Title: BREASTFEEDING METER SYSTEM

Abstract: A breastfeeding meter system comprising an alternating current (AC) source wired to a first pair of electrodes and a processing unit wired to a second pair of electrodes and a casing encasing the AC source and the processing unit. The electrodes may be placed on the surface of a breast tissue and the processing unit may measure the impedance of the breast tissue.
BREASTFEEDING METER SYSTEM

FIELD OF THE INVENTION

The embodiments disclosed herein relate to a breastfeeding meter system. In particular, the system is configured to determine parameters related to breast milk extrusion based on electrical impedance of the breast tissue.

BACKGROUND

The World Health Organization (WHO) and the American Academy of Pediatrics recommend breastfeeding exclusively for the first six months. Few succeed. For example, in the UK, only one per cent of babies are exclusively breastfed at six months. Eighty-two percent of mothers start breastfeeding, but two-thirds stop within six months. In the U.S., three out of four mothers start out breastfeeding, but only thirteen per cent are exclusively breastfed at six months. The primary reason for the high dropout rates is the mother's concern that she is not breastfeeding adequately: Mothers are worried that they are not producing and giving enough milk, and therefore turn to the bottle where they can measure and quantify their feeding practices. Thus, there is a need for a tool that can help nursing mothers measure and quantify their breastfeeding, and make them feel comfortable and secure that they are breastfeeding adequately.

SUMMARY OF THE EMBODIMENTS

It is therefore according to one aspect of the current disclosure to present a breastfeeding meter system comprising an alternating current (AC) source wired to a first pair of electrodes and a processing unit wired to a second pair of electrodes and a casing encasing the AC source and the processing unit. The electrodes may be configured to be placed on the surface of a breast tissue; and the processing unit may be configured to measure the impedance of the breast tissue.

Optionally, the AC source is configured to produce a current of less than 500 microamperes. Additionally or alternatively, the AC source is configured to produce a current having a frequency of less than 100 kilohertz.

Where appropriate, the breastfeeding meter system may further comprise at least one pad situated in at least one portion of the casing configured to contact the surface of the breast tissue. Optionally, at least one pad surrounds at least one of the electrodes. In some embodiments, at least one pad may cover at least one of the electrodes and the pad is
conductive. Variously, the pad may comprise at least one material selected from the group consisting of a silicone gel, an air-permeable foam and a non-woven fabric.

In some embodiments, the casing may comprise a clip. Optionally, the casing may be in the shape of a pendant and attached to a strap. Alternatively or additionally, the breastfeeding meter may be incorporated into a nursing bra.

As suit requirements, the breastfeeding meter system may be configured to be wirelessly connectable to a device comprising a display and a memory unit. Such a device may be selected from the group consisting of a computer, a tablet, a personal digital assistant (PDA) and a smartphone. Optionally, the device may comprise a bracelet.

It is noted that the processing unit may be configured to measure the impedance of the breast tissue, calculate at least one sample value based on the impedance and generate a breast milk parameter based on the sample value. Accordingly, the sample value is the phase of the impedance. Optionally, the breast milk parameter may be selected from the group consisting of an amount of milk extruded from the breast, the amount of breast milk in the breast and the rate of breast milk extrusion from the breast.

Optionally, the initiation of breast milk parameter generation is gated by at least one automatic process. Accordingly, the automatic process is the detection of the placement of the electrodes onto the surface of the breast tissue. Additionally or alternatively, the automatic process is the detection of an increase in temperature. Variously, the automatic process may be the detection of a suckling sound.

Where appropriate, the processing unit may be configured to determine the left-breast or right-breast placement of the system.

**BRIEF DESCRIPTION OF THE FIGURES**

For a better understanding of the embodiments and to show how it may be carried into effect, reference will now be made, purely by way of example, to the accompanying drawings.

With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of selected embodiments only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects. In this regard, no attempt is made to show structural details in more detail than is necessary for
a fundamental understanding; the description taken with the drawings making apparent to
those skilled in the art how the several selected embodiments may be put into practice. In the
accompanying drawings:

Figures 1A shows a schematic illustration of a breastfeeding meter system.

Figure 1B shows a schematic illustration of a breastfeeding meter system on a breast surface.

Figure 2A shows a schematic illustration of the breastfeeding meter system with a casing.

Figure 2B shows a schematic illustration of the breastfeeding meter system with a casing on a breast surface.

Figure 2C shows a schematic illustration of the electrodes situated in the casing of the breastfeeding meter system.

Figure 2D shows a schematic illustration of the electrodes, with pads, situated in the casing of the breastfeeding meter system.

Figure 3 is an illustration of the breastfeeding meter system incorporated into a bra.

Figure 4 is an illustration of a breastfeeding meter system communicating wirelessly with a device.

Figure 5 is an illustration of the breastfeeding meter system used in the experiments described in Example 1.

DETAILED DESCRIPTION

Reference is now made to Figures 1A-B which shows a schematic diagram representing the main components of an embodiment of a breastfeeding meter system 100. The system 100 includes an alternating current (AC) source 110 wired to two electrodes, 130A and 130D. The system 100 further includes a processing unit 120 wired to two electrodes, 130B and 130C. The four electrodes 130A-D contact a breast skin surface 200, such that the alternating current passing between electrodes 130A and 130B, as well as electrodes 130C and 130D, must pass through the breast tissue 200. The two electrodes wired to the processing unit may be configured to measure voltage.

The AC source may be configured to produce a current of less than 500 micro amperes (microA). The AC source 110 may further be configured to produce a current
having a frequency of less than 100 kilohertz (KHz). The AC source 110 may be capable of producing a current of varying amplitudes and frequencies.

With reference to Figure 2A, the system 100 may be encased within a casing 300. The casing 300 is configured to fully surround and provide protection for the AC source 110 and the processing unit 120. With reference to Figure 2B, the casing 300 may allow for the electrodes to be situated on the portion of the casing 300 designated to face the surface of the breast tissue 200. The electrodes 130 may be exposed and contact the surface of the breast tissue 200 directly (Figure 2C). Each of the electrodes 130A-D may be covered or surrounded by pads 140A-D (Figure 2D).

The casing 300 may include an on/off button. The casing 300 may include a display and a memory unit. Alternatively, the casing may lack a display or a memory unit.

With reference to Figure 2D, the pad may be constructed of a material that is flexible and may form around the contours of the surface of the breast tissue. The pad 140 may cover the electrodes 130 and be conductive. Alternatively, or in addition, the pad 140 may be non-conductive and surround the electrode 130. Alternatively, the pad 140 may comprise conductive and non-conductive portions, with the conductive portion being situated against the electrode 130 and the non-conductive portion surrounding the electrode 130. The pad 140 may be present in other portions of the casing 300, where an electrode is not present, but is configured to contact the surface of the breast tissue. The pad 140 may be disposable. The conductive pad 140 may be comprise various materials as required, for example silicone gel, air-permeable foam, non-woven fabric, or a combination thereof. The material conductive pad 140 may be selected for various desirable properties such as electrical conductivity, resistivity, thermal conductivity, water resistance, strength, adhesive properties, cost or the like as well as combinations thereof. In particular, the conductive pad 140 may be adhesive. Optionally, the conductive pad 140 may comprise a self-adhesive silicone gel.

Where appropriate, the electrodes 130 may be situated in a flexible portion of the casing 300, such that said flexible portion may form around the contours of the surface of the breast tissue.

Alternatively, the casing 300 itself may be constructed of a material that is flexible and may form around the contours of the body, such that the pads 140 may be incorporated into the casing 300, with the desired portions of the casing 300 being treated with a conductive material to provide the electrodes 130.
The casing 300 may include a clip that allows the system 100 to be placed securely on the surface of the breast tissue 200 by attaching to a piece of the user's attire, such as an item of clothing or jewelry. For example the casing may be configured to attach to a nursing bra, a blouse, a necklace or the like. Optionally, the casing 300 may include a strap attachment, such that the casing 300 may be worn as a pendant.

With reference to Figure 3, the system 100 may be incorporated into an article of clothing. The article of clothing may be a bra. The bra may be a nursing bra.

Multiple sets of electrodes (e.g., 130 and 130' as shown in Figure 3) may be wired to a single processing unit, such that measurement of both the left and right breast may be conducted with no need to move the system 100. The location within the bra of the electrodes 130, 130' is not limited to the location shown in Figure 3. The electrodes 130, 130' may be placed at other parts of the bra (and thus other parts of the breast surface) as appropriate.

Reference is now made to Figure 4, which shows a communication device 400 that may be configured to allow a user to control the operation of the system 100, to visualize and store the data gathered by the system 100, and the like. The system 100 may transmit to and receive data from a communication device 400. The data transfer between the system 100 and the communication device 400 may be wireless. Many wireless communication schemes are known in the art. The wireless communication scheme may be Bluetooth, low energy Bluetooth (BTLE), ANT, or the like.

The communication device 400 may be a computer, a tablet, a smartphone, a PDA, a watch or the like. The interaction with the system 100 on the device 400 may be mediated by a software application executed on the communication device 400. Additionally or alternatively, the communication device 400 may be a dedicated device perhaps including a user interface, display, a processor, a memory unit or the like. The dedicated device may further include a data input mechanism such as a touchscreen, keypad, control panel or the like. The dedicated device may be an accessory, such as a bracelet or a watch.

*Data gathering by the system 100*

Referring back to Figure 1, the processing unit 120 is configured to measure the complex impedance of the breast tissue 200, through which the AC generated in the AC source 110 must pass through to reach the processing unit 120. The processing unit 120 is configured to:
- Determine the real component (resistance, \( R \)) and the imaginary component (reactance, \( I \)) of the complex impedance of the breast tissue 200.

- Calculate one or more parameters derived from the \( R \) and \( I \) of the complex impedance ("sample values"); and

- Provide a breast milk parameter based on said one or more sample values.

Sample values

The sample value may be a parameter derived from the \( R \) and \( I \) of the complex impedance. The sample value may be derived from the real component \( R \), the imaginary component \( I \), or a combination of the two. The sample value may be the phase \( \Theta \) (theta) of the complex impedance in polar form. Alternatively or in addition, sample value may be the magnitude \( |Z| \) of the complex impedance in polar form. Alternatively or in addition, the sample value may be derived from a combination of the phase \( \Theta \) and the magnitude \( |Z| \) of the complex impedance. Other sample values that may be calculated from the \( R \) and \( I \) of the complex impedance are also considered.

The phase \( \Theta \) may be calculated by the formula:

\[
\text{Phase } \Theta = \arctan \left( \frac{I + \text{Offset}_I}{R + \text{Offset}_R} \right).
\]

The magnitude \( |Z| \) may be calculated by the formula:

\[
|Z| = \sqrt{\left( (I + \text{Offset}_I)^2 + (R + \text{Offset}_R)^2 \right)}^{0.5}
\]

For the calculation of the phase as well as the magnitude, the offsets of \( \text{Offset}_I \) and \( \text{Offset}_R \) may be calculated offline on a database to provide the best results, e.g., offsets that provide the best correlation between the calculated milk output and the actual milk output.

Sample values may be obtained, in addition, from other sources. For example, the system 100 may further include a microphone. Characteristic suckling sounds produced by the baby may unlock to the initiation of the sampling period. Suckling may be detected my other means as well. Motion associated by suckling may be detected by an accelerometer. Suckling by the baby, even without breast milk extrusion, may result in characteristic changes in breast tissue impedance.

Sample value gathering

The processing unit may be configured to sample the complex impedance at a defined sampling rate over the course of a sampling period. The processing unit be configured to
batch-calculate the sample values after the termination of the sampling period. Alternatively, processing unit may be configured to calculate the sample value(s) during the sampling period ("live mode") at a defined calculation rate.

The processing unit may create one or more data arrays, each data array being a series of one sample value collected over the sampling period.

The sampling rate may be, e.g. about 0.1 Hertz (Hz), about 0.2 Hz, about 0.25 Hz, about 0.3 Hz, about 0.4 Hz, about 0.5 Hz, about 0.6 Hz, about 0.75 Hz, about 1 Hz, about 2 Hz, about 3 Hz, about 4 Hz, about 5 Hz, between 0.5 and 2 Hz, or between 0.1 Hz and 5 Hz. Preferably, the sampling rate is 1 Hz.

The calculation rate may be the same or less frequent than the sampling rate and may be, e.g., about 0.01 Hz, about 0.02 Hz, about 0.033 Hz, about 0.05 Hz, about 0.1 Hz, about 0.2 Hz, about 0.25 Hz, about 0.3 Hz, about 0.4 Hz, about 0.5 Hz, about 0.6 Hz, about 0.75 Hz, about 1 Hz, about 2 Hz, about 3 Hz, about 4 Hz, about 5 Hz, between 0.5 and 2 Hz, or between 0.1 Hz and 5 Hz. Preferably, the calculation is 0.033 Hz.

The complex impedance of biological tissue may vary with the frequency of the applied alternating current. As such, the AC source 110 may be configured to apply the AC at a variety of frequencies. The frequency of the applied AC may be set in a calibration step that determines the AC frequency providing sample values that change most robustly with milk extrusion, and selects that AC frequency for use during the sampling period. Alternatively, multiple AC frequencies may be sampled over the course of the sampling period.

The sampling period may be started and stopped manually by the user, perhaps via a user interface. Alternatively or in combination, the sampling period may be started and stopped automatically through various measures, as described below.

*Filtering the sample values*

The sample values may be filtered with a linear filter. Alternatively or in addition, the sample values may be filtered with a non-linear filter. Various forms of linear and non-linear filtering processes are known in the art.

By way of example, steep changes ("jumps") in the sample values may be caused by electrode movement or other causes not dependent on the amount of milk in the breast tissue. The processing unit may be configured to identify such jumps of the sample values. If there
are two consecutive jumps in opposite direction, the sample values between them may be removed from the data array. If there is a single increasing jump, the jump may be compensated for by reducing all the sample values after the jump by the jump amplitude. If there is a single decreasing jump, the jump may be compensated for by increasing all the sample values after the jump by the jump amplitude.

**Function fitting**

The relationship between the sample value(s) and the breast milk parameter(s) may be characterized by a linear function, a parabolic function, a polynomial function, or the like. The function characterizing the relationship between the sample value(s) and the breast milk parameter(s) may be variable over time, e.g., the function may be weighted at a certain level at the beginning of a breast milk extrusion session, and the weighting of the function may change over the course of the session. A breast milk parameter may be based on a relationship to multiple sample parameters. As noted above, the sample parameters may be those based solely on one or more aspects of the measured impedance of the breast tissue, or a combination of breast tissue impedance and other factor, such as suckling motion measured by, e.g., an accelerometer.

The breast milk parameter may be any parameter related to breast milk produced in the breast tissue being assayed by the system, being relatable to sample value(s).

The breast milk parameter may be based on a single sample value (or an average of multiple sample values) an amount of milk present in a breast tissue 200.

The breast milk parameter may be based on a change in the sample value from one point to another: an amount of milk that has been extruded from the breast (through breastfeeding, pumping, or any other method) over a defined start time and finish time. The amount of milk extruded may be expressed as volume of liquid, e.g., milliliters.

The breast milk parameter may be based on rate of change in the sample value over time: the rate of milk flow. A related parameter is the starting or termination of milk flow. The transition of the rate of milk flow from zero to non-zero may indicate the beginning of milk flow, and the transiting of the rate of milk from non-zero to zero may indicate the termination of milk flow.

The breast milk parameter may be in standard units of measurement. The amount of milk may be expressed in, e.g., milliliters. The rate of milk extrusion may be expressed in,
e.g., milliliters per second. Alternatively, the value may be expressed by an arbitrary value (for example - a range from one to ten, a color code, and the like).

As with the sample value(s) described above, the processing unit may be configured to batch-calculate the breast milk parameter(s) after the termination of the sampling period. Alternatively, processing unit may be configured to calculate the breast milk parameter(s) along with the sample value(s) during the sampling period ("live mode") at the defined calculation rate.

In addition, the amount of milk output may be compared with the pattern of suckling, as determined by, e.g., an accelerometer. The comparison may provide further breast milk parameters, such as identifying when a reduction in the rate of milk output is due to the baby stopping the suckling activity or the baby engaging in non-productive suckling activity.

The conversion from the sample value to the breast milk parameter may be adjusted based on one or more calibration factors to yield the breast milk parameter in said standard unit of volume, e.g., in milliliters.

At least one of the calibration factor(s) may be a value based on one or more biological properties of the nursing woman, e.g., age, ethnicity, weight, height, body-mass index, body fat percentage, breast size, and the like.

Alternatively or in addition, at least one of the calibration factors may be determined for sampling session, based on all or a portion of the sample values gathered from a sampling session. Both empirical and computational calibration methods may a yield unique calibration factor per session.

Alternatively or in addition, at least one of the calibration factors may be a pre-determined calibration factor applied to all calculations independent of the user, e.g., based on previously obtained measurements from a test population comparing one or more sample values to actual milk output.

**Automation**

The initiation of breast milk parameter generation is gated by at least one automatic process, some of which are described below.

The processing unit 120 may be configured to automatically determine correct electrode 130 placement on the surface of the breast. The processing unit 120 may compare the measured impedance against a pre-determined range of impedances, such that the
sampling period is prevented from starting, or is paused, when the impedance is above or below said pre-determined range.

The system 100 may further include a temperature sensor. Accordingly, an increase in temperature may signal the proximity of a baby and unlock the initiation of the sampling period.

Other baby detection sensors may be used as appropriate, alternatively or in combination. For example, the system 100 may further include a microphone. Characteristic suckling sounds produced by the baby may unlock to the initiation of the sampling period. Suckling may be detected my other means as well. Motion associated by suckling may be detected by an accelerometer. Suckling by the baby, even without breast milk extrusion, may result in characteristic changes in breast tissue impedance.

The system 100 may by capable of automatically determining whether the breast it is placed on is the left breast or the right breast. Such a determination may be achieved through monitoring the electrical signals produced by cardiac activity. One or more of the electrodes 130 may periodically measure passive electrical signals (without the injection of AC) to monitor electrical signals from cardiac activity. Because the heart is located towards the left side of the chest, cardiac electric signals will be stronger (e.g., in amplitude) when the system 100 is placed on the left breast compared to when the system is placed on the right breast. Thus, comparing the cardiac signals to system placement (left vs. right) or to pre-determined values allows the system 100 to determine left breast or right breast placement automatically.

EXAMPLES

A more complete understanding of the more general disclosure presented above may be obtained by reference to the following specific examples. These examples are described solely for the purpose of illustration and are not intended to limit the scope of the disclosure.

Example 1

We test a device for monitoring breastfeeding based on bioimpedance of breast tissue with nursing mothers extracting milk using a breast pump. The use of the breast pump allows the comparison of actual milk output against calculated bioimpedance-based milk output.

With reference to Figure 5, the nursing mothers are connected to four electrodes on each breast (Kendall™, Arbo H124SG). The electrodes are connected to a metering device, which is connected to a laptop computer running an analysis software (Analog Devices™,
AD5933 EVAL). The mother is also provided with a breast milk pump attached to a bottle receptacle having a measuring scale (in milliliters).

The electrodes are attached to the breasts of the nursing mother, and the impedance of the breast tissue is measured at regular intervals, e.g., every minute or 30 seconds, with the pump turned off, for an initial period (e.g., 2.5 minutes) to measure baseline. Following the baseline session, the nursing mother turns on the pump. The mother uses a logging program to enter the milk quantity pumped whenever a clear reading of the from the pump's bottle is available (typically at 10 ml intervals, as marked on the bottle), with the logging program automatically logging the time of the volume measurement entry. The mother also logs special events during the pumping that may influence the bioimpedance measurement, such as coughing, drinking, sudden movement, etc., and noting the time of such entries. The bioimpedance measurement continues until the mother has no more milk to pump. Another period (e.g., 2.5 minutes) of post-pumping baseline bioimpedance is measured following the end of pumping. The process is then repeated with the second breast, when possible.

This experimental setup allows a comparison of how well the measured milk output matched with various calculated milk outputs, for example, a first calculated milk output based on be the phase \( \Theta \) (theta) of the impedance of the breast tissue in polar form and a second calculated milk output based on the magnitude \( |Z| \) of the impedance of the breast tissue in polar form.

The calculated milk output based on the phase of the impedance matches the measured milk output better than the calculated milk output based on the magnitude of the impedance. In addition, the magnitude-based calculated milk output is more susceptible to noise.

The scope of the disclosed embodiments may be defined by the appended claims and includes both combinations and sub combinations of the various features described hereinabove as well as variations and modifications thereof, which would occur to persons skilled in the art upon reading the foregoing description.

Technical and scientific terms used herein should have the same meaning as commonly understood by one of ordinary skill in the art to which the disclosure pertains. Nevertheless, it is expected that during the life of a patent maturing from this application many relevant systems and methods will be developed.

As used herein the term "about" refers to at least \( \pm 10\% \).
The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to" and indicate that the components listed are included, but not generally to the exclusion of other components. Such terms encompass the terms "consisting of" and "consisting essentially of".

The phrase "consisting essentially of" means that the composition or method may include additional ingredients and/or steps, but only if the additional ingredients and/or steps do not materially alter the basic and novel characteristics of the claimed composition or method.

As used herein, the singular form "a", "an" and "the" may include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

The word "exemplary" is used herein to mean "serving as an example, instance or illustration". Any embodiment described as "exemplary" is not necessarily to be construed as preferred or advantageous over other embodiments or to exclude the incorporation of features from other embodiments.

The word "optionally" is used herein to mean "is provided in some embodiments and not provided in other embodiments". Any particular embodiment of the disclosure may include a plurality of "optional" features unless such features conflict.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases "ranging/ranges between" a first indicate number and a second indicate number and "ranging/ranges from" a first indicate number "to" a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween. It should be understood, therefore, that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the disclosure. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6 as well as non-integral intermediate values. This applies regardless of the breadth of the range.
It is appreciated that certain features of the disclosure, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the disclosure, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the disclosure. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the disclosure has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present disclosure. To the extent that section headings are used, they should not be construed as necessarily limiting.
CLAIMS

1. A breastfeeding meter system comprising an alternating current (AC) source wired to a first pair electrodes and a processing unit wired to a second pair of electrodes and a casing encasing the AC source and the processing unit, wherein:
   said electrodes are configured to be placed on the surface of a breast tissue; and
   the processing unit is configured to measure the impedance of the breast tissue.

2. The breastfeeding meter system of claim 1, wherein the AC source is configured to produce a current of less than 500 micro amperes.

3. The breastfeeding meter system of claim 1, wherein the AC source is configured to produce a current having a frequency of less than 100 kilohertz.

4. The breastfeeding meter system of claim 1, further comprising at least one pad situated in at least one portion of the casing configured to contact the surface of the breast tissue.

5. The breastfeeding meter system of claim 4, wherein at least one pad surrounds at least one of said electrodes.

6. The breastfeeding meter system of claim 4, at least one pad covering at least one of said electrodes, wherein the pad is conductive.

7. The breastfeeding meter system of claim 4, wherein the pad comprises at least one material selected from the group consisting of a silicone gel, an air-permeable foam and a non-woven fabric.

8. The breastfeeding meter system of claim 1, wherein the casing comprises a clip.

9. The breastfeeding meter system of claim 1, wherein the casing is in the shape of a pendant and attached to a strap.

10. The breastfeeding meter system of claim 1, incorporated into a nursing bra.

11. The breastfeeding meter system of claim 1, configured to be wirelessly connectable to a device comprising a display and a memory unit.

12. The breastfeeding meter system of claim 11, wherein the device is selected from the group consisting of a computer, a tablet, a personal digital assistant (PDA) and a smartphone.

13. The breastfeeding meter system of claim 11, wherein the device comprises a bracelet.
14. The breastfeeding meter system of claim 1, wherein the processing unit is configured to measure the impedance of the breast tissue, calculate at least one sample value based on the impedance and generate a breast milk parameter based on the sample value.

15. The breastfeeding meter system of claim 14, wherein the sample value is the phase of the impedance.

16. The breastfeeding meter system of claim 14, wherein the breast milk parameter is selected from the group consisting of an amount of milk extruded from the breast, the amount of breast milk in the breast and the rate of breast milk extrusion from the breast.

17. The breastfeeding meter system of claim 14, wherein the initiation of breast milk parameter generation is gated by at least one automatic process.

18. The breastfeeding meter system of claim 17, wherein the automatic process is the detection of the placement of said electrodes onto the surface of the breast tissue.

19. The breastfeeding meter system of claim 17, wherein the automatic process is the detection of an increase in temperature.

20. The breastfeeding meter system of claim 17, wherein the automatic process is the detection of a suckling sound.

21. The breastfeeding meter system of claim 1, wherein the processing unit is configured to determine the left-breast or right-breast placement of the system.
**INTERNATIONAL SEARCH REPORT**

International application No.
PCT/IB2013/060624

A. CLASSIFICATION OF SUBJECT MATTER

IPC (2014.01) A61B 5/053, A61B 5/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC (2014.01) A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Databases consulted: THOMSON INNOVATION, Esp@cenet, Google Patents

Search terms used: breastfeeding, lactation, "breastfeeding", "milk consumption", "milk excretion", "breast milk", fluid, excret, extrude, organ, tissue, meter, measure, calculate, monitor, impedance, resistance, electrode, transducer

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
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<tbody>
<tr>
<td>X</td>
<td>US 2010217148 A1 INOLACT LTD. 26 Aug 2010 (2010/08/26) para.[0035]-[0037], [0040], [0043], [0054], [0060], [0061], [0063]-[0065], [0068], [0069], [0071], [0075], [0077], [0086], [0112], [0113]; fig. 4, 6A, 6B</td>
<td>1,3,6,10-12,14,16, 17,19,20</td>
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<td>Y</td>
<td>US 20102925044 A1 YEDA RES. &amp; DEV. 18 Nov 2010 (2010/11/18) para.[0028], [0033], [0069], [0082], [0083], [0086], [0091], [0092], [0096], [0097], [0099], [0110], [0117], [0122]; fig. 2, 3</td>
<td>7,9,13,15, 18,21</td>
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<tr>
<td>X</td>
<td>US 2010292604 A1 YEDA RES. &amp; DEV. 18 Nov 2010 (2010/11/18) para.[0028], [0033], [0069], [0082], [0083], [0086], [0091], [0092], [0096], [0097], [0099], [0110], [0117], [0122]; fig. 2, 3</td>
<td>1-6,8,10,14,16</td>
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☑ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

A: Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on the priority claim(s) or which is of special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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