

# **Symphony**®

- Breast pump for healthcare professionals Instructions for use
- 吸乳器 适用于专业的健康顾问 使用说明书



EN 4–37

ZH 38–75

# 1. Important safety information

Any serious incident that has occurred in relation to the Symphony breast pump should be reported to Medela AG and the relevant Competent Authority.



Please read all instructions before using this product. Keep these instructions for future reference.

Warnings identify all instructions that are important for safety. Failure to observe these instructions can lead to personal injury or damage to the product.

The following symbols and signal words show the significance of the warnings:

<b>⚠ WARNING</b>	Can lead to serious injury or death.
<b>⚠ CAUTION</b>	Can lead to minor injury.
NOTICE	Can lead to material damage (not related to personal injury).
i Information	Useful or important information that is not related to safety.

#### **MARNING**

To reduce the risk of electric shock:

- Plug the power cord into the breast pump first and then into the wall socket.
- Keep the device dry. Never immerse in water or other liquids.
- Do not spray or pour liquid directly onto the pump unit.
- Do not place or store the device where it can fall or be pulled into a sink or tub.
- Do not use the Symphony breast pump while bathing or showering.
- Do not reach for any electrical device if it has fallen into water. Unplug immediately.

#### **MARNING**

To avoid fire, electric shock or serious burns:

- The Symphony breast pump is not heat-resistant: keep away from radiators and open flames.
- Do not expose the pump unit to direct sunlight.
- Do not operate the Symphony breast pump where aerosol (spray) products are being used or where oxygen is being administered.
- Do not use the device in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.
- Do not thaw frozen breast milk, or do not warm breast milk in a microwave or in a pan of boiling water. Microwaving can cause severe burns to the baby's mouth from hot spots that develop in the milk during microwaving. Microwaving can also change the composition of breast milk.
- Only use the power cord that comes with the Symphony breast pump.
- Never operate an electrical device if it has a damaged power cord, if it is not working properly, if it has been dropped or damaged, or dropped into water.
- Always inspect power cord wires prior to use for damage or exposed wire. If any damage is found, immediately stop using the power cord. Contact the local Medela representative.
- The Symphony breast pump should never be left unattended when plugged into a power source.
- Separation from the mains is only assured by disconnecting the power cord from the wall socket.
- Position the pump unit such that it is easy to disconnect the power cord from the wall socket.
- Keep the power cord away from heated surfaces.

# Important safety information (cont.)

#### **⚠ WARNING**

To avoid health risk and reduce risk of injury:

- Do not continue pumping for more than two consecutive pumping sessions if no results are achieved.
- If problems or pain occur, consult a lactation consultant or breastfeeding specialist.
- Never use while pregnant, unless prescribed/advised by a physician, as pumping can induce labour.
- For mothers who are infected with Hepatitis B, Hepatitis C or Human Immuno-deficiency Virus (HIV): pumping breast milk will not reduce or remove the risk of transmitting the virus to the baby through breast milk.
- Inspect all components of the Symphony breast pump as well as all parts of the pump set(s) before each use.
- Never use a device, components or parts that are damaged.
- Never use a device, components or parts if dirt, mould or other contamination is visible.
- Replace mouldy, damaged or worn parts.
- There are no user-serviceable parts inside the Symphony pump unit. Repairs must only be performed by an authorised service agency. Do not attempt to repair the pump or parts by yourself.
- Only use the Symphony breast pump for its intended use as described in these instructions for use.
- Only use Medela original accessories.
- $\bullet$  Do not modify any parts of the pump or the pump set.
- $\bullet\,\mbox{Do}$  not use the Symphony breast pump while operating a motor vehicle.
- Do not drive whilst hands-free pumping.
- Never drop or insert any object into any opening or tubing.
- Do not use outdoors.
- Supervision is necessary when the Symphony breast pump is used in the vicinity of children.
- Portable and mobile radio frequency communications equipment can affect the Symphony breast pump.
- The Symphony breast pump needs special precautions regarding EMC (Electro Magnetic Compatibility). Install and put into service according to the EMC information provided in these instructions for use.

#### **A** CAUTION

To avoid risk of contamination:

- Wash hands thoroughly with soap and water before touching the breast pump, the pump set(s) and breasts. Avoid touching the inside of containers or lids.
- Do not use the Symphony breast pump while sleeping or overly drowsy.
- Only use drinking-quality tap or bottled water for cleaning.
- Do not store wet or damp parts as mould may develop.

To avoid health risk and reduce risk of injury:

- Only pump with the breast pump in an upright position.
- Pressing shields too firmly onto the breasts may affect the milk flow.
- Do not express with a vacuum that is too high and uncomfortable (painful). Pain, along with potential breast and nipple trauma, may decrease the milk output.
- Do not attempt to remove the breast shield from the breast while pumping. Turn the breast pump off and break the seal between the breast and the breast shield with a finger, then remove the breast shield from the breast.
- If pumping is uncomfortable or causing pain, turn the unit off, break the seal between breast and breast shield with a finger and remove the breast shield from the breast.
- Do not shorten the tubing between breast shield and pump.
- Do not use abrasive washing-up liquids/detergents when cleaning the breast pump, pump components or pump set parts.
- Never put the pump unit in water or in a steriliser, as this can cause permanent damage to the breast pump.
- Do not use Medela Symphony pump sets with non-compatible breast pumps.
- Do not use the Medela Symphony pump sets for any other purpose than expressing breast milk.

#### NOTICE

- Plastic bottles and component parts become brittle when frozen and may break when dropped.
- Also, bottles and component parts may become damaged if mishandled, e.g. dropped, over-tightened, or knocked over.
- Take appropriate care in handling bottles and components.
- Do not use the breast milk if bottles or components show signs of damage.

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#### 2. Intended use/indications

#### 2.1 Intended purpose

The Symphony breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts.

#### 2.2 Indications for use

The Symphony breast pump is indicated to express and collect milk from the breasts of a lactating woman. It is also indicated to initiate, build and maintain a mother's milk supply to support the provision of human milk for infants who are not able to directly or effectively breastfeed (e.g. latch-on problems such as flat or inverted nipples, cleft palate and prematurity). The breast pump removes milk from affected breast/s to alleviate the symptoms of engorgement and milk stasis as well as support the healing process of sore or cracked nipples and mastitis.

#### 2.3 Contraindications

There are no known contraindications for the Symphony breast pump.

# 3. Product description

#### 3.1 Symphony hospital breast pump and accessories

Medela's Symphony hospital-grade breast pump is a multi-user breast pump with research-based pumping programs which were developed specifically to support mothers of preterm and term infants to initiate, build and maintain an adequate milk production.

For adequate initiation and building of milk supply, the breasts should be drained

- early: within 1-3 hours after birth
- frequently: every 2 -3 hours
- effectively: baby with a healthy sucking behaviour or double pumping.

It is recommended to record the date, time and volumes pumped.

The Symphony breast pump is provided with the Symphony PLUS program card, which contains two pump suction pattern programs.



#### The INITIATE program with Medela's initiation technology

The INITIATE program mimics the irregular and more rapid sucking and pausing pattern of a term born infant in the first few days of lactation. This program is intended for use in the first few days after birth before secretory activation to support pump-dependent mothers to initiate milk production.



The MAINTAIN program with Medela's 2-Phase Expression technology
The MAINTAIN program mimics the term born infant's sucking pattern during
established lactation. This program is designed to optimise milk output after
secretory activation to support all mothers to build and maintain lactation.

In some cases, the Symphony breast pump is provided with the Standard program card. This program card contains the MAINTAIN program. While the Standard card can be used to initiate lactation, Medela recommends using the INITIATE program of the Symphony PLUS program card.

#### Required accessories

Only operate the Symphony breast pump with Medela pump sets and milk bottles. Pump sets and bottles are available as reusable or as disposable products.

#### Reusable products:

Symphony Hospital Multibox (25 reusable pump sets in sizes S or M).

#### Disposable products:

Medela's disposable products are intended for single-use or one-day use in hospitals, without a need for cleaning prior to first use:



Medela's Ready-to-Use products are hygienically safe to use without prior cleaning, for all hospitals where the use of non-sterile products is allowed.



Medela's sterile products are EO sterile and fulfil the EN/ISO standards for medical devices ISO 11607-1, ISO 11607-2, ISO 11135.

# **Product description (cont.)**

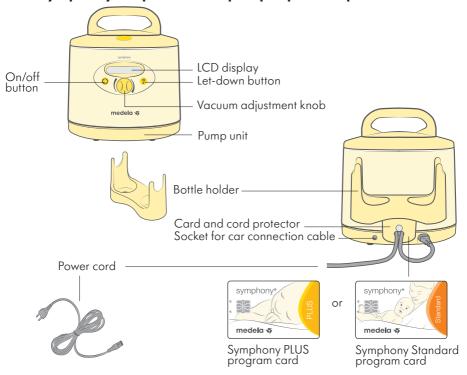
#### Available disposable products:

- Sterile single-use Symphony Pump Set (size S, M, L or XL).
- Ready-to-Use one-day Symphony Pump Set (size S, M, L or XL).
- Colostrum container (35 ml)
- Sterile single-use bottle (available sizes: 80, 150 and 250 ml)
- Ready-to-Use single-use bottle (available sizes: 80, 150 and 250 ml)

#### Optional accessories and other products to be used in combination

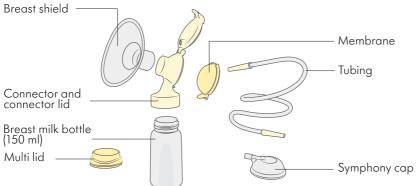
Mobile stand for the breast pump, hard case for the pump unit, card and cord protector.

#### 3.2 Symphony hospital breast pump – product parts



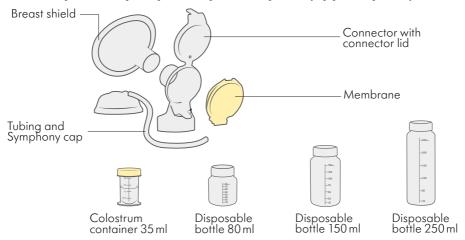
Accessories available for order can be found in **chapter 11**. Articles may not be available in all countries. For further information about Medela products, visit www.medela.com and look for location finder.

#### 3.3 Reusable pump set – product parts (applied parts)



Symphony reusable pump sets are available with different size breast shields.

#### 3.4 Disposable pump set – product parts (applied parts)



Symphony disposable pump sets are available with different size breast shields.

#### **i** Information

All pictures shown are for illustration purpose only. Actual product may vary due to product enhancement. Refer to the instructions for use provided with the Symphony pump sets for product description and instruction on handling.

See **chapter 11** for ordering information.

#### **A** CAUTION

- Unplug the breast pump before cleaning.
- These recommendations are not substitutes for official hospital procedures that may differ among institutions. Refer to hospital policy for cleaning of shared capital equipment.
- In the event of conflicting national cleaning and disinfection requirements, these shall prevail over the Medela recommendations.
- Surface disinfectant agents for medical devices will not cause mechanical damage to the Symphony breast pump.
- Follow the instructions provided by the supplier of the surface disinfectant agent.
- Provide personal protection for operators in accordance with the supplier's instructions and safety data sheets.
- Check the suitability of the surface disinfectant agents for medical devices by reference to the supplier's information and/or physical testing.

#### 4.1 Breast pump – cleaning and disinfection

Clean and disinfect the breast pump as needed.



1. To clean the breast pump, wipe the pump housing with a clean, damp (not wet) cloth. Drinking-quality water and a basic washing-up liquid or non-abrasive detergent may be used.



 To disinfect the pump, wipe the pump housing with a clean, damp (not wet) cloth that is impregnated with a surface disinfectant agent for medical devices. Medela recommends using an alcohol-based surface disinfectant agent.

#### 4.2 Cleaning pump sets

Refer to the instructions for use provided with the Symphony pump sets for product description and instruction on handling.

# 5. Preparing for pumping

#### **MARNING**

- Only use the power cord that comes with the Symphony breast pump.
- Make sure the voltage of the power cord is compatible with the power source.

#### **i** Information

#### Optional for pump with battery:

- The built-in battery must be charged for 12 hours on receipt of the device.
- The pump can be used during charging.
- If the pump is to remain unused for a long time, charge the battery every two months (for 12 hours each time).
- The optimum service life of the battery is achieved if it is not fully discharged on a regular basis or if the pump is charged while not in use

#### Pumping time (fully charged battery):

approx. 60 minutes

#### Charging time (for full charge):

12 hours

#### 5.1 Installation of the program card



- The program card must be inserted in the card compartment on the back of the breast pump.
- → For more information on the use of the program card and the selection of the appropriate program, see section 6.2.

#### 5.2 Installation of the card and cord protector (optional)



- 1. Insert the cord into the card and cord protector in a loop around the pin.
- → Ensure that there is sufficient cord length to insert the power cord into the power socket in the back of the pump.

# Preparing for pumping (cont.)



**2.** Push the card and cord protector over the guide rail on the back until it stops and tighten the screw.



**3.** To remove, unscrew the card and cord protector and slide out of the guide rail.

#### 5.3 Mains operation



1. Insert the power cord into the power socket on the back of the pump.



2. Plug the power cord into the mains socket.

#### 5.4 Assembling the Symphony pump set

#### **A** CAUTION

- Wash hands thoroughly (at least one minute) with soap and water before touching the breast, the clean pump and the clean pump set parts.
- $\bullet$  Dry your hands with a fresh towel or a single-use paper towel.

#### NOTICE

- Use Medela original accessories only.
- Refer to instructions for use provided with the Symphony pump set for description and instruction on handling the pump set.
- Check pump set parts for wear or damage before use. Replace damaged or worn parts.
- All parts must be completely dry before use.



- 1. Carefully assemble the Symphony pump set according to the instructions for use provided with the pump set.
- Screw a bottle into the connector. Use a bottle according to the individual needs (various bottle sizes available).

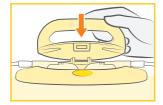
#### 5.5 Connecting the pump set to the pump housing



1. Open the lid of the breast pump: Press the oval button on the top of the Symphony pump and lift the handle.



- Position the Symphony cap firmly on the breast pump membrane to form a seal.
- → Make sure that the Symphony cap engages and lies flush to the surface.
- **3.** Centre the tubing connector in the recess in the pump housing.



#### **i** Information

Always close the lid when pumping. The lid keeps the membrane cap pushed down to prevent a loss of vacuum that could occur if the membrane cap came off.

4. Close the lid.

# 6. Expression

#### 6.1 Selecting the correct Medela breast shield size

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

#### Understanding Medela's breast shield sizing

Pumping should not hurt. For maximum comfort and pumping efficiency, Medela offers five breast shield sizes.

This guide is a starting point to help determine the optimal size based on the 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). Do not include the areola.

#### • Step 2

Based on the measurement, determine the Medela breast shield size.

Example: If the nipple size measures 16 mm in diameter, the recommended Medela breast shield size is 21 mm

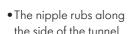


See chapter 11 for ordering information.

#### Optimising the breast shield size

- Centre the nipple and gently hold the breast shield against the breast.
- Adjust for Maximum Comfort Vacuum to achieve optimum suction level.
- Refer to the images below while pumping in the expression phase (after the stimulation phase).





• Try a larger size.



• The nipple is centred and moves freely.



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

#### Reasons for trying a new size

- If the nipple rubs against the tunnel sides to the point of causing discomfort.
- If excessive areola is being pulled into the tunnel.
- If there is any redness.
- If the nipple or areola is turning white.
- If the mother feels unexpressed milk after pumping.
- As levels of tissue edema subside post birth.

If any of these conditions occur, consider trying a different size by following the measuring instructions above.

#### 6.2 Selecting the right program

The Symphony breast pump is installed with the Symphony PLUS program card, which contains two pump programs.

The goal of the INITIATE program is to initiate milk production. The MAINTAIN program is designed to build and maintain milk production.

Until secretory activation (milk 'coming in') or a maximum of 5 days:

# **Use the INITIATE program from birth** until secretory activation has occurred, as indicated by:

 Pumping 20 mL or more from both breasts combined, during one pumping session.

OR

 Physiological markers, such as breast fullness.

If secretory activation has not occurred after 5 completed days, switch to the MAINTAIN program.

After secretory activation (milk 'coming in') or from day 6:

# Use the MAINTAIN program after secretory activation has occurred, as indicated by:

 Pumping 20 mL or more from both breasts combined, during one pumping session.

OR

 Physiological markers, such as breast fullness.

 $\bigcirc R$ 

• From day 6, whichever comes first.

For more detailed information on the program card refer to the card's instructions for use.

#### 6.3 Operation: INITIATE program

#### **A** CAUTION

• Wash hands thoroughly (at least one minute) with soap and water before touching the breast, the clean pump and the clean pump set parts. Dry your hands with a fresh towel or a single-use paper towel.



- 1. Press the on/off button ( ) to switch on the breast pump.
- → The display text shows "INITIATE press •".



- 2. Press the "Let-down" button 😯 within ten seconds.
- → The display text will change to "INITIATE running".



- 3. Set the maximum comfort vacuum (see section 6.5).
- → The bullets on the display show the vacuum level. The more bullets, the stronger the vacuum.



- **4.** The INITIATE program runs automatically for 15 minutes with stimulation, expression and pause phases.
- → An acoustic signal indicates the end of the program. The display shows "Program complete". The pump switches off automatically.

It is important to complete the entire INITIATE program.

#### **NOTICE**

• Always disconnect the Symphony breast pump from the power source after expression.

#### 6.4 Operation: MAINTAIN program

#### **A** CAUTION

• Wash hands thoroughly (at least one minute) with soap and water before touching the breast, the clean pump and the clean pump set parts. Dry your hands with a fresh towel or a single-use paper towel.

#### **i** Information

• If the pump has been running for 30 minutes without any manipulations (e.g. adjustment of the vacuum), the Symphony breast pump will automatically switch off.



- 1. Press the On/off button 🔘 to switch on the breast pump.
- → The MAINTAIN program will automatically start with the stimulation phase after pressing the On/off button.



- 2. Set the maximum comfort vacuum (see section 6.5).
- → The drops on the display show the vacuum level. The more drops, the stronger the vacuum.



- 3. The pump will automatically switch to the expression phase after two minutes.
- **4.** If the milk starts to flow sooner, press the Let-down button \$\foatin \text{ to change to the expression phase.}



- 5. Set the maximum comfort vacuum (see section 6.5).
- → The bars on the display show the vacuum level. The more bars, the stronger the vacuum.



- 6. Continue pumping until the breast feels well drained and soft all over (Medela recommends a pumping time of at least 15 minutes).
- 7. Switch off the pump by pressing the on/off button ().



#### i Information

• Press the "Let-down" button 🕏 to revert from the expression phase to the stimulation phase if necessary. If milk has not begun to flow after two successive stimulation phases, the mother should take a break and try again in 15 to 30 minutes. Also, she could try breast massage and then pump using the expression phase.

#### **NOTICE**

• Always disconnect the Symphony breast pump from the power source after expression.

#### 6.5 Set maximum comfort vacuum



Set the maximum comfort vacuum by rotating the vacuum adjustment knob.

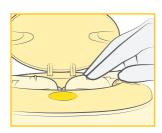
- 1. First rotate to the right to increase the vacuum until there is a slight discomfort.
- Then rotate to the left to reduce the vacuum until it is comfortable.

#### 6.6 Expression by single pumping

#### **i** Information

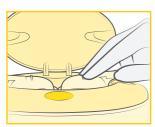
Medela recommends double pumping.

- Double pumping saves time and increases the energy content of milk. Milk production may be increased and maintained long term.
- For single pumping, step **7** of **section 6.7** can be ommitted.
- Do not kink the tubing during expression.



- 1. Prepare one bottle and pump set for expression.
- Mount only one Symphony cap on the breast pump (see section 5.5).
- **3.** Continue as described in **section 6.7 step 3** for double pumping.

#### 6.7 Expression by double pumping



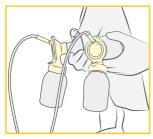
- 1. Prepare two bottles and pump sets for expression.
- **2.** Mount the Symphony caps on the breast pump (see **section 5.5**).



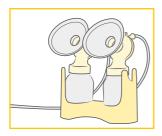
- **3.** Place the breast shield on the breast so that the nipple is properly centred in the tunnel.
- **4.** Hold the breast shield onto the breast with the thumb and index finger. Support the breast with the palm of the hand.



- **5.** Switch the breast pump on with O.
- 6. Proceed with the program selection (see sections 6.2, 6.3 and 6.4).



- 7. Place the breast shield of the second bottle on the other breast so that the nipple is properly centred in the tunnel.
- **8.** Operate the pump as appropriate for the selected program (see **sections 6.3** and **6.4**).



**9.** When expression is finished, place the bottles in the stand or bottle holder in order to prevent the bottles from tipping over.



10. Close the bottles with the lid.

# 7. Storing and thawing breast milk

#### 7.1 Storage and thawing guidelines

Use of a medical grade refrigerator with temperature uniformity and constant temperature monitoring is recommended.

Refer to www.medela.com for a recommendation on storing and thawing of breast milk. You can contact your local customer service in order to get a printed version if requested.

# 8. Troubleshooting and error codes

# 8.1 Troubleshooting

Problem	Solution
If the motor is not running	Check whether mains power/battery is available. Check that the device is switched on. Check whether program card is inserted correctly in the card compartment on the back of the breast pump.
If there is low or no suction	Assemble the pump set in accordance with the instructions in section 5.4.  Check whether all connections to the pump set and breast pump are secure.  Express in accordance with chapter 6. Make sure that the breast shield forms a complete seal around the breast.  Check that the pump set components are clean and not damaged.  Check that the pump set is correctly assembled according to section 5.4 and 5.5:  Check that the ends of the tubing are firmly connected.  Do not kink or trap the tubing during expression.  All components must be completely dry prior to pumping.
If there is an overflow	<ul> <li>Place the pump set into the bottle holder.</li> <li>Turn off the pump and unplug the power cord from the socket.</li> <li>Use a damp (not wet) cloth to wipe the pump and membrane area.</li> <li>If there is milk, condensation or visible residues in the tubing: For disposable pump set: Dispose of the pump set and replace with a new one.</li> <li>For reusable pump set: Dispose of the silicone tubing and replace with a new one. Reprocess the remaining parts according to section 4.2.</li> <li>When components are completely dry, reassemble breast pump and accessories set.</li> </ul>

# Troubleshooting and error codes (cont.)

#### 8.2 Error codes

The following table describes error codes that may be displayed indicating an issue with the unit, potential causes, and steps to correct the issue.

Display	Potential issues	Actions
Invalid card	Program card is not a Symphony card Program was inserted incorrectly	<ul> <li>Check if the correct program card is being used</li> <li>Make sure that the card is positioned correctly</li> </ul>
	Program card is damaged and not working	Replace program card
No card	Program card is not inserted Program card is not completely inserted	<ul><li>Insert program card</li><li>Push card all the way in</li></ul>
Battery low	Battery needs charging soon, will beep every 20 seconds (15 minutes of pumping time remaining from when the indication started)	<ul> <li>Make sure that the power cord is plugged into the back of the pump</li> </ul>
Motor overload	Motor is drawing too much current	<ul> <li>Contact your local Medela representative if this happens repeatedly</li> </ul>
Error	Potential fault in electronics of gear control	<ul> <li>Contact your local Medela representative if this happens repeatedly</li> </ul>
Power fault	Potential fault in electronics of power supply	<ul> <li>Contact your local Medela representative if this happens repeatedly</li> </ul>

# 9. Warranty and maintenance

#### Warranty

Three-year warranty for the unit from the date of purchase, excluding pump set and accessories. Six month warranty for the batteries. The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage or use by unauthorised persons. Routine checks, servicing and battery exchange may only be carried out by Medela-authorised personnel.

#### **Electical safety**

The engineering of the Medela Symphony breast pump has been verified by independent test institutes for compliance with the EN/IEC 60601-1 standard. Copies of such certificates may be obtained upon request. Because of the method of construction used, Medela does not expect electrical safety to be affected at any time during the life of the product – provided that it is used properly in accordance with the intended use as well as these instructions for use, and that the device is serviced and repaired at authorised service centres. There are no prescribed or recommended electrical safety checks or recurrent tests to be carried out.

Manufacturer's information provided in accordance with EN/IEC 62353:2014 "Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment".

#### Maintenance

Besides the cleaning procedure(s) described in **chapter 4** and battery charging for pumps with optional batteries as described in **chapter 5**, there is no further maintenance required. Besides the inspection procedures described in **chapter 1**, e.g. visual signs of damage on pump or power cord, pump dropped or dropped into water, there are no further inspections required. As pointed out in **chapter 1**, service and repair must be performed only by an authorised service agency (centre) in full accordance with the Symphony Service Manual using original Medela spare parts mentioned therein. The service manual, wiring diagrams, and descriptions are available upon request from Medela.

Medela deems that the final production testing replaces on-site testing of the device before putting into service.

The service life of the device is seven years, internal batteries life included.

The service life of the accessories is two years.

#### Disposal of electrical and electronic equipment

The Symphony breast pump is made of metals and plastics and should be disposed of in accordance with the European directives 2011/65/EU and 2012/19/EU. Additionally, local guidelines must also be observed. With the AC/DC versions, the electronic components and the rechargeable battery must be disposed of separately, in accordance with the local regulations. Please take care that you dispose of the Symphony and its accessories in accordance with your local disposal guidelines.

# User information for the disposal of electrical and electronic equipment This symbol means that the electrical and electronic equipment must not be disposed of together with unsorted municipal waste. Correct disposal of this device protects and prevents possible damage to the environment or human health. For more information about the disposal contact the manufacturer, your local caregiver or healthcare provider. This symbol is only valid in the European Union. Please respect the relevant state laws and rules in your country for the disposal of electrical and electronic equipment.

# 11. Accessories list

#### Symphony PLUS program card

Article number	Product
200.9186	Symphony PLUS program card English
200.9187	Symphony PLUS program card German
200.9188	Symphony PLUS program card French
200.9189	Symphony PLUS program card Dutch
200.9190	Symphony PLUS program card Spanish
200.9191	Symphony PLUS program card Italian
200.9192	Symphony PLUS program card Portuguese
200.9193	Symphony PLUS program card Swedish
200.9194	Symphony PLUS program card Norwegian
200.9195	Symphony PLUS program card Danish
200.9196	Symphony PLUS program card Finnish
200.9197	Symphony PLUS program card Polish
200.9198	Symphony PLUS program card Japanese

#### Symphony Standard program card

Article number	Product
800.0540	Symphony Standard program card German
800.0541	Symphony Standard program card English
800.0542	Symphony Standard program card French
800.0543	Symphony Standard program card Italian
800.0544	Symphony Standard program card Dutch
800.0545	Symphony Standard program card Swedish
800.0546	Symphony Standard program card Danish
800.0547	Symphony Standard program card Finnish
800.0548	Symphony Standard program card Norwegian
800.0549	Symphony Standard program card Polish
800.0550	Symphony Standard program card Spanish
800.0551	Symphony Standard program card Portuguese
800.0552	Symphony Standard program card Greek
800.0553	Symphony Standard program card Hungarian
800.0554	Symphony Standard program card Czech

Articles may not be available in all countries. For further information about Medela products, visit www.medela.com and look for the location finder.

# Accessories list (cont.)

#### Disposable single-use pump sets

Article number	Product
008.0397	Sterile single-use Symphony pump set size M (24 mm)
008.0398	Sterile single-use Symphony pump set size L (27 mm)
008.0399	Sterile single-use Symphony pump set size XL (30 mm)
101033930	Symphony Pump Set with PersonalFit PLUS, sterile, S (21mm) (30 pcs)
101033931	Symphony Pump Set with PersonalFit PLUS, sterile, M (24mm) (30 pcs)
101033932	Symphony Pump Set with PersonalFit PLUS, sterile, L (27mm) (30 pcs)
101033933	Symphony Pump Set with PersonalFit PLUS, sterile, XL (30mm) (30 pcs)

#### Disposable one-day pump sets

Article number	Product
008.0276	Ready-to-Use one-day Symphony pump set, size M (24 mm)
008.0277	Ready-to-Use one-day Symphony pump set, size L (27 mm)
008.0278	Ready-to-Use one-day Symphony pump set, size XL (30 mm)
101033934	Symphony Pump Set with PersonalFit PLUS, RtU, S (21mm) (30 pcs)
101033935	Symphony Pump Set with PersonalFit PLUS, RtU, M (24mm) (30 pcs)
101033936	Symphony Pump Set with PersonalFit PLUS, RtU, L (27mm) (30 pcs)
101033937	Symphony Pump Set with PersonalFit PLUS, RtU, XL (30mm) (30 pcs)

#### Disposable single-use bottles

Article number	Product
200.2110	Colostrum container, set of 2 disposable bottles 35 ml with lids (50 pcs)
200.2957	Ready-to-Use single-use bottle, 80 ml, with lid (480 pcs)
200.2956	Ready-to-Use single-use bottle, 150 ml, with lid (320 pcs)
200.4802	Ready-to-Use single-use bottle, 250 ml, with lid (160 pcs)
008.0297	Sterile single-use bottle, 80 ml, with lid (120 pcs)
008.0304	Sterile single-use bottle, 150 ml, with lid (85 pcs)
008.0305	Sterile single-use bottle, 250 ml, with lid (60 pcs)

Articles may not be available in all countries. For further information about Medela products, visit www.medela.com and look for the location finder.

#### Reusable pump sets

Article number	Product
008.0486	Symphony pump set hospital multibox (S) (25 pcs)
008.0465	Symphony pump set hospital multibox (M) (25 pcs)

#### Other accessories

Article number	Product
008.0467	PersonalFit PLUS breast shield S (21 mm) (25 pcs)
008.0468	PersonalFit PLUS breast shield M (24 mm) (25 pcs)
008.0469	PersonalFit PLUS breast shield L (27 mm) (25 pcs)
008.0470	PersonalFit PLUS breast shield XL (30 mm) (25 pcs)
008.0471	PersonalFit PLUS breast shield XXL (36 mm) (25 pcs)
008.0466	Connector kit (25 pcs)
008.0472	Membrane (25 pcs)
008.0473	Tubing (25 pcs)
008.0474	Symphony cap (25 pcs)
800.0625	Breast milk bottle 150 ml (25 pcs)
008.0475	Multi lid (25 pcs)
800.0627	Lid with opening (25 pcs)
800.0628	Disc (25 pcs)
800.0629	Cap (25 pcs)
600.0832	Mobile stand for Symphony complete
810.0552	Bottle stand for Symphony
600.0973	Hard case for Symphony with strap
600.7073	Hard case for Symphony without strap
600.0816	Symphony card and cord protector
928.1017	Car connection cable for Symphony
600.0387	Test vacuum meter

Articles may not be available in all countries. For further information about Medela products, visit www.medela.com and look for the location finder.

# 12. Meaning of symbols

#### Symbols used in these instructions

General safety alert symbol, points to information related to safety.



Identifies the manufacturer.



Defines a temperature range (e.g. for operation, transport or storage).



Defines a relative humidity range (e.g. for operation, transport or storage).



Defines an atmospheric pressure range (e.g. for operation, transport or storage).



 $\bigcap_{n_{123}}$  Indicates compliance with the EU requirements concerning medical devices.

#### Symbols on the display

Vacuum level indicator, stimulation phase – Standard program card and Symphony PLUS program card (MAINTAIN program).

Vacuum level indicator, expression phase – Standard program card and Symphony PLUS program card (MAINTAIN program).

....

Vacuum level indicator - Symphony PLUS program card (INITIATE program).

#### Symbols on the device and packaging



On/off button



Let-down button



Read and follow the instructions for use.



ig(ig) Indicates compliance with the EU requirements concerning medical devices.



Identifies the manufacturer



Do not dispose of electric/electronic devices together with unsorted municipal waste (dispose of the device in accordance with local regulations).



Indicates compliance with additional USA and Canada safety requirements for medical electrical equipment.



**EC REP** Authorized representative in the European Community / European Union



Importer

∱	Indicates compliance with international requirements for protection from electric shock (Type BF applied parts).
SN	Indicates the serial number of the device.
REF	Indicates the part number of the device.
IP21	Indicates the degree of protection against ingress of foreign objects and moisture.
$\mathbb{A}$	Indicates the date of manufacturing.
	Indicates equipment meeting the safety requirements specified for Class II equipment according to IEC 61140
	Indicates the fuse (to identify fuse boxes or their location).
S	Indicates that the fuse box is safety tested.
$\Diamond$	Indicates that the cover of the mains socket should be opened.
MD	Indicates a medical device
$\odot$	Indicates that the material is part of a recovery/recycling process.
Karton Carton Board	Indicates that the package is made of cardboard.
类	Keep away from sunlight.
Ţ	Contains fragile goods. Handle with care.
X.,	Defines a temperature range (e.g. for operation, transport or storage).
<u></u>	Defines a relative humidity range (e.g. for operation, transport or storage).
€••€ isPa	Defines an atmospheric pressure range (e.g. for operation, transport or storage).
<del>*</del>	Keep away from rain. Keep in dry conditions.
77	Indicates that the packaging contains products intended to come in contact with food according to regulation (EC) No 1935/2004.
,	Indicates unique GSI Global Trade Item Numbers (GTIN).

# 13. Electromagnetic compatibility (EMC)

The Symphony breast pump is EMC-tested in conformity with the requirements of IEC 60601-1-2:2007 and 60601-1-2:2014 4th Edition according to clause 7 and 8.9.

#### **MARNING**

- The Symphony breast pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Symphony electric breast pump should be monitored to verify normal operation in the configuration in which it will be used.
- Wireless communications equipment such as wireless home network devices, mobile
  phones, cordless telephones and their base stations, and walkie-talkies can affect the
  Symphony electric breast pump and should be kept at a distance of at least 30 cm from
  the equipment.
- Do not use other accessories than those specified or sold by the manufacturer as replacement parts for internal components as it may result in increased emissions or decreased immunity of the Symphony device.

For technical details (English only) refer to section 15.1 in the appendix.

# 14. Technical specifications



Vacuum (approx.) -50 to -250 mmHg -7 to- 33 kPa 35 to 120 cpm



100 to 240 V ~ 50 / 60 Hz 0.5 A



T 0.8 A, 250 V (slow blow) 5 x 20 mm L = Low Breaking Capacity



Car adapter 12 V == /1.2 A T 2.5 A (slow blow)



2x6V, 1200 mAh Pb (lead acid) Yuasa NP 1.2-6





2.841 kg 2.241 kg



Operation



Transport/Storage



Operation



Transport/Storage



Operation/Transport/Storage

# 1. 重要安全信息

如果发生任何与 Symphony (心韵) 吸乳器相关的严重事故, 应向 Medela AG (美德乐)和相关主管部门报告。



使用本产品前,请阅读所有使用说明。 请妥善保存这些说明以供将来参考。

警告表示所有与安全相关的重要说明。不遵从这些说明可能导致人身伤害或损坏 产品。

以下符号和信号词显示了相应警告的重要性:

▲ 警告	可能导致严重人身伤害或死亡。
△当心	可能导致轻微伤害。
注意	可能导致材质损坏(不涉及人身伤害)。
信息	
□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□	与安全无关的有用或重要信息。

## ▲ 警告

为降低触电风险:

- •首先将电源线连接到吸乳器上,然后再插入墙壁插座。
- •保持设备干燥。切勿浸入水或其他液体中。
- 请勿将液体直接喷或倒在吸乳器上。
- •放置或存放设备时,避免放在容易跌落或掉入水槽或浴缸的地方。
- ●禁止在洗澡或冲淋浴时使用 Symphony (心韵) 吸乳器。
- ●任何电气设备如落入水中, 切勿用手去拿。请立即拔下电源。

### ▲ 警告

为避免火灾、触电或严重烫伤:

- •Symphony (心韵) 吸乳器不耐高温: 远离散热器和明火。
- 避免阳光 直射吸乳器。
- ●请勿在使用气溶胶(喷雾)产品或氧气受控的地方操作 Symphony(心韵) 吸乳器。
- 请勿在易燃麻醉剂与空气、氧气或氮氧化物混合的场合下使用本设备。
- ●请勿使用微波炉或煮沸的热水为母乳解冻或加热。用微波炉加热母乳时,乳汁会变得很烫,可能导致宝宝嘴巴被严重烫伤。微波炉加热还可能会改变母乳成分。
- •请务必使用 Symphony (心韵) 吸乳器原配的电源线。
- •如果电气设备的电源线损坏,工作不正常、被摔或被损坏或掉入水中,切勿操作。
- ●使用前务必检查并确定电源线有无破损或裸露。如果发现任何破损,请立即停止使用 该电源线。请与当地的 Medela (美德乐) 代表联系。
- •Symphony(心韵)吸乳器通电时必须有人监督使用。
- •必须将电源线与墙壁插座断开后,方可确保与电源分离。
- •妥善放置吸乳器,以便可以从墙壁插座上轻松拔下电源线。
- 使电源线远离高温物体表面。

# 重要安全信息(续上页)

## ▲ 警告

为避免健康风险并降低受伤风险:

- •如果无乳汁流出,请勿连续进行两次以上的吸乳过程。
- •如果出现问题或疼痛,请咨询哺乳顾问或母乳喂养专家。
- •除非医师处方要求/建议, 否则切勿在怀孕时使用吸乳器, 吸乳过程可能会引起宫缩。
- •对于感染乙型肝炎、丙型肝炎或艾滋病病毒 (HIV) 的妈妈: 吸乳不会降低或避免将病毒通过乳汁传给宝宝的风险。
- ●每次使用前, 检查 Symphony (心韵) 吸乳器的所有组件以及吸乳配件的所有部件。
- •禁止使用已损坏的设备、组件或部件。
- •禁止使用沾染灰尘、发霉或其他污染物的设备、组件或部件。
- 更换发霉、损坏或磨损的部件。
- •Symphony (心韵) 吸乳器的所有组件, 均不可由用户自行维修。维修必须由授权服务机构进行。请不要尝试自行修理吸乳器或部件。
- ●仅允许按照本使用说明书中所述的用途使用 Symphony (心韵) 吸乳器。
- ●只能使用 Medela (美德乐) 原装配件。
- 请勿改装吸乳器或吸乳配件的任何部件。
- •请勿在驾驶机动车时使用 Symphony (心韵) 吸乳器。
- •请勿在开车时进行免手扶吸乳。
- •切勿将任何物体掉进或插入任何开口或软管中。
- 请勿在户外使用。
- •如果将 Symphony (心韵) 吸乳器放置在儿童可触及的范围内, 则需要成人看管。
- 便携式和移动无线电频率通讯设备可能会对心韵 Symphony 吸乳器的使用产生影响。
- Symphony (心韵) 吸乳器需要针对 EMC (电磁兼容性) 采取特别预防措施。请按照这些使用说明中提供的 EMC 电磁兼容信息安装和使用。

# △ 当心

#### 为避免污染风险:

- ●在触碰吸乳器、吸乳配件和乳房前, 用肥皂水彻底清洗双手。避免接触容器或盖子内侧。
- •请勿在睡眠或过于困倦时使用 Symphony (心韵) 吸乳器。
- 只能用可安全饮用的自来水或瓶装水进行清洁。
- 为避免发霉, 请勿存放潮湿部件。

#### 为避免健康风险并降低受伤风险:

- •吸乳时, 务必保持吸乳器处于垂直位置。
- •如果过紧地将吸乳护罩按压在乳房上,可能会影响乳汁流出。
- ●吸乳时请勿将负压调得过高或感觉不舒适(疼痛)。疼痛和可能随之而来的乳房和乳头损伤,可能会降低泌乳量。
- 请勿在吸乳时移走乳房上的吸乳护罩。关闭吸乳器,用手指隔开乳房与吸乳护罩,然后从乳房上移走吸乳护罩。
- ●如果吸乳时感觉不舒适,或吸乳导致疼痛,请关闭吸乳器,用手指隔开乳房与吸乳护罩,然后从乳房上移走吸乳护罩。
- 请勿缩短吸乳护罩与吸乳器之间的软管。
- •请勿使用研磨颗式洗洁剂/去污剂清洁吸乳器、吸乳器组件或吸乳配件。
- •切勿将吸乳器零件置于水中或灭菌器中, 这会对吸乳器造成永久损坏。
- ●请勿将 Medela (美德乐) Symphony (心韵) 吸乳器吸乳配件与不兼容的吸乳器一起使用。
- •请勿将 Medela (美德乐) Symphony (心韵) 吸乳器吸乳配件用于吸乳以外的任何其他用途。

# 注意

- •塑料收集瓶和组件冷冻后会变脆, 掉落时可能易破损。
- •此外, 收集瓶和组件拿放不当, 如掉落、拧得过紧、或打翻, 都可能会被损坏。
- •拿放奶瓶和组件时应小心。
- •请勿使用已出现损坏迹象的奶瓶或组件中的乳汁。

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# 2. 用途及适用范围

# 2.1 用途

Symphony (心韵) 吸乳器可供哺乳期女性在医院或家中吸乳。Symphony (心韵) 吸乳器适用于启动, 建立和维持哺乳期女性的母乳供给。

- 此外, 还适用于
- •缓解泌乳造成的乳胀和乳汁淤积症状。
- 患有乳腺炎时用吸乳器将母乳从感染的乳房中吸出, 辅助治疗过程。
- •缓解乳头疼痛和皲裂。
- •辅助扁平或凹陷的乳头凸出来。
- 为无法直接哺喂的宝宝(例如,衔乳问题,唇腭裂或早产)提供母乳。

# 2.2 适用范围

该产品用于解决乳液淤积,避免因乳液淤积而导致的问题,并对乳头凹陷有矫正作用。

# 2.3 禁忌症

Symphony (心韵) 吸乳器目前没有已知禁忌症。

# 3. 产品说明

# 3.1 Symphony(心韵)医用级吸乳器和配件

Medela (美德乐) Symphony (心韵) 的医用级吸乳器是一款多用户吸乳器,带有研究吸乳程序专门用于帮助早产婴儿和足月婴儿妈妈启动,建立和维持充足的泌乳。

Symphony (心韵) 吸乳器安装有 Symphony PLUS 程序卡, 其中包含两个吸乳模式程序。



#### 拥有Medela (美德乐) 泌乳启动技术的 INITIATE (泌乳启动) 程序

在哺乳的最迟几日, INITIATE (泌乳启动) 程序模拟足月婴儿的不定期和更快速吸吮与停顿方式。该程序适合在产后最初几日和激活泌乳之前使用, 以帮助依靠吸乳器的妈妈启动泌乳。



# 拥有 Medela (美德乐) 2-Phase Expression (双韵律吸乳) 技术的 MAINTAIN (泌乳维持) 程序

MAINTAIN (泌乳维持) 程序可在泌乳稳定期模拟足月婴儿的吸吮模式。本程序适合于激活泌乳之后优化泌乳量, 以支持所有妈妈建立与维持泌乳。

在某些情况下, Symphony (心韵) 吸乳器安装有 Standard (标准) 程序卡。该程序卡包含 MAINTAIN (泌乳维持) 程序。使用 Standard (标准) 程序卡可以启动泌乳, 但 Medela (美德乐) 更建议使用 Symphony PLUS 程序卡的 INITIATE (泌乳启动) 程序。

### 必需配件

Symphony (心韵) 吸乳器只能与 Medela (美德乐) 吸乳配件和收集瓶一起使用。吸乳配件和收集瓶分为可重复使用型和一次性使用型。

#### 可重复使用的产品:

Symphony (心韵) 医用级多个装吸乳配件 (25 套可重复使用的吸乳配件, 提供两个规格: S 和 M)。

### 一次性产品:

Medela (美德乐) 的一次性产品适用于在医院一次性使用或一天内使用, 首次使用前无需清洁:



Medela (美德乐) 的 Ready-to-Use 即用型产品是无需在使用前清洁的卫生安全的产品,适用于允许使用非灭菌产品的所有医院。



Medela (美德乐) 的灭菌产品是环氧乙烷灭菌制品, 符合 EN/ISO 标准中有关医疗器械的 ISO 11607-1、ISO 11607-2、ISO 11135 的要求。

# 产品说明(续上页)

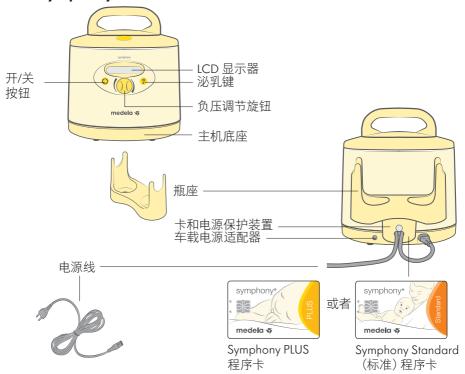
### 可供选择的一次性产品:

- ●无菌型一次性 Symphony (心韵) 单人即用型多选吸乳配件 (规格: S、M、L 或 XL)
- ●Ready-to-Use Symphony (心韵) 单日单人即用型多选吸乳配件 (规格: S、M、L 或 XL)
- ●收集瓶 (35 ml)
- 无菌型一次性收集瓶 (可用规格: 80、150 和 250 ml)
- Ready-to-Use 即用型一次性收集瓶 (可用规格: 80、150 和 250 ml)

# 可选部件和其他可组合使用的产品

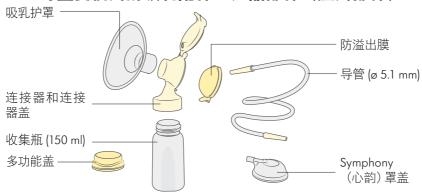
吸乳器移动支架、吸乳器手提箱、卡和电源保护装置。

# 3.2 Symphony 医用级吸乳器 – 产品部件



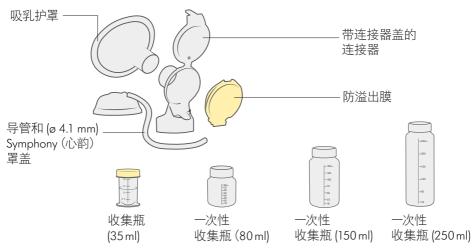
第 11 章中所列部件可供订购。并非所有国家/地区都提供这些物品。有关 Medela (美德乐)产品的更多信息,请访问 www.medela.cn. 使用位置搜索功能进行查找。

# 3.3 可重复使用的吸乳配件 - 产品部件(应用部件)



Symphony (心韵) 可重复使用吸乳配件可与不同规格的吸乳护罩一起使用。

# 3.4 一次性吸乳配件 - 产品部件(应用部件)



Symphony(心韵)一次性吸乳配件可与不同规格的吸乳护罩一起使用。

### i信息

所有图片仅供说明使用。实际产品可能因产品升级有所不同。有关产品说明和操作说明,请参阅 Symphony (心韵) 吸乳器吸乳配件随附的使用说明书。

有关订购信息,请参阅第11章。

# △ 注意

- 在清洗前拔掉吸乳器插头。
- ●不同医疗机构可能规定不同,这些建议不可替代医院(及医疗机构)的官方规定。请参阅医院多人用资产设备的清洁规定。
- ●当 Medela (美德乐) 的推荐做法与国家清洁和消毒要求存在冲突时, 请以后者为准。
- ●医疗器械表面消毒剂不会对 Symphony (心韵) 吸乳器造成机械损坏。
- •请遵循表面消毒剂供应商提供的使用说明。
- 按照供应商的说明和安全数据表为操作人员提供个人防护。
- 通过参考供应商的信息和/或物理测试检查医疗器械表面消毒剂的适用性。

# 4.1 吸乳器 - 清洁和消毒

根据需要对吸乳器进行清洁和消毒吸乳器。



1. 要清洁吸乳器, 请使用干净湿润 (不滴水) 的布巾擦拭 吸乳器机体。可使用饮用水和碱性洗洁剂或不含研磨 颗粒的清洁剂。



2. 消毒吸乳器时,请用沾有医疗器械表面消毒剂的干净 湿润(不滴水)的布巾擦拭吸乳器机体。Medela(美德 乐)推荐使用醇基表面消毒剂。

# 4.2 清洁吸乳配件

有关产品说明和操作说明,请参阅 Symphony (心韵) 吸乳器吸乳配件随附的使用说明书。

# 5. 吸乳准备

## ⚠ 警告

- •请务必使用 Symphony (心韵) 吸乳器原配的电源线。
- •确保电源线的电压与电源相匹配。

### i信息

#### 吸乳器可选用电池:

- ●在收到吸乳器后,必须对内置电池充电 12 小时。
- 充电时也可使用吸乳器。
- •如果很长时间未用吸乳器,则每两个月对电池充电一次(每次12小时)。
- •如果定期不完全放电或者不用时对吸乳器充电,则可实现电池的最长使用寿命。

#### 吸乳时间(电池已完全充满):

大约 60 分钟

#### 充电时间(完全充满):

12 小时

# 5.1 安装程序卡



- 1. 必须将程序卡插到吸乳器背面的卡槽中。
- → 有关使用程序卡和选择相应程序的更多信息,请参阅 第 6.2 节。

# 5.2 安装程序卡和电源保护装置(可选)



- 1. 将电源线旋绕着卡销,插入程序卡与电源保护装置中。
- → 确保有足够的电线长度可将电源线插入吸乳器背面的 电源插座中。

# 吸乳准备 (续上页)



2. 将程序卡与电源保护装置沿背部导轨推到停为止, 然后旋紧螺丝。



**3.** 拆卸时, 先拧松螺丝, 松开程序卡与电源保护装置, 然后将其沿导轨滑出。

# 5.3 电源模式



1. 将电源线插入吸乳器背面的电源插座中。



2. 将电源线插入电源插座。

# 5.4 Symphony(心韵)吸乳配件的组装

# △ 注意

- •在触碰乳房、清洁的吸乳器和吸乳配件部件之前,用肥皂水彻底清洗双手(至少一分钟)。
- 使用干净的毛巾或一次性纸巾擦干双手。

### 注意

- ●只能使用 Medela (美德乐) 原装配件。
- ●有关吸乳配件的说明和操作说明,请参阅 Symphony (心韵) 吸乳器吸乳配件随附的使用说明书。
- •使用前,检查吸乳配件有无磨损或损坏。请更换损坏或磨损部件。
- •使用前,必须保证所有部件完全干燥。



- 1. 根据吸乳配件随附的使用说明书小心组装 Symphony (心韵) 吸乳器吸乳配件。
- **2.** 将收集瓶旋在连接器上。根据个人需求使用收集瓶 (提供多种规格)。

# 5.5 将吸乳配件连接到吸乳器机身上



1. 打开吸乳器盖子: 按下 Symphony (心韵) 吸乳器顶部的 椭圆按钮并提起手柄。



- **2.** 将 Symphony (心韵) 吸乳器外盖紧按到吸乳器防溢出膜上, 以便完全贴合。
- → 确保Symphony (心韵) 吸乳器外盖扣合, 且与表面齐平。
- 3. 将导管连接器置于吸乳器机体凹槽处的中间位置。



# i信息

吸乳时务必合上盖子。吸乳器盖子可保证防溢出膜罩保持按下的状态,防止防溢出膜罩掉落后,可能带来负压的降低。

4. 盖上盖子。

# 6.1 选择适合的 Medela (美德乐) 吸乳护罩尺寸

确保使用适合的吸乳护罩尺寸。这是进行有效吸乳的重要组件,有助于促进乳汁流出。

## 了解 Medela (美德乐) 吸乳护罩的尺寸

吸乳不应造成疼痛。为确保更高的舒适度和更高的吸乳效率, Medela (美德乐) 提供了五种吸乳护罩尺寸。

本指南能帮助您在开始时根据乳头直径来确定适合的吸乳护罩尺寸。

- ●步骤 1
  - 使用直尺或卷尺在基底部 (横跨中间) 测量乳头直径, 以毫米 (mm) 表示。不要包括乳晕。
- 步骤 2

根据测量结果. 确定 Medela (美德乐) 吸乳护罩的尺寸。

示例: 如果测得的乳头直径为 16 mm, 则建议使用 21 mm 的 Medela (美德乐) 吸乳护罩。



有关订购信息,请参阅第11章。

# 优化吸乳护罩尺寸

- •保持乳头居中. 轻轻握住吸乳护罩贴到乳房上。
- •调整以找到最大舒适负压,来实现尽可能理想的吸力水平。
- •在吸乳模式(刺激泌乳模式之后)下吸乳时,请参考下图。



- 乳晕
- 大大

- •乳头碰到护罩管道 侧面。
- •尝试更大尺寸。
- ●乳头居中且可自由 移动。
- •乳头和过多乳晕被吸入 护罩管道中。
- •尝试更小尺寸。

## 尝试新尺寸的原因

- •乳头碰到管道侧面,造成不舒适的感觉。
- •过多乳晕被吸入管道中。
- •出现红肿的情况。
- •乳头或乳晕变白。
- 妈妈在吸乳后感觉有未吸出的乳汁。
- 分娩后组织水肿的情况消退。

如果出现上述任何一种情况,则考虑按照上述测量说明尝试不同尺寸。

# 吸乳 (续上页)

# 6.2 选择正确程序

Symphony (心韵) 吸乳器安装有 Symphony PLUS 程序卡, 其中包含两个吸乳程序。 INITIATE (泌乳启动) 程序用于启动泌乳。MAINTAIN (泌乳维持) 程序用于建立和维持 泌乳。

直到沙乳启动 (开始大量分沙乳汁) 或最多 5 天:

从婴儿出生开始使用 INITIATE (泌乳启 动)程序,直到泌乳启动,如下所示:

•单次吸乳,双侧乳房吸出 ≥20 mL 乳 汁。

或者

•生理指标,如乳房感到充盈。 如果产后5天未达到泌乳启动,请在第六 天切换至 MAINTAIN (泌乳维持) 程序。

泌乳启动(开始大量分泌乳汁)之后或从第 在乳腺活化期之后使用 MAINTAIN(沙 6天起:

乳维持)程序,如下所示:

•单次吸乳,双侧乳房吸出 ≥20 mL 乳 汁。

或者

- 牛理指标. 如乳房感到充盈。 动者
- •从第6天开始,以先到者为准。

有关程序卡的更多详细信息, 请参阅其使用说明。

# 6.3 操作方法: INITIATE (泌乳启动)程序

## △ 注意

●在触碰乳房、清洁的吸乳器和吸乳配件部件之前,用肥皂水彻底清洗双手(至少一分钟)。使用干净的毛巾或一次性纸巾擦干双手。



- 1. 按下开/关按钮 🔘 打开吸乳器。
- → 显示屏上显示 "INITIATE press" ("泌乳启动, 按 🎳 )。



- **2.** 在 10 秒内按 "Let-down" (泌乳) 按钮 ♡。
- → 显示屏上的文字将变为 "INITIATE running"("泌乳启 动正在运行")。



- 3. 设置最大舒适负压(请参阅第6.5节)。
- → 显示屏上的圆点显示负压水平。圆点越多, 负压越大。

# 吸乳 (续上页)



- **4.** INITIATE (泌乳启动) 程序通过刺激泌乳、吸乳和暂停相结合的模式自动运行 15 分钟。
- → 程序结束时会有声音提示。显示屏显示 "Program complete" ("程序完成")。吸乳器自动关闭。 完成整个 INITIATE (泌乳启动) 程序非常重要。

### 注意

•吸乳后请务必将 Symphony (心韵) 吸乳器断开电源。

# 6.4 操作方法: MAINTAIN (泌乳维持) 程序

# △ 注意

●在触碰乳房、清洁的吸乳器和吸乳配件部件之前,用肥皂水彻底清洗双手(至少一分钟)。使用于净的毛巾或一次性纸巾擦干双手。

# i信息

●如果吸乳器已经运行 30 分钟而没有任何操作 (如调整负压值), Symphony (心韵) 吸乳器将自动断电。



- 1. 按下开/关按钮 🔿 打开吸乳器。
- → 按下开/关按钮后, MAINTAIN (泌乳维持) 程序将自动 开始运行刺激泌乳模式。



- 2. 设置最大舒适负压(请参阅第6.5节)。
- → 显示屏上的水滴显示负压水平。水滴越多, 负压越大。



- 3. 两分钟后, 吸乳器将自动切换至吸乳模式。
- **4.** 如果乳汁快速流出,按下泌乳键 ♥ 切换至吸乳模式。



- 5. 设置最大舒适负压(请参阅第6.5节)。
- → 显示屏上的竖条形显示负压水平。竖条形越多, 负压越大。



- 6. 持续吸乳直至乳房感觉完全排空并全部变软 (Medela(美德乐)建议一次吸乳过程至少持续 15分钟)。
- 7. 按下开/关按钮 () 关闭吸乳器。

# i信息

●如果需要, 按下"泌乳"按钮 ♥, 可从吸乳模式转换回刺激泌乳模式。如果经过连续两次刺激泌乳模式后仍然没有乳汁流出, 则妈妈可以休息 15 至 30 分钟后, 再次尝试。此外, 也可尝试按摩乳房, 然后使用吸乳模式进行吸乳。

# 吸乳 (续上页)

## 注意

•吸乳后请务必将 Symphony (心韵) 吸乳器断开电源。

# 6.5 设置最大舒适负压



通过旋转负压调节旋钮,设置最大舒适负压。

- 1. 先向右旋转以提高负压,直至出现轻微不适感。
- 2. 然后向左旋转一些,稍微降低负压,直至感觉舒适。

# 6.6 单侧吸乳

### i信息

Medela (美德乐) 建议进行双侧吸乳。

- •双侧吸乳可帮助您节省宝贵的时间并增加母乳中的能量含量。还可提高泌乳量,帮助妈妈延长母乳喂养时间。
- •对于单侧吸乳,可以忽略第6.7节的步骤7。
- 吸乳时请不要让导管打结。



- 1. 准备一个收集瓶和吸乳配件进行吸乳。
- **2.** 在吸乳器上只安装一个 Symphony (心韵) 罩盖 (请参阅**第 5.5 节**)。
- 3. 按第6.7节的步骤3所述继续进行双侧吸乳。

# 6.7 双侧吸乳



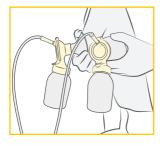
- 1. 准备两个收集瓶和吸乳配件进行吸乳。
- **2.** 在吸乳器上安装 Symphony (心韵) 罩盖 (请参阅 **第 5.5 节)**。



- **3.** 保持吸乳护罩与乳房贴合,让乳头刚好位于吸乳护罩 管道中央。
- **4.** 用拇指和食指扶住吸乳护罩, 使其固定在乳房上。用手掌托住乳房。

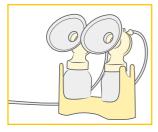


- 5. 按下 〇 打开吸乳器开关。
- 6. 继续选择程序(请参阅**第 6.2 节、第 6.3 节**和**第 6.4 节**)。



- 7. 将第二个收集瓶连接的吸乳护罩放在另一侧乳房上, 使乳头刚好位于吸乳护罩管道中央。
- 8. 按所选程序对应的正确操作过程操作吸乳器(请参阅 第6.3节和第6.4节)。

# 吸乳 (续上页)



9. 完成吸乳后, 将收集瓶放在支架或瓶座中, 以防收集瓶倾翻。



10. 用瓶盖将收集瓶盖好。

# 7. 储存和解冻母乳

# 7.1 储存和解冻指南

使用温度分布均匀的医用级冰箱,建议进行恒温监视。

有关母乳储存和解冻的建议,请访问www.medela.cn。您可以联系当地的客户服务部门,以便在需要时获得打印版本。

# 8. 故障排除和错误代码

# 8.1 故障排除

问题	解决办法
若马达不工作	检查电源/电池是否已插好。 检查设备开关是否打开。 检查程序卡是否已正确插入到吸乳器背面的卡槽中。
吸力很小或 没有吸力	按照 <b>第 5.4 节</b> 中的说明组装吸乳配件。 检查吸乳配件和吸乳器的所有连接是否紧密。 按照 <b>第 6 章</b> 中所述吸乳。确保吸乳护罩与乳房完全贴合。 检查吸乳配件组件是否干净无损坏。 根据 <b>第 5.4 节</b> 和 <b>第 5.5 节</b> 检查吸乳配件是否正确安装: •检查软管端部是否牢固连接。 •吸乳时请不要让软管打结或堵住。 •吸乳前,必须保证所有组件完全干燥。
如果乳汁流量 过大	<ul> <li>将吸乳配件放到瓶座上。</li> <li>Turn 关掉吸乳器开关,并从插座上拔下电源线。</li> <li>使用一块湿润(不滴水)的布巾擦拭吸乳器和防溢出膜区域。</li> <li>如果导管中有乳汁、凝固物或可见的残留物: 对于一次性吸乳配件:对吸乳配件进行废弃处理并更换新的吸乳配件。 对于可重复使用的吸乳配件:对导管进行废弃处理并更换新的硅管。按照第4.2节中所述对其余部分进行再处理。</li> <li>当部件完全干燥时,重新组装吸乳器及其配件。</li> </ul>

# 故障排除和错误代码 (续上页)

# 8.2 错误代码

下表介绍了可能出现的错误代码, 指示出设备问题、可能起因及纠正问题的步骤。

显示器	可能问题	操作
无效卡	程序卡不是 Symphony (心韵) 吸乳器卡	●检查是否使用了正确的程序卡
	程序未正确插入 程序卡损坏, 无法使用	●确保程序卡正确放置 ●更换程序卡
无卡	未插入程序卡 程序卡未完全插入	●将程序卡插入 ●将程序卡完全插入
电池电量低	电池需要尽快充电, 每隔 20 秒蜂鸣一次 (从开始出现指示时起, 还可吸乳 15 分钟)	•确保电源线已插入吸乳器背部
马达过载	马达承载的电流过大	●如果重复出现此情况,请与当地 的 Medela (美德乐) 代表联系
错误	传动控制电子组件中可能出现故障	●如果重复出现此情况,请与当地 的 Medela (美德乐) 代表联系
电源故障	电源的电子组件中可能出现故障	●如果重复出现此情况, 请与当地 的 Medela (美德乐) 代表联系

# 9. 质保和维护

#### 产品质保

本设备自购买之日起质保 3 年 (除吸乳配件及其他部件外)。电池保修期为 6 个月。因操作错误、使用不当及未获授权者使用而造成的损坏或后续损失,制造商对此不承担质保义务。常规检查、保养和电池更换只能由 Medela (美德乐) 授权人员执行。

### 电气安全

Medela (美德乐) Symphony (心韵) 吸乳器的机械设计已经过独立测试机构的验证, 符合 EN/IEC 60601-1 标准。可索取此类证书的副本。鉴于所用的制造方法, 只要按照预期用途并遵循这些使用说明正确使用, 且在授权的维修中心对设备进行维护和修理, Medela (美德乐) 确保在设备使用寿命内不会影响电气安全。没有规定或建议的电气安全检查或周期性测试需要执行。

提供的制造商信息符合 EN/IEC 62353:2014 "医用电气设备 - 医用电气设备的周期性测试和修理后测试"的要求。

#### 维护

除**第 4 章**中所述的清洁过程以及**第 5 章**中所述的针对带可选电池的吸乳器进行电池充电外,无需更多维护。除**第 1 章**中所述的检查过程(如目视检查吸乳器或电源线上有无损坏痕迹、在吸乳器掉落到地上或掉入水中后目视检查有无损坏痕迹)外,无需更多检查。如**第 1 章**中所述,只能由授权维修机构(中心)完全按照 Symphony(心韵)吸乳器维修手册并使用其中提及的原装 Medela(美德乐)备件进行维护和修理。服务手册、接线图和说明可向 Medela(美德乐)索取。

Medela (美德乐) 认为设备使用前, 最终生产测试可替代设备的现场测试。

设备使用寿命为七年,包括内置电池的使用寿命。

部件的使用寿命为两年。

# 电气和电子设备的废弃处理

Symphony (心韵) 吸乳器由金属和塑料制成, 应按照欧洲指令 2011/65/EU 和 2012/19/EU 进行废弃处理。此外, 还必须遵守当地政策。对于交流/直流型号, 必须按照当地法规对电子组件和充电电池进行单独废弃处理。请按照当地废弃处理政策规定对 Symphony (心韵) 吸乳器及其配件进行废弃处理。

### / 对电气和电子设备进行废弃处理的用户信息

此符号表示不得将电气和电子设备与未分类城市废弃物一起处理。正确处理该设 备可保护环境和人身健康,防止造成可能的损害。有关废弃处理的更多信息,请与制造商、当地护理人员或医疗保健提供商联系。此符号仅在欧盟有效。对电气

和电子设备进行废弃处理时,请遵照所在国家/地区的相关法律和规定。

# 11. 配件列表

# Symphony PLUS 程序卡

产品货号	产品
200.9186	Symphony PLUS 程序卡 (英语)
200.9187	Symphony PLUS 程序卡 (德语)
200.9188	Symphony PLUS 程序卡 (法语)
200.9189	Symphony PLUS 程序卡 (荷兰语)
200.9190	Symphony PLUS 程序卡 (西班牙语)
200.9191	Symphony PLUS 程序卡 (意大利语)
200.9192	Symphony PLUS 程序卡 (葡萄牙语)
200.9193	Symphony PLUS 程序卡 (瑞典语)
200.9194	Symphony PLUS 程序卡 (挪威语)
200.9195	Symphony PLUS 程序卡 (丹麦语)
200.9196	Symphony PLUS 程序卡 (芬兰语)
200.9197	Symphony PLUS 程序卡(波兰语)
200.9198	Symphony PLUS 程序卡 (日语)

# Symphony Standard(标准)程序卡

产品货号	产品
800.0540	Symphony Standard (标准) 程序卡 (德语)
800.0541	Symphony Standard (标准) 程序卡 (英语)
800.0542	Symphony Standard (标准) 程序卡 (法语)
800.0543	Symphony Standard (标准) 程序卡 (意大利语)
800.0544	Symphony Standard (标准) 程序卡 (荷兰语)
800.0545	Symphony Standard (标准) 程序卡 (瑞典语)
800.0546	Symphony Standard (标准) 程序卡 (丹麦语)
800.0547	Symphony Standard (标准) 程序卡 (芬兰语)
800.0548	Symphony Standard (标准) 程序卡 (挪威语)
800.0549	Symphony Standard (标准) 程序卡 (波兰语)
800.0550	Symphony Standard (标准) 程序卡 (西班牙语)
800.0551	Symphony Standard (标准) 程序卡 (葡萄牙语)
800.0552	Symphony Standard (标准) 程序卡 (希腊语)
800.0553	Symphony Standard (标准) 程序卡 (匈牙利语)
800.0554	Symphony Standard (标准) 程序卡 (捷克语)

并非所有国家/地区都提供这些物品。有关 Medela (美德乐) 产品的更多信息,请访问www.medela.cn,并使用位置搜索功能进行查找。

# 配件列表(续上页)

## 一次性负压吸乳配件

产品货号	产品
008.0397 008.0398 008.0399	无菌型一次性Symphony (心韵) 单人即用型多选吸乳配件 规格 M (24 mm) 无菌型一次性Symphony (心韵) 单人即用型多选负压吸乳配件 规格 L (27 mm) 无菌型一次性Symphony (心韵) 单人即用型多选负压吸乳配件 规格 XL (30 mm)
101033930	无菌型 Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版,规格 S (21 mm) (30 件)
101033931	无菌型 Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版, 规格 M (24 mm) (30 件)
101033932	无菌型 Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版,规格 L (27 mm) (30 件)
101033933	无菌型 Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版, 规格 XL (30 mm) (30 件)

## 一次性单日用吸乳配件

产品货号	产品
008.0276 008.0277 008.0278	Ready-to-Use Symphony (心韵) 单日单人即用型多选吸乳配件, 规格 M (24 mm) Ready-to-Use Symphony (心韵) 单日单人即用型多选吸引配件, 规格 L (27 mm) Ready-to-Use Symphony (心韵) 单日单人即用型多选吸引配件, 规格 XL (30 mm)
101033934	Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版, RtU, 规格S (21 mm) (30 件)
101033935	Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版, RtU, 规格M (24 mm) (30 件)
101033936	Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版, RtU, 规格L (27 mm) (30 件)
101033937	Symphony (心韵) 吸乳配件, 配PersonalFit PLUS 多选型吸乳护罩升级版, RtU, 规格XL (30 mm) (30 件)

## 一次性收集瓶

产品货号	产品
200.2110	收集瓶, 2 个带盖的 35 ml 一次性收集瓶 (50 件)
200.2957	Ready-to-Use 即用型一次性收集瓶 (带瓶盖) , 80 ml,(480 件)
200.2956	Ready-to-Use 即用型一次性收集瓶 (带瓶盖) , 150 ml,(320 件)
200.4802	Ready-to-Use 即用型一次性收集瓶 (带瓶盖) , 250 ml,(160 件)
008.0297	灭菌型一次性收集瓶 (带瓶盖), 80 ml, (120 件)
008.0304	灭菌型一次性收集瓶 (带瓶盖), 150 ml, (85 件)
008.0305	灭菌型一次性收集瓶 (带瓶盖), 250 ml, (60 件)

并非所有国家/地区都提供这些物品。有关 Medela (美德乐) 产品的更多信息,请访问 www.medela.cn, 并使用位置搜索功能进行查找。

# 可重复使用吸乳配件

产品货号	产品
008.0486	医用级 Symphony (心韵) 吸乳配件多盒装 (S)(25 件)
008.0465	医用级 Symphony (心韵) 吸乳配件多盒装 (M)(25 件)

# 其他配件

产品货号	产品
008.0467	PersonalFit PLUS 多选型负压吸乳护罩升级版 S (21 mm)(25 件)
008.0468	PersonalFit PLUS 多选型负压吸乳护罩升级版 M (24 mm)(25 件)
008.0469	PersonalFit PLUS 多选型负压吸乳护罩升级版 L (27 mm)(25 件)
008.0470	PersonalFit PLUS 多选型负压吸乳护罩升级版 XL (30 mm)(25 件)
008.0471	PersonalFit PLUS 多选型负压吸乳护罩升级版 XXL (36 mm)(25 件)
008.0466	连接器配件 (25 件)
008.0472	防溢出膜 (25 件)
008.0473	导管 (ø 5.1 mm) (25 件)
008.0474	Symphony (心韵) 吸乳器隔膜帽 (25 件)
800.0625	收集瓶 150 ml (25 件)
008.0475	多功能盖 (25 件)
800.0627	带开口的盖子 (25 件)
800.0628	盖片 (25 件)
800.0629	隔膜帽 (25 件)
600.0832 810.0552 600.0973 600.7073 600.0816 928.1017 600.0387	Symphony (心韵) 完整可移动支架 Symphony (心韵) 瓶架 Symphony (心韵) 手提箱 (带背带) Symphony (心韵) 手提箱 (无背带) Symphony (心韵) 卡与电源保护装置 Symphony (心韵) 车载电源适配器 负压检测表

并非所有国家/地区都提供这些物品。有关 Medela (美德乐) 产品的更多信息,请访问www.medela.cn,并使用位置搜索功能进行查找。

# 12. 符号含义

### 这些说明中使用的符号

一般安全警示符号, 指向安全相关的信息。



表示制造商。



定义温度范围(例如,用于操作、运输或储存)。



定义相对湿度范围(例如,用干操作、运输或储存)。



定义大气压范围(例如,用干操作、运输或储存)。

【 € 1123 表示符合欧盟对医疗设备的要求。

### 显示屏上的符号

负压水平显示器, 刺激泌乳模式 - Standard (标准) 程序卡和 Symphony PLUS 程序卡 (MAINTAIN (沙乳維持) 程序)。

负压水平显示器, 吸乳模式 - Standard (标准) 程序卡和 Symphony PLUS 程序卡 (MAINTAIN (沙乳维持) 程序)。

....

负压水平显示器 - Symphony PLUS 程序卡 (INITIATE (泌乳启动) 程序)。

## 设备和包装上的符号

开/关按钮



Let-down (沙乳) 按钮



请阅读并遵守使用说明书。

【 € 0123 表示符合欧盟对医疗设备的要求。

表示制造商。



废弃时不得将电气/电子设备与未分类的城市垃圾一起处理(按照当地法规对设备进行废 弃处理)。



表示设备符合美国与加拿大的其他医用电气设备安全要求。

EC REP 欧共体/欧盟的获授权代表。

	进口商。
<b>†</b>	表示符合国际防电击要求 (BF 型触身部分)。
SN	表示设备的序列号。
REF	表示设备的部件编号。
IP21	表示防止异物和水进入的防护等级。
$\mathbb{A}$	表示制造日期。
	表示设备符合 IEC 61140 规定的 II 类设备安全要求。
-	表示保险丝(用于辨识保险丝盒或其位置)。
(\$)	表示保险丝盒已通过安全性测试。
<b>♦</b>	表示应打开电源插座盖。
MD	表示医疗设备。
$\odot$	表示产品材料可进行回收/再利用。
Karton Carton Board	表示包装由纸板制成。
类	远离光照。
Ī	包含易碎品。小心轻放。
<b>/</b>	定义温度范围 (例如, 用于操作、运输或储存)。
<b></b>	定义相对湿度范围(例如,用于操作、运输或储存)。
∳•∳ kPa	定义大气压范围 (例如, 用于操作、运输或储存)。
<del>*</del>	远离雨水。保持干燥。
77	表示包装内含产品符合 (EC) No 1935/2004 法规要求, 可以直接接触食品。
	表示独有的 GSI 全球贸易产品编号 (GTIN)。

# 13. 电磁兼容性 (EMC)

Symphony (心韵) 吸乳器经 EMC 测试, 符合 IEC 60601-1-2:2007 和 IEC 60601-1-2:2014 第 4 版中第 7 条和第 8.9 条的要求。

# ▲ 警告

- •Symphony (心韵) 吸乳器不可在其他设备附近使用或与其他设备堆叠使用。如果必须在其他设备附近使用或堆叠使用, 应观测 Symphony (心韵) 电动吸乳器以确认能够在所用配置中正常操作。
- •诸如无线家庭网络设备、手机、无绳电话及其基站和对讲机等无线通信设备会影响 Symphony (心韵) 电动吸乳器, 应至少与此类设备保持 30 厘米的距离。
- ●请勿使用制造商指定或销售配件以外的部件作为内部组件的更换部件, 因为这可能会导致 Symphony (心韵) 吸乳器的辐射增加或抗扰度降低。

有关技术详细信息(仅英文),请参阅附录中的第15.1节。

# 14. 技术规格



负压(近似值) -50 至 -250 mmHg -7 至 - 33 kPa 35 至 120 cpm



100至240V~ 50/60Hz 0.5A



T 0.8 A, 250 V (缓熔) 5x20mm L = 低断流容量



车用适配器 12 V == /1.2 A T 2.5 A (缓熔)



2x6V, 1200 mAh Pb (铅酸) Yuasa NP 1.2-6





2.841 kg 2.241 kg



操作



√+50 运输/储存





运输/储存



操作/运输/储存

# 15.1 电磁兼容性

基本性能: 吸乳器无基本性能。

### 注意

- ●吸乳器的购买者或使用者应在表1、2、3、4规定的电磁环境下使用吸乳器,否则可能导致吸乳器不正常工作。
- ●便携式和移动式射频通信设备可能会影响吸乳器的正常使用, 请在推荐的电磁环境下使用吸乳器。

# ▲ 警告

- ●除吸乳器的制造商提供的附件和电缆外,使用规定外的附件和电缆可能导致吸乳器发射的增加或抗扰度的降低。
- •吸乳器不应与其它设备接近或叠放使用, 如果必须接近或叠放使用, 则应观察验证在 其使用的配置下能正常运行。

#### 表1

### 指南和制造商的声明 - 电磁发射

吸乳器预期在下列规定的电磁环境中使用, 购买者或使用者应保证它在这种电磁环境下使用:

发射试验	符合性	电磁环境-指南	
射频发射 GB 4824	1组	吸乳器仅为其内部功能而使用射频能量。因此, 它的射频发射很低,并且对附近电子设备产生干 扰的可能性很小	
射频发射 GB 4824	B类		
谐波发射 GB 17625.1	A类	吸乳器适于在所有的设施中使用,包括家用设施 和直接连接到家用住宅公共低压供电网	
电压波动/闪烁发射 GB/T 17625.2	符合		

#### 表2

# 指南和制造商的声明 – 电磁抗扰度

吸乳器预期在下列规定的电磁环境中使用, 购买者或使用者应保证它在这种电磁环境中使用:

抗扰度试验	IEC 60601 试验电平	符合电平	电磁环境一指南
静电放电 GB/T 17626.2	±6 kV接触放电 ±8 kV空气放电	±6 kV接触放电 ±8 kV空气放电	地面应是木质、混凝土或瓷砖,如果地面用合成材料覆盖,则相对湿度应至少30%
电快速瞬变脉冲 群 GB/T 17626.4	±2 kV对电源线 ±1 kV对输入/ 输出线	±2 kV对电源线 不适用	网电源应具有典型的商业或医院环 境中使用的质量
浪涌 GB/T 17626.5	±1 kV线对线 ±2 kV线对地	±1 kV线对线 不适用	网电源应具有典型的商业或医院环 境中使用的质量
电源输入线上电压暂降、短时中断和电压变化 GB/T 17626.11	$<5\%$ $U_{,\cdot}$ 持续0.5周期 (在 $U_{,\cdot}$ L, $>95\%$ 的暂降) $40\%$ $U_{,\cdot}$ 持续5周期 (在 $U_{,\cdot}$ L, $60\%$ 的暂降) $70\%$ $U_{,\cdot}$ 持续25周期 (在 $U_{,\cdot}$ L, $30\%$ 的暂降) $<5\%$ $U_{,\cdot}$ 持续5s (在 $U_{,\cdot}$ L, $>95\%$ 的暂降)	$<5\%$ $U_{\rm T}$ , 持续0.5周期 (在 $U_{\rm T}$ 上, >95%的暂降) 40% $U_{\rm T}$ , 持续5周期 (在 $U_{\rm T}$ 上, 60%的暂降) 70% $U_{\rm T}$ , 持续25周期 (在 $U_{\rm T}$ 上, 30%的暂降) $<5\%$ $U_{\rm T}$ , 持续5s (在 $U_{\rm T}$ 上, >95%的暂降)	网电源应具有典型的商业或医院环境中使用的质量。如果吸乳器的用户在电源中断期间需要连续运行,则推荐吸乳器采用不间断电源或电池供电
工频磁场 (50 Hz/60 Hz) GB/T 17626.8	3 A/m	3 A/m	工频磁场应具有在典型的商业或医 院环境中典型场所的工频磁场水平 特性

注: $U_{\scriptscriptstyle T}$ 指施加试验电压前的交流网电压。

#### 表3

#### 指南和制造商的声明 - 电磁抗扰度

吸乳器预期在下列规定的电磁环境中使用, 购买者或使用者应保证其在这种电磁环境中使用:

抗扰度试 验	IEC 60601 试验电平	符合电平	电磁环境一指南
			便携式和移动式射频通信设备不应比推荐的隔离 距离更靠近吸乳器的任何部分使用,包括电缆。该 距离应由与发射机频率相应的公式计算。
射频传导 GB/T 17626.6	3 V (有效值) 150 kHz~ 80 MHz	3 V (有效值)	推荐的隔离距离 $d=1.2\sqrt{P}$
射频辐射 GB/T 17626.3	3 V/m 80 MHz~ 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			式中: P—根据发射机制造商提供的发射机最大额定输出功率,单位为瓦特 (W);
			d 一推荐的隔离距离,单位为米 (m).
			固定式射频发射机的场强通过对电磁场所勘测。
			来确定, 在每个频率范围 <sup>b</sup> 都应比符合电平低。
			在标记下列符号的设备附近可能出现干扰。(😭)

- 注1: 在80 MHz 和800 MHz频率点上,采用较高频段的公式。
- **注 2**: 这些指南可能不适合所有的情况, 电磁传播受建筑物、物体及人体的吸收和反射的影响。
- 。固定式发射机,诸如:无线(蜂窝/无绳)电话和地面移动式无线电的基站、业余无线电、调幅和调频无线电广播以及电视广播等,其场强在理论上都不能准确预知。为评定固定式射频发射机的电磁环境,应考虑电磁场所的勘测。如果测得吸乳器所处场所的场强高于上述适用的射频符合电平,则应观测吸乳器以验证其能正常运行。如果观测到不正常性能,则补充措施可能是必需的,比如重新调整吸乳器的方向或位置。
- b 在150 kHz~80 MHz整个频率范围, 场强应低于3 V/m。

#### 表4

#### 便携式及移动式射频通信设备和吸乳器之间的推荐隔离距离

吸乳器预期在射频辐射骚扰受控的电磁环境中使用。依据通信设备最大额定输出功率,购买者或使用者可通过下面推荐的维持便携式及移动式射频通信设备(发射机)和吸乳器之间最小距离来防止电磁干扰

	Separation distance according to frequency of transmitter M				
发射机的最大额定 输出功率 W	$150 \text{ kHz} \sim 80 \text{ MHz}$ $d = 1.2\sqrt{P}$	80 MHz $\sim$ 800 MHz $d = 1.2\sqrt{P}$	800 MHz $\sim$ 2.5 GHz $d = 2.3\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

对于上表未列出的发射机最大额定输出功率, 推荐隔离距离 d, 以米 (m) 为单位, 可用相应发射机频率栏中的公式来确定, 这里 P 是由发射机制造商提供的发射机最大额定输出功率, 以瓦特 (W) 为单位。

注 1: 在 80 MHz 和 800 MHz频率点上, 采用较高频范围的公式。

**注 2:** 这些指南可能不适合所有的情况, 电磁传播受建筑物、物体及人体的吸收和反射的影响。





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