modulus materials (e.g., metals (e.g., brass, copper, etc.), composite materials, and the like). It should be noted that the use of a different substrate material will not change the output voltage/power/energy of a symmetric bimorph transducer having the same design in every other respect, since the torque-neutral axis or boundary TNB and resulting strain of the piezoelectric layers remain unchanged.

[0124] It should be noted that the use of a metal, such as stainless steel, sintered stainless steel, brass, copper, etc., for substrate **302** affords embodiments in accordance with the present disclosure significant advantages over the prior art, including an ability to match the yield strengths of the substrate material and that of the piezoelectric layers, low cost, well-known production methods, and most metals can be sawed, diced, laser cut, water-jet cut, etc. without requiring exotic methods. Furthermore, most metals suitable for use in substrate **302** are available in sheets suitable for use in large production environments, such as large area flat panel or roll-to-roll manufacture.

[0125] At optional sub-operation **402**, electrodes **304-1**A and **304-1**B are formed on the top and bottom surfaces, respectively of substrate **302**.

[0126] Although not shown in FIG. **3**C (for clarity), adhesion layers are typically deposited on the top and bottom surfaces of substrate **302** prior to the formation of electrodes **304-1**A and **304-1**B. Such adhesion layers normally have a thickness of less than 1000 nm and typically are 100 nm or less and comprise the same material as that of piezoelectric layers. In some embodiments, these adhesion layers comprise an alternate metal, such as titanium or molybdenum, as discussed in detail in parent application U.S. patent application Ser. No. 17/373,690. Using titanium (Ti), molybdenum (Mo) or other conduction material as the adhesion layer allows for electrical connection from lower electrodes **304-1**A and **304-1**B to the metal substrate **302**, which may be more manufacturable to electrically connect to by external wiring post fabrication.

[0127] Electrodes **304-1**A and **304-1**B are layers of conductive material suitable for providing electrical connectivity to piezoelectric layers **306**A and **306**B, respectively. In the depicted example, each of electrodes **304-1**A and **304-1**B is a layer of sputter-deposited molybdenum (Mo) having a thickness of approximately 2 microns. Preferably, each electrode has a thickness within the range of approximately 100 nm to approximately 2 microns.

[0128] It should be noted that the material and thickness used for the electrodes is a matter of design choice and is affected by the choice of material M2 used for piezoelectric layers **306**A and **306**B. For example, sputtered PZT is preferably deposited on copper or copper alloys (e.g. brass). In each of these cases (AlN or PZT), the aforementioned electrode metals yield the best polycrystalline orientation, which yields the best piezoelectric coefficients d_{ij} (i or j=1, 2 or 3 or equivalently x, y or z), voltage and power/energy output. Yet, provided adequate adhesion can be realized, any metal can be used for the electrodes.

[0129] At sub-operation **403**, piezoelectric layers **306**A and **306**B are formed on electrodes **304-1**A and **304-1**B, respectively.

[0130] Each of piezoelectric layers **306**A and **306**B is a layer of piezoelectric material M2 having a yield strength that exceeds the plastic-deformation point of substrate **302**. Typically, each of piezoelectric layers **306**A and **306**B has a thickness that is within the range of approximately 0.1 microns to approximately 10 microns; however, thicknesses of up to several hundred microns can be used for at least one of piezoelectric layers without departing from the scope of the present disclosure. It is preferable that both piezoelectric layers **306**A and **306**B are equal in thickness so that the torque neutral boundary (or axis) is located at the center of the substrate **302**. Such a configuration yields substantially optimal output voltage and power/energy generation. Preferably, material M2 is a low-K piezoelectric material.

[0131] In the depicted example, piezoelectric layers **306**A and **306**B are sputter-deposited layers of undoped aluminum nitride (AlN) having a thickness of approximately one micron. Preferably, the thickness of undoped aluminum nitride used in piezoelectric layers **306**A and **306**B is within the range of approximately 0.1 to approximately 4.0 microns (provided adhesion of such layers is sufficient to ensure long-term reliability).

[0132] In some embodiments, piezoelectric layers **306**A and **306**B comprise sputtered scandium-doped aluminum nitride (ScAlN), which can have a Young's modulus that is reduced by as much as 20% from that of undoped AlN by up to 20%, making it more flexible. As a result, ScAlN is particularly attractive for use as material M2 in some embodiments because it gives rise to larger piezoelectric coefficients d_{ij} (up to 2.5×) for the same deformation as compared to undoped AlN.

[0133] Furthermore, as will be apparent to one skilled in the art, after reading this Specification, to first order, the voltage, V, generated by a piezoelectric layer is proportional to (d_{31}/K) and the power, P, generated is proportional to (d_{31}^2/K). Since output voltage is proportional to d_{ij} and E_y and output power is proportional to d_{ij}^2 and E^2, increased energy harvesting can be achieved using the same thickness piezoelectric layers, thereby enabling more voltage/power/energy generation and more flexibility and/or low-profile effectively thinner transducers. However, the introduction of scandium (and associated defects) into AlN can also reduce the fracture point of material M2 below the plastic deformation point of material M1, which would reduce the maximum curvature that could be imparted on transducer **106**.

[0134] The use of undoped aluminum nitride or scandium-doped aluminum nitride in piezoelectric layers **306**A and **306**B affords embodiments in accordance with the present disclosure significant advantages over transducers and wearables known in the prior art, including:

- **[0135]** higher voltage and power/energy generation capability; or
- **[0136]** higher yield strength; or
- **[0137]** significantly lower bending profile; or
- **[0138]** increased flexibility; or
- **[0139]** differentially matched yield strength with a steel substrate allowing for fabricating pre-bent structures post AlN or ScAlN deposition; or
- **[0140]** environmental friendliness (no lead content, as opposed to PZT); or
- **[0141]** any combination of i, ii, iii, iv, v, and vi.

[0142] It should be noted that, although undoped aluminum nitride or scandium-doped aluminum nitride is pre-

ferred for material M2, other piezoelectric materials can be used for at least one of piezoelectric layers **306**A and **306**B without departing from the scope of the present disclosure. Materials suitable for use in accordance with the present disclosure include, without limitation, thin, magnetron sputtered, low-K piezoelectric materials (e.g., undoped zinc oxide (ZnO), doped ZnO, undoped polyvinylidene fluoride (PVDF), doped PVDF, chromium-doped AlN, yttrium-doped AlN, lithium niobate ($LiNbO_3$), etc.), thick high-K piezoelectric materials (e.g., undoped Sol-gel lead zirconate titanate (PZT), doped Sol-gel PZT, etc.), and the like.

[0143] Dopants suitable for inclusion in piezoelectric layers **306**A and/or **306**B include, without limitation, strontium, lanthanum, iron, barium, niobium, europium, cerium oxide, lithium aluminum, sodium, potassium, boron, graphene, trifluoro ethylene, zinc oxide, nitrogen, magnesium, magnesium oxide, scandium, chromium, yttrium, silver, tin, and lithium, as well as combinations thereof.

[0144] Although it is preferable that material M**2** is a low-K piezoelectric material, material M**2** can comprise a high-K piezoelectric material without departing from the scope of the present disclosure. For example, in some embodiments, one or both of piezoelectric layers **306**A and **306**B comprises a very thick (e.g. 25 to 250 or more microns) layer of Sol-gel lead-zirconate-titanate (PZT) or doped Sol-gel PZT. Such a layer can be formed, for example, by spin coating, extrusion, lamination, etc. The significantly greater thickness of such a layer can compensate for the high dielectric constant of these materials (PZT has a K in the range of 1700-3500, for instance), which would normally lead to low voltage and poor power generation.

[0145] Furthermore, deposition methods other than sputter deposition can be used to form one or both of piezoelectric layers **306**A and **306**B without departing from the scope of the present disclosure. Alternative deposition methods suitable for forming piezoelectric layers **306**A and **306**B include, without limitation, Sol-gel coating, chemical-vapor deposition (CVD), plasma-enhanced chemical vapor deposition (PECVD), wet-chemical processing, doctor-blade deposition, spin coating, and the like.

[0146] At sub-operation **404**, electrode **304-2** is formed on piezoelectric layer **306**A and electrodes **304-3**A and **304-3**B are formed on piezoelectric layer **306**B. Electrodes **304-2**, **304-3**A, and **304-3**B are analogous to electrodes **304-1**A and **304-1**B described above.

[0147] As will be apparent to one skilled in the art, the dimensions of electrodes **304-2**, **304-3**A, and **304-3**B define the sizes of transducer elements TE**1**, TE**2**, and TE**3**, respectively. As a result, transducer element TE**1** has width W**1** and length L**1**, transducer element TE**2** has width W**2** and length L**2**, and transducer element TE**3** has width W**3** and length L**2**. As will be apparent to one skilled in the art, the values of L**1**, L**2**, W**1**, W**2**, and W**3** depend upon the application for which transducer **104** is intended. In the depicted example, wearable **104** is an insole configured to fit within a women's shoe, which normally has an approximately 7-cm width. As a result, each of L**1** and L**2** is 6 cm, width W**1** is 3 cm, and widths W**2** and W**3** are 2.75 cm. In some embodiments, wearable **100** is an insole configured for insertion into a men's shoe, which has an approximately 9-cm width, enabling transducer lengths of approximately 8 cm.

[0148] In some embodiments, electrode **304-2** comprises two discontinuous electrode portions that are separated by a small gap such that they are electrically disconnected. In some such embodiments, an electrically conductive jumper is formed to electrically connect the two electrode portions. When electrically connected via a jumper, the two electrode portions substantially function as one complete electrode on the top of piezoelectric layer **306**A.

[0149] At optional sub-operation **405**, passivation layers (e.g., silicon oxide, silicon nitride, polyimide, etc.) are formed over electrodes **304-1**A, **304-1**B, **304-2**, **304-3**A, and **304-3**B. Typically, the passivation layers have a thickness within the range of approximately 0.5 micron to approximately 3 microns. In the depicted example, the passivation layers are PECVD-deposited silicon nitride having thickness of approximately 1 micron.

[0150] At optional sub-operation **406**, vias are formed through the passivation layers to enable access to each of at least one of electrodes **304-1**A, **304-1**B, **304-2**, **304-3**A, and **304-3**B.

[0151] At optional sub-operation **407**, contact pads are formed in the vias to enable electrical connections to be made to at least one of electrodes **304-1**A, **304-1**B, **304-2**, **304-3**A, and **304-3**B.

[0152] As noted above, the use of certain low-K piezoelectric materials (e.g., undoped aluminum nitride or scandium-doped aluminum nitride, etc.) enables a very thin transducer to generate more voltage/power/energy. It is an aspect of the present disclosure that the transducer thickness, T**1**, of transducer **104** (as depicted in FIG. **3**C) can be kept within the range of approximately 10 microns to approximately 1.6 mm, while still generating sufficient output for many applications. As a result, embodiments in accordance with the present disclosure are better suited than prior-art transducers for some wearable applications, such as shoe-sole elements, bras, etc., where a transducer thicker than a few millimeters would be noticeable and could even cause discomfort. In the depicted example, the transducer thickness, T**1**, of transducer **104** is approximately 612 microns.

[0153] At sub-operation **408**, transducer **104** is provided its quiescent non-planar shape.

[0154] In the depicted example, transducer **104** is formed into a "u-shaped" channel having flanged edges by heating it above the glass-transition point of substrate **302** and applying mechanical force to "press" the transducer into its desired quiescent shape. Once formed, transducer **104** defines underlying cavity **310**.

[0155] In its quiescent state, the total transducer height TTQ of transducer **104** is equal to the sum of transducer thickness T**1** and the cavity height, Hc, of cavity **310**.

[0156] It is an aspect of the present disclosure that the non-planar quiescent shape into which transducer **104** can be formed is limited only by the yield strength of material M**2**, as long as:

[0157] the material of piezoelectric layers **306**A and **306**B and electrodes **304-1**A, **304-1**B, **304-2**, **304-3**A, and **304-3**B have melting points that are greater than the glass-transition point of the substrate; and

[0158] the plastic-deformation point of the substrate material (i.e., M**1**) is less than or equal to the yield strength of the material (i.e., M**2**) of the piezoelectric layers.

[0159] However, there are several other factors that inform the desired values for T**1** and Hc, as well as the material choices for substrate **302**, piezoelectric material M**2**, and electrodes **304**. These factors are, in large part, dictated by the application for which a transducer is intended.

[0160] For example, when transducer **104** is intended for use in an insole, it is desirable that TTQ be small enough to avoid user discomfort during use, thereby placing an upper bound on transducer thickness T**1** and/or cavity height Hc. At the same time, a transducer must be able to develop sufficient restoring force when deformed by force F to enable it to return to its quiescent state when the force is removed (e.g., when the user's foot lifts during walking, even if the shoe is tied very tightly). In addition, preferably, a transducer exhibits maximum deformation, without undergoing plastic deformation, in response to the applied force so that it generates as much electrical energy as possible.

[0161] As discussed below and with respect to FIGS. **6**A-B, typical practical values for TTQ are within the range of approximately 1.5 mm to approximately 9.5 mm for transducers designed for use in an insole. In the depicted example, wearable **100** is an orthotic insole and TTQ is approximately 3.5 mm; however, TTQ can have any practical value without departing from the scope of the present disclosure.

[0162] Flanges **308** are located at the lower edges of substrate **302**. Flanges **308** are configured such that they have more surface area to compress the material of insole body **102** when transducer **104** is deformed by an applied force. In the depicted example, flanges **308** are portions of the substrate that are "rolled" inward such that they have thickness t**2**, which is greater than the thickness of the rest of the substrate (i.e., t**1**). As a result, flanges **308** As discussed in more detail below and with respect to FIGS. **6**A-B, the increased surface area of flanges **308** increases the amount of material displaced along the x-direction when transducer **104** is flattened, thereby increasing the potential energy stored by the insole-body material, which is typically resilient. As a result, flanges **308** increase the magnitude of a lateral restoring force on the transducer that arises as the transducer is flattened.

[0163] In some embodiments, transducer **104** is formed into its non-planar quiescent shape via a different conventional method, such as die stamping, etc.

[0164] Returning now to method **200**, in operation **203**, transducers **104** are arranged in the molding form for insole body **102**. In the depicted example, transducers **104** are arranged in a substantially linear arrangement in which the short axis, SA**1**, of each transducer is substantially aligned with longitudinal axis LA**1** of insole body **102**. As a result, the arrangement of transducers can "roll up" along longitudinal axis LA**1** (like a venetian blind) as insole **102** deforms during a stride of the user.

[0165] Although the depicted example includes a plurality of substantially identical transducers **104** that is arranged in a linear arrangement within wearable **100**, a plurality of transducers within a wearable can include different transducers and/or be arranged in any practical one-, two-, or three-dimensional arrangement without departing from the scope of the present disclosure. For example, a smart connected insole in accordance with the present disclosure can include a plurality of transducers **104** having a shorter length, or circular transducers, etc., in the narrower instep region of the insole. Some non-limiting examples of alternative transducer arrangements are disclosed in detail in parent application U.S. patent application Ser. No. 17/373,690.

[0166] At operation **204**, the components within wearable **100** are electrically connected such that power is provided by the non-resonant energy harvesters of transducers **104** via energy storage module **112**.

[0167] FIG. **5** depicts a block diagram showing component connectivity for a wearable in accordance with the present disclosure.

[0168] As seen in connectivity diagram **500**, wearable **100** includes two substantially independent networks-power network **502** and communications network **504**.

[0169] In power network **502**, energy storage module **112** receives energy from each of rapid-charging module **108** and the non-resonant energy harvesters TE**1** included in the plurality of transducers **104** and distributes the energy, as needed, to other components within wearable **100**, including processor **108**, sensor module **106**, the force/load/pressure sensors TE**2** included in the plurality of transducers **104**, the haptic devices TE**3** included in the plurality of transducers **104**, and communications module **110**.

[0170] In communications network **504**, energy data and control signals are transmitted between processor **108** and the components in sensor module **106**, communications module **110**, and energy storage module **112**.

[0171] At operation **205**, insole body **102** is formed by filling the mold to fully encase transducers **104-1** through **104**-N, sensor module **106**, processor **108**, communications module **110**, energy-storage module **112**, rapid-charging module **114**, and display **116**. By fully encasing these components within the insole, they are substantially protected from damage due to water, sweat, and the like. In some embodiments, display **116** is encased within insole body **102** such that its display elements are visible to the user when desired.

[0172] FIGS. **6**A-B depict schematic drawings of simplified sectional views of a region of completed wearable **100** in its quiescent and deformed states, respectively. The sectional views of transducer **104** are taken through line a-a, as depicted in FIG. **3**A.

[0173] In the depicted example, insole body **102** includes a pair of layers of material having different mechanical properties-HD layer **602**, which is located below transducers **104**, and LD layer **604**, which completely surrounds the transducers and electrical components. Preferably, HD layer **602** is formed prior to operation **201**. When transducer **104** is in its quiescent state, HD layer **602** has thickness THD and LD layer **604** has thickness TLD.

[0174] HD layer **602** comprises material M**3**, which has a relatively higher density, while LD layer **604** comprises material M**4**, which has a relatively lower density. In the depicted example, material M**3** is a high-density polyurethane (PU) and material M**4** is a low-density polyurethane; however, a wide range of materials are suitable for use in either of HD layer **602** and LD layer **604**.

[0175] It is an aspect of the present disclosure that the two-layer structure of insole body **102** fosters bending-strain-based operation of transducers **104**. It should be noted, however, that one or both of materials M**3** and M**4** can include any suitable material, such as a monolayer of polyurethane, mono- or multi-layers of viscoelastic gels, neoprene rubbers, foams, and the like without departing from the scope of the present disclosure.

[0176] As will be apparent to one skilled in the art, insole thickness can vary over quite a large range, depending upon the specific type of insole. The preferred thicknesses of HD

layer **602** and LD layer **604**, therefore, are based on the particular type of insole application for which wearable **100** is intended.

[0177] Table 1 below shows approximate thicknesses in the heel and ball areas of the foot for different types of conventional insoles.

TABLE 1

Representative dimensions for typical insole types.

Type of Conventional Insole	Thickness at Heel (mm)	Thickness at Ball of Foot (mm)
Orthotic	10	4.5
Non-orthotic	3.5	2.5
Military Boot	3.5	2.5
Sports Shoe	3	2

[0178] The total operational thickness, TTO, of transducer **104** within wearable **100** is equal to the sum of THD and the total quiescent thickness TTQ (i.e., transducer thickness, T**1** and the height, Hc, of cavity **310** when the transducer is in its quiescent shape). As noted above, wearable **100** is an orthotic insole, which sets an upper bound on the value of TTO. In the depicted example, TLD is approximately 1 mm, THD is 2 mm, T**1** is approximately 0.612 mm, and Hc is approximately 0.9 mm (i.e., TTQ is approximately 1.5 mm), resulting in a TTO of only 2.5 mm; however, these values are merely exemplary and matters of design. As a result, TLD, THD, T**1**, and Hc can have any practical values without departing from the scope of the present disclosure. Furthermore, in some embodiments, transducers having different values of TTO are used in the heel and ball of foot regions.

[0179] When wearable **100** is subjected to force F (e.g., when foot pressure is applied to the insole), the applied force flattens the structure of transducer **104**, thereby bending the transducer out of its quiescent shape to make it "flatter" and longer (in the x-direction). This bending of the transducer reduces its curvature about bending axis BA.

[0180] It should be noted that the curved shape of transducer **104** mitigates compression of piezoelectric layers **306**A and **306**B, themselves, in response to force F. In some embodiments, standoffs, such as posts, reside within the piezoelectric layers to mitigate their compression in response to an applied force. As will be appreciated by one skilled in the art, after reading this Specification, compression of a piezoelectric layer configured to operate in bending mode is undesirable, as it negatively affects the bending response of the transducer. Specifically, the output signal from a piezoelectric element is proportional to the charge it builds up in response to strain. While a piezoelectric element responds to bending with a negative charge buildup, while it responds to compression with a positive charge buildup. As a result, any compression of a bending-mode piezoelectric element will cancel out at least some, if not all, of its response to bending. Embodiments in accordance with the present disclosure, therefore, are afforded advantages over the prior art.

[0181] In some embodiments, transducer **104** includes features that project from one or both of its major surfaces to inhibit compression of piezoelectric layers **306**A and **306**B. In some embodiments, transducer **104** is mounted in a seat that inhibits compression of piezoelectric layers **306**A and **306**B. Some non-limiting examples of structures suitable for facilitating bending-mode operation of a piezoelectric transducer while simultaneously inhibiting compression of its piezoelectric materials are disclosed in detail in parent application U.S. patent application Ser. No. 17/373,690.

[0182] When transducer **104** is flattened, material M**4** beneath the transducer is compressed. Since M**4** is a resilient material, it provides restoring force RF**1** that acts to return the transducer to its quiescent state once force F is removed.

[0183] In addition, as noted above, substrate **302** is configured such that its ends are shaped into flanges **308** which have greater surface area in the y-z plane. As a result, more material M**4** is displaced along the x-direction when transducer **104** elongates as it is flattened. This laterally displace material M**4** gives rise to additional restoring force RF**2**, thereby augmenting restoring force RF**1**.

[0184] Flanges **308** provide additional advantage because they reduce the chance of damage due to substrate **302** cutting into LD layer **504** or abrading HD layer **502**, thereby improving the lifetime and reliability of wearable **100**.

[0185] As noted above, the choices of materials and thicknesses of substrate **302** and piezoelectric layers **306**A and **306**B typically depend upon the application for which a transducer is designed and the desired performance parameters of the transducer. For example, the design of the depicted example can provide substantially maximum generation of energy per user step—even with a TTO of only 1.5-2.0 mm. In some cases, however, less energy generation is required, allowing for more latitude in transducer design. For example, a transducer having a 1000-micron-thick brass substrate, 200-micron-thick piezoelectric layers comprising PZT sol-gel material, and having a TTO of 4 millimeters can produce significant energy when employed in an orthotic insole.

[0186] FIGS. **7**A-B depict schematic drawings of sectional views of an alternative embodiment of a transducer, in its quiescent and deformed states, in accordance with the present disclosure. Transducer **700** is analogous to transducer **104**; however, in transducer **700**, substrate **702** is configured such that transducer **700** has a plurality of peaks and valleys arranged along the x-dimension when in its quiescent state, thereby giving rise to a "ruffled transducer."

[0187] Each peak and valley of transducer **700** is substantially aligned with a different bending axis BA. In some embodiments, a ruffled transducer is shaped such that it has peaks and valleys along two dimensions (e.g., the x- and y-dimensions). In some embodiments, a ruffled transducer has a cross-section having a known curved shape along at least one dimension, such as sinusoidal, parabolic, catenary, and the like. In some such embodiments, the shape of transducer is defined such that strain is distributed substantially evenly along at least one dimension.

[0188] FIG. **8** depicts a schematic drawing of a sectional view of an alternative arrangement of transducers within a wearable in accordance with the present disclosure. Wearable **800** includes transducers **700**A and **700**B, plates **802**A and **802**B, and material M**4**.

[0189] Plates **802**A and **802**B are substantially rigid plates of structural material (e.g., metal, plastic, etc.), which are configured to substantially uniformly transfer an applied force to transducers **700**A and **700**B.

[0190] Wearable **800** is configured such that each of transducers **700**A and **700**B will be compressed by force F, thereby substantially doubling the magnitude of the output signals from their transducer elements.

[0191] In some embodiments, transducer **104** is configured such that an applied force causes it to stretch and/or bend like a cantilever element in one or more dimensions. A stretchable transducer is particularly well-suited for use in wearable applications such as an energy-scavenging strap that powers a bra, a belt, a chest strap, stretchy pants, a backpack, and the like.

[0192] FIGS. **9**A-C depict schematic drawings of cross-sectional views of a cantilevered ruffled transducer under different force conditions in accordance with the present disclosure.

[0193] In FIG. **9**A, transducer **700** is depicted in its quiescent state while affixed to anchor **902**. In other words, transducer **700** is depicted without any applied force.

[0194] In FIG. **9**B, transducer **700** is depicted in a stretched state in response to applied force FL, which is a lateral force directed only along the x-direction. As transducer **700** is stretched along the x-axis, the transducer is deformed from its quiescent shape by being pulled into a flatter profile.

[0195] In FIG. **9**C, transducer **700** is depicted in a stretched state in response to applied forces FL and FV, which are lateral and vertical forces directed along the x- and y-directions, respectively.

[0196] FIGS. **10**A-D depict schematic drawings of cross-sectional views of wearables having alternative arrangements of bimorph transducers within a wearable in accordance with the present disclosure. Each of wearables **1000**, **1002**, **1004**, and **1006** is analogous to wearable **100** and comprises insole body **102** and one or more transducers analogous to transducer **104**. It should be noted that, for clarity, only transducers **104** and their respective bending axes are shown in FIGS. **10**A-D.

[0197] Wearable **1000** includes transducer **104**A, which is a long version of transducer **104** and arranged within insole body **102** such that bending axis BA**1**A is aligned with longitudinal axis LA**1**. As a result, transducer **104**A can generate voltage and energy in response to a rolling motion of the user's foot, as well as during each step as the shoe meets the ground or lifts from it.

[0198] Wearable **1002** includes a pair of transducers **104**B, each of which is a short version of transducer **104**. Transducers **104**B are arranged within insole body **102** such that each of their bending axes BA**1**B is aligned with longitudinal axis LA**1**. Although the depicted example includes two transducers that are displaced from longitudinal axis LA**1**, in some embodiments, the bending axis of at least one transducer is colinear with the longitudinal axis of its wearable.

[0199] Wearable **1004** includes a combination of transducers that includes one transducer **104**A and a pair of transducers **104**B. Transducers **104**A and **104**B are arranged within insole body **102** such that each of their bending axes BA**1**A and BA**1**B is aligned with longitudinal axis LA**1**.

[0200] Wearable **1006** includes a plurality of transducers **104**B, which is arranged within insole body **102** such that each of their bending axes BA**1**A and BA**1**B is aligned with longitudinal axis LA**1**. The arrangement of transducers includes two linear arrays located approximately at the heel and ball-and-foot areas of the insole body, as well as a single transducer **104**B located near the arch region of the insole body.

[0201] In some embodiments, a wearable includes transducers whose bending axes are aligned along different directions (e.g., some along the x-axis and some along the y-axis, at different angles with respect to at least one of the x- and y-axes, etc.). In some embodiments, a wearable includes a mixture of transducer types, such as any combination of ruffled, waffled, channel, and/or circular transducers.

[0202] FIG. **11** depicts a block diagram of a system **1100** in accordance with one embodiment of the present disclosure. As shown in the figure, system **1100** comprises a computing device **1110** and a wearable device **1120**. Computing device **1110** may be a smartphone, a tablet, a laptop computer, a desktop computer, etc. that is equipped with a touchscreen and is capable of executing a graphical user interface (GUI). Wearable device **1120** may be, for example, an embodiment of a wearable disclosed in this application (e.g., an embodiment of wearable **100**, an embodiment of wearable **1000**, an embodiment of wearable **1002**, an embodiment of wearable **1004**, an embodiment of wearable **1006**, etc.); a smart watch such as an Apple Watch® or Google Pixel Watch®; a fitness tracker such as a Fitbit® or Amazon Halo View®; etc. As shown in the figure, computing device **1110** and wearable device **1120** communicate bi-directionally. In some embodiments, the communication might be via a short-range wireless technology such as Bluetooth, Bluetooth Low Energy [BLE], Zigbee, etc., while in some other embodiments the communication might be via a wireless local area network (LAN) technology such as Wi-Fi, while in yet other embodiments the communication might be via a wired connection such as Universal Serial Bus [USB] or Ethernet. FIG. **12** depicts a block diagram of computing device **1110** operating in accordance with aspects and implementations of the present disclosure. Computing device **1110** may be a smartphone, a tablet, a laptop computer, a desktop computer, or any other computing or communication device. As shown in FIG. **12**, computing device **1110** comprises processor **1201**, main memory **1202**, storage device **1203**, touch screen **1204**, and transceiver **1205**, interconnected as shown (e.g., via one or more busses, etc.).

[0203] Processor **1201** represents one or more general-purpose processing devices such as a microprocessor, central processing unit, or the like. More particularly, processor **1201** may be a complex instruction set computing (CISC) microprocessor, reduced instruction set computing (RISC) microprocessor, very long instruction word (VLIW) microprocessor, or a processor implementing other instruction sets or processors implementing a combination of instruction sets. Processor **1201** may also be one or more special-purpose processing devices such as an application specific integrated circuit (ASIC), a field programmable gate array (FPGA), a digital signal processor (DSP), network processor, or the like. Processor **1201** is capable of executing instructions stored in main memory **1202** and storage device **1203**, including instructions for executing an implementation of GUI **1500**, as described below; of reading data from and writing data into main memory **1202** and storage device **1203**; of receiving input signals from and transmitting output signals to touch screen **1204**; and of receiving input signals from and transmitting output signals to transceiver **1205**. While a single processor is depicted in FIG. **12** for simplicity, computer system **1200** might comprise a plurality of processors.

[0204] Main memory **1202** is capable of storing executable instructions and data, including instructions and data for executing an implementation of GUI **1500**, and may

include volatile memory devices (e.g., random access memory [RAM]), non-volatile memory devices (e.g., flash memory), and/or other types of memory devices.

[0205] Storage device **1203** is capable of persistent storage of executable instructions and data, including instructions and data for executing GUI **1500**, and may include a magnetic hard disk, a Universal Serial Bus [USB] solid state drive, a Redundant Array of Independent Disks [RAID] system, a network attached storage [NAS] array, etc. While a single storage device is depicted in FIG. **12** for simplicity, computing device **1110** might comprise a plurality of storage devices.

[0206] Touch screen **1204** is a combination of a display device (e.g., an LCD display, an AMOLED display, an OLED display, etc.) and a touch panel input device. In accordance with one embodiment, touch screen **1204** is capable of displaying GUI **1500** and receiving inputs to GUI **1500** via user touch (e.g., presses, gestures, etc.).

[0207] Transceiver **1205** is capable of transmitting signals to and receiving signals from wearable device **1120**, as well as to/from other computing and communications devices. Transceiver **1205** is further capable of receiving signals from processor **1201** (e.g., requests and/or data to be transmitted to wearable device **1120**, etc.), and of transmitting signals to processor **1201** (e.g., data received from wearable device **1120**, etc.) It should be noted that depending on the particular application programming interface (API) provided by wearable device **1120** and the terminology that the API employs, functionality of the API (e.g., taking a measurement, providing measurement data, etc.) might be invoked via "instructions" rather than "requests." For the purposes of this specification, the term "requests" will be used to encompass instructions as well as requests.

[0208] In one embodiment, transceiver **1205** transmits and receives wireless signals (e.g., via Bluetooth, Bluetooth Low Energy [BLE], Zigbee, Wi-Fi, cellular, satellite, etc.). In some other embodiments, transceiver **1205** might communicate over a wired connection, such as USB or Ethernet. In still other embodiments, computing device **1110** might comprise a plurality of transceivers (e.g., a wireless transceiver and a wireline transceiver, etc).

[0209] FIG. **13** depicts a block diagram of salient elements of wearable device **1120**, in accordance with one embodiment of the present disclosure. As shown in the figure, wearable device **1120** comprises a processor **1310**, a transceiver **1320**, and a health/fitness sensor array **1330**, interconnected as shown.

[0210] Processor **1310** is capable of receiving measurement data from health/fitness sensor array **1330**; of processing measurement data (e.g., estimating calories burned based on heart rate, estimating respiratory rate based on heart rate, etc.); of providing an application programming interface (API) for invoking functions of wearable device **1120**; of transmitting data and/or requests to health/fitness sensory array **1330** (e.g., a request to take one or more measurements, a request to provide measurement data, etc.); of providing data and/or requests to transceiver **1320** for transmission (e.g., to computing device **1110**, etc.), and of receiving data and/or requests from transceiver **1320** (e.g., data and/or requests from computing device **1110**, etc.). In one embodiment, processor **1310** comprises a real-time clock that enables processor **1310** to know the time, day, and date at each moment.

[0211] Transceiver **1320** is capable of transmitting signals (e.g., to computing device **1110**, etc.), of receiving signals (e.g., from computing device **1110**, etc.), and of communicating with processor **1310**.

[0212] Health/fitness sensor array **1330** is capable of obtaining measurements of parameters such as body temperature, blood oxygen, heart rate, steps taken, etc.; of providing measurement data to processor **1310**; and of receiving data and/or requests from processor **1310** (e.g., requests to take measurement(s), etc.). In some embodiments, health/fitness sensor array **1330** may comprise one or more elements in common with sensor module **106** disclosed above.

[0213] FIG. **14** depicts a block diagram of salient elements of health/fitness sensor array **1330**, in accordance with one embodiment of the present disclosure. As shown in the figure, health/fitness sensor array **1330** comprises a body temperature sensor **1401**, a blood oxygen saturation sensor **1402**, a heart rate sensor **1403**, a blood pressure sensor **1404**, and a motion sensor **1405**. In one embodiment, motion sensor **1405** is a three-dimensional micro-electro-mechanical systems ("MEMS") accelerometer/gravimetric sensor, similar to the multi-axis accelerometer of wearable **100** disclosed above. It should be noted that in some embodiments, health/fitness sensor array **1330** might employ one or more sensors that are capable of measuring a plurality of parameters (e.g., a pulse oximeter capable of measuring both blood oxygen saturation and heart rate, etc.). It should be further noted that in some embodiments, health/fitness sensor array **1330** might further comprise other types of sensors not depicted in FIG. **14**.

[0214] FIG. **15** depicts a graphical user interface (GUI) **1500**, in accordance with one embodiment of the present disclosure. In one example, GUI **1500** executes on computing device **1110**, enabling a user to interact with wearable device **1120** via computing device **1110**.

[0215] GUI **1500** is capable of displaying text, images, and graphical elements such as icons and buttons, and of receiving user input via a touch screen (e.g., a gesture performed by a user, such as a swipe or a pinch; a press of a graphical element; etc.). As shown in the figure, GUI **1500** comprises three areas **1510**, **1520** and **1530**. Area **1510** displays a plurality of icons arranged in a ring (a "globe carousel"), as described in detail below. Area **1520** displays an overall "wellness" score, which may be a composite of a plurality of health/fitness parameters. Area **1530** displays historical parameter data (e.g., body temperature measurements over the last two weeks, heart rate measurements over the last six hours, etc.). In one embodiment, the historical parameter data is obtained from wearable device **1120**.

[0216] As shown in FIG. **15**, area **1510** displays a three-quarter view of a ring **1511** of icons **1512-1** through **1512-8**. As will be appreciated by those skilled in the art, the number of icons in the ring is merely illustrative; in some embodiments there might be fewer than eight icons, or more than eight icons.

[0217] In one embodiment, each icon **1512-*i*** is associated with a particular health/fitness parameter, such as body temperature, heart rate, blood oxygen saturation, blood pressure, respiratory rate, steps taken, traveling speed (e.g., walking speed, running speed, crawling speed, speed while engaging in sports or other activities, etc.), distance traveled, calories burned, etc. In one implementation, each icon **1512-*i*** pictorially conveys the particular health/fitness

parameter with which it is associated (e.g., an icon depicting a heart and signal for heart rate, an icon depicting lungs for respiratory rate, etc.). In one example, health/fitness parameter values are obtained from wearable device **1120**.

[0218] In one implementation, each of icons **1512-1** through **1512-8** is depicted inside a respective two-dimensional projection of a sphere (or "globe"), which is rendered as a circle with light shading, as shown in the figure. Because the ring is rendered in perspective, the globes in the front (or "lower") portion of the ring appear larger than the icons in the rear (or "upper") portion of the ring. As will be appreciated by those skilled in the art, in some other implementations, one or more of icons **1512** might be depicted inside a different type of shape/object (e.g., an unshaded circle, an ellipse, a square, a projection of a cube, etc.), rather than inside a projection of a sphere, while in yet other implementations, one or more of icons **1512** might be depicted on their own, without any surrounding shape/object.

[0219] In one implementation, the background of each icon **1512-***i* is displayed in a color reflecting a state of the associated health/fitness parameter. In examples where an icon is displayed within a shape/object (e.g., a globe, etc.), the background is the shape/object, and the background color is a fill color of the shape/object. It should be noted that while in FIG. **15** the backgrounds of icons **1512** are depicted in gray scale, and are the same shade of gray, this in no way limits the use of color or variations in shades of gray/black/white in embodiments of GUI **1500**.

[0220] In one example, the background color of an icon **1512-***i* is: (1) green when (a) the value of an associated health/fitness parameter value, such as heart rate or blood oxygen saturation, is in a normal range, or when (b) the value of an associated health/fitness parameter, such as calories burned, is considered "good" with respect to one or more criteria; (2) yellow when (a) the value of an associated health/fitness parameter is in a borderline normal range approaching an abnormal and/or dangerous range, or is considered "ok but not good," "mediocre," "neutral," etc. with respect to one or more criteria; (3) red when the value of an associated health/fitness parameter is in an abnormal range, or is considered "bad," "dangerous," etc. with respect to one or more criteria. As will be appreciated by those skilled in the art, in some examples one or more of the normal/abnormal ranges, and/or what is considered good/dangerous/etc. for a particular parameter, and/or the criteria for determining what is considered good/dangerous/etc., might be user-specific, while in other examples they might be the same for all users.

[0221] As will further be appreciated by those skilled in the art, some embodiments of the present disclosure might characterize health/fitness parameter values using an alternative background color scheme. In implementations where there are no shapes/objects surrounding icons, colors might be assigned to the icons themselves, rather than their backgrounds. As will further be appreciated by those skilled in the art, some embodiments of the present disclosure might convey parameter values using one or more alternative types of visual schemes, either instead of color, or in addition to color (e.g., changing the size of an icon, changing the size of the surrounding shape, changing the orientation of an icon, animating an icon in some fashion, etc.)

[0222] As disclosed above, area **1520** displays an overall "wellness" score, which might be a composite of a plurality of the health/fitness parameters. In one embodiment, the wellness score takes into account heart rate, blood oxygen saturation, blood pressure, and respiratory rate, such that a high score indicates good health. In one implementation, the wellness score is an integer with a maximum value of 100, where 100 means that every parameter taken into account in the wellness score is in normal range or is "good," as described above.

[0223] Area **1530** displays historical parameter data (e.g., body temperature measurements over the last two weeks, heart rate measurements over the last six hours, etc.). In one embodiment, the historical parameter data is obtained from wearable device **1120**. As described in detail below, the particular health/fitness parameter that is displayed in area **1530** is determined by user input to touch screen **1204**, and more particularly, to user touches/gestures in area **1510**.

[0224] In accordance with embodiments of the present disclosure, a user can interact with GUI **1500**, and can interact with wearable device **1120** via GUI **1500**, in a variety of ways.

[0225] In one embodiment, the depiction of ring **1511** in area **1510** is responsive to user input, such that when a user performs a left-to-right swiping gesture across some or all of the front portion of ring **1511**, the ring **1511** rotates counterclockwise, in animated fashion. The rotation appears as icons **1512** traveling around the center of ring **1511**, in a manner similar to orbiting planets or satellites. Similarly, when a user performs a right-to-left swiping gesture across some or all of the front portion of ring **1511**, ring **1511** rotates clockwise. In some implementations, GUI **1500** may also rotate ring **1511** in response to a swiping gesture below the front portion of ring **1511** (e.g., in the lower portion of area **1510** below ring **1511**, etc.), in a manner similar to a swiping gesture across some or all of the front portion of ring **1511**.

[0226] In one embodiment, ring **1511** may also rotate in response to a swiping gesture across some or all of the rear portion of ring **1511** (e.g., a clockwise rotation in response to a left-to-right swiping gesture across some or all of the rear portion of ring **1511**, a counterclockwise rotation in response to a right-to-left swiping gesture across some or all of the rear portion of ring **1511**, etc.). Further, in some implementations ring **1511** may rotate in response to a swiping gesture above the rear portion of ring **1511** (e.g., in the upper portion of area **1510** above ring **1511**, etc.), in a manner similar to a swiping gesture across some or all of the rear portion of ring **1511**.

[0227] In one embodiment, GUI **1500** further enables a user to interact with GUI **1500**, and with wearable device **1120** through GUI **1500**, via pressing of one or more icons **1512**. In some implementations, GUI **1500** may be responsive to presses of icons in the front portion of ring **1511** only, while in some other implementations, GUI **1500** may be responsive to presses of all icons **1512**, regardless of their location in ring **1511**.

[0228] In accordance with one embodiment, when a user presses a particular icon **1512-***i*, historical data for the associated health/fitness parameter for the user (e.g., one or more prior measurements for the user, etc.) during a particular time period (e.g., the last 30 minutes, the last four hours, the last three days, the last week, the last month, a prior time period [e.g., a prior day, a prior week, a prior month, etc.], etc.) is displayed in area **1430** (e.g., as a line

graph, as a bar graph, as a table, etc.). In one embodiment, the historical data is obtained from wearable device **1120**.

[0229] In some implementations, the time period might be a fixed value specified a priori (e.g., ten minutes, one hour, etc.), while in some other implementations the time period may have a default value that can be changed by a user (e.g., via a settings menu, etc.). For the latter case, in some examples a user might specify the time period via a selection among possible choices, while in other examples a user might enter a particular desired numerical value. As will be appreciated by those skilled in the art, in some implementations each health/fitness parameter might have its own time period (e.g., ten minutes for heart rate, 30 minutes for blood pressure, etc.), while in other implementations there might be a single time period for all parameters.

[0230] As noted above, in some implementations the historical data might be displayed as a graph (e.g., a line graph, a bar graph, etc.), while in some other implementations the historical data might be displayed in some other fashion (e.g., as a table, etc.). In the example depicted in FIG. **15**, GUI **1500** displays the historical data as a line graph. In one implementation, one or more of the points on the graph may be labeled with the associated numerical value. In some examples, it may be desirable to include the most recent parameter measurement in the labeled point(s).

[0231] As will be appreciated by those skilled in the art, in some implementations the manner in which historical data is displayed might differ among parameters (e.g., a graph for heart rate, a table for blood pressure, etc.), while in other implementations there might be one type of data presentation for all parameters. As will further be appreciated by those skilled in the art, in some implementations the manner in which historical data is presented might be selectable by a user. Further, in some implementations, GUI **1500** might be capable of displaying historical data for a plurality of health/fitness parameters at the same time (e.g., a graph for one parameter underneath a graph for another parameter; two graphs side-by-side; a table for one parameter underneath a graph for another parameter; a graph and a table side-by-side, etc.).

[0232] In accordance with one embodiment, GUI **1500** enables further user interaction with GUI **1500** and wearable device **1120** via pressing-and-holding of icons. In one implementation, when a user presses an icon **1512**-*i* and holds the press for at least N units of time, and optionally, for less than M units of time, where M>N (e.g., N=3 seconds and M=5 seconds, etc.), a request is sent to wearable device **1120** to take one or more measurements of the health/fitness parameter associated with icon **1512**-*i* and return measurement data for that parameter to computing device **1110** (e.g., one or more of the measurement(s) themselves, one or more numeric values derived from the measurement(s), etc.). In this way, each icon provides two functions when pressed, where the particular function performed depends on the duration of the press. In some examples, the value of N also serves as a maximum duration threshold for "regular" (or "short") presses, such that a press lasting for less than N units of time is interpreted as a regular press, and a press lasting for at least N units of time (and optionally, for less than M units of time) is interpreted as a "long" press.

[0233] Accordingly, a regular press of an icon **1512**-*i* results in GUI **1500** displaying historical data for the health/fitness parameter associated with that particular icon, as described above, and a long press of icon **1512**-*i* results in computing device **1110** sending a request to wearable device **1120** to (1) take one or more measurements of the health/fitness parameter associated with icon **1512**-*i*, and (2) return measurement data associated with that parameter to computing device **1110**. In one embodiment, GUI **1500** displays the measurement data in area **1530**, either by itself, or appended to historical data as the most recent value of the parameter (e.g., a graph in which the most recent measurement is the rightmost data point in the graph, a table in which the most recent measurement is the last entry in the table, etc.).

[0234] FIG. **16** depicts a first implementation of GUI **1500** executing on a computing device, in accordance with one embodiment of the present disclosure. In one example, the computing device is computing device **1110**. FIG. **17** depicts a second implementation of GUI **1500** executing on a computing device, in accordance with one embodiment of the present disclosure. In one example, the computing device is computing device **1110**.

[0235] FIGS. **20-21**, **23-24** and **26-27** depict optical sensor placement in accordance with other embodiments of the present invention. It is believed that optical and other sensors embedded in a smart insoles offers key advantages over placement in a smart watch or smart ring, including a meaningful impact on measurement accuracy.

[0236] First, a smart insoles' large volume inside the wireless sensor electronics compartment as compared to inside a watch case and especially a ring case is beneficial. Miniaturize of electronic components and sensors beyond commercial-off-the-shelf "COTS" components and sensors is not required. Many more electrical components and/or sensors, and/or larger versions of the devices can be included in the insole. For example, measuring blood pressure may require two optical sensors separate by 2.5 mm to 11 mm. Also, for example, measuring blood glucose may require three or more optical sensors may require larger LEDs and larger photodiodes (PDs) to generate near infrared (NIR) and collect photons. Also, for example, detecting diabetes and/or cardiovascular issues may require three optical sensors with appropriate separation.

[0237] Second, use of sensors in smart insoles substantially eliminates external light interference. Wearable Devices such as watches rings are relatively loose-fitting devices that create air gaps between the skin and the sensor, allowing external light to interfere with measurements. This can degrade the accuracy of heart rate (HR), blood oxygen saturation (SpO2), blood pressure (BP), and blood glucose (BG) readings. With an insole inside a shoe, the air gap between the sensor and the foot's skin or sock is insulated from external light. The enclosed environment of the shoe substantially prevents light interference, ensuring that the sensor only detects signals generated by the body's physiological parameters.

[0238] Third, placement of sensors inside a shoe in an insole provides for a stable temperature environment. Other wearable Devices, such as watches or rings, have air gaps that expose sensors to ambient air, which can create temperature gradients. This affects the sensor's performance and potentially skews measurements, especially in varying room temperatures. Inside the shoe, the foot, sock, and sensor share a substantially uniform, enclosed temperature. This stability enhances the reliability of physiological readings since temperature is a critical factor in accurate sensor function.

[0239] Fourth, there is reduced impact of motion artifacts. Shoes often fit snugly and uniformly distribute pressure, reducing motion artifacts that commonly affect wearables on the wrist or finger. Combined with the stable sensor environment, this enhances measurement consistency.

[0240] Fifth, there is enhanced sensor-to-skin (or sock) contact. While loose-fitting wearables struggle with consistent contact due to motion or air gaps, a shoe/insole design inherently keeps sensors closer to the skin or sock. Even if some separation occurs, it does not compromise accuracy as significantly as in wearables exposed to external conditions.

[0241] Finally, particularly for applications in managing diabetes and cardiovascular disease detection, these advantages make smart insoles a more dependable tool for continuous monitoring. The consistent measurement conditions provided by the shoe environment ensure more reliable data for early detection and management of these conditions.

[0242] For insoles, optical sensor measurement through socks is highly desirable. It is believed that there is substantially no difference in the measurement for heart rate or SpO_2 through socks as compared to measurements made directly on the foot's skin. That is, measurements through socks are believed to be "clinically accurate" and "highly accurate" as defined by the medical industry. Thicker socks may cut off the amount of light or number of photons getting through the sock; more light scattering may take place as the sock's thickness increases. This can be compensated by increasing the LEDs' intensity I_o (increasing the LED power P in Watts=Joules/second) and number of photons generated per second. Darker socks, for example, black socks, absorb more photons, whereas white socks absorb the least. Again, increasing I_o increases the number of photons through the sock to the skin, and back again through the sock to the photodiodes (PDs). Too much I_o (over saturation) can become an issue as well. In the present invention, the color of the user's socks is detected (as well as she color of the user's skin) with a sensor. Using advanced artificial intelligence (AI) and machine learning (ML) algorithms, I_o and other parameters (e.g., filters) may be adjusted to obtain the most accurate HR and SpO_2 readings.

[0243] With respect to skin color measurements, it has been known since the early 1980s that skin color or skin pigment causes an error in SpO_2 measurements. Skin pigment absorbs the same wavelength λ photons as oxygen in the blood. Hence, there is a 1.4-1.7% increased absorption of photons of this λ for "blood oxygen" measurements for Asian, Hispanic, and Black people's skin due to the larger amount of skin pigment. Therefore, it seems that the person of color's blood oxygen is higher than it is in their blood. For example, if a black person goes to the emergency room for suspected COVID-19 and the person's SpO_2 reads 88%, this is considered "borderline" and the person will not be admitted for COVID-19. But, since their SpO_2 is reading for their blood oxygen is 1.7% too high, then the person's SpO2 is actually lower, the measurement would be 86%. At this level, SpO_2 is outside the normal range and the doctor, nurse, and/or respiratory therapist would recommend admitting them for COVID-19. This is the so-called "racial bias" built into optical sensors. (SpO2>88% normal, <88% abnormal).

[0244] A smart watch or smart ring measures using its optical sensor on the darker side of the wrist or finger when worn "normally" where there is more skin pigment. This is believed to be the worst side to make the SpO_2 measurements.

[0245] The present invention may therefore obtain more accurate SpO_2 readings on people of color's feet where skin typically has substantially less pigment, thereby reducing or eliminating racial bias.

[0246] As can be seen in FIGS. **18**A and **18**B, the effect of force (e.g., body weight) on optical sensors **2010** in the insole can have effect on optical readings. FIG. **18**A shows the force F_a of a digit **2012** of a user on an optical sensor **2010**. As the force F_a is applied on the optical sensor **2010** on the glass lid **2014** of the optical sensor **2010**, light rays **2016** from the light emitting diode (LED) **2018** of the optical sensor **2010** project onto an artery **2020** in the digit **2012** and reflect back to the photodiodes (PDs) **2022** of the optical sensor **2010**. With a small force F_a applied to the glass lid **2014** as shown in FIG. **18**A, intensity I at the PDs **2022**/incident intensity I_o creates a high-quality signal-to-noise ratio for heart rate (HR) and blood oxygen saturation (SpO_2). However, as shown in FIG. **18**B, if a large force F_a or pressure is applied to the glass lid **2014**, this distorts the light path such that much less light from the LED **2018** is reflected to the PDs **2022**. Incident intensity at the PDs **2022**/projected intensity (I/I_o) decrease significantly, causing the signal-to-noise ratio to drop drastically, such that measurements of HR and SpO_2 are compromised. The same result or worse will happen under the foot's heal and ball, and under low arches and flat feet under full body weight. FIGS. **19**A and **19**B depict two ways to address this issue.

[0247] First, as can be seen in FIG. **19**A, a thicker glass lid **2014**A and/or additional support walls **2024** may be added to the optical sensor **2010**. For example, the glass may be 2 to 7 mm or more thick. Second, as can be seen in FIG. **19**B, a double glass lid (i.e., a first glass element **2014**B and a second glass element **2014**C) may be added to the optical sensor, where the second glass element **2014**C is, for example, 1 to 6 mm or more thick.

Single Optical Sensor Placement within Smart Insole:

[0248] Optimal placement of optical sensors ensures accurate and precise PPG readings. As shown in FIGS. **20-22**, certain insoles **2026**A may include a single optical sensor **2028**A to measure, for example, heart rate and blood oxygen saturation. Optimally, the single optical sensor **2028** is placed in the insole **2026** under the foot **2030** adjacent to the top surface **2032** of the plantar arch **2034**. Optimally, the single optical sensor **2028** is placed in a non-weight bearing location (assuming no thicker glass **2014**A or double glass **2014**B, **2014**C, as described above). As shown in FIG. **22**, the only area of the foot **2030** that is non-weight (or less) bearing for substantially all feet is the plantar arch **2034** as shown. Hence, the only artery containing oxygenated blood that can be measured is the Medial Plantar Artery (MPA) **2036**. Beneficially, there is less or no callus in the arch area, that would lower penetration of light photons into or out of the foot. A single optical sensor **2028** is placed along the MPA **2036** within the plantar arch support **2038** (preferably made from polyurethane PU) attached to the top-insole **2032**, preferably visible at its top surface such that it is in direct contact with the foot or skin or sock. This leads to highly accurate HR, heart rate variability (HRV), and SpO_2. For example, the single optical sensor **2028** may be centered under foot 1 to 2 cm from the edge of the planter arch **2034** since arch lengths are generally equivalent for men and women. For example, green LEDs (520 nm) may be used to measure heart rate, and red LEDs (660 nm) and IR LEDs (940 nm) may be used to measure SpO_2.

[0249] Blood Pressure can also be estimated using a single optical sensor **2028** by analyzing pulse wave morphology or employing machine learning algorithms trained on waveform characteristics. Pulse wave analysis identifies key markers such as pulse wave velocity, systolic timer interval, and the dicrotic notch position, which provide insight into arterial stiffness and vascular health. By assessing the rate of change in the optical sensor waveform and the timing of the reflected waves, arterial compliance and resistance can be inferred, enabling non-invasive blood pressure estimation. Machine learning models can further refine this estimation by correlating waveform features with known blood pressure values, though calibration against standard cuff-based measurements is required. This approach is particularly advantageous for continuous, real-time monitoring in wearable devices, offering a compact and efficient alternative to traditional blood pressure monitoring while maintaining accuracy through optimized sensor placement, advanced filtering techniques, and periodic recalibration.

[0250] Ideally, sizing for the insole **2026** may include separate sizes for different plantar arch heights. Plantar arch height H measured from the navicular tuberosity point on the side of the foot to the floor. The navicular tuberosity point is a nubby point of the navicular bone within the foot. It is measured by a user standing with his or her body weight bearing down on both feet. An H of 30-60 mm is normal, an H greater than 60 mm is high, an H of 20-30 mm is low and an H less than 20 is flat. Optimally, insoles **2026** would be available in four sizes that correspond to normal, high, low, and flat. Plantar arch height is well known. See, for example, Nilsson, M. K., Friis, R., Michaelsen, M. S. et al. Classification of the height and flexibility of the medial longitudinal arch of the foot. *J Foot Ankle Res* 5, 3 (2012). https://doi.org/10.1186/1757-1146-5-3. The availability of different size insoles **2026** provides for an appropriate arch support height H to keep the optical sensor **2010** up against the sock/skin/foot in a firm, yet non-weight bearing position.

Dual Optical Sensor Placement within Smart Insole:

[0251] As can be seen in FIGS. **23-25**, certain insoles **2026**B may include dual optical sensors **2028**A, **2028**B to measure, for example, blood oxygen saturation (in addition to heart rate and blood oxygen saturation discussed above). Optimally, both optical sensors **2028**A and **2028**B are placed along the same, medial plantar artery (MPA) **2036**. Again, for example, a green LED (520 nm) may be used to measure heart rate and red LEDS (660 nm) and/or IR LEDs (940 nm) may be used for SpO_2. Ideally, the two optical sensors **2028**A, **2028**B should be approximately 2.5 cm to 11.0 cm (distance D) or more away from one another

[0252] Calculations are made of Pulse Transit Time (PTT) between optical sensor **2028**A and optical sensor **2028**B. Blood pressure is calculated using the PTT.

[0253] To calculate the PPT, pulse arrival times are determined. Here both optical sensors are synchronized for accurate measurements. t_1 is determined which is the time of pulse wave arrival at optical sensor **2028**A and t_2 is determined which is the time of pulse wave arrival at optical sensor **2028**B. The PTT is calculated as:

$$PTT = t_2 \cdot t_1$$

[0254] The Pulse Wave Velocity (PWV) is calculated (the distance D between optical sensor **2028**A and **2028**B must be known):

$$PWV = D/PTT$$

[0255] Systolic Blood Pressure and Diastolic Blood Pressure are calculated. Blood pressure (both systolic and diastolic) is estimated using an inverse relationship between PTT and blood pressure. Separate equations are used for systolic blood pressure (SBP) and diastolic blood pressure (DBP):

$$SBP = A_S \times PTT^{-Bs} + C_s$$

[0256] where A_S, B_S and C_S are calibration constants for SBP

$$DBP = A_d \times PTT^{-Bd} + C_d$$

[0257] where A_d, B_d and C_d are calibration constants for SBP

[0258] A calibration process may be as follows:

[0259] To produce physiologically accurate results (e.g., SBP≈120 mg Hg; DBP≈89 mm Hg, reference data is first collected. PTT and BP are measured using standard cuff-based blood pressure monitor under various activities (e.g., rest, activity). Next, calibration constants are determined using a regression analysis to fit collected data to the equations for SBP and DBP. Constants are adjusted so that blood pressure values fall in the normal range for typical PTT values (e.g., 0.1 to 0.3 seconds). The calibration is validated by comparing estimated blood pressure values with additional reference measurements.

[0260] A practical example is as follows:

$$SBP = 50 \times PTT^{-1.5} + 80$$

$$DBP = 30 \times PTT^{-1.5} + 50$$

$$\text{Input } PTT = 0.2 \text{ seconds}$$

$$SBP = 50 \times (0.2)^{-1.5} + 80 = 50 \times 5.63 + 80 = 120 \text{ mm Hg}$$

$$DBP = 30 \times (0.2)^{-1.5} + 50 = 30 \times 5.63 + 50 = 800 \text{ mm Hg}$$

[0261] Key considerations are as follows:

[0262] Sensor Synchronization: Ensures precise time alignment between sensors

[0263] Calibration Requirements: Individual calibration is necessary, as vascular properties vary among people.

[0264] Signal Quality: PPG signals are preprocessed to remove noise and artifacts to enhance the signal-to-noise ratio.

[0265] Physiological PTT Range: Normal PTT values typically range from 0.1 to 0.3 seconds.

Triple Optical Sensor Placement within Smart Insole:

[0266] As can be seen in FIGS. **26-28**, certain insoles **2026**C may include triple optical sensors **2028**A, **2028**B,

2028C to detect, for example, diabetes and cardiovascular issues. Optimally, two optical sensors **2028**A and **2028**B are placed along the MPA **2036** as described above. Again, for example, a green LED (520 nm) may be used to measure heart rate and red LEDS (660 nm) and/or IR LEDs (940 nm) may be used for SpO_2. Ideally, the two optical sensors **2028**A and **2028**B should be approximately 2.5 cm to 11.0 cm (distance D) or more away from one another. Pulse Transit Time (PTT) between optical sensor **2028**A and optical sensor **2028**B are measured and blood pressure is calculated in a similar manner to that of the Dual optical sensor placement within the smart insole discussed above. A third, multi-wavelength optical sensor **2028**C is placed in the metatarsal arch support **2028**, as shown in FIG. **27**. The foot is "mapped" using all three optical sensors **2028**A, **2028**B and **2028**C and to determine if the user has diabetes (or a progression of diabetes over time) and/or cardiovascular disease issues.

[0267] Use of triple optical sensors, as described here, has not been used for feet. Utilizing three optical sensors placed strategically, as discussed above, can allow data to inferred about diabetes and cardiovascular issues by analyzing:

[0268] PTT and PWV along the noted arterial paths;

[0269] Differences in perfusion and vascular resistance between the medial and lateral arteries;

[0270] Arterial stiffness and abnormalities in waveforms are indicative of diabetes or cardiovascular issue

Detection of Diabetes

[0271] Diabetes impacts peripheral circulation, leading to microvascular dysfunction and arterial stiffness. The three optical sensors of the present invention can detect early signs of these changes:

[0272] Increased PTT or reduced PWV in the arteries is associated with reduced vascular elasticity (due to high blood sugar damaging arterial walls), and peripheral neuropathy affects blood flow dynamics.

[0273] Comparing PTT and PWV between medial and lateral arteries can detect diabetes related asymmetry that may result from uneven arterial stiffening due to microvascular damage.

[0274] Perfusion and blood flow may be measured using the PPG waveform amplitude (perfusion index). Reduced amplitude in the lateral plantar artery (from optical sensor **2028**A) compared to the medial plantar artery **2026** indicates vascular occlusion or poor perfusion, common in diabetic patients. The dicrotic notch (secondary wave in the PPG signal) may be evaluated. A flattened or absent dicrotic notch indicates increased vascular resistance, a sign of diabetes related vascular damage.

[0275] Blood oxygen saturation (SpO_2) may be compared based on the three optical sensors. Decreased SpO_2 in the lateral plantar artery compared to the medial artery can indicate ischemia or poor circulation, common in advanced diabetes.

Detection of Cardiovascular Issues

[0276] Cardiovascular conditions, such as hypertension, arteriosclerosis, and peripheral artery disease (PAD) affect arterial stiffness, blood flow, and pressure dynamics, which can be detected using the three optical sensors.

[0277] Arterial Stiffness: Medial PTT vs. Lateral PTT may be measured. Longer PTT or slower PWV along any arterial pathway indicates increased arterial stiffness, a hallmark of cardiovascular issues like hypertension or arteriosclerosis. When comparing PWV across the medial and lateral arteries, uneven stiffness could indicate localized arterial disease.

[0278] Pulse waveform analysis may be made, analyzing the shape of the PPG waveforms. Flattened waveforms or reduced pulse amplitude suggests reduced compliance of the arteries (common in arteriosclerosis). A delayed dicrotic notch may indicate abnormal vascular resistance.

[0279] The Pulse Amplitude Ratio may be determined where the amplitude of the PPG signals between the medial proximal sensor (optical sensor **2928**A) and the distal site (optical sensor **2028**B) is determined. The amplitudes of the PPG signals between optical sensor **2028**A and optical sensor **2028**B, and optical sensor **2028**A and optical sensor **2028**C are determined. Discrepancies between these ratios can indicate peripheral artery disease (PAD) (reduced amplitude in distal sensors) and localized blockages (asymmetry in blood flow between the medial and lateral plantar arteries).

[0280] Sympathetic Nervous System Activity can be detected, for example, cardiovascular stress, arrhythmias, or autonomic dysfunction. by variability in pulse intervals or heart rate variability (HRV) derived from PPG signals. Irregular intervals can indicate arrythmias or other heart issues.

[0281] With respect to smart insoles **2026**A, **2026**B and **2026**C, FIG. **29** depicts a simplified cross-sectional view of the insole showing optical sensors, ribbon cables **2024** connecting the optical sensors **2028**A, **2028**B (**2028**C not shown), and a fabric top **2042**. Preferably, as shown, the top surface of the optical sensors are flush (and exposed) with the top surface of the insole.

Single, Dual, and Triple Optical Sensor Placement within Smart Insole for Accurate Continuous Blood Glucose Monitoring

[0282] With respect to the present invention, there are several key design points when adapting the present invention for continuous blood glucose monitoring (CGM) from a smart insole **2026**A with a single optical sensor **2028**A, a smart insole **2026**B with a dual optical sensor **2028**B, or a smart insole **2026**C with a triple optical sensor **2028**C, as follows:

[0283] 1. Use reflective-mode optical sensor(s) inside the top surface of plantar arch support or metatarsal arch supports snugly up against sock/skin/foot (in arch supports eliminate body weight issues bending PPG and distorting light path of photons towards the foot and reflected back at the photodetectors).

[0284] 2. Use larger near infrared (NIR) or mid infrared (MIR) or both (a.k.a. multi-wavelength) LEDs to generate more NIR and MIR photons to enhance signal-to-noise-ratio (SNR).

[0285] 3. Use larger near infrared (NIR) or mid infrared (MIR) or both (a.k.a. multi-wavelength) photodetectors to capture more NIR and MIR photons to enhance signal-to-noise-ratio (SNR).

[0286] 4. Use a convex aspheric lens on top of the optical sensors **2010** to direct long wavelength NIR and MIR photons at sock/skin/foot, and direct shorter wavelength light (e.g. visible) away from photodetectors, such that the SNR improves.

[0287] 5. Use edge computing/machine learning (ML) inside the smart insole to accurately calculate blood glucose quickly.

[0288] 6. A single optical sensor can be used, but dual or triple may be superior from an accuracy, averaging, and redundancy point of view.

Optical Sensor Lens Design

[0289] FIG. **30** depicts a simplified cross-sectional diagram of incident light through a foot/sock interface that is collected by a photodetector in an optical sensor **2010**. An example of a lens on the optical sensor **2010** may be a convex, aspheric curvature lens, as shown in FIG. **31** which optimizes performance by converging to a diffraction-limited focused spot. FIG. **32** depicts a simplified cross-sectional view of the various insoles **2026**A, **2026**B, **2026**C in accordance with the various embodiments of the present invention, including optical sensors having added convex aspheric lenses **2044**. Larger optical sensors, with larger area LEDs, multiple LEDs with different wavelengths, and larger area photodetectors and multiple photodetectors for different photon capture may enhance the signal-to-noise ratio.

[0290] While embodiments described herein include convex aspheric lenses, it will be apparent to one skilled in the art, after reading this specification, that embodiments can include any suitable optical element, including one or more refractive optical elements, diffractive optical elements, reflective optical elements, metasurface-based optical elements, and the like. For example, lenses may include mirrors, off-axis parabolic elements, diffractive optical elements (DOE), Fresnel zone plates, reflective lenses, refractive lenses, prisms, holographic elements, metalenses and metasurfaces.

[0291] Finally, FIG. **33** depicts a table of optical sensor placement having a summary and additional information related to the present invention.

VO_2 max Estimation with Smart Insoles

[0292] VO_2 max, the maximal oxygen uptake capacity can be estimated using smart insoles equipped with optical sensors and motion tracking technology. By analyzing heart-rate response, pulse wave characteristics, and gait dynamics during physical activity, a wearable system can infer cardiovascular fitness levels. Resting and exercise heart rate measurements, in combination with pulse wave transit time and stride efficiency, provide insights into an individual's aerobic capacity. The ability to monitor fluctuations in oxygen saturation during exertion further enhances the accuracy of the estimation, allowing for real-time physiological assessment. While direct gas exchange analysis remains the clinical standard, smart insoles provide a portable and continuous monitoring solution, making them highly valuable for fitness tracking, athletic performance optimization, and endurance training. To ensure reliable and accurate results, motion artifact correction and adaptive physiological modeling are integrated, enabling precise, real-time VO_2 max estimation in everyday and high-performance settings.

[0293] It is to be understood that the disclosure teaches just some exemplary embodiments and that many variations of the invention can easily be devised by those skilled in the art after reading this disclosure and that the scope of the present invention is to be determined by the following claims.

What is claimed is:

1. A method comprising:

displaying, via a touch screen of a computing device, an icon associated with a parameter related to one or both of health and fitness;

receiving, via the touch screen, a first press of the icon that lasts for less than N units of time, wherein N is a positive real number;

displaying via the touch screen, in response to the first press of the icon, historical data for the parameter associated with the icon, wherein the historical data is associated with the user and is based on one or more prior measurements taken by the wearable device and transmitted to the computing device;

receiving, via the touch screen, a second press of the icon that lasts for at least N units of time and at most M units of time, wherein M is a positive real number greater than N; and

transmitting by the computing device, in response to the second press of the icon, a request to the wearable device to (1) take one or more new measurements of the parameter associated with the icon, and (2) transmit the one or more new measurements to the computing device.

2. The method of claim **1** further comprising displaying via the touch screen, in response to the second press of the icon, at least one of the one or more new measurements.

3. The method of claim **1** wherein the parameter is one of body temperature, heart rate, blood pressure, respiratory rate, blood oxygen saturation, or blood glucose.

4. The method of claim **1** wherein the parameter is one of steps taken, traveling speed, distance traveled, or calories burned.

5. The method of claim **1** wherein the one or more prior measurements comprises at least one of a measurement of body temperature, a measurement of heart rate, a measurement of blood oxygen saturation, or a measurement of blood glucose.

6. The method of claim **1** wherein the one or more new measurements comprises at least one of a measurement of body temperature, a measurement of heart rate, a measurement of blood oxygen saturation, or a measurement of blood glucose.

7. The method of claim **1** further comprising processing the one or more new measurements.

8. The method of claim **7** wherein the processing comprises estimating respiratory rate based on one or more heart rate measurements.

9. The method of claim **7** wherein the processing comprises estimating calories burned based on one or more heart rate measurements.

10. The method of claim **7** wherein the processing comprises estimating at least one of systolic blood pressure or diastolic blood pressure based on respective signals from one or more optical sensors.

11. The method of claim **1** wherein the icon is displayed with a color that is based on at least one of: (1) the one or more new measurements for the parameter associated with the icon, or (2) the one or more prior measurements for the parameter associated with the icon.

12. The method of claim **1** wherein the icon is displayed with an orientation that is based on at least one of: (1) the one or more new measurements for the parameter associated with the icon, or (2) the one or more prior measurements for the parameter.

13. The method of claim **1** wherein the icon is animated based on at least one of: (1) the one or more new measurements for the parameter associated with the icon, or (2) the one or more prior measurements for the parameter.

14. The method of claim **1** wherein the icon is displayed within a shape.

15. The method of claim **14** wherein the shape is a two-dimensional projection of a sphere.

16. The method of claim **14** wherein the shape is one of a circle, an ellipse, a square, or a projection of a cube.

17. The method of claim **14** wherein the shape is displayed with a fill color that is based on at least one of: (1) the one or more new measurements for the parameter associated with the icon, or (2) the one or more prior measurements for the parameter associated with the icon.

18. The method of claim **17** wherein a green fill color for the shape is associated with a normal range for the parameter, and wherein a red fill color for the shape is associated with an abnormal range for the parameter.

19. The method of claim **14** wherein the shape is displayed with a size that is based on at least one of: (1) the one or more new measurements for the parameter associated with the icon, or (2) the one or more prior measurements for the parameter associated with the icon.

20. The method of claim **1** further comprising displaying a wellness score that is based on measurements of a plurality of parameters, the plurality of parameters including the parameter associated with the icon.

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