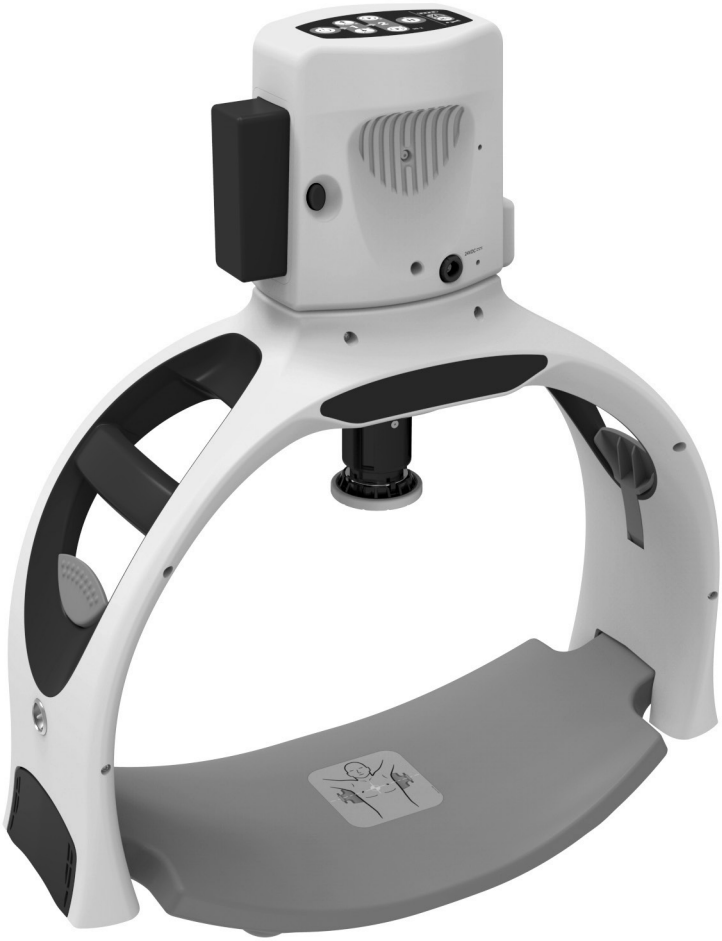
Defibtech RMU-1000 Automated Chest Compression System



User Manual

ELECTRONIC DISTRIBUTION

RAC-A1510EN-DP rev C

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Copyright

Patents

For patent information, see www.defibtech.com/patents.

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Introduction to the RMU-1000 ACC

This User Manual provides information to guide trained operators in the use and maintenance of the Defibtech RMU-1000 Automated Chest Compressor (ACC) and its accessories.

This chapter includes an overview of the ACC, intended use information, a discussion of when it should and should not be used, and information on operator training.

1.1 Overview

The RMU-1000 ACC is an automated, portable, battery-powered device that provides chest compressions on adult patients who have cardiac arrest.

The ACC, when applied to a patient who is unconscious and not breathing, is designed to:

- Provide consistent depth and rate chest compressions.
- Allow for automated chest compressions in both the in-hospital and out-of-hospital settings including during patient transport.
- Be applied to the patient with minimal interruption of CPR.

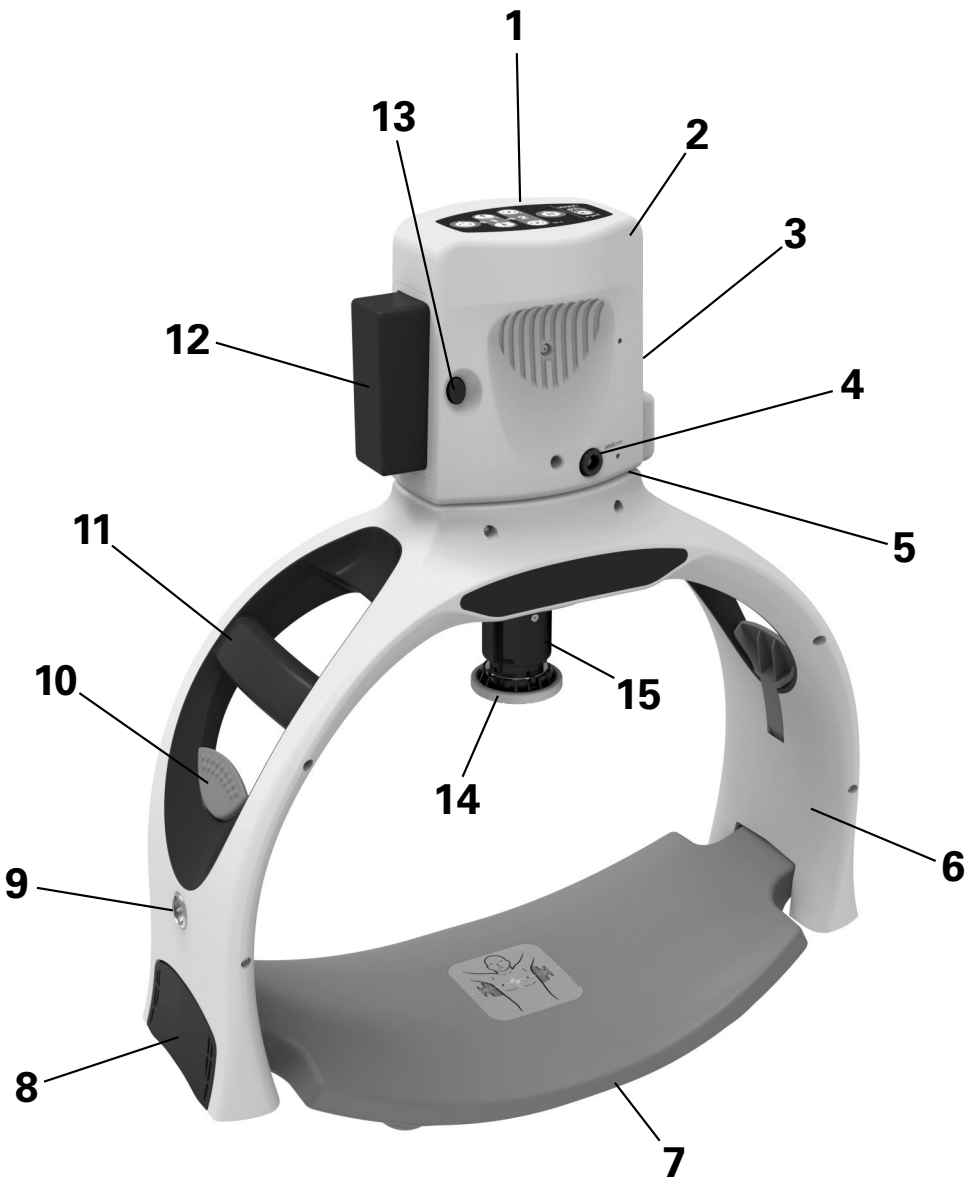
The major components of the RMU-1000 ACC are the Backboard, the Frame and the Compression Module. The Backboard is placed under the patient to provide a base for the ACC system. The Frame is placed over the patient and snaps into the Backboard with self-locking latches. The Compression Module mounts into the Frame and contains the user interface, a replaceable Battery Pack and the piston drive used to generate the chest compressions.

Compressions are initiated using a simple three-step operational sequence once the RMU-1000 ACC has been applied to a patient: the unit is turned on, the piston height is adjusted for the patient's chest size, and the compressions button is pushed. Additional user interface features include a pause function, a warning indicator to notify the operator for possible misuse or malfunction, an audible warning mute, and a Battery Pack capacity gauge.

The RMU-1000 ACC can be operated using a replaceable, rechargeable Battery Pack or with an external power adapter. A fully-charged, new Battery Pack can provide continuous operation for over an hour and can be recharged in the Compression Module.

A USB port on the Compression Module allows the Module to be connected to a personal computer and for ACC data retrieval and event reporting when used in conjunction with utility software available at www.defibtech.com.

1.2 The Defibtech RMU-1000 ACC



1. **User Control Panel.** The User Control Panel contains the user interface for the ACC system.
2. **Compression Module.** The Compression Module contains all the therapeutic components of the ACC system, including the piston drive mechanism, the control electronics, the User Control Panel, and the Battery Pack interface.
3. **Serial Number.** The serial number can be found on the Compression Module.
4. **External Power Input.** The External Power Input jack is used to connect an external power adapter to operate the unit or to charge the Battery Pack.
5. **USB Port.** The USB Port is located on the bottom of the Compression Module. It allows the Module to be connected to a personal computer and for ACC data retrieval and event reporting when used in conjunction with utility software available at www.defibtech.com. It is not intended to be used during rescue operation.
6. **Frame.** The Frame attaches to the Backboard and holds the Compression Module. It is used to maintain the Compression Module's position over the patient.
7. **Backboard.** The Backboard is the base for the ACC system. It is placed under the patient and provides an interface that the Frame attaches to.
8. **Backboard Latches.** One on each side of the Frame, the Backboard Latch is the mechanism that secures the Frame to the Backboard.
9. **Stabilization Strap Connectors.** One on each side of the Frame, the Stabilization Strap Connectors allow the Stabilization Strap to be secured to the Frame to maintain the ACC position over the patient's chest.
10. **Backboard Release Lever.** One on each side of the Frame, the Backboard Release Levers are used to release the Frame from the Backboard.
11. **Handles.** One on each side of the Frame, the Handles provide a secure way to grasp the Frame during ACC assembly and patient transport.
12. **Battery Pack.** The Battery Pack provides a replaceable primary power source for the Compression Module.
13. **Battery Pack Release.** The Battery Pack Release ejects the Battery Pack from the Compression Module.
14. **Patient Interface Pad.** The Patient Interface Pad is a user-replaceable, single use component that provides the interface between the piston and the patient's chest.
15. **Compression Piston.** The Compression Piston is driven by a motor housed inside the Compression Module and, with the Patient Interface Pad attached to the distal end of the Piston, provides the compressions to the patient's chest.

1.3 Indications for Use

The RMU-1000 ACC is intended for use as an adjunct to manual cardiopulmonary resuscitation (CPR) when effective manual CPR is not possible (e.g., during patient transport, or extended CPR when fatigue may prohibit the delivery of effective/consistent compressions to the victim, or when insufficient personnel are available to provide effective CPR).

Federal Law (USA) restricts this device to sale by or on the order of a physician.

1.4 Contraindications

Do not use the RMU-1000 ACC in the following cases:

- It is not possible to position the ACC safely or correctly on the patient's chest
- The patient is too small for the starting piston height to reach the patient's chest
- The patient is too large for the Frame to attach to the Backboard or if the Compression Module/Piston cannot be mounted without compressing the patient's chest

Always follow local and/or recognized resuscitation guidelines for CPR when using the RMU-1000 ACC.

1.5 Side Effects

The International Liaison Committee on Resuscitation (ILCOR) states the following side effects of CPR:

"Rib fractures and other injuries are common but acceptable consequences of CPR given the alternative of death from cardiac arrest. After resuscitation, all patients should be reassessed and re-evaluated for resuscitation-related injuries." *(From the 2005 International Consensus Conference on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations, hosted by the American Heart Association in Dallas, Texas, January 23–30, 2005. Published in Circulation. 2005; 112: III-5-III-16.)*

The above side effects, as well as bruising and soreness of the chest, may commonly occur after the use of the RMU-1000 ACC. *(Black CJ, Busuttil A, Robertson C. Chest wall injuries following cardiopulmonary resuscitation. Resuscitation. 2004 Dec;63(3):339-43.)*

1.6 Intended Use

The RMU-1000 ACC, when applied to a patient who is unconscious and not breathing, is intended to:

- Provide consistent depth and rate chest compressions.
- Allow for automated chest compressions in both the in-hospital and out-of-hospital settings including patient transport.
- Be applied to the patient with minimal interruption of CPR.

1.7 Operator Training Requirements

In order to safely and effectively operate the RMU-1000 ACC, it is the responsibility of the operator to obtain the following training:

- RMU-1000 ACC training in accordance with the User Manual including handling of the actual device
- CPR training in accordance with resuscitation guidelines as required by local, state, provincial, and/or national regulations, e.g. American Heart Association, European Council of Resuscitation
- Thorough knowledge and understanding of the material presented in this User Manual

The RMU-1000 ACC is intended for use by qualified medical personnel certified to administer CPR (e.g. first responders, ambulatory personnel, nurses, physicians or medical staff).

2 Warnings and Cautions

This chapter includes a list of warnings and cautions that relate to the RMU-1000 ACC and its accessories. Many of these messages are repeated elsewhere in this User Manual and on the RMU-1000 ACC or accessories.

2.1 ⚠ WARNINGS:

Immediate hazards that will result in serious personal injury or death.

None known.

Conditions, hazards, or unsafe practices that may result in serious personal injury or death.

- Improper use can cause injury to patient. Use the RMU-1000 ACC only as instructed in the User Manual.
- Improper use can cause injury to operator or bystander. Keep fingers and hands away from Piston during operation.
- Improper maintenance can cause the RMU-1000 ACC not to function. Maintain the RMU-1000 ACC and rechargeable Battery Pack only as described in the User Manual. Failure to maintain the Battery Pack per the instructions outlined in this User Manual will result in the RMU-1000 ACC becoming inoperable.
- No modification of this equipment is allowed. The RMU-1000 ACC contains no user-serviceable parts. Do not disassemble, repair or alter the RMU-1000 ACC or any of its components.
- Do not immerse Compression Module or Battery Pack in water or other liquids. Immersion in fluids may result in fire or explosion.
- Do not sterilize the RMU-1000 ACC or its accessories.
- Do not let fluids get into the RMU-1000 Compression Module. Avoid spilling fluids on the ACC or its accessories. Spilling fluids into the RMU-1000 ACC may damage it or cause a fire or shock hazard.
- If the patient is too large for the Frame, remove Frame and continue manual CPR compressions. Do not use the ACC if the Frame cannot be latched to the backboard.
- If the Piston cannot be adjusted to reach the patient's chest, the patient is too small. Remove Frame and continue with manual CPR compressions.
- Do not initiate ACC compressions if the Piston is not in the proper position. An incorrect start position may compromise the patient’s blood circulation.
- Do not use the ACC if the Frame cannot be latched in place (for any reason).
- Incorrect position over chest can result in injury or lack of effectiveness.
- Incorrect Piston start height can result in injury or lack of effectiveness.
- Carefully monitor the position of the Piston on the patient's chest to ensure that it has not moved from the appropriate target area.
- Changed position over the chest during operation can result in injury or lack of effectiveness.
- Do not leave the ACC running while unattended. Patient injury may result if the unit is left unattended.

WARNINGS (continued)

- The ACC can become hot during extended use. The applied part of the piston may rise 5°C above ambient.
- If the position of the Piston changes as a result of defibrillation or other therapies, immediately stop compressions and re-adjust the position of the ACC.
- Mechanical chest compressions may cause artifact and interfere with ECG analysis. Always pause compressions before performing ECG analysis with other equipment.
- When the Battery Pack indicator shows one red segment, replace the Battery Pack as soon as possible with a sufficiently charged Battery Pack or apply external power.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- If a spare Battery Pack or external power source are not available and the ACC stops compressions, remove the unit from the patient and begin manual compressions immediately.
- If there is a malfunction, the compressions are not sufficient, or something unusual occurs during operation, then push the ON/OFF Button for one second to stop the ACC from delivering compressions and remove the unit from the patient. Start manual chest compressions as soon as possible.
- If there is a malfunction and the unit will not turn OFF, remove Battery Pack to stop compressions. Remove the unit from the patient. Start manual chest compressions as soon as possible.
- The Patient Wrist Straps are designed only for use with Defibtech RMU-1000 Automated Chest Compression Systems. Do not apply to other items such as a stretcher or bedside rails.
- Do not use the Patient Wrist Straps if damaged, soiled, or if Velcro does not bond sufficiently to securely fasten the patient's wrists to the RMU-1000 ACC.
- Do not over-tighten the Patient Wrist Straps to prevent potential injury. If the Patient Wrist Straps are too loose, they may not securely fasten the patient's arms to the ACC appropriately.
- Do not use the Patient Wrist Straps to lift the patient. The straps are only intended to attach the patient's arms to the RMU-1000 ACC during transport.
- Observe the patient's arms during use of the Patient Wrist Straps. Do not leave a patient unattended when using the ACC or its accessories (e.g. Patient Wrist Straps).
- Do not obstruct intravenous (IV) access when deploying the RMU-1000 or when attaching the Patient Wrist Straps.
- Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator.
- The ACC system components must be cleaned and the Patient Interface Pad replaced between patients to avoid cross contamination.
- The use of accessories other than those specified may result in increased emissions or decreased immunity of the RMU-1000 ACC.
- Portable and mobile RF communications equipment should be used no closer to any part of the RMU-1000 ACC, including cables, than necessary.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Do not use in the presence of flammable gases or anesthetics. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move away from patient, if necessary.

2.2 ⚠ CAUTIONS:

Conditions, hazards, or unsafe practices that may result in minor personal injury, damage to the RMU-1000 ACC, or loss of data.

- The Compression Module must be assembled and locked to the Frame for proper operation.
- The Frame must be latched to the Backboard for proper operation.
- A new battery is set to ship mode. Must be activated before use! Activate battery by charging in unit or charger.
- Follow all Battery Pack labeling instructions. Do not use a Battery Pack after its expiration date.
- Use only Defibtech approved batteries and accessories.
- The ACC must be paused in order to replace a Battery Pack. Failure to do so will require the user to power up the ACC and reset the start position in order to resume compressions.
- Only use Defibtech accessories to power the ACC from an external power source.
- The Battery Pack must always be installed to operate the ACC from external power. Without the Battery Pack, the ACC will flash the warning indicator and will not perform compressions.
- The mains power quality must be that of a typical commercial or hospital environment.
- Defibrillation electrodes and pads should not be in contact with and be clear of the Piston and other ACC components.
- Make sure other equipment and/or drugs are applicable for use with the ACC. Consult the equipment's operating instructions.
- Avoid gel on chest. Gel on the chest (e.g. from defibrillation pads or ultrasound) in the Patient Interface Pad target area may result in movement of the piston. Be sure to remove any gel before use.
- Defibrillation pads or electrodes must be removed or moved away from the Patient Interface Pad target area.
- Do not use on open wounds or if visible signs of existing injuries.
- The ACC should be applied to the patient's bare chest. Remove clothing, undergarments and jewelry before use.
- If the RMU-1000 ACC becomes hot, prolonged contact with the patient's skin could result in skin burns. If necessary, remove the patient's arms from the Patient Wrist Straps.
- Do not allow the use of Stabilization Strap to delay or prevent other treatment of the patient. Apply strap as soon as possible after beginning compressions and always before patient movement.

CAUTIONS (continued)

- Recycle or dispose of lithium-ion batteries in accordance with local, state, provincial, and/or national regulations. To avoid fire and explosion hazard, do not burn or incinerate the Battery Pack. Do not crush.
- Use and store the RMU-1000 ACC only within the range of environmental conditions specified in the technical specifications.
- Always store the ACC so it is ready to go for use. Store the Compression Module with a fully charged Battery Pack installed and a Patient Interface Pad attached to the Piston. It is recommended to maintain a charged spare Battery Pack and have the external power adapter available with the unit at all times.
- Although the RMU-1000 ACC is designed for a wide variety of field use conditions, rough handling beyond specifications may result in damage to the unit.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

3 Setting Up the RMU-1000 ACC

This chapter describes the steps required to make your Defibtech RMU-1000 ACC operational. The RMU-1000 ACC is designed to be stored in a Carrying Case with a small number of easy to assemble components or stored in a fully assembled "ready" state. This chapter explains how to set up the RMU-1000 ACC device.

3.1 Overview

The following components and accessories are included with the RMU-1000 ACC. Replacement and other accessories are detailed in the "*RMU-1000 ACC Accessories*" section. Before getting started, identify each component and ensure that the package is complete.

Backboard

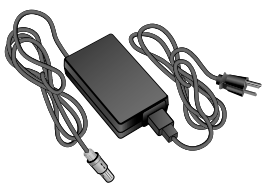
Battery Pack

Frame

Compression Module

Carrying Case

AC Adapter



Patient Interface Pad *(package of 3)*

Top *Bottom*

Stabilization Strap

Patient Wrist Straps

User Manual and Quick Reference Guide

3.2 Complete Initial Assembly of the ACC

Before being placed into service, the RMU-1000 ACC unit should be completely assembled and operationally checked to ensure that all components are present and functional.

3.3 The Backboard

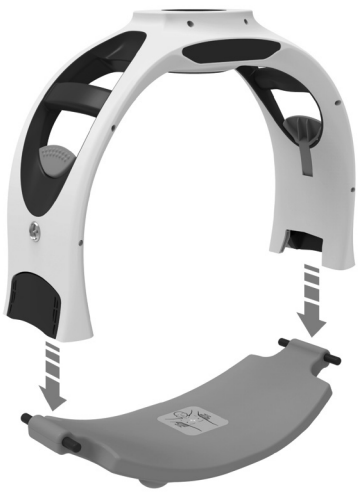
The Backboard is the base for the ACC system. It is placed under the patient and has attachment points to which the Frame latches. There are no moving parts on the Backboard.

3.4 The Frame

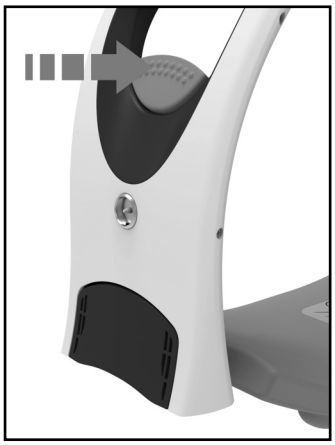
The Frame holds the Compression Module. It attaches to the Backboard and is used to maintain the Compression Module's position over the patient.

To attach the Frame to the Backboard:

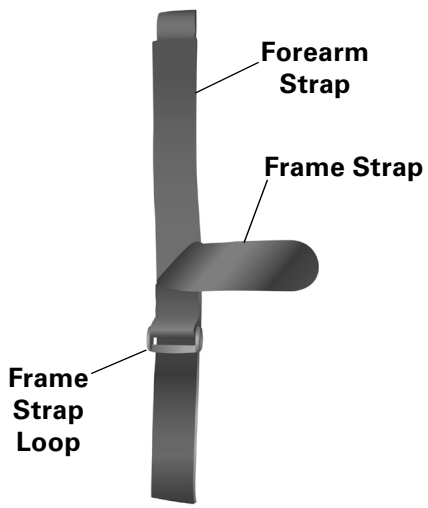
- Place the Backboard on a flat surface, such that the patient position diagram is visible.
- Attach the Frame to the Backboard by aligning the Frame latches over the Backboard pins and pushing down until the latches snap into place. The latches may be clicked into place one at a time or simultaneously.

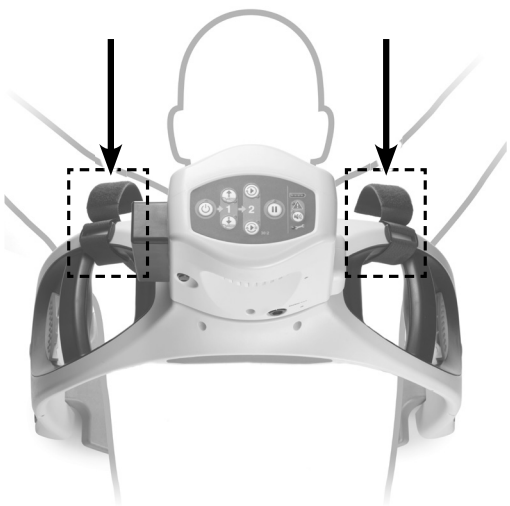


To remove the Frame, push in on the two backboard release levers and lift the Frame off of the Backboard. The latches may be released together or one at a time.



3.5 Attaching the Patient Wrist Straps to the Frame



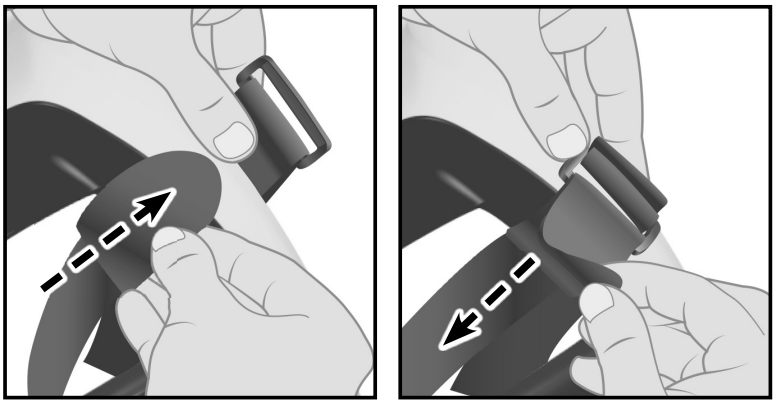


The Patient Wrist Straps are designed to attach a patient's arms to the ACC for ease of transporting the patient and the ACC. As shown in the above left illustration, each Patient Wrist Strap is comprised of two main strap sections: a Frame Strap that attaches to the ACC's Frame and a Forearm Strap that wraps around the patient's wrist.

Note: As shown in the above right illustration, when attaching the ACC's Frame to the Backboard, the Patient Wrist Straps can be oriented towards the patient's head to maintain access to the ACC Frame's Backboard Release Levers or on the opposite side of the ACC Frame as appropriate.

Attaching the Patient Wrist Straps to the Frame (continued)

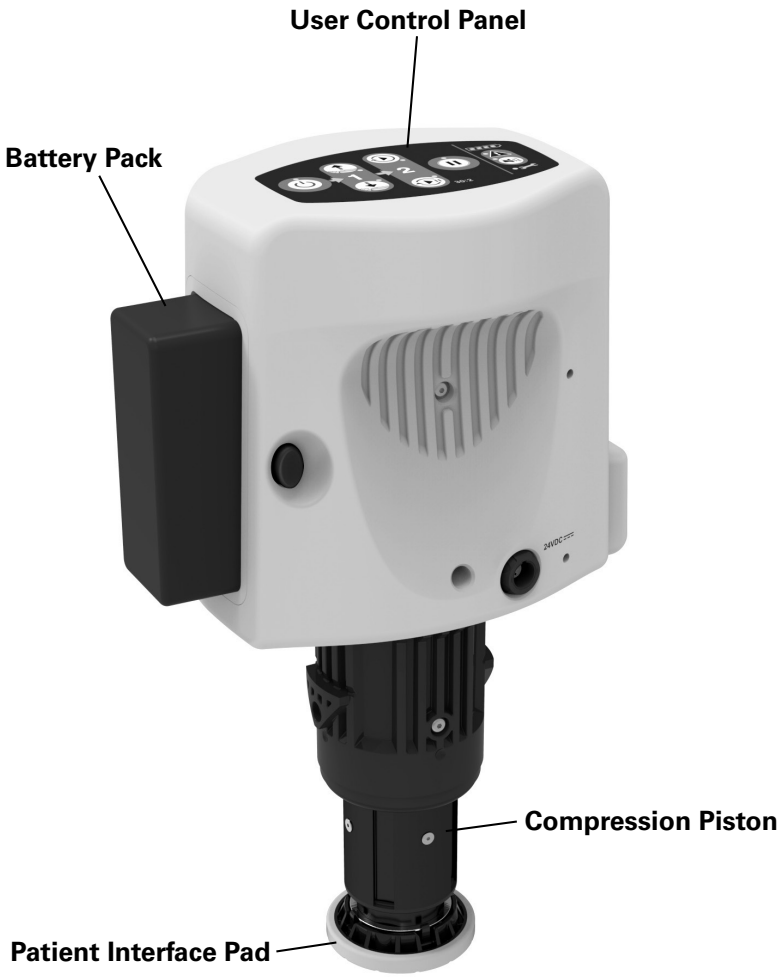
To maximize the available time to perform a rescue, Defibtech recommends that the Patient Wrist Straps be affixed to the ACC Frame using the instructions shown below **prior** to a rescue and that the Frame be stored in the ACC's Carrying Case with the Patient Wrist Straps already attached to the Frame.



1. Attach the Frame Strap to the ACC Frame by inserting the rounded end of the Frame Strap through the Frame Strap Loop, as shown in the above left illustration.
2. After the Frame Strap has been inserted through the Frame Strap Loop, pull the end of the Frame Strap in the opposite direction so that the Frame Strap is tightly wrapped around the ACC Frame, as shown in the above right illustration. Secure in place using the Velcro® on the underside of the Frame Strap.
3. If necessary, rotate the attached Patient Wrist Strap so that the Forearm Strap component faces up. This allows the procedure described in Section 4.5 to be performed.
4. Repeat the above three steps to attach the second Patient Frame Strap's Frame Strap to the ACC Frame.

3.6 The Compression Module

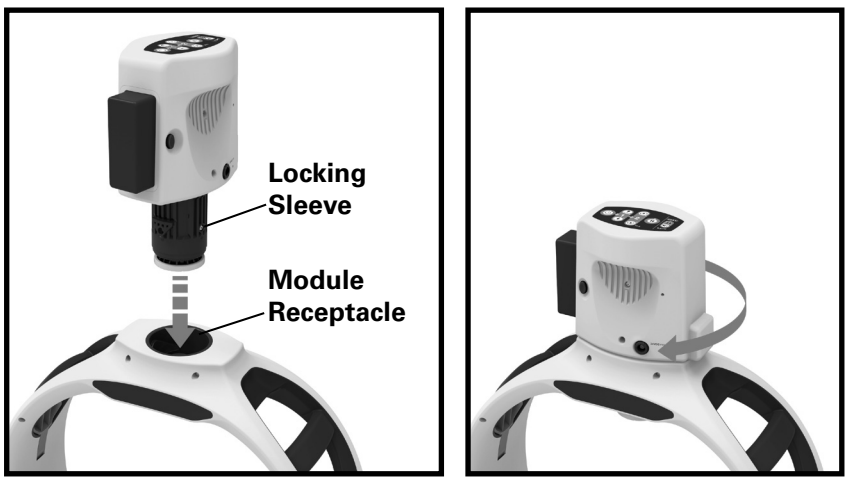
The Compression Module contains all the active components of the ACC system, including the User Control Panel, the Battery Pack and the Compression Piston. It easily attaches to the Frame and locks into place for operation.



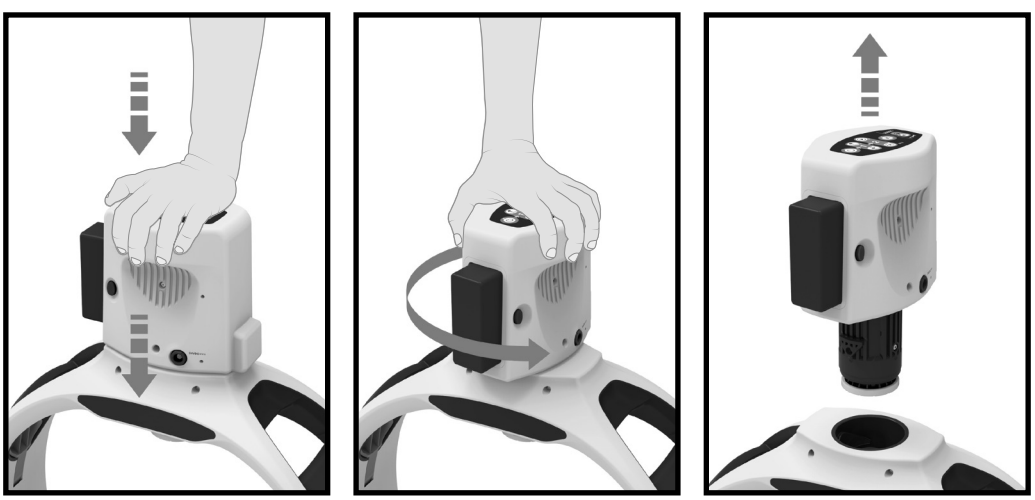
The Compression Module (continued)

To attach the Compression Module to the Frame, perform the following steps:

- Attach the Frame to the Backboard (described in Section 3.4).
- Insert the locking sleeve of the Compression Module into the module receptacle of the Frame as shown below. The Module should be inserted at approximately 90 degrees to the Frame at which point it should rest in the Frame. Rotate the Module in either direction until it is in line with the Frame and snaps to lock into place. When properly attached, the Compression Module should be securely attached to the Frame.



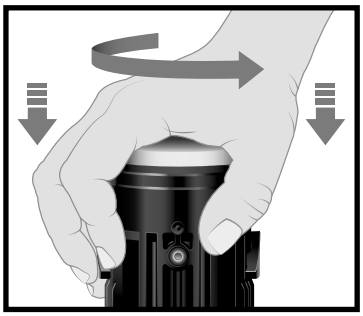
To remove the Compression Module from the Frame, push down on the Compression Module and then rotate it approximately 90 degrees to either direction. The Compression Module can then be lifted out of the Frame. Be careful not to drop the Module.



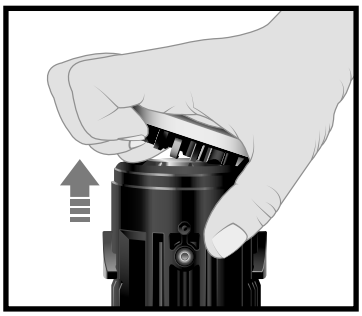
3.7 Installing and Removing the Patient Interface Pad

Attach a Patient Interface Pad to the distal end of the Piston by pressing the pad onto the piston until it snaps into place, rotating pad if necessary. To remove the Patient Interface Pad, grasp the pad and pull, as shown below.

Note: Prior to installation, check to make sure that the Patient Interface Pad is clean and is undamaged. If the Patient Interface Pad is damaged (e.g. one or more of the pins on underside of the pad is crushed and/or missing), discard it and install an undamaged pad.



Installing



Removing

3.8 Installing and Removing the Battery Pack

The Battery Pack provides power to the RMU-1000 ACC. Do not install the Battery Pack after the expiration date printed on the label.

Before inserting the Battery Pack into the RMU-1000 ACC, ensure that the Battery Pack opening in the side of the Compression Module is clean and clear of any foreign objects. Insert the Battery Pack into the opening on the side of the ACC Compression Module. Push the Battery Pack all the way in until the latch clicks. The Battery Pack will operate in either orientation (with the contacts toward the unit).

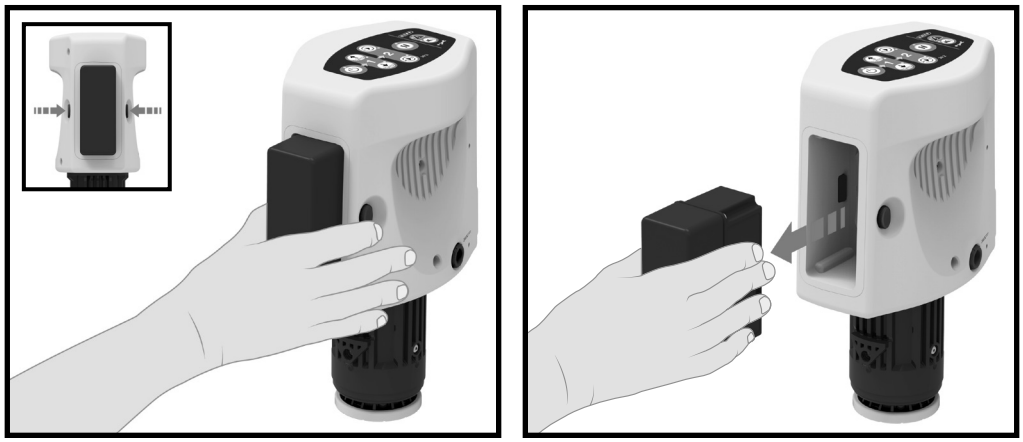
When the Battery Pack is inserted, the RMU-1000 ACC will display the status of the Battery Pack on the Compression Module's Battery Pack indicator for approximately three seconds.

Ship Mode: Battery Packs are shipped from the factory at less than 30% charge capacity in a low-power state known as ship mode to minimize energy loss during shipment. Any Battery Pack in ship mode cannot power the ACC until it is taken out of ship mode and should be transferred from ship mode to active mode as soon as possible upon receipt. To transfer a Battery Pack from ship mode to active mode, insert the Battery Pack into the Compression Module as described earlier in this section. Then connect the AC Adapter to the Compression Module, as described in Section 3.9, *"Charging the Battery Pack."* Upon detecting external power (allow at least 10 seconds for this to occur), the Battery Pack will automatically switch from ship mode to active mode. The optional Battery Pack Charging Station (see Section 6.7) can also be used to switch Battery Packs from ship mode to active mode. Defibtech recommends charging any Battery Pack that has been brought out of ship mode to full capacity (see Section 3.9 for details). In addition, a Battery Pack should not be stored in ship mode for any longer than 12 months before charging it to full capacity.

CAUTION

A new battery is set to ship mode. Must be activated before use!
Activate battery by charging in unit or charger.

To remove the Battery Pack, squeeze the Battery Pack eject release latches on either side of the Battery Pack opening. After the Battery Pack is partially ejected, pull the Battery Pack out.

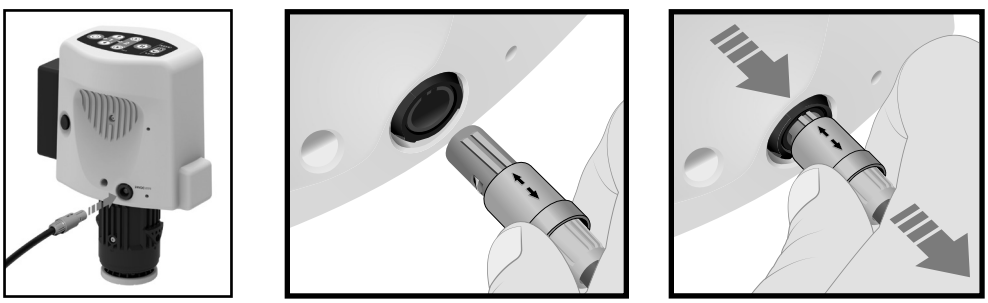


CAUTION

The Battery Pack must always be installed in the unit in order to operate the RMU-1000, even when powered by the AC adapter.

3.9 Charging the Battery Pack

The ACC battery is a proprietary rechargeable Battery Pack. Make sure to fully charge a Battery Pack as part of preparing the ACC for service. To charge the Battery Pack, install it into the Compression Module and connect the AC Adapter to the external power input jack on the Compression Module. The Battery Pack can also be charged using an optional Battery Pack Charging Station (see Section 6.7 for details).



To connect the AC Adapter to the ACC, insert the AC adapter plug into the Compression Module's external power input jack as shown in the center illustration above. As the jack is keyed, the raised notch on the plug must align with the notch on the jack in order for the plug to seat properly and lock into place. To remove the plug, grasp the top-most portion of the plug barrel and pull, as shown in the right-most illustration above.

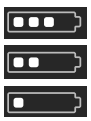
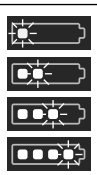
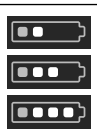
A fully charged Battery Pack condition is indicated by all-green LEDs on the User Control Panel's Battery Pack status indicator. (To determine Battery Pack status, see the "Battery Pack Indications and Alerts" charts that follow.)

Note: The Battery Pack may become unresponsive and non-functional if improperly maintained and left fully depleted. See Section 5.1, *"Routine Unit Maintenance"*, for ACC maintenance information.

CAUTION

Only use approved accessories with the RMU-1000. The Battery Pack, Battery Charger, and AC adapter are specifically designed for use with the ACC. Using other accessories can cause permanent damage and void the warranty.

Battery Pack Indications and Alerts (User Control Panel)

LED Indications	*Visual Indication*	*Description*	*Action*
All green		Battery Pack fully-charged (>80%)	None
Partial green		Number of bars show percent of Battery Pack charge (20% per bar)	None (if possible, charge to full capacity)
Red bar (solid)		Battery Pack low (<20% charge remaining)	If performing a rescue, replace Battery Pack with a charged Battery Pack or connect external power. Otherwise, charge Battery Pack as soon as possible.
Red bar (slow flashing)		Battery Pack low (<10% charge remaining)	If performing a rescue, replace Battery Pack with a charged Battery Pack or connect external power. Otherwise, charge Battery Pack as soon as possible.
Red bar (fast flashing)		Battery Pack not installed	Install a charged Battery Pack
		Battery Pack is in ship mode	Transfer Battery Pack from ship mode to active mode. See "*Ship Mode*" in Section 3.8, "*Installing and Removing the Battery Pack*," for more information.
		Battery Pack malfunction	Replace Battery Pack with a charged Battery Pack
		Battery Pack depleted	If performing a rescue, replace Battery Pack with a charged Battery Pack or connect external power. Otherwise, charge Battery Pack as soon as possible.
Partial green (slow flashing)		Battery Pack charging	None
Left LED is amber color		Battery Pack has reached end of life	Replace with a new Battery Pack
All off		Battery Pack depleted	If performing a rescue, replace Battery Pack with a charged Battery Pack or connect external power. Otherwise, charge Battery Pack as soon as possible.
		Battery Pack malfunction	Replace Battery Pack with a charged Battery Pack

Battery Pack Indications and Alerts (Battery Pack)

To check the charge of a Battery Pack while it is not installed in the ACC, press the button on the bottom of the Battery Pack for about a second. The Battery Pack charge indicator will show the amount of remaining charge:

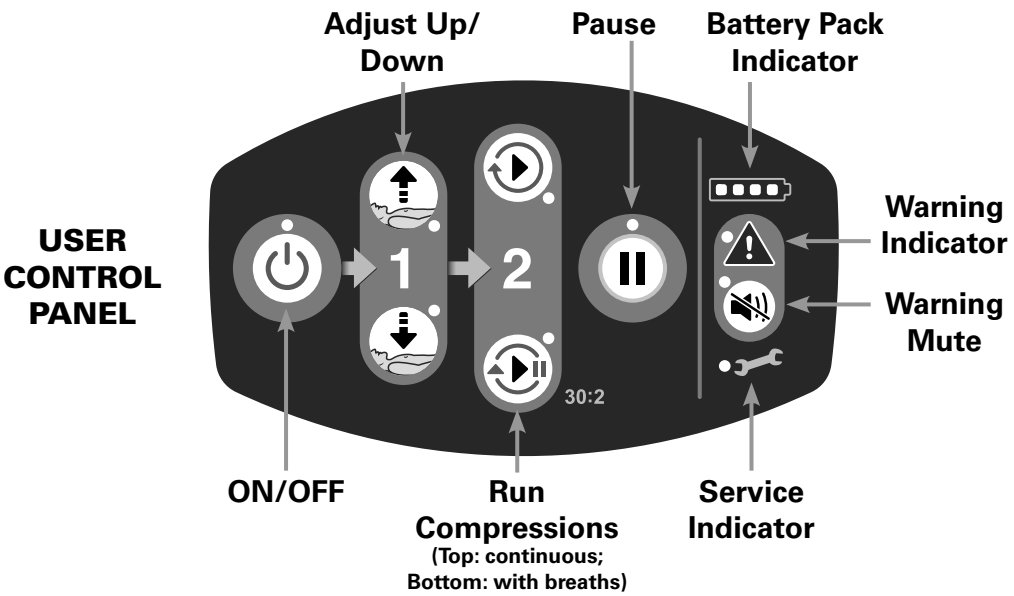
>80%	<80%	<60%	<40%	<20%	Depleted or Malfunction*

***NOTE:** If the Battery Pack indicators do not illuminate after the button on the Battery Pack is pressed, see Section 5.4, *"Troubleshooting"*.

3.10 Completing and Testing the RMU-1000 ACC

Once the previous steps have been completed to set up your RMU-1000 ACC, follow this procedure to perform an initial test of the unit:

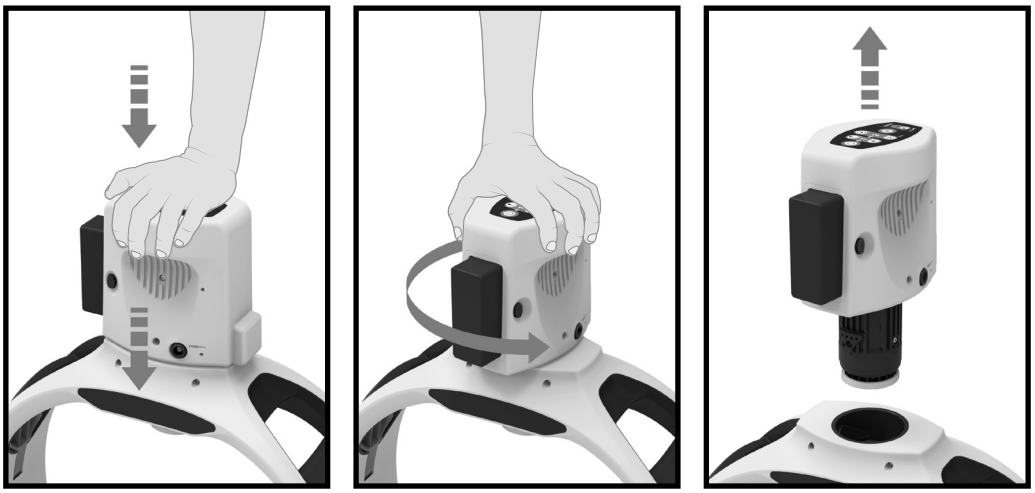
1. Turn the unit on by pressing the **ON/OFF** button for at least one second.
2. Verify that piston is fully retracted into the Compression Module, the **Warning Indicator** is not illuminated and the **Battery Pack Indicator** is green.
3. Press the **Adjust Down** button to drive the piston to the bottom of its stroke.
4. Press the **Adjust Up** button to bring the piston back to the home position.
5. Turn unit off by pressing and holding the **ON/OFF** button for more than one second.



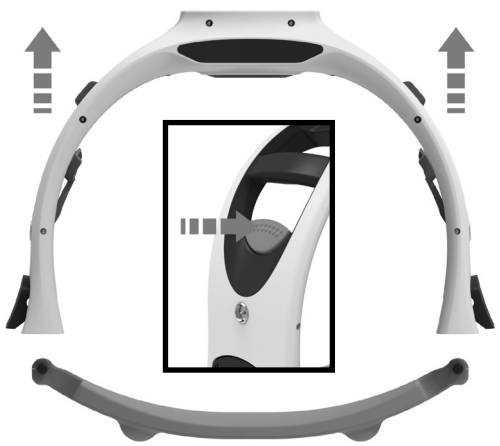
3.11 Disassembling and Storing the RMU-1000 ACC

The RMU-1000 ACC should be stored in the Carrying Case. Use the following steps to disassemble and store the unit in the case:

- Remove the Compression Module from the Frame by pushing down and rotating the Compression Module approximately 90 degrees in either direction. Lift the Compression Module from Frame and place in the appropriate storage section of the case. Always leave a fully charged Battery Pack inserted in the Compression Module when storing.



- Release the Frame from the Backboard by pressing the Backboard release levers and lifting the Frame from the Backboard. Note that the Frame can be released one side at a time.
- Place the components, User Manual, and Quick Reference Guide in the Carrying Case.
- Place at least one Patient Interface Pad in the Carrying Case.



Store the RMU-1000 ACC in environmental conditions within range of the specifications (see "Environmental" section in Chapter 7 of this manual).

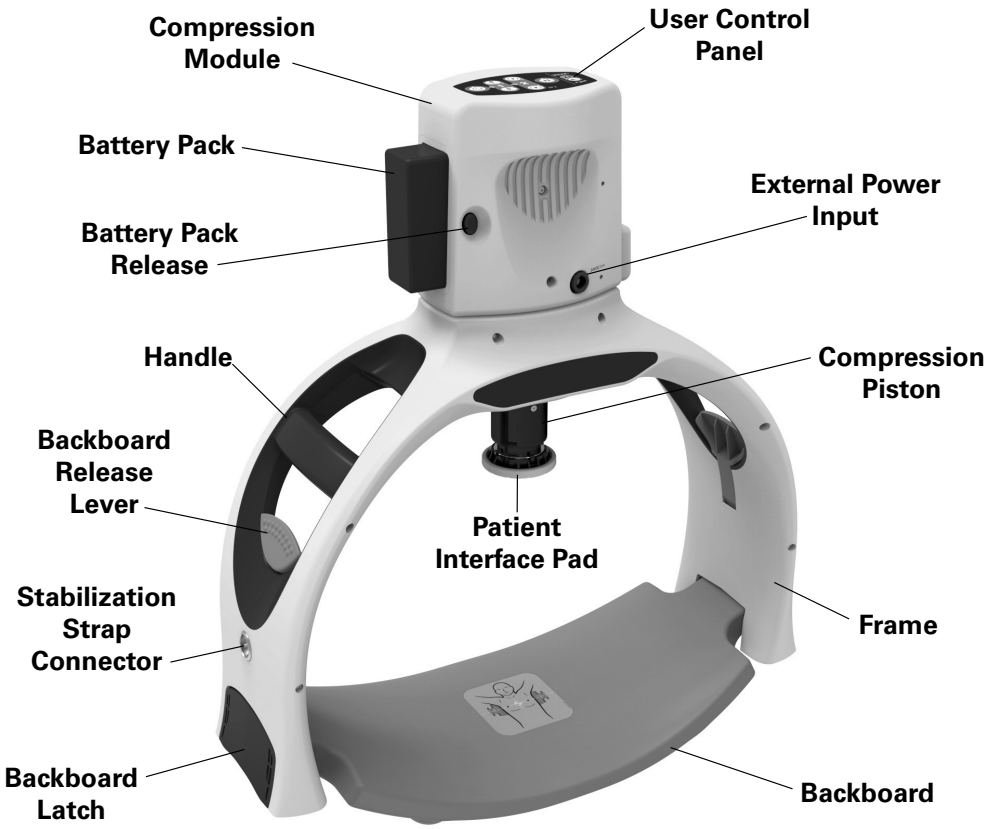
4 Using the RMU-1000 ACC

This chapter describes how to use the RMU-1000 ACC during an event. The RMU-1000 ACC was designed for simple operation allowing the operator to focus on providing care to the patient.

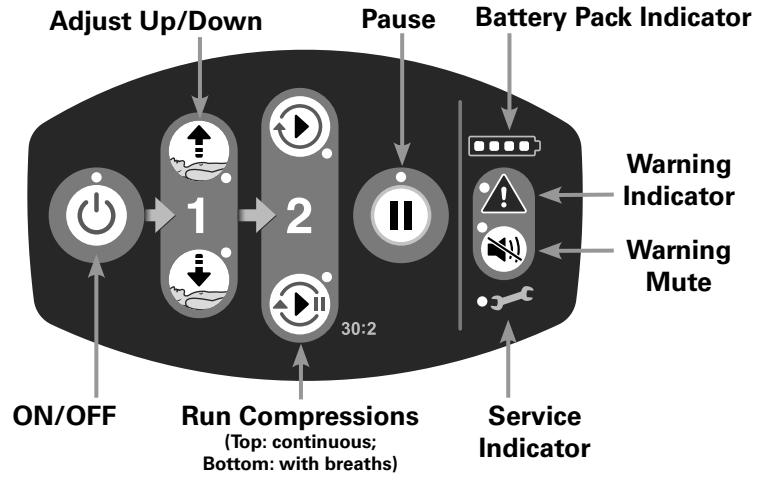
The following sections describe in detail how to use the RMU-1000 ACC. The basic steps for use are:

- Place Backboard under patient
- Attach Frame to Backboard
- Attach Compression Module to Frame
- Press ON/OFF button for at least one second to turn ON
- Adjust piston height
- Press Run button to perform compressions

4.1 Overview



Control Panel



ON/OFF Button – Press the ON/OFF button for at least one second to turn the ACC on or off.

Adjust Up/Down Buttons – These buttons are used to move the Piston up or down relative to the patient's chest. LED indicators adjacent to the Adjust Up/Down Buttons illuminate and blink when the ACC is requesting that the piston be adjusted to the patient's chest.

Adjust Up retracts the piston into the Compression Module.

Adjust Down moves the piston toward the patient.

Run Compressions Buttons – These buttons start chest compressions.

The **Run Continuous** button performs compressions until the Pause or Off button is pressed. The adjacent LED flashes at the rate the AHA/ERC/ILCOR suggests for giving rescue breaths without the ACC stopping for delivery of breaths (approximately 1 breath every 6 seconds).

The **Run With Breaths** button performs compressions according to the compressions-with-breaths protocol and pauses for the operator to give rescue breaths. A reminder chirp and flashing LED occur during the 3 compressions prior to the ventilation pause.

Pause Button – The Pause button stops compressions when running. Push Pause a second time to resume compressions.

Battery Pack Indicator – Indicates the approximate remaining Battery Pack capacity. When the Battery Pack is getting low, only one indicator segment will be visible and it will turn red – replace Battery Pack as soon as possible or apply external power (see Section 3.9 for details).

Warning Indicator – The Warning Indicator illuminates to notify the user that the ACC has determined that there is a problem (see Section 5.4, *"Troubleshooting"*).

Warning Mute Button – The Warning Mute button silences the audible sound associated with a warning. The Warning Mute will automatically disable after 1 minute.

Service Indicator – The Service Indicator illuminates when the ACC requires servicing. See Section 5.4, *"Troubleshooting,"* for more details.

4.2 Arrival and Setup

This section details the steps required to use the RMU-1000 ACC during an emergency. Based on performance testing, the expected deployment time* is less than 45 seconds.

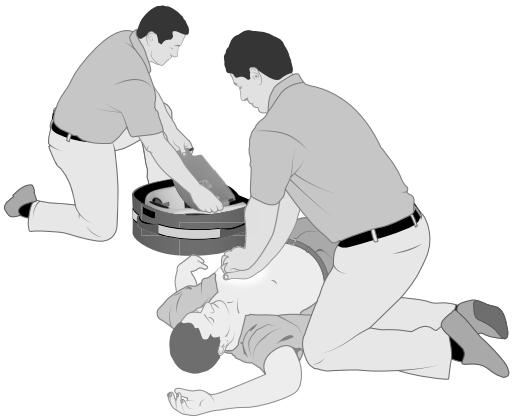
Note: **To minimize CPR interruptions and to most effectively use the RMU-1000, two rescuers are recommended.**

Note: **Providing manual chest compressions takes precedence over setting up and initiating use of the RMU-1000.**

Note: **Refer to Section 5.4 ("Troubleshooting") if any problems are encountered during ACC setup.**

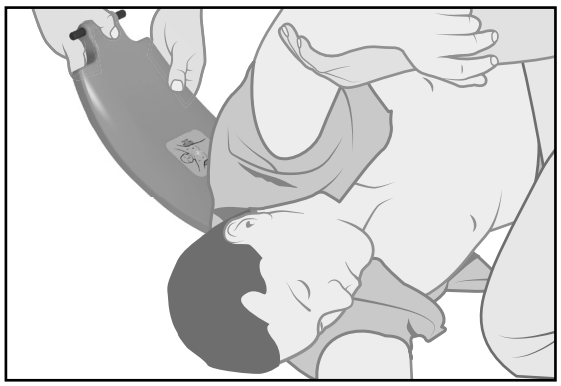
The following instructions are for a two-rescuer scenario.

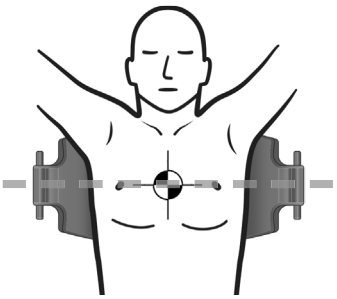
STEP 1) Confirm that the patient is unresponsive and not breathing. Remove clothing from the patient's chest and begin manual CPR immediately.



STEP 2) Open the Carrying Case and remove the ACC Backboard.

STEP 3) Place the Backboard under patient just below armpits. Lift patient body slightly and slide the Backboard under patient or roll patient from side to side, as needed. The center of the Backboard should be in line with the nipple line of the patient. Accurate placement of the Backboard will help with the alignment step later.

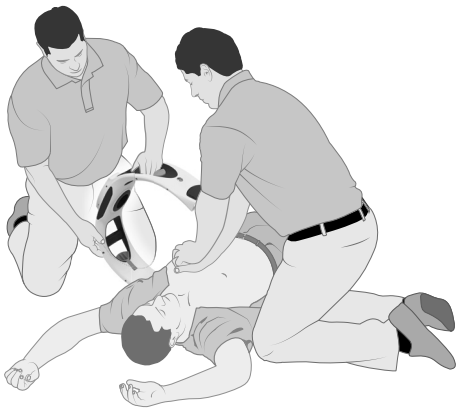




STEP 4) Resume manual CPR.

*From the time the Backboard is used to the first compression.

STEP 5) Place Frame over patient such that the Backboard is aligned with the mounting pins on the Frame. Push down firmly until the Frame latches to the Backboard. Alternatively, attach the side of the Frame nearest to you to the Backboard and then rotate the Frame to latch to the opposite side of the Frame. Continue manual CPR compressions while attaching the Frame to the Backboard.



STEP 6) Pull up on the Frame to make sure that Frame is securely latched to the Backboard.

WARNING

If patient is too large for the Frame, remove Frame and continue manual CPR compressions. Do not use the ACC if the Frame cannot be latched to the backboard.

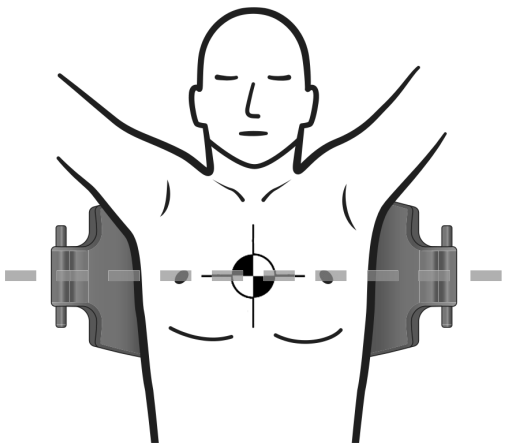
STEP 7) Remove Compression Module from case. Check to make sure a Patient Interface Pad is installed. If not, install a Patient Interface Pad per the instructions in Section 3.7, *"Installing and Removing the Patient Interface Pad."* Also make sure that a Battery Pack is installed. If not, install a Battery Pack per the instructions in Section 3.8, *"Installing and Removing the Battery Pack."*

STEP 8) Mount the Compression Module in the Frame by inserting it at approximately 90 degrees to the Frame and twisting the Module in either direction until it is aligned with the Frame and locks in place as shown:

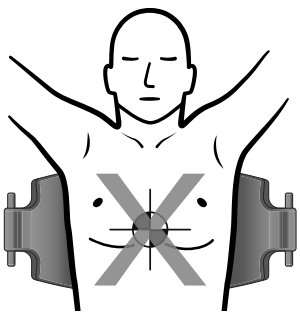
Arrival and Setup (continued)

CAUTION Compression Module must be locked to Frame for proper operation.

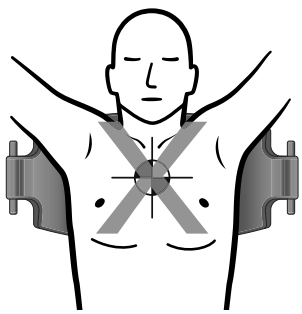
STEP 9) If needed, adjust the Frame and Backboard assembly so that the Compression Module piston is positioned over the chest and directly in line with the nipples. Note that the compression target point is the same location as that used for manual compressions according to resuscitation guidelines *(Rajab,T et al. Technique for chest compressions in adult CPR. World J Emerg Surg. 2011; 6:41)*.



WARNING Do not initiate ACC compressions if the piston is not in the proper position.



Too low

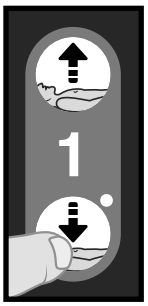


Too high

4.3 Operation and Adjustment

STEP 1) Press the ON/OFF button for at least one second to turn the unit on. If the Battery Pack indicator shows red (low battery), or the ACC does not turn on, replace the Battery Pack or connect external power. See Section 4.7 *"Power"* for details.

STEP 2) The Piston must be adjusted to the height appropriate for the specific patient to ensure that compressions are delivered to the proper depth. Adjust the height of the Piston by pressing the Adjust Down and Adjust Up buttons until the Piston is firmly touching the patient's chest as shown.



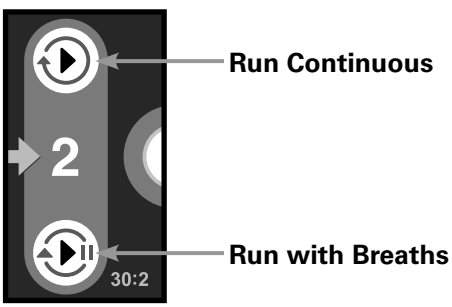
Correct **Too High**

Note: The ACC will automatically stop if the Piston encounters excessive resistance.

WARNING

If the Piston cannot be adjusted to reach the patient's chest, the patient is too small. Remove Frame and continue with manual CPR compressions.

STEP 3) Once the Piston is properly adjusted, start compressions, in accordance with your emergency response protocol, by pushing the **Run Continuous** button OR the **Run with Breaths** button:



To temporarily stop compressions for any reason, press the pause button. If necessary, make adjustments to the Piston position using the Adjust Up/Down Buttons so that it is making firm contact with the patient's chest. To resume compressions, push the **Run Continuous** button OR the **Run with Breaths** button.

Compressions may also stop or fail to start because the Piston requires adjustment to the patient's chest. The ACC will indicate that Piston adjustment is required by blinking the Adjust Up/Down LEDs. Press the Pause button to clear a Piston adjustment error condition. Readjust the Piston using the Adjust Up/Down Buttons so that it is making firm contact with the patient's chest. To resume compressions, push the **Run Continuous** button OR the **Run with Breaths** button.

Note: While in use, the Compression Module's internal fan may activate in order to maintain an optimal operational temperature level inside the Module. The fan will deactivate when that level has been achieved and may subsequently reactivate, if needed. This behavior is normal.

Operation and Adjustment (continued)

Note: If there is no user action after the ACC is powered on and the device is not performing compressions, the Compression Module will automatically power itself off after 10 continuous minutes of inactivity have elapsed.

Incorrect position of the Piston over chest can result in injury or lack of effectiveness.

Incorrect Piston start height can result in injury or lack of effectiveness.

Carefully monitor the position of the Piston on the patient's chest to ensure that it has not moved from the appropriate target area.

Changed position over the chest during operation can result in injury or lack of effectiveness.

ACC compressions may interfere with ECG analysis. Pause compressions during ECG analysis.

When Battery Pack indicator shows one red segment, replace Battery Pack as soon as possible or apply external power.

Do not leave the ACC running while unattended. Patient injury may result if the unit is left unattended.

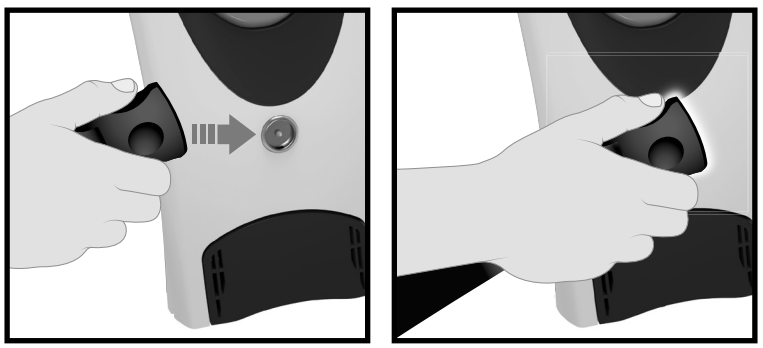
If there are malfunctions, interruptions, the compressions are not sufficient, or something unusual occurs during operation, then push the ON/OFF Button for one second to stop the ACC from delivering compressions and remove the unit from the patient. Start manual chest compressions as soon as possible.

Improper operation may injure operator or bystander. Keep fingers and hands away from Piston during operation.

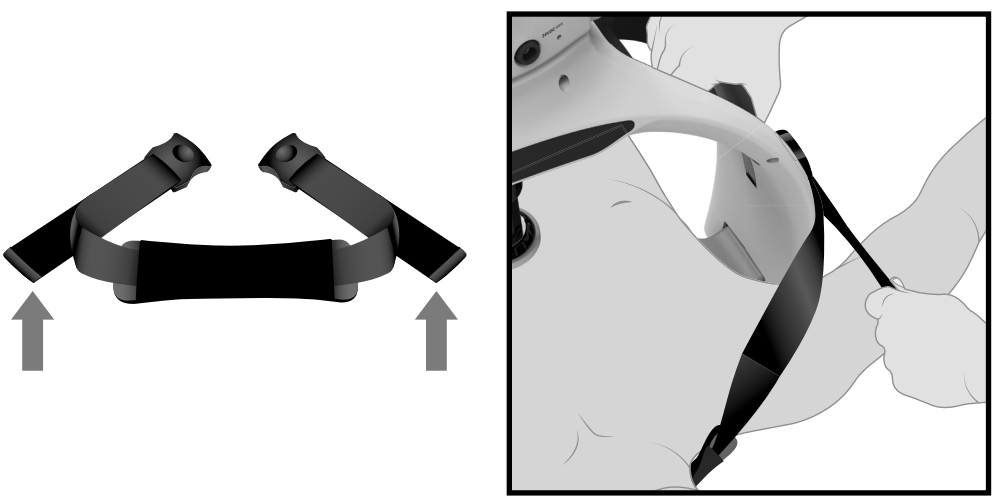
4.4 Stabilization

Once compressions have started, to help ensure the ACC remains appropriately positioned, apply the Stabilization Strap as described below:

- Remove the Stabilization Strap from Carrying Case, if not already at the patient's side.
- Lift patient's head and place strap behind patient's neck. ***Note:*** Use other accepted patient handling techniques if the patient has or may be suspected to have head, neck, spine or other bone-structure compromising injuries.
- Connect the Stabilization Strap to the Frame by pushing the strap clips into the Frame's Stabilization Strap Connectors until they click into place.



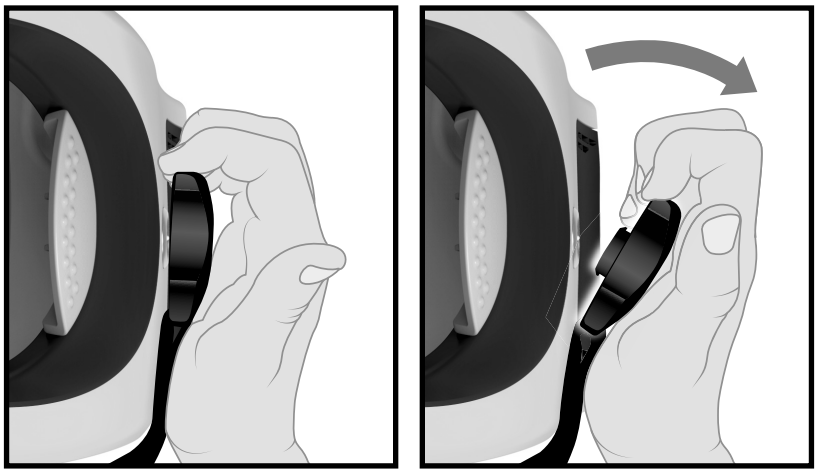
- The Stabilization Strap's length can be adjusted using the self-adhesive Velcro that holds both strap clips to the Strap. Be sure that the Strap is sufficiently tightened so that the ACC's correct position over the patient's chest can be maintained.



- Make sure the Piston is correctly positioned on patient's chest. If not, stop compressions, loosen the Stabilization Strap and readjust as instructed above. ***Note:*** As with any step in using the ACC, it is important to minimize the time CPR is not being performed. If the ACC is not performing compressions for any reason, always consider performing manual CPR.

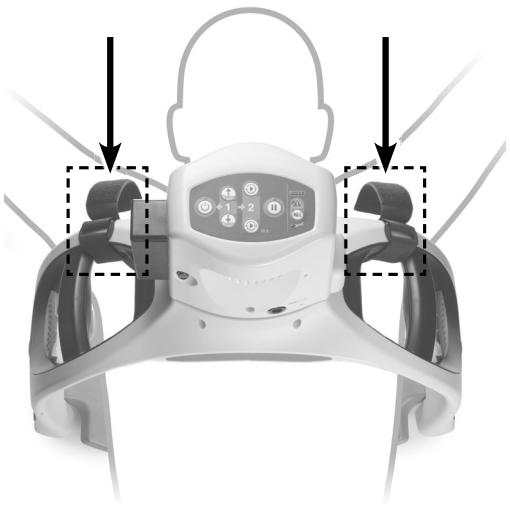
Stabilization (continued)

- To remove the Stabilization Strap, grip the top of the strap clip and pull the clip away from the Frame in a angled motion, as shown in the images below.



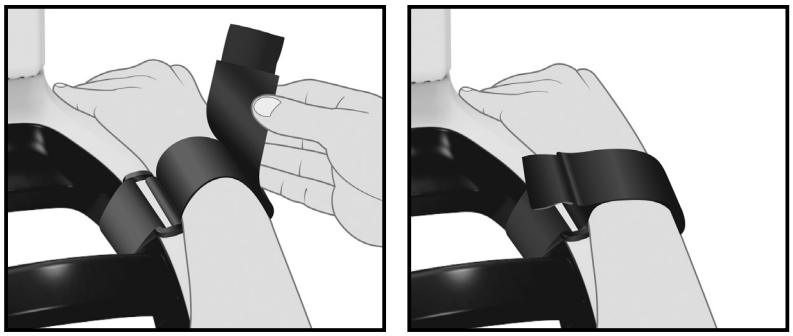
4.5 Securing the Patient Wrist Straps to the Patient

Note: To maximize the available time to perform a rescue, Defibtech recommends that the Patient Wrist Straps be affixed to the ACC Frame using the instructions shown in Section 3.5 **prior** to a rescue and that the Frame be stored in the ACC's Carrying Case with the Patient Wrist Straps already attached to the Frame.



As shown in the illustration above, when attaching the ACC's Frame to the Backboard, the Patient Wrist Straps can be oriented towards the patient's head to maintain access to the ACC Frame's Backboard Release Levers or on the opposite side of the ACC Frame as appropriate.

Securing the Patient Wrist Straps to the Patient (continued)



To secure the Patient Wrist Straps to the patient's wrists:

- Secure the Forearm Strap of the Patient Wrist Strap by placing the patient's wrist on top of the Forearm Strap and placing the soft Velcro part of the strap across the patient's wrist, as shown in the above left illustration.
- Secure the patient's wrist to the ACC's Frame by wrapping the hooked Velcro onto the soft Velcro section, as shown in the above right illustration. Make sure that the strap securely holds the patient's arm in place.

WARNING Do not over-tighten the Patient Wrist Straps to prevent potential injury.

- Repeat the above two steps to secure patient's other arm to the ACC's Frame.

WARNING Observe the patient's arms during use. Do not leave a patient unattended when using the ACC or its accessories (e.g. Patient Wrist Straps).

WARNING Make sure that intravenous (IV) access is not obstructed in any way due to use of the Patient Wrist Straps.

WARNING Do not use the Patient Wrist Straps to lift the patient. The straps are only intended to attach the patient's arms to the ACC during transport.

CAUTION If the ACC becomes hot, prolonged contact with the patient's skin could result in skin burns. If necessary, remove the patient's arms from the Patient Wrist Straps.

4.6 Transport

Note: Prior to transporting a patient with an affixed RMU-1000 ACC, make sure that the Stabilization Strap has been attached to the unit and that a stretcher or other transportation equipment is nearby.

To move the patient to a stretcher or another piece of transportation equipment:

- Prepare the stretcher/transport equipment near the patient.
- Position two people on either side of the patient. Other personnel may be needed to stabilize the patient's head and limbs, as necessary.
- When ready to move the patient, push Pause to temporarily stop compressions.
- Lift the patient by grabbing the Handle with one hand and use the other hand to support the lower torso by grasping the patient's leg, belt or pants.
- After the patient is safely on the stretcher/transport equipment, check that the RMU-1000 ACC and the Piston have not changed their position or readjust them to the target area, if necessary.
- Push Pause again or the appropriate Run Compressions button to resume compressions.

During transport, the RMU-1000 ACC can be active if the RMU-1000 ACC and patient are safely and securely positioned on the stretcher/transport equipment and the RMU-1000 ACC remains in the target area and angle on the patient's chest.

WARNING

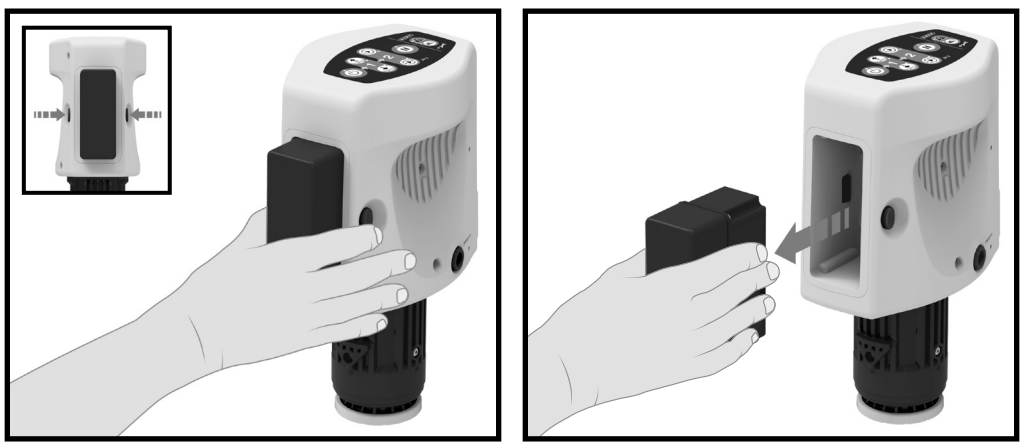
Carefully monitor the position of the piston on the patient's chest to ensure that it has not moved from the appropriate target area. Pause compressions and readjust position if needed.

4.7 Power

If the Battery Pack charge becomes low during use, the warning and Battery Pack indicators will flash. The Battery Pack status indicator will show only one red indicator bar.

OPTION 1) If a charged spare Battery Pack is available:

- Obtain the spare Battery Pack and have it ready for installation.
- Push Pause to temporarily stop compressions.
- Quickly eject the Battery Pack from the ACC by pressing the Battery Pack Release and remove the depleted Battery Pack.
- With minimal interruption, install the spare Battery Pack.
- Wait for the Pause LED indicator to illuminate.
- Re-start compressions by pushing the Pause button again or one of the Run buttons.



Note: If the Battery Pack change takes more than approximately 15 seconds, the unit will power off with the piston in place. Upon spare Battery Pack insertion, the Compression Module must be powered on and the piston will automatically retract to set its start position. The piston should then be re-adjusted to patient's chest.

OPTION 2) At any time, the ACC can be connected to an external power source by connecting the AC adapter to the external input jack of the Compression Module. See Section 3.9 for details.

Power (continued)

The Battery Pack must always be installed to operate the ACC from external power.

Only use Defibtech accessories to power the ACC from an external power source.

The ACC must be paused in order to replace a Battery Pack. Failure to do so will require the user to power up the ACC and reset the start position in order to resume compressions.

If there is a malfunction during emergency use and the RMU-1000 ACC cannot be paused or powered off, remove the Battery Pack from the Compression Module. When the ACC has stopped, remove the Frame from the patient (as the Piston does not automatically retract when the Battery Pack is removed). Start manual compressions as soon as possible.

If a spare Battery Pack or external power source are not available and the ACC stops compressions, remove the unit from the patient and begin manual compressions immediately.

4.8 Other Therapies

The ACC may be used in conjunction with other therapies such as defibrillation and other patient procedures, as appropriate.

Make sure other equipment and/or drugs are applicable for use with the ACC. Consult the equipment's operating instructions.

Defibrillation electrodes and pads should not be in contact with and be clear of the Piston and other ACC components.

If the position of the Piston changes as a result of defibrillation or other therapies, immediately stop compressions and re-adjust the position of the ACC.

Chest compressions may interfere with shock delivery and ECG analysis. Always pause compressions when providing a shock and during ECG analysis with other equipment.

4.9 Removal from Patient

To remove the ACC from the patient:

- Turn the ACC off by pressing and holding the ON/OFF button for at least one second.
- To release a patient's arm from the Patient Wrist Strap, pull up on the fabric tab on the end of the Forearm Strap until the Velcro is no longer holding the patient's arm in place. Repeat for the patient's other arm.
- Remove the Stabilization Strap (see Section 4.4).
- Press down and rotate the Compression Module approximately 90 degrees in either direction. Lift Compression Module from Frame. (***Note:*** This step may be performed after Frame is removed from patient.)
- Press the latch release levers to disconnect the Frame from the Backboard.
- Remove the Backboard from underneath the patient.

4.10 Post-Use Procedures

After the RMU-1000 ACC has been used on a patient, the unit should be cleaned following procedures in the "Cleaning" section in Chapter 5 of this manual and prepared for the next use. The following steps should be performed:

- Remove and dispose of the used Patient Interface Pad.
- Remove and clean the Stabilization Strap.
- The Patient Wrist Straps may be removed for cleaning purposes or if they need to be replaced (see Section 5.2). To remove the Patient Wrist Straps from the ACC's Frame, pull up on the rounded end of the Frame Strap until it can be slid through the Frame Strap Loop. ***Note:*** To maximize the available time to perform a rescue, Defibtech recommends that the Patient Wrist Straps remain affixed to the ACC's Frame and that the Frame be stored in the ACC's Carrying Case with the Patient Wrist Straps already attached to the Frame.
- Clean all the components that have been in contact with the patient and let them dry (see Section 5.2).
- Replace the Battery Pack with a fully charged Battery Pack or fully charge the Battery Pack in the ACC unit.
- Install a new Patient Interface Pad.
- Repack the ACC components and spares in the Carrying Case.

4.11 Operational Environment

The Defibtech ACC is designed to operate in a wide range of environmental conditions. To ensure the reliability and safety of the ACC in a given environment, refer to the "Environmental" section in Chapter 7 of this manual for a detailed list of specified environmental conditions.

5 Maintenance and Troubleshooting

This chapter describes the maintenance and troubleshooting procedures for the RMU-1000 ACC. The unit warnings and alerts are described along with recommended routine maintenance. A troubleshooting guide is provided to help diagnose user serviceable problems.

The RMU-1000 ACC contains no user serviceable parts.

5.1 Routine Unit Maintenance

The RMU-1000 ACC is designed to be very low maintenance. Simple maintenance tasks are to be performed regularly to ensure its readiness (see sample maintenance table below). Different maintenance intervals may be appropriate depending on the environment where the RMU-1000 ACC is deployed, and ultimately the maintenance program is at the discretion of the emergency response program's medical director. As with all rechargeable batteries, the rechargeable Battery Pack self-discharges over time, and therefore, must be maintained in accordance with the User Manual in order to be ready for use.

Weekly	***After Each Use***	***Action***
•	•	Make sure the Battery Pack is fully charged (see Section 3.9, "Charging the Battery Pack").
•	•	Check the condition of the system. Make sure the Carrying Case contains accessories including Patient Interface Pad(s), AC Adapter, Stabilization Strap, and Patient Wrist Straps.
•	•	Make sure a Patient Interface Pad is installed on the Compression Module.
•	•	Make sure at least one unused Patient Interface Pad is stored in the Carrying Case.
•		Check the Battery Pack expiration date.
•	•	Turn the ACC on to perform a self-test. Make sure the piston is retracted and the PAUSE indicator comes on with no warning indicators.

Note: If the unit has been dropped, mishandled, or abused, a thorough evaluation of operation should be performed.

5.2 Cleaning

After each use, clean any dirt or contaminants from the RMU-1000 ACC's Frame, Backboard, and Compression Module. The following are important guidelines that must be adhered to when cleaning the device:

- To clean the RMU-1000 ACC's Frame, Backboard, or Compression Module, use a soft cloth dampened with one of the following recommended cleaning agents:
  – Soapy water
  – Ammonia-based cleaners
  – Hydrogen peroxide
  – Isopropyl alcohol (70 percent solution)
  – Chlorine bleach (30 ml/liter water)
- Do not immerse the RMU-1000 ACC's Frame, Backboard, or Compression Module, components in fluids or allow fluids to enter the unit.
- Do not spray cleaning solutions directly on the unit or its connectors.
- Do not use abrasive materials or strong solvents such as acetone or acetone-based cleaning agents.

Cleaning (continued)

- After cleaning, allow the unit to completely dry. Before returning it to service, always turn the unit on for a few seconds. If the unit detects a problem, the Warning Indicator will be illuminated. Otherwise, turn the unit off.
- When necessary, clean the Stabilization Strap by removing both strap clips by loosening the Velcro that holds the clips in place. Machine wash the Stabilization Strap and air dry (do not tumble dry). Replace both strap clips after the strap has been cleaned and return the Stabilization Strap to the ACC's Carrying Case. Otherwise, discard the Stabilization Strap and replace it with a new one.
- When necessary, clean the Patient Wrist Straps by detaching them from the RMU-1000 ACC and loosening all Velcro. Machine wash and air dry (do not tumble dry). When dry, Defibtech recommends re-affixing the Patient Wrist Straps to the ACC's Frame (see Section 3.5). If the Patient Wrist Straps cannot be cleaned, are damaged, or the Velcro is worn out, dispose of them and replace with new ones.

Please note that none of the items provided with the RMU-1000 ACC are sterile or require sterilization.

WARNING Do not sterilize the RMU-1000 ACC or its accessories.

5.3 Storage

The RMU-1000 ACC should be stored in its Carrying Case and placed in a readily accessible location. In general, the unit should be stored in clean, dry and moderate temperature conditions. Make sure that the environmental conditions of the storage location are within the ranges detailed in the "Environmental" section in Chapter 7 of this manual.

Note: If stored outside of the Compression Module, a Battery Pack in active mode (see Section 3.8 for details about battery states) should be recharged to full capacity at least every 6 months. If stored in the Compression Module, the Battery Pack should be recharged to full capacity at least every 2 months.

5.4 Troubleshooting

The following table lists the symptoms, the possible causes, and the possible solutions for common problems. Refer to the other sections of the user manual for detailed explanations on how to address any issues. If the unit continues to be non-functional, refer the unit for servicing. (Refer to Chapter 10 of this manual for contact information.)

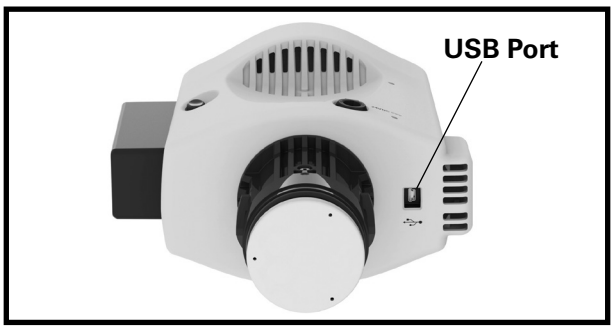
Symptom/Observation	*Possible Cause*	*Corrective Action*
ACC will not turn on	On/Off button pressed but not held down for at least one second	Press and hold the On/Off button for a full one second. All Control Panel LEDs will briefly illuminate and a beep will be heard when the ACC is powered on.
	Battery Pack is not installed	Install charged Battery Pack (see Section 3.8).
	Battery Pack depleted	Charge depleted Battery Pack (see Section 3.9) or replace depleted Battery Pack with a charged Battery Pack (see Section 3.8).
	Battery Pack malfunction	Replace Battery Pack with a charged Battery Pack (see Section 3.8).
	ACC malfunction	Remove ACC from patient (see Section 4.9) and start manual chest compressions as soon as possible.

Symptom/Observation	*Possible Cause*	*Corrective Action*
ACC immediately turns off	Battery Pack is depleted	Charge depleted Battery Pack (see Section 3.9) or replace depleted Battery Pack with a charged Battery Pack (see Section 3.8).
	Battery Pack malfunction	Replace Battery Pack (see Section 3.8).
	ACC malfunction	Remove ACC from patient (see Section 4.9) and start manual chest compressions as soon as possible.
Battery Pack Indicator on User Control Panel is red	Battery Pack has less than 20% charge remaining	If performing a rescue, replace Battery Pack with a charged Battery Pack or connect external power (see Section 4.7). Otherwise, charge Battery Pack as soon as possible (see Section 3.9).
Battery Pack Indicator on User Control Panel is slowly flashing red	Battery Pack has less than 10% charge remaining	If performing a rescue, replace Battery Pack with a charged Battery Pack or connect external power (see Section 4.7). Otherwise, charge Battery Pack as soon as possible (see Section 3.9).
Battery Pack Indicator on User Control Panel is quickly flashing red	Battery Pack is not installed	Install a charged Battery Pack (see Section 3.8).
	Battery Pack is in ship mode	Transfer Battery Pack from ship mode to active mode. See "*Ship Mode*" in Section 3.8, "*Installing and Removing the Battery Pack*", for more information.
	Battery Pack malfunction	Replace Battery Pack with a charged Battery Pack (see Section 3.8).
	Battery Pack depleted	If performing a rescue, replace Battery Pack with a charged Battery Pack or connect external power (see Section 4.7). Otherwise, charge Battery Pack as soon as possible (see Section 3.9).
First LED of Battery Pack Indicator on User Control Panel is amber	Battery Pack has reached end of life	Replace Battery Pack with a new Battery Pack (see Section 6 for ordering information; see Section 3.8 for installation instructions).
Battery Pack Indicators on Battery Pack do not illuminate after button on Battery Pack is pressed	Battery Pack is in ship mode	Transfer Battery Pack from ship mode to active mode (see "*Ship Mode*" in Section 3.8, "*Installing and Removing the Battery Pack*", for more information).
	Battery Pack depleted	Charge Battery Pack as soon as possible (see Section 3.8).
Warning Indicator flashing; audible alert (beeping); compressions stop (if running)	The ACC has detected a problem	Check for proper Piston position and height. Press Pause button to clear the condition and try again (see Section 4.3). If condition persists, remove ACC from patient (see Section 4.9) and start manual chest compressions as soon as possible. *Note:* Pressing the Warning Mute button (see Section 4.1) will silence the audible alert for 1 minute.
Adjust Up/Down LED indicators blinking	Piston position adjustment required	Adjust the Piston until it is firmly touching the patient's chest (see Section 4.3). Retry compressions. If condition persists, push the On/Off Button for at least one second to power off the ACC. Retry Operation and Adjustment (see Section 4.3). If condition persists after troubleshooting, remove ACC from patient (see Section 4.9) and start manual chest compressions as soon as possible.
ACC fails to start compressions	Piston position adjustment required or ACC malfunction	
ACC stops during compressions		
Compressions are not sufficient, or something unusual occurs during operation		
Service Indicator is lit and Warning Indicator is NOT flashing	ACC requires periodic service (see Section 5.7 for details) and/or has detected a problem that should be serviced	ACC will perform a rescue properly (*Note:* If the Warning Indicator is flashing while the Service Indicator is lit, the ACC may not perform a rescue properly). Have ACC serviced as soon as practical (see Chapter 10 for contact information).

If the error condition persists or service is required, call your Authorized Distributor or Defibtech. Refer to Chapter 10 of this manual for contact information.

5.5 USB Port

The USB Port is located on the bottom of the Compression Module. It allows the Module to be connected to a personal computer and for ACC data retrieval and event reporting when used in conjunction with utility software available at www.defibtech.com. It is not intended to be used during rescue operation.



WARNING

Do not use the USB cable during emergency use as it interferes with patient care.

5.6 Event Data

As part of Defibtech's on-going regulatory compliance activities, event data shared with Defibtech may be used by Defibtech to fulfill regulatory obligations. Any identifying personal data or health information received is considered confidential within Defibtech and will not be used for any other purpose. Please contact Defibtech at support@defibtech.com should there be any further questions.

5.7 Service

The RMU-1000 ACC contains no user serviceable parts. Defibtech recommends periodic maintenance every 18 months of use. After approximately 200 hours of operation (based upon performing 100 compressions per minute), the Service Indicator will flash to indicate that the unit requires maintenance. If the unit needs servicing, call your Authorized Distributor or Defibtech. Refer to Chapter 10 of this manual for contact information.

5.8 Recycling Information

At the end of useful life, recycle the ACC and its accessories.

Recycling Assistance

For recycling assistance contact your local Defibtech distributor.
Recycle in accordance with local and national regulations.

Preparation For Recycling

Items should be clean and contaminant-free prior to being recycled.
When recycling used items, follow local clinical procedures.

Packaging For Recycling

Packaging should be recycled in accordance with local and national requirements.

6 RMU-1000 ACC Accessories

This chapter describes the component parts and the accessories that can be used with the Defibtech RMU-1000 ACC. For contact information on obtaining replacement component parts and accessories, refer to Chapter 10 in this manual.

6.1 Patient Interface Pad

The Patient Interface Pad is a user-replaceable, single-use component that provides the interface between the piston and the patient's chest.

Top *Bottom*

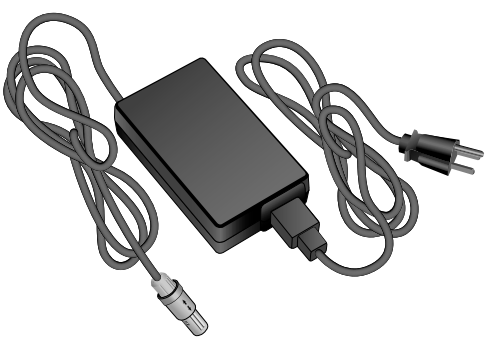
6.2 Battery Pack

The Battery Pack provides a replaceable primary power source for the Compression Module.

6.3 External AC Adapter

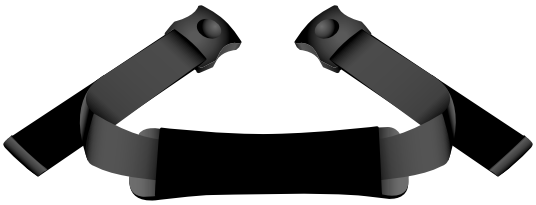
The external AC Adapter provides external power to run the ACC and charge the installed Battery Pack.

Note: A Battery Pack must be installed to operate the ACC using an external power source.



6.4 Stabilization Strap

The Stabilization Strap is used to stabilize the RMU-1000 ACC while compressions are being applied by the unit to the patient (see Section 4.4 *"Stabilization"* for details).



6.5 Patient Wrist Straps

The Patient Wrist Straps attach a patient's arms to the RMU-1000 ACC for ease of transporting the patient and the ACC (see Sections 3.5 and 4.5 for details).

6.6 USB Cable

An optional USB Cable (USB-A to Mini-B) allows the RMU-1000 ACC's Compression Module to be connected to a personal computer and for ACC data retrieval and event reporting when used in conjunction with utility software available at www.defibtech.com. The ACC's USB port is located on the bottom of the Compression Module (see Section 5.5 *"USB Port"* for details). For more information, contact Defibtech or your authorized distributor (see Chapter 10, *"Contacts"*).

6.7 Battery Pack Charging Station

The Battery Pack Charging Station is an optional accessory that charges up to two Battery Packs simultaneously. For more information, visit www.defibtech.com or contact Defibtech or your authorized distributor (see Chapter 10, *"Contacts"*).

6.8 Tactical Case

A compact Tactical Case is available as an optional accessory. For more information, visit www.defibtech.com or contact Defibtech or your authorized distributor (see Chapter 10, *"Contacts"*).

7 Technical Specifications

7.1 Defibtech RMU-1000 ACC

General

Category	*Specification*
Size (assembled)	23.5 x 20.75 x 9 inches (59.7 x 52.7 x 22.9 cm)
Size (in carrying case)	24 x 18 x 10 inches (61.0 x 45.7 x 25.4 cm)
Weight (with Battery Pack)	15.9 lbs (7.1 kg)
Power	Rechargeable Battery Pack or 24V DC input
Design standards	Meets applicable requirements of • IEC 60601-1 • ANSI/AAMI ES60601-1 • CAN/CSA C22.2 60601-1 • IEC 60601-1-2
Device classification	Internally powered Class II (with external power source)

Patient and CPR

Category	*Specification*
Patient	Adult patients that fit into the ACC • Chest width – 18 inches (45.7 cm) maximum • Chest height – 6.5 to 11.8 inches (16.5 to 30 cm) Use of the RMU-1000 ACC System is not restricted by patient weight.
Compression depth	2.1 inches ±0.1 inches (5.3 cm ±0.3 cm) from Start Position (nominal patient)
Compression frequency	101 ±1 compressions per minute
Compression duty cycle	50% ±5%
Compression modes	• Continuous compressions • Compressions with breathing (30:2, 30 compressions with 3-second pause for ventilation) factory default; future protocols via field updates

Environmental

Category	*Specification*
Operating/maintenance temperature	0 – 40°C (32 – 104°F)
Standby/storage/transport temperature	-20 – 70°C (-4 – 158°F)
Humidity	5% – 95% (non-condensing)
Vibration	MIL-STD-810G 514.6 Category 20 (Ground)
Sealing/water resistance	IEC 60529 class IP43 (Battery Pack installed)
Electromagnetic compatibility (emissions and immunity)	• IEC 60601-1-2 (refer to Chapter 8 for details) • RTCA/DO-160G Environmental Conditions and Test Procedures for Airborne Equipment, Sections 20 and 21 » Radiated susceptibility (category S, T) » Radiated emissions (category M, L) » Conducted emissions (category L, M, and H)
Altitude	Up to 2000m
Atmospheric pressure	99 kPa

7.2 Battery Pack

Use only Defibtech Battery Packs in the RMU-1000 ACC.

RBP-1000 Battery Pack

Category	*Specification*
Model number and battery type	RBP-1000-EC and RBP-1000-JG: 18.25V, 5300 mAh, Lithium-ion; Rechargeable, recyclable. RBP-1000-KG: 18.0V, 5600mAh, Lithium-ion; Rechargeable, recyclable.
Operation time	1 hour (nominal patient)*
Battery Pack charge time	Less than 3 hours in ACC* Less than 2 hours if charging one Battery Pack in optional external battery pack charging station (less than 3 hours if charging two Battery Packs; see Section 6.7 for details)*
Battery Pack useful life	Recommended to replace Battery Pack every 3 years or if Battery Pack indicator displays a replace Battery Pack condition (~300 charge/discharge cycles**).
Battery Pack operating and charging temperatures	0 – 40°C (32 – 104°F) ambient
Storage temperature	0 – 40°C (32 – 104°F); -20 – 60°C (-4 – 140°F) short-term <1 month.
Sealing / water resistance	IEC 60529 class IP44

*typical, new battery, at 25°C

**one charge/discharge cycle is defined as charging and discharging the full capacity of the Battery Pack

7.3 AC Power Adapter

RPM-1000 and RPM-2000 External AC Power Adapter

Category	*Specification*
Model number	RPM-1000 and RPM-2000
Input voltage	100 – 240VAC, 50/60Hz nominal
Input current	RPM-1000-BA: ≤2.3A RPM-1000-CA and RPM-2000: 1.5A
Rated output	24.0VDC (±5%)
Maximum input cable length	80.7 inches (205 cm)
Maximum output cable length	62.2 inches (158 cm)
Operating / storage temperature	See *"Environmental"* specifications chart in Section 7.1
Emissions and immunity	Refer to Chapter 8 for details

7.4 Notice to European Union Customers

The crossed-out wheeled bin symbol indicates that this equipment has been put on the market after 13 August 2005, and is included in the scope of the directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and of the national decree(s), which transpose provisions of such directive.

At the end of its lifetime, this equipment can only be disposed of in compliance with the provisions of the above-mentioned European directive (and as amended) as well as with the corresponding national regulations. Severe penalties are possible for unauthorized disposal.

Electrical and Electronic Equipment (EEE) may contain polluting components and hazardous substances, the accumulation of which could pose serious risk for the environment and human health. It is for this reason that local administrations provide regulations, which encourage reuse and recycling, and prohibit the disposal of WEEE as unsorted municipal waste and require the collection of such WEEE separately (at specifically authorized treatment facilities). Manufacturers and authorized distributors are required to supply information about a safe treatment and disposition of the specific equipment.

You may also return this equipment to your distributor when purchasing a new one. As for reuse and recycling, notwithstanding the limits imposed by the nature and the use of this equipment, the manufacturer will do its best to develop recovery processes. Please contact the local distributor for information.

8 Electromagnetic Conformity

8.1 Guidance and Manufacturer's Declaration

The essential performance of the RMU-1000 ACC and its accessories is to provide accurate chest compression depths and rates.

The RMU-1000 ACC is intended for use within the electromagnetic environment specified below. The customer or the user of the RMU-1000 ACC should assure that it is used within the stated environmental specifications.

The following electromagnetic conformity tables and relevant warnings and cautions apply to the RBC-1000 Battery Pack Charging Station optional accessory as well.

Electromagnetic Emissions

Emissions test	*Compliance*	*Electromagnetic environment – guidance*
RF emissions CISPR 11	Group 1 Class B	The RMU-1000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The RMU-1000 is suitable for use in all buildings including domestic homes and places directly connected to the public low-voltage Power Supplies Network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Immunity test	*IEC 60601 test level*	*Compliance level*	*Electromagnetic environment – guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	There are no special requirements with respect to electrostatic discharge.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power line supply lines ±1 kV for input/output lines	±2 kV for power line supply lines ±1 kV for input/output lines	The mains power quality must be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±2 kV	±2 kV	The mains power quality must be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Ut = 0%, 0.5 cycle Ut = 0%, 1 cycle Ut = 70%, 25/30 cycles Ut = 0%, 250/300 cycles	Ut = 0%, 0.5 cycle Ut = 0%, 1 cycle Ut = 70%, 25/30 cycles Ut = 0%, 250/300 cycles	The mains power quality must be that of a typical commercial or hospital environment. If the user of the [Equipment or System] requires continued operation during power mains interruptions, Defibtech recommends that the [Equipment or System] is energized from a Power Supply or Battery Pack that cannot be interrupted.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should not be greater than levels characteristic of a typical location in a commercial or hospital environment.

Electromagnetic Immunity (continued)

Immunity test	***IEC 60601 test level***	***Compliance level***	***Electromagnetic environment – guidance***	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	20 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the RMU-1000, including cables, than necessary. The recommended separation distance calculated from the equation applicable to the frequency of the transmitter is shown in the following table.	
Conducted RF IEC 61000-4-6	10 Vrms 150 KHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	10 Vrms 6 Vrms (ISM)		Interference may occur in the vicinity of equipment marked with this symbol.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RMU-1000 is used exceeds the applicable RF compliance level above, the RMU-1000 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the RMU-1000.

Separation Distances

The RMU-1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RMU-1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RMU-1000 as recommended below, according to the maximum output of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the RMU-1000		
	Separation distance according to frequency of transmitter (m)	
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz 80 MHz to 800 MHz d = 1.2√P**	**800 MHz to 2.5 GHz d = 2.3√P**
0.01	0.12	0.23
0.1	0.38	0.73
1	1.20	2.30
10	3.79	7.27
100	12.00	23.00

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

Note 1: As 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

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

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

The use of accessories other than those specified may result in increased emissions or decreased immunity of the RMU-1000 ACC.

Portable and mobile RF communications equipment should be used no closer to any part of the RMU-1000 ACC, including cables, than necessary.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The mains power quality must be that of a typical commercial or hospital environment.

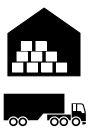
9 Glossary of Symbols

Symbol	Meaning
	ON/OFF Button • Turns the device on or off (hold button for at least one second).
	Adjust Down Button • Drives the piston down toward the patient.
	Adjust Up Button • Retracts the piston up away from the patient.
	Run Continuous Compressions Button • Performs compressions until the Pause or Off button is pressed.
	Run Compressions with Breaths Button • Performs compressions according to the compressions-with-breaths protocol and pauses for the operator to give breaths.
	Pause Button • Stops compressions when running (or resumes compressions when paused).
	Warning Indicator • Flashes to alert the user that the ACC has determined that there is a problem.
	Warning Mute Button • Silences audible sound associated with the Warning Indicator.
	Service Indicator • The Service Indicator illuminates when the ACC requires servicing.
	Battery Pack Indicator • Indicates the approximate remaining Battery Pack capacity.
	Check Battery Pack Charge Button (on Battery Pack) • Checks the charge of the Battery Pack when it is not installed in the ACC.
24VDC ⎓	Connection point for AC Adapter. Only use the AC Adapter supplied with the Defibtech ACC.
	USB Port.

Glossary of Symbols (continued)

Symbol	Meaning
	Caution, consult accompanying documents.
	Pinch point. Keep hands and fingers clear.
	Do not expose to high heat or open flame. Do not incinerate.
	Recyclable.
	Lithium batteries.
	Consult operating instructions.
	Refer to instruction manual / booklet.
	Do not damage or crush.
	Follow proper disposal procedures.
	Follow proper disposal procedures.
	Meets the requirements of the European Medical Device Directive.
	Operational temperature limitation.
	Use by yyyy-mm-dd.
	RBP-1000 Battery Packs that include this symbol on their label are only compatible with RMC Series Compression Modules running system software version 1.109 or greater. For more information, contact your authorized distributor or Defibtech (see Chapter 10).

Glossary of Symbols (continued)

Symbol	Meaning
	Defibrillation proof - Can withstand the effects of an externally applied defibrillation shock. Internally powered with defibrillator-proof BF-type patient applied parts (per EN 60601-1).
	Manufacturer.
 YYYY-MM-DD	Date of manufacture.
 YYYY-MM-DD	Manufacturer and date of manufacture.
	Do not reuse.
	Quantity per box.
	For USA users only.
Rx ONLY	Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Catalogue number.
	Keep dry.
	Keep away from sunlight.
	Handle with care.
	Transportation and storage requirements. See environmental requirements on packaging.

Glossary of Symbols (continued)

Symbol	Meaning
EC REP	Authorized European Representative: EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
LATEX	Not made with natural rubber latex.
LOT	Lot number.
IP43	Protected against solid objects over 1 mm; Protected against direct water sprays up to 60° from the vertical. Refer to IEC 60529 for further information.
IP44	Protected against solid objects over 1 mm; Protected against water sprayed from any direction. Refer to IEC 60529 for further information.
TÜV SÜD C US	Conformity to product safety testing requirements.
C US MH522328	UL Recognized Component Mark for Canada and the United States and Defibtech RBP-1000 file number.
PS E	Product Safety Electrical Appliance & Material certification mark for Japan.
SN	Serial number.
(xx)xxxxxxxxxxxxxx (xx)xxxxxx (xx)xxxxxxxxx	Unique Device Identification (UDI) information. *(**NOTE:** Sample shown at left is for visual reference purposes only; actual UDI information specific to this device appears on a physical label affixed to the unit's components and/or its packaging.)*
	Battery specification.
NON-STERILE	Product is not sterile.

10 Contacts

Manufacturer

Defibtech, L.L.C.
741 Boston Post Road, Suite 201
Guilford, CT 06437 USA

Tel.: 1-(866) 333-4241 (Toll-free within North America)
1-(203) 453-4507

Fax: 1-(203) 453-6657

Email:
sales@defibtech.com (Sales)
reporting@defibtech.com (Medical Device Reporting)
service@defibtech.com (Service and Repair)

Authorized European Representative:

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE
0197

11 Warranty Information

ORIGINAL END USER'S LIMITED WARRANTY

COVERAGE
Defibtech, L.L.C. provides a LIMITED WARRANTY that the Automated Chest Compressor (ACC) (i.e., Backboard, Frame, and Compression Module) and its associated components (i.e., Battery Pack, AC Adapter, Stabilization Strap, Patient Wrist Straps, and Patient Interface Pad (PIP)), and accessories (e.g., Carrying Case, USB Cable) (collectively referred to as "Products" and singularly as "Product") whether purchased concurrently or separately, shall be substantially free from defects in material and workmanship appearing under normal service and use. To qualify for WARRANTY SERVICE, the Product must have been continuously owned by the original purchaser and the original purchaser must have purchased the Product from Defibtech or an authorized Defibtech retailer. This LIMITED WARRANTY may not be assigned or transferred.

WARRANTY PERIOD
The Products shall have a WARRANTY PERIOD of one (1) year beginning on the date of delivery. The WARRANTY PERIOD for a single use Product (e.g., Patient Interface Pad) and Products having an expiration date shall end upon the earlier of use, expiration (if applicable), or end of the WARRANTY PERIOD. Any WARRANTY SERVICE, including but not limited to repair or replacement shall not extend a Product's WARRANTY PERIOD.

LIMITED WARRANTY SCOPE
This LIMITED WARRANTY does not cover damage of any sort resulting from, but not limited to, accidents, misuse, improper storage, improper operation, alterations, unauthorized service, tampering, abuse, neglect, fire, flood, war, or acts of God. Misuse shall include but not be limited to: use of the ACC with unapproved components; use of a Product with unapproved devices; or use of the Product in uncertified environments or settings. Defibtech does not warranty error-free or interruption-free performance of any Product.

LIMITED WARRANTY VOIDED
The LIMITED WARRANTY is immediately voided if: the Product is serviced or repaired by any entity, including persons, not authorized by Defibtech; specified Product maintenance is not performed; the Product is used with one, or more, unauthorized components or devices; or the Product is not used in accordance with Defibtech approved instructions.

WARRANTY SERVICE
At Defibtech's sole discretion, Defibtech shall have the option to repair, replace, or provide a credit. In the event of repair or replacement, Defibtech shall have the right at its sole discretion to replace the Product with a new, or refurbished, same or similar Product, and all Products or parts replaced shall become the property of Defibtech. Determination of a similar Product shall be at the sole discretion of Defibtech. In the case of replacement, the replacement at a minimum shall reflect the prorated time remaining for the Product based on the remaining WARRANTY PERIOD. In the case of a credit, the credit shall be the prorated value of the Product based on the lower of the original Product cost of the same or similar Product and the remaining WARRANTY PERIOD. Repair or replacement of a Product under this LIMITED WARRANTY does not extend the Product's WARRANTY PERIOD.

WARRANTY SERVICE (CONTINUED)
In order to obtain WARRANTY SERVICE, the original owner must contact the Defibtech authorized retailer from whom the Product was purchased, or Defibtech customer service. In the event a Product must be returned, a Defibtech issued Return Material Authorization (RMA) number is required. Products returned without a Defibtech authorized RMA number will not be accepted. The Product shall be shipped at the original end user's expense to a destination specified by the retailer or Defibtech.

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