

S2209.PK

PREMIETM HAL

USER GUIDE



The Premie Hal Simulator 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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1. INTRODUCTION

1.1 SPECIFICATIONS

Dimensions

Weight: 2.9 lb (1.32 kg)

Length: 15.7 " (39.9 cm)

1.2 CARE AND MAINTENANCE

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.

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

Operating Conditions

- Operating temperature: 50°-95° F (10°-35° C).
- Humidity: 5%-95% (non-condensing).

Storage Conditions

- Store Simulator in a cool, dry place. Extended storage should be between 32-85 degrees Fahrenheit (0-29 Celsius). Other temperatures 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 box.

CAUTION: Do not store the simulator with a discharged battery. It is good practice to recharge the battery at the end of every simulation session. In addition, make sure the battery is recharged at least once every 2 months even if the simulator is not being used.

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



Procedures

- Do not attempt to intubate without lubricating the airway adjunct with mineral oil lubricant. Failure to lubricate the device will make intubation very difficult and is likely to result in damage to the simulator.
- Mouth to mouth resuscitation without a barrier device is not recommended, as it will contaminate the airway.
- Treat the simulator with the same precautions that would be used with a real patient.

IV Arm

- Only use Gaumard's provided simulated blood. Any other simulated blood containing sugar
 or any additive may cause blockage and/or interruption of the vasculature system.
- The use of needles larger than 22 to 23 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 "Routine Maintenance" section of the guide. For more information regarding the replacement of veins and other consumable items please contact customer service.

ECG Monitoring

- It is good practice to remove gel residues after every use. Failure to do so will leave behind a film of electrode gel that hardens causing arcing and pitting.
- · Do not re-use the gel-adhesive pads. Do not leave them on for next day use.
- NEVER attempt to service or modify any of the electrical connections, especially those between conductive skin sites and the internal electronics.
- Discontinue use if any wires are found exposed with damaged insulation.
- Real medical products, especially electrodes, sometimes use powerful adhesives that can be difficult to remove. A gentle, degreasing cleanser may be needed.

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.



1.3 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. OVERVIEW

2.1 FEATURES

Neurological

· Crying synchronized with breathing

Airway

- Supports oral and nasal endotracheal intubation
- Esophageal intubation (placement only)
- · Airway sounds synchronized with breathing

Breathing

- · Automatic spontaneous breathing
- Programmable respiratory rates and I:E ratio
- · Normal and abnormal lung sounds
- · Compliant lungs present visible chest rise following guideline recommended flow, PIP, and PEEP values
- · Supports standard positive pressure ventilation devices including bag-valvemasks, resuscitators, mechanical ventilators, and CPAP, and more
- · Real-time PPV ventilation feedback via UNI interface

Circulation

- Central cyanosis with variable intensities
- Contains library of ECG rhythms
- Supports ECG monitoring using real devices
- Normal and abnormal heart sounds
- · eCPR real time quality feedback and reporting
- · Automatic and palpable pulses dependent on the virtual blood pressure settings
- » Fontanelle, brachial, umbilicus, and femoral
- Supports IV cannulation
- Dorsum of hand (bilateral)

- Umbilical catheterization (UVC/UAC)
- Left foot access
- Intraosseous access at right tibia supports continuous infusion
- Temperature sensor placement detection

2.2 OPTIONS

Beside Virtual Patient Monitor

• Touch-Screen All-in-One PC Gaumard Vitals virtual monitor

Mobile Virtual Patient Monitor

• Tablet PC Vitals virtual patient monitor



3. INITIAL SETUP

3.1 CARE AND CAUTIONS DURING UNBOXING

- · Lift the simulator from the box with both hands at the body and remove the clear bag it is shipped in.
- Rest the simulator on a bed or clean, flat surface for use.
- Do not pull or drag the simulator across hard surfaces as this may cause the skin to tear.

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

3.2 PACKAGE CONTENTS



- 1. Carrying Bag
- 2. Filling Kit
- 3. Charger with label
- 4. Power Supply
- 5. Newborn Leg Bone Cover (Right)

- 6. Newborn Lower IV Arm (Right)
- 7. Newborn Spare I/O Bones
- 8. Oil-Based Mineral Lubricant
- 9. Tube with Squeeze Bulb
- 10. Diapers

3.3 PREMIE HAL'S BATTERY

The Premie Hal is equipped with a built - in rechargeable battery and a battery run time of up to 2 hours.

Premie Hal includes two separate power adapters labeled "Premie Hal Charger" and "Premie Hal Power Supply". Please review the use for each adapter before using the simulator for the first time.

CAUTION: Do not store the simulator with a discharged battery. Recharge the battery at the end of every simulation session. If the simulator will not be used for an extended period, recharge the battery at least once every 30 days. Doing so will prevent damaging the battery due to discharging. Refer to "8.2 Battery Etiquette" on page 65 for more information.

Charging the Premie Hal Battery

1. Identify the Premie Hal's charger.



2. Plug the charger into the charging port located on the right side of the simulator.



3. Allow the simulator's battery to charge until the LED light indicator turns green.

NOTE: It approximately takes 2 hours to fully charge the simulator.

NOTE: Avoid using the simulator while the battery charger is connected.





Using the Power Supply for Premie Hal

The power supply adapter allows the simulator to operate through long simulations sessions by drawing power from the wall outlet and not battery reserve. Use the power supply for simulation sessions lasting 2 hours or more. If simulation sessions are shorter than 2 hours, using the simulator's battery reserve is recommended.

CAUTION: The power supply adapter will not re-charge the battery. Avoid using the power supply adapter if the simulator's battery is completely depleted.

1. To operate the simulator using wall power, fully recharge the simulator's battery using the battery charger adapter.



2. Disconnect the charger and connect the power supply adapter.



3. When connecting the power supply to the simulator's port, make sure the pins on the power supply are aligned with the port.



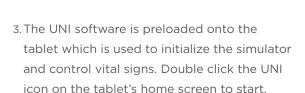
3.4 INITIALIZING THE SIMULATOR WITH UNI™

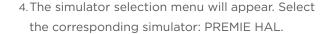
Turning on the Simulator

 Connect the simulator's USB RF module to the tablet PC.

WARNING: Use the correct RF Communications
Module to turn on the simulator. RF Modules
have a SN sticker on the side to confirm
the simulator it is intended to work with.

2. After reading the manufacturer's care and caution information, press the power button to turn on the Tablet PC





NOTE: When selecting the appropriate profile, be sure that the correct serial number from your simulator is entered into the profile and click 'Start'. The serial number will be located on the Premie HAL once his back is unzipped.

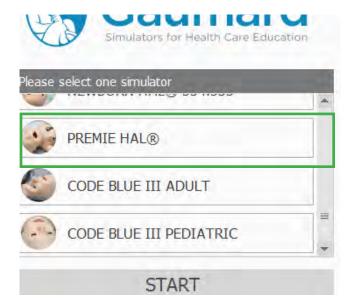
5. Once the software is turned on and loads, the simulator will establish communication and turn on.

To turn off the simulator, close the UNI software.







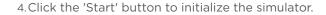




Adding a Serial Number to the Profile

- 1. Select the desired profile.
- 2. Click the "+" button to the right of the default serial number.

3. A "New Serial Number" pop-up will appear. Type in the numerical serial number of the simulator and click "SET!"



NOTE: After clicking 'Start', the wireless link between UNI and the simulator will be established.

A pop-up will appear stating the simulator is establishing communication and once the gray bar loads completely blue, the simulator will turn on.





4. WORKING WITH PREMIE HAL®

4.1 NEUROLOGICAL

Crying

Premie HAL's crying is synchronized with breathing.

To activate crying:

1. Click the 'Crying' vital in the UNI software.

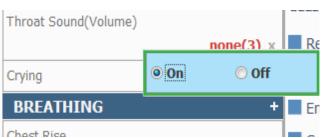
2. Select the 'On' option to activate crying.

To adjust the volume of the crying:

1. Click on 'Throat Sound'.

2. Adjust the slider to the left to decrease volume and adjust to the right to increase volume.









4.2 AIRWAY

Oral and Nasal Intubation

The Premie HAL's airway supports BVM, nasal/oral intubation, and suctioning with the following medical devices:

- Endotracheal (ET) tubes,
- · Nasogastric (NG) tubes, and
- Laryngeal Mask Airways (LMA)



Recommended Device Sizes

Procedure	Device Size
Intubation (Blade size)	0 MAC or MIL
Nasal Intubation	3.0 Fr
Oral Intubation	3.0 Fr (uncuffed)
NG/OG tube	6 Fr

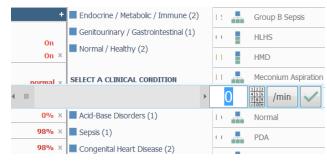
WARNING: Lubricate any airway device tubes using mineral oil before intubating. Do NOT introduce liquids into the airway or spray mineral oil into the airway. Doing so may permanently damage the system.

Intubation Setup

1. Under the 'Breathing' section in the UNI software, select 'Respiratory Rate'.

2. Set the respiratory rate to zero by adjusting the slide bar to the left or typing in the value.





3. Lubricate the adjunct with mineral oil.



NG/OG Placement

Premie HAL supports NG or OG tube placement.

WARNING: Do NOT introduce liquids or spray mineral oil into the esophagus. Doing so may permanently damage the system.

To perform the NG/OG procedure:

1. Lubricate the tube with mineral oil.



2. Insert the tubing through either nare.





Airway Sounds

Premie HAL can produce audible throat sounds.

Throat sounds include none, soft grunting, strong grunting, and inspiratory stridor.

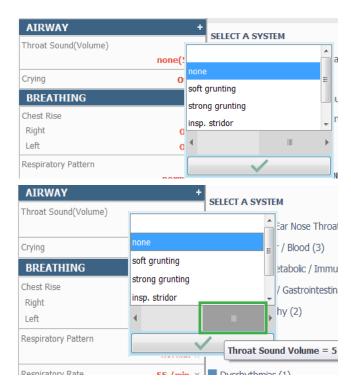
To select the desired throat sound:

1. Under the 'Airway' section in the UNI software, select 'Throat Sound'.

2. Select the type of 'Throat Sound' from the list.

3. Adjust the slider to the left to decrease volume and adjust to the right to increase volume





4.3 BREATHING

Chest Rise

Premie HAL has automatic bilateral chest rise and fall. Use the UNI software controls to:

- Enable or disable the lungs independently
- Select respiratory pattern
- · Adjust the breathing rate
- · Adjust the virtual inspiratory percentage

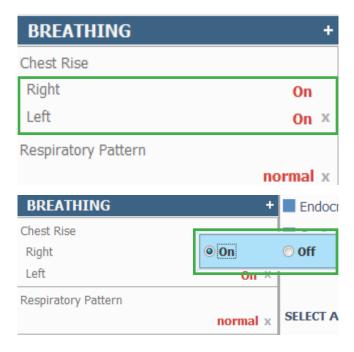
To enable or disable the lungs independently:

1. Under the 'Breathing' section, select either 'Right' or 'Left' chest rise.

Select 'On' to enable a lung or 'Off' to disable a lung.

To select different respiratory patterns:

1. Select 'Respiratory Pattern' under the 'Breathing' section in UNI.

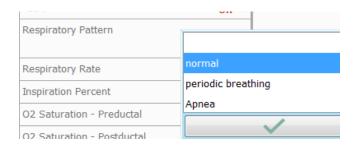




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2. Select the desired respiratory pattern.



To adjust the breathing rate:

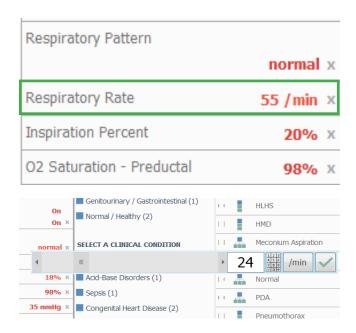
1. Select 'Respiratory Rate' under the 'Breathing' section.

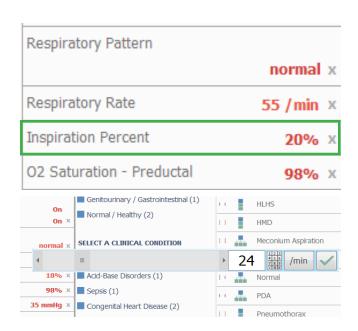
2. Adjust the slider bar or type in the value for the respiratory rate.

To adjust the virtual inspiratory percentage:

1. Select 'Inspiration Percent' under the 'Breathing' section.

2. Adjust the slider bar or type in the value for the inspiration percent.





Lung Sounds

Premie HAL generates anterior lung sounds which includes a selection of normal, none, inspiratory stridor, crackles, or grunting.

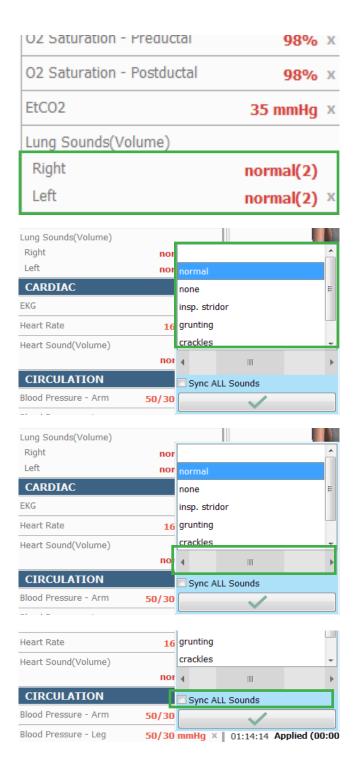
To select the desired lung sounds and volume for each lung independently:

 Select either 'Right' or 'Left' under the 'Lung Sounds' section of breathing.

2. For the selected lung, choose the desired lung sound.

3. Adjust the volume of the lung sound by adjusting the slider bar. Slide to the right to increase the volume or slide to the left to decrease the volume.

4. Check the 'Sync ALL Sounds' box to apply the chosen lung sound and volume to both lungs.





Compliant Lungs

Premie HAL supports standard positive pressure ventilation and will present visible chest rise.

Premie HAL will withstand up to 20 cm H₂O levels of PIP and 5 cm H₂O levels of PEEP.

The simulator supports bag-valve-masks, resuscitators, mechanical ventilators, CPAP, and more.



To use the UNI interface to monitor in real-time PPV ventilation feedback:

1. Turn respiratory rate to zero before ventilating.

Respiratory Pattern normal x Respiratory Rate 55 / min × Inspiration Percent 20% X O2 Saturation - Preductal 98% X



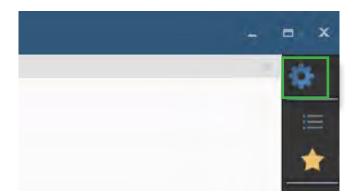


2. Monitor the ventilations through the UNI software by clicking the 'CPR' tab.

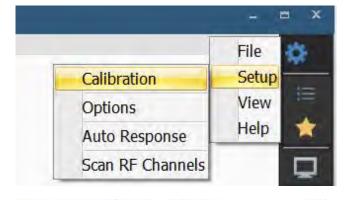
Ventilation Calibration

It is recommended to calibrate the ventilation feature before use.

1. Click the settings icon in the upper right corner.



2. Select "Setup" and "Calibration".



3. In the calibration menu, select "Artificial Ventilations" and "Next".



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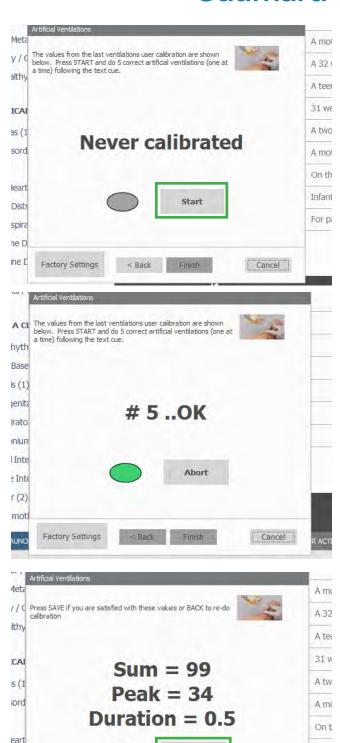
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4. Click "Start".

5. Perform 5 separate ventilations.

NOTE: The oval will turn green after each ventilation.

6. Click "Save" and "Finish" after the ventilations.



Cancel

Save

Finish

< Back

Distr

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Factory Settings

Infar

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Chest Compressions

Perform chest compressions on Premie HAL and measure and log them in UNI

NOTE: Performing proper chest compressions results in palpable femoral and umbilical pulses.

Use the CPR tab in UNI to monitor the effectiveness of the compressions.

NOTE: Refer to the UNI User Guide for more information on the CPR tab. Access the guide by clicking on the settings icon, "Help", and "Instruction Manual".

Chest Compression Calibration

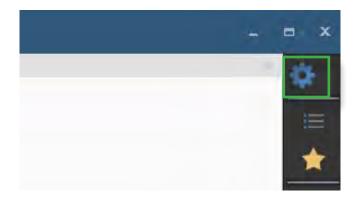
It is recommended to perform chest compression calibration before first time use.

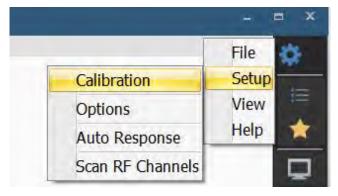
1. Click the settings icon in the upper right corner.

2. Select "Setup" and "Calibration".









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3. In the calibration menu, select "Compressions" and "Next".

4. Click "Start".

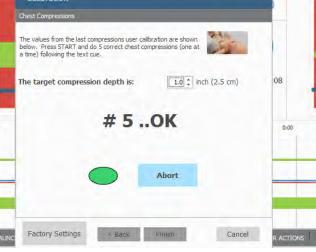
5. Perform 5 separate compressions

NOTE: The oval will turn green after each correct compression.

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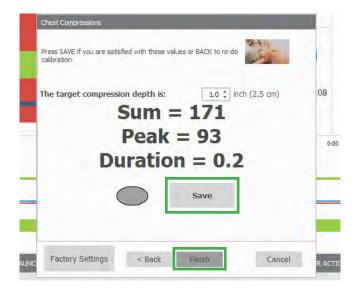






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6. Click "Save" and "Finish" after the compression calibration.



4.4 CARDIAC

EKG Monitoring

Premie HAL supports the use of real EKG monitoring equipment to track cardiac rhythms.



To utilize the ECG sites:

1. Disconnect the Premie HAL from any power supply or charger.



2. Connect the EKG electrodes to the EKG sites on the simulator.





3. Connect the leads to a monitor and turn on the monitor.





WARNING: Do NOT physically pace or defibrillate Premie Hal with real medical equipment. Doing so may damage the electrical components.

To utilize EKG electrode patches with Premie HAL:

1. Attach the EKG electrode adapters to the EKG sites.



2. Apply EKG electrode patches to the adapters.

NOTE: If the neonate electrode patches being used have snaps, attach the electrode cables to the snaps



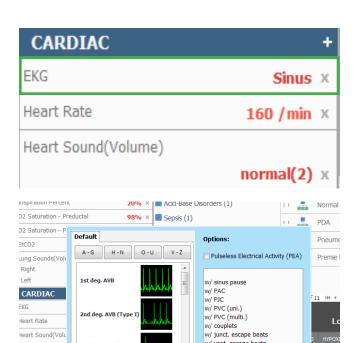
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To select different EKG rhythms within the UNI software:

1. Select 'EKG' under the 'Cardiac' section in the UNI software.

2. Select the desired EKG rhythm from the library of EKGs and click the green check mark button.



w/ vent. escape beats w/ PSVT w/ VT runs

Heart Rate Heart Sound(Volu

CIRCULATIO Blood Pressure

Blood Pressure

Blood Glucose

Capillary Refill Tir

2nd deg. AVB (Type II)

Heart Rate Min: 15

Max: 240

3rd deg. AVB

Heart Sounds

Auscultate with a stethoscope Premie HAL's normal and abnormal heart sounds.

Premie HAL's heart sounds are also in sync with the selected heart rate as well.



To adjust the volume and select different heart sounds:

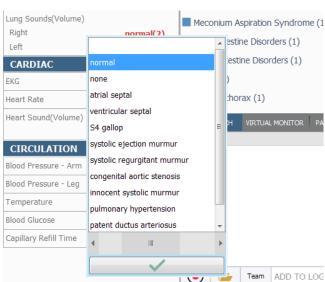
1. Under the 'Cardiac' section in the UNI software, select 'Heart Sound'.

2. Select the desired heart sound.

Heart Sounds include:

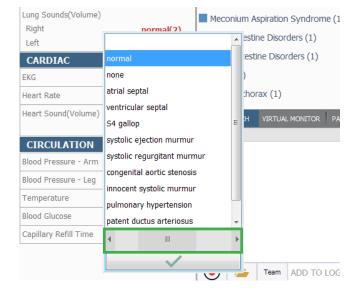
- » normal
- » none
- » atrial septal
- » ventricular septal
- » S4 gallop
- » systolic ejection murmur
- » systolic regurgitant murmur
- » congenital aortic stenosis
- » innocent systolic murmur
- » pulmonary hypertension
- » patent ductus arteriosus



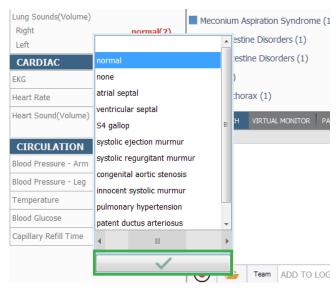




3. To adjust the heart sound volume, adjust the slider to the right to increase the volume or adjust the slider to the left to decrease the volume.



4. To apply the select settings, click the green check mark button.



4.5 CRCULATION

Cyanosis

Premie Hal can display varying levels of central cyanosis.

To adjust the intensity of cyanosis:

- 1. Under the 'Cephalic' section in the UNI software, click on 'Cyanosis'.
- 2. The cyanosis intensity ranges from 0-100%. Adjust the slider bar to right to increase the intensity or adjust the slider bar to the left to decrease the intensity.

NOTE: Refer to the Hypoxia Modeling Section for more information on how to automate the change in cyanosis as the provider performs ventilations.







Palpable Pulses

Premie HAL has palpable fontanelle, bilateral brachial, bilateral femoral, and umbilical pulse sites.



Fontanelle



Femoral

To palpate the pulses either clamp the umbilical cord or install the navel.



Brachial



Umbilical



To install the navel on Premie HAL:

1. Gently pull on the umbilical cord to reveal the connecting hose.



2. Disconnect the umbilical cord from the connecting hose above the white junction.



3. Connect the navel attachment to the connecting hose.



4. Slide the connection back into the simulator.



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5. Gently pinch the skin around the navel to adjust the appearance.



Premie HAL's pulses are automatic and synchronized with the heart rate and blood pressure parameters.

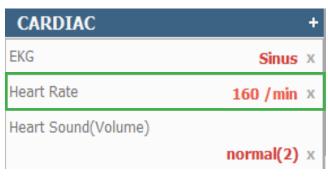
To change the heart rate:

1. Under the 'Cardiac' section in the UNI software, select 'Heart Rate'.

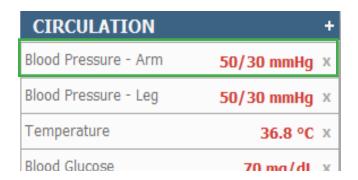
2. Adjust the heart rate by moving the slider bar or typing in the value.

To change the virtual blood pressure:

1. Under the 'Circulation' section in the UNI software, select 'Blood Pressure- Arm'





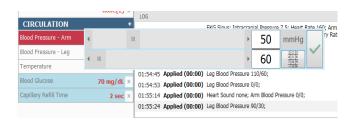


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2. Use the slider bar or type in the values to change the systolic and diastolic pressures.

NOTE: When changing the Blood Pressure- Arm the Blood Pressure-Leg will also change. Select the 'Blood Pressure- Leg' and follow the above steps to independently change that vital.



IV Cannulation

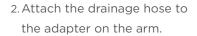
Premie HAL has bilateral IV arms and lower left leg access.

It is recommended to use needle size 22 gauge or smaller to extend the life of the veins and skin.

The skin and tubing is latex free.

IV Arm Setup

1. Twist the IV adapters into the ports of the arms.







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3. Leave the clamp on the drainage hose open and place the end of the hose into a receptacle.



4. Fill the IV arm syringe with blood.

CAUTION: 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.



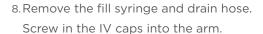
5. Connect the fill syringe to the other port adapter on the arm.



6. Inject the simulated blood into the arm.



7. Close the clamp on the drainage hose when there are no more air bubbles going through the drain hose.



NOTE: Leave the drain hose as an option to do continuous IV infusion.





Cleaning the IV Arm

Clean and dry the forearm vasculature at the end of each simulation day to prevent mold or clogs from forming.

1. Fill the fill syringe with a solution of a 70:30 water to isopropyl alcohol ratio.



2. Connect the fill syringe to the arm and unclamped drain hose.



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3. Flush the arm with the solution until the fluid runs clear through the drain hose.

NOTE: This may take more than one syringe of the cleaning solution.

4. Disconnect the syringe, fill it with air, and then purge the vasculature with air to dry the system.





Left Foot Access

Premie HAL has an IV vascular access site on the lower left leg on the top of the foot.

To fill the vasculature:

1. Twist the adapters onto the ports on the back of the leg.



2. Attach the drainage hose to one adapter on the back of the lower left leg.



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3. Leave the clamp open on the drainage hose and place the end in a receptacle.



4. Fill the IV syringe with simulated blood.

CAUTION: 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.



5. Attach the IV fill syringe to the other adapter on the back of the lower left leg.



6. Inject the simulated blood into the leg.



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7. Close the clamp on the drainage hose when there are no more air bubbles going through the drain hose.



8. Remove the fill syringe and drain hose. Screw in the IV caps into the leg.

NOTE: Leave the drain hose as an option to do continuous IV infusion.



Cleaning the IV Leg

Clean and dry the leg vasculature at the end of each simulation day to prevent mold or clogs from forming.

1. Fill the fill syringe with a solution of 70:30 water to isopropyl alcohol.



2. Connect the fill syringe and the unclamped drain hose to the lower leg.



3. Flush the vasculature until the fluid runs clear.

NOTE: This may take more than one syringe of the cleaning solution.









Umbilical Catheterization

Perform umbilical catheterization exercises on Premie HAL on either the vein or the artery.

Procedure	Device Size	Capacity
Catheterization	6 Fr	2 mL

To perform an umbilical catheterization, install the umbilical cord:

1. Gently lift the navel from the edge.



2. Lift the navel out from the simulator to reveal the hose connection.



3. Gently remove the navel above the white junction on the connection.



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4. Connect the umbilical cord.

5. Tuck in the umbilical cord into the naval cavity and pinch the skin to adjust the appearance.





Filling the Umbilical Cord

To perform a blood draw, prefill the umbilical cord with simulated blood.

1. Locate the umbilical adapter fill kit.



2. Remove the gray piece from the umbilical adapter.





3. Insert the clear adapter into either the vein or artery on the umbilical cord.

4. Fill the syringe with up to 2 mLs of simulated blood and connect it to the adapter.

CAUTION: 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.



5. Inject the simulated blood into the umbilical cord reservoir.

NOTE: If drugs are to be injected into the umbilical cord, do not pre-fill the umbilical cord.



Intraosseous Access

Premie HAL has an intraosseous (IO) site in the lower right leg that allows for infusion of fluids and/or medications or extractions. To fill the IO bone:

1. Screw in the adapters to the back of the right leg.



2. Connect the drain hose to one of the adapters and leave the clamp open.





3. Fill the syringe with simulated blood

CAUTION: 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.



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4. Connect the syringe to the other adapter in the back of the right leg.



5. Inject the simulated blood and close the clamp on the drainage hose when air bubbles are no longer present.



6. Remove the fill syringe and perform the IO exercise.

NOTE: Leave the drainage hose connected and the clamp open when doing a large infusion of fluid.



7. Remove the fill syringe and drain hose. Screw in the IV caps into the leg.

NOTE: Leave the drain hose as an option to do continuous IV infusion.



Cleaning the Intraosseous Leg

1. Fill the fill syringe with a solution of 70:30 water to isopropyl alcohol.



2. Connect the fill syringe and the unclamped drain hose to the lower leg.



3. Flush the vasculature until the fluid runs clear.

NOTE: This may take more than one syringe of the cleaning solution.



4. Push the air through the vasculature to dry out the leg.





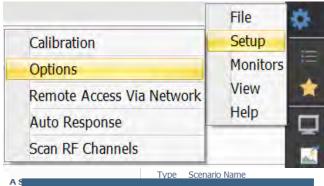
Temperature Probe

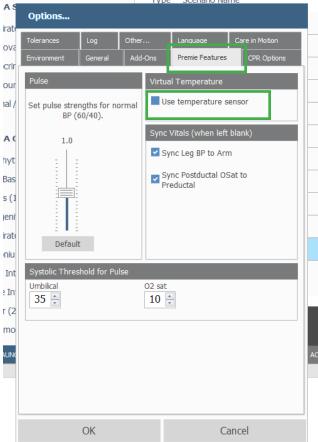
Premie HAL has a sensor that detects the placement of a temperature probe.

To enable the temperature probe feature:

1. In the UNI software click in the upper right hand corner the blue gear icon-> Setup-> Options.

2. Select the 'Premie Features' tab and check the box 'Use temperature sensor'.



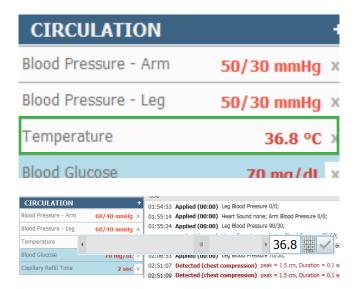


Place the probe on the lower right abdomen.

To change the virtual temperature in the UNI software:

 Under the 'Circulation' section, select 'Temperature'.

2. Use the slider bar or type in the value to change the temperature.

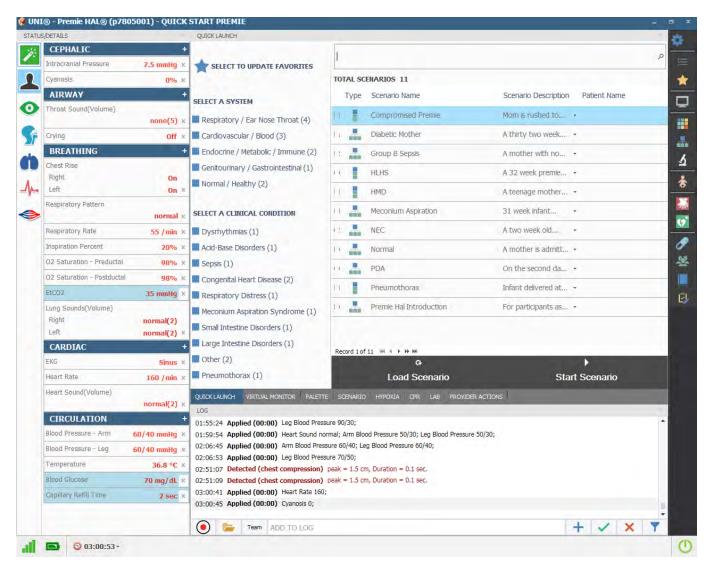




5. WORKING WITH UNITH

5.1 UNI™INTERFACE

- The UNI software is used to control the simulator, monitor the vital signs, and evaluate the provider's performance. The simulation technician or facilitator carrying out the simulation operates the UNI software.
- The UNI control elements and scenario programming procedures are consistent throughout the Gaumard family of high fidelity simulators. Some software controls and features covered in this guide may be hidden depending on the simulator's hardware configuration and optional upgrade.



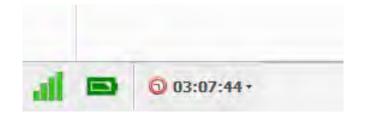
Connection Status

The communication indicator displays the status of the radio link between the tablet's USB RF module and the simulator. Full bars indicate excellent communication or normal operation.



Pemie HAL Battery Indicator

- The battery indicator is located on the lower left corner of the UNI software.
- A question mark appears for the battery indicator when there is no communication with the simulator and software and the battery information cannot be retrieved.
- The battery status indicator changes as the battery in the simulator is used.
- When the battery is depleted, the simulator is set to STAND-BY mode automatically to protect the simulator's internal components. The simulator will not initialize until it has been recharged.
- Before the simulator shuts off due to a depleted battery, a message will pop up on the screen to notify the user of the low battery.

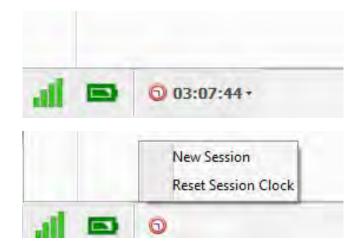


Session Clock

The session timer allows the facilitator to maintain a chronological record of individual simulation sessions. The session timer can be reset from the file menu when a new simulation session begins. Events during the simulation are logged in accordance to the session time.

Reset or Start a New Session

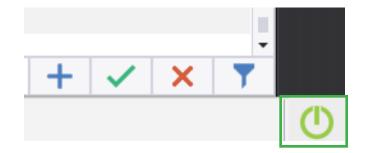
- Click the time in the lower left corner of the UNI software, next to the clock icon, to activate the selection menu.
- 2. Select the option to either Reset Session Clock or to start a New Session.





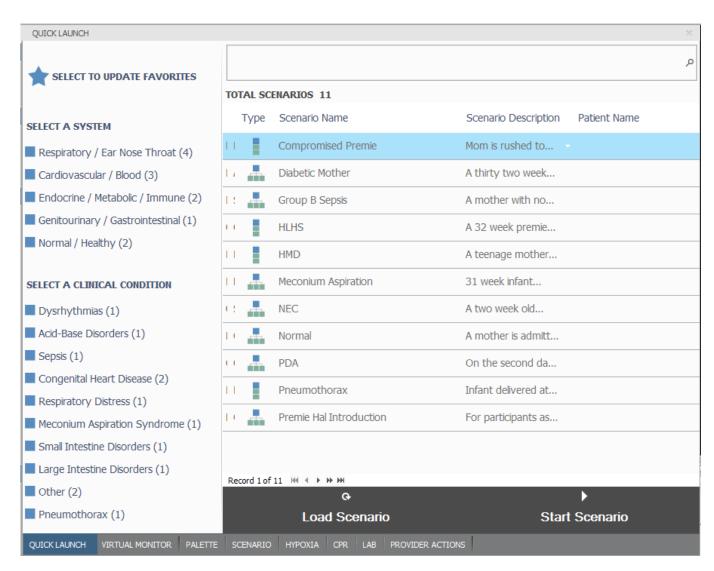
Power/Stand-by Button

The standby button is located on the bottom right corner of the UNI software. Use the stand-by feature to conserve battery.



Quick Launch

The UNI interface opens to the quick launch page listing the scenarios. This page is used to easily access the preprogrammed scenarios saved on each profile.



Select A System

The scenarios are categorized by physiological systems to the left of the Quick Launch page; i.e. respiratory, cardiovascular, etc.

Clinical Condition

The scenarios may be categorized by clinical conditions on the left of the Quick Launch page; i.e. dysrhythmias, sepsis, etc.

SELECT A SYSTEM

- Respiratory / Ear Nose Throat (4)
- Cardiovascular / Blood (3)
- Endocrine / Metabolic / Immune (2)
- Genitourinary / Gastrointestinal (1)
- Normal / Healthy (2)

SELECT A CLINICAL CONDITION

- Dysrhythmias (1)
- Acid-Base Disorders (1)
- Sepsis (1)
- Congenital Heart Disease (2)
- Respiratory Distress (1)
- Meconium Aspiration Syndrome (1)
- Small Intestine Disorders (1)
- Large Intestine Disorders (1)
- Other (2)



Selecting a Scenario

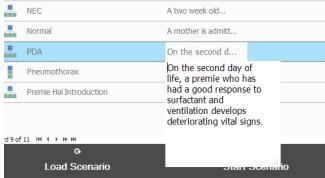
1. Click on one of the scenarios listed to highlight it then click Start Scenario or Load Scenario.

Clicking Start Scenario loads the desired scenario and starts running it without any further intervention through software.

2. Click on the drop down arrow to the right to read a scenario description.

NOTE: For more information on the provided scenarios, please refer to the Simulation Learning Experiences (SLE) binder.







Favorites

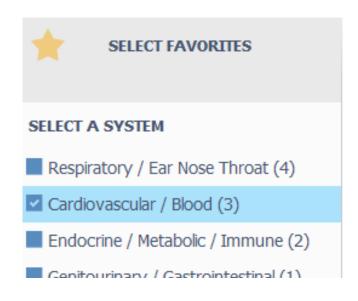
There is also a Favorites feature added to the quick launch program.

This feature allows users to reduce the number of scenarios highlighted to those within the categories that will be used most frequently.

Enabling the Favorites Feature

1. Click the star icon.

2. Select the desired categories or scenario types. Once the category or scenario is selected, it will appear highlighted with a check in the box to the left of the title.





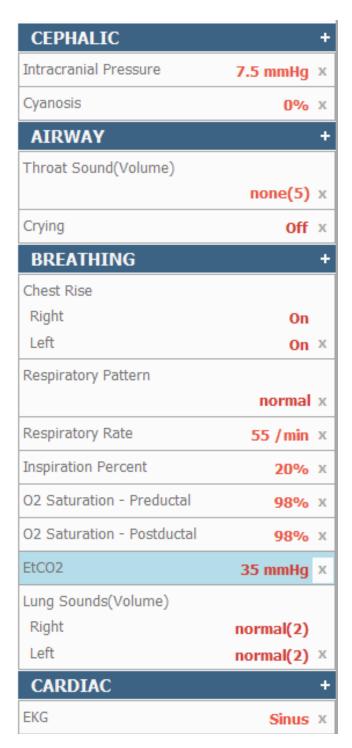
Status/Details Controls

- The Status/Details tab displays the vital signs controls in a list format.
- The Status/Details panel is used to monitor and control the simulator's vital signs. The individual controls displayed on the details tab provide the simplest method for controlling the simulator's vital signs, sounds, and features.

Systems List View

The vital signs controls are divided into separate categories:

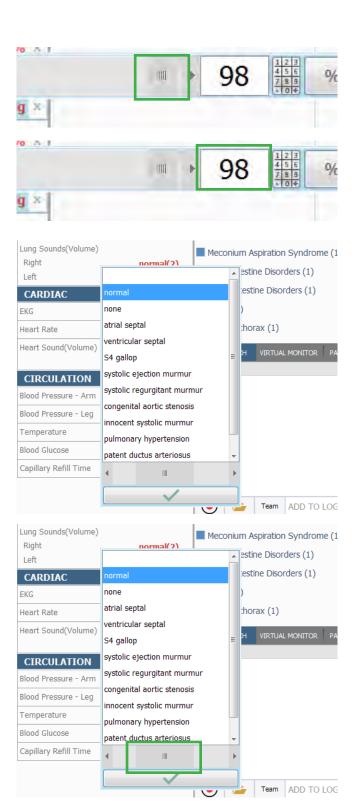
- · Cephalic
- Airway
- Breathing
- Cardiac
- Circulation



Changing Vital Signs

- To adjust numerical values. (e.g. heart rate, blood pressure, respiratory rate, etc.) click and drag the slider control
- You may also use the keyboard for manual entry and click the green check mark to confirm the change.
- 3. To change patterns, sounds, and rhythms, click on the specific control to display the library (e.g. EKG rhythms, heart and lung sounds, respiratory patterns, etc.)

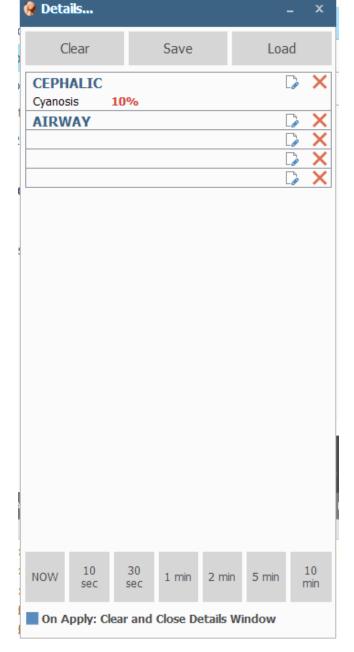
4. Click the slider control below the sound library to adjust the volume of the sounds.





Applying Changes

- No changes will be made to the simulator's condition until the new settings are submitted using the Apply panel.
- After the list of changes is created, click NOW to update the vital signs instantly.
- You may also click a trending time to update numerical vital sign parameters (e.g. heart rate, blood pressure) gradually.



 Enable the Instant Apply option by clicking the wand to change the vital sign to a new value without the need of using the Apply panel.

NOTE: Vital signs undergoing change blink yellow.

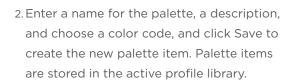


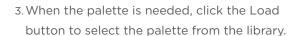


Creating Palette Items

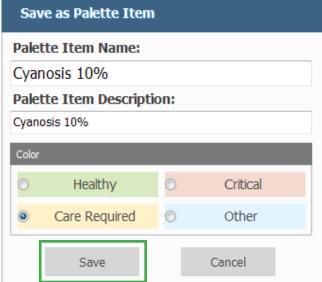
A palette item stores one or more vital sign settings into a single loadable object. Use a palette item to update a set of vital signs quickly. For example, one palette item can be created to update all the cardiac parameters to a healthy state.

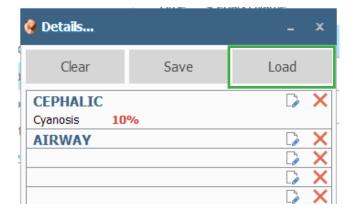
1. To create a new palette item, set the values for the desired vital signs parameters using the Details control panel and click Save.







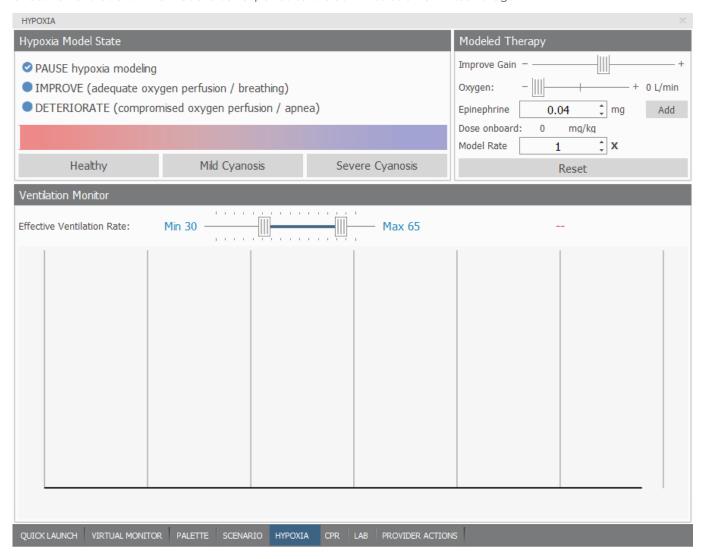






5.2 HYPOXIA MODELING PREMIE S2209

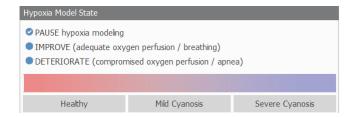
Use the Hypoxia tab to evaluate the effectiveness of provider interventions on an apneic patient. The model adjusts cardiac, oxygen saturation, and cyanosis dynamically in response to effective ventilations. The model also responds to the administration of virtual drugs.



Hypoxia Model State

The hypoxia model options improve or deteriorate the cardiac and respiratory vital signs gradually.

- Pause: Model will pause at the current state
- Improve: Trend the vital signs to a healthy state
- Deteriorate: Trend the vital signs to a severe cyanotic state. Ventilations are detected when the respiratory rate is at zero.



Cyanosis Levels

Select the cyanosis level to move to any of the following states immediately:

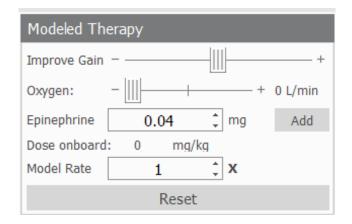
- Healthy: Pediatric is pink with adequate oxygenation
- Mild Cyanosis: Pediatric is slightly blue and the vital signs are starting to deteriorate.
- Severe Cyanosis: Pediatric is blue, apneic, and vital signs are rapidly worsening.

Hypoxia Model State PAUSE hypoxia modeling IMPROVE (adequate oxygen perfusion / breathing) DETERIORATE (compromised oxygen perfusion / apnea) Healthy Mild Cyanosis Severe Cyanosis

Modeled Therapy

The modeled therapy menu provides additional intervention options:

- Improve Gain: Adjust the slider to increase or decrease the cyanotic response to ventilations
- Oxygen: Adjust the slider to administer oxygen to the pediatric in liters per minute
- Epinephrine: Administer epinephrine to the model. Set the epinephrine dose and then click "Add". Administering epinephrine increases the heart rate.
- Reset: Click Reset to clear the oxygen flow and the epinephrine dose onboard.





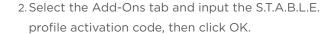
6. OPTIONS

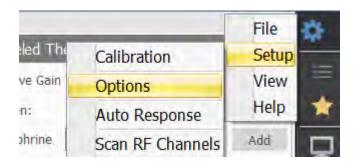
6.1 S.T.A.B.L.E. PROFILE

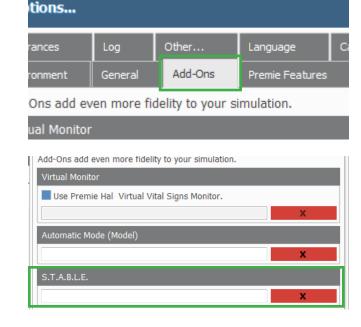
The S.T.A.B.L.E. profile is a complete simulation curriculum designed for comprehensive neonatal resuscitation and stabilization care. There are 13 preprogrammed branching scenarios designed for Tory® S2210 and Newborn HAL® S3010. One scenario patient is a 32-week gestation infant and includes 3 branching scenarios each for Newborn and Premie HAL®. Also includes 2 simulator orientation scenarios.

Activate S.T.A.B.L.E. profile

1. Click the gear icon in the upper right hand corner of the UNI software then -> Setup -> Options.



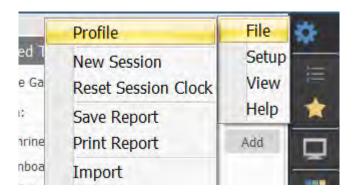




Switching to S.T.A.B.L.E. profile

1. Click the gear icon in the upper right hand corner of the UNI software, then File ->Profile.

2. Under Running Mode select Automatic and click 'Load'.



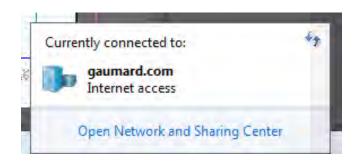




6.2 VIRTUAL PATIENT MONITOR

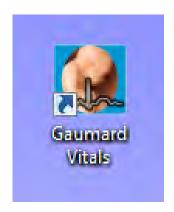
Virtual Monitor

- The control PC and the bedside virtual monitor PC automatically establish a wireless link at startup. The wireless connection allows the Gaumard control software to transmit the vital signs information to the Gaumard Vitals software.
- To verify the wireless link between the two computers, click the Wi-Fi icon. The wireless network name is configured at the factory and may differ from the one seen here.
- Be sure both the control tablet that runs UNI and the virtual monitor that runs Gaumard Vitals are connected to the same Wi-Fi network.

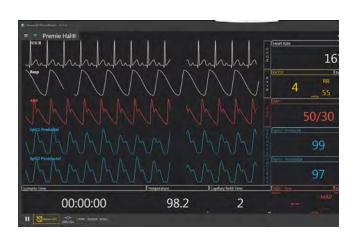


Gaumard Vitals

 After the wireless connection is established, double click or tap the Gaumard Vitals icon to start the vital signs software.



- The Gaumard Vitals software is now ready to receive the vital signs information generated by the UNI control software.
- For more details on using the UNI software, see the UNI user guide





7. TROUBLESHOOTING

7.1 COMMUNICATION WITH THE SIMULATOR CANNOT BE ESTABLISHED

Probable Cause	Solution
Battery needs charging	Connect the charger to the simulator and allow it to charge for approximately 2 hours or when the LED light indicator on the charger is green.
RF Module not plugged in	Connect the RF Module via USB to the control tablet and ensure that the tablet recognizes the RF module is plugged in.

7.2 CPR IS NOT DETECTED

Probable Cause	Solution
Compressions are not detected	Reset the Compression sensor. Click the blue gear icon in the upper right hand corner of the UNI software->Setup-> Calibration. On the Calibration menu click the 'Factory Settings' button. Reset the Compressions Sensor. Then, calibrate chest compressions as shown in section 4.3.
Ventilations are not detected	Reset the Ventilations sensor. Click the blue gear icon in the upper right hand corner of the UNI software->Setup-> Calibration. On the Calibration menu click the 'Factory Settings' button. Reset the Ventilations Sensor. Then, calibrate ventilations as shown in section 4.3.



8. ROUTINE MAINTENANCE

8.1 LIMB REPLACEMENT

The lower limbs on Premie HAL are considered consumables and will need to be replaced accordingly. Refer to section 9. Appendix for item numbers. To remove the lower arms:

1. Flip the arm skin slightly down and gently hold above and below the elbow crease.



2. Pull in opposite directions to unplug the lower arm.



To install the new lower arms:

1. Plug the new lower arm to the upper arm.

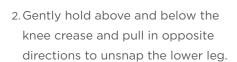


2. Adjust the skin around the elbow crease until flush.



To remove the lower legs:

1. Un-Velcro the top of the lower leg.







To install the new lower legs:

1. Snap the new lower leg to the upper leg.



2. Adjust the skin around the knee crease until flush.





8.2 BATTERY ETIQUETTE

The battery is an integral part of your simulator and requires appropriate care to maintain efficiency and longevity.

Overcharging or leaving the battery idle for long periods of time will damage the battery and lower the amount of potential charge.

To ensure maximum battery life, cycle the battery and avoid overcharging by adhering to the following warnings and guidelines.

Avoid Overcharging the Battery

WARNING: Do NOT leave the simulator charging continuously for extended periods of time (i.e., several days). The battery may attempt to hold more charge than it is supposed to thus damaging the battery.

- It is recommended to charge the simulator the day or night before a simulation to allow the battery time to fully charge.
- · Unplug the simulator when in use unless while running a simulation the UNI software indicates a critically low battery. In these cases, it is advisable to plug in the simulator's battery charger to finish the simulation. Once the simulation is completed, turn the simulator off and allow the simulator's battery to charge.

Avoid Battery Idleness

WARNING: Do NOT leave the simulator idle for extended periods of time (i.e., months, years). The battery's capacity for charge will deteriorate if there is no cycling in the level of charge.

• If you plan to store away and not use the simulator for an extended period of time, it is recommended to fully charge the battery before storage. As part of routine maintenance, plan a time each month to cycle the battery and fully charge it before storing the simulator away again.

Cycling the Battery

1. Obtain the correct battery charger for the simulator and plug the wall adapter end into a voltage source.



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2. With the simulator turned off, plug the charger into the charging port on the simulator.



3. Leave the simulator plugged into the charger until the LED light on the charger transitions to a green light.



4. Disconnect the simulator from the charger.



- 5. The simulator is ready to be used for simulation.
- 6. Use the simulator's battery charge until depleted.
- 7. Repeat this process as needed.

NOTE: If preparing the simulator for storage, arrange for a time every month to "cycle the battery" of the simulator. Then store the simulator with a fully charged battery until the next scheduled usage.

WARNING: Never store your simulator with a depleted battery for an extended period.



9. APPENDIX

9.1 PARTS LIST

Product	Item Number	Contents
Battery	S2209.010	Consumable
Lower Left Arm	S2209.023L	Consumable
Lower Right Arm	S2209.023R	Consumable
Umbilical Cord Kit	S2209.137	Consumable



9.2 GAUMARD SALES TERMS AND CONDITIONS

These Gaumard Scientific Company, Inc. ("Gaumard") Sales Terms and Conditions ("Terms") apply to the sale or use of Gaumard equipment ("Equipment"), Software ("Software" as defined in paragraph 13), and supplies ("Supplies"), collectively referred to as "Product" or "Products" between Gaumard and the entity named on the applicable Gaumard Purchase Order ("Customer") (collectively, "Party" or "Parties"). The Parties, intending to be legally bound, agree as follows.

- 1. Agreement. Customer agrees to purchase from Gaumard the Products set forth in quotes and purchase orders accepted by both Customer and Gaumard from time-to-time. These Terms, along with any Exhibits, any applicable Gaumard Purchase Order documents, Gaumard Warranty documents, Gaumard Cares Service Plan documents, and any other purchasing or service documents executed by the Parties constitute the complete and entire agreement between Gaumard and Customer (collectively referred to herein as the "Agreement"). This Agreement will supersede all other quotations, agreements, understandings, warranties, and representations (whether written or oral) between the Parties with respect to the subject matter set forth in the Agreement. Any Customer documentation (including Customer's purchase order terms and conditions) that conflicts with or attempts to modify the Agreement in any way is hereby rejected and of no effect unless specifically agreed to in writing and signed by the Parties. No provision of this Agreement sHAL*I be waived, amended, modified, superseded, canceled, terminated, renewed, or extended except in a written document signed by both Parties or signed by the Party against whom the modification is sought to be enforced. This agreement can be terminated by Gaumard without cause by giving thirty (30) days prior written notice to Customer.
- 2. Prices, Prices, fees, and charges for Products and services (including maintenance, installation, and training as described in the applicable Gaumard Purchase Order documents, Gaumard Warranty documents, Gaumard Cares Service Plan documents) ("Service" or "Services") are payable in United States (U.S.) Dollars only, and do not include any applicable taxes or shipping charges. If Customer claims any tax exemption, it must furnish a valid tax exemption certificate before shipment of Products. Unless such certificate is furnished, Customer agrees to pay at its sole expense all applicable taxes, assessments, fees, penalties, import duties, and merchandise processing fees that may be levied or assessed upon Customer or Gaumard with respect to this Agreement, the Products, or any interest thereon. Gaumard reserves the right to increase prices on thirty (30) days written notice to Customer.
- 3. Payment. Unless otherwise agreed to in writing by Gaumard, Customer sHAL*I pay invoices net twenty (20) days from the invoice date. A late charge will be due on any unpaid balance at a rate of 1.0% per month or the maximum rate otherwise permitted by law, whichever is lower. Gaumard may charge interest at the maximum rate permitted by law on all amounts not paid by the invoice due date. Gaumard retains a purchase money security interest in all Products sold to Customer to secure payment of the total purchase price thereof. Customer hereby grants Gaumard the right to file a copy of this Agreement with any appropriate authorities to evidence this security interest. Customer agrees to execute and deliver such other documents as Gaumard may request in connection therewith. Gaumard sHAL*I not be obligated to deliver any Product or perform any Service during any period when Customer payment is past due. Customer will be responsible for all costs (including reasonable attorneys' fees) incurred by Gaumard to collect overdue payments and/or to take possession or otherwise dispose of Products for which payment is overdue.
- 4. Product Shipment and Risk of Loss. Unless otherwise agreed to in writing by Gaumard, all Products will be shipped F.O.B. Origin, regardless of any provisions for payments of freight, insurance, the form of shipping documents, or selection of carrier by Gaumard. F.O.B. Origin means title to the Products passes to the Customer at the shipping dock of Gaumard or Gaumard's supplier or authorized agent. Customer is responsible for shipping charges and for the cost of insurance paid to cover any losses from Gaumard's shipment point to Customer's receipt. Gaumard will assist Customer in processing any loss claims. Gaumard sHAL*I use reasonable efforts to meet the specified delivery dates. If Gaumard fails to make delivery within a reasonable time for reasons other than Customer's fault or circumstances beyond Gaumard's reasonable control, then Customer's only remedy is the right to terminate the applicable Purchase Order, whereupon Gaumard will refund any prepayments received from Customer relating to such Purchase Order.
- 5. Installation and Acceptance. Product orders are subject to 1) written acceptance by Gaumard, 2) receipt of specified deposits, as applicable and 3) continuing credit approval. If applicable, Gaumard will install Equipment at an agreed upon location ("Installation"). Installation sHAL*I be complete upon Gaumard's demonstration that the Equipment meets Gaumard's then-current operating specifications ("Installation"). Installation is subject to Customer cooperating in preparing and maintaining the site in compliance with Gaumard specifications, including but not limited to, applicable electrical and other connection regulations and all environmental conditions. If Customer fails to accept shipment of Products other than for breach of warranty, Customer sHAL*I immediately pay the full purchase price as if shipment and Installation had occurred. If Customer fails to accept Products and if Gaumard decides to store ordered Products, Customer sHAL*I be responsible for Gaumard's reasonable insurance, handling, and storage charges. If Gaumard elects not to store ordered Products, Gaumard may arrange shipment and storage in a bonded warehouse at Customer's sole risk and expense.
- 6. Delay of Performance. The Parties' obligations under this Agreement are subject to force majeure, including but not limited to, civil insurrection, terrorism, fire, flood, labor disputes, shortages, delays of suppliers or contractors, or government priority systems, actions taken or threatened by any governmental agencies, acts of God or other contingencies or acts not within the sole control of the Parties. Gaumard reserves the right during any shortage period to (a) make Supplies available to Customer (as it sees fit) without any liability to Customer, and (b) to make substitutions and modifications in the specification of any Products, provided such substitutions or modifications do not materially affect the performance of Products.
- 7. WARRANTIES. Gaumard warrants that if a Product proves to be defective in material or workmanship within one year from the date on which title to the Product passes to the Customer ("Warranty Period"), 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: (a) Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product; (b) 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 (c) Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative. Replacement parts are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer. Services are warranted to be supplied in a workman-like manner. Gaumard



does not warrant that use of the Products will be uninterrupted or error-free, or that the Products will operate with non-Gaumard authorized third-party products. THE FOREGOING WARRANTIES ARE IN LIEU OF AND EXCLUDE ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT. SUCH LIMITED WARRANTY IS GIVEN SOLELY TO THE ORIGINAL CUSTOMER AND IS NOT GIVEN TO ANY THIRD PARTY INCLUDING, WITHOUT LIMITATION, SUBSEQUENT PURCHASERS OR USERS OF THE PRODUCTS OR CUSTOMERS OF THE CUSTOMER. THIS WARRANTY IS VOID UPON TRANSFER OF PRODUCT BY CUSTOMER TO ANY OTHER ENTITY. SOME STATES DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES SO THE ABOVE EXCLUSIONS MAY NOT APPLY TO CUSTOMER. These warranties do not apply to any Products that are supplied on a pre- release or "as-is" basis.

- 8. Warranty Claims and Remedies. In the event of any warranty claim, Gaumard will replace with new or repaired items any Product part or component that is in breach of the above limited warranties. Alternatively, Gaumard may elect to repay or credit to Customer an amount equal to the purchase price of the defective Product. Items replaced sHAL*I become Gaumard property. All claims sHAL*I be initiated by contacting Gaumard within the applicable Warranty Period and within thirty (30) days after discovery of the non- conformity. If Customer has failed to notify Gaumard within the Warranty Period, then Customer sHAL*I be barred from instituting any action thereafter. Customer sHAL*I not return the Product to Gaumard without prior authorization from Gaumard. If the necessary repairs to the Product are covered by this limited warranty, then Customer 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 Customer will be liable for all repair costs in addition to costs of shipping and handling. Upon request, Gaumard must be given access to and an opportunity to inspect the Product and any working areas and storage areas. These remedies sHAL*I comprise Gaumard's entire liability and Customer's exclusive remedy for breach of warranty and are in lieu of any other remedies at law or equity.
- 9. LIMIT OF LIABILITY. GAUMARD SHAL*L NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL LOSSES, DAMAGES, OR EXPENSES (INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS, DATA, OR USE), DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, HANDLING, SERVICE, OR USE OF PRODUCT OR SERVICES ORDERED OR FURNISHED, OR FROM ANY CAUSE RELATING THERETO. EXCEPT FOR PERSONAL INJURY OR DEATH TO THE EXTENT RESULTING FROM GAUMARD'S NEGLIGENT OR INTENTIONALLY WRONGFUL ACTS OR OMISSIONS, IN NO EVENT SHAL*L GAUMARD BE LIABLE UNDER ANY LEGAL THEORY OR FOR ANY CAUSE RELATED TO A PRODUCT OR SERVICE, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, NEGLIGENCE, OR OTHER THEORY, EVEN IF ADVISED OF THE POSSIBILITY THEREOF, FOR ANY AMOUNT IN EXCESS OF THE PRICE, FEE, OR CHARGE RECEIVED BY GAUMARD FOR SUCH PRODUCT OR SERVICE.
- 10. Governmental Authorizations. Customer is responsible for compliance and costs associated with all required licenses, permits, or other governmental authorizations, including but not limited to, any license or certification needed for Customer to use the Product, and any export or import license, exchange permit, or the like ("Licenses"), even if applied for by Gaumard on Customer's beHAL*f. If any authorization is delayed, denied, revoked, restricted, or not renewed, Gaumard sHAL*f not be liable, and Customer is not relieved of its obligations. Customer represents and agrees that it will handle all Product and technical data related to the Licenses so that it conforms to all applicable U.S. laws and regulations, including U.S. export licensing laws and the U.S. Foreign Corrupt Practices Act. Customer sHAL*f not trans-ship, divert, re-export or otherwise dispose of any U.S. origin goods or technology obtained from Gaumard except as U.S. laws and regulations expressly permit.

11. Indemnity.

- a. Gaumard agrees to indemnify, defend and hold Customer, its officers, directors, employees, agents and contractors harmless from and against all loss, damage, liability, cost and expense (including reasonable attorneys' fees and expenses) by reason of any claims or actions by third parties against Customer for (1) bodily injury or death, and damage, loss or destruction of any real or tangible personal property, which third party claims arise out of or relate to Gaumard's gross negligence or willful misconduct or (2) infringement or misappropriation by Gaumard of any intellectual property rights under this Agreement.
- b. Customer agrees to indemnify, defend and hold Gaumard, its officers, directors, employees, agents and contractors harmless from and against all loss, damage, liability, cost and expense (including reasonable attorneys' fees and expenses) by reason of any claims or actions by third parties against Gaumard for (1) bodily injury or death or damage, loss or destruction of any real or tangible personal property, which third party claims arise out of or relate to Customer's gross negligence or willful misconduct; (2) infringement or misappropriation by Customer of any intellectual property rights; or
- (3) Customer's or its customer's use of the Products or Services, including without limitation, defamation, libel, slander, obscenity, pornography, or violation of the rights of privacy or publicity, or spamming or any other tortious or illegal conduct.
- 12. Software License. For purposes of these Terms, the term "Software" includes all Gaumard computer software, firmware, and associated documentation, whether in printed or machine-readable form, supplied by reason of this Agreement or for use in connection with Equipment or Services. To the extent the Product includes Software, Customer's use of the Software is governed by the Gaumard End User License Agreement attached as Exhibit A to these Terms.
- 13. Confidential Information. Customer sHAL*I maintain the confidentiality of any information provided or disclosed by Gaumard relating to the Software (as defined above), business or customers of Gaumard, as well as this Agreement and its terms (including the pricing and other financial terms under which the Customer will be obtaining the Services hereunder). Customer sHAL*I use reasonable care to protect the confidentiality of Gaumard's information disclosed, but no less than the degree of care it would use to protect its own confidential information, and sHAL*I only disclose Gaumard's confidential information to its employees and agents having a need to know this information and who are subject to confidentiality agreements having terms at least as restrictive as those contained herein. The obligations of confidentiality set forth herein sHAL*I not apply to any information in the public domain at the time of disclosure.
- 14. Intended Uses. Products are only intended for the uses described in the applicable user's manual or instructions for use. Customer assumes all risks associated with non-listed uses of Products and hereby indemnifies and holds Gaumard harmless from any claim associated with such non-listed uses.



- Compliance with Laws. Gaumard and Customer agree to comply with all federal and state laws that govern the enforceability and performance of this Agreement.
- HIPAA Compliance. As of the Effective date, the Parties are not planning to transfer any personal patient information between them. However, the Parties understand and agree that this Agreement may become subject to the Health Insurance Portability and Accountability Act of 1996 as amended ("HIPAA"), the privacy and security regulations promulgated thereunder, including 45 C.F.R. 160, 162 and 164, as amended (the "HIPAA Regulations"), and Title XIII of Division A and Title IV of Division B (the "Health Information Technology for Economic and Clinical Health Act ("HITECH"), part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) ("ARRA"). The Parties agree to strictly comply with HIPAA and to execute any documents that may be required by HIPAA, HITECH, and any other applicable federal or state privacy laws and regulations. The Parties agree that if they directly or indirectly gain access to Protected Health Information ("PHI") held by the other Party during any interaction, the receiving Party will keep the PHI confidential under the terms of this Agreement
- State Reporting and Disclosure Laws. Unless otherwise noted in this Agreement, the cost of any Product training provided by Gaumard sHAL*I be included in the purchase price of the Product where applicable. Customer acknowledges and agrees that state reporting laws may require Gaumard to disclose certain aspects of this arrangement.
- Fraud and Abuse. Gaumard hereby certifies that it is not currently a listed vendor in the: (a) Federal General Services Administration's "List of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with Presidential Executive Orders 12549 and 12689 "Debarment and Suspension;" and (b) in the Office of the Inspector General of the Department of Health and Human Services' "List of Excluded Individuals/Entities." Any discounted pricing terms offered under this Agreement may be a "discount or other reduction in price" under the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Customer sHAL®I take all actions necessary to comply with the Anti-Kickback Statute discount safe harbor regulations, 42 C.F.R. § 1001.952(h), including but not limited to, (1) maintaining accurate records reflecting the pricing terms of items and Services purchased under this Agreement, (2) fully and accurately report any discount received under this Agreement if applicable, and (3) make available information provided to Customer by Gaumard concerning cost reports and other filings with the government, including but not limited to, the Secretary of the U.S. Department of Health and Human Services or other state agencies.
- Bankruptcy. Except as may be prohibited by applicable bankruptcy laws, a Party to this Agreement may elect to terminate this Agreement (including any Purchase Orders) if any of the following situations arise: (1) the other Party becomes insolvent or is unable to pay debts as they become due; (2) a voluntary or involuntary bankruptcy proceeding is instituted by or against a Party hereto; or (3) an appointment of a receiver or assignee for the benefit of creditors occurs on beHAL®f of a Party hereto.
- Waiver and Severability. If either Party fails to perform obligations under this Agreement, such nonperformance sHAL*I not affect the other Party's right to enforce performance at any time. Waiver of any remedy or material breach of any subject matter contained in this Agreement sHAL®I not be viewed as a waiver unless agreed to by the Parties in writing. Each provision of this Agreement is separate and independent of one another, and the unenforceability of any provision will not affect the enforceability of any other provision. If any provision is held to be excessively broad or unenforceable, such provision sHAL* be modified so that it is enforceable to the fullest extent possible by law.
- Assignment. Customer sHAL*I not assign this Agreement without the prior written consent of Gaumard, which consent sHAL*I not be unreasonably withheld or delayed. Subject to the foregoing, the rights and obligations herein will be binding upon the successors and assigns of Customer.
- 22. Notices. Any required notices will be given in writing to Gaumard as set forth in the applicable Gaumard Purchase Order or other purchasing document.
- 23 Governing Law. Upon execution, this Agreement sHAL®I be governed and viewed under the laws of the State of Florida without reference to its conflict of laws provisions. Customer and Gaumard specifically agree that any action relating to the relationship between the Parties, the Agreement, or Products provided, purchased or licensed hereunder, sHAL*I be brought and tried in the Courts of Dade County, Florida. Customer waives all objections to, and consents to the jurisdiction of such Courts.
- Miscellaneous. See applicable Gaumard Purchase Order documents, Gaumard Warranty documents, and Gaumard Cares Service Plan documents for other terms and conditions, which may include, but are not limited to: Term, Termination, Customer Training and Support, and Product Repairs and Tune Ups.

9.3 END USER LICENSE AGREEMENT

GAUMARD END USER LICENSE AGREEMENT

This End User License Agreement ("EULA") sets forth the respective rights and responsibilities between the entity named in the Purchase Order associated with this EULA ("End User") and Gaumard Scientific Company, Inc., a Florida corporation ("Gaumard"), relative to the Gaumard Software (as defined below). This EULA is effective as of the date Gaumard accepts and confirms the Purchase Order (the "Effective Date"). BY USING THE GAUMARD SOFTWARE, END USER IS AGREEING TO BE BOUND BY THE TERMS OF THIS EULA. IF END USER DOES NOT AGREE, END USER MAY NOT USE THE GAUMARD SOFTWARE.

- 1. Definitions.
- 1.1 "Gaumard Documentation" means the Gaumard user and operations manuals, guides, and related materials provided by Gaumard to End User to facilitate use of the Gaumard Products.
- 1.2 "Gaumard Equipment" means Gaumard hardware components for medical simulation and training, including manikins and associated instrumentation, and other hardware and tangible products sold by Gaumard to End User.
- 1.3"Gaumard Products" means Gaumard Software licensed and Gaumard Equipment sold or otherwise made available by Gaumard to End User currently or in the future.



- 1.4 "Gaumard Software" means the object code form of computer programs and Gaumard Documentation owned by Gaumard or its licensors and licensed to End User in accordance with this EULA. Gaumard Software includes (a) computer programs embedded in firmware in the Gaumard Equipment; (b) computer programs embedded in a separate medium (such as CD or flash drive) for use in conjunction with the Gaumard Equipment; (c) computer programs downloaded or received via mail from Gaumard; (d) computer programs used on servers storing or processing data related to the Gaumard Products; and (e) computer programs used to create and manage a network for the Gaumard Equipment, interface with the components of the Gaumard Equipment, manage and compute location information related to the Gaumard Equipment, and monitor health of the Gaumard Equipment.
- 2. Software License and Restrictions.
- 2.1License. Subject to End User's compliance with the terms and conditions of this EULA, the Gaumard Sales Terms and Conditions, the Purchase Order, and the Gaumard Cares Service Plan Agreement, Gaumard grants End User a non-exclusive, non-transferable (except as otherwise set forth herein), personal license to execute and use the Gaumard Software for End User's internal purposes, but only so long as the Gaumard Software is installed on the Gaumard Product on which it was originally installed. End User may not, directly or indirectly, sell, sublicense, display, timeshare, loan, lease, distribute, or create derivative works of the Gaumard Software.
- 2.20wnership. All rights, title, and interest in and to the Gaumard Software, and any derivative works thereof, whether created by Gaumard, End User, or a third party, will remain at all times solely and exclusively owned by Gaumard. Nothing in this EULA or the Purchase Order will be construed to grant End User any rights of any kind with respect to the Gaumard Software, except as expressly set forth in this EULA.
- 2.3 Reverse Engineering and Other Restrictions. End User will not, and will not allow any third party to, tamper with, modify, decompile, disassemble, derive the source code of, reverse engineer, or attempt to obtain the internal design of the Gaumard Software or Gaumard Products for any purpose whatsoever (collectively, "Restricted Acts"). If applicable law permits End User to take any of the Restricted Acts notwithstanding the previous prohibition, and End User wishes to take any Restricted Act notwithstanding the previous prohibition, End User will first provide Gaumard with thirty (30) days prior written notice. Gaumard may terminate this EULA at any time during such notice period without liability arising from such termination. The parties agree that all information needed for interoperability is available from Gaumard in accordance with applicable government directives.
- 2.4Updates. From time to time Gaumard may develop new versions or updates for the Gaumard Software that may be made available to the End User as agreed under the terms of the Gaumard Sales Terms and Conditions, Gaumard Purchase Order documents, Gaumard Warranty documents, or Gaumard Cares Service Plan documents. Unless otherwise agreed to by Gaumard, End User sHAL*I be responsible for installing the provided new versions or updates for the Gaumard Software.
- 2.5Proprietary Notices. End User agrees to maintain and reproduce on all copies of the Gaumard Software, any names, logos, copyright notices, trademarks, other proprietary markings, and legends that appear on the Gaumard Software.
- 2.6Control of Duplication. End User will not, nor will it allow any third party to, circumvent the protection controlling the duplication or use of the Gaumard Software, for example and without limitation, any software lock controlling the number of copies End User may make of the Gaumard Software.
- 2.7No Source Code. End User acknowledges and agrees that its rights under this EULA do not include rights to source code. In its exercise of the rights granted under this EULA, End User agrees not to take any action that would result in any requirement to disclose or make available to other parties the Gaumard Software in source code format.
- 2.8 Certification. Upon thirty (30) days written notice to End User from Gaumard, End User sHAL*I certify End User's compliance with the restrictions and obligations in this EULA. Such requests will not occur more frequently than once per calendar year. If End User has used the Gaumard Software in violation of this EULA, End User sHAL*I, in addition to any other remedies Gaumard may have, pay Gaumard additional fees for the excess use according to Gaumard's then-current price list and policies, plus a late payment charge of one percent (1.0%) per month (or the highest amount allowed by applicable law, if lower) for each month of excess use from the date of initial excess use.
- 2.9Privacy and Recordings. End User will comply with all applicable laws, rules and regulations related to privacy, publicity and data protection related to use of the Gaumard Products. End User sHAL*I not use the Gaumard Software to record or collect personal data from any person in violation of End User's policies or privacy statements. End User sHAL*I receive express consent from all persons recorded by the Gaumard Software sufficient for End User's use, storage, and distribution of such recordings.
- 3. Term and Termination
- 3.1Term. This EULA commences on the Effective Date and continues perpetually, unless terminated earlier in accordance with the terms hereof.
- 3.2Termination for Cause. This EULA is automatically terminated by Gaumard if the other party materially breaches this EULA, the Gaumard Sales Terms and Conditions, the Purchase Order, or the Gaumard Cares Service Plan Agreement. In addition, Gaumard may terminate this EULA if (a) End User becomes insolvent or makes an assignment for the benefit of End User's creditors; or (b) a receiver is appointed or a petition in bankruptcy is filed with respect to End User and such petition is not dismissed within thirty (30) days.
- 3.3Effect of Termination. Upon the termination of this EULA for any reason, all licenses granted in Section 2 above will immediately cease and terminate. Upon termination, End User will immediately cease using the Gaumard Software.
- 3.4 Survival. Sections 3 through 6 will survive the termination of this EULA.
- 4. Confidential Information; Trademarks.
- 4.1Confidential Information. End User acknowledges and agrees that the Gaumard Software is confidential information and contains trade secrets of Gaumard. End User agrees to (i) hold the Gaumard Software in the strictest confidence, (ii) not disclose the Gaumard Software to any third party for any purpose, and (iii) use at least the same security measures as End User to protect its own confidential and trade secret information but no less than reasonable measures to protect the confidentiality of the Gaumard Software. End User agrees and acknowledges that any breach of the provisions regarding ownership or confidentiality contained in this Agreement sHAL®I cause Gaumard irreparable harm and Gaumard may obtain injunctive relief without the requirement to post a bond as well as seek all other remedies available to Gaumard in law and in equity in the event of breach or threatened breach of such provisions.
- 4.2Trademarks. End User may not use Gaumard's trademarks, logos, service marks, or names in press releases, web sites, marketing, or other forms of public materials without the prior written consent of Gaumard. All use of the Gaumard trademarks and all goodwill associated with them will inure solely to the benefit of Gaumard.
- 5. Disclaimer; Limitation of Liability; Infringement Indemnification
- 5.1 Warranty and Disclaimer. For a period of twelve (12) months from the Effective Date, Gaumard will (a) provide all updates to the Software that are made available generally, and (2) use reasonable efforts to fix or provide a workaround for any Gaumard Software defect or bug which prevents operation in substantial conformity with the Gaumard Documentation. Other than the above, the Gaumard Software is provided "as- is," with no express or implied warranties of any kind, including the warranties of merchantability, fitness for a particular purpose, or non-infringement.
- 5.2Limitation of Liability, THE TOTAL LIABILITY, IF ANY, OF GAUMARD TO END USER OR ANY THIRD PARTY FOR ALL DAMAGES BASED ON ALL



CLAIMS, WHETHER ARISING FROM BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, INDEMNITY, STRICT LIABILITY, TORT, OR OTHERWISE, ARISING FROM THE GAUMARD PRODUCTS IS LIMITED TO ONE HUNDRED DOLLARS. IN NO EVENT WILL GAUMARD BE LIABLE TO END USER OR ANY THIRD PARTY FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES, INCLUDING BUT NOT LIMITED TO, LOSS OF REVENUES, LOSS OF PROFITS, OR LOSS OF DATA, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

5.3 Infringement Indemnification. Gaumard will, as further described below, indemnify, defend, and hold End User harmless, at its expense, against any claim or suit brought by a third party against End User alleging that any Gaumard Software furnished under this EULA infringes the United States patent, trademark, copyright or other intellectual property right of a third party. Gaumard will pay all settlements entered into or damages finally awarded, including attorneys' fees and costs, based on any such claim or suit; provided that End User gives Gaumard prompt written notice of such claim and gives Gaumard information, reasonable assistance, and sole authority to defend or settle the claim. In defense or settlement of the claim, Gaumard may obtain for End User the right to continue using the Gaumard Software, replace or modify the Gaumard Software so that it becomes non-infringing, or, if such remedies are not reasonably available, grant End User a refund for the associated Gaumard Products (depreciated over three years) and accept their return. Gaumard will not have any liability if the alleged infringement is based upon (a) the use or sale of the Gaumard Software in combination with other products or devices not furnished by or approved by Gaumard; (b) the use of the Gaumard Software in a manner for which they were not designed as described by the Gaumard Documentation; (c) any modification of the Gaumard Software not performed by or authorized by Gaumard;

(d) any use of Gaumard Software by End User after End User learns of such allegation of infringement; or (e) any failure by End User to utilize a non-infringing version of the Gaumard Software made available by Gaumard along with notice that such update is non-infringing. The obligations set forth in this Section 5.3 are Gaumard's sole obligations, and End User's sole and exclusive remedy, for the Gaumard Software infringing third party intellectual property rights.

6. Miscellaneous.

6.1Binding Effect; Assignment. This EULA will be binding upon, and inure to the benefit of, End User's and Gaumard's respective permitted successors and permitted assigns. Neither party may assign or transfer this EULA or any of the rights, privileges, duties or obligations under this EULA without the prior written consent of the other party, except that either party may assign this Agreement to any entity controlled by, controlling, or under common control with such party at such time, as well as in connection with the sale, transfer, merger, or acquisition, whether by operation of law or otherwise, of substantially all of the assets of such party. In addition, if End User transfers the Gaumard Product on which the Gaumard Software is installed to a third party, End User may assign this EULA to such third party, provided that the third party agrees in writing with Gaumard to be bound by this EULA.

6.2Notices. Any written notice required by this EULA will be deemed made (a) when delivered by personal service, (b) one (1) business day after being sent by recognized international overnight courier service (such as FedEx), or (c) when received, if sent by certified or registered mail, postage prepaid, return receipt requested. Any such notice given to a party sHAL* be sent to the addresses on the attached Purchase Order. By giving to the other party written notice thereof, the parties hereto and their respective permitted successors and assigns will have the right from time to change by written notice their respective addresses or address for notices.

6.3 Applicable Law. The validity of this EULA and the rights, obligations and relations of the parties hereunder sHAL* be construed and determined under and in accordance with the substantive laws of the State of Florida. All disputes arising under or related to this EULA sHAL* be resolved exclusively in the State or Federal Courts located in Dade County, Florida. The parties consent to the jurisdiction and venue of such courts and waive any claims as to inconvenient forum. The judgments of such courts may be enforced in any court of competent jurisdiction.

6.4 Export Control. End User will not export or re-export the Gaumard Software, including any technical data, except as authorized and permitted by, and in compliance with, the laws and regulations, including but not limited to all export and re-export laws and regulations, of the United States.

6.5Severability. If any provision of this EULA is invalid or unenforceable in any circumstances, it will be interpreted as much as possible to reflect the intent of the parties, and its application in any other circumstances and the remaining provisions of this EULA will not be affected thereby.

6.6 Entire Agreement. This EULA constitutes the entire agreement and understanding of the parties relating to the subject matter thereof. This EULA supersedes all prior written and oral agreements and all other communications between End User and Gaumard (or a Gaumard distributor) regarding the subject matter hereof. No contradictory terms and conditions of any purchase order, invoice, or other document issued by End User relating to the subject matter of this EULA sHAL*I be binding, unless agreed by the parties.

6.7 Waiver of Breach. No waiver by a party of any breach of this EULA will constitute a waiver of any other breach of the same or other provisions of this EULA. No waiver by a party will be effective unless made in a record signed or otherwise authenticated by an authorized representative of such party.

6.8Relationship of the Parties. The parties are independent contractors. Nothing in this EULA or in the activities contemplated by the parties will be deemed to create an agency, partnership, employment or joint venture relationship between the parties. Neither party will have any responsibility nor liability for the actions of the other party except as expressly provided in this EULA. Neither party will have any right or authority to bind or obligate the other party in any manner or make any representation or warranty on beHAL*f of the other party. This EULA is made and entered into for the sole protection and benefit of Gaumard, its licensors and suppliers, and End User, and no other person or entity sHAL*I be a direct or indirect beneficiary of or sHAL*I have any direct or indirect cause of action or claim arising from this EULA.

All rights not expressly granted in this license agreement are reserved by Gaumard.

ACKNOWLEDGMENT

By installation of this software, you acknowledge that you have read and understand the foregoing and that you agree to be bound by its terms and conditions. You also agree that this agreement is the complete and exclusive statement of agreement between the parties and supersedes all proposed or prior agreements, oral or written, and any other communications between the parties relating to the license described herein.



9.4 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;
- » 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. However, third-party products are covered by the warranties provided by the respective third-party manufacturers and such warranties are transferred from Gaumard to purchaser upon purchase of the Gaumard product. Defects in third-party products are covered exclusively by the warranties provided by the third-parties. Gaumard does not provide any warranty, express or implied, with respect to any third-party products. Please contact the third-party manufacturer for information regarding the availability of extended warranties for third-party products.

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.

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.



9.5 CONTACT TECHNICAL SUPPORT

Before contacting Technical Support, please make sure to have the following:

- 1. Your simulator's serial number
- 2. Access to the simulator for possible troubleshooting as needed

Technical Support

Email: support@gaumard.com

USA: 800-882-6655 INT: 01-305-971-3790

9.6 GENERAL INFORMATION

Sales and Customer Service

E-mail: sales@gaumard.com

USA: 800-882-6655 INT: 01-305-971-3790 Fax: 305-252-0755

Post

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

Office Hours

Monday-Friday, 8:30am - 7:30pm EST (GMT-5)



Gaumard*, ZOE*, Michelle*, Mike*, PEDI*, Susie Simon*, Susie*, Simon* Code Blue*, SIMA Models*, SIMA GYN/AID*, Virtual Instruments*, Codemaker*, Code Blue*, NOELLE*, Simulation Made Easy™, HAL*, eCPR™, Zack™, RITA™, Chloe™, Seatbelt Susie™, Krash Kids™, Premie™, UNI™, Omni*, Omni* 2, SmartSkin™ are trademarks of Gaumard Scientific Company.

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

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