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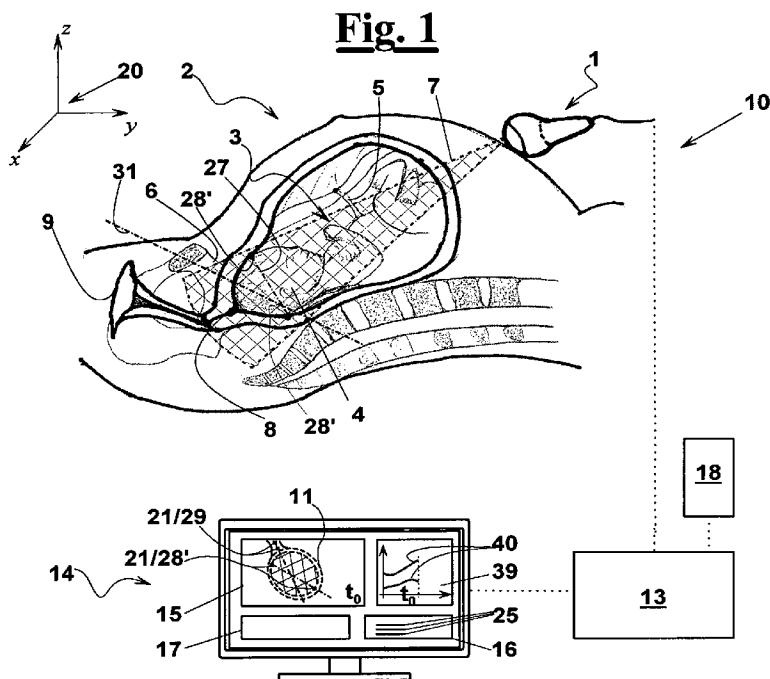
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(54) Title: ULTRASONIC APPARATUS FOR MEASURING A LABOR PROGRESS PARAMETER



(57) Abstract: An apparatus (10) for measuring one or more labor progress parameters (25) as the dilation and the position of the head (8), the rotation and the position of the head (4) of the foetus (3) during the descent, the duration and the intensity of the uterine contractions, other morphological and physiological parameters, without introducing foreign objects into the body of a pregnant woman (2) and independently from the sensitivity of the operator. The apparatus (10) comprises automatic means for tracking, in a sequence of ultrasound images (11,12) that are obtained by an ultrasound probe (1), one or more regions of interest (ROI, 21), that may be both two-dimensional or three-dimensional and are centred about anatomic reference points (28) that define said parameters selected in a reference image by a displaying unit (14). The tracking means comprises: a) a means for calculating a function (f) at the pixels of the ROI of the reference image and of images preferably sampled among the images of the sequence, b) a means for calculating iteratively at the positions of the ROI in subsequent images, by a means of comparison between the values of the function (f) calculated in the pixels of the ROI of a current image and the values of the function (f) calculated in the pixels of the ROI of a subsequent ultrasound image; c) a means for comparing each position of the ROI with the position of the ROI in the reference image and for calculating the labor progress parameter responsive to said comparison. The new position of the region of interest may be defined as a domain in which a predetermined object function assumes a minimum value.

tween the values of the function (f) calculated in the pixels of the ROI of a current image and the values of the function (f) calculated in the pixels of the ROI of a subsequent ultrasound image; c) a means for comparing each position of the ROI with the position of the ROI in the reference image and for calculating the labor progress parameter responsive to said comparison. The new position of the region of interest may be defined as a domain in which a predetermined object function assumes a minimum value.



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TITLE

ULTRASONIC APPARATUS FOR MEASURING
A LABOR PROGRESS PARAMETER

DESCRIPTION

5 Field of the invention

The present invention relates to an ultrasound-based apparatus for monitoring one or more morphological and physiological parameters that are related to the progress of a childbirth.

Background of the invention

10 A need is particularly felt of a method and an equipment that allow to monitor the conditions of a pregnant woman and her foetus before entering the childbirth room, and during the childbirth itself, in particular in childbirth stage 2 but even in stage 1 and 3. In particular, it is important to monitor such morphological and physiological parameters as uterine contractions intensity,
15 frequency and duration, foetal cardiac frequency, endocervical canal dilation, endocervical canal length, foetal head station, in particular the distance of the foetal head from an anatomical reference, such as a parturient's bone, pubis, and the like, as well as the foetal head rotation, umbilical cord unwinding, and the evolution of all these parameters.

20 Various techniques are known for evaluating the imminence of the childbirth, and monitoring the childbirth progress. These methods provide the introduction of an operator's finger and/or such objects as sensors and/or instruments into the vagina, to reach the uterine cervix or the head of the foetus. These invasive techniques may also lead to infections and/or lesions of
25 the parturient and/or the foetus.

Furthermore, in most cases the accuracy of the data that can be obtained depend upon the operator's sensitivity, therefore objectivity and precision of the measurement cannot be guaranteed. To cope with this problem, ultrasound devices have been developed such as the Barnev's cervicometer, described in
30 Sharf et al., "Continuous monitoring cervical dilation and foetal head station

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during labor" (Med. Eng. Phys. 2007; 29:61-71). Barnev's cervicometer comprises three ultrasound transmitters to be located on the abdomen of the pregnant woman, and a plurality of receivers to be located, typically, on the foetal head and at the edges of the cervical os. The analysis of the response
5 time of the waves, and a subsequent triangulation of the distance obtained this way, allow to univocally evaluate the endocervical canal dilation and the foetus position. However, this device is still an invasive one, as well as the devices and the methods described in Sharf et al., "Continuous monitoring cervical dilation and foetal reaction during labor" Medical Engineering & Physics 29
10 (2007) 61-71, in "Novel technologies for minimally invasive therapies", Lupensis Biomedical Publications, as well as in WO199849942, WO2008084486 and WO2005015499. Apart from the nuisance they can cause to the pregnant woman, these techniques can only be employed if the pregnant woman keeps a lying-down position.

15 Furthermore, the operator must hold the ultrasound probe and continually adjust its position on the woman's abdomen.

Moreover, only a limited number of parameters can be displayed and monitored at the same time, normally no more than two, by means of known equipment.

20 Summary of the invention

It is therefore an object of the invention to provide an apparatus for measuring morphological parameters that allow monitoring the progress of a labor, such as, in particular, the endocervical canal dilation of a parturient, the position of the foetus before and during the descent through the endocervical
25 canal, as well as physiological parameters of the parturient and of the foetus, without requiring the introduction of any foreign matter into the pregnant woman's body.

It is, furthermore, an object of the invention to provide an apparatus for real-time monitoring such parameters, by qualitatively and/or quantitatively
30 displaying them on a user interface.

It is another object of the invention to provide an apparatus that allows automatic measurement of such parameters.

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It is still an object of the invention to provide an apparatus that allows objectively measuring such parameters, i.e. independently from the sensitivity and the skills of the operator.

It is a particular object of the invention to provide such an apparatus for
5 monitoring at the same time a number of morphological and physiological parameters as desired by the operator.

It is a further particular object of the invention to provide such an apparatus that allows the parturient to assume any desired position during the childbirth, for example a standing or a sitting position, as well as a lying-down
10 position.

These and other objects are achieved through an apparatus for measuring a labor progress parameter during childbirth by ultrasound images obtained by ultrasonic pulses, the apparatus comprising:

- an ultrasound probe;
- 15 - a fastening means for fastening the ultrasound probe onto a parturient's body so that the probe has a visual field that includes a portion of the parturient's body and of a foetus, in particular the parturient's endocervical canal and/or the pubis;
- a control unit for receiving and analysing signals from the ultrasound
20 probe, said control unit creating or receiving as input by said probe a reference ultrasound image and a plurality of subsequent ultrasound images, which are taken in succession after the reference ultrasound image;
- a user interface for selecting a region of interest in the reference
25 ultrasound image by an operator, the user interface adapted to select the region of interest substantially centred about the portion of the parturient's body, the region of interest comprising a plurality of pixels.

The main feature of the apparatus is that the control unit comprises:

- an automatic tracking means for tracking the region of interest, said
30 automatic tracking means adapted to identify respective derived regions of interest in selected images of the plurality of subsequent ultrasound images, the derived regions of interest deriving from the region of interest that is selected in the reference ultrasound image, the tracking means comprising:
 - a means for calculating a predetermined local pixel function for each

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pixel or group of pixels of the region of interest in the reference ultrasound image and in each selected image of the plurality of subsequent ultrasound images,

– a means for iteratively calculating, starting from the reference ultrasound image, the position of the derived region of interest in each selected image, the means for iteratively calculating adapted to perform comparisons between:

– values of the local pixel function calculated at the pixels of the region of interest of an image of the selected images;

– values of the local pixel function calculated at pixels of the region of interest of a subsequent ultrasound image;

– a means for comparing each position of the derived regions of interest with the position of the region of interest in the reference ultrasound image or of In another image and for calculating a labor progress parameter, in particular of a previous image.

The automatic tracking means allow to track, substantially in real time and with a predetermined level of accuracy, before and during the childbirth, one or more morphological and physiological labor parameters that are related with the progress of the childbirth, and that allow evaluating the correct evolution of the childbirth itself, without inserting in the parturient's body foreign objects, such as intrusive instruments and sensors.

Furthermore, the device is adapted to integrate existing ultrasound instruments.

Advantageously, the control unit is adapted to select a further region of interest that is substantially centred about the portion of the parturient's body, the labor progress parameter during childbirth defined by a combination of the region of interest and of the further region of interest. This way, the parameter is totally defined without any reference to reference points external to the parturient's body or the foetus, and the tracking of the regions of interest is more reliable, in particular it is independent from movements of the parturient. The same do not apply to the case of one anatomic reference point only, even if the position of the probe with respect to an absolute coordinate system is known to the control unit. In this case, a point of the probe itself provides the

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second reference, which is needed to define together with the anatomic point a distance parameter or a line which defines an angle parameter.

Advantageously, the user interface is adapted to provide to the operator an option of selecting a further reference image among one of the subsequent
5 ultrasound images, such that a first and a second tracking on two pluralities of pixels are carried out contemporaneously, the means for iteratively calculating adapted to perform the steps of:

– comparing values of the local pixel function calculated at pixels of the region of interest of the reference ultrasound image, and values of the local
10 pixel function calculated at pixels of the region of interest of a subsequent ultrasound image, such that a first position of the derived region of interest is identified;

– comparing between values of the local pixel function calculated at pixels of the further reference image, and values of the local pixel function calculated
15 at pixels of the region of interest of a subsequent ultrasound image, such that a second position of the derived region of interest is identified;

– identifying a further derived region of interest through a comparison between the trackings of the first and the second positions of the derived region of interest according to a prefixed criterion.

20 This way, with the first tracking it is possible to take into maximum account any possible change of the tissues during the childbirth, whereas with the second tracking it is possible to eliminate artifacts that may affect the calculation of the derived region of interest.

Advantageously, the user interface is adapted to provide to said operator
25 an option of selecting the criterion for carrying out the comparison between the first and the second tracking.

Preferably, such criterion is selected from the group comprised of:

- the position that is identified by the lowest object function value;
- the position that is closer to a predetermined set of values;
- 30 – the position that is farther from a predetermined set of values;
- an average position between the first and the second position.

In particular, the portions of the mother's body and of the child that are included in the visual field of the probe are those portions that markedly

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change their configuration and their position during the childbirth, in particular the edges of the external os and the head of the foetus; furthermore, portions of the foetus may be included in the visual field, for example the shoulders, which provide an absolute reference for evaluating the rotation of the head.

5 The regions of interest may be used for automatically tracking one of the moving portions in the images that follows the reference image, in terms of position with respect to portions of the woman's body that remains substantially fixed during the childbirth, for example the head of the foetus with respect to the pelvis.

10 Preferably, the apparatus comprises a means for measuring a position parameter of the ultrasound probe with respect to a coordinate system external to the parturient, and the control unit has a means for receiving the position parameter and a means for summing said position parameter and the position of said derived region of interest with respect to said probe, such that said
15 means for comparing performs a comparison between the actual position of said regions of interest taking into account said coordinate system external to said parturient .

This way, an alignment is possible between the position of the region of interest in the reference image, and of the corresponding regions of interest on
20 the subsequent images, and an univocal coordinate system, external to the woman's body, in particular a fixed coordinate system, in order to take into account the movements of the woman during the childbirth, more precisely during the time since the reference image is taken until the subsequent images are elaborated.

25 In particular the user interface is adapted to define as input a plurality of regions of interest selected by an operator on the reference image.

In particular, each region of interest defines a same labor progress parameter.

30 The labor progress parameter defined by the selected region of interest may be the dilation of the parturient's endocervical canal, which may be associated to a distance between two regions of interest selected on the edge of the endocervical canal.

The labor progress parameter defined by the selected region of interest

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may be the position of the head of the foetus during the descent along the outlet path through the endocervical canal, i.e. the "foetal head station"; the position may be associated with a region of interest that is selected on a fixed portion of the parturient's body and with a region of interest that is selected on the head of the foetus. In particular, the fixed portion of the parturient's body may be the pubis.

The labor progress parameter defined by the region of interest may be the rotation of the head of the foetus, i.e. the "foetal head position"; the rotation is then associated with an angle that is formed by a line that is defined by two regions of interest that are centred on a fixed portion of the parturient's body and by a line that is defined by two regions of interest integral to the foetus.

This way, the system allows reading all the physiological parameters of the foetus and of the parturient during the childbirth, in particular vital parameters by which the safety conditions for the foetus and the parturient can be monitored.

Reliable measures of this angle may be obtained by having as a reference the only the line that is defined by two regions of interest of the foetus.

In particular, the length of the endocervical canal is evaluated by measuring the dilation of an upper part and the dilation of a lower part of the endocervical canal, a computing means calculating the length by comparing the dilation of the upper part and of the dilation of the lower part.

In particular the ultrasound reference image and/or the subsequent ultrasound images are images of any cross sectional plane of the visual field selected by the operator.

Preferably, the region of interest is a region of a three-dimensional space.

In particular, the region of interest is a three-dimensional region that is directly obtained through a 3D real time or native matricial acquisition.

In alternative, the region of interest may be obtained as an union of regions of interest of a plurality of ultrasound images of plane sections of the visual field, wherein the plurality of reference images are obtained by rotating the visual field about an axis that is common to the plane sections.

The technique of reconstructing three-dimensional images starting from

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two-dimensional images reduces the calculations that are needed to obtain the reference three-dimensional image, with respect to the case of a direct acquisition of a volumetric image, i.e. a 3D-image.

Advantageously, the means for iteratively calculating positions of the region of interest comprises:

- a means for calculating the local pixel function in a plurality of domains of the subsequent ultrasound images;
- a means for calculating a predetermined object function in each of the domains, the object function associating to each domain a deviation value between the local pixel function as calculated in the domain and the local pixel function as calculated in the region of interest;
- a means for determining a domain of a subsequent ultrasound image in which the object function has a minimum value.

Preferably, the object function is the sum of the square of the differences between a value of the local pixel function as calculated at each pixel of the region of interest of an ultrasound image, and the value of the local pixel function as calculated at each corresponding pixel in a domain of a subsequent ultrasound image, which may not immediately follow the reference image.

Advantageously, the images of the plurality of subsequent images in which the derived region is identified are selected by sampling at a predetermined frequency.

Preferably, the position of the head of the foetus is associated with a further region of interest that is selected on a fixed portion of the parturient's body and/or with a further region of interest that is selected at the head of the foetus.

For example, the local pixel function is a function that associates to a number each pixel of the region of interest and of the domains. In particular, the number that is associated by the local pixel function to a pixel may be related to a grey tonality of a grey scale. In alternative, such number may be a value that is deduced by a radiofrequency spectral analysis of an ultrasound image. In alternative, but not exclusively, such number may deduced by an analytic technique that is different from radiofrequency spectral analysis.

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5 Preferably, the user interface provides a means for signalling an anomalous value of a labor progress parameter or of a foetus physiological parameter with respect to a predetermined range, or an anomalous combination of a plurality of labor progress parameters and/or of physiological parameters.

Such anomalous values may represent a condition that is dangerous for the foetus and/or for the mother, with consequent risks for the onset of critical and potentially harmful configurations.

10 Preferably, the apparatus comprises a means for storing values of the labor progress parameters, in particular the anomalous value and the anomalous combination of values. This way, an off-line consultation of the childbirth history is possible, which is useful in case of doubts concerning the correct application of a safety procedure or of a good childbirth practice by a medical team, in particular, in case of unexpected complications that may have
15 occurred during the childbirth. In some cases, for instance, the uterine contractions are not followed by cervix dilation, which causes foetal suffering; this is normally overcome by Caesarean section. The apparatus according to the invention enables the medical team to evaluate on an objective basis whether a Caesarean section is necessary, and to support by documentary
20 evidence the need of such a practice.

An anomalous parameter value may also be generated that is far away from a physically acceptable range of parameter values, which requires checking equipment reliability, and/or resetting the means for calculating and/or starting again the calculations.

25 Advantageously, the apparatus comprises a means for displaying the parameter on the ultrasound images. A simplified image of the portions of the parturient 's genital and reproductive system, as well as of the foetus, may be useful for evaluating the progression stage and the correct evolution of the childbirth. The numeric values of monitored parameters and/or of physiological
30 data and/or of other useful parameters or images of various types measured with compatible devices may usefully accompany the ultrasound images on a same user interface or on a separate interface.

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The aforementioned objects are still achieved through an ultrasound-based method for measuring a labor progress parameter, the method providing the steps of:

- 5 – fastening an ultrasound probe onto the body of a parturient so that the probe has a visual field that includes a portion of the parturient's body and of a foetus, in particular the parturient 's endocervical canal and/or the pubis;
- providing a control unit for receiving and analysing signals from the ultrasound probe, creating or receiving as input by said probe a reference ultrasound image and a plurality of subsequent ultrasound images, which are
10 taken in succession after the reference ultrasound image;
- selecting through a user interface at least one region of interest in the reference ultrasound image, the region of interest substantially centred about the portion of the parturient's body, the region of interest comprising a plurality of pixels;
- 15 – automatic tracking the region of interest and identifying respective derived regions of interest in selected images of the plurality of subsequent ultrasound images, the derived regions of interests corresponding to the region of interest that is selected in the reference ultrasound image, the tracking step comprising in turn the steps of:
 - 20 – calculating a predetermined local pixel function for each pixel or group of pixels of the region of interest of the reference ultrasound image and in each selected image of the plurality of subsequent ultrasound images,
 - iteratively calculating, starting from the reference ultrasound image,
25 the position of the derived region of interest in each selected image, and carrying out a comparison between:
 - values of the local pixel function calculated at the pixels of the region of interest of an image of the selected images;
 - values of the local pixel function calculated at pixel of the
30 region of interest of a subsequent ultrasound image;
 - comparing each position of the derived region of interest with the position of the region of interest in the reference ultrasound image and calculating a labor progress parameter, in particular of a previous image.

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Advantageously, a step is provided of selecting at least a further region of interest that is substantially centred about said portion of the parturient's body, the labor progress parameter during childbirth defined by a combination of the region of interest and of the further region of interest.

5 Advantageously, a step is provided of selecting by the operator a further reference image among one of the subsequent ultrasound images, such that a first and a second tracking on two pluralities of pixels are carried out contemporaneously; in this case, further steps are provided of:

- 10 – comparing values of the local pixel function calculated at pixels of the region of interest of the reference ultrasound image, and values of the local pixel function calculated at pixels of the region of interest of a subsequent ultrasound image, such that a first position of the derived region of interest is identified;
- 15 – comparing between values of the local pixel function calculated at pixels of the further reference image, and values of the local pixel function calculated at pixels of the region of interest of a subsequent ultrasound image, such that a second position of the derived region of interest is identified;
- 20 – identifying a further derived region of interest through a comparison between the trackings of the first and the second positions of the derived region of interest according to a prefixed criterion.

Advantageously, a step is provided of selecting the above-mentioned criterion, which is selected, in particular, from the group comprised of:

- 25 – an average position between the first and the second position;
- the position that is identified by the lowest object function value;
- the position that is closer to a predetermined set of values;
- the position that is farther from a predetermined set of values.

Preferably, further steps are provided of:

- 30 – measuring a position parameter of the ultrasound probe with respect to a coordinate system external to the parturient,
- summing the position parameter and the position of the derived region of interest with respect to the probe, such that the means for comparing performs a comparison between the actual position of the regions of interest taking into account the coordinate system external to the parturient.

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In particular, the step of receiving and analysing signals provides:

- receiving a plurality of 2-D ultrasound images that are obtained by rotating the visual field about an axis that is common to the plane sections along which respective 2-D image extends;
- 5 - joining together said 2-D images such that a 3-D ultrasound image is reconstructed, and such that a 3-D region of interest, i.e. a region of interest of a three-dimensional space, is also reconstructed.

Advantageously, the step of iteratively calculating positions of the region of interest provides:

- 10 - calculating the local pixel function in a plurality of domains of the subsequent ultrasound images;
- calculating a predetermined object function in each of the domains, the object function associating to each domain a deviation value between the local pixel function as calculated in the domain and the local pixel function as
15 calculated in the region of interest;
- determining a domain of the subsequent ultrasound image in which the object function has a minimum value.

Preferably, the object function is the sum of the squares of the differences between a value of the local pixel function as calculated at each
20 pixel of the region of interest of an ultrasound image, and the value of the local pixel function as calculated in a domain of a subsequent ultrasound image, which may not immediately follow the reference image.

Advantageously, a step is provided of selecting the images in which the derived region is identified from the plurality of subsequent ultrasound images
25 by sampling at a predetermined frequency.

The use of the procedure may be continuous or intermittent, responsive to the childbirth stage and to monitoring needs.

Preferably, the position of the head of the foetus is associated with a further region of interest that is selected on a fixed portion of the parturient's
30 body and/or with a further region of interest that is selected on the head of the foetus.

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Preferably, the method provides a step of signalling an anomalous value of a labor progress parameter with respect to a predetermined range, or an anomalous combination of a plurality of the labor progress parameters.

Preferably, the method provides a step of storing values of the labor progress parameters, in particular the anomalous value and the anomalous combination of values.

Brief description of the drawings

The invention will now be shown with the following description of an exemplary embodiment thereof, exemplifying but not limitative, with reference to the attached drawings, in which:

- Fig. 1 is a schematic views of the apparatus according to the invention, for monitoring one or more morphological and physiological childbirth-related parameters, considered at different instants during the tracking of a parameter;
- Fig. 2 shows more in detail the displaying unit 15 of the apparatus, along with a reference ultrasound image;
- Fig. 3 diagrammatically shows a region of interest that is produced for identifying and tracking points on subsequent ultrasound images;
- Fig. 4 shows a subsequent ultrasound image;
- Fig. 5 diagrammatically shows the steps of scanning the ultrasound image of Fig. 4, by which previously defined anatomic points are retrieved;
- Fig. 6 shows the displaying unit of Fig.2, where an ultrasound image is displayed subsequent to reference image.
- Fig. 7 represents more in detail a genital and reproductive apparatus of a parturient;
- Fig. 8 is a block diagram that represents the steps to be performed by an operator who interacts with the apparatus according to the invention;
- Fig. 9 is a block diagram of the method that is carried out by the algorithm-based program means that is resident in the control unit of the apparatus.

Description of preferred exemplary embodiments

With reference to Figs. 1 to 7, an apparatus 10 is described, according to the invention, for monitoring one or more morphological and physiological

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parameters that are related to the labor progress during childbirth. In a basic exemplary embodiment, the apparatus comprises an ultrasound probe 1, which is equipped with a means, not shown, for fixing the probe itself on the skin of a parturient 2 outside the upper ventral region or just below the sternum (fig. 1), depending on the configuration that is actually most suitable for obtaining a satisfactory visualization of the desired portions of the woman's body and of the foetus 3. In the case displayed in Fig.1, visual field 7 of ultrasound probe 1 includes substantially the whole foetus 3, in particular the head 4 as well as the whole endocervical canal 8 and a portion of the umbilical cord 5. As shown in Fig. 7, another possible suitable position of probe 1, is close to the pubis.

Ultrasound probe 1 is connected to a control unit 13 that provides an ultrasound image 11 on a displaying unit 15, substantially in real time t_0 . In the exemplary embodiment, displaying unit 15 is integrated in an interactive graphic user interface 14 that comprises furthermore a device 16 for introducing the parameters 25 to be monitored; displaying unit 15, which is shown more in detail in Fig. 2, is used both for displaying ultrasound images 11 and for indicating the parameters 25 to be monitored by selecting anatomic reference points 28',28'',29 directly on the reference ultrasound image 11. Graphic user interface 14 is also provided with a section 17 for displaying the numerical values of the selected parameters.

In order to monitor parameters 25, an operator interacts with apparatus 10, in particular with control unit 13, according to the steps of Fig. 8, which are referred to within parentheses.

The operator firstly fastens ultrasound probe 1 to the parturient's body 2 (51), in a position suitable for obtaining a satisfactory ultrasound image 11 (52) of the desired portions of the woman's body 2 and of foetus 3, as previously described.

Then, through device 16, the operator selects parameters 25 to be monitored during the next labor stages (53). Such parameters 25 may be selected, in particular among:

- the dilation 26 of endocervical canal 8 (Fig. 7);
- the length of endocervical canal 8;

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- the "foetal head station", i.e. the position of head 4 of foetus 3 with respect to a coordinate measured along the outlet path;
- the "foetal head position" 30 (Fig.2), i.e. the rotation of head 4 of foetus 3 with respect to a predetermined axis 31;
- 5 - uterine contractions intensity, frequency, duration;
- the position of one or more points of umbilical cord 5.

The operator selects, directly on reference ultrasound image 11 as displayed by screen 15, anatomic reference points 28',28" that are needed for real-time calculation of the value of each parameters 25 that have been
10 selected (54). For example, for monitoring dilation 26 of endocervical canal 8, the operator selects a couple of points 28" on the edges 9 of the endocervical canal 8 (Fig. 7), or, preferably, a plurality of couples of points that are distributed along edges 9. In the case of the foetal head position 30, instead, the operator may select for instance a reference axis 31 integral with pelvis 6
15 of the parturient 2 and a couple of points 28' that identify biparietal diameter 27 of foetus 3 (Figs. 1, 2 and 7), whose inclination with respect to reference axis 31 represents a rotation that is the above-mentioned foetal head position 30. Also in this case, this evaluation is preferably done in a redundant way, for instance by considering more than one couple of points 28'; in alternative to
20 reference axis 31 integral with pelvis 6, the operator may choose a reference axis that is defined by a couple of points 28" that have been selected for monitoring dilation 26 of endocervical canal 8 (Fig.7).

Through the above described technique of selection of anatomical reference points, the operator can define a parameter of interest, which may
25 be different from the above-listed ones, provided that the new parameter can be expressed as a distance between two points or as a rotation angle of an axis with respect to a reference axis defined on foetus head or on parturient's body, for instance on parturient's pelvis 6. For the sake of conciseness, reference will be made only to the case of foetal head position 30, which is the
30 only parameter shown through Figs 2-6, even if the apparatus is adapted to track a virtually unlimited plurality of parameters, provided that a suitable computing power is available.

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Once parameters 25 to be monitored, and respective anatomic reference points 28',28",29, have been selected, and options 55, 56, described hereinafter, have been fulfilled, the operator starts the elaboration (57), which is carried out by control unit 13 according to an algorithm-based program means that is resident in it. Control unit 13 works as described hereinafter, performing the steps of the block diagrams of Fig. 9, to which reference is made within parentheses.

The algorithm carries out a monitoring phase, or automatic "tracking", of specific "pixel patterns" through a sequence of consecutive ultrasound images. More in detail, and with reference to Figs. 2 and 3, control unit 13 creates a region of interest (ROI) 21 about each reference point (61). Each ROI 21 has a prefixed size and comprises a set of pixels 23, which represents the pixel pattern 24 to be retrieved in the subsequent ultrasound images. For each pixel 23, the value of a prefixed local pixel function f is calculated. For example, the local pixel function f may associate a numerical value to a grey tonality of a pixel 23 in a grey scale, where the lowest/highest value is used for a white pixel and a highest/lowest value for a black pixel, respectively, or vice-versa.

At a time t_1 , control unit 13 defines an ultrasound image 12 (62; Fig. 4) that has been taken by the ultrasound probe, subsequent to reference image 11, in whose pixels the above mentioned reference function f is calculated; as shown in Fig. 5, control unit 13 carries out then a scanning step of subsequent image 12 (63), defining a plurality of domains 36 that have the same shape and size of ROI 21 (64), in order to track a group of pixels which has features that match the features of pixel pattern 24 as initially defined by the algorithm. To this purpose, and still by means of the resident algorithm, control unit 13 compares the set of the values calculated in ROI 21 with the values calculated in each domain 36, and finds out the domain 22 where the distribution of the values is the most similar to the distribution of the values calculated in ROI 21. The identified domain 36 is the domain where a predetermined object function F , or distance function, has a minimum value 34. For instance, according to a known method, the object function F may be the sum of the squares of the differences of values of the local pixel function f calculated for corresponding pixels in ROI 21 and in the domain 22. The coordinates x_1, x_2 of this recognized

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or tracked or derived ROI 22 are displayed substantially in real time on displaying unit 15 (66; Fig. 6), along with a line or a plurality of lines that represent the parameter of interest corresponding to selected groups of anatomic reference points (67), i.e. with simplified images of anatomic details, overlapped to the ultrasound current image. The anatomic detail may be, for example, the head of the foetus, together with such orientation parameters as foetal head position 30 or the inclination or the rotation with respect to the shoulders.

The computing means calculate then the distance and the angles of inclination that are needed for quantitatively expressing parameters 25, and the corresponding values are displayed in section 17 of displaying unit 15. Afterwards, the derived ROIs 22 that are retrieved in the subsequent image 12 are used in an iterative process, for recognizing the ROIs in further subsequent ultrasound images, not shown, up to the end of the session (70).

Parameter values 25 may furthermore be displayed as graphs 40 on a section 39 of graphic user interface 14 (68,69), in order to highlight their temporal evolution. Parameter values 25 may also be recorded in a mass memory unit 18, to be displayed in an off-line session. Anomalous parameter values and anomalous combinations of parameter values are advantageously saved in a separate memory device, preferably after being highlighted in a separate display unit or mode, not shown. The off-line consultation of the data recorded in mass memory unit 18 is useful, for instance, in case of doubts concerning a correct application of safety procedures and/or of good childbirth practice, in particular in case of unexpected complications that may have occurred during the childbirth.

In the above description, it has been assumed that the reference pixel patterns 24 to be tracked are identified in the initial image 11; however, for any anatomic reference point, in subsequent image 12 a pixel pattern 24 may be used which is identified in another ultrasound image, advantageously in an image that is produced immediately before image 12.

The algorithm will also offer the operator the option 55 (Fig. 8) of considering both types of pixel patterns, in order to maximize the accuracy in ROI recognition, at the expenses of some reduction in temporal resolution of

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the analysis. In this specific case, the operator will be also prompted to define the criterion (56) to be employed by control unit 13 to determine, in each elaborated image, the derived ROI 22 for each initially selected ROI 21. In fact, in this case, for each initial ROI 21 the algorithm will first provide two possible
5 derived ROIs 22 as the result of two independent pattern trackings, and then a choice will be automatically made based on the operator-defined criterion. For instance, the position of each derived ROI 22 can be chosen as the average position between two alternatives that are provided by the algorithm, or it can be chosen as the position of the ROI that has the lowest object function F
10 value 34 between the two values that are provided, or it can be chosen as the position that is closer to or farther from a determined range of possible “expected values”, etc.

An external coordinate system 20 may be employed to correct, due, for instance to a parturient's movement. This way, any possible displacements of
15 probe 1 can be taken into account, due for instance to an incidental movement of the parturient 2, starting from the control of the reference image up to the control of the subsequent images, and the position of ROI 21 of reference image 11 and of the corresponding derived ROIs 22 on subsequent images 12. To this purpose, (Fig. 1) an external or “absolute” coordinate system 20
20 may be provided, as well as a position sensor that can be associated to probe 1 and connected to control unit 13, in such a way that the absolute position of probe 1 with respect to coordinate system 20 is detected by control unit 13 that is provided with a summing means, which is adapted to sum the position of ROI 21 in the reference ultrasound image 11 and the position of the derived
25 displaced ROI 12 with their corresponding positions in the fixed coordinate system 20. This way, a comparison is made between the positions of the ROIs 21,22 that takes into account the coordinate system 20 external to the parturient 2. The position sensor and the summing means may be easily implemented by a skilled person, therefore they are not described in detail
30 here.

Notwithstanding reference has been made to pixels and local pixel functions, it is clear to a skilled person that they include both 2D and 3D pixels.

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The foregoing description of a specific embodiment will so fully reveal the invention according to the conceptual point of view, such that others, by applying current knowledge, will be able to modify and/or adapt for various applications such embodiment without further research and without parting
5 from the invention, and it is therefore to be understood that such adaptations and modifications will have to be considered as equivalent to the specific embodiment. The means and the materials to realise the different functions described herein could have a different nature without, for this reason, departing from the field of the invention. It is to be understood that the
10 phraseology or terminology employed herein is for the purpose of description and not of limitation.

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CLAIMS

1. An apparatus (10) for measuring a labor progress parameter during childbirth by ultrasound images obtained by ultrasonic pulses, said apparatus (10) comprising:

5 – an ultrasound probe;
 – a fastening means for fastening said ultrasound probe (1) onto the body of a parturient (2) so that said probe (1) has a visual field (7) that includes a portion of the body of said parturient (2) and of a foetus (3), in particular the endocervical canal (8) or the pubis of said parturient (2);

10 – a control unit (13) for receiving and analysing signals from said ultrasound probe (1), said control unit (13) creating or receiving as input by said probe a reference ultrasound image (11) and a plurality of subsequent ultrasound images (12), which are taken in succession after said reference ultrasound image (11);

15 – a user interface (14) for selecting a region of interest (21) in said reference ultrasound image (11) by an operator, said user interface (14) adapted to select said region of interest (21) substantially centred about said portion of the parturient's body, said region of interest (21) comprising a plurality of pixels (23);

20 wherein said control unit (13) comprises:

 – an automatic tracking means for tracking said region of interest (21), said automatic tracking means adapted to identify derived regions of interest (22) in selected images of said plurality of subsequent ultrasound images (12), said derived regions of interest (22) deriving from said region of interest (21) that is selected in said reference ultrasound image (11), said tracking means comprising:

25 – a means for calculating a predetermined local pixel function for each pixel (23) or group of pixels of said region of interest (21) in said reference ultrasound image (11) and in each selected image of said plurality of subsequent ultrasound images (12),

30 – a means for iteratively calculating, starting from said reference ultrasound image (11), the position of said derived region of interest (22) in each selected image, said means for iteratively calculating

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adapted to perform comparisons between:

- values of said local pixel function calculated at the pixels (23) of said region of interest (21) of an image of the selected images;
 - 5 - values of said local pixel function calculated at pixels of said region of interest (22) of a subsequent ultrasound image (12);
 - a means for comparing each position of said derived region of interest (22) with the position of said region of interest (21) in said reference ultrasound image (11) or in another image of said selected
10 images and for calculating a labor progress parameter.
2. An apparatus (10) according to claim 1, wherein said control unit (13) is adapted to select a further region of interest (21) that is substantially centred about said portion of said parturient's body, said labor progress
15 parameter during childbirth defined by a combination of said region of interest (21) and of said further region of interest (21).
3. An apparatus (10) according to claim 1, wherein said user interface (13) is adapted to provide to said operator an option of selecting a further reference image among one of said subsequent ultrasound images, such
20 that a first and a second tracking on two pluralities of pixels (23) are carried out contemporaneously, said means for iteratively calculating adapted to perform the steps of:
- comparing values of said local pixel function (f) calculated at pixels (23) of said region of interest (21) of said reference ultrasound image
25 (11), and values of said local pixel function (f) calculated at pixels (23) of said region of interest (22) of a subsequent ultrasound image (12), such that a first position of said derived region of interest is identified;
 - comparing between values of said local pixel function (f) calculated at pixels of said further reference image, and values of said local pixel
30 function (f) calculated at pixels (23) of said region of interest (22) of a subsequent ultrasound image (12), such that a second position of said derived region of interest is identified;

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- identifying a further derived region of interest through a comparison between the trackings of the first and said second positions of said derived region of interest according to a prefixed criterion, such that with said first tracking it is possible to take into maximum account any possible change of the tissues during the childbirth, whereas with the second tracking it is possible to eliminate artifacts that may affect the calculation of said derived region of interest.

4. An apparatus (10) according to claim 3, wherein said user interface (14) is adapted to provide to said operator an option of selecting said criterion among:

- a position that is identified by the lowest object function (F) value (34);
- the position that is closer to a predetermined set of values;
- the position that is farther from a predetermined set of values;
- an average position between said first and said second position.

5. An apparatus (10) according to claim 1, wherein a means is provided for measuring a position parameter of said ultrasound probe (1) with respect to a coordinate system (20) external to said parturient (2), and said control unit (13) has a means for receiving said position parameter and a means for summing said position parameter and the position of said derived region of interest (22) with respect to said probe, such that said means for comparing performs a comparison between the actual position of said regions of interest (21) taking into account said coordinate system (20) external to said parturient (2).

6. An apparatus (10) according to claim 1, wherein said user interface (14) is suitable for defining as input a plurality of regions of interest (21) selected by an operator in said reference image (11), in particular, each region of interest (21) defining a same labor progress parameter.

7. An apparatus (10) according to claim 1, wherein said labor progress parameter (25) is selected from the group comprised of:

- the dilation (26) of the endocervical canal (8) of said parturient (2), said dilation (26), in particular, associated to a distance between at least

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one couple of regions of interest (12) selected on the edge (9) of said endocervical canal (8);

– the position of the head (4) of said foetus (3) during the descent along the outlet path through said endocervical canal (8), i.e. the foetal head station, said position associated, in particular, with a region of interest (12) that is selected on a fixed portion of said body of said parturient (2) and with a region of interest (12) that is selected on the head (4) of said foetus (3);

– the rotation of the head (4) of said foetus (3), i.e. the foetal head position (30), said rotation associated with an angle that is formed by a line that is defined by two regions of interest (21) centred on a fixed portion of said body of said parturient (2) and by a line that is defined by two regions of interest (21) integral to said foetus (3).

8. An apparatus (10) according to claim 1, wherein said ultrasound reference image (11) and/or said subsequent ultrasound images (12) are images of any cross sectional plane of said visual field (7) selected by said operator.

9. An apparatus (10) according to claim 1, wherein said region of interest (21) is a region of a three-dimensional space, in particular, a three-dimensional region, said three-dimensional region, in particular, obtained as an union of regions of interest (21) of a plurality of ultrasound images of plane sections of said visual field (7), said plurality of ultrasound images obtained by rotating said visual field (7) about an axis common to said plane sections.

10. An apparatus (10) according to claim 1, wherein said region of interest (21) is a region of a three-dimensional space, in particular, obtained directly through a 3D real time matricial acquisition.

11. An apparatus (10) according to claim 1, wherein said means for iteratively calculating positions of said region of interest (22) comprises:

- a means for calculating said local pixel function (f) in a plurality of domains (36) of said subsequent ultrasound images (12);
- a means for calculating a predetermined object function (F) in each

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of said domains (36), said object function associating to each of said domains (36) a deviation value between said local pixel function (f) as calculated in said domain (36) and said local pixel function (f) as calculated in said region of interest (12);

5 – a means for determining a domain (22) of a subsequent ultrasound image in which said object function (F) has a minimum value (34).

12. An apparatus (10) according to claim 1, wherein said images of said plurality of subsequent images (12) in which said derived region (22) is identified by sampling at a predetermined frequency.

10 **13.** An apparatus (10) according to claim 1, wherein said position of the head (4) of said foetus (3) is associated with a further region of interest (22) that is selected on a fixed portion of said body of said parturient (2) and/or with a further region of interest (22) that is selected at the head (4) of said foetus (3).

15 **14.** An apparatus (10) according to claim 1, wherein said user interface (14) provides a means for signalling an anomalous value of a labor progress parameter or a foetus physiological parameter (25) with respect to a predetermined range, or an anomalous combination of a plurality of labor progress parameters and/or or of foetus physiological parameters (25).

20 **15.** An apparatus (10) according to claims 1 or 14, comprising a means (18) for storing values of said labor progress parameters (25), in particular said anomalous value and said anomalous combination of values.

Fig. 1

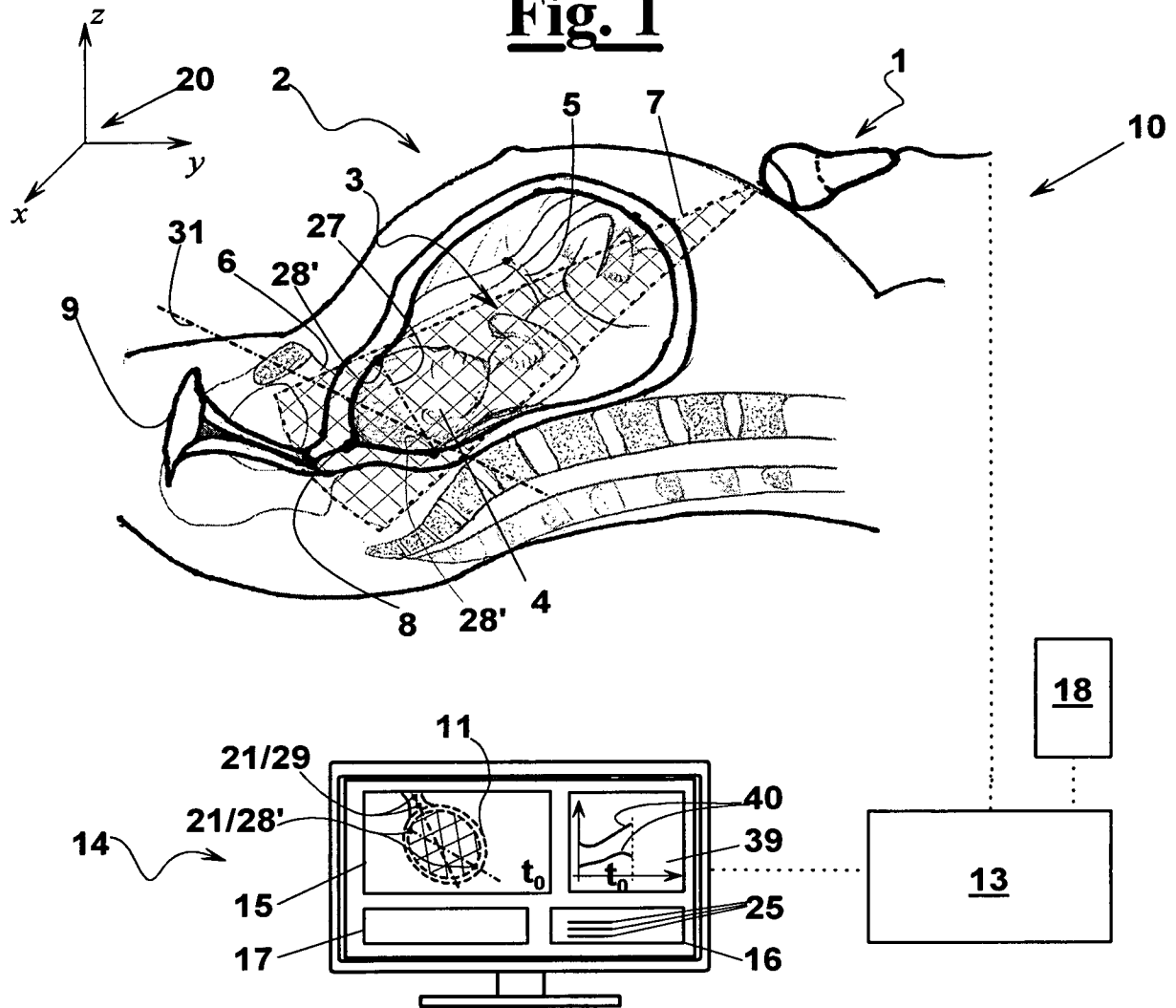


Fig. 2

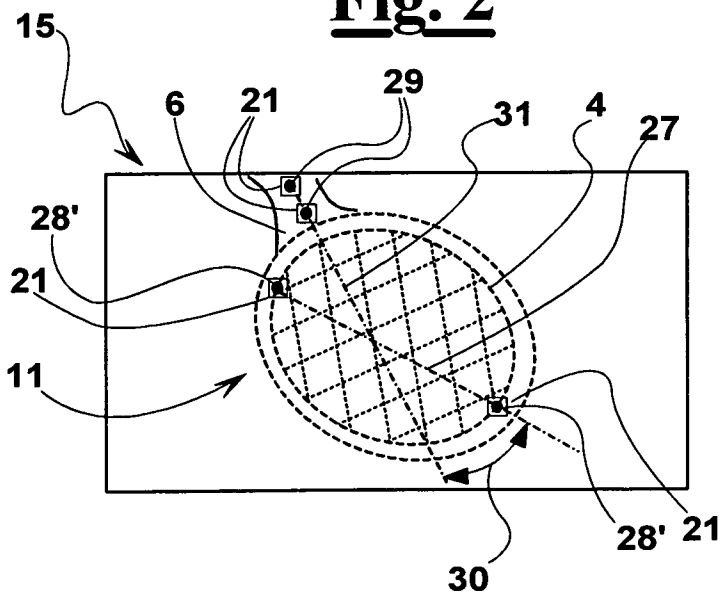


Fig. 3

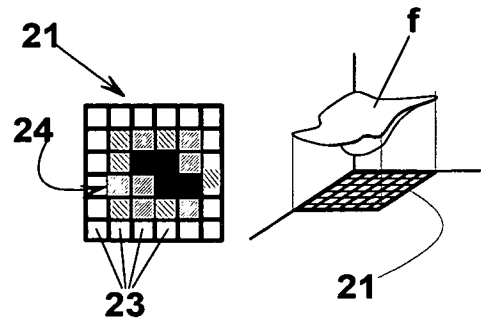


Fig. 4

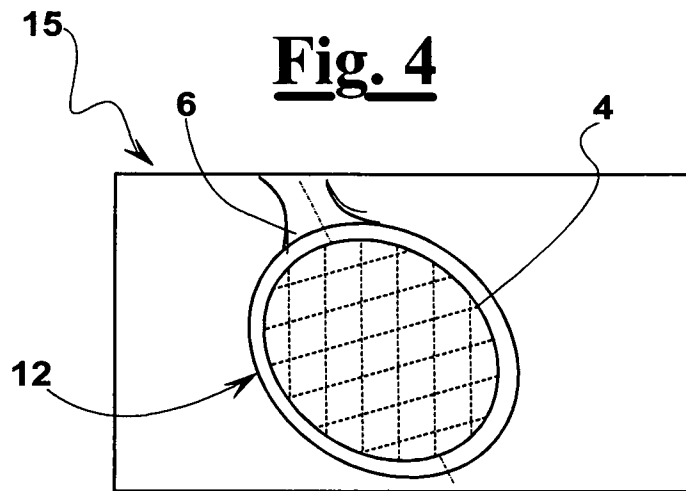
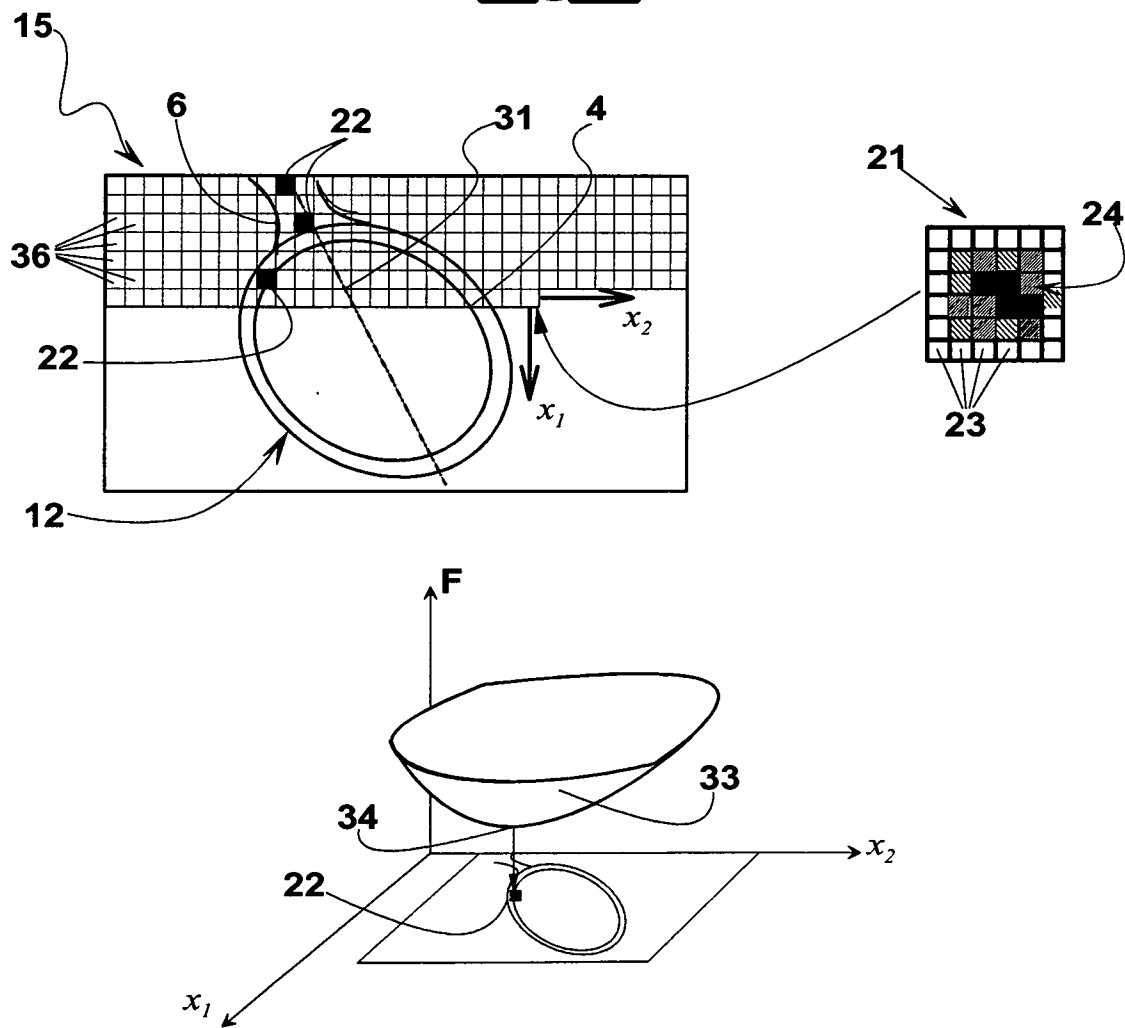


Fig. 5



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Fig. 6

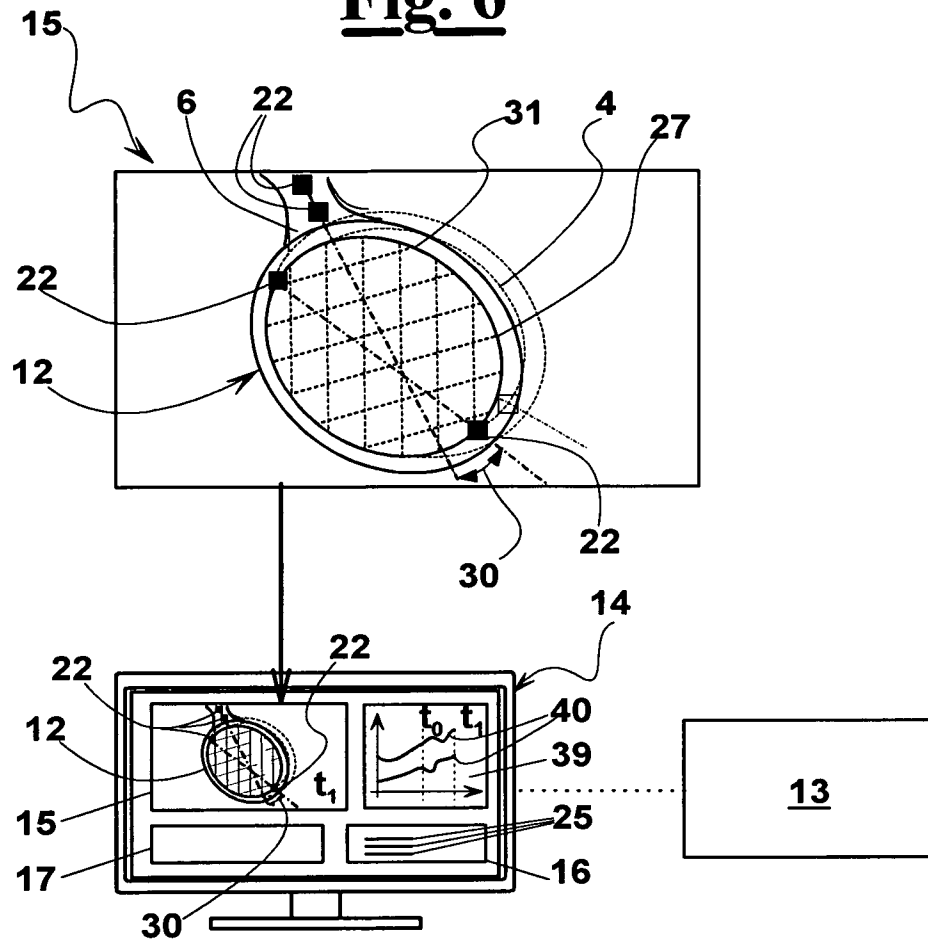
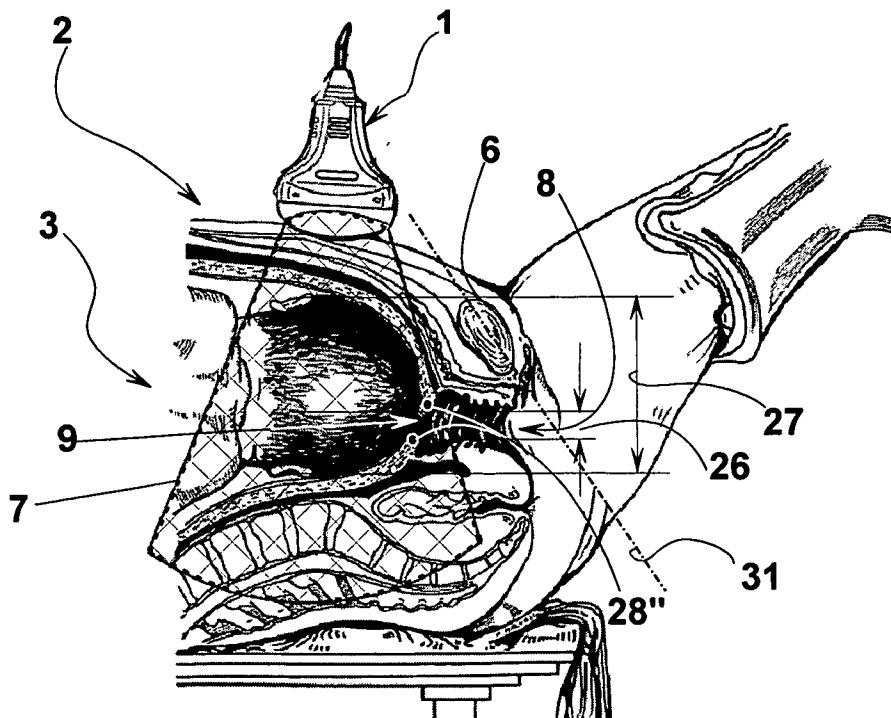
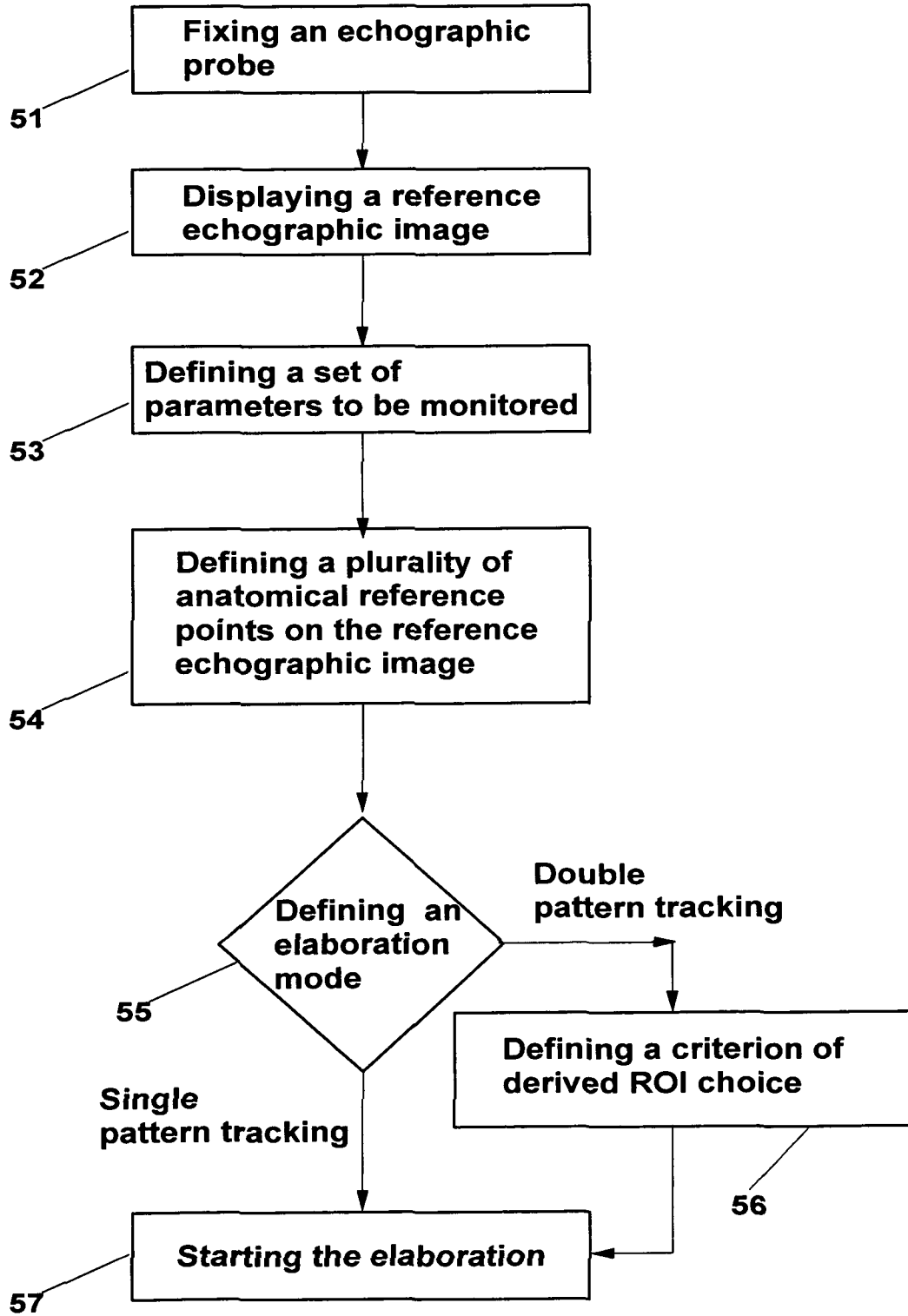


Fig. 7



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Fig. 8



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/008321

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/107 A61B8/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/114779 A1 (PALTIELI YOAV [IL]) 19 June 2003 (2003-06-19) paragraphs [0072], [0069]	1-10
A	US 2008/167581 A1 (PALTIELI YOAV [IL]) 10 July 2008 (2008-07-10) cited in the application the whole document	1-10
X,P	DE 10 2008 037411 A1 (GEN ELECTRIC [US]) 9 April 2009 (2009-04-09) the whole document	1-10

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

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

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

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

18 March 2010

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Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2009/008321

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003114779 A1	19-06-2003	NONE	
US 2008167581 A1	10-07-2008	EP 2120723 A2 WO 2008084486 A2	25-11-2009 17-07-2008
DE 102008037411 A1	09-04-2009	JP 2009090107 A US 2009093716 A1	30-04-2009 09-04-2009

专利名称(译)	用于测量劳动力进度参数的超声波设备		
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申请号	EP2009795901	申请日	2009-11-23
[标]申请(专利权)人(译)	国家研究委员会		
申请(专利权)人(译)	CNR CONSIGLIO NAZIONALE DELLE RICERCHE		
当前申请(专利权)人(译)	CNR CONSIGLIO NAZIONALE DELLE RICERCHE		
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发明人	CASCIARO, SERGIO CASCIARO, ERNESTO CONVERSANO, FRANCESCO		
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其他公开文献	EP2375980B1		
外部链接	Espacenet		

摘要(译)

用于测量一个或多个产程进展参数 (25) 作为宫颈管的扩张 (8) , 旋转和胎儿 (3) 的头部 (4) 的下降过程中的位置 , 持续时间的设备 (10) 和子宫收缩 , 其他形态和生理参数的强度 , 而不会引入异物进入孕妇 (2) 和独立地从操作的灵敏度的身体。的装置 (10) 包括用于跟踪的自动装置 , 在由超声波探头 (1) , 所关注的一个或多个区域 (ROI , 21) 中得到的超声波图像 (11,12) 的序列 , 其可以是两个2三维或三维并且关于解剖学参考点 (28) 居中 , 所述解剖学参考点定义了由显示单元在参考图像中选择的所述参数 (14) 。跟踪装置包括 : a) 用于计算参考图像的ROI的像素处的函数 (f) 和优选地在序列的图像中采样的图像的装置 , b) 用于迭代地计算序列的位置的图像的装置。通过当前图像的ROI的像素中计算的函数 (f) 的值与在后续超声的ROI的像素中计算的函数 (f) 的值之间的比较来比较后续图像中的ROI图片; c) 用于将ROI的每个位置与参考图像中的ROI的位置进行比较并且用于响应于所述比较来计算劳动力进度参数的装置。感兴趣区域的新位置可以被定义为预定对象函数呈现最小值的域。