

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
16 February 2006 (16.02.2006)

PCT

(10) International Publication Number  
WO 2006/017004 A1

(51) International Patent Classification<sup>7</sup>:

A61B 5/00

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(21) International Application Number:

PCT/US2005/022670

(22) International Filing Date: 28 June 2005 (28.06.2005)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/521,814 7 July 2004 (07.07.2004) US

(71) Applicant (for all designated States except US): OBSTECARE INC. [US/US]; Fasth Law Offices, 26 Pinecrest Plaza, Suite 2, Southern Pines, , North Carolina 28387-4301 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): ITZEL, Johan [SE/SE]; Ridvagen 14, S-182 39 Danderyd (SE). ITZEL, Eva [SE/SE]; Ridvagen 14, S-182 39 Danderyd (SE).

(74) Agent: FASTH, Rolf; Fasth Law Offices, 26 Pinecrest Plaza, Suite 2, Southern Pines, North Carolina 28387-4301 (US).

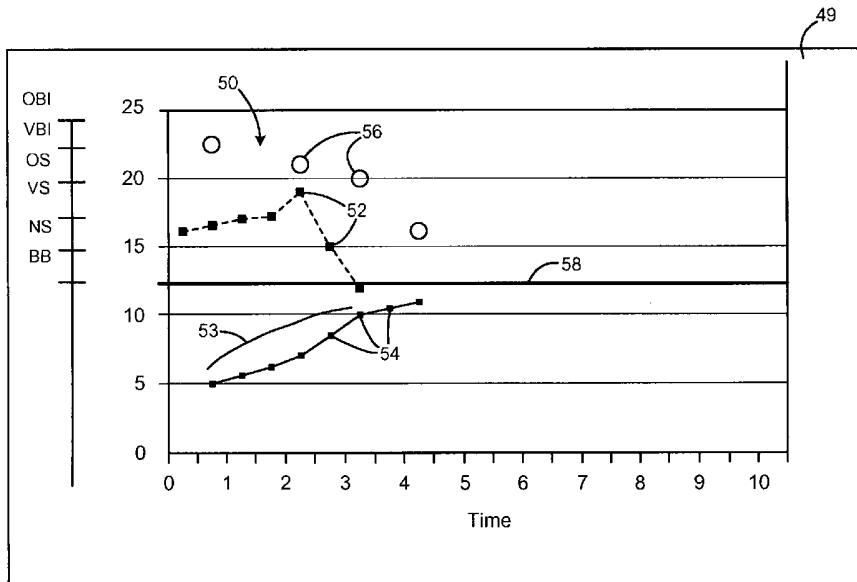
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

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: METHOD FOR MONITORING A CHILDBIRTH PROCESS



(57) Abstract: The method is for monitoring a childbirth process of a pregnant woman. A plurality of cervix dilatation data (56) and fetal positioning data (54) are obtained and fed to a device (49). A plurality of lactate concentrations (52) is measured at time intervals. The measured lactate concentrations (52) are shown on a display (50) of the device (49) at the time intervals to show a trend of the lactate concentrations (52). The cervix dilation data (56) and the fetal positioning data (54) are also shown on the display (50). The lactate concentrations (52) are evaluated to determine whether the lactate concentrations (52) are rising to indicate that an individual lactate threshold value (58) of the pregnant woman has been exceeded. The medical practitioner may also evaluate the cervix dilation data (56) and the fetal positioning data (54).

WO 2006/017004 A1

METHOD FOR MONITORING A CHILDBIRTH PROCESSTechnical Field

5        The present invention relates to a method for monitoring a childbirth process of a pregnant woman.

Background of the Invention

10      One problem in today's delivery methods is that women suffer from dystocya during labor. This could result in that the delivery does not progress as desired and that the labor is drawn out without a successful natural childbirth. The pregnant woman may become frustrated and it may be necessary to use methods such as, vacuum, forceps or caesarean to 15 deliver the baby. The dystocya of the pregnant woman may also expose the fetus to injury and fatigue.

20      The lactate concentration in the blood of the fetus has been measured in the past to control that the fetus does not suffer from oxygen deficiency. However, the lactate concentration in the fetus does not indicate the condition of the pregnant woman. There is a need to more effectively determine and control the condition of woman suffering from dystocya at an early stage to avoid unnecessary labor before using surgical and alternative childbirth methods.

25      There is also a need for an effective apparatus to be able to determine the above-outlined conditions. In addition to the above needs, the apparatus should also handle at least cervix dilatation data, fetal positioning data and fetal lactate and pH measurements. Apart from measuring, entering 30 and displaying the information from the respective methods and sensors, the apparatus should provide a decision guiding function. The decision function should provide the tending obstetrician and midwife advice on how to act in different situations. The advice should be based on established science.

The advice should include functions to prompt for needed measurements and to prompt for new measurements after a given time. It should also indicate needed actions like early instrumental delivery.

5

#### Summary of the Invention

The method of the present invention provides a solution to the above-outlined problems. More particularly, the method is for monitoring a childbirth process of a pregnant woman. A plurality of cervix dilatation data and fetal positioning data are obtained and fed to a measurement and/or presentation device. A plurality of lactate concentrations is measured at time intervals. The measured lactate concentrations are shown on a display of the device at the time intervals to show a trend of the lactate concentrations. The cervix dilation data and the fetal positioning data are also shown on the display. The lactate concentrations are evaluated to determine whether the lactate concentrations are rising to indicate that an individual lactate threshold value of the pregnant woman has been exceeded. The medical practitioner may also evaluate the cervix dilation data and the fetal positioning data.

#### Brief Description of the Drawing

25 Fig. 1 is a schematic flow chart showing some of the steps of the method of the present invention; and

Fig. 2 is a schematic illustration of graphical representation of measured data.

#### 30 Detailed Description

With reference to Fig. 1, the method 10 of the present invention includes a measuring step 12 that measures a lactate concentration 15a in fluids, such as vaginal fluids, in connection with pregnancy to determine whether the amniotic

fluids have passed or are in the process of being passed from the amnion. In general, the uterus muscle of pregnant women produces lactate so that the lactate concentration of the vaginal fluids may be measured to provide a measurement of the 5 amount of lactate produced by the uterus muscle. Non-pregnant women often have no or very little lactate in the vaginal fluids.

If the lactate concentration 15a is higher than a predetermined lactate concentration 13, such as 4-5 mmol/l, 10 more preferably higher than 4.5 mmol/l, as indicated in a comparison step 14 then it may be concluded that the membrane has ruptured and amniotic fluids likely have passed and that the childbirth labor is likely to start after a waiting period 16. It is to be understood that the 4-5 mmol/l is an 15 illustrative example that applies to most women and that the invention is not limited to the values used in the examples.

If the lactate concentration is lower than 4.5 mmol/l then there is a high likelihood that the amniotic fluids are still contained within the amnion. The lactate concentration 20 may again be measured in a measuring step 20 after a waiting period 18. It is again determined in the comparison step 14 whether the lactate concentration is more or less than 4.5 mmol/l. If the lactate concentration is again below 4.5 mmol/l, a second measuring may be conducted later and the 25 measuring may be repeated at suitable time intervals until the lactate concentration exceeds 4.5 mmol/l or it is obvious that the amniotic fluids have passed.

As indicated above, if the lactate concentration measured in the measuring step 12 is above 4.5 mmol/l, the 30 next step is to wait for about two days or so to see if the woman starts the labor by herself. In a determining step 22, it is determined whether the labor has started or not. If the labor has started and is progressing normally then the childbirth procedure 24 may proceed. If it is determined in

the determining step 22 that the labor has not started or the labor is not progressing normally, a lactate concentration 15b is measured in a measuring step 26.

In a comparison step 28 it is then determined if the lactate concentration 15b as measured in the measuring step 26 is within a lactate threshold interval 29 that may be about 8-10 mmol/l. If the lactate concentration as measured in the step 26 is not within the threshold interval 29, then it is determined in a comparison step 30 whether the lactate concentration is less than the threshold interval 29 or about 8 mmol/l. If the lactate concentration as measured in step 26 is greater than the threshold interval 29 then a waiting step 32, such as a couple of hours, may start to see if the labor progress normally. If labor does not progress normally, alternative childbirth options may be considered such as caesarean, forceps or the use of suction cups that are connected to vacuum to draw out the baby. An important feature of the present invention is that the monitoring of the lactate concentration may be used to predict whether the woman is likely to give a natural birth or not without forcing the pregnant woman to go through long and agonizing efforts to give birth. It is therefore possible to use alternative childbirth options at a relatively early stage. It is to be understood that the 8-10 mmol/l is an illustrative example that applies to most women and that the invention is not limited to the values used in the examples.

If the lactate concentration, as measured in step 26, is less than the threshold interval 29, then the woman may be stimulated with drugs or other aids to give birth in a stimulation step 34. In a determining step 36, it may be determined if the labor is progressing normally. If the labor is progressing normally the woman may proceed to give birth 38. If the labor is not progressing normally, the lactate concentration may again be measured in the measuring step 26

and the process continues in the comparison step 28, as described above.

If it is determined in the comparison step 28 that the lactate concentration, as measured in step 26, is at the 5 threshold interval 29, such as between 8-10 mmol/l, then it is determined whether the labor is progressing normally in a determining step 40. If labor is progressing normally, the woman may proceed to give birth 42. If labor is not progressing normally, the woman may be stimulated to give 10 birth in the stimulation step 34 and the process continues to the determining step 36, as described above.

The various processing loops may continue until the woman either gives birth by herself or is subjected to alternative childbirth options. As indicated above, an 15 important feature of the present invention is that the woman may be prevented from agonizing and long childbirth efforts before alternative childbirth options are used. Alternative childbirth options may be used at an earlier stage when the lactate concentration indicates that the uterus muscle is 20 operating above the lactate threshold without resulting in a natural childbirth.

Another important feature of the present invention is to use a measuring and presentation device to effectively 25 present the measured lactate values together with the time lapsed. The depicted time intervals could be both on a relative time (time from start) or absolute time (time of day) to indicate the trends of the measured lactate values. In addition, the device may also be used to measure lactate levels in the fetus such as in the scalp blood of the fetus. 30 The device may also be used to present the how far down in the pelvis the head of the fetus has penetrated and the dilation of the cervix.

Fig. 2 is a display 50 is an illustrative example that shows lactate data 52 of the pregnant woman over time,

lactate data 53 of the fetus, cervix dilation data 54 and fetal head positioning data 56. For example, the lactate data 52 shows an upward trend until the addition of stimulation substances to the pregnant woman is turned off and the lactate 5 level is dramatically reduced. Because the display 50 shows that the lactate levels of the woman is already very high and rising, such as values above 15 mmol/l, the medical practitioners may learn that there is no longer a need to provide stimulation to the pregnant woman. In this way, the 10 display 50 may be used to prevent the misuse of stimulating substances. The medical practitioner may also use the trends indicated by the data 53, 54, 56 so that the practitioner can see all the data together and take all the information into account before making a decision about what action to take 15 including medication required and the need for performing a caesarian or any other such aided child birth. For example, the cervix dilation data 54 may be compared to a normal cervix dilation curve 55 that applies to most women. The medical practitioner may also use the display 50 to see how the 20 pregnant woman and fetus are reacting to treatment.

The practitioner may take a plurality of measurements of the lactate concentrations 52 at time intervals. The measured lactate concentrations 52 are then presented at the time intervals on the display 50. The lactate concentrations 25 52 are evaluated to determine whether the lactate concentrations 52 are rising to indicate that an individual lactate threshold value 58 of the pregnant woman has been exceeded. To be able to determine that the individual lactate threshold has been exceeded is particularly important for 30 women who have an unusually high or low lactate threshold.

All the data 52, 53, 54, 56 and other data that have been displayed on the display 50 may be saved for later retrieval together with information of the time the data was measured. The data may be stored together with patient

information. This data may be electronically transferred to remote equipment such as electronic medical records by using wireless or wired communication. The device may also be equipped with an automatic decision guiding and alarm system

5 that is based on measured lactate values from mother, measured fetal lactate values, measured fetal pH values. The system may also base decisions and alarms on the opening size of cervix and the progression of the fetus head in the pelvis. Of course, a combination of the above information may be used.

10 The device should be designed so that it can handle several childbirth processes at the same time in the same device. The stored data in the device may have the ability to enter and present the measured data in electronic medical records.

While the present invention has been described in accordance with preferred compositions and embodiments, it is to be understood that certain substitutions and alterations may be made thereto without departing from the spirit and scope of the following claims.

## Claims:

1. A method of monitoring a childbirth process of a pregnant woman, comprising:

measuring a plurality of lactate concentrations of amniotic

5 fluid at time intervals;

showing the measured lactate concentrations to show a trend of the lactate concentrations for evaluating a childbirth process.

10 2. The method according to claim 1 wherein the method further comprises evaluating the lactate concentrations to identify a trend.

15 3. The method according to claim 1 wherein the method further comprises determining whether the lactate concentrations are rising to indicate that an individual lactate threshold value of the pregnant woman has been exceeded.

20 4. The method according to claim 2 wherein the method further comprises using the trend as a mean to decide how to administer stimulating substances to the pregnant woman.

25 5. The method according to claim 1 wherein the method further comprises measuring lactate concentrations in blood of a fetus at time intervals and presenting the lactate concentration from the fetus simultaneously with the lactate concentration from the pregnant woman.

30 6. The method according to claim 1 wherein the method further comprises obtaining a plurality of cervix dilatation data, feeding the cervix dilatation data to a device and showing the cervix dilation data on a display.

7. The method according to claim 1 wherein the method further comprises obtaining a plurality of fetal positioning data, feeding the fetal positioning data to a device and showing the fetal positioning data on a display.

5

8. The method according to claim 1 wherein the method further comprises presenting the lactate concentration from the pregnant woman simultaneously with a presentation of lactate concentration from a fetus, the cervix dilation data and fetal positioning data on a display.

10

9. The method according to claim 8 wherein the method further comprises storing data and later retrieving the data together with time of measurement of the data.

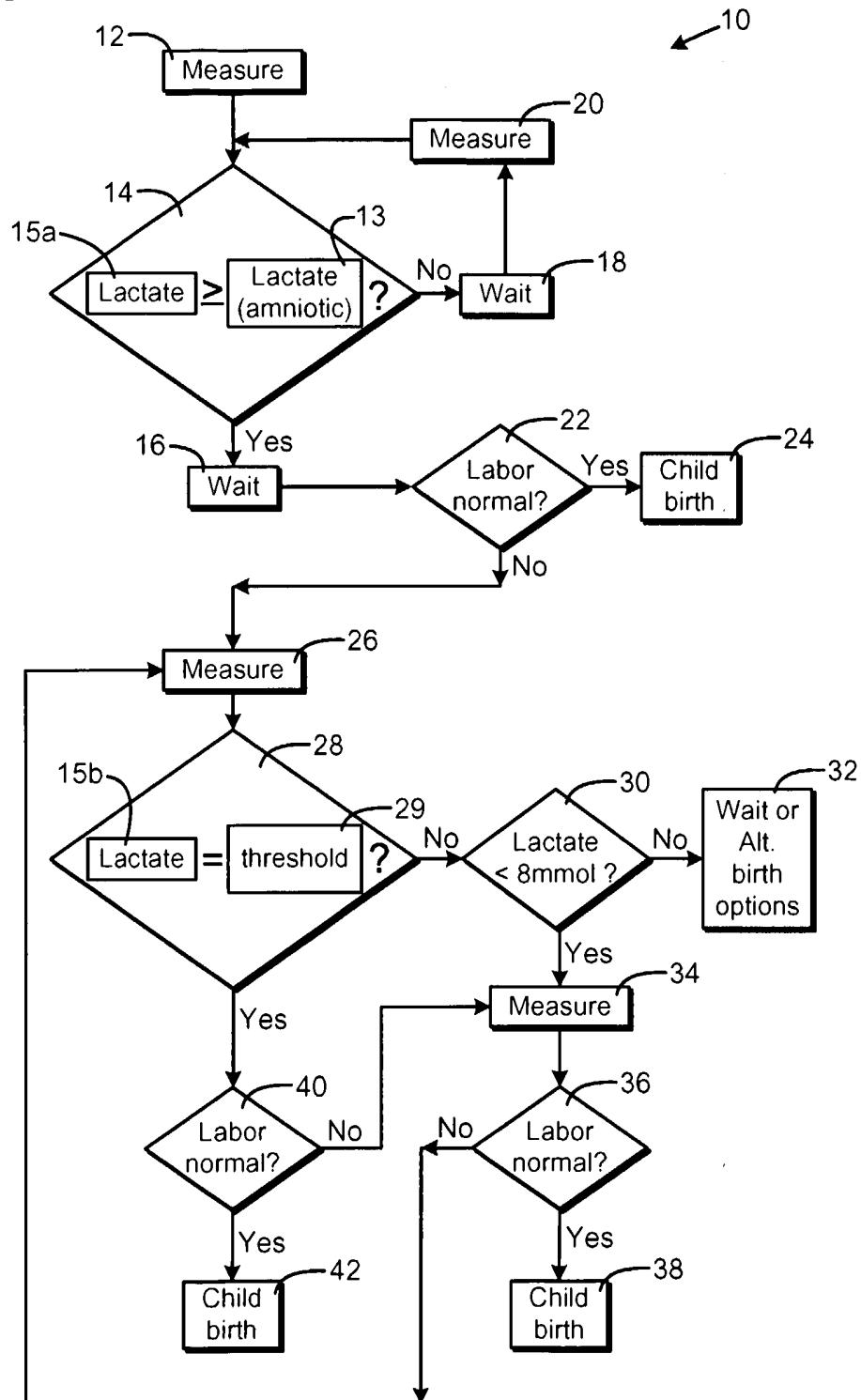
15

10. The method according to claim 9 wherein the method further comprises storing and presenting the data in electronic medical records.

20

1/2

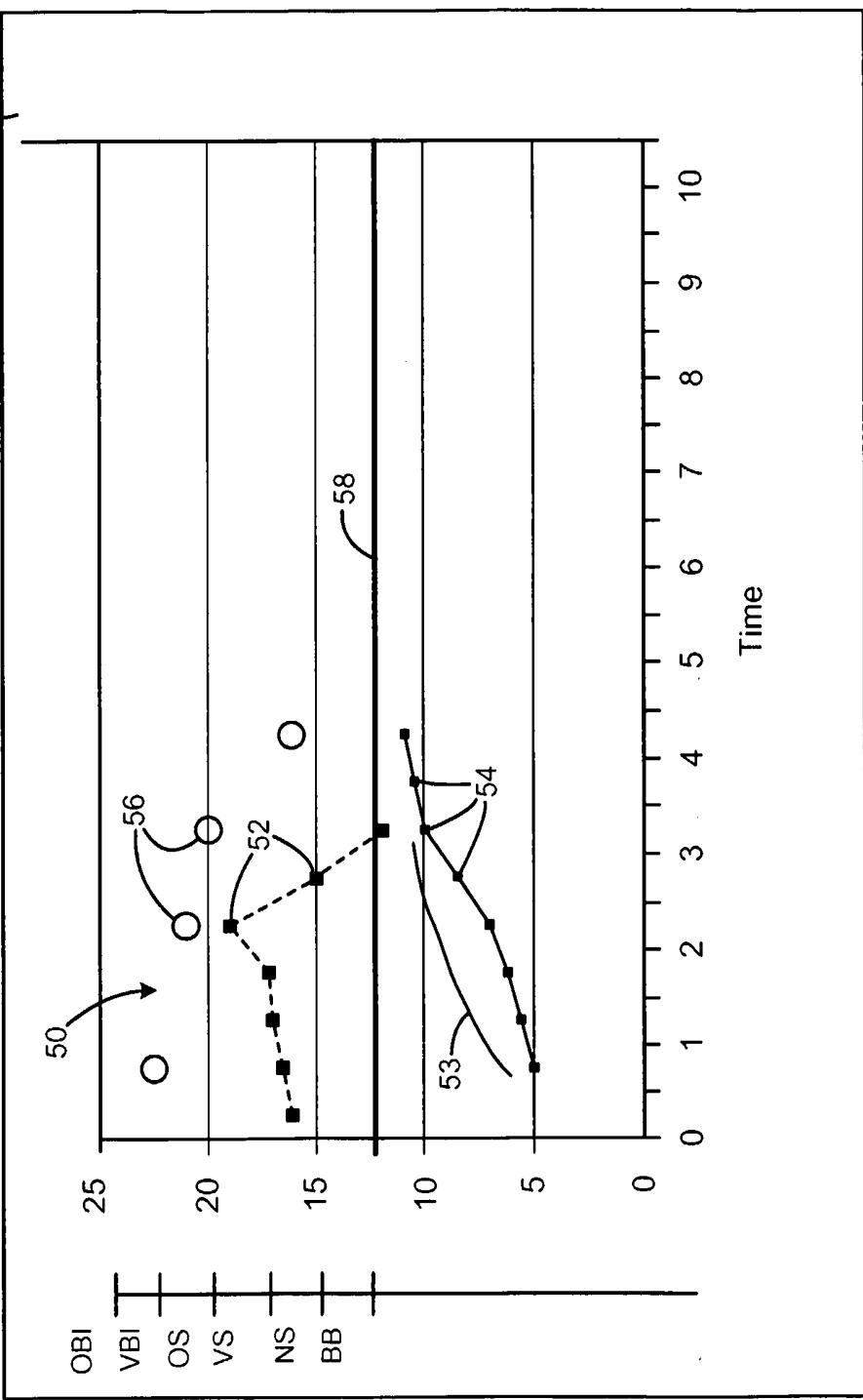
FIG. 1



2/2

49

FIG. 2



# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/22670

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61B 5/00  
US CL : 600/309

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)  
U.S. : 600/309,310,322,513,519,520,551;482/5,8,900;514/557,558

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 practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,951,680 A (Kirk et al.) 28 August 1990 (28.08.1990), column 1, line 30 - column 10, line 15.	1-10
A	US 5,377,673 A (Van Dell et al.) 3 January 1995 (03.01.1995), column 3, line 9 - column 6, line 56	1-10
A	US 2004/0100376 A1 (Lye et al.) 27 May 2004 (27.05.2004), [0006] - [0177].	1-10
A, P	WO 2005/034762 A1 (Obstecare inc.) 21 April 2005 (21.04.2005), entire document.	1-10

Further documents are listed in the continuation of Box C.

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	"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
"E" earlier application or patent published on or after the international filing date	"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
"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)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

30 August 2005 (30.08.2005)

Date of mailing of the international search report

13 OCT 2005

Name and mailing address of the ISA/US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (703) 305-3230

Authorized officer  
**FOR:**  
Max Hindenburg  
Telephone No. (571)272-3700

  
MONICA A. GRAVES