SPECTRA® Wearable

INSTRUCTIONS FOR USE

Table of Contents

01. GLOSSARY

Definition of Terms

Warning
This section describes serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Precaution
This section describes information regarding any special care to be exercised by the patient for the safe and effective use of the device.

Contraindication
This section describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit.

- Warning symbols

These symbols identify all instructions that are important to the safety of the user. Failure to observe these instructions can lead to injury or damage to the breast pump.

WARNING can lead to serious injury or death.

General prohibition sign

CAUTION can lead to minor injury.
NOTE can lead to material damage.
TIP useful or important information that is not related to safety.

• Glossary of Symbols

Graphic of the Symbol	Standard from which the symbol was referenced	Reference/ Registration Number	Symbol Title	Symbol Description
	IEC 60601-1	Table D2-9	General Action sign	General mandatory action sign
	IEC 60601-1	Table D1-20	Type BF	Type BF Applied Part
	IEC 60417	5009	Power On / Off	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition
	ISO 15223-1:2016	5.3.8	Transport/Storage/ Operation Humidity	Indicates the range of humidity to which the medical device can be safely exposed
	ISO 15223-1:2016	5.3.1	Fragile	Indicates a medical device that can be broken or damaged if not handled carefully
	ISO 15223-1:2016	5.1.3	Date of Manufacture	Indicates the date when the medical device was manufactured
	ISO 7000	0623	This Way Up	Indicates correct upright position of the transport package
	IEC 60601-1	Table D2-2	Danger, Warning	Can lead to serious injury or death

Graphic of the Symbol	Standard from which the symbol was referenced	Reference/ Registration Number	Symbol Title	Symbol Description
	IEC 60417	5031	DC	Direct current
	ISO 15223-1:2016	5.3.7	Operation Temperature	Indicates the temperature limits to which the medical device can be safety exposed
	ISO 15223-1:2016	5.3.4	Keep Dry	Indicates a medical device that needs to be protected from moisture
	EN 50419:2006	-	This product should not be mixed with other commercial wastes for disposal.	WEEE—Subject to waste electrical and electronic equipment regulations, i.e. not for general waste
	ISO logo	-	Quality System	These trademarks for the ISO logo
	ISO 7010	P001	General Prohibition Sign	General prohibition sign and template for constructing a prohibition sign
	IEC 60417	5172	Class II	CLASS II equipment
	ISO 15223-1:2016	5.1.1	Manufacturer	Indicates the medical device manufacturer

Graphic of the Symbol	Standard from which the symbol was referenced	Reference/ Registration Number	Symbol Title	Symbol Description
	ISO 15223-1:2016	5.3.9	Operation Atmospheric Pressure	Indicates the range of atmospheric pressure to which the medical device can be safety exposed
	ISO 15223-1:2016	5.1.7	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 7000	2403	Stacking Limit by Number	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves
	IEC 60601-1	Table D.2-10	Refer to IFU	Refer to Instructions for use that should be followed

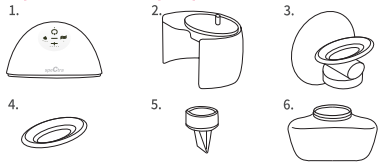
02. INDICATIONS FOR USE

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

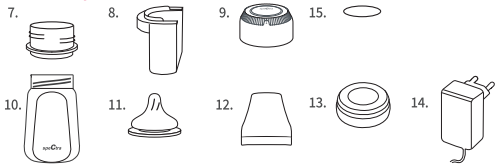
03. DEVICE DESCRIPTIONS

1) COMPONENTS AND ASSEMBLY

Components of breast pump



Other components

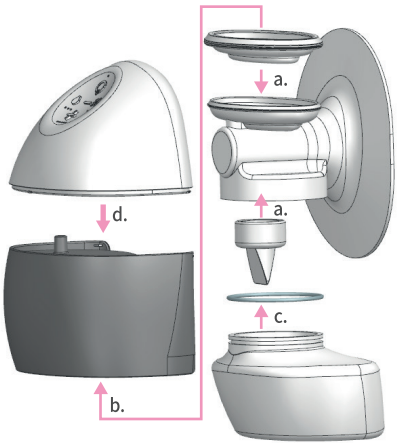


1. Wearable Breast Pump
2. Wearable Cover - a cover that connects the wearable breast pump and the wearable flange
3. Wearable Flange - a part that attaches to the breast for breast pumping
4. Backflow Protector - assembled on a wearable breast flange to prevent backflow of breast milk into the wearable breast pump
5. Duckbill Valve - a valve that directs breast milk into the bottle
6. Wearable Bottle - a bottle used to collect or store breast milk
7. Bottle Connector - used when connecting a screw cap, an airtight cap, or nipple mounting ring to the wearable bottle
8. Bottle Clip - helps the wearable bottle and the bottle connector to be more securely fastened
9. Airtight Cap with Date Marker - a lid that seals the bottle so you can store the pumped breast milk immediately (wearable feeding bottle, or Spectra milk storage bottle is compatible)
10. Milk Storage Bottle - a bottle used to store and feed the pumped breast milk
11. Nursing Nipple - used after connecting it to the nipple mounting ring when feeding the pumped breast milk
12. Cover - the lid of the bottle
13. Nipple Mounting Ring - the middle cap that connects the nursing nipple to the milk storage bottle
14. Power Adapter Assembly – a device that provides power to the breast pump
15. O-Ring - placed on wearable bottle to secure the bottle connector for feeding or wearable flange for pumping

The kits are designed for individual use. Never share the kits.

NOTE
To prevent distortion or damage, do not boil for more than 5 minutes during sanitization process, as parts may become distorted. **Prior to first use**, charge pump and follow the washing and sanitizing instructions included in this manual.

How to assemble



NOTE
Reference numbers correspond to components and assembly, page 6.

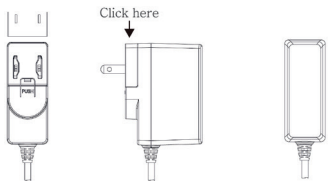
a. Insert the **duckbill valve** (5) and the **backflow protector** (4) into the **wearable flange** (3).

b. Combine the **wearable cover** (2) with the **wearable flange** (3).

c. Insert the **wearable bottle** (6) into the **wearable flange** (3).

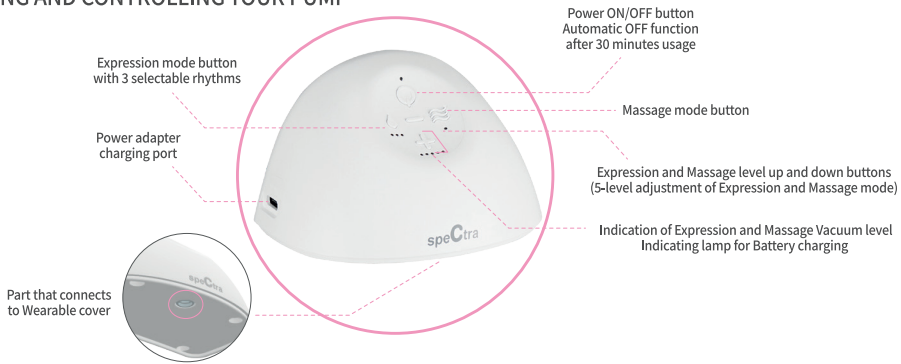
d. Connect the assembled wearable breast flange with the **wearable breast pump** (1) and start using the product.

How to assemble the power adapter cord



1. Hold power cord base and slide the adapter on the 2 flat prongs.
2. You should hear a loud click once the 2 parts are well-connected.
3. When assembled correctly, the 2 parts cannot be easily separated, and the assembly looks like one-piece.

2) USING AND CONTROLLING YOUR PUMP



- **Mode** : Massage Mode - / Expression Mode -
  The SPECTRA WEARABLE has two modes. Massage Mode and Expression Mode. Massage mode has 5 levels of massage for natural suckling. Expression mode has 5 levels and 3 selectable rhythms. The 3 selectable rhythms use different suction patterns.

- **Adjust Vacuum Level**
  Vacuum mode 1-5 level / Massage mode 1-5 level
  To adjust the vacuum level and massage mode, press the +/- buttons.

- **Charging the battery**
  To charge the battery, insert the power adapter into pump, and then plug it into the outlet.
  Charge the battery for at least 2 hours and 30 minutes. When fully charged, the battery light will light up.
  When the battery is low or charging, the battery light will flicker.
  The battery can be used for approximately 1 hour and 30 hours when fully charged.

3) PUMPING GUIDE

1. Relax, clear your mind, listen to relaxing music. If your baby is not present, look at pictures or videos of your baby.
2. Sit in a comfortable chair and if needed to support lower back, use a pillow.
3. Stimulate your letdown reflex before pumping. Some women have found that gently massaging their breasts with a circular motion from the wall of their chest toward the nipple or applying a warm compress on their breasts prior to pumping triggers their letdown reflex.
4. Always wash hands well with soap and water before pumping.

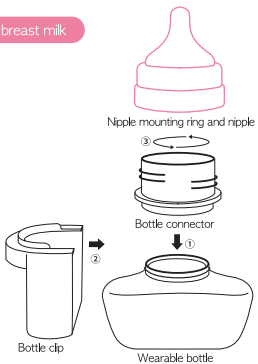
4) GETTING STARTED

1. Wash your hands and wipe your breast with a warm towel.
2. Attach the product to your breast. At this time, make sure that the nipple is in the center of the inner tube of the funnel.
3. Fix the product in close contact with the breast by using a breast-feeding bra. Ensure the bra is good and tight fit.
4. Press the power button. The previously used set value is stored in the memory and the device starts with the previously used set value, so check vacuum setting before use.
5. Press the massage mode conversion button to set the massage mode in order to massage the breast before breast pumping.
6. In the massage mode, you can adjust the massage level by the + or - button. (1-5 level)
7. After massaging the breast sufficiently, press the expression mode conversion button to set the expression mode.

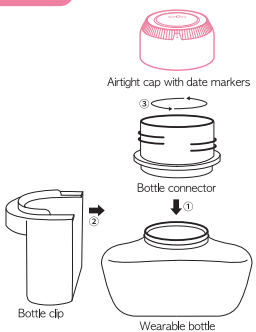
8. There are 3 programmed expression mode rhythms, after selecting the one that suits you, press the + or - button to adjust the vacuum level. (3 types of expression mode, 1-5 level)
9. When you finish pumping, lower the pressure level and turn off the power, lean forward slightly, and insert your finger into the flange attached to the breast and separate it slowly.
10. You can feed the pumped breast milk immediately or keep it, or move it to a general feeding bottle or a breast milk storage bag for use later.

※ At this time, connect the upper part of the bottle clip so that it can cover the bottle connector.

a. feeding breast milk



b. storing breast milk



5) SANITIZING AND CLEANING

NOTE: Use a designated basin to clean your pump parts; do not wash them in the sink.

a. How to clean

1) Do not wash the wearable pump or power adapter assembly. Wipe them with a dry towel.
2) Other components are washable. After separating them, wash them with warm soapy water.
   Components: Wearable cover, Wearable flange, Backflow Protector, Duckbill valve, Wearable bottle, Bottle connector, Bottle clip, Airtight cap, Nipple mounting ring, Milk bottle, Nipple, and Cover.

For handwashing instructions

- Wash hands. Wash your hands well with soap and water for 20 seconds.
- Separate all bottle parts.
- Rinse bottle parts by holding them under running water. Do not set them in the sink. The water can be warm or cold.
- Wash feeding items.
  - Place all items in a clean basin or container used only to clean infant feeding items. Do not wash directly in the sink because it may contain germs that could contaminate these items.
  - Fill wash basin with hot water and add soap.
  - Scrub items using a clean brush that is used only to clean infant feeding items.
  - Squeeze water through nipple holes to be sure they get clean.
- Rinse by holding items under running water, or by holding completely under fresh water in a separate basin that is used only for cleaning infant feeding items.
- Allow to air-dry. Place bottle parts, wash basin, and bottle brush on a clean, unused dish towel or paper towel in an area protected from dirt and dust. Allow to air dry thoroughly.
  - Do not use a dish towel to rub or pat items dry because doing so may transfer germs to the items.

- Clean the wash basin and bottle brush. Rinse the wash basin and brush well and allow them to air-dry after each use. Wash them every few days, either in a dishwasher with hot water and a heated drying cycle (if they are dishwasher -safe) or by hand with soap and warm water. If your baby is less than 2 months old, was born prematurely, or has a weakened immune system due to illness (such as HIV) or medical treatment (such as chemotherapy for cancer), wash basin and bottle brush after every use.

In the dishwasher (*Ref. Page 6 product numbers)

- **Note: Cleaning the wearable bottle #6, wearable cover #2, and airtight cap #9 in warm soapy water is recommended.**
- Do not place the Wearable Breast Pump #1, Wearable Cover #2, and Power Adapter Assembly #14 in the dishwasher.
- Rinse bottle parts and any other feeding items by holding them under running water. The water can be warm or cold.
- Place parts in the top rack of the dishwasher. (Be sure to place small items inside a closed-top basket or mesh laundry bag so they don't end up in the dishwasher filter.) If possible, run the dishwasher using hot water and a heated drying cycle (or sanitizing setting); this can help kill more germs.
- Wash your hands with soap and water before removing and storing cleaned items.
- Remove parts from dishwasher
  - If items are not completely dry, place them on a clean, unused dish towel or paper towel to air dry thoroughly before storing in an area free of dust or dirt. Do not use a dish towel to rub or pat items dry because doing so may transfer germs to the items.

b. Sanitizing

NOTE

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

: For extra germ removal, sanitize feeding items at least once daily. Sanitizing is particularly important when your baby is younger than 2 months, was born prematurely, or has a weakened immune system. Daily sanitizing of feeding items may not be necessary for older, healthy babies, if those items are cleaned carefully after each use.

1) After washing, sanitizing with boiling water is common, but the method may differ depending on the material used.

• Boil:
- Place disassembled feeding items into a pot and cover with water.
- Put the pot over heat and bring to a boil.
- See below chart for boiling times.
- Carefully remove items with clean tongs.

- PA (Wearable bottle): up to 3 minutes
- PP (all plastics except Wearable bottle): up to 1 minute
- Silicone (Backflow protector, Duckbill valve, Nipple): up to 30 seconds

WARNING
Exceeding boiling times or extended exposure to heat may damage your accessories.

TIP: Do not expose silicone accessories (Backflow protector, Duckbill valve, Nipple) to high heat to prevent melting, warping, or damaging them.

2) After sanitizing in boiling water, allow to air dry. Place bottle parts, wash basin, and bottle brush on a clean, unused dish towel or paper towel in an area protected from dirt and dust. Allow to air dry thoroughly.
   - Do not use a dish towel to rub or pat items dry because doing so may transfer germs to the items.
3) Keep parts covered when not in use.
4) Deformation or discoloration may occur during long-term UV disinfection. Discoloration is cosmetic and does not affect the chemical composition of the parts and they may be used.

WARNING

- Microwaving your parts can result in distortion and/or discoloration of the parts. Discoloration is cosmetic and does not affect the chemical composition of the parts. Microwave bags can be used if the proper amount of water is added. Follow the instructions of the bag manufacturer.
- If using a dishwasher, place items on wash cycle on the top rack using a close top basket or a mesh bag, and air dry.

NOTE

The above guidelines are for healthy, term babies. If your baby was born prematurely, has a weakened immune system due to illness, has other health challenges or is hospitalized, follow the recommendation of the hospital and your child's health care provider.

04. CONTRAINDICATIONS

- "No known contraindications"

05. WARNINGS

- If you are a mother who is infected with Hepatitis B, Hepatitis C or Human Immunodeficiency Virus (HIV), pumping breast milk will not reduce or remove the risk of transmitting the virus to your baby through your breast milk.
- Powered breast pumps that are designed for single users should never be rented or shared.
- Pregnant women should not use the breast pump, as pumping can induce contractions or premature labor.

1) IMPORTANT SAFEGUARDS

Before each use, visually inspect each individual component for cracks, chips, tears, discoloration or deterioration. If component damage is observed, please discontinue use until the parts have been replaced.

READ THIS ENTIRE MANUAL BEFORE USING PUMP AND KEEP IT FOR FUTURE REFERENCE.

When using electrical products, basic safety precautions should always be followed.

TO REDUCE THE RISK OF ELECTROCUTION:

1. Do not use while bathing.
2. Do not place or store product where it can fall or be pulled into water or other liquids.
3. Do not place in or drop into water or other liquids.
4. Never reach for a product that has fallen into water or other liquids; unplug the product immediately.
5. Never immerse pump unit in water.
6. Always unplug electrical devices immediately after using.
7. Inspect cords and electrical components before each use. Never use the product if insulation damage, exposed wiring, kinking, abrasion, or other mechanical damage is noted.

TO REDUCE THE RISK OF BURNS, ELECTROCUTION, FIRE, OR INJURY TO PERSONS.

1. This product should never be left unattended when plugged into an electrical outlet.
2. Do not leave this product unattended around infants or children. Close supervision is necessary when this product is used near infants or children.
3. Use this product only for its intended use as described in this manual. Do not use any attachments or accessories not recommended by the Uzinmedicare Co., Ltd / Spectra Baby USA.
4. Never operate this product if it has a damaged cord or plug.
5. Do not use the product If it is not working properly, if it has been dropped or damaged, dropped into water, or if any parts are broken or missing.
6. Keep the cord away from heated surfaces.

7. Never use while driving, sleeping or if drowsy.
8. Do not use outdoors or operate where aerosol spray products are being used or where oxygen is being administered.
9. Do not disassemble or modify the product.
10. Do not place small parts in mouth. Do not inhale or swallow small parts.
11. Allergic reactions may occur. Immediately discontinue use of the product if allergic reactions occur.
12. The product must be stored properly, away from excessive lint, dust, light (including sunlight), etc. Improper storage can adversely affect the safety and essential performance of this product.
13. The power adaptor must be in a position that is easy to unplug from power outlet.
14. Use only the power adapter that comes with the SPECTRA WEARABLE breast pump. Before using, check to be certain that the voltage of the power source is compatible.
15. If the power adapter outer casings become loose or are separating, stop using the product immediately and contact Spectra Baby USA - separation of the casing can result in electric shock.
16. This breast pump is prohibited from use on airplanes.
17. Plug the power cord into the breast pump first and then into the wall outlet.
18. Dry all parts thoroughly after cleaning. Do not store wet or damp part(s) as they may develop mold.
19. When cleaning the pump unit, unplug it before you start.
20. Pumping can induce labor; do not use when pregnant.
21. Always disconnect pump from charger before using.

06. PRECAUTIONS

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

07. BREAST MILK STORAGE

Following recommended storage and preparation techniques can maintain the safety and quality of expressed breast milk for the baby's health.

These are general guidelines for storing human milk at different temperatures. Various factors affect how long human milk can be stored safely. Such factors include milk volume, room temperature when milk is expressed, temperature fluctuations in the refrigerator and freezer, and cleanliness of the environment.

STORAGE RECOMMENDATION OF FRESHLY EXPRESSED BREAST MILK
Guidelines for Healthy, Full-Term Babies

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

Source: CDC - Human Milk Storage Guidelines (https://www.cdc.gov/breastfeeding/recommendations/handling_breastmilk.htm)

- Storage times may vary for premature or sick babies. Please contact your health care provider for instructions.
- When storing breast milk, use breast milk storage bags, which are made for freezing human milk. You can also use clean glass or hard BPA-free plastic bottles with tight-fitting lids. Do not use containers with the recycle number 7, which may contain BPA. Do not use disposable bottle liners or other plastic bags to store breast milk.
- Write the date on the storage container. Include your child's name if you are giving the milk to a childcare provider.
- Refrigerate or chill milk right after it is pumped, if possible. You can put it in the refrigerator, place it in a cooler or insulated cooler pack, or freeze it in small (2 to 4 ounce) batches for later feedings. If you're not going to use refrigerated breast milk within 4 days of pumping, freeze it right after pumping. Freeze in small amounts (2 to 4 ounces, or ¼ to ½ cups) for later feedings. Leave an inch or so from the milk to the top of the container, because it will get bigger when freezing. Wait to tighten bottle caps or lids until the milk is completely frozen. Store milk in the back of the freezer, not on the shelf of the freezer door, so that it doesn't start to thaw out. Milk stored at 0°F or colder is safe for longer durations, but the quality of the milk might not be as high.

08. HOW TO THAW AND USE STORED BREAST MILK

- Always make sure to check the date on the milk's container before using. Do not use undated milk, or milk that has been stored too long.
- Thaw the oldest breast milk first. Thaw frozen milk in the refrigerator or under cool, running water.
- Breast milk does not need to be warmed. Some moms prefer to serve it at room temperature. Some moms serve it cold.
- If you decide to warm the breast milk:
  - Keep the container sealed while warming.
  - Hold it under warm, not hot, running water, or set it in a container of water that is warm, not hot.
  - Never put a bottle or bag of breast milk in the microwave. Microwaving creates hot spots that could burn your baby and damage the milk.
  - Test the temperature before feeding it to your baby by dropping some on your wrist. The milk should feel warm, not hot.
- Gently swirl the container to mix the cream part of the breast milk that may rise to the top back into the rest of the milk. Do not shake the milk. This can make some of the milk's valuable parts break down.
- After thawing, milk should be stored in the refrigerator for no more than 24 hours. If warm water is not available, heat a pan of water on the stove. Once the water is warm, not boiling, remove the pan from the stove and place the milk container in the pan. It may take approximately 20 minutes to bring cold milk to room temperature. Never warm the milk container directly on the stove.
- Never refreeze thawed milk. Throw away previously frozen milk that is not used within 24 hours.
- If you are combining freshly expressed breast milk and stored breast milk, make sure all the milk is at the same temperature.

- Feeding Breast Milk

It is recommended that you establish and maintain your milk supply prior to introducing the bottle to your baby (approximately 6 weeks.)

- Inspect bottle, nipple, and other feeding tools before and after each use. Stop using and replace damaged--cracked and/or torn--nipples immediately.
- When bottle feeding, paced feed only to prevent flow confusion.
- Do not attempt to enlarge the nipple hole.
- Do not bottle feed an infant without adult supervision.
- Do not use your bottle nipple as a pacifier.

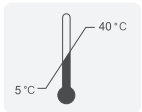
09. TROUBLESHOOTING

Condition	Possible Causes	Checks	Solutions
No power	Battery discharged	Check the battery indicator.	Using the power adapter assembly, connect the pump to an appropriate power source. Charge pump.
No Suction	Duckbill Valve	Check if they are connected to the Wearable Flange properly	Attach silicone valve to breast shield - Twist valve into breast shield to attach. If silicone valve check for tear/damage
Low Suction	Vacuum Level	Check vacuum level	Increase vacuum level.
	Duckbill Valve	Check for damage. Ex. tear or other damage	Replace the silicone valve.
Pain	Vacuum Level	Too high suction	Set to a lower suction level.

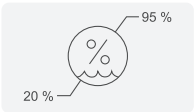
If suggested solution does not resolve the issue, turn off pump, stop pumping, and break suction to remove flange.
If your pump appears to be malfunctioning, contact the warranty team at warranty@spectrababyusa.com.
If you have questions on how to properly use your pump or on lactation issues, consult a lactation or health professional. You can make an appointment with one of our lactation consultants for an online consult at www.spectrababyusa.com/lactationservices. If pain persists, seek medical attention from a qualified health professional.

10. USE AND STORAGE ENVIRONMENT

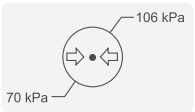
Environment to use



Temperature

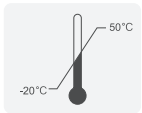


Humidity



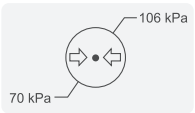
Pressure

Storage environment



Temperature

Humidity



Pressure

11. TECHNICAL SPECIFICATIONS

Protection Type: Class II
Weight: 305g
Power consumption: 20VA
Expected SPECTRA WEARABLE Service Life is 3 years.

The following adapter must be used
Manufacturer: Dongguan Shilong Fuhua Electronic Co., Ltd.
Model: UES12LCP-050200SPA
Input: 100-240V~ 50/60 Hz, 500mA
Output: 5V ⎓2A
Battery : Li-Polymer 3.7V 1,500mAh

1. Type of protection against electric shock: Class II equipment
2. Degree of protection against electric shock: Type BF applied parts
3. Classification according to the degree of protection against ingress of water: IP22
4. This equipment is not suitable for use in the presence of flammable anesthetics or oxygen
5. Mode of operation: continuous operation

VACUUM SUCTION PRESSURE(mmHg)		CYCLE SPEED(Cycle)			
Expression Mode (Mode 1/2/3)	Massage Mode	Expression Mode			Massage Mode
		Mode 1	Mode 2	Mode 3	
Level 1: 100	Level 1: 50	Level 1: 53	Level 1: 31	Level 1: 18	Level 1: 100
Level 2: 150	Level 2: 80	Level 2: 43	Level 2: 26	Level 2: 17	Level 2: 90
Level 3: 200	Level 3: 100	Level 3: 33	Level 3: 20	Level 3: 15	Level 3: 80
Level 4: 240	Level 4: 120	Level 4: 28	Level 4: 18	Level 4: 14	Level 4: 70
Level 5: 270	Level 5: 130	Level 5: 25	Level 5: 16	Level 5: 12	Level 5: 60

12. WARRANTY

This product is warranted by SPECTRA BABY USA, to the purchaser to be free from defects in material and workmanship for a maximum period of two (2) years from the date of purchase. In the event of a defect or failure to conform to this warranty, SPECTRA BABY USA will, at SPECTRA BABY USA's option, replace this product without charge for such replacement or parts at the SPECTRA BABY USA office listed below. The purchaser shall bear all responsibility and expense for returning this product, including risk of loss prior to receipt by SPECTRA BABY USA, as well as shipping, packing and insurance costs.

ANY AND ALL IMPLIED WARRANTIES ARE LIMITED TO THE DURATION OF TWO (2) YEARS FROM THE DATE OF PURCHASE. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO YOU.

THE LIABILITY OF SPECTRA BABY USA, FOR BREACH OF ANY WRITTEN OR IMPLIED WARRANTY IS LIMITED TO THE REPLACEMENT OF THIS PRODUCT. SPECTRA BABY USA WILL HAVE NO LIABILITY UNDER ANY CIRCUMSTANCES FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS MAY NOT APPLY TO YOU.

THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY ALSO HAVE OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

SPECTRA BABY USA will have no obligation under this warranty to replace this product and/or its components due to any malfunction or damage caused by accident or arising from misuse, abuse, improper maintenance, unauthorized modification, or connection to an improper power supply. Without limiting the generality of the foregoing, bending or dropping of this product or its components and visible cracking of the equipment housing will be presumed to be defects resulting from misuse or abuse. Accessories that are not expressly manufactured by SPECTRA BABY USA and intended for use with the SPECTRA WEARABLE breast pump will immediately void this warranty. A charge will be made for replacement of damaged parts.

If you wish to make a claim under this warranty, please contact the warranty team at warranty@spectrababyusa.com for instructions. You will be required to provide a proof of purchase or receipt.

13. ELECTROMAGNETIC COMPATIBILITY (EMC)

This equipment needs to be installed and put into service in accordance with the information provided in the user manual.

Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least 1.0m away from the equipment.

This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device.
-Increase the separation between the equipment.
-Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
Consult the manufacturer or field service technician for help.

Essential Performance:
Vacuum level setting: Expected value ± 50mmHg (Max. 270mmHg)
Cycle setting: Expected value ± 10%
Backflow protection: Backflow mechanism works at all stages of the pumping session whether the milk collection container is full or not.

It has been tested for immunity to electromagnetic disturbances and passed testing based on certain criteria, such as component failures, changes in programmable parameters or operating mode, cessation or interruption of any intended operation or initiation of any unintended operation.

1) Guidance and manufacturer's declaration – Electromagnetic emissions.

This equipment is intended for use in the electromagnetic environment specified below. It is the responsibility of the user of the SPECTRA WEARABLE breast pump to ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	This equipment uses RF energy only for internal function. Its RF emissions thus are very low and are not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class B	This equipment is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

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

2) Guidance and manufacturer's declaration – electromagnetic immunity

This equipment is intended for use in the electromagnetic environment specified below. It is the responsibility of the user of the SPECTRA WEARABLE breast pump to ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	Contact ± 8 kV, Air ± 2, 4, 8, 15 kV	Contact ± 8 kV, Air ± 2, 4, 8, 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100kHz repetition frequency	± 2 kV 100kHz repetition frequency	Mains power quality should be typical of a commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line(s) to line(s)	±0.5 kV, ±1 kV line(s) to line(s)	Mains power quality should be typical of a commercial or hospital environment.
Power frequency and magnetic field IEC 61000-4-8	30 A/m at 50 and 60 Hz	30 A/m at 50 and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips and interruptions 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 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0% UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be typical of a commercial or hospital environment. During a power outage, the equipment should be powered from battery or other constant, appropriate power supply.
Conducted RF IEC 61000-4-6	3 VRMS ISM & Amateur Bands 6 VRMS	3 VRMS ISM & Amateur Bands 6 VRMS	Portable and mobile RF communications equipment should be used no closer to the SPECTRA WEARABLE breast pump (including cables) than the recommended separation distance (d), based on the following equations: $d = [3.5/V1]\sqrt{P}$ for 150 KHz – 80 MHz $d = [3.5/E1]\sqrt{P}$ for 80 MHz – 800 MHz $d = [7/E1]\sqrt{P}$ for 80 MHz – 2.7 GHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2700 MHz	10 V/m 80 MHz – 2700 MHz	

			P is maximum output power rating of the transmitter in watts. d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol. 

3) Immunity to proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Modulation	Immunity Test Level (V/m)	Compliance Level
385	380-390	Pulse modulation 18 Hz, 50%	27	380-390 MHz 27 V/m; PM 18 Hz, 50%
450	430-470	FM ±5 kHz deviation 1 kHz sine	28	430-470 MHz 28 V/m; FM ±5 kHz, 1 kHz sine
710	704-787	Pulse modulation 217 Hz, 50%	9	704-787 MHz 9 V/m; PM 217 Hz, 50%
745				
780				
810	800-960	Pulse modulation 18 Hz, 50%	28	800-960 MHz 28 V/m; PM 18 Hz, 50%
870				
930				
1720	1700-1990	Pulse modulation 217 Hz, 50%	28	1700-1990 MHz 28 V/m; PM 217 Hz, 50%
1845				
1970				
2450	2400-2570	Pulse modulation 217 Hz, 50%	28	2400-2570 MHz 28 V/m; PM 217 Hz, 50%
5240	5100-5800	Pulse modulation 217 Hz, 50%	9	5100-5800 MHz 9 V/m; PM 217 Hz, 50%
5500				
5785				

a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted accurately. If you wish to use the equipment in the vicinity of fixed RF transmitters and you are uncertain about the electromagnetic environment, please consider obtain an electromagnetic site survey. If the measured field strength in the location where the equipment is being used exceeds the applicable RF compliance level above, it is the user's responsibility to verify that the equipment is operating normally. If abnormal performance is observed, additional measures, such as re-orienting or relocating the equipment, may be necessary.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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