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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 June 2015 (25.06.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/092733 A1

(51) International Patent Classification:
A61B 5/00 (2006.01) *A61B 5/042* (2006.01)
A61B 5/01 (2006.01) *A61B 5/053* (2006.01)
A61B 5/0205 (2006.01) *A61B 5/1459* (2006.01)
A61B 5/03 (2006.01) *A61J 15/00* (2006.01)

(21) International Application Number:
PCT/IB2014/067070

(22) International Filing Date:
18 December 2014 (18.12.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/917,670 18 December 2013 (18.12.2013) US

(71) Applicant: **KONINKLIJKE PHILIPS N.V.** [NL/NL]; High Tech Campus 5, NL-5656 AE Eindhoven (NL).

(72) Inventors: **MEFTAH, Mohammed**; c/o High Tech Campus 5, NL-5656 AE Eindhoven (NL). **BONGERS, Edwin Gerardus Johannus Maria**; c/o High Tech Campus 5, NL-5656 AE Eindhoven (NL).

(74) Agents: **STEFFEN, Thomas** et al.; High Tech Campus Building 5, NL-5656 AE Eindhoven (NL).

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

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

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))*

Published:

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

(54) Title: APPARATUS AND METHOD TO SUPPRESS OR PREVENT FALSE ALARMS IN AN ESOPHAGEAL TEMPERATURE PROBE AND FEEDING TUBE

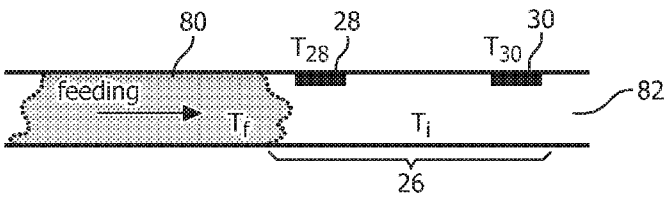

FIG. 4A

(57) Abstract: A method of preventing or suppressing a false alarm during administration of food or medicine to a human or animal through a feeding tube having one or more sensors that generate a signal, comprises analyzing the signals to determine whether food or medicine is being administered and, if it is determined that food or medicine is present, preventing or suppressing an alarm. In a further step, the time and length of administration of food or medicine is recorded. When the feeding tube has at least two temperature sensors, differences in the temperatures recorded for the different temperature sensors indicate that food or medicine was administered. In a case where there is only one temperature sensor, the rate and extent of any temperature change of temperatures recorded from that temperature sensor are compared to an algorithm to determine whether feeding occurred. If the feeding tube has two or more electrodes that sense a change in impedance (galvanic or non-galvanic), that change indicates whether food or medicine is being administered. The signals are analyzed by a processor, monitor, or controller that generates an alarm signal.

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Apparatus And Method To Suppress Or Prevent False Alarms In An Esophageal Temperature Probe And Feeding Tube

FIELD OF THE INVENTION

[0001] The present application relates to an esophageal feeding tube useful in patient care and, more particularly, to an apparatus and method to suppress and/or prevent false alarms in an esophageal temperature probe and feeding tube.

BACKGROUND OF THE INVENTION

[0002] When newborn babies are cared for, the size of the patient is an obvious difference when compared to the care of adult patients or other pediatric patients. Because the patient is so much smaller, instruments, sensors, and the like have to be redesigned to be used with newborn patients.

[0003] Neonates that need tube feedings typically are monitored electronically by a physiologic monitor. Such monitors use multiple electrodes and sensors adhered to the patient's chest and abdomen to capture ECG signals for calculating heart rate and for obtaining a respiration-impedance waveform for calculating respiration rate. Adhesion of skin electrodes is a problem for neonates. Not only must the adhesive have the proper electrical characteristics to transmit electrical signals, it also must adhere well enough to maintain adequate signal integrity despite motion artifacts. In addition, due to poor skin development and the criticality for fluid balance in the presence of insensible water loss (evaporation), neonates are frequently maintained in humidity and temperature controlled incubators. This not only compounds the problem of electrode adhesion but creates a need to obtain a feedback signal for the thermoregulation apparatus typically found in the incubator. Each time an electrode or sensor falls off, a caregiver must intervene immediately, which increases the workload of the care giving staff and is disruptive to the important sleep cycle of the neonate.

[0004] Further, a preterm neonate typically lacks skin integrity, and the frail skin is subject to irritation and laceration as a result of adhesives or sensors that are applied. Removal of electrodes or sensors for routine skin integrity checks and cleaning can further irritate the delicate skin of the neonate during removal. In practice, there is no perfect adhesive for a

neonatal skin electrode. External electrodes and their cables also complicate routine care of the neonate (e.g., washing) and may be disturbing to parents trying to bond with the infant (a technique known as Kangaroo Care).

[0005] As with all intensive care patients, temperature changes in a neonate can indicate fever or another medical situation requiring attention. In the case of premature neonates, however, the thermoregulatory system is not yet fully developed. Therefore, unlike the temperature of an adult patient, a neonate's temperature can go into crisis within minutes (as opposed to hours for an adult) and thus must be monitored closely. Consequently, routine and continuous temperature monitoring of a neonate is conducted in the neonatal intensive care unit (NICU). Such monitoring is typically done with a thermistor probe temporarily placed in the armpit, groin, or skin. These temperature sensors entail excessive stimulation for the neonate, a factor which is believed to negatively impact development. Often, NICU patients are kept in incubators. Opening and closing the incubator to maintain temperature signals makes it difficult to maintain desired air temperature control inside an incubator.

[0006] Size can vary greatly from infant to infant. Viable premature babies are much smaller than their full term counterparts, in both weight and length. In the case of a neonatal feeding tube, the size of the tube is tailored to the size of the infant. To accommodate a range of sizes of infants, different sizes of tubes are typically required so the tip of the feeding tube rests in the stomach. Moreover, since newborn babies grow rapidly, an infant's feeding tube may need to be changed and or repositioned during the infant's stay in the NICU.

[0007] During insertion of a new feeding tube, care must be taken and verification checks made to assure that the tube has followed the esophageal path to the stomach and not the bronchial path into the lungs. Further, the opening(s) in the tube must be properly positioned in the stomach, not the esophagus, and the end of the tube must terminate before reaching the bottom of the stomach. Incorrect positioning of the feeding tube can result in aspiration of stomach contents and feeding material into the lungs, which can lead to a life-threatening lung infection or injury.

[0008] Almost all neonates staying in the NICU are fed by feeding tubes. Therefore, integration of vital signs sensors into a feeding tube can be very beneficial. For example, it eliminates the need for the standard adhesive electrodes, performs temperature spot checks, and the like. This improves the development and recovery of ill neonates, reduces the workload of caregivers, and fosters bonding between neonate and parents.

[0009] A neonatal esophageal temperature probe and feeding tube is described in U.S. Published Patent Application No. 2011/0084881, incorporated herein by reference. The feeding tube described, an embodiment of which is available as the INNERSENSE® esophageal temperature and feeding tube from Koninklijke Philips N.V., combines a neonatal feeding tube with a temperature sensor. Other vital signs sensors can optionally be integrated as well.

[00010] As described above, maintaining the temperature of a neonatal is critical, and temperature sensing systems useful in the NICU are designed to generate an alarm in a neonatal's temperature suddenly increases or decreases significantly. One characteristic of current neonatal feeding tubes is that feeding itself may trigger false alarms. A clinical study was executed where an INNERSENSE feeding tube with an integrated temperature probe was used for feeding. The results of the study are set forth in FIG. 1, where it can be seen that the indicated temperature recordings were disturbed dramatically during feeding periods, when the recorded temperatures dropped below a pre-set lower temperature limit of 36.7°C (NICU limits: 36.7 – 37.4°C). However, these anomalies reflected false alarms, which counterproductively disturb and stress a neonate and worsen a caregiver's workload.

SUMMARY OF THE INVENTION

[00011] Accordingly, it is an object to overcome the deleterious effects of false alarms that may occur in the feeding and care of humans or animals.

[00012] In accordance with one aspect, temperature or other sensors in a neonatal temperature probe and feeding tube provide signals that are compared to determine whether feeding is occurring. Sensors in a feeding tube may sense a change in a parameter such as temperature, pressure, capacitance, or the like, where such change is capable of indicating whether feeding

occurred. If it is determined that feeding is occurring, a change in an indicated parameter such as temperature of the neonate does not trigger an alarm.

[00013] In accordance with another aspect, a temperature or other sensor in a neonatal temperature probe and feeding tube provides a signal that is compared to an algorithm. If the signal reflects a change in the temperature of the neonate, the rate and extent of the temperature change are analyzed by an algorithm to determine whether feeding is occurring. If it is determined that feeding is occurring, a change in indicated temperature of the neonate does not trigger an alarm.

[00014] In accordance with another aspect, one or more sensors in or in a neonatal temperature probe and feeding tube provide a signal that indicates the presence of food or a liquid in a lumen of the feeding tube. If it is determined that feeding is occurring, a change in indicated temperature of the neonate does not trigger an alarm.

[00015] In accordance with another aspect, a method of preventing or suppressing false alarms in the care of a neonate comprises:

analyzing signals from one or more sensors in a temperature probe and feeding tube to determine the presence of food or a liquid; and

preventing or suppressing the generation of a low or high temperature alarm.

[00016] In accordance with one aspect, an esophageal temperature probe and feeding tube incorporates at least one lumen for feeding and provides a pathway for nourishment, for example, soft food or a liquid, or medicine from the outside of a subject into the stomach of the subject. At least one, but optimally two or more uniformly or non-uniformly spaced sensors are on an exterior surface of the feeding tube, within a wall of the feeding tube, or within the feeding tube for measuring temperature.

[00017] An advantage is that the neonate does not need to be disturbed unnecessarily to be treated for an apparent low or high temperature emergency.

[00018] Another advantage is that the caregiver does not need to address a perceived emergency that is not really an emergency.

[00019] Another advantage is that a caregiver's workload will not be unnecessarily increased or disturbed.

[00020] Another advantage is that the apparatus and system described herein are compatible with existing patient monitors.

[00021] Consistent with the disclosure herein, it should be appreciated that the terminology "feeding tube" comprises an orogastric or nasogastric feeding tube particularly useful in the care of a neonate for insertion through and/or into the neonate's esophagus. The feeding tube will sometimes be referred to as an esophageal feeding tube or an esophageal temperature probe and feeding tube. Also, the term "food" as used herein encompasses soft, semi-liquid, or liquid nutritional substances, including, but not limited to, formula or breast milk, given or administered to a neonate through a feeding tube. The term "food" also includes any medicine or other soft, semi-liquid, or liquid material that might be given or administered to the neonate through a feeding tube.

[00022] Still further advantages of the present invention will be appreciated to those of ordinary skill in the art upon reading and understanding the following detailed description. Therefore, it should now be apparent that the invention substantially achieves all the above aspects and advantages. Additional aspects and advantages of the invention will be set forth in the description that follows, and in part will be inherent from the description, or may be appreciated by practice of the invention. Moreover, the aspects and advantages of the invention may be realized and obtained by means of the instrumentalities and combinations particularly pointed out in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[00023] The accompanying drawings illustrate presently preferred embodiments of the invention, and together with the general description given above and the detailed description

given below, serve to explain the principles of the invention. As shown throughout the drawings, like reference numerals designate like or corresponding parts.

[00024] The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

[00025] FIG. 1 represents a graph of the measured temperature of a neonate versus time;

[00026] FIG. 2 represents a neonatal feeding tube with sensors and instrumentation;

[00027] FIG. 3 is a flow chart representing the use of a neonatal temperature probe and feeding tube according to the invention;

[00028] FIG. 4A is a schematic representation of a portion of a cross-sectional view of a feeding tube of FIG. 2;

[00029] FIG. 4B is a graph that represents temperature measurements and calculations during feeding according an embodiment of the invention;

[00030] FIG. 5 is a graph that represents temperature versus time during feeding of a neonate; and

[00031] FIGs. 6A and 6B are each a schematic of an oblique view of a section of a cross-sectional view of a feeding tube showing different arrangements of sensors.

DETAILED DESCRIPTION OF THE INVENTION

[00032] The present invention, in the various embodiments described herein, relates to an apparatus, system, and method to suppress or prevent false alarms during feeding of a neonate with an esophageal temperature probe and feeding tube. The invention can perhaps be better understood from the drawings. In FIG. 2, a neonatal feeding tube 10 is depicted. In one embodiment, tube 10 is an instrumented disposable feeding tube for newborn infants (neonates) who have not yet developed their sucking capabilities, or who are unable to feed normally for some other reason. Tube 10 is a 5 French tube, or 1.67 mm in diameter, in one embodiment.

Appropriate scaling can be performed for larger or smaller tubes. For convenience, tube 10 is shown segmented, though its actual length may be, for example, approximately 300 mm.

[00033] Neonates are fed formula, breast milk, or other nutritional soft, semi-liquid or liquid substances or medicines through tube 10. Tube 10 is typically inserted into the neonate's nose or mouth and advanced into the esophagus, and into the stomach. Similar to a standard feeding tube, there is a tip 12 at the distal portion 14 of tube 10. An end hole 16 in tip 12 permits soft, liquid, or semi-liquid food, such as infant formula or breast milk, or medicine to exit tube 10. One or more additional holes 18, offset from tip 12, allow food to exit should end hole 16 become clogged or otherwise blocked. Tip 12 and cross holes 18 are preferably positioned in the neonate's stomach in one embodiment. Distal portion 14 is molded of a soft, biocompatible material, such as, in one embodiment, silicone rubber.

[00034] Feeding tube 10 also includes electrodes 20. Electrodes 20 are on or within an exterior surface of feeding tube 10 and, when inserted, make contact with the patient's esophagus (not shown). Insulated leads (not shown) extend proximally from each electrode, either inside feeding tube 10 or inside the outer wall of feeding tube 10. At least one thermal sensor or thermistor 22 is inside feeding tube 10 for taking temperature measurements. In one embodiment, at least one thermistor 22 is distal to electrodes 20.

[00035] Thermistor 22 is assembled to a pair of wires, at least one of which is insulated. Preferably all wires that carry signals are insulated and located on an inner wall or the outer surface of feeding tube 10. In one embodiment, thermistor 22 is calibrated to meet the requirements of a specific patient monitor or series of monitors. Calibration is checked. Resistance is measured and compared to the specification. Resistance is then increased if necessary until the thermistor resistance meets specification. This process brings the thermistor in compliance with appropriate standards for accuracy. Thermistor 22 may be one piece of semiconductor material or it may be two or more segments connected in parallel, with a small gap between each segment. This allows the assembly to flex in two directions and to twist, even if the length is several multiples of the tube diameter. This is important, because the overall resistance of the thermistor is proportional to its thickness and inversely proportional to the area. Because the width of the thermistor and the thickness of the thermistor are constrained by the

size of tube 10, the effective length of the thermistor assembly needs to be selected based on the electrical requirements of the monitoring system, without further constraint. This method of construction also minimizes difficulty and discomfort during insertion, removal, and use. It is also more flexible and more resistant to breakage during manufacture, insertion, and use. In one embodiment, thermistor 22 has a resistance of approximately 2250Ω at 25° C. and approximately 1360Ω at 37° C.

[00036] In a single-thermistor embodiment, thermistor 22 is preferably located in the esophagus to accurately measure core temperature, rather than the stomach or pharynx, where readings would be less accurate. Placement in the stomach is undesirable due to the corrosive effects of gastric fluids and the inaccuracy that might be caused by air or food in the stomach. Whether thermistor 22 is located distal to the electrodes, proximal to them, or among them is determined by practical design issues and patient size. However, a dual lumen with at least one thermistor in the hypopharynx can provide respiration measurement.

[00037] Proximal to electrodes 20 is a nasopharyngeal section 26 of feeding tube 10. Nasopharyngeal section 26, as the name indicates, lies inside the pharynx and nose when inserted. This section is smooth and small in diameter to avoid irritating the patient or interfering with air flow during breathing. In an alternate embodiment, however, feeding tube 10 has a non-circular shape and/or concave flutes to reduce the possibility of complete blockage of a nare. In yet another embodiment, a hypopharynx thermistor 28 and an oropharynx thermistor 30 are included in the nasopharyngeal section 26. Thermistors 28, 30 are used to measure respiration flow, in addition to the distal or caudal thermistor 22 provides a core temperature measurement. The respiration flow is measured as a relative temperature change between oropharynx thermistor 30 and hypopharynx thermistor 28. An array of these thermistor pairs may accommodate variations of patient sizes.

[00038] A pressure differential ΔP is measured by a pressure gradient between a sub-diaphragmatic (or caudal) port 32 and a supra-diaphragmatic (or cephalic) port 34. ΔP represents the respiration effort of the patient. Flow can be measured separately (with thermistors 28 and 30), as an airway obstruction may produce increased effort but no ΔP. Respiration flow and respiration effort are measured separately and can differ. For example, in the case of an airway

obstruction, effort will increase but flow will decrease. The measured flow can be cross-checked against ΔP for accuracy, and can signal an alarm if the two do not coincide.

[00039] Proximal to the supra-diaphragmatic pressure port 34 are two fiber optic windows 35. Fiber optic windows 35 are polished ends of many fiber optic strands. At the proximal end of feeding tube 10 fiber optic strands separate into a source fiber (run from a light source, not shown) and a return fiber. Both fiber bundles run down the interior of feeding tube 10 to fiber optic windows 35. One fiber optic bundle is in the esophagus, and another is at the distal tip of the feeding tube. The distal fiber bundle does not need to be separated into a sending and receiving bundle as it is used only to send light down which would emanate from the small patient due to the thin membranes and relatively translucent nature of the skin. This tip light is used for placement verification by energizing the fibers from an external light source and in a darkened room and visualizing the location of the light emanating from the patient's abdomen (if properly placed) or thorax (if not properly placed). The pulse of the subject is measured by reflectance photo-plethysmogram through the fiber optic window using traditional reflectance pulse oximetry techniques. Core SpO_2 is also measured at fiber optic windows 35. Supra-diaphragmatic port 34 serves as a flush location to clean fiber optic windows 35 as needed.

[00040] The manufacture and structure of a temperature probe and feeding tube according to the invention is consistent with the manufacture and structure of the esophageal feeding tube described in U.S. Published Patent Application No. 2011/0084881, incorporated herein by reference in its entirety.

[00041] A feeding lumen extension 54 may pass through the approximate center of a tube-side connector 52 and terminates in an oral style fitting 56 that permits food such as baby formula or breast milk or medicine to be injected by syringe, drip, pump, or other means. In one embodiment, fitting 56 is marked or physically differentiated to distinguish it from ports meant for vascular injection.

[00042] Typically, only three electrodes are required for ECG readings. For small neonates, the distal three electrodes 20 are used. For medium neonates, the middle three electrodes 20 are used. For larger neonates, the proximal three electrodes 20 are used. In one embodiment, the

electrodes are selected manually based on the size of the neonate, and the judgment of the caregiver. The setting can be selected by the caregiver by temporarily disconnecting the connector, rotating a cable-side part 58 relative to connector 52, and then re-connecting, thereby changing which internal contacts are used. In another embodiment, the electrodes are selected by the monitor. Once the feeding tube is inserted, all electrodes 20 send signals to a monitor (not shown). The monitor displays multiple wave-forms, and the operator selects the clearest display. In other embodiments, all signals are recorded or the monitor automatically chooses the best electrodes.

[00043] It should be noted here that respiration rate can be determined by injecting a low-voltage electrical signal into the patient via a pair of spaced ECG electrodes. The electrical impedance of the connection varies during the act of respiration, so the rate and depth of respiration can be deduced. In some embodiments of this invention, the respiration rate is derived from a choice of electrodes selected from the array of available electrodes.

[00044] In an alternate embodiment a U-shaped connector on the monitor side is used so that feeding tube 10 can be in the center, with mating in the axial direction. The U-shape allows the electrical connection and the feeding connection to be made or disconnected in any sequence, without mutual interference.

[00045] In another alternate embodiment, a connector is on the side of the feeding tube, with mating in the radial or oblique direction.

[00046] In another alternate embodiment, feeding tube 10 has a rectangular (linear) connector rather than a circular or U-shaped connector. In this embodiment, the feeding tube side would have a number of sockets (pins) equal to the number of electrodes, while the cable side would have a number of pins equal to the number of electrodes used by the monitor. The cable could then be plugged into feeding tube 10 in a number of locations, thereby selecting which electrodes are operative.

[00047] In another alternate embodiment, feeding tube 10 has a connector where the selection of the electrodes is performed by a switching device inside cable-side connector 58, or cable 62 itself.

[00048] In another alternate embodiment, feeding tube 10 has a connector with a rotating collar or other device which could be locked into place to assure that the connector, after disconnection, can only be re-connected in the selected position.

[00049] In another alternate embodiment, feeding tube 10 has a slide or rotary switch on the connector to allow the caregiver to manually select the electrodes with the strongest signal as shown on a monitor display.

[00050] Placing the tube properly can be problematic in some instances. Feeding tube 10 is to be inserted to a depth that places tip 12 of feeding tube 10 in the stomach of a neonate. It is undesirable to insert feeding tube 10 too far, into the duodenum, and it is also undesirable to leave it short, such that openings 16 and 18 are in the esophagus. A distal electrode 64 on tip 12 of feeding tube 10 is included to facilitate placement confirmation. While distal electrode 64 remains in the esophagus, contact with the wall of the esophagus produces electrical continuity. However, when this electrode passes through the esophageal sphincter into the larger opening of the stomach, conductivity disappears. Because the relative location of electrode 64 and openings 18 is established by the detailed design of the device, the location of openings 18 is now known to the clinician relative to the beginning of the patient's stomach.

[00051] In conjunction with electrode 64, a light source 66 can be used to judge the position of tip 12 as it is passed down the patient's esophagus. A neonate's chest is relatively thin and translucent. Light source 66, if bright enough, can be seen through the neonate's chest, and the caregiver can visually verify the position of tip 12. Light source 66 may be illuminated by a lamp outside proximal portion 14 and an optic fiber running the length of feeding tube 10. It is also contemplated that a fiber optic camera (not shown) could be located at or fiber optically connected to tip 12 and used as a traditional endoscope to aid in positioning feeding tube 10. In some embodiments, the fiber optic device is a permanent part of feeding tube 10, whereas, in alternative embodiments, the fiber optic device is inserted into a feeding lumen 36 prior to placement in the body and removed after feeding tube 10 is properly placed, so that the lumen 36 may be used for feeding.

[00052] When feeding tube 10 is inserted, it is important to follow the esophagus and not veer into the lungs. One way to tell which path is being followed is by a temperature measurement with thermistors at tip 12. If different temperatures are measured with inhale and exhale respiration, the tip is in an air passage. If the temperature is constant, the tip is in the esophagus. Monitoring pressure at tip 12 can be used analogously. Pressure can be measured by sealing one of the lumens and adding a pressure port.

[00053] Another aid in positioning feeding tube 10 is to include a sensor that measures pH. If tip 12 is properly in the stomach, the measured pH should be acidic. If tip 12 is in the lungs, the measured pH will be neutral. If tip 12 is in the esophagus, the measured pH will be somewhat acidic, depending on reflux, etc.

[00054] The esophageal temperature probe and feeding tube described herein and in U.S. Published Patent Application No. 2011/0084881 comprise physiologically acceptable materials that can be sterilized. In particular, all sensing elements, such as electrodes and thermistors, should preferably be soft, flexible, and biocompatible.

[00055] According to an aspect of the invention, feeding tube 10 has sensors such as electrodes and thermistors that register parameters such as temperature, pressure, pH, or capacitance. One or more of such parameters can be measured and then analyzed to determine whether feeding occurred. If it is determined that feeding occurred, this determination results in the prevention or suppression of a false alarm.

[00056] FIG. 3 is a flow chart that broadly represents care of a neonatal that incorporates the invention described and claimed herein. The start of the process is the measurement of one or more signals from one or more thermistors or sensors at step 70, leading to analysis in a processor or monitor in step 72. If the processor or monitor determines that there was feeding, the temperature measurement is categorized as "unreliable" as in step 74, whereupon an alarm is suppressed or prevented. In addition, in step 74 the feeding details, such as time, duration, etc., are logged automatically, which is a highly advantageous feature of this invention. If the processor, monitor, or controller determines that feeding did not occur, a temperature signal is sent to step 76, where the system checks to see whether the temperature measured is within pre-set limits (T_L=lower temperature limit, T_H= upper temperature limit). If the measured

temperature is within the pre-set limits, no action is taken. However, if the measured temperature is not within the pre-set limits, an alarm signal is triggered.

[00057] As mentioned above, an important aspect of the invention set forth herein is to prevent or suppress false alarms that can result when feeding a neonate. As set forth above, a useful feeding tube comprises thermal sensors or thermistors (such as thermistors 22, 24, 28, 30) placed at different locations along the exterior of feeding tube 10 to measure the (core) temperature of a neonate at those locations. In addition, two pressure ports (sub-diaphragmatic port 32 and supra-diaphragmatic port 34) are included to extract the neonate's respiration effort. In one embodiment a feeding period is detected by utilizing these existing sensing elements. The basic principle is that food, breast milk, or other nutritional liquids or semi-liquids flowing though the feeding tube will create a short pulse in the signal difference between sensors along the feeding tube.

[00058] This embodiment will be explained by using thermistors. However, in principle all other sensing elements mentioned above can be used.

[00059] In the description above, hypopharynx thermistor 28 and oropharynx thermistor 30 are included in nasopharyngeal section 26 to extract respiration flow by measuring the temperature difference between thermistor 28 and thermistors 30. In the schematic of a cross-section of a portion of feeding tube 10 depicted in FIG. 4A, food 80 having a temperature T_f advances distally through a lumen 82 in feeding tube 10. Thermistors 28 and 30 each register a temperature T_i of an empty feeding tube corresponding to a neonate's internal temperature until each thermistor is in turn contacted by food 80 with temperature T_f. The temperatures of the respective thermistors 28 and 30 over time and the difference between the temperatures of thermistor 30 and thermistor 28 are set forth in the graph of FIG. 4B. The pulse in the lower portion of FIG. 4B ($T_i - T_f$) is a function of the difference between the neonate's internal temperature, the distance from thermistor 28 to thermistor 30, and the velocity of food 80. A processor, monitor, or controller (not shown) will recognize that the pulse represents feeding and will not send an alarm signal or will otherwise prevent or suppress the generation of an alarm.

[00060] In another embodiment of the invention, an algorithm is used to recognize feeding with an esophageal feeding tube. Temperature variation in a neonate during feeding as measured by a feeding tube such as described herein, and as set forth in FIG. 5, is totally different from

temperature variation in a neonate due to physical or medical problems or issues. After starting the feeding period the temperature drops about 2°C within 4 seconds (the exact drop mainly depends on the feeding temperature, speed of administration, feeding volume, and the core temperature). This drop is so huge and fast that it cannot be the real core temperature of a neonate. An algorithm in a processor, monitor, or controller (not shown) will evaluate a temperature pattern sensed by, for example, thermistors on a feeding tube 10 and recognize that the pattern represents feeding, not a temperature change of physiological origin. The processor, monitor, or controller will not send an alarm signal or will otherwise prevent or suppress the generation of an alarm. Thus, by means of an algorithm it easily possible to analyze the temperature pattern/course and extract whether or not it was a feeding.

[00061] In another embodiment of the invention, impedance measurements can be used to detect feeding. In the section of a feeding tube 90 shown in FIG. 6A, two electrodes 92 are attached to the inner surface 94 of the section. Electrodes 92 are attached by wires (not shown) to a processor, monitor, or controller (not shown), which registers a variation in impedance when food or medicine flows through feeding tube section 90. Similarly, as shown in FIG. 6B, electrodes 98 are positioned on or, preferably, within the outer surface 100 of a section of feeding tube 102. Movement of food or medicine is detected by a galvanic or non-galvanic coupling, that is, capacitance coupling, which causes a variation in impedance that is registered by the processor.

[00062] While preferred embodiments of the invention have been described and illustrated above, it should be understood that these are exemplary of the invention and are not to be considered as limiting. Additions, deletions, substitutions, and other modifications can be made without departing from the spirit or scope of the present invention. Accordingly, the invention is not to be considered as limited by the foregoing description but is only limited by the scope of the appended claims.

What is claimed is:

1. A method of preventing or suppressing a false alarm during administration of food or medicine to a human or animal through a feeding tube having one or more sensors that generate a signal, which comprises:

analyzing the signals to determine whether food or medicine is being administered; and

if it is determined that food or medicine is present, preventing or suppressing an alarm.

2. The method of claim 1, wherein the feeding tube has at least two temperature sensors and there are differences in the temperatures recorded for the different temperature sensors that indicate that food or medicine was administered.

3. The method of claim 1, wherein there is one temperature sensor and temperatures recorded from that temperature sensor are compared to an algorithm to determine whether feeding occurred.

4. The method of claim 3, wherein the rate and extent of any temperature change are analyzed by an algorithm to determine whether feeding is occurring.

5. The method of claim 1, wherein the sensors are two or more electrodes that sense a change in impedance that indicates whether food or medicine is being administered.

6. The method of claim 1, wherein the signals are analyzed by a processor, monitor, or controller that generates an alarm signal.

7. The method of claim 1, wherein the sensors sense a change in a parameter such as temperature, pressure, or capacitance.

8. The method of claim 1, which comprises an additional step in which details regarding the feeding are recorded.

9. The method of claim 8, wherein time and length of administration are recorded.

10. The method of claim 1, wherein the human is a neonate.

11. In a system comprising a feeding tube for administering food or medicine to a human or animal and a processor, monitor, or controller that generates an alarm signal if certain pre-set parameter limits are exceeded, the improvement whereby the processor, monitor, or controller is capable of recognizing that food or medicine is being administered and then preventing or suppressing any alarm.

12. The system of claim 11, wherein the human is a neonate.

13. The system of claim 11, wherein the processor, monitor, or controller records feeding details.

14. The system of claim 13, wherein the processor, monitor, or controller records details regarding time and length of administration.

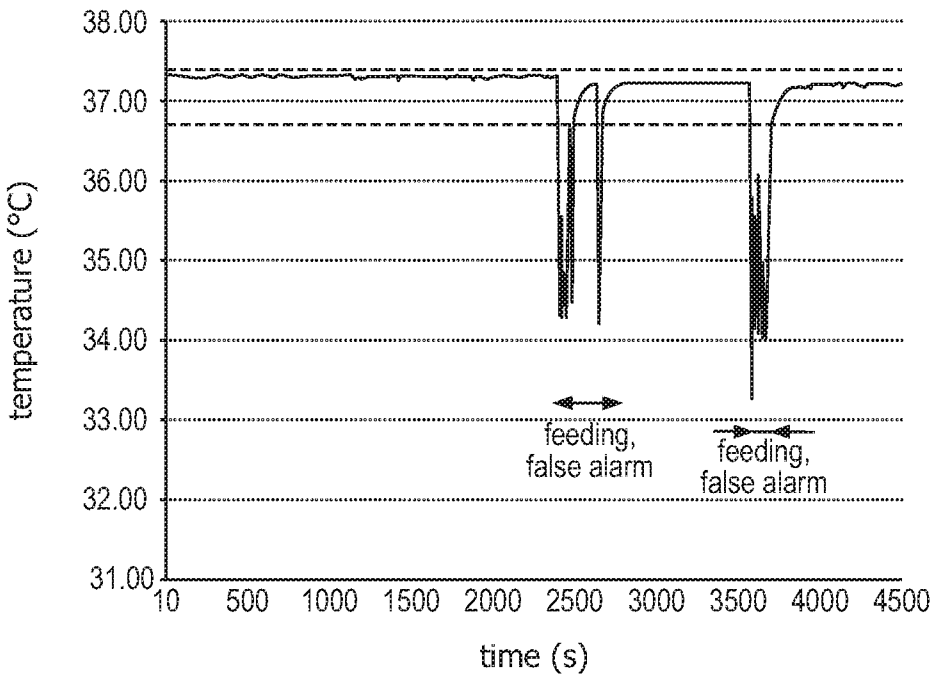
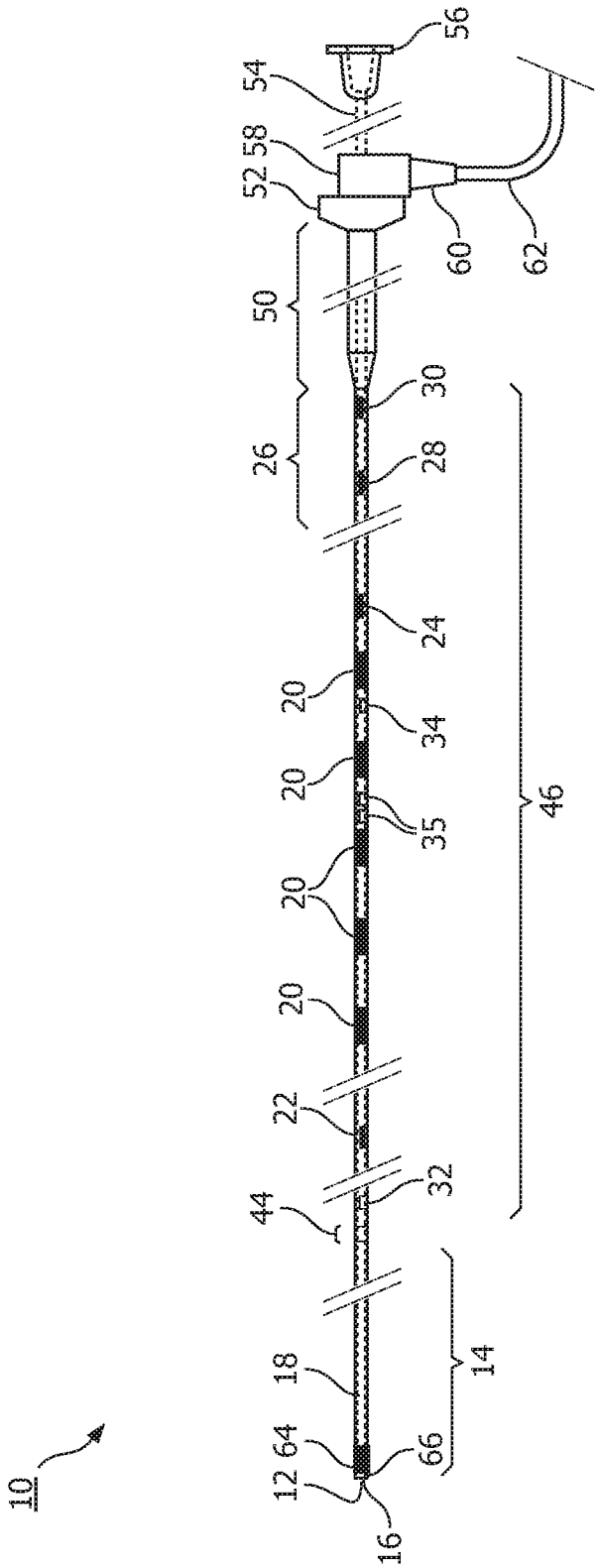

38.00
37.00
36.00
35.00
34.00
33.00
32.00
31.00
temperature (°C)
10
500
1000
1500
2000
2500
3000
3500
4000
4500
time (s)
feeding,
false alarm
feeding,
false alarm

FIG. 1


56
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16
10

FIG. 2

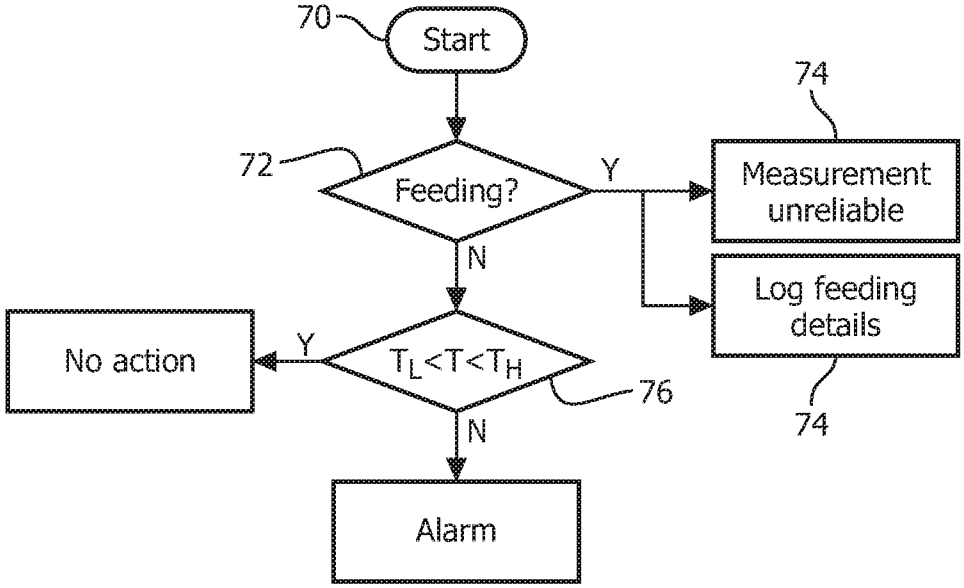

FIG. 3

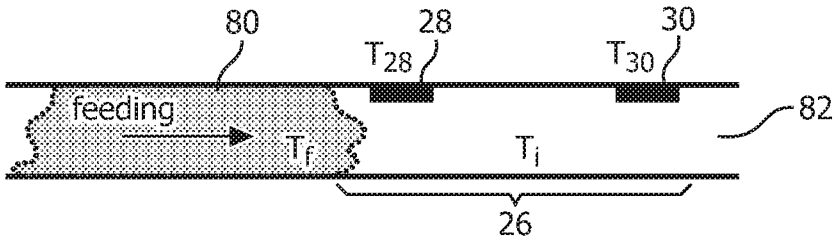

FIG. 4A

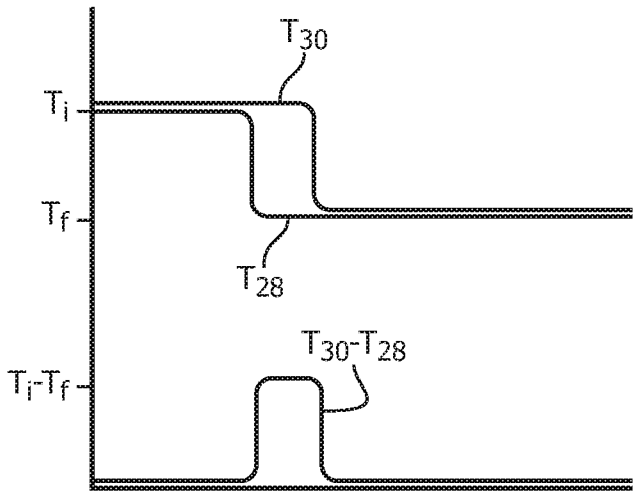

FIG. 4B

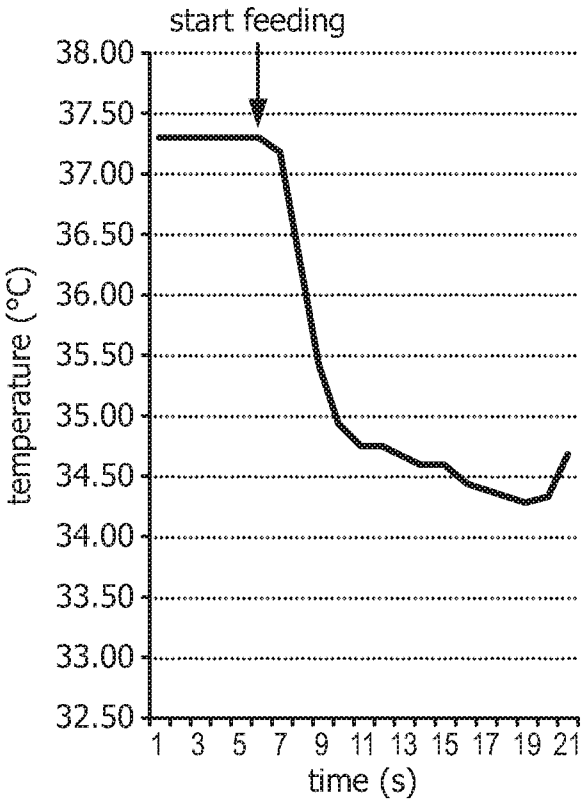

FIG. 5

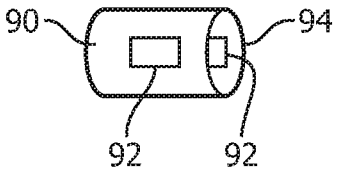

FIG. 6A

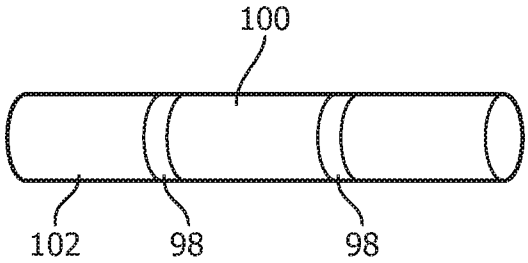

FIG. 6B

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/067070

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/01 A61B5/0205 A61B5/03 A61B5/042
A61B5/053 A61B5/1459 A61J15/00
ADD.
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)
A61B A61J

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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/015230 A2 (BIOMEDICAL RES ASSOCIATES LLC [US]; VALENTA HARRY L JR [US]; LIPP ELIZ) 9 February 2006 (2006-02-09) page 5, line 19 - page 6, line 2; figures 1,5	1-14
X	US 2010/087715 A1 (VAN BOMMEL MARCUS JOZEF [NL] ET AL) 8 April 2010 (2010-04-08) paragraph [0028]; claims 8-10	1-14
X	US 2011/144481 A1 (FEER DAVID L [US] ET AL) 16 June 2011 (2011-06-16) paragraphs [0031] - [0033], [0051]; figure 1	1-14

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"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
23 March 2015	30/03/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lommel, André

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/067070

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/036229 A1 (WEEKAMP JOHANNES WILHELMUS [NL] ET AL) 11 February 2010 (2010-02-11) abstract ----	1-14
X	US 2010/082011 A1 (LEWIS THOMAS G [US] ET AL) 1 April 2010 (2010-04-01) paragraphs [0008], [0025], [0029]; figure 3 ----	1-14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2014/067070

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006015230 A2	09-02-2006	NONE	
US 2010087715 A1	08-04-2010	CN 101534707 A	16-09-2009
		EP 2081489 A1	29-07-2009
		JP 5295119 B2	18-09-2013
		JP 2010509970 A	02-04-2010
		US 2010087715 A1	08-04-2010
		WO 2008059415 A1	22-05-2008
US 2011144481 A1	16-06-2011	CN 102137620 A	27-07-2011
		EP 2344026 A1	20-07-2011
		JP 5591239 B2	17-09-2014
		JP 2012500700 A	12-01-2012
		RU 2011111412 A	20-10-2012
		US 2011144481 A1	16-06-2011
		US 2013225946 A1	29-08-2013
		WO 2010023579 A1	04-03-2010
US 2010036229 A1	11-02-2010	AT 516004 T	15-07-2011
		CN 101557790 A	14-10-2009
		EP 2091499 A1	26-08-2009
		JP 5379694 B2	25-12-2013
		JP 2011505878 A	03-03-2011
		US 2010036229 A1	11-02-2010
		WO 2008072150 A1	19-06-2008
US 2010082011 A1	01-04-2010	US 2010082011 A1	01-04-2010
		US 2014296775 A1	02-10-2014