



Gaumard[®]
Simulators for Health Care Education

NOELLE[®] S552.250 Maternal Birthing Simulator User Guide



NOELLE 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 17.71
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1. Introduction

1.1 Specifications

NOELLE

- Noelle Weight: 18.7 lbs (8.48 kg)
- Noelle Length: 33 in (83.82 cm)
- Power Supply:
 - › Power input: 100-240 VAC, 50/60 Hz, 500 ma/ 50 VA
 - › Power output: 12 VDC/ 2 A/ 24VA
- Weight:
 - › Birthing baby: 2 lbs (0.9 kg)
- Length:
 - › Birthing baby: 16.5" (41.91 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.
- Marks made with ballpoint pens, ink or marker cannot be removed.
- Replacement parts are available from Gaumard Scientific or from your Distributor

Operating Conditions

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

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

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.

Procedures

- Treat the simulator with the same precautions that would be used with a **real** patient.
- Always keep clear of the birthing mechanism while the system is on.
- Never operate the birthing mechanism without the tummy cover in place.

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.

Birth Canal Maintenance

- Ball point pens, ink and markers permanently stain the birth canal insert.
- Do not wrap this or any other Gaumard product in newsprint.
- The birth canal insert can be cleaned with a mild solution of soap and water. After cleaning, dust with talcum powder.
- Store the spare birth canal in a cool, dry location.
- Always lubricate the birth canal with silicone oil lubricant prior to delivery.
- Do not store the fetus inside the abdomen.

2. Getting Started

2.1 Overview

The NOELLE S552.250 teaching system permits students to appreciate the complete birthing experience from the onset of labor, to delivery, and treatment of the mother.

Appearance

- Light skin tone is the standard simulator color; medium or dark is available at no extra cost.

Simulator

- Delivering mechanism
- Manage vertex, breech, dystocia, and instrument assisted deliveries
- Soft and flexible birth canal
- Multiple placenta positions
- Practice postpartum suturing on vulval inserts
- Practice Leopold Maneuvers

Options

- C-section abdominal cover
- Palpation abdominal cover

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.

2.3 Birthing Package

Check List

- Abdomen cover with speaker attached
- Articulating birthing fetus
- Automatic birthing mechanism (installed)
- Birthing fetus face skin
- Birth canal (installed)
- Inflatable cushion for Leopold Maneuvers
- OMNI® 2 Tablet (tablet, charger, USB cable, Quick Start Guide)
- Power supply
- One Silicone lubricant
- Talcum powder
- Two mechanical adaptors
- Two episiotomy suture trainer
- One placenta with fragments
- Two umbilical cords
- One umbilicus
- One Umbilical clamp
- User Guide

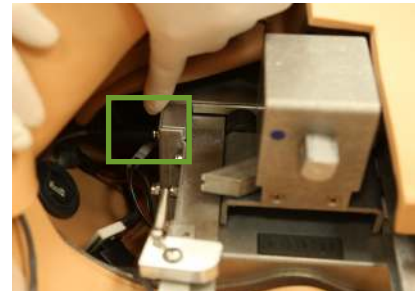
3. Equipment Setup

3.1 Overview

NOELLE is shipped assembled. The birthing fetus is fully assembled. Perform the following steps as part of the first install process.

Fetal Heart Rate Speaker

Connect the speaker cable, exiting NOELLE's abdominal cover, to the right side of the birthing mechanism.



Power Supply

Connect the power supply to the power input located on NOELLE's right side, and then connect the power supply to the wall outlet.



Always operate NOELLE with the power supply connected.

OMNI® 2 Connection Setup

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

Noelle can be operated using a wired connection. Please refer to the OMNI 2 user guide to set up a wired connection.

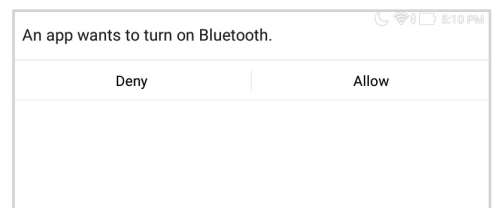
Follow the steps below to connect to OMNI® 2:

1. Connect the power supply to Noelle



2. Turn on OMNI® 2 by pressing and holding the ON button on the right side of the tablet.

3. Select “Allow” to turn on Bluetooth for the tablet.

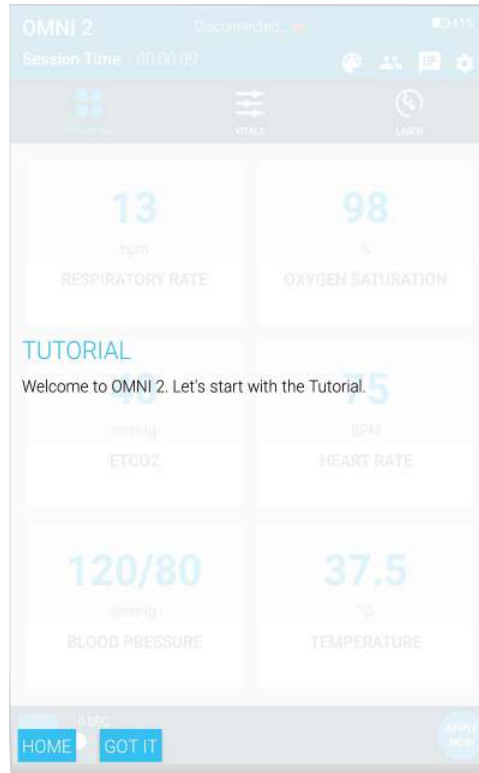


4. A startup screen is shown while OMNI® 2 is detecting the simulator features.



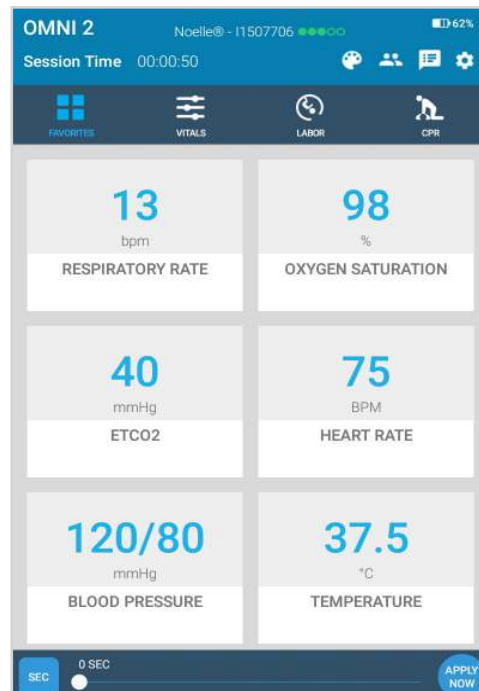
5. Follow the on-screen tutorial for a brief overview of OMNI® 2's features.
6. Move onto the next steps in the tutorial by selecting "GOT IT".
7. Exit the tutorial at any time by selecting "HOME".

Complete the tutorial one time to avoid it from appearing at start-up in the future.



After the tutorial, OMNI® 2 will proceed automatically to the Favorites Page and establish a connection to NOELLE.

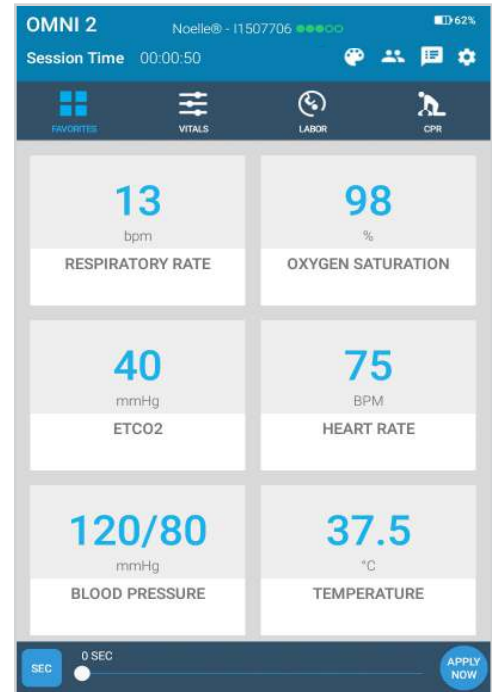
WARNING: Do not connect NOELLE or OMNI® 2 to a computer. LAN network or unauthorized diagnostic equipment. Doing so will cause serious damage to the equipment.



4. Using OMNI® 2

4.1 Main Screen

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



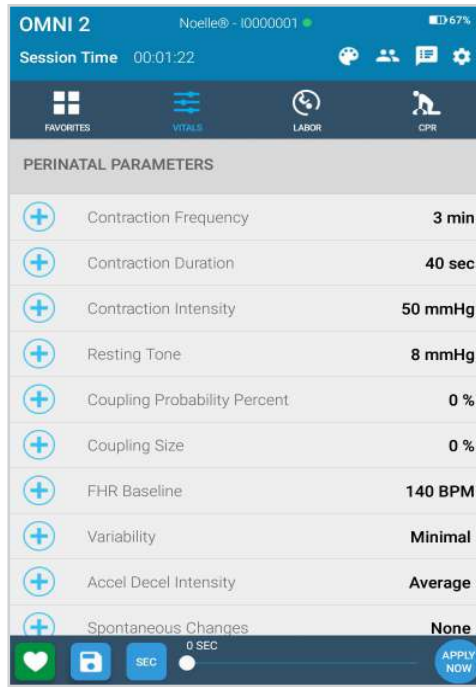
4.2 Perinatal Parameters

Change the fetal vital signs in the Vitals Page. Observe the changes on the optional Virtual Monitor. Find all the parameters in the Vitals Page.



For more information on how to use the Virtual Monitor, please refer to the OMNI® 2 User Guide.

In order to change one of these parameters, follow the steps below:



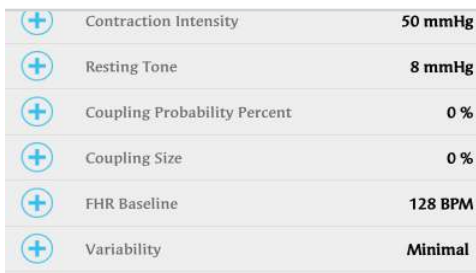
1. Tap on a vital sign.



2. Adjust the value utilizing the +/- icons or the slider dot.



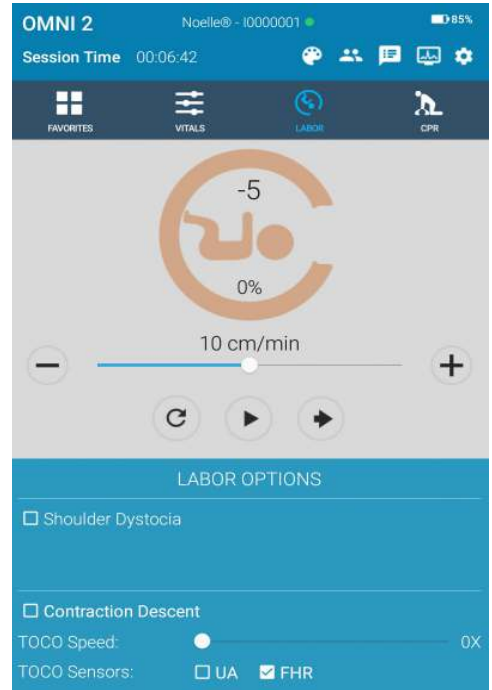
3. Select "APPLY NOW".



4.3 Labor Page

In the Labor Page, carry out and monitor a delivery.

Enable or disable shoulder dystocia and turtle signs during delivery.



Actions

Make changes to the delivery on the fly using the buttons.

Buttons	Function
	Increase or Decrease the current labor duration
	Increase or Decrease the current labor duration
	Reset birthing mechanism to initial position
	Play the delivery
	Push to end
<input type="checkbox"/> Shoulder Dystocia	Activate or deactivate Shoulder Dystocia
	Generate Turtle Signs

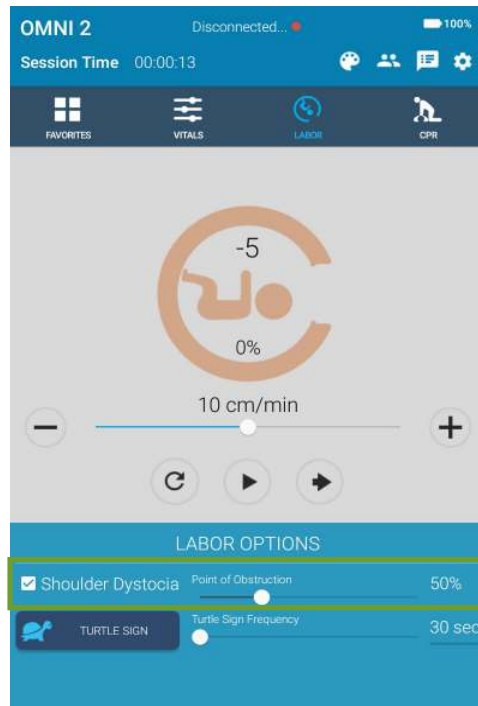
Feedback Graphics

The diagram here is a representation of the delivery of the fetus through the birth canal. The percentage and the -5 values will change in correspondence to the movement of the motor.



Dystocia Menu

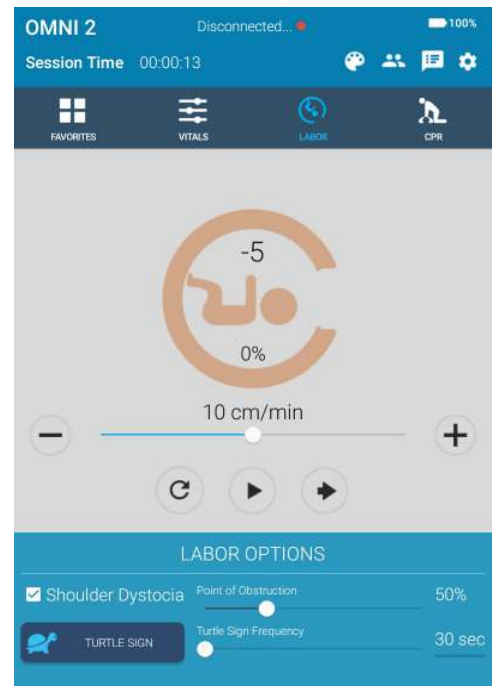
Check the Shoulder Dystocia option to activate the condition. When shoulder dystocia is check marked, labor sub menus will appear.



These options provide a quick way to generate turtle signs anytime.



The percentage specifies when the shoulder dystocia will be applied. When the percentage is set to 50%, the fetus will display a shoulder dystocia when it is about 50% through the labor cycle.



The timer on the right specifies how long until the next turtle sign. The slider dot can adjust the time anywhere between 30 to 120 seconds.



5. Working with NOELLE

5.1 Obstetrics

The NOELLE birthing mechanism offers the ability to demonstrate a variety of obstetric techniques including:

- Fetal palpation
- Vaginal delivery
- Shoulder dystocia
- Complete, frank and footling breech deliveries
- External version
- Cord prolapse
- Placenta previa
- Vacuum or forceps delivery

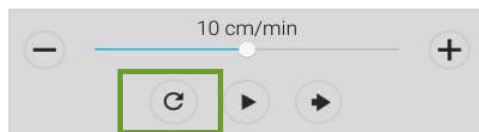
Automatic Birthing Mechanism and the OMNI® 2

NOELLE is supplied with an electromechanical system to automatically deliver the fetus using the OMNI® 2 tablet. The system, configured with the OMNI® 2, provides internal rotation, linear motion to “crowning”, and a second rotation to present the fetal shoulders parallel to the longitudinal axis of the vulva.

Leopold Maneuvers

Practice Leopold Maneuvers with NOELLE.

1. Retract the birthing mechanism and remove the articulating birthing baby.



2. Place elevating pillow within simulator.



- Place birthing fetus in the vertex, breech, or transverse position onto the elevating pillow and lift fetus anteriorly using squeeze bulb.



- Route the inflation bulb outside NOELLE through any space provided on the left side and inflate the elevating pillow.

- Lubricate the fetus and elevating pillow.

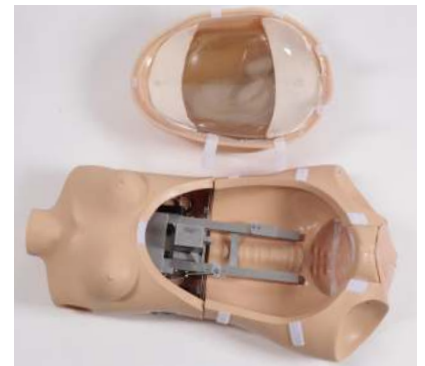


- Secure the abdominal cover into place with the velcro.

- Conduct the Leopold Maneuvers.

Optional Palpation Abdominal Cover

NOELLE has an optional silicone Leopold Maneuver abdominal cover. The fetus float freely inside an amniotic sack which provides tactile feedback and resistance when performing the Leopold Maneuvers or external version exercise.



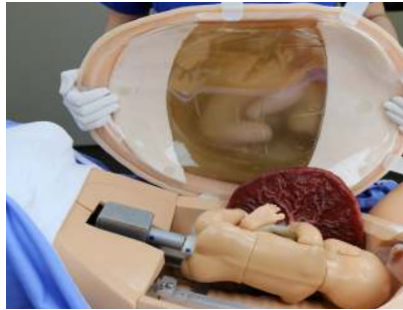
WARNING: Always remove the cover at the end of the palpation exercise to prevent damage to the simulator. The weight of the palpation cover can add unnecessary stress to NOELLE's midsection if left installed for more than two hours.

To set up the Leopold Maneuver cover, simply secure the cover into place with the velcro. Perform the maneuvers on the silicone cover.



The fetus can be set up in Noelle's abdominal cavity and birthed for a scenario.

Please refer to the Normal Labor and Delivery Section to set up NOELLE for a birth.



Dilating Cervix

As the fetus proceeds down the birth canal it pushes against a simulated uterus/cervix. Students can measure birth descent and cervical dilation which may be used to plot the progress of labor.



Normal Labor and Delivery

To complete a normal delivery, follow the instructions below:

1. Remove the abdominal cover.
2. Lubricate the articulating birthing fetus.



WARNING: Always lubricate the baby and the birth canal prior to every delivery. Poor lubrication may damage the birth canal, fetus, and the birthing mechanism.

3. Lubricate the vulva and cervix internally and externally using silicone lubricant.



4. Attach the umbilical cord to the baby.



WARNING: Route the cord so that it does not bind in the mechanism. The umbilical cord can be wrapped around the fetal neck or coiled out of the way.

5. Attach the umbilicus to the placenta.



6. Lubricate the placenta and umbilicus.



7. Place the placenta against the abdominal wall.



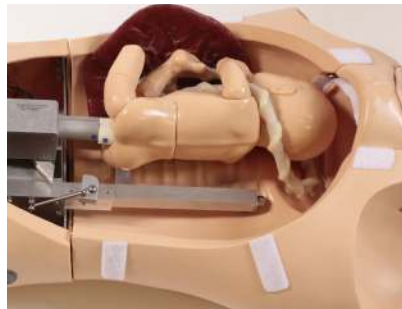
8. Connect the cylindrical adapter, with blue markers aligned, to the automatic birthing mechanism.



9. Attach the fetus to the birthing mechanism.

Ensure that the marker of the automatic birthing mechanism aligns with the markers of the mechanical adapters and the birthing fetus.

10. Position the baby so that its head faces toward the left side of the simulator. This position will result in ROA presentation at the end of the delivery cycle.



Placing the fetus in the right occipital anterior (ROA) position at the beginning of the simulation will result in a “nose down” crowning followed by shoulder rotation. Placing the fetus in the left occipital posterior (LOP) position will result in a “nose up” presentation.

Any other delivery position may be chosen; however, take care that the fetal shoulders are aligned with the long axis of the vulva insert.

WARNING: If the fetal shoulders are NOT aligned with the vulva, binding may occur.

11. Attach the Fetal Heart Rate Speaker to the side of the motor and put the abdominal cover in place.

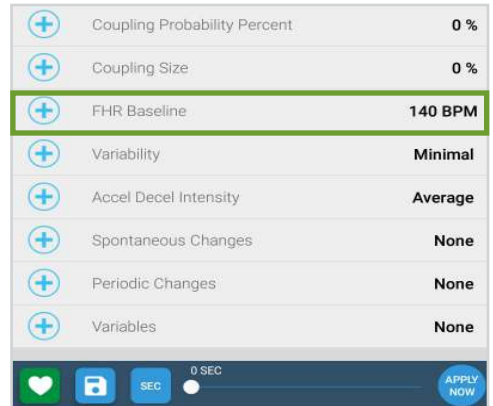


WARNING: Please make sure that the fetal heart rate speaker cable is out of the way of the birthing mechanism.

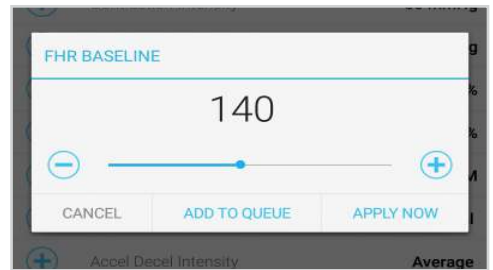
12. Connect OMNI® 2 to NOELLE.

Refer to the Equipment Set Up section to connect.

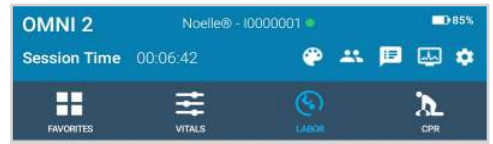
13. Select desired fetal heart rate using the OMNI® 2 Vitals Page by pressing + or - button or the slider, tap “Apply Now” to accept the value.



14. You may adjust the heart rate at any time during the delivery to simulate episodes of bradycardia or tachycardia.



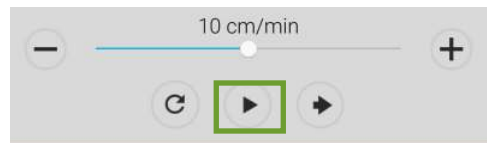
15. Navigate to the Labor Page.



16. Adjust the speed of the delivery by adjusting the cm/min either by tapping the +/- or with the slider button.



17. After confirming the settings for the labor, tap the Play button to begin the delivery.



The birthing cycle can be paused at any point and then resumed.

Note that the fetus rotates internally as it moves forward after the head is delivered and before the shoulders are delivered.

In the event the birthing baby binds in the birth canal, the mechanism will pause and back up. If this occurs, remove the abdominal cover, PAUSE the birthing mechanism from the OMNI® 2. Disconnect the fetus from the labor motor and reset the labor motor. Start the delivery again.

During delivery, fetal heart tones can be heard by placing the bell of a conventional stethoscope on the abdomen.



Change the fetal heart rate using OMNI® 2 by accessing the Vitals Page.

The cervix dilates as the fetal head moves down the birth canal. Crowning of the fetal head can be seen.



External fetal rotation aligns shoulders with the longitudinal axis of the vulva.



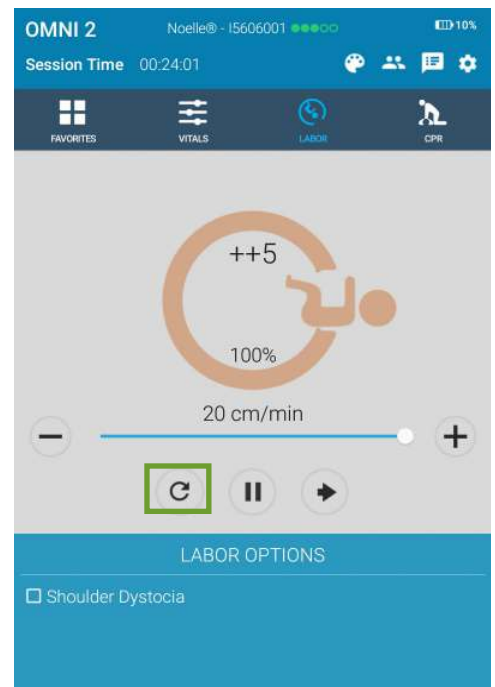
18. Deliver the fetus.



- Practice umbilical cord clamping and cutting on the consumable cords.



- Reset the labor motor.



- Birth the placenta.

For more information on the placenta, please refer to Section 5.5 Placenta Delivery.



Vacuum-Assisted Delivery

Vacuum-assisted delivery may be practiced with the NOELLE simulator using a vacuum cup.

1. Begin the vacuum-assisted delivery by inserting the soft scalp over the skull of the birthing fetus.



Placing the soft scalp over the skull improves the vacuum seal between the fetal head and the vacuum.

2. Lubricate the fetus as described in the Normal Labor and Delivery section.



3. Connect NOELLE to OMNI® 2.
4. Select Play from the Labor page.

OMNI® 2 will load with predetermined settings. Fetal heart rate of 140 BPM, delivery speed of 10 cm/min and the dystocia feature off.

Activating the delivery mechanism will move the fetus down the birth canal.

5. Select the Pause button as soon as the cervix is fully dilated.

6. Use the manual vacuum pump to attach the cup to the skull and apply traction with each contraction.



- Await the next contraction that may be simulated by the OMNI® 2.
- Select the play button, then the pause button again to move the fetus slightly down the birth canal.

Shoulder Dystocia

- To demonstrate shoulder dystocia, place the fetal baby in the ROA position.



- Connect NOELLE to OMNI® 2.
- Set the labor duration by pressing the “+” or “-” buttons.

- Activate dystocia by tapping “Shoulder Dystocia”. Dystocia enables the “turtle signs”.



- Set the “Point of Obstruction” using the slider dot



- Select “TURTLE SIGN” and set the frequency of the turtle signs



Activate or deactivate dystocia at any time during the delivery.

If the fetus cannot be delivered, the Instructor can uncheck the Shoulder Dystocia box which will cause the fetus to resume the movement down the birth canal.

WARNING: Do not place the fetus in the LOA position as it will attempt to birth with its shoulders at right angles to the axis of the vulva causing undo stress on the delivery mechanism.

Optional Cesarean Delivery

Demonstrate a C-section using NOELLE. To complete this procedure follow the steps below.

1. Retract delivery mechanism.
2. Insert inflatable cushion and fetus.
3. Attach abdominal cover using the velcro.
4. Birth the neonate between the stomach cover and pubic bone.



Prolapse of the Umbilical Cord

Simulate prolapse of the umbilical cord by positioning cord on a critical position.

Decrease the fetal heart rate from the OMNI® 2 tablet.



Placenta Previa

To simulate placenta previa with NOELLE, place the placenta in the desired position to simulate the condition, with the maternal side against the uterine wall or the cervical os. Then place the fetus within the uterine cavity with the presenting part closest to the placenta.



WARNING: This is for demonstration only. Do not birth the fetus with the placenta covering the cervix opening.

Breech Birth

To simulate breech presentations with the Noelle:

1. Fully retract the birthing mechanism.
2. Remove the fontanelle plug from the fetus.
3. Lubricate the fetus and birth canal.
4. Insert the birthing mechanism into the fetal head using **two** adapters.



Please note that only one adapter is used for a normal birth. Two adapters should be used for a breech delivery.

5. Place the fetal legs in either an extended position to simulate “foot-
ing” delivery or retract the legs for a “frank” delivery.
6. Press “Play” in the Labor
Page.
7. Deliver the fetus.



Placenta Delivery

Birth the placenta.

The placenta supplied with NOELLE requires manual removal.



In addition, note that the placenta is designed with two removable placental fragments. These fragments are attached to the body of the placenta with Velcro®.



You may reverse one or both fragments causing one or both to birth with the placenta or remain affixed to the uterine wall.



8. Inspect the placenta for retained fragments.



Episiotomy Repair

Remove the fully dilated vulva used during delivery and select one of the two episiotomy repair modules. Velcro a repair module into place. Use a “000” size suture and small curved needle to repair the surgical incision or repair.



“000” sized sutures are recommended to extend the life of the repair modules.



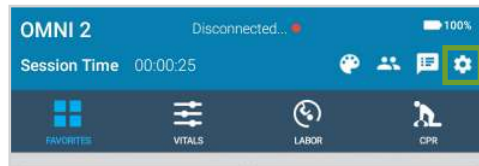
6. Virtual Monitor Setup (Optional)

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

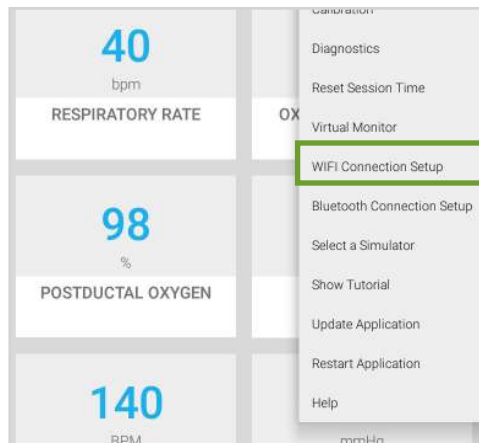
The simulator must be connected to the OMNI® 2 tablet in order to establish a connection to the Virtual Monitor.

1. Connect the provided router to the wall.

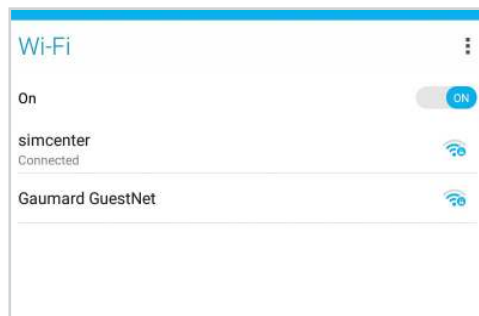
2. Tap the gear on the top right of the screen.



3. Select “WIFI Connection Setup”.



4. Connect to a wireless network.



The network name will be “GaumardSimulatorSerialNumber”

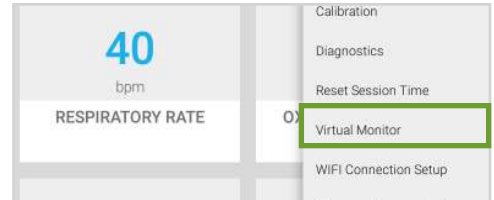
5. Exit the page by tapping the back button.



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

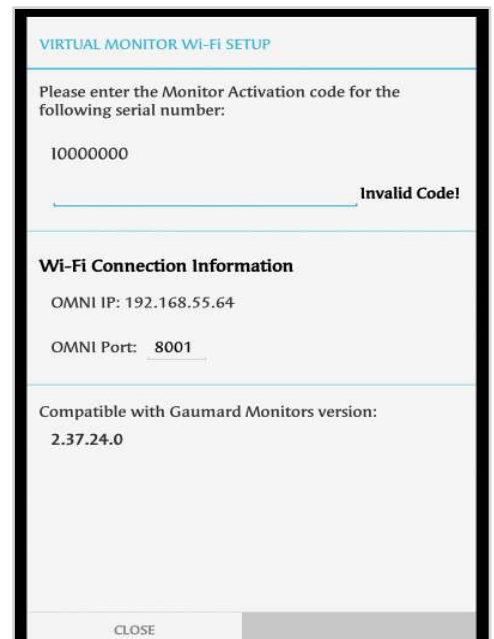


- Select "Virtual Monitor".



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

- Verify that the serial number corresponds to the manikin.

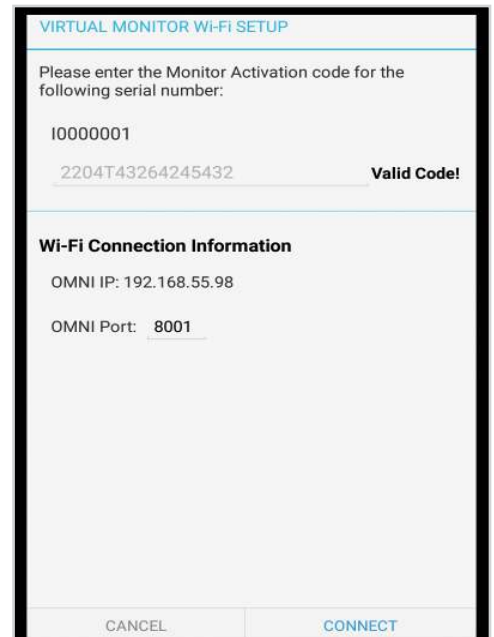


- Input a valid activation code.

The activation code is case-sensitive.

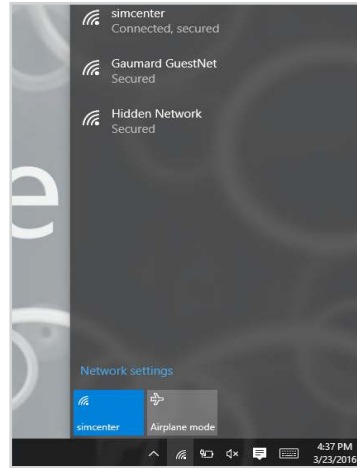
Note that the activation code here is just an example. It is not a valid code.

- Take note of the OMNI IP and OMNI port.



12. Select “CONNECT”.

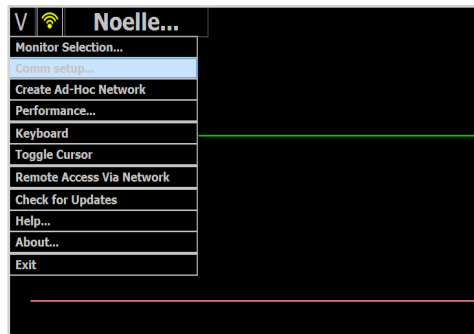
13. On the monitor, connect to the same network as OMNI® 2.



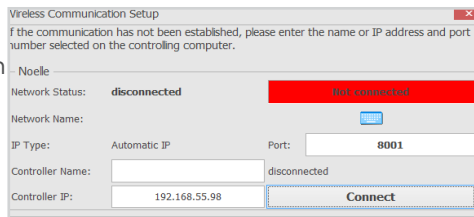
14. Once connected to the WIFI, open the Gaumard Monitors software.



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”.

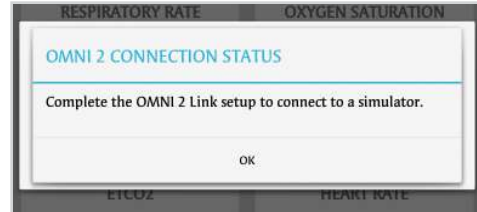
The Vital Signs Monitor icon will appear on the top right when it is connected.



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

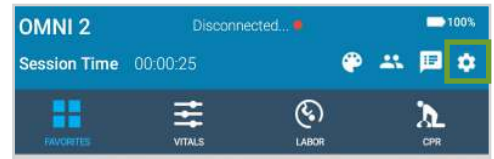
7. OMNI® Link Setup

Follow steps 1-5 if the notification below appeared:

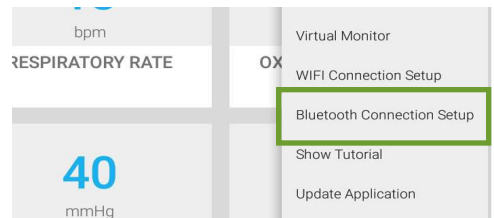


OMNI® 2 has to be paired to a simulator to establish a connection with the simulator.

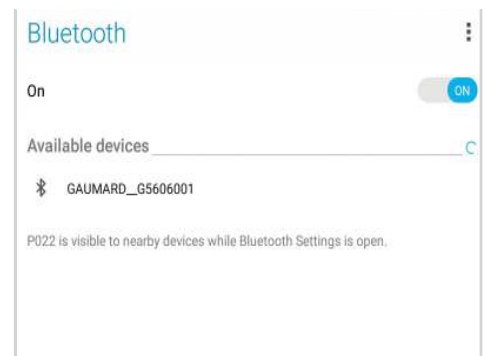
1. Tap the Gear on the upper-right corner of the screen.



2. Tap “Bluetooth Connection Setup”.

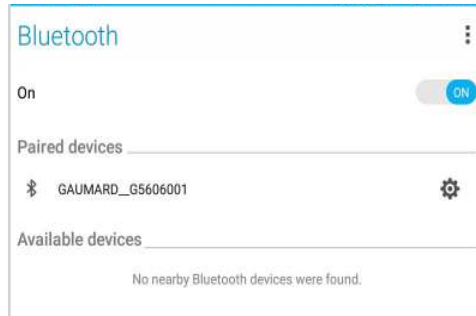


3. Select the simulator’s serial number under “Available Devices”.



The device name will be Gaumard_SimulatorSerial-Number

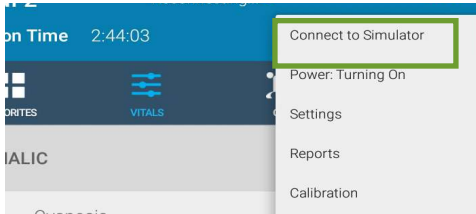
4. Wait for the device to pair with the OMNI® 2. This can take up to 30 seconds.



5. Once paired, tap the back arrow to return to the main screen.



6. Tap the gear on the upper-right and select "Connect to Simulator"



7. Select the simulator you wish to connect to and tap "Connect and Save as Default"



The name of the simulator and the serial number appear at the top of the screen. The green dots indicate the strength of connection.



OMNI® 2 can be operated up to 10 meters from the simulator.

8. Appendix

8.1 Consumables and Replacements

Selected Parts List

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

Item	Type	Code
Birth Canal (Light, Medium, Dark)	Consumable	S552.971.(D/L/M)
Placenta with detachable fragments	Replacement	S552.136.R2
Umbilical Cords (Set of 2)	Consumable	S552.137.R2
Umbilicus (Set of 2)	Consumable	S552.147.R2
Oil-Based Silicone Lubricant	Consumable	S552.974
Episiotomy Repair (Light, Medium, Dark)	Consumable	S552.250.133.R2.L/M/D
Power Supply	Replacement	S552.968

8.2 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
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More than one device is paired	Open Bluetooth Connection Setup. Select the Gear to the right and click “Forget” the unwanted connection.
--------------------------------	---

Manikin is not paired	Follow the OMNI Link setup steps from section 7
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Power supply is not connected to simulator	Ensure that the power supply is connected to the simulator
--	--

Labor Motor

Labor motor is not descending or not resetting to initial position	Tap the Gear on the top right and select Calibration. Reset the labor motor from that menu
--	--

9. Warranty

9.1 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.

10. Contact Gaumard

10.1 Contacting Technical Support

Before contacting Technical Support you must:

1. Have the simulator's serial number
2. 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

10.2 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 - 7:30pm EST



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

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