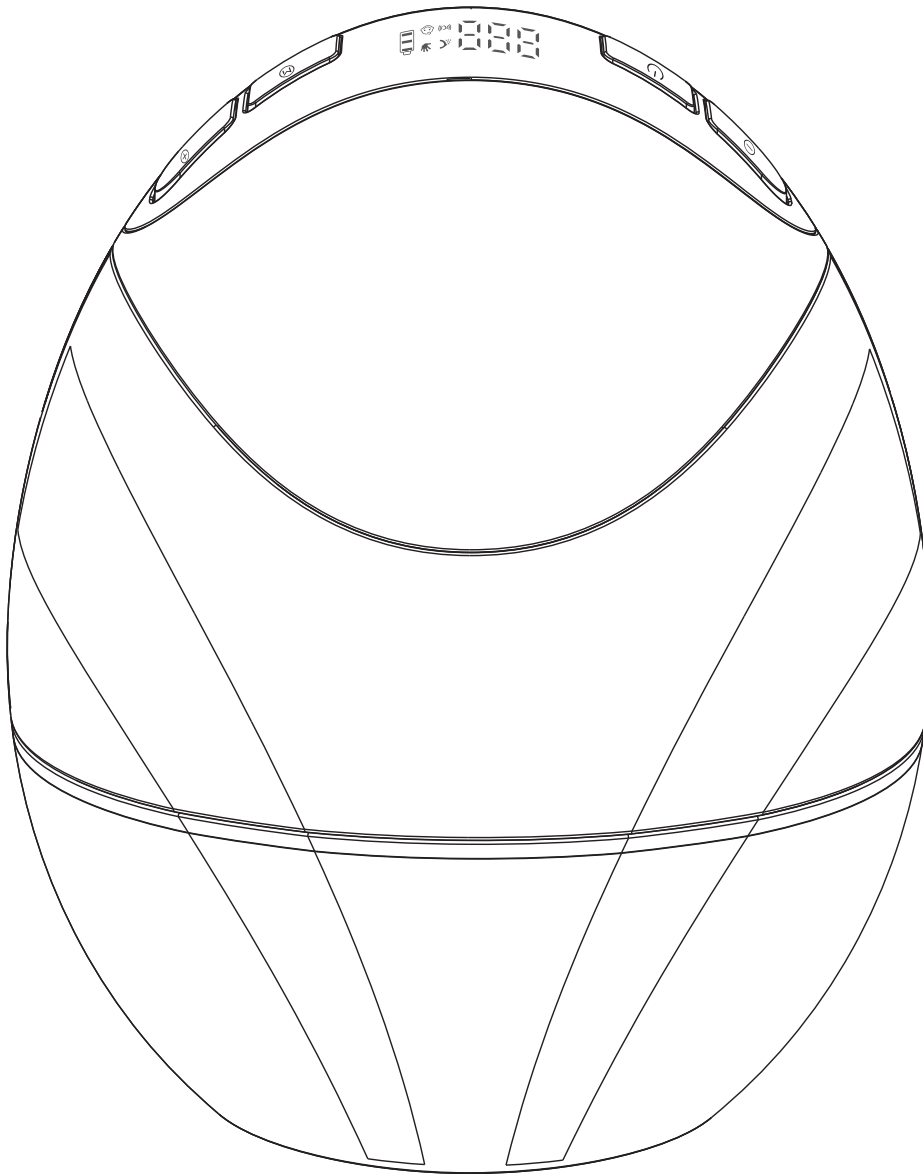


Breast Pump

User Manual



Model number: YM-806

Read this user manual carefully before using this device
and keep this manual for future reference.

1. Product Introduction

Congratulations on your new journey as a mother!

If this is your first time using a breast pump, please allow yourself a gentle learning period to become familiar with its operation. This device is designed for your personal use only to ensure comfort and hygiene.

2. Warning Instruction and Precautions

The warning signs and graphic symbols in the manual are intended to enable you to use the product safely and correctly and to prevent harm to you and others. Warning marks and graphic symbols are described as follows:

Warning/precaution symbols	
 Warning	A warning alerts the reader about a situation that, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
 Precautions	Indicating a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.
Contraindications	Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. There may be persons for whom the device should not be used because of their health status.
Notes	Indicates the need for attention, if not attention may lead to incorrect use of the product or property device damage.

Symbol Description

	Keep Dry		Pile Limit 5 layers
	Applied part of type BF		Refer to instruction manual.
	Batch code		Manufacture date
	Manufacturer information: The manufacturer name and address		Serial Number
	Distribution packages shall not be exposed to sunlight		For food contact
IP22	The first number 2: Protected against solid foreign objects of 12.5mm diameter and greater. The second number 2: Protected against vertically falling water drops when enclosure tilted up to 15°.		
	Disposal in accordance with Directive 2012/19/EU (WEEE)		
	This device has not been tested for use in an MR environment and should not be used exposed to MR environments while patients are wearing the device. Keep it outside the MRI scanner room.		
	FCC		

3.Indications for Use/Intended Use

[Indications for Use / Intended use]

The Wearable Breast Pump (model: YM-806) is intended to express milk from lactating women in order to collect milk from their breasts. The device is intended for a single user

[Intended users]

Can read and understand the user manual

The PATIENT is an intended OPERATOR

[Patient Population]

Lactating women

[Intended use environment]

Home Healthcare Environment

4. Contraindications

Do not use this Pump if you have an active implanted device that would be affected by a magnetic field (e.g., pacemaker, implantable cardioverter-defibrillator)

5. Safety Information

When using electrical products, especially if children are present, the following basic safety information should always be maintained.

5.1 Warning

- 1) Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical interference, or death.
- 2) This breast pump is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge. Such persons can only use this breast pump if they are supervised by or have received proper instruction concerning use of the appliance by a person responsible for their safety.
- 3) Danger: To reduce the risk of electrocution.
 - Always unplug electrical devices immediately after charging.
 - Do not use while bathing, showering, driving or swimming.
 - Do not reach for electrical product that has fallen into water, please unplug the power adapter from wall outlet immediately.
- 4) Wearable Breast Pump is a personal care item and for hygienic reasons should never be shared between mothers or resold from one mother to another. Either of these actions will void the warranty.
- 5) If you are a mother who is infected with Hepatitis B, Hepatitis C or Human Immunodeficiency Virus (HIV), pumping breast milk using the Wearable Breast Pump will not reduce or remove the risk of transmitting the virus to your baby through your breast milk.

- 6) Close supervision is necessary when product is used near children or invalids. Do not allow children or pets to play with the motor unit, packaging materials or accessories.
- 7) Use product only for intended use as described in this manual.
- 8) Do not use attachments or other milk collection components other than those recommended by manufacturer.
- 9) Check the power adapter before charging, never use the damaged power adapter.
- 10) Never leave the product unattended while charging.
- 11) Keep the product and all attachments away from heated surfaces.
- 12) Never use it while sleeping or drowsy.
- 13) Do not operate where aerosol spray products are being used or oxygen is being administered.
- 14) 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.
- 15) Avoid strangulation resulting from Charging cable.
- 16) Users are not allowed to repair the product. If you do so, your warranty becomes invalid. For repairs, sent to the manufacturer or a designated franchise distributor.
- 17) Always switch off the breast pump before you remove the pump body from your breast, in order to release the vacuum.
- 18) Powered breast pumps that are designed for single users should never be rented or shared.
- 19) Never use the breast pump while you are pregnant, as pumping can induce labor.
- 20) The high level temperature of applied part can reach max 43°C, excessive temperature may cause skin burns, please make sure that your skin of breast must be intact and healthy before use. If you feel overheated, please turn off the device. In order to avoid Low temperature burn, the maximum continuous use shall not exceed 30min each time, the interval between two uses shall be at least 5min to allow the device to cool down.
- 21) For product service life (i.e. working life)
The device has no life life, the service life of the product is 500 hours. The expected operating life of the washable parts is one to three months. Please check whether the product can run normally before use. Use beyond the service life may lead to degradation of product performance. Such as, the product cannot control the vacuum correctly, excessive vacuum may cause injuries.
- 22) Keep the product away from children or pets, and avoid swallowing small parts.

Do not place or store where product can fall or be pulled into bathtub, sink or pool.

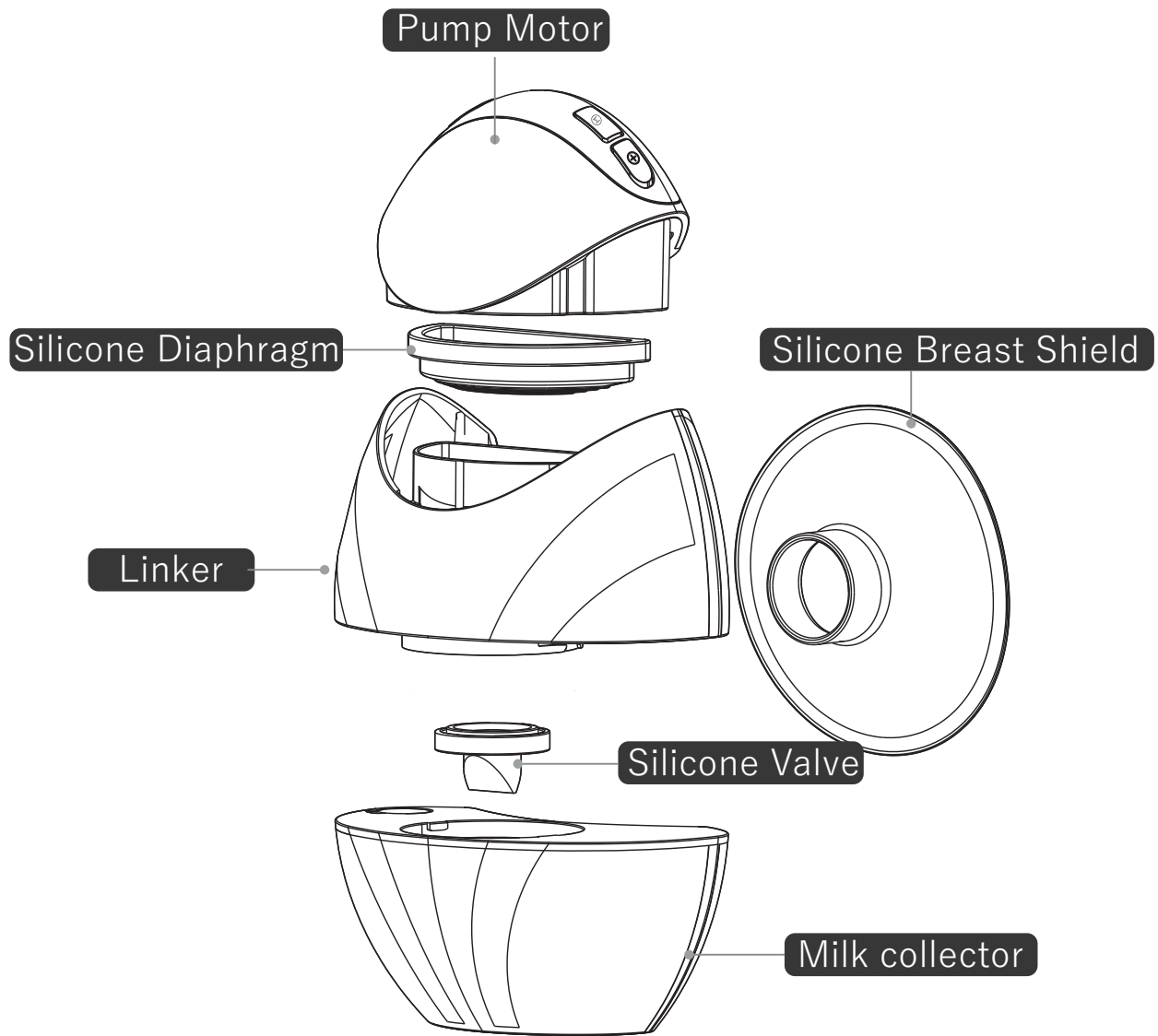
5.2 Precaution

- Do not place or store where product can fall or be pulled into bathtub, sink or pool.
- Do not place or drop product into water or other liquid.
- Do not immerse in any liquid for any reason or subject the unit to extreme shocks, such as dropping the pump.
- Do not continue pumping for more than five minutes at a time if you do not succeed in expressing any milk. Try to express at another time during the day.
- If discomfort is felt, then suction can be broken by inserting a finger between the breast and the flange.
- If irritation or discomfort occurs, discontinue use and see a health care provider.
- If the power adapter casing or wiring become s loose, separated, or frayed, stop use of the power adapter immediately and contac t the device manufacturer. Stop using the device immediately if you note any smoke or burning from the pump unit or power adapter.
Statement: If you feel excessive warmth from the Wearable breast pump while pumping, stop pumping immediately and r emove pump.

Notes:

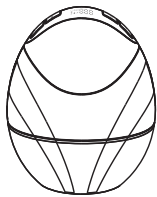
Avoid direct sunlight to the main unit.

6.Product Description



Description of breast pump unit	
Item	Description
Pump Motor	Power source of breast pump
Silicone Diaphragm	All of these components make up the milk collection set
Silicone Breast Shield	
Linker	
Silicone Valve	
Milk collector	

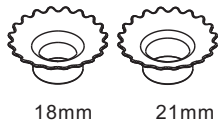
6.1 Packing List



Breast Pump x2



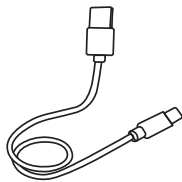
Drawstring bag x1



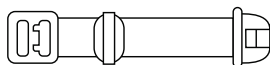
(18mm/21mm)
Flange x2



Milk collector
Cover x2



Type-c cable x2

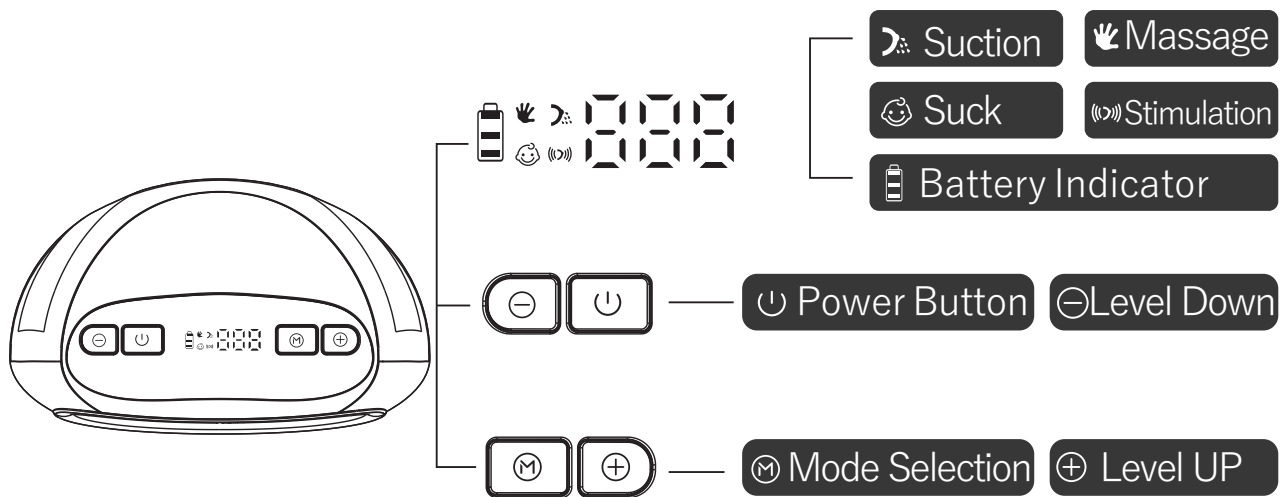


Bra adjustment
buckle x2



User Manual x1

7.Control Panel



Follow the principle of massage first, then deep pumping.

4 Modes

Massage function: 12 levels

(Massage first to stimulate milk production.)

Suction function: 12 levels

(Please choose the optimum level, the pumping mode is designed for slow suction, deep suction.)

Auto: 9 levels

(Massage and suction used simultaneously which is excellent for sunken nipples or first-time new mother, open milk adopts 3+1 mode. 3 short-frequency massages and 1 deep suction.)

Suck: 9 levels

(Simulate the sucking frequency of the baby, discharge the milk from the breast through negative pressure, and help the milk secretion.)

Turn on/off: Press and hold the power button  for 1.5 seconds.

Pause and resume: Press the power button .

Mode Change: Press the mode key .

Level change: Press the  and  to increase or decrease level.

8. Battery and Charging Indicator

Battery Level Indicator		
Low Battery: Blinking	In Charging: Lights up one by one	Fully Charged: Solid White
  000	  000	  000

Flash Red: Low battery(requires charging)

Solid White: The battery is fully charged (flashes white while charging)

Auto-off: The pump will auto-off every 20 minutes

9. Operating Instructions

9.1 Charging battery

Please charge the product before using it for the first time. The breast pump is powered using an internal rechargeable lithium battery.

Our products are packaged with a Charging cable (USB2.0/Type - C line) but not with a power adapter. Please purchase the power adapter by yourself before charging. Make sure to buy the power adapter which matches the USB 2.0 interface, and please make sure the input power of the power adapter is AC 100~240V 50/60 Hz and the output power is DC 5V 1A.

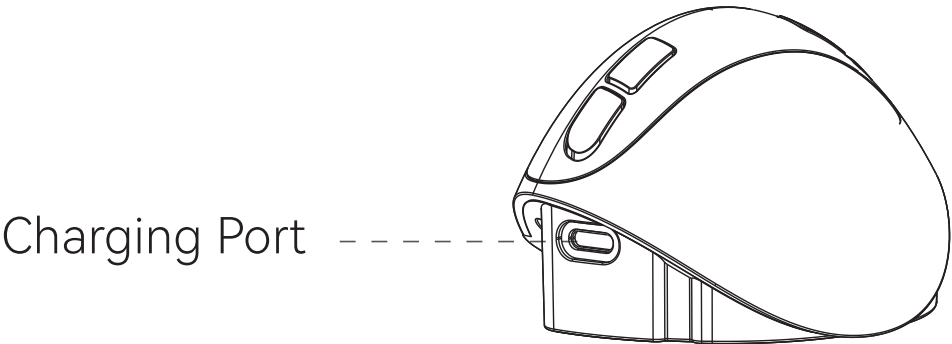
- Flash Red: Low battery (require charging)
- After being fully charged, it can be used for 5 - 6 sessions (about 180 minutes) of pumping, 30 minutes per session.

Battery
Level - - - - -
Indicator



Charge the battery as below:

- a. Insert the USB end of Charging cable into the USB interface of power adapter;
- b. Insert power adapter plug into AC socket;
- c. Insert the Type-C end of Charging cable into the charging port.



Position of Charging port

The device will take approximately 150 minutes to fully charge
Charging.

Charging display			
Charging with one bar of battery: The sequence cycles continuously from left to right: Bar 1 – Bar 2 – Bar 3	Charging with two bars of battery: Bar 1 remains constantly illuminated, while cycling continuously between Bar 2 and Bar 3	Charging with three bars of battery: Bars 1 and 2 remain constantly illuminated, while Bar 3 flashes	Fully charged: all three bars remain constantly illuminated
			

Unplug the power adapter from the socket, disconnect the Charging cable from the power adapter and main unit after charging is completed.

Warning

The breast pump cannot be used during charging!

The Charging cable is only used to connect between the power adapter and the Wearable Breast Pump unit for charging, please do not connect to other equipment, otherwise, it may cause electric shock accident!

- If the power adapter casing becomes loose, separated, or frayed, stop use of the power adapter immediately and contact the manufacturer of power adapter.
- If the Charging cable is damaged, broken or cracked, stop the use of the Charging cable immediately and contact the manufacturer to replace a new one (See the last page of this manual for contact information).
- Stop using the device immediately if you note any smoke or burning from the pump unit or power adapter.

Caution:

Using the wrong type of adapter or purchasing a poor – quality adapter may be reduced the device's safety, and may damage your property and health. Please purchase the medical adapter that meets the IEC 60601 – 1 and IEC 60601 – 1 – 2 standards in professional medical markets, and make sure the output of the power adapter is DC 5V 1A.

Notes:

- After fully charging the battery, if the working time of the battery is shorter than before and you want to replace it, don't try to replace the rechargeable battery by yourself. Please contact the manufacturer for replacement. Self – disassembly and replacement of the battery may cause damage to the main unit and battery.
- When the product is not used for a long time, the battery will discharge slowly. In order to avoid battery damage due to low voltage for a long time, please charge the device every three months.

10.How to Use the Breast Pump App

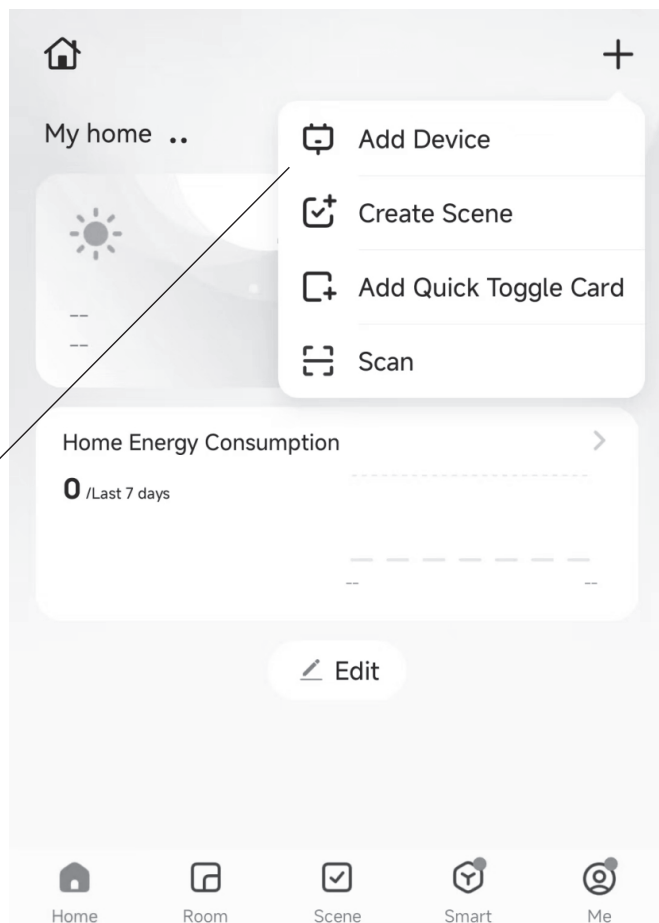
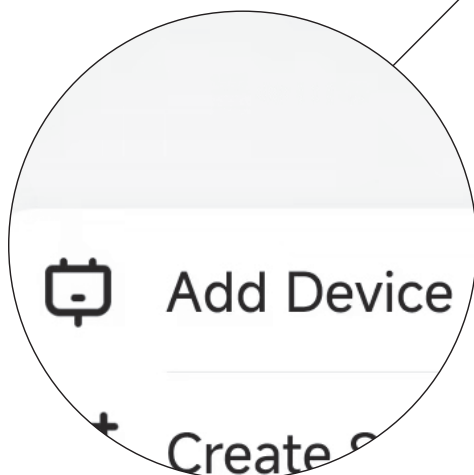
10.1 How to Download the tuyu App.



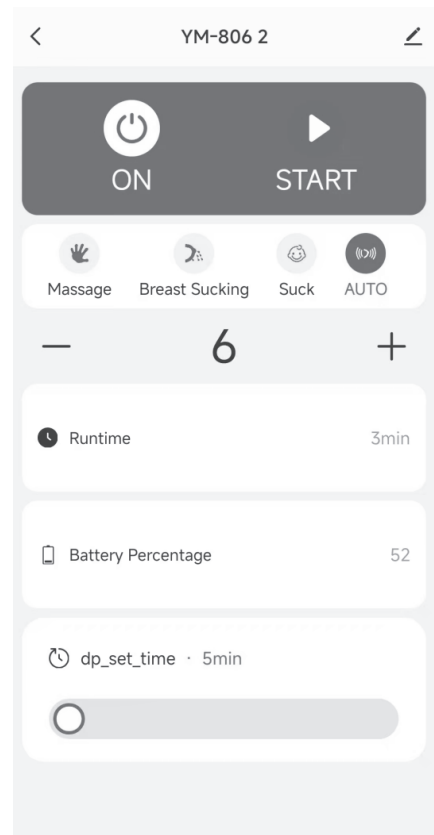
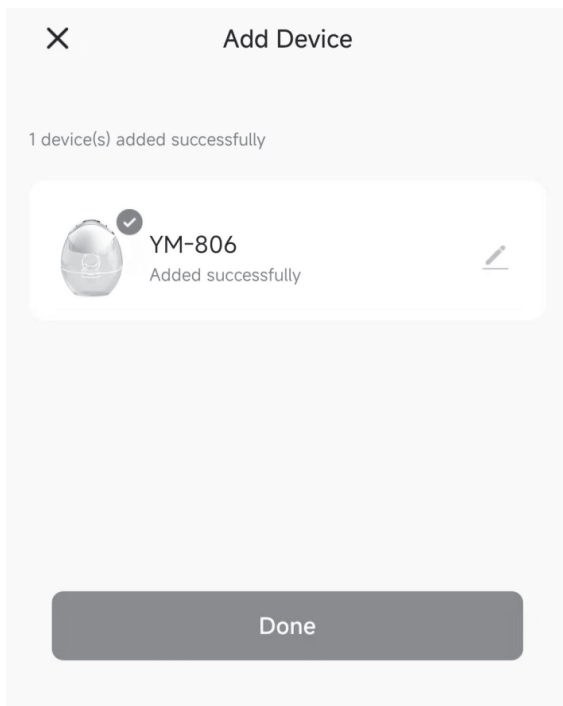
Scan the QR code with your phone to download the app

10.2 Pair the pump via Tuya APP.

- ① Install the Tuya app.
- ② Open the Tuya app.
- ③ For the first time opening Tuya, please tap 'Agree' and register an account to log in.
- ④ Enable Bluetooth on your phone.
- ⑤ Reset procedure:
Press "⏏" for 10s →
Wait for "📶" display
→ Pair with Tuya.
- ⑥ On the app homepage, tap the + icon and select 'Add device'.



⑦ "Tap 'Done' to complete pairing.



⑧ Once paired, access the APP control page.

10.3 How to Use the APP Features.

① Tap "⏻" to power ON/OFF.

② Tap "▶" to power STOP/START.

4 Modes

 **Massage function: 12 levels**

(Massage first to stimulate milk production.)

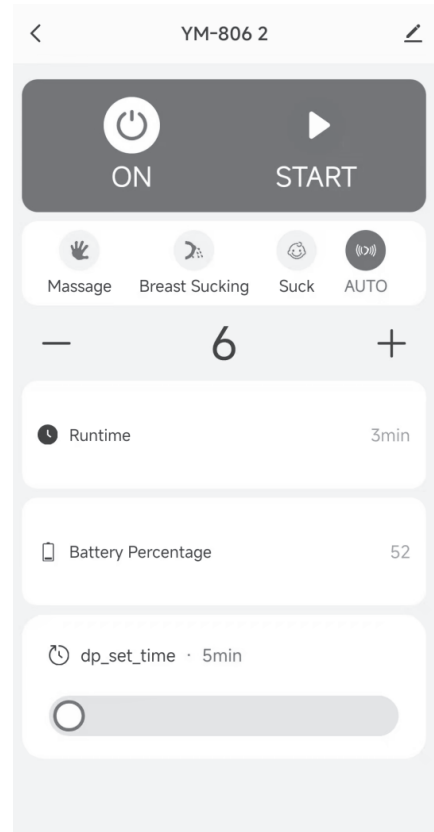
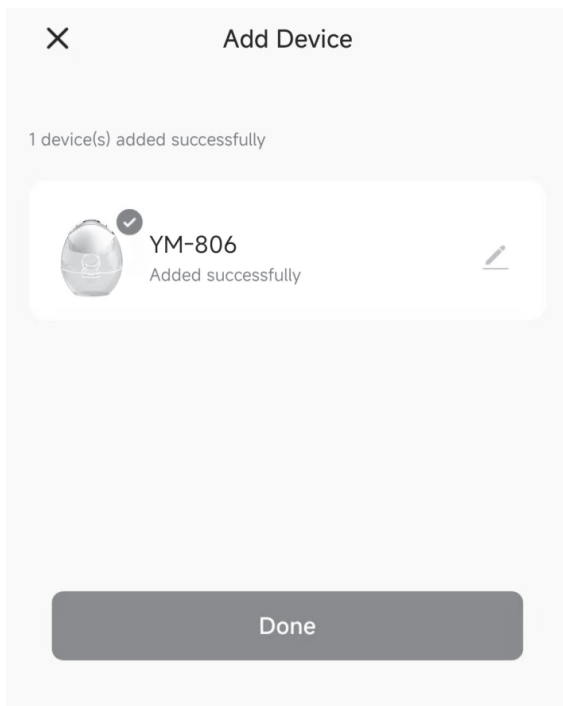
 **Suction function: 12 levels**

(Please choose the optimum level, the pumping mode is designed for slow suction, deep suction.)

 **AUTO: 9 levels**

(Massage and suction used simultaneously which is excellent for sunken nipples or first-time new mother, open milk adopts 3+1 mode. 3 short-frequency massages and 1 deep suction.)

⑦ "Tap 'Done' to complete pairing.



⑧ Once paired, access the APP control page.

10.3 How to Use the APP Features.

① Tap "⏻" to power ON/OFF.

② Tap "▶" to power STOP/START.

4 Modes

 **Massage function: 12 levels**

(Massage first to stimulate milk production.)

 **Suction function: 12 levels**

(Please choose the optimum level, the pumping mode is designed for slow suction, deep suction.)

 **AUTO: 9 levels**

(Massage and suction used simultaneously which is excellent for sunken nipples or first-time new mother, open milk adopts 3+1 mode. 3 short-frequency massages and 1 deep suction.)

Suck: 9 levels

(Simulate the sucking frequency of the baby, discharge the milk from the breast through negative pressure, and help the milk secretion.)

Level change: Press the  and  to increase or decrease level.

Runtime

Tracks pump working time.

Battery Percentage

Displays battery percentage.

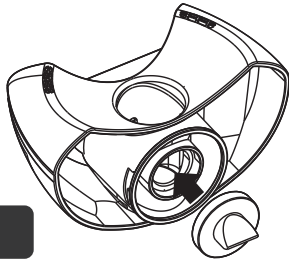
dp_set_time

Set shutdown timer by dragging the slider.

10.4 If Bluetooth device often offline. How can I troubleshoot it?

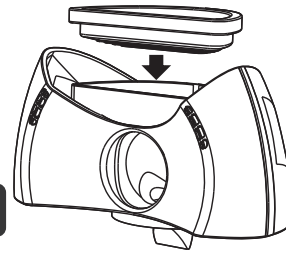
1. Power and Battery Check: Ensure the device is powered on properly or has sufficient battery level.
2. Location Permission Confirmation: Check if the location permissions for Bluetooth and the App on your phone are enabled.
3. Device Access Restrictions: Without a Bluetooth gateway, a Bluetooth device can only be controlled by one phone at a time. Check for any unauthorized access to your App account that may be manipulating the device.
4. Device Distance and Connectivity: In the absence of a Bluetooth gateway, make sure the distance between the Bluetooth device and your phone is within a reasonable range to avoid connectivity issues due to being too far apart.
5. Gateway Connection Status: If there is a Bluetooth gateway, check if the distance between the Bluetooth device and the gateway is too far or if the gateway is offline.
6. By following these steps, you can identify and resolve potential factors causing Bluetooth devices to go offline to ensure their proper functionality. If the issue persists, it is recommended to contact the device manufacturer for further assistance and guidance.

11.Assembly



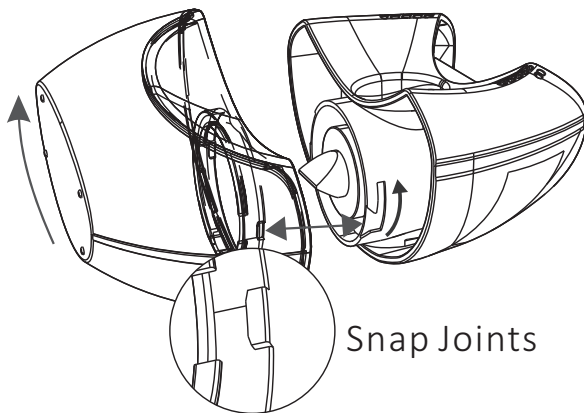
STEP 1

Install the Silicone Valve into the bottom of the linker, make sure it is installed in the correct direction.



STEP 2

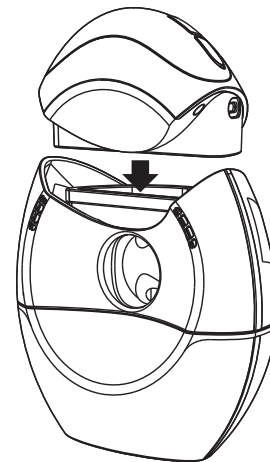
Put the silicone diaphragm into the linker and press it with your hands to make the edges fasten tightly to ensure a perfect seal.



Snap Joints

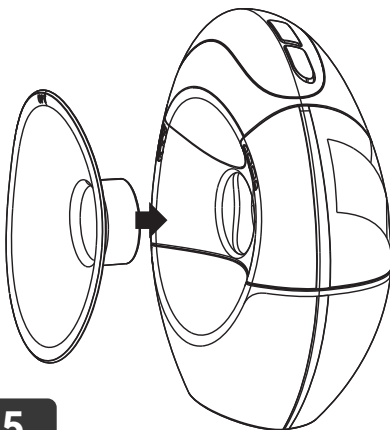
STEP 3

Align the Milk collector Snap Joints with the Linker slot and rotate it in the direction of the arrow to install it.



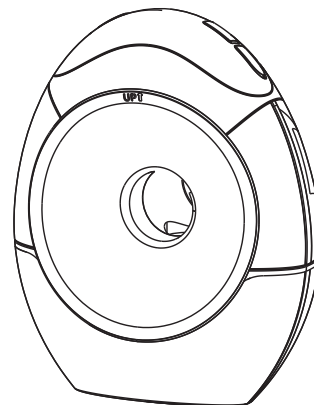
STEP 4

Install the milk collector, align silicone diaphragm, clip it first, and connect the linker with the pump motor perfectly.



STEP 5

Install the breast shield into the pump, align the up mark on the top, and ensure it connects well with the linker and perfectly seal.



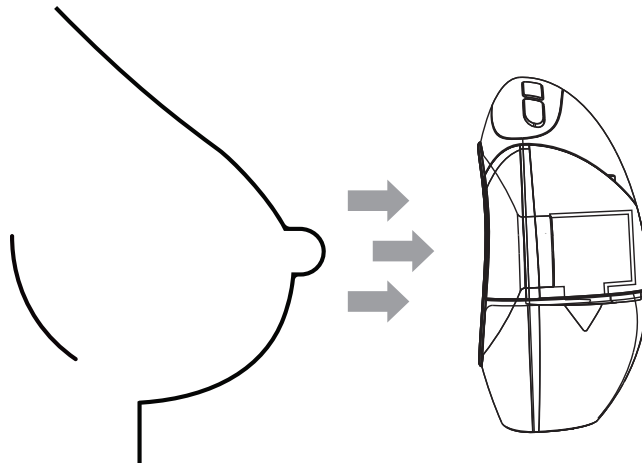
12.Direction For Use

In The Bra Placement



Press the breast shield firmly against the breast, leave no gaps and make sure your nipples are centered. keep it upright. Be careful not to distort the position of the product and the chest, otherwise the breast pump will not have suction.

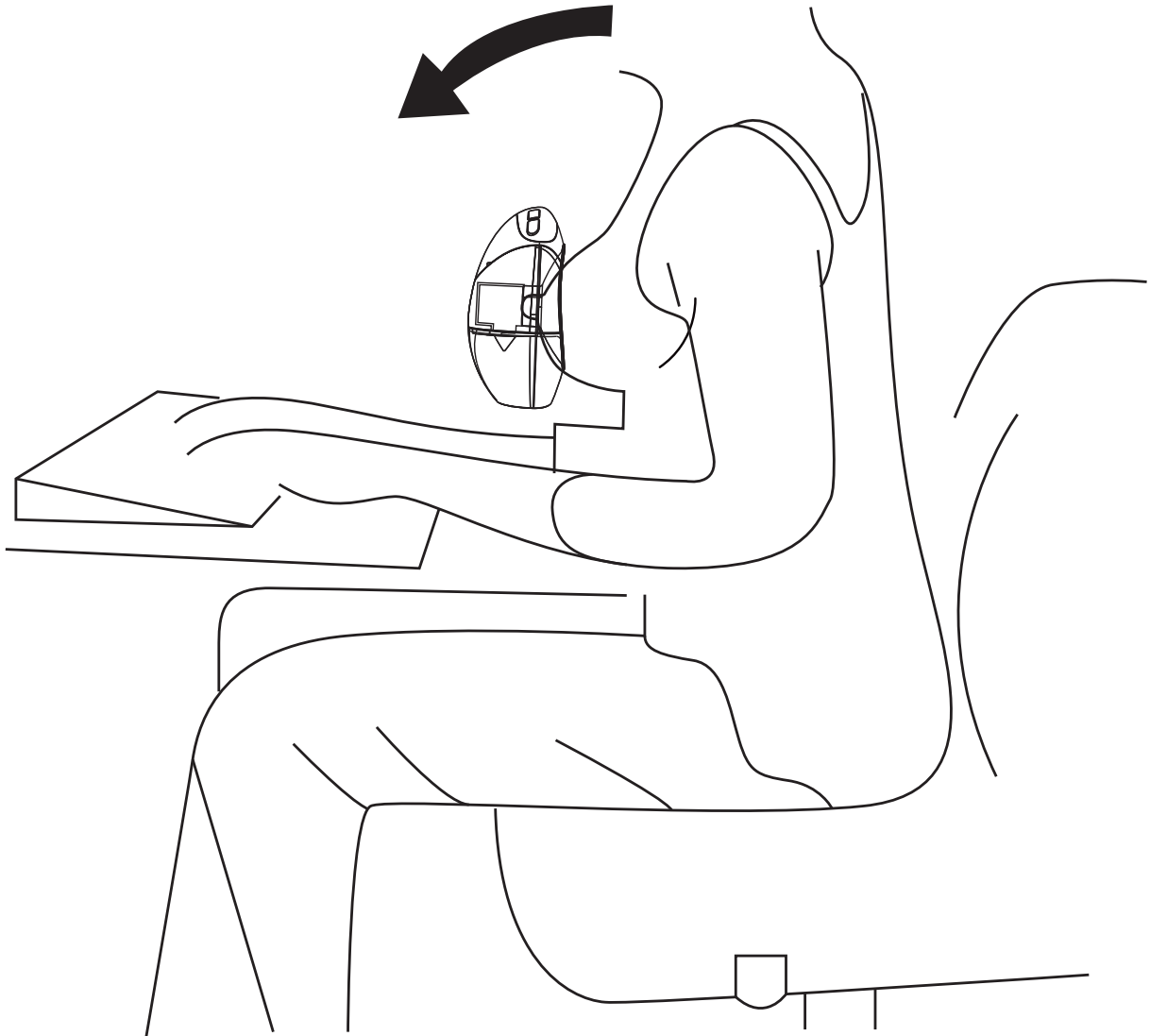
Turn off and remove the pump carefully



Note: Do not lie down while using the breast pump. If you feel any discomfort while expressing or notice blisters/ or chafing on your nipple or breast, try reducing the breast pump suction level.

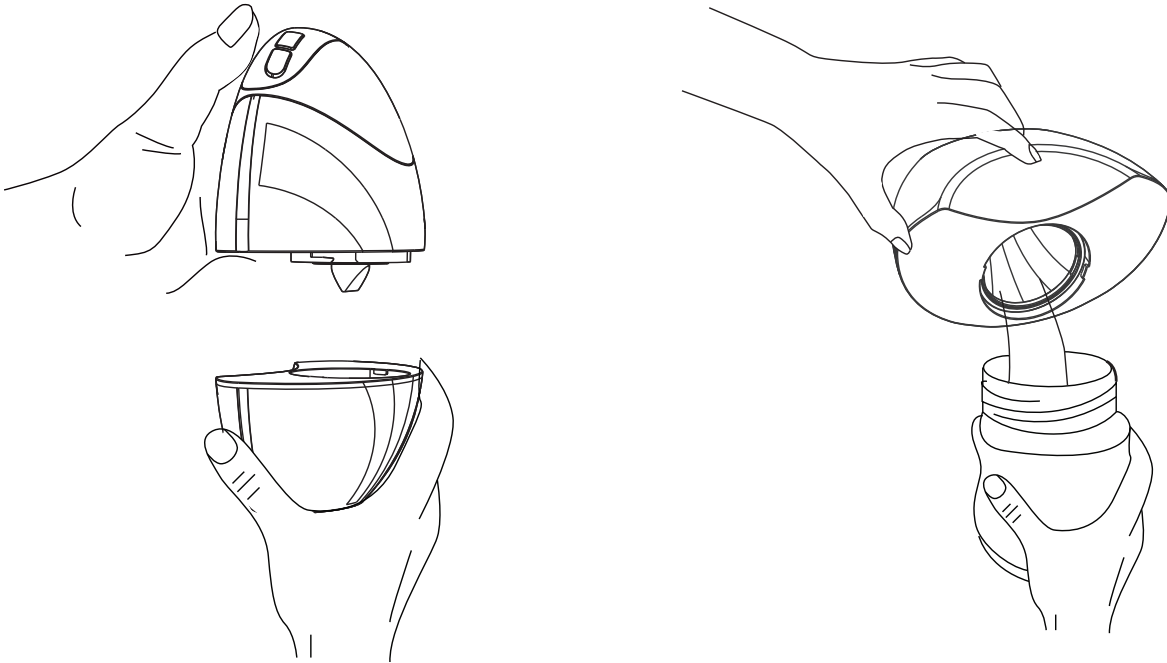
13. Sitting Posit On For Suction

Relax the body, sit in a comfortable chair and lean slightly forward (use cushion to support back). Make sure to keep the breast pump and milk collector upright.



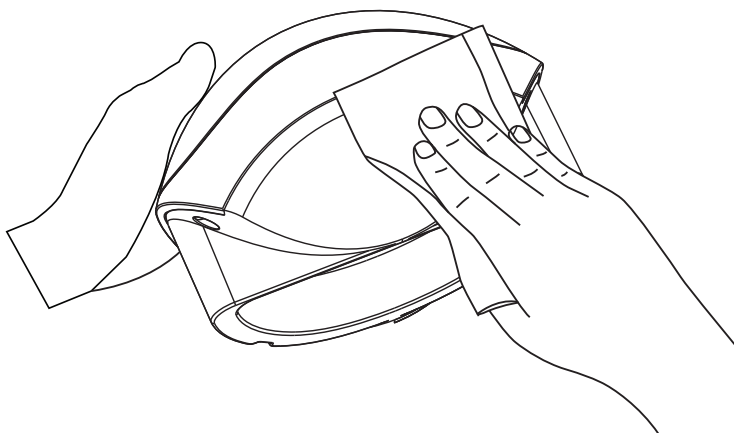
14. Pour Milk

Remove the breast pump from the body carefully, keep the breast pump thwartwise and the gap upright before opening the gap, then pour the milk into the bottle, ensuring the gap of the milk collector against the bottle mouth.

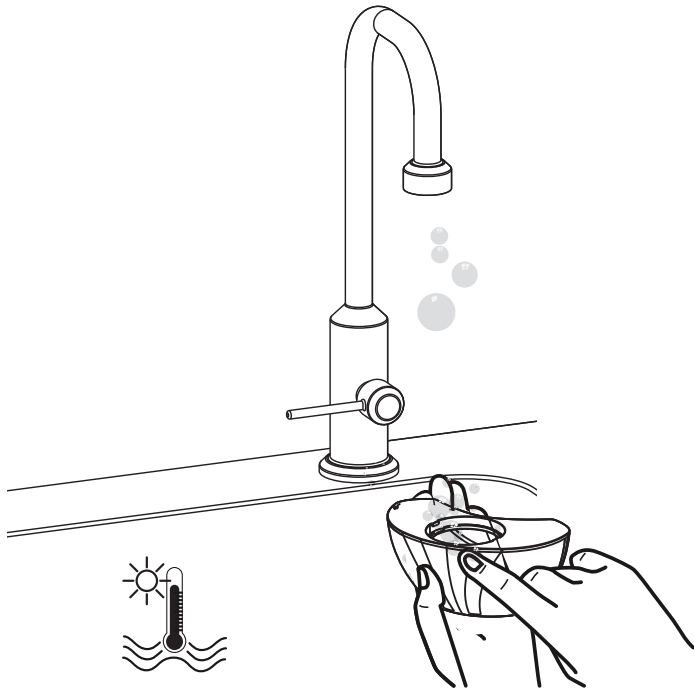


15. Wipe the Pump Motor

The pump motor is not waterproof, just wipe it clean with a wet towel or paper towel



15.1 Cleaning



1: Rinse all parts with clean drinking water at approximately 20° C (68° F).

2: Wash all parts thoroughly in warm soapy water at approximately 30° C (86° F). It's recommended to use a pH-neutral detergent that you can purchase, preferably one without artificial fragrances and colors.

3: Rinse the parts with clean drinking water at approximately 20° C (68° F) for 10-15 seconds. then dry after washing

15.2 Cleaning Instructions

Before Use

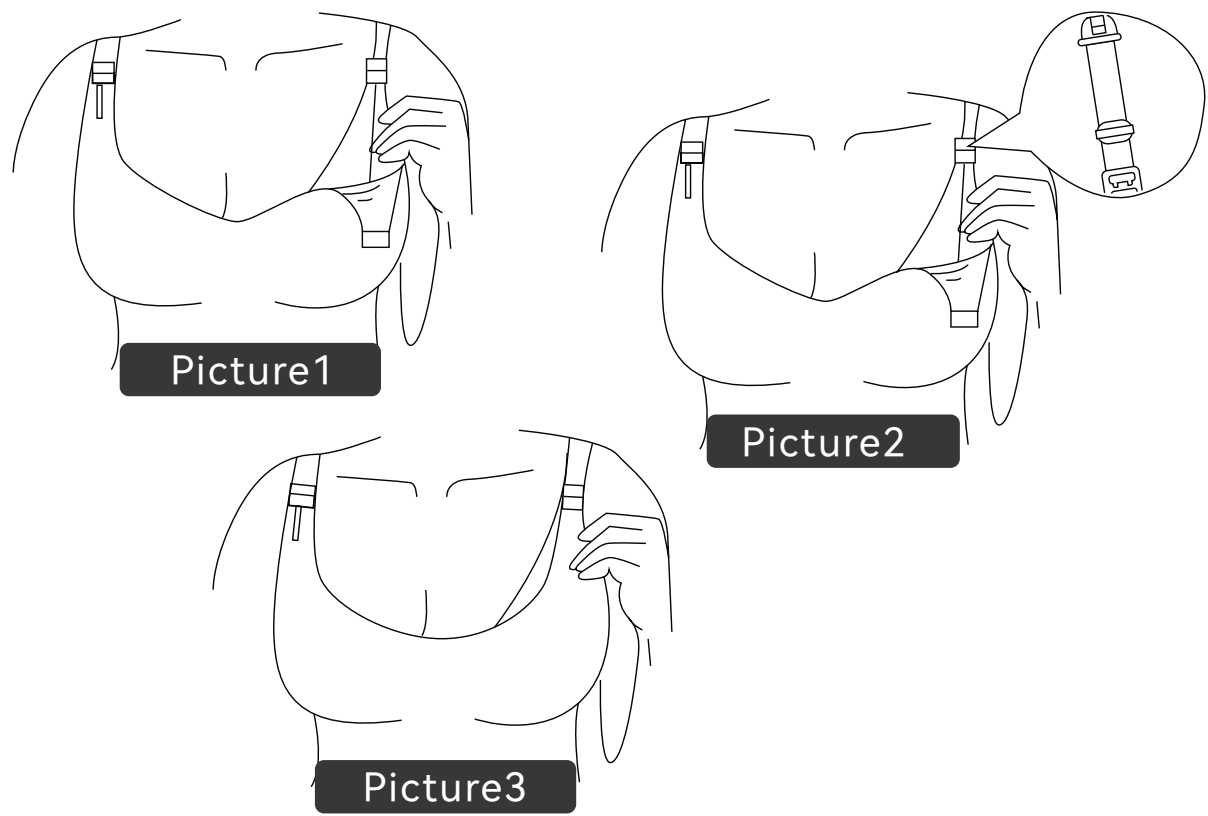
- ① Remove the pump motor.
- ② Place all the silicone parts in boiling water for 3 to 5 minutes.
- ③ Wash the milk collector and Linker with warm soapy water and rinse well.
- ④ Wipe down the parts with cloth or air dry before use.

After Use

- ① Rinse the milk collector, valve and Linker immediately after use.
- ② Place all the silicone parts in boiling water for 3 to 5 minutes.
- ③ Wipe down the parts with cloth or air dry before storage.
- ④ Do not submerge electrical device in water.

16.Instructions For Bra Adjusting Buckle

Adjust the length of bra straps, make suction more comfortable. One end of the bra adjustment buckle hung on the inside buckle of nursing bra. The length of the bra strap can be adjusted by hanging the nursing bra buckle on the other end of the bra adjustment buckle.



Troubleshooting	
Weak or No Suction	1. Check that the valve is properly installed. 2. Charge the device before use. 3. Check that the product is placed correctly, otherwise the breast pump will not have suction.
Nipple pain	1. Massage first and adjust the comfortable suction level. 2. Seek a lactation consultant or breastfeeding specialist for advice.
No / little milk expressed	1. Find yourself in a comfortable position. 2. If you've been pumping for 5-10 minutes, take a break and try again at the right time. 3. Ensure optimum suction level during use. 4. Relax and try again.

17. Transfer

When traveling, please use the charging cable provided and adjust it to the right power source for your current location. Before boarding the plane, please consult the airline for advice about carrying or using this pump on the plane.

Temperature: -20 to 60 °C/-4 to 140 °F

Relative Humidity: 15% – 90%

Ambient Pressure: 70 – 106kPa

18. Storage Condition

How to store the pump

- * Short-term storage

- * Please keep the breast pump out of direct sunlight. Store the breast pump and its accessories in a safe, clean, and dry place, and away from children.

- * Long-term storage

First, please charge the pump before long-term storage in which way the service life of this pump can be prolonged. Second, keep it in a place away from direct sunlight in avoidance of discoloration.

Third, clean and dry the washable parts before storing them.

- * Temperature: -20 to 60 °C / -4 to 140 °F

- * Relative Humidity: 15% – 90%

- * Ambient Pressure: 70 to 106 kPa

- * Generally 30 minutes is required to warm from the minimum storage temperature and/or cool from the maximum storage temperature until it is ready for operation.

19. Maintenance and Replacement Parts

The device contains no user serviceable parts inside: Opening or tampering with this device will void the warranty. In the event the device requires repair, it should be returned to the medical equipment company or to retailer directly. Modification of any kind is prohibited.

The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of the device that are designated by the MANUFACTURER as repairable by the SERVICE PERSONNEL. When the product is not used for a long time, the battery will discharge slowly. In order to avoid battery damage due to low voltage for a long time, please charge the device every three months.

Warning

Warning: the replacement of lithium batteries by inadequately trained personnel could result in a hazard.

Do not clean or maintain the device while the device is in use or while charging.

20. Declaration of Conformity

Shenzhen Root Innovation Technology Co.,Ltd. declares that the device conforms to the following standards IEC60601-1, IEC60601-1-2, IEC60601-1-11, IEC62304, ISO10993-5, ISO10993-10, ISO10993-1, ISO 14971, ISO10993-23.

21. Disposal



At the end of the product life cycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic equipment and battery. Waste Electrical and Electronic Equipment may have potentially harmful effects on the environment. Improper disposal may lead to the accumulation of harmful toxins in the air, water, and soil, which is harmful to human health. you have obligation to dispose of the device correctly. Consult your municipal authority for information about disposal.

22. Warranty

Please contact the manufacturer in case of a claim under the warranty, the contact information please refer to last page of this user manual. If you have to send the unit, enclose a copy of your receipt with clear statement of defect description.

The warranty terms are as below:

1. The warranty period for the device is one year from the date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs under warranty do not extend the warranty period either for the device or for the replacement parts.
3. The following cases are excluded under the warranty
 - All damages which are arisen due to improper treatment, e.g. non-observance of the user instruction.
 - All damages which are arisen due to repairs or tampering by the customer or unauthorized third parties.
 - Damages which are arisen during transport from the manufacturer to the consumer or during transport to the service center.
 - Accessories which are subject to normal wear and tear.
 - Device damage due to privately disassemble devices.
 - Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

23. Warranty

The equipment with following ESSENTIAL PERFORMANCE is intended used in Home healthcare environment facility environment.

Essential Performance:

Device-Specific Function	Device-Specific Pass/Fail Criteria	Detection/Testing Method
Vacuum strength	Suction levels (stimulation): -75mmHg to -145mmHg Suction levels (Expression): -120mmHg to -295mmHg Suction levels (Mix): -75mmHg to -295mmHg	Vacuum manometer Observation
Cycle speed (cycles/min)	Suction levels (stimulation): 70-88 Suction levels (Expression): 27-60 Suction levels (Mix): 56-82	Observation
Maximum vacuum	≤-300mmHg	Vacuum manometer Observation
Software for suction pressure regulation	-300mmHg	Vacuum manometer Observation
Backflow prevention mechanism	No leakage at maximum vacuum	Observation

If Essential Performance is lost or degraded due to electromagnetic disturbances, this may result in loss of product function or injury to patients, please read below important information before to avoid possible electromagnetic disturbances.

Warning

- Using cell phone or microwave oven, HF surgical equipment, magnetic resonance imaging or other radio radiant equipment near this product may cause malfunction.

- 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.
- 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 Momcozy Wearable Breast Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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.

Caution:

- 1) Security, antitheft, and radiofrequency identification (RFID) devices. Some electromagnetic anti-theft systems and metal detectors such as those used at entrances or exits of department stores, libraries, and other public places, and airport security screening devices may affect the Momcozy Wearable Breast Pump. Please do not use Momcozy Wearable Breast Pump near these places. Additionally, RFID devices, which are often used to read identification badges, as well as some tag deactivation devices, such as those used at payment counters at stores and loan desks at libraries, may also affect the Momcozy Wearable Breast Pump. Please do not use Momcozy Wearable Breast Pump near these places. If you have to go through one of these devices, turn off your Momcozy Wearable Breast Pump. Before each usage, checking the status of your Momcozy Wearable Breast Pump to ensure it can operate normally.
- 2) Using short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) and electrocautery devices near this product may cause malfunction or lead to loss of performance, please do not use Momcozy Wearable Breast Pump near this equipment.

A list of cables and maximum length of cables is as follows:

Cables name	Cable length	Whether shielding
Charging cable	800±10mm	No

Guidance and manufacture's declaration – electromagnetic emission		
The Momcozy Wearable Breast Pump is intended for use in the electromagnetic environment specified below. The customer of the user of the Momcozy Wearable Breast Pump should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
Conducted and Radiated RF emissions CISPR 11	Group 1 Class B	The Momcozy Wearable Breast Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted and Radiated RF emissions CISPR 11	Group 1 Class B	The Momcozy Wearable Breast Pump is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes except for near active HF surgical equipment and the RF shielded room for magnetic resonance imaging.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Momcozy Wearable Breast Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Momcozy Wearable Breast Pump should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge IEC 61000-4-2	±8kV contact; ±2kV, ±4kV, ±8kV, ±15 kV air	±8kV contact; ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Radiated RF EM fields IEC 61000-4-3	10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	10V/m (Home healthcare environment) 80MHz – 2.7GHz 80% AM at 1kHz	
Electrical fast transients/bursts IEC 61000-4-4	±2kV AC power supply lines; ±1kV DC power/Signal lines. 100 kHz repetition frequency	±2kV AC power supply lines;	power quality should be that of a HOME HEALTHCARE ENVIRONMENT.
Surges IEC 61000-4-5	±0.5kV, ±1kV lines to lines; ±0.5kV, ±1kV, ±2kV lines to earth	±0.5kV, ±1kV lines to lines;	power quality should be that of a HOME HEALTHCARE ENVIRONMENT.
Conducted disturbances induced by RF fields IEC 61000-4-6	3V 0.15MHz – 80MHz, 6V in ISM bands between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15MHz – 80MHz, 6V in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	power quality should be that of a HOME HEALTHCARE ENVIRONMENT.
Note: The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			
Rated power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a HOME HEALTHCARE ENVIRONMENT.
Voltage dips IEC 61000-4-11	0% UT , 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315°; 0% UT , 1 cycle and 70% UT , 25/30 cycle Single phase: at 0°	Applicable	Power quality should be that of a home healthcare environment.
Voltage interruptions IEC 61000-4-11	0% UT , 250/300 cycle	Applicable	

NOTE: UT is the a.c. mains voltage prior to application of the test level.
E.g.: 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz.

Guidance and manufacture's declaration – electromagnetic immunity

The Momcozy Wearable Breast Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Momcozy Wearable Breast Pump should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See the following table	Complies	
Proximity magnetic fields IEC 61000-4-39	See the following table	Complies	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13, 17	Pulse modulation ^{b)} 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	28
870				
930				

1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28
1845				
1970				
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9
5500				
5785				

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the MEEQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz, While it does not represent actual modulation, it would be worst case.

Test specifications for enclosure port immunity to proximity magnetic fields

Test frequency	Modulation	Immunity test level (A/M)
30 kHz ^{a)}	CW	8
134.2 kHz	Pulse modulation ^{b)} 2.1 kHz	65 ^{c)}
13.56 MHz	Pulse modulation ^{b)} 50 kHz	7.5 ^{c)}
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the home healthcare environment. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s, before modulation is applied.		

24.Travelor internationalUse Statement

Since the performance of the Momcozy Wearable Breast Pump may be affected by the external environment, in view of the uncertainty and instability of the travel environment, please do not use the device during travel or on the aircraft.

The Momcozy Wearable Breast Pump can be internationally used, but it must be used and stored in the environment specified in this user manual, and please make sure the input power of your power adapter is AC 100~240V 50/60 Hz and output power is DC 5V 1A, and please make sure you have a converter to convert to the proper voltage of the target country. To ensure that the Momcozy Wearable Breast Pump is not affected during carrying, please check the following items before use to ensure it can operate normally:

- Check the Momcozy Wearable Breast Pump to ensure that it is free from damage and
- Before each usage, check the status of your Momcozy Wearable Breast Pump to ensure it can operate normally.

If there is any abnormality, please stop using it.

25.Manufacturer Information



Dongguanshi Yiyongmei Technology Co., Ltd
Room 701, No. 31 Tangxi Street Shatou, Chang'an
Town Donguang, Guangdong 523000
CHINA

If assistance in setting up, using, or maintaining the device when needed or to report unexpected operation or events, please contact us.

26.FCC Caution

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.

Any 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.
- The device has been evaluated to meet general RF exposure requirement. The device

27. Reporting adverse events

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself. You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA Use one of the methods below?to submit voluntary adverse event reports to the FDA:

1) Report

Online?at:?www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.
home

2) Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see?MedWatchLearn. The form is available at:
www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

3) Call FDA at 1-800-FDA-1088?to report by telephone

4) Reporting Form FDA 3500?commonly used by health professionals.?The form is available at:
www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

28.USAGE & OPERATING LIFE

The BASEN™ Wearable Pump has an expected operating life of 12 months. The Pump Diaphragm, Container Duckbill Valve, Container Bowl, container Back, and Flange are reusable parts and should be cleaned after each use. The expected operating life of these components is 3 months.

POWER

Only use the UsB Charging Cables included with your Pump.

Additional charging cables and chargers are available at onewillow.com. Recommended Charger Specifications:

Input: 100-240V AC, 50/60Hz 0.28A

Output: 5V DC 1.0A min. per port

The adapter meets the requirements of the IEC 60601-1 standard

CHARGING

Check battery status by pressing the Power button.

. If battery is low, charge Pump with provided USB Charging Cables.

. When Pump is charging, the LED Indicator will pulse. When Pump is fully charged, the LED Indicator light will turn off.

. Pump can be fully charged in about 2 hours when using a 5V/1A charger

SPECIFICATIONS

Cycling control mechanism	Microcontroller
Product life	Approximately three 15-minute sessions per day, for one year
Accessory life	3 months
Backflow Protection	Yes
Suction Modes	Stimulation Mode and Expression Mode
Suction levels	9
Adjustable suction levels	Yes
Flange Size	24 mm and 27 mm
Vacuum range: Stimulation	-40 to -105(+5)mmHg
Vacuum range: Expression	-40 to -245(+5)mmHg
Cycle Speed: Stimulation	70 to 114 cycles/minute
Cycle Speed: Expression	23 to 90 cycles/minute