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(54) **DISPOSABLE SPO2 GRIPS**

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(56) References cited:
EP-A1- 0 568 380
EP-A2- 0 898 933
WO-A1-2004/069046
WO-A2-03/001180
US-A- 5 337 386
US-A1- 2007 244 378

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Description

[0001] The present innovation, defined by the appended claims, finds application in magnetic resonance imaging (MRI) systems, particularly with regard to SpO_2 probes that are attached to a patient to monitor blood oxygen levels while the patient is positioned in an MRI device. However, it will be appreciated that the described techniques may also find application in other imaging systems, other magnetic resonance scenarios, other SpO_2 monitoring scenarios, and the like.

[0002] Conventional SpO_2 probes with electrical leads cannot be used in an MRI environment, since electrical cables and conductors can cause burns to a patient when currents are induced therein due to the high magnetic field generated in an MRI device. Therefore, oximetry probes for use during MRI scans typically employ fiber optic cables that guide light to the patient's limb or finger and back to the measurement electronics. The different kind probes offered vary in the way they can be attached to a patient's limb or finger. Multiple sizes of grips are provided to cover patients from neonates to adult. Special cables with alligator type of clips are available for quick and easy attachment.

[0003] However, conventional grips do not stick well to patient skin and do not fit all sizes of patients well, which can lead to measurement artifacts. Traditional clips do not fit smaller patients well. Reusable clips suffer from the risk of cross contamination because they are difficult to disinfect between patients.

[0004] Fiber optic probes are more expensive than electrical standard SpO_2 probes, thus preventing hospitals from maintaining a large range of sizes and attachment varieties to cover different patient sizes. In addition, some probe plugs require a tool to unscrew the fiber optic cable from the module, making it difficult to exchange a whole probe in between MR scans of different patients.

[0005] Patent document EP0568380 A1 is an example of a photo-plethysmograph for use during magnetic resonance imaging, having a probe detachably connected to two optical fibres.

[0006] The present application provides new and improved systems and methods for monitoring blood oxygen levels in a patient using an SpO_2 probe with enhanced flexibility, which overcome the above-referenced problems and others.

[0007] In accordance with one aspect, an appendage clip for use in an oximetry probe includes first and second rigid clip portions. At least one of the clip portions includes a receiving aperture (clip portion aperture) on the exterior side of the clip portion, wherein the receiving aperture releasably engages and aligns a fiber optic cable head through which light is transmitted into and/or received from an appendage received in the clip. The clip portion further includes a compressible foam or plastic layer affixed to the interior side of the clip portion, the compressible foam or plastic layer defining an aperture in alignment with the receiving aperture, and a retaining structure (attachment structure) that releasably attaches to a fiber optic cable head in alignment with the receiving aperture. The receiving aperture and/or the retaining structure is configured to be permanently deformed upon removal of the fiber optic cable head from the receiving aperture, such that it is rendered non-functional, to ensure that the appendage clip is not reused.

[0008] In accordance with another aspect, a releasably attachable fiber optic oximetry probe system for use with disposable appendage clips includes a pair of fiber optic cable heads that respectively transmit and receive light for monitoring blood oxygen levels in a patient, each fiber optic cable head having a coupling portion that releasably snaps into a respective retaining structure on an appendage clip that is attached to an appendage of a patient. The probe system further includes a patient monitor that receives light from the fiber optic cable heads and determines a blood-oxygen level of the patient therefrom. The coupling portion is configured to cause the retaining structure to further permanently deform upon removal of the coupling portion to a point where it is non-functional for retaining the coupling portion, such that the appendage clip is not reusable

[0009] According to yet another aspect, a method measuring blood-oxygen content in a patient includes coupling one or more detachable fiber optic cable heads to respective flexible retaining structures on an appendage clip attached to an appendage of a patient, and coupling a fiber optic cable connected to the or more detachable fiber optic cable heads to a patient monitor. The method further includes emitting light from the patient monitor through the one or more detachable fiber optic cable heads, and receiving light from the one or more fiber optic cable heads. Additionally, the method includes monitoring a blood-oxygen level of the patient, removing the appendage clip from the patient, and detaching the one or more fiber optic cable heads from the appendage clip. The flexible retaining structures are rendered inoperable upon detachment of the one or more fiber optic cable heads, rending the appendage clip unsuitable for subsequent use

[0010] One advantage resides in the easy disconnection and reconnection of the fiber optic leads and the the fiber optic heads, making the heads detachable.

[0011] Another advantage is that the SpO_2 probes can be color-coded according to size.

[0012] Another advantage resides in easy alignment of the finger and the clip. A further advantage is that the leads pivot relative to the clip.

[0013] Other advantages include reduced cross-contamination between patients, simplified cleaning and disinfection, and disposability.

[0014] Still further advantages of the subject innovation will be appreciated by those of ordinary skill in the art upon reading and understand the following detailed description.

[0015] The drawings are only for purposes of illustrating various aspects and are not to be construed as lim-

iting.

FIGURE 1 illustrates a blood-oxygen level probe apparatus that includes a foam or plastic cushion coupled to an interior surface of a clip, which fits over a patient's finger.

FIGURE 2 illustrates a disposable clip having a rigid body with a fiber head receiving aperture.

FIGURE 3 illustrates a disposable clip that combines the ease of attachment and alignment of the fiber heads (e.g., transmitter and receiver) through the clip with the advantages of low-weight, comfort, secure fit, and low cost.

FIGURE 4 illustrates an oximetry clip that includes a curved lower portion and a substantially linear or flat upper portion, coupled together by a hinge.

FIGURE 5 illustrates an alligator-type blood-oxygen monitoring clip having first and second portions coupled together by a hinge.

FIGURE 6 illustrates a blood-oxygen level monitoring clip that includes first and second portions coupled together by a hinge.

FIGURE 7 illustrates an SpO_2 monitoring probe that includes first and second fiber heads (e.g., a receiver head and a transmitter head), shown in "Detail A," which is delineated by a circle with an "A."

FIGURE 8 is an enlarged view of "Detail A", showing the fiber heads in detail.

FIGURE 9 illustrates a top-down view of an open disposable blood oximetry clip that includes first and second clip portions coupled together by a hinge.

FIGURE 10 illustrates an elevated perspective view of an open disposable blood oximetry clip that includes first and second clip portions coupled together by a hinge.

[0016] In accordance with various features described herein, detachable and rotatable fiber optic sensor heads (e.g., "fiber heads") are provided, which can be easily attached to and detached from different oximetry clips. The oximetry clips described herein may be disposable or reusable, and may be of several different sizes to accommodate the entire range of patient sizes, from premature neonatal patients through obese adults or adults suffering from a pituitary dysfunction such as gigantism. The described clips include a compressible foam or plastic layer that conforms to the patient appendage or finger, thereby providing additional fine-tuning of the fit to the patient. By making the fiber heads detachable, a health care facility or hospital need only keep one or a few sets of cables on hand. The disposability of the oximetry clips mitigates cross-infection among patients that might otherwise occur with reusable clips.

[0017] FIGURE 1 illustrates a blood-oxygen level probe apparatus **10** that includes a foam or plastic cushion layer **12** coupled to an interior surface of a clip **14,** which fits over a patient's finger. A receiving fiber optic head **16,** or "receiver," is coupled to a first side of the clip **14,** and a transmitting fiber optic head **18,** or "transmitter," is coupled to a second side of the clip. The receiver head **16** is coupled to a first fiber optic cable **20,** while the transmitter head **18** is coupled to a second fiber optic cable **22.** In this manner, flexible attachments are made to the fiber optics cables for SpO_2 measurement.

[0018] The interface between the transmitter and receiver heads and the clip is designed for easy and quick change of the attachment means (e.g., clips, grips, etc.). In one embodiment, the clip **14** is disposable (e.g., designed for single-use). In another embodiment, the foam or plastic layer **12** includes an adhesive material that couples the clip on the limb (e.g., finger) securely, as well as mitigates cross-infection.

[0019] The snap-in fiber heads **16, 18** provide for greater flexibility in selecting from a broad variety of clips of grips, which allows for quick insertion into the clips or grips and removal after use. Thus, the fiber optic cables can be reused with a number of disposable clips. The clip **14,** which comes into contact with the patient, can be designed in various shapes and sizes to adapt to various limbs (e.g., fingers, toes, wrist, foot, ear, nose, forehead), and all patient sizes. In one embodiment, the reusable clips are alligator-like clips that attach to fingers and are provided different sizes.

[0020] The clip of Figure 1, as well as the clips described herein in various other embodiments, may be contoured to the patient appendage (e.g., finger, toe, etc.) to which they are attached. This feature facilitates accurate positioning of the clip. Since the apertures to which the fiber heads are coupled are in a fixed position on the clip surfaces, the fiber heads are automatically aligned when they are snapped onto or otherwise affixed to the clip. When the clip is subsequently positioned on the patient appendage, the fiber heads are correctly positioned for blood-oxygen monitoring.

[0021] FIGURE 2 illustrates a disposable clip **28** having a rigid body **30** with a fiber head receiving aperture **32.** A foam or soft plastic piece **34** is coupled to the clip, and may be constructed in several different ways. For instance, in the illustrated embodiment, the foam or plastic piece **34** has butterfly-like wings **35** that wrap around the side of the finger and have an adhesive layer **36** that sticks to the upper portion of the foam/plastic and/or clip and optionally the side of the finger. This embodiment is advantageous when the rigid body **30** is preformed to a cuff shape and has no hinge. In this case, the inner surface of the foam or plastic in contact with the top and bottom of a patient's finger is not covered with adhesive and the finger to be slipped in and out. When the front of the finger engages the front of the clip, fiber head receiving apertures are properly aligned to face each other and properly aligned across the finger tip (e.g., the fingernail) of the patient. An advantage of this construction is that ambient light from the side is prevented from entering the interior of the clip and interfering with the fiber optic light transmission and detection.

[0022] In one embodiment, foam or plastic pieces are

pre-cut to fit the clip surface. Adhesive (e.g., medical transfer adhesive or the like) is applied to one or both sides of the foam or plastic piece. The adhesive on one side fixes the foam or plastic piece to the clip. The adhesive on the other side of the foam or plastic piece may be covered with a removable layer of material (e.g., a waxed paper or some other release liner), which is removed immediately prior to affixation of the clip to a patient appendage (e.g., finger, toe, etc.)

[0023] According to another embodiment, the foam (or plastic) pieces described herein are approximately 3-6 mm in thickness. Optionally, when foam (or plastic) pieces near the 3mm end of the thickness range are used, a relatively stiff foam (or plastic) can be used, while a relatively softer and compressible foam (or plastic) can be used when the pieces are nearer the 6mm thickness.

[0024] FIGURE 3 illustrates a disposable clip **40** that combines the ease of attachment and alignment of the fiber heads (e.g., transmitter and receiver) through the clip with the advantages of low-weight, comfort, secure fit, and low cost. The clip **40** comprises a rigid, hard plastic body **42** that includes. The clip includes a window **44** for collecting or emitting light. Fiber head couplers **46** provide a snap feature for the fiber heads (not shown). A hinge **48** facilitates both easier application of a foam or plastic layer **50** and easier attachment to the finger. Optionally, the layer **50** is coated with an adhesive layer **52** that adheres to the patient's finger. A transparent plastic layer **54** seals the window **44** from the fiber head to protect it from being contaminated. The transparent layer **54** is in direct contact with the skin. This also mitigates a need for the fiber cross section to meet biocompatibility requirements.

[0025] In one embodiment, the foam or plastic layer is fitted to the rigid piece and forms a cushion. The foam or plastic layer is coated with the adhesive and is attached to the finger by folding the rigid piece with the hinge **48** around the finger. The clip **40** can be constructed in different sizes and shapes. The rigid body **42** can be constructed in different colors indicative of size and/or application. Additionally, the fiber heads can be snapped in either of two directions, with cable exiting towards the finger tips or towards the hand.

[0026] In another embodiment, a reusable clip such as an alligator clip, which consists of cleanable components, can be used instead of a disposable clip. In this example, the reusable clip includes similar snap-in couplers **46** for the fiber heads.

[0027] FIGURE 4 illustrates an oximetry clip **70** that includes a curved lower portion **72** and a substantially linear or flat upper portion **74,** coupled together by a hinge **76.** The clip receives a patient's finger **78,** and is closed thereabout. When the end of the finger engages the end of the curved lower portion **72,** the clip and finger are aligned. A foam or soft plastic layer **80** is provided on the interior (e.g., finger side) of the upper and lower portions of the clip. Optionally, the foam or plastic layer is overlaid with an adhesive (not shown) that fixes the clip to the patient's finger. The foam or plastic is compressible to facilitate improved fit on the patient's finger. In this manner, a plurality of different sizes of clips can be provided, and a closest fit selected. The compressible foam or plastic layer then ensures that the selected clip provides a snug fit.

[0028] FIGURE 5 illustrates an alligator-type blood-oxygen monitoring clip **90** having first and second portions **92** coupled together by a hinge **93.** A fiber head receiving aperture **94** receives a coupling portion **96** of a fiber head **98.** The coupling portion has a truncated conical shape, the base of which forms a circular retaining "barb" **100** that releasably and rotatably engages the receiving aperture. In one embodiment, the receiving aperture **94** has grooves or slots **95** that extend radially outward from its circumference to provide a flexible, releasable, snug fit when mated to the coupling portion of the fiber head. The fiber head **98** is this removable attachable to the clip **90.** The clip may be disposable or may be reusable (e.g., cleanable).

[0029] In another embodiment, coupling the fiber head to the disposable clip causes the receiving aperture to deform. Removal of the fiber head then causes permanent deformation of the receiving aperture and/or retaining structures positioned there around. For instance, the coupling portion of the fiber head may be made of a harder material than the clip into which the aperture is cut or stamped, and may include one or more barbs or projections, thereby permitting the coupling portion to be forced through the aperture to achieve a snug fit while requiring a greater force for removal. In another embodiment, the coupling portion has a truncated conical shape that snaps into retaining structures around the receiving aperture. Pulling the fiber head coupling portion back out of the aperture destroys the shape of the aperture so that a snug fit cannot again be achieved upon an attempt to reconnect the fiber head. This aspect ensures that the clip is not reused, thereby preventing cross-contamination between patients.

[0030] In another embodiment, the receiving aperture has a unique shape that complements the shape of the coupling portion of the fiber head so that the fiber head mates with the receiving aperture in a lock-and-key fashion. In this manner, the fiber head can be lockably attached to the clip. Optionally, the coupling portion includes a rotatable ring or the like that permits the fiber head to swivel 360° about the coupling portion while the coupling portion remains in a locked position. To further this example, the receiving aperture may include a one or more slots, and the coupling portion of the fiber head may include complementary projections that fit into the slots. The coupling portion may then be rotated (e.g., 1/8 turn. 1/6 turn, or some other amount) to lock into place.

[0031] FIGURE 6 illustrates a blood-oxygen level monitoring clip **110** that includes first and second portions **112** coupled together by a hinge **114.** The first and second portions **112** have similar or identical shape, thereby facilitating manufacture of the clip and permitting the clip

to be applied to a patient's finger in opposite orientations without affecting function.

[0032] FIGURE 7 illustrates an SpO_2 monitoring probe **130** that includes first and second fiber heads **131, 132** for snap connection with one of the clips (e.g., a receiver head and a transmitter head), shown in "Detail A," which is delineated by a circle with an "A." Each fiber head is coupled to a fiber optic cable **133, 134** near the patient end of the probe. The cables **133, 134** are passed through a boot **136** that is slidable over a sheath **138** that holds the cables together at a monitor end of the probe, and may be coupled together at one or more points using a heat-shrink material **139.** One of the cables is passed through a bifurcation block **140** that divides the fibers therein into two fiber bundles **141, 142** that are passed through respective sheaths **143, 144** and end pieces **146, 148.** The other cable continues through its sheath **150,** and the fiber bundle **151** therein exits through another end piece **152.** The fiber bundles are coupled to a patient monitor **154** that sends red and/or IR light to and receives attenuated or reflected red and/or IR light carrying blood-oxygen measurement information and generates an output indicative of the blood-oxygen level.

[0033] According to an example the fiber bundle **141** is a 0.071-inch diameter (randomized) fiber bundle, and the fiber bundle **142** is a 0.122-inch diameter (randomized) fiber bundle. The end pieces **146, 148** are stainless steel end tips, each having an inner diameter of sufficient width to accommodate the fiber bundle passing through it. The fiber bundle **151** is a 0.141-inch diameter fiber bundle, and the end piece **152** is a stainless steel end tips having an inner diameter of sufficient width to accommodate the fiber bundle **151** passing through it. In this example, the sheath **143** is a 0.160-inch outer diameter silicone sheath, and the sheaths **144, 150 are** 0.215-inch outer diameter silicone sheaths. It will be appreciated that the foregoing dimensions and materials are provided for illustrative purposes only, and that other dimensions and materials may be used in accordance with the herein-described features and embodiments.

[0034] FIGURE 8 is an enlarged view of "Detail A", showing the fiber heads **131, 132** in detail. Each fiber head includes a fiber bundle **170** that passes through a bushing **172.** The end **174** of each fiber bundle is polished down until it is flush with the surface of a coupling portion **176** of the fiber head. The coupling portion includes a barb ring or lip **178** (shown in cross section) that releasably connects the fiber head to retaining structures around a receiving aperture in a finger clip or the like. In this manner, the fiber head can be releasably connected to multiple disposable clips.

[0035] In one embodiment, the fiber bundle **170** has a numerical aperture of 0.66 and a 4.0mm diameter.

[0036] FIGURES 9 and 10 illustrate, respectively, a top-down view and an elevated perspective view of an open disposable blood oximetry clip **190** that includes first and second clip portions **192** coupled together by an integral hinge **194.** The clip portions each have a receiving aperture **196** that receives a coupling portion (not shown in Figures 9 and 10) of a fiber head, as described herein. The perimeter of each receiving aperture has a plurality of integral flexible retaining clips **198** that lockably and removably receive and temporarily retain the coupling portion of the fiber head.

[0037] Dimensions of the clip **190** are labeled as a width W, a length L, a radius of curvature R (at a distal end of the clip), and a distance D from the center of the receiving aperture to the proximal end of the clip. In one embodiment, the length L is approximately twice the width W of the clip portion. The radius of curvature is approximately 0.5. The distance D is approximately ¾ of the distance from the proximal end of the clip portion to the distal end of the clip portion. The dimensions, of course, vary with the size of the finger or other appendage to be measured. Although the herein-described systems may be employed for any SpO_2 measurement application, they are particularly useful in an MR environment (e.g., in or near an MR device).

Claims

1. An appendage clip (40, 70, 90, 110, 190) for use in an oximetry probe (130), including first and second rigid clip portions (42, 72, 74, 92, 112, 192),
at least one of the clip portions (42, 72, 74, 92, 112, 192) including:

> a receiving aperture (94, 196) on the exterior side of the clip portion (42, 72, 74, 92, 112, 192), wherein the receiving aperture (94, 196) is arranged to releasably engage and align a fiber optic cable head (16, 18, 98, 131, 132) through which light is transmitted into and/or received from an appendage received in the clip;
> a compressible foam or plastic layer (12, 34, 50, 80) affixed to the interior side of the clip portion (42, 72, 74, 92, 112, 192), the compressible foam or plastic layer defining an aperture in alignment with the receiving aperture;
> a retaining structure (44, 95, 198) arranged to releasably attach to a fiber optic cable head (16, 18, 98, 131, 132) in alignment with the receiving aperture (94, 196);

characterized in that the receiving aperture (94, 196) and/or the retaining structure (44, 95, 198) is configured to be permanently deformed upon removal of the fiber optic cable head (16, 18, 98, 131, 132) from the receiving aperture (94, 196), such that it is rendered non-functional, to ensure that the appendage clip (40, 70, 90, 110, 190) is not reused.

2. The appendage clip (40, 70, 90, 110, 190) according to claim 1, further including:

a transparent window layer (54) that acts as a barrier between a patient's skin and the fiber optic cable head (16, 18, 98, 131, 132) and permits light to pass therethrough to or from the fiber optic cable head (16, 18, 98, 131, 132).

3. The appendage clip (40, 70, 90, 110, 190) according to claim 1, wherein the retaining structure includes:

one or more slots (95) extending radially outward from the circumference of the receiving aperture (94, 196), the slots (95) permitting the receiving aperture (94, 196) to expand to accommodate the fiber optic cable head (16, 18, 98, 131, 132), and to releasably hold the fiber optic cable head (16, 18, 98, 131, 132) in place.

4. The appendage clip (40, 70, 90, 110, 190) according to claim 1, wherein the retaining structure includes:

one or more flexible retaining clips (44, 198) positioned around the circumference of the receiving aperture (94, 196), the retaining clips flexing outward to accommodate the fiber optic cable head (16, 18, 98, 131, 132), and returning to an original position upon receiving the fiber optic cable head (16, 18, 98, 131, 132) to releasably hold the fiber optic cable head (16, 18, 98, 131, 132) in place.

5. The appendage clip (40, 70, 90, 110, 190) according to claim 1, wherein both the first and second rigid clip portions (42, 72, 74, 92, 112, 192) are substantially identical in shape and form, and wherein a hinge (48, 76, 93, 114, 194) is coupled to distal ends thereof.

6. The appendage clip (40, 70, 90, 110, 190) according to claim 5, wherein the first and second rigid clip portions and the hinge are integrally molded plastic.

7. The appendage clip (40, 70, 90, 110, 190) according to claim 1, further including an adhesive layer (52) that overlays the compressible foam or plastic layer.

8. The appendage clip (40, 70, 90, 110, 190) according to claim 1, being color-coded to indicate a size of the appendage clip (40, 70, 90, 110, 190).

9. An oximetry probe (130) including
an appendage clip (40, 70, 90, 110, 190) according to claim 1, and
a fiber optic cable head (16, 18, 98, 131, 132) including a coupling portion (96, 176) that releasably attaches to the retaining structure (44, 95, 198) of the appendage clip (40, 70, 90, 110, 190).

10. The oximetry probe (130) according to claim 2, wherein the coupling portion (96, 176) has a truncated conical shape, a base of which forms a circular lip (178) that snaps into the retaining structure (44, 95, 198) and releasably locks the fiber optic cable head (16, 18, 98, 131, 132) to the appendage clip (40, 70, 90, 110, 190).

11. A releasably attachable fiber optic oximetry probe system (130) for use with disposable appendage clips (40, 70, 90, 110, 190), including:

a pair of fiber optic cable heads (16, 18, 98, 131, 132) arranged to respectively transmit and receive light for monitoring blood oxygen levels in a patient, each fiber optic cable head (16, 18, 98, 131, 132) having a coupling portion (96, 176) arranged to releasably snaps into a respective retaining structure (44, 95, 198) on an appendage clip (40, 70, 90, 110, 190) that is attached to an appendage of a patient;
a patient monitor (154) arranged to receive light from the fiber optic cable heads (16, 18, 98, 131, 132) and determine a blood-oxygen level of the patient therefrom; **characterized in that**

the coupling portion (96, 176) is configured to cause the retaining structure (44, 95, 198) to further permanently deform upon removal of the coupling portion (96, 176) to a point where it is non-functional for retaining the coupling portion (96, 176), such that the appendage clip (40, 70, 90, 110, 190) is not reusable.

12. The oximetry probe system (130) according to claim 11, wherein the coupling portion (96, 176) has a truncated conical shape that snaps into, and is aligned by, the retaining structure (44, 95, 198), causing the retaining structure (44, 95, 198) to deform to accommodate the coupling portion (96, 176).

13. The oximetry probe system (130) according to claim 11, wherein the coupling portion (96, 176) is circular such that the fiber optic cable heads (16, 18, 98, 131, 132) are rotatable while attached to the appendage clip (40, 70, 90, 110, 190).

14. A method of measuring blood-oxygen content in a patient, including:

coupling one or more detachable fiber optic cable heads (16, 18, 98, 131, 132) to respective flexible retaining structures (44 95, 198) on an appendage clip (40, 70, 90, 110, 190) attached to an appendage of a patient;
coupling a fiber optic cable connected to the one or more detachable fiber optic cable heads (16, 18, 98, 131, 132) to a patient monitor (154);
emitting light from the patient monitor (154)

through the one or more detachable fiber optic cable heads (16, 18, 98, 131, 132);
receiving light from the one or more fiber optic cable heads (16, 18, 98, 131, 132);
monitoring a blood-oxygen level of the patient;
removing the appendage clip from the patient;
detaching the one or more fiber optic cable heads (16, 18, 98, 131, 132) from the appendage clip (40, 70, 90, 110, 190);

characterized in that the flexible retaining structures (44, 95, 198) are rendered inoperable upon detachment of the one or more fiber optic cable heads (16, 18, 98, 131, 132), rending the appendage clip (40, 70, 90, 110, 190) unsuitable for subsequent use.

Patentansprüche

1. Gliedmaßeclip (40, 70, 90, 110, 190) zur Verwendung in einer Oximetriesonde (130), umfassend erste und zweite starre Clipabschnitte (42, 72, 74, 92, 112, 192),
wobei mindestens einer der Clipabschnitte (42, 72, 74, 92, 112, 192) Folgendes umfasst:

eine Aufnahmeapertur (94, 196) auf der Außenseite des Clipabschnitts (42, 72, 74, 92, 112, 192), wobei die Aufnahmeapertur (94, 196) ausgelegt ist zum lösbaren Eingreifen in und Ausrichten eines faseroptischen Kabelkopfes (16, 18, 98, 131, 132), durch den Licht in eine in den Clip aufgenommene Gliedmaße übertragen und/oder von dieser empfangen wird;
eine komprimierbare Schaum- oder Kunststoffschicht (12, 34, 50, 80), die an der Innenseite des Clipabschnitts (42, 72, 74, 92, 112, 192) befestigt ist, wobei die komprimierbare Schaum- oder Kunststoffschicht eine Apertur in Ausrichtung mit der Aufnahmeapertur definiert;
eine Haltestruktur (44, 95, 198) zum lösbaren Anbringen eines faseroptischen Kabelkopfs (16, 18, 98, 131, 132) in Ausrichtung mit der Aufnahmeapertur (94, 196);

dadurch gekennzeichnet, dass die Aufnahmeapertur (94, 196) und/oder die Haltestruktur (44, 95, 198) konfiguriert sind, um beim Entfernen des faseroptischen Kabelkopfs (16, 18, 98, 131, 132) von der Aufnahmeapertur (94, 196) dauerhaft verformt zu werden, so dass sie funktionsunfähig gemacht wird, um sicherzustellen, dass der Gliedmaßeclip (40, 70, 90, 110, 190) nicht wiederverwendet wird.

2. Gliedmaßeclip (40, 70, 90, 110, 190) nach Anspruch 1, der weiterhin Folgendes umfasst:

eine transparente Fensterschicht (54), die als eine Barriere zwischen der Haut eines Patienten und dem faseroptischen Kabelkopf (16, 18, 98, 131, 132) dient und zulässt, dass Licht zum oder vom faseroptischen Kabelkopf (16, 18, 98, 131, 132) hindurchtritt.

3. Gliedmaßeclip (40, 70, 90, 110, 190) nach Anspruch 1, wobei die Haltestruktur Folgendes umfasst:

einen oder mehrere Schlitze (95), die sich von dem Umfang der Aufnahmeapertur (94, 196) ausgehend radial nach außen erstrecken, wobei die Schlitze (95) erlauben, dass sich die Aufnahmeapertur (94, 196) ausdehnen kann, um den faseroptischen Kabelkopf (16, 18, 98, 131, 132) aufzunehmen und um den faseroptischen Kabelkopf (16, 18, 98, 131, 132) lösbar festzuhalten.

4. Gliedmaßeclip (40, 70, 90, 110, 190) nach Anspruch 1, wobei die Haltestruktur Folgendes umfasst:

eine oder mehrere flexible Halteclips (44, 198), die um den Umfang der Aufnahmeapertur (94, 196) positioniert sind, wobei sich die Halteclips nach außen biegen, um den faseroptischen Kabelkopf (16, 18, 98, 131, 132) aufzunehmen, und nach dem Aufnehmen des faseroptischen Kabelkopfs (16, 18, 98, 131, 132) in ihre ursprüngliche Position zurückkehren, um den faseroptischen Kabelkopf (16, 18, 98, 131, 132) lösbar festzuhalten.

5. Gliedmaßeclip (40, 70, 90, 110, 190) nach Anspruch 1, wobei sowohl der erste als auch der zweite starre Clipabschnitt (42, 72, 74, 92, 112, 192) im Wesentlichen identisch in Gestalt und Form sind, und wobei ein Scharnier (48, 76, 93, 114, 194) mit den distalen Enden hiervon gekoppelt ist.

6. Gliedmaßeclip (40, 70, 90, 110, 190) nach Anspruch 5, wobei der erste und der zweite Clipabschnitt und das Scharnier aus einstückig geformtem Kunststoff sind.

7. Gliedmaßeclip (40, 70, 90, 110, 190) nach Anspruch 1, weiterhin umfassend eine Haftschicht (52), die über der komprimierbaren Schaum- oder Kunststoffschicht liegt.

8. Gliedmaßeclip (40, 70, 90, 110, 190) nach Anspruch 1, der farbcodiert ist, um eine Größe des Gliedmaßeclips (40, 70, 90, 110, 190) anzugeben.

9. Oximetriesonde (130), die Folgendes umfasst:

einen Gliedmaßeclip (40, 70, 90, 110, 190) nach

Anspruch 1, und
einen faseroptischen Kabelkopf (16, 18, 98, 131, 132) mit einem Kopplungsabschnitt (96, 176), der lösbar an der Haltestruktur (44, 95, 198) des Gliedmaßeclips (40, 70, 90, 110, 190) angebracht ist.

10. Oximetriesonde (130) nach Anspruch 2, wobei der Kopplungsabschnitt (96, 176) eine Kegelstumpfform hat, deren Basis eine kreisförmige Lippe (178) bildet, welche in die Haltestruktur (44, 95, 198) einschnappt und den faseroptischen Kabelkopf (16, 18, 98, 131, 132) lösbar mit dem Gliedmaßeclip (40, 70, 90, 110, 190) verriegelt.

11. Lösbar anbringbares faseroptisches Oximetriesondensystem (130) zur Verwendung mit Einweg-Gliedmaßeclips (40, 70, 90, 110, 190), das Folgendes umfasst:

ein Paar faseroptische Kabelköpfe (16, 18, 98, 131, 132) zum Aussenden bzw. Empfangen von Licht zur Überwachung des Sauerstoffgehalts im Blut eines Patienten, wobei jeder faseroptische Kabelkopf (16, 18, 98, 131, 132) einen Kopplungsabschnitt (96, 176) zum lösbaren Einschnappen in eine jeweilige Haltestruktur (44, 95, 198) an dem Gliedmaßeclip (40, 70, 90, 110, 190) hat, der an einer Gliedmaße eines Patienten angebracht ist;
einen Patientenmonitor (154), der dafür vorgesehen ist, Licht von den faseroptischen Kabelköpfen (16, 18, 98, 131, 132) zu empfangen und den Sauerstoffgehalt im Blut des Patienten daraus zu bestimmen, **dadurch gekennzeichnet, dass** der Kopplungsabschnitt (96, 176) konfiguriert ist, um dafür zu sorgen, dass sich die Haltestruktur (44, 95, 198) beim Entfernen des Kopplungsabschnitts (96, 176) weiterhin dauerhaft bis zu einem Punkt verformt, an dem sie unfähig ist, den Kopplungsabschnitt (96, 176) aufzunehmen, so dass der Gliedmaßeclip (40, 70, 90, 110, 190) nicht wiederverwendbar ist.

12. Oximetriesondensystem (130) nach Anspruch 11, wobei der Kopplungsabschnitt (96, 176) eine Kegelstumpfform hat, die in die Haltestruktur (44, 95, 198) einrastet und von dieser ausgerichtet wird, so dass sich die Haltestruktur (44, 95, 198) verformt, um den Kopplungsabschnitt (96, 176) aufzunehmen.

13. Oximetriesondensystem (130) nach Anspruch 11, wobei der Kopplungsabschnitt (96, 176) kreisförmig ist, so dass die faseroptischen Kabelköpfe (16, 18, 98, 131, 321) drehbar sind, während sie an dem Gliedmaßeclip (40, 70, 90, 110, 190) angebracht sind.

14. Verfahren zum Messen des Sauerstoffgehalts im Blut eines Patienten, das Folgendes umfasst:

Koppeln von einem oder mehreren abnehmbaren faseroptischen Kabelköpfen (16, 18, 98, 131, 132) mit jeweiligen flexiblen Haltestrukturen (44, 95, 198) an einem Gliedmaßeclip (40, 70, 90, 110, 190), der an einer Gliedmaße eines Patienten angebracht ist;
Koppen eines faseroptischen Kabels, das mit einem oder mehreren abnehmbaren faseroptischen Kabelköpfen (16, 18, 98, 131, 132) verbunden ist, mit einem Patientenmonitor (154);
Emittieren von Licht von dem Patientenmonitor (154) durch den einen oder mehrere abnehmbare faseroptische Kabelköpfe (16, 18, 98, 131, 132);
Empfangen von Licht von dem einen oder mehreren faseroptischen Kabelköpfen (16, 18, 98, 131, 132);
Überwachen eines Sauerstoffgehalts im Blut des Patienten;
Entfernen des Gliedmaßeclips von dem Patienten;
Abnehmen des einen oder mehrerer faseroptischer Kabelköpfe (16, 18, 98, 131, 132) von dem Gliedmaßeclip (40, 70, 90, 110, 190);

dadurch gekennzeichnet, dass die flexiblen Haltestrukturen (44, 95, 198) beim Abnehmen des einen oder mehrerer faseroptischer Kabelköpfe (16, 18, 98, 131, 132) funktionsunfähig gemacht werden, so dass der Gliedmaßeclip (40, 70, 90, 110, 190) für die nachfolgende Verwendung ungeeignet ist.

Revendications

1. Pince pour appendice (40, 70, 90, 110, 190) destinée à être utilisée dans une sonde d'oxymétrie (130), comprenant des première et seconde parties de pince rigides (42, 72, 74, 92, 112, 192),
au moins l'une des parties de pince (42, 72, 74, 92, 112, 192) comprenant :

une ouverture de réception (94, 196) sur le côté extérieur de la partie de pince (42, 72, 74, 92, 112, 192), dans laquelle l'ouverture de réception (94, 196) est agencée pour entrer en prise amovible avec et aligner une tête de câble à fibres optiques (16, 18, 98, 131, 132) par le biais de laquelle de la lumière est transmise dans et/ou reçue d'un appendice reçu dans la pince ;
une couche de mousse ou de plastique compressible (12, 34, 50, 80) fixée sur le côté intérieur de la partie de pince (42, 72, 74, 92, 112, 192), la couche de mousse ou de plastique compressible définissant une ouverture en aligne-

ment avec l'ouverture de réception ;
une structure de retenue (44, 95, 198) destinée à être fixée de manière amovible à une tête de câble à fibres optiques (16, 18, 98, 131, 132) en alignement avec l'ouverture de réception (94, 196) ;
caractérisée en ce que
l'ouverture de réception (94, 196) et/ou la structure de retenue (44, 95, 198) est/sont configurée(s) pour être déformée(s) de façon permanente lors du retrait de la tête de câble à fibres optiques (16, 18, 98, 131, 132) de l'ouverture de réception (94, 196), de manière à devenir non fonctionnelle(s), pour garantir que la pince pour appendice (40, 70, 90, 110, 190) ne soit pas réutilisée.

2. Pince pour appendice (40, 70, 90, 110, 190) selon la revendication 1, comprenant en outre :

une couche de fenêtre transparente (54) qui agit comme une barrière entre la peau d'un patient et la tête de câble à fibres optiques (16, 18, 98, 131, 132) et permet à la lumière de passer à travers celle-ci vers ou depuis la tête de câble à fibres optiques (16, 18, 98, 131, 132).

3. Pince pour appendice (40, 70, 90, 110, 190) selon la revendication 1, dans laquelle la structure de retenue comprend :

une ou plusieurs fente(s) (95) s'étendant radialement vers l'extérieur à partir de la circonférence de l'ouverture de réception (94, 196), les fentes (95) permettant à l'ouverture de réception (94, 196) de s'étendre pour accueillir la tête de câble à fibres optiques (16, 18, 98, 131, 132), et de maintenir de manière amovible la tête de câble à fibres optiques (16, 18, 98, 131, 132) en place.

4. Pince pour appendice (40, 70, 90, 110, 190) selon la revendication 1, dans laquelle la structure de retenue comprend :

une ou plusieurs pince(s) de retenue flexible(s) (44, 198) positionnée(s) autour de la circonférence de l'ouverture de réception (94, 196), les pinces de retenue fléchissant vers l'extérieur pour accueillir la tête de câble à fibres optiques (16, 18, 98, 131, 132), et revenant vers une position d'origine lors de la réception de la tête de câble à fibres optiques (16, 18, 98, 131, 132) pour maintenir de manière amovible la tête de câble à fibres optiques (16, 18, 98, 131, 132) en place.

5. Pince pour appendice (40, 70, 90, 110, 190) selon la revendication 1, dans laquelle la forme des deux première et seconde parties de pince rigides (42, 72, 74, 92, 112, 192) est sensiblement identique, et dans laquelle une charnière (48, 76, 93, 114, 194) est accouplée à des extrémités distances de celles-ci.

6. Pince pour appendice (40, 70, 90, 110, 190) selon la revendication 5, dans laquelle les première et seconde parties de pince rigides et la charnière sont composées de plastique moulé d'une seule pièce.

7. Pince pour appendice (40, 70, 90, 110, 190) selon la revendication 1, comprenant en outre une couche adhésive (52) qui recouvre la couche de mousse ou de plastique compressible.

8. Pince pour appendice (40, 70, 90, 110, 190) selon la revendication 1, codée par couleur pour indiquer une taille de la pince pour appendice (40, 70, 90, 110, 190).

9. Sonde d'oxymétrie (130) comprenant
une pince pour appendice (40, 70, 90, 110, 190) selon la revendication 1, et une tête de câble à fibres optiques (16, 18, 98, 131, 132) comprenant une partie d'accouplement (96, 176) qui se fixe de manière amovible à la structure de retenue (44, 95, 198) de la pince pour appendice (40, 70, 90, 110, 190).

10. Sonde d'oxymétrie (130) selon la revendication 2, dans laquelle la partie d'accouplement (96, 176) présente une forme tronconique, dont une base forme une lèvre circulaire (178) qui s'encliquette dans la structure de retenue (44, 95, 198) et verrouille de manière amovible la tête de câble à fibres optiques (16, 18, 98, 131, 132) à la pince pour appendice (40, 70, 90, 110, 190).

11. Système de sonde d'oxymétrie à fibres optiques à fixation amovible (130) destiné à être utilisé avec des pinces pour appendice jetables (40, 70, 90, 110, 190), comprenant :

une paire de têtes de câble à fibres optiques (16, 18, 98, 131, 132) conçues pour respectivement transmettre et recevoir de la lumière pour contrôler des taux d'oxygène dans le sang chez un patient, chaque tête de câble à fibres optiques (16, 18, 98, 131, 132) comprenant une partie d'accouplement (96, 176) conçue pour s'encliqueter de manière amovible dans une structure de retenue respective (44, 95, 198) sur une pince pour appendice (40, 70, 90, 110, 190) qui est fixée sur un appendice d'un patient ;
un moniteur pour patient (154) conçu pour recevoir de la lumière des têtes de câble à fibres optiques (16, 18, 98, 131, 132) et déterminer un taux d'oxygène dans le sang du patient à partir

de celles-ci ;
caractérisé en ce que
la partie d'accouplement (96, 176) est configurée pour amener la structure de retenue (44, 95, 198) à se déformer encore de façon permanente lors du retrait de la partie d'accouplement (96, 176) à un point où elle devient non fonctionnelle pour retenir la partie d'accouplement (96, 176), de sorte que la pince pour appendice (40, 70, 90, 110, 190) ne puisse pas être réutilisée.

12. Système de sonde d'oxymétrie (130) selon la revendication 11, dans lequel la partie d'accouplement (96, 176) présente une forme tronconique qui s'encliquette dans, et est alignée par, la structure de retenue (44, 95, 198), amenant la structure de retenue (44, 95, 198) à se déformer pour accueillir la partie d'accouplement (96, 176).

13. Système de sonde d'oxymétrie (130) selon la revendication 11, dans lequel la partie d'accouplement (96, 176) est circulaire de sorte que les têtes de câble à fibres optiques (16, 18, 98, 131, 132) soient rotatives tout en étant fixées à la pince pour appendice (40, 70, 90, 110, 190).

14. Procédé de mesure du taux d'oxygène dans le sang chez un patient, comprenant :

l'accouplement d'une ou de plusieurs tête(s) de câble à fibres optiques amovible(s) (16, 18, 98, 131, 132) à des structures de retenue flexibles respectives (44, 95, 198) sur une pince pour appendice (40, 70, 90, 110, 190) fixée sur un appendice d'un patient ;
l'accouplement d'un câble à fibres optiques connecté à la/aux tête(s) de câble à fibres optiques amovible(s) (16, 18, 98, 131, 132) à un moniteur pour patient (154) ;
l'émission de lumière à partir du moniteur pour patient (154) par le biais de la/des tête(s) de câble à fibres optiques amovible(s) (16, 18, 98, 131, 132) ;
la réception de lumière de la/des tête(s) de câble à fibres optiques (16, 18, 98, 131, 132) ;
le contrôle d'un taux d'oxygène dans le sang du patient ;
le retrait de la pince pour appendice du patient ;
le détachement de la/des tête(s) de câble à fibres optiques (16, 18, 98, 131, 132) de la pince pour appendice (40, 70, 90, 110, 190) ;
caractérisé en ce que
les structures de retenue flexibles (44, 95, 198) sont rendues inopérantes lors du détachement de la/des tête(s) de câble à fibres optiques (16, 18, 98, 131, 132), rendant la pince pour appendice (40, 70, 90, 110, 190) inappropriée pour une utilisation ultérieure.

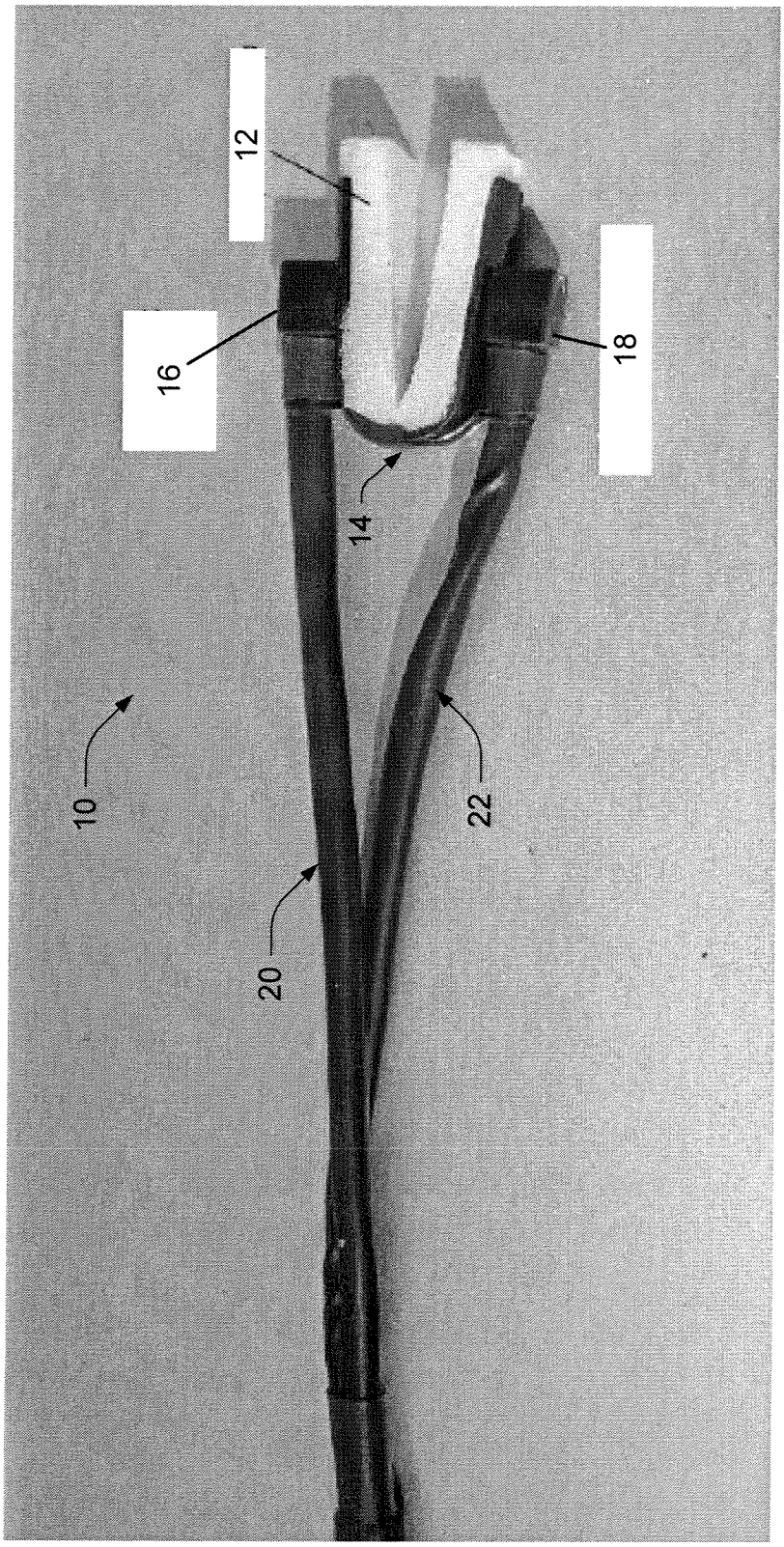

FIG. 1

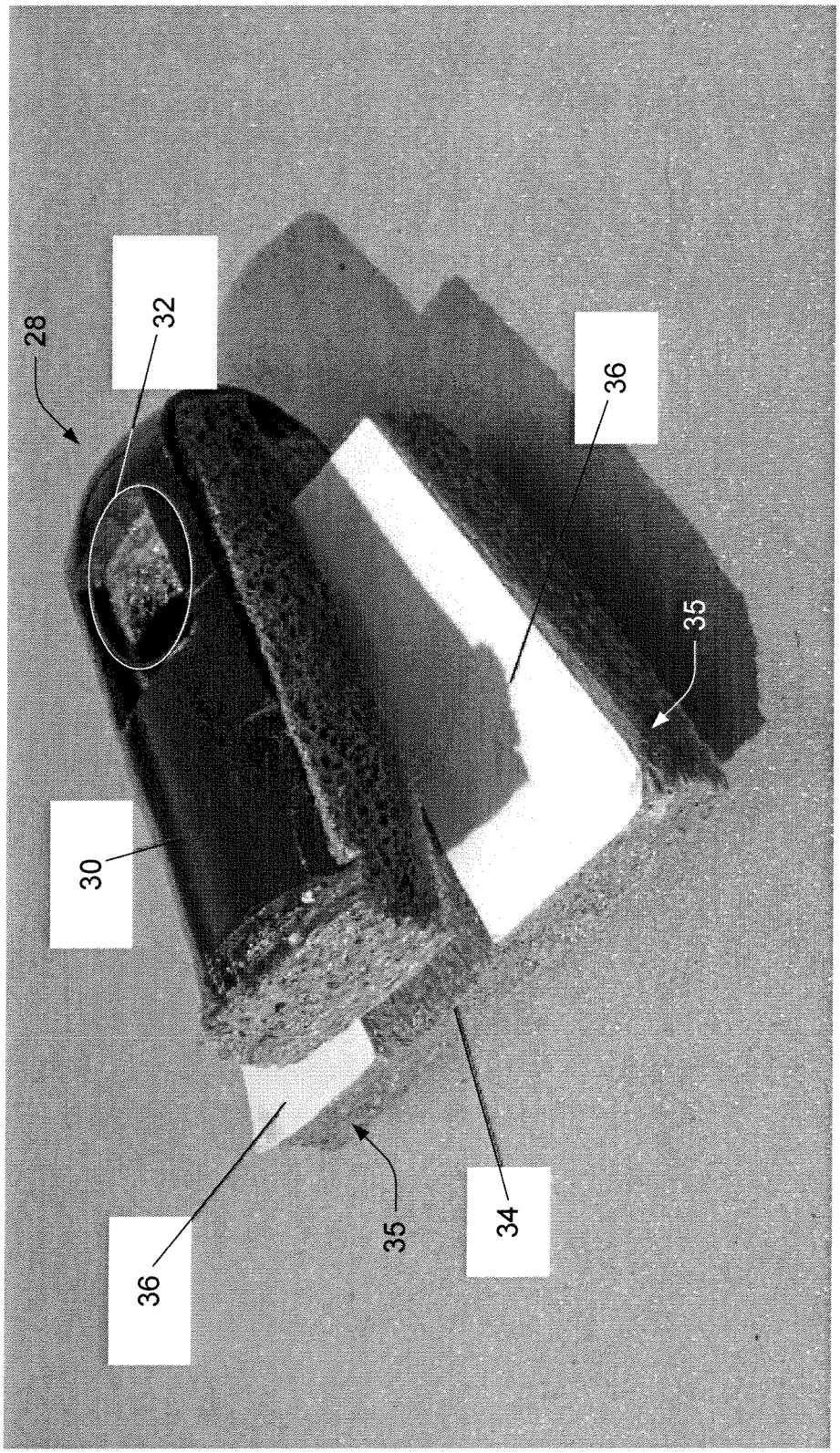

FIG. 2

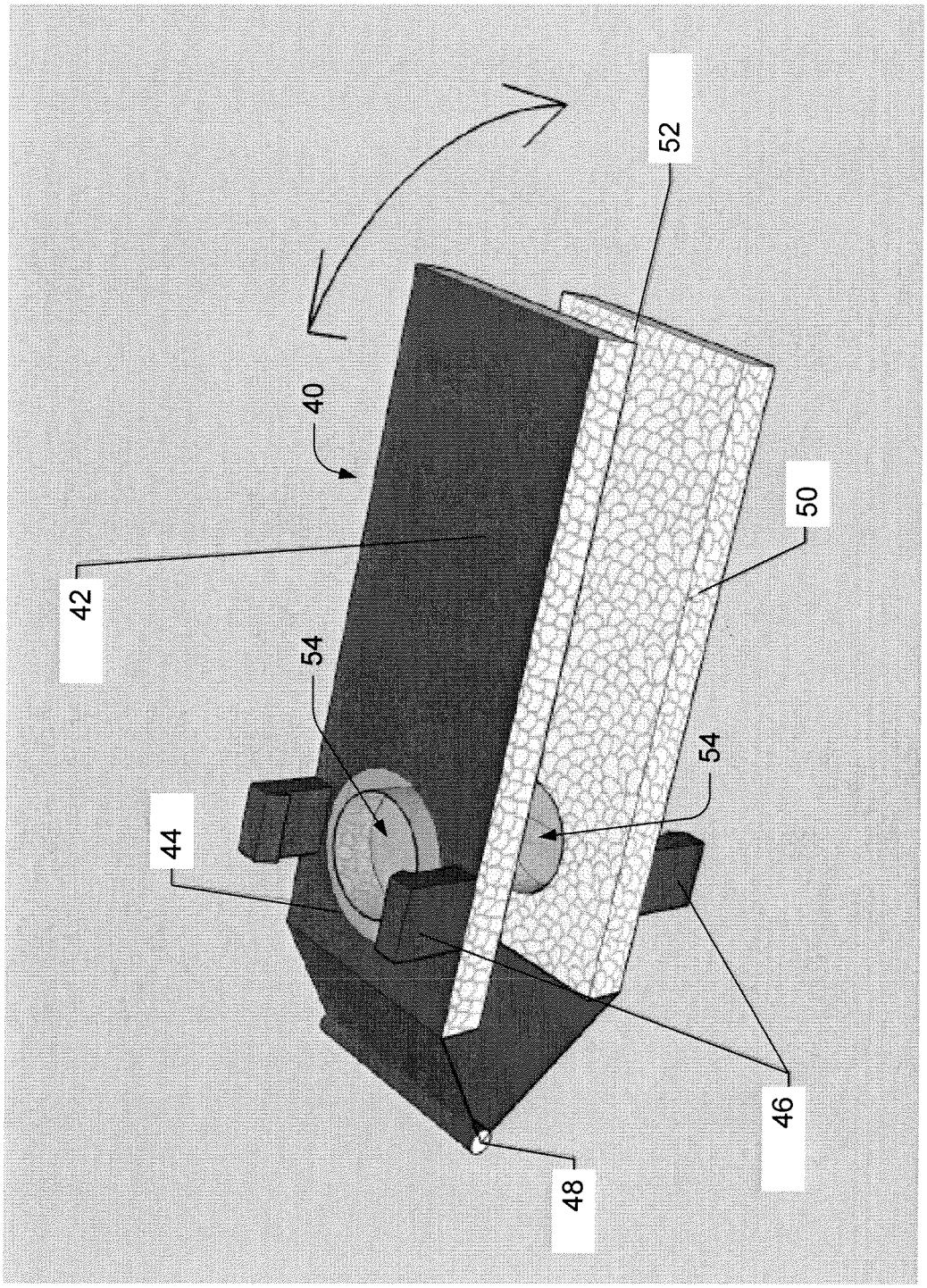

FIG. 3

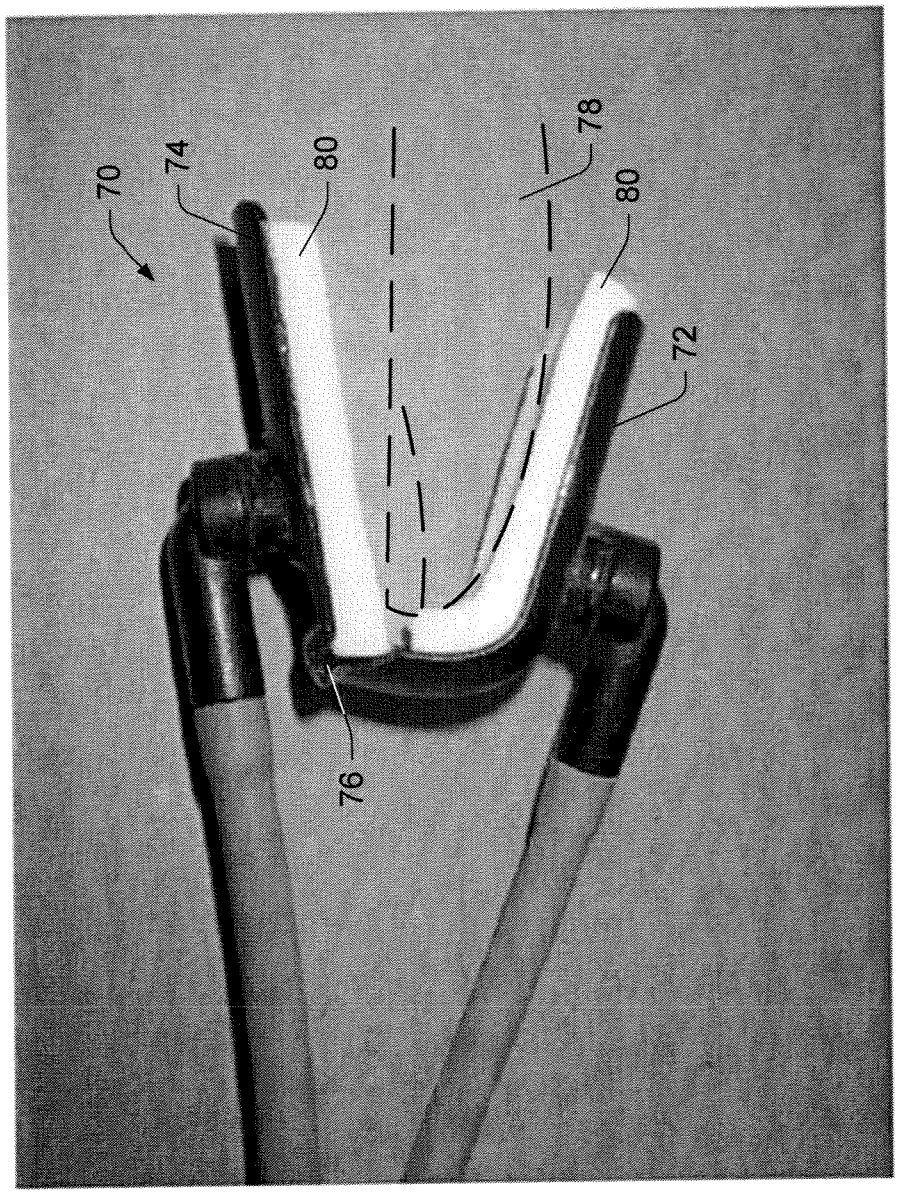

FIG. 4

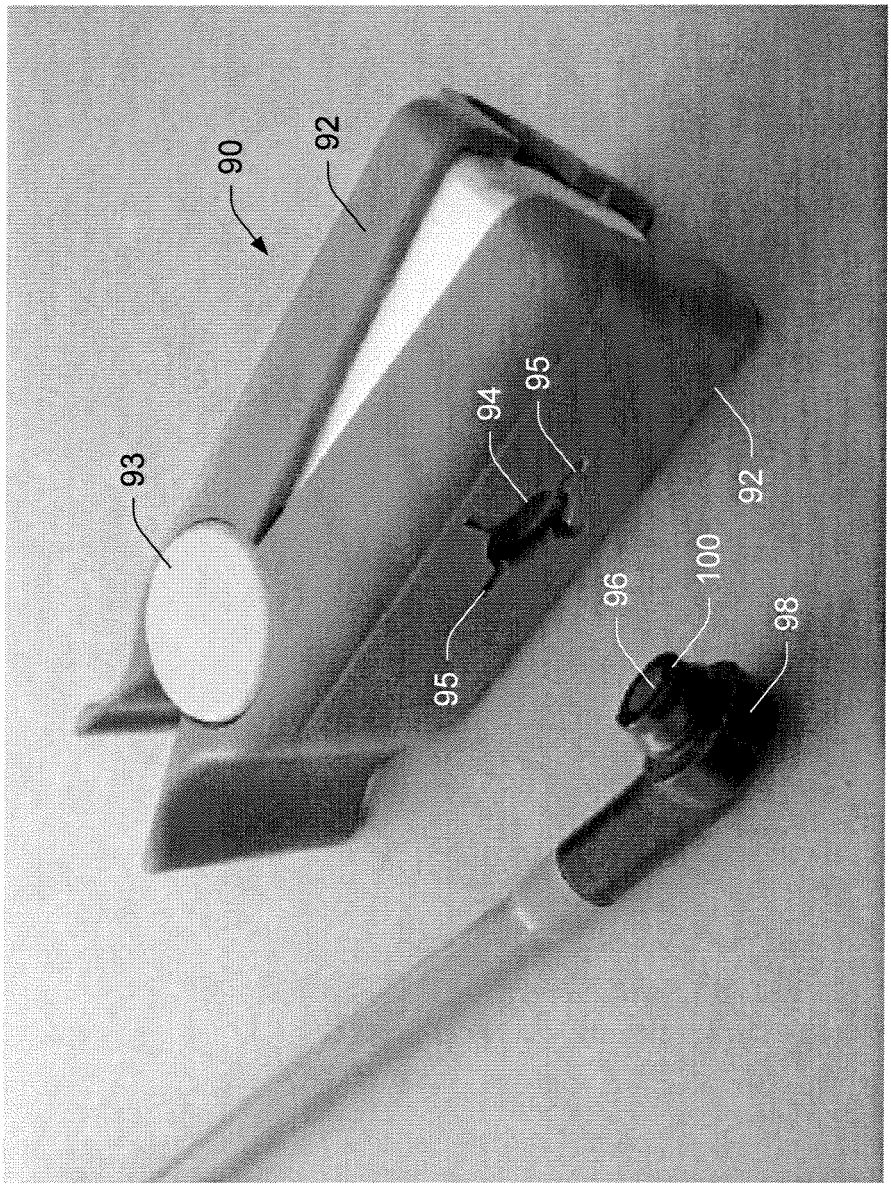

FIG. 5

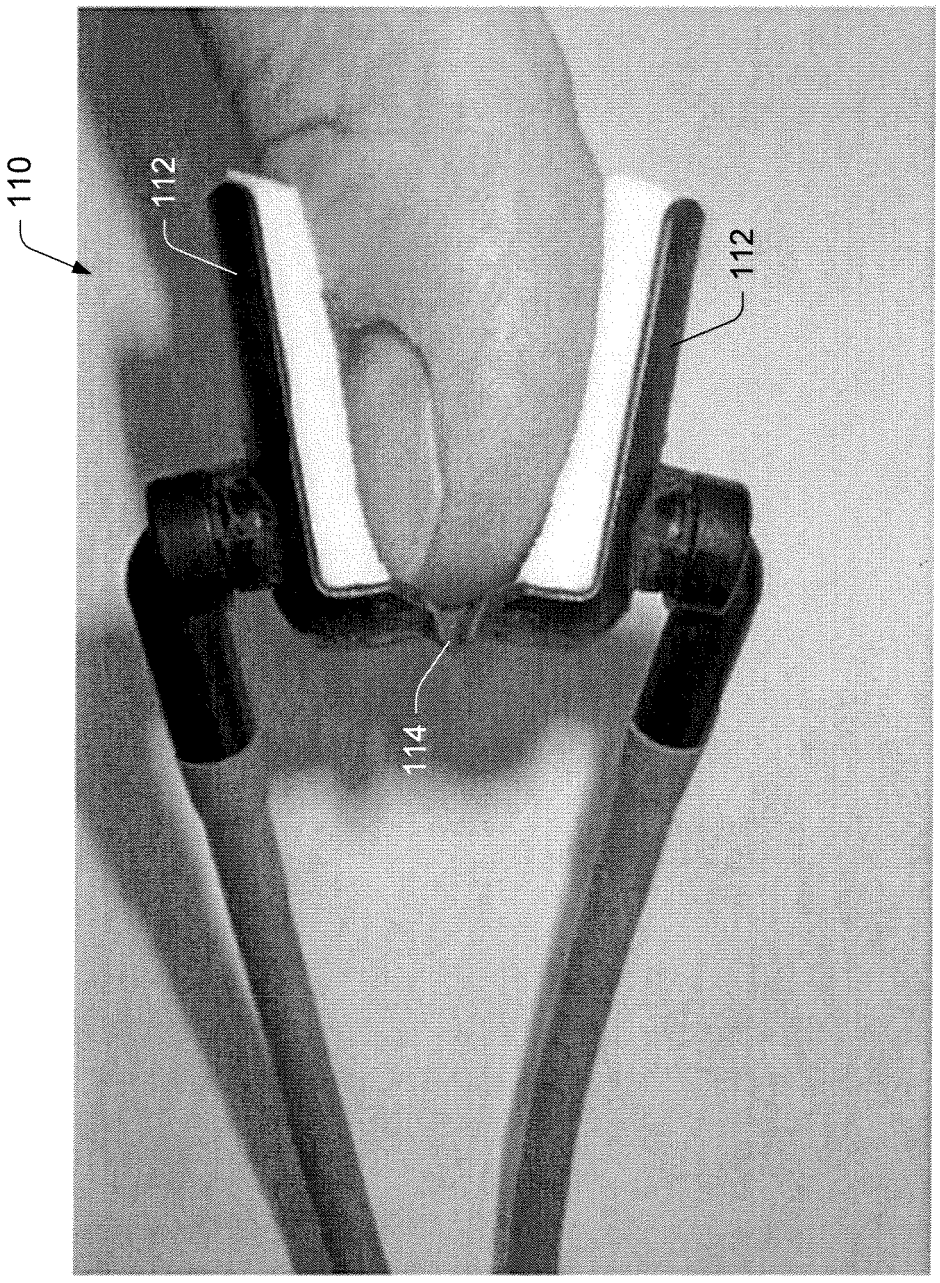

FIG. 6

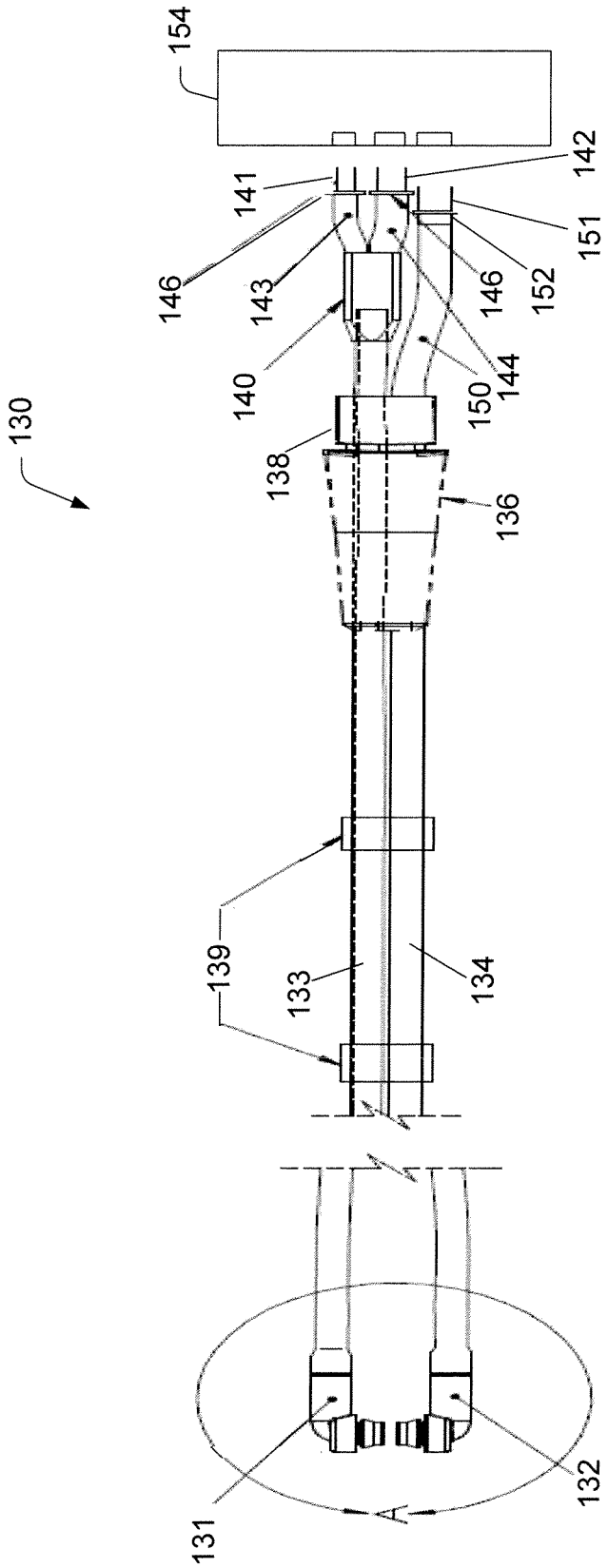
154
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FIG. 7

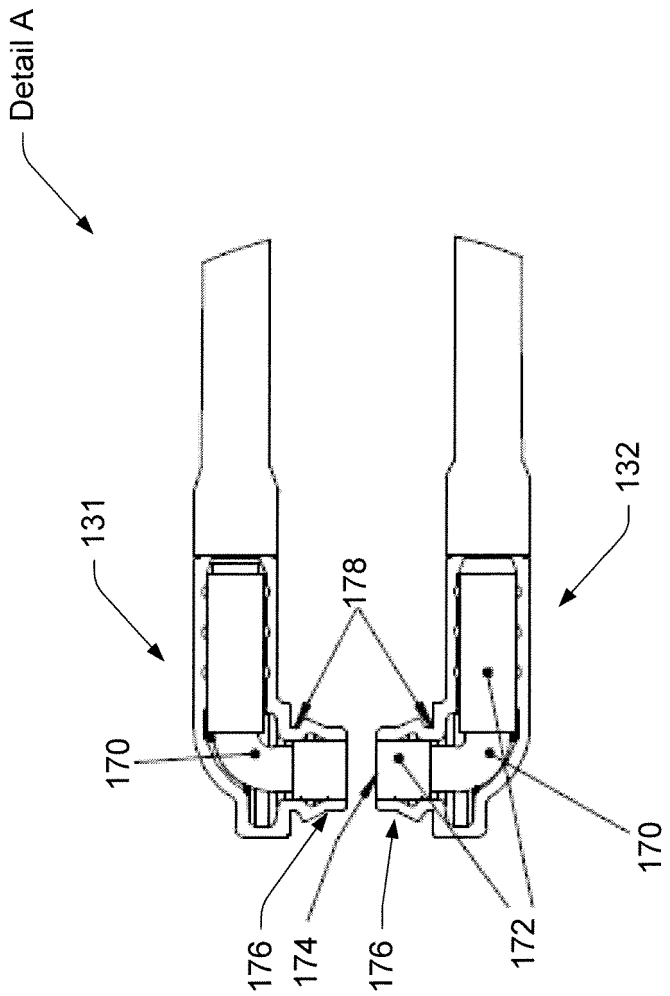

FIG. 8

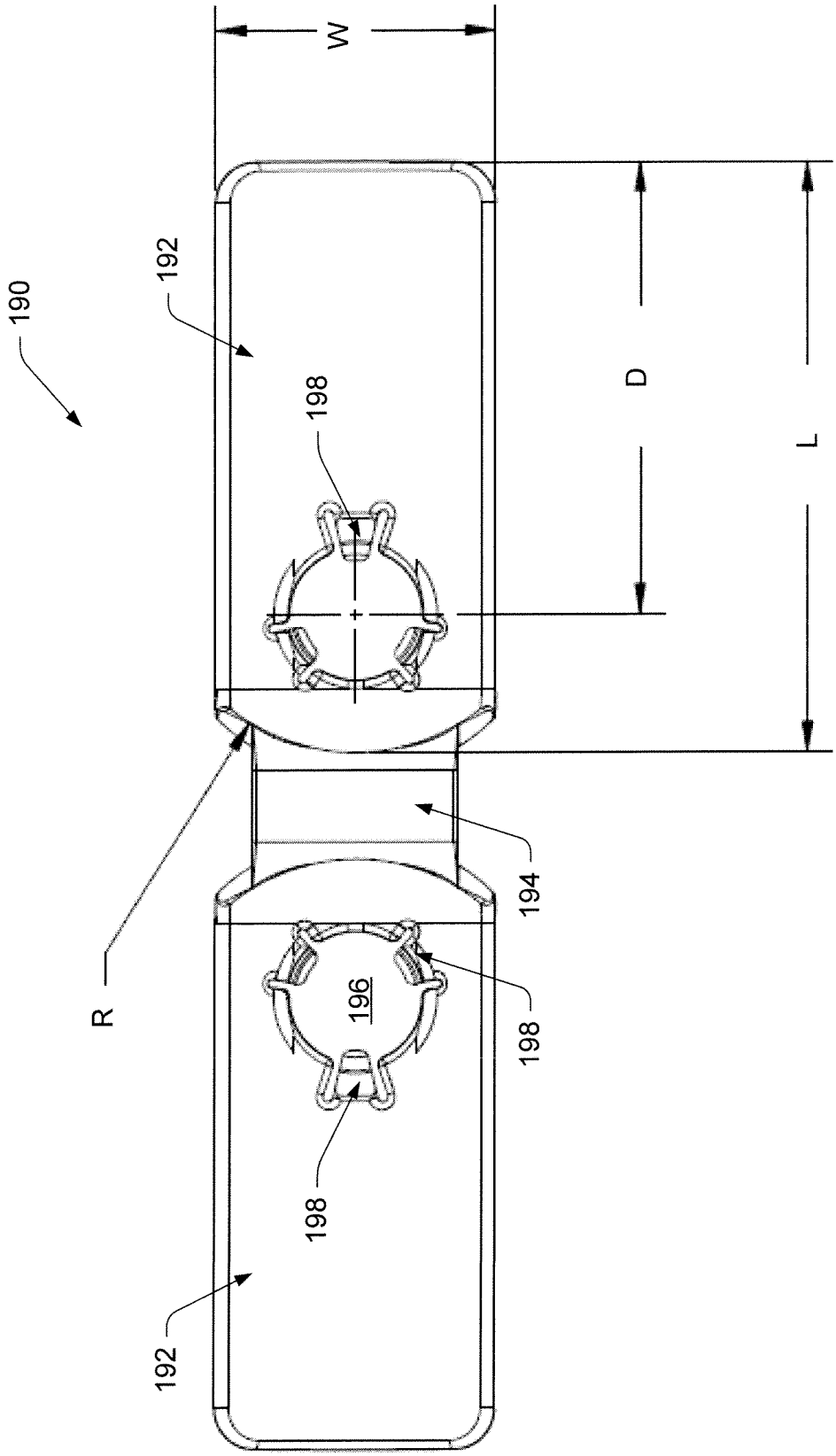

FIG. 9

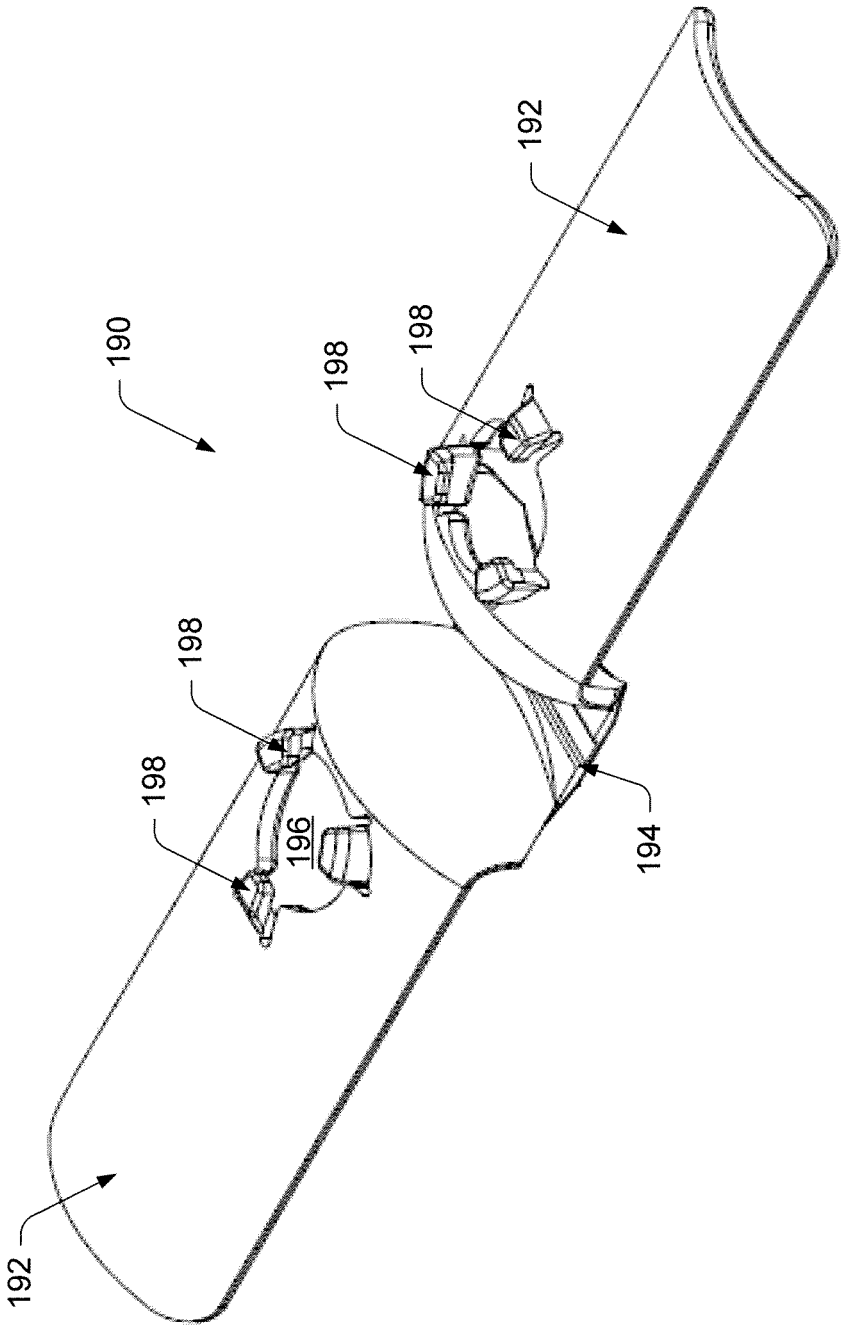

FIG. 10

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- EP 0568380 A1 **[0005]**

专利名称(译)	一次性spo2手柄		
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[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦电子N.V. 飞利浦知识产权及标准部GMBH		
当前申请(专利权)人(译)	皇家飞利浦N.V. 飞利浦知识产权及标准部GMBH		
[标]发明人	KAESTLE SIEGFRIED		
发明人	KAESTLE, SIEGFRIED		
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CPC分类号	G02B6/3897 A61B5/14552 A61B5/6826 A61B5/6838 G02B6/0008		
优先权	61/185216 2009-06-09 US		
其他公开文献	EP2440113A1		
外部链接	Espacenet		

摘要(译)

在磁共振扫描过程中监测患者的血氧水平时，可拆卸和可重复使用的光缆头（16、18、98、131、132）与SpO2监测器和铰接的手指夹（40、70、90）连接（110、190）。指夹（40、70、90、110、190）包括孔（94、196）和固定结构（44、95、198），光纤头（16、18、98、131，132）是可释放的。保持结构包括保持夹（44、198），狭槽（95）等，它们可灵活地容纳并对准光纤头（16、18、98、131、132）。保持结构（44、95、198）可能是可变形的，以使MR扫描结束时光纤头（16、18、98、131、132）的脱离使手指夹（40、70、90，110、190）无法使用，以确保不会重复使用夹子，从而防止患者之间发生交叉感染。替代地，指夹（40、70、90、110、190）可以是可重复使用的，并且固定夹可以被设计成承受纤维头（16、18、98、131、132）的重复附接和分离。可压缩的泡沫或塑料层连接到夹子部分的内部，以提供紧密的配合。附接到泡沫或塑料层的透明层（54）允许光穿过泡沫/塑料孔，同时防止纤维头（16、18、98、131、132）接触患者的皮肤。

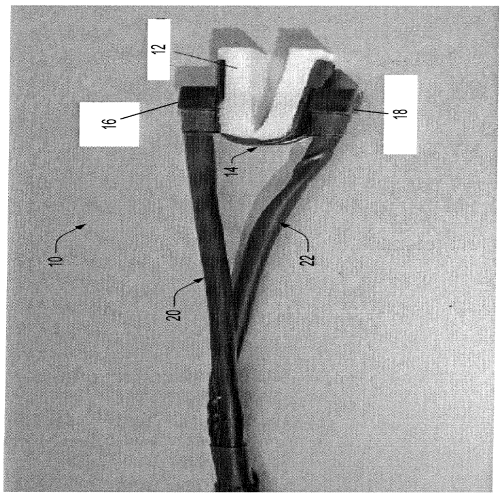

FIG. 1