Spontaneous Breathing Lung (SBL™) Operation Manual

Michigan Instruments

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Thank you for your purchase of the Michigan Instruments
Spontaneous Breathing Lung.

This manual provides instructions to describe the SBL software set up and functionality.

For additional assistance -

- Free Technical Support.
    Phone: +1 616.554.9696 ext. 1319
    techsupport@michinst.com

Additional Operation Manuals – Traning &Test Lung and PneuView3 can also be found on our website.

https://www.michiganinstruments.com/user-manuals/

Don't forget to register your device
https://www.michiganinstruments.com/product-registration/

Contact us at any time with questions or concerns – +1 616.554.9696
Or email mii@michinst.com

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General Description

The Spontaneous Breathing Lung (SBL™) module is an electrically powered accessory made specifically to work with TTL® or PneuView® lung simulation systems*.

The SBL Module requires physical connection to the lung simulator. It may be ordered as a new system or can be retrofitted** to an existing device later by Michigan Instruments.

With the SBL module and associated software, the user may simulate ongoing spontaneous breathing that can be used for testing, demonstration, teaching and research and development applications.

Single Adult Lung Simulator with SBL™
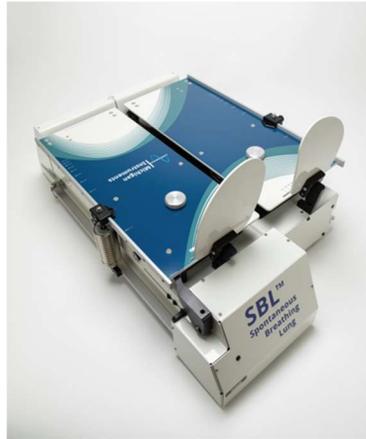
Dual Adult Lung Simulator with SBL™

Adult-Infant Lung Simulator with SBL™

IMPORTANT: This is not a technical service manual and does not contain the information to fully service the SBL. Please contact Michigan Instruments directly if service or assistance is required. The Michigan Instruments' Service Department can be reached at 1.616.554.9696 x 1343 or service@michinst.com.

*Refer to the Training and Test Lung and/or PneuView3 Operation Manuals for detailed instructions relative to their set up, specifications and functions.

**Retrofits can only be performed on Michigan Instruments generation 3 (Gen3) or newer models. Earlier versions will not accommodate the SBL module.

Specifications

Breath Rate	2-30 Breaths per Minute
Tidal Volume	100 to 1800* mL
Inspiratory Time	0.5 to 5.0 seconds
Flow Waveform (Insp.)	Square or Sinusoid
Power Supply	110-240 VAC (110 default, 240 set at factory, upon request at time of order)
Size and Weight	5x7x9 in. / 13x18x23 cm 8 lbs. / 3.6 kg
Compatibility (hardware)	Gen3 TTL/PneuView models- (AIN/AI3, DAN/DA3, SLN/SL3 only)
Compatibility (software)	Windows® 10 or later
Data Source/Connection	USB 2.0

* **Specification NOTE:** Maximum tidal volumes can be limited by other factors (Compliance setting, Breath Rates, Flow Rates, etc.). See Table 1 for available simulations.

Safety Information

Warning identifies hazardous conditions and actions that could cause bodily harm or death.

Caution identifies conditions and actions that could harm the product, the equipment under test, or cause permanent loss of data.

⚠️ Warnings

To prevent possible electrical shock, fire, or personal injury: Read all safety information before you use the Product.

Carefully read all instructions.

- Use the Product only as specified, or the protection supplied by the product can be compromised.

- Do not use the Product if it operates incorrectly.

- Do not use the Product if it is damaged.

- Disable the Product if it is damaged.

- **The SBL (Spontaneous Breathing Lung) Module has moving parts that apply significant force to the Michigan Instruments Lung Simulator. There is a danger of pinching and injury if hands or fingers are caught between the Lifting Arm of the SBL and the Top Plate of the Lung Simulator, or between the Lifting Arm of the SBL and the SBL enclosure.**

- Connect an approved three-conductor mains power cord to a grounded power outlet.

- Never use a two-prong plug adapter to connect primary power to the Product.

- Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.

- Turn the Product off and remove the mains power cord before cleaning the outer surface of the Product.

- Make sure the ground conductor in the mains power cord is connected to a protective earth ground. Disruption of the protective earth ground could put voltage on the chassis that could cause injury or death.

- Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.

- The SBL enclosure should only be removed by an authorized factory representative.

- Do not use the Product around explosive gas, vapor, or in damp or wet environments.

- The Product is intended for use with single-phase, grounded power. It is not intended for dual, split-phase or three-phase power configurations. But it can be used with any power system that supplies the correct voltages for single-phase and is grounded.

⚠ Cautions

- Operate the SBL and Lung Simulator in accordance with specified instructions and guidelines. Failure to do so could cause damage to the Product.
- SBL Modules for the PneuView System incorporate all connections for SBL and PneuView electronics. For safety and proper operation, it's important to ensure that connections are made properly.
- Monitor the lung and airway pressures generated during spontaneous breathing simulations. Excessive positive or negative pressures could cause damage to the product.

NOTE: There are safety features built into the SBL Software that will limit or pause the operation of the SBL if excessive negative pressures are generated. You may see the following message: **"Flow rate limited to avoid excessive negative pressure".** If you see this message, you should make changes to your SBL settings or Lung Simulator to avoid these negative pressures and prevent damage to the system.

Description (Hardware)

The SBL Module incorporates an electric stepper motor and drives a metal Lifting Arm that is engaged with the Top Plate of the TTL or PneuView system. This lifting movement expands the elastomer bellows of the lung simulator and generates negative pressure in the lung. This causes gas to be drawn into the lung through the simulated airway (or any other opening in the system). The SBL software program allows the user to manipulate and control the breathing characteristics of the lung.

Lifting Arm of SBL Module

Connections/Controls (SBL Module on PneuView Systems)
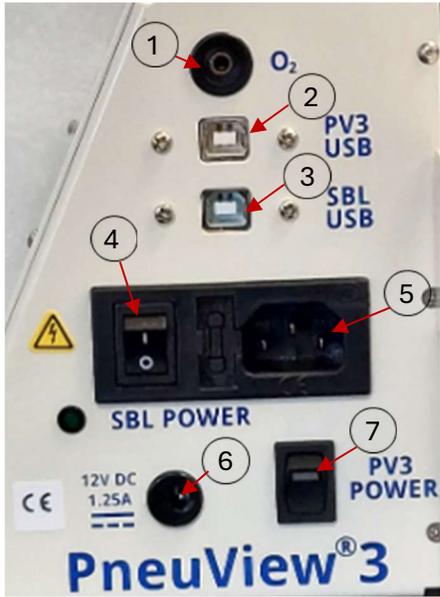
| 1	O2 Sensor Jack	Connection for O2 sensor cord when working with PneuView System
2	PV3 USB	Communication for PneuView System
3	SBL USB	Communication for SBL Module
4	I/O Switch	Power switch for SBL Module
5	SBL Power Receptacle	115V Mains input receptacle for SBL power
6	12V DC Input	Power input for PneuView System
7	PV3 Power	Power switch for PneuView System

Connections/Controls (SBL Module on TTL Simulators)

1	SBL USB	Communication for SBL Module
2	I/O Switch	Power switch for SBL Module
3	SBL Power Receptacle	115V Mains input receptacle for SBL power

Note: Head Simulation Modules from Michigan Instruments may be connected to the simulated airway of the TTL or PneuView to further enhance the spontaneous breathing simulation.

Description (Software)
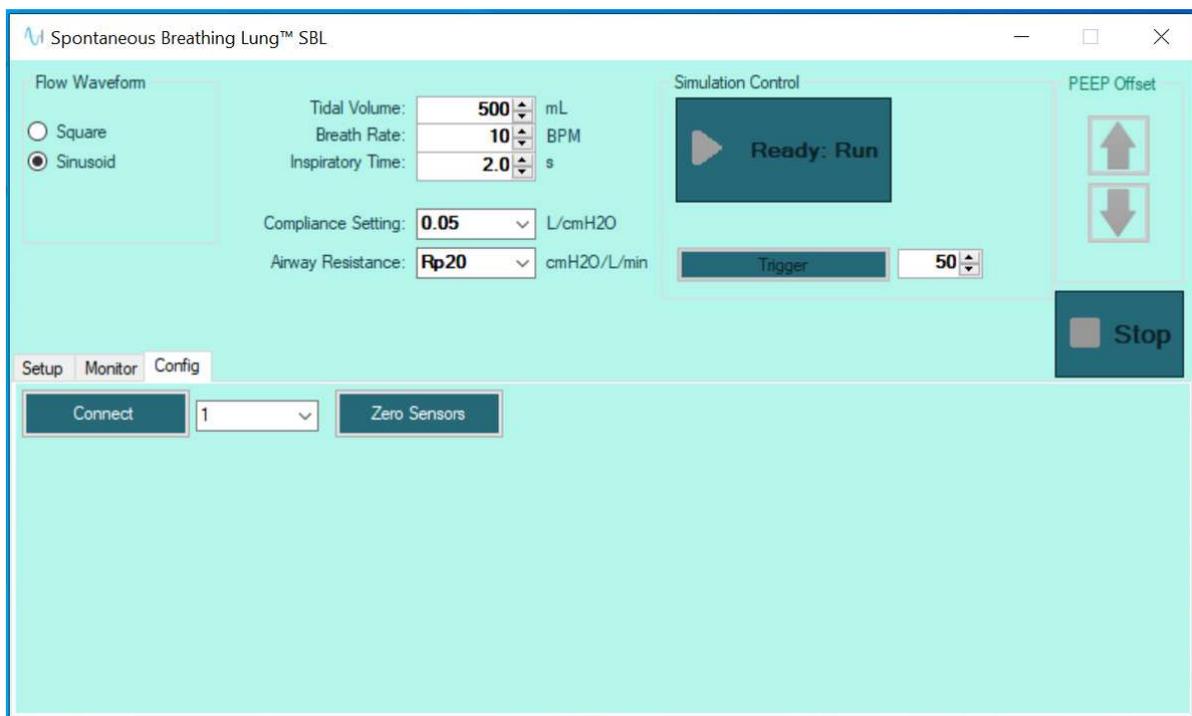
The Spontaneous Breathing Lung (SBL) software is a relatively simple application that facilitates control of the SBL Module. With this software you can select the tidal volume, breath rate, inspiratory time, and inspiratory waveform of the breathing simulation.

You may also start and stop the simulation, set the starting position of the test lung Top Plate (PEEP Offset) or trigger small patient efforts to test the response of the ventilator or respiratory support mechanism in question. There are entries for the lung compliance and airway resistance settings of the test lung. These are used to reference and adjust the lift required to achieve the SBL's set breathing parameters.

Lastly, there are also controls on the software screen for the general Setup, Monitor, and Configuration of the system.

Software Installation

The installer program for the SBL Control Software is generally provided on a USB flash/thumb drive and comes with your SBL Module. This software may be installed to a local desktop or laptop computer and is used to control the SBL Module that is physically connected (via the supplied USB cable) to a Michigan Instruments lung simulator (TTL or PneuView System).

To install the software:

1. Locate the SBL Software installer program (SBLSetup.msi) on your flash drive or wherever you may have copied or downloaded this program. To begin installation and setup of the software, double-click on the SBLSetup installer program. The following setup window should appear:

2. Follow the instructions in the Setup Wizard, then click "Finish" to complete the installation and setup.

3. During setup, the installation program will add the SBL Control Software to your Program files, and an SBL icon will be added to the Desktop of your device.

Initiating the SBL Software

1. **Note:** Make sure the SBL Module is powered ON (indicated by green light) and the USB cable is connected from the SBL Module to a USB connection on the computer where the SBL Control Software is installed.
2. Double click on the desktop icon for the SBL Spontaneous Breathing Lung.
3. The application will load, and the following start-up screen will appear.

Note: If connecting for the first time you will be asked to select a com port. Select the proper port and click connect.

4. Verify your test lung is not pressurized and click Zero to continue.

5. The default screen below should then appear.
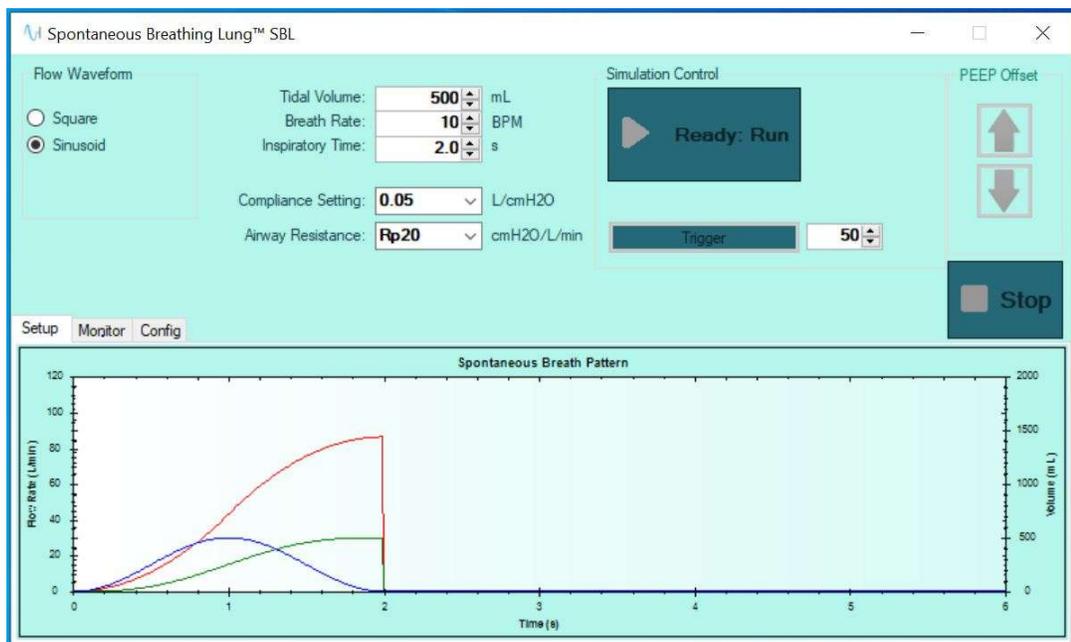
Hardware Operation

1. Plug the SBL Module into an appropriate, grounded 115VAC mains power source.
2. Connect the USB cable from an available port on your computer to "SBL USB" port on the SBL Module.
3. Turn SBL Power ON/OFF switch to the ON position.

Software Operation

1. Use the **Config** tab in the lower half of the screen. (see below)
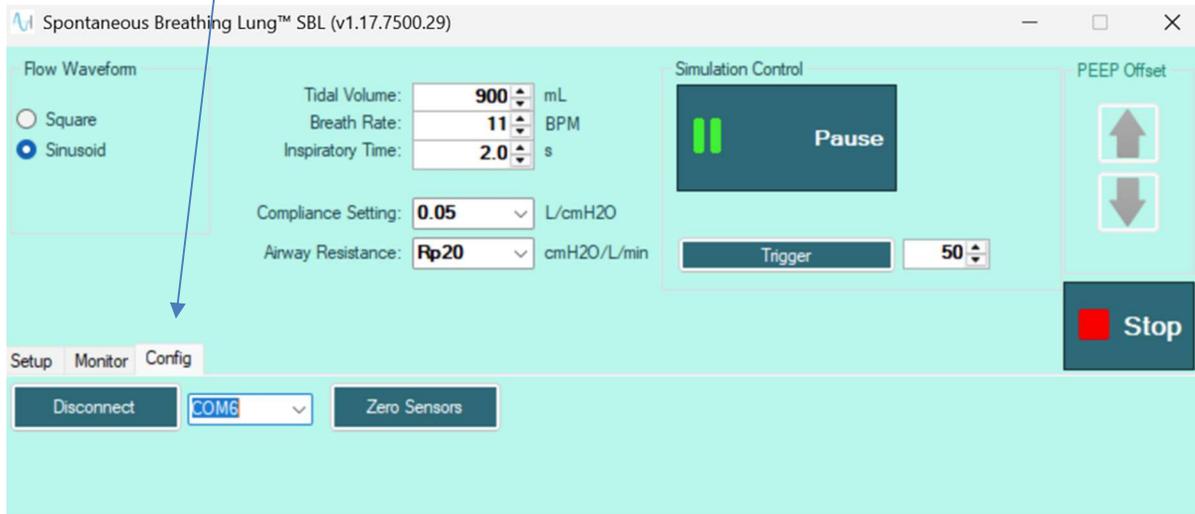
2. **Note:** your computer may already be connected to the software from the start-up screen or from previous use. If so, the button on the left will read Disconnect. If not, assign an available port from the dropdown menu and click on the **Connect** button.
3. You can zero the sensors by clicking on the **Zero Sensors** button.
   Note: this may not be necessary as the sensors are zeroed when the program is started. However, anytime you do zero the sensors it is important to make sure you don't have any pressure in the lung or anything connected to the lung.

Setting Up for Use

4. Use the **PEEP Offset** arrows to adjust the Lifting Arm of the SBL Module to just make contact with the side rail of the Top Plate of the lung simulator.
   ⚠️ **CAUTION:** If the lifting arm isn't properly contacting the side rail of Lung Simulator, the device will not function correctly.
   ⚠️ **CAUTION:** If PEEP or CPAP values are changed, the PEEP Offset should be used to reset the starting point of the lifting arm.

5. Enter the **Compliance Setting** and **Airway Resistance** as you have set on the lung simulator. (These values are not only there for reference purposes. They play a role in accurately operating the SBL.)

⚠ **CAUTION:** Certain volume levels are not available depending on the compliance setting. It is **very important** to have the actual compliance setting entered accurately into the software to avoid damage to the system.)
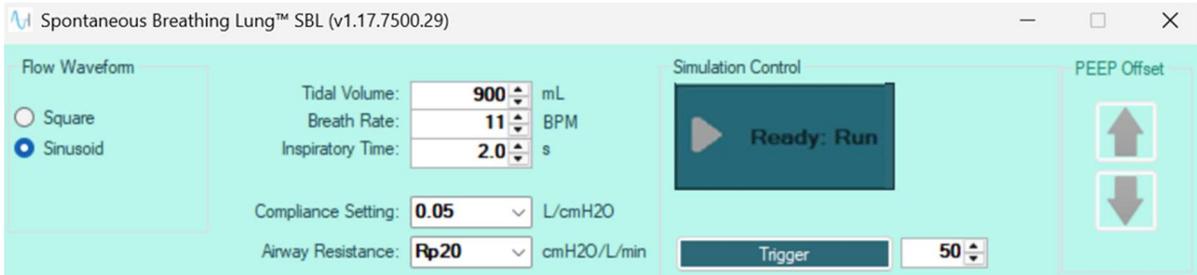
6. Adjust the available breath settings, Tidal Volume, Breath Rate and Inspiratory Time, to create the breathing simulation you desire.
7. Select **Ready: Run** to begin the simulation.
8. Select **Pause** to pause the simulation.
9. Changes can be made to the breath parameter values while running or paused but will only be initiated when the simulation is paused then resumed by selecting Ready: Run.
10. Select **Stop** or **Pause** to end the simulation.
11. If you use **Stop** to end the simulation, it will be necessary to press **Reset** before beginning a new simulation. In this case, you will be reminded to check the position of the Lifting Arm relative to the top plate rail and reposition it if necessary, using the PEEP Offset.
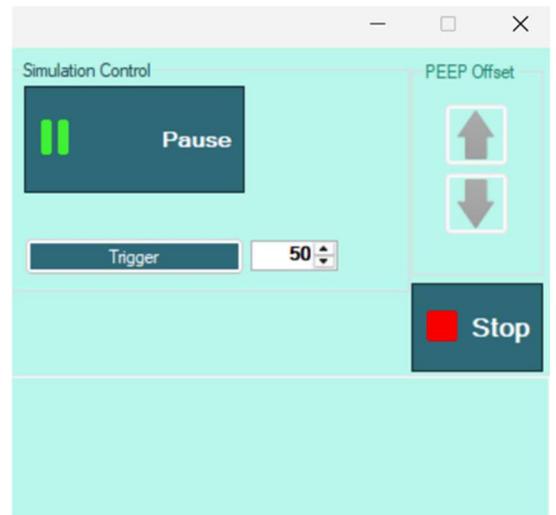
12. The **Setup** tab (see below) displays the expected flow and volume waveforms for the values you have selected for volume, breath rate and inspiratory time.
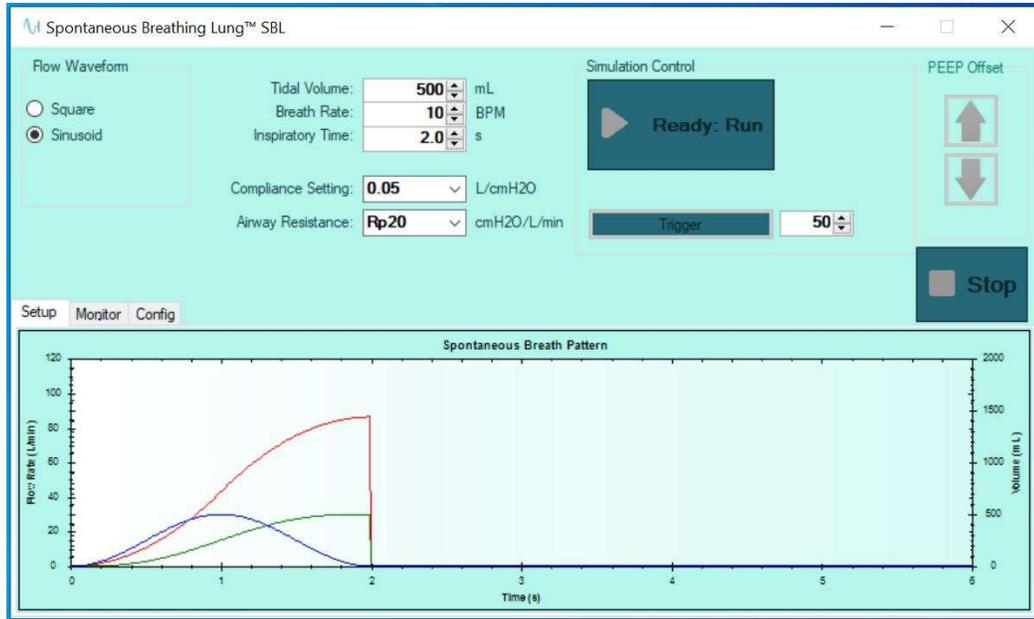
13. The **Monitor** tab displays the waveforms (volume and intra-lung pressure) in real-time as you run a simulation.
    Note: The Monitor window may be scaled by positioning the cursor, clicking/holding, and outlining the area of the field that you wish to expand. On a touchscreen, you may also use 2 fingers to expand and contract the scaling of the waveform window.


Note: The Monitor display can be reset by right clicking on the graph and selecting undo all zoom/pan.

The "Trigger" Command

This is a manual command that is activated by left-clicking on the Trigger field. The Trigger is available if you wish to use the SBL to trigger the operation of a mechanical ventilator or other external device. This is basically a low-volume breathing effort that can be used to test or validate the trigger function or sensitivity of a ventilation support device. The Trigger function may be used while the SBL is running, paused, or stopped.

Important Note: The set values in the SBL Control Software (and Trigger function) assume that the Lifting Arm of the SBL is engaged (just touching) the bottom of the Top Plate of the Lung Simulator prior to simulated breathing. (See below)
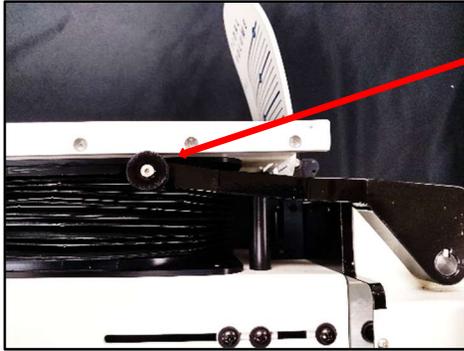
Lifting Arm engaged with Top Plate

EG. a tidal volume setting of 500 mL will result in the Lifting Arm moving a specific distance from the starting point. For this reason, it is important to establish the appropriate starting point. The PEEP Offset controls in the software can be used to step the lifting arm to the appropriate starting position.   A left click on a PEEP arrow (Up or down) will advance the lifting arm one position while a right click will move the lifting arm 10 positions.

Table 1 – Available Tidal Volume Settings (mL) ●

Tidal Volume Setting (mL)

Compliance Setting (Liters/cmH2O)

	50	100	200	300	400	500	600	700	800	900	1000	1100	1200	1300	1400	1500	1600	1700	1800
.10	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
.09	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
.08	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
.07	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
.06	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●
.05	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●	●	●
.04	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			
.03	●	●	●	●	●	●	●	●	●	●	●	●	●						
.02	●	●	●	●	●	●	●	●	●										
.015	●	●	●	●	●	●	●												
.01	●	●	●	●	●														

NOTE: Available tidal volumes may be limited by other factors (e.g. Breath Rates, Flow Rates, Airway Resistance, etc.)
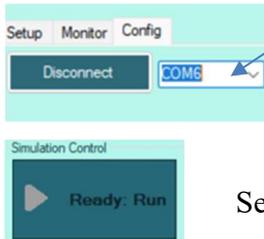
Troubleshooting

1. Unable to make communication with the SBL Module.

   Make sure SBL is plugged in and turned ON.

   Make sure the USB cable is connected from the USB port on computer to the correct USB connection on SBL Module.

   Open the SBL Software application. Select the 'Config" tab and assign new Com port. (Com numbers may vary)

   Select "Run" in the SBL Software.

2. Set (desired) tidal volume is not being achieved.
   - Make sure the Lifting Arm is just touching the bottom of the Top Plate before breath is initiated. Use the "PEEP Offset" control in the software to set the position properly.
   - Make sure the Compliance setting in the software matches the Compliance setting on the Lung Simulator.
   - Make sure the Volume Pointer on the Lung Simulator is set to match the Compliance Spring setting.

3. There is a clicking or jerky motion during the filling (inspiration) of the Lung Simulator.
   - This phenomenon occurs when there is excessive negative intra-lung pressure or the driving motor of the SBL is being pushed beyond its limits and ability to lift smoothly.
   - Either increase the lung compliance, increase the inspiratory time, decrease the airway resistance, or make other changes to lessen the load on the SBL motor.

4. The SBL Module shuts down due to excessive negative pressure created by the lifting motion.
   - This is a safety feature built into the SBL Software to prevent physical damage to the pressure gauges and other components of the Lung Simulator.
   - Either increase the lung compliance, decrease the airway resistance, decrease the tidal volume or increase the inspiratory time to reduce the negative pressure created during inspiration (filling) of the Lung Simulator.

Care and Maintenance

There are no user-serviceable components in the SBL Module.

The external surface of the SBL Module may be wiped down with standard surface disinfectants but take care not to introduce any fluids into the module.

Storage and Shipping

The SBL models come with a protective cover to keep the device clean from dust. The SBL models are slightly heavier than the Lung Simulators due to the additional module added.   It is recommended that the SBL models be stored on a table, bench or sturdy rolling cart (for convenience).

⚠️ **CAUTION:** If the instructions below are not followed, your device may incur damage during transport.

Securing the SBL for Transport

Detailed instructions for packing the Lung Simulator are found on page 23 of the TTL manual. The Spontaneous Breathing Lung requires additional steps for protection of the device.

1. Lower the volume scales.

2. Adjust the compliance springs (.02 Adult, .001 Infant).

3. Place SBL into plastic wrapping or reasonable option.

4. Using the original shipping carton, place the SBL unit on the bottom portion of the foam nest.

5. Insert protective blocks in front of the device and the back of the device (as pictured)*.

6. Place to top portion of the foam nest on the unit, ensuring that the insert is flush with the carton lid.

7. Close the lid and apply packing tape to the top, bottom and both upper side seams of the carton.

Shipping the SBL without using the original shipping carton

1. Perform steps 1-3 above.

2. Utilizing a sturdy corrugated carton (200 lb burst rated), large enough to allow a minimum of 2" clearance on all sides for packaging material.

3. Center the device on the packing material and fill the sides and top.

4. Insert protective blocks specific to the front and back of the device*.

5. Close the lid and apply packing tape to the top, bottom and both upper side seams of the carton.

⚠️ ***WARNING**: The device will incur damage during shipping if protective blocks/materials are not placed in the front and back of the device.

FAQ's

FAQ: Can I use the SBL in conjunction with the PneuView Software?

> *Answer: There is nothing to prevent the use of the PneuView software (PV3) in conjunction with the SBL. However, keep in mind there are limitations to the use of the PV3 software in spontaneous breathing simulations. The PV3 software has difficulty interpreting the negative pressures developed in a spontaneous breathing simulation. As a result, certain values displayed by the PV3 software will not be accurate when the PV3 software is used in conjunction with the SBL. Contact us for more details.*

FAQ: Sometimes, I'm not able to get the rate and volume combination that I set in the SBL software. Is that a problem?

> *Answer: Certain combinations of breathing patterns and lung mechanics are simply beyond the capacity of the SBL Module. Specifically, the set lung compliance limits the available tidal volume options in the software. Table 1 shows these restrictions/limitations.*

FAQ: Why does the SBL stutter during inspiration or completely stop running sometimes?

> *Answer: When the SBL stutters during inspiration, or stops completely, it is usually due to protections programmed into the software to limit excess negative intra-lung pressure. If the lifting load is too great or the negative pressure seen during inspiration is excessive, the motor operation will stutter or cease completely. This is done intentionally to prevent damage to the Lung Simulator. In such cases, settings should be adjusted to a safe operating range (E.G., reduce airway resistance, increase compliance, increase inspiratory time and/or reduce tidal volume).*

FAQ: Can I program breath patterns or parameters that are not included in the default offerings?

Answer: At this time, you are not able to program your own breath patterns in the SBL software. You must work with the rates, volumes, and timing available in the main SBL screen.

FAQ: Which models of TTL and PneuView can be driven by the SBL Spontaneous Breathing Lung Module?

Answer: The SBL Module is currently designed to operate on an adult Michigan Instruments lung simulator. It can be used on the Single Adult, Dual Adult, and the adult side of Adult-Infant models of TTL and PneuView products.

FAQ: Can the SBL Module be added to any TTL or PneuView System that I own?

Answer: No, the SBL is designed to be installed on one of the newer Michigan Instruments Lung Simulator models (TTL or PneuView – version 3.x). The SBL Module will not physically fit onto older models of TTL and PneuView. The SBL can be incorporated into your new Michigan Instruments Lung Simulator or it can be retrofitted to Gen3 units.

FAQ: Can I do the SBL retrofit to my Michigan Instruments TTL in the field?

Answer: The addition of the SBL to an existing Lung Simulator must be done at the Michigan Instruments factory. The retrofit process requires several modifications to the TTL or PneuView device.

Please contact Michigan Instruments for any other questions.

+1(616)554-9696 or email mii@michiganinstruments.com

Thank you for choosing the Spontaneous Breathing Lung!