

ardo iris

Wearable Breast Pump

Instructions for use



How-to videos in
English & Español

Instrucciones de Uso
en Español



 ardo
SWITZERLAND

Overview

Thank you for purchasing the Ardo Iris wearable breast pump.

Breast milk is the best source of nutrition for babies in the first year as recommended by doctors, and it contains antibodies that help protect your baby from infections and allergies. Using the Ardo Iris for pumping your breast milk, your baby can still enjoy the benefits of your breast milk when you are away, for example because you return to work or study.

The Ardo Iris has a soft silicone breast shell and intuitive design to make whole pumping experience more comfortable and convenient. And because the Ardo Iris is easy to assemble and small, you can take it with you anywhere, allowing you to pump at your convenience and maintain your milk supply.

Conventions used in these instructions for use



WARNING. Improper use may lead to moderate injury.



CAUTION. Improper use may lead to minor injury.



NOTE. Improper use may lead to material damage.



TIPS. Useful or important information that is not related to safety.

Please read these instructions for use carefully before using your Ardo Iris and save them for future reference. Failure to follow these instructions and safety information may lead to injury from the Ardo Iris.

1 Important safety information

1.1 Indications for use

The Ardo Iris wearable breast pump is meant to express and collect breast milk from the lactating mother's breast. The device is intended for a single user.

1.2 Safety Precautions



WARNINGS

- Do not share the Ardo Iris or its accessories with others.
Only use products or parts described in these instructions for use.
- Close supervision is necessary when the Ardo Iris is used near children.
- Do not modify the Ardo Iris yourself or attempt to open or repair the Ardo Iris or its charger.

- The Ardo Iris is not provided as sterile. Prior to first use, boil breast shell, breast shell insert, silicone diaphragm, lip valve, valve base with funnel, and outer shell. Ensure that these parts have cooled sufficiently before being assembled. Do NOT boil the pump motor.
- Do not use harsh chemicals to clean membrane, valve base with funnel, lip valve, outer shell, breast shell, membrane cap, tube, tube connector and silicone insert.
- Do not wash or immerse pump motor in water. Wipe it with clean, damp cloth only.
- Do not place pump motor in refrigerator or freezer.
- Do not store wet or damp components. Dry them thoroughly before storage.
- Do not warm up breast milk in the microwave or in hot water.
- Do not refreeze defrosted breast milk.
- Plug charger into an electrical outlet that is visible and easily accessible. To remove main power cord, unplug the power supply from the wall.
- Do not operate the Ardo Iris if the power cord or plug is damaged, wet, or submerged in water.
- Do not drop or insert any object into any openings on pump.
- Do not use the Ardo Iris in an airplane.
- Do not operate where aerosol spray products are used or oxygen is being administered.
- The Ardo Iris will not work while connected to charger; always disconnect the Ardo Iris from charger before using.
- Do not attempt to reset the Ardo Iris during use.
- Consult your healthcare practitioner to understand how long you should pump in a pumping session before using the Ardo Iris.
- Pregnant women should not use the Ardo Iris, as pumping can induce contractions or premature labor.
- 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.

1.3 Precautions

- Ensure membrane, valve base with funnel, lip valve, outer shell, breast shell, membrane cap, tube, tube connector and silicone insert are clean. Do not rinse the tubing.
- Ensure membrane, valve base with funnel, lip valve, outer shell, breast shell, membrane cap, tube, tube connector and silicone insert are securely assembled and connected to pump motor.
- Before each use visually inspect the individual components for cracks, chips, tears, discoloration or deterioration. If damage to the Ardo Iris is observed, please discontinue use until the parts have been replaced.
- If the Ardo Iris is stored at minimum temperature, please wait 2 hours before use to allow it to warm up to room temperature.

- If the Ardo Iris is stored at maximum storage temperature, please wait 2 hours before use to allow it to cool down to room temperature.
- If you feel discomfort, suction can be broken by inserting a finger between the breast and the breast shell.
- If you feel irritation or discomfort, discontinue use and see a doctor.
- If the power adapter casing or wiring becomes loose, separated, or frayed, stop using the power adapter immediately and contact the device manufacturer.
- Stop using the Ardo Iris immediately if you notice any smoke, smell, or burning from the pump unit or power adapter.
- If the package appears damaged or tampered with before use, do not use and contact the distributor of the Ardo Iris.

1.4 Contraindication

No known contraindications.

1.5 Usage & operating life

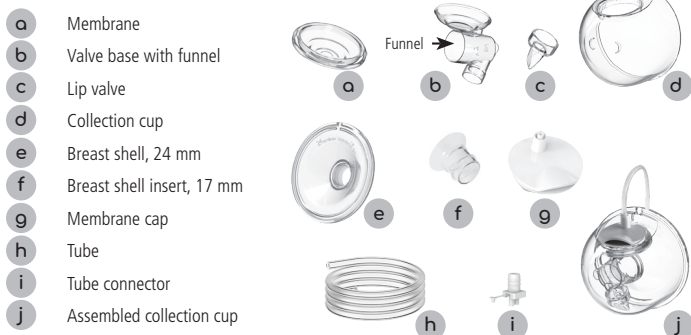
- The Ardo Iris is usable by a single user.
- The Ardo Iris has an expected operating life of 1 year
- The Ardo Iris comes with a 1-year warranty (unless indicated otherwise by your regional Ardo office).
- The membrane, valve base with funnel, lip valve, outer shell, breast shell, silicone insert and membrane cap should be cleaned prior to use.
- Replacement of the following silicone parts is recommended every 3 months or whenever they appear damaged: breast shell, breast shell insert, membrane and valve

2 Product description

2.1 Package Content

- 1 × Ardo Iris pump motor
- 2 × membrane
- 2 × valve base with funnel
- 2 × lip valve
- 2 × collection cup
- 2 × breast shell, 24 mm
- 2 × breast shell insert, 17 mm
- 2 × strap extension
- 2 × membrane cap
- 2 × tube
- 1 × tube connector
- 1 × lanyard

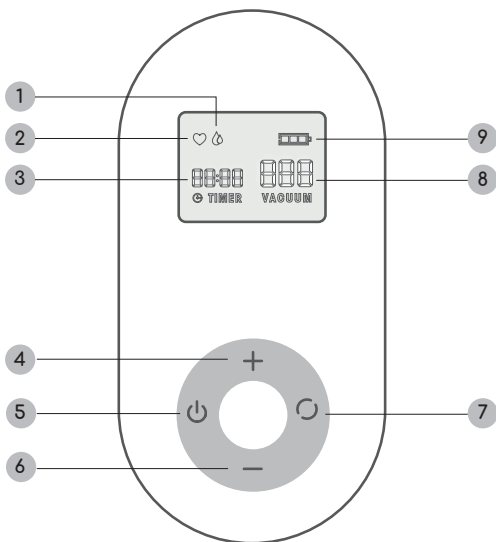
2.2 Components of the pump set



- Note: Additional breast shell sizes / inserts and spare parts are available in online shops, and in some countries also from midwives, lactation consultants, pharmacies, or drugstores. For wholesale prices contact Ardo directly.

3 Display and button functions

No.	Component Name.	Function description
1	Expression mode symbol	When Expression mode selected
2	Stimulation mode symbol	When Stimulation mode selected
3	Timing indicator	Indicate how long the pump is in use
4	Level up button	Increase suction level
5	Power Button	Power ON/OFF switch
6	Level down button	Decrease suction level
7	Mode selection button	Mode selection switch
8	Level and suction value indication	Indicate vacuum level and suction value in mmHg
9	Battery Indicator	Indicates battery status



4 Getting started

Assembling the pump set

Important: Before using for the first time and after every expressing process, wash parts a–g with water and washing-up liquid in accordance with section 10: Cleaning. Only use the pump set if it is dry. Do not wash or rinse parts h (tube) and i (tube connector).

To assemble the Ardo Iris, follow the steps below.



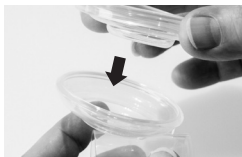
CAUTIONS

- Make sure that you clean the Ardo Iris as instructed in these instructions for use.
- Make sure that you assemble the pump correctly as instructed in these instructions for use.
- To avoid leakage, remove any residue from the edge of the outer shell and the breast shell before assembling.
- Wash your hands thoroughly before assembling cleaned components.

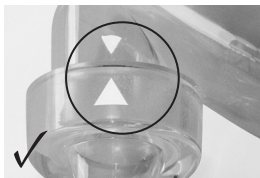
Wash hands thoroughly with soap.



Insert the membrane (a) into the valve base (b) and press in firmly.

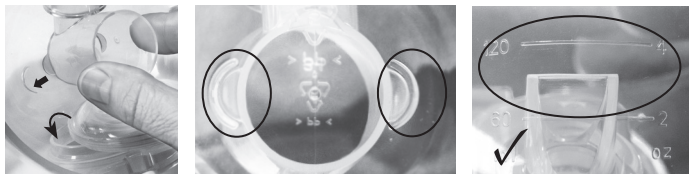


Put the lip valve (c) over the valve base (b). The arrows must line up! If they do not, Ardo Iris will not work properly!



Insert the valve base (b) into the outer shell (d). When doing so, fit the semicircular tabs of the funnel into the semicircular slots on the outer shell and firmly put the membrane (a) over the edge of the round opening of the outer shell. Now the lip valve is parallel to the lines on the outer shell, and the

valve lips are closed. The lip valve should NOT touch the inner wall of the collection cup. If it does, the arrows probably were not aligned as shown in the picture above.



Insert the breast shell (e), ensuring that the slot on the edge of the breast shell comes to rest on the slot of the outer shell (d). (This forms a spout opening for pouring the breast milk after pumping.) Put the edge of the breast shell over the edge of the outer shell and press down firmly.



Firmly press the membrane cap (g) onto the outer shell (d) as shown.



Important: To avoid accidental kinking of the tubes, which might diminish suction, the membrane caps may be turned such that the tube entries are oriented towards each other.

Connect one end of the tube (h) – the one without a tube connector – to the membrane cap (g).



Connect the other end of the tube (h) to the breast pump using the tube connector (i).



Assemble and connect the second collection cup in the same way.



WARNING:

The breast pump does not work while charging!

5 Pumping

Washing hands

Wash hands thoroughly with soap and make sure your breasts are clean.



Before pumping

Inspect the pump set to make sure it is clean before every use.

Clean the LCD display screen, power switch, and countertop with disinfectant wipes.

Relax in a comfortable chair, leaning slightly forward (use cushions to support your back).

To begin pumping

Placing the collection cup in the bra

Fasten the bra, but do not put the cups of the bra over the breast yet. Now place an assembled

collection cup on the breast. When doing so, position the nipple in the center of the funnel. Then pull the bra cup over the collection cup. Now do the same on the other side.

If necessary, adjust the size of the funnel using a breast shell insert or a different size of breast shell, see also section 6.



The collection cup should not be too snug in the bra. Loosen the bra straps or use a bra strap extension to ensure that the collection cup is positioned comfortably and effectively. If the fit is too snug, there is a risk that the breast will not be able to be fully drained or that the collection cup will tilt towards the body and the milk will not be able to flow through, which would result in a leak.



TIPS

Bra tips

Choose a bra made of stretchy material. The collection cups will usually fit into a breastfeeding bra better than into a normal bra. Some women who are breastfeeding find that a bustier or sports bra works better for them than a regular bra.

On the size of the collection cups

The amount of milk expressed varies from woman to woman. Our collection cups hold up to 6 fl.oz. (180 ml) breast milk.

Stimulation and Expression

- The stimulation mode triggers the let-down reflex and starts the flow of breast milk. It can be set at the beginning of a pumping session.
- Switch from stimulation mode to expression mode as soon as your milk begins to flow. Use the expression mode for efficient expressing of breast milk after triggering the let-down reflex.
- **As a rule, expressing is most effective at the highest vacuum level that still feels comfortable for you. You do not need to use the highest setting.** Avoid increasing the level too much, as any discomfort or pain can reduce milk flow.

Starting the Ardo Iris

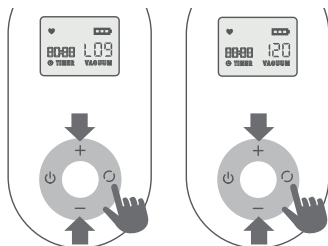
Press and hold the power button to turn on the breast pump.

a) Stimulation Mode

Press the mode selection button to enter **Stimulation Mode**. A heart icon ♥ appears on the display to indicate that the pump is in Stimulation Mode.

This mode has **9 suction levels**. Select the level that feels comfortable by pressing the **+** button to increase or the **-** button to decrease suction.

After selecting a level, the display shows the suction setting for **3 seconds** (e.g., L03 for suction level 3). After 3 seconds, the screen automatically switches to show the corresponding **vacuum value in mmHg**.

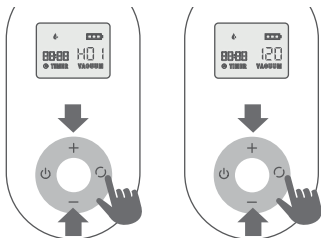


b) Expression Mode

Press the mode selection button again to switch to **Expression Mode**. A drop icon 💧 appears on the display to indicate this mode.

Expression Mode also has **9 suction levels**. Adjust the suction to your comfort by pressing the **+** or **-** button.

As in Stimulation Mode, the display shows the selected suction level for **3 seconds** (e.g., H05 for suction level 5). After 3 seconds, the screen shows the corresponding **vacuum value in mmHg**.



Timer Function

The timer starts automatically when the Ardo Iris breast pump is turned on.

After 1 second of operation, the timer shows 00:01. The timer counts in seconds.

Automatic Shut-Off

The Ardo Iris will automatically turn off after 30 minutes of continuous operation.



TIPS

- Choose a time when you are not rushed or easily interrupted.
- Having your baby or a photograph of your baby nearby increases the level of the “happiness hormone” Oxytocin which can help improve your milk flow.
- Before pumping, place a warm towel on your breast and use light manual stimulation for a few minutes. This encourages milk flow and helps avoid pain.
- Warmth and relaxation can encourage milk flow. Try pumping after a warm bath or shower.
- Try pumping from one breast while you breastfeed on the other; or continue pumping after breastfeeding your baby if you feel you have more milk.
- Repositioning the pump on the breast from time to time can help stimulate your milk flow.
- Stop the expression immediately when the expression reaches the 6 oz / 180 ml scale, and pour the breast milk into a bottle or milk storage bag to prevent overfilling and overflow. For checking look at the milk level in the outer shell in your bra.

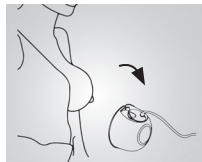
Finishing Pumping

a) When you have finished pumping, lean slightly forward while the pump is still running. This will ensure that all the milk flows out of the funnel and into the collection cup.

b) Turn off the Ardo Iris by pressing and holding the power button.

c) Removing collection cups from the bra

Carefully remove the collection cups from the bra while keeping them upright and put them down “on the back”, with the soft breast shell looking up (see picture below). Then carefully disconnect the tubes from the collection cups by holding the membrane cap (g) firmly in place.



d) Decanting the breast milk

Do not keep the expressed breast milk in the collection cups. Instead decant the milk through the spout in the collection cup into a milk bottle (e.g. Ardo Bottle Set) or a milk storage bag (e.g. Ardo Easy Store). Information on correct storage of breast milk can be found in section 7.



e) Cleaning

Clean the fully disassembled collection cups after every use and disinfect them once per day in accordance with section 10. Do NOT rinse or wash the pump motor, the tube or the tube connector.

6 The right size of breast shell

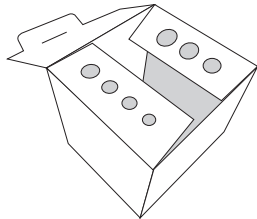
The correct breast shell size is essential for successful pumping. If the breast shell is too big or too small, this may cause sore nipples and may be painful. You should therefore use the right breast shell size or an appropriate insert to fit your breast and nipple.

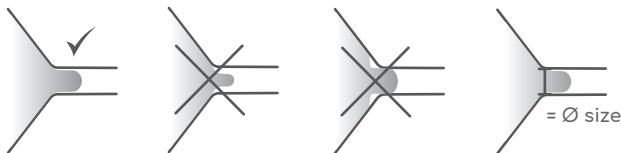
The size is right if:

- in the breast shell or insert funnel there is around 2 mm space free around the nipple.
- the nipple moves freely in the breast shell or insert funnel during pumping and can follow the rhythmic movements of the pump.
- there is no areolar tissue in the funnel.
- the milk flows and the breast feels soft all over after pumping

The side panels of the Ardo Iris retail box feature a breast shell sizing gauge for measuring nipple diameter.

Cut out the sizing gauges from the end panels and use them to measure your nipple diameter. This makes it easy to find the correct size of breast shell or breast shell insert where needed. If your nipple rubs uncomfortably against the inner side of the breast shell or insert funnel, use a larger breast shell or insert. If the areola is also sucked into the breast shell or insert funnel, use a smaller breast shell insert.





Please note that the silicone inserts of the Ardo Hands-Free Pumpset and the Ardo Melia ARE compatible with the Ardo Iris. However, silicone inserts of TRADITIONAL Ardo bottle pump sets ARE NOT compatible with the Ardo Iris pump set.

7 Storing breast milk

Keep breast milk in a suitable container, for example a milk bottle like the Ardo Bottle Set or a milk storage bag like the Ardo Easy Store. Recommended storage time:

- at room temperature: 3–4 hours at 60 – 85°F (16 – 29°C)
- in the refrigerator: 3 days at ≤ 39°F (4°C)
- in the freezer compartment: 6 months to 1 year at ≤ 0°F (17°C)



ATTENTION: Do not heat breast milk in the microwave.

8 Possible problems and troubleshooting

Weak or no vacuum:

- Ensure that the collection cups are put together correctly, particularly making sure the lip valves are inserted in the correct orientation (arrows must match up) and that the lips of the valves close.
- Check if the valves are cracked or the lips are stuck together.
- Ensure that each part of the collection cups are not damaged and the breast shell fit snugly over the collection cup.
- Ensure that the tube connector forms a tight seal.

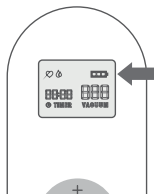
Pain when pumping:

- Ensure that the nipple is in the middle of the funnel.
- Check that the breast shell or insert size is right for your nipples.
- Check that the vacuum intensity is not set too high.
- Contact a professional for help.

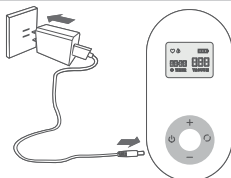
If you have problems with breastfeeding, please contact your midwife, lactation consultant or a medical specialist.

9 Charging your Ardo Iris

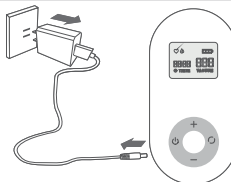
Check the battery indicator after each use of the device or before pressing the power button to turn it off. If the battery is low, charge it with the recommended charger.



Plug the charger into pump's port; plug other end of the charger into any standard electrical outlet.



Once Ardo Iris is fully charged, remove the charger from Ardo Iris and unplug it from the electrical outlet. Do not leave the wall charging block plugged in.



Battery display and charging

Battery status indicator displayed	Remaining pump time left
3 bars	minimum 120 minutes
2 bars	minimum 80 minutes
1 bar	minimum 40 minutes
Power display empty	minimum 2 minutes

Charging times

During the charging process, the display indicates the progress. As soon as three bars are constantly lit, the rechargeable battery is fully charged. Full charge takes approximately 120 minutes. Once

fully charged, the Ardo Iris is usually designed for an operating duration of at least 120 minutes. In exceptional cases, the actual running time may vary slightly depending on various factors such as usage behavior, ambient temperature, or the age of the rechargeable battery.



TIPS

- The Ardo Iris contains a rechargeable lithium-Ion battery and can be used only without a charging cable connected. The Ardo Iris cannot be operated while charging.
- The Ardo Iris has a 3-bar battery indicator. When the power is off or the charger is not connected, the battery indicator DOES NOT light up.
- When the Ardo Iris is switched off and the charger is connected, the battery indicator lights up. The battery indicator flashes whilst charging. Once charging is complete, the three bars remain lit.
- When the Ardo Iris is being operated and the charger is not connected, the battery indicator will indicate the battery level. The last bar will only start blinking if the battery level is low.
- When the Ardo Iris is being operated and the charger is connected, the pump will stop operation and begin charging to protect the device.



WARNING:

Only use the adaptor we recommend, certified DC 5V/ 1A, that meets requirement of standard IEC 60950. The adapter should be placed outside the patient environment when they are working.

10 Cleaning and disinfection

Cleaning and disinfection

Cleaning and disinfection are two separate processes. Cleaning removes any milk residue, while disinfection reduces the number of germs that may be on the surfaces of the parts. Both steps must be performed separately to guarantee hygiene for mother and child and to maintain the functionality of the Ardo Iris.

10.1 Cleaning

Before using for the first time and after every subsequent use

- Disassemble the Ardo Iris pump set into its individual parts
- Rinse the parts a–g in cold tap water for 1 minute.
- The following parts must NOT be rinsed or washed: pump motor, tubes (h), tube connector (i), lanyard.
- Then clean parts a–g using standard washing-up liquid and warm water (not over 104 °F / +40 °C).
- Rinse them using lots of clean water. Ensure that all washing-up liquid residue is removed. Be careful when cleaning the valve and the membrane. If they are damaged, there will be no vacuum or only a weak vacuum. Clean the valve between your thumb and index finger using washing-up liquid and warm water (do not use any brushes).

- Alternatively, you can clean the parts in their disassembled state (apart from the pump motor) in the dishwasher.
- Drying: Place all the parts on a clean, unused dish towel or paper towel and leave them to air dry thoroughly in a clean place.

Clean in dishwasher

Clean pump parts in a dishwasher, be sure to place small items into a closed-top basket or mesh laundry bag. Add soap and if possible, run the dishwasher using hot water and a heated drying cycle. Remove from dishwasher with clean hands. If items are not completely dry, place items on a clean, unused dish towel or paper towel to air-dry thoroughly before storing. Do not use a dish towel to rub or pat items dry.

10.2 Disinfection

Before using for the first time and 1× daily after cleaning

- Place the pump set **parts a–f**, disassembled, in a pan of water and boil them for 5 minutes (no longer, otherwise they may be damaged). The following parts must NOT be boiled: membrane cap (g), tubes (h), tube connector (i).
- Make sure there is enough water in the pot in order to prevent damage/ deformation.
- Allow the parts to cool down and dry on a clean surface. Only assemble the pump set once all the parts are completely dry.
- Check the individual parts for cracks and changes to the surface according to the cleaning and disinfection process. If you discover any changes, dispose of the part affected and replace with a new one.

Important notice regarding disinfection: It has been demonstrated that sterilization programs on steamers can damage the parts. Please therefore do not use any steamers to disinfect components.

Pump motor: Do not rinse or submerge the pump motor in water. If needed, wipe with a clean cloth moistened with 70% alcohol (ethanol or isopropanol).



TIPS

- Silicone can discolor quickly. Avoid contact with staining substances (e.g. carrot juice, tomato sauce), including in a dishwasher.
- If you are in a hard water area, limescale deposits can build up on pump parts after several cleaning and disinfection cycles, causing parts to look cloudy. This can be prevented or removed by adding a few drops of lemon juice to the water when disinfecting parts.

Materials:

- Polypropylene (PP): outer shell, valve base: dishwasher-safe and sterilizable, e.g. in Ardo Easy Clean
- Silicone: breast shell, insert, lip valve, membrane: dishwasher-safe and sterilizable, e.g. in Ardo Easy Clean.

**WARNINGS:**

- Take care when removing and cleaning the lip valve, as the Ardo Iris will no longer work correctly if it is damaged.
- To clean the lip valve, please rub it gently in warm water with a couple of drops of dish soap. Do not put any objects into the lip valve, as this may lead to damage. Do not clean the lip valve with a washing-up brush or similar utensils.
- The motor unit must NOT be rinsed or immersed in water. It must also not be cleaned by hand or in the dishwasher. If necessary, wipe with a clean cloth moistened with 70% alcohol (ethanol or isopropanol).
- The tubes, the tube connector and the lanyard must NOT be rinsed or immersed in water.
- Do not use harsh chemicals to clean membrane, valve base with funnel, lip valve, outer shell, breast shell, membrane cap, tube, tube connector and silicone insert.
- Do not store wet or damp parts.

11 Warranty

There are legally prescribed minimum warranty periods from the date of purchase that are specific for each country. The warranty coverage is limited to the first purchaser.

11.1 General terms and conditions

Ardo medical AG guarantees that its products are free of material and manufacturing defects.

The warranty period starts from the date of purchase. Defective materials are replaced during the warranty period free of charge, provided that the warranty has not been voided by improper use or access to the device. To ensure the warranty coverage and flawless function of the device, the instructions for use must be followed and only Ardo accessories used. The warranty is void if the device has been opened or manipulated.

12 Technical information

Technical specifications

- Home or office use
- No prescription necessary: over-the counter and retail sale.
- Pump dimensions: 140 x 70 x 35 mm
- Package dimensions: 140 x 165 x 165 mm
- Weight: 187 g
- Milk collector capacity: 180 ml / 6 fl. oz
- Single user device (personal breast pump)
- Provided non-sterile
- Re-usable
- Pump option: Double, but use as single pump possible.
- Pump type: diaphragm pump
- Vacuum range: Stimulation: Single pumping: 40-120 mmHg / Double pumping: 40-120 mmHg.
Expression: Single pumping: 120-245 mm Hg / Double pumping: 120-245 mmHg
- Cycle speed: Stimulation: Single pumping: 45-51 cycles/minute / Double pumping: 38-45 cycles/minute. Expression: Single pumping: 22-40 cycles/minute / Double pumping: 19-34 cycles/minute
- 9 adjustable suction levels
- LCD display
- Automatically turn-off after 30 minutes

Power requirements

Only use a charger recommended as below:

- Power Supply:
 - o Charged power: 5V DC by adapter (UL-listed or UL-certified; not included)
 - o Operating power: internal rechargeable lithium-ion polymer battery
- Charger specifications:
 - o Adapter input: 100-240 Vac, 50-60Hz, 0.4A-0.2A
 - o Adapter output: 5V DC, 1A

Operating conditions

- Ambient temperature: 41–104 °F (5–40 °C)
- Relative humidity: 15–90% (non-condensing)
- Air pressure: 90–106 kPa

Transport and storage conditions

- Transport and storage temperature: -4 °F to 140 °F (-20 to 60 °C)
- Relative humidity: 15–90% (non-condensing)
- Air pressure: 70–106 kPa

EMC Declaration

- The Ardo Iris may be used at home, office, or other general areas.
- Special consideration should be given to use
 - o during medical procedures: Do not use the Pump during any medical procedure or during imaging. For example, do not use pump during RF ablation of a skin anomaly, x-ray, MRI, or ultrasound.
 - o with other equipment: 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, the pump and the other equipment should be observed to verify that they are operating normally.
 - o in high electrostatic discharge environments: If the air is very dry, use the pump where floors are wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. If you notice shocks when you touch things, as sometimes happens in very dry winter months, be sure to touch a metal item such as a table before handling the pump.
 - o in industrial settings: avoid using the pump near arc welding equipment, radar installations, and similar industrial settings.
 - o near RF emitters: Keep devices that use Wi-Fi, Bluetooth, and other international RF emitters at least 30 cm from the pump during operation. This includes communications equipment peripherals such as antenna cables and external antennas. Otherwise, degradation of the performance of the pump could result.
- If you know the power output the RF emitter, the table labeled "Electromagnetic Compatibility Compliance Statement Information" can be used for more precise information about separation distances.



WARNING

- Use of accessories other than those specified by us may result in increased emissions or decreased immunity of the Ardo Iris.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - o This device may not cause harmful interference, and;
 - o 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.

Guidance and manufacturer's declaration - electromagnetic immunity

Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC 61000-4-6	Not applicable	Not applicable
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz
NOTE U_T is the a.c. mains voltage prior to application of test level.		

13 Disposal information

The pump motor contains a rechargeable lithium-ion battery. Use your local return and collection system for electrical waste and electronic equipment (including batteries).

The other parts should be disposed of in your home's waste management container.



WARNINGS

- This device should not be used in the vicinity or on the top of other electronic equipment such as cell phones, transceivers or radio control products. If you have to do so, the device should be observed to verify normal operation.
- The use of accessories and power cords other than those specified, except for cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

14 Symbol definitions

The warning symbol identifies all instructions that are important for safety. Failure to observe these instructions can lead to injury or damage to the breast pump! When used in conjunction with the following words, the warning symbol stands for:

Pump control buttons

Button symbol	Function description
	On/off
	Stimulation/expression
	Level down = decrease suction level
	Level up = increase suction level

Symbols on the packaging

Symbol	Definition
	FSC Mix Label: Information about the origin of the packaging material.
	Indicates the material from which an item is made.
	Keep the device dry.
	Keep the device away from sunlight.
	Keep out of reach of children.
	Temperature limitation for operation, transport and storage
	Humidity limitation for operation, transport and storage.
	Atmospheric pressure limitation for operation, transport and storage.

Symbols on the device

Symbol	Definition
	Read and follow the instructions for use.
	Indicates compliance with international requirements for protection from electric shock (Type BF applied parts.).
IP22	Indicates direct current
	Indicates the distributor

Guidance and manufacturer's declaration - electromagnetic Immunity

Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service
	385	380-390	TETRA 400
	450	430-470	GMRS 460, FRS 460
	710	704-787	LTE Band 13, 17
	745		
	780		
	810	800-960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5
	870		
	930		
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS
	1845		
	1970		
	2450	2400-2570	Bluetooth, WLAN
	5240	5100-5800	WLAN 802.11 a/n
	5500		
	5785		

Modulation	Maximum Power (W)	Distance (m)	IEC 60001-1-2 Test Level (V/m)	Compliance level (V/m)
Pulse modulation 18 Hz	1.8	0.3	27	27
FM $\pm$ 5 kHz deviation 1 kHz sine	2	0.3	28	28
Pulse modulation 217 Hz	0.2	0.3	9	9
Pulse modulation 18 Hz	2	0.3	28	28
Pulse modulation 217 Hz	2	0.3	28	28
Pulse modulation 217 Hz	2	0.3	28	28
Pulse modulation 217 Hz	0.2	0.3	9	9

15 Emissions and immunity tests

ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration - electromagnetic emissions

Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable

Notes

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