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(54) CERVIMETRY CONTROL APPARATUS

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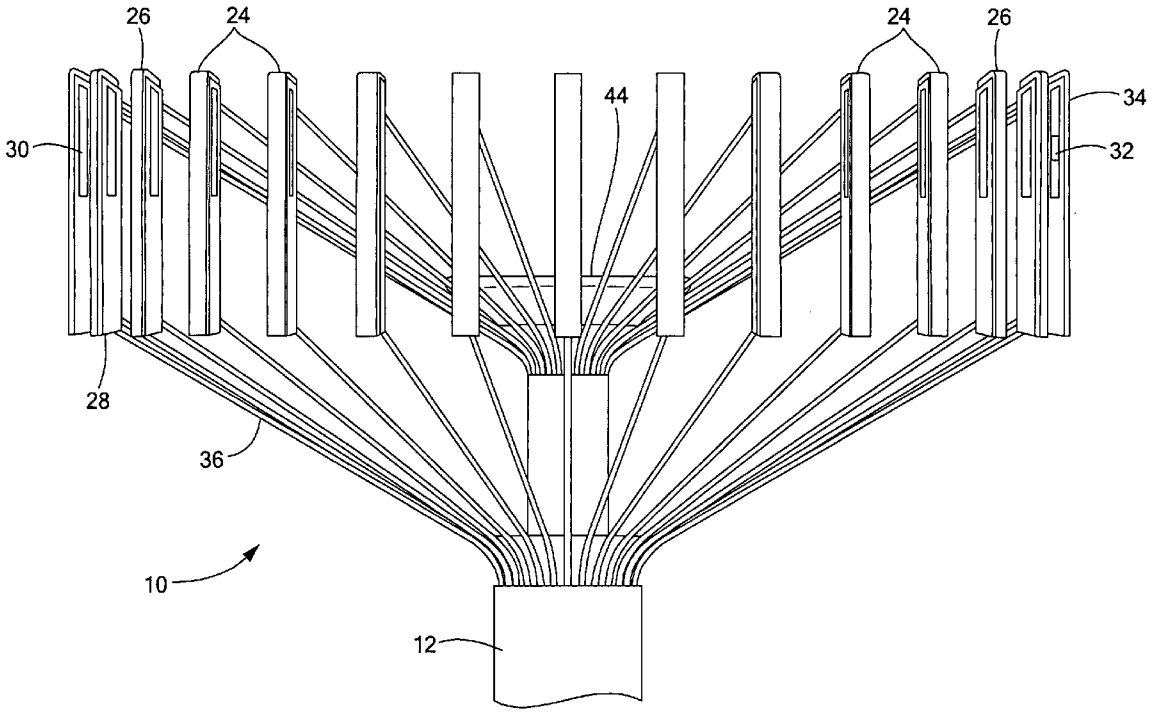
A61B 5/117 (2006.01)

(52) **U.S. Cl.** **600/588**; 600/591

(57) **ABSTRACT**

The present invention provides a medical device for measuring cervical dilation including an elongate body defining a proximal end and a distal end, as well as an expandable element coupled to the distal end of the elongate body. An array of movable elements may be disposed circumferentially about the elongate body, where the array of movable elements is movably coupled to the distal end of the elongate body by a plurality of wires. The medical device may further include a measurement mechanism able to determine a radial spacing of the array of movable elements, as well as a dilation indicator in communication with the measurement mechanism. One or more pressure sensors may be coupled to the array of movable elements, whereby a control element is in communication with the pressure sensors. In addition, an inflation source may be included in fluid communication with the expandable element.



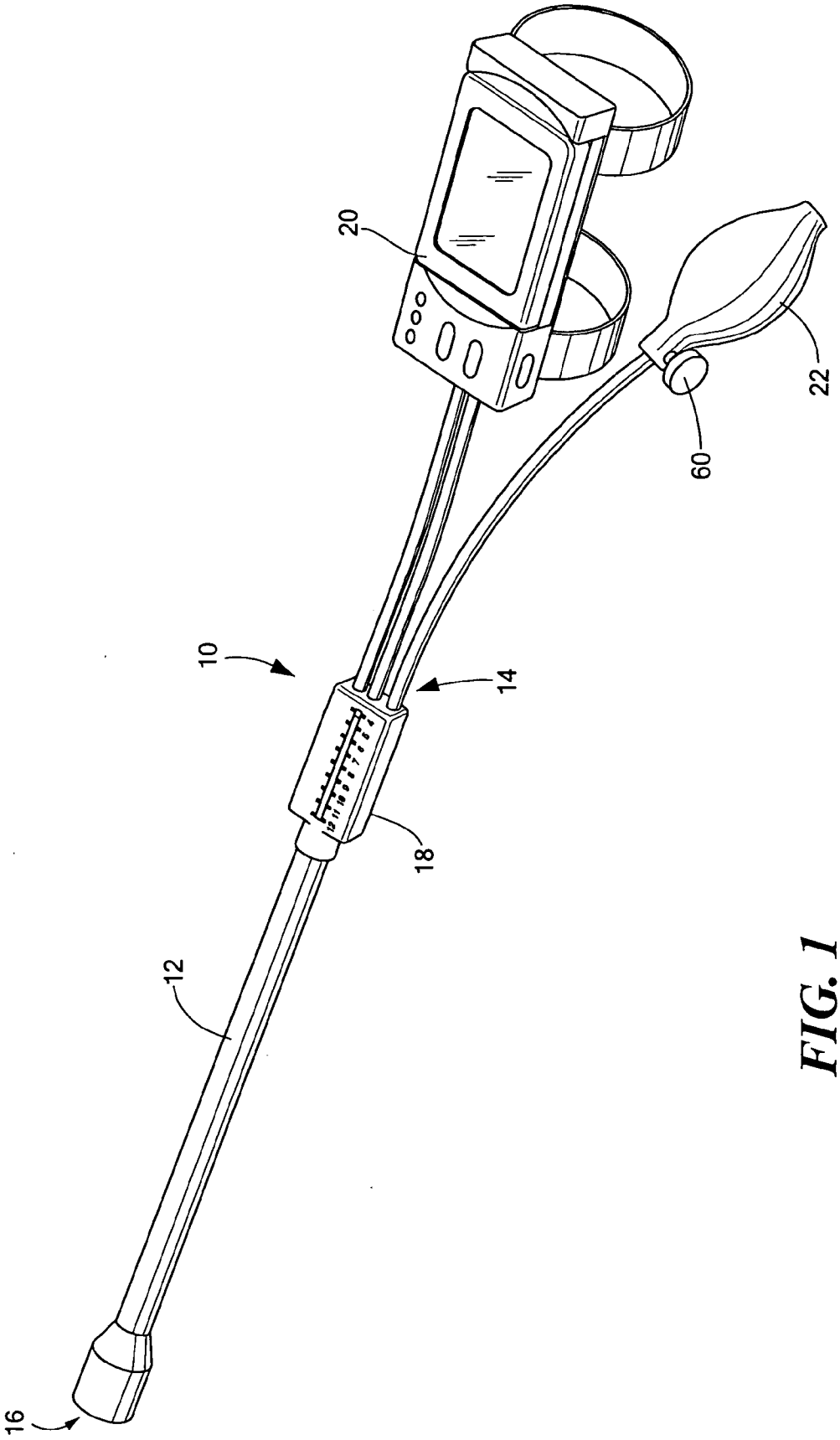


FIG. 1

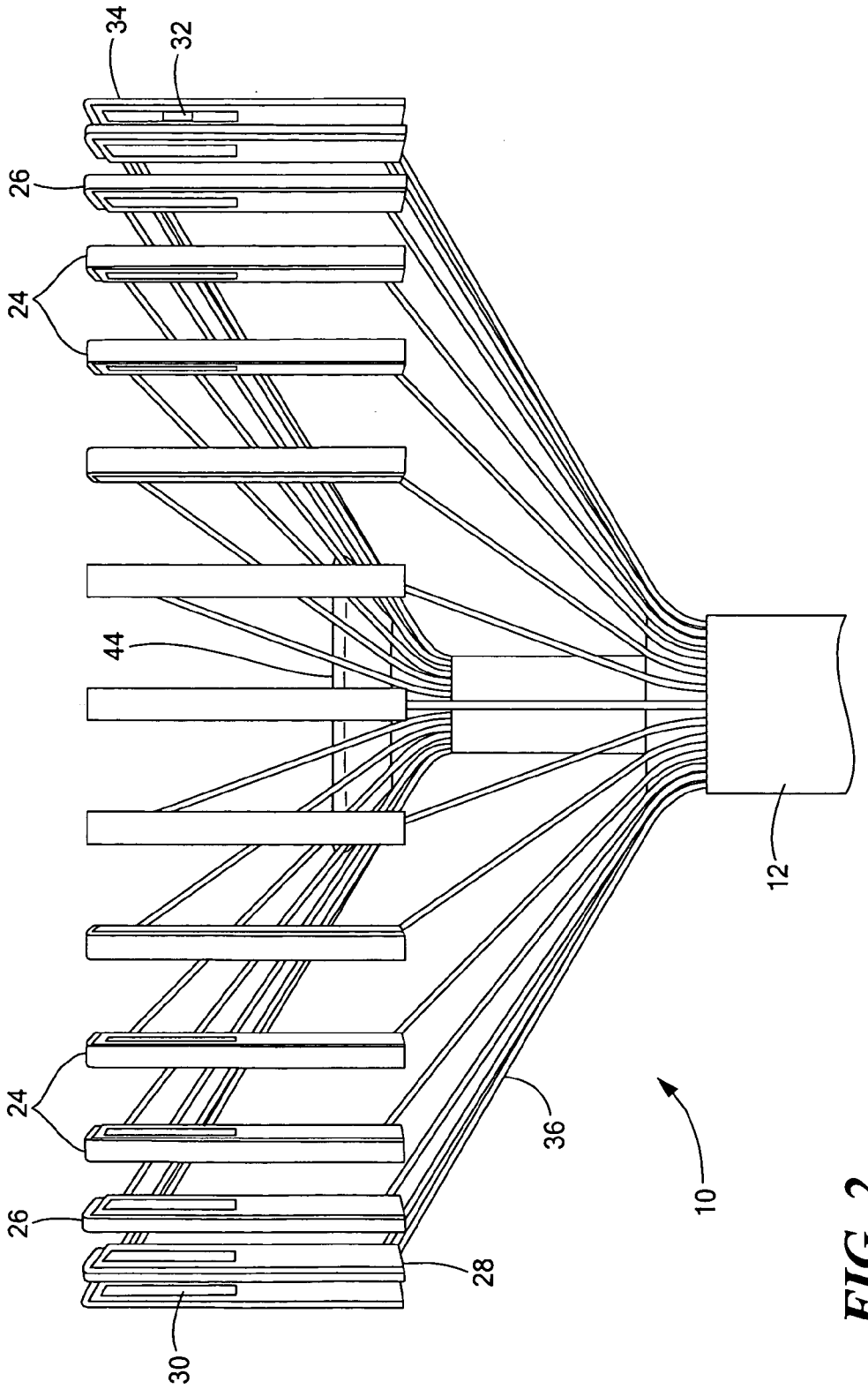


FIG. 2

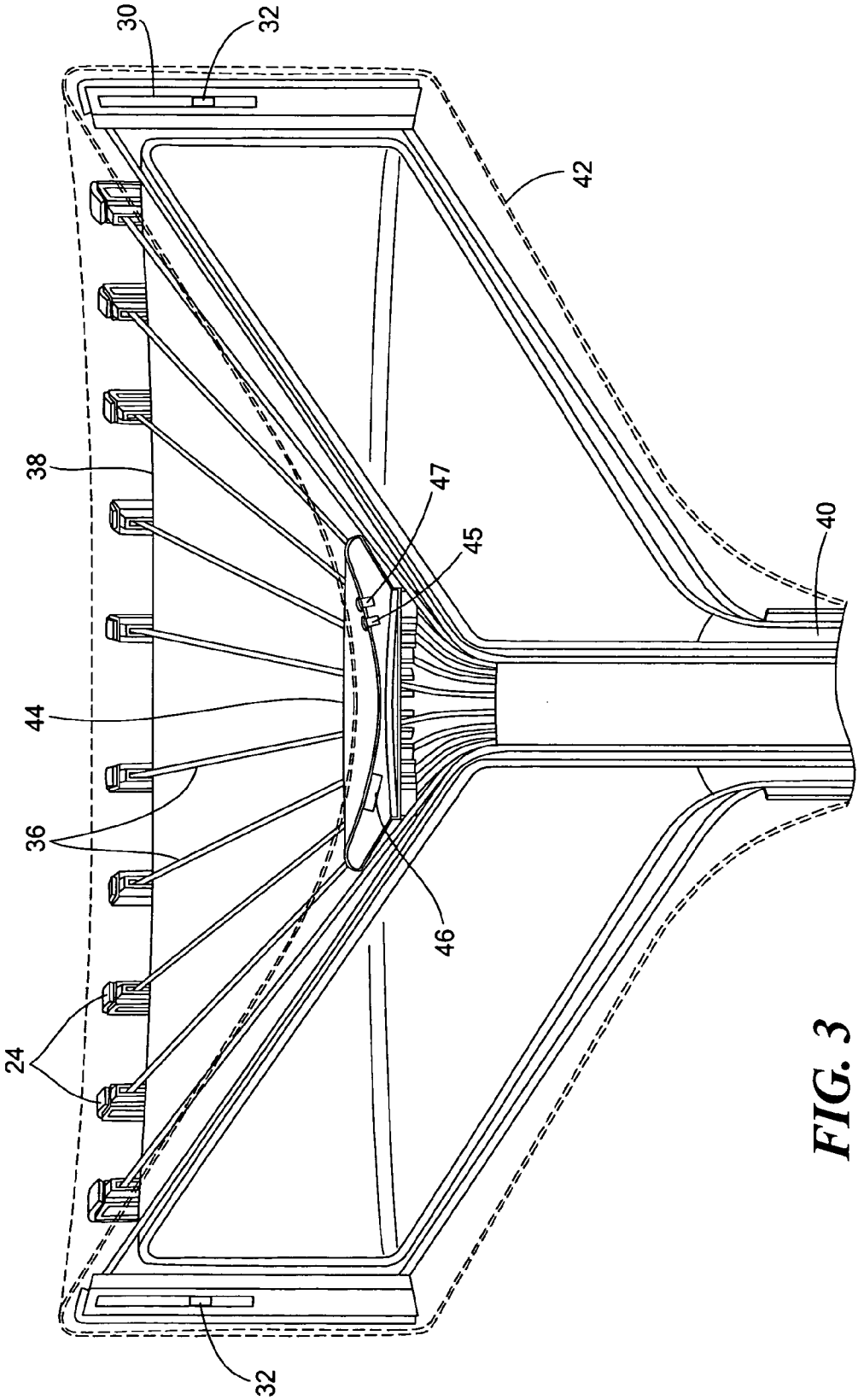


FIG. 3

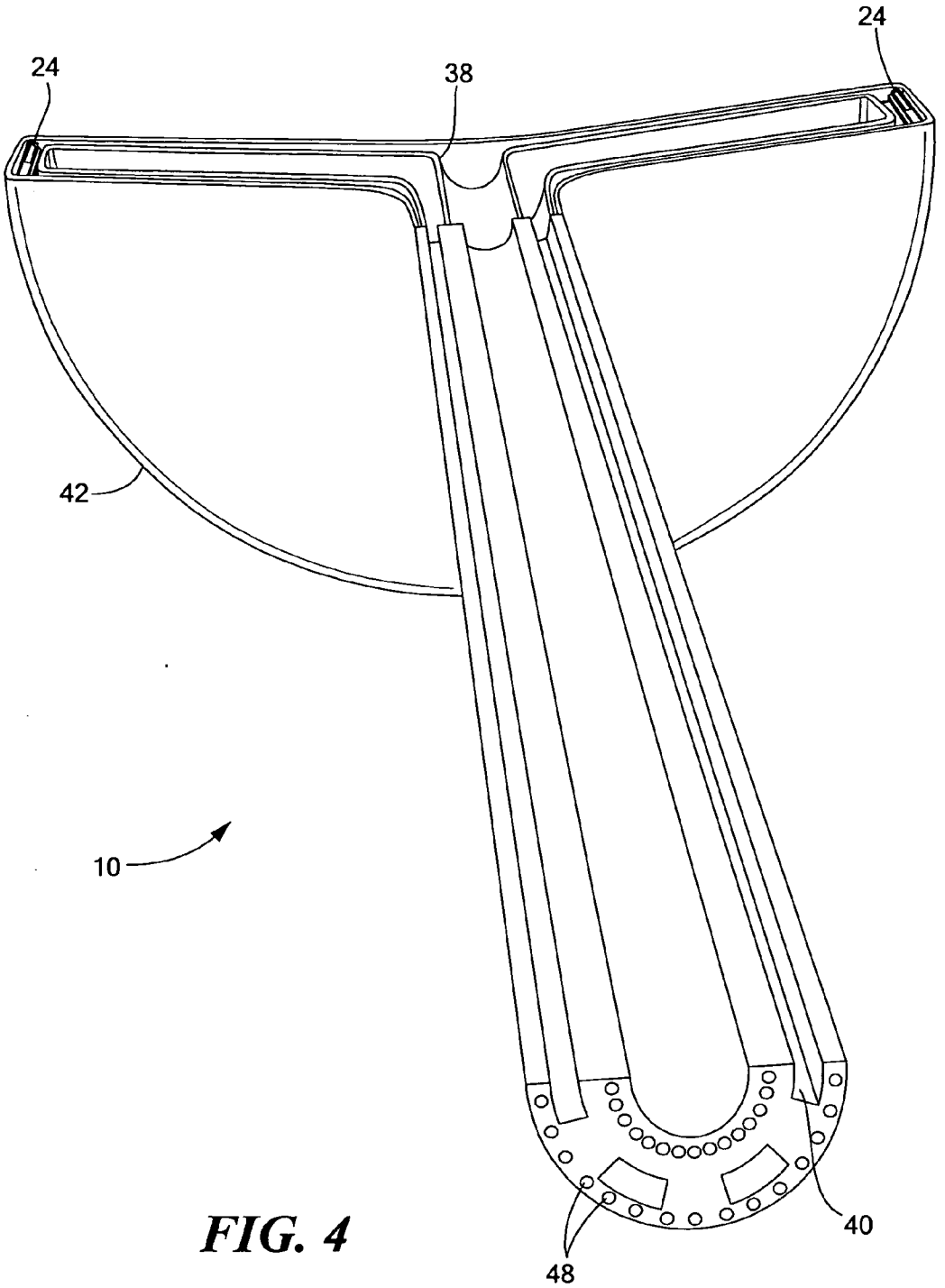


FIG. 4

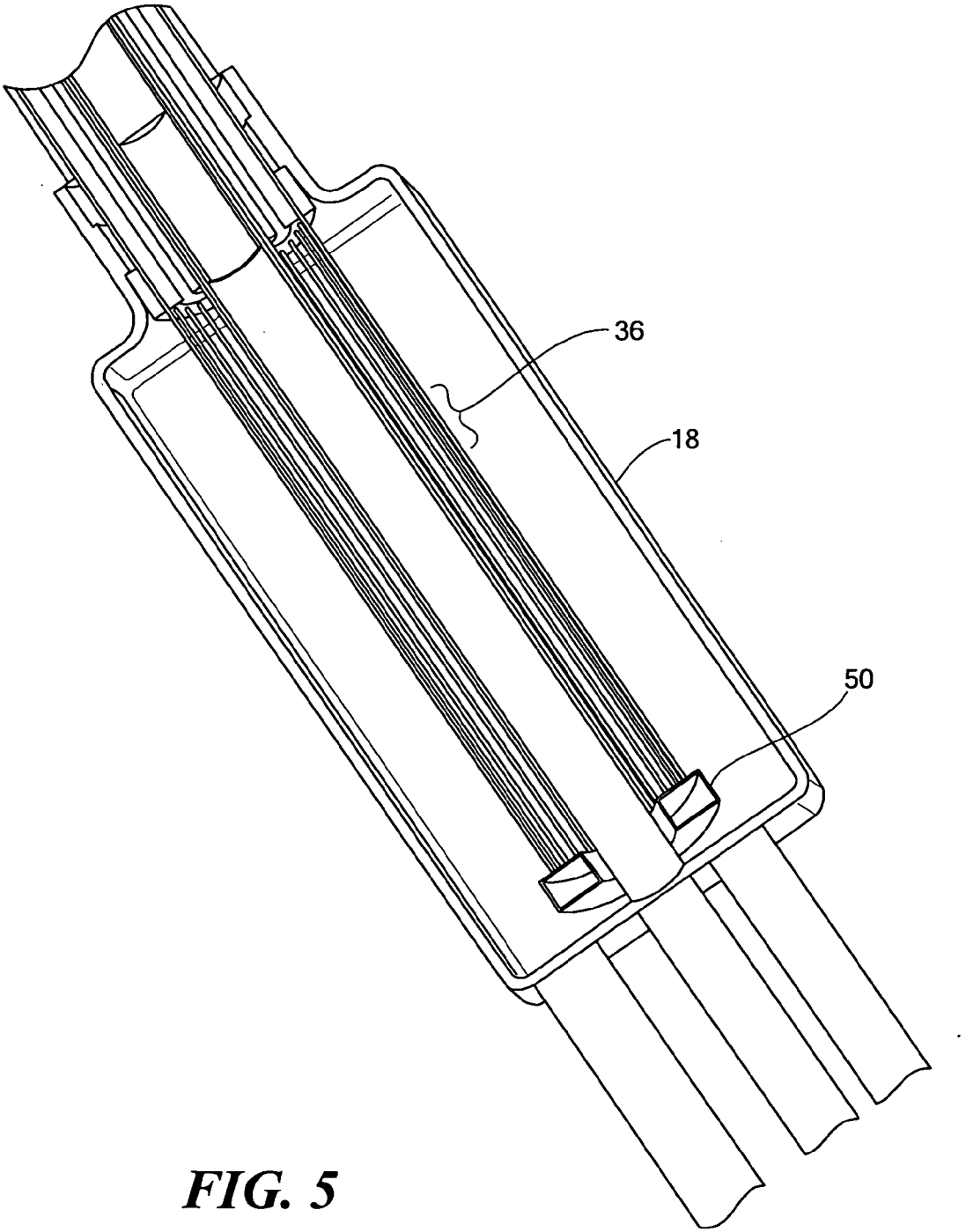
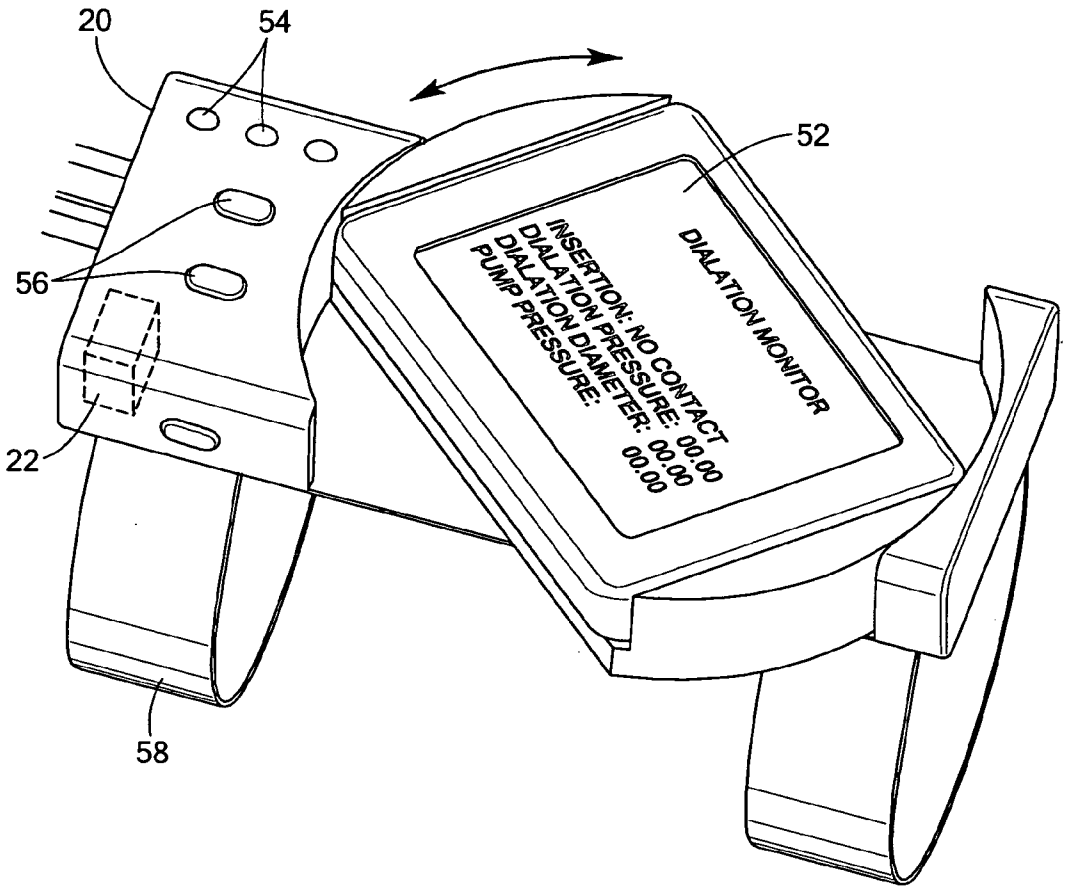


FIG. 5


20
54
52
56
22
58
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DIALATION PRESSURE: 00.00
DIALATION DIAMETER: 00.00
PUMP PRESSURE: 00.00

FIG. 6

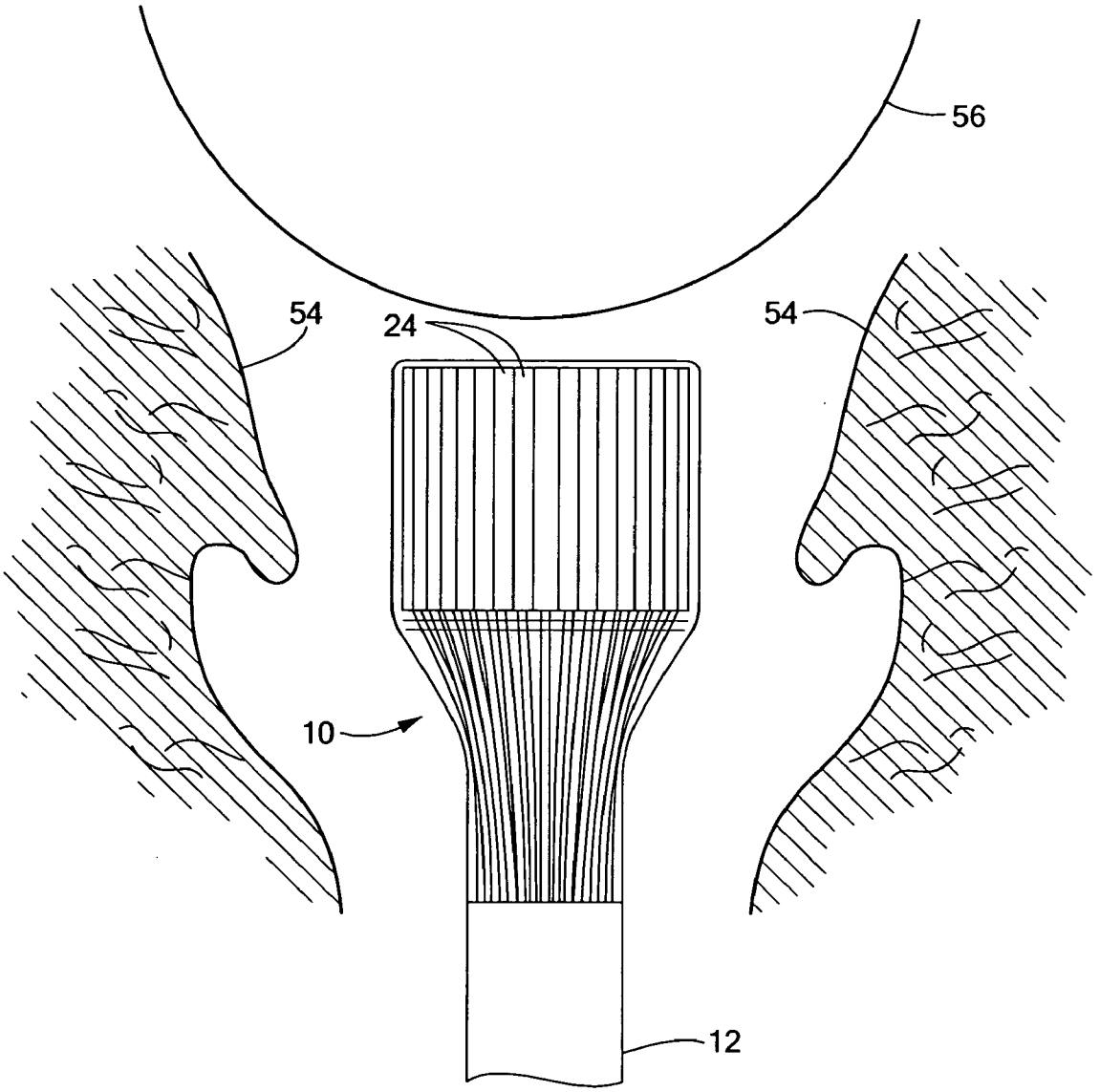

FIG. 7

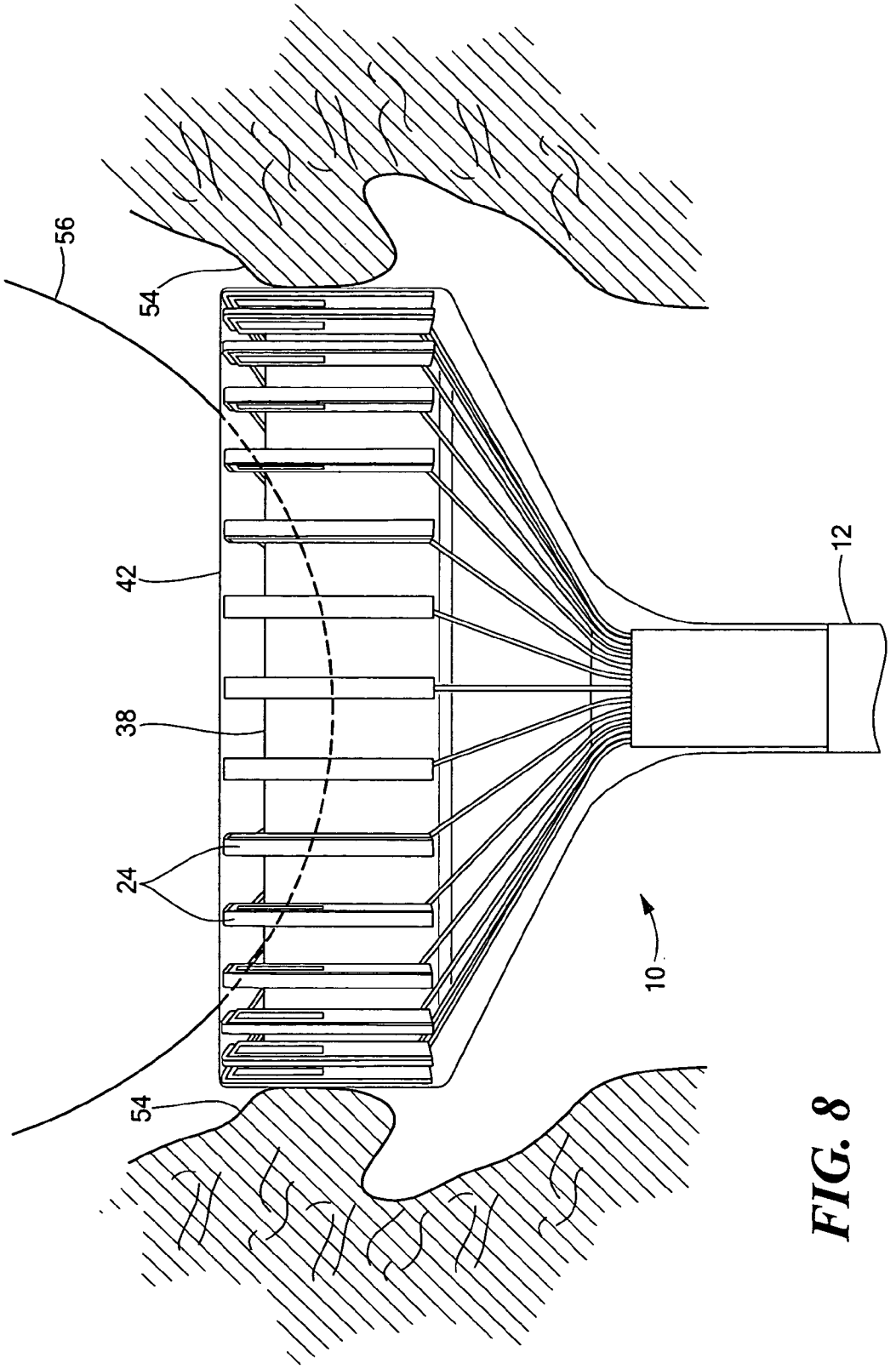

FIG. 8

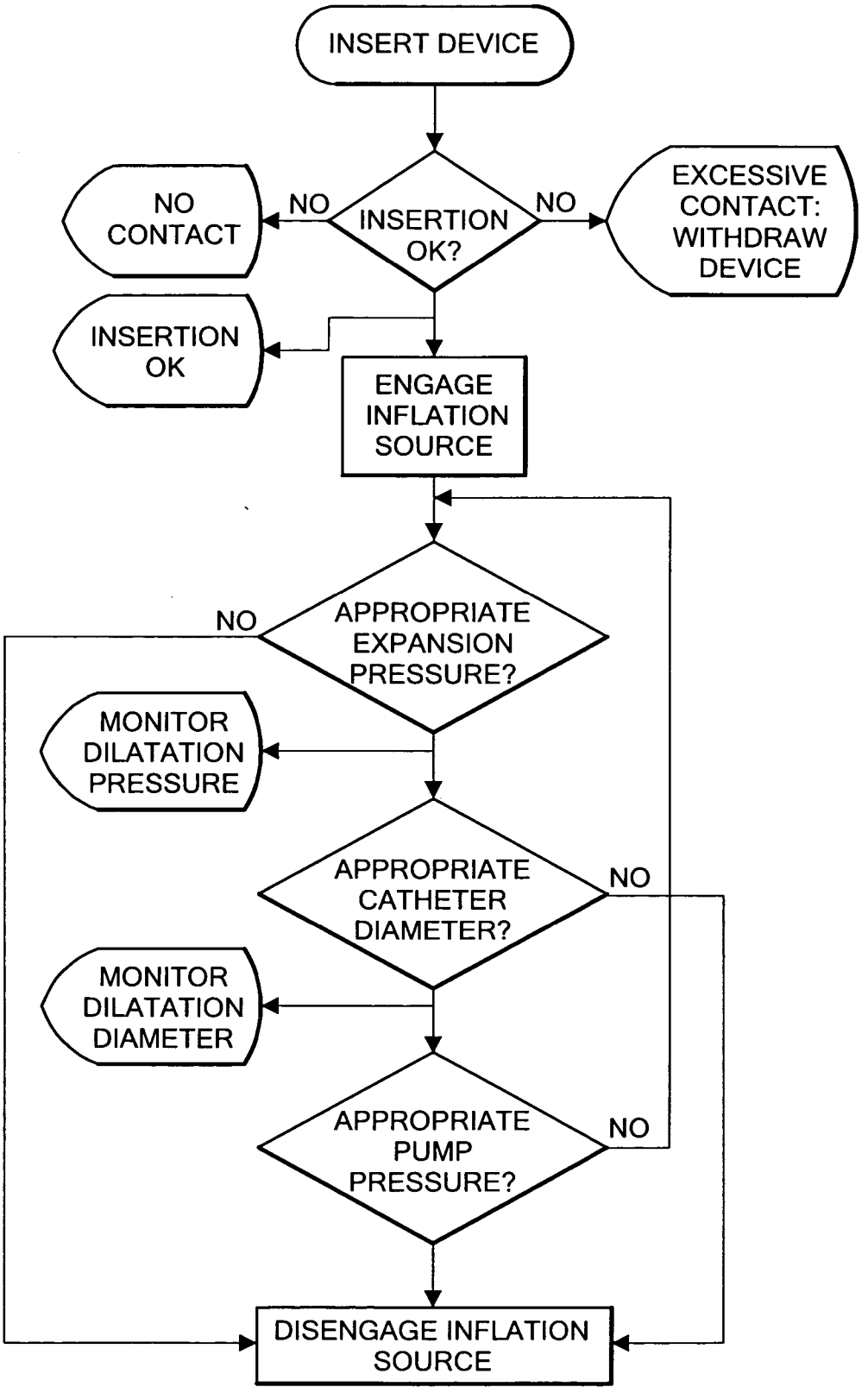
INSERT DEVICE
INSERTION OK?
NO
NO CONTACT
NO
EXCESSIVE CONTACT: WITHDRAW DEVICE
INSERTION OK
ENGAGE INFLATION SOURCE
NO
APPROPRIATE EXPANSION PRESSURE?
MONITOR DILATATION PRESSURE
APPROPRIATE CATHETER DIAMETER?
NO
MONITOR DILATATION DIAMETER
APPROPRIATE PUMP PRESSURE?
NO
DISENGAGE INFLATION SOURCE

FIG. 9

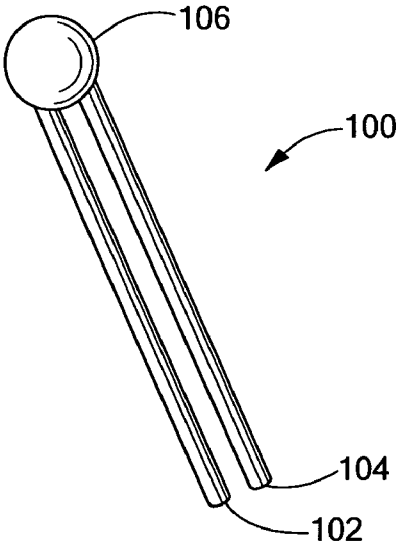

FIG. 10

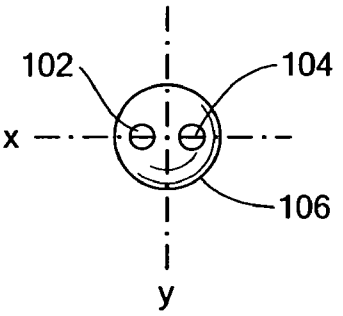

FIG. 11

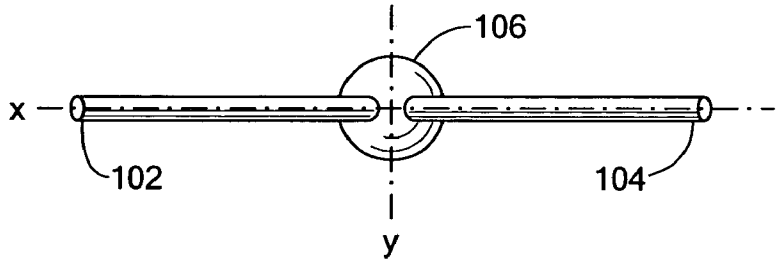

FIG. 12

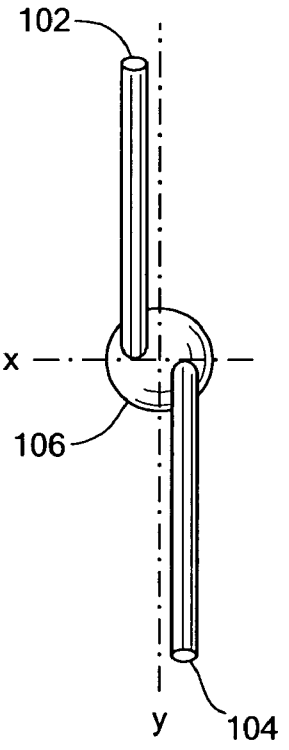

FIG. 13

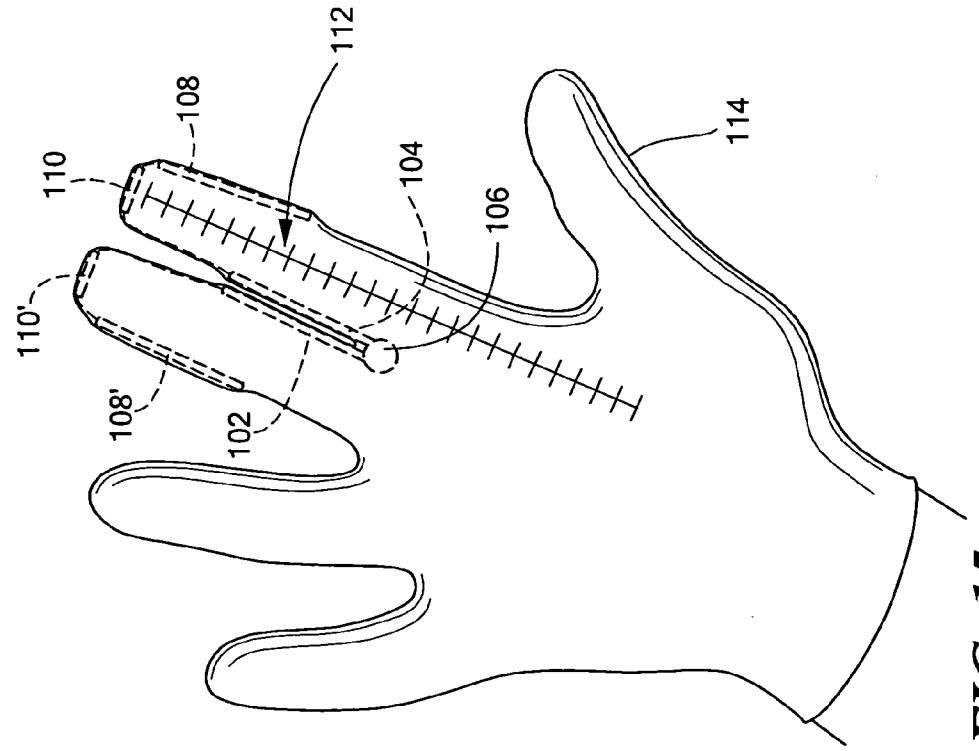

FIG. 15

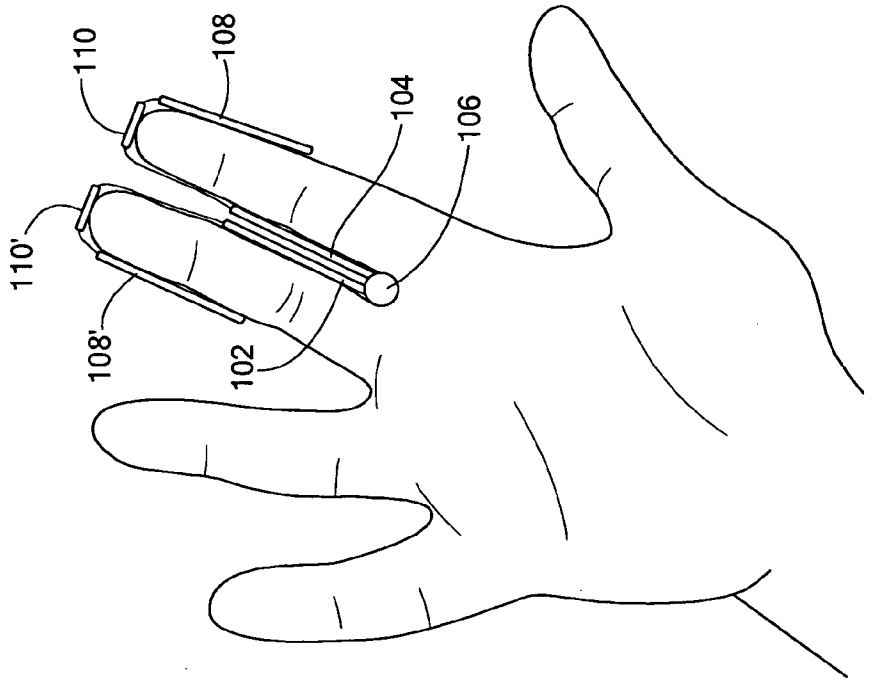

FIG. 14

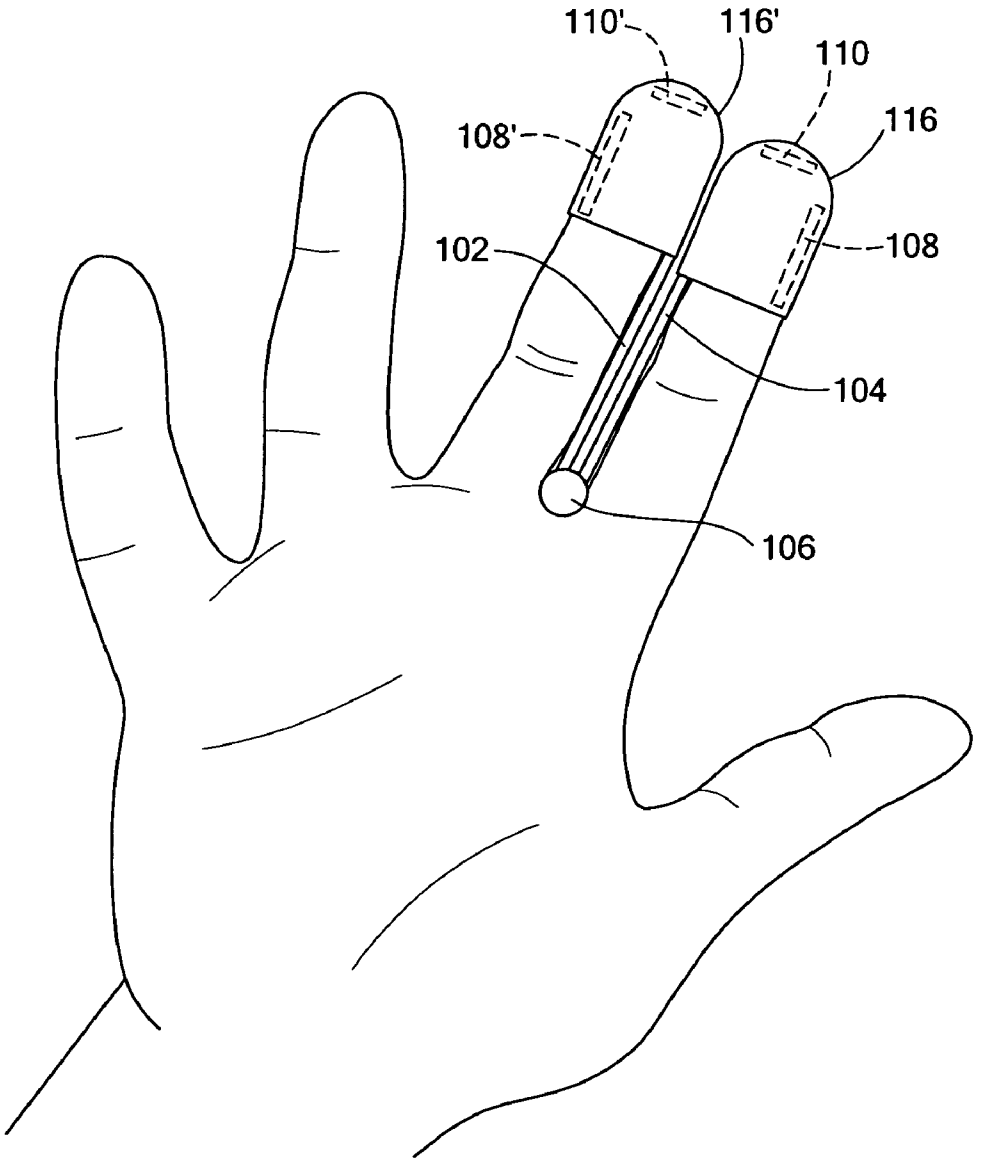

FIG. 16

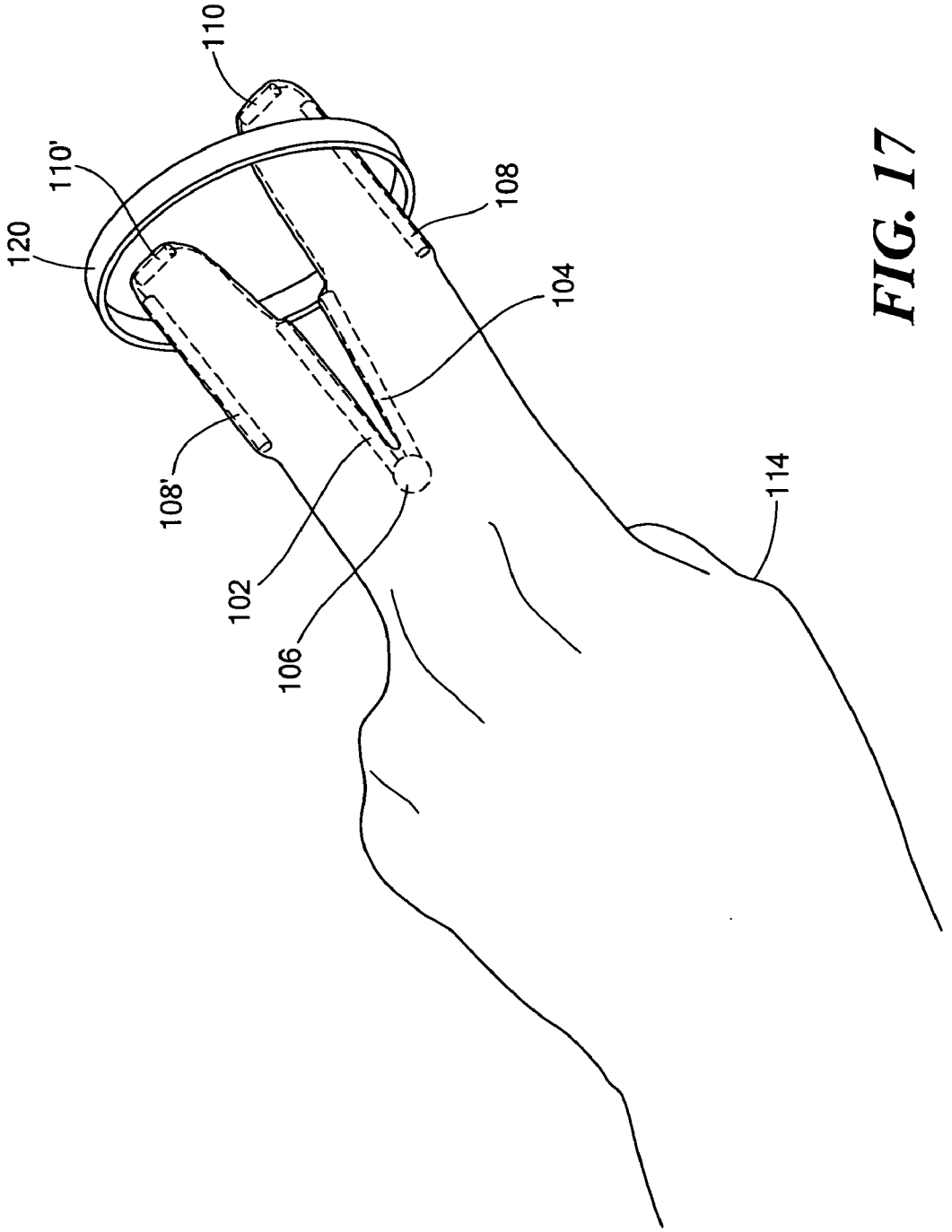

FIG. 17

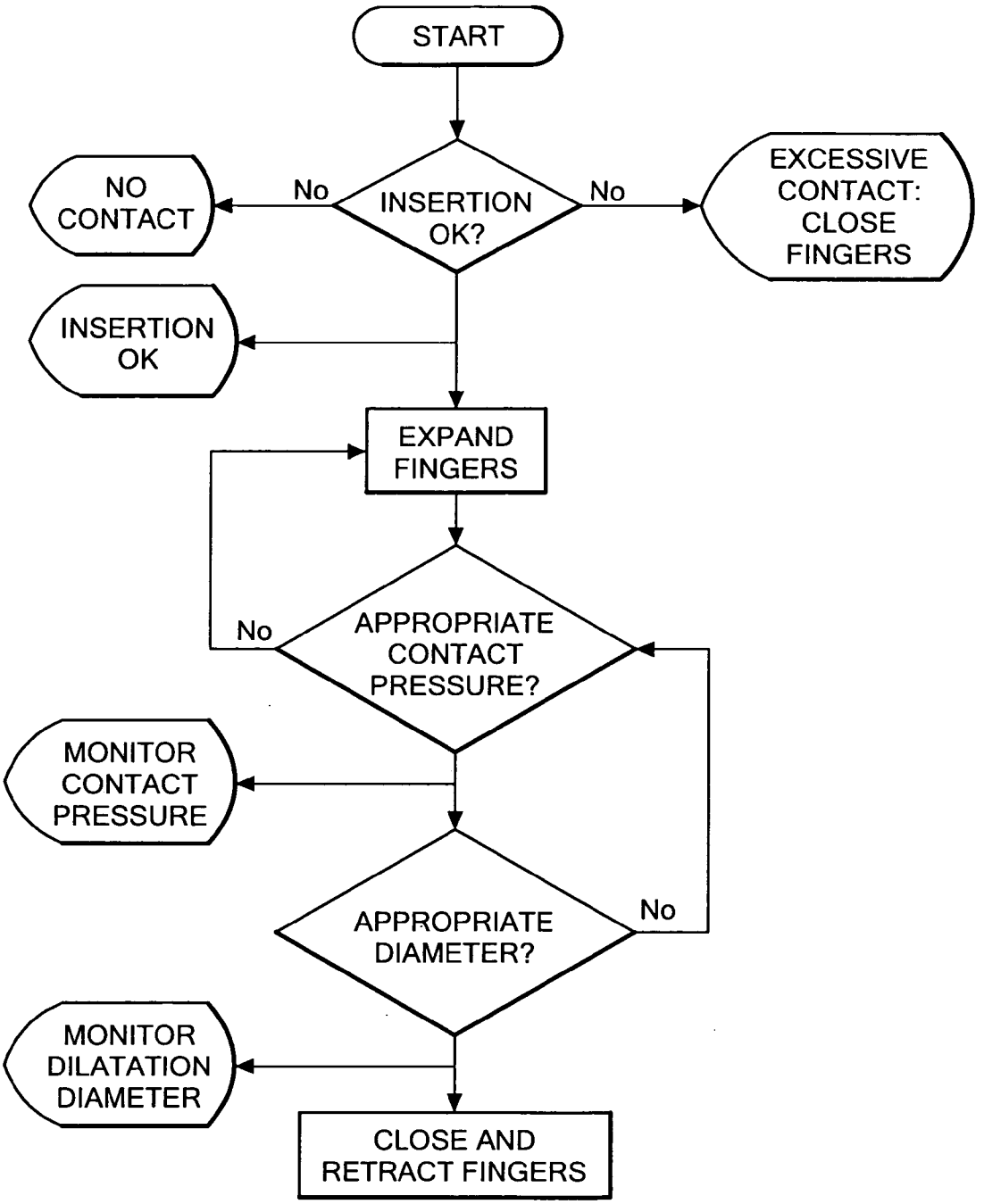
START
INSERTION OK?
No
NO CONTACT
No
EXCESSIVE CONTACT: CLOSE FINGERS
INSERTION OK
EXPAND FINGERS
No
APPROPRIATE CONTACT PRESSURE?
MONITOR CONTACT PRESSURE
APPROPRIATE DIAMETER?
No
MONITOR DILATATION DIAMETER
CLOSE AND RETRACT FINGERS

FIG. 18

CERVIMETRY CONTROL APPARATUS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation-in-part of and claims priority to both pending Utility patent application Ser. No. 11/401,623, filed Apr. 10, 2006, entitled METHOD FOR CERVICAL DILATION AND/OR MEASUREMENT, and pending Utility patent application Ser. No. 11/401,749, filed Apr. 11, 2006, entitled CERVICAL DILATION MEASUREMENT APPARATUS, each of which is a continuation-in-part of and claims priority to pending Utility patent application Ser. No. 11/321,061, filed Dec. 29, 2005, entitled CERVIMETER, the entirety of each of which is incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] n/a

FIELD OF THE INVENTION

[0003] The present invention relates to obstetric devices and more particularly, to a method and apparatus for monitoring and controlling cervical dilation.

BACKGROUND OF THE INVENTION

[0004] During the later stages of pregnancy, the cervix typically undergoes numerous physical changes which provide increased safety and ease with which the fetus can be delivered. Particularly, the cervical canal tissue softens and increases in pliability, and subsequently, the diameter of the cervical canal begins to increase. Eventually, the dilation of the cervix is completed, allowing for the unobstructed passage of the fetus.

[0005] Cervical diameter is monitored throughout labor and is instrumental in diagnosing such conditions as dysfunctional or arrested labor, to determine whether labor augmentation or a cesarean section should be performed, as well as to establish whether or when various pharmaceutical agents should be administered. Physical examination of the cervical diameter is generally performed by inserting two fingers into the vagina and up to the cervix. Upon reaching the cervix, the fingers are spread apart to determine the approximate dilated diameter. While an obstetrician may be fairly experienced in performing a manual cervical diameter measurement, the accuracy of such a measurement can be highly subjective and can further vary depending on the particular experience, judgment, and even finger size of the attending physician. Considering the importance of the cervical dilation measurement in assessing labor progression, it is crucial to provide dilation information that is precise as well as reproducible among different healthcare providers or physicians.

[0006] Given the subjectivity and probability of inaccurate or imprecise dilation measurements, it would be desirable to provide for the precise and accurate attainment of cervical dilation measurements on a repeat basis during the course of labor. In addition, it would be desirable to provide for ease of monitoring and control of cervical dilation to assist a physician throughout labor management.

SUMMARY OF THE INVENTION

[0007] The present invention advantageously provides a method and system for the accurate and precise measuring of cervical dilation during labor, as well as a method and system for performing cervical dilation. The medical device of the present invention may include an elongate body defining a proximal end and a distal end, with the elongate body further including an inflation lumen. An expandable element may be coupled to the elongate body in fluid communication with the inflation lumen, and an array of movable elements may be circumferentially disposed about the elongate body, with the array of movable elements being movably coupled to the elongate body by a plurality of wires. The medical device may also include a measurement mechanism able to determine a radial spacing of the array of movable elements, where the measurement mechanism can include a tension ring coupled to the plurality of wires. In addition, a dilation indicator can be provided in communication with the measurement mechanism, while at least one pressure sensor may be coupled to at least one of the array of movable elements. Moreover, a distal pressure sensor can be coupled to the distal end of the elongate body, with the medical device also providing a control element in communication with the at least one pressure sensor and the distal pressure sensor. The medical device can also include an inflation source in fluid communication with the expandable element, as well as an exhaust valve in fluid communication with the expandable element. Furthermore, the medical device may include a camera as well as a lighting element coupled to the distal end of the elongate body, thereby providing visual feedback to aid in the positioning of the device.

[0008] The control element of the present invention may further provide for monitoring and controlling the operation of the medical device. The control element may be in communication with the one or more sensors disposed on the medical device, as well as being in communication for control and/or monitoring of the additional components of the medical device, such the camera, lighting source, inflation source, or the like. The control element may provide a display or other indication elements for conveying information, such as pressure, size, etc. to a physician during a particular procedure. Moreover, the control element may provide for additional patient safety by having an automatic alarm and/or shut down process in response to measurements and/or conditions that differ from a pre-determined set of parameters.

[0009] In an alternative embodiment, the present invention also provides a cervical dilation sensor to aid in the manual, two-finger approach commonly employed. The cervical dilation sensor may include a first rod, a second rod, and a sensor housing. The first and second rods may be rotatably and pivotably coupled to the sensor housing, as to freely move about the housing in at least two planes of motion. The sensor housing may include one or more sensors coupled to the first and second rods as to measure the relative movement of the two rods, while the cervical dilation sensor may also include a control monitor in communication with the

one or more sensors in the sensor housing for displaying and monitoring information provided by the sensors.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] A more complete understanding of the present invention, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

[0011] FIG. **1** is an illustration of an embodiment of a medical device in accordance with the present invention;

[0012] FIG. **2** is a side view of a distal end of the medical device of FIG. **1**;

[0013] FIG. **3** is a cross-sectional view of a distal end of the medical device of FIG. **1**;

[0014] FIG. **4** is an additional cross-sectional view of the medical device of FIG. **1**;

[0015] FIG. **5** is a cross-sectional view of an embodiment of a dilation indicator in accordance with the present invention;

[0016] FIG. **6** is an illustration of an embodiment of a control element in accordance with the present invention;

[0017] FIG. **7** is an illustration of a distal end of a medical device in a deflated state in accordance with the present invention;

[0018] FIG. **8** is an illustration of a distal end of a medical device in an inflated state in accordance with the present invention;

[0019] FIG. **9** is a flow chart of an embodiment of a method of use of a medical device of the present invention;

[0020] FIG. **10** is a perspective illustration of an embodiment of a cervical dilation sensor in accordance with the present invention;

[0021] FIG. **11** is a side view of the cervical dilation sensor of FIG. **10**;

[0022] FIG. **12** is an additional illustration of the cervical dilation sensor of FIG. **10**;

[0023] FIG. **13** is yet another depiction of the cervical dilation sensor of FIG. **10**.

[0024] FIG. **14** shows an embodiment of a cervical dilation sensor coupled to a hand;

[0025] FIG. **15** depicts an embodiment of a cervical dilation sensor within a glove;

[0026] FIG. **16** illustrates an additional embodiment of a cervical dilation sensor coupled to a hand;

[0027] FIG. **17** shows an embodiment of a calibration element for use with a cervical dilation sensor in accordance with the present invention; and

[0028] FIG. **18** is a flow chart of an embodiment of a method of use of a cervical dilation sensor in accordance with the present invention;

DETAILED DESCRIPTION OF THE INVENTION

[0029] As shown in FIG. **1**, the present invention provides a medical device **10** for measuring and performing cervical dilation. The medical device **10** includes an elongate body **12** defining a proximal end **14** and a distal end **16**. The medical device **10** may further include a dilation indicator **18** coupled to the proximal end **14** of the elongate body **12** that is capable of providing a visual indicator of the dilation measurement made by the medical device **10**, as well as a control element **20** and an inflation source **22**, which will be discussed in more detail below.

[0030] Now referring to FIG. **2**, the medical device **10** may further include an array of movable elements **24** disposed circumferentially about an axis of the elongate body **12**, where the array of movable elements **24** is located in proximity to the distal end **16** of the elongate body **12**. The array of movable elements **24** are movable in a radial direction as to expand and contact with the tissue of the cervix when positioned for measurement of cervical dilation. Moreover, the array of movable elements **24** may be retracted upon completion of the desired measurement to ease the withdrawal of the medical device **10** from the patient. Each movable element may define an upper portion **26** and a lower portion **28**. In addition, each movable element may define a channel **30** such that one or more pressure sensors **32** may be mounted or otherwise positionable within the channel **30** of the movable element. Moreover, an outer cushion **34** may be coupled to an outer surface of each movable element, where the outer cushion **34** may be constructed from a gel-like material or other suitable padding. The array of movable elements **24** may further be movably coupled to the elongate body **12** of the medical device **10** by a plurality of wires **36** coupled to the upper and lower portions of the movable elements **24**, where the plurality of wires **36** further extend through a length of the elongate body **12**.

[0031] While the array of movable elements **24** may be extended and retracted by manipulating the plurality of wires **36**, an actuating mechanism may be provided to facilitate movement of the array of movable elements **24** from a retracted position to an extended position, and vice versa. The actuating mechanism may include a spring mechanism, a telescoping element, or, alternatively, the medical device **10** may include an expandable element **38**, such as a balloon. Now referring to FIG. **3**, the medical device **10** of the present invention may further include the expandable element **38** coupled to or otherwise disposed on the elongate body **12** at or near the distal end **16** of the elongate body **12**. The expandable element **38** may be configured in a myriad of shapes, including a toroidal configuration in which the expandable element **38** defines a ring-like, "O" shape. Moreover, an inflation lumen **40** can be included in fluid communication with the expandable element **38**, where the inflation lumen **40** is disposed within and traverses a substantial length of the elongate body **12**.

[0032] The medical device **10** of the present invention may include additional features providing safety, ease of use, and the like. For example, the medical device **10** may include a protective sheath **42** encasing at least a portion of the distal end **16** of the elongate body **12**. The sheath **42** may include one or more layers of various materials to provide a water-tight seal around the medical device, as well as adding to patient comfort by having additional padding and/or a lubricious coating to ease positioning of the device. For example, a first layer may completely enclose the medical device to ensure the device is not exposed to external fluids or objects. A second layer may be placed over the first layer as a protective layer which is removable by a physician or operator after each use, thereby providing a sterile layer and the possibility for re-use of the medical device. A third layer may be provided over the second layer and include a lubricious property allowing for smooth insertion, operation, and removal of the device.

[0033] Furthermore, a distal pad **44** may be coupled to the elongate body **12** at or near the distal end **16**, where the distal pad **44** may be contoured or shaped to conform to the curvature of the head of a baby. In addition, a distal pressure sensor **46** may be coupled to the distal pad **44** to aid in monitoring the positioning of the medical device **10** and for determining contact with the cervix or with the baby. The distal pad **44** and distal pressure sensor **46** may provide feedback to a physician and aid in the axial positioning of the medical device **10** upon insertion into a patient. Furthermore, a camera **45** and a lighting element **47** may also be coupled to the distal portion of the medical device. The camera **45** may be a miniaturized instrument or pin-hole camera as commonly employed in endoscopic surgical procedures, while the lighting element **47** may include a diode, fiber optic, or other illumination mechanism as is known in the art. The camera **45** and lighting element **47** may provide visual feedback to a physician to further aid in maneuvering and positioning the medical device when in use.

[0034] As shown in FIG. **4**, the elongate body **12** may define a plurality of wire lumens **48** for slidably receiving a portion of each of the plurality of wires **36** coupled to the array of movable elements **24**. Each wire of the plurality of wires **36** may be slidably positioned within each of the plurality of wire lumens **48** as to slide freely with little friction, thereby facilitating the movement of the array of movable elements **24** when the medical device **10** is in use. The wires **36** may have sufficient length as to extend through the entire length of the respective wire lumens **48**, and may further extend out of the proximal end **14** of the elongate body **12**.

[0035] The medical device **10** of the present invention may further include a measurement mechanism for monitoring and/or quantifying the movement of the array of movable elements **24** when the medical device **10** is in use. For example, as shown in the FIG. **5** illustration of a cross-section of the dilation indicator **18**, the medical device **10** may include a tension ring **50** coupled to the plurality of wires **36** such that the tension ring **50** moves as the wires **36** extend and retract in response to the movement of the array of movable elements **24**. The tension ring **50** may further be slidably coupled to the dilation indicator **18**, where the dilation indicator **18** conveys a dilation measurement in response to the relative motion of the tension ring **50**, the plurality of wires **36**, and thus, the array of movable elements **24**. The dilation indicator **18** may include predetermined values calculated from the movement of the tension ring **50** as to eliminate the need for a physician to do any calculating to determine the dilation measurement.

[0036] Again referring to FIG. **1**, in an exemplary system, the proximal end **14** of the medical device **10** of the present invention is coupled to the control element **20**, through which a physician may monitor and/or control the various components of the medical device **10**. The control element **20** may be in communication with any of the numerous sensors provided on the medical device **10**, and may further be in communication with additional components of the medical device **10**, such as the inflation source **22**, the camera **45**, and/or the lighting element **47**. In an exemplary embodiment, the control element **20** may include a console that may be wrist-mounted to ease the overall use of the medical device **10**.

[0037] The control element **20** may include a display, such as an LCD screen or the like, as well as other visual, audio, or tactile indicators to convey information regarding the various operating characteristics and conditions of the medical device **10** to an operator or physician, including dilation measurements, dilation pressure exerted by the medical device, inflation pressure, etc. The control element **20** may further include one or more control actuators, such as push-buttons, switches, a touch-screen, or the like, to enable a physician to provide input to the control element in order to manipulate and/or control a particular component or function of the medical device **10**.

[0038] In addition, the control element **20** may include a processor component and an electronic storage medium (not shown) for storing patient information, measurements and/or procedural information obtained during use of the medical device. The control element **20** may provide calculations and graphical illustrations including, but not limited to, a display of air pressure versus time, air pressure versus diameter, upper and lower limits of expansion pressure, etc. The control element **20** may further contain date/time information for measurements, the physician or nurse performing the procedure, and the like. Moreover, the control element **20** may be able to communicate such recorded information to other devices and/or systems in the hospital environment through the use of portable media and/or wireless technologies as is known in the art.

[0039] In an exemplary embodiment, as shown in FIG. **6**, the control element may include a housing including an visual display **52**, a plurality of LEDs **54**, and a plurality of control actuators **56** (shown as push buttons) which may be in communication with the camera **45**, light **47**, and/or the inflation source **22**, as previously described. In addition, the housing of the control element **20** may be mounted on the wrist of a physician through one or more coupling elements **58**. Moreover, to further ease use, the visual display **52** may be movably coupled to the housing so that a physician may change the viewing angle or orientation of the screen during use of the medical device. A particular use of the control element **20** during a cervical procedure with the medical device is described further below.

[0040] The inflation source **22** of the medical device may be coupled to the inflation lumen **40** at the proximal end **14** of the elongate body **12**, where the inflation source **22** is able to provide a fluid or gas into the inflation lumen **40** for subsequent delivery to the expandable element **38**. Examples of a suitable inflation source **22** may include manual pumps, powered pumps, or the like. The inflation source may be either separate from the control element, as shown in FIG. **1**, or integral with the control element **20** as shown in FIG. **6**. Moreover, an exhaust valve **60** may be in fluid communication with both the inflation source **22** as well as the inflation lumen **40** for subsequent control of the release of fluid from the medical device **10**, and may further be in communication with and/or controlled by the control element **20**.

[0041] Referring now to FIGS. **7** and **8**, in an exemplary use of the medical device **10** of the present invention, a precise dilation measurement may be performed during the various stages of labor. The medical device **10**, in a deflated state, may be positioned such that the distal end **16** of the elongate body **12** is in proximity to the dilated region of the cervix **54**. Proper positioning can be aided by feedback provided by the distal pressure sensor **46** when contacting the cervix or the head **56** of the baby, as well as monitoring the visual feedback from the camera **45**. The sensor feed-

back as well as images obtained by the camera **45** may be displayed on the LCD screen of the control element. Upon proper positioning, the array of movable elements **24** may be extended to contact the tissue of the cervix **54**, for example, by actuating the inflation source **22** to inflate the expandable element **38**. As the expandable element **38** is inflated and subsequently expands, the array of movable elements **24** located around the periphery of the expandable element **38** will move outward in a radial direction, while lengths of the plurality of wires **36** will be drawn further into the respective plurality of wire lumens **48**. As the array of movable elements **24** is coupled to the plurality of wires **36**, which are further coupled to the tension ring **50**, the expandable element **38** will expand outward uniformly from the elongate body **12**.

[0042] The inflation source **22** may continue to inflate the expandable element **38** until the movable elements **24** of the medical device **10** come into contact with the dilated or undilated cervix **54**. Such contact can be indicated and monitored through information provided by the pressure sensors **32** coupled to the movable elements **24**, which, again, may be relayed to a physician or operator through the control element. In particular, the control element may provide a visual indicator of the pressure being exerted on the cervical tissue by the expansion of the medical device as well as the overall dilation measurements of the cervix. Furthermore, the control element **20** may include an algorithm or computational ability to determine if the pressure sensor feedback indicates a substantially uniform circular state. That is to say, that the pressure measurements from each of the pressure sensors **32** disposed about the movable elements **24** are approximately the same. When the desired inflation level or diameter has been attained as indicated by pressure sensor measurements or from the dilation indicator, the inflation source **22** may be deactivated, or, alternatively, the exhaust valve **60** may be triggered to prevent additional fluid from entering the expandable element **38**. Each of these events may be triggered and/or controlled by actuator elements included on the housing of the control element.

[0043] Once appropriately inflated, the measuring mechanism and the dilation indicator **18** can provide the dilation measurement as indicated by the distance the plurality of wires **36**, and thus the tension ring **50**, traveled in reaching the expanded state. As previously stated, the dilation indicator **18** can directly correlate the distance traveled by the wires **36**, and thus, the measured expansion of the movable elements **24**, to an accurate and precise dilation measurement.

[0044] Upon completion of the desired measurement, the movable elements **24** are retracted towards the elongate body **12**, i.e., by deflating the expandable element **38** by opening the exhaust valve **60**, upon which the movable elements **24** will retract to a closed position for the removal of the medical device **10** from the patient. Both the tension ring **50** and the plurality of wires **36** may be biased towards a closed, retracted position, such that when the expandable element **38** is not under positive inflation pressure, the medical device **10** retains a closed, retracted state. Furthermore, as described above, the medical device **10** may include an outer sheath **42** which, if used, may be removed and replaced for subsequent uses of the medical device **10**, thereby providing a re-usable device while maintaining the sterility of the medical environment.

[0045] Referring to FIG. **8**, in an alternative use of the medical device **10** of the present invention, the distal portion of the medical device **10** may be employed to produce a safe and uniform cervical dilation where a desired dilated condition has not yet occurred or otherwise been achieved. The medical device **10** may be positioned proximate to a region of an undilated cervix and the array of movable elements **24** of the medical device **10** may be expanded to contact the cervical tissue **54**. Similar to obtaining a dilation measurement as described above, the distal pad, pressure sensors or camera may provide feedback to a physician or operator to aid in the axial positioning of the device. Through monitoring information from any of the aforementioned components, through the control element for instance, the medical device may traverse the length of the cervix while reducing the likelihood of accidentally perforating the uterus, which may occur with the use of conventional devices.

[0046] Upon initiating the desired contact, the array of movable elements **24** may then be extended further, for example, through a controlled inflation of the expandable element **38**, in order to provide a desired rate of expansion, and thus, dilation. Alternatively, the array of movable elements may be actuated to extend outward through pressure or force applied through the plurality of wires **36**, or by other actuating mechanisms as known in the art. At any point during the dilation procedure, information may be provided regarding the amount of force being applied to the cervical tissue via the one or more pressure sensors **32** coupled to the array of movable elements **24**, as well as the radial spacing of the array of movable elements. As such, through the monitoring of sensor feedback information, the dilating force applied to the array of movable elements either through the plurality of wires **36** or by the expandable element **38** may be appropriately adjusted in order to achieve the desired dilation without unnecessarily damaging the cervical tissue. Additionally, the spacing of the array may be monitored to achieve a desired dilated state. Through the monitoring and manipulation of the operating characteristics of the medical device, including the rate of extension of the array, the pressure between the medical device and the tissue, and/or the distance traveled and thus the radial spacing of the array, a precise and accurate dilation may be induced.

[0047] The above-described dilation may be performed for obstetrical uses, for example, in cervical "ripening" to assist in the induction of labor in cases of poorly dilated or effaced cervices. In addition, pre-operative dilation may be performed using the medical device of the present invention in cases of uterine curettage for failed pregnancy, miscarriage, or retained products of conception. Moreover, the medical device may be used for gynecological purposes of cervical dilation in cases of curettage of the endocervix or endometrium, elective termination of pregnancy, diagnostic and operative hysteroscopy, thermal endometrial ablation techniques, as well as treatment of cervical stenosis.

[0048] While it has been discussed that the control element may provide a variety of information from the numerous sensors and other components to a physician or operator during the above-mentioned procedures, the control element may further provide for enhanced safety during use by including pre-determined circumstances and/or threshold values for safe operation, irrespective of whether the aim is to take measurements or to cause dilation. Now referring to FIG. **9**, for example, the medical device may be positioned

initially in the cervix, while values obtained from the distal pressure sensor are monitored. Should a particular pressure be experienced that exceeds a pre-determined safe operating pressure that could damage the baby or surrounding tissue, the control element **20** may provide an audio, visual, or tactile alarm to the operator to withdraw the device. Upon proper positioning, the inflation source **22** may be actuated. Should a pressure in the inflation lumen, RPM, or other indicator of the operation of the inflation source **22** differ from expected values, the control element **20** may again cause an alarm and/or automatically terminate operation of the inflation source **22**. Similarly, during use of the medical device **10**, if the pressure being exerted on the cervical tissue during expansion is greater than desired, or should the diameter of the expanded portion of the medical device appear out of the desired range, the control element **20** may convey these circumstances through visual, audio or tactile indicators and/or initiate a shut-down sequence of events, which may include deflation, retracting the array or movable elements, etc.

[0049] Now referring to FIGS. **10-13**, in an alternative embodiment of the present invention, a cervical dilation measurement device **100** is provided to aid in the manual, two-finger approach of measuring cervical dilation. The measurement device **100** may include a first extension element **102**, a second extension element **104**, and a base element **106**. The first and second extension elements **102**, **104** may be rotatably and pivotably coupled to the base element **106**, as to freely move about the housing in at least two planes of motion. The base element **106** may include a dilation indication mechanism to measure the distance between and/or the relative movement of the two extension elements. The dilation indication mechanism may include one or more sensors coupled to or otherwise in communication with the first and second extension elements **102**,**104**. Sensors suitable for monitoring the movement of the first and second extension elements **102**,**104** may include sensors mechanically coupled to the extension elements capable of measuring their displacement or movement directly, including but not limited to torque or strain gauges, or may alternatively include sensors positioned in the tips of the first and second extension elements that can monitor distance between the two tips via radiofrequency, optical energy, or the like. A third sensor may be incorporated, in the base element **106** for example, to provide increased accuracy and precision through triangulation methods. The measurement device **100** may also include the control element **20**, as previously described and illustrated in FIG. **1**, in communication with the base element **106** and one or more sensors for displaying and monitoring information provided by the sensors.

[0050] Now referring to FIGS. **14-16**, the measurement device **100** of the present invention may also include one or more lateral sensors **108**,**108'** positionable about the sides of the first and second fingers used in the manual cervical dilation measurement technique. The lateral sensors **108**, **108'** may provide pressure feedback information when in contact with the cervix that may assist a physician in making a measurement while avoiding or minimizing cervical distension. As such, the reduced likelihood of cervical distension increases the ability to provide an accurate and precise dilation measurement. The lateral sensors **108**,**108'** may include one or more thin film pressure sensors, as known in the art, to minimize the increase in width or thickness of the device, thereby providing ease of use and reducing discomfort of the patient, and may further be placed in communication with the control element **20**.

[0051] The measurement device **100** of the present invention may also include one or more finger-tip pressure sensors **110**,**110'** positionable about the tips of the first and second fingers used in the manual cervical dilation measurement technique. The finger-tip pressure sensors **110**,**110'** may indicate pressure feedback information via the control element **20** upon contact with the head of the baby. In addition to providing feedback information to prevent excess pressure on the head of the baby, upon recognition that the finger tips are indeed contacting the head of the baby, a marker or other measurement indicator may be used to gauge the position and descent of the baby, as described below.

[0052] Historically, practitioners have used the ischial spine as the index point (0 station) for a determination of fetal descent, and assigned an arbitrary number in centimeters above and below the ischial spine. More specifically, "station" refers to the level of the presenting fetal part in the birth canal as described in relationship to the ischial spines, which are halfway between the pelvic inlet and the pelvic outlet. When the lowermost portion of the fetal presenting part is at the level of the ischial spine, it is designated as being at zero (0) station. In the past, the long axis of the birth canal has been arbitrarily divided into segments for a determination of the position of the baby. Thus, as the presenting fetal part descends from the inlet toward the pelvic outlet, the typical designation is −5, −4, −3, −2, −1, 0 station, +1, +2, +3, +4, +5. Using this method, the degree of accuracy (in centimeters) is difficult to achieve clinically. In practice, physicians may generally make an educated guess about the station of the presenting part of the baby, since after the "0" point (0 station), the baby's head covers the ischial spine point and eliminates the ability to measure and reproduce distance caudal to this point. Contrary to the typical method employed, where accuracy and precision may be difficult to maintain, the feedback from the finger-tip sensors may provide an indication of contact with the head of the baby. Upon such indication, a marking or other descent indicator **112** on the portion of the hand of the physician external to the genitalia may be used to provide an accurate and precise measurement of the location and descent of the baby. Measurements over the course of labor indicate rates of progression which are practical, relatively easier to standardize and explainable to the patient or other practitioners. This approach of measurement is termed "Advancement".

[0053] In an exemplary use, the measurement device **100** is coupled to the hand of a physician, with the first extension element **102** being paired to a first finger, the second extension element **104** being paired to a second finger, and the base element **106** being positioned in between the first and second fingers. Moreover, where the lateral sensors **108**,**108'** or finger-tip sensors **110**,**110'** are included, the sensors will be positioned about the sides and tips of the fingers, respectively, as described above. The coupling may be achieved through the integration of the measurement device **100** with a glove **114**, or through direct adhesion of the various components to the fingers themselves. Additionally, the cervical dilation measurement device **100** may include two cap elements **116**,**116'** positionable about the finger tips, with the first and second extension elements **102**,**104** extending from the cap elements **116**,**116'** and

towards the base element **106**, and with the lateral and finger-tip sensors coupled to the cap elements in the appropriate positions. Any wires or other communicative elements connecting the sensors to the control element **20** may be routed through the glove or positioned down the back of the hand as needed to provide connectivity while preventing interference with the use of the device. Alternatively, the various sensors may communicate with the control element **20** wirelessly as known in the art.

[0054] Subsequently, the physician may position the first and second fingers and the cervical dilation measurement device **100** in proximity to the cervix. Upon reaching the desired location, the two fingers can be spread either into a "V" shape or an "L" shape, and the relative movement of the first and second extension elements **102**,**104** may be measured by the one or more sensors in the base element **106**, with the lateral sensors **108**,**108'** preventing cervical distension as previously described. As a result, the physician will not be required to make a subjective observation as to the actual cervical dilation, as the actual width between the spread fingers can be accurately assessed by the cervical dilation measurement device **100** and provided to the physician through the control element **20**. In addition, upon contacting the head of the baby with the finger-tip sensors, the descent indicator **112** may be referenced to determine the location of the baby.

[0055] While the method of measurement as described above may provide an accurate and precise measurement of cervical dilation, it is realized that different physicians may have variations in both finger length and thickness which may affect the accuracy of the measured dilation. Now referring to FIG. **17**, the present invention may include a calibration element **120** for use with the measurement device **100** to compensate for the variations in the finger dimensions of a physician. The calibration element **120** may include an object of known dimensions, thereby providing a reference value from which the measurement device **100** may be calibrated. For example, the measurement device **100** may be coupled or otherwise positioned about the hand of a physician or operator, with the first extension element **102** being paired to a first finger, the second extension element **104** being paired to a second finger, and the base element **106** being positioned in between the two fingers. Subsequently, the first and second fingers may be extended such that an outer portion of the first and second fingers contact a portion of the calibration element **120**, providing a "simulated" distance measurement. Upon contacting the calibration element **120**, the first and second fingers will be separated by a known distance, and the relative movement of the first and second extension elements **102**,**104** about the base element **106** can be appropriately modified to reflect an accurate and precise measurement. Such modification may include, for example, an algorithm or other computational calculation taking into account the known, fixed dimensions of the calibration element **120**, the known length of the first and second extension elements **102**,**104**, as well as the angle formed between them at the intersection with the base element **106**. The suggested calibration procedure may be performed a single time for each operator who may thereafter use the measurement device **100**, and such values and calibration modifications may be stored in the control element **20** for ease of subsequent use without the need to re-calibrate the device. Alternatively, the suggested calibration procedure may be performed prior to each dilation measurement to ensure accuracy and precision.

[0056] As discussed above, the control element **20** may be coupled to the measurement device **100** similarly to that of the medical device **10** in order to provide a variety of information from the numerous sensors and other components of the measurement device **100** to a physician or operator during the above-mentioned procedures. Once again, the control element **20** may further provide for enhanced safety during use by including pre-determined circumstances and/or threshold values for safe operation, irrespective of whether the aim is to take measurements or to cause dilation. Now referring to FIG. **18**, for example, the measurement device **100** may be initially positioned in the cervix, while values obtained from the finger-tip sensors **110**, **110'** are monitored. Should a particular pressure be experienced that exceeds a pre-determined safe operating pressure that could damage the baby or surrounding tissue, the control element **20** may provide an audio, visual, or tactile alarm to the operator to withdraw the device. Upon proper positioning, the operator or physician may expand their fingers. Subsequently, during use of the measurement device **100**, if the pressure being exerted on the cervical tissue during expansion is greater than desired as indicated or otherwise measured by lateral sensors **108**, **108'**, or should the diameter of the expanded fingers as measured by the measurement device **100** appear out of the desired range, the control element **20** may convey these circumstances through visual, audio or tactile indicators, upon which the physician or operator may close and retract their fingers and the accompanying measurement device **100**.

[0057] It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope and spirit of the invention, which is limited only by the following claims.

What is claimed is:

1. A cervimetry device for measuring cervical dilation, comprising:

an expandable element;

an inflation source in communication with the expandable element; and

a control element for controlling the inflation source and indicating a cervical dilation measurement.

2. The cervimetry device according to claim **1**, further comprising an array of movable elements disposed circumferentially about the expandable element.

3. The cervimetry device according to claim **2**, further comprising at least one pressure sensor coupled to at least one of the movable elements, the pressure sensor being in communication with the control element.

4. The cervimetry device according to claim **1**, further comprising an exhaust valve in fluid communication with the expandable element, wherein the exhaust valve is also in communication with the control element.

5. The cervimetry device according to claim **1**, wherein the control element includes a display.

6. The cervimetry device according to claim **1**, wherein the control element includes a control actuator for receiving input from a user.

7. The cervimetry device according to claim 1, wherein the control element includes an electronic storage medium.

8. The cervimetry device according to claim 1, further comprising an elongate body defining a proximal end and a distal end, wherein the expandable element is movably coupled to the distal end of the elongate body, and the control element is coupled to the proximal end of the elongate body.

9. The cervimetry device according to claim 8, further comprising a distal pad coupled to the distal end of the elongate body.

10. The cervimetry device according to claim 9, further comprising a distal pressure sensor coupled to the distal pad, wherein the distal pressure sensor is in communication with the control element.

11. The cervimetry device according to claim 8, further comprising a camera coupled to the distal end of the elongate body, wherein the camera is in communication with the control element.

12. The cervimetry device according to claim 8, further comprising a lighting element coupled to the distal end of the elongate body, wherein the lighting element is in communication with the control element.

13. A cervimetry device for measuring cervical dilation, comprising:

an expandable element;

an array of movable elements disposed about the expandable element;

an inflation source in communication with the expandable element;

at least one pressure sensor coupled to at least one of the array of movable elements; and

a control element for controlling the inflation source and indicating a cervical dilation measurement, wherein the control element is in communication with the at least one pressure sensor.

14. A method for performing a cervical procedure, comprising the steps of:

providing a cervimetry device including an expandable element, an inflation source in communication with the expandable element, and a control element for controlling the inflation source and indicating a cervical dilation measurement;

positioning the cervimetry device proximate to a cervical tissue region;

operating the inflation source to expand the expandable element and contact the cervical tissue region;

measuring a contact pressure between at least a portion of the cervimetry device and the cervical tissue region; and

terminating operation of the inflation source in response to the measured pressure level.

15. The method according to claim 14, wherein the cervimetry device further includes an exhaust vale in fluid communication with the expandable element, and further comprising the step of actuating the exhaust valve in response to the measured pressure level.

16. The method according to claim 14, wherein the cervimetry device further includes an array of movable elements disposed about the expandable element.

17. A method for performing a cervical procedure, comprising the steps of:

providing a cervimetry device including an expandable element, an inflation source in communication with the expandable element, and a control element for controlling the inflation source and indicating a cervical dilation measurement;

positioning the cervimetry device proximate to a cervical tissue region;

operating the inflation source to expand the expandable element;

measuring a dimension of the expandable element; and

terminating operation of the inflation source in response to the measured dimension.

18. The method according to claim 17, wherein the cervimetry device further includes an exhaust vale in fluid communication with the expandable element, and further comprising the step of actuating the exhaust valve in response to the measured pressure level.

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