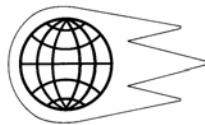


Thumper[®] Model 1007 Mechanical CPR System Operations Manual



Manufactured by:



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SECTION A

INTRODUCTION

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

INDICATION FOR USE

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

The most current version of the American Heart Association Guidelines does not recommend the use of mechanically performed CPR on infants and children.

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 Thumper[®] into your arrest management regimen of care.

INTRODUCTION

With the purchase of the Thumper[®] CPR System, you join thousands of other health care professionals worldwide who benefit from the many advantages of mechanical CPR. These benefits are well recognized by key professional groups. The Advanced Cardiac Life Support Manual published by the American Heart Association describes 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."

The Thumper[®] CPR system provides consistent, optimal CPR support for cardiac arrest patients even under conditions which may hinder the effectiveness of manual techniques. It is designed to perform in exact accordance with the AHA's Guidelines for CPR and Emergency Cardiac Care and will achieve these standards continuously and without tiring. The Thumper[®] provides advanced, definitive therapy to patients without the need to continuously perform manual CPR.

The Thumper[®] is currently in use worldwide with a variety of EMS and hospital applications. It can be found on all types of EMS vehicles including fire rescue vehicles, mobile trauma and ACLS units. The Thumper[®] is frequently used on both fixed and rotary wing rescue and transport aircraft because of the specific difficulties associated with performing CPR in the air. Hospital emergency departments, critical care and intensive care units also rely on mechanical CPR to assist them in their lifesaving efforts.

In all applications, the Thumper[®] provides proven advantages in resuscitation efforts. It allows all members of the emergency team better access to the patient, gives uninterrupted CPR support through all aspects of the code, and permits precise control over all parameters of CPR.

THE THUMPER[®] MODEL 1007 MANUAL

The purpose of the Operations Manual is to explain the use, care, and user maintenance of the Thumper[®] Model 1007, and not to teach cardiopulmonary resuscitation.

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

Keep the 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, located on the first page, can be used to find major headings and topics. For example, the Set Up and Operation section will guide a new user through the proper procedures for using the equipment. The Care, Cleaning, and Maintenance section can be used to plan an effective preventative maintenance program.

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

SECTION B

PRODUCT DESCRIPTIONS

THUMPER® CARDIOPULMONARY RESUSCITATOR

The Michigan Instruments, Inc. Thumper® Model 1007 is a portable, automatic cardiopulmonary resuscitation (CPR) medical device which has been in use since 1964. The present Thumper® Model 1007 is functionally the same as the previous models 1003, 1004, and 1005.

The 1007 model has been redesigned in appearance and form to be smaller, lighter, and conform directly with American Heart Association (AHA) CPR guidelines. The function of the Model 1007 remains identical to the previous models.

The Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care published in the Journal of the American Medical Association (JAMA) in 1992 describes automatic mechanical chest compressions as an aid to performing CPR. Advantages cited include:

- standardizes the technique of 5:1 compression-ventilation ratio;
- standardizes the 50% chest compression ratio;
- produces hemodynamics comparable to (proper) manual CPR;
- delivers optimal rate of compression and depth of compression;
- eliminates variables as (inadequate) rescuer technique and fatigue;
- Thumper® can remain on patient during defibrillation;
- trained rescuers are freed to participate in the delivery of ACLS when needed; and,
- assures adequacy of compressions and ventilation when a patient requires continued resuscitation during transportation.

GENERAL DESCRIPTION

The Thumper® Model 1007 system provides consistent CPR support for cardiac arrest patients under conditions, which might otherwise hinder the effectiveness of manual techniques. It performs external cardiac compression in conjunction with synchronized ventilation in conformance with AHA CPR guidelines.

The Thumper® Model 1007 is a mechanical “automatic” CPR device that can be set up in seconds. It is totally oxygen powered and electrically insulated, allowing it to be freely and safely used in conjunction with routine patient

monitoring and defibrillation procedures. The Thumper® Model 1007, once correctly applied over the patient's sternum, is designed to measure the patient's anterior-posterior (A-P) chest diameter and "prescribe" sternal deflection at 20% of that diameter.

Thumper® Model 1007 placements extend into all types of EMS and hospital applications. Fire-Rescue, Mobile ICU's, and fixed and rotary wing aircraft illustrate some of the EMS applications. Within the hospital, utilization of the Thumper® Model 1007 can be found in the Emergency Department, Coronary and Intensive Care Units, and Cardiac Catheterization Labs.

SUMMARY OF FEATURES AND BENEFITS

The new Thumper® Model 1007 CPR System offers a number of features not found in competitive products. The following table summarizes these features and their benefits.

Feature	Benefit
Fixed, Rigid Assembly	Consistent point on chest placement minimizes trauma from incorrect hand placement.
One piece design	Set up and ready for application in seconds.
Time-cycled, full volume ventilation	Maximum ventilation effectiveness, and easy detection of chest rise.
Only three controls	Ease of operation.
Compact, lightweight, and portable	Easily carried from vehicle to patient.
Timed, consistent compressions	Regular, repeatable performance.
Only one operator needed	In a moving vehicle, operator can sit with safety belt fastened while Thumper® performs CPR.
Totally oxygen powered	No battery to maintain or external power supplies to keep on hand.

Monitoring and defibrillation possible with Thumper® in place No need to remove Thumper® from patient

Very little maintenance required A cost effective device

THUMPER® COMPONENTS AND ACCESSORIES

The Thumper® Model 1007 consists of four major components:

- (1) the Thumper 1007 Backboard;
- (2) the Time Cycled Constant Flow Ventilator;
- (3) the Arm and Column Assembly, which includes all system components; and,
- (4) the Mobile Oxygen Carrier/appropriate O₂ wall access adapter.

A description of each component follows.

Backboard

The Thumper® Model 1007 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, with a slight hyper extension of the neck facilitated for upper airway management. Two separate sets of straps help immobilize the patient and secure the 1007 Board to a stretcher or spineboard. *Please see Figure 1 for display of Thumper® Model 1007 Board.*



Figure 1 - Thumper® Model 1007 Board.

Arm and Column Assembly

The arm and column assembly 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 drive the Thumper[®] for several seconds during an oxygen source change.

Time Cycled Constant Flow Ventilator

The Thumper[®] Model 1007 has a Patient Demand Valve (PDV) attached to the arm/column assembly and an associated tidal volume control (No. 3) which provides a fully integrated ventilator. This ventilator is an oxygen powered, time cycled, constant flow unit, intended for emergency and transport situations. The delivered tidal volume can be set from 400 ml to 1200 ml. The ventilation rate is preset to be synchronized with the Thumper[®] chest compressions to provide ventilation on every 5th upstroke. If the compressions are stopped, the ventilator rate remains fixed at 13 breaths per minute. The ventilator inspiratory to expiratory ratio (I/E ratio) is fixed at 1:2. It is pressure limited to 55 cm H₂O of airway pressure. *Please see Figure 2 for display of the Arm/Column Assembly, which also houses the ventilator.*



Figure 2 – Arm/Column Assembly

MOC/ Mobile Oxygen Carrier, or Appropriate Wall Access Adapter

The Thumper® Model 1007 is equipped with an oxygen input hose, used to connect the unit to a source of compressed medical oxygen. It incorporates an adapter on each end and a check valve to retain the oxygen during a source change. Wall adapters designed to allow access to the various and most common hospital (and ambulance) pipeline O₂ systems are available.

The Mobile Oxygen Carrier is a dual oxygen tank carrier, which provides constant pressure and high flow source gas for the Thumper® Model 1007 and up to two additional outlets. It is designed to operate the Thumper® Model 1007 whenever the unit is in use (for example, when transporting an arrest patient between an ambulance and a pipeline, wall accessed O₂ system within the hospital). One of the MOC's three outlets is designed to accept the Thumper® Model 1007 Oxygen Input Hose, while two outlets of O₂ connection configuration remain available to the rescuer to supply other devices. It will accommodate both "D" and "E" size tanks. *Please see Figure 3 for display of the Mobile Oxygen Carrier.*



Figure 3 – Mobile Oxygen Carrier (MOC)

The Carrying/Storage Case

Two different types of carrying/storage cases are available for the Thumper®. The “hard” case is constructed of an impact resistant plastic. The “soft” case is constructed of a durable Cordura® 1000 denier nylon. The Thumper® is stored in the case in a manner which permits immediate access to the unit and facilitates easy set up at an emergency site.

CONTROLS AND LABELING

The Thumper® Model 1007’s controls are conveniently located in one area to assist the user. *Please see Figure 4 for display of control label as seen on the Thumper® Model 1007.*

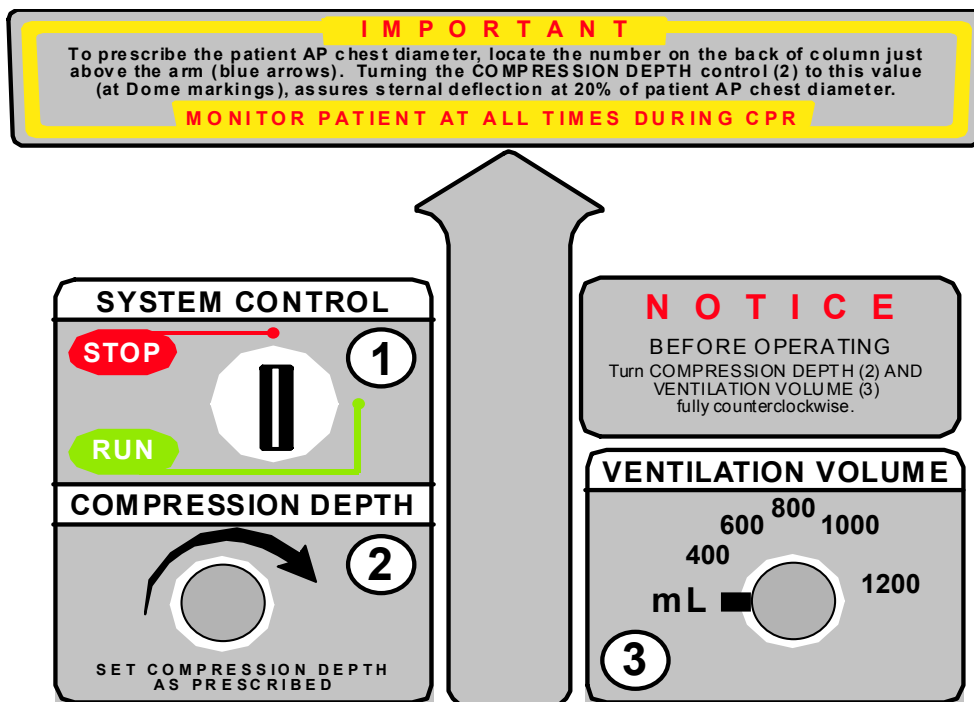


Figure 4 – Control Label

Control Layout: Once the system has been properly set-up and connected to an adequate (50 - 90 psi) compressed oxygen source, the user must then work with the following controls/labels to provide correct operation:

IMPORTANT - This is to remind the operator to find the correct patient AP chest diameter by locating the number on the back of the column just above the arm where the blue arrows are located. This assures sternal deflection at 20% of patient AP chest diameter. *Please see Figure 5 for display of this label.*

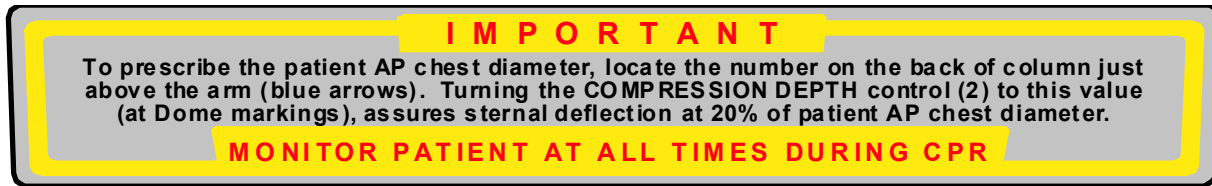


Figure 5 – IMPORTANT Label

NOTICE - Before Operating: This label advises the user to make certain that all controls are in the “STOP” or “decreased” (fully counter-clockwise) position

before connection of oxygen or placement on the patient. By validating the position of all controls prior to operation, the user is assured of proper operation of the Thumper® 1007 and patient safety. *Please see Figure 6 for display of this label.*



Figure 6 – NOTICE Label

The following controls operate the Thumper® Model 1007 System:

- 1. System Control RUN / STOP (No.1):** This control allows the operator to turn on (RUN) or turn off (STOP) the system. The system is controlled by moving the single switch into the desired position (RUN or STOP).

RUN: With the control in this position, the system is now operational and ready for use. Ventilation and compressions are available in the RUN position.

STOP: With the control in this position, chest compressions are disabled and not available. This control can also be turned to STOP during operation to stop the compression function. Ventilations are still available and operational in the STOP position. *Please see Figure 7 for display of this label.*

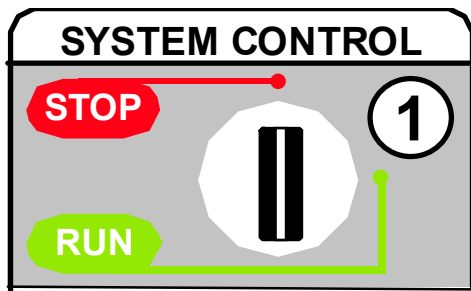


Figure 7 – Control No. 1

2. **COMPRESSION DEPTH (No. 2):** This rotational-knob is responsible for controlling the depth of compression on the patient. The depth of compression corresponds to the measured A-P (Anterior - Posterior) Diameter shown on the back of the column. The compression depth is increased with a “clockwise” rotation and decreased with a “counter-clockwise” rotation. *Please see Figure 8 for display of this label.*

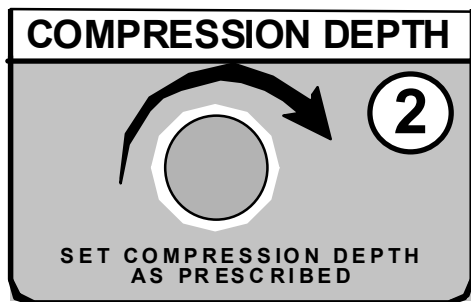


Figure 8 – Control No. 2

3. **VENTILATION VOLUME (No. 3):** This rotational-control is used to control the volume (ml) of oxygen that is delivered by the Thumper 1007 ventilator to the patient (400 to 1200 ml). The tidal volume is increased with a “clockwise” rotation of the control and decreased with a “counter-clockwise” rotation of the control. The scale for this control is marked in milliliters (ml) and incrementally spaced by 200 ml. *Please see Figure 9 for display of this label.*

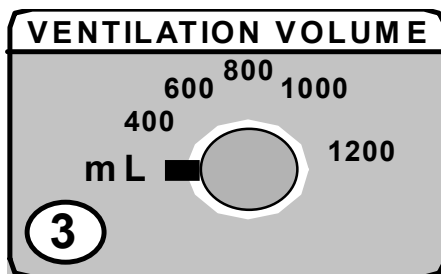


Figure 9 – Control No. 3

NOTES

SECTION C

SET UP AND OPERATION

Before setting up and using the Thumper[®], there are several important precautions that must be observed at all times.

1. The Thumper[®] 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 victim immediately. Do not postpone CPR while waiting for the Thumper[®]. The Thumper[®] can be easily set up and put into service without interrupting manual CPR delivery.
3. The Thumper[®] may be used in all cases 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 Thumper[®] operation in the unlikely event of a mechanical failure

Throughout the Set Up and Operation Section, it is assumed that two rescuers are available and the Thumper[®] is being used with the Thumper[®] Backboard (with straps) and the Mobile Oxygen Carrier.

NOTE: The Thumper[®] can also be used by a single rescuer at the scene of cardiac arrest because it is designed to be setup and put into operation very quickly. The conversion from manual to mechanical CPR should be done as soon as possible. With practice, this can be accomplished in a matter of seconds.

ADULT PATIENTS

Always begin manual CPR initially, utilizing the Thumper[®] Model 1007 Board or a spine board as patient support. Affix the Thumper[®] Model 1007 Board using the supplied strap to either the long spine board or to whatever firm surface will be

utilized prior to being placed upon a stretcher. Using the Thumper[®] Model 1007 Board will facilitate the rapid application and set-up of the Thumper[®] Model 1007 and, as would be with any spine board or firm surface, provide a firm support for the CPR effort.

1. “Log roll” the patient into position, taking care to keep the cervical spine immobilized, as one would when applying any spine board.
2. Center the patient onto the Thumper[®] Model 1007 Board by centering the patient’s shoulders across the uppermost part of the board.

When using the 1007 Board in cases of suspected C-spine injury always support the patient’s head in a neutral position.

3. With the patient now properly centered upon the Thumper[®] Model 1007 Board, affix the straps from over the shoulder and under the arm, buckling and then tightening the straps.

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. Begin manual CPR

Manual CPR should be started on the victim immediately. Do not postpone CPR while waiting for the Thumper.

THUMPER[®] MODEL 1007 DEPLOYMENT

1. Thumper[®] Model 1007 set-up:

- a. Remove the Thumper[®] Model 1007 assembly from the case.
- b. Attach the oxygen supply line from either the portable O₂ supply (dual O₂ system), or the wall outlet. If using the portable O₂ system, turn one of the two tanks to the ‘ON’ position.

- c. Connect the breathing hose and face mask (if the mask is to be utilized). Please see Figures 10a – 10c for suggested Thumper® set-up.



Figure 10a

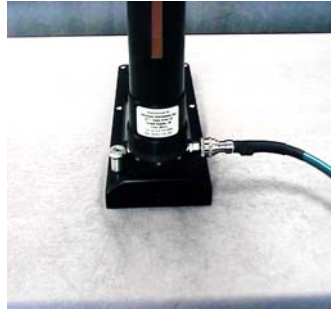


Figure 10b



Figure 10c

Figure 10a – Removal of Thumper® 1007 from case

Figure 10b – Connection of Oxygen to Thumper®

Figure 10c – Connection of breathing circuit to ventilator

Submersion of the Thumper® Model 1007 in fresh, ocean, or pool water will cause infiltration of water into internal critical parts, corrosion and eventual operational failure. This also applies to inadvertent injection of water, as from a “wet” oxygen cylinder.

Infiltration of sand or other foreign material into the Thumper® Model 1007 is likely to cause operational failure.

2. Thumper® Model 1007 application:

- a. When a pause for ventilation occurs during the manual CPR effort, grasp the Thumper® Model 1007 assembly, with one hand at the base of the column, and the other at the arm, close to the arm locking knob.
- b. Insert the base of the column into the mounting system on the Thumper® Model 1007 Board.

- c. With the Thumper® Model 1007 assembly now locked into place, loosen the arm locking knob and lower the arm over the chest, locating the massager pad over the sternum, as you would for the heel of your hand when performing manual CPR. *Please see Figures 11a – 11c for Thumper® application.*



Figure 11a



Figure 11b



Figure 11c

Figure 11a – Grasp Thumper® assembly with one hand at the base and the other hand at the column.

Figure 11b – Insert the base of the Thumper® into the board.

Figure 11c – Loosen the arm locking assembly and lower the arm over the chest until the top of the piston reads '0' on the dome.

BEFORE turning the Number One control to RUN, make certain the No. 2 and No. 3 Control Knobs are turned fully counter-clockwise.

3. Thumper® Model 1007 activation:

With the RUN/STOP in the 'STOP' position:

- a. Make sure No. 2 is rotated fully counterclockwise, and
- b. No. 3 is turned to 400 ml.
- c. Ensure the pressure indicator reads "green" indicating adequate O₂ pressure.
- d. Activate the Thumper® Model 1007 by first turning (No. 1) to RUN, and

- e. Rotate clockwise COMPRESSION DEPTH (No. 2) until sufficient compression depth is demonstrated by viewing the Piston at eye level. Increase the chest compression depth until the top of the Piston reaches the number on the Dome corresponding to the reading on the column.

With the Thumper[®] Model 1007 in use, care must be taken to prevent kinking or collapsing of the input hose by wheels of carts, or ambulance cots, or other mechanical interference.

The Thumper[®] Model 1007 is designed to operate on compressed medical grade oxygen, at an input pressure of 50-90 psi. Always verify proper input pressure as described herein, taking care to handle the oxygen cylinder and its' regulator assembly(ies) as you would for any other pneumatic medical device.

4. Thumper[®] Model 1007 Ventilator Activation:

- a. Next, rotate clockwise VENTILATION VOLUME, (No. 3), in accordance with AHA Guidelines, and/or local protocol, to desired ventilation level.
- b. Apply the breathing hose to the patient via mask or ET tube.
- c. The ventilator contains a Pressure Relief Valve that is set at 55 cmH₂O. When airway pressure exceeds 55 cmH₂O, an audible alarm will be heard from the ventilator. The user must monitor the patient airway and identify the cause for the increased pressure. Appropriate responses must then be taken.

During ventilation, the operator must maintain constant attention to observe the patient's chest rise and maintain an open airway.

If the maximum pressure limit is reached, the pre-set tidal volume may not be delivered to the patient. Inspiratory time will remain constant, however, and an inspiratory hold will be maintained with no additional volume being delivered until the ventilator cycles to the expiratory phase.

TO REMOVE THE THUMPER[®] FROM THE PATIENT:

- A. Turn Control #1 to STOP.
- B. Turn Control #2 fully counterclockwise.
- C. Turn Control #3 fully counterclockwise.
- D. Disconnect the O₂ Supply Hose first from the Thumper[®] O₂ 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 source end first may not allow the device to properly vent the internal pneumatic ports, possibly causing them to bind and not allow the device to cycle.

Note: Upon detaching the O₂ Supply Hose from the Thumper[®], an abrupt and loud release of oxygen from the Column buffer will occur. This is intentional and required to purge the Thumper[®] of its reserve oxygen and not to be interpreted as a leak.

- 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 Thumper[®] from the Backboard.
- H. Remove the Backboard from the patient.
- I. Clean and inspect the Thumper[®] per the recommended Shift Check (Daily or after each use).

Should the blue rubber diaphragm blow outward from the alarm module's air relief ports, discontinue the use of the Thumper® Model 1007 PDV / Breathing Hose Assembly. Contact Michigan Instruments, Inc. for service at 1-800-530-9939.

An audible pressure limit alarm is located in the Patient Valve Assembly. This alarm sounds whenever the patient airway pressure approaches the designed pressure limit of 55 cm H₂O. The Pressure Limit Alarm will continue to sound during the inspiratory phase until either the airway pressure decreases or the ventilator cycles off to begin the expiratory phase.

5. Procedure for periodic pulse checks and/or defibrillation:

To perform pulse checks, or to perform analysis with an AED (and/or defibrillate manually), simply turn the No. 1 control to the STOP position. This will only interrupt compression performance, while ventilation continues at 13 breaths per minute. To resume compressions, simply turn No. 1 to RUN.

The same depth of compression will continue.

When the Thumper® Model 1007 is used in conjunction with automatic external defibrillators (AED's), or other therapeutic devices which must utilize an ECG signal, interruption of the cardiac compressions as described herein may be required to avoid the ECG motion artifact associated with cardiac compressions.

The Thumper® Model 1007 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. It is advised operators should not touch the Thumper® Model 1007 during defibrillation.

TO REMOVE THE THUMPER[®] FROM THE PATIENT:

- A. Turn Control #1 to STOP.
- B. Turn Control #2 fully counterclockwise.
- C. Turn Control #3 fully counterclockwise.
- D. Disconnect the O₂ Supply Hose first from the Thumper[®] O₂ 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 source end first may not allow the device to properly vent the internal pneumatic ports, possibly causing them to bind and not allow the device to cycle.

Note: Upon detaching the O₂ Supply Hose from the Thumper[®], an abrupt and loud release of oxygen from the Column buffer will occur. This is intentional and required to purge the Thumper[®] of its reserve oxygen and not to be interpreted as a leak.

- 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 Thumper[®] from the Backboard.
- H. Remove the Backboard from the patient.
- I. Clean and inspect the Thumper[®] per the recommended Shift Check (Daily or after each use).

SECTION D

STORAGE AND SHIPPING

STORAGE

Careful storage of the Thumper[®] 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 unit or its accessories. We recommend that it be stored fully assembled in the Thumper[®] Carrying/ Storage Case.

For storage during normal transportation, the Thumper[®] Case offers maximum protection for the unit. It provides convenient storage for the basic components of the system and allows quick access to the Thumper[®] at an emergency site.

A Thumper[®] that is stored assembled should be placed on a “crash cart” or other surface where it will be used. The Arm should be positioned at the top of the Column and locked into place. Coil the Breathing Hose and Oxygen Input Hose on the base for easy access.

SHIPPING

If a Thumper must be shipped for any reason, a factory carton with protective foam inserts must be used. Replacement cartons are available from Michigan Instruments, Inc.

Do not ship the Thumper[®] CPR System in the Carrying/Storage Case! Shipping the Thumper[®] in any container other than the factory carton with foam inserts will void the warranty and may damage the unit!

SECTION E

CARE, CLEANING, AND MAINTENANCE

PERIODIC PREVENTATIVE MAINTENANCE

General Cleaning

Wipe all external surfaces of the Thumper[®] Model 1007 free of foreign material after each use. Refer to the Shift Check (Daily or after each use) check sheet for the proper procedure for cleaning / re-fitting after each use.

Clean the Patient Demand Valve (PDV) after each use. (Refer to the page titled “Cleaning and Disinfecting the Patient Valve Assembly”).

Always store the Thumper[®] Model 1007 in a clean, dry place. When not in use, a means is provided for storage of the Thumper[®] Model 1007 Board in, or on, the Thumper[®] Model 1007 Carry / Storage Case.

Preventive Maintenance

No calibrations or adjustments are required for routine use, however, the overall operating readiness of the system should be evaluated on a regular basis. Refer to the following with their appropriate check sheets, to determine how often you should perform equipment checks.

“Frequent” means use of the Thumper[®] Model 1007 more than once per week on average over a month period. “Infrequent” use means use of the Thumper[®] Model 1007 less than once per week on average, over a month.

Frequent Use of Thumper[®] Model 1007 (or after each use):

“Shift Check”, per attached check sheet (after each use or beginning of each shift)

“Functional Check” per attached check sheet (weekly on designated shift)

Infrequent use of Thumper[®] Model 1007:

“Shift Check”, per attached check sheet (after each use or beginning of each shift)

“Functional Check” (monthly), per attached check sheet.

Shift Check (Daily, or after each use)

Date: _____ Shift: _____ Location: _____ Serial Number: _____

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

	Acceptable as Found	Corrective Action/Remarks
1. Thumper Unit		
Clean, no spills, clear of objects on top, casing intact		
2. Hoses		
Inspect for cracks, cuts, damaged connectors		
3. Supplies		
a. Mask(s)		
b. Spare hose(s)		
c. Spare connectors		
4. MOC/O2 Input Hose		
a. Fully connected – readied		
b. Wall adapter on hand		
c. Tanks on full pressure/readied for use		
5. Indicators/Controls/Operation		
a. Attach O2 input/breathing hose		
b. Turn on (audible click), No. 1 “RUN” OK		
c. O2 input pressure OK		
d. No. 2 & 3 OK - knob tight and unbroken		
e. No. 2 & 3 moves smoothly		
f. Arm moves freely on column		
g. No. 2 adjusts freely		
h. No. 3 activates/adjusts		
i. Turn all controls off; remove/re-stow		
j. No visible abnormalities		
Major Problem(s) Identified (OUT OF SERVICE)		

Signature: _____

Functional Check (Weekly or Monthly)

Date: _____ Shift: _____ Location: _____ Serial Number: _____

Directions: Check unit every week when not frequently used. Indicate whether all requirements have been met. Note any corrective actions taken. Sign the form.

	Acceptable as Found	Corrective Action/Remarks
1. Thumper Unit		
Clean, no spills, clear of objects on top, casing intact		
2. Hoses		
Inspect for cracks, cuts, damaged connectors		
3. Indicators/Controls		
a. Attach O2 input/breathing hose		
b. Turn on No. 1		
c. O2 input pressure OK		
d. No. 2 & 3 OK - knob tight and unbroken		
e. No. 2 & 3 moves smoothly		
f. No visible abnormalities		
4. Thumper Operation		
a. Set up Thumper with mannequin onto board/stretcher		
b. Verify Arm moves freely on column		
c. Turn No. 1 to "RUN";		
d. Turn No. 2 clockwise to verify chest compressions are functioning		
5. Ventilator Operation		
a. Set no. 3 to 800 ml, (must adjust freely)		
b. Verify ventilator is operating		
c. Occlude outlet and verify audible alarm		
6. Prepare for Next Use		
a. Turn all controls off; remove/re-stow		
Major Problem(s) Identified (OUT OF SERVICE)		

Signature: _____

Cleaning and Disinfecting the Patient Valve Assembly

- 1) Remove the outlet adapter and exhalation valve assembly from the Patient Valve Assembly.
- 2) Clean all foreign matter from the components with a mild soap solution, being careful not to get any liquid inside the Patient Valve Assembly. Rinse the parts thoroughly in clean water.
- 3) Immerse the outlet adapter and the exhalation valve assembly from the Patient Valve in a disinfectant or bactericidal solution for a minimum of 10 minutes.
- 4) Remove the outlet adapter and the exhalation valve assembly from the solution and rinse thoroughly with water. Rinse repeatedly to assure that all the solution is removed.
- 5) Place the Patient Valve, outlet side down, into a shallow container with not more than ½ inch of disinfectant or bactericidal solution. The Patient Valve should remain in this solution for a minimum of 10 minutes. Leave tubing assembly connected.
- 6) Remove the Patient Valve from the solution and rinse thoroughly with water. Dry assembly using approved standard methods such as hot air drying.
- 7) After drying, carefully examine the parts of the Patient Valve Assembly. Discard any cracked or damaged parts and replace as necessary.
- 8) Prior to reassembling the entire unit, inspect all lines and tubing filters for contaminants, replacing as necessary.
- 9) Reconnect the tubing assembly to the fittings.
- 10) Check the exhalation valve assembly to assure the flapper valve is not twisted and the locating bosses are properly positioned.

If the flapper valve is twisted or the locating bosses are not properly positioned, the Patient Valve Assembly will not function properly. Always make sure the valve is flat and properly seated.

- 11) Immediately after cleaning, reassemble the Patient Valve Assembly and re-connect to the Thumper® Model 1007. Turn on the Thumper® Model 1007 and allow the ventilator to cycle several times to blow out any liquid which may have entered during the cleaning process.
- 12) Test the unit for proper function

Cleaning the Non- Rebreathing Valve:

Clean after each use. All components of the Non-Rebreathing Valve are autoclavable. To disassemble, unscrew the valve inlet from the outlet and remove the lip valve. The individual components can now be cleaned. If autoclaving systems are not available, you may also sterilize via Cidex or other bactericidal solution. Be sure to rinse and dry all parts thoroughly before reassembling. After cleaning, inspect all parts for damage or breakage. Replace any damaged or broken or broken parts. If disposable non-rebreathing valve is used, discard after each use.)

AVOIDING CONTAMINATION

Contamination can enter the system through the Oxygen Input Hose. When filling oxygen tanks, be certain that proper procedures are followed to prevent foreign matter from entering the tanks.

TROUBLESHOOTING - ROUTINE FUNCTIONAL CHECK

A complete functional check of the Thumper® should be made at regular intervals. The frequency will depend on specific circumstances and should be determined by the user. However, a functional check after each use and a monthly functional check using a CPR mannequin or a Test Spring (Michigan Instruments, Inc. P/N T106) is recommended.

TROUBLESHOOTING GUIDE:

Should the unit fail to operate properly at any time, refer to the Troubleshooting Guide below. Disconnect the patient from the ventilator 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
Unit fails to RUN	Inadequate O ₂ supply	Verify O ₂ supply is ON Verify proper input pressure
No compressions with increase of No. 2 control	Inadequate O ₂ supply	Verify O ₂ supply is ON Verify proper input pressure Verify No. 2 control setting Verify proper flow
Ventilations do not occur	Control Adjustment Breathing hose obstruction PDV needs cleaning Leak around face mask or patient valve tubing Decreased lung compliance Increase lung resistance Airway secretions	Verify No. 3 volume setting Check breathing hose Remove PDV and clean Check breathing circuit for leaks Evaluate patient and adjust Evaluate patient and adjust Clean patient airway

STERILIZATION GUIDELINES

Breathing Circuit Sterilization

The Breathing Hose, facemask, and NRV are disposable. These items are intended for single-use only.

The Pressure Relief Valve and Hose Adapter may be sterilized according to the following outline (as well as reusable type NRV's, if used):

1. Autoclaving: Items may be autoclaved or flash autoclaved at normal temperatures for this method of sterilization.
2. Gas Sterilization: Items may be gas sterilized in ethylene oxide, using temperatures recommended by the sterilizer manufacturer.
3. Chemical Disinfectants: Items may be sterilized using any standard colorless chemical sterilization compound recommended for plastics and rubber is satisfactory.

NOTE: Iodine disinfectants will stain these items, therefore, Cidex[®] is preferred.

NOTE: If an alternate, reusable breathing hose, NRV, or face mask is used in the Breathing Hose Assembly, follow the original manufacturer's recommended procedure for the cleaning and sterilization of these items.

Thumper[®] Sterilization

Standard colorless chemical disinfectant solutions may be used for "wipe down" of external surfaces.

The entire Thumper[®] unit may be gas sterilized using a normal sterilization cycle. Make sure that all control knobs on the Thumper[®] are in the ON position.

Following gas sterilization, aeration must take place for 24 hours, followed by one hour of operation on 50 psi oxygen. This may be reduced to 3 hours by using a forced aeration cabinet followed by 15 minutes of operation.

- Operating Environment: -20 °C to 55 °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)
 - Water resistance per IPX standard 14.2.3
 - Sealed piston shaft and bearing to disallow any contamination
- The 1007 will be comprised of parts assembled, manufactured, and purchased by Michigan Instruments Inc.
- Ergonomically easy to set-up and operate
 - Eliminated open ports to keep out any foreign contamination
 - Provided means of draining fluids that could build up inside the unit
 - The Thumper® can mount to either the right or left side of the patient
 - All internal components are mounted in the arm with covers attached
 - Provided handle to carry the Thumper® to the situation that it is needed
 - A lock is provided to position the arm on the column at various positions
 - The column is a buffer tank

If you have any questions about the Thumper® Model 1007, please call 1-800-530-9939.

SECTION F

MODEL 1007 THUMPER® CARDIOPULMONARY RESUSCITATOR WARRANTY AGREEMENT

Your CARDIOPULMONARY RESUSCITATOR (Model 1007) 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 its receipt by the end purchaser.

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. 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 damaging accidents.

This warranty is VOID unless the equipment to be repaired is returned in the original factory carton and protective foam. If necessary, the protective carton and foam may be obtained from the manufacturer.

If the attached warranty registration CARD IS NOT RETURNED, the warranty period will begin the DATE THE INSTRUMENT WAS SHIPPED FROM FACTORY.

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.

PURCHASE RECORDS

SERIAL NUMBER:

DATE OF RECEIPT:

PURCHASED FROM:

DATE WARRANTY CARD SENT:

FACTORY SERVICE POLICY

The Thumper® 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 preventative maintenance procedures are performed regularly. (See Section F.) In addition to the regular maintenance performed by the user, factory service and recalibration is recommended every five years.

What to do if your Thumper® CPR System requires service:

- A.** Refer to Section F in the Operation Manual. Many minor repairs and adjustments can be accomplished by following the instructions provided. Do not attempt repairs that are not outlined in the manuals. Many components are critical to the proper operation of the unit 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. Requests for repair parts or any service related questions should also be directed to the Service Department.
- C.** If your Thumper® CPR System must be returned to Michigan Instruments, Inc., please observe the following procedures:
 - 1. 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.

2. Place all components in plastic bags before putting them in the shipping container. This will keep dirt and other debris from entering the unit through unprotected openings.
3. Include with the unit:
 - a. A description of the problem(s), or,
 - b. A copy of the Problem/Failure Report.
 - c. The name and phone number of a contact person.
 - d. A packing slip listing all of the components being returned.
 - e. A purchase order, if appropriate.
4. Ship via United Parcel Service insured for \$4000 to:
Michigan Instruments, Inc.
4717 Talon Court SE
Grand Rapids, MI 49512

Attention: Service Department

UPS call tag service is available. Charges will be added to the repair invoice. Upon receipt the unit 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. This will normally be between two and four weeks depending on factory demands and the extent of the repairs.

- D. All units returned to Michigan Instruments, Inc. must be evaluated and require a \$50 evaluation fee plus shipping charges. This fee will be charged even if repairs are not authorized and the unit must be returned unrepared. Because of federal regulations pertaining to Class III medical devices, we are obligated to label and tag as "unusable" any Thumper[®] CPR System that requires authorized factory service.
- E. All repairs, parts and labor, are covered by this warranty for 90 days. New parts have a one-year warranty. These warranties are subject to limitations and conditions of the original warranty, and apply only to those components actually repaired, rebuilt, or replaced.
- F. A limited number of loaner units are available. Ask for details.

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.

Please fill out and return the attached Problem/Failure report whenever you return a unit, or call to notify Michigan Instruments, Inc. of your intent to return a unit for repair. This information will help speed up the repair procedure and get your Thumper[®] back to you as quickly as possible.

Any questions may be directed to the Michigan Instruments Inc. Service Department at (800) 530-9939.

Thumper® CPR System Problem/Failure Report

Please fill out and return this form whenever you return a unit to Michigan Instruments. This information will help speed up the repair procedure and get your Thumper back to you as soon as possible.

Any questions may be directed to the Michigan Instruments Service Department at (800)-530-9939.

Section 1

Unit Identification:

Model Number: _____ Serial Number* _____

*NOTE: This number is located on the column of the Thumper, just above the baseplate.

Section 2

Description of Problem:

Date of Problem/Failure: _____ Date of Report: _____

Describe in detail the specific problem/failure: _____

Was this problem/failure found during routine maintenance/functional check?

Yes _____ No _____

If no, when was problem found: _____

Section 3

Contact Information:

Name of individual present during problem/failure Title Telephone

Name of individual completing report Title Telephone

Organization Address

City State Zip Fax Number

SECTION G

GLOSSARY

TERMS USED IN MANUAL

ACLS Advanced Cardiac Life Support.

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.

Carotid Artery The principal artery located in the neck.

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

Cardiac Output Amount of blood, expressed in liters per minute, which is pumped by the heart through the ascending aorta.

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.

Diastole The period of dilation of the ventricles of the heart; also, the dilation itself. It is the period in which the ventricles fill with blood from the atria.

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

EMS Emergency Medical Service

Endotracheal Intubation Placement of a semi-rigid tube through the glottis and into the trachea to insure patency of the upper airway and facilitate mechanical support of ventilation.

EOA (Esophageal Obturator Airway) Means of occluding the esophagus and forcing high flow oxygen by default through the oropharynx into the trachea and lungs.

External Defibrillation The stopping of fibrillation of the heart by externally applied electric shock.

Hypothermia Subnormal body temperature. If below 30½°C (86½°F), condition is called "deep hypothermia".

MOC Mobile Oxygen Carrier - a dual oxygen tank carrier manufactured by Michigan Instruments, Inc.

Non-rebreathing Valve (NRV) One way valve, which prevents the breathing of exhaled gas.

Palpable Perceptible by touch.

Patency The condition of being fully open.

Pneumatic Operated by air pressure.

Pressure Relief Valve (PRV) A safety valve in the patient breathing circuit, which prevents excessive airway pressures.

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

Pulmonary Pertaining to the lungs.

Saline A solution containing salt or salts.

Sternum The breastbone.

Systole The period of contraction of the ventricles of the heart; also, the contraction itself. During this period blood is expelled from the ventricles of the heart.