(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 November 2018 (15.11.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/208759 A1

(51) International Patent Classification:
G09B 23/28 (2006.01) *G09B 23/34* (2006.01)
G09B 23/30 (2006.01)

(21) International Application Number:
PCT/US2018/031568

(22) International Filing Date:
08 May 2018 (08.05.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/504,635 11 May 2017 (11.05.2017) US

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(54) Title: BLOOD CAPILLARY REFILL SIMULATOR

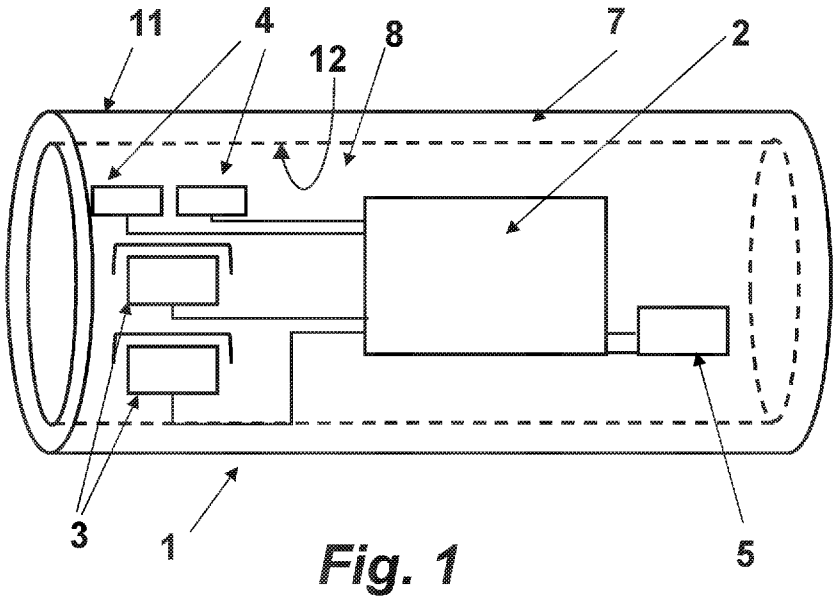


Fig. 1

(57) Abstract: The blood capillary refill simulator provides a dynamic method of simulating capillary refill action in a patient, especially adolescents. The simulator as a teaching device is capable of simulating the refill action multiple times across multiple simulations. The blood capillary refill simulator uses a pressure sensor(s) in the fingertip of a simulation finger or arm that, when pressed, activates a light source housed within the fingertip. When the pressure sensor(s) is released, the light will fade out completely. A program controls the length of time it takes for the light to completely fade out. A user can select a time interval in seconds for the light to fade out which can be modified during the simulation by the operator. If the pressure sensor(s) is pressed while the fade out is occurring, the light source will restart at full brightness and fade out for the specified time interval.

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[Continued on next page]

(81) **Designated States** *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

BLOOD CAPILLARY REFILL SIMULATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to and the benefit of U.S. Provisional Application 62/504,635 titled "BLOOD CAPILLARY REFILL SIMULATORS" filed May 11, 2017, the entire disclosure of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

The present disclosure is generally related to a blood capillary refill simulator.

BACKGROUND

Nearly 2.2 million children die each year due to dehydration, with millions more dying due to related complications involving shock and artery disease. Symptoms associated with shock and dehydration are often subtle and unapparent to the untrained eye. In diagnosing shock or dehydration, a series of tests are available to a nurse or clinician, all of varying complexity. One of the easiest and most practical tests for shock-related conditions, however, is the measurement of Capillary Refill Time (CRT).

CRT testing works by applying pressure to the fingertip or palm and recording the time required for capillaries in the area to refill. The refill rate can be recorded by observing the time it takes for the area where force is applied to go from a blanched state (white) to the normal light-pink color indicating the presence of blood in the area. A healthy child has an average CRT of two seconds. A time difference longer than this would indicate the child may suffer from such as hypoxia, shock, dehydration or a combination of such conditions and that there is a need for more extensive patient testing.

SUMMARY

Accordingly, one aspect of the disclosure encompasses embodiments of a blood capillary refill simulator comprising an adjustable lighting system, wherein the lighting system can comprise: at least one pressure-sensitive sensor operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, and a translucent polymer positioned to be illuminated by the light source.

In some embodiments of this aspect of the disclosure, the light source can be a light-emitting diode (LED) or an array of LEDs.

In some embodiments of this aspect of the disclosure, the light source when activated can emit a white light, a non-white light, or a combination thereof.

In some embodiments of this aspect of the disclosure, the lighting system can comprise a plurality of superimposed pressure-sensitive sensors.

In some embodiments of this aspect of the disclosure, the light source can be positioned between the translucent polymer and the at least one pressure-sensitive sensor.

In some embodiments of this aspect of the disclosure, the translucent polymer can be a sheet attached to a support means.

In some embodiments of this aspect of the disclosure, the translucent polymer can be configured as a tube defining a lumen, wherein the at least one pressure-sensitive sensor and the light source can be disposed in the lumen of the tube.

In some embodiments of this aspect of the disclosure, the at least one pressure-sensitive sensor and the light source can be embedded in the translucent polymer.

In some embodiments of this aspect of the disclosure, the at least one pressure-sensitive sensor and the light source are disposed in a human digit simulator. In some embodiments of this aspect of the disclosure, the human digit simulator can be attached to a human arm simulator or a human mannequin.

In some embodiments of this aspect of the disclosure, the at least one pressure-sensitive sensor, the light source, and the electronic control means are disposed in a human arm simulator or mannequin, and wherein the translucent polymer is a region of skin of the human arm simulator or mannequin.

In some embodiments of this aspect of the disclosure, the electronic control means can comprise a computer-controlled electronic circuit configured for regulating at least one of the intensity and duration of the light emitted by the light source.

In some embodiments of this aspect of the disclosure, the electronic control means can further comprise a wireless receiver and a remote wireless signal emitter configured for remotely adjusting at least one of the intensity and duration of the light emitted by the light source.

Another aspect of the disclosure encompasses embodiments of a blood capillary refill simulator comprising an adjustable lighting system, wherein the adjustable lighting system comprises: at least two superimposed pressure-sensitive sensors operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, and wherein the blood capillary refill simulator further comprises a translucent polymer material positioned to be illuminated by the light source, wherein: (i) the light source can be superimposed over at least one of the pressure-sensitive sensors; (ii) the lighting system can be within a human anatomical simulator and the translucent polymer layer is disposed over the light source, and (iii) the duration of illumination of the translucent polymer is adjustable by the amount of pressure applied to the at least two superimposed pressure-sensitive sensors.

In some embodiments of this aspect of the disclosure, the light source is a light-emitting diode (LED) or an array of LEDs.

Yet another aspect of the disclosure encompasses embodiments of a blood capillary refill simulator comprising an adjustable lighting system, wherein the adjustable lighting

system comprises: at least one pressure-sensitive sensor operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, wherein the electronic control means further comprises a wireless receiver configured for receiving a signal controlling the intensity and duration of light emission from the light source, and a remote regulatory signal emitter configured to communicate with the wireless receiver, and wherein the blood capillary refill simulator further comprises a translucent polymer material positioned to be illuminated by the light source, wherein: (i) the light source is superimposed over the pressure-sensitive sensor(s); (ii) the lighting system is at least partially enclosed by a human anatomical simulator having the translucent polymer layer disposed over the light source, and (iii) the duration of illumination of the translucent polymer is adjustable by a signal transmitted from the remote regulatory signal emitter to the electronic control means.

In some embodiments of this aspect of the disclosure, the signal emitted from the remote regulatory signal emitter can be a radio frequency, a visible or infra-red light frequency, or a sound wave.

In some embodiments of this aspect of the disclosure, the light source can be a light-emitting diode (LED) or an array of LEDs

In some embodiments of this aspect of the disclosure, the human anatomic simulator can be a finger simulator.

In some embodiments of this aspect of the disclosure, the pressure-sensitive sensor, the light source, the power source, and the electronic control circuit can be embedded in the translucent polymer configured as a human anatomic simulator.

BRIEF DESCRIPTION OF THE DRAWINGS

Further aspects of the present disclosure will be more readily appreciated upon review of the detailed description of its various embodiments, described below, when taken in conjunction with the accompanying drawings.

Fig. 1 illustrates an embodiment of the blood capillary refill simulator of the disclosure having a plurality of light sources and pressure-sensitive sensors within a translucent tube and operably connected to an electronic control means and a power source.

Fig. 2 illustrates an embodiment of the blood capillary refill simulator of the disclosure having a plurality of light sources and pressure-sensitive sensors within a translucent tube and operably connected to an electronic control means, and a power source, together with an external remote controller connected to the electronic control means by a wired connection.

Fig. 3 illustrates an embodiment of the blood capillary refill simulator of the disclosure having a plurality of light sources and pressure-sensitive sensors within a translucent tube

and operably connected to an electronic control means, and a power source, together with an external remote controller wirelessly connected to the electronic control means.

Fig. 4 illustrates an embodiment of the blood capillary refill simulator of the disclosure having a plurality of light sources and pressure-sensitive sensors within a translucent tube and operably connected to an electronic control means, and a power source, and an external remote controller wirelessly connected to the electronic control means and located in the lumen of a human digit (finger) simulator.

Fig. 5 illustrates an embodiment of the blood capillary refill simulator of the disclosure having a plurality of light sources and pressure-sensitive sensors positioned beneath a translucent sheet supported by a support means.

Fig. 6 illustrates an embodiment of an electronic circuit for regulating the duration of dimming of two light sources.

Fig. 7 illustrates the positioning of the blood capillary simulator of the disclosure in an artificial human limb (arm) showing a polymer layer disposed on the arm.

Fig. 8 illustrates the positioning of the blood capillary simulator of the disclosure in an artificial human limb (arm) showing a polymer layer disposed on the arm.

Fig. 9 illustrates the positioning of the blood capillary simulator of the disclosure in an artificial human limb (arm) showing a polymer layer disposed on the arm.

DETAILED DESCRIPTION

Before the present disclosure is described in greater detail, it is to be understood that this disclosure is not limited to particular embodiments described, and as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges and are also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosure, the preferred methods and materials are now described.

All publications and patents cited in this specification are herein incorporated by reference as if each individual publication or patent were specifically and individually indicated to be incorporated by reference and are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided could be different from the actual publication dates that may need to be independently confirmed.

As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosure. Any recited method can be carried out in the order of events recited or in any other order that is logically possible.

It must be noted that, as used in the specification and the appended claims, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to “a support” includes a plurality of supports. In this specification and in the claims that follow, reference will be made to a number of terms that shall be defined to have the following meanings unless a contrary intention is apparent.

As used herein, the following terms have the meanings ascribed to them unless specified otherwise. In this disclosure, "comprises," "comprising," "containing" and "having" and the like can have the meaning ascribed to them in U.S. patent law and can mean " includes," "including," and the like; "consisting essentially of" or "consists essentially" or the like, when applied to methods and compositions encompassed by the present disclosure refers to compositions like those disclosed herein, but which may contain additional structural groups, composition components or method steps (or analogs or derivatives thereof as discussed above). Such additional structural groups, composition components or method steps, etc., however, do not materially affect the basic and novel characteristic(s) of the compositions or methods, compared to those of the corresponding compositions or methods disclosed herein.

Prior to describing the various embodiments, the following definitions are provided and should be used unless otherwise indicated.

Description

The blood capillary refill simulator of the disclosure makes use of a small pressure sensor(s) in the fingertip of the simulation arm that, when pressed, turns on a light source housed within the fingertip. When the pressure sensor(s) is released, the light will fade out

completely. A program controls the length of time it takes for the light to completely fade out. Before the simulation, the user can select a time interval in seconds for the light to fade out, which can be modified during the simulation by the operator. If the pressure sensor(s) is pressed while the fade out is occurring, the light source will restart at full brightness and fade out for the specified time interval.

The blood capillary refill simulator of the disclosure provides a dynamic method of simulating the capillary refill action in humans, including infants, adolescents, and adults. The simulator as a teaching device is capable of simulating the refill action multiple times across multiple simulations.

The present disclosure encompasses embodiments of a blood capillary refill simulator comprising an adjustable light system for dimming a light source that is activated by applying a pressure to a pressure-sensitive sensor and progressively dimmed over a selected period of time. The blood capillary refill simulator further comprises a translucent material that can replicate the compressibility or resilience and appearance of an animal tissue, and in particular the skin of a human. The translucent material, preferably a translucent polymer such as, but not limited to a silicone polymer, is positioned so that the light emitted from the light source can be observed from the surface of the material distal to the light source. Advantageous translucent polymers for use in the simulators of the disclosure include but are not limited to such as Dragon Skin.RTM (Smooth-on, Inc, PA), or any other moldable polymer that has a resilience similar to that of human skin and is translucent to allow light emitted from the light source to provide a simulation of blood capillary evacuation.

In these embodiments, when the light source is unlit, the translucent material can have the appearance of a healthy skin surface with a normal capillary flow as suggested by tinting of the polymer that approximates the hue of a skin surface. When the light source is activated as a result of pressure applied to the pressure-sensitive sensor(s) underlying the translucent material, the appearance of the distal surface of the translucent material illuminated by the light source is transformed from a tinted hue to a white, or reduced tint coloration. The change to a white area beneath the point at which the pressure is applied simulates the effect of a localized pressure to a person's skin, such as to the fleshy portion of the distal end of a finger, which compresses blood capillaries, reduces the blood in said capillaries, and significantly lightens the appearance of the skin.

Once the light source is activated, an electronic control means can regulate current applied to the light source to allow the light emission from the light source to progressively dim, simulating the return of the blood flow to the capillaries and restoring the original tint of the unilluminated translucent polymer.

Accordingly, one aspect of the disclosure encompasses embodiments of a capillary refill simulator useful for assisting hospital staff and trainees to learn how to rapidly assess whether a patient is in shock and/or suffering from another condition that can increase capillary refill time. The capillary refill simulators of the disclosure can provide variations in the dimming of the light source to simulate various conditions of a patient. For example, but not intended to be limiting, at least two pressure-sensitive sensors can be superimposed so that at one pressure one of the pressure-sensitive sensors is closed allowing one rate of light source dimming. Application of a greater pressure will also close the second pressure-sensor sensor and extend the dimming period. Alternately, a remote control means operably connected to the electronic control means can be used to select one or more dimming rates.

Referring now to Fig. 1, shown is an embodiment of the blood capillary refill simulator **1** of the disclosure comprising an adjustable light system comprising an electronic control means **2** electrically connected to two superimposed pressure-sensitive sensors **3**, two light-emitting diode (LED) light sources **4**, and a power source **5**. It is understood, however, that embodiments of the blood capillary refill simulator **1** of the disclosure can have one or more than one light source **4** and one or more than one pressure-sensitive sensor **3**. A plurality of the pressure-sensitive sensors **3** can be superimposed, as shown in Fig. 1, so that a pressure applied to one pressure-sensor sensor **3**, if increased, will further apply to the second pressure-sensor sensor **3**. The electrical control means **2** can be configured such that if one of the pressure-sensor sensors is pressure-activated dimming of the activated light source **4** occurs over a pre-determined period and if the second pressure-sensitive sensor **4** is pressure-activated, then the light source dims over a different (most advantageously extended) period.

In the embodiments of the disclosure such as shown in Figs, 1 and 2, for example, the light sources are most advantageously positioned between the pressure-sensitive sensor(s) **4** and a translucent polymer tubular housing **7** the inner surface **12** of which defines a lumen **8**. Accordingly, when the light sources **3** are activated by pressure applied to the pressure-sensitive sensors **4**, the inner surface **12** of the translucent polymer tubular housing **7** is illuminated. The light emitted by the activated light source(s) **4**, because of the translucency of the polymer, is visible in the area of the distal surface **11** of the translucent polymer tubular housing **7** closest to the light source(s) **4** and where the pressure was applied to the distal surface **11** of the translucent polymer tubular housing **7**.

Referring now to Fig. 2, shown in another embodiment of the blood capillary refill simulator **1** of the disclosure wherein the duration of the dimming of the activated light source(s) **4** is regulated by a remote controller **6** operably connected to the electronic control means **2** by a wire. For example, but not intended to be limiting, the remote controller **6** may have a toggle switch or buttons that when depressed indicate to the electronic control means

2 that the period of light source(s) **4** dimming should be increased or decreased as desired by an operator.

Referring now to Fig. 3, shown is an embodiment of the blood capillary refill simulator **1** of the disclosure wherein the duration of the dimming of the activated light source(s) **4** is regulated by a remote controller **9** operably connected wirelessly to the electronic control means **2**, said control means **2** further comprising a wireless receiver. It is further understood that the remote controller **9** can communicate wirelessly to a receiver of the electronic control means **2** by radio frequencies including by Bluetooth, infra-red frequencies, ultrasound, or any other means known in the art that allows operating instructions to be transmitted upon activation or adjustment of a switch or buttons of the remote controller **9**. For example, but not intended to be limiting, the remote controller **9** may have a toggle switch or buttons that when depressed transmit a signal to the electronic control means **2** via the wireless receiver indicating that the period of light source(s) **3** dimming should be increased or decreased as desired by an operator.

Referring to Figs. 1-3, in some embodiments of blood capillary refill simulator **1** of the disclosure, the translucent polymer tubular housing **7** can be a tube defining a lumen **8** that can house the light source(s) **4**, the pressure-sensitive sensor(s) **3**, and, optionally, the electrical control means **2**, and a power source **5**. When configured as a tube, at least one end of the tube can be closed. The translucent polymer tubular housing **7** may be a molded tube that has the shape of an anatomic simulator, advantageously, but not limited to, a replica of a human digit (finger) as shown, for example, in Fig. 4. In the embodiment shown in Fig. 4, the light source(s) **4** can be positioned such that when activated they illuminate the area of the molded digit simulating the fleshy tip of the finger. In some embodiments, the translucent polymer tube may be molded at least in the form of a palm of a hand simulator to allow simulating a blood capillary refill time of the fleshy regions of the palm of a hand. In some embodiments, the blood capillary refill simulator **1** can be placed within the forearm region of replica arm, as shown in Figs. 7-9 to allow the determination of a blood capillary refill time of the skin tissues of a forearm. It is further understood, however, that the blood capillary refill stimulator **1** may be located anywhere within a replica of the human body, including but not limited to the anatomic features of a hand, arm, leg, torso, neck, and the like, to replicated the capillary refill of any region of the body. It is further understood that in some embodiments of the blood capillary refill simulator **1** of the disclosure, the adjustable lighting system may be embedded in a translucent polymer that can be molded to conform to the shape of a human finger, arm or other region of the body.

In some embodiments of the blood capillary refill simulator, the translucent polymer **7** may be a sheet supported by a support frame **10** over the light source(s) **4** as shown in Fig. 5.

Accordingly, in embodiments of the blood capillary refill simulator **1** of the disclosure, as shown in Figs. 7-9, the blood capillary refill simulator **1** can be inserted into a forearm region of a replica arm by any means known to one of skill in the art such as, for example, by cutting into the model arm and generating a cavity to receive the light source(s) **4**, pressure-sensitive sensor(s) **3**, power source **5** and, optionally, the electronic control means **2**. The blood capillary refill simulator **1** may be concealed by an outer skin layer that protects and dissipates the light in a realistic manner to simulate the area of the forearm to which the pressure is applied. A zipper may also applied to this outer layer polymer to allow for easier access to implementing the simulation as well as to make it easier for operators to remove or replace the simulator. In other embodiments, the blood capillary refill simulator **1** of the disclosure can be placed beneath a translucent polymer skin simulation at any point of a human mannequin.

An example of an electronic control circuit for use with two pressure-sensitive sensors **3** (as shown, for example, in Fig. 6) contained within the electronic control means **2** may comprise, but are not limited to, two 10 M Ω resistors, two 500Ω resistors, and three 470 mF capacitors. The electronic circuit is operably connected to both the pressure-sensitive sensors **3** and the LEDs **4**. When pressure is applied to the translucent polymer **7** immediately above the superimposed pressure-sensitive sensors **4** one of the two states of blood refill time will be activated depending on the current simulation state. The capacitors are the components that slow the damping of the light when the pressure-sensor sensor **4** is released and a remote switch **6** can toggle between if a slow or normal refill. The 500 Ω resistors regulate the brightness of the LEDs **3** while the 10 M Ω resistors allow current to flow through the remote switch **6** at all times.

Illumination of the light source(s) **4** initially provides a light of an intensity that overwhelms the tint of the translucent polymer to provide an illuminated area of the translucent polymer surface **11** that visually simulates what can be observed when, for example, one fingertip is pressed against the fleshy region of a second fingertip to expel blood from underlying capillaries thereof. Releasing the pressure applied to the polymer then allows the electronic control means **2** to progressively dim the illuminated light source(s) **4** to gradually restore the original observable tint of the polymer. The gradual light diminution and concomitant restoration of the polymer tinting simulates return of blood to evacuated capillaries.

In some embodiments of the disclosure, the electronic control means **2** may be adjusted to provide a progressive diming of the illumination over any desired period, including, but not limited to, from about 0 to about 30 seconds, from about 0 to about 20 seconds, from about 0 to about 10 seconds, from about 0 to about 5 seconds, from about 0

to about 3 seconds, from about 0 to about 2 seconds, etc. In some embodiments the instruction to adjust the light source dimming can be by the amount of pressure applied to the translucent polymer overlaying a pressure-sensitive sensor and/or whether the applied pressure activated one or more than one pressure-sensitive sensor. In other embodiments, the electronic control means **2** can comprise a wireless receiver configured for receiving a radio signal to allow remote adjustment of the light source dimming period and a remote regulatory signal emitter configured to communicate with the wireless receiver. In this embodiment, advantageously, an operator may adjust the simulated blood refill time while not being in the immediate vicinity of the blood refill simulator.

A power source **5** advantageous for use with the blood capillary refill simulator 1 of the disclosure can be any known in the art, including, but not limited to, a battery, a wired connection to a mains electrical outlet, a solar-generated power supply, and the like.

Light source(s) **4** useful in the blood capillary refill simulator **1** of the disclosure can be any light source known in the art that can provide a light of intensity sufficient to overcome the tinting of the translucent polymer and provide a visible whitening of the polymer in a region of the polymer over the light source. While an incandescent light bulb can be the light source **4**, the heat generated may damage or destroy the integrity of the translucent polymer material.

Accordingly, the most advantageous light source **4** for use in the simulators of the disclosure is a light-emitting diode (LED), or an ordered array of such LEDs, that emits visible light but with little, if any, heat generation. In some embodiments of the disclosure, the LED, or array of LEDs, emits what is perceived as a white light. In other embodiments, however, the LEDs may be selected for the emission of a single color or a plurality of colors, either simultaneously or successively, to provide variation in the visual appearance of the illuminated translucent polymer.

Translucent polymers useful for providing a simulated skin can be any resilient polymer well known in the art that, when a pressure is applied, can transfer the force to an underlying pressure-sensitive sensor. When the applied pressure is removed, the translucent polymer reverts to its original dimensions. Advantageously, the translucent polymer has a degree of resilience that approximates that of a human skin. In some embodiments, the translucent polymer has a resilience that approximates that of a human fingertip. When it is desired to illustrate or simulate blood capillary refill at another point of the human anatomy, a translucent polymer may be selected that most closely simulates that of the desired skin surface.

The translucent material used in the blood capillary simulators of the disclosure, while allowing the light emission from the underlying light source to be visible through the polymer, may also be tinted to replicate a tissue having an undisturbed blood flow. While the

polymer can be tinted to have a pink, rose, or flesh-colored hue, when the simulator is required to show capillary refill of injured tissue, the tint or hue can be, for example, blue, blue-gray, violet, yellow, or any combination thereof to replicate a bruised area of skin. Most advantageous, the translucent polymer is tinted such that when the light source is activated, the intensity of light produces a visible lightening of the polymer distinct from the tinted color of the polymer. Hence, a dimming of the light emission visibly restores the tint color, replicating blood flow back into the skin.

Due to limitations when molded to scale, and especially if the molded digit is intended to represent that of a child, it is advantageous to position the electronic control means **2** and power source **5** distant from the molded finger. However, in other embodiments, the molded finger can be attached to an arm replica or a human-like mannequin, wherein the control means **2** also may be disposed in the arm or mannequin, as shown, for example, in Figs. 4 and 7-9.

Embodiments of the digital finger, arm or mannequin may include a hollow space defined by the translucent polymer or the polymer can embed, i.e. surround and be in contact with, the light source(s) **4**, pressure-sensitive sensor(s) **3**, and optionally the electronic control means **2** and the power source **5**. It is understood, however, that in all of the embodiments of the disclosure, the means necessary for operably connecting the electrically powered elements of the blood capillary refill simulator **1**, such as the pressure-sensitive sensor(s) **3**, the light source **4**, etc. including but not limited to wires are also disposed beneath or embedded in the translucent polymer material.

In an advantageous embodiment of the blood capillary refill simulator of the disclosure, a pressure-sensitive sensor(s) **3** is disposed in the fingertip of a digit of a human limb simulator. Further incorporated is an electronic control means **2** such as, but not limited to, an Arduino board and software that allow an operator such as an instructor to adjust the simulated capillary refill time remotely using an adjustable switch **9** communicating with the Arduino board via such as a Bluetooth link. Using Bluetooth as a simulation communication mechanism has the advantage of safety in the presence of nearby sensitive devices since low-power signals are typically used in its communication protocol. Bluetooth is also not limited by line-of-sight required by some communication protocols. Thus, a medical professional who is acting as the operator or teacher can change the simulation conditions while being in a different area of a room or in another room. Furthermore, the Bluetooth protocol disallows another device from listening in once a connection is made. Accordingly, multiple devices can be used in close proximity without disrupting previously paired devices.

Some embodiments of the blood capillary refill simulator **1** of the disclosure, therefore, can include a mini-arduino module that contains code that can cycle through a range of capillary refill times selected at the discretion of an operator. A range of times can

be programmed into the device, from about a 1 second fade time to, for example, about 10 or more seconds of fade time. The mini-arduino is operably connected to a pressure sensor(s) **3** that returns an electrical output defined by the resistance value of the pressure sensor(s).

In operation, as pressure increases, resistance increases and the light source is turned on. The arduino module for the model appendage is embedded in the model arm and enclosed in a protective housing. The light source such as an LED and the pressure sensor(s) combination can be embedded in a resilient, preferably translucent, material such as silicone that is molded, for example, in the shape of a finger. The molded digit optionally is attached to or is molded integrally with the hand of a model arm.

The mini-arduino module can be connected to a control means **2** via a bluetooth module. The controller can employ a controlling means such as, but not limited to, a joystick for switching between a pre-defined range of refill values. Advantageously, this embodiment can allow variation of the time of fading of the light source light over a wide range of values to simulate the capillary refill under a variety of physiological or pathological conditions.

Accordingly, one aspect of the disclosure encompasses embodiments of a blood capillary refill simulator comprising an adjustable lighting system, wherein the lighting system can comprise: at least one pressure-sensitive sensor operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, and a translucent polymer positioned to be illuminated by the light source.

In some embodiments of this aspect of the disclosure, the light source can be a light-emitting diode (LED) or an array of LEDs.

In some embodiments of this aspect of the disclosure, the light source when activated can emit a white light, a non-white light, or a combination thereof.

In some embodiments of this aspect of the disclosure, the lighting system can comprise a plurality of superimposed pressure-sensitive sensors.

In some embodiments of this aspect of the disclosure, the light source can be positioned between the translucent polymer and the at least one pressure-sensitive sensor.

In some embodiments of this aspect of the disclosure, the translucent polymer can be a sheet attached to a support means.

In some embodiments of this aspect of the disclosure, the translucent polymer can be configured as a tube defining a lumen, wherein the at least one pressure-sensitive sensor and the light source can be disposed in the lumen of the tube.

In some embodiments of this aspect of the disclosure, the at least one pressure-sensitive sensor and the light source can be embedded in the translucent polymer.

In some embodiments of this aspect of the disclosure, the at least one pressure-sensitive sensor and the light source are disposed in a human digit simulator. In some embodiments of this aspect of the disclosure, the human digit simulator can be attached to a human arm simulator or a human mannequin.

In some embodiments of this aspect of the disclosure, the at least one pressure-sensitive sensor, the light source, and the electronic control means are disposed in a human arm simulator or mannequin, and wherein the translucent polymer is a region of skin of the human arm simulator or mannequin.

In some embodiments of this aspect of the disclosure, the electronic control means can comprise a computer-controlled electronic circuit configured for regulating at least one of the intensity and duration of the light emitted by the light source.

In some embodiments of this aspect of the disclosure, the electronic control means can further comprise a wireless receiver and a remote wireless signal emitter configured for remotely adjusting at least one of the intensity and duration of the light emitted by the light source.

Another aspect of the disclosure encompasses embodiments of a blood capillary refill simulator comprising an adjustable lighting system, wherein the adjustable lighting system comprises: at least two superimposed pressure-sensitive sensors operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, and wherein the blood capillary refill simulator further comprises a translucent polymer material positioned to be illuminated by the light source, wherein: (i) the light source can be superimposed over at least one of the pressure-sensitive sensors; (ii) the lighting system can be within a human anatomical simulator and the translucent polymer layer is disposed over the light source, and (iii) the duration of illumination of the translucent polymer is adjustable by the amount of pressure applied to the at least two superimposed pressure-sensitive sensors.

In some embodiments of this aspect of the disclosure, the light source is a light-emitting diode (LED) or an array of LEDs.

Yet another aspect of the disclosure encompasses embodiments of a blood capillary refill simulator comprising an adjustable lighting system, wherein the adjustable lighting system comprises: at least one pressure-sensitive sensor operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, wherein the electronic control means further comprises a wireless receiver configured for receiving a signal controlling the intensity and duration of light emission from the light source, and a remote regulatory signal emitter configured to communicate with the wireless receiver, and wherein the blood capillary refill simulator further comprises a translucent polymer material positioned to be illuminated by

the light source, wherein: (i) the light source is superimposed over the pressure-sensitive sensor(s); (ii) the lighting system is at least partially enclosed by a human anatomical simulator having the translucent polymer layer disposed over the light source, and (iii) the duration of illumination of the translucent polymer is adjustable by a signal transmitted from the remote regulatory signal emitter to the electronic control means.

In some embodiments of this aspect of the disclosure, the signal emitted from the remote regulatory signal emitter can be a radio frequency, a visible or infra-red light frequency, or a sound wave.

In some embodiments of this aspect of the disclosure, the light source can be a light-emitting diode (LED) or an array of LEDs

In some embodiments of this aspect of the disclosure, the human anatomic simulator can be a finger simulator.

In some embodiments of this aspect of the disclosure, the pressure-sensitive sensor, the light source, the power source, and the electronic control circuit can be embedded in the translucent polymer configured as a human anatomic simulator.

CLAIMS

We claim:

1. A blood capillary refill simulator comprising an adjustable lighting system, wherein the lighting system comprises:

at least one pressure-sensitive sensor operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, and

a translucent polymer material positioned to be illuminated by the light source.

2. The blood capillary refill simulator of claim 1, wherein the light source is a light-emitting diode (LED) or an array of LEDs.

3. The blood capillary refill simulator of claim 1, wherein the light source when activated emits a white light, a non-white light, or a combination thereof.

4. The blood capillary refill simulator of claim 1, wherein the lighting system comprises a plurality of superimposed pressure-sensitive sensors.

5. The blood capillary refill simulator of claim 1, wherein the light source is positioned between the translucent polymer and the at least one pressure-sensitive sensor.

6. The blood capillary refill simulator of claim 1, wherein the translucent polymer is a sheet attached to a supporting means.

7. The blood capillary refill simulator of claim 1, wherein the translucent polymer is configured as a tube defining a longitudinal lumen, wherein the at least one pressure-sensitive sensor and the light source are disposed in the lumen of the tube.

8. The blood capillary refill simulator of claim 1, wherein the at least one pressure-sensitive sensor and the light source are embedded in the translucent polymer.

9. The blood capillary refill simulator of claim 1, wherein the at least one pressure-sensitive sensor and the light source are disposed in a human digit simulator.

10. The blood capillary refill simulator of claim 9, wherein the human digit simulator is attached to a human arm simulator or a human mannequin.

11. The blood capillary refill simulator of claim 1, wherein the at least one pressure-sensitive sensor, the light source, and the electronic control means are disposed in a human arm simulator or mannequin, and wherein the translucent polymer is a region of skin of the human arm simulator or mannequin.

12. The blood capillary refill simulator of claim 1, wherein the electronic control means comprises a computer-controlled electronic circuit configured for regulating at least one of the intensity and duration of the light emitted by the light source.

13. The blood capillary refill simulator of claim 1, wherein the electronic control means further comprises a wireless receiver and a remote wireless signal emitter configured for remotely adjusting at least one of the intensity and duration of the light emitted by the light source.

14. A blood capillary refill simulator comprising an adjustable lighting system, wherein the lighting system comprises:

at least two superimposed pressure-sensitive sensors operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, and

wherein the blood capillary refill simulator further comprises a translucent polymer material positioned to be illuminated by the light source, and wherein:

(i) the light source is superimposed over at least one of the pressure-sensitive sensors;

(ii) the lighting system is within a human anatomical simulator having a translucent polymer layer disposed over the light source, and

(iii) the duration of illumination of the translucent polymer is adjustable by the amount of pressure applied to the at least two superimposed pressure-sensitive sensors.

15. The blood capillary refill simulator of claim 14, wherein the light source is a light-emitting diode (LED) or an array of LEDs.

16. The blood capillary refill simulator of claim 14, wherein the human anatomic simulator is a finger simulator.

17. The blood capillary refill simulator of claim 14, wherein the pressure-sensitive sensors, the light source, the power source, and the electronic control means are embedded in the translucent polymer configured as a human anatomic simulator.

18. A blood capillary refill simulator comprising an adjustable lighting system, wherein the lighting system comprises:

at least one pressure-sensitive sensor operably connected to a light source, a power source, and an electronic control means for regulating the intensity and duration of light emission from the light source, wherein the electronic control means further comprises a wireless receiver configured for receiving a signal controlling the number of operable pressure-sensitive sensors, and a remote regulatory signal emitter configured to communicate with the wireless receiver, and

wherein the blood capillary refill simulator further comprises a translucent polymer material positioned to be illuminated by the light source, and wherein:

(i) the light source is superimposed over the pressure-sensitive sensors;

(ii) the lighting system is at least partially enclosed by a human anatomical simulator having the translucent polymer layer disposed over the light source, and

(iii) the duration of illumination of the translucent polymer is adjustable by a signal transmitted from the remote regulatory signal emitter to the electronic control means.

19. The blood capillary refill simulator of claim 18, wherein the signal emitted from the remote regulatory signal emitter is a radio frequency, a visible or infra-red light frequency, or a sound wave.

20. The blood capillary refill simulator of claim 18, wherein the light source is a light-emitting diode (LED) or an array of LEDs.

21. The blood capillary refill simulator of claim 18, wherein the human anatomic simulator is a finger simulator.

22. The blood capillary refill simulator of claim 18, wherein the pressure-sensitive sensors, the light source, the power source, and the electronic control means are embedded in the translucent polymer configured as a human anatomic simulator.

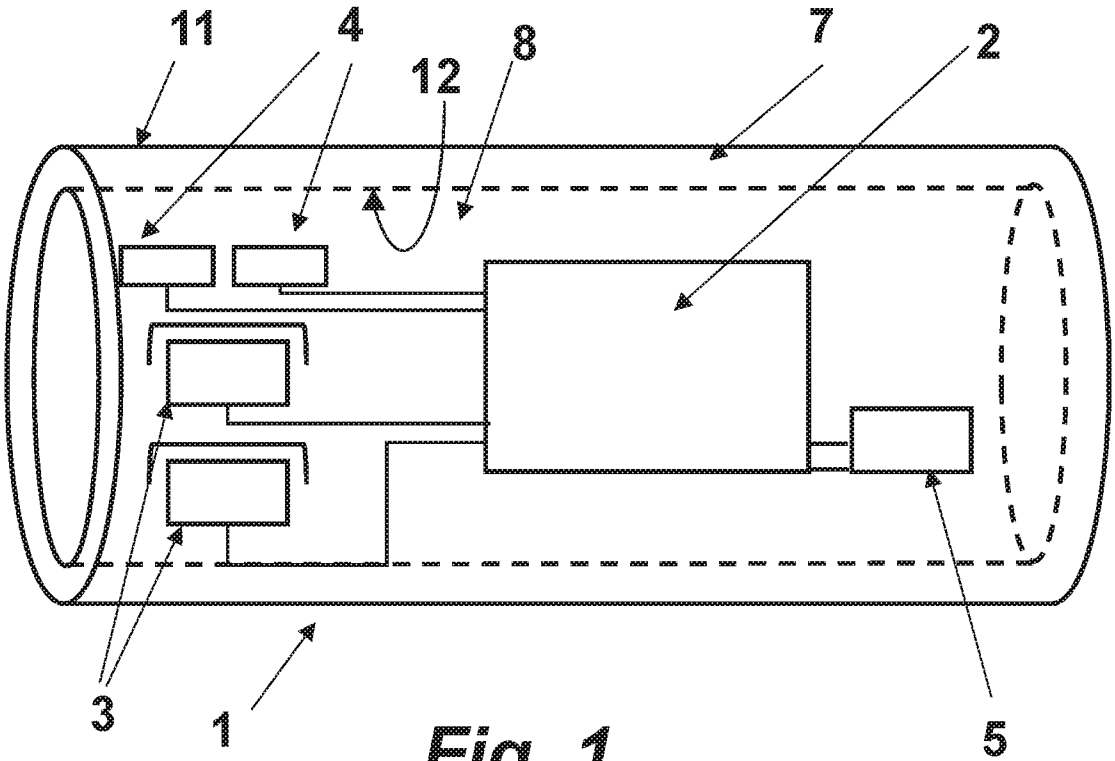


Fig. 1

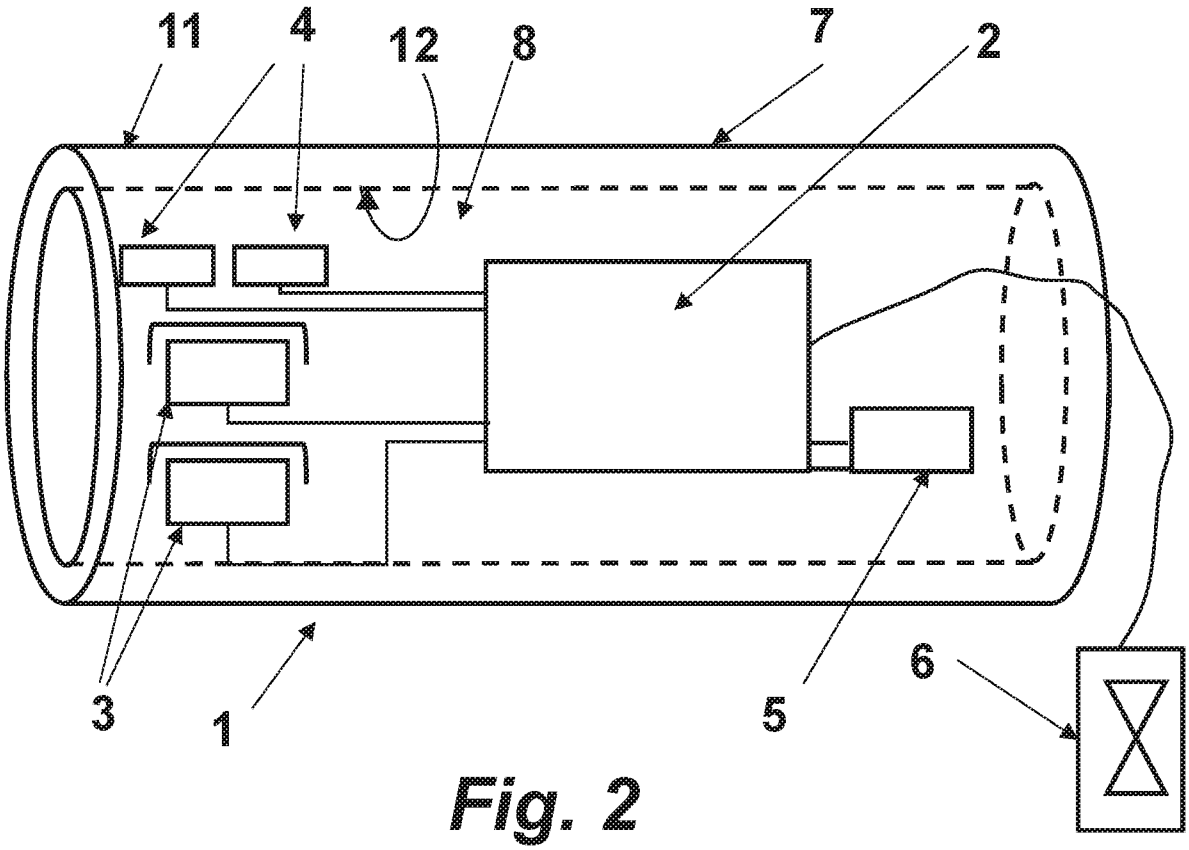


Fig. 2

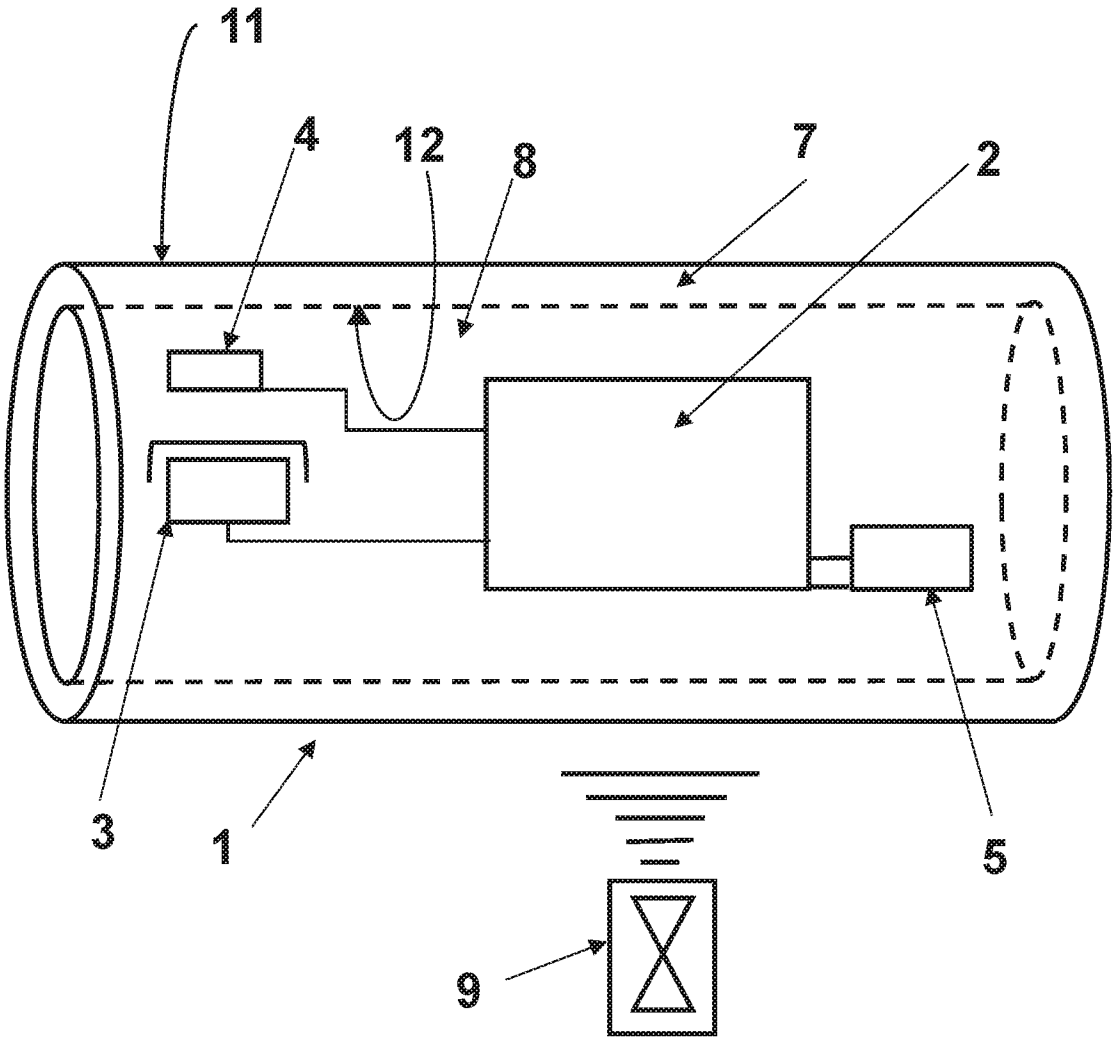


Fig. 3

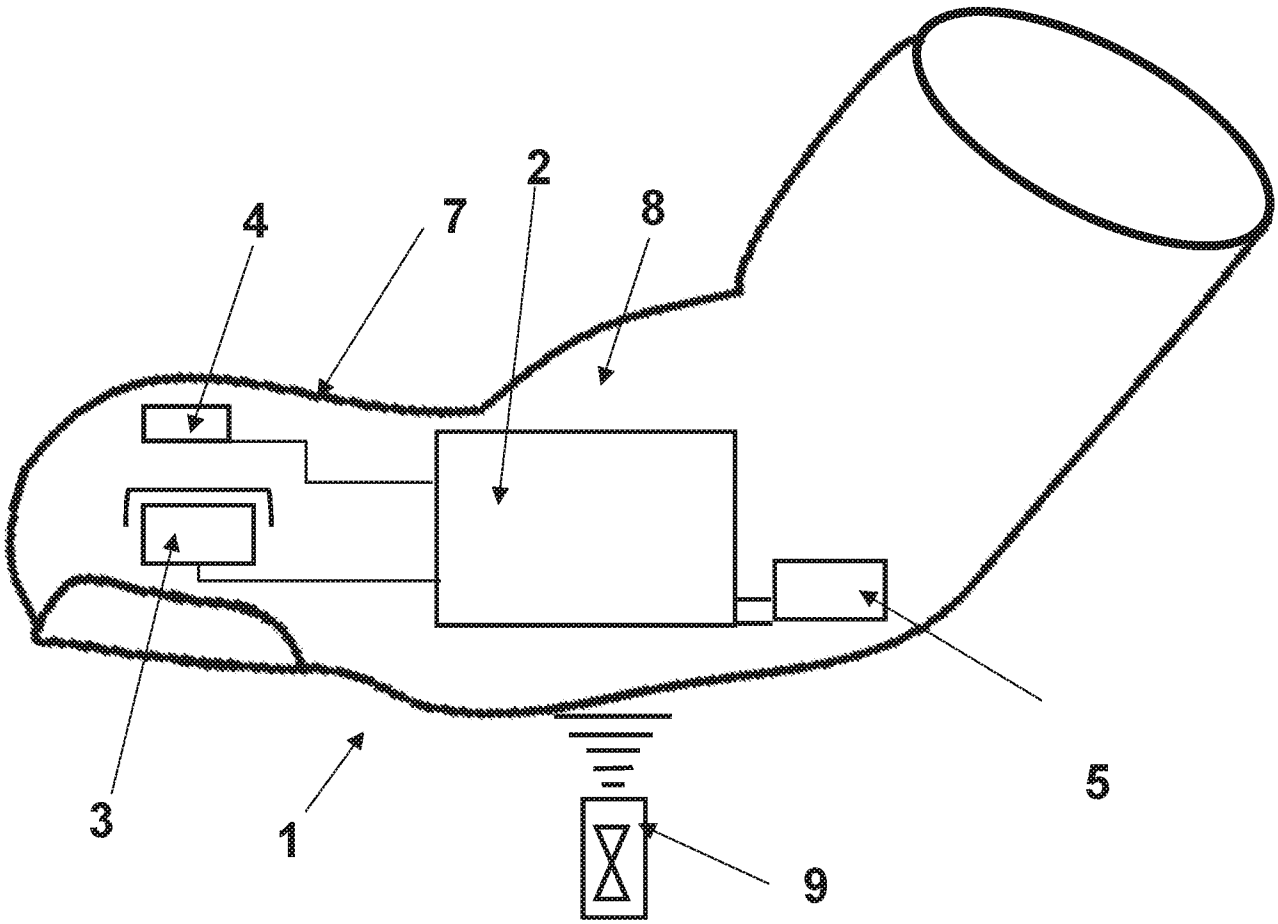


Fig. 4

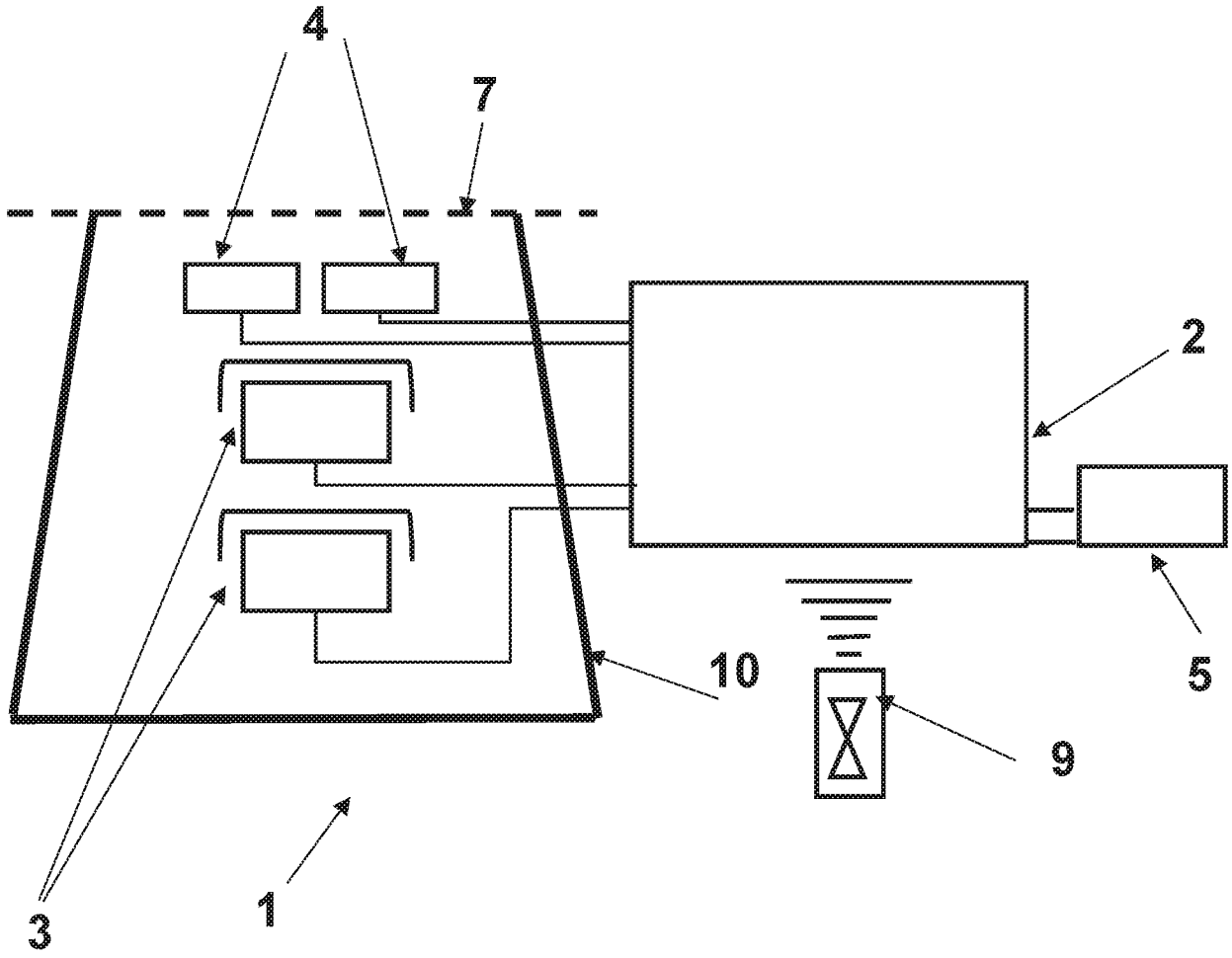


Fig. 5

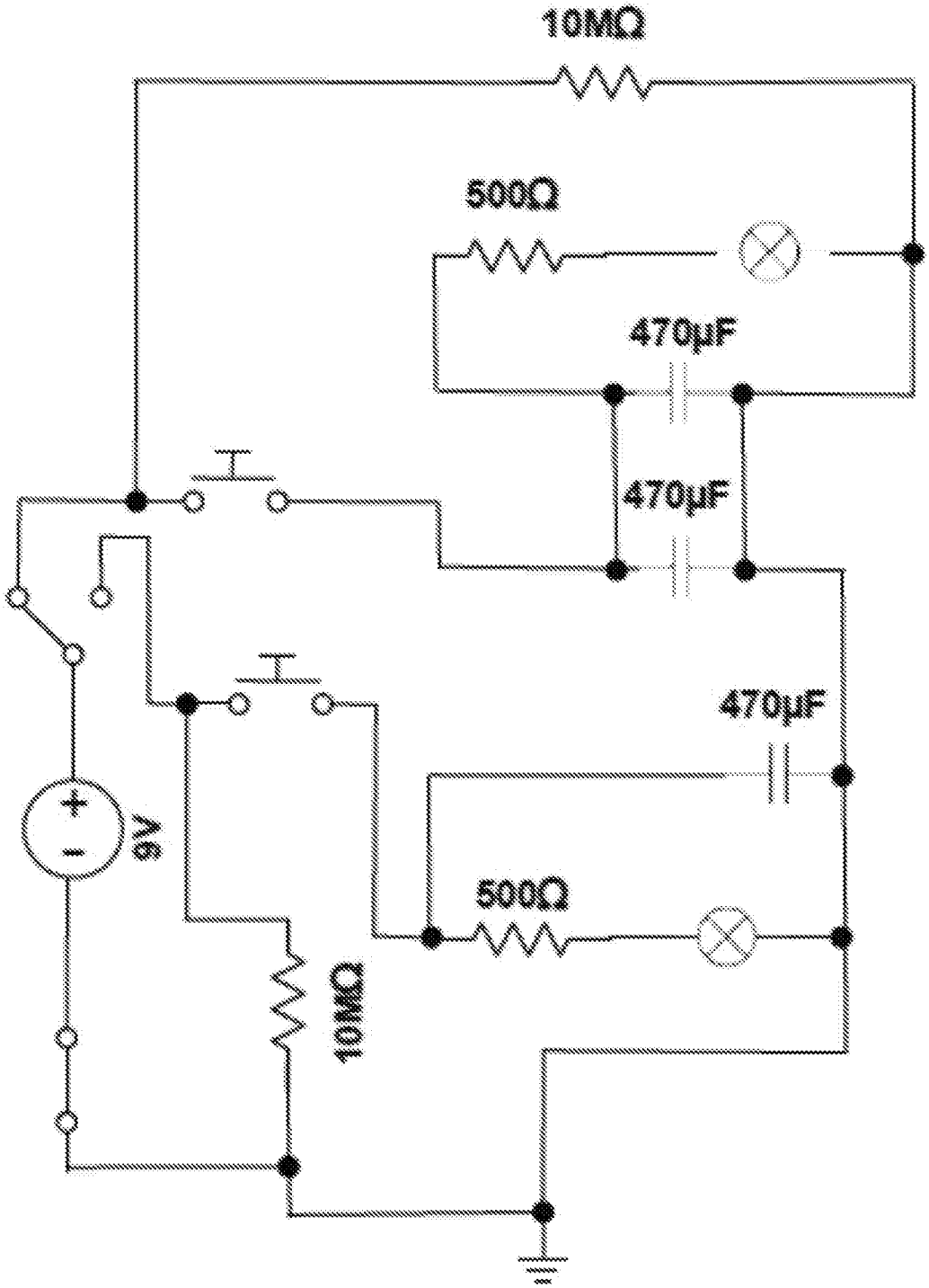


Fig. 6

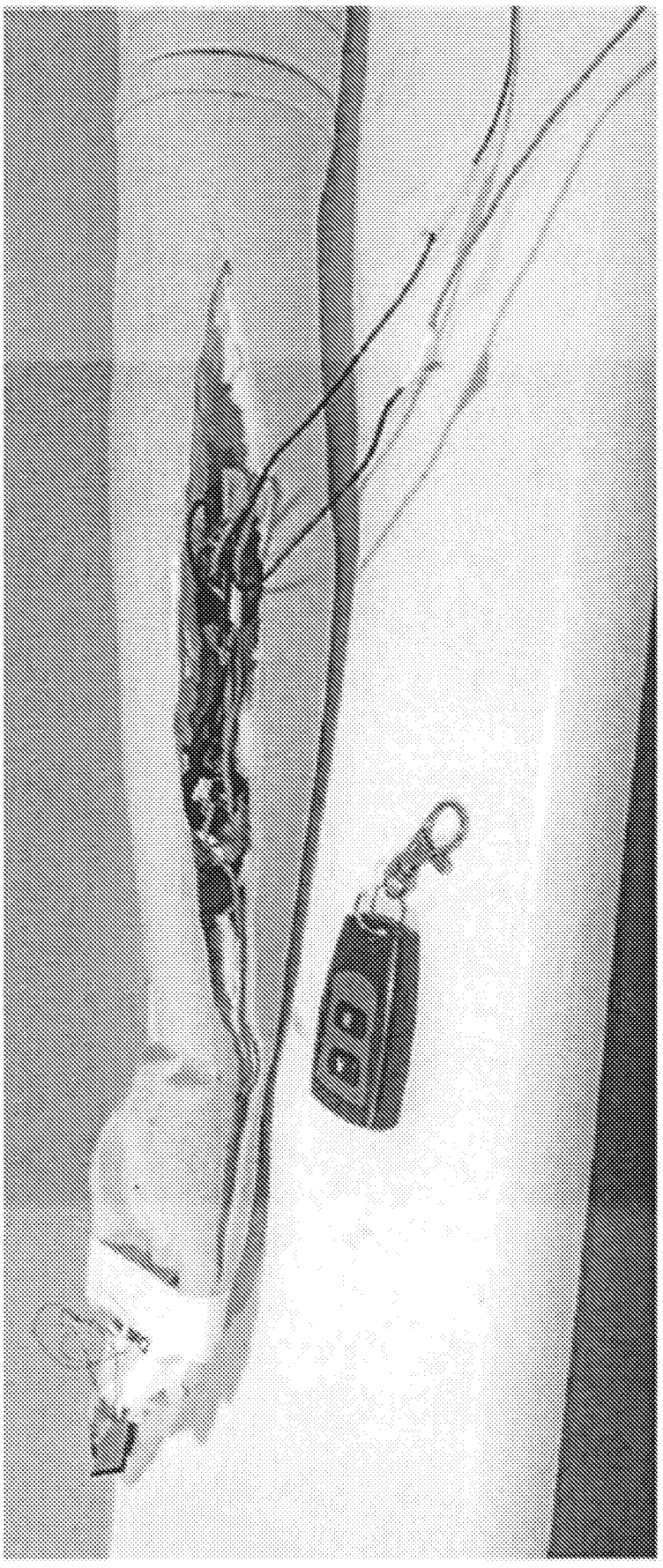


Fig. 7



Fig. 8



Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 18/31568

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - G09B 23/28, G09B 23/30, G09B 23/34 (2018.01)
CPC - G09B 23/28, G09B 23/30, G09B 23/303, G09B 23/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	US 2009/0011394 A1 (MEGALN et al.) 08 January 2009 (08.01.2009), entire document, Fig. 2, Fig. 3, Fig. 5, para [0031], [0036], [0044]-[0045], [0062]	1-13 --- 14-22
Y --- A	WO 2014/176496 A1 (UAB RESEARCH FOUNDATION) 30 October 2014 (30.10.2014), entire document, Fig. 1, Abstract, page 2, ln 3-12, page 6, ln 27-28	1-13 --- 14-22
Y --- A	US 2011/0223573 A1 (MILLER et al.) 15 September 2011 (15.09.2011) entire document, para[0054], para [0056]	13 --- 18-22
A	US 8,827,720 B1 (LAZARUS et al.) 09 September 2014 (09.09.2014), entire document	1-22
A	Todd P. Chang et al., "Use of a Novel, Portable, LED-Based Capillary Refill Time Simulator within a Disaster Triage Context" Prehospital and Disaster Medicine 27 March 2017 (27.03.2017), entire document	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 July 2018	02 AUG 2018
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774