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(54) **SYSTEM AND METHOD TO CONTROL TEMPERATURE**

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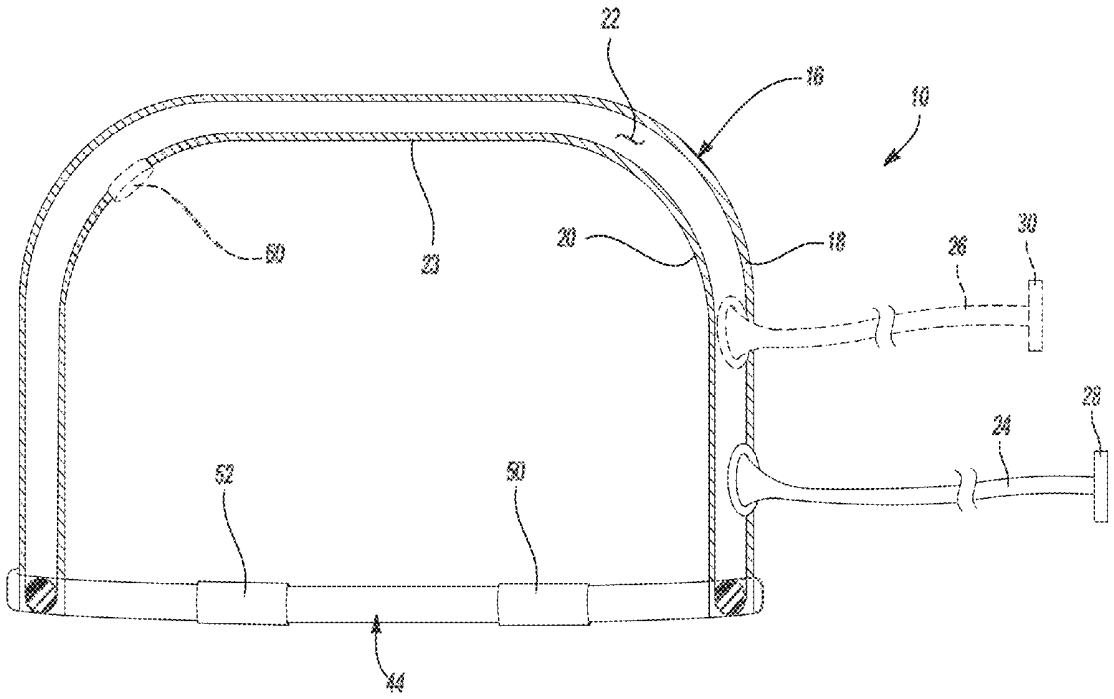
| ***A61F 7/10*** | (2006.01) |

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

CPC ..... ***A61B 5/448*** (2013.01); *A61F 2007/0004* (2013.01); ***A61F 7/10*** (2013.01); ***A61N 5/0617*** (2013.01)

(57) **ABSTRACT**

Disclosed is a device and method of controlling blood flow to a selected area. Also disclosed is a system and method to regulate a temperature at a selected location. The system and method may be applied to a subject for a selected period of time.



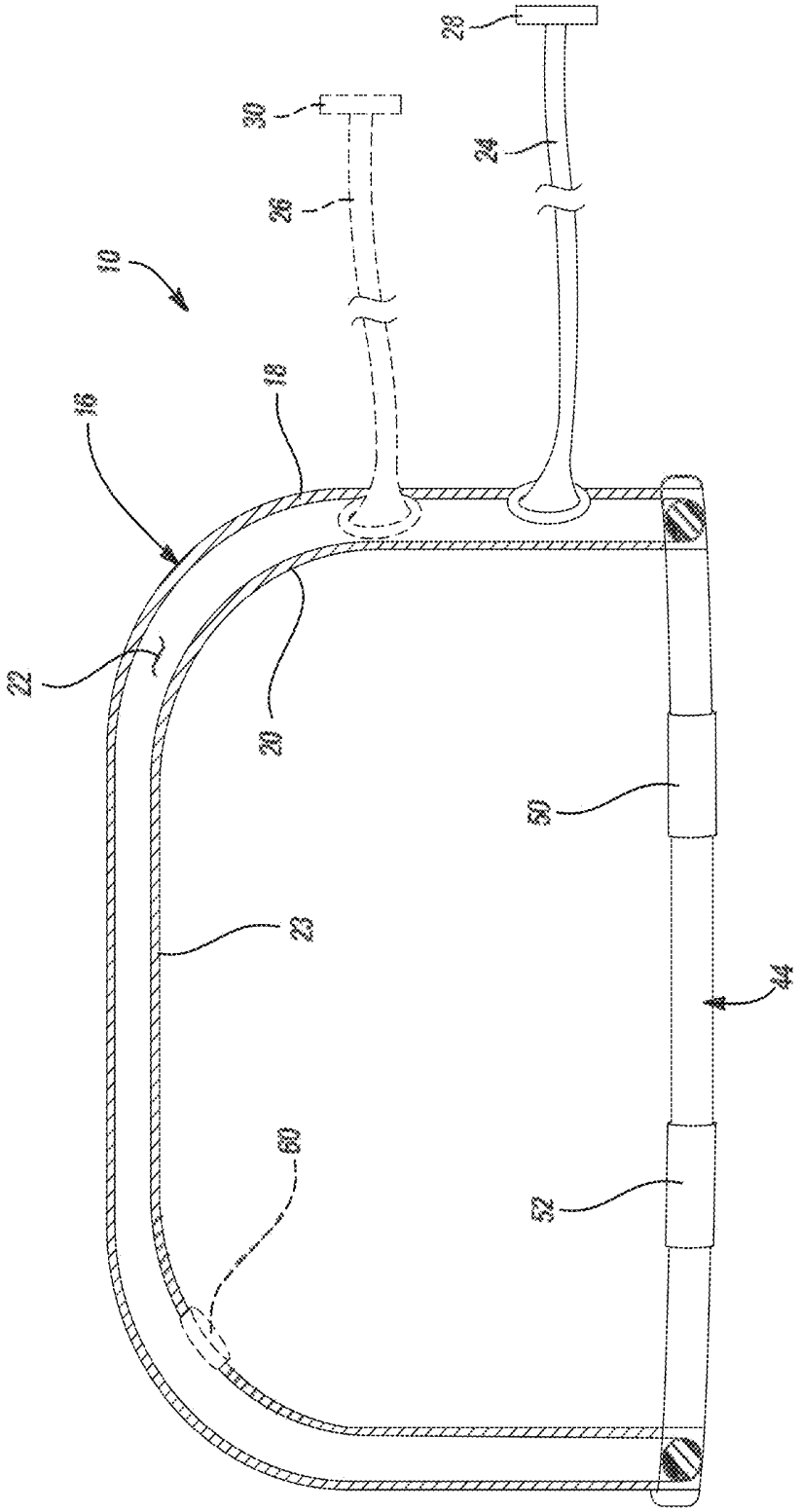



Fig - 1

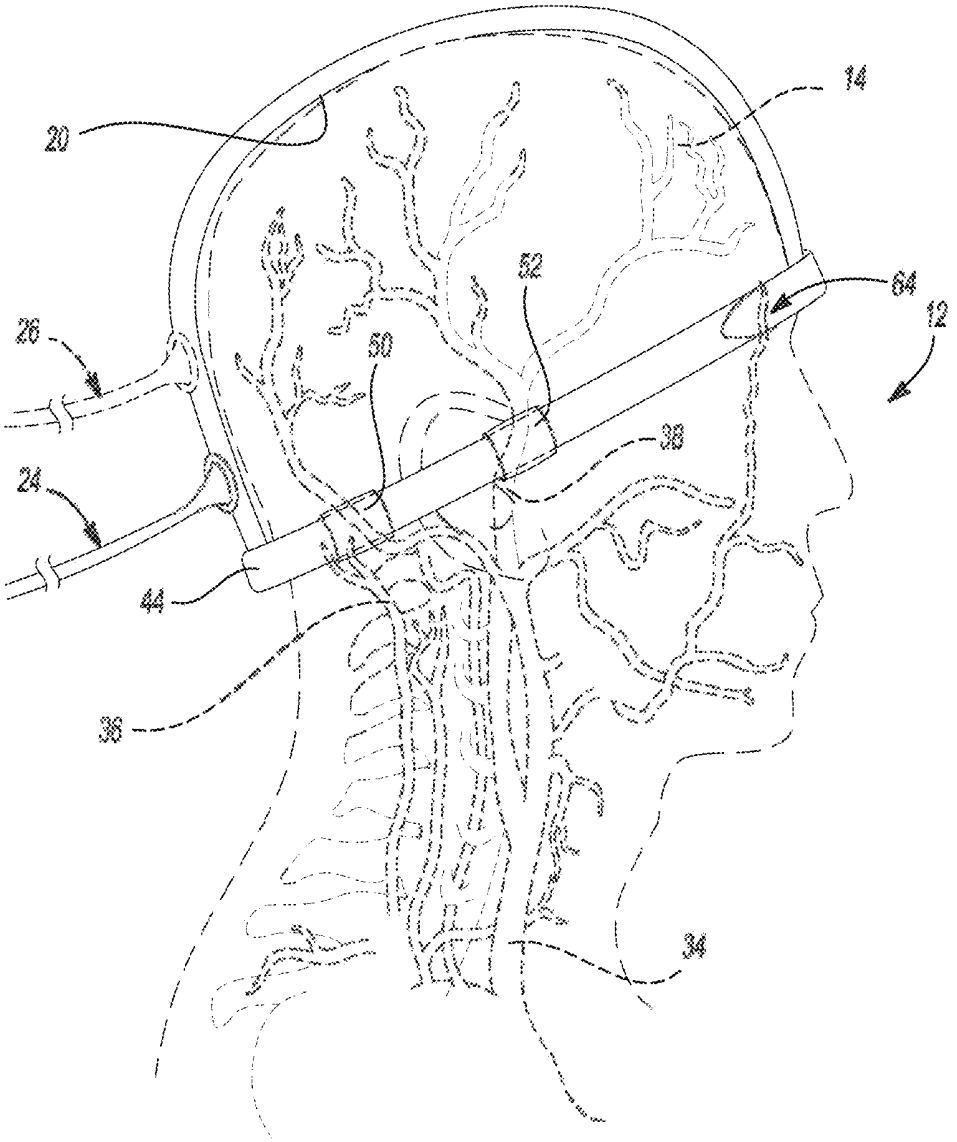



Fig-2

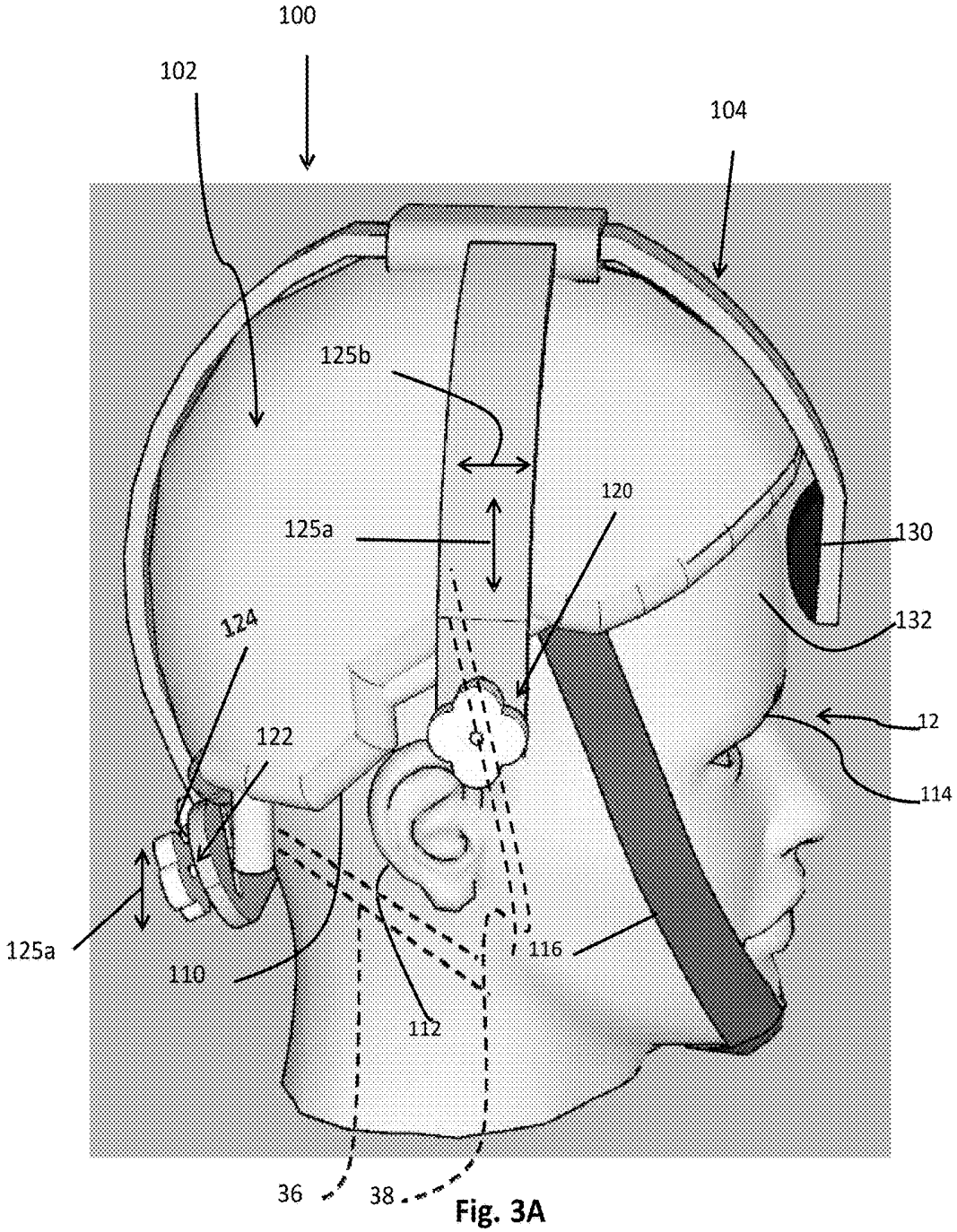

100
102
104
125b
125a
120
130
132
124
122
12
114
125a
110
116
112
36
38

Fig. 3A

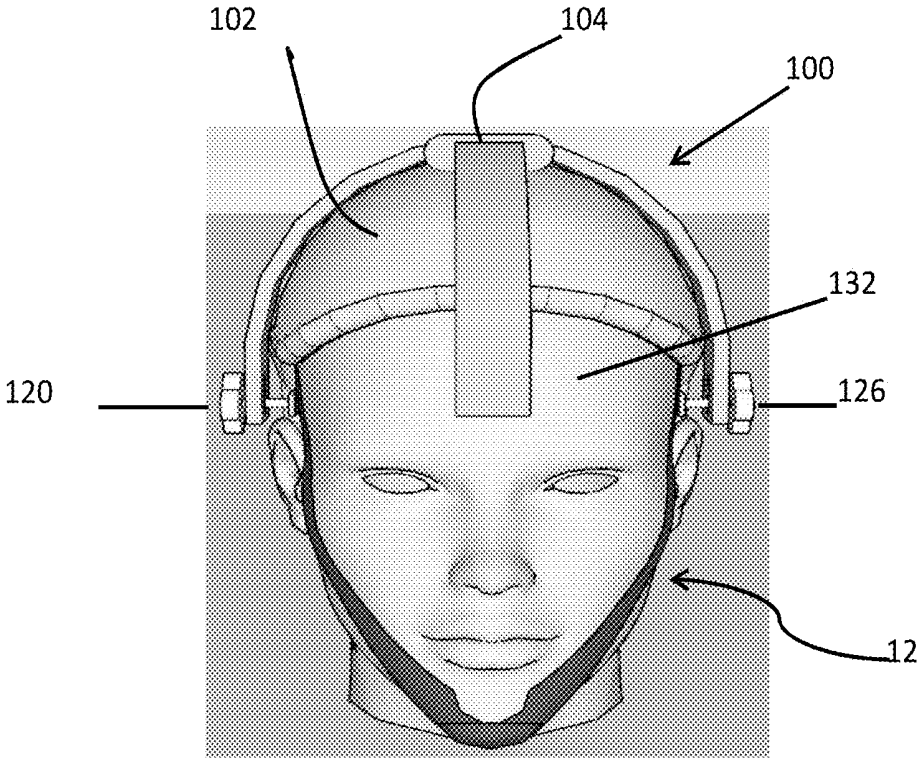



Fig. 3B

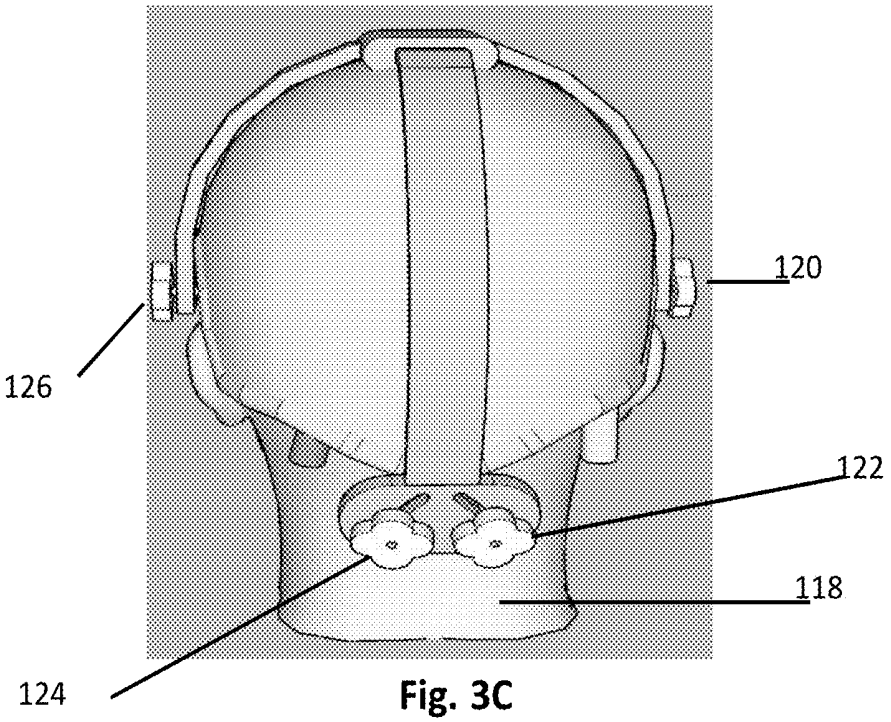



Fig. 3C

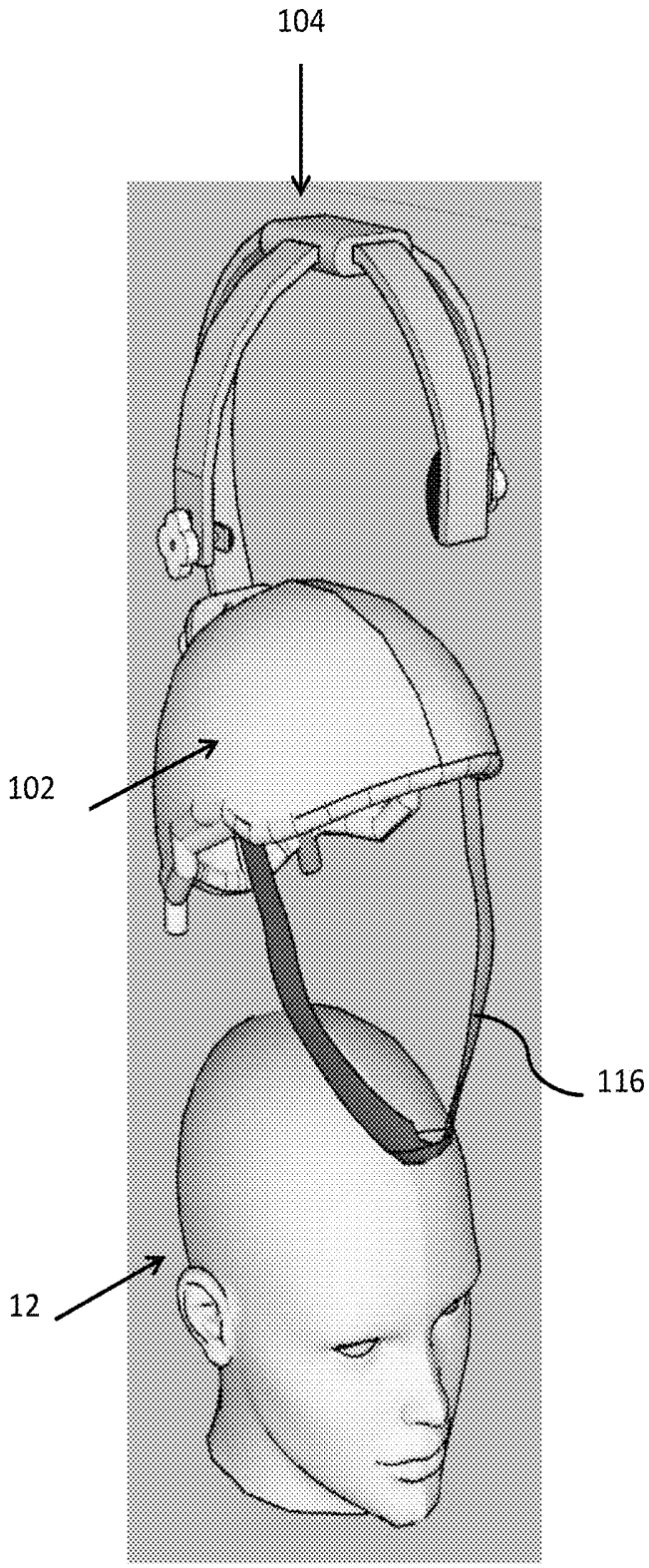



Fig. 4

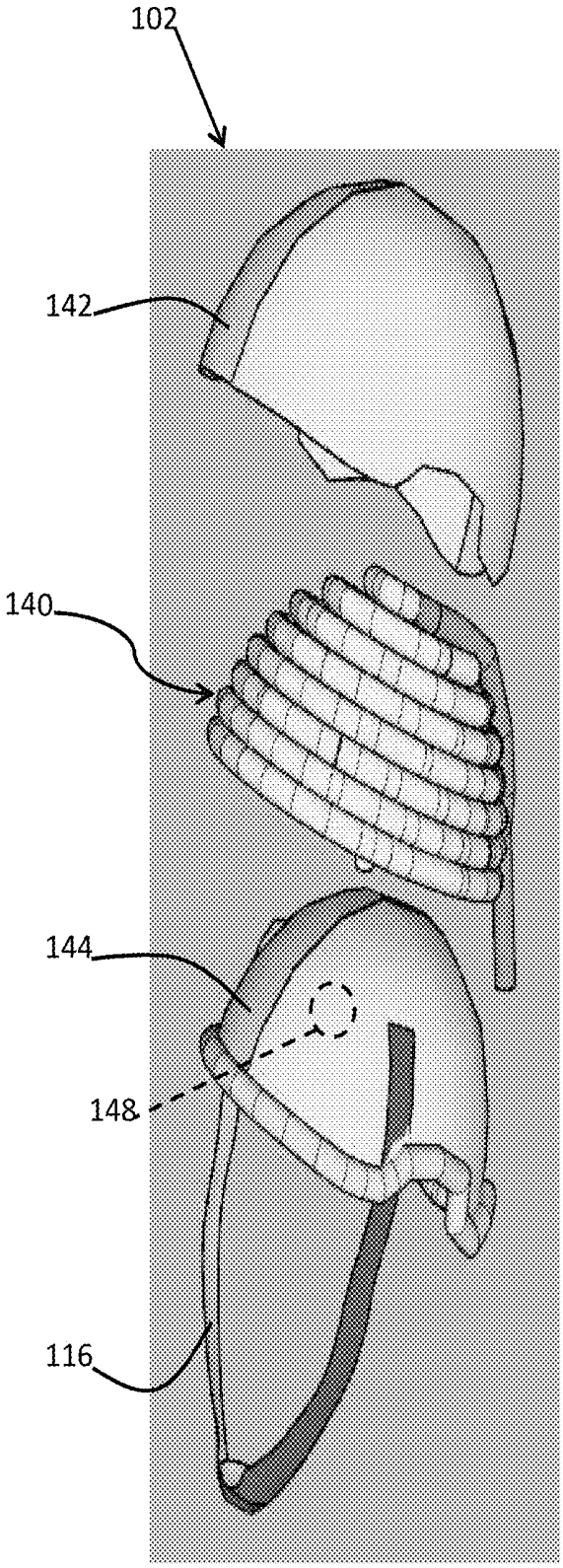



Fig. 5A

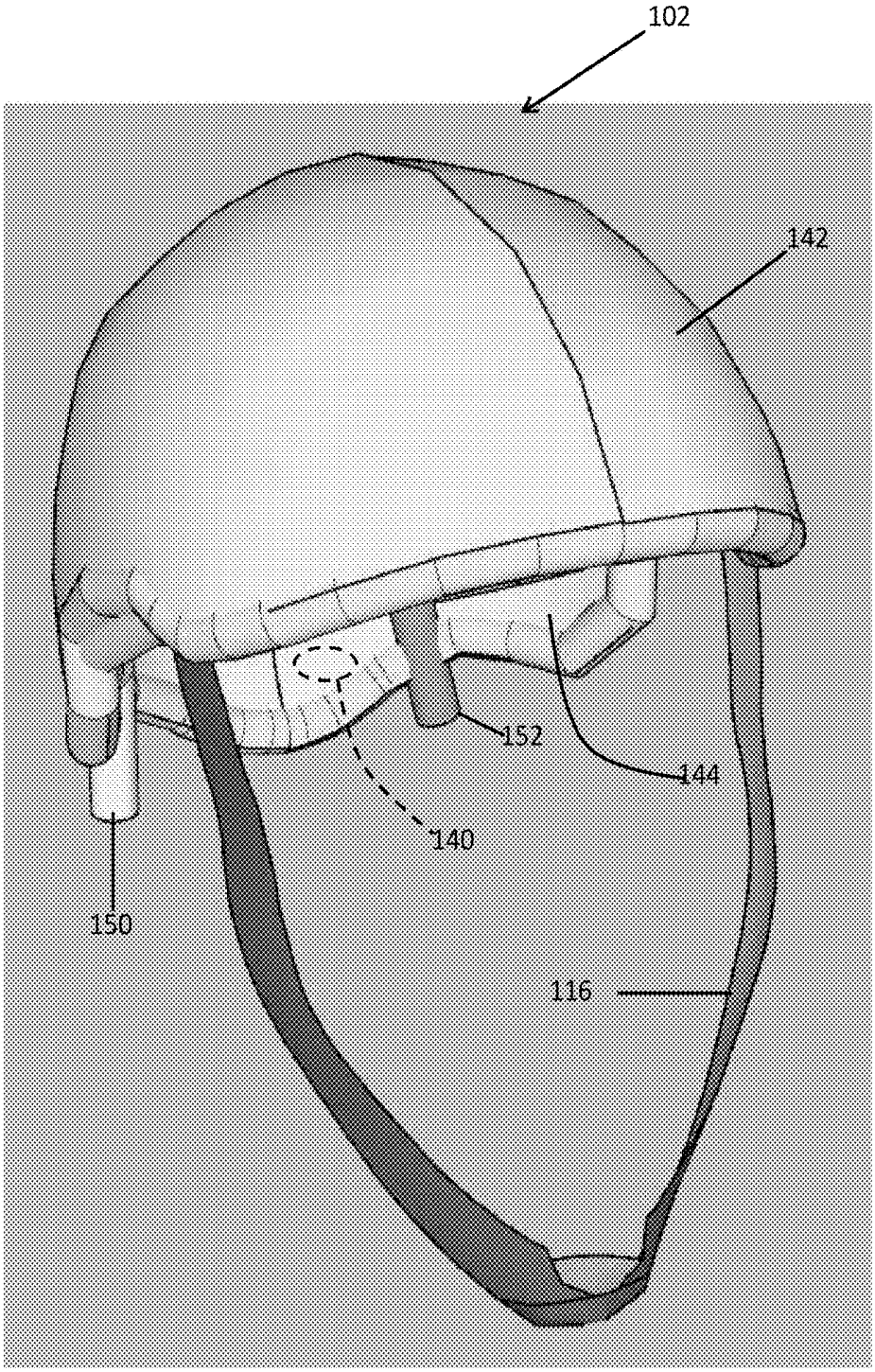



Fig. 5B

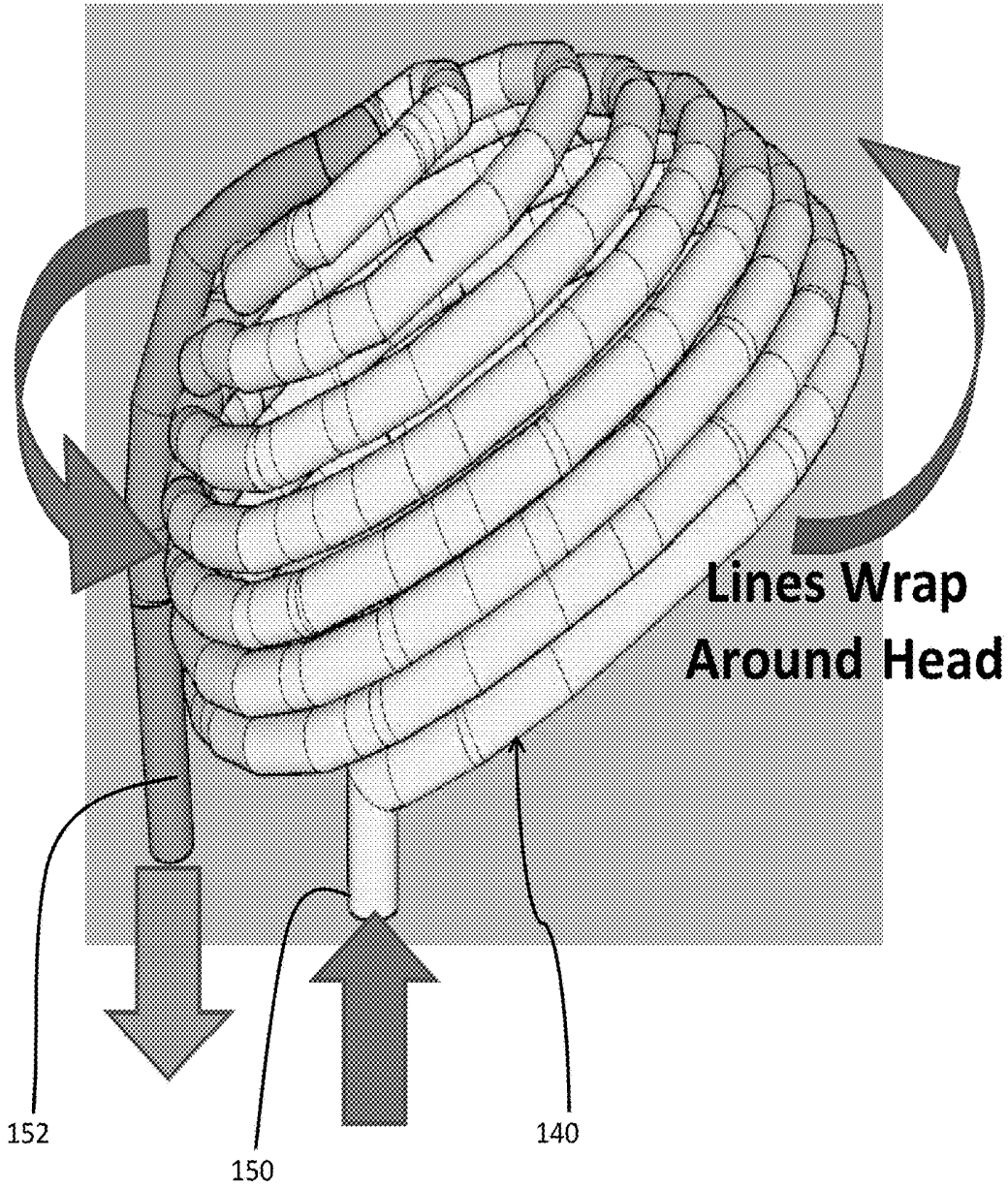
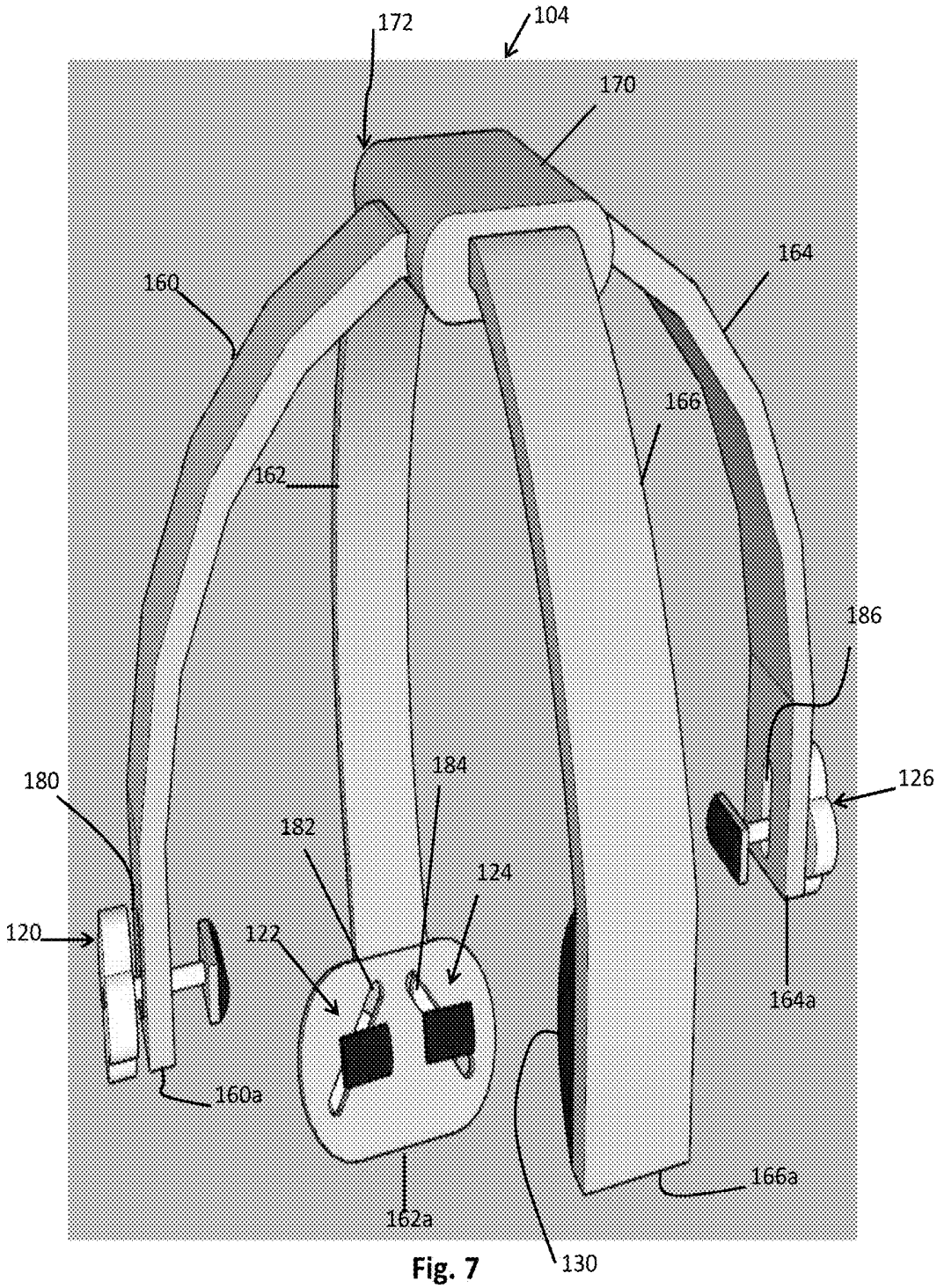



Fig. 6


172
104
170
164
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166
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186
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126
182
124
120
122
164a
160a
166a
162a
130

Fig. 7

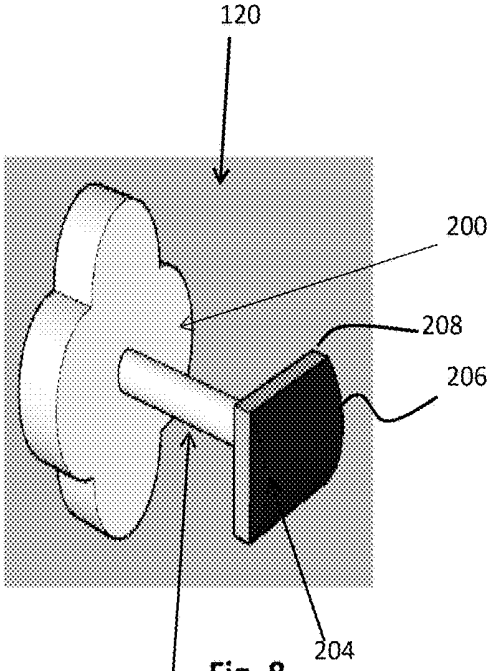



Fig. 8

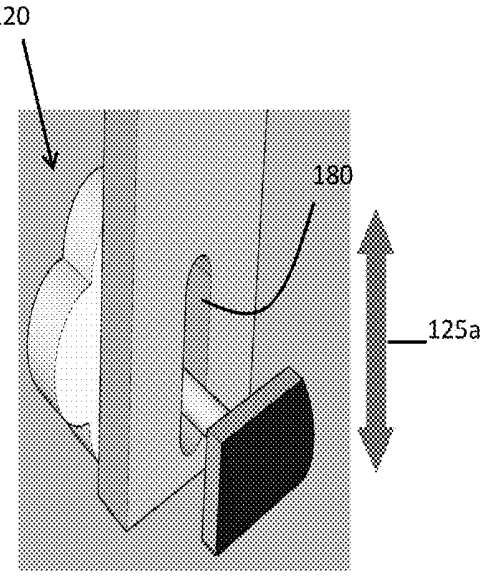



Fig. 9A

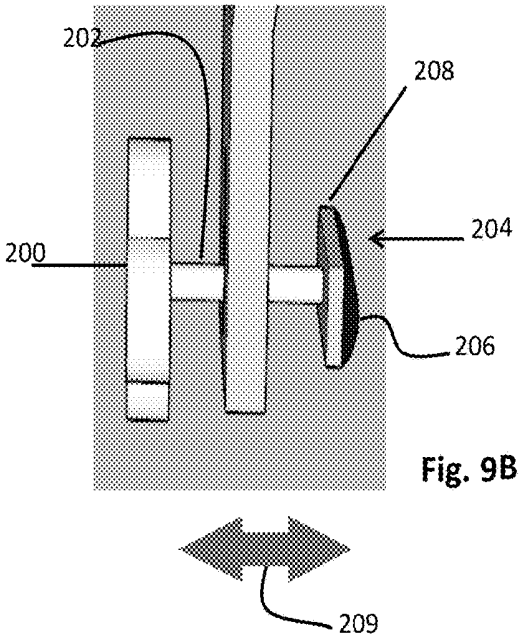



Fig. 9B

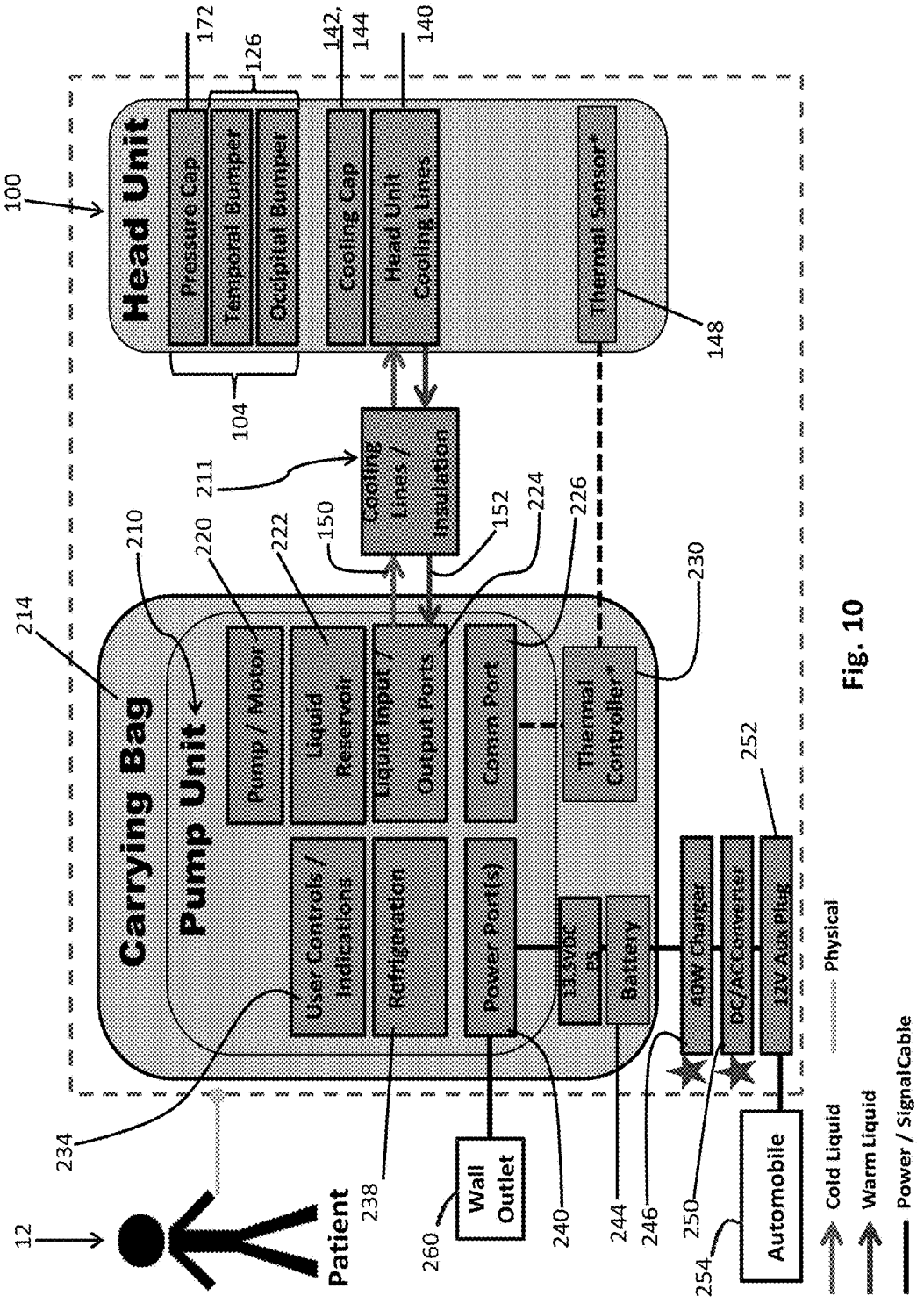
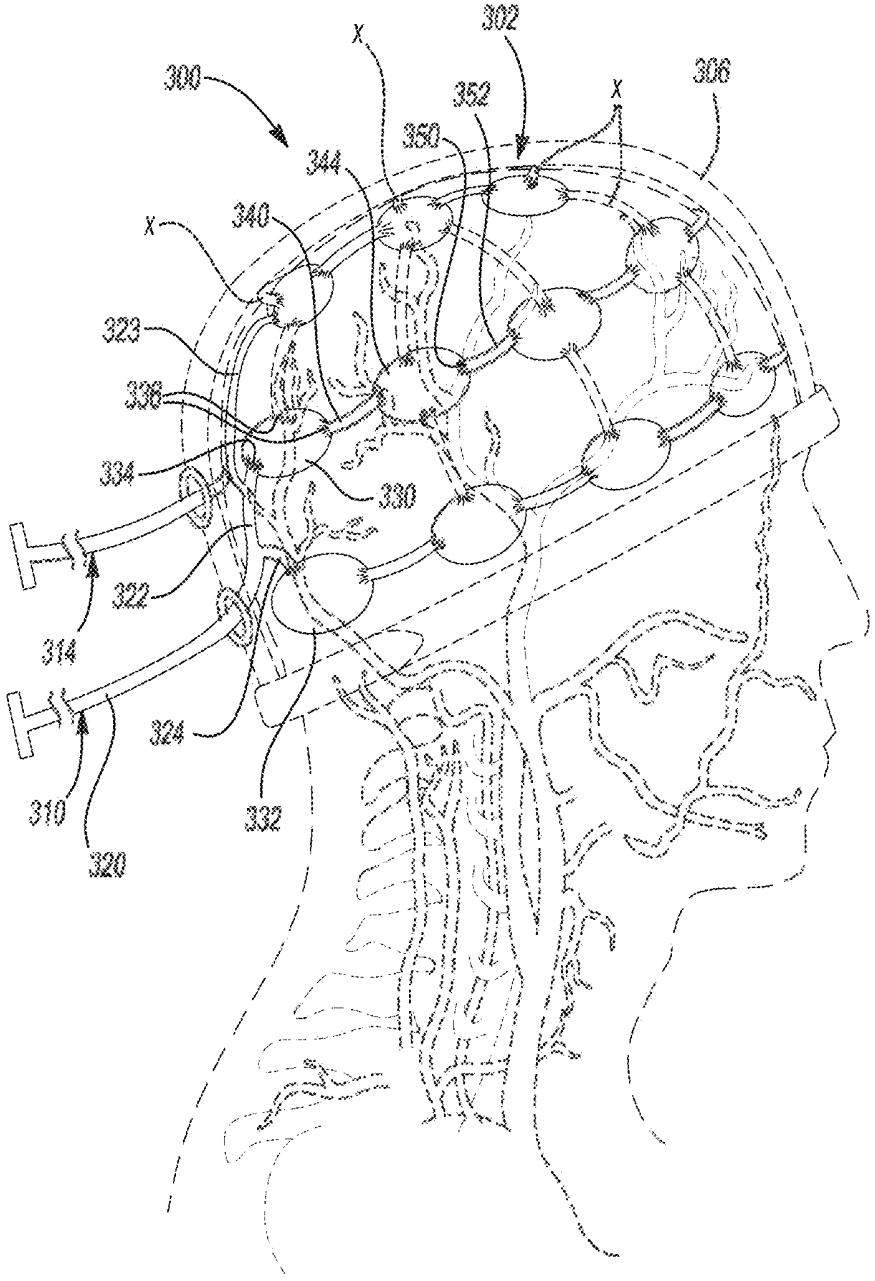

Head Unit
Pressure Cap
Temporal Bumper
Occipital Bumper
Cooling Cap
Head Unit Cooling Lines
Thermal Sensor*
Carrying Bag
Pump Unit
Pump / Motor
Liquid Reservoir
Liquid Input / Output Ports
Comm Port
Thermal Controller*
User Controls / Indications
Refrigeration
Power Port(s)
13.5VDC PS
Battery
40W Charger
DC/AC Converter
12V Aux Plug
Cooling Lines / Insulation
Patient
Wall Outlet
Automobile
100
104
126
140
142, 144
148
172
210
211
214
220
222
224
226
230
234
238
240
244
246
250
252
254
260
12
Physical
Cold Liquid
Warm Liquid
Power / SignalCable

Fig. 10


300
302
306
X
X
X
352
350
344
340
323
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334
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310
320
332

Fig-11

# SYSTEM AND METHOD TO CONTROL TEMPERATURE

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. Provisional Application No. 62/447,379, filed on Jan. 17, 2017. The entire disclosure of the above application is incorporated herein by reference.

## FIELD

**[0002]** The subject disclosure relates to hair loss prevention therapy, and particularly to a method and system of thermal regulation.

## BACKGROUND

**[0003]** This section provides background information related to the present disclosure which is not necessarily prior art.

**[0004]** In various procedures, such as treating selected diseases in a living subject, side effects may occur. Various individuals may desire to reduce certain side effects. In some individuals administering certain chemotherapy drugs as a treatment for cancers may cause hair growth to be limited or stopped. In some instances, certain devices, such as those disclosed in U.S. Pat. No. 9,101,463 and U.S. Pat. No. 9,421,125, may be placed on a patient's head to assist in regulating a temperature of a portion of the patient's head.

## SUMMARY

**[0005]** This section provides a general summary of the disclosure, and is not a comprehensive disclosure of its full scope or all of its features.

**[0006]** Disclosed is a system that is configured to cool and/or maintain a selected temperature of at least a surface of a scalp and/or to a selected depth of dermis.

**[0007]** In addition the system and method includes limiting blood flow to selected regions of the head, including the scalp, at least by restricting and reducing blood flow through selected arteries into the head. For example, restriction or pressure application members may engage or be applied to arteries at or near a patient's head. Pressure application members may be placed at substantially specific locations, adjusted to be at specific locations, or positioned at known and selected placements around a circumference of a patient's head. In various embodiments, the pressure application members may be positioned to apply pressure at or near both occipital arteries and temporal arteries on the patient's head to mechanically restrict or apply pressure to the arteries to restrict flow of blood into the head.

**[0008]** Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

## DRAWINGS

**[0009]** The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

**[0010]** FIG. **1** is a schematic illustration of a regulating device, according to various embodiments;

**[0011]** FIG. **2** is a schematic illustration of the device of FIG. **1** on a subject;

**[0012]** FIG. **3**A is a side view of a subject wearing a regulating device, according to various embodiments;

**[0013]** FIG. **3**B is an anterior view of a subject wearing the device of FIG. **3**A;

**[0014]** FIG. **3**C is a posterior view of a subject wearing the device of FIG. **3**A;

**[0015]** FIG. **4** is an exploded environmental view of the device of FIG. **3**A;

**[0016]** FIG. **5**A is an exploded view of the device of FIG. **3**A;

**[0017]** FIG. **5**B is a perspective assembled view of the device of FIG. **3**A;

**[0018]** FIG. **6** is a detailed view of a medium transfer tubing;

**[0019]** FIG. **7**A is a detailed perspective view of a compression device of FIG. **3**A;

**[0020]** FIG. **8** is a detailed view of a bumper member assembly, according to various embodiments;

**[0021]** FIG. **9**A is a detailed view of the compression device and bumper member assembly;

**[0022]** FIG. **9**B is a detailed view of a bumper of the compression device and bumper member assembly;

**[0023]** FIG. **10** is a schematic view of a regulating device and pump assembly; and

**[0024]** FIG. **11** is a cross-sectional view of a schematic of a regulating device, according to various embodiments.

**[0025]** Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

## DETAILED DESCRIPTION

**[0026]** Example embodiments will now be described more fully with reference to the accompanying drawings.

**[0027]** With reference to FIG. **1** and FIG. **2**, a regulating device **10** is illustrated. The device **10** may include various portions, as discussed further herein, but is generally shaped and configured to be positioned on a head or scalp of a subject **12**. The device **10** may be configured to appear as a cap for a human. For example, the device **10** may be positioned on a head or over a skull **14** of the patient **12**. Generally the device **10** includes a reservoir system **16** formed between an exterior wall **18** and an interior wall **20**. Generally the interior wall **20** may be formed to be positioned on the external skin or hair on the head of the patient **12**.

**[0028]** The reservoir system **16** may be formed as a single volume container having no internal walls or features. It understood, however, that the reservoir system **16** may include internal baffles or connective members. The reservoir system **16** may be formed of a compliant material or flexible material such as selected polymers. Generally, the reservoir system **16** includes or forms a volume **22** between the two walls **18**, **20**. The volume **22** may be filled with a selected material that may act or operate as a heat transfer medium, such as a fluid. The heat transfer medium may include water, appropriate low freezing temperature solutions of water (e.g. a mixture of water and about 20% to about 70% glycerol), or other appropriate materials or other appropriate selected solutions. Whether filled or not a surface **23** of the wall **20** is generally formed to remain substantially in contact with the scalp **14** of the patient **12**.

**[0029]** Selected ports may be made to the container **16**, such as an inlet **24** and an outlet **26**. The inlet **24** may include a connection or connector **28** and the outlet **26** may include a connection or connector **30**. The connectors **28**, **30** may connect to selected supply and return line, according to various embodiments, as discussed further herein. In various embodiments, only a single port, such as the port **24** may be provided. Thus, filling and emptying of the volume **22** may be performed through the single port.

**[0030]** For example, the single inlet line **24** may also be an outlet line where a user connects a supply to the connector **28** and fills the volume **22** with a selected material, such as the heat transfer medium discussed above. After a selected period of time, such as a selected set period of time or when the material in the volume **22** reaches a selected temperature, the line **24** may be used to empty the material from the volume **22** through the line **24**. The user may then again connect a volume of material to the connector **28** and refill the volume **22** with a selected material. Accordingly, it is understood, that the container **16** may include only a single port as an inlet and outlet line that may be sequentially or serially used for either inlet or outlet depending upon a selected state of the material within the volume **22**.

**[0031]** Schematically illustrated in FIG. **2** are arteries into the head **14** of the patient **12** that provide a blood supply to the head **14** of the patient **12**. Generally, a blood supply is provided to at least a portion of the scalp or skull **14** through a carotid artery **34**. The carotid artery **34** may branch into other arteries including an occipital artery **36** and a temporal artery **38**. It is understood that other arteries may branch from the carotid artery **34**, and they may also be engaged (e.g. compressed or restricted), as discussed herein, when selected.

**[0032]** The device **10** further includes a band or region **44**. The reservoir system **16** may be fixed to and/or separate from the band, such as at a perimeter of the reservoir system **16**. The band **44** may be formed of a selected material. The band may be formed of an elastic material and a selected size, thus will apply a selected and fixed amount of force to the head **14**. The band **44** may also, and/or alternatively, be substantially or completely inelastic that is adjustable in length. The adjustable band **44** may provide for selecting a force applied to the head **14**. It is understood, however, that the band **44** may be both elastic and adjustable. Regardless of the material the band **44** may be positioned and/or adjusted to apply a force, such as pressure, to the skin or dermis of the patient **12** relative to the skull **14**.

**[0033]** The band **44** may include an elastic material and/or an adjustment member or assembly **64** (e.g. an adjustable buckle or strap) to adjust pressure or size of the band **44** relative to the patient **12**. The adjustment of the band **44** allows the force applied, such as the pressure, of the band **44** and, therefore, the bumpers **50**, **52** to be adjusted. In various embodiments, therefore, the pressure applied may be adjusted for patient comfort and/or selecting an amount of restriction of blood flow through the selected vessels. Generally the band **44**, therefore, may apply pressure around the skull of the patient **12**. In addition to the band **44** alone, one or more members, which may also be referred to as vascular pods, bumpers or pressure application members may be provided. The bumpers may include an occipital bumper **50** and a temporal bumper **52** that may be positioned relative to or on the band **44**. The bumpers may be formed into or surround the band **44**. Further, occipital bumpers **50** and temporal bumpers **52** may be provided on both a left and right side of the head **14**. The bumpers **50**, **52** may be an appropriate selected length, such as about 1 centimeters (cm) to about 8 cm, including about 4 cm to about 6 cm, and further about 5 cm (about 2 inches). The bumpers **50**, **52** may be fixed or moveable relative to the band **44**.

**[0034]** In various embodiments the bumpers **50**, **52** may be formed as cylindrical members that are positioned on the band **44** and held in place relative to the skull **14**. Further the bumpers **50**, **52** may be substantially ridged members that are positioned between the band **44** and the skull of the patient **14** generally in the region of the selected arteries, such as the occipital artery **36** and the temporal artery **38**. Nevertheless, by tightening or applying force with the band **44** to the patient **12**, the regions where the bumpers **50**, **52** are present will experience an increased pressure point.

**[0035]** Accordingly, an increased pressure or pressure points may be applied generally at or on top of the selected arteries, such as the occipital artery **36** and/or the temporal artery **38**. In various embodiments, the bumpers **50**, **52** may be sized, shaped, and positioned to apply pressure selectively to specific regions, such as vessels. Thus, the bumpers **50**, **52** may be placed to apply pressure substantially only to the occipital artery **36** and/or the temporal artery **38**. In this way, blood flow may be restricted through substantially only or entirely only the occipital artery **36** and/or the temporal artery **38**.

**[0036]** By applying pressure to the arteries **36**, **38**, while not being bound by the theory, a reduction in blood flow through the arteries **36**, **38** will occur due to mechanical pressure and restriction of size of the selected arteries **36**, **38**. By increasing the pressure and/or decreasing a circumference of the band **44**, a force may be increased on the selected arteries **36**, **38**. In so doing blood flow may be limited to the skull **14** of the patient **12**, at least for a selected period of time.

**[0037]** With continuing reference to FIGS. **1** and **2**, the device **10** is configured to be positioned on the patient **12** and to allow for a material, such as the selected liquid, to be intermittently positioned or used to fill the volume **22** and removed from the volume **22**. The introduction and removal of the material from the volume **22** may be based on a selected interval of time (e.g. 30 minutes), a selected measured temperature on the interior wall **20** of the cap **10** (e.g. about 2 degrees Celsius (C) to about 8 degrees C., including about 3 degrees C. (about 38 degrees Fahrenheit (F)) to about 7 degrees C. (about 45 degrees F.)), or other appropriate selected interval.

**[0038]** In various embodiments a thermal sensor **60** is positioned on the internal wall **20**. The thermal sensor **60** may be any appropriate thermal sensor, such as a thermistor, or other selected thermal sensor. The thermal sensor **60** is configured to sense a temperature at the inner wall **20** of the device **10**. The thermal sensor **60**, therefore, may be used by a user to determine the temperature at the internal wall **20**.

**[0039]** The thermal sensor **60** may send a signal to a control or display unit in a selected manner, such as wirelessly, wired, or other appropriate configuration. Wireless transmissions may include data transmission according to the Bluetooth® wireless data transmission protocols. The transmissions may be received by a receiver and used to display or evaluate the temperature at the inner wall **20**. The user may then determine whether or not to refill the volume **22** based upon various protocols such as a selected range or

threshold temperature of the inner wall **20**, the remaining time of treatment, or other appropriate considerations.

**[0040]** The band **44**, as discussed above, may include appropriate configurations to assist in providing a pressure or fit to the patient **12**. In various embodiments a pull tab or other member may be used to cinch the band **44** onto the patient **12**. In addition, other tightening or connection mechanisms **54** may be used to tighten the band **44** onto the patient **12**. For example, the connection or tensioning mechanism **64** may include a ratcheting system that allows the band **44** to be ratcheted to a selected tightness or pressure on the patient **12** and/or released from the patient **12**.

**[0041]** Turning reference to FIGS. **3**A-**9**B a device **100** to regulate the head **14** of the patient **12** is illustrated. Certain features or portions of the device **100** are similar to those of the device **10**. The device **100** includes various features and elements that are identical to or substantially similar to those of the device **10**, and will not be repeated here. Various elements or features of the device **100**, however, are in addition to or different than those illustrated and referenced with reference to the device **10**. It is understood, however, that various features of the device **100** may be used in combination with the features and elements of the device **10**, and vice versa.

**[0042]** The device **100** may include a thermal transfer system or assembly **102** and a pressure or bumper unit or assembly **104**. The device **100**, therefore, may include two separate portions, as discussed further herein, rather than having the thermal transfer portion **102** integrated as a single member with the pressure or bumper assembly **104**. It is understood, therefore, similarly that the device cap **10** may also have the band **44** and the associated pressure application members separate from the cap **10** defining the volume **22**. Nevertheless, they may also be integrated as a single unit. Accordingly the thermal transfer assembly **102** separate from the pressure application assembly **104** in the cap **100**, is merely exemplary.

**[0043]** The thermal transfer unit **102** is positioned on the patient **12**, as exemplarily illustrated in FIGS. **3**A-**3**C, so as to cover at least a portion of the scalp or head **14**, similar to the device **10**. The thermal transfer unit **102** may include a proximal edge **110** that has a selected shape or contour to fit over various portions of the anatomy of the subject **12**, such as an ear **112**, eyebrows **114**, or other anatomical features of the patient **12**. Further, a retention strap or member **116** may be attached to a portion of the thermal transfer unit **102** to hold the thermal transfer unit **102** onto the patient **12** for a selected period of time. The retention strap **116** may be a soft elastic material to provide a gentle tension or snug fit of the thermal transfer unit **102** onto the patient **12**.

**[0044]** The thermal transfer unit **102** may be shaped and configured to extend over a selected portion of the patient **12**, such as a distance over the forehead or anterior portion of the head **14** and extending generally to near a base of the skull near or at the occipital bone and/or near the neck **118**.

**[0045]** Generally the thermal transfer unit **102** may include various thermal transfer elements, as discussed further herein, to assist or provide a means of reducing or transferring heat or thermal energy from a surface or portion of the patient **12** away therefrom, such as with a flow of a heat transfer medium (e.g. heat transfer fluid), as discussed further herein.

**[0046]** As illustrated in FIG. **4**, the thermal transfer unit **102** is configured to be positioned on the patient **12** and may be positioned on the patient **12** separate from the pressure application unit **104**. Generally, the thermal transfer unit **102** may be positioned on the patient **12** and at least temporarily secured in place with the tension strap **116**. The bumper unit **104** may then be positioned onto the patient **12**, such as over the thermal transfer unit **102**, as illustrated in FIGS. **3**A-**3**C. The device **100**, therefore, may be positioned on the patient **12** in a stepwise manner to assist in ensuring a selected position of the thermal transfer unit **102** on the patient **12** and of the bumper unit **104** separate therefrom. As discussed herein, positioning of the bumper unit **104** separate from the thermal transfer unit **102** may allow for a difference between selected patients and an optimization of positioning the bumper unit relative to the patient **12**, such as relative to the selected arteries as discussed above and herein.

**[0047]** Returning reference to FIGS. **3**A-**3**C, the bumper unit **104** may include various individual units or pods, which may also be referred to as vascular or arterial pods or bumpers, such as a first temporal artery bumper unit **120**, a first occipital artery bumper unit **122**, a second occipital artery bumper unit **124**, and a second temporal artery bumper unit **126**. Each of the artery bumper units **120**-**126** may be selectively moved to apply pressure to the selected temporal and occipital arteries **38**, **36** of the patient **12**. An increased pressure or pressure points may be applied generally at or on top of the selected vessels, such as the occipital artery **36** and/or the temporal artery **38** with the bumper unit **104** including the bumper units **120**-**124**. Further, the bumpers may be adjusted in the directions of arrows **125***a*, **125***b* (as illustrated in FIG. **3**A) to align the respective bumpers over the appropriate occipital artery **36** and/or the temporal artery **38**. In various embodiments, the bumper units **120**-**124** may be sized, shaped, and positioned to apply pressure selectively to specific regions, such as vessels. Thus, the bumper units **120**-**124** may be placed to apply pressure substantially only to the occipital artery **36** and/or the temporal artery **38**. In this way, blood flow may be restricted through substantially only or entirely only the occipital artery **36** and/or the temporal artery **38**.

**[0048]** A positioning or counterbalance bumper or member **130** may also be formed with the pressure unit **104** to contact a portion of the patient **12**, such as a forehead **132** of the patient **12**. The counterbalance unit **130** may assist in holding the bumper unit **104** relative to the patient **12** during the application of the pressure to the selected arteries, such as the temporal artery **38** and the occipital arteries **36**. Generally, the bumper unit **104**, therefore, may apply pressure to the selected arteries to assist in constricting or applying a mechanical pressure to the arteries similar to the band **44** and respective bumpers **50**, **52** as discussed in relation to the cap **10**.

**[0049]** With continuing reference to FIGS. **3**A-**4** and additional reference to FIGS. **5** and **6**, the cooling or thermal transfer unit **102** is discussed in greater detail. The thermal transfer unit **102** may include a fluid transfer line or circulation line **140**. The line **140** may include a tubing of selected materials and wall thickness. In various embodiments, it is understood that the fluid transfer line **140** may be substantially the only element of the thermal transfer unit **102**. For example, the thermal transfer line **140** may be placed directly on the patient **12** and the pressure or bumper unit **104** may be positioned over the fluid transfer lines **140**. For various reasons, such as ease of use and/or cleaning, the thermal transfer unit **102** may include a cover **142** and a head

or contact layer or wall **144**. The tension strap **116** may be connected to the inner or second wall **144**.

**[0050]** Further, as discussed above, a thermal sensor **148** may be positioned on the inner or second wall **144**. Again the thermal sensor **148** being near the patient **12** may assist in determining a temperature at a surface of the patient's skin or other appropriate region. It is understood, however, that the thermal sensor **148** may also be positioned on the fluid transfer lines **140**. In various embodiments the thermal transfer lines **140** may be positioned between the first all **142** and the second wall **144**, such as in a manufacturing phase, and the two walls **142**, **144** may be connected together. For example, the two walls **142**, **144** may be formed with a selected flexible material or textile and may be at least partially stitched together to hold the two walls **142**, **144** together.

**[0051]** The thermal transfer line **140** may include a length of tubing that is formed as a single piece and/or connected pieces. Regardless the thermal transfer tubing **140** may include a single inlet **150** and a single outlet **152** that are fluidly connected by the line **140**. The heat transfer medium, such as a heat transfer fluid, may then be delivered through the thermal transfer tubing **140** by delivering it and passing it through the inlet **150** and allowing it to exit through the outlet **152**. As the fluid circulates through the tubing **140** heat may be transferred from the patient **12** to the fluid and then the heated fluid may be passed out of the tubing **140** through the outlet **152**. It is understood that the fluid may be any appropriate fluid such as those discussed above. The heat transfer fluid may include liquid fluids, gaseous fluids, or materials that change states within the tubing to assist in efficient or rapid cooling, such as a liquid that turns to a gas within the tubing **140**. Regardless the fluid may transfer through the tubing **140** from the outlet **152**.

**[0052]** Turning reference to FIGS. **7**, **8**, and **9**A-**9**B, and with continuing reference to FIGS. **3**A-**3**C, the bumper or pressure unit **104** will be described in greater detail. The bumper unit **104**, as illustrated in FIG. **7**, may include various arms or limbs **160**, **162**, **164**, and **166** that extend from a central hub or connection region **170**. It is understood that the limbs **160-166** and the connection area **170** may be formed as a single member, such as by injection molding or other molding process to form a biasing or holding structure **172** substantially defined by the four limbs **160-166** and the central hub or connection **170**. It is further understood that having individual limbs is not a requirement, and rather that the holding or biasing unit **172** may be formed as a dome, such as semispherical or hemispherical to fit the head **14** of the patient **12**. In various embodiments, however, the individual limbs **160-166** may allow for greater adjustability of the biasing member **172**.

**[0053]** The arms **160-166** may extend from the central hub or connection **170** in generally an arced or curved manner or shape to respective terminal ends **160***a*-**166***a*. The arms **160-166** may be adjustable in length relative to the central hub **170**, such as by sliding relative to the hub **170**. Alternatively, or in addition thereto, the unit **172** may be formed in different sizes such as the length to the arms **160-166** from the hub **170** may be selected in different sizes.

**[0054]** Nevertheless, near each of the ends **160***a*, **162***a*, and **164***a* are one or more of the adjustable bumpers or artery bumper units **120-126**, as discussed above. Each of the artery bumper units **120-126** are positioned relative to a through-bore such as a first through-bore **180**, a second through-bore **182**, a third through-bore **184**, and a fourth through-bore **186**. The through-bores **180-186** may be formed in any appropriate configuration, such as substantially elongated slots. For example, slots may be elongated generally along a longitudinal axis of the patient **12**. Therefore the artery bumper units **120-126** may move along a long axis of the through-bore, generally along the double headed arrow **125***a* as illustrated in FIG. **9**A. As an example only, the compression unit **120** is illustrated in FIGS. **8-9**B and passes through the through-bore **180**. It is understood that the through-bores may be positioned at an angle relative to the longitudinal axis of the patient **12**, such as an angel thereto for example for the through-bores **182** and **184**.

**[0055]** Each of the artery bumper units **120-126** may include substantially identical features, including those illustrated in FIGS. **8-9**B. Accordingly, the discussion of the first bumper unit **120** and the features thereof may be included in the other bumpers **122-126** but will not be repeated.

**[0056]** According to various embodiments, the artery bumper unit **120** may include a handle or manipulation member **200**. A shaft **202** may extend from the handle **200** and engage a bumper assembly **204**. The bumper assembly **204** may include a bumper member **206** that is connected to a holding or fixed portion **208**. It is understood that the bumper portion **204** may be formed as a single member and having two members is merely exemplary. Nevertheless, the handle **200** may be threaded, such as having an internal thread to engage an external thread of the shaft **202**. By turning the handle **200** relative to the shaft **202** the handle **200** may move axially along the shaft generally in the direction of arrow **209**. By moving the handle **200** along the shaft **202**, the bumper assembly **204** may also move generally in the direction of arrow **209** to allow adjustment and movement of the bumper assembly **204** for selected purposes, as discussed herein. Therefore, the bumper unit **204** may move closer to the patient to increase a force (e.g. pressure) on the patient **12**, such as on the temple artery **38**. Twisting the handle **200** in an opposite direction may move the shaft or handle in an opposite direction of the arrow **209** and decrease the pressure on the artery, such as the temple artery **38**. The shaft **202** may be fixed to the bumper assembly **204**, such as the second member **208**. The adjustment of the bumper units, such as unit **120**, in the direction of arrow **209** may, therefore, be used to apply and/or adjust the application of force applied to the patient **12**, such as the vessels. In various embodiments, therefore, the pressure applied may be adjusted for various purposes, such as patient comfort and/or selecting an amount of restriction of blood flow through the selected vessels, including the occipital and/or temporal arteries **36**, **38**. It is further understood, the patient **12** and/or a user may adjust the bumper units. Further, each of the bumper units may be adjusted separately to allow for a selected force applied by each bumper. Although, it is understood, that all of the bumpers may be adjust in a single manner.

**[0057]** In various embodiments the handle **200**, shaft **202**, and holding portion **208** of the bumper assembly may be formed of a substantially ridged material, such as a selected metal or rigid polymer. This may provide rigidity and stiffness to allow for pressure to be applied to the subject **12**. The bumper portion **206** may be formed of a selected material that may be softer than the shaft **202** and/or the handle **200** to apply a gentle and selected pressure to the patient **12**. For example, the bumper member **206** may be

formed of rubber, gel, sponge, or an encapsulated air volume or air chamber. For example, a soft rubber or gel may be provided to form the bumper member **206**. Alternatively, or in addition thereto, an air-chamber may be provided as the bumper member **206**. The bumper member **206** may have a selected plasticity or bending modulus that provides force to the selected region, such as the vessel, to reduce a blood flow there through (such as about reduction of about 10% to about 80%, including about 40% to about 60%) without causing trauma to the surrounding soft tissue or death or damage to the vessel.

**[0058]** With reference to FIG. **10**, the device **100** may be connected to a powered delivery system or assembly usable by the patient **12**. As schematically illustrated in FIG. **10**, the device **100** may include the pressure or bumper assembly **104** including the arm and hub unit **172** and the respected bumpers **120-126**. The device **100** may further include the shell portions **142**, **144** and the flow or transfer lines **140**. The inlet **150** and the outlet **152** may extend from the device **100** along supply lines or tubing **2111**. The supply lines **211** may be insulated with selected insulation. The lines **2111** may connect to a pump assembly or unit **210** that may be in a selected location or may be substantially portable in a carry or portable bag **214**.

**[0059]** The pump unit **210** may include various portions such as a pump motor **220** that can pump the heat transfer medium, such as a fluid from a liquid or fluid reservoir **222**. Inlets and outlets may be associated with the reservoir **222** such as inlets and outlets **224**. The inlets and outlets **224**, through the lines **211**, may be connected to respective inlet **150** and outlet **152** of the device **100**, or other appropriate connections of the device **10**.

**[0060]** The pump unit **210** may have various communication ports, such as a communication port **226** to communicate with a control or a sensor, such as a thermal controller **230** that may be connected with the selected or optional thermal sensor **148**. The pump unit **210** may be operated based upon instructions regarding a temperature threshold which may be measured by the thermal sensor **148** and communicated or monitored by the thermal controller **230** through the communication (comm) unit **226** to a control unit **234**. The control unit **234** may be any appropriate selected controller such as an application specific integrated circuit, a general purpose programmable processor, or other appropriate controller. The control unit **234** may also have an external control or user information system. For example, a separate control or information display may receive a signal from the control unit **234** regarding operation and/or transmit a signal to the control unit **234** regarding operational parameters (e.g. temperature range, flow rate, etc.). The communication with the control unit **234** may be from a selected system (e.g. hand held device) and using appropriate and selected communication protocols (e.g. Bluetooth® wireless communication protocols).

**[0061]** The pump unit **210** may include an optional refrigeration assembly **238** to allow regenerative cooling of the fluid in the reservoir when transmitted to the pump unit **210** from the device **100**. Refrigeration or regeneration of the cooling or thermal transfer medium, however, may be done outside of the pump unit **210**. Further, a constant supply of medium at a selected temperature may be provided from a source separate from the pump unit **210**.

**[0062]** Power may be provided to the pump unit **200** through various power inlets **240** such as through a battery **244** that may be charged with selected chargers, including a 40 watt charger **246** connected to various converters such as a DC-AC convertor **250** that may convert direct current power through a selected plug, such as a 12 volt auxiliary power supply **252** in an automobile **254**. Selected other power may also be direct from a selected AC converter, such as an all outlet/converter **260**. Regardless the pump unit **210** may be powered at a selected rate to power the pump to pump the fluid through the lines to the inlet **150** to the device **100** and from the device **100** through the outlet line **152** to allow regenerative cooling of the fluid within or for transfer to the device **100**.

**[0063]** The pump unit **210** may be moved by the patient **12** and/or other user. In various embodiments, the pump unit **210** may be provided with the carry bag **214** to ease and efficient transport. It is understood, however, that the pump unit may be provided with any appropriate transfer system.

**[0064]** With reference to FIG. **11**, a device assembly **300** is illustrated. The device assembly **300** includes a transfer or circulation assembly **302**. The transfer assembly **302** may be used to circulate or transfer the heat transfer medium, as discussed above.

**[0065]** The transfer assembly **302** may be placed directly on the head **14** or on a first layer, similar to the layer **144** discussed above. Similarly a cover or optional over layer **306** may be positioned over the fluid circulation assembly **302**. The cover **306** may include an elastic or lightly compressive construction to assist in holding the fluid circulation assembly **302** in place on the head **14**. Although not illustrated in FIG. **11**, the compression or pressure assembly **104** may also be positioned over the fluid transfer circulation assembly **302** to assist in mechanically compressing or constricting arteries in the patient **12**, similar to as illustrated in FIGS. **3A-3C**.

**[0066]** The fluid flow assembly **302** may include an inlet **310** and an outlet **314**. The inlet and outlet may be a single port, such as only the inlet **310** or outlet **314** that are connected in a continuous web or connection of lakes or bags, which may also be referred to as anastomosis. Generally, the fluid flow assembly may include a first or main line **320** extending from the inlet **310**. The main or first line **320** may branch into at least two or more lines (e.g. secondary lines) **322** and **324**. Each of the branch lines **322**, **324** may enter an anastomosis bag or region, respectively, **330** and **332**.

**[0067]** The branch lines further branch into smaller branch lines or constructions (e.g. tertiary or capillary lines) **334** as it enters or within the bag **330**. The tertiary branches **334** may be formed to have a selected small internal diameter, as discussed herein. At a second end or side of the bag **330** may be a second grouping of capillaries lines **336**. These may then combine into a secondary branch or connection **340**. Again the secondary branch **340** may connect or extend to an additional bag **344**. At a second side of the bag **344** may be a further assembly or construction of capillary lines **350** that are fluidly connected to a subsequent secondary line **352**.

**[0068]** As illustrated in FIG. **11**, it is understood that a plurality of the anastomosis bags may be positioned in a fluidly connected network or spaced apart configuration. Each of the secondary lines may lead to one of the bags **330** and in the bag formed as a plurality of small tubes or capillaries having a selected diameter. Generally the diameter of the small tubes, such as the capillaries **334** may be

substantially less, such as about 10% to about 0.01% a diameter of the secondary or tertiary lines, such as the secondary line **322**. The network that is fluidly connected may be seized to cover a selected portion of the head **14**, as exemplary illustrated in FIG. **11**.

**[0069]** The pressure of a fluid entering any of the bags, such as the bag **330**, on one side may or will cause fluid to flow through the bag **330** to the capillaries **336** on the second side and throughout the network to the outlet **314**. The transfer assembly **302**, therefore, will allow a transfer of a fluid throughout the assembly **302**. In various embodiments, the device **300** may be provided where each of the bags **330** have only two connections or ports (such as an inlet and an outlet) and only one connection to any one other of the bags **330**. In this configuration, referred as "in series", the bags **330** are more able to have a consistent and equal or even flow regardless of the position on the patient **12**. It is understood, however, that more than two connections from each of the bags **330** may be provided (illustrated in phantom lines (exemplarily "x") in FIG. **11**). With multiple connections a lattice or parallel configuration is achieved. Regardless, it may be selected to have the single include **310** and single outlet **314**.

**[0070]** The bags, such as the bag **330**, may be positioned at selected locations or positions on the patient **12** to assist in having a high flow rate and/or high volume at a specific and selected locations. The high flow rate may increase a cooling effect or thermal conduction in the specific selected location. In this way the device **300** could be provided to provide a selected, such as high, cooling effect at specific locations on the head of the patient **12**. In this way the user could selectively position areas that would be cooled greater than other areas on the patient **12**.

**[0071]** It is further understood that the various transfer lines may be molded as shapes or as passages and bags (e.g. volumes) in a solid structure. For example, rather than the cover **306** being separate from the cooling or fluid flow assembly **302**, the lines (e.g. the secondary lines **322** the capillaries **334**) and the bag **330** could be molded into a solid or unitary member with the inlet **310** and the outlet **314** extending therefrom. Therefore although the fluid flow assembly **302** is illustrated as a connection of the bags **330** and selected tube sizes in diameters, it is understood that they may be formed as a channels and voids in a single member.

**[0072]** Further the fluid flow assembly **302** may be connected to the pump unit **210**, as discussed above in FIG. **10**. The pump unit **210** including the inlet and outlet connections **224** may be connected to the inlet and outlet **310**, **314**, respectively, of the fluid transfer unit **302**. Therefore the fluid transfer unit **302** may also be connected to the pump unit **210** and operated as discussed above.

**[0073]** According to various embodiments, therefore, as discussed above, a device may be provided to regulate a portion of a subject. The regulation may include cooling and/or limiting blood flow to a portion of the subject. The regulation may allow for selected results or reduction in side effects, such as reduction in hair loss or elimination of hair loss, of the subject. Moreover, as discussed above, the bumpers, according to various embodiments, may be provided to apply a force (e.g. pressure) to only or substantially only selected arteries, occipital and/or temporal arteries. In various embodiments, therefore, the pressure applied may be adjusted for various purposes, such as patient comfort and/or selecting an amount of restriction of blood flow through the selected vessels, including the occipital and/or temporal arteries **36**, **38**. It is further understood, the patient **12** may adjust the bumper units and/or the user. Further, each of the bumper units may be adjusted separately to allow for a selected force applied by each bumper. Although, it is understood, that all of the bumpers may be adjust in a single manner.

**[0074]** Example embodiments are provided so that this disclosure will be thorough, and will fully convey the scope to those who are skilled in the art. Numerous specific details are set forth such as examples of specific components, devices, and methods, to provide a thorough understanding of embodiments of the present disclosure. It will be apparent to those skilled in the art that specific details need not be employed, that example embodiments may be embodied in many different forms and that neither should be construed to limit the scope of the disclosure. In some example embodiments, well-known processes, well-known device structures, and well-known technologies are not described in detail.

**[0075]** The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

What is claimed is:

**1**. A system for regulating a portion of a subject, the method comprising:

an elongated member configured to extend relative to a head of a subject;

a bumper member held with the elongated member relative to the head of the subject; and

a reservoir configured to hold a volume of a fluid relative to the head of the subject;

wherein the bumper member is selectively pressed against the head of the subject.

**2**. The system of claim **1**, wherein the elongated member is adjustable in length to increase or decrease a pressure applied to the head of the subject.

**3**. The system of claim **2**, wherein the bumper member is sized and shaped to press on an artery within the head of the subject.

**4**. The system of claim **3**, wherein the bumper member includes a plurality of bumper members;

wherein each bumper member of the plurality of bumper members is positioned on the head of the subject to apply pressure to the temporal artery or the occipital artery.

**5**. The system of claim **1**, wherein the reservoir includes an access port;

wherein the access port is configured to allow removal and replacement of the fluid within the reservoir.

**6**. The system of claim **5**, further comprising:

a pump to automatically and/or continuously exchange the fluid in the reservoir.

**7**. The system of claim **6**, wherein the access port includes an inlet access port and an outlet access port;

wherein the reservoir is configured to be emptied through the outlet access port and filled through the inlet access port.

**8**. The system of claim **1**, wherein the elongated member includes:

a first arm; and

a second arm;

wherein the bumper member includes a plurality of bumper members;

wherein the first arm includes a first bumper member moveably connected thereto and the second arm includes a second bumper member moveably connected thereto.

**9**. The system of claim **8**, wherein the first arm is configured to position the first bumper member relative to a temporal artery and the second arm is configured to position the second bumper member relative to an occipital artery.

**10**. The system of claim **8**, further comprising:

a third arm; and

a fourth arm;

wherein the third arm includes a third bumper member and a fourth bumper member both moveably connected thereto.

**11**. The system of claim **10**, wherein the first arm is configured to position the first bumper member relative to a left temporal artery, the second arm is configured to position the second bumper member relative to a right temporal artery, and the third arm is configured to position the third bumper member relative to a right occipital artery and the fourth bumper member relative to a left occipital artery.

**12**. The system of claim **1**, wherein the reservoir includes:

a main line;

a secondary inlet line branching from and in fluid connection with the main line;

a plurality of capillary inlet lines extending from and in fluid connection with the secondary line;

a bag surrounding the plurality of capillary inlet lines a plurality of capillary outlet lines in fluid connection with the bag; and

a secondary outlet line in fluid connection with the plurality of capillary outlet lines;

wherein the fluid is able to flow into the main line, secondary inlet line, plurality of capillary inlet lines, the bag, the plurality of capillary outlet lines, and the secondary outlet line.

**13**. The system of claim **1**, further comprising:

a pump to automatically and/or continuously exchange the fluid in the reservoir.

**14**. The system of claim **13**, further comprising:

a thermal sensor to sense a temperature at least at a surface of the head of the subject.

**15**. The system of claim **14**, further comprising:

a controller configured to control the pump to pump fluid through the reservoir based on instructions regarding a temperature sensed with the thermal sensor.

**16**. A system for regulating a portion of a subject, the method comprising:

an elongated member configured to extend relative to a head of a subject;

a bumper member held with the elongated member relative to the head of the subject, wherein the bumper member is selectively pressed against the head of the subject; and

a reservoir configured to hold a volume of a fluid relative to the head of the subject;

wherein the reservoir includes,

a main line;

a secondary inlet line branching from and in fluid connection with the main line;

a plurality of capillary inlet lines extending from and in fluid connection with the secondary line;

a bag surrounding the plurality of capillary inlet lines a plurality of capillary outlet lines in fluid connection with the bag; and

a secondary outlet line in fluid connection with the plurality of capillary outlet lines;

wherein the fluid is able to flow into the main line, secondary inlet line, plurality of capillary inlet lines, the bag, the plurality of capillary outlet lines, and the secondary outlet line.

**17**. A system for regulating a portion of a subject, the method comprising:

a reservoir configured to hold a volume of a fluid relative to the head of the subject, wherein the reservoir includes a single tube having an inlet port and an outlet port and configured to be positioned on a head of a subject;

a bumper assembly having,

a first arm having a first bumper member moveably connected thereto,

a second arm having a second bumper member moveably connected thereto,

a third arm having a third bumper member and a fourth bumper member both moveably connected thereto, and

a fourth arm,

wherein the first arm is configured to position the first bumper member relative to a left temporal artery, the second arm is configured to position the second bumper member relative to a right temporal artery, and the third arm is configured to position the third bumper member relative to a right occipital artery and the fourth bumper member relative to a left occipital artery.

**18**. A method of limiting hair-loss in a subject, comprising:

compressing at least one artery in a head of the subject during a treatment period; and

regulating a temperature of the head of the subject with a heat transfer medium.

**19**. The method of claim **18**, wherein compressing at least one artery in the head of the subject during the treatment period includes:

placing a bumper member over an artery in the head of the subject; and

applying a force to the bumper member operable to restrict a flow of blood through the artery.

**20**. The method of claim **18**, wherein compressing at least one artery in the head of the subject during the treatment period includes:

placing a first bumper member over an occipital artery in the head of the subject;

applying a first force to the first bumper member operable to restrict a flow of blood through the occipital artery;

placing a second bumper member over a temporal artery in the head of the subject;

applying a second force to the second bumper member operable to restrict a flow of blood through the temporal artery.

**21**. The method of claim **18**, wherein regulating the temperature of the head of the subject with the heat transfer medium includes exchanging a first volume of the heat transfer medium with a second volume of the heat transfer medium when the first volume reaches a selected temperature.

**22**. The method of claim **21**, wherein exchanging the first volume of the heat transfer medium with the second volume of the heat transfer medium when the first volume reaches the selected temperature includes pumping the heat transfer medium through a reservoir.

**23**. The method of claim **22**, further comprising:

placing the reservoir on the head of the subject.

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摘要(译)

公开了一种控制到选定区域的血流的装置和方法。还公开了一种调节所选位置处的温度的系统和方法。该系统和方法可以在选定的时间段内应用于受试者。