Acute Shortage Ventilator

Operation and Troubleshooting Manual

Version 1.0

September 14, 2020

Contents

The Acute Shortage Ventilator and this manual have been prepared by the ASV Team. See our web page at https://www.slac-asv.net/

1 Introduction

The Acute Shortage Ventilator (ASV) is intended for use in hospitals when commercial ventilators are not available. The ASV can operate in Volume Controlled Assist Control (VC-AC) mode or Pressure Controlled Assist Control (PC-AC) mode. In both modes, the Respiration Rate (RR) and the Inspiratory Time can be set, as can the Inspiratory pressure that will trigger an assist breath.

In VC-AC mode, a Volume Maximum (VMax) is set. The flow measured by the spirometer is integrated to calculate the volume, and the bag compression is stopped when VMax is reached. An adaptive algorithm adjusts the precise stop point to accurately approach VMax. In VC-AC mode, the PIP Valve and PMax setting to the microcontroller provide independent limits on the airway pressure.

In PC-AC mode, the target inspiratory pressure is set manually on the PIP Valve. The pressure sensor provides an independent check on the pressure; it halts the bag compression for the current cycle if the PMax parameter is exceeded and it generates a high-priority alarm.

In both modes, the bag is held in its compressed state until the Inspiratory Time is reached. The bag is released, lowering the pressure, and exhalation occurs through the exhaust port of the Patient Valve into an optional PEEP Valve (set manually). The cycle then repeats, triggered either by the RR clock or by a voluntary inhalation.

This document describes the initial setup, use, and troubleshooting of the Acute Shortage Ventilator (ASV). The patient circuit is single use, and a sample is provided in the kit. The parts list for the included patient circuit is found in the Table 3. This manual covers the components included in the ASV, the setup process, and troubleshooting. Once setup, the ASV should be calibrated/tested between each patient or when components in the patient circuit have been replaced to check the patient circuit.

2 Description of System

Figure 1 shows a schematic overview of the system. The ASV consists of three main systems, each of which are detailed in the following sections:

1. A Patient Circuit including a oxygen supply and self-inflating bag

2. Mechanical frame with pneumatic valves and cylinder to compress the self-inflating bag

3. Electronics that operate the pneumatic system and measure the pressure and volume of air delivered to the patient.

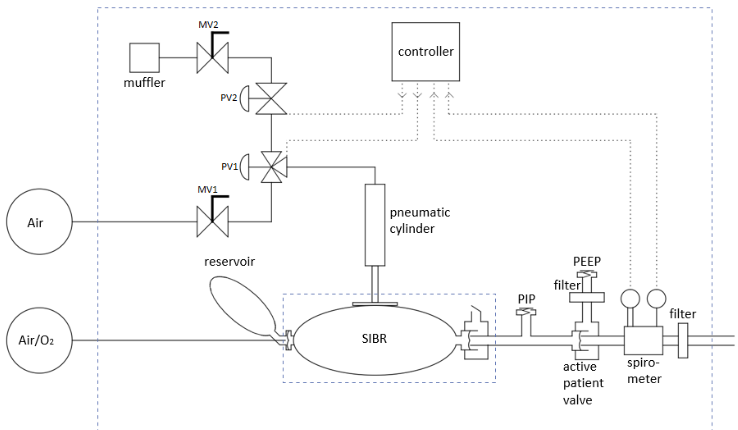

Figure 1: System diagram of the ASV. The SIBR represents a standard unmodified self-inflating bag resuscitator. The patient circuit to the right consists of standard ICU parts except for a modified PEEP valve and the pressure and flow sensors.

2.1 Patient Circuit

The patient circuit encompasses all of the components that handle the breathable air/oxygen that is delivered to the patient. This circuit includes a number of valves and filters to allow the ASV to work properly; these items are detailed below:

- Self-Inflating Bag Resuscitator — This bag should have an oxygen-input and reservoir bag for increasing FIO2. The delivered concentration of oxygen is neither measured nor adjusted by the ASV.

- PIP Valve — This valve sets/limits the maximum inspiratory pressure delivered to the patient. The PIP valve has been constructed by modifying a PEEP valve. It is critical to differentiate the modified PEEP valve with clear markings. The modification adds a short spacer, increasing the spring force and therefore pressure required to open the valve. This results in a PIP valve with a pressure range of approximately 20 to 40 cm H_2O. The markings on the modified valve will not correspond to the actual pressures and must be translated using a calibration curve. Testing/calibrating the PIP valve is a critical part of setup and is covered in the setup of the patient circuit. The actual modification of the PEEP valve into a PIP valve and its calibration check is described in appendix A.

- Active Patient Valve — This valve directs the inhalation air to the patient, and the exhalation to the exhaust port which has a HEPA-filter and a PEEP valve. The Active Patient Valve is critical to the functioning of the ASV.
- Spirometer — The spirometer provides ports for measuring the flow and pressure of delivered air. Three sensing tubes connect the spirometer to the ASV's pressure sensors using unique plugs. The orientation of the spirometer is important for correct flow measurements. A small modification to the pressure tube is described in the Initial Setup section.
- Heat Moisture Exchange Filter (HMEF) — This filter protects the spirometer from being clogged by patient excretions and provides some humidity exchange function.
- Exhaled air goes back through the HMEF and spirometer and is diverted by the Active Patient Valve to the exhaust branch. It is critical that the total volume of tubing and parts from the Active Patient Valve to the patient is minimized to limit re-breathing of exhaled air.
- HEPA-Filter (exhaust branch) — Prevents contagion from spreading into the air from the patients exhalation.
- PEEP Valve (exhaust branch) — Provides positive end-expiatory pressure that is settable on the valve.

Figure 2 shows the complete patient circuit, and Fig 4 shows the close up of the region near the patient.

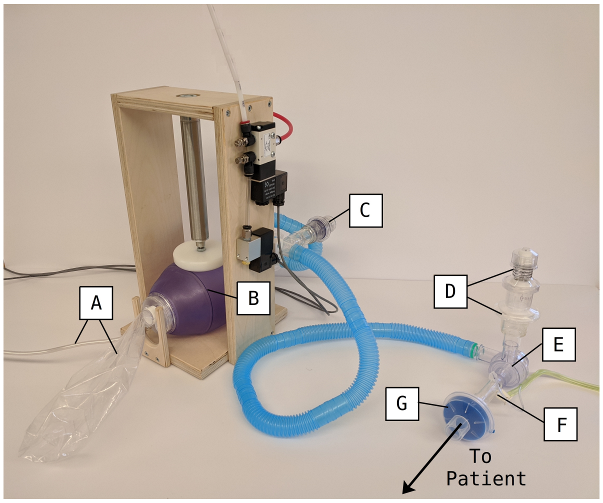

Figure 2: Close up of patient circuit . A: Patient air supply hose and reservoir bag; B: Self-inflating bag; C: PIP valve; D: HEPA filter and PEEP valve; E: Active patient valve; F: Spirometer; G: HMEF filter.

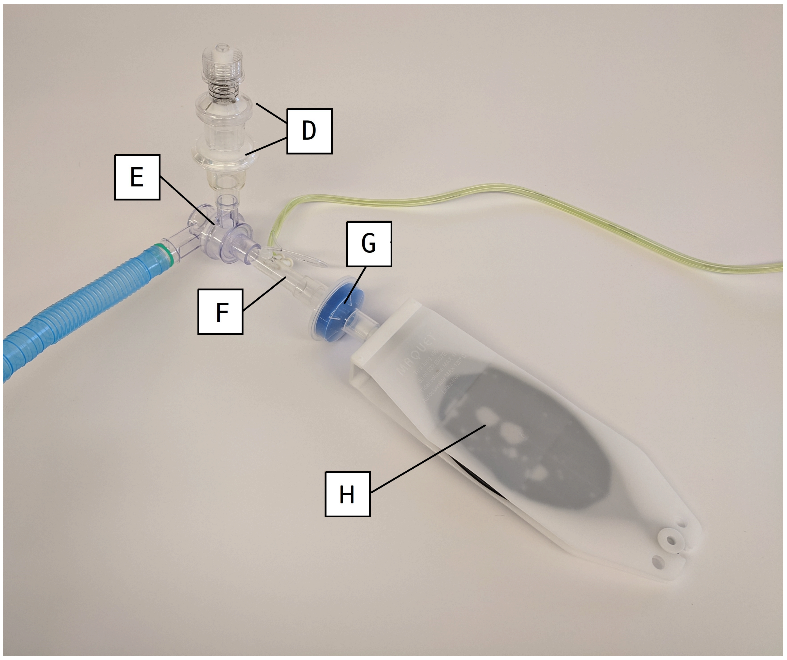

Figure 3: Close up of patient connection to test lung (right). D: HEPA filter and PEEP valve; E: Active patient valve; F: Spirometer; G: HMEF filter; H: Simple test lung.

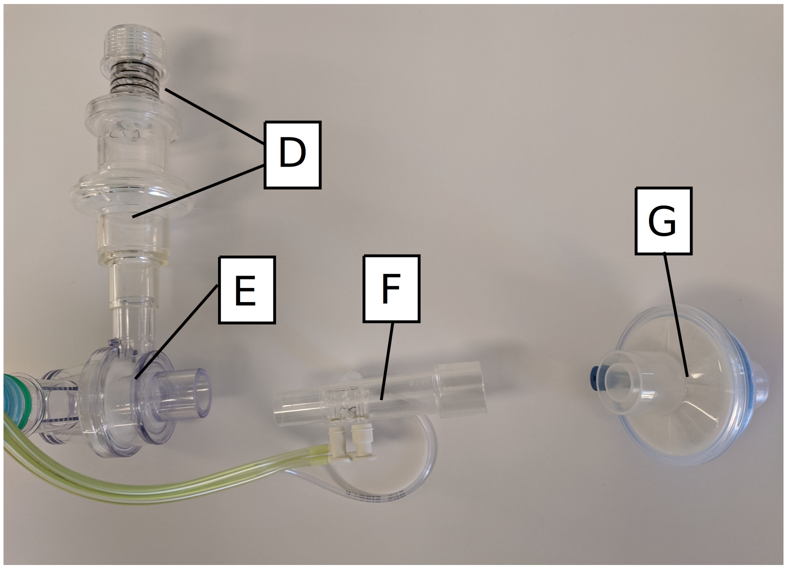

Figure 4: Close up of the spirometer connection in the patient circuit, disassembled. D: HEPA filter and PEEP valve; E: Active patient valve; F: Spirometer; G: HMEF filter;

2.2 Pneumatic System

The ASV piston is driven by compressed air (or Nitrogen). A stable supply of air at ≈ 50 psi (3 bar) is required. The ASV consumes about 3 liters per minute (0.1 scfm) at an RR of 20 bpm; thus a standard K-size gas cylinder would support a ventilator for about 30 hours. The ASV compressed air consumption is roughly half that of patient oxygen. In a situation where patient oxygen and ASV air is coming from bottles, less ASV air bottles than oxygen are likely to be consumed per day.

The pneumatic system includes a single-action spring return cylinder. This kind of cylinder uses air pressure is to extend the plunger, and release of the air pressure allows the plunger to retract under the force of the internal spring. Two solenoid valves are used to control the air flow into and out of the cylinder, and are shown in Fig 5. The input pneumatic air enters the top port of the top valve. When activated by 12V this solenoid valve diverts pneumatic air to the cylinder, extending the plunger. When the plunger is set to stop, the electronics will shut off 12V to the top valve. This diverts air from the cylinder (out the lower port) to the second valve which is normally closed. To retract the plunger, 12V is sent

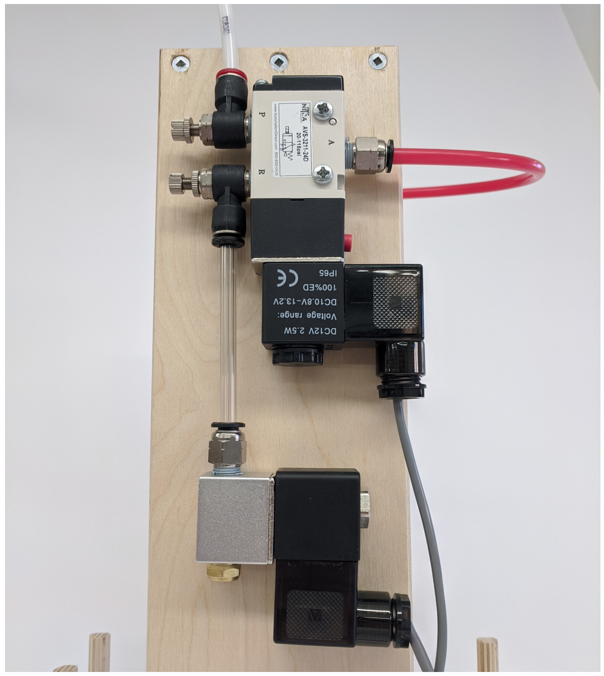

Figure 5: Close-up view of the pneumatic valves. The upper valve controls the direction of air into the cylinder. The compressed air input is in the upper left port. The lower valve opens to vent the air from the cylinder so that it can retract.

to the lower valve, opening it and allowing the air to escape from the cylinder to the atmosphere through a muffler.

Two adjustable valves on the input and output of the upper valve control the speed that the plunger descends and ascends during the stroke. Their proper settings are established in Section 3.4.

2.3 Electronics

The electronics are housed in two separate enclosures. The primary enclosure contains the processors and control electronics for the ASV. This enclosure also contains several connectors for power input, computer-data output, pneumatic valves power, and sensor input. A display on the primary enclosure also displays current running conditions and allows most setting to be adjusted using the knob input. A second smaller enclosure containing the sensors is wired to the main electronics box, and is also connected via the sensing tubes on the spirometer to the patient circuit.

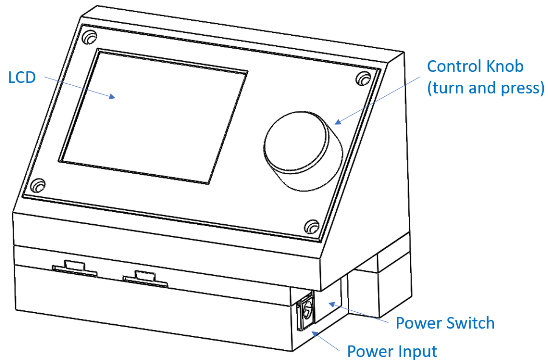

Figure 6: Main electronics box front view.

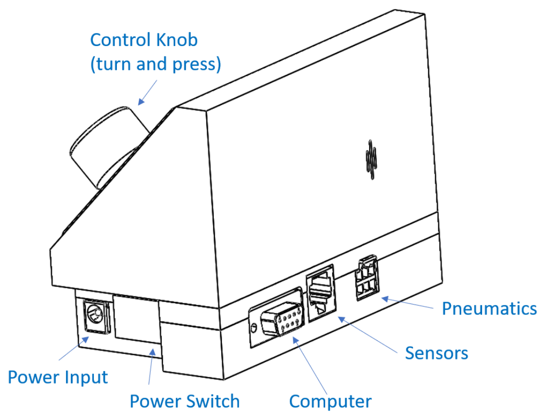

Figure 7: Main electronics box back view.

Inside the primary enclosure is a 9V battery backup that provides diagnostic and alarm capabilities upon power failure. The ASV cannot actuate the pneumatic valves in the event of primary power failure, however, and an external UPS is recommended.

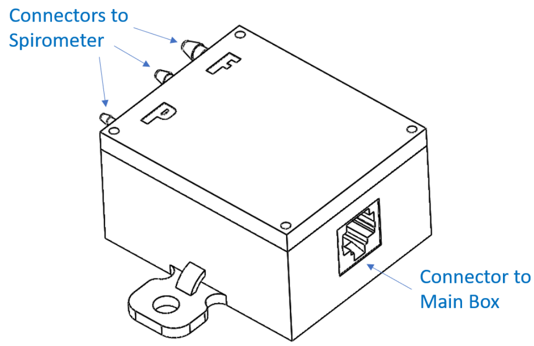

Figure 8: Sensor electronics box.

3 Operation

The ASV operates in two modes and has a number of settable and displayed parameters. These parameters are described in the next section 3.1, and then the modes are described in section 3.2.

3.1 Parameters

The settable parameters are shown in Table 1.

The parameters measured and displayed are shown in Table 2. Both the Main Electronics Box and the Laptop GUI can change the settable parameters and show the displayed parameters. On the Main Electronics Box, there is one knob that enables control. The knob is pushed in to begin. Rotating the knob changes the focus on the display by changing the color of one parameter. At the desired parameter, push the button in. Then rotation adjusts that parameter. Click when finished. The focus will time out after 10 seconds.

Abrev.	Parameter Name	Modes	Description
RR	Respiratory Rate	P/V	Sets the respiratory rate in breaths per minute
IT	Inspiritory Time	P/V	Sets the inspiration time in seconds.
TH	Trigger Thresh-old	P/V	Sets the pressure threshold that will trigger a voluntary breath. If this threshold is not meet a breath will be delivered at the set Respiratory Rate.
VMax	Volume Maxi-mum	V	Sets the volume set point in volume-limited mode. When this volume is reached the inhala-tion breath will stop and wait until the IT time is reached. Once IT is reached the cylinder will retract and the exhalation will begin.
PMax	Pressure Maxi-mum	P/V	Sets the maximum pressure that, if exceeded will set off an alarm and stop the ASV. This is used to detect a stuck exhaust valve prevent and over-pressuring the patient lungs. This should be set to more than the PIP valve.
PMin	Pressure Mini-mum	P/V	Sets an alarm on low pressure if the patient cir-cuit goes below this.

Table 1: Settable parameters for the ASV. The modes are abbreviated V for Volume-Control Assist Control and P for Pressure-Control Assist Control.

Display	GUI	Description
PEEP	PEEP Min (cm H_2O)	The lowest pressure seen in the previous cycle in cm H_2O
PIP	Max PIP (cm H_2O)	The highest pressure seen in the previous cycle in cm H_2O
Vol	Max Volume (mL)	Previous cycle volume delivered in mL
I:E	IE Ratio	The calculated inspiritory time to expiritory time ratio. This may differ from settings if the patient is using the assist-control by requesting breaths at a faster rate then the RR setting.

Table 2: Display parameters updated every cycle with information on ventilator performance.

3.2 Modes of Operation

The ASV supports two modes of operation which must be selected using either the display or GUI interface. The default mode is Volume-Limited Assist Control.

- **Volume-Limited Assist Control** — This mode attempts to deliver the specified volume each cycle to the patient. The Max Volume (VMax) setting determined this volume. Upon startup the first few breaths may fall short of VMax – the ASV is programmed to ramp up the volume as it learns the system response.
- **Pressure-Limited Assist Control** — This mode uses the PIP valve to limit the pressure of the inhalation, which terminates at the set inspiritory-time (IT).

Both Modes provide Assist Control, meaning that a breath can be initiated by the patient if the patient pressure reaches the trigger-threshold (TH).

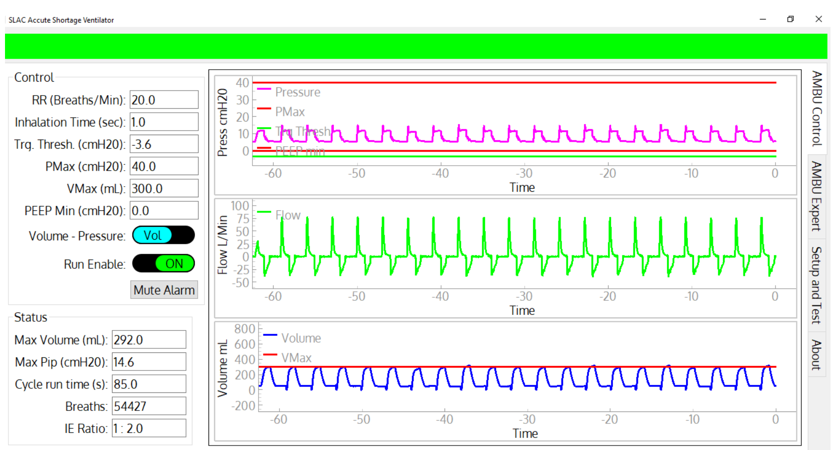

Figure 9: The Control and Monitoring GUI. All primary controllable parameters described above are on the upper left. The time histories, along with the levels for PMax, Trigger Threshold, PEEP Min, and VMax are displayed on the right. The major status values are on the lower left. The green banner on the top indicates no alarm conditions. Given an alarm, it changes to red or amber, flashes, and displays the alarm condition text.

The Expert page permits adjustment of the vertical scales of the time history display. It displays the status of each possible alarm and warning state sepa-

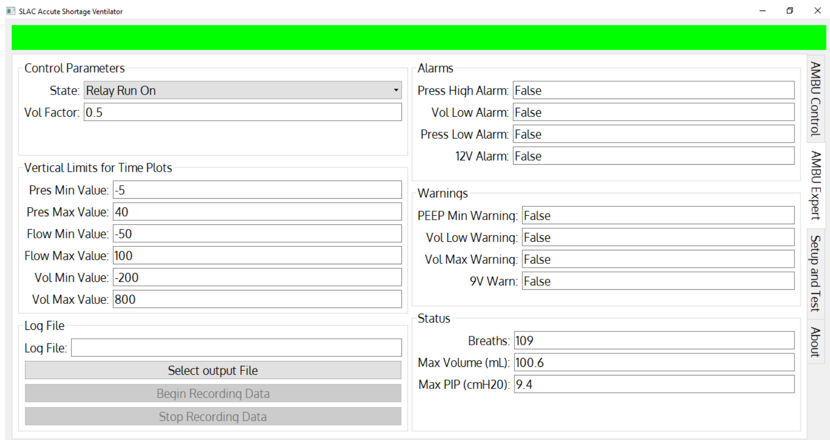

Figure 10: The Expert page of the GUI.

rately. It also permits data logging for offline use.

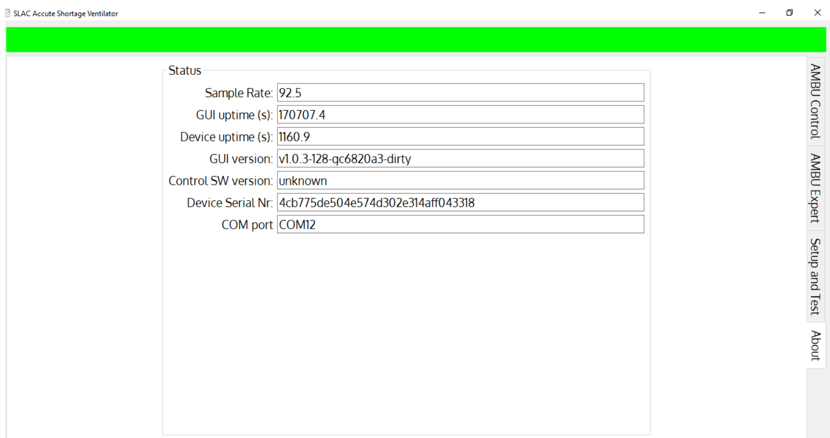

Figure 11: The About page of the GUI.

The About page displays information about the ASV overall performance and code versions. The Sample rate is the number of times per second that the sensors are read and the internal control parameters are updated. It should be above 80. Next is the uptime in seconds for the GUI running on the laptop, followed by the uptime in seconds of the ASV microcomputers.

Figure 11 shows the ASV GUI. The ASV can operate in Volume Controlled Assist Control (VC-AC) mode or Pressure Controlled Assist Control (PC-AC) mode. In both modes, the Respiration Rate (RR) and the Inspiratory Time can be set, as can the Inspiratory Pressure that will trigger an assist breath.

In VC-AC mode, a Volume Maximum (VMax) is set. The flow measured by the spirometer is integrated to calculate the volume, and the bag compression is stopped when VMax is reached. An adaptive algorithm adjusts the precise stop point to accurately approach VMax. In VC-AC mode, the PIP Valve and PMax setting to the microcontroller provide independent limits on the airway pressure.

In PC-AC mode, the target Inspiratory Pressure is set manually on the PIP valve. The pressure sensor provides an independent check on the pressure; it halts the bag compression for the current cycle if the PMax parameter is exceeded, and it generates a high-priority alarm.

In both modes, the bag is held in its compressed state until the Inspiratory Time is reached. The bag is released, lowering the pressure, and exhalation occurs through the exhaust port of the Patient valve into an optional PEEP valve (set manually). The cycle then repeats, triggered either by the RR clock or by a voluntary inhalation.

3.3 Monitoring and Alarm System

The ASV monitors status of electrical power and key operational data. It generates medium and high priority alarms annunciated by a sound generator and visual signals on the GUI and local display. A summary of the required alarms is found in Table **??**. The visual indications remain on the display until the alarm condition is no longer met. The alarm conditions are:

- Electrical Power Lost (Priority level: High): The 12 V electrical power is lost. The ASV cannot run in this state, but the alarms will be powered by the standby battery.

- PMax (High): The patient-circuit pressure has exceeded the PMax parameter. This indicates there may be a problem with the PIP valve, the hoses, the endotracheal tube, or the patient. The ASV continues running, but stops the compression of the bag at PMax on each cycle.

- Pressure Low (High): The patient-circuit pressure is low. Possible reasons are the ASV has stopped due to loss of the pneumatic system, or a disconnected patient hose.

- Volume Low (High/Medium): In PC-AC mode this is a high alarm when the volume drops below 250 ml. In VC-AC mode this is a medium alarm when the volume drops below 80% of VMax. The expected volume has not been met, possibly due to a disconnected or kinked hose.
- Volume High (Medium): In VC-AC mode this is a medium alarm when the pressure exceeds 120% of VMax.
- 9 V Battery Low (Medium): The 9 V standby battery must be replaced to prevent failure of the Electrical Power Lost high-priority alarm. However, in the absence of this 9 V battery power, the ASV continues running normally.

3.4 Setup and Test

This page is available only from the laptop GUI. It should be used whenever new patient circuit parts are introduced to ensure proper assembly. The procedure guides the operator through a series of steps requiring the attention of the operator. If something is wrong, it must be fixed before going to the next step.

- ”The ASV should be off and the plunger up. Check that the patient circuit is connected and a test lung in place. Make sure the compressed air supply is connected and on” State: Plunger Up
- ”Press the plunger down by hand. The pressure, flow, and volume plots should indicate the bag compression” State: Plunger up The pressure and flow should increase (up on the graph) as the bag is compressed. If the pressure goes down, the spirometer may be connected incorrectly. If the flow is reversed, check that the direction of spirometer is correct, so that the three tubes from the spirometer are next to the Active Patient Valve.
- ”Set the mode to Pressure, set PMax to 40, and set VMin to 10. The ASV is now cycling. Check that the plunger pushes the AMBU bag down smoothly, about ½ second, before the plunger comes up. Adjust the air supply valve as needed. Adjust the exhaust valve so paddle rises smoothly” State: Plunger Cycling
- ”Leak Check. After the plunger goes down, observe the pressure plot. The pressure should decline slowly, taking at least 10 seconds to reach

0. Faster indicates a leak in the patient circuit." State: Plunger up for 5 seconds, then plunger down.

- "PIP Check: Check that the PIP valve has a marked cap indicating it has been modified for higher pressure. Set PIP to maximum (clockwise) position State: Plunger Up
- "Check on pressure vs time display that peak pressure is not more than about 40 cm H2O. If higher, PIP Valve is not working properly. Replace." State: Run 10 cycles
- Set PIP valve back to 30 cm H2O. Set PMax parameter to 20 cm H2O" State Plunger UP. "The ASV is running. Check the pressure plot to see that the paddle cycle stops when PIP is reached, and that an alarm is generated. State: Cycling /item"Reset the Pmax parameter to 30, matching the valve. Set mode = Volume. Set VMax to 300" State: Plunger UP. "The ASV is cycling. The volume should home in on VMax." State: Plunger cycling /item"The ASV should be ready for use" State: Run OFF

4 Patient Circuit Bill of Materials

Description	Source	Qnty	Unit Price	Total Price
Peep Valve	Smiths Medical 8501	2	\$22.26	\$44.52
HME Filter	Medline DYNJAAHME1	1	\$2.12	\$2.12
MRI Active Patient Circuit	Medline DYN-JAA300NF	1	\$23.64	\$23.64
Manual Resuscitator w/ Reservoir Bag	Smiths Medical 8500P	1	\$40.84	\$40.84
Exhalation Filter	N/A (price estimated)	1	≈ \$10.00	≈ \$10.00
Straight Connector with Port	Vyaire 004081	1	\$1.91	\$1.91
22-15-22mm Tee Connector	Westmed 0219	1	\$0.51	\$0.51
22mm Cuff Connector	Vyaire 001821	3	\$0.98	\$2.94
Spirometer	GE 8004382	1	\$14.30	\$14.30
1L Test Lung	SunMed 4-0050-XX	1	\$21.95	\$21.95
			Total	**\$162.73**

Table 3: Build of Materials for the patient circuit.

5 Appendix A

To modify the standard PEEP valve into a PIP valve a short spacer is added into the PEEP valve. The short spacer is 3-D printed, is approximately 26 mm long and the schematics (" PEEP to PIP converter 26 mm.STL") can be found at https://www.slac-asv.net/documentaton. It can be printed in both PLA or PETG, takes about 1 g of material and less than 10 minutes to print on fine settings. Once the spacer is printed it can be inserted into the PEEP valve with the following steps:

1. Loosen the small flat screw on the side of the PEEP valve with a screwdriver. It only needs to be loosened about half way to not interfere with the next step.

2. Remove the pressure adjuster cap of the PEEP valve by fully unscrewing it (left side turns) till it comes off.

3. Insert the spacer into the cap and screw it back on the PEEP valve. It only fits in one way, the narrow part goes into the cap open tab, the wider part fits on the little plastic spring compressor.

4. Fasten the small flat screw on the side of the PEEP valve with a screwdriver.

The resulting PIP valve should give pressures within a range of 15 to 35 $\pm$ 5 H_2O, and should be cross checked with the pressure sensor of the ASV in the calibration tab of the GUI before use.

6 Appendix B

The ASV is shipped as:

1. A printed copy of the latest version of this manual.

2. A bag with all components for the patient circuit.

3. A bag with the main frame including pneumatic cylinder, valves, valve cable, and sensor box.

4. A bag with the main air supply tubing and assorted connectors.

5. A bag with the Display Module and GUI USB drive.
6. A bag with the power supply, ethernet cable (for the sensors), a small Phillips Head screwdriver, a 9V battery , and the serial cable.