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2928365

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(54) **CSF SHUNT FLOW EVALUATION APPARATUS USING A CONFORMABLE EXPANDED DYNAMIC RANGE THERMOSENSOR**

CSF-SHUNT-FLUSSAUSWERTUNGSVORRICHTUNG MIT EINEM KONFORMEN THERMOSENSOR MIT ERWEITERTEM DYNAMIKBEREICH

APPAREIL D'ÉVALUATION D'ÉCOULEMENT DE DÉRIVATION DE LIQUIDE CÉPHALO-RACHIDIEN ET UTILISATION D'UN CAPTEUR THERMIQUE DE PLAGE DYNAMIQUE EXPANSÉE ADAPTABLE

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EP 2 928 365 B1

Description

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This PCT application claims the benefit under 35 U.S.C. §119(e) of Provisional Application Serial No. 61/797,389 filed on December 6, 2012 entitled EXPANDED DYNAMIC RANGE CSF SHUNT FLOW THERMOSENSOR AND TEST PACK and also claims the benefit under 35 U.S.C. §119(e) of Provisional Application Serial No. 61/960,026 filed on September 9, 2013 entitled CONFORMABLE EXPANDED DYNAMIC RANGE CSF SHUNT FLOW THERMOSENSOR.

BACKGROUND OF THE INVENTION

1. FIELD OF INVENTION

[0002] This present invention generally relates to cerebrospinal fluid (CSF) shunts and, more particular, to a device and method for testing for the presence, absence and/or rate of CSF flow through shunt tubing implanted under the skin in hydrocephalus patients.

2. DESCRIPTION OF RELATED ART

[0003] Hydrocephalus is a condition of abnormal cerebrospinal fluid (CSF) homeostasis, resulting in an accumulation of CSF in the brain ventricles. Approximately 69,000 people are diagnosed with hydrocephalus each year in the United States, most commonly as a congenital condition, making it one of the most common birth defects. Untreated hydrocephalus leads to progressive neurological dysfunction and death.

[0004] The most commonly used treatment for hydrocephalus is diversion of CSF from the ventricles to the peritoneal cavity by means of a permanent prosthetic shunt. A CSF shunt is comprised of a valve connected to a tube. The proximal end of the tube is surgically inserted into the ventricle of the brain, and runs subcutaneously through the body into the abdominal cavity (Fig. 1). There are approximately 300,000 shunted hydrocephalus patients in the US. 41,000 shunt procedures are performed each year, approximately 12,000 of which are new shunt placements.

[0005] Improved materials, diagnostic, and treatment technologies, have improved shunt therapy since the 1970s. However, shunt failure is still almost inevitable during a patient's life. The one-year failure rate of ventriculoperitoneal shunts has been estimated to be approximately 40% , and the mean period to failure of an implanted shunt is typically only 5-10 years. Obstruction of the ventricular catheter, usually from tissue ingrowth or clots, is overwhelmingly the greatest cause of shunt failure. Shunt failure can rapidly progress to life-threatening elevation in intracranial pressure, so revision surgery, and re-placement of the blocked ventricular catheter is indicated. More than half of all shunt procedures in the United States are revisions.

[0006] However, since catheter replacement surgery carries risks of life-threatening complications such as infection or embolism, a need for shunt revision needs to be reasonably established. The problem is that the usual clinical manifestations of shunt failure, such as headaches, vomiting, or loss of vision, are non specific and are difficult to differentiate from common, less serious illnesses, particularly in pediatric patients. This leads to two extremes of management: patient families who present persistently at emergency rooms for every headache or flu symptom, and patient families who dangerously dismiss symptoms of a shunt blockage as a common ailment. A study at the Children's Hospital of Philadelphia (CHOP) indicates that they see three false alarms for every true shunt malfunction. There is a need for objective methods to evaluate suspected shunt obstruction.

[0007] An unacceptably high number of hydrocephalic children still die as a result of shunt malfunction, primarily because of a failure to identify shunt blockage at an early stage. The early diagnosis of shunt obstruction is complex and difficult. While a number of shunt flow detection methods are available, none are diagnostic when used alone or are without complication, and there is little standardization to guide physicians in their interpretation (Table 1). Physical examination of the patient, including pumping of the shunt reservoir, is unreliable. Measuring CSF pressure by "shunt tap" is invasive, painful, and can be misleading. CT and MR, either alone, or in combination with plain radiographs, remain the gold standards for diagnosis of shunt malfunction. However, these imaging techniques are static, and so must be performed multiple times to detect ventricular enlargement. This results in repeated radiological exposures of patients (often children), a safety concern for pediatric neurosurgeons. Furthermore, the reliability of these techniques for detecting CSF accumulation has been questioned. For a while, radionuclide markers were widely used to derive truly dynamic information about CSF flow in the brain and in shunts. However, their promise was never wholly realized, and they are not routinely utilized in most clinical settings. Because of the expense and technical complexity of advanced imaging techniques, they cannot be used to investigate every headache.

Table 1			
Diagnostic Procedure	**Sensitivity** (Detecting No Flow)	**Specificity** (Detecting Flow)	**Features**
Static Imaging Procedures			
CT Scan [36]	68%	90%	Expensive, time-consuming, radiation dose. Shunt malfunction must have gone on long enough for the scan to detect visible changes, i.e. ventricle enlargement. Rising concern about radiation.
X-ray Series [36]	27%	99%	Expensive and time-consuming. As with CT, the shunt must have malfunctioned long enough for visible changes to be detected.
Dynamic Flow Measurements			
Shunt Tap [37]	79%	56%	Method is painful, risks infection and can be inconclusive if blockage is upstream of the tap area.
Radio Isotope [38]	80%	53%	Requires an invasive shunt tap and 24 hours lead time for isotope. This method is considerably more involved than either the CT or MRI.

[0008] Table 1: Performance of Commonly-Used Diagnostic Procedures for Suspected CSF Shunt Obstruction

[0009] The current, non-invasive imaging procedures have relatively low sensitivity and better specificity - making them reasonable rule-in tests but poor rule-out tests. The invasive procedures are somewhat better rule-out tests, but are painful and present an infection risk. Furthermore, children are often sent to CT Scans, the most commonly used procedures, when they present to the ER and such repeat exposure to radiation may be harmful. What is needed is a simple and reliable method for determining CSF shunt flow rates that can be interpreted by neurosurgeons and non-neurosurgeons with equal confidence.

[0010] To meet the need for rapid and sensitive methods for determining shunt function, Applicant has developed a method to allow non-invasive detection of cerebrospinal fluid flow through subcutaneous shunts under the rubric "Shunt-Check."ShuntCheck involves devices using thermal dilution technology - detecting a transcutaneous change in temperature as cooled cerebrospinal fluid flows through the subcutaneous portion of a ventriculoperitoneal shunt. See U.S. Patent Application No. 2013/0109998, owned by the same Applicant as the present application, namely, ShuntCheck, Inc. As shown most clearly in Fig. 2A, one early version 10 of ShuntCheck, namely, "ShuntCheck v2.2", comprises a single use disposable thermosensor 12 which is placed on the skin 11 over a subcutaneous shunt 13; a personal digital assistant (PDA)-based BioDisplay 14 which includes an A/D converter for converting and conditioning the analog sensor signal into digital signal; this PDA-based BioDisplay includes ShuntCheck software which analyzes temperature data from the thermosensor and provides a time-temperature graph and a flow or no-flow result. Side 12A of the thermosensor 12 faces upward when placed against the skin 11 and side 12B (Fig. 2B) is adhesively secured to the skin 11, once a release strip 15 is removed. ShuntCheck also includes the "Micro-Pumper" (see Figs. 2C and 2D), a device which generates a temporary increase in CSF flow in patent, but not in occluded CSF, shunts. See U.S. Patent Publication No. 2013/0102951, also owned by ShuntCheck, Inc..

[0011] As shown in Fig. 2D, the Micro-Pumper 300 is hand-held device that is positioned against the skin 11 over the dome portion 210 of the CSF shunt's valve 211; the valve 211 is typically implanted over bone 220 of the patient's skull. A foot 301 having short rods 302 is reciprocated against the dome 210 by a Micro-Pumper drive system (Fig. 2C) including a shaft 306, a spring 305, a piston 304 and a cam 307 driven by a motor (not shown).

[0012] As shown in Fig. 2B, the thermosensor 12 comprises a plurality of temperature sensors TS (e.g., thermistors, e.g., GE thermistors, by way of example only) and is adhesively placed on the skin 11 where the shunt 13 crosses the clavicle. Ice 17 (or, e.g., ice within a receptacle) is placed on the skin, "upstream" of the CSF flow (viz., in window 19) from the plurality of temperature sensors 17, to cool the CSF in the shunt 11. Temperature sensors TS placed over the shunt 13 detect the change in temperature as cooled fluid flows beneath them. The presence of flowing fluid is interpreted as a decrease in temperature detected by the temperature sensors TS, while no change in temperature indicates the

absence of flow. The ShuntCheck method/devices can assess the rate of CSF fluid flow through shunts. The temperature drop recorded by ShuntCheck method/devices varies linearly with flow rate-the deeper the temperature drop, the faster the flow (see Fig. 3).

[0013] Further testing of the thermosensor 12 determined that intermittent CSF flow is likely to be a limiting factor on specificity performance of any method in which shunt patency or obstruction is being inferred from fluid flow measurements. As a result, the Micro Pumper was developed. As discuss previously, the Micro Pumper 300 is a miniature, non-invasive device which is held against the shunt valve (which is typically implanted under the scalp behind the ear) and which provides a specific vibration pulse to the valve. The vibration pulses act like a manual shunt pumping in miniature and generate a temporary increase in shunt flow through patent, but not through occluded shunts. However, in certain instances flows enhanced by use of the Micro Pumper 300 resulted in flows beyond the detection of the ShuntCheck v 2.2 device

[0014] Document WO 2011/146757 (A2) discloses a similar sensor pad provided with insulated means to apply thermal therapy.

[0015] Thus, there remains a need for an improved thermosensor design and a new method for providing thermal dilution cooling which permits the non-invasive detection of cerebrospinal fluid flow through subcutaneous shunts.

BRIEF SUMMARY OF THE INVENTION

[0016] A sensor pad is disclosed which is adapted for releasable application to the skin of a patient having a subcutaneous cerebrospinal fluid (CSF) shunt having CSF that flows from an upstream location in the patient towards a downstream location and also wherein the sensor pad is also adapted for use with a cerebrospinal fluid (CSF) analyzer. The sensor pad comprises: a body (e.g., an EVA foam) comprising a plurality of temperature sensors (e.g., NTC thermistors) that are positioned transversely across the body at predetermined positions, wherein the plurality of temperature sensors are aligned such that when the sensor pad is applied to the skin over the CSF shunt, one of the plurality of temperature sensors is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt; the body further comprises an alignment member that protrudes from an edge of the pad, wherein the alignment member acts as a guide for a user in positioning a cold source (e.g., an instant ice pack, 3" x 3" or larger) against the skin of the patient to maintain the cold source at a predetermined upstream position (e.g., between 16mm and 36mm, preferably 28mm) away from the plurality of temperature sensors over the CSF shunt, and wherein the sensor pad is disposable.

[0017] An apparatus is disclosed for evaluating cerebrospinal fluid (CSF) flow rate or flow status in a CSF shunt within a patient. The apparatus comprises: a sensor pad having a body (e.g., an EVA foam) comprising a plurality of temperature sensors (e.g., NTC thermistors) that are positioned transversely across the body at predetermined positions, wherein the plurality of temperature sensors are aligned such that when the sensor pad is applied to the skin over the CSF shunt, one of the plurality of temperature sensors is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt; each of the temperature sensors is configured to generate respective temperature data related to movement of a temperature pulse introduced into the CSF from a cold source (e.g., an instant ice pack, 3" x 3" or larger) applied to the skin for a predetermined period; the body further comprises an alignment member that protrudes from an edge of the pad, wherein the alignment member acts as a guide for a user in positioning the cold source against the skin of the patient to maintain the cold source at a predetermined upstream position (e.g., between 16mm and 36mm, preferably 28mm) away from the plurality of temperature sensors over the CSF shunt, and wherein the sensor pad is disposable; and a sensor processing device that is electrically coupled to the sensor pad for receiving temperature data from each of the temperature sensors, wherein the sensor processing device uses the temperature data to determine a flow rate or flow status of the CSF through the shunt when the cold source is applied at the predetermined upstream position.

[0018] A method for evaluating cerebrospinal fluid (CSF) flow rate or flow status in a subcutaneous CSF shunt is disclosed. The method comprises: applying a disposable pad having a body (e.g., an EVA foam) including a plurality of temperature sensors (e.g., NTC thermistors) that are positioned transversely across the body at predetermined positions, wherein the plurality of temperature sensors are aligned such that when the sensor pad is applied to the patient's skin over the CSF shunt, one of the plurality of temperature sensors is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt; applying a cold source (e.g., an instant ice pack, 3" x 3" or larger) over the CSF shunt and upstream of the plurality of temperature sensors for a predetermined period, wherein the step of applying the cold source comprises positioning the cold source above an alignment member that protrudes from an edge of the pad for maintaining the cold source at a predetermined upstream position (e.g., between 16mm and 36mm, preferably 28mm) away from the plurality of temperature sensors over the CSF shunt; collecting temperature data from the plurality of temperature sensors; generating a resultant temperature signal from the temperature data; and determining a flow rate or flow status of the CSF through the shunt from the resultant temperature signal.

[0019] An apparatus for measuring changes in skin temperature above a subcutaneous CSF shunt is also disclosed. The apparatus comprises: a sensor pad having a body (e.g., an EVA foam) comprising a plurality of temperature sensors that are positioned transversely across the body at predetermined positions, wherein the plurality of temperature sensors (e.g., NTC thermistors) are aligned such that when the sensor pad is applied to the skin over the CSF shunt, one of the plurality of temperature sensors is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt; each of the temperature sensors is configured to generate respective temperature data related to movement of a temperature pulse introduced into the CSF from a cold source (e.g., an instant ice pack, 3" x 3" or larger) applied to the skin for a predetermined period; the body further comprises an alignment member that protrudes from an edge of the pad, wherein the alignment member acts as a guide for a user in positioning the cold source against the skin of the patient to maintain said cold source at a predetermined upstream position (e.g., between 16mm and 36mm, preferably 28mm) away from the plurality of temperature sensors over the CSF shunt, and wherein the sensor pad is disposable; and a sensor processing device that is electrically coupled to the sensor pad for receiving temperature data from each of the temperature sensors, wherein the sensor processing device comprises an algorithm for taking the difference between the temperature data of the one of the plurality of temperature sensors that is positioned over the CSF shunt and an average of the temperature data of the remaining plurality of temperature sensors positioned on opposite sides of the CSF shunt, and wherein the algorithm adjusts the difference between the temperature data based on the location of the CSF shunt below the skin surface by multiplying the temperature difference by a ratio of actual skin thickness to average skin thickness.

[0020] A method for measuring changes in skin temperature above a subcutaneous CSF shunt is disclosed. The method comprises: applying a disposable pad having a body (e.g., an EVA foam) including a plurality of temperature sensors (e.g., NTC thermistors) that are positioned transversely across the body at predetermined positions, wherein the plurality of temperature sensors are aligned such that when the sensor pad is applied to the patient's skin over the CSF shunt, one of the plurality of temperature sensors is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt; applying a cold source (e.g., an instant ice pack, 3" x 3" or larger) over the CSF shunt and upstream of the plurality of temperature sensors for a predetermined period, wherein the step of applying the cold source comprises positioning the cold source above an alignment member that protrudes from an edge of the pad for maintaining the cold source at a predetermined upstream position (e.g., between 16mm and 36mm, preferably 28mm) away from the plurality of temperature sensors over the CSF shunt; collecting temperature data from the plurality of temperature sensors; generating a resultant temperature signal from the temperature data by taking a difference between the temperature data of the one of the plurality of temperature sensors that is positioned over the CSF shunt and an average of the temperature data of the remaining plurality of temperature sensors positioned on opposite sides of the CSF shunt; and correcting the temperature data based on the location of the CSF shunt below the skin surface by multiplying the temperature difference by a ratio of actual skin thickness to average skin thickness.

[0021] An apparatus for quantifying temperatuare sensor signal noise generated by poor contact of a plurality of temperature sensors applied to the skin of the patient is disclosed. The apparatus comprises: a sensor pad having a body (e.g., an EVA foam) comprising a plurality of temperature sensors (e.g., NTC thermistors) that are positioned transversely across the body at predetermined positions, wherein the plurality of temperature sensors are aligned such that when the sensor pad is applied to the skin over the CSF shunt, one of the plurality of temperature sensors is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt; each of the temperature sensors is configured to generate respective temperature data related to movement of a temperature pulse introduced into the CSF from a cold source (e.g., an instant ice pack, 3" x 3" or larger) applied to the skin for a predetermined period; the body further comprises an alignment member that protrudes from an edge of the pad, wherein the alignment member acts as a guide for a user in positioning the cold source against the skin of the patient to maintain the cold source at a predetermined upstream position (e.g., between 16mm and 36mm, preferably 28mm) away from the plurality of temperature sensors over the CSF shunt, and wherein the sensor pad is disposable; and a sensor processing device that is electrically coupled to the sensor pad for receiving temperature data from each of the temperature sensors, wherein the sensor processing device comprises an algorithm for quantifying signal noise generated by poor contact of the sensor pad to the skin of the patient, and wherein the algorithm comprises: measuring each rise and fall in temperature detected by each one of the plurality of sensors; converting each fall in temperature, comprising a negative number, into a positive number for each one of the plurality of sensors; totaling all temperature changes for each one of plurality of sensors to form a total error for each sensor; and comparing the total error of each sensor to a predetermined threshold to determine if the total error exceeds the predetermined threshold or not and re-applying the sensor pad to the skin and obtaining a new set of temperature data for all of the plurality of temperature sensors with the cold source applied if the predetermined threshold is exceeded.

[0022] A method for quantifying temperatuare sensor signal noise generated by poor contact of a plurality of temperature sensors applied to the skin of the patient is disclosed. The method comprises: applying a disposable pad having a body (e.g., an EVA foam) including a plurality of temperature sensors (e.g., NTC thermistors) that are positioned transversely

across the body at predetermined positions, wherein the plurality of temperature sensors is aligned such that when the sensor pad is applied to the patient's skin over the CSF shunt, one of the plurality of temperature sensors is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt; applying a cold source (e.g., an instant ice pack, 3" x 3" or larger) over the CSF shunt and upstream of the plurality of temperature sensors for a predetermined period, wherien the step of applying the cold source comprises positioning the cold source above an alignment member that protrudes from an edge of the pad for maintaining the cold source at a predetermined upstream position (e.g., between 16mm and 36mm, preferably 28mm) away from the plurality of temperature sensors over the CSF shunt; collecting temperature data from the plurality of temperature sensors; and quantifying signal noise generated by poor contact of the sensor pad to the skin of the patient, wherein the step for quantifying comprises: measuring each rise and fall in temperature detected by each one of the plurality of sensors; converting each fall in temperature, comprising a negative number, into a positive number for each one of the plurality of sensors; totaling all temperature changes for each one of the plurality of sensors to form a total error for each sensor; and comparing the total error of each sensor to a predetermined threshold to determine if the total error exceeds the predetermined threshold or not and re-applying the sensor pad to the skin and obtaining a new set of temperature data for all of the plurality of temperature sensors with the cold source applied if the predetermined threshold is exceeded.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[0023] The invention will be described in conjunction with the following drawings in which like reference numerals designate like elements and wherein:

Fig. 1 is an illustration showing the anatomy of a typical CSF ventriculoperitoneal (VP) shunt;
Fig. 2A shows the ShuntCheck v2.2 device having a thermosensor which is placed upon the skin of a patient over a CSF shunt, shown in phantom, with a cold source (e.g.,. an ice cube) placed within a thermosensor window and wherein the thermosensor is about to be coupled to a PDA-based BioDisplay unit for analyzing the collected temperature data and/or for relaying to a remote analyzer;
Fig. 2B shows the ShuntCheck v2.2 thermosensor from its back side which is adhesively coupled to the skin of the patient;
Fig. 3 is a graph showing a temperature drop vs. flow rate that is typical for the ShuntCheck thermo-dilution method;
Fig. 4 is an isometric view of a first exemplary construction showing the extended dynamic range (EDR) disposable thermosensor about to be coupled to a data acquisition unit for analyzing the collected temperature data and/or for relaying to a remote analyzer;
Figs. 5A-5B compare the thermosensor of the ShuntCheck v2.2 against the EDR thermosensor of the present invention and with both thermosensors being associated with respective cold sources and with Fig. 5A showing their front sides and Fig. 5B showing their back sides;
Fig. 5C is a functional diagram showing the relationship of the temperature sensor data designators with regard to the temperature sensors used in the disposable pad;
Fig. 6 is an exploded view of the EDR thermosensor of Fig. 4;
Fig. 6A shows how the EDR thermosensor is positioned on the skin of the patient over the patient's clavicle; and
Fig. 7 is top view of the EDR thermosensor 22 with the label removed;
Fig. 8 depicts exemplary dimensions of the EDR thermosensor of the present invention;
Fig. 9 depicts an exemplary kit for the EDR thermosensor;
Fig. 10 is an isometric view of a second, more preferred, exemplary construction showing the conformable extended dynamic range (CEDR) disposable thermosensor about to be coupled to a data acquisition unit for analyzing the collected temperature data and/or for relaying to a remote analyzer;
Fig. 11 is a plan view of the CEDR disposable thermosensor depicting the flex circuit that is applied directly against the skin of the patient, with the corresponding cable shown partially;
Fig. 11A is an enlarged cross-sectional view of the CEDR thermosensor taken along line 11A-11A of Fig. 10;
Fig. 12 depicts exemplary dimensions of the CEDR thermosensor of the present invention;
Fig. 13A is a plan view of the CEDR disposable thermosensor showing the cable coupled to the flex circuit;
Fig. 13B is an enlargement of a portion of the flex circuit of Fig. 13A showing the cable connection to the flex circuit;
Fig. 14 shows a cold source applied in close proximity to the CEDR thermosensor of the present invention using the upper "ice edge" of the thermosensor to properly place the cold source;
Fig. 15 shows how the CEDR thermosensor is positioned on the skin of the patient while properly conforming to the patient's clavicle;
Fig. 16A is a timing diagram for a natural flow and Micro-Pumper flow test procedure;
Fig. 16B is an exemplary display screen depicting patient information using the ShuntCheck device which includes the CEDR thermosensor;

Fig. 17A is an exmplary display screen showing a patient's temperature sensor data indicating a no flow characteristic;
Fig. 17B is an exemplary display screen showing a patient's temperature sensor data indicating a CSF flow charateristic; and
Fig. 17C is an exemplary display screen showing a patient's temperature sensor data that a ShuntCheck flow algorithm would alert an operator that a patient warming response was occurring and that the resultant temperature signal may not be accurate.

DETAILED DESCRIPTION OF THE INVENTION

[0024] The invention is solely defined by the appended claims.

[0025] As shown most clearly in Fig. 4, the present invention 20 comprises an extended dynamic range (EDR) thermosensor 22 which is coupled to a sensor processing device 114. By way of example only, the sensor processing device 114 may comprise a data acquisition unit (DAQ) 114A that converts and conditions analog temperature sensor signals into digital format for use with, by way of example only, a workstation 114B, a laptop/tablet computer 114C, or handheld computer device (e.g., personal digital assistant, PDA), or any known computer known in the art, etc., either wired or wirelessly, running ShuntCheck software which analyzes temperature data from the temperature sensors and provides a time-temperature graph and a flow or no-flow result. Although Fig. 4 shows the DAQ 114A relaying the data to the other computer devices, it should be understood that it within the broadest scope of the invention 20 that the DAQ may comprise the ShuntCheck software thereby collecting and analyzing the temperature sensor data itself, or the other computer devices can be coupled directly to the EDR thermosensor 22 and provide the analyzed data to the operator in that manner. Thus, it should be understood that the devices which condition and/or analyze the temperature sensor data do not form a limitation on the present invention 20. The present invention 20 may be used in conjunction with the Micro-Pumper 300, a device which generates a temporary increase in CSF flow in patent, but not in occluded, CSF shunts.

[0026] ShuntCheck was developed to help physicians differentiate patent shunts from obstructed shunts, but early ShuntCheck results indicated that patent shunts flow intermittently which meant that a no-flow ShuntCheck result did not indicate obstruction. This led to the development of the Micro-Pumper. ShuntCheck testing without Micro-Pumper 300 assesses "natural flow" through the shunt 11 while ShuntCheck testing including the Micro-Pumper 300 assesses the patency or "flowability" of the shunt.

[0027] As will be described in detail later, the present invention 20 improves upon the ShuntCheck v2.2 device by providing an EDR thermosensor 22 which increases the gap between test temperature sensors (e.g., thermistors, e.g., 103JT-025 Thermistor NTC 10KΩ manufactured by Semitec, by way of example only) and control temperature sensors (e.g., thermistors, e.g., 103JT-025 Thermistor NTC 10kΩ manufactured by Semitec, by way of example only) of the EDR thermosensor 22 and which is also independent of the temperature source 25 (e.g., a test pack, such as a cool pack) that cools a much larger area of the skin above the CSF shunt catheter 13 and introduces a temperature pulse into the CSF. As such, the EDR thermistor 22 also increases the gap between the cold source 25 and the test/control temperature sensors 28A-28B. This distinction can be seen most clearly in Figs. 5A-5B which shows the two thermosensors 12 and 22 side by side. In particular, in Fig. 5A, the thermosensor 12 of ShuntCheck v2.2 is shown on the left and the EDR thermosensor 22 of the present invention 20 is shown on the right. The cold source 19 used in the ShuntCheck v2.2 device is an ice cube, or an ice cube with a receptacle 17, that is positioned within a window 19 in the thermosensor 12. In contrast, in the EDR thermosensor 22, the cold source (e.g., ice pack or test pack) 25 is placed closely adjacent the EDR thermosensor 22 against the skin of the patient (not shown) when in use. Fig. 5B shows the respective back sides (12B for the ShuntCheck v2.2 and 22B for the EDR thermosensor 22 of the present invention).

[0028] As shown most clearly in Fig. 6 and Table 2 below, the components of the disposable EDR thermosensor 22 are all medical grade and biocompatible. The EDR thermosensor 22 comprises a body 24 formed of, for example, an EVA (ethylene-vinyl acetate) insulated foam, having a plurality of apertures (e.g., three apertures 26A-26C) into which three respective temperature sensors 28A-28C (e.g., thermistors GE MA100BF103B or MA100BF103A or 103JT-025 Thermistor NTC 10kΩ manufactured by Semitec, by way of example only) are positioned. In particular, the temperature sensors 28A-28C are mounted in injection-molded plastic cradles 30A-30B which are inserted into the respective apertures 26A-26C. The EVA foam insulates the temperature sensors from all temperature sources except the skin. The three temperature sensors 28A-28C, as mentioned previously, may comprise thermistors which are negative-temperature-coefficient (NTC) fast-responding (e.g., 2-second response time in still water) thermistors. The temperature sensors 28A-28C are positioned at predetermined distance PD (Fig. 8) from an upper edge 27 of the body 24; this edge is also referred to as the "ice edge" which sets the distance from a cold source 25 (e.g., ice pack, discussed below) to the temperature sensors 28A-28C. The temperature sensors 28A-28C are also positioned at fixed distances from each other. Each temperature sensor 28A-28C is electrically coupled to a connector 32 (e.g., Inteprod connector box RJ45 connector) via a wire harness or cable 34. By way of example only, where thermistors are used, two wires from each thermistor may be soldered to a single flexible cable (e.g., 22.3 cm in length) comprising six internal wires; these wires may be soldered to the connector 32 (e.g., RJ45 (Ethernet-type) connector) that is compatible with a jack mounted on

or within the DAQ 114A. The back side 22B of the EDR thermosensor 22 comprises an adhesive layer 36 (e.g., I-832 adhesive item #MED 5634) which is covered by release liner 38. A label 40 with indicia 42 thereon (e.g., instructions on how to properly align the EDR thermosensor 22 when securing it to the skin of the patient) is secured to the front side 22A of the body 24. The EDR thermosensor 22 is applied to the patient's skin by first removing the release liner 38 and then adhering the thermosensor 22 directly to the skin 11, for example, over the clavicle 8 of the patient as shown in Fig. 6A.

Table 2: Performance Characteristics of the Thermosensor Array Patch

Thermosensor element	***Manufacturer: model***	***Performance Characteristic***	***Contacts Patient?***
EVA Foam with adhesive film and paper backing	Avery Dennison MED 5634	Forms the body of the patch Adheres patch to skin Protects adhesive	Yes
Thermistors	GE: MA100BF103B *or* GE: MA100BF103A	Collects temperature data with a response time of 2 seconds	Yes
Cable	GE: MA100BF103B *or* GE: MA100BF103A		No
Connector	Inteprod connector box RJ45 connector		No
Thermistor cradles	Rynel Lexan HP2	Holds thermistors in foam	Yes
Label	Avery	Identifies Orientation of Thermosensor to Shunt	No

[0029] Fig. 7 is top view of the EDR thermosensor 22 with the label 40 removed showing the relative positions of the two control temperature sensors 28A and 28C and the test temperature sensor 28B. Fig. 8 depicts exemplary dimensions of the EDR thermosensor 22.

[0030] The cold pack 25 (e.g., 3" x 3") provides a significantly larger cold temperature source than the ice cube 17, or ice cube in receptacle used in ShuntCheck v2.2. A T-shaped member 29 (see Figs. 5A-5B) having upper edge 27 at the top of the EDR thermosensor 22 guides the operator to place the cooling source 25 at uniform and equal distance from the test temperature sensor 26B and the control temperature sensors 28A/28C. The preferred separation distance (SD) is 16mm < SD < 36mm. If the separation distance is less than 16mm, this results in too much ambient skin cooling that reaches the sensors 28A-28C, thereby creating test "noise". If, on the other hand, the separation distance SD is greater than 36mm, this lengthens the test time and reduces the test signal, since the chilled CSF rewarms as it moves down the shunt 13. A specific distance in the range of 24 to 28mm combined with ice-on time of 60 seconds strikes an optimal balance in cold-to-sensor distance and thermal input. The control thermistors 28A/28B are 15mm (center-to-center) from the test thermistor 28B, reducing impact of minor misalignment on test results.

[0031] The preferred construction of the cold source 25 is an instant cold pack, specifically 4" x 6" over-the-counter instant ice pack used according to label (thereby eliminating the need for ice stored in a freezer). As shown in Figure 5A, the ice pack 25 is placed along the top edge 27 of the thermosensor 22, at a separation distance SD of 28 mm from the temperature sensors 28A-28C. The combination of the larger ice "footprint" and the greater ice-to-temperature sensor distance allows EDR thermosensor 22 to detect a wider range of shunt flows.

[0032] In general, the temperature sensor data from the plurality of sensors 28A-28C is analyzed by the sensor processing device 114 to yield a differential temperature signal, (also referred to as "resultant temperature signal") based on:

$$T1 - (T2 + T3)/2$$

where T1 represents temperature sensor data from the test sensor aligned over the shunt 13, namely, sensor 28B, while T2 and T3 represent the temperature sensor data from the control sensors 28A and 28C, respectively, located on opposite sides of the shunt 13. Thus, the average of the control sensor data is subtracted from the test temperature sensor data, in accordance with U.S. Patent Publication No. 2011/0054382. Fig. 5C provides a functional diagram that associates the plurality of temperature sensors with the differential temperature signal.

[0033] The ShuntCheck software in the analyzer 114 uses this data to compare it to a threshold to determine if CSF flow is present or not. A CSF flow rate can then also be automatically determined from monitoring the CSF flow over time. The threshold is determined by the geometry of the EDR thermosensor 22 and the temperature source 25. In

particular, how far the temperature sensors 28A-28C are displaced from the temperature source 25, how far the temperature sensors 28A-28C are spread apart, and the "power" and geometry of the temperature source 25. Fig. 16B, by way of example only, shows the curve T1 - (T2 + T3)/2 having a "flow confirmed" threshold of -02°C.

[0034] Furthermore, it is desirable to determine an approximation of the steady state of the differential temperature signal. The approximation for this steady state can be represented as the lowest point in the curve T1 - (T2 + T3)/2. The steady state occurs when the cooling source 25, and CSF flow rate are constant and continuous. For a certain geometry (e.g., depth, passageway size) and certain flow rate, a continuous cooling source 25 generates a particular distribution of temperatures. The lowest point on the graph (e.g., see Fig. 16B) can be treated as an approximation of this steady state. The difference T1 - (T2+T3)/2 eliminates, to a certain extent, temperatures caused by other sources of heating/cooling (e.g., bio heat) and other than shunt heat conductors (e.g., arteries). This "lowest point," referred to as T_{sensor} is given by:

$$T_{sensor} = T_{CSF} + (2\pi RQL_{shunt})/\rho cF$$

where T_{CSF}

$$T_{CSF} = \Delta T e^{\left(-\frac{L_{ice}}{F^2 kc}\right)} + T_{cold}$$

Where T_{CSF} = CSF temperature;
ΔT = Temperature difference between normal body temperature and cold tissue cooled by the ice cube (assumed to be 15°C);
T_{cold} = cold tissue temperature;
R = shunt radius;
Q = rate of heat exchange;
L_{ice} = length of the ice cube;
L_{shunt} = distance between ice cube and the sensor;
ρ = specific density of CSF;
c = specific heat of CSF;
k = specific conductivity of CSF; and
F = CSF flow rate.

[0035] This ShuntCheck algorithm or formula can be used to assess monotonic range for the thermosensor 22, as well as the influence of the distance (L_{shunt}) between the ice pack 25 and the temperatures sensors 28A-28C and the ice pack 25 length on the temperature drop. Although skin temperatures will be much higher than those predicted by the formula, and depend on skin thickness and bio-heat level, the maximum of the temperature curve will hold its position.

[0036] The EDR thermosensor 22, the instant ice pack 25 and a single use, commercially available skin marker pen 29 are packaged in a plastic clamshell 31 to form a kit (see Fig. 9). This ensures that all single use items used in a test procedure are combined in a convenient single pack.

[0037] Bench testing demonstrates that the EDR thermosensor 22 plus the instant cold pack 25 cooling method can detect the robust, temporary shunt flow generated by using the Micro-Pumper 300, as shown in Table 3, can detect lower levels of shunt flow than could be detected by the v2.2 thermosensor, as shown in Table 4 and is less sensitive to minor misalignment errors as shown in Table 5.

Table 3: ShuntCheck III Results for Typical Flow conditions

Flow Before MP (ml/hr)	Flow During MP (ml/hr)	Flow After MP (ml/hr)	Results	% Flow Not Confirmed	% Flow Confirmed
0	0	0	Flow Not Confirmed	100%	-
0	15	0	Flow Confirmed)	-	100%
0	50	0	Flow Confirmed	-	100%

(continued)

Table 3: ShuntCheck III Results for Typical Flow conditions					
Flow Before MP (ml/hr)	**Flow During MP (ml/hr)**	**Flow After MP (ml/hr)**	**Results**	**% Flow Not Confirmed**	**% Flow Confirmed**
0	100	0	Flow Confirmed	-	100%
10	15	10	Flow Confirmed	-	100%
10	50	10	Flow Confirmed	-	100%
10	100	10	Flow Confirmed	-	100%
10	200	10	Flow Confirmed	-	100%

Table 4 Bench Test Results for ShuntCheck III vs v2.2 at a Range of Flow Rates							
Actual Flow [ml/hour]	**0**	**3.5**	**4.25**	**5**	**7.5**	**10**	**20**
ShuntCheck III % Flow Confirmed On Thermal Bench	0	0	30	100	100	100	100
ShuntCheck v2.2 % Flow Confirmed on Thermal Bench	0	N/A	N/A	0	70	90	100
ShuntCheck v2.2 % Flow Confirmed from previous 510(k) testing on Porcine model	0	N/A	N/A	0	70	90	100

Table 5: Comparison Test Results for ShuntCheck III and ShuntCheck v2.2 at with Placement Misalignments				
Positional Misalignment		**2 mm**	**4 mm**	**6 mm**
EDR Thermosensor 22	**Number "Flow Confirmed"**	5	10	9
	Number of "Flow Not Confirmed"	0	0	1
	% Flow Confirmed	100	100	90
ShuntCheck v2.2 Thermosensor	**Number "Flow Confirmed"**	5	0	0
	Number of "Flow Not Confirmed"	0	5	5
	% Flow Confirmed	100	0	0

[0038] Therefore, the EDR Thermosensor 22 plus the larger cooling source 25 (e.g., the instant cold pack) when used in conjunction with the DAQ 114A: (1) permit the detection of the robust, temporary CSF flow generated by the Micro-Pumper 300; (2) permit the detection of the lower level of CSF flow common in pediatric patients; and (3) are less sensitive to minor misalignment errors.

[0039] To address test variability caused by differing catheter depth, two easy-to-use methods have been developed for assessing shunt depth and a method for adjusting the ShuntCheck result to compensate for differing depths.

[0040] Catheter depth at the clavicle (e.g., the preferred site of the ShuntCheck thermal reading; see Fig. 6A) can be measured by pinching the patient's at the clavicle, measuring the thickness with a caliper and dividing the measurement by 2. Preliminary assessments have determined that the skin thickness at the clavicle is approximately 5mm but wherein that value can be adjusted as more test data is obtained.

[0041] An alternative method is for the test operator to classify patients into groups based upon palpation of the shunt at the clavicle. Patients whose catheter creates a visible ridge on the clavicle can be classified as thin skin or shallow shunt depth. Patients whose catheter is not visible but is easily palpated would be classified as medium skin thickness or shunt depth. Patients whose catheter can be palpated but with difficulty are classified as thick or deep. Patients whose catheter cannot be palpated are classified as very thick very deep. For thin skin (wherein preliminary data suggests is about ½ average thickness), the temperature drop is adjusted down 50% (e.g., a reading of 0.8°C would be adjusted to 0.4°C). For thick skin (which wherein preliminary data suggests is about 2 times average thickness), the temperature drop is adjusted upward by 100% (e.g., a 0.2°C reading is adjusted to 0.4°C).

[0042] The ShuntCheck result, which is a temperature change measurement, can be adjusted by the equation:

$$\text{Temperature Drop adjusted} = \text{Temperature Drop} \times \text{Actual Skin Thickness/Average Skin Thickness.}$$

[0043] During the ShuntCheck process, the computation of the adjusted temperature drop is accomplished as follows: The test operator takes the caliper or palpation reading before ice pack placement and inputs the data into the sensor processing device 14 which comprises the ShuntCheck software. The ShuntCheck software containing the algorithms or formulae discussed above, adjusts the temperature data and either reports only the adjusted result or the actual and adjusted result. Thus, it should be understood that the construction 20 of the present invention is also an apparatus/method for measuring changes in skin temperature above a subcutaneous CSF shunt.

[0044] A second more preferred construction 120 of the present invention is shown in Fig. 10. In this construction the EDR thermosensor 22 has been replaced with a conformable EDR thermosensor 122, hereinafter referred to as the "CEDR thermosensor 122." As with the EDR thermosensor 22, the CEDR thermosensor 122 is disposable. Similarly, the CEDR thermosensor uses a plurality of temperature sensors (e.g., thermistors GE MA100BF103B or MA100BF103A or 103JT-025 Thermistor NTC 10kΩ manufactured by Semitec, by way of example only) which are also referenced as 28A-28C. The CEDR thermosensor 122 couples to the data acquisition unit 114 that analyzes the collected temperature data and/or relays such data to a remote analyzer (not shown). As with the first construction 20, the second construction 120 is coupled to the sensor processing device 114 which operates in the same manner and is therefore not discussed further. The present invention 120, as with the first construction 20, may be used in conjunction with the Micro-Pumper.

[0045] It is desirable to releasably secure the thermosensor over the patient's clavicle 8 because the shunt catheter 11 is easy to locate via palpation and few major blood vessels which can interfere with the ShuntCheck thermal signal cross the clavicle. However, because the clavicle 8 comprises a curved surface, it does pose a mechanical challenge for temperature sensor signals, namely, if the thermosensor does not wrap around and adhere tightly to the clavicle, the sensor pad lifts up away from the skin, thereby most likely generating faulty thermal readings. To that end, Applicant has designed the CEDR thermosensor 122 which comprises a flexible design (as discussed below), especially for adhesive placement on the patient where the shunt 11 crosses the clavicle 8 (see Fig. 15). Furthermore, the CEDR thermosensor 122 also minimizes the conduction of heat or cold to the temperature sensors that can be introduced from the flex circuit leads which could introduce error into the temperature sensor readings.

[0046] In particular, as shown most clearly in Fig. 11, the CEDR thermosensor 122 has a side 122B that is adapted to be adhesively-coupled to the patient's skin 11, especially over the clavicle 8. Side 122B comprises an "E-shaped" flex circuit 123 upon which the temperature sensors 28A-28C are mounted. The E-shaped flex circuit 123 in turn is mounted on the body of the CEDR thermosensor 122, e.g., a foam pad. The E-shaped flex circuit 123 minimizes the bulk of the circuit leads near the temperature sensors 28A-28C (see Figs. 13A-13B), thereby reducing thermal conductivity and therefore thermal crosstalk between the temperature sensors 28A-28C which yields higher quality temperature signals. It also enhances the conformability of the flex circuit 123 and therefore the conformability of the overall thermosensor 122 since the flex material (e.g., polyimide) is malleable; thus, the flex material is stiff and cannot be stretched but it can be bent or curved in multiple directions. As a result, not only the segments or prongs of the E-shaped flex circuit 123 can be bent but the long side that connects all of them can also be bent or curved. The E-shaped legs or traces is key to conformability by allowing simultaneous bending in two directions, along and around the clavicle 8.

[0047] The flex circuit 123 and the temperature sensors 28A-28C mounted on the circuit 123 are flat and therefore create no upward pressure on the pad when placed on the skin 11 since there are no protrusions. The lack of protrusions also allows the entire surface 122B with adhesive layers 130A/130B (see Fig. 11A) to be in contact with the skin 11 providing more surface area with adhesive. This also eliminates the leverage that the non-adhesive areas around the protrusion had - which made it peel off more easily from the skin since in effect it had already begun to peel. Thus, the omission in the CEDR thermosensor 122 of the cradles 30A-30C of the EDR thermosensor 22 that hold the temperature sensors 28A-28C enhances conformability and skin adhesion.

[0048] Fig. 12 provides dimensions of the CEDR thermosensor 122 by way of example only. The polyimide material of the flex circuit legs 122 are only 3mm wide. This constructions is also an improvement over the EDR thermosensor

22 by reducing thermal conductivity between the temperature sensors 28A-28C since polyimide is more conductive than the foam pad and improves the CEDR thermosensor 122 conformability.

[0049] The flex circuit 123 leads are approximately 4 mil wide traces of copper (see Fig. 12), which are thinner than the more typical 10 mil traces. This further reduces thermal conductivity to more slowly transfer temperature from other non-desirable points (e.g., along the traces), which otherwise result in averaging and inaccuracy for the temperature measurement at the precise point desired and further improves conformability; see data in Table 6 below.

[0050] To secure the flex circuit 123 to the insulating foam pad of the thermosensor side 122B, a first adhesive layer 130A is applied on side 122B and the flex circuit 123 is applied thereon.

[0051] The flex circuit 123 is then covered with a second adhesive layer 130B which holds the thermosensor 122 on the patient's skin 11. This second adhesive layer maximizes skin adhesion and reduces the risk of poor sensor-to-skin contact. This second adhesive layer keeps the individual temperature sensors 28A-28C secured to the pad 122 and the temperature sensors secured to the skin 11 because there is an adhesive layer on both sides of the temperature sensors 28A-28C and the flex circuit 123, resulting in lower noise since temperature sensors (e.g., thermistors) move with and do not lift off the skin; see data in Table 7 below.

[0052] Both layers of adhesive 130A/130B are adhesive only. This compares to many adhesive applications where the adhesive comes mounted on a carrier material. Using a carrier-free adhesive enhances conformability

[0053] A sensor label 140 (Fig. 10) comprises a thin, flexible lower modulus (i.e., less stiff) material (low-density polyethylene (LDPE) vs typical polyester) allowing it to strain (stretch) easier in tension in multiple directions, enhancing conformability.

[0054] In a preferred construction of the CEDR thermosensor 122, the sensor label 140 is omitted and product information is printing directly on the top surface 122A of the foam pad 122, further enhancing conformability.

[0055] The flex circuit 123 is fixedly secured 125 (e.g., soldered; see Fig. 13B) to the sensor cable at the distal end of the thermosensor pad 122 and the solder joint is sandwiched between the two layers of adhesive. This strengthens the cable 34-to-pad 122 connection which allows a lift tab 127 (Figs. 10 and 13A) on the adhesive release paper to be located at the bottom of the thermosensor pad 122. The user can grip the sensor cable 34 while peeling up the liner paper 138. This makes that operation easier to complete and reduces the risk of the liner paper 127 tearing. The large inside radii (8mm) of the liner where it meets pad also reduces susceptibility for tearing. It also allows the user to remove the sensor pad from the patient's skin by pulling up on the sensor cable.

[0056] The flex circuit 123 design allows the use of a non-custom flat cable and an RJ-45 connector, also reducing cost of goods. Alternatively, a telephone-style jack can also be used for the connector.

[0057] The components (see Table 6 below) of the disposable CEDR thermosensor 122 are all medical grade and biocompatible. As discussed above, the CEDR thermosensor 122 comprises layering a number of adhesive and insulating materials formed to specific dimensions and shape. The configuration of the CEDR thermosensor 122 array patch is shown in Fig. 12. The body of the thermosensor 122 comprises an EVA insulated foam. The plurality of temperature sensors comprises three thermistors that are surface mount devices and are soldered 125 to the flexible printed circuit 123 which is adhered to the EVA foam. As with the EDR thermosensor 22, the EVA foam in the CEDR thermosensor 122 insulates the thermistors from all temperature sources except the skin. The three thermistors are NTC fast-responding (2.2 second response time in air) obtained from a commercial supplier (Semitec), and are arranged at precise distances from the upper edge of the EVA foam (the ice edge which sets the distance from the ice pack and the thermistors) and from each other. The flexible printed circuit traces are soldered to a cable 34 (e.g., a single flat ribbon flexible cable (e.g., 60 cm in length) comprising six conductors) These conductors are attached to an RJ45 (Ethernet-type) connector 32 that is compatible with a jack mounted on the DAQ 114A. A label 140 indicating the correct placement and orientation of the CEDR thermosensor 122 array patch is adhered to the uppermost surface. A medical grade adhesive with a disposable protective paper layer on one side is placed over the flexible circuit board 123. The CEDR thermosensor 122 array patch is applied by first removing this paper layer and then adhering the patch directly to the skin 11.

Table 6: Performan ce Characteristics of the CEDR T hermosensor Array Patch

Thermosensor element	***Man ufacturer: model***	***Performance Characteristic***	***Contacts Patient?***
EVA Foam with adhesive film	Avery Dennison MED 5634	Forms the body of the patch	No
Thermistors	Semitec: 103KT1005T-1P	Collects temperature data with a response time of 2 seconds	No

(continued)

Table 6: Performan ce Characteristics of the CEDR T hermosensor Array Patch			
Thermosensor element	***Man ufacturer: model***	***Performance Characteristic***	***Contacts Patient?***
Cable	3M: 3756 series, Round Conductor Flat Cable, 30 AWG, TPE	TPE material provides better soldering ability because it has higher melting temp.	No
Connector	RJ45 connector	Using 28 gauge connector with 30 ga flat cable allows it to be assembled because of flash between conductors after separation allowing reduced cost	No
Adhesive Layer	3M product #1524	Attaches to patient	Yes
Label	Avery	Identifies Orientation of Thermosensor to Shunt	No

[0058] As with the EDR thermosensor 22, the preferred construction of the cold source 25 for use with the second construction 120 is also an instant cold pack for introducing a temperature pulse into the CSF, discussed previously. As shown most clearly in Fig. 14, a T-shaped member 129 having an upper edge 127 at the top of the CEDR thermosensor 122 guides the operator to place the cooling source 25 at uniform and equal distance from the test sensor 28B and the control temperature sensors 28A/28C. The separation distance SD discussed previously with the EDR thermosensor 22 applies to the CEDR thermosensor 122 and, as such, is not repeated here. Similarly, the CEDR thermosensor 122 forms a portion of another ShuntCheck Test Pack, similar to the kit discussed previously with regard to Fig. 9. As such, the kit including the CEDR thermosensor 122 also includes a marker for placing a skin marker "upstream" of the CSF flow from the CEDR thermosensor 122, to cool the CSF in the shunt 13. Thus, the temperature sensors 28A-28C placed over the shunt 13 detect the change in temperature as cooled fluid flows beneath them. The presence of flowing fluid is interpreted as a decrease in temperature detected by the temperature sensors, while no change in temperature indicates the absence of flow. In addition, the ShuntCheck algorithm or formula discussed previously with respect to the first construction 20, applies to the second construction 122 and is therefore also not repeated here.

[0059] Data in Table 7 below shows 22% lower (better) Short Term Noise (STN) for the CEDR thermosensor 122 vs the EDR thermosensor 22. ShuntCheck tests on unshunted skin without ice were run and the noise value calculated by the ShuntCheck software was compared for each thermistor. The noise algorithm accumulates the deviations from the average over a fixed period (10s).

Table 7 Short term noise data						
			STN value			
run order		**Thermosensor**	**t1 (Sensor 28B)**	**t2 (sensor 28A)**	**t3 (sensor 28C)**	
1		EDR 22	0.43	0.41	0.67	
2		EDR 22	0.44	0.44	0.53	
3		EDR 22	0.46	0.46	0.72	
1		CEDR 122	0.47	0.39	0.39	
2		CEDR 122	0.4	0.37	0.35	
3		CEDR 122	0.47	0.36	0.35	
		avg-EDR	0.44	0.44	0.64	.51
		avg-CEDR	0.45	0.37	0.36	.39
		T-test	0.9035	0.0286	0.0340	
		Effect (delta)	0.00	0.06	0.28	.11

(continued)

Table 7 Short term noise data						
			STN value			
run order		Thermosensor	t1 (Sensor 28B)	t2 (sensor 28A)	t3 (sensor 28C)	
	3 run avg of t1, t2, t3		EDR		0.51	
	3 run avg of t1, t2, t3		CEDR		0.39	
			Delta		0.11	
	CEDR short term noise improvement over EDR				22%	

[0060] The data in Table 8 below shows that 4mil wide traces yield an average improvement in ShuntCheck signal Amplitude of about 10% over 10 mil wide traces. ShuntCheck tests were run using a heated bench test fixture that simulates a flowing implanted shunt at skin temperature with a syringe pump attached to control the flow rate.

[0061] It should also be understood that the preferred construction 120 also forms an apparatus/method for measuring changes in skin temperature above a subcutaneous CSF shunt as discussed previously with regard to the embodiment 20.

Table 8	
Trace Width	Signal Amplitude @ 10ml/hr
4	0.65
4	0.64
4	0.65
4	0.67
4	0.52
4	0.66
4	0.64
4	0.66
avg	**0.64**
sd	**0.05**
10	0.63
10	0.64
10	0.6
10	0.54
10	0.49
10	0.56
10	0.63
10	0.57
avg	**0.58**
sd	**0.05**
ttest	**0.05**
effect	**0.05**

(continued)

Table 8	
Trace Width	Signal Amplitude @ 10ml/hr
4 vs 10 mil avg improvement	0.05
avg 10 mil	0.58
% Improvement of 4 mil over 10 mil	9%

Error Check for Quantifying Signal Noise Based on Poor Sensor-to-Skin Contact

[0062] The present invention 20/120 also comprises an error check for quantifying signal noise based on poor sensor-to-skin contact and to alert the user in both a pre-test setting and a post-test setting. Thus, both inventions 20/120 also form an apparatus/method for quantifying temperatuare sensor signal noise generated by poor contact of a plurality of temperature sensors applied to the skin of the patient.

Pre-Test Setting

[0063] Signal noise is quantified by measuring each rise and fall in temperature recorded by each temperature sensor 28A-28C, converting each negative change (i.e., each fall in temperature) into a positive number, and totaling all changes for each sensor. This method is then used to quantify the signal noise in previous tests which were evaluated to have acceptable or unacceptable levels of signal noise. This allows for the establishment of a signal noise threshold for each sensor 28A-28C. Tests which generate a signal noise level for any sensor which is higher than this threshold trigger a warning to the test operator that the test has generated a high level of noise, indicates which sensor is generating the signal noise (which should be addressed) and suggests that the temperature sensors are not making proper contact and that the overall test run should not be initiated until corrected, as well as re-applying or adjusting the EDR thermosensor 22 or CEDR thermosensor 122 against the skin.

Post-Test Setting

[0064] Assuming that the pre-test setting was satisfied and that the present invention 20/120A was activated to collect temperature sensor data, a post-test is conducted before the CSF flow status or flow rate is determined. This post-test check breaks the test into small time increments of multiple seconds (e.g., five seconds), establishes a straight line for each sensor reading from the temperature at the beginning of the time increment to the temperature at the end of the increment, computes the standard deviation of the actual signal vs the straight line, averages all the standard deviation in the test and compares the average standard deviation to an experimentally established threshold. Tests which generate a signal noise standard deviation average for any sensor which is higher than this threshold, trigger a warning to the test operator that the test has generated a high level of noise, indicates which temperature sensor 28A-28C is generating the signal noise (which should be addressed) and suggests that the test should be restarted or repeated.

Natural CSF Flow and Micro-Pumper Enhanced Flow

[0065] To address the long test time needed to assess natural flow and Micro-Pumper flow, a combined test procedure was developed. A timing diagram of this test procedure is shown in Fig. 16A. This procedure is implemented by the algorithm of the ShuntCheck software which instructs the operator as follows. This procedure begins with a natural flow assessment of a first ice placement and response measurement by a second ice placement (e.g., phases I and II) and a Micro-Pumper 300 procedure and a second response measurement (e.g., phases III-V). This procedure allows for an assessment of natural flow - the period prior to the placement of the Micro-Pumper 300 - and an assessment of Micro-Pumper 300 flow - the period beginning with the Micro-Pumper placement.

[0066] The temperature signal for the Natural Flow period and for the total test are given, allowing the physician to quantify natural flow vs enhanced flow. A color coded time-temperature graphs is also provided, making test interpretation intuitive.

[0067] The combined natural and Micro-Pumper 300 test procedure begins with a natural flow assessment of 60 seconds ice placement and 120 seconds of response measurement. This is followed by a second 60 second ice placement, a 60 second Micro-Pumper 300 procedure and a 3 minute response measurement. This procedure allows for an assessment of natural flow - the period prior to the placement of the Micro-Pumper 300 - and an assessment of Micro-

Pumper 300 flow - the period beginning with the Micro-Pumper 300 placement.

[0068] The test result, shown in Fig. 16B (as an exemplary display screen), shows patient and test information, quantifies the temperature decrease during the Natural Flow phase of the test and the total temperature decrease during the test, reports Flow Confirmed or Flow Not Confirmed and provides the test operator notes on the left side of the results report and shows a time-temperature graph on the right side. This graph includes vertical blue bars which note the time periods when ice is applied and a vertical green bar which notes the time period of micro-pumping using the Micro-Pumper 300. The graph also includes a red-dashed line with shows the threshold temperature decrease required for a "Flow Confirmed" result. These graphical elements make graph interpretation easier and more intuitive.

Flow Algorithm for Identifying Asymmetric Warming Response to Cold Source Placement

[0069] In accordance with the previous discussion, cold source (e.g., ice pack) placement usually results in relatively uniform ambient cooling of the skin adjacent to the cooling source, including the skin under the temperature sensors 28A-28C. As a result, when there is no CSF flow through the shunt 13, the three temperture sensors 28A-28C register similar temperature readings as show in Fig. 17A. Conversely, when there is CSF flowing through the shunt 13, the test temperature sensor 28B indicates such by manifesting a greater temperature decrease due to the flow of the chilled CSF flow; this is clearly shown in Fig. 17B.

[0070] However, some patients exhibit non-uniform vasculature in their skin near the area of the thermosensor 22 (or 122) placement. As a result, these blood vessels may respond to the cold source placement and warm an area of the skin in a non-uniform manner. If this warming includes an area of skin covered by a control temperature sensor (e.g., 28A or 28C), the temperature sensors can indicate results similar to those shown in Fig. 17C, where the test temperature sensor 28B and one of the control temperature sensors (28A or 28C) track together, indicating a "no-CSF flow" condition, while the remaining control temperature sensor indicates a more pronounced temperature increase. In view of such a scenario, the differential temperature signal T1 -(T2+T3)/2 actually calculates a "CSF flow" condition, which is not correct.

[0071] Therefore, in order to alert an operator that such a patient "warming" response that may provide incorrect CSF flow data, a flow algorithm for identifying a warming response is provided. In particular, the ShuntCheck software monitors the parameters T1-T2 and T1-T3 to determine if either of these quanitites fails to exceed a predetermined threshold, an alert is provided to the operator that the differential temperature signal T1 -(T2+T3)/2 may not be generating accurate CSF flow status/rate due to a patient "warming" response. Namely,

$$\text{Is } T1\text{-}T2 \text{ or } T1\text{-}T3 < \text{a threshold value?}$$

If the answer is "yes", the ShuntCheck software continues to calculate the differential temperature signal but accompanied by an operator warning that such data is subject to a patient warming response. Furthermore, this threshold value would be > 0°C but it would need to be ≤ the "flow confirmed" threshold (e.g., 0.2°C) discussed previously.

[0072] An alternative, and less preferred alternative, to continue calculating the differntial temperature signal T1 -(T2+T3)/2 while issuing an operator warning about the patient warming response is to replace the differential temperature signal with the lesser of T1-T2 and T1-T3 during that patient warming response.

[0073] The present inventions 20 and 120 thus represent a new tool and clinical method for the diagnosis and early diagnosis of CSF shunt malfunction in hydrocephalus patients who arrive at the emergency department (ED) with symptoms consistent with shunt obstruction. Up to 30% of mortalities in shunted patients are attributed to shunt malfunction and there are currently no non-invasive techniques that can reliably be used as stand-alone diagnostic instruments for shunt obstruction. ShuntCheck rapidly determines (e.g., within 9 minutes) shunt patency. Its portability, ease of use, safety, and relative inexpensiveness enable it to be used routinely in EDs and in neurosurgical clinical settings.

[0074] There are currently 300,000 people in the U.S. with CSF shunts. Approximately 30,000 shunt revision surgeries are conducted annually in the U.S. Each year 120,000 patients present with symptoms of shunt failure to hospital emergency rooms - primarily to the 453 level I and II emergency rooms in the U.S. Strong sensitivity and specificity results demonstrated in a clinical study combined with the present invention's 20 non-invasive procedure can result in the ShuntCheck-thermo dilution method and ShuntCheck Micro-Pumper 300 combination becoming a standard of care for symptomatic hydrocephalus patients and enables neurosurgeons and emergency medicine physicians to reduce the number of CT Scans conducted on "false alarm" symptomatic patients and thereby reduce the radiation build-up caused by the scans.

Claims

1. A sensor pad (22; 122) adapted for releasable application to the skin of a patient having a subcutaneous cerebrospinal fluid (CSF) shunt having CSF that flows from an upstream location in the patient towards a downstream location and also wherein said sensor pad is also adapted for use with a cerebrospinal fluid (CSF) analyzer, said sensor pad (22; 122) comprising:

   a body (24) comprising a plurality of temperature sensors (28A, 28B, 28C) that are positioned transversely across said body (24) at predetermined positions, said plurality of temperature sensors (28A, 28B, 28C) being aligned such that when said sensor pad (22; 122) is applied to the skin over the CSF shunt, one of said plurality of temperature sensors (28A, 28B, 28C) is positioned over the CSF shunt while the remaining plurality of temperature sensors are equally positioned on opposite sides of the CSF shunt;
   said sensor pad being disposable (22; 122);
   wherein:

      said body (24) further comprising an alignment member (29; 129) that protrudes from an edge of said pad, said alignment member is configured to act as a guide for a user in positioning a cold source (25) against the skin of the patient to maintain the cold source (25) at a predetermined upstream position away from said plurality of temperature sensors (28A, 28B, 28C) over the CSF shunt, wherein said alignment member (29; 129) is a T-shaped member having an upper edge (27; 127) at the top of the sensor pad;
      characterized in that,
      said body (24) being formed of an insulated foam.

2. The sensor pad of Claim 1 wherein said plurality of temperature sensors (28A, 28B, 28C) are coupled to a flexible circuit (123) secured to a first side (122b) of said body, said flexible circuit (123) being in contact with the skin and being conformable to the clavicle (8) of the patient when said sensor pad is applied to the skin.

3. The sensor pad of Claim 2 wherein said plurality of temperature sensors (28A, 28B, 28C) comprises three temperature sensors (28A, 28B, 28C) and wherein said flexible circuit (123) comprises an E-shaped trace whose long side is traversely positioned across said body, and wherein each of said three temperature sensors (28A, 28B, 28C) is mounted to a respective segment of said E-shaped trace.

4. The sensor pad of Claim 3 wherein said three temperature sensors (28A, 28B, 28C) are positioned 15mm from each other.

5. The sensor pad of Claim 1 wherein said predetermined upstream position (SD) away from said plurality of temperature sensors is defined as 16mm < SD < 36mm.

6. The sensor pad of Claim 2 wherein said flexible circuit (123) is coupled to the body using a first adhesive layer (130A) applied to said first side (122B).

7. The sensor pad of Claim 6 wherein a second adhesive layer (130B) is applied over said flexible circuit (123) on said first side (122B) and wherein a release liner (138) is applied over said second adhesive layer (130B).

8. The sensor pad of any of the preceding claims
   wherein said body comprises a corresponding aperture (26A, 26B, 26C) for receiving therein a corresponding one of each of said plurality of sensors, and
   wherein said plurality of temperature sensors comprises three temperature sensors (26A, 26B, 26C).

9. An apparatus for evaluating cerebrospinal fluid (CSF) flow rate or flow status in a CSF shunt within a patient, said apparatus comprising:

   a sensor pad (22; 122) according to one of the preceding claims; and
   a sensor processing device (114) that is electrically coupled to said sensor pad (22; 122) for receiving temperature data from each of said temperature sensors (26A, 26B, 26C), said sensor processing device (114) is configured to use said temperature data to determine a flow rate or flow status of said CSF through said shunt.

10. The apparatus of Claim 9 wherein said sensor processing device (114) is configured to use an algorithm for deter-

mining said flow rate or flow status from taking the difference between said temperature data of said one of said plurality of temperature sensors that is positioned over the CSF shunt and an average of said temperature data of said remaining plurality of temperature sensors positioned on opposite sides of the CSF shunt.

11. The apparatus of Claim 10 wherein said algorithm adjusts said difference between said temperature data based on the location of the CSF shunt below the skin surface by multiplying said temperature difference by a ratio of actual skin thickness to average skin thickness.

12. The apparatus of Claim 11 wherein said algorithm determines a lowest point in said difference for determining a steady state of said temperature difference data.

13. The apparatus of Claim 10 wherein said algorithm instructs an operator to apply said cold source (25) for said predetermined applying said cold source (25) for a first time period at said predetermined upstream position; removing said cold source (25) from said predetermined upstream position for a second time period; and re-applying said cold source (25) for a third time period at said predetermined upstream position.

14. The apparatus of Claim 9 wherein said sensor processing device (114) further comprises an algorithm for quantifying signal noise generated by poor contact of said sensor pad to the skin of the patient before said flow rate or flow status is determined, said algorithm comprising:

measuring each rise and fall in temperature detected by each one of said plurality of sensors;
converting each fall in temperature, comprising a negative number, into a positive number for each one of said plurality of sensors;
totaling all temperature changes for each one of plurality of sensors to form a total error for each sensor; and
comparing said total error of each sensor to a predetermined threshold to determine if said total error exceeds said predetermined threshold or not and re-applying said sensor pad to the skin and obtaining a new set of temperature data for all of said plurality of temperature sensors (26A, 26B, 26C) with said cold source applied if said predetermined threshold is exceeded.

15. The apparatus of Claim 14 wherein said algorithm comprises a post-test setting in which said predetermined threshold is not exceeded, said algorithm:

separating temperature data collected from each one of said plurality of temperature sensors into small time increments of multiple seconds;
establishes a straight line for each temperature data point within each small time increment;
computes a standard deviation of an actual temperature signal with said straight line;
averages all of said standard deviation;
compares said average standard deviation to an experimentally-established threshold; and
activates a warning to the operator whenever said average standard deviation exceeds said experimentally-established threshold in order to have the operator re-collect temperature data from said plurality of temperature sensors.

Patentansprüche

1. Ein Sensorpolster (22; 122), angepasst zum lösbaren Applizieren auf die Haut eines Patienten mit einem subkutanen Liquor-cerebrospinalis(CSF)-Shunt mit CSF, der von einer stromaufwärts liegenden Stelle in dem Patienten zu einer stromabwärts liegenden Stelle strömt, und wobei das Sensorpolster auch zur Verwendung mit einem Liquor-cerebrospinalis(CSF)-Analysengerät angepasst ist, wobei das Sensorpolster (22; 122) Folgendes beinhaltet:

einen Hauptteil (24), der eine Vielzahl von Temperatursensoren (28A, 28B, 28C) beinhaltet, die quer über dem Hauptteil (24) an vorbestimmten Positionen positioniert sind, wobei die Vielzahl von Temperatursensoren (28A, 28B, 28C) so ausgerichtet sind, dass wenn das Sensorpolster (22; 122) auf die Haut über dem CSF-Shunt appliziert wird, einer von der Vielzahl von Temperatursensoren (28A, 28B, 28C) über dem CSF-Shunt positioniert wird, während die übrigen von der Vielzahl von Temperatursensoren auf gegenüberliegenden Seiten des CSF-Shunts gleich positioniert sind;
wobei das Sensorpolster (22; 122) ein Einwegartikel ist;
wobei:

der Hauptteil (24) ferner ein Ausrichtungselement (29; 129) beinhaltet, das von einem Rand des Polsters hervorragt, wobei das Ausrichtungselement dazu ausgelegt ist, als Orientierungshilfe für einen Benutzer beim Positionieren einer Kältequelle (25) gegen die Haut des Patienten zu dienen, um die Kältequelle (25) in einer vorbestimmten stromaufwärts liegenden Position weg von der Vielzahl von Temperatursensoren (28A, 28B, 28C) über dem CSF-Shunt zu halten, wobei das Ausrichtungselement (29; 129) ein T-förmiges Element ist, das eine Oberkante (27; 127) oben auf dem Sensorpolster hat;
dadurch gekennzeichnet, dass
der Hauptteil (24) aus einem isolierten Schaumstoff gebildet ist.

2. Sensorpolster gemäß Anspruch 1, wobei die Vielzahl von Temperatursensoren (28A, 28B, 28C) mit einem flexiblen Kreislauf (123) gekoppelt sind, der an einer ersten Seite (122b) des Hauptteils befestigt ist, wobei der flexible Kreislauf (123) in Kontakt mit der Haut ist und sich an das Schlüsselbein (8) des Patienten anpassen kann, wenn das Sensorpolster auf die Haut appliziert ist.

3. Sensorpolster gemäß Anspruch 2, wobei die Vielzahl von Temperatursensoren (28A, 28B, 28C) drei Temperatursensoren (28A, 28B, 28C) beinhaltet und wobei der flexible Kreislauf (123) eine E-förmige Spur beinhaltet, deren Längsseite quer über dem Hauptteil positioniert ist, und wobei jeder der drei Temperatursensoren (28A, 28B, 28C) jeweils an einem Segment der E-förmigen Spur angebracht ist.

4. Sensorpolster gemäß Anspruch 3, wobei die drei Temperatursensoren (28A, 28B, 28C) 15 mm voneinander positioniert sind.

5. Sensorpolster gemäß Anspruch 1, wobei die vorbestimmte stromaufwärts liegende Position (SD) weg von der Vielzahl von Temperatursensoren als 16 mm < SD < 36 mm definiert ist.

6. Sensorpolster gemäß Anspruch 2, wobei der flexible Kreislauf (123) unter Verwendung einer auf die erste Seite (122B) applizierten ersten Klebeschicht (130A) mit dem Hauptteil gekoppelt ist.

7. Sensorpolster gemäß Anspruch 6, wobei eine zweite Klebeschicht (130B) über den flexiblen Kreislauf (123) auf der ersten Seite (122B) appliziert ist und wobei eine Ablösefolie (138) über der zweiten Klebeschicht (130B) appliziert ist.

8. Sensorpolster gemäß einem der vorhergehenden Ansprüche,
wobei der Hauptteil eine entsprechende Öffnung (26A, 26B, 26C) zum Aufnehmen eines entsprechenden von einer Vielzahl von Sensoren darin beinhaltet, und
wobei die Vielzahl von Temperatursensoren drei Temperatursensoren (26A, 26B, 26C) beinhaltet.

9. Eine Vorrichtung zum Evaluieren der Liquor-cerebrospinalis(CSF)-Strömungsrate oder des Strömungsstatus in einem CSF-Shunt innerhalb eines Patienten, wobei die Vorrichtung Folgendes beinhaltet:

ein Sensorpolster (22; 122) nach einem der vorhergehenden Ansprüche; und
ein Sensorverarbeitungsgerät (114), das mit dem Sensorpolster (22; 122) elektrisch gekoppelt ist, zum Empfangen von Temperaturdaten von jedem der Temperatursensoren (26A, 26B, 26C), wobei das Sensorverarbeitungsgerät (114) dazu ausgelegt ist, die Temperaturdaten zu verwenden, um eine Strömungsrate oder einen Strömungsstatus des CSF durch den Shunt zu bestimmen.

10. Vorrichtung gemäß Anspruch 9, wobei das Sensorverarbeitungsgerät (114) dazu ausgelegt ist, einen Algorithmus zu verwenden, um die Strömungsrate oder den Strömungsstatus zu bestimmen, indem es die Differenz zwischen den Temperaturdaten von dem einen von der Vielzahl von Temperatursensoren, der über dem CSF-Shunt positioniert ist, und einem Durchschnittswert der Temperaturdaten der übrigen von der Vielzahl von Temperatursensoren, die auf den gegenüberliegenden Seiten des CSF-Shunts positioniert sind, ermittelt.

11. Vorrichtung gemäß Anspruch 10, wobei der Algorithmus die Differenz zwischen den Temperaturdaten, basierend auf der Lage des CSF-Shunts unter der Hautoberfläche, anpasst, indem er die Temperaturdifferenz mit einem Verhältnis der tatsächlichen Hautdicke zur durchschnittlichen Hautdicke multipliziert.

12. Vorrichtung gemäß Anspruch 11, wobei der Algorithmus einen niedrigsten Punkt in der Differenz bestimmt, um einen Beharrungszustand der Temperaturdifferenzdaten zu bestimmen.

13. Vorrichtung gemäß Anspruch 10, wobei der Algorithmus einen Bediener anweist, die Kältequelle (25) für das vorbestimmte Applizieren der Kältequelle (25) für einen ersten Zeitraum an der vorbestimmten stromaufwärts liegenden Position zu applizieren;
Entfernen der Kältequelle (25) von der vorbestimmten stromaufwärts liegenden Position für einen zweiten Zeitraum; und
erneutes Applizieren der Kältequelle (25) für einen dritten Zeitraum an der vorbestimmten stromaufwärts liegenden Position.

14. Vorrichtung gemäß Anspruch 9, wobei das Sensorverarbeitungsgerät (114) ferner einen Algorithmus zum Quantifizieren des Signalrauschens beinhaltet, das durch einen schlechten Kontakt des Sensorpolsters auf der Haut des Patienten erzeugt wird, bevor die Strömungsrate oder der Strömungsstatus bestimmt wird, wobei der Algorithmus Folgendes beinhaltet:

Messen jedes Temperaturanstiegs und -abfalls, der von jedem von der Vielzahl von Sensoren detektiert wird;
Umwandeln jedes Temperaturabfalls, der eine negative Zahl beinhaltet, in eine positive Zahl für jeden von der Vielzahl von Sensoren;
Addieren aller Temperaturänderungen für jeden von der Vielzahl von Sensoren, um einen Gesamtfehler für jeden Sensor zu bilden; und
Vergleichen des Gesamtfehlers von jedem Sensor mit einem vorbestimmten Schwellwert, um zu bestimmen, ob der Gesamtfehler den vorbestimmten Schwellwert überschreitet oder nicht, und erneutes Applizieren des Sensorpolsters auf die Haut und Erhalten eines neuen Satzes von Temperaturdaten für jeden der Vielzahl von Temperatursensoren (26A, 26B, 26C), wobei die Kältequelle appliziert wird, wenn der vorbestimmte Schwellwert überschritten wird.

15. Vorrichtung gemäß Anspruch 14, wobei der Algorithmus eine Nach-Test-Einstellung beinhaltet, in der der vorbestimmte Schwellwert nicht überschritten wird, wobei der Algorithmus:

Temperaturdaten, die von jedem der Vielzahl von Temperatursensoren erfasst werden, in kleine Zeitinkremente von mehreren Sekunden trennt;
eine Gerade für jeden Temperaturdatenpunkt innerhalb jedes kleinen Zeitinkrements etabliert;
eine Standardabweichung eines tatsächlichen Temperatursignals mit der Geraden berechnet;
alle Standardabweichungen mittelt;
die gemittelte Standardabweichung mit einem experimentell etablierten Schwellwert vergleicht; und
immer dann eine Warnung für den Bediener aktiviert, wenn die gemittelte Standardabweichung den experimentell etablierten Schwellwert überschreitet, um den Bediener zu veranlassen, erneut Temperaturdaten von der Vielzahl von Temperatursensoren zu erfassen.

Revendications

1. Pastille de détecteur (22 ; 122) adaptée pour une application détachable sur la peau d'un patient présentant une dérivation de liquide céphalo-rachidien (CSF) sous-cutanée présentant un CSF qui s'écoule d'un emplacement en amont dans le patient vers un emplacement en aval et également dans laquelle ladite pastille de détecteur est également adaptée pour une utilisation avec un analyseur de liquide céphalo-rachidien (CSF), ladite pastille de capteur (22 ; 122) comprenant :

un corps (24) comprenant une pluralité de capteurs de température (28A, 28B, 28C) qui est positionnée dans le sens transversal à travers ledit corps (24) à des positions prédéterminées, ladite pluralité de capteurs de température (28A, 28B, 28C) étant alignée de telle sorte que lorsque ladite pastille de détecteur (22 ; 122) est appliquée sur la peau sur la dérivation de CSF, un de ladite pluralité de capteurs de température (28A, 28B, 28C) est positionné sur la dérivation de CSF tandis que le reste de la pluralité de capteurs de température est positionné de manière égale sur des côtés opposés de la dérivation de CSF ;
ladite pastille de capteur étant jetable (22 ; 122) ;
dans laquelle :

ledit corps (24) comprenant en outre un élément d'alignement (29 ; 129) qui fait saillie d'un bord de ladite pastille, ledit élément d'alignement est configuré pour agir comme guide pour un utilisateur pour un positionnement d'une source de froid (25) contre la peau du patient pour maintenir la source de froid (25) à

une position en amont prédéterminée distante de ladite pluralité de capteurs de température (28A, 28B, 28C) sur la dérivation de CSF, dans laquelle ledit élément d'alignement (29 ; 129) est un élément en forme de T présentant un bord supérieur (27 ; 127) en haut de la pastille de capteur ;
caractérisée en ce que
ledit corps (24) est formé d'une mousse isolante.

2. Pastille de capteur selon la revendication 1 dans laquelle ladite pluralité de capteurs de température (28A, 28B, 28C) est couplée à un circuit souple (123) fixé à un premier côté (122b) dudit corps,
ledit circuit souple (123) étant en contact avec la peau et étant adaptable à la clavicule (8) du patient lorsque ladite pastille de capteur est appliquée sur la peau.

3. Pastille de capteur selon la revendication 2 dans laquelle ladite pluralité de capteurs de température (28A, 28B, 28C) comprend trois capteurs de température (28A, 28B, 28C) et dans laquelle ledit circuit souple (123) comprend une trace en forme de E dont le coté long est positionné dans le sens transversal à travers ledit corps, et dans laquelle chacun desdits trois capteurs de température (28A, 28B, 28C) est monté sur un segment respectif de ladite trace en forme de E.

4. Pastille de capteur selon la revendication 3 dans laquelle lesdits trois capteurs de température (28A, 28B, 28C) sont positionnés à 15 mm les uns des autres.

5. Pastille de capteur selon la revendication 1 dans laquelle ladite position en amont (SD) prédéterminée distante de ladite pluralité de capteurs de température est définie telle que 16 mm < SD < 36 mm.

6. Pastille de capteur selon la revendication 2 dans laquelle ledit circuit souple (123) est couplé au corps en utilisant une première couche adhésive (130A) appliquée audit premier côté (122B).

7. Pastille de capteur selon la revendication 6 dans laquelle une seconde couche adhésive (130B) est appliquée sur ledit circuit souple (123) sur ledit premier côté (122B) et dans laquelle un film détachable (138) est appliqué sur ladite seconde couche adhésive (130B).

8. Pastille de capteur selon l'une quelconque des revendications précédentes dans laquelle ledit corps comprend une ouverture (26A, 26B, 26C) correspondante pour y recevoir un correspondant de chacun de ladite pluralité de capteurs, et
dans laquelle ladite pluralité de capteurs de température comprend trois capteurs de température (26A, 26B, 26C).

9. Appareil pour une évaluation d'un débit ou d'un statut d'écoulement de liquide céphalo-rachidien (CSF) dans une dérivation de CSF à l'intérieur d'un patient, ledit appareil comprenant :

une pastille de capteur (22 ; 122) selon une des revendications précédentes ; et
un dispositif de traitement de capteur (114) qui est couplé électriquement à ladite pastille de capteur (22 ; 122) pour une réception de données de température à partir de chacun desdits capteurs de température (26A, 26B, 26C), ledit dispositif de traitement de capteur (114) est configuré pour utiliser lesdites données de température pour déterminer un débit ou un statut d'écoulement dudit CSF à travers ladite dérivation.

10. Appareil selon la revendication 9 dans lequel ledit dispositif de traitement de capteur (114) est configuré pour utiliser un algorithme pour une détermination dudit débit ou d'un statut d'écoulement en prenant la différence entre lesdites données de température dudit un de ladite pluralité de capteurs de température qui est positionné sur la dérivation de CSF et une moyenne desdites données de température dudit reste de la pluralité de capteurs de température positionnés sur des côtés opposés de la dérivation de CSF.

11. Appareil selon la revendication 10 dans lequel ledit algorithme ajuste ladite différence entre lesdites données de température sur la base de l'emplacement de la dérivation de CSF sous la surface de la peau en multipliant ladite différence de température par un rapport d'une épaisseur de peau réelle sur une épaisseur de peau moyenne.

12. Appareil selon la revendication 11 dans lequel ledit algorithme détermine un point le plus bas dans ladite différence pour une détermination d'un état stable desdites données de différence de température.

13. Appareil selon la revendication 10 dans lequel ledit algorithme indique à un opérateur d'appliquer ladite source de

froid (25) pour ladite application prédéterminée de ladite source de froid (25) pour une première période de temps à ladite position en amont prédéterminée ;
un retrait de ladite source de froid (25) de ladite position en amont prédéterminée pour une deuxième période de temps ; et
une ré-application de ladite source de froid (25) pour une troisième période de temps à ladite position en amont prédéterminée.

14. Appareil selon la revendication 9 dans lequel ledit dispositif de traitement de capteur (114) comprend en outre un algorithme pour une quantification d'un bruit de signal généré par un mauvais contact de ladite pastille de capteur sur la peau du patient avant que ledit débit ou un statut d'écoulement ne soit déterminé, ledit algorithme comprenant :

une mesure de chaque augmentation et baisse de température détectée par chacun de ladite pluralité de capteurs ;
une conversion de chaque baisse de température, comprenant un nombre négatif, en un nombre positif pour chacun de ladite pluralité de capteurs ;
une totalisation de l'ensemble des changements de température pour chacun d'une pluralité de capteurs pour former une erreur totale pour chaque capteur ; et
une comparaison de ladite erreur totale de chaque capteur à un seuil prédéterminé pour déterminer si ladite erreur totale dépasse ledit seuil prédéterminé ou non et une ré-application de ladite pastille de capteur sur la peau et une obtention d'un nouveau jeu de données de température pour l'ensemble de ladite pluralité de capteurs de température (26A, 26B, 26C) avec ladite source de froid appliquée si ledit seuil prédéterminé est dépassé.

15. Appareil selon la revendication 14 dans lequel ledit algorithme comprend un paramétrage post-test dans lequel ledit seuil prédéterminé n'est pas dépassé, ledit algorithme :

séparant des données de température collectées à partir de chacun de ladite pluralité de capteurs de température en petits incréments de temps de multiples secondes ;
établit une ligne droite pour chaque point de données de température à l'intérieur de chaque petit incrément de temps ;
calcule un écart-type d'un signal de température réel avec ladite ligne droite ;
réalise une moyenne de l'ensemble dudit écart-type ;
compare ledit écart-type moyen à un seuil établi de manière expérimentale ; et
active un avertissement à l'opérateur chaque fois que ledit écart-type moyen dépasse ledit seuil établi de manière expérimentale afin d'obtenir de l'opérateur qu'il collecte à nouveau des données de température à partir de ladite pluralité de capteurs de température.

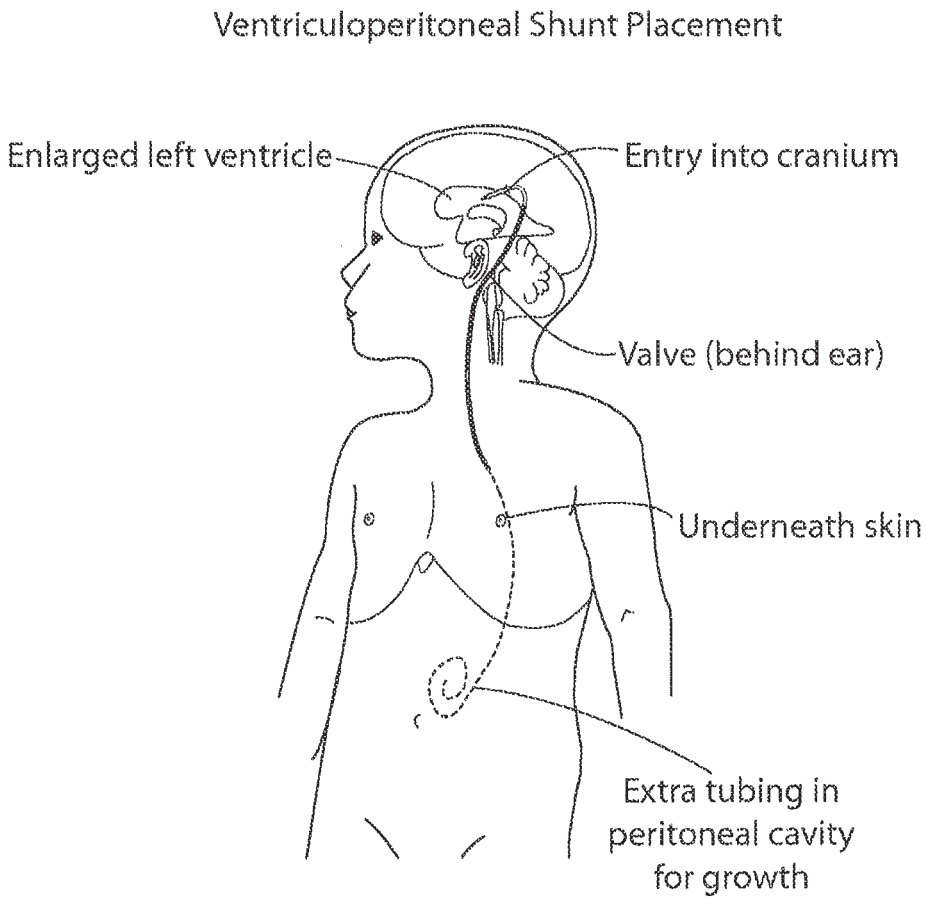

FIG. 1
(PRIOR ART)

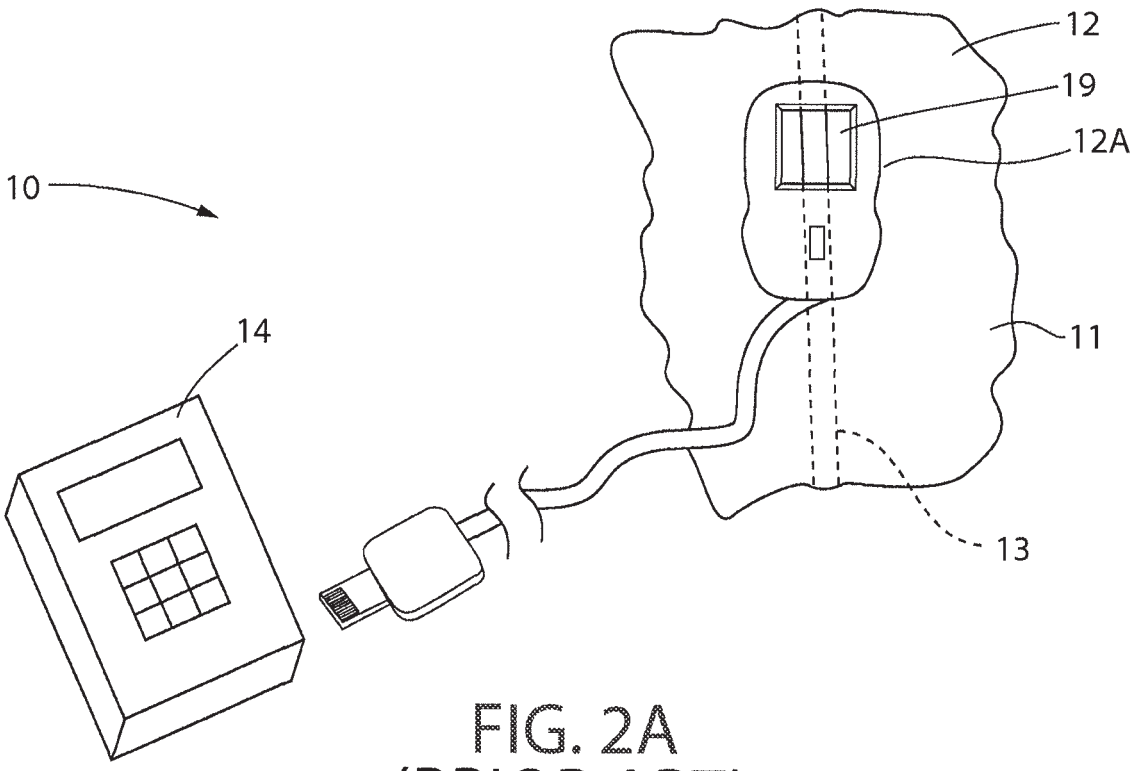

FIG. 2A
(PRIOR ART)

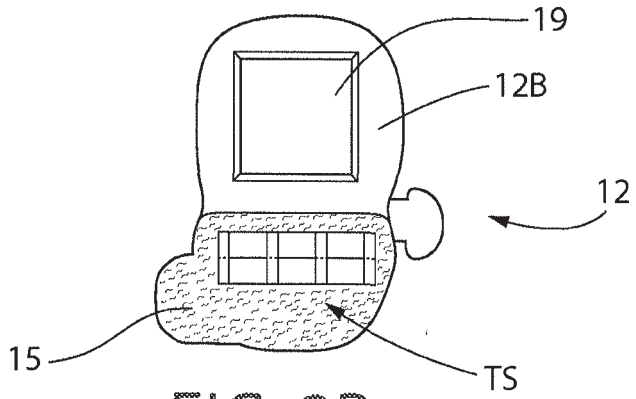

FIG. 2B
(PRIOR ART)

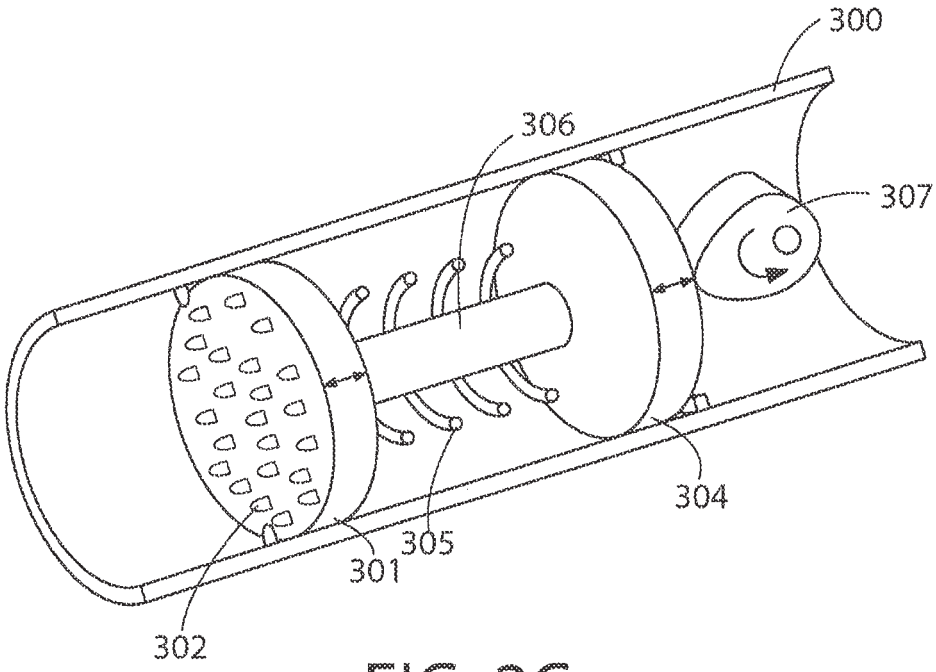

FIG. 2C
(PRIOR ART)

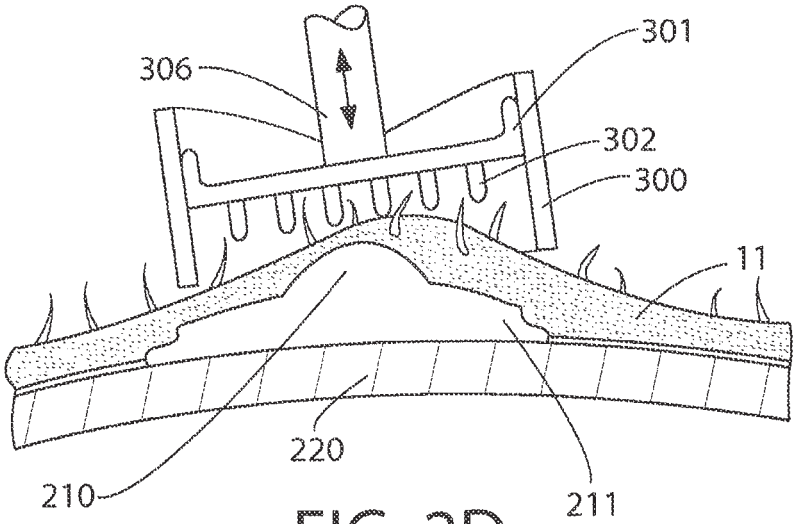

FIG. 2D
(PRIOR ART)

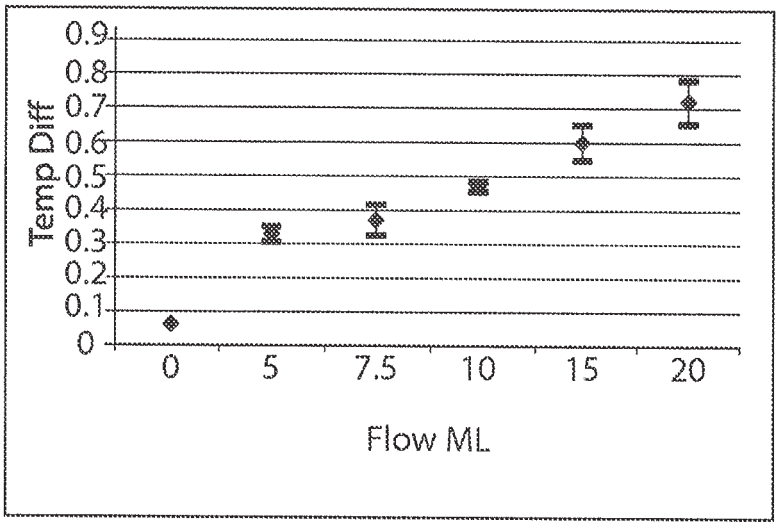

FIG. 3
(PRIOR ART)

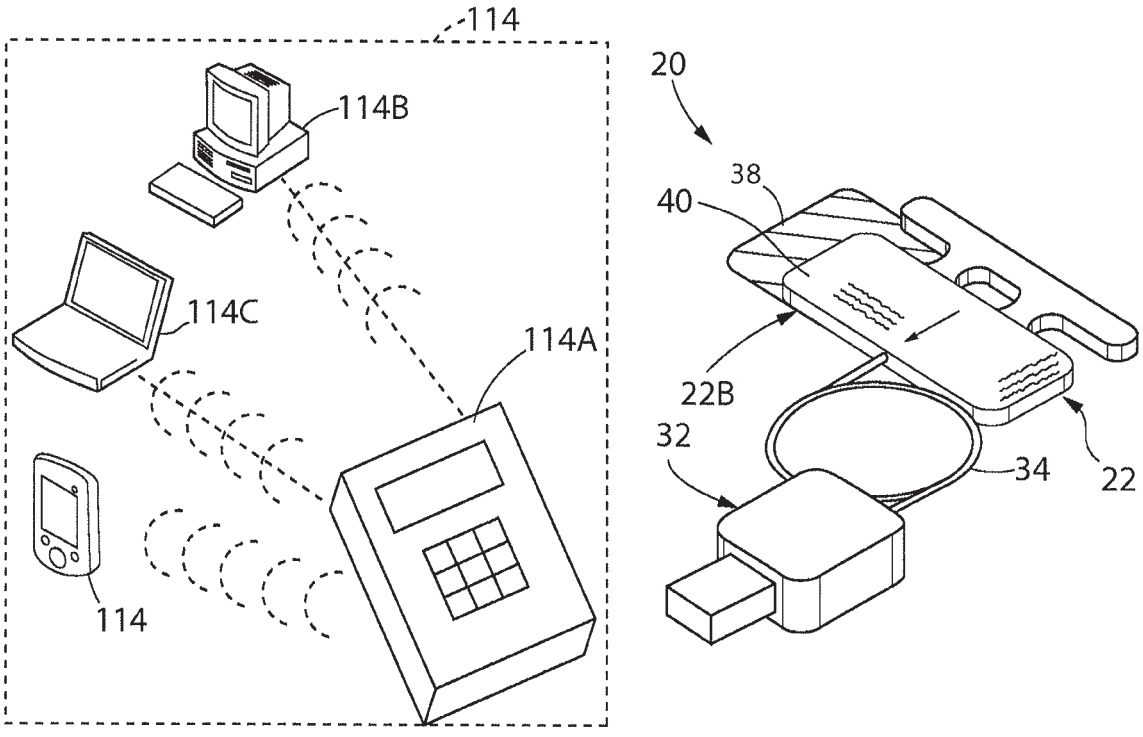

FIG. 4

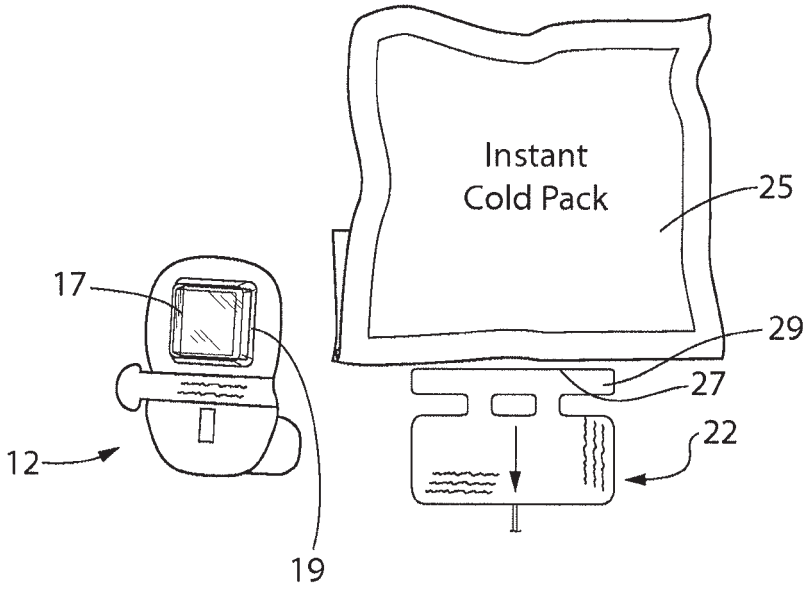
Instant
Cold Pack
25
17
29
27
22
12
19

FIG. 5A

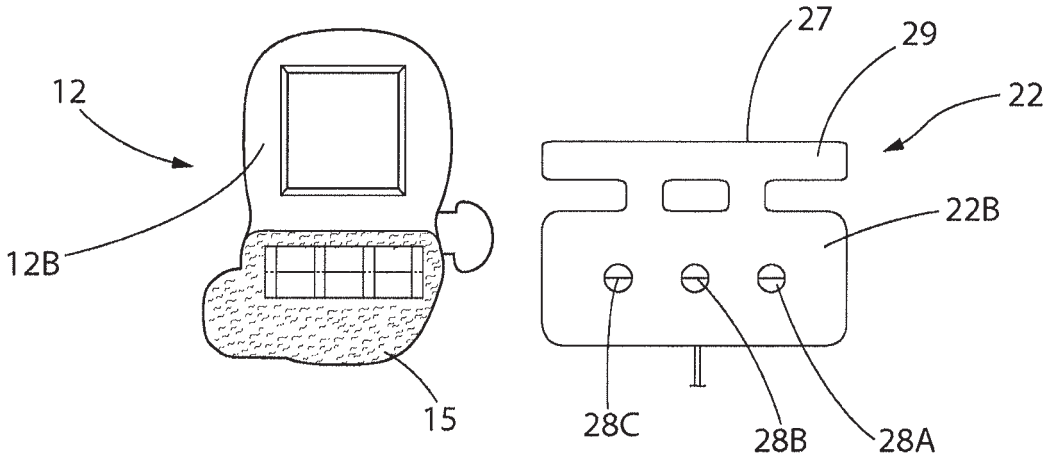
27
29
22
12
22B
12B
15
28C
28B
28A

FIG. 5B

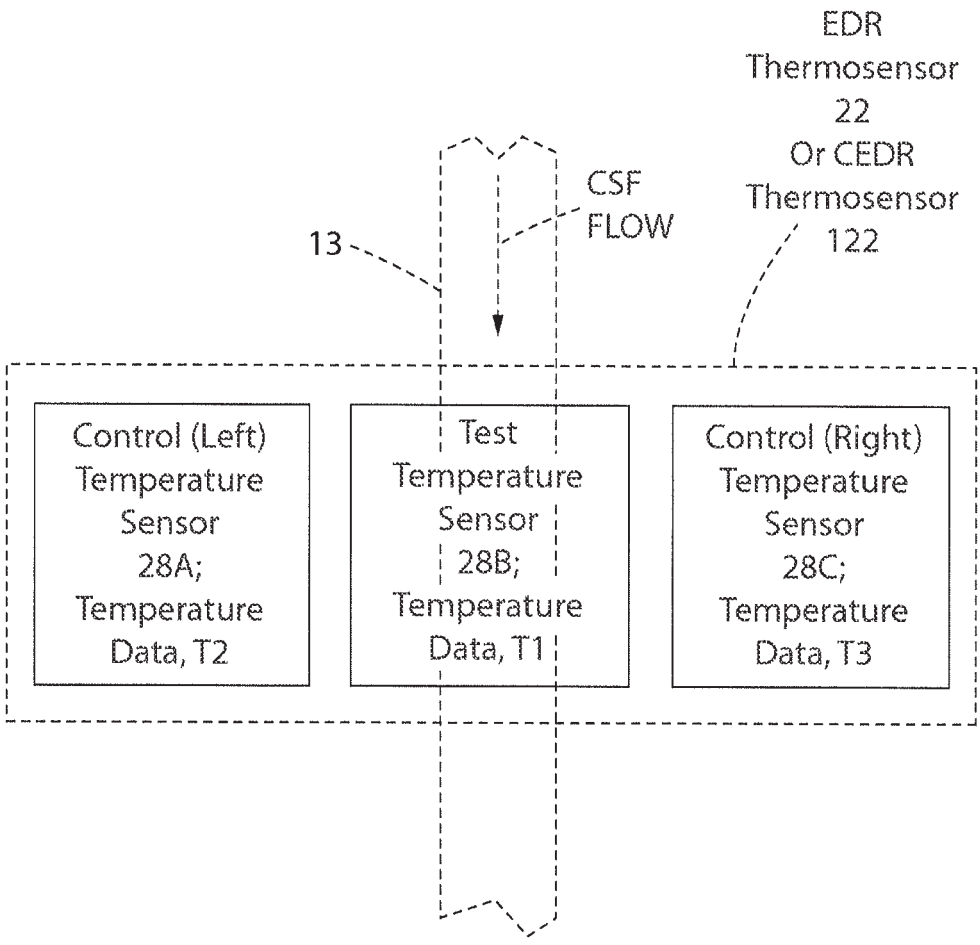
EDR
Thermosensor
22
Or CEDR
Thermosensor
122
CSF
FLOW
13
Control (Left)
Temperature
Sensor
28A;
Temperature
Data, T2
Test
Temperature
Sensor
28B;
Temperature
Data, T1
Control (Right)
Temperature
Sensor
28C;
Temperature
Data, T3

FIG. 5C

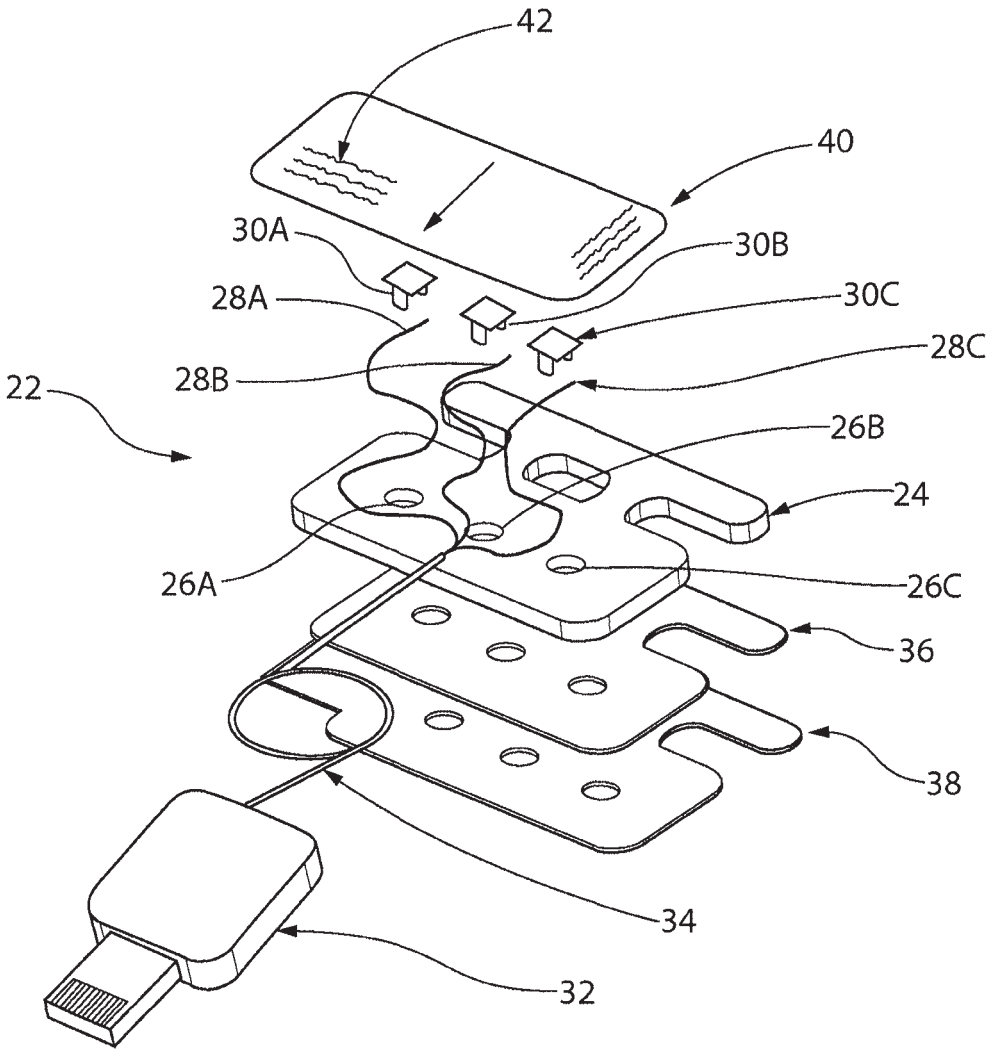

FIG. 6

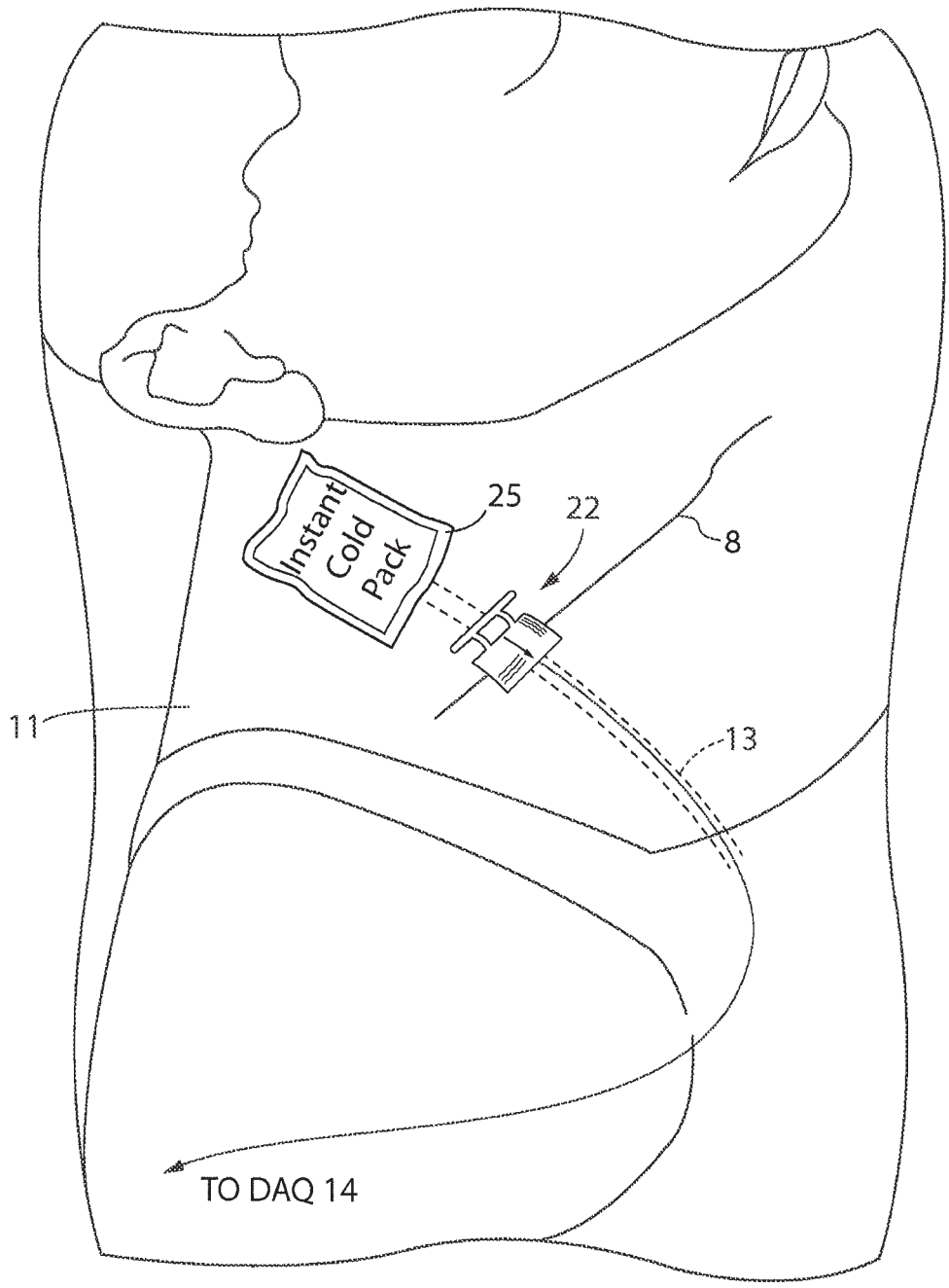

FIG. 6A

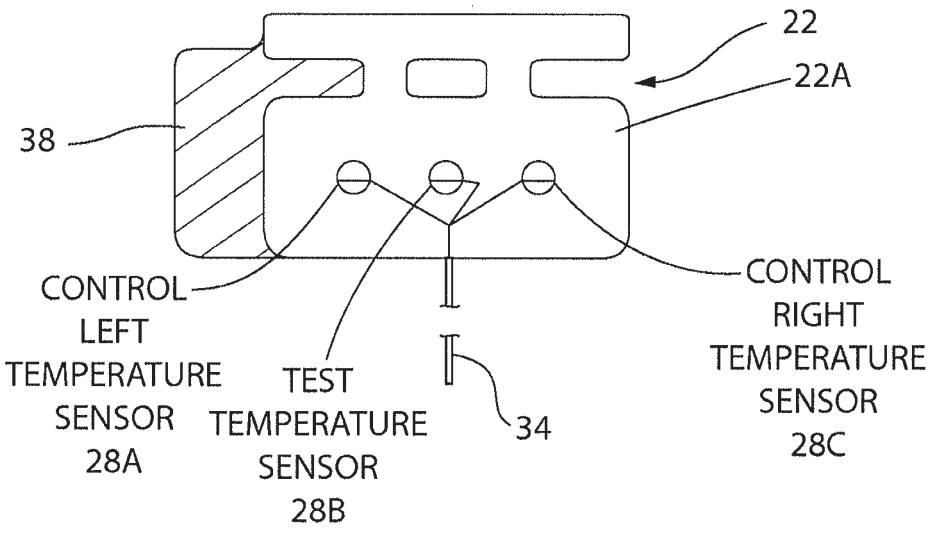
22
22A
38
CONTROL
LEFT
TEMPERATURE
SENSOR
28A
TEST
TEMPERATURE
SENSOR
28B
34
CONTROL
RIGHT
TEMPERATURE
SENSOR
28C

FIG. 7

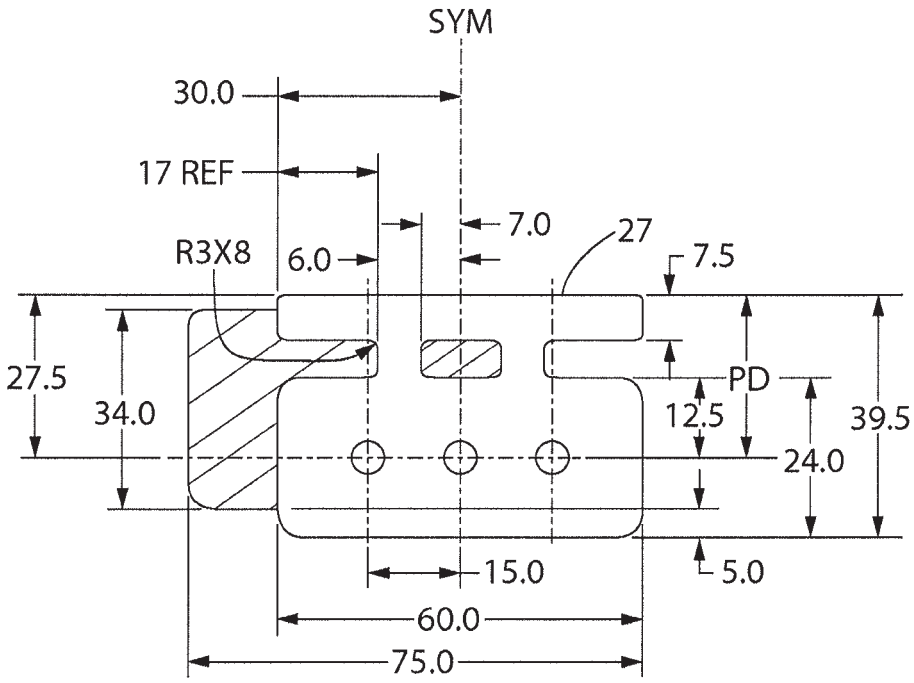
SYM
30.0
17 REF
7.0
27
7.5
R3X8
6.0
27.5
34.0
PD
12.5
39.5
24.0
15.0
5.0
60.0
75.0

FIG. 8

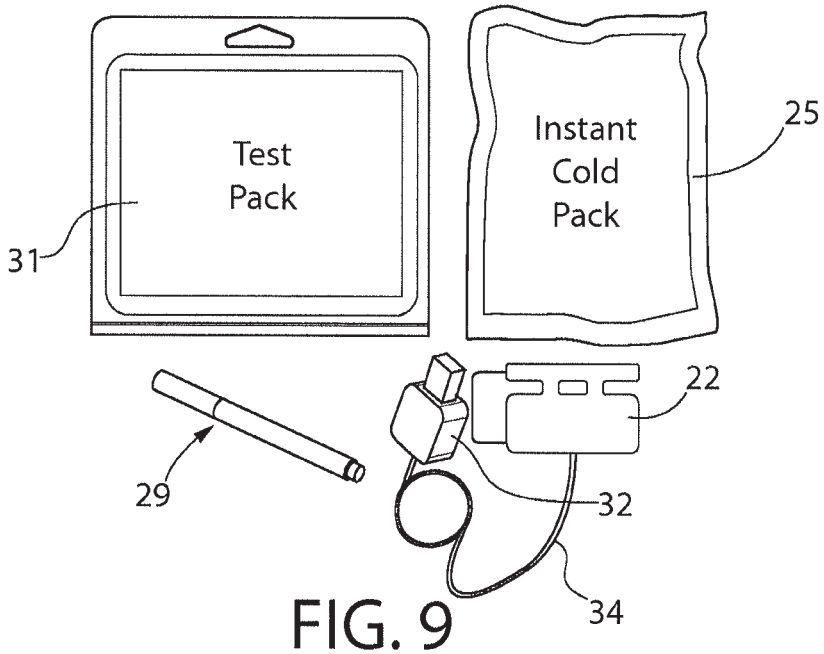
Test
Pack
31
Instant
Cold
Pack
25
22
29
32
34

FIG. 9

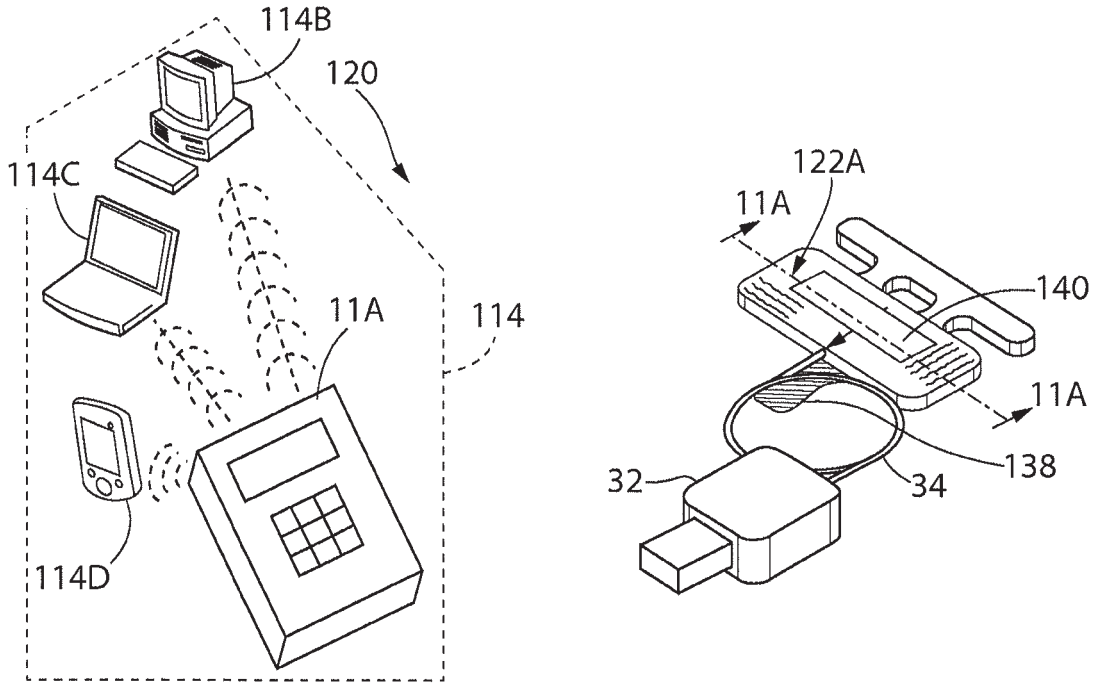
114B
120
114C
11A
114
114D
122A
11A
140
11A
32
34
138

FIG. 10

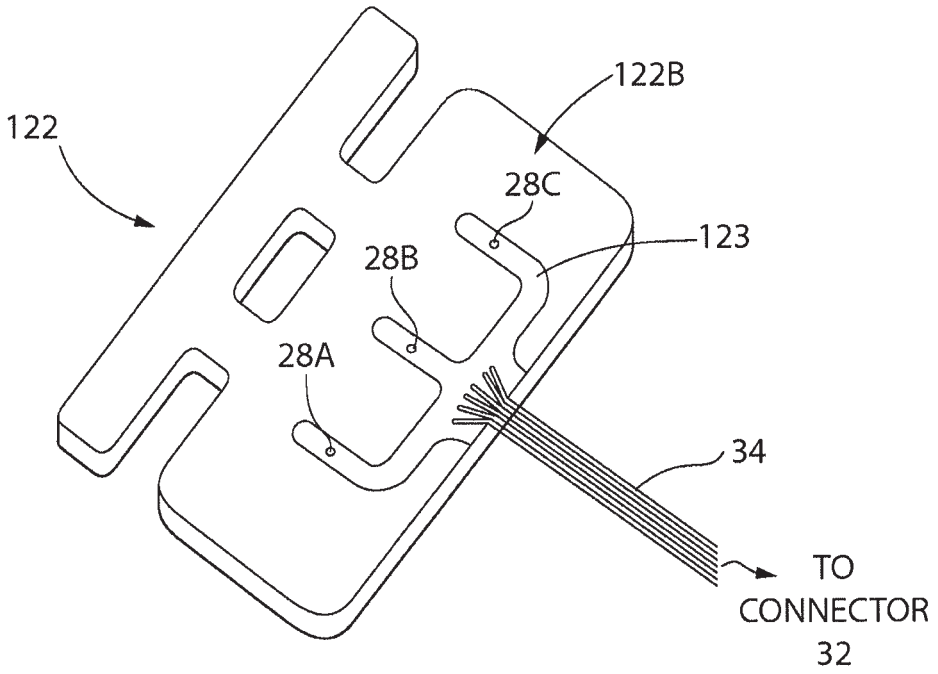

FIG. 11

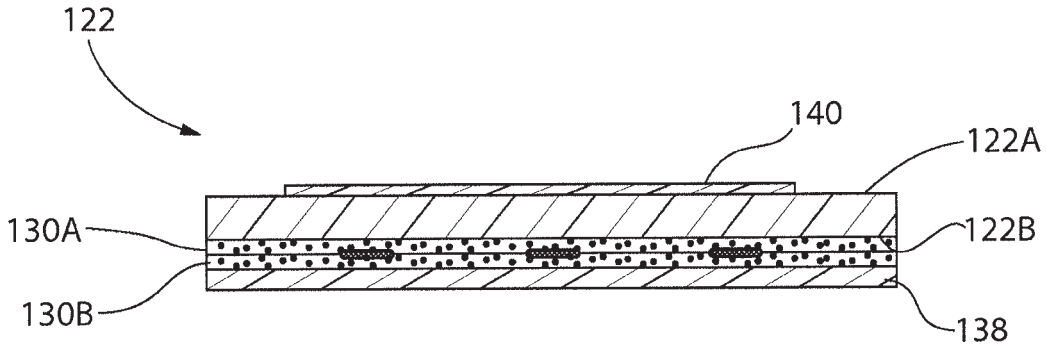

FIG. 11A

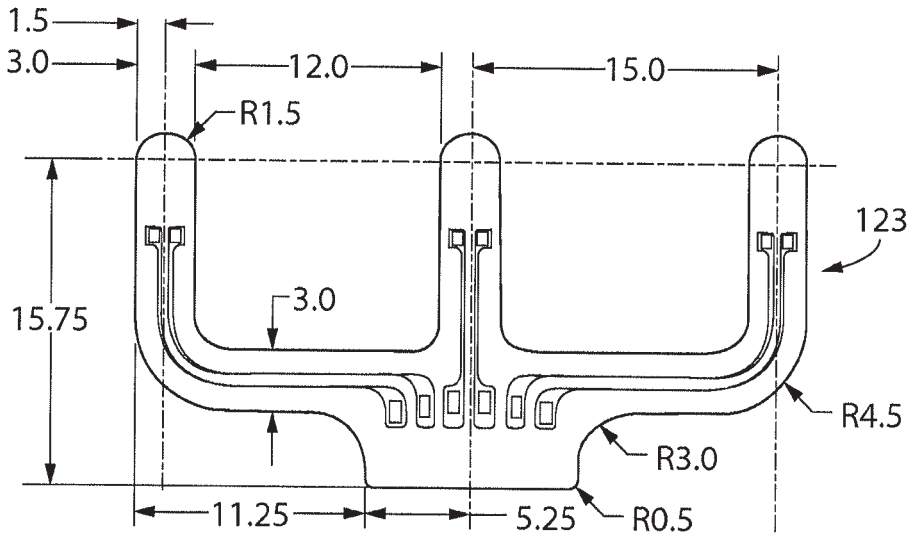

FIG. 12

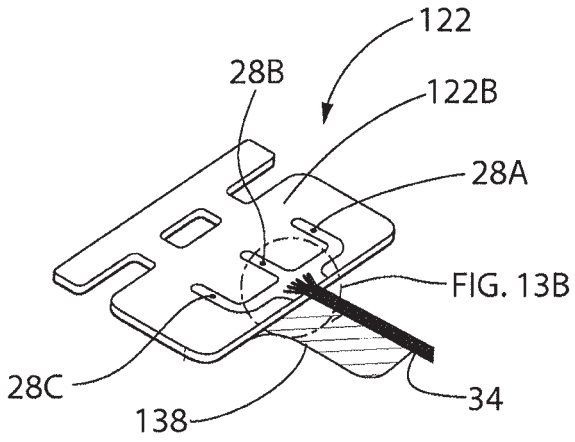

FIG. 13A

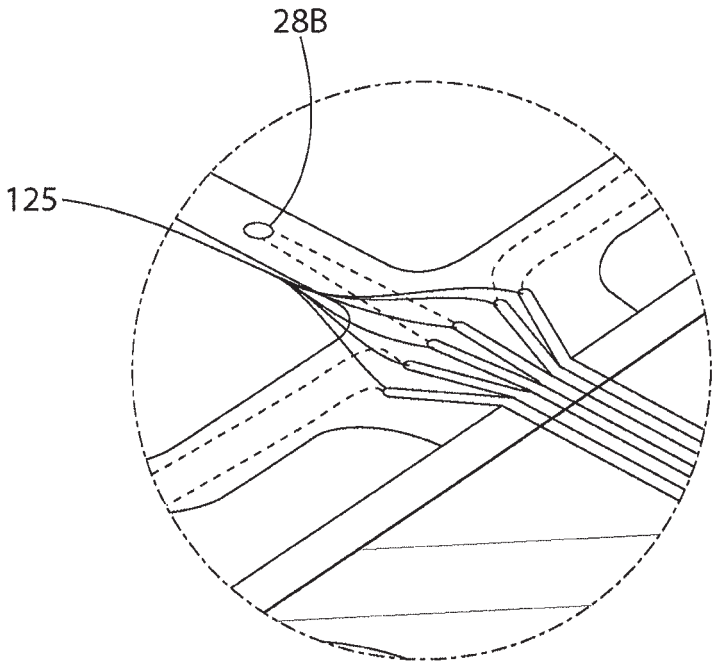

FIG. 13B

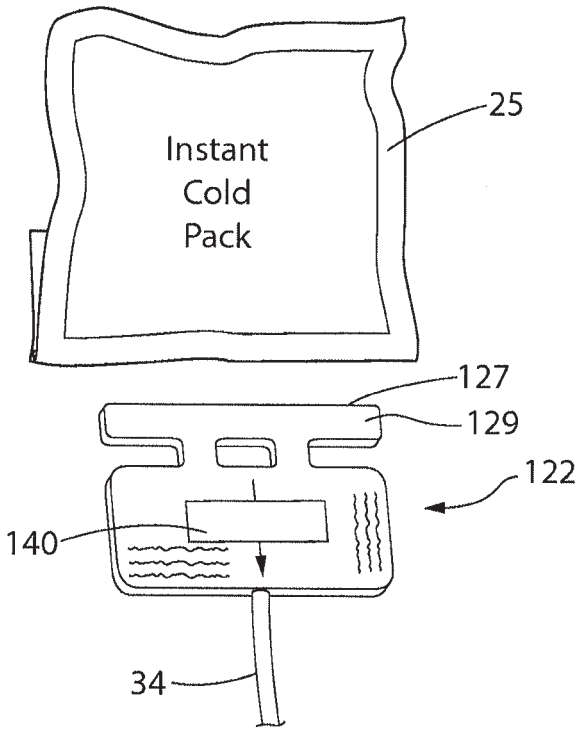

FIG. 14

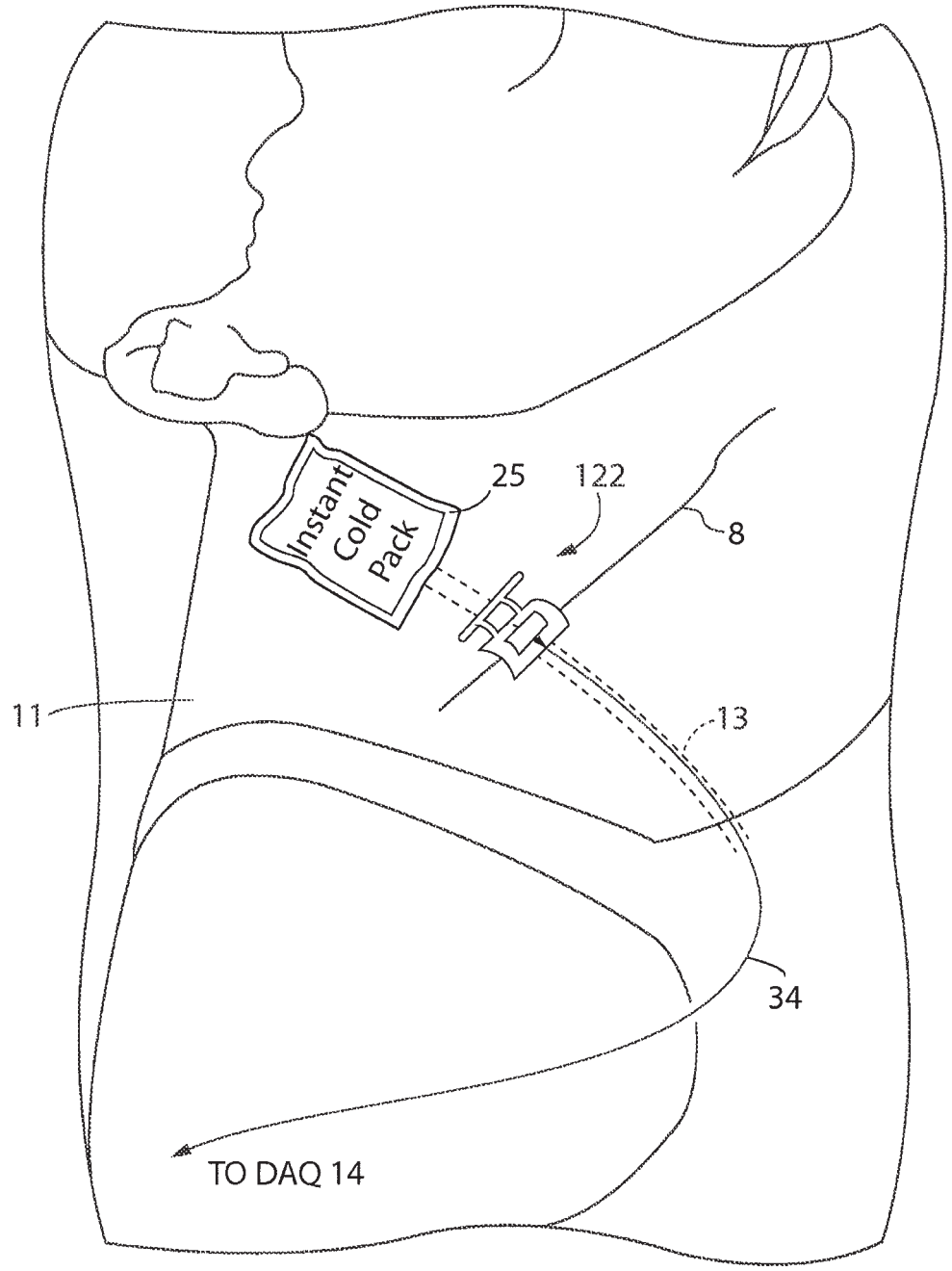

FIG. 15

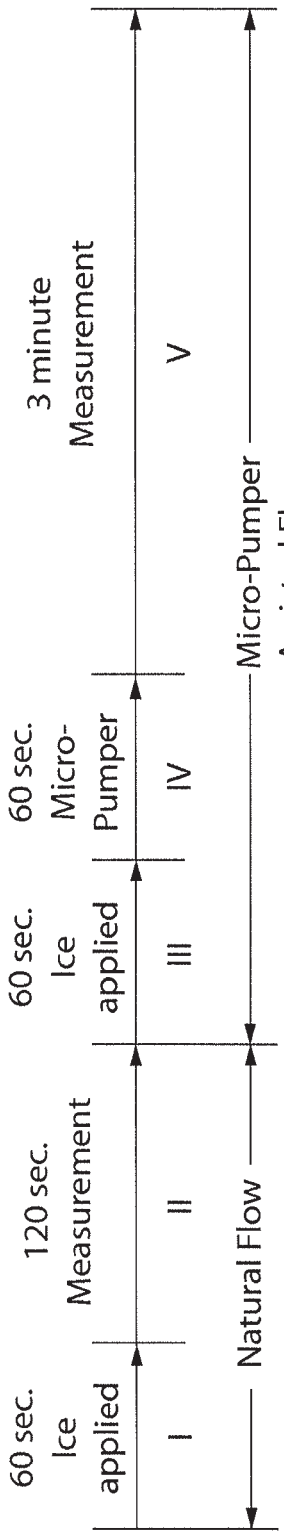

FIG. 16A

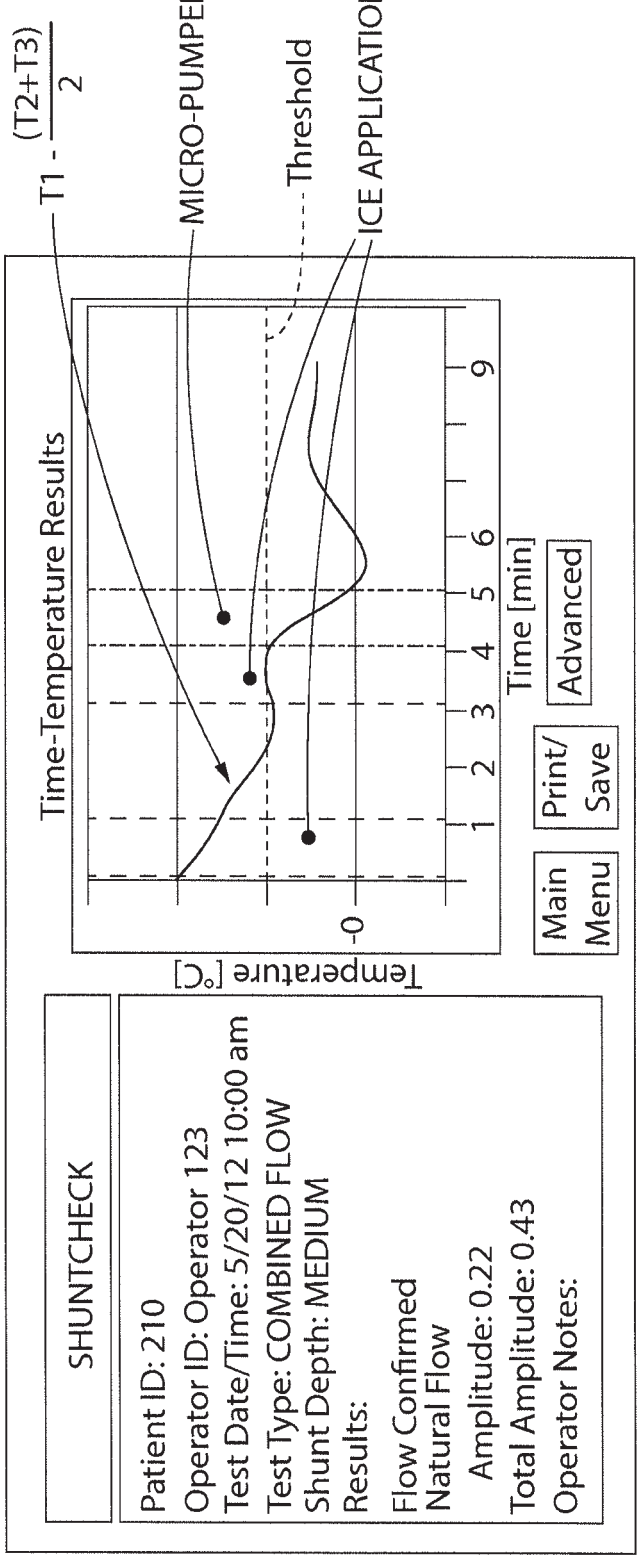

FIG. 16B

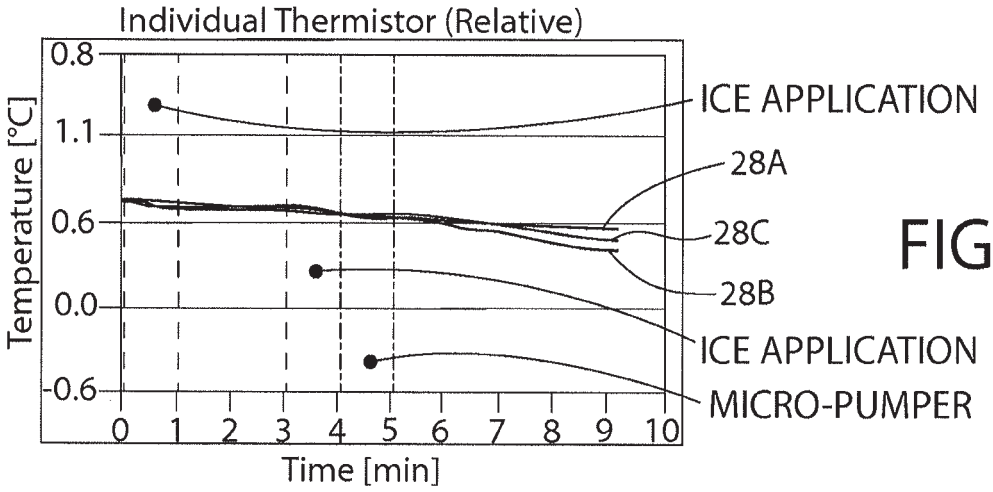

FIG. 17A

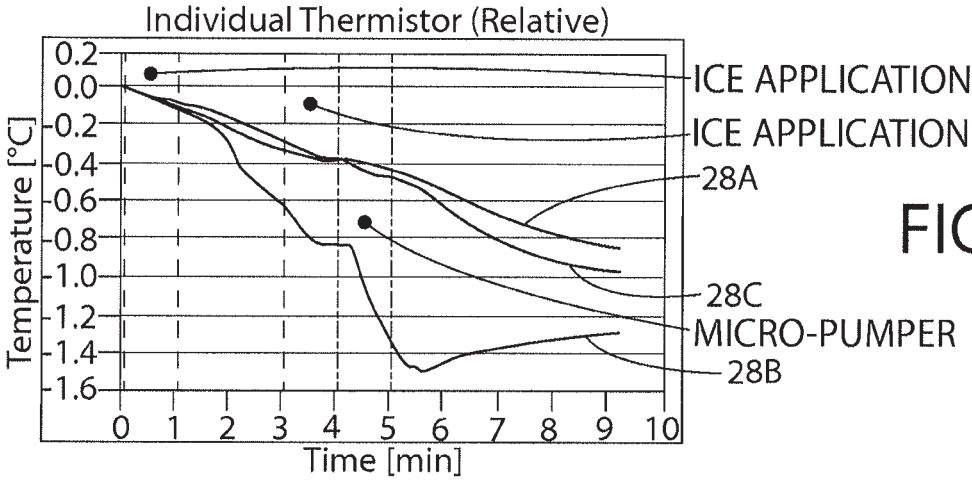

FIG. 17B

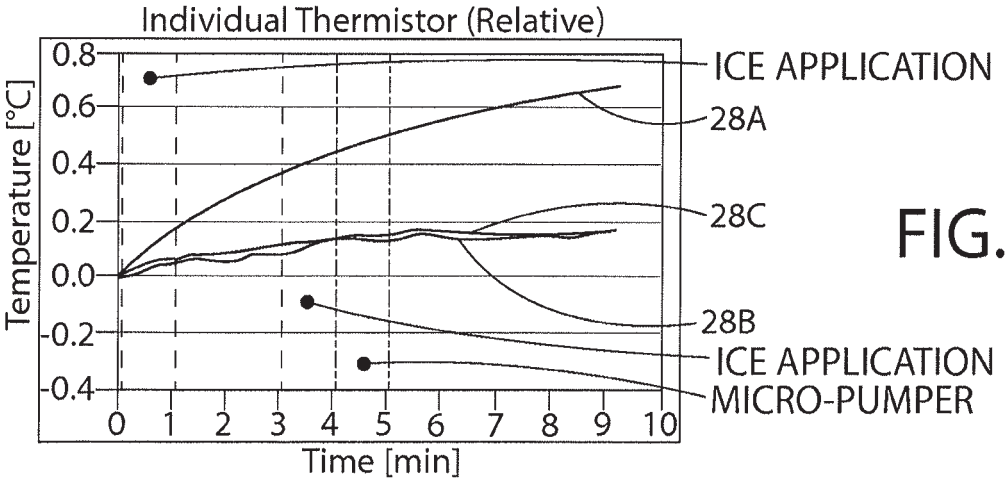

FIG. 17C

REFERENCES CITED IN THE DESCRIPTION

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