

Hygeia Evolve™ Instructions for Use



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1. INTRODUCTION

Congratulations on joining the Hygeia family!

We are excited to be a part of your breastfeeding journey and help you meet your breastfeeding goals. With your Hygeia Evolve Breast pump and the Hygeia Evolve Personal accessory kit, you can express and collect your breast milk safely and effectively. When babies breastfeed, they latch on and start expressing quickly to help your body release hormones that signal your breasts to release your milk. This is called let-down. Once Let-down occurs, your baby sucks longer and slower to help manage the milk flow that is spraying into your baby's mouth. With the Evolve breast pump, the separate modes allow you to mimic your baby's comfortable expressing pattern.

The Hygeia Evolve Personal accessory kit is a closed system that contains a back-flow protector silicone disk that keeps the air from the pump and tubing separate from the pump parts that are exposed to your breast milk, so your tubing stays dry. This back-flow protector silicone disk helps prevent milk backup into tubing.

If you have any questions regarding the Evolve breast pump or Evolve Personal accessory Kit, we have our customer service reps available to help you. Have your breast pump and parts nearby when you call. Customer Service is available by phone during business hours on weekdays at 888-PUMP-4-MOM (888-786-7466). Please check www.hygeiahealth.com for up-to-date available times.

For more information about breastfeeding, breast pumping or Hygeia products visit www.hygeiahealth.com.

1.1 Intended Use

The Evolve breast pump is intended to be used by lactating women to express and collect milk from their breasts.

1.2 Warning






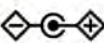









⚠ WARNING: Multiple-user pumps are designed so that the breast milk can never touch the working parts of the pump that are shared. The only part of a multiple-user breast pump that you can safely share is the pump itself.

The Hygeia Evolve Personal Accessory Set (PAS) is the supported and compatible PAS for the Hygeia Evolve Breast pump.

Use of other Personal Accessory Sets with the Hygeia Evolve Breast pump will void the pump warranty, possibly allow milk to enter and damage the pump, and may result in personal injury due to high suction levels.

SAVE THESE INSTRUCTIONS

2. TECHNICAL SYMBOLS

SYMBOL	TITLE	DESCRIPTION	STANDARD REFERENCE	STANDARD
	Stand-by	This symbol indicates to turn system on into a standby mode.	5009	IEC 60417-DB:2002 Graphical symbols for use on equipment Part 1: Overview and application
	Type BF Applied part	Indicates a part normally coming into physical contact with a user of the device where a high degree of protection against electric shock is provided	5333	IEC 60417-DB:2002 Graphical symbols for use on equipment Part 1: Overview and application
	Class II Equipment	Indicates protection against electric shock not only by basic insulation, but also by additional safety precautions such as double or reinforced insulation, functional earth terminals, etc.	5172	IEC 60417-DB:2002 Graphical symbols for use on equipment Part 1: Overview and application
	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	5032	IEC 60417-DB:2002 Graphical symbols for use on equipment Part 1: Overview and application
	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.	5031	IEC 60417-DB:2002 Graphical symbols for use on equipment Part 1: Overview and application
	Polarity of d.c. power connector	To identify the positive and negative connections (the polarity) of a d.c. power supply, or the positive and negative connections on a piece of equipment to which a d.c. power supply may be connected.	5926	IEC 60417-DB:2002 Graphical symbols for use on equipment Part 1: Overview and application
	Dangerous voltage	To indicate hazards arising from dangerous voltages.	5036	IEC 60417-DB:2002 Graphical symbols for use on equipment Part 1: Overview and application
IP21	Ingress Protection	Indicates that the device is protected against intrusion of half-inch diameter objects and falling water drops	Table D.3, Symbol 2	ANSI/AAMI ES60601-1:2005/(R)2012 Medical electrical equipment— Part 1: General requirements for basic safety and essential performance
	Keep dry	Indicates that the device needs to be protected from moisture	5.3.4	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Manufacturer	Indicates the medical device manufacturer.	5.1.1	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Date of Manufacture	Indicates the date when the medical device was manufactured	5.1.3	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Follow instructions for Use	Indicates the need for the user to refer to the instruction manual/booklet	Table D.2, Symbol 10	ANSI/AAMI ES60601-1:2005/(R)2012 Medical electrical equipment— Part 1: General requirements for basic safety and essential performance
SN	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified	5.1.7	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	5.1.5	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6	ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
	Wheelie Bin	Indicates that the product should not be disposed of as unsorted municipal waste	N/A	EN 50419:2016 Marking of Electrical and Electronic Equipment in Accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
	Non-ionizing Electromagnetic Radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems.	5140	IEC TR 60878:2015 – Graphical symbols for electrical equipment in medical practice
	UL Safety Certification Mark	To indicate compliance with standards for electrical safety and electromagnetic emissions.	N/A	Underwriters Laboratories Inc.

2.1 Manufacturer

 **Manufacturer**
Hygeia II Medical Group, Inc
 6241 Yarrow Drive, Suite A
 Carlsbad, CA 92011 USA

2.2 Disposal



Disposal

Medical Equipment and devices should be disposed of in proper containers that meet Environmental Protection Agency Standards. Check with Local State Laws & Regulations to see what is required in your state or contact your local representatives.

3. What comes with your new Hygeia pump



3.1 Hygeia contact information

• 6241 Yarrow Dr, Suite A
Carlsbad, CA 92011

• info@HygeiaHealth.com
www.HygeiaHealth.com

• 888-PUMP-4-MOM
(888-786-7466)

Hygeia Customer Care M-F 7:00am to 4:00pm PST

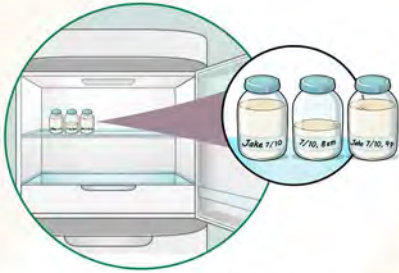
4. CLEANING

Illustrations from CDC - <https://www.cdc.gov/healthywater/pdf/hygiene/breast-pump-fact-sheet-p.pdf>



BEFORE EVERY USE

1. **Wash hands** with soap and water for 20 seconds.
2. **Inspect and assemble** clean pump kit. If your tubing is moldy, discard and replace immediately.
3. **Clean pump and counter top** with disinfectant wipes, especially if using a shared pump.



AFTER EVERY USE

1. **Store milk safely.** Cap milk collection bottle or seal milk collection bag, label with date and time, and immediately place in a refrigerator, freezer*, or cooler bag with ice packs.
2. **Clean pumping area,** especially if using a shared pump. Clean pump and counter top with disinfectant wipes.
3. **Take apart** breast pump tubing and separate all parts that come in contact with breast/breast milk.
4. **Rinse** breast pump kit parts that come into contact with breast/breast milk by holding under running water to remove remaining milk. Do not place parts in sink to rinse.



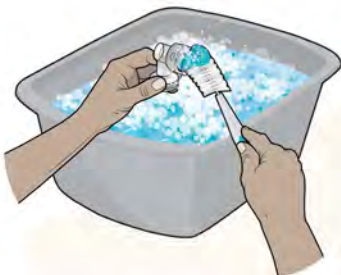
5. **Clean pump kit parts** that come into contact with breast/breast milk as soon as possible after pumping. You can clean your pump kit parts **in a dishwasher or by hand** in a wash basin used only for cleaning the pump kit and infant feeding items.

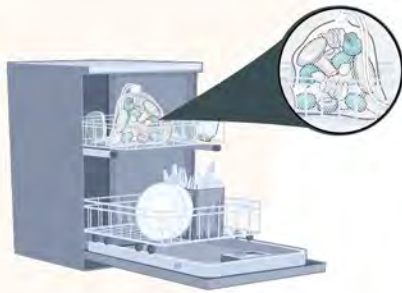
**We do not recommend placing bottles in the freezer as they may shatter if dropped.*

6. Follow the cleaning steps below

a. **CLEAN BY HAND**

- i. **Place pump kit parts in a clean wash basin** used only for infant feeding items. **Do not place pump kit parts directly in the sink!**
- ii. **Add soap and hot water** to basin.
- iii. **Scrub** items using a clean brush used only for infant feeding items.
- iv. **Rinse** by holding items under running water, or by submerging in fresh water in a separate basin.
- v. **Air-dry thoroughly.** Place pump kit parts, wash basin, and bottle brush on a clean, unused dish towel or paper towel in an area protected from dirt and dust. Do not use a dish towel to rub or pat items dry!
- vi. **Clean wash basin and bottle brush.** Rinse them well and allow them to air-dry after each use. Wash them by hand or in a dishwasher at least every few days.





b. OR CLEAN IN DISHWASHER

i. **Clean pump kit parts in a dishwasher**, if they are dishwasher-safe. 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 (or sanitizing setting).**

ii. **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



SANITIZE

For extra germ removal, sanitize pump kit parts, wash basin, and bottle brush **at least once daily after they have been cleaned.** Items can be sanitized using boiling water, or a dishwasher with a sanitize setting.

Detailed instructions on sanitizing your pump kit parts can be found at www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding.html

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

For extra germ removal, sanitize feeding items at least once daily. Sanitizing is particularly important when your baby is younger than 3 months, was born prematurely, or has a weakened immune system. Daily sanitizing of feeding items may not be necessary for older, healthy babies, if those items are cleaned carefully after each use.

Before sanitizing, make sure you have cleaned feeding items, bottle brushes, and wash basins using one of the methods above. Sanitize all items (even the bottle brush and wash basin!) by boiling per these instructions.

Boil:

1. Place disassembled feeding items into a CLEAN pot and cover with water.
2. Put the pot over heat and bring to a boil.
3. Boil for 10 minutes.
4. Remove items with clean tongs.

After sanitizing, place items on a clean, unused dish towel or paper towel in an area protected from dirt and dust. Allow to air-dry thoroughly before storing. Do not use a dish towel to rub or pat items dry because doing so may transfer germs to the items.

REMEMBER: DO NOT STORE wet or damp parts as mold may develop.



Do not wet tubing. If milk or condensation occur inside the tubing, refer to our troubleshooting section for further instruction

4.1 Inspecting Before Pumping

! IMPORTANT: Before using the Hygeia Evolve Breast pump and Evolve Personal Accessory Kit, check the parts for cracks, chips, tears, discoloration, or wear. They can affect the function of the kit. If parts need replacing due to defects, please call your local distributor or the location where you purchased the pump. Do not use damaged parts.

4.2 Batteries

! WARNING: DO NOT install backward, charge, put in fire, or mix with other battery types. May explode or leak causing injury. Replace all batteries at the same time. The Evolve Cordless pump has a non-removable internal battery. The Evolve corded pump has an internal battery compartment.

1. OPEN battery compartment on the bottom of the pump base.
2. INSERT four new AA batteries into battery compartment
3. CLOSE the battery compartment

4.3 Power Supply

! WARNING: Always inspect the AC power adapter for damage such as kinking or twisting of cords or frayed or exposed wires. If damaged, discontinue use immediately and call customer service at 888-PUMP-4-MOM (888-786-7466).

4.4 Maintenance

The Breast Pump base does not require service or maintenance.

Breast Pump Valve Check

Inspect the valves for tears or holes. Replace any damaged valves prior to pumping. Wash valves per cleaning section. Do not insert bottle brush or something similar into the valves. We recommend replacing the valves approximately every 1-3 months but this can vary depending on cleaning and use.

Storing and Transporting Hygeia Evolve and Personal Accessory Sets

Disconnect the Evolve Personal Accessory Kit and power adapter from the pump before transporting or storing the product. When storing product, store in conditions as described in these instructions (see Technical Information section 11). Handle with care when transporting product.

! WARNING: DO NOT attempt servicing and maintenance while the Breast Pump is in use (IEC 60601-1 CLAUSE 7.9.2.1)

! WARNING: If the power adapter outer casings become loose or are separating, contact the device manufacturer immediately. Separation of the casing can result in electric shock.

4.5 Cleaning the Evolve Pump

Make sure it is unplugged prior to wiping the Evolve Breast Pump and power adapter with a clean, damp cloth.

5. DISINFECTION

1. Separate all parts that come in contact with breastmilk.
 2. Wash hands thoroughly.
 3. Fill pot with enough water to cover all parts. Bring water to a boil. Place parts in boiling water for 10 minutes.
 4. Allow water to cool and gently remove parts from water with tongs.
 5. Place parts on a clean surface and/or towel.
 6. Allow all parts to air dry.
 7. Store dry parts in a clean, cool place when not in use. Do NOT store wet or damp parts.
- Unplug the unit from the adapter before cleaning.
 - Please clean the valve, bottle, screw ring, and bottle cap after use with warm soapy water and rinse them with clean water. Do not clean or wet the tubing.

Please clean, sanitize and disinfect the breast pump, parts and accessories as shown in the table below. See section 4 for Cleaning Methods.

The pump surface should only be cleaned with damp, soft cloth with mild dish soap. Use of other cleaners or abrasive cloths may damage the display or degrade its performance.

 **Warning:** The tubing should not be disinfected.

COMPONENT	CLEAN (BY HAND OR DISHWASHER)	SANITIZE (BY BOILING) ⁶	DISINFECT
Tubing	Do not clean	NO	NO
Flanges	After every use	Daily	NO
Valves	After every use	Daily	NO
Milk Containers	After every use	Daily	NO
Container Locking Rings	After every use	Daily	NO
Container Locking Discs	After every use	Daily	NO
Back-Flow Protector Case Top	After every use	Daily	NO
Back-Flow Protector Silicone Disk	After every use	Daily	NO
Back-Flow Protector Case Bottom	After every use	Daily	NO
Pump Surface	If needed. Do not immerse the pump in water or run water over it.	NO	If soiled, use ethyl or isopropyl alcohol (70 – 90 %) with at least 1 minute exposure time.
Power Adaptor	Wipe with clean, damp cloth if dirty	NO	NO

⁶Boil for 10 minutes; CDC guidelines found here:

<https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding/breastpump.html>

6. SET UP

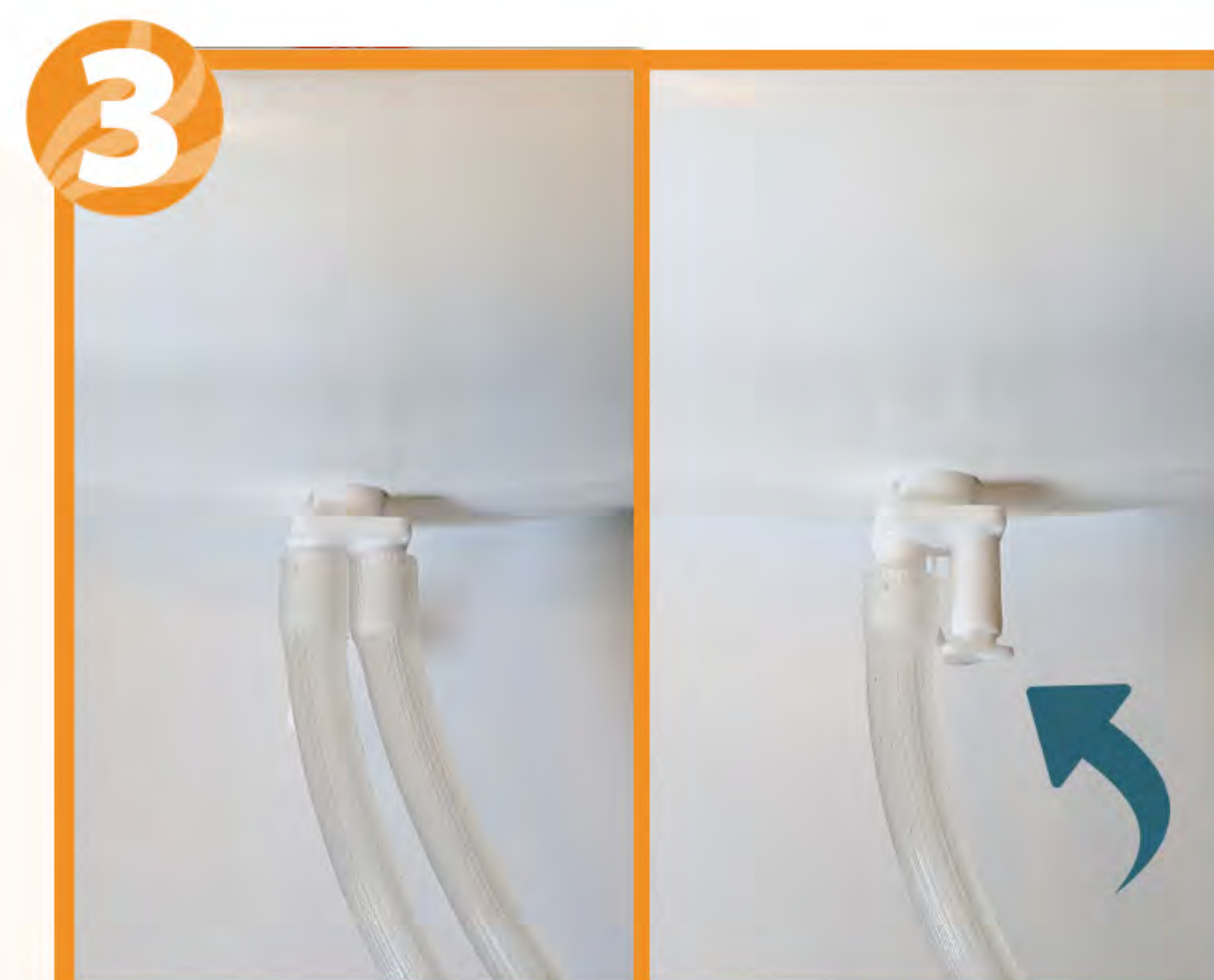
Setting up your pump and personal accessories set for use:



1. Plug power cord into any standard electrical outlet. Make sure you are using a Hygeia Evolve approved Power cord. The cordless model require recharging after 2 hours of use.



2. Attached the other end of the power adapter to the pump. Cordless models battery life is approx. 2 hours at maximum settings; refer to section 11.4 for cordless model's battery information. To use the cordless model, remove the AC adapter from the pump.



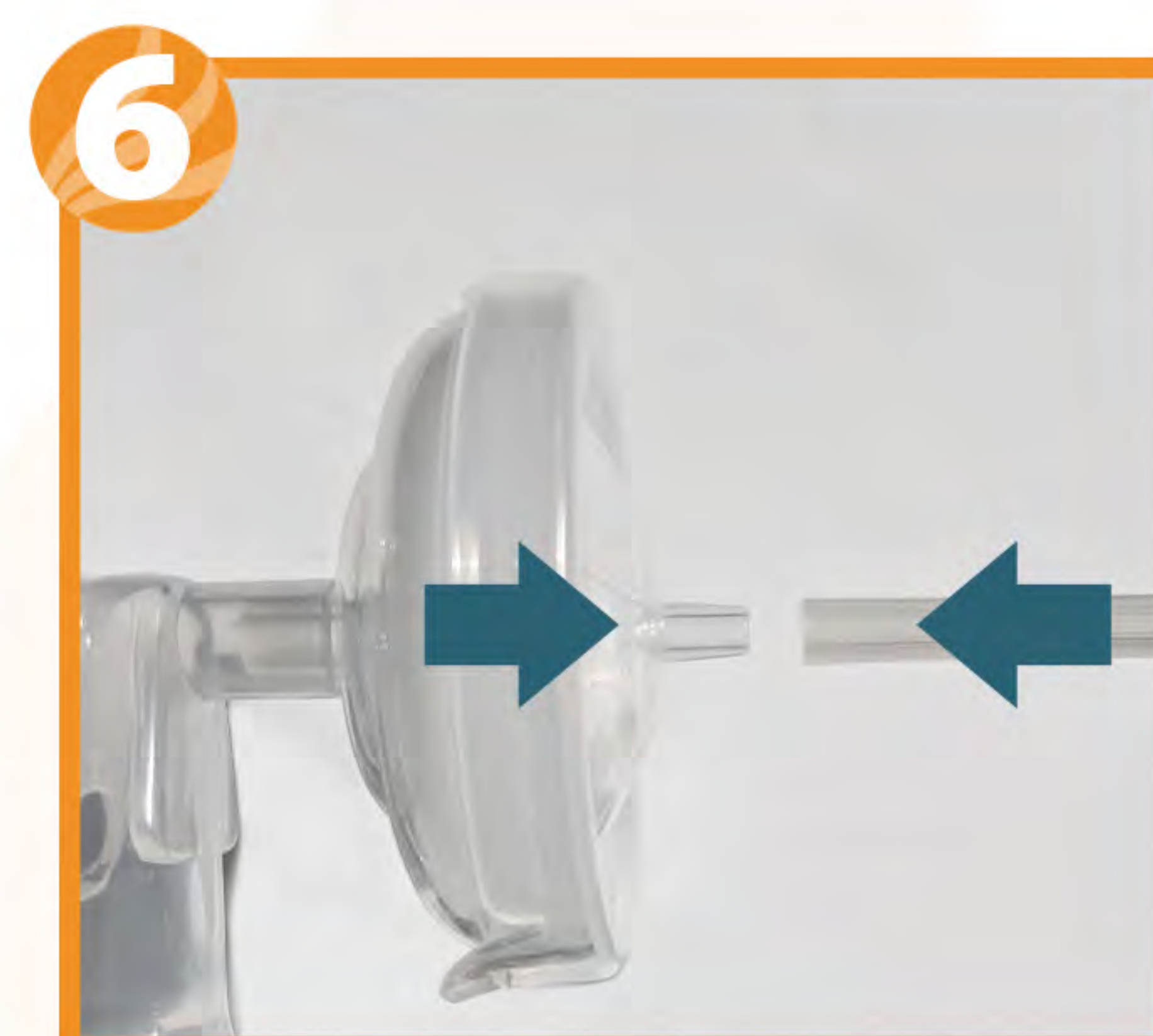
3. Place the tubing adapter into the hole in the front center of the Evolve pump. If you wish to pump one breast only, secure the port cap on one stem of the pump port.



4. Attach the duckbill valve to breast flange and tighten onto the bottle.



5. Assemble the Back-flow protector- bottom, silicone disk, and cap. Connect to the top of the flange.



6. Connect the back-flow protector to the tubing.

7. PUMPING CENTER

7.1 Precautions

- If discomfort is felt, then suction can be broken by inserting a finger between the breast and the flange.
- If irritation or discomfort occurs, discontinue use and see a doctor.
- Tubing- When used correctly, breast pump tubing does not touch the pumped milk and does not need to be cleaned. Inspect the tubing. If your tubing has water droplets in it at the end of a pumping session, disconnect the tubing from the flange/pump kit, but leave it attached to the pump. Run the pump for a few more minutes until the tubing is dry. If your tubing has milk or mold in it, throw it away immediately. Replace it with a set of new tubing, and check to see if the problem happened because:
 - The Valves or membranes need to be replaced
 - The tubing was attached to the pump incorrectly.

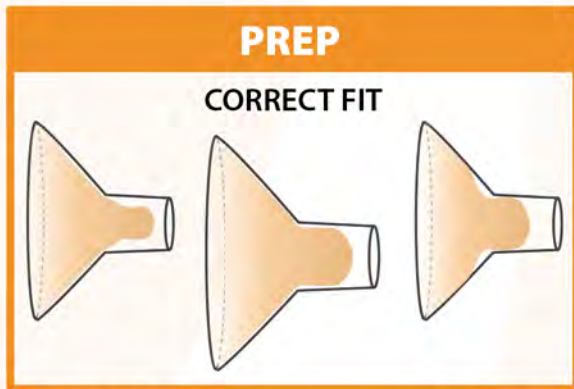
If the outside of your tubing is soiled, wipe with a damp cloth or disinfectant wipe. Keep a spare set of tubing on hand in case the set you are using gets soiled or damaged.

<https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding/breastpump.html>

7.2 Pumping Terms

- **Stimulation Mode:** The pump performs in higher cycle rates, lower pressure settings to simulate a baby's initial, natural suckling motion that promotes the flow of breast milk.
- **Expression Mode:** The pump performs in lower cycle rates, higher pressure settings and used after milk starts flowing as this mode simulates a baby's low rate, deep suction effort to produce milk flow.
- **Double Pumping:** This is pumping two breasts at the same time and the port cap is not secured over any stem of the two pump ports located on the front of the pump.
- **Single Pumping:** This is pumping one breast and is accomplished by securing the port cap on either of the two pump ports located on the front of the pump.

7.3 Using the Breast Pump



Too Large

Too Small

BEFORE PUMPING

- Wash hands with soap and water for 20 seconds.
- Inspect and assemble clean pump kit. If your tubing is moldy, discard and replace immediately.
- Clean pump and counter top with disinfectant wipes, especially if using a shared pump.
- Get yourself into a comfortable relaxed position
- Warm packs and/or gentle breast massage may help milk production
- Center the flange(s) over your nipple(s)

7.4 Breast Pump Settings



Turn on pump by pressing and holding On/Off button for 1 second. Pump will be in **Stimulation Mode**



Adjust 5 speed levels of pump by pressing "-" and "+" Speed Buttons



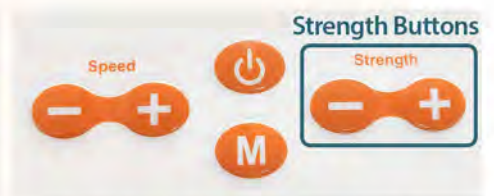
Adjust 10 suction levels of pump by pressing "-" and "+" Strength Buttons



When milk begins to flow push Mode button to switch pump into **Expression Mode**



Adjust 5 speed levels of pump by pressing "-" and "+" Speed Buttons



Adjust 10 suction levels of pump by pressing "-" and "+" Strength Buttons

8. TROUBLESHOOTING

Pump will not turn on	<ul style="list-style-type: none"> • Make sure the device is plugged into a working electrical outlet and the connection is secure on the pump. Make sure your cordless model is charged.
No or very low suction	<ul style="list-style-type: none"> • Make sure all kit connections are secure to the breast pump. • Make sure that the tubing is fitted securely into the breast-flange. • If single pumping, make sure the unused dual-port is sealed with cap. • Check to ensure that all valves are properly secured on the underside of the breast-flanges. Recommended to change the valve 1-3 months
Milk appears in the tubing	<ul style="list-style-type: none"> • Turn off the pump and unplug from power source. • Remove and disassemble the tubing. • Replace tubing.
Condensation appears in tubing	<ul style="list-style-type: none"> • If your tubing has water droplets in it at the end of a pumping session, disconnect the tubing from the flange/pump kit, but leave it attached to the pump. Run the pump for a few more minutes until the tubing is dry.
Pain – Discomfort	<ul style="list-style-type: none"> • Verify you are using the proper and supported Personal Accessory Set for your Hygeia Evolve Breast pump. The Hygeia Evolve Personal Accessory Set is the intended Accessory Set for the Hygeia Evolve and FIT Breast pumps. Personal Accessory Sets designed for other breast pumps have not been confirmed by Hygeia for safe use with the Hygeia Evolve Breast pump. <u>Using other Personal Accessory Sets with the Hygeia Evolve Breast pump voids the pump's warranty, may result in milk in the pump, and possibly result in personal injury due to high suction levels.</u>

8.1 DANGER: To reduce the risk of electrocution:

- Always unplug this product immediately after use.
- Do not use while bathing or showering.
- Do not place in or drop product into water or other liquids.
- Do not place or store product where it can fall or be pulled into a tub or a sink.
- Do not reach for this product if it has fallen into water or other liquid.
- Unplug Immediately.

8.2 WARNING: To reduce the risk of burns, electrocution, fire or injury:

1. 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.
2. This breast pump should not be operated while traveling on an airplane.
3. This product should never be left unattended when plugged into an electrical outlet.
4. Only use the pump for its intended use as described in this manual.
5. Do not operate this product if any of the following occur:
 - a. Damaged cord or plug
 - b. Dropped or damaged
 - c. Dropped or placed in water
6. Keep the cord away from heated surfaces.
7. Never operate this product while sleeping or feeling drowsy.
8. Supervision is necessary when this product is in the vicinity of children.
9. Do not unplug this product by pulling on the cord.
10. Do not use this product unless the voltage of the device is compatible with the power source.
11. When pump is not in use, be sure all tubing, parts and accessories are stored safely away from children to avoid strangulation by hoses and small parts being inhaled or swallowed.
12. Do not pump while driving.
13. Pump sitting upright in a chair with a slight lean back.
14. Do not pump while laying down.
15. Do not use this product unless pump is located on a level, flat surface that permits airflow below and around pump.
16. Do not modify this equipment without authorization of the manufacturer (IEC 60601-1 CLAUSE 7.9.3.1)
17. Use only the Evolve Personal Accessory set with the Evolve Breast Pump. DO NOT use parts not recommended by the manufacturer.

8.3 Warranty Information

For warranty information, or for assistance with setting up, using or maintaining the Breast Pump, or to report unexpected operation or events please visit: www.HygeiaHealth.com

8.4 Reference Guide

1. <https://www.womenshealth.gov/breastfeeding/pumping-and-storing-breastmilk>
2. https://www.cdc.gov/breastfeeding/recommendations/handling_breastmilk.htm
3. For directions for use, please refer to the CDC Breast Pump Recommendations: <https://www.cdc.gov/healthywater/pdf/hygiene/breast-pump-fact-sheet.pdf>
4. For cleaning process, please refer to FDA recommended cleaning instructions (<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/homehealthandconsumer/consumerproducts/ucm061950.htm>) or CDC recommended cleaning instructions (<https://www.cdc.gov/healthywater/pdf/hygiene/breast-pump-fact-sheet.pdf>)
5. For disinfection, please refer to CDC low-level disinfectant recommendations (see Table 1): http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
6. Boil for 5 minutes only, per CDC guidelines found here: <https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding/breastpump.html>

Evolve multiple-user pump is designed so breast milk can never touch working parts of the pump that is shared. The only part of a multiple-user breast pump that you can safely share is the pump itself. Operator is the patient. Manufacture will provide sufficient information to the department/people that handles the repair/maintenance.

9. BREASTMILK STORAGE GUIDELINES

9.1 Storing Breast Milk

Breastmilk Storing and Thawing Guidelines for Healthy Full-Term Babies				
	Room Temperature	Cooler with Frozen Ice Packs	Refrigerator	Freezer
	up to 77° F (25° C)	59° F (15° C)	39° F (4° C)	0° F (-18° C)
Freshly pumped breast milk	Up to 4 hours	24 hours	3 days	Up to 6 months.
Thawed breast milk	1-2 hours	Don't store	24 hours	Never re-freeze

Source: Adapted from ABM Clinical Protocol #8 Human Milk Storage Information for Home Use for Full-Term Infants(link is external) (2017).

9.2 Storage Tips for Breast Milk

- Write the date on the storage container. Include your child's name if you are giving the milk to a child care provider.
- Refrigerate or chill milk right after it is pumped, if possible. You can put it in the refrigerator, place it in a cooler or insulated cooler pack, or freeze* it in small (2- to 4-ounce) batches for later feedings. Pumped milk is OK without being refrigerated for up to 4 hours after pumping.
- When your pumping session is complete, turn off the pump and unplug the tubing from the back of the flange(s)
- Unscrew the breastmilk storage container and cap
- Refer to the Breastmilk Storage Chart for storing information
- Thaw the oldest breastmilk first.
- Breastmilk does not need to be warmed. Some moms prefer to serve it at room temperature. Some moms serve it cold.
- Thaw the bag of frozen milk by putting it in the refrigerator overnight.
- If you decide to warm the breastmilk:
 - Keep the container sealed while warming.
 - Hold it under warm, not hot, running water, or set it in a container of water that is warm, not hot.
 - **Never put a bottle or bag of breastmilk in the microwave.** Microwaving creates hot spots that could burn your baby and damage the milk.
 - Test the temperature before feeding it to your baby by dropping some on your wrist. The milk should feel warm, not hot.
- Swirl the milk to mix the fat, which may have separated. Do not shake the milk.
- Use breastmilk within 24 hours of thawing it in the refrigerator. This means 24 hours from when the breastmilk is no longer frozen, not from when you take it out of the freezer.
- Once breastmilk is thawed to room temperature or warmed after being in the refrigerator or freezer, use it within 2 hours. If you have any leftover milk when the baby is finished feeding, be sure to throw it out within 2 hours.
- Do not refreeze breastmilk after it has been thawed.
- Please refer to the CDC's Proper Storage and Preparation of Breast Milk guidelines for more information: https://www.cdc.gov/breastfeeding/recommendations/handling_breastmilk.htm

*We do not recommend placing bottles in the freezer as they may shatter if dropped.

10. HYGEIA ACCESSORIES AND SPARE PARTS

Some pumps may also include some of these accessories:

You may also be able to order these additional accessories or spare parts online, at a Hygeia insurance covered provider or our website, visit www.hygeiahealth.com for more information.



Deluxe Tote



AC Power Adapter



Tubing and Tubing Adapter



Milk Storage Containers



28mm Flange Funnel



30mm Flange Funnel



Flange Base



Storage Container Locking Discs



Storage Container Locking Rings



Duckbill Valves



Back-flow Protector Case Top



Back-flow Protector Silicone Disk



Back-flow Protector Case Bottom

11. TECHNICAL INFORMATION

11.1 Power Adapter

AC Input Voltage Range: 100-240VAC / Operating Frequency: 50/60HZ

Input Current: 500mA, MAX

Output: 5.0V== 3.0A

Power Supply Model Number: UES18LCP-050300SPA



11.2 Environmental Conditions for Operation

Noise Level: ≤ 50 dB(A) at 1m distance

Highest Negative Pressure At Stimulation Stage: ≤160mmHg

Highest Negative Pressure At Expression Stage: ≤260mmHg

11.3 Main Unit

Model: Hygeia Evolve

Dimensions for Main Unit: 133mm Length X 127mm Width X 95mm Height

Weight of Main Unit: .45kg

Operating Atmospheric Pressure: 700hPa-1060hPa

Storage Conditions: Temperature: -25°C-70°C / Humidity: 5-90%

Operating Conditions: Temperature: 5°C-40°C / Humidity: 15-90%

Shelf Life (exclude the battery): 2 years upon manufacturing date

Operation Life Time: 1200 hours (Corded Model)

Device Use-Life (Cordless Model) = 337 days based on 900 hours battery life and expected daily use of eight, 20-minute sessions (900 hours ÷ 2²/₃ hours/day = 337 days)

Vacuum Strength and Cycle Speed (Single and Double Pumping):

<u>Mode</u>	<u>Vacuum Pressure (Strength)</u>	<u>Cycles Per Minute (Speed)</u>
Stimulation	-60 to -160 mmHg	CPM 60-80
Expression	-100 to -260 mmHg	CPM 30-50

11.4 Battery Information

Corded Model Only

Requires 4 AA batteries. Use new premium batteries, insert them correctly.

⚠ WARNING: DO NOT install backwards, charge, put in fire, or mix with other battery types. May explode or leak causing injury. Replace all batteries at the same time.

1. OPEN battery compartment on the bottom of the pump base.
2. INSERT 4 new AA batteries, batteries not included.

Corded version with 4 AA batteries lasts 1 hour











Cordless Model Only

Battery: 3.7V 2600mAh Lithium Battery (UL62133 Certified)

Standard Charge Time, 0 to 100% Capacity: Approximately 4 Hours

Blinking Battery Percentage Bar = Battery Charging

Battery Icon Status	Approximate Remaining Run Time	Suggested Action
	105 minutes	
	80 minutes	
	60 minutes	
	50 minutes	Connect AC Adapter Soon
	40 minutes	 Connect AC Adapter
Steady Icon 	0 minutes	 Connect AC Adapter

11.5 Electromagnetic Interference

Complies with EMC Standard 60601-1-2:2014. Unlikely to interfere with other electrical equipment. Device may emit RF energy, if interfering with other devices, relocate.

11.6 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The breast pump is intended for use in the electromagnetic environment specified in section 12. The user of the breast pump should assure device is used in such environment.

The Evolve breast pump has no essential performance but was tested for immunity to electromagnetic disturbances and passed the following criteria:

1. No visible change in operation of the breast pump
2. No change to settings of the breast pump while operating

12. ELECTROMAGNETIC COMPATIBILITY

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC provided in these Instructions for use.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

Warning: The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of The Hygeia Evolve Breast Pump as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the Hygeia Evolve Breast Pump.

Warning: The Hygeia Evolve Breast Pump should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Hygeia Evolve Breast Pump should be observed to verify normal operation in the configuration in which it will be used.

Warning: Portable RF Communications Equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of The Hygeia Evolve Breast Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.


Guidance and manufacturer's declaration – electromagnetic emissions

The Hygeia Evolve Breast Pump is intended for use in the electromagnetic environment specified below.		The customer or the user of the Hygeia Evolve Breast Pump should assure that it is used in such an environment.	
Emissions test	Compliance	Electromagnetic environment – guidance	
RF emissions CISPR 11	Group 1	The Hygeia Evolve Breast Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The Hygeia Evolve Breast Pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	Class A		
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies		

Guidance and manufacturer's declaration – electromagnetic immunity

The Hygeia Evolve Breast Pump is intended for use in the electromagnetic environment specified below.		The customer or the user of the Hygeia Evolve Breast Pump should assure that it is used in such an environment.	
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EFT - Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV line(s) to line(s)	± 0.5 kV, ±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U _t ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U _t ; 1 cycle and 70% U _t ; for 25/30 cycles Single phase: at 0°	0% U _t ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% U _t ; 1 cycle and 70% U _t ; for 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical Commercial or hospital environment. If the user of the Hygeia Evolve Breast Pump requires continued operation during power mains interruptions, it is recommended that the Hygeia Evolve Breast Pump be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U _t is the ac. mains voltage prior to application of the test level.			

12. ELECTROMAGNETIC COMPATIBILITY *CONTINUED*

Guidance and manufacturer's declaration – electromagnetic immunity			
The Hygeia Evolve Breast Pump is intended for use in the electromagnetic environment specified below. The customer		or the user of the Hygeia Evolve Breast Pump should assure that it is used in such an environment.	
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Hygeia Evolve Breast Pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured</p>		<p>electromagnetic site survey should be considered. If the measured field strength in the location in which the Hygeia Evolve Breast Pump is used exceeds the applicable RF compliance level above, the Hygeia Evolve Breast Pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Hygeia Evolve Breast Pump.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>	