Gaumard®
Simulators for Health Care Education

S108.250
PREMIE™ Blue
User Guide

PREMIE™ Blue S108.250 is an interactive educational system developed to assist a certified instructor. It is not a substitute for a comprehensive understanding of the subject matter and not intended for clinical decision making.

User Guide 17.1.1
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1. Introduction

1.1 Specifications

Premie™ Blue

- Weight: 2 lbs (0.907 kg)
- Length: 17” (43.2 cm)

1.2 Care and Maintenance

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

WARNING: 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.

General

- Ball point pens, ink, and markers permanently stain the skin.
- Do not wrap this or any other Gaumard product in newsprint.
- Replacement parts are available from Gaumard Scientific or from your Distributor

IV Arm

- Only use Gaumard’s provided simulated blood. Any other simulated blood containing sugar or any additive may cause blockage and/or interruption of the vasculature system.
- The use of needles larger than 25 to 27 gauge will reduce the lifetime of the lower arms’ skin and veins.
- Always purge with clean water and then drain the vein reservoirs at the end of the simulation session. Doing so will retard the formation of mold and prevent clogging of the system.
- We recommend flushing veins with 70:30 solution of clean water to isopropyl alcohol (IPA) at least once per month to prolong the life of the vasculature.
- When the arm skin and/or arm requires replacement, refer to the “Consumables” section of this guide. For more information regarding the replacement of consumable items please contact customer service.

Operating Conditions

- The simulator will only power on when connected to the AC power supply.
- Operating temperature: 50°-95° F (10°-35° C)
- Humidity: 5%-95% (non-condensing)

Storage Conditions

- Store Simulator in a cool, dry place. Extended storage above 85 degrees Fahrenheit (29 Celsius) 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 carton.

> **WARNING: To avoid damage to the simulator, please store and ship it in the clear poly bag provided.**

Procedures

- 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 will contaminate the airway.
- Treat the simulator with the same precautions that would be used with a **real** patient.

Cleaning

- The simulator should be cleaned with a cloth dampened with diluted liquid dish washing soap.
- Remove all traces of any lubricant.
- Do not clean with harsh abrasives.
- Do not use povidone iodine on the simulator.
- Dry thoroughly.
- The simulator is “splash-proof” but not water-proof. Do not submerge or allow water to enter the interior of the simulator.

2. Getting Started

2.1 Overview

- Powerful yet intuitive user controller and interface software
- Resuscitation modeling
- Quality CPR with measured and logged feedback

Airway

- Oral and nasal intubation
- Use an ET tube or LMA
- Oral intubation plus suctioning
- Perform Sellick's maneuver

Appearance

- Color responds to hypoxic events and interventions (healthy, mild cyanosis, severe cyanosis)
- Articulated head, neck, jaw, arms and legs

Artificial Respiration

- Bilateral lung expansion with realistic chest rise
- Accommodates assisted ventilation
- Ventilation is measured and logged

Circulation

- Chest compressions are measured and logged
- Umbilical pulse

Simulator

- Physical size is 50th percentile at 28-30 weeks gestational age
- Realistic airway with tongue, vocal cords, trachea and esophagus
- Heart, lungs and ribs

Venous Access

- Patent umbilicus
- Intraosseous access at tibia
- IV training arm

2.2 Terminology

Facilitator

The person conducting the simulation; an instructor or lab staff member.

Provider

A person participating in the simulation as a healthcare provider.

3. Equipment Setup

3.1 Overview

Unpacking

Lift the simulator from the soft blue case carefully with two hands. Remove the clear poly bag and lay him on a flat surface.

> **WARNING: To avoid damage to the simulator, please store and ship it in the clear poly bag provided.**

Power Supply

Connect the power supply to the power input located on Premie Blue's left side, and then connect the power supply to the wall outlet.

> **Always operate Premie Blue with the power supply connected.**

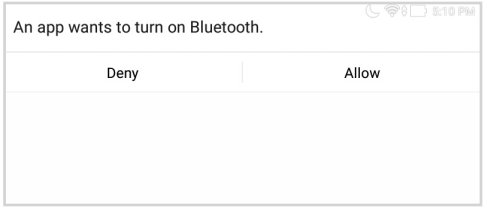
OMNI® 2 Connection

OMNI® 2 controls Premie Blue's responses with the touch of a button. The tablet operates Premie Blue wirelessly.

> **Premie Blue can be operated using a wired connection. Please refer to the OMNI® 2 user guide to set up a wired connection.**

Follow the steps below to connect to OMNI® 2:

1. Turn on OMNI® 2 by pressing and holding the ON button on the right side of the tablet.
2. Select "Allow" to turn on Bluetooth for the tablet.

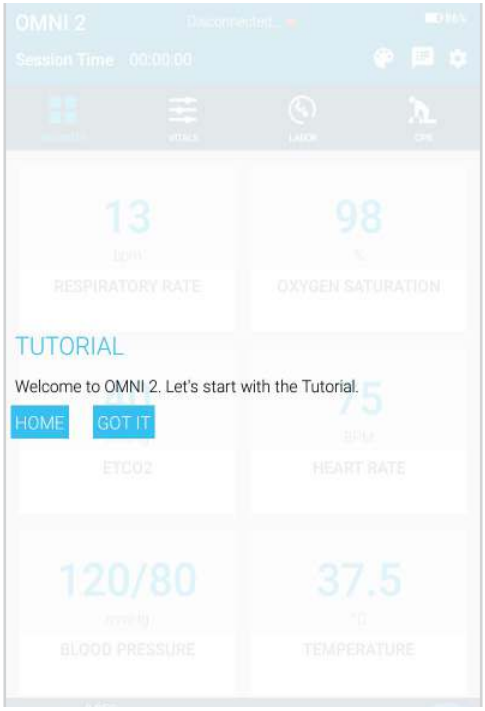


3. A startup screen is shown while OMNI® 2 is detecting the simulator features.

4. Follow the on-screen tutorial for a brief overview of the features of OMNI® 2.

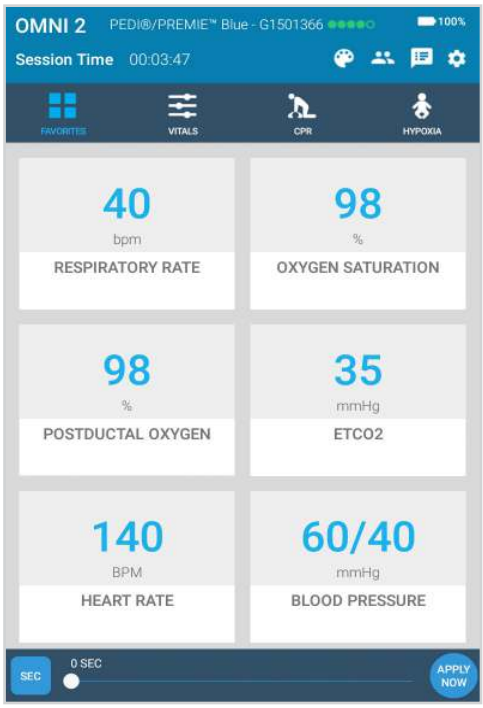
5. Move onto the next steps in the Tutorial by selecting “GOT IT”.

6. Exit the Tutorial at any time by selecting “HOME”.



Please complete the tutorial once or it will continue to appear at start-up.

After the tutorial, OMNI® 2 will automatically proceed to the Favorites page and establish a connection to Premie Blue.



WARNING: Do not connect Premie Blue or OMNI® 2 to a computer, LAN network or unathorized diagnostic equipment. Doing so will cause serious damage to the equipment.

4. Premie® Blue Features

4.1 Airway Management

Pulmonary Ventilation

Practice BVM techniques using an infant sized mask. Bilateral lung expansion is perceived with realistic chest rise. Effective CPR with Premie Blue and obtain feedback information via the OMNI® 2 tablet on the cadence and depth of chest compressions and airway ventilations.

Practice BVM techniques using an infant sized mask having a thick seal.

Intubation

Premie Blue airway can be intubated orally and nasally using a 2.5 mm ID Endotracheal tube. An LMA can be used to ventilate Premie Blue orally.

WARNING: Nasogastric intubation is only for teaching placement technique. Fluids cannot be inserted through nasogastric tubes as internal damage will result.

WARNING: Before inserting ET, NP, or OP tubes always lubricate the distal end of the tube with provided lubricant. Failure to do so will damage the airway.

Procedure	Device Size
Laryngoscope	Miller 0
LMA	Size 1
Nasal Intubation	8 Fr catheter
Oral Intubation	ETT 2.5 no cuff, 6 Fr suction catheter

Suction

Premie Blue can be used to simulate suction procedures.

4.2 Circulation

Palpable Pulses

Generate palpable umbilical pulses using the squeeze bulb.
Connect the squeeze bulb to the port on the left side of the simulator.

IV Access

Premie Blue has IV access in the lower right arm that can be used for bolus or intravenous infusion as well as for draining fluids.

The lower arm contains a vein groove which is fitted with a soft tube closely simulating the consistency of the veins.

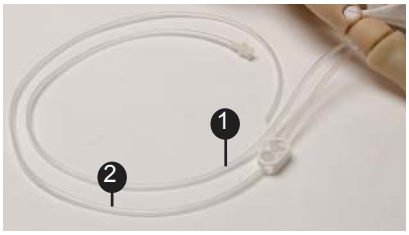
Applying pressure via the syringe permits the vein to stand out, simulating a clenched fist or a tourniquet situation. Release of the pressure simulates collapsed veins.

The IV training kit includes a blood dispensing syringe, synthetic blood concentrate, and spare arm skin.

Directions for Use

Filling IV System

Tube 1: filling
Tube 2: drainage tube



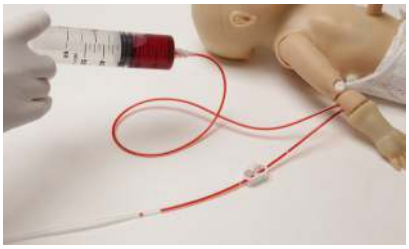
1. Place the end of the tube 2 into a drainage container and open the adjustable clamp.

> **Drainage container not included in kit.**

2. Fill the dispensing syringe with fluid.

3. Connect the syringe to the filling tube.

4. Allow fluid to flow through the system and into the drainage container.



5. Close the adjustable clamp of drainage tube.

6. Remove the syringe from the filling tube.

For IV simulations, place the end of the tube into a drainage container and open the adjustable clamp.

WARNING: Use only Gaumard's provided simulated blood. Any other simulated blood brand containing sugar or any additive may cause blockage and/or interruption of the vasculature system.

Use a 25-27 gauge needle set.

IV Maintenance

Replacing the arm skin

1. Gently pull the IV arm skin.
2. Add a small amount of lubricant to the arm.

3. Slide the replacement skin onto the arm.

Replacing IV arm

Replace the lower arm in case of damage or excessive fluid leakage.

The lower arm is connected to the upper arm at the elbow joint with a screwdriver and its recessive socket.

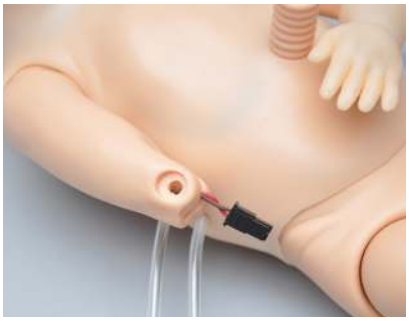
1. Undo the screw at the elbow joint.

2. Remove the screw and its socket from the joint.

3. Gently pull out the lower arm until the black electrical connector is visible.

4. Unfasten the connector by pressing on the clip.

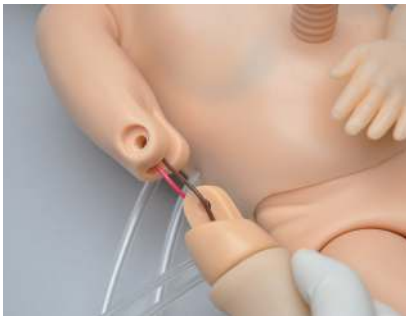
5. The male electrical connector resides in the upper arm.



6. Locate the replacement item.

7. Take the female connector of the lower arm and attach to the male connector of the upper arm.

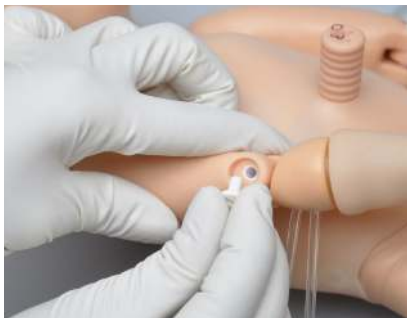
8. Push in the black electrical connector into the upper arm of the simulator.



9. Attach the lower arm to the elbow joint.

10. Insert the screw socket into the elbow joint colser to the median plane of the simulator.

11. Place the screw into the other side of the elbow joint and fasten until the connection is secure.



4.3 Intraosseous Access

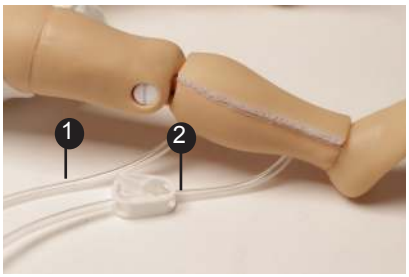
Setting up an intraosseous access line is an invasive procedure that can be simulated with the Premie Blue.

The intraosseous access kit includes: modified tibia bones, a fluid dispensing syringe, synthetic blood concentrate, and an additional skin cover.

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.

Directions for Use

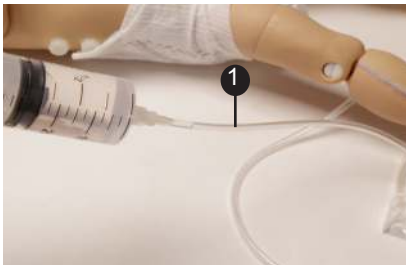
Tube 1: filling
Tube 2: drainage tube



1. Place the end of tube 2 into a drainage container and open the adjustable clamp.

2. Fill the dispensing syringe with fluid.

3. Connect the syringe to tube 1 and release the fluid. Allow fluid to flow through the system and into the drainage container.



4. Once fluid is seen draining, close the tube 1 adjustable clamp.

Use 17-20 gauge bone aspiration needle to perform IO exercises.

5. Perform IO exercises.

6. When the training session is completed, open the drainage tube 2 adjustable clamp and drain the fluid. If needed, use the dispensing syringe full with air to push remaining fluid out the system.

If blood mix is used, flush the system with 2-3 syringes full of clean water.

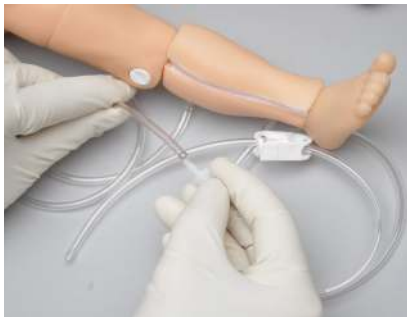
> **Holes in the bone(s) that are made by the IO needle can be sealed with "Superglue".**

Replacing the Tibia Bones

Items needed:

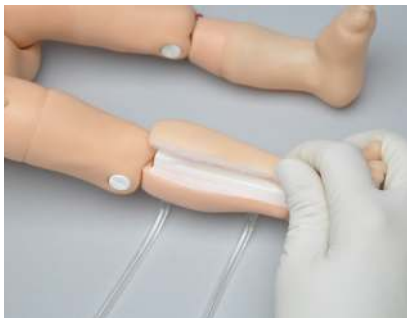
- Tibia bone skin cover
- Replacement tibia bone
- Drainage container

1. Drain all the fluids from the system.

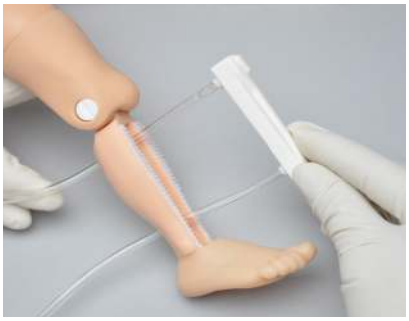


2. Remove the syringe connector from the filling tube and clamp from the draining tube.

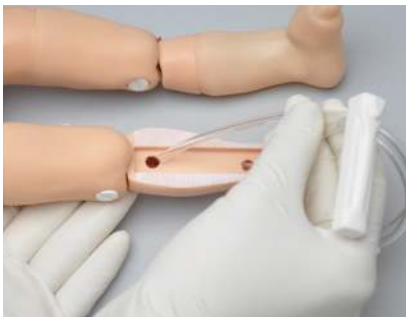
3. Remove the tibia cover.



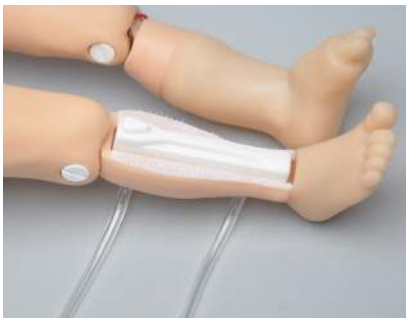
4. Pull out the tibia bone out of the leg.



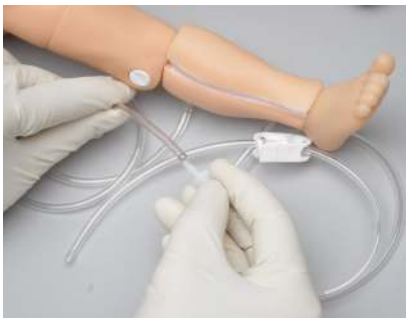
5. Insert the new tibia. The filling and drainage tubes are first, followed by the bone.



6. Re-attach tibia cover.



7. Connect the syringe connector to the filling tube and the clamp to the draining tube.



4.4 Cyanosis

Premie Blue features the SmartSkin 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 features the SmartSkin in the cheeks to indicate central cyanosis. This feature is controlled by the OMNI® 2 tablet.

Perform ventilations, and OMNI® 2 will automatically detect the ventilations to determine whether they meet or exceed conventional neonatal CPR standards. If acceptable, the OMNI® 2 tablet causes the skin to turn to a more healthy color, if inadequate or non-existent, OMNI® 2 causes the skin to turn toward a blue color. This feature is designed to work in tandem with the hypoxia model in th OMNI® 2 tablet control program.

4.5 Umbilical Catheterization

Premie Blue's umbilical cord can be filled with 1-2 cc of water using the syringe provided. Students can insert a lubricated umbilical catheter.

Directions for Use

1. Remove the caps on the ports

2. Attach the drainage tube provided to the port on the Premie Blue's right side

3. Place the end of the tube into a drainage container and open the adjustable clamp.

4. Fill the syringe with fluid.

5. Connect the syringe to the port on the right side of the Premie Blue and push in fluid. Allow the fluid to flow through the system and into the drainage container.

6. Once the fluid is seen draining, close the adjustable clamp.

For catheterization, use an umbilical catheter.

WARNING: Lubricate the distal tip of the catheter before inserting in umbilical cord.

7. Perform umbilical catheterization exercises.

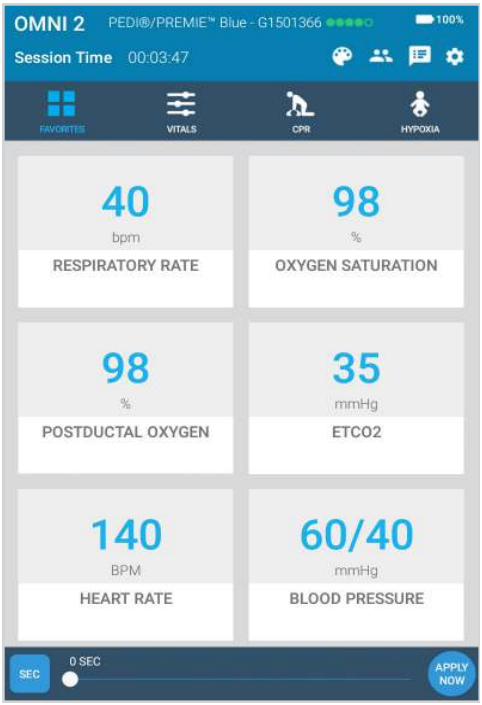
Heelstick

The right heel is molded of a soft material suitable for use with conventional Heelstick devices. Simulate Heelstick maneuver for capillary blood sample.

5. Using OMNI® 2

5.1 Main Screen

OMNI® 2 opens at the Favorites Page upon start up.



Changing a Vital Sign

Vital signs can be quickly changed from the Favorites Page or from the "Vitals" page. Follow the steps below to change one of the parameters:

1. Tap on a vital sign.

2. Adjust the vital sign by utilizing the slider or the +/- buttons.

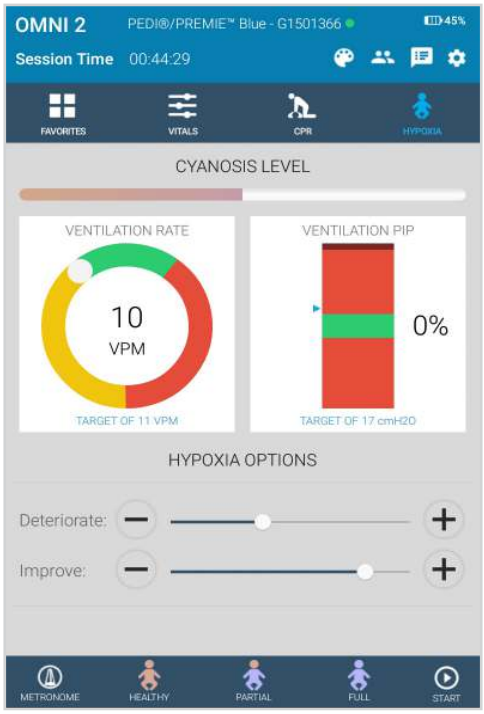
3. Select "APPLY NOW".

Refer to the OMNI® 2 User Guide for more information on changing vital signs.

5.2 Hypoxia

In order to simulate a hypoxic event, navigate to the Hypoxia Page. This model allows users to treat the emergency with appropriate airway and ventilation exercises.

OMNI® 2 will detect ventilations automatically and will measure whether or not they meet or exceed documented CPR standards.



To start a hypoxia session, follow the steps below:

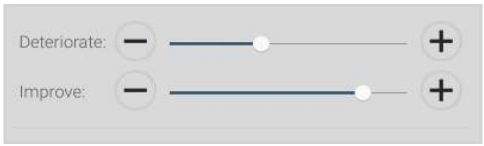
1. Select the initial state of the simulator. Choose from none, peripheral, or central cyanosis.

> **Premie Blue will display full cyanosis or partial cyanosis or a healthy state from these Hypoxia Stages.**

2. Change the rate of deterioration and improvement so that the patient becomes more hypoxic if no ventilations are performed.

3. Increase or decrease rate of deterioration

4. Increase or decrease rate of improvement per round of correct ventilation

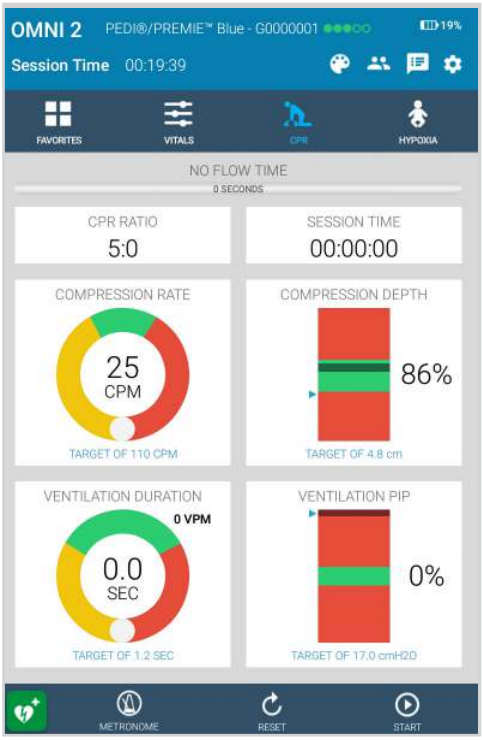


5. Tap “START” to begin the session.

5.3 CPR

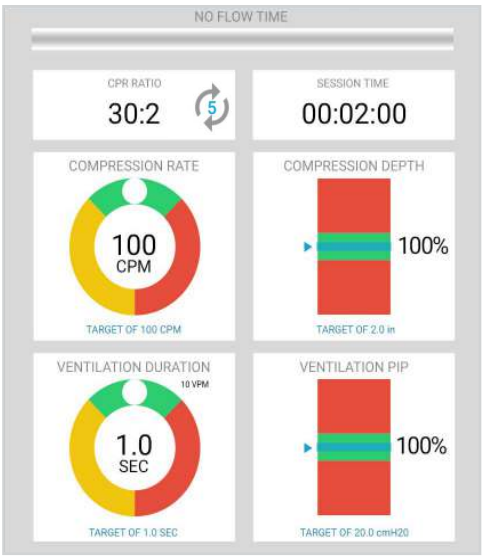
The CPR Page incorporated in the OMNI® 2 tablet was designed to help teach CPR by monitoring cadence and depth of cardiac compressions and airway ventilations in real time.

WARNING: Do not perform mouth to mouth ventilation since the simulator airway can be difficult to clean afterwards and will contaminate the air-way.



Feedback Graphics

Monitor the CPR session in real time. The CPR value ranges are AHA compliant.



Actions

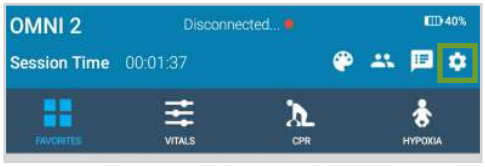
Buttons	Function
START STOP	Begin and end a CPR session
RESET	Reset a CPR session
METRONOME	Activate an audible coach for training
	Virtually defibrillate the simulator

Calibration

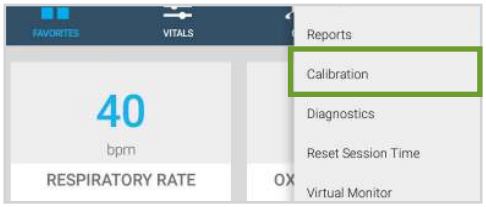
Before running a CPR scenario, please make sure to calibrate the compressions.

Perform the following to calibrate the compressions:

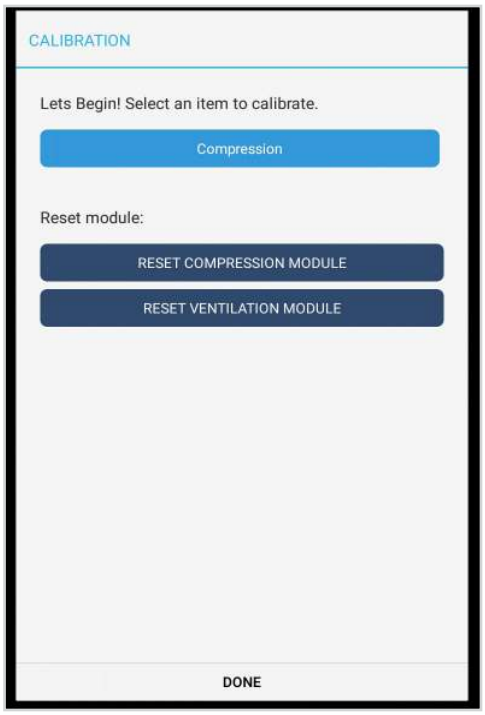
1. Tap the gear on the upper-right of the screen.



2. Select “Calibration”.

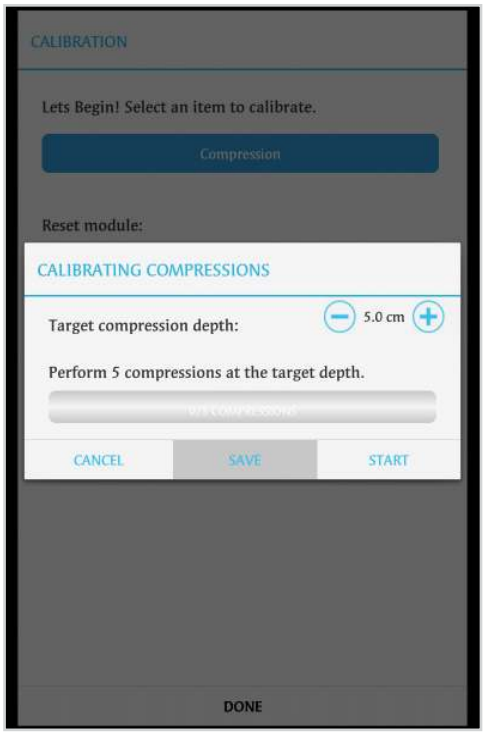


3. Select “Compression” once the calibration window appears.

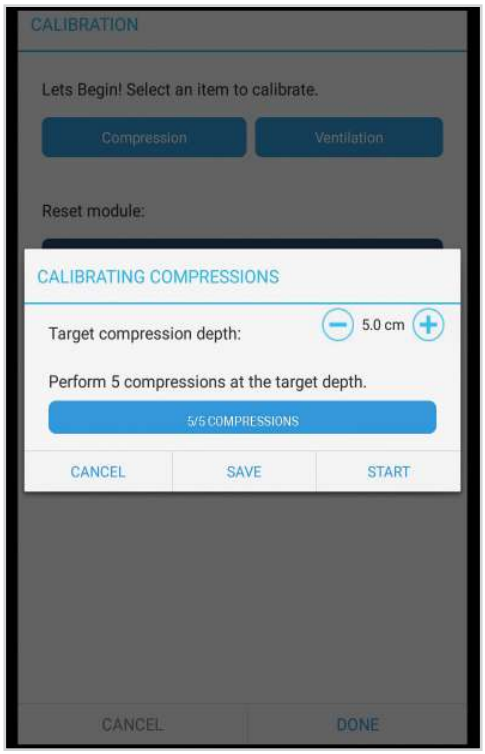


4. Adjust the Target compression depth with the +/- and tap “START”

5. Follow the prompts to calibrate the target compression depth



6. Select “SAVE” to apply the changes.



7. Tap “Start” to begin a CPR session.

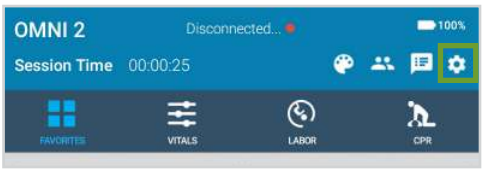
For more information about the CPR monitoring and reporting, refer to the OMNI® 2 User Guide.

6. Virtual Monitor Setup (Optional)

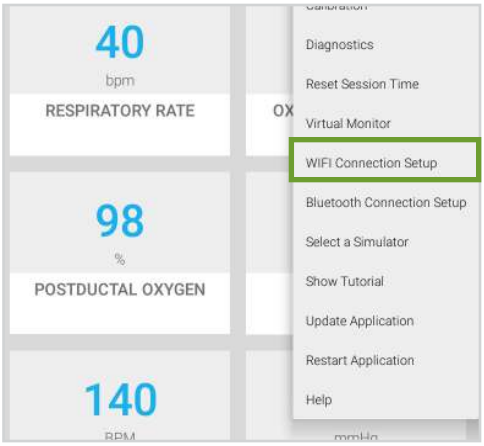
A patient virtual monitor is an optional purchase with OMNI® 2. Follow the steps below in order to activate this feature:

1. Connect the provided router to the wall.

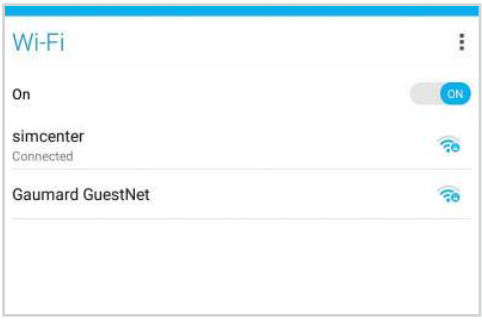
2. Tap the gear on the top right of the screen.



3. Select “WIFI Connection Setup”.



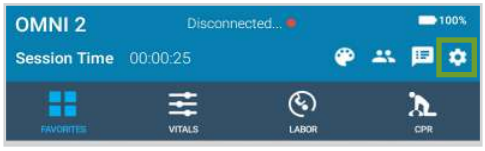
4. Connect to a wireless network.



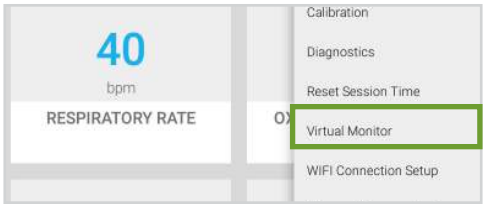
> **The network name will be “GaumardSimulatorSerialNumber”**

5. Exit the page by tapping the back button.

6. Tap the gear on the top right of the screen.

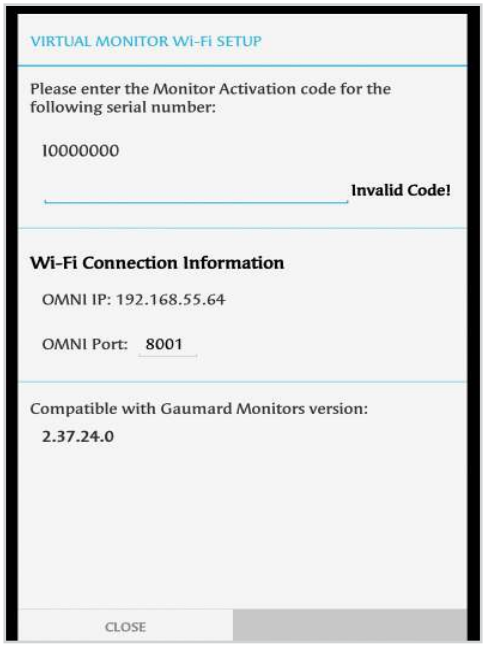


7. Select “Virtual Monitor”.



8. Follow steps 9-10 if the activation code was not inputted.

9. Verify that the serial number corresponds to the manikin.



10. Input a valid activation code.

> **The activation code is case-sensitive.**

> **Note that the activation code above is just an example. It is not a valid code.**

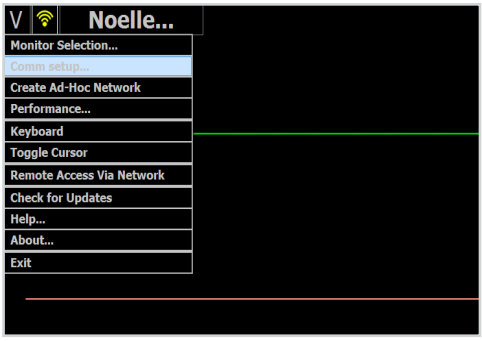
11. Take note of the OMNI IP and OMNI port.

12. Select “CONNECT”.

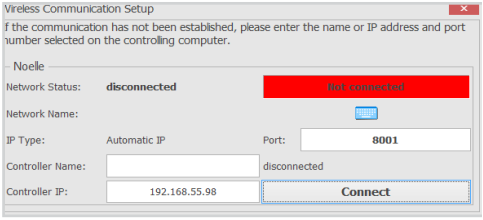
13. On the monitor, connect to the same network as OMNI® 2.

14. Once connected to the WIFI, open the Gaumard Monitors software.

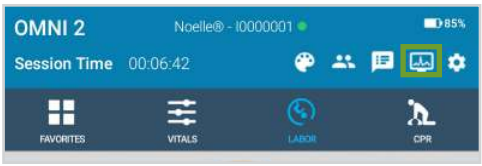
15. Tap the V on the top left and then select “Comm Setup”.



16. Verify that the IP address in the “Wireless Communication Setup” matches the Omni IP and Omni Port noted before.



17. Select “Connect”.



The Vital Signs Monitor icon will appear on the top right when it is connected.

> **For more information on how to use the Virtual Monitor, please refer to the Omni 2 User Guide.**

7. Appendix

7.1 Selected Parts List

Contact Gaumard Scientific for a complete list of consumables and replacement parts and their prices.

Item	Type	Code
Artificial Blood Concentrate	Consumable	S108.812
Lubricant	Consumable	S108.974
Arm Skin	Replacement	S108.813.L/M/D
Lower Intravaneous Right Training Arm	Replacement	S108.803R.IV.L/M/D
Intraosseous Tibial Bones	Consumable	S108.835
Intraosseous Skin and Bone Cover	Consumable	S108.836.L/M/D

7.2 Troubleshooting

Communication/Power Issues

Communication with the simulator cannot be established	
Controlling tablet is too far away from simulator	Minimize the distance between simulator and the tablet. Should not be over 10 meters away
More than one device is paired	Open Bluetooth Connection Setup. Select the Gear to the right and click “Forget” the network
Manikin is not paired	Disconnect the simulator from the power supply, turn off bluetooth on OMNI® 2 tablet. Plug the simulator back in and turn on bluetooth.
Power supply is not connected to simulator	Ensure that the power supply is connected to the simulator

Miscellaneous Issues

CPR is not detected	
Compression sensor is not calibrated	Tap the Gear on the top right and select Calibration. Calibrate the compressions
Ventilations are not detected	Tap the Gear on the top right and select Calibration. Reset the Ventilations sensor.

8. Warranty

8.1 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 property 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 handheld) and monitors (standard or touch-screen) are not covered by this limited warranty. Gaumard does not provide any warranty, express or implied, with respect to any third-party products. Defects in third-party products are covered exclusively by the warranty, if any, provided by the third-party.

- 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:
  - Contact Gaumard and request authorization to return the Gaumard product. Do NOT return the Gaumard product to Gaumard without prior authorization.
  - 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.

8.2 Extended Warranty

In addition to the standard one year of coverage we offer a range of service plans through our Gaumard Cares program. For more information about Gaumard Cares service planes please contact customer service.

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Simulators for Health Care Education

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Always dispose of this product and its components in compliance with local laws and regulations.

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