

Relative Humidity: 15% – 90%
Ambient Pressure: 70 – 106kPa

09. Storage conditions

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 is is ready for operation.

10. Specification

10.1 The pump

Model No.	BP334
Name	Momcozy Wearable Breast Pump
Power requirements	Input: 100-240Vac, 50/60Hz; Output: 5V $\overline{\text{---}}$ 2A (Charge through provided USB 2.0/ Type-C Charging cable and self-purchased power adapter)
Power supply	DC 3.8 V / 1800mAh Rechargeable lithium battery
Rated power	10W

Suction modes	Stimulation mode, expression mode, and mixed mode
Vacuum range	Stimulation mode: -67.5mmHg~-172.5(±15) mmHg Expression mode: -105mmHg~-280 (±15) mmHg Mixed mode: -67.5mmHg~-280(±15) mmHg
Cycle speed	Stimulation mode: 54~90 (±2) cycle/min Expression mode: 25~60 (±2) cycle/min Mixed mode: 46~84 (±2) cycle/min
Dimensions	125mm X 110mm X 61mm
Weight	260g (Pump)
Product use life	500 hours
Noise level	≤ 45dBA
Type of protection against electric shock	Internally powered equipment
Degree of protection against electric shock	Type BF applied part (milk collection set)
Operating conditions	Temperature: 0 °C to 40 °C ; Humidity: 15% to 90%, Atmospheric pressure: 70 kPa to 106 kPa
Transportation & storage environment	Temperature: -20 °C to 60 °C; Humidity: 15% to 90%, Atmospheric pressure: 70 kPa to 106 kPa
Battery charging time	140 minutes
Battery usage time	180 minutes

10. 1 The charging case

Power requirements	Input: 100-240Vac, 50/60Hz; Output: 5V $\overline{\text{---}}$ 3A (Charge through provided USB 2.0/ Type-C Charging cable and self-purchased power adapter)
Power supply	DC 3.8 V / 5500mAh Rechargeable lithium battery
Dimensions	238*189*87mm
Weight	450g
Battery usage time	Fully charge the case only about 3 hours Fully charge the case and two breast pumps inside the case about 5 hours

11. 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

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.

12. 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, ISO10993-23, ISO10993-1, ISO 14971.

13. Trouble shooting

Problems	Causes & solutions
Pump does not work	• If let-down has not yet occurred, consider leaving the pump on breast for longer period of time to observe for possible delayed let-down. Note: Initial milk let-down time is unique for each person and varies by many factors. • Check nipple alignment, pause the pump, and remove it from breast. Realign the pump as described below. • You may not have the correct Flange size.
Milk does not flow	• Pause the pump and remove it from breast. Realign it correctly. • You may also separate the pump from the flange to realign . Then, center your nipple in the flange tunnel and bring the pump to your breast.
Need to realign	• Pause the pump and remove it from breast. Realign it correctly. • You may also separate the pump from the flange to realign. Then, center your nipple in the flange tunnel and bring the pump to your breast.
Feel discomfort while pumping	• If you're experiencing excessive discomfort, please try the following: • Make sure to press the pump firmly against your breast during Stimulation mode.

	• Tighten bra to make sure the pump is held firmly against the breast. • Decrease suction level. • Realign the pump. • You may be pumping for too long. This pump shuts off automatically after running for 30 minutes. • You may not have the correct flange size. Stop and see a medical professional or breastfeeding specialist.
Decreased (low) pump suction	• The Pump has 15 suction settings. Press the increase button to increase suction level. • Check the condition of your washable parts. They should be replaced after three months of use. • If that does not work, try the following: 1. Check connections between all washable parts to ensure all are secure. 2. Visually inspect all washable parts and replace them if damaged. 3. Check that power is on. 4. Press the Pump securely against the breast.
Stop pumping	Short press On/Off button will pause the pump, press again will resume.
Pump does not stop pumping	• If the issue persists, then break the seal by inserting a finger between the breast tissue and the flange. Then long press the On/Off button to turn the pump off.
Pump or Charger gets wet (immersed in water).	• Dry the pump immediately. Prop the pump upright with charger port down and suction controls up, and let it air dry overnight. Do not use the pump or charger within 24 hours. • Contact Customer Care.

Remark: If the above methods still do not solve the problem, please contact the manufacturer, see the last page for contact information.

14. 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.

15. 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) 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. nonobservance 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.

16. EMC information

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 (error: ± 5 mmHg)	Stimulation mode: -67.5mmHg~-172.5(± 15) mmHg Expression mode: -105mmHg~-280 (± 15) mmHg Mixed mode: -67.5mmHg~-280(± 15) mmHg	Vacuum manometer Observation
Cycle speed (cycles / min) (error: ± 2 cycles/min)	Stimulation mode: 54~90 (± 2) cycle/min Expression mode: 25~63 (± 2) cycle/min Mixed mode: 25~90 (± 2) cycle/min	Observation
Maximum vacuum	≤ -285 mmHg	Vacuum manometer Observation
Software for suction pressure regulation	-285mmHg	Vacuum manometer Observation
Back flow 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	1000±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 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
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/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	704 – 787	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	9
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				
5786				

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT 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 files

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

17. 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

18. Travel or international use 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  2A, 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 cracks.
- 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

19. Manufacturer information

Manufacturer: Shenzhen Root Innovation Technology Co., Ltd.

Address: #2-2, Floor 2 Hasee Computer Building, No.2 Beier Rd, Bantian Street, Longgang, Shenzhen, Guangdong Province, China

E-mail: support@momcozy.com

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

20. FCC Warning

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: The Grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. such modifications could void the user's authority to operate the equipment.

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

momcozy

www.momcozy.com

注：此页无需印刷，文件每一页含有
3mm 出血位，实际印刷时请裁切！

图档名称	Momcozy Air 1 吸奶器 英文说明书		版本号	A1	日期	2024-10-25
规格尺寸	100*130 (h) mm , 公差 ±0.5mm			平面设计师	刘诗琪	
材质工艺	封面 150g 铜版纸, 内页 90g 书纸					
印刷颜色	CMYK	项目负责人	余莉	文案编写/审核人	余莉 / 沈颂林	
备注	出血线为2mm; 刀模线仅供参考请勿印刷; 图档版权归深圳市路特佳成网络科技有限公司所有。私自泄露、修改、使用文档所产生的一切责任后果我司将追究到底。				ROOT路特	