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(12) **United States Patent**
Ray

(10) **Patent No.: US 9,757,058 B2**
(45) **Date of Patent: Sep. 12, 2017**

(54) **SYSTEMS, DEVICES, AND METHODS FOR PERFORMING TRANS-ABDOMINAL FETAL OXIMETRY AND/OR TRANS-ABDOMINAL FETAL PULSE OXIMETRY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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A61B 5/1455 (2006.01)
A61B 5/145 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/14552*** (2013.01); ***A61B 5/0011*** (2013.01); ***A61B 5/01*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/0002; A61B 5/0059; A61B 5/1455; A61B 5/14551; A61B 5/14552;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,911,167 A * 3/1990 Corenman A61B 5/14551 600/324
5,348,002 A * 9/1994 Caro A61B 5/1455 356/39

(Continued)

FOREIGN PATENT DOCUMENTS

WO 2009/032168 A1 3/2009

OTHER PUBLICATIONS

"Narrow beam LED in Dragon Dome package (850nm)", OSRAM Opto Semicondutors (Mar. 10, 2014), Version 1.3, SFH 4783, pp. 1-12.

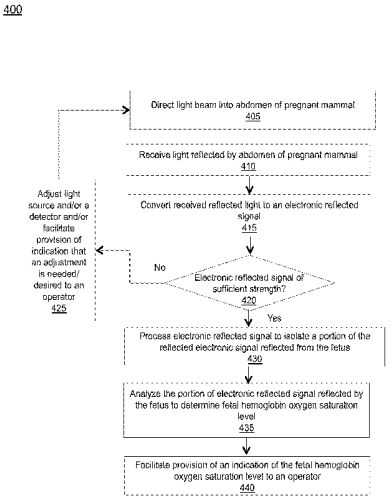
(Continued)

Primary Examiner — Eric Winakur
Assistant Examiner — Chu Chuan (JJ) Liu
(74) *Attorney, Agent, or Firm* — Ascenda Law Group, PC

(57) **ABSTRACT**

Light beams emitted from one or more light sources may be directed into an abdomen of a pregnant mammal toward a fetus contained therein. Some of the light may be reflected by the pregnant woman and fetus and received at a detector over a first time. A photo detector into an electronic reflected signal, which may be communicated to a computer, may then convert the received light. The electronic reflected signal may then be processed and/or analyzed to isolate a portion of the electronic reflected signal reflected from the fetus. The isolated portion of the electronic reflected signal reflected from the fetus may then be analyzed to determine a fetal hemoglobin oxygen saturation level of the fetus. An indication of the fetal hemoglobin oxygen saturation level may then be provided to an operator by way of, for example, a computer display.

21 Claims, 28 Drawing Sheets



(51) **Int. Cl.**

A61B 5/0205	(2006.01)
A61B 5/00	(2006.01)
A61B 5/01	(2006.01)
A61B 8/00	(2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/02055*** (2013.01); ***A61B 5/14546*** (2013.01); ***A61B 5/4356*** (2013.01); ***A61B 8/4483*** (2013.01); ***A61B 8/56*** (2013.01)

(58) **Field of Classification Search**
CPC A61B 5/0205; A61B 5/021; A61B 5/6823; A61B 5/72; A61B 5/6813
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,807,271	A *	9/1998	Tayebi	A61B 5/02411 600/511
7,047,055	B2	5/2006	Boas et al.	
7,469,158	B2	12/2008	Cutler et al.	
2003/0073910	A1*	4/2003	Chance	A61B 5/0059 600/473
2004/0116789	A1	6/2004	Boas et al.	
2005/0280531	A1*	12/2005	Fadem	A61B 5/0006 340/539.12
2006/0122475	A1	6/2006	Balberg et al.	
2009/0281402	A1	11/2009	Chance	
2010/0081901	A1*	4/2010	Buice	A61B 5/14551 600/324
2011/0218413	A1	9/2011	Wang et al.	
2012/0190946	A1	7/2012	Bernreuter	
2013/0338460	A1*	12/2013	He	A61B 5/0205 600/324
2015/0099950	A1*	4/2015	Al-Ali	A61B 5/14552 600/323
2016/0015304	A1	1/2016	Esenaliev et al.	

OTHER PUBLICATIONS

"OSRAM Opto Semiconductors GF CSHPM1.24-3S4S-1", Mouser Electronics (accessed Dec. 2016), 2 pgs.

"Philips proprietary camera based monitoring technology is first in the world to measure absolute arterial blood oxygenation (SpO2) levels without ever touching the patient", Philips (Jun. 6, 2016), 4 pgs.

Aaronson; et al., "Android-Based Tocodynamometer and Fetal Heart Rate Monitor", tocotronics (2013), 21 pgs.

Bansal; et al., "An Optoelectronic Muscle Contraction Sensor", EPSRC (accessed Dec. 2016), University of St Andrews, 1 pg.

Bansal; et al., "Wearable Organic Optoelectronic Sensors for Medicine", Advanced Materials (2014), 7 pgs.

Mannheimer; et al., "Wavelength Selection for Low-Saturation Pulse Oximetry", IEEE Transactions on Biomedical Engineering (Mar. 1997), 44(3):148-158.

Verkruysse; et al., "Calibration of Contactless Pulse Oximetry", Anesthesia and Analgesia (Jan. 2017), 124(1):136-145.

Zourabian; et al., "Trans-abdominal monitoring of fetal arterial blood oxygenation using pulse oximetry", Journal of Biomedical Optics (Oct. 2000), 5(4):391-405.

"Corometrics™ 250 Series Monitor Operator's Manual", GE Healthcare, Revision E (Apr. 28, 2009), 258 pgs.

"Fetal Pulse Oximetry System Clinical Use Guide", OxiFirst, Nellecor (2003), 60 pgs.

Bottrich; et al, "Principle study on the signal connection at transabdominal fetal pulse oximetry", Current Directions in Biomedical Engineering (2016), 2(1): 659-663.

Bottrich; et al., "Simulation based investigation of source-detector con gurations for non-invasive fetal pulse oximetry", Current Directions in Biomedical Engineering (2015), 1:450-453.

Choe; et al., "Transabdominal near infrared oximetry of hypoxic stress in fetal sheep brain in utero", PNAS (Oct. 28, 2003), 100(22):12950-12954.

Dildy; et al., "Intrapartum fetal pulse oximetry: Fetal oxygen saturation trends during labor and relation to delivery outcome", Am J Obstet Gynecol (Sep. 1994), 171(3):679-684.

Jurovata; et al., "Simulation of Photon Propagation in Tissue Using Matlab", Faculty of Materials Science and Technology in Trnava Slovak University of Techology in Bratislava, Research Papers (2013), 21:31-37.

Laqua; et al., "A phantom with pulsating artificial vessels for non-invasive fetal pulse oximetry", Conf Proc IEEE Eng Med Biol Soc. (2014), pp. 5631-5634.

Laqua; et al., "FPGA controlled artificial vascular system", Current Directions in Biomedical Engineering (2015), 1:446-449.

Laqua; et al "Improved FPGA controlled artificial vascular system for plethysmographic measurements", Current Directions in Biomedical Engineering (2016), 2(1): 689-693.

Mawn; et al., "Trans-Abdominal Monitoring of Fetal Arterial Oxygen Saturation Using Pulse Oximetry", Bioengineering Conference, 2002. Proceedings of the IEEE 28th Annual Northeast (Apr. 21, 2002), pp. 227-228.

Ramanujam; et al., "Antepartum, Transabdominal Near Infrared Spectroscopy: Feasibility of Measuring Photon Migration Through the Fetal Head in Utero", The Journal of Maternal-Fetal Medicine (1999), 8:275-288.

Ramanujam; et al., "Photon migration through fetal head in utero using continuous wave, near infrared spectroscopy: clinical and experimental model studies", Journal of Biomedical Optics (Apr. 2000), 5(2)173-184.

Stipcevic; et al., "Characterization of a novel avalanche photodiode for single photon detection in VIS-NIR range", Optics Express (Aug. 2, 2010), 18(16):17448-17459.

Subramaniam, "An IR Muscle Contraction Sensor", Cornell University, student project (last modified Jun. 10, 2014), retrieved from: https://people.ece.cornell.edu/land/courses/eceprojectsland/STUDENTPROJ/2013to2014/ras578/Writeup/An%20IR%20Muscle%20Contraction%20Sensor.html, 6 pgs.

Tu; et al., "An Analytical Model for Optimization of Frequency-domain System", Bioengineering Conference, 2002. Proceedings of the IEEE 28th Annual Northeast (Apr. 21, 2002), pp. 79-80.

Vishnoi; et al., "Photon migration through fetal head in utero using continuous wave, near-infrared spectroscopy: development and evaluation of experimental and numerical models", Journal of Biomedical Optics (Apr. 2000), 5(2):163-172.

International Search Report and Written Opinion dated Mar. 13, 2017, from the International Searching Authority, for International Patent Application No. PCT/US2016/068994 (filed Dec. 28, 2016), 18 pages.

* cited by examiner

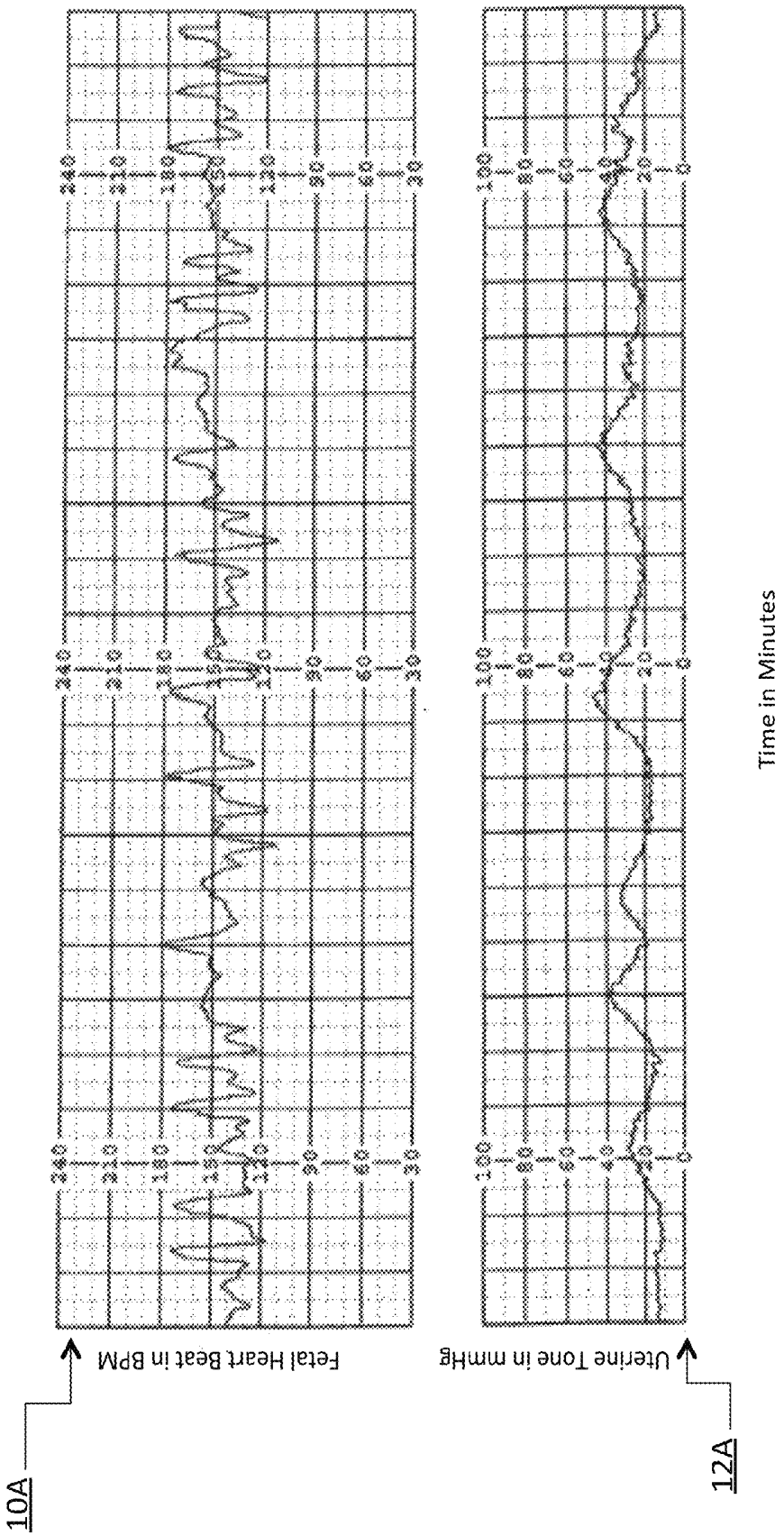

Fetal Heart Beat in BPM
Uterine Tone in mmHg
Time in Minutes
10A
12A

FIG. 1A

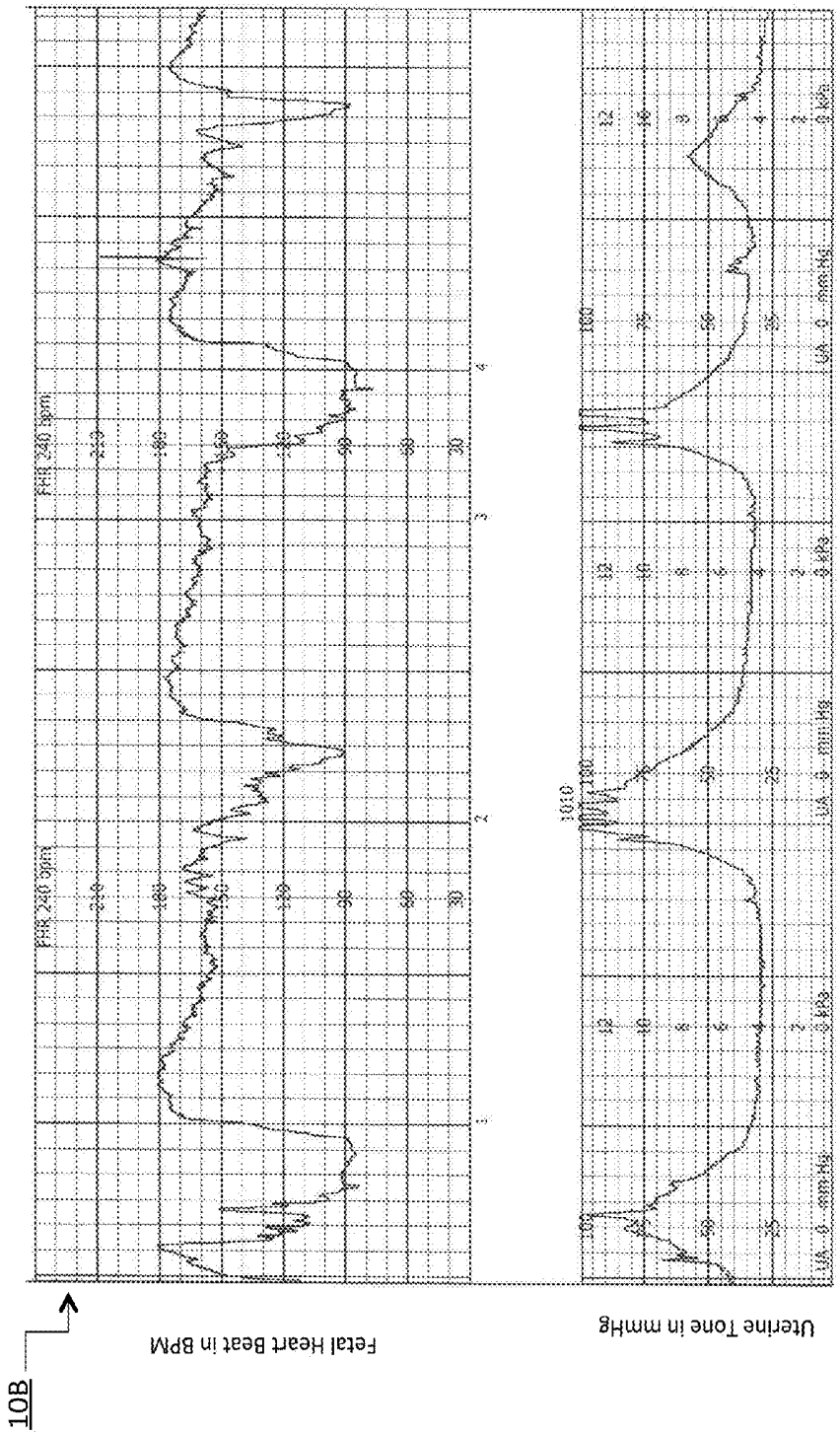

10B
Fetal Heart Beat in BPM
FHR 240 bpm
FHR 240 bpm
Uterine Tone in mmHg
12B
Time in Minutes

FIG. 1B

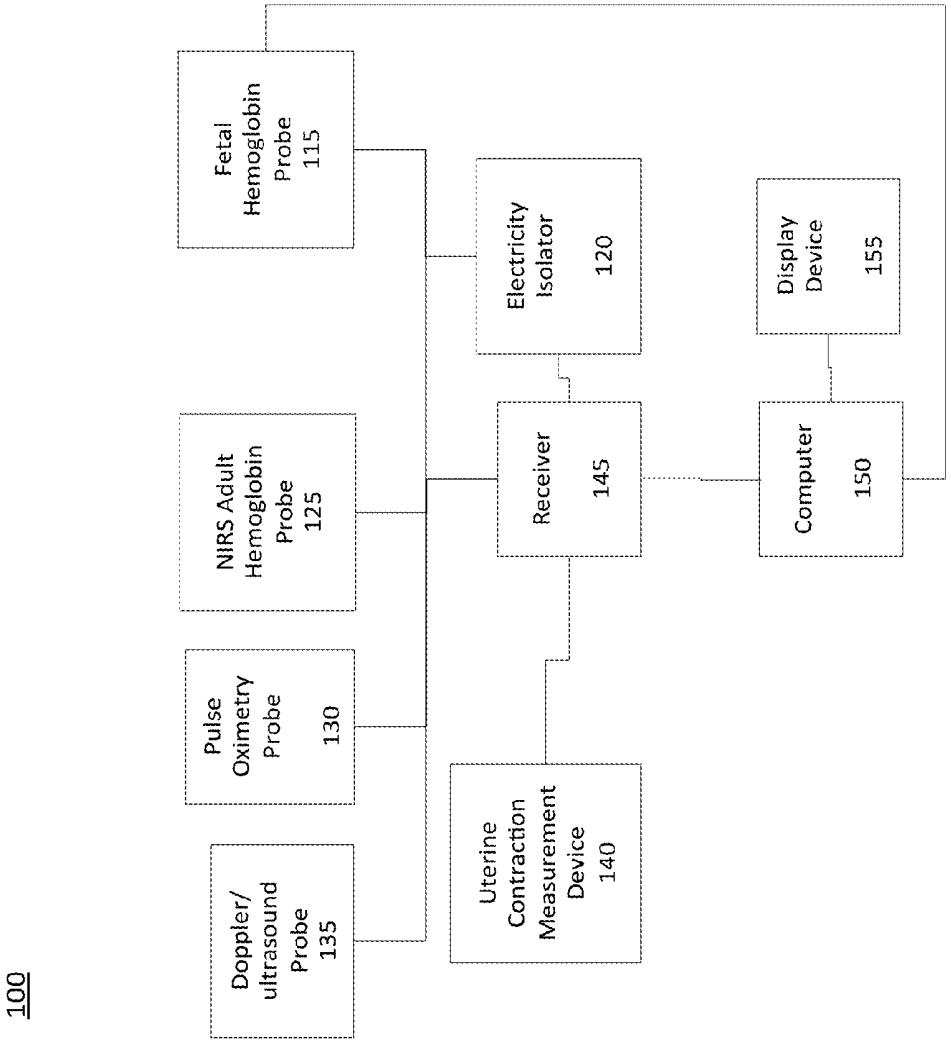

100
Fetal Hemoglobin Probe 115
NIRS Adult Hemoglobin Probe 125
Pulse Oximetry Probe 130
Doppler/ ultrasound Probe 135
Electricity Isolator 120
Receiver 145
Uterine Contraction Measurement Device 140
Display Device 155
Computer 150

Figure 2A

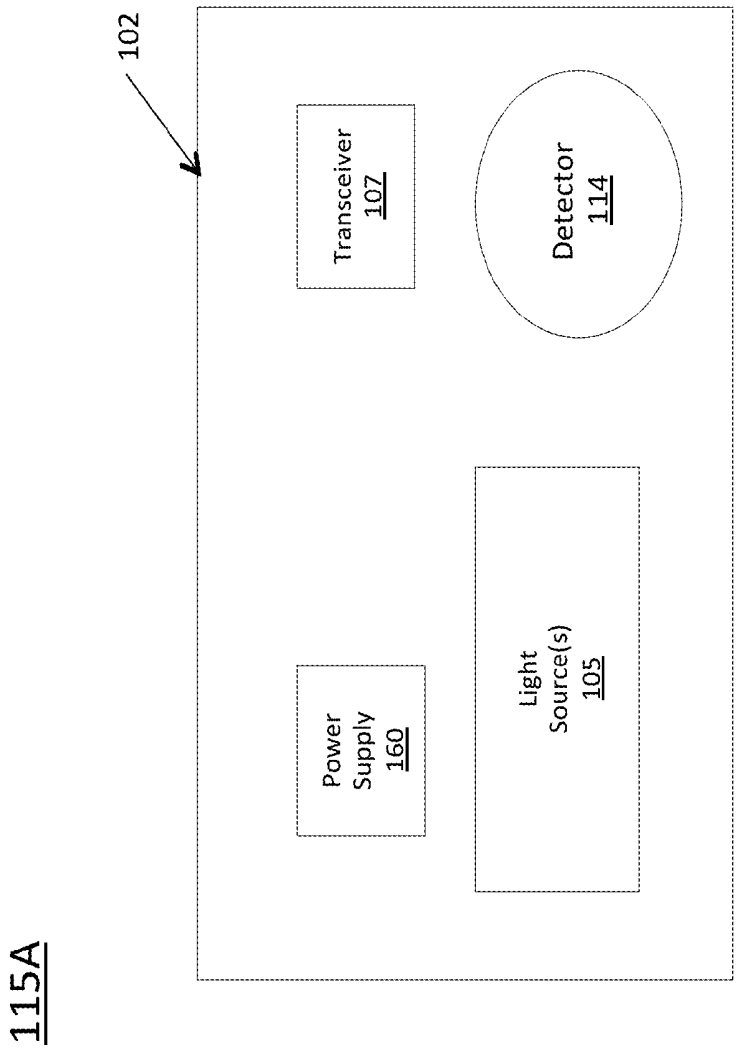

115A
102
Transceiver
107
Detector
114
Power
Supply
160
Light
Source(s)
105

FIG. 2B

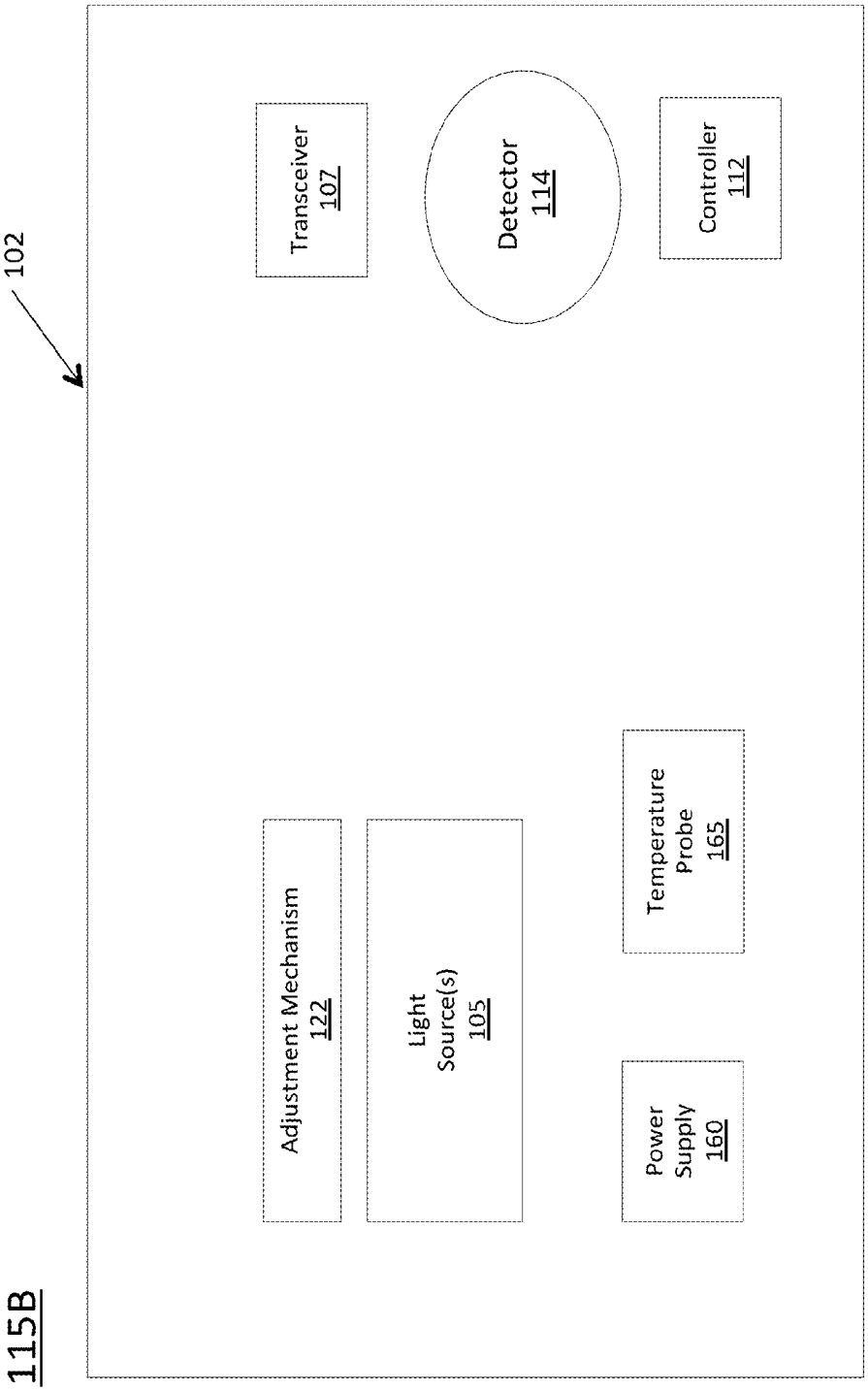

115B
102
Transceiver 107
Detector 114
Controller 112
Adjustment Mechanism 122
Light Source(s) 105
Temperature Probe 165
Power Supply 160

FIG. 2C

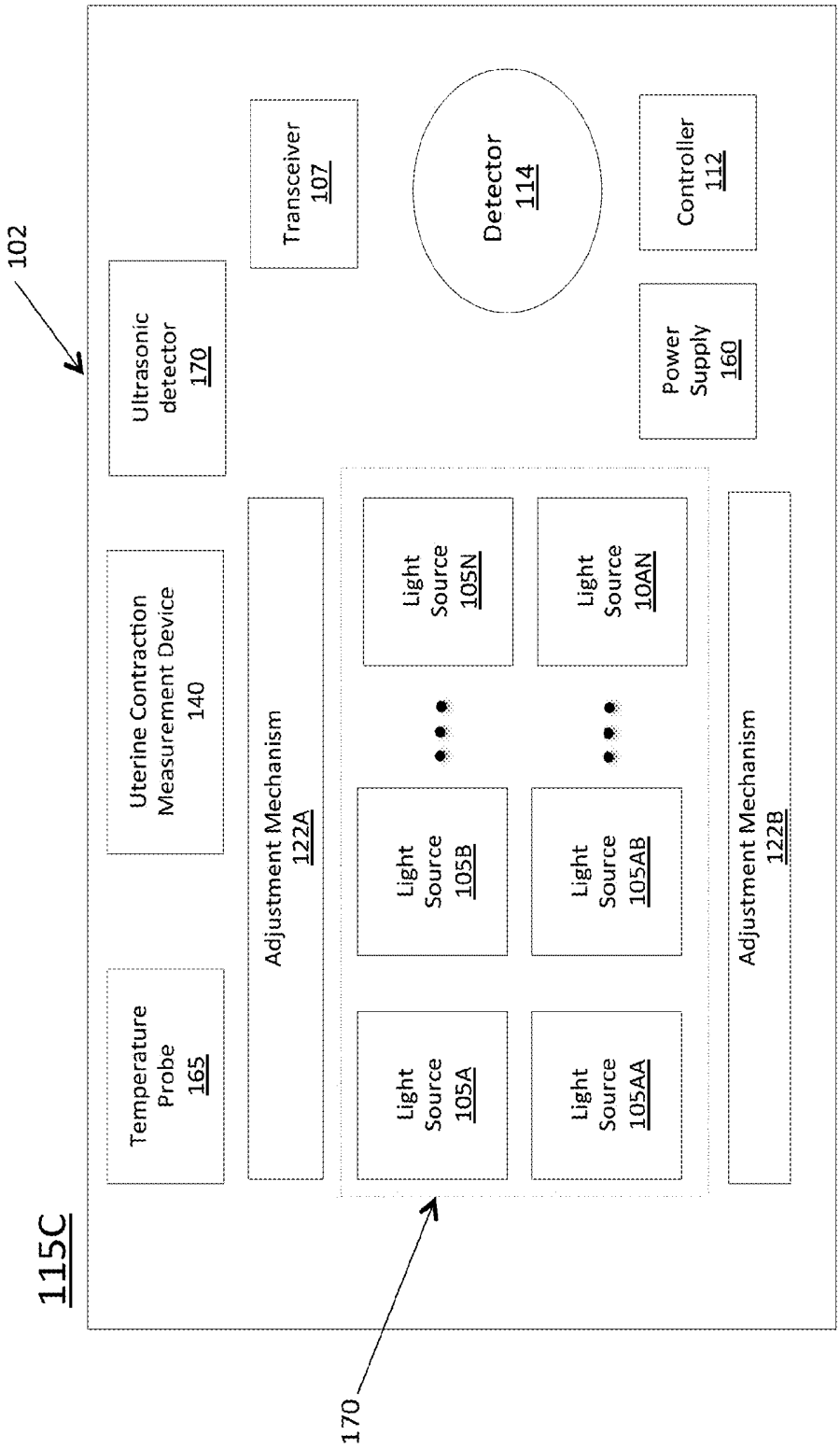

102
115C
170
Temperature Probe 165
Uterine Contraction Measurement Device 140
Ultrasonic detector 170
Adjustment Mechanism 122A
Light Source 105A
Light Source 105B
Light Source 105N
Light Source 105AA
Light Source 105AB
Light Source 10AN
Adjustment Mechanism 122B
Transceiver 107
Detector 114
Power Supply 160
Controller 112

FIG. 2D

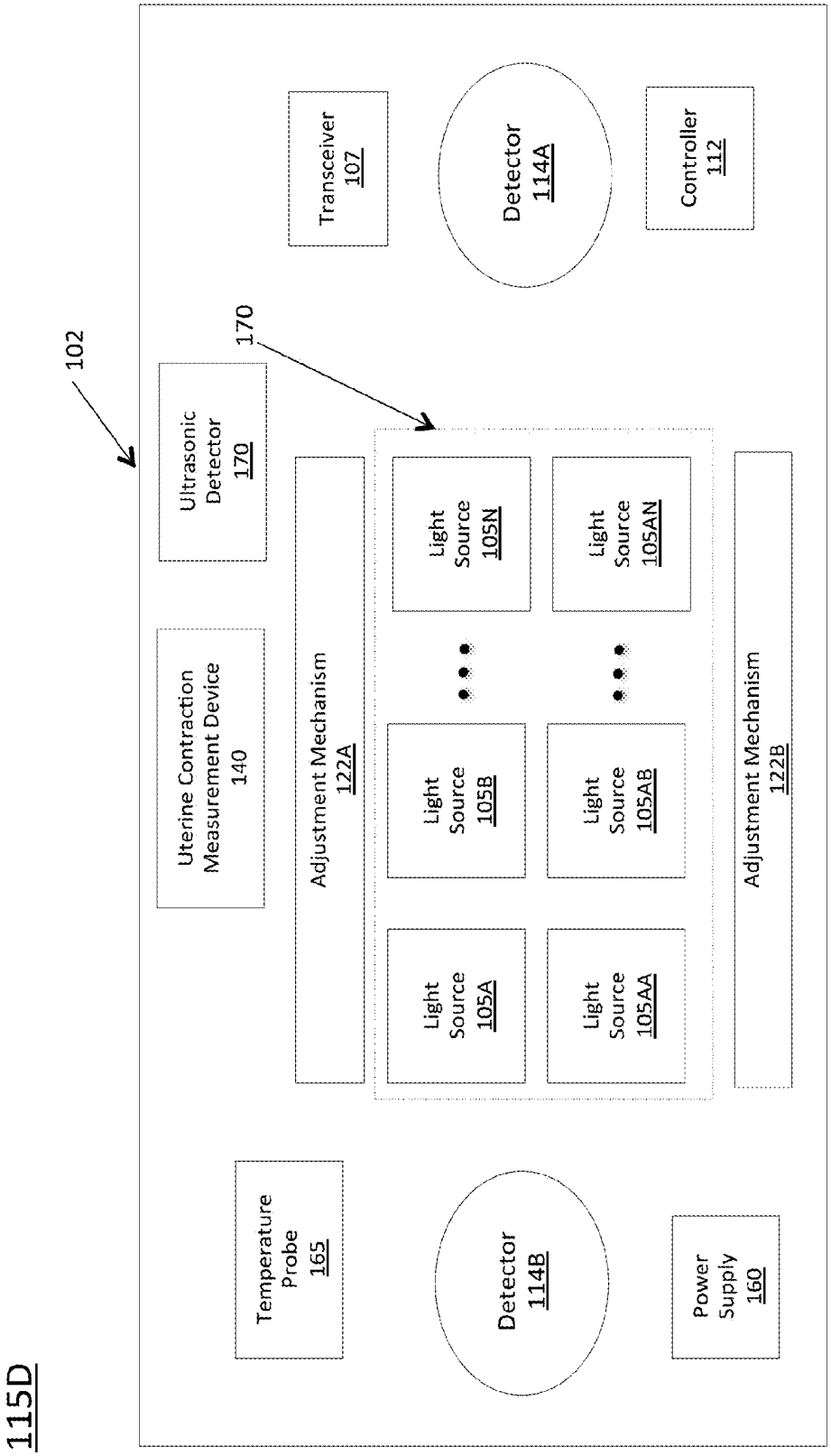

115D
102
170
Ultrasonic Detector 170
Transceiver 107
Detector 114A
Controller 112
Uterine Contraction Measurement Device 140
Adjustment Mechanism 122A
Light Source 105N
Light Source 105AN
Light Source 105B
Light Source 105AB
Light Source 105A
Light Source 105AA
Adjustment Mechanism 122B
Temperature Probe 165
Detector 114B
Power Supply 160

FIG. 2E

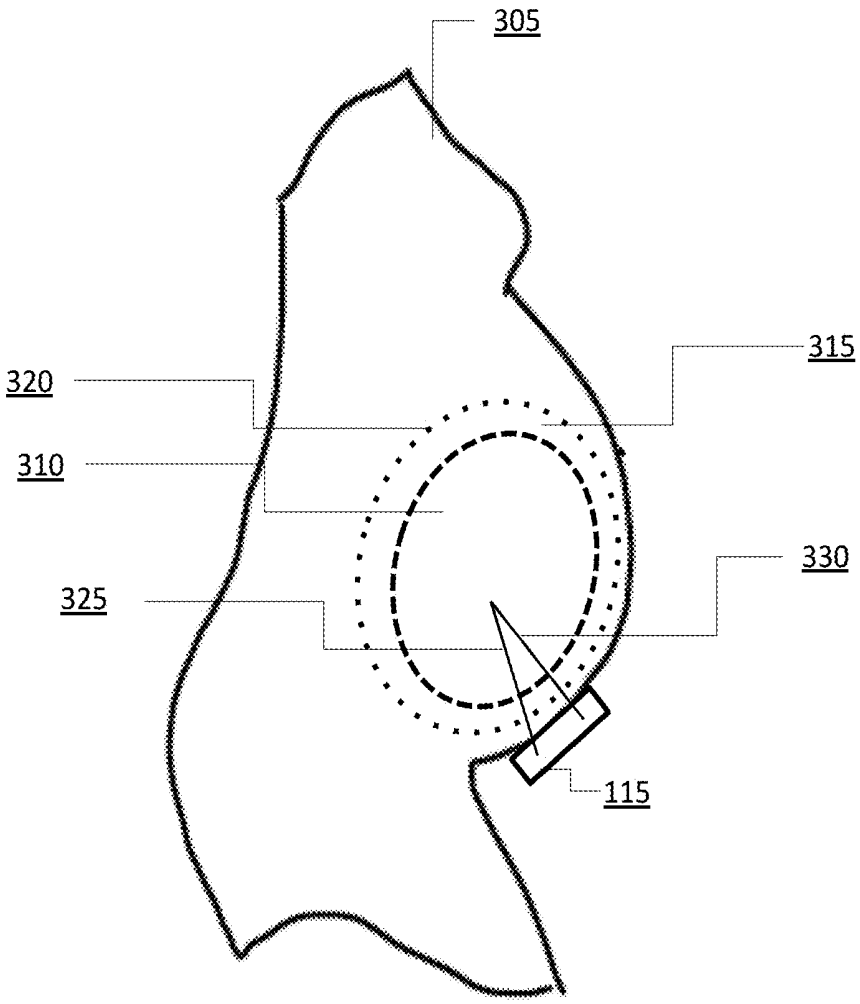


Figure 3A

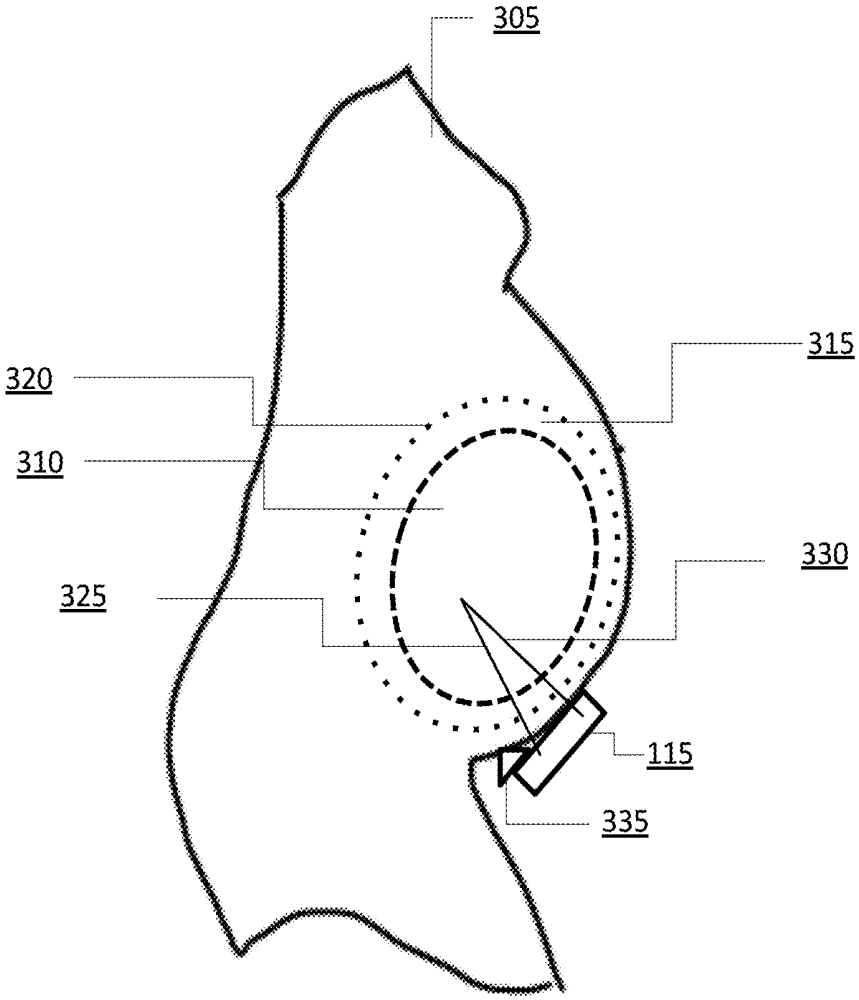


Figure 3B

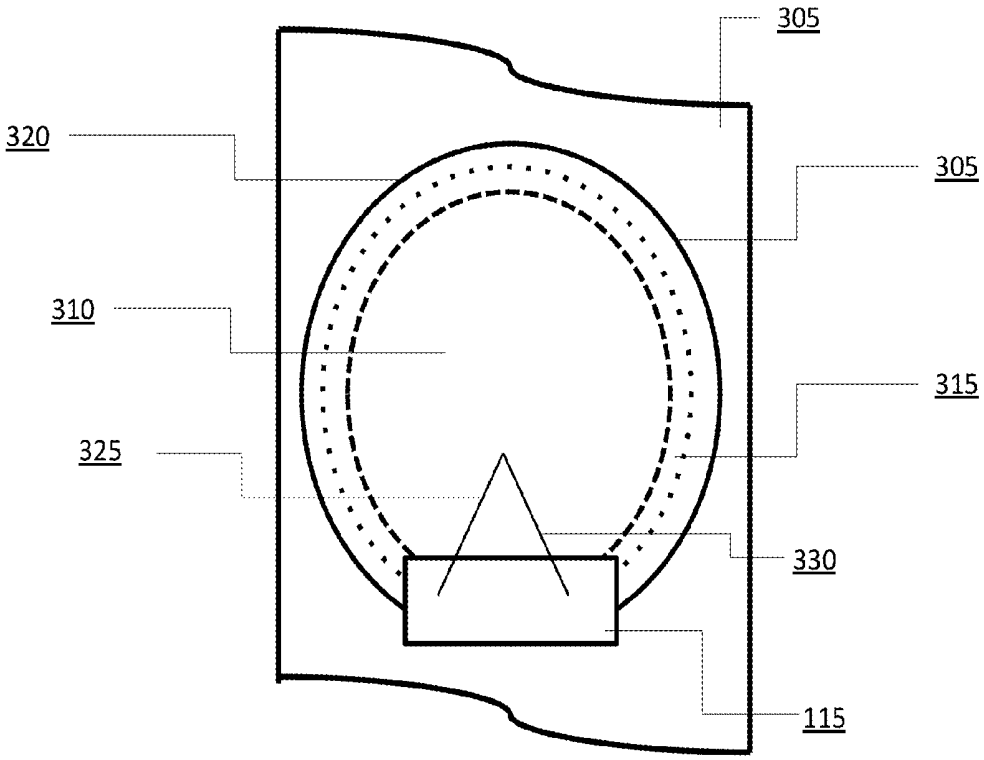


Figure 3C

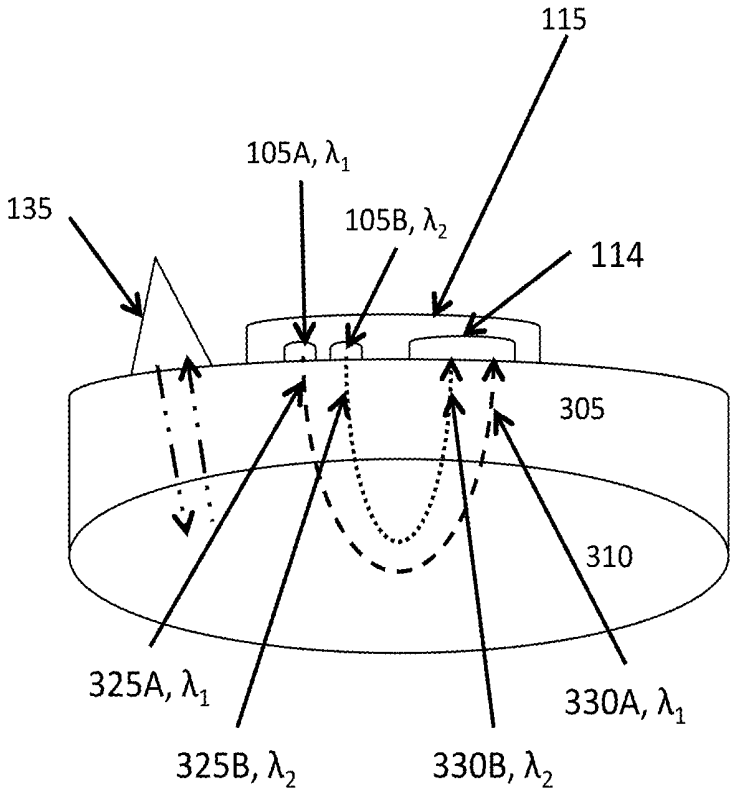

115
105A, λ1
135
105B, λ2
114
305
310
325A, λ1
330A, λ1
325B, λ2
330B, λ2

Figure 3D

400

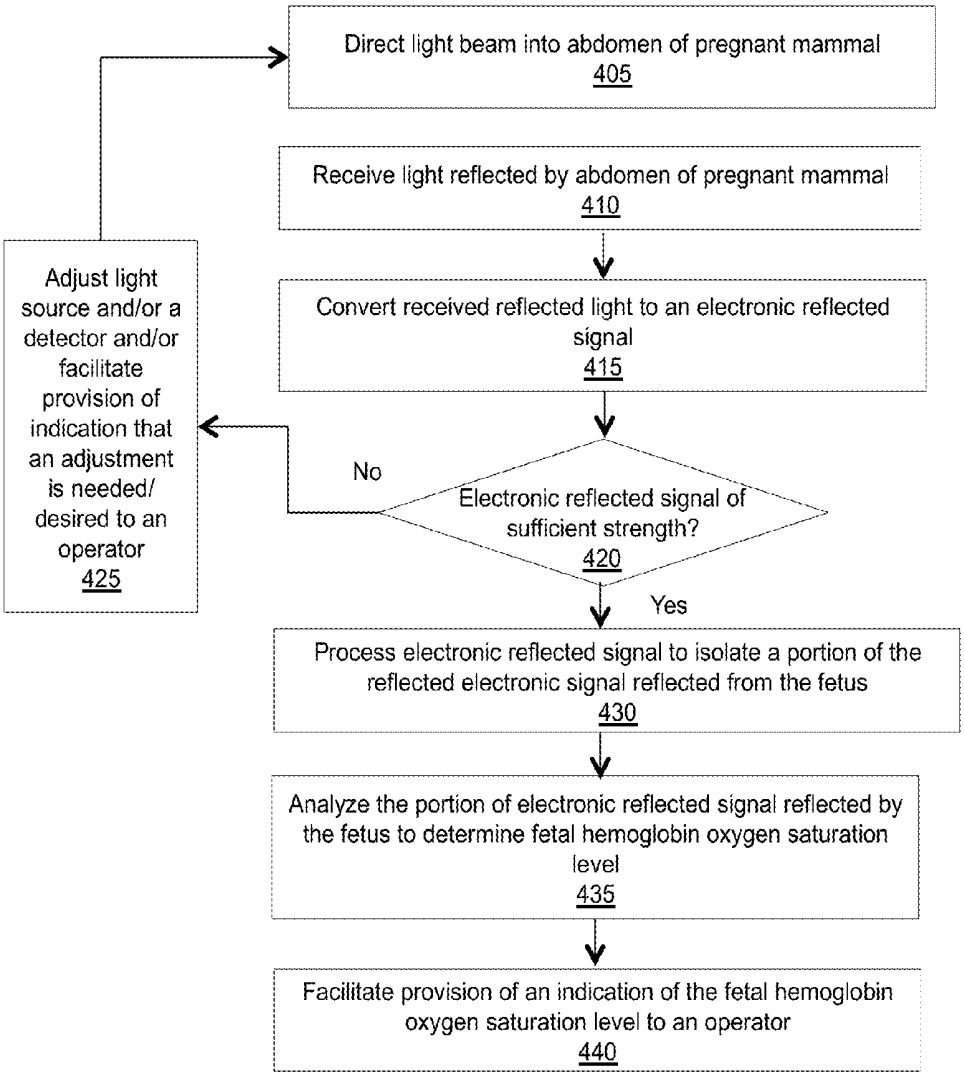


Figure 4A

401

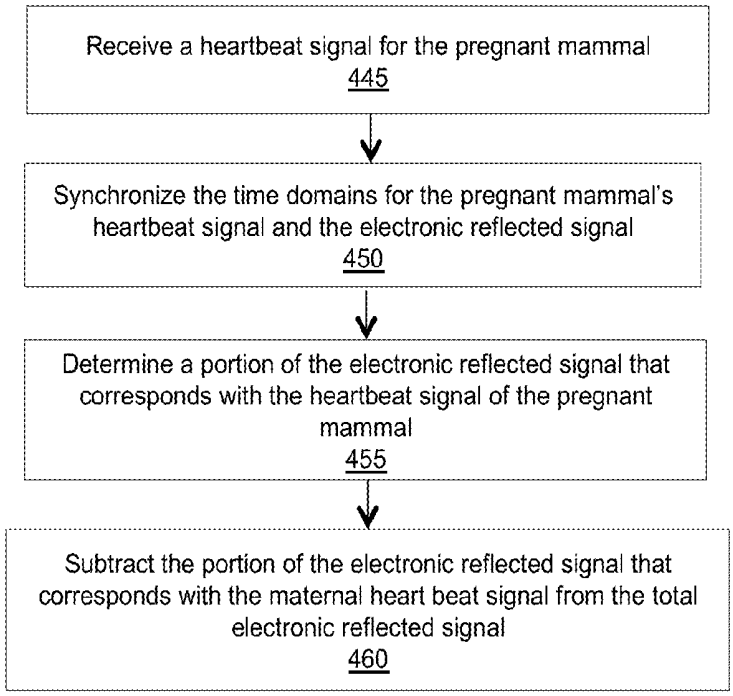


Figure 4B

402

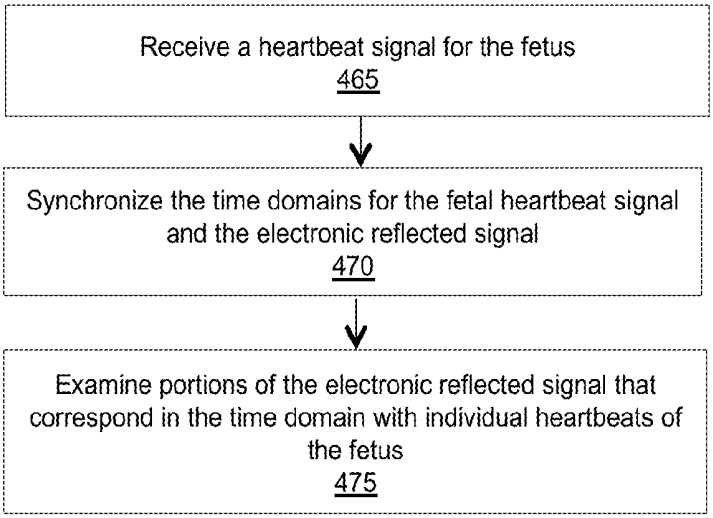


Figure 4C

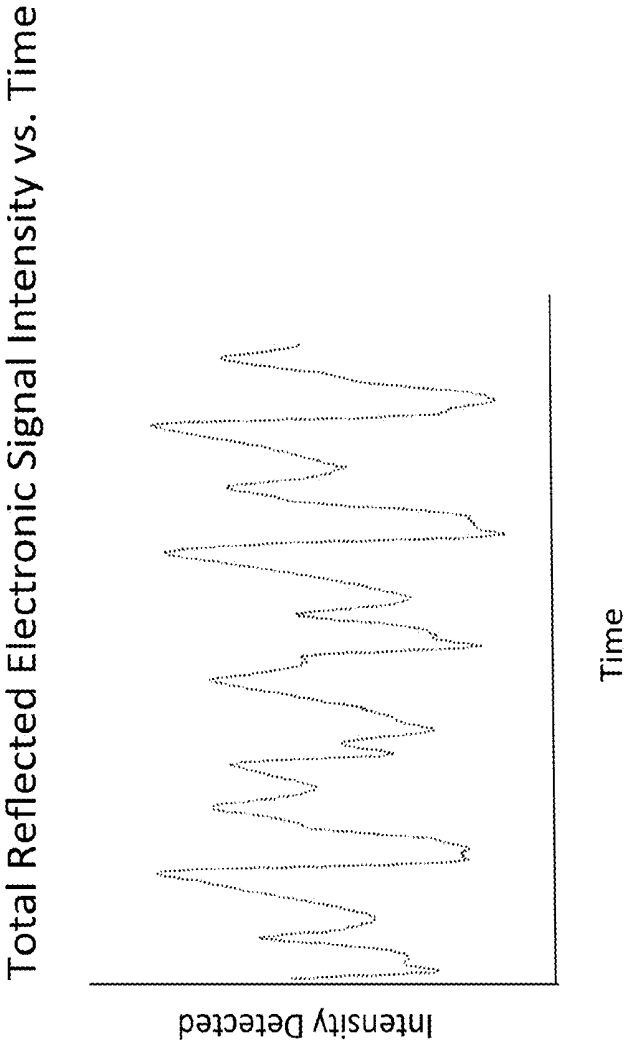

Total Reflected Electronic Signal Intensity vs. Time
Intensity Detected
Time
500

Figure 5A

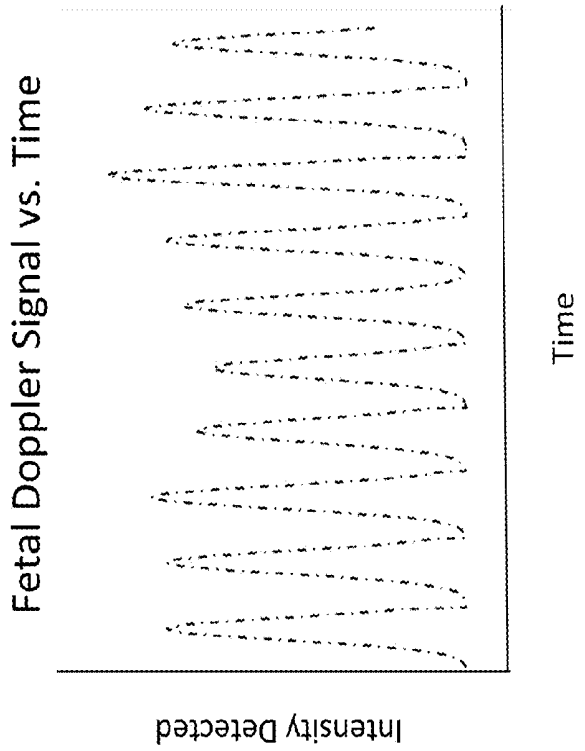


Figure 5B

501

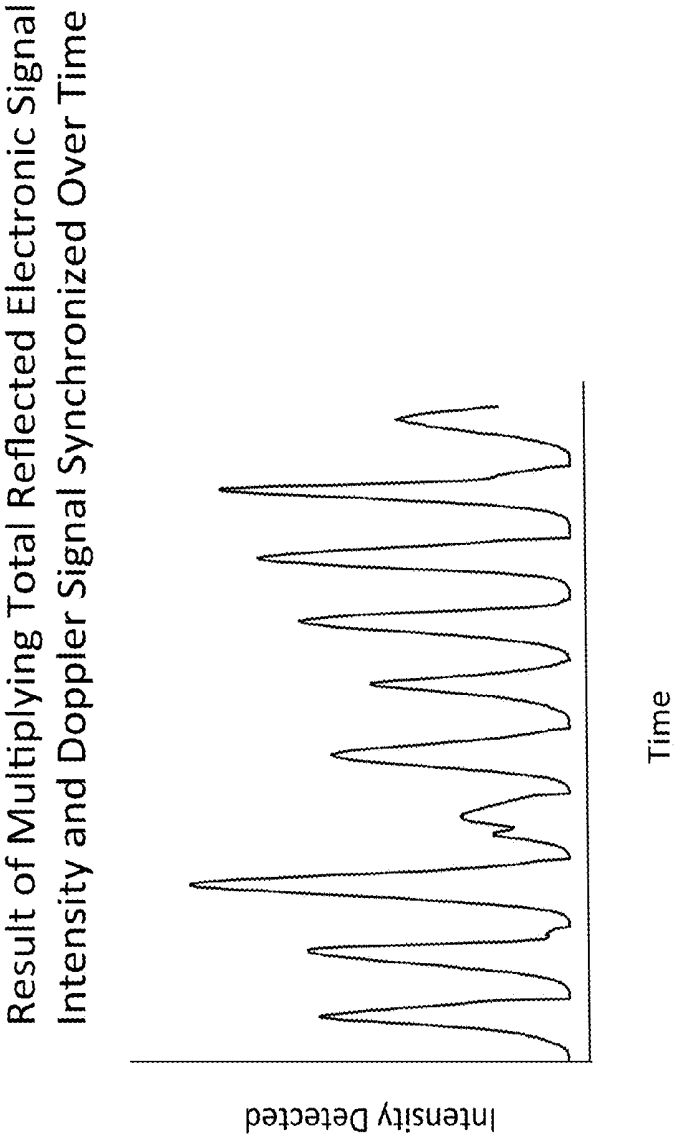
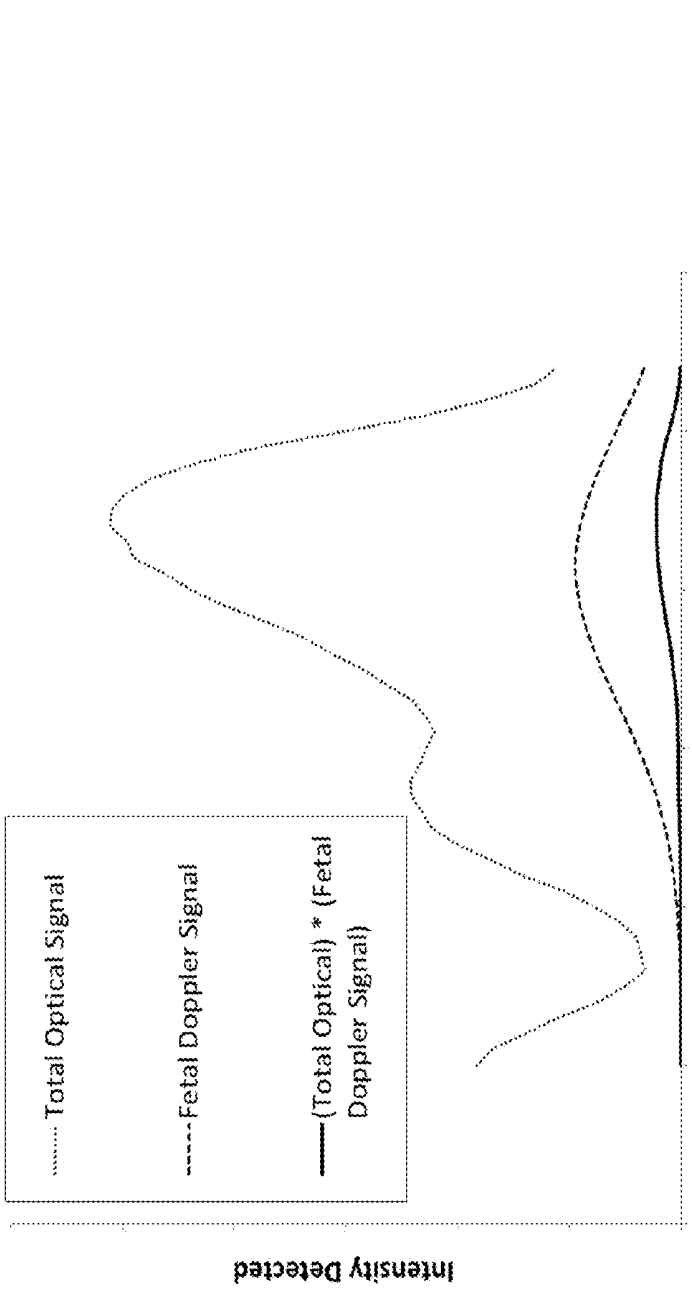

Result of Multiplying Total Reflected Electronic Signal Intensity and Doppler Signal Synchronized Over Time
Intensity Detected
Time
502

Figure 5C



503

Figure 5D

601

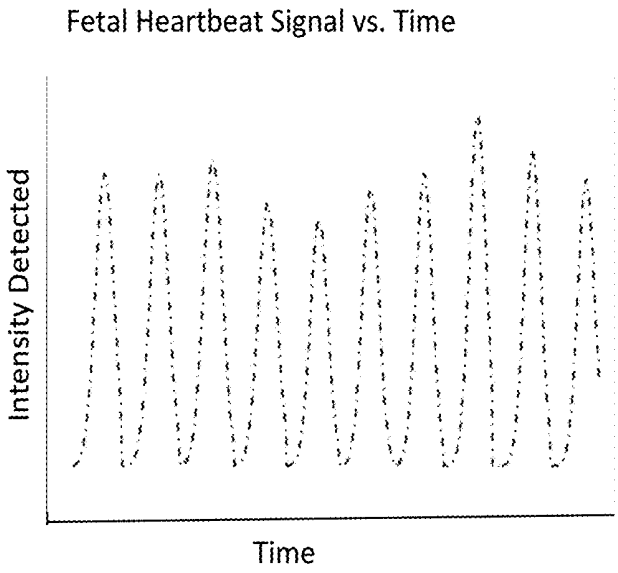


Figure 6A

602

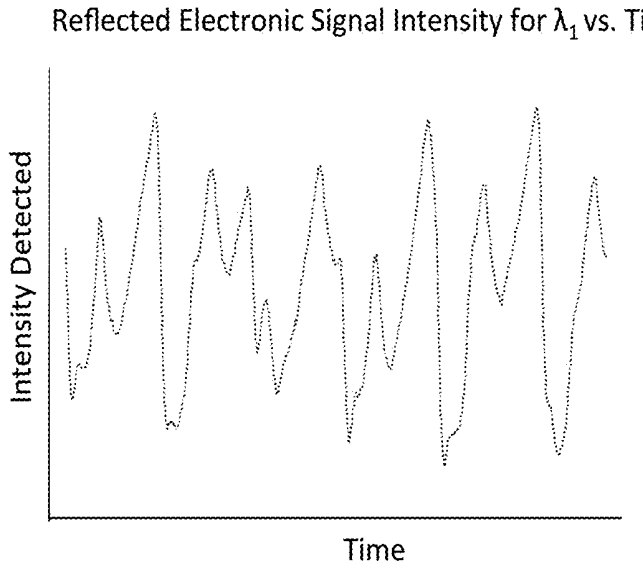


Figure 6B

603

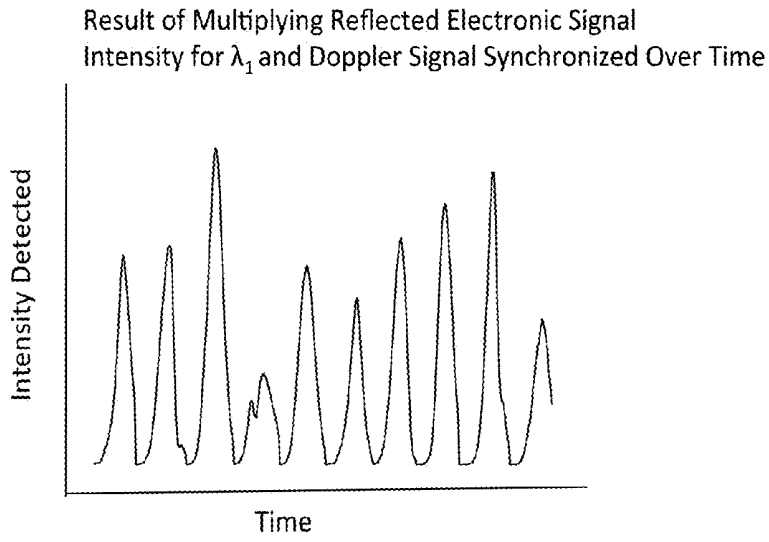


Figure 6C

604

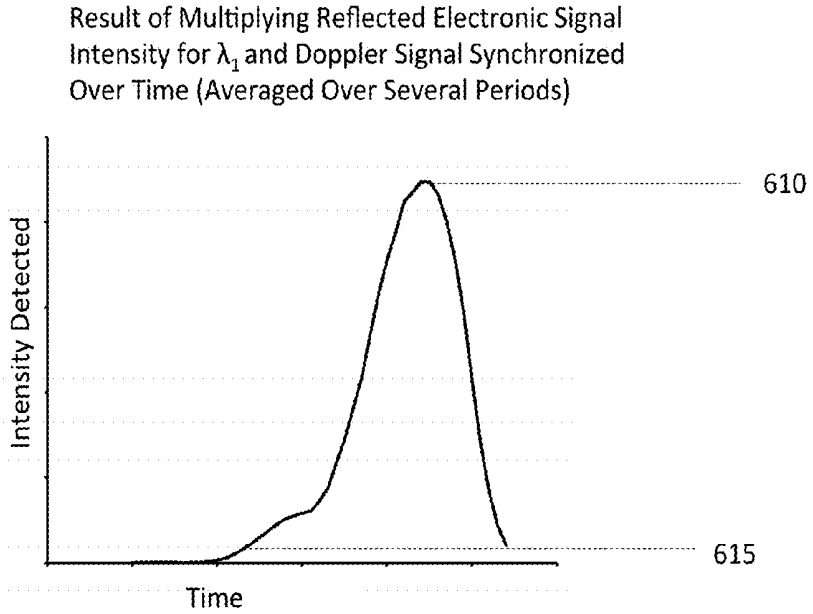


Figure 6D

605

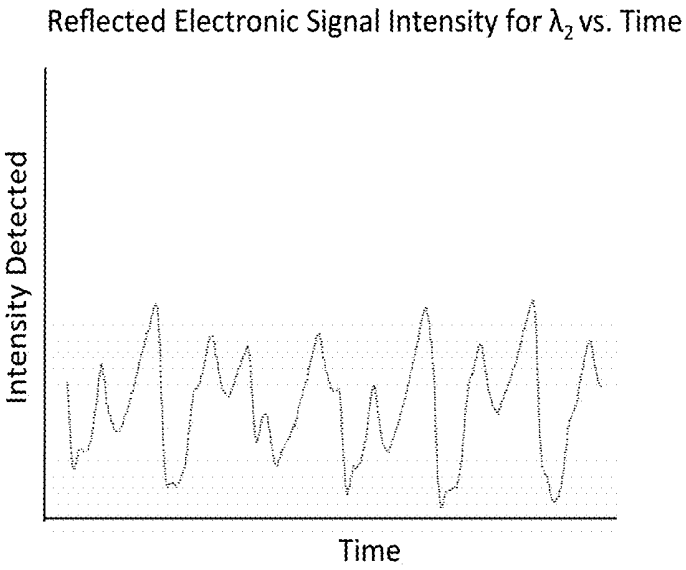


Figure 6E

606

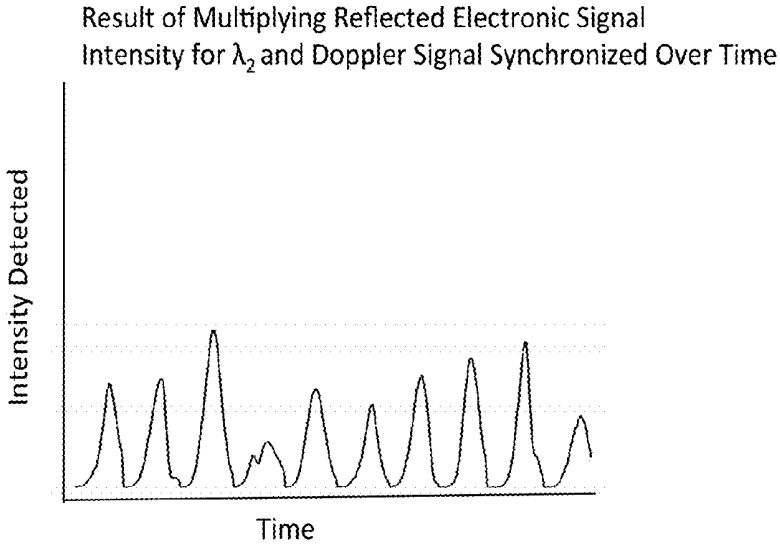


Figure 6F

607

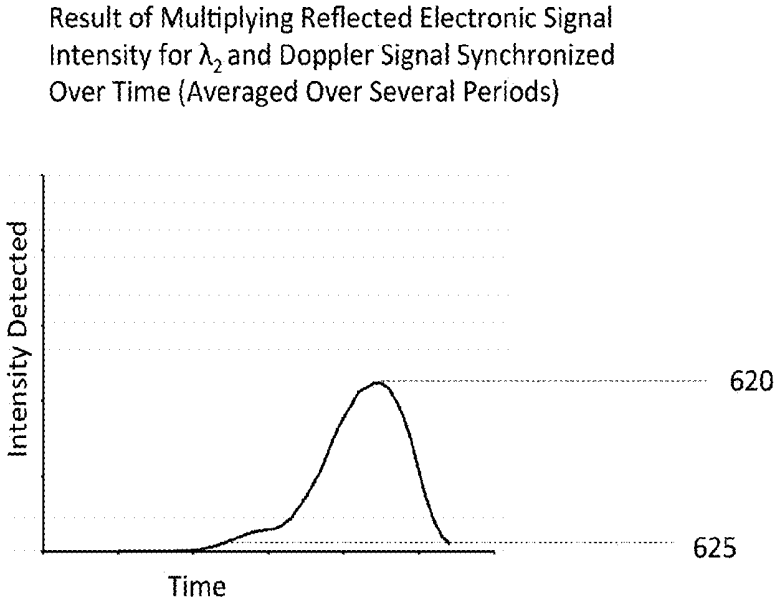


Figure 6G

608

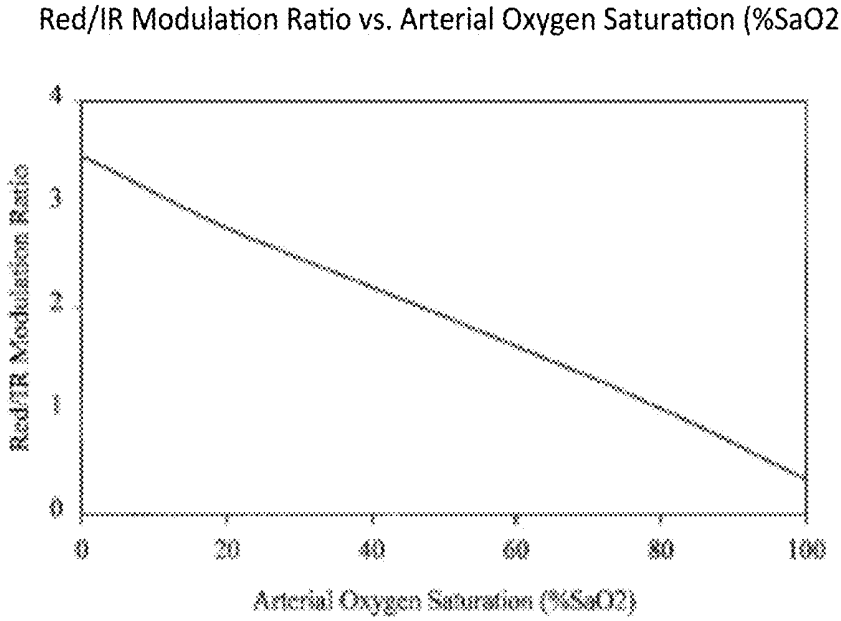


Figure 6H

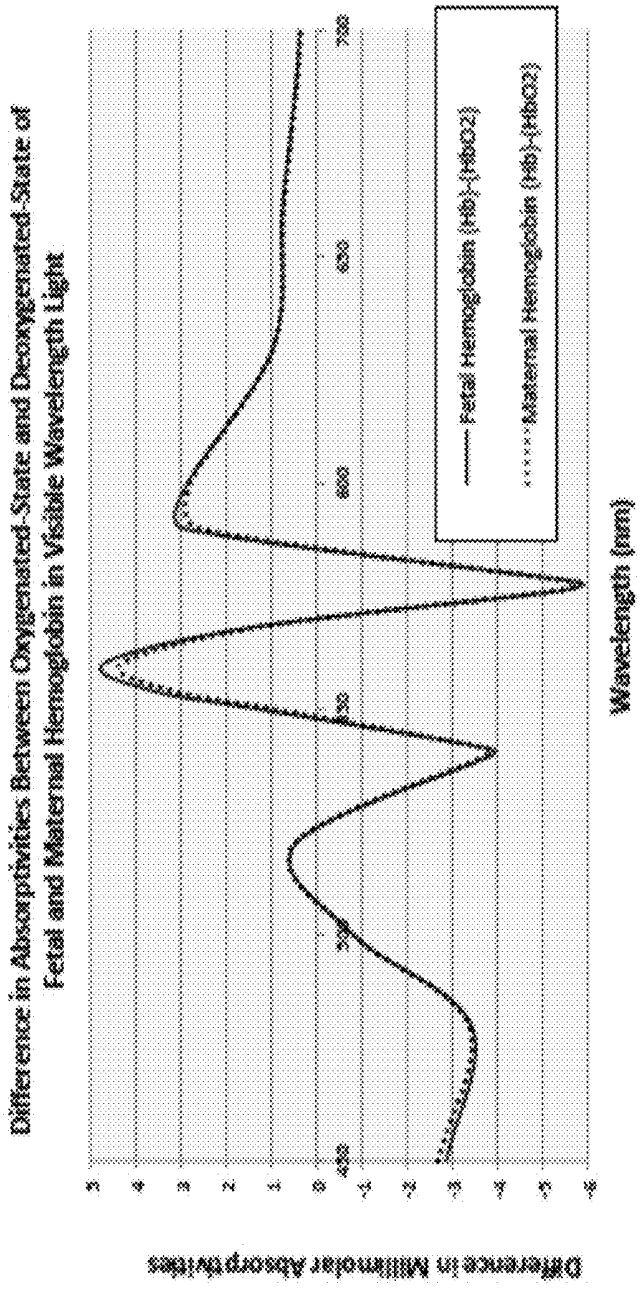
700

	Hb			HbO2		Difference	Difference	Ratio
Wavelength (nm)	HbF	HbA	HbF	HbA	HbF (Hb-HbO2)	HbA (Hb-HbO2)	HbF (Hb-HbO2)/HbO2
450	12.94	13.51	15.82	16.2	-2.88	-2.69	-0.182048004
480	3.18	3.35	6.61	6.72	-3.43	-3.37	-0.518910741
500	4.25	4.34	5.08	5.15	-0.83	-0.81	-0.163385827
520	6.5	6.48	6.03	5.98	0.47	0.5	0.077943615
540	10.57	10.5	14.48	14.32	-3.91	-3.82	-0.270027624
542	11.19	11.09	14.62	14.52	-3.43	-3.43	-0.234610113
550	13.15	12.97	11.84	12.01	1.31	0.96	0.110641892
554	13.55	13.35	9.95	10.17	3.6	3.18	0.361809045
560	13.3	13.09	8.6	8.77	4.7	4.32	0.546511628
568	11.97	11.85	10.49	10.5	1.48	1.35	0.141086749
576	10.06	10.07	15.38	15.27	-5.32	-5.2	-0.345903771
578	9.6	9.62	15.45	15.36	-5.85	-5.74	-0.378640777
590	6.94	6.87	4	4.26	2.94	2.61	0.735
600	3.74	3.74	0.9	0.96	2.84	2.78	3.155555556
630	1.05	1.06	0.1	0.11	0.95	0.95	9.5
660	0.83	0.81	0.07	0.08	0.76	0.73	10.85714286
680	0.62	0.61	0.08	0.09	0.54	0.52	6.75
700	0.45	0.44	0.08	0.09	0.37	0.35	4.625
750	0.4	0.39	0.13	0.14	0.27	0.25	2.076923077
775	0.29	0.29	0.16	0.17	0.13	0.12	0.8125
800	0.21	0.2	0.19	0.2	0.02	0	0.105263158
805	0.2	0.2	0.19	0.21	0.01	0.01	0.052631579
840	0.18	0.19	0.23	0.25	-0.05	-0.06	-0.217391304
845	0.18	0.19	0.24	0.25	-0.06	-0.06	-0.25
880	0.19	0.2	0.27	0.28	-0.08	-0.08	-0.296296296
904	0.2	0.21	0.28	0.3	-0.08	-0.09	-0.285714286
920	0.2	0.21	0.29	0.3	-0.09	-0.09	-0.310344828
940	0.17	0.18	0.28	0.29	-0.11	-0.11	-0.392857143
960	0.12	0.14	0.27	0.28	-0.15	-0.14	-0.555555556
1000	0.04	0.06	0.25	0.25	-0.21	-0.19	-0.84

* Notation:
Hb = hemoglobin in deoxy-state
HbO2 = hemoglobin in oxy-state
HbF = fetal hemoglobin
HbA = adult hemoglobin

** Reference: Zijlstra et al, Clin. Chem 37/9, 1633-1638 (1991)

Figure 7A



701

Figure 7B

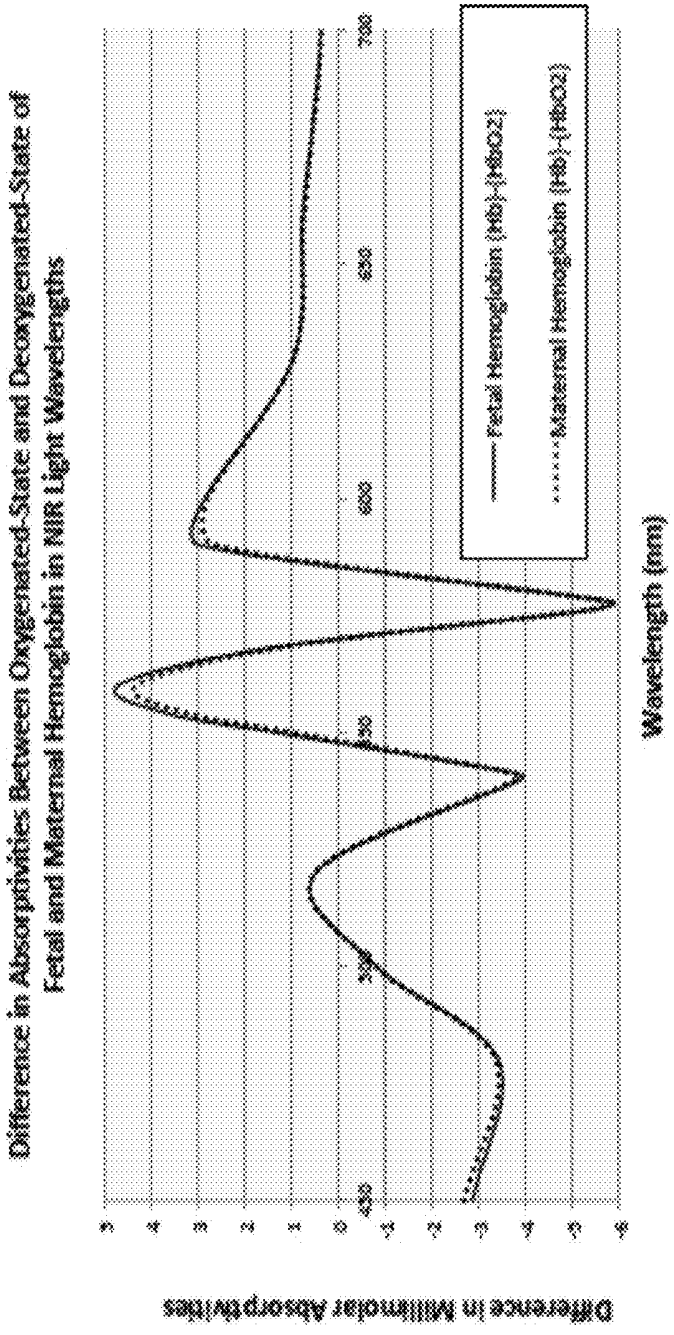


Figure 7C

702

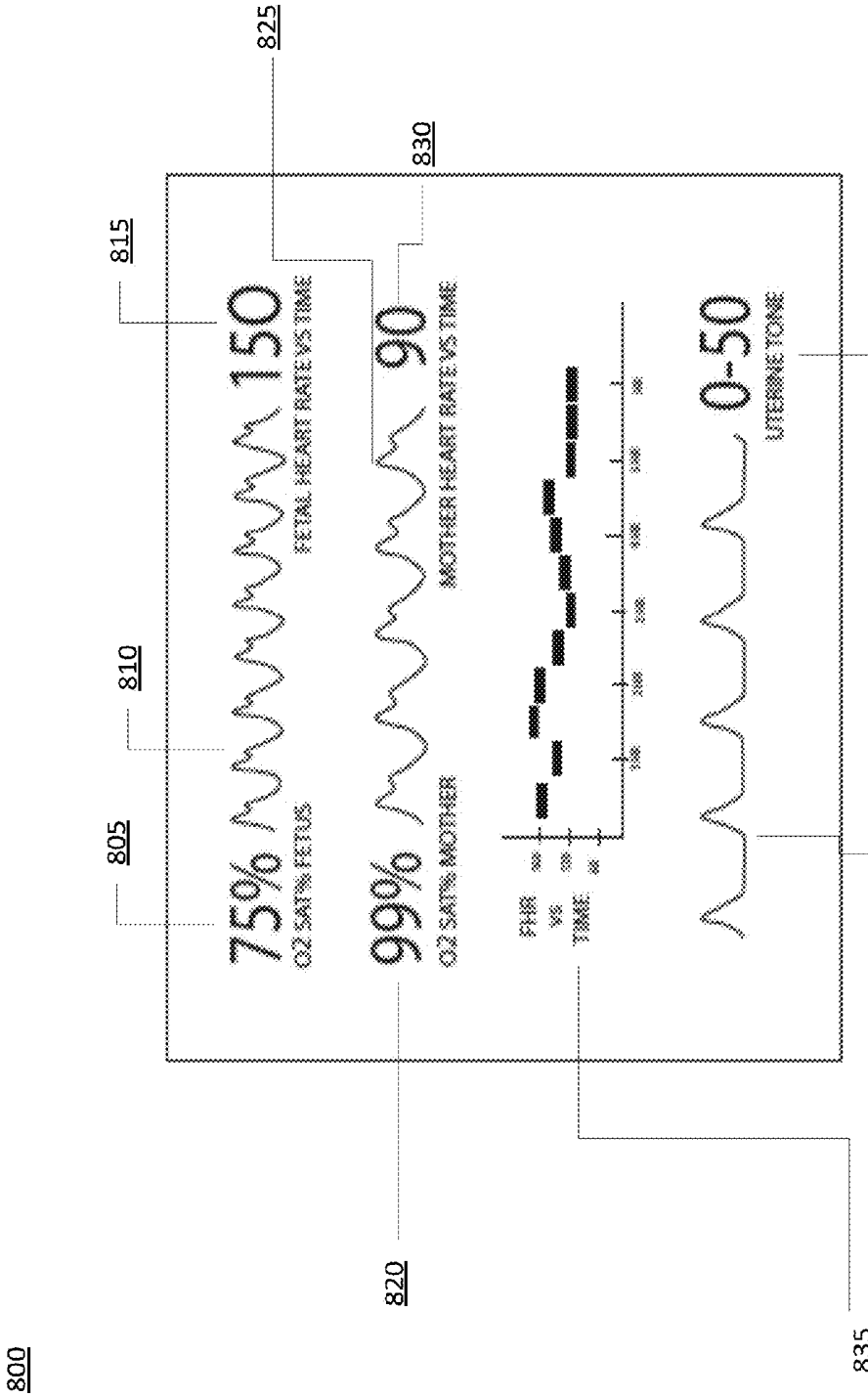

800
805
810
815
820
825
830
835
840
845
75%
O2 SATN FETUS
150
FETAL HEART RATE VS TIME
99%
O2 SATN MOTHER
90
MOTHER HEART RATE VS TIME
FHR
VS
TIME
0-50
UTERINE TONE

Figure 8A

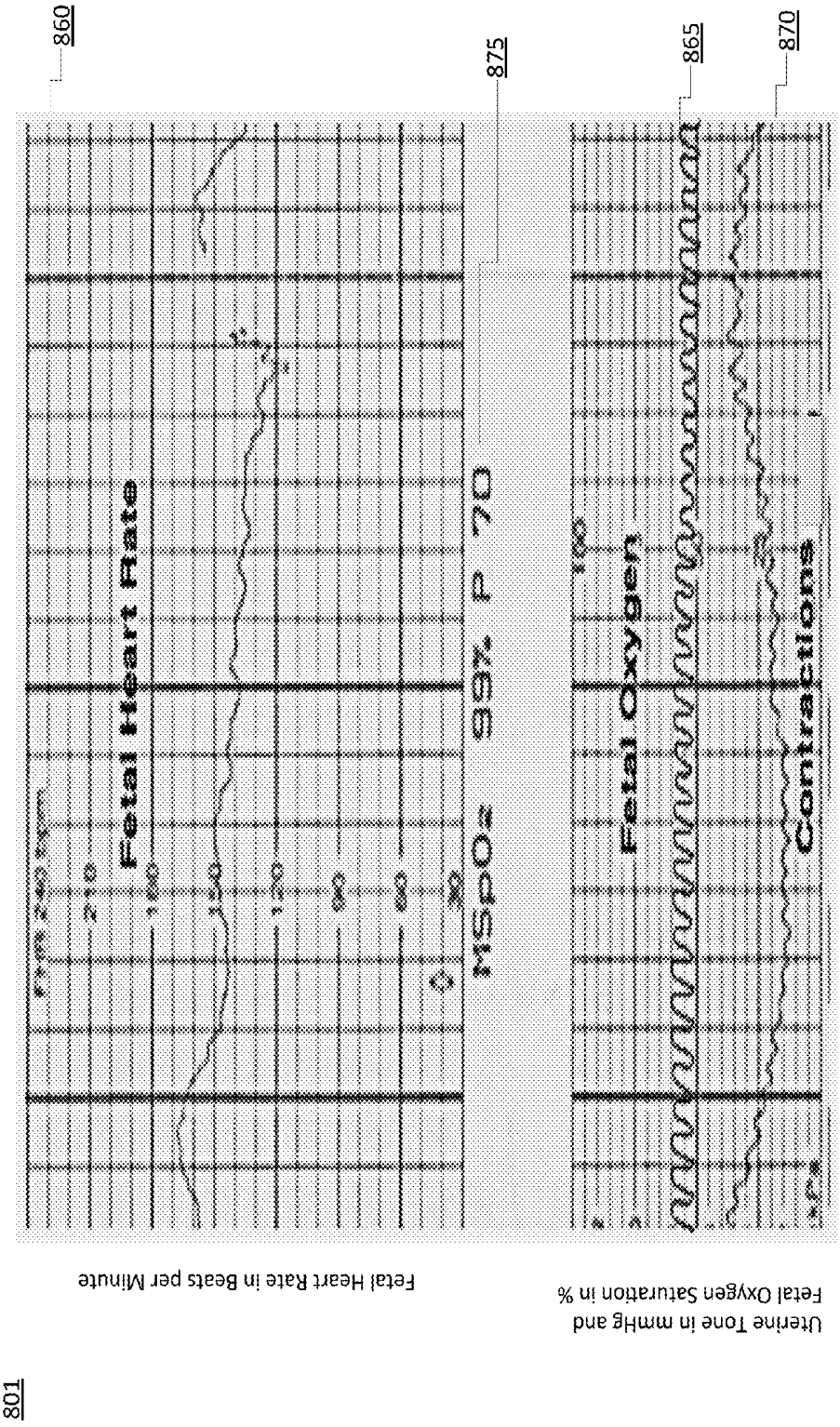

801
860
875
865
870
Fetal Heart Rate
MSpO2 99% P 70
Fetal Oxygen
Contractions
Fetal Heart Rate in Beats per Minute
Uterine Tone in mmHg and
Fetal Oxygen Saturation in %
Time in Minutes

Figure 8B

SYSTEMS, DEVICES, AND METHODS FOR PERFORMING TRANS-ABDOMINAL FETAL OXIMETRY AND/OR TRANS-ABDOMINAL FETAL PULSE OXIMETRY

RELATED APPLICATION

This application is a non-provisional of, and claims priority to, U.S. Provisional Patent Application No. 62/273,196 entitled "SYSTEMS, DEVICES, AND METHODS FOR DETECTING/DETERMINING FETAL HEMOGLOBIN OXYGEN SATURATION LEVELS" filed Dec. 30, 2015, which is incorporated by reference, in its entirety, herein.

FIELD OF INVENTION

The present invention is in the field of medical devices and, more particularly, in the field of trans-abdominal fetal oximetry and trans-abdominal fetal pulse oximetry.

BACKGROUND

When a pregnant mammal is engaged in the labor and delivery process for her fetus, a common practice is to monitor both the heart rate of the fetus and the uterine tone of the pregnant mammal. The uterine tone of the pregnant mammal provides information regarding the uterine contractions of the pregnant mammal by measuring the pressure exerted by the uterine muscle in units of pressure, for example, millimeters of mercury (mmHg) and/or kilo Pascals (kPg). One way to provide information regarding the fetal heartbeat and uterine tone to a doctor or other healthcare provider is to provide a graph, either in paper or electronic form, that displays a fetal heart rate over time and uterine tone over time. In most cases, this information is synchronized so that the fetal heartbeat and uterine tone for a particular moment in time may be simultaneously observed. By comparing the fetal heart rate at a particular moment in time with the uterine tone at that same moment in time, a doctor may be able to determine whether the fetal heart rate decreases when the pregnant mammal experiences a contraction.

FIGS. **1**A and **1**B provide two examples of simultaneously displayed fetal heartbeat and uterine tone for corresponding moments in time. In FIGS. **1**A and **1**B, graphs **10**A and **10**B, respectively, display fetal heartbeat in beats per minute as a function of time where each vertical line provided on the grid represents one minute. In FIGS. **1**A and **1**B, graphs **12**A and **12**B, respectively, display uterine tone in mmHg and kPa as a function of time. In FIG. **1**A, graph **10**A shows fetal heart rate within a normal range of 120-180 beats per minute and there are no obvious fluctuations in the fetal heart rate that correspond with changes in uterine tone. With the information provided by FIG. **1**A, a doctor may draw the conclusion that the fetus is not being negatively impacted by the uterine contractions and is not in distress. In contrast, graph **10**B shows a fetal heart rate that experiences significant dips (e.g., from approximately 150 beats per minute prior to a uterine contraction to below 90 beats per minute during an immediately following a uterine contraction) that correspond with uterine contractions (i.e., increases in pressure within the uterus). With the information provided by FIG. **1**B, a doctor may draw the conclusion that the fetus is being negatively impacted by the uterine contractions and may be in distress (e.g., experiencing a lack of oxygen that may cause neurologic damage). Upon drawing this conclusion, the doctor may decide that the fetus' health is in danger and, therefore, it should be surgically removed from the uterus via a Caesarian section (C-section). However, a change in fetal heart rate of the type shown in FIG. **1**B does not always indicate that the fetus is in distress as there are many other possible causes for a drop in fetal heart rate. Thus, the doctor may prescribe a C-section when one is not needed causing undue harm to the pregnant mammal.

Oximetry is a method for determining the oxygen saturation of hemoglobin in a mammal's blood. Typically, 90% (or higher) of an adult human's hemoglobin is saturated with (i.e., bonded to) oxygen while only 30-60% of a fetus's blood is saturated with oxygen.

Pulse oximetry is a type of oximetry that uses changes in arterial blood volume through a heart beat cycle to internally calibrate oxygen saturation measurements of the oxygen level of the blood.

Current methods of performing fetal oximetry are flawed for many reasons. For example, while U.S. Patent Publication No. 2004/0116789 describes a fetal oximeter using pulse oximetry, this oximeter is flawed for at least three reasons. First, the wavelengths of the electro-magnetic radiation used by the '789 Publication to determine fetal oximetry are short and consequently cannot travel a distance through the abdomen of the pregnant mammal so as to reach the fetus with sufficient strength. Thus, the signal reflected signal is too weak to decipher. Second, the '789 Publication is flawed because of the assumptions included therein are based on research with adult hemoglobin, which is fundamentally different from fetal hemoglobin because fetal hemoglobin has a different structure than adult hemoglobin and therefore absorbs/reflects light differently. Finally, the '789 application does not process the received signal to reduce noise.

Like the '789 Publication, Patent WO 2009032168 describes a fetal oximeter using near-infrared spectroscopy but fails to provide a signal processing algorithm. In addition, the WO 2009032168 uses assumptions regarding adult hemoglobin to determine fetal oximetry, which yields inaccurate results because, as noted above, fetal hemoglobin and adult hemoglobin have different structures and, therefore reflect light differently.

U.S. Patent Publication No. 2011/0218413 describes an algorithm for signal processing that uses maternal electrocardiography (ECG), Doppler, and pulse oximetry. However, for at least the reasons pointed out above, trying to obtain a fetal oximetry signal using maternal (i.e., adult) pulse oximetry won't work. Furthermore, the '413 Publication fails to make any compensation for structural differences in fetal and adult hemoglobin.

U.S. Patent Publication No. 2011/0218413 provides another example wherein a pregnant mammal wears a belt that shines light towards the belly and fetus that is detected on the other side of the abdomen. The distance traveled by the light would be 15-30 inches, or 35 to 75 cm, and this is not technically feasible because the signal received by the detector would be too weak to decipher. The light looses intensity quickly and there are FDD limitations on how intense the light directed into a pregnant mammal's abdomen can be because light that is too intense could cause, for example, burns to the pregnant mammal and retinal damage to the fetus.

SUMMARY

Disclosed herein are systems, devices, and methods for performing trans-abdominal fetal oximetry and/or trans-

abdominal fetal pulse oximetry. The systems, devices, and methods may be performed using one or more fetal hemoglobin probes that are in contact with an abdomen of pregnant mammal (i.e., attached to the pregnant mammal via an adhesive, strap, harness, etc.). In some embodiments, all, or a portion of, a fetal hemoglobin probe may not be in contact with the pregnant mammal's abdomen as may be the case when performing a contactless pulse oximetry measurement and calculation. When a contactless pulse oximetry measurement and calculation is used, fetal hemoglobin probe and/or parts thereof may be positioned above the pregnant mammal's abdomen on, for example, a scaffold or cart.

Exemplary fetal hemoglobin probes disclosed herein may include a housing, a plurality of light sources, one or more detectors, a transceiver, and a power source. Exemplary systems disclosed herein include one or more fetal hemoglobin probes and a processor or computer that may be coupled with a display device (e.g., monitor or touch screen). More particularly, the housing of a fetal hemoglobin probe may be configured to house a first light source, a second light source, a detector, a transceiver, and a power source. In some cases the housing, first light source, second light source, detector, transceiver, and/or power source are configured to be disposable following a single use.

The first light source adapted to project light of a first wavelength into the abdomen of a pregnant mammal toward a fetus contained therein and the second light source adapted to project light of a second wavelength into the abdomen of the pregnant mammal toward the fetus. In some instances, the first and second light sources may reside in a single light housing configured with multiple light sources (e.g., LEDs) and, in other instances, the first and second light sources may be separately housed. Exemplary wavelengths for light emitted from the first light source may be between 700 nm and 740 nm and exemplary wavelengths for light emitted from the second light source may be between 800 and 900 nm.

The detector may be adapted to detect light reflected from the pregnant mammal's abdomen and the fetus. Exemplary detectors include but are not limited to photo detectors, light sensors, photodiodes and cameras. When the detector is a photo detector (or the like) the detector may also convert the detected light into an electronic reflected signal and communicate the electronic reflected signal to the transceiver.

The transceiver may be adapted to receive the electronic reflected signal from the detector and communicate the received electronic reflected signal to a processor or computer. The transceiver may be any device capable of receiving information from the detector and communicating information from the fetal hemoglobin probe.

The power source may be electrically coupled to the first light source, the second light source, and the detector and adapted to provide electrical power to first light source, the second light source, the detector, and the transceiver. Exemplary power sources include, but are not limited to, batteries and equipment to couple the fetal hemoglobin probe to a conventional power source (e.g., wall socket).

The processor may be configured to receive the electronic reflected signal from the detector and isolate a portion of the reflected electronic signal that is reflected from the fetus. The processor may then analyze the isolated portion of the reflected electronic signal to determine a fetal hemoglobin oxygen saturation level and provide an indication of the oxygen level of fetal blood to a display device, such as a monitor.

In some embodiments, the system may include an adjustment mechanism coupled to at least one of the first and second light sources. The adjustment mechanism may be adapted to adjust, for example, a frequency of light emitted by the respective first and/or second light sources, an incident angle of the light emitted by the respective first and/or second light sources when projected into the pregnant mammal's abdomen, and focus a beam of light as it is projected into the pregnant mammal's abdomen as it emitted from the respective first and/or second light sources.

In one exemplary embodiment, the system further includes an adjustment device coupled to the housing, or a portion thereof. The adjustment device may be adapted to adjust, for example, a frequency of light emitted by the respective first and second light sources, an incident angle of the light emitted by the respective first and/or second light sources when projected into the pregnant mammal's abdomen, and focus a beam of light as it is projected into the pregnant mammal's abdomen as it emitted from the respective first and/or second light sources.

In some embodiments, the system may include an additional detector, the additional detector may be positioned within the housing and coupled to the transceiver and power source. The additional detector may be adapted to detect light reflected from the pregnant mammal's abdomen and the fetus, convert the detected light into an additional electronic reflected signal, and communicate the additional electronic reflected signal to the transceiver and/or processor or a computer.

In some embodiments, the system and/or fetal hemoglobin probe may include four or more additional light sources housed within the housing, or housed in a separate housing. Each of the additional light sources being coupled to a power source. These embodiments may also include an additional detector. The additional detector may be positioned within the housing and coupled to the transceiver and power sources and may be adapted to detect light reflected from the pregnant mammal's abdomen and the fetus, convert the detected light into an additional electronic reflected signal, and communicate the additional electronic reflected signal to the transceiver and/or processor or a computer. In these embodiments, the housing may be adapted to have a length of at least 10 cm so as to extend around a portion of the pregnant mammal's abdomen and direct light at multiple positions (e.g., two or more sides) of the fetus. In these embodiments, the detector may be positioned on a first side of the housing and the additional detector may be positioned on a second side of the housing and the light sources are positioned between the first and second sides of the housing.

In some cases, the system may include a temperature probe housed within the housing and coupled to the power supply and transceiver. The temperature probe may be adapted to measure a temperature of the pregnant mammal's abdomen and/or skin and communicate the temperature measurements to, for example, the transceiver and/or controller. At times, a temperature measurement in excess of a threshold may indicate that the system is too hot and may cause injury to the pregnant mammal and/or fetus. When this happens, controller may shut off one or more components of the system and/or notify an operator of the pregnant mammal's elevated temperature.

In another embodiment, the system may include an ultrasonic detector being housed within the housing and coupled to the power supply and transceiver. The ultrasonic detector may be adapted to detect ultrasonic emissions of the pregnant mammal's abdomen and fetus caused by transient thermoelastic expansion resultant from an interaction of the

pregnant mammal's abdomen and the fetus' tissue to light emitted from at least one of the first light source and the second light source due to the so-called photoacoustic effect.

In another embodiment, the system may further include a uterine contraction measurement that is housed within the housing and coupled to the power supply and transceiver, processor, and/or a computer. The uterine contraction measurement may be adapted to measure changes in a muscular state of the pregnant mammal's uterus and communicate these measurements to the transceiver, the processor, and/or a computer.

Exemplary methods described herein may include directing, by a light source, a light beam emitted from the light source into an abdomen of a pregnant mammal toward a fetus contained therein. Light reflected by the pregnant mammal and the fetus may be received at a detector over a first time domain. The detector may then convert the received light into an electronic reflected signal and communicate the electronic reflected signal to a computer/processor.

The computer may then process the electronic reflected signal to isolate a portion of the electronic reflected signal reflected from the fetus and analyze the portion of the electronic reflected signal reflected from the fetus to determine a fetal hemoglobin oxygen saturation level of the fetus. The computer may then facilitate provision of an indication of the fetal hemoglobin oxygen saturation level to an operator, such as a doctor or medical technician.

In some embodiments, processing the electronic reflected signal to isolate a portion of the electronic reflected signal reflected from the fetus includes receiving a heartbeat signal for the pregnant mammal over a second time domain. The heartbeat signal indicates when, in the second time domain, a pregnant mammal's heartbeat occurs. The electronic reflected signal and the pregnant mammal's heartbeat signal may then be synchronized over the first time domain and the second time domain and a portion of the electronic received signal that corresponds in the synchronized first and second time domains with the heartbeat signal for the pregnant mammal may be determined. The portion of the electronic received signal that corresponds with the heartbeat signal for the pregnant mammal from the electronic received signal may then be subtracted electronic received signal.

In another embodiment, the processing of the electronic reflected signal to isolate a portion of the electronic reflected signal reflected from the fetus may include receiving a fetal heartbeat signal for the fetus over a second time domain. The fetal heartbeat signal may indicate when, in the second time domain, a fetal heartbeat occurs. The electronic reflected signal and the fetal heartbeat signal may then be synchronized over the first time domain and the second time domain and portions of the electronic reflected signal that correspond in the synchronized first and second time domains with individual heartbeats of the fetus as indicated by the received heartbeat signal for the fetus may be examined to determine the fetal hemoglobin saturation level of the fetus.

In a further embodiment, processing the electronic reflected signal to isolate a portion of the electronic reflected signal reflected from the fetus comprises receiving a fetal heartbeat signal for the fetus over a second time domain, the heartbeat signal indicating when, in the second time domain, a fetal heartbeat occurs. The electronic reflected signal and the fetal heartbeat signal might then be synchronized over the first time domain and the second time domain. Then, the synchronized electronic reflected signal may be multiplied by the synchronized fetal heartbeat signal.

BRIEF DESCRIPTION OF THE FIGURES

The present invention is illustrated by way of example, and not limitation, in the figures of the accompanying drawings in which:

FIGS. **1**A and **1**B provide examples of simultaneously displayed fetal heartbeat and uterine tone for corresponding moments in time.

FIG. **2**A provides an exemplary system **100** for determining a fetal oxygen level, consistent with an embodiment of the invention;

FIGS. **2**B-**2**E provide block diagrams of exemplary fetal hemoglobin probes, consistent with embodiments of the invention;

FIGS. **3**A, **3**B, **3**C, and **3**D provide illustrations of how light from a fetal hemoglobin probe may be directed into a pregnant mammal's abdomen, consistent with embodiments of the invention;

FIG. **4**A is a flowchart illustrating a process for determining fetal hemoglobin saturation level, consistent with embodiments of the invention;

FIGS. **4**B and **4**C are flowcharts illustrating processes for processing the reflected electronic signal to isolate the portion of the reflected electronic signal reflected from the fetus, consistent with embodiments of the invention;

FIG. **5**A provides a graph of total reflected electronic signal intensity vs. time, consistent with an embodiment of the invention;

FIG. **5**B provides a graph of a fetal Doppler signal vs. time, consistent with an embodiment of the invention;

FIG. **5**C provides a graph that shows the product of multiplying the total reflected electronic signal intensity and the Doppler signal together while synchronizing over time, consistent with an embodiment of the invention;

FIG. **5**D, provides a graph of the total reflected electronic signal intensity, the fetal heartbeat/Doppler signal and the result of multiplying total reflected electronic signal intensity and Doppler signal synchronized over time, consistent with an embodiment of the invention;

FIG. **6**A provides a graph of a fetal Doppler signal vs. time, consistent with an embodiment of the invention;

FIG. **6**B provides a graph of reflected electronic signal intensity for λ_1 vs. time, consistent with an embodiment of the invention;

FIG. **6**C provides a graph that shows the product of multiplying the total reflected electronic signal intensity for λ_1 and the fetal Doppler signal together while synchronizing over time, consistent with an embodiment of the invention;

FIG. **6**DD, provides a graph that shows the product of multiplying the total reflected electronic signal intensity for λ_1 and the fetal Doppler signal together while synchronizing over time averaged over several periods, consistent with an embodiment of the invention;

FIG. **6**E provides a graph of reflected electronic signal intensity for λ_2 vs. time, consistent with an embodiment of the invention;

FIG. **6**F provides a graph that shows the product of multiplying the total reflected electronic signal intensity for λ_2 and the fetal Doppler signal together while synchronizing over time, consistent with an embodiment of the invention;

FIG. **6**G, provides a graph that shows the product of multiplying the total reflected electronic signal intensity for λ_2 and the fetal Doppler signal together while synchronizing

over time averaged over several periods, consistent with an embodiment of the invention;

FIG. **6**H provides a graph that shows a relationship between a red/IR wavelength modulation ration and arterial oxygen saturation (% SaO2);

FIG. **7**A provides a table of various hemoglobin measurements as a function of light wavelength shone into the blood of an adult donor and fetal blood obtained by puncture of the umbilical cord immediately after delivery, consistent with an embodiment of the invention;

FIG. **7**B depicts a graph that shows difference in absorptivities between oxygenated and deoxygenated state of fetal and the pregnant woman's hemoglobin in visible wavelengths of light, consistent with an embodiment of the invention;

FIG. **7**C depicts a graph that shows difference in absorptivities between oxy- and deoxy-state of fetal and the pregnant woman's hemoglobin in the near infrared (NIR) wavelengths of light, consistent with an embodiment of the invention;

FIG. **8**A provides an exemplary display that provides a level of fetal hemoglobin oxygen saturation along with other information regarding measurements of the pregnant mammal and fetus, consistent with an embodiment of the invention; and

FIG. **8**B provides an exemplary display of synchronized fetal heartbeat, fetal hemoglobin oxygen saturation rate, and uterine tone for corresponding moments in time, consistent with an embodiment of the invention.

Throughout the drawings, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components, or portions of the illustrated embodiments. Moreover, while the subject invention will now be described in detail with reference to the drawings, the description is done in connection with the illustrative embodiments. It is intended that changes and modifications can be made to the described embodiments without departing from the true scope and spirit of the subject invention as defined by the appended claims.

DESCRIPTION

Described herein are systems, devices, and methods for fetal oximetry and/or fetal pulse oximetry both trans-abdominally and in-utero. A key output of fetal oximetry and/or fetal pulse oximetry is the level of oxygen saturation of the fetus's blood (also referred to herein as "fetal hemoglobin oxygen saturation level" and "oxygen saturation level", which may also be understood as the percentage of hemoglobin present in the fetus' blood that is bound to oxygen. The oxygen saturation level of a fetus' blood may be used by trained medical professionals to assess the health of a fetus as well as a level of stress it may be under during, for example, a labor and delivery process. Typically values of oxygen saturation for fetal blood fall within the range of 30-60% with anything lower than 30% indicating that the fetus may be in distress.

For the purposes of the following discussion, the terms "pregnant mammal" or "maternal" "mother" is used to refer to female human being or animal (e.g., horse or cow) pregnant with a fetus. In most embodiments, the pregnant individual will be a human being but this need not be the case as the invention may be used for nearly any pregnant mammal. Whether, or not, the pregnant mammal is the biological mother of the fetus (i.e., source of the egg from which the fetus grows) is not relevant to this invention. What is relevant is that the woman is pregnant with the fetus.

Typically, fetal well being is assessed during labor and delivery by looking at the absolute fetal heart rate as measured in beats per minute and observing how fetal heart rate changes, or reacts to, uterine contractions. It is generally accepted that a fetal heart rate within the range of 120-160 beats per minute is normal and does not indicate fetal distress. However, sudden changes in fetal heart rate as well as fetal heart rates that are too high (e.g., 180 beats per minute) or too low (e.g., 100 or 80 beats per minute) are cause for concern, especially if these changes occur during a prolonged, difficult, or otherwise complicated labor and delivery process.

For example, as the uterus contracts to expel the baby out of the birth canal, the contracting uterus constricts the blood vessels and hence blood flow to and from the placenta, which supplies blood to and from the fetus. It is expected that restricted blood flow to the fetus may result in a slowing of the fetal heart rate. However, a drop in fetal heart rate from 150 to 120 after every uterine contraction may be an indication of fetal distress and may prompt intervention (e.g., a C-section, drug administration, etc.) by a physician or other clinician during the birthing process.

However, in some instances, this intervention may not be necessary because not all drops in fetal heart rate are caused by fetal distress. In fact, the fetus is frequently just fine when its heart rate changes—but the physician has no further information to assist in determining whether the change in fetal heart rate is normal or pathological. Thus, an indication of the oxygen saturation level of the fetus' hemoglobin would be a useful additional indication of fetal well being when, for example, determining whether to intervene in the labor and delivery process with surgery or other treatment administration. For example, an indication that the fetal hemoglobin oxygen saturation level is constant provides an indication to the physician that the fetus is in good health even when the heart rate of the fetus drops or changes. Conversely, a drop in the fetal hemoglobin oxygen saturation level following uterine contractions coupled with a decreasing heart rate would be a cause for concern and may indicate to the physician that an intervention, like a C-section, is necessary.

Currently, many C-sections are performed solely because of variations in, or drops of, fetal heart rate, which are seen by physicians as a sign of fetal distress. 2 million C-sections are performed annually in the United States and, in some regions of the United States, C-sections are performed in nearly half (50%) of all births. In some instances, these C-sections may not be necessary because the fetus may not truly be in distress. However, without further information (as may be provided via fetal pulse oximetry), physicians may over-prescribe C-sections and other interventions out of an abundance of caution

The present invention provides a more complete picture of fetal health during the labor and delivery process and may thereby reduce the number of unnecessarily performed C-sections when the decision to perform a C-section is based on fetal heart rate readings alone. It is expected that reducing the number of unnecessarily performed C-sections will reduce the overall cost of health care for pregnant women and newborns and reduce the number of complications that result from C-sections, which can be very significant. For example, 1 in 1000 C-sections will result in a major complication such as a blood clot, requirement of a blood transfusion, or surgical wound infection and 1 in 10,000 C-sections will result in death of the mother.

Fetal hemoglobin has a structure that is slightly different from the structure hemoglobin of adult hemoglobin. More

specifically, adult hemoglobin has 2 alpha and 2 beta polypeptide chains and fetal hemoglobin has 2 alpha and 2 gamma polypeptide chains. Additionally, fetal hemoglobin has a stronger affinity for oxygen than adult hemoglobin. Because of these factors, fetal hemoglobin absorbs light differently than maternal hemoglobin.

Additionally, fetal hemoglobin has a conformation when bound to oxygen that is different from the conformation of the fetal hemoglobin when unbound to oxygen. These different conformations of the hemoglobin absorb light at different amounts and hence reflect light at different amounts. Therefore, observation of fetal venous hemoglobin oxygen saturation levels may be clinically more useful than fetal arterial hemoglobin oxygen saturation levels.

Disclosed herein are systems, devices, and methods for performing non-invasive in-utero fetal oximetry using near infrared spectroscopy (NIRS) to determine the oxygen saturation level of arterial and/or venous fetal hemoglobin. The determined oxygen saturation level of arterial and/or venous fetal hemoglobin may then be used by, for example, a physical or other caregiver to ascertain information regarding fetal health and/or distress. In some embodiments, the systems, devices, and methods may employ a non-invasive monitor that can be placed on a pregnant mammal's abdomen to monitor fetal oxygen saturation levels.

Because fetal hemoglobin is microscopic, it cannot be observed directly. However, reflections of near infrared light from the fetal hemoglobin may be observed. Furthermore, different intensities for different wavelengths of light that are reflected by the fetal hemoglobin may also be observed. Additionally, different intensities for light that is reflected by fetal oxyhemoglobin when compared to fetal de-oxyhemoglobin may also be observed. Processing of this observed reflected light might yield a determination of a fetal oxygen saturation level.

FIG. **2**A provides an exemplary system **100** for determining a fetal oxygen level and, in some instances, detecting and/or determining fetal hemoglobin oxygen saturation levels. The components of system **100** may be coupled together via wired or wireless communication links. In some instances wireless communication of one or more components of system **100** may be enabled using short-range wireless communication protocols designed to communicate over relatively short distances (e.g., BLUETOOTH® near field communication (NFC), radio-frequency identification (RFID), and Wi-Fi) with, for example, a computer or personal electronic device as described below. In some embodiments, one or more components of system **100** may include one or more devices configured to communicate via one or more short-range communication protocols (e.g., near field communication (NFC), Bluetooth, Radio-frequency identification (RFID), and Wi-Fi).

System **100** includes a number of independent sensors/probes designed to monitor various aspects of maternal and/or fetal health and be in contact with a pregnant mammal. These probes/sensors are a fetal hemoglobin probe **115**, a NIRS adult hemoglobin probe **125** a pulse oximetry probe **130**, and a Doppler and/or ultrasound probe **135**. In some embodiments, system **100** may also include an electrocardiography (EKG, or ECG) machine (not shown) that may be used to determine the pregnant mammal's and/or fetus' heart rate and/or an intrauterine pulse oximetry probe that may be used to determine the fetus' heart rate. The Doppler and/or ultrasound probe **135** may be configured to be placed on the abdomen of the pregnant mammal and may be of a size and shape that approximates a silver U.S. dollar coin. Pulse oximetry probe **130** may be a conventional pulse oximetry probe placed on pregnant mammal's hand and/or finger to measure the pregnant mammal's oxygen saturation. NIRS adult hemoglobin probe **125** may be placed on, for example, the pregnant mammal's 2nd finger and may be configured to, for example, use near infrared spectroscopy to calculate the ratio of adult oxyhemoglobin to adult de-oxyhemoglobin. NIRS Adult hemoglobin probe **125** may also be used to determine the pregnant mammal's heart rate.

Optionally, system **100** may include a uterine contraction measurement device **140** configured to measure the strength and/or timing of the pregnant mammal's uterine contractions. In some embodiments, uterine contractions will be measured by uterine contraction measurement device **140** as a function of pressure (measured in e.g., mmHg) over time. In some instances, the uterine contraction measurement device **140** is and/or includes a tocotransducer, which is an instrument that includes a pressure-sensing area that detects changes in the abdominal contour to measure uterine activity and, in this way, monitors frequency and duration of contractions.

In another embodiment, uterine contraction measurement device **140** may be configured to pass an electrical current through the pregnant mammal and measure changes in the electrical current as the uterus contracts. Additionally, or alternatively, uterine contractions may also be measured via near infrared spectroscopy because uterine contractions, which are muscle contractions, are oscillations of the uterine muscle between a contracted state and a relaxed state. Oxygen consumption of the uterine muscle during both of these stages is different and these differences may be detectable using NIRS.

Measurements from NIRS adult hemoglobin probe **125**, pulse oximetry probe **130**, Doppler and/or ultrasound probe **135**, and/or uterine contraction measurement device **140** may be communicated to receiver **145** for communication to computer **150** and display on display device **155**. In some instances, one or more of NIRS adult hemoglobin probe **125**, pulse oximetry probe **130**, a Doppler and/or ultrasound probe **135**, uterine contraction measurement device **140** may include a dedicated display that provides the measurements to, for example, an operator or medical treatment provider.

As will be discussed below, measurements provided by NIRS adult hemoglobin probe **125**, pulse oximetry probe **130**, a Doppler and/or ultrasound probe **135**, uterine contraction measurement device **140** may be used in conjunction with fetal hemoglobin probe **115** to isolate a fetal pulse signal and/or fetal heart rate from a maternal pulse signal and/or maternal heart rate.

It is important to note that not all of these probes may be used in every instance. For example, when the pregnant mammal is using fetal hemoglobin probe **115** in a setting outside of a hospital or treatment facility (e.g., at home or work) then, some of the probes (e.g., NIRS adult hemoglobin probe **125**, pulse oximetry probe **130**, a Doppler and/or ultrasound probe **135**, uterine contraction measurement device **140**) of system **100** may not be used.

Receiver **145** may be configured to receive signals and/or data from one or more components of system **100** including, but not limited to, fetal hemoglobin probe **115**, NIRS adult hemoglobin probe **125**, pulse oximetry probe **130**, Doppler and/or ultrasound probe **135**, and/or uterine contraction measurement device **140**. Communication of receiver **145** with other components of system may be made using wired or wireless communication.

In some instances, receiver **145** may be configured to process or pre-process received signals so as to, for example, make the signals compatible with computer **150** (e.g., con-

vert an optical signal to an electrical signal), improve SNR, amplify a received signal, etc. In some instances, receiver **145** may be resident within and/or a component of computer **150**. Also, while receiver **145** is depicted in FIG. **2**A as a single receiver, that is not necessarily the case as any number of appropriate receivers (e.g., 2, 3, 4, 5) may be used to receive signals from system **100** components and communicate them to computer **150**. In some embodiments, computer **150** may amplify or otherwise condition the received reflected signal so as to, for example, improve the signal-to-noise ratio.

Receiver **145** may communicate received, pre-processed, and/or processed signals to computer **150**. Computer **150** may act to process the received signals, as discussed in greater detail below, and facilitate provision of the results to a display device **155**. Exemplary computers **150** include desktop and laptop computers, servers, tablet computers, personal electronic devices, mobile devices (e.g., smart phones), and so on. Exemplary display devices **155** are computer monitors, tablet computer devices, and displays provided by one or more of the components of system **100**. In some instances, display device **155** may be resident in receiver **145** and/or computer **150**.

Fetal hemoglobin probe **115** may be used to direct NIR light into the abdomen of the pregnant mammal so as to reach the fetus and to detect light reflected from the fetus. The NIR light may be emitted by fetal hemoglobin probe **115** in, for example, a continuous and/or pulsed manner. This reflected light might then be processed in order to determine how much light, at various wavelengths, is reflected and/or absorbed by the fetal oxyhemoglobin and/or de-oxyhemoglobin so that a fetal hemoglobin oxygen saturation level may be determined. This processing will be discussed in greater detail below. In some embodiments, fetal hemoglobin probe **115** may be configured, partially or wholly, as a single-use, or disposable, probe that is affixed to the pregnant mammal's skin on, for example, the pregnant mammal's abdomen and, in some embodiments, in the supra-pubic (bikini) region.

Exemplary dimensions for fetal hemoglobin probe **115** include, but are not limited to, 2-16 inches in length and 0.5-8 inches in width. In some instances, fetal hemoglobin probe **115** may come in a variety of sizes so as to, for example, accommodate varying clinical needs, the size of the fetus, fetal position, the size of the pregnant mammal, and/or the size of the pregnant mammal's abdomen.

Fetal hemoglobin probe **115** may include one or more components as will be described in greater detail below with regard to FIGS. **2**B-**2**E, of which the fetal hemoglobin probes of FIG. **2**B-**2**D (i.e., **115**A, **115**B, **115**C, and **115**D) are trans-abdominal fetal hemoglobin probes. The fetal hemoglobin probes **115** disclosed herein may include a housing **102** configured to house one or more components of fetal hemoglobin probe **115**. Although the embodiments disclosed herein have all of the components of fetal hemoglobin probes **115** contained within a single housing **102**, this is not necessarily the case as, for example, two or more components of a fetal hemoglobin probe **115** may be housed in separate housings **102**. Housings **102** may be, for example, square, circular, or rectangular in shape and may be designed to be, in some instances, adjustable depending on, for example, a topology of the pregnant mammal's abdomen, a level of skin pigmentation for the pregnant mammal and/or her fetus, and so on.

In some embodiments, fetal hemoglobin probe **115** and/or housing **102** may be disposable and in other embodiments, fetal hemoglobin probe **115** (including and/or housing **102**) may be configured for multiple uses (i.e., reusable). In some embodiments, (e.g., when fetal hemoglobin probe is configured to be disposable), may include an adhesive designed to be applied to the skin of the pregnant mammal's abdomen (e.g., glue, tape, etc.) configured to apply housing **102**/fetal hemoglobin probe **115** directly to the skin of the pregnant mammal's abdomen and hold it in place there in a manner similar to a sticker. In some instances, the fetal hemoglobin probe **115** may be applied to the pregnant mammal's skin via tape or a strap that cooperates with a mechanism (e.g., snap, loop, etc.) (not shown) provided by the housing **102**. In some circumstances, housing **102** may be attached/adjacent to the pregnant mammal's skin so that it does not move and, in other instances, it may be allowed to move in order to, for example, attain better measurements/readings. In some cases, housing **102** and/or a portion thereof may not be adapted to be in contact with the pregnant mammal's abdomen.

In some embodiments, housing **102** and/or a portion thereof may cooperate with a reusable and/or disposable sleeve (not shown) that fits over fetal hemoglobin probe **115** so that fetal hemoglobin probe **115** may be placed within a housing **102** reusable and/or disposable sleeve so that it may be applied to the pregnant mammal's skin.

Fetal hemoglobin probe **115** may be adapted to direct, or shine, light of one or more wavelengths into the abdomen of a pregnant mammal and receive a signal corresponding to a reflection of a portion of that light from the pregnant mammal's tissue and fluid as well as the tissue and fluids of the fetus.

Optionally, fetal hemoglobin probe **115** may include one or more mechanisms that enable the emitted light to be directed in a particular direction. Such mechanisms include, but are not limited to, wedges or adhesive material, that may be transparent or substantially transparent. For example, a fetal hemoglobin probe **115** may include a wedge positioned on one side that operates to direct the light in a particular direction relative to the surface of the pregnant mammal's skin and/or position a detector or transceiver to receive an optimized amount of reflected light.

In some embodiments, a fetal hemoglobin probe **115** may be adapted to be worn by a pregnant mammal for an extended period of time (e.g., days, weeks, etc.) that is not necessarily coincident with the labor and delivery process in order to, for example, monitor the health of a fetus. In some embodiments, one or more components of fetal hemoglobin probe **115** may be positioned outside the fetal hemoglobin probe **115** and may be optically connected thereto via, for example, one or more fiber optic or Ethernet cable(s).

A fetal hemoglobin probe **115** may be of any appropriate size and, in some circumstances, may be sized so as to accommodate the size of the pregnant mammal using any appropriate sizing system (e.g., waist size and/or small, medium, large, etc.). Exemplary lengths for a fetal hemoglobin probe **115** include a length of 4 cm-40 cm and a width of 2 cm-10 cm. In some circumstances, the size and/or configuration of a fetal hemoglobin probe **115**, or components thereof, may be responsive to skin pigmentation of the pregnant mammal and/or fetus.

It will be understood that although the components of fetal hemoglobin probe **115** are described herein as being included in a single probe, that is not necessarily so as the components of fetal hemoglobin probe **115** may be present in two or more different objects/devices applied to a pregnant mammal. In some instances, more than one fetal hemoglobin probe **115** may be used so as to, for example, improve accuracy of the fetal oxygen saturation measure-

ment. For example, a first fetal hemoglobin probe **115** (or a component thereof) may be placed on a left side of a pregnant mammal's abdomen and a second fetal hemoglobin probe **115** (or a component thereof) may be placed on a right side of the pregnant mammal's abdomen.

In some embodiments, fetal hemoglobin probe **115** and/or a pregnant mammal wearing a fetal hemoglobin probe **115** may be electrically insulated from one or more components of system **100** by, for example, an electricity isolator **120**. Exemplary electricity insulators **120** include circuit breakers, ground fault switches, and fuses.

Turning now to FIGS. **2**B-**2**E, which show different embodiments of exemplary fetal hemoglobin probes **115** labeled as **115**A, **115**B, **115**C, and **115**D, respectively, intended to be used trans-abdominally. It will be understood that reference to fetal hemoglobin probe **115** made herein may also refer to, and include, other embodiments of fetal hemoglobin probe including fetal hemoglobin probe **115**A, fetal hemoglobin probe **115**B, fetal hemoglobin probe **115**C, and fetal hemoglobin probe **115**D. FIG. **2**B illustrates exemplary fetal hemoglobin probe **115**A, which includes a power supply **160**, light source(s) **105**, a transceiver **107**, and a detector **114**.

Exemplary power supplies **160** include an on-board battery and/or an electrical connection to an external power source. Detector **114** may be adapted to receive a light signal reflected from the pregnant mammal and/or the fetus and convert this light signal into an electronic signal, which may be communicated to transceiver **107**. Some embodiments of fetal hemoglobin probe **115** may not include a transceiver **107** as may be the case when, for example, detector **114** is in direct communication with, for example, computer **150**. Exemplary detectors **114** include, but are not limited to, cameras, traditional photomultiplier tubes (PMTs), silicon PMTs, avalanche photodiodes, and silicon photodiodes. In some embodiments, the detectors will have a relatively low cost (e.g., $50 or below), a low voltage requirement (e.g., less than 100 volts), and non-glass (e.g., plastic) form factor. However, these alternatives do not have the same sensitivity to PMTs. In other embodiments, (e.g., contactless pulse oximetry) an extremely sensitive camera may be deployed to receive light reflected by the pregnant mammal's abdomen.

Light source(s) **105** may transmit light at various wavelengths, including NIR, into the pregnant mammal's abdomen. Typically, the light emitted by light source(s) **105** will be focused or emitted as a narrow beam so as to reduce spreading of the light upon entry into the pregnant mammal's abdomen. Light source(s) **105** may be, for example, a LED and/or a LASER. In some embodiments, light source(s) **105** may be an array of two or more light source(s) **105** as will be discussed below with regard to FIGS. **2**C-**2**E. An exemplary light source **105** is one with a relatively small form factor and high efficiency so as to limit heat emitted by the light source **105**. In one embodiment, light source **105** is configured to emit light at 850 nm an example of which is the LED in Dragon Dome Package that Emits Light of 850 nm manufactured by OSRAM Opto Semiconductors (model number SFH 4783), which has a length of 7.080 mm and a width of 6.080 mm. Another exemplary light source **105** is a LED configured to emit light of 730 nm, such as the GF CSHPM1.24-3S4S-1 manufactured by OSRAM Opto Semiconductors, which has a height of 1.58 mm and a length of 3.1 mm. Exemplary flux ratios for light source(s) include, but are not limited to a luminous flux/radiant flux of 175-260 mW, a total radiant flux of 300-550 mW and a power rating of 0.6W-3.5W.

In some embodiments, one or more light sources **105** may be a fiber optic cable transmitting light produced by another source (e.g., a LASER or tunable light bulb or LED) not resident within fetal hemoglobin probe **115**. In some instances, the light source(s) **105** may be tunable or otherwise user configurable while, in other instances, one or more of the light sources may be configured to emit light within a pre-defined range of wavelengths. Additionally, or alternatively, one or more filters (not shown) and/or polarizers may filter/polarize the light emitted by light source(s) **105** to be of one or more preferred wavelengths. These filters/polarizers may also be tunable or user configurable.

In some embodiments, the fetal hemoglobin probe **115** may direct NIR light of a plurality of wavelengths (e.g., 7, 6, 5, 4, 3, 2) via light sources **105**. In a preferred embodiment, five different wavelengths are used wherein a first wavelength is used to measure an oxygen saturation level of adult oxyhemoglobin, a second wavelength is used to measure an oxygen saturation level of adult de-oxyhemoglobin, a third wavelength is used to measure an oxygen saturation level of fetal oxyhemoglobin, and a fourth wavelength is used to measure an oxygen saturation level of fetal de-oxyhemoglobin. The fifth wavelength may be used to clean up/improve the signal by assisting in the detection of portions of the reflected signal that may be caused and/or distorted by substances other than the pregnant mammal's and/or the fetal hemoglobin. For example, melanin and bilirubin are known to absorb infrared light. Thus, in instances where the fetus and/or pregnant mammal has a darker pigment or when either or both are jaundiced, the associated melanin and/or bilirubin may distort the readings of the fetal hemoglobin probe **115** which may result in incorrectly calculating the oxygen saturation of the fetal and/or pregnant mammal's hemoglobin. The fifth wavelength may acts to test for these distortions so that they may be removed from the received signal and accurate oxygen saturation levels may be determined.

In some embodiments, detector **114** may be a sensitive camera adapted to capture small changes in fetal skin tone caused by changes in cardiovascular pressure as the fetus' heart beats. In these embodiments, fetal hemoglobin probe **115** may be in contact with the pregnant mammal's abdomen, or not, as this embodiment may be used to perform so-called contactless pulse oximetry. In these embodiments, light source(s) **105** of fetal hemoglobin probe **115** may be adapted to provide light (e.g., in the visible spectrum, near-infrared, etc.) directed toward the pregnant mammal's abdomen so that the detector **114** is able to receive light reflected by the pregnant mammal's abdomen and fetus. The reflected light captured by detector **114** in this embodiment may be communicated, via transceiver **107**, to computer **150** for processing so as to convert the images to a measurement of fetal hemoglobin oxygen saturation according to, for example, one or more of the processes described herein.

In this embodiment, adjustment mechanism **122** may be adapted to, for example, focus light source(s) **105**, change a frequency of light emitted by light source(s) **105**, change a distance light source(s) **105** and/or detector **114** is positioned away from the surface of the pregnant mammal's abdomen, and/or change a incident location of the emitted light.

Optionally, fetal hemoglobin probe **115** may also include one or more polarizers (not shown). A polarizer may act to polarize one more of the wavelengths of light prior to emission by fetal hemoglobin probe **115**. Polarizing the light and giving it a specific orientation may serve to, for example, assist in the identification of a signal and/or

distinguish a desired signal from noise and thereby improve a signal to noise ratio (SNR) of the received signal.

Transceiver **107** may be configured to the electronic signal (corresponding to the reflected light signal detected by detector **114**) from detector **114** and communicate the electronic signal to equipment (e.g., receiver **145** and/or computer **150**) external to fetal hemoglobin probe **115** via, for example, a fiber optic cable (in the case of a light signal) and/or a wireless or a wired signal (e.g., via an Ethernet port or hard-wired connection in the case of an electrical signal). In some instances, transceiver **107** may be a solid-state transceiver. In some embodiments, transceiver **107** may be resident in and/or a part of detector **114** and may be configured to detect light and/or photons reflected from the pregnant mammal and fetus and convert the detected light/photons into an electrical signal.

FIG. **2**C shows another exemplary fetal hemoglobin probe **1156** that includes power supply **160**, light source(s) **105**, transceiver **107**, detector **114**, an adjustment mechanism **122**, a temperature probe **165**, and a controller **112**.

Temperature probe **165** may be any appropriate mechanism for obtaining a temperature measurement for the pregnant mammal. Adjustment mechanism **122** may be one or more mechanisms adapted to adjust one or more properties of the light emitted by light source(s) **105** and/or a direction/incident angle of the light directed into the abdomen of the pregnant mammal. Exemplary adjustment mechanisms include, but are not limited to, filters and polarizers that may be used to adjust a frequency/wavelength of the light emitted by light source(s) **105** and/or an orientation for the light. Other exemplary adjustment mechanisms **122** include lenses adapted to, for example, focus or spread light directed into the pregnant mammal's abdomen. In some instances, the lenses may also change the angle of incidence for the light directed to the pregnant mammal's abdomen. In some embodiments, adjustment mechanisms **122** may also include mechanisms enabled to move a light source **105** and/or operate a lens, filter, or polarizer. In some embodiments, adjustment mechanism **122** may include a material that is sensitive to electricity and may be enabled to become transparent and/or partially opaque upon application of electricity. Often times, adjustment mechanism(s) **122** may receive instructions from controller **112** that may control (wholly or partially) the operation of the adjustment mechanism **122**.

Optionally, fetal hemoglobin probe **115** may also include one or more one or more ultrasonic detectors **170**. An ultrasonic detector **170** may be employed in embodiments of fetal hemoglobin probe **115** configured to perform optoacoustic/photoacoustic and/or thermoacoustic imaging by way of directing a light or radio frequency pulse from light source(s) **105** into the pregnant mammal's **305** abdomen. A portion of the incident light may be absorbed by the fetus and pregnant mammal and converted into heat, which leads to transient thermoelastic expansion, which causes an ultrasonic emission from the fetus and pregnant mammal. This ultrasonic emission may be detected by ultrasonic detector **170** and analyzed to determine a level of oxygen saturation for the fetus' and/or pregnant mammal's blood. In some instances, deploying fetal hemoglobin probe **115** to perform optoacoustic/photoacoustic and/or thermoacoustic imaging may require use of a laser and/or radio frequency pulse emitter (not shown).

Controller **112** may be adapted to control one or more components (e.g., adjustment mechanism **122**, light source(s) **105**, power supply **160**, temperature probe **165**, detector **114**, and/or transceiver **107**) of fetal hemoglobin probe **115**. In some circumstances, controller **112** may include a processor adapted to receive measurements/information from one more components (e.g., adjustment mechanism **122**, light source(s) **105**, power supply **160**, temperature probe **165**, detector **114**, and/or transceiver **107**) of fetal hemoglobin probe **115**. The processor may be further adapted to process the received measurements, make decisions therewith, and communicate instructions based on those decisions and/or measurements to one or more components of fetal hemoglobin probe **115**. For example, temperature probe **165** may act to measure the body temperature of the pregnant mammal and may provide these measurements to controller **112** and/or transceiver. In some embodiments, these measurements may be used to determine whether the temperature of the pregnant mammal exceeds a threshold measurement, which in some instances, may indicate that light source(s) **105** and/or fetal hemoglobin probe **115** are delivering too much heat/energy to the pregnant mammal. Upon reaching such a determination, controller **112** may provide instructions to light source(s) **105** and/or adjustment mechanism **122** to correct for this. Exemplary instructions include, but are not limited to, directions to redirect incident light, turn off, adjust a frequency, and adjust an intensity of one or more of the light source(s) **105**.

In some instances, instructions provided by controller **112** may be based on, for example, feedback from, for example detector **114** and/or transceiver **107** regarding, for example, the strength/intensity of the reflected signal, the frequency/wavelength of light received in the reflected signal. For example, if controller **112**, transceiver **107**, and/or detector **114** determines that a received signal reflected from the pregnant mammal's abdomen is of insufficient strength/intensity, then controller **112** may provide instructions to adjustment mechanism **112** and/or light source(s) **105** to increase the intensity and/or wavelength/frequency of the light incident on the abdomen of the pregnant mammal.

In another example, temperature probe **165** may act to measure the body temperature of the pregnant mammal and may provide these measurements to controller **112** and/or transceiver. In some embodiments, these measurements may be used to determine whether the temperature of the pregnant mammal exceeds a threshold measurement, which in some instances, may indicate that light source(s) **105** and/or fetal hemoglobin probe **115** are delivering too much heat/energy to the pregnant mammal. Upon reaching such a determination, controller **112** may provide instructions to light source(s) **105** and/or adjustment mechanism **122** to correct for this. Exemplary instructions include, but are not limited to, directions to redirect incident light, turn off, adjust a frequency, and/or adjust an intensity of one or more of the light source(s) **105**.

In some instances, light source(s) **105** may be tunable, or otherwise user configurable, by, for example, a physician or clinician assisting the pregnant mammal during the delivery process. For example, a light source **105** may be configured to emit light in multiple frequencies/wavelengths and/or intensities and the light source **105** may be tuned via, for example, direct physical manipulation of the light source **105** (e.g., via a button on knob), or the entering of an instruction regarding the desired frequency/wavelength and/or intensity into, for example, computer **150** and/or controller **112**.

Tuning the frequency/wavelength and/or intensity of light emitted by one or more light source(s) **105** may be helpful in achieving a return signal of sufficient strength or clarity in a variety of circumstances (e.g., fetus position, fetus size, the amount of melanin in the skin of the pregnant mammal

and/or fetus, the size and/or shape of the pregnant mammal, etc.). For example, light of a relatively higher intensity may be desired when the pregnant mammal has a relatively high body mass index (BMI) or body fat positioned in such a way as to inhibit the strength of a signal reflected from the fetus (i.e., return signal). In another example, a fetus may be positioned against the internal organs of the pregnant mammal (i.e., away from the skin of the belly), and light of relatively higher intensity and/or different wavelength may be desired so that the light reaches the fetus with a sufficiently strong signal so that a return signal may be detected by, for example, detector **114**.

When fetal hemoglobin probe **115** includes more than one light source **105**, the light sources **105** may be arranged in an array adapted to maximize the strength of the returned signal such as array **170** as discussed below with regard to FIGS. **2**D and **2**E. Array **170** may include any appropriate number of light sources **105**. In some instances, array **170** may include a first row of a first type of light source **105**A, **105**B, through **105**N and a second row of a second type of light source **105** AA, **105**AB, through **105**AN. The different types of light sources may be configured to, for example, emit light of a particular frequency/wavelength and/or intensity. For example, light sources **105** A, **105**B, through **105**N may be configured to emit light with wavelengths in the red spectrum and light sources **105** AA, **105**AB, through **105**AN may be configured to emit light with wavelengths in the infrared or near-infrared spectrum. Although array **170** to have two rows, it will be appreciated that any number of rows (e.g., 3, 4, 5, 6, 7, 8, and so on) may be included in array **170**.

Embodiments of fetal hemoglobin probe **115** with a relatively large length (e.g., 10 cm-40 cm) may have arrays **170** with rows of multiple light sources long fetal hemoglobin probe **115** that include, for example, 10, 15, 20, 25, 30, 35, 40, 45, or 50 light sources **105** each. A fetal hemoglobin probe **115** may also include more than one detector **114**, as shown in FIG. **2**E, which includes a first detector **114**A and a second detector **114**B. In some embodiments, first detector **114**A may be the same as second detector **114**B and, in other embodiments, they may be different. For example, first detector **114**A may be sensitive to a first range of frequencies for reflected light and second detector **114**B may be sensitive to a second range of frequencies for reflected light. Additionally, or alternatively, first detector **114**A may be of a different size than second detector **114**B. Any of the fetal hemoglobin probes **115** disclosed herein may include multiple detectors adapted to, for example, detect light reflected for one or more the light source(s) **105** included in array **170**.

Although shown as a separate component in FIGS. **2**C-**2**E, it will be appreciated by those of skill in the art that adjustment mechanism **122** may be partially and/or wholly positioned within and/or adjacent to one or more light sources **105**.

Components of system **100** may be applied to a pregnant mammal in any acceptable manner. For example, NIRS adult hemoglobin probe **125** may be placed on the second finger of the pregnant mammal **305**, pulse oximetry probe **130** may be placed on the thumb of the pregnant mammal **305**, and Doppler and/or ultrasound probe **135** may be placed on the abdomen of the on the pregnant mammal.

In some implementations, uterine contraction measurement device **140** may also be on placed on the abdomen of the pregnant mammal. In other implementations, uterine contraction measurement device **140** may be embodied in the fetal hemoglobin device **115**. In some cases, uterine contraction measurement device **140** may be a pressure sensor configured to detect the changes in pressure of the uterine muscle in units of pressure (mmHg and/or kPa).

In some embodiments, one or more light source(s) **105** and detector(s) **114** may act as an optoelectronic muscle contraction sensor without the need for a separate uterine contraction measurement device **140**. In these embodiments, the light reflected from the pregnant mammal's uterus might change in nature when the uterus is in a relaxed state (more scattering) as opposed to a contracted state (less scattering). These changes in the rate of scattering of the light may be detected by one or more detector(s) **114** and processed by, for example, computer **150** to determine changes in the state of the uterine muscle. In some embodiments, one or more light source(s) **105** may direct light of a particular frequency/wavelength so that measurements of uterine contractions have a dedicated beam/frequency of light.

Preferably, the fetal hemoglobin probe **115** is placed at, or near, the bikini/supra-pubic region of the pregnant mammal **305**. This area is typically right above the pubic hairline. This position is advantageous in the later stages of pregnancy, for example, after 9 months or 36 weeks of gestational development because the fetus's head will engage into the cervical birth canal and will, therefore, be in a fairly predictable location within the abdomen of the pregnant mammal. Additionally, when the head of the fetus is positioned within the cervical birth canal, the distance between pregnant mammal and fetus is minimal and therefore NIR light passing through the abdomen of the pregnant mammal is more likely to come into contact with the fetus and be reflected back to the fetal hemoglobin probe **115**.

FIGS. **3**A, **3**B, and **3**C provide illustrations of how light from fetal hemoglobin probe **115** may be directed into a pregnant mammal's **305** abdomen and reflected light may be detected by one or more detectors **114** of fetal hemoglobin probe **115**. More specifically, FIG. **3**A provides a cross sectional view of fetal hemoglobin probe **115** and of the pregnant mammal **305** as divided along a midline extending through the center of pregnant mammal **305** when she is viewed from the front (i.e., through the center of the face, between the breasts, etc.). FIG. **3**A depicts an approximation of a fetus **310** that is surrounded by amniotic fluid and other tissue **315** present in a uterus **320** of the pregnant mammal **305**. fetal hemoglobin probe **115** is show in FIG. **2**C to be positioned on the lower abdomen of the pregnant mammal **305** at, or near, the bikini/supra-pubic region of the pregnant mammal **305**.

As shown in FIG. **3**A, a beam of light **325** (also referred to herein as an "incident beam") emitted from one or more light source(s) **105** is incident on pregnant mammal's **305** abdomen and is directed toward fetus **310**. Beam of light **325** may be of any wavelength/frequency or combination of wavelengths/frequencies. In one embodiment, incident beam **325** may include light that is in the red spectrum and the near infrared spectrum.

In some embodiments, incident beam **325** may include two or more beams of light that may be emitted from, for example a single light source **105** (that emits two beams of light of the same frequency and/or a beam of light of two different frequencies) or two different light sources **105** (e.g., one frequency per light source). When two or more beams are included in incident beam **325**, they may, on occasion be directed in slightly different directions so as to, for example, accommodate differences in the frequency of the light of the beam, a condition of the pregnant mammal **305** (e.g., skin pigmentation, body mass index, etc.) and/or a condition of the fetus (e.g., size, position, location within the uterus, skin pigmentation, etc.).

A portion of incident beam **325** may reflect from the fetus **310**, amniotic fluid and other tissue **315**, and uterus **320** as a reflected beam **330** and may be received by one or more detectors **114** provided by fetal hemoglobin probe **115**. Although reflected beam **330** is shown as one beam, it may be any number of beams or individual photons. It is expected that not all of the light of incident beam **325** will be included in reflected beam **330** as some of the light of incident beam **325** may be lost/undetected due to, for example, scattering and/or absorption.

FIG. **3**B provides an image of fetal hemoglobin probe **115** with an adjustment device **335** positioned between the skin of the pregnant mammal's **305** abdomen and a portion of fetal hemoglobin probe **115**. In the embodiment of FIG. **3**B, adjustment device **335** is triangular in shape and acts as a wedge to change an orientation/position of fetal hemoglobin probe **115** (and the corresponding orientation/position of light source(s) **105** and/or detector(s) **114**) relative to the pregnant mammal's abdomen. In some cases, adjustment device **335** may change the angle of incidence for incident beam **325** and/or an orientation of one or more detectors **114**. In some embodiments, adjustment device **335** may be transparent so as to allow for the passage of light into, and out of, the pregnant mammal's **305** abdomen. In other embodiments, adjustment device **335** may be semi-transparent or opaque so as to, for example, change a frequency of the incident beam **325** and/or reflected beam **330**.

Adjustment device **335** may be configured to adjust for physiological conditions of the pregnant mammal's **305** abdomen that make it difficult to receive a reflected beam of sufficient strength. For example, for a pregnant mammal **305** with a high fat content around her abdomen, applying the fetal hemoglobin probe **115** directly to the pregnant mammal's **305** skin may not direct the incident beam **325** in the proper direction and/or enable detection of the reflected beam **330**. Additionally, or alternatively, adjustment device **335** may be configured to adjust for physiological conditions of the fetus **310** including the size and/or placement of the fetus **310** within the uterus **320**. For example, adjustment device **335** may be deployed so as to direct incident beam **325** toward the head of fetus **310**.

In some embodiments, two or more adjustment mechanisms **335** may be used. An adjustment device **335** may be of any appropriate shape and/or configuration including, but not limited to, a triangle, circle, or rectangle and may be configured to adjust the positioning or operation of some, or all, of the components of fetal hemoglobin probe **115**. In some instances, adjustment device **335** may be designed to improve the comfort of the pregnant mammal **305** while wearing fetal hemoglobin probe **115** and, to that end, may be configured to include soft and/or flexible material (e.g., foam) designed to adapt to a contour of the pregnant mammal's abdomen. In these instances, adjustment device **335** would be designed to engage with fetal hemoglobin probe **115** in a manner that does not obscure one or more components thereof.

In another embodiment, adjustment device **335** may include optics, filters, or other mechanical and/or electrical components configured to adjust one or more features of incident beam **325** and/or reflected beam **330**. In some instances, one or more operations of adjustment device **335** may be performed upon receipt of instructions from, for example, a component of fetal hemoglobin probe **115** and/or computer **150**.

FIG. **3**C provides a front view of pregnant mammal's **305** abdomen with fetal hemoglobin probe **115** affixed thereto. The perspective is somewhat adjusted for FIG. **3**C so that incident beam **325** and reflected beam **330** may be seen. In reality, both incident beam **325** and reflected beam **330** are directed into/reflected from the pregnant mammal's **305** abdomen along the −Z-axis.

FIG. **3**D provides a front cross section view of pregnant mammal's **305** abdomen with fetal hemoglobin probe **115** and Doppler/ultrasound probe **135** coincident therewith. As shown in FIG. **3**D, Doppler/ultrasound probe **135** transmits a beam into pregnant mammal's **305** abdomen towards fetus **310** and receives a reflected signal. Doppler/ultrasound probe **135** is then uses this reflected signal to determine a fetal heart beat signal and/or determine a number of fetal heart beats per minute. and

The fetal hemoglobin probe **115** of FIG. **3**D has two light sources, a first of which, **105**A, emits a light beam **325**A of a first wavelength (λ_1) (noted on the figure as **105**A, λ_1 and **325**A, λ_1, respectively) and a second of which, **105**B, emits a light beam **325**B of a second wavelength (λ_2) (noted on the figure as **105**B, λ_2 and **325**B, λ_2, respectively). A portion of incident beams **325**A and **325**B is reflected by the pregnant mammal **305** and fetus **310** and received by detector **114** as reflected beam **330**A and **330**B, respectively ((noted on the figure as **330**A, λ_1 and **330**B, λ_2, respectively).

FIG. **4**A illustrates an exemplary process **400** for performing fetal oximetry and/or fetal pulse oximetry trans-abdominally and/or in-utero to determine fetal hemoglobin oxygen saturation level. Process **400** may be performed by, for example, system **100** and/or a component thereof.

Initially, a light beam, such as incident beam **325**, is directed into the abdomen of a pregnant mammal, such as pregnant mammal **305** (step **405**) by, for example, one or more light sources such as light source(s) **105** provided by one or more of the fetal hemoglobin mammal' pregnant mammal's abdomen may be directed toward the pregnant mammal's fetus, such as fetus **310** as shown in FIGS. **3**A and **3**B discussed above.

The light beam directed into the pregnant mammal's abdomen may include any number of light beams and/or frequencies/wavelengths of light as described above with regard to incident beam **325**. In some instances, the light beam of step **405** may be a plurality of light beams emitted from a plurality of light sources positioned at a plurality of different locations along the abdomen of the pregnant mammal as shown in, for example, FIGS. **2**D and **2**E. Additionally, or alternatively, the light beam of step **405** may include a plurality of wavelengths/frequencies emitted by a single of light source that may, for example, include multiple LEDs.

In some embodiments, the light beam of step **405** may include light of first and second wavelengths with a first of the wavelength being in the red portion of the electromagnetic spectrum (i.e., 620-750 nm) and a second of wavelengths in the near-infrared (NIR) portion of the electromagnetic spectrum (e.g., 750 nm-2,500 nm). Use of these wavelengths is preferred, but not required, because light of wavelengths in the red and near-infrared spectrum are known to travel through, and/or be reflected by, skin and body tissue. In some embodiments, light of, for example, a third, fourth, fifth, or more different wavelengths may be directed toward the abdomen of the pregnant mammal. In some circumstances, use of more than two wavelengths of light may be useful to enhance reflected signal strength and/or clarity in various circumstances including, but not limited to, distance of the fetus from the external skin, or uterine wall, of the pregnant mammal (i.e., depth of the fetus), level of melanin/pigment in the skin of the pregnant mammal and/or fetus, strength of fetal pulse signal, how

much the fetus moves within the placenta and/or uterus of the pregnant mammal, and so on.

In some embodiments, an intensity of the light directed into the pregnant mammal at step **405** may be varied and/or different for different wavelengths of light. For example, the intensity of red light directed into the pregnant mammal's abdomen may be greater than the intensity of the near-infrared light due to the transmission/reflection properties of red light verses near infrared light (i.e., near-infrared light is know to reflect more light when shown into body tissue than red light). However, it is expected that an intensity of the light beam of step **405** will be safe for both the pregnant mammal and her fetus (e.g., not cause burns to the pregnant mammal's skin and/or damage to fetal tissue (e.g., eyes)).

In step **410**, light (e.g., waves and/or photons) reflected by the abdomen of the pregnant mammal (and the fetus) may be received by one or more detectors (e.g., photo-sensor, photo detectors or photodiodes), such as detector **115** and/or transceiver **107** and converted (step **415**) into an electronic signal that represents the reflected light (this signal may be referred to herein as a "reflected electronic signal" by the photo-sensor/photodiode/photo detector. In some instances, the light directed into the abdomen of the pregnant mammal, may travel a distance of, for example, 3-5 cm to contact the fetus and another 3-5 cm once reflected from the fetus to be detected by the detector. Thus, the total travel distance for the incident and reflected beam may be as high as 8 or 10 cm. When traveling this distance, a substantial amount of scattering and other interference in the detection of a reflected signal may occur and it is possible that only a small fraction (e.g., 0.5-5%) of the light incident on the abdomen of the pregnant mammal will be reflected by the fetus and received by detector.

Optionally, in step **420**, it may be determined whether the electronic reflected signal is of sufficient strength to detect, for example, the pulse and/or fetal oxygen saturation of the fetus. Exemplary signal strengths that are sufficient are in the range of 30-500 dB with a signal-to-noise (SNR) ratio of 1-8, with a preferred SNR of approximately 3-4.5.

When the signal isn't of sufficient strength, the light source(s) and/or detector(s) may be adjusted automatically (i.e., without operator intervention) and/or provision of an indication that an adjustment of the light source(s) and/or detector(s) may be desired or needed to an operator (e.g., doctor or nurse) may be facilitated (step **425**). Exemplary indications provided in step **425** include, but are not limited to, an alarm, a message (e.g., written or audio), and a recommendation. Exemplary automatic adjustments include, but are not limited to, adjusting a lens positioned between the pregnant mammal's abdomen and the light source(s) and/or detector(s) so as to focus the light emitted by the light source(s) and/or received by the detector(s), adjusting an amount of power delivered to the light source(s) and/or detector(s), adjusting an intensity and/or frequency of the light emitted by one or more of the light source(s) and so on. In some embodiments, activation of additional light sources to direct light into the pregnant mammal's abdomen may be responsive to a determination that the electronic reflected signal is not of sufficient strength.

In some instances, the adjustment(s) of step **425** may be performed and/or facilitated by one or more adjustment mechanisms, such as adjustment mechanisms **122** and/or controllers, such as controller **112**. Once adjusted, the light beam may again be directed into the pregnant mammal's abdomen (i.e., step **405** may be repeated) and steps **410**-**420** may be repeated. When the electronic reflected signal is of sufficient strength, or when steps **420** and **425** are not performed, process **400** may advance to step **430**.

In step **430**, the electronic reflected signal may be processed to isolate a portion of the reflected electronic signal reflected from the fetus (as opposed to the pregnant mammal or noise). For ease of discussion, the portion of the reflected electronic signal reflected from the fetus may be referred to herein as the fetal reflected electronic signal. Examples of how step **430** may be executed are discussed below with regard FIGS. **5**A-**5**D. Following step **430**, the fetal reflected electronic signal may be analyzed to determine the oxygen saturation level of hemoglobin contained in the fetus' blood via, for example, oximetry and/or pulse oximetry techniques (step **440**). Typical values for the oxygen saturation of fetal blood fall with in the range of 30-70%. An exemplary method of determining fetal hemoglobin saturation level uses a version of the Beer-Lambert law modified to account for the scattering effect of the reflected light as it is scattered by tissues in the body as described by Zourabian, Anna, et al., *Trans-abdominal Monitoring of Fetal Arterial Blood Oxygenation Using Pulse Oximetry*, Journal of Biomedical Optics, 5(4), pp. 391-405 (October 2000), which is incorporated by reference herein. Further details regarding execution of step **435** is provided below with regard to FIGS. **6**A-**6**H.

Then, in step **440**, provision of an indication of fetal oxygen level to an operator may be facilitated. Exemplary operators include, but are not limited to, doctors, nurses, and other caregivers. Exemplary indicators include a waveform shown on a display device (e.g., computer monitor), a numerical value provided via a display device and/or message (e.g., SMS text message), such as a fetal hemoglobin oxygen saturation level. Facilitating provision of the indication of step **465** may include providing the indication to a computer, such as computer **150** and/or a display device such as display device **155**. An example of such a display of fetal hemoglobin oxygen saturation level is provided by FIGS. **8**A and **8**B and is discussed below.

One method of processing the signal to isolate the portion of the reflected electronic signal reflected from the fetus from the total reflected electronic signal is to multiply the total reflected electronic signal by signal that provides the fetal heart (i.e., perform step **430**) beat as may be provided by, for example, a Doppler and/or ultrasound probe such as Doppler/ultrasound probe **135**. The resultant signal (i.e., the signal that is the product of multiplying the total reflected electronic signal and the fetal heartbeat signal) may approximate the portion of the total reflected electronic signal reflected by the fetus. To improve this approximation, the signal reading may be averaged over a number of cycles to provide a more accurate approximation of the portion of the total reflected electronic signal reflected by the fetus. An example of this process is provided by FIGS. **5**A-**5**D, of which FIG. **5**A provides a graph **500** of total reflected electronic signal intensity vs. time and represents light reflected by the abdomen of the pregnant mammal detected in step **410**. FIG. **5**B provides a graph **501** of a Doppler signal vs. time. This signal and represents light reflected by the abdomen of the pregnant mammal detected in step **410**. The Doppler signal represents the fetus' heartbeat. This signal may be received from, for example, Doppler/ultrasound probe **135**. FIG. **5**C provides a graph **502** that shows the product of multiplying the total reflected electronic signal intensity (from FIG. **2**A) and the Doppler signal (from FIG. **2**B) together while synchronizing over time so that a signal intensity of the total reflected electronic signal at a particular moment in time is multiplied by the Doppler

signal intensity at that same particular moment in time. The resultant signal shown in FIG. **5**C approximates the portion of the total reflected electronic signal reflected from the fetus. This signal may then be analyzed to determine fetal oxygen saturation levels using, for example, oximetry or pulse oximetry techniques.

In some embodiments, the accuracy of the approximated portion of the total reflected electronic signal reflected from the fetus may be improved by averaging a number of signal intensities over a period of time (e.g., a number of periods) as shown in FIG. **5**D, which provides a graph **503** of the total reflected electronic signal intensity, the fetal heartbeat/Doppler signal and the result of multiplying total reflected electronic signal intensity and Doppler signal synchronized over time (referred to on graph **503** as "fetal reflected signal."

Another method of processing the electronic reflected signal to isolate the portion of the reflected electronic signal reflected from the fetus from the total reflected electronic signal is to multiply the total reflected electronic signal by signal that provides the fetal heart (i.e., perform step **430**) is provided by FIG. **4**B, which shows sub-process **401**.

In step **445** of sub-process **401**, a heartbeat signal for the pregnant mammal is received from, for example, a pulse oximetry probe like pulse oximetry probe **130** and/or an adult hemoglobin probe like NIRS adult hemoglobin probe **125**. Next, the received pregnant mammal's heartbeat signal may be synchronized in the time domain with the electronic reflected signal (step **450**). Then a correlation between the pregnant mammal's heartbeat and changes in the electronic reflected signal may be established so as to determine a portion of the electronic reflected signal that is reflected by the pregnant mammal (step **455**). In step **460**, the portion of the portion of the electronic reflected signal that is reflected by the pregnant mammal is then subtracted from the electronic reflected signal with the portion of the electronic reflected signal reflected by the fetus being thereby isolated.

Another method of processing the signal to isolate the portion of the reflected electronic signal reflected from the fetus from the total reflected electronic signal is to multiply the total reflected electronic signal by signal that provides the fetal heart (i.e., perform step **430**) is provided by FIG. **4**C, which shows sub-process **402**.

In step **465** of sub-process **402**, a heartbeat signal for the fetus may be received from, for example, an ultrasound device and/or a Doppler device, such as Doppler/ultrasound probe **135**. Next, the received fetus' heartbeat signal may be synchronized in the time domain with the electronic reflected signal (step **470**). Then, portions of the electronic reflected signal that correspond in the time domain with the individual heartbeats may be examined (step **475**). In this way, the entire electronic reflected signal does not have to be processed/analyzed; only the portions of the electronic reflected signal where a fetal heartbeat, or pulse, occur are examined. This saves processing time and resources because the entire signal does not have to be processed.

In some embodiments, the processing of step **430** and/or analysis of step **435** may include processing the reflected electronic signal in order to ascertain a signal that corresponds to the absorption/reflection of NIR light by oxygenated hemoglobin and deoxygenated hemoglobin of the fetus. Using this information, a level (or percentage) of fetal hemoglobin oxygen saturation (step **435**) may be determined.

Because fetal hemoglobin is structurally different from adult hemoglobin it absorbs light differently and the signal reflected from the fetal hemoglobin at various wavelengths will be of a different magnitude when compared to the magnitude of the signal at those same wavelengths reflected by the pregnant woman. In this way, measuring a quantity of light reflected from the hemoglobin of the pregnant woman and fetus at various wavelengths will provide an indication of the amount of light of a particular wavelength that is absorbed by the fetal hemoglobin as well as the pregnant woman's hemoglobin. Looking at the ratios of light reflected at various wavelengths will provide a benchmark that correlates to a specific fetal blood oxygen level. In some instances, the variations in wavelength absorption of the fetal hemoglobin when compared to the pregnant woman's hemoglobin may not be sufficient to provide an adequately strong or clear signal indicating fetal hemoglobin oxygen saturation levels for clinical and/or diagnostic purposes. Therefore, one or more signal processing techniques may be applied to the signal received by the fetal hemoglobin probe **115** to determine fetal hemoglobin oxygen saturation as will be discussed in detail below.

In an exemplary signal processing technique, a signal received from the pregnant woman's pulse oximetry probe (e.g., pulse oximetry probe **130**) may be used to determine the oxygen saturation level of the pregnant woman's arterial blood, which corresponds to an oxygenated state of pregnant woman's hemoglobin. The pulse oximetry probe is used to make this determination because the depth of a human finger is 1-2 cm, a measurable amount of light can pass through the finger tip and there is no interference from fetal blood flow or circulating fetal hemoglobin at the pregnant woman's fingertip position. Hence, a reading from pulse oximetry probe **130** will directly correspond to how much light is absorbed and/or reflected at various wavelengths by the pregnant woman's adult hemoglobin. This information may be used to understand how the light is interacting with pregnant woman's hemoglobin near the fetus and this information may be subtracted from the signal received by the fetal hemoglobin probe **115** to determine how much light is absorbed and/or reflected at various wavelengths by the fetus' hemoglobin.

Additionally, or alternatively, the signal received by the fetal hemoglobin probe **115** may be processed using a heart rate of the fetus and/or pregnant woman. The timing of the pregnant woman's heartbeat correlates to the timing for various levels of blood oxygen saturation for the pregnant woman. This correlation may be used to detect a signal corresponding the level of blood oxygen saturation for the pregnant woman within the signal received by the fetal hemoglobin probe **115**. The fetal oxygen saturation level may then determined by subtracting, or otherwise filtering, the detected signal corresponding the level of blood oxygen saturation for the pregnant woman from signal received by the fetal hemoglobin probe **115**.

Additionally, or alternatively, the fetal heartbeat correlates to the timing for various levels of blood oxygen saturation for the fetus. This correlation may then be used to detect a signal corresponding the level of blood oxygen saturation for the fetus within the signal received by the fetal hemoglobin probe **115**. For example, Doppler/ultrasound probe **135** and/or an ultrasound device may indicate that the fetus' heart rate is in the range of 120-160 beats per minute and this fetal heart rate may be used to gate and/or correlate a NIR signal from the fetus.

In the rare circumstance when the fetal heart rate and maternal heart rate are similar (fetal bradycardia and maternal tachycardia) the two heartbeats may be distinguished from one another using the known fact that there is a slight pause in the heart rate during respiration. So, by monitoring

the heart rate signal (via, e.g., pulse oximetry probe **130**), one may observe that the pregnant woman's the heart rate slows down for a moment when she takes in a deep breath. This slowing will only be present in the signal providing the pregnant woman's heart rate because fetuses do not breathe while in utero. In this way, the two heart rates may be distinguished from one another.

In some embodiments, a signal from NIRS adult hemoglobin probe **125** may be processed to determine a ratio of adult oxyhemoglobin to adult de-oxyhemoglobin. This ratio may then be used to subtract readings from the pregnant woman's blood flow so that a signal from the fetus's blood flow may be isolated and analyzed to, for example, determine a level of fetal hemoglobin oxygen saturation.

In other embodiments, processing the signals received by the fetal hemoglobin probe **115** may include oscillating between time domain and frequency domain analysis. This oscillation may allow identification signals that have a cyclical (periodic) component as opposed to signals that are random or non-periodic (acyclic/aperiodic). Random or non-periodic signals are more likely to be noise and examining the received signal for random or non-periodic signals will assist in determining a noise level of the signal as well as portions of the signal that may be filtered or otherwise removed therefrom.

In some embodiments, process **400** may include the establishment of a set of correlations between the intensity of light reflected/absorbed at certain wavelengths by fetal oxyhemoglobin and de-oxyhemoglobin and the oxygen saturation levels of the fetal oxyhemoglobin and de-oxyhemoglobin. This set of correlations may be performed prior to executing process **400** for a particular pregnant mammal during the fetal labor and delivery process and may be stored in, for example, computer **150**. An exemplary correlation may be a reflection of light of wavelength A with an intensity X and a reflection of light of wavelength B with an intensity 0.8X to an fetal oxygen saturation level of 50% of fetal hemoglobin being bound to oxygen. Another exemplary correlation may be a reflection of light of wavelength A with an intensity X and a reflection of light of wavelength B with an intensity 0.5X to an fetal oxygen saturation level of 25% of fetal hemoglobin being bound to oxygen.

(noted on the figure as **105**A, λ_1 and **325**A, λ_1, respectively) and a second of which, **105**B, emits a light beam **325**B of a second wavelength (λ_2) (noted on the figure as **105**B, λ_2 and **325**B, λ_2, respectively). A portion of incident beams **325**A and **325**B is reflected by the pregnant mammal **305** and fetus **310** and received by detector **114** as reflected beam **330**A and **330**B, respectively ((noted on the figure as **330**A, λ_1 and **330**B, λ_2,

FIGS. **6**A-**6**H provide information in the form of graphs regarding an example of how reflected electronic signal is analyzed to determine fetal hemoglobin oxygen saturation level. At times, fetal hemoglobin oxygen saturation level may also be referred to herein as fetal arterial oxygen saturation level, which may be abbreviated to (% SaO2). More specifically, FIG. **6**A provides a graph **601** of a Doppler signal vs. time. The Doppler signal corresponds to a fetal heart beat signal. The Doppler signal of FIG. **6**A is similar to the Doppler signal of FIG. **5**B.

FIG. **6**B provides a graph **602** of reflected electronic signal intensity for λ_1 vs. time. This graph may correspond to reflected signal **330**A, λ_1. Any of the processes discussed above may be used to isolate the portion of the signal reflected by the fetus from the reflected electronic signal intensity for λ_1. In the example provided, the total reflected electronic signal intensity for λ_1 and the fetal Doppler signal are multiplied together while synchronizing over time to provide the product of multiplying the total reflected electronic signal intensity for λ_1 and the Doppler signal together while synchronizing over time as shown in graph **603** of FIG. **6**C.

FIG. **6**D provides a graph **604** that shows the product of multiplying the total reflected electronic signal intensity for λ_1 and the fetal Doppler signal together while synchronizing over time averaged over several periods. This graph (or the data used to generate the graph) is analyzed to determine an intensity of a systolic value for the first wavelength λ_1 **610**, which corresponds to the peak of the curve (i.e., highest value) and an intensity of a diastolic value for the first wavelength λ_1 **615**, which corresponds to the trough of the curve (i.e., lowest//smallest value).

FIG. **6**E provides a graph **605** of reflected electronic signal intensity for λ_2 vs. time. Any of the processes discussed above may be used to isolate the portion of the signal reflected by the fetus from the reflected electronic signal intensity for λ_2. In the example provided, the total reflected electronic signal intensity for λ_2 and the fetal Doppler signal are multiplied together while synchronizing over time to provide the product of multiplying the total reflected electronic signal intensity for λ_2 and the Doppler signal together while synchronizing over time as shown in graph **606** of FIG. **6**F.

FIG. **6**G provides a graph **607** that shows the product of multiplying the total reflected electronic signal intensity for λ_2 and the fetal Doppler signal together while synchronizing over time averaged over several periods. This graph (or the data used to generate the graph) is analyzed to determine an intensity of a systolic value for the second wavelength λ_2 **620**, which corresponds to the peak of the curve (i.e., highest value) and an intensity of a diastolic value for the second wavelength λ_2 **625**, which corresponds to the trough of the curve (i.e., lowest/smallest value).

A modulation ratio (R) between the reflected intensity of two wavelengths of light may be calculated as follows:

$$R = \log\left(\frac{T_{sys\lambda 1}}{T_{dias\lambda 1}}\right) \Big/ \log\left(\frac{T_{sys\lambda 2}}{T_{dias\lambda 2}}\right) \qquad \text{Equation 1}$$

where:

$T_{sys\lambda 1}$ is the intensity of the systolic value for the first wavelength (λ_1);

$T_{dias\lambda 1}$ is the intensity of the diastolic value for the first wavelength (λ_1);

$T_{sys\lambda 2}$ is the intensity of the systolic value for the second wavelength (λ_2); and

$T_{dias\lambda 2}$ is the intensity of the diastolic value for the second wavelength (λ_2).

The modulation ratio, R, may then be used to determine a level of arterial oxygen saturation value (% SaO2) in one of at least two fashions. When a relationship between a modulation ratio, R, for a pair of wavelengths (i.e., λ_1 and λ_2) and arterial oxygen saturation is known (from, for example, experimentally determined values), then the value of R may be used to look up a corresponding arterial oxygen saturation level. FIG. **6**H[1] provides an exemplary graph that plots a known relationship between values for R (when λ_1 is in the red spectrum and λ_2 is in the infrared spectrum) with arterial oxygen saturation values.

[1] Source of FIG. **6**H: Paul D. et al., *Wavelength Selection for Low-Saturation Pulse Oximetry*, IEEE Transactions on Biomedical Engineering, Vol. 44, No. 3, March 1997, p. 149.

Following through with the above example (with the appropriate reference numbers for intensity values inserted from graphs **604** and **607**), would yield the following calculation for equation 1:

$$R = \log\left(\frac{610}{615}\right) \Big/ \log\left(\frac{620}{625}\right)$$

The ratio, R, calculated from this equation may then be used to find a corresponding arterial oxygen saturation level for the fetus (i.e., fetal hemoglobin oxygen saturation level).

Fetal oxygen saturation level may also be calculated using the following equation (Equation 2):

$$S = \frac{\epsilon_{Hb}^{\lambda_2} R(B^{\lambda_2}/B^{\lambda_1}) - \epsilon_{Hb}^{\lambda_1}}{(\epsilon_{HbO}^{\lambda_1} - \epsilon_{Hb}^{\lambda_1}) - R(B^{\lambda_2}/B^{\lambda_1})(\epsilon_{HbO}^{\lambda_2} - \epsilon_{Hb}^{\lambda_2})}. \quad \text{Equation 2}$$

where:

S is the hemoglobin oxygen saturation,

R is the modulation ratio calculated using equation 1;

ϵ_{Hb} is the molar extinction coefficient for deoxygenated hemoglobin;

ϵ_{HbO} is the molar extinction coefficient for oxygenated hemoglobin; and

B is a factor the can be estimated by solving the photon diffusion equation for the appropriate measurement geometry via the following expression (Equation 3):

$$B = \frac{1}{2}\left(\frac{3\mu_s'}{\mu_a^{inital}}\right)^{\frac{1}{2}}\left(1 - \frac{1}{1 + L(3\mu_3'^{initial}\mu_a^{initial})^{\frac{1}{2}}}\right). \quad \text{Equation 3}$$

where:

L is the length;

μ_s is the scattering coefficient;

μ_a is the absorption coefficient;

μ_s' is the transport scattering coefficient, which is provided by the following expression (Equation 4):

$$\mu_s' = \mu_s(1-g), \quad \text{Equation 4}$$

where:

g is the anisotropy factor of scattering equal to the average cosine of the sing phase scattering function.

Further details regarding the calculations using equations 1, 2, 3, and 4 as well as how to determine fetal hemoglobin oxygen saturation levels are provided by Mannheimer, Paul D. et al., *Wavelength Selection for Low-Saturation Pulse Oximetry*, IEEE Transactions on Biomedical Engineering, Vol. 44, No. 3, March 1997, pp. 148-158 and Zourabian, Anna, et al., *Trans-abdominal Monitoring of Fetal Arterial Blood Oxygenation Using Pulse Oximetry*, Journal of Biomedical Optics, 5(4), pp. 391-405 (October 2000), both of which are incorporated by reference herein.

FIG. **7**A provides a table **700** of various hemoglobin measurements as a function of light wavelength shone into the blood of an adult donor and fetal blood obtained by puncture of the umbilical cord immediately after delivery[2]. The values in columns 2-8 of the table are measured in millimolar absorptivities ($L*mmol^{-1}*cm^{-1}$). More specifically, the first column of table **700** provides a list of wavelengths measured in nanometers (nm) ranging from 450 nm to 1000 nm, the second column of table **700** provides a fetal hemoglobin (HbF) measurement in a deoxyhemoglobin state (Hb), the third column of table **700** provides an adult hemoglobin (HbA) measurement in a deoxyhemoglobin state (Hb), the fourth column of table **700** provides a fetal hemoglobin measurement in an oxyhemoglobin state (HbO2), the fifth column of table **700** provides an adult hemoglobin measurement in an oxyhemoglobin state (HbO2), the sixth column of table **700** provides a value representing a difference between the fetal hemoglobin measurement deoxyhemoglobin state and the fetal hemoglobin measurement in an oxyhemoglobin state (Hb-HbO2), the seventh column of table **700** provides a value representing a difference between the adult hemoglobin measurement in a deoxyhemoglobin state and the adult hemoglobin measurement in an oxyhemoglobin state (Hb-HbO2), and the eighth column of table **700** provides a ratio of the fetal (Hb-HbO2)/HbO2. The data from table **700** is used to make the graphs depicted in FIGS. **7**B and **7**C.

[2] Experimental results are provided by Zijistra, W. G., et al. *Absorption Spectra of Human Fetal and Adult Oxyhemoglobin, De-Oxyhemoglobin, Carboxyhemoglobin, and Methemoglobin*, Clin. Chem. Vol. 39/9, pp. 1633-1638 (1991).

FIG. **7**B depicts a graph **701** that shows difference in absorptivities between oxygenated (oxy-) and deoxygenated (deoxy-) state of fetal and the pregnant woman's hemoglobin in visible wavelengths of light from 450 nm to 700 nm wherein the green dashed line represents the difference in absorptivities between oxy- and deoxy-state of fetal hemoglobin as a function of wavelength and the red dashed line represents the difference in absorptivities between oxy- and deoxy-state of fetal hemoglobin of the pregnant woman as a function of wavelength.

FIG. **7**C depicts a graph **702** that shows difference in absorptivities between oxy- and deoxy-state of fetal and the pregnant woman's hemoglobin in the near infrared (NIR) wavelengths of light from 700 nm to 1000 nm wherein the green dashed line represents the difference in absorptivities between oxy- and deoxy-state of fetal hemoglobin as a function of wavelength and the red dashed line represents the difference in absorptivities between oxy- and deoxy-state of fetal hemoglobin of the pregnant woman as a function of wavelength.

As can be seen in FIGS. **7**A-**7**C, the greatest difference in absorbativities between the fetus and the pregnant woman occur within the wavelength ranges of approximately 700-750 nm and 950-1000 nm. Thus, emission of infrared light in these wavelength ranges by fetal hemoglobin probe **115** is preferred so as to achieve optimal differentiation between the signal from the pregnant woman's hemoglobin and the fetus' hemoglobin.

All of the signal processing and analysis techniques described herein may employ one or more noise reduction techniques including, but not limited to, cancelling out of ambient noise as may occur from lights in the room where the pregnant mammal is located and the operation of electrical equipment near the pregnant mammal. Noise cancelling techniques may also include looking for non-periodic modulations of the electronic reflected signal and cancelling such modulations from the signal because it is unlikely that a non-periodic contribution to the signal is indicative of blood flow for either the pregnant mammal or the fetus.

Additionally, or alternatively, one or more of signal processing and analysis techniques described herein may be combined with one another. For example, an electronic reflected signal may be processed using process **401** and **402** so as to isolate the portion of the electronic reflected signal reflected by the fetus.

FIG. **8**A provides an exemplary display **800** that provides a level of fetal hemoglobin oxygen saturation along with other information regarding measurements of the pregnant mammal and fetus. Display **800** provides a fetal hemoglobin oxygen saturation level **805** that is, for example, expressed

as a percentage of **100**, a continuous waveform (i.e., a plethysmogram) that represents the fetal heart rate over time **810**, and a numerical value representing fetal heart rate represented in beats per minute **815**. Display **800** also provides, the pregnant mammal's hemoglobin oxygen saturation level **820** that is, for example, expressed as a percentage of **100**, a continuous waveform that represents the pregnant mammal's heart rate over time **825**, a numerical value representing the pregnant woman's heart rate represented in beats per minute **830**. Display **800** further provides a graph showing fetal heart rate over time as measured in hours 835, and an indication of uterine tone or pressure generated by uterine contractions as measured over time as measured in mmHG vs. time in minutes is provided as numerical value **845**. The fetal heart rate over time graph **835** enables a physician to visually assess how the fetal heart rate changes during uterine contractions and may determine how well the fetus is tolerating the labor and delivery process. Uterine contraction numerical value **845** is a number from 0-50 calculated by a pressure sensor and it allows the physician to assess how long contractions are lasting, the intensity of the contractions, and the frequency of the contractions.

FIG. **8**B provides an exemplary display **801** of synchronized fetal heartbeat, fetal hemoglobin oxygen saturation rate, and uterine tone for corresponding moments in time. Display **801** is provided on a paper tape that has a Cartesian grid printed thereon with the vertical lines representing the passage of time (e.g., each vertical line represents a minute) and horizontal lines indicating a measurement scale. Paper tape of this type is not printed with a specific time scale as these tapes are typically used continuously through a monitoring period that may last many hours so, starting a time scale at 1, and progressing to 2, 3, 4, etc. is not relevant to the information being provided to the physician attending the pregnant mammal.

The upper graph of display **801** provides a graph of fetal heart rate as measured in beats per minute over time **860**. The second graph of display **801** provides a graph of fetal hemoglobin oxygen concentration (termed "fetal oxygen" for brevity's sake on the graph) over time **865**. The third graph of display **801** provides a graph of uterine tone (termed "contractions" for brevity's sake on the graph) **870**. All three of graphs **860**, **865** and **870** are synchronized in the time domain so that a measurement of fetal heartbeat for a particular moment in time corresponds with the fetal hemoglobin oxygen concentration level and the uterine tone at that particular moment in time. In this way, the attending doctor (or other medical professional) can simultaneously monitor pregnant mammal's uterine tone, the fetus' heartbeat and the fetus' hemoglobin oxygen concentration level during, for example, the labor and delivery process, to assess the health of the fetus.

Hence, systems, devices, and methods for determining fetal oxygen level have been herein disclosed. In some embodiments, use of the systems, devices, and methods described herein may be particularly useful during the labor and delivery of the fetus (e.g., during the first and/or second stage of labor) because it is difficult to assess fetal health during the labor and delivery process.

I claim:

1. A system comprising:

a housing configured to house a first light source, a second light source, a detector, a transceiver, and a power source;

the first light source adapted to project light of a first wavelength into the abdomen of a pregnant mammal toward a fetus contained therein;

the second light source adapted to project light of a second wavelength into the abdomen of the pregnant mammal toward the fetus;

the detector, the detector being adapted to detect light reflected from the pregnant mammal's abdomen over a first time domain and the fetus and convert the detected light into an electronic reflected signal and communicate the electronic reflected signal to the transceiver;

the transceiver, the transceiver being adapted to receive the electronic reflected signal from the detector and communicate the received electronic reflected signal to a processor;

the power source electrically coupled to the first light source, the second light source, and the detector, the power source being adapted to provide electrical power to first light source, the second light source, the detector, and the transceiver; and

the processor, the processor being configured to:

receive the electronic reflected signal from the detector;

isolate a portion of the reflected electronic signal that is reflected from the fetus, the isolation comprising:

receiving a fetal heartbeat signal for the fetus from a fetal heartbeat monitor over a second time domain, the fetal heartbeat signal indicating when, in the second time domain, a fetal heartbeat occurs;

synchronizing electronic reflected signal and the fetal heartbeat signal over the first time domain and the second time domain; and

multiplying the synchronized electronic reflected signal by the synchronized fetal heartbeat signal;

analyze the isolated portion of the reflected electronic signal to determine a fetal hemoglobin oxygen saturation level of the fetus, and

provide an indication of the oxygen level of fetal blood to a display device.

2. The system of claim **1**, further comprising:

an adjustment mechanism coupled to at least one of the first and second light sources, the adjustment mechanism being adapted to adjust at least one of a frequency of light emitted by the respective first and second light sources, an incident angle of the light emitted by the respective first and second light sources when projected into the pregnant mammal's abdomen, and focus a beam of light as it is projected into the pregnant mammal's abdomen as it emitted from the respective first and second light sources.

3. The system of claim **1**, further comprising:

an adjustment device coupled to the housing, the adjustment device being adapted to adjust at least one of a frequency of light emitted by the respective first and second light sources, an incident angle of the light emitted by the respective first and second light sources when projected into the pregnant mammal's abdomen, and focus a beam of light as it is projected into the pregnant mammal's abdomen as it emitted from the respective first and second light sources.

4. The system of claim **1**, wherein the housing, first light source, second light source, detector, transceiver, and power source are configured to be disposable following a single use thereof.

5. The system of claim **1**, further comprising:

an additional detector, the additional detector being positioned within the housing and coupled to the trans-

ceiver and the power source, the additional detector being adapted to detect light reflected from the pregnant mammal's abdomen and the fetus, convert the detected light into an additional electronic reflected signal, and communicate the additional electronic reflected signal to the transceiver.

6. The system of claim **1**, further comprising:

four additional light sources housed within the housing, each of the additional light sources being coupled to the power source;

an additional detector, the additional detector being positioned within the housing and coupled to the transceiver and power sources, the additional detector being adapted to detect light reflected from the pregnant mammal's abdomen and the fetus, convert the detected light into an additional electronic reflected signal, and communicate the additional electronic reflected signal to the transceiver

wherein the housing is adapted to have a length of at least **10**cm so as to extend around a portion of the pregnant mammal's abdomen and direct light at two sides of the fetus, further wherein the detector is positioned on a first side of the housing and the additional detector is positioned on a second side of the housing and the additional light sources are positioned between the first and second sides of the housing.

7. The system of claim **1**, wherein the first light source emits a light of a wavelength between 700 nm and 740 nm and the second light source emits a light of a wavelength between 800 and 900 nm.

8. The system of claim **1**, further comprising:

a temperature probe, the temperature probe being housed within the housing and coupled to the power supply and transceiver, the temperature probe being adapted to measure a temperature of the pregnant mammal's abdomen and communicate the temperature measurements to the transceiver.

9. The system of claim **1**, further comprising:

an ultrasonic detector, the ultrasonic detector being housed within the housing and coupled to the power supply and transceiver, the ultrasonic detector being adapted to detect ultrasonic emissions of the pregnant mammal's abdomen and fetus caused by transient thermoelastic expansion resultant from an interaction of the pregnant mammal's abdomen and the fetus' tissue to light emitted from at least one of the first light source and the second light source.

10. The system of claim **1**, further comprising:

a uterine contraction measurement device, the uterine contraction measurement being housed within the housing and coupled to the power supply and transceiver, the uterine contraction measurement being adapted to measure changes in a muscular state of the pregnant mammal's uterus and communicate these measurements to the transceiver.

11. A method comprising:

directing, by a light source, a light beam emitted from the light source into an abdomen of a pregnant mammal toward a fetus contained therein;

receiving light reflected by the pregnant mammal and the fetus at a detector over a first time domain;

converting, by the detector, the received light into an electronic reflected signal;

communicating, by the detector, the electronic reflected signal to a computer;

processing, by the computer, the electronic reflected signal to isolate a portion of the electronic reflected signal reflected from the fetus, the processing of the electronic reflected signal comprising:

receiving a fetal heartbeat signal for the fetus over a second time domain, the fetal heartbeat signal indicating when, in the second time domain, a fetal heartbeat occurs;

synchronizing the electronic reflected signal and the fetal heartbeat signal over the first time domain and the second time domain; and

multiplying the synchronized electronic reflected signal by the synchronized fetal heartbeat signal;

analyzing, by the computer, the portion of the electronic reflected signal reflected from the fetus to determine a fetal hemoglobin oxygen saturation level of the fetus; and

facilitating, by the computer, provision of an indication of the fetal hemoglobin oxygen saturation level to an operator.

12. The method of claim **11**, wherein the light directed into the pregnant woman's abdomen has a plurality of wavelengths.

13. A fetal hemoglobin probe comprising:

a housing configured to house a first light source, a second light source, a detector, a transceiver, and a power source;

the first light source adapted to project light of a first wavelength into the abdomen of a pregnant mammal toward a fetus contained therein;

the second light source adapted to project light of a second wavelength into the abdomen of the pregnant mammal toward the fetus;

the detector, the detector being adapted to detect light reflected from the pregnant mammal's abdomen and the fetus and convert the detected light into an electronic reflected signal and communicate the electronic reflected signal to the transceiver;

the transceiver, the transceiver being adapted to receive the electronic reflected signal from the detector and communicate the received electronic reflected signal to a processor;

the power source electrically coupled to the first light source, the second light source, the detector, and a controller, the power source being adapted to provide electrical power to first light source, the second light source, the detector, and the transceiver;

an adjustment mechanism coupled to at least one of the first and second light sources, the adjustment mechanism being adapted to adjust at least one wavelength of light emitted by the respective first and second light sources and an incident angle of the light emitted by the respective first and second light sources when projected into the pregnant mammal's abdomen, and focus a beam of light as it is projected into the pregnant mammal's abdomen as it emitted from the respective first and second light sources; and

the controller, the controller being communicatively coupled to the adjustment mechanism and at least one of the detector and the transceiver, the controller being configured to provide instructions to the adjustment mechanism that control an operation of the adjustment mechanism regarding the adjustment of the at least one wavelength of emitted light and the incident angle of the emitted light, the instructions being responsive to feedback from at least one of the detector and the transceiver regarding an aspect of the reflected light detected by the detector.

14. The fetal hemoglobin probe of claim 13, further comprising:

an adjustment device coupled to the housing, the adjustment device being adapted to adjust at least one of a frequency of light emitted by the respective first and second light sources, an incident angle of the light emitted by the respective first and second light sources when projected into the pregnant mammal's abdomen, and focus a beam of light as it is projected into the pregnant mammal's abdomen as it emitted from the respective first and second light sources.

15. The fetal hemoglobin probe of claim 13, wherein the housing, first light source, second light source, detector, transceiver, and power source are configured to be disposable following a single use thereof.

16. The fetal hemoglobin probe of claim 13, further comprising:

an additional detector, the additional detector being positioned within the housing and coupled to the transceiver and the power source, the additional detector being adapted to detect light reflected from the pregnant mammal's abdomen and the fetus, convert the detected light into an additional electronic reflected signal, and communicate the additional electronic reflected signal to the transceiver.

17. The fetal hemoglobin probe of claim 13, further comprising:

four additional light sources housed within the housing, each of the additional light sources being coupled to the power source; and

an additional detector, the additional detector being positioned within the housing and coupled to the transceiver and power sources, the additional detector being adapted to detect light reflected from the pregnant mammal's abdomen and the fetus, convert the detected light into an additional electronic reflected signal, and communicate the additional electronic reflected signal to the transceiver

wherein the housing is adapted to have a length of at least 10 cm so as to extend around a portion of the pregnant mammal's abdomen and direct light at two sides of the fetus, further wherein the detector is positioned on a first side of the housing and the additional detector is positioned on a second side of the housing and the light sources are positioned between the first and second sides of the housing.

18. The fetal hemoglobin probe of claim 13, wherein the first light source emits a light of a wavelength between 700 nm and 740 nm and the second light source emits a light of a wavelength between 800 and 900 nm.

19. The fetal hemoglobin probe of claim 13, further comprising:

a temperature probe, the temperature probe being housed within the housing and coupled to the power supply and transceiver, the temperature probe being adapted to measure a temperature of the pregnant mammal's abdomen and communicate the temperature measurements to the transceiver.

20. The fetal hemoglobin probe of claim 13, further comprising:

an ultrasonic detector, the ultrasonic detector being housed within the housing and coupled to the power supply and transceiver, the ultrasonic detector being adapted to detect ultrasonic emissions of the pregnant mammal's abdomen and fetus caused by transient thermoelastic expansion resultant from an interaction of the pregnant mammal's abdomen and the fetus' tissue to light emitted from at least one of the first light source and the second light source.

21. The fetal hemoglobin probe of claim 13, further comprising:

a uterine contraction measurement device, the uterine contraction measurement being housed within the housing and coupled to the power supply and transceiver, the uterine contraction measurement being adapted to measure changes in a muscular state of the pregnant mammal's uterus and communicate these measurements to the transceiver.

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专利名称(译)	用于进行经腹部胎儿血氧测定和/或经腹胎儿脉搏血氧测定的系统，装置和方法		
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发明人	RAY, NEIL PADHARIA		
IPC分类号	A61B5/1455 A61B8/00 A61B5/01 A61B5/145 A61B5/0205 A61B5/00		
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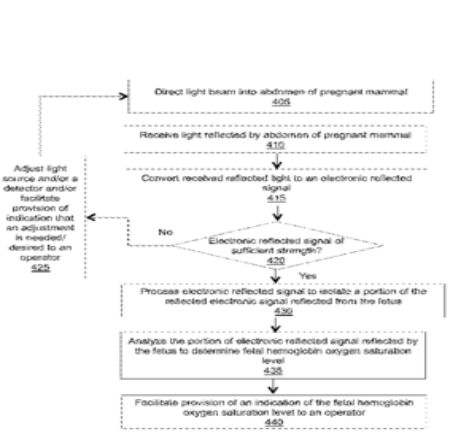
摘要(译)

从一个或多个光源发射的光束可以被引导到怀孕哺乳动物的腹部朝向其中包含的胎儿。一些光可以被孕妇和胎儿反射并且在第一次在检测器处被接收。可以将电子反射信号的光电检测器传送到计算机然后可以转换所接收的光。然后可以处理和/或分析电子反射信号以隔离从胎儿反射的电子反射信号的一部分。然后可以分析从胎儿反射的电子反射信号的孤立部分以确定胎儿的胎儿血红蛋白氧饱和度水平。然后可以通过例如计算机显示器向操作者提供胎儿血红蛋白氧饱和度水平的指示。