Movement and Compressions System

(Model RF1400)

User Manual

UM1400-00-09

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A. Introduction

A.1 How Does the Movement and Compressions System Work?

The Movement and Compressions System works by providing intermittent compressive forces to the legs, increasing the blood flow in the veins, moving blood towards the direction of the heart and reducing the risk of clot formation.

To perform intermittent compression for DVT Prophylaxis, a single-patient use disposable fabric moisture wicking strap (MAC Strap) is wrapped around a patient's calf muscle just below the knee. The controller is attached to the strap in two places; the strap mounts and securement ring (see Figure 2). Inside the controller is a small DC motor that moves the securement ring in and out of the controller, thus contracting and retracting the strap. When the strap is contracted, compression is applied to the patient's calf muscle. When the strap is retracted, compression force is released to the patient's calf muscle. This provides the blood flow 'pumping' action once per minute that prevents blood clots from forming.

Based upon this mode of action, the MAC System™ uses mechanical force to provide intermittent compression, not pneumatic force. The system does not require a powered air supply, so the risk of aerosolization of potential contaminants or germs is mitigated as there is no blowing air. Also, the device components are either disposable (the MAC Strap) or the surfaces are easily disinfected (MAC Controller and Charging Hub) allowing for ease of cleaning and mitigation of cross-contamination. There are no air connections or pneumatic pumps to clean between patients.

A.2 Intended Use & Indications for Use

The Movement and Compressions System is intended to be a portable and wearable system, prescribed by healthcare professionals, to treat the following conditions by stimulating blood flow in the legs:

- Aid in the prevention of DVT (deep vein thrombosis);
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, chronic lymphedema, and reduction of edema in the lower limbs;

- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.
- Reduction of edema associated with soft tissue injuries, such as burns, postoperative or post-immobilization edema, or ligament sprains.

During use, the system also monitors patient orientation and movement. It allows healthcare providers and users to implement individualized patient management plans for DVT prophylaxis and mobility protocols by utilizing data accumulated by the patient on the previous day as a benchmark. The data displayed on the device allows providers to monitor the patient's orientation, and activity, which can be used to identify risk factors for hospital-acquired events linked to immobility such as: deep vein thrombosis, pressure ulcers, and pneumonia.

The device can be used in the home or clinical setting. The device is intended for use in an adult patient population.

A.3 Contraindications

Do not use the Movement and Compressions System in the following cases:

- Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, blood clots, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection
- On the legs where the cuffs (the Strap) would interfere with the following conditions: vein ligation, gangrene, dermatitis, swollen or inflamed areas, open wounds, a recent skin graft, massive edema or extreme deformity of the leg
- Medical situations where increased venous and lymphatic return are undesirable
- On extremities that are insensitive to pain or any neuropathy
- Presence of unexplained calf pain.

A.4 Document Definitions, and Abbreviations

WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in serious injury.

CAUTION: Indicates a potentially hazardous situation which, if not avoided, may results in minor or moderate injury, or damage to the equipment or other property.

NOTE: Indicates a practice not related to personal injury which if not avoided, may result in property damage.

RF1400 - Is a registered trademark of Recovery Force, LLC.

DVT - Deep Vein Thrombosis

MAC – Movement and Compressions

A.5 Safety Guidelines, Warnings and Cautions

Read all instructions before using the Movement and Compressions System for the first time. A healthcare provider is not needed to train the user. Training is obtained through reading the User Manual.

WARNING:

1. Movement and Compressions System is designed for single patient use only. Consult your physician prior to use.
2. Device is to be used only by the patient prescribed, and only for its intended use.
3. Do not use device with persons who are unable to communicate due to physical, sedation, cognitive or emotional deficiencies.
4. If you are, or may be, pregnant, consult with your physician before use.
5. Recharge battery using Charging Hub provided with MAC System.
6. Operation of this device should be done by a registered healthcare professional, if available, but can also be used by the individual user.
7. Keep and store when not in use out of reach of children, pets, pests, and away from water.
8. The Movement and Compressions System utilizes a Controller and Strap for each leg and a Charging Hub to charge the batteries of the Controller.
9. No modification of this equipment is allowed. No user serviceable parts inside. Direct all issues to Recovery Force Customer Service.
10. If you experience pain, swelling, sensation changes, discomfort or any unusual reactions (including sensitivity or skin reactions) while using the MAC System, stop using the device and consult your physician immediately.

11. This device should not be used adjacent to or stacked upon other devices, or if necessary, to be adjacent or stacked, observation of the proper function in the position used should be verified.
    a. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
        i. Reorient or relocate the receiving device
        ii. Increase the separation between the equipment
        iii. Connect the equipment to an outlet on a different circuit from that to which the other device(s) are connected and consult the factory field service technician for help
12. Magnetic and electrical fields are capable of interfering with the proper performance of the unit. For this reason, make sure that all external devices operated in the vicinity of the unit comply with the relevant EMC requirements. X-Ray equipment, MRI devices, radio systems, cell phones and radiant warmers are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the device away from such equipment.
13. Remove the Controller from the Strap before storing or cleaning.
14. Keep the Charging Hub and AC power cord away from heated surfaces.
15. Do not reach for the product if it has fallen into water while the device is on. Wet devices may cause electric shock when activated.
16. Keep the Controller, Charging Hub, and AC power cord dry. Do not operate while bathing, in a shower, in or around water. Inadvertent spills should be wiped immediately to prevent liquid ingress into the device. Wet devices may cause electric shock when activated.
17. Never operate this product if it is damaged, or is not working properly, or if it has been dropped and damaged in any manner, or dropped into water, or if the product shows any sign of damage or deterioration, such as cracks or worn parts. Please contact Recovery Force Customer Service for repair.
18. If ingested, the electronic materials and fasteners may cause problems.

19. Do not use with a power supply/charger/strap not recommended by the Manufacturer. This could damage the components of the device.

CAUTIONS

1. Movement and Compressions System is latex-free and not made with natural rubber latex.
2. Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF communication equipment can be affected by other medical electrical devices. If you believe interference is occurring, please consult Electromagnetic Compatibility (EMC) section.
3. In the event that the device is stored outside of its storage temperature range prior to use, wait approximately 15 minutes while in the operating temperature range before powering on the device.
4. Fully charge battery before each use. Failure to do so may adversely affect performance.
5. Do not immerse in any liquid for any reason.
6. Do not operate the device in a wet environment.
7. Equipment should be used in a lint-free and dust-free environment.

RECOMMENDATIONS FOR USE

1. The Movement and Compressions System should be applied snugly around the calf muscle for best performance.
2. Make sure the Controller is securely locked into position on the mounts of the Strap before initiating device.
3. Before using, check Controller and Strap visually for any damage.
4. Always follow the storage and operating instructions.
5. The Movement and Compressions System should be worn directly on the skin via the Strap.

A.6 What is the Duration and Frequency of Use?

Each treatment session is determined by a physician, please consult a physician for duration and frequency of use.

The total compression cycle is approximately 4 seconds long consisting of following sequence:

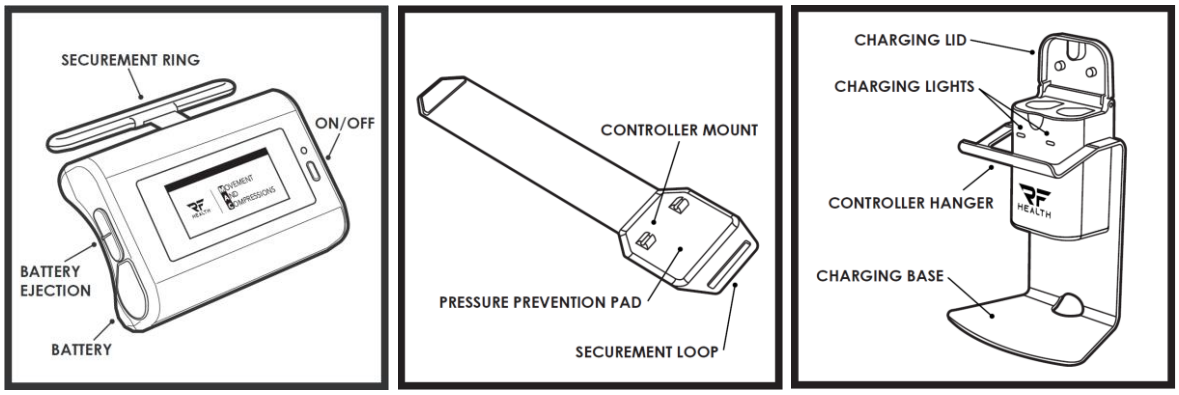
1. Compression for ≤ 1 second
2. Hold for 1 second
3. Compression release for ≤ 2 seconds
4. No compressions for ~ 56 seconds

Device will operate for approximately 48 hours on a fully charged battery. Expected service life is 15 days.

B. Instructions for Use

B.1 Parts Definition

MAC Controller **MAC Strap** **MAC Charging Hub**

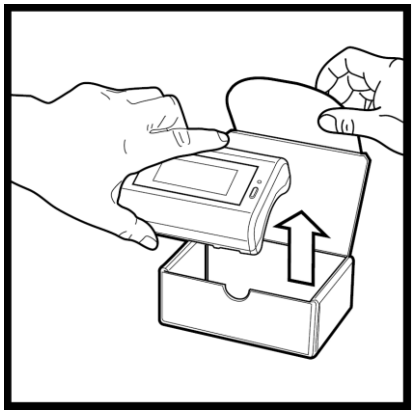


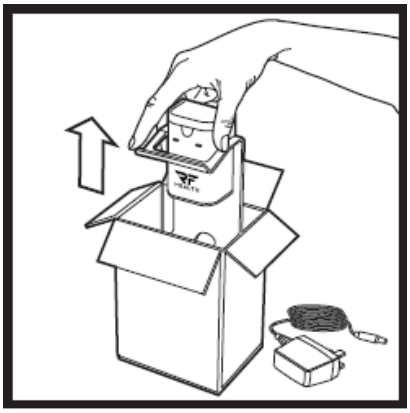
Parts List:

- Applied Parts:
  - **MAC Controller** (Includes Electronics & Battery)
    Part #: RF1410-00-00
  - **MAC Strap (2 sizes)**
    Standard Strap: 11” – 17” (27.9cm – 43.2cm)
    Part #: RF1420-00-00
    Extra Large Strap: 17” – 24.5” (43.2cm – 62.2cm)
    Part #: RF1421-00-00
- Accessible Parts:
  - **MAC Charging Hub**
    Part #: RF1430-00-00
  - **Charging Hub AC Power Cord**
    Part #: RF1314-00-00 OTS Part #: WA-20F05FU-AAAA
  - **Replacement Battery**
    Part #: RF1030-00-00

B.2 Unpacking

a. Open the cardboard box for both the Controller and Charging Hub.
b. Remove the Controller, Charging Hub, and AC Power Cord located in the internal corrugated packaging core. Lift flap and remove items.





NOTE: Before using, check Controller and Charging Hub visually for any damage.

B.3 Device Operation

The Movement and Compressions System comes partially charged and will likely need to be charged before first use.

For directions on how to charge the MAC System, see section **Charging Movement and Compressions System**

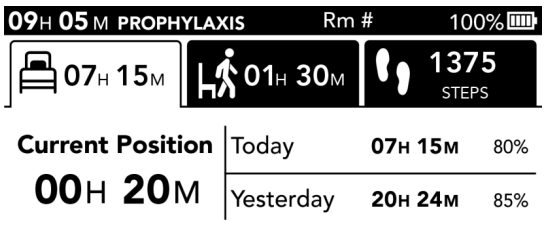
Device Operation Indicator

A user will be able to monitor the activity by an LED light on the Controller.

SOLID RED: If the device is powered ON and active, the LED on the Controller shall indicate a solid RED light.

The battery indicator is always in the upper right-hand corner of the screen indicating battery % left on the device. An alarm will sound at 15% on battery 'fuel gauge'.

In addition to the SOLID RED LED on the Controller, the display will show the message "DVT Prophylaxis Is Now Running" and immediately show the Mobility Screen showing that the device is ON and operational. See example below:

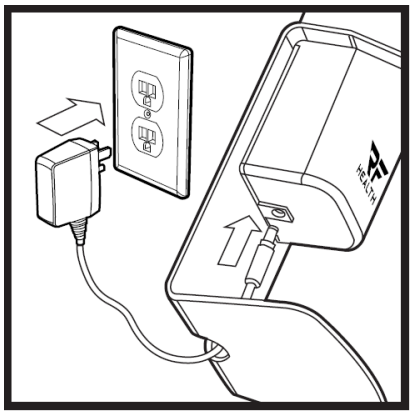


For additional information on the Mobility Screens, please see section **Mobility Screens**.

Quick-Start Guide

STEP 1 Plug-in the Charging Hub

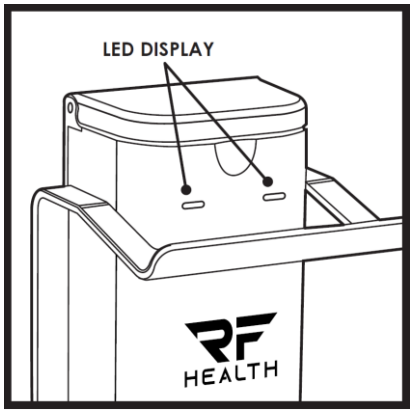
a. The Charging Hub should be plugged into the wall immediately after unboxing to begin charging the batteries that come inside the Charging Hub.



b. The Charging Hub has LED lights indicating the charging status of the battery

FLASHING GREEN: When a battery is present in the Charging Hub yet not fully charged, the LED shall indicate charging by flashing green.

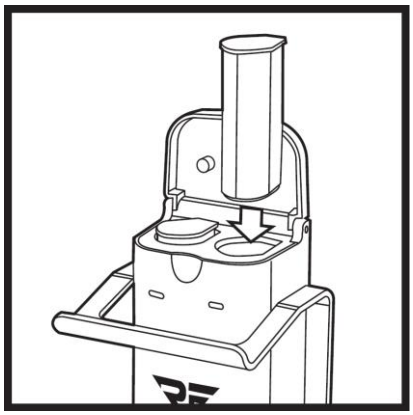
SOLID GREEN: When a battery is present in the Charging Hub and fully charged, the LED shall indicate fully charged by displaying solid green.

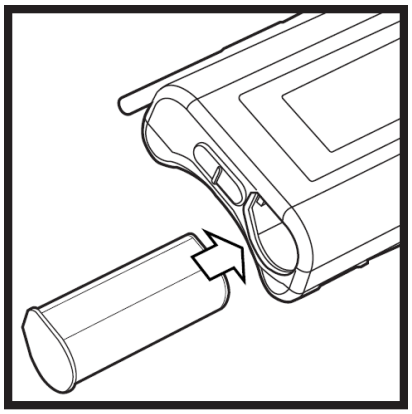


STEP 2 Insert Battery into Controller

a. Once the solid green LED is illuminated on the Charging Hub, remove the battery from the Charging Hub, replace that battery with the battery that came inside the Controller, and insert the fully charged battery from the Charging Hub into the Controller.

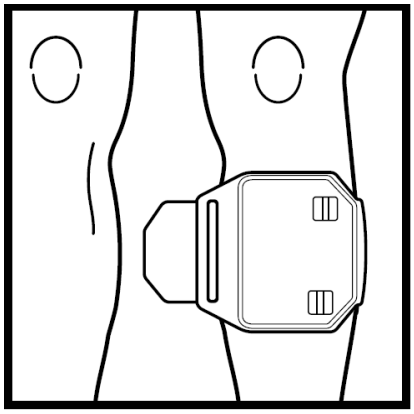
NOTE: The battery that came inside the Controller will likely need to be charged before being used.





STEP 2 Apply Strap

a. Place leg horizontal to the ground and apply MAC Strap just below the knee with the securement loop on the inside of the leg.

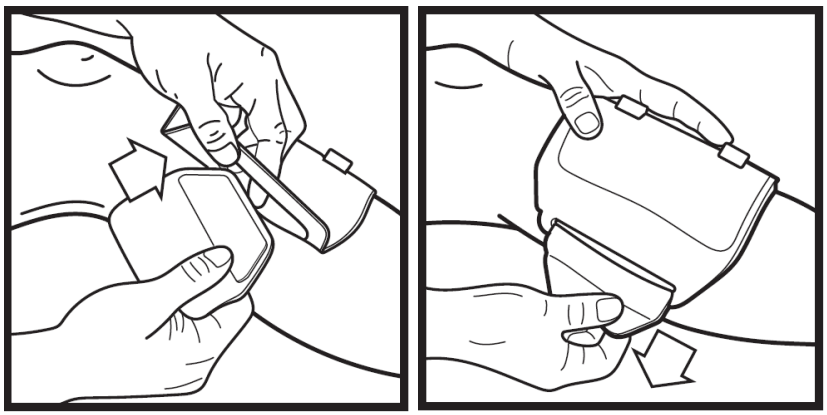


Note: Placement of the Strap immediately below the knee is extremely important to insure the Movement and Compressions System stays in place.

STEP 3 Secure Strap

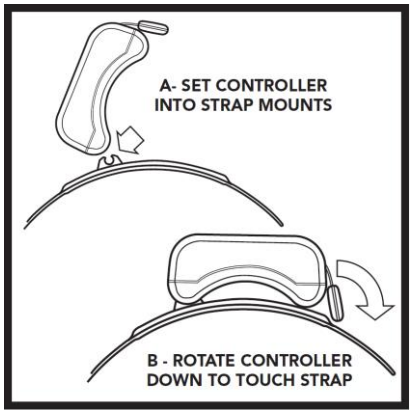
a. Feed the end of the strap through the securement loop and secure Velcro.

NOTE: Securement Loop should always be placed on inside part of the leg



STEP 4 Connect Controller to Strap

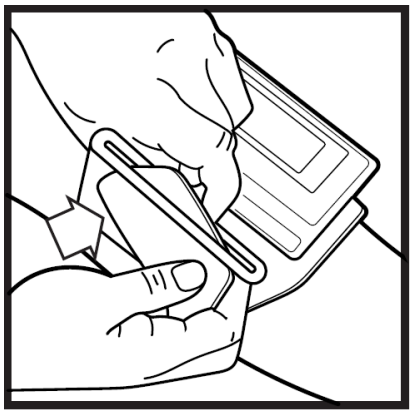
a. Drop and lock the MAC Controller vertically to the blue mounts on the face of the strap.



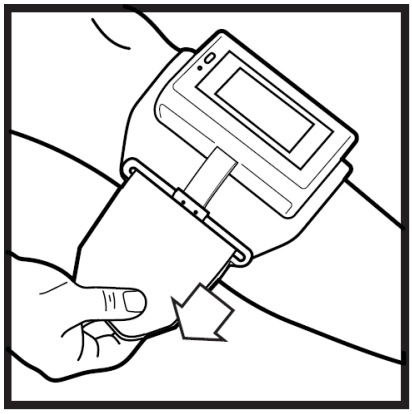
CAUTION: The Controller must be secured and engaged by both Controller mounts on strap to perform properly.

STEP 5 Secure Controller to Strap

a. Disconnect Velcro and feed the strap through the black securement ring on the Controller.

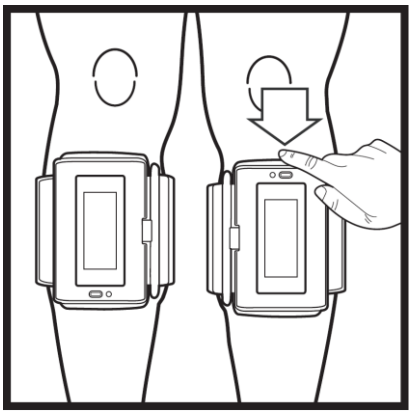


b. Re-secure Velcro around leg comfortably, but not too snug.



STEP 6 Power On Controller

a. Once the Controller has successfully been secured to the Strap, power on Controller by pressing the ON / OFF button for ONE second until a SOLID RED light appears.



NOTE: The Movement and Compressions System will illuminate with a SOLID RED LED when device is turned on and ready to be used.

STEP 7 Begin Mechanical Prophylaxis and Mobility Tracking

a. Once powered on, the Controller will show a calibration screen followed automatically by the *Attach Controller to Strap* screen.

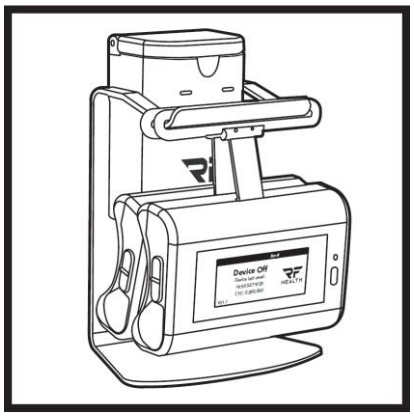
b. Press the START button to begin mechanical prophylaxis and mobility tracking

Turning Off the Movement and Compressions System

a. To turn the device OFF, PRESS the ON / OFF button again for THREE seconds until the SOLID RED light no longer appears.

b. When not in use, the Controllers should be stored by hanging the securement ring from the Charging Hub.

NOTE: The screen on the Controller will read *Device Off* when device has been turned off properly and also display when the device was last used.



Frequently Used Functions

Power button ON / OFF for initiating the process to set up intermittent compressions.

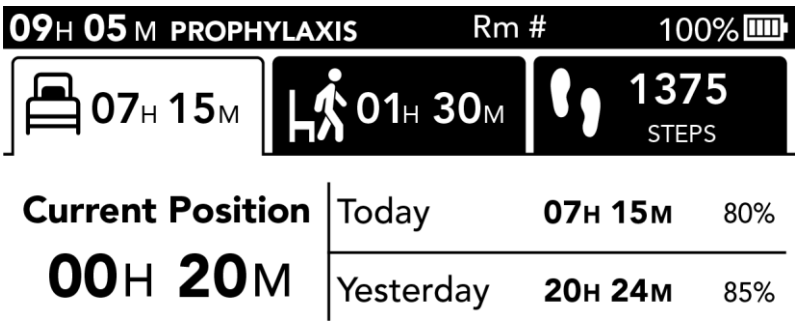
Adjust hook and loop fasteners (i.e. Velcro) for tightening.

Mobility Screens

When the Movement and Compressions System is running mechanical prophylaxis, it also provides the user's orientation and mobility data via the touchscreen display.

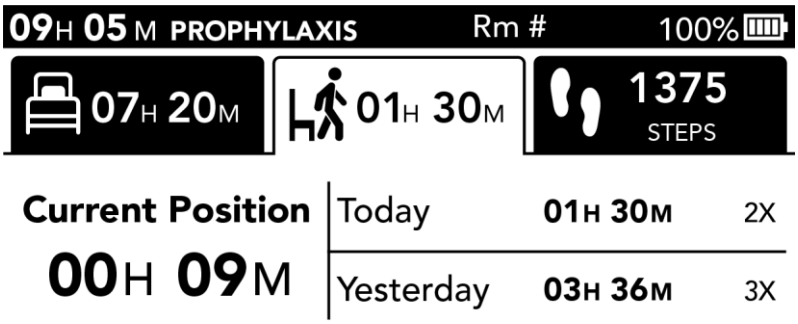
The following are example screens offered while using the Movement and Compressions System:

BED SCREEN: USER IS CURRENTLY LAYING DOWN



This screen example shows the highlighted Bed tab because the user has currently been laying down for 20 consecutive minutes without changing position for more than 1 minute. It also displays that the user has a total of 7 hours and 15 minutes laying down and has spent 80% of the day in the laying down position. Yesterday's data is also displayed allowing for the user to compare today's data vs. yesterday's.

UPRIGHT SCREEN: USER IS CURRENTLY IN AN UPRIGHT POSITION (SITTING, STANDING, WALKING)

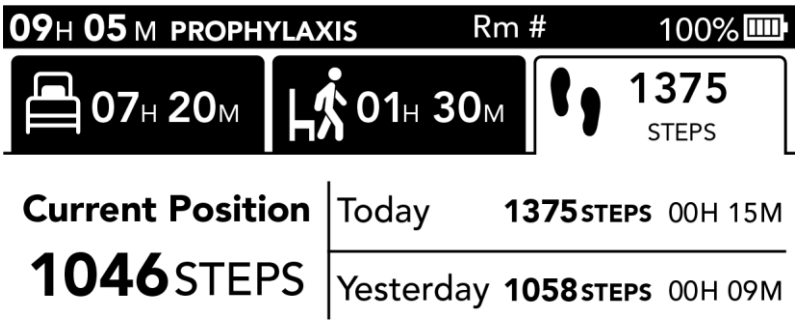


This screen example shows the highlighted Upright tab because the user has currently been in an Upright position for 9 consecutive minutes without changing position for more than 1 minute. It also displays that the user has a total of 1 hour and 30 minutes in an Upright position today and has stayed in an Upright

position for more than 1 minute two times. Yesterday's data is also displayed allowing for the user to compare today's data vs. yesterday's.

Note: The Upright position includes sitting, standing, and walking.

STEPS SCREEN: USER IS CURRENTLY WALKING

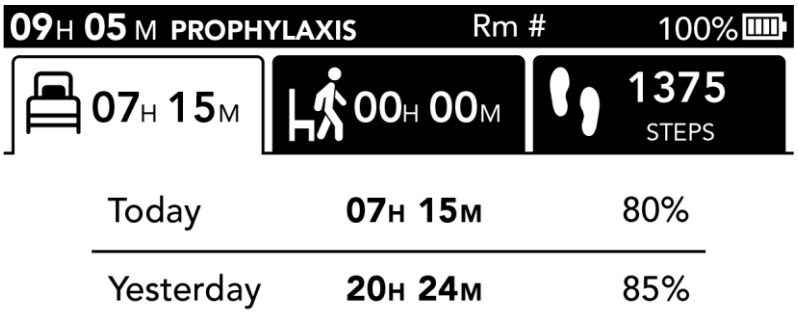


This screen example shows the highlighted Steps tab because the user is walking. It also displays that the user has a total of 1046 steps in this current session with a total of 1375 steps taken today over the course of 15 minutes. Yesterday's data is also displayed allowing for the user to compare today's data vs. yesterdays.

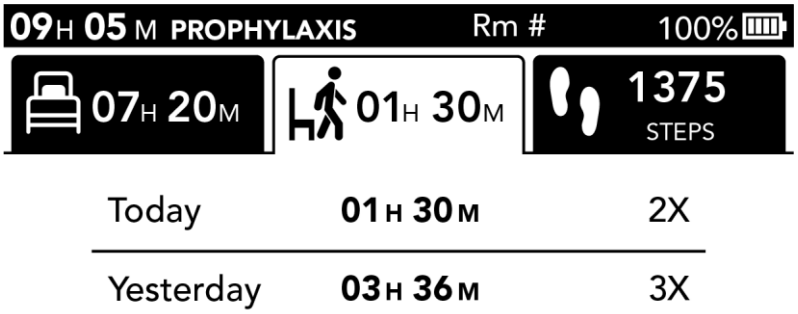
Dynamic Touchscreen Display

Additionally, the touchscreen display on the Controller allows for the user to push the tab of each activity at any given time to display the corresponding data. Below is a visual example of each screen if the tab is pushed:

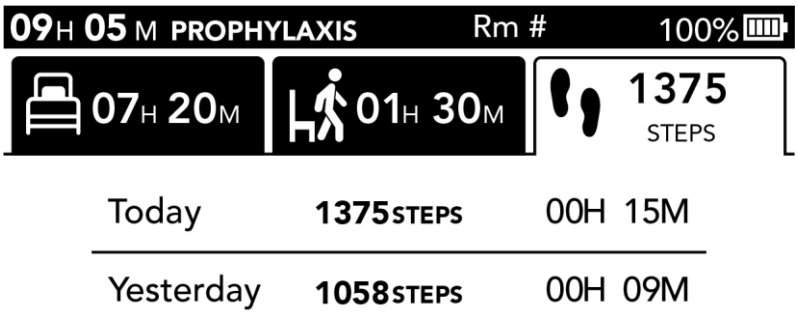
INACTIVE BED SCREEN



INACTIVE UPRIGHT SCREEN



INACTIVE STEPS SCREEN



Note: Once one of the activity tabs has been pressed, the screen will automatically return to the current activity after 10 seconds.

Charging Movement and Compressions System

CHARGING THE BATTERY: USE ONLY THE CHARGING HUB PROVIDED BY RECOVERY FORCE to charge the MAC System batteries.

The Charging Hub is the only way to charge the replaceable batteries of the Movement and Compressions System.

Only place the batteries of the Movement and Compressions System in the Charging Hub.

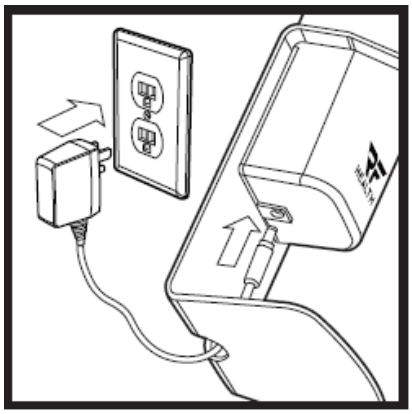
NOTE: The batteries for the Movement and Compressions System come partially charged and will likely need to be charged before first use. Use of the wrong charger can cause excessive heat, damage to the charging circuit and shorten the life of the battery

It should take approximately 4 hours to charge a fully depleted battery.

When Controller is not in use, hang on Charging Hub for storage.

To charge the battery:

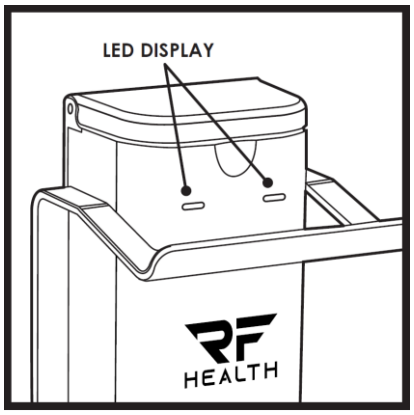
a. The AC Power Cord of the Charging Hub must be plugged into a wall outlet. Verify that the outlet is not obstructed in any way for quick disconnect from outlet.



Charging Hub Indicator Lights

FLASHING GREEN: When the Charging Hub is plugged into the wall outlet with batteries present but not fully charged, the LED shall indicate charging by flashing green.

SOLID GREEN: When the device is fully charged, the LED shall indicate a full charge by a solid green light.



B.4 Ending of Treatment Period

To end therapy, push the ON / OFF button and hold for 1 second. Remove Controller from the Strap and then remove the Strap from the leg.

If the Movement and Compressions System stops working or displays an error message, refer to the **Troubleshooting** section to resolve the issue.

B.5 Safety Features

Movement and Compressions System is equipped with overload fuses and will protect against thermal or electrical events.

Fuses are not able to be reset by the user. Return the Movement and Compressions System to Recovery Force Customer Service.

There is no shock or safety risk in case of loss of power from the battery. The device will stop the treatment if there is loss of battery power.

C. Maintenance, Cleaning and Storage

C.1 User Maintenance

Inspect the device and parts for any damage that may have occurred during handling prior to each use (for example, frayed or cut charging cord, cracked housings, torn wraps, broken connectors, etc.).

Do not attempt to operate the device if any damage is noticed.

Avoid subjecting the units to shocks, such as dropping the Controller.

There are no serviceable parts inside the device.

Contact Recovery Force Customer Service at 1 866.745.7445 to report unexpected operation or events and to receive replacement instructions for any damaged items.

If you have any questions or comments about setting up or maintaining this device, call us at 1 866.745.7445 or visit our website www.recoveryforcusa.com/contactus

C.2 Cleaning the Movement and Compressions System

The Movement and Compression System hardware (Controller, Charging Hub, and battery) can be cleaned wiping down the outer surfaces using a soft cloth dampened with water or a mild detergent. To sanitize the hardware, apply cleaning agent with a cloth or wipe. Avoid excessive spraying, especially in the areas of the connection ports of the Controller. If any liquid enters the ports, then internal component damage will likely result. The table below provides optional cleaning products and their chemical components.

Chemical Cleaners (approximate concentrations)	**Commercial Example**
90% Isopropanol Alcohol	Generic
0.63% Bleach	PDI® Sani-Cloth Bleach Germicidal Disposable Wipe
0.25% dimethyl ethylbenzyl ammonium chlorides, 0.25% dimethyl benzyl ammonium chlorides, 55.00% Isopropyl Alcohol	PDI® Super Sani-Cloth Germicidal Disposable Wipe
8.704% Didecyl dimethyl ammonium chloride, dimethyl benzyl ammonium chloride 8.190% used at a 1:256 dilution	Diversey™ Virex II 256 One-Step Disinfectant Cleaner & Deodorant

CAUTION: The Strap should ONLY be wiped down with mild soap and water due to the contact and exposure to the user's leg.

CAUTION:

Do not spill any liquids on the device

Do not immerse in liquid for any reason.

Do not hand or machine wash, dry clean, hand or power wring, iron, tumble or force heat dry.

C.3 Storage and Transport Conditions

Temperature: -13°F to 158°F (-25°C to 70°C)

Relative Humidity: 10% to 90%, non-condensing, >35 °C to 70 °C at a water vapor pressure up to 50 hPa

Atmospheric Pressure: 50 kPa to 106 kPa

Do not store in direct sunlight

Keep unit clean and protected from dust and lint

To disassemble, cables are unplugged from the Charging Hub.

C.4 Operating Conditions

Temperature: 41°F and 104°F (5°C to 40°C)

Relative Humidity: 15% to 90%, non-condensing, but not requiring water vapor partial pressure greater than 50 hPa

Atmospheric Pressure: 700 hPa to 1060 hPa

C.5 Disposal and Recycling

This electromechanical device includes printed circuit boards and rechargeable batteries.

When the Strap, Controller, battery or Charging Hub reaches the end of their useful life, recycle or dispose of the equipment according to specific local regulations.

Do not discard device in regular waste. Do not discard in landfill.

Bring the device to your local recycle or disposal center or contact Recovery Force Customer Service for proper disposal and recycling of the device.

D. Technical Details

D.1 Technical Specifications

Specifications	
Model	RF1400 Movement and Compressions System
Catalog No.	RF1400
Class	II
Max Force	5.5 lbs
Voltage	3.6V Lithium rechargeable Battery
Battery charger	115V~ 60 Hz
Power Consumption	10.44 Wh
Fuses Rating	2A

Sizing		
Strap Size	Length (in)	Height (in)
Standard Strap	22	4
XL Strap	29	4
Weight		
Net Weight including Controller	11 oz	

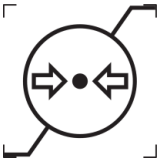
Service and Repair

The MAC system is not serviceable. Additional Straps, Controllers, Charging Hub, batteries, and AC Power Cords can be requested or ordered separately and do not need to be replaced by service personnel.

Classifications:

- Class II Medical Device
- Type BF Applied Parts
- IP22 for Controller and Charging Hub.
- Internally Powered Equipment
- No Sterilization Necessary
- Not intended for an Oxygen Rich Environment
- Continuous Operation Device

D.2 Product Symbols Definition

Symbol	Explanation	Location
	Temperature limitations for storage and/or transport & Operation of the device. Storage & Transport Temperature: -13°F to 158°F (-25°C to 70°C) Operating Temperature: 41°F and 104°F (5°C to 40°C)	On Charging Hub and Controller
	Humidity limitations for storage and/or transport & Operation of the device. Storage & Transport Relative Humidity: 10% to 90%, non-condensing, >35 °C to 70 °C at a water vapor pressure up to 50 hPa Operating Relative Humidity: 15% to 90%, non-condensing, but not requiring water vapor partial pressure greater than 50 hPa	On Charging Hub and Controller
	Atmospheric Pressure limitations for storage and/or transport & Operation of the device. Storage & Transport Atmospheric Pressure: 50 kPa to 106 kPa Operating Atmospheric Pressure: 700 hPa to 1060 hPa	On Charging Hub and Controller
	The name and address next to this factory symbol is the manufacturer.	On packaging, Controller, and Charging Hub
	Nonsterile	On packaging, Controller, and Strap

	Catalog Model number reference	On packaging, Controller, Charging Hub, and Strap
UDI	Unique Device Identifier.	On packaging, Controller, Charging Hub, and Strap
	This indicates that an object is capable of being recycled, not that the object has been recycled or will be accepted in all recycling collection systems.	On packaging, Controller, and Charging Hub
	TYPE BF APPLIED PARTS	On Controller
IP22	IP22 - Protected against solid foreign objects of 12.5mm diameter and greater and protected against vertically falling water drops when enclosure tilted up to 15°	On Controller and Charging Hub
	Keep dry	On Controller and Charging Hub
	Read the user manual before use	On Strap packaging, Controller, and Charging Hub
	Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.	On Strap packaging, Controller, and Charging Hub
	Do not dry clean	On Strap packaging
	Do not immerse	On Controller and Charging Hub

Strap not made with natural rubber latex	Not manufactured with natural rubber latex	On Strap packaging
	This electromechanical device includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Contact local requirements for proper disposal instructions.	On Controller and Charging Hub
Single Patient Use Only	Indicates Single Patient use item	On Strap and Strap Packaging
	The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the Movement and Compressions System as replacement parts, may result in increased emissions or decreased immunity of the Movement and Compressions System	On Controller

Symbols on the Power Adaptor

Symbol	Explanation	Location
	Refer to the user manual before proceeding with installation or maintenance	On Power Supply
	This electromechanical device includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Contact local requirements for proper disposal instructions.	On Power Supply
	"CE" marking indicating European conformity	On Power Supply
	Class II medical electrical equipment	On Power Supply
RoHS	Restriction of Hazardous Substances Directive	On Power Supply
	Indoor Dry Location Use only	On Power Supply
IP22	IP22 - Protected against solid foreign objects of 12.5mm diameter and greater and Protected against vertically falling water drops when enclosure tilted up to 15°	On Power Supply

D.3 Electromagnetic Interference
EMC Manufacturer Declarations

Movement and Compressions System - electromagnetic emissions - manufacturer declaration		
The **Movement and Compressions System** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Movement and Compressions System** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **Movement and Compressions System** 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.
RF emissions CISPR 11	Class BF	The **Movement and Compressions System** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Movement and Compressions System - electromagnetic immunity - manufacturer declaration			
The **Movement and Compressions System** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Movement and Compressions System** should assure that it is used in such an environment. For Charging Hub.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	Complies	Mains power quality should be that of a typical commercial, home use or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Complies	Mains power quality should be that of a typical commercial, home use or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip in U_T for 10ms 60% dip in U_T for 100ms 30% dip in U_T for 500ms >95% dip in U_T for 5000ms	Complies	Mains power quality should be that of a typical commercial, home or hospital environment.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial home use or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level!

Movement and Compressions System - electromagnetic immunity - manufacturer's declaration

The **Movement and Compressions System** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Movement and Compressions System** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the **Model RF1400**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2 = 2{,}3\ R\sqrt{800}$ MHz to 2,5 GHz $P\ 80\sqrt{}$ MHz to 800 MHz d Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range" [b] Interference may occur in the vicinity of equipment marked with the following 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"

a 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 **Movement and Compressions System** is used exceeds the applicable RF compliance level above, the **Movement and Compressions System** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Movement and Compressions System** "

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m"

Recommended separation distances between portable and mobile RF communications equipment and the Movement and Compressions System

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated 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: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies"

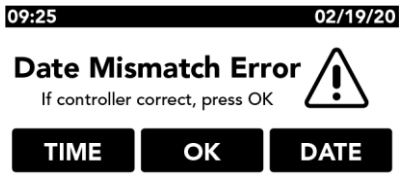
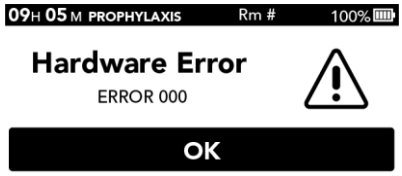
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CAUTION: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or reorient interfering equipment.
- Increase distance between interfering equipment and your system.
- Manage use of frequencies close to the system frequencies.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within the facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter)

E. Troubleshooting

NOTE: Before continuing, check visually for any defects.

Error Screen	Error Description	Corrective Action
	Battery was removed during operation.	Insert charged battery into the MAC System Controller
	An incorrect date has been set in the Controller.	Press OK and then set correct date on Controller
	Date and/or time is not correct on Controller.	Set correct date and time on Controller
	A critical error has occurred with the Controller. Error Code: 000: No Error 001: Battery Low 002: Battery Critically Low 003: Battery Empty 004: Motor Running Error 005: I2C Communication Error 006: SPI Communication Error 007: UART Communication Error 008: ADC Sampling Error 009: PWM Output Error 010: Battery Unhealthy 011: Battery Over-Temperature	Power down the Controller. Replace the Controller if the issue is not resolved by powering down the device and rebooting.

	012: Board Over-Temperature 013: Strap Read/Write Error 014: RTC Error	
	A valid Strap is not connected to the Controller.	Connect the Controller to a MAC System Strap.
	The battery is critically low.	Replace the battery with a fully charged battery from the Charging Hub.
	Date or time of Controller does not match the date or time of the data in the Strap from the previously used Controller.	The device is unable to keep the previous data on the strap due to an incorrect date/time. Press OK to continue because the previous data is unable to be retrieved.
	Strap is too loose on patient's leg.	Adjust and tighten Strap on patient's leg.
	Strap is too tight on patient's leg.	Adjust and loosen Strap on patient's leg.
	Strap has reached its maximum usage.	Initiate a new MAC System Strap.
	A nonauthorized Strap is attempting to be used.	Initiate new authentic MAC System Strap

F. Warranty and Contact Information

F.1 Contact Information

Recovery Force
10022 Lantern Rd., Suite 100
Fishers, IN 46037
www.recoveryforceusa.com

Customer Service

Recovery Force
10022 Lantern Rd., Suite 100
Fishers, IN 46037
1 866.745.7445

F.2. Warranty

The Recovery Force Movement and Compressions System includes the Strap, Controller, Charging Hub, and AC Power Cord all of which are warranted by Recovery Force against manufacturing defects in material and workmanship for a period of one year from the date of purchase. In the event of any such defect occurring during the warranty period, Recovery Force will, at its option, (a) correct the defect by repair or by replacement of the applicable part or component that fails as a result of such defect, without charge for parts and labor; or (b) replace the device with one of the same or current design.

This warranty applies for a period of twelve (12) months from date of purchase.
This warranty does not include or cover malfunctions caused by:

- Unreasonable use,
- Non-compliance with user instructions and maintenance,
- Not following instructions,
- Damage caused by unauthorized or unqualified repairs.

The foregoing Warranties do not cover normal wear and tear or cosmetic damage, and are void if the device are not used in accordance with the User Manual, is otherwise misused or modified in any way, and/or are repaired or altered by anyone other than an authorized service representative of Recovery Force. These Warranties expressly exclude transportation, shipping or insurance costs, or defects, damages or failure resulting from misuse, abuse, improper or abnormal usage, or neglect.

EXCEPT AS PROVIDED ABOVE, RECOVERY FORCE MAKES NO EXPRESS WARRANTIES OR ANY IMPLIED WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE, AND ARE LIMITED IN DURATION AS STATED ABOVE. EXCEPT AS EXPRESSLY STATED ABOVE, RECOVERY FORCE SHALL HAVE NO LIABILITY OR RESPONSIBILITY TO ITS CUSTOMER, OR ANY OTHER PERSON OR ENTITY, WITH RESPECT TO ANY LIABILITY, LOSS OR DAMAGE CAUSED DIRECTLY OR INDIRECTLY BY USE OR PERFORMANCE OF THE PRODUCT OR ARISING OUT OF THE USE, INABILITY TO USE OR ANY BREACH OF THESE WARRANTIES, INCLUDING BUT NOT LIMITED TO ANY DAMAGES RESULTING FROM INCONVENIENCE, LOSS OF TIME, PROPERTY OR INCOME, OR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. These Warranties give you specific legal rights, and you may also have other rights, which vary from state to state. In the event of a product defect covered by the foregoing Warranties during the applicable warranty period, call the toll-free number of Recovery Force for instructions.

All replaced parts and products become the property of Recovery Force.
New parts and products may be used in the performance of Warranty service. Replaced products are warranted for the remainder of the original warranty period only.

NOTE:This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.

CAUTION: Please note that changes or modifications of this product is not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.