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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
10 November 2011 (10.11.2011)

PCT

(10) International Publication Number
WO 2011/139499 A1

(51) International Patent Classification:
*A61F 5/44* (2006.01)

(21) International Application Number:
PCT/US2011/032270

(22) International Filing Date:
13 April 2011 (13.04.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/330,518 3 May 2010 (03.05.2010) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,

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(54) Title: INDWELLING DRAINAGE APPLIANCE FOR BODY WASTE

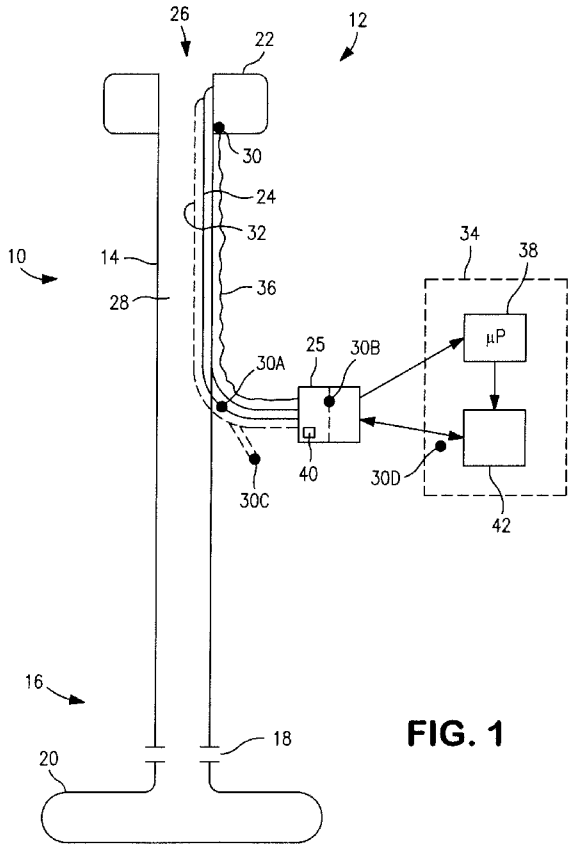



FIG. 1

(57) Abstract: An indwelling drainage appliance having an indwelling portion insertable into a natural or artificial body opening for drainage therethrough, an inflatable balloon cuff at the indwelling portion for engaging internal body tissue in use, and a sensor for directly or indirectly sensing the inflation status of the balloon. The sensor may generate an electronic signal fed from the sensor by one or more wires, or a wireless signal, or an optical signal fed by an optical fiber. A processing circuit is configured to process the signal generated by the sensor, in order to derive fill status information therefrom. The appliance may be an intestinal appliance for insertion through the abdominal wall into the intestine at the cecal valve, or it may be a rectal or urinary tract waste management appliance.

WO 2011/139499 A1

NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

**Declarations under Rule 4.17**:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

— *of inventorship (Rule 4.17(iv))*

**Published**:

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

# INDWELLING DRAINAGE APPLIANCE FOR BODY WASTE

## Field of the Invention

The present invention relates to an indwelling drainage appliance for body waste, having a distal portion for insertion into a natural or artificial body orifice. The invention is especially directed to such an appliance having an inflatable balloon for engaging internal body tissue. The invention is especially, but not exclusively, useful for an appliance in the form of a drainage catheter.

## Background to the Invention

Indwelling drainage appliances are typically used to drainage fecal or urine waste from the body. The distal portion of the appliance is inserted through a natural body orifice, such as the rectum or urethra, or it may be inserted through an artificial opening, such as a stoma or incision. The inflatable balloon performs one or both of: (i) anchoring the distal portion by engaging internal body tissue; and (ii) providing a seal against the internal tissue to prevent leakage of body waste past the balloon, thereby ensuring that the body waste is properly diverted to drain through the appliance.

By way of example, WO 2009/131992A describes an indwelling transcecal drainage catheter having distinct retention and sealing balloons. WO 2009/135141A describes an indwelling rectal catheter having a single balloon that performs both sealing and retention functions, and a pressure state indicator therefor.

The effectiveness in draining waste from the body is dependent on correct inflation of the balloon. The degree of inflation determines the balloon's ability to retain the appliance properly seated in situ, and/or provide a seal against the internal tissue. Occasionally, the balloon may deflate prematurely or be under inflated and the appliance becomes dislodged from or misfit in its position, resulting in ineffective waste management. There are several reasons for premature deflation: loss of fluid due to leaks; relaxation of the locations anatomy; and permeation of fluid through the material of the balloon wall. Shifting of placement within the body or changes in available space due to physological actions can result in under or over inflation as more

or less space can become available In addition, there is a need to avoid sustained application of high pressure on the anatomy surrounding the inflated balloon, because such pressure may cause damage to local tissues.

A further characteristic of such drainage catheters is that they remain in situ in the body for extended durations. For example, the transcecal catheter referred to above remains in situ for up to 42 days. The transcecal catheter would require a surgical operation to replace or reposition. The rectal catheter referred to above remains in situ for up to 29 days. This makes the drainage appliances very different in nature from temporary stoppers used to treat the symptoms of incontinence, and that block passage of body waste and are manually removable whenever the wearer needs to discharge body waste. The requirement that a drainage appliance needs to be able to stay in situ for an extended duration greatly exacerbates the importance of correct inflation of the balloon. Solutions for temporary incontinence stoppers cannot be used for drainage appliances.

The present invention has been devised bearing the above issues in mind.

## Summary of the Invention

Broadly speaking, one aspect of the invention provides an indwelling drainage appliance having an indwelling portion insertable into a natural or artificial body opening for drainage therethrough, an inflatable balloon at the indwelling portion for engaging internal body tissue in use, and a sensor for directly or indirectly sensing the inflation status of the balloon.

The sensor may generate an electronic signal fed from the sensor by one or more wires, or a wireless signal, or an optical signal fed by an optical fiber. A processing circuit is configured to process the signal generated by the sensor, in order to derive fill status information therefrom.

The provision of a fill status sensor provides important information that can be processed to enable the appliance to be maintained in an optimum inflation state compatible with the body, and the desired drainage operation, and also enable the fill status to be adapted to dynamic changes in local anatomy.

The fill status of a balloon can be determined by measuring the pressure within the balloon. The sensor may be a pressure sensing transducer. This pressure is a result of the combination of the pressure (if any) required to stretch the balloon and the pressure of the surrounding tissue on the balloon. During the development of the invention, the inventors discovered that transient pressures are placed on the balloon during use, due to changes in local anatomy (e.g. contractions of the bowel, shifting of weight, stress, relaxation, etc). By monitoring the inflation pressure by means of a pressure transducer, the appliance can be correctly seated, operated and maintained in position, with less risk of complication should the balloon become underinflated or overinflated for whatever reason. This can significantly enhance the efficacy of an indwelling drainage appliance, and reduce the burden on attending caregivers.

The invention is especially advantageous when used for an intestinal drainage appliance that is inserted through an artificial incision in the abdominal wall, and through an artificial incision in the intestinal wall, into the intestine near or at the cecal-valve. Once positioned, the indwelling portion of the appliance is not easily visible or accessible for caregivers. A surgical operation may be required to replace or reposition the appliance. The invention enables the inflation state of the otherwise hidden indwelling balloon to be observed and monitored to ensure that the appliance can be maintained and operated correctly seated throughout its extended use, despite the indwelling portion being inaccessible for caregivers.

Although features believed to be of importance are highlighted herein and in the appended claims, protection may be sought for any novel feature or idea described herein and/or illustrated in the drawings whether or not emphasis has been placed thereon.

Brief Description of the Drawing:

Fig. 1 is a schematic block diagram illustrating an embodiment of the invention.

Fig. 2 is a schematic flow diagram showing an example algorithm used by the processing unit in Fig. 1; and

Fig. 3 is a schematic diagram illustrating a metric for establishing allowable limit ranges for sensed pressure.

Detailed Description of the Preferred Embodiment:

Fig. 1 illustrates generally a drainage appliance 10 having an indwelling portion 12 insertable into the body. The term "indwelling" means indwelling in use when inserted into the body. The appliance 10 is illustrated in the form of a catheter tube 14, although the appliance 10 may have any suitable form including a tube. The indwelling portion 12 may be configured for insertion through a natural body orifice, for example the anus or urethra, or it may be configured for insertion through an artificial body orifice, for example a stoma or surgical opening. In one form, the appliance may be an intestinal drainage appliance, and the indwelling portion may be configured to be inserted, in use, through an artificial incision in the abdominal wall and through an artificial incision in the intestinal wall, so as to drain body waste from within the intestine. The indwelling portion 12 is typically at, or includes, a distal portion of the appliance. A proximal portion 16 of the appliance 10 is coupled, or coupleable via a separable coupling 18, to an effluent collection device 20, here illustrated as a pouch.

The indwelling portion 12 is provided with at least one inflatable cuff or balloon 22, for engaging internal body tissue when the distal portion 12 is in situ in the body. The balloon 22 extends peripherally (e.g. circumferentially) around an outer surface of the catheter tube 14 at the indwelling portion 12, and is such that the balloon 22, when inflated, defines an outward projection with respect to the surface of the tube 14. The balloon 22 may function as a retention balloon to retain the indwelling portion 12 in a predetermined position in the body; or, the balloon 22 may function to seal between the indwelling portion 12 and the internal body tissue, to prevent effluent passing the seal, and ensure correct diversion of effluent into the drainage appliance 10; or the balloon 22 may perform both. In one form, the appliance includes a single balloon 22, for example, as in a rectal catheter embodiment (further constructional details of which may be found in the aforementioned WO 2009/135141A the contents of which are incorporated herein by reference).

The single balloon 22 can perform both seal and retention functions. In an alternative form, the appliance includes first and second balloons (not shown specifically), for example, as in a cecal-valve (e.g., transcecal) catheter embodiment (further constructional details of which may be found in the aforementioned WO 2009/131992A, the contents of which are incorporated herein by reference).

The balloon 22 is inflatable by means of an inflation conduit 24, one portion of which communicates with the balloon 22, and another portion of which communicates with a connector 25 coupled or coupleable to an inflation fluid supply. The balloon 22 may be made of any suitable material. One example is a balloon 22 made of substantially non-stretching material, for example polyurethane in which case the balloon is preformed 100% or greater of it's fully-inflated volume. Alternatively, the balloon 22 may be made of elastic material. Elastic material may also be preformed in fully inflated shape, or in at least a nearly a fully inflated shape but may stretch slightly to accommodate inflation or anatomical variation. Alternatively, the elastic material may be molded in a substantially non-inflated form, and be required to stretch elastically to an inflated form. A suitable elastic material is silicone rubber.

The connector 25 (or another part of the appliance 10) may optionally include an identification and/or usage circuit 40 that uniquely identifies the appliance 10, or stores information about usage. This is useful for monitoring the use-time of the appliance 10, to ensure that the appliance does not remain in use for longer than is recommended for the appliance.

A feature of a drainage appliance 10 is that it is configured to remain in situ in the body for extended periods. For example, a rectal catheter is configured to remain in situ for up to 29 days, and an intestinal catheter is configured to remain in situ for up to 56 days. The drainage appliance 10 is not intended to be removed to discharge effluent. Instead, while the appliance 10 is in situ, effluent is diverted to enter an aperture or mouth 26 at the distal portion 12, and the drain out of the body through a discharge channel 28 within the tube 14. In the present embodiment, the mouth 26 and the channel 14 are configured to be permanently open and/or non-obstructed, to allow substantially unobstructed drainage of effluent from the body. This is

a further feature of the appliance 10 that can avoid accumulation of pressure within internal body organs.

The appliance 10 is provided with at least one pressure-sensitive transducer 30 for directly or indirectly measuring the pressure of inflation fluid in the balloon 22. The provision of a pressure transducer 30 provides important information that can be processed to enable the appliance 10 to be maintained in an optimum inflation state compatible with the body, and the desired operation, and also enable the inflation pressure to be adapted to dynamic changes in local anatomy. During the development of the invention, the inventors discovered that transient pressures are placed on the balloon 22 during use, due to changes in local anatomy (e.g. contractions of the bowel, shifting of weight, stress, relaxation, etc). By monitoring the inflation pressure by means of the pressure transducer 30, the appliance 10 can be correctly seated, operated and maintained in position, with less risk of complication should the balloon 22 become underinflated or overinflated for whatever reason. Where plural balloons or cuffs are employed, plural transducers may optionally be used to enable independent monitoring of the balloons/cuffs. In one form, a respective transducer is provided for each balloon. In another embodiment, plural transducers are used, but the number of transducers is less than the number of balloons (for example, only the pressure-critical balloons are monitored).

The transducer 30 is of a type that generates an electrical output signal, or a wireless signal, or an optical signal via an optical fiber. Specific examples include a piezo-electric transducer, or a capacitive transducer. In the case of an electrical or optical output signal, the signal is fed from the transducer by one or more wires or fibers (36). The wires or fiber may also serve to supply power to the transducer 30. The fiber or wires may couple through the connector 25, or by another connector distinct from the connector 25.

In one form, the transducer 30 is positioned at, or in, the balloon 22 to directly measure the inflation pressure of the balloon 22. In an alternative form, the transducer 30 is remote, or spaced, from the balloon 22 and in fluid communication with the balloon 22 via a fluid communication channel. This may enable the transducer to be positioned outside the body, instead of the

transducer being indwelling. The fluid communication channel may be the inflation conduit 24, or it may be a separate pressure-sensing conduit (shown in phantom at 32) distinct from the inflation conduit 24, or a combination of portions of both. A separate sense conduit 32 has the advantage that the pressure measured is generally independent of any pressure differential along the inflation conduit whenever there is substantial flow of inflation fluid in the inflation conduit 24 during inflation or deflation of the balloon 22. Such pressure differential results from pressure drop of fluid flowing in a channel. The pressure as measured in the inflation conduit 24 is only accurately representative of the inflation pressure in the balloon 22 when quiescent. Of course, inclusion of a distinct sense conduit 32 may add to the cost of the tube 14, and to the manufacturing cost of the appliance 10. Depending on the application, it may be more cost effective to include the transducer 30 coupled to the inflation conduit 24. The output signal may be processed so as to remove effects caused by pressure differential in the inflation conduit 24 during inflation or deflation.

By way of example only, a spaced transducer 30 may be provided at any of the following positions:

(A) intermediate the balloon 22 and the connector 25;

(B) at the connector 25. The connector 25 may serve as a protective housing for the transducer 30, and avoid additional flying tubes or cables coupled to the transducer 30. If the connector 25 is additionally separable from the remainder of the appliance 10, this may permit replacement of, for example, a transducer in case of malfunction. It may also permit the same transducer to be used multiple times with different appliances;

(C) on a flying portion of the sense conduit 32. The transducer 30 may be permanently attached to the sense conduit 32, or it may be separable therefrom;

(D) in a control console 34 , if provided and if the pressure measured at the console is representative of the inflation pressure of the balloon 22. This further discussed below.

An electronic processing circuit 38 receives the pressure signal generated by the transducer 30. The electronic processing circuit 38 may be part of the appliance 10, or it may be part of auxiliary equipment to which the

appliance 10 is coupled in use. In one form described below, the electronic processing circuit 38 is comprised in an auxiliary control console 34 to which the appliance 10 is coupled.

Depending on the application, the processing circuit 38 may perform one of more of the following functions:

(i) to process or clean the signal to generate a stable value therefrom. The processing may include exclusion of pressure differential effects as explained above, or merely suspending pressure indication during periods of active inflation or deflation of the balloon 22 via the inflation conduit 24. Occurrences of inflation or deflation may be known within the processing circuit 38, or may be detected automatically by a flow sensor (not shown) or a sensor (not shown) detecting the attachment of a filling syringe to the inflation conduit 24.

(ii) to determine whether the actual pressure of the balloon 22 exceeds, or falls below, one or more safety thresholds. For example, a threshold may indicate the maximum safe inflation pressure. A maximum safe continuous pressure may, for example, be 35 mmHg. Additionally or alternatively, a threshold may indicate a minimum safe pressure for operation, below which the appliance 10 may be unreliable.

(iii) to determine, and optionally monitor, one or more trends in the pressure indication over time. For example, the pressure may be monitored to determine whether the pressure (or a time averaged pressure) exceeds, or falls below, a pressure threshold for a respective time duration associated with the threshold. The time averaged pressure may be an average over the respective time duration, or some other time duration. Examples may include (a) whether the average pressure exceeds 30mmHg for more than 5 minutes, and/or (b) whether the average pressure exceeds 40mmHg for more than 1 minute. Several different time and pressure criteria may be monitored simultaneously. For example, if both of above criteria (a) and (b) are monitored, should either criterion be met, this may indicate that the balloon pressure is too elevated, and should be reduced. In addition, or as an alternative, the trend in pressure may be used to detect and/or monitor leakage of inflation fluid from the balloon 22. Leakage may be a result of a fault in the appliance (e.g. a puncture in the balloon 22), or it may be a design

characteristic of the appliance. For example, especially when gaseous inflation media is used, there may be leakage by permeation through the material of the balloon wall. Such leakage is not a fault, but should be monitored and compensated in order to enable the drainage appliance to remain in situ for the desired extended duration. Additional or alternative parameters that may be monitored may include the average pressure over a most recent time interval (e.g. 5 minutes), and the maximum and/or minimum pressure over one or more certain time intervals, such as: the last 1 hour; the last 6 hours; the last 12 hours; the last 24 hours.

(iv) to detect passage of effluent into the drainage appliance, for example, at the occurrence of a bowel movement. This may be detected by an identifiable pattern of pressure waves that correspond to the anatomy moving material through.

(v) to detect intestinal distress by, for example, looking for changes in the pressure patterns, specifically extended periods of pressure or long periods of pressure waves indicating attempts for the organ to pass material. It can also look for periods of high rate of pressure pulses or high pressure pulses as an indication of distress.

(vi) to determine the GI motility of the patient, for example, by keeping track of bowel movements (e.g., detected as described above in (iv)) over extended periods of time and looking for trends or variations against predetermined norms.

(viii) to read the unique identification from the identification circuit 40, and monitor the wear-time of the appliance 10 compared to a recommended wear-time or use-life of the appliance 10. In one form, the identification circuit 40 of the appliance 10 may contain a count register that is incremented or decremented in response to signals from the processing circuit 38 to indicate, e.g. minutes or hours of use. If the count register is set initially to have a predetermined value, the register may be decremented progressively to zero, at which point the appliance has been in use for the recommended wear-time. Alternatively, if the count register is set initially at zero, it may be incremented progressively until a maximum threshold is reached. The threshold may optionally be programmed into the identification circuit 40, or it may be a global value stored in the processing circuit 38. A yet further alternative is for

identification circuit 40 merely to store the unique identifier, and for the processing circuit 38 to monitor the duration of use for that identifier.

(ix) to generate one or more alert signals for altering a caregiver or supervisor, should an improper operating condition occur. The improper condition may, for example, be over-pressure within the balloon (e.g. an instant pressure, or a time-average pressure), or too low a pressure, or detection of a leak, or an improperly seated catheter if no changes are detected in the pressure over time, or a low battery condition (if the processing circuit 38 is battery powered), or the appliance 10 having reached the end of its recommended use-life. The alert signals may optionally include one or more of: a visual alert; an audible alert; a remote alert signal for triggering an alert in a remote or central monitoring station with which the processing circuit 38 is configured to communicate via a wired or wireless connection.

(x) to generate a report of one of more monitored values, optionally in response to an interrogation request from a use. As explained above, the monitored values may include an average pressure over a certain time duration, and one or more maxima and/or minima over predetermined preceding durations. The monitored values may also include the remaining use-life of the appliance.

(xi) to generate one or more inflation and/or deflation control signals for controlling an optional inflation and/or deflation control system 42 coupled to the inflation conduit 14 at the connector 25, in order to increase or decrease the inflation pressure, as appropriate. In one form, the system 42 comprises a source of pressurized inflation fluid (e.g. a pressurized bottle, or a connector for coupling to a central supply), and one or more electronically controlled valves (not shown). The valves may be electromagnetic, or electroactive. The valves may be pulse modulated on/off valves, or variable throttle. In another form, the system 42 comprises a pump, for example, a micro-pump, a peristaltic-pump, or a motorized syringe. The pump may be electromagnetic, or electroactive including driven by heat actuated shape memory wire. The shape memory wire would be cyclically actuated eclectically by the controller to drive a fluid pump to fill or empty the retention balloon.

For example, in response to detected over-pressure, the system 42 may be controlled to decrease the balloon pressure by extracting or venting inflation fluid via the inflation conduit 24. Additionally, or alternatively, in response to detected under-pressure, the system 42 may be controlled to increase the balloon pressure by admitting more inflation fluid via the inflation conduit 14.

Additionally, or alternatively, the processing circuit 38 may be configured to alternate the inflation pressure of the balloon 22 in a cyclic manner. For example, the pressure may be increased to a suitable operating level (such as 20mmHg) to maintain seating of the device in the patient. After a bowel movement (as can be measured by the pressure transducer 30), the balloon inflation pressure may be lowered to a resting pressure (e.g. about 5mmHg). The resting pressure may be maintained for a short duration (e.g. about 5 to 10 minutes) to allow for enhanced perfusion of blood into the local tissues. The balloon pressure may then be increased back up to the operating pressure for further use.

(xii) The device may also follow an algorithm which senses a sudden initial high pressure and by correlating the pressure with pressure drop in the device, calculates the approximate fill volume. It can then indicate to the clinician to stop filling, wait a predetermined time (e.g,, in the range of 0.25 to 10 seconds, or more preferably between about 1 and about 5 seconds) and then indicate the pressure of the static system.

The processing circuit 38 is preferably in integrated circuit form, for example, a microcontroller, or system-on-a-chip, or a digital signal processor (DSP), or a logic circuit, or a programmable logic array (PLA). The processing circuit 38 may include a transceiver for communicating with an external unit, either wirelessly or via a wired connection. The external unit may, for example, be a display unit for displaying messages to an operator, or a data-logging unit, or an alarm unit for generating one or more alarms signals when desired to alert a caregiver that attention is needed. It may also comprise communication drivers, e.g. for lights, audio transducers, a display unit, etc, to present information and alerts to attending caregivers or the patient. It may be disposable and be powered by a built in power source. The processing unit may optionally be integrated with the tubular portion of

the appliance, and disposable as an integral item therewith after the tube has been used. If the processing unit is integrated as part of the tube, the processing unit may incorporate the identification unit 40.

Optionally, the processing circuit 38 and the system 42 are provided in a combined control console 34 referred to above. The control console 34 may be coupled to the connector 25, to automate inflation, deflation and monitoring of the appliance 10. If there is permanently open fluid communication between the balloon 22 and the console 34 via the connector 25, the pressure transducer 30 may optionally be integrated as part of the console 34.

Purely by way of example, Fig. 2 illustrates one example processing algorithm that may be executed by the processor. The algorithm starts at step 50 of reading a current pressure value from the pressure transducer. At step 52, the current pressure value is combined with previously read pressure values to calculate one of more pressure value trends. As explained previously, the trends may, for example, include a value averaged over the last minute (a “one-minute trend”), and/or a value averaged over the last 5 minutes (a “five-minute trend”), and/or a value averaged over the last hour (a “one-hour trend”).

At step 54, the calculated trends and/or the most recent instantaneous value, are compared with a metric or reference model to determine whether the pressure parameters of the cuff are acceptable. Fig. 3 illustrates an example metric, defined on a two-dimensional graph of pressure (e.g. vertical axis 56) vs trend time (e.g., horizontal axis 58). In the form illustrated, the trend time is represented with a logarithmic scale. The acceptable pressure parameters are those in the shaded region 60 bounded between upper limit line 70 and lower limit line 72. Factors limiting the acceptable pressure region 60 in the graph may include:

(a) a pain threshold 62 defining a maximum tolerable pressure on body tissue before the wearer experiences pain;

(b) a pressure necrosis threshold 64, represented by a relationship between both pressure and the time over which that pressure is exerted, before there is a risk of onset of tissue necrosis damage. A relatively high pressure may be tolerated for a short time before there is a risk of necrosis. However, a smaller pressure may also create a risk if the pressure is

maintained for an extended duration. In the metric a safety gap 66 is also applied to ensure that the acceptable region 60 is clear of the necrosis threshold 64 by a considerable margin of safety.

(c) a lower pressure limit 72, defining a minimum pressure for retention of the cuff in the body. If the pressure falls below the lower limit 72, there is a risk that the cuff may fall out, or be ejected by the body.

The upper limit 70 of the acceptable pressure parameter 60 therefore includes a short duration "peak" under the pain threshold 62, to enable the cuff to withstand short term pressure fluctuations, such as transient pressure increases due to coughing or peristalsis. The peak may last for up to a second in time duration. Thereafter, the upper limit 70 gradually reduces from about 100mmHg, with increasing time. The lower limit 72 of the acceptable pressure parameter 60 includes a local minimum of about 5mmHg for a fraction of a second. Thereafter, the lower limit rises to a steady value of about 10mmHg, representing a minimum pressure that should be maintained. In an alternative implementation, the lower limit 72 may be a fixed value in the range of 1 to 15 mmHg.

It will be appreciated that the information in Fig. 3 is highly schematic and intended for the purpose of explanation. Depending on implementation, only some of the information might be needed. For example, if the only pressure trends being evaluated are the one-minute, five-minute and one-hour trends, it will be appreciated that the metric need only store upper and lower limit values from the lines 70 and 72 for the respective times of one minute, five minutes and one-hour.

Referring back to Fig. 2, if at step 54 the pressure trends and/or the instantaneous pressure value are all within the acceptable limits from the metric, this indicates that no adjustment of the inflation pressure of the cuff is needed. The process loops back, via return 74, to the step 50, and the method repeats to continue monitoring the cuff inflation pressure.

If at step 54 one or more of the pressure trends, or the instantaneous pressure value is not within the acceptable limits from the metric, this indicates that the inflation pressure of the cuff is not optimal and should be corrected. There may be a variety of reasons why the inflation pressure is no longer optimal, including changes in anatomical positioning, slow leakage of

inflation fluid from the cuff (e.g. by slow permeation through the cuff wall, or by small leaks in the cuff construction), or a pinched line or fault in the appliance apparatus.

The process passes to step 76 at which one or more trends of pressure correction are processed, as explained later below. Unless there is a trend of the pressure being incorrect, the process will pass through step 76 to step 78. At step 78, an adjustment of the cuff inflation pressure is calculated and implemented with a view to correct the cuff inflation. In one example, step 78 calculates one or more correction parameters according to proportional difference calculations. In another example, existing values are used to look up one or more pre-calculated corrections in a pre-stored data map. The calculation at step 78 may optionally be adaptive, so as to refine the correction calculation according to the success of previous corrections. After step 78, the process returns via return path 74 to step 50 for a next pressure reading.

As mentioned above, step 76 analyzes one or more trends of pressure correction, in order to determine the degree of success of the correction calculated previously (e.g. as a trend) in step 78. Step 76 may, optionally, provide one or more adaptation parameters for refining the calculation in step 78 if step 78 is an adaptive calculation. Additionally or alternatively, step 76 judges whether the correction process is coping with the sub-optimal inflation pressure condition, or whether the sub-optimal inflation pressure condition is too severe to be accommodated by the correction process. An example of a condition that may be accommodated is a slow leakage of inflation fluid, either by permeation through the cuff wall or through small leaks. Step 78 can accommodate such slow leakage by commanding the inflation source to admit more fluid to boost the inflation pressure. This may be sufficient to keep the device seated and in continued use as normal. However, if an inflation fluid source reservoir runs low, or the leak becomes more serious, the condition may become non-correctable by the apparatus. Other non-correctable conditions may include a pinched conduit, a faulty component such as the pressure sensor, or an excessive internal pressure reading that cannot be vented. When step 76 judges that the correction is ineffective, the process branches to an error handling step 80, also referred to as error debug / report.

Step 80 may command several system and/or component tests, test for fill/pressure transient response, leak response testing, battery power, etc. If the fault cannot be resolved automatically, step 80 may stop the process, and generate an alarm or other indication to alert the user or caregiver of the non-correctable situation.

It will be appreciated that the foregoing description is illustrative of one preferred form of the invention, and does not limit the scope of the invention. Many modifications, equivalents and improvements may be included without departing from the scope of the invention as claimed.

CLAIMS

1. An intestinal drainage appliance comprising:

a drainage tube having an indwelling portion configured to be inserted, in use, through an artificial incision in the abdominal wall and through an artificial incision in the intestinal wall, so as to drain body waste from within the intestine;

an inflatable cuff carried on the indwelling portion of the drainage tube for engaging body tissue within the intestine behind the abdominal wall; and

a sensor for directly or indirectly sensing the inflation status of the cuff, the sensor being configured to generate an output signal selected from: a wired electrical signal; a wireless signal; and an optical signal.

2. The intestinal drainage appliance of claim 1, wherein the indwelling portion is configured to pass through the cecal valve.

3. The intestinal drainage appliance of claim 1, wherein the indwelling portion is configured to reside in the large intestine near the cecal valve and obstruct flow through the large intestine, diverting the effluent into the drainage tube.

4. The intestinal drainage appliance of claim 1, wherein the sensor comprises a pressure sensor.

5. The intestinal drainage appliance of claim 1, further comprising a processing unit for processing the output signal generated by the sensor.

6. The intestinal drainage appliance of claim 5, wherein the processing unit is operable to generate a control signal for controlling an inflation regulator coupled to the cuff.

7. The intestinal drainage appliance of claim 6, wherein the inflation regulator comprises at least one selected from: a pressurization source for increasing inflation pressure; a vent for decreasing inflation pressure.

8. The intestinal drainage appliance of claim 7, wherein the pressurization source comprises a pump.

9. The intestinal drainage appliance of claim 8, wherein the pump comprises heat activated shape memory material that is responsive to heat generated by passage of an electrical heating current.

10. The intestinal drainage appliance of claim 5, wherein the processing unit is operable to determine at least a first trend of the cuff inflation over a first predetermined time interval.

11. The intestinal drainage appliance of claim 10, wherein the processing unit is operable to judge whether the first trend is within a predetermined acceptable first range.

12. The intestinal drainage appliance of claim 11, wherein the processing unit is further operable to determine a second trend of cuff inflation over a second predetermined time interval, and to judge whether the second trend is within a predetermined acceptable second range.

13. The intestinal drainage appliance of claim 5, wherein the processing unit is operable to determine at least one selected from:

(i) whether the inflation pressure of the cuff exceeds a first safety threshold;

(ii) a pattern of signal variation indicative of passage of effluent into the appliance;

(iii) a pattern of signal variation indicative of intestinal distress;

(iv) a GI motility value for the wearer;

(v) an approximate fill volume of the cuff, by monitoring pressure drop following set pressure level.

14. The intestinal drainage appliance of claim 5, wherein the processing unit is selected from: a processing unit integrated with the appliance to be

disposable as part of the appliance; a processing unit separate or separable from the appliance whereby the processing unit is reusable with a replacement appliance.

15. The intestinal drainage appliance of claim 1, further comprising a second inflatable cuff at the indwelling portion, and a second sensor for directly or indirectly sensing the inflation status of the second cuff.

16. A rectal or urinary tract drainage appliance comprising:

a drainage catheter having an indwelling portion configured to be inserted into the rectum or urinary tract, and a drainage passage extending in the catheter for drainage of body waste therethrough;

an inflatable cuff at the indwelling portion for engaging body tissue inside the body; and

a sensor for directly or indirectly sensing the inflation status of the cuff, the sensor being configured to generate an output signal selected from: a wired electrical signal; a wireless signal; and an optical signal.

17. The rectal or urinary tract drainage appliance of claim 16, wherein the catheter has a permanently open mouth for permanently allowing entry of body waste into the catheter for drainage.

18. The rectal or urinary tract drainage appliance of claim 16, wherein the sensor comprises a pressure sensor.

19. The rectal or urinary tract drainage appliance of claim 16, further comprising a processing unit for processing the output signal generated by the sensor.

20. The rectal or urinary tract drainage appliance of claim 19, wherein the processing unit is operable to generate a control signal for controlling an inflation regulator coupled to the cuff.

21. The rectal or urinary tract drainage appliance of claim 20, wherein the inflation regulator comprises at least one selected from: a pressurization source for increasing inflation pressure; a vent for decreasing inflation pressure.

22. The rectal or urinary tract drainage appliance of claim 21, wherein the pressurization source comprises a pump.

23. The rectal or urinary tract drainage appliance of claim 22, wherein the pump comprises heat activated shape memory material that is responsive to heat generated by passage of an electrical heating current.

24. The rectal or urinary tract drainage appliance of claim 19, wherein the processing unit is operable to determine at least a first trend of the cuff inflation over a first predetermined time interval.

25. The rectal or urinary tract drainage appliance of claim 23, wherein the processing unit is operable to judge whether the first trend is within a predetermined acceptable first range.

26. The rectal or urinary tract drainage appliance of claim 25, wherein the processing unit is further operable to determine a second trend of cuff inflation over a second predetermined time interval, and to judge whether the second trend is within a predetermined acceptable second range.

27. The rectal or urinary tract drainage appliance of claim 19, wherein the processing unit is operable to determine at least one selected from:

(i) whether the inflation pressure of the cuff exceeds a first safety threshold;

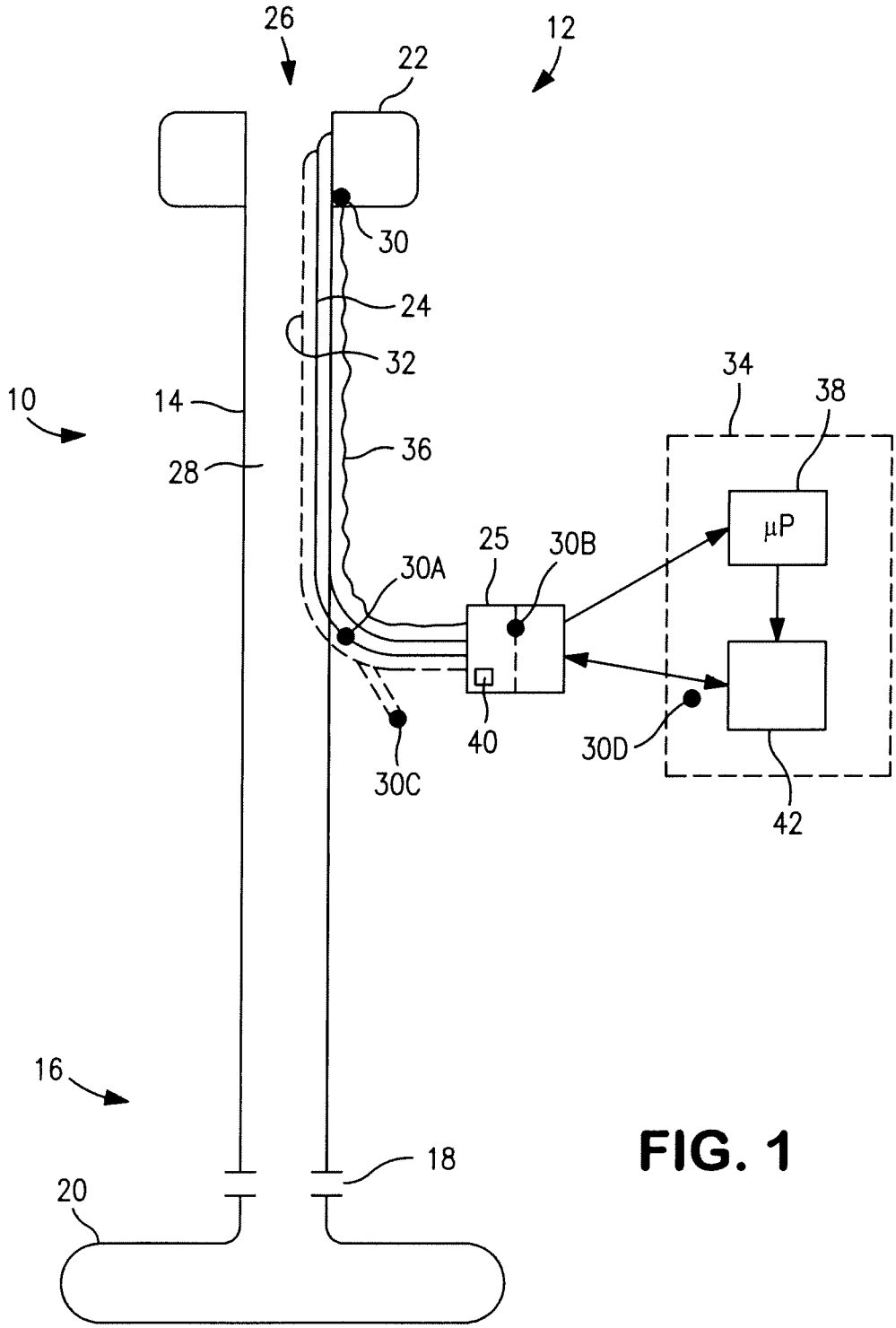
(ii) a pattern of signal variation indicative of passage of effluent into the appliance;

(iii) a pattern of signal variation indicative of intestinal distress;

(iv) a GI motility value for the wearer;

(v) an approximate fill volume of the cuff, by monitoring pressure drop following set pressure level.

28. The rectal or urinary tract drainage appliance of claim 19, wherein the processing unit is selected from: a processing unit integrated with the appliance to be disposable as part of the appliance; a processing unit separate or separable from the appliance whereby the processing unit is reusable with a replacement appliance.


26
12
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34
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μP
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30B
30A
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30D
30C
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FIG. 1

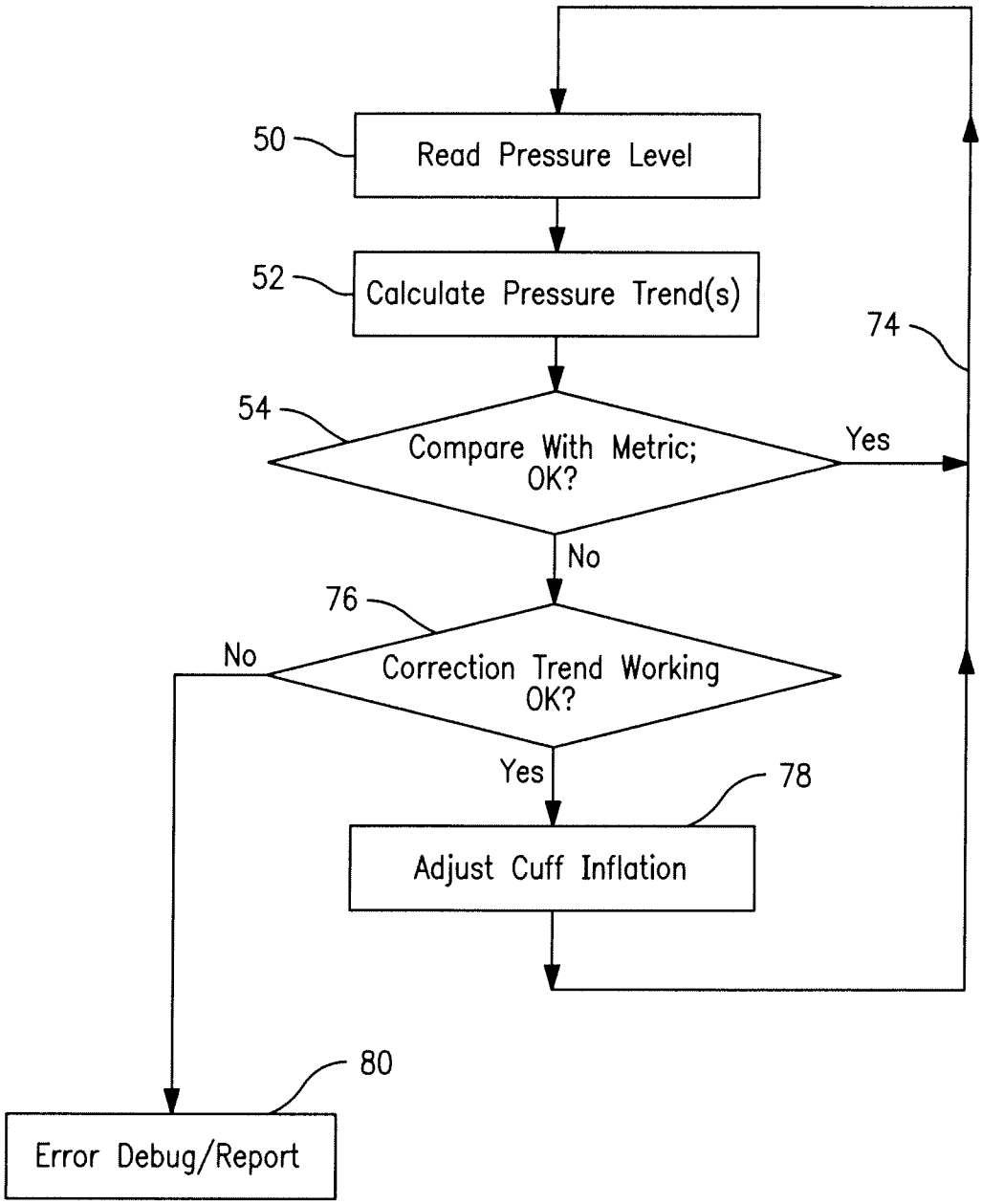
50
Read Pressure Level
52
Calculate Pressure Trend(s)
74
54
Compare With Metric; OK?
Yes
No
76
No
Correction Trend Working OK?
Yes
78
Adjust Cuff Inflation
80
Error Debug/Report

FIG. 2

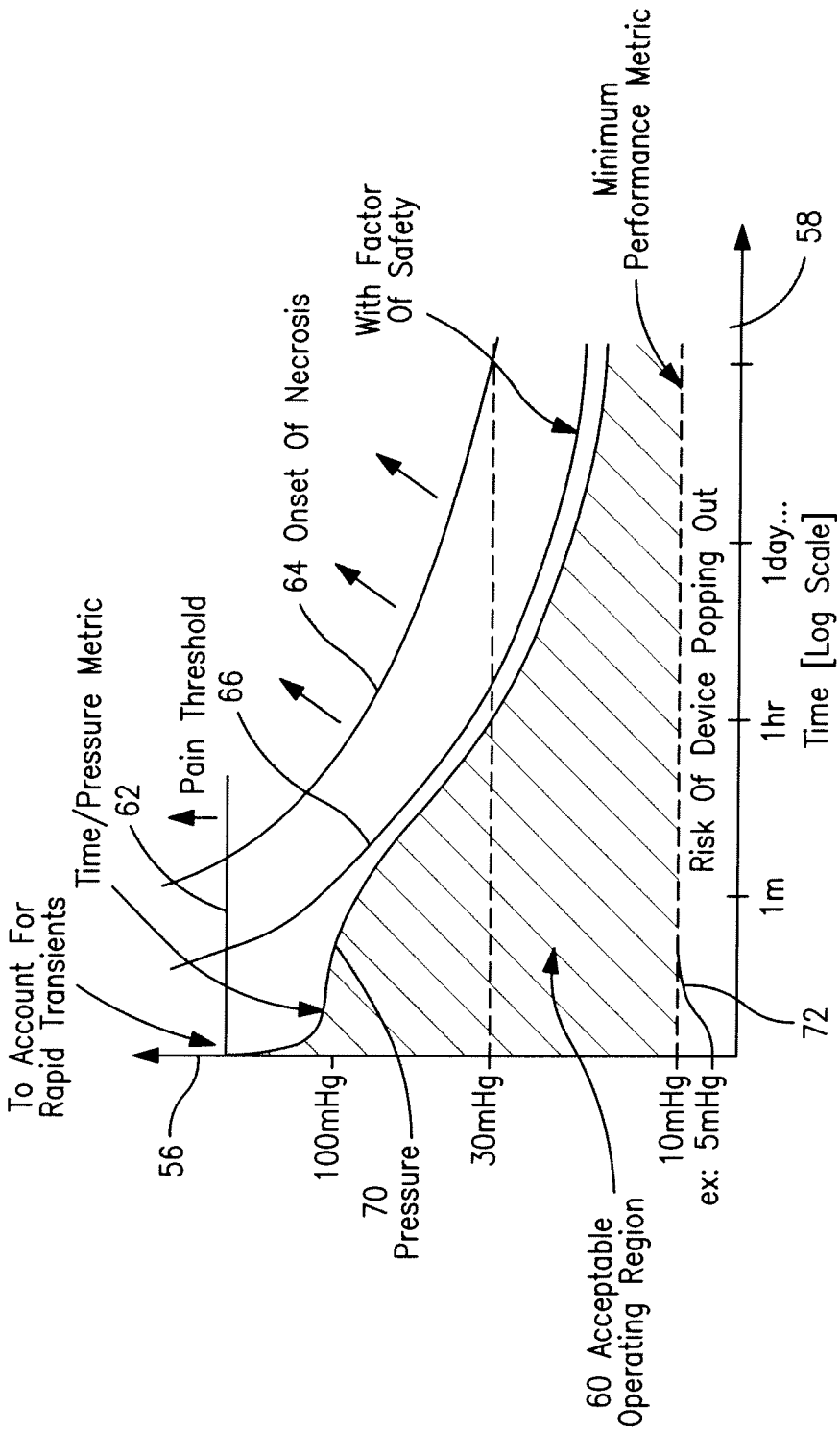
To Account For Rapid Transients
Time/Pressure Metric
62
Pain Threshold
66
64 Onset Of Necrosis
With Factor Of Safety
Minimum Performance Metric
58
56
100mHg
70
Pressure
30mHg
10mHg
ex: 5mHg
60 Acceptable Operating Region
Risk Of Device Popping Out
72
1m
1hr
1day...
Time [Log Scale]

FIG. 3

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/032270

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 5/44 (2011.01)
USPC - 604/96.01
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 5/44, 5/445 (2011.01)
USPC - 604/8, 96.01, 97.01, 99.01, 332

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | WO 2009/131992 A1 (GREGORY) 29 October 2009 (29.10.2009) entire document | 1-15 |
| Y | US 5,361,753 A (POTHMANN et al) 08 November 1994 (08.11.1994) entire document | 1-28 |
| Y | WO 2009/94431 A2 (VAINGAST et al) 30 July 2009 (30.07.2009) entire document | 8, 9, 22, 23 |
| Y | US 6,375,638 B2 (NASON et al) 23 April 2002 (23.04.2002) entire document | 9, 23 |
| Y | US 3,931,822 A (MARICI) 13 January 1976 (13.01.1976) entire document | 15, 28 |
| Y | WO 2009/135141 A1 (GREGORY) 05 November 2009 (05.11.2009) entire document | 16-28 |

☐ Further documents are listed in the continuation of Box C. ☐

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

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 16 June 2011 | 20 JUL 2011 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Authorized officer:<br>Blaine R. Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

Form PCT/ISA/210 (second sheet) (July 2009)