

INTRAUTERINE PROBE

This invention relates to an intrauterine probe which is suitable for use in monitoring conditions during labour, i.e. the condition of the fetus and also the condition of the mother.

The desirability of monitoring fetal heart rate (FHR) and intrauterine pressure (IUP) during a difficult labour is well known. In practice, IUP has been measured using a pressure catheter, and a separate device has been used to monitor FHR. Generally, FHR has been monitored by recording the voltage between two electrodes of which one is in the form of a body clip and the other (the "indifferent" or "reference" electrode) is spaced a short distance from the clip in contact with surrounding tissue (usually maternal).

The clip is attached to that part of the fetus which is presented for delivery. Normally, therefore, it is a scalp clip. A clip is necessarily invasive to the fetus, and is a disincentive to routine monitoring during labour. It is desirable clinically to carry out fetal monitoring routinely but this is unlikely to be achieved unless the procedure can be made more acceptable to women.

It would also be desirable to devise a system which would enable FHR and other factors to be monitored without the need to make separate trans-vaginal insertions.

According to one aspect of the present invention, there is provided an intrauterine probe for monitoring the condition of the fetus during labour which comprises an elongate flexible, flattened body member formed from

electrically insulating material having a rounded distal end and having at least one electrode located in one flat face of the body member, said body member being sufficiently directionally stable to be insertable into the cervix and capable of being guided around the fetus without twisting and having a bending stiffness about an axis transverse to the plane of the body member of between 1 and 10 mega Newtons/m², and the or each electrode being mounted in the body member so that it can be in close proximity with fetal skin.

Preferably portions of the insulating material bounding the or each electrode are formed from a resilient foam material having non-communicating cells and/or have a rounded upper surface in cross-section.

Preferably there are at least two electrodes spaced longitudinally, and the geometry of the portion of insulating material between the electrodes may be such that, in use, a thin electrolyte film of amniotic fluid is trapped between the fetal skin and the area of probe between the electrodes.

The probe may be provided with a distal electrode and/or a group of electrodes, the electrodes being spaced over a distance which, in use, is sufficient to encompass the fetal head and neck, and in a probe having a distal electrode and two or more additional electrodes located in a group, the spacing between the distal electrode and the proximal additional electrode is preferably greater than the spacing between the electrodes in the group.

The probe may also include a pressure transducer.

The probe is preferably used in connection with a

processor which is adapted to distinguish between signals representing fetal heart rate and maternal heart rate.

We have found that consistent and reliable signal detection can be achieved using the probe according to the invention, which is at least comparable with that from a conventional fetal scalp clip electrode.

According to another aspect, the invention provides a method of monitoring fetal heart rate during labour which comprises introducing into the cervix an intrauterine probe comprising an elongate, flexible, flattened body member formed from electrically insulating material having a rounded distal end and having at least one electrode located in one face of the body member, said body member being sufficiently directionally stable to be insertable into the cervix and capable of being guided around the fetus without twisting and having a bending stiffness about an axis transverse to the plane of the body member of between 1 and 10 mega Newtons/m², guiding the probe around the fetus with the electrode towards the fetus, the or each electrode being mounted in the body member so that it can be in close proximity with fetal skin, and analysing the signal output from the electrode and a reference electrode by discriminating the fetal heart rate from the maternal heart rate on the basis of difference in R wave signal width or frequency.

According to a further aspect, the invention provides a method of monitoring the condition of a fetus during labour which comprises introducing into the cervix an intrauterine probe comprising an elongate flexible, flattened body member

formed from electrically insulating material having a rounded distal end and having at least one electrode located in one flat face of the body member, said body member being sufficiently directionally stable to be insertable into the cervix and capable of being guided around the fetus without twisting and having a bending stiffness about an axis transverse to the plane of the body member of between 1 and 10² mega Newtons/m, guiding the probe around the fetus with the electrode towards the fetus, the or each electrode being mounted in the body member so that it can be in close proximity with fetal skin, and observing the output signal from the electrode.

Details of construction and operation of intrauterine probes in accordance with the invention will be apparent from the following description and accompanying drawings in which:-

Figure 1 is a perspective view of an embodiment of a probe in accordance with the invention;

Figure 2 is a cross-sectional view through an electrode of the probe of Figure 1;

Figure 2A is a cross sectional view through the probe between electrodes;

Figure 3 is a schematic section of a uterus showing the probe in use;

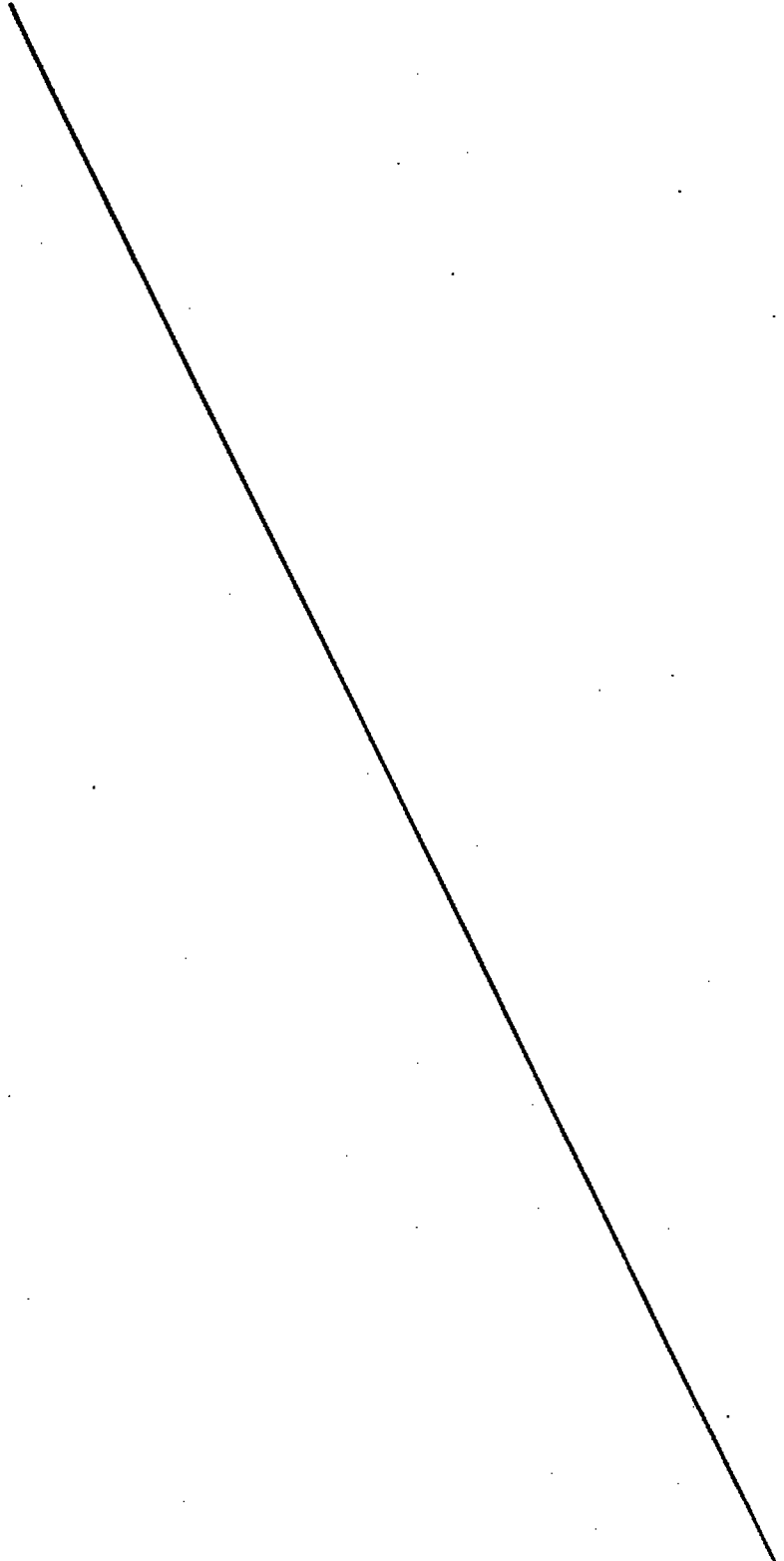
Figure 4 is a diagrammatic exploded view illustrating one method of manufacturing the probe;

Figure 5 is an exploded view of a pressure sensor on an enlarged scale;

Figure 6 is a schematic representation of the

connection of the electrodes to a signal processor;

Figure 7 is a typical trace showing the fetal and maternal heart beats.



Referring to the drawings and in particular Figures 1
2 & 2A, the probe comprises an elongate body 1 about 40 to
50 cms in total length. As best seen in Figures 2 & 2A,
the probe has a flattened configuration with rounded edges
2, 3 and generally flat upper and lower faces 4,5.
Typically, the probe is about 1 cm wide and about 3 mm
thick. A flexible printed circuit board 6 carries spaced
electrodes e.g. of stainless steel 7, 8, 9 & 10 each having
a domed head 11 and is encapsulated in a flexible plastics
potting compound, such as a 2-part polyurethane composition.
The dimensions and inherent flexibility of the plastics
material are such that the probe takes up the position shown
in Figure 3 when inserted in the uterus. The particular
potting composition employed was a 2-part polyurethane
composition obtainable from Emerson & Cumming Ltd. 866
Uxbridge Road, Hayes, Middlesex, under the trade name CPC 19
flexible polyurethane potting compound. Probes having
a stiffness (Young's Modulus) in the range of 1 to 10
meganewtons per square metre are suitable.

As shown in Figure 2, the domed head 11 of the
electrode 8 is effectively shrouded by rounded portions 12 &
13 of the insulating material of the body. The surface of
the domed portion 11 lies substantially in the same plane as
the flat face 5 of the body. In use, this ensures that
amniotic fluid is squeezed out to form a thin electrolyte
film between the electrode 8 and the reference electrode
when the probe is suitably located in relation to the
uterine or cervical walls.

As can be seen from Figure 1, the electrodes are spaced so that the distal electrode 7 is spaced from the other electrodes 8, 9 & 10. As a consequence, the distance between electrode 7 and its nearest electrode 8 is greater than the inter-electrode spacing in the group of electrodes 8, 9 & 10. Because of its greater spacing the electrode 7 is generally used as the reference electrode. However, as will be described below, the signals detected by any pair of electrodes may be used for measuring the FHR. The spacing between electrode 7 and electrode 8 may typically be 8 to 12 cms, while the inter-electrode spacing in the group of electrodes 8, 9 & 10 may be, for example, 3 to 6 cms. As the birth progresses, the signals detected by each electrode may vary in strength and the signals may be processed by selecting, at any one time, the outputs from the pair of electrodes which give the best signal.

In contrast with the experience of scalp-clip monitors, the quality of the signals obtained from the probes of the invention often improve as the birth progresses. This is believed to be because the probe is pressed more firmly against the baby's back as the fetal head passes into the birth canal.

Referring again to Figure 2, the portion of insulating material surrounding the electrodes may be formed from a unicellular or closed cell foam. These portions 15 & 16 are shown in cross hatching in Figures 2 & 2A. This may enable the probe to be pressed less tightly against the fetal skin while still minimising the effective

'electrolyte' film thickness.

Manufacture of the probe is illustrated in Figure 4. The electrodes 7, 8, 9 & 10 and also a pressure transducer 19 are attached to a printed circuit board 6. Board 6 includes conductor strips linking the electrodes to a multifilament cable 20 which is connected to a processor (see Figure 6). Conveniently, the processor may include a digital display unit but may incorporate an oscilloscope and a chart recorder (not shown). Circuit board 6 and attached electrodes are encapsulated in a potting compound to form a shaped probe body having the configuration shown in Figures 1, 2 & 2A by moulding between upper and lower moulds 22 & 23. A foaming agent may be introduced into the potting composition, or into a portion which will form the parts 16 & 17 of the probe body (see Figure 2).

The minimum number of electrodes in the group 8, 9 & 10 is one but the more electrodes are present, the better the chance of maintaining good signal quality during birth. Generally 2 to 4 electrodes in the group are usually satisfactory. The group of electrodes are preferably spaced over a distance sufficient to encompass the fetal head and neck, e.g. at least about 5 cms, typically 5 to 15 cms. Interelectrode spacing is generally less than the distance between the electrode nearest the tip, i.e. electrode 8, and the distal electrode 7. This distance is commonly about 15 to 20 cms, e.g. about 18 cms. At present, the preferred configuration is a distal electrode 7 and three equally-spaced additional electrodes 8, 9 & 10.

The interelectrode spacing being about 5 cms and the spacing from the distal electrode 18 cms.

In use, therefore, one at least of the group of electrodes 8, 9 & 10 is to a large extent redundant. At least one of the electrodes in the group will be useful, depending to some extent on the length of the fetus, and fetal movement after insertion. Sometimes two of the electrodes in the group will be utilised.

A probe of the invention can be used from the time at which the cervix is dilated to, say, 1 cm. The probe is inserted around the head or neck of the fetus and towards its lower trunk, and the flattened shape ensures that one face is stably oriented in contact with at least the head of the fetus. The intention is that the probe should be inserted to the extent that the distal electrode is on or adjacent to the lower trunk of the fetus, while one at least of the group of electrodes is in good contact with the head or neck of the fetus (see Figure 3). At a later stage of labour to that shown in Figure 3, the fetus' head and neck will be pressed against the electrodes 8, 9 & 10.

A probe of the invention in its preferred form includes a pressure sensor specifically to measure Intrauterine amniotic fluid Pressure (IUP). The location of this sensor is such that the point at which IUP is measured is both reasonably well known and unlikely to be influenced by unknown causes. By contrast with a pressure catheter, a pressure transducer and other sensors operating as miniature load cells (force sensors) for use in the invention can be

constructed very cheaply.

5 Preferably the IUP sensor 19 is located at or close to the distal end of the probe. Its internal construction is shown in Figure 5 and comprises a base carrier 30 which may be manufactured in metal (e.g. stainless steel), but is preferably moulded from plastics material (e.g. ABS plastic) and supporting a cantilever strain gauge (sensor) 31. The output from the strain sensor is connected to the printed circuit board 6. Overlying the base carrier is an
10 assembly 33 comprising an annular thin film membrane 34 which supports a rigid plastics disc 35. The pressure sensor is completed by a sealing ring 36, which may be moulded in a rigid plastic e.g. ABS, or in a soft rubber-like material, over the base carrier and may include a grid
15 structure to protect the membrane. In use, variations of IUP will cause the disc 35 to move inwardly and outwardly, thus applying more or less force to the strain gauge 31 via a contact button 37.

20 A probe of the invention provides a single device for the measurement of those criteria which are presently considered to be important for the good health of the mother and her baby. The probe can also be used, without changing its essential function, to measure further or different parameters; for example, there may be a
25 temperature sensor which could be used to detect maternal hyperthermia or temperature variation during contraction, and/or an optical sensor which could be used to detect, say, meconium and/or fetal blood oxygen levels when used as a

trans-cutaneous oximeter.

For use, a probe of the invention is in connection with a processor and display means. An arrangement for processing and displaying the output from the probe is shown in Figure 6. Typical traces produced by a chart recorder connected to a probe in accordance with the invention are shown in Figure 7. The output from the electrode pairs is a mixture of maternal and fetal heart rates and background 'noise' deriving from other muscular activity. The specific processing to distinguish the maternal and fetal ECG complexes takes advantage of the differing morphologies of each. Results with the invention have demonstrated that the relative amplitudes of the fetal and maternal complexes during a given labour are unpredictable but the measured width of the fetal complex is consistently less than that of the maternal complex during the same labour. Hence, either frequency domain pattern recognition of the spectral components (amplitude and/or phase) after Fourier transformation of each complex, or temporal/spatial pattern recognition in real time and/or by retrospective analysis can be applied. Although the fetal heart rate signal cannot always be recognised uniquely by the measured width of its 'R' component, a combination of R wave width recognition in conjunction with comparison with a stored pattern can be used to separate unambiguously the fetal and maternal heart rates from each other and from background noise. In this way, those signals recorded by the electrodes processed in order to provide separate displays of FHR and MHR, together

with the data obtained from the IUP sensor and other sensors at least. The display is visual, e.g. on a screen, but for the purposes of record a chart recorder will be used (no other display may be necessary). Alternatively, the processed fetal heart signal and IUP can be made compatible with current commercial fetal monitors from which the FHR and IUP can be presented in the normal way.

Figure 6 shows an arrangement in accordance with the invention for processing and displaying the signals detected by the probe.

Signals from the electrodes are fed to a multi-channel ECG amplifier and the amplifier output connected to the processing equipment via a patient isolation link such as a fibre optic cable. The transmitted signals are re-amplified and then passed to a signal selector which monitors the signals and selects the best signals from any pair of electrodes. The selected signal is passed via a data store to a band width filter and a low pass filter (to establish the isoelectric line for the wave form). A feedback to the signal selector is provided via a signal quality monitor to enable the signal selector to select signals on the basis of quality of fetal heart signal content as well as signal strength. After processing by an ECG pattern recognition unit, the signals are separated by an ECG R wave width discriminator into the fetal and maternal signals and the outputs displayed on rate meter display units, such as digital display units.

CLAIMS

1. An intrauterine probe for monitoring the condition of the fetus during labour which comprises an elongate flexible, flattened body member formed from electrically insulating material having a rounded distal end and having at least one electrode located in one flat face of the body member, said body member being sufficiently directionally stable to be insertable into the cervix and capable of being guided around the fetus without twisting and having a bending stiffness about an axis transverse to the plane of the body member of between 1 and 10 mega Newtons/m², and the or each electrode being mounted in the body member so that it can be in close proximity with fetal skin.
2. A probe according to Claim 1 in which portions of the insulating material surrounding the or each electrode are formed from a resilient foam material having non-communicating cells.
3. A probe according to Claim 1 or Claim 2 in which portions of the insulating material bounding the or each electrode have a rounded upper surface in cross-section.
4. A probe according to any one of the preceding Claims which has at least two electrodes spaced longitudinally thereof.
5. A probe according to any one of the preceding Claims having a distal electrode.
6. A probe according to any one of the preceding Claims which has a group of electrodes, the electrodes being spaced over a distance which, in use, is sufficient to



encompass the fetal head and neck.

7. A probe according to any one of the preceding Claims having a distal electrode and two or more additional electrodes located in a group, the spacing between the distal electrode and the proximal additional electrode being greater than the spacing between the electrodes in the group.

8. A probe according to any one of the preceding Claims which also includes a pressure transducer.

9. A probe according to any one of the preceding Claims in connection with a processor which is adapted to distinguish between signals representing fetal heart rate and maternal heart rate.

10. A method of monitoring fetal heart rate during labour which comprises introducing into the cervix an intrauterine probe comprising an elongate, flexible, flattened body member formed from electrically insulating material having a rounded distal end and having at least one electrode located in one face of the body member, said body member being sufficiently directionally stable to be insertable into the cervix and capable of being guided around the fetus without twisting and having a bending stiffness about an axis transverse to the plane of the body member of between 1 and 10² mega Newtons/m², guiding the probe around the fetus with the electrode towards the fetus, the or each electrode being mounted in the body member so that it can be in close proximity with fetal skin, and analysing the signal output from the electrode and a reference electrode by discriminating the fetal heart rate from the maternal heart rate on the basis



of difference in R wave signal width or frequency.

11. A method of monitoring the condition of a fetus during labour which comprises introducing into the cervix an intrauterine probe comprising an elongate flexible, flattened body member formed from electrically insulating material having a rounded distal end and having at least one electrode located in one flat face of the body member, said body member being sufficiently directionally stable to be insertable into the cervix and capable of being guided around the fetus without twisting and having a bending stiffness about an axis transverse to the plane of the body member of between 1 and 10 mega Newtons/m², guiding the probe around the fetus with the electrode towards the fetus, the or each electrode being mounted in the body member so that it can be in close proximity with fetal skin, and observing the output signal from the electrode.
