NOELLE® S551 | User Guide

Maternal Birthing Simulator

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.
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Care and Cautions

Overall Warnings

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

Procedures

Do not attempt to intubate without lubricating the airway adjunct with silicone lubricant (provided). Failure to do so will make intubation very difficult and is likely to result in damage.

When simulating drug administration via endotracheal tube, providers must use an empty syringe. Passing liquids into the trachea or esophagus may cause internal damage.

Mouth to mouth resuscitation without a barrier device is not recommended, as it will contaminate the airway.

Treat NOELLE 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.

Storage

Store NOELLE in a cool, dry place. Extended storage above 85 degrees Fahrenheit (29 Celsius) will cause the simulator to soften and slowly warp.

It is acceptable to operate NOELLE at an ambient temperature of 95 degrees Fahrenheit (35 Celsius).

Cleaning

NOELLE should be cleaned with a cloth dampened with diluted liquid dishwashing soap.

Remove all traces of any lubricant.

Do not clean with harsh abrasives.

Dry thoroughly.

NOELLE is “splash-proof” but not water-proof. Do not submerge or allow water to enter the interior of the simulator.

Set Up

NOELLE will only power on when connected to the AC power supply.

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 by wiping with a mild solution of soap and water. After cleaning, dust with talcum powder.

Store the unit in a cool, dry place.

After exercise is completed, DO NOT leave birthing baby in contact with the birth canal.

Post-partum Hemorrhage Warnings

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.

At the end of every simulation, always flush the system with distilled water to prevent clogging.
Getting Started

Overview
The NOELLE® S551 Maternal system permits students to appreciate the complete birthing experience from the onset of labor, to delivery, and treatment of the mother after delivery. It provides capabilities in ALS, obstetrics and neonatal resuscitation protocols.

Airway
- Oral and nasal intubation
- Use an ET tube or LMA

Accessories
- Postpartum hemorrhage kit

Simulator
- Delivering mechanism
- Articulating body

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

Circulation
- Bilateral carotid, radial and brachial pulses
- Chest compressions are measured and logged

Venous Access
- Bilateral arm with venous network in forearms
- Bilateral quadriceps and deltoid intramuscular injection sites

Other
- Powerful yet intuitive user controller and interface software
- One year limited warranty, available extended warranty to three years
- Technical support

Terminology
Facilitator - the person conducting the simulation; an instructor or lab staff member.
Provider - a person participating in the simulation as a healthcare provider.
Code Blue® –feature of Omni to monitor, train and evaluate CPR.
CPRLink™ - the application to monitor, train and evaluate CPR on a PC.

The Birthing Package contains the following:

Check List
- 48 hour postpartum uterine assembly
- Abdomen cover with speaker attached
- Articulating birthing fetus
- Automatic birthing mechanism
- Cervix Holder
- Inflatable cushion for Leopold Maneuvers
- Instructional demo on CD-ROM
- NOELLE head and torso assembly with IV arm
- NOELLE Training Guide with basic and advanced scenarios
- Omni™ Code Blue Pack
- Postpartum hemorrhage kit
- Postpartum perineum insert
- Power supply
- Silicone lubricant
- Talcum powder
- Three vulva insert for episiotomy repair
- Two dilating cervices
- Two fully dilated vulva
- Two mechanical adaptors
- Two placentas with fragments
- Two umbilical cords
- Umbilical clamp
- User Guide
Equipment Set Up

NOELLE is shipped partially assembled. Perform the following steps as part of the first install process.

Leg Assembly

1. Place NOELLE on a flat surface.
2. Remove the abdominal cover and other materials packed within the abdomen.
3. Remove the wing nuts, washers and springs from bolts on hips.
4. Remove IM site from each leg and slide bolt through hole.
5. Reach through the IM site and attach to the bolt the washer, spring, second washer and lastly the wing nut.
6. Tighten the wing nut until the spring is compressed slightly.

Fetal Heart Rate Speaker

Connect the speaker cable, exiting NOELLE’s belly cover, to the left 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.

Information

Always operate NOELLE with the power supply connected.
Omni™ Controller

Omni controls NOELLE responses with the touch of button. Connect the communication cable to NOELLE and to Omni.

A startup screen is shown while Omni is detecting the simulator features.

After the start up screen, Omni will automatically proceed to the main screen.

⚠️ Warning
Do not connect NOELLE or Omni to a computer, LAN network or unauthorized diagnostic equipment. Doing so will cause serious damage to the equipment.
Using Omni™

Main Screen

The Omni main screen is divided in three sections, the Feedback Graphics, Current Settings and Navigation Menus. Pressing each button will display each menu item in detail.

Feedback Graphics

Monitor and evaluate depth and cadence of compressions and ventilations in real time.

Current Settings

Current settings information is listed at the center of the screen.

Navigation Menus

Edit NOELLE settings using the navigation menus. Select a menu item by pressing the soft key buttons located on the right side of the controller. Each menu has additional submenus or toggle selection. Use the submenus to decrease, increase, accept, or cancel values.

<table>
<thead>
<tr>
<th>Menu</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>FHR</td>
<td>Set fetal heart rate</td>
</tr>
<tr>
<td>SPEED</td>
<td>Set labor duration</td>
</tr>
<tr>
<td>DYSTOCIA</td>
<td>Enable/disable turtle signs</td>
</tr>
<tr>
<td>PAUSE/RESUME</td>
<td>Stop/continue delivery</td>
</tr>
<tr>
<td>RESET</td>
<td>Return delivery motor to start position</td>
</tr>
<tr>
<td>HELP</td>
<td>Reset delivery mechanism, set backlight time and view Omni and Simulator serial number</td>
</tr>
</tbody>
</table>

Fetal Heart Rate Menu

To change the vital signs parameters, press the + and - buttons. Pressing and holding this button will continuously increase or decrease the parameter value. Pressing OK accepts the changes and returns to the previous screen. Pressing CANCEL returns to the previous screen with no changes applied.
Fetal Heart Rate Submenus

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>Increase the current FHR</td>
</tr>
<tr>
<td>OK</td>
<td>Accept the value and return to main screen</td>
</tr>
<tr>
<td>CANCEL</td>
<td>Returns to previous screen with no changes applied</td>
</tr>
<tr>
<td>-</td>
<td>Decrease the current FHR</td>
</tr>
<tr>
<td>HELP</td>
<td>Reset delivery mechanism, set backlight time and view Omni and Simulator serial number</td>
</tr>
</tbody>
</table>
+      | Increase the current FHR                     |

Delivery Speed Menu

Changes to the delivery speed can be made by increasing or decreasing minutes with the + and - buttons. The speed ranges from 1 to 30 minutes. Pressing and holding a button will continuously increase or decrease the parameter value. Pressing OK accepts the changes and returns to the previous screen. Pressing CANCEL returns to the previous screen with no changes applied.

Dystocia Menu

Enable or disable “turtle signs” during delivery. Toggle between DYSTOCIA ON and DYSTOCIA OFF. When Omni displays ON, the dystocia feature is activated. Similarly, when it displays OFF the dystocia feature is deactivated.

Resume Menu

Toggle between PAUSE and RESUME. The RESUME option will start the automatic birthing mechanism. PAUSE will stop the delivering mechanism.

Reset Menu

When selecting RESET, the automated birthing mechanism will move to its initial position. A message on the Main Screen will confirm the command.
More
Press MORE to access the CPR tools navigation menus.
Working with NOELLE®

Bandaging
The fingers and toes of NOELLE are separated to permit bandaging exercises. The surface of the simulator is smooth and resistant to water, oil and liniments.

Ear
The ear cavity may be filled with about 10 mL of fluid.

Eyes/Ophthalmologic Exercises
The head has separately inset and removable eyes, permitting:
- Administration of orbital medicines, including drops/ointments into the conjunctival sac
- Removal of foreign bodies
- Eye irrigation

Hygienic Care
NOELLE’s hair can be shampooed; bathing exercises and head draping may also be practiced.

Range of Movement
NOELLE’s head and jaw articulate. The legs and arm articulate in a normal fashion.

Breathing
Chest Rise
Lungs expand normally permitting realistic chest rise. Chest compressions are measured and logged.

CPR
Use a normal size adult BVM which will seal around the mouth and nose. The ribs have normal anatomical landmarks and the lungs permit an adequate chest rise.

⚠️ Warning
Do not perform mouth to mouth ventilation since NOELLE’s airway can be difficult to clean afterwards.

Circulation
Bilateral Pulses
NOELLE’s palpable pulses (carotid, brachial, radial, femoral) can be simulated by pumping the squeeze bulb located beneath NOELLE lower left arm.

Injection Sites
Sites on the upper left and right arms and legs permit IM injections. An IV training arm provides an extensive venous network to start IVs or infuse fluids.

Injection Training Arm and Hand
IV, IM or SubQ exercises can be performed. Always use needle sets sized #22 or thinner to extend the life of the veins and skin. Always use clean water in the veins and drain after use.

Airway
Nasal and Oral Intubation
The nose is patent, permitting feeding exercises or passage of a nasal/tracheal catheter.

The trachea extends to the bronchi and lungs. Lungs expand normally permitting realistic chest rise.
Airway management techniques can be practiced on NOELLE including BVM, nasal/oral intubation, and suctioning. Endotracheal tubes, NG tubes and LMAs can be used. Use the Sellick maneuver if needed to bring the vocal folds into view.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Recommended Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation (Blade size)</td>
<td>Miller 4 or MAC 3.5</td>
</tr>
<tr>
<td>LMA</td>
<td>Size 4</td>
</tr>
<tr>
<td>Nasal Intubation</td>
<td>8 mm outer diameter max</td>
</tr>
<tr>
<td>Oral Intubation</td>
<td>ETT Fr 7 or 7.5</td>
</tr>
</tbody>
</table>

⚠️ **Warning**

Do not introduce liquids when performing nasal and oral intubation. Doing so can permanently damage the system.

Always lubricate tubing, airway and nasal opening prior to performing any nasal or oral intubation.

**Resuscitation**

Ventilation and manual chest compressions are measured and logged showing the instructor exactly how students are performing.

**Teeth and tongue**

NOELLE is supplied with fixed upper and lower dentures. The tongue may be moved gently from side to side.
Obstetrics

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

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

Automatic Birthing Mechanism and the Omni™

NOELLE is supplied with an electromechanical system to automatically deliver the fetus using the Omni controller. The system, configured with the Omni, 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.
3. Route the inflation bulb outside NOELLE through any space provided on the left side.
4. Place birthing fetus in the vertex, breech, or transverse position onto the elevating pillow and lift fetus anteriorly using squeeze bulb.
5. Snap abdominal cover into place.
6. Lift fetus anteriorly using squeeze bulb.
7. Conduct the four Leopold Maneuvers.

Dilating Cervix

As the fetus proceeds down the birth canal it pushes against a simulated uterus/cervix. The simulated cervix is designed to permit considerable distension. During delivery, the cervix dilates as the fetus moves down the birth canal. At crowning the head passes through the cervix and through the vulval insert. 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 head and shoulders of the articulating birthing fetus.
3. Lubricate the vulva and cervix internally and externally using silicone lubricant.

**Warning**
Always lubricate the baby and the birth canal prior to every delivery. Poor lubrication may damage the birth canal, fetus and the birth mechanism.

4. Attach the umbilical cord to the baby.

**Warning**
Route the cord so it does not bind in the mechanism. The umbilical cord can be wrapped once around the fetal neck.

5. Attach umbilicus to placenta.
6. Attach the placenta to the abdominal wall using the Velcro® fastener. The abdominal wall has three placement sites to attach the placenta.

Information

Orienting the Velcro patches in parallel causes the placenta to be retained; orienting them at right angles causes the placenta to release with modest traction.

7. Connect the cylindrical adapters, with blue markers aligned, to automatic birthing mechanism.

8. Attach fetus to birthing mechanism.

9. Position the baby so that its head faces toward the left side of the simulator. This is the ROA or right occipital anterior position.

Information

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

Information

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 which may require some assistance on the part of the student or instructor. Breech deliveries may also be performed as detailed later.

Warning

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

10. Connect the communication cable to NOELLE and to Omni.

11. Select desired fetal heart rate using the Omni controller by pressing the + or – button and, press OK to accept the value.

Information

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

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

12. Now, select the speed of the delivery by accessing the SPEED menu and increasing or decreasing minutes. Press OK to accept the changes.
13. After confirming the settings for the labor, press the RESUME button to begin the delivery.

The birthing cycle can be paused at any point and then resumed. To return the birthing mechanism to its initial position, press RESET.

Note that the fetus rotates internally as it moves forward after the head is delivered and before the shoulders are delivered. The student or instructor may help the fetal head and shoulders through the vulva, as in real life. Once the shoulders are delivered, the student can complete delivery of the baby and placenta.

**Information**

In the event the birthing baby binds in the birth canal, the mechanism will pause and back up. It will automatically try a second time. If this occurs, remove the abdominal cover, PAUSE the birthing mechanism from the Omni and determine the cause. In most cases, binding can be prevented by thoroughly lubricating the fetus, the dilating cervix and the vulva.

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

Move the bell of the stethoscope around until the heart tones are clearly heard. Change the fetal heart rate using Omni by accessing the FHR menu.

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

   ![Image of NOELLE simulator with soft scalp over skull]

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

2. Lubricate the fetus supplied with NOELLE and, place it onto the delivery system in the normal ROA position.

3. Connect the Omni to NOELLE using the communication cable.

4. Select RESUME from Omni.

   ![Image of Omni selection on NOELLE]

   **Information**
   Omni will load with predetermined settings. Fetal heart rate of 140 BPM, delivery speed of 2 minutes and the dystocia feature OFF.

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

5. Select PAUSE as soon as the cervix is fully dilated.

6. Insert a lubricated vacuum cup into the vagina and place the cup onto the flexion point of the skull located between the fontanelles. Use the manual vacuum pump supplied with such devices to cause the attachment of the cup to the skull. Wait a few minutes for the “chignon” to form.

   ![Image of vacuum cup on NOELLE simulator]

7. Await the next contraction that may be simulated by asking NOELLE to bear down.

8. Have the student apply a steady traction, perpendicular to the plane of the cup.

9. Select the “RESUME” key, then the “PAUSE” key again to move the fetus slightly down the birth canal.

Some vacuum-assisted delivery devices are equipped with a means for measuring the amount of traction which may be on the order of about 15 pounds.

The student must stop traction when the simulated contraction ceases. Repeat this procedure of waiting for the simulated contraction and providing traction during the contraction if and only if the fetus is moving down the birth canal with each contraction.

The student may also assess the potential need for an episiotomy to facilitate delivery. In the event delivery progress is not being made, NOELLE must be immediately referred as a potential “C” section candidate.
Shoulder Dystocia

During dystocia, the fetal shoulders become wedged behind the pubic bone. NOELLE may be used to practice the resolution of dystocia using episiotomy techniques, the McRoberts maneuver, suprapubic pressure, posterior arm sweep, or elbow-knee delivery.

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

2. Locate a small squeeze bulb on the left side of NOELLE. The bulb is attached to an inflatable bag near the dilating cervix.

3. Inflate the bag using the manual squeeze bulb. The fetal head and shoulders will rise toward the maternal symphysis pubis, simulating locking the shoulder behind pubic bone. Note that the fetal head is palpable beneath the stomach cover.

4. Connect the Omni to NOELLE using the communication cable.

5. Select SPEED of delivery and activate DYSTOCIA by turning ON the feature.

6. If the fetus cannot be delivered the Instructor can press the “RESUME” key which will cause the fetus to resume the movement down the birth canal.

7. Activate DYSTOCIA by turning ON the feature from Omni main screen. Dystocia enables the “turtle signs”.

8. Information

Activate or deactivate dystocia at any time during the delivery.

Students must use various maneuvers to deliver the baby.

9. If the fetus cannot be delivered the Instructor can press the “RESUME” key 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.

At any time the Instructor may completely retract the delivery mechanism by selecting RESET in the Omni controller.

Cesarean Delivery

Demonstrate a C-section using NOELLE. Remove the metal snaps just above the pubic bone and birth the baby between the stomach cover and the pubic bone. To complete this procedure follow the steps below.

1. Retract delivery mechanism.

2. Insert inflatable cushion.

3. Attach abdominal cover using the metal snaps except for snaps above the pubic bone.

4. Birth the neonate between the stomach cover and pubic bone.

Information

To demonstrate midline or “bikini” incisions with NOELLE, utilize an optional abdominal cover. The optional C-section cover is available as P/N 560.029.
Prolapse of the Umbilical Cord
Simulate prolapse of the umbilical cord by positioning cord on a critical position and decreasing the fetal heart rate from Omni.

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.

External Version
Version may be attempted to rotate the fetus from a breech position into one permitting normal vertex presentation.
1. To practice external version, remove the abdominal cover and the fetus.
2. Retract the delivery mechanism.
3. Insert the inflatable cushion.
4. Remove the foam in the abdominal cover.
5. Thoroughly lubricate the inside surface of the abdominal cover, the fetus, and the inflatable cushion.
6. Place the lubricated fetus onto the lubricated inflatable cushion and snap the lubricated abdominal cover into place.
7. Inflate the cushion lifting the fetus anteriorly.
8. Inflate the cushion at the base of the pelvic cavity to position fetus.
9. Confirm the breech position and attempt to manually turn the fetus within the uterus by transabdominal manipulation.

Breech Birth
1. To simulate breech presentations with the NOELLE, fully retract the birthing mechanism.
2. Remove the soft scalp from the fetal head.
**Information**

The fetus has a receptacle at the rectum and frontal fontanelle location into which the matching pin located on the birthing mechanism is inserted.

**Information**

Removing plug reveals aperture for birthing mechanism. Insert the plug into the rectum of birthing fetus during delivery.

3. Insert the birthing mechanism into the fetal head using one or two adapters.

4. Place the fetal legs in either an extended position to simulate “footling” delivery or retract the legs for a “frank” delivery.

**Warning**

Lubricate the lower torso and legs of the fetus.

The Pinard or Leg-Flip maneuver frees one leg then another. The fetal arms may also require a similar maneuver during delivery. The fetal arms are delivered and the fetus rotated anteriorly to birth the head.

**Delivery of the Placenta**

The placenta supplied with NOELLE may be positioned so that it births spontaneously or requires either modest cord traction or manual removal.

In addition, 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.

Students must carefully inspect the birthed placenta to make sure it is complete and that no fragments remain internally. If retained fragments are noted, the student must retrieve them using a gloved hand under appropriate aseptic conditions.
NOELLE® Postpartum Activity

After delivery the uterus normally contracts reducing postpartum bleeding. Under certain conditions contraction does not occur and extensive bleeding may continue. If this condition is not recognized and treated in a timely manner the new mother may go into shock and die. Inadequate uterine contraction may present as a “boggy” or soft uterus assessed through abdominal palpation. Uterine contraction may be augmented using certain drugs and/or uterine massage.

Information

Simulate pharmacologic interventions with NOELLE’s bilateral injection sites.

Fundal Massage and Postpartum Bleeding

1. To practice uterine massage, remove NOELLE’s fully dilated vulval insert.

2. Snap the postpartum perineum insert into place.

3. Attach the large postpartum uterine assembly to the distal end of the vagina using the locking ring assembly.

4. Use the squeeze bulb attached to the postpartum uterine assembly to inflate the space between the two uteri, expanding the soft external skin sufficient to simulate a “boggy” uterine condition.

5. Use the syringe to insert simulated blood to the postpartum uterine assembly.

6. Lift the uterus anteriorly using the inflatable cushion.

The picture below shows the inflatable cushion fully inflated.
The white Velcro patch on the fundus may be used to position the uterus at various orientations within the abdominal cavity.

Bimanual massage will cause air to leak from the thumb screw in the squeeze bulb causing the outer skin to contract. When sufficient air is released the student will begin to feel the harder inner uterus which simulates the contracted postpartum state.

**Episiotomy Repair**

Remove the fully dilated vulva used during delivery and select one of the three episiotomy repair modules. Snap 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.
CPR Tools

CODE Blue®

Code Blue is a CPR training tool incorporated in the Omni controller. It 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.

Code Blue Components

Code Blue consists of the Feedback Graphics and specialized menus to control:
- CPR Operational mode - TEST or COACH mode
- C:V Ratio - customize the compression to ventilation ratio
- Compression/Ventilation Rate - customize the compressions per minute

Furthermore, Code Blue can be calibrated to a specific standard to assess compressions and ventilations.

Code Blue Menus

Press MORE from Omni Main Screen to access Code Blue.

MODE

Toggle between COACH and TEST mode. The COACH mode generates audible tones to coach CPR ratio. A high-pitched beep signals the care provider to perform a compression and a low pitched-beep signals a ventilation. Toggle to the TEST mode to perform CPR without the audible cues.

C : V RATIO (Compression to ventilation ratio)

Adjust the compression to ventilation ratio using the ↑ and ↓ buttons. Press OK to save the changes and return to previous screen. The default value for the C:V Ratio is 30 compressions to 2 ventilations.

CMP/VNT RATE (Compression or Ventilation rate)

The default value for the compression rate is 100 compressions per minute. Adjust rate using the ‘+’ and ‘-’ buttons. Press OK to save the changes and return to previous screen.

CALIB. (Calibration)

Calibrate the sensors inside the simulator using the calibration menu (CALIB.), to set the standard against which compression and ventilation will be evaluated during the exercise.

Choose which function you would like to calibrate between chest compressions (C CAL.) and artificial ventilations (V CAL.).

The chest compression and artificial ventilation calibration procedures follow similar steps.

Calibrating chest compressions:

Depending on the simulator detected, the calibration menu (CALIB.) is found in the main screen or in the MORE menu.
1. Select **CALIB.** to enter the calibration menu.
2. For this example, select **C CAL.**

3. Press **START** to begin with the calibration. Omni will ask you to perform a number of correct chest compressions. The facilitator should follow the text cue on the screen to perform just one compression at a time, until finished.

4. When Omni is ready to calibrate it will display **COMPRESS.**
5. Perform a correct compression. Follow the text cue on the screen to perform the remaining four compressions. When the calibration is complete Omni will display **DONE.**
6. Press **SAVE.**
7. Select **V CAL.** and repeat steps 3-5 to calibrate ventilations.

**Resetting Omni’s Pressure Sensor**
It is recommended that the Omni’s pressure sensor is reset at altitudes greater than 1000 ft. to avoid inaccurate compressions and ventilations readings. **Perform the sensor reset procedure only as part of the initial calibration process.**

1. Select **RESET** within the compression / ventilation calibration menu.

After resetting the sensor, Omni will display **DONE.**
2. Select **SAVE** to finish.

**HELP**
Every screen on the Omni controller has a HELP menu. The help window provides access to global settings such as delivery mechanism reset, backlight time and Omni/Simulator serial number.
Delivery Mechanism Reset
The INIT MTR button can be used to help the delivery mechanism find its initial position after an abnormal shutdown, such as, a power outage during a delivery. Use only during troubleshooting.

Backlight
The default value for Omni’s backlight timer is 10 minutes. After 10 minutes the backlight will turn off.
To increase the backlight duration, adjust the backlight timer with the plus or minus sign. Press OK to accept the changes.

Serial
View Omni and simulator serial number. Press OK to return to the HELP menu.

CPRLink™
CPRLink is an application that enables monitoring and logging of compressions and ventilations performed in real time by the user in a Windows XP or Windows 7 PC.

This software aims to provide additional testing and teaching tools for CPR using an interface to display a waveform graph of the compressions and ventilations.
To use CPRLink, connect the simulator to Omni using the communication cable. Run the CPRLink CD in your computer and connect Omni to the PC using provided USB cable.

CPRLink Minimum System Requirements
- Operating System: Windows XP or Windows 7
- Computer and processor: 1 gigahertz (GHz) or faster 32-bit (x86) or 64-bit (x64) processor
- Memory: 1 gigabyte (GB) RAM (32-bit) or 2 GB RAM (64-bit)
- Hard disk: 4 gigabyte (GB) available disk space
- Install media: CD/DVD Drive
- I/O Ports: USB port

Setup
CPRLink Software Installation
If installing the CPRLink software for the first time, follow the instructions listed below:
1. Insert the CPRLink installation CD in your PC.
2. Double click the installation file on the enclosed media.
3. Follow the instructions on your screen.
Equipment Set Up
1. Connect the power supply to the power input on the simulator, and then connect the power supply to the wall outlet.
2. Connect the communication cable to the simulator and to Omni.
3. Connect the USB cable to Omni and to the USB port of your PC.
Omni will display a small heart icon on the lower left side of the screen, when a connection with the PC has been established.

Warning
Do not start the CPRLink software until Omni is connected to the PC.

Starting CPRLink
Double click on the CPRLink icon on the desktop of your PC.

CPR Screen
The initial window of CPRLink contains the drop down menus used to save and clear session logs, change the software options, and access the program’s help.
The main window also contains the controls used to evaluate compressions and ventilations.

- **Grey** - No intervention was detected.
- **Yellow** - Compression was too shallow. Ventilation was too weak.
- **Green** - Compression/ventilation was performed correctly.
- **Red** - Compression was too deep. Ventilation was too strong.

Compression and ventilation data is displayed at the bottom of the window as CPR is performed by the provider.
**Compression Data**

- **Rate** - Rate of compressions in real time.
- **Ct** (Compression time) - Average length of each compression in seconds.
- **LC** (Last Compression) - Time elapsed since the last compression performed.

**Ventilation Data**

- **Rate** - Ventilation rate in real time.
- **PIP** - (approx.) Peak Inspiratory Pressure
- **Ti** - Time Inspiration
- **I:E** - Inspiratory: Expiratory Ratio
- **PEEP** - (approx.) Positive end-expiratory pressure.
- **LV** (Last Ventilation) - Time elapsed since the last ventilation performed.

**Trainer**

The CPRLink software generates a visual cue of the compression to ventilation ratio programmed in the CPR Options menu. When the Trainer button is clicked, the V (ventilations) and C (compressions) box borders blink to indicate the correct reference CPR rate.

**Performance Examples**

Compressions are too shallow. Waveforms mostly do not reach the green zone. Compression indicator is yellow.

Compressions are too deep. Waveforms mostly exceed the green zone. Compression indicator is red.

Compressions are performed correctly. Waveform peaks are mostly inside the green zone.

Ventilations are too shallow. Waveform peaks do not reach the green zone.
Ventilations are too strong. Waveform peaks exceed the green zone.

Ventilation was performed correctly. Waveform peak is inside the green zone.

Provider Actions Screen

The provider actions screen allows the facilitator to keep track of every event during a session. It automatically creates an entry whenever a detected event occurs. Also, the facilitator can log provider actions with a simple click.

Session Info

The header section consists of the ‘Session Title’ and ‘Facilitator’ fields at the top of the Team Logging section. Type the session title and facilitator name directly in the note field. It serves assisting with record keeping purposes when a report is saved or printed.

Team Logging

The Team Logging feature allows the facilitator to designate which member of the team performed a particular action. The Team Logging section is right above the Provider Actions section.

First, the facilitator should add all providers in the team, one by one, by clicking the Add button and filling out the Add Provider dialog box.

Open the Provider Actions Screen by clicking on the shortcut icon located on the upper right side of the application.
A colored button is inserted on the Team Logging region for the provider just added. There can be up to six different providers, each with a corresponding button. Every time one of the provider buttons is clicked, that person becomes the active provider. To indicate the active provider, the vertical bars on each side of the Log page will match the color chosen for that person.

On the Log Page image, for example, the provider “Steve” is the active provider, so the vertical bars are teal colored. While there is an active provider, every time a Provider Action or Evaluation log entry is created it will have the name of the provider as follows:

"00:07:41 [Steve Parker] Action (Ventilate): BVM"

To deselect the active provider and return to general logging, click the Team button and the vertical bars will return to neutral color.

All provider buttons can be edited or deleted by right-clicking them and selecting an option from the menu.

**Provider Actions**

This section refers to the collection of buttons in the middle of the page. It allows the facilitator to accurately keep track of provider actions. The buttons are grouped into 6 groups: Basic, Airway, Breathing, Circulation, and Trauma Care. Anytime the facilitator clicks one of the buttons, a time-stamped log entry is generated with that particular action.

For example, if the ‘Assess responsiveness’ button is clicked when the session clock reads 00:03:36, the following entry is automatically generated:

"00:03:36 Action (Assess responsiveness)"

**Special Buttons**

There are special buttons that add additional functionality to the provider actions section.

The first special button, ‘+’, allows the facilitator to be more specific on the provider action he/she wishes to log. For example, if the button ‘Ventilate’ is clicked, the following entry is created:

"00:02:24 Action (Ventilate)"
On the other hand, if the ‘+’ button next to ‘Ventilate’ is clicked, a list of additional options appears.

The facilitator can be more specific and choose, for example, ‘transport ventilator’... and the following entry is added:

"00:01:28 Action (Ventilate): transport ventilator"

Text Log

This is the large panel at the bottom of the Log Page, containing all the time-stamped text entries. Every event on a session is reflected as an entry in the Text Log.

Open the Text Log by clicking on the shortcut icon located on the upper right side of the application.

The different types of entries are classified as Actions, Detected Events, Evaluations, and Notes.

Text Log is subdivided in four different functions:

Actions

Actions refer to those performed by one of the providers in the session. The facilitator can quickly log actions from the Provider Actions section and make the entry more specific using the Team Logging feature. The following is an example of an Action entry:

"00:07:24 Action (Assess responsiveness)"

Detected Events

Each time one of the various sensors in the simulator detects a provider action, it is automatically logged as a ‘Detected’ entry. These actions include intubation, BP cuff placement, artificial ventilations, and chest compressions. The following example shows an entry after a provider administrates a chest compression:

"00:05:36 Detected (chest compression): too weak"
Evaluations
The facilitator adds evaluations by clicking on the ‘Satisfactory’ or ‘Unsatisfactory’ buttons next to Text Log.

The facilitator can evaluate individual providers with a single click.

For example, if provider Steve Parker did a correct procedure, the Evaluation entry would be:

"00:36:01 [Steve Parker] Evaluation (Care Provided): Satisfactory"

Notes
Notes can be entered directly in the Text Log. The following is an example of a Note entry:

"00:51:09 [Steve Parker] Note: provider took too long to assess patient."

CPRLink Menus

File

New Session
Clicking New Session in the file menu will:

- Start a new simulation session
- Clear out log page
- Restart the session clock

The session clock is located at the bottom of the Log box.

You can also start a new session by clicking on the session clock drop down menu, located at the bottom of the Log box, and selecting New Session.

Reset Session Clock
Clicking on Reset Session Clock resets the clock back to zero.

Reset the session Clock by clicking on the session clock drop down menu, located at the bottom of the Log box, and selecting Reset Session Clock.

Save Report
This option allows you to save all the information recorded in the log page as a text file. Clicking on it brings up the Save As dialog box:
Select the desired name and path, and click “Save”.

A sample report is below:

![Sample Report]

**Print Report**

This option allows you to print a text file containing all the information in the log for the latest session. Clicking on Print Report brings up the Print dialog box.

**Exit**

You can exit the software at any time by going to File, Exit or by clicking on the “x” button at the top right corner of the CPRLink.

**Set-up**

The Options window contains the parameters accessible to the user for configuration.

**CPR Options**

- Select the number of desired compressions per minute.
- Specify the compression/ventilation ratio
- Select number of ventilations per minute (if the ‘Only Ventilations’ option is selected).

CPRLink will retain the options, tolerances and calibration data last entered.

![CPR Options Window]

**Tolerances**

Select the tolerance and intensity of both chest compressions and ventilations. These parameters change the percentage deviation permitted while evaluating a compression or ventilation.

Intensity Tolerances: if the user has calibrated the software, these tolerances represent permissible deviation from the compressions or ventilations entered during the calibration procedure, otherwise the program uses default sensor values.

Rate Tolerances: the rate tolerance parameter sets the permissible deviation from the selected compression set. For example, if the user sets the Compression Rate at 100 compressions / minute and the Compression Rate Tolerance at 10 %, any compression frequency between 90 and 110 compressions per minute will be considered correct.
Calibration

This tool allows you to easily calibrate the sensors inside the simulator. First choose which function you would like to calibrate: chest compressions or artificial ventilations.

The procedures for each specific calibration are described in the sections below.

Chest Compressions/Artificial Ventilations

This tool allows you to calibrate the chest compressions and the artificial ventilations to your specific criteria. That is, you will be telling the system what a correct chest compression is and/or what a correct artificial ventilation is. Providers will be evaluated by the system based on this criteria.

The chest compressions and ventilations are calibrated in the same way. After making a selection, this dialog box is displayed:

Click next to proceed with the calibration.

The software will now ask you to perform a number of “correct” chest compressions or artificial ventilations, depending on which was selected.
The facilitator should follow the text cue on the screen to perform just ONE compression or ventilation at a time, until prompted for successive compressions/ventilations.

For example, if calibrating chest compressions:

The wizard prompts you with a “#1”.

1. Perform one correct chest compression.
   A green filled oval indicates that the chest compression was successfully recorded.

2. Perform a second correct chest compression.
   A green filled oval indicates that the chest compression was successfully recorded.

3. Continue the process.

At the end of the calibrating session, the wizard shows the average peak, depth, and duration values for the procedure.

| Sum = 56 |
| Peak = 34 |
| Duration = 0.2 |

Help

Instructional Manual
Open the instructional manual.

About
Click to view the version of the software.
# Consumables and Replacements

## Selected Parts List

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

<table>
<thead>
<tr>
<th>Item ID</th>
<th>Description</th>
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<tbody>
<tr>
<td>S551.180</td>
<td>Omni Controller</td>
</tr>
<tr>
<td>S551.180.1</td>
<td>Communication Cable</td>
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<tr>
<td>S551.180.2</td>
<td>USB Cable</td>
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<tr>
<td>S551.004.L.L</td>
<td>Lower Left Arm Skin Cover</td>
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<tr>
<td>S551.004.R.L</td>
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<td>S551.007.L</td>
<td>C-Section Abdominal Cover</td>
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<tr>
<td>S551.008.L</td>
<td>Abdominal Cover</td>
</tr>
<tr>
<td>S551.011</td>
<td>AC Power Supply</td>
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<tr>
<td>S551.013</td>
<td>Birthing Mechanism</td>
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<tr>
<td>S551.016.L</td>
<td>Birth Canal</td>
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<tr>
<td>S551.018.L</td>
<td>Elevating Pillow</td>
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<td>Placenta</td>
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<tr>
<td>S551.020</td>
<td>Umbilical Cord Set</td>
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<td>S551.031</td>
<td>Manual Boggy Uterus</td>
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<td>S551.033</td>
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<td>S551.039.L</td>
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<tr>
<td>S551.048</td>
<td>Adult IV Filling Kit</td>
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<td>S551.080</td>
<td>Simulated Blood Concentrate</td>
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<td>S551.081</td>
<td>Lubricant</td>
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<tr>
<td>S551.083</td>
<td>Allen-Key</td>
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<tr>
<td>S551.EXW</td>
<td>Two Year Extended Warranty</td>
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<th>Description</th>
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<tbody>
<tr>
<td>S551.INST</td>
<td>In-Service Training</td>
</tr>
</tbody>
</table>
Contact Us

E-mail Technical Support: support@gaumard.com
Before contacting Tech Support you must:
1. Have Omni/simulator's Serial Number
2. Be next to Omni/simulator if troubleshooting is needed.

E-mail Sales and Customer Service: sales@gaumard.com

Phone:
Toll-free in the USA: (800) 882-6655
Worldwide: 01 (305) 971-3790

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

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

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:

1. Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product;
2. 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
3. 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:

1. Contact Gaumard and request authorization to return the Gaumard product. Do NOT return the Gaumard product to Gaumard without prior authorization.
2. 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.
3. 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.

Extended Warranty

In addition to the standard one year of coverage, the following support plans are available:

- Two-Year Extension (covers second and third years)
- Call for pricing (USA only)