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A foetal probe

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ABSTRACT

The present invention relates to an intrauterine probe for measuring a physical condition of a foetus. In one form the probe comprises a sensor body with an active surface for contacting the foetus. The probe is also
5 provided with means for inserting the sensor body between the uterine wall and the foetus. A bladder is disposed on an opposite surface of the sensor body for contacting the uterine wall and for biasing the active surface
10 against the foetus.



AUSTRALIA
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COMPLETE SPECIFICATION
STANDARD PATENT



Applicant:

NELLCOR INCORPORATED

Invention Title:

A FOETAL PROBE

The following statement is a full description of this invention, including the best method of performing it known to me/us:

BACKGROUND OF THE INVENTION

This invention relates to foetal probes and, more particularly, to foetal probes having improved foetal contact.

5 During *in utero* labor and delivery foetal probes are used to monitor health of the foetus. Typical parameters monitored include arterial blood oxygen saturation levels, pulse rate, heart rate and temperature. Pulse oximeters are typically used to measure various blood
10 characteristics including arterial blood oxygen saturation and pulse rate. An electrocardiogram (ECG) is used to monitor heart rate. A thermal sensor is used to monitor temperature. In order to achieve accurate measurements, the aforementioned sensing devices must
15 maintain good contact with the foetus during parameter measurement.

Improper contact to the foetus with a pulse oximetry probe may result in inaccuracies caused by shunting of light between the emitter and detector. Fig. 1 shows a
20 transreflectance pulse oximetry probe 110 comprising a light emitter 114 and a light detector 118 disposed within a housing 122. If the probe 110 is in poor contact with the skin 134, (e.g. due to extraneous material 138 such as hair, mucous, etc., between the
25 probe and skin 134), light may be directly reflected from the top surface of the skin or piped through the extraneous matter as shown by path 2. Alternatively, the light may scatter below the surface of the skin, but may not travel deep enough to penetrate the blood perfused layer 130. Instead, the light travels through bloodless
30 layer 132 as shown by path 3.

The depth uniformity and/or location of layer 132 is negatively affected by local vasoconstriction, excessive force applied to the back surface of the probe (which
35 locally exsanguinates blood from the tissue beneath the probe), and site-to-site variations of the distance to the blood perfused layer. The aforementioned factors negatively affect blood oxygen saturation measurements.

Unless probe placement is well controlled in an environment free of excessive applied force and other light shunting causes, accuracy of the calculated saturation will be suspect.

5 To improve contact to the foetus, the foetal probe described in U.S. patent application No. 07/775,315 which was filed October 11, 1991 and issued as US patent No. 5,377,675, incorporates a fixed curved sleeve and an oppositely curved removable stiffener. The stiffener is inserted in the probe
10 to make the handle substantially straight during insertion of the sensor housing. When the stiffener is removed, the curved sleeve presses the sensor housing against the foetus.

Similarly PCT Application No. WO 91/07910 discloses a foetal probe which has an inflatable bladder connected to
15 the non-sensing side of the probe. The bladder has a hemispherical or spherical shape in order to provide a wedging action which will maintain the position of the foetal sensor during contractions, or foetal or maternal movements. Although the addition of an inflatable bladder improves
20 foetal contact, unequal forces are applied to different contact points of the foetus. In addition, because of the position of the bladder, there are site-to-site variations between the sensor and the blood perfused layer. An improved method for contacting an oximeter probe to a foetus is
25 needed.

SUMMARY OF THE INVENTION

The present invention is directed towards a method and apparatus for improved foetal contact with a foetal sensor. The present invention provides an easily insertable
30 foetal probe which includes a means for adjusting the force to the probe sensor so that a force of sufficient magnitude is applied to prevent shunting. Proper force application increases the accuracy of measurement of the desired parameter.

35 In one aspect, the present invention provides an intrauterine probe for measuring a physical condition of a foetus. The intrauterine probe comprises a sensor body having a longitudinal axis and an active surface for contacting a foetus and an opposite surface; inserting means
40 for inserting the sensor body into a uterus between a foetus



and a uterine wall; and a bladder disposed on the opposite surface of the sensor body for contacting the uterine wall and for biasing the active surface against the foetus. The said bladder has a generally rectangular shape and is
5 elongated such that the length of the bladder attached to the sensor body is greater than the height the bladder extends above the sensor body when the bladder is filled.

In one embodiment the bladder is only partially filled with a fluid so that the fluid moves within the
10 bladder to adjust to fill gaps between the uterus and the foetus.

In another embodiment the bladder widens from the opposite surface of the sensor to an end contacting the uterine wall.

In a another aspect, the invention provides an
15 intrauterine probe for measuring a physical condition of a foetus. The probe comprises a sensor body having a longitudinal axis and an active surface for contacting a foetus and an opposite surface; inserting means for inserting
20 the sensor body into a uterus between a foetus and a uterine wall; and a first bladder disposed on the opposite surface of the sensor body for contacting the uterine wall and for biasing the active surface against the foetus. The probe additionally comprises a second bladder disposed on the
25 opposite surface of the sensor body for contacting the uterine wall and for biasing the active surface against the foetus and a passageway in fluid communication with the first bladder and the second bladder for equalising pressure within the first and second bladders. The said first and second
30 bladders have a generally rectangular shape and are elongated such that the lengths of the first and the second bladder attached to the sensor body are greater than the height that the first and the second bladders extend above the sensor body when the bladders are filled. The said first and second
35 bladders are aligned with the longitudinal axis of the probe.

In one embodiment the said active surface includes a first sensor and a second sensor, wherein the first bladder is aligned with the first sensor and wherein the second bladder is aligned with the second sensor.

In another embodiment the said passageway includes



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a restrictive orifice for controlling the flow of fluid between the first and the second bladders. In a further embodiment the passageway includes a pressure responsive valve for controlling the flow of fluid between the first and
5 the second bladders.

Accordingly, in an embodiment of the invention the position of the contact segment relative to the presenting part of the foetus may be adjusted through the use of an adjustable bladder. The contact segment of the oximeter
10 probe includes a first contacting surface for sensor contact to the foetus and second face for contact to the uterine wall. An adjustable bladder is connected to the surface opposite to the sensor. In one form, the adjustable bladder is filled with fluid prior to insertion. In an alternate
15 form, the bladder is inflated after insertion via an inflation tube which runs along the longitudinal axis of the probe. The bladder is generally rectangular so that each contact point along the bladder surface is equidistant to the sensing sensor contact surface. Moreover, the fluid in the
20 bladder can be adjusted to apply pressure to the sensor contact surface. The pressure within the bladder can therefore be adjusted to substantially prevent exsanguination.

In another aspect the invention provides an
25 intrauterine probe for measuring a physical condition of a foetus. The probe comprises a sensor body having an active face, wherein the sensor body has a channel disposed therein; an inserting means for inserting the sensor body into a uterus between a foetus and a uterine wall; a usually
30 deformed resilient biasing means integral with the sensor body and which is disposed entirely on the portion of the probe within the uterus for applying force between the foetus and the uterine wall; and a straightening means for straightening the resilient biasing means, the straightening
35 means including a stylet removably disposed in the channel.

In another aspect the invention provides a method for measuring a physical condition of a foetus. The method comprises the steps of providing a sensor having a usually deformed resilient portion and an active face; inserting the
40 sensor into a uterus such that the active face is adjacent to



the foetus and the resilient portion is entirely with the uterus; temporarily straightening the resilient portion while permitting the sensor into the uterus; and permitting the sensor to apply force between the active face and the uterus
5 using only the deformation of the resilient portion and without the application of any additional force from outside the uterus.

In another aspect the invention provides an intrauterine probe for measuring a physical condition of a
10 foetus. The probe comprises a sensor body having a longitudinal axis and an active surface for contacting a foetus; inserting means for inserting the sensor body into a uterus between a foetus and a uterine wall; and a resilient first biasing segment usually extending at a predetermined
15 non-zero angle from the sensor body and being rotatable about a first axis of rotation.

Accordingly, contact to the presenting part of the foetus is adjusted via a resilient biasing segment of the probe. The probe is a flexible elongate member having a
20 proximal and distal end. A probe contact segment is located at the distal end of the elongate member. The probe contact segment is comprised of an active segment and a resilient biasing segment integral with the sensor body. The biasing segment changes its form during insertion of the probe to
25 fill the space between the uterine wall and the foetus. During insertion of the probe, the biasing segment is in a deformed flattened position to make insertion into the space between the uterine wall and the foetus easier. When the probe reaches an expanded space, the biasing segment region
30 conforms to its return position. In attempting to move to its return position, the biasing segment acts as a lever to force the probe sensor on the contact segment surface against the foetus.

In the related embodiment shown in Figure 2, a
35 channel for stylet insertion exists along the longitudinal axis of the elongate body through the contact segment to the probe tip. Before insertion of the probe into the space between the uterine cavity and the presenting part of the foetus, a stylet is inserted into the cavity. Since the
40 stylet is straight, the biasing segment is deformed so that



the contact segment forms a straight line. Straightening the contact segment makes insertion of the probe easier. After the probe is inserted, the stylet is removed and the biased segment attempts to conform to its return position.

5 A further understanding of the invention may be had with reference to the following description and drawings.

In the claims which follow and in the preceding summary of the invention, except where the context requires otherwise due to express language or necessary implication, 10 the word "comprising" is used in the sense of "including", i.e. the features specified may be associated with further features in various embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

15 Figure 1 is a cross-sectional diagram of a foetal probe showing light transmission through various layers of tissue;

Figure 2 is a side view of an integral end fulcrum type foetal probe;

20 Figure 3 is a side view of an integral end fulcrum type foetal probe;

Figure 4 is a cross-sectional view of an integral end fulcrum type foetal probe of Figure 3 inserted in the space between the uterine cavity and the presenting part of the foetus;

25 Figure 5 is side representational view of a fulcrum type foetal probe shown in Figure 2 in its deformed and return positions;

Figure 6 shows a side representational view of a foetal probe having a corrugated contact segment;

30 Figure 7 shows a side view of a foetal probe having a corrugated contact segment;

Figure 8 is a top view of a foetal probe having collapsible runners;

35 Figure 9 is a side cross-sectional view of the foetal probe of Figure 8 having collapsible runners;

Figure 10 is an end view of a modified fulcrum type foetal probe having flexible wings;

Figure 11 is a side view of a foetal probe embodied



by the present invention having a bladder type contact member;

Figure 12 is a cross-sectional view of a pulse oximetry probe with contact bladder surface inserted in the gap between the uterine wall and the foetus;

Figure 13 is a side view of a bladder type probe oximeter where the bladder is shaped in the form of bellows;

Figure 14 is a cross-sectional view of the foetal probe shown in Figure 15 with an inflated bladder;

Figure 15 is a cross-sectional view of the foetal probe with a bladder in a shape of bellows of Figure 13 with a deflated bladder;

Figure 16 is a side view of another foetal probe embodied by the invention having two bladders joined by a connecting passage;

Figure 17 is a side view of a foetal probe having two bladders joined by a connecting passage with a restrictor in the connecting passage;

Figure 18 is a side view of a foetal probe having at least two inflatable bladders joined by a connecting passage with a pressure responsive valve coupled to the connecting passageway; and

Figure 19 is a side view of a foetal probe having a first and second bladder joined by a connecting passage wherein the fluid flow between the two bladders are controlled by an actuation means.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Figure 2 shows a side view of a foetal probe 200 having an integral end fulcrum in its undeformed return position. The probe has an elongate body with a proximal end 202 and a distal end 204. The probe includes a handle or insertion means 206 which functions as an insertion aid. The handle 206 is generally cylindrical having a radius of 0.1 inches and is typically 13 inches long.

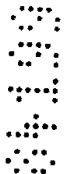
The probe is formed using standard manufacturing processes. A stiffener (not shown), cables forming a bus

(not shown), and a channel 208 extend along the longitudinal axis of the elongate body. The steel stiffener provides the general shape of the probe and in one embodiment terminates at the handle 206 of the probe.

5 The stiffener allows for bending in a first direction while resisting bending in a second direction. The channel 208 is formed using standard extrusion techniques by extruding over an aluminum spacer that is removed after the formed cable is cut into individual lengths.

10 In one embodiment, the channel 208 provides a space for stylet insertion. The cables are soldered to an electrical optical module to achieve electrical contact. This assembly is then over molded with a thermoplastic rubber by an injection molding process designed to

15 maintain good shut-off with electrical sensing surface and optical sensing surface. A mandril is used to form a channel in sensor body for the insertion of removable stylet.



The probe extends from the insertion means at the proximal end of the probe slightly widening into the contact segment 210. The contact segment 210 is located at the distal end 204 of the probe and is comprised of an active segment 211 and resilient biasing segment 213. In the embodiment shown in Figure 2, the active segment 211 extends from the inserting means 206 and the resilient biasing segment 213 extends from the distal end of the active segment 211. In the embodiment shown in Fig. 2, the contact segment 210 has a first foetal contact surface 212, for contact to the foetus, and second contacting surface 214 for contacting the maternal tissue. An emitter 216 and photodetector 218 are located on the first contacting surface 212 of the contact segment 210. In order to receive an accurate measurement, the emitter and photodetector 216 and 218

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302 is located at the distal end of the elongate member. Similar to the embodiment shown in Figure 2, the probe contact segment 302 is comprised of an active segment 304 and a resilient biasing segment 306. The biasing segment 5 306 changes its form during insertion of the probe, expanding to fill the space between the uterine wall and the foetus. During insertion of the probe, the biasing segment 306 is deformed or preloaded to a flattened position to make insertion into the space between the 10 uterine wall and the foetus easier. When the probe reaches an expanded space, the biasing segment adjusts to its return position. In attempting to move to its return position, the resilient biasing segment acts as a lever to force the probe sensor on the surface of the contact 15 segment against the foetus.

The shape of the contact segment 302 shown in Figure 3 differs from the contact segment 210 of the foetal probe shown in Figure 2. Although both probes include a resilient biasing segment, the probe tip of the biasing 20 segment shown in Figure 3 is tapered to make insertion easier. Also, the deformation region 306 (in its return position) is curved in contrast to the linear biasing segment 213 shown in Figure 2. The curvature of the biasing segment 306 is similar to the curvature of the 25 foetus head. The curved deformation region 306 makes insertion easier.

Figure 4 shows a cross-sectional view of an integral end fulcrum type foetal probe of Figure 3 inserted in the space between the uterine cavity and the 30 presenting part of the foetus. The foetal probe is positioned in the space between the uterine cavity and the foetus to provide good sensor contact. When the distal end is in contact with the mother's uterine wall, the region forces the emitter 316 and photodetector 318 35 against the foetus. To firmly contact the emitter and photodetector 318, the contact segment 302 is in its bent, undeformed position. However, although this position provides a good contact, the undeformed position



makes probe insertion difficult.

Figure 5 is a side representational view of the integral end fulcrum oximeter probe shown in Figure 2 in a first deformed and second return position. The contact segment 210 of the probe includes a fulcrum point 506 and a biasing segment 504. Since insertion of the probe is difficult with the biasing segment 504 bent towards the longitudinal axis of the handle 206, the present invention presents a second straightened position for insertion of the probe. In the first position (represented by dotted lines) the biasing segment 213 is in a position for insertion of the probe. The body of the probe is straightened for insertion by introduction of a stylet into the cavity 208 along the longitudinal axis of the probe, thereby preloading the biasing segment 504. The stylet 502 is typically a substantially flat rod made of stainless steel having a width .125 inches and an approximate length of 14 inches. The width of the stylet must be less than the width of the cavity 208.

When the stylet 502 is removed, the biasing segment 504 of the probe returns to its original position by rotating around its fulcrum point 506 to form an angle. The angled position of the biasing segment 213 presses the emitter and photodetector 216, 218 on the first contacting surface of the contact segment against the foetus. As the biasing segment 213 moves closer to the longitudinal axis of the probe, the emitter and photodetector 216, 218 are moved into a closer contact position with the foetus.

Although the embodiment shown in Figures 2 and 5 include a channel for stylet insertion, deformation of the biasing segment by a stylet is not necessary if the biasing segment is sufficiently resilient. In the embodiment shown in Figure 3, no stylet is needed to deform the biasing segment 305.

Figure 6 is an alternate embodiment of an integral end fulcrum foetal probe. Instead of the probe contact segment forming an angle around the fulcrum as seen in



Figures 2, 3 and 5, the contacting segment 602 is aligned with the longitudinal axis of the handle. The contacting segment includes at least one corrugation 604 aligned to the longitudinal axis of the probe.

5 The dotted lines shown in Figure 6 are representative of the probe during stylet insertion. The corrugated region 604 of the contact segment 602 is straightened during insertion of the probe into the space between the interuterine cavity and the foetus by
10 introduction of a stylet. Moving the stylet causes the sensor to straighten (as seen in the dotted lines), thereby preloading this resilient biasing segmentor to become more "arched". This allows external control of the contact pressure between the sensor and the foetal tissue when the sensor is positioned between the foetus
15 and the uterine wall. Removal or withdrawal of the stylet allows the sensor body to return to its normally corrugated shape. The corrugated shape conforms to gaps between the foetus and the uterine wall, firmly
20 positioning the probe so that the sensors on the first contacting surface 212 of the probe make good contact to the foetus.



To make good contact, the emitter 216 and photodetector 218 must be located on a contact surface in
25 a region generally parallel to the surface of the foetus. In Figure 6, the first contacting surface 212 contacts the foetus. Alternatively as shown in Figure 7, the emitters and photodetector 216, 218 can be positioned in the region parallel to the foetus between the handle 206
30 and the peak 706 of the peak of the corrugation 704.

Figure 8 shows an alternate embodiment of an integral end fulcrum type oximeter probe. In the embodiment shown in Figure 8, the contact segment 802 extends from the probe handle 804 such that the width of
35 the contact segment 802 is wider than the handle 804. The width gradually increases to a second width which is the contact segment width. The wider body of the contact segment 802 increases the stability of the probe making

it more resistant to movement within the gap between the foetus and uterine wall.

The contact segment 802 has first contact surface 804 and a second contact surface (not shown), on the reverse side. The second contact surface 806 contacts the uterine wall and includes a plurality of runners 808 which extend substantially parallel to the longitudinal axis of the handle 804. The runners 808 are flexible elements which deflect downwards into slots inside the contact segment 802 at insertion so that insertion of the probe is not impeded. The insertion slots 902 shown in Figure 9 allows the runners to deflect downwards below the contacting surface of the contact segment upon insertion to preload the biasing runners 808.

Figure 10 is an end view of the contact segment 1001 fulcrum type sensor which is modified to include a first and second biasing segments fold 1002, 1004 (wings) to improve contact to the foetus. The biasing segments 1002, 1004 extend from the lateral edges of the active face 1006 of the contact segment 1001. Unlike the fulcrum type sensor shown in Figures 2 and 3 where the rotation occurs perpendicular to the longitudinal axis of the probe, the rotation of the first and second folds occurs along a first and second axis parallel to the longitudinal axis of the probe. In a first embodiment, the contact segment is made of a flexible rubber compound which easily deforms upon insertion of the probe into the space between the uterine wall and the presenting part of the foetus. No stylet is necessary for deformation.

In a second embodiment the biasing segment 1002, 1004 are relatively inflexible. In order to straighten the folds 1002, 1004 of the contact segment for insertion, the type of stylet used in Figure 2 must be modified to include a first and second flexible protrusion along the sides of the stylet. The flexible protrusion are withdrawn into insertion slots during probe insertion. When the modified stylet reaches the contact segment, the modified stylet moves the stylet



folds of the contact segment to a second position such that the first and second folds are at a 180° angle from each other to preload the biasing segments.

5 An alternate foetal probe connects an adjustable expansion means, typically a balloon, to the non-sensing side of the contact means. The adjustable expansion means is typically filled with a fluid to control the force and pressure between the sensors and the foetus and compensates for the gaps between the foetus and the
10 uterine wall. A fluid, such as saline, is typically used.

Figure 11 is a side view of a pulse oximetry probe embodied by the invention with a bladder connected to the non-sensing side of the contact segment. The side of the
15 probe opposite to the bladder 1102 includes an emitter 1104 and photodetector 1106. In one embodiment, a fluid transmission cavity 1108 exists within the handle means and extends from the handle means 1110 into the bladder 1102. The bladder 1102 is deflated upon insertion for ease of insertion. After insertion, fluid is transferred
20 via the fluid transmission cavity, slowly filling the bladder 1102 until a desired pressure is reached. In a preferred embodiment, the bladder is filled with fluid and sealed before insertion into the uterus. The bladder
25 may not be completely filled so that the fluid may move within the bladder to adjust to fill the gap between the uterus and foetus.

Figure 12 is a cross-sectional view of the pulse oximetry probe with bladder of Figure 11 inserted in the
30 space between the uterine wall and the foetus. As can be seen from Figure 12, the space between the uterine wall and the foetus on a first side of the probe 1202 is smaller than the space between the uterine wall and the foetus at a second side of the probe 1204. Although the
35 space between an uterine wall and the foetus varies between the two sides 1202, 1204 of the probe, the compliant property of the fluid in the bladder 1206 and the length of the bladder allows a uniform pressure

between the sensor 1208 and the foetus 1210 by movement of the fluid within the bladder to provide contact with the uterine wall along multiple points. The bladder 1206 is sufficiently long to allow the fluid to move from one part of the chamber to a more distant part, making it thin at one end and thick at the other. This allows the sensor to pass through a narrow gap. As it initially enters the gap, the distal end thins as liquid is forced back. After the distal end passes through the gap, the liquid can shift again, making the distal end thick and the proximal end passing through the gap thin. This process may be reversed with fluid being transferred from the distal end to the proximal end of the bladder.

The fluid filled bladder may be filled before insertion into the uterine gap or after insertion into the gap between the uterus and the foetus. If the bladder is filled with fluid before insertion of the probe into the gap, the volume in the bladder is non-varying. Although an equal pressure is applied to the sensors, this pressure may vary based on forces due to contraction of the uterus during labor. During a contraction, the space between the uterine wall and the foetus will decrease applying a larger force to the sensor. Thus, the pressure to the sensor is increased. Since excess force may cause local exsanguination, it may be desirable to adjust the amount of fluid in the chamber in order to apply an equal pressure at all times. This is accomplished since the length of the bladder allows the shifting of the fluid in the bladder away from any local constriction.

In an embodiment shown in Figure 11, the shape of the inflatable bladder is generally rectangular so that each point of the surface of the bladder is equal distant from the sensing means. In the alternate embodiment shown in Figures 13-15, the shape of the adjustable expansion means is that of a bellows. When the adjustable expansion means 1302 is deflated, the bladder includes a plurality of folds parallel to the

longitudinal axis of the probe handle. Figure 13 shows a side view of a bladder type expansion means after inflation of the bladder. The bladder 1302 is generally rectangular as in the embodiment shown in Figure, 11, however, a slight widening occurs from the base of the sensor to the end of the sensor contacting the uterine surface. Figure 14 shows an end view of the contact segment when the bladder 1402 is inflated. Figure 15 shows an end view of the contact segment when the bladder 1502 is deflated. The deflated bellows shape is very compact, allowing easy insertion.

In another embodiment of the invention as shown in Figure 16, the expansion means consists of a first and second bladder 1602 and 1604 - sufficiently separated - connected by a connecting passageway 1606. The connecting passageway 1606 between the two chambers allows the pressure to equalize within the first and second bladders. In one embodiment, the first bladder 1602 is vertically aligned with a first sensor 1608 while the second bladder 1604 is vertically aligned with a second sensor 1610 so that an equal pressure is applied directly over each sensor.

In the embodiment shown in Figure 17, a restrictive orifice 1702 is located within the connecting passageway 1704. The restrictive orifice 1702 limits the volume of fluid which can be transmitted between the first and second bladders 1706, 1708, controlling the flow of fluid between the chambers.

Restriction of the fluid flow controls the responsiveness of fluid movement to high frequency transients which occur due to changes in intrauterine pressure. This allows shifting due to prolonged changes in the gap between the foetus and the uterine wall, while avoiding noise or artifact caused by shifting of the fluid in response to short transient movements.

In the embodiment shown in Figure 18, a pressure responsive valve 1802 is placed in the connecting passageway 1804 between the first and second bladders

1806, 1808. The pressure responsive valve may be used to equalize pressure between the two bladders. Typically the pressure responsive valve 1802 is used to equalize the pressure between the two bladders. Thus, if the pressure gets too high in the first bladder, fluid is transmitted from the first bladder to the second bladder. This improves control over transients for long-term shifts.

The embodiment shown in Figure 19 shows two bladders 1902, 1904 connected by a connecting passageway 1906 where an actuation means 1908 is placed in the connecting passageway 1906 to control the fluid flow between the two chambers. The actuation means 1908 may be activated remotely externally to the uterus. Actuation of the device is accomplished via a connection running along the longitudinal axis of the probe. Actuation of the valve controls the movement and the direction of the flow of fluid.

The above description is illustrative and not restrictive. Many variations of the invention will become apparent to those skilled in the art on review of this disclosure. The scope of the invention should, therefore, be determined not with reference to the above description, but instead be determined with reference to the appended claims along with their full scope of equivalence.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An intrauterine probe for measuring a physical condition of a foetus comprising:
 - 5 (a) a sensor body having a longitudinal axis and an active surface for contacting a foetus and an opposite surface;
 - (b) inserting means for inserting the sensor body into a uterus between a foetus and a uterine wall; and
 - 10 (c) a bladder disposed on the opposite surface of the sensor body for contacting the uterine wall and for biasing the active surface against the foetus;wherein the bladder has a generally rectangular shape and is elongated such that the length of the bladder attached to the sensor body is greater than the height the bladder extends above the sensor body, when the bladder is filled.
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2. The probe according to claim 1 wherein the bladder is only partially filled with a fluid so that the fluid moves within the bladder to adjust to fill gaps between the uterus and foetus.
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3. The probe according to claim 1 wherein the bladder widens from the opposite surface of the sensor to an end contacting the uterine wall.
- 30 4. An intrauterine probe for measuring a physical condition of a foetus comprising:
 - (a) a sensor body having a longitudinal axis and an active surface for contacting a foetus and an opposite surface;

(b) inserting means for inserting the sensor body into a uterus between a foetus and a uterine wall;

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(c) a first bladder disposed on the opposite surface of the sensor body for contacting the uterine wall and for biasing the active surface against the foetus;

(d) a second bladder disposed on the opposite surface of the sensor body for contacting the uterine wall and for biasing the active surface against the foetus;

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(e) a passageway in fluid communication with the first bladder and the second bladder for equalizing pressure within the first and second bladders;

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wherein the first and second bladders have a generally rectangular shape and are elongated such that the lengths of the first and the second bladder attached to the sensor body are greater than the height that the first and the second bladders extend above the sensor body, when the bladders are filled; and wherein the first and the second bladders are aligned with the longitudinal axis of the probe.

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5. The probe according to claim 4, wherein the active surface includes a first sensor and a second sensor, wherein the first bladder is aligned with the first sensor, and wherein the second bladder is aligned with the second sensor.

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6. The probe according to claim 4 wherein the passageway includes a restrictive orifice for controlling the flow of fluid between the first and the second bladders.

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7. The probe according to claim 4 wherein the passageway includes a pressure responsive valve for controlling the flow of fluid between the first and the second bladders.

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8. An intrauterine probe substantially as herein described with reference to any one of Figures 11 to 19 of the accompanying drawings.

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9. A method for measuring a physical condition of a foetus, the method comprising the step of measuring the physical condition of the foetus with an intrauterine probe wherein the probe is substantially as herein described with reference to any one of Figures 11 to 19 of the accompanying drawings.

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DATED this 11th day of September 1998

NELLCOR INCORPORATED

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By their Patent Attorneys

GRIFFITH HACK



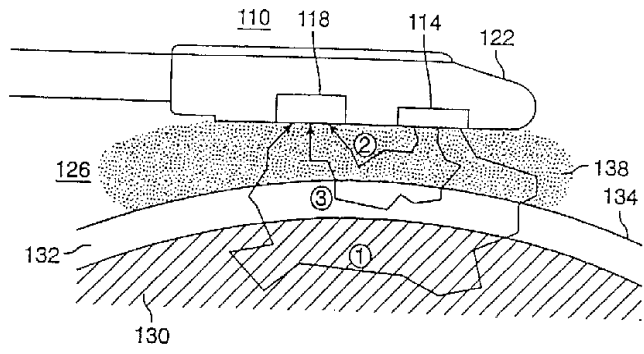


FIG. 1

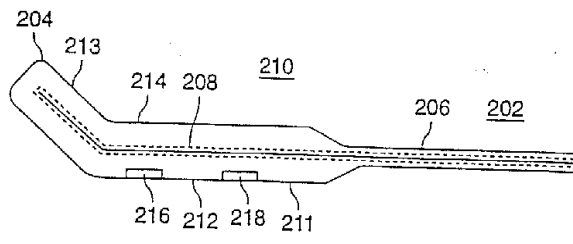


FIG. 2

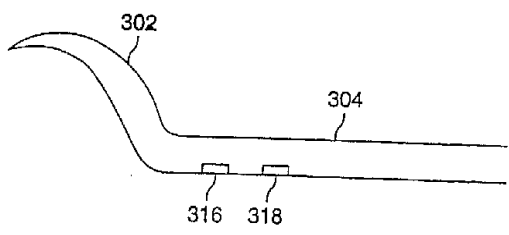


FIG. 3

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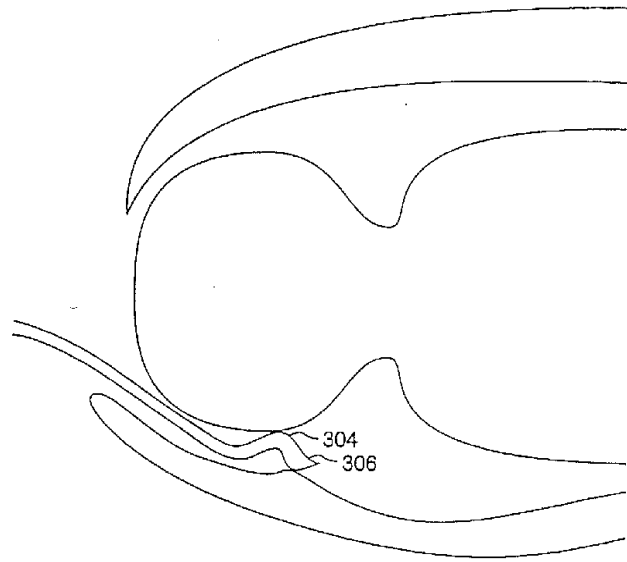


FIG. 4

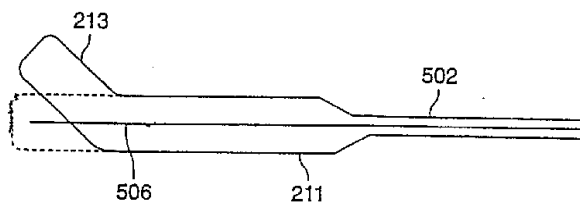


FIG. 5

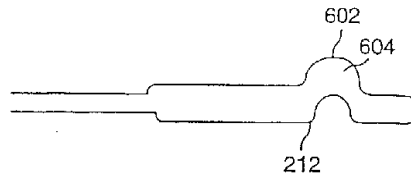


FIG. 6

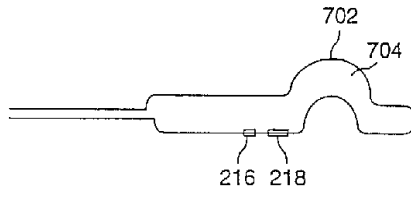


FIG. 7

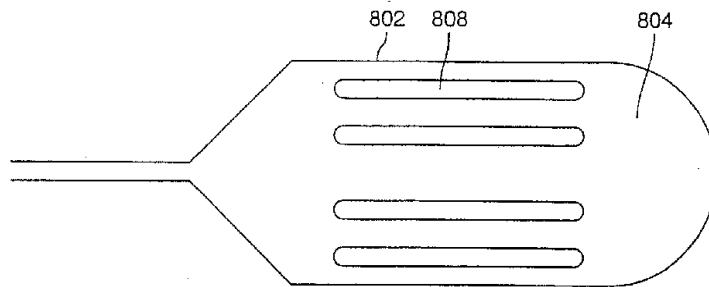


FIG. 8

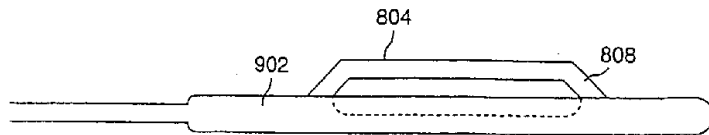


FIG. 9



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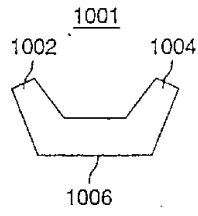


FIG. 10

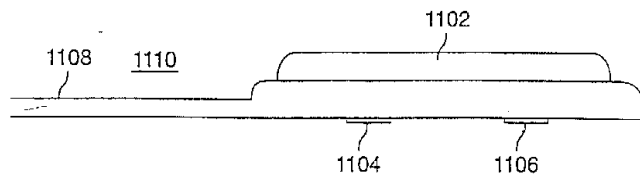


FIG. 11

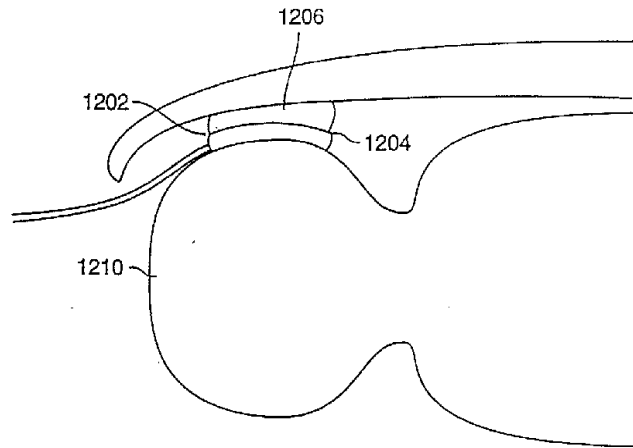


FIG. 12



FIG. 13

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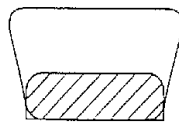


FIG. 14



FIG. 15

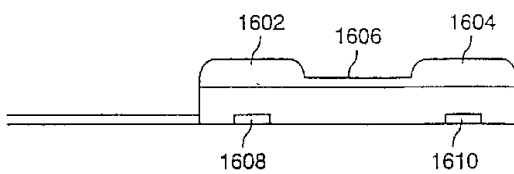


FIG. 16

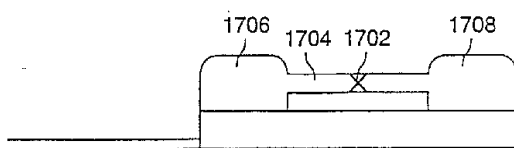


FIG. 17

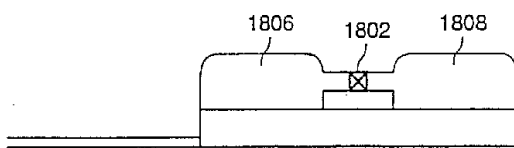


FIG. 18

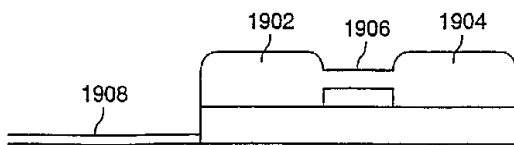


FIG. 19

