Thumper® Model 1007*CCV*Mechanical CPR System Operation Manual

(Part Number 14799-02)



Manufactured in the USA by:



PROTECTED UNDER ONE
OR MORE OF THE
FOLLOWING U.S. PATENTS:
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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 <u>adult patients only</u> in cases of clinical death as defined by a lack of spontaneous breathing and pulse.

Warning: The Thumper® is to be used solely for the purpose of delivering mechanical cardiopulmonary resuscitation (CPR) in accordance with established American Heart Association (AHA) guidelines for manual CPR. 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.

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 cardiac arrest management regimen of care.

Caution: Current American Heart Association guidelines do not recommend the use of mechanical CPR on infants and 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.

BENEFITS OF MECHANICAL CPR

With the purchase of the Thumper® CPR System, you join thousands of health care professionals worldwide who benefit from the many advantages of mechanical CPR. These benefits are well recognized by key professional groups. The <u>Advanced Cardiac Life Support Manual</u> 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."

THE THUMPER® MODEL 1007CCV OPERATION MANUAL

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

Proper use of the Thumper[®] 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 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 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 Maintenance section can be used to plan an effective preventive maintenance program.

USE OF WARNINGS, CAUTIONS AND NOTES

As used in this Operation 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.

GENERAL WARNINGS AND CAUTIONS

Warning: Improper application of this equipment can cause serious injury. This Operation 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 by 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 Maintenance section of this manual.

Caution: Submersion of the Thumper[®] Arm 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.

Caution: Infiltration of sand or other foreign material into the Thumper[®] may cause operational failure.

Caution: When carrying the Thumper® 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.

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SECTION B PRODUCT DESCRIPTION

THUMPER® CARDIOPULMONARY RESUSCITATOR

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

GENERAL DESCRIPTION

The Thumper[®] Model 1007*CCV* system provides consistent CPR support for cardiac arrest patients under conditions, which might otherwise hinder the effectiveness of manual techniques. The Thumper[®] Model 1007*CCV* performs two modes of CPR support in conformance with AHA CPR guidelines. One mode will perform external cardiac compression continuously (Vent Mode OFF). The other mode will perform external cardiac compression with synchronized ventilation delivered at a 5:1 ratio respectively (Vent Mode ON). A toggle switch on the control panel allows 'on demand' selection of either mode without interruption of CPR support.

The Thumper[®] Model 1007*CCV* is a mechanical "automatic" CPR device that can be set up in seconds. It is powered by compressed oxygen and is electrically insulated, allowing it to be freely and safely used in conjunction with routine patient monitoring and defibrillation procedures. The Thumper[®] Model 1007*CCV*, 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.

THUMPER® SYSTEM COMPONENTS AND ACCESSORIES

The Thumper® Model 1007*CCV* consists of four major components:

- (1) The Thumper® Model 1007CCV Arm/Column/Base Assembly
- (2) The Time Cycled Constant Flow Ventilator
- (3) The Thumper® Model 1007 Backboard
- (4) The Mobile Oxygen Carrier / appropriate O2 wall access adapter

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

A description of each component follows.

Thumper® Model 1007CCV Arm/Column/Base Assembly

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 drive the Thumper® for several compressions during an oxygen source change.

Time Cycled Constant Flow Ventilator

The Thumper[®] Model 1007*CCV* incorporates an oxygen powered time cycled constant flow ventilator commonly known as a Patient Demand Valve (PDV) to deliver ventilation. Tidal volume can be set from 400ml to 1200ml with delivery synchronized to every 5th chest compression upstroke. With compressions stopped, the ventilator delivers a fixed rate of 13 breaths per minute. The inspiratory to expiratory ratio (I/E ratio) is fixed at 1:2 and limited to 55cm H₂O of airway pressure. The PDV operates only when the device is in Vent Mode ON.

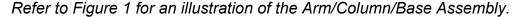




Figure 1 – Thumper® Model 1007CCV Arm/Column/Base Assembly

Thumper® Model 1007 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, and a slight hyperextension of the neck to facilitate upper airway management. It allows use of the Thumper[®] on either right or left side of patient. Two separate sets of straps help immobilize the patient and secure the Backboard to a stretcher or spine board.

Note: Optimal Thumper® CPR performance requires using the Backboard.

Refer to Figure 2 for an illustration of the Thumper® Model 1007 Backboard.

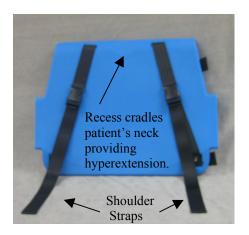




Figure 2 – Thumper® Model 1007 Backboard.

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

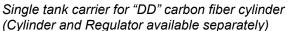
The Thumper[®] Model 1007CCV is equipped with an O_2 Supply Hose used to connect the device to a source of compressed medical oxygen. It incorporates couplers on each end and a check valve to retain the oxygen during a source change. Wall adapters are available that connect to the O_2 Supply Hose to 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 Thumper[®] Model 1007*CCV* and an additional DISS outlet. It is designed to power the Thumper[®] Model 1007*CCV* 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 Thumper[®] Model 1007*CCV* O₂ Supply Hose, while the other DISS outlet is available to supply other oxygen driven devices. MOC regulator(s) are preset to satisfy Thumper[®] requirements.

A single tank version is available that will accept a "DD" size carbon fiber cylinder. A dual tank version is available in two sizes that accept either "D" or "E" size aluminum cylinders.

Refer to Figure 3 for an illustration of the Mobile Oxygen Carriers available.







Dual tank carrier for "D" or "E" aluminum cylinders (Cylinders available separately)

Figure 3 – Mobile Oxygen Carriers (MOC)

The Carrying/Storage Case

The carrying/storage case is constructed of a durable Cordura 1000 denier nylon. The Thumper $^{\text{®}}$, Backboard, 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.

Refer to Figure 4 for an illustration of the Carrying/Storage Case.

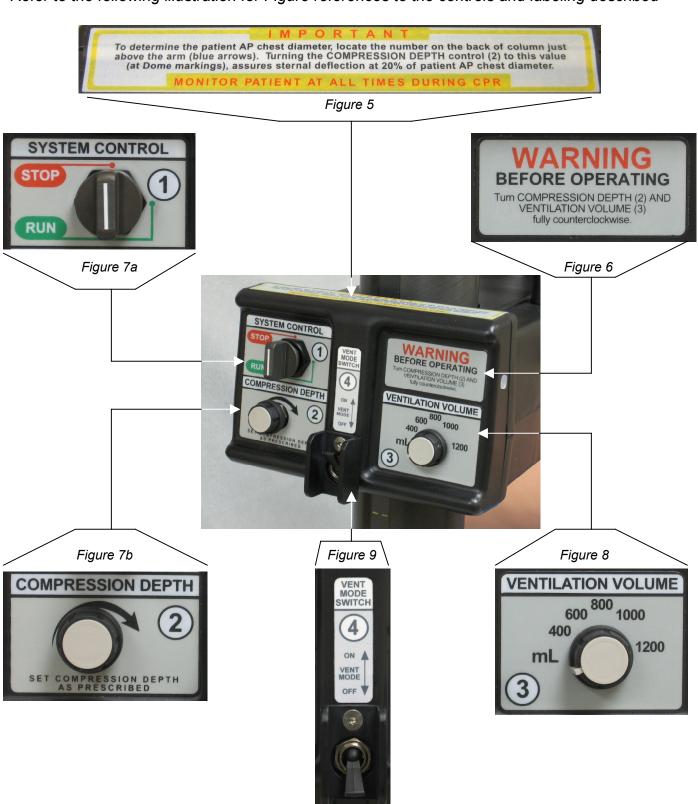


Figure 4 – Carrying/Storage Case

CONTROLS AND LABELING

The Thumper[®] Model 1007*CCV*'s controls are conveniently located in one area to assist the user.

Refer to the following illustration for Figure references to the controls and labeling described



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 -- The correct patient A-P chest diameter is determined by locating the number on the back of the Column just above the Arm where the blue arrows are located. Set the compression depth indicator number on the Dome to match the A-P diameter number indicated on the Column. This label also serves to remind the operator to monitor the patient at all times during CPR.

Refer to Figure 5 for an illustration of this label.

WARNING / BEFORE OPERATING -- Ensure that all controls are in the "STOP" or "decreased" (fully counterclockwise) position before connection of oxygen or placement on the patient. By verifying the position of all controls prior to operation, the user is assured of proper operation.

Refer to Figure 6 for an illustration of this label.

The following controls operate the Thumper[®] Model 1007*CCV* System:

1. SYSTEM CONTROL RUN/STOP (Control #1): This control allows the operator to turn on (RUN) chest compressions or turn off (STOP) chest compressions. The system is controlled by pressing in and rotating the switch to the desired position (RUN or STOP).

RUN: With the control in this position, the system will deliver chest compressions to the depth set by COMPRESSION DEPTH (Control #2).

STOP: With the control in this position, chest compressions are suspended and not delivered. In the STOP position, chest compressions can be suspended to assist in patient monitoring. Ventilations are still available and operational in the STOP position.

Refer to Figure 7a for an illustration of this control.

Note: The compression timing circuit cycles whenever oxygen pressure is applied, even when the System Control is in the STOP position. This cycling can be detected as an audible clicking sound emanating from the Thumper[®].

2. COMPRESSION DEPTH (Control #2): This control is used for setting the depth of compression on the patient. The depth of compression corresponds to the measured A-P (Anterior - Posterior) Diameter shown on the scale located on the back of the Column. The compression depth is increased with a clockwise rotation and decreased with a counterclockwise rotation.

Refer to Figure 7b for an illustration of this control.

3. VENTILATION VOLUME (Control #3): This control adjusts the tidal volume (400 - 1200ml) of oxygen delivered to the patient by the PDV. The tidal volume is increased with a clockwise rotation and decreased with a counterclockwise rotation. The scale is in milliliters (ml) from 400 to 1200 in 200ml increments. With the control in the fully counterclockwise position, no tidal volume is delivered.

Refer to Figure 8 for an illustration of this control.

4. VENT MODE SWITCH (Control #4): This toggle switch selects the ventilation mode of the Thumper[®] Model 1007*CCV* (ON or OFF). The arrows on the label indicate the switch position for the desired mode. With the switch in the "up" or ON position, ventilation is delivered after every five compression cycles. With the switch in the "down" or OFF position, no ventilations are delivered.

ON: With the switch in this position, the ventilator (PDV) is activated and will deliver tidal volumes set by the VENTILATION VOLUME (Control #3) on the upstroke of every fifth compression.

OFF: With the switch in this position, the ventilator (PDV) is inactive allowing the device to deliver continuous compressions.

Refer to Figure 9 for an illustration of this switch.

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SECTION C SETUP 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 applied to the patient without interrupting manual CPR efforts.
- **3.** The Thumper[®] 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 Thumper[®] operation in the unlikely event of a mechanical failure. Should a failure occur that prevents the device from performing mechanical CPR, it is recommended to remove the device from the patient and re-apply manual CPR to the patient.
- **5.** When transporting the patient with the Thumper[®] in operation, ensure the Backboard is secured tightly to the stretcher or transport device using the cot straps provided underneath the Backboard. Failure to do so can allow the Thumper[®] and Backboard to shift position on the patient possibly causing the Massager Pad to wander off the patient's sternum.

THUMPER® BACKBOARD POSITIONING UNDER PATIENT

- 1. Remove the Backboard from the case. "Log roll" the patient into position, taking care to keep the cervical spine immobilized, as one would when applying any spine board.
- 2. Position the patient onto the Backboard by centering their shoulders across the widest part of the board, cradling the patient's neck in the recess to provide hyperextension.

Warning: When using the Backboard in cases of suspected C-spine injury, always support the patient's head in a neutral position.

3. With the patient now properly centered on the Backboard, affix the retaining straps from over the shoulder and under the arm of patient, then buckle and tighten the straps securely.

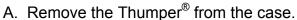
Warning: Do not place retention straps or other restraints over the patient's abdominal area. Tight garments around the abdomen should be removed or loosened.

4. Begin manual CPR on the victim immediately. Do not postpone CPR while waiting for Thumper[®] deployment and application to the patient.

THUMPER® MODEL 1007CCV DEPLOYMENT

1. Thumper® Model 1007CCV Setup:







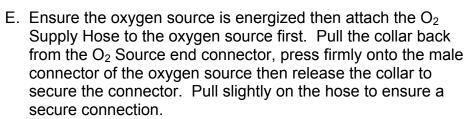
B. Ensure the RUN/STOP switch (Control #1) is set to STOP and the Compression Depth (Control #2) is turned fully counterclockwise.



C. Ensure the Ventilation Volume (Control #3) is turned fully counterclockwise.



 D. Choose the mode of operation by moving the Vent Mode Switch (Control #4) to the desired position (ON or OFF).
 If ON is chosen attach the Breathing Hose/Non Rebreathing Valve (and face mask, if used) to the PDV.





F. Attach the opposite end of the hose to the Thumper[®] O₂ Supply Connector by inserting the hose connector while slightly turning it at the same time to align the hexagons then press firmly to attach. Pull slightly on hose to ensure a secure connection. Do not press the release button while attaching the connector. Only press the release button to disconnect the connector.



G. Listen for audible clicks (cycling) and verify that the green Pressure Indicator shows an adequate input pressure is available.



Caution: The Thumper[®] requires an oxygen source with an inlet pressure of 50 to 90 psi, and a minimum flow rate of at least 45 LPM.

2. Thumper® Model 1007CCV Application to the Patient:

A. Before inserting the Thumper[®] into the Backboard, ensure the Arm is raised high enough on the Column to clear the patient's chest. When a pause occurs during the manual CPR effort, grasp the Thumper[®] with one hand at the Base of the Column, and the other by the Handle.



B. Insert the Base into the side slot of the Backboard on whichever side of the patient is most convenient. Slide the Base into the Backboard until the Massager Pad is centered over the patient's sternum.



C. With the Thumper[®] now located in the correct position, loosen the Arm Lock Lever 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. 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.

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

Warning: Do NOT use the Thumper[®] if the blue arrows indicate in the red area of the scale.



3. Thumper® Model 1007CCV Activation:

Warning: Failure to ensure that Control #2 COMPRESSION DEPTH is turned fully counterclockwise upon initial application to the patient and prior to turning Control #1 RUN/STOP to the RUN position will deliver compressions to the patient at the depth last set by Control #2. This depth may not be the correct A-P Diameter for that patient and could possibly cause serious injury or death to the patient.

Warning: Failure to ensure that Control #3 VENTILATION VOLUME is turned fully counterclockwise upon initial application to the patient and prior to turning Control #1 RUN/STOP to the RUN position will deliver ventilations to the patient (if the breathing hose is attached) at the tidal volume last set by Control #3. This setting may not be correct for that patient and could deliver either excessive or insufficient tidal volumes to the patient.

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

- A. Ensure Control #2 and Control #3 are rotated fully counterclockwise and the Pressure Indicator at the top of the Column shows "green" indicating adequate O₂ pressure.
- B. Choose the ventilation mode desired by setting Control #4 to the desired position (OFF for continuous compression, ON for compressions with ventilation). If ON is chosen, initially turn Control #3 to 400ml.
- C. Activate the Thumper® Model 1007CCV by first turning the RUN/STOP Control #1 to RUN.
- D. Rotate COMPRESSION DEPTH Control #2 slowly clockwise until sufficient compression depth is demonstrated by viewing the Piston at eye level. Increase the control 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 (Control #2) is set too deep or inadvertently bumped.

Warning: Patient chest compressions may be insufficient if Compression Depth (Control #2) is set too shallow or inadvertently bumped.

Warning: With the Thumper[®] Model 1007*CCV* in use, care must be taken to prevent kinking or collapsing of the O₂ Supply Hose by wheels of carts, or ambulance gurneys.

Caution: The Thumper[®] Model 1007*CCV* 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 as you would for any other oxygen driven device.

4. Thumper® Model 1007CCV Ventilator (PDV) Activation: (if applicable)

- A. Move the VENT MODE SWITCH (Control #4) to the ON position (if not already selected).
- B. Rotate the VENTILATION VOLUME (Control #3) clockwise in accordance with AHA guidelines, and/or local protocol to desired ventilation level.
- C. Apply the Breathing Hose/Non Re-breathing Valve to the patient via mask or ET tube.
- D. The ventilator contains a Pressure Limit Alarm that will sound an audible alarm when the airway pressure exceeds 55cm H₂O. 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 observe patient chest rise and maintain an open airway to ensure the patient is properly ventilated.

Warning: Excessive ventilation may be delivered to the patient if Ventilation Volume (Control #3) is set too high or inadvertently bumped.

Warning: Patient ventilation may be insufficient if Ventilation Volume (Control #3) is set too low or inadvertently bumped.

Warning: Should the blue rubber diaphragm blow outward from the Pressure Limit Alarm's relief ports, discontinue the use of the Thumper[®] Model 1007*CCV* PDV / Breathing Hose Assembly. 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 pre-set tidal volume may not be delivered to the patient. Inspiratory time will remain constant and an inspiratory hold will be maintained with no additional volume being delivered until the ventilator cycles to the expiratory phase.

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 $55 \text{cm H}_2\text{O}$. 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 to Interrupt (Suspend) Compressions:

To perform pulse checks or perform analysis with an AED (and/or defibrillate manually), simply turn Control #1 to the STOP position. This will interrupt compressions. If the Vent Mode Switch Control #4 is set to ON, ventilations continue at 13 breaths per minute. To resume compressions turn Control #1 to RUN. The same depth of compression previously set by Compression Depth Control #2 will be delivered. If stopping the delivery of ventilations is desired temporarily, simply set the Vent Mode Switch to the OFF position. To resume ventilations, set the Vent Mode Switch back to the ON position. Ventilations will resume at the tidal volume set by Ventilation Volume Control #3.

Caution: When the Thumper® Model 1007CCV 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*CCV* 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[®] during defibrillation.

Warning: Operators should not touch the Thumper® 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. Turn Control #4 to the OFF position.
- E. Disconnect the O_2 Supply Hose first from the Thumper $^{\tiny{\textcircled{\$}}}$ 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 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 O_2 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.

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

Warning: The Breathing Hose (PN 14669)/Non Re-breathing Valve (PN 14384) supplied with the device is intended for single use only. Re-use of these items could cause cross contamination and is strongly discouraged.

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

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

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 device or its accessories. It is recommended it be stored fully assembled in the Carrying/Storage Case.

For storage during normal transportation, the Carrying/Storage Case offers maximum protection for the device. 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/Non Re-breathing Valve and O₂ Supply Hose on the Base for easy access.

SHIPPING

If the Thumper[®] 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 Thumper® 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.

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SECTION E CARE, CLEANING AND MAINTENANCE

General Care

Always store the Thumper[®] Model 1007*CCV* in a clean, dry place. When not in use, storage is provided for the Thumper[®] and Backboard in the Carrying/Storage Case.

Avoiding Contamination

Contamination can enter the system through the O₂ 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.

General Cleaning

Wipe all external surfaces of the Thumper[®], O₂ 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, if applicable. Clean the Patient Demand Valve (PDV) after each use per the Cleaning and Disinfecting the Patient Demand Valve section below.

Disinfection Guidelines

Standard colorless chemical disinfectant solutions may be used to "wipe down" external surfaces of the Thumper® device, O₂ 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 Thumper[®].

Caution: Do not spray cleaning or disinfecting solutions directly on the Thumper[®]. Dampen a clean cloth with the solution and use that to wipe down external surfaces.

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 cleaning 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 are not easily accessed for cleaning/disinfecting, return for factory service citing contaminated PDV as the reason for return. The PDV will be cleaned/disinfected or replaced depending on the severity of the contamination. Using a contaminated PDV may cross contaminate the patient.

- 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. Check the Lip Valve to assure the flapper is not twisted. Properly align the locating bosses and set the Lip Valve inside the Pressure Limit Alarm. Install the Hose Adaptor on the Pressure Limit Alarm and tighten snugly.

Caution: If the flapper of the Lip Valve is twisted or the locating bosses are not properly positioned, the PDV will not function properly. Always ensure the Lip Valve is flat and properly seated.

G. After cleaning/disinfecting the PDV, it is recommended to verify its operation. Turn Control #1 to STOP, Control #2 and Control #3 fully counterclockwise. Turn Control #4 to the ON position. Attach the O₂ Supply Hose to an energized oxygen source first then connect the opposite end to the Thumper®. With the device cycling, turn Control #1 to RUN and Control #3 to 1200ml. 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. Turn Control #3 down to 600ml and attach a Breathing Hose/Non Re-breathing Valve to the Hose Adaptor of the PDV. During a ventilation cycle, verify oxygen is delivered out of the Non Re-breathing Valve and the Lip Valve is operating properly. Next, plug the end of the Non Re-breathing Valve to simulate a patient. During a ventilation cycle, turn Control #3 to 1200ml. The Pressure Limit Alarm should sound indicating it is operating properly.

- H. Remove the Breathing Hose/Non Re-breathing Valve from the PDV. Turn Control #3 fully counterclockwise, Control #1 to STOP and Control #4 to OFF. Disconnect the O₂ 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.

Cleaning the Non Re-breathing Valve

Note: The Non Re-breathing Valve typically supplied with the device is intended for single use only. If a Non Re-breathing Valve is used that is not intended for single use, follow the instructions below for cleaning/disinfecting (or follow manufacturer's recommended procedure).

To disassemble, unscrew the adaptor from the housing and remove the lip valve. The individual components can now be cleaned. If an autoclave is unavailable, sterilize using Cidex or other bactericidal solution. Be sure to rinse and dry all parts thoroughly before reassembling. Inspect all parts for damage or breakage and replace if needed. Place the lip valve into the adaptor ensuring the lip points to the outlet of the adaptor (patient side). Attach the housing and secure snugly. Ensure the lip valve is setting flat, the lip is extended into the adaptor and the lips are closed.

Mobile Oxygen Carriers (MOC)

- Should you require maintenance of the regulator(s) employed in the MOCs, it is advised to contact the vendor of the regulator to arrange for service. This 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 Thumper[®]. 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.

Periodic Preventive Maintenance

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

Note: There are no user serviceable parts inside the Thumper[®] CPR system 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 Thumper[®]. (See procedure below.)
- 3. **Factory service** A recalibration and routine maintenance of internal components performed at the manufacturer by factory trained personnel.

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

Thumper [®] Use	Shift Check	Functional Check	Factory Service
Heavy use: > 2 times per week	After each use	Monthly	Every three years
Frequent use: 6 - 10 times per month	After each use	Quarterly	Every four years
Infrequent use: < 6 times per month	After each use	Semi annually	Every five years

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.

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.
- 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 (PN 14769-01 Cot, 14769-02 Shoulder) on the Backboard when they show signs of wear or fraying. Otherwise, the ability to adequately secure the system to the patient and/or transport mechanism will be jeopardized.

Caution: Replace the Backboard (PN 14790-01) if the formed plastic becomes cracked or broken. Otherwise, patient support during CPR or the ability to properly apply the Thumper® to the patient may be jeopardized.

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

Caution: Thumper® CPR performance may be jeopardized if the device is operated with worn, loose, or damaged parts.

B. Set up for operation

(Ensure Control#1 is set to STOP, Controls #2 and #3 are fully ccw and Control #4 is OFF before continuing)

- 4. Loosen the Arm Lock Lever and check that the Arm moves freely on the Column. Raise Arm to bring the blue arrows to the 6 position and tighten the Arm Lock Lever.
- 5. Inspect the O₂ Supply Hose for kinks, cracks, cuts, worn hose or damaged connectors. Connect the O₂ Supply Hose to the oxygen source first then connect it to the Thumper[®].
- 6. Verify that the device cycles when the O₂ Supply Hose is connected and the green Pressure Indicator at the top of the Column is functional.
- 7. Attach a Breathing Hose/Non Re-breathing Valve to the PDV. Turn Control #4 to the ON position and Control #3 to 600ml. Verify that ventilation is delivered. Block the end of the Non Re-breathing Valve and turn Control #3 to 1200ml. Verify that the Pressure Limit Alarm sounds on the next ventilation.
- 8. Turn Control #4 to OFF. Allow the device to cycle for 20 seconds and verify that no ventilation is delivered. Turn Control #3 fully counterclockwise and remove the Breathing Hose/Non Re-breathing Valve. Ensure Control #3 turns smoothly and is not loose.
- 9. Remove the O₂ Supply Hose from the Thumper[®] first, then from the oxygen source.
- 10. With the O₂ Supply Hose disconnected, verify that the Run/Stop Control #1 engages, rotates, and releases smoothly and the Compression Depth Control #2 turns smoothly and is not loose.

C. Prepare device for next use

- 11. Turn Control #1 to the STOP position, Control #2 and Control #3 fully counterclockwise. Turn Control #4 to OFF.
- 12. Check that all accessories and supplies are available: O₂ Supply Hose, Breathing Hoses/Non Re-breathing Valves, Backboard, etc.
- 13. Ensure oxygen cylinder(s) in the MOC have an adequate oxygen supply.
- 14. Place the Thumper[®], O₂ Supply Hose, Breathing Hoses/Non Re-breathing valves and Backboard into the Carrying/Storage Case.

Shift Check of Thumper® Model 1007CCV (Daily, or after each use)

Directions: (see procedure above). At the beginning of each shift, inspect the device. Indicate whethe all requirements have been met. Note any corrective actions taken. Sign the form.			
Acceptable as Found	Corrective Action/Remarks		
Yes / No			
	Acceptable as Found		

REV: 07/06 32

Signature:

Functional Check

Procedure:

A. Visual and Mechanical Inspection

1. Appearance (Check the general 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 Thumper[®] 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 O₂ 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 base release latch located on the Base 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 device into both sides of the Backboard ensuring smooth insertion and removal.

4. Ventilation/Compression test

(Ensure Control#1 is set to STOP, Controls#2 & #3 are fully ccw and Control #4 is OFF before continuing) Set up the Thumper® 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 O₂ Supply Hose to the oxygen source first.

- b. Check the operation of the O₂ Supply Hose by connecting and disconnecting the Thumper[®] end of the supply hose a few times. The connector should attach and release smoothly.
- c. Verify that the device cycles when the O₂ Supply Hose is connected and 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 #4 to the ON position and Control #3 to 600ml. Verify that ventilation is delivered. Block the end of the Non Re-breathing Valve and turn Control #3 to 1200ml. Verify that the Pressure Limit Alarm sounds on the next ventilation.
- e. Turn Control #4 to OFF. Allow the device to cycle for 20 seconds and verify that no ventilation is delivered. Turn Control #3 fully counterclockwise and remove the Breathing Hose/Non Re-breathing Valve. Ensure Control #3 turns smoothly and is not loose.

Turn the Control #1 to "Run" to activate the chest compressor.

f. Ensure the Run/Stop Control operates smoothly.

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 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 that the Piston does not exceed "5" nor should it register less than "3½".

B. Prepare device for next use

- 1. Turn Control #1 to the STOP position, Controls #2 & #3 fully counterclockwise and Control #4 OFF.
- 2. Remove the O₂ Supply Hose from the Thumper® first then from the oxygen source.
- 3. Check that all accessories and supplies are available: O₂ Supply Hose, Breathing Hoses/Non Re-breathing Valves, Backboard, etc.
- 4. Ensure oxygen cylinder(s) in the MOC have an adequate oxygen supply.
- 5. Place the Thumper[®], O₂ Supply Hose, Breathing Hoses/Non Re-breathing Valves and Backboard into the Carrying/Storage Case.

Functional Check of Thumper Model 1	007CCV (Weekly, mont	thly, or per determined schedule
Date:// Shift: L	_ocation:	Serial Number:
Directions: (see procedure above). Per the determir requirements have been met. Note any corrective ac	, ·	e. Indicate whether all

Requirement	Acceptable as Found	Corrective Action/Remarks
A Manual and Manhanisal Income Airco	as Found	
A. Visual and Mechanical Inspection		_
1. Appearance		
a. Thumper® is clean and free of contaminants		
Backboard " " " " " " " " " " " " " " " " " " "		
MOC/related adaptors " " " " "		
b. Thumper® has no worn. loose or damaged parts Backboard " " " " " "		
O ₂ Supply Hose " " " " " "		
MOC/related adaptors " " " " " "		
c. Thumper® 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. Base travels in/out smoothly in both Backboard slots		
Ventilation/Compression test		
a. Piston reads "-" and Arm Lock Lever secures Arm in place		_
b. O ₂ Supply Hose connects and disconnects easily		
c. Device cycles and Pressure Indicator shows green		
d. Ventilation delivered at 600ml		
Pressure Limit Alarm activates		
e. No ventilation with Vent Mode OFF		
Control #3 rotates and secure		
f. Run/Stop Control operates smoothly		
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 at STOP Controls#2 & #3 fully ccw. Control #4 OFF		
2. O ₂ Supply Hose disconnects properly		
3. Accessories and supplies inventory:		
Thumper® device		
O ₂ Supply Hose		
Breathing Hoses/Non Re-breathing Valves		
Backboard		
Carrying/Storage Case		
MOC/related adaptors		
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	Yes / No	
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.		

Signature:				

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
No audible sound with oxygen	Inadequate O ₂ supply	Verify O ₂ supply is ON
source connected and Control #1 in STOP position		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 by checking Pressure Indicator is up and green
No audible sound with oxygen source connected and Control #1 in STOP position	Seized internal pneumatic component	Return to factory for service
No compressions with increase of Control #2	Control #1 not turned to RUN position	Turn Control #1 to RUN position
No ventilation with increase of Control #3	Control #4 not turned to ON position	Turn Control #4 to ON position
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
be properly aligned to deliver the	true pressure indicated. Proper ver	ightened, the indicator on the knob may not ntilation tidal volumes must then be evice to the factory to calibrate Control #3 is
No compressions with increase of Control #2	Inadequate O ₂ supply	Verify O ₂ supply is ON
-or-		Verify proper input pressure of 50-90 psi by checking Pressure Indicator is up and green
No ventilation with increase of Control #3		Verify oxygen source is delivering proper minimum flow of 45 LPM
Inadequate Ventilation to patient	Control #3 knob setting	Verify Control #3 setting. Increase to provide sufficient ventilation as evidenced by chest rise
	Improper Lip Valve	Verify proper type of Lip Valve is installed
	Improper Lip Valve placement	Verify Lip Valve is oriented and seated properly
	Breathing Hose obstruction or leakage	Check Breathing Hose for obstruction or leakage
	Non Re-breathing Valve obstruction	Check Non Re-breathing Valve for blockage and/or proper Lip Valve orientation
	Face Mask/Airway obstruction or leakage	Check Face Mask/Airway for obstruction or leakage
	Decreased lung compliance	Evaluate patient and adjust as needed
	Increased lung resistance	Evaluate patient and adjust as needed

THUMPER® MODEL 1007CCV DETAILED SPECIFICATIONS

Input:

- Compressed O₂ at 50 to 90 psi (3.515 to 6.327 kgf/cm²)
- Gas Consumption: Maximum 45 LPM (11.88 gal/min.)
- Indicator to show adequate input pressure: 50 ± 3 psi $(3.515 \pm 0.211 \text{ kgf/cm}^2)$
- Pressure relief valve set at 100 ± 5 psi $(7.030 \pm 0.351 \text{ kgf/cm}^2)$
- Filter to prevent contamination
- Oxygen checked quick connector

Compression:

- Compression Frequency: 100 ± 6 compressions per minute
- Compression Stroke Range: Continuously Adjustable, 0 to 8 cm (0.0 to 3.15 in)
- Compression to Ventilation Ratio: 5:1
- 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: $400-1200\pm100$ mL or 10%: adjustable from 400 1200 mL (0.105 0.317 \pm 0.026 gal or 10%; adjustable 0 0.317 gal)
- Deliver 95% \pm 5% oxygen to the patient
- Inspiratory Time: 1.48 \pm 0.5 seconds or .98 to 1.98 seconds
- Inspiratory Flowrate: 0 to 50.0 \pm 2.5 LPM (0 to 13.20 \pm 0.66 gal)
- Pressure Relief Valve: < 55.0 cmH₂0 (0.782 psi)

Controls:

- Run/Stop: system control (run/release chest compressor)
- Compression Control: Continuous Compression Depth
- Ventilation Control: Calibrated Tidal Volume
- Vent Mode Switch: ON = 5 Compressions to 1 Ventilation
 OFF = Continuous Compression

Environmental:

- 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 contamination

Questions about the Thumper® Model 1007CCV? Please call 1-800-530-9939.

PARTS LIST FOR THUMPER® MODEL 1007CCV

Part No.	Description
Resuscitation	TI
15370	Thumper® Model 1007 <i>CCV</i>
14790-01	Backboard w/straps
14850	Carrying/Storage Case
Replacement Parts	
14799-02	Thumper® Model 1007CCV Operation Manual
14769-01	Cot Straps Backboard
14769-02	Shoulder Straps Backboard
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
11732	Aluminum Oxygen Tank "D" size
11733	Aluminum Oxygen Tank "E" size
45040	Caff Caga fan Carlon Filon Callindan
15040	Soft Case for Carbon Fiber Cylinder
14986	Carbon Fiber Oxygen Cylinder "DD" size
15030-01	Oxygen Regulator CGA 870 (1 DISS, 1 TPR Connection)
10657	Oxygen Regulator CGA 540 w/Nut
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.

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SECTION F WARRANTY/FACTORY SERVICE

MODEL 1007*CCV* THUMPER[®] CARDIOPULMONARY RESUSCITATOR WARRANTY AGREEMENT

Your CARDIOPULMONARY RESUSCITATOR (Model 1007*CCV*) 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.

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 improper packaging.

The Thumper[®] is designed to be used during resuscitation and transportation of patients in cardiac arrest. The normal duration of use is typically 15 to 30 minutes per resuscitation. Prolonged use of the Thumper may cause excessive wear, and void this warranty.

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 (fill in the following information for your 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 preventive maintenance procedures are performed regularly (See Section E). In addition to the regular maintenance performed by the user, factory service and recalibration is recommended every five years if not sooner. Refer to the table titled "Factory Recommended Maintenance/Service Intervals" in the Periodic Preventive Maintenance portion of Section E for recommended intervals.

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

- **A.** Refer first to Section E in the Operation Manual. 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 Thumper[®] CPR System must be returned to Michigan Instruments, Inc., please observe the following procedures:
 - First and foremost, <u>clean and sterilize the device</u> to remove any contaminants or body fluids. Failure to do so will result in additional charges. If contamination is severe enough, 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.) <u>DO NOT USE THE CARRYING/STORAGE CASE AS A SHIPPING CONTAINER.</u> 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. Any accessory item returned to the factory that is not in need of service will be promptly returned. The customer will be responsible for the return shipping charges accrued which will be added to the final repair invoice.
 - 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), or,
 - 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.

- **D.** All devices returned to Michigan Instruments, Inc. must be evaluated and require a \$75 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 Thumper[®] CPR System that requires authorized factory service.
- **E.** 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.

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.

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SECTION G 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.

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