Revision

3

Gaumard® Scientific Company, Inc.

Instruction Manual

THE S108 PEDI® PREMIE SIMULATOR FOR ADVANCED LIFE SUPPORT

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PLEASE READ THE FOLLOWING INSTRUCTIONS PRIOR TO COMMENCING TRAINING EXERCISES ON YOUR NEW MANIKIN.

HANDLE YOUR PATIENT - HANDLE YOUR SIMULATOR IN THE SAME MANNER AS YOU WOULD WITH CARE AND CONSIDERATION.

SHOULD YOU HAVE ANY QUESTIONS AFTER READING THIS INSTRUCTION MANUAL, PLEASE CALL OUR CUSTOMER SERVICE DEPARTMENT.

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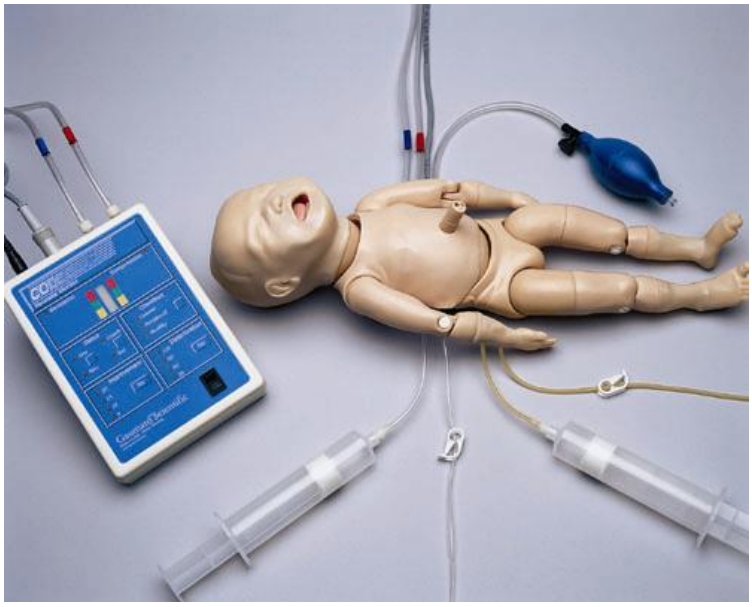
Section I - Airway Management

The **Pedi® Premie Simulator** changes color based upon the effectiveness of oxygenation supplied by students**. Pedi** is sized to simulate a newborn under 30 weeks gestation. It is to be used only as part of an approved training program for emergency care. The simulator has the conventional features found in Airway Simulators.

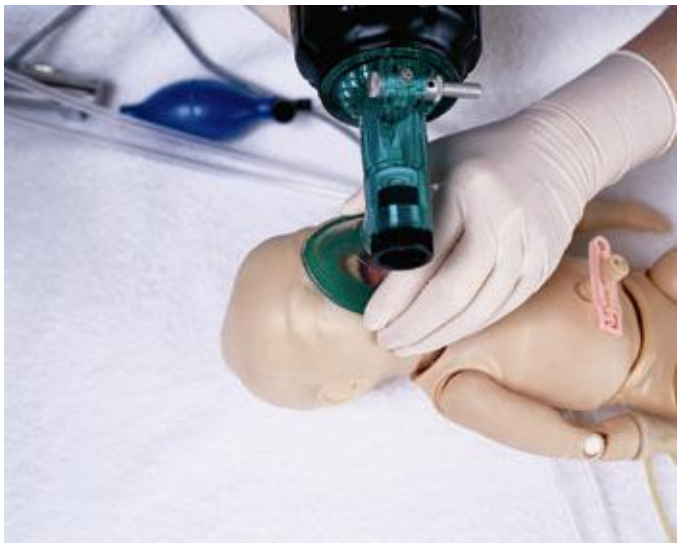


1. Realistic airway with tongue, vocal cords, trachea and esophagus.
2. Articulating head, neck, jaw, arms and legs.
3. Heart, lungs and ribs.
4. BVM or CPR.
5. Oral intubation plus suctioning.
6. Crico prominence permits the Sellick maneuver.
7. Bilateral lung expansion with realistic chest rise.

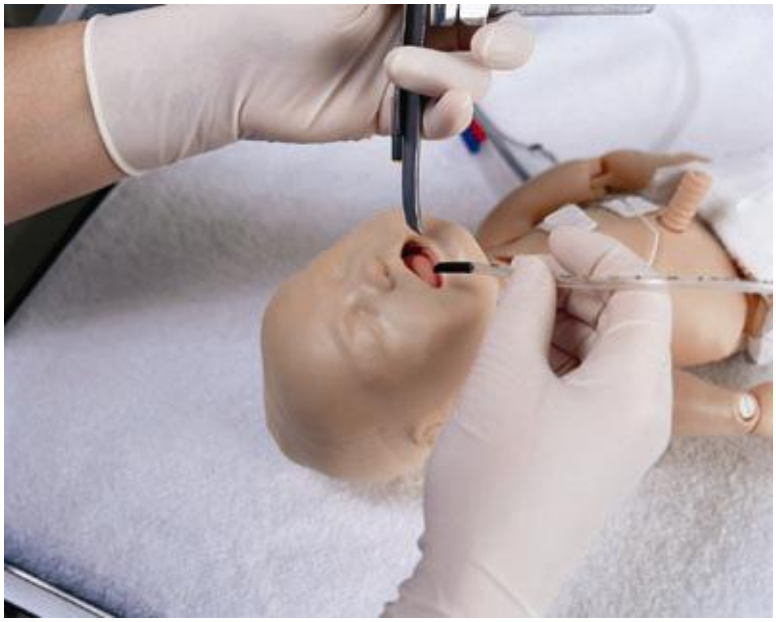
The **Pedi Premie** simulator has the unique ability to change color based upon an initial pre-selected condition and the effectiveness of airway ventilation and chest compression provided.

Airway Management

Before using **Pedi® Premie,** thoroughly lubricate the airway using the water based silicone lubricant provided. Also lubricate the distal end of an ET, NP, or OP tube prior to insertion. When providing positive pressure ventilation, we suggest a Neonatal BVM having a supple cushion seal that easily fits over the face with minimal air loss. With reasonable care, air leakage between the mask and nose can be minimized and students will observe the chest rising and falling with each ventilation.



When intubating, we suggest a Miller 1 blade and an uncuffed 2.5 mm ET tube with appropriate stylet. Take care to visualize the vocal cords clearly and insert the lubricated tube gently past the vocal folds.



Color Change

The simulator has devices in its forearms and lower legs to cause the skin to turn from a normal healthy color to a blue color indicative of peripheral cyanosis. It also has devices in the cheeks which cause the skin to turn from a normal color to an ominous blue color indicative of central cyanosis. These devices which we call SmartSkin are controlled by the **Premie Blue®** monitor. The monitor contains a small computer that starts the **Pedi® Premi** simulator in one of three selected states: central, peripheral, or healthy. The monitor observes the ventilations and compressions and determines whether they meet or exceed conventional neonatal CPR standards. If acceptable, the monitor causes the skin to turn to a more healthy color, if inadequate or non-existent, the monitor causes the skin to turn toward an ominous blue color.

The rate of *improvement* and *deterioration* is defined as the time between each of the three states; i.e. healthy, peripheral or central. For example, if an *improvement* of 5 seconds is selected, the monitor will require adequate ventilation and compression for 5 seconds to gradually progress from *central cyanosis* to *peripheral cyanosis* and 5 seconds to go from *peripheral* cyanosis to a completely *healthy* skin color. In similar fashion, the rate of deterioration is selected.

The monitor also permits *One Rescuer* or *Two Rescuers*, as well as *Coach* and *Test*. During coaching, the student will heart the appropriate sounds for ventilation and compression and will also see whether the rescue efforts are judged as being too high, too low, or just right.

Getting Started

1. Attach the red chest compression and blue airway ventilation tubes to the monitor.
2. Attach the simulator's electrical cable to the monitor.
3. Connect the power supply to the monitor and connect to a 100/240 VAC outlet
4. Switch the monitor ON and note that the monitor will default to the following:
    a. One Rescuer
    b. Test
    c. Central cyanosis
    d. Improvement rate from state to state of 20 seconds
    e. Deterioration rate from state to state of 30 seconds
5. Perform BVM or CPR in the normal manner. If no action is taken, the simulator will gradually turn toward that ominous blue color. Adequate ventilation will cause the simulator to progress to a healthy skin color.

Changing the Default Settings

1. Locate status and select One Rescuer or Two Rescuers.
2. Select either Coach or Test. The Coach mode provides audible and visual prompts.
3. Locate Condition and select Central, Peripheral or Healthy.
4. Locate Improvement and select one of the four rates of improvement.
5. Locate Deterioration and select one of the four rates of Deterioration.
6. Perform BVM or CPR in the normal manner. The condition of the simulator will worsen if no action is taken.

Care and Maintenance

This simulator is constructed of material that approximates skin texture. Therefore, in handling the model, use the same gentle techniques as you would in working with a patient.

1. Clean the skin after every training session using mild soap and rinse with clean water.
2. Do not write on the skin with any type of marker or pen. These marks cannot be removed.
3. Do not use alcohol, acetone, Betadine® or any other antiseptic which contains iodine. These products could damage or stain the skin of the product.
4. Store the simulator in the carrying bag provided.
5. Do not wrap the simulator in newspaper.

SECTION II - Other Care

II.1. Intraosseous Infusion and Injection Simulator

The Intraosseous Trainer may be an effective tool for instruction in intraosseous infusion. Intraosseous entry is recommended after two quick unsuccessful attempts at peripheral venous cannulation. This simulator is to be used only as a part of an approved program for the care of patients. The Intraosseous Trainer includes a set of eight (8) modified tibia bones, a fluid dispensing syringe, synthetic blood concentrate, and two (2) spare skin covers.

Instructions For Use

CAUTION:

The tibia bones supplied with your simulator are made from hard plastic that can be pierced by an intraosseous needle. Once holes have been made in the tibia it CAN leak. We have minimized leakage by controlling fluid pressure in the bone using inlet and drain valves. Proceed as follows:

1. Fill tank with water, open the inlet and drain valves and allow water to flow thru the system into a catch basin.

2. Once the water is seen draining, close the inlet valve.

3. Perform IO exercises (17-20 gauge bone aspiration needle recommended)

4. After about 10-20 sticks you may need to add water to the tibia bone. To do so, open the inlet valve a few seconds and re-close the valve.

5. Continue your IO exercises.

6. To change the tibia bones, first open the outlet and drain the fluid, remove the skin cover and remove the bone. Either use one end of the used bone or insert and re-attach the skin. Return to step 2.

7. When the training session is completed, open the outlet and drain the fluid.

8. Remove the syringe and drain the fluid.

9. Replace the bones and dry them for next session.

10. Instructor may seal the holes in the bone(s) that are made by the IO needle with "Superglue".

INTRAOSSEOUS ACCESS

Intraosseous infusion is the infusion of fluids, blood and/or drugs directly into the bone marrow of the tibia or other large bone. It is a quick, simple solution to venous access when the alternate peripheral veins are barely visible or palpable. Contraindications to intraosseous access include bone disorders, infected burns, cellulitis, or recent fractures.

THE TIBIA ACCESS IS THE CHOICE IN THE EVENT THE VICTIM ALSO REQUIRES CPR INTERVENTION. THE HUMERAL ACCESS IS ONE CHOICE IN THE EVENT SEVERE ABDOMINAL TRAUMA OR BILATERAL FRACTURES ARE EVIDENT.

Setting up an intraosseous access line is an invasive procedure requiring an aseptic technique. The site most recommended for the tibia is the anterior medial aspect of the tibia. Although any portion of the tibia can be used, the preferred site for properly locating the point of insertion of the needle is below, and medial to the tibial tuberosity (the tibial tuberosity is the bump below the kneecap). Note that each tibial bone provided is modified, having a tibial tuberosity at the top and bottom of the tibial bone. This allows the bone to be rotated after repeated needle sticks. You may wish to apply conventional "SuperGlue" or PVC sealant to the holes created by the needle sticks to prevent fluid leakage from the needle sticks.

Locate the tibial site and clean the area with alcohol. Avoid the use of povidone-iodine, as this will discolor the simulator. The needle recommended for this procedure is a 17 to 20 gauge disposable bone marrow aspiration needle.

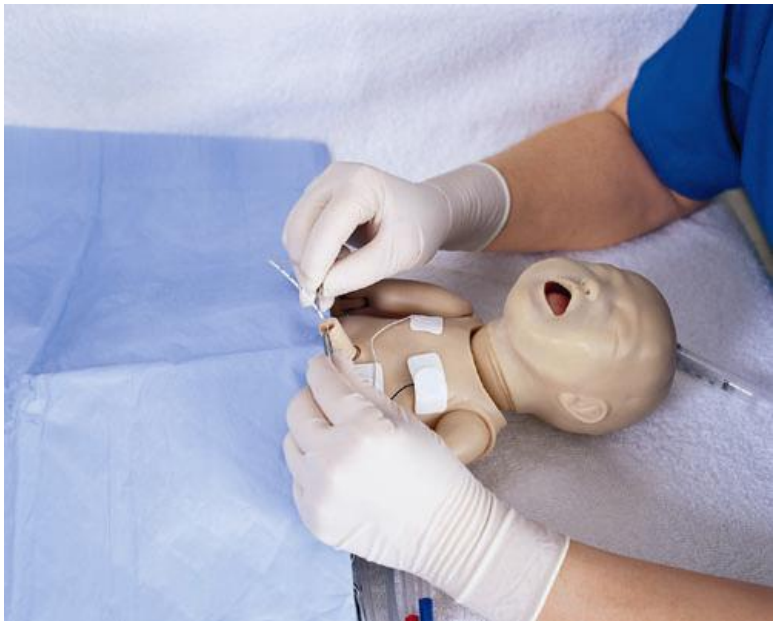
Caution must be used when inserting the needle. Once the insertion point is located, insert the needle and cannula by applying downward pressure while rotating the needle back and forth until the bony cortex has been penetrated. A "pop," or sudden decrease in resistance signal entrance into the cavity. Now remove the central needle, leaving the cannula in place. If the needle/cannula has been properly inserted, fluid may be withdrawn using a standard syringe. In the event "blood" return is not observed, the student may not have penetrated the bone marrow cavity. The intraosseous access is only marginally stable and is easily dislodged. Therefore the student should practice stabilizing the needle using, for example, a hemostat clamped to the needle hub and taped to the leg of the patient.

Once stabilized, the intraosseous access may be used to infuse fluids, drugs, and blood products. Be sure to flush the cannula with saline after each use.

It is recommended in the literature that the intraosseous infusion be conducted for the briefest amount of time, usually an hour or two, until a more secure intravenous line has been established.

II.2. Umbilical Catheterization

At birth and for only a few hours thereafter, the umbilicus can be used for intravenous access, and for measuring arterial blood gasses/pressure. This simulator features umbilical venous access.

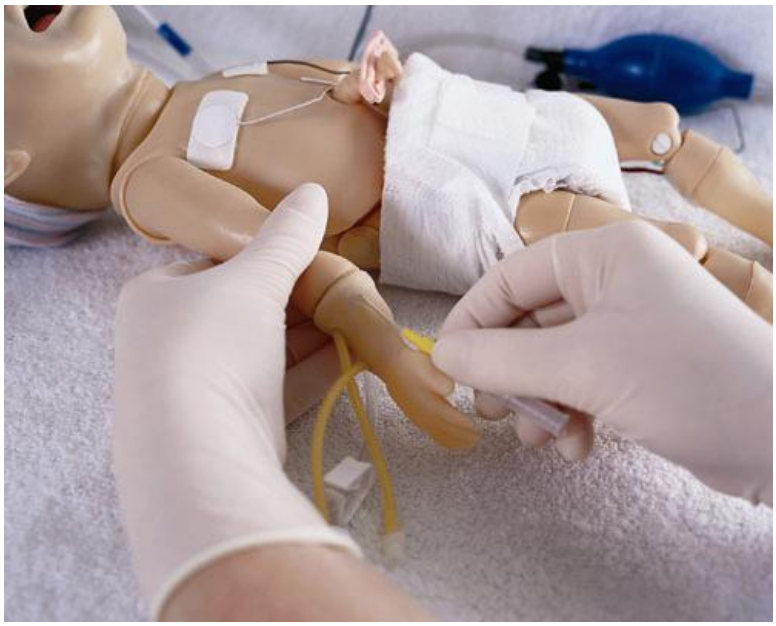


You may access this using an appropriately-sized umbilical catheter. Lubricate the distal tip and insert the tip JUST BELOW the level of the skin. Infusion exercises may then be practiced. A reservoir within the simulator collects the fluid, which can be drained via a port on the torso.

II.3. Premie Injection Training Arm

The **Premie** Injection Training Arm may be an effective training tool for intravenous exercises. It is only to be used as part of an approved program for **Premie** care.

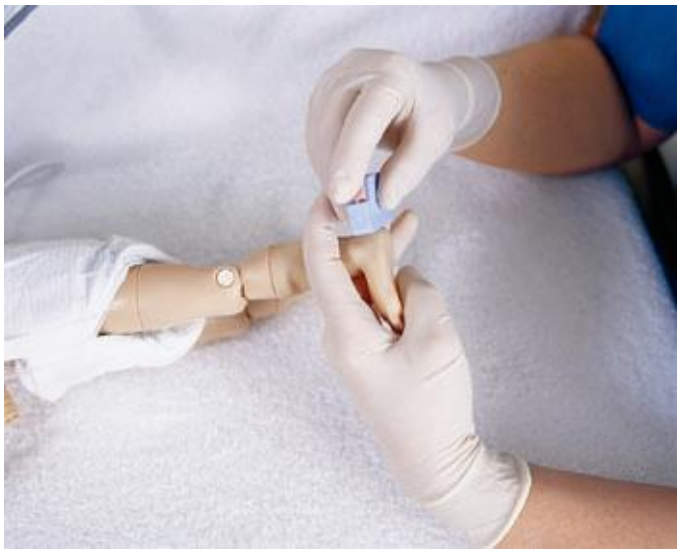
The **Premie** Injection Arm includes a blood dispensing syringe, synthetic blood concentrate, and a spare arm skin. The training arm contains venous grooves which are fitted with soft latex tubes closely simulating the consistency of the veins. A translucent, pliable skin, which is removable and washable, is stretched over the training arm.



Applying pressure via the syringe permits the veins to stand out, simulating a clenched fist or a tourniquet situation. Release of the pressure simulates collapsed veins. Use of the syringe permits the palpability of the veins to be varied as seen in routine hospital or emergency situation. We suggest a 25 to 27 gauge needle set.

II.4. Heelstick

The right heel is molded of a soft material suitable for use with conventional heelstick devices.



SECTION III - GENERAL NOTES

III.1. Lubrication

When introducing any invasive device, always use a lubricant, such as one of the following:

- a drop of soap with water
- water based silicone spray

For intubation, USE A WATER BASED SILICONE SPRAY.

III.2 Cleaning

1. This manikin may be cleaned with a mild detergent, or with soap and water. DO NOT use harsh abrasives.

2. Indelible marks made with ballpoint pens, ink or markers will remain.

3. Do not wrap this manikin or any **GAUMARD** product in newsprint.

4. Do not use povidone-iodine on this manikin or any GAUMARD simulator.

III.3. Limited Warranty

Gaumard® Scientific Company (Gaumard) warrants that if the accompanying product proves to be defective in material or workmanship within one (1) year from the date of the original purchase, Gaumard will, at Gaumard's option, either repair or replace same without charge. This limited warranty may be enforced only by the first consumer user. All subsequent purchasers acquire the product "as is" without this limited warranty.

This warranty covers all defects in material or workmanship, except:

1. Damage resulting from accident, misuse, neglect, or from other than normal and ordinary use of the product.
2. Damage resulting from failure to clean or use the product in accordance with the instructions.
3. Damage resulting from repair or attempted repair by anyone other than Gaumard.

When repair is indicated, the user must:

1. Contact Gaumard and request service authorization
2. At the customer's expense, ship the product with a copy of the bill of sale to Gaumard.

Gaumard disclaims liability for incidental and consequential damages for breach of any express or implied warranty, including any implied warranty of merchantability, with respect to this product. This writing constitutes the entire agreement of the parties with respect to the subject matter hereof, no waiver or amendment shall be valid unless in writing signed by Gaumard.

Technical Support

Feel free to contact us if you experience any difficulties or your system requires repair.

toll-free in USA: (800) 882-6655
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fax: (305) 667-6085
email: sima@gaumard.com

Office hours: Monday-Friday, 8:30-4:30 EST (GMT-5:00)

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