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WO 92/00699 A1

(58) Field of Search
UK CL (Edition L) **G1A AAM**
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Online databases :WPI INSPEC

(54) MONITORING OF THE CONDITION OF A FETUS DURING LABOUR.

(57) A system for in vivo monitoring of the presence and concentration of meconium and/or blood in amniotic fluid includes a probe having a flexible body housing an optical cell (11). The probe has at least one aperture (17 or 18) so that amniotic fluid can enter the cell. A fibre optic cable (10) connects the cell to a light source and to a spectral analyser for measuring light backscattered by the amniotic fluid. The probe includes shielding means (13) to shield the fibre optic cable from any light scattered by the wall of the uterus or fetus.

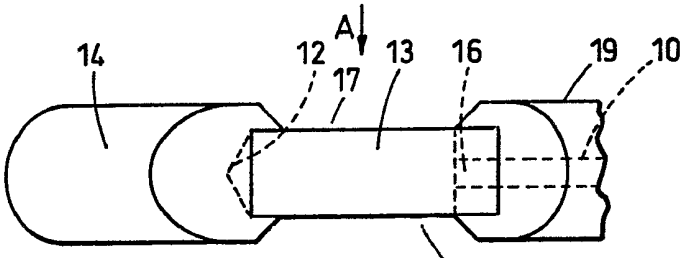

Fig.2A

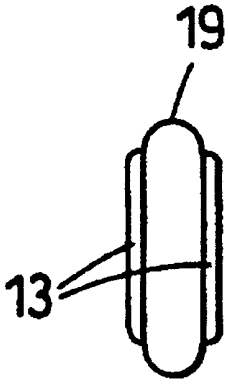

Fig.2B

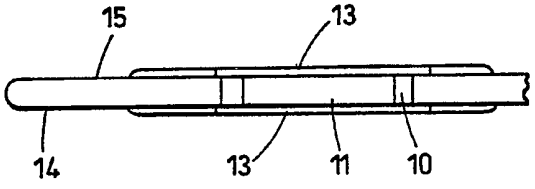

Fig.2C

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

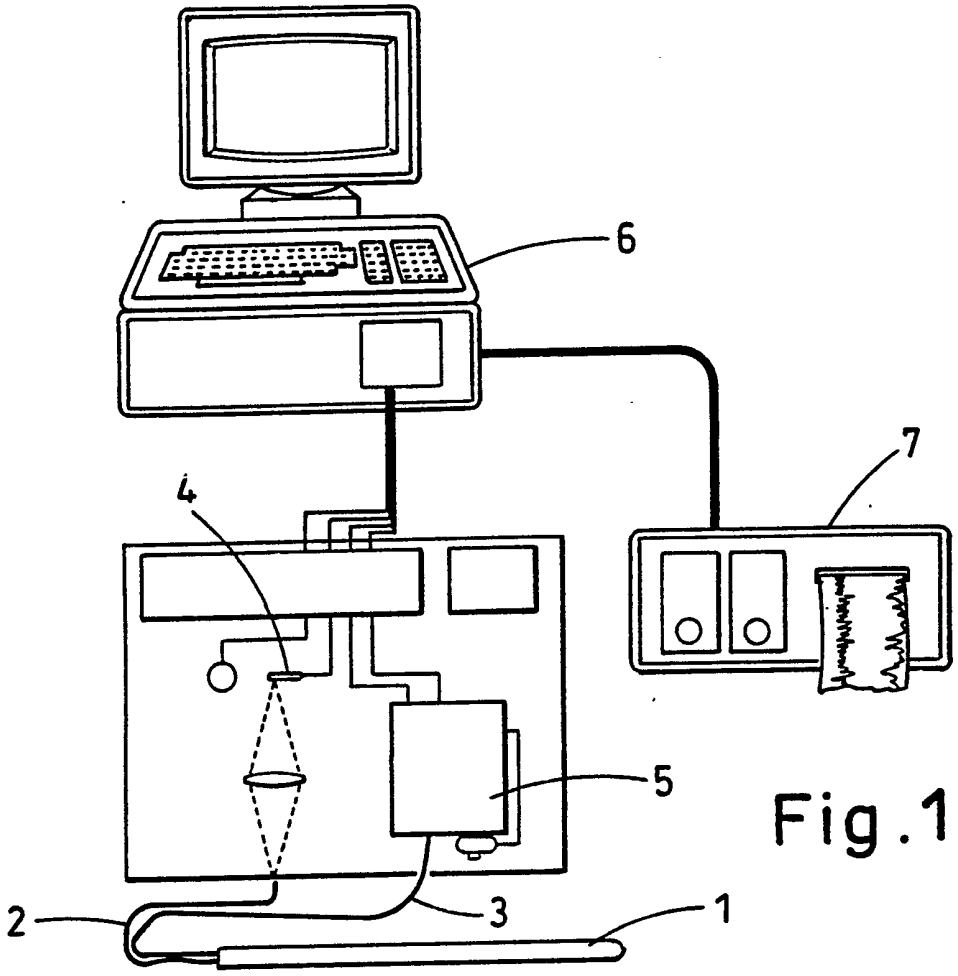

Fig.1

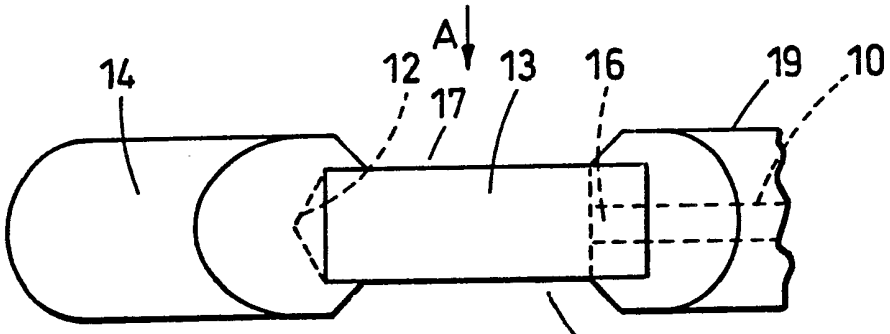

Fig.2A

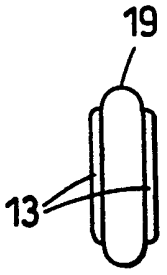

Fig.2B

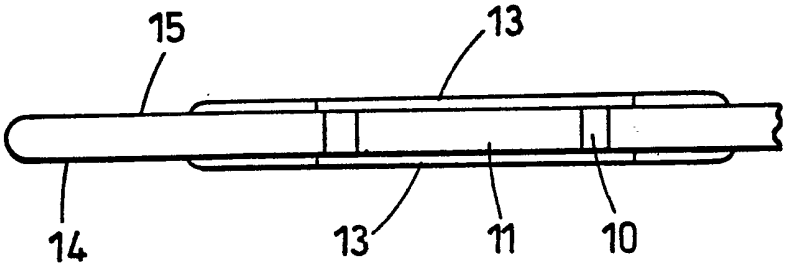

Fig.2C

MONITORING OF THE CONDITION OF A FETUS DURING LABOUR

This invention relates to the monitoring of the condition of a fetus during labour. In our PCT application Publication No. WO 92/00699, we describe a method and system for monitoring the quality of amniotic fluid (AF) during labour. Experience with the system described in our prior application has demonstrated the importance of excluding any light which is scattered by the uterine wall or the skin of the fetus. Such randomly scattered light tends to give a spurious signal indicative of the presence of blood because the uterine wall is richly supplied with blood vessels. Also, it has been found that it is advantageous to design the probe so that amniotic fluid flows freely to and through the optical cell.

According to one aspect of the present invention there is provided an intrauterine probe which comprises a flexible body housing an optical cell, said cell including at least one aperture permitting entry of amniotic fluid and being connected at one end to a fibre optic cable for conducting light reflected from the amniotic fluid to spectral analysis means, said cell also having shielding means to shield the fibre optic cable from any light scattered by the wall of the uterus or the fetus.

Preferably, the probe has a flattened form and is designed so that the generally flat faces of the probe

contact the fetus on one side and the wall of the uterus on the other. With such a design, the entry to the optical cell for amniotic fluid is via the sides which are generally at right angles to the flattened faces of the probe and the optical cell within the probe is shielded by flattened portions of the sides of the probe. It is also preferred that the optical cell has at least two apertures so that amniotic fluid can flow freely through the optical cell.

One embodiment of the present invention will now be described with reference to the accompanying drawings, in which:-

Figure 1 is a general arrangement showing the layout of the system;

Figure 2A is a side elevation of the tip of the probe;

Figure 2B is an end view of the tip of the probe; and

Figure 2C is a view of the tip of the probe seen in the direction of the arrow A in Figure 2A.

The system layout is similar to that described in our above PCT application and incorporates a flexible probe 1 which is linked by fibre optic cables 2 and 3 respectively to a broad spectrum light source such as a tungsten halogen lamp or a xenon arc lamp. A xenon arc lamp is preferred since it is rich in radiation around the 405-415 nm band which includes the meconium absorption peak.

Fibre optic cable 3 is connected to spectral analysis equipment 5 for measuring back scattered light from the amniotic fluid. A typical system is the Monolight Optical Spectrum Analyser System 6800, manufactured by Monolight Limited of Weybridge, Surrey. This system consists of a diffraction grating with an input slit width of 0.89 mms achieving a band width resolution of 10 nm and has a photomultiplier tube with a variable output gain and a 12 bit analogue to digital converter. The converter is connected to an IBM PC and the results displayed on the screen. The spectra of the back scattered light were measured in the range of 300 to 900 nm. The probe may also include a pressure sensor and/or electrodes, e.g. as described in UK Patents Nos. 2195897 and 2216904 and EP No. 0325605, and the data collected, i.e. fetal heart rate and intrauterine pressure displayed on the screen or on a separate monitor 7.

The fibre optic cables 2 and 3 were merged together in the body of the probe 1 to form a merged bundle 10 which terminated at one end of the optical cell 11. The other end 12 of the optical cell opposite to the ends of the fibre optic cable constitutes a "beam dump" and forms a cavity having sides forming an approximate right angle. This shape and the black colouration of the probe body ensures that light striking end 12 of the cell, e.g. light entering from the transmission part of the fibre optic

bundle is efficiently absorbed and not reflected back into the receptor fibres of the cable.

As shown, the sides of the optical cell comprise a pair of strip-like shielding members 13 which ensure that any light reflected from the uterine wall against which the face 14 or 15 may be pressed is not reflected into the end of the fibre optic bundle 16. In the embodiment illustrated the members 13 are formed separately from the body of the probe and are bonded to the distal end and the main body of the probe to form the optical cell. Alternatively, of course, the parts 13 may be constructed integrally with the body of the probe (e.g. as a moulding or extrusion). It is, however, thought to be advantageous that the entry to the apertures 17 and 18 are recessed from the general upper surface 19 of the probe body. It is believed that in the uterus during labour the amniotic fluid may be trapped in pools between portions of the uterine wall and the fetus and the design shown in Figures 2A to 2C tends to encourage amniotic fluid to flow along the surfaces 19 of the probe and into the optical cell.

Half the fibres in the silica optic fibre bundle of approximately 1000 fibres were randomly chosen for transmitting light and the others to receive light back scattered from the amniotic fluid. The fibre bundle was encapsulated in the body of the intrauterine probe with its tip 16 emerging at one end of the optical cell 11,

approximately 50 mms from the tip of the probe.

The thickness of the probe body was approximately 4 mms and was made from polyurethane with a total length of about 400 mms and a width of about 14 mms.

The thickness of the shielding parts 13 was about 1 mm and in the design shown in the attached drawings was formed from hard PVC so as to be stiff and not to allow significant distortion of the cell during use. The cell itself was approximately 1 cm long.

Other features of the probe may be as described in our above PCT application.

CLAIMS:-

1. An intrauterine probe which comprises a flexible body which houses an optical cell, said cell including at least one aperture permitting the entry of AF and being connected at one end to a fibre optic cable, for conducting light reflected from the AF to spectral analysis means, said cell having shielding means to shield the fibre optic cable from any light scattered by the wall of the uterus or the fetus.

2. A probe according to claim 1 in which the probe has a generally flattened form so that in use one of the flat faces of the probe contacts the wall of the uterus.

3. A probe according to claim 2 in which the shielding means are generally planar with the faces of the probe.

4. A probe according to claim 2 or claim 3 in which the generally flat faces of the probe include one or more longitudinal ribs.

5. A probe according to any one of the preceding claims in which the aperture opens into a surface of the probe which in use faces away from the uterine wall.

6. A probe according to any one of the preceding claims in which there are at least two apertures thereby facilitating a flow of amniotic fluid through the cell.

Amendments to the claims have been filed as follows

1. An intrauterine probe which comprises a flexible body which houses an optical cell, said probe including at least one aperture permitting the entry of amniotic fluid (AF) and being connected at one end to a fibre optic cable, for conducting light reflected from the AF to spectral analysis means, said probe having shielding means to shield the fibre optic cable from any light scattered by the wall of the uterus or the fetus.

2. A probe according to claim 1 in which the probe has a generally flattened form so that in use one of the flat faces of the probe contacts the wall of the uterus.

3. A probe according to claim 2 in which the shielding means are generally planar with the faces of the probe.

4. A probe according to claim 2 or claim 3 in which the generally flat faces of the probe include one or more longitudinal ribs.

5. A probe according to any one of the preceding claims in which the aperture opens into a surface of the probe which in use faces away from the uterine wall.

6. A probe according to any one of the preceding claims in which there are at least two apertures thereby facilitating a flow of amniotic fluid through the cell.

7. A system for monitoring the content of amniotic fluid during labour which comprises a probe as claimed in

any one of the preceding claims which is connected optically to a source of light (having a suitable spectral bandwidth), and to photodetecting means for detecting the spectral response of the amniotic fluid to illumination with said source and processing means for determining the presence of meconium and/or blood in the amniotic fluid by analysis of the spectral response.

Patents Act 1977
Examiner's report to the Comptroller under Section 17 (The Search Report)

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Relevant Technical fields

(i) UK Cl (Edition L) G1A (AAM)

(ii) Int Cl (Edition 5) A61B 5/00; G01N 21/01

Search Examiner
R S CLARK

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASES: WPI, INSPEC

Date of Search
10 SEPTEMBER 1993

Documents considered relevant following a search in respect of claims

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	WO 92/00699 A1 (IMPERIAL COLLEGE) pages 10 and 11	1,2,5,6

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

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