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(54) **DEVICE CONFIGURED TO INDUCE VASODILATION OF A SUPERFICIAL VEIN**

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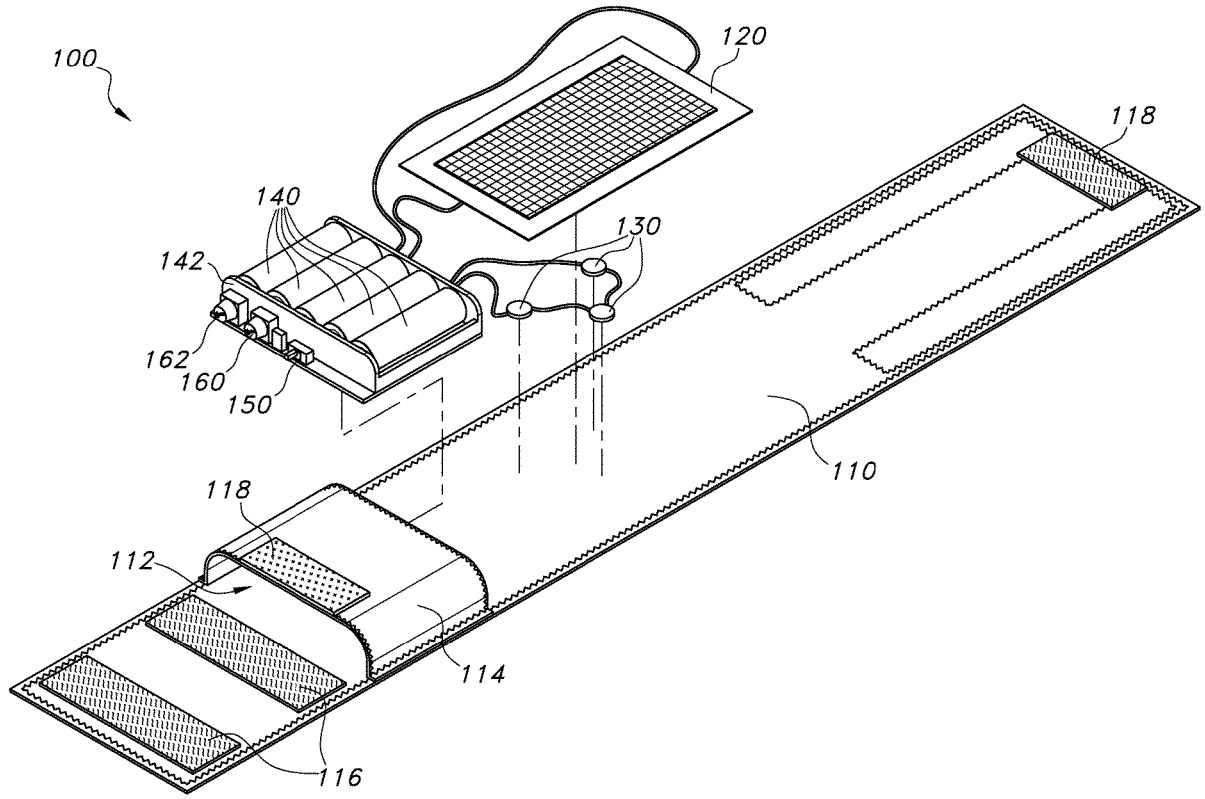
(57) **ABSTRACT**

Implementations of a device configured to induce vasodilation of a superficial vein and methods of using the device are provided. The device is configured to ease the process of venipuncture by increasing blood flow to a superficial vein. The device is configured to increase local blood flow to a superficial vein by applying heat and/or vibration at, or near, a prospective puncture site. In this way, vasodilation of the superficial vein may be induced. The device comprises a strap, a flexible heating element, at least one vibration element, a power source, and an ON/OFF switch for selectively energizing both the heating element and the at least one vibration element. In some implementations, the device may further comprise a thermal control switch configured to vary the temperature reached by the heating element and/or a vibratory element control switch configured to vary the vibratory intensity of the at least one vibration element.



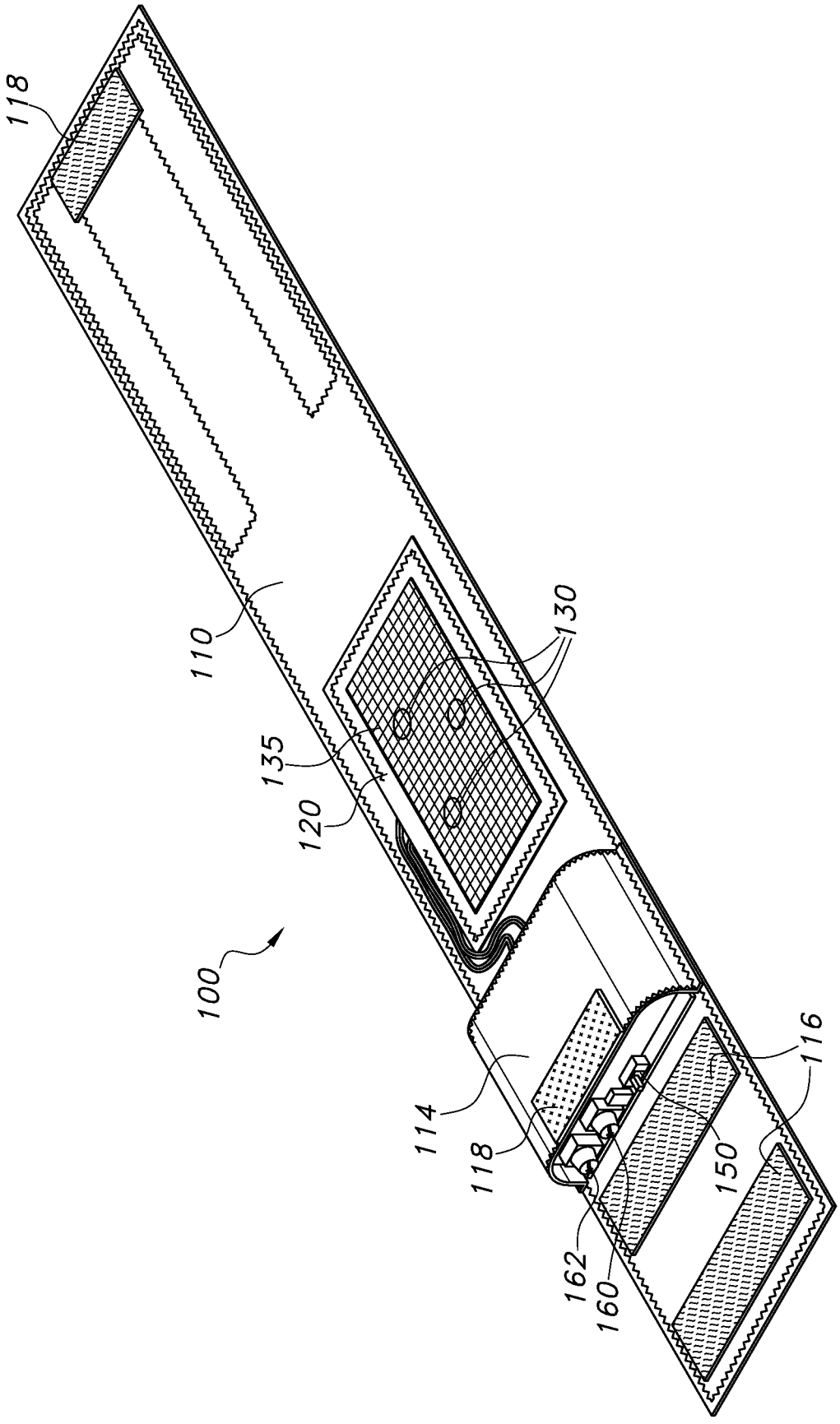


FIG. 1

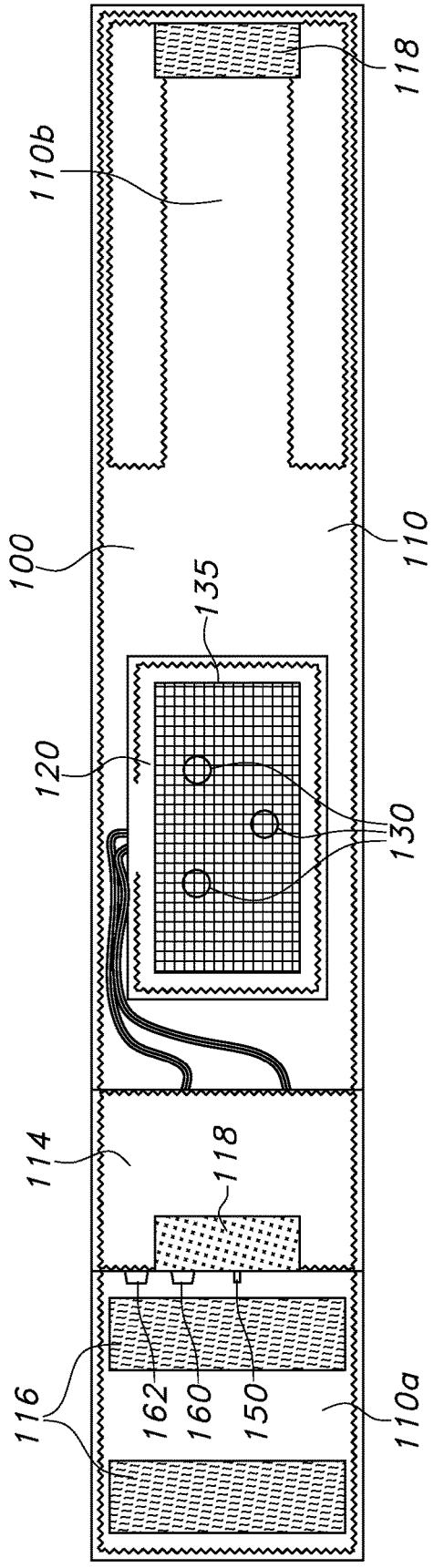

118
110b
100
110
135
120
130
114
118
116
162
160
150
110a

FIG. 2

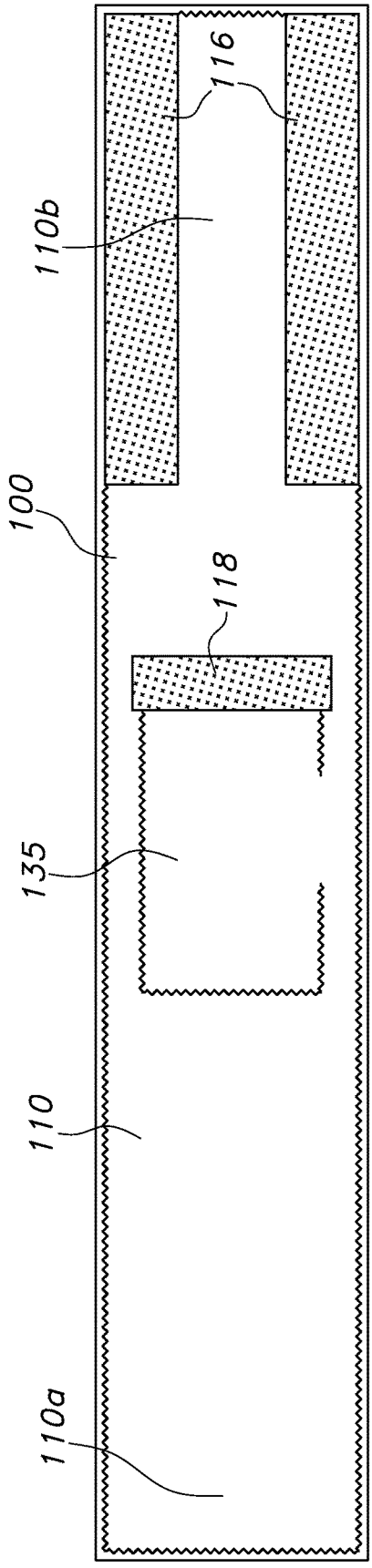

116
110b
100
118
135
110
110a

FIG. 3

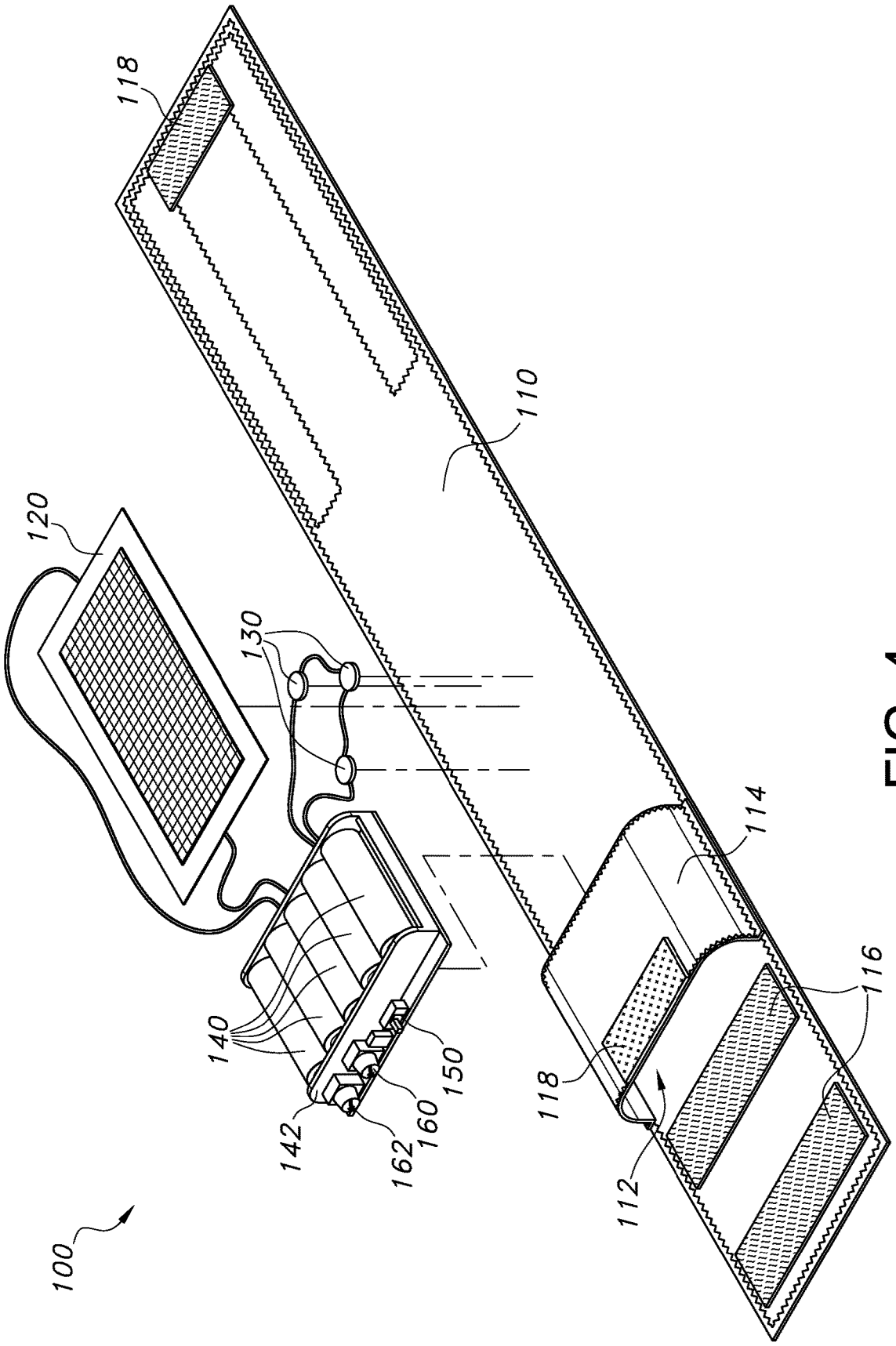


FIG. 4

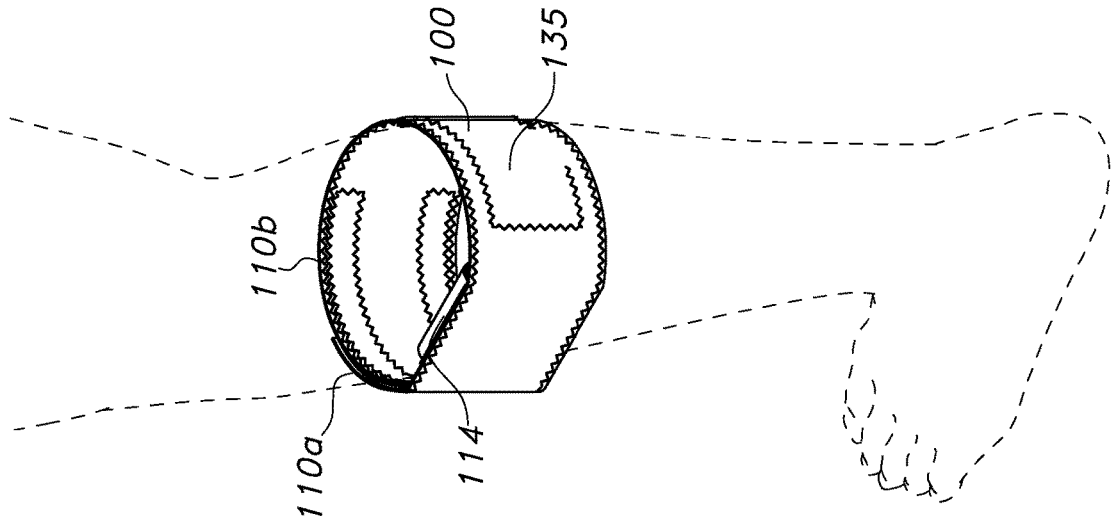
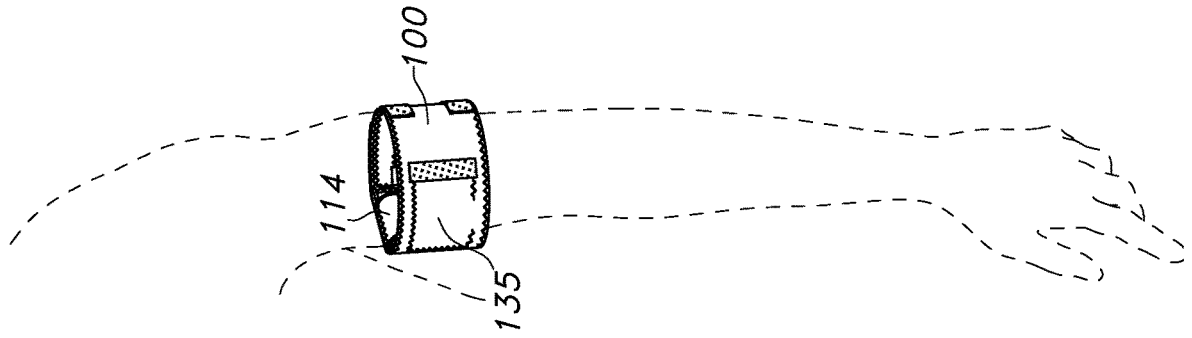


FIG. 5

FIG. 6



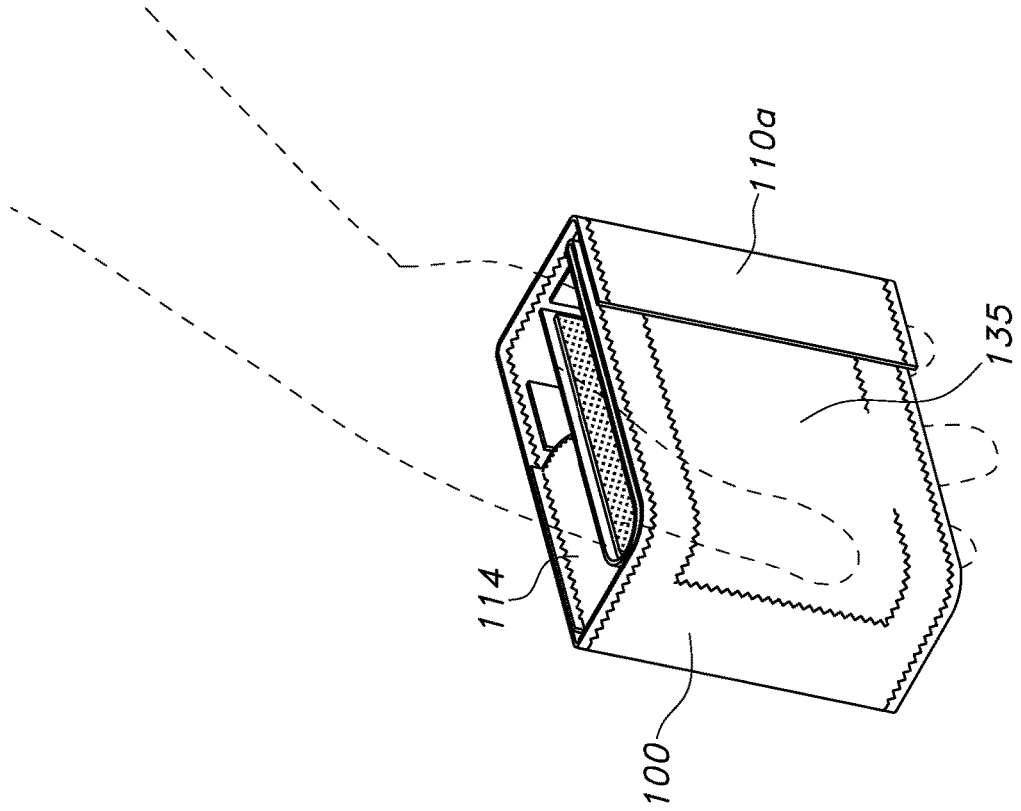


FIG. 7

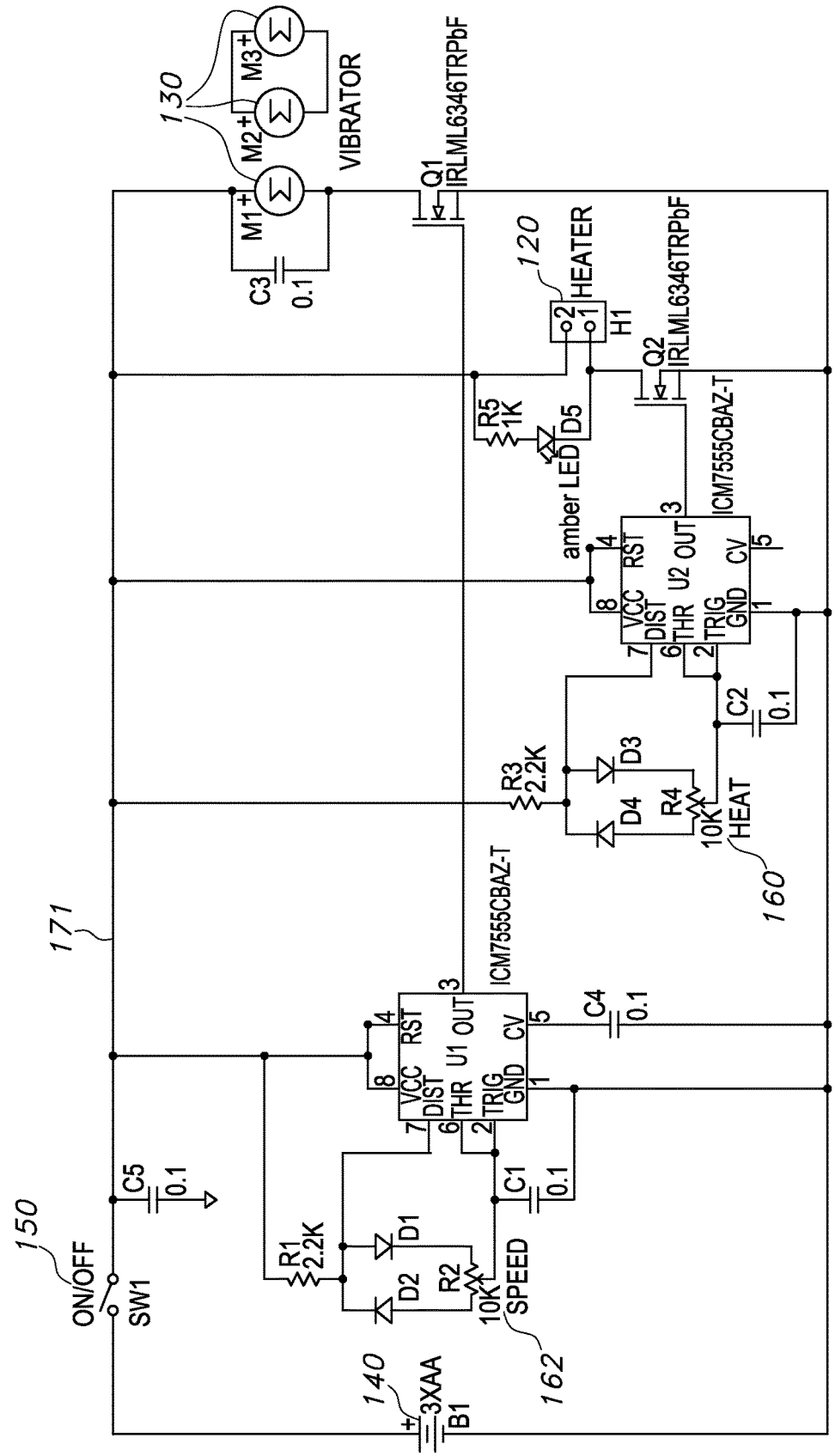

130
M1+
M2+
M3+
VIBRATOR
C3
0.1
Q1
IRLML6346TRPbF
120
HEATER
H1
Q2
IRLML6346TRPbF
R5
1K
D5
amber LED
ICM7555CBAZ-T
U2
RST
OUT
CV
VCC
DIST
THR
TRIG
GND
C2
0.1
R3
2.2K
D3
D4
R4
10K
HEAT
160
171
ICM7555CBAZ-T
U1
C4
0.1
150
ON/OFF
SW1
C5
0.1
R1
2.2K
D1
D2
R2
10K
SPEED
C1
0.1
140
3XAA
B1
162

FIG. 8

DEVICE CONFIGURED TO INDUCE VASODILATION OF A SUPERFICIAL VEIN

TECHNICAL FIELD

[0001] This disclosure relates to implementations of a device configured to induce vasodilation of a superficial vein and methods of using the device.

BACKGROUND

[0002] Venipuncture is the process of obtaining intravenous access to a vein for the purpose of blood sampling or intravenous therapy. This procedure is typically performed by phlebotomist, laboratory scientist, and health care providers. During a venipuncture procedure, blood is usually obtained from the superficial veins of an arm, but blood may also be obtained from the superficial veins of a leg, a hand, or the neck.

[0003] Each venipuncture attempt damages the vein wall whether the attempt was successful or not. This consideration is of particular importance when a patient with difficult venous access is encountered. Therefore, increasing the success of each venipuncture attempt is important to patient health. Increasing vein diameter (i.e., vasodilation) is an effective way to increase venipuncture success. Vasodilation of superficial veins may be induced through the application of heat and/or vibratory stimulation to the prospective puncture site.

[0004] Accordingly, it can be seen that needs exist for the device configured to induce vasodilation of a superficial vein and the methods of using the device disclosed herein. It is to the provision of a device that is configured to address these needs, and others, that the present invention in primarily directed.

SUMMARY OF THE INVENTION

[0005] Implementations of a device configured to induce vasodilation of a superficial vein and methods of using the device are provided. The device is configured to ease the process of venipuncture by increasing blood flow to a vein that is going to be punctured for the purpose of blood sampling or intravenous therapy. The device is configured to increase local blood flow to a vein by applying heat and/or vibration at, or near, the prospective puncture site. In this way, vasodilation of the superficial vein may be induced.

[0006] In some implementations, the device may comprise a strap that can be used to position the device over a prospective puncture site, a heating element able to conform to the contour of a surface, at least one vibration element, a power source, and an ON/OFF switch for selectively energizing both the heating element and the at least one vibration element. The device defines an application area comprising the heating element and the at least one vibration element. The strap can be used to secure the device to a portion of a subject's body (e.g., a leg, an arm, a hand) and/or used to form a grip into which a user (e.g., a subject or a phlebotomist) can insert their hand and thereby position the device over a prospective puncture site.

[0007] In some implementations, the device may further comprise a thermal control switch configured to vary the temperature reached by the heating element and/or a vibratory element control switch configured to vary the vibratory intensity of the at least one vibration element.

[0008] In some implementations, the strap includes a slot configured to receive the power source therein. The slot may be defined by a strip of material, the ends of which are secured (e.g., sewn) to the strap.

[0009] The heating element and the at least one vibration element of the device are secured to a first side of the strap, the heating element overlaps the vibration element(s) thereby forming the application area. In some implementations, the portion of the strap to which the heating element and the at least one vibration element are secured is sufficiently thin, and/or has sufficient thermal transfer characteristics, as to allow the efficient transfer of heat from the heating element, and vibration from the at least one vibration element, to the subject.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. **1** illustrates an isometric flat view of a device configured to induce vasodilation of a superficial vein according to the principles of the present disclosure.

[0011] FIG. **2** illustrates a top view of the device shown in FIG. **1**.

[0012] FIG. **3** illustrates a bottom view of the device shown in FIG. **1**.

[0013] FIG. **4** illustrates an isometric exploded view of the device shown in FIG. **1**.

[0014] FIG. **5** illustrates the device shown in FIG. **1** being worn on the lower leg of a subject.

[0015] FIG. **6** illustrates the device shown in FIG. **1** being worn on an arm of a subject.

[0016] FIG. **7** illustrates the device shown in FIG. **1** being worn on the hand of a user.

[0017] FIG. **8** is a schematic of an example circuit configured to operate the device shown in FIG. **1**.

[0018] Like reference numerals refer to corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

[0019] FIGS. **1-4** illustrate an example device **100** configured to induce vasodilation of a superficial vein and FIGS. **5-7** illustrate example methods of using the device **100**. The device **100** is configured to ease the process of venipuncture by increasing blood flow to a vein that is going to be punctured for the purpose of blood sampling or intravenous therapy. In some implementations, the device **100** is configured to increase local blood flow to a vein by applying heat and/or vibration at, or near, the prospective puncture site. In this way, vasodilation of the superficial vein may be induced.

[0020] As shown in FIGS. **1**, **2**, and **4**, in some implementations, the device **100** may comprise a strap **110**, a heating element **120**, vibration elements **130**, a power source **140**, and an ON/OFF switch **150** for selectively energizing both the heating element **120** and the vibration elements **130**. The device **100** defines a two-sided application area **135** comprising the heating element **120** and the vibration elements **130**. In some implementations, the device **100** may further comprise a thermal control switch **160** and/or a vibratory element control switch **162**.

[0021] As shown in FIGS. **5-7**, the strap **110** can be used to secure the device **100** to a portion of a subject's body (e.g., a leg, an arm, a hand). Prior to using the strap **110** to secure the device **100** to a portion of a subject's body (e.g., a leg or an arm), the application area **135** (i.e., the heating

element **120** and the vibration elements **130**) should be positioned over a prospective puncture site (see, e.g., FIGS. **5** and **6**). Alternatively, the strap **110** could be used to secure the device **100** to a user's hand so that the application area **135** is positioned over the palm thereof (see, e.g., FIG. **7**). In this way, the user (e.g., a subject or a phlebotomist) can position and hold the application area **135** of the device **100** over a prospective puncture site. As another alternative, the application area **135** of the device **100** could be positioned over a prospective puncture site on the neck of a subject, the ends of the strap **110** could then be pulled and thereby used to hold the application area **135** of the device **100** in contact with the prospective puncture site (not shown).

[0022] In some implementations, the strap **110** may be a flexible length of material (e.g., one or more layers of neoprene or another suitable material) capable of being wrapped about a portion of a subject's body. The strap **110** includes a slot **112** configured to receive the power source **140** therein (see, e.g., FIG. **4**). The slot **112** may be defined by a strip of material **114**, the ends of which are secured (e.g., sewn) to the strap **110**. The heating element **120** and the vibration elements **130** of the device **100** are secured to a first side of the strap **110**, the heating element **120** overlaps the vibration elements **130** thereby forming the application area **135**. In some implementations, the portion of the strap **110** to which the heating element **120** and the vibration elements **130** are secured is sufficiently thin, and/or has sufficient thermal transfer characteristics, as to allow the efficient transfer of heat from the heating element **120** and vibration from the vibration elements **130** to the subject. The ends of the strap **110** include hook-and-loop fasteners **116** for securing the device **100** about a portion of a subject's body. In some implementations, the ends of the strap **110** may include another type of fastening device (e.g., a buckle) in-lieu of hook-and-loop fasteners **116**. In some implementations, as discussed in greater detail below, the strap **110** may include additional fasteners **118** (e.g., hook-and-loop fasteners) that are used to secure the device **110** about the hand of a user and/or for forming the strap **110** into a grip that can be held (see, e.g., FIG. **7**).

[0023] In some implementations, the heating element **120** may be a flexible heating pad. By being flexible, the heating element **120** is able to conform to the contour of a surface (e.g., a portion of a subject's body). When the ON/OFF switch **150** is used to close the circuit **171**, the heating element **120** heats up. In some implementations, the thermal control switch **160** may be used to vary the voltage applied to the heating element **120**. In this way, the temperature reached by the heating element **120** can be adjusted (or set). The thermal control switch **160** can be a rotary potentiometer, or another suitable variable resistor.

[0024] As shown in FIGS. **1** and **2**, in some implementations, the heating element **120** can be sewn to the strap **110** of the device **100**. In some implementations, the heating element **120** may be secured to the strap **110** by a suitable adhesive. One of ordinary skill in the art, having the benefit of the present disclosure, would know of other suitable ways to secure the heating element **120** to the strap **110** of the device **100** (e.g., the heating element **120** could be positioned within a pocket that includes at least one sidewall that is sufficiently thin, or has sufficient thermal transfer characteristics, as to allow the efficient transfer of heat from the heating element **120** to the subject).

[0025] In some implementations, each vibration element **130** may be a shaftless vibratory motor. When the ON/OFF switch **150** is used to close the circuit **171**, each vibration element **130** begins to vibrate. In some implementations, the vibratory element control switch **162** may be used to vary the voltage applied to the vibration elements **130**. In this way, the vibratory intensity of each vibration element **130** can be adjusted (or set). The vibratory element control switch **162** can be a rotary potentiometer, or another suitable variable resistor.

[0026] While three vibration elements **130** are shown in the figures, it should be understood that, in some implementations, a device **100** may comprise less than three or more than three vibration elements **130**. In some implementations, each vibration element **130** is secured to the strap **110** by an adhesive backing. One of ordinary skill in the art, having the benefit of the present disclosure, would know of other suitable ways to secure each vibration element **130** to the strap **110** of the device **100**.

[0027] As shown in FIG. **4**, in some implementations, the power source **140** may be one or more electrochemical cells (e.g., AA batteries) held by a battery holder **142** that is conductively connected to the heating element **120** and the vibration elements **130**. In some implementations, the ON/OFF switch **150**, the optional thermal control switch **160**, the optional vibratory element control switch **162**, or a combination thereof, may be mounted on the battery holder **142**. In some implementations, the power source **140** may be a pouch cell (e.g., a lithium-ion polymer battery) held by a battery holder (not shown).

[0028] As shown in FIG. **1**, in some implementations, the power source **140** can be held within the slot **112** of the strap **110** by friction. In some implementations, the power source **140** may be held within the slot **112** of the strap **110** by a removable adhesive, one or more fasteners, or a combination thereof.

[0029] In some implementations, the device **100** may be configured so that a conventional AC power line can be used to power it's circuit **171** in lieu of batteries (not shown).

[0030] FIG. **8** illustrates an example circuit **171** that is configured to operate the device **100**. The example circuit **171** comprises the heating element **120**, the vibration elements **130**, the power source **140**, the ON/OFF switch **150**, and in some implementations, the thermal control switch **160** and/or the vibratory element control switch **162**. Although not fully disclosed in the drawings, it will be understood that suitable wiring (or traces) connects the electrical components of the device **100** disclosed herein (e.g., the heating element **120**, vibration element(s) **130**, power source **140**, ON/OFF switch **150**, and the optional switches **160**, **162**).

[0031] As disclosed above, one or more implementations of the device **100** may be used to induce vasodilation of a superficial vein. In some implementations, the following steps may be taken to induce vasodilation using the device **100** disclosed herein. Initially, the device is turned ON using the provided ON/OFF switch **150**. In this way, the heating element **120** and the vibration elements **130** are energized. Then, in some implementations, the temperature and vibratory intensity of the heating element **120** and the vibration elements **130**, respectively, may be adjusted (and set) using the provided thermal control switch **160** and vibratory element control switch **162**. Next, a side of the application area **135** is positioned over a prospective puncture site.

While the application area **135** of the device **100** is positioned on a prospective puncture site and after a sufficient amount of time has passed, any adjacent superficial vein(s) may vasodilate due to the heat and vibratory stimulation emanating from the device **100**. Once vasodilation has occurred, the device **100** may be removed and the venipuncture procedure initiated. One of ordinary skill in the art would know how long to leave the device **100** in position for the purpose of inducing vasodilation.

[0032] In some implementations, the strap **110** may be used to secure the device **100** to a portion of a subject's body (see, e.g., FIGS. **5** and **6**) or used to form a grip into which the user can insert their hand (see, e.g., FIG. **7**).

[0033] As shown in FIGS. **5** and **6**, in some implementations, the following steps may be used to secure the device **100** to a portion of a subject's body (e.g., a leg or an arm). Initially, a first side of the application area **135** is positioned over a prospective puncture site (i.e., the heating element **120** is placed in direct contact with the prospective puncture site). Then, the strap **100** is wrapped about the leg (or arm) and the provided hook-and-loop fasteners **116** are used to secured a first end **110***a* of the strap **110** to a second end **110***b* thereof.

[0034] As shown in FIG. **7**, in some implementations, the following steps may be used so that the device **100** can be easily grasped by a user (e.g., a subject or a phlebotomist). Initially, the second end **110***b* of the strap **110** is folded over the heating element **120** and secured to the strip of material **114** that defines the slot **112** for the power source **140**. The second end **110***b* of the strap **110** is secured to the strip of material **114** by the provided hook-and-loop fasteners **118**. Then, the second end **110***b* of the strap **110** is folded over again so that the first end **110***a* of the strap **110** can be secured to the hook-and-loop fasteners **118** located on the second side of the strap **110**, adjacent the second side of the application area **135**. Next, the user may insert a portion of their hand into an opening formed by the strap **110** and thereby grasp the device **110** prior to applying the second side of the application area **135** to a prospective puncture site.

[0035] Reference throughout this specification to "an embodiment" or "implementation" or words of similar import means that a particular described feature, structure, or characteristic is included in at least one embodiment of the present invention. Thus, the phrase "in some implementations" or a phrase of similar import in various places throughout this specification does not necessarily refer to the same embodiment.

[0036] Many modifications and other embodiments of the inventions set forth herein will come to mind to one skilled in the art to which these inventions pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings.

[0037] The described features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. In the above description, numerous specific details are provided for a thorough understanding of embodiments of the invention. One skilled in the relevant art will recognize, however, that embodiments of the invention can be practiced without one or more of the specific details, or with other methods, components, materials, etc. In other instances, well-known structures, materials, or operations may not be shown or described in detail.

[0038] While operations are depicted in the drawings in a particular order, this should not be understood as requiring that such operations be performed in the particular order shown or in sequential order, or that all illustrated operations be performed, to achieve desirable results.

1. A device configured to induce vasodilation of a superficial vein, the device comprising:
- a strap that can be used to position the device over a prospective puncture site;
- a heating element that is configured to conform to the contour of a surface;
- at least one vibration element;
- a power source; and
- an ON/OFF switch configured to selectively energize the heating element and the at least one vibration element, the ON/OFF switch is conductively connected to the power source, the heating element, and the at least one vibration element;
- wherein the device defines an application area comprising the heating element and the at least one vibration element.

2. The device of claim **1**, wherein the strap includes a slot configured to receive the power source therein, the slot is defined by a strip of material, each end of the strip of material is secured to the strap.

3. The device of claim **1**, wherein the heating element is a flexible heating pad.

4. The device of claim **1**, wherein the at least one vibration element is a shaftless vibratory motor.

5. The device of claim **1**, wherein the heating element overlaps the at least one vibration element.

6. The device of claim **5**, wherein the heating element and the at least one vibration element are secured to a first side of the strap, the portion of the strap to which the heating element and the at least one vibration element are secured is configured to allow heat and vibration generated by the heating element and the at least one vibration element, respectively, to transfer to a second side thereof.

7. A device configured to induce vasodilation of a superficial vein, the device comprising:
- a strap that can be used to position the device over a prospective puncture site;
- a heating element that is configured to conform to the contour of a surface;
- at least one vibration element;
- a power source;
- an ON/OFF switch configured to selectively energize the heating element and the at least one vibration element, the ON/OFF switch is conductively connected to the power source, the heating element, and the at least one vibration element;
- a thermal control switch configured to vary the temperature reached by the heating element, the thermal control switch is conductively connected to the power source and the heating element; and
- a vibratory element control switch configured to vary the vibratory intensity of the at least one vibration element, the vibratory element control switch is conductively connected to the power source and the at least one vibration element;
- wherein the device defines an application area comprising the heating element and the at least one vibration element.

8. The device of claim **7**, wherein the strap includes a slot configured to receive the power source therein, the slot is defined by a strip of material, each end of the strip of material is secured to the strap.

9. The device of claim **7**, wherein the heating element is a flexible heating pad.

10. The device of claim **7**, wherein the at least one vibration element is a shaftless vibratory motor.

11. The device of claim **7**, wherein the heating element overlaps the at least one vibration element.

12. The device of claim **11**, wherein the heating element and the at least one vibration element are secured to a first side of the strap, the portion of the strap to which the heating element and the at least one vibration element are secured is configured to allow heat and vibration generated by the heating element and the at least one vibration element, respectively, to transfer to a second side thereof.

13. A method of using a device configured to induce vasodilation of a superficial vein, the method comprising:

providing a device comprising: a strap that can be used to position the device over a prospective puncture site; a heating element that is configured to conform to the contour of a surface; at least one vibration element; a power source; and an ON/OFF switch configured to selectively energize the heating element and the at least one vibration element; wherein the device defines an application area comprising the heating element and the at least one vibration element;

actuating the ON/OFF switch of the device to energize the heating element and the at least on vibration element; and

positioning the application area of the device over a prospective puncture site on a subject.

14. The method of claim **13**, further comprising: orienting the application area of the device so that the heating element is placed in direct contact with the prospective puncture site; and wrapping the strap about a limb of the subject and securing a first end of the strap to a second end thereof.

15. The method of claim **13**, further comprising: folding the strap to form an opening into which a user may insert a portion of their hand, thereby allowing the user to grasp the device while holding the application area over the prospective puncture site.

16. The method of claim **13**, wherein the devices further comprises: a thermal control switch configured to vary the temperature reached by the heating element, and a vibratory element control switch configured to vary the vibratory intensity of the at least one vibration element; the method further comprises:

using the thermal control switch to set the temperature reached by the heating element; and

using the vibratory element control switch to set the vibratory intensity of the at least one vibration element.

17. The method of claim **13**, wherein the heating element of the device is a flexible heating pad.

18. The method of claim **13**, wherein the at least one vibration element of the device is a shaftless vibratory motor.

19. The method of claim **13**, wherein the heating element of the device overlaps the at least one vibration element.

20. The method of claim **19**, wherein the heating element and the at least one vibration element of the device are secured to a first side of the strap, the portion of the strap to which the heating element and the at least one vibration element are secured is configured to allow heat and vibration generated by the heating element and the at least one vibration element, respectively, to transfer to a second side thereof.

* * * * *