

Weil™ Mini Chest Compressor (MCC)

INSTRUCTIONS FOR USE



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IMPORTANT USER INFORMATION

All users must read and understand the entire instruction for use before operating the miniature chest compressor (MCC). The purpose of the instructions for use is to explain the use, care, and user maintenance of the MCC and is not intended to teach cardiopulmonary resuscitation.

Instructions for use should always be easily accessible to the users of MCC.

Required skills

Personnel who intend to use the MCC must be trained in Basic Life Support and/or Advanced Life Support techniques. Resuscitation International LLC strongly recommends that the MCC only be operated by: emergency medical technicians, paramedics, nurses, physicians, police, fire rescue personnel, medical staff, and people who are certified according to the American Heart Association Guidelines for cardiopulmonary resuscitation, or equivalent. In addition, proper use of the MCC requires a thorough understanding of the product, appropriate training, and adequate practice with the device.

Disclaimer

Resuscitation International LLC assumes no responsibility for the use of MCC by personnel that do not fulfill the requirements listed above.

Resuscitation International LLC does not accept liability for injury to personnel or damage to equipment that may result from misuse of the MCC.

Under no circumstances shall Resuscitation International LLC be liable for incidental or consequential damage arising from the use of MCC.

The use of drugs or medical equipment in combination with external chest compressions may reduce the effectiveness of the compressions. Always refer to the instructions for use for other medical equipment to assure that the MCC is appropriate to use in conjunction with the mechanical chest compressions being performed.

Side Effects:

Bruising, injury, vomiting, fractured or broken ribs, and soreness of the chest can be possible side effects of performing CPR^①. Side effects of CPR are common and considered acceptable ramifications given that the alternative is clinical death. If the patient is resuscitated, all patients should be evaluated and assessed for post CPR related injuries.

^① Susan Robin (2010, January 24). Side Effects of CPR. Retrieved from <http://www.livestrong.com/article/75926-side-effects-cpr/>. Summary of Arkansas State University: Basic Life Support CPR and 123 CPR Inc: Complications of CPR.



GENERAL WARNINGS AND CAUTIONS



- Federal Law restricts this device to sale by or on the order of a physician.
- The MCC is intended for use on adults only.
- The MCC is not intended for pregnant patients.
- The current version of the American Heart Association Guidelines does not recommend the use of mechanical CPR on infants and children.
- The MCC is not intended for patients with traumatic injury (wounds resulting from sudden physical injury or violence).
- When CPR is indicated, manual CPR should start immediately and should not be postponed.
- The MCC must be used only in cases where manual CPR would normally be initiated.
- Personnel certified in manual CPR must always be present during the use of the MCC.
- If for any reason the MCC stops operation or mechanical problem occurs, immediately revert to manual CPR.
- Do not leave the patient or device unattended while the MCC is in operation.
- If the MCC is not positioned correctly in relation to the sternum, there is an increased risk of damage to the internal organs, ribcage, and circulation may be compromised.
- During transport, regular checks of the position of the MCC on the patient should be performed. Failure to properly position the MCC may cause injury to the patient.
- Straps or restraints used during transportation must not interfere with the operation of the MCC.
- Do not block the vent of the MCC.
- Do not submerge the MCC in liquid or operate in water.
- Do not re-use single use disposable components. Reuse of these items, which may have become contaminated during its first use, may result in subsequent health deterioration of the patient due to contamination.
- Single use disposable components are not intended for reprocessing or sterilization. This could pose a risk of harm to the patient.

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1. INTRODUCTION

Important: Throughout the set-up and operation of the MCC there should be two qualified personnel working as a team. This allows one person to immediately begin manual CPR while the additional person unpacks, set-ups, and prepares the MCC for immediate use.

1.1 Indications for Use

The MCC is used to perform mechanical external cardiac compressions otherwise known as CPR (cardiopulmonary resuscitation) on adult patients who have acute circulatory arrest and are clinically dead defined as absence of spontaneous breathing, no pulse, and loss of consciousness.

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

1.2 Contraindications

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 miniaturized chest compressor into your arrest management regime or regiment of care.



DO NOT USE THE MCC in the following cases:

- If there is no indication that chest compression is likely to help the patient.

1.3 Device Description

The MCC is an automated, portable chest compressor, which provides continuous chest compressions as an adjunct to performing manual CPR. It is powered by compressed air.

The MCC provides consistent CPR support for cardiac arrest patients under conditions, which might otherwise hinder the effectiveness of manual techniques. A typical application of the device is shown in Figure 1.

1.3.1 System Components

The major components of the MCC are shown in Figure 2.

1. The **compressor assembly** contains a pneumatic controller that provides periodic compressed air to the piston, which acts on the patient's chest via a pressure pad. **The MCC includes the air hose and the control valve.**
2. The **torso restraint** is placed underneath and around the back of the patient to firmly secure the compressor to the patient.
3. The **stabilizer** serves a dual purpose; providing a head rest and also secures to the torso restraint to provide stability during **continuous** operation of the MCC especially during patient transport.

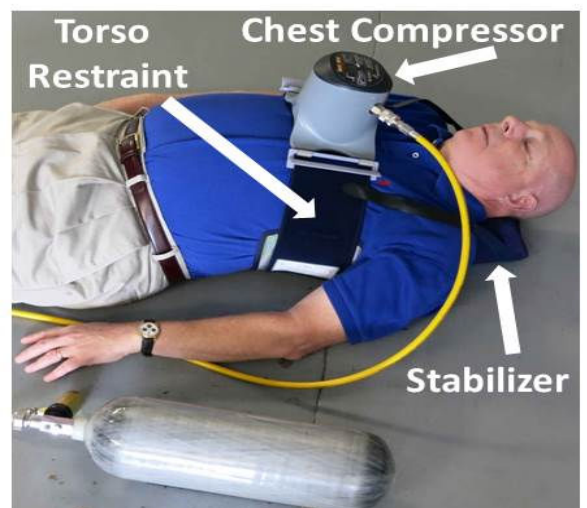


Figure 1 Miniaturized Chest Compressor (MCC)

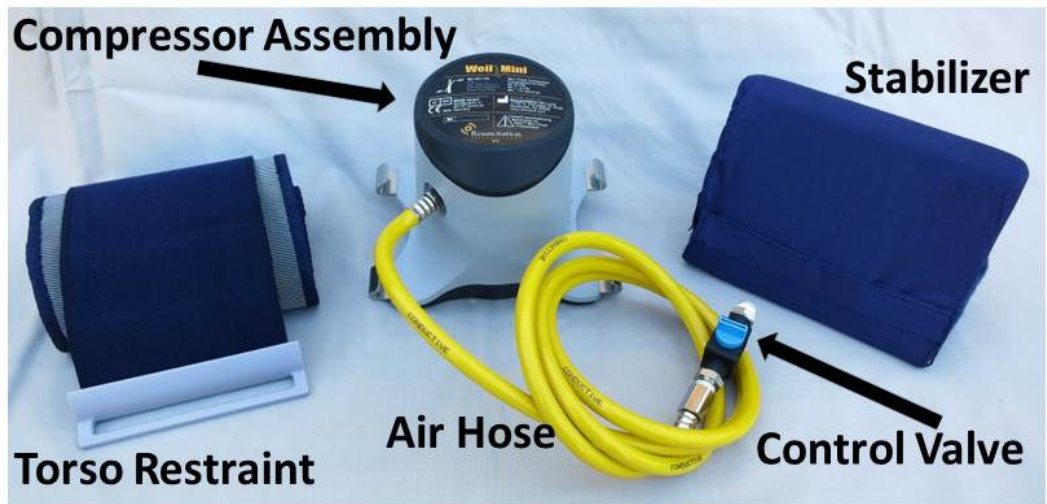


Figure 2 Components of the MCC

1.3.2 Compressed Air Source

The MCC is powered by compressed air from a wall outlet in a hospital, an ambulance, or a cylinder tank. The MCC can be operated with a pre-set or an adjustable regulator. We suggest using a pre-set regulator. **CAUTION:** When using the MCC with a regulator on a SCBA Tank, open the tank valve slowly to minimize stress and wear on the regulator, which may damage or greatly reduce the life of the regulator.

1.3.3 User Control

The only control on the MCC is a control valve (Figure 4). The **CONTROL VALVE** is an integral part of the air hose with a male connector at the open end (Figure 2). The male connector fits into a female connector, which could be part of a wall outlet or a regulator of a cylinder tank (Figure 3). The **CONTROL VALVE** has two positions – **ON** and **OFF** (Figure 4).

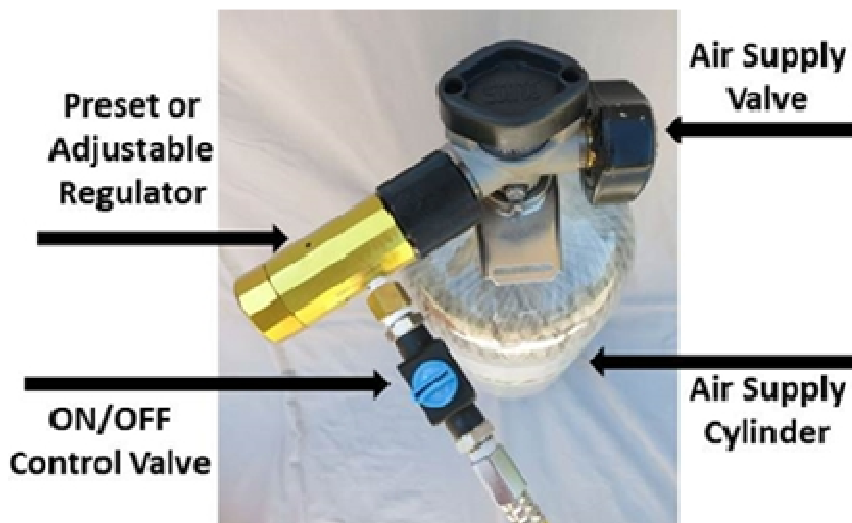


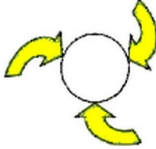
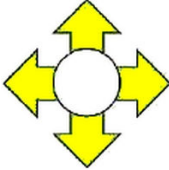
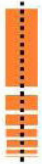


Figure 3 Air Source



Figure 4 Control Valve Positions

1.3.4 Annotation of Symbols

Symbols	Description
	Caution: please refer to user manual. All users must read the manual completely before using the MCC on patients.
	Warning: Moving parts. When MCC is connected to a pressure source, the bottom of the piston will have a high force during operation.
	Input for air Indicates the location of input connectors.
	Exhaust for air Warning: Do not block this outlet. The MCC may not operate properly.
	Guide for alignment of the chest compressor to an imaginary line that connects the nipples. NOTE: This position is important to the efficacy of the MCC.

1.3.5 Location of Symbols (Figure 5)

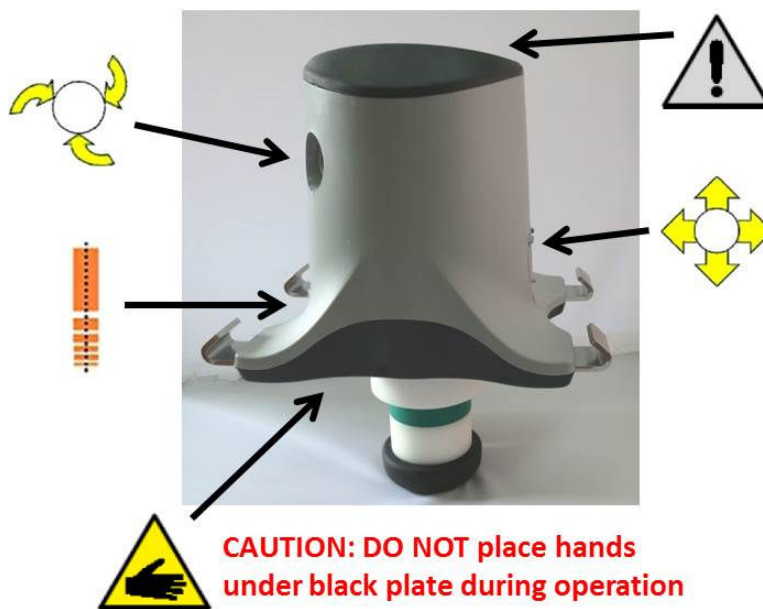


Figure 5 Locations of Symbols

2.0 SET-UP AND OPERATION

The MCC system is delivered fully assembled with the compressor module, air hose, control valve, stabilizer, and torso restraint. Before setting up and using the MCC, there are several important precautions that must be observed at all times.

1. The MCC is intended for use on adults.
2. Manual CPR should be started immediately upon arrival. If manual chest compression has already started, immediately unpack and set-up the MCC for use.
3. The MCC is not intended for patients with traumatic injury (wounds resulting from sudden physical injury or violence).
4. The MCC must be used only in cases that manual CPR would normally be initiated. Personnel certified in manual CPR must always be present during the operation of the MCC.

2.1 Preparing the MCC

- Place the carrying case on the ground (Figure 6).
- Unpack the compressor module, torso restraint and the stabilizer (Figure 7).
- Ensure the **CONTROL VALVE** is in the **OFF** position (Figure 3 & 4).
- The **REGULATOR** should already be attached to the air source and a female connector attached to the regulator.
- Insert the male coupler (which should have been attached prior to unpacking) on the **CONTROL VALVE** to the female connector on the **REGULATOR** or **AIR SOURCE**.
- Open the air supply valve.



Figure 6 Emergency Carrying Case

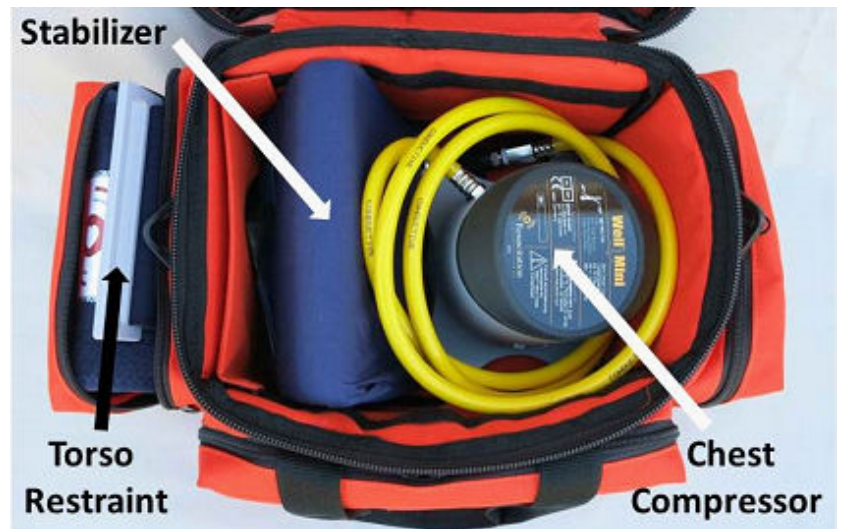


Figure 7 Unpacking

2.2 Attaching the MCC

- Lift the back of the patient, and slip the torso restraint under the back of the patient (Figure 8).
- Position the center of the compressor pad along an imaginary line connecting the nipples. Approximately 3-4cm/1.2-1.6in (1-2 fingers) from the bottom of the sternum notch (Figure 9).
- Wrap the Torso Restraint around the patient and secure the compressor assembly to the body of the patient (Figure 10).



Figure 8 Placement of Torso Restraint



Figure 9 Positioning of Chest Compressor



Figure 10



Figure 11

Warning: It is important to properly position the compressor on the chest. Incorrect positioning diminishes the quality of compression and more importantly, injury to the patient may occur.

2.3 Operating the MCC

- Verify that the MCC is properly positioned and secured on the patient (Section 2.2 Figure 10).
- Start compressions by placing the **CONTROL VALVE** to the **ON** position (Figure 4 & 11).
- If using an **ADJUSTABLE REGULATOR** adjust until sufficient depth of compression is demonstrated by viewing the color-coded piston as shown in Figure 12.

The color-coding for depth of compression is defined as follows:

- WHITE 0 - 38 millimeters / 0 - 1.5 inches
- GREEN 38 - 51 millimeters / 1.5 - 2 inches
- RED 51 - 60 millimeters / 2 - 2.4 inches

Warning: If using a Pre-Set regulator, placing the **CONTROL VALVE** in the **ON** position will immediately start chest compressions. The color-coded piston as shown in Figure 12 indicates the compression depth.

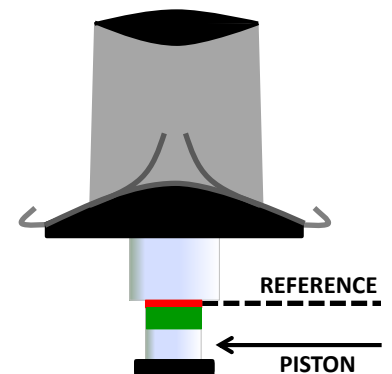


Figure 12 Visual Feedback

2.4 Interrupting Compression

When the MCC is used in conjunction with defibrillators or with other therapeutic devices that must monitor an ECG signal, interruption of the compression cycles may be required to avoid ECG motion artifact associated with mechanical chest compressions. To temporarily interrupt the MCC's active operation, place the **CONTROL VALVE** in the **OFF** position. To restart the MCC follow the procedures in Section 2.3, "Operating the MCC."

2.5 Ending Active Use of the MCC

When the resuscitation effort is terminated, place the **CONTROL VALVE** in the **OFF** position to stop the compression cycles.

2.6 Preparing the MCC for its Next Use

- Disconnect the air hose from the supply.
- Disconnect the torso restraint from the compressor assembly.
- Remove the compressor from the patient's chest.
- Remove, discard, and **replace** the torso restraint and the stabilizer cover. The torso restraint and stabilizer cover are single-use disposable components.

NOTE: Reuse of the single-use disposable components may result in harm to the patient. Reuse of these items, which may have become contaminated during its first use, may result in subsequent health deterioration of the patient due to contamination.

NOTE: Single use disposable components are not intended for reprocessing or sterilization.

NOTE: Treat the torso restraint and stabilizer cover as contaminated medical waste and dispose of it accordingly.

- Clean the compressor assembly before its next use. Refer to Section 3.0, "Cleaning and Maintenance."

2.7 Transporting the Patient

The MCC can be used in conjunction with a transportation device such as a gurney or a backboard during transport to hospital. However, care must be taken to ensure that the patient is properly strapped to the transportation device using locally-approved procedures for safe transport. For added safety and to insure that the compressor remains in a stable position, make sure the stabilizer is supporting the patient's head and secure to the torso restraint with the Velcro strap (Figure 13 & 14).



Figure 13 Stabilizer and Transporting

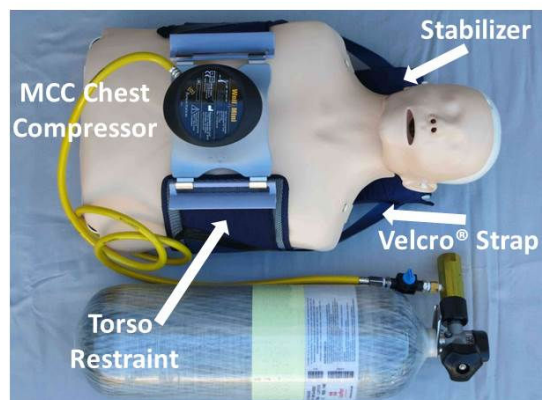


Figure 14 Stabilizer

Warning: Straps or restraints used for transportation purposes **must not interfere** with the operation of the MCC. Specifically, straps across the patient's chest may restrict the compression/ decompression of the chest. In general, strapping schemes must not alter the alignment of the patient to the MCC. During transport, regular checks must be performed to insure that the MCC is secured to the patient. (Section 2.2)

3.0 CLEANING AND MAINTAINENCE

Always store the MCC in a clean, dry place when not in use. Storage is provided for the MCC in the Carrying/Storage Case.

3.1 Avoid Contamination

Contamination can enter the system through the air supply hose. When filling air tanks, be certain that proper procedures are followed to prevent foreign matter from entering the tanks.

3.2 General Cleaning

Wipe all external surfaces of the MCC, air supply hose, stabilizer, carrying/storage case and related accessories to remove foreign matter after cleaning and disinfecting if necessary. Discard the single use items which are the torso restraint and the stabilizer cover.

3.3 Maintenance

There are no user serviceable parts inside the MCC 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.

Consideration should be given to the frequency of product use, storage conditions and knowledge of all product users to determine your local operator maintenance schedule.

- If the MCC is used more than once a week, daily inspection is appropriate.
- If the MCC is used less than once per week, a minimum of 1 weekly inspection is appropriate.

Inspect the MCC in accordance with the inspection checklist provided. Follow the recommended actions as appropriate.

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.

Sign each item on the sheet attached in Appendix A.

- Check that the device is clean.
- Check that the stabilizer is clean.
- Check that the air hose does not have any cracks and fits tightly to the compressor assembly.
- Check that the CONTROL VALVE and the connector are undamaged.
- Check that the CONTROL VALVE is in the OFF position.
- Verify that a new torso restraint is in the carrying/storage bag.
- Verify that all major components are packed and ready for next use.

Functional Check:

- Attach the MCC to a test manikin as in Section 2.0 (Setup and Operation)
- Attach the MCC to an air supply and operate the device for approximately 1 – 2 minutes.
- Check that it is operating normally. Calculate the number of compressions per minute. 80 – 100/min is acceptable.

3.4 Storage

Careful storage of the MCC 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 the MCC be stored fully assembled in the Carrying/Storage Case ready for its next use.

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 MCC at an emergency site.

3.5 Service

- The warranty period is 1 year from the time the customer received the device.
- Contact your distributor or the manufacturer for maintenance in case of malfunctions.
- Under no circumstances should the housing cover of the MCC be removed. There are no user serviceable parts inside.
- Authorized technicians must repair the device.
- Use the original package, when returning the device. For this purpose, store the package and padding that came with MCC when you first received it.

4.0 TECHNICAL SPECIFICATIONS

The MCC is to be used on adults with chest circumference of 78 - 130 cm / 30.7 - 51.1 in.

Table 1 Operating Specifications

Category	Specifications
Chest displacement	Pre-set Regulator (37 – 51) millimeter* Adjustable Regulator 1. White: 0 - 38 mm / 0 - 1.5 in 2. Green: 38 - 51 mm / 1.5 – 2 in 3. Red: 51 - 60 mm / 2 – 2.4 in
Compression Rate	110 ± 22 compressions/min
Physiological duty Cycle	46± 8 %

*These depths are for most individuals, but not all. Some patients will be outside the 37-51 mm depth of compression due to some patient's chest compliance in combination with the non-adjustable regulator.

Table 2 Power Requirements

Category	Specifications
Power source	Compressed air
Air consumption	88 ± 5 liters/min (50 psi, 20° C)
Air source requirement	Adjustable air source: 45 to 70 PSI Pre-set regulators: 50 ± 5 PSI Peak flow rate : minimum of 110 liters/min

Table 3 Environmental Specifications





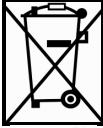


Category	Specifications
Operating Temperature	5 to 50° C / 41 to 122° F
Storage Temperature	-15 to 50° C / 5 to 122° F
Relative Humidity	5% to 90%, non-condensing

Table 4 Physical Specifications

Category	Specifications
Size (L x W x H)	19.3 cm X 14.0 cm X 16.3 cm (7.6 in X 5.5 in X 6.4 in)
Weight	2.5 kg (5.5 lbs.)

SYMBOLS

The following symbols are used on the MCC and/or in the accompanying documentation.

SYMBOL	MEANING
	Caution, consult accompanying documents.
	Single use only. Do not re-use.
	Serial Number
	Catalogue number
	Dispose in accordance with institution or local government environmental regulations
	Manufacturer
	EC Representative



Manufactured for:

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Appendix

Use the following checklist as required according to Section 3.3. Store the completed checklist. Copying of this sheet is permitted.

Date: _____

Signature: _____

Action procedure	Problems	Corrective Actions/Remarks
Check that the device is clean		
Check that the stabilizer is clean		
Check that the air hose does not have any cracks and fits tightly to the compressor assembly		
Check that the CONTROL VALVE and the connector are undamaged		
Check that the CONTROL VALVE is in the OFF position		
Check that the compressor pad is intact		
Verify that a new torso restraint is in the carrying/storage bag		
Verify that all major components are packed and ready for next use		
Functional Check		
Attach the MCC to a test manikin as in Section 2.0 (Setup and Operation)		
Attach the MCC to an air supply and operate the device for approximately 1 – 2 minutes.		
Check that it is operating normally. Calculate the number of compressions per minute. 80 – 100/min is acceptable.		