Model 1008MII
Mechanical CPR System
Instructions for Use (IFU) Manual

(Part Number REF 16005)

Manufactured in the USA by:

4717 Talon Court SE
Grand Rapids, MI 49512 USA
Tel: (800) 530-9939 or (616) 554-9696
Fax: (616) 554-3067
e-mail: mii@michiganinstruments.com
website: www.life-stat.com

Copyright

PROTECTED UNDER ONE OR MORE OF THE FOLLOWING U.S. PATENTS: 6,171,267 5,743,864

Michigan Instruments, Inc.
4717 Talon Court SE
Grand Rapids, MI 49512 USA

EC REP

ProCare / Lode BV
Zernikepark 16a
9747 AN GRONINGEN
The Netherlands
Phone: +31(0)50 57 15074

CE 0297

Symbols used on the device and in this IFU:

Symbol	Meaning		Symbol	Meaning
	Manufacturer – Name/Address information. Date of manufacture appears under symbol in YEAR-MO format (on device).			Caution - Attention: Consult Accompanying Documents. Operators are to refer to information provided with the device.
EC REP	Authorized Representative in the European Community – Name/Address information.			Defibrillation Protection (Type BF Patient)
CE	CE Mark & Notified Body ID#		SN	Serial Number
	Direct Current – (9V indicated)			Gas Supply (operating range indicated)
	Consult Instructions for Use – additional information available.			Do Not Reuse - Dispose after use.
	Special Disposal Required		REF	Catalog Number – Part number reference.
	Read Operator's Manual or Instructions For Use (IFU).			

Contents

1-Introduction

Federal law restricts this device to sales to, or on the order of, a licensed medical practitioner.

1.1 The Life-Stat® Model 1008MII Instructions for Use (IFU)

NOTE: The purpose of this manual is to explain the use, care, and user maintenance of the device, not to teach cardiopulmonary resuscitation.

Proper use of the Life-Stat® requires a thorough understanding of this manual, appropriate training, and adequate practice with the device. This manual contains important information on all aspects of operating and maintaining the device. After a complete review, use it as a guide to practice with the Life-Stat® until completely confident and comfortable with its operation.

Keep this manual in a location where it is available for quick reference. The format is designed to allow each section to be scanned quickly for answers to specific questions. The Table of Contents can be used to find major headings and topics. For example, the Setup and Operation section will guide a new user through the proper procedures for using the equipment. The Care, Cleaning, and Disinfection section can be used to plan an effective preventive maintenance program.

1.2 Use of Warnings, Cautions, and Notes

As used in this manual-- Warnings, Cautions and Notes are depicted as:

WARNING: intended to alert users to the possibility of injury, serious adverse reaction, or death associated with use or misuse.

CAUTION: intended to alert users to the possibility of a problem associated with use or misuse.

NOTE: intended to alert users to particularly useful information.

1.3 Indication for Use

The Life-Stat® CPR System is used to perform Cardiopulmonary Resuscitation (CPR) on adult patients only in cases of clinical death, as defined by a lack of spontaneous breathing and pulse.

WARNING: The Life-Stat® is to be used solely for the purpose of delivering mechanical cardiopulmonary resuscitation (CPR) in accordance with established American Heart Association (AHA) guidelines. It is to be used in cases of clinical death to provide CPR support under the direction and control of a licensed physician. Use of this device for any other purpose is strongly discouraged.

1.4 Contraindication

There are situations where CPR is not the appropriate method of intervention. Familiarity with accepted medical practices in your area is very important. Always consult local protocol for the proper integration of the Life-Stat® into your cardiac arrest management regimen of care.

CAUTION: Current American Heart Association guidelines do not recommend the use of mechanical CPR on infants or children.

WARNING: This device is to be used by personnel knowledgeable in safe and effective first response (first aid) practices and techniques. Always observe safe and proper first aid procedures in the application and use of this device.

1.5 Benefits of Mechanical CPR

With the purchase of the Life-Stat® CPR System, you join thousands of health care professionals worldwide who benefit from the many advantages of mechanical CPR. The Advanced Cardiac Life Support Manual published by the American Heart Association, describes some of the benefits of mechanical CPR devices as follows:

> "... they can 1) standardize the technique of CPR, 2) eliminate user fatigue, 3) free trained persons to participate in the delivery of ACLS when there is a limited number of rescuers, and 4) assure adequacy of compression when a patient requires continued resuscitation during transportation."

1.6 General Warnings and Cautions

WARNING: Improper application of this equipment can cause serious injury. This manual must be thoroughly understood in order to use this device correctly and to avoid possible serious injury.

WARNING: Federal law restricts this device to sales to, or on the order of, a licensed medical practitioner.

WARNING: As this device is powered by compressed medical grade Oxygen, safe Oxygen handling practices and procedures are to be implemented with its use.

CAUTION: It is very important to follow the instructions for preventive maintenance and cleaning procedures after each use. They are found in the Care, Cleaning, and Disinfection section of this manual.

CAUTION: Submersion of the Life-Stat® in water will cause infiltration of water into internal critical parts. This may lead to corrosion and eventual operational failure. This includes inadvertent injection of water as from a contaminated Oxygen cylinder or humidified gas supplies.

CAUTION: Infiltration of foreign material into the Life-Stat® may cause operational failure.

CAUTION: When carrying the Life-Stat® or moving the Arm up or down the Column, always use the Handle provided. Do NOT use the hose spanning the Column and Arm as a handle as this will stress the hose and clamps.

(Blank Page Intentional)

2-Product Description

2.1 Life-Stat® Cardiopulmonary Resuscitator

The Michigan Instruments, Inc. Life-Stat® is the latest model of our portable, automatic cardiopulmonary resuscitation (CPR) medical devices which have been in use since 1964.

2.2 General Description

The Life-Stat® system provides consistent CPR support for cardiac arrest patients under conditions which might otherwise hinder the effectiveness of manual techniques. The Life-Stat® performs two modes of CPR support in conformance with AHA CPR guidelines. In either mode, compressions are delivered at a frequency of 100 per minute.

- **30:2** mode will provide thirty (**30**) chest compressions, then pause compressions to deliver two (**2**) ventilations. This 30 to 2 pattern will repeat continuously.
- **CCV** mode will provide **c**ontinuous **c**ompressions with asynchronous **v**entilations delivered at 9 breaths per minute.

The Life-Stat® is a mechanical "automatic" CPR device that can be set up in seconds. The chest compressor is powered by compressed Oxygen while timing is controlled by a 9V electronic circuit. The device is electrically insulated, allowing it to be freely and safely used in conjunction with routine patient monitoring, external pacing and defibrillation procedures. The Life-Stat®, once correctly applied over the patient's sternum, is designed to measure the patient's anterior-posterior (A-P) chest diameter and deliver the equivalent sternal deflection of 20% of that diameter.

> **NOTE:** 2010 AHA Guidelines recommend for adult patients, a minimum compression depth of at least 2" (5cm). If the A-P chest diameter number indicated on the Life-Stat® is less than 5, then deliver compressions minimally to the depth indicated by the -5- marking on the dome.

2.3 Life-Stat® System Components and Accessories

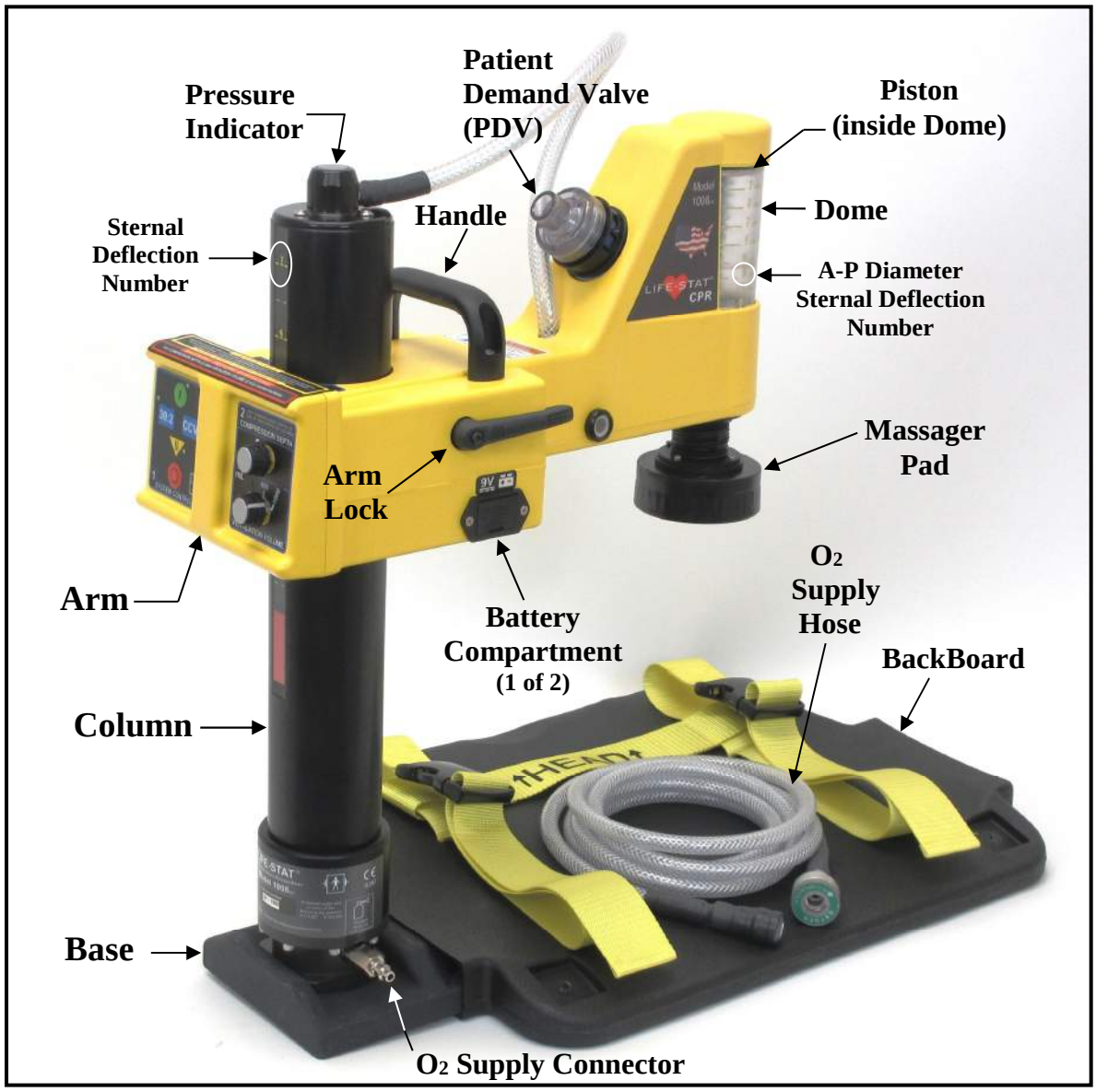
The Life-Stat® System consists of three major components:

- Life-Stat® (Arm/Column/Base Assembly)
- BackBoard (BackBoard/Shoulder Straps)
- Mobile Oxygen Carrier / appropriate O_2 wall access adaptor.

A fourth component, the Carrying/Storage Case is available to transport/store the device when not in use.

2.3.1 Life-Stat® System

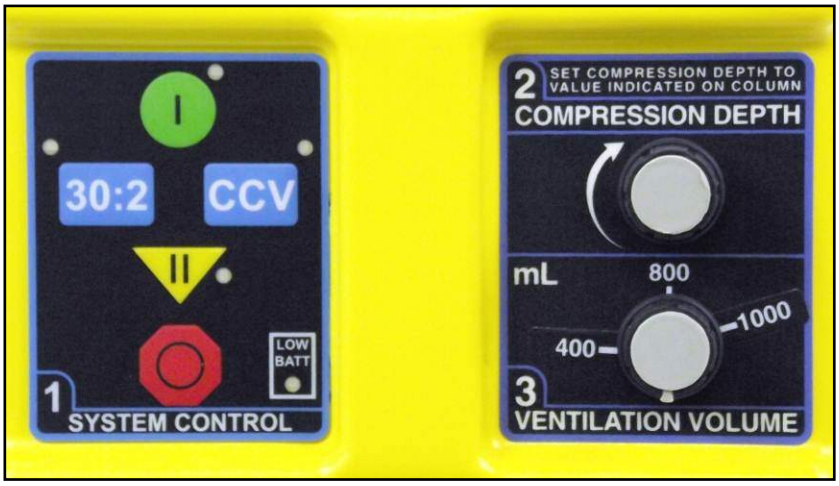
The Arm and Column positions the Piston and Massager Pad correctly over the patient's sternum. It is designed to provide a sternal deflection percentage based on the patient A-P chest diameter. Sternal deflection is nominally set to 20% of the A-P diameter. The depth of each chest compression is easily monitored using the markings on the Dome surrounding the Piston. The Column also serves as a storage tank that holds sufficient Oxygen to continue to drive the Life-Stat® for several compressions during an Oxygen source change.



The Life-Stat® System

2.3.2 Controls and Labeling

The Life-Stat® controls are located on the back of the Arm.



Control Panel

1. **SYSTEM CONTROL (Control#1):** This membrane keypad is used to control the Life-Stat®. It is comprised of 5 electronic buttons, described below.

START/ON button. Pressing this button will activate the electronic control module and perform a self test. The green LED indicator next to the button will illuminate to indicate that the unit is on after completion of a successful self test.

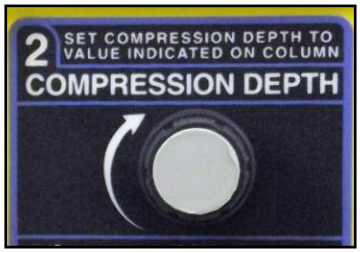
STOP/OFF button. Pressing this button will return the chest compressor piston to the 'up' position, turn off the ventilator and shut down the electronic control module.

30:2 button. Pressing this button will activate the 30 compressions to 2 ventilations operating mode and the blue LED indicator next to the button will illuminate.

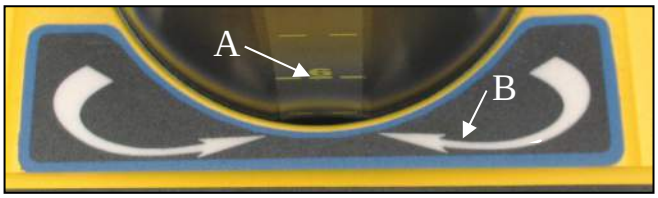
CCV button. Pressing this button will activate the Continuous Compressions/ Ventilations operating mode and the blue LED indicator next to the button will illuminate.

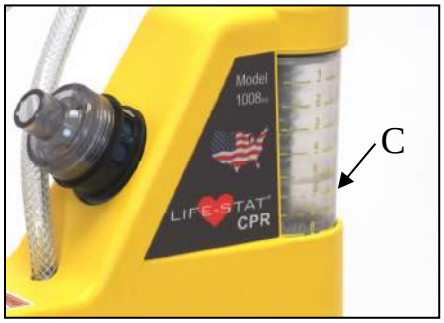
PAUSE button. Pressing this button will return the chest compressor piston to the 'up' position and pause compressions. Ventilations will continue and the yellow LED indicator next to the button will illuminate. To resume compressions, press the desired mode button (30:2 or CCV).

LOW BATTERY indicator. The red LED indicator will illuminate when the battery voltage is too low to sufficiently power the device. When the power level reaches a critical stage, an auto shutdown will bring the chest compressor piston to the 'up' position; turn off the ventilator and the electronic control module.



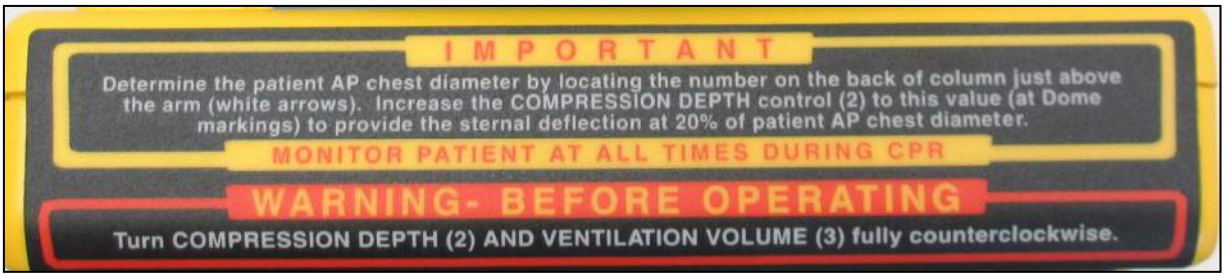
2. **COMPRESSION DEPTH (Control #2):** This control is used for setting the depth of compression on the patient. The depth is set to correspond to the measured A-P diameter shown on the scale located on the back of the Column. As indicated by the arrow, turn the knob clockwise to increase the compression depth and counterclockwise to decrease compression depth.





NOTE: After the massager pad has been lowered to the patient's chest, the correct patient A-P chest diameter is determined by locating the number on the back of the Column (A) just above the Arm where the white arrows (B) are located. Set the compression depth to the corresponding indicator number on the Dome (C) to match the A-P diameter number indicated on the Column.

3. **VENTILATION VOLUME (Control #3):** This control adjusts the tidal volume (0-1000mL) of Oxygen delivered to the patient from the PDV. The tidal volume is increased with a clockwise rotation and decreased with a counterclockwise rotation. With the control in the fully counterclockwise position, no (0mL) tidal volume is delivered.

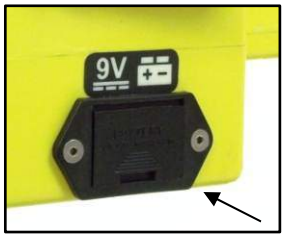


WARNING: Before operation, ensure that all controls are in the "OFF" or "decreased" (fully counterclockwise) position before connecting to an Oxygen supply or placing the unit on the patient. By verifying the position of all controls the operator is assured of proper operation.

2.3.3 Battery Power Supply

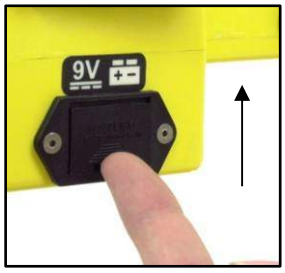
The Life-Stat® electronic control module is powered by two (2) 9V alkaline batteries. ⎓

CAUTION: Do NOT use excessive force to install the battery in the tray. Ensure the polarity is oriented per the label and to the diagram embossed on the bottom of the tray (+ on left, - on right). Failure to install either battery in the correct position will prevent the device from operating and may lead to failure of the device which will void the warranty.



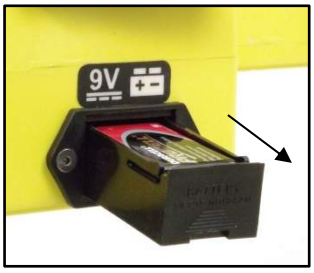
The batteries that power the electronic module are located on either side of the Arm.

CAUTION: Only use batteries that conform fully to IEC 60086-2 or ANSI C18.1M.



To install/replace the batteries:

1. To access the battery, place fingernail into slot near bottom of the battery compartment and push upwards slightly to release the tray.
2. Pull out the battery tray. Install the battery by orienting it to the diagram. The battery tray is spring loaded to keep the battery secure. Ensure the battery is properly seated.



3. Re-insert the tray and push in until an audible click is heard ensuring the tray is properly seated inside the compartment.
4. Repeat for the battery located on the opposite side.

<u>Important Battery Information</u>:

- Always use name brand batteries of the same brand and type. Never install generic and/or differing brand batteries together.
- Always replace BOTH batteries with fresh new ones. Never install just one fresh battery and leave a used battery in the opposite side.
- ALWAYS operate the device with BOTH batteries installed and of equal strength.

WARNING: Operating the device with only one battery installed is not advised. If only one battery is installed and coincidentally removed during operation when performing a "Hot Swap", the device could possibly stop in a "piston down" position requiring removal of O2 Supply Hose from the base of the device to release the piston. ALWAYS OPERATE the device with BOTH BATTERIES INSTALLED.

- Always use 9V <u>alkaline</u> batteries. Do not mix battery types.
- Do NOT use re-chargeable batteries of ANY type.
- The battery trays are not tethered to the compartments. Take care when removing them to ensure they are not lost or damaged.

- If stored for extended periods with batteries installed, inspect both batteries prior to use to ensure they have not corroded.
- Dispose of used batteries properly.

2.4 Important Safety Features

Changing a battery during operation -- Should a low battery level occur during resuscitation efforts, either battery may be removed and replaced, (one at a time), from its compartment and a fresh battery can be "hot swapped' providing uninterrupted CPR.

WARNING: The "Hot Swap" should ONLY be performed when it is KNOWN that both batteries are installed and have equal energy. If no battery power is available, the device will stop without resetting. This could result in a "piston down" position requiring removal of the O2 Supply Hose from the base of the device to release the piston.

To "Hot Swap" the battery

1. Remove only one battery tray from either side of the Life-Stat® allowing the battery installed on the opposing side to continue to power the device.
2. Remove the used battery by pushing it back against the retaining spring and lifting up.
3. Insert a fresh battery in its place ensuring it is oriented properly (+ on left, - on right) per the diagram embossed on the bottom of the tray.
4. Re-insert the tray until a click is heard to ensure it is seated properly.
5. Discard the used battery appropriately when convenient.

The opposing battery may be 'hot-swapped' also following the above steps at this time. If it is not replaced immediately, install a fresh battery as soon as possible to ensure both batteries are fresh.

After replacement of either or both batteries, the LOW BATT LED will remain illuminated for approximately 2 - 5 minutes.

Auto Shutdown feature-- When the batteries reach a critical low level condition, the Life-Stat® will initiate an auto shutdown procedure. If the Life-Stat® is not physically turned off via the STOP/OFF button on the System Control (#1) keypad –or- the batteries are not 'hot-swapped' out as explained above, the compressor piston will return to the 'up' position, the ventilator will turn off, and the electronic control module will automatically shut down.

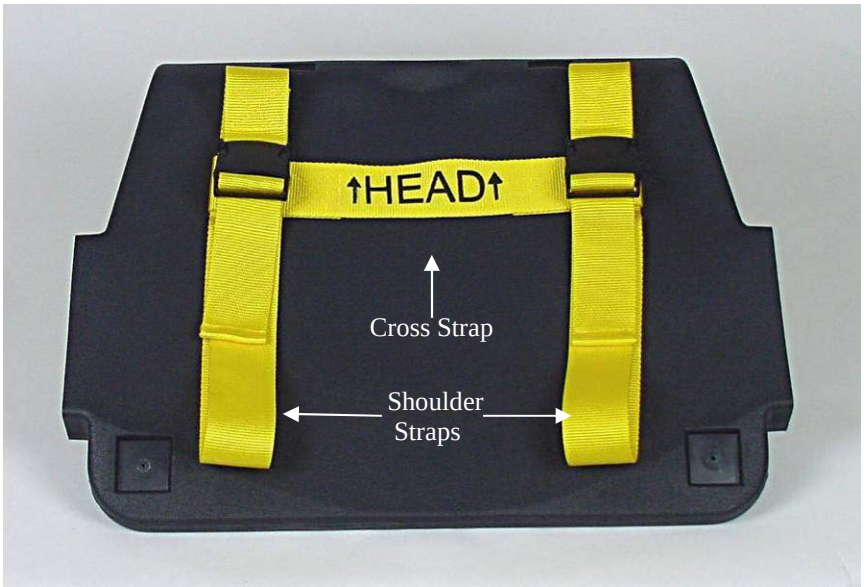
Also, if the unit is turned on (the START/ON button is pressed) but no CPR mode (30;2 or CCV) is selected within 16 minutes, the device will shutdown to conserve the batteries.

Service Interval Indicator— After the Life-Stat® has delivered over 1,000,000 (1 million) cycles, the START/ON LED indicator will flash. It is recommended to return the device to the factory for service after this occurs. The Life-Stat® will continue to function, however diminished performance may result if the recommended service is not performed to replace potentially worn components.

2.5 The BackBoard

The BackBoard is intended for either manual or mechanical CPR. It is designed to provide a firm, non-rebounding surface upon which CPR can be performed, and introduces a slight hyperextension of the patient's neck to facilitate upper airway management. It allows use of the Life-Stat® on either side of the patient. Two shoulder straps help immobilize the patient securing them to the BackBoard. The cross strap helps to keep the shoulder straps from separating and indicates the position of the head relative to the BackBoard.

NOTE: Optimal Life-Stat® CPR performance requires use of the BackBoard.

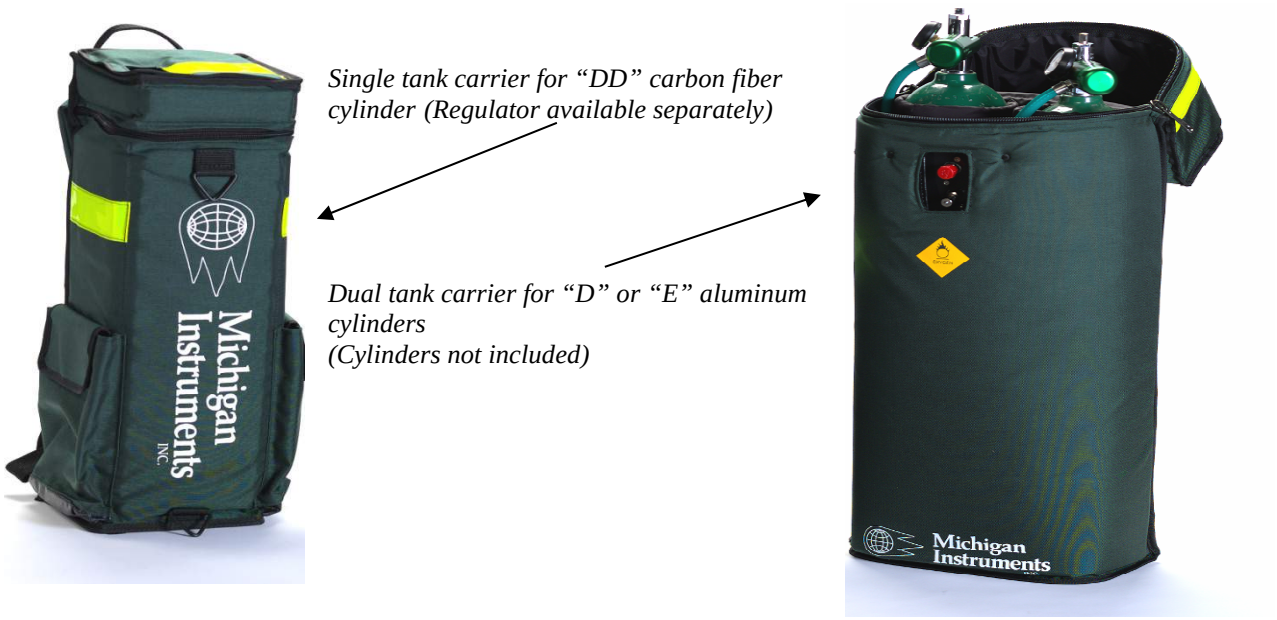


The BackBoard

2.6 Mobile Oxygen Carrier (MOC), or Appropriate Wall Access Adapter

The Life-Stat® is equipped with an O_2 Supply Hose used to connect the device to a source of compressed medical Oxygen. It incorporates couplers on each end and a check valve to retain the Oxygen during a source change. Wall adapters are available that connect to the O_2 Supply Hose to allow connection to the various and most common hospital (and ambulance) Oxygen pipeline systems.

The Mobile Oxygen Carrier is an Oxygen tank carrier, available in two configurations, which provide constant pressure and high flow source gas for the Life-Stat® and an additional DISS outlet. It is designed to power the Life-Stat® whenever the device is in use where no Oxygen pipeline source is available (for example, when transporting a cardiac arrest patient from the scene to the ambulance and from the ambulance to the hospital). One of the two outlets is dedicated to accept the Life-Stat® O_2 Supply Hose, while the other DISS outlet is available to supply other Oxygen-driven devices. MOC regulator(s) are preset to satisfy Life-Stat® requirements.



Mobile Oxygen Carrier (MOC)

2.7 The Carrying/Storage Case

The Carrying/Storage Case is constructed of a durable nylon. The Life-Stat®, O_2 Supply Hose and code-related supplies are stored in the Case in a manner which permits immediate access to the device and facilitates easy setup at an emergency site.

Carrying/Storage Case – shoulder strap (left) backpack straps (right)

3-Setup and Operation

3.1 Precautions

Before setting up and using the Life-Stat®, there are several important precautions that must be observed at all times.

1. The Life-Stat® must only be used in cases of clinical death as defined by lack of spontaneous breathing and pulse.

2. Manual CPR should be started on the patient immediately. Do not postpone CPR while waiting for the Life-Stat®. The Life-Stat® can be easily set up and applied to the patient without interrupting manual CPR efforts.

3. The Life-Stat® may be used in all cases with adult patients where manual CPR would normally be initiated. However, there are situations where CPR is not the appropriate method of intervention. Familiarity with accepted medical practices in your area is very important.

4. Personnel certified in manual CPR must always be present to monitor the patient during Life-Stat® operation in the event of a mechanical failure.

5. When transporting a patient with the Life-Stat® in operation using the BackBoard, ensure the patient is secured snugly to the BackBoard using the provided shoulder straps. Also, ensure the patient is properly secured (using retention straps) to the stretcher as well. Failure to do so can allow the Life-Stat® and BackBoard to shift position on the patient possibly causing the Massager Pad to wander off of the patient's sternum.

6. When applying the Life-Stat® to an obese patient, place the arm of the patient around the Life-Stat® so that the Column is positioned near the arm pit of the patient. This will better facilitate positioning the Massager Pad directly over the patient's sternum.

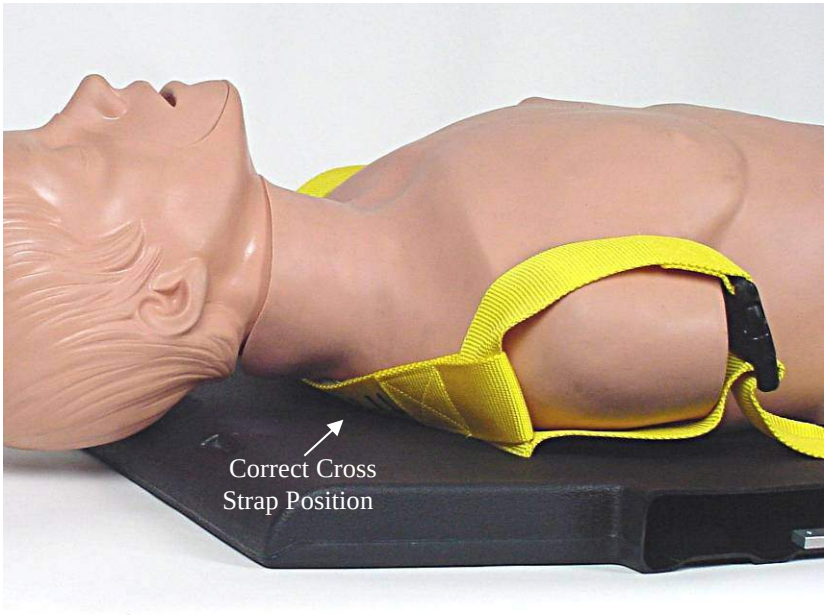
3.2 Recommendations

It is recommended that the Arm/Column of the Life-Stat® be attached to the Base while stored in the Carrying/Storage Case.

Additionally, the Arm should be positioned over the Base so that it is perpendicular to the O_2 Supply Connector located at the bottom of the Column. Lower the Arm until the white arrow is positioned at the -4- location on the Column and lock in place.

By doing so, the Life-Stat® is ideally positioned to expedite removal from the Carrying/Storage case and application to the patient.

When placing the BackBoard under the patient, ensure the cross strap is positioned under the patient's neck. Do not position the cross strap over the neck of the patient.



Training with a CPR Manikin can be beneficial in becoming familiar with:

- ✓ **Setup on the patient using the BackBoard**
- ✓ **Transitioning from manual CPR to mechanical CPR**
- ✓ **Setting the compression depth and delivering ventilations**
- ✓ **Interventions such as pausing operation to monitor the patient**
- ✓ **Performing the 'hot swap' of a battery**

3.3 Positioning the Patient

The following steps are provided as a recommendation.

1. When applying the BackBoard, “Log roll” the patient into position, taking care to keep the cervical spine immobilized.

WARNING: When moving a patient in cases of suspected C-spine injury, always support the patient’s head in a neutral position.

2. Place the BackBoard under the patient orienting the head of the patient in the direction indicated by the HEAD marking on the cross strap. Ensure the cross strap is positioned under the patient's neck. Connect the retaining straps over the shoulder and under the arm pit of the patient, then buckle and tighten the straps securely on both sides of the patient.

3. Secure the patient to the spine board with retention straps at the forehead, hips and feet.

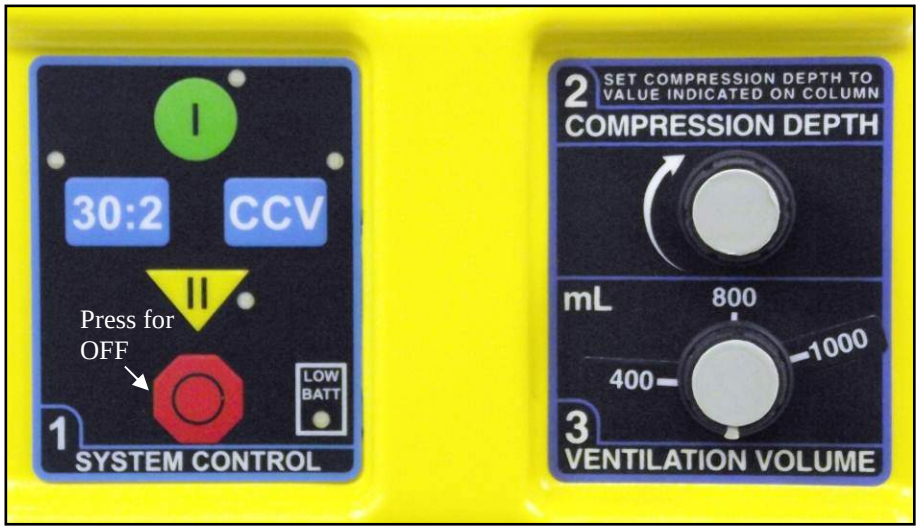
WARNING: Do not place retention straps or other restraints over the patient’s abdominal area. Tight garments around the abdomen should be removed or loosened.

4. Manual CPR can begin on the patient immediately. There is no need to postpone CPR while waiting for Life-Stat® deployment and application to the patient.

3.4 Life-Stat® Deployment

3.4.1 Life-Stat® Setup:

A. Remove the Life-Stat® from the Case.

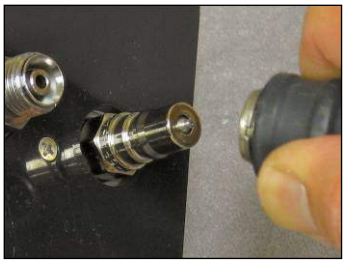


B. Ensure the System Control (#1) is OFF.

C. Ensure Controls (#2) & (#3) are both turned fully counterclockwise.

D. Attach the Breathing Hose/Non Re-breathing valve (and mask, if used) to the PDV.

E. Ensure the Oxygen source is energized then attach the O_2 Supply Hose to the Oxygen source. Pull the collar back from the O_2 Source-end connector, press firmly onto the male connector of the Oxygen source, then release the collar to secure the connector. Pull gently on the hose to ensure a secure connection.



F. Attach the opposite end of the hose to the Life-Stat® O_2 Supply Connector by inserting the hose connector while slightly turning it at the same time to align the hexagons, and then press firmly to attach. Pull gently on hose to ensure a secure connection. <u>Do not press the release button while attaching the connector</u>. Only press the release button to disconnect the connector.

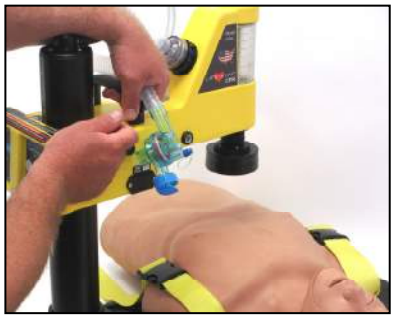
G. Verify that the green Pressure Indicator located on the top of the column shows an adequate input pressure is available.

CAUTION: The Life-Stat® requires a medical grade Oxygen source capable of delivering pressure from 50 to 90 psi (3.515 to 6.327 kgf/cm^2), with a minimum flow rate of at least 45 LPM. Always follow safe Oxygen handling practices with Oxygen cylinders and regulators.

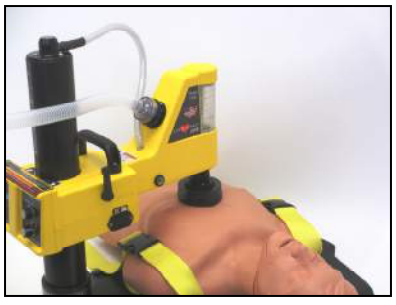
3.4.2 Life-Stat® Application to the Patient:

A. Before inserting the Life-Stat® into the BackBoard, ensure the Arm is raised to and locked near the top of the Column and positioned so that the dome is towards the patient's feet. NOTE: When oriented in this position, the Life-Stat® is top-heavy and prone to fall over. Grasp the Life-Stat® at the Base and Handle.

B. Insert the Base into the side slot of the BackBoard on whichever side of the patient is most convenient.



C. With the Base fully inserted into the BackBoard and during a pause in the manual CPR effort, loosen the Arm Lock and swing the Arm over the patient's chest locating the Massager Pad over the sternum, as you would for the heel of your hand when performing manual CPR.



D. Lower the Arm until the Massager Pad contacts the patient's chest. Then, apply slight downward pressure on the Arm to position the Piston inside the Dome to align with the "-" mark on the Dome. Tighten the Arm Lock Lever.

WARNING: The Massager Pad must not extend over the xiphoid process. This could result in injury to the patient.

WARNING: Injury to patient may occur if Arm is adjusted too low, as indicated by the top of the Piston moving up beyond "-" on the Dome.

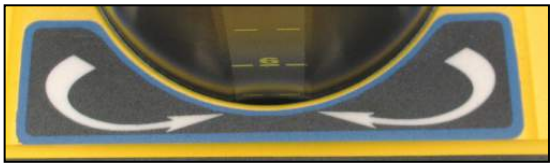
WARNING: Patient chest compressions may be insufficient to be effective if Arm is adjusted too high as indicated by the top of the Piston not moving up to "-" on the Dome.

WARNING: Patient is more likely to shift from optimum position relative to Massager Pad if Arm is adjusted too high, as indicated by the top of the Piston not moving up to "-" on the Dome.

CAUTION: If the Arm Lock Lever is not securely tightened, Arm height or Massager Pad location may shift position relative to the patient.

3.4.3 Determine Compression Depth:

Determine the depth of compression by referring to the Sternal Deflection Number located on the scale on the back of the Column. The white arrows indicate the depth required to provide the 20% A-P sternal deflection for the patient.



WARNING: Do NOT use the Life-Stat® if the white arrows indicate in the red area of the scale.

NOTE: 2010 AHA Guidelines recommend for adult patients, a minimum compression depth of at least 2" (5cm). If the A-P chest diameter number indicated on the Life-Stat® is less than 5, then deliver compressions minimally to the depth indicated by the -5- marking on the dome.

3.4.4 Life-Stat® Activation:

WARNING: Failure to ensure that the COMPRESSION DEPTH knob (Control #2) is turned fully counterclockwise upon initial application to the patient and prior to selecting a CPR mode via the SYSTEM CONTROL #1 will deliver compressions to the patient at the depth last set by Control #2. This depth may not be set for the correct A-P Diameter and could possibly cause serious damage or inhibit resuscitating the patient.

WARNING: Failure to ensure that the VENTILATION VOLUME knob (Control #3) is turned fully counterclockwise upon initial application to the patient and prior to selecting a CPR mode via the SYSTEM CONTROL #1 will deliver ventilations to the patient (if the breathing hose is applied to the patient) at the tidal volume last set by Control #3. This setting may not be correct and could deliver either excessive or insufficient tidal volumes to the patient.

With the SYSTEM CONTROL (#1) in the STOP/OFF position:

A. Ensure:
   a. COMPRESSION DEPTH knob (#2) is rotated fully counterclockwise
   b. VENTILATION VOLUME knob (#3) is rotated fully counterclockwise
   c. The pressure Indicator at the top of the Column shows "green" indicating adequate O_2 pressure.

B. Press the START/ON button on the SYSTEM CONTROL (#1) keypad. The system will perform a quick self check. When the system is ready the green LED indicator next to the START/ON button will illuminate.

C. Choose the desired CPR mode by pressing the desired mode button (30:2 or CCV). The blue LED indicator near the selected mode button will illuminate.

D. Rotate COMPRESSION DEPTH knob (#2) clockwise until sufficient compression depth is demonstrated by viewing the Piston at eye level. Increase the depth until the top of the Piston reaches the A-P Diameter Sternal Deflection Number on the Dome corresponding to the Sternal Deflection Number reading taken from the scale on the back of the Column. This will deliver the recommended A-P Diameter for the patient.

WARNING: Injury to patient may occur if compression depth is set too deep or the knob is inadvertently moved clockwise.

WARNING: Patient chest compressions may be insufficient if compression depth is set too shallow or the knob is inadvertently moved counterclockwise.

WARNING: With the Life-Stat® in use, care must be taken to prevent kinking or collapsing of the O_2 Supply Hose.

3.4.5 Life-Stat® Ventilator- Patient Demand Valve (PDV) Activation:

A. Rotate the VENTILATION VOLUME knob (#3) clockwise in accordance with AHA guidelines, and/or local protocol to desired volume (mL).

B. Apply the Breathing Hose/Non Re-breathing Valve to the patient via mask or ET tube.

C. The ventilator contains a Pressure Limit Alarm that will sound an audible alarm when the airway pressure exceeds 55cm H_2O. Monitor the patient airway to identify the cause for the increased pressure and take the appropriate corrective action.

WARNING: During ventilation, the operator must maintain constant attention to ensure the patient is properly ventilated.

WARNING: Excessive ventilation may be delivered to the patient if the ventilation volume is set too high or the knob inadvertently moved clockwise.

WARNING: Patient ventilation may be insufficient if the ventilation volume is set too low or the knob inadvertently moved counterclockwise.

WARNING: Should the blue rubber diaphragm blow outward from the Pressure Limit Alarm's relief ports, discontinue the use of the Life-Stat® ventilator. It is recommended to manually ventilate the patient until such time that a spare replacement alarm can be installed.

CAUTION: If the maximum pressure limit is reached (the pressure limit alarm sounds), the pre-set tidal volume may not be delivered to the patient. No additional volume will be delivered until the next ventilation cycle.

NOTE: An audible Pressure Limit Alarm is attached to the PDV. This alarm sounds whenever the patient airway pressure reaches the designed release pressure limit of 55cm H_2O. The Pressure Limit Alarm will continue to sound during the inspiratory phase until either the airway pressure decreases or the next ventilation cycle begins.

3.4.6 Procedure to Interrupt (Suspend) Compressions:

To perform pulse checks or perform analysis with an AED (and/or defibrillate manually), simply press the PAUSE button. This will interrupt compressions only, while ventilations continue at the previous rate and volume setting. To resume compressions, press the desired mode button (30:2 or CCV). The same depth of compression previously set by the COMPRESSION DEPTH knob will be delivered. If stopping the delivery of ventilations is desired temporarily, rotate the VENTILATION VOLUME knob fully counterclockwise. To resume ventilations, rotate the VENTILATION VOLUME knob clockwise to the desired volume.

CAUTION: When the Life-Stat® is used in conjunction with automatic external defibrillators (AEDs), or other therapeutic devices which must utilize an ECG signal, interruption of the cardiac compressions as described may be required to avoid the ECG motion artifact associated with cardiac compressions.

The Life-Stat® is electrically insulated and should cause no interference during routine cardiac monitoring or manual defibrillation. However, conductive fluids or gels may provide stray current paths.

WARNING: DO NOT touch the Life-Stat® during defibrillation.

3.5 To Remove the Life-Stat® from the Patient:

A. Press the STOP/OFF mode button on the SYSTEM CONTROL (#1) keypad.
B. Turn COMPRESSION DEPTH (#2) knob fully counterclockwise.
C. Turn VENTILATION VOLUME (#3) knob fully counterclockwise.
D. Disconnect the O_2 Supply Hose first from the Life-Stat® O_2 Supply Connector by pressing the release button. Then, disconnect the connector from the Oxygen source by pulling the collar back from the connector to release it.

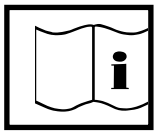
CAUTION: Disconnecting the Oxygen hose from the Oxygen source end first may not allow the device to properly vent the internal pneumatic ports. <u>Always</u> disconnect the O_2 Supply Hose from the Life-Stat® first.

NOTE: Upon detaching the O_2 Supply Hose from the Life-Stat®, an abrupt and loud release of Oxygen from the Column Buffer will occur. This is intentional and required to purge the Life-Stat® of its reserve Oxygen.

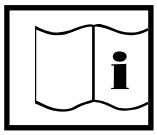
E. Remove the Breathing Hose/Non Re-breathing Valve from the patient and the PDV. Discard the Breathing Hose. Discard the Non Re-breathing Valve if a single use type.

F. Loosen the Arm Lock Lever and raise the Arm on the Column high enough to clear the patient. Tighten the Arm Lock Lever.
G. Remove the Life-Stat® from the BackBoard.
H. Clean and inspect the Life-Stat® per the recommended Shift Check (Daily or after each use).

WARNING: The Breathing Hose (REF 14669) and Non Re-breathing Valve (REF 14384) supplied with the device is intended for single use only. Do not re-use.



CAUTION: It is very important to follow the instructions for preventive maintenance and cleaning procedures after each use. They are found in the Care, Cleaning and Disinfection section of this manual.



NOTE: The Hose Adaptor (REF 14785), Lip Valve (REF 14781) and Pressure Limit Alarm (REF 14682) housed on the PDV may be cleaned and disinfected per the recommended procedure in the Care, Cleaning and Disinfection Section of this manual.

4-Storage and Shipping

4.1 Storage

Careful storage of the Life-Stat® is important. It should be stored in a location that is easily accessible and in a manner that does not allow dirt, debris, or moisture to get into the device or its accessories.

For storage during normal transportation, the Carrying/Storage Case holds the basic components of the system and allows quick access to the Life-Stat® at an emergency site.

A Life-Stat® that is stored assembled (for example, in a hospital ER setting) should be placed on a "crash cart" or other surface where it will be used. The Arm should be positioned near the middle of the Column and locked into place positioned over the Base. Coil a Breathing Hose/Non Re-breathing Valve and the O_2 Supply Hose on the Base for easy access.

4.2 Shipping

If the Life-Stat® must be shipped for any reason, a factory carton with protective foam inserts is recommended to protect the device. Replacement cartons are available from Michigan Instruments, Inc.

CAUTION: Do not ship the Life-Stat® in the Carrying/ Storage Case! Shipping in any container other than the original factory carton with foam inserts may damage the device and possibly void the warranty.

Refer to additional information and recommendations in the Factory Service Policy in Section F when returning the device for service.

4.3 Disposal

The corrugated breathing hose and Non Re-breathing Valve (NRV) are one-use items and are to be disposed after use on a single patient.

The Life-Stat® is designed for years of dependable service. When disposal is required, we recommend returning to the factory for recycling. The Life-Stat® contains electronic components that must be disposed of according to local laws.

(Blank Page Intentional)

5-Care, Cleaning, and Disinfection

NOTE: This section comprises the extent of serviceable items for the Life-Stat®. NO SERVICE, REPAIR or MAINTENANCE other than what is explained in this section should be performed by the user. **Any service, repair or maintenance not listed in this section is to be PERFORMED ONLY by FACTORY AUTHORIZED SERVICE PERSONNEL**.

5.1 General Care

Always store the Life-Stat® in a clean, dry place. When not in use, storage is provided for the Life-Stat® and BackBoard in the Carrying/Storage Case.

5.2 Avoiding Contamination

Contamination can enter the system through the O_2 Supply Hose. When filling Oxygen tanks, be certain that proper procedures are followed to prevent foreign matter from entering the tanks. Also, refer to additional **Cautions** listed in the General Warnings, Cautions and Notes section.

5.3 General Cleaning

Wipe all external surfaces of the Life-Stat®, O_2 Supply Hose, BackBoard, Carrying/Storage Case and related accessories to remove foreign matter after each use. Discard single-use items such as the Breathing Hose and the Non Re-breathing Valve. Clean the Patient Demand Valve (PDV) after each use per the Cleaning and Disinfecting the Patient Demand Valve section below.

5.4 Disinfection Guidelines

Standard colorless chemical disinfectant solutions may be used to "wipe down" external surfaces of the Life-Stat® device, O_2 Supply Hose, BackBoard, Carrying/Storage Case and related accessories.

CAUTION: Do not use disinfectants or cleaning solutions containing alcohol or ammonia to clean the Massager Pad.

CAUTION: Do not autoclave or Gas Sterilize the Life-Stat®.

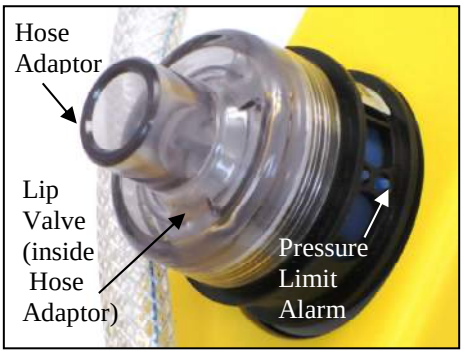
CAUTION: Do not spray cleaning or disinfecting solutions directly on the Life-Stat®. Dampen a clean cloth with the solution and use that to wipe down external surfaces.

Stain Removal from the BackBoard straps:

To clean the straps of stains, pre-treat with either Shout or OxyClean Spray Gel and follow product directions. Launder on gentle cycle, (place strap in a pillow case and tie end closed to protect the buckles). DO NOT USE bleach or fabric softener. Air dry only. Polyester straps & plastic buckles could melt from the heat of a dryer.

If stains remain, repeat the procedure. As with any stain, the longer it is allowed to set, the harder it may be to remove.

5.5 Cleaning and Disinfecting the Patient Demand Valve



A. Remove the Hose Adaptor, Lip Valve and Pressure Limit Alarm from the Patient Demand Valve (PDV).

B. Using a small soft bristle brush, clean all foreign matter from the components with a mild soap solution. Rinse the parts thoroughly in clean water. Using a cleaning cloth lightly dampened with the mild soap solution wipe the threads and exposed end of the PDV to remove any debris. Wipe away any soap solution with a clean cloth dampened lightly with clean water.

C. Immerse the Hose Adaptor, Lip Valve and Pressure Limit Alarm in a disinfectant solution for a minimum of 10 minutes. Rinse thoroughly with clean water repeatedly to ensure that all disinfectant solution is removed. Set aside to dry thoroughly.

D. Using a cleaning cloth lightly dampened with the disinfectant solution, wipe the threads and exposed end of the PDV. Allow to stand for 10 minutes then wipe repeatedly with a cleaning cloth dampened lightly with clean water to remove any remaining disinfectant solution.

WARNING: If there are contaminants present inside the PDV that cannot be accessed for cleaning/disinfecting, return for factory service.

E. Once all items are completely dry, carefully examine the Hose Adaptor, Lip Valve and Pressure Limit Alarm. Discard any cracked or damaged parts and replace as necessary.

F. Install the Pressure Limit Alarm on the PDV and tighten snugly. Properly center the Lip Valve inside the Pressure Limit Alarm and ensure it is seated uniformly. Install the Hose Adaptor on the Pressure Limit Alarm and tighten snugly.

G. After cleaning/disinfecting the PDV, it is recommended to verify its operation. Turn Control #2 and Control #3 fully counterclockwise and ensure the SYSTEM CONTROL #1 is OFF. Attach the O_2 Supply Hose to an energized Oxygen source first, and then connect the opposite end to the Life-Stat®. Turn the device on using the START/ON button on the System Control (#1), select CCV and turn VENTILATION VOLUME (#3) to 1000ml. Allow the ventilator to cycle several times to blow out any remaining cleaning/disinfecting solution. Wipe any residue expelled from the PDV and the device covers. During a ventilation cycle, block the end of the Hose Adaptor on the PDV and ensure the Pressure Limit Alarm sounds indicating it is operating properly.

H. Turn VENTILATION VOLUME (#3) fully counterclockwise, SYSTEM CONTROL #1 to OFF. Disconnect the O_2 Supply Hose from the device first then from the Oxygen source.

I. Return the device and related accessories to the Carrying/Storage Case or preferred method of storage.

5.6 Mobile Oxygen Carrier (MOC)

- Should you require maintenance of the regulator(s) used in the MOC, contact the manufacturer of the regulator to arrange for service. Vendor information is provided with the MOC regulator at the time of purchase.
- Ensure the regulator(s) contain the Oxygen seal when replacing Oxygen cylinder(s).
- Monitor pressure of the cylinder(s) regularly to ensure enough Oxygen supply is available.
- For the dual carrier, it is recommended to have only one cylinder open when powering the Life-Stat®. When the Oxygen level is low, the other cylinder can then be opened and the low cylinder closed.
- Refer to additional **Warnings** listed in the General Warnings, Cautions and Notes section on the use of Oxygen-related equipment.

5.7 Periodic Preventive Maintenance

The following recommended preventive maintenance procedures and checks can help increase the life of the Life-Stat®, its related accessories and assure they are in proper operating condition.

NOTE: There are no user-serviceable parts inside the Life-Stat® and no calibrations or adjustments are needed for routine use. However, the general readiness and function of the system can, and should, be evaluated on a regular basis. These checks are performed on three levels.

1. **Shift check** – A series of checks that should be done after each use and at the start of every shift. (See procedure below.)

2. **Functional check** – A complete visual and functional check of the Life-Stat®. (See procedure below.)

3. **Factory service** – A recalibration and routine maintenance of internal components performed at the manufacturer by factory trained personnel after the device has delivered over 1,000,000 (1 million) compression cycles. This is indicated by the START/ON green LED flashing continuously.

The schedule for performing these procedures should be determined by the user, taking into consideration specific circumstances and frequency of use. Use the table below as a guide.

Factory-Recommended Maintenance/Service Intervals

Life-Stat® Use	Shift Check	Functional Check	Factory Service
Heavy use: Daily	After each use	Monthly	Every 2 years
Frequent use: 10 - 15 times per month	After each use	Quarterly	Every 3 - 4 years
Infrequent use: < 10 times per month	After each use	Semi annually	Every 5 years

(Use based on a 20 minute average run time.)

In addition to the procedures for the Shift Check and Functional Check, checklists are also provided to document these procedures. It is recommended to complete the checklists when these procedures are performed to provide a document trail to demonstrate that the proper recommended maintenance is being performed at the recommended/user determined intervals.

5.8 Shift Check

Procedure:

A. Visual inspection

1. Make sure that the device and all accessories are clean and free of any contaminants.
2. Check the device and all accessories for any worn, loose or damaged parts.
3. Discard any used Breathing Hose (and Non Re-breathing Valve, if single use). Clean and disinfect the PDV components if necessary.

WARNING: Using a contaminated PDV may cross contaminate the patient.

CAUTION: Replace the straps (REF 15440) on the BackBoard when they show signs of wear or fraying. Otherwise, the ability to adequately secure the system to the patient will be jeopardized.

CAUTION: Replace the BackBoard (REF 14790-01) if the formed plastic becomes cracked or broken. Otherwise, patient support during CPR or the ability to properly apply the Life-Stat® to the patient may be jeopardized.

CAUTION: Inspect the Massager Pad (REF 14780). Replace if damaged (cover loose, peeling away, punctured, etc.)

CAUTION: Life-Stat® CPR performance may be jeopardized if the device is operated with worn, loose, or damaged parts.

B. Set up for operation--(Ensure System Control#1 is set to OFF, Controls #2 and #3 are turned fully counterclockwise (ccw) before continuing)

4. Loosen the Arm Lock Lever and check that the Arm moves freely on the Column. Raise Arm to bring the white arrow to the 6 position and tighten the Arm Lock Lever.
5. Inspect the O_2 Supply Hose for kinks, cracks, cuts, worn hose or damaged connectors. Connect the O_2 Supply Hose to the Oxygen source first, and then connect it to the Life-Stat®.
6. Turn the System Control #1 ON then select the CCV position. Verify that the green Pressure Indicator at the top of the Column is extended. Verify the LOW BATT LED is not blinking or illuminated.
7. Attach a Breathing Hose/Non Re-breathing Valve to the PDV. Turn Control #3 to 800ml. Verify that a ventilation is delivered. Block the end of the Non Re-breathing Valve and turn Control #3 to 1000ml. Verify that the Pressure Limit Alarm sounds on the next ventilation.
8. Turn Control #3 fully counterclockwise and remove the Breathing Hose/Non Re-breathing Valve. Ensure Control #3 turns smoothly and is not loose. Turn System Control #1 OFF.
9. Remove the O_2 Supply Hose from the Life-Stat® first, then from the Oxygen source.
10. With the O_2 Supply Hose disconnected, verify that the Compression Depth Control #2 turns smoothly and is not loose.

C. Prepare device for next use

11. Ensure System Control #1 is OFF, Control #2 and Control #3 are turned fully counterclockwise.
12. Check that all accessories and supplies are available: O_2 Supply Hose, Breathing Hoses/Non Re-breathing Valves, BackBoard, fresh spare 9V batteries, etc.
13. Ensure Oxygen cylinder(s) in the MOC have an adequate Oxygen supply.
14. Place the Life-Stat®, supplies and accessories into the Carrying/Storage Case.

Shift Check of Life-Stat® *(Daily, or after each use)*

Date: ____/____/____ Shift: _____ Location: _____ Serial Number:_____

At the beginning of each shift, inspect the device. Indicate whether all requirements have been met. Note any corrective actions taken. Sign the form.

Requirement	Acceptable as Found	Corrective Action/Remarks
A. Visual inspection		
1. Life-Stat® is clean and free of contaminants		
BackBoard " " " " " "		
O_2 Supply Hose " " " " " "		
MOC/related adaptors " " " " " "		
2. Life-Stat® has no worn, loose or damaged parts		
BackBoard " " " " " " "		
O_2 Supply Hose " " " " " " "		
MOC/related adaptors " " " " " " "		
3. Used Breathing Hose/Non Re-Breathing Valve discarded		
PDV/Components clean/disinfected		
B. Set up for operation		
4. Arm moves freely on Column		
5. O_2 Supply Hose connects and no signs of wear present		
6. Pressure Indicator shows green		
LOW BATT LED not blinking or illuminated		
7. Ventilation is delivered at 800ml		
Pressure Limit Alarm activates		
8. Control #3 rotates and is secure		
9. O_2 Supply Hose disconnects properly		
10. Controls #2 rotates and is secure		
C. Prepare device for next use		
11. Control#1 OFF & Controls#2 & #3 turned fully ccw.		
12. Accessories and supplies inventory:		
Life-Stat® device		
O_2 Supply Hose		
Breathing Hoses/Non Re-breathing Valves		
BackBoard		
Carrying/Storage Case		
MOC/related adaptors		
Fresh Spare 9V batteries		
Other code related supplies:		
13. MOC cylinder(s) Oxygen supply adequate		
14. All items needed packed in Carrying/Storage Case		
Any major problem(s) identified to warrant taking the device OUT OF SERVICE? (circle one) **If yes, explain in the remarks section and submit this form and the device to the authorized personnel in your organization responsible for the coordination of equipment service requests.**	**Yes / No**	

Signature: _____

5.9 Functional Check

Procedure:

A. Visual and Mechanical Inspection

1. Appearance *(Check the overall appearance and condition of the device.)*

a. Make sure the device and all accessories are clean and free of any contaminants.
b. Check the device and all accessories for any worn, loose or damaged parts (refer to Cautions: listed in the Shift Check section).
c. Check the plastic covers of the Life-Stat® for any cracks or damage.
d. Discard any used Breathing Hose (and Non Re-breathing Valve, if single use). Clean and disinfect the PDV components if necessary.
e. Inspect the O_2 Supply Hose for kinks, cracks, cuts, worn hose or damaged connectors.
f. Ensure that all required labeling is in place, legible and properly adhered to the surfaces.

2. Arm motion and Arm Lock Lever

a. Loosen the Arm Lock Lever and raise and lower the Arm on the Column. It should move freely.
b. Tighten the Arm Lock Lever. The Arm should remain in place.

3. Mounting system test

a. Detach the Arm and Column assembly from the Base by pressing the Arm/Column release button to the left of the Column and rotating the Column. Re-attach and verify a smooth and secure attachment of the device to the mounting Base.
b. Insert and remove the device into both sides of the BackBoard ensuring smooth insertion and removal.

4. Ventilation/Compression test-- (Ensure Control#1 is set to OFF and Controls#2 & #3 are turned fully counterclockwise (ccw) before continuing)

Set up the Life-Stat® simulating use on a patient using either a test spring (MII P/N T106) or a suitable CPR training manikin. Do not use a pillow, it will not provide the needed force (via a test spring or manikin) to properly perform the compression test.

a. Lower the Arm until the Massager Pad contacts the test spring or manikin then apply slight downward pressure until the Piston reads "-" on the Dome. Tighten the Arm Lock Lever.

Attach the O_2 Supply Hose to the Oxygen source first.

b. Check the operation of the O_2 Supply Hose by connecting and disconnecting the Life-Stat® end of the supply hose a few times. The connector should attach and release smoothly.
c. Verify that when the O_2 Supply Hose is connected the green Pressure Indicator at the top of the Column is functional.
d. Attach a Breathing Hose/Non Re-breathing Valve to the PDV. Turn Control #1 to the START/ON position and Control #3 to 800ml. Select CCV mode. Verify that ventilation is delivered. Block the end of the Non Re-breathing Valve and turn Control #3 to 1000ml. Verify that the Pressure Limit Alarm sounds on the next ventilation.
e. Turn Control #3 fully ccw. Verify the Green ON indicator LED is lit. Select 30:2 and CCV mode ensuring the blue LED is lit for each mode. Select the PAUSE mode ensuring the yellow LED is lit. Verify the LOW BATT LED is not blinking or illuminated.
f. Remove the Breathing Hose/Non Re-breathing Valve. Ensure Control #3 turns smoothly and is not loose.

Select CCV mode to activate the chest compressor.
Set the Compression Depth Control #2 as close to the "4" mark as possible. Allow the system to operate for 4 - 5 minutes, while monitoring the chest compression depth.

g. Verify that the Compression Depth Control (#2) works smoothly and allows proper adjustment of the compression depth.
h. Verify that the Piston motion is smooth and consistent.
i. While monitoring the compression depth, ensure the Piston does not exceed "5" nor should it be less than "3½".

B. Prepare device for next use

1. **Press the STOP/OFF button on Control #1 and turn Controls #2 & #3 fully counterclockwise.**
2. **Remove the O_2 Supply Hose from the Life-Stat® first then from the Oxygen source.**
3. **Check that all accessories and supplies are available: O_2 Supply Hose, Breathing Hoses/Non Re-breathing Valves, BackBoard, spare fresh 9V batteries, etc.**
4. **Ensure Oxygen cylinder(s) in the MOC have an adequate Oxygen supply.**
5. **Place the Life-Stat®, supplies and accessories into the Carrying/Storage Case.**

Functional Check of Life-Stat® (*Weekly, monthly, or per determined schedule)*

Date: ____/____/____ Shift: _____ Location: _____ Serial Number:_____

Per the determined schedule, inspect the device. Indicate whether all requirements have been met. Note any corrective actions taken. Sign the form.

Requirement	Acceptable as Found	Corrective Action/Remarks
A. Visual and Mechanical Inspection		
1. Appearance		
a. Life-Stat® is clean and free of contaminants		
BackBoard " " " " " "		
O_2 Supply Hose " " " " " "		
MOC/related adaptors " " " " " "		
b. Life-Stat® has no worn, loose or damaged parts		
BackBoard " " " " " " "		
O_2 Supply Hose " " " " " " "		
MOC/related adaptors " " " " " " "		
c. Life-Stat® covers not cracked or damaged		
d. Used Breathing Hose/Non Re-breathing Valve discarded		
PDV/Components clean/disinfected		
e. O_2 Supply Hose connects and no signs of wear		
f. Labeling is in place, legible and properly adhered		
2. Arm motion and Arm Lock Lever		
a. Arm moves freely on Column		
b. Arm locks to the Column		
3. Mounting system test		
a. Arm and Column mounts to the Base securely		
b. Smooth insertion/removal into both sides of the BackBoard slots		
4. Ventilation/Compression test		
a. Piston reads "-" and Arm Lock Lever secures Arm in place		
b. O_2 Supply Hose connects and disconnects easily		
c. Pressure Indicator shows green		
d. Ventilation is delivered at 800ml		
Pressure Limit Alarm activates		
e. ON / 30:2 / CCV / PAUSE LED indicators illuminate		
LOW BATT LED not blinking or illuminated		
f. Control #3 rotates and secure		
g. Compression Depth Control works smoothly/depth adjusts		
h. Piston motion is smooth and consistent		
i. Compression depth consistent		
B. Prepare device for next use		
1. Control#1 OFF& Controls#2 & #3 turned fully ccw.		
2. O_2 Supply Hose disconnects properly		
3. Accessories and supplies inventory:		
Life-Stat® device		
O_2 Supply Hose		
Breathing Hoses/Non Re-breathing Valves		
BackBoard		
Carrying/Storage Case		
MOC/related adaptors		
Spare fresh 9V batteries		
Other code related supplies:		
4. MOC cylinder(s) Oxygen supply adequate		
5. All items needed packed in Carrying/Storage Case		
Any major problem(s) identified to warrant taking the device OUT OF SERVICE? (circle one) **If yes, explain in the remarks section and submit this form and the device to the authorized personnel in your organization responsible for the coordination of equipment service requests.**	**Yes / No**	

Signature: _____

5.10 Troubleshooting Guide:

Should the device fail to operate properly at any time refer to the following Troubleshooting Guide. Disconnect the ventilator from the patient any time the unit does not appear to be operating properly. If unable to determine the cause of problem, contact Michigan Instruments for service.

Indication	Probable Cause(s)	Solution
System Control #1 not functioning	Batteries not installed or expired Batteries installed improperly System error	Install 2 fresh 9V batteries Check for proper orientation of batteries Return to factory for service
START/ON, 30:2, CCV or PAUSE LED not lit when button activated START/ON LED blinking	LED burned out System error Service Interval Indicator	Return to factory for service Return to factory for service Return to factory for service
No function with Oxygen source connected, Control #1 in START/ON position and either 30:2 or CCV mode selected	Inadequate O_2 supply Software malfunction Seized internal pneumatic component	Verify O_2 supply is ON Verify O_2 supply tank is not empty or low Verify O_2 Supply Hose connections are secure Verify proper input pressure of 50-90 psi (3.515 to 6.327 kgf/cm^2) by checking Pressure Indicator is up and green Release BOTH battery compartments in tandem and re-seat Return to factory for service
No compressions with increase of Control #2	No mode selected	Select either 30:2 or CCV mode
No ventilation with increase of Control #3	No mode selected	Select wither 30:2 or CCV mode
No compressions with increase of Control #2	Control #2 knob not secured to valve shaft	Verify Control #2 knob is secured to shaft
No ventilation with increase of Control #3	Control #3 knob not secured to valve shaft	Verify Control #3 knob is secured to shaft
CAUTION: If Control #3 is found loose on the shaft and subsequently tightened, the indicator on the knob may not be properly aligned to deliver the true volume indicated. Proper ventilation tidal volumes must then be determined by monitoring chest rise during ventilation. Returning device to the factory to calibrate Control #3 is recommended.		
No compressions with increase of Control #2 -or- No ventilation with increase of Control #3	Inadequate O_2 supply	Verify O_2 supply is ON Verify proper input pressure of 50-90 psi (3.515 to 6.327 kgf/cm^2) by checking Pressure Indicator is up and green Verify Oxygen source is delivering proper minimum flow of 45 LPM
Inadequate Ventilation to patient	Control #3 knob setting Improper Lip Valve Improper Lip Valve placement Breathing Hose obstruction or leakage Non Re-breathing Valve obstruction Face Mask/Airway obstruction or leakage Decreased lung compliance or Increased lung resistance	Verify Control #3 setting. Increase to provide sufficient ventilation as evidenced by chest rise Verify proper type of Lip Valve is installed Verify Lip Valve is oriented/seated properly Check Breathing Hose for obstruction or leakage Check Non Re-breathing Valve for blockage and/or proper Lip Valve orientation Check Face Mask/Airway for obstruction or leakage Evaluate patient and adjust as needed

5.11 Life-Stat® Model 1008MII Detailed Specifications

Input:
- Compressed O_2 at 50 to 90 psi (3.515 to 6.327 kgf/cm^2)
- Gas Consumption: Maximum 45 LPM (11.88 gal/min.)
- Indicator to show adequate input pressure: 50 ± 3 psi (3.515 ±0.211 kgf/cm^2)
- Pressure relief valve set at 100 ± 5 psi (7.030 ± 0.351 kgf/cm^2)
- Filters to prevent contamination
- Oxygen checked quick connector (provided on O_2 Input Hose)

Compression:
- Compression Frequency: 100 ± 2 compressions per minute
- Compression Stroke Range: Continuously Adjustable, 0 to 8 cm (0.0 to 3.15 in)
- Compression to Ventilation Ratio: 30:2 (30:2 mode)
- Continuous Compression with simultaneous Ventilation (CCV mode)
- Relaxation Force range: Upstroke force of at least 1.361 kg (3.0 lbs)
- Duty Cycle: constant at 50:50 (Systolic:Diastolic)
- Chest Compression waveform:
  Exponential waveform with a time constant of less than 60.0 msec

Ventilation:
- Time-cycled, constant-flow ventilator
- Calibrated Volume Control: 0-1000 ± 100 mL; adjustable from 0 - 1000 mL
  (0. - 0.317 ± 0.026 gal; adjustable 0 - 0.317 gal)
- Deliver 95% ± 5% Oxygen to the patient
- Inspiratory Time: 1.0 ± 0.25 seconds
- Inspiratory Flowrate: 0 to 50.0 ± 2.5 LPM (0 to 13.20 ±0.66 gal)
- Inspiratory:Expiratory (I:E) ratio: (30:2) – 1:1.5
- Inspiratory:Expiratory (I:E) ratio: (CCV) – 1:5.5
- Pressure Relief Valve: < 55.0 cm H_20 (0.782 psi)

Controls:
- System Control membrane switch pad
  START/ON / 30:2 / CCV / PAUSE / STOP/OFF
- Compression Control: Continuous Compression Depth
- Ventilation Control: Calibrated Tidal Volume
- Low Battery indicator
- Service interval indicator

Environmental:
- Operating Environment: -20 °C to 45 °C (-4 °F to 131 °F)
- Storage Environment: -30 °C to 60 °C (-22 °F to 140 °F)
- Humidity: 0 to 98% RH (non-condensing)
- Sealed piston shaft and bearing to prevent contamination

Dimensions:
Height: 22-1/2" (57.2cm) Width: 7-5/8" (19.4cm) Length: 18-1/4" (46.4cm)
Weight: 16 lbs (7.26kg) 19.5 lbs (8.85kg) (with base attached)

Questions about the Life-Stat®? Please call 1-800-530-9939.

5.12 Electromagnetic Environmental Declaration

NOTE: The Life-Stat is powered by 9V DC batteries and does not use a Public Mains Power Network.

Guidance and manufacturer's declaration- electromagnetic emissions		
The Life-Stat is intended for use in the electromagnetic environment specified below. The customer or the user of the Life-Stat should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR11	Group 1	The Life-Stat 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 CISPR11	Class B	The Life-Stat is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration- electromagnetic immunity			
The Life-Stat is intended for use in the electromagnetic environment specified below. The customer or the user of the Life-Stat should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not Applicable Not Applicable	Not Applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not Applicable Not Applicable Not Applicable Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration- electromagnetic immunity			
The Life-Stat is intended for use in the electromagnetic environment specified below. The customer or the user of the Life-Stat should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Life-Stat, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	Not Applicable	Not Applicable
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Life-Stat is used exceeds the applicable RF compliance level above, the Life-Stat should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Life-Stat.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than (Not applicable) V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Life-Stat

The Life-Stat is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Life-Stat can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Life-Stat as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter m			
Rated maximum output power of transmitter W	**150 kHz to 80 MHz outside ISM bands** **Not Applicable**	**150 kHz to 80 MHz in ISM bands** **Not Applicable**	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	Not Applicable	Not Applicable	0.12	0.23
0.1	Not Applicable	Not Applicable	0.38	0.73
1	Not Applicable	Not Applicable	1.2	2.3
10	Not Applicable	Not Applicable	3.8	7.27
100	Not Applicable	Not Applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

5.13 Parts List (Life-Stat®)

REF

Part No.	Description
Resuscitation	
16000Y	Life-Stat® Model 1008$_{MII}$ (Yellow)
14790-01	BackBoard
14850	Carrying/Storage Case (shoulder strap)
15450	CPR Carrying Case- Backpack
Replacement Parts	
16005	Life-Stat® Instructions for Use (IFU) Manual
15440	BackBoard Replacement "H" Strap Kit
14910	O_2 Supply Hose 10 Ft.
14950	O_2 Supply Hose 15 Ft.
14780	Massager Pad Assembly, Urethane
14669	Breathing Hose – disposable
14384	Non Re-breathing Valve (NRV) – disposable (5/pkg)
14682	Pressure Limit Alarm
14781	PDV Replacement Lip Valve
14785	PDV Replacement Cap (Hose Adaptor)
Oxygen Management	
15290	MOC Dual D Tank Soft Case
15300	MOC Dual E Tank Soft Case
15040	Soft Case for Carbon Fiber Cylinder
15030-01	Oxygen Regulator CGA 870 (1 DISS, 1 TPR Connection)
11117	Oxygen Regulator CGA 540 w/Hand wheel
10411-01-01	Oxygen Adaptor Assy. - OHIO
10411-02-01	Oxygen Adaptor Assy. - DISS
10411-06-01	Oxygen Adaptor Assy. - NCG
10411-07-01	Oxygen Adaptor Assy. - Puritan Bennett

Other Oxygen adaptors are available for purchase

For pricing or to place an order, please contact our customer service department at (800) 530-9939.

6-Warranty and Factory Service Information

6.1 Model 1008MII Life-Stat® Cardiopulmonary Resuscitator Warranty Agreement

Your CARDIOPULMONARY RESUSCITATOR (Model 1008MII) is warranted by Michigan Instruments, Inc., Grand Rapids, Michigan to be free of defects in material and workmanship for a period of two (2) years from the date of receipt by the end purchaser **or** 1,000,000 (1 million) cycles, whichever comes first. (The 1,000,000 (1 million) cycles is indicated by the START/ON green LED blinking.)

All repairs necessitated by malfunction of this equipment during the warranty period when in normal use in accordance with instructions provided will be accomplished at the Michigan Instruments, Inc. factory, or authorized service facility, without charge other than the cost of transportation to the factory or authorized service facility. Michigan Instruments, Inc. hereby reserves the right to perform warranty repairs with used and/or reconditioned components that meet or exceed the original component specifications. Michigan Instruments, Inc. undertakes NO LIABILITY HEREUNDER FOR SPECIAL OR CONSEQUENTIAL DAMAGES, or any other expense liability beyond the furnishing of materials and labor for the repairs covered hereby. This warranty does not cover mars and blemishes, scratches, or dents, which may result from normal use of this equipment or malfunctions due to mishandling or improper packaging. This warranty does not cover batteries.

If the warranty registration IS NOT PERFORMED, the warranty period will begin the DATE THE INSTRUMENT WAS SHIPPED FROM THE FACTORY. For Warranty Registration information refer to the Warranty Agreement supplied with the device. Visit www.life-stat.com or www.michinst.com for on-line registration.

This warranty is IN LIEU OF ALL OTHER WARRANTIES EXPRESS OR IMPLIED, and shall be void as to any products which have been repaired or altered by others or have been subject to misuse or abuse. Buyer agrees that this written warranty constitutes the entire agreement as to warranties between the parties. Any prior or contemporaneous oral statements, which have not been written into this agreement, are not binding and this contract shall not be rescinded or modified except by a signed writing.

6.2 Purchase Records (fill in the following information for your records)

SERIAL NUMBER:

DATE OF RECEIPT:

PURCHASED FROM:

DATE WARRANTY CARD SENT:

6.3 Factory Service Policy

The Life-Stat® CPR System is manufactured to very demanding quality standards. It is designed to provide years of trouble-free service if proper care is taken in its operation and required preventive maintenance procedures are performed regularly. In addition to the regular maintenance performed by the user, factory service is recommended after the device has delivered1,000,000 (1 million) cycles as indicated by the START/ON green LED flashing continuously. Refer to the table titled "**Factory Recommended Maintenance/Service Intervals"** in the Periodic Preventive Maintenance portion for recommended intervals.

6.3.1 What to do if the Life-Stat® CPR System requires service:

A. Do not attempt repairs that are not outlined in this manual. Many components are critical to the proper operation of the device and MUST be serviced at the factory.

B. If you find that factory service is required, call the Michigan Instruments, Inc. Service Department at (800) 530-9939 between the hours of 9:00am and 5:00pm EST. Please have available the model number, serial number, and a description of the problem. An RMA Number will be issued at that time. Requests for repair parts or any service related questions should also be directed to the Service Department.

C. If your Life-Stat® CPR System must be returned to Michigan Instruments, Inc., please observe the following procedures:

1. First and foremost, **clean and sterilize the device** to remove any contaminants or body fluids. Failure to do so will result in additional charges. If contamination is severe, the unit will be returned, at customer's expense, to remove contamination and resubmit for service.

2. Use the original carton and packing material. It will provide maximum protection during shipping. (Shipping cartons may be purchased from Michigan Instruments, Inc.) **DO NOT USE THE CARRYING/STORAGE CASE AS A SHIPPING CONTAINER.** It is not designed to withstand rigorous handling during shipping. Returning the Case is not necessary unless it also requires repair. The Case should be packaged separately, if returned.

3. Return only those items that require service and specify the service requested on a packing list.

4. Place all components in plastic bags before putting them in the shipping container. This will keep dirt and other debris from entering the device through unprotected openings.

5. Include with the device:
   a. A description of the problem(s).
   b. The name and phone number of a contact person.
   c. A packing slip listing all of the components being returned and specify service requested. Cite RMA# on the packing slip as well.
   d. A purchase order, if appropriate.

6. Ship via your preferred carrier (FedEx, UPS, etc) PREPAID and insured to:

Michigan Instruments, Inc.
4717 Talon Court SE
Grand Rapids, MI 49512
Attention: Service Department RMA# XXXXX

Upon receipt the device will be evaluated and a repair estimate prepared for approval. Written approval and/or a purchase order are required before any repairs will be started. After approval is received a completion date will be established.

6.3.2 Additional Terms:

All non-warranty devices returned to Michigan Instruments, Inc. must be evaluated and require an evaluation fee plus return shipping charges. This fee will be charged ONLY if repairs are not authorized and the device must be returned unrepaired. We are obligated to label and tag as "unusable" any Life-Stat® CPR System that requires authorized factory service.

Michigan Instruments, Inc. reserves the right to install used/refurbished components that meet or exceed original manufacture specifications when performing repairs.

All repairs, parts and labor, are covered by a factory service warranty for 90 days. The warranty is subject to the same limitations and conditions of the original warranty. The factory service warranty applies only to those components repaired, rebuilt or replaced at time of service.

6.4 Warranty Repairs

Warranty repairs are subject to the same policies and procedures as regular repairs regarding shipping and notification.

The customer is not responsible for the evaluation fee, but is required to pay for shipping charges to the factory or repair facility.

THIS FACTORY SERVICE POLICY IS SUBJECT TO CHANGE WITHOUT NOTICE. CONTACT THE MICHIGAN INSTRUMENTS INC. CUSTOMER SERVICE DEPARTMENT FOR A COPY OF THE CURRENT FACTORY SERVICE POLICY.

(Blank Page Intentional)

GLOSSARY

TERMS USED IN MANUAL

ACLS Advanced Cardiac Life Support.

AED Automatic external defibrillator

AHA American Heart Association.

A-P Diameter Anterior-Posterior dimension of the chest. Thickness of chest over the sternum measured front to back.

CPR (Cardiopulmonary Resuscitation) Resuscitation, combining both artificial circulation of the blood and artificial breathing.

Cardiac Arrest Cessation of cardiac function with disappearance of arterial blood flow.

Clinical Death Condition where all external signs of death are present although the body cells may still be viable. Specifically, clinical death is manifested by:

1. Lack of breathing
2. Lack of pulse and heart sounds.

ECG (Electrocardiogram) A graphic tracing of the electrical current caused by contraction of the heart muscle.

EMS Emergency Medical Service

MOC Mobile Oxygen Carrier – a single or dual Oxygen tank carrier.

Pneumatic Operated by air pressure.

Protocol The timing and sequencing of the various steps of cardiopulmonary resuscitation. (Meaning as used in this Manual.)

Pulmonary Pertaining to the lungs.

Sternum The breastbone.

Therapy The treatment of disease.
Definitive Therapy--Treatments aimed at curing or removing the disease.
Supportive Therapy--Treatments aimed at maintaining or relieving the patient, which are not directly curative in nature.

Viable Capable of living.

Xiphoid Process The pointed process of cartilage, supported by a core of bone, connected to the lower end of the sternum.

(Blank Page Intentional)