

Breast Pump

Model: # BR11B

EN



IP 22

RoHS

REACH

EC **REP**

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INSTRUCTION MANUAL

Please read this instruction manual carefully before operating this unit

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Intended Use

This device is intended to express and collect milk from the breast of a lactating woman, and to alleviate engorgement of the breast. The device is intended for a single user.

Warranty / Service center

Read this user manual carefully before you use the breast pump and save it for future reference. This product is operated by the lactating woman herself. You can use this breast pump in an everyday environment.

Contraindications



- Never use the breast pump while you are pregnant, as pumping can induce labor.

Warnings



Warnings to avoid choking, strangulation and injury:

- Do not allow children or pets to play with the motor unit, the adapter, packaging materials or accessories. As strangulation may occur due to excessive length of the cables.
- Always unplug the breast pump after use and when fully charged.
- Store the break pump away where children, pets and pests cannot access when not in use.
- 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.

Warning to prevent transmitting infectious diseases:

- If you are a mother who is infected with Hepatitis B, Hepatitis C or Human Immunodeficiency Virus (HIV), expressing breast milk will not reduce or remove the risk of transmitting the virus to your baby through your breast milk.

Warnings to avoid contamination and to ensure hygiene:

- For hygienic reasons, the breast pump is only intended for repeated use by a single user.
- Clean and disinfect all parts before first use and after each use.
- Do not use antibacterial or abrasive cleaning agents to clean the breast pump parts as this may cause damage.
- Wash your hands thoroughly with soap and water before you touch breast pump parts and breasts to prevent contamination. Avoid touching the inside of containers or lids.

Warnings to avoid breast and nipple problems including pain:

- Do not use the breast pump if the silicone diaphragm appears to be damaged or broken.
- There are no user serviceable parts inside the motor unit of the breast pump.
- No modification of the breast pump is allowed. If you do so, your warranty becomes invalid.
- Never use the breast pump while you are sleepy or drowsy to avoid lack of attention during use.
- Always switch off the breast pump before you remove the pump body from your breast, in order to release the vacuum.
- If the vacuum is uncomfortable or causes pain, switch off and remove the breast pump from your breast.
- 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 the process becomes very uncomfortable or painful, stop using the

pump and consult your healthcare professional. You can press and hold the On/Off Button for 3 seconds to shut down.

Warnings to prevent damage and malfunction of the breast pump:

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Battery safety instructions

- Only use this product for its intended purpose and follow the general and battery safety instructions as described in this user manual. Any misuse can cause electric shock, burns, fire and other hazards or injuries.
- Do not use an extension cord.
- Charge, use and store the product at the temperature ranges indicated in the technical specifications table in this user manual.
- Always unplug the product when it is fully charged.
- Do not burn products and their batteries and do not expose them to

direct sunlight or to high temperatures (e.g. in hot cars or near hot stoves). Batteries may explode if overheated.

- If the product becomes abnormally hot, gives off an abnormal smell, changes color or if charging takes much longer than usual, stop using and charging the product and contact your local dealer.
- This product contains a rechargeable battery that is nonreplaceable. Do not open the product to replace the rechargeable battery.
- 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.



CAUTION:

Cautions to prevent damage to and malfunctioning of the breast pump:

- Prevent the motor unit from coming into contact with water.

- Never put the motor unit in water or in a dishwasher, as this causes permanent damage to these parts.
- Keep the silicone tubes away from heated surfaces to avoid overheating and deformation of these parts.

Important Information Before Use

1. If breastfeeding goes well, it is advisable (unless recommended otherwise by your healthcare professional) to wait until your milk supply and breastfeeding schedule are established (normally at least 2 to 4 weeks after giving birth) before you start expressing.
2. Disassemble, clean and disinfect all parts that come into contact with breast milk before you use the breast pump for the first time and after every use.
3. Fully charge the device before you use it for the first time or after a long period of non-use.
4. If in need of assistance of setting up, using, maintaining or to report

unexpected operation/events please contact manufacturer or local representative for further information and assistance.

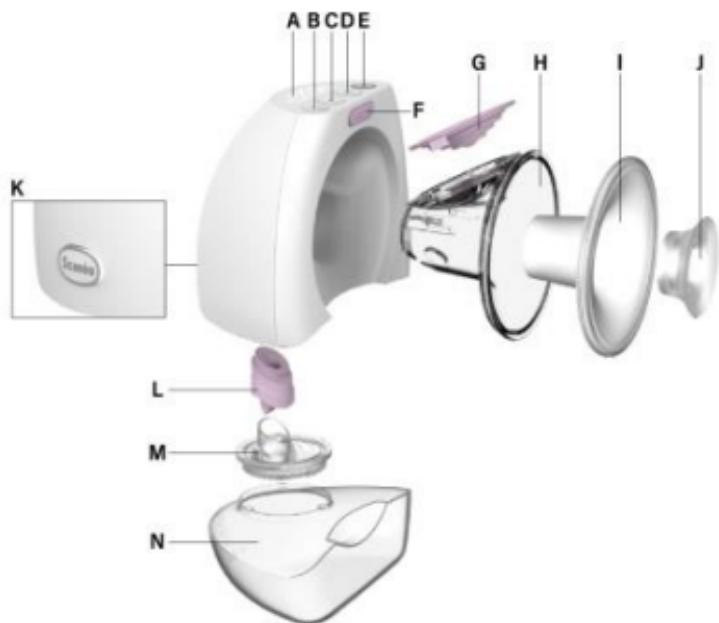
5. The performance of the device can be affected by extremes of temperature, humidity and altitude, Please refer to the instructions for use.
6. The device should not be used while charging.
7. To prevent tipping, do not transport the equipment over surfaces inclined more than 10° from horizontal. Always ensure stability during movement between rooms.



CAUTION:

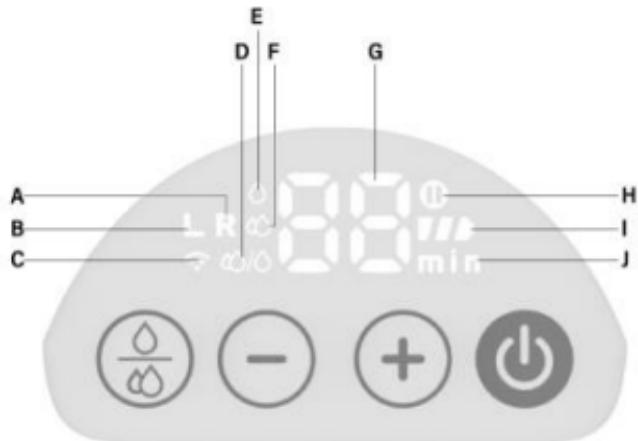
- Avoid potential allergic reactions; please avoid the Massage cushion in direct contact with patient's wound.
- User potential allergic reaction may occur due to skin contact with the plastic parts, please seek professional medical help if allergic reaction occurs.
- Please keep away from children and pets, because small parts may be inhaled or swallowed.
- Please keep this device away from pets, pests, and children.
- No modification of this equipment is allowed.

Product Identification



- A: LED Display
- B: Mode selection button
- C: 'Level down' button
- D: 'Level up' button
- E: On/off button with pause/play function
- F: USB Type C Cover
* USB Type C power inlet inside
- G: Silicone diaphragm
- H: Breast Shield
- I: Massage cushion
- J: Flange
- K: Bottle Release
- L: Valve
- M: Spout
- N: Bottle

LED display description



- A: Side Selector Right
- B: Side Selector Left
- C: Bluetooth status display symbol
- D: Dual-frequency phase indicator
- E: Stimulation phase indicator
- F: Expression phase indicator
- G: Suction Level Display
- H: Pause icon
- I: Battery indicator
- J: Time unit

Using the breast pump

Charging the breast pump

- Fully charge the battery before you use the breast pump for the first time and when the battery is low.
- Fully charging the battery takes up to 2.5 hours. Charged battery operates approximately 60 min.

Battery indicator light description

	<p>The battery display shows the state of the battery and its charging level.</p> <p>The display of all three bars indicates that the battery is full.</p>
	<p>With decreasing battery capacity fewer bars appear.</p> <p>Two bars: approx. 75% of the capacity is remaining.</p>
	<p>With decreasing battery capacity fewer bars appear.</p> <p>One bar: approx. 40 % of the capacity is remaining.</p>

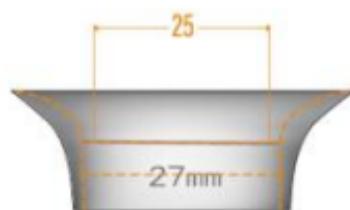
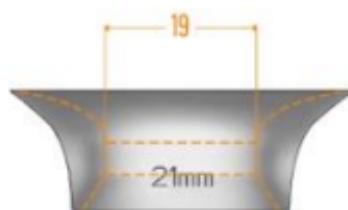
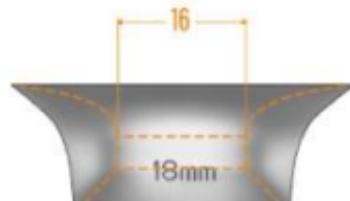
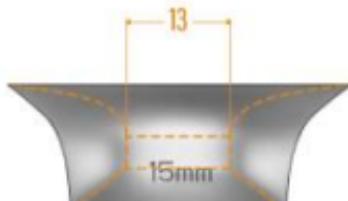
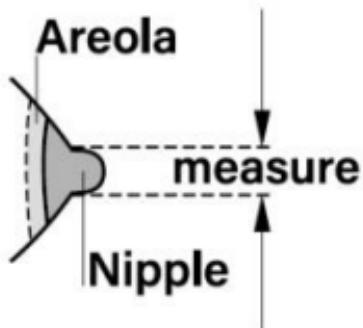
	Empty battery with flashing indicate shutting down soon.
	Battery lights light up one by one and go out all together. The battery is charging.

Selecting the correct Flange

Make sure to use the correct Flange size. It is an essential component of effective pumping, helping to optimize milk flow.

Understanding Flange sizing

- Pumping should not hurt. For maximum comfort and pumping efficiency, we offers multiple breast shield sizes.
- This guide is a starting point to help determine your optimal size based on your nipple diameter.



Step 1

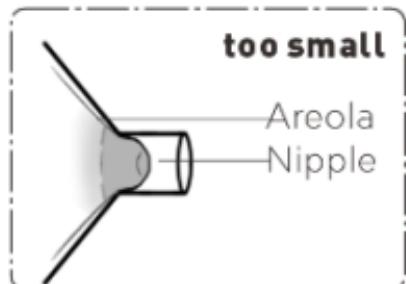
- Using a ruler or measuring tape, measure the diameter of the nipple at the base (across the middle) in millimeters (mm).

Step 2

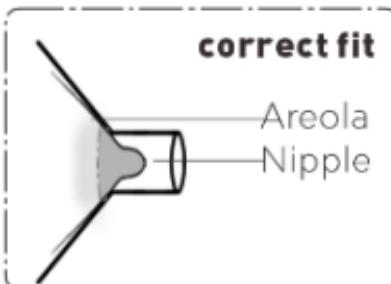
- Based on the measurement, determine the Flange size.
- Example: If the nipple size measures 18mm in diameter, the recommended Flange size is 21mm.

Optimizing the Flange size

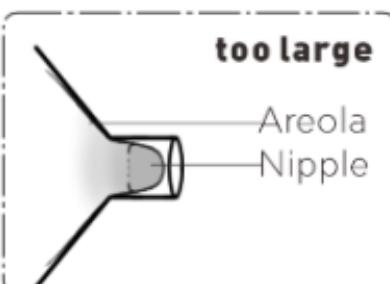
- Start with the Flange that came with your pump, or the size determined by measuring.
- Center the nipple and gently hold the Flange against the breast.
- Adjust for maximum comfort vacuum to achieve optimum suction level.
- Refer to the images below while pumping in the expression phase.



- The nipple rubs along the side of the funnel.
- Try a larger size.



- The nipple is centered and moves freely.



- The nipple and excessive areola are pulled into the funnel.
- Try a smaller size.

Assembling the breast pump

Make sure you have cleaned and disinfected the parts of the breast pump that come into contact with milk.



Warnings

- Be careful, when you have disinfected the breast pump parts by boiling them, they can be very hot. To prevent burns, only start assembling the breast pump when disinfected parts have cooled down.
- Wash your hands thoroughly with soap and water before you touch breast pump parts and breasts to prevent contamination. Avoid touching the inside of containers or lids.



CAUTION:

- Before each use, visually inspect the individual components for cracks, chips, tears, discolouration or deterioration. In the event that damage to the device is observed, discontinue use until the parts have been replaced.

Note:

1. Correct placement of the cushion, silicone diaphragm is essential for the breast pump to form a proper vacuum.
2. Make sure that you clean and sterilise the pump as instructed in this user manual.
3. Make sure that you assemble the pump correctly as instructed in this user manual.
4. To avoid leakage, remove the residue around the rim before assembling.
5. Wash your hand thoroughly before you take sterilised components.

Accessories assembly

	Step 1	Step 2
		
Parts photos	Assemble the breast shield and silicone diaphragm	Photos after assembly

Step 3	Step 4	Step 5
		
Assemble the breast shield and massage cushion	Photos after assembly	Assemble the spout and bottle

Step 6	Step 7	Step 8
		
Photos after assembly	Assembling the Bottle and Valve	Photos after assembly

Step 9	Step 10	Step 11
		
Install the accessories completed in step 4 onto the device	Photos after assembly	Install the accessories completed in step 6 onto the device

Step 12



Photos after assembly

Operation instructions

Step 1	Step 2	Step 3
		
	<p>Press and hold the On/Off Button for 3 seconds to turn on.</p>	Full screen display

Step 4	Step 5	Step 6
		
The screen is in paused state after booting up.	Press the On/Off Button one time.	The device will start.

Step 7	Step 8	Step 9
		
Press the Level up Button to increase the vacuum adjustment in nine levels.	Press the Level down Button to reduce the vacuum adjustment in nine levels.	Press the mode button to switch between three modes (Stimulation mode)

Step 10	Step 11	Step 12
		

Press the mode button to switch between three modes (Expression mode)

Press the mode button to switch between three modes (Dual-frequency mode)

You can also press and hold the **On/Off Button** for 3 seconds to shut down

Pumping instructions



Warnings

- Before you remove the device from your breast, always switch off the breast pump to release the vacuum.
- Do not continue pumping for more than 5 minutes at a time if you do not succeed in expressing any milk. Try to express at another time during the day.
- If the process becomes very uncomfortable or painful, stop using the pump and consult your healthcare professional.



CAUTION:

If discomfort is felt, then suction can be broken by inserting a finger between the breast and the cushion.

Expressing your breast milk

- Refrain from attempting to express milk with a vacuum that is excessively high and uncomfortable (painful). The associated pain, coupled with potential trauma to the breast and nipple, may reduce milk output.
- Reach out to your healthcare professional or breastfeeding specialist if you can only express minimal or no milk, or if you experience pain during expression.

Storing and thawing breast milk

General storage guidelines

Storage guidelines for freshly expressed breast milk (for healthy term babies)			
Room temperature 60 to 77 °F (16 to 25 °C)	Refrigerator 39 °F (4 °C) or colder	Freezer 0 °F (-18 °C) or colder	Breast milk thawed in the refrigerator
Up to 4 hours is best *Up to 6 hours for milk expressed under very clean conditions	Up to 3 days is best *Up to 5 days for milk expressed under very clean conditions	Up to 6 months is best *Up to 9 months for milk expressed under very clean conditions	At room temperature: Up to 2 hours Refrigerator: Up to 24 hours Do not refreeze!

*Guidelines for expressing milk under very clean conditions:
Before expressing breast milk, mothers should wash their hands with soap and water or an alcohol-based hand sanitizer. The pump parts, bottles and pumping area must be clean.
Breasts and nipples do not need to be washed before pumping.

- These guidelines for storage and thawing of breast milk are a recommendation. Contact your lactation consultant or breastfeeding specialist for further information.
- Store breast milk in the coldest spot of the refrigerator (at the back of the glass shelf above the vegetable compartment).

Freezing

- Repeated freeze/thaw cycles destroy the structure of the milk. Therefore, never refreeze breast milk.
- Freeze expressed breast milk in plastic bottles or milk storage bags. Do not fill the bottles or bags more than 3/4 full to allow space for possible expansion.

- Label the bottles or bags with the date and volume of expression.
- Plastic bottles and parts become brittle when frozen and may break when dropped.
- Do not use the breast milk from bottles that show signs of damage.

Thawing

- Do not thaw or warm breast milk in a microwave or a pan of boiling water.
- To preserve breast milk components, thaw the milk overnight in the refrigerator.
- Alternatively, hold the bottle or bag under warm water (max. 98.6 °F/37 °C).

Feeding breast milk

- It is recommended that breastfeeding is well established prior to bottle feeding your baby.
- Always inspect the bottle, the nipple and other components

immediately before and after each use. If the nipple appears cracked or torn, discontinue use immediately.

- To prevent a possible choking hazard, test the strength of the nipple by pulling on the end of the nipple.
- Do not attempt to enlarge the nipple hole.
- Infants must not be bottle fed without adult supervision.
- Do not use the nipple as a pacifier.

Data Transferring

This product is a breast pump. Design without entering personal information. The device has a transmission function. During the transmission process, the measurement data is designed to be encrypted, and will not be tampered with unauthorized access nor retrieve user-related information. The firmware and software of the product have been pre-programmed in the production stage. Both the burned in microcontroller programmer and the software were designed encrypted; there is no concern about the software safety.

Bluetooth function requirement:

An Android device with Android version 4.3 or above and hardware support for Bluetooth 4.2.

An iOS device with iOS version 5 or above and hardware support for Bluetooth 4.2.

Set Up Process

- (1) Please determine your mobile phone or computer has BLE4.2.
- (2) Press and hold the On/Off Button for 3 seconds to turn on and enter pause mode.
- (3) In pause mode, choose whether to connect via Bluetooth.
- (4) If you don't want to connect Bluetooth. Please select the desired mode and intensity.
- (5) Press the On/Off Button again to work.
- (6) If you need to change the mode and intensity, you can adjust it manually.
- (7) To pause, press the On/Off button once during use.
- (8) At the end of use, please press and hold the On/Off Button for 3 seconds to shut down.

Note:

When the battery indicator light flashes, please stop using it and charge it immediately.

Error code list for BR11B Possibly occur when working:

Err Code	Meaning	Corrective Action
E1	Milk storage reaches full	<ul style="list-style-type: none">• Remove the milk cup and pour out the breast milk. Store breast milk in the coldest part of the refrigerator.
E2	Milk storage detect error	<ul style="list-style-type: none">• Please restart and try again.• Contact Customer Service.

Recycling

Do not throw away the product with the normal household waste at the end of its life, but hand it in at an official collection point for recycling.

By doing this, you help to preserve the environment.

Follow your country' s rules for the separate collection of electrical and electronic products. Correct disposal helps prevent negative consequences for the environment and human health.

Troubleshooting

In case of an unexpected behaviour of your breast pump check with the troubleshooting table if you find the issue in the column "Problem" and follow the instructions in the column "Solution" .

Troubleshooting table

Problem	Solution
I experience pain when I use the breast pump.	<ul style="list-style-type: none">• Choose a suction level that is comfortable for you.• Check if the silicone diaphragm is not damaged (does not have small cracks, holes etc.).• Make sure that your nipple is placed in the center of the cushion.• If the pain persists, stop using.
The breast pump does not switch on while it is connected to power outlet.	<ul style="list-style-type: none">• Unable to use device while charging

Problem	Solution
The display does not light up after you pressed the On/Off button.	Make sure that the battery is charged.
The breast pump is not charging.	<ul style="list-style-type: none">• Make sure that the adapter has been inserted correctly into the power outlet and that the small plug has been inserted correctly into the motor unit.• The breast pump is too cold or too hot for charging. Let the breast pump acclimatize to room temperature for 30 minutes.• Use another adapter to charge the motor unit.

Problem	Solution
Charging the breast pump takes a very long time.	<ul style="list-style-type: none">• Make sure that the adapter has been inserted correctly into the power outlet and that the small plug has been inserted correctly into the motor unit.• The breast pump is too cold or too hot. It is recommended to charge the breast pump at room temperature.• The battery may have already aged.

Problem	Solution
I do not feel any suction/the suction level is too low.	<ul style="list-style-type: none">• If possible, try a higher suction level.• Check if the silicone diaphragm is assembled correctly.• Check if the valve is not damaged and assembled correctly.• Check if the other parts of breast pump are intact and assembled correctly.• Make sure that the pump is positioned correctly on the breast to allow a seal between breast pump and breast.

Problem	Solution
The suction of the breast pump is too strong.	<ul style="list-style-type: none">• If possible, try a lower suction level. When you express for the first time, start with the default suction level and increase/decrease the level when needed. During different expression sessions, different levels may feel most comfortable for you.• Make sure that you only use the breast pump parts provided with this breast pump.• Check if the silicone diaphragm is not damaged (does not have small cracks, holes etc.).

Problem	Solution
The breast pump exterior got wet.	<ul style="list-style-type: none">• Unplug the breast pump from the power source and switch it off.• Dry off the exterior of the breast pump.
The breast pump has been submerged in water.	<ul style="list-style-type: none">• Unplug the breast pump from the power source and switch it off.• Contact Customer Service.

Cleaning and Disinfecting

Overview

Clean and disinfect the parts that come into contact with the breast and breast milk as described below:

	When	How
 (Figure 1)	Clean and disinfect before first use and after every use.	Refer to 'Cleaning the accessories'.

The following parts do not come into contact with the breast and breast milk; clean them as described below:

	When	How
 (Figure 2)	Clean when needed.	Refer to 'Cleaning the motor unit'.

Cleaning the accessories

Step 1: Disassembling

- Prepare common household cooking pot.
- Place the baby bottle accessories in the pot, and fill the pot with tap water.
The amount of water must completely cover the accessories.
- Boil the water until it boils (100°C)
- Once the water is boiled, continue for 5 minutes
- When the time is up, remove the accessories from the boiled water and let them air dry completely at room temperature for about two hours.

Step 2: Cleaning

- Completely disassemble the baby bottle accessories (as shown in the figure 1)
- Prepare mild detergent
- Use general cold drinking water (about 20°C) to rinse the disassembled parts except the pipes for about two minutes.
- Use mild detergent to clean each part. The cleaning time is about five minutes.
- After cleaning with mild detergent, rinse with cold drinking water (about 20°C) for about two minutes.
- After the cleaning operation is completed, place all parts in a room temperature environment to completely air dry for about two hours.

Warnings



- Do not use antibacterial or abrasive cleaning agents to clean the breast pump parts as this may cause damage.



CAUTION:

- Never put the motor unit in water or in a dishwasher, as this causes permanent damage to these parts.
- Be careful when you remove and clean the valve. If it gets damaged, your breast pump does not function properly. To remove the valve, gently pull at the ribbed tab on the side of the valve. To clean the valve, rub it gently between your fingers in warm water with some dishwashing liquid. Do not insert objects into the valve, as this may cause damage.

Step 2A: Manual cleaning

Do not place the parts directly in the kitchen sink for rinsing and washing. Use a dedicated wash basin for infant feeding items.

1. Wash your hands before cleaning or handling clean parts
2. Rinse the disassembled parts, except for the tubing, with cold, clear drinking-quality water (approx. 20 °C).
3. Clean these parts with plenty of warm, soapy water (approx. 30 °C). Use a commercially available washing-up liquid, preferably without artificial fragrances and colouring (pH neutral).
4. Rinse the parts with cold, clear drinking-quality water for 10 to 15 seconds (approx. 20 °C).
5. Leave all parts to airdry on a clean, unused tea towel or drying rack in an area protected from dirt and dust. Do not use a tea towel to rub or to pat the items dry.

Step 2B: Cleaning in the dishwasher

1. Place all accessory parts on the top rack of the dishwasher.
2. Put dishwashing liquid or a tablet in the machine. Run a standard program using hot water and a heated drying cycle (or sanitizing setting).
3. Remove the accessories from dishwasher with clean hands. If items are not completely dry, place items on a clean, unused tea towel or paper towel to air-dry thoroughly before storing. Do not use a tea towel to rub or pat the items dry.
4. Please refer to the dishwasher manual for dishwasher operation.

Note:

1. Food colorings may discolor parts.
2. If using the dishwasher, parts may become discoloured. This will not impact the part function.

Step 3: Disinfecting

Sanitising is important for hygiene and serves to kill living organisms, such as bacteria or viruses.

1. Fill a household pot with enough water to cover all accessories and place all accessories in the pot . Let the water boil for 5 minutes. Make sure the parts do not touch the side of the pot.
2. Allow the water to cool down.
3. Gently remove the parts from the water. Place the parts on a clean surface/tea towel or drying rack to air-dry.
4. Store the dry items safely until needed. Ensure the clean pump parts, bottle brushes and wash bowls have air-dried thoroughly before storing. Items must be completely dry to help prevent germs and mold from growing. Store the dry items in a clean, protected area.



CAUTION:

- During disinfection with boiling water, prevent the bottle or other parts from touching the side of the pot.

Cleaning the motor unit

1. Switch the breast pump off.
2. Unplug the breast pump from the power source.
3. Wipe the motor unit with a clean towel moistened with drinking-quality water.
4. Wipe the motor unit dry with a clean, dry towel.



CAUTION:

- Unplug the breast pump before cleaning the motor unit.

- Do not immerse the motor unit in water; do not run water over the motor unit.
- Do not spray or pour liquid directly onto the pump.
- When cleaning the motor unit display, only use a damp, soft towel with mild dish soap. Other cleaners or abrasive cloths may degrade the display performance.
- Never place any heavy objects on the instrument.

Federal communications commission interference statement

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.

 **CAUTION:**

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

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.

RF exposure warning

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.

The equipment must not be co-located or operating in conjunction with any other antenna or transmitter.

Technical Specification

- Vacuum level: -40 to -220 mmHg
- Motor unit rated input : 5 V d.c. / 1 A
- Battery : Li-Ion 3.7 V, 1200 mAh (non-replaceable)
- Power port : USB Type-C
- Adaptor :
 - Input: 100-240V~; 50/60HZ; 0.2A Max
 - Output: 5V ; 1A
- Operating environment :
 - 5°C~40°C (41°F~104°F)
 - Relative humidity: 15 to 90 % (non-condensing)
 - Ambient Pressure: 700~1060 hPa
- Storage/ Transportation environment :
 - 20°C~+60°C (-4°F~+140°F)
 - Relative humidity: 10 to 95 % (non-condensing)
 - Ambient Pressure: 700~1060 hPa

- Weight : approx. 250g
- Dimensions : approx. L 124.2 mm x W 81.1 mm x H 128.3 mm
- Life time: 300 hours
- Noise: only 50 dB at highest level (distance 1.5m)
- Ingress protection : IP22
- Materials
 - ABS, silicone (motor unit)
 - Polypropylene, silicone (other parts)

All parts that come in contact with breast milk are not made with BPA (Bisphenol A).

EMC Tables

BR11B is intended for use in the electromagnetic environment specified below. The customer or the user of AViTA **BR11B** must make sure that it is used in such an environment.

Guidance and manufacturer's declaration - Electromagnetic emissions

Phenomenon	CISPR 11 Group 1 Class B (Not BLE Function)	
Conduction	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested	
Radiation	Applicable	
Harmonic distortion	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested	

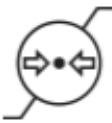
Voltage fluctuations and flickering	Not applicable (Note: Power by Battery or DC Input) Only the AC input needs to be tested		
<p>a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive acceptance limits of Group 1 Class B (CISPR 11) have been considered and applied. The equipment is suitable for use in the mentioned environments when directly connected to the Public Mains Network.</p> <p>b) The test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEM used will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.</p>			
Guidance and manufacturer's declaration - Electromagnetic immunity - Enclosure port			
Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare	HOME HEALTHCARE ENVIRONMENT

		facility environment	
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8kV contact ± 2 kV, ±4kV ±, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	a) 10 V/m b) 80MHz - 2.7 GHz 80% AM at 1kHz	
RATED power frequency magnetic fields.	IEC 61000-4-8	30 A/m c) 50 Hz or 60 Hz	
<p>a) The equipment is suitable for use in Home Health Environments and Professional Health Care Environments limited to patient rooms and respiratory treatment facilities in hospital or clinics. The more restrictive IMMUNITY acceptance limits have been considered and applied.</p> <p>b) Before modulation is applied.</p> <p>c) This test level assumes a minimum distance of at least 15 cm between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic fields.</p>			

Explanation of Symbols

 2797	The CE marking with the Registration Number of the Notified Body. This denotes the compliance of Regulation (EU) 2017/745
	Medical Device
	Manufacturer

EC REP	Authorized representative in the European Community
	Date of manufacture (YYYY-MM-DD or YYYY-MM or YYYY)
LOT	Batch code LOT WWWXXXXX LOT: Lot Number; WWW: working sheet; XXXXX: serial no.
SN	Serial number SN YYMWWWXXXXX YY: year; M:month; WWW: working sheet; XXXXX: serial no.

	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

	Caution
	Consult the instruction for use
	Disposal information: Should you wish to dispose of the article, do so in accordance with current regulations. Details are available from your local authority. WEEE 2012/19/EU Directives
RoHS	This product fulfilling the requirements of the RoHS Directive 2011/65/EU.

REACH	This product fulfilling the requirements of the REACH Directive EC 1907/2006 and its amendments, do not contain Substances of Very High Concern in concentration above the limit of 0.1 %. No substance(s) is/are present in the parts of the product above the concentration of 0.1 % weight by weight.
	"ON/OFF" (push-push)
	Device classification type BF

IP 22	This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test (protection against solid foreign objects of 12.5mm Ø and greater and against vertically falling water drops when enclosure tilted up to 15°)
	The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.
	Importer

	Distributor
	Model Number
	Country of Manufacturer
	Unique Device Identifier
	Keep away from sunlight

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