



Movement and Compressions System

(Model RF1400)

User Manual **UM1400-00-18**

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 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, first, a single patient use Comfort+ Sleeve is applied to the patient's leg. Then, 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. 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 securely locked 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 ≤ 1 second
2. Hold for 1 second
3. Compression release for ≤ 2 seconds
4. No compressions for ~ 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:

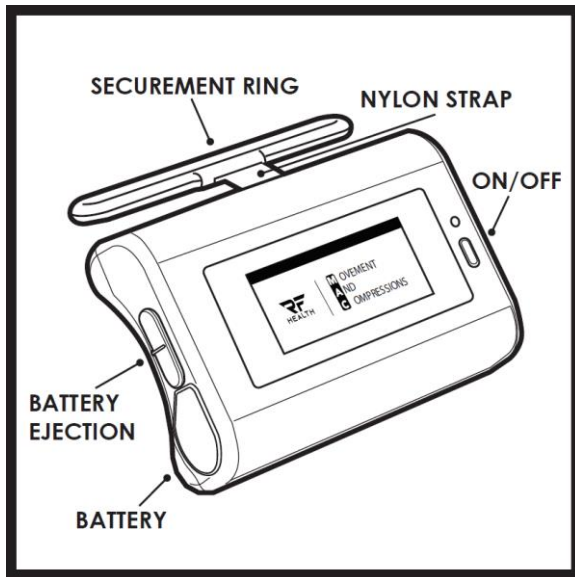
1. MAC Strap – 10,800 cycles (Strap will not function with Controller after 10,800 cycles and a ‘Strap Expired’ error will be displayed on Controller.)
2. MAC Controller – 500,000 cycles (# of Cycles is indicated on the display of Controller when powered off.)
3. MAC Charging Hub – 2,000 battery installations and charges (LED will indicate error status, charging status, and functionality of the Charging Hub at all times.)

B. Instructions for Use

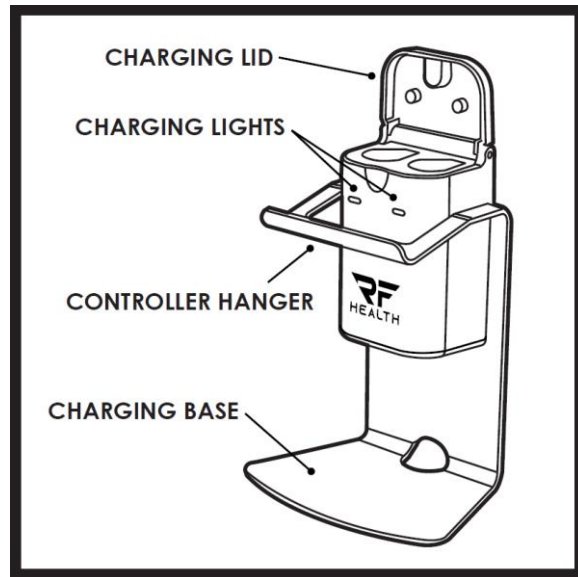
B.1 Parts Definition

MAC Hardware

Controller

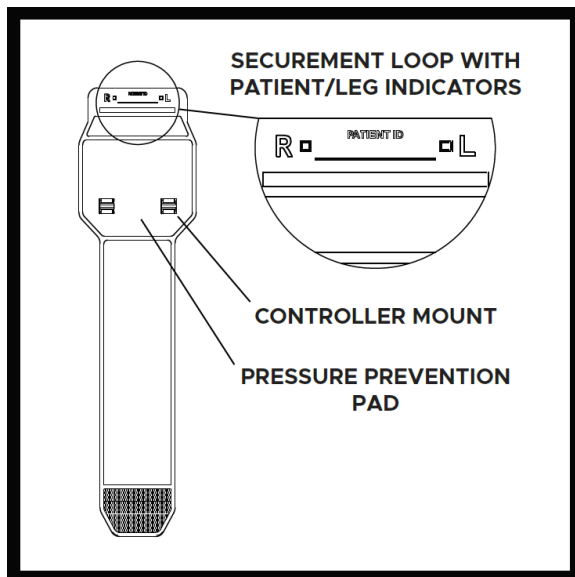


Charging Hub

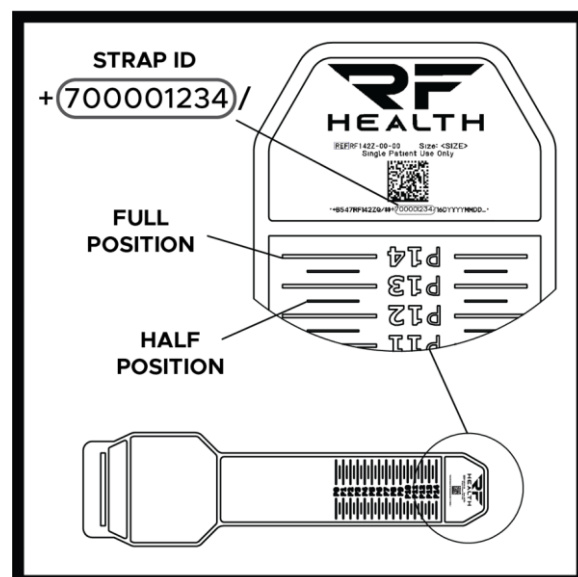


MAC Single-Use Disposable Strap

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**

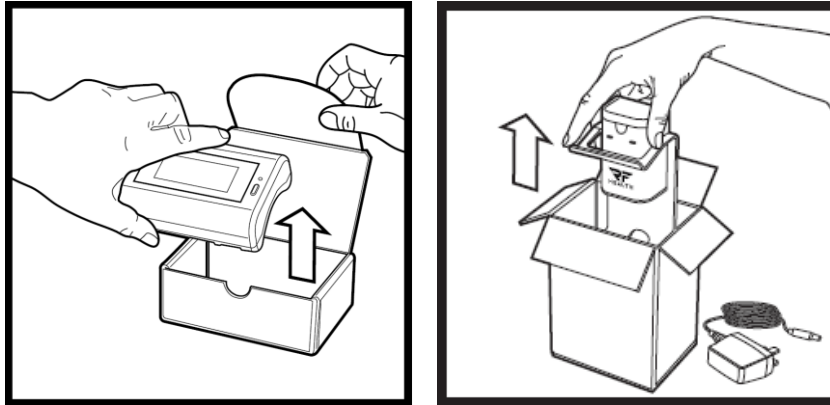
Part #: RF1314-00-00 OTS Part #: WA-20F05FU-AAAA

- **Replacement Battery**

Part #: RF1030-00-00

B.2 Unpacking

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



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

- 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.

RF HEALTH
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: 1-800-999-6434
www.rfhealth.com

Patented
Made in USA

UDI Sticker goes here

TEAR HERE

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

APPLICATION INSTRUCTIONS

- STEP 1** - Apply Comfort+ Sleeve by pulling it up and over the calf, right below the knee.
- STEP 2** - Gently tug at each end of the Comfort+ Sleeve to distribute fabric evenly over the upper calf.
- STEP 3** - Place leg horizontal to the ground and apply MAC Strap just below the knee with the securement loop on the inside of the leg.
- STEP 4** - Feed the end of the strap through the securement loop and secure Velcro.
- STEP 5** - Drop and lock the MAC Controller vertically to the blue mounts on the face of the strap.
- STEP 6** - Disconnect Velcro and feed the strap through the black controller securement ring.
- STEP 7** - Re-secure Velcro around leg comfortably, but not too snug.
- STEP 8** - Power on controller and follow instructions on the screen.

Scan QR code for instructional video

*See User Manual for full instructions
www.rfhealth.com

NOTE: The QR code on the back of the packaging provides a step-by-step education video on how to use the MAC System.

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**.

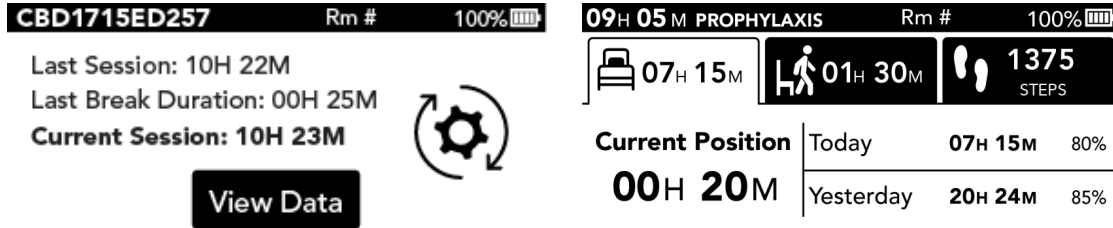
Device Operation Indicator

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

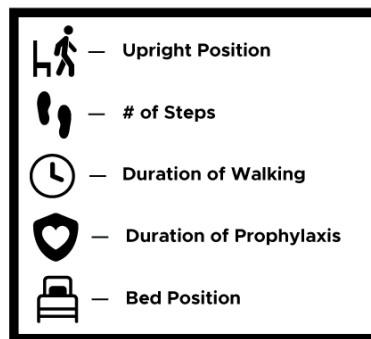
-  **SOLID RED:** If the device is powered ON and active, the LED on the Controller shall indicate a solid RED light.

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 “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:



The MAC System utilizes symbols to reflect certain data and patient positions on the Controller’s touchscreen display, which are defined and listed below:

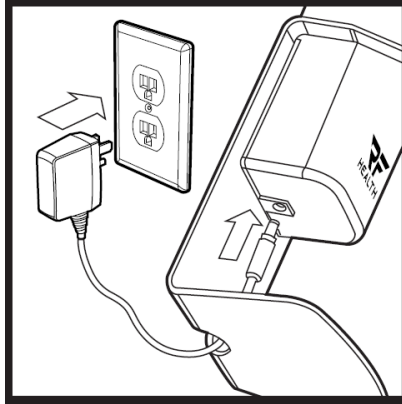


NOTE: For additional information on the Mobility Screens, please see section **Mobility Screens**.

Quick-Start Guide

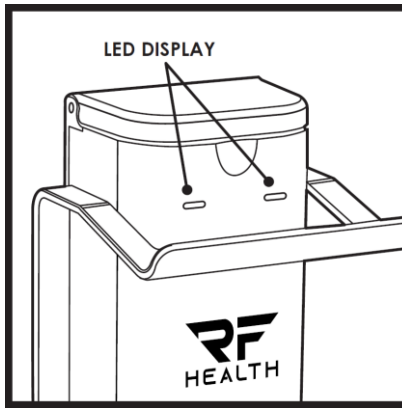
STEP 1 Plug in the Charging Hub

- 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.

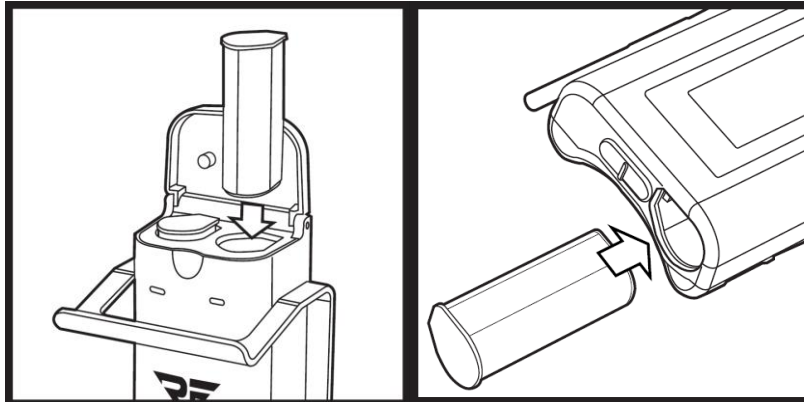
- FLASHING GREEN:** When a battery is present in the Charging Hub yet not fully charged, the LED shall indicate charging by flashing green.
- SOLID GREEN:** When a battery is present in the Charging Hub and fully charged, the LED shall indicate fully charged by displaying solid green.
- FLASHING RED:** 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.



STEP 2 Insert Battery into Controller

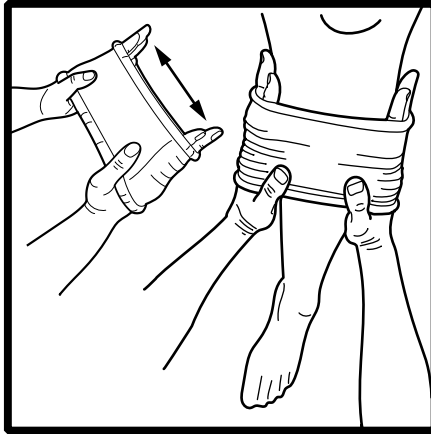
- a. Once the solid green LED is illuminated on the Charging Hub, remove the battery from the Charging Hub, replace that battery with the battery that came inside the Controller, and insert the fully charged battery from the Charging Hub into the Controller.

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



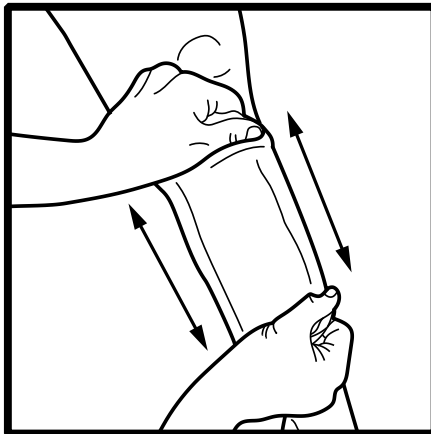
STEP 3 Apply Comfort+ Sleeve

- a. Apply Comfort+ Sleeve by pulling it up and over the calf, right below the knee.



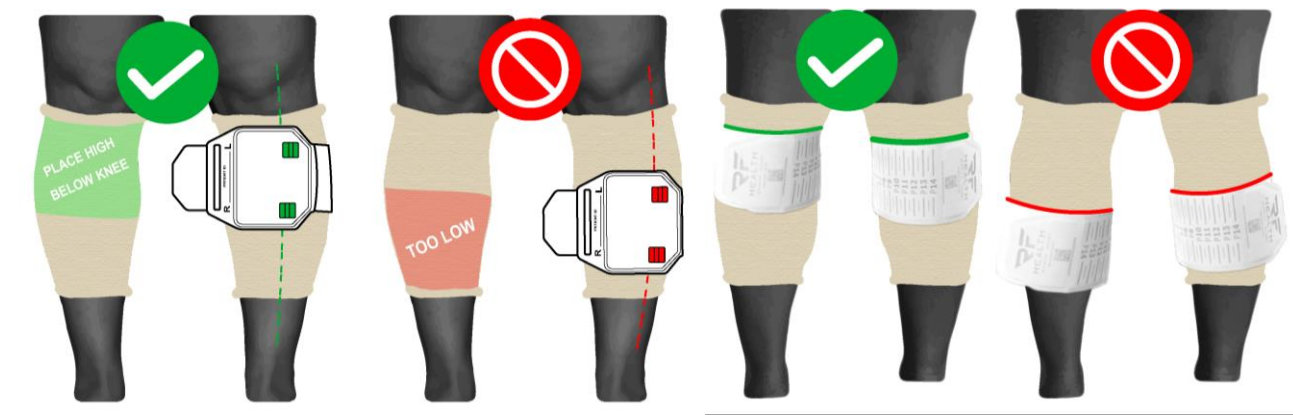
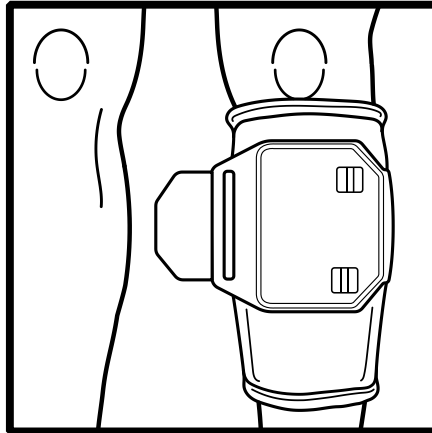
STEP 4 Stretch Comfort+ Sleeve

- a. Gently tug at each end of the Comfort+ Sleeve to distribute fabric evenly over the upper calf.



STEP 5 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.

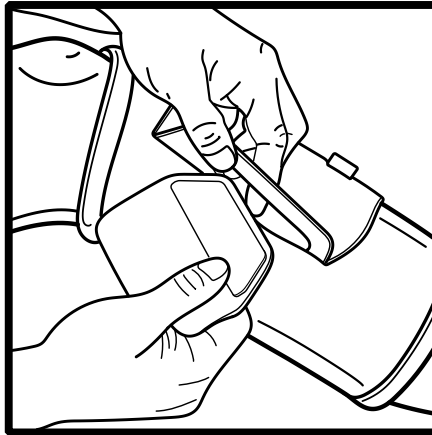


NOTE: The Strap is applied correctly when the 'L' on the Securement Loop is facing up towards the knee on the left leg and the 'R' on the Securement Loop is facing up towards the knee on the right leg. For patients with a prominent tibial ridge, it is recommended to offset the strap slightly medial aligning the Strap mounts with the tibial ridge.

CAUTION: It is important to conduct periodic skin assessments while the MAC System is in use particularly on patients that are potentially high risk for skin integrity issues.

STEP 6 Secure Strap

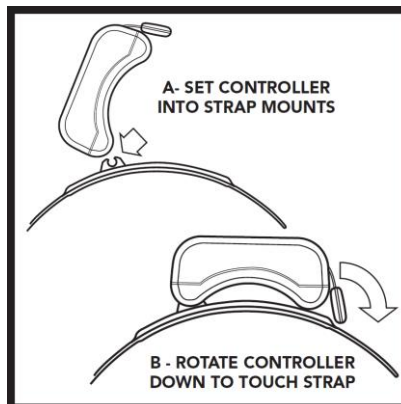
- a. Feed the end of the Strap through the securement loop and secure Velcro.



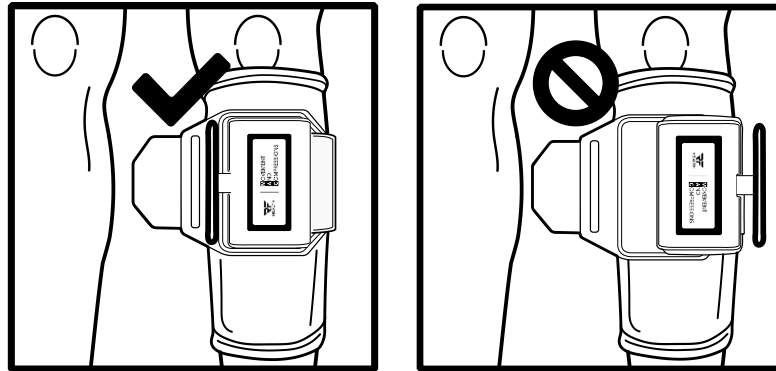
NOTE: Securement Loop should always be placed on inside part of the leg.

STEP 7 Connect Controller to Strap

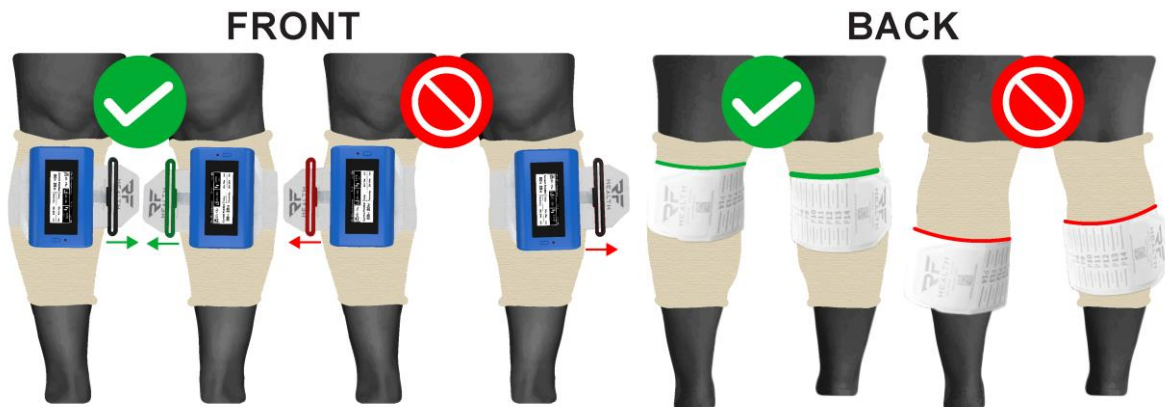
- a. Drop and lock the MAC Controller vertically to the blue mounts on the face of the Strap.



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

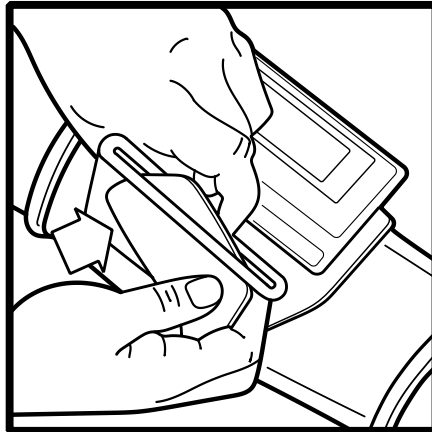


NOTE: Below is the proper placement and orientation of the MAC System once both Controllers have been mounted to the Strap on each leg:

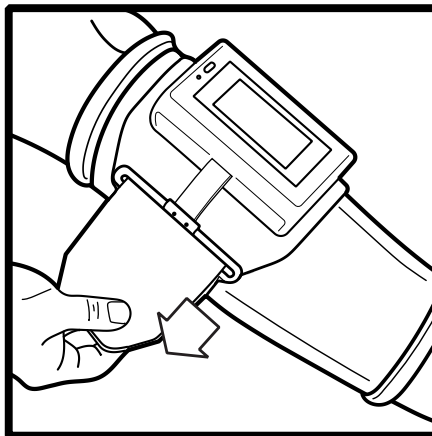


STEP 8 Secure Controller to Strap

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



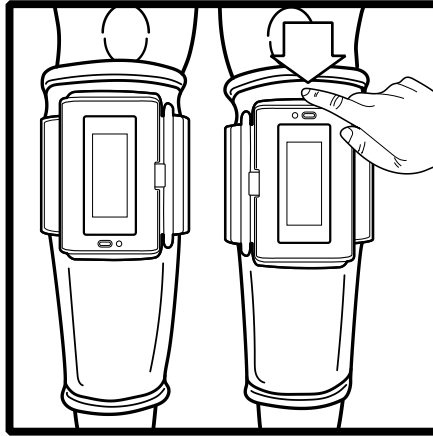
- b. Re-secure Velcro around leg comfortably, but not too snug.



NOTE: After Controller is secured to the Strap, device should be snug enough to stay positioned on the leg.

STEP 9 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 1: The Movement and Compressions System will illuminate with a SOLID RED LED when device is turned on and ready to be used.

STEP 10 Begin Mechanical Prophylaxis and Mobility Tracking

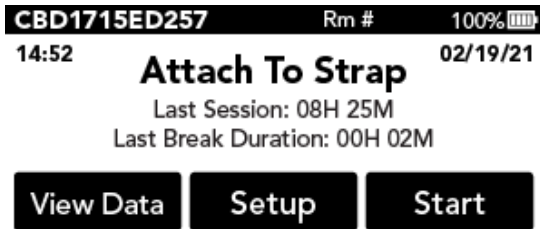
- a. Once powered on, the Controller will show a calibration screen followed automatically by the *Attach to Strap* screen. (This will take approximately 30-40 seconds).



**Calibrating
Please Wait**



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

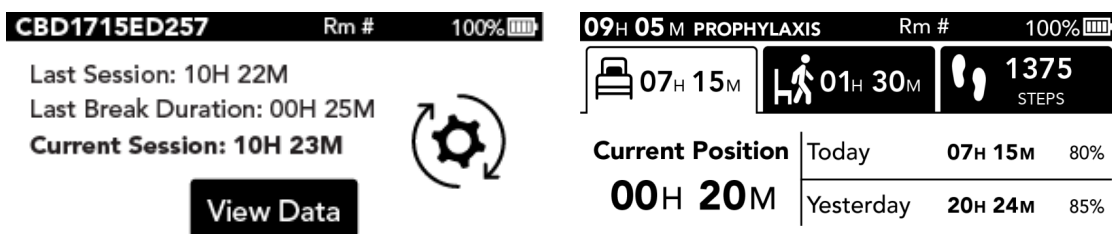


NOTE: If display reads 'No Strap Connected' after pressing START, refer to Step 7 to ensure Controller has been properly mounted on the Strap.

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.

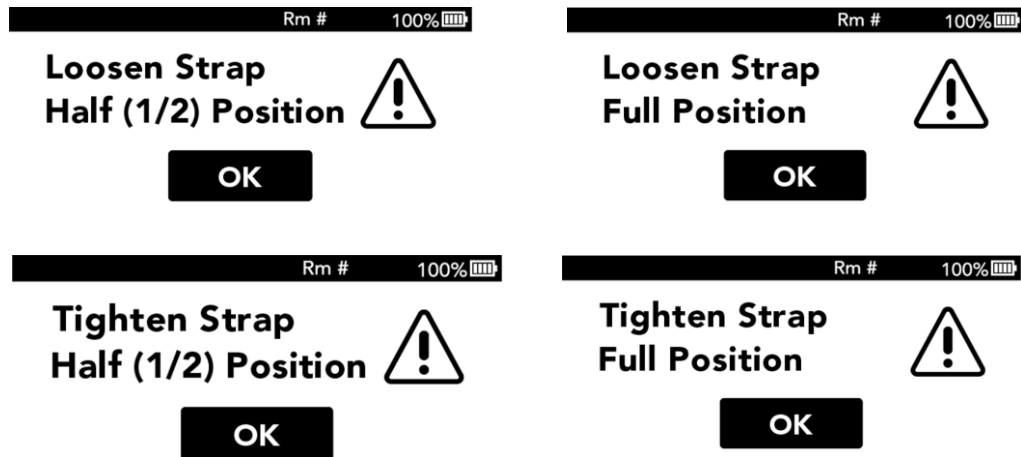


d. Once the device reaches the desired Strap tension after pressing START, the display will show the "Current Session" screen, which details the duration of the Last Session, the duration of the Last Break the patient had, and the Current Session duration. This screen also provides access to view the patient's In-Bed, Upright, and Step data by selecting the "View Data" button which accesses the Mobility Screens. See example below:



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.

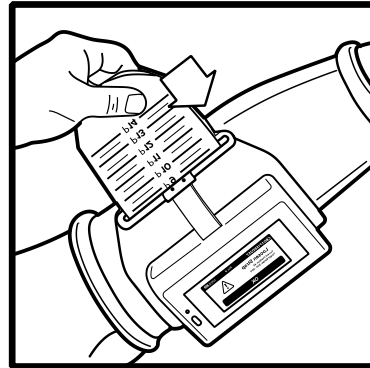
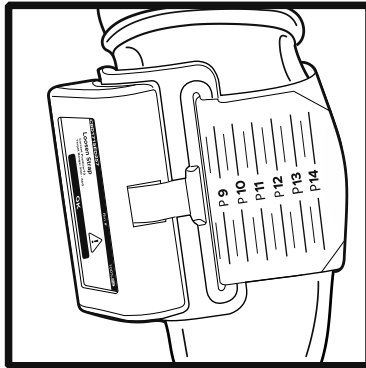
NOTE: When small adjustments to the Strap tension are necessary, it is recommended to tighten or loosen the tension by a half position. When larger adjustments to the Strap tension are necessary, it is recommended to tighten or loosen the tension by a full position.



Loosen Strap by Half Position Example:

Current Strap Position – P8.5

New Strap Position – P9

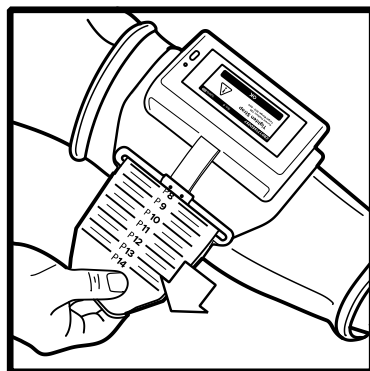
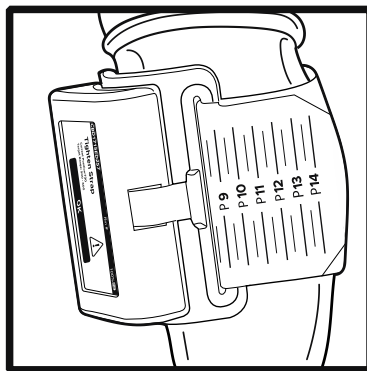


NOTE: A full position adjustment would result in a new Strap position of P9.5

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 11 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.

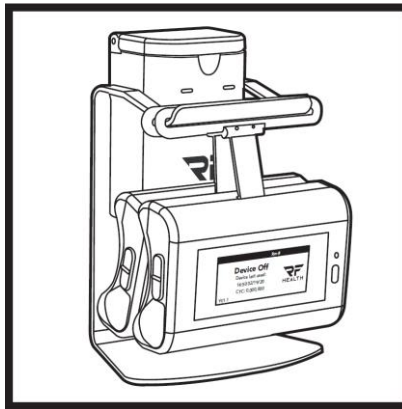


NOTE 1: If this is a WiFi enabled Controller, compliance and mobility data will be uploaded to the RF Cloud during the powering down process. This could take up to approximately two minutes.

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



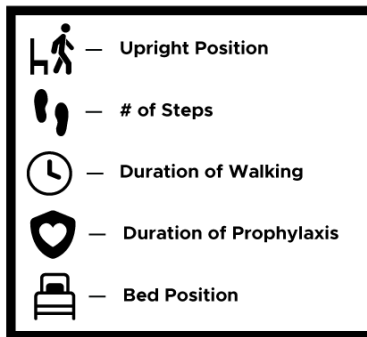
- b. When not in use, the Controllers should be stored by hanging the securement ring from the Charging Hub.



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:

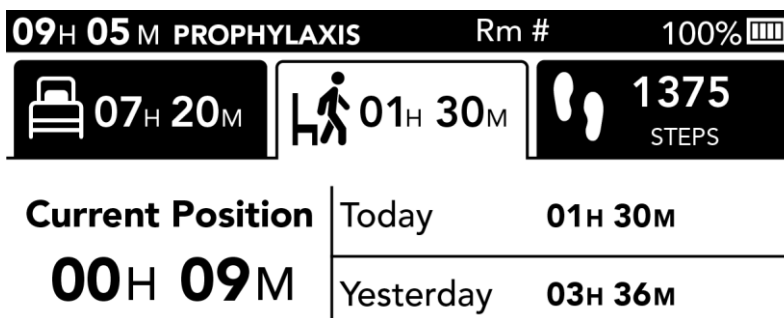
BED SCREEN: CONTROLLER IS CURRENTLY HORIZONTAL

09H 05 M PROPHYLAXIS		Rm #	100%
07H 15M	01H 30M	1375	STEPS

Current Position 00H 20M	Today	07H 15M	80%
	Yesterday	20H 24M	85%

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 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.

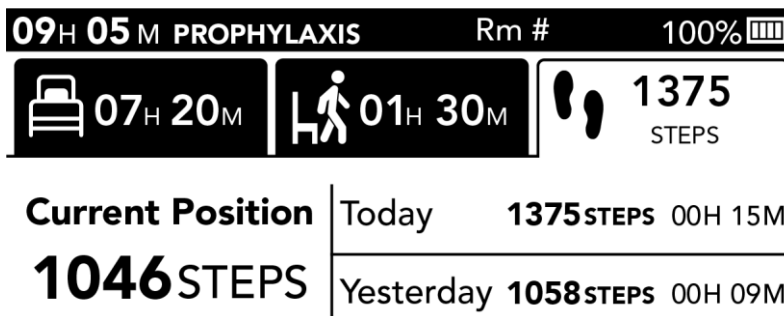
UPRIGHT SCREEN: CONTROLLER IS CURRENTLY VERTICAL



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

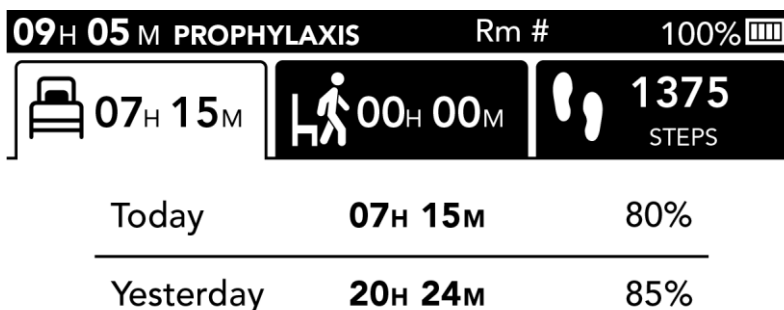


This screen example shows the highlighted Steps tab because the user is walking. It also displays the Controller has recorded 1046 steps in this current session with a total of 1375 steps taken today over the course of 15 minutes. Up to 48 hours of data is displayed for day-to-day comparison.

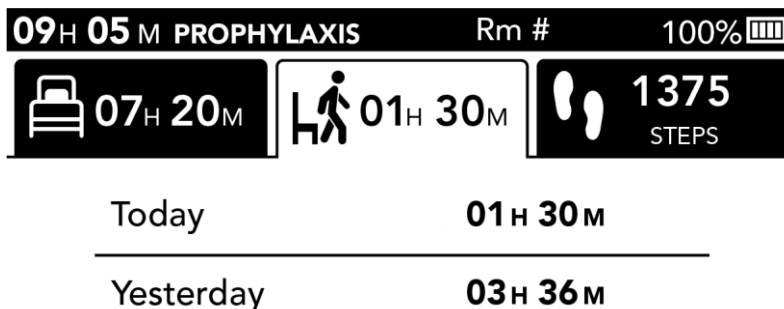
Dynamic Touchscreen Display

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:

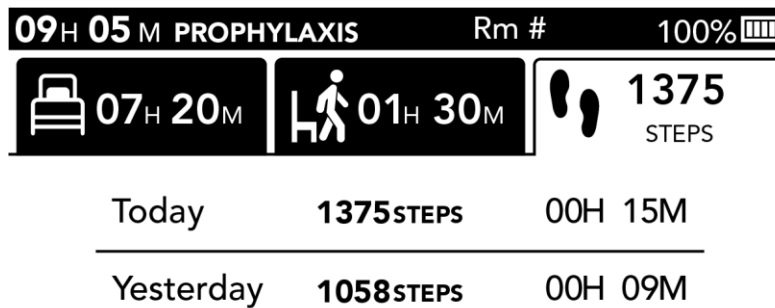
INACTIVE BED SCREEN



INACTIVE UPRIGHT SCREEN



INACTIVE STEPS SCREEN

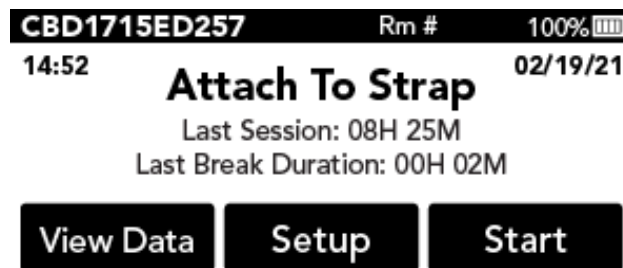


NOTE: Once one of the activity tabs has been pressed, the screen will automatically return to the current activity after 10 seconds.

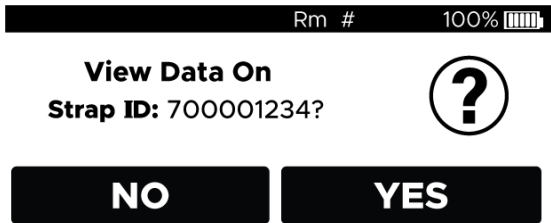
View Data Screen

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 in order 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.

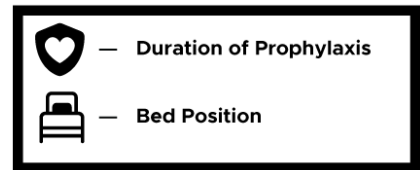
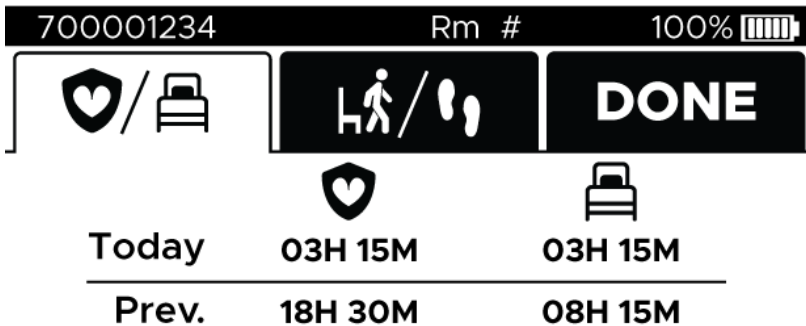


The Controller will ask to confirm the Strap ID prior to showing the data. The Strap ID is located underneath the barcode at the top of the Strap.

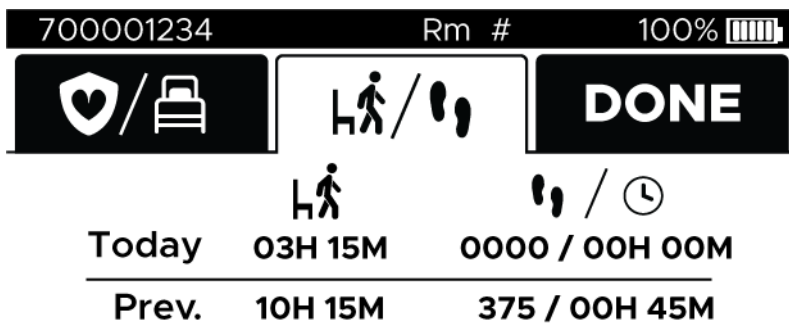


Once the Strap ID is confirmed, the data that is saved on the Strap will be displayed on the Controller screen via the tabs.

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



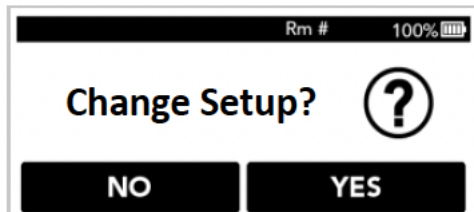
The second tab on the 'VIEW DATA' screen will display the Upright duration, # of Steps, and duration of Walking.



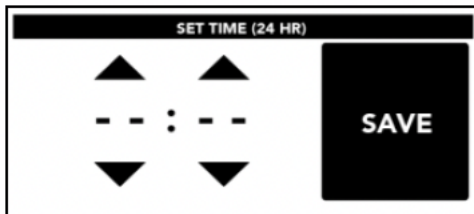
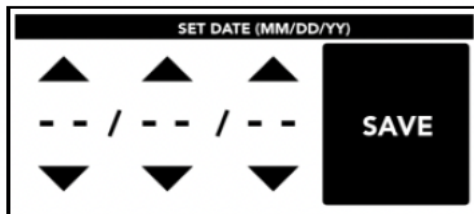
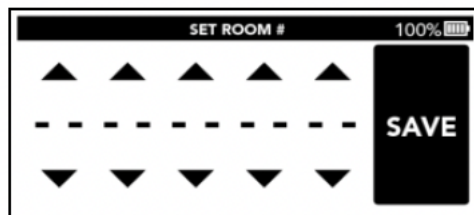
NOTE: Only data on the Strap used today and yesterday will be displayed when the 'VIEW DATA' button is pressed. Straps that have not been used in the last 48 hours will not show data for today and yesterday.

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.

Charging Movement and Compressions System

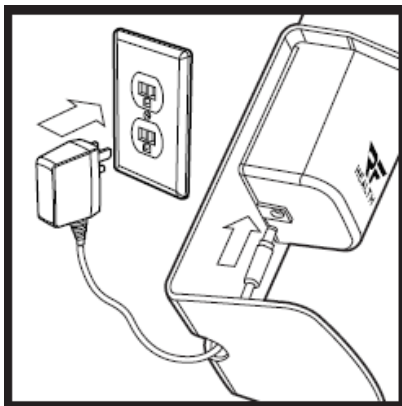
Only use the Charging Hub provided by Recovery Force Health to charge the MAC System batteries. The Charging Hub is the only way to charge the replaceable batteries of the Movement and Compressions System. Additionally, only place the batteries of the Movement and Compressions System in the Charging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

NOTE: 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.

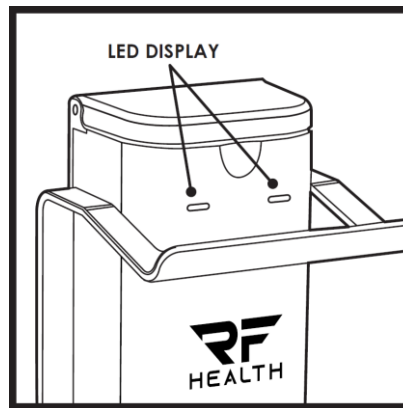
To Charge the Battery

- 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.
-  **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 are not able to 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 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

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, as recommended below, between patients and at regular intervals while in use, as it may come into contact with blood or bodily fluids.

The cleaning and disinfection process of the Controller and Charging Hub will include three wipes used in sequence. The same 3-step process should be used regardless of whether the goal is to clean or disinfect. The first wipe will be used to remove heavy soil. The second wipe will be used to further remove soil residues that may be present but are not readily visible. The third wipe provides disinfection for any microorganisms remaining after cleaning. During this 3-wipe sequence, the surface being cleaned should remain wet for a minimum of 4 minutes. If residual soil is still visible after the cleaning and disinfection process, repeat the same three wipe process sequence again until there is no visible inspection of residual soil.

Each wipe should be unfolded and used to thoroughly wet the device surface while applying firm pressure in a back-and-forth motion, tracing the same pattern repeatedly a minimum of 5 times or until no visible soil remains on the area being cleaned. Particular attention must be paid to two primary areas: 1. The crevice area that surrounds the Power Button. 2. The crevice areas where the nylon strap enters the Controller and where the nylon strap interfaces the ring.

1. Cleaning around the Power Button: While depressing and holding down the power button, an unsoiled portion of the wipe will be pushed deeply into the recess that surrounds the power button and traced multiple times around the circumference to ensure any trapped soil or bacteria are removed. This process will be repeated with each wipe. If at any point in the process described above the portion of the wipe being used becomes visibly soiled, the wipe should be repositioned to an unused area on the same wipe and wiping continued.
2. Cleaning around the Nylon Strap: An unsoiled portion of the wipe must be pushed deeply into the small opening of the housing where the strap enters and traced back and forth multiple times for a minimum of 30 seconds or until no soil is visible on the wipe when removed from the opening. This process also will be used for cleaning the interface of where the strap attaches to the ring. If at any point in the process described above the portion of the wipe being used becomes visibly soiled, the wipe should be repositioned to an unused area on the same wipe and wiping continued.

NOTE: When cleaning and disinfecting, please be aware of high touch surfaces identified for potential soiling:

- 1) Surfaces most likely to contact the patient or caregivers during normal use.
- 2) Surfaces most likely to retain soil during cleaning due to the presence of uneven surfaces, seams or recesses where components join or as part of power button or battery compartment release mechanism.

**Controller Touch Screen
& Power Button**



**Controller Battery
Compartment**



Controller Nylon Strap



Charging Hub Compartment Lid



Do not allow water or cleaning solutions to collect on the surface of the device. 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.

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

Recovery Force Health recommends disinfecting the Controller and Charging Hub by wiping all cleaned surfaces with a chlorine-releasing agent, such as the solutions listed below. The following agents should be applied as described in the cleaning agent manufacturer’s instructions for use.

Chemical Cleaners (approximate concentrations)	Commercial Example
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, we recommend that suitability for use is confirmed with the chemical supplier prior to use.

Avoid excessive liquid, especially in the areas of the connection ports of the Controller and Charging Hub. If any liquid enters the ports, then internal component damage could result.

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	Strap Size	Length (in)	Height (in)
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	Weight		
Power Consumption	10.44 Wh	Net Weight including Controller	11 oz	
Fuses Rating	2A			



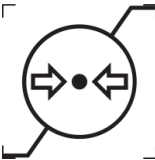


Service and Repair







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

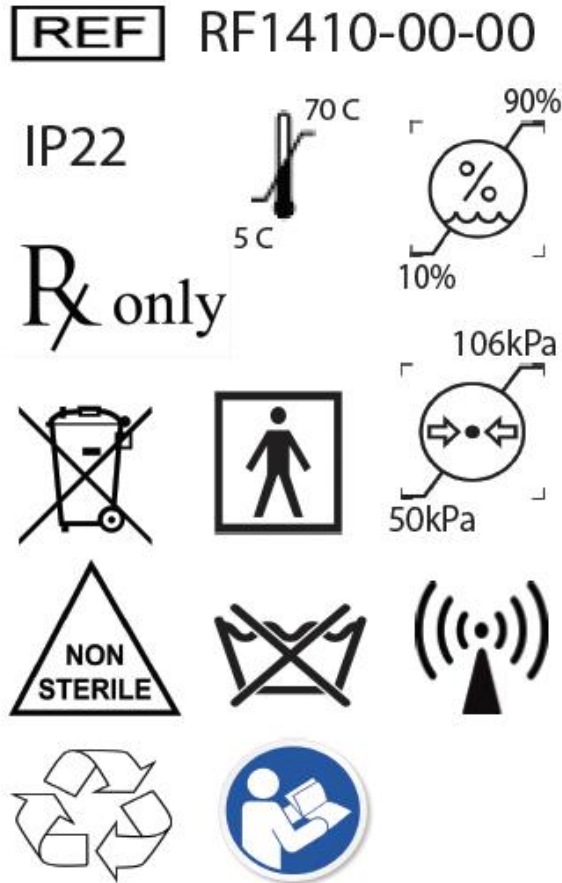
D.2 Product Symbols Definition

Symbol	Explanation	Location
	<p>Temperature limitations for storage and/or transport & Operation of the device.</p> <p>Storage & 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 & Operation of the device.</p> <p>Storage & Transport Relative Humidity: 10% to 90%, non-condensing, >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 & Operation of the device.</p> <p>Storage & 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>

Symbol	Explanation	Location
	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 _X 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

Symbol	Explanation	Location
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



Battery: 3.6 V ===

FCC ID: 2AXDCRF1410-00

RF Health

10022 Lantern Rd Suite 100

Fishers, IN 46037

PH: 1-866-604-6458

www.rfhealth.com



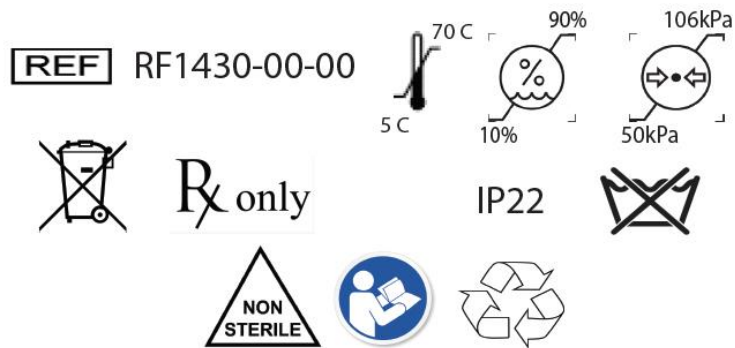
Assembled in U.S.A.



Patent Pending

Labeling on the Charging Hub



*+B547RF14300/\$+70000001/16DYMMMD*_



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



REF RF1420-00-00 Size: Standard
Single Patient Use Only

UDI & 2D Matrix goes here

Labeling on the individual Strap bag



RF HEALTH


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)

NON STERILE 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: 1-866-604-6458
www.rfhealth.com

Patented
Made in USA

UDI Sticker goes here


TEAR HERE

STANDARD


TEAR HERE

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


APPLICATION INSTRUCTIONS




STEP 1 - Apply Comfort+ Sleeve by pulling it up and over the calf, right below the knee.




STEP 2 - Gently tug at each end of the Comfort+ Sleeve to distribute fabric evenly over the upper calf.




STEP 3 - Place leg horizontal to the ground and apply MAC Strap just below the knee with the securement loop on the inside of the leg.




STEP 4 - Feed the end of the strap through the securement loop and secure Velcro.




STEP 5 - Drop and lock the MAC Controller vertically to the blue mounts on the face of the strap.




STEP 6 - Disconnect Velcro and feed the strap through the black controller securement ring.



STEP 7 - Re-secure Velcro around leg comfortably, but not too snug








STEP 8 - Power on controller and follow instructions on the screen.



Scan QR code for instructional video

*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
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 B	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	Class A (only valid for Charging Hub)	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies (only valid for Charging Hub)	
<p>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.</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"> -- 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. 		

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	±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_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
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 Model RF1400 , 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	$d = 1,2 = 2,3 P \sqrt{800}$ MHz to 2,5 GHz $P \sqrt{80}$ MHz to 800 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, ^a P 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 $d = 1,2 P^{\sqrt{}}$	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).


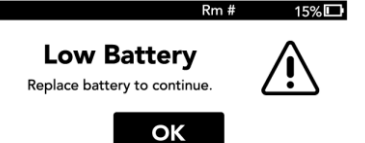

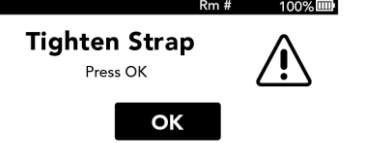
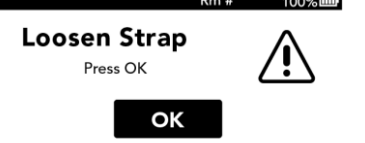
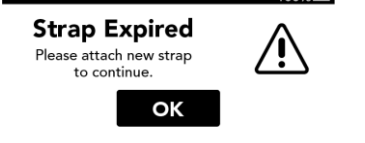
- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or reorient interfering equipment.
- Increase distance between interfering equipment and your System.
- Manage use of frequencies close to the System frequencies.
- Remove devices that are highly susceptible to EMI.
- 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
	<p>Battery was removed during operation.</p>	<p>Insert charged battery into the MAC System Controller.</p>
	<p>An incorrect date has been set in the Controller.</p>	<p>Press OK and then set correct date on Controller.</p>
	<p>Date and/or time is not correct on Controller.</p>	<p>Set correct date and time on Controller.</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</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>

Error Screen	Error Description	Corrective Action
	010: Battery Unhealthy 011: Battery Over-Temperature 012: Board Over-Temperature 013: Strap Read/Write Error 014: RTC Error	
	A valid Strap is not connected to the Controller. Or, the Strap RFID tag is out of range from the Controller.	Connect the Controller to a MAC System Strap. (If no Strap is connected, Device will not function for DVT Prevention or mobility tracking)
	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 gently tighten Strap on patient's leg. Restart DVT Prophylaxis.
	Strap is too tight on patient's leg.	Adjust and gently loosen Strap on patient's leg. Restart DVT Prophylaxis.
	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.)

Error Screen	Error Description	Corrective Action
	<p>Strap is either too tight or too loose on patient's leg.</p>	<p>Press OK and follow next screen instructions to either loosen or tighten Strap.</p>
	<p>Unsuccessful read/write of data to the Strap by the Controller</p>	<p>Confirm Controller is securely engaged to both mounts on the Strap</p>
	<p>A nonauthorized Strap is attempting to be used.</p>	<p>Acquire a new authentic MAC System Strap. (If a Strap other than an authentic MAC System Strap is connected, device will not function for DVT Prevention or mobility tracking.)</p>
	<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>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

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.