

DRAFT 29-NOV-2016

Monarch™ Airway Clearance System,
Model 1000

User Manual

ProductNo.PMACS1



Rx Only Federal USA law restrict this device to sale by or on the order of a physician

195292 REV G

Enhancing outcomes for
patients and their caregivers:

Hill-Rom.

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NOTES:

DOCUMENT SYMBOLS

This manual contains different typefaces and symbols to make the content easier to read and understand:

- Standard text—used for regular data.
- **Boldface text**—emphasizes a word or phrase.
- **NOTE:**—sets apart special data or important instruction clarification.
- WARNING or CAUTION



- A WARNING identifies situations or actions that may have an effect on patient or user safety. To ignore a warning could cause patient or user injury.
- A CAUTION identifies special procedures or precautions that persons must obey to help prevent equipment damage.

IMPORTANT SAFEGUARDS

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following important safeguards.

READ ALL INSTRUCTIONS BEFORE USING

Training shall be provided by a qualified trainer or respiratory therapist before the user utilizes the product for therapy delivery. The training should last no more than 60 minutes or until the user is comfortable with the safe and effective use of the product.

The Monarch™ product is for Single Patient Use (SPU) in the Home Care Environment. Always unplug this product immediately after using or charging the battery.

Remove the rechargeable battery pack from the product if the product is not going to be used for an extended period of time.



WARNING:

To reduce the risk of burns, electrocution, fire, or personal injury, follow these instructions. Failure to do so could cause personal injury or equipment damage.

1. Patients that may have difficulty clearing secretions from the upper airway (such as those with DMD or other advanced neuromuscular or neurological disorders) may require specialized therapy regimens involving manually or mechanically assisted coughing or other techniques in conjunction with Monarch™ Airway Clearance System, Model 1000 therapy. Please consult your physician to determine if additional therapy is appropriate.
2. It is recommended that a single layer of cotton clothing be worn beneath the wearable garment.
3. Close supervision throughout the treatment is necessary when this product is used by patients with physical limitations or impaired cognitive abilities.
4. Do not store or use the device around pets, pests, or unsupervised children.
5. We recommend your first use of this product be in a supervised setting such as a doctor's office or at home with a clinical trainer.
6. Use this product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
7. Do not use unauthorized parts or accessories with this device.
8. Use only Hill-Rom authorized garment outer shells to avoid allergic skin reactions.
9. If this product has a damaged Power Cord or plug which is not working properly or damaged, do not operate it. For examination and repair, contact Hill-Rom.
10. Store and keep Power Cord out of reach from toddlers and young children to prevent strangulation risks.
11. Keep the unit, battery, the AC/DC adapter and its Power Cord away from heated surfaces.
12. Do not use the device near to any heat source such as a fireplace or radiant heater.
13. Do not use the device in a dusty environment.
14. Do not use the device in a heavy moisture environment.
15. When removing product from storage conditions, let the Monarch™ Airway Clearance System return to its recommended operating temperature range before using the product.
16. Read and follow all instructions for setup, use, and cleaning of Monarch™ Airway Clearance System. Failure to do so could cause patient injury or equipment damage.

17. Machine wash and dry the external garment shell monthly or when visibly soiled.
18. If conditions exist that prohibit using Monarch™ Airway Clearance System, do **not** use the unit. Death or serious injury could occur.
19. Federal USA law restricts this device to sale by or on the order of a physician.
20. Only authorized personnel should service Monarch™ Airway Clearance System. Servicing by unauthorized personnel could cause personal injury or equipment damage.

NOTE:

If service is necessary, use this contact information:

- In the USA, call Hill-Rom at 800-426-4224.
 - Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.
21. The potential for electrical shock exists with electrical equipment. Failure to follow protocols may cause death or serious personal injury.
 22. Make sure the position of the Monarch™ Airway Clearance System is such that you can quickly, without obstruction, disconnect the power cord from the main power supply if necessary.
 23. Do not expose the unit to excessive moisture or immerse it in water.
 24. If the display on the Monarch™ pendant is faulty, do **not** use the unit.
 25. If Monarch™ Airway Clearance System is wet or damp, do **not** plug it into a power source or use it. Patient injury, personal injury, or equipment damage could occur.
 26. Before cleaning, unplug the unit from its power source and remove the battery. Failure to do so could cause personal injury or equipment damage.
 27. You are recommended to remove the external garment shell for machine wash on a monthly basis or when it is dirty.

Do not expose the unit to excessive moisture or immerse it in water.

28. Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.
29. Retain the original packaging material. If shipping is required, the original packing material provides the best protection for Monarch™ Airway Clearance System.
30. Do not eat or drink during a therapy session. To do so could cause a choking hazard.
31. Discard Monarch™ Airway Clearance System product in accordance with your local government regulations.
32. This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.
33. The maximum temperature of the Monarch™ Airway Clearance System applied parts will not exceed 109° F (43°C) under all conditions.

SAVE THESE INSTRUCTIONS

INTENDED USE

The Monarch™ Airway Clearance System is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.



This manual includes instructions for setup, use, and cleaning of the Monarch™ Airway Clearance System, Model 1000. It is to be used as a reference guide. Please review all the sections carefully before you use the system.

INTENDED PATIENT POPULATION

The Monarch™ Airway Clearance System, Model 1000 is intended for adolescent to adult population (15 years and above) or as prescribed by a physician.

INTENDED USERS

The users of the system are patients in the home care environments. They are expected to operate the device to self-administer therapy treatment, handle the setup, cleaning, and storage of the device.

The users of the Monarch™ product include patients in the home care environment. Users should have the ability to read and understand western Arabic numerals and the native language used in the manual. We recommend that the users of the device have an education level comparable to that of an 8th grader. We recommend that patients who do not meet this education level get assistance from clinical trainers or respiratory therapists while using this device for therapy.

The patient should also have the ability to start or stop the therapy physically either via pendant or mobile app buttons or pause/resume control on the garment.

INDICATIONS FOR USE

The Monarch™ product is intended to provide Airway Clearance Therapy and promote bronchial drainage where external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.

The Monarch™ Airway Clearance System is intended to be used in the Home Care environment by patients, 15 years and older.

CONTRAINDICATIONS



WARNING:

If the patient conditions exist that cause the use of Monarch™ Airway Clearance System to present a risk to the patient, **do not use the unit except as directed by a physician**. Death or serious injury could occur.

Monarch™ Airway Clearance System is **contraindicated** if these conditions are present:

- Head and/or neck injury that has not yet been stabilized
- Active hemorrhage with hemodynamic instability

RELATIVE CONTRAINDICATIONS

- According to the American Association for Respiratory Care (AARC) Guidelines for Postural Drainage Therapy, the decision to use the unit for Airway Clearance Therapy requires careful consideration and assessment of the individual patient's case if the following conditions exist:
 - Intracranial pressure (ICP) greater than 20 mm Hg
 - Recent spinal surgery or acute spinal injury
 - Bronchopleural fistula
 - Pulmonary edema associated with congestive heart failure
 - Large pleural effusions or empyema
 - Pulmonary embolism

- Rib fractures, with or without flail chest
- Surgical wound or healing tissue or recent skin grafts or flaps on the thorax
- Uncontrolled hypertension
- Distended abdomen
- Recent esophageal surgery
- Active or recent gross hemoptysis
- Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal
- Subcutaneous -emphysema
- Recent epidural spinal infusion or spinal anesthesia
- Burns, open wounds, and skin infections on the thorax
- Recent placement of transvenous or subcutaneous pacemaker
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Osteoporosis or osteomyelitis of the ribs
- Coagulopathy
- Complaint of chest wall pain

CLEANING

Obey all **warnings** throughout the manual and also the warnings below. Failure to do so could cause injury and/or equipment damage:

- The potential for electrical shock exists with electrical equipment. Failure to follow protocols may cause death or serious personal injury.
- Unplug the unit from its power source after therapy or charging the battery. Failure to do so could cause personal injury or equipment damage.
- Do not expose the unit to excessive moisture. Injury or equipment damage could occur.
- Failure to use cleaning products in accordance with the manufacturer's instructions could cause equipment damage.
- Inspect the product before each use. In addition, after each cleaning cycle, visually inspect each component for any wear, tear, or deformity. If you have any concern about a component,

do **not** use it, and replace that component before the next therapy session. Failure to do so could cause injury.



CAUTION:

Do not use harsh cleansers, solvents, or detergents. Equipment damage could occur.

The Monarch™ Airway Clearance System has been tested for compatibility with cleaning solutions containing the following active ingredients:

Chemical Class	Active Ingredient
Quaternary ammonium chloride	Didecyl dimethyl ammonium chloride Alkyl dimethyl benzyl ammonium chloride
Quaternary ammonium chloride	Alkyl dimethyl benzyl ammonium chloride Alkyl dimethyl ethylbenzyl ammonium chloride
Phenolic	Ortho-Phenylphenol Ortho-Benzyl-para-Chlorophenol
Alcohol	Isopropyl alcohol

GENERAL CLEANING—GARMENT

We recommend that you wipe clean the garment with recommended cleaning solutions and warm water. Do not use excessive liquid or harsh cleansers, and do **not** submerge The Monarch™ Airway Clearance System in water or any solution.

Dilute the cleaning solution as specified on the manufacturer's label.

WASHABLE GARMENT SHELL

To remove difficult spots or stains, we recommend that you use standard laundry cleaner and either hand wash or machine wash in cold water. Then either line dry or tumble dry in the dryer with low heat. To loosen heavy, dried-on soil, you may first need to saturate the spot.

Machine wash and dry the external garment shell monthly or when visibly soiled.

Note: Only the Garment Shell can be machine washed. Shoulder Strap Pads, Backpack Cover, and POD covers should be wiped clean with an approved cleaner.

1. Remove the Garment Shell from the Garment.
2. Fasten all the hook and loop straps to each other to limit snagging.
3. Machine wash, or hand wash, in cold cycle only (86°F (30°C) maximum). Non-chlorine bleach may be used as necessary.
4. Hang dry or tumble dry on lowest temperature (120°F (49°C) maximum).

NOTE:

Do not iron any parts on the device.

ACRONYMS

Acronym	Meaning
HFCWO	High Frequency Chest Wall Oscillation

FEATURES



Item	Description	Item	Description
A	Pod	H	Battery access panel
B	Pendant	I	Backpack cover
C	Front opening	J	Shoulder Strap
D	Charging port	K	Shoulder pads
E	Cam buckle—waist adjustment	L	Handle
F	Pause/resume control button	M	Pod cover
G	Garment Shell		Power adapter (not shown)

**CAUTION:**

Obey these **cautions** to help prevent equipment damage:

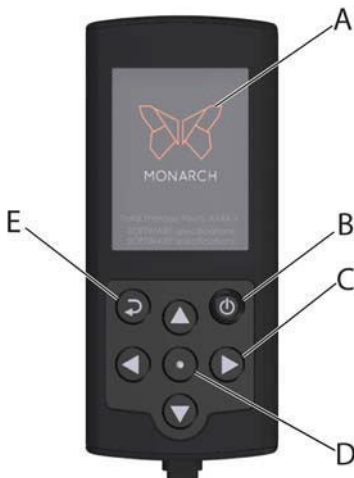
- Use only with the Hill-Rom approved AC/DC power adapter (Hill-Rom Part Number 195500 (MEGMEET model number MANGO120-24CK-HR)).
- Use only with the Hill-Rom approved battery (Hill-Rom part number 194566 (Inventus Power, Inc. model number 194566)).

Item	Image	Item	Image
Garment		Shoulder Adjustment	
Pod		Shoulder Pads	
Front Closer		Waist Adjustments	
Garment Shell		Waist Adjustment—cam buckle	

Item	Image	Item	Image
Backpack Cover		Battery	
Charging Port		Battery Compartment	
Pause/Resume Button		Pendant Dock	

PENDANT


Press the power button for 3 seconds to activate the pendant. The pendant allows for features and functions of the garment to be activated, edited, and deactivated.




















Item	Description
A	Screen
B	ON/OFF button
C	Navigation buttons
D	Center button
E	Back button




PRODUCT SYMBOLS

These symbols are used on your model of Monarch™ Airway Clearance System:

Symbol	Definition
	<p>Type B equipment with an F-type applied part, according to IEC 60601-1</p> <p>NOTE: The external pod covers of the actuator pods are considered as applied part of this equipment.</p>

Symbol	Definition
	WARNING OR CAUTION
	Follow the operating instructions
	Class II equipment (double insulated), according to EN60601-1
IP42	Protected against ingress of solid foreign objects ≥ 1.0 mm in diameter and dripping water (at 15° tilt).
	Read the operating instructions
	Medical—General Medical Equipment as to Electrical Shock, Fire, and Mechanical Hazards Only in Accordance with Control No. E336914 ANSI/AAMI ES60601-1 (2005) + AMD (2012) CAN/CSA-C22.2 No. 60601-1 (2008) + (2014)
	Monarch™ Airway Clearance System, Model 1000 conforms to the European Medical Device Directive 93/42/EEC.
	Manufacturer or distributor complies with the Waste Electric and Electronic Equipment Directive 2012/19/EU

Symbol	Definition
	Do not iron*
	Machine wash cold
	No chlorine bleach*
	Tumble dry low heat*
	Catalog number
	Batch number
	Date of manufacture
	Manufacturer
	Manufacturer and date of manufacture
	Physician prescription required (for US only)

Symbol	Definition
	ACMA RCM compliance mark
	Single Patient Use
	Pause/Resume control button—press the button to stop therapy and press again to resume therapy

*Applicable only for external shell of the product.















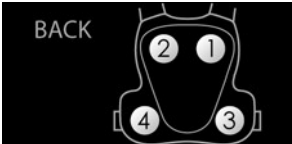
PENDANT SCREEN SYMBOLS

These symbols are used on your model of Monarch™ Airway Clearance System:



Main Screen

Item	Description	Item	Description
A	Frequency setting	C	Duration setting
B	Intensity setting		

Symbol	Definition	Symbol	Definition
	The unit is plugged into power and not running off the battery.		Recovery of error list is in progress (icon will rotate)
	WiFi connected		The battery has 75% to 100% charge on the battery.
	Bluetooth® connected		The battery has 50% to 75% charge on the battery.
	Battery is charging		The battery has 25% to 50% charge on the battery.
	The battery charge has under 20% charge on the battery.		The battery has 20% to 25% charge on the battery.
	Frequency		Duration
	Intensity		
	FRONT		Front view of the garment with POD locations identified
	BACK		Back view of the garment with pod locations identified

MOBILE DEVICE SYMBOLS



Main Screen

Item	Description	Item	Description
A	Current therapy Mode	G	Frequency setting
B	Settings	H	Countdown therapy duration
C	Therapy 2 control	I	Therapy 1 control
D	Intensity setting	J	Manual control
E	Duration setting	K	Monarch™ Airway Clearance battery status
F	Start therapy control	L	Previous screen button

component, do **not** use it, and replace that component before the next therapy session. Failure to do so could cause injury.

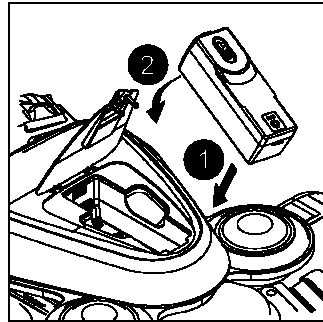
- If the garment is wet or damp, do not plug it into a power source or use it.

NOTE:

If your physician has prescribed aerosol therapy to be used during the treatment, set up the appropriate equipment.

Getting StartedInstall Battery

1. Lift the battery access panel.
2. Align the battery so the battery latch is toward the top of the garment.
3. Insert the bottom of the battery into the battery panel first.
4. Slide the latch then proceed to insert the top of the battery until the battery locks into place.

**NOTE:**

The images show how to confirm the battery is locked into place. If you see an orange color in the latch area, then the battery is not fully locked into place. Press down on the battery until the orange color is no longer visible.

**CAUTION:**

Fully charge the battery to 100% before first time use.

Charge Garment

1. Plug the power adapter into the garment.
2. Plug the power cord into an applicable power outlet if the battery is not fully charged.

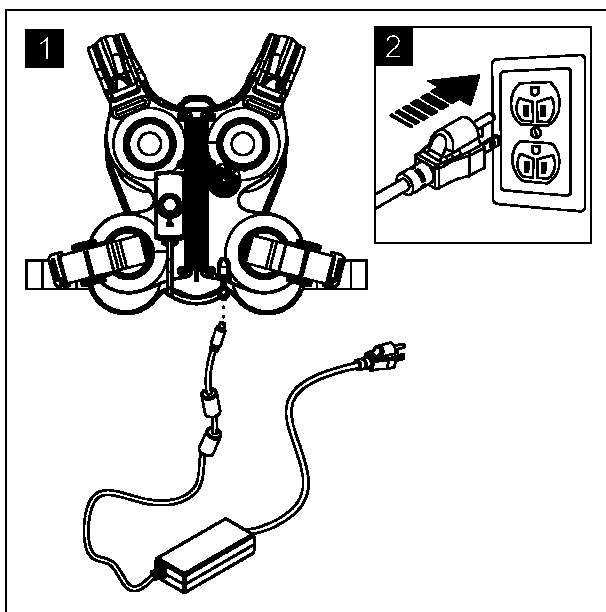
NOTE:

The power cord required for your country may be different than shown.



CAUTION:

The battery must be at a minimum 25% charge to start a therapy session.



Attaching the Garment Shell

1. Lay the garment on a flat surface.
2. Lay right and left garment shell panels on a flat surface.
3. Align and put one side of the garment shell on to the garment. For the left garment shell, slide the pendant dock through the slots on the garment shell.



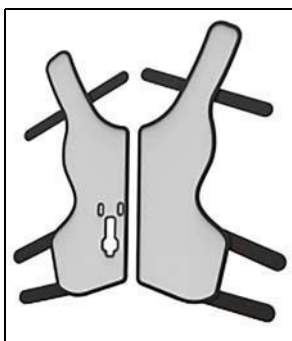
4. Snap the three snaps along the side of the garment shell closest to the zipper.
5. Attach the hook and loop around the cam buckle to secure the bottom garment shell to the cam buckle.



6. Attach the hook and loop straps around the shoulder strap on the garment to secure the top of the garment shell.



7. Repeat for the other side of the garment.



NOTE:

Machine wash and dry the garment shells as needed see “General Cleaning—Garment” on page 7.

Garment Fitting

SHOULDER ADJUSTMENT

1. Open the hook and loop to the top shoulder pad and remove.
2. Slide over the cable assembly to expose the hook and loop shoulder straps.



3. Adjust the hook and loop to accommodate the patient’s shoulder height. See “Size Guide Reference” on page 23.



4. Firmly press the shoulder strap together to engage the hook and loop fastener.
5. Slide the cable assembly cover over the shoulder strap.

6. Put the shoulder pad on the shoulder strap assembly and firmly press together to engage the hook and loop.
7. Repeat on the other shoulder strap.

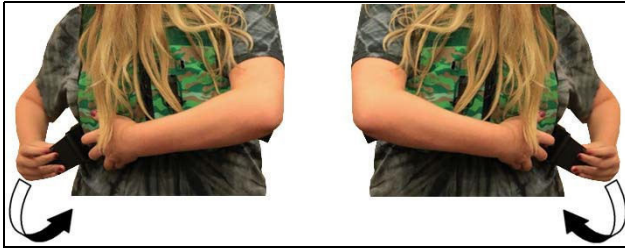
The garment pods should rest comfortably on the upper chest and back when the garment is fastened. If the garment does not rest comfortably on the chest and back, repeat the shoulder adjustments.

WAIST ADJUSTMENTS

8. Slide the waist clip into the appropriate slot to accommodate the patient's waist. See "Size Guide Reference" on page 23.

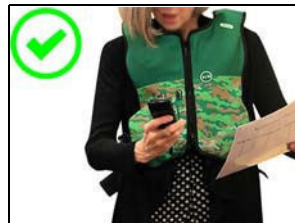


9. Fitting the garment on the body—put on the garment one shoulder at a time like you are putting on a backpack.
10. Fully zip the front zipper closure.
11. Engage the cam buckle on both sides.



NOTE:

The garment should fit snug against the body but not hinder normal breathing.



If the garment is either too tight or loose in the waist, then adjust the waist band.

Too Loose



Too Tight



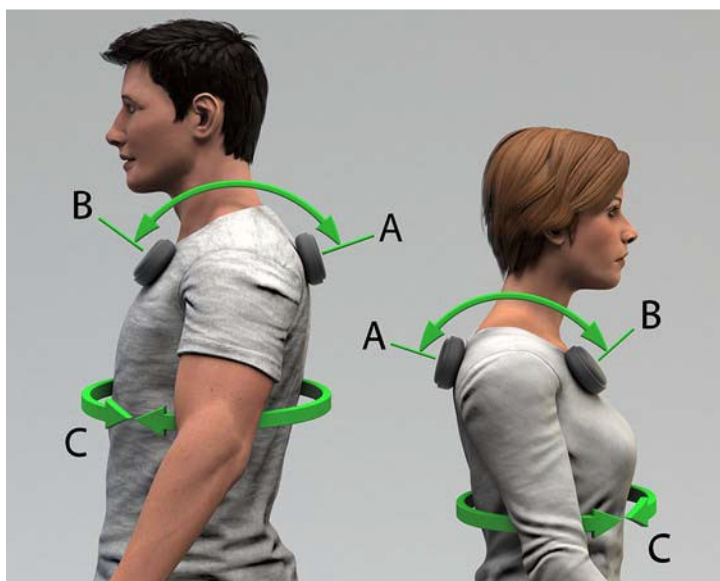
NOTE:

First disengage the cam buckles and then unzip the garment.

Size Guide Reference

1. Measure from point **A** to **B**, see the figure under “Size Guide Measurements” on page 23.
2. Measure the circumference around point **C** of the ribs.

Size Guide Measurements



Item	Description
A & B	Ideal POD contact point

Item	Description
C	Circumference measure point

Shoulder Strap Adjustment

Shoulder Measurement: _____ (inches)

Measurement (inches)	Hook Loop Hash Line
10	0 (no hash line visible)
11	1
12	2
13	3
14	4

Torso Adjustment

Mid Chest Measurement: _____ (inches)

Measurement (inches)	Hook Loop Hash Line
22 - 24	1
24 - 26	2
27 - 29	3
30 - 32	4
33 - 35	5
36 - 38	6
39 - 41	7
42 - 44	8
45 - 47	9
48 - 50	10

PROGRAM THE GARMENT

The pendant is used to select and start the therapy.

The pendant dock is located on the front of the garment. Place the pendant in the pendant dock when the pendant is not in use.



PROGRAM THERAPY

1. Slide the pendant up and away from the garment to remove the pendant from the pendant dock.
2. Press and hold the **Power** button for 3 seconds to power the pendant.



NOTE:

The pendant screen will dim after 3 minutes if there are no user inputs. Any button press will return the screen normal brightness. The Monarch™ Airway Clearance System will shut down after 10 minutes of no activity.

Treatment Options

Mode of Operation	Description
Manual mode	Manual mode uses one frequency and intensity for a set time of the entire therapy session.

Mode of Operation	Description
Program modes	Therapy 1 and Therapy 2 are programmed therapy sessions. Each program is a quick start therapy session. A single therapy session can have up to eight (8) steps. You can also set a cough pause (reminder to cough) in these therapy sessions.

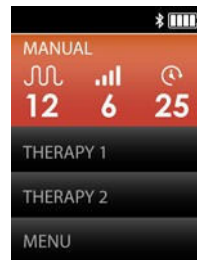
PROGRAM MANUAL MODE

Manual Mode will run one frequency and one intensity for a set amount of time. The therapy settings can be changed at any time during therapy. The treatment continues while the user adjusts different frequencies, intensities, and duration values.

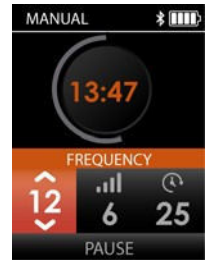
The timer starts from the total duration and counts down to zero.

Program Manual Mode—Pendant

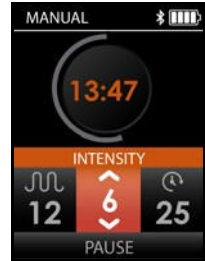
1. Press the **Up** or **Down** navigation buttons to select **Manual** therapy.
2. Press the **Center** button to confirm selection.
3. Press the **Up** navigation button to select the manual therapy settings.



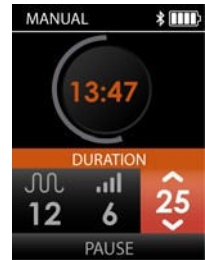
4. Press the **Center** button. Set frequency will be selected by default.
5. Press the **Up** or **Down** navigation buttons to select the **frequency** value.
6. Press the **Center** button to set the frequency value.



7. Press the **Right** navigation button to select **Intensity**.
8. Press the **Up** or **Down** navigation button to select the intensity value.
9. Press the **Center** button to set the intensity value.



10. Press the **Right** navigation button to select **therapy duration**.
11. Press the **Up** or **Down** on the navigation buttons to select the treatment time.
12. Press the **Center** button to set the duration time.

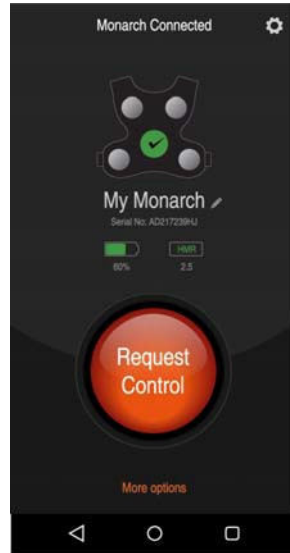


13. Press the **Back** button to return to the previous menu screen or press the **Down** navigation button to select **Start**.
14. See "Start Therapy" on page 37 to learn how to start therapy.



Program Manual Mode—Mobile App

1. From the mobile phone, tap **RequestControl**.



2. Tap the **Frequency** to select the frequency to change, swipe up or down until the frequency value needed is highlighted.



3. Tap the **Intensity** to select the intensity to edit, swipe up or down until the intensity value needed is highlighted



4. Tap the **Duration** to select the duration to edit, swipe up or down until the duration value needed is highlighted.

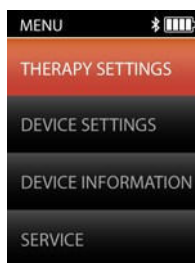
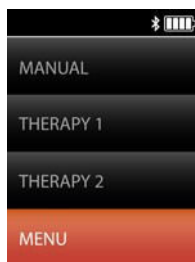


5. See “Start Therapy” on page 37 to learn how to start therapy.

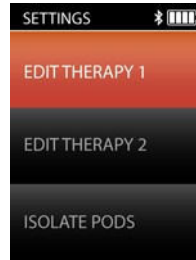
PROGRAM THERAPY MODE

Program Therapy—Pendant

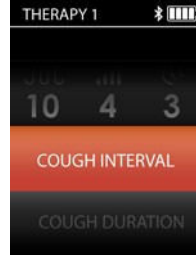
1. From the Home screen, select **Menu**.
2. Press the **Up** or **Down** navigation buttons to select **Therapy Settings**.
3. Press the **Center** button.



4. Select **EditTherapy 1** or **EditTherapy 2** to change a pre-programed therapy.
5. Press the **Center** button.



6. By default, **CoughInterval** is selected.

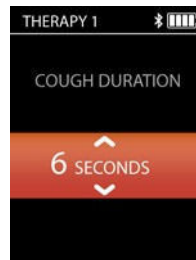


7. Press the **Center** button to edit the Cough Interval.
8. Press the **Up** or **Down** navigation buttons to increase or decrease the frequency of the Cough Interval.

9. Press the **Center** button to confirm the Cough Interval frequency.

10. Press the **Down** navigation button to select **Cough Duration**.

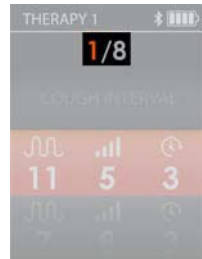
11. Press the **Center** button to edit the Cough Duration.
12. Press the **Up** or **Down** navigation buttons to increase or decrease the pause of the Cough Duration time.
13. Press the **Center** to confirm the Cough Duration time.



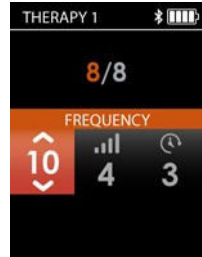
14. Press the **Up** or **Down** navigation buttons to select the therapy step to edit.
15. Press the **Center** button.

NOTE:

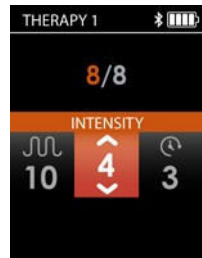
The step number will show on the top of the screen. This screen shows that you are on step one of eight. Press the **down** navigation button to the next step.



16. Press the **Center** button to select the **Frequency**.
17. Press **Up** or **Down** navigation buttons until the prescribed frequency is shown.



18. Press the **Right** button to select the **Intensity**.
19. Press **Up** or **Down** navigation buttons until the prescribed intensity is shown.



20. Press the **Right** button to select the **Frequency**.
21. Press **Up** or **Down** navigation buttons until the prescribed time is shown.

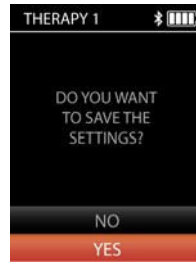


- 22. Press the **Down** navigation button to select the next step or Add New Step.
- 23. Repeat Step 4 through Step 22 until all steps in the therapy are programmed as prescribed by the physician.

NOTE:

To eliminate a step and all the steps that follow, set the duration to 0.

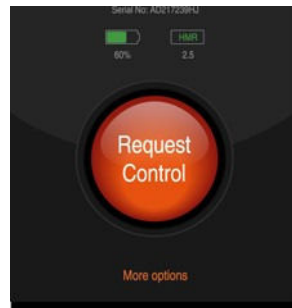
- 24. Press the **Center** or **Back** button to go back a menu and you will be prompted to save your settings, if any changes were made
- 25. Select **Yes** or **No** to save the changes made to the therapy settings.



- 26. Press the **Back** button to go back to the previous screen.
- 27. See "Start Therapy" on page 37 to learn how to start therapy.

Program Therapy—Mobile App

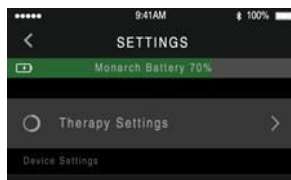
- 1. From the mobile phone, tap **RequestControl**.



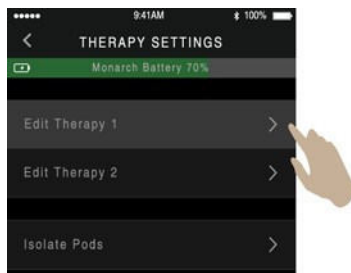
- 2. Tap the **Settings** icon on the top right of the app.



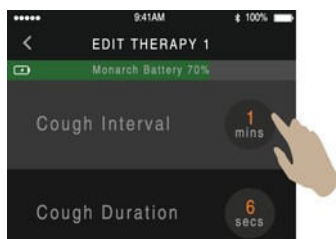
3. Tap **Therapy Setting**.



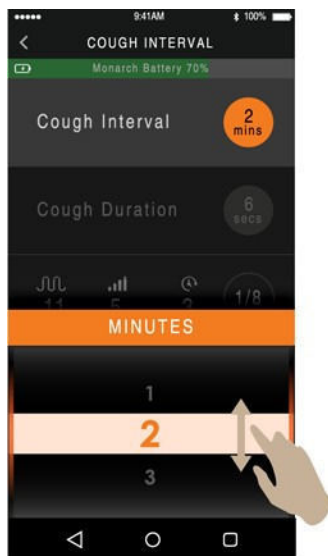
4. Tap **Edit Therapy 1** or **Edit Therapy 2** to select the programmed therapy to change.



5. Tap the **Cough Interval** to select the interval.



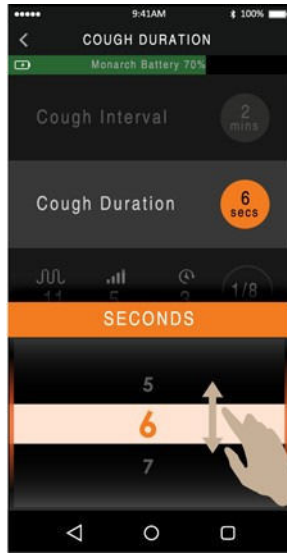
6. Swipe up or down until the **Cough Interval** value needed is highlighted.



7. Tap the **Cough Duration** to select the duration.

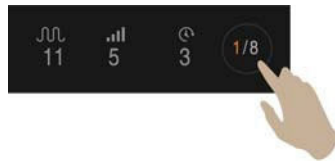


8. Swipe up or down until the **Cough Duration** needed is highlighted.



NOTE:

The steps are labeled by X/X meaning current step out of the total steps. Example: 2/6 means it is the second step out of a total of 6 steps.



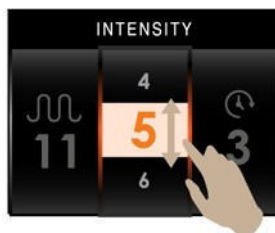
9. Tap the step you want to edit.



10. Tap the **Frequency** to select the frequency for editing, swipe up or down until the frequency value needed is highlighted.



11. Tap the **Intensity** to select the intensity for editing, swipe up or down until the intensity value needed is highlighted.



12. Tap the **Duration** to select the duration for editing, swipe up or down until the duration value needed is highlighted.



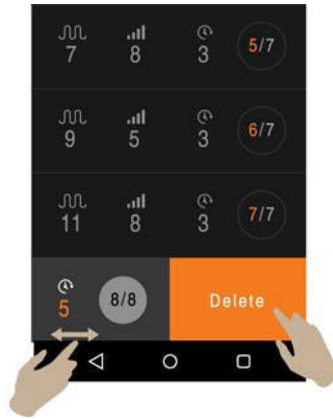
NOTE:

The maximum number of steps is 8.

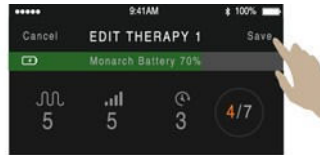
13. To add a step, swipe to the bottom of the steps list and tap **Add New Step**.



14. To delete a step, swipe the step you want to delete to the left and tap **Delete**.



15. Click **Save** to save the change or click **Cancel** to discard the changes.



16. See "Start Therapy" on page 37 to learn how to start therapy.

STARTTHERAPY

RUN MANUAL MODE THERAPY

Using the Pendant

1. Press the navigation buttons to select **Start** and press the **Center** button.



NOTE:

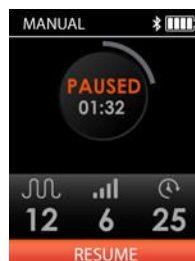
The therapy settings can be adjusted while the therapy session is in progress.

Pause Therapy

2. Select **Pause** and the **Center** button or press the **Pause/Resume** control button on the garment.



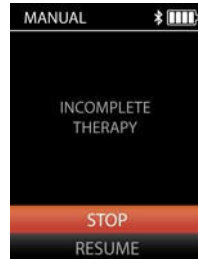
3. Press the **Center** button to resume therapy or press the **Pause/Resume** button on the garment.



4. If the therapy has been paused for 8 minutes, this screen will appear. Select **Resume** or **Stop** and press the **Center** button.



5. If **Stop** is selected, an **Incomplete Therapy** screen will show.



6. When the therapy session is complete, the following screen will show.



The Monarch™ Airway Clearance System will go into standby mode after 5 minutes of no active therapy or inputs. The system will completely shut down after 10 minutes.

Using The Mobile App

NOTE:

A trainer will install the mobile application to your device. For assistance with an installation to a device, contact Hill-Rom 800-426-4224.

Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.



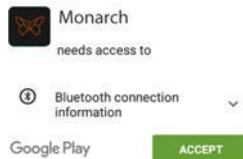
CAUTION:

The first time you launch the mobile application, Notifications screens will appear. Press **OK** to allow Notifications.

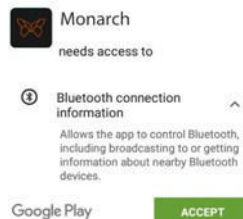
Notification Screens

Notifications allow the Monarch™ app to send information to your phone (via pop up message) even when the app is not in use.

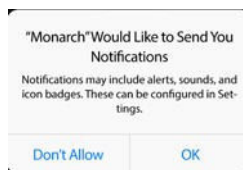
1. Tap **Accept**.



2. Tap **Accept**.

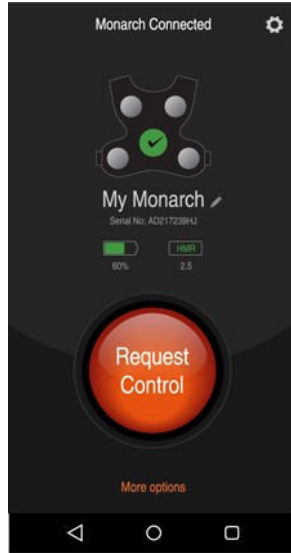


3. Tap **OK** to allow Notifications.

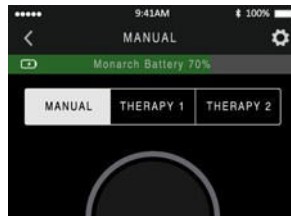


Start Therapy

1. From the mobile phone, Tap **Request Control**. Also, tap “Allow Control” on the pendant



2. Tap **Manual** on the top menu bar.



3. Tap **Start**.



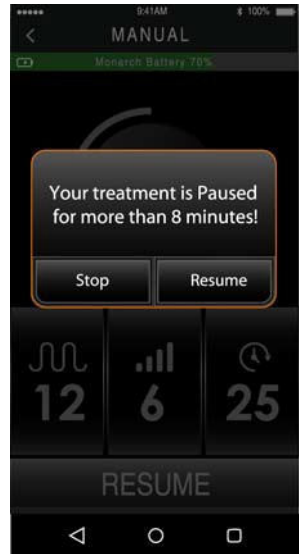
4. You can **Pause** during the therapy by tapping Pause.



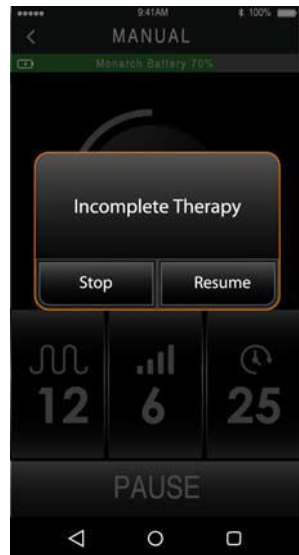
5. Tap **Resume** to resume the therapy.



6. If the therapy has been paused for 8 minutes, this screen will appear. Select **Resume** or **Stop**.



7. If Stop is selected, an Incomplete Therapy screen will show and press the center button.



- When the therapy session is complete, the following screen will appear.



NOTE:

The Monarch™ Airway Clearance System will go into standby mode after 5 minutes of no active therapy or inputs. The system will completely shut down after 10 minutes.

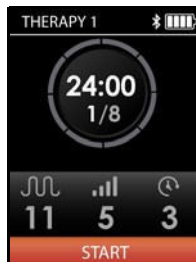
RUN PROGRAM MODE—THERAPY 1 AND THERAPY 2

Using the Pendant

- See “Program Therapy Mode” on page 29 to set up and save a therapy program as prescribed by a physician.
- Select **Therapy 1** or **Therapy 2** and press the **Center** button.

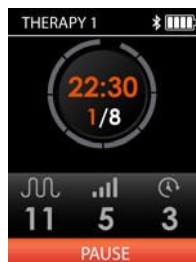


- Use the navigation buttons to select **Start** and press the **Center** button.

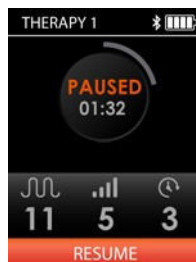
**NOTE:**

The therapy settings can be adjusted while a therapy session is in progress.

- To pause the therapy, select **Pause** and press the **Center** button.



- To resume the therapy, select **Resume** and press the **Center** button.

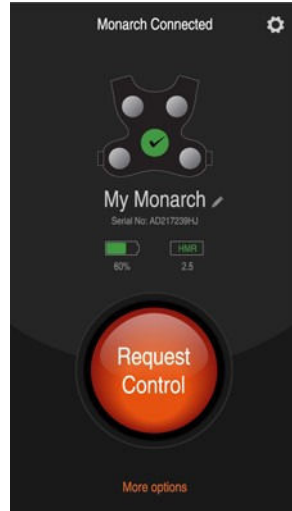


- When the therapy is complete, the screen will show Therapy Complete and the percussion will stop.



Using the Mobile App

1. From the mobile phone, tap **Request Control**. Also, tap “Allow Control” on the pendant



2. Tap **Therapy 1** or **Therapy 2** on the top menu bar.



3. Tap **Start**.



NOTE:

You can change the settings during therapy by tapping on the setting you want to change.

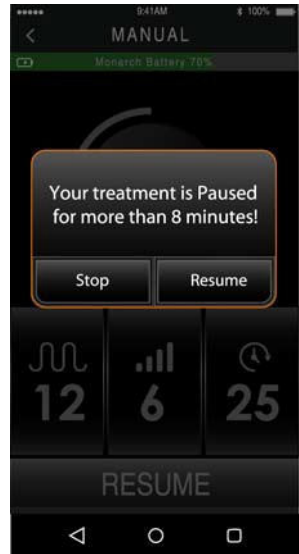
4. You can pause during the therapy by tapping **Pause**.



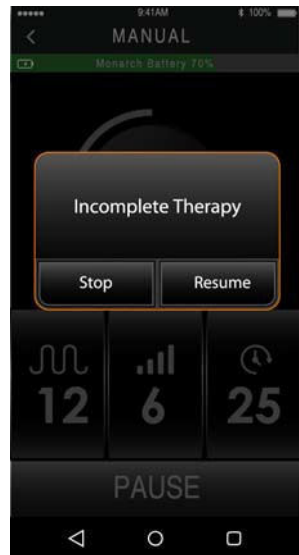
5. Tap **Resume** to resume the therapy.



6. If the therapy has been paused for 8 minutes, this screen will appear. Select **Resume** or **Stop** and press the Center button.



7. If Stop is selected, an Incomplete Therapy screen will show.



- When the therapy session is complete, the following screen will appear.

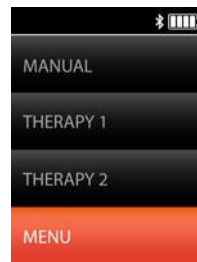


NOTE:

The Monarch™ Airway Clearance System will go into standby mode after 5 minutes of no active therapy or inputs. The system will completely shut down after 10 minutes.

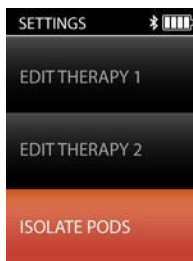
Isolate POD—Pendant

- From the Home screen, select **Menu**.



- Press the **Center** button.

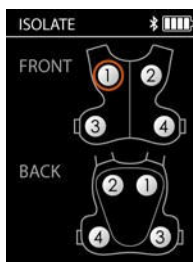
3. Select the **Isolate Pods** menu.



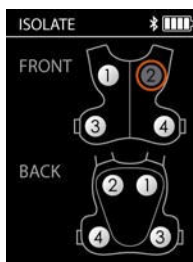
4. A colored circle around the pod shows which pod is selected. Select the pod that is to be turned on or off.

NOTE:

White indicates that the pod will be active. Grey indicates that the pod is not active.



5. Press the **Center** button to turn the pod on or off.



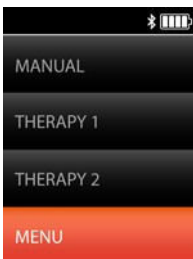
6. Press the **Back** button to exit to the previous screen.

NOTE:

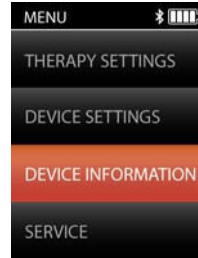
The system will not allow all pods to be in an off state.

DEVICE INFORMATION

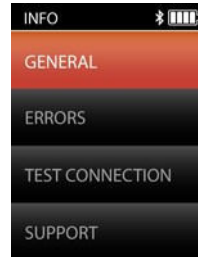
1. From the Home screen, select **Menu**.



2. Press the **Center** button.
3. Select the **Device Information** menu.



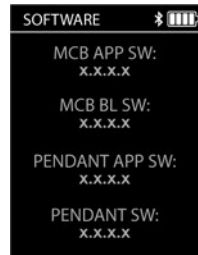
4. Select the **General** menu.



5. Select the **Software Information** menu.



6. The following general information will show:
 - MCB (Master Control Board) APP Software
 - MCB BL (battery level) Software
 - Pendant APP Software
 - Pendant Software

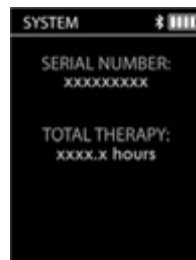


7. Select the **System Information** menu.



8. The following general information will show:

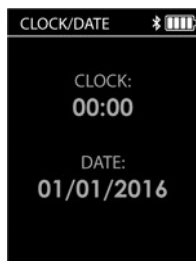
- Software Revision
- Total Therapy Hours



9. Select the **System Clock and Date** menu.



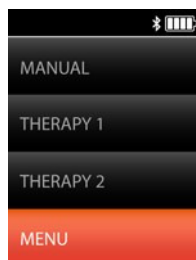
10. The time and date information will display.



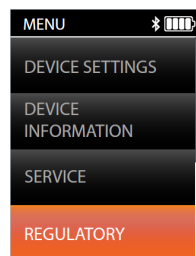
11. Press the **Back** button on the pendant to return to the previous screen.

REGULATORY

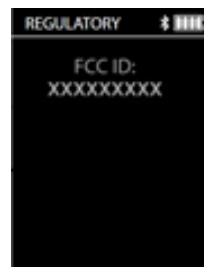
1. From the Home screen, select **Menu**.



2. Select the **Regulatory** menu.



3. View regulatory information.
Press **BACK** button to return.

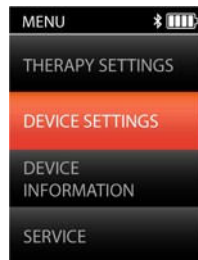


SET THE LANGUAGE

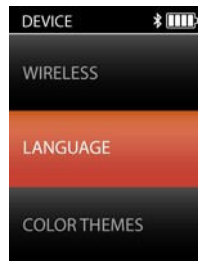
1. From the **Home** screen, select **Menu**.



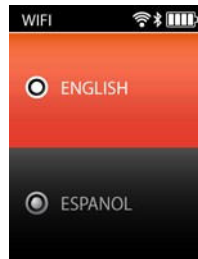
2. Select the **Device Settings** menu and press the **Center** button.



3. Select the **Language** menu and press the **Center** button.



4. Use **Up** or **Down** navigation buttons to select the language.

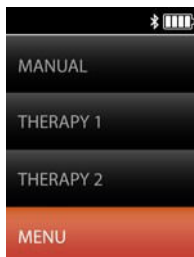


5. Select the **Center** button.
6. Press the **Back** button on the pendant to return to the previous screen.

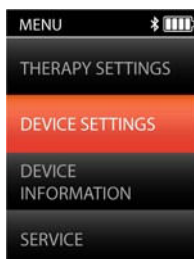
BLUETOOTH® DEVICES

TURN BLUETOOTH® ON OR OFF

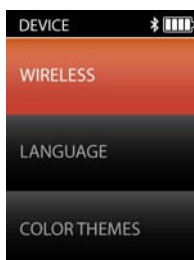
1. From the **Home** screen, select **Menu**.



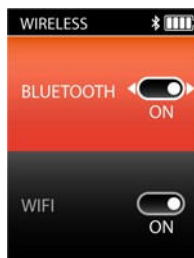
2. Press the **Center** button.
3. Select **DeviceSettings** menu.



4. Press the **Center** button.
5. Select the **Wireless** menu.

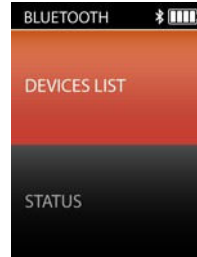


6. Press the **Center** button.
7. Select the **Bluetooth®** feature. Use the **Left** and **Right** navigation buttons to turn on or off Bluetooth® feature.



CONNECT DEVICE

8. Select the **Device List** menu.



9. A list of Paired Devices and Other Devices will show.



10. Select the device to connect.



11. Press the **Center** button.



- This screen will show to indicate the system is trying to connect with the device.



- Once Paired, the device will show under Paired Devices.



DELETE DEVICE

- Do Step 1 through Step 8 of “Bluetooth® Devices” on page 51.
- Select the device to delete.



- Press the **Center** button.
- Select **Delete**.
- Press the **Center** button.



The device will no longer be listed under Paired Devices.

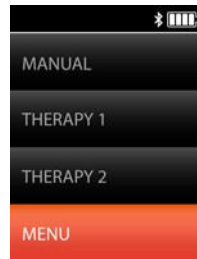


6. Press the **Back** button on the pendant to return to the previous screen.

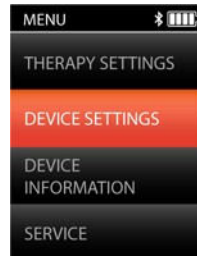
The Monarch™ Airway Clearance System must be within about 33 feet (10 meters) of the Bluetooth® device with no obstructions.

WiFi

1. From the **Home** screen, select **Menu**.

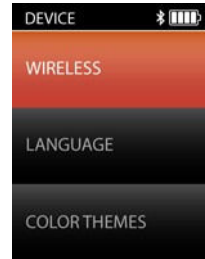


2. Press the **Center** button.
3. Select **Device Settings**.

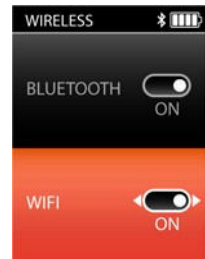


4. Press the **Center** button.

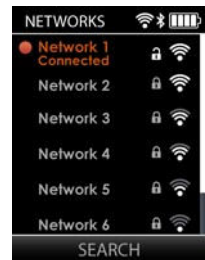
5. Select **Wireless**.



6. Press the **Center** button.
7. Select the **WiFi** feature. Use the **Left** and **Right** navigation buttons to turn on or off Bluetooth® feature.



8. Select **Network 1** for your primary WiFi connection.



9. Use the navigation buttons on the pendant to select the letter or number to enter your network password.
10. Press the **Center** button to accept each character.



11. Once your password is entered, select **Okay** and then press the **Center** button.

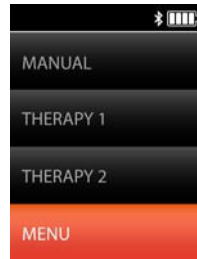


12. The screen will show that the system is searching for the network.

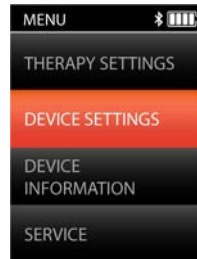


CHANGE COLOR THEMES

1. From the **Home** screen, select **Menu**.

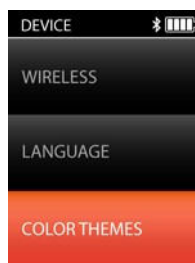


2. Press the **Center** button.
3. Select the **Device Settings** menu.

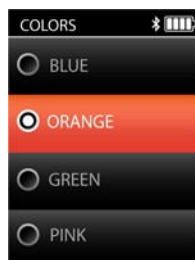


4. Press the **Center** button.

5. Select the **ColorThemes** menu.



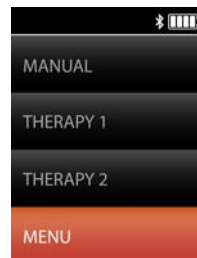
6. Press the **Center** button.
7. Select the desired color.



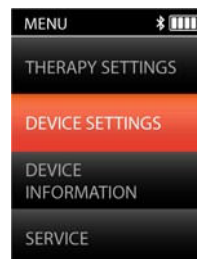
8. Press the **Center** button.

SUPPORT

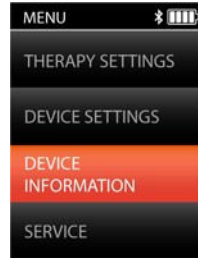
1. From the **Home** screen, select **Menu**.



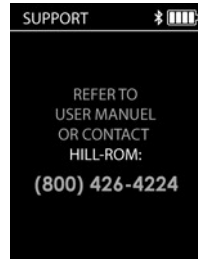
2. Press the **Center** button.
3. Select the **Device Information** menu.



4. Press the **Center** button.
5. Select the **Support** menu.

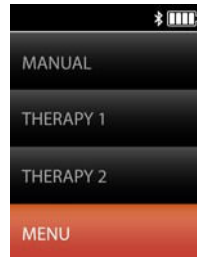


6. The **Support** screen will show a phone number to contact Hill-Rom.

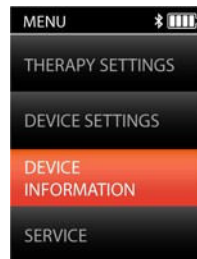


ERRORS

1. From the **Home** screen, select **Menu**.

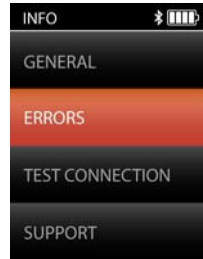


2. Press the **Center** button.
3. Select **Device Information** menu.

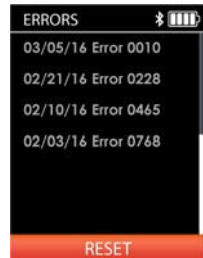


4. Press the **Center** button.

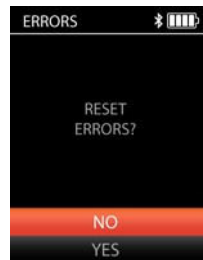
5. Select **Errors** to review system error codes.



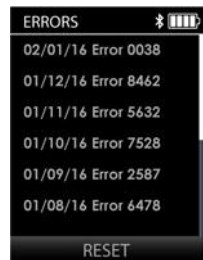
6. Select **Reset list** to remove the error information.



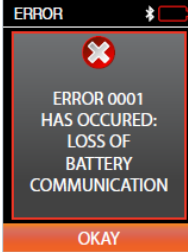

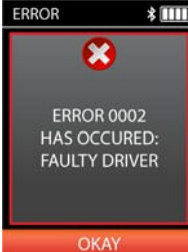

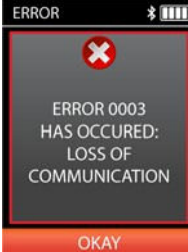

7. Select **No** or **Yes** to reset the error list and press the center button.

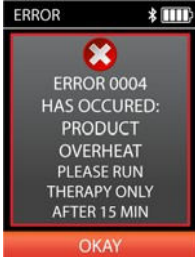
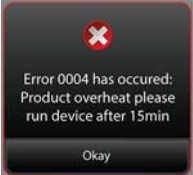


8. Once **Yes** is selected, the screen will show the last ten errors the system had.



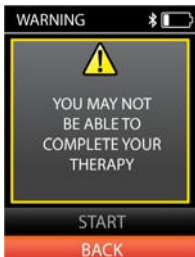










CRITICAL ERRORS









Error	Pendant	Mobile App
<p>Loss of Battery Communication—battery lost communication and will not charge.</p> <ol style="list-style-type: none"> 1. Remove the battery and reinstall. See “Battery Replacement” on page 70. 	 <p>The pendant screen shows a red 'X' icon at the top, followed by the text: 'ERROR 0001 HAS OCCURED: LOSS OF BATTERY COMMUNICATION'. At the bottom is an orange bar with the word 'OKAY' in white.</p>	 <p>The mobile app screen shows a red 'X' icon at the top, followed by the text: 'Error 0001 has occurred: Loss of Battery Communication'. At the bottom are two buttons: 'Okay' and 'Support'.</p>
<ol style="list-style-type: none"> 2. After pressing the push button on the battery, confirm that a battery indicator light is lit on the front of the battery. If the lights are flashing or no light is observed, plug the unit in to power. 3. If error is not resolved, contact Hill-Rom at 800-426-4224. If outside 		
<p>Faulty Driver—power is interrupted between main control board and the pod drivers.</p> <p>Contact Hill-Rom at 800-426-4224.</p> <p>Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.</p>	 <p>The pendant screen shows a red 'X' icon at the top, followed by the text: 'ERROR 0002 HAS OCCURED: FAULTY DRIVER'. At the bottom is an orange bar with the word 'OKAY' in white.</p>	 <p>The mobile app screen shows a red 'X' icon at the top, followed by the text: 'Error 0002 has occurred: Faulty Driver'. At the bottom are two buttons: 'Okay' and 'Support'.</p>
<p>Loss of Communication—pendant lost the communication with the main control board.</p> <p>Contact Hill-Rom at 800-426-4224.</p> <p>Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.</p>	 <p>The pendant screen shows a red 'X' icon at the top, followed by the text: 'ERROR 0003 HAS OCCURED: LOSS OF COMMUNICATION'. At the bottom is an orange bar with the word 'OKAY' in white.</p>	 <p>The mobile app screen shows a red 'X' icon at the top, followed by the text: 'Error 0003 has occurred: Loss of Communication'. At the bottom are two buttons: 'Okay' and 'Support'.</p>

Error	Pendant	Mobile App
<p>Product Overheat—temperature exceeds the garments operating temperature.</p> <ol style="list-style-type: none"> 1. Press Okay to terminate the therapy to allow the system to cool for 15 minutes. 2. If error is not resolved, contact Hill-Rom at 800-426-4224. If outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com. 	 <p>The pendant screen displays 'ERROR' at the top with a red 'X' icon. The main text reads: 'ERROR 0004 HAS OCCURED: PRODUCT OVERHEAT PLEASE RUN THERAPY ONLY AFTER 15 MIN'. At the bottom is a red bar with the word 'OKAY' in white.</p>	 <p>The mobile app screen displays a red 'X' icon at the top. The text reads: 'Error 0004 has occured: Product overheat please run device after 15min'. At the bottom is a button labeled 'Okay'.</p>

CAUTION ERRORS

Error	Pendant	Mobile App
<p>Pod Not Working—one or more of the therapy pods is not working. The location of the pod will be identified in the caution statement. Therapy can continue if one or more of the pods is not working.</p> <p>Contact Hill-Rom at 800-426-4224 or if outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.</p>	 <p>The pendant screen displays 'WARNING' at the top with a yellow triangle icon. The main text reads: 'FRONT POD 2 IS NOT WORKING'. At the bottom is a red bar with the word 'OKAY' in white.</p>	 <p>The mobile app screen displays a yellow triangle icon at the top. The text reads: 'Front Pod 2 is not working'. At the bottom are two buttons: 'Okay' and 'Support'.</p>
<p>Battery under 25%—There might not be enough battery charge to complete the therapy session. Plug the system in to power.</p>	 <p>The pendant screen displays 'WARNING' at the top with a yellow triangle icon. The main text reads: 'YOU MAY NOT BE ABLE TO COMPLETE YOUR THERAPY'. At the bottom are two buttons: 'START' and 'BACK'.</p>	 <p>The mobile app screen displays a yellow triangle icon at the top. The text reads: 'Monarch Battery Under 25% You may not be able to complete your therapy'. At the bottom are two buttons: 'Back' and 'Start'.</p>

Error	Pendant	Mobile App
<p>Low battery—Plug the system in to power.</p>		
<p>Pod Isolation—One pod must be active for therapy.</p>		
<p>Stuck button—Make sure that a button is not inadvertently pressed or held close. Contact Hill-Rom at 800-426-4224.</p>		<p>Not applicable</p>
<p>WiFi—Reconnect to the WiFi communication, see “WiFi” on page 54.</p>		

Error	Pendant	Mobile App
<p>Bluetooth®—Reconnect to the Bluetooth® communication, see “Bluetooth® Devices” on page 51.</p>		
<p>Battery Communication—</p> <ol style="list-style-type: none"> 1. Remove the battery and reinstall. 2. After pressing the push button on the battery, confirm that a battery indicator light is lit on the front of the battery. If the lights are flashing or no light is observed, plug the unit in to power. 		
<p>Datastorage—Contact Hill-Rom at 800-426-4224.</p>		
<p>Unauthorized USB— Remove the USB device from the system</p>		

SERVICE



WARNING:

Only authorized person should service The Monarch™ Airway Clearance System. Servicing by unauthorized person could cause personal injury or equipment damage.

The Monarch™ Airway Clearance System does not require periodic preventive maintenance.

The product shall not be serviced or cleaned while in use by a patient.

If service is necessary, use this contact information:

- In the USA, call Hill-Rom at 800-426-4224.
- Outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.hill-rom.com.

EXPECTED LIFE

The expected service life for the garment is five years from date of purchase.

The expected service life of the battery is one year from date of purchase.

Hill-Rom will repair or replace a defective unit as part of a warranty package specified at the time of purchase of the device.

Note: For proper disposal make sure to follow your local, state or country electronic and battery regulations to safely discard or recycle Monarch™ Airway Clearance System, parts and batteries.

SERVICE CALLS

When you contact Hill-Rom about The Monarch™ Airway Clearance System, be prepared to give the serial number from the product identification label. The product identification label is located under the backpack cover just over the battery compartment.

When you give the serial number, the Hill-Rom representative can identify your unit and give you the information you need more quickly.



TROUBLESHOOTING



WARNING:

Only authorized personnel should service The Monarch™ Airway Clearance System, Model 1000. Servicing by unauthorized personnel could cause personal injury or equipment damage.



WARNING:

Do not modify this device without the authorization of the manufacturer. To do so could cause personal injury or equipment damage.

GARMENT DOES NOT POWER ON

1. Make sure the DC connector from the AC adapter is securely plugged into the charging port on bottom of the Monarch™ system garment. Make sure the battery is fully charged and is properly seated into its location on the garment. If necessary, unplug the DC connector from the garment, and then reconnect.
2. If the problem still exists, contact Hill-Rom.

POD(S) DO NOT ACTIVATE

1. Use the pendent to get to the Localize screen (see “Start Therapy” on page 37). Confirm that all pods are white to indicate that the pods are active for therapy.
2. If the problem still exists, contact Hill-Rom.

SCREEN SHOWS “PLEASE CALL FOR SERVICE” MESSAGE

The system has experienced an unexpected event. Do as follows:

1. Follow the steps on the screen.
2. If the problem still exists, contact Hill-Rom.

THE GARMENT NO LONGER FITS

Adjust the garment to accommodate growth:

- To adjust fit of garment, refer to “Garment Fitting” on page 21.

STORAGE AND HANDLING

To store or transport The Monarch™ Airway Clearance System, do as follows:

1. Place the garment in the roller bag.
2. Insert the AC/DC adapter, power cord, and other accessories into the compartments above the garment in the roller bag.
3. Close the roller bag to secure the garment inside.

SHIPPING THE UNIT



WARNING:

Do not ship the battery with over 30% charge or injury and/or equipment damage may occur.



CAUTION:

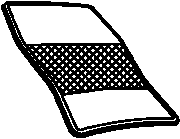
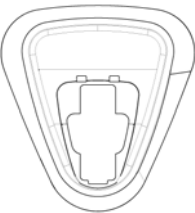
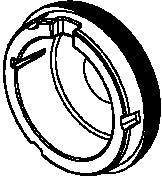
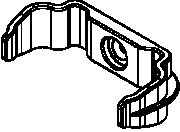
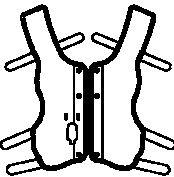
If shipping is required, the original packing material provides the best protection for The Monarch™ Airway Clearance System. Retain the original packaging material. Failure to do so could cause equipment damage.

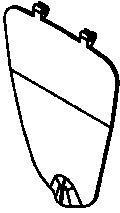
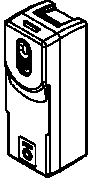

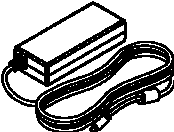

If shipping is required, ship the unit in its original packing material.

FREQUENTLY ASKED QUESTIONS

- How does The Monarch™ Airway Clearance System effectively treat areas of my lungs?
 - The system is designed to oscillate the chest wall to create airflow by applying percussion to the lung area to treat the lobes of the lung.
- How long should my Airway Clearance Therapy treatment session last?
 - Common prescriptions specify a treatment session Time to be between 10 and 30 minutes. Prescribed treatment session times may be different. Refer to the physician's order.
- How often should my treatment sessions be given?
 - The Frequency of treatment sessions depends on your underlying disease, age, and state of health. Your physician will prescribe a schedule for your individual needs.
- Is chest physiotherapy still necessary?
 - Refer to the physician's order.
- Is postural drainage still necessary?
 - Refer to the physician's order.
- What will happen if I miss a treatment session?
 - One missed treatment session of the system may or may not affect your health. However, the key to help maintain your health is consistent, effective therapy. Try to follow the physician's care plan as closely as possible. Consult your physician if a treatment session is missed.
- Is there a best time to do a therapy with The Monarch™ Airway Clearance System?
 - Establish a schedule that works for you and your family, and lets you do the therapy consistently.
- Do all patients receive the same benefits from The Monarch™ Airway Clearance System?
 - The overall benefit depends on many factors, which include the underlying disease, patient's age, and present state of health.

REPLACEMENT PARTS LIST AND INSTRUCTIONS

Symbol	Part Number	Description
	197811	Assembly, padding shoulder
	195499	Assembly, back cover
	198221	Foam, cover VCA bottom
	198457	Cradle, pendant clip
	198683	Washable garment shell, orange
	198684	Washable garment shell, blue
	198685	Washable garment shell, green
	198686	Washable garment shell, pink
	198687	Washable garment shell, red

Symbol	Part Number	Description
	198678	Lid, back cover_green
	198679	Lid, back cover_red
	198680	Lid, back cover_pink
	198681	Lid, back cover_blue
	198682	Lid, back cover_orange
	194566	Battery
	198656	Carry case
	195500	AC/DC adaptor
	M07437	Powercord, NA_Canada (NEMA1-15P)

BATTERY REPLACEMENT

NOTES:

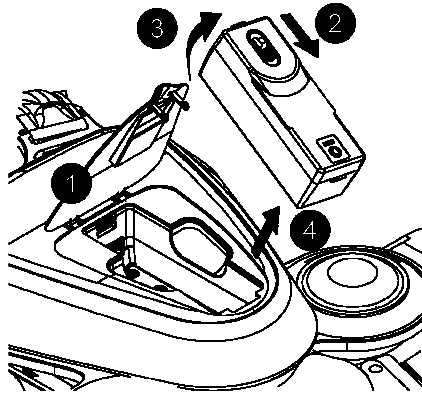
- Consult your local regulations to safely discard or recycle the batteries.
- Do not return the battery unless specifically requested by customer service.
- Remove the battery before returning the main garment for repairs.



WARNING:

Do not ship the battery with over 30% charge or injury and/or equipment damage may occur.

1. Lift the battery access panel.
2. Slide and hold the latch down to unlock battery.
3. Pull on the top battery while the latch is unlocked.
4. Remove the bottom of the battery from the garment.



BATTERY ACCESS PANEL REPLACEMENT

1. Open the battery access panel by lifting the bottom of the panel and lifting up.
2. Grip the battery access panel close to the hinge and slowly pull away from the backpack to remove the hinge.
3. Grip the new battery access panel with the logo facing away from the backpack.
4. Insert the left hinge on to the backpack until it clicks and insert the right hinge until it clicks.
5. Close the battery access panel until it clicks closed.

AC/DC CHARGER

Only use a Hill-Rom approved Monarch AC/DC Charger.

MEGMEET
MEDICAL AC/DC ADAPTER

MODEL : MANGO120-24CK-HR
HILL-ROM P/N : 195500
INPUT : 100-240V~, 50/60Hz 2.0-1.0A
OUTPUT : 24V === 5A
EFFICIENCY LEVEL : Ⓢ
MANUFACTURED FOR HILL-ROM

  IP 22
  
  
Regional Production
Supervisory
Safety
Type Approval
www.hill-rom.com
ID: MANGO120



深圳麦格米特电气股份有限公司
SHENZHEN MEGMEET ELECTRICAL CO., LTD.
REV1.0 MADE IN CHINA/中国制造

The Monarch™ Airway Clearance System is a HFCWO therapeutic device that is used to aid mobilization of secretions from the airways and help improve airway health. This is achieved by advanced microprocessor control of 8 electromechanical actuators (PODS) which oscillate against the chest wall. The PODs provide a targeted kinetic energy to the lungs which thin mucus and generate airflow to move the mucus from the small airways to the large airways where it can be coughed out or suctioned.

No user initiated calibration is required during the service life of the Monarch™ Airway Clearance System.

SPECIFICATIONS

Feature	Dimension
Monarch™ weight (with battery)	13.2 lbs (6 kg)
Size guide	Fits mid chest circumference of 22 inches to 50 inches (56 cm to 127 cm)
Base garment	EVA foam
Garment shell	Polyester
Electrical Requirements	Nominal voltage: 24V DC +/- 1.5 V DC Nominal Power Consumption: ~65 W max
A/C Power Supply	Model MANGO120-24CK Input: 100-240 V, 50/60 Hz 1.0-2.0A
Lithium-ion Battery	Part number: 194566 Output: 24 V DC +/- 1.5 V DC, Capacity : 2700mAh
Fuse requirement	Power adapter/cord only

Environmental Conditions for Transport and Storage

Condition	Range
Temperature	-4°F to 140°F (-20°C to 60°C)
Relative humidity	15% to 90%, non-condensing
Atmospheric pressure	50 kPa to 106 kPa

Environmental Conditions for Use

Condition	Range
Temperature	41°F to 95°F (5°C to 35°C)

Condition	Range
Relative humidity	15% to 90%, non-condensing
Atmospheric pressure	70 to 106 kPa

Wireless Communication

The Monarch™ Airway Clearance System features a Bluetooth® interface to connect to a smartphone mobile application as secondary control for the device. The Monarch™ Airway Clearance System also features an optional Wi-Fi module to export device use data in home care environments.

Feature	Dimension
Bluetooth® Specification (Built-in)	
Bluetooth® compliance	Bluetooth® V4.0 (BLE Mode)
Frequency	2.40 to 2.48 GHz
Transmit Power	+8 dBm (max) + 0.5dBm upper tolerance
Receive Sensitivity	-90 dBm (typical)
Modulation	Frequency shift keying Frequency hopping spectrum
Wi-Fi (Optional Configuration)	
WLAN	IEEE 802.11a, 802.11b, 802.11g, 802.11n
Frequency	2412 – 2462 MHz, 5180 – 5240 MHz, 5745 – 5825 MHz
Transmit Power (+/- 2dBm)	17.5 dBm for 802.11b DSSS 17.5 dBm for 802.11g/n OFDM 12 dBm for 802.11a/g/n OFDM
Receive Sensitivity (+/- 2dBm)	1Mbps -95.5 dBm (< 10% PER) 54 Mbps -74.5 dBm (< 10% PER) MCS7(20MHz) -71.5 dBm (< 10% PER) MCS7(40MHz) -68 dBm (< 10% PER)
Security Authentication/Encryption	WPA/WPA2-Personal, WEP 64/128bits

DRAFT 29-NOV-2016

Classification and Standards

Technical and Quality Assurance	ANSI/AAMI ES60601-1 CAN/CSA-C22.2 No. 60601-1 IEC 60601-1 ISO 13485: 2003 Medical Devices Quality Mgt Systems EN ISO 14971:2012
Safety Class	Class II (double insulation)
Equipment Classification	Percussor, powered electric Class II
Patient Applied Part	External pod cover of actuator pods
Degree of Protection Against Electric Shock	Class II (double insulation)
Classification According to Directive 93/42/EEC: IIa	
Degree of Protection Against Ingress of Water: IP42	
Maximum Sound Pressure Level	65 dBA
Not for use with flammable anesthetics.	

The Monarch™ Airway Clearance System, Model 1000 is a continuous operation device classified with Underwriters Laboratories, Inc.® (UL) in the United States and licensed with Health Canada.

There are no user accessible fuses. Refer to the *Monarch™ Airway Clearance System Service Manual (195291)* for fuse ratings and replacement procedures.

Electromagnetic Compatibility Guidance

The Monarch™ Airway Clearance System is suitable for the electromagnetic environment of typical home healthcare environment settings.



WARNING:

The Monarch™ Airway Clearance System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Monarch™ Airway Clearance System should be observed to verify normal operation. If operation is not normal, the Monarch™ Airway Clearance System or the other equipment should be moved.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The Monarch™ Airway Clearance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Monarch™ Airway Clearance System should make sure it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic - Environment—Guidance
RF Emissions CISPR 11	Group 1	The Monarch™ Airway Clearance System uses RF energy only for its internal functions. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Monarch™ Airway Clearance System is suitable for use in all establishments, including domestic establishments, and those directly connected to the public low-volt- age power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
The Monarch™ Airway Clearance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Monarch™ Airway Clearance System should make sure it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic - Environment—Guidance
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity Guidance


Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Monarch™ Airway Clearance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Monarch™ Airway Clearance System should make sure it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic - Environment—Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8kV Contact Discharge ± 15kV Air Discharge	± 8kV Contact Discharge ± 15kV Air Discharge	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	± 2 kV for Power Supply Lines	Mains power quality should be that of a typical home healthcare environment
Surge IEC 61000-4-5	± 1 kV Line(s) to Line(s)	± 1 kV Line(s) to Line(s)	Mains power quality should be that of a typical home healthcare environment

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Monarch™ Airway Clearance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Monarch™ Airway Clearance System should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic - Environment—Guidance
Voltage Dips, Short Interruptions, and Voltage Variations On Power Supply Input Lines IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single Phase: at 0° 0% UT; 250/300 cycle	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single Phase: at 0° 0% UT; 250/300 cycle	Mains power quality should be of a typical home healthcare environment. If the user of the Monarch™ Airway Clearance System requires continued operation during power mains interruption, it is recommended that the Monarch™ Airway Clearance System be powered from an uninterruptedly power supply or a battery.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment

Note: U_T is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Monarch™ Airway Clearance System is intended for use in the electromagnetic environment specified below. The customer or the user of the Monarch™ Airway Clearance System should make sure it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 150 kHz to 80 MHz</p> <p>10 V/m 80 MHz to 2.7 GHz</p>	<p>3 V/m</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Monarch™ Airway Clearance System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2\sqrt{P}$ <p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz</p> $d = 2.33\sqrt{P}$ 800 MHz to 2.7 GHz <p>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 in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey¹, should be less than the compliance level in each frequency range².</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> <div style="text-align: center;">  </div>
<p>Note 1: At 80 MHz and 800 MHz, the higher the frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

- 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 Monarch™ Airway Clearance System is used exceeds the applicable RF compliance level above, the Monarch™ Airway Clearance System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Monarch™ Airway Clearance System .
- b. Over the frequency range of 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Monarch™ Airway Clearance System.			
The Monarch™ Airway Clearance System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Monarch™ Airway Clearance System prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Monarch™ Airway Clearance System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.			

Federal Communications Commission (FCC) Radiation Exposure Statement

This device complies with Part 15 of the FCC rules and Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

For body worn operation, the device is designed and tested to meet the applicable limits for radio frequency (RF) exposure established by the Federal Communications Commission (U.S.A.) Specific Absorption Rate; (SAR) refers to the rate at which the body absorbs RF energy. To maintain compliance, the device must be used with specified Hill-Rom Holdings, Inc. accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

NOTE:

The module must be used in strict accordance with the manufacturer's instructions as described in the user documentation that comes with the product. Modifications not expressly approved by Hill-Rom could void your authority to operate the equipment.

The module must not be co-located or operated in conjunction with any other antenna or transmitter.

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