



# Express

## Powered Breast Pump



## Congratulations on joining the Hygeia family!

We are excited to help you meet your breastfeeding goals along your breastfeeding journey with your baby. With our Hygeia Express breast pump and Personal Accessory Set Milk Collection System, you can express and collect your breast milk safely and effectively.

The Hygeia Personal Accessory Set is a closed system that contains a diaphragm 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 diaphragm helps prevent milk backup into tubing.




























If you have any questions regarding your Hygeia Express Powered breast pump or Personal Accessory Set, we have a customer service team 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 **714-515-7571 Option #2**. Please check [www.hygeiahealth.com](http://www.hygeiahealth.com) for up-to-date available times.

For more information about breastfeeding, breast pumping or Hygeia products visit [www.hygeiahealth.com](http://www.hygeiahealth.com).

## TABLE OF CONTENTS

1.	WARNINGS & CAUTIONS .....	5
2.	INTENDED USE.....	8
3.	CONTRAINDICATIONS FOR USE .....	8
4.	PRODUCT DESCRIPTION.....	9
5.	SET-UP INSTRUCTIONS .....	10
5.1	Before First Use: Clean The Personal Accessory Set.....	10
5.2	Assembling the Personal Accessory Set (PAS) Milk Collection System .....	11
6.	INSPECTING BEFORE PUMPING .....	13
7.	OPERATING INSTRUCTIONS .....	14
7.1	Plug into Power Source.....	14
7.2	Button Control.....	14
7.3	LCD Icons & Modes.....	15
7.4	To Begin Pumping.....	16
7.5	How to Fit Your Flange .....	18
7.6	Breast Milk Storage Guidelines.....	18
8.	CLEANING .....	19
8.1	General Guidance .....	19
8.2	Before Each Use .....	19
8.3	After Every Use.....	20
8.4	AFTER CLEANING .....	22
9.	MAINTENANCE .....	23
9.1	Breast Pump Valve and Diaphragm Check .....	23
9.2	Storing & Transporting .....	23
10.	TROUBLESHOOTING .....	23
11.	WARRANTY.....	25
12.	TECHNICAL DATA.....	26
12.1	Specifications .....	26
12.2	Electromagnetic Compatibility.....	27
12.3	Product Disposal.....	31
13.	OPERATIONAL & STORAGE CONDITIONS .....	31
14.	TRAVEL .....	31
15.	SYMBOLS REFERENCE .....	32

## Icon Glossary See reference detail in Section 15

	Warning		Temperature range <sup>4</sup>		Unit of measure		For indoor use only <sup>17</sup>
	Caution		Humidity range <sup>5</sup>		Class II electrical appliance (double insulated) <sup>11</sup>		Non-ionizing Electromagnetic Radiation <sup>18</sup>
	Important		Atmospheric pressure range <sup>6</sup>		Type BF Applied Part <sup>12</sup>		Waste electrical and electronic equipment <sup>13</sup>
	Refer to Instruction manual		Expiration		Ingress Protection classification		Alternating Current <sup>14</sup>
	Fragile, handle with care <sup>1</sup>		Manufacturer <sup>7</sup>		Direct Current <sup>15</sup>		Date of Manufacture <sup>19</sup>
	Protect from sunlight <sup>2</sup>		Lot number <sup>8</sup>		On/Off Button <sup>16</sup>		
	Keep dry <sup>3</sup>		Serial number <sup>9</sup>				
	Wash hands		Catalogue Number <sup>10</sup>				

# 1. WARNINGS & CAUTIONS

## IMPORTANT SAFEGUARDS




When using electrical products, especially if children are present, the following basic safety precautions should always be followed.

### READ ALL INSTRUCTIONS BEFORE USING THIS PRODUCT

#### WARNING:

- Always unplug electrical product immediately after use.
- **DO NOT** use while bathing, showering or swimming.
- **DO NOT** place or store where product can fall or be pulled into a bathtub, shower, sink, or pool.
- **DO NOT** place or drop product into water or other liquid.
- **DO NOT** use an electrical outlet that has been exposed to water or other liquids.
- **DO NOT** reach for electrical product that has fallen into water. Immediately unplug from electrical outlet.
- **DO NOT** run water over breast pump.

The following symbols identify all instructions that are important to safety. Failure to observe these instructions can lead to injury or damage to the breast pump or yourself.

	<b>WARNING</b> Can lead to serious injury or death.
	<b>CAUTION</b> Can lead to minor injury.
	<b>IMPORTANT</b> Can lead to material damage.



## **WARNING:** To avoid fire, electrocution, serious burns or injury:

- **NEVER** leave product unattended when plugged into an electrical outlet.
- Close supervision is necessary when product is used near children or persons with disabilities.
- Use product for its intended use **ONLY**, as described in this manual.
- **DO NOT** use parts that are not recommended by the manufacturer.
- If the power adapter casing or wiring becomes loose, separated, or frayed, stop use of the power adapter immediately and contact Hygeia Customer Service at **714-515-7571 Option #2**. Stop using the device immediately if you note any smoke or burning from the pump unit or power adapter.
- **NEVER** operate electrical product: if it has a damaged cord or plug; if it is not working properly; if it has been dropped, damaged, or becomes wet.
- Keep cord away from heated surface.
- **NEVER** use while sleeping or when drowsy.
- **NEVER** insert or drop any object into any opening or into tubing.
- **Keep** the breast pump and accessory kit away from heated surfaces or open flames.
- **DO NOT** use near flammable materials.

*Environmental Conditions That Affect Use*

- **DO NOT** use outdoors with electrical cord.
- **DO NOT** operate where oxygen or aerosol spray products are being used.



## **WARNING:** To avoid health risk and reduce the risk of injury:

This product is a personal care item and intended for use by only one user. Powered breast pumps that are designed for single users should never be rented or shared. Pumping does not prevent transmission of substances or infections carried via breast milk to baby.

*Note: Do not use product if damaged. Use product only for intended use as described in this manual.*

- **DO NOT** use pump while driving.
- Pumping can induce labor, **DO NOT** use while pregnant unless approved by your breastfeeding specialist or healthcare professional.
- **DO NOT** pump while sleeping, it could result in tissue damage.
- Prior to first use and after every use, clean all parts (flange, diaphragm, valve and bottle) that come in contact with your breast and breastmilk.
- **DO NOT** use attachments other than those recommended by manufacturer.
- **DO NOT** make mechanical or electrical modifications to breast pump base.
- Before each use visually inspect the individual components for cracks, chips, tears, discoloration, or deterioration. In the event that damage to the device is observed, please discontinue use until the parts have been replaced. Contact Hygeia Customer Service at **714-515-7571 Option #2** immediately.
- **DO NOT** repair device by yourself. Do not modify the device or parts, please contact Hygeia Customer Service for help.
- **DO NOT** continue pumping for more than 2 consecutive pumping sessions if breast milk is not collected.
- **DO NOT** heat or thaw frozen breastmilk in a microwave or boiling water. Microwaving can heat liquids unevenly. Both microwaving and boiling water can result in burns.
- Clean and disinfect all parts that come into contact with your breast and breast milk prior to first use.
- 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.
- If irritation or discomfort occurs, discontinue use and see a doctor.
- Accessible materials may cause allergic reactions.

**STRANGULATION HAZARD:** Keep tubing and power adapter cords out of reach of children or persons with disabilities.

**CHOKING HAZARD:** Small parts, **NOT** for children under 3 years.



## **CAUTION:** Can lead to minor injury:

- **DO NOT** attempt to remove or replace battery. **BATTERY CANNOT BE REMOVED.**
- **DO NOT** wrap cord around the body of the adapter.
- Use **ONLY** the AC power adapter that is recommended for the Hygeia Express Breast Pump.
- **DO NOT** use the breast pump in an aircraft.
- **DO NOT** shorten tubing or modify the breast pump kit.
- Plug the AC power adapter into the pump base prior to plugging into the wall socket.
- Keep pump and kit away from dust, lint and direct sunlight.
- **DO NOT** attempt to remove the breast flange from your breast while pumping. If you are not feeling comfortable or feeling pain with pumping, turn off the pump, break the seal between the breast and breast flange with your finger, and remove breast flange from your breast gently.
- **ALWAYS** place pump on a horizontal flat surface when using product.
- This product contains a Lithium-ion battery. The battery or internal components cannot be replaced. **DO NOT** attempt to open pump base.
- Wash all parts that are exposed to breast milk immediately after use. This will help remove breast milk residue and prevent growth of bacteria.



## **IMPORTANT:** Can lead to material damage.

- **NEVER** put electrical product in water or a sterilizer, as you can cause permanent damage to the breast pump.
- **DO NOT** use antibacterial or abrasive cleaners/detergents when cleaning breast pump or breast pump parts.
- When plastic bottles and plastic breast pump kit parts are frozen, they can become brittle and may break when dropped.
- **DO NOT** over-fill bottles. Replace bottles before they overflow.
- Do not use the pump while lying down so that expressed milk flows down into the milk container and not into the tubing.
- Bottles and breast pump kit parts may become damaged if mishandled, e.g., dropped, overtightened, or knocked over.
- Always check bottles or breast pump kit parts prior to pumping. Discard breastmilk if bottles or breast pump kit parts are damaged.

## **WARNING**

- Portable and mobile RF communications equipment, RFID readers, electronic article surveillance (anti-theft) equipment and metal detectors can affect the performance of the Hygeia Express Powered Breast Pump. Please use the guidelines and recommendations specified in Tables 3 and 4 in Section 12.2 of this manual, “Electromagnetic Compatibility” to mitigate the effects of any disturbances.
- Other electronic or medical equipment (such as MRI, diathermy, and electrocautery devices) can produce electromagnetic emissions that can interfere with the functionality of the HYGIEIA Express Powered Breast Pump. Move away from such equipment if your pump behaves erratically. Verify normal pump operation in a different location.
- The HYGIEIA Express Powered Breast Pump is not safe for use in an MRI environment.
- **NOTE:** The Express Breast Pump has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2014 4<sup>th</sup> edition. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation.



## **SAVE THESE INSTRUCTIONS**

### **2. INTENDED USE**

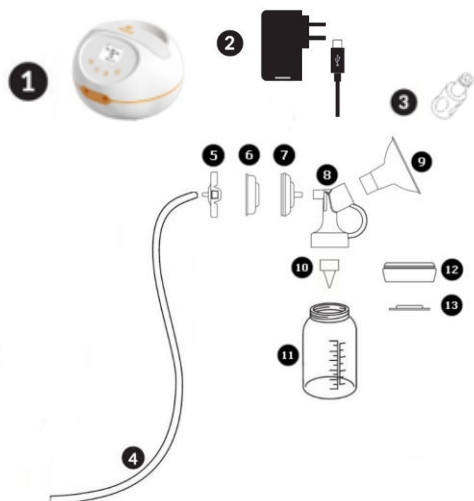
The Hygeia Express Powered Breast Pump is a powered breast pump intended to express and collect milk from the breasts of a lactating woman. It is intended for a single user only.

### **3. CONTRAINDICATIONS FOR USE**

There are no known contraindications for use with this product.



## 4. PRODUCT DESCRIPTION



### Pump Assembly

1. Hygeia Express Powered Breast Pump Unit

2. AC Power Adapter

3. Connector for Tubing

4. Tubing

5. Backflow Protector Case Top

6. Diaphragm - Backflow Protector Silicone Disc

7. Backflow Protector Case Bottom

8. Flange Base

9. Flange Funnel (28mm and 24mm included) \*

10. Valve, Duckbill

11. Bottle

12. Bottle Locking Ring

13. Bottle Locking Disc

**Hygeia Personal  
Accessory Set  
(PAS)  
Milk Collection  
System**

*Pump parts may vary*

NOTE: Only use the Hygeia Personal Accessory Set (PAS) and Hygeia replacement parts with this pump. The Express Powered breast pump may also be used with the Hygeia Wearable PAS. Using the Hygeia Wearable PAS may result in your having to select a different suction level to achieve maximum comfort during pumping.

\*More flange sizes are available for purchase on the Hygeia website. [www.hygeiahealth.com](http://www.hygeiahealth.com)

## 5. SET-UP INSTRUCTIONS

### 5.1 Before First Use: Clean The Personal Accessory Set

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



**WASH HANDS THOROUGHLY** with soap and water before touching breast pump, kit and breasts.

Before first use, unless otherwise directed by your healthcare provider, prepare product for use as follows:

1. **Disassemble all parts and place Breast Pump and AC Power Adapter and Cord off to the side.**
2. **SET ASIDE tubing adapter ③ and tubing ④**- after your first use, you do not need to take these apart from each other. The tubing adapter and tubing **DO NOT need to be washed** before first use or typically after each use because milk does not come into direct contact with these parts. If condensation does appear in the tubing, follow the directions below for *cleaning the tubing*.
3. **Clean remaining pump kit parts as directed using cleaning instructions in Section 8 of this manual.** For additional cleaning guidelines visit the Center for Disease Control website: <https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding/breastpump.html>.

**NOTE: Inspect the tubing.** If you find condensation in the air tube, wash and dry it immediately or replace the tubing. If you see breast milk inside the tubing or tubing connector do not attempt to wash, clean or sterilize the tubing or tubing connector. Instead contact Hygeia Customer Service at 714-515-7571 Option #2.



#### IF YOU DISINFECT BY BOILING

**DO NOT** allow boiling parts to contact bottom of pot. It may cause damage to parts.



**WARNING: DO NOT** leave boiling parts unattended. Remove parts carefully from boiling water to avoid burning. Boiled water and steam from boiled water can cause severe skin burns, so use caution when boiling parts in water and removing parts from boiling water.

- Please check pump kit parts for cracks, chips, tears or deformation before and after disinfection.

**CLEAN TUBING:** It is necessary to wash the tubing only if condensation is present. If condensation is present in the tube, wash and dry it immediately or replace the tubing. If milk is present in the tubing, do not attempt to wash or clean the tubing. Instead contact Hygeia Customer Service at 714-515-7571 Option #2.

#### HOW TO WASH TUBING:

1. Rinse tubing by pouring cool water and make sure the water flows through the entire tubing from one end to the other.
2. Wash the tubing in warm, soapy water and rinse thoroughly.

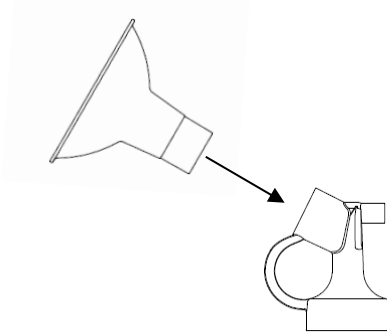
#### HOW TO DRY TUBING:

Hang the tubing to air dry and make sure that the tubing is completely dry before using.

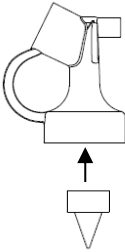
## 5.2 Assembling the Personal Accessory Set (PAS) Milk Collection System

Once your pump parts are completely dry before use, wash your hands thoroughly and assemble the Personal Accessory Set Milk Collection System (Pump Kit).

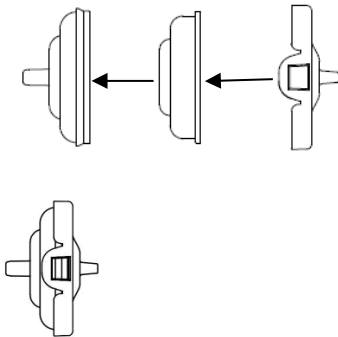
1. Attach the Flange Funnel to the Flange Base



2. Attach the Duckbill Valve into the bottom of the Flange base.

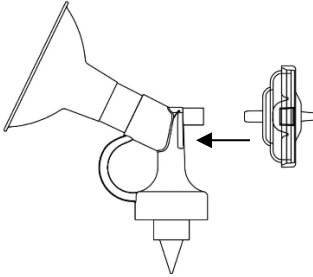


3. Assemble the Backflow protector case bottom, Diaphragm- Backflow protector Silicone Disc and Backflow protector case top. You should hear a “click” once they are properly fitted together.

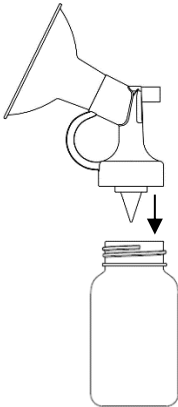


4. Connect the 3-piece assembled Backflow protector to the top of the Flange Base pushing in firmly.

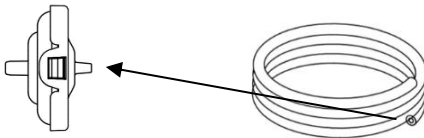
NOTE: When removing the backflow protector, twist and pull it straight out, away from the flange base. **Do not bend the backflow protector** to remove it. Doing so may result in damage.



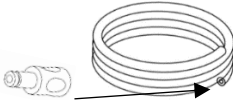
5. Add the Assembled Flange Funnel, Flange Base and Duckbill valve onto the storage container.



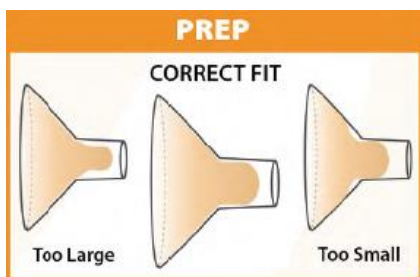
6. Connect one end of the tubing to the back of the Backflow protector



7. Firmly press a connector on to the other end of the tubing



8. When you are ready to start pumping, center the breast shield on your breast so that the nipple is drawn into the flange. It's important that breast shield is positioned properly before pumping begins in order to avoid any pain that may result due to rubbing or twisting of your nipple onto the side of the flange. If double pumping, place the second breast shield in place as well.



While some discomfort may be felt when first using a breast pump, using a breast pump should not cause pain. If you are unsure about breast shield sizing, please contact a healthcare professional or Hygeia representative who can help you get a proper flange fit.

## 6. INSPECTING BEFORE PUMPING



**IMPORTANT:** Before using the Hygeia Express and Personal Accessory Set system, check the parts for cracks, chips, tears, or wear. They can affect the function of the kit. If parts need replacing due to defects, please call Hygeia Customer Service at 714-515-7571 Option #2 OR visit [www.hygeiahealth.com](http://www.hygeiahealth.com).

## 7. OPERATING INSTRUCTIONS

### 7.1 Plug into Power Source

*Choosing and checking your electrical source*

#### AC POWER ADAPTER



**WARNING:** Use **ONLY** the AC power adapter recommended for the Hygeia Express Powered Breast Pump.

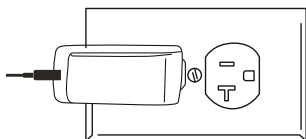


**WARNING:** Always inspect the AC power adapter for damage such as kinking or twisting of cords or frayed or exposed wires. If damaged, discontinue use immediately and call customer service at **714-515-7571 Option #2**.

1. **PUSH** the small plug on the cord end of the AC power adapter into the opening on the back side of the pump base.



2. **PLUG** the main body of the AC adapter into an AC outlet.



### 7.2 Button Control

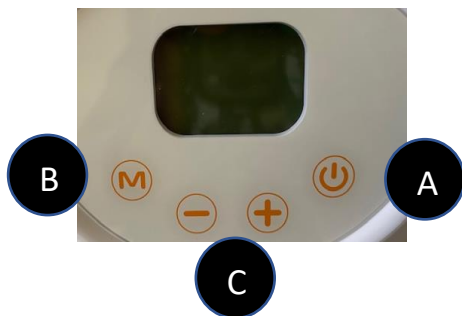
#### A. POWER ON/OFF BUTTON

#### B. MODE SELECTION BUTTON

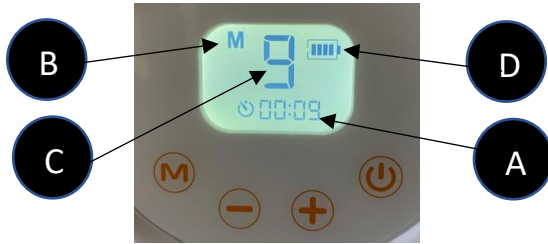
Switches between Massage (M), Expression (E) and Stimulation (S) Modes

#### C. - / + VACUUM LEVEL

Decreases or increases suction strength during pumping



## 7.3 LCD Icons & Modes



### A. TIMER DISPLAY

Tracks elapsed pumping time. Pump automatically powers off after 30 minutes.

### B. PUMPING MODE

Massage (M) mode mimics baby's fast suction pattern with fast speed and low suction to start milk flowing. This icon is displayed at start up of the pump. Press Mode button to switch to Expression (E) mode, where higher suction should allow more efficient milk flow. Press the mode button for 3 seconds to switch to Stimulation (S) mode, where fast short cycles of low suction combine with slower cycles of high suction to restimulate the flow of milk. Depending on your comfort, you may choose Stimulation mode over Expression mode as your main pumping preference.

**NOTE:** After two minutes, the pump will automatically switch to Expression (E) Mode unless you manually adjust mode beforehand.

### C. SUCTION STRENGTH LEVEL

Level of suction strength during pumping. The Hygeia Express Powered Breast Pump has 9 suction levels in each of the three pumping modes

Increase suction by pressing the "+" button and decrease suction by pressing the "-" button.

### D. BATTERY LEVEL

The time required to charge the battery to full capacity will be close to five hours when the pump is new and a little more than four hours after extended use on battery alone. A blinking battery icon means the battery is charging. The pump can operate on a fully charged battery for at least 2 hours before a recharge is required.



Battery Icon Status and approximate remaining run time:



## 7.4 To Begin Pumping

### STEP 1: INSERT TUBING

Insert Connector end of Tubing into the front port holes of the Hygeia Express Powered breast pump and gently push it to make sure it connects firmly.

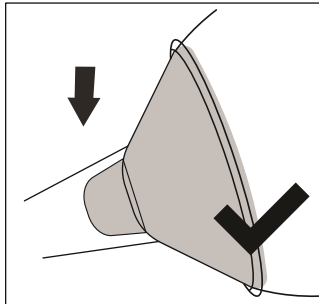
For **DOUBLE PUMPING**: Attach both connectors with tubing to the Hygeia Express Powered breast pump.

For **SINGLE PUMPING**: Attach only one connector with tubing into either of the two holes on the front of the Express Powered breast pump. When single pumping do not plug the extra port hole, this may increase single pumping suction.



### STEP 2: PLACE THE FLANGE ON BREAST

Center flange on breast to create seal. Check breast flange fit, if pumping causes discomfort a larger or smaller breast flange size may be needed. See section 7.5 below on how to properly fit your flange.



### STEP 3: POWER ON THE PUMP

Press and hold the Power button for 3 seconds to turn on the device. It will begin in Massage (M) Mode.



Hold Power  
button for 3  
seconds to turn  
on

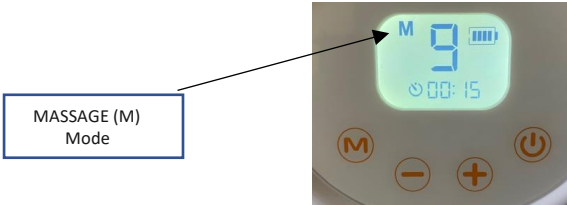
### STEP 4: ADJUST VACUUM LEVEL



Adjust the Massage (M) Vacuum Level between 1 and 9 to your preferred comfort level. Never set to an uncomfortable level.

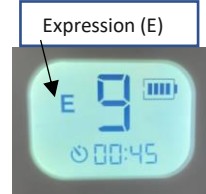
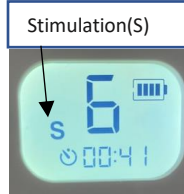
*TIP: Start off with the suction low, and then gradually increase the suction setting to your most comfortable level. You may find that the level of comfortable suction varies day-to-day, during the day and even during the same expression session.*

**NOTE:** After two minutes, the pump will automatically switch to Expression (E) Mode unless you manually adjust it before two minutes have elapsed.



### STEP 5: CHANGING MODES

Once your milk starts to flow, press the Mode button to switch into Expression (E) Mode if it has not switched automatically after 2 minutes. To restimulate milk flow hold the mode button for 3 seconds to switch to Stimulation (S) mode. Choose the mode and vacuum level that feels best for you.



### STEP 6: ADJUST VACUUM LEVEL +/-

Adjust the Massage (M), Expression (E) or Stimulation (S) Mode Vacuum Levels between 1 and 9 to your preferred comfort level. Never set to an uncomfortable level. Press + to increase and - to decrease levels

*TIP: Start off with the suction low, and then gradually increase the suction setting to your comfort level. You may find that the level of suction that you are comfortable with varies from day to day, during the day and even during the same expression session.*



### STEP 7: END PUMPING SESSION

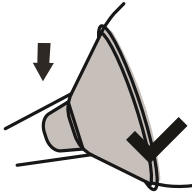
When you wish to stop expressing milk, press and hold the Power button for 1 second, then remove the milk collection kit from your breast.

*TIP: After pump is off, if necessary, INSERT a finger between breast and breast flange to break suction.*



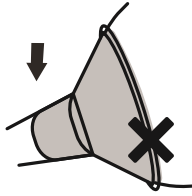
## 7.5 How to Fit Your Flange

Check breast flange fit, if pumping causes discomfort a larger or smaller breast flange size may be needed.



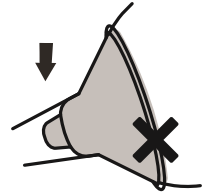
### GOOD FIT

During pumping, your nipple moves freely in the breast flange tunnel. You see space around the nipple. Not much areola is drawn into the tunnel with the nipple.



### FLANGE TOO SMALL

During pumping, some or all of your nipple rubs against the sides of the breast flange tunnel.



### FLANGE TOO LARGE

During pumping, more areola is drawn into the breast flange with your nipple. Your areola may rub against the side of the breast flange tunnel.

## 7.6 Breast Milk Storage Guidelines

- 1: Use breast milk storage bags or clean, food-grade containers to store expressed breast milk. Make sure the containers are made of glass or plastic and have tight fitting lids. **Avoid bottles with the recycle symbol number 7**, which indicates that the container may be made of a BPA-containing plastic. Never store breast milk in disposable bottle liners or plastic bags that are not intended for storing breast milk.
- 2: Write the date on the storage container. Include your child's name if you are giving the milk to a child care provider.
- 3: Gently swirl the container to mix the cream part of the breastmilk that may rise to the top back into the rest of the milk. Do not shake the milk. This can make some of the milk's valuable parts break down.
- 4: Refrigerate or chill breast milk right after it is pumped, if possible. Do not store breast milk in door of refrigerator or freezer. This will help protect the breast milk from temperature changes due to the opening and closing of the door. If you don't plan to use freshly expressed breast milk within 4 days, freeze it right away to protect the quality of the breast milk. You can put breast milk 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. When freezing breast milk, leave about one inch of space at the top of the container because breast milk expands as it freezes. Pumped milk is OK without being refrigerated for up to 4 hours after pumping.

	Room Temperature 77°F (25°C)	Time in Refrigerator 40°F (4°C)	Time in Freezer 0°F (-18°C)
Fresh Expressed or Pumped	Up to 4 hours	Up to 4 days	<b>6 Months</b> - Best <b>12 Months</b> - Acceptable
*Thawed, Previously Frozen	1-2 Hours	Up to 1 day (24 hours)	Do Not Refreeze
Leftover from Feeding (baby did not finish bottle)	Use within <b>2 hours</b> after the baby is finished feeding		

**\*NOTE:** When thawing frozen milk, label as thawed when completely thawed (i.e., no ice crystals present). Use the time when completely thawed to base acceptable time limits for use rather than when it is taken from the freezer.

**These guidelines for storage and thawing of breast milk are a recommendation. Contact your lactation consultant or breastfeeding specialist for further information.**

**These guidelines are for healthy full-term babies and may vary for premature or sick babies. Check with your health care provider.** Find more breastfeeding resources at: [WICBreastfeeding.fns.usda.gov](http://WICBreastfeeding.fns.usda.gov) and [www.cdc.gov/breastfeeding/](http://www.cdc.gov/breastfeeding/)

## 8. CLEANING

### 8.1 General Guidance

Appropriate cleaning instructions may be found on the FDA website (<https://www.fda.gov/medical-devices/breast-pumps/cleaning-breast-pump>).

Additional cleaning guidelines are available at the CDC website <https://www.cdc.gov/healthywater/hygiene/healthychildcare/infantfeeding/cleansanitiz e.html>

#### Pump Body

The pump body which houses the electrical components, motor and battery, should be wiped down with a clean paper towel or soft cloth after each use. The pump body should never be submerged or exposed to water or other liquids for cleaning. It should also never be cleaned using a microwave sterilizer.

#### Breast Pumping Kit

Components that contact the breast and breastmilk (breast shields, flanges, bottles, containers, cups, lids, connectors, membranes, and valves) should be hand-washed in the sink or washed in the top rack of the dish washer with a mild dish soap or detergent.

Tubing should not be cleaned unless condensation is in the tubing. If condensation is in the air tube, it should be washed and dried immediately or replaced. If breast milk is seen inside the tubing or tubing connector, they should not be washed, cleaned, or sterilized. Instead, contact Hygeia customer service at 714-515-7571 Option #2 for a replacement.

#### HOW TO WASH TUBING:

1. Rinse tubing by pouring cool water and make sure the water flows through the entire tubing from one end to the other.
2. Wash the tubing in warm, soapy water and rinse thoroughly.

#### HOW TO DRY TUBING:

Hang the tubing to air dry and make sure that the tubing is completely dry before using.



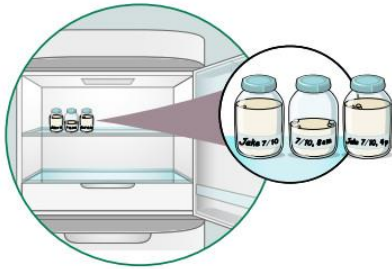
**WASH HANDS THOROUGHLY** with soap and water before touching breast pump, kit and breasts.

### 8.2 Before Each Use

Illustrations from <https://www.cdc.gov/hygiene/childcare/breast-pump.html>



1. **Wash hands** well 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 control buttons** and countertop with disinfectant wipes, especially if using a shared pump.



**1. Wash hands** well with soap and water for 20 seconds.

**2. 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.

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

**3. Clean pumping area,** especially if using a shared pump. Clean the pump control buttons and countertop with disinfectant wipes.

**4. Take apart** breast pump tubing and separate all parts that come in contact with breast/breast milk.

**5. Rinse** breast pump 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.**

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



## 6. CLEAN PUMP KIT PARTS BY HAND cleaning steps

a. Place pump parts in a clean wash basin used only for infant feeding items. **Do not place pump parts directly in the sink!**

b. Add soap and hot water to basin.

c. **Scrub** items carefully to carefully clean accessible surfaces. If using a brush, use a clean one that is used only to clean infant feeding items.

d. **Rinse** by holding items under running water, or by submerging in fresh water in a separate basin.

e. **Air-dry thoroughly.** Place pump 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!

f. **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.

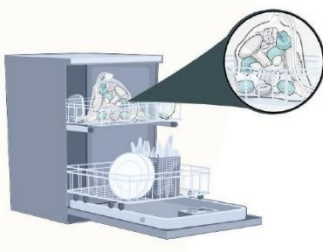


## 7. CLEAN PUMP KIT PARTS IN DISHWASHER cleaning steps

**!** **IMPORTANT:** The flanges and milk storage containers can also be washed on upper rack of a standard, household dishwasher. **DO NOT** use solvents or abrasives. Allow to air dry on a clean surface.

a. **Clean the pump kit parts in a dishwasher** by placing the small items into a closed-top basket or mesh laundry bag on the top rack of the dishwasher. Add soap and, if possible, **run the dishwasher using hot water and a heated drying cycle (or sanitizing setting).**

b. **Remove parts 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!



## 8.4 AFTER CLEANING



### 1. FOR EXTRA PROTECTION, DISINFECT

For extra germ removal, disinfect pump kit parts, wash basin, and bottle brush **at least once daily after they have been cleaned**. Items can be disinfected using boiling water, or in a dishwasher with a sanitize setting. Disinfection is especially important if your baby is younger than 3 months old, was born prematurely, or has a weakened immune system due to illness or medical treatment



### 2. STORE PUMP KIT PARTS SAFELY

**Store dry items safely until needed.** Ensure the clean pump parts, bottle brushes, and wash basins have air-dried thoroughly before storing. Items must be completely dry to help prevent germs and mold from growing. Store dry items in a clean, protected area.



**NOTE: Inspect the tubing.** If you find condensation in the tubing, wash and dry it immediately or replace the tubing. If you see breast milk inside the tubing or tubing connector do not attempt to wash, clean or sterilize the tubing or tubing connector. Instead contact Hygeia Customer Service at 714-515-7571 Option #2.



#### IF YOU DISINFECT PARTS BY BOILING

**DO NOT** allow boiling parts to contact bottom of pot. It may cause damage to parts.



**WARNING: DO NOT** leave boiling parts unattended. Remove parts carefully from boiling water to avoid burning. Boiled water and steam from boiled water can cause severe skin burns, so use caution when boiling parts in water and removing parts from boiling water.

- Please check pump kit parts for cracks, chips, tears or deformation before and after disinfecting them.

## 9. MAINTENANCE

The breast pump base does not require service or maintenance.

### 9.1 Breast Pump Valve and Diaphragm Check



Inspect the valves and diaphragms for tears or holes. Replace any damaged valves and diaphragms prior to pumping. Wash valves and diaphragms per the instructions in Cleaning Section 8.2 above, "After Every Use". Do not insert a bottle brush or something similarly rough into the valves. We recommend replacing valves and diaphragms every 8-12 weeks depending on cleaning and use.

### 9.2 Storing & Transporting

Disconnect Personal Accessory Set and power adapter from pump before transporting or storing the product. Handle with care when transporting the product. Store the product under the conditions specified in the row titled "Storage Environment Transportation" in the table of section 12.1 and in a location where the pump will not be exposed to direct sunlight or become wet (see icons in Section 13).

## 10. TROUBLESHOOTING

<p><b>SLOW MILK FLOW, UNEVEN OR NO SUCTION</b></p>	<p><b>VALVE AND DIAPHRAGM CHECK</b></p> <p>Inspect the valves and diaphragms for tears or holes.</p> <p>Replace any damaged valves and diaphragms prior to pumping. Wash valves and diaphragms per cleaning section. Do not insert bottle brush or similar into valves. We recommend replacing valves and diaphragms every 8-12 weeks depending on cleaning and use.</p> <p><b>CONNECTION CHECK</b></p> <p>Check assembly is correct and connection points are securely attached.</p> <ul style="list-style-type: none"><li>• Connector for Tubing into tubing port</li><li>• Connector for Tubing into tubing</li></ul> <p>Check that adapter cap is attached to the breast flange. It may be useful to remove adapter cap and reattach it to the breast flange.</p> <p><b>FLANGE/BOTTLE CHECK</b></p> <p>Check flanges, adapter cap or bottles for chips, cracks, breaks, or other damage. Replace any damaged flanges/adapter caps/bottles prior to pumping.</p> <p><b>BREAST FLANGE FIT CHECK</b></p> <ul style="list-style-type: none"><li>• <b>Good Fit:</b> Nipple is moving freely in tunnel of flange</li><li>• <b>Too Small:</b> Nipple is rubbing against tunnel of flange</li><li>• <b>Too Large:</b> Areola is being pulled into tunnel of flange</li><li>• Check to make sure the breast shields form a complete seal around the breast while pumping</li></ul>
--	---

<p><b>HISSING NOISE OR AUDIBLE AIR LEAKAGE</b></p>	<p><b>VALVE AND DIAPHRAGM CHECK</b></p> <p>Inspect the valves and diaphragms for tears or holes. Replace any damaged valves and diaphragms prior to pumping. Wash valves and diaphragms per cleaning section. Do not insert bottle brush or similar into valves. We recommend replacing valves and diaphragms every 8-12 weeks depending on cleaning and use.</p> <p><b>CONNECTION CHECK</b></p> <p>Check assembly is correct and connection points are securely attached.</p> <ul style="list-style-type: none"> <li>• Connector for tubing into pump port</li> <li>• Connector for tubing into tubing</li> </ul>
<p><b>NO POWER</b></p>	<p><b>AC POWER ADAPTER</b></p> <p>Hygeia Express Powered Breast Pump is optimized for use with the AC Power Adapter provided by Hygeia. Make sure the power button in the right front of the pump face is fully pressed for 3 seconds to power on/off. Make sure the outlet is working and that the two connections, adapter to pump and adapter to outlet, are secure and not loose.</p> <p><b>BATTERIES</b></p> <p>The breast pump base comes equipped with a Lithium-ion rechargeable battery. Make sure the battery is charged before using the pump without the AC Power Adapter. The battery is neither removeable nor serviceable.</p> <p><b>NOTE:</b> Recharge the lithium-ion battery every 3 months if the pump is not used.</p>

If there are still questions or issues, please call Hygeia's customer service at **714-515-7571 Option #2**.

**FCC STATEMENT**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

*Caution:* Changes or modifications to this device not expressly approved by Hygeia may void the user's authority to use the device.

**Note:**

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help



## 11. WARRANTY

**THE HYGEIA WARRANTY IS NONTRANSFERABLE BETWEEN INDIVIDUALS. THE HYGEIA EXPRESS POWERED BREAST PUMP (“PRODUCT”) IS WARRANTED TO THE ORIGINAL USER — WHETHER INSTITUTIONAL OR INDIVIDUAL (“FIRST USER”) — ONLY.**

From the date of the Individual User’s purchase of this product, Hygeia II Medical Group, Inc (“Hygeia”) warrants the Product to the Individual User against defects in material or workmanship for a period of one year for the pump mechanism and 90 days on other pump components except for breast pump valves. Hygeia’s sole obligation under this limited warranty shall be to replace, at Hygeia’s option, any Product that is determined to be defective by Hygeia and determined to be covered by this express limited warranty. Replacement under this limited warranty is the sole and exclusive remedy of the First User.

**PROOF OF PURCHASE IN THE FORM OF A RECEIPTED INVOICE OR BILL OF SALE EVIDENCING THAT THE PRODUCT IS WITHIN THE WARRANTY PERIOD MUST BE PRESENTED TO OBTAIN WARRANTY SERVICE.**

This limited warranty is extended by Hygeia ONLY to the First User and is not assignable or transferable. For warranty service contact Hygeia at 714-515-7571 Option #2.

EXCEPT TO THE EXTENT PROHIBITED BY APPLICABLE LAW, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE ON THE PRODUCT IS HEREBY DISCLAIMED. HYGEIA SHALL NOT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OF ANY KIND FOR BREACH OF THE EXPRESS LIMITED WARRANTY ON THE PRODUCT OR ANY WARRANTY IMPLIED BY OPERATION OF LAW. OTHER THAN THE EXPRESS LIMITED WARRANTY SET FORTH ABOVE, THERE ARE NO OTHER WARRANTIES THAT ACCOMPANY THIS PRODUCT AND ANY ORAL, WRITTEN OR ANY OTHER REPRESENTATION OF ANY KIND IS HEREBY DISCLAIMED.

### **NON-APPLICABILITY OF WARRANTY**

In addition to any other limitations on the warranty discussed above, the warranty shall expire and be of no force or effect upon the occurrence of any of the following:

- (i) the cause of damage to the Product is due to improper handling or use.
- (ii) opening of the pump motor, modifications, self-repair or use outside the instructions in this manual will void the warranty.
- (iii) the Product is not properly maintained by the Individual User as determined by Hygeia.
- (iiii) Hygeia investigation concludes that accessories or spare parts not marketed by Hygeia or intended for use with this pump have been used.

If any of the above occurs, Hygeia shall not be responsible for damage to the Product, parts thereof or injuries arising therefrom, either directly or indirectly. The warranty terms set forth above replaces all prior warranties with respect to the purchased Product, whether in writing or otherwise.

## 12. TECHNICAL DATA

### 12.1 Specifications

Product Description	Hygeia Express Powered Breast Pump
<b>Model</b>	Hygeia Express Powered Breast Pump
	The pump is capable of single and double pumping.
<b>Suction</b>	Massage mode: Dual-kit: -50mmHg to -170mmHg
	Massage mode: Single-Kit: -50mmHg to -170mmHg
	Expression mode: Dual-Kit: -70mmHg to -250 mmHg
	Expression mode: Single-Kit: -70mmHg to -250 mmHg
	Stimulation mode: Dual-Kit: -70mmHg to -250 mmHg
	Stimulation mode: Single-Kit: -70mmHg to -250 mmHg
<b>Vacuum Levels</b>	Massage mode: 9 levels
	Expression mode: 9 Levels
	Stimulation mode: 9 Levels
<b>Cycles Per Minute</b>	Massage Mode: 150 CPM (at low vacuum) to 70 CPM (at high vacuum)
	Expression mode: 136 CPM (at low vacuum) to 36 CPM (at high vacuum)
	Stimulation mode: 33 CPM (at low vacuum) to 20 CPM (at high vacuum)
<b>Breast shield Sizes (supplied)</b>	28mm and 24mm
<b>Power Source</b>	AC Adapter – Output: 5VDC, 1.0 A, 5W Input: 100-240VAC, 50/60Hz, 0.2A. Model # UE05LU2-050100SPA
	2600 mAh Lithium-ion rechargeable battery
<b>Operation on Battery alone</b>	Approx. 170 minutes
<b>Additional Function</b>	Automatic Power-off after 30 min
<b>Unit Weight</b>	Approx. 15.2 ounces
<b>Unit Dimensions</b>	146mm diameter x 108mm high
<b>Operating Environment</b>	Temperature: + 5°C to +40°C (41°F to 104°F)
	Humidity: 15 to 90%RH
	Pressure: 90kPa to 106kPa
<b>Storage &amp; Transportation Environment</b>	Temperature: -20°C to 55°C (-4°F to 131°F)
	Humidity: 10 to 90%RH
<b>Device Life</b>	360 hours
<b>Ingress Protection Rating</b>	IP22
<b>Classification</b>	Internal Powered Equipment, Type BF Applied Part
<b>Protection Class</b>	Class II/Double Insulated

*Specifications are subject to change without notice.*

Note: Actual suction pressure may be slightly lower than shown above if the pump is operated at higher altitudes.

This product conforms to the following safety standards:

IEC 60601-1 (electrical safety of medical electrical equipment); IEC 60601-1-11 (home healthcare medical electrical equipment) and IEC 60601-1-2 (electromagnetic compatibility).

The Hygeia Express Powered Breast Pump and Personal Accessory Sets are manufactured in a facility certified to the International Quality Management Standard, ISO 13485:2016.

## 12.2 Electromagnetic Compatibility

The essential performance of the Hygeia Express Powered Breast Pump is to maintain suction level at maximum setting and not exceed 275 mmHg. The pump was tested for immunity to electromagnetic disturbances and passed according to these criteria.

**TABLE 1**


Guidance and declaration of manufacturer-electromagnetic emissions.		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1, class B	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1, class B	The device 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	

**WARNING:** Do not use this device adjacent to or stack this device with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation.

**TABLE 2**

Guidance and declaration of manufacturer-electromagnetic immunity. (For home healthcare environment)			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	± 8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transients/bursts IEC 61000-4-4	± 2 kV for AC power port, 100kHz repetition frequency	± 2 kV for AC power port, 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV (line-to-line)	±0.5kV, ±1kV (line-to-line)	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 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. It may be necessary to position the pump further from the sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the location to assure that it is sufficiently low.

**TABLE 3**

Guidance and declaration of manufacturer–electromagnetic immunity. (For home healthcare environment)			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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	3V for 0.15- 80MHz; 6V in ISM and amateur radio bands between 0.15- 80MHz 80% AM at 1kHz	3V for 0.15- 80MHz; 6V in ISM and amateur radio bands between 0.15- 80MHz 80% AM at 1kHz	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 Express, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.  Interference may occur in the vicinity of equipment marked with the following symbol:  
Radiated RF IEC 61000-4-3	10V/m, 80MHz - 2.7GHz, 80% AM at 1kHz	10V/m, 80MHz - 2.7GHz, 80% AM at 1kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	According to Table 9 of IEC 60601-1 2:2014	According to Table 9 of IEC 60601-1 2:2014	

**TABLE 4**

IEC 60601-1-2:2014 Table 9 — Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM <sup>c)</sup> 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 hZ	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	2	0,3	28
870						
930						
1720	1 700 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
5 240	5 100 - 5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0,2	0,3	9
5 500						
5 785						
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT OR ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included.						
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.						
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

#### IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

This electrical medical equipment needs special precautions regarding EMC and shall be put into service according to the EMC information provided in this user manual. The equipment conforms to IEC 60601-1-2:2020 for both immunity and emissions. Nevertheless, special precautions need to be observed. This equipment is intended for Home Healthcare environment. **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment should be avoided because it could result in

improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**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 Express, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**WARNING:** If the use location is near (e.g., less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life. When the AC input voltage is interrupted, the equipment will stop battery charging and if the power supply restored, it could be recovered automatically. This degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

## 12.3 Product Disposal

This product contains electrical and electronic components.



1. The internal components of this product may contain hazardous materials. Dispose of this product according to local or regional waste administration systems and regulations. Caution: Hazardous materials present in electric and electronic equipment may harm human health and the environment if the equipment is not properly disposed of.
2. Do not dispose of electric or electronic equipment together with unsorted municipal waste.
3. The breast pump and parts are made of plastics which have an impact on the environment when disposed of. Please recycle according to local regulations.

## 13. OPERATIONAL & STORAGE CONDITIONS



Operational Conditions



Transport/Storage Conditions

## 14. TRAVEL



**WARNING:** Use **ONLY** the AC power adapter recommended for the Hygeia Express Powered Breast Pump.

**INFORMATION:** This breast pump contains a lithium-ion battery. Carrying such batteries on airplanes may be restricted. Confirm airline policies prior to travel. Please consult with the country you are visiting to find out if there are any restrictions that pertain to traveling with lithium-ion batteries.

The rechargeable lithium-ion battery in this device has not been tested for safety in aircraft, so pump use in aircraft is not recommended.

## 15. SYMBOLS REFERENCE

1. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.1, Fragile, handle with care / ISO 7000-0621, Graphical symbols for use on equipment, Fragile, handle with care
2. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.2 Keep away from sunlight / ISO 7000-0624, Graphical symbols for use on equipment, Keep away from sunlight
3. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.4, Keep away from rain / ISO 7000-0626, Graphical symbols for use on equipment, Keep away from rain
4. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.7 Temperature Limit / ISO 7000-0632, Graphical symbols for use on equipment, Temperature Limit
5. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.8 Humidity Limit / ISO 7000-2620, Graphical symbols for use on equipment, Humidity Limit
6. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.3.8 Humidity Limit / ISO 7000-2620, Graphical symbols for use on equipment, pressure Limit
7. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.1 Manufacturer
8. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.6 Article number / ISO 7000- 2493, Graphical symbols for use on equipment, batch code
9. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.7 Serial number / ISO 7000-2498, Graphical symbols for use on equipment, Serial number
10. ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements, Clause 5.1.6 Article number / ISO 7000- 2493, Graphical symbols for use on equipment, Catalogue number
11. IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.1 Symbol 9 Class II equipment
12. IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.1 Symbol 20 Type BF applied parts
13. EN 50419, Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
14. IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.1 Symbol 4 Alternating current
15. IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.1 Symbol 1 Direct current
16. IEC 60601-1, Medical electrical equipment – Part 1: General Requirements for basic safety and essential performance, Table D.1 Symbol 29 Stand-by
17. IEC 60417-5957, Graphical symbols for use on equipment
18. IEC TR 60878:2015 — Graphical symbols for electrical equipment in medical practice
19. ISO 15223-1, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements, Table 1, reference number 5.1.3 Date of Manufacture / ISO 7000-2497, Graphical symbols for use on equipment, date of manufacture



Manufactured for:

**Hygeia II Medical Group, Inc.**

6241 Yarrow Drive Suite A

Carlsbad, CA 92011

714.515.7571

[www.hygeiahealth.com](http://www.hygeiahealth.com)



**Hygeia II Medical Group Inc.**

6241 Yarrow Drive

Suite A

Carlsbad, CA 92011

©2023 Hygeia, Inc.