



# **Movement and Compressions System**

(Model RF1400)

## **User Manual UM1400-00-19**

### **Recovery Force Health**

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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 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, first, a single-patient use Comfort+ Sleeve is applied to the patient's leg. Then, a single-patient use disposable 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 the securement ring. 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 from 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 and Comfort+ Sleeve) or the surfaces are easily disinfected (MAC Controller and Charging Hub) allowing for ease of cleaning and mitigation of cross-contamination, as there are no air tube 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) by enhancing blood circulation; and,
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.

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 patient 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, pneumonia, atrophic muscles, and delirium.


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 result 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 Health.

**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. The device is to be used only by the prescribed patient, and only for its intended use.
3. The device is not intended for use with patients with venous valvular incompetence, as the device has not been studied in that patient population.
4. Do not use device with persons who are unable to communicate due to physical, sedation, cognitive or emotional deficiencies.
5. If you are, or may be, pregnant, consult with your physician before use.
6. Recharge battery only using Charging Hub provided with MAC System.
7. Do not use where aerosol (spray) products are being used or oxygen is being administered. Electromedical devices have the potential for explosion in these situations.
8. Never use pins or other metallic fasteners with this product as these could damage the device.
9. Care must be taken when operating this equipment around other equipment to avoid reciprocal interference. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with this device.
10. Operation of this device should be done by a registered healthcare professional, if available, but can also be used by the individual user.
11. Keep and store when not in use out of reach of children, pets, pests, and away from water.

12. The Movement and Compressions System utilizes a Controller and Strap for each leg and a Charging Hub to charge the batteries of the Controller and should not be used or interconnected to any other device.
13. No modification of this equipment is allowed. No user serviceable parts inside. Direct all issues to Recovery Force Health Customer Service.
14. If a patient experiences pain, swelling, sensation changes, discomfort or any unusual reactions (including sensitivity or skin reactions) while using the MAC System or if a caregiver witnesses these patient experiences, the device should be stopped, and the prescribing physician should be contacted immediately.
15. 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
16. 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, security systems, electrocautery equipment, diathermy equipment, and radiant warmers are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the device away from such equipment and verify its performance before use.
17. Remove the Controller from the Strap before storing or cleaning.

18. Equipment should not be used in the presence of any flammable anesthetic mixture with air, oxygen, or nitrous oxide.
19. Use caution to avoid the risk of strangulation from the cable of the Charging Hub and/or AC power cord.
20. Keep the Charging Hub and AC power cord away from heated surfaces.
21. 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.
22. Keep the Controller, Charging Hub, and AC power cord dry. Do not operate while bathing, in a shower, in or around water, or in a wet or moist condition. Inadvertent spills should be wiped immediately to prevent liquid ingress into the device. Wet devices may cause electric shock when activated.
23. 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. If damage or deterioration is observed, please contact Recovery Force Health Customer Service.
24. If ingested, the electronic materials and fasteners may cause problems.
25. Do not use with a power supply/charger/strap not recommended by the Manufacturer. This could damage the components of the device.

**CAUTION:**

1. Movement and Compressions System is not made with natural rubber latex.
2. Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF communication (RFID) 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 Comfort+ Sleeve should be worn directly on the skin.
2. The Movement and Compressions System should be applied comfortably around the upper calf muscle for best performance.
3. Make sure the Controller is secured into position on the mounts of the Strap before initiating device.
4. Before using, check Controller and Strap visually for any damage.
5. Always follow the storage and operating instructions.

#### **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 sequence:

1. Compression for  $\leq 1$  second
2. Hold for 1 second
3. Compression release for  $\leq 2$  seconds
4. No compressions for  $\sim 56$  seconds

Device will operate continuously for approximately 40 hours on a fully charged battery.

Expected service life for the MAC System is the following:

1. MAC Strap – 10,800 cycles (Strap will not function with Controller after 10,800 cycles and a ‘Strap Expired’ error will be displayed on Controller.)
2. MAC Controller – 500,000 cycles (# of Cycles is indicated on the display of Controller when powered off.)

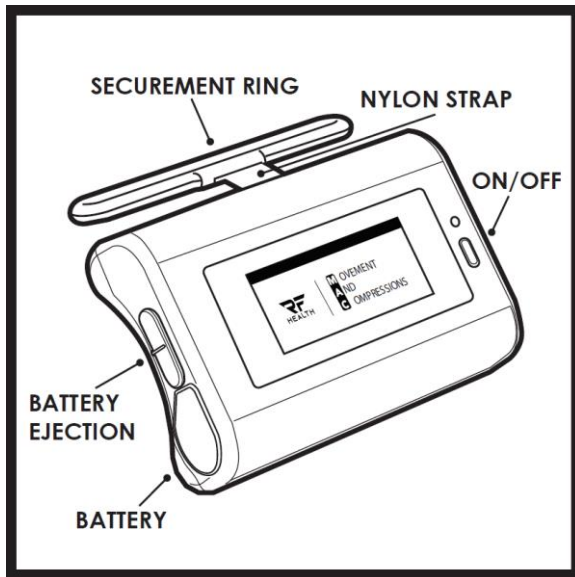
- MAC Charging Hub – 2,000 battery installations and charges (LED will indicate error status, charging status, and functionality of the Charging Hub at all times.)

## B. Instructions for Use

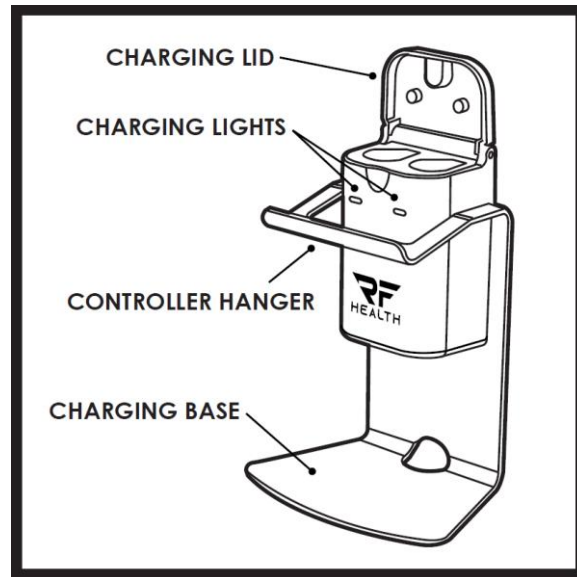
### B.1 Parts Definition

#### MAC Hardware

##### Controller

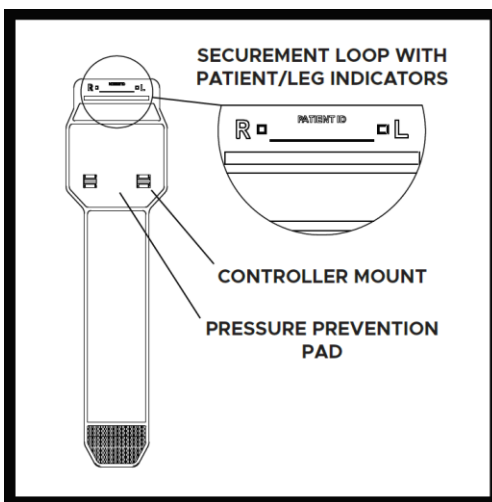


##### Charging Hub

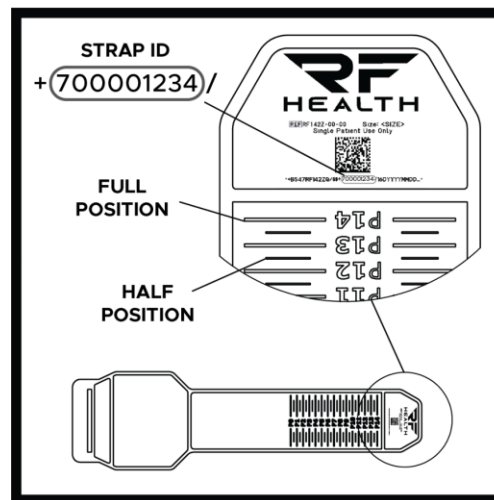


#### MAC Single-Use Disposable Strap

##### Strap – Front



##### Strap - Back



## Parts List:

- Applied Parts:
  - **MAC Controller** (Includes Electronics & Battery)  
Part #: RF1410-00-00
  - **MAC Strap & Comfort+ Sleeve (4 sizes)**
    - Petite Strap & Comfort+ Sleeve:** 8” – 11” (20.3cm – 27.9cm)  
Comfort+ Sleeve (Small)  
Part #: RF1423-00-00
    - Standard Strap & Comfort+ Sleeve:** 11” – 17” (27.9cm – 43.2cm)  
Comfort+ Sleeve (Medium)  
Part #: RF1420-00-00
    - Extra Large Strap & Comfort+ Sleeve:** 17” – 24.5”  
(43.2cm – 62.2cm)  
Comfort+ Sleeve (Large)  
Part #: RF1421-00-00
    - Bariatric Strap & Comfort+ Sleeve:** 24.5” – 31” (62.2cm – 78.7cm)  
Comfort+ Sleeve (Large)  
Part #: RF1422-00-00
  
- 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 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.’

### Quick-Start Guide

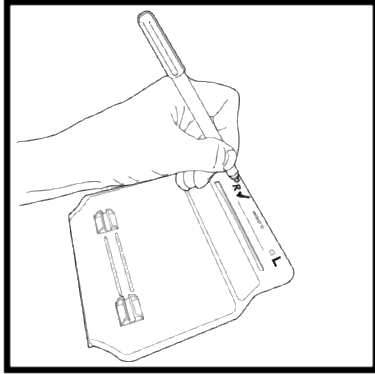
#### **STEP 1:**

Remove the Strap and Comfort+ Sleeve from the package by tearing the perforation which is located on both the front and back side of the Strap packaging.



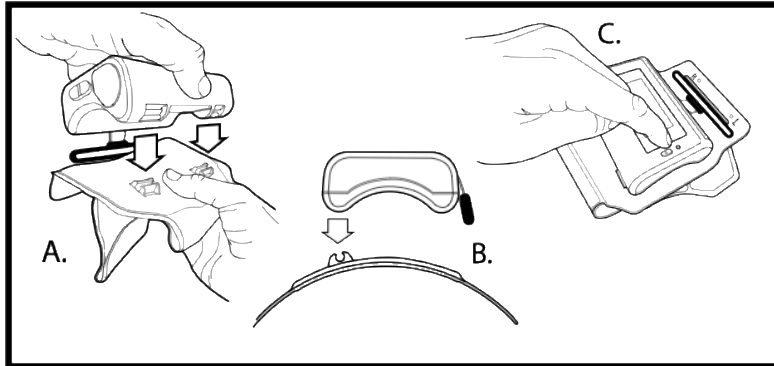
**NOTE:** The QR code on the back of the Strap package provides additional resources for application and use of the MAC System.

**STEP 2:**



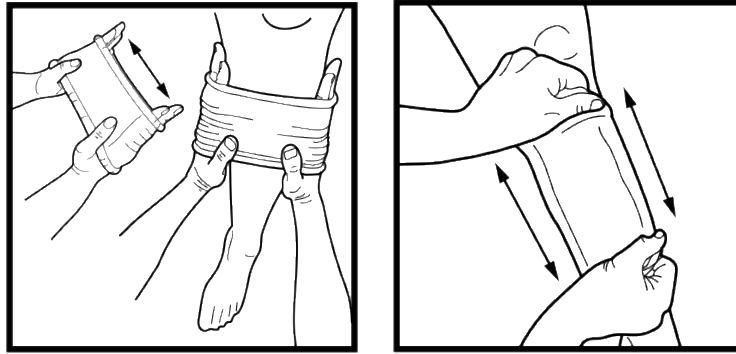
Mark the 'L' or 'R' on the Strap indicating which leg the Strap will be placed on in Step 6.

**STEP 3:**



- a. Align the Controller with the blue Strap mounts as shown
- b. Press down to snap the Controller into the mounts
- c. Once the Controller has successfully been secured to the Strap, power on the Controller by pressing the ON/OFF button for a few seconds until the SOLID RED light appears.

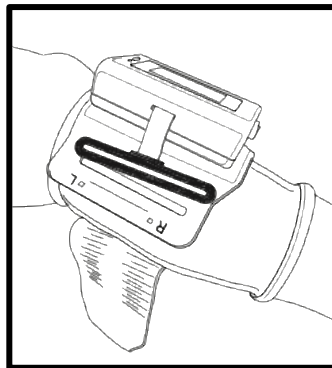
## **STEP 4:**



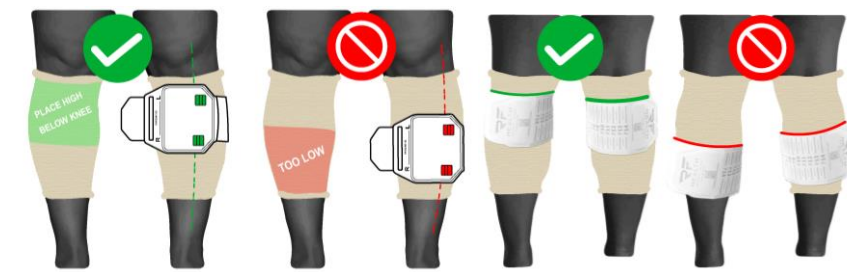
The Comfort+ Sleeve should be applied directly onto the skin. Place hands inside the sleeve, starting at the foot begin guiding the sleeve up and over the calf. It should sit right below the knee.

***To ensure proper placement, gently tug at each end of the sleeve to distribute fabric evenly over the calf.***

## **STEP 5:**



With the leg horizontal, position the Strap & Controller just below the knee. **\*Keep the Strap securement loop and black Controller securement ring on the inside of the leg.**

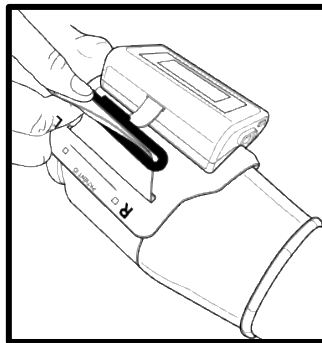


**NOTE:** The Strap is applied correctly when the 'L' on the Securement Loop is facing up towards the knee on the left leg and the 'R' on the Securement Loop is facing up towards the knee on the right leg.

For patients with a prominent tibial ridge, it is recommended to offset the strap slightly medial aligning the Strap mounts with the tibial ridge.

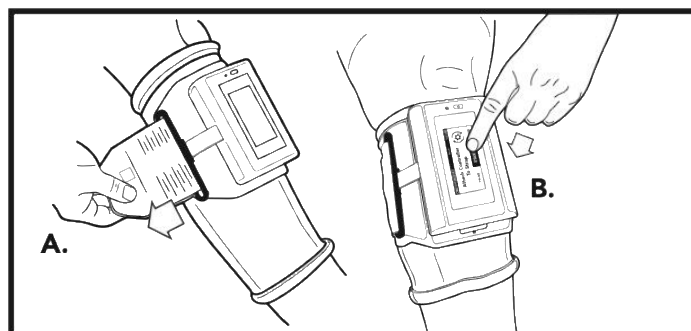
**CAUTION:** It is important to conduct periodic skin assessments and breaks from the device, consistent with hospital or physician protocols. Recovery Force Health recommends providing a break every 10 hours for high-risk skin integrity patients.

**STEP 6:**



Feed the Strap through the Strap securement loop & black Controller securement ring.

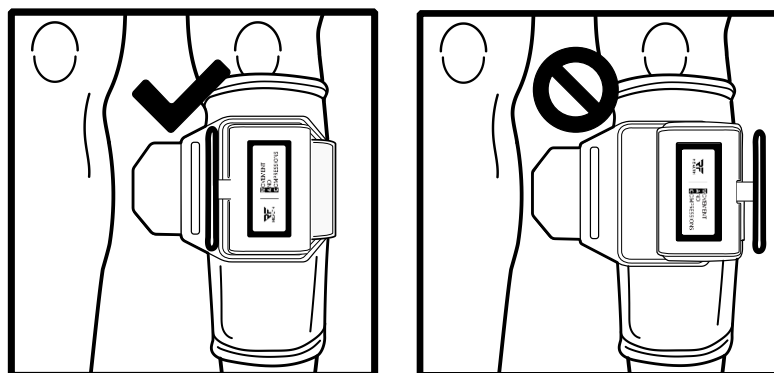
**STEP 7:**



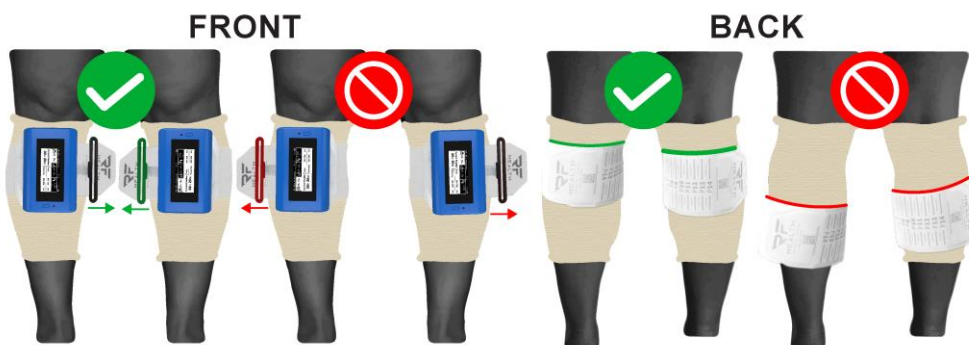
a. Secure Velcro around the leg comfortably, but not too snug.

- b. Press START on the Controller screen to begin Mechanical Prophylaxis and Mobility Tracking.

**CAUTION:** The Controller must be secured by both Controller mounts on Strap to perform properly. Both the securement ring of the Controller and the securement loop of the Strap will line up so the Strap can feed through both loops as seen below:



**NOTE:** Below is the proper placement and orientation of the MAC System once both Controllers have been secured to the Strap on each leg:



### **STEP 8: Begin Mechanical Prophylaxis and Mobility Tracking**

- a. Once powered on, the Controller will show a calibration screen followed automatically by the *Attach to Strap* screen. (This will take approximately 30-40 seconds).



- b. Hold the Controller in position on the leg and press the START button to begin mechanical prophylaxis and mobility tracking.



**NOTE:** If display reads 'No Strap Connected' after pressing START, refer to Step 7 to ensure Controller has been properly mounted on the Strap.

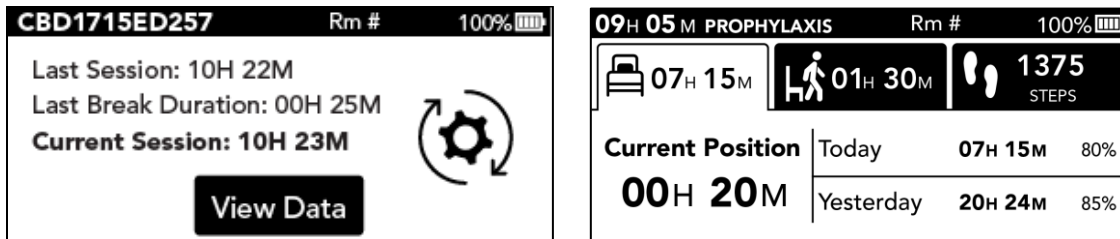
- c. The MAC System will recognize when there is existing data on a Strap and when a new Strap is initiated. Select the appropriate response by either pressing 'New Patient' to erase the data on the Controller and start over, or 'Same Patient' to continue tracking the progress of the patient where the last Strap left off.



- d. Once the device reaches the desired Strap tension after pressing START, the display will show the "Current Session" screen, which details the duration of the Last Session, the duration of the Last Break the

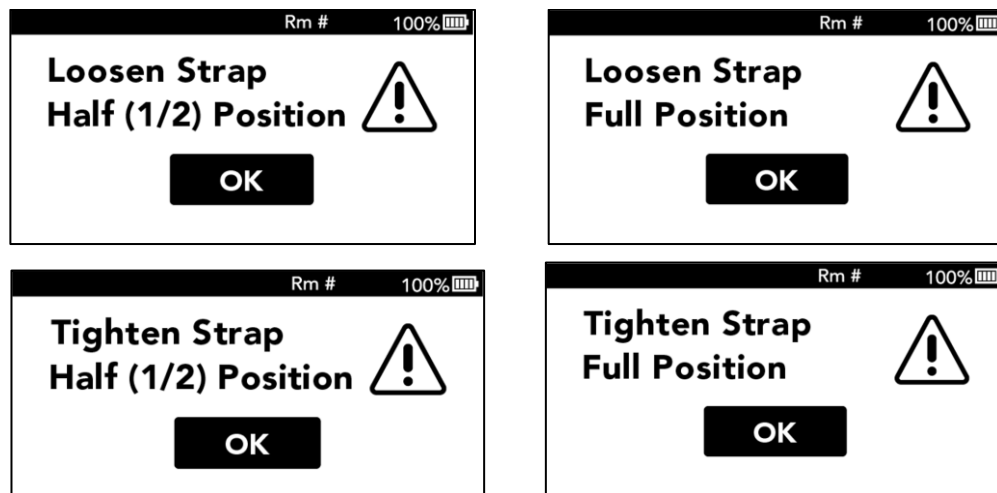
patient had, and the Current Session duration. This screen also provides access to view the patient’s In-Bed, Upright, and Step data by selecting the “View Data” button which accesses the Mobility Screens. See example below:

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



e. If the device does not reach the desired Strap tension after pressing START, the screen will give an indication notifying the user that the Strap needs to be loosened or tightened by either a half or full position, as marked on the Strap.

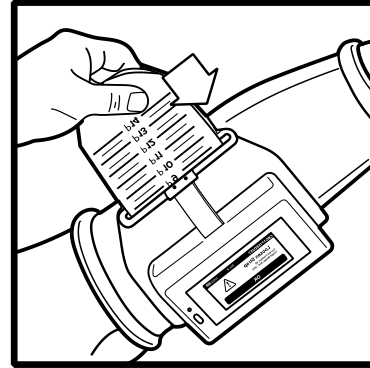
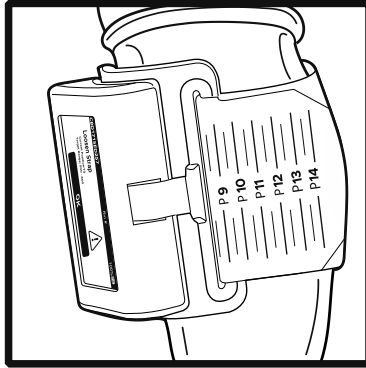
**NOTE:** When small adjustments to the Strap tension are necessary, it is recommended to tighten or loosen the tension by a half position. When larger adjustments to the Strap tension are necessary, it is recommended to tighten or loosen the tension by a full position.



Loosen Strap by Half Position Example:

Current Strap Position – P8.5

New Strap Position – P9

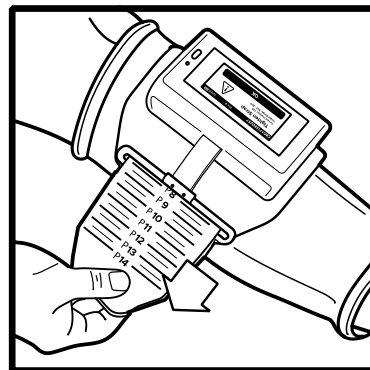
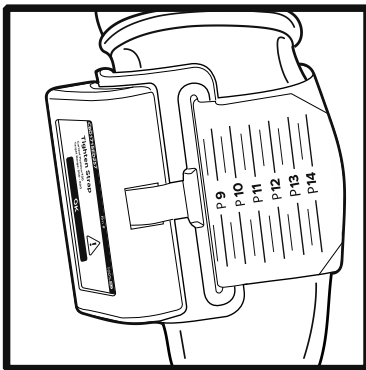


**NOTE:** A full position adjustment would result in a new Strap position of P9.5

Tighten Strap by Half Position Example:

Current Strap Position – P8.5

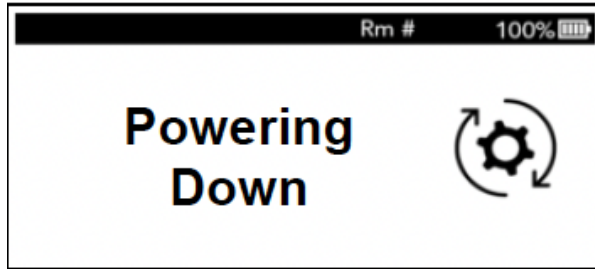
New Strap Position – P8



**NOTE:** A full position adjustment would result in a new Strap position of P7.5

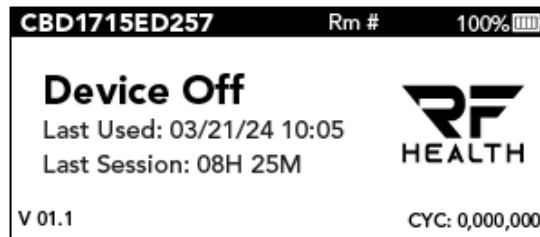
## **STEP 9: Turning Off the Movement and Compressions System**

- a. To turn the device OFF, PRESS the ON / OFF button again for THREE seconds. The “*Powering Down*” screen will appear. See below. When the controller is off, the SOLID RED light will no longer appear.



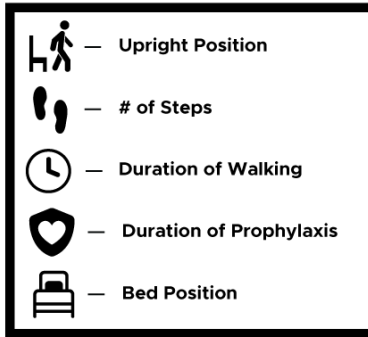
**NOTE 1:** If this is a WiFi enabled Controller, compliance and mobility data will be uploaded to the RF Cloud during the powering down process. This could take up to approximately two minutes.

**NOTE 2:** The screen on the Controller will read *Device Off* when the device has been turned off properly. It will display when the device was last used and duration of the last session.



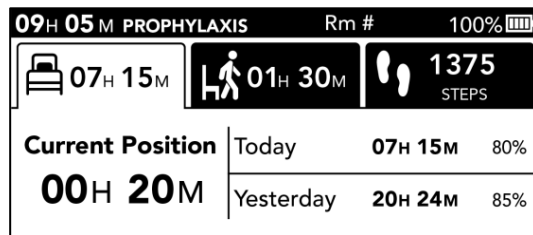
## **Mobility Screens**

When the Movement and Compressions System is running mechanical prophylaxis, it provides the Controller’s orientation and mobility data via the Controller’s touchscreen display. The MAC System also utilizes symbols to reflect certain data and patient positions on the touchscreen display, which are defined and listed below:



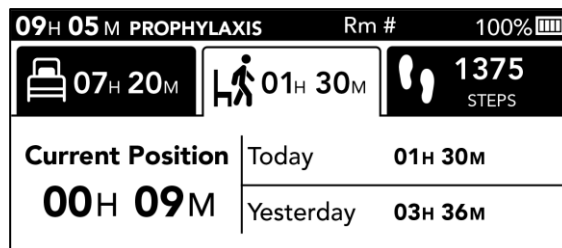
The following are example screens offered while using the Movement and Compressions System:

**BED SCREEN: CONTROLLER IS CURRENTLY HORIZONTAL**



This screen example shows the highlighted Bed tab because the Controller has currently been horizontal for 20 consecutive minutes without changing position for more than 1 minute. It also displays that the Controller has recorded 7 hours and 15 minutes and has spent 80% of its wear time in the horizontal position. Up to 48 hours of data is displayed for day-to-day comparison.

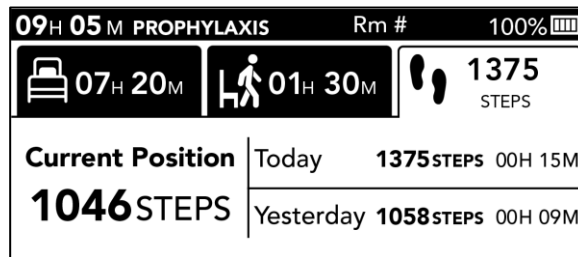
**UPRIGHT SCREEN: CONTROLLER IS CURRENTLY VERTICAL**



This screen example shows the highlighted Upright tab because the Controller has currently been in an Upright position for 9 consecutive minutes without changing position for more than 1 minute. It also displays that the Controller has recorded 1 hour and 30 minutes in an Upright position. Up to 48 hours of data is displayed for day-to-day comparison.

**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 Controller has recorded 1046 steps in this current session with a total of 1375 steps taken today over the course of 15 minutes. Up to 48 hours of data is displayed for day-to-day comparison.

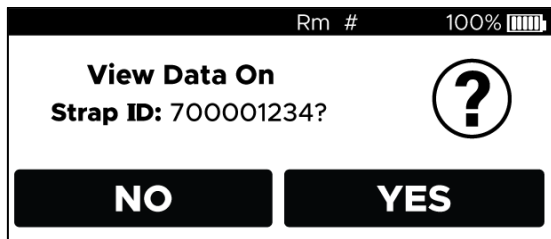
**View Data Screen**

The Movement and Compressions System also has the capability to display the patient’s mechanical prophylaxis duration and mobility data when the device is not in use, but the Controller must be locked into the mount on the Strap to access the data on the Strap.

The data can be accessed on the initial screen via the ‘VIEW DATA’ button once the Controller is powered on.

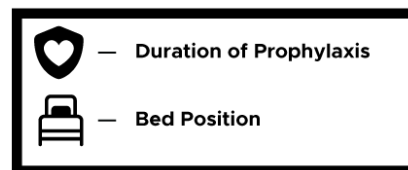
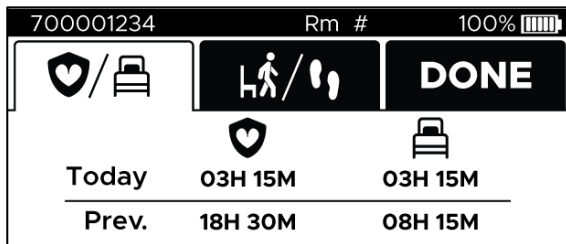


The Controller will ask to confirm the Strap ID prior to showing the data. The Strap ID is located underneath the barcode at the top of the Strap.

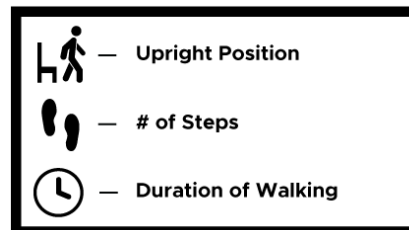
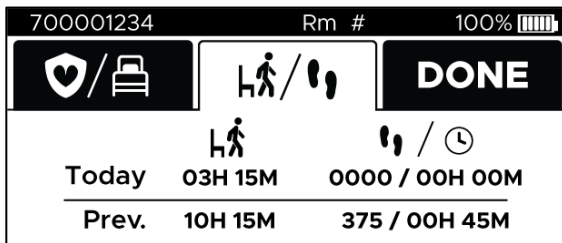


Once the Strap ID is confirmed, the data that is saved on the Strap will be displayed on the Controller screen via the tabs.

The first tab on the 'VIEW DATA' screen will display both the duration of Prophylaxis and Bed position.



The second tab on the 'VIEW DATA' screen will display the Upright duration, # of Steps, and duration of Walking.



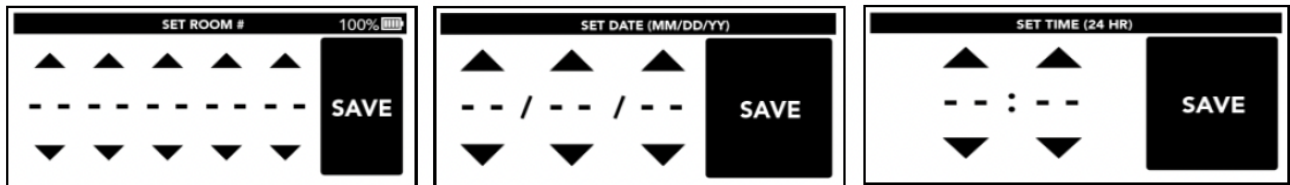
**NOTE:** Only data on the Strap used today and yesterday will be displayed when the 'VIEW DATA' button is pressed. Straps that have not been used in the last 48 hours will not show data for today and yesterday.

## **Setup Screen**

The Movement and Compressions System also has the capability of setting the time and date, along with setting the Room # manually. (Note: If Wi-Fi enabled and connected to Wi-Fi, the time and date will automatically sync with the RF Cloud.). Pressing the 'SETUP' button will bring up the following screen.



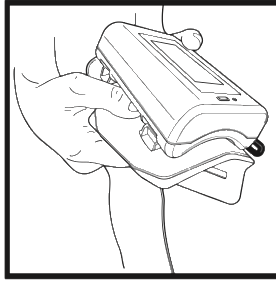
Pressing the 'NO' button returns the user to the *Attach to Strap* screen. Pressing the 'YES' button continues to the following sequence of screens that allow the user to set the time, date, and room #. After adjusting these by pressing the up/down arrows, pressing the 'SAVE' button progresses the user to the next screen.



After pressing 'SAVE' on the last screen, the user will be returned to the *Attach to Strap* screen.

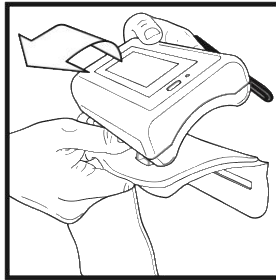
## Removal Instructions

### STEP 1:



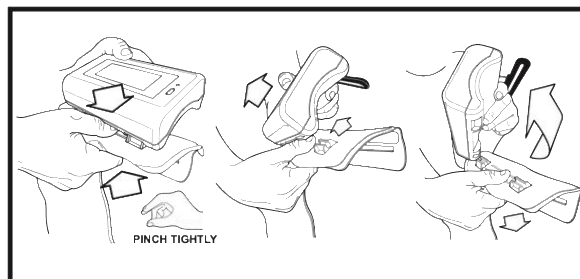
Remove the Strap & Controller from the patient's leg. Once removed, place your thumb between the two blue Controller mounts.

### STEP 2:



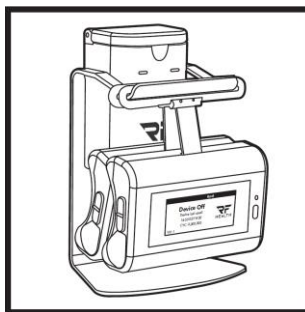
Next, lift the Controller away from the Strap securement ring.

### STEP 3:



Ensure you are pinching tightly between the blue Controller mounts then slowly peel the Controller towards yourself, lifting off each mount one at a time.

- a. If a patient is transferring units or being discharged, the Controllers should be stored by hanging the black Controller securement ring from the Charging Hub. Ensure the Straps are re-applied to the patient's leg prior to transfer.
- b. If a patient is receiving a break, the Controllers remain attached to the Strap and are stored by hanging both the Strap securement loop & black Controller securement ring from the Charging Hub.



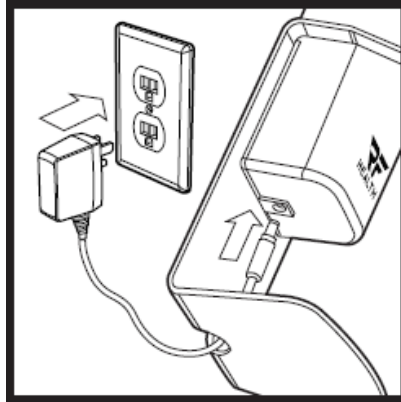
### **Charging Movement and Compressions System**

Only use the Charging Hub provided by Recovery Force Health to charge the MAC System batteries. The Charging Hub is the only way to charge the replaceable batteries of the Movement and Compressions System. Additionally, only place the batteries of the Movement and Compressions System in the Charging Hub.

**NOTE:** Use of the wrong charger can cause excessive heat, damage to the charging circuit, and shorten the battery life.




## To Charge the Battery

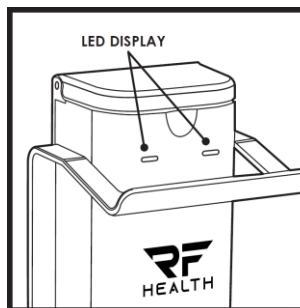
- a. The AC Power Cord of the Charging Hub must be plugged into a wall outlet. Verify that the outlet is not obstructed in any way for quick disconnect from the outlet.



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

## 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.
-  **FLASHING RED:** When a battery is present in the Charging Hub and is permanently damaged, the LED shall indicate the error by flashing red. Replace battery with a new battery if this occurs.



## Wi-Fi Enabled MAC Controller

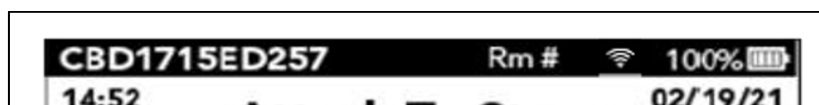
The user interface and user functionality of the Wi-Fi Enabled MAC Controller is the same as the standard non-connected MAC Controller. However, the Wi-Fi enabled MAC Controller provides the ability for compliance data, mobility data, and hardware error information to be uploaded to the RF Cloud.

**NOTE:** The MAC System does NOT contain or store any Personally Identifiable Information (PII), Protected Healthcare Information (PHI), or Payment Card Industry data (PCI).

The Wi-Fi enabled MAC Controller will automatically connect to the wi-fi network that it has been pre-configured to connect to and then proceed to upload data to the RF Cloud every hour and upon powering-down. If the controller cannot connect and upload data upon the powering-down process, the following screen is displayed:



The Wi-Fi enabled controller is not always connected to wi-fi. It connects to wi-fi only long enough to upload data (approximately 15 seconds) and then disconnects. The black information bar at the top of every screen will display an icon indicating whether the previous data upload attempt was successful or not. If it was a successful wi-fi connection and data upload, the information bar will include a “wi-fi” icon as follows:



If it was not a successful wi-fi connection and data upload, the information bar will include a “no wi-fi” icon as follows:



## **B.4 Safety Features**

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

Fuses cannot be reset by the user. Return the Movement and Compressions System to Recovery Force Health 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 a 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.) and replace if damaged.

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 Health Customer Service at 1 866.604.6458 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 1 866.604.6458 or visit our website

[www.rfhealth.com/contact-us](http://www.rfhealth.com/contact-us)

## C.2 Cleaning and Disinfecting the Movement and Compressions System

The Movement and Compressions System is comprised of the following components: Controller, Charging Hub, Strap, and Comfort+ Sleeve. No disassembly is required for cleaning or disinfecting the components of the MAC System other than removing the Strap and Comfort+ Sleeve. The MAC System should be routinely cleaned and disinfected between patients and at regular intervals while in use.

Recovery Force Health recommends cleaning and disinfecting the Controller and Charging Hub by wiping all surfaces with prepared healthcare grade cleaning agents such as the solutions listed below. The following agents should be applied as described in the cleaning agent manufacturer's instructions for use.

<b>Chemical Cleaners (approximate concentrations)</b>	<b>Commercial Example</b>
0.25% dimethyl ethylbenzyl ammonium chlorides, 0.25% dimethyl benzyl ammonium chlorides, 55.00% Isopropyl Alcohol	PDI® Super Sani-Cloth Germicidal Disposable Wipe
0.63% Bleach	PDI® Sani-Cloth Bleach Germicidal Disposable Wipe

If an alternative disinfectant is selected from the wide variety available commercially, we recommend that suitability for use is confirmed with the chemical supplier prior to use.

**Cleaning:** To clean, use a wipe to remove any heavy soil from device surface. Make sure all the soil is removed, using more wipes if necessary. Note: You do not need to wait for the contact time for the cleaning step.

**Disinfecting:** To disinfect, there must be no visible soil on the device surface. Thoroughly wipe the surface of the device, paying particular attention to high touch features of the device and areas most likely to retain soil, such as uneven surfaces, seams or recesses where components join, as pictured below. The treated surface must remain wet for the full contact time as described in the cleaning agent manufacturer's instructions for use.

**Controller Touch Screen  
& Power Button**



**Controller Battery  
Compartment**



**Controller Nylon Strap**



**Charging Hub Compartment Lid**



Do not allow liquid to pool on the surface of the device. If any liquid enters the ports, then internal component damage could result. Do not use anything abrasive to clean the Controller display.

### **To Clean the Strap and Comfort+ Sleeve**

The Strap and Comfort+ Sleeve are single patient use and can be cleaned using a soft cloth dampened with water or a mild detergent. The Strap and Comfort+ Sleeve are single patient use only and should not be reused on multiple patients. If heavily soiled, replace.

### **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, Comfort+ Sleeve, 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 Health Customer Service for proper disposal and recycling of the device.

## D. Technical Details

### D.1 Technical Specifications

Specifications		Sizing		
Model	RF1400 Movement and Compressions System	<b>Strap Size</b>	<b>Length (in)</b>	<b>Height (in)</b>
Catalog No.	RF1400	Petite	17	4
Class	II	Standard Strap	22	4
Max Force	5.5 lbs.	XL Strap	29	4
Voltage	3.6V Lithium rechargeable Battery	Bariatric Strap	36	4
Battery charger	115V~ 60 Hz	<b>Weight</b>		
Power Consumption	10.44 Wh	Net Weight including Controller	11 oz	
Fuses Rating	2A			



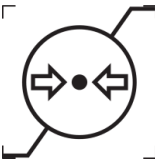


### Service and Repair







The MAC System is not serviceable by the user. No modification of this equipment is allowed. Direct all issues to Recovery Force Health Customer Service. 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
	<p>Temperature limitations for storage and/or transport &amp; Operation of the device.</p> <p>Storage &amp; Transport Temperature: -13°F to 158°F (-25°C to 70°C)</p> <p>Operating Temperature: 41°F and 104°F (5°C to 40°C)</p>	<p>On Charging Hub and Controller</p>
	<p>Humidity limitations for storage and/or transport &amp; Operation of the device.</p> <p>Storage &amp; Transport Relative Humidity: 10% to 90%, non-condensing, &gt;35 °C to 70 °C at a water vapor pressure up to 50 hPa</p> <p>Operating Relative Humidity: 15% to 90%, non-condensing, but not requiring water vapor partial pressure greater than 50 hPa</p>	<p>On Charging Hub and Controller</p>
	<p>Atmospheric Pressure limitations for storage and/or transport &amp; Operation of the device.</p> <p>Storage &amp; Transport Atmospheric Pressure: 50 kPa to 106 kPa</p> <p>Operating Atmospheric Pressure: 700 hPa to 1060 hPa</p>	<p>On Charging Hub and Controller</p>
	<p>The name and address next to this factory symbol is the manufacturer.</p>	<p>On packaging, Controller, and Charging Hub</p>
	<p>Nonsterile</p>	<p>On packaging, Controller, and Strap</p>

	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
	Read the user manual before use.	On Strap packaging, Controller, and Charging Hub
R <sub>X</sub> Only	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 packaging, On Strap packaging, Controller, and Charging Hub
	Do not dry clean.	On Strap packaging
	Do not immerse.	On Controller and Charging Hub



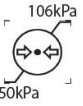
Strap not made with natural rubber latex	Not manufactured with natural rubber latex	On Strap packaging
	This electromechanical device includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Contact local requirements for proper disposal instructions.	On Controller and 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
FCC ID:	FCC ID is an ID employed on electronic products manufactured or sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission (FCC).	On Controller




### **Labeling on the Controller**



**REF** RF1410-00-00


IP22  

**Rx only**


  

Battery: 3.6V 

FCC ID: 2AXDCRF1410-00

RF Health  
10022 Lantern Rd Suite 100  
Fishers, IN 46037  
PH: 1-866-604-6458   
www.rfhealth.com



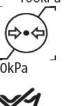
Assembled in U.S.A.  
Patent Pending



## Labeling on the Charging Hub




HEALTH







\*+B547RF14300/\$\$+700000001/16DYRYMMMD\*

**REF** RF1430-00-00   

 **Rx only** IP22 

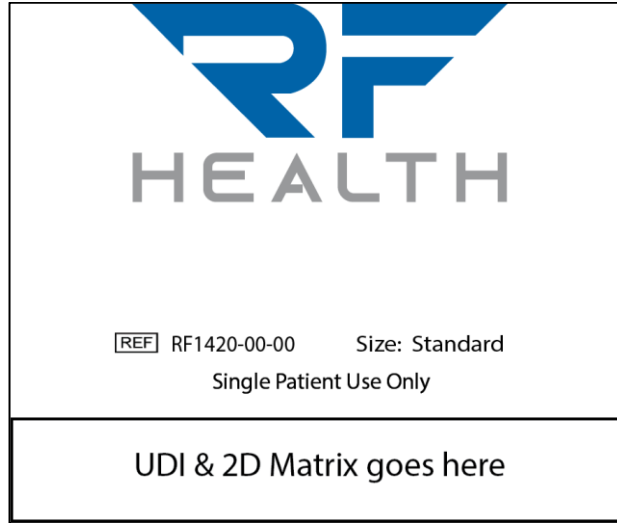
  

Battery: 3.6V   
Power Supply: 5V 

RF Health  
10022 Lantern Rd. Suite 100  
Fishers, IN 46037  
PH: 1-866-604-6458   
www.rfhealth.com

Assembled in U.S.A.  
Patent Pending

# Labeling on Strap



# Labeling on the individual Strap bag

**Movement And Compressions™**

One RF Health MAC Strap And Comfort+ Sleeve  
Size: Standard

	REF #	Size Description	Circumference
	RF1423-00-00	Petite	8" - 11" (20.3cm - 27.9cm)
X	RF1420-00-00	Standard	11" - 17" (27.9cm - 43.2cm)
	RF1421-00-00	Extra Large	17" - 24.5" (43.2cm - 62.2cm)
	RF1422-00-00	Bariatric	24.5" - 31" (62.2cm - 78.7cm)

Strap not manufactured with natural rubber latex

Single Patient Use Only

Manufactured by Recovery Force Health  
10022 Lantern Rd. Ste 100  
Fishers, IN 46037  
PH: 1-800-604-6458  
www.rfhealth.com

Patented  
Made in USA

UDI Sticker goes here

STANDARD

TEAR HERE

TEAR HERE

**Movement And Compressions™**  
Measuring Patient Recovery One Step at a Time

APPLICATION INSTRUCTIONS

1. USE THE LEFT HAND TO HOLD THE STRAP TO THE LEFT OF THE PATIENT'S ANKLE.

2. PRESS AND BREEZELY HOLD THE POWER BUTTON TO TURN ON THE CONTROLLED STRAP. DO NOT HOLD THE STRAP TO THE PATIENT.

3. PRESS AND BREEZELY HOLD THE POWER BUTTON TO TURN ON THE CONTROLLED STRAP. DO NOT HOLD THE STRAP TO THE PATIENT.

4. ADJUST THE STRAP TO THE PATIENT'S ANKLE.






5. PRESS AND BREEZELY HOLD THE POWER BUTTON TO TURN ON THE CONTROLLED STRAP. DO NOT HOLD THE STRAP TO THE PATIENT.

6. PRESS AND BREEZELY HOLD THE POWER BUTTON TO TURN ON THE CONTROLLED STRAP. DO NOT HOLD THE STRAP TO THE PATIENT.

7. PRESS AND BREEZELY HOLD THE POWER BUTTON TO TURN ON THE CONTROLLED STRAP. DO NOT HOLD THE STRAP TO THE PATIENT.

\*SEE USER MANUAL FOR FULL INSTRUCTIONS  
www.rfhealth.com

## 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
<b>RoHS</b>	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

<b>Movement and Compressions System - electromagnetic emissions - manufacturer declaration</b>		
The <b>Movement and Compressions System</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>Movement and Compressions System</b> should assure that it is used in such an environment.		
<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The <b>Movement and Compressions System</b> 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 B	The <b>Movement and Compressions System</b> 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	Class A (only valid for Charging Hub)	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies (only valid for Charging Hub)	
<p><b>NOTE:</b> 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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>-- Reorient or relocate the receiving antenna.</li> <li>-- Increase the separation between the equipment and receiver.</li> <li>-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.</li> <li>-- Consult the dealer or an experienced radio/TV technician for help.</li> </ul>		

**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.

<b>Immunity Test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 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 (only valid for Charging Hub)	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 (only valid for Charging Hub)	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 at 50Hz, 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°  >95% dip in $U_T$ for 20ms at 50Hz, 0°  30% dip in $U_T$ for 500ms at 50Hz, 0°  >95% dip in $U_T$ for 5000ms at 50Hz	Complies (only valid for Charging Hub)	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	30 A/m 50Hz or 60Hz	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial home use or hospital environment.

**NOTE:**  $U_{RT}$  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.

<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz (only valid for Charging Hub)	3 Vrms 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz (only valid for Charging Hub)	Portable and mobile RF communications equipment should be used no closer to any part of the <b>Model RF1400</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	$d = 1,2 = 2,3 P \sqrt{800 \text{ MHz to } 2,5 \text{ GHz}}$ $P \sqrt{80 \text{ MHz to } 800 \text{ MHz } d}$
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 380-390 MHz  28 V/m 430-470 MHz  9 V/m 704-787 MHz  28 V/m 800-960 MHz  28 V/m 1700-1990 MHz  28 V/m 2400-2570 MHz  9 V/m 5100-5800 MHz	27 V/m 380-390 MHz  28 V/m 430-470 MHz  9 V/m 704-787 MHz  28 V/m 800-960 MHz  28 V/m 1700-1990 MHz  28 V/m 2400-2570 MHz  9 V/m 5100-5800 MHz	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, <sup>a</sup> P should be less than the compliance level in each frequency range" <sup>b</sup> 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 $d = 1,2 P^{\sqrt{}}$	80 MHz to 800 MHz $d = 1,2 P^{\sqrt{}}$	800 MHz to 2,5 GHz $d = 2,3 P^{\sqrt{}}$
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).

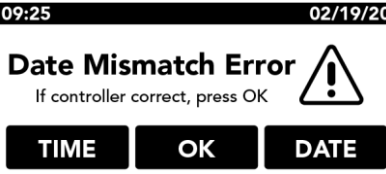


- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or reorient interfering equipment.
- Increase distance between interfering equipment and your System.
- Manage use of frequencies close to the System frequencies.
- Remove devices that are highly susceptible to EMI.
- 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).

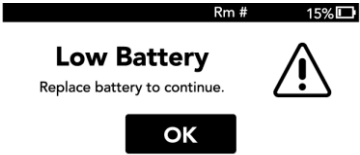



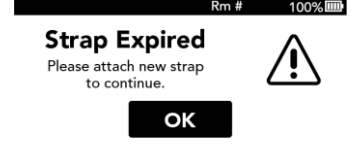



## E. Troubleshooting




**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.

Error Screen	Error Description	Corrective Action
 <p>09:25 02/19/20  <b>Date Mismatch Error</b>          If controller correct, press OK          TIME OK DATE</p>	<p>Date and/or time is not correct on Controller.</p>	<p>Set correct date and time on Controller.</p>
 <p>09:05 M PROPHYLAXIS Rm # 100%  <b>Hardware Error</b>          ERROR 000          OK</p>	<p>A critical error has occurred with the Controller and device will not function for DVT prevention or mobility tracking.</p> <p>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          012: Board Over-Temperature          013: Strap Read/Write Error          014: RTC Error</p>	<p>Power down the Controller. Replace the battery with a fully charged battery and power on.</p> <p>Replace the Controller if the issue is not resolved by powering down the device and rebooting.</p>
 <p>Rm # 100%  <b>No Strap Connected</b>          OK</p>	<p>A valid Strap is not connected to the Controller. Or, the Strap RFID tag is out of range from the Controller.</p>	<p>Connect the Controller to a MAC System Strap. (If no Strap is connected, Device will not function for DVT Prevention or mobility tracking)</p>

Error Screen	Error Description	Corrective Action
 <p><b>Low Battery</b> Replace battery to continue.</p> <p>OK</p>	The battery is critically low.	Replace the battery with a fully charged battery from the Charging Hub.
 <p><b>Strap Date / Time Error</b> Strap Data Will Be Reset!</p> <p>OK</p>	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.
 <p><b>Tighten Strap</b> Press OK</p> <p>OK</p>	Strap is too loose on patient's leg.	Adjust and gently tighten Strap on patient's leg. Restart DVT Prophylaxis.
 <p><b>Loosen Strap</b> Press OK</p> <p>OK</p>	Strap is too tight on patient's leg.	Adjust and gently loosen Strap on patient's leg. Restart DVT Prophylaxis.
 <p><b>Strap Expired</b> Please attach new strap to continue.</p> <p>OK</p>	Strap has reached its maximum usage.	Acquire a new MAC System Strap. (If no new Strap is connected, device will not function for DVT Prevention or mobility tracking.)
 <p><b>Strap Tension Alarm</b></p> <p>OK</p>	Strap is either too tight or too loose on patient's leg.	Press OK and follow next screen instructions to either loosen or tighten Strap.
 <p><b>Strap Read / Write Error</b></p> <p>OK</p>	Unsuccessful read/write of data to the Strap by the Controller	Confirm Controller is securely engaged to both mounts on the Strap
 <p><b>Strap Not Compatible</b> Use genuine strap</p> <p>OK</p>	A nonauthorized Strap is attempting to be used.	Acquire a new authentic MAC System Strap. (If a Strap other than an authentic MAC System Strap is connected, device will not function)

Error Screen	Error Description	Corrective Action
	<p>A WiFi enabled Controller cannot connect to the WiFi network that it was configured to connect to. Therefore, compliance and mobility data will not be uploaded to the RF Cloud.</p>	<p>for DVT Prevention or mobility tracking.)</p> <p>Make sure WiFi network is operational and that the username and/or password has not been changed.</p> <p>If username and/or password has been changed on the WiFi network, the Controller must be re-configured to connect. Contact RF Health.</p>

## F. Warranty and Contact Information

### F.1 Contact Information

Recovery Force Health  
 10022 Lantern Rd., Suite 100  
 Fishers, IN 46037  
[www.rfhealth.com](http://www.rfhealth.com)

### Customer Service

Recovery Force Health  
 10022 Lantern Rd., Suite 100  
 Fishers, IN 46037  
 1 866.604.6458

### F.2 Warranty

The Recovery Force Health Movement and Compressions System includes the Strap, Controller, Charging Hub, and AC Power Cord all of which are warranted by Recovery Force Health 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 Health 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 is not used in accordance with the User Manual, is otherwise misused or modified in any way, and/or is repaired or altered by anyone other than an authorized service representative of Recovery Force Health. 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 HEALTH 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 HEALTH 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 Health for instructions.

All replaced parts and products become the property of Recovery Force Health. 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.