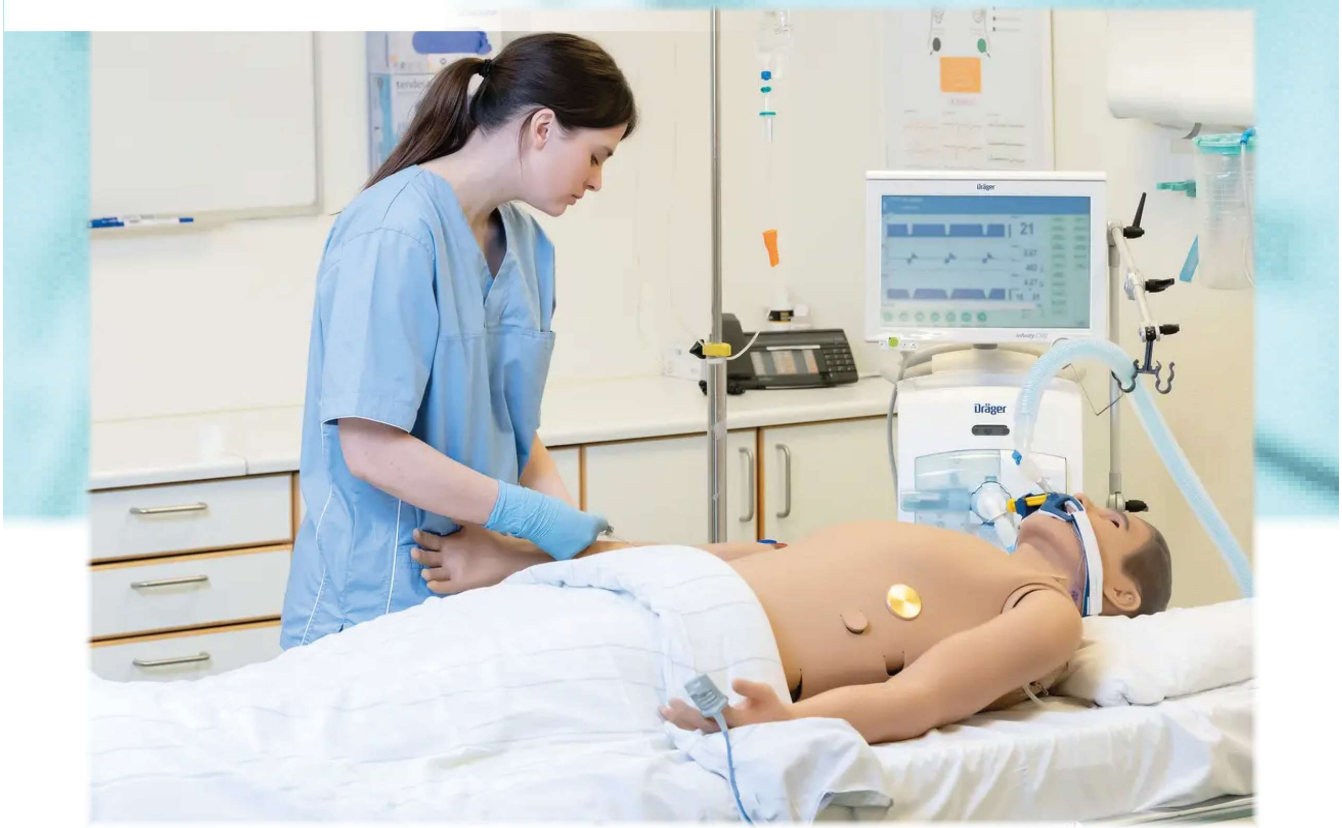
INGMAR MEDICAL
Respiratory Simulation Specialists

Advanced Lung Module
User's Manual
420-00050



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Document History

Revision History	Date	Authors
Rev. 1	04/16/2024	Michael Bails

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Table of Contents

1 SAFETY CONSIDERATIONS

1.1 Operator Safety

For correct and effective use of the product it is mandatory to read and to observe all INSTRUCTIONS, WARNINGS, and CAUTION statements in this manual. If the product is not used as instructed, the safety protection provided may be impaired.

WARNING!

Indicates a potentially harmful condition that can lead to personal injury.

CAUTION!

Indicates a condition that may lead to equipment damage or malfunction.

NOTE

Indicates points of interest or emphasis for more efficient or convenient operation.

1.2 Intended Use

The **Advanced Lung Module** is part of the Laerdal SimMan® Critical Care manikin simulator, merging the best-in-class IngMar Medical Internal Simulated Lung (ISL), based on the ASL 5000® Breathing Simulator technology, into the Laerdal LLEAP simulation environment. This integration improves the true-to-life experience with embedded lungs that provide realistic airway response to ventilators, anesthesia machines, CPAP, etc. A software component provides a series of windows which are added directly to the LLEAP environment. These windows give the user direct control of the internal lung parameters that also interact with LLEAP's Patient Monitor and *Airway & Breathing* windows.

NOTE

In this manual the name SimMan® applies to SimMan® Critical Care manikin simulator unless otherwise stated.

The software provided for the Lung Solution is designed for LLEAP version 8.5 or greater for the SimMan®. Please contact IngMar Medical, LLC (sales@ingmarmed.com) for details on future integration into additional Laerdal manikin simulators. LLEAP software and firmware are directly accessible from the Laerdal website www.laerdal.com. Please verify the software and firmware are up to date before using the Lung Solution.

WARNING!

The use of supplemental oxygen is prohibited with the SimMan®, SimBaby™, Nursing Anne™, and the SimMan® Critical Care with the embedded Advanced Lung Module products. The ASL 5000® Breathing Simulator, part of the Lung Solution application, allows use of Oxygen-rich gas with these manikins disconnected but through the Local Connection option (ASL 5000®as a stand-alone simulator connected directly to a ventilator, CPAP, or anesthesia machine). Please refer to the Lung Solution User Manual for details on using the ASL 5000® Breathing Simulator).

CAUTION!

Do not allow aerosols to contaminate the cylinder of the ALM. Contamination with aerosols may result in equipment damage or malfunction. Use of the ALM in the presence of flammable anesthetics may present an explosion hazard.

2 An Introduction to the Advanced Lung Module

The **Advanced Lung Module (ALM)** is an embedded set of lungs for the Laerdal SimMan® Critical Care manikin simulator. With these lungs, the user can experience a high-fidelity respiratory system added to the many features already available with this SimMan® manikin simulator.

This includes the ability to ventilate the patient with a wide range of lung resistance, compliance, and spontaneous breathing parameters. The ALM can hold physiologically relevant levels of PEEP and is able to exert and receive typical ventilator volumes up to 1L.

2.1 ALM Inside the SimMan®

The ALM is a permanent installation to the SimMan® Critical Care manikin simulator. The ALM is composed of two (2) distinct lung simulators that operate as a left and right lung that can have variable resistances and compliances depending on the models or parameters selected in the LLEAP environment. The ALM has a physical connection to the SimMan® trachea allowing for realistic responses like right mainstem intubation sensing.

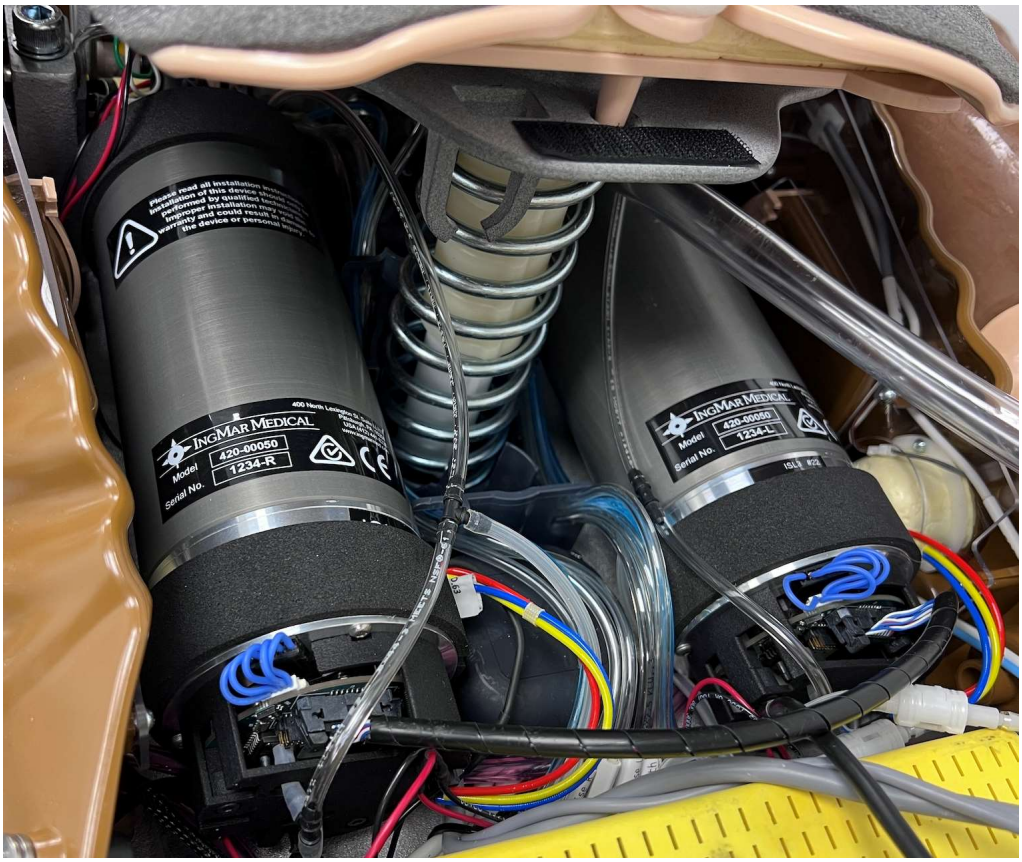

Figure 2-1 – ALM Installed in SimMan® Critical Care

2.2 Lung Plugin Windows

The lung plugin software enhances realism in the LLEAP environment by providing six (6) additional windows that work with the embedded electromechanical lungs. These windows are explained below.

Lung Session Control – This window controls the connection to the ALM. This window also displays connection status and controls the simulation with Play, Pause, and Stop functionality. The Play button is directly linked to the LLEAP Session Control Play button and will start a full simulation (LLEAP and the internal lungs).

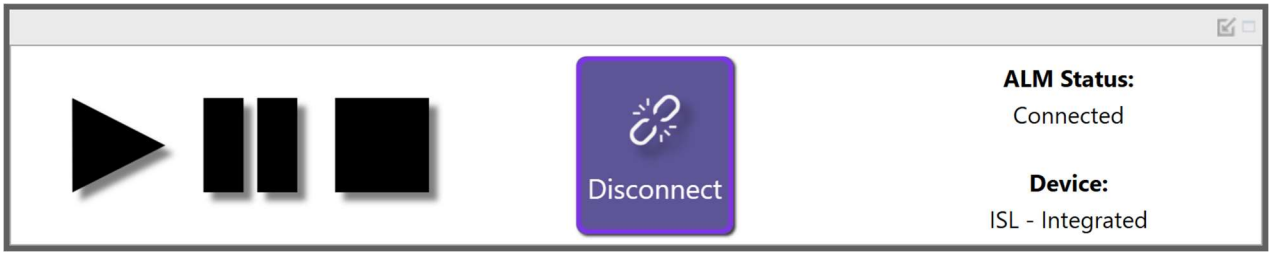

Figure 2-2 – Lung Session Control

Quick Choice Menu – This window provides predefined patient types and disease states. The window gives the user easy access to various lung / airway diseases with the ability to adjust the severity of those diseases. Simply click on a disease, click apply and adjust the severity. Custom or user-defined disease states are also accessible from this window via the Custom Models toggle switch. The simulated patient can also mimic a passive (or paralyzed) patient via the Apnea toggle switch.

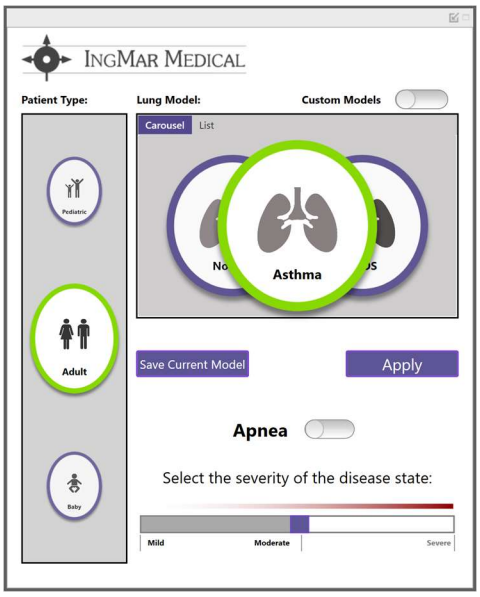

Figure 2-3 - Quick Choice Menu

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Lung Model Control – This window controls the airway resistance and lung compliance of the internal lungs. The user can select a simplified lung model consisting of a single resistance and compliance. Switching to the Advanced view, the user can create a more complex dual lung model, which can include (but is not limited to) variations in inspiratory versus expiratory resistance.

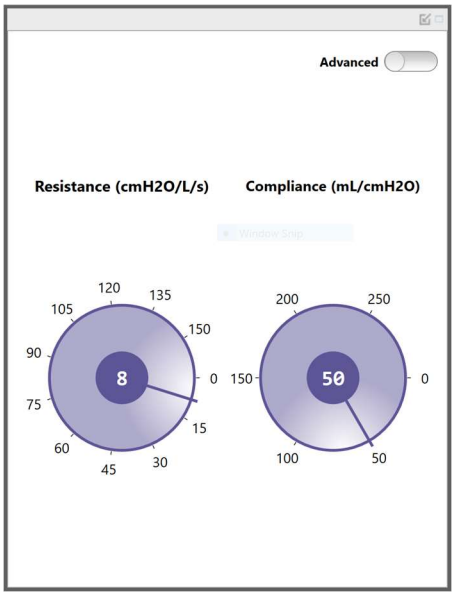

Figure 2-4 - Lung Model Control

Breath Effort Control –This window has basic settings for Breath Rate and Muscle Pressure (patient effort required to take a breath), the driving force for volume in the lungs. Switch to the Advanced view and create a complex muscle pressure profile for an accurate representation of spontaneous breathing.

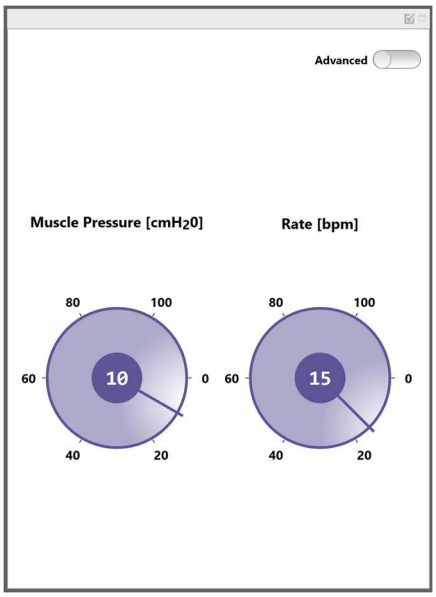

Figure 2-5 - Breath Effort Control

Lung Monitor – This window provides feedback from the point of view of the lung. The window includes waveforms for the lung's pressure, flow, and volume. Also displayed are relevant breath parameters including PEEP, PIP, Minute Ventilation, and Tidal/Total Volume.

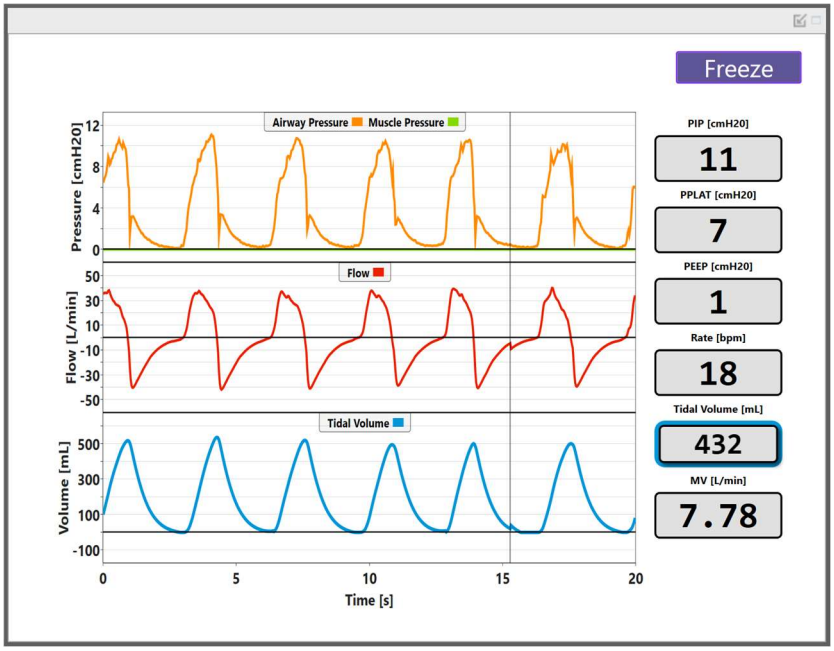

Figure 2-6 - Lung Monitor

Equation of Motion – This window provides a graphical representation of the equation of motion of air in the system (as a teaching tool). At any time during the simulation, view the most recent breath in better detail by clicking the View Last Breath toggle.

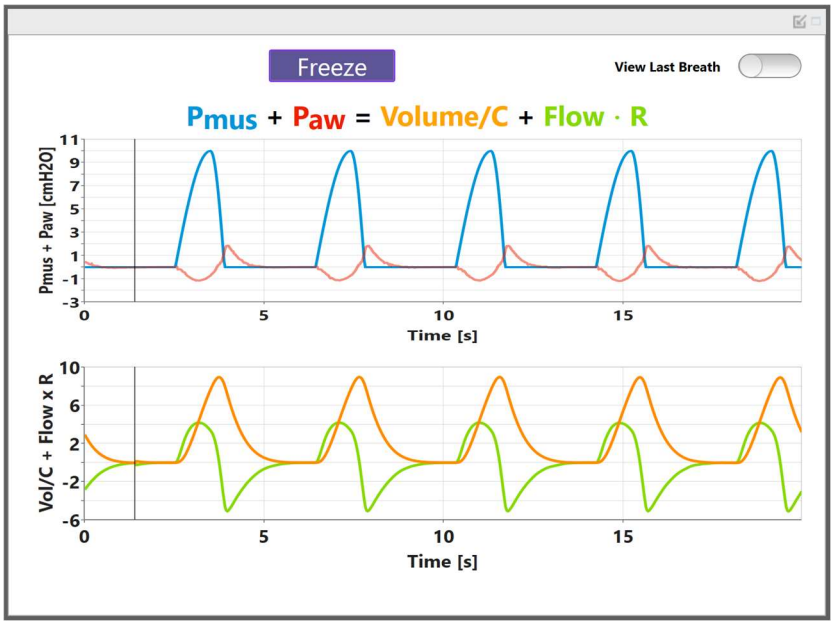

Figure 2-7 **- Equation of Motion**

2.3 Components

The **Advanced Lung Module** has two major components: the physical lungs embedded into the SimMan® and a plugin software installer.

Because the software is designed as an add-on to the LLEAP environment, the user can access any of the lung windows via the file menu, “View” dropdown.

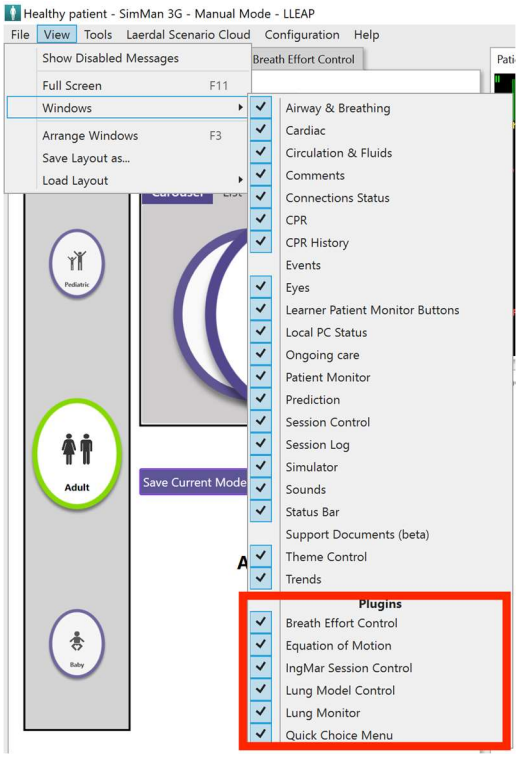

Figure 2-8 – Lung Plugin Window Access

Each of the Lung Plugin windows allows for direct control of the IngMar Lung. This includes changing a predefined disease state / lung model or directly controlling lung mechanics (resistance, compliance, etc.). At any time during a simulation, the user can invoke real-time changes to the patient and observe a direct reaction from an external device (e.g. ventilator, CPAP, etc.).

By accessing the View -> Load Layout menu dropdown, users can load the “IngMarDefault” layout for the SimMan® family, the SimBaby™ and Nursing Anne™. This layout organizes the LLEAP and Lung Plugin windows into a user-friendly view.

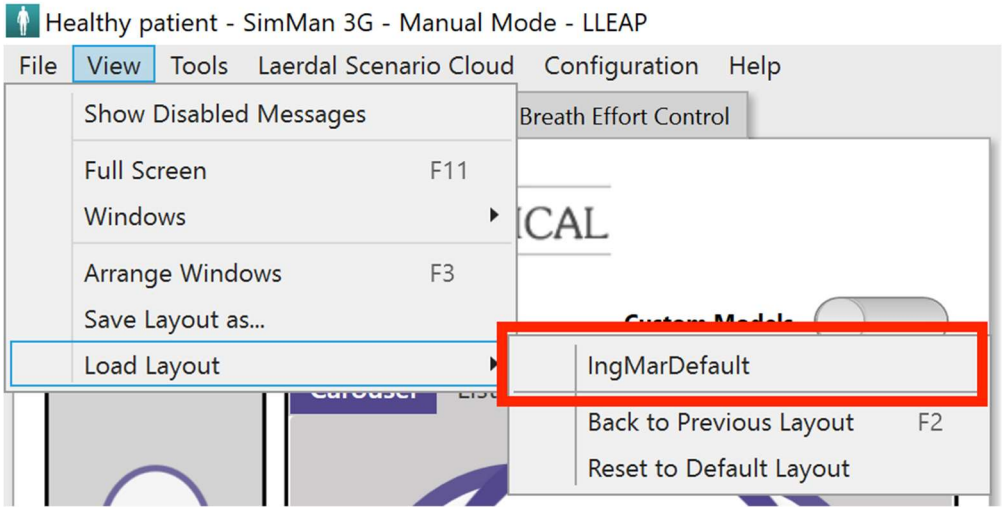

Figure 2-9 - Default Layout

To improve the simulation experience, IngMar Medical has also created a custom view for the Respiratory themes provided by LLEAP, called "IngMarUnhealthy". These include:

- Adult -> Respiration -> Asthma
- Adult -> Respiration -> Morphine Overdose
- Adult -> Respiration -> Pneumothorax

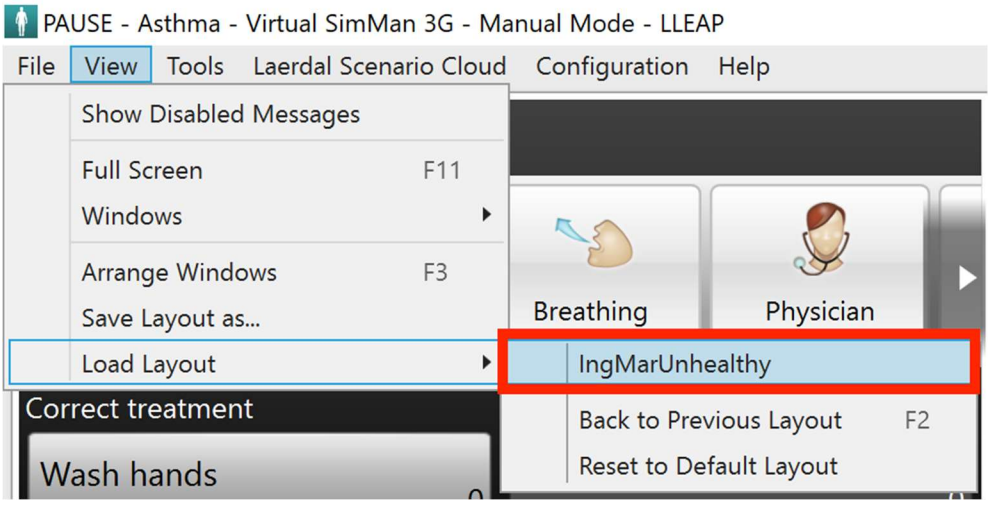

Figure 2-10 - Unhealthy Layout

3 USING THE LUNG WINDOWS IN LLEAP

3.1 The LLEAP Environment with Lung Windows

With the SimMan® Critical Care manikin and ALM lungs, LLEAP interface now has the enhanced respiratory features. Get started by loading the LLEAP software with the additional IngMar windows. As stated above in the Overview (Section 2.1), each lung window is accessible via the **View Menu** option. The instructor can place the lung windows into convenient positions within the LLEAP view. IngMar Medical has created respiratory-centered views for some of the themes defined in the LLEAP **Select Theme** window. The following figures display the LLEAP default themes and an example of a respiratory-centered theme:

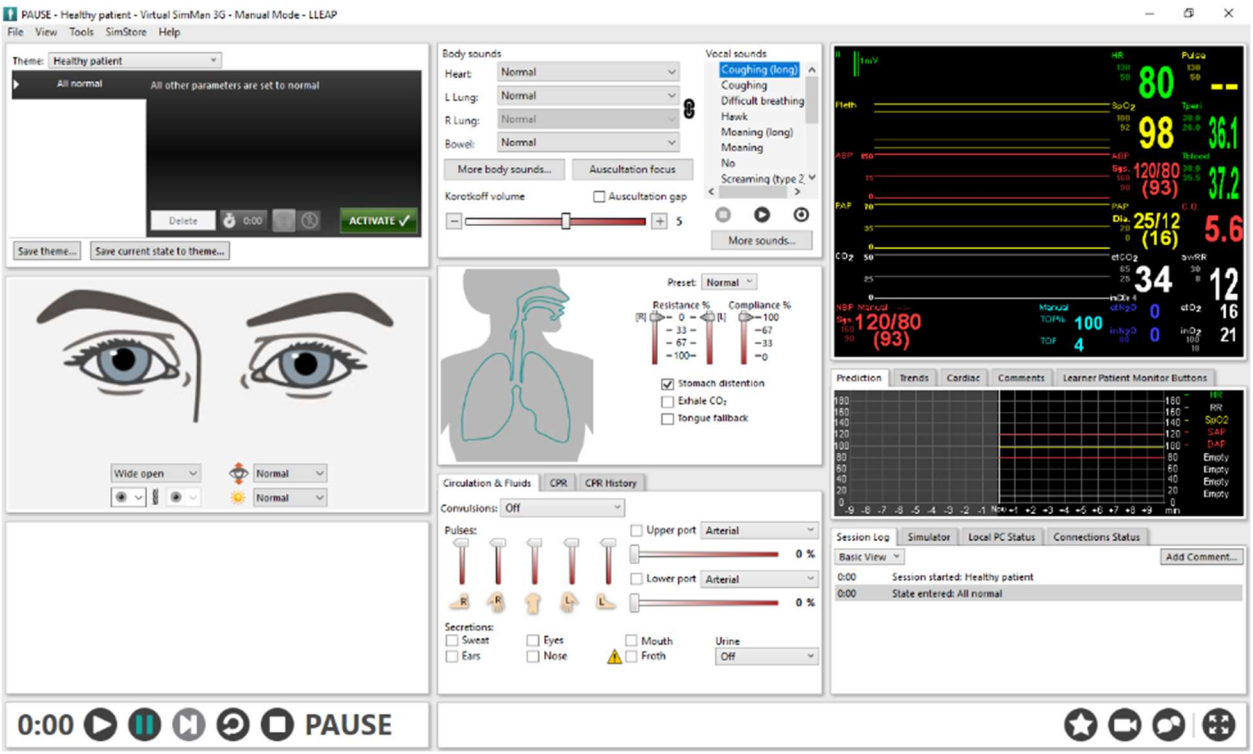

Figure 3-1 - LLEAP Healthy Patient Theme

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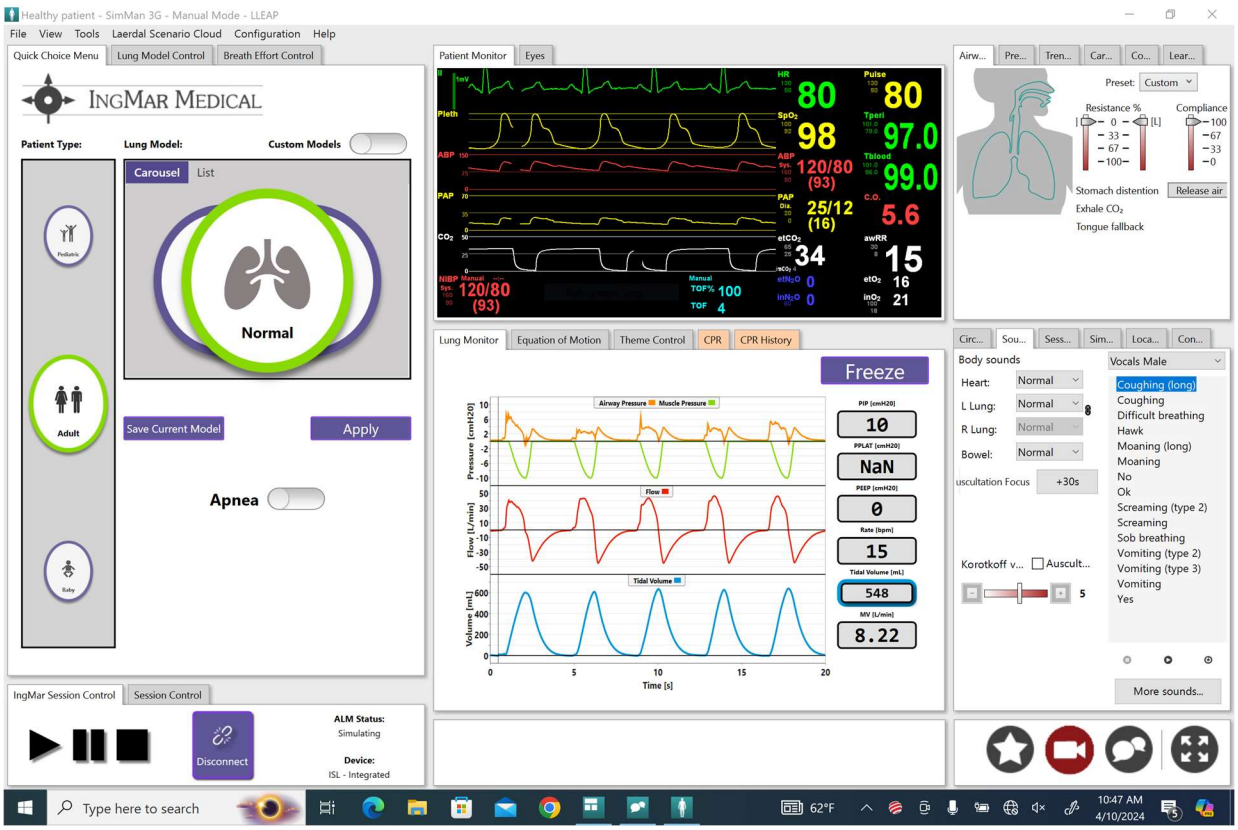

Figure 3-2 - Respiratory-centered Healthy Patient Theme

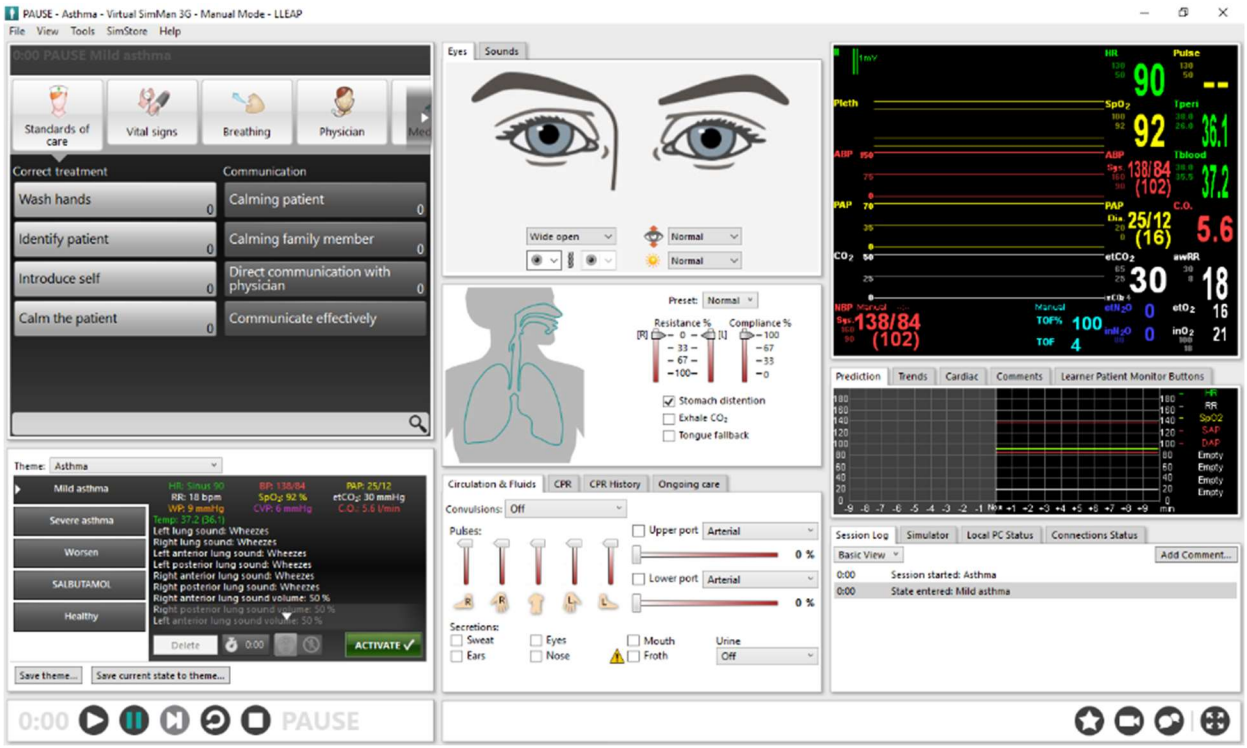

Figure 3-3 – LLEAP Asthma Patient Theme

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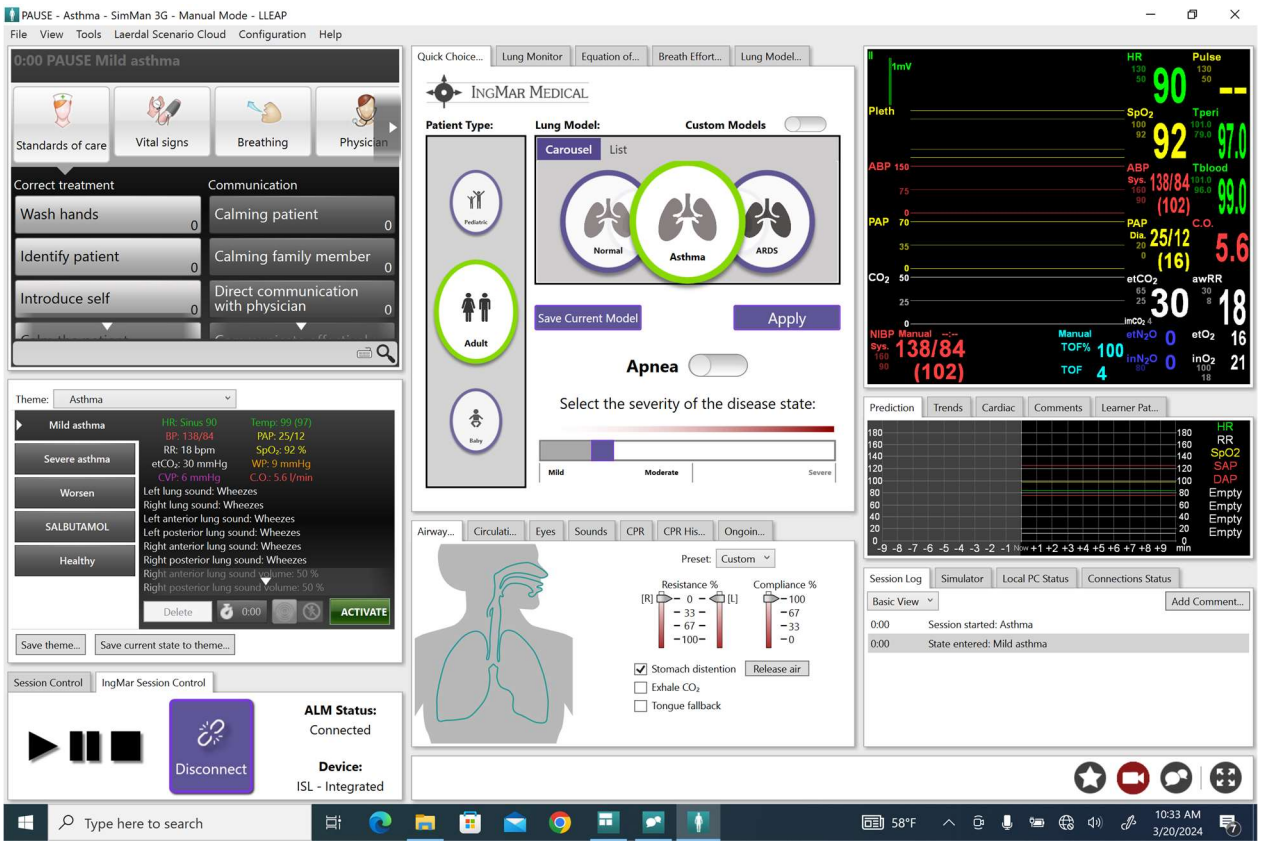

Figure 3-4 – Asthma Theme with IngMarUnhealthy Layout

NOTE

Please refer to the LLEAP tutorials for information about working with windows and themes. Details can be found at www.laerdal.com

3.2 IngMar Session Control

3.2.1 Connect / Control buttons

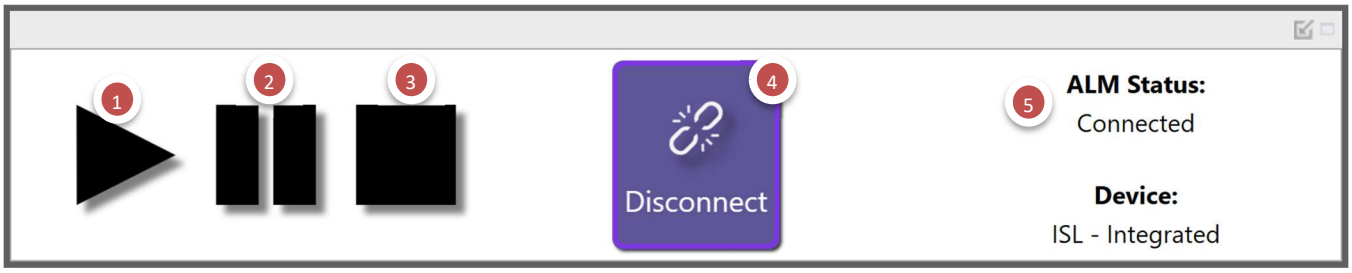

Figure 3-5 - ASL Session Control

The **IngMar Session Control** window includes control of the ALM lungs and simulation session.

1. The ▶ (Play) button mimics the function of the same button in the LLEAP Session Control

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2. The (Pause) button mimics the function of the same button in the LLEAP Session Control. It also sets the lung breath effort to zero (a passive lung) to avoid any ventilator alarms.
3. The (Stop) button ONLY stops the ALM lungs. The other components of the LLEAP simulation are unaffected.
4. The (Connect / Disconnect) button connects or disconnects ALM lungs (by default, the lungs will be connected on startup).
5. The Status and Device monitors provide connection and device feedback.

3.3 QuickChoice Menu

The **QuickChoice Menu** window provides an array of preconfigured patient types and lung disease states. The Quick Choice Menu is a great starting point for working with the SimMan® Critical Care manikin simulator through the LLEAP software interface.

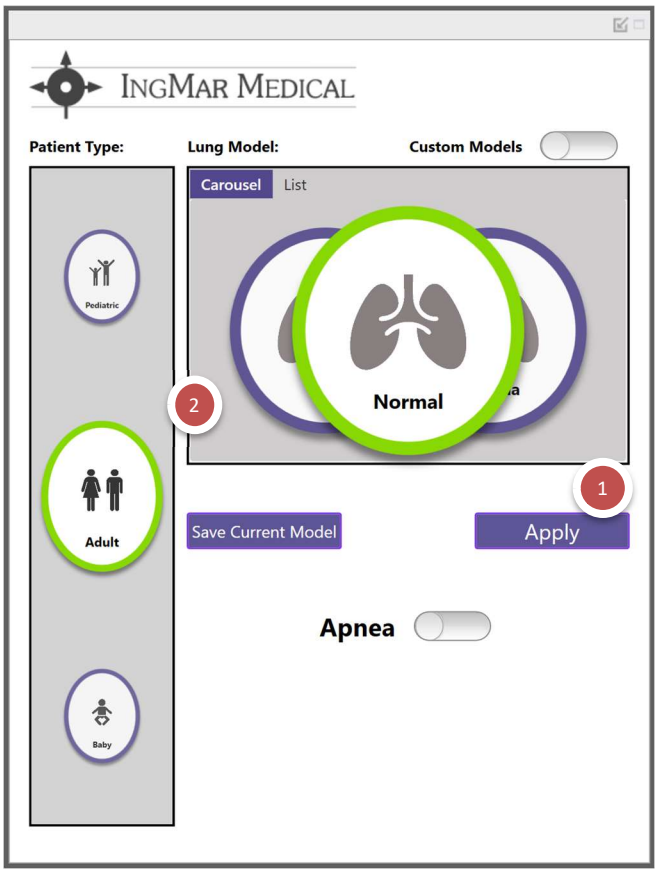

Figure 3-6 - QuickChoice Menu

1. Select a **Patient Type** and **Lung Model** by clicking the appropriate "eggs," then clicking Apply
2. The selected Lung Model will be highlighted in green

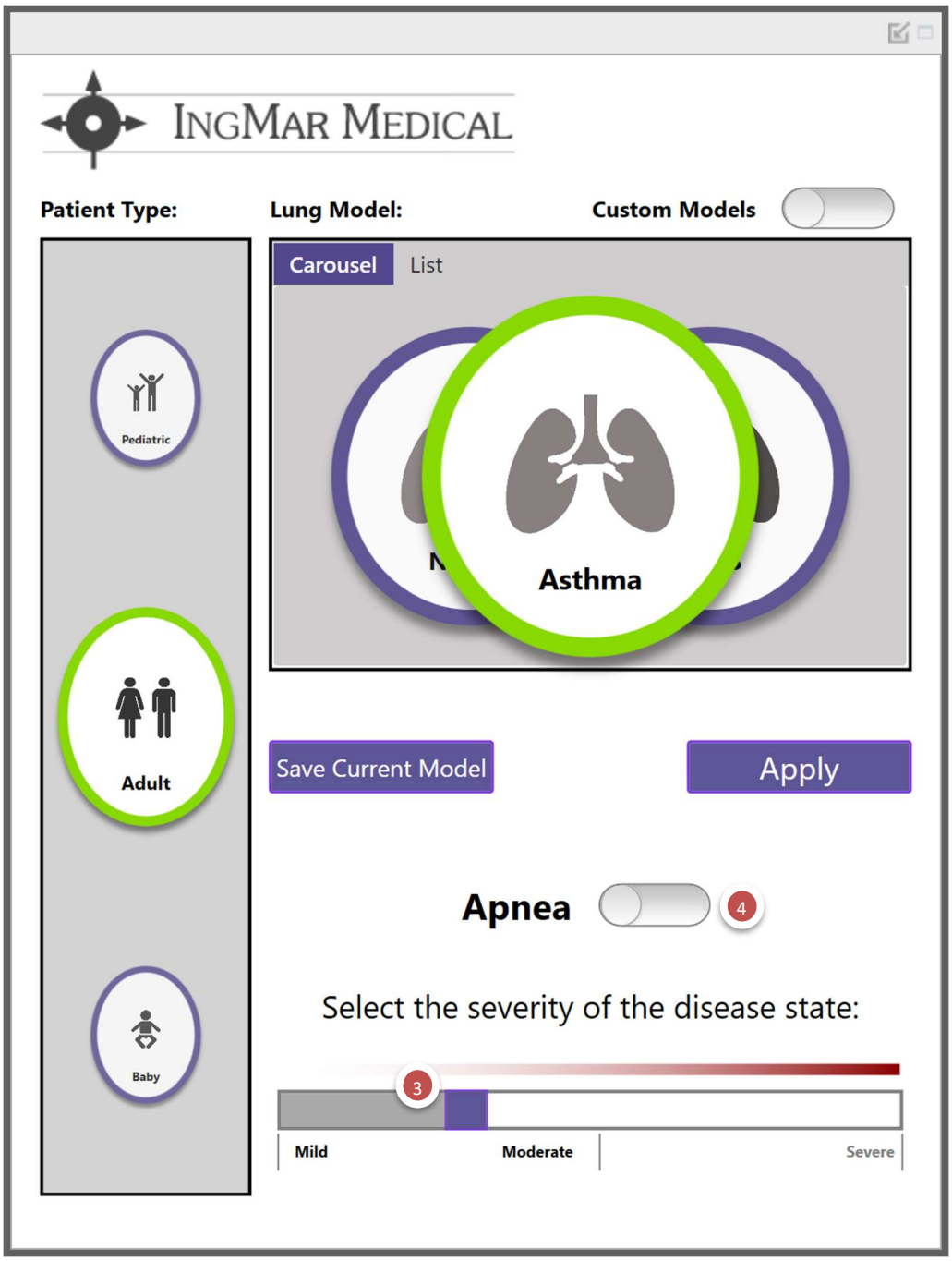

Figure 3-7 - QuickChoice Menu with Asthma

3. When selecting a disease other than **Normal**, the user can adjust the severity of the disease
4. At any time during the simulation, the patient can be set to become completely passive by clicking the **Apnea** switch

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The table below displays the lung settings for all the patient models in the Quick Choice library:

Table 1 - Patient Model Definitions

Adult Normal						
	Compliance	Resistance	Patient Rate	Effort	Rise %	Release %
Healthy	50	8	15	10	25%	10%
Adult Asthma						
	Compliance	Insp/Exp Resistance	Patient Rate	Effort	Rise %	Release %
Mild	80	30/50	20	15	20%	15%
Moderate	40	40/90	30	15	35%	20%
Severe	35	50/120	35	30	20%	20%
Adult ARDS						
	Compliance	Resistance	Patient Rate	Effort	Rise %	Release %
Mild	40	16	25	7	35%	10%
Moderate	25	30	30	10	40	20%
Severe	10	35	40	20	30	10
Adult COPD						
	Compliance	Insp/Exp Resistance	Patient Rate	Effort	Rise %	Release %
Mild	50	12/15	12	4	20%	15%
Moderate	53	21/23	22	8	35%	30%
Severe	53	21/23	30	5	35%	42%
Adult ILD						
	Compliance	Insp/Exp Resistance	Patient Rate	Effort	Rise %	Release %
Severe	18	35	27	10	18	10

In any given simulation, the instructor may believe that the lung diseases provided by the software do not fully represent the teaching goals. For example, an asthmatic patient model should have a much higher inspiratory resistance than what the QuickChoice model provides (see Severe Adult Asthma in the table above). The user can make changes directly to the Lung Model and Breath Effort windows and see the resulting waveforms in the ASL Monitor window. Once a satisfactory response is created, the user can click the Save Current Model button. This will prompt the user for a custom model name.

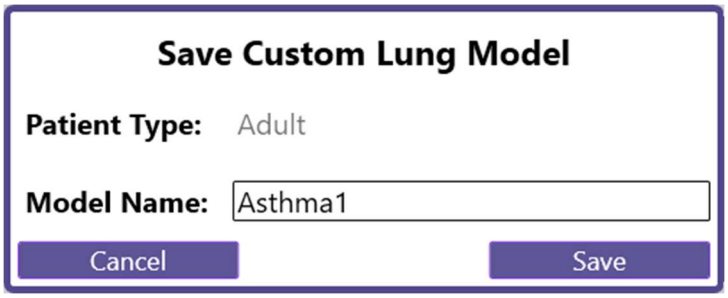


Figure 3-8 - Save Custom Model Prompt

Once saved, view all custom patient models by clicking the Custom Models toggle switch. This gives the instructor a listing of all custom patient models that have been created. Use the search function to quickly find your custom patient models.

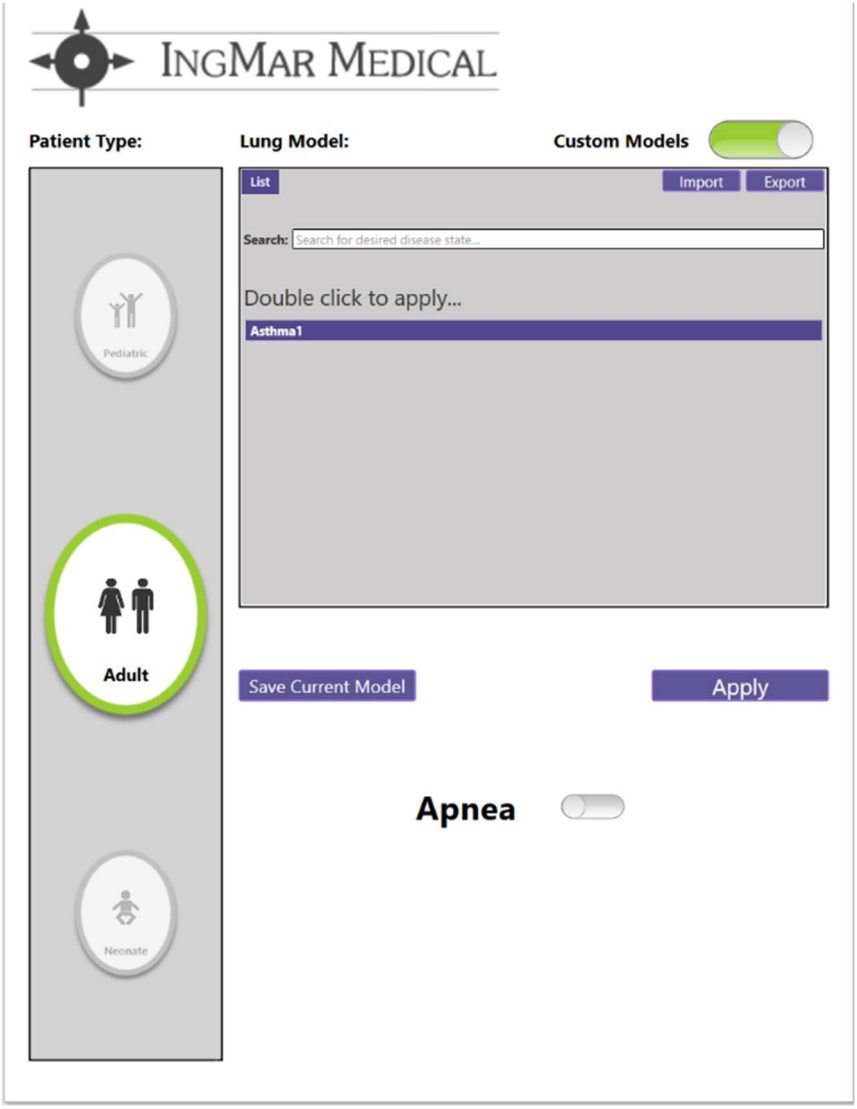


Figure 3-9 - Custom Disease States

Delete any unwanted custom disease states by clicking the file name and pressing the delete key on a keyboard. This will open prompt confirming the deletion.

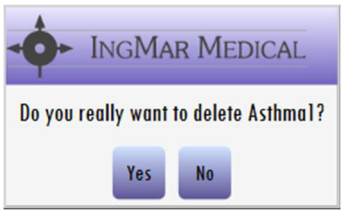


Figure 3-10 - Deleting Custom Disease State

The QuickChoice window gives the user the ability to import and export custom lung models.

Exporting a model:

After a model is created and saved as a custom model, click the Export button from the Custom Model window. This opens the *Export Custom Lung Models* window.

Figure 3-11 - Export Custom Models

Click the model to export from the Available Models. Clicking the right-facing arrow will shift the selected models to the Models to Export field. More than one model can be exported at a time. When the models are ready to export, click the Export Models button which will open a navigation window with the default MyPatientModels.pat filename and format.

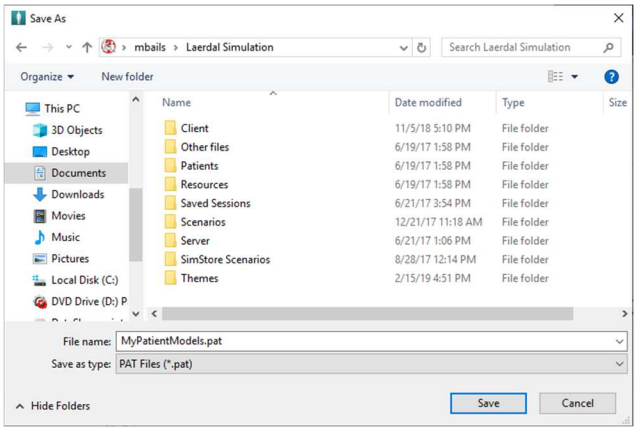


Figure 3-12 - Exporting Lung Models

Clicking the Save button will confirm the export is complete with the following message:

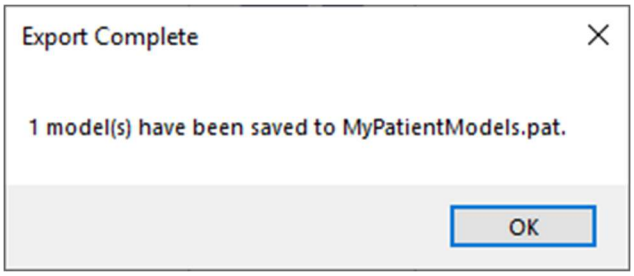


Figure 3-13 - Export Confirmed

Importing a Model:

The process for importing a lung model is like exporting. Click the Import button which opens a navigation window. Browse and select the [filename].pat and click Open.

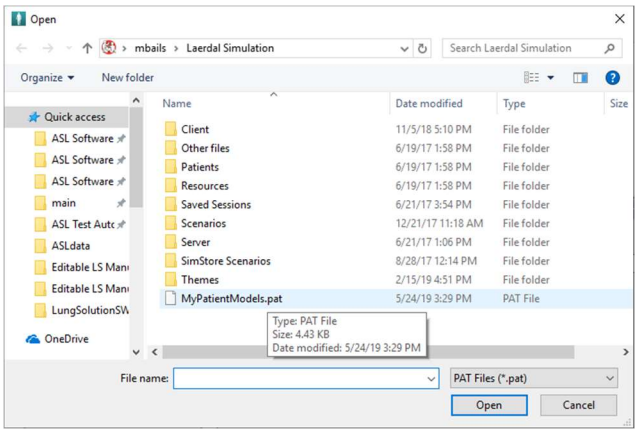


Figure 3-14 – Importing Lung Models

The *Import Custom Lung Models* window opens.

Figure 3-15 - Import Custom Models

Click the model to import from the Available Models. Clicking the right-facing arrow will shift the selected models to the Models to Import. More than one model can be imported at a time. Clicking the Import Models button will confirm the import is complete with the following message:

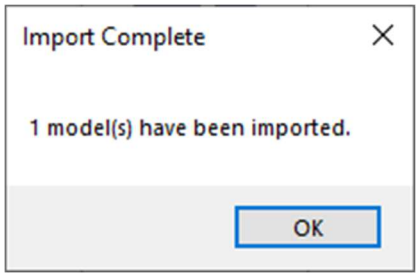


Figure 3-16 - Import Confirmed

3.4 Lung Monitor

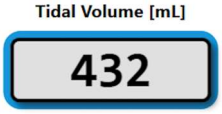
The **Lung Monitor** window includes two views for the instructor, the **Monitor** view, and the **Equation of Motion** view.

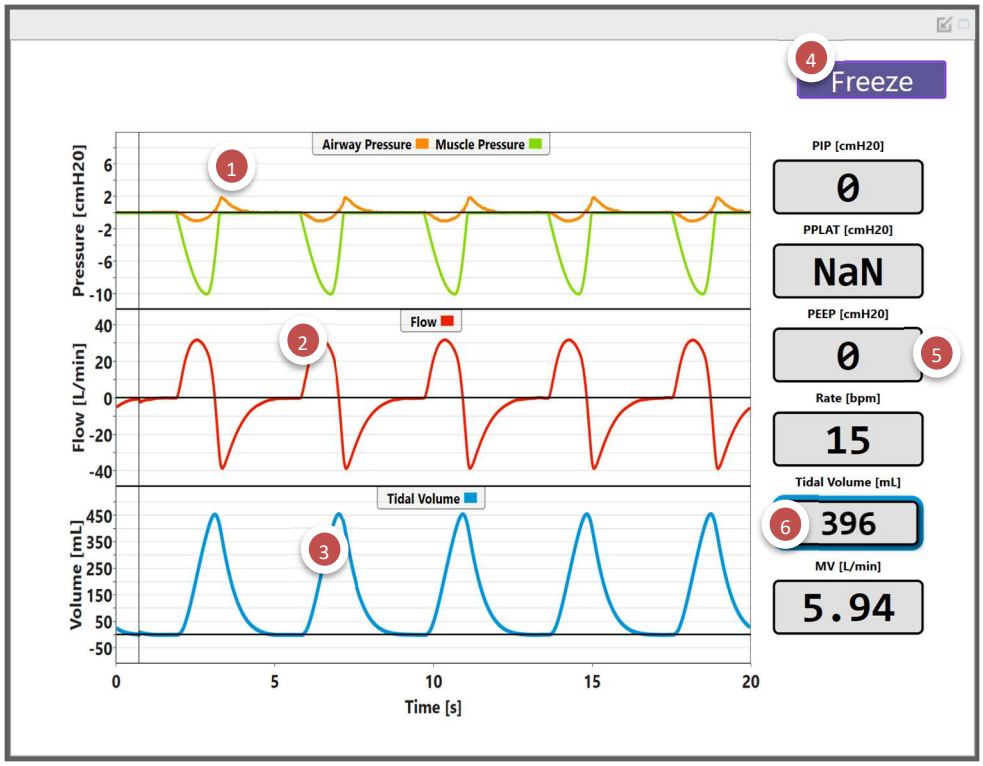
The **Monitor** view is a useful tool for analyzing the waveforms and readings directly from the lung. These include pressure (cmH2O), flow (L/min) and volume (mL) waveforms. Relevant lung parameters are also monitored and are updated upon the completion of a patient breath.

The volume and pressure data are, by default, viewed with Tidal volume in the waveforms. Clicking the "Tidal Volume" cell to the right of the waveform changes the view from Tidal Volume to Total Volume. Note that Total Volume represents waveforms from both the left and right lungs and includes any trapped volume in the lungs (e.g. due to Asthma)

NOTE

Tidal volume is represented by the change in volume that is not affected by PEEP or air-trapping within the lung. Thus, Tidal Volume always returns to zero on the x-axis. Total volume is a more detailed representation of what is happening inside the lungs. Total volume includes the volume offset due to PEEP and/or air-trapping. Switch between Tidal and Total by clicking the Tidal Volume cell next to the waveforms.





3-17 - Tidal Volume – Default Waveform View

1. Pressure waveforms include airway (external) and muscle (spontaneous breathing)
2. Flow is the total flow in the system
3. Volume waveforms are based on Tidal Volume and always return to a zero baseline
4. At any time during the simulation, click Freeze to freeze the waveform view for debriefing purposes
5. Seven (7) breath parameters provide lung details that may be essential to a simulation
6. Click the Tidal Volume cell and switch between Total and Tidal volume views of the waveforms

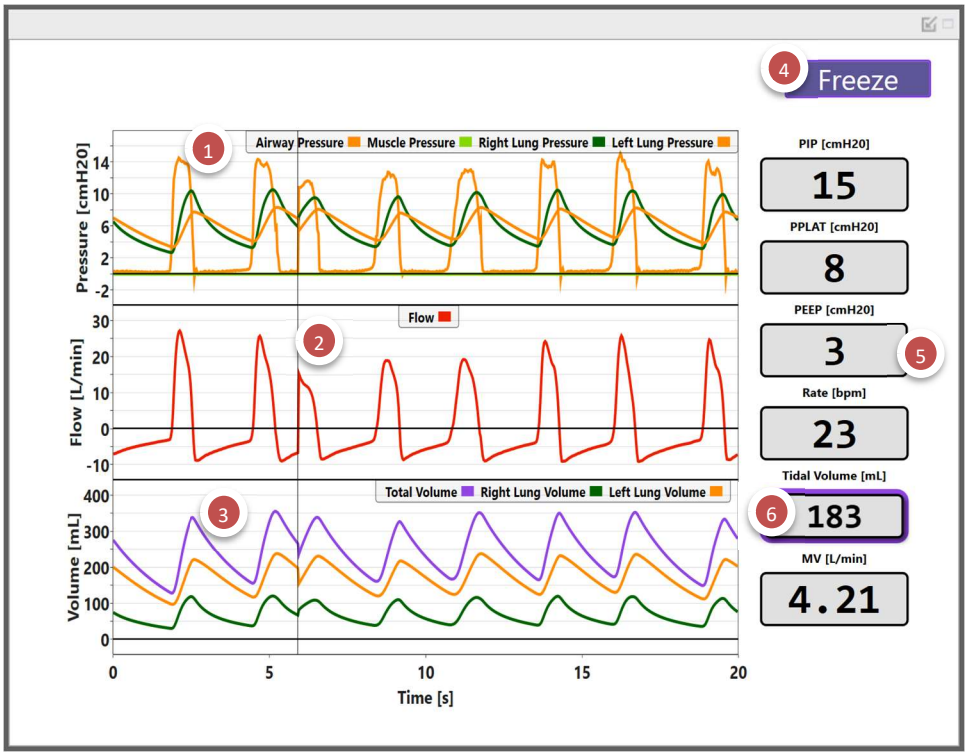


Figure 3-18 – Total Volume – Waveform View

1. Pressure waveforms include airway (external), muscle (spontaneous breathing), as well as left and right internal lung pressures
2. Flow is the total flow in the system
3. Volume waveforms include total, right, and left lung volumes as well as a representation of air trapping (or breath-stacking) due to PEEP or lung mechanics (resistance or compliance)
4. At any time during the simulation, click Freeze to freeze the waveform view for debriefing purposes
5. Seven (7) breath parameters provide lung details that may be essential to a simulation. The Tidal Volume calculation is based on the maximum volume over baseline (e.g. volume due to the presence of PEEP)
6. Click the Tidal Volume cell and switch between Total and Tidal volume views of the waveforms

3.5 Lung Equation of Motion

The **Equation of Motion** (EOM) window gives the user a different way to look at the patient breathing. This is a real-time analysis of the mechanics of breathing represented by the components of the EOM.

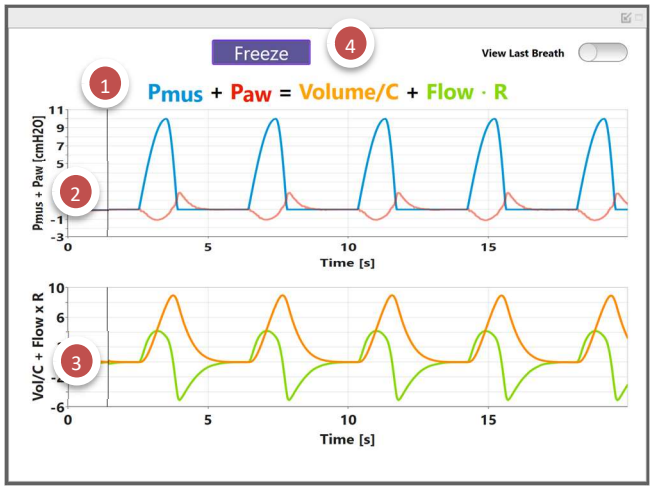


Figure 3-19 - Equation of Motion Window

1. Definition of the Equation of Motion where Pmus is the patient's spontaneous muscle pressure in cmH2O, Paw is external pressure sensed by the ALM lungs in cmH2O. Volume is in mL, C is lung compliance in mL/cmH2O, Flow is in L/min and R is airway resistance in cmH2O/L/s
2. The left side of the equation is shown in the top graph
3. The right side of the equation is shown in the bottom graph
4. Click the Freeze button to freeze the waveform view for debriefing purposes

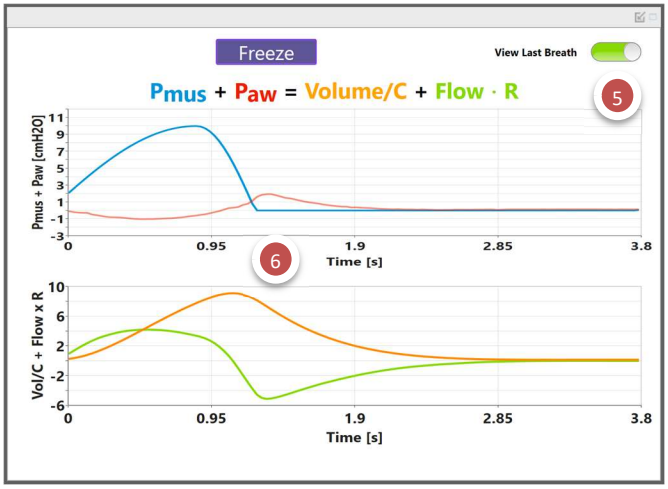


Figure 3-20 - Equation of Motion Last Breath

5. Switch between the real-time view and a snapshot of the last recorded breath
6. Follow the changes in a single breath for better understanding of how pressures, flows and volumes relate to the patient's lung conditions (Resistance and Compliance)

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3.6 Lung Model Control

The **Lung Model Control** window provides direct control of the patient's lung and airway mechanics related to resistance and compliance. This includes single or dual lung models and inspiratory versus expiratory resistance.

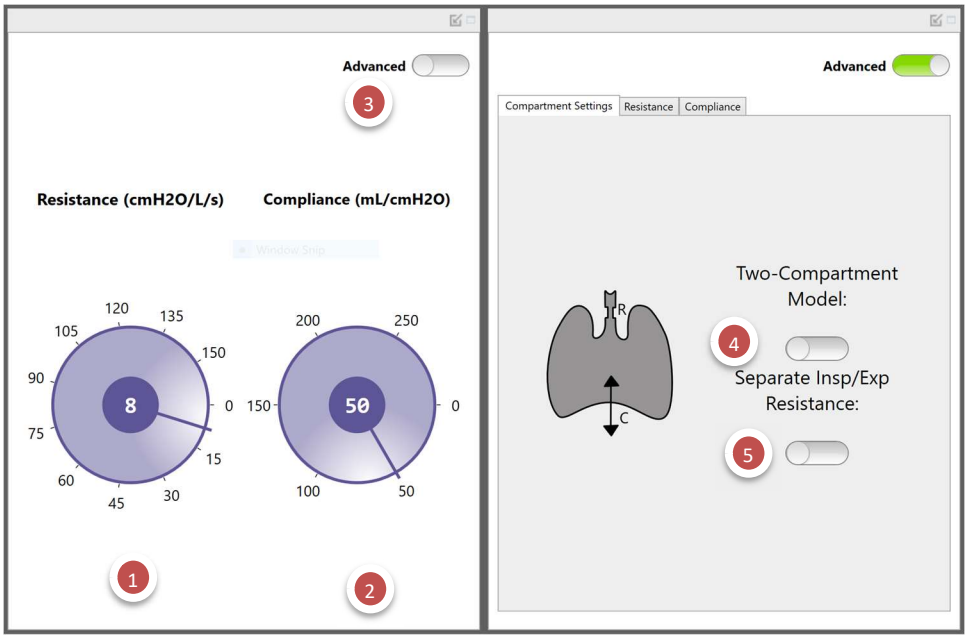

Figure 3-21 - Lung Model Control

1. **Resistance** knob: the user can also double click the number inside and directly type a value.
    a. Total resistance range is from 8 – 150 cmH2O/L/s
2. **Compliance** knob: the user can also double click the number inside and directly type a value.
    a. Total compliance range is from 0.5 – 250 mL/cmH2O
3. Switch to the **Advanced** view for greater control of the lung characteristics. The figures below provide the different control options for the lung models
4. Switch defining **One** or **Two** compartment lung models
5. Switch defining Resistance where inspiratory and expiratory resistances are equal or unequal (e.g. Asthmatic patients typically have unequal inspiratory and expiratory resistances Rin ≠ Rout)

3.6.1 Advanced – Single Compartment Lung Model

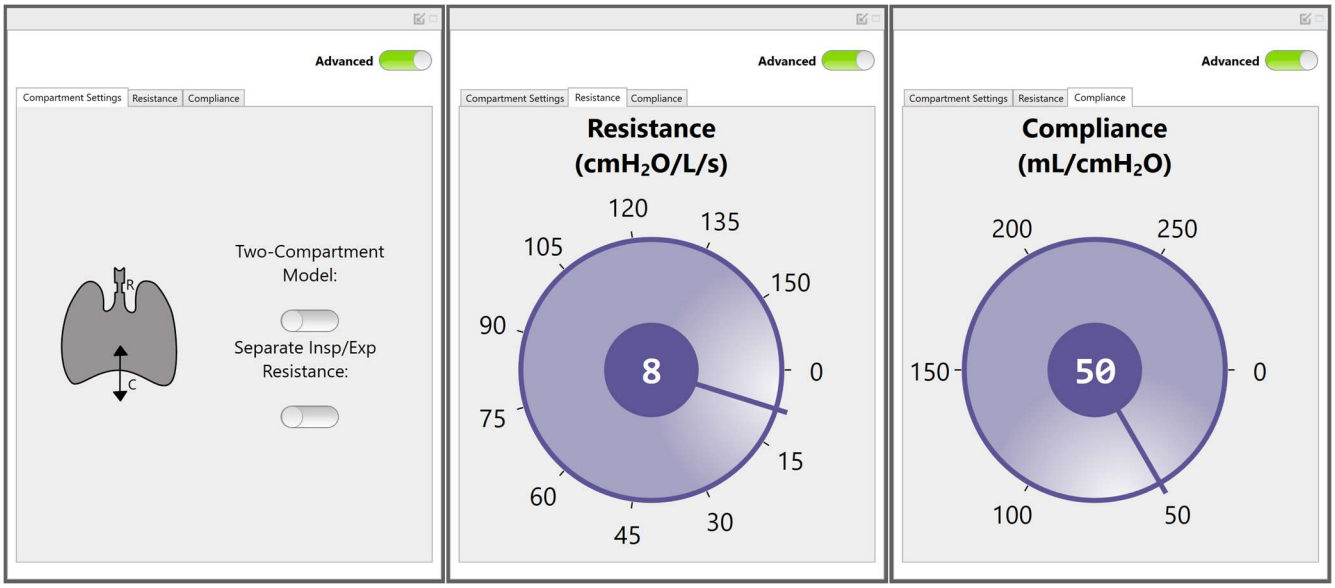

Figure 3-22 - Lung Model – Simplified Lung Model 1 Compartment with Equal Resistances

3.6.2 Advanced – Two Compartment Lung Model, Equal Resistance (Rin = Rout)

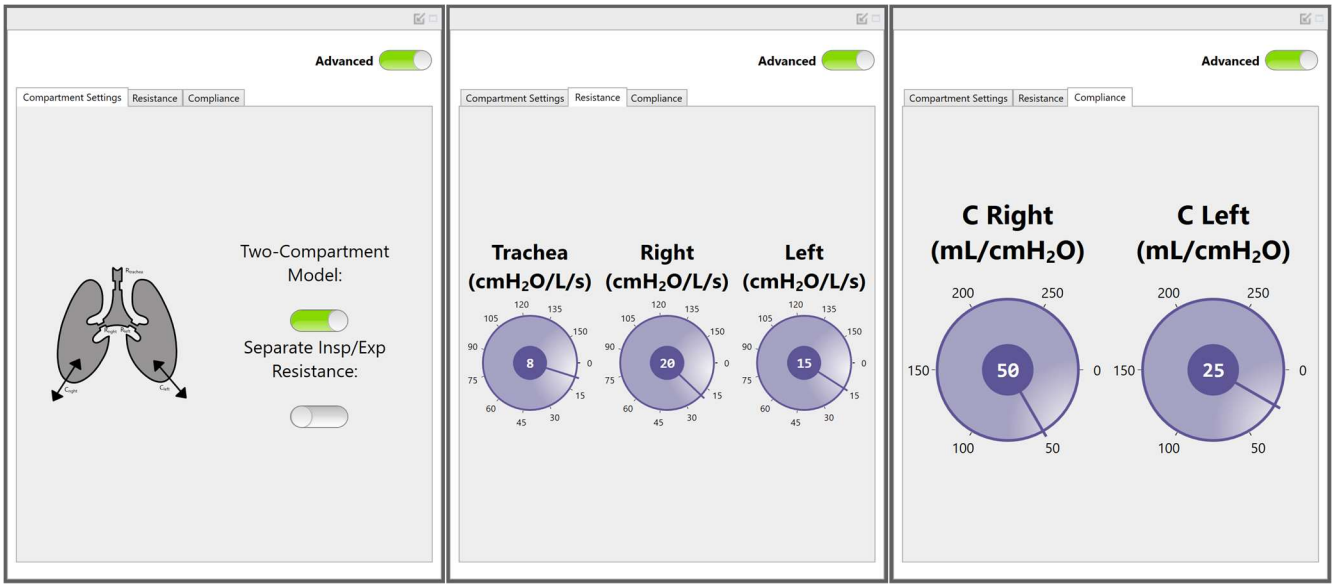

Figure 3-23 - Lung Model - 2 Compartment with Equal Resistances

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3.6.3 Advanced – Single Compartment Lung Model, Unequal Resistance (Rin ≠ Rout)

Figure 3-24 - Lung Model - 1 Compartment with Resistance_in not equal to Resistance_out

3.6.4 Advanced – Two Compartment Lung Model, Unequal Resistance (Rin ≠ Rout)

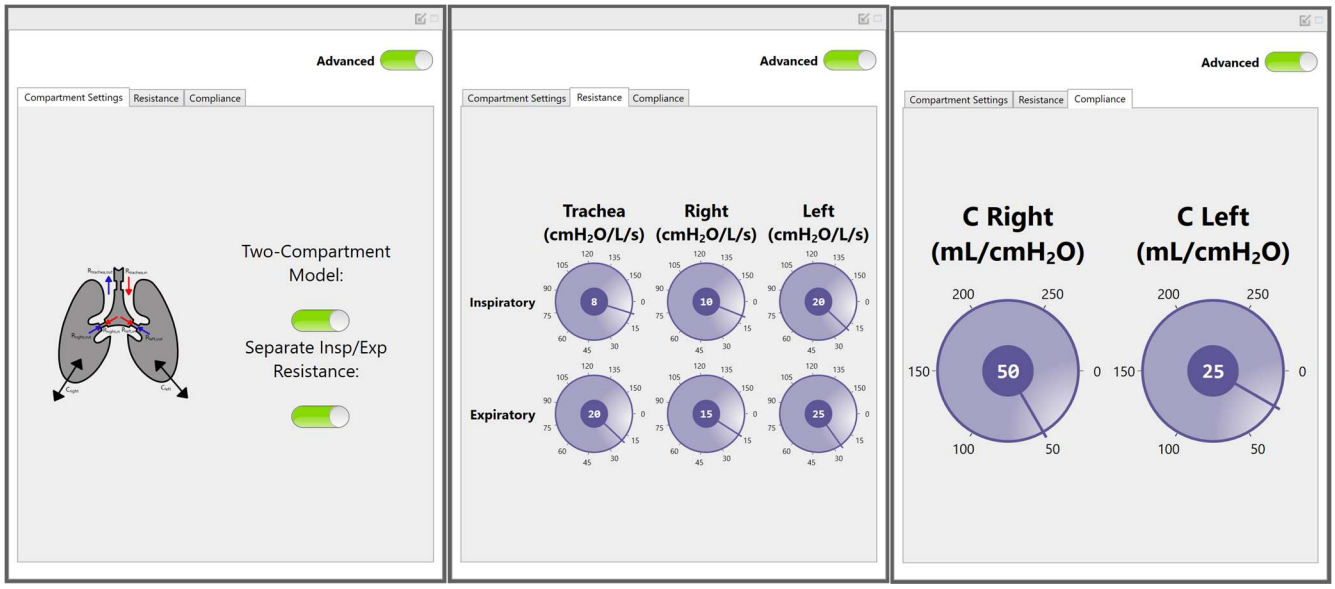

Figure 3-25 - Lung Model - 2 Compartment with Resistance_in not equal to Resistance_out

3.7 ASL Breath Effort Control

The **Breath Effort Control** window controls spontaneous breathing and breath rate.

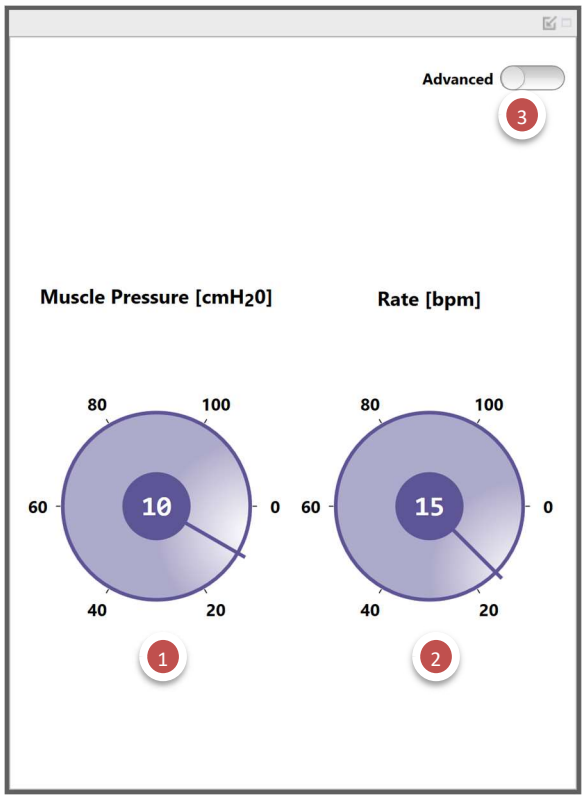

Figure 3-26 - Simple Effort Control

1. **Muscle Pressure** knob: Patient muscle pressure (negative pressure inside the lungs creating flow into the mouth). The user can also double-click the number inside and directly type a value.
    a. Muscle pressure range is from 0 - 50 cmH2O

NOTE

A value of zero (0) Muscle Pressure represents a passive, paralyzed or apneic patient. It is also important to note that this cannot be accomplished by setting the Rate to zero. The ALM lungs do not allow a Rate of zero but do allow a muscle pressure of zero.

2. **Rate** knob: the user can also double-click the number inside and directly type a value. Breath rates range from 3 to 100 breaths per minute.
3. Switch to the **Advanced** view for greater control of the breath effort.

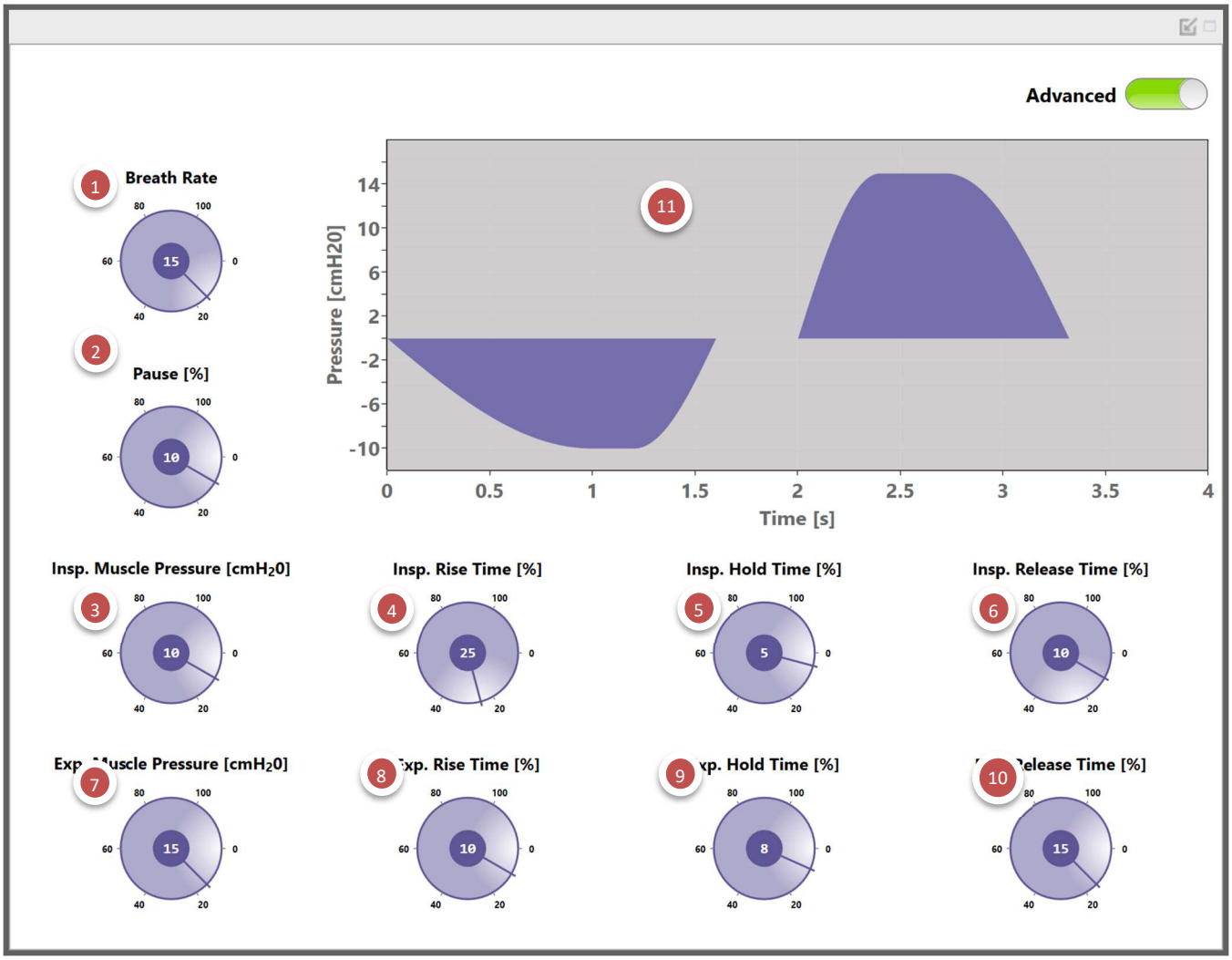

Figure 3-27 - Advanced Breath Effort Control

1. ***Breath Rate*** (breaths per minute)
2. ***Pause %*** (percent of total breath time between insp. vs exp. muscle pressure)
3. ***Insp. Muscle Pressure*** (maximum negative muscle pressure in the lung)
4. ***Insp. Rise Time*** (percent of total breath time for rise to peak negative muscle pressure, similar to i-time)
5. ***Insp. Hold Time*** (percent of total breath time for holding peak negative muscle pressure)
6. ***Insp. Release Time*** (percent of total breath time for release of the negative muscle pressure, similar to the passive component of e-time)
7. ***Exp. Muscle Pressure*** (maximum positive pressure in the lung – forced exhalation. It is recommended that when setting an Exp. Muscle Pressure, the Insp. Release Time should be set to zero %)
8. ***Exp. Rise Time*** (percent of total breath for rise to peak positive muscle pressure)
9. ***Exp. Hold Time*** (percent of total breath time for holding peak positive muscle pressure)
10. ***Exp. Release Time*** (percent of total breath time for release of the positive muscle pressure)
11. Graphical representation of spontaneous pressure profile over the defined breath cycle

4 TECHNICAL DATA

4.1 Performance Specifications

Modes of Operation	Passive Spontaneous Interactive (change lung parameters in pseudo-real time)
Volumes	Total (both lungs): 860 mL Tidal (both lungs): 800 mL
Flow	Peak Flow (per cylinder): 50 LPM Peak Flow (total): 100 LPM

4.2 Electrical Specifications

Supply Voltage (from SimMan®)	Input: Universal 100 to 240 VAC, 2.0A Max, 50-60Hz Output: 24V, 6.25A Max, 150W
ALM Electrical Specifications	24V, 4.0A Max

4.3 Physical Specifications

Dimensions	
ALM lung cylinder (each)	9 inches length (228.6 mm length) 3 inches diameter (72.2 mm diameter)
Weight (each)	2.34 lbs. (1.06 kg)

4.4 Communication Specifications

Interface	USB from primary lung to Auxiliary USB connector in SimMan®

4.5 Environmental Specifications

Operation	Temperature: 10°C to 40°C Humidity: 10 to 95%, non-condensing

Specifications are subject to change without notice.

5 TROUBLESHOOTING

The following conditions are problems that can be easily identified and remedied by the user.
For any help/support related to the ALM product please send an e-mail to: *support@ingmarmed.com*.

5.1 Lung Solution Software Installer Fails

Problem
When installing the Lung Solution software, the installer fails.

Resolution
Make sure LLEAP is installed prior to running the Lung Solution installer. Once this is verified, try to run the installer again. If upgrading to a newer version of the LLEAP software, make sure to uninstall the IngMar plugin first, upgrade to the new LLEAP, then install the IngMar plugin software.

5.2 IngMar Session Control Shows Unconnected Status

Problem

After loading the LLEAP software and confirming connection to the SimMan® Critical Care manikin, the IngMar Session Control window shows Status: Unconnected and Device: No Device.

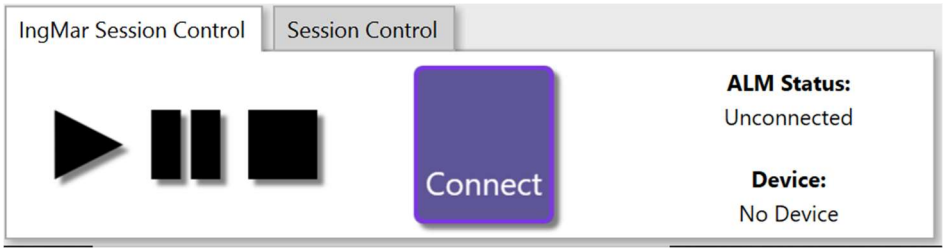

Figure 5-1 – Unconnected / No Device

Resolution

1. Confirm that the internal lungs completed their homing maneuver when powering on the manikin where the lungs make an audible move (this should always happen at startup)
2. Close the LLEAP software completely.
    a. Open Task Manager by right-clicking the windows logo and selecting Task Manager
    b. Click “More Details” at the bottom left is Task Manager is not expanded.
    c. From the “Processes” tab, scroll down to find LaerdalSimulationBridge (32 bit), select this task and at the bottom right of the window, click “End Task”.
    d. Restart LLEAP – the ALM Status should show Connected and the Device should show ISL-integrated

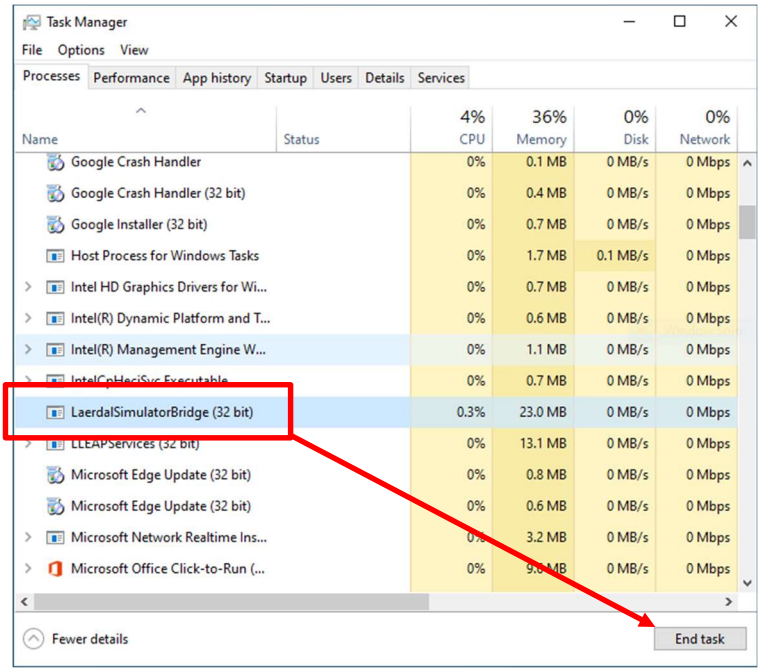

Figure 5-2 – End Task - LaerdalSimulationBridge

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