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(54) **Title**: MULTI-STATE CLIP-ON FIXATION METHOD FOR PULSE OXIMETER

(57) **Abstract**: A device (10, 10', 10") includes a light source (12) and a light detector (14) spaced from, and in communication with, the light source (12). An electronic processor (18) is programmed to compute pulse oximetry data from output of the light detector (14). A clamping member (26) is included, on or in which the light source (12) and the light detector (14) are disposed. The clamping member (26) is configured for attachment to a human body part with the body part disposed between the light source (12) and the light detector (14) such that light from the light source (12) passes through the body part to reach the light detector (14). The clamping member (26) is configured to attach to the body part by transitioning from a first stable state to a second stable state via a compression force applied to the clamping member (26).

Multi-State Clip-On Fixation Method For Pulse Oximeter

FIELD

The following relates generally to measuring indications of pulse rate and arterial oxygen saturation (SpO_2) of a patient. It finds particular application in conjunction with a pulse oximeter of the "clip-on" type in which the pulse oximeter clips onto a finger, earlobe, or so forth. However, it is to be understood that it also finds application in other usage scenarios and is not necessarily limited to the aforementioned application.

BACKGROUND

Pulse oximetry has become a standard of care in clinical practice. It provides a continuous non-invasive readout of critically important information about the patient's pulse rate and SpO_2.

In pulse oximetry, red and infrared light is passed through the tissue and is picked up by a light detector. The cardiac pulse rate is derived from a pulsatile light signal that is caused by the pulsating arterial blood volume. A measurement of oxygenation is made based on the ratio of pulse amplitudes at red and infrared signals, based on the difference in color between oxygen-bound hemoglobin and oxygen-unbound hemoglobin.

Typically, pulse oximeters are attached to the human body with various clip mechanisms. In one example, a "compression-handle mechanism" or "clothespin mechanism" is used, in which the pulse oximeter consists of a spring or flexible material under tension. The user opens the clip mechanism by compressing a handle (*e.g.*, like a clothes peg), positioning the sensor on the patient, and releasing the compression force on the handle. Compression-handle mechanisms can be used on a target location of a patient (*e.g.* a finger, an ear lobe, an alar wing, and the like). The compression handles, however, can be heavy and bulky. As a result, such compression-handle mechanisms are restricted to larger body parts (e.g., fingers, ears, and the like) and cannot be used on smaller body parts (e.g., an alar wing and the like).

In another example, the clip mechanism can include an adhesive-wrap mechanism, where an adhesive sensor is wrapped onto a target tissue and fixated with an extra adhesive or a hook-and-loop fastener. Adhesive-wrap mechanisms can be used on a target location of a patient (*e.g.* a finger, a forehead, and the like).

In a further example, a clip mechanism with a flexible structure that deforms when attached to a target tissue. The flexible structure does not use a compression handle. Flexible structures can be used on a target location of a patient (*e.g.,* an ear concha, a finger, and the like).

Other designs include a compression handle mechanism in which a removable compression handle is used to apply the pulse oximeter to a target location, and then the applicator is removed. To later remove the pulse oximeter from the patient, the applicator is reattached before the sensor can be removed.

The following provides new and improved methods and systems which overcome the above-referenced problems and others.

BRIEF SUMMARY

It is recognized herein that existing pulse oximeter designs have certain deficiencies. The "clip on" design has the potential to pinch the finger, earlobe, or other target location, which can cause pain and lead to tissue necrosis. For example, the devices can fully close and pinch the patient, thereby causing pain and discomfort to the patient. Designs including an applicator are complex two-piece components that can be difficult to manipulate, and the applicator is a separable component. As a result, the applicator can often become lost and thus unavailable when a nurse needs it to remove the sensor from the patient. If an applicator is unavailable when the nurse or other medical person is removing the pulse oximeter, there is a temptation to remove it without using an applicator, which can be uncomfortable for the patient. In addition, the sensor can be clamped incorrectly (*i.e.*, loosely) on the patient, and fall off during use.

Various improvements are disclosed herein.

In some illustrative embodiments disclosed herein, a mechanism is provided in which the pulse oximeter can be in a stable open or closed state. In the open state, the pulse oximeter can easily be placed over the target location (*e.g.*, the alar wing, the ear lobe, and the like). When the pulse oximeter is positioned on the target tissue, an optical source of the pulse oximeter is disposed on one side of the target tissue, and the detector is disposed on an opposing second side of the target tissue. When the sensor is properly positioned, a user applies a compression force on the two parts of the pulse oximeter such that it transitions into a closed state. In the closed state, the separation of the detector part and the source part is decreased such that fixation of the sensor is ensured (*i.e.*, it will not fall off). By lifting either the detector or the source, the pulse oximeter can transition into its open state, after which it can be removed from the target tissue. The mechanism does not include a compression handle, which allows the sensor to be made much smaller and lighter for attachment to small spaces (*e.g.*, the alar wing) while increasing patient comfort. In addition, the mechanism does not easily fall off without a force applied thereto. The mechanism also does not include a separable applicator, thereby increasing the ease of attachment to the patient.

In the closed state, the source and detector each exert a limited compression force on the target location to prevent necrosis and pain. To achieve this, the resulting separation between the source and detector part in the closed-state in one example is larger than zero (*i.e.*, not fully closed). In another example, the separation between the source and the detector in the closed-state is zero (*i.e.*, the source and the detector contact each other). To accomplish this, various mechanisms that can be included with the pulse oximeter (*e.g.*, using magnets, leaf springs, hinges, mechanical stops and the like).

In accordance with one aspect, a pulse oximeter includes a light source and a light detector spaced from, and in communication with, the light source. An electronic processor is programmed to compute pulse oximetry data from output of the light detector. A clamping member is included, on or in which the light source and the light detector are disposed. The clamping member is configured for attachment to a human body part with the body part disposed between the light source and the light detector such that light from the light source passes through the body part to reach the light detector. The clamping member is configured to attach to the body part by transitioning from a first stable state to a second stable state via a compression force applied to the clamping member.

In accordance with another aspect, a pulse oximeter includes a light source, a light detector, and a clamping member. The clamping member includes a first end portion that supports the light source. A second end portion supports the light detector. A bi-stable hinge connects the first end portion and the second end portion. The bi-stable hinge has, in the absence of anything being disposed between the light source and the light detector: (i) an open stable state in which the light source and the light detector are spaced apart by an open state gap; and (ii) a closed stable state in which the light source and the light detector are spaced apart by a closed state gap that is non-zero or zero, and that is smaller than the open state gap.

In accordance with another aspect, a pulse oximeter for measuring oxygen saturation in a target is provided. The pulse oximeter includes a clamping member configured for at least partial attachment to a portion of the target. The clamping member is configured for transition from a first stable state to a second stable state via a compression force applied thereto. The compression force is applied by an actuating member.

One advantage resides in placement of a pulse oximeter without the need for a removable component.

Another advantage resides in a pulse oximeter transitionable between a stable open state and a stable closed state.

Another advantage resides in increased patient comfort in a closed state of the device.

Another advantage resides in a smaller and lighter pulse oximeter for attachment to a small space on a patient.

Still further advantages of the present invention will be appreciated to those of ordinary skill in the art upon reading and understand the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

FIGURE 1 illustrates a device in communication with one or more processors in one embodiment of the present disclosure;

FIGURES 2A-F are cross-sectional perspective views of a first embodiment the device of FIGURE 1;

FIGURES 3A-F are cross-sectional perspective views of a second embodiment the device of FIGURE 1;

FIGURES 4A-E are cross-sectional perspective views of a third embodiment the device of FIGURE 1; and

FIGURE 5 is a perspective view of a fourth embodiment the device of FIGURE 1;

DETAILED DESCRIPTION

It is recognized herein that existing pulse oximeter designs have certain deficiencies. The “clip on” design has the potential to pinch the finger, earlobe, or other target location, which can cause pain and lead to tissue necrosis (*e.g.*, by fully closing and thus pinching the patient). Designs including an applicator are complex two-piece devices that can be difficult to manipulate, and the applicator is a disposable component, which can often be lost or misplaced. If an applicator is unavailable when the nurse or other medical person is removing the pulse oximeter, there is a temptation to remove the pulse oximeter without using an applicator, which can be uncomfortable for the patient. In addition, the sensor can be clamped loosely on the patient, and thus fall off during use

Pulse oximeters disclosed herein comprise a clamping member with a bi-stable hinge that is transitionable between a stable open state and a stable closed state. With reference to FIGURE 1, the device **10** includes a light source **12** and a light detector **14** that are clamped onto a body part **P**, such as an earlobe, finger, infant's foot, alar wing, or so forth, so that each is positioned on, or adjacent to, the target tissue **P**. The body part **P** is generally a human body part, although it is contemplated to employ the device in a veterinary setting in which case the body part may be of an animal. The body part comprises target tissue carrying or perfused with blood whose oxygenation is to be assessed. As used herein, the term "target tissue" refers to any desired target tissue (*e.g.,* tissue of a body part **P** such as an alar wing, a finger, an ear lobe, a forehead, an ear concha, a septum, inside a nostril, behind the ear, inside the ear, an area above the eye brow, in the eye pit, inside the esophagus, the oral mucosal, the skull, on the forehead, *etc.*) of a patient. As described herein, the device **10** is a pulse oximeter for measuring oxygen saturation in a patient. However, it will be appreciated that the device **10** can be any suitable device to measure of physiological characteristic of a patient (*e.g.,* a photoplethymography sensor, a perfusion device, a device to measure more than one wavelength, and the like). To this end, a clamping member **26** includes a first end portion **30** supporting the light source **12** and a second end portion **32** supporting the light detector **14**. The optical components **12**, **14** may be variously mounted on or in the respective end portions **30**, **32**, for example being embedded into housings integrally formed in the end portions **30**, **32**, mounted on facing surfaces of the end portions **30**, **32**, or so forth. Any such housings or mountings may optionally include spacers, offsets, or so forth. As used herein, the optical components **12**, **14** include their respective housings, spacers, or the like, so that the light source **12** and detector **14** can be considered as physical units that contact/press onto the body part **P**. The clamping member **26** further includes a bi-stable hinge **28** connecting the first end portion **30** and the second end portion **32**. The clamping member **26** allows the light source **12** and light detector **14** to be clamped onto a body part **P**, such as an earlobe, with the body part **P** disposed between the light source **12** and the light detector **14**. Light **L** generated by the light source **12** passes though the body part **P** and is detected after transmission by the light detector **14**. The illustrative pulse oximeter **10** thus operates in a transmission mode.

The output of the light detector **14** is processed to generate pulse oximetry data. In some embodiments, the pulse oximeter **10** is in communication with a computer, multi-function patient monitor, or other electronic data processing device **16** that includes one or more processors (or units, or electronics) **18** executing computer executable instructions that are stored on one or more memories **20** associated with the one or more processors **18**. It is, however, contemplated that at least some of the data processing functionality can be implemented in hardware without the use of processors. For example, analog circuitry can be employed. Further, the electronic data processing device **16** includes a communication interface **22** communicating with the pulse oximeter **10** via a communication link **24** (*e.g.,* a wireless communication link such as a Bluetooth or Zigbee link, a wired communication link via a physical cable, or the like). In one example, the pulse oximeter **10** is mechanically connected (*e.g.,* with a cable) to the computer **16**. In another example, the pulse oximeter **10** is electronically connected (*e.g.,* over a wireless network) to the computer **16**. Stated another way, the light source **12** and the light detector **14** are in communication with the processors **18**. In other embodiments, a processor **18'** is integral with the pulse oximeter **10** (*e.g.* mounted on or in the clamping member **26** in the diagrammatic illustrative example). In this case, the unit **18'** may include an on-board display, e.g. an LCD display, to show the oximetry data. It will be appreciated that the pulse oximeter **10** may be viewed as including only the optical components **12**, **14** and associated mounting hardware **26**, or may be viewed as further including the electronics **18** or **18'**.

The processors **18**, **18'** are programmed to compute oximetry data generated from the output of the light detector **14** which detects light **L** from the light source **12** after transmission through the body part **P**. Optical pulse oximetry is a well-known technique, one approach of which is described briefly in the following. In this example, the light source **12** is configured to emit red light and infrared light. In one example, the light source **12** can include at least one pair of LEDs (not shown) with a first LED configured to emit red light, and a second LED configured to emit infrared light. In another example, the light source **12** is a single broadband source (e.g. a phosphorized UV LED) with band pass optical filters to pass red and infrared light.

The light detector **14** is configured to absorb the emitted red and infrared light from the light source **12** after transmission through the body part **P**. The absorption of the emitted red and infrared light from the light source **12** differs significantly between blood containing oxygen and blood lacking oxygen. Oxygenated hemoglobin in the target tissue **P** absorbs more infrared light and allows more red light to pass through. Deoxygenated hemoglobin, on the other hand, allows more infrared light to pass through and absorbs more red light. The light detetcor **14** responds to the red light and infrared light seperately. The transmitted red and infrared light intensities are measured, and separate normalized signals are produced for each wavelength by the processors **18**. By subtracting the minimum transmitted light from the peak transmitted light in each wavelength over the cardiac cycle, the effects of other tissues is corrected for. The ratio of the red light measurement to the infrared light measurement (which represents the ratio of oxygenated hemoglobin to deoxygenated hemoglobin) is then calculated by the processor **18**. This ratio is then converted to SpO_2 by the processor **18** via a lookup table stored within the computer **16** (*e.g.*, in the memories **20**). Optionally, the pulse oximetry data also includes a pulse rate (i.e. heart rate) which is derived from the periodicity of the red and infrared signals. This is merely an illustrative example, and other pulse oximetry optical configurations and associated data processing algorithms are also contemplated. The pulse oximetry data (*e.g.* SpO_2 and optional heart rate) are suitably displayed on a display of the computer or patient monitor **16** as a numerical value that is updated on a real-time basis, and/or plotted as a trendline, or is displayed on an on-board LCD display in embodiments with self-contained electronics **18'**.

In the pulse oximetry embodiments disclosed herein, the clamping member **26** includes the bi-stable hinge **28**. The hinge **28** has, in the absence of anything being disposed between the light source **12** and the light detector **14**, the following stable states: (i) an open stable state in which the light source **12** and the light detector **14** are spaced apart by an open state gap; and (ii) a closed stable state in which the light source **12** and the light detector **14** are spaced apart by a closed state gap that is non-zero and that is smaller than the open state gap. This differs from a conventional clip-on pulse oximeter that is spring-biased to a closed position, and does not have a closed stable state with a non-zero gap. Rather, a typical clip-on pulse oximeter is biased fully closed, so that the light source and light detector have a zero gap, i.e., contact each other, when nothing is disposed between the light source and detector. As a result, a conventional clip-on pulse oximeter when clamped onto a body part exerts substantial, and generally uncontrolled, clamp force on the body part, which can lead to physical discomfort and, over time, can produce physical effects such as bruising or tissue necrosis. In some examples, the clamping member **26** can have a closed stable state in which the light source **12** and the light detector **14** are spaced apart by a closed state gap that is zero while the hinge **28** does not apply an uncomfortable force to the patient.

In the following, some illustrative examples of some pulse oximeters with suitable clamping members incorperating various bi-stable hinge configurations are described.

With reference to FIGURES 2A-F, the pulse oximeter **10** of one embodiment includes the light source **12**, the light detector **14**, a clamping member **26**, and a biasing member or a bi-stable hinge **28**. As shown, the clamping member **26** generally has a U-shaped configuration; however, other shapes are possible (*e.g.,* circular, square, trapezoidal, n-polygonal, and the like). The clamping member **26** is sized and dimensioned (*e.g.,* surface area, thickness, and the like) to allow the device **10** to be attached to the target tissue without causing discomfort to the patient. The clamping member **26** can be made from any suitable material (*e.g.,* a hard plastic, a soft plastic, a thin metal, an elastomer (*i.e.,* silicone), and the like). Advantageously, the clamping member **26** includes the bi-stable hinge **28**, thereby allowing the clamping member **26** to support the light source **12** and the light detector **14** while simultaneously allowing the clamping member **26** to transition from a first (i.e. open) stable state to a second (i.e. closed) stable state, as described in more detail below.

The clamping member **26** includes a first end portion **30**, a second end portion **32** spaced from the first end portion **30**, and an intermediary portion **34** including the hinge **28** disposed therebetween. As shown, the light source **12** is attached to the clamping member **26** at the first end portion **30**, and the light source **14** is attached to the clamping member **26** at the second end portion **32**. However, it will be appreciated that the light source **12** can be attached at the second end portion **32** and the light detector **14** can be attached at the first end portion **30**.

The clamping member **26** is configured for attachment to a portion of the target tissue. For example, the clamping member **26** is configured for transition from a first stable state to a second stable state when a compression force is applied thereto. The compression force can be applied in any known manner (*e.g.,* pushing with a finger, pushing with another object, pinching, and the like). For example, a finger can be pressed against a leaf spring **29** of the first illustrative hinge **28** to apply the compression force to cause the clamping member **26** to transition from the first stable state to the second stable state. Transitioning to the closed state can for example also be achieved by applying an external biasing force to the source **12** and detector **14**. The hinge **28** is disposed on a portion of the clamping member **26**. As shown, a first end portion of the hinge **28** is disposed on the second end portion **32** and a second end portion of the hinge **28** is disposed on the intermediary portion **34** (which in turn connects with the first end portion **30**). A length of the leaf spring **29** is longer than the distance at points on the second end portion **32** and the intermediary portion **34** to which the leaf spring **29** is attached.

In the embodiment shown in FIGURES 2A-F, the hinge **28** includes a leaf spring member **29** configured to apply the compression force to the clamping member **26**. The spring member **29** is bendable in lateral directions, and it is neither compressible nor stretchable along a longitudinal axis thereof. The unconstrained shape of the spring member **29** is flat (i.e., such that an energetically lowest state thereof is a flat state). The spring member **29** is moveable between an unlocked position in which the spring is arced in a first direction, and a locked position in which the spring is arced in an opposite second direction.

As shown in FIGURES 2A-C, the clamping member **26** is shown in a first stable state. The first stable state of the clamping member **26** provides an open configuration for the clamping member **26** – hence, the first stable state of the hinge **28** is also referred to as the "open" stable state of the hinge **28**. In the open configuration, the spring member **29** is in an unlocked position. In the unlocked position, the spring member **29** is disposed within the interior area of the U-shaped configuration of the clamping member **26**. When the spring member **29** is in the unlocked position (i.e. open stable state), the second end portion **32** of the clamping member **26** is moveable relative to the first end portion **30** thereof. Stated another way, the second end portion **32** is laterally offset from the spring member (*i.e.,* in a "right" direction). Consequently, the light detector **14** is spaced from the light source **12** is at a first distance L_1. Since this is the open configuration, the first distance L_1 is also referred to herein as the "open state gap" L_1. When the clamping member **26** is in the open configuration, the pulse oximeter **10** is positioned on, or over, the target tissue. To this end, in the open configuration the light source **12** and the light detector **14** are sufficiently spaced to allow the target tissue to fit therebetween.

The second stable state of the clamping member **26** is shown in FIGURES 2D-F. The second stable state of the clamping member **26** provides a closed configuration for the clamping member **26** – hence, the second stable state of the hinge **28** is also referred to as the "closed" stable state of the hinge **28**. In the closed configuration, the spring member **29** is in a locked position. For example, in the locked position, the spring member **29** has been laterally moved (for example, by pushing or pulling) so that the leaf spring member **29** is disposed outside of the interior area of the U-shaped configuration of the clamping member **26**. When the spring member **29** is in the locked position (i.e. closed stable state), the second end portion **32** of the clamping member **26** is fixed relative to the first end portion **30** thereof (in the absence of anything being disposed in-between). Stated another way, the second end portion **32** is laterally offset from the spring member **28** (*i.e.,* in a "left" direction). Consequently, the light detector **14** is spaced from the light source **12** is at a second distance L_2 that is non-zero (or zero), but is less than the first distance L_1. Since this is the closed configuration, the second distance L_2 is also referred to herein as the “closed state gap” L_2. When the clamping member **26** is in the closed configuration, the device **10** is clamped to the target tissue disposed between the optical components **12**, **14**. For example, the light source **12** and the light detector **14** are sufficiently positioned relative to each other to connect the device **10** to the target tissue without causing discomfort to the user.

The second distance L_2 is obtained if nothing is disposed between the light source **12** and the detector **14**. In actual use, the body part **P** will be placed in the gap before switching from the open stable state to the closed stable state. The separation L_2 is chosen so that it is just slightly smaller than the expected thickness of the body part **P**, so that some clamping force is applied, but less than would be applied if a conventional spring-loaded clip was used. To provide some clamping force, the illustrative clamping member **26** includes at least one flexible member that accommodates the body part **P** by flexing when the hinge **28** is in the closed stable state to allow the gap between the light source **12** and the light detector **14** to be larger than the closed state gap L_2 in the absence of anything being disposed between the light source **12** and the light detector **14**. The at least one flexible member may, for example, include one or more of the first end portion **30**, the second end portion **32**, and/or the intermediary portion **34**.

Advantageously, each of the open and closed configurations is a stable state. In the illustrative example of FIGURE 2, the leaf spring **28** is arced in a first direction in the first (open) stable state (FIGURES 2A, 2B, and 2C), and is arced in an opposite second direction in the second (closed) stable state (FIGURES 2D, 2E, and 2F). The stable states are stable in that the hinge **28** stays in the stable state unless and until a compression force is applied to transition to the other stable state. Once the device **10** is affixed to the target tissue, it cannot come loose or be removed without moving the spring member **28** from the locked position to the unlocked position. For example, in the locked position, an overlapping connection between the spring member **28** and the light detector **14** is rigid such that any rotation or movement of the light detector **14** causes deformation of the spring member **28**. In the closed configuration, a resulting tissue force is determined by: (1) the thickness of the target tissue, (2) the closed state gap or separation L_2 of the light source **12** and the light detector **14** in the absence of anything being disposed in the gap, and (3) the stiffness (i.e. flexibility) of the whole device (*e.g.,* based on the geometry and material thereof). Consequently, the device **10** reduces this resulting tissue force.

In the embodiment of FIGURE 2, the bi-stable hinge **28** is provided with bi-stability by the leaf spring **29** which has two stable states defined by the leaf spring being arced in one of two possible, and opposite, arc directions. This can be seen by comparing FIGURES 2A-2C with FIGURES 2D-2F. In other designs, the bi-stable hinge **28** includes the following components: a first mechanical stop that is engaged in the open stable state; a second mechanical stop that is engaged in the closed stable state; and a biasing element (e.g. a spring or sets of magnets) configured to respond to disengagement of the first mechanical stop by rotating the hinge to engage the second mechanical stop to place the bi-stable hinge into the closed stable state. In some such embodiments, the biasing element is further configured to respond to disengagement of the second mechanical stop by rotating the hinge to engage the first mechanical stop to place the bi-stable hinge into the open stable state. Some illustrative examples of hinges of this general design are presented in the following.

FIGURES 3A-F show an alternative embodiment of a device **10'**. For conciseness, repeated descriptions of elements common to the device **10** and the device **10'** will be omitted. The device **10'** includes the light source **12**, the light detector **14**, the clamping member **26**, and a bi-stable hinge **36** which replaces the bi-stable hinge **28** of the previous embodiment. As shown, the bi-stable hinge **36** is centrally located on the intermediary portion **34** of the clamping member **26**. However, it will be appreciated that the hinge **36** can be disposed on any suitable portion of the clamping member **26** (*e.g.,* adjacent the first or second end portion **30** or **32**).

The bi-stable hinge **36** includes a first component **38** and a second component **40** configured to interact with the first component **38**. The first component **38** includes a first hard stop **42** connected to the intermediary portion **34** at a first end portion **44** of the first component **38**, and a protrusion **46** disposed at a second end portion **48** of the first component **38**. In some examples, the first component **38** has a tapered configuration such that the second end portion **48** thereof tapers from the first end portion **44** thereof. The second component **40** includes a second hard stop **50** adapted to engage the first hard stop **42**, and a notch **52** adapted to receive the protrusion **46**. These features collectively define: (i) a first mechanical stop comprising the protrusion **46** and mating notch **52**; and (ii) a second mechanical stop comprising the hard stops **42**, **50**. A hinged region **58** disposed on a portion of the intermediary portion **34** interconnects the first and second components **38** and **40**.

As shown in FIGURES 3A-D, the bi-stable hinge **28** further comprises a biasing element in the form of a first magnet **54** disposed on the light source **12**, and a second magnet **56** disposed on the light detector **14**. The first and second magnets **54** and **56** are configured to be attracted to each other to apply the compression force to the clamping member **26**, as described in more detail below. In one alternative example, the first and second magnets **54** and **56** are integrated into the hinge **36**. In another alternative example, the first and second magnets **54** and **56** are disposed on the opposing sides of the hinge **36** on the intermediary portion **34**. It is also possible to replace one of the magnets **54** or **56** with a non-magnetized ferromagnetic mass.

In a variant embodiment, as shown in Figs. 3E-F, the first and second mechanical stops have the same configuration as in the embodiment of FIGURES 3A-D, but the biasing element comprises a spring member **60** (*e.g.,* a leaf spring, a compression spring, a tension spring, a coil spring, and the like) that interconnects, and is operably embedded within portions of each of, the first and second components **38** and **40**. The spring member **60** is tensioned to apply the compression force to the clamping member **26**, as described in more detail below.

In FIGURES 3A, 3B, and 3E, the clamping member **26** is shown in the first stable state (i.e., the open configuration). In the open configuration, the hinge **36** is in an unlocked position. For example, in the unlocked position, the first and second hard stops **42** and **50** are spaced from each other, and the protrusion **46** is received in the notch **52**. When the hinge **36** is in the unlocked position, the second end portion **32** of the clamping member **26** is moveable relative to the first end portion **30** thereof. Consequently, the light detector **14** is spaced from the light source **12** is at the first distance L_1. When the clamping member **26** is in the open configuration, the device **10** is positioned on or within the target tissue.

In FIGURES 3C, 3D, and 3F, the clamping member **26** is shown in the second stable state (*i.e.,* the closed configuration). In the closed configuration, the hinge **36** is in a locked position. In one example, in the locked position, the second end portion **32** has been rotated (for example, by pushing or pulling), until the first and second magnets **54** and **56** are magnetically attracted to each other to lock the clamping member **26**. The first and second magnets **54** and **56** cooperate to apply the compression force to the clamping member **26**, thereby preventing further movement of the second end portion **30** of the clamping member **26**. In another example, in the locked position, the second end portion **32** has been rotated (for example, by pushing or pulling), until the spring member **60** tensions to apply the compression force to the clamping member **26**, thereby preventing further movement of the second end portion **30** of the clamping member **26**. As a result, the second component **40** rotatably moves such that the protrusion **48** is disengaged with, and thus spaced from, the notch **54**, thereby allowing the first and second hard stops **42** and **50** to abut each other. When the hinge **36** is in the locked position, the second end portion **32** of the clamping member **26** is fixed relative to the first end portion **30** thereof. Consequently, the light detector **14** is spaced from the light source **12** is at the second distance L_2. When the clamping member **26** is in the closed configuration, the device **10** is clamped to the target tissue. For example, the light source **12** and the light detector **14** are drawn towards each other to connect the device **10** to the target tissue without causing discomfort to the user.

In the embodiment of FIGURES 3A-3D, the biasing element **54**, **56** provides only single-directional bias. In other words, the magnets **54**, **56** are attracted to each other in order to respond to disengagement of the first mechanical stop **46**, **52** by rotating the hinge **36** to engage the second mechanical stop **42**, **50** to place the bi-stable hinge **36** into the closed stable state, but the magnets **54**, **56** do not operate in the opposite direction – indeed, to the contrary the user must pull apart the ends **12**, **14** against the attractive force of the magnets **54**, **56** to disengage the second mechanical stop **42**, **50** and continue pulling apart until the first stop **46**, **52** engages to hold the ends open against the magnetic force. On the other hand, the leaf spring **60** of the embodiment of FIGURES 3E-F operates similarly to the leaf spring **29** of the embodiment of FIGURE 2 in order to respond to disengagement of the second mechanical stop **42**, **50** by rotating the hinge **36** to engage the first mechanical stop **46**, **52** to place the bi-stable hinge into the open stable state.

FIGURES 4A-E show another embodiment of the device **10**" which employs first and second mechanical stops in combination with a biasing element. For conciseness, repeated descriptions of elements common to the device **10**, the device **10**', and/or the device **10**" will be omitted. The device **10**" includes the light source **12**, the light detector **14**, the clamping member **26**, and a bi-stable hinge **62**. As shown, the hinge **62** is centrally located on the intermediary portion **34** of the clamping member **26**. However, it will be appreciated that the hinge **62** can be disposed on any suitable portion of the clamping member **26** (*e.g.,* adjacent the first or second end portion **30** or **32**).

The hinge **62** includes a hinged connection **64** that interconnects the first end portion **30** of the clamping member **26** and the second end portion **32** thereof. Disposed on a first side of the hinged connection **64** (*e.g.,* a "left" side) are a first abutment member **66** disposed on a first side of the first end portion **30** (*i.e.,* the interior area defined by the clamping member **26**) and a second abutment member **68** disposed on the opposing side of the first end portion **30** (*i.e.,* "exterior" to the clamping member **26**). Disposed on a second side of the hinge **62** (*e.g.,* a "right" side) are a third abutment member **70** diametrically opposed from the first abutment member **62** relative to the hinged connection **64**, and a fourth abutment member **72** diametrically opposed from the second abutment member **68** relative to the hinged connection **64**. In some instances, the first and third abutment members **66** and **70** are selectively engaged with each other, and the second and fourth abutment members **68** and **72** are selectively engaged with each other. These features collectively define: (i) a first mechanical stop comprising the abutment members **68**, **72**; and (ii) a second mechanical stop comprising the abutment members **66**, **70**. The clamping member **26** is in the open configuration when the second and fourth abutment members **68** and **72** are engaged with each other (that is, when the first mechanical stop **68**, **72** is engaged), and the clamping member **26** is in the closed configuration when the first and third abutment members **66** and **70** are engaged with each other (that is, when the second mechanical stop **66**, **70** is engaged). In one example embodiment, as shown in FIGURES 4A-C, a biasing element includes first, second, third, and fourth magnets, **74**, **76**, **78**, and **80** disposed on a corresponding one of the first, second, third, and fourth abutment members **66**, **68**, **70**, and **72**. In another example embodiment, as shown in FIGURES 4D-E, the biasing element includes a spring member **82** (*e.g.,* a leaf spring, a compression spring, a tension spring, a coil spring, and the like) interconnects, and is operably embedded within portions of each of, the first and second end portions **30** and **32**. The spring member **82** is tensioned to apply the compression force F to the clamping member **26**. Stated another way, the spring member **82** is operably engaged with each of the first, second, third, and fourth abutment members **66**, **68**, **70**, and **72**.

The device **10**", as shown in FIGURES 4A-C operates substantially similarly to the device **10**' shown in FIGURES 3A-D. In an unlocked position of the hinge **62**, the second and fourth abutment members **68** and **72** are engaged with each other when the clamping member **26** is in the open configuration, thereby providing an expansion force on the clamping member **26**. The clamping member **26** maintains the open configuration until the compression force is applied to the hinge **62** upon movement of the second end portion **32** of the clamping device **26**. As a result, in a locked position of the hinge **62** the second and fourth abutment members **68** and **72** are disengaged with each other, and the first and third abutment members **66** and **70** are engaged with each other.

In addition, the device **10**", as shown in FIGURES 4D-E operates in a substantially similar manner to the embodiment shown in FIGURES 4A-C, in which the spring member **82** is tensioned to allow the second and fourth abutment members **68** and **72** to engage with each other when the clamping member **26** is in the open configuration, thereby providing an expansion force on the clamping member **26**. The clamping member **26** maintains the open configuration until the compression force is applied to the hinge **62** by the spring member **82** upon movement of the second end portion **32** of the clamping device **26**. As a result, in a locked position of the hinge **62** the second and fourth abutment members **68** and **72** are disengaged with each other, and the first and third abutment members **66** and **70** are engaged with each other.

In the embodiments of FIGURES 4A-C, the biasing element provides bi-directional force, i.e. magnets **74**, **76** operate to close the clamping member **26** when the first mechanical stop **68**, **72** is disengaged; while magnets **78**, **80** operate to open the clamping member **26** when the second mechanical stop **66**, **70** is disengaged. The operation here depends upon the fact that the magnetic force decreases with increasing separation of the magnets, so that the magnet pair with smallest separation “wins”. Such bi-directional force is also provided by the embodiment of FIGURES 4D-E because the force applied by the spring **82** reverses in direction when the centerline of the spring **82** crosses the hinged connection or pivot point **64**.

In some examples, as shown in FIGURE 4C, the hinge **62** can include a first cover member **84** connected to the first end portion **30** of the clamping member **26**, and a second cover member **86** connected to the second end portion **32** thereof. Advantageously, the first and second cover members **84** and **86** prevent portions of the target tissue from entering the hinge **62** upon attachment of the device **10**" thereto, thereby increasing the comfort of the patient while decreasing the chances of target tissue getting caught within the hinge **62**. In other words, the covers block the hinge **62** from pinching the tissue. As shown in FIGURE 4C, the second cover member **84** substantially surround the first, second, third and fourth abutment members **66**, **68**, **70**, and **72**, and the first cover member **82** substantially surrounds the second cover member **84**. It will be appreciated that the first cover member **82** can surround the abutment members **66**, **68**, **70**, and **72**, and the second cover member **84** can surround the first cover member **82**.

In some embodiments, as shown in FIGURE 5, the device **10**, **10**', and/or **10**" can include a handle **88** connected to a portion of the clamping member **26** (*e.g.*, the intermediary portion **34**). The handle **88** is ergonomic to help a user transition the clamping member **26** from the first stable state (*i.e.,* the open configuration) to the second stable state (*i.e.,* the closed configuration). Advantageously, the handle **88** has a shape that follows the contour of a finger, thereby allowing a user to easily apply a force thereto to rotate the second end portion **32** relative to the first end portion **30** without a risk of the user's fingers slipping off the handle **88**. In some examples, the handle **88** is provided when the device **10**, **10'**, and/or **10''** is located on a difficult target tissue .*e.g.,* a part of the alar wing sensor inside the nose of the subject). The handle **88** allows a user to easily attach the device **10**, **10'**, and/or **10''** to the target tissue.

The invention has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be constructed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS:

1. A device (**10**, **10'**, **10"**) including:

a light source (**12**);

a light detector (**14**) spaced from, and in communication with, the light source (**12**);

an electronic processor (**18**) programmed to compute pulse oximetry data from output of the light detector (**14**);

a clamping member (**26**) on or in which the light source (**12**) and the light detector (**14**) are disposed, the clamping member (**26**) configured for attachment to a human body part with the body part disposed between the light source (**12**) and the light detector (**14**) such that light from the light source (**12**) passes through the body part to reach the light detector (**14**);

wherein the clamping member (**26**) is configured to attach to the body part by transitioning from a first stable state to a second stable state via a compression force applied to the clamping member (**26**).

2. The device according to claim 1, wherein the first stable state of the clamping member (**26**) includes an open configuration and the second stable state of the clamping member (**26**) includes a closed configuration in which there is a minimum gap between the light source **(12)** and the light detector **(14)**.

3. The device according to either one of claims 1 and 2, further including a bi-stable hinge (**28**) configured to apply the compression force to the clamping member (**26**), thereby allowing the clamping member (**26**) to transition from the first stable state to the second stable state.

4. The device according to claim 2, wherein the bi-stable hinge (**28**) includes a leaf spring (**29**) configured to apply the compression force to the clamping member (**26**), the leaf spring (**29**) being movable between an unlocked position and a locked position.

5. The device according to claim 4, wherein, when the leaf spring (**29**) is in the unlocked position, the clamping member (**26**) is in the first stable state and, when the leaf spring (**29**) is in the locked position, the clamping member (**26**) is in the second stable state.

6. The device according to either one of claims 4 or 5, wherein, when the leaf spring member (**29**) is in the unlocked position, the light detector (**14**) is at a first distance (L_1) from the light source (**12**) and, when the leaf spring (**29**) is in the locked position, the light detector (**14**) is at a second distance (L_2) from the light source (**12**) that is less than the first distance (L_1).

7. The device according to claim 6, wherein L_2 is zero and L_1 is greater than zero.

8. The device according to any one of claims 1-7, further including a hinge (**36**, **62**) with a first component (**38**) and a second component (**40**), the first component (**38**) having a first hard stop (**42**) and a protrusion (**46**), and the second component (**40**) having a second hard stop (**50**) configured to engage the first hard stop (**42**) and a notch (**52**) configured to receive the protrusion (**46**).

9. The device according to claim 8, wherein, when the clamping member (**26**) is in the first stable state, the first and second hard stops (**42**, **50**) are spaced from each other and the protrusion (**46**) is disposed within the notch (**52**), and, when the clamping member (**26**) is in the second stable state, the first and second hard stops (**42**, **50**) are engaged with each other and the protrusion (**46**) is spaced from the notch (**52**).

10. The device according to either one of claims 8 or 9, further including a spring member (**60**) connected to the first and second components (**38**, **40**) of the hinge (**36**, **62**) to apply the compression force to the clamping member (**26**).

11. The device according to any one of claims 1-7, wherein the hinge (**62**) includes:

a first abutment member (**66**);

a second abutment member (**68**);

a third abutment member (**70**) selectively engageable with the first abutment member (**66**);

a fourth abutment member (**72**) selectively engageable with the second abutment member (**68**); and

a bi-stable hinge (**62**) configured to apply the compression force to the clamping member (**26**), thereby allowing the clamping member (**26**) to transition from the first stable state to the second stable state;

wherein the clamping member (**26**) is in the first stable state when the second and fourth abutment members (**68**, **72**) are engaged with each other and the clamping member (**26**) is in the second stable state when the first and third abutment members (**66**, **70**) are engaged with each other.

12. The device according to claim 11, wherein the actuating member (**28**) includes one of:

(i) first, second, third, and fourth magnets (**74**, **76**, **78**, **80**) disposed on a corresponding respective one of the first, second, third, and fourth abutment members (**66**, **68**, **70**, **72**); and

(ii) a spring member (**82**) operably engaged with each of the first, second, third, and fourth abutment members (**66**, **68**, **70**, **72**).

13. A pulse oximeter comprising:

a light source **(12)**;

a light detector **(14)**; and

a clamping member **(26)** including a first end portion **(30)** supporting the light source, a second end portion **(32)** supporting the light detector, and a bi-stable hinge **(28, 36, 62)** connecting the first end portion and the second end portion, the bi-stable hinge **(28, 36, 62)** having, in the absence of anything being disposed between the light source **(12)** and the light detector **(14)**:

(i) an open stable state in which the light source **(12)**and the light detector **(14)** are spaced apart by an open state gap; and

(ii) a closed stable state in which the light source **(12)** and the light detector **(14)** are spaced apart by a closed state gap that is non-zero and that is smaller than the open state gap.

14. The pulse oximeter of claim 13, wherein the bi-stable hinge comprises:

a leaf spring **(29)** that is arced in a first direction in the open stable state and is arced in an opposite second direction in the closed stable state.

15. The pulse oximeter of claim 13, wherein the bi-stable hinge comprises:

a first mechanical stop **(46, 52, 68, 72)** that is engaged in the open stable state;

a second mechanical stop **(42, 50, 66, 70)** that is engaged in the closed stable state; and

a biasing element **(54, 56, 60, 74, 76, 82)** configured to respond to disengagement of the first mechanical stop **(46, 52, 68, 72)** by rotating the hinge **(28, 36, 62)** to engage the second mechanical stop **(42, 50, 66, 70)** to place the bi-stable hinge **(28, 36, 62)** into the closed stable state.

16. The pulse oximeter of claim 15, wherein the biasing element **(60, 78, 80, 82)** is further configured to respond to disengagement of the second mechanical stop **(42, 50, 66, 70)** by rotating the hinge **(28, 36, 62)** to engage the first mechanical stop **(46, 52, 68, 72)** to place the bi-stable hinge **(28, 36, 62)** into the open stable state.

17. The pulse oximeter of any one of claims 15-16, wherein the biasing element comprises:

a spring **(29, 60, 82)** or one or more sets of magnets **(54, 56, 74, 76, 78, 80)**.

18. The pulse oximeter of any one of claims 15-17, wherein each of the first mechanical stop and the second mechanical stop comprises one of:

a protrusion **(46)** and mating recess or opening **(52)**; and

a pair of abutments **(42, 50, 66, 70, 68, 72)**.

19. The pulse oximeter of any one of claims 13-18, further comprising:

an electronic processor (**18**) programmed to compute pulse oximetry data from output of the light detector (**14**);

wherein the electronic processor **(18)** is either: (1) disposed on or in the clamping member **(26)** or (2) separate from the clamping member and operatively connected with the light detector **(14)** by wired or wireless communication.

20. A device (**10**, **10'**, **10''**) for measuring oxygen saturation in a target, the device (**10**, **10'**, **10''**) including:

at least one light source (**12**);

at least one light detector (**14**) spaced from, and in communication with, the at least one light source (**12**);

one or more processors (**18**) programmed to compute data generated from an interaction between the at least one light source (**12**) and the at least one light detector (**14**), the one or more processors (**18**) being in communication with the at least one light source (**12**) and the at least one light detector (**14**);

a clamping member (**26**) configured for at least partial attachment to a portion of the target, the clamping member (**26**) being connected to a portion of each of the at least one light source (**12**) and the at least one light detector (**14**);

wherein the clamping member (**26**) is configured for locking with at least one set of magnets (**54**, **56**, **74**, **76**, **78**, **80**) disposed on a portion thereof.

21. The device according to claim 20, wherein the at least one set of magnets (**54**, **56**, **74**, **76**, **78**, **80**) includes a first magnet (**54**) disposed on a portion of the at least one light source (**12**) and a second magnet (**56**) disposed on a portion of the at least one light detector (**14**).

22. The device according to either one of claims 20 or 21, wherein the clamping member (**26**) further includes a bi-stable hinge (**28, 36, 62**).

23. The device according to any one of claims 20-22, further including an ergonomic handle (**88**) attached to a portion of the clamping member (**26**).

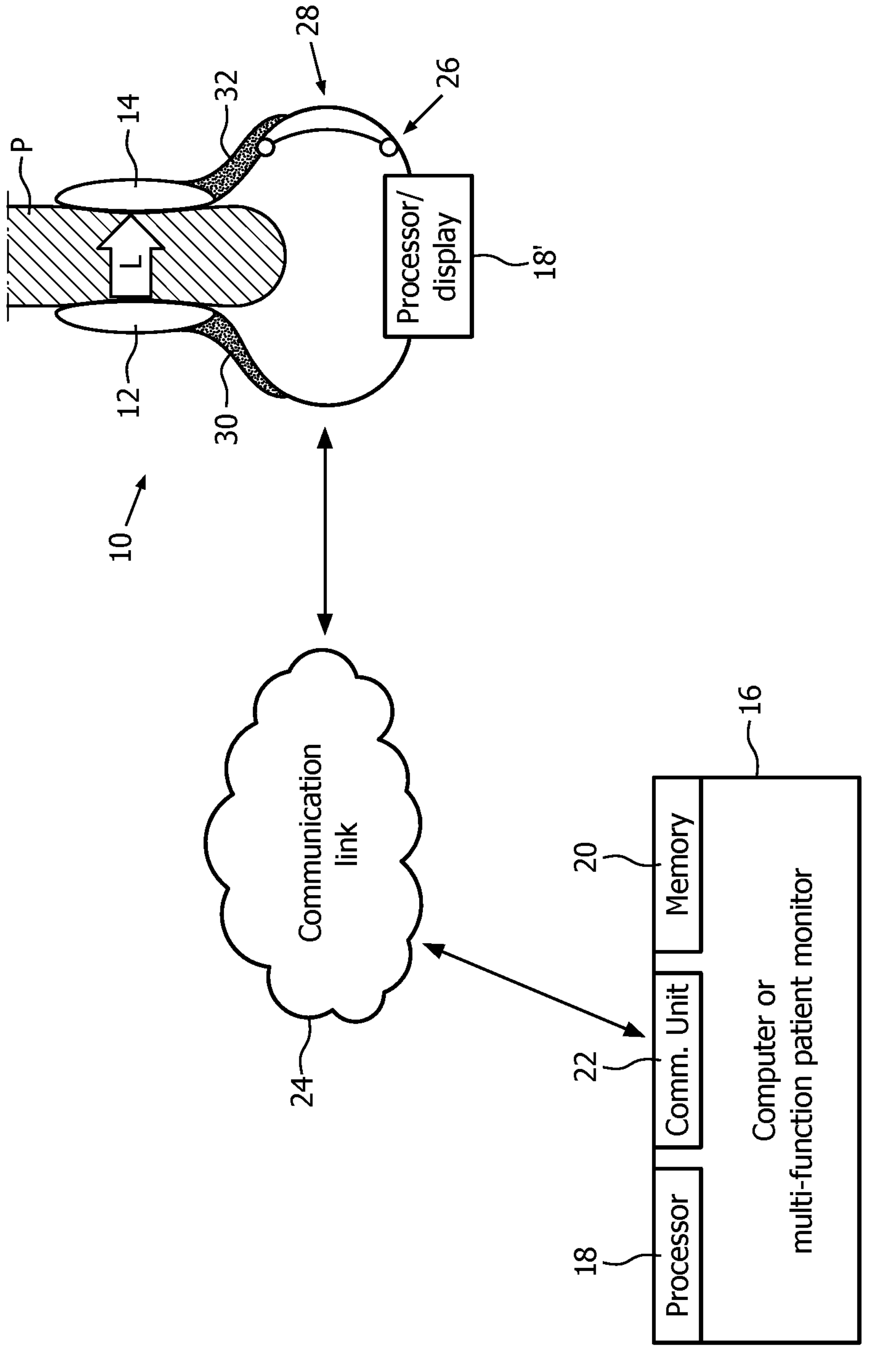
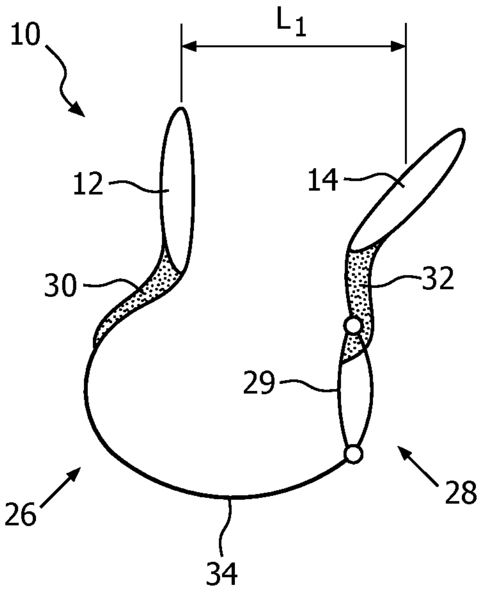
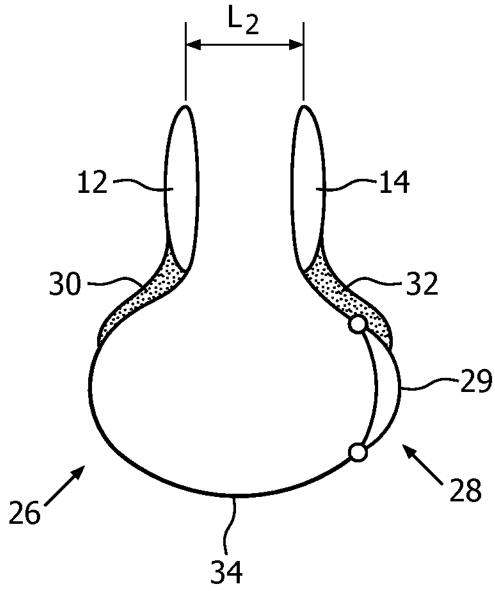

P
14
32
28
26
L
Processor/
display
18'
12
30
10
Communication
link
24
16
20
Memory
22
Comm. Unit
18
Processor
Computer or
multi-function patient monitor

FIG. 1



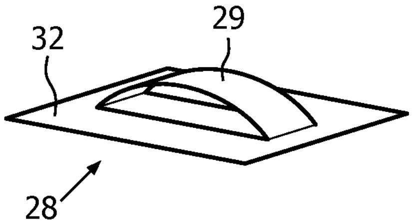
Open stable state

FIG. 2A



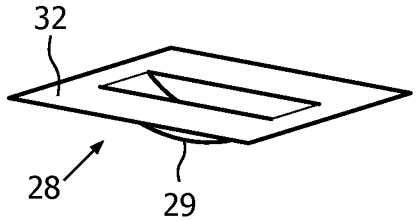
Closed stable state

FIG. 2D



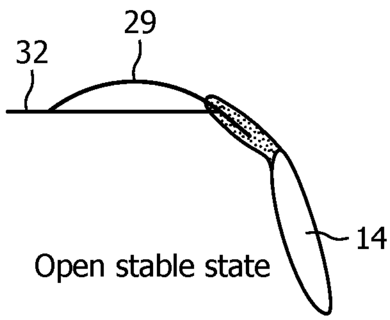
Open stable state

FIG. 2B



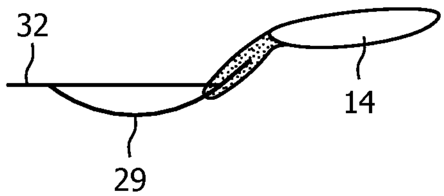
Closed stable state

FIG. 2E



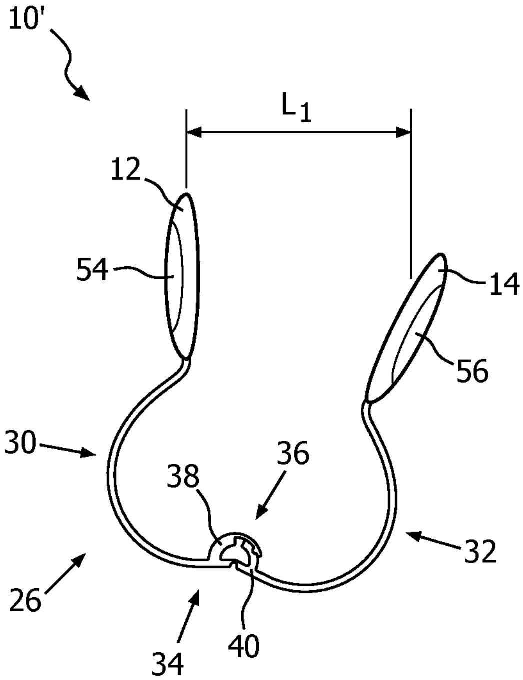
Open stable state

FIG. 2C



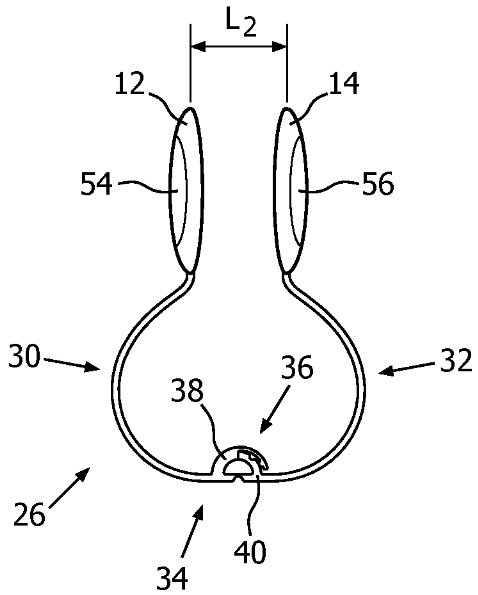
Closed stable state

FIG. 2F



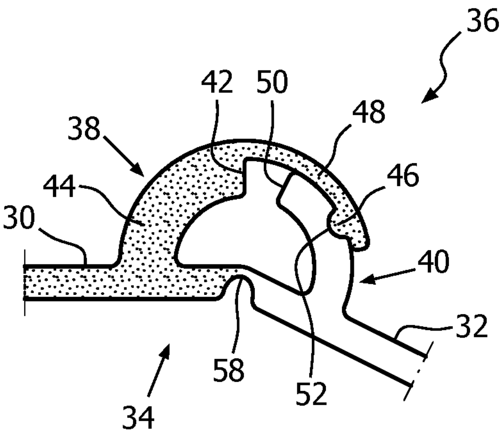
Open stable state

FIG. 3A



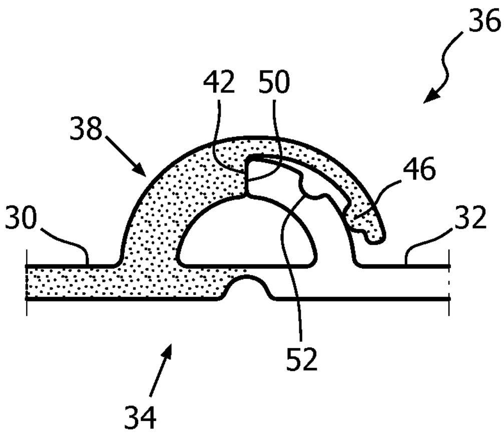
Closed stable state

FIG. 3C



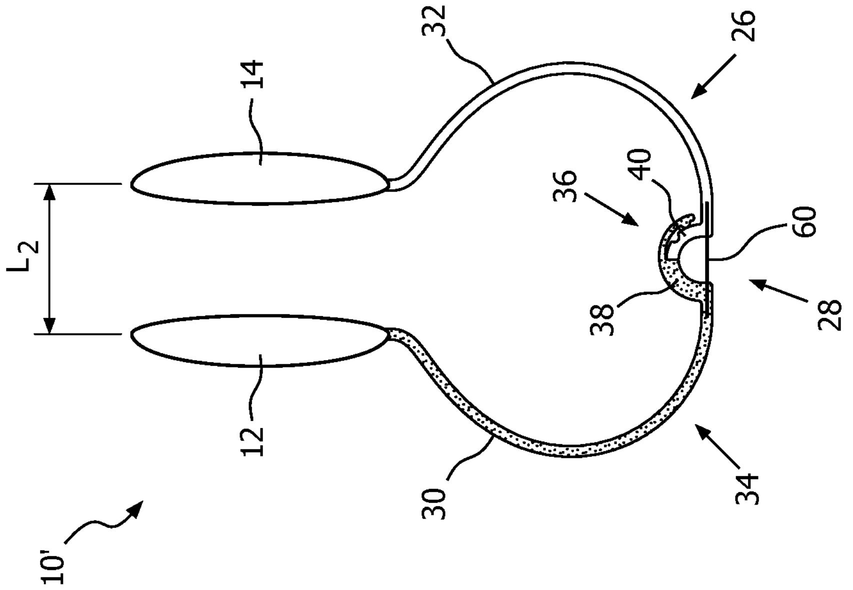
Open stable state

FIG. 3B



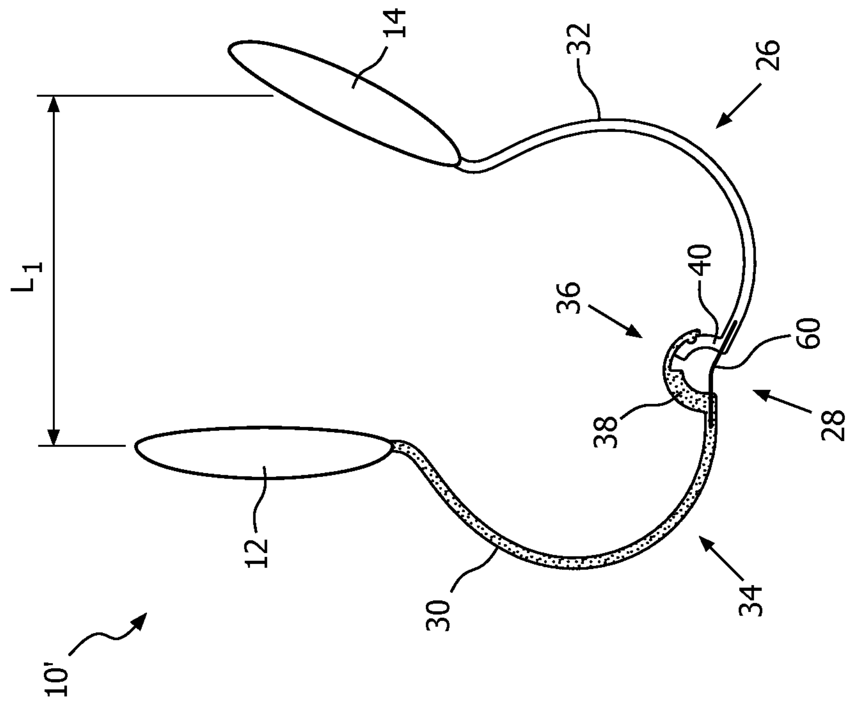
Closed stable state

FIG. 3D



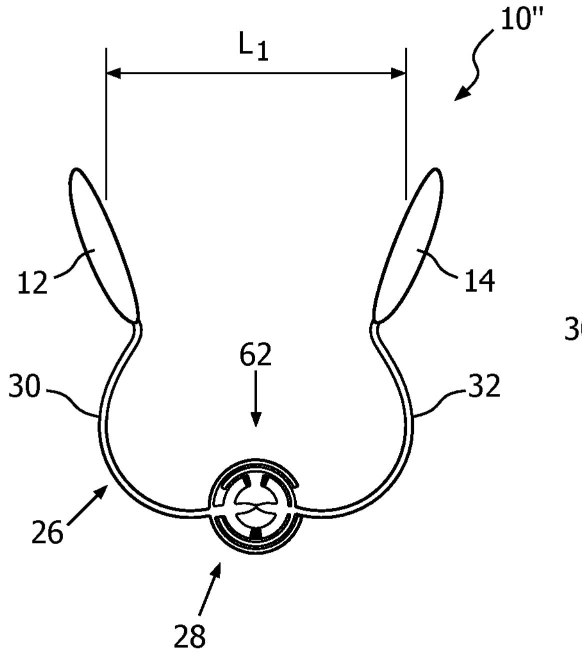
Closed stable state

FIG. 3F



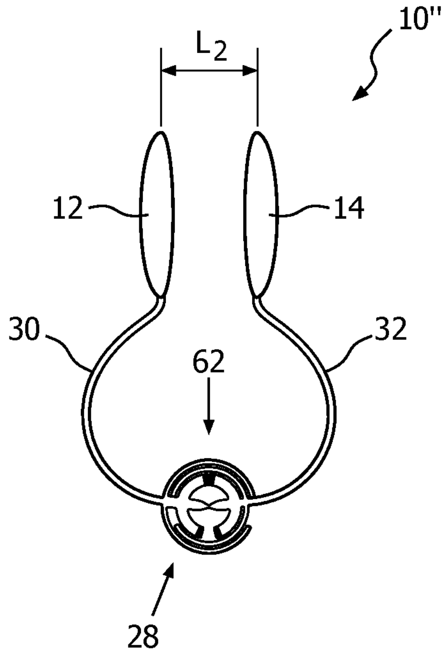
Open stable state

FIG. 3E



Open stable state

FIG. 4A



Closed stable state

FIG. 4B

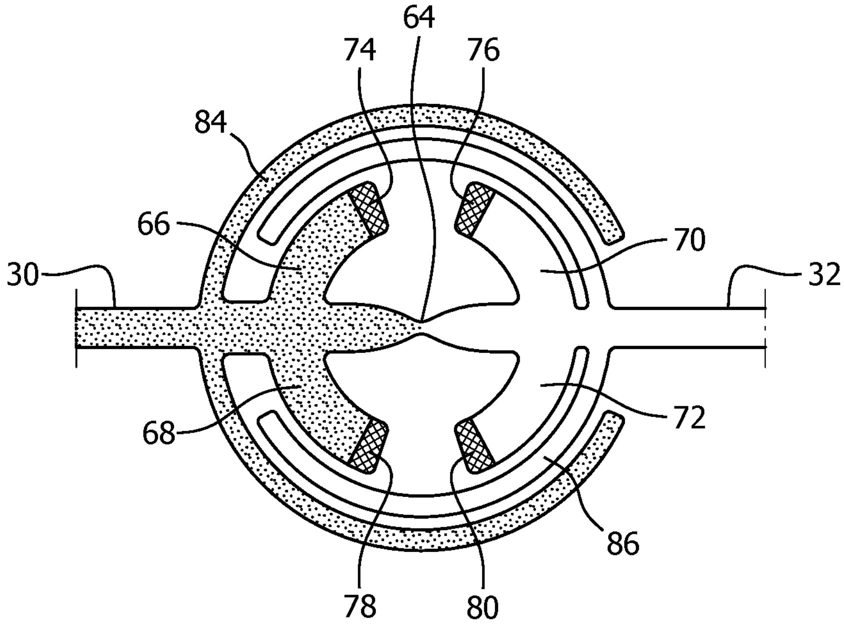
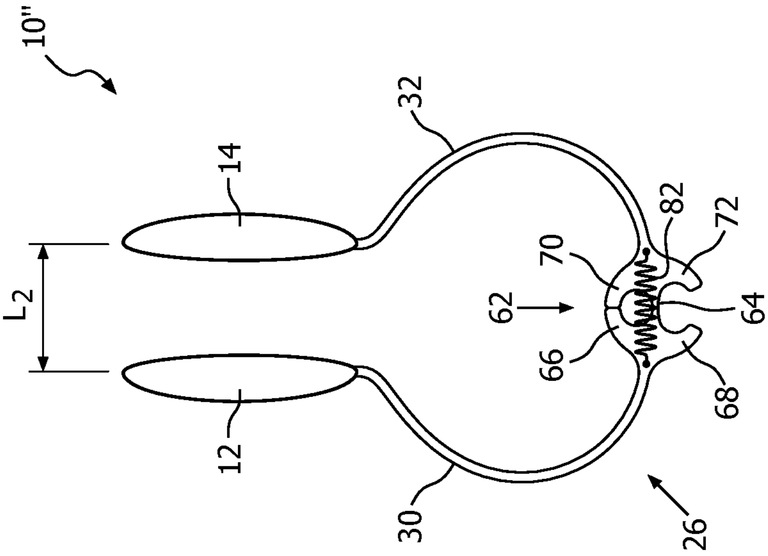
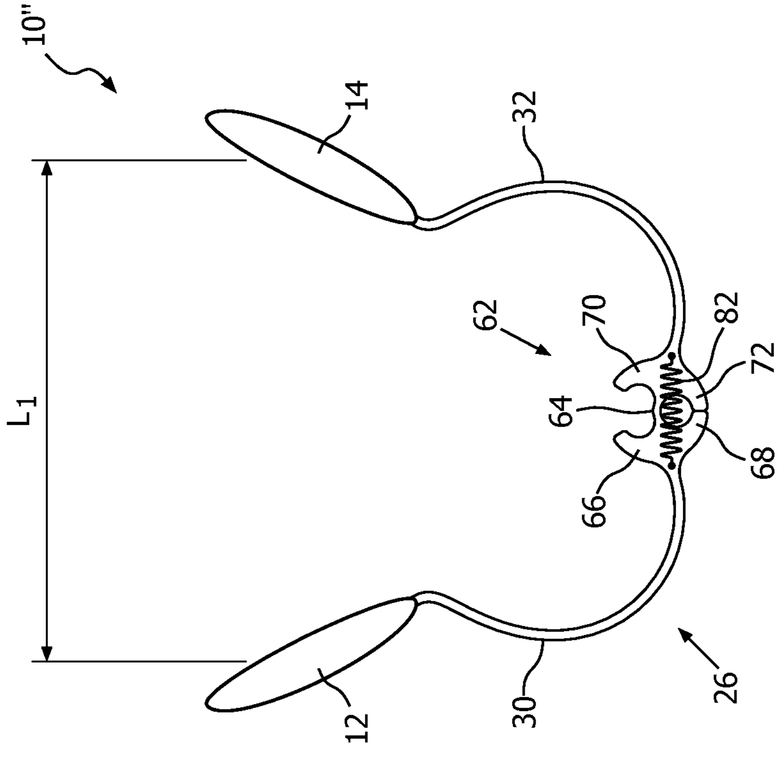


FIG. 4C



Closed stable state

FIG. 4E



Open stable state

FIG. 4D

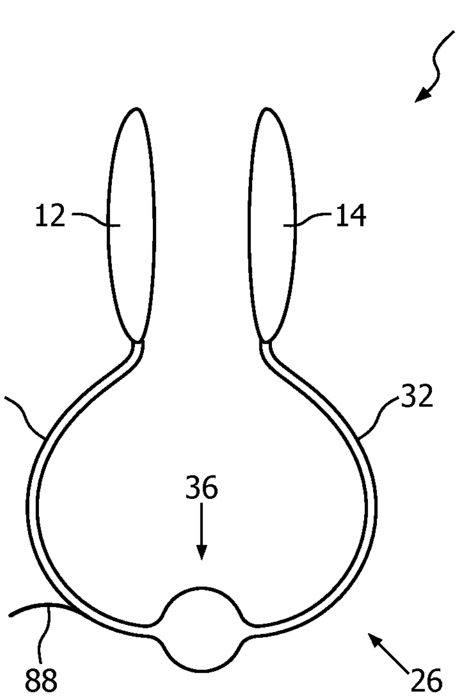


FIG. 5