



(51) International Patent Classification:

A43B 3/00 (2022.01) A43B 7/00 (2006.01)

(21) International Application Number:

PCT/EP2021/085859

(22) International Filing Date:

15 December 2021 (15.12.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

LU102323 17 December 2020 (17.12.2020) LU

(71) Applicants: **IEE INTERNATIONAL ELECTRONICS & ENGINEERING S.A.** [LU/LU]; Zone industrielle, 12, rue Pierre Richardot, 6468 Echternach (LU). **ZI-MAFLEXX GMBH** [DE/DE]; 23, Rudi-Dutschke-Str., 10969 Berlin (DE).

(72) Inventors: **MEYER, Tobias**; 27A, rue de la Montagne, 2162 Luxembourg (LU). **THINNES, Martin**; Brunnenstrasse 12, 54311 Trierweiler (DE).

(74) Agent: **BEISSEL, Jean et al.**; Office Freylinger S.A., 234, Route d'Arlon, BP 48, 8001 Strassen (LU).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: METHOD AND SYSTEM TO MONITOR AND ANALYZE HUMAN LOCOMOTION FOR FEEDBACK AND PREVENTION OF PROGRESSIVE DISEASES OR RELATED MEDICAL CONDITIONS

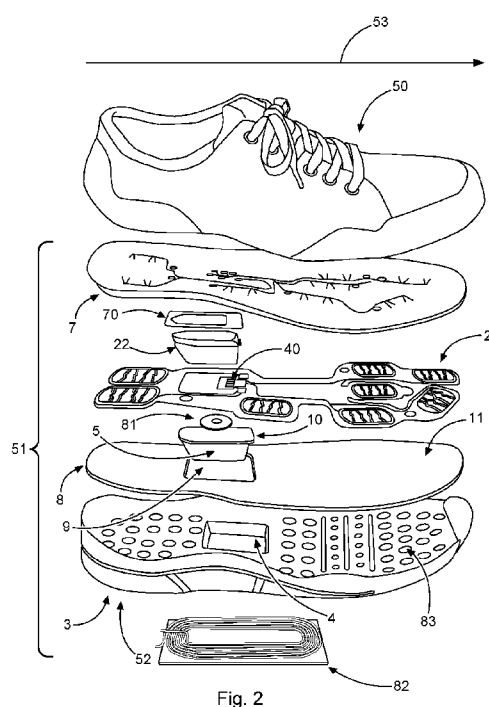


Fig. 2

(57) Abstract: A system for monitoring and analyzing human locomotion comprises a footwear item (1) including a sole structure (51), a plurality of sensors (2) arranged within the sole structure (51), an electronic unit (22) operatively connected to the sensors (2), wherein the sole structure (51) comprises a receiving compartment (4) for receiving and supporting the electronic unit (22), and an electronic communication interface for transferring raw or processed sensor data to an external electronic device (6). The plurality of sensors (2) comprises a proper subset of force-sensitive sensors (12-19) and at least one out of a proper subset of inertial measurement sensors and a proper subset of temperature-sensitive sensors (21). Each of the subsets comprises a at least one sensor if applicable.

Method and System to Monitor and Analyze Human Locomotion for Feedback and Prevention of Progressive Diseases or Related Medical Conditions

Technical field

[0001] The invention relates to a system for monitoring and analyzing human locomotion and/or body posture, the system comprising a footwear item, and a method of using such system.

Background of the Invention

[0002] In the field of footwear design it is known to furnish a footwear article with a sensor system for sensing parameters related to the person wearing the footwear article. The nature of the employed sensors depends on the application.

[0003] By way of example, WO 2013/182633 A1 describes a pressure sensor, e.g. for being arranged in the sole structure of an article of footwear, for measuring a pressure exerted by the wearer's foot. The pressure sensor has one or more pressure-sensing cells. Each cell has a first flexible carrier film and a second flexible carrier film. The first and second carrier films are attached to one another by a spacer film having an opening. A plurality of first electrodes formed as resistive electrodes is arranged on the first carrier film, and a plurality of second electrodes is arranged on the second carrier film. The plurality of first electrodes has a first group of electrodes and a second group of electrodes. The first and second groups of electrodes are arranged so as to interdigitate with delimiting gaps there between. One or more electrically insulating overprints are arranged on the first carrier film so as to cover the gap. The plurality of first electrodes and the plurality of second electrodes are arranged in facing relationship with each other in the opening in such a way that the first and second electrodes may be brought into contact with one another when pressure is exerted on the pressure-sensing cell and that contact areas between the first and second electrodes increase with increasing pressure. A pressure-dependent cell resistance of the pressure-sensing cell is based on a size and/or shape of the one or more electrically insulating overprints. The pressure sensor may comprise a trough-shaped receptacle for an electronic control module. The electronic control circuit may be arranged in a cavity or well of the midsole and is configured for wirelessly transmitting the collected pressure data.

[0004] Further, a film-type pressure sensor e.g. for an article of footwear is known from WO 2013/000728 A1. The film-type pressure sensor includes a carrier structure including a first carrier film, a second carrier film and a spacer film arranged between the first and second carrier films. One or more pressure-sensing cells are disposed in the carrier structure, each of which includes an electrode arrangement for producing an impedance change in response to a compressive force. An electrical interface is provided for mechanically and electrically connecting the pressure sensor to an evaluation circuit, wherein some terminals of the interface are connected with the electrode arrangements of the cells so as to allow them to be read out, such that one or more electrical components interconnect at least two of the terminals in pairs so as to form a combination of terminal pair impedances that represents uniquely coded identifying information relating to the pressure sensor. The coded identifying information is readable by the evaluation circuit before triggering the film-type pressure sensor.

[0005] Moreover, US 10,314,361 B2 proposes a footwear having a sensor system. The sensor system comprises a plurality of first force sensors that is connected to a first insert member engaged with a first sole structure, and is configured to sense a force exerted on the first insert by a foot of a user. The first force sensors include a first phalange sensor, a first metatarsal sensor, a fifth metatarsal sensor, and a heel sensor. The sensor system is operably connected to a communication port. Performance data is collected by the system and can be transferred for further use via the communication port. The shoe may contain an electronic module configured to gather data from the sensors. The module may also transmit the data to an external device for further processing. Users can use the collected data for a variety of different uses or applications. The footwear may contain a well located in the sole structure that is configured for removably receiving the electronic module. The well may have a communication port connected with the sensors and configured for communication with the module.

[0006] A medical application of a sensor system-furnished footwear article is described in US 5,929,332 A, in which a sensor shoe for monitoring the condition of a foot is provided. The sensor shoe is particularly suited for diabetics. The sensor shoe is attached to a power source for sensing conditions of a foot positioned within the sensor shoe. The sensor shoe includes a base, a foot receiving portion

extending from the base and an inner sole positioned within the foot receiving portion and atop the base. The inner sole includes a plurality of sensors positioned about an area of the inner sole for sensing conditions within the foot receiving portion and generating signals representative of the sensed conditions. Conditions may include temperature, moisture, or texture changes in the skin on the foot of the shoe wearer. A microcomputer is connected to receive the generated signals from the plurality of sensors and to analyze the signals to determine if a critical situation exists. A medication reservoir containing medication therein is connected to the microcomputer for releasing the medication upon a determination by the microcomputer that a critical situation exists. The sensor shoe comprises a digital display having a light emitting diode positioned on the outer side of the foot receiving portion, and connected to the microcomputer for displaying a message indicative of the conditions analyzed by the microcomputer. The display includes an alarm for indicating a condition requiring attention.

Object of the invention

[0007] It is an object of the invention to provide a sensor system-equipped footwear item with improved health monitoring capability for improved health analysis.

General Description of the Invention

[0008] In one aspect of the present invention, the object is achieved by a system for monitoring and analyzing human locomotion, in particular for supporting a medical diagnosis.

[0009] The system comprises a footwear item including a sole structure for supporting a foot from below and an upper arranged atop, by which a chamber is defined for receiving the foot. Further, the system includes a plurality of sensors arranged within the sole structure, and an electronic unit that is operatively connectable to the sensors for at least receiving sensor data. The sole structure comprises a receiving compartment for receiving and directly or indirectly supporting the electronic unit. Moreover, the system comprises an electronic communication interface that is operatively connectable to the electronic unit for transferring raw or processed sensor data to an external electronic device.

[0010] In accordance with the invention it is proposed that the plurality of sensors comprises a proper subset of force-sensitive sensors and at least one out of a proper subset of inertial measurement sensors and a proper subset of temperature-sensitive sensors, wherein each of the subsets comprises at least one sensor if applicable. In other words, each of the subsets included in the plurality of sensors comprises at least one sensor. In an alternative variant, the plurality of sensors comprises a proper subset of temperature-sensitive sensors and at least one proper subset of inertial measurement sensors, wherein each of the subsets comprises at least one sensor.

[0011] The term “footwear item”, as used in this patent application, shall particularly be understood to encompass, without being limited to, a shoe, a boot, a sandal, and, in particular, a comfort shoe, a medical shoe, an orthopedic shoe, a health shoe and a diabetic’s shoe. The term “proper subset”, as used in this patent application, shall particularly be understood in its mathematical meaning. It will further be noted that the temperature-sensitive sensors according to the present invention are provided for the measurement of local temperature, i.e. the temperature in the vicinity of a foot inserted into the footwear. In other words the temperature refers to localized temperature at specific defined areas/spots beneath the foot, not the environmental temperature. This temperature at specific areas beneath the foot may provide reliable information e.g. about an inflammation in the area which can be an indicator for a beginning ulceration and/or about a harmful environment for the foot, since high temperature (especially in a humid environment) is bad for the skin, especially for people with a diabetic foot syndrome.

[0012] The proposed system can enable to measure and analyze physiological parameters of a user. The physiological parameters may comprise, without being limited to, human locomotion, specifically human gait, body posture, postural sway and local temperature. By the proposed sensor fusion approach, a substantial reduction of an uncertainty can be accomplished towards more accurate, more complete, and more dependable data sets. The provision of such improved data sets can enable or at least facilitate an automatic preparation of analysis reports containing suggestions for improvements and an indication of a need for medical attention. The automatic preparation of analysis reports may be accomplished, for

instance, by use of an appropriate artificial intelligence (AI) device such as a trained artificial neural network.

[0013] A combined measurement of plantar pressure and inertial forces, in a synchronized manner, in order to detect changes in human locomotion, posture and/or postural sway caused by slow progressive diseases and related medical conditions combined with an automated data analysis can serve as a novel and innovative tool for medical treatment, and can for instance be capable of

- performing a detailed activity analysis;
- monitoring high-risk plantar pressure sites underneath the foot to prevent a development of pressure ulcers by detecting high pressure events, detecting continuous low pressure events for extended periods of time (e.g. sitting, standing, etc.), recommending offload cycles/activities, providing feedback on changes in gait, and monitoring lifetime of footwear;
- performing movement analysis to provide feedback for balance;
- recording gait-related data for analysis and extraction of relevant tempo-spatial gait metrics and parameters; and
- performing movement analysis to provide optional feedback for ground contact through haptic, audio, video or electrical stimulation.

[0014] The addition of temperature-sensitive sensors close to the user's foot further can expedite an analysis of foot-related changes, such as blood circulation, inflammation, etc., over time, and, by that, can enable a superior medical feedback system.

[0015] Adding information of temperature-sensitive sensors, positioned close to/beneath the foot or in proximity of the foot sole, in the described system can allow to monitor blood circulation in the foot as a general condition of the user, can be related to applied pressure to the foot sole, can provide a way to detect changes over time pointing to starting implications due to progressing medical conditions (e.g. diabetic foot syndrome). Further, monitoring the actual temperature at (or close to) the user's foot sole can be enabled to obtain a comparison between the left and the right foot, and potential variations in temperature profiles between both feet can be detected. Then, locally rising temperature zones in high-risk pressure areas can be detected, which can be a first indicator of an inflammation as a first step to a beginning ulceration of the foot.

[0016] Preferably, the sensor data are available in digital form at least before transferring them to the external electronic device.

[0017] Preferably, the electronic communication interface that is operatively connectable to the electronic unit for transferring raw or processed sensor data to an external electronic device is configured for wireless transmission of the sensor data to the external electronic device. By that, an easy-to-handle data transfer with a large degree of freedom for the user of the footwear item can be accomplished.

[0018] The proposed system can beneficially contribute in support to

- prevent a development of foot ulcers and lesions in humans due to sensory loss of feeling caused by progressive neurological disorders, in particular to prevent the development of diabetic foot syndromes;
- support users with locomotion disorders (e.g. shaking, tremoring, bradykinesia, rigidity, gait freeze, postural instability, etc.) to maintain independency and to achieve an as normal as possible gait;
- provide support for postural stability to increase confidence and safety while walking;
- provide support for evaluating a risk of falling (e.g. for elderly people, Parkinson's patients, etc.)
- provide optional feedback during safe walking training by audio, video and/or sensorial means (e.g. electrical stimulation, haptic feedback, etc.) in order to cope with sensory loss of feeling in general;
- promote a healthy and more active lifestyle; and
- support national healthcare systems by decreasing overall treatment expenses and staff time allocation (e.g. by preventing amputations, etc.).

[0019] The present invention may serve as a preventive measure addressing several degrees of medical prevention, in particular for diabetic cases applications. Here, the main objective is to keep the diabetics' feet save, to early detect a developing neuropathy and to prevent/detect a formation of ulcers on the feet in order to avoid amputation of the foot or to, at least, postpone such implications as far as possible.

[0020] In general terms, the proposed system can serve to address several levels of medical prevention. These can be for example:

1. Primary prevention level

Using means aiming to prevent a disease or injury before it even occurs. The present invention can support this level by preventing exposures to hazards that cause disease or injury, altering unhealthy or unsafe behavior that can lead to disease or injury, and by enabling to continue an unobstructed lifestyle in the case complications due to disease or injury should occur. Here, examples may include education about healthy and safe habits, such as regular exercise, periodic gait analysis and foot care.

2. Secondary prevention level

Using means aiming to reduce the impact of a disease or injury that has already occurred. The proposed invention can support, by early detecting and treating, a disease or injury in an early stage so as to halt or slow down its progress. Further, early detection can help to encourage affected persons to follow personal strategies to prevent reinjury or recurrence, and to prevent long-term problems. Here, examples may include

- providing regular data analysis and feedback to detect disease-related developments in its earliest stages (e.g. gait change for diabetic patients);
- performing screening tests by recording and analyzing pictures taken of sensible areas (e.g. foot sole by diabetic patients with neuropathy to avoid pressure ulcer forming); and
- daily exercise and activity programs to maintain physical condition

3. Tertiary prevention level

Using means aiming to reduce the impact of an existing medical condition or injury with long-term effects. The described invention can support users with long-term, often complex health problems and injuries (e.g. chronic diseases, permanent impairments) by improving as much as possible their ability to stay active, hence improving the general quality of life and furthermore the overall life expectancy. Here, examples may include

- executing diabetic rehabilitation programs;
- performing chronic disease management programs (e.g. for diabetes, etc.); and
- social support groups allowing to share well-being strategies and progress.

[0021] In preferred embodiments of the system, the sole structure comprises at least an inner sole, an intermediate sole and an outer sole, wherein the intermediate sole is arranged between the outer sole and the inner sole. Further, the plurality of sensors is attached to or close to an upper surface of the intermediate sole. In particular in case of the plurality of sensors comprising a proper subset of temperature-sensitive sensors, this configuration provides a good compromise between mechanical protection, for instance from wear, and a position as close as possible to the user's foot for achieving a low systematic error of measurement. Further, the proposed design of the intermediate sole and the plurality of sensors attached thereto can be implemented in the footwear item in a removable manner in order to facilitate recycling of the footwear item after its lifetime by avoiding mixed electronic waste and an easy separation of electronic parts and footwear item parts.

[0022] In preferred embodiments, the system further comprises an electronic unit housing having at least a bottom wall and side walls, for receiving and directly supporting the electronic unit, wherein an outer shape of at least a bottom portion of the electronic unit housing is adapted to match the receiving compartment of the sole structure. In this way, mechanical protection and stable support can be provided for the electronic unit without compromising a user's comfort or usual gait by adding a height offset to the foot placed inside the footwear item, which may alter a height difference between heel and toes or the balance point of foot.

[0023] Preferably, the receiving compartment is formed at least for the most part within the outer sole, and the intermediate sole comprises an opening providing access for the electronic unit housing to the receiving compartment, wherein the shape of a rim of the opening is adapted to match the shape of a cross-sectional area of an upper portion of the electronic unit housing. The expression "for the most part", as used in this application, shall particularly be understood as a portion of equal to or more than 70%, more preferably more than 80%, and, most preferably, more than 90% of the receiving compartment, and shall also encompass the case of a portion of 100%, i.e. that the receiving compartment is formed completely within the outer sole. In this way, a particularly stable solution for supporting and fixing the electronic unit within the footwear item can be provided.

[0024] Further preferably, the system includes a housing lid that is attached to a top portion of the electronic unit housing and is designed so as to project beyond the side walls in the lateral direction. In an assembled state, the housing lid is arranged above the opening of the intermediate sole, with a bottom surface of the housing lid being in contact with an upper surface of the intermediate sole. By that, the housing lid can provide a sandwich-like arrangement of the intermediate sole, potentially some sensors of the plurality of sensors and the electronic unit housing for achieving a strong relative mechanical hold between the sandwiched components.

[0025] In preferred embodiments, the system further includes a scanning and coding device. The scanning and coding device comprises a plurality of input lines that are fixedly electrically connected to each sensor of the plurality of sensors. Further, the scanning and coding device includes at least one output line that is electrically connectable to the electronic unit. The scanning and coding device is configured to operatively connect the electronic unit to the sensors by automatically establishing a predetermined sequence of electrical connections between the output line or the output lines and selected input lines. The scanning and coding device can allow for a larger number of sensors to be arranged within the sole structure despite existing space constraints. Further, the scanning and coding device includes coding means and is configured, by the coding means, to add a coding to the received sensor data for uniquely identifying the respective sensor that is connected to the electronic unit when sensor data are received.

[0026] The phrase “being configured to”, as used in this application, shall in particular be understood as being specifically programmed, laid out, furnished or arranged.

[0027] Preferably, the scanning and coding device is configured to establish the predetermined sequence of the electrical connections automatically and periodically, which can enable an automatic or a semi-automatic operation of the system.

[0028] The coding means of the scanning and coding device may comprise a memory chip for adding a digital coding. Alternatively, the coding means may comprise one or more coding resistors that are electrically connectable to the respective sensor when sensor data are received.

[0029] Preferably, the electronic control unit comprises a processor unit that forms an integral part of a microcontroller. Microcontrollers that are suitably equipped and include, for instance, a processor unit, a digital data storage unit, a microcontroller system clock, a multiplexer switching unit and analog-to-digital converters are nowadays readily available in many variations.

[0030] In preferred embodiments, the system comprises at least one external electronic device that is at least configured for receiving raw or processed sensor data by wireless transmission, and is further configured to wirelessly transfer the received raw or processed sensor data to cloud-based data acquisition and cloud-based computational means. This can enable to analyze the received sensor data with powerful computational means, while at the same time options for remote access to the received sensor data or analysis results can be provided, for instance for care service organizations or medical staff. The external electronic device may comprise electronic computational means that are configured for performing at least a preliminary analysis of the received raw or processed sensor data.

[0031] Preferably, the external electronic device is designed as a smartwatch, a smartphone, a tablet computer or a personal computer (PC).

[0032] In preferred embodiments, the system includes cloud-based data acquisition means that are configured for receiving wirelessly transferred sensor data from the external electronic device, and cloud-based computational means that are configured for analyzing the received sensor data and for providing an output signal that is indicative of a medical condition of the foot received in the chamber of the footwear item. The cloud-based data acquisition means may for instance comprise a computer program for organizing and assigning the received sensor data.

[0033] In preferred embodiments of the system, at least one sensor of the plurality of sensors includes a transponder for wirelessly transmitting information that is unique for at least one property of the at least one sensor. Further, the system comprises a transponder module that is configured for at least receiving the information transmitted by the transponder of the at least one sensor.

[0034] The term “property”, as used in this patent application, shall particularly be understood to encompass, without being limited to, a sensor type, a serial number and a measurement range.

[0035] The proposed use of a transponder or transponders and a transponder module can allow for an error-free detection of the sensors and assignment of their data. Further, it can enable a removable design of the electronics parts, i.e. the plurality of sensors, the electronic unit and the electronic communication interface, such that they can be used as well in a different footwear item without the risk of false positive alerts or an incorrect analysis of the user's health.

[0036] Suitable transponder or transponders and transponder modules are commonly available and may for instance be based on the well-known Near Field Communication (NFC) technology. Using such NFC technology, it is possible for e.g. a temperature sensor to communicate with the transponder module and transmit the detected temperature signal to the transponder module. It will be noted that a NFC interface may also being utilized to power the temperature sensor electronics parts to start/enable communication.

[0037] Preferably, the inner sole includes a transponder for transmitting to a transponder module an information that is unique for at least one property of the inner sole. Furthermore, it is also conceivable within the scope of the present invention that a medically prescribed insole can be used as inner sole. The NFC interface may e.g. be used to read out information stored in the insole like insole type, age, usage, etc... data which can be used to optimize the data analysis and provide better support to the customer (e.g. need of new insoles, use of wrong insoles, etc).

[0038] This can allow for

- automatically detecting an inner sole/insole and/or a change of the inner sole/insole, respectively, and accounting for possible inner sole/insole-related effects on the sensor data;
- controlling whether medically prescribed insoles are in fact being used;
- providing advice on when to replace the insole at the end of its lifetime.

[0039] In preferred embodiments, the system further includes a permanent digital data storage unit that is operatively connectable to the electronic unit, and that is

further configured at least for storing at least one of received sensor data and data representing characteristic properties of components of the system.

[0040] The permanent digital data storage unit can allow for storage of traceability information for the complete system, such as general information, serial number(s), production date(s), and so on.

[0041] Preferably, the receiving compartment is arranged in a region between 55% and 65% of the overall sole structure length of the footwear item, measured from the front of the outer sole. In this region, a compression force exerted by a user of the footwear item is usually lower than average. For a normal foot, this region is located beneath the arch of the foot, so that the electronic unit can be kept at a particularly protected location within the footwear item.

[0042] Preferably, the system further includes an inductive charging unit comprising at least one charging coil/antenna (secondary coil/antenna) and at least one electrical energy storage device that is electrically connectable to the charging coil/antenna and to the electronic unit. Besides the benefit of relieving the need to have to move any electronic part for charging and thus the ease of use can be improved, the needs of an expected main user group are also addressed, which also includes the elderly with potentially multiple health and motoric impairments.

[0043] In another aspect of the invention, a method of using an embodiment of the system disclosed herein is provided. The method includes at least the following steps:

- operating the external electronic device for receiving a plurality of sensor data,
- operating the external electronic device for wirelessly transferring the received sensor data to the cloud-based data acquisition and computational means,
- operating the cloud-based data acquisition means for receiving and processing the transferred sensor data, and
- operating the cloud-based computational means for monitoring and analyzing human locomotion based on the transferred and processed sensor data.

[0044] The benefits described in context with the system disclosed herein apply to the proposed method to the full extent.

[0045] These and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter.

[0046] It shall be pointed out that the features and measures detailed individually in the preceding description can be combined with one another in any technically meaningful manner and show further embodiments of the invention. The description characterizes and specifies the invention in particular in connection with the figures.

Brief Description of the Drawings

[0047] Further details and advantages of the present invention will be apparent from the following detailed description of not limiting embodiments with reference to the attached drawing, wherein:

Fig. 1 schematically illustrates a system for monitoring and analyzing human locomotion in accordance with the invention, including a footwear item designed as an orthopedic shoe,

Fig. 2 is a schematic exploded view of the system pursuant to Fig. 1,

Fig. 3 is a schematic view onto the intermediate sole of the footwear item pursuant to Fig. 2,

Fig. 4 schematically shows a bottom side of the intermediate sole of the footwear item pursuant to Fig. 3 with an installed electronic unit housing,

Fig. 5 is a detailed view of the bottom side of the intermediate sole pursuant to Fig. 4,

Fig. 6 is a schematic view onto the fully assembled intermediate sole of the footwear item pursuant to Fig. 2 and 3,

Fig. 7 schematically shows the electronic unit of the system in a plan view, and

Fig. 8 schematically shows the electronic unit pursuant to Fig. 7 in a perspective side view.

In the different figures, the same parts are always provided with the same reference symbols or numerals, respectively. Thus, they are usually only described once.

Description of Preferred Embodiments

[0048] Fig. 1 schematically illustrates a system for monitoring and analyzing human locomotion in accordance with the invention. The system includes a footwear item 1 designed as an orthopedic shoe. The system further includes a plurality of

sensors 2 (Fig. 2) arranged within the sole structure 51, which will be described in detail hereinafter.

[0049] The system comprises an external electronic device 6 (Fig. 1) that is configured for receiving raw or processed sensor data by wireless transmission, for instance by using Bluetooth® Low Energy (BLE) technology. The external electronic device 6 may be designed as a smartwatch to be worn by the user of the footwear item 1 or as a user's smartphone. The external electronic device 6 is further configured to wirelessly transfer the received raw or processed sensor data to cloud-based data acquisition means 90 and cloud-based computational means 91. The cloud-based data acquisition means 90 and cloud-based computational means 91 may form part of the system itself, or they may be cloud-based data acquisition and cloud-based computational means that are outside of the system and are, for instance, owned by a provider of cloud-based computer services.

[0050] The external electronic device 6 comprises computational means that are configured to carry out a preliminary analysis of the received raw or processed sensor data, and, based on the results of the analysis, to provide an output signal indicating a determined medical condition out of a plurality of predefined medical conditions.

[0051] The cloud-based data acquisition means 90 are configured for receiving wirelessly transferred sensor data from the external electronic device 6. The cloud-based computational means 91 are configured for analyzing the received sensor data in more detail and for providing an output signal that is indicative of a medical condition of the foot received in the chamber of the footwear item 1.

[0052] Fig. 2 is a schematic exploded view of the system pursuant to Fig. 1. The footwear item 1 comprises a sole structure 51 for supporting a foot from below, and an upper 50 arranged atop the sole structure 51 and attached to it. The sole structure 51 and the upper 50 define a chamber for receiving the foot of a user or wearer of the footwear item 1. The plurality of sensors 2 and electronic components are arranged within the sole structure 51.

[0053] The sole structure 51 comprises an inner sole 7, which may be formed as a medical insole, an intermediate sole 8 and an outer sole 3, which comprises a plurality of recesses 83 for adjusting a stiffness of the sole structure 51, as is well

known in the art. The intermediate sole 8 is arranged between the outer sole 3 and the inner sole 7. The plurality of sensors 2 is attached to an upper surface 11 of the intermediate sole 8, for instance by applying an adhesive. The plurality of sensors 2 is designed in a generally planar arrangement and can readily be formed to match the upper surface 11 of the intermediate 8 sole. Each sensor of the force-sensitive sensors may comprise two flexible layers made from a flexible polymeric material, as is well known in the art.

[0054] The plurality of sensors 2 is best shown in Fig. 3, which is a schematic view onto the intermediate sole 8 of the footwear item 1 pursuant to Fig. 2. In this specific embodiment, the plurality of sensors 2 comprises a proper subset of eight force-sensitive sensors 12-19 and a proper subset of temperature-sensitive sensors 21, one of which is exemplarily indicated in Fig. 3. In other embodiments, the plurality of sensors 2 may include the proper subset of force-sensitive sensors 12-19 and a proper subset of inertial measurement sensors either in addition to or replacing the proper subset of temperature-sensitive sensors 21.

[0055] The system comprises an electronic unit 22 (Fig. 2) that is operatively connectable to the sensors for receiving data from the plurality of sensors 2. To this end, the system includes a scanning and coding device 40. The scanning and coding device 40 includes a plurality of input lines that are fixedly electrically connected to each sensor of the plurality of sensors 2 by electrically conductive tracks 20 (Fig. 3). Further, the scanning and coding device 40 comprises a plurality of output lines that are fixedly electrically connected to an array of electrical contacts 41. Fig. 7 schematically shows the electronic unit 22 of the system in a plan view. The electronic unit 22 is furnished with a plurality of electrical contacts 38 designed as pins (or pads, springs, etc.) whose distances are adapted to the array of electrical contacts 41. The electronic unit 22 is furnished with three straight side walls 23, 24, 25 and one concave-shaped rear side wall 26. The plurality of electrical contacts 38 of the electronic unit 22 is arranged at the straight side wall 24 facing the front in an assembled state.

[0056] Fig. 8 schematically shows the electronic unit 22 pursuant to Fig. 7 in a perspective side view. In this view it is apparent that a bottom wall 27 of the electronic unit 22 is connected to edges of three straight side walls 29, 30, 31 and also to an additional straight side wall 32. In the assembled state, all straight

sidewalls 29, 30, 31, 32 are generally oriented vertically. A top wall 28 of the electronic unit 22 is connected to edges of the three straight side walls 22, 23, 24 opposite to the bottom wall 27. The top wall 28 has a larger size than the bottom wall 27. The excess area overlaps an arcuate extension 34 of the electronic unit 22, whose ends 35, 36 are basically triangular. The arcuate extension 34 is firmly attached to and spans between edges of the straight side walls 29, 31 that are joined to edges of the additional straight wall 32. This results in a well-defined area 37 below the arcuate extension 34. The arcuate extension 34 features a latching hook 80 for secure support.

[0057] The system further comprises a permanent digital data storage unit (not shown) that is operatively connected to the electronic unit 22. The digital data storage unit is configured for storing received sensor data and data representing characteristic properties of components of the system, and may form an integral part of the electronic unit 22.

[0058] The system is further equipped with an electronic communication interface (not shown) that is operatively connected to the electronic unit 22 for transferring raw or processed sensor data to the external electronic device 6, using a wireless communication protocol. In this specific embodiment, just like the external electronic device 6, the electronic communication interface may be based on Bluetooth® Low Energy (BLE) technology and may be an integral part of the electronic unit 22.

[0059] The electronic unit 22 may be powered by an electrical energy storage device (not shown) that is electrically connected to the electronic unit 22 and to a charging coil 81 (Fig. 2), both of which form part of the system. The electrical energy storage device can be charged by inductively coupling the charging coil 81 and a transmission coil 82 of an inductive charging unit that is external to the system.

[0060] Referring now to Fig. 4, the system comprises an electronic unit housing 5 having a bottom wall 44 and side walls 43, 46, 60 for receiving and directly supporting the electronic unit 22, a housing rim 10 (Fig. 2) formed at the top of the electronic unit housing 5, and a housing lid 70.

[0061] The outer sole 3 comprises a receiving compartment 4 for receiving and indirectly supporting the electronic unit 22 via the electronic unit housing 5. To this end, an outer shape of the bottom wall 44 and the side walls 43, 46, 60 of the

electronic unit housing 5 (Fig. 4) is adapted to match the receiving compartment 4 of the sole structure 51 (Fig. 2) such that a tight fit of the electronic unit housing 5 in the receiving compartment 4 of the outer sole 3 is established in the assembled state of the system.

[0062] The receiving compartment 4 is almost completely formed within the outer sole 3, and is arranged in a region between 55% and 65% of an overall sole structure length of the footwear item 1, measured from the front of the outer sole 3, which is defined by the forward direction 53 indicated in Fig. 2.

[0063] The intermediate sole 8 comprises an opening 9 providing access for the electronic unit housing 5 to the receiving compartment 4, wherein the shape of a rim of the opening 9 is adapted to match the shape of a cross-sectional area of an upper portion of the electronic unit housing 5.

[0064] For installing the electronic unit 22, the electronic unit housing 5 is inserted through the opening 9 of the intermediate sole 8 into the receiving compartment 4 until the housing rim 10 is in contact with the upper surface 11 of the intermediate sole 8. Further, the electronic unit 22 is inserted into the electronic unit housing 5, which also receives the array of electrical contacts 41 and a portion of the scanning and coding device 40 through a housing opening 61 of the electronic unit housing 5. Then, the housing lid 70 may be attached to a top portion of the electronic unit housing 5, namely to the housing rim 10.

[0065] The housing lid 70 is designed so as to project beyond the side walls 43, 46, 60 of the electronic unit housing 5 in the lateral direction, and, in the assembled state, is arranged above the opening 9 of the intermediate sole 8, with a bottom surface of the housing lid 70 being in contact with the upper surface 11 of the intermediate sole 8. Fig. 6 provides a schematic view onto the fully assembled intermediate sole 8 of the footwear item 1.

[0066] By creating a permanent mechanical connection with the housing rim 10, the housing lid 70 supports in stabilizing the plurality of sensors 2 and the scanning and coding device 40, holding in position the electronic unit housing 5, the intermediate sole 8 and the plurality of sensors 2 in a sandwich-like manner.

[0067] In this configuration, the electrical contacts 38 of the electronic unit 22 are electrical connected to the array of electrical contacts 41 of the scanning and coding

device 40, so that the output lines of the scanning and coding device 40 are electrically connected to the electronic unit 22. The scanning and coding device 40 is configured to operatively connect the electronic unit 22 to the sensors of the plurality of sensors 2 by automatically establishing a predetermined sequence of electrical connections between the output line or the output lines and selected input lines. The automatic establishing of the predetermined sequence of electrical connections may be carried out periodically. To this end, the scanning and coding device 40 may be controlled by the electronic unit 22.

[0068] Fig. 4 schematically shows a bottom side of the intermediate sole 8 of the footwear item 1 pursuant to Fig. 2 with an installed electronic unit housing 5. A vertical front side wall 60, the bottom wall 44, vertical side walls 43 and a rear concave-shaped, tilted side wall 46 with the housing opening 61 define a hollow compartment 42 for receiving the electronic unit 22.

[0069] Fig. 5 is a detailed view of the bottom side of the intermediate sole 8 pursuant to Fig. 4, clearly showing a fixing member 39 formed in the rear concave-shaped side wall 46. The fixing member 39 is configured to interlock with the latching hook 80 of the arcuate extension 34 of the electronic unit 22 in the assembled state. The fixing member 39 and the latching hook 80 provide strong hold of the electronic unit 22 at an intended location within the electronic unit housing 5. The concave shape of the tilted side wall 46 provides easy access for inserting and removing the electronic unit 22 to and from the electronic unit housing 5, respectively.

[0070] Optionally, the system may include a transponder module that may form part of the electronic unit 22, and the plurality of sensors 2 and/or the inner sole 7 may each include a transponder for transmitting to the transponder module an information that is unique for properties of the plurality of sensors 2 given by the type of sensor and a serial number, and for a property of the inner sole 7, respectively. The information received by the transponder module can be stored in the permanent digital data storage unit, among others for providing system component traceability.

[0071] While the invention has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be

considered illustrative or exemplary and not restrictive; the invention is not limited to the disclosed embodiments.

[0072] Other variations to be disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word “comprising” does not exclude other elements or steps, and the indefinite article “a” or “an” does not exclude a plurality, which is meant to express a quantity of at least two. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. Any reference signs in the claims should not be construed as limiting scope.

List of Reference Symbols

1	footwear item	29	vertical side wall
2	plurality of sensors	30	vertical side wall
3	outer sole	31	vertical side wall
4	receiving compartment	32	vertical side wall
5	electronic unit housing	34	arcuate extension
6	external electronic device	35	triangular end
7	inner sole	36	triangular end
8	intermediate sole	37	area
9	opening	38	electrical contact
10	housing rim	39	fixing member
11	upper surface	40	scanning and coding device
12	pressure sensor cell	41	electrical contact
13	pressure sensor cell	42	hollow compartment
14	pressure sensor cell	43	vertical side wall
15	pressure sensor cell	44	bottom wall
16	pressure sensor cell	46	concave-shaped side wall
17	pressure sensor cell	50	upper
18	pressure sensor cell	51	sole structure
19	pressure sensor cell	53	forward direction
20	electrically conductive track	60	vertical side wall
21	temperature-sensitive sensor	61	housing opening
22	electronic unit	70	housing lid
23	straight side wall	80	latching hook
24	straight side wall	81	charging coil
25	straight side wall	82	transmission coil
26	concave-shaped side wall	83	outer sole recess
27	bottom wall	90	cloud-based data acquisition means
28	top wall	91	cloud-based computational means

Claims

1. A system for monitoring and analyzing human locomotion, posture or postural sway, comprising
 - a footwear item (1) including a sole structure (51) for supporting a foot from below and an upper (50) arranged atop, by which a chamber is defined for receiving the foot,
 - a plurality of sensors (2) arranged within the sole structure (51),
 - an electronic unit (22) that is operatively connectable to the sensors (2) for at least receiving sensor data, wherein the sole structure (51) comprises a receiving compartment (4) for receiving and directly or indirectly supporting the electronic unit (22),
 - an electronic communication interface that is operatively connectable to the electronic unit (22) for transferring raw or processed sensor data to an external electronic device (6),
- 15 characterized in that the plurality of sensors (2) comprises a proper subset of force-sensitive sensors (12-19) and at least one out of a proper subset of inertial measurement sensors and a proper subset of temperature-sensitive sensors (21), wherein each of the subsets comprises at least one sensor if applicable.
- 20 2. A system for monitoring and analyzing human locomotion, posture or postural sway, comprising
 - a footwear item (1) including a sole structure (51) for supporting a foot from below and an upper (50) arranged atop, by which a chamber is defined for receiving the foot,
 - a plurality of sensors (2) arranged within the sole structure (51),
 - an electronic unit (22) that is operatively connectable to the sensors (2) for at least receiving sensor data, wherein the sole structure (51) comprises a receiving compartment (4) for receiving and directly or indirectly supporting the electronic unit (22),
 - an electronic communication interface that is operatively connectable to the electronic unit (22) for transferring raw or processed sensor data to an external electronic device (6),

characterized in that the plurality of sensors (2) comprises a proper subset of temperature-sensitive sensors (21) and at least one proper subset of inertial measurement sensors, wherein each of the subsets comprises at least one sensor if applicable.

- 5 3. The system as claimed in claim 1 or 2, wherein
 - the sole structure (51) comprises at least an inner sole (7), an intermediate sole (8) and an outer sole (3), wherein the intermediate sole (8) is arranged between the outer sole (3) and the inner sole (7), and
 - the plurality of sensors (2) is attached to or close to an upper surface (11) of
10 the intermediate sole (8).
4. The system as claimed in any one of claims 1 to 3, wherein the system further comprises an electronic unit housing (5) having at least a bottom wall (44) and side walls (43, 46, 60), for receiving and directly supporting the electronic unit (22), wherein an outer shape of at least a bottom portion of the electronic
15 unit housing (5) is adapted to match the receiving compartment (4) of the sole structure (51).
5. The system as claimed in claim 3 or 4, wherein
 - the receiving compartment (4) is formed at least for the most part within the outer sole (3), and
 - 20 - the intermediate sole (8) comprises an opening (9) providing access for the electronic unit housing (5) to the receiving compartment (4), wherein the shape of a rim of the opening (9) is adapted to match the shape of a cross-sectional area of an upper portion of the electronic unit housing (5).
6. The system as claimed in claim 4 or 5, wherein the system further comprises a
25 housing lid (70) that is attached to a top portion of the electronic unit housing (5), and is designed so as to project beyond the side walls (43, 46, 60) in the lateral direction, and, in an assembled state, is arranged above the opening (9) of the intermediate sole (8), with a bottom surface of the housing lid (70) being in contact with an upper surface (11) of the intermediate sole (8).
- 30 7. The system as claimed in any one of the preceding claims, further including a scanning and coding device (40) comprising

- a plurality of input lines that are fixedly electrically connected to each sensor of the plurality of sensors (2),
- at least one output line that is electrically connectable to the electronic unit (22), and

5 - coding means,

wherein the scanning and coding device (40) is configured to operatively connect the electronic unit (22) to the sensors (2) by automatically establishing a predetermined sequence of electrical connections between the output line or the output lines and selected input lines, and, by the coding means, to add a
10 coding to the received sensor data for uniquely identifying the respective sensor (2) that is connected to the electronic unit (22) when sensor data are received.

8. The system as claimed in any one of the preceding claims, wherein the system further comprises at least one external electronic device (6) that is at least
15 configured for receiving raw or processed sensor data by wireless transmission, and is further configured to wirelessly transfer the received raw or processed sensor data to cloud-based data acquisition (90) and cloud-based computational means (91).

9. The system as claimed in claim 8, wherein the system further comprises cloud-
20 based data acquisition means (90) that are configured for receiving wirelessly transferred sensor data from the external electronic device (6), and cloud-based computational means (91) that are configured for analyzing the received sensor data and for providing an output signal that is indicative of a medical condition of the foot received in the chamber of the footwear item (1).

10. The system as claimed in any one of the preceding claims, wherein at least one
25 sensor of the plurality of sensors (2) includes a transponder for wirelessly transmitting information that is unique for at least one property of the at least one sensor, and wherein the system further comprises a transponder module that is configured for at least receiving the information transmitted by the
30 transponder of the at least one sensor.

11. The system as claimed in in any one of the preceding claims, wherein the inner sole (7) includes a transponder for transmitting to a transponder module an information that is unique for at least one property of the inner sole (7).
- 5 12. The system as claimed in any one of the preceding claims, wherein the system further comprises a permanent digital data storage unit that is operatively connectable to the electronic unit (22), and that is further configured at least for storing at least one of received sensor data and data representing characteristic properties of components of the system.
- 10 13. The system as claimed any one of the preceding claims, wherein the receiving compartment (4) is arranged in a region between 55% and 65% of an overall sole structure length of the footwear item (1), measured from the front of the outer sole (3).
- 15 14. The system as claimed any one of the preceding claims, wherein the system further comprises an inductive charging unit comprising at least one charging coil (81) or antenna and at least one electrical energy storage device that is electrically connectable to the charging coil (81) or antenna and to the electronic unit (22).
- 20 15. A method of using the system as claimed in any one of claims 8 to 14, the method comprising at least the following steps:
- operating the external electronic device (6) for receiving a plurality of sensor data,
 - operating the external electronic device (6) for wirelessly transferring the received sensor data to the cloud-based data acquisition (90) and computational means (91),
 - 25 - operating the cloud-based data acquisition means (90) for receiving and processing the transferred sensor data, and
 - operating the cloud-based computational means (91) for monitoring and analyzing human locomotion based on the transferred and processed sensor data.

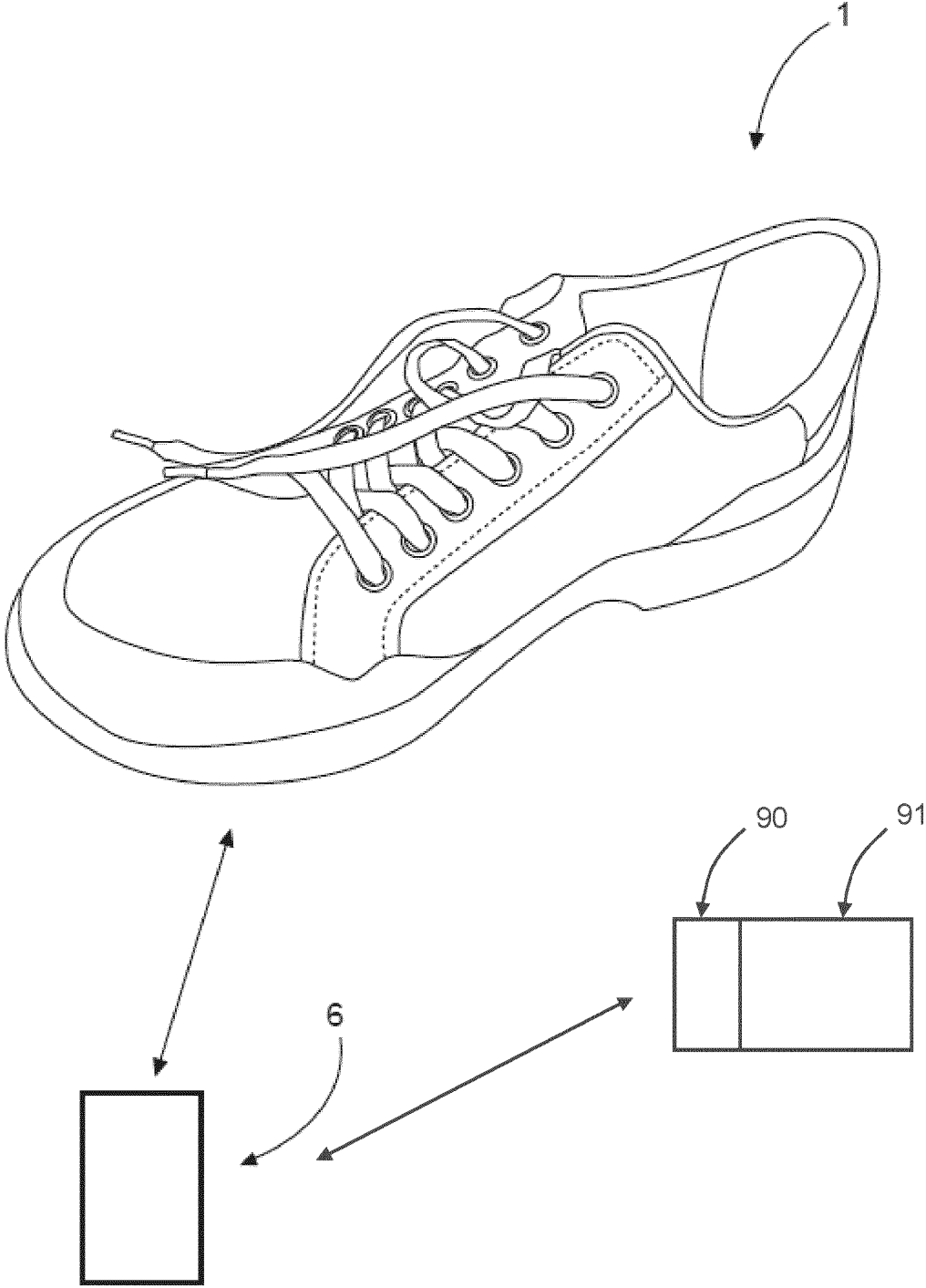


Fig. 1

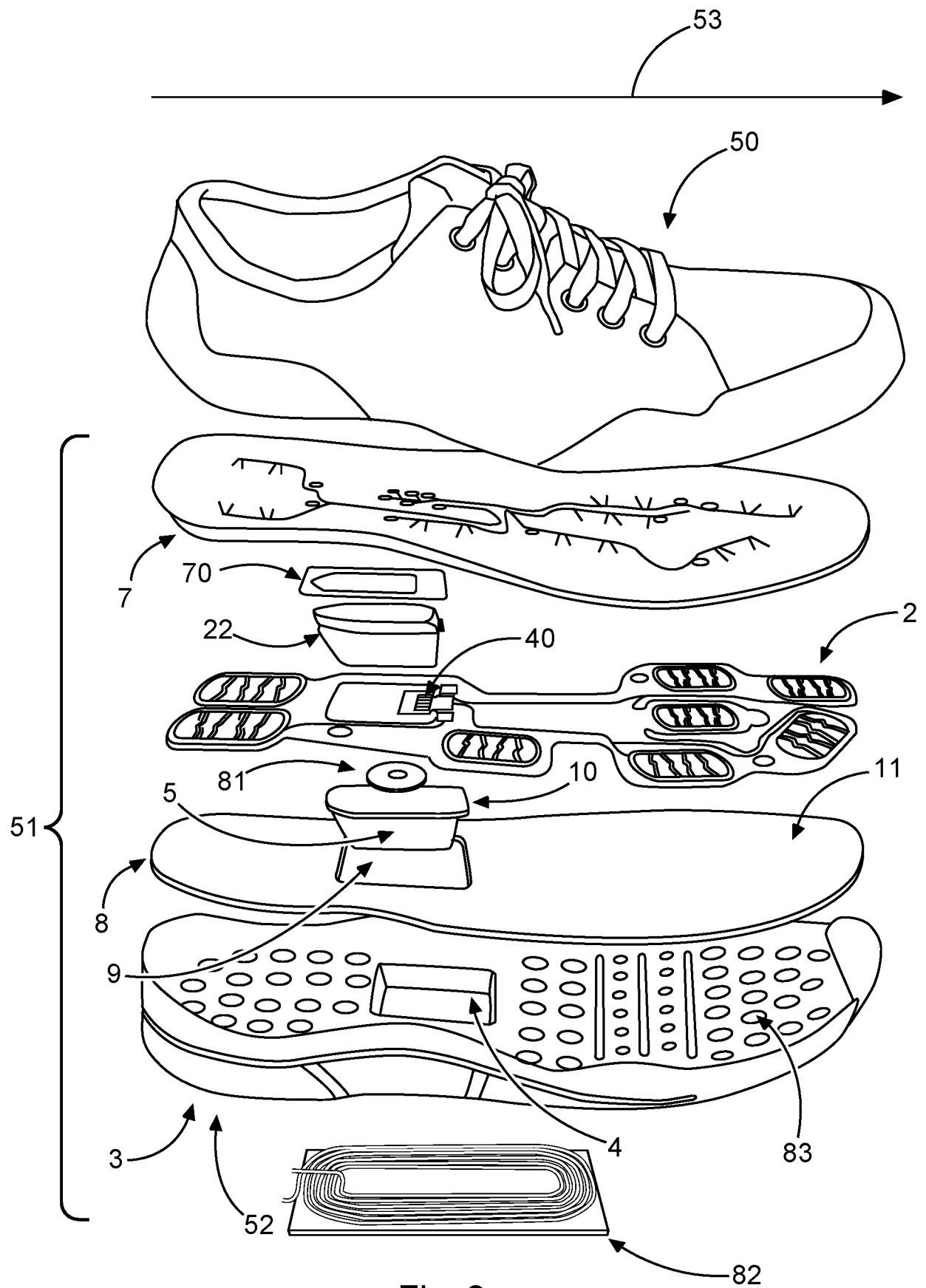


Fig. 2

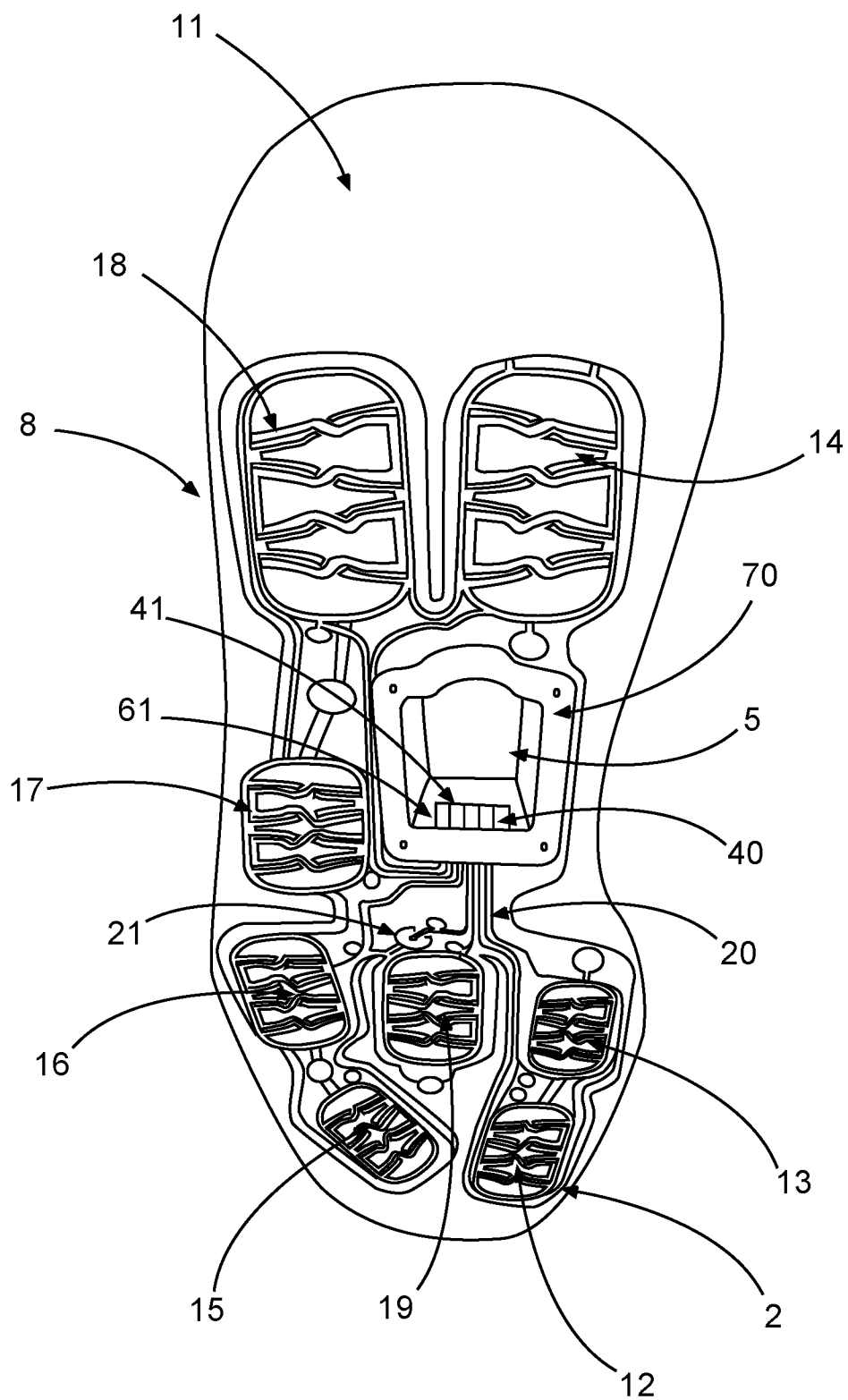


Fig. 3

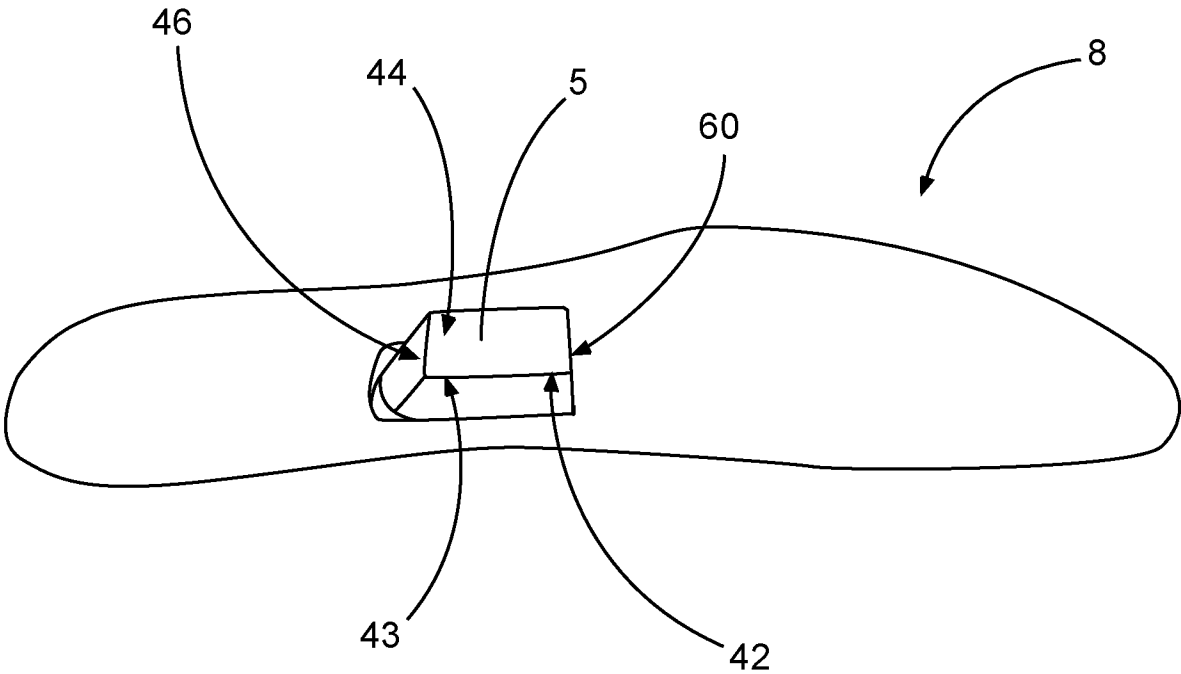


Fig. 4

5/8

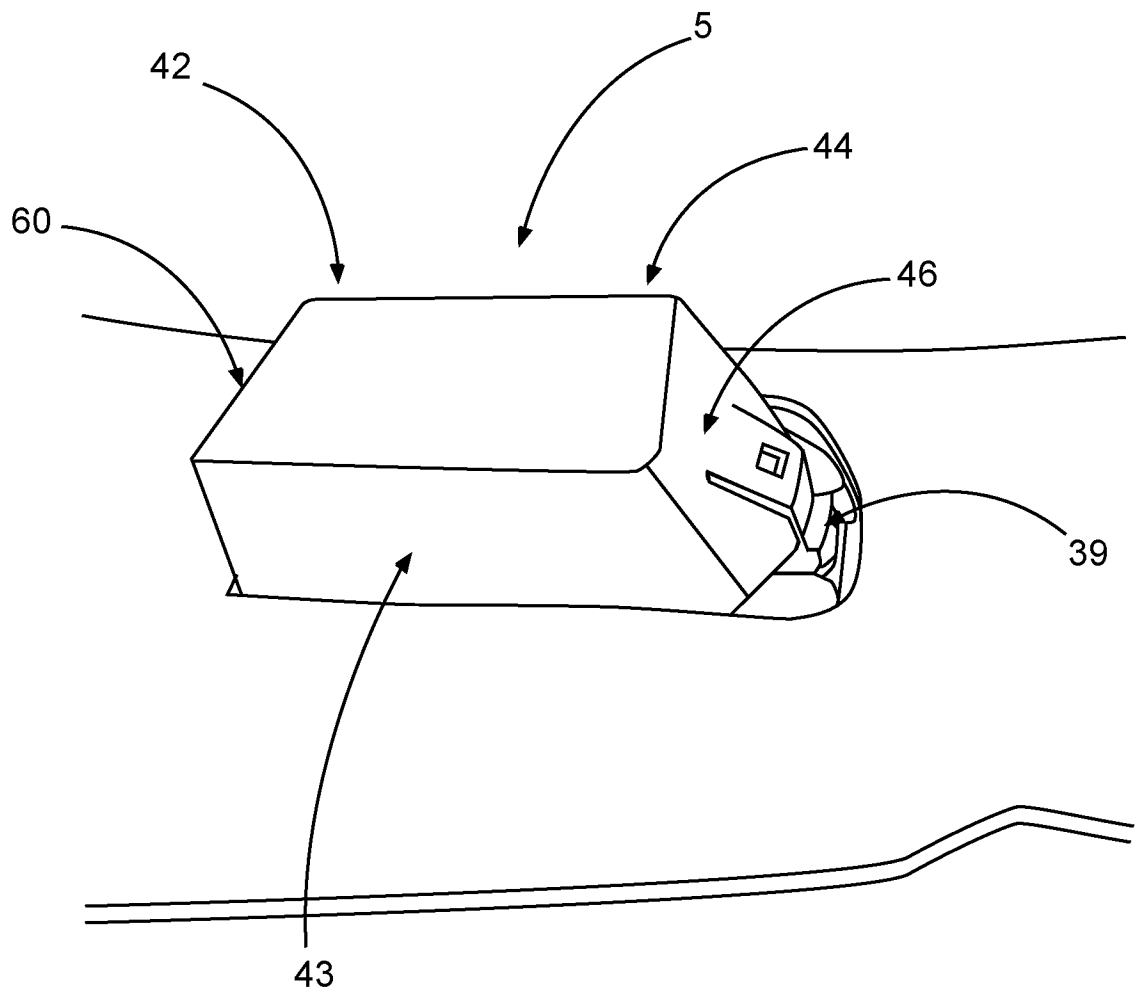


Fig. 5

6/8

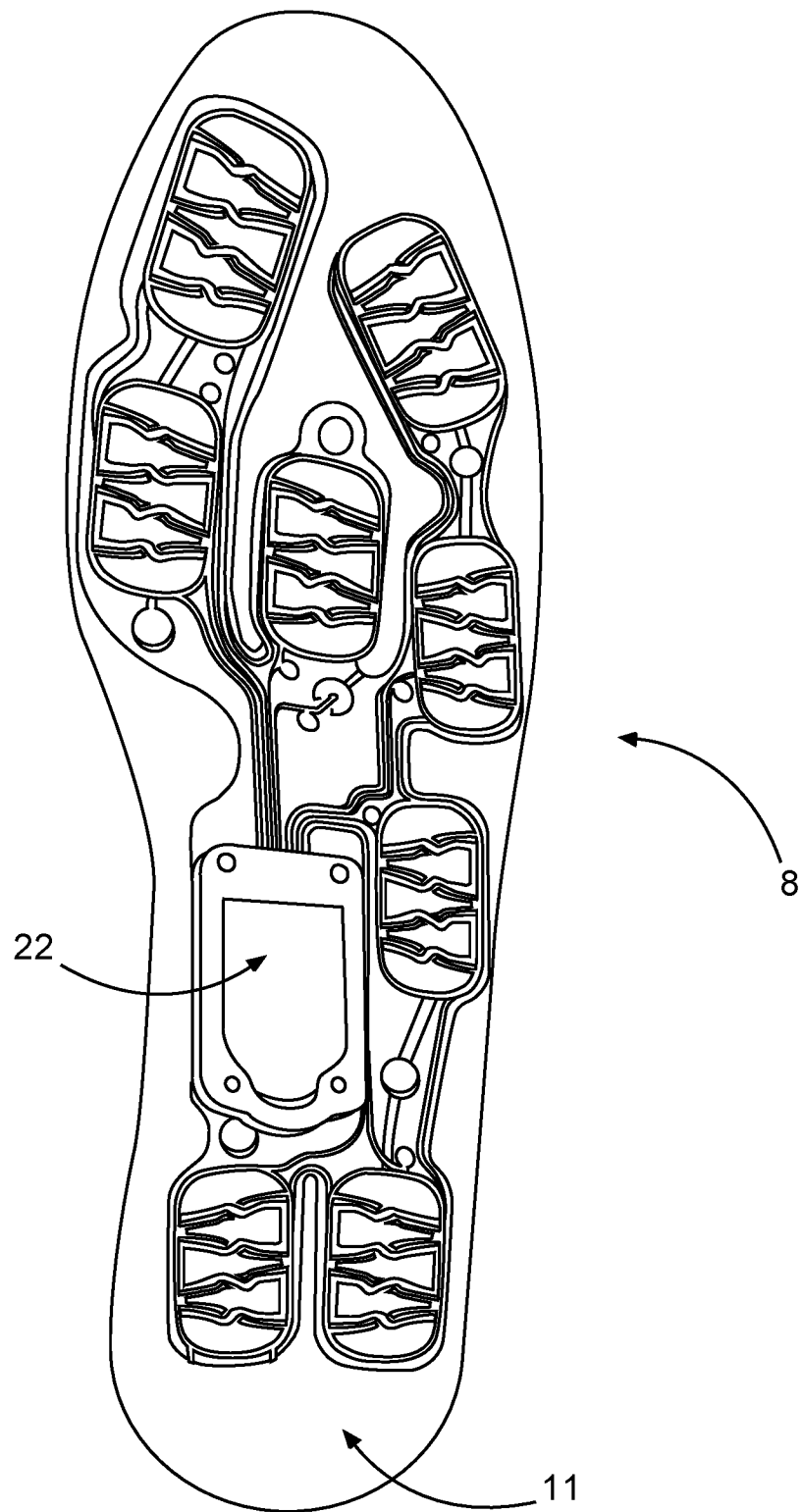


Fig. 6

7/8

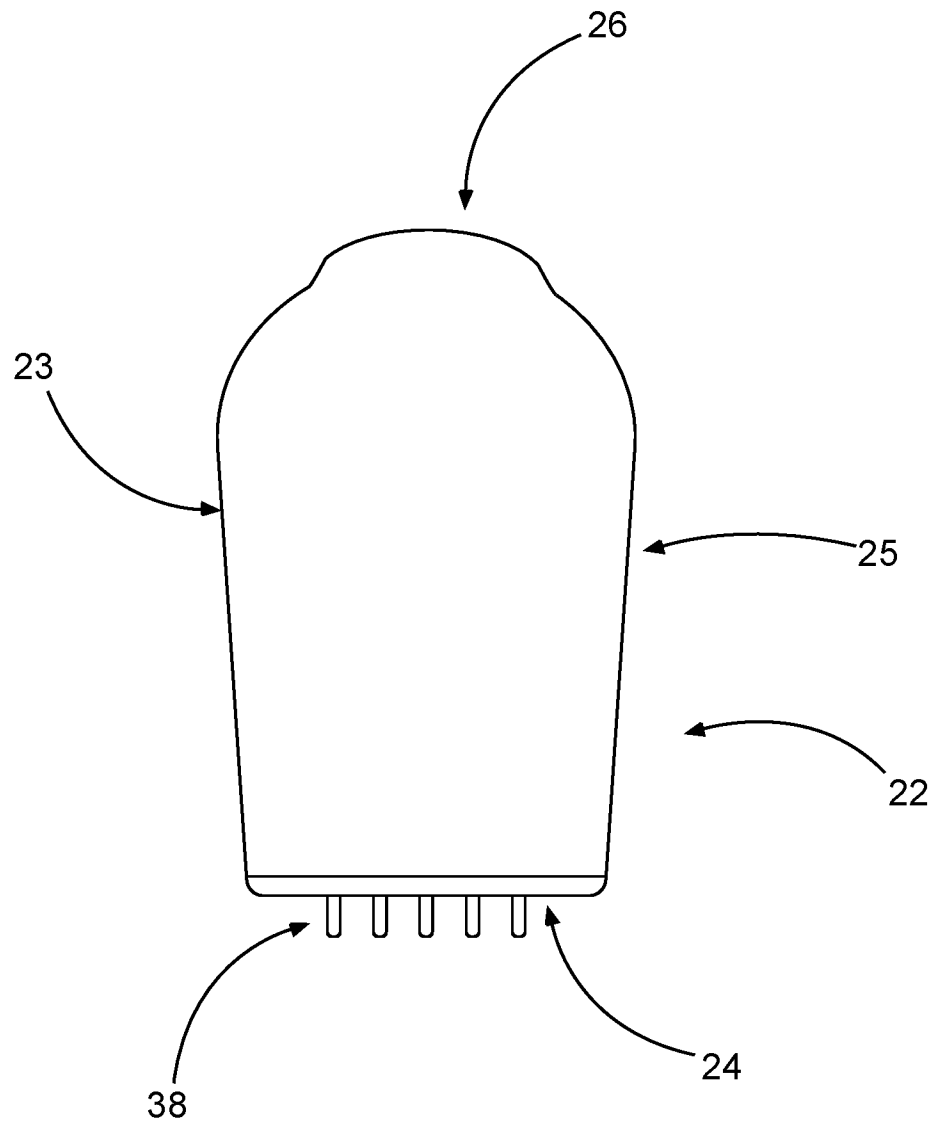


Fig. 7

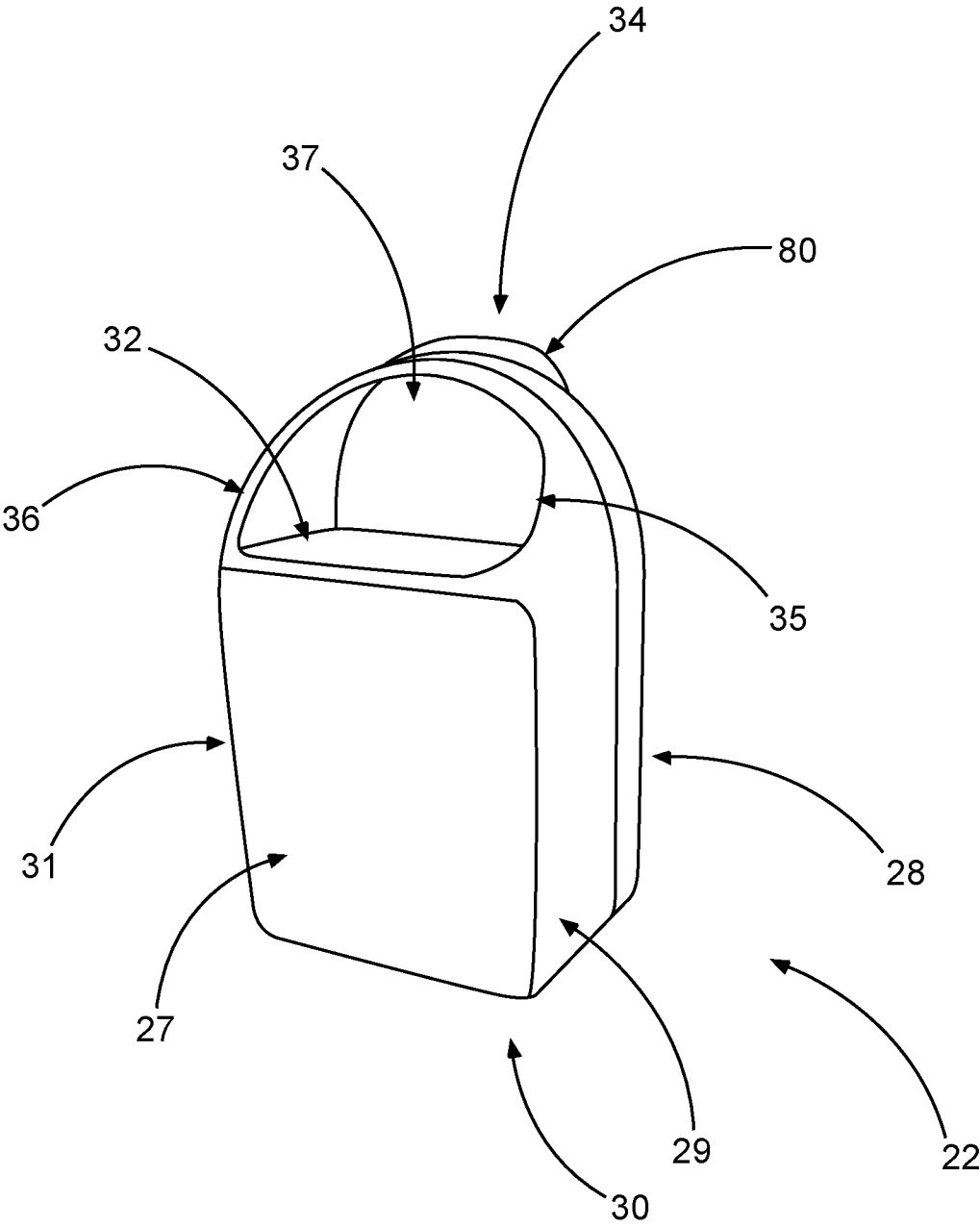


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2021/085859

A. CLASSIFICATION OF SUBJECT MATTER
INV. A43B3/00 A43B7/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A43B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/019694 A1 (MOLYNEUX JAMES [US] ET AL) 24 January 2013 (2013-01-24) paragraphs [0002], [0004], [0005], [0007], [0008], [0069], [0070], [0074], [0076], [0077], [0081]; figures 1, 6, 7, 9, 10, 11, 12, 25 -----	1-15
X	US 2020/021896 A1 (FITZGERALD COLIN EDWARD [CA] ET AL) 16 January 2020 (2020-01-16) paragraphs [0006], [0039], [0040], [0045], [0047], [0048]; figures 1-4 -----	1, 2, 8-15
A		3-7
X	US 6 195 921 B1 (TRUONG VINNCENTE HOA GIA [US]) 6 March 2001 (2001-03-06) column 1, line 5 - line 12; figures 1, 4, 12 column 3, line 55 - column 4, line 54 column 3, line 46 - line 59 -----	1-15

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

2 March 2022

Date of mailing of the international search report

11/03/2022

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Baysal, Kudret

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2021/085859

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013019694 A1	24-01-2013	BR 112013021141 A2	10-12-2019
		CA 2827687 A1	23-08-2012
		CN 103476285 A	25-12-2013
		CN 107411215 A	01-12-2017
		CN 112545101 A	26-03-2021
		EP 2675311 A2	25-12-2013
		EP 3153046 A1	12-04-2017
		JP 5841616 B2	13-01-2016
		JP 6379082 B2	22-08-2018
		JP 2014505577 A	06-03-2014
		JP 2016034579 A	17-03-2016
		KR 20130130053 A	29-11-2013
		KR 20160042145 A	18-04-2016
		KR 20170061718 A	05-06-2017
		US 2013019694 A1	24-01-2013
		US 2016309829 A1	27-10-2016
		US 2018184751 A1	05-07-2018
		US 2020297064 A1	24-09-2020
		WO 2012112938 A2	23-08-2012

US 2020021896 A1	16-01-2020	EP 3602079 A1	05-02-2020
		US 2020021896 A1	16-01-2020
		WO 2018170581 A1	27-09-2018

US 6195921 B1	06-03-2001	NONE	
