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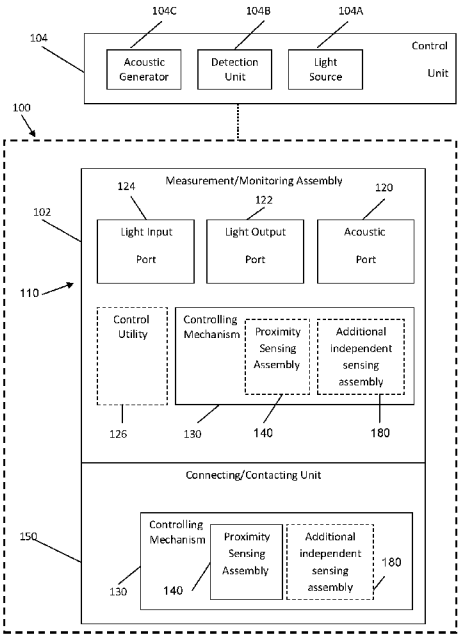

Fig. 1a

(57) Abstract: A probe for use in monitoring one or more parameters of a subject is provided. The probe comprises a monitoring assembly comprising at least one acoustic port for transmitting acoustic radiation into a region of interest in the subject, at least one light output port for transmitting incident light towards the region of interest, and at least one light input port for receiving light returned from the subject. The probe comprises also at least one control mechanism comprising at least one sensing assembly configured for sensing at least one of proximity, attachment and signal quality conditions, and being configured for controlling a condition of coupling between the probe assembly and the subject, enabling to control operation of the monitoring assembly.

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PROBE FOR NON INVASIVE OPTICAL MONITORING

TECHNOLOGICAL FIELD AND BACKGROUND

This invention is generally in the field of medical devices, and relates to a probe device and a monitoring system utilizing such a probe device for carrying out measurements on a subject utilizing ultrasound tagging of light. The invention is particularly useful for monitoring various parameters, e.g. flow velocity and oxygen saturation in blood vessels, capillaries and venules, and oxygen saturation in deep tissues, such as brain, muscle, kidney and other organs.

Various techniques of non invasive monitoring of conditions of a subject have been developed. These techniques include impedance-based measurement techniques, photoacoustic measurements, acoustic measurements (Doppler measurements), and optical measurements (e.g. oxymetry).

Another approach, based on use of ultrasound tagging of light in measurements of various chemical and physiological parameters, has been developed and disclosed for example in WO 06/097910, WO 05/025399, and WO 2009/116029 all assigned to the assignee of the present application. According to the technique of WO 2009/116029, a probe assembly is used for monitoring one or more parameters of a subject, where the probe assembly comprises an acoustic port for transmitting acoustic radiation into a region of interest in the subject, at least one light output port for transmitting incident light towards the region of interest, at least one light input port for receiving light returned from the subject, and a control utility. The latter is configured for controlling at least one condition of a monitoring procedure and enabling the monitoring procedure upon detecting that said at least one condition is satisfied.

GENERAL DESCRIPTION

The present invention provides a novel probe assembly enabling effective attachment of the probe to the subject (i.e. allowing continuous monitoring of one or more conditions of a subject) and enabling the attachment part of the probe to be disposable.

The present invention takes advantage of the monitoring techniques utilizing the principles of ultrasound tagging of light, for example as disclosed in the above-indicated patent publications WO 05/025399, WO 06/097910, WO 2009/116029 assigned to the assignee of the present application. The probe assembly of the invention is thus configured and operable to irradiate a region of interest with acoustic waves while taking optical measurements on said region of interest.

The inventors have found that with such a probe assembly it is desirable to prevent generation of acoustic and light radiation at conditions other than a measurement session. More specifically, the probe assembly should be configured to enable self-monitoring of its position with respect to a subject, such that upon detecting that the probe assembly is properly attached to the subject's tissue, or that another predetermined condition exists, the probe assembly can be activated to take measurements.

Thus, the present invention, according to its one broad aspect, provides a probe assembly for use in monitoring one or more parameters of a subject. The probe assembly comprises at least one acoustic port for transmitting acoustic radiation into a region of interest in the subject, at least one light output port for transmitting incident light towards the region of interest, at least one light input port for receiving light returned from the subject, and at least one control mechanism.

In some embodiments of the invention, the probe assembly may comprise at least one acoustic port for receiving acoustic radiation from a region of interest in the subject. This may be implemented using the same acoustic port for both transmitting and receiving acoustic radiation, or by using separate acoustic ports for these functions. In the latter case, there are at least two acoustic ports included in the probe assembly, at least one for transmitting and at least one for receiving acoustic radiations.

The at least one control mechanism is configured for controlling a condition of coupling between the acoustic and light output ports and the subject, and controlling the operation of the probe (monitoring procedure) accordingly, e.g. preventing the probe assembly from operation upon identifying that said condition is not satisfied and/or alerting the operator that said condition is not satisfied and/or providing the operator with a quantitative measure of said conditions. Such control mechanism(s) may comprise at least a proximity sensing assembly, an attachment sensing assembly, or a signal quality sensing assembly.

It should be noted that the probe may be shifted between its operative and inoperative states, based on the control mechanism determination, either automatically, or upon user decision.

In some embodiments of the invention, the proximity sensing assembly of the control mechanism comprises a magnetic assembly, which may include a magnetic sensor (detector) and a magnet. The magnetic assembly may operate such that when the magnet is brought proximally to a detection range of the magnetic sensor corresponding to the condition of the desired coupling between the probe assembly and the subject, the magnetic field of the magnet is detected by the magnetic sensor allowing for the acoustic as well as the optical radiation to be safely activated, however, as long as the magnet is outside the detection region of the magnetic sensor the probe's operation is not allowed.

In some embodiments, in addition to or as an alternative to the magnet-based assembly, the control mechanism may include any other proximity detection assembly such as capacitive based assembly, as well as one or more other sensing assemblies, such as optical assembly, ultrasound distance sensing assembly, pressure measurement assembly, or RFID based assembly.

In some embodiments,, the attachment sensing assembly of the control mechanism comprises a mechanical or electro-mechanical assembly that utilizes mechanical properties of the probe assembly in order to allow activation of the probe assembly (e.g. activation of the acoustic and/or optical radiation).In some embodiments, the probe assembly is configured as a two-part device, where the two parts are attachable/detachable between them. This enables one part, by which the probe assembly is brought in contact with the subject to be disposable, and enabling the other part to carry the elements of a measurement unit (acoustic and light ports/elements) and be thus a reusable part. It should be understood that in the single- or two-part design of the probe assembly, the probe assembly includes a so-called measurement and contacting/connecting portions, while in the two-part design these portions are attachable/detachable. In the description below these parts/portions are referred to as respectively reusable and disposable parts, but it should be understood that generally both may be disposable or reusable.

In some embodiments, the signal quality sensing assembly of the control mechanism comprises a light emitter (e.g. LED) that may be associated with a logic controller and may be used to wirelessly transmit information from the disposable part

to the reusable part or to the control unit. The information may include a serial number for identification of the disposable part, an authentication signal for certifying that the disposable part is a certified one, a counter indicator for the amount of time since the activation of the disposable part, a signal indicating the degree of coupling between the reusable and disposable parts, a signal indicating the degree of coupling between the probe assembly (reusable and/or disposable parts) with the tissue. The information transmitted may also serve for carrying sensor information, e.g. output from optical detectors when positioned on the disposable part.

Thus, according to a first broad aspect of the invention, there is provided a probe for use in monitoring one or more parameters of a subject, the probe comprising: a monitoring assembly which comprises at least one acoustic port for transmitting acoustic radiation into a region of interest in the subject, at least one light output port for transmitting incident light towards the region of interest, at least one light input port for receiving light returned from the subject, and at least one control mechanism comprising at least one sensing assembly configured for sensing at least one of proximity, attachment and signal quality conditions, and being configured for controlling a condition of coupling between the probe assembly and the subject, thus enabling to control operation of the monitoring assembly, e.g. preventing its operation if the at least one condition is not satisfied.

The probe may include a first flexible portion, and a second portion on which the monitoring assembly is mounted, such that pressing the probe against the subject causes a deformation of the flexible portion, thereby reducing a distance between the monitoring assembly and the subject detectable by the proximity and/or attachment sensing assemblies.

The proximity sensing assembly may comprise a magnetic sensing assembly. Preferably, the magnetic sensing assembly comprises a magnet carried by the first flexible portion and a magnetic sensor located at the second portion, the magnetic sensor defines a sensing region in its vicinity and is configured for sensing a magnetic field of the magnet when the magnetic field overlaps with the sensing region. Alternatively or additionally, the proximity sensing assembly may comprise a pressure sensing assembly utilizing techniques known in the art, such as capacitive, resistive and electro-mechanical strain gauges.

The control mechanism may comprise the at least one proximity sensing assembly and the sensing assembly of a different type for controlling the condition of

coupling between the probe assembly and the subject. Such at least two different sensing assemblies control the operation of the monitoring assembly, e.g. prevent the operation of the monitoring assembly as long as the coupling condition is not satisfied. In some embodiments, the coupling sensing assembly is a mechanical assembly, and in this case the mechanical assembly may include a switch located on a flexible portion, such that pressing the probe against the subject causes a deformation of the flexible portion thereby activating the switch to allow operation of the monitoring assembly.

According to some embodiments, the first and second portions of the probe are removably attachable to one another.

The flexible portion may be configured as a probe-subject adhesive unit being associated with a probe-subject adhesive media.

According to another broad aspect of the invention, there is provided a probe for use in monitoring one or more parameters of a subject, the probe comprising: a portion carrying a monitoring assembly configured for radiating the subject with acoustic and optical radiation, and a flexible portion by which the probe faces the subject when in operation, and at least one control mechanism comprising at least one proximity and/or attachment sensing assembly located at least partially on the flexible portion, such that pressing the probe against the subject causes a deformation of the flexible portion thereby reducing a distance between the monitoring assembly and the subject detectable by the at least one control mechanism, thereby enabling to control a condition of coupling between the probe and the subject to control operation of the monitoring assembly.

According to yet another broad aspect of the invention, there is provided a probe for use in monitoring one or more parameters of a subject, the probe comprising: a portion that carries a monitoring assembly and is configured for radiating the subject with acoustic and optical radiations, and a flexible portion by which the probe faces the subject when in operation; and at least first and second control mechanisms comprising at least first and second sensing assemblies respectively of same or different first and second types, each is independently operable to control a condition of coupling between the probe and the subject to prevent operation of the monitoring assembly if the at least first and second different sensing assemblies identify that the condition is not satisfied, wherein at least one of the at least first and second sensing assemblies is a proximity sensing assembly

located at least partially on the flexible portion, pressing the probe against the subject causes a deformation of the flexible portion thereby reducing a distance between the monitoring assembly and the subject detectable by the at least one proximity sensing assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

Fig. 1a is a block diagram of an example of a probe assembly according to one aspect of the invention;

Fig. 1b is a block diagram of an example of a probe assembly according to another aspect of the invention;

Fig. 1c is a block diagram of an example of a probe assembly according to yet another aspect of the invention;

Fig. 2 is an isometric upper view of a specific but not limiting example of the probe assembly of the invention;

Fig. 3 illustrates an isometric bottom view of the probe assembly of Fig. 2;

Fig. 4 shows an example of a two-part design of the probe assembly of Figs. 2 and 3, and illustrates more specifically a flexible part/portion of the probe assembly, which may be a disposable portion; the figure more specifically shows a part of a proximity sensing assembly (magnetic sensing assembly in this example) partially located in the flexible part of the probe assembly;

Figs. 5 and 6 are cross-section side views of the probe assembly of Figs. 2-4 showing more specifically two different sensing assemblies of the control mechanism in their activated states (corresponding to inoperative position of the probe assembly, i.e. its monitoring assembly);

Figs. 7 and 8 are respectively a cross-section side view of a probe assembly according to another embodiment and an isometric view of a flexible part/portion of the probe assembly, which may be a disposable portion, the probe assembly not having a proximity sensing assembly;

Figs. 9a and 9b show examples of the probe assembly comprising dual sensing mechanical assemblies located inside the probe assembly;

Fig. 10 is a schematic presentation of a two-part design of the probe assembly of the invention comprising several possibilities of controlling mechanisms, specifically a signal quality sensing assembly;

Fig. 11 shows a probe design in which the light source is located inside the probe itself.

DETAILED DESCRIPTION OF EMBODIMENTS

Referring to **Figs. 1a-1c**, there is illustrated, by way of a block diagram, three examples of a probe **100** according to the invention for monitoring one or more parameters of a subject. The probe **100** includes a measurement/monitoring unit **102** adapted for carrying out ultrasound tagging based optical measurements, and accordingly includes one or more ports, generally at **120**, associated with (i.e. includes or is connectable to) acoustic transducer for transmitting acoustic radiation into a region of interest in the subject, at least one light output port **122** associated with (i.e. includes or is connectable to) a light source for transmitting incident light towards the region of interest, and at least one light input port **124** (i.e. includes or is connectable to) a light detector for receiving light returned from the subject. It should be noted although not specifically shown that the probe may also include additional acoustic transducer for receiving reflected acoustic radiation, or the same acoustic transducer may be configured for transmitting and receiving acoustic radiation. Optionally, the probe may also include, though not shown, indications about its operation mode as well as identification of the illumination condition (e.g. LEDs ON/OFF/Flashing).

The probe assembly **100** may be associated with a control unit **104**, which is typically configured as a computing system and logic, and may include among other things a light source unit **104A** and/or a detection unit **104B** and/or an acoustic generator **104C** (e.g. arbitrary waveform generator). Generally, the control unit **104** may be configured as an external unit as shown in **Figs. 1a-1b** being connectable to the measurement/monitoring unit **102**, or as an internal unit accommodated within the probe assembly **100**, as shown in **Fig. 1c**, or as a hybrid unit (not shown) in which part of the functional units **104A**, **104B** and **104C** are located internally in the probe assembly **100**, while the rest are located externally to the probe assembly **100**. When configured totally or partially as an external unit, the communication between the probe assembly **100** and the external control unit **104** may be via wires or by means of wireless signal/data transmission (e.g. RF, IR, acoustic).

Preferably, a light guide connecting an external light emitter (e.g. in the control unit) and a light output port at the probe device is a small core fiber (e.g. a single-mode, a 50 μm or a 62.5 μm core fiber). As for a light guide connecting an external light detector (e.g. in the control unit) and a corresponding light input port at the probe device, it has an appropriate cross-sectional dimension of the core in order to satisfy the collection efficiency requirement. For example, a fiber or a fiber bundle, having a core of a diameter equal to or higher than 100 μm can be used. The maximal diameter and numerical aperture of a collecting fiber is determined so that the total path difference between light traveling in different paths in the fiber core is less than the coherence length of the light source. When the light source and/or detector forms an integral part of the probe **100**, the optical fibers are eliminated. Electrical wires (or wireless means) are used to connect the probe **100** or the external control unit **104** with a monitor for displaying an image or data related to a diagnosis/monitoring procedure and/or the parameters chosen for carrying out the procedure.

The probe device **100** also includes an internal control utility **126**. The control utility **126** may be configured generally similar to that described in the above-indicated patent publication WO 2009/116029 in that it is installed with appropriate electronic utility (coding chip operating with a unique activation code) allowing for identifying whether the probe assembly is a certified one (i.e. authentication procedure); and/or includes a memory unit adapted for recording data indicative of measurements taken on a specific subject during a certain period of time (thus enabling use of this data as a measurement history of the specific subject). Such data may serve as a measurement history of a specific subject, as a measure to record a duration of measurement or an expiration/prevention of use following a specific duration or date. The memory unit may also store data including information about the probe serial-number or any specific technical parameters that are relevant to the probe (e.g. calibration).

The probe device **100** may be configured as a two-part assembly, one part **110** carries the elements of the measurement/monitoring unit **102** and may be reusable, while the other part **150** by which the probe is brought in contact with the subject is configured to provide the desired coupling between the probe and the subject, as well as desired coupling with the reusable part **110**, and may be disposable. The two parts

110 and **150** of the probe device are appropriately attachable / detachable to/from one another.

When performing measurements utilizing acoustic radiation, and especially ultrasound tagging of light, a sufficient degree of acoustic coupling between the acoustic port and the subject is needed, as well as certain degree of coupling between the subject and the output light port (to eliminate/reduce eye exposure to the light radiation), so as to actuate and operate measurements upon identifying that desired coupling has been established. According to the present invention, the probe device **100** includes an appropriately designed control mechanism **130**, which is configured to satisfy the above two requirements, namely ensure that the measurement/monitoring unit **102** (i.e. reusable part **110**) is properly attached to the other, contacting part **150** (disposable), and that said contacting part **150** and the measurement part **110** are attached to the subject under monitoring. To facilitate understanding, the top and bottom parts **110** and **150** of the probe **100** which are functionally different parts, so-called measurement and contacting parts, are referred to hereinbelow as respectively reusable and disposable parts, although it should be understood that generally both may be disposable or reusable.

The control mechanism **130** includes at least a first sensing assembly **140** (such as magnetic and/or optical and/or pressure-based, and/or mechanical and/or electrical and/or resistive etc.), and preferably also includes at least one additional independently operable sensing assembly **180** of the same or different type as the first sensing assembly. Thus, preferably, the control mechanism is a double-sensing mechanism where the two sensing assemblies operate independently, and the measurement procedure is allowed-actuated upon detection by both these assemblies that the proper coupling is achieved.

It should be clear, as can be seen in the **Figs. 1a-1c**, that at least part of the control mechanism **130** is located inside the measurement part **110**. Another complementary part of the control mechanism may be located outside the measurement part **110**, e.g. within the connecting/contacting unit **150** as shown in **Figs. 1a** and **1c**.

It should be noted that the invention is not limited to the specific configurations shown in the block diagrams of **Figs. 1a-1c**, for example another possible embodiment may be a combination of the configurations shown in **Figs. 1b** and **1c**, i.e. that the control unit **104** is integrated within the probe **100** (as in **Fig. 1c**)

and the control mechanism **130** does not form part of the connecting/contacting unit **150** (as in **Fig. 1b**).

Referring to **Fig. 2**, there is schematically illustrated a probe assembly **100** according to an example of the present invention. To facilitate illustration, the same reference numbers are used to identify the common components in all the figures. The probe assembly **100** is constructed from two parts, a reusable unit **110** (carrying/presenting a measurement unit) and a disposable unit **150** (i.e. a contacting part of the probe), which are attached together. The reusable unit **110** includes a housing **112** carrying therein the elements of the measurement/monitoring system. The housing may include a top cover **112A** which may be made from rigid plastic. Generally, the top cover **112A** may be a single-part structure; however, to facilitate assembling and servicing thereof, it may be composed of multiple parts attachable to one another. In addition, the housing can encapsulate LED for indication of laser emission, or for indication of mode of operation in the case of several probes connected to the same system, each probe may emit light with a different color or signature.

The reusable unit **110** may further include a strain relief member **114** which is configured for securing the connection and bending point of the reusable unit **110** with cables and/or fibers. Optical fibers as well as other cables pass through the member **114** and connect the light input/output ports and the acoustic port, all will be described below, with a proper light source, such as a laser, and an ultrasound transducer respectively. It should be understood that in some embodiments of the invention, the reusable unit **110** includes an ultrasound transducer, while in others it only includes an acoustic port responsible for passing the ultrasound radiation generated by a transducer located outside the reusable unit **110**. Further shown in the figure is a strain relief cap **116** that may be used to lock the strain relief member **114**. The cap **116** can be manufactured and assembled in various colors to indicate and mark various versions of the reusable unit **110**.

The reusable unit **110** houses various functional elements/units which are not shown in the figure. As described above with reference to Fig. 1, such elements/units include an ultrasound transducer or acoustic port/s for transmitting/receiving acoustic radiation, at least one light output port/source, at least one light input port/detector. Also, the reusable unit carries control mechanisms (e.g. magnetic sensor, mechanical micro-switch), as will be described below with reference to Figs. 3-5.

The disposable unit **150** includes an attachment pad **152** (such as adhesive pad and/or strap) that assists in attaching the probe to the patient skin. The attachment pad **152** may be relatively wide. The attachment pad **152** may be made of a combination of a bio-compatible adhesive layer and a light blocking fabric layer, both enabling some degree of air ventilation to the patient skin. To support and provide additional ventilation, the pad **152** may include additional through-holes **154**. The pad **152** is generally flexible and in order to enhance its flexibility and attachment to the patient's skin matching the curvature thereof, the pad may include additional through-cuts **156** around its circumference. The disposable unit **150** on the one hand serves as a secure support to the reusable unit **110**, and, on the other hand serves as a coupler (as an adhesive) of the probe to the patient skin. To this end, the disposable unit **150** includes a support frame **160** which surrounds an opening configured in accordance with the geometry of the reusable unit to be placed therein. The frame **160** is formed with appropriate spaced-apart locking elements **162**, **164** and **166** for holding the reusable unit **110** when placed in said opening. More specifically, the support frame **160** has front lock **162**, side locks **164** and back supporters **166**, which all together operate to position the reusable unit **110** securely and firmly, in place. The front lock **162** prevents a forward motion of the reusable unit **110**, and also provides a counter-pressure to the front face of the reusable unit **110** when pushed against the patient tissue. The side locks **164** prevent movements of the reusable unit along the lateral axis (to the sides), and also lock and provide the major counter-pressure to the reusable unit when pushed against the patient tissue. The side locks **164** are preferably designed to enable easy attachment and a single hand removal of the reusable unit. The back supporters **166** prevent backward motion of the reusable part **110** and guide the reusable unit **110** into position when snapped into the disposable unit **150** as will be described further below.

As indicated above, the probe device includes the control mechanism including at least the magnetic sensing assembly **140**. In **Fig. 2**, a part of such mechanism associated with the disposable unit **150** of the probe is partially seen.

Turning to **Fig. 3**, a rear side surface of the probe assembly **100** of **Fig. 2** is schematically illustrated. The figure illustrates the housing **112** of the reusable unit located within / held by the respective opening in the disposable unit **150** and being surrounded by the adhesive pad **152**. The bottom side of the reusable unit housing **112** may include a cover **112B** made from an elastic material and configured to be

received by the opening in the frame of the disposable unit. The bottom cover **112B** is also used to protect the reusable unit from the environment (water and dust resistance). The bottom cover **112B** holds the acoustic port **120** (or acoustic (ultrasound) transducer as the case may be), the light input port **124** and the light output port **122**. As further shown in the figure, a part **140A** of the magnetic assembly **140** that is incorporated in the disposable unit **150** includes a holder element **172** holding a magnetic element **170** (e.g. permanent magnet). The configuration is such that the magnet **170** is mounted in the disposable unit such that it is aligned with the other part (not seen here) of the magnetic assembly located in the reusable unit **110**.

According to this non-limiting embodiment of the invention, the bottom side of the housing of the reusable unit (e.g. the cover **112B**) is configured to enable displacement/deformation of the cover when brought in contact with and pressed against the subject, such that the reusable unit moves towards the subject. To this end, the cover **112B** is made of appropriate elastic/deformable material(s) (e.g. elastomeric materials such as rubber or silicone) and possibly also is geometrically designed (e.g. has somewhat curved outer surface) to enable slight movement into and out of the opening. As will be described further below, this configuration is aimed at enabling measurements only upon attaining the desired attachment of the reusable unit with the subject, identifiable by the double-assembly control mechanism. Thus, when the probe device is brought in contact with the subject and a mechanical pressure is applied, the reusable unit and accordingly the acoustic element (port/transducer) and the optical element (input light port(s)) are pushed towards the patient skin, thus providing desired attachment to allow a monitoring procedure to start. When the device is moved away from the subject, the bottom cover **112B** returns to its initial shape (e.g. non-deformed state). It should be noted that, in some embodiments of the invention, the cover **112B** might be constructed from a rigid/inelastic material being fixed in place, and no movement of the cover would be needed, e.g. if no mechanical micro-switch mechanism (marked **180** in the different figures) is used, or if the mechanical micro-switch mechanism is used in a different configuration being activated by another moving part.

The disposable unit is more specifically illustrated in **Fig. 4**, showing the magnetic assembly **140A** including magnet **170** and the magnet holder **172** which form a part of the control mechanism. As shown, the magnet holder **172** includes a rod-like **172A** member which by its opposite ends **172B** and **172C** is mounted on the

opposite side walls of the disposable unit, e.g. mounted on the frame **160**, and has a portion **172D** carrying the magnet **170**. As seen in **Figs. 3** and **4**, the configuration is such that the magnet **170** projects from the bottom side of the disposable unit. Also, the configuration is such that the magnet **170** is pivotal with respect to an axis defined by the rod-like holding member. As a result, when the probe device is put in operation and is pressed against the subject, this causes the pivotal movement of the magnet.

According to one possible embodiment, at least the magnet carrying portion **172D** of the rod-like member **172A** is made from an elastic / deformable material such that when the probe **100** is pressed against a subject, the magnet carrying portion deforms causing rotation of the magnet. Alternatively or additionally, the rod-like element **172A** may be rotatable, and thus when the probe is brought to a subject's skin, the magnet carrying portion **172D** is pushed causing rotation of the rod **172B** which further contributes in the rotation of the magnet.

Thus, the magnetic assembly part **140A** in the disposable unit **150** is configured such that a magnet therein is movable towards and away of the reusable unit and thus moves towards and away of a sensing element in the magnetic assembly part installed in the reusable unit. This movement of the magnet towards the reusable unit results in that the magnet **170** becomes located within a sensing region of the magnetic sensing element, which is located inside the reusable unit, thus indicating that the probe is close enough to the subject's skin, being one of the control mechanism conditions.

Figs. 5 and **6** are side cross-section views of the probe assembly **100** according to one possible embodiment of the present invention. Specifically shown in the two figures are two control mechanisms **140** and **180**. In this specific not limiting example, the probe assembly is configured to provide double safety check before any radiation can be generated. As described earlier, the control mechanisms allow the safe application of the radiation used during the monitoring procedure, where the activation position of the control mechanisms prevents the probe assembly from operation, i.e. keeps the probe assembly in an inoperative state thereof, while in their deactivated position, the control mechanisms allow the probe assembly to operate. **Fig. 5** illustrates the activated state of the two control mechanisms **140** and **180**, i.e. the mechanisms prevent the activation of any radiation (optic or acoustic) from the probe **100**, and **Fig. 6** illustrates the inactivated state of the control mechanisms, i.e.

the control mechanisms are neutralized to allow the safe activation of the radiation from the probe **100**.

The first control mechanism is the magnetic (generally, proximity-type) sensing assembly **140** which includes the magnet **170** and the elastic magnet holder **172** located in the disposable unit **150**, and a magnetic sensing element **142** located in the reusable unit **110** and being at the vicinity of the magnet **170** without physical contact between them. When the probe assembly **100** is not attached properly to the subject, the elastic magnet holder **172** remains in its deactivated position and turns down outside the disposable unit. As a result, the magnetic field of the magnet **170** is not detected by the magnetic sensor **142** and the latter thus does not generate an activating signal. On the other side, when the probe assembly is properly (securely) attached to the subject, the magnet holder **172** changes its orientation upwards into the activated position, as shown in **Fig. 6**, and consequently the magnetic field of the magnet **170** triggers the magnetic sensor **142**, permitting the activation of the radiation source/s. It should be noted that the hysteresis detection range of the magnetic sensor **142** is selected so as to provide an angular range of active-state angles of the magnet **170** which in turn depends on the position of the magnet holder **172**, thus enabling the use of the probe over a wide range of patient body curvatures.

It should be noted that, generally, additionally or alternatively, the control mechanism may include any suitable proximity sensing assembly, such as capacitive, optical, ultrasound, mechanical micro-switch, pressure or RFID-based assembly. The construction and operation of such sensing assemblies are known *per se* and do not form part of the invention, and therefore need not be described in details.

The additional control mechanism may be the mechanical micro switch mechanism **180**. This mechanism is located in the reusable unit **110** and includes a micro switch **182** and an elastic lever **184**. The latter is located on the bottom cover **112B** so as to be aligned with the micro switch **182**. This mechanism utilizes the elasticity of the elastomeric bottom cover **112B**. As shown in **Fig. 5**, when the probe assembly **100** is not properly attached to the patient tissue, the elastomeric bottom cover **112B** of the reusable unit **110** pops out of the reusable unit's enclosure. In this state, the elastic lever **184** attached to the bottom cover **112B** is distanced from and thus not pressing the micro switch **182** located above it, thus the micro switch **182** is not activated. On the other side, when the probe assembly **100** is properly (securely) attached to the patient, as shown in **Fig. 6**, the elastomeric bottom cover **112B** is

pushed into the internal cavity of the reusable unit **110**, and the elastic lever **184** presses the micro switch **182**, thus activating the micro switch **182** to close a respective electric circuit (not shown). It should be noted that the elastic property and the design of the lever **184** provides a larger stroke than the stroke of the micro switch **182**, thus extending the available stroke range of the bottom cover **112B** and the micro-switch.

Fig. 5 further shows some more details of the reusable unit including the already explained strain relief part **114** and cap **116** alongside with the ultrasound port/transducer **120**, the light output port **122** and the light input port **124**. It is also shown in this specific but not limiting example that the light output port **122** and the light input port **124** terminate longitudinal rods (light guides) **123** and **125** respectively, along which the transmitted and received light pass. Lenses/prisms **126** and **128** are used to redirect the light to/from the rods from/towards optical fibers (not shown) that mediate between the source/detector and the reusable part **110**.

Referring to **Figs. 7 and 8,** there is shown another example of a two-part design of a probe **100A** according to an embodiment of the present invention. In this particular design, the controlling mechanism/s is/are located inside the reusable part **110A** only, and the disposable part **150A** provides mechanical support. More specifically, the reusable part **110A**, seen in **Fig. 7**, is built and has the same -structure as the part **110** in **Figs. 5 and 6**, except that it does not have a magnetic sensing assembly, i.e. neither the magnetic sensor **142** nor the circuitry associated with it exist. Alternatively, the controlling mechanism of the probe of **Fig. 7** includes the mechanical micro-switch mechanism **180** having the same parts and features as explained above with respect to **Figs. 5 and 6**, i.e. the mechanism **180** is located in the reusable unit **110A** and includes a micro switch **182** and an elastic lever **184**. The elastic lever is located on the bottom cover **112B** so as to be aligned with the micro switch **182**. The mechanism utilizes the elasticity of the elastomeric bottom cover **112B** that pushes the micro-switch/es.

The disposable part **150A**, shown in **Fig. 8**, has the same parts and features of the disposable part shown in **Fig. 4**, except that it neither has the magnet holder **172** nor the magnet **170**, as there is no magnetic sensing assembly in this specific configuration. The controlling mechanism **180** of the probe **100A** works in the same way as explained above with respect to **Figs. 5 and 6**.

Reference is made to **Figs. 9a and 9b** showing other examples of the reusable part **110B** of a probe according to embodiments of the invention. The controlling mechanism includes two mechanical micro switches **180.1** and **180.2** that are located inside the reusable part **110B**. The reusable part **110B** may be used with the disposable part **150A** shown in **Fig. 8**. In **Fig. 9b,** the micro switches **180.1** and **180.2** are located in direct or indirect contact (e.g. via the transducer structure) with the elastomeric bottom cover **112B,** such that when they are pressed against the ceiling of the reusable part **110B** a control condition is activated. There is no elastic lever **184** in this design. The fence on the ceiling part of the reusable part **110B** limits the movement of the elastomeric bottom cover **112B** and keeps the micro-switches and optical lens separated. In these specific examples, only when the two micro switches **180.1** and **180.2** are both activated, the probe is allowed to operate and radiate the acoustic and optical radiations. The dual configuration is advantageous in that it provides safer control of the activation on one side, and allows using cost-effective micro-switches available on the market on the other side. A control logic which may be used in the control unit or elsewhere in the probe assembly, periodically verifies that the two micro-switches provide the same proximity indication, so that any mismatch is indicated as a fault. Accordingly, this would serve as an alert for the user that care should be taken and the device should be repaired. It should be noted that more than two micro switches can be used for ensuring safe operation, with a similar control logic system.

Fig. 10 shows a schematic and functional drawing of more design examples of the design of a single or two-part design of a probe assembly, according to an embodiment of the present invention. In the figure, the probe assembly **100C** is configured as a two-part probe including a reusable part **110C** and a disposable part **150C**. In the reusable part **110C**, the probe assembly includes one or more acoustic ports **120**, associated with (i.e. includes or is connectable to) acoustic transducer for transmitting/receiving acoustic radiation into/from a region of interest in the subject. The probe assembly also includes at least one light output port **122** associated with (i.e. includes or is connectable to) a light source for transmitting incident light towards the region of interest. Alternatively or in addition to light input port/s **124** integrated in the reusable part and associated with an integral or external light detector, the probe assembly may include one or more light detector/s mounted on the disposable part. In

this specific example, two spaced-apart detectors **104.1** and **104.2** are shown and may serve to receive light having one or more of these characteristics: arriving from different regions of the examined subject, having travelled through different paths or depths, being of different wavelengths/frequencies. Either or both detectors can be used for analyzing tagged or untagged light.

In this particular example, as shown in the figure, the controlling mechanism may include one or more of the following components: a light emitting element (e.g. LED) **190** with a logic element (microcontroller) **192** for controlling the light emitter; a power source **194** (e.g. a battery) for the light emitter and/or light detectors **140.1** and **140.2**; a pressure sensor **196** and/or an ohmmeter **198** (or resistance meter or electrical current meter). The logic controller is configured to encode or convert signals that are transmitted by the lighting element according to a predetermined code.

The light emitter **190** with the associated logic controller **192** may be used to wirelessly transmit information from the disposable part to the reusable or the control unit (**104**). The information may include: a serial number for identification of the disposable part, an authentication signal for certifying that the disposable part is a certified one, a counter indicator for the amount of time since the activation of the disposable part (or the logic element), a signal indicating the degree of coupling between the reusable and disposable parts, a signal indicating the degree of coupling between the probe assembly (reusable and/or disposable parts) with the tissue, optical information detected by the light detectors, and more. This degree of coupling may be measured by the pressure sensor **196** or the ohmmeter **198**, or any other proximity or attachment sensing assembly used in the invention or is known in the art, encoded by the logic controller to activate the lighting element, and transmitted optically to the control unit located internally or externally to the reusable part. This enables to transmit the information without wires or electrical connections that may unintentionally couple electric currents to the tissue, if not properly isolated. According to the invention, the same light detector may be used for receiving both of the information transmitted by the lighting element **190** and the optical signals that were emitted from the light output port **122**. The operation of the lighting element may be synchronized with the operation of the light source included/connected to port **122**. This synchronization can be done by firstly sensing by the light detectors on the disposable part that light is not emitted from port **122** and then triggering the operation of the lighting element **190** through the logic controller **192**. Alternatively, a

communication/synchronization signal can be emitted from light output port **122** to indicate that the light output port **122** will not operate for a specific period of time, allowing operation of the LED **190**. It should be noted that the optical link achieved by the lighting element **190** and used for transmitting the information described above, may be substituted by other wireless links and technologies such as RF.

The pressure sensor **196** may be used instead or in addition to any of the previously mentioned proximity and/or attachment sensing assemblies. The pressure sensor **196** may be used for measuring and communicating the amount of pressure that the probe assembly applies on the tissue. The measured pressure is transmitted (through the operation of the lighting element **190** as described above) to the control unit. When the pressure is lower or higher than predetermined minimal or maximal thresholds, the logic controller **192** can display an alert to the user, or cease the operation of the probe assembly completely.

The ohmmeter **198** (or resistance/current meter) measures the resistance between the disposable part **150C** and the tissue, or between sensing electrodes mounted on the disposable part, and sends a signal (e.g. through the operation of the lighting element **190**) to the control unit. This signal can indicate the coupling between the probe assembly and the tissue, or the amount of gel, or any other coupling substance or media, positioned between the probe assembly and the tissue. When the resistance is lower or higher than predetermined min/max thresholds, the logic controller **192** can display an alert to the user, or cease the operation of the probe system completely.

In the examples above (e.g. Figs. 5, 6, 7, 9), the light source (**104A**) is exemplified as being located inside the control unit which is external to the probe (the reusable part). However, as said earlier, the control unit, or part of it, comprising the light source and/or the acoustic transducer and/or the detection unit may form an integral part of the probe assembly, e.g. may be mounted on the reusable part, as long as the conditions for operating the light source inside the probe, such as temperature, are fulfilled. This is shown in **Fig. 11**, in which the light source **104A** is placed inside the reusable part **110D**. Also shown in the figure, the light output port **122**, the light input port **124** and the acoustic port (or transducer) **120**. The light source **104A** is located on an elastomeric bottom cover **112D** and pressed to the subject together with US transducer and light input port. The reusable housing **110D** consists of two parts: a metal part connected to the light source **104A**, serves as a heat sink and moves with

the light source **104A**, and elastomeric bottom cover **112D** and plastic part which closes the entire design.

CLAIMS:

1. A probe for use in monitoring one or more parameters of a subject, the probe comprising:

a monitoring assembly comprising at least one acoustic port for transmitting acoustic radiation into a region of interest in the subject, at least one light output port for transmitting incident light towards the region of interest, and at least one light input port for receiving light returned from the subject, and

at least one control mechanism comprising at least one sensing assembly configured for sensing at least one of proximity attachment and signal quality conditions, and being configured for controlling a condition of coupling between the probe assembly and the subject, enabling to control operation of the monitoring assembly.

2. The probe of claim 1, comprising a first flexible portion, and a second portion on which said monitoring assembly is mounted, pressing the probe assembly against the subject causing a deformation of said flexible portion thereby reducing a distance between the monitoring assembly and the subject detectable by the proximity sensing assembly.

3. The probe of claim 1 or 2, wherein the proximity sensing assembly comprises a magnetic sensing assembly.

4. The probe of claim 2, wherein said proximity sensing assembly comprises a magnetic sensing assembly comprising a magnet carried by said first flexible portion and a magnetic sensor located at said second portion, the magnetic sensor defining a sensing region in the vicinity thereof and being configured for sensing a magnetic field of said magnet when said magnetic field overlaps with the sensing region of the magnetic sensor.

5. The probe of any one of claims 1 to 4, wherein the controlling mechanism further comprises an additional sensing assembly being of the same or different type as compared to said at least one sensing assembly, and being operable independent from said at least one sensing assembly, said additional sensing assembly being configured for controlling a condition of coupling between the probe and the subject, the at least two independent sensing assemblies enabling to control operation of the monitoring assembly.

6. The probe of claim 5, wherein said additional sensing assembly is a mechanical assembly.

7. The probe of claim 6, comprising a first flexible portion, and a second portion on which said monitoring assembly is mounted, said mechanical assembly comprising a switch located on said flexible portion, pressing the probe assembly against the subject causing a deformation of said flexible portion thereby activating said switch to allow operation of the monitoring assembly.

8. The probe of any one of claims 2 to 7, wherein said first and second portions are removably attachable to one another.

9. The probe of any one of Claims 2 to 8, wherein said flexible portion is configured as a probe-subject adhesive unit being associated with a probe-subject adhesive media.

10. The probe of any one of claims 2 to 9, comprising a light emitting element and a logic controller associated therewith.

11. The probe of claim 10, wherein said light emitting element is carried by said flexible portion.

12. The probe of claim 11, wherein said light emitting element is configured to wirelessly transmit information to one or more other parts of the monitoring assembly or to an external control unit.

13. The probe of claim 12, wherein said information comprises one or more of the following: a serial number for identification of the flexible portion, an authentication signal for certifying that the flexible portion is a certified one, a counter indicator for the amount of time since the activation of the probe assembly, a signal indicating the degree of coupling between the first and second portions, a signal indicating the degree of coupling between the probe assembly and the subject.

14. The probe of any one of the preceding claims, comprising a light source connected to said light output port, and a mechanical support comprising a heat sink structure associated with the light source.

15. The probe of any one of claims 10 to 13, wherein said light emitting element is connected to said light output port, the probe comprising a mechanical support comprising a heat sink structure associated with the light emitting element.

16. A probe for use in monitoring one or more parameters of a subject, the probe comprising:

a portion carrying a monitoring assembly configured for radiating the subject with acoustic and optical radiations, and a flexible portion by which the probe faces the subject when in operation; and

at least one controlling mechanism comprising at least one proximity sensing assembly at least partially located on said flexible portion, pressing the probe assembly against the subject causing a deformation of said flexible portion thereby reducing a distance between the monitoring assembly and the subject detectable by said at least one proximity sensing assembly, thereby enabling to control a condition of coupling between the probe and the subject to thereby control operation of the monitoring assembly.

17. The probe of claim 16, wherein said proximity sensing assembly comprises a magnetic sensing assembly.

18. The probe of claim 17, wherein the magnetic sensing assembly comprises a magnet carried by said flexible portion and a magnetic sensor located at said portion of the monitoring assembly, the magnetic sensor defining a sensing region in the vicinity thereof and being configured for sensing a magnetic field of said magnet when said magnetic field overlaps with the sensing region of the magnetic sensor.

19. The probe of any one of claims 16 to 18, wherein the controlling mechanism further comprises an additional sensing assembly being of the same or different type as compared to said at least one proximity sensing assembly and being operable independent from said at least one proximity sensing assembly, said additional sensing assembly being configured for controlling a condition of coupling between the probe and the subject, the at least two independent sensing assemblies enabling to control operation of the monitoring assembly.

20. The probe of claim 19, wherein said additional sensing assembly is a mechanical assembly.

21. The probe of claim 20, wherein said mechanical assembly comprises a switch located on said flexible portion, pressing the probe assembly against the subject causing a deformation of said flexible portion thereby activating said switch to allow operation of the monitoring assembly.

22. The probe of any one of claims 16 to 21, wherein said first and second portions are removably attachable to one another.

23. A probe for use in monitoring one or more parameters of a subject, the probe comprising:

a portion carrying a monitoring assembly configured for radiating the subject with acoustic and optical radiations, and a flexible portion by which the probe faces the subject when in operation; and

at least first and second controlling mechanisms comprising at least first and second sensing assemblies respectively of the same or different first and second types, each being independently operable to control a condition of coupling between the probe and the subject to control operation of the monitoring assembly if said at least first and second different sensing assemblies identify that said condition is not satisfied, wherein at least one of said at least first and second sensing assemblies being a proximity sensing assembly at least partially located on said flexible portion, pressing the probe against the subject causing a deformation of said flexible portion thereby reducing a distance between the monitoring assembly and the subject detectable by said at least one proximity sensing assembly.

24. The probe of claim 23, wherein said proximity sensing assembly comprises a magnetic sensing assembly.

25. The probe of claim 24, wherein the magnetic sensing assembly comprises a magnet carried by said flexible portion and a magnetic sensor located at said portion of the monitoring assembly, the magnetic sensor defining a sensing region in the vicinity thereof and being configured for sensing a magnetic field of said magnet when said magnetic field overlaps with the sensing region of the magnetic sensor.

26. The probe of any one of claims 24 to 25, wherein the at least one second sensing assembly is a mechanical assembly.

27. The probe of claim 26, wherein said mechanical assembly comprises a switch located on said flexible portion, pressing the probe assembly against the subject causing a deformation of said flexible portion thereby activating said switch to allow operation of the monitoring assembly.

28. The probe of any one of claims 24 to 25, wherein said first and second portions are removably attachable to one another.

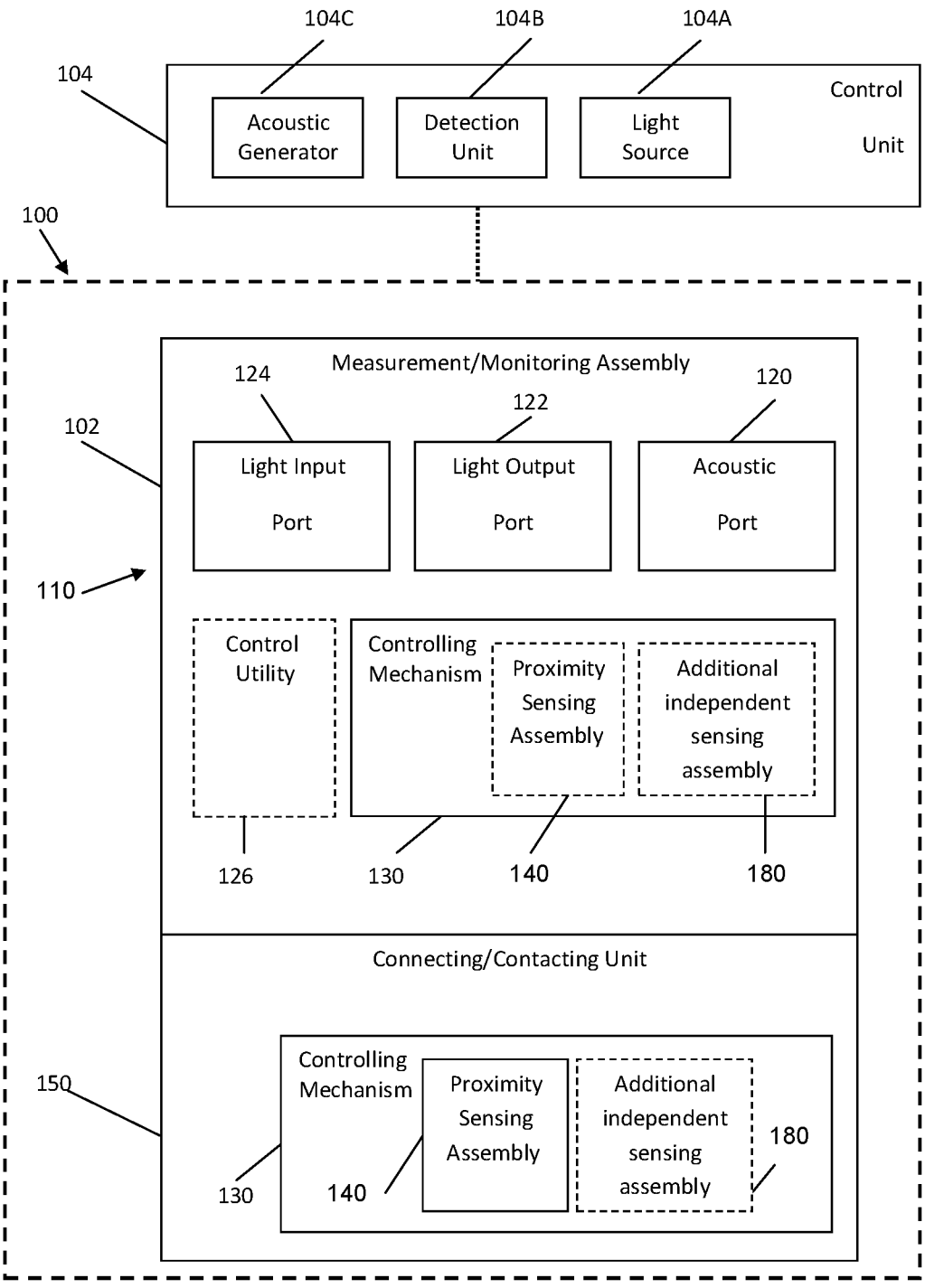
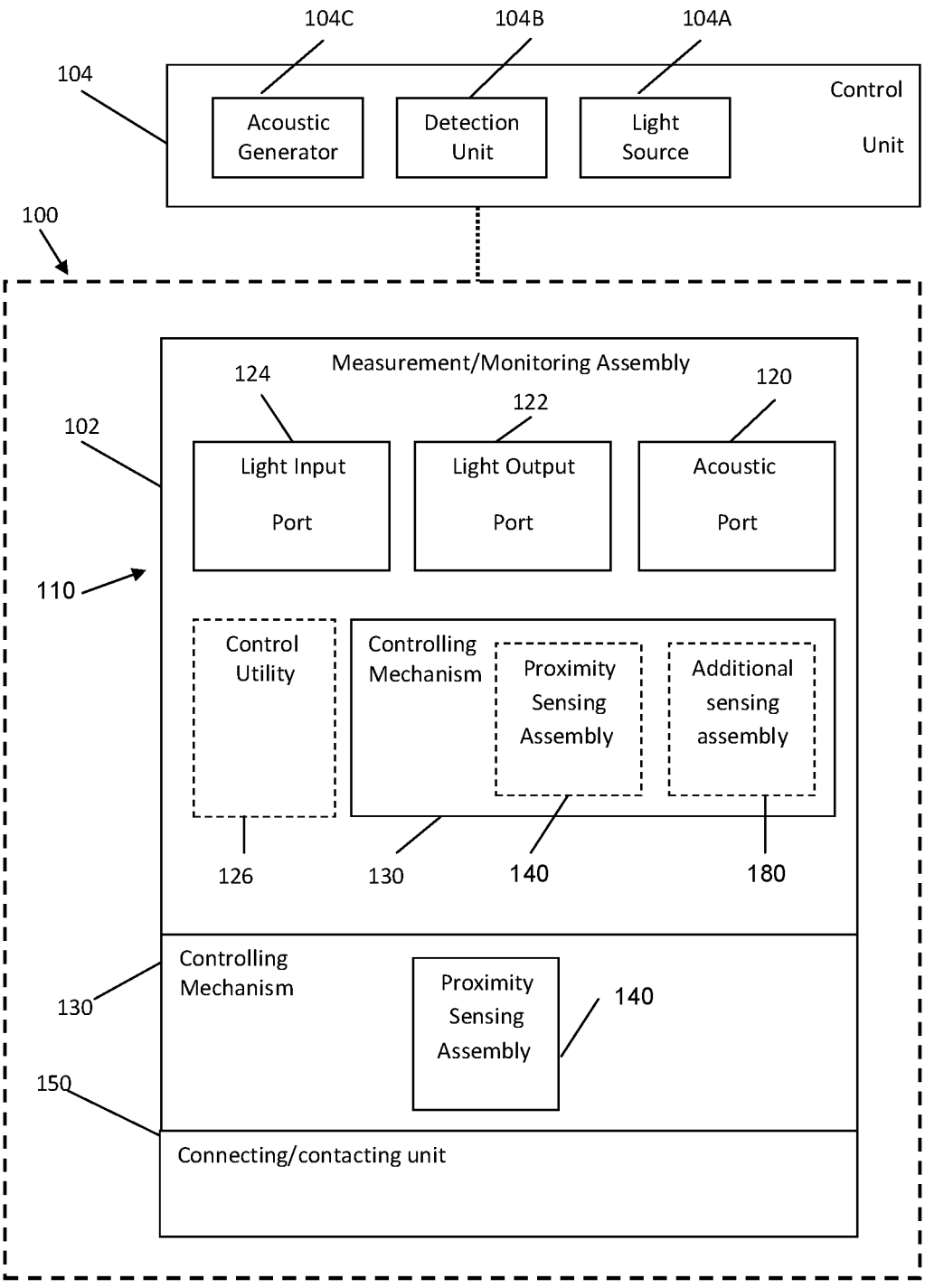

104C
104B
104A
104
Control Unit
Acoustic Generator
Detection Unit
Light Source
100
Measurement/Monitoring Assembly
124
122
120
102
Light Input Port
Light Output Port
Acoustic Port
110
Control Utility
Controlling Mechanism
Proximity Sensing Assembly
Additional independent sensing assembly
126
130
140
180
Connecting/Contacting Unit
150
Controlling Mechanism
Proximity Sensing Assembly
Additional independent sensing assembly
130
140
180

Fig. 1a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Acoustic Generator
Detection Unit
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Measurement/Monitoring Assembly
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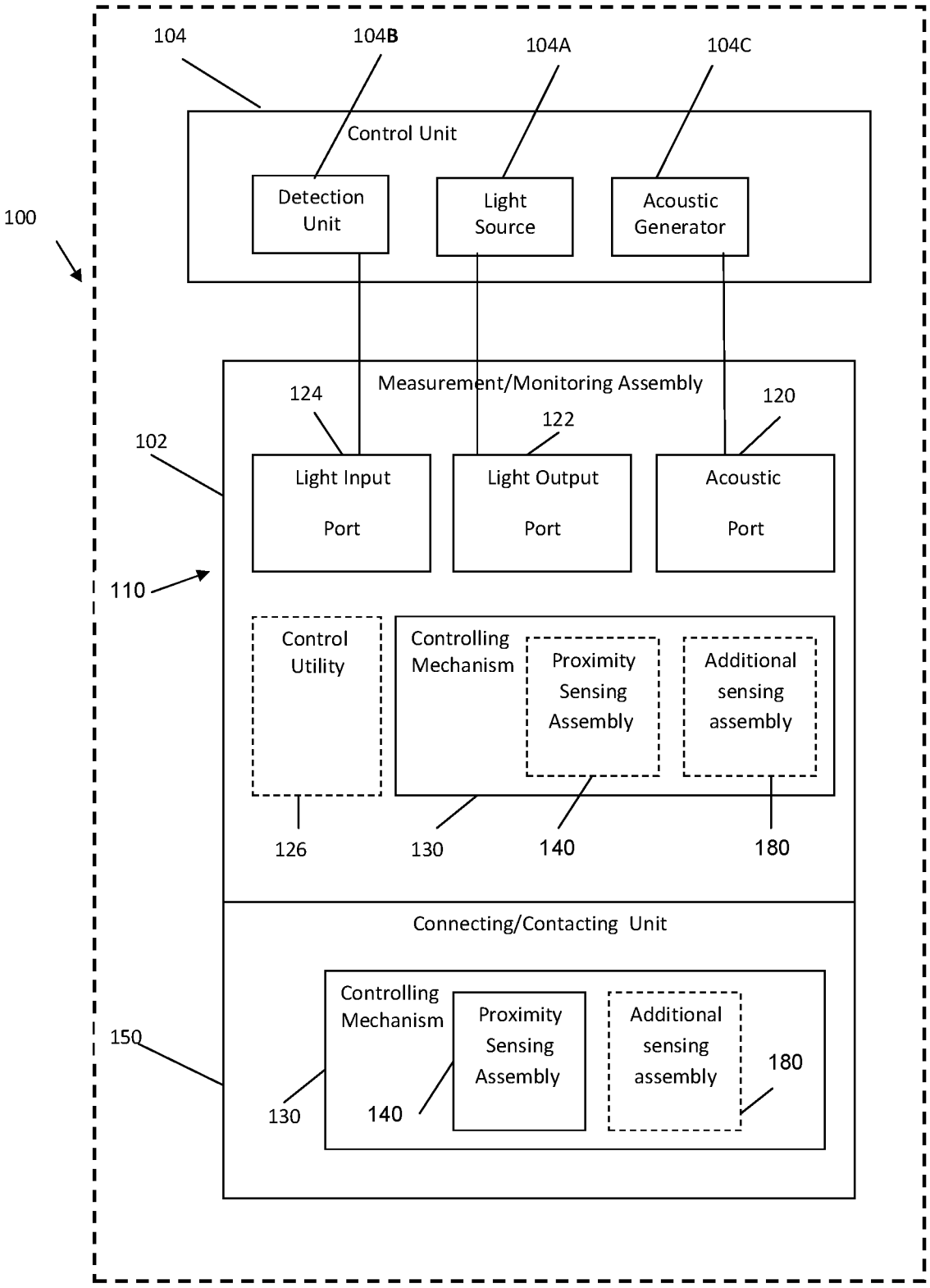
Light Input Port
Light Output Port
Acoustic Port
110
Control Utility
Controlling Mechanism
Proximity Sensing Assembly
Additional sensing assembly
126
130
140
180
Controlling Mechanism
130
Proximity Sensing Assembly
140
150
Connecting/contacting unit

Fig. 1b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104
104B
104A
104C
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Detection Unit
Light Source
Acoustic Generator
Measurement/Monitoring Assembly
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120
102
Light Input Port
Light Output Port
Acoustic Port
110
Control Utility
Controlling Mechanism
Proximity Sensing Assembly
Additional sensing assembly
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Connecting/Contacting Unit
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Controlling Mechanism
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Additional sensing assembly
130
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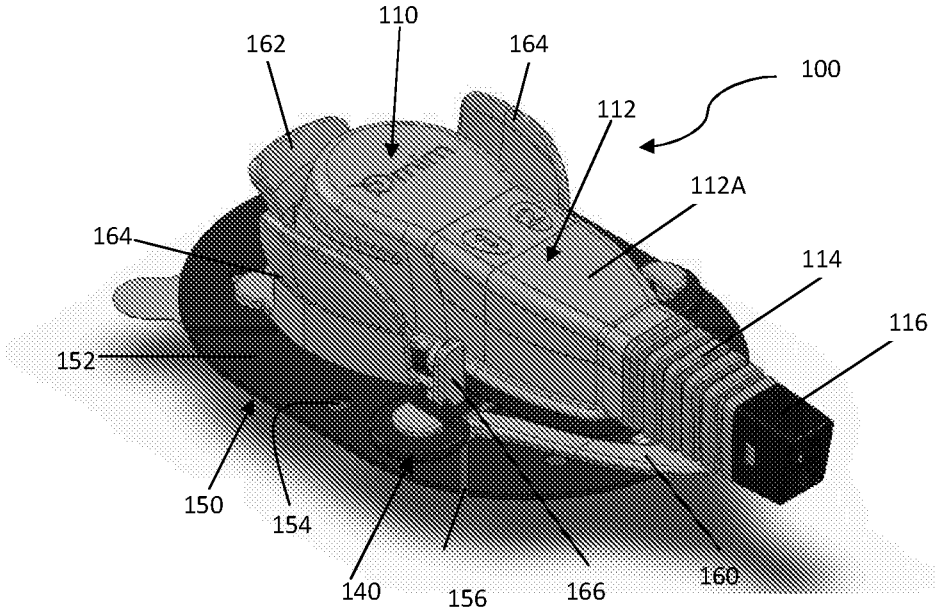
180

Fig. 1c


110
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100
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112A
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114
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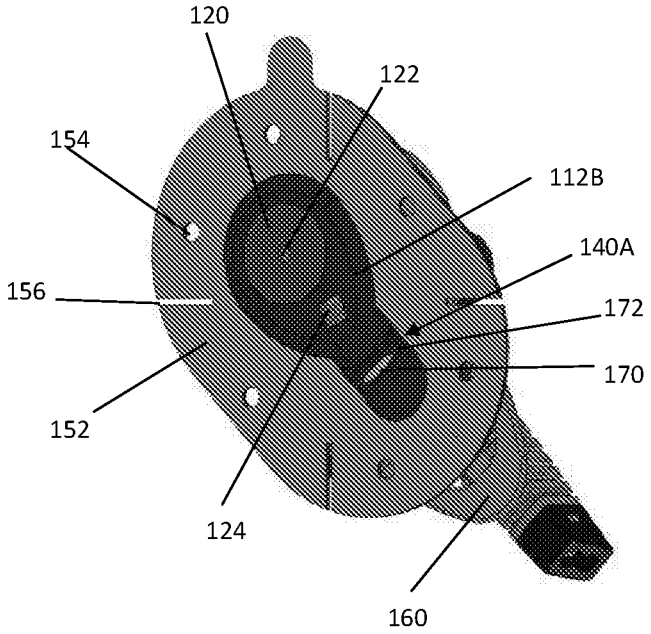
Fig. 2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112B
140A
156
172
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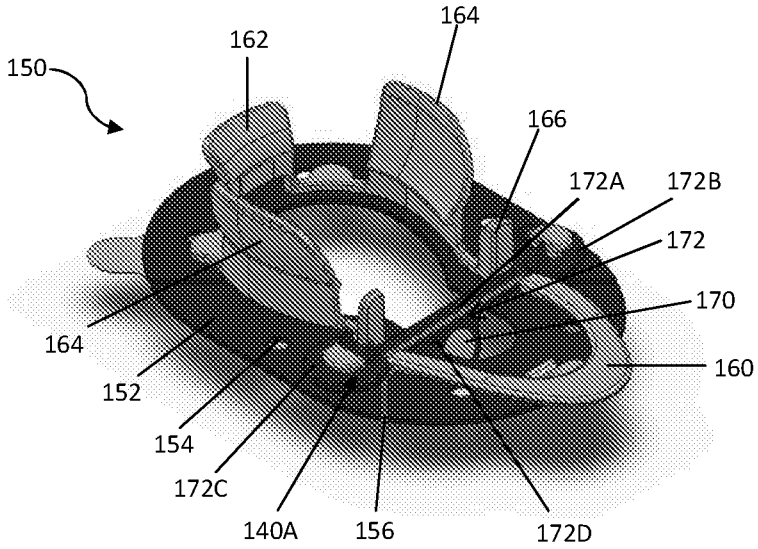
124
160

Fig. 3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166
172A
172B
172
170
160
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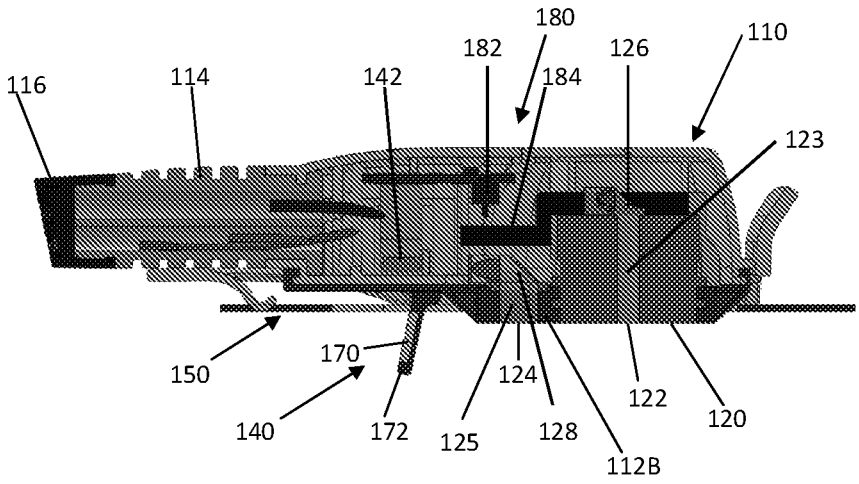
154
172C
140A
156
172D

Fig. 4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182
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110
116
114
142
184
123
150
170
124
122
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140
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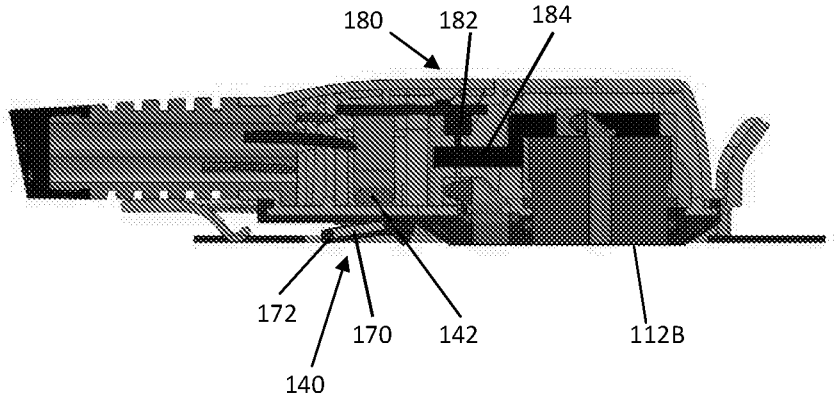
128
112B

Fig. 5


180
182
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172
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142
112B
140

Fig. 6

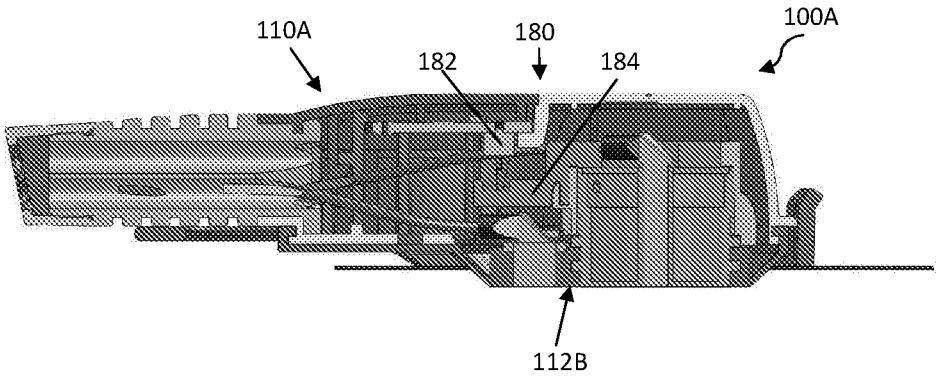

Fig. 7

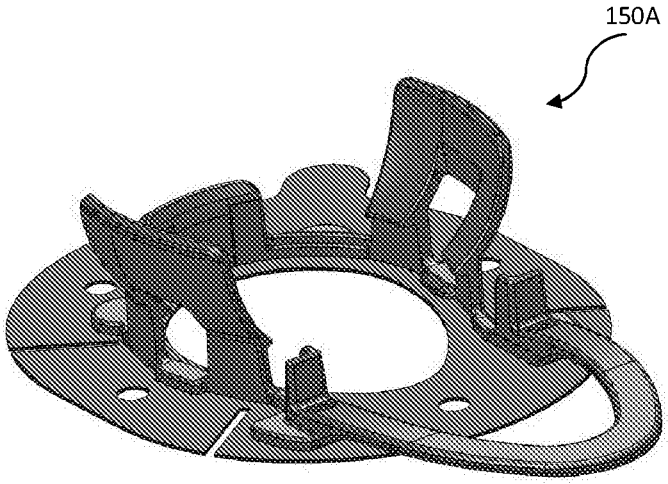

Fig. 8

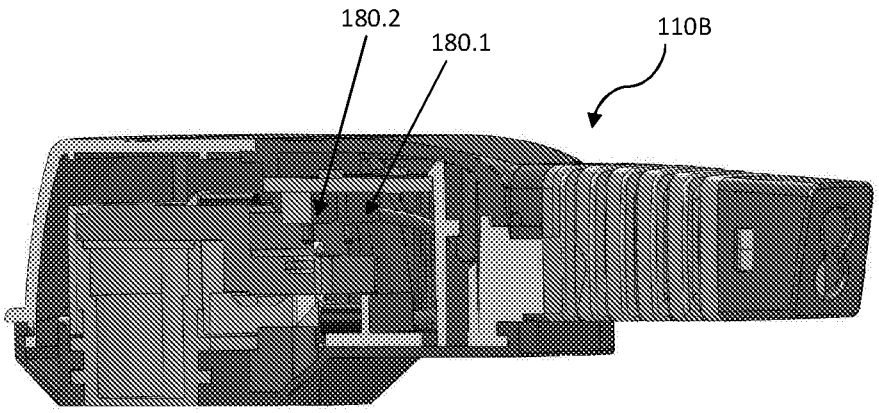

Fig. 9a

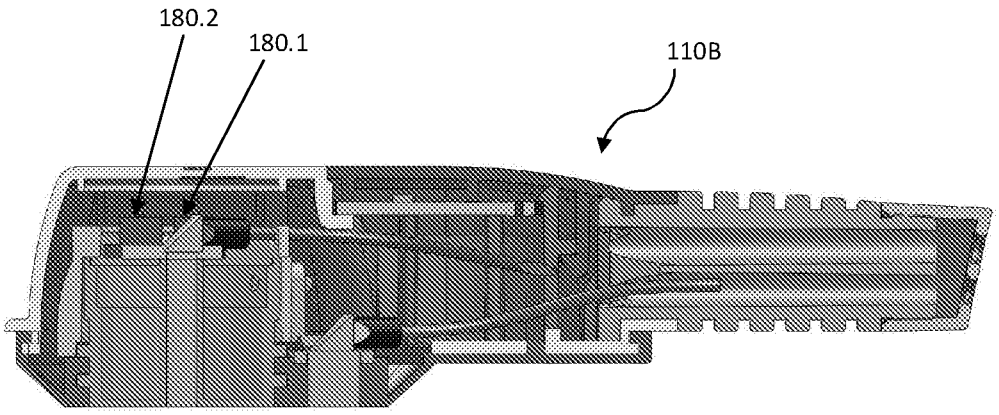

Fig. 9b

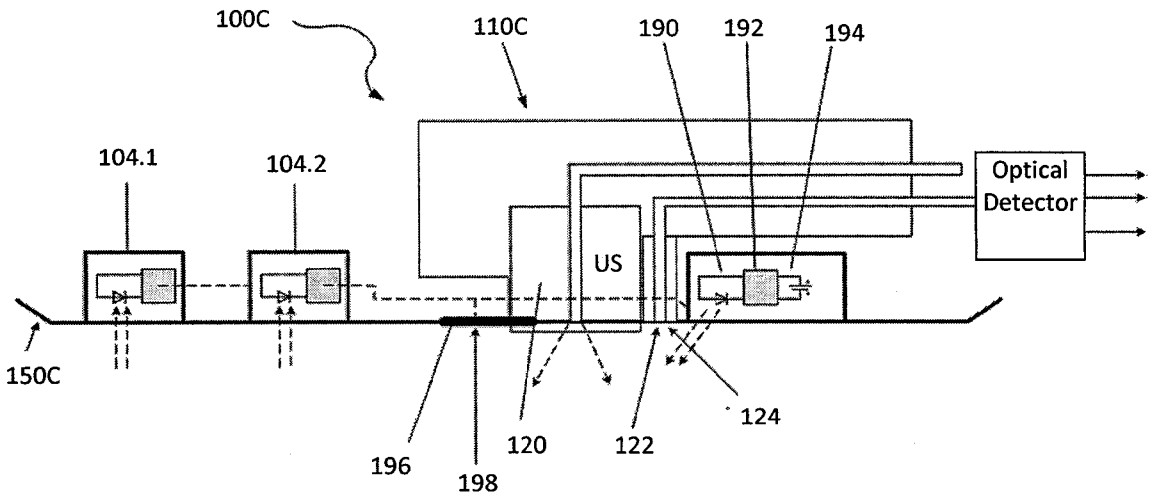
100C
110C
190
192
194
104.1
104.2
Optical Detector
US
150C
196
198
120
122
124

Fig 10

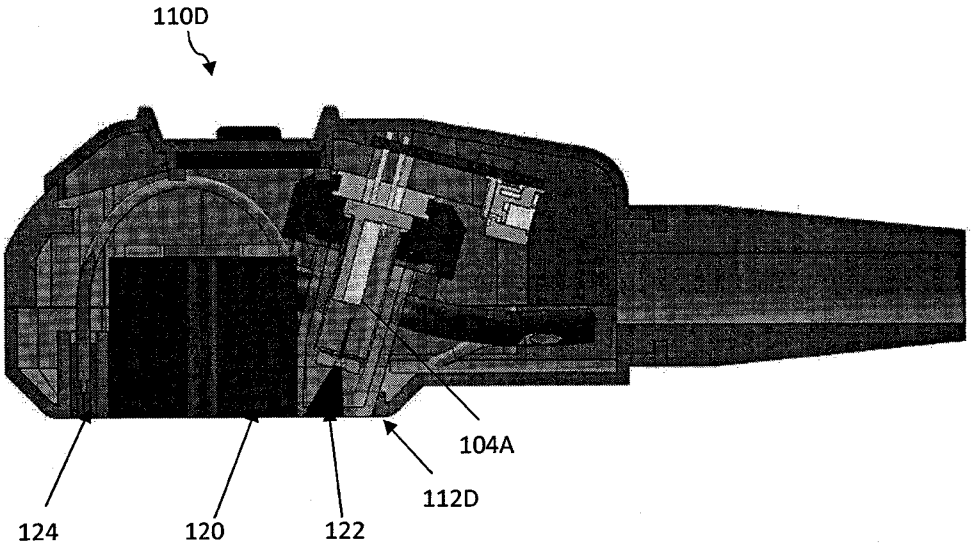
110D
104A
112D
124
120
122

Fig 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2014/050280

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B8/00 A61B5/1455
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)
A61B

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	WO 2009/116029 A2 (OR NIM MEDICAL LTD [IL]; PINTEL OFER [IL]; BENDKOWSKI MICHAEL [IL]; BR) 24 September 2009 (2009-09-24) cited in the application the whole document	1-28
A	US 2006/089547 A1 (SARUSSI ISRAEL [IL]) 27 April 2006 (2006-04-27) paragraphs [0002], [0036] - [0040]; figure 5B	1-28
A	US 2007/197880 A1 (MAYNARD JOHN D [US] ET AL) 23 August 2007 (2007-08-23) abstract paragraph [0101]; figure 41	1-4,6,7, 16-18, 20,21, 23-27

☐ 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	Date of mailing of the international search report
8 July 2014	15/07/2014

Name and mailing address of the ISA/	Authorized officer
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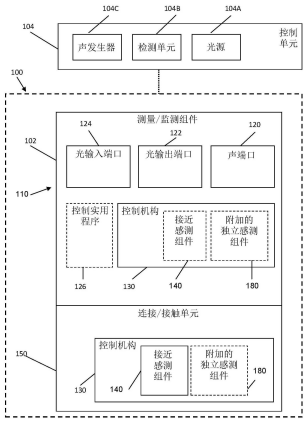
(54)发明名称

用于非侵入式光学监测的探头

(57)摘要

提供了一种在监测对象的一个或更多个参数时使用的探头。该探头包括监测组件，该监测组件包括用于将声辐射发送到所述对象内的感兴趣区域中的至少一个声端口、用于朝向所述感兴趣区域发射入射光的至少一个光输出端口、以及用于接收从所述对象返回的光的至少一个光输入端口。所述探头还包括至少一个控制机构，其包括被配置用于感测接近、附接和信号质量条件中的至少一个感测组件，并且被配置用于控制在所述探头组件与所述对象之间的连接的条件，使得能够控制所述监测组件的操作。



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1. 一种在监测对象的一个或更多个参数时使用的探头，该探头包括：

监测组件，其包括用于将声辐射发送到所述对象内的感兴趣区域中的至少一个声端口、用于朝向所述感兴趣区域发射入射光的至少一个光输出端口、以及用于接收从所述对象返回的光的至少一个光输入端口，以及

至少一个控制机构，其包括被配置用于感测接近、附接和信号质量条件中的至少一个的至少一个感测组件，并且被配置用于控制在所述探头组件与所述对象之间的连接的条件，使得能够控制所述监测组件的操作。

2. 根据权利要求 1 所述的探头，所述探头包括第一柔性部以及安装有所述监测组件的第二部，按压所述探头组件抵靠所述对象导致所述柔性部变形，因此减小能由所述接近感测组件检测的、所述监测组件与所述对象之间的距离。

3. 根据权利要求 1 或 2 所述的探头，其中，所述接近感测组件包括磁感测组件。

4. 根据权利要求 2 所述的探头，其中，所述接近感测组件包括磁感测组件，所述磁感测组件包括由所述第一柔性部承载的磁体以及位于所述第二部处的磁传感器，所述磁传感器限定其附近的感测区域，并且被配置用于在所述磁体的磁场与所述磁传感器的所述感测区域交叠时感测所述磁体的所述磁场。

5. 根据权利要求 1 至 4 中的任一项所述的探头，其中，所述控制机构还包括附加的感测组件，所述附加的感测组件具有与所述至少一个感测组件相比相同或不同的类型，并且能独立于所述至少一个感测组件操作，所述附加的感测组件被配置用于控制所述探头与所述对象之间的连接的条件，所述至少两个独立的感测组件使得能够控制所述监测组件的操作。

6. 根据权利要求 5 所述的探头，其中，所述附加的感测组件是机械组件。

7. 根据权利要求 6 所述的探头，所述探头包括第一柔性部以及安装有所述监测组件的第二部，所述机械组件包括位于所述柔性部上的开关，按压所述探头组件抵靠所述对象导致所述柔性部变形，因此激活所述开关以使得能够操作所述监测组件。

8. 根据权利要求 2 至 7 中的任一项所述的探头，其中，所述第一部和所述第二部彼此能移除地附接。

9. 根据权利要求 2 至 8 中的任一项所述的探头，其中，所述柔性部被配置为与探头 - 对象粘接介质关联的探头 - 对象粘接单元。

10. 根据权利要求 2 至 9 中的任一项所述的探头，所述探头包括发光元件以及与所述发光元件关联的逻辑控制器。

11. 根据权利要求 10 所述的探头，其中，所述发光元件由所述柔性部承载。

12. 根据权利要求 11 所述的探头，其中，所述发光元件被配置为向所述监测组件的一个或更多个其它部件或者向外部的控制单元无线地发送信息。

13. 根据权利要求 12 所述的探头，其中，所述信息包括下面的项中的一个或更多个：用于识别所述柔性部的序列号、用于验证所述柔性部是经验证的柔性部的认证信号、自激活所述探头组件开始的时间量的计数器指示器、指示所述第一部与所述第二部之间的连接的程度的信号、指示所述探头组件与所述对象之间的连接的程度的信号。

14. 根据前述权利要求中的任一项所述的探头，所述探头包括：光源，其与所述光输出端口连接；以及机械支承件，其包括与所述光源关联的散热器结构。

15. 根据权利要求 10 至 13 中的任一项所述的探头，其中，所述发光元件与所述光输出端口连接，所述探头包括机械支承件，所述机械支承件包括与所述发光元件关联的散热器结构。

16. 一种在监测对象的一个或更多个参数时使用的探头，该探头包括 ：

承载监测组件的部分，所述监测组件被配置用于利用声辐射和光辐射来辐射所述对象，以及柔性部，其使所述探头在操作中面对所述对象 ；以及

至少一个控制机构，其包括至少部分地位于所述柔性部上的至少一个接近感测组件，按压所述探头组件抵靠所述对象导致所述柔性部变形，因此减小能由所述至少一个接近感测组件检测的、所述监测组件与所述对象之间的距离，因此使得能够控制所述探头与所述对象之间的连接的条件以由此控制所述监测组件的操作。

17. 根据权利要求 16 所述的探头，其中，所述接近感测组件包括磁感测组件。

18. 根据权利要求 17 所述的探头，其中，所述磁感测组件包括由所述柔性部承载的磁体以及位于所述监测组件的所述部分处的磁传感器，所述磁传感器限定其附近的感测区域，并且被配置用于在所述磁体的磁场与所述磁传感器的所述感测区域交叠时感测所述磁体的所述磁场。

19. 根据权利要求 16 至 18 中的任一项所述的探头，其中，所述控制机构还包括附加的感测组件，所述附加的感测组件具有与所述至少一个接近感测组件相比相同或不同的类型，并且能独立于所述至少一个接近感测组件操作，所述附加的感测组件被配置用于控制所述探头与所述对象之间的连接的条件，所述至少两个独立的感测组件使得能够控制所述监测组件的操作。

20. 根据权利要求 19 所述的探头，其中，所述附加的感测组件是机械组件。

21. 根据权利要求 20 所述的探头，其中，所述机械组件包括位于所述柔性部上的开关，按压所述探头组件抵靠所述对象导致所述柔性部变形，因此激活所述开关以使得能够操作所述监测组件。

22. 根据权利要求 16 至 21 中的任一项所述的探头，其中，所述第一部和所述第二部彼此能移除地附接。

23. 一种在监测对象的一个或更多个参数时使用的探头，该探头包括 ：

承载监测组件的部分，所述监测组件被配置用于利用声辐射和光辐射来辐射所述对象，以及柔性部，其使所述探头在操作中面对所述对象 ；以及

至少第一控制机构和第二控制机构，其分别包括相同或不同的第一类型和第二类型的至少第一感测组件和第二感测组件，第一控制机构和第二控制机构分别能独立地操作以控制所述探头与所述对象之间的连接的条件，使得如果不同的所述至少第一感测组件和第二感测组件识别出不满足所述条件，则控制所述监测组件的操作，其中，所述至少第一感测组件和第二感测组件中的至少一个是至少部分地位于所述柔性部上的接近感测组件，按压所述探头抵靠所述对象导致所述柔性部变形，因此减小能由所述至少一个接近感测组件检测的、所述监测组件与所述对象之间的距离。

24. 根据权利要求 23 所述的探头，其中，所述接近感测组件包括磁感测组件。

25. 根据权利要求 24 所述的探头，其中，所述磁感测组件包括由所述柔性部承载的磁体以及位于所述监测组件的所述部分处的磁传感器，所述磁传感器限定其附近的感测区

域，并且被配置用于在所述磁体的磁场与所述磁传感器的所述感测区域交叠时感测所述磁体的所述磁场。

26. 根据权利要求 24 至 25 中的任一项所述的探头，其中，所述至少一个第二感测组件是机械组件。

27. 根据权利要求 26 所述的探头，其中，所述机械组件包括位于所述柔性部上的开关，按压所述探头组件抵靠所述对象导致所述柔性部变形，因此激活所述开关以使得能够操作所述监测组件。

28. 根据权利要求 24 至 25 中的任一项所述的探头，其中，所述第一部和所述第二部彼此能移除地附接。

用于非侵入式光学监测的探头

[0001] 技术领域和背景技术

[0002] 本发明总体上处于医学装置的领域，并且涉及一种探头装置以及一种利用这种探头装置来利用光的超声标记 (tagging) 对对象 (subject) 执行测量的监测系统。本发明对于监测例如以下参数的各种参数特别有用 :血管、毛细血管和小静脉中的流速和氧饱和度，以及诸如脑、肌肉、肾和其它器官这样的深部组织中的氧饱和度。

[0003] 已经开发出非侵入地监测对象的条件的各种技术。这些技术包括基于阻抗的测量技术、光声测量、声学测量 (多普勒测量) 以及光学测量 (例如，血氧定量法)。

[0004] 已经开发出基于光的超声标记在各种化学和生理参数的测量中的使用的另一方法，并且例如在全部被转让给本申请的受让人的 WO 06/097910、WO 05/025399 和 WO 2009/116029 中公开了这种方法。根据 WO 2009/116029 的技术，一种探头组件被用于监测对象的一个或更多个参数，其中，所述探头组件包括用于将声辐射发送到对象内的感兴趣区域中的声端口、用于朝向该感兴趣区域发射入射光的至少一个光输出端口、用于接收从该对象返回的光的至少一个光输入端口、以及控制实用程序 (utility)。后者被配置用于控制监测过程的至少一个条件，并且在检测到满足所述至少一个条件时能够实现该监测过程。

发明内容

[0005] 本发明提供了一种新颖的探头组件，该新颖的探头组件使得探头能够有效地附接到对象 (即，使得能够连续地监测对象的一个或更多个条件) 并且使得所述探头的附接部能够是一次性的。

[0006] 本发明利用了利用光的超声标记的原理的监测技术，例如如同在被转让给本发明的受让人的以上指出的专利公开 WO 05/025399、WO 06/097910、WO 2009/116029 中公开的。本发明的探头组件被如此配置，并且可操作以在对感兴趣区域进行光学测量的同时利用声波来辐射所述感兴趣区域。

[0007] 发明人已经发现，利用这种探头组件，可期望在除测量会话以外的条件下防止产生声辐射和光辐射。更具体地，所述探头组件应该被配置为使得能够自我监测所述探头组件相对于对象的位置，使得在检测到所述探头组件适当地附接到所述对象的组织或者检测到存在另一预定条件时，所述探头组件能够被激活以进行测量。

[0008] 因此，根据其一个广泛的方面，本发明提供了一种在监测对象的一个或更多个参数时使用的探头组件。所述探头组件包括 :至少一个声端口，其用于将声辐射发送到对象内的感兴趣区域中 ;至少一个光输出端口，其用于朝向所述感兴趣区域发射入射光 ;至少一个光输入端口，其用于接收从所述对象返回的光 ;以及至少一个控制机构。

[0009] 在本发明的一些实施方式中，所述探头组件可以包括至少一个声端口，所述至少一个声端口用于从所述对象内的感兴趣区域接收声辐射。这可以用于既发送且接收声辐射的相同的声端口来实现，或者通过使用用于这些功能的单独的声端口来实现。在后者情况下，存在包括在所述探头组件中的至少两个声端口，至少一个声端口用于发送声辐射，并且

至少一个声端口用于接收声辐射。

[0010] 所述至少一个控制机构被配置用于控制所述声端口及所述光输出端口与所述对象之间的连接的条件，并且因此控制所述探头的操作（监测过程），例如，在识别到不满足所述条件时阻止操作所述探头组件和/或向操作员提醒不满足所述条件和/或给所述操作员提供所述条件的定量测量。这种控制机构可以至少包括接近感测组件、附接感测组件或者信号质量感测组件。

[0011] 应该注意的是，所述探头可以自动地或者在用户决定时基于控制机构确定在所述探头的操作状态与非操作状态之间转换。

[0012] 在本发明的一些实施方式中，所述控制机构的所述接近感测组件包括磁组件，该磁组件可以包括磁传感器（检测器）和磁体。所述磁组件可以操作成使得当使所述磁体接近于与所述探头组件和所述对象之间的期望的连接的条件对应的所述磁传感器的检测范围时，所述磁体的磁场由所述磁传感器检测到，使得能够安全地激活所述声辐射以及所述光辐射，然而，只要所述磁体在所述磁传感器的所述检测区域之外，就不允许所述探头的操作。

[0013] 在一些实施方式中，除基于磁体的组件之外或者作为基于磁体的组件的另选方案，所述控制机构可以包括任何其它接近检测组件（诸如基于电容的组件）、以及一个或更多个其它感测组件（诸如光学组件、超声距离感测组件、压力测量组件或者基于 RFID 的组件）。

[0014] 在一些实施方式中，所述控制机构的所述附接感测组件包括机械或机电组件，该机械或机电组件利用所述探头组件的机械特性以便使得能够激活所述探头组件（例如，激活声辐射和/或光辐射）。在一些实施方式中，所述探头组件被配置为两部件装置(two-part device)，其中，这两个部件可彼此附接/分离。这使得用于使所述探头组件与所述对象接触的一个部件能够是一次性的，并且使得另一部件能够承载测量单元的元件（声端口/元件以及光端口/元件）并因此是可重复使用的部件。应该理解的是，在所述探头组件的单部件设计或两部件设计中，所述探头组件包括所谓的测量和接触/连接部，然而在所述两部件设计中，这些部是可附接的/可分离的。在以下描述中，这些部件/部被分别称为可重复使用部件和一次性部件，但是应该理解的是，通常这两者可以是一次性的或者可重复使用的。

[0015] 在一些实施方式中，所述控制机构的所述信号质量感测组件包括光发射器（例如 LED)，该光发射器可以与逻辑控制器关联，并且可以被用来将信息从所述一次性部件无线地发送到所述可重复使用部件或者所述控制单元。所述信息可以包括用于识别所述一次性部件的序列号、用于验证所述一次性部件是经验证的一次性部件的认证信号、针对自激活所述一次性部件开始的时间量的计数器指示器、指示所述可重复使用部件与所述一次性部件之间的连接的程度的信号、指示所述探头组件（可重复使用部件和/或一次性部件）与组织之间的连接的程度的信号。所发送的信息还可以用于承载传感器信息，例如，当被设置在所述一次性部件上时从光检测器输出。

[0016] 因此，根据本发明的第一广泛的方面，提供了一种在监测对象的一个或更多个参数时使用的探头，该探头包括：监测组件，该监测组件包括用于将声辐射发送到所述对象内的感兴趣区域中的至少一个声端口、用于朝向所述感兴趣区域发射入射光的至少一个光输

出端口、用于接收从所述对象返回的光的至少一个光输入端口；以及至少一个控制机构，该至少一个控制机构包括至少一个感测组件，该至少一个感测组件被配置用于感测接近条件、附接条件和信号质量条件中的至少一个，并且被配置用于控制所述探头组件与所述对象之间的连接的条件，因此使得能够控制所述监测组件的操作，例如，如果不满足所述至少一个条件，则阻止其操作。

[0017] 所述探头可以包括第一柔性部以及安装有所述监测组件的第二部，使得按压所述探头抵靠所述对象导致所述柔性部变形，因此减小可由所述接近和/或附接感测组件检测的、所述监测组件与所述对象之间的距离。

[0018] 所述接近感测组件可以包括磁感测组件。优选地，所述磁感测组件包括由所述第一柔性部承载的磁体以及位于所述第二部处的磁传感器，所述磁传感器限定其附近的感测区域，并且被配置用于在所述磁体的磁场与所述感测区域交叠时感测所述磁体的磁场。另选地或者附加地，所述接近感测组件可以包括利用本领域中已知的技术的压力感测组件，诸如电容式、电阻式和机电式应变仪。

[0019] 所述控制机构可以包括所述至少一个接近感测组件以及用于控制所述探头组件与所述对象之间的连接的条件的不同类型的感测组件。这样的至少两个不同的感测组件控制所述监测组件的操作，例如，只要不满足连接条件，就阻止所述监测组件的操作。在一些实施方式中，连接感测组件是机械组件，并且在这种情况下，所述机械组件可以包括位于柔性部上的开关，使得按压所述探头抵靠所述对象导致所述柔性部变形，由此激活所述开关以使得能够操作所述监测组件。

[0020] 根据一些实施方式，所述探头的第一部和第二部彼此可移除地附接。

[0021] 可以将所述柔性部配置为与探头-对象粘接介质关联的探头-对象粘接单元。

[0022] 根据本发明的另一广泛的方面，提供了一种在监测对象的一个或更多个参数时使用的探头，该探头包括：承载监测组件的部分，该监测组件被配置用于利用声辐射和光辐射来辐射所述对象；柔性部，该柔性部使得所述探头在操作中面对所述对象；以及至少一个控制机构，该至少一个控制机构包括至少部分地位于所述柔性部上的至少一个接近和/或附接感测组件，使得按压所述探头抵靠所述对象导致所述柔性部变形，因此减小可由所述至少一个控制机构检测的、所述监测组件与所述对象之间的距离，从而使得能够控制所述探头与所述对象之间的连接的条件以控制所述监测组件的操作。

[0023] 根据本发明的又一个广泛的方面，提供了一种在监测对象的一个或更多个参数时使用的探头，该探头包括：一部分，该部分承载监测组件，并且被配置用于利用声辐射和光辐射来辐射所述对象，以及柔性部，该柔性部使所述探头在操作中面对所述对象；以及至少第一控制机构和第二控制机构，该至少第一控制机构和第二控制机构分别包括相同或不同的第一类型和第二类型的至少第一感测组件和第二感测组件，第一控制机构和第二控制机构分别可独立地操作以控制所述探头与所述对象之间的连接的条件，使得如果不同的所述至少第一感测组件和第二感测组件识别出不满足所述条件，则阻止所述监测组件的操作，其中，所述至少第一感测组件和第二感测组件中的至少一个是至少部分地位于所述柔性部上的接近感测组件，按压所述探头抵靠所述对象导致所述柔性部变形，因此减小可由所述至少一个接近感测组件检测的、所述监测组件与所述对象之间的距离。

附图说明

[0024] 为了理解本发明，并且为了领会在实践中可以如何实现本发明，现在将参照附图仅通过非限制性的示例来描述实施方式，其中：

[0025] 图 1a 是根据本发明的一个方面的探头组件的示例的框图；

[0026] 图 1b 是根据本发明的另一方面的探头组件的示例的框图；

[0027] 图 1c 是根据本发明的又一方面的探头组件的示例的框图；

[0028] 图 2 是本发明的探头组件的特定但非限制性的示例的等距上部视图；

[0029] 图 3 例示了图 2 的探头组件的等距底部视图；

[0030] 图 4 示出了图 2 和图 3 的探头组件的两部件设计的示例，并且更具体地例示了探头组件的可以作为一次性部分的柔性部件 / 部；该图更具体地示出了部分地位于探头组件的柔性部件中的接近感测组件（在该示例中的磁感测组件）的一部分；

[0031] 图 5 和图 6 是更具体地示出了控制机构的处于其激活状态的两个不同的感测组件（对应于探头组件的非操作位置，即，其监测组件）的图 2 至图 4 的探头组件的横截面侧视图；

[0032] 图 7 和图 8 分别是根据另一实施方式的探头组件的横截面侧视图以及探头组件的可以作为一次性部分的柔性部件 / 部的等距视图，该探头组件不具有接近感测组件；

[0033] 图 9a 和图 9b 示出了包括位于探头组件内部的双重感测机械组件的探头组件的示例；

[0034] 图 10 是本发明的包括控制机构（具体地信号质量感测组件）的多种可能性的探头组件的两部件设计的示意图示；

[0035] 图 11 示出了光源位于探头本身内部的探头设计。

具体实施方式

[0036] 参照图 1a 至图 1c，通过框图的方式例示了根据本发明的用于监测对象的一个或更多个参数的探头 100 的三个示例。探头 100 包括适合于执行基于超声标记的光学测量的测量 / 监测单元 102，并且因此包括与用于将声辐射发送到对象内的感兴趣区域中的声换能器关联（即，包括声换能器或者可连接到声换能器）的一个或更多个端口（总体上在 120 处）、与用于朝向感兴趣区域发射入射光的光源关联（即，包括光源或者可连接到光源）的至少一个光输出端口 122、以及与用于接收从对象返回的光的光检测器关联（即，包括光检测器或者可连接到光检测器）的至少一个光输入端口 124。应该注意的是，尽管未具体地示出，然而探头还可以包括用于接收反射的声辐射的附加的声换能器，或者相同的声换能器可以被配置用于发送和接收声辐射。可选地，尽管未示出，然而探头还可以包括与其操作模式以及光照条件的识别（例如，LED 开启 / 关闭 / 闪烁）有关的指示。

[0037] 探头组件 100 可以与控制单元 104 关联，该控制单元 104 通常被配置为计算系统和逻辑，并且除了其它方面以外，还可以包括光源单元 104A 和 / 或检测单元 104B 和 / 或声发生器 104C（例如，任意波形发生器）。一般地，控制单元 104 可以被配置为如图 1a 和图 1b 中所示的可连接到测量 / 监测单元 102 的外部单元，或者被配置为如图 1c 中所示的容纳在探头组件 100 内的内部单元，或者被配置为其中功能单元 104A、104B 和 104C 的一部分位于探头组件 100 的内部，而剩余部分位于探头组件 100 的外部的混合单元（未示出）。当被

全部地或部分地配置为外部单元时，在探头组件 100 与外部控制单元 104 之间可以经由导线或者借助于无线信号 / 数据传输（例如 RF、IR、声音）进行通信。

[0038] 优选地，连接外部光发射器（例如，在控制单元中）以及探头装置处的光输出端口的光导 (light guide) 是小芯光纤（例如单模、50μm或62.5μm芯光纤）。至于连接外部光检测器（例如，在控制单元中）以及探头装置处的相应的光输入端口的光导，该光导具有适当的横截面尺寸的芯，以便满足收集效率要求。例如，能够使用具有直径等于或大于100μm的芯的光纤或光纤束。收集光纤的最大直径和数值孔径被确定为使得在光纤芯内的不同路径中行进的光之间的总路径差小于光源的相干长度。当光源和 / 或检测器形成探头 100 的整体部分时，消除了光纤。导线（或无线装置）被用来连接探头 100 或者具有监视器的外部控制单元104，该监视器用于显示与诊断 / 监测过程有关的图像或数据和 / 或为了执行该过程而选择的参数。

[0039] 探头装置 100 还包括内部控制实用程序 126。控制实用程序 126 可以被配置为与以上指出的专利公开 WO 2009/116029 中描述的控制实用程序大体上相似的原因在于，控制实用程序 126 安装有适当的电子实用程序（利用唯一激活代码操作的编码芯片），使得能够识别探头组件是否是经验证的探头组件（即，认证过程）；和 / 或控制实用程序 126 包括适合于记录指示在特定时间段期间对特定对象进行的测量的数据的存储单元（因此使得能够使用该数据作为该特定对象的测量历史）。这样的数据可以用作特定对象的测量历史，作为用于记录测量的持续时间或者遵循特定持续时间或日期的使用的期满 / 阻止的措施。存储单元还可以存储包括与探头序列号或者与探头相关的任何特定技术参数（例如，校准）有关的信息的数据。

[0040] 探头装置 100 可以被配置为两部件组件，一个部件 110 承载测量 / 监测单元 102 的元件，并且可以是可重复使用的，而使得探头与对象接触的另一部件 150 被配置为提供探头与对象之间的期望的连接以及与可重复使用部件 110 的期望的连接，并且可以是一次性的。探头装置的两个部件 110 和 150 可彼此适当地附接 / 分离。

[0041] 当利用声辐射以及特别是利用光的超声标记来执行测量时，需要声端口与对象之间的足够程度的声连接、以及对象与输出光端口之间的一定程度的连接（以消除 / 减少眼睛对光辐射的暴露），以便在识别到已建立期望的连接时驱动并且操作测量。根据本发明，探头装置 100 包括适当地设计的控制机构 130，该控制机构 130 被配置为满足以上两个要求（即，确保测量 / 监测单元 102（即，可重复使用部件 110）适当地附接到另一接触部件 150（一次性的），以及确保所述接触部件 150 和测量部件 110 附接到在监测下的对象。为了便于理解，作为功能上不同的部件（所谓的测量部件和接触部件）的探头 100 的顶部部件 110 和底部部件 150 在下文中被分别称为可重复使用部件和一次性部件，但是应该理解的是，通常这两者都可以是一次性的或可重复使用的。

[0042] 控制机构 130 包括至少第一感测组件 140（诸如基于磁的和 / 或基于光的和 / 或基于压力的、和 / 或机械的和 / 或电的和 / 或电阻式的等），并且优选地还包括与第一感测组件相同或不同的类型的至少一个附加的可独立地操作的感测组件 180。因此，优选地，控制机构是两个感测组件独立地操作的双感测机构，并且在通过这两个组件检测到实现了适当的连接时，使得能够驱动测量过程。

[0043] 应该清楚的是，如能够在图 1a 至图 1c 中看到的，控制机构 130 的至少一部分位于

测量部件 110 的内部。控制机构的另一补充部件可以位于测量部件 110 的外部，例如，在如图 1a 和图 1c 中所示的连接 / 接触单元 150 内。

[0044] 应该注意的是，本发明不限于图 1a 至图 1c 的框图中所示的特定配置，例如，另一可能的实施方式可以是图 1b 和图 1c 中所示的配置的组合（即，控制单元 104 被集成在探头 100 内（如图 1c 中所示），并且控制机构 130 不形成连接 / 接触单元 150 的一部分（如在图 1b 中一样））。

[0045] 参照图 2，示意性地例示了根据本发明的示例的探头组件 100。为了便于例示，在所有的图中，相同的附图标记被用来标识共同的组件。探头组件 100 由附接在一起的可重复使用单元 110（承载 / 表示测量单元）和一次性单元 150（即，探头的接触部分）这两个部件构成。可重复使用单元 110 包括外壳 112，该外壳 112 在其中承载有测量 / 监测系统的元件。外壳可以包括顶盖 112A，该顶盖 112A 可以由硬质塑料制成。通常，顶盖 112A 可以是单部件结构；然而，为了利于其组装及服务，它可以由可彼此附接的多个部件组成。另外，外壳能够封装 LED，以指示激光发射，或者以指示在多个探头连接到同一系统的情况下的操作模式，每个探头可以发出具有不同的颜色或标记图 (signature) 的光。

[0046] 可重复使用单元 110 还可以包括应变消除构件 114，该应变消除构件 114 被配置用于利用线缆和 / 或光纤来固定可重复使用单元 110 的连接和弯曲点。光纤以及其它线缆穿过构件 114，并且连接光输入 / 输出端口和声端口，全部将在下面分别用诸如激光器这样的适当的光源和超声换能器来描述。应该理解的是，在本发明的一些实施方式中，可重复使用单元 110 包括超声换能器，然而在其它实施方式中，它仅包括负责传递由位于在可重复使用单元 110 外部的换能器生成的超声辐射的声端口。该图中还示出了应变消除帽 116，该应变消除帽 116 可以被用来锁定应变消除构件 114。能够用各种颜色制造并组装帽 116，以指示并且标记可重复使用单元 110 的各种版本。

[0047] 可重复使用单元 110 容纳该图中未示出的各种功能元件 / 单元。如以上参照图 1 描述的，这些元件 / 单元包括用于发送 / 接收声辐射的超声换能器或声端口、至少一个光输出端口 / 源、至少一个光输入端口 / 检测器。另外，如将在下面参照图 3 至图 5 描述的，可重复使用单元承载控制机构（例如磁传感器、机械微型开关）。

[0048] 一次性单元 150 包括协助将探头附接到患者皮肤的附接垫 152（诸如粘接垫和 / 或带）。附接垫 152 可以是相对宽的。附接垫 152 可以由生物相容的粘接层和遮光织物层（两者能够实现一定程度的空气流通到患者皮肤）的组合制成。为了支持并且提供附加的空气流通，垫 152 可以包括附加的通孔 154。垫 152 通常是柔性的，并且为了增强其柔性以及与和其曲率匹配的患者皮肤的附接，该垫可以在其周边周围包括附加的直通切口 156。一次性单元 150 一方面用作对可重复使用单元 110 的固定支承，并且另一方面用作探头到患者皮肤的连接器（作为粘接剂）。为此，一次性单元 150 包括支承框架 160，该支承框架 160 包围根据要设置在其中的可重复使用单元的几何结构而配置的开口。框架 160 利用适当间隔开的锁定元件 162、164 和 166 形成，以当被放置在所述开口中时保持可重复使用单元 110。更具体地，支承框架 160 具有前锁 162、侧锁 164 和后支承件 166，其全部一起操作以将可重复使用单元 110 安全且牢固地定位在适当的位置。前锁 162 阻止可重复使用单元 100 前向运动，并且当被推抵靠患者组织时，还向可重复使用单元 110 的正面提供反压力。侧锁 164 阻止可重复使用单元沿着横向轴（向侧部）移动，并且当被推抵靠患者组织时，还

锁定可重复使用单元并且向它提供主要的反压力。侧锁 164 被优选地设计为使得能够容易地附接和单手去除可重复使用单元。如将在下面进一步描述的，后支承件 166 阻止可重复使用单元 110 后向运动，并且当被卡扣 (snap) 到一次性单元 150 中时，将可重复使用单元 110 引导到位置中。

[0049] 如以上指示的，探头装置包括控制机构，该控制机构至少包括磁感测组件 140。在图 2 中，部分地看到这种机构的与探头的一次性单元 150 关联的一部分。

[0050] 转到图 3，示意性地例示了图 2 的探头组件 100 的后侧表面。该图例示了位于一次性单元 150 中的相应开口内 / 由一次性单元 150 中的相应开口保持并且由粘接垫 152 包围的可重复使用单元的外壳 112。可重复使用单元外壳 112 的底侧部可以包括盖 112B，该盖 112B 由弹性材料制成，并且被配置为由一次性单元的框架中的开口接纳。还使用底盖 112B 来保护可重复使用单元免受环境的影响（防水并防尘）。底盖 112B 保持声端口 120（或者视情形而定的声（超声）换能器）、光输入端口 124 和光输出端口 122。如该图中进一步示出的，并入一次性单元 150 中的磁组件 140 的一部分 140A 包括保持磁元件 170（例如，永久磁体）的保持器元件 172。所述配置是这样的 :磁体 170 被安装在一次性单元中，使得它与位于可重复使用单元 110 中的磁组件的另一部分（这里未看到）对准。

[0051] 根据本发明的本非限制性实施方式，可重复使用单元的外壳的底侧部（例如，盖 112B) 被配置为当与对象接触并且被按压抵靠对象时，能够实现盖的位移 / 变形，使得可重复使用单元向对象移动。为此，盖 112B 由适当的弹性 / 可变形材料（例如，诸如橡胶或者硅树脂这样的弹性体材料）制成，并且可能还被几何学上地设计（例如，具有稍微弯曲的外表面）为使得能够稍微移入和移出开口。如将在下面进一步描述的，该配置旨在仅在达到可由双组件控制机构识别的可重复使用单元与对象的期望的附接时能够实现测量。因此，当使探头装置与对象接触并且施加了机械压力时，可重复使用单元以及因此声学元件（端口 / 换能器）和光学元件（输入光端口）被推向患者皮肤，因此提供期望的附接以使得能够开始监测过程。当使装置远离对象移动时，底盖 112B 返回到其初始形状（例如，非变形的状态）。应该注意的是，在本发明的一些实施方式中，盖 112B 可以由被固定在适当的位置的刚性 / 非弹性材料构成，并且例如如果未使用机械微型开关机构（在不同的图中被标记为 180)，或者如果在正由另一移动部件激活的不同的配置中使用机械微型开关机构，则将不需要使盖移动。

[0052] 在图 4 中更具体地例示了一次性单元，图 4 示出了包括磁体 170 和磁体保持器 172 的磁组件 140A，该磁体 170 和磁体保持器 172 形成控制机构的一部分。如示出的，磁体保持器 172 包括杆状构件 172A，杆状构件 172A 通过其相对的端部 172B 和端部 172C 安装在一次性单元的相对的侧壁上（例如，被安装在框架 160 上），并且具有承载磁体 170 的部分 172D。如图 3 和图 4 中看到的，所述配置是这样的 :磁体 170 从一次性单元的底侧部伸出。另外，所述配置是这样的 :磁体 170 相对于由杆状保持构件限定的轴枢转。结果，当探头装置投入操作并且被按压抵靠对象压时，这导致磁体的枢转移动。

[0053] 根据一个可能的实施方式，杆状构件 172A 的至少磁体承载部 172D 由弹性 / 可变形材料制成，使得当探头 100 被按压抵靠对象时，磁体承载部变形，导致磁体转动。另选地或者附加地，杆状构件 172A 可以是可转动的，因此当使探头引入到对象的皮肤时，磁体承载部 172D 被推动，导致杆 172B 转动，这进一步地有助于磁体的转动。

[0054] 因此，一次性单元 150 中的磁组件部件 140A 被配置为使得其中的磁体可朝向以及远离可重复使用单元移动，因此朝向和远离安装在可重复使用单元中的磁组件部件中的感测元件移动。磁体朝向可重复使用单元的这种移动导致磁体 170 变得位于磁感测元件的感测区域内，所述磁感测元件位于可重复使用单元的内部，因此指示探头足够靠近对象的皮肤，成为控制机构条件中的一个。

[0055] 图 5 和图 6 是根据本发明的一个可能的实施方式的探头组件 100 的侧横截面图。在这两个图中具体地示出了两个控制机构 140 和 180。在该特定但非限制性的示例中，探头组件被配置为在能够产生任何辐射之前提供双重安全检查。如更早描述的，控制机构使得能够安全地施加在监测过程期间使用的辐射，其中，控制机构的激活位置阻止探头组件操作（即，使探头组件保持在其非操作状态下），而在其停用位置中，控制机构使得能够操作探头组件。图 5 例示了两个控制机构 140 和 180 的激活状态（即，这些机构阻止激活来自探头 100 的任何辐射（光的或声学的）），并且图 6 例示了控制机构的未激活状态（即，使控制机构失效，以使得能够安全地激活来自探头 100 的辐射）。

[0056] 第一控制机构是磁（通常地，接近型）感测组件 140，该磁感测组件 140 包括位于一次性单元 150 中的磁体 170 和弹性磁体保持器 172、以及位于可重复使用单元 110 中并且在磁体 170 附近但彼此之间没有物理接触的磁感测元件 142。当探头组件 110 未适当地附接到对象时，弹性磁体保持器 172 保持在其停用位置中，并且向下转向一次性单元外部。结果，磁传感器 142 未检测到磁体 170 的磁场，因此不生成激活信号。另一方面，当探头组件适当地（牢固地）附接到对象时，磁体保持器 172 将其定向向上改变成激活位置，如图 6 中所示，因此，磁体 170 的磁场触发磁传感器 142，允许激活辐射源。应该注意的是，选择磁传感器 142 的磁滞检测范围，以便提供磁体 170 的激活状态角度的角度范围，其进而取决于磁体保持器 172 的位置，因此使得能够在患者身体曲率的宽范围内使用探头。

[0057] 应该注意的是，通常，附加地或另选地，控制机构可以包括任何适当的接近感测组件，诸如基于电容的、基于光的、基于超声的、基于机械微型开关的、基于压力的或者基于 RFID 的组件。这些感测组件的构造和操作本身是已知的，并且不形成本发明的一部分，因此不需要被详细地描述。

[0058] 附加的控制机构可以是机械微型开关机构 180。该机构位于可重复使用单元 110 中，并且包括微型开关 182 和弹性杠杆 184。后者位于底盖 112B 上，以便与微型开关 182 对准。该机构利用弹性底盖 112B 的弹性。如图 5 中所示，当探头组件 100 未适当地附接到患者组织时，可重复使用单元 110 的弹性底盖 112B 弹出可重复使用单元的外壳。在这种状态下，附接到底盖 112B 的弹性杠杆 184 远离位于其上方的微型开关 182 并因此不按压该微型开关 182，因此使微型开关 182 不被激活。另一方面，如图 6 中所示，当探头组件 100 适当地（牢固地）附接到患者时，弹性底盖 112B 被推到可重复使用单元 110 的内部腔中，并且弹性杠杆 184 按压微型开关 182，因此激活微型开关 182 以关闭相应的电路（未示出）。应该注意的是，杠杆 184 的弹性特性和设计提供了比微型开关 182 的冲程大的冲程，因此扩展了底盖 112B 和微型开关的可用的冲程范围。

[0059] 图 5 进一步地示出了包括与超声端口 / 换能器 120、光输出端口 122 和光输入端口 124 并排的已经解释的应变消除部件 114 和帽 116 的可重复使用单元的一些更多的细节。在该特定但非限制性的示例中还示出了光输出端口 122 和光输入端口 124 分别使纵向

杆（光导）123 和 125 停止，发送和接收的光沿着所述纵向杆通过。透镜 / 棱镜 126 和 128 被用来使光朝向光纤（未示出）重新定向到这些杆 / 朝向所述光纤重新定向来自这些杆的光，所述光纤在源 / 检测器与可重复使用部件 110 之间进行调节。

[0060] 参照图 7 和图 8，示出了根据本发明的实施方式的探头 100A 的两部件设计的另一示例。在该特定设计中，控制机构仅位于可重复使用部件 110A 内部，并且一次性部件 150A 提供机械支承。更具体地，在图 7 中看到的，可重复使用部件 110A 被建立，并且具有与图 5 和图 6 中的部件 110 相同的结构，除了该可重复使用部件 110A 不具有磁感测组件（即，不存在与该可重复使用部件 110A 关联的磁传感器 142 和电路）。另选地，图 7 的探头的控制机构包括具有与以上针对图 5 和图 6 说明的相同的部件和特征的机械微型开关机构 180（即，该机构 180 位于可重复使用单元 110A 中，并且包括微型开关 182 和弹性杠杆 184）。该弹性杠杆位于底盖 112B 上，以便与微型开关 182 对准。该机构利用了推微型开关的弹性底盖 112B 的弹性。

[0061] 除了其既不具有磁体保持器 172，也不具有磁体 170 以外，图 8 中所示的一次性部件 150A 具有与图 4 中所示的一次性部件相同的部件和特征，因为在该特定配置中不存在磁感测组件。探头 100A 的控制机构 180 按照与以上针对图 5 和图 6 说明的相同的方式工作。

[0062] 参照示出了根据本发明的实施方式的探头的可重复使用部件 110B 的其它示例的图 9a 和图 9b。控制机构包括位于可重复使用部件 110B 内部的两个机械微型开关 180.1 和 180.2。可重复使用部件 110B 可以与图 8 中所示的一次性部件 150A 一起使用。在图 9b 中，微型开关 180.1 和 180.2 被定位成与弹性底盖 112B 直接接触或者间接接触（例如，经由换能器结构），使得当它们被按压抵靠可重复使用部件 110B 的顶板 (ceiling) 时，激活控制条件。在该设计中不存在弹性杠杆 184。可重复使用部件 110B 的顶板上的栅栏限制弹性底盖 112B 的移动，并且使微型开关和光学透镜保持分离。在这些特定示例中，仅当这两个微型开关 180.1 和 180.2 都被激活时，才能使得探头操作并且辐射声辐射和光辐射。双重配置是有利的原因在于，它一方面提供了对激活的更安全的控制，另一方面使得能够使用市场上可得到的划算的微型开关。可以在控制单元中或者在探头组件中的其它地方使用的控制逻辑定期地验证这两个微型开关提供相同的接近指示，使得任何失配被指示为故障。因此，这将用来向用户提醒应该小心并且应该修理该装置。应该注意的是，能够使用超过两个微型开关，以利用相似的控制逻辑系统来确保安全操作。

[0063] 图 10 示出了根据本发明的实施方式的探头组件的单部件设计或两部件设计的更多的设计示例的示意和功能图。在该图中，探头组件 100C 被配置为包括可重复使用部件 110C 和一次性部件 150C 的两部件探头。在可重复使用部件 110C 中，探头组件包括一个或更多个声端口 120，该一个或更多个声端口 120 与用于将声辐射发送到对象内的感兴趣区域中 / 从对象内的感兴趣区域接收声辐射的声换能器关联（即，包括声换能器或者可连接到声换能器）。探头组件还包括至少一个光输出端口 122，该至少一个光输出端口 122 与用于朝向感兴趣区域发射入射光的光源关联（即，包括光源或者可连接到光源）。另选地或者除集成在可重复使用部件中并且与集成的或外部的光检测器关联的光输入端口 124 之外，探头组件可以包括在一次性部件上安装的一个或更多个光检测器。在该特定示例中，两个间隔开的检测器 104.1 和 104.2 被示出，并且可以用来接收具有这些特性中的一个或更多个的光：从被检查的对象的不同的区域到达、已经过不同的路径或者深度、具有不同的波长

/ 频率。任何一个或两个检测器能够被用于分析加标记的光或者未加标记的光。

[0064] 在该特定示例中，如该图中所示，控制机构可以包括下面的组件中的一个或更多个：具有用于控制光发射器的逻辑元件（微控制器）192 的发光元件（例如，LED)190；用于光发射器和 / 或光检测器 140.1 和 140.2 的电源 194（例如，电池）；压力传感器 196 和 / 或欧姆计 198（或者电阻计或电流计）。逻辑控制器被配置为根据预定代码对由照明元件发送的信号进行编码或转换。

[0065] 具有关联的逻辑控制器 192 的光发射器 190 可以被用来将信息从一次性部件无线地发送到可重复使用单元或控制单元 (104)。所述信息可以包括：用于识别一次性部件的序列号、用于验证一次性部件是经验证的一次性部件的认证信号、针对自激活一次性部件（或者逻辑元件）开始的时间量的计数器指示器、指示可重复使用部件与一次性部件之间的连接的程度的信号、指示探头组件（可重复使用部件和 / 或一次性部件）与组织之间的连接的程度的信号、由光检测器检测的光学信息、以及更多。这种连接程度可以由压力传感器 196 或欧姆计 198、或者在本发明中使用的或在本领域中已知的任何其它接近感测组件或附接感测组件来测量，由逻辑控制器来编码以激活照明元件，并且光学地发送到位于可重复使用部件内部或外部的控制单元。这使得能够在没有导线或电连接的情况下发送信息，如果未被适当地隔离，则所述导线或电连接可能无意地将电流连接到组织。根据本发明，相同的光检测器可以被用于接收由照明元件 190 发送的信息以及从光输出端口 122 发出的光学信号这两者。照明元件的操作可以与包括端口 122/ 连接到端口 122 的光源的操作同步。能够通过以下方式来完成该同步：首先由在一次性部件上的光检测器感测到未从端口 122 发出光，然后通过逻辑控制器 192 来触发照明元件 190 的操作。另选地，能够从光输出端口 122 发出通信 / 同步信号，以指示光输出端口 122 将在特定时间段内不操作，使得能够操作 LED 190。应该注意的是，由照明元件 190 实现并且用于以上所述地发送信息的光学链路可以用诸如 RF 这样的其它无线链路和技术代替。

[0066] 代替或者除了以前提到的接近感测组件和 / 或附接感测组件中的任一个之外，还可以使用压力传感器 196。压力传感器 196 可以被用于测量并且传送探头组件在组织上施加的压力的量。所测量的压力（通过如以上描述的照明元件 190 的操作）被发送到控制单元。当压力低于或高于预定的最小阈值或最大阈值时，逻辑控制器 192 能够向用户显示提醒，或者完全地停止探头组件的操作。

[0067] 欧姆计 198（或者电阻 / 电流计）测量一次性部件 150C 与组织之间的电阻或者安装在一次性部件上的感测电极之间的电阻，并且将信号（例如，通过照明元件 190 的操作）发送给控制单元。该信号能够指示探头组件与组织之间的连接、或者设置在探头组件与组织之间的胶体 (gel) 或者任何其它连接物质或介质的量。当电阻低于或高于预定的最小阈值 / 最大阈值时，逻辑控制器 192 能够向用户显示提醒，或者完全地停止探头系统的操作。

[0068] 在以上示例（例如，图 5、图 6、图 7、图 9) 中，光源 (104A) 被例示为位于在探头（可重复使用部件）的外部的控制单元内部。然而，如更早说过的，包括光源和 / 或声换能器和 / 或检测单元的控制单元或者其一部分可以形成探头组件的整体部件，例如，可以被安装在可重复使用部件上，只要满足用于操作探头内部的光源的条件（诸如温度）即可。这被示出在图 11 中，其中，光源 104A 被设置在可重复使用部件 110D 内部。在该图中还示出了光输出端口 122、光输入端口 124 和声端口（或换能器）120。光源 104A 位于弹性底盖 112D

上，并且连同 US 换能器和光输入端口一起被压向对象。可重复使用外壳 110D 包括下面的两个部件：连接到光源 104A 的金属部件，其用作散热器 (heat sink) 并且与光源 104A 和弹性底盖 112D 一起移动；以及塑料部件，其关闭整个设计。

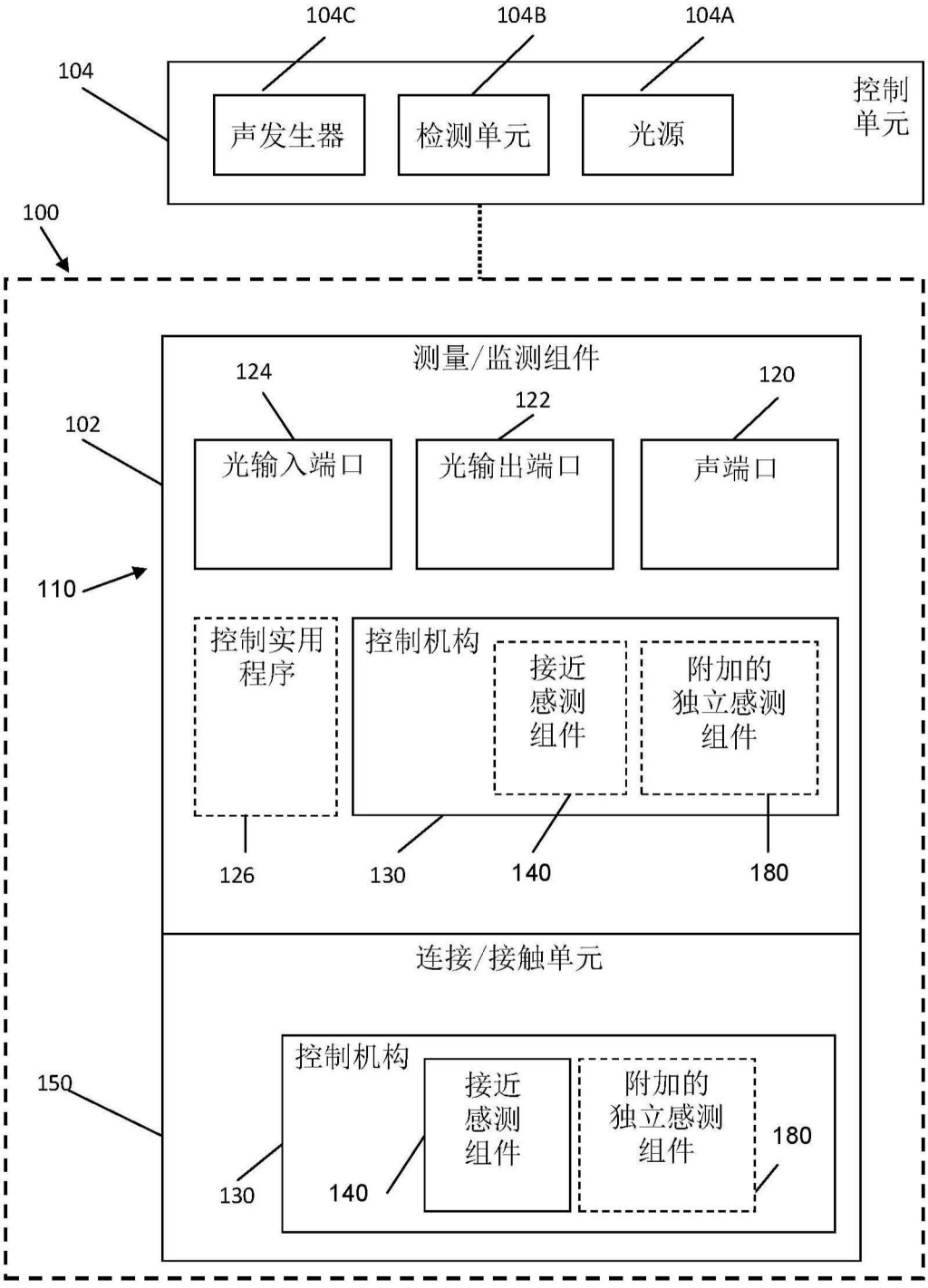
104C
104B
104A
104
声发生器
检测单元
光源
控制单元
100
测量/监测组件
124
122
120
102
光输入端口
光输出端口
声端口
110
控制实用程序
控制机构
接近感测组件
附加的独立感测组件
126
130
140
180
连接/接触单元
控制机构
150
接近感测组件
附加的独立感测组件
180
130
140

图 1a

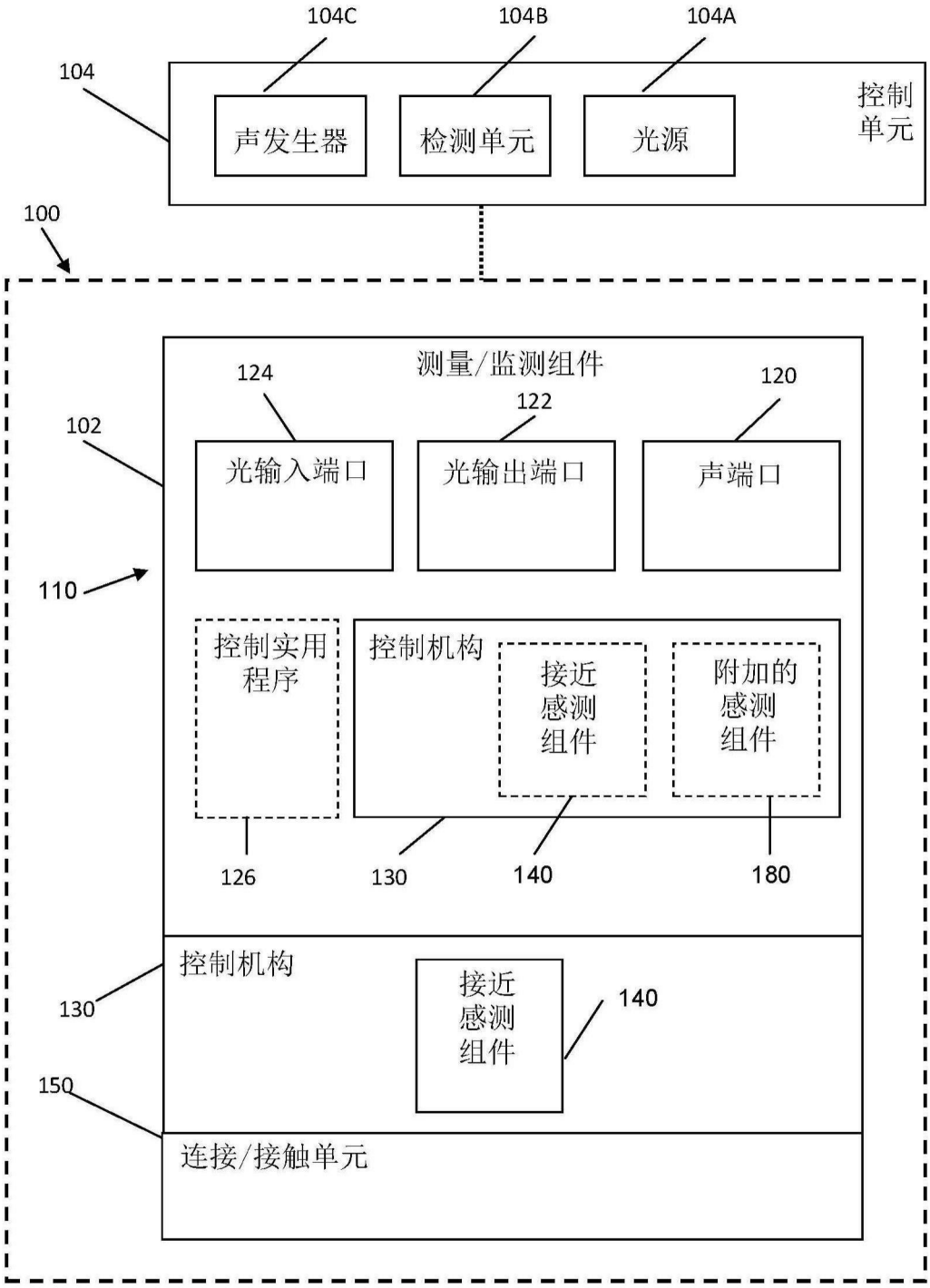
104C
104B
104A
104
声发生器
检测单元
光源
控制单元
100
测量/监测组件
124
122
120
102
光输入端口
光输出端口
声端口
110
控制实用程序
控制机构
接近感测组件
附加的感测组件
126
130
140
180
控制机构
130
接近感测组件
140
150
连接/接触单元

图 1b

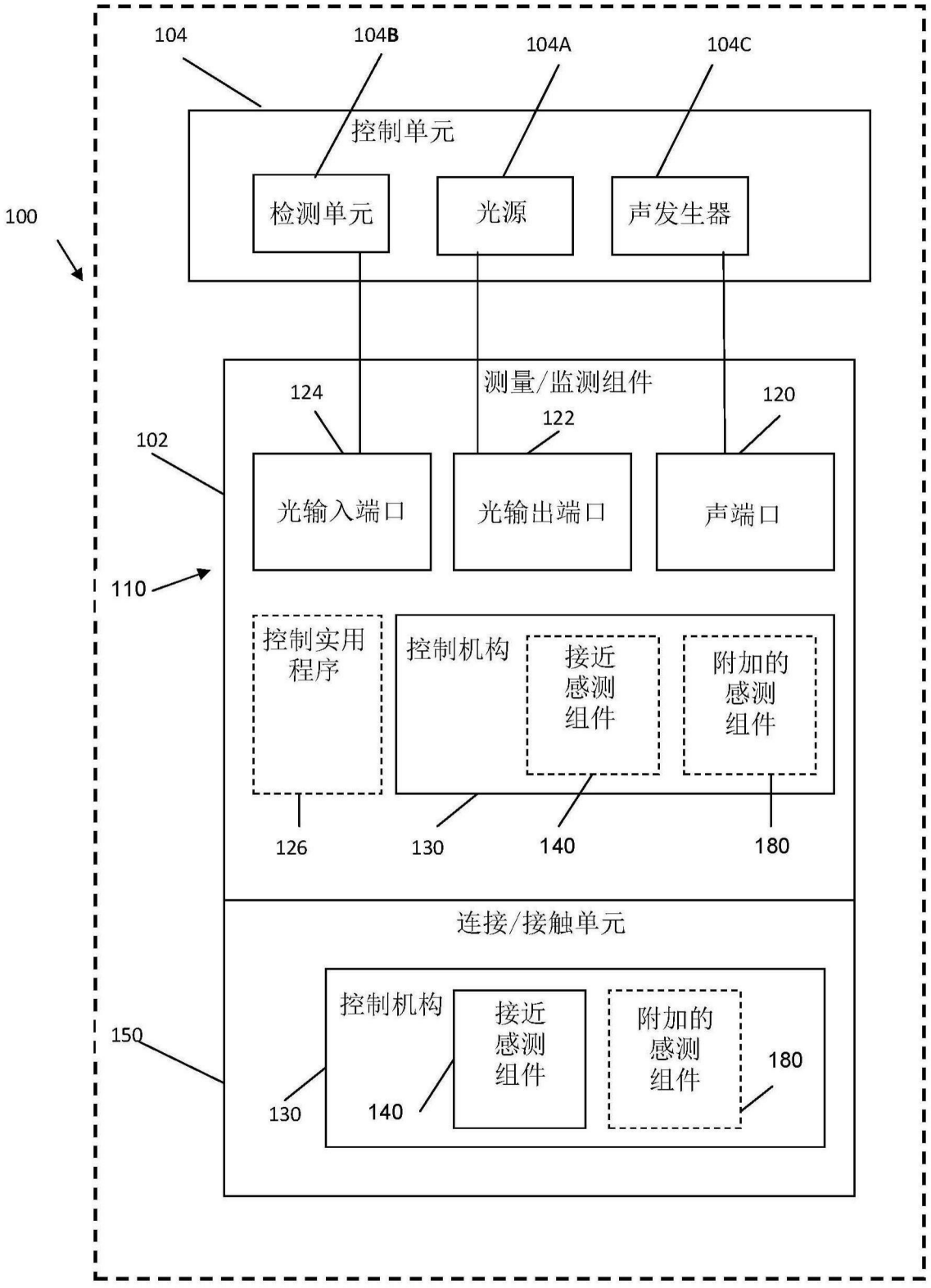
104
104B
104A
104C
控制单元
检测单元
光源
声发生器
100
测量/监测组件
124
122
120
102
光输入端口
光输出端口
声端口
110
控制实用程序
控制机构
接近感测组件
附加的感测组件
126
130
140
180
连接/接触单元
控制机构
接近感测组件
附加的感测组件
150
130
140
180

图 1c

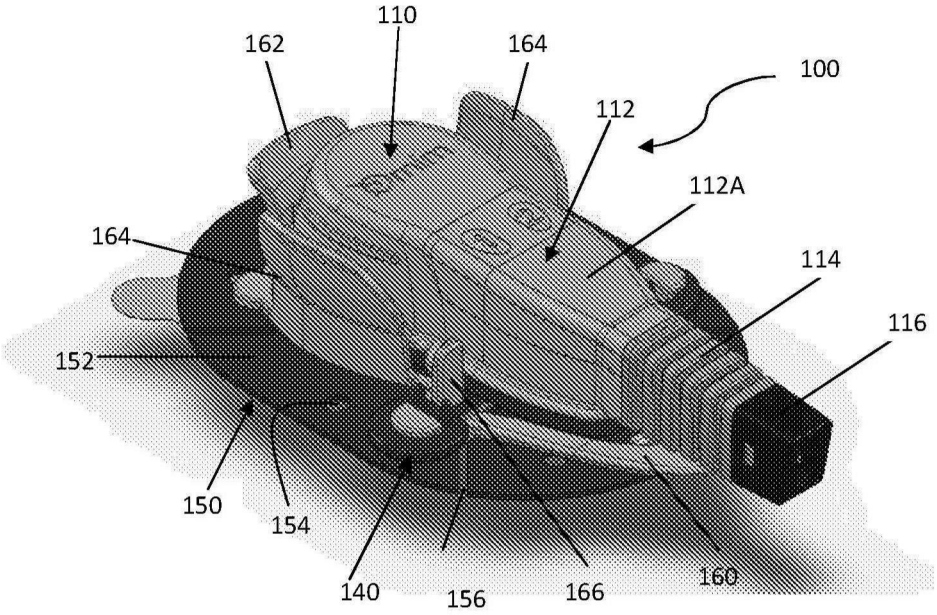
110
162
164
100
112
112A
164
114
116
152
150
154
140
156
166
160

图 2

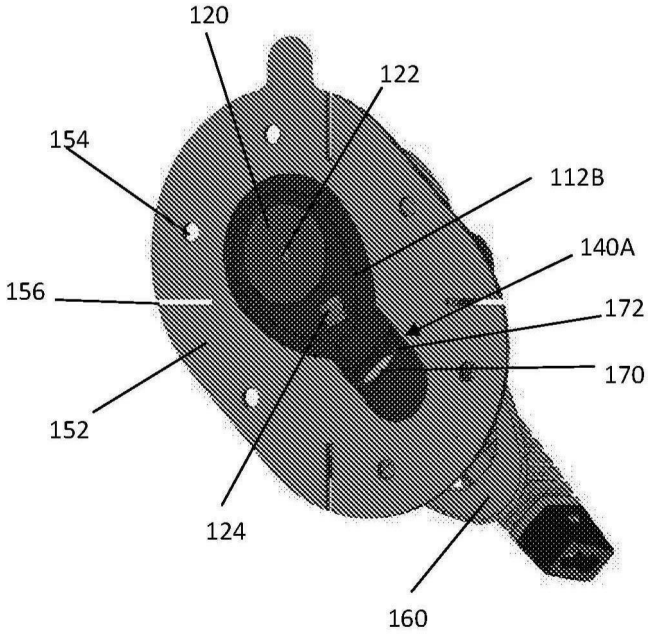
120
122
154
112B
140A
156
172
170
152
124
160

图 3

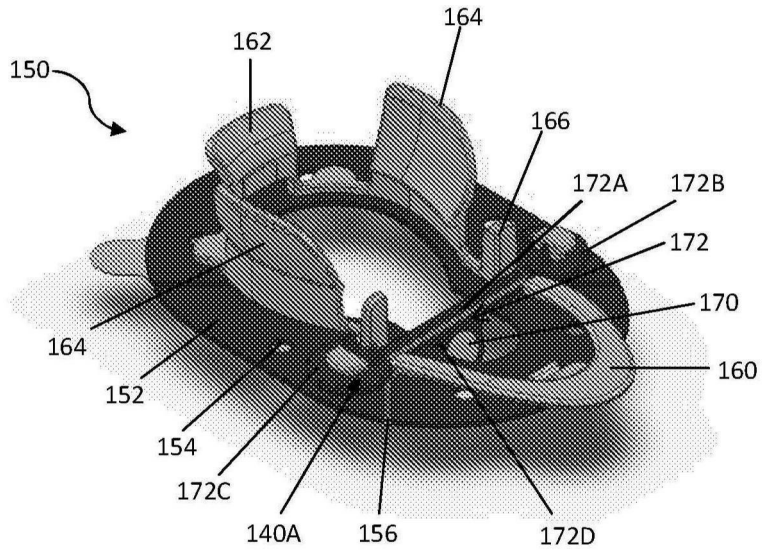
164
162
150
166
172A
172B
172
170
160
164
152
154
172C
140A
156
172D

图 4

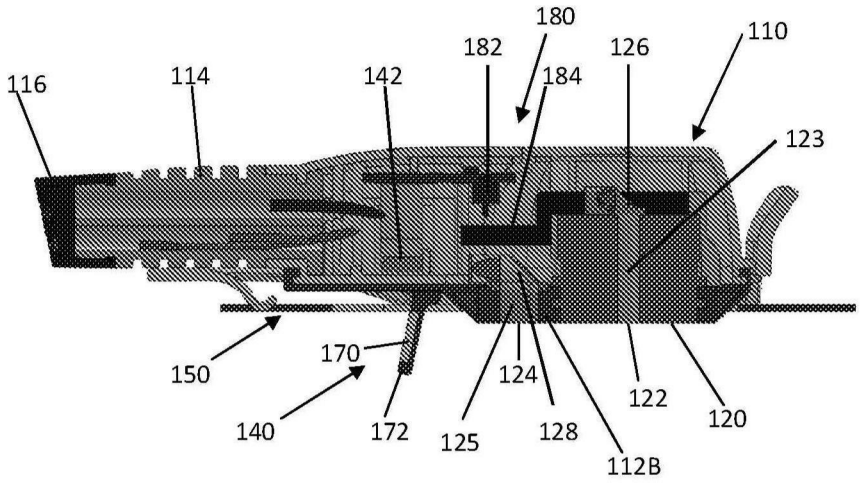
180
182
126
110
116
114
142
184
123
150
170
124
122
120
140
172
125
128
112B

图 5

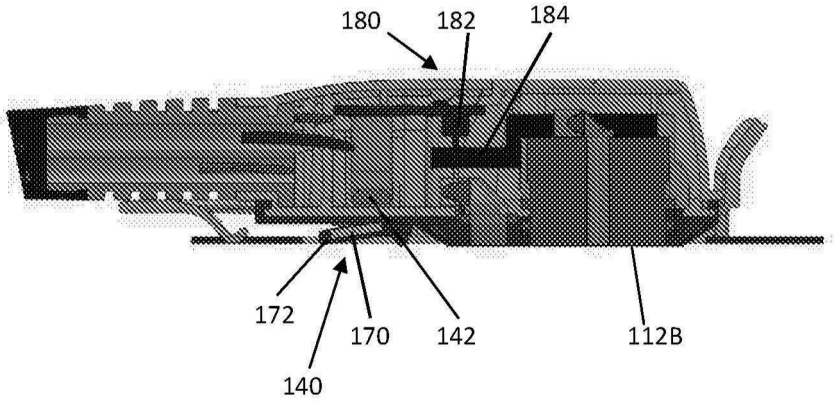
180
182
184
172
170
142
112B
140

图 6

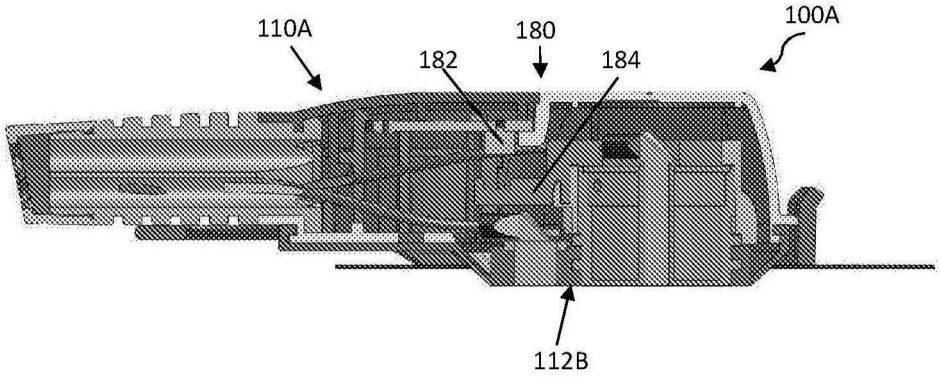
110A
180
100A
182
184
112B

图 7

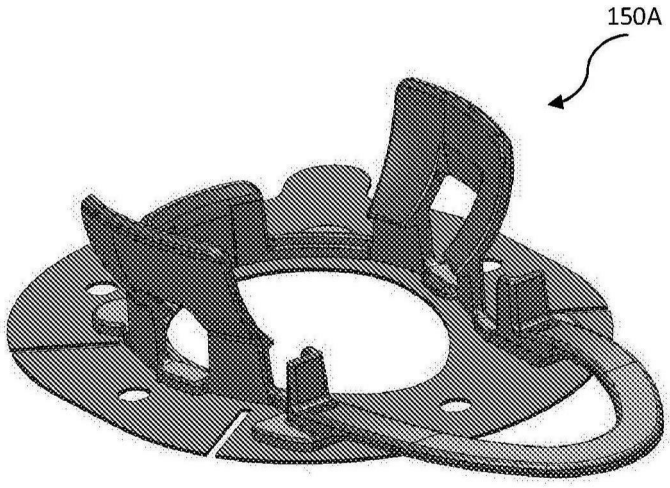
150A

图 8

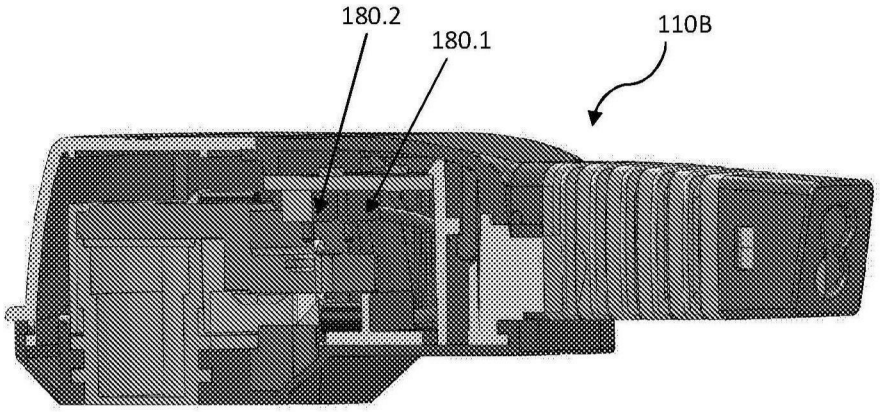
180.2
180.1
110B

图 9a

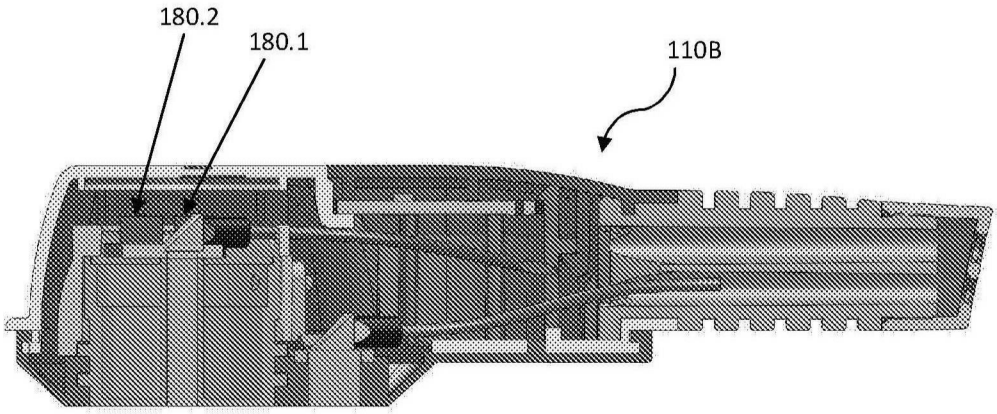
180.2
180.1
110B

图 9b

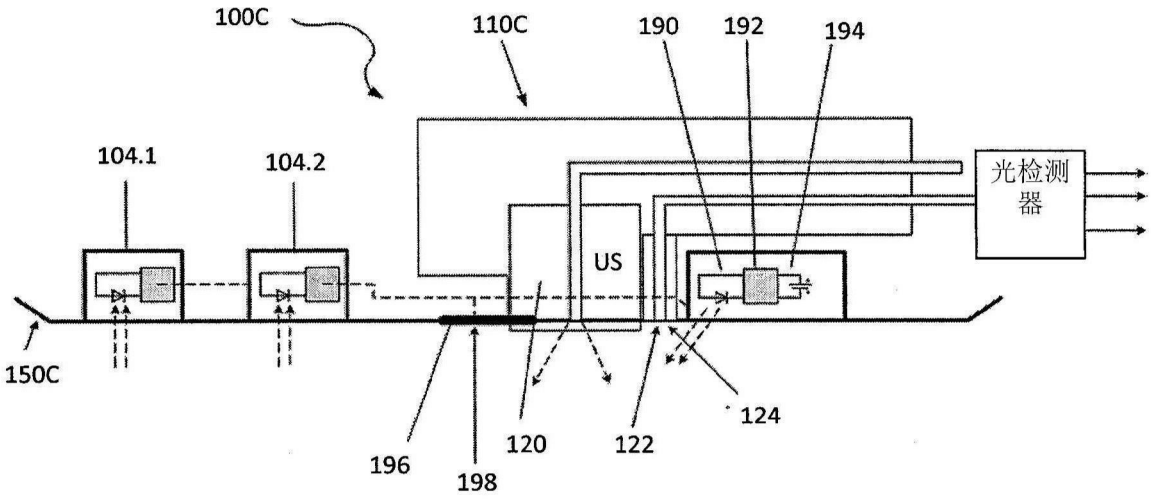
100C
110C
190
192
194
104.1
104.2
光检测器
US
150C
196
198
120
122
124

图 10

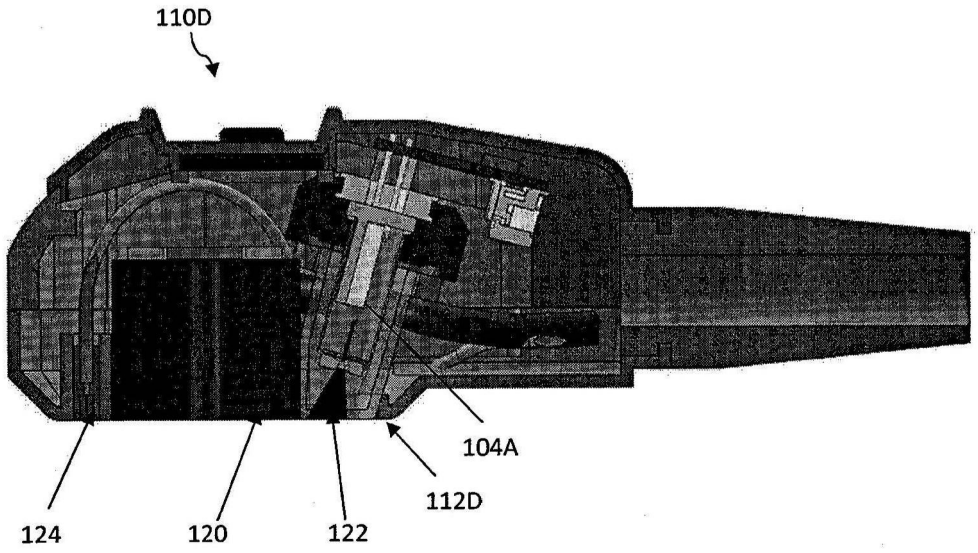

图 11

Abstract

A probe for use in monitoring one or more parameters of a subject is provided. The probe comprises a monitoring assembly comprising at least one acoustic port for transmitting acoustic radiation into a region of interest in the subject, at least one light output port for transmitting incident light towards the region of interest, and at least one light input port for receiving light returned from the subject. The probe comprises also at least one control mechanism comprising at least one sensing assembly configured for sensing at least one of proximity, attachment and signal quality conditions, and being configured for controlling a condition of coupling between the probe assembly and the subject, enabling to control operation of the monitoring assembly.

摘要

提供了一种在监测对象的一个或更多个参数时使用的探头。该探头包括监测组件，该监测组件包括用于将声辐射发送到所述对象内的感兴趣区域中的至少一个声端口、用于朝向所述感兴趣区域发射入射光的至少一个光输出端口、以及用于接收从所述对象返回的光的至少一个光输入端口。所述探头还包括至少一个控制机构，其包括被配置用于感测接近、附接和信号质量条件中的至少一个感测组件，并且被配置用于控制在所述探头组件与所述对象之间的连接的条件，使得能够控制所述监测组件的操作。