PEDI[®] Blue

Neonate Simulator with Newborn HAL body and SmartSkin[™] Technology S320.101



PEDI BLUE is an interactive educational system developed to assist a certified instructor. It is not a substitute for a comprehensive understanding of the subject matter and not intended for clinical decision making. User Guide PB.12.5.1 © Gaumard Scientific Company,2012 All Rights Reserved www.Gaumard.com

Contents

END USER LICENSE AGREEMENT	
CARE AND CAUTIONS	6
OVERALL WARNINGS	7
GETTING STARTED	8
Overview Terminology	
EQUIPMENT SET UP	10
Power Supply Omni™ Setup	11 11
USING OMNI™	12
MAIN SCREEN	
NAVIGATION MENUS	
PEDI [®] BLUE FEATURES	14
PEDI [®] BLUE FEATURES AIRWAY BREATHING. CIRCULATION. SYSTEMIC. CEPHALIC.	14
PEDI [®] BLUE FEATURES AIRWAY. BREATHING. CIRCULATION. SYSTEMIC. CEPHALIC. CPR TOOLS.	14

End User License Agreement

This is a legal agreement between you, the end user, and Gaumard[®] Scientific Company, Inc. ("Gaumard"). This software is protected by copyright laws and remains the sole property of Gaumard. By installing the CPRLink (the "Software") media, you agree to be bound by the terms of this agreement. If you do not agree to the terms of this agreement, promptly return the uninstalled media and accompanying items to Gaumard at the address indicated below.

1. Grant of License. Gaumard hereby grants to you (an individual or institution) the right to install and activate the Software on one computer for use with one Interactive patient simulator system. The software may also be installed on any number of other computers at the same institution so that students may access the learning resources. One copy of the software may be made for backup purposes. You may not network this Software, or allow multiple users unless you purchased a multi-user workstation license. Sharing this Software with other individuals or allowing other individuals to view the contents of this Software is in violation of this license.

2. Copyright. The Software is owned by Gaumard and protected by United States copyright laws and international treaty provisions. Therefore, you must treat this Software like any other copyrighted material. You may not make this Software or copies thereof available in any manner or form or use, copy or transfer the Software, in whole or in part, except as provided herein.

3. Other Restrictions. You may not rent or lease this Software to any other party. You may not alter, merge, modify, adapt, reverse engineer, decompile or disassemble the software, or disclose the contents of this Software to any other party.

4. Electronic Transmission of Software. If you received the Software by electronic transmission or by Internet delivery, by installation of the Software, you acknowledge that you have read and understand this license agreement and agree to be bound by its terms and conditions.

5. Term of Agreement. The term of this Agreement and the license granted to you pursuant hereto shall commence upon installation of this Software. This Agreement and the license granted herein may otherwise be terminated by Gaumard in the event that you are in breach of any provision of this Agreement. In the event of termination, you agree to immediately return this Software, accompanying items, and any copies thereof to Gaumard.

6. LIMITED WARRANTY

(A) THE CD-ROM MEDIA (THE "MEDIA") WHICH CONTAINS THIS SOFTWARE IS WARRANTED, FOR A PERIOD OF 30 DAYS FROM THE DATE OF PURCHASE, TO BE FREE FROM DEFECTS IN MATERIAL AND WORKMANSHIP. ELECTRONIC TRANSMISSION IS WARRANTED TO BE FREE FROM DEFECTS AT THE MOMENT OF TRANSMISSION. YOUR SOLE AND EXCLUSIVE REMEDY, AND GAUMARD'S SOLE LIABILITY, IS TO REPLACE THE DEFECTIVE MEDIA OR TO REPEAT THE ELECTRONIC TRANSMISSION PROVIDED THAT YOU NOTIFY GAUMARD IN WRITING OF SUCH DEFECT OR DEFECTIVE TRANSMISSION AND RETURN THE DEFECTIVE MEDIA, IF ANY, DURING THE 30-DAY WARRANTY PERIOD. (B) EXCEPT AND TO THE EXTENT EXPRESSLY PROVIDED IN PARAGRAPH (A), THE SOFTWARE AND ACCOMPANYING WRITTEN MATERIALS ARE PROVIDED ON AN "AS IS" BASIS, WITHOUT ANY WARRANTIES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. NO ORAL OR WRITTEN INFORMATION OR ADVICE GIVEN BY GAUMARD, ITS DEALERS, DISTRIBUTORS, AGENTS OR EMPLOYEES SHALL CREATE A WARRANTY OR IN ANY WAY INCREASE THE SCOPE OF THIS WARRANTY, AND YOU MAY NOT RELY ON ANY SUCH INFORMATION OR ADVICE. GAUMARD DOES NOT WARRANT, GUARANTEE, OR MAKE ANY REPRESENTATIONS REGARDING THE USE OR THE RESULTS OF USE, OF THE SOFTWARE OR WRITTEN MATERIALS IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, CURRENTNESS, OR OTHERWISE, AND THE ENTIRE RISK AS TO THE RESULTS AND PERFORMANCE OF THE SOFTWARE IS ASSUMED BY YOU. IF THE SOFTWARE OR WRITTEN MATERIALS ARE DEFECTIVE, YOU AND NOT GAUMARD OR ITS DEALERS, DISTRIBUTORS, AGENTS, OR EMPLOYEES, ASSUME THE ENTIRE COST OF ALL NECESSARY SERVICING, REPAIR OR CORRECTION OTHER THAN EXPRESSLY DESCRIBED ABOVE.

(C) NEITHER GAUMARD NOR ANYONE ELSE WHO HAS BEEN INVOLVED IN THE CREATION, PRODUCTION OR DELIVERY OF THIS PRODUCT SHALL BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES (INCLUDING DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, AND THE LIKE) ARISING OUT OF THE USE OR INABILITY TO USE SUCH PRODUCT OR RELATED TO THIS AGREEMENT EVEN IF GAUMARD HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. GAUMARD SHALL NOT BE LIABLE TO YOU FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OR LOST PROFITS ARISING OUT OF OR RELATED TO THIS AGREEMENT OR YOUR USE OF THE SOFTWARE AND/OR THE RELATED DOCUMENTATION, EVEN IF GAUMARD HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL GAUMARD'S LIABILITY HERE UNDER, IF ANY, EXCEED THE PURCHASE PRICE PAID BY YOU FOR THE SOFTWARE.

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.

Care and Cautions

Overall Warnings

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

GENERAL

Ball point pens, ink and markers permanently stain the skin.

Do not wrap this or any other Gaumard product in newsprint.

Indelible marks made with ballpoint pens, ink or marker cannot be removed.

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.

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

Replacement parts are available from Gaumard Scientific or from your Distributor.

PROCEDURES

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

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

Treat PEDI Blue with the same precautions that would be used with a real patient.

STORAGE

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

Do not stack or store heavy materials on top of the carton.

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

CLEANING

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

Remove all traces of any lubricant.

Do not clean with harsh abrasives.

Do not use povidone iodine on the simulator.

Dry thoroughly.

PEDI Blue is "splash-proof" but not waterproof. Do not submerge or allow water to enter the interior of the simulator.

SET UP

PEDI Blue will only power on when connected to the AC power supply.

Getting Started

Overview

PEDI Blue neonate is a life support training simulator equipped with the following features:

CONTROLLER

- Powerful yet intuitive user controller and interface software
- Resuscitation modeling

AIRWAY

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

APPEARANCE

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

BREATHING

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

CIRCULATION

- Chest compressions are measured and logged
- Umbilical pulse

SIMULATOR

- Heart, lungs and ribs
- Optional Intraosseous access at tibia
- Optional IV training arm
- Physical size is 50th percentile at 40 weeks gestational age
- Realistic airway with tongue, vocal cords, trachea and esophagus
- Patent umbilicus

Terminology

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

Provider - a person participating in the simulation as a healthcare provider.

Code Blue[®] –feature of Omni to monitor, train and evaluate CPR.

CPRLink[™] - the application to monitor, train and evaluate CPR on a PC.

Equipment Set Up

10 |User Guide| | PEDI Blue |

Power Supply

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





Always operate PEDI Blue with the power supply connected.

Omni[™] Setup

Omni controls PEDI Blue with the touch of button.

1. Connect the communication cable to PEDI Blue.





2. Connect the other end of the communication cable to Omni.



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



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

WARNING:

Do not connect PEDI Blue or Omni to a computer, LAN network or unauthorized diagnostic equipment using the communication cable (Ethernet cable). Doing so will cause serious damage to the equipment.

Using Omni[™]

Main Screen

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



FEEDBACK GRAPHICS

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



CURRENT SETTINGS

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



Navigation Menus

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



PEDI[®] Blue Features



Airway

NASAL AND ORAL INTUBATION

PEDI Blue's airway can be intubated orally using LMA or endotracheal tubes and nasally using a nasogastric tube.

WARNING:

Always lubricate tubing and nasal opening prior to performing nasal or oral exercises.

Failure to do so will make intubation very difficult and is likely to result in damage. It is not recommended that you spray silicone oil directly into the mouth and airway.

Procedure	Recommended Device Size
Intubation (Blade size)	Miller 0
LMA	Size 1
Nasal Intubation	8 Fr catheter
Oral Intubation	ETT 3.0 no cuff, 6 Fr suction catheter

SUCTION

PEDI Blue can be used to simulate suction procedures.

Breathing

PULMONARY VENTILATION

Practice BVM techniques using an infant sized mask having a thick seal. Bilateral lung expansion is perceived with realistic chest rise. Train CPR with PEDI Blue and obtain feedback information via the Omni controller on the cadence and depth of chest compressions and airway ventilations.

Circulation

PALPABLE PULSE

The umbilical cord remains patent for several hours after birth and may be used to infuse medications in a critically ill neonate.

Generate palpable umbilical pulses using the squeeze bulb.

IV ACCESS (OPTIONAL S320.101.2)

Pedi Blue has IV access in the lower right arm that can be used for bolus or intravenous infusion as well as for draining fluids. It is only to be used as part of an approved program for Pediatric care.

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

A translucent, pliable skin, which is removable and washable, is stretched over the lower arm.

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

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

FILLING IV SYSTEM

Fill the IV system with the tubing located on the right arm of the simulator. Designate one tube to fill and the other to drain.

- 1. Place end of drainage tube into a container and open the adjustable clamp.
- 2. Fill the dispensing syringe with fluid.
- 3. Connect the syringe to fill tube and release the fluid. Allow fluid to flow through the system and into the drainage container.
- 4. Close the adjustable clamp of drainage tube.
- 5. Remove the syringe from the filling tube.

DIRECTIONS FOR USE

For IV infusion simulations, place the end of drainage tube into a container and open the adjustable clamp. Leave clamp open until the IV infusion is stopped to prevent damage to simulator.

WARNING:

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

Systemic

INTRAMUSCULAR INJECTION SITES

IM sites are located on both deltoids and quadriceps for placement and technique exercises.

WARNING:

Do not inject fluids into the intramuscular sites.

INTRAOSSEOUS ACCESS (OPTIONAL S320.101.1)

Intraosseous access is used for the infusion of fluids, blood and/or drugs directly into the bone marrow of the tibia or other large bone. Setting up an intraosseous access line is an invasive procedure that can be simulated with the Pedi Blue's lower right leg.

The intraosseous access kit includes: modified tibia bones with filling and drainage tubing, a fluid dispensing syringe and synthetic blood concentrate.

INSTRUCTIONS FOR USE

The following procedure describes how to use the I/O access feature:

1. Palpate tibial tuberosity.

2. Insert bone aspiration needle below tibial tuberosity. Note the sharp decrease in needle resistance as it passes into the bone marrow cavity. Remove stylet, aspirate bone marrow, and infuse fluids.

REPLACING THE TIBIA

- 1. Remove the skin cover from the right lower leg.
- 2. Remove the tibia bone insert.
- 3. Connect the fill syringe to the tibia bone insert.
- 4. Fill the tibia insert with fluid to maximum capacity.
- 5. Re-insert the tibia bone into the cavity and replace the skin.

WARNING:

Always drain and flush the reservoirs after simulation.

UMBILICAL CORD

Pedi Blue's umbilical cord can be catheterized or injected with fluid.

FILLING THE UMBILICAL CORD

To fill the umbilical cord with fluid, follow the instructions listed below.

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

4. Once the water is seen draining, close the adjustable clamp.

For catheterization, use a 6 Fr urethral round tip catheter lubricated with silicon oil.

Cephalic

CYANOSIS

Pedi Blue has devices in its forearms, lower legs and face to cause the skin to turn from a normal healthy color to a blue color indicative of peripheral and central cyanosis. These devices which we call SmartSkin are controlled by the Omni Controller.

Perform CPR, and Omni will automatically detect the compressions and ventilations to determine whether they meet or exceed conventional neonatal CPR standards. If acceptable, the Omni controller causes the skin to turn to a more healthy color, if inadequate or non-existent, Omni causes the skin to turn toward an ominous blue color.

CPR Tools

CODE Blue[®]

Code Blue is a CPR training tool incorporated in the Omni controller. It was designed to help teach CPR by monitoring cadence and depth of cardiac compressions and airway ventilations in real time.

WARNING:

Do not perform mouth to mouth ventilation since the simulator airway can be difficult to clean afterwards.

CODE BLUE COMPONENTS

Code Blue consists of the Feedback Graphics and specialized control menus. The menus are:

- CPR operational mode TEST or COACH mode
- Cyanosis control the blue discoloration of the skin of the simulator
- C:V Ratio customize the compression to ventilation ratio to match correct guidelines
- Compression/Ventilation Rate adjust the number of compressions and ventilations per minute
- Status toggle the condition of the simulator between improve, worsen or pause.

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

CODE BLUE MENUS

MODE MENU

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

CYANOSIS MENU

Adjust the cyanosis intensity to control the blue discoloration of the skin of the simulator. The range of cyanosis is 0% to 100%.

C: V RATIO Menu (COMPRESSION TO VENTILATION RATIO)

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

CMP/VNT RATE Menu (COMPRESSION OR VENTILATION RATE)

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

STATUS MENU

Toggle between PAUSE, WORSEN and IMPROVE.

Improve: simulator will trend to a healthy state until the cyanosis percentage is at zero.

Worsen: simulator will trend to a severely cyanotic state. If CPR given to the neonate is of correct depth and rate, cyanosis level will decrease. Otherwise, it will continue to increase.

Pause: simulator will pause at current cyanotic state.

MORE MENU

Press MORE to access additional menu selections.

CALIBRATING CHEST COMPRESSIONS (C CAL.)

Your simulator comes pre-calibrated to current CPR guidelines at time of manufacture. If the CPR guidelines change, calibrate the sensors inside the simulator using this option.

Set the standard against which compression will be evaluated during the exercise.

Calibrating chest compressions:

- 1. Select C CAL.
- 2. Press **START** to begin the calibration procedure.

Omni will ask you to perform several correct chest compressions. The facilitator should follow the text cue on the screen to perform just one compression at a time until finished.

When Omni is ready to calibrate it will display **COMPRESS**.

3. Perform a correct compression.

Follow the text cue on the screen to perform the remaining four compressions. When the calibration is complete Omni will display **DONE**.

4. Press SAVE.

CALIBRATING AIRWAY VENTILATIONS (V CAL.)

Calibrate the sensors inside the simulator using this option. Set the standard against which ventilation will be evaluated during the exercise.

Calibrating airway ventilations:

- 1. Select V CAL.
- 2. Press **START** to begin the calibration procedure.

Omni will ask you to perform a number of correct airway ventilations. The facilitator should follow the text cue on the screen to perform just one ventilation at a time, until finished.

- 3. When Omni is ready to calibrate it will display **VENTILATE**.
- 4. Perform a ventilation.

Follow the text cue on the screen to perform the remaining four ventilations. When the calibration is complete Omni will display **DONE**.

5. Press SAVE.

RESETTING OMNI'S PRESSURE SENSOR

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

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

After resetting the sensor, Omni will display DONE.

2. Select **SAVE** to finish.

LEVEL

Set the number of CPR cycles to define when the simulator will respond to treatment and fully recuperate from a cyanotic state.

For example, if the user sets the level to 5 and cyanosis to 100%, after every CPR cycle the cyanosis level will decrease by 20% until reaching 0% when the last CPR cycle is completed.

Unless the status of the simulator is set to pause or improve, cyanosis level will continue to increase.

TOLERANCES (%TOL)

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

CPR tolerance sets the permissible deviation from the selected compression or ventilation. For example, if the user sets the Compression Rate at 100 compressions / minute and the Compression Rate Tolerance at 10 %, any compression frequency between 90 and 110 compressions per minute will be considered correct.

BACK

Return to previous screen.

HELP

The help window provides access to global settings such as backlight time and Omni/Simulator serial number.

Backlight

The default value for Omni's backlight timer is 10 minutes. After 10 minutes the backlight will turn off.

To increase the backlight duration, adjust the backlight timer with the plus or minus sign. Press \mathbf{OK} to accept the changes.

Serial Number

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

CPRLink™

CRPLink is an application that enables monitoring and logging of compressions and ventilations performed in real time by the user on a PC.

This software aims to provide additional testing and teaching tools for CPR using an interface to display a waveform graph of the compressions and ventilations.

CPRLINK MINIMUM SYSTEM REQUIREMENTS

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

SETUP

CPRLINK SOFTWARE INSTALLATION

If installing the CPRLink software for the first time, follow the instructions listed below:

- 1. Insert the CPRLink installation CD in your PC.
- 2. Double click the installation file on the enclosed media.

In case the auto run is disabled, open My Computer. In the My Computer window, open the drive that contains the CPRLink CD. Double-click on CPRLink and locate setup. Double-click on setup to start the installation.

3. Follow the instructions on your screen.

EQUIPMENT SET UP

- 1. Connect the power supply to the power input on the simulator, and then connect the power supply to the wall outlet.
- 2. Connect the communication cable to the simulator and to Omni.
- 3. Connect the USB cable to Omni and to the USB port of your PC.

Omni will display a heart icon on the lower left side of the screen, when a connection with the PC has been established.

WARNING:

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

STARTING CPRLINK

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

CPR SCREEN

The CPRLink main screen contains the drop down menus used to save and clear session logs, change the application options, and access the program's help.

The main screen also contains the controls used to evaluate compressions and ventilations.

Open the CPR evaluator by clicking on the shortcut icon located on the upper right side of the application.

The provider performance indicator boxes are located on the right. The V (ventilation) and C (compression) box fill color changes between the following states:

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

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

COMPRESSION DATA

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

VENTILATION DATA

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

TRAINER

The CPRLink application generates visual and audible cues of the compression to ventilation ratio programmed in the CPR Options menu. When the **Trainer** button is clicked, the V (ventilations) and C (compressions) box borders blink to indicate the correct reference CPR rate. A high-pitched beep signals the care provider to perform a compression and a low pitched-beep signals a ventilation.

PERFORMANCE EXAMPLES

Compressions are too shallow. Most waveform peaks do not reach the green zone. Compression indicator is yellow.

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

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

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

Ventilations are too strong. Waveform peaks exceed the green zone.

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

PROVIDER ACTIONS SCREEN

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

rder Actors		_				manage on Parde
tousiers: T	un				Facilitatar:	
Basic Annen Report Annen Call for essetance	Arrivay Determine Determine Determine menagement + Opensimus + Insbeson-Check + Insbeson-Check +	Breathing Assess breathing + 02 device + 02 fless + Chest sube + Needle +	Creukation Anuch electrodes « Check for pulses « Extrability by	Trauma Care Ganal stabilisation * Nanaga bleeding *		
i Trovder Actors	Vertilate + Critidate +					Team

Open the provider actions screen by clicking on the shortcut icon located on the upper right side of the application.

The Provider Actions screen consists of four different areas (from top to bottom): session info, team logging buttons, provider action buttons, and text log.

SESSION INFO

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

FIOVIDEL ACUONS

Session Title:

Facilitator:

TEAM LOGGING

OK

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

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

Session Title:		
Providers:	Team	
Add Provider		
Name:		
Steve Parker		
Color:	< Change	

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

Cancel

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

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

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

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

PROVIDER ACTIONS

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

Basic	Airway	Breathing	Circulation	Trauma Care
Assess responsiveness +	Determine patency	Assess breathing +	Attach electrodes +	Spinal + stabilization +
Call for +	Airway management +	O2 device +	Check for pulses +	Manage bleeding +
	Open airway +	O2 flow +	Establish IV	
	Intubation Check +	Chest tube +		
	Intubation eval. +	Needle decompression +		
	Ventilate +			
	Extubate +			
DD Descrides Astisses				

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

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

SPECIAL BUTTON

The special button adds additional functionality to the provider actions section.

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

"00:02:24 Action (Ventilate)"

Basic	Airway				
Assess responsiveness +	Determine patency				
Call for +	Airway management +				
	Open airway +				
	Intubation Check +				
	Intubation eval. +				
	Ventilate +				
	Extubate +				
CPR Provider Actions					
00:02:24 Action (Ventilate)					

On the other hand, if the '+' button next to 'Ventilate' is clicked, a list of additional options appears.

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

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

Ventilate	Options:
	BVM
Extubate	transport ventilator
	mechanical ventilator
	Use correct hand
	СРАР
	BIPAP

TEXT LOG

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

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

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

Text Log is subdivided in four different functions:

ACTIONS

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

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

DETECTED EVENTS

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

"00:05:36 Detected (chest compression): too weak"

EVALUATIONS

The facilitator adds evaluations by clicking on the 'Satisfactory' or 'Unsatisfactory' buttons next to Text Log.

The facilitator can evaluate individual providers with a single click.

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

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

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

NOTES

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

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

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

CPRLINK MENUS

FILE

NEW SESSION

Clicking New Session in the file menu will:

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

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

Dession Time: 00:31:19 *	ø	Session	Time:	00:31:19 -
--------------------------	---	---------	-------	------------

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

😳 Session Time: 00:01:03 🗸		
	New Session	
	Reset Session Clock	

RESET SESSION CLOCK

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

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

SAVE REPORT

This option allows you to save all the information recorded in the log page as a text file. Clicking on it brings up the Save As dialog box:

🚱 Save As				X
C Repor	ts	• 4 ₇	Search Reports	٩
Organize 🔻 New fo	older		833 -	• • • •
> 🔆 Favorites	Name	<u>^</u>	Date modified	Туре
> 🧊 Libraries		No items match y	your search.	
🖻 🜏 Homegroup				
🖻 🌉 Computer				
🖻 📬 Network				
	•	m		Þ
File <u>n</u> ame: Re	port 1			•
Save as type: Te	d files (*.txt)			-
Hide Folders			<u>S</u> ave Ca	incel

Select the desired name and path, and click "Save".

A sample report is below:

	Gaumard® Scientific - Gaumard CPR
3/13/2012 Session:	10:40:27 AM
Facilitator:	
Providers:	[Team]
00:00:04	Detected (chest compression): peak = 44 mmHg , duration = 0.4 seconds.
00:00:04	Detected (chest compression): peak = 39 mmHg, duration = 0.1 seconds.
00:00:04	Detected (chest compression): peak = 48 mmHg, duration = 0.3 seconds.
00:00:05	Detected (chest compression): peak = 52 mmHg, duration = 0.2 seconds.
00:00:05	Detected (chest compression): peak = 39 mmHg, duration = 0.1 seconds.
00:00:06	Detected (chest compression): peak = 53 mmHg, duration = 0.1 seconds.
00:00:06	Detected (chest compression): peak = 10 mmHg, duration = 0.1 seconds.
00:00:08	Detected (chest compression): peak = 48 mmHg, duration = 0.2 seconds.
00:00:08	Detected (chest compression): peak = 43 mmHg, duration = 0.2 seconds.
00:00:09	Detected (chest compression): peak = 25 mmHg, duration = 0.1 seconds.
00:00:10	Detected (chest compression): peak = 22 mmHg, duration = 0.2 seconds.
00:00:11	Detected (chest compression); peak = 21 mmHg, duration = 0.1 seconds.
00:00:11	Detected (chest compression): peak = 54 mmHg, duration = 0.3 seconds.
00:00:12	Detected (chest compression): peak = 68 mmHg, duration = 0.6 seconds.
00:00:12	Detected (chest compression): peak = 58 mmHg, duration = 0.3 seconds.
00:00:14	Detected (chest compression): peak = 24 mmHg, duration = 0.1 seconds.
00:00:15	Detected (chest compression): peak = 42 mmHg, duration = 0.3 seconds.
00:00:16	Detected (chest compression): peak = 25 mmHg , duration = 0.2 seconds.
00:00:16	Detected (chest compression): peak = 46 mmHg , duration = 0.2 seconds.
00:00:16	Detected (chest compression): peak = 49 mmHg, duration = 0.1 seconds.

PRINT REPORT

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

EXIT

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

SET-UP

aumard Scientific - OMNI™				
Setup	p Help			
0	Options			
C	alibration			

OPTIONS

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

CPR Options

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

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

Options		
CPR Options Tolerances		
Ventilations and Compressions		
100 Compressions per minute		
Compression : Ventilation Ratio		
Only Ventilations		
12 Ventilations per minute		
Compression		
Ventilation		
OK Cancel		

Tolerances

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

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

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

otions		
CPR Options	Tolerances	
CPR Intensity Toleran Artificial ventilation in	ces itensity evaluation tolerance:	
	10 %	
Chest compression in	tensity evaluation tolerance:	
	10 %	
CPR Rate Tolerances Artificial ventilation ra	ate evaluation tolerance:	
	10 %	
Chest compression rate evaluation tolerance:		
	10 %	
ОК	Cancel	

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

Calibration
Calibration Wizard Welcome to the calibration wizard. Proceed only after you have reviewed the calibration section in the user manual. Please select the function you would like to calibrate:
Chest Compressions Artificial Ventilation
< Back Next > Cancel

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

Chest Compressions/Artificial Ventilations

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

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

Click next to proceed with the calibration.

The application will now ask you to perform a number of "correct" chest compressions or artificial ventilations, depending on which was selected.

< Back Finish

Cancel

The facilitator should follow the text cue on the screen to perform just ONE compression or ventilation at a time, until prompted for successive compressions/ventilations.

For example, if calibrating chest compressions:

The wizard prompts you with a "#1".

1. Perform one correct chest compression.

A green filled oval indicates that the chest compression was successfully recorded.

The wizard prompts you with #2".

2. Perform a second correct chest compression.

A green filled oval indicates that the chest compression was successfully recorded.

3. Continue the process.

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

Scientific - OMNI™	
Help)
	Instruction Manual
	About

INSTRUCTIONAL MANUAL

Open the instructional manual.

ABOUT

Click to view the version of the software.

Consumables and Replacements

Selected Parts List

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

Item ID	Description
S320.101.080	Simulated Blood Concentrate
S320.101.081	Lubricant
S230.101.180	Omni Controller
S230.101.180.1	Communication Cable
S230.101.180.2	USB Cable

Contact Us

E-MAIL TECHNICAL SUPPORT:

support@gaumard.com

Before contacting Tech Support you must:

- 1. Have Omni/simulator's Serial Number
- 2. Be next to Omni/simulator if troubleshooting is needed.

E-MAIL SALES AND CUSTOMER SERVICE:

sales@gaumard.com

PHONE:

Toll-free in the USA: (800) 882-6655

Worldwide: 01 (305) 971-3790

POST:

Gaumard Scientific

14700 SW 136 Street

Miami, FL 33196-5691

USA

OFFICE HOURS:

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

Warranty

EXCLUSIVE ONE-YEAR LIMITED WARRANTY

Gaumard warrants that if the accompanying Gaumard product proves to be defective in material or workmanship within one year from the date on which the product is shipped from Gaumard to the customer, Gaumard will, at Gaumard's option, repair or replace the Gaumard product.

This limited warranty covers all defects in material and workmanship in the Gaumard product, except:

- 1. Damage resulting from accident, misuse, abuse, neglect, or unintended use of the Gaumard product;
- 2. Damage resulting from failure to properly maintain the Gaumard product in accordance with Gaumard product instructions, including failure to property clean the Gaumard product; and
- 3. Damage resulting from a repair or attempted repair of the Gaumard product by anyone other than Gaumard or a Gaumard representative.

This one-year limited warranty is the sole and exclusive warranty provided by Gaumard for the accompanying Gaumard product, and Gaumard hereby explicitly disclaims the implied warranties of merchantability, satisfactory quality, and fitness for a particular purpose. Except for the limited obligations specifically set forth in this one-year limited warranty, Gaumard will not be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory regardless of whether Gaumard has been advised of the possibilities of such damages. Some jurisdictions do not allow disclaimers of implied warranties or the exclusion or limitation of consequential damages, so the above disclaimers and exclusions may not apply and the first purchaser may have other legal rights.

This limited warranty applies only to the first purchaser of the product and is not transferable. Any subsequent purchasers or users of the product acquire the product "as is" and this limited warranty does not apply.

This limited warranty applies only to the products manufactured and produced by Gaumard. This limited warranty does <u>not</u> 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 <u>not</u> covered by this limited warranty. Gaumard does not provide any warranty, express or implied, with respect to any third-party products. Defects in third-party products are covered exclusively by the warranty, if any, provided by the third-party.

Any waiver or amendment of this warranty must be in writing and signed by an officer of Gaumard.

In the event of a perceived defect in material or workmanship of the Gaumard product, the first purchaser must:

- 1. Contact Gaumard and request authorization to return the Gaumard product. Do <u>NOT</u> 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.
- 3. If the necessary repairs to the Gaumard product are covered by this limited warranty, then the first purchaser will pay only the incidental expenses associated with the repair, including any shipping, handling, and related costs for sending the product to Gaumard and for sending the product back to the first purchaser. However, if the repairs are not covered by this limited warranty, then the first purchaser will be liable for all repair costs in addition to costs of shipping and handling.

Extended Warranty

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

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

© 2012 Gaumard Scientific Company, Inc. All rights reserved.

Gaumard®, CODE BLUE®, PEDI® Blue are trademarks of Gaumard Scientific Company, Inc.

Patented; other patents pending.

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