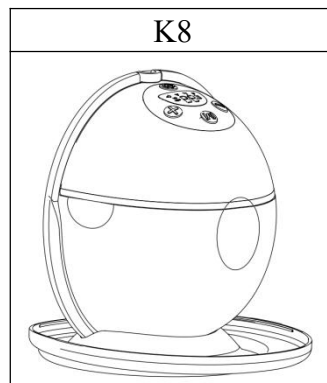


User manual for **Wearable Breast Pump**

MODEL: K8, K8-APP



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1. Specifications

The Wearable Breast Pump (Model: K8, K8 -APP) is an over-the-counter, non-sterile, single-user, powered breast pump intended to be used by lactating women to express and collect milk from their breasts. The device is intended for daily use in a home environment. The device uses a diaphragm-type vacuum pump driven by software embedded in the device to generate suction required to stimulate and express breast milk. The software provides control over vacuum pressure and cycle speed.

A pumping session shall be at most 30 minutes long, and the device automatically shuts down after 30 minutes without operation.

This breast pump is a personal-use wearable breast pump. There are 4 modes can be chosen:

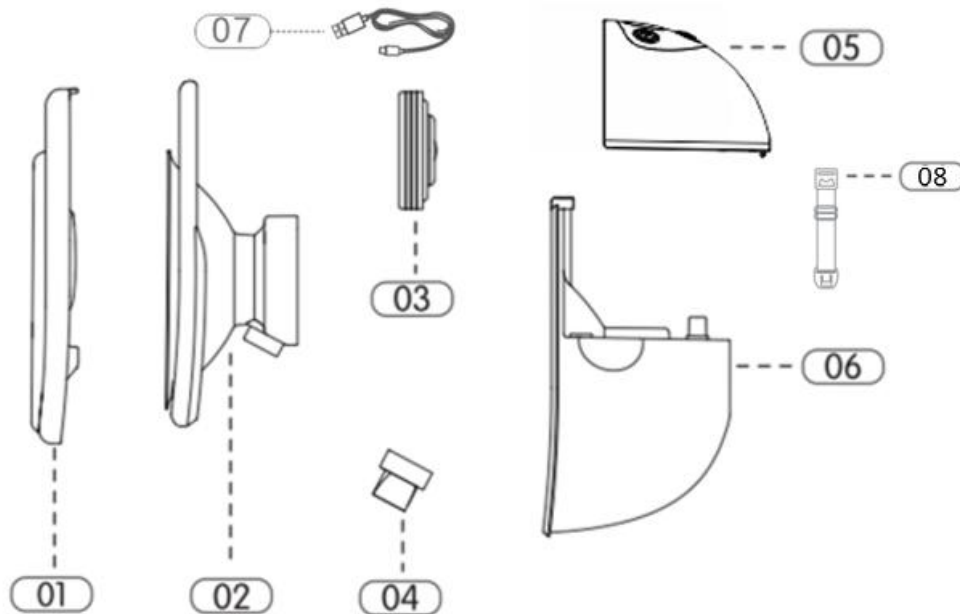
- ◆ Stimulation mode: In this mode, the breast pump begins with a quick and short sucking pattern to get your milk to start flowing.
- ◆ Expression mode: The breast pump begins with a slow and long sucking pattern for milk expression, where the suction is deeper and more effective.
- ◆ Massage Mode: This mode is specially designed for breastfeeding moms with inverted and flat nipples. In this mode, the breast pump begins with low suction-pause-high suction-release and repeats this process, sucking more sufficiently.
- ◆ Automatic Mode: In this mode, the breast pump begins with 5 quick and short sucking patterns, followed by a slow and long sucking pattern. There are 12 suction levels to choose from.

Product Name	Wearable Breast Pump	
Model	K8	K8-APP
Weight	515g	515g
Rate Power	5W	
Adaptor Voltage	Input AC100-240V 50/60Hz 0.3A Max. Output 5V --- 1A	
Li Battery Capacity	102030*2 DC3.7V 1200mAh 4.44Wh	
Maximum Suction	300 ± 5 mmHg	
Material of Contect	PP	
Pump options	Single	
Suction levels	12 levels	
Software version	V0	
Noise	≤60dB	
Vacuum range and cycle speed		
Vacuum range (stimulation mode):	110~220±5 (mmHg)	
Cycle speed	79~187±2 (cycles/min)	

(stimulation mode):	
Vacuum range (expression mode):	135~300±5 (mmHg)
Cycle speed (expression mode):	31~77±2 (cycles/min)
Vacuum range (massage mode):	135~300±5 (mmHg)
Cycle speed (massage mode):	31~44±2 (cycles/min)
Vacuum range (automatic mode):	135~300±5 (mmHg)
Cycle speed (automatic mode):	3~6±2 (cycles/min)
Use-life	1 year
Operate environmental conditions	
Temperature	5~40°C
Relative Humidity	15%~85%RH
Atmospheric Pressure	700hPa~1060hPa
Transport/ Storage environmental conditions	
Temperature	-20~50°C
Relative Humidity	15%~85%RH
Atmospheric Pressure	700hPa~1060hPa

2. Breast pump system parts

Display instructions:
detail instruction can refer to
section 7 in User Manual

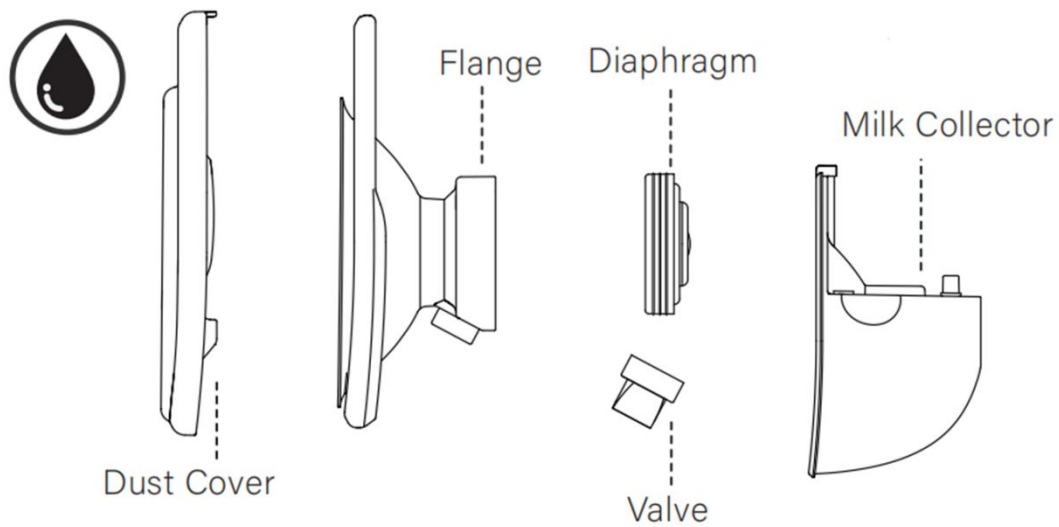


Parts No.	Parts Name	Quantity	Raw Material
1	Dust Cover	1	PP
2	Breast shield	1	Silicon
3	Diaphragm	1	Silicon
4	Duck Valve	1	silicon
5	Pump Motor	1	ABS
6	Milk Collector	1	PP
7	Type-C Charging Cable	1	PVC&Cu
8	Bra Clip (Optional)	1	PP

3. How to clean

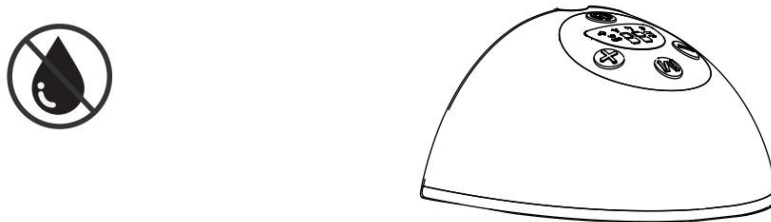
Please clean and disinfect all parts except the pump motor (shown in below picture).

*** Washable parts:**



Please disinfect the pump motor with a low-level disinfectant such as ethyl or isopropyl alcohol (70-90%).

*** Non-washable parts:**



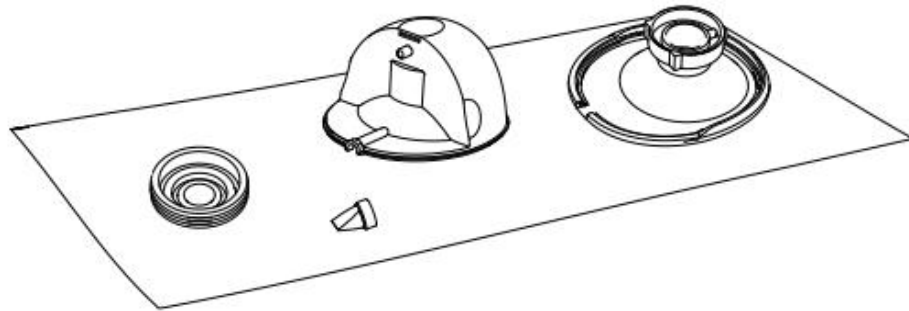
3.1 Before each use

1. Wash hands. Wash your hands well with soap and water for 20 seconds.
2. Assemble. Assemble clean pump kit. Inspect whether the pump kit has become moldy or soiled during storage.

3.2 After every use

1. Store milk safely. Cap milk collection bottle or seal milk collection bag, label with date and time, and immediately place in a refrigerator, freezer, or cooler bag with ice packs. The more detail can refer to section How to store breast milk in this user manual.

- If milk collection container will be stored at a hospital or childcare facility, add name to the label.
- 2. Clean pumping area, clean the dials, power switch, and countertop with disinfectant wipes.
- 3. Take apart and inspect pump kit. Separate all parts that come in contact with breast/breast milk.



4. Rinse pump kit. Rinse breast pump parts that come into contact with breast/breast milk under running water to remove remaining milk.
5. Clean pump kit. As soon as possible after pumping, clean pump parts that come into contact with breast/breast milk in one of the following ways.

- Clean by hand.
 - 1) Use a wash basin. Place pump parts in a clean wash basin used only for washing infant feeding equipment. Do not place pump parts directly in the sink, because germs in sinks or drains could contaminate the pump.
 - 2) Add soap and water. Fill wash basin with hot water and add soap.
 - 3) Scrub. Scrub items according to pump kit manufacturer's guidance. If using a brush, use a clean one that is used only to clean infant feeding items.
 - 4) Rinse. Rinse by holding items under running water, or by submerging in fresh water in a separate basin that is used only for cleaning infant feeding items.
 - 5) Dry. Allow to air-dry thoroughly. Place pump parts, wash basin, and bottle brush on a clean, unused dish towel or paper towel in an area protected from dirt and dust. Do not use a dish towel to rub or pat items dry because doing so may transfer germs to the items.
- Clean in a dishwasher

- 1) Wash. Place disassembled pump parts in dishwasher. Be sure to place small items into a closed-top basket or mesh laundry bag so they don't end up in the dishwasher filter. If possible, run the dishwasher using hot water and a heated drying cycle (or disinfection setting); this can help kill more germs.
 - 2) Remove from dishwasher. Wash your hands with soap and water before removing and storing cleaned items. If items are not completely dry, place items on a clean, unused dish towel or paper towel to air-dry thoroughly before storing. Do not use a dish towel to rub or pat items dry because doing so may transfer germs to the items.
6. Clean wash basin and bottle brush. If you use a wash basin or bottle brush when cleaning your pump parts, rinse them well and allow them to air-dry after each use. Consider washing them every few days, either in a dishwasher with hot water and a heated drying cycle, if they are dishwasher-safe, or by hand with soap and warm water.

3.3 For Extra Protection, Disinfect

For extra germ removal, disinfect pump parts at least once daily. Disinfecting is especially important if your baby is less than 2 months old, was born prematurely, or has a weakened immune system due to illness or medical treatment (such as chemotherapy for cancer). Daily disinfecting of pump parts may not be necessary for older, healthy babies, if the parts are cleaned carefully after each use. Disinfect all items (even the bottle brush and wash basin) by using one of the following options.

Note: If you use a dishwasher with hot water and a heating drying cycle (or disinfecting setting) to clean infant feeding items, a separate disinfecting step is not necessary.

1. Clean first. Pump parts, bottle brushes, and wash basins should be disinfected only after they have been cleaned.
2. Disinfect. Disinfect the pump kit, bottle brushes, and wash basins using one of the following options.
 - Steam:
 - 1) Use a microwave or plug-in steam system according to the manufacturer's

directions.

- Boil:
 - 1) Place disassembled items that are safe to boil into a pot and cover with water.
 - 2) Put the pot over heat and bring to a boil.
 - 3) Boil for 5 minutes.
 - 4) Remove items with clean tongs.
- 3. Allow to air-dry thoroughly. Place disinfected pump parts, wash basin, and bottle brush on a clean, unused dish towel or paper towel in an area protected from dirt and dust. Do not use a dish towel to rub or pat items dry because doing so may transfer germs to the items.
- 4. Disinfect the pump at least once daily.

3.4 Store Safely Until Needed

Allow the clean pump parts, bottle brushes, and wash basins to air-dry thoroughly before storing to help prevent germs and mold from growing. Once completely dry, the items should be stored in a clean, protected area to prevent contamination during storage.

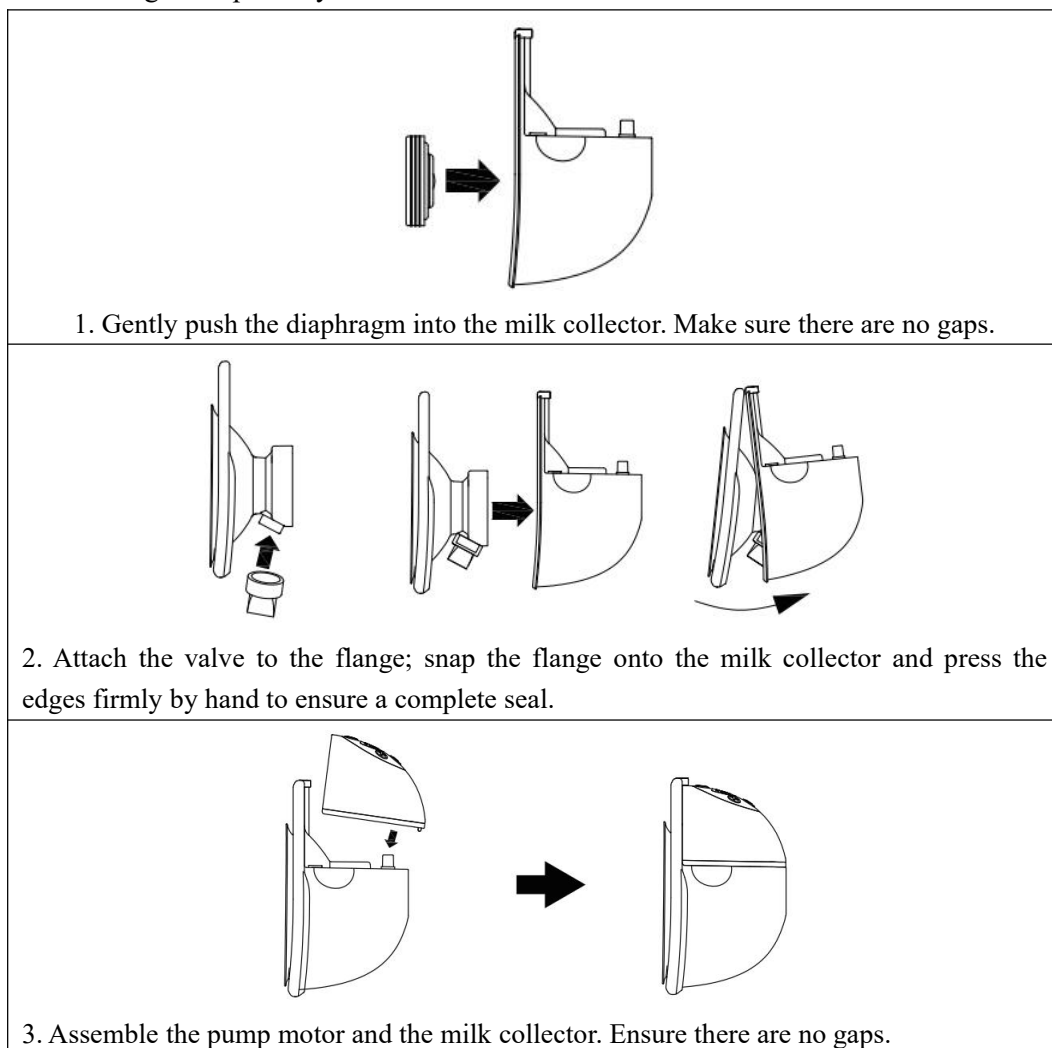
1. Wash hands. Wash hands well with soap and water.
2. Reassemble. Put together the clean, dry pump parts.
3. Store safely. Place reassembled pump kit in a clean, protected area such as inside an unused, sealable food storage bag. Store wash basins and bottle brushes in a clean area.

4. Indications for Use

Wearable Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The device is intended for a single user.

5. Putting together your breast pump kit

※ All accessories must be installed well, otherwise the suction function will be affected and milk leakage will possibly occur.



Caution: The device is not be used when lying down or sleeping to ensure proper orientation is maintained during use.

6. APP Installation & Connection (For K8 Model with APP Function Only)

6.1 Intended Use of the APP

This APP is a companion control application intended for use by lactating women to remotely control the compatible wearable breast pump (Model K8-APP). It does not provide clinical monitoring or therapeutic functions; all core safety functions are controlled by the breast pump device itself.

6.2 Compatibility Requirements

- iOS: iOS 14 or latest
- Android: Android 10.0 or latest
- The APP relies on Bluetooth wireless communication to connect with the breast pump.

6.3 APP Download and Installation



Figure 6-1 APP Download

- 1) Search for LVB Breast pump in the App Store (iOS) or Google Play / built-in Android app store (Android).
- 2) If the APP is unavailable in the Android app store, scan the official QR code provided by the manufacturer to download and install.
- 3) Install the APP to your smartphone.

6.4 Add Device to APP Homepage

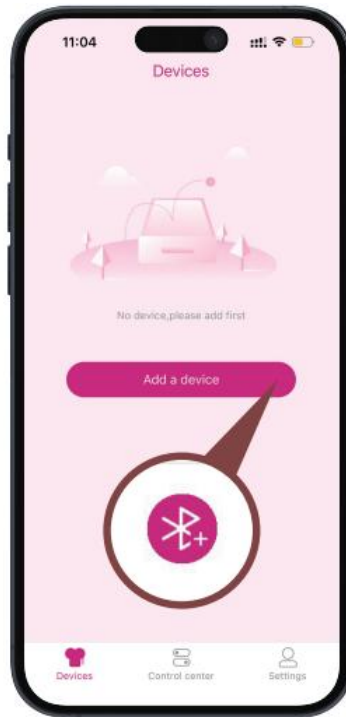


Figure 6-2 Add Device to Homepage

- 1) After installation, open the APP.
- 2) Follow prompts to add the breast pump device to the APP homepage.

6.5 Device Pairing and Connection

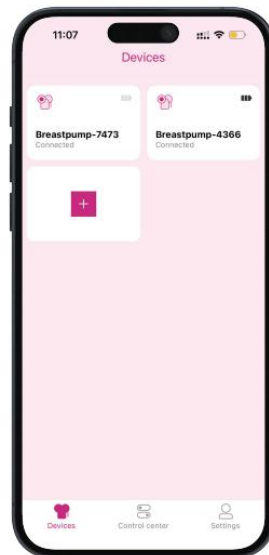


Figure 6-3 Bluetooth Pairing

- 1) Turn on Figure 6-3 Bluetooth Pairing Bluetooth on your smartphone.
- 2) Turn on the breast pump.
- 3) In the APP, tap the “+” icon and Bluetooth icon to search and pair the device.
- 4) Confirm pairing when the device is detected.

6.6 APP Control Functions

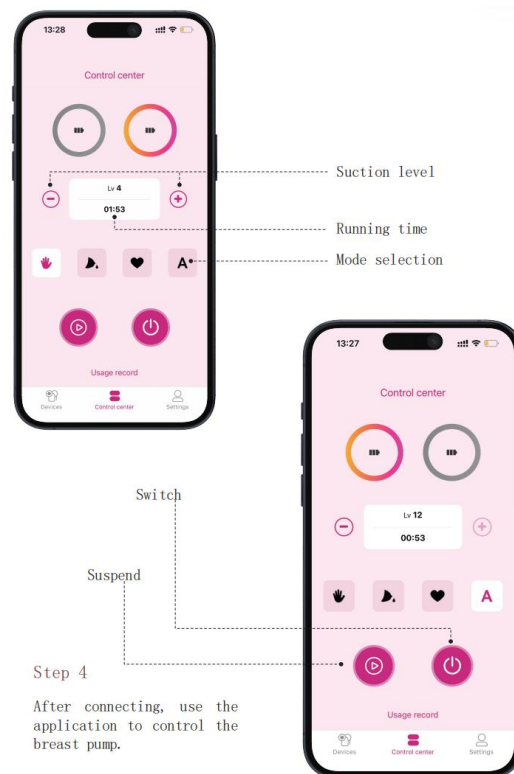


Figure 6-4 APP Control Screen

After connection, use the APP to control:

- 1) Suction level: Adjust suction intensity;
- 2) Running time: View working duration
- 3) Mode selection (Switch among modes: Stimulation, Expression, Massage, Automatic)
- 4) Switch: Turn on/off the pump
- 5) Suspend: Pause pumping temporarily

6.7 Settings

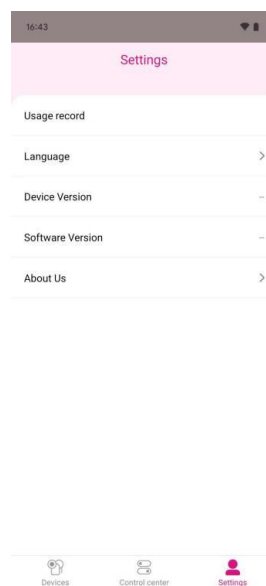


Figure 6- 5 APP Settings Screen

The Settings menu allows users to configure and view basic information related to the breast pump and the mobile application:

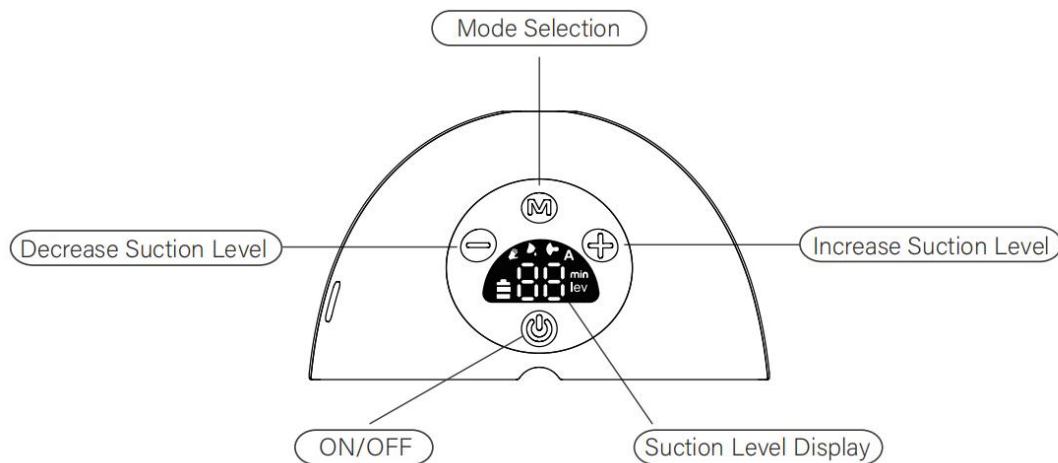
- 1) Usage Record: View historical usage data of the breast pump, including usage duration, mode selection, and suction levels.
- 2) Language: Select the display language for the mobile application.
- 3) Device Version: View the hardware/firmware version of the connected breast pump.
- 4) Software Version: View the current version of the mobile application.
- 5) About Us: Access product information, contact details, or other related content.

Safety and Operational Notes

- 1) The APP depends on Bluetooth communication. If communication fails, use the physical buttons on the pump.
- 2) The pump's safety limits (30-minute auto-shutoff, 5-minute cooling interval) are controlled by the device, not the APP.
- 3) Do not operate the APP while driving, bathing, or in unsafe environments.
- 4) Keep the APP and phone system updated for stable performance.

7. Display instructions

K8



Buttons and LEDs	Description
	ON/OFF button

	Mode Selection button
	Increase Suction Level button
	Decrease Suction Level button
	Stimulation Mode indicator
	Expression Mode indicator
	Massage Mode indicator
	Automatic Mode indicator
	Level/Time display
	Battery level indicator

1. Before pumping, please wash your hands and it is recommended to wipe your breasts with a warm towel.
2. This device provides 4 modes: Stimulation mode, Expression mode, Massage mode, Automatic mode.

3. Long-press the ON/OFF button  for 2 seconds to turn the device on and start the stimulation mode (to stimulate breast milk secretion). If you are using this product for the first time, the device will enter the single-side stimulation mode-Level 3 by default.
4. Increase/ Decrease Suction Level button ( / ): you can press the “Levels increase/reduction button ( / )” to adjust the stimulation force that suits you. There are 12 levels can be selected.
5. Mode button  : It can be freely switched through the “Mode button  ”. Short-press to switch to the next mode in the following order: Stimulation-Expression-Massage-Automatic (order of cycle). If you are using this product for the first time, the device will enter the single-side stimulation mode-Level 3 by default.

Note: The breast pump features a memory function which allow it to remember and start with the previously set suction level and mode the next time you use it.



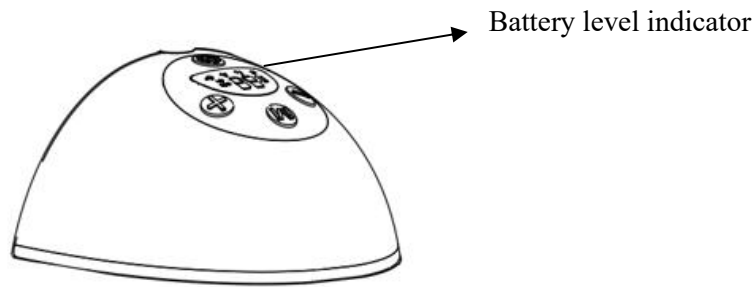
6. Level / Time indicator  : Display the number of levels during adjustment mode or level. Level Display: The indicator shows the current suction level, with the "lev" indicator illuminated during level adjustment or operation. Operation Duration Display: The numeric indicator steadily displays the accumulated operation time, with the "min" indicator illuminated. The device automatically switches from suction level display to operation duration display 3 seconds after the pump motor starts running. For the first minute of operation, the time is displayed in seconds; after 1 minute of continuous operation, the display switches to minutes.
7. Stimulation mode: Under the stimulation mode, the indicator will be on.
8. Expression mode: Under the expression mode, the indicator will be on.
9. Massage mode: Under the massage mode, the indicator will be on.
10. Automatic mode: Under the automatic mode, the indicator will be on.
11. Battery level indicator: It indicates battery level.
For K8: When the battery indicator is green, it indicates fully charged. If the battery indicator is red, it indicates a low battery. If the red-light flashes 3 times, the motor will shut down immediately.
12. After the expression is completed, long-press the ON/OFF button  for 2 seconds to turn off the device.

Note:

- [1]. The breast pump features a memory function which allow it to remember and start with the previously set suction level and mode the next time you use it.

8. Power description

1. The device contains 1200mAh lithium battery, which can store electricity and collect milk. One full charge takes about 2.5 hours.
2. The maximum continuous operating time of battery: 300 cycles of charging and discharging, the maximum operation of 150 minutes per cycle, that is, the total effective operating time of the built-in battery is $300 \times 150/60 = 750$ hours.



3. During discharging, If the battery indicator is  & flash , it indicates a low battery. During

charging, When the battery indicator is  , it indicates fully charged.

4. Battery indicator information in terms of time:

-  indicates capacity is $60\% < vbat \leq 100\%$, corresponding to 3 to 2 bars, Wearable Breast Pump will be functional for 64 minutes;
-  indicates capacity is $30\% < vbat \leq 60\%$, corresponding to 2 to 1 bars, Wearable Breast Pump will be functional for 48 minutes;
-  indicates capacity is $10\% < vbat \leq 30\%$, corresponding to 1 bar to flash, Wearable Breast Pump will be functional for 32 minutes;
-  & flash indicates capacity is $vbat \leq 10\%$, Wearable Breast Pump will be functional for 16 minutes;

8.1 Power supply description

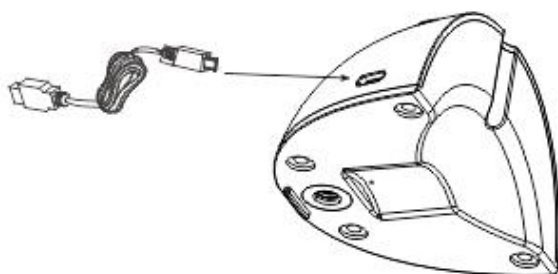
1. Please use the plug with the specification recommended by the original supplier and the original charging cable for power supply.
2. After charging for about 2.5 hours, it can be fully charged and unplugged. It will then be

powered by the included lithium battery.

3. The original charging cable can be used to connect the computer or mobile power supply for power supply.
4. The breast pump contains lithium battery. In order to maintain good power storage function please avoid long-term over-charging.
5. Lithium battery is a natural consumable. With the increase of charging and use times, it is normal that the power storage function decreases gradually.
6. If the power adapter casing or wiring becomes loose, separated, or frayed, stop use of the power adapter immediately and contact the device manufacturer. Stop using the device immediately if you note any smoke or burning from the pump unit or power adapter.
7. The product cannot be used while charging.
8. The product does not include an adapter, please purchase the power adapter by yourself before charging. Make sure to buy the power adapter which match the Type-C interface, and please make sure the input power of power adapter is AC 100~240V 50/60 Hz and output power is DC 5V 1.0A. 2MOPP between mains supply input and output sides according to IEC 60601-1 or IEC 62368-1 or IEC 60950. Protection against electric shock: Class II.
9. The USB port only for charging, it is incapable of transferring data.

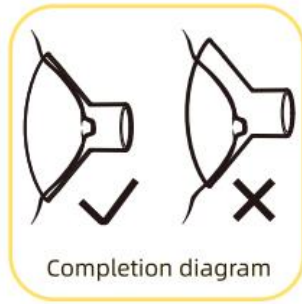
8.2 How to charge

Insert the port of the charging cable into the power adapter, and the other end of charging cable into the charging port of the main unit.



9. Usage tips

1. The size of the breast shield will not affect the amount of milk sucked, but will affect the comfort of use.
2. The breast shield should be aligned with the center of the breast (as shown in the left figure). Please avoid to make the nipple touch around the breast shield, otherwise you might feel stimulating friction pain.



3. If you feel any pain or discomfort please turn off the power and reject the obstacles, and then start again with the first level of suction. If you still feel pain and discomfort, please stop using it immediately and consult your doctor before using it.
4. When the doctor determines that the size of the breast shield is inappropriate, other sizes can be purchased separately.

10. How to pour out the breast milk

1. After milk collection, please pull out the pump first and face the Flange upward to avoid breast milk overflow.
2. Please prepare the milk storage bottle and pour out the breast milk according to the correct milk pouring method shown below.



11. How to store breast milk

11.1 Storing breast milk after expressing:

- Use breast milk storage bags or clean, food-grade containers to store expressed breast milk. Make sure the containers are made of glass or plastic and have tight fitting lids.
 - ✧ Avoid bottles with the recycle symbol number 7, which indicates that the container may be made of a BPA-containing plastic.
- Never store breast milk in disposable bottle liners or plastic bags that are not intended for storing breast milk.
- Gently swirl the container to mix the cream part of the breastmilk that may rise to the top back into the rest of the milk. Do not shake the milk. This can make some of the milk's valuable parts break down.
- Refrigerate or chill milk right after it is pumped, if possible. You can put it in the refrigerator, place it in a cooler or insulated cooler pack, or freeze it in small (2- to 4-ounce) batches for later feedings. Pumped milk, at room temperature (< 77°F) is safe to use without being refrigerated for up to 4 hours after pumping.

- Freshly expressed or pumped milk can be stored:
 - ✧ At room temperature (77°F or colder) for up to 4 hours.
 - ✧ In the refrigerator for up to 4 days.
 - ✧ In the freezer for about 6 months is best; up to 12 months is acceptable. Although freezing keeps food safe almost indefinitely, recommended storage times are important to follow for best quality.
 - ✧ The Storage Location and Temperatures from CDC guideline as followed table.

Type of Breast Milk	Countertop 77°F (25°C) or colder (room temperature)	Refrigerator 40°F (4°C)	Freezer 0°F (-18°C) or colder
Freshly Expressed or Pumped	Up to 4 Hours	Up to 4 Days	Within 6 months is best Up to 12 months is acceptable
Thawed, Previously Frozen	1–2 Hours	Up to 1 Day (24 hours)	NEVER refreeze human milk after it has been thawed
Leftover from a Feeding (baby did not finish the bottle)	Use within 2 hours after the baby is finished feeding		

11.2 Storage tips:

- Clearly label the breast milk with the date it was expressed.
- Do not store breast milk in the door of the refrigerator or freezer. This will help protect the breast milk from temperature changes from the door opening and closing.
- If you don't think you will use freshly expressed breast milk within 4 days, freeze it right away. This will help to protect the quality of the breast milk.
- When freezing breast milk:
 - ✧ Store small amounts to avoid wasting milk that might not be finished. Store in 2 to 4 ounces or the amount offered at one feeding.
 - ✧ Leave about one inch of space at the top of the container because breast milk expands as it freezes.
- If you deliver breast milk to a child care provider, clearly label the container with the child's name. Talk to your child care provider about any other requirements for labeling and storing breast milk.
- Breast milk can be stored in an insulated cooler with frozen ice packs for up to 24 hours when you are traveling. At your destination, use the milk right away, store it in the refrigerator, or freeze it.

11.3 Safe Thawing of Breast Milk

- Always thaw the oldest breast milk first. Remember first in, first out. Over time, the quality of breast milk can decrease.
- There are several ways to thaw your breast milk:
 - ✧ In the refrigerator overnight.
 - ✧ Set in a container of warm or lukewarm water.
 - ✧ Under lukewarm running water.
- Never thaw or heat breast milk in a microwave. Microwaving can destroy nutrients in breast milk and create hot spots, which can burn a baby's mouth.
- If you thaw breast milk in the refrigerator, use it within 24 hours. Start counting the 24 hours when the breast milk is completely thawed, not from the time when you took it out of the freezer.
- Once breast milk is brought to room temperature or warmed, use it within 2 hours.
- Never refreeze breast milk after it has thawed.

12. Warning

1. If you are a mother who is infected with Hepatitis B, Hepatitis C or Human Immunodeficiency Virus (HIV), pumping breast milk will not reduce or remove the risk of transmitting the virus to your baby through your breast milk.
2. This breast pump should not be operated while traveling on an airplane.
3. This product is a precision electronic appliance. Do not use electrical devices while bathing, showering, driving, or swimming. Do not reach for electrical products that have fallen into water, please unplug the power adapter from the wall outlet immediately. Please keep it in a cool dry and ventilated place, avoid direct sunlight, and keep the device away from hot surface.
4. Check the power adapter before charging, never use the damaged power adapter. Unplug the power adapter after charging.
5. Never leave the device unattended when charging.
6. This product is for personal use only. Do not use it between more than one person to avoid cross infection. Either of these actions will void the warranty.
7. Pregnant women should not use the breast pump, as pumping can induce contractions or premature labor.
8. Do not forcibly remove breast shield from breast. Please power off and gently release the seal between the breast and the breast shield, and then remove breast shield from the breast.
9. When disassembling or assembling the pump, make sure to assemble each part according to the installation Guide. When disassembling and cleaning, please be careful not to misplace/lose the small parts.
10. Please clean with water and disinfect before use.
11. Please disassemble the product parts and disinfect them. and let them cool for about 5 minutes before assembling them for use.

12. Please keep the device out of reach of infants, children or pets, inhalation or swallowing to small parts is dangerous or even fatal.
13. This breast pump is not intended for use by persons (including children) with impaired physical, sensory, or mental capabilities, or those lacking experience and knowledge. Such persons can only use this breast pump under the supervision of adult or after having received proper instruction concerning the use of the appliance by the person responsible for their safety.
14. Powered breast pumps that are designed for single users should never be rented or shared.
15. The device is not to be used when lying down, experiencing drowsiness, or sleeping to ensure proper orientation is maintained during use.
16. If the temperature difference in the usage environment reaches 20°C or above (from low temperature environment to high temperature environment, or vice versa), please turn off the instrument and let it stand for about 2 hours before using it again.
17. Do not repair or modify the product without due permission. Doing so invalidates any warranty. For repairs, send the product to the manufacturer or a designated franchise distributor.
18. Do not use a damaged product. And use the product only for its intended use as described in this manual.
19. The intended user is lactating women, and the operator of the breast pump is the intended user.
20. The power adapter specified by manufacturer can be used for charging your breast pump.
21. Upon request, manufacturer will make available circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of the equipment that are designated by the manufacturer as repairable by service personnel.
22. Children should be monitored to ensure they do not play with equipment to avoid the risk of fire.
23. Breast Shield is applied part.
24. Only use attachments or milk collection components recommended by the manufacturer.
25. It is expected that the equipment can be used for half a day from the minimum storage temperature of -20 °C to the usage environment of 20 °C.
26. It is expected that the equipment can be used in 2 hours from the maximum storage temperature of 50 °C to the usage environment of 20 °C.
27. Under normal use, if any abnormalities occur with this product, the power adapter plug can achieve the function of disconnecting the network power supply.
28. The temperature of the portion of the device applied to the skin can reach temperatures as high as 43.9 °C. Excessively high temperatures may cause skin burns. Therefore, please ensure that the skin of your breast is intact and healthy before use. If you feel the device is overheating, please turn off the device. In order to avoid low-temperature burns, the maximum period of continuous use shall not exceed 30 min per instance, with at least 5 min intervals between uses to allow the device to cool down.
29. For product service life (i.e. working life) The device has no shelf life but a product service life of one year. Please check to ensure the product operates normally prior to use. Use beyond the indicated service life may lead to degradation of product performance. For example, the

product may not be able to correctly control the vacuum, resulting in excessive vacuum pressure which may cause injuries.

30. Do not operate where aerosol spray products are being used or where oxygen is being administered.
31. Avoid strangulation resulting from charging cables.
32. Do not use the device around explosive or flammable material, in an MRI environment, in a hyperbaric chamber, or near a fireplace or radiant heater.
33. Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic/electronic devices. Such use may cause electrical interference, which could result in serious injury or death.
34. If irritation or discomfort occurs, discontinue use and see a doctor.

13. Contraindications

Do not use this product if you have any of the following conditions:

- 1) Acute mastitis, breast abscess, or other breast diseases.
- 2) Cracked, damaged, or swollen nipples or areola.
- 3) Unhealed surgical wounds or skin injuries in the breast area.
- 4) Known allergy to any materials used in this product.

14. Precautions

1. If you feel excessive warmth from the device while pumping, stop pumping immediately and remove pump.
2. If discomfort is felt, then suction can be broken by inserting a finger between the breast and the flange.
3. If irritation or discomfort occurs, discontinue use and see a healthcare provider.
4. Before each use visually inspect the individual components for cracks, chips, tears, discoloration or deterioration. In the event that damage to the device is observed, please discontinue use until the parts have been replaced.

15. Troubleshooting

Below summarizes the most common problems you could encounter with the device. If you are unable to solve the problem with the information below, please contact LVB:

Problem	Solution
The pump unit can't be turned on	• Make sure the power adapter is well connected to the wall socket and the pump unit. • Make sure there is power left in the Li-ion battery.
No/ Weak suction	• Check all the connection parts are assembled correctly

	and well • Make sure the breast shield forms a complete seal around the breast. • Made sure all the plastic parts are not distorted
Slow suction	Milk pumping speed is different from person to person and affected by the structure of the breast, breast patency and mood pleasure. Before pumping milk, use a hot towel to compress the breast, and then select the stimulation mode to massage for 2 minutes or massage the breast by hand, to dredge the breast.
Breast milk remains after pumping	Human mammary gland structure is reticular distribution, any kind of breast pumping way can not be completely clean.
Inability to pump or breast pain	• When the suction pain is felt, straighten the breast shield to ensure that the nipple is aligned with the hole, in addition, decrease the vacuum level. • It could be an impassable mammary gland. Mammary obstruction can cause mastitis, should go to the hospital in time.
The treatment method of inability to pump or breast pain: A. Breast massage: Place both hands on the upper and lower parts of the breast and massage in a circular direction. Hold the breast in one hand, while the thumb and index finger of the other hand press and knead the nipple in a spiral shape. Place your hands at the sides of the breast and squeeze from the breast toward the nipple. B. Slowly adjust the vacuum level, the level that can suck milk without pain felt is the most appropriate. C. Keep in a good mood and enough sleep.	

16. Disposal



■ This product bears the selective sorting symbol for Waste electrical and electronic equipment (WEEE). This means that this product must be handled pursuant to European directive 2012/19/EU in order to be recycled or dismantled to minimize its impact on the environment. User has the choice to give his product to a competent recycling organization or to the retailer when he buys a new electrical or electronic equipment.

17. EMC Statements

- Wearable Breast Pump conforms to the relevant requirements in IEC 60601-1-2.
- Wearable Breast Pump needs special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in the accompanying document.
- Guidance and manufacturer's statement can be seen in the appendix.
- The device may be affected by temperature, humidity, atmospheric pressure, and electromagnetic compatibility. The user must strictly follow the instructions to operate the device.



Warning:

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: Do not use the device when in an environment with security systems like Radio-Frequency Identification (RFID) systems, electromagnetic anti-theft systems (EAS) or metal detectors.

Warning: Do not use this device in the same room as an MRI scanner, electrosurgical unit, or diathermy device while it is in operation.

Manufacturer's essential performance requirements:

The performance of the device is suction function.

Vacuum range:

Stimulation mode: ≤ 225 mmHg

Expression mode: ≤ 305 mmHg

Massage mode: ≤ 305 mmHg

Automatic mode: ≤ 305 mmHg

Cycle speed:

Stimulation mode: ≤ 189 cycles/min

Expression mode: ≤ 79 cycles/min

Massage mode: ≤ 46 cycles/min

Automatic mode: ≤ 8 cycles/min

Guidance and Manufacturer's Declaration – Electromagnetic Emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Guidance and Manufacturer's Declaration – Electromagnetic Immunity							
Immunity Test	IEC 60601-1-2 Test level			Compliance level			
Electrostatic discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air			± 2 kV, ± 4 kV, ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air			
Electrical fast transient/burst IEC 61000-4-4	0.5kV, 1kV, 2kV, 4kV for power supply lines 0.25kV, 0.5kV, 1kV, 2kV for input/output lines			0.5kV, 1kV, 2kV, 4kV for power supply lines 0.25kV, 0.5kV, 1kV, 2kV for input/output lines			
Surge IEC 61000-4-5	0.5kV, 1kV, 2kV, 4kV for open-circuit			0.5kV, 1kV, 2kV, 4kV for open-circuit			
Voltage dips, short interruptions and voltage	Test level %	Voltage dip	Duration	Test level %	Voltage dip	Duration	

variations on power supply input lines IEC 61000-4-11	U _T	and short interruptions % U _T		U _T	and short interruptions % U _T	
	0	100	0.5p	0	100	0.5p
	40	60	5p	40	60	5p
	70	30	25p	70	30	25p
	0	100	250p	0	100	250p
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz			30 A/m 50Hz/60Hz		
Conducted RF IEC61000-4-6	150 kHz to 80 MHz			150 kHz to 80 MHz		
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz			10 V/m 80 MHz – 2,7 GHz		
NOTE U _T is the a.c. mains voltage prior to application of the test level.						

MANUFACTURER 'S declaration – electromagnetic IMMUNITY –for ME EQUIPMENT and ME SYSTEMS that are not LIFE - SUPPORTING			
The Wearable Breast Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Wearable Breast Pump should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61 000-4-6	3 Vrms 1 50 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Wearable Breast Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$
Radiated RF	3 V/m	10 V/m	$d = 0.35\sqrt{P}$ (80 MHz to 800

IEC 61 000-4-3	80 MHz to 2,5 GH		MHz) $d = 0.70\sqrt{P}$ (800 MHz to 2,5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Wearable Breast Pump is used exceeds the applicable RF compliance level above, the Wearable Breast Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Wearable Breast Pump. b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Wearable Breast Pump
The Wearable Breast Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wearable Breast Pump can help prevent electromagnetic interference by maintaining a minimum distance

between portable and mobile RF communications equipment (transmitters) and the Wearable Breast Pump as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2,5 GHz $d = 0.70\sqrt{P}$
0.01	0.117	0.035	0.07
0.1	0.38	0.11	0.22
1	1.17	0.35	0.7
10	3.7	1.11	2.21
100	11.7	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

18. Cybersecurity and Interoperability Instructions

1) Network Ports and Interfaces List

A list of network ports and other interfaces expected to receive and/or send data.

No.	Interface purpose/name	Port Number	Communication Protocol	Function Description	Status
1	Bluetooth	/	Bluetooth 5.0 +	The breast pump connects to the mobile app via Bluetooth, allowing you to pair and control the device.	Enabled by default

2) Critical Function Protection and Configuration Management

To protect critical functions, the relevant device debugging interfaces on the breast pump have been disabled at the factory.

Please store the device securely after use to prevent unauthorized access or pairing.

19. FCC Declaration

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.

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.

NOTE: “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

CAUTION: To comply with the limits of the Class B digital device, pursuant to Part 15 of the FCC Rules, this device is to comply with Class B limits. All peripherals must be shielded and grounded. Operation with non-certified peripherals or non-shielded cables may result in interference to radio or reception.

19.1 FCC RF Radiation Exposure Statement

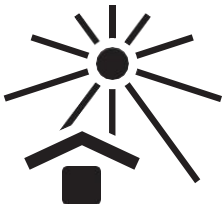
1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

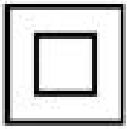
19.2 FCC Caution

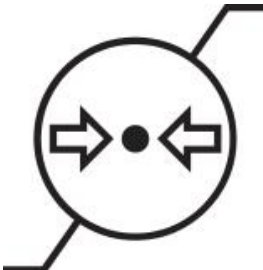
Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

20. Symbols Used and Explanation

Symbol	Standard	Ref #	Title	Description
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC, and EU Regulation 2017/745.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.3	Date of manufactu re	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	ISO 15223-1	5.3.4	Keep dry	Indicates a

	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied			medical device that needs to be protected from moisture.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7000/IEC 60417 Graphical symbols for use on equipment	5333	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	ISO 7010 Graphical symbols – Safety colours and safety signs – Registered safety signs	M002	Refer to User manual/ booklet	To signify that the User manual/ booklet must be read.
	BS EN 50419 Marking of electrical and	Fig. 1	Recycle: Electronic Equipment	Separate collection for electrical and electronic equipment.

	electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) WEEE Directive 2012/19/EU			
IP22	IEC 60529 Degrees of protection provided by enclosures (IP Code)	N/A	Ingress protection rating NOTE: The higher the number, the greater the protection. When a number is not required to be specified, it is replaced by the letter X.	The first digit indicates the level of protection that the enclosure provides against the ingress of solid foreign objects. The second digit indicates the level of protection of the equipment inside the enclosure against the ingress of liquids.
	ISO 7000/IEC 60417 Graphical symbols for use on equipment	5172	Class II ME equipment	CLASS II term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE

				INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.9	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed