



LIVe ventilator

Easy to use automatic ventilator Operator guide MODEL: 600x10

LIVe Ventilator

Life Improving Ventilator

Operator's Manual Model 600x10

P/N: UM3010 Date:8-Nov-23 Rev1.50

Table of Contents

GLOSSARY	7
SPECIFICATION OVERVIEW	8
FEATURES	8
ADVANTAGES	8
INTRODUCTION & BACKGROUND	9
LIVE OVERVIEW	10
WHEN THE LIVE SHOULD BE USED / INDICATION FOR USE STATEMENT	10
WHEN THE LIVE SHOULD NOT BE USED	10
TRAINING REQUIREMENTS	10
RISKS AND BENEFITS	11
GENERAL WARNINGS AND CAUTIONS	11
IMPORTANCE OF THE NEED TO ADHERE TO INSTRUCTIONS	12
PRE-DEPLOYMENT CHECKOUT PROCEDURE	12
STEP 1 – VERIFY KIT CONTENTS	13
STEP 2 – DEBRIS FILTER	14
STEP 3 – BATTERY LIFE	15
STEP 4 – HIGH PRESSURE ALARM	15
STEP 5 – LOW PRESSURE ALARM	15
OPERATING THE LIVE	16
CONTROL KNOB POSITIONS	16
PATIENT CIRCUIT (VALVE)	16
USING THE LIVE	17
IMPORTANCE OF THE NEED TO MONITOR THE ACTIVITY OF THE DEVICE	19
INDICATORS AND ALARMS	19
BATTERY LEVEL INDICATOR	19
LOW BATTERY ALARM	19
HIGH TEMPERATURE ALARM	19
PATIENT-RELATED (CORRECTABLE) ALARM	20
DEVICE (NON-FIELD SERVICEABLE) ALARM	20
INSTRUCTIONS ON USE OF ACCESSORIES	20
USE OF MASK	21
USE OF ET-TUBE	22
USE WITH SUPPLEMENTAL O2	22
SECURING THE LIVE TO THE PATIENT	23
MAINTENANCE	24
REGULAR MAINTENANCE	24
PRIOR TO USE	24
AFTER USE	24
CHARGING	25
CLEANING	25
EXTERIOR	25
DEBRIS FILTER	26
PATIENT CIRCUIT	26
ANNUAL MAINTENANCE	26

STORAGE	26
EXPECTED FAILURE TIME AND MODE AND THE EFFECT ON THE PATIENT	26
INSTRUCTIONS ON HOW TO SAFELY DISPOSE OF THE DEVICE	26
TROUBLESHOOTING	27
ALARM OVERVIEW	27
PATIENT ALARMS	27
DEVICE ALARMS	28
LOW BATTERY ALARM	28
HIGH TEMPERATURE ALARM	28
LIMITED WARRANTY	28
ELECTROMAGNETIC EMISSIONS AND IMMUNITY	30
TECHNICAL OVERVIEW	32
ACCESSORY ORDER INFORMATION	34
REGISTERING THE LIVE	34

Glossary

CO2	Carbon Dioxide
ET-	Endotracheal Tube
Tube	Oxygen
02	Positive End Expiratory Pressure
PEEP	Life Improving Ventilator
LIVe	Peak Inspiratory Pressure
PIP	Bag Valve Mask
BVM	

Apneic Patient - Patient that is not breathing.

SPECIFICATION OVERVIEW

Model 600x10

OPERATION MODES:CMV, CMP, IMV, SIMV, Pressure Triggered, PSV, PCV, NIPPV, IPPVBATTERY LIFE:up to 2.5 hoursUNIT WEIGHT:3.1 lbs (1.4 kg)UNIT SIZE:6.75" x 6.25" x 2.5" (17 x 16 x 6 cm)TIDAL VOLUME:270 to 800 mL/breathRESPIRATORY RATE:8 to 20 BPMPIP LIMIT:38 cmH2O

FEATURES

- Variable tidal volume and respiratory rate corresponding with lung capacity.
- Ease Of Use: Single knob operation
- Does NOT require compressed gas source
- System can accept supplemental O2
- Pressure limited to avoid over-pressurization of lungs
- · Fail-safe mechanisms and visual/audible alarms
- High-pressure alarm detects airway blockage
- Compatible with colorimetric detector for ETCO2 in patient exhale
- Rechargeable battery last for up to 5.5 hours per charge

ADVANTAGES

- Fills an underserved need in emergency resuscitation
- More consistent tidal volume and breath rate
- Compact design makes it highly portable
- Reduced training requirements
- Quick turnaround between patients
- Disposables avoid cross contamination
- · Long shelf life and durability
- Designed for remote/austere locations
- The LIVe will run over 4 times longer on a single charge than a pneumatic ventilator running on a D tank

Introduction & Background

Proper ventilation of patients is difficult even in an ideal conditions. Sometimes, the first ventilation is performed on a patient outside the hospital environment, which requires a portable ventilator with simple use. LIVe ventilator is designed with the aim of saving human lives and increasing the ability of medical and rescue teams.

Usually, in emergency situations outside the hospital, access to large and heavy ventilators is not possible, and for this reason, in the past, in order to save patients outside the hospital, bag valve masks (BVM) or pneumatic resuscitators which are connected to the oxygen capsule had been used. Complications after ventilation with BVM or pneumatic resuscitators led to the production of lightweight ventilators. LIVe ventilator is designed with the purpose of automatic detection of lung volume and compliance, and adjusting the breath rate. This ventilator works without an oxygen capsule. The volume and pressure of the patient's lungs are monitored and it works completely automatically and does not require an expert user to set the parameters of the device. If the ventilator is used under the supervision of a specialist, the correct way of connecting the patient circuit is ensured and the rescue will be done more quickly. In addition, by equipping the device with alarms related to the patient and related to the device, such as detecting airway obstruction or airway leakage, the performance of the device is guaranteed.

The use of BVM in patient resuscitation makes one of the rescuers only responsible for ventilation and cannot help with the patient's injuries or take care of other patients at the ideal time. The current respiratory volume and variable breath rate in each ventilation of the patient are serious problems of BVM. Due to the high adrenaline that is released in the rescuer's body, it is almost impossible to maintain a low and stable breath rate. In addition, improperly performing BVM can accelerate hypoxia and exacerbate airway obstruction, and can even lead to serious injury or death. Excessive ventilation with an BVM (hyperventilation) can push air into the stomach and lead to gastric obstruction or vomiting and subsequent airway obstruction or aspiration. Hyperventilation of patients has a negative effect on hemodynamics, especially in patients who have suffered shock or severe brain injuries, it may lead to the death of the patient.

Due to the problems of BVM, pneumatic resuscitators were created, whose function depends on the oxygen capsule, and they perform ventilation with fixed FIO2 and do not control the respiratory volume and respiratory rate, and generally do not have the ability to monitor the patient. This device is designed for personnel without expertise in respiratory care and brings with it several secondary problems. The impossibility of adapting ventilation to the volume and lung compliance leads to the fight of the patient with ventilation. Fighting the ventilator leads to an increase in carbon dioxide in the patient's blood and an imbalance of gases in the body. The decrease in FIO2, which is the concentration of oxygen consumed by the patient, creates the need for more oxygen for the patient, as a result, the patient makes more effort to breathe and as a result, hypoxia occurs for the patient. The lack of coordination between the patient's breathing and the ventilator leads to respiratory distress. Symptoms of acute respiratory distress include dyspnea, agitation, use of auxiliary ventilatory muscles, movement of the nasal fins with open-mouth inspiratory effort, tachycardia, abdominal paradox, hypertension, expression of fear and sweating.

Subsequently, due to the problems of emergency ventilation devices such as BVMs and pneumatic resuscitator, lightweight portable ventilators that operate without oxygen capsules have emerged. **LIVe Ventilator is one of the new generation of portable ventilators.**

Due to the fact that the LIVe ventilator is set up by the paramedic in less than 30 seconds, the paramedic has the ability to take care of other patients after setting it up according to the priorities of the rescue. Due to the accompanying head strap for the mask, there is no need for a rescuer to keep the mask fixed on the patient's

face. This capability gives the specialist rescuer the opportunity and choice to do other relief activities such as serum injection, drug delivery, or care for other injured people who have more serious injuries. In the first stage, a mask is used for ventilation, but if necessary, it is necessary to use intubation. The use of a mask or other airways depends on the condition of the injured patient. It is necessary to always follow the instructions of the medical center and the doctor's orders. To that end, Milad daru developed the LIVe for EMS.

LIVe Overview

The LIVe is a time cycled, constant flow, volume-targeted device with a peak inspiratory pressure limit of 38

cmH₂O designed as a safety measure to prevent barotrauma. The LIVe delivers a variable tidal volume at a variable respiratory rate.



Figure 1: LIVe Unit

The LIVe does not require a compressed gas source to operate. Instead, it uses a rechargeable battery driven pump to deliver ambient air to the patient. Actual runtime depends on many factors including the patient's lung compliance, ambient temperature when it is being used, the storage temperature and time since it was last charged. When the battery is low, the unit can be connected to an external power supply. This will run the unit as well as recharge the battery.

When the LIVe Should be Used / Indication for Use Statement

The LIVe is intended to provide short-term ventilatory support for individuals during CPR or when positive-pressure ventilation is required to manage acute respiratory failure. The LIVe is appropriate for individuals that weigh at least 40 kilograms (approximately 90 lbs.). It is intended to be used in field hospitals, transport and pre-hospital environments.

When the LIVe Should Not be Used

The LIVe is not intended for long-term use. The LIVe is not intended for children or adults weighing less than 40 kilograms (approximately 90 lbs.). Extreme care should be practiced when using the LIVe on patients that have non-compliant lungs as the pressure cut off may be reached before the targeted tidal volume is delivered.

Training Requirements

The LIVe should only be used by individuals who have been trained to provide primary response to respiratory distress.

Risks and Benefits

The LIVe is designed to enable a medic or other first responder with limited training to provide life-saving ventilation until the patient can be evacuated to a higher level of care. The device is easy to use, lightweight, and is intended to be used on the EMS situations, battlefield, during transport and other pre-hospital environments. The LIVe utilizes a variable Tidal Volume and Respiratory Rate in different patients. This eliminates guesswork and reduces the operator error associated with bag-valve ventilation.

The LIVe has a number of benefits over a bag-valve-mask (BVM). First, it offers a breath to-breath consistency that is not achievable with a BVM. This is especially important during high stress situations. The LIVe will ensure the patient receives a consistent tidal volume at a consistent rate in each person. Second, the LIVe, unlike a BVM, frees up the medic to address other injuries, attend to other patients or further assist in the evacuation. Third, the LIVe will provide up to 2.5 hours of ventilation on a full charge. It is impractical to expect a medic to be able to provide resuscitation manually for that duration with a BVM.

The LIVe uses a rechargeable battery-driven pump to deliver ambient air to the patient and does not need compressed air to operate. The LIVe accepts low pressure supplemental oxygen but it is not required. Devices that rely on high-pressure oxygen tanks pose a fire and explosion hazard, tend to be large and only provide air for a short period of time.

Although the LIVe automates the task of delivering breaths, the medic administering care must monitor the patient to ensure adequate gas exchange is taking place. The LIVe is designed to prevent immediate harm to the patient if a problem should occur. In addition to sounding an alarm, the unit will cut off power to the pump when the delivery of additional air may cause harm to the patient. Although this is a safety feature that protects the patient, a medic must respond quickly to fix the fault that triggered the alarm or the patient may suffer serious harm from a lack of air.

The LIVe is not designed to provide definitive care. The patient should be evacuated to a higher level of care as quickly as possible and connected to fully-featured ventilator by an individual with an appropriate level of training.

General Warnings and Cautions

Failure to adhere to the WARNINGs and CAUTIONS below as well as to all of the instructions given in the manual could lead to death or serious injury to the user and/or to the patient.



WARNING: Read the instructions contained within this manual BEFORE operating the LIVe



WARNING: If using supplemental oxygen, avoid smoking or naked flames. To avoid the risk of ignition, do not use oil, grease, or combustible lubricants (only those approved for oxygen use) in contact with any part of the ventilator, regulator, or cylinder.



WARNING: The device may deliver tidal volumes outside of the stated range if stored or operated in extreme temperatures outside of those identified within the Product Specification. CAUTION: When operating the LIVe in wet environments, users should take precautions and protect the device by covering it with a protective barrier (e.g. small tarp, etc.). CAUTION: Use of the LIVe outside of normal operating conditions may materially impact device performance and may permanently damage and/or shorten life of the device. CAUTION: Storage of the LIVe outside of normal storage conditions may materially impact device performance.



WARNING: Electric shock hazard. Do not open the enclosure casing. CAUTION: Internal components are susceptible to damage from static discharge. CAUTION: Potential electromagnetic interference may occur at levels greater than 20 V/m. Avoid use of the device in unknown environments that may have high electromagnetic levels. CAUTION: Portable and mobile RF communications equipment can affect Medical Electrical Equipment.



CAUTION: Reuse of patient circuit may cause cross contamination. Do not reuse the patient circuit.

WARNING: The LIVe should not be used on unattended patients.

WARNING: The use of a mask increases the risk of gastric insufflation.

WARNING: An alternative method of ventilating the patient should be available in the unlikely event the LIVe malfunctions.

WARNING: Correct operation of the ventilator does not guarantee required blood gas levels; these should be monitored independently.

WARNING: Do not obstruct the air intake or patient exhaust ports of the patient circuit valve.

WARNING: If a mask is being used, a less than stated tidal volume may be delivered to the patient if an adequate seal is not maintained or if patient airway is compromised.

WARNING: The use of accessories not approved for use by Milad daru could result in unsatisfactory performance.

WARNING: The debris filter will not protect the patient from contaminated environments. Do not use the LIVe in contaminated environments.

WARNING: If the unit's PIP limit is reached, the pump will enter an expiratory phase and deliver less than stated tidal volume at a greater than stated respiratory rate.

WARNING: Alarm suppression should ONLY be utilized in situations where audible or visual alarms would compromise the safety of human life. Alarms should be immediately returned to a fully functional state (audible and visual) as soon as safely possible.

WARNING: Be aware that if using an ETCO2 detector, vomitus may obstruct the airway.

WARNING: Any unit that does not pass all checks during normal use or regular maintenance should be taken out of service and reported to Milad daru

immediately. WARNING: Pre-use checks should be performed prior to every use.

CAUTION: The LIVe may not be appropriate for someone with ARDS-type symptoms. CAUTION: If the LIVe is used on a patient that exhibits a low compliant lung, an advanced airway (ET-Tube or Supraglottic Airway) should be used.

CAUTION: Only use Milad daru -approved power supplies with the LIVe.

CAUTION: Do not allow water, oil, grease, sand or other particulates to enter the ports.

CAUTION: Operation of the LIVe without the debris filter properly installed may damage the unit. CAUTION: Service is to be performed by qualified biomedical equipment technicians only. Internal components should not be touched unless ESD precautionary procedures are used. It is recommended that all technicians involved with servicing be trained to ESD precautionary procedures.

Importance of the Need to Adhere to Instructions

The LIVe is a life-supporting medical device. Improper use of the device could lead to harm of the patient.

Suppressing, neglecting or otherwise not responding quickly to alarms may cause serious harm or death.

Pre-Deployment Checkout Procedure

The procedures outlined below should be performed prior to using the LIVe. Ideally, this should be done prior to deploying the LIVe on a mission. These procedures are modified from full preventative maintenance procedures such that they may be performed quickly in the field by the end user.

Step	Procedure	Description
1	1 Kit Verify the LIVe kit is complete and contents are in proper	
	Contents	working order. At a minimum, the LIVe should be packaged with
		a new patient circuit, debris filter and mask or airway.
	i i	Verify that a debris filter is installed.
2	Debris	Turn the control knob to the first ON () position. Verify that the
	Filter	unit has adequate battery life. Charge the unit as necessary. Unit
		should be charged after each use. Turn the control knob to the
3	Battery	first ON () position. Verify operation of the high pressure alarm
		by closing the "Patient Circuit Port Cover." The patient alarm
		should activate and the pump should quickly cycle between the
Pressure inspirat		inspiratory and expiratory phases.
	Alarm	Turn the control knob to the first ON () position. Open the patient
		circuit port cover.
		The patient alarm should continue to activate but the pump should
5	Low	_ deliver a full cycle.
	Pressure	
	Alarm	_

STEP 1 – Verify Kit Contents

The LIVe is typically kitted with the contents in the table below.



At a minimum, the LIVe unit must be packaged with a new patient-circuit, debris filter, and airway such as a mask or ET-Tube.

If kitted with a mask, verify that the mask is fit for use. The inflation of inflatable masks with an inflation valve may be adjusted by inserting a standard male syringe. Please see the separate mask instructions for details.

Kit LIVe Ventilator with Hard	P/N Case 740001	Picture	
Kit LIVe Unit	P/N 17423004	Qty Pi	cture
Patient Circuit w/ Debris F	ilter1100002	2	
Externa Power Supply	720004	1	b



1 Head Strap 720009 Patient Mask 1 720001 Supplemental O2 Tubing 1 720005 Hard Case 1 100001 LIVé User Manual 1 740005

STEP 2 – Debris Filter

It is necessary for a filter to be installed into the ventilator's air intake port to prevent dirt, sand, or other debris and contaminates from entering the ventilator and potentially damaging the ventilator or harming the patient.

The air intake port is located on the right side of the ventilator (**Figure 2**). The debris filter is a foam disk approximately 1.6 inches in diameter and 0.375 inches thick. A picture of a correctly installed debris filter is provided in **Figure 3**.



Figure 2: Installed Filter



Figure 3: Air Intake Port

Pictur



Never use the LIVe without the debris filter installed. Only use debris filters manufactured by Milad daru.

The debris filter will not protect the patient from harm due to contaminated environments. Do not use the LIVe in contaminated environments

Once the debris filter has been properly installed, it should appear flush against the side of the ventilator housing. The debris filter should be cleaned or replaced whenever visible buildup of dirt is observed or it has been exposed to biomaterial such as blood or vomitus. Milad daru recommends cleaning or replacing the debris filter after each patient use.

STEP 3 – Battery Life

The battery life of the LIVe should be verified prior to deployment. Turn the control knob to the first ON (|) position and determine how many lights are illuminated. Use the chart below to estimate remaining battery life.

BATTERY INFO

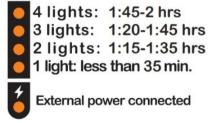


Figure 4: Battery Information

If the LIVe unit has insufficient battery life remaining, refer to the Maintenance section for instruction on how to charge the battery. Please note that even if all charge indicator lights are illuminated the device may last as little as 3.5 hours. A fully depleted battery requires 14 hours to fully recharge.

STEP 4 – High Pressure Alarm

The high pressure alarm is a critical safety feature that detects a blockage of the air pathway. Verify the operation of the high pressure alarm by using the patient circuit port cover to block the patient circuit port and then turn the device to the first ON (|) position as illustrated in Figure 5. When testing, make sure the patient circuit port is adequately blocked by the patient circuit port cover. The LIVe should quickly cycle between the inspiratory and expiratory phases and the visual and audible patient alarms should activate.



Figure 5: High Pressure Alarm Test Test



Figure 6: Low Pressure Alarm

The low pressure alarm is another critical safety feature of the LIVe that detects a disconnection of the patient circuit or severe leak in the air pathway. Verify the correct operation of the low pressure alarm by opening

the patient circuit port cover and turning the device to the first ON (|) position as indicated in Figure 6. The LIVe should cycle normally with the exhalation phase lasting twice as long as the inspiratory phase and the patient visual and audible alarms should activate within 3 breath cycles.

Operating the LIVe

Control Knob Positions

All switch positions other than the OFF (O) position will activate the ventilator (see **Figure 7**). Because battlefield use may require suppression of audible or visual alarms, additional alarm configurations are provided. The ON (|) position will activate the ventilator and both visual and audible alarms. The following position to the right of the ON (|) position will operate visual alarms and audible alarms will be suppressed. The following switch position to the right will activate audible alarms and suppress visual alarms. The final setting suppresses all audible and visual alarms. **Alarms should only be fully suppressed when absolutely necessary**. Icons at each position have been provided as a visual reminder.



Figure 7: Control Knob Positions

When operating with all alarms suppressed, the patient must be constantly monitored since there is no means for the LIVe to alert nearby personnel of a patient-related or device related error condition. This is especially true if using a mask as the airway could become compromised by the head tilting forward or if the seal is lost. If an alarm condition should occur, the status of the various LEDs will help the user troubleshoot the problem. Please see Indicators, Errors and Alarms section for further details.

Patient Circuit (Valve)

The LIVe Patient Circuit is intended to connect the LIVe control unit to the airway device or mask. When the pump is not pushing air, the patient circuit valve allows the patient to exhale to the ambient environment through the valve's exhalation port. The design of the breathing circuit allows the patient to breathe ambient air with minimal resistance from the valve through the exhaust port if a spontaneous breath occurs during the ventilator's exhale state or even if the unit is powered off. A properly assembled patient circuit is illustrated in Figure 8 below. If debris or patient vomitus enters the valve, replace the entire breathing circuit. If a new patient circuit is not available, remove debris or patient vomitus by disconnected the patient circuit valve from patient breathing circuit and shaking it to remove debris or vomitus. The valve may be cleaned with a damp cloth. If the debris or vomitus cannot be adequately removed and a replacement breathing circuit is unavailable, an alternative means of ventilation should be used.



It may be necessary to remove the patient valve from the circuit and clear any debris which may be blocking the airway. Reconnect patient connection port to valve once cleared.



Do NOT block valve ports.



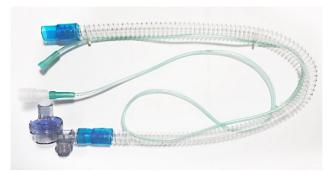


Figure 8: Correctly Assembled Patient Circuit Figure 9: Patient Connection Port Removed

Using the LIVe

Step	Procedure		
1	Look, listen and feel for breathing and pulse. Do not connect the LIVe to spontaneously breathing patient who may become out of sync with, or "buck", the ventilator.		
2a	Verify the airway is not blocked		
2b	Clear any visible debris or excess fluids from the patient's mouth. If additional personnel are available, instruct them to begin rescue breathing.		
3	Open cover labeled "Patient Breathing Circuit" and connect patient circuit main tube and pressure tube to the appropriate ports.Make sure the main tube and pressure tube are securely attached		
4	Insert airway device (if using advanced airway).		
5	Connect the patient connection port to the airway device or mask.		



Only use masks approved by Milad daru. Never use a mask with a pop-off valve or filter.



Step	Procedure
6	Turn the LIVe ON by rotating the knob one position from (O) to (I). Do not turn past first ON (I) position unless absolutely necessary to suppress the alarms.

7a	If using a mask, use the "head tilt chin lift" or if neck injury is suspected the "jaw thrust maneuver" to open and maintain the airway.		
7b	Use two hands to maintain the seal of the mask. Verify adequate chest rise, feel for leaks, and listen for exhale at the valve.		
8	Verify battery level and that no patient or device alarms are activating. PATIENT ALARM Check for disconnects, kinks, leaks, mask seal, and patient-related issues. DEVICE ALARM Turn unit off and back on. Replace the unit if problems persists.		
9	Supplemental O2 may be connected to the patient if necessary. The use of supplemental O2 may slightly increase delivered volume. The FiO2 chart indicates the oxygen concentration delivered to the patient within $\pm 10\%$.		
10	Secure LIVe to the patient. When operating the LIVe in wet environments, users should take precautions and protect the device by covering it with a protective barrier (small tarp, plastic sheet, etc.)		

	11	Evacuate to a higher level of care and 11 transfer to a more capable device as quickly as possible.	
--	----	---	--



Importance of the Need to Monitor the Activity of the Device

The LIVe is a life-supporting medical device. DO NOT leave the patient unattended, especially if a mask is being used. Improper use of the device could ultimately lead to harm of the patient. Neglecting alarms and not responding in a timely manner could leave the patient without ventilation, potentially causing severe harm or death.

Indicators and Alarms

Battery Level Indicator



The LIVe operates primarily from an internal, rechargeable battery. Located on the front panel of the LIVe is a battery icon with four power level indicators. The bottom LED (below the lightning bolt) is the external power supply indicator. During operation when the visual alarms and indicators have not been suppressed, the battery icon estimates the remaining charge in the battery.

The chart below gives the approximate run time remaining for a given battery level. When the LIVe is connected to an external power supply, the external power indicator (below the lightning bolt) will illuminate, indicating the unit is being powered externally and the battery is recharging.

4

NOTE: Operation time is materially affected by the following factors:

- Time since last charge
- Temperature conditions during storage
- Temperature of the environment where ^{BI}
 LIVe is used ²
- Age of battery and number of charge / discharge

cycles

• Patient specific factors such as lung compliance and airway resistance (i.e. higher resistance decreases operation time as does lower lung compliance)

bigigtas	
2 Lights	Duration
1 Light (blinking)	1:45 – 2 hours
(2g)	1:20 - 1:45
	hours 1 – 1:20
	hours Less
	than 60 min

For more detailed battery specifications, contact Milad daru.

Low Battery Alarm

Once the bottom battery LED begins to blink, the ventilator has approximately 45-60 minutes of battery life remaining. Connect the unit to a charger, if available, and be prepared to replace the unit or ventilate the patient by other means. If the device alarm is engaged with the low battery alarm, little or no air is being delivered to the patient. Immediately plug in the device to external power or manually resuscitate.

High Temperature Alarm

The four battery lights will begin to blink when the internal temperature of the LIVe reaches 60°C. This indicates the internal temperature is too high and the ventilator

may not operate properly. Replace unit if possible. If another unit is unavailable, ventilate patient by other means or begin rescue breathing.

Patient-Related (Correctable) Alarm

The patient alarm will activate to indicate low pressure, high pressure or if a positive pressure is maintained through several breath cycles.

	·····	
- A ğ	Low Pressure Severe leak	Disconnect of main tube or pressure tube
	High Pressure air	Patient-related Blockage Blockage somewhere in
	·	pathway
	Constant Pressure	Valve malfunction

There are a number of conditions that may trigger the patient alarm, including: <u>Low Pressure</u>

- A disconnected patient circuit anywhere between the ventilator and the mask or ET-Tube
- A broken or punctured patient circuit

• A poor seal between the patient and breathing mask. The absence of an alarm does not indicate a proper seal has been created.

<u>High Pressu</u>re

- The patient airway is compromised
- Tension pneumothorax
- The patient is improperly intubated
- A blockage of the intake port (where debris filter is located)
- A blockage of the patient connection port (where patient circuit connects to the mask or ET-Tube)
- The patient is capable of breathing sufficiently enough to fight the ventilator's function

Constant Pressure

- A blockage of the exhaust air flow ports (patient circuit valve)
- Malfunction of the patient circuit valve

Please see the Troubleshooting section for information on responding to the patient alarms. In the event that corrective action does not resolve the alarm condition, ventilate by alternative means as quickly as possible.

Device (Non-Field Serviceable) Alarm



In the event of a device-related error, indicated by the flashing red indicator light next to the device alarm icon, immediately begin ventilating the patient by other means. The LIVe is not fieldserviceable for device-related errors unless it is in conjunction with a low battery alarm which will require connecting the device to an external power source. Some possible failures that may lead to a device alarm include the failure of internal components that control the inhalation and exhalation timing, a fully depleted battery or pump failure.

Please see the Troubleshooting section for more information.

Instructions on Use of Accessories

The LIVe can be used with a number of accessories including a mask, head strap, ET-Tube, ETCO2 detector, and/or supplemental O2. Please contact Milad daru to determine if an accessory is compatible with the LIVe.

The LIVe has been kitted for immediate use situations; however, the mask, head strap and ETCO2 detector which may be included with the kit are not manufactured by Milad daru. Please refer to their instructions for use.

This manual includes instructions and information on accessories manufactured by Milad daru and instructions for those accessories not manufactured by Milad daru. All accessories should be kept in their original packaging until they are to be used. Any accessory in an open or torn bag should not be used and should be discarded. All accessories are for single patient use. The LIVe is only to be used with accessories pre-approved by Milad daru.

Use of Mask

It is at the discretion of the prescribing physician or user to determine if application of the device and any accessories are appropriate for a given patient. The LIVe kit includes a face mask that can be used with the LIVe. This face mask is intended to fit a broad range of patients but may not be ideal for all patients. It may be difficult or impossible to achieve a proper seal on patients with significantly smaller or larger than average faces or individuals with facial hair. If using an inflatable face mask, always check the cushion's inflation for appropriate fit and seal to the patient's face. Medium inflation generally provides the best fit and seal. The mask may be inflated using the accompany syringe or any standard male syringe without a needle by inserting the syringe into the inflation valve located on the side of the mask.

Whether you use a mask or an airway is a training issue. Follow the instructions of your medical director or chain of command. When a mask is used, two hands should be used to perform a head tilt chin lift or jaw thrust maneuver. This will open the patient's airway and enable the user to hold the seal of the mask. Special care must be given to ensure the head remains tilted and chin lifted. If the head tilts forward, the airway may become compromised. Most leaks will occur around the mouth and chin. Listen for air from the patient to exhaust through the valve and watch for adequate chest rise.



When using a mask, there is a greater risk of gastric insufflation.



Do not use damaged or deformed masks which may cause an incomplete seal and leak.



Always assume that a mask is going to leak. Remember to watch for the rise of the patient's chest, listen for the patient's exhale at the valve, feel for leaks and visually verify the corners of the mouth are inside the seal of the mask.



Do not suppress the alarms unless absolutely necessary, especially while using a mask.



Only use masks approved by Milad daru. Under no circumstances should a mask equipped with any type of filter, one way valve, or open oxygen/air port be used.



Over-inflating the mask bladder or using excessive pressure to hold the mask in place may restrict the usable surface area or close the patient's airway.

Once the LIVe is turned on, it will alarm until the mask is applied to the patient's face. Tilt the head and lift the chin. Hold the mask around the patient's face using two hands as shown in **Figure 10**. If a spinal injury is suspected, the jaw thrust maneuver is usually the preferred technique.





Figure 10: Mask of LIVe

Maintaining a seal is a skill that can be easily learned but requires practice. It is recommended to use a pulse oximeter to monitor the patient's oxygen saturation. A head strap that may be used to help secure the mask to the patient is included with the LIVe kit. This head strap is intended to aid the operator and does not replace the need for the use of two hands.

Use of ET-Tube

The LIVe may be attached directly to an ET-Tube which has been properly inserted into the patient. Always ensure the ET-Tube is properly inserted into the patient before connecting the patient circuit. Refer to **Figure 11** and **Figure 12** below.

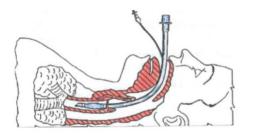


Figure 11: ET-Tube Insertion



Figure 12: ET-Tube Connection

Use with Supplemental O2

The LIVe has the capability to accept low pressure supplemental air or oxygen. Standard medical grade tubing is connected from the air source's flow-regulated output valve to the supplemental O2 port on the LIVe (see Figure 14). The O2 must be regulated at the source. The use of supplemental oxygen may slightly increase the delivered tidal volume of the LIVe.



Figure 13: LIVe Supplemental O2 Port

The oxygen flowing through the supplemental port is blended with the ambient air being drawn in through the air intake port. Changing the flow rate of the oxygen from the source will change the concentration of oxygen delivered to the patient. The maximum acceptable flow rate from the air source is 6 liters per minute. The associated fraction of inspired oxygen (FIO2) at different flow rates is shown in the following table. Values may vary by several percentage points.



Never deliver more than 6 LPM as it could cause harm to the device and patient. Delivering more than 6 LPM may inadvertently create positive end expiratory pressure (PEEP) and / or stacking breathes.

Flow Rate	Oxygen Concentration
0	21
1	33
2	40
4	51
6	62

Accuracy: \pm 10% of stated FIO ₂

Securing the LIVe to the Patient

During evacuation or transport, it is strongly recommended that the LIVe be secured to the patient or litter. Milad daru recommends using rolled gauze (ex: Kerlix) to wrap the LIVe and patient together, generally using an arm. When securing the LIVe to the patient, keep in mind the following:

1. Be aware of the flexibility and length of the patient breathing circuit between the LIVe and the patient mask or endotracheal tube. This tubing should retain some flexibility of movement once the LIVe has been secured.

2. Do not block the air intake port (on the side of the unit behind the debris filter)

or the patient circuit's exhaust valve (reference Figure 8 and Figure 9 above).

3. Do not secure the LIVe to an injured limb.

4. Keep visual access to the error alarm icons and battery indicator LEDs.

5. Ensure the switch is oriented such that it cannot be accidentally moved.





Figure 14: View of Attachment Points (Rear Panel) for LIVe

The LIVe also provides two alternative methods of secure attachment. First, two belt loops (Section A of **Figure 14**) are attached to the rear panel of the LIVe. A belt or strap may be positioned through these loops and used to tighten the LIVe against the patient. Second, two cord attachment (Section B of **Figure 14**) loops are provided. To attach a cord (**Figure 15**) (shoelace, etc.) to this loop, pass the center of the cord through the loop on the LIVe and then pass the ends of the cord through the loop of cord created. Tighten the cords by pulling on both ends. The free ends of the cord may now be used to tie or secure the unit.

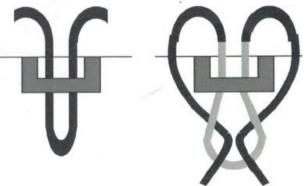


Figure 15: Connecting an Attachment Cord

Maintenance

The procedures contained within this manual are intended to be performed in the field by the end user. A Preventative Maintenance Manual containing complete maintenance information is available. To request this manual, please contact Milad daru at (0098) 21-22658404-5 or email at info@miladdrug.health

Regular Maintenance

Prior to Use

Please see Pre-use Checkout Procedure.

After Use

After the LIVe is used on a patient, the following tasks should be completed to prepare the LIVe for the next patient.

1. Single-use items including the ET-Tube, patient circuit, mask, debris filter, supplemental O2 tubing, and head strap should be disposed of properly.

2. The pressure tube port on the LIVe should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth between patient uses.



3. The LIVe should be visually inspected for any damage that may affect operation. Do not use a damaged ventilator. Dirt and debris should be cleaned from the unit.

4. A new single-use patient breathing circuit, and a new ET-Tube or patient mask should be packaged and stored with the LIVe.

5. The LIVe should be fully charged.

Charging

If the LIVe has insufficient battery power, use the external power supply (P/N: E10478) to recharge the unit. The external power supply can be used to simultaneously recharge the battery and power the unit, if necessary.



Ensure the external power indicator light, which is below the lightning bolt, is illuminated to verify the unit is properly charging.

Take care to ensure the power cord is not inadvertently detached from the external power jack.

By design it requires very little pressure to detach.

The Power Supply can accept an AC voltage between 100 and 240V at frequencies of 50-60 Hz. The battery will lose a portion of its charge every month. A completely depleted battery requires approximately 14 hours to fully re-charge. Always recharge the device after it is used. Storing the device with a low charge may shorten the life of the battery. To ensure the LIVe retains at least 65% of its charge, follow the following guidelines.

	Interval of Charge (refresh
Below 68 F (20 C) 68 F (20 C) to 86 F (30	9 Months
C	6 Months
86 F (30 C) to 104 F	
(40 C)	3 Months
internal battery is not field real	nlaceable Please contact Milad

NOTE: The LIVe internal battery is not field replaceable. Please contact Milad daru for further instructions if the battery must be replaced.

Cleaning

Keep the LIVe and its accessories clean at all times. Under no circumstances should the LIVe unit be disassembled. Do not clean any portion of the LIVe or its accessories with abrasives or chlorinated hydrocarbon cleansers

Do not allow dirt, sand, debris, grease, oil, or caustic chemicals to enter, coat, or otherwise contaminate its components. To prevent debris from entering the LIVe, the patient breathing circuit port cover should always be securely in place when the unit is not in use or being cleaned.

Under no circumstances should the LIVe or its accessories be immersed in liquid or exposed to an autoclave. Should the LIVe become wet, the unit should be dried using a lint-free cloth immediately, or once the unit is no longer in use. Should the LIVe become immersed, discontinue use and return to manufacturer for refurbishing and testing. DO NOT expose the switch, external power jack, or audible alarm port directly to liquids.

Exterior

The exterior housing of the LIVe may be cleaned as necessary using a damp cloth and dried using a lint-free cloth. The front panel of the LIVe should be cleaned as necessary using only a lint-free cloth.

Carefully clean the port covers with a damp cloth and dry using a lint-free cloth. Examine the insides of patient circuit tubing ports for dirt or debris. Removal of objects, if required, may be attempted using forceps or similar non-sharp objects. Cleaning may be attempted, if required, using a dry lint-free cloth. If the insides of

the patient circuit tubing ports cannot be cleaned, DO NOT attempt to use the LIVe. Return the LIVe to Milad daru for refurbishment and testing.

Debris Filter

The debris filter should be replaced with a new filter following each use. If the debris filter becomes damaged or soiled during use, replace it with a new debris filter.

Patient Circuit

Examine the patient circuit tubes for cracking, discoloration, sharp edges, or other signs of damage. DO NOT attempt to use or repair damaged patient circuits. Damaged patient circuits must be replaced. If necessary, exterior walls of tubing may be cleaned with a damp cloth and dried using a lint-free cloth.



Only a new patient circuit freshly removed from its packaging should be used. Do not re-use any portion of the patient circuit.

Annual Maintenance

After 2000 hours of use or 1 year, whichever comes first, the LIVe must complete a testing inspection to ensure continued operation within the specifications. The testing must be completed by an Milad daru authorized facility. There are a number of approved biomedical testing sites within the U.S. military. Please contact Milad daru by email at info@miladdrug.health or by phone at (0098) 21-2265-8404-5 for details.

Storage

Prior to storing the LIVe unit, ensure that the unit is fully charged. Storing the unit in a discharged state will reduce the life of the internal battery.

For extended storage periods, the LIVe should be stored indoors, out of direct sunlight, and in a clean environment. The best storage temperature is between 0 and 30°C (32 to 86°F). For short-term storage, the temperature can range from -15 to 40°C (5 and 104°F). In both cases, the relative humidity in the storage facility should be low. It is recommended that if the device is to be stored for extended periods that it be kept in the hard case manufactured by Milad daru.

To ensure optimum performance it is recommended that the LIVe is recharged at regular intervals as follows:

	Interval of Charge (refresh
Below 68 F (20 C) 68 F (20 C) to 86 F (30	9 Months
С	6 Months
86 F (30 C) to 104 F	
(40 C)	3 Months

Expected Failure Time and Mode and the Effect on the Patient

The internal pump of the LIVe is the first expected component to fail over the life of the unit due to normal wear and tear. This is expected to occur following 2,000 to 3,000 hours of ventilator use. When the pump fails, the device alarm will be triggered (reference section regarding Device Errors above) and the ventilator will cease pumping air to the patient. The medic should replace the unit immediately or begin ventilating by other means.

Instructions on How to Safely Dispose of the Device

If the LIVe unit is no longer in use, please return the unit to Milad daru`s facilities for proper disposal. Please contact Milad daru for packaging and mailing instructions.

Troubleshooting

The LIVe has three alarm types as described below. Ensure that the light indicators are not suppressed while troubleshooting.

Alarm Overview

Patient Device	Battery		
	 4 lights: 1:45-2 hrs 3 lights: 1:20-1:45 hrs 2 lights: 1:15-1:35 hrs 1 light: less than 35 min. 		
Patient alarms can be one battery LED left, the device	Device Alarm can NOT When there is only		
fixed by the operator	be fixed by operator will alarm		
approximately 30 min unets of battery life			
remain			

Figure 16: Alarm Overview

Patient Alarms

The patient alarm may be triggered by one of the events listed below. Please note once the problem that triggered the alarm is fixed, the alarm will cease and the ventilator will begin proper operation on its own.

Troubleshooting patient alarms may involve clearing debris from the patient.

Situation	The ventilator motor repeatedly attempts to start but quickly stops			
Likely Source Blockage				
Possible	Begin troubleshooting with the patient and work towards the			
ventilator				
Solution	1. If the problem cannot be addressed quickly, consider ventilating by			
other means				
	begin rescue breathing.			
	2. If using a mask:			
	 Ensure head is tilted back and chin is lifted 			
	 Ensure there is no debris or vomitus in mouth, mask, or valve If using an ET-Tube: 			
	Ensure tube is properly placed in trachea			
	 If ETCO2 detector is being used, verify that it has indicated proper intubation of the patient 			
	 Ensure there is no debris or vomitus in the airway adjunct 			
	4. Ensure there is no debris in the patient circuit valve			
	5. Ensure air intake port is not blocked			
	Ensure patient tubing is not kinked			
	7. If problem is not identified, replace patient circuit.			

Situation The ventilator motor turns on for a couple of seconds and then turns off for a couple of

seconds. Aside from the alarm, the device seems to

function normally Likely Source A leak or disconnect

Possible1. If the problem cannot be addressed quickly, consider ventilating
patient by otherSolutionmeans or begin rescue breathing.

Solution means or begin rescue breathing.
 2. Ensure both tubes leading to patient are properly connected to the ventilator.

3. If using a mask, ensure there is a tight seal to the patient's face.	
If using an ET-Tube, ensure it is not dislodged.	

- 5. Ensure the patient circuit is properly connected to the ET-Tube or mask.
- 6. Ensure there is no hole or leak in the patient breathing circuit. If a leak is found, replace patient circuit immediately.
- 7. If problem is not identified, replace patient breathing circuit.

Situation The ventilator cuts off for more than 10 seconds			
Likely Source A malfunctioning exhaust valve			
Possible	Replace patient breathing circuit immediately		
Solution			

Situation The alarm is intermittent. The alarm sounds and the pump turns off for several seconds

and as air is released, the alarm ceases and the pump resumes again, repeating every several breaths.

Likely Source Breath stacking (insufficient amount of air is being exhaled from the lungs between

	breaths).		
Possible	1. Ensure valve on patient circuit is parallel/horizontal to the ground		
(i.e. patient o	ircuit		
Solution	valve is not upright or vertical to the ground).		
	2. If the problem cannot be addressed quickly, ventilate patient by		
	other means or begin rescue breathing.		
	3. Ensure that the patient circuit exhaust valve is not blocked.		
	4. If problem is not identified, replace patient circuit.		

Device Alarms

- 1. If the battery indicator has only one LED lit and a device alarm comes on, plug the device into an electrical outlet immediately. If alarm continues, ventilate by other means or begin rescue breathing. These two alarms together indicate little or no air is being delivered to the patient due to low power.
- 2. For all other device related alarms, ventilate patient by other means or begin rescue breathing.

Low Battery Alarm

Once the bottom battery LED begins to blink, the ventilator has approximately 30 minutes of battery life remaining. Connect the unit to a charger, if available, and be prepared to replace the unit or ventilate the patient by other means. If the device alarm is engaged during a low battery, little or no air is being delivered to the patient. Immediately plug in the device or manually resuscitate.

High Temperature Alarm

The four battery lights will begin to blink when the internal temperature of the LIVe reaches 60°C. This indicates the internal temperature is too high and the ventilator may not operate properly. Replace unit if possible. If another unit is unavailable, ventilate patient by other means or begin rescue breathing.

Limited Warranty

Limited Warranty Applicable to the LIVe

Milad daru warrants to the original purchaser ("Customer") of the LIVe that if there is a defect in material or workmanship in the LIVe and Milad daru is notified of such defect within one (1) year of Customer's original purchase, Milad daru shall, in its sole and absolute discretion, repair or provide a replacement of such defective part(s) at no charge to the Customer, provided that this warranty provision is not applicable to batteries or used consumables.

Limited Warranty Applicable to the Battery

The life of the battery, as noted above, is materially affected by many factors. As such, Milad daru warrants to the Customer of the LIVe that, if there is a defect in material or workmanship in the battery contained in the LIVe and Milad daru is notified of such defect within ninety

(90) days of Customer's original purchase, Milad daru shall, in its sole and absolute discretion, repair or provide a replacement of such defective battery at no charge to the Customer.

Sole Remedy

The sole remedy for a defect in materials or workmanship of the LIVe (or the battery or any other component of the LIVe) shall be, at Milad daru's sole and exclusive discretion, repair or replacement of the defective LIVe or component thereof, as the case may be.

Exclusions

Milad daru's warranty shall not apply to defects or conditions resulting from: (a) repairs by an unauthorized party; (b) improper maintenance; (c) modifications made without written permission of Milad daru; (d) damage by accident, abuse, misuse, or misapplication; or (e) operation otherwise than in accordance with this manual or other instructions furnished by Milad daru I. Milad daru's warranty shall not apply if the unit has been disassembled. Milad daru's warranty shall not apply to: (a) any Product if the serial number of such Product has been altered, defaced or removed or (b) any used consumables. Milad daru's warranty is neither assignable nor transferable. All warranty repairs shall be subject to return postage billing.

Disclaimer of Warranty and Limitation on Remedies

THE WARRANTY AND REMEDIES SET FORTH ABOVE ARE EXCLUSIVE AND IN LIEU OF ALL OTHERS, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. Milad daru SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Milad daru IS NOT RESPONSIBLE FOR DIRECT, INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER LEGAL THEORY.



Electromagnetic Emissions and Immunity



Guidance and Manufacturer's Declaration - Electromagnetic Emissions				
The LIVe Portable Ventilator is intended for use in the electromagnetic environment				
specified below. The customer or the user of the LIVe Portable Ventilator should				
assure that it is used	l in such an	environment.		
Emissions Test	: L	Electromagnetic Environment - Guidance		
<u>Compliance</u>		The LIVe Dertable Ventilator uses DE energy only for		
RF Emissions CISP 11	Group 1	The LIVe Portable Ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.		
RF Emissions CISP	२ Class B			
11 Harmania Emissions		The LIVe Portable Ventilator is suitable for use in		
Harmonic Emissions	Class B	all establishments including domestic and those		
IEC 61000-3-2		directly connected to the public low-voltage		
Voltage Fluctuations	Complies	power supply network power supply that supplies		
Flicker Emissions	complies	buildings used for domestic purposes.		



Guidance and Manufacturer's Declaration - Electromagnetic Immunity				
ble Ventilator is	intended fo	r use in the electromagnetic environment		
v. The <u>custome</u>	e <mark>r or the u</mark> se	er of the LIVe Portable Ventilator should		
	-	Electromagnetic Environment -		
Test Level		Guidance		
		Floors should be wood, concrete, or		
		ceramic tile. If		
±8kV Air		floors are covered with synthetic		
	Complies	material, the		
	complice	relative humidity should be at least		
80MHz		30%.		
		Field strengths outside the shielded		
to 2.5GHz		location from		
3Vrms	Complies	fixed RF transmitters, as determined		
150kHz		by an		
		electromagnetic sit survey, should be		
to 80MHz		less than 20		
+ 2kV nower		V/m. Interference may occur in the		
•		vicinity of		
-	15	equipment marked with the following		
	Complies	symbol:		
+1kV				
	a "			
	Complies			
		Mains power quality should be that of a		
		typical		
	Comulias	commercial or hospital environment		
2.4/	Complies			
3 A/m				
		Power frequency magnetic fields should		
		be at levels		
	Complias	characteristic of a typical location in		
	Complies	a typical		
		commercial or hospital environment.		
>95% dip 0.5		Mains power quality should be that of a		
cycle 60% dip		typical commercial or hospital environment. If		
5		the user of		
cycles 70%		the LIVe Portable Ventilator requires		
dip		continued		
25 cycles		operation during power mains		
95%	Complies	interruptions, it is		
	Complies	recommended that the LIVe Portable		
dip 5 sec		Ventilator be		
		powered from an uninterruptible power		
		supply or		
		battery.		
	v. The <u>custome</u> used in such ar IEC60601 Test Level ±6kV Contact ±8kV Air 20 V/m 80MHz to 2.5GHz 3Vrms 150kHz to 80MHz ±2kV power line ±1kV I/O lines ±1kV I/O lines ±1kV differential ±2kV common 3 A/m 3 A/m	A. The <u>customer or the used</u> used in such an environmer IEC60601 Test Level ±6kV Contact ±8kV Air 20 V/m 80MHz to 2.5GHz 3Vrms 150kHz to 80MHz ±2kV power line ±1kV I/O lines ±1kV //O lines ±1kV differential ±2kV common 3 A/m Complies 3 A/m Complies 5 cycles 70% dip 25 cycles 95% Complies Complies		

Technical Overview

The LIVe's pneumatic subsystem uses an internal air pump to deliver ambient air to the patient. During the inhalation cycle, ambient air is drawn into the pump through the air input port. If needed, supplemental O2 may be connected to an additional port.

As air is pushed from the pump into the internal manifold, a pneumatically connected pressure sensor monitors the pressure of the air delivered to the patient. The air manifold interfaces to the patient breathing circuit by way of a standard 22mm (outer diameter) port. The patient breathing circuit contains a bi-directional valve that directs air to the patient when the pump is running. When the pump is not pushing air, the valve allows the patient to exhale to the ambient environment through the valve's exhalation port. The design of the breathing circuit allows the patient to breathe ambient air with minimal resistance from

the valve through its exhaust port if a spontaneous breath occurs during the ventilator's exhale state or even if the unit is powered off.

The second pressure sensor is connected through tubing to a sampling port between the bi directional valve and the patient. This second pressure sensor monitors the patient's airway pressure, assuring the patient's airway pressure during the entire breathing cycle is within expected limits. An optional colorimetric ETCO2 detector to detect approximate ranges of end-tidal CO2 in intubated patients may be connected in-line between the patient connection port and ET-Tube.

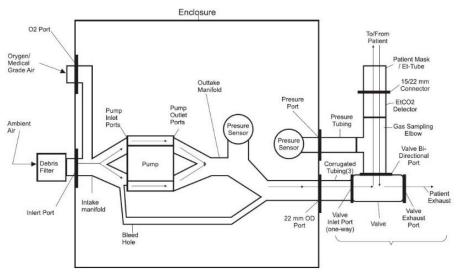
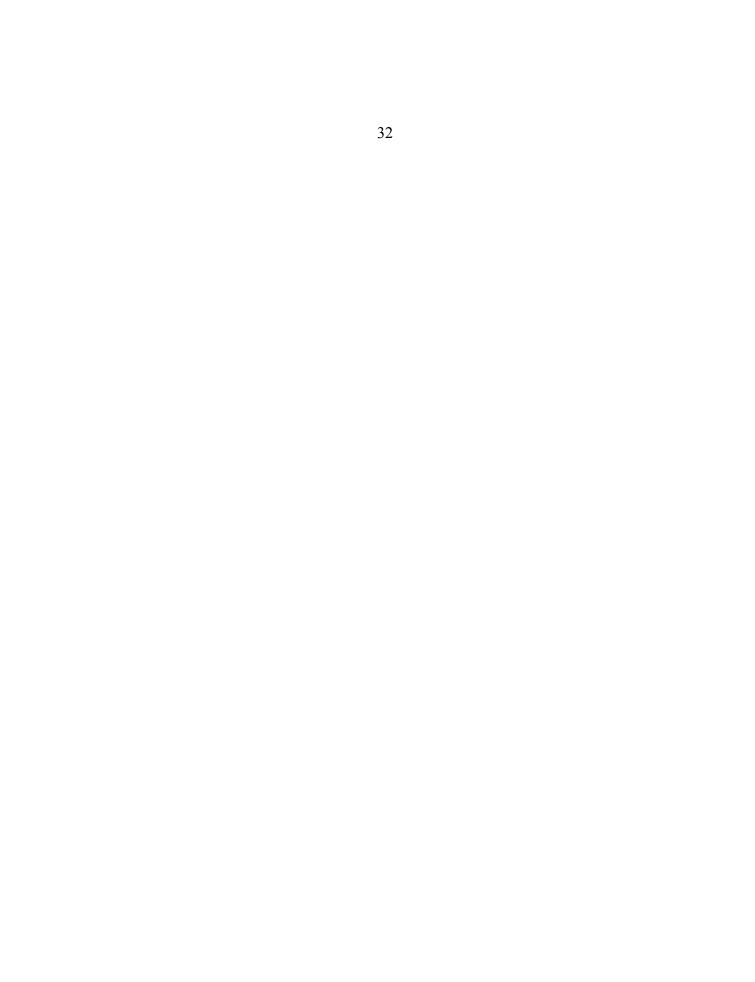


Figure 17: LIVe Technical Overview

The LIVe consists of numerous safety and alarm features to prevent harm to the patient and alert the medic immediately of a problem. These features include monitoring for a disconnection of the patient circuit, a blockage in the airway, exhaust valve malfunction, and excessive Positive End-Expiratory Pressure (PEEP). If the patient's lung pressure reaches the Peak Inspiratory Pressure (PIP) limit during inhalation, the LIVe immediately enters into an exhale cycle. If it reaches that limit quickly, it triggers an alarm suggesting there is a blockage. The audible alarm sounds at a minimum decibel level of 70 db. The LIVe is an FDA Class II device. The patient breathing circuit and accompanying accessories are all "Type B" parts classified under IEC 60601-1 (i.e. applied parts not conductive and can immediately be released from the patient).



Product Specification1

		Dual Control Continuous Mandatory
	Operating Modes:	Ventilation
		(DC-CMV), IMV, Auto SIMV, Pressure
		PSV, PCV, NIPPV, IPPV
	Primary Control:	Time
	Secondary Control:	Pressure
	Breath Target:	Volume Targeted
	Flow Rate ² :	18 LPM
	Breath Rate ² :	10 BPM
	Minute Volume ² :	6 LPM
Tidal Volume ²	Max	800 ±10 mL/breath
Airway Resistance		
= 5	Min	270 ±10 mL/breath
cmH2O/L/sec		270 110 mL/breath
Inspiratory to E	xpiratory Time (I:E	
	ratio):	1:2
	FIO2	
Book Incrimat	Inadvertent PEEP:	< <u>2 cmH20</u>
Peak Inspiratory Pressure (PIP) Limit:		38 cmH2O
	Oxygen Input Flow:	0-6LPM
	LIVe Unit Input	
	Voltage:	15VDC
External Power		
Supply	Input:	100 – 240VAC/ 55 Hz/ 700 mA
	Output:	15VDC / 2A
	Operating Time:	4 – 5.5 Hours at max charge
Audible Alarm Characteristics:		minimum 70 dB at 30 cm
	Pressure Sensor	0
	Range:	0 - 40 cmH20
Dationt Circuit	Dead Space:	
Patient Circuit	t valve Resistance:	Spontaneous Breath – 3.5 cmH2O/L/sec Exhalation – 1 cmH2O/L/sec
Temperature		
Ranges	Normal Operating:	0 to 40°C (32 to 104°F)
nanges	Extreme Operating:	-15 to 50°C (5 to 122°F)
	Short-Term Storage:	-15 to 40°C (5 to 104°F)
	Long-Term Storage:	0 to 30°C (32 to 86°F)
	Size:	6.75" x 6.25" x 2.5" (17 x 16 x 6 cm)
	Weight:	3.1 lbs. (1.4 kg)
	Warranty:	1 Year Limited
1 All measurements include a tole	erance of +10% of nominal value unle	ess stated otherwise. Test conditions available upon request.

1 All measurements include a tolerance of ±10% of nominal value unless stated otherwise. Test conditions available upon request.

2 Delivered Tidal Volume is materially affected by low lung compliance. At a compliance of 10 mL/cmH₂O and airway resistance of 5 cmH₂O/L/sec the LIVe is pressure limited. Due to an abbreviated inspiratory and expiratory phase, the resultant Tidal Volume is 325 mL/br and the Respiratory Rate is 15 breaths/minute which calculates to a Minute Volume of 5 L/min.

Accessory Order Information

Please contact Milad daru at (0098) 21-2265-8404-5 to order any accessory. The LIVe is only to be used with accessories pre-approved by Milad daru.

Part #	Description	Weight	Dimensions
	Ruggedized Patient		L×W×D 40×30×17.5cm
740001	Breathing	2560 gr	$(16^2 \times 12^2 \times 7^2)$
	Circuit w/ Debris Filter		
			L×W×D 10×12.5×7.5 cm
720001	Mask	60 gr	$(4^2 \times 5^2 \times 3^2)$
			L×W×D 400×6.2×8.7 cm
720004	Power Supply	280 gr	(157 ² ×2.5 ² ×3.5 ²)
110000			L×W×D 60×37.5×3 cm
2	Head-strap	50 gr	(24 ² ×15 ² ×1.2 ²)
110000			L×W×D 12.5×2.5×2.5cm
1	Syringe	10 gr	$(5^2 \times 1^2 \times 1^2)$
	Supplemental O2		L×W×D 17×0.68×12.5cm
720005	Tubing	90 gr	(6.8 ² ×0.25 ² ×5 ²)
720006	Debris Filter (5 pack)	7 gr	3.75×0.68 cm (1.5 ² ×0.25 ²)
			L×W×D 40×30×17.5cm
740002	Hard Case	2270 gr	(16 ² ×12 ² ×7 ²)

Registering the LIVe

To ensure that you are eligible to take advantage of the product warranty and that you are notified of any changes in the Operator's Manual or Training Materials, please take a minute to register your LIVe unit by going to www.miladdrug.health