Newborn PEDI® is an interactive educational system developed to assist a certified instructor. It is not a substitute for and not intended for clinical decision making.
1. INTRODUCTION

1.1 SPECIFICATIONS

Premie HAL® S108.100
» 1.2 lbs.
» 12.5 inches

The Premie HAL® is a lifelike, 24 week preterm patient simulator designed to facilitate the training of healthcare professionals in the areas of airway management, respiratory support, and resuscitation.

1.2 TERMINOLOGY

Facilitator: The person conducting the simulation; an instructor or lab staff member
Provider: A person participating in the simulation as a healthcare provider

1.3 CARE AND MAINTENANCE

The lubricants and other accessories provided are for use with the accompanying patient simulator only. The lubricants and other accessories are not suitable for human use or medical treatment/diagnosis and should never be used for such purposes.

CAUTION: Damage caused by misuse is not covered by your warranty. It is critical to understand and comply with the following guidelines.

General

• Do not wrap this or any other Gaumard product in newsprint.
• Marks made with ballpoint pens, ink or marker cannot be removed.
• Replacement parts are available from Gaumard or from your distributor.
• Do not use povidone iodine or Betadine-type antiseptic solutions as these may permanently stain the simulator.
• Only use simulated blood provided by Gaumard. Other simulated blood containing sugars and other additives may cause blockage of the fluid system.
Cautions

- Treat the simulator with the same precautions used with a real patient.
- Have providers wash their hands prior to use to prevent dirt and oils from clinging to the material.
- Do not palpate using fingernails as this may tear the skin; palpate using the pads of the fingers.
- Do not attempt to intubate without lubricating the airway adjunct with mineral oil lubricant. Failure to lubricate the device will make intubation very difficult and is likely to result in damage to the simulator.
- Mouth to mouth resuscitation without a barrier device is not recommended as it may contaminate the airway.

Storage

- Store the simulator in a cool, dry place. Extended storage above 85° F (29° C) will cause the simulator to soften and slowly warp.
- Humidity: 40% - 60% (non-condensing)
- Do not stack or store heavy materials on top of the box. Please store and ship it in the clear bag provided.

Cleaning

- Remove all traces of lubricant at the end of each simulation session.
- Remove the fluid using the fill and drain kits provided.
- Flush the fluid reservoir with a 30:70 mix of isopropyl alcohol to water after each day of simulation letting it drain through the drainage tube. Reference Section 5.1 “Flush the Fluid System” for more details.
- Push air through the filling tube and out of the drainage port to ensure mold does not form in the vasculature or other reservoirs.
- This simulator does not have electronic components, however, submerging it in water without properly draining it may cause mold to form inside.
- The simulator should be cleaned with a cloth dampened with diluted liquid dish washing soap.
- Do not clean with harsh abrasives.
- Dry thoroughly after every cleaning.
- After drying, application of talcum powder can return the simulator to its lifelike feel.
2. OVERVIEW

2.1 FEATURES

- 24 to 25 week preterm neonate has full range of motion with smooth, full body skin and articulating joints
- Anatomically accurate airway, and oral cavity with appropriately sized and shaped vocal cord
- Realistic mouth with lifelike gums and tongue
- Patent nasopharyngeal and oropharyngeal airway
- True-to-life lung compliance that supports standard positive pressure ventilation devices like BVM, CPAP, and Mechanical ventilators
- Visible chest rise with assisted ventilation
- CPR landmarks and realistic chest recoil
- Fontanelle, umbilical, brachial, and femoral manual pulses
- IV cannulation, umbilical artery catheterization, and left peripheral intravascular access
- UVC/UAC infusion and sampling
- Post detachment navel

2.2 PROCEDURES

General

- Practice proper bathing technique and diaper change
- Perform temperature control procedures
- End of life care

Airway

- Anatomically accurate epiglottis, glottis and trachea provides realism for endotracheal intubation and supports the Sellick maneuver
- Patent trachea supports use of suctioning and airway adjuncts
- Perform airway exercises with an ET Tube, and BVM.
- Pulmonary compliance aids in positive pressure ventilation
- Simulate nasogastric feeding with patent nostril
Respiratory
- Visible chest rise following guideline recommended flow, PIP, and PEEP values
- Practice standard positive-pressure ventilation exercises including resuscitators and mechanical ventilators, and interpret actual PV waveforms.
- BVM with chest rise

Cardiac
- Practice palpating pulses at the fontanelle, right femoral and brachial regions, and the umbilical cord
- Perform CPR with realistic chest recoil

Vascular Access
- Practice drug administration
- Train on IV cannulation in the hand, scalp and umbilicus
- Umbilical access for catheterization exercises, continuous infusion, and sampling
- Interchangeable umbilical stumps allows for multiple umbilical vein and artery catheterization exercises
- Practice PICC line placement

Gastrointestinal
- Practice NG/OG intubation placement
- Perform gastric feeding and suctioning
- Practice gastric distension management
3. INITIAL SETUP

3.1 CARE AND CAUTIONS WHEN UNBOXING

• Lift the simulator from the box with both hands at the body and remove the clear bag it is shipped in.
• Rest the simulator on a bed or clean, flat surface for use.
• Do not pull or drag the simulator across hard surfaces as this may cause the skin to tear.

3.2 PACKAGE CONTENTS

1. Preterm neonate
2. Blood dispensing bag, stand, and tubing
3. Fluid Fill Kit
4. Fluid Drainage kit
5. Pneumatic Fill Kit
6. Navel Assembly (installed)
7. Umbilicus (3)
8. Pre-cut Umbilical Stumps (3)
9. Pre-filled Scalp Vein Inserts (1 installed, 4 spare)
10. Left Hand (1 installed, 2 spare)
11. Baby Blanket
12. Diaper
13. Mineral Oil Lubricant
14. Concentrated Blood
15. Silicone Repair Kit
16. Silicone 3M Tape
17. Canvas Carrying Bag
3.3 ASSEMBLY

Premie HAL® is provided with a normal umbilicus, and a replaceable left IV hand. No assembly is required before using the Premie HAL® simulator.

3.4 BLOOD DISPENSING BAG AND STAND ASSEMBLY

1. To assemble the blood bag stand, place the lucite base on a clean, flat surface.

2. Place the black prongs onto the metal stand at the edge that sits on the base.

3. Align the prongs with their corresponding holes and gently press the black prongs into the hole to secure the metal stand to the base.
4. Place the dispensing IV bag on the stand provided, and clamp the tube connected to it.

5. Fill it with fluid using the syringe in the fill kit. The dispensing bag holds up to 1.5 Liters.

6. Connect the fill tube to the top fill port located on the right side of the simulator for continuous flow.

   **NOTE:** Lubricate the end of the fill tube that will be inserted to the port to ease insertion.
3.5 FILLING THE FLUID SYSTEM

The fluid system connects the nostril, esophagus, and the umbilical stump. The fluid system should be drained and flushed at the end of every simulation day.

1. To fill the fluid system without the dispensing bag, connect the drainage tube to the bottom drainage port on the right side of the simulator.

2. Lubricate the end of the fill tube that will be inserted to the port to ease insertion.

3. Place the other end of the drainage tube in a receptacle with the clamp open.

**CAUTION:** Do not fill the reservoir with nasal or oral intubation tubes present.
4. Fill the syringe provided with fluid and connect the blue fill tube to the top port on the right side of the simulator. If the umbilical stump is attached, it should be unclamped while filling.

5. Fill the fluid system until it is draining out of the drainage tube without any bubbles then clamp the drainage tube. If the umbilical stump is attached, also clamp it closed after filling the reservoir.

   NOTE: The fluid system holds up to 10 mL of fluid if the drainage tube is clamped. For draining instructions, refer to Section 5.1 “Flushing the Fluid System.”

6. To remove the fluid port, hold it down and gently pull the fill tube at the base.
4. WORKING WITH THE SIMULATOR

4.1 RECOMMENDED DEVICE SIZES

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Recommended Device Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation (Blade size)</td>
<td>Miller / Mac 00</td>
</tr>
<tr>
<td>Gastric Suctioning and Feeding</td>
<td>2.5 F</td>
</tr>
<tr>
<td>Nasal Intubation</td>
<td>6 F (or smaller)</td>
</tr>
<tr>
<td>Oral Intubation</td>
<td>ETT 2.0 mm - 2.5 mm (no cuff)</td>
</tr>
<tr>
<td>PICC Line Catheter</td>
<td>1.9 F</td>
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<tr>
<td>Scalp Vein Infusion / Catheterization</td>
<td>25 G</td>
</tr>
<tr>
<td>UVC / UAC</td>
<td>2.5 F</td>
</tr>
<tr>
<td>IV Butterfly Catheter</td>
<td>26 F</td>
</tr>
</tbody>
</table>

4.2 AIRWAY TRAINING

- When using any tool for airway training, lubricate the tool with mineral oil lubricant to ensure easy insertion and avoid damage to the simulator.
- An airtight seal is created in the airway when it is intubated.
4.3 RESPIRATORY

Premie HAL’s lungs are made to approximate those of a premature infant and react like real lungs when ventilated using manual or mechanical ventilation.

Manual Ventilation

• Use a premature infant sized mask to create a secure seal around the simulator’s face to achieve visible chest rise.

• Excessive BVM does not cause gastric distension since there is no stomach reservoir. See Section 4.8 “Gastric Distension” for details on simulating gastric distension.

   NOTE: During BVM ventilation, clamp the drainage tube and if the umbilicus is attached, clamp it closed to ensure fluid does not escape.

Mechanical Ventilation

• With proper ventilation, the lungs display realistic chest rise and interacts with a mechanical ventilator as a real patient would.

• The lungs support high frequency ventilation with the same values and pressures as a premie of this age and size.
4.4 GENERATING PULSES

- Connect the squeeze bulb and tube to the top port on the left side of the simulator.
- To generate a pulse, gently squeeze the squeeze bulb at the desired pulse rate.
- The fluid system must be filled in order for pulses to be generated.

NOTE: Make sure the drain tube is clamped and the navel is on. If the umbilical stump is attached, it should be clamped. To remove the umbilicus, see section 4.7 "Changing the Umbilicus."

Pulse Sites

The pulse sites are located at the fontanelle, the umbilicus, right brachial, and the right femoral arteries.
4.5 CPR

- Anatomical landmarks and realistic chest recoil support continuous CPR exercises.
- Practice advanced, neonatal respiratory care and interpret actual PV waveforms.

4.6 VASCULAR ACCESS

**IV Hand**

- The left IV hand is attached to the lower arm with a magnet and a self-contained reservoir not associated with the fluid system; it includes a pre-filled vein.
- Once the vein is empty, it cannot be refilled.
- Depending on the needle size used, the hand may be used several times for IV exercises.
- To change the IV hand, gently pull it from the lower arm and attach the new hand by aligning it to the magnet on the end of the lower arm.

**CAUTION:** Do not bend, twist, or strain the arm. Doing so can damage components and compromise its durability.
PICC Line

- The PICC line site is located on the right forearm and is only intended for placement exercises.
- Do not inject fluids into the PICC line.
- Lubricate the catheter with the mineral oil provided before inserting it into the arm.

Scalp Vein

- It is recommended to use a 25 gauge needle to access the scalp vein on the left side of the scalp.
- See section 5.2 “Repairing the Silicone Skin at the Scalp vein Site” for details on maintenance of this scalp vein site.
Changing the Scalp Vein

1. To replace the scalp vein, unzip the back.

2. Gently pull the skin off from around the skull.

3. Remove the scalp vein insert.
4. Insert each end of the new scalp vein insert into the holes on the skull.

5. Press the scalp vein insert to secure it down.

6. Gently tuck the airway into the facial opening in the skull to ensure it is not pinched or occluded.
7. Gently pull the skin back over the skull, then pull the zipper back down to secure the silicone skin.

NOTE: Add mineral oil lubricant to ease the skin back onto the scalp.

UAC / UVC

- When practicing infusion exercises, be sure to connect the unclamped drainage tube to the fluid system.
- Lubricate the catheter to ease insertion.
- Be sure to drain and flush the fluid reservoir after each simulation day. See Section 5.1 "Flushing the Fluid System" for more details.
Changing the Umbilicus

The navel and two types of umbilicus are interchangeable.

1. To change the navel, gently lift it out of the abdomen to reveal the clear fluid line.

2. Hold the navel at the base and gently pull it from the end of the fluid line and attach either the umbilicus or pre-cut umbilicus.
3. Once the fluid line is attached, gently twist the umbilicus into the abdomen. This avoids kinking in tubing.

**NOTE:** Gently spread the opening around the navel to allow for the umbilicus to be inserted without tearing the skin.

4. The base of the navel and umbilicus has a small V shaped notch indicating the top. This part should always be lined up with the top of the abdomen. This will ensure a more secure fit.
4.7 GASTROINTESTINAL

Nasogastric and Orogastric Intubation

• The newborn’s nostril and airway connects to the esophagus and fluid reservoir. NG and OG tubes can be inserted for placement and feeding exercises.

• Make sure to unclamp the drainage tube if fluids are being introduced to the fluid system through these means.

  NOTE: Lubricate the tubes before placement, to avoid damage to the simulator.

• The newborn’s left nostril and mouth connects to the esophagus and fluid reservoir to perform nasogastric and orogastric feeding and suctioning.

  NOTE: Lubricate the tubes before placement, to avoid damage to the simulator.
Gastric Suctioning

- The newborn’s patent esophagus supports exercises for gastric suctioning.

- If fluid is in the esophagus or mouth, suction the fluid out with a bulb syringe.

- The dispensing bag should be attached if constant fluid supply is required.

 NOTE: Drain and flush the fluid reservoir after each simulation day. See Section 5.1 "Flushing the Fluid System" for more details.
Gastric Distension

1. To simulate gastric distension, connect the squeeze bulb to the bottom port on the simulator’s left side.

2. Gently squeeze the bulb to fill it to the desired level.

3. To relieve gastric distension, loosen the valve on the squeeze bulb.
5. ROUTINE MAINTENANCE

5.1 FLUSHING THE FLUID SYSTEM

1. Be sure to unclamp the drainage tube and place it in a receptacle or on a towel.

2. If the umbilical stump is attached, unclamp the umbilicus to prepare for drainage.

3. If synthetic blood was used, flush the fluid system with 30:70 mix of isopropyl alcohol to water by injecting the mixture into the fluid system via the top right fill port until the fluid runs clear. If water was used to fill the fluid system, skip this step.
4. Push air through the fluid system to ensure mold does not form.

5.2 REPAIRING THE SILICONE SKIN AT THE SCALP VEIN SITE

1. Clean the damaged area of the skin with alcohol wipes.
   
   NOTE: Use gloves during the steps that follow.

2. Remove the white cap from the silicone adhesive tube to begin the repair. The end of the cap has a sharp point to puncture the seal on the tube.
3. Gently apply the silicone adhesive over the damaged area. Dispense the material in a slow continuous stream.

4. Use a soft lint free cloth to remove excess bonding material.

5. Allow the repaired area to dry for a minimum of 2 hours before resuming use. Place the white cap back on the tube to preserve any remaining silicone adhesive.
6. APPENDIX

6.1 PARTS LIST

<table>
<thead>
<tr>
<th>Product</th>
<th>Classification</th>
<th>Item Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filling Kit</td>
<td>Replacement</td>
<td>S108.100.985</td>
</tr>
<tr>
<td>Drainage Kit</td>
<td>Replacement</td>
<td>S108.100.718</td>
</tr>
<tr>
<td>Left Arm Assembly</td>
<td>Consumable</td>
<td>S108.100.803L.1</td>
</tr>
<tr>
<td>Scalp Vein Insert</td>
<td>Consumable</td>
<td>S108.100.772</td>
</tr>
<tr>
<td>Umbilicus</td>
<td>Replacement</td>
<td>S108.100.840</td>
</tr>
<tr>
<td>Umbilicus Stumps</td>
<td>Consumable</td>
<td>S108.100.840.1</td>
</tr>
<tr>
<td>Squeeze Bulb</td>
<td>Replacement</td>
<td>S108.100.816</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>Consumable</td>
<td>GU.181</td>
</tr>
<tr>
<td>Artificial Blood Concentrate</td>
<td>Consumable</td>
<td>GU.080</td>
</tr>
<tr>
<td>Silicone 3M Tape</td>
<td>Consumable</td>
<td>R.704</td>
</tr>
<tr>
<td>Carrying Bag</td>
<td>Replacement</td>
<td>S108.100.807</td>
</tr>
<tr>
<td>Dispensing Blood Bag and Stand Kit</td>
<td>Replacement</td>
<td>S108.100.719</td>
</tr>
</tbody>
</table>
6.2 EXCLUSIVE ONE-YEAR LIMITED WARRANTY

Gaumard warrants that if the accompanying Gaumard product proves to be defective in material or workmanship within one year from the date on which the product is shipped from Gaumard to the customer, Gaumard will, at Gaumard's option, repair or replace the Gaumard product.

This limited warranty covers all defects in material and workmanship in the Gaumard product, except:

- Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product;
- Damage resulting from failure to properly maintain the Gaumard product in accordance with Gaumard product instructions, including failure to properly clean the Gaumard product; and
- Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative.

This one-year limited warranty is the sole and exclusive warranty provided by Gaumard for the accompanying Gaumard product, and Gaumard hereby explicitly disclaims the implied warranties of merchantability, satisfactory quality, and fitness for a particular purpose. Except for the limited obligations specifically set forth in this one-year limited warranty, Gaumard will not be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory regardless of whether Gaumard has been advised of the possibilities of such damages. Some jurisdictions do not allow disclaimers of implied warranties or the exclusion or limitation of consequential damages, so the above disclaimers and exclusions may not apply and the first purchaser may have other legal rights.

This limited warranty applies only to the first purchaser of the product and is not transferable. Any subsequent purchasers or users of the product acquire the product “as is” and this limited warranty does not apply.

This limited warranty applies only to the products manufactured and produced by Gaumard. This limited warranty does not apply to any products provided along with the Gaumard product that are manufactured by third parties.

For example, third-party products such as computers (desktop, laptop, tablet, or hand-held) and monitors (standard or touch-screen) are not covered by this limited warranty. However, third-party products are covered by the warranties provided by the respective third-party manufacturers and such warranties are transferred from Gaumard to purchaser upon purchase of the Gaumard product. Defects in third-party products are covered exclusively by the warranties provided by the third-parties. Gaumard does not provide any warranty, express or implied, with respect to any third-party products. Please contact the third-party manufacturer for information regarding the availability of extended warranties for third-party products.

Any waiver or amendment of this warranty must be in writing and signed by an officer of Gaumard.

In the event of a perceived defect in material or workmanship of the Gaumard product, the first purchaser must:

1. Contact Gaumard and request authorization to return the Gaumard product. Do NOT return the
2. Gaumard product to Gaumard without prior authorization.
3. Upon receiving authorization from Gaumard, send the Gaumard product along with copies of (1) the original bill of sale or receipt and (2) this limited warranty document to Gaumard at 14700 SW 136 Street, Miami, FL, 33196-5691 USA.

If the necessary repairs to the Gaumard product are covered by this limited warranty, then the first purchaser will pay only the incidental expenses associated with the repair, including any shipping, handling, and related costs for sending the product to Gaumard and for sending the product back to the first purchaser. However, if the repairs are not covered by this limited warranty, then the first purchaser will be liable for all repair costs in addition to costs of shipping and handling.
6.3 CONTACT GAUMARD

Before contacting technical support, please make sure to have your simulator and user guide readily available.

Email: support@gaumard.com
USA: 800-882-6655
INT: 01-786-478-3838

6.4 GENERAL INFORMATION

E-mail: sales@gaumard.com
USA: 800-882-6655
INT: 01-305-971-3790
Fax: 305-252-0755

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