



Gaumard[®]
Simulators for Health Care Education

S320.100.250/S320.200.250
PEDI[®] Blue Neonate Simulator
with SmartSkin[™] Technology
User Guide

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1. 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.

1.1 General

- Ball point pens, ink, and markers permanently stain the skin.
- 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 Scientific or from your Distributor

1.2 IV Arm

WARNING: Vein tubing contains latex which may cause allergic reactions. Users allergic or sensitive to latex should avoid contact. Discontinue use of this product and seek medical attention if an allergic reaction occurs.

- 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 22 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 veins require replacement, refer to the "Consumables" section of this guide. For more information regarding the replacement of veins and other consumable items please contact customer service.

1.3 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)

1.4 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.

1.5 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.

1.6 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

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
- Right femoral, brachial, and radial pulse site (optional)
- Left tibial and popliteal pulse site (optional)

Simulator

- Physical size is 50th percentile at 40 weeks gestational age
- Realistic airway with tongue, vocal cords, trachea and esophagus
- Heart, lungs and ribs

Venous Access

- Femoral vein and artery (optional for S320.100.250)
- Patent umbilicus
- Intraosseous access at tibia (optional for S320.100.250)
- IV training arm (optional S320.100.250)

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.

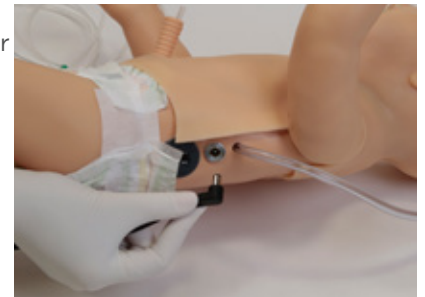
3. Equipment Setup

3.1 Overview

Power Supply

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

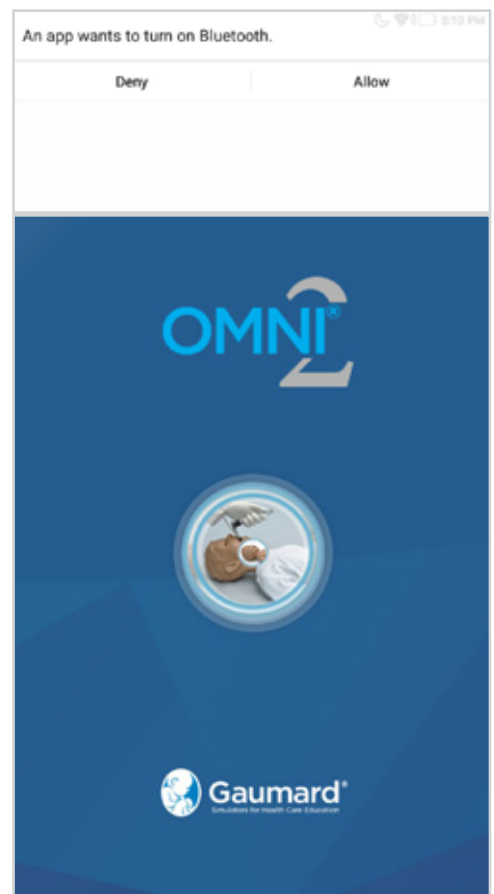
Always operate PEDI Blue with the power supply connected.



OMNI® 2

OMNI® 2 controls PEDI Blue with the touch of a button. 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.



- Run through the on-screen tutorial for a brief overview of OMNI® 2's features.

Move onto the next steps in the Tutorial by selecting "GOT IT".

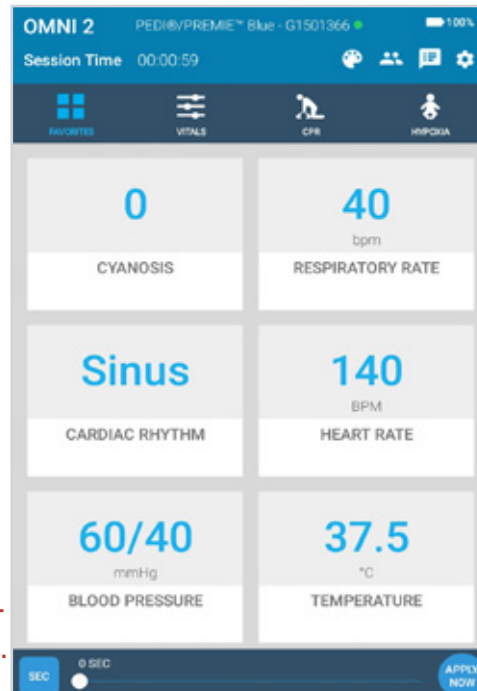
Exit the Tutorial at any time by selecting "HOME".

Please note that you have to go through the tutorial once or it will continue to appear at start-up.



After the startup screen, OMNI® 2 will proceed automatically to the Favorites Page and establish a connection to PEDI Blue.

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

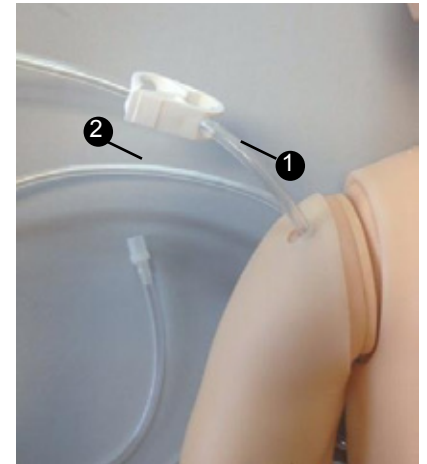


4. Using PEDI Blue

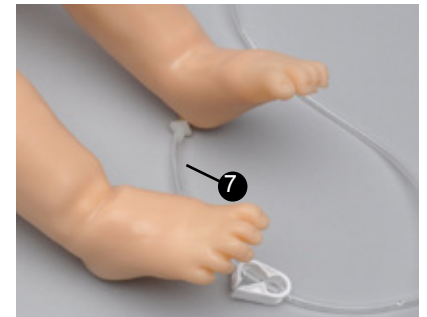
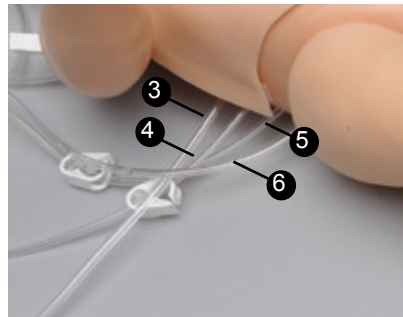
4.1 PEDI Blue Features

The filling and drainage tubes of PEDI Blue S320.200.250 are located on the right side of the neonate, except tube 7.

- Tube 1 - drain the IV arm system.
- Tube 2 - fill the IV arm system.
- Tube 3 - fill the umbilical cord system.
- Tube 4 - drain the umbilical cord system.
- Tube 5 - drain gastric contents introduced orally.
- Tube 6 - fill the tibia bone.
- Tube 7 - drain the contents of the tibia bone from the left foot.



The S320.100 features tubes 3, 4, and 5 only.



4.2 Airway Management

Train CPR techniques with PEDI 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. When intubating, use a Miller 1 blade and an uncuffed 3-3.5 mm endotracheal tube (ETT) with appropriate stylet.

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.

Intubation

Conduct oral or nasal intubation plus suctioning. Bilateral lung expansion is perceived with realistic chest rise.



Nasogastric Tube Feeding

For added realism, fluids may be introduced via a nasogastric tube into the stomach reservoir. Use tube 5 to drain these contents.



4.3 Cyanosis

PEDI Blue features SmartSkin technology 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 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 the OMNI® 2 tablet control program.



4.4 Intraosseous Access (S320.200.250)

Option not available for the Noelle S550.100.250 package.

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

Femoral Venous Access

Venous access can be obtained through the intraosseous route or through the left femoral site.

Right femoral vein and artery are standard in the S320.200.250.

Directions for Use

1. Place the end of tube 7 into a drainage container and open the adjustable clamp.
2. Fill the dispensing syringe with fluid.
3. Connect the syringe to tube 4 and push the fluid. Allow fluid to flow through the system and into the drainage container.
4. Once fluid is seen draining, close the tube 7 adjustable clamp.

Use 17-16 gauge bone aspiration needle to perform IO exercises.

5. Perform IO exercises.
6. After 10-20 sticks follow steps 2 - 4 to dispense more fluid into the system.
7. Continue your IO exercises.
8. When the training session is completed, open the tube 7 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:

- Flat head screwdriver
- Replacement tibia bone
- Drainage container

1. To replace the tibia bone, place the end of tube 5 into a drainage container and open the adjustable clamp.

2. Drain all the fluids from the system.

3. Evenly apply heat to the leg skin for 10 – 15 seconds.

4. Remove the leg skin and the tibia cover.

5. Gently remove the bone using a flat head screwdriver.

6. Replace tibia with a new insert or rotate to use the other end of the bone.

7. Re-attach tibia cover.

8. Place the leg skin back on the leg.



Palpable Pulses

Umbilical Cord

Generate palpable umbilical pulses using the squeeze bulb.



Femoral, Tibial, and Popliteal Pulses (Optional)

Right femoral and left tibial and popliteal pulses are available in the PEDI Blue S320.100.1 and S320.200.250. This option is not available with the S550.100.250 package.

Generate palpable femoral and left tibial, and popliteal pulses using the squeeze bulb.

Brachial and Radial Pulse (Optional)

Right brachial and radial pulses are available in the PEDI Blue S320.100.2 and S320.200.250. This option is not available with the S550.100.250 package.

A brachial and radial pulse site is available on the right arm. Generate pulses using the squeeze bulb located on the left hand side of the simulator.

Umbilical Catheterization

PEDI Blue's umbilical cord can be filled with 2-3 cc of water using the syringe provided. Students can insert a lubricated umbilical catheter.

Directions for Use

1. Place the end of tube 4 into a drainage container and open the adjustable clamp.
2. Fill the fluid dispensing syringe with water.
3. Connect the syringe to tube 3 and release the water. Allow water to flow through the system and into the drainage container.
4. Once the water 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.

5. Perform umbilical catheterization exercises.



4.5 PEDI Injection Training Arm (S320.200.250)

The PEDI Blue S320.200.250 includes the injection training arm feature.

WARNING: Vein tubing contains latex which may cause allergic reactions. Users allergic or sensitive to latex should avoid contact. Discontinue use of this product and seek medical attention if an allergic reaction occurs.

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.

The PEDI Injection Arm includes a blood dispensing syringe, synthetic blood concentrate, and a spare arm skin.

Use a 23 to 25 gauge needle set.

Filling the Training Arm Vasculature

1. Place the end of the drainage tube 1 into a container and open the adjustable clamp.
2. Fill the dispensing syringe with fluid.
3. Connect the syringe to tube 2 release the fluid.
4. Allow fluid to flow through the system and into the drainage container.
5. Close the adjustable clamp of the drainage tube once water is seen draining.
6. Remove the syringe from tube 2.

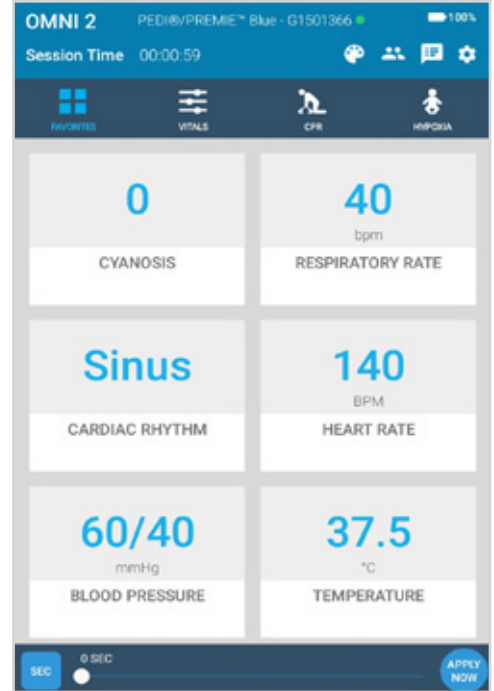
Instructions for Use

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

5. Using OMNI® 2

5.1 Main Screen

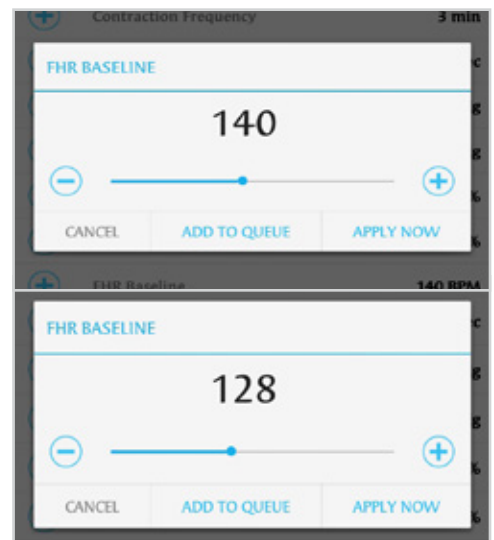
OMNI® 2 opens at the Favorites Page upon start up.



Changing a Vital Sign

Vital signs can be quickly changed from the Favorites Page or from the Vitals Page. In order to change one of these parameters, follow the steps below:

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.



PEDI Blue will display central cyanosis or peripheral 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

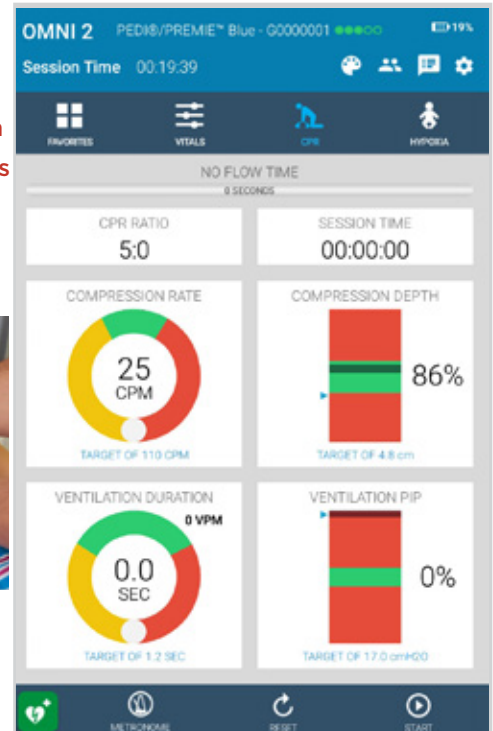


5. Tap "START" to begin the session.

5.3 CPR

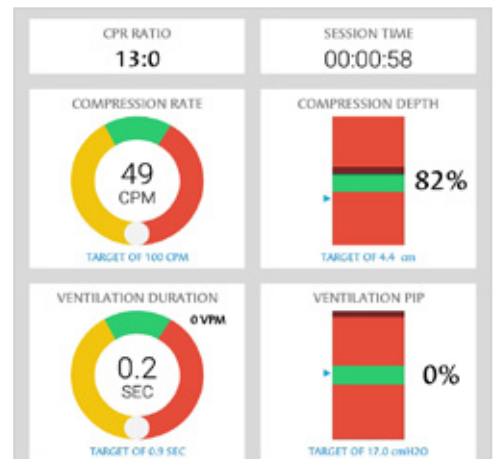
The CPR Page incorporated into the OMNI® 2 tablet was designed to help teach CPR by monitoring cadence and depth of cardiac compressions and airway ventilations in real time.

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

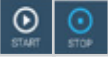





Feedback Graphics

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



Actions

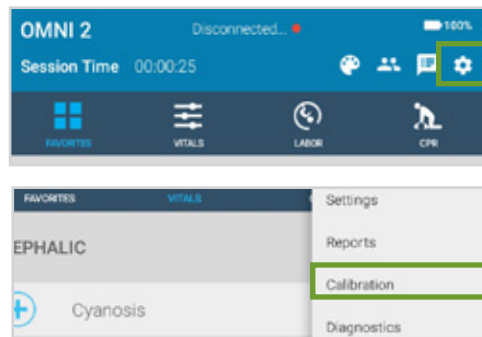
Buttons	Function
	Begin and end a CPR session
	Reset a CPR session
	Activate an audible coach for training
	Virtually defibrillate the simulator

Calibration

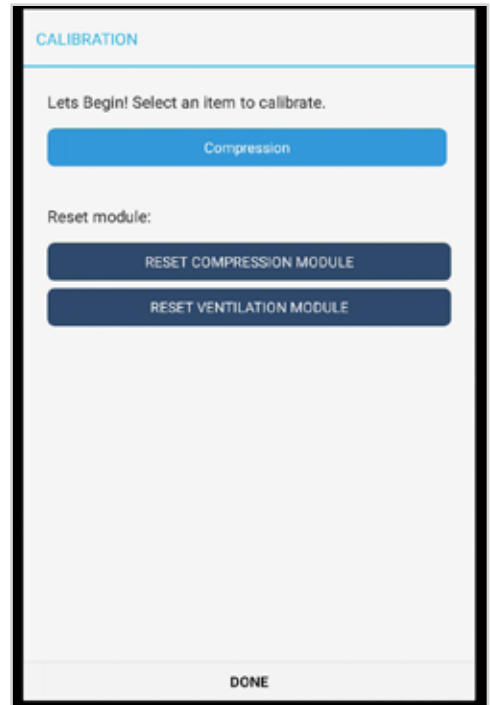
Before running a CPR scenario, please make sure to calibrate the compressions.

Perform the following to calibrate the compressions:

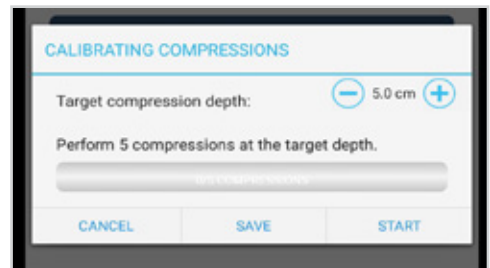
1. Tap the Gear on the upper-right of the screen
2. Select "Calibration"



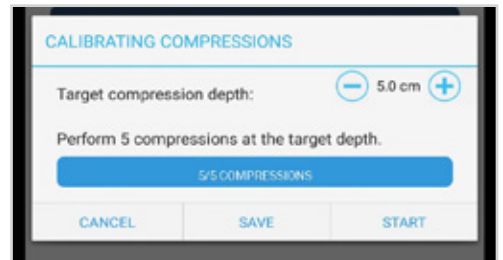
3. Select “Compression” once the Calibration window appears



4. Adjust the Target compression depth and tap “START”



5. After completing 5 compressions click “CANCEL”, “SAVE”, or “START”



6. Tap “Save” if you are satisfied with the calibration and ready to do CPR.

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

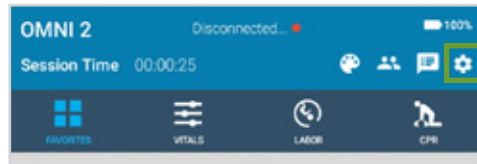


For more information about the CPR monitoring and reporting, refer to the OMNI® 2 User Guide.

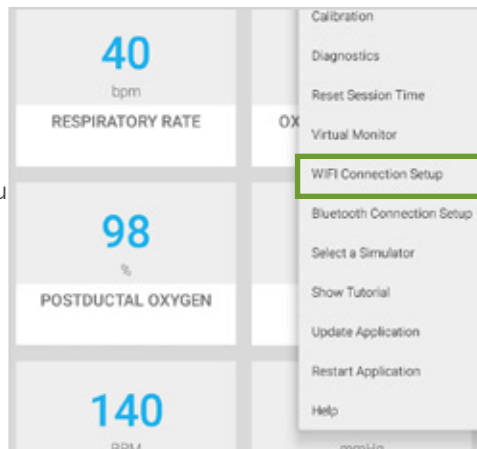
6. Virtual Monitor Setup (Optional)

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

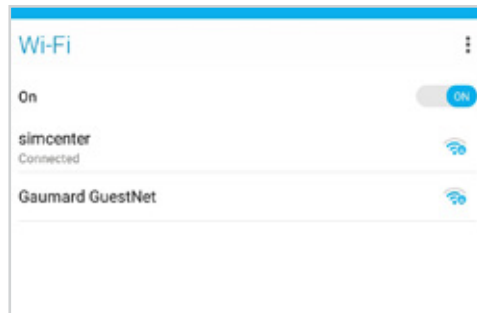
1. Connect the router to the wall.
2. Tap the gear on the upper-right of the screen.



3. Select "WIFI Connection Setup"



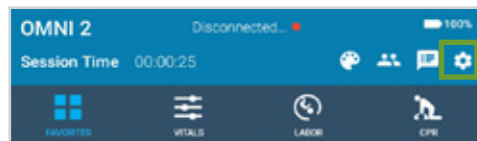
4. Connect to a wireless network.



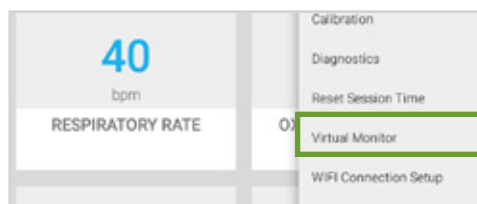
5. Exit the page by tapping the back button.



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



7. Select "Virtual Monitor".



- Follow steps 9-10 if the activation code input was not performed correctly.

- Verify that the serial number corresponds to the manikin.



- Input a valid activation code.

The activation code is case-sensitive.

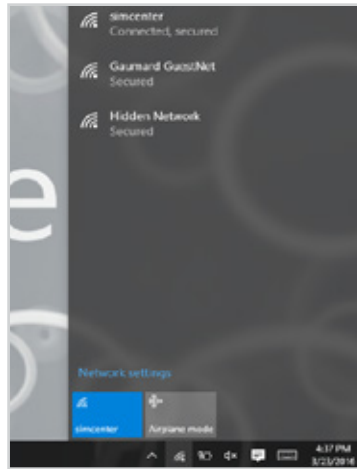
Note that the activation code above is just an example. It is not a valid code.

- Take note of the OMNI IP and OMNI port.

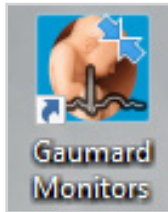
- Select "CONNECT".



- Connect to the same network as Omni.

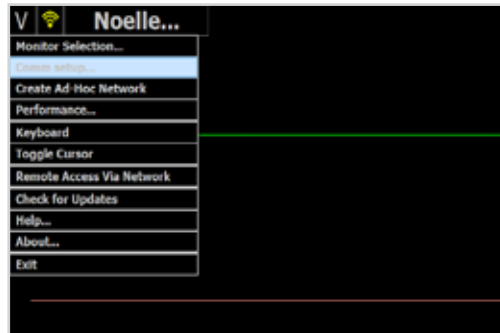


- Once connected to the WIFI, open the Gaumard Monitors software.

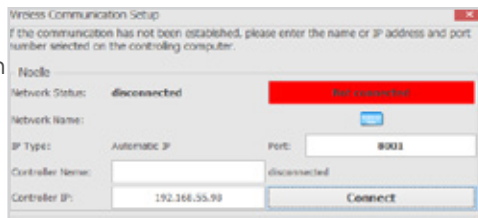


If connection is not established, please follow the steps below:

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

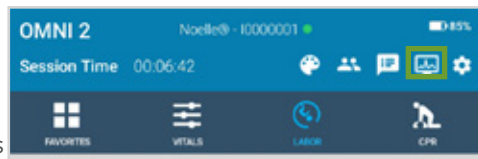


- Verify that the IP address in the “Wireless Communication Setup” matches the Omni IP and Omni Port noted before.



- Select “Connect”.

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



Please refer to the OMNI® 2 User Guide for more information on using the Virtual Monitor.

7. Appendix

Selected Parts List

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

Item	Type	Code
Simulated Blood Concentrate	Consumable	S320.100.080
Lubricant	Consumable	S320.100.081
I/O Tibia Bones	Consumable	S320.200.835
I/O Skin and Bone cover (light, medium, dark)	Consumable	S320.200.836.L
Arm Skin right and left (light, medium, dark)	Consumable	S320.200.813.L

7.1 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"
Manikin is not paired	Disconnect the simulator from the power supply, disconnect OMNI® 2 Link (if applicable), turn off bluetooth on OMNI® 2 tablet. Plug the simulator and OMNI Link 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 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 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.

9. Contact Gaumard

9.1 Contacting Technical Support

Before contacting Technical Support you must:

18. Have the simulator's serial number
19. Have access to the simulator for possible troubleshooting as needed

Technical Support:

Email: support@gaumard.com

USA: 800-882-6655

INT: 01-305-971-3790

9.2 General Information

Sales and Customer Service:

E-mail: sales@gaumard.com

USA: 800-882-6655

INT: 01-305-971-3790

Fax: 305-667-6085

Post:

Gaumard Scientific
14700 SW 136 Street
Miami, FL 33196-5691
USA

Office Hours:

Monday-Friday, 8:30am - 4:30pm EST (GMT-5, -4 Summer Time)



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

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