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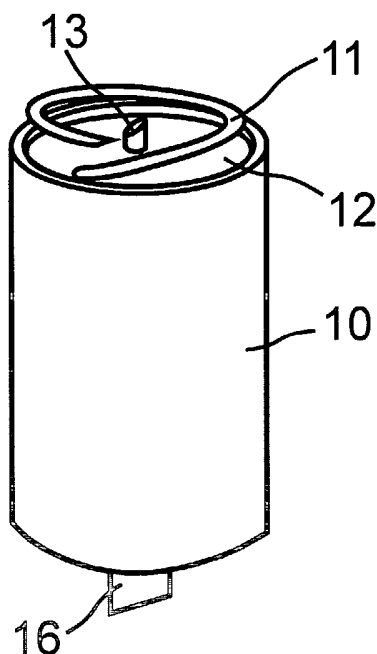
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- Published:**
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- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: A DEVICE AND A METHOD FOR MONITORING A FOETUS



(57) Abstract: Device for foetal temperature measuring, wherein a temperature sensing micro sensor (13) is combined with a scalp electrode (10). The temperature measuring and a recording of CTG are performed simultaneously with a common device (10; 13).



WO 03/088837 A1

A device and a method for monitoring a foetus**BACKGROUND**

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In connection with maternity care there is a need for measuring the foetal temperature during delivery. In this connection there has been a discussion whether different factors, such as the CTG pattern, PH value, lactate and medication of the mother, different states of ill-health etc., possibly can be correlated to the foetal temperature, and also to a possible temperature difference between mother and foetus.

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PRIOR ART

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Many attempts already made for measuring foetal temperatures have failed, mainly because the measured quantity rather being the temperature of the mother. There have also been suggested detailed and not exactly methods that have not given the desired results. An object of the present invention is to provide a device that can be used to obtain in a secure and simple way the foetal temperature.

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SUMMARY OF THE INVENTION

In accordance with the invention existing techniques from two different areas have been combined, and as a result a secure and compact measuring apparatus is presented. One basic element included is a so called scalp electrode which has been available and in use for at least 20 years. Normally, a scalp electrode is used for measuring purposes in connection with a CTG device (cardiotocograph) indicating among other things the foetal heart rate and together with a tocodynamometer also uterine contractions. In accordance with the invention the scalp electrode is used also for positioning a temperature transducer. A specifically designed micro sensor, also included in the temperature transducer, forms a second basic element. Said micro sensor preferably is insulated and designed for measuring the temperature in real time with high accuracy.

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By combining the scalp electrode and the temperature transducer the invention can be used in practice in line with previously known methods of working by the personnel also henceforth. Thus, no further education of the personnel is required in

this respect. Also, the use will be cost-efficient because no further education is required and because the sensor can be produced together with other components of the scalp electrode.

5 The device in accordance with the invention readily can be implemented together with existing monitoring equipment. It will also produce needed foetal information in a way corresponding to information from other categories of patients. The combined device including a scalp electrode and a micro sensor will be very stable mechanically and thus improve the reliability. In use existing personnel can continue to use existing techniques for the placement of the combined device. The scalp electrode can be provided with an electrode tip that in use is inserted under the foetal skin.

BRIEF DESCRIPTION OF THE DRAWINGS

15 The invention will be further described below by means of embodiments with reference to the accompanying drawings in which

- Fig. 1 is a schematic side elevational view of a device in accordance with one embodiment of the invention,
- 20 Fig. 2 is a schematic perspective view of the device in Fig. 1,
- Fig. 3 is a schematic perspective view, partly in a longitudinal section, of the device in Fig. 1 somewhat enlarged, and
- Fig. 4 is a schematic perspective view of an alternative embodiment of an electrode tip of the scalp electrode.

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DETAILED DESCRIPTION

Fig. 1 and Fig. 2 show a practical embodiment of a device in accordance with the invention. In the embodiment shown a standard type scalp electrode 10 is used.

30 The scalp electrode is designed as a circularly cylindrical solid body and is in a first end provided with a helix electrode tip 11. The helix electrode tip 11 extends from an embedded circular section 12 in said first end.

In a central position of the embedded section 12 there is provided a micro sensor 13 for measuring the temperature. The micro sensor is connected to a temperature measuring device 14 over a measuring wire 15. The micro sensor 13 is de-

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signed for real time measuring. One end of the sensor is pointed and extends approximately only 1 mm, thus not being able to harm the foetus. As shown in Fig. 1 the pointed end is located below an upper section of the electrode tip and can be formed as a conventional needle point or a specifically formed needle point, cf. also Fig. 3. A temperature transducer is arranged in the needle point. Preferably the temperature transducer comprises a thermocouple. Data measured by the temperature measuring device 14 can be stored in databases in the temperature measuring device or in another storing unit connected thereto, such as a computer 24. It is possible also to transfer measured data continuously or gradually to another device for analysis.

In a conventional manner the scalp electrode 10 can be provided with an earth terminal 16. A twisted pair wire 17 connects in a conventional manner the electrode tip and the earth terminal, respectively, to a measuring apparatus, which can be integrated with the temperature measuring device 14. As an alternative said earth terminal 16 can be connected to an outer lead in the measuring wire 15.

The perspective view in Fig. 2 shows in more detail the helix electrode tip 11 and the micro sensor 13 located in a central position inside the electrode tip. Also the circularly cylindrical shape of the scalp electrode 10 is shown. The micro sensor 13 can be arranged correspondingly with other types of scalp electrodes. In the shown embodiment the earth terminal 16 is formed as a flat plate extending to some extent outside the scalp electrode and centrally through the major part thereof.

Fig. 3 shows in more detail one embodiment of the micro sensor 13 situated in the scalp electrode 10. The micro sensor 13 comprises in this embodiment a tipped end shaped as a conventional needle point 18, which is located centrally in the embedded circular section 12. The helix electrode tip 11 forms a circular protection around and above the micro sensor 13.

Inside the needle point 18 there is provided a temperature transducer 19. Preferably a soldered seam 20 made by silver or a similar material connects the temperature transducer 19 to the needle point 18. The measuring wire 15 extends from the temperature transducer 19 and in the shown embodiment the measuring wire 15 is formed by a shielded cable having an inner conductor 21 and a grounded outer conductor 22. An embodiment with a shielded and grounded measuring wire

will ensure that the temperature measuring process and the CTG measuring process will not interfere.

The measuring wire 15 runs through an opening 23 extending from a bottom of the scalp electrode 10 opposite the embedded section 12 to a lower section of the needle point 18. The orientation and length of the opening 23 may vary in dependence of the design of the scalp electrode 10 and the earth terminal 16.

Fig. 4 shows schematically a modified electrode tip 24. In this embodiment a modified temperature transducer 25 is integrated in the modified helix electrode tip 24. Thus, no separate needle point for the temperature measuring has to be provided. In other aspects this embodiment corresponds to what was mentioned above.

When applying the scalp electrode the temperature transducer 19 will penetrate, in a preferred embodiment, the foetal skin and also will press with some pressure on the foetal skull. As a result of penetrating the skin it is prevented that amniotic fluid or a part of the body of the mother has an influence on the recording of temperature data. The fixed positioning normally provided by the scalp electrode will ensure that also the temperature transducer is positioned. In other embodiments the micro sensor can be bevelled and be forced to engage at some pressure the foetal scalp in connection with the scalp electrode being screwed under the foetal scalp skin.

A further improvement of the monitoring possibilities can be achieved by connecting at least one further temperature transducer to the temperature measuring device 14. The further temperature transducer should be thermally connected to the mother, who can be monitored continuously. Temperature data from the foetus also can be combined with temperature data from the mother and as a result it will be possible to discover relations between different courses of events and types of diseases on one hand and the temperature data on the other hand. Similar advantages can be obtained by combining the device and the method in accordance with the invention with a device and a measuring method for measuring the foetal oxygen level (pulse oximetry).

CLAIMS

1. Device for foetal temperature measuring, *characterised* in
5 that a temperature sensing micro sensor (13) is combined with a scalp electrode
(10).
2. Device in accordance with claim 1, wherein said scalp electrode (10) com-
prises a projecting helix electrode tip (11) and wherein said micro sensor (13) is pro-
10 vided in a central position inside said projecting helix electrode tip.
3. Device in accordance with claim 1, wherein said scalp electrode (10) com-
prises a projecting helix electrode tip (11) and wherein said micro sensor (13) is inte-
grated with said projecting helix electrode tip.
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4. Device in accordance with claim 1, wherein said micro sensor (13) is opera-
tively connected to a temperature measuring device (14) for measuring temperatures
in real time.
- 20 5. Device in accordance with claim 4, wherein said temperature measuring de-
vice (14) is connected to a storing device for storing measured data in a database.
6. Device in accordance with claim 1, wherein said micro sensor (13) com-
prises a pointed end (18) projecting from the scalp electrode (10).
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7. Device in accordance with claim 1, wherein said micro sensor (13) com-
prises a temperature transducer (19) arranged thermally in contact with said pointed
end (18).
- 30 8. Device in accordance with claim 7, wherein said temperature transducer
(19) is soldered to a needle point forming said pointed end (18).
9. Device in accordance with claim 1, wherein said temperature transducer
(19) is a thermocouple.

10. Device in accordance with claim 4, wherein a shielded measuring wire (15) connects said micro sensor (13) to said temperature measuring device (14).

5 11. Method for foetal temperature measuring, *characterised* by performing the temperature measuring and a recording of CTG simultaneously with a common device (10; 13).

10 12. Method in accordance with claim 11, further including the step of placing a scalp electrode in contact with the foetal scalp while simultaneously inserting a temperature sensing micro sensor (13) partially under the skin of the foetal scalp.

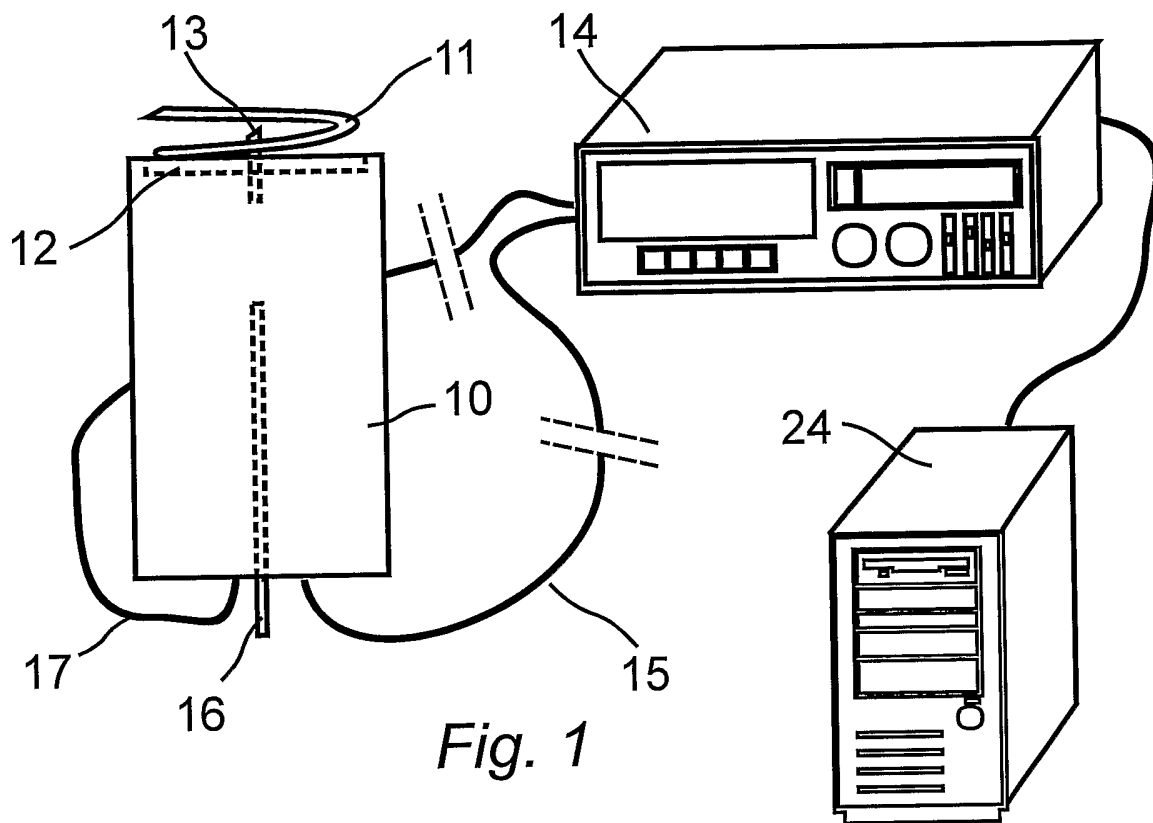


Fig. 1

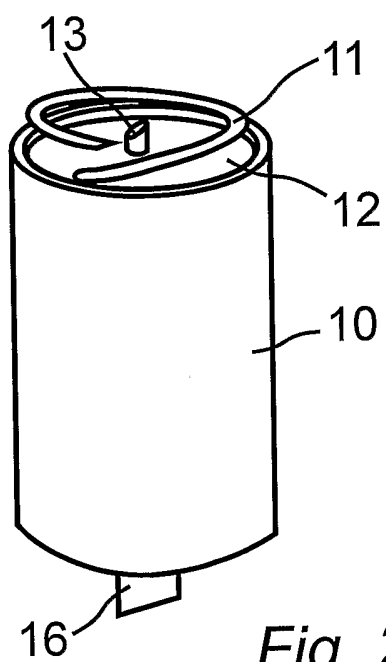


Fig. 2

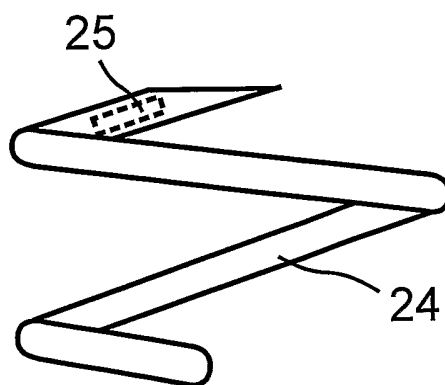
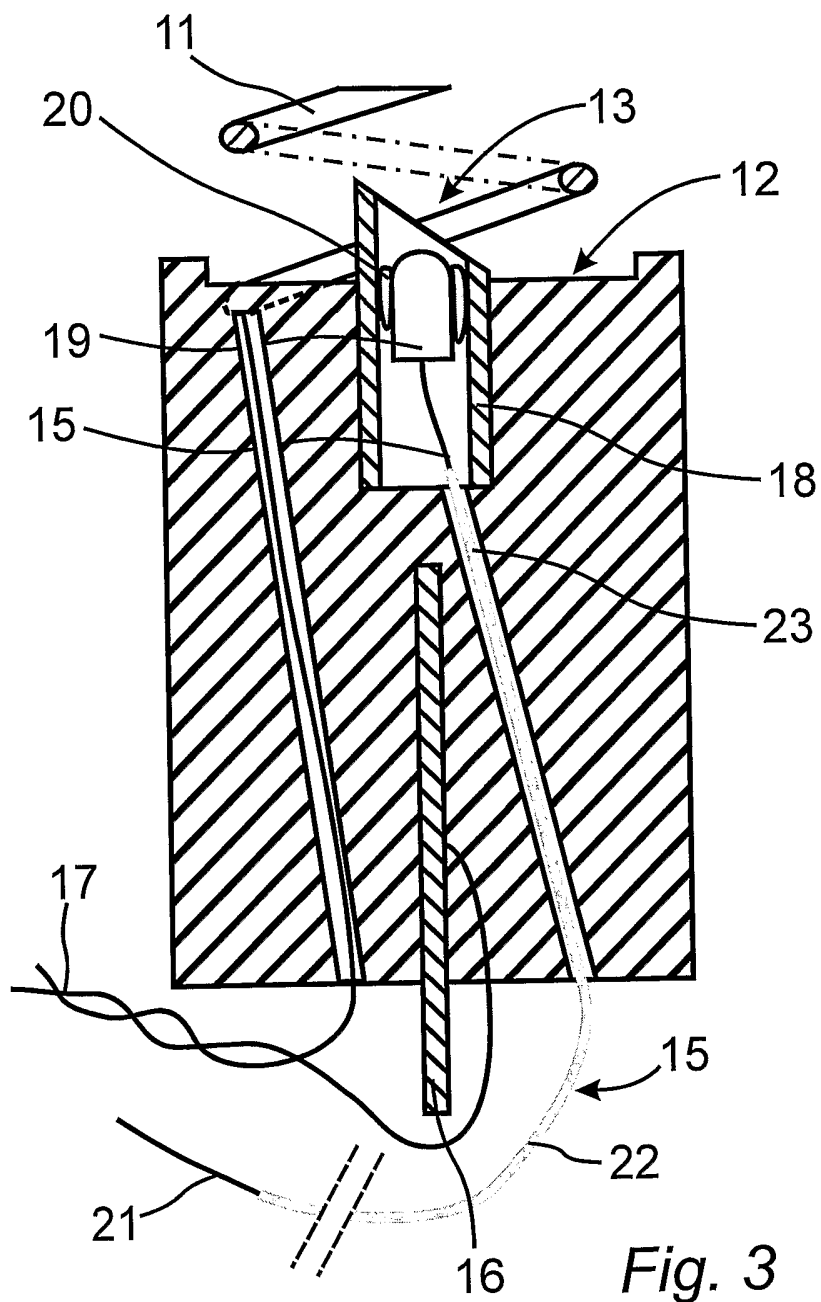


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 02/01666

A. CLASSIFICATION OF SUBJECT MATTER		
IPC7: A61B 5/01, A61B 5/0205 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)		
IPC7: A61B, G01K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
EPO-INTERNAL, WPI DATA, PAJ, INSPEC, MEDLINE, BIOSIS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4488558 A (SIMBRUNER ET AL), 18 December 1984 (18.12.84), column 3, line 49 - line 52; column 5, line 43 - line 46, claim 5, abstract	1-10
A	--	11-12
A	EP 0839496 A1 (GRAPHIC CONTROLS CORPORATION), 6 May 1998 (06.05.98), column 7, line 34 - line 42, abstract	1-12
A	GB 2216804 A (ST MARY'S HOSPITAL MEDICAL SCHOOL), 18 October 1989 (18.10.89), abstract	1-12
	--	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "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 "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "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		Date of mailing of the international search report
2 December 2002		16-12-2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer SOFIE CARLSSON/BS Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 02/01666

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5425362 A (SIKER ET AL), 20 June 1995 (20.06.95), column 2, line 58 - line 69, abstract --	1-12
A	US 5373852 A (HARRISON ET AL), 20 December 1994 (20.12.94), column 13, line 13 - line 26; column 14, line 15 - line 34, abstract -----	11-12

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **11-12**
because they relate to subject matter not required to be searched by this Authority, namely:
see next sheet

2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

Claims 11-12 disclose a method that comprises introducing an instrument into the vagina, cervix, or womb of a woman and affixing an invasive scalp electrode on a fetus. Accordingly, claims 11-12 relate to a surgical method. Thus, the International Search Authority is not required to carry out an international search for these claims (Rule 39.1(iv)). Nevertheless, a search has been executed for claims 11-12.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

28/10/02

PCT/SE 02/01666

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
US	4488558	A	18/12/84	AT	267881 A	15/11/82
				AT	371326 B	27/06/83
				DE	3277059 D	00/00/00
				EP	0069113 A,B	05/01/83

EP	0839496	A1	06/05/98	CA	2217666 A	30/04/98
				US	5833622 A	10/11/98

GB	2216804	A	18/10/89	AU	618252 B	19/12/91
				AU	1440888 A	12/10/89
				CA	1328123 A	29/03/94
				DE	3789446 D,T	30/06/94
				EP	0325605 A,B	02/08/89
				GB	2195897 A,B	20/04/88
				GB	8906582 D	00/00/00
				JP	2579657 B	05/02/97
				JP	3504441 T	03/10/91
				US	5025787 A	25/06/91
				WO	8802616 A	21/04/88
GB	8807482 D	00/00/00				

US	5425362	A	20/06/95	AU	7368094 A	28/02/95
				EP	0711125 A	15/05/96
				WO	9503738 A	09/02/95

US	5373852	A	20/12/94	NONE		
