

Mylee

Breast Milk Sensing Device User Guide

MYLEE

WHAT'S IN THE BOX

MyLee milk sensing device

2 x Milk sample wells

Cleaning accessory (MyLee cleaner)

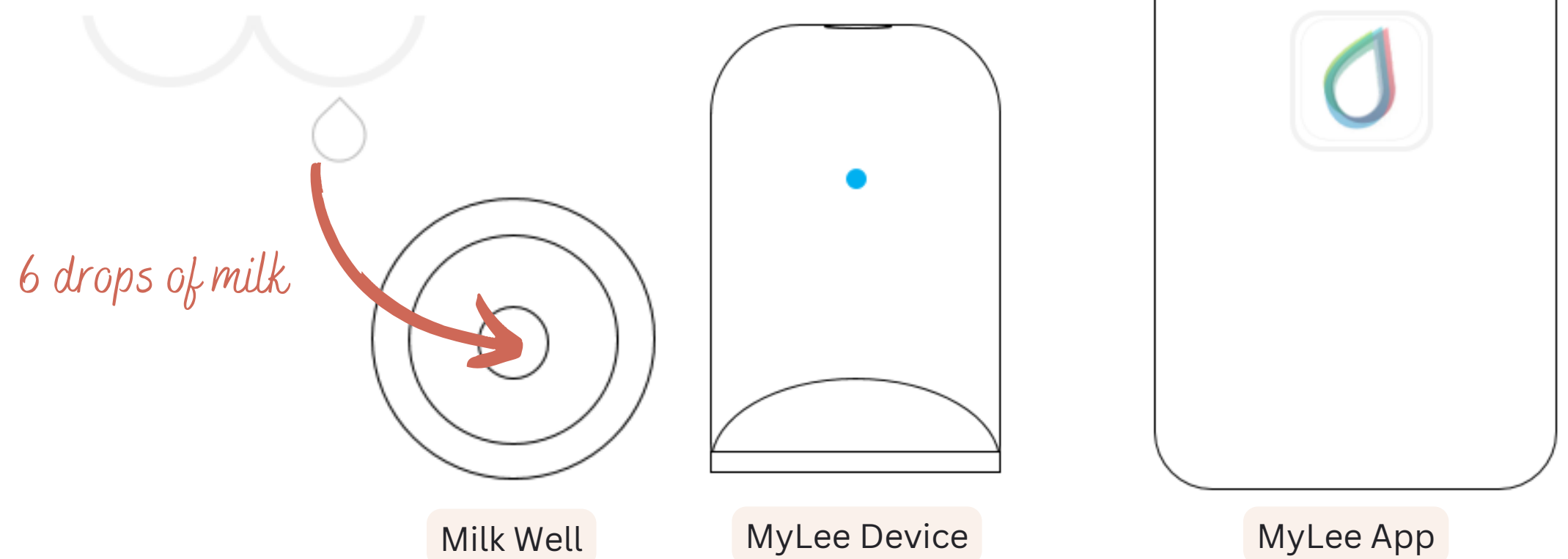
USB-C cable

Quick start guide

HOW DOES THE MYLEE BREASTMILK SENSING DEVICE WORK?

The mylee milk sensor device connects to Mylee App to provide a breastfeeding monitoring solution to the mother. The Mylee system uses an innovative technology to track your breastfeeding efficiency and milk supply establishment, at real time, at your home, by sensing few drops of mother's milk.

The milk sensing device sends the milk sample data to your phone via Bluetooth, and the Mylee App generates alerts, tips and insights.



HOW TO SET UP AND USE THE MYLEE DEVICE

Requirements

The mylee milk sensing device requires access to an iOS or Android device with the Mylee App downloaded. Minimum OS versions apply, see app stores for details.

Bluetooth connections and wireless internet connections are required for performing a scan, data restoring and some App features.

Download the Mylee App and sign in

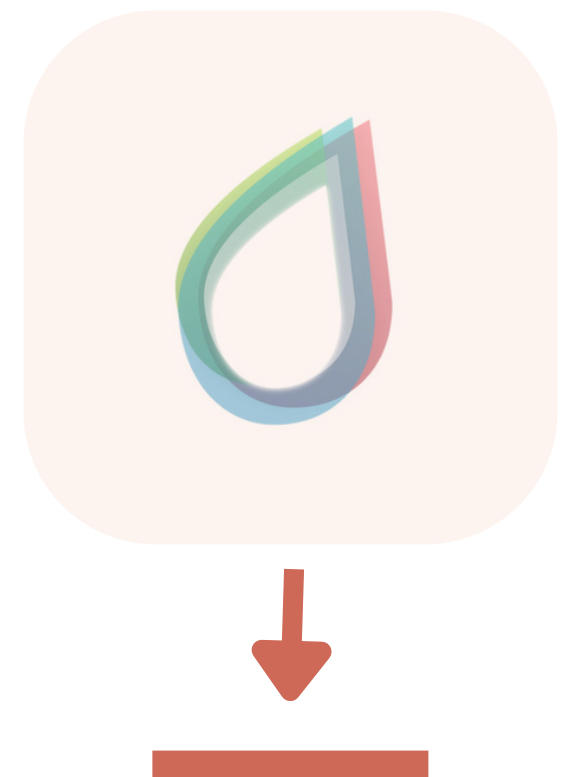
Install the Mylee App from App Store available for iOS and Android, and follow the in-app instruction to create an account.

Password must be at least 8 digit long. Complete your profile data.

Create your child profile. It is critical to **record birth date and HOUR accurately**. App Registration should be done after birth. You can install and start registration before delivery, and complete birth date after birth.

Go through App tutorial screens to learn of Mylee basics, and read and accept privacy and term of use notes in the App.

Follow in App instructions to add your Ob/Gyn profile. You can skip and return to complete it any time from my account setting. This will improve your insights personalization.



Activate your MyMilk Scanner, and Start scanning

Register your Mylee device barcode in the App. Connect the Mylee via Bluetooth, and Scan 6 drops of milk.

ACTIVATE.

Follow the in App instructions to Register your Mylee device barcode. Your device barcode is found on the box.

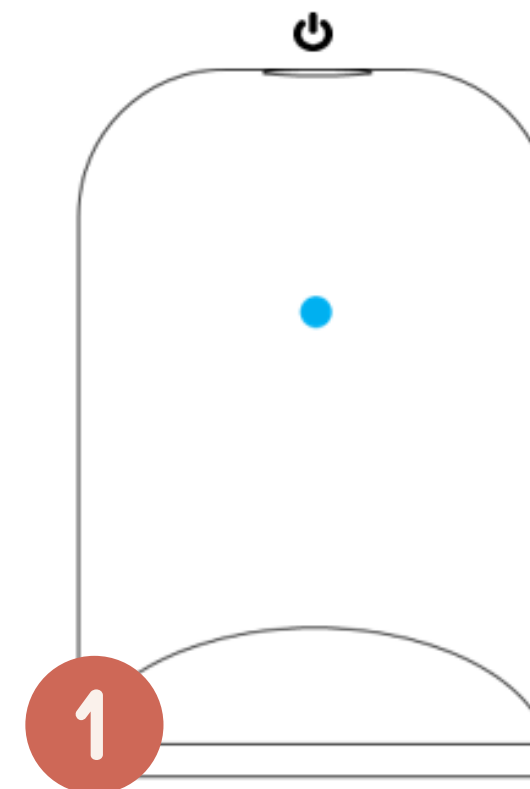
Go to settings (Top, right) and press MyMilk Scanner, and Register your device barcode and press Apply. You can scan barcode via the barcode reader to avoid typing errors.

MILK SAMPLE.

The Mylee device comes with two milk wells. Place the well on a stable surface, and fill the inner cavity of the milk well with milk using a teaspoon. Make sure the inner circle is completely filled (about 6 drops ~0.35ml). Use a separate well for each Breast side (Right/Left).

SCAN.

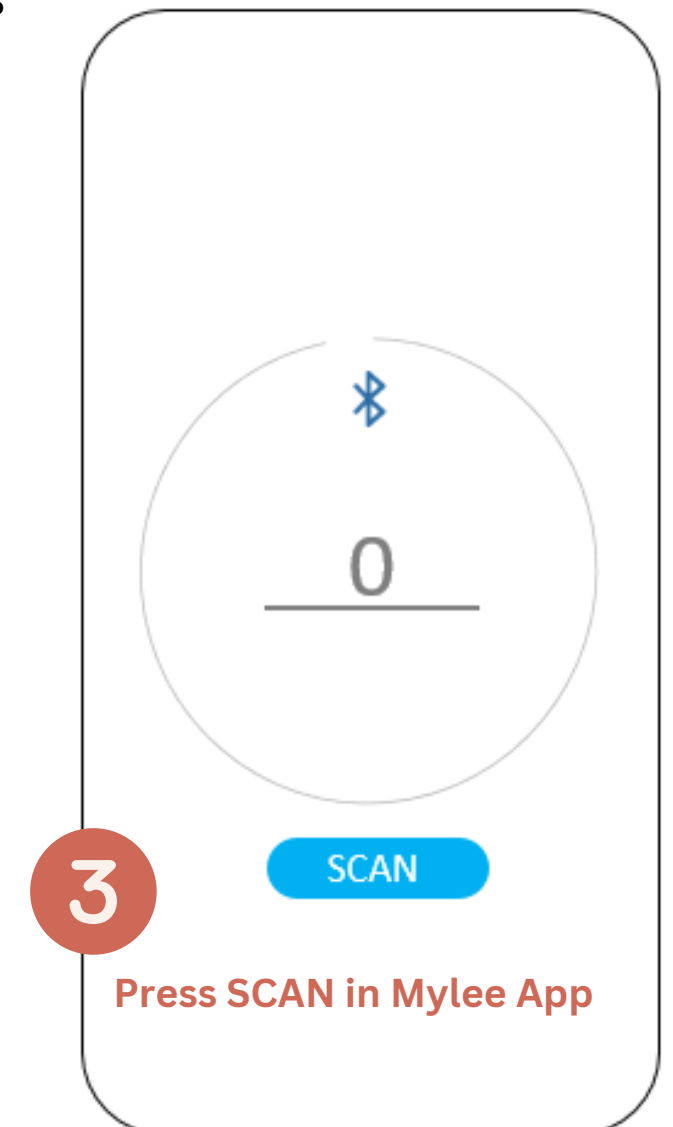
Go to home screen and add right/Left scan - the My Scan screen appears. Turn-on the Mylee device, and link it via Bluetooth by tapping the 'Connect' link in My Scan screen. Place the Mylee device on the milk-filled well,, let go the device placed on the milk well, and tap SCAN in the App and SAVE the reading. It takes about 20 seconds for a scan to be performed. Perform another SCAN with the other milk well for the other breast. Go to My Insights to get your milk maturation status and insights.



1 Turn on the device & connect it via Bluetooth to Mylee APP



2 Place Mylee device on a full milk well



3 Press SCAN in Mylee App

WASH.

After use, flush the milk wells under tap water and air dry. Make sure milk wells are complete dry before reuse.

For device cleaning, use the cleaning accessory provided in the box. Fill the inner circle of the accessory with tap water, and rotate the device on it. Avoid wetting the device outer shield. Tap lightly on drying paper to remove water drops.

! Do not rinse the device under water. No soap, No boiling water. Keep the electronic device away from liquids.

TIPS:

- It is recommended to perform daily scans, to track your day-to day process.
- It is recommended to scan each breast separately, to allow the system to detect side differences and you to balance them.
- It is recommended to start scanning from the first days after birth, to get early feedback.

Track your milk supply & Get involved

Get your milk maturation status and insights. Track each breast maturation dynamics, see color index, and get tips and alarms based on your status.

Log daily data about your breastfeeding practice & your baby, and get enhanced tips and insights. The more you track, the personal it gets.

Hand expression in the first days may be challenging, and mother may be reluctant to use milk drops for use other than feeding. Be aware that according to a Stanford Medical study, hand expression in the first days higher than five times a day, in addition to breastfeeding, was found to encourage breast milk production and improve milk intake

THE MYLEE DEVICE

General Function:

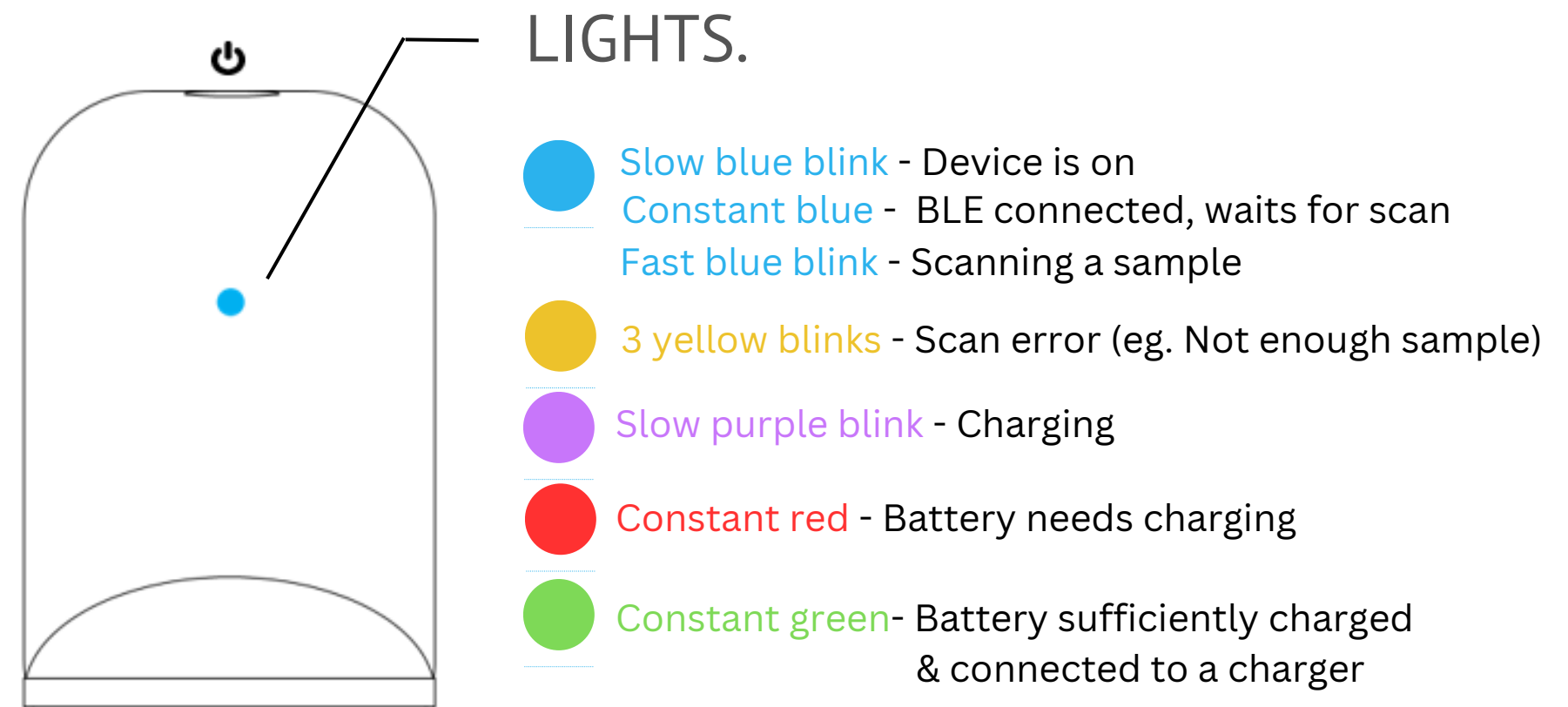
The Mylee device has a single On/Off button and light dot. On-off by short press. Device shuts off automatically after 3 minutes. When device is OFF, light is off. When device is ON, light is on.

The device's SW can be upgraded remotely, pending on user acceptance.

The device is rechargeable. A scan cannot be performed while charging.

ACTIVATION CODE

On the package label you will find the activation code number, that you will be asked to enter in the device activation process. The application will guide you through it.



PAIRING (BROADCASTING)

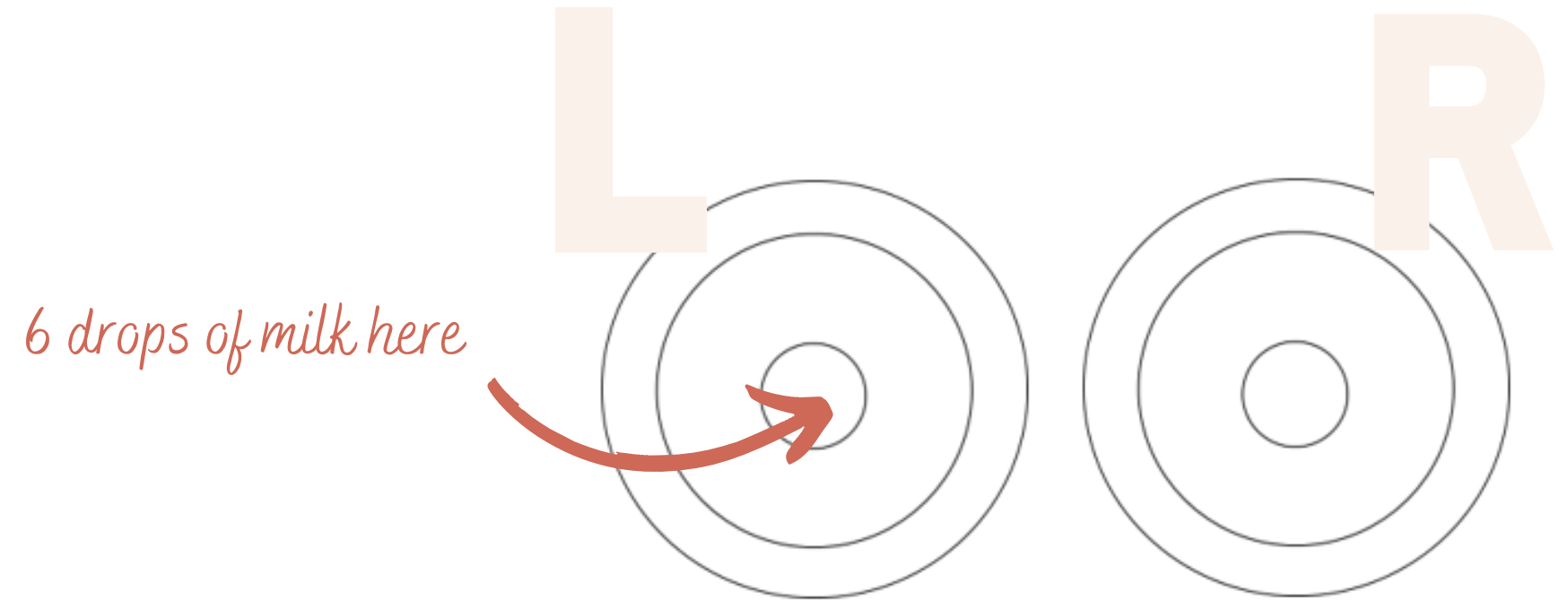
The mylee device sends information to the phone via Bluetooth. Turn on your Bluetooth for device connection, and Connect device via Scan screen. The App will alert you if Bluetooth is off. Make sure device is ON before connecting it via the App. Once connected, constant Blue light will appear on the Mylee device, and connectivity will be indicated in the App.

In case of connection lost, a prompt will appear on App screen, and device blue light will start blinking. If power button is pressed, the device will turn off and connectivity will be lost; Light will be turned off as well.

Getting scans and prompt

BREAST MILK SAMPLE PREPARATION

- Collect a tiny sample, about 6 drops of breast milk, by hand expression, for scanning.
- Each breast should be sampled and scanned separately.
- For improved accuracy, it is recommended to collect the sample before breastfeeding and not directly after feeding.
- Milk can be collected directly into the inner circle of the milk well, or through a clean container (e.g. a spoon). Do not let sample wait in an open container or in the milk wells as it can evaporate and reduce reliability of the scan.



- It is recommended to scan fresh samples. If needed, the sample can be kept up to 2h in room temperature in a closed container. If scanning a refrigerated sample, it is important to bring the sample to room temperature first.
- In the first hours after birth – and in the first two days it may be difficult for you to collect the minimum sample volume. In such case you can either combine several attempts, or mix right and left samples.
- If you use any nipple cream, wipe ointment leftovers from the nipple and wash with running water, before milk collection.

Getting scans and prompt

HOW TO PERFORM A SCAN?

- Place the milk well on a clean stable surface. Insert 6 drops of milk in the inner circle of the milk well. Make sure the center well is full, and milk is covering the walls of the central well.
- In the App, go to home screen, and press to add a right/Left scan. The Scan screen appears.
- Turn-on the mylee device by shortly pressing the top button. Blue blinking light will appear on the device.
- Make sure your phone Bluetooth is on. Go to the Mylee App and Link the Mylee device via Bluetooth by pressing the “connect” link Scan screen. When the Mylee device is connected via Bluetooth the blue light on the device become still stable.
- Place the Mylee device on the filled milk well. Don't keep holding the device while a read is performed; it can destabilize it.
- Press SCAN on the App. It takes up to 20 seconds. Don't touch the device while a read is performed. Blue light blinks fast while a scan is performed.
- SAVE the reading.

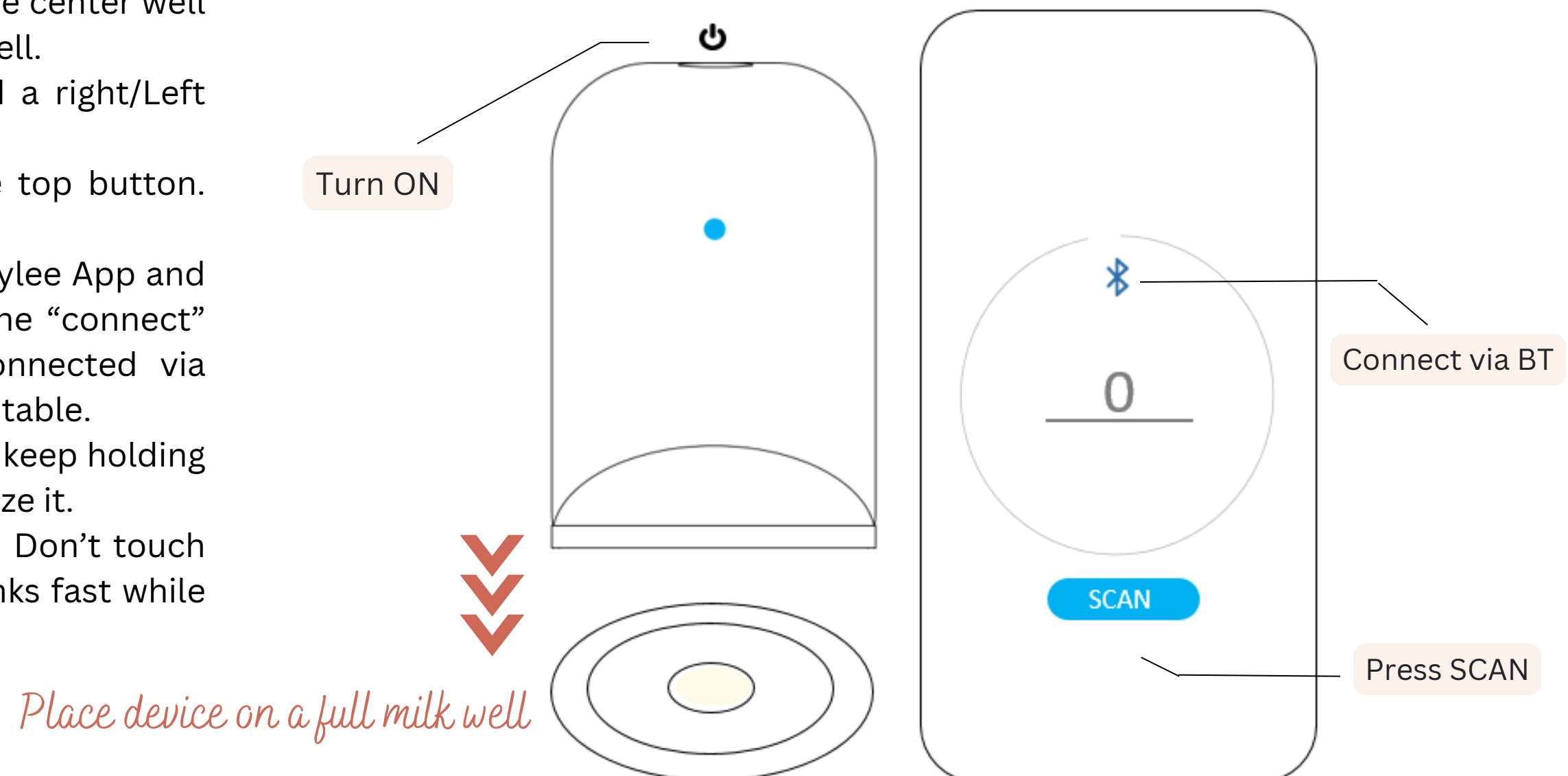
- A milk sample should be read from each breast separately. Use a separate milk well for each side.
- Go to Insights to get your milk maturation status and insights.
- Clean the MyLee device by the water-filled MyLee cleaner accessory as instructed below.
- Disregard milk sample, and wash milk wells as instructed below. .

*It's OK if milk is spilled to the outer circles of the wells. The milk well is designed to hold a certain volume of sample for accurate result, and lets overloads to spill to the circles.

**Notice any ERROR prompts on the App screen indicating not enough milk, low battery, high temperature, etc.

**Do not leave the device or milk wells in touch with milk as it may harm next results accuracy.

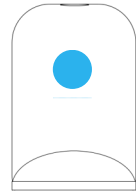
***Do not feed or otherwise use the milk sample that was in contact with device.



Getting scans and prompt

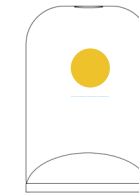
DEVICE PROMPTS

When device is OFF, light is off. When device is ON, light is on. The milk sensing device communicates different stages with the colored lights. Light color does not say anything about your milk result.



BLUE LIGHT

Device is functional. Flashing rate is indicative of scanning mode. When the device is on, a slow flashing blue light appears. Once device is connected to Bluetooth via Mylee App, light is static blue. Once device is performing a reading, blinking is fast.

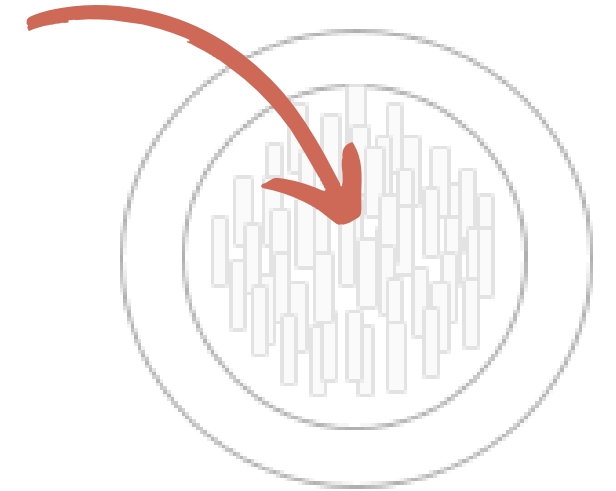


YELLOW LIGHT

Three blinks of yellow light are indicative of technical error state detected during the scan. An alert will appear in the App to specify the error. Error can be indicative of not enough milk sample, out of range values, or extreme sample temperatures.

It is recommended to avoid saving a scan with technical error, and to repeat the scan after controlling the indication detailed in the App alert.

Fill the cleaner with Tap water



Clean device & Wash wells

DEVICE CLEANING AND STORAGE

WASH MILK WELLS

Milk wells are intended for multiple use, and need to be washed right after each use.

- Wash wells right after use; Do not let milk sample stand in the wells.
- Flash each milk well with plenty of running Tap water.
- Dry thoroughly. Use a clean paper towel for drying.

*It is important that no water drops remain in the milk wells for the next measurement. Drops of water in the wells will lead to incorrect result.

**Do NOT sterilize the device or its parts. Do not expose it to boiled or hot water.

CLEAN MYLEE DEVICE

- Fill the spiky center of the Mylee cleaner with tap water (2-3 ml).
- Place and rotate the device on the Mylee cleaner, while gently pressing the device downwards.
- Dry the sensor gently with a clean piece of paper towel.
- Wash and dry the MyLee cleaner.

! Keep the Mylee device away from liquids. Only the wells and sensor are intended for liquid contact as specified. The device contains electronics parts that can be damaged by contact with liquids in any way other than its intended use as described.

STORAGE

Keep the device shut down, in room temperature, in a dry safe place. Don't keep wet parts in a closed bag/box. Protect the device from falling, as it will break. Avoid exposures to liquids.

Clean device & Wash wells

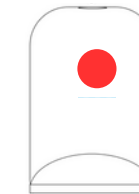
CHARGING THE DEVICE

For charging the mylee device, please connect the USB-C cable provided to a UL certified wall charger, and Plug to a power source. Place the USB-C connector into the charging port on the back side of the mylee device. Place the device on a stable surface, make sure it stands stably. Slow dimming purple light indicates charging is in process. Disconnect from charger once green light is indicated. Battery is now fully charged.

BATTERY LEVELS

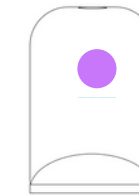
You can check the device battery level in the App. Once the device is connected via Bluetooth, the battery level appears in the Scan screen. If your device battery level is getting low you will be prompted in the App. The device will not show light indication at that stage. You can still run scans with this mode, but it is advised to charge the device after completing the scan.

Device light indicators help to identify battery status.



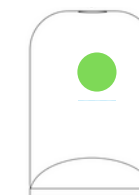
RED LIGHT

Battery is getting extremely low, and charging is needed.



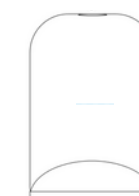
PURPLE LIGHT

Device is plugged to power supply and is charging. Do not perform a scan while charging.



GREEN LIGHT

Device is plugged to a power supply & battery is fully charged.



NO LIGHT

If device is not turning ON, and light is off, it may indicate that battery is empty, and charging is needed. Light should appear upon connection to a power source.

Get insights

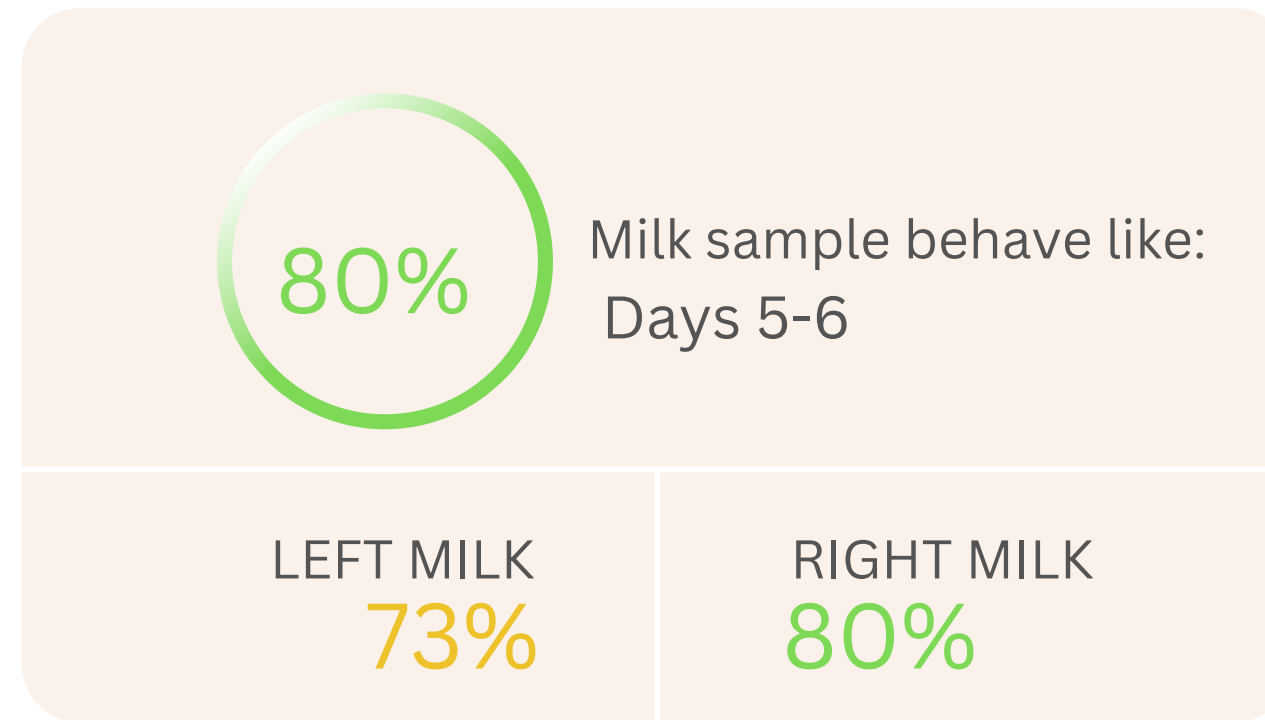
MILK MATURATION

Milk maturation % is not a clinical term, but rather a wellness use index developed by MyMilk professionals to better understand day-to-day routine breastfeeding establishment progress.

The milk sensing device sends the milk sample data to your phone, and the Mylee App computes a numeric milk maturation (MM%) parameter from 0% to 100%, that reflects the progress of milk from colostrum to matured milk, a gradual process that takes 2-3 weeks with a sharp dynamics in the first days.

It does NOT measure milk 'quality' but serves as a biomarker for breastfeeding efficiency and milk secretory activation process.

Day-to-day progress of each breast is monitored in the Mylee App. The Mylee App also provides alerts, tips and insights.



For each milk sample reading, the Mylee App computes a milk maturation % and assign a color indication, reflecting whether the sample is above (Green) or below (Orange) MyMilk benchmarks in comparable day after birth. Your best daily scan is presented as the large circular icon.

The milk maturation board generate a 'milk matched day' index as set by MyMilk benchmarks. Milk “behave like day” is expected to match the actual day after birth.

The milk maturation board is managed separately to each breast side, and system alerts differences in breast dynamics when monitored.

Day to day progress can be followed in milk maturation chart, and Logged scans can be viewed, edited and deleted via All my scans table.

Clean device & Wash wells

SHARING YOUR REPORT

You can share Mylee Report with a care giver contact directly via the App Care Team screen. You can add care team contacts, or connect with alike mothers that the App linked you with.

It is recommended to use Mylee in close contact with a lactation consultant. In any concern about Your breastfeeding, milk supply or baby, do not delay contact with a lactation consultant or other care giver.

HELP & SUPPORT

You can also contact us via Care team contacts screen with any question, or a problem. Don't hesitate to contact us with any small or big positive or negative issue.

You can also write us to contact@mymilklab.com

For more information go to: www.mymilklab.com

DIRECTIONS & SAFETY INFORMATION

Please read the following directions and safety information carefully before you use the Mylee breastmilk sensing device.

WARNING: The Mylee Breast Milk Sensing Device is not a medical device

It is not intended for use as medical device or to substitute for a healthcare provider’s consultation. It does not and is not intended to diagnose, cure, treat, alleviate or prevent any disease or health condition or to replace or modify the anatomy of or any physiological process.

the Mylee device is meant for healthy mothers to a healthy baby as a wellness tool, and the notification alerts and thresholds do not infer on clinically accepted standards.

System is intended to monitor your breastfeeding, and cannot and is not intended to imply of your baby's feeding. Do not use device as a reason for introducing feeding supplementations. Follow your professional care recommendations.

Remember: this product is only intended to assist you in monitoring your breastfeeding wellbeing and is not indicative of your or your baby's wellbeing, and should not be used to make medical decisions, and is not intended in any case to replace your responsibility for your breastfeeding management, breast health, or your role as a caregiver. You are responsible for the health and wellbeing of you and your baby and following health and care guidelines. It is advised to consult with a lactation consultant or a health provider about your reports.

In any concern about your breastfeeding, your baby or your own health, contact with lactation consultant or your healthcare provider.

ADDITIONAL DEVICE WARNINGS

Only charge the device with the Mylee charging cable provided. Never use a damaged cable or charger to charge your device

The charger (AC/DC adapter) is not supplied, yet the recommendation is a UL certified wall mount charger.

The device can heat up during charging. Do not place on or close to flammable surfaces when charging.

This device cannot be serviced or repaired. Do not repair it yourself.

This device consists of small parts that may be hazardous to children and pets. Keep the device out of reach of pets and children.

DEVICE PRECAUTIONS

Do not use the device if there is visible damage.

The device contains a Li-Po battery. Do not attempt to remove the battery from the device.

Do not apply mechanical stress.

Do not disassemble, repair, or modify the device. Do not open the enclosure.

Do not use the device more than a year after the first use.

Do not use your device while charging it.

Do not charge a wet device.

BUILT-IN BATTERY PRECAUTIONS

This product contains rechargeable battery. There is a risk of explosion if batteries are not handled or disposed in the correct way.

The batteries are not designed to be replaced.

Do not expose the device to temperatures exceeding 40°C/104°F, or to cold conditions below 5°C.

Charging should be between 10°C to 30°C/50°F to 86°F. Charging below 0°C/32°F might damage both battery and device.

Do not dismantle, short circuit, open or shred the battery.

Do not expose the battery to heat or fire. Avoid storage in direct sunlight.

Do not subject to, store or transport the device at low air pressure, as it may result in an explosion or the leakage of flammable liquid or gas.

Do not dispose the device in a fire, the battery could explore.

OPERATION & STORAGE PRECAUTIONS

The device is designed to operate in closed environments. Only work or store the device with ambient temperature between 15°C and 40°C, in environment with 15% - 90% relative humidity, non-condensing.

Materials are not ‘food grade’: Do not directly insert the milk wells, the device or its' parts into a container meant for feeding.

Discard milk drops used for scanning and do not use milk that was in contact with the scanner parts or milk wells for feeding.

Do not insert anything to the wells except to human milk or tap water.

Do not drop, knock, or shake the device.

Do not leave it in the car. Avoid heat or direct sunlight.

The device is not waterproof. Avoid contact of other device parts with liquids. Do not wet the device. Only the wells and sensor are intended for liquid contact.

Dry all parts completely before storing. Don’t keep wet parts in a closed bag/box.

CLEANING PRECAUTIONS

Make sure that the device and the milk wells are free from dirt or liquids. Liquid drops, oily residues, salts precipitations, and dust can lead to incorrect measurement.

Do NOT sterilize the device or its parts.

Do not expose it to boiling or hot water.

Do not use soap for cleaning. Only tap water.

Do not use harsh chemicals, cleaning solvents or powerful detergents to clean the device.

Milk wells only are dishwasher safe, and can be occasionally washed in dishwasher.

Make sure that the USB port of the device is free from dirt and fluids

Do not clean the device while charging.

Use a clean, damp cloth to clean the device surface occasionally when needed. Never wash the device under a faucet.

Warranty

MyMilk proudly stands behind the MyLee product. Our limited warranty are detailed at www.mymilklab.com/myleewarranty

We warrant that if you use our product as it is intended, it will be free from defects in materials and workmanship for a period of 1 year from device purchasing for new products and 6 months for refurbished products.

We do not warrant our product against erosion, grinding, exhaustion, fatigue from regular use, or any damage as a result of misuse, modifications or improper maintenance.

If you believe you have received a defective product, we will either repair or replace the defective product or its defective component part(s) in accordance with the terms of this limited warranty. We warranty the replacement for the remaining unexpired period of the original product’s warranty.

TERMS & CONDITIONS

Mylee product is subjected to term and conditions found at https://www.mymilklab.com/home/mylee_milkscan_terms
By using the Mylee product you agree to those terms.



The device transmits the data to phone via Bluetooth Low Energy (BLE). It uses a Nordic nRF52810 IC that supports the standard BLE modulation and communication techniques



Dispose of this device appropriately. Substances in this device and its battery may harm the environment or cause injury if handled and disposed improperly.
For responsible disposal or recycling, reach out to local authorities or email us at contact@mymilklab.com



US-Pat-No US17/426,523 Pending
IL-Pat-No: IL285181A, IL303514 Pending



FCC ID: 2BCG2MLK2023A

Changes or modification to this unit not expressly approved by the partly responsible for compliance could void the user's authority to operate this equipment. Please ONLY use the supplied charging cable. Failure to do so may void our limited warranty.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

RF Exposure Compliance
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Mylee
www.mymilklab.com

