

# MilkSense model BFM1

## USER MANUAL

Dear customer,

Thank you for purchasing the MilkSense device. With this home care device you will be able to determine the amount of milk your baby receives from your breast.

Please read this instruction manual carefully before use, and keep for future reference.



## Safety Precautions

### Danger:

- Never use the MilkSense device in combination with any other medical electronic aid such as:
  - (1) Electronic implant heart pacemakers.
  - (2) Electronic life support systems.
  - (3) Electrocardiogram equipment.The breastfeeding monitor device may cause these devices to malfunction.
- Take care to secure the baby while handling the MilkSense device.

### Warning:

- The device is not a substitute for medical supervision. Be sure to undergo routine checkups of yourself and your baby at the appropriate clinic.
- Avoid relying on the device alone in any important decision about your baby care; do not stop breastfeeding or overrule baby illness based on apparent low feeding.
- Pay attention to signs of behavioral changes exhibited by your baby and not just to the readings registered by the device. Inadequate breastfeeding poses the immediate risk of dehydration of the baby. Seek an immediate medical consultation in any case of behavioral changes of your baby. Be aware that improper use of the device may show false readings of the milk intake. Refer to the instructions for proper calibration of the device.
- The device is not suitable for premature babies.
- Keep the device and its accessories out of the reach of children. The device and its accessories contain small parts that pose choking hazard.
- If the electrode solution should accidentally get in yours or the baby's eyes, immediately rinse with plenty of clean water.
- Avoid touching the electrodes when the device is connected by a USB cable to the PC.
- Remove batteries from the device when it will not be in use for a long period of time to prevent battery spill inside the device.

### Caution:

- Avoid wetting the sponge with any fluid other than the specific fluid supplied.
- The device is not suitable for monitoring other parts of the body, only the breast.
- Do not disassemble, repair, or remodel the device.
- Keep the electrode solution away from heat sources.
- For reasons of hygiene, avoid sharing the device with others.

# 1. Know Your Unit

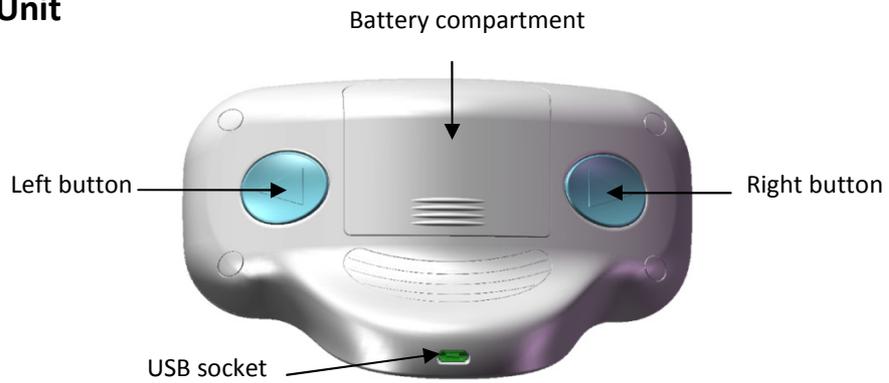


Figure 1. MilkSense top view

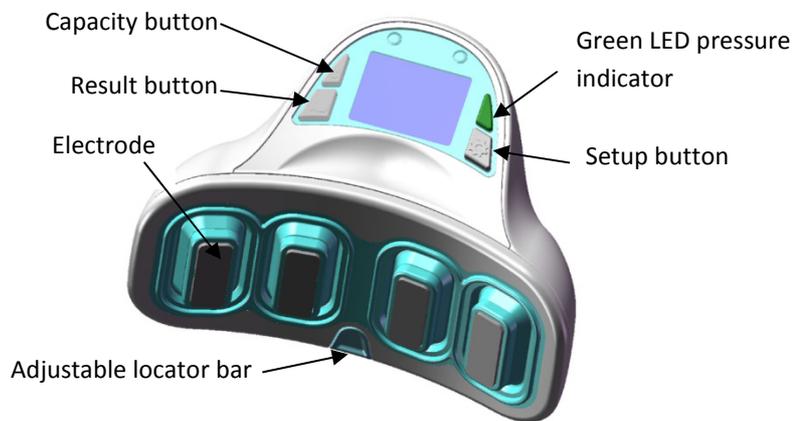


Figure 2. MilkSense side view

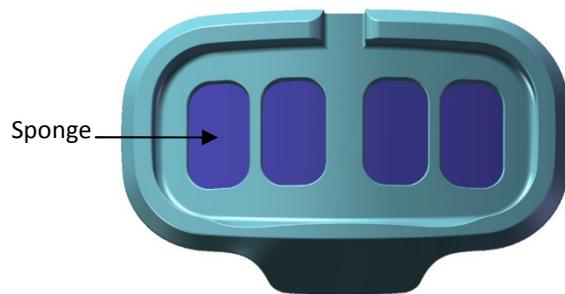


Figure 3. Cradle of the MilkSense device with wet sponge

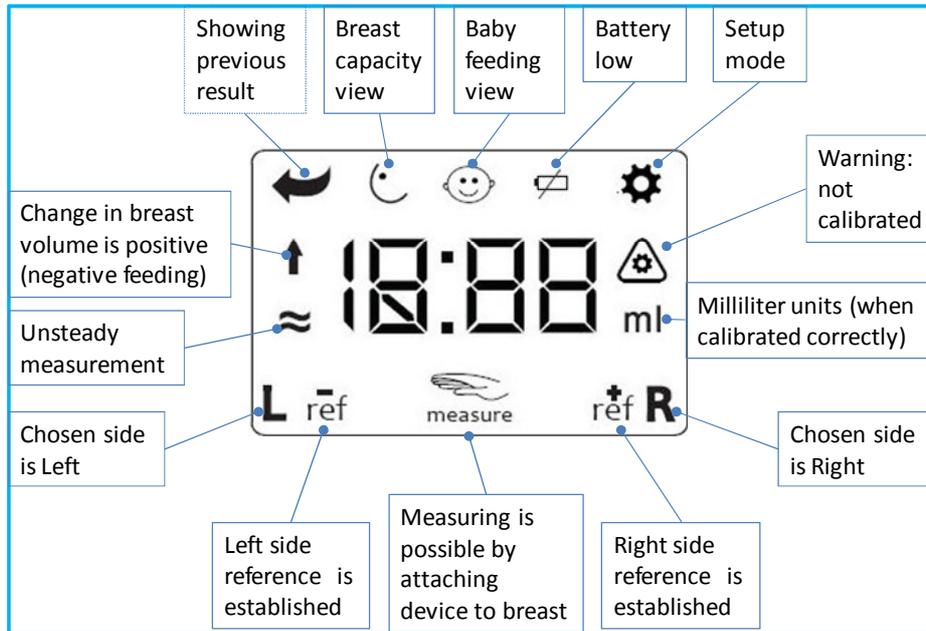


Figure 4. Marks on the display

## **2. Step by step operation of MilkSense BFM-1**

### **2.1 Filling fluid in the sponge**

1. Remove the device from its cradle.
2. Soak the sponge in the cradle with the electrode solution from the supplied bottle until you observe that the sponge is saturated. For accurate results use only the specific fluid supplied for this device.
3. Return the device to its tray in order to reduce evaporation.

Repeat this operation at least twice a week in order to keep fresh fluid in the cradle.

The purpose of the fluid is to prepare the skin and electrode contact for steady conductivity in order to facilitate accurate electrical measurement.

### **2.2 Inserting and Replacing the Batteries**

1. Open the battery cover by holding its entire area with a dry hand and sliding it outwards.
2. Install three AAA Alkaline batteries in correct polarity as marked inside the battery compartment.
3. Slide the battery cover back to close.

Upon correct battery placement, the display will show 0:00. The display light will go off after 30 seconds.

#### ***Battery Replacement***

When the low battery warning appears, the batteries will soon become too low for correct operation. Replace all three batteries immediately after performing the last measurement in a breastfeeding session.

Please note that removing the batteries causes the reference measurement to expire (reference is the data collected in a measurement before breastfeeding). Also, replacing batteries causes the breast capacity indicator (described in 2.3.7) to reset. However, the calibration parameters and history of measurements are retained in the device's memory.

Three Alkaline AAA size batteries (LR03) should last approximately three months with typical use.

### **2.3 Taking a Breast Measurement**

The MilkSense device measures changes in the milk alveoli in order to determine the amount of milk the baby receives from the breast. The device should be attached to the breast for 10 seconds before breastfeeding and for another 10 seconds after breastfeeding to acquire the result.

#### ***2.3.1 Correct Posture of Measurement***

The posture of your body influences the accuracy of the measurement. The following details are important:

1. Sit upright preferably without a support for your back.
2. The arm on the side of the breast you are measuring should be limp, so that the Pectoralis muscle of your breast is relaxed.
3. Hold the device in the opposite hand to the breast side that you are measuring.

### 2.3.2 How to position the electrodes on the breast

When placing the device on your breast, the locator bar (shown in Fig.2) should be pointing to the center of the upper edge of the aureole, and the electrodes placed in contact with the upper part of the breast. The four electrodes should be aligned horizontally and in complete contact with the breast (see Fig. 5). It is important to perform all measurements always in the same position over the upper part of the breast.

### 2.3.3 Adjusting the locator bar according to the shape of breast

According to the shape of your breast, you may need to extend the length of the locator bar by sliding it outward to one of 3 positions. After adjusting the position of the locator bar it should remain the same in all subsequent measurements.

In cases where the breast is "uplifted", as shown in Fig.6 case A, choose the inner most state of the locator bar. Similarly, the locator bar should be fully closed if the upper edge of the aureole (marked with an arrow in Fig.6) is higher than the fold line of the breast. Otherwise, if similar to case B in Fig.6, please extend the length of the locator bar as least as possible so the condition shown in Fig.5 is met: The electrodes of the device should touch the breast just above the height of the fold line. Thus the measurement location is not too far above the nipple and yet not too near the hanging section of the breast.

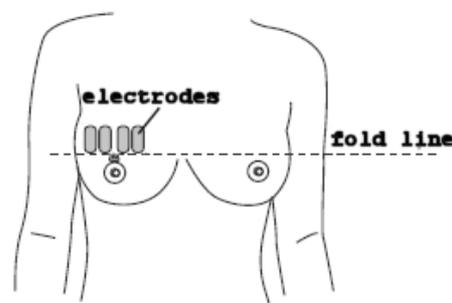


Figure 5. Electrodes aligned horizontally. Locator bar may need to be extended so the electrodes are above the fold line.

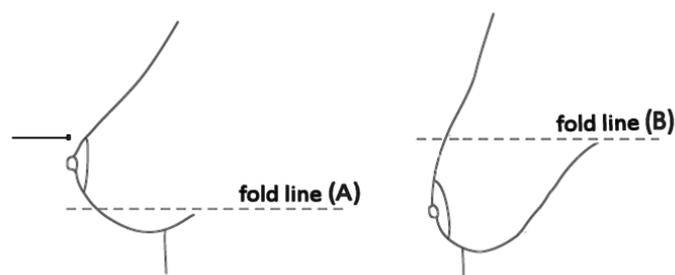
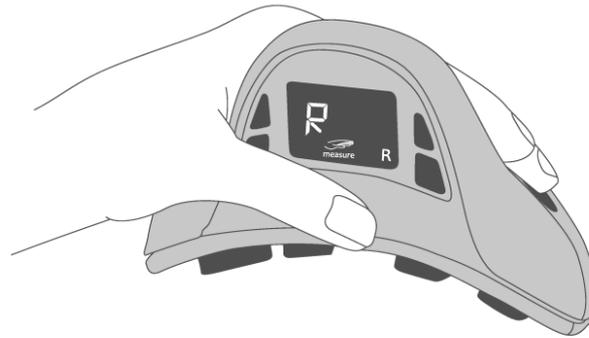


Figure 6. Comparing the fold line of the breast with the upper edge of the aureole

### 2.3.4 Measurement Operation

1. The device should be placed in the cradle to ensure that all the electrodes are sufficiently wet. The correct time for measurement is just before breastfeeding. However, if milk starts to drip or you feel that the breast is engorged it is too late to obtain an accurate measurement



**Figure 7. Holding the MilkSense device**

2. Hold the device as shown in Fig.7 and press the button that is located below your 3<sup>rd</sup> finger [on button "Left" or "Right" (Fig 1) according to the side of breast that you choose]. A hand symbol (  ) and the chosen side letter ("L" or "R") appear on screen, and the device waits for body contact. If you change your mind about the side you want to measure, you can press the other side button and change the holding hand. In order to abort the procedure, you may press on any of the inquiry buttons beside the display. After 30 seconds the display turns off and you will need to press the Left/Right button again in order to resume measurement.

3. To make good body contact, point the locator to the upper edge of the aureole of your breast and press all four electrodes against the skin. Apply gentle pressure, just enough to turn on the green pressure indicator light, that will initiate the measurement. Keep the same pressure applied until the end of the procedure (green light should stay on during more than half of the measurement time).

4. Once the device is attached to the body the display shows the letters "SnS" for two seconds and then a count-down is shown until the end of measurement (clicking sound serves for audible notice). A chirp sound signals the end of measurement.

5. Detach the device from the breast and observe the output. The letters REF mean that the current state of the breast has been recorded as reference (valid for one hour), and the time is considered the beginning of breastfeeding in the chosen side. Return the device to its cradle and start breastfeeding freely.

6. About 1-4 minutes after completing the breastfeeding (and after the breast has stopped dripping), re-measure the breast exactly as in the reference measurement (repeat steps 2-4). At the end of the measurement the device shows the calculated amount of milk fed to the baby. Note that until calibration is established, this amount is in arbitrary units (see section 3).

Notes:

\*Keep the MilkSense in its cradle. This ensures that the electrodes are ready for use and prevents fluid evaporation.

\* If the duration of the breastfeeding is likely to exceed 1 hour, then interim measurement should be taken or else the reference reading will become obsolete. Repeated measurements show the state of the breast compared to the initial reference measurement of that same breast.

\*The device senses the volume of alveoli in the breast whereas the milk in the ducts is not taken into account. Normally the ducts fill only after the start of breastfeeding, and become empty until the end of breastfeeding. Thus, this process will not affect accuracy.

\*Measure as close as possible to the start and end of breastfeeding (wait 1-4 minutes after the end of breastfeeding), except in the case of measuring both breasts, which is described below.

### **2.3.5 Measuring both breasts**

If you intend to breastfeed from both sides intensively (expecting to take less than 1 hour), it is recommended to measure both sides before and after the entire session. After measurement of one side return the device to its cradle for several seconds (to fully moisten the electrodes) and then measure the other side. The lower part of the display shows the chosen side (L/R) and the reference status (the small mark "ref" appears after the initial measurement of each side). The milk result refers only to the chosen side. Results of the other side can be viewed by pressing the left/right button and then on the relevant inquiry button beside the display (result button to show fed milk / capacity button to show level / setup button to show time since last measurement).

### **2.3.6 The result (or previous result) button**

The Result / Previous Result button (  ) shows the feeding amount currently measured or previously measured. When the display is off, or in time mode, one click on the result button will show the current result of milk. Clicking once more on the button will show the previous measurement result (for two seconds).

### **2.3.7 The Capacity button**

The Capacity button (  ) shows the estimated amount of milk in the breast by simply comparing the current measurement result with all previous measurement records since the time the battery was entered. In order to start assessing the breast afresh, you may remove and reinsert the batteries. The results are for each breast separately. Correct results also depend on proper calibration (section 3).

\*This function assumes that in at least one previous measurement the breast was empty, and that the composition of the breast tissue has not changed since then. If not enough previous measurements are available then the empty result mark is shown ("---").

### **2.3.8 Empty display and clear function**

When the display shows the sign "---" it means there is no fresh reference value for one of the breasts. In such a situation the measurement that comes first is interpreted as a reference measurement for the chosen breast side. The reference value expires after one hour. In the event that you wish to perform a reference measurement sooner than one hour you can click the "setup" button together with the "result" button. The two buttons pressed simultaneously act as a clear button (only for the reference values).

### **2.3.9 Time Indication**

Immediately after the device is removed from the cradle the display shows the length of time, in hours and minutes, which has passed since the last measurement and which side of breast was measured. After choosing the side of breast,

it is possible to view the time that has elapsed since the last measurement by pressing the "setup" button (  ) and immediately releasing it.

### ***2.3.10 Twin breastfeeding***

If two babies are being fed, it is possible to mark the feedings of one of the babies. To do so, when starting the measurement double click the left or right measurement buttons, either before or after feeding. After double clicking the button a colon sign (:) appears beside the letter "L" or "R" on the display of the device. After clicking the button once the mark is cancelled. After downloading of the data from the device to the PC, the lines on the PC screen that refer the second twin feeding (marked with a double click) will appear with a "twin (:)" sign.

### 3. Calibration

It is necessary to calibrate the MilkSense device according to your individual breast. The calibration can be performed either after automatic collection of data or after manual entry in several steps as described below.

#### *What calibration means*

Using the MilkSense device on your breast is like having an accurate gauge without scales. The initial results of measurements are not scaled properly before you perform the calibration. In order to determine the settings specific to your breasts it is necessary first to compare the measurements taken by the device with a verified method that can indicate how much milk is expressed from the breast. With this information the system identifies your calibration factor and changes the settings accordingly. After proper calibration, the device only requires measurement before and after breastfeeding in order to find the changes in milk content of the breast.

#### 3.1 Automatic calibration using Bscale

The recommended way to collect data required for calibration is by using the Bscale, a USB weighing device for a baby in a baby car seat (please refer to the safety section of the Bscale manual). The main purpose of the Bscale is to weigh the baby (with clothes on) before and after breastfeeding, and thus provide verified input of the quantity of milk that is expressed from the breast. The Bscale attaches to the handle of a baby car seat (the combination is safe at home only) and connects to a PC computer. It is recommended to repeat the procedure at least 3 times for each side of breast.

Before you begin, install the MilkSense PC Suite software on your windows PC (refer to section 4), since the installation may take some time. Then measure the empty baby seat as follows: connect the Bscale to the PC via USB cable, fix the Bscale to the handle of the baby seat, press "Run scale", wait 3 seconds, choose the option to measure empty seat, and lift the baby seat from the handle of the Bscale. Lower it down and press OK. The empty seat weight is now stored in the PC baby file.

Please ensure that the MilkSense is not connected to the PC during breast measurements.

Please follow the steps below for collection of the data required for calibration:

1. Before breastfeeding, run the MilkSense PC Suite software on your PC.
2. Connect the Bscale to the handle of the baby seat. Place the baby securely in the seat.
3. Connect the Bscale to the PC via the supplied USB cable.
4. Make sure that the handle of the Bscale is properly in place and pointing upward. Click with your mouse on the screen button "Run Scale". Wait for three seconds without touching the handle, so that the zero balancing can be self-performed.
5. Hold the Bscale handle and lift your baby in his seat slightly above ground. Wait for the selected result to appear on the PC screen. Avoid any possible interference to the weight measurement (for example, avoid leaning the seat over your legs). Lower the baby down, and press OK. (Leave the USB cable connected and software running on the PC).
6. Before breastfeeding measure with the MilkSense device on the breast. Feed your child. Then measure with the MilkSense device after breastfeeding. Note that the results are not scaled and therefore may appear unreasonable but they are still needed for the calibration.

7. Place the baby in the seat again after breastfeeding (make sure that the baby is wearing the same clothes and holding the same toys as before breastfeeding) and weigh the baby and seat as in steps 4-5. You will observe how much the baby was fed based on the change in weights. In case you are not satisfied with the condition of the measurement, press on the screen button "Cancel", otherwise press "OK".

After acquiring the results of 3 successful breastfeeding sessions in each side please follow the steps below in order to operate the calibration itself:

Run the MilkSense PC-Suite software, and connect the MilkSense device to the PC via the supplied USB cable. Press on the screen button "Read MilkSense". Wait for the download to complete. Then press on the "Calibrate" button (enabled after 3 breastfeeding sessions with consistent MilkSense and Bscale data). The new left/right breast calibration factors will appear on the screen at the end of the breastfeeding data list. A V-mark should appear beside the "Calibrate" button if the calibration factors are sufficiently certain; otherwise, more combined MilkSense and Bscale measurements may be required to achieve reliable calibration accuracy.

## 3.2 Manual Calibration

In case you cannot use a computer with Windows operating system, the last option is to perform a manual calibration by using the setup button on the MilkSense device. You need to know the amount of milk that expresses from the breast, preferably by weighing the baby before and after feeding. Using a breast milk pump is not recommended as a verified input since in most cases, at the time chosen for pumping, the breast is not in a normal condition, usually suffering from engorgement or mechanical stress. Manual calibration is only possible within one hour after the milk measurement is acquired, and may be successful only if the amount is sufficient (50ml or more) and accurately verified. The manual calibration allows only one calibration factor for both sides, which is suitable in most cases (accuracy may be impaired if the two sides are not similar, only automatic calibration handles all cases).

Follow these steps for manual calibration:

1. Press and hold the setup button (  ) for 4 seconds to enter the setup (calibration) mode, and keep the button pressed. If after 4 seconds an error message appears, it indicates there is no appropriate value of measurement to refer to.

In this mode the calibration factors for the two breast sides can be modified as one. The change is effective for all subsequent measurements until you modify the setup again.

2. The last feeding amount that was measured appears on the display and you can change this value to reach the amount you consider is correct. Changing the number (that should correspond to the volume of last fed milk) is done in steps by pressing on the Left (-) or Right (+) buttons while still pressing on the setup button. In case a change in units is desired (change between milliliter "ml" to fluid ounce "oz" or vice versa) then press the capacity button (  ) for one second while keeping the setup button pressed.

3. When the setup button is released the calibration factor is updated. Release the button when the correct amount of fed milk appears on the display. In order to abort the update it is possible to return the device to its tray before the release of the setup button (otherwise, the calibration can be corrected by repeating steps 1-3).

\* After successful calibration the warning sign (  ) disappears, meaning you can read the results of milk quantities in true units of milliliter/ounces.

## 4. Using the PC software.

Using the supplied PC software "MilkSense PC Suite" you may choose among several routes of performing calibration. In addition, the software enables you to show the history of measurements and to present the progression of your baby's feeding in graphs.

In order to install the software, use the supplied CD and run the setup program. There is no special driver needed for the device. The software allows a full communication with the MilkSense and Bscale devices.

In order to change the units of the MilkSense device from "ml" to "oz" connect it to the PC via the USB cable provided, choose "units: oz/lb" on the top menu line, and press "Read MilkSense". The MilkSense will then operate with ounce units. The action can be reversed in a similar manner.

All operations with the software are automatically saved, therefore there is no save button. All measurements are stored in a baby file (default file is first.baby), which you can change by clicking the <File> and <New...> buttons on the upper menu bar. It is recommended to keep a backup copy of your baby file and share it with a breastfeeding counselor that has access to the software.

Please consult the help function of the software for further instructions.

## 5. Troubleshooting the MilkSense device

<b>Problem</b>	<b>Cause</b>	<b>Correction</b>
<b>Measurement countdown aborts in the middle with error message.</b>	Skin is not wet, or no contact with electrodes.	Wet the electrodes by filling the tray with intended fluid and placing the device in the tray for one minute. Press the device over breast until all four electrodes are in full contact with skin.
<b>Measurement countdown aborts in the middle with reset.</b>	Battery is low. A low battery mark should appear as well.	Replace with new Alkaline batteries.
<b>The result of breastfeeding quantity seems wrong.</b>	Possible causes: 1) User did not follow the instructions correctly. 2) Calibration is not successful due to location of glandular tissue being too far from the electrodes.	First try to perform correct calibration and to follow instructions as accurately as possible. If results are not satisfactory try changing electrode location on your breast according to the place you feel surplus when you are late in breastfeeding.
<b>Unsteady results in repeated measurements.</b>	Possible causes: 1) Unsteady measurement conditions (indicated with sign "≈" on the display). 2) Milk ducts in the breast are filled during measurement, 3) Local distortions in the breast, just below the electrodes.	1) Measure while in correct posture of the body, at the exact point on the breast each time. Use the device at home in relaxed conditions, 2) Avoid measuring if the breast drips. Pay attention to emotions and state of mind that influence your breast activity and that cause milk ducts to be filled, 3) As a last possibility, consider changing the location of electrodes 1cm to the right or left and stick to it in all measurements.
<b>The MilkSense device does not communicate with the PC with USB cable connected.</b>	Possible causes: 1) There are no batteries in the MilkSense device. 2) General USB failure.	1) Insert new batteries into the MilkSense device. 2) Check the USB cable by replacing with another micro-USB cable.
<b>Device does not react to buttons pressed.</b>	Device is locked when held in tray or connected via USB cable.	Remove USB cable and take the device out of its tray in order to operate.
<b>Display light is not turned on when taking device out of cradle</b>	Device rests in wrong orientation on the cradle	Place the display side of the device on the MilkSense logo side of the cradle.

## 6. Technical Data

**Product:** MilkSense - model BFM1

**Technical Description:** The device transmits 40KHz and 20KHz signals to the breast tissue at an electric current of about 0.5mA and measures the response signals via electrodes contact over the skin. The measurement is sensitive to the average volume of milk alveoli in the breast.

**Power Supply:** 3 Alkaline AAA batteries (LR03)

**Rated supply voltage:** 4.5Vdc - Internally powered equipment.

**Display of Milk Intake by Baby:** 0 to 999 ml / 0 to 19.9 oz

**Display of Breast Milk Content:** 0 to 1999 ml / 0 to 99.9 oz

**Deviation from Accuracy (in tests):** 20% for quantity above 60ml, 14ml for lower quantities.

**Battery Life:** Approximately 3 months

**Service:** Electrode solution should be poured onto sponge by the user every 2-3 days. Sponge should be replaced by the user every 3 months. Sponge and electrode liquid are available at the place of purchase.

**Memory size:** Up to 1500 measurements (exceeding this number overrides older data).

**Operating Temperature**

+15°C to +30°C

**Storage Temperature/ Humidity**

4°C to +40°C, 10% to 95% RH.

**Weight:** Approximately 0.5 kg

**External Dimensions:** 15X10X9 cm.

**Method of cleaning:** Plastic parts are cleaned with Alcohol and the electrodes are cleaned with boiling water at the factory. The electrode solution supports sterilization of the parts during use.

**Ingredients of the electrode solution:** Water, Alcohol (20%), Sodium Chloride, Potassium Sorbate.

**Package Contents:** MilkSense device and cradle, Bscale device, bottle of electrode solution, user manuals, micro-USB cable, Software CD (for Windows operation system).



= Applied Part Type BF



= CE mark means that this device fulfills the provisions of the EC directive 93/42/EEC (Medical Device Directive) amended by Council Directive 2007/47/EC.



= Avoid disposing to general waste (environment protection): Electrodes and metallic parts are made of stainless steel that should be recycled after use in order to protect the environment.

### Manufacturer address:

Bradley & Luka, Pinhas Rozen 25, Tel-Aviv, Israel.

URL: [http:// www.bradleyandluka.com](http://www.bradleyandluka.com)

### European representative address:

Bebe' Due España, s.a.

C Anoia 3, P.I. Can Bernades- Subirà

08130 Sta. Perpètua de Mogoda (Barcelona), Spain

Tel. +34 93 574 7500 Fax: +34 93 574 1592