Thumper[®] Model 1007*CC*_{MI} Mechanical CPR System **Operation Manual**

(Part Number REF 14799-01)



Manufactured in the USA by:



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EC REP

ProCare / Lode BV Zernikepark 16a 9747 AN GRONINGEN The Netherlands Phone: +31(0)50 57 15074 PROTECTED UNDER ONE OR MORE OF THE FOLLOWING U.S. PATENTS: 6,171,267 5,743,864



Symbol	Meaning	Symbol	Meaning
	Manufacturer – Name/Address information. Date of manufacture appears under symbol in YEAR-MO format (on device).		Caution - Attention: Consult Accompanying Documents. Operators are to refer to information provided with the device.
EC REP	Authorized Representative in the European Community – Name/Address information.		Defibrillation Protection (Type BF Patient)
C€	CE Mark & Notified Body ID#	SN	Serial Number
i	Consult Instructions for Use – additional information available.	₽	Gas Supply (operating range indicated)
X	Special Disposal Required	REF	Catalog Number – Part number reference.
	Read Operator's Manual or Instructions For Use (IFU).		

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SECTION A INTRODUCTION

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

THE THUMPER[®] MODEL 1007*CC*^{MI} OPERATION MANUAL

Note: The purpose of the Operation Manual is to explain the use, care, and user maintenance of the Thumper[®] Model 1007*CC*_{MI}, 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 Disinfection 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.

INDICATION FOR USE

The Thumper[®] CPR System is used to perform Cardiopulmonary Resuscitation (CPR) on <u>adult</u> <u>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</u> <u>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."



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 Disinfection section of this manual.

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

Caution: Infiltration of foreign material into the 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. (Blank Page Intentional)

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*CC*_{MI} is functionally similar to the previous models 1003, 1004, 1005, and 1007 in regards to cardiac compression delivery. The 1007*CC*_{MI} model does not incorporate a synchronized ventilator as previous models had.

NOTE: The 1007CC_{MI} model is designed to provide continuous chest compressions only. Ventilation must be delivered to the patient by auxiliary means such as mouth to mouth resuscitation, a ventilation bag, demand valve or other ventilator type. The 1007CC_{MI} model provides a RUN/STOP switch to suspend compressions for ventilation delivery, patient monitoring and other intervention measures.

GENERAL DESCRIPTION

The Thumper[®] Model 1007*CC*_{MI} system provides consistent CPR support for cardiac arrest patients under conditions, which might otherwise hinder the effectiveness of manual techniques. It can be used to perform external cardiac compression in conformance with AHA CPR guidelines.

The Thumper[®] Model 1007*CC*_{MI} 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*CC*_{MI}, once correctly applied over the patient's sternum, is designed to measure the patient's anterior-posterior (A-P) chest diameter and deliver the equivalent sternal deflection of 20% of that diameter.

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

THUMPER[®] SYSTEM COMPONENTS AND ACCESSORIES

The Thumper[®] system consists of three major components:

(1) The Thumper[®] Model 1007*CC*^{MI} Arm/Column/Base Assembly

- (2) The BackBoard (BackBoard/Shoulder Straps)
- (3) The Mobile Oxygen Carrier / appropriate O₂ wall access adapter

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

Thumper[®] Model 1007 CCm 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.

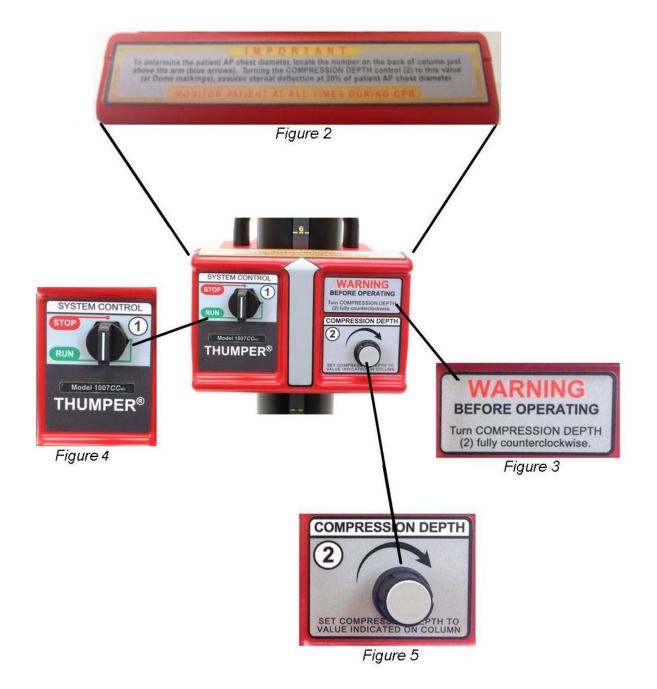


Figure 1 – Thumper[®] Model 1007CC_{MI} Arm/Column/Base Assembly

CONTROLS AND LABELING

The Thumper[®] Model 1007*CC*_{MI}'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 (3.515 to 6.327 kgf/cm²)) 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 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 2 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 3 for an illustration of this label.

The following controls operate the Thumper[®] Model 1007*CC*_{MI} 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.

Refer to Figure 4 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 5 for an illustration of this control.

The BackBoard

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



Figure 6 – The BackBoard

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

The Thumper[®] Model 1007*CC*_{MI} is equipped with an O₂ 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 O₂ 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*CC*_{MI} and an additional DISS outlet. It is designed to power the Thumper[®] Model 1007*CC*_{MI} 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*CC*_{MI} 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.





Single tank carrier for "DD" carbon fiber cylinder (Cylinder and Regulator available separately)

Dual tank carrier for "D" or "E" aluminum cylinders (Cylinders not included)

Figure 7 – Mobile Oxygen Carriers (MOC)

The Carrying/Storage Case

The carrying/storage case is constructed of a durable nylon. The Thumper[®], O₂ 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.



Figure 8 – Carrying/Storage Case – shoulder strap (left) backpack straps (right)

SECTION C SETUP AND OPERATION

PRECAUTIONS

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 patient 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 unfortunate event of a mechanical failure.
- 5. When transporting the patient with the Thumper[®] in operation, ensure the patient is secured snugly to the BackBoard using the provided shoulder straps. Also, ensure the patient is properly secured (using retention straps) to the stretcher as well. Failure to do so can allow the Thumper[®] and BackBoard to shift position on the patient possibly causing the Massager Pad to wander off the patient's sternum.
- 6. When applying the Thumper[®] to an obese patient, place the arm of the patient around the Thumper[®] so that the Column is positioned near the arm pit of the patient. This will better facilitate positioning the Massager Pad directly over the patient's sternum.

RECOMMENDATIONS

It is recommended that the Arm/Column of the Thumper[®] be attached to the Base while stored in the Carrying/Storage Case.

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

By doing so, the Thumper[®] is ideally positioned to expedite removal from the Carrying/Storage case and application to the patient.



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



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

- Setup on the patient using the BackBoard
- ✓ Transitioning from manual CPR to mechanical CPR
- ✓ Setting the compression depth
- ✓ Interventions such as pausing operation to monitor the patient

POSITIONING THE PATIENT

The following steps are provided as a recommendation.

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

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

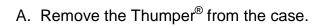
- 2. Place the BackBoard under the patient orienting the head of the patient in the direction indicated by the HEAD marking on the cross strap. Ensure the cross strap is positioned under the patient's neck. Connect the retaining straps over the shoulder and under the arm pit of the patient, then buckle and tighten the straps securely on both sides of the patient.
- 3. Secure the patient to the spine board with retention straps at the forehead, hips and feet.

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

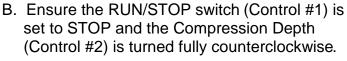
4. Manual CPR can begin on the patient immediately. There is no need to postpone CPR while waiting for Thumper[®] deployment and application to the patient.

THUMPER[®] MODEL 1007CCm DEPLOYMENT

1. Thumper[®] Model 1007*CC*^{MI} Setup:



- C. Ensure the Oxygen source is energized then attach the O_2 Supply Hose to the Oxygen source first. Pull the collar back from the O₂ Source end connector, press firmly onto the male connector of the Oxygen source then release the collar to secure the connector. Pull slightly on the hose to ensure a secure connection.
- D. 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.
- E. Listen for audible clicks (cycling) and verify that the green Pressure Indicator shows an adequate input pressure is available.
 - CAUTION: The Life-Stat[®] requires a medical grade Oxygen source capable of delivering pressure from 50 to 90 psi (3.515 to 6.327 kgf/cm²), with a minimum flow rate of at least 45 LPM. Always follow safe Oxygen handling practices with Oxygen cylinders and regulators.



SYSTEM CONTROL

Model 1007CCm **THUMPER[®]**

STOP

RUN









COMPRESSION DEPTH





2. Thumper[®] Model 1007CC_{MI} Application to the Patient:

- A. Before inserting the Thumper[®] into the BackBoard, ensure the Arm is raised and locked near the top of the column and positioned so that the dome is towards the patient's feet. NOTE: When oriented in this position, the Thumper[®] is top-heavy and prone to fall over. Grasp the Thumper[®] at the Base and Handle.
- B. Insert the Base into the side slot of the BackBoard on whichever side of the patient is most convenient.
- C. With the base fully inserted into the BackBoard and during a pause in the manual CPR effort, loosen the arm lock and swing the Arm over the patient's chest locating the Massager Pad over the sternum, as you would for the heel of your hand when performing manual CPR.
- D. Lower the Arm until the Massager Pad contacts the patient's chest. Then, apply slight downward pressure on the Arm to position the Piston inside the Dome to align with the "-" mark on the Dome. Tighten the Arm Lock Lever.





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

Warning: Injury to patient may occur if Arm is adjusted too low, as indicated by the top of the Piston moving up beyond "-" on the Dome. Warning: Patient chest compressions may be insufficient to be effective if Arm is adjusted too high as indicated by the top of the Piston not moving up to "-" on the Dome.

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

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

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



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

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

3. Thumper[®] Model 1007*CC*_{MI} 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.

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

- A. Ensure Control #2 is rotated fully counterclockwise and the Pressure Indicator at the top of the Column shows "green" indicating adequate O2 pressure.
- B. Activate the Thumper[®] Model 1007*CC*^{MI} by first turning the RUN/STOP Control #1 to RUN.
- C. 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*CC*^{MI} in use, care must be taken to prevent kinking or collapsing of the O₂ Supply Hose.

4. Procedure to Interrupt (Suspend) Compressions:

To perform pulse checks, ventilate the patient or perform analysis with an AED (and/or defibrillate manually), simply turn Control #1 to the STOP position. This will interrupt compressions. To resume compressions turn Control #1 to RUN. The same depth of compression previously set by Compression Depth Control #2 will be delivered.

Caution: When the Thumper[®] Model 1007CC_{MI} 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*CC*_{MI} 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: Do 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. 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 hose from the Oxygen source end first may not allow the device to properly vent the internal pneumatic ports. <u>Always</u> disconnect the O_2 Supply Hose from the Thumper[®] first.

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.

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



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

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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.

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

A Thumper[®] that is stored assembled (for example, in a hospital ER setting) should be placed on a "crash cart" or other surface where it will be used. The Arm should be positioned near the middle of the Column and locked into place positioned over the Base. Coil the 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.

DISPOSAL



The Thumper® is designed for years of dependable service. When disposal is required, we recommend returning to the factory for recycling.

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SECTION E CARE, CLEANING AND DISINFECTION

General Care

Always store the Thumper[®] Model 1007*CC*^{MI} 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 O_2 Supply Hose. When filling Oxygen tanks, be certain that proper procedures are followed to prevent foreign matter from entering the tanks. Also, refer to additional **Cautions:** listed in the General Warnings, Cautions and Notes section.

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.

Disinfection Guidelines

Standard colorless chemical disinfectant solutions may be used to "wipe down" external surfaces of the Life-Stat[®] 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 Life-Stat[®].

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

Stain Removal from the BackBoard straps:

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

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

Mobile Oxygen Carrier (MOC)

- Should you require maintenance of the regulator(s) employed in the MOCs, contact the manufacturer 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.

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

Factory Recommended Maintenance/Service Intervals

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.

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.

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

Caution: Replace the BackBoard (= 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 (m 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 and Control#2 is fully ccw before continuing)

- 3. Loosen the Arm Lock Lever and check that the Arm moves freely on the Column. Raise Arm to bring the arrows to the 6 position and tighten the Arm Lock Lever.
- 4. 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[®].
- 5. Verify that the device cycles when the O_2 Supply Hose is connected and the green Pressure Indicator at the top of the Column is functional.
- 6. Remove the O_2 Supply Hose from the Thumper[®] first, then from the Oxygen source.
- 7. 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

- 8. Turn Control #1 to the STOP position and Control #2 fully counterclockwise.
- 9. Check that all accessories and supplies are available: O₂ Supply Hose, BackBoard, etc.
- 10. Ensure Oxygen cylinder(s) in the MOC have an adequate Oxygen supply.
- 11. Place the Thumper[®], O₂ Supply Hose and BackBoard into the Carrying/Storage Case.

Date: ___/__/ Shift: _____ Location: _____

Serial Number:_____

Directions: (see procedure above). At the beginning of each shift, inspect the device. Indicate whether all requirements have been met. Note any corrective actions taken. Sign the form.

	Requirement	Acceptable as Found	Corrective Action/Remarks
Α.	Visual inspection		
1.	Thumper [®] is clean and free of contaminants BackBoard """""""		
	BackBoard " " " " " "		
	O ₂ Supply Hose """"""""		
	MOC/related adaptors " " " " " "		
2.	Thumper [®] has no worn, loose or damaged parts		
	BackBoard """"""""""		
	O ₂ Supply Hose """""""""""""		
	MOC/related adaptors " " " " " " "		
В.	Set up for operation		
3.	Arm moves freely on Column		
4.	O ₂ Supply Hose connects and no signs of wear		
	Device cycles and Pressure Indicator shows green		
6.	O ₂ Supply Hose disconnects properly		
7.	Controls (#1 and #2) rotate and secure		
С.	Prepare device for next use		
8.	Control#1 at STOP and Control#2 turned fully ccw		
9.	Accessories and supplies inventory:		
	Thumper [®] device		
	O ₂ Supply Hose		
	BackBoard		
	Carrying/Storage Case		
	MOC/related adaptors		
Ot	her code related supplies:		
	MOC cylinder(s) Oxygen supply adequate		
11.	All items needed packed in Carrying/Storage Case		
tak	y major problem(s) identified to warrant ing the device OUT OF SERVICE? (circle	Yes / No	
one)		
forr you	es, explain in the remarks section and submit this n and the device to the authorized personnel in r organization responsible for the coordination quipment service requests.		

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. Inspect the O₂ Supply Hose for kinks, cracks, cuts, worn hose or damaged connectors.
- e. 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. Compression test (Ensure Control#1 is set to STOP and Control#2 is fully ccw 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.

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

d. 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.

- e. Verify that the Compression Depth Control works smoothly and allows proper adjustment of the compression depth.
- f. Verify that the Piston motion is smooth and consistent.
- g. 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 and Control #2 fully counterclockwise.
- 2. Remove the O_2 Supply Hose from the Thumper[®] first then from the Oxygen source.
- 3. Check that all accessories and supplies are available: O₂ Supply Hose, BackBoard, etc.
- 4. Ensure Oxygen cylinder(s) in the MOC have an adequate Oxygen supply.
- 5. Place the Thumper[®], O₂ Supply Hose and BackBoard into the Carrying/Storage Case.

Functional Check of Thumper[®] Model 1007CC_{MI} (Weekly, monthly, or per determined schedule)

Date: ___/__/ Shift: ____ Location: _____

Serial Number:_____

Directions: (see procedure above). Per the determined schedule, inspect the device. Indicate whether all requirements have been met. Note any corrective actions taken. Sign the form.

Requirement	Acceptable as Found	Corrective Action/Remarks
A. Visual and Mechanical Inspection		
1. Appearance		
a. Thumper [®] is clean and free of contaminants BackBoard """"""" O ₂ Supply Hose """""""		
BackBoard " " " " " "		
O ₂ Supply Hose """""""		
MOC/related adaptors " " " " " "		
b. Thumper [®] has no worn, loose or damaged parts BackBoard """""""""		
BackBoard " " " " " " "		
O ₂ Supply Hose """""""""""		
MOC/related adaptors " " " " " "		
c. Thumper [®] covers not cracked or damaged		
d. O_2 Supply Hose connects and no signs of wear		
e. 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		
4. 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. Run/Stop Control operates smoothly		
e. Compression Depth Control works smoothly/depth adjusts		
f. Piston motion is smooth and consistent		
g. Compression depth consistent		
B. Prepare device for next use		
1. Control#1 at STOP and Control#2 turned fully ccw		
2. O ₂ Supply Hose disconnects properly		
3. Accessories and supplies inventory:		
Thumper [®] device		
O ₂ Supply Hose		
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 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. If unable to determine the cause of problem, contact Michigan Instruments for service.

Indication	Probable Cause(s)	Solution
No audible sound with Oxygen source connected and Control #1 in STOP position	Inadequate O ₂ supply	Verify O ₂ supply is ON Verify O ₂ supply tank is not empty or low Verify O ₂ Supply Hose connections are secure
		Verify proper input pressure of 50-90 psi 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 compressions with increase of Control #2	Control #2 knob not secured to valve shaft	Verify Control #2 knob is secured to shaft
No compressions with increase of Control #2	Inadequate O ₂ supply	Verify O ₂ supply is ON Verify proper input pressure of 50-90 psi by checking Pressure Indicator is up and green Verify Oxygen source is delivering proper minimum flow of 45 LPM

THUMPER® MODEL 1007CCm DETAILED SPECIFICATIONS

Input:

- Compressed O_2 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 ± 0.211 kgf/cm²)
- Pressure relief valve set at 100 \pm 5 psi (7.030 \pm 0.351 kgf/cm²)
- Filter to prevent contamination
- Oxygen checked quick connector (provided on O₂ Input Hose)

Compression:

- Compression Frequency: 100 ± 6 compressions per minute
- Compression Stroke Range: Continuously Adjustable, 0 to 8 cm (0.0 to 3.15 in)
- 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

Controls:

- Run/Stop: system control (run/release chest compressor)
- Compression Control: Continuous Compression Depth

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)
- Sealed piston shaft and bearing to prevent contamination

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

PARTS LIST FOR THUMPER® MODEL 1007CCm

REF

Part No.	Description
Resuscitation	
15350	Thumper [®] Model 1007 <i>CC</i> MI
14790-01	BackBoard
14850	Carrying/Storage Case (shoulder strap)
15450	CPR Carrying Case- Backpack
13430	Crit Carrying Case- Dackpack
Replacement Parts	
14799-01	Thumper [®] Model 1007 <i>CC</i> MI Operation Manual
15440	BackBoard Replacement "H" Strap Kit
14910	O ₂ Supply Hose 10 Ft.
14950	O_2 Supply Hose 15 Ft.
14780	Massager Pad Assembly, Urethane
Oxygen Management	
15290	MOC Dual D Tank Soft Case
15300	MOC Dual E Tank Soft Case
15040	Soft Case for Carbon Fiber Cylinder
15030-01	Oxygen Regulator CGA 870 (1 DISS, 1 TPR Connection)
11117	Oxygen Regulator CGA 540 w/Hand wheel
10411-01-01	Oxygen Adaptor Assy OHIO
10411-02-01	Oxygen Adaptor Assy DISS
10411-06-01	Oxygen Adaptor Assy NCG
10411-07-01	Oxygen Adaptor Assy Puritan Bennett
	crygen naaptol nooy. I antan Donnott

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*CC*^{MI} THUMPER[®] CARDIOPULMONARY RESUSCITATOR WARRANTY AGREEMENT

Your CARDIOPULMONARY RESUSCITATOR (Model 1007*CC*_{MI}) 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. Visit <u>www.michinst.com</u> for on-line registration.

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

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.** 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.) DO NOT USE THE CARRYING/STORAGE CASE AS A SHIPPING CONTAINER. It is not designed to withstand rigorous handling during shipping. Returning the case is not necessary unless it also requires repair. The case should be packaged separately if returned.
 - 3. Return only those items that require service and specify the service requested on a packing list.
 - 4. Place all components in plastic bags before putting them in the shipping container. This will keep dirt and other debris from entering the device through unprotected openings.
 - 5. Include with the device:
 - a. A description of the problem(s).
 - b. The name and phone number of a contact person.
 - c. A packing slip listing all of the components being returned and specify service requested. Cite RMA# on the packing slip as well.
 - d. A purchase order, if appropriate.

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

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

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

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

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

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. (Blank Page Intentional)

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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