# Monarch™ Airway Clearance System, Model 1000

# **User Manual**

Product No. PMACS1



Rx only: Federal USA law restricts this device to sale by or on the order of a physician.



Apply Serial Number Label here or record Serial Number

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# Manufacturer:

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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 Hill-Rom qualified trainer or respiratory therapist before the user uses the product for therapy delivery. The training may last 60 minutes or until the user is comfortable with the safe and effective use of the product.

The Monarch™ product is intended for Single Patient Use (SPU) in the Home Care environment.

Always unplug this product immediately after use or after you charge 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.

- 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 regiments involving manually or mechanically assisted coughing or other techniques in conjunction with Monarch™ Airway Clearance System 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.
- We recommend your first use of this product be in a supervised setting such as at home with a clinical trainer or in a doctor's office.
- 6. Use this product only for its intended use as described in this manual.
- 7. Do not use attachments not recommended by the manufacturer.
- 8. Do not use unauthorized parts or accessories with this device.
- 9. Use only Hill-Rom authorized garment vest shells to avoid allergic skin reactions.
- 10. If this product has a damaged Power Cord or plug, or the product does not operate correctly, do not use it. For examination and repair, contact Hill-Rom.
- 11. Store and keep the Power Cord out of reach from toddlers and young children to prevent strangulation risks.
- 12. Keep the unit, battery, AC/DC power adapter, and Power Cord away from heated surfaces.
- 13. Do not use the device near to any heat source such as a fireplace or radiant heater.
- 14. Do not use the device in a dusty environment.
- 15. Do not use the device in a heavy moisture environment.
- 16. When you remove the product from storage conditions, let the Monarch™ Airway Clearance System return to its recommended operating temperature range before you use the product.
- 17. 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.
- 18. Machine wash and dry the vest shell monthly or when visibly soiled.

- 19. If conditions exist that prohibit use of the Monarch™ Airway Clearance System, do **not** use the unit. Death or serious injury could occur.
- 20. Federal USA law restricts this device to sale by or on the order of a physician.
- 21. Only authorized persons should service Monarch™ Airway Clearance System.

### 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.respiratorycare.hill-rom.com.
- 22. The potential for electrical shock exists with electrical equipment. Failure to follow protocols may cause death or serious personal injury.
- 23. 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.
- 24. Do not expose the unit to excessive moisture or immerse it in water.
- 25. If the display on the Monarch™ pendant is faulty, do **not** use the unit.
- 26. If the Monarch™ Airway Clearance System is wet or damp, do **not** plug it into a power source or use it.
- 27. Before cleaning, unplug the unit from its power source and remove the battery.
- 28. Do not use harsh cleansers, solvents, or detergents.
- 29. Retain the original packaging material. If shipping is required, the original packing material provides the best protection for the 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.
- 34. Do not allow metallic conductive objects to contact the battery terminals. Do not short circuit a battery or throw it into a fire; it can explode and cause severe personal injury.
- 35. Improper battery use may result in a fire, explosion, or other hazard.
- 36. Risk of fire and burns: do not open, crush, or heat the battery above 140°F (60°C).

# **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 older) 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.

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 8th grade education level or comparable. We recommend that patients who do not meet this education level get assistance from Hill-Rom qualified trainers before using this device for therapy.

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

### CONTRAINDICATIONS



# **WARNING:**

If any patient conditions exist that could 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:

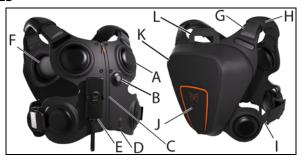
- Intracranial pressure (ICP) greater than 20 mm Hg
- Recent spinal surgery or acute spinal injury
- Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- Large pleural effusions or empyema
- Pulmonary embolism
- Rib fractures, with or without flail chest
- Surgical wound 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

# **ACRONYMS**

Acronym	Meaning
HFCWO	High Frequency Chest Wall Oscillation
POD	Pulmonary Oscillating Disc
LTE	Long Term Evolution (4G)
UTC	Coordinated Universal Time

# **FEATURES**



Item	Description	Item	Description
Α	POD	Н	Shoulder pads
В	Pause/resume control button	I	Torso Adjustment—Cam buckle
C	Front opening	J	Battery access panel
D	Charging port	K	Backpack cover
E	Pendant	L	Handle
F	POD cover		Power adapter (not shown)
G	Shoulder strap		



# 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).
- 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 Adjust- ment	
POD		Shoulder Pads	
Front Closer		Torso Adjust- ments—clip	
Vest Shell	並	Torso Adjust- ment—Cam buckle	

Item	Image	Item	Image
Backpack Cover		Battery	
Charging Port		Battery Access Panel and Bat- tery Compart- ment	TI U
Pause/ Resume But- ton		Pendant Dock	8

# **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
Α	Screen
В	ON/OFF button
С	Navigation buttons
D	Center button
E	Back button

# **PRODUCT SYMBOLS**

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

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

Symbol	Definition
<u> </u>	WARNING OR CAUTION
	Follow the operating instructions
	Class II equipment (double insulated), according to EN60601-1
IP42	Protected against ingress of solid foreign objects ≥0.04" (1.0 mm) in diameter and dripping water (at 15° tilt).
c S36914	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) + (2016)
	Manufacturer or distributor complies with the Waste Electric and Electronic Equip- ment Directive 2012/19/EU
X	Do not iron*
<u>~</u>	Machine wash cold

Symbol	Definition
×	No chlorine bleach*
0	Tumble dry low heat*
REF	Catalog number
LOT	Batch number
, , , , , , , , , , , , , , , , , , ,	Date of manufacture
	Manufacturer
YYYY	Manufacturer and date of manufacture
RxOnly (USA)	Physician prescription required (for US only)
	ACMA RCM compliance mark
	Single Patient Use

Symbol	Definition
(11/8)	Pause/Resume control button—press the button to stop therapy and press again to resume therapy*

<sup>\*</sup>Applicable only for vest shell of the product.

# **PENDANT SCREEN SYMBOLS**

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

# **Main Screen**

Symbol	Definition	Symbol	Definition
$\mathcal{M}$	Frequency	$\bigcirc$	Duration
.11	Intensity	$\bigcup$	The recovery of the error list is in progress. (icon will rotate)
*	The unit is plugged into power and not running off the battery.		The battery has 75% to 100% charge on the battery.
<b>*</b>	The battery is charging.		The battery has 50% to 75% charge on the battery.
<b>(</b>	The WiFi is connected. (only available on the WiFi enabled Mon- arch® Systems)		The battery has 25% to 50% charge on the battery.
*	The Bluetooth® is connected.		The battery has 20% to 25% charge on the battery.

Symbol	Definition	Symbol	Definition
	The LTE is connected. (only available on the LTE enabled Monarch® Systems during trans- mission)		The battery charge has under 20% charge on the battery.
FRONT (1) (2)		Front view of the garment with POD locations identified	
ВАС	2 <b>0</b>	Back view locations i	of the garment with POD dentified

# **MOBILE DEVICE SYMBOLS**



# NOTE:

The mobile device App images in this manual are examples only. Since mobile device screens may vary by brand, your screen may not look exactly like the images shown.

# **Main Screen**

Item	Description	Item	Description
Α	Current therapy mode	G	Frequency setting (5-20 hertz)
В	Settings menu	Н	Countdown therapy duration
C	Therapy 2 control	I	Therapy 1 control
D	Intensity setting (1-10)	J	Manual control
E	Duration setting (1-30 minutes)	K	Monarch™ Airway Clearance battery status
F	Start therapy control	L	Previous screen button

# INSTRUCTIONS FOR USE

# 

If you have any questions or concerns, contact Hill-Rom:

- 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.respiratorycare.hill-rom.com.

### **SETTING UP THE UNIT**



# **WARNING:**

To help prevent injury and/or equipment damage, obey these:

- Inspect the garment and accessories 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.
- If the garment is wet or damp, do not plug it into a power source or use it.
- Use the supplied battery charger only. Failure to do so may cause a fire, which may result in personal injury and property damage.



# **CAUTION:**

Do not open, crush, puncture, incinerate, immerse in water, or heat over 140°F (60°C) the battery.

### NOTE:

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

# **Getting Started**

# Install Battery

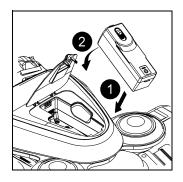


# **CAUTION:**

Obey these cautions to help prevent equipment damage:

- Use only with the Hill-Rom approved battery (Hill-Rom part number 194566 (Inventus Power, Inc. model number 194566)).
- Fully charge the battery to 100% before first time use.

- 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 (1).
- 4. Slide the latch, then proceed to insert the top of the battery until the battery locks into position (2).







**Fully Locked** 

Not Fully Locked

# NOTE:

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

# **Charge Battery**



# **CAUTION:**

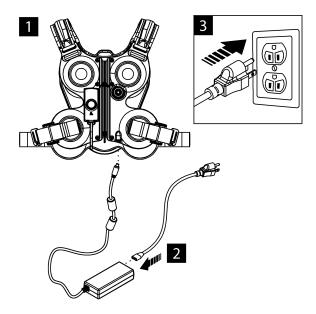
Use only with the Hill-Rom approved AC/DC power adapter (Hill-Rom part number 195500 (MEGMEET model number MANGO120-24CK-HR)) to prevent equipment damage.

- 1. Plug the power adapter into the garment.
- 2. Plug the power adapter into the power cable.
- 3. Plug the power cord into an applicable power outlet.



# **CAUTION:**

If the battery charge is below 20%, you may not be able to complete your therapy session.



# NOTE:

The Power Cord required for your country may be different than shown.

# **Attaching the Vest Shell**

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







Pendant dock

- 4. Snap the three snaps along the side of the vest shell closest to the zipper.
- Attach the hook and loop fastener straps around the cam buckle to secure the bottom of the vest shell to the cam buckle.



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



7. Repeat for the other side of the garment.

### NOTE:

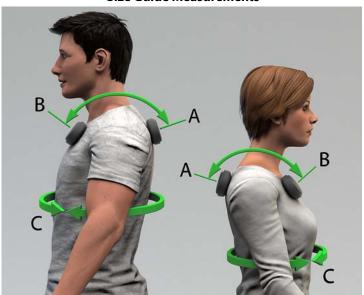
Machine wash and dry the vest shell as needed (see "General Cleaning—Garment" on page 77).

# **Garment Fitting**

# **SIZE GUIDE REFERENCE**

- 1. Measure from point **A** to **B**, see the image below.
- 2. Measure the circumference around point **C**, the mid-chest of the patient.





Item	Description
A and B	Ideal POD contact point
С	Circumference measure point

# **Shoulder Strap Adjustment**

Measure the patient's shoulder height with a flexible tape measure. Place the end of the flexible tape measure in position **A** and pull the tape measure taunt over the shoulder to position **B**. Write the shoulder height in the Shoulder Measurement field below. Use the table to determine the adjustment needed to the shoulder strap.

Shoulder Measurement: \_\_\_\_\_

Measurement	Hook and Loop Adjustment Line
10" (25.4 cm)	All of the orange lines are covered by the shoulder strap.
11" (27.9 cm)	1 orange line is visible
12" (30.5 cm)	2 orange lines are visible
13" (33.0 cm)	3 orange lines are visible
14" (35.6 cm)	4 orange lines are visible





# **Torso Adjustment**

Measure the patient's mid chest with a flexible tape measure. Place the end of the tape measure on the patient's side, below the bust line. Pull the tape measure taunt around the mid chest as shown in the image on page 20 for position **C**.Write the mid chest circumference in the field below. Use the table to determine the adjustment needed to the torso clip.

Mid Chest Measurement:

Measurement	Torso Clip Adjustment	
22" - 24" (55.9 - 61 cm)	1 (closest to the back panel or smallest fitting)	
25" - 27" (63.5 - 68.6 cm)	2	
28" - 30" (71.1 - 76.2 cm)	3	
31" - 33" (78.7 - 83.8 cm)	4	
34" - 36" (86.4 - 91.4 cm)	5	
37" - 39" (94 - 99.1 cm)	6	
40" - 42" (101.6 - 106.7 cm)	7	
43" - 45" (109.2 -114.3 cm)	8	
46" - 48" (116.8 - 121.9 cm)	9	
49" - 50" (124.5 - 127 cm)	10 (furthest from the back panel or largest fitting)	
Back panel	Front panel	

### SHOULDER ADJUSTMENT

- Open the shoulder pad, and remove the pad from the garment to free the shoulder straps for adjustment.
- 2. Slide the top stretchable band over to access the adjustable strap.
- 3. Separate and adjust the shoulder strap to fit the patient's shoulder height. See "Garment Fitting" on page 20.





- 4. Once the strap is set to the correct orange line, firmly press the shoulder strap together to engage the hook and loop fastener.
- 5. Slide the top stretchable band over the adjustable shoulder strap.
- 6. Put the cushion of the shoulder pad under the shoulder straps.
- 7. Wrap the shoulder pad panels around the shoulder straps.
- 8. Firmly press the shoulder pad panels together to engage the hook and loop fastener.

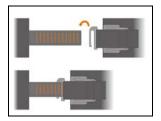


9. Repeat on the other shoulder strap.

The PODs should rest comfortably on the upper chest and back of the patient. If the garment does not rest comfortably on the chest and back, repeat the shoulder adjustments.

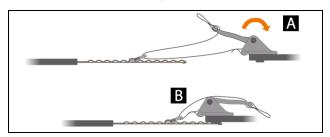
### TORSO ADJUSTMENTS

 Slide the clip into the appropriate slot to accommodate the patient's midchest measurement. See "Garment Fitting" on page 20.



### CONFIRM GARMENT SIZING ADJUSTMENTS

- 11. Put on the garment one shoulder at a time like you are putting on a backpack.
- 12. Fully zip the front zipper closure.
- 13. Close the cam buckle on both sides.
  - **To close**—hold and pull the cam buckle in the direction of the arrow (A) to close the cam buckle (B). See the image below.
  - To open—hold and pull the cam buckle in the opposite direction of the arrow to open the cam buckle.



# NOTE:

The garment should fit snug against the body but not make it difficult to breathe.

If the garment is either too tight or loose in the torso, adjust the torso band. If the PODs are not fitting comfortably against the body, adjust the shoulder straps to either be longer or shorter.

# NOTE:

First disengage the cam buckles, and then unzip the garment. Remove one shoulder at a time, like you are removing a backpack.

### SET UP THE MOBILE APP

### NOTE:

For assistance with the installation of the mobile application (app) to a device, contact Hill-Rom: in the USA, call 800-426-4224; outside of the USA, contact your distributor or local Hill-Rom representative, or go to www.respiratorycare.hill-rom.com.

- 1. From your mobile device, go to your device's app store.
- 2. In the Search box, enter "Monarch System" to find the app.
- 3. Choose to get or download the Monarch System app, and follow the guided instruction to load the free app to your mobile device.
- 4. Tap the Monarch app icon to open the app on your mobile device.



- When you first open the Monarch app, you will have two options to choose from:
  - a. I have a Monarch

or

b. Take Me to Demo Mode



6. If you choose to demo the app without connecting to a Monarch device, tap **Take Me to Demo Mode**.

# **NOTE:**

In Demo Mode, all screens are in gray to show no connectivity to a Monarch device.

If you want to connect to your Monarch device, tap I Have a Monarch.

### NOTE:

Make sure that Bluetooth® is enabled on your mobile device before you select I Have a Monarch.

8. Enter the serial number of your Monarch device. See "Device Information" on page 59 for the serial number location.



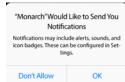
9. The Monarch app needs to have specific parameters enabled to operate successfully with different mobile devices. You will see one or two pop-up messages asking for permissions to be allowed on your mobile device. Tap **Accept** on these messages.



 If Bluetooth® is not enabled, the Monarch app will notify you. Tap **Turn** on, and follow the on-screen instructions.



11. Tap **OK** to allow Notifications.





# **CAUTION:**

The first time you launch the mobile application a Notification screen will show. Press **OK** to allow notifications.

# NOTE:

Notifications allow the Monarch app to send information to your phone (via pop-up messages) even when the app is running in the background.

# PROGRAM THE GARMENT

The pendant is used to program the garment and start the therapy.

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



### **TURN GARMENT ON**

- Slide the pendant up and away from the garment to remove the pendant from the pendant dock.
- Press and hold the **Power** button for up to 5 seconds to power the pendant. You will see the Monarch System startup screen momentarily. This screen shows the software version and the hour meter reading.



### NOTE:

The pendant screen will dim after 3 minutes if there are no user inputs when using the battery. Any button press will return the screen to 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.
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 steps. You can also set cough pauses (reminders to cough) in these therapy sessions.

## **PROGRAMING 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. You can program the Monarch™ Airway Clearance System through the pendant or a mobile device.

# **Program Manual Mode—Pendant**

 Press the **Up** or **Down** navigation buttons to select **Manual** therapy, and press the Center button to confirm selection.



2. Press the **Up** navigation button to select the manual therapy settings.



- 3. Press the **Center** button. Frequency will be selected by default.
- 4. Press the **Up** or **Down** navigation buttons to select the **frequency** value.



- 5. Press the **Right** navigation button to select **Intensity**.
- 6. Press the **Up** or **Down** navigation button to select the intensity value.



- 7. Press the **Right** navigation button to select **Duration**.
- 8. Press the **Up** or **Down** navigation buttons to select the therapy duration.
- Press the **Center** button to confirm the therapy settings.



- Press the **Back** button to return to the previous menu screen, or press the **Down** navigation button to the select **Start**.
- 11. See "Start Therapy" on page 42 to learn how to start therapy.



# **Program Manual Mode—Mobile App**

See "Set Up the Mobile App" on page 25 for steps on how to download the Monarch app.

- 1. After you turn on the Monarch garment from the pendant, open the Monarch app on your mobile device.
- 2. From the mobile device, tap **Request Control**.

## NOTE:

The Monarch app will automatically pair with the Monarch garment during the first two minutes after the Monarch garment is powered on.

After the first two minutes, the Monarch garment must be manually paired with the Monarch app by going into the pendant menu. See "Manage Bluetooth® Connections" on page 67.

 From the pendant, press the Center button to select Allow.







#### NOTE:

The pendant screen will show a message that your mobile device is controlling the Monarch garment.

4. From the mobile device, tap **Go to Therapy**.



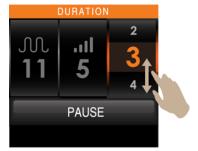
5. Tap the **Frequency** to select and change the frequency; swipe up or down until the frequency value needed is highlighted. Tap the selected number to confirm the frequency setting.



 Tap the **Intensity** to select and change the intensity; swipe up or down until the intensity value needed is highlighted. Tap the selected number to confirm the intensity setting.



7. Tap the **Duration** to select and change the duration; swipe up or down until the duration value needed is highlighted. Tap the selected number to confirm the duration setting.



8. See "Start Therapy" on page 42 to learn how to start therapy.

## **PROGRAM THERAPY MODE**

# **Program Therapy—Pendant**

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



Press the **Up** or **Down** navigation buttons to select **Therapy Settings**, and press the **Center** button.



 Select Edit Therapy 1 or Edit Therapy 2 to change a programmed therapy, and press the Center button.



**Cough Interval** will be selected by default.



- 4. Press the **Center** button to edit the Cough Interval.
- Press the **Up** or **Down** navigation buttons to increase or decrease the frequency of the cough pause.

#### NOTE:

To remove the cough pause, set the Cough Interval to zero.



- 6. Press the **Center** button to confirm the Cough Interval frequency.
- 7. Press the **Down** navigation button to select **Cough Duration**.
- 8. Press the **Center** button to edit the Cough Duration.
- 9. Press the **Up** or **Down** navigation buttons to increase or decrease the cough duration time.
- 10. Press the **Center** button to confirm the Cough Duration time.



#### NOTE:

The therapy steps are labeled by X/X meaning current step out of total steps. Example: 1/8 means it is the first step out of a total of 8 steps. The maximum number of steps allowed is 8 steps. Each therapy step can have a different Frequency, Intensity, and Duration setting.

- 11. Press the **Up** or **Down** navigation buttons to select the therapy step to edit.
- 12. Press the **Center** button to edit the selected step.
- 13. Press the **Center** button to edit the **Frequency**.
- 14. Press the **Up** or **Down** navigation buttons to select the frequency value.





- Press the **Right** navigation button to edit the **Intensity**.
- 16. Press the **Up** or **Down** navigation buttons to select the intensity value.



- 17. Press the **Right** navigation button to edit the therapy duration.
- 18. Press the **Up** or **Down** navigation buttons to select the therapy duration.



- 19. Press the **Center** button to confirm the step settings.
- 20. Press the **Down** navigation button to select the next step or Add New Step.
- 21. Repeat Step 3 through Step 20 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.

- 22. Press the **Back** button to go back to the previous screen. You will be prompted to save your settings, if any changes were made.
- 23. Select **Yes** or **No** to save the changes made to the therapy settings.



- 24. Press the **Back** button to go back to the previous screen.
- 25. See "Start Therapy" on page 42 to learn how to start therapy.

# **Program Therapy—Mobile App**

See "Set Up the Mobile App" on page 25 for steps on how to download the Monarch app.

- 1. After you turn on the Monarch from the pendant, open the Monarch app on your mobile device.
- From your mobile device, tap Request Control.

## NOTE:

The Monarch app will automatically pair with the Monarch garment during the first two minutes after the Monarch garment is powered on.

After the first two minutes, the Monarch garment must be manually paired with the Monarch app by going into the pendant menu. See "Manage Bluetooth® Connections" on page 67.

 From the pendant, press the Center button to select Allow

# Monarch Connected My Monarch Serial Not AD2172284U EQUEST Control More options





#### NOTE:

The pendant screen will show a message that your mobile device is controlling the Monarch garment.

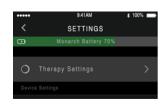
4. From your mobile device, tap **Go to Therapy**.



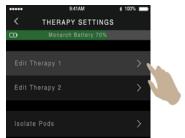
5. Tap the **Settings** icon on the top right of the app.



6. Tap Therapy Settings.



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



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



 Swipe up or down until the Cough Interval value needed is highlighted. Tap the selected number to confirm the cough interval setting.



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



 Swipe up or down until the Cough Duration needed is highlighted. Tap the selected number to confirm the cough duration setting.



all

# NOTE:

The therapy steps are labeled by X/X meaning current step out of total steps. Example: 1/8 means it is the first step out of a total of 8 steps. The maximum number of steps allowed is 8 steps. Each therapy step can have a different Frequency, Intensity, and Duration setting.

12. Tap the step you want to edit.



13. Tap the **Frequency** to select and change the frequency; swipe up or down until the frequency value needed is highlighted. Tap the selected number to confirm the frequency setting.



14. Tap the Intensity to select and change the intensity; swipe up or down until the intensity value needed is highlighted. Tap the selected number to confirm the intensity setting.



15. Tap the **Duration** to select and change the duration; swipe up or down until the duration value needed is highlighted. Tap the selected number to confirm the therapy duration setting.



#### NOTE:

The maximum number of steps is 8.

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



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



 Tap Save to save the changes, or tap Cancel to discard the changes.



19. See "Start Therapy" on page 42 to learn how to start therapy.

## START THERAPY

## **RUN MANUAL MODE THERAPY**

# **Using the Pendant**

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



## **NOTES:**

- The therapy settings can be adjusted while the therapy session is in progress.
- The timer starts from the total duration and counts down to zero.

- 2. To pause therapy, do these:
  - Select Pause, and the Center button or press the Pause/Resume control button on the garment.



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



c. If the therapy has been paused for 8 minutes, this screen will show. Use the Up and Down navigation buttons to select Stop or Resume, and press the Center button.



 d. If Stop is selected, an Incomplete Therapy screen will show. Use the Up and Down navigation buttons to select Stop or Resume, and press the Center button.



 When the therapy session is complete, the Therapy Complete screen will show. Press the Center button to return to the main screen.



#### NOTE:

The pendant screen will dim after 3 minutes of no active therapy or inputs. The system will completely shut down after 10 minutes when used with the battery pack.

# Using the Mobile App

- 1. Press and hold the power button on the pendant for 5 seconds.
- 2. From your mobile device, tap the **Monarch app** to open the app.
- 3. Tap Request Control.

#### NOTE:

The Monarch app will automatically pair with the Monarch garment during the first two minutes after the Monarch garment is powered on.

After the first two minutes, the Monarch garment must be manually paired with the Monarch app by going into the pendant menu. See "Manage Bluetooth® Connections" on page 67.



4. From the **pendant**, select **Allow**, and press the **Center** button.



5. Tap **Go to Therapy**.



6. From the mobile device, tap **Manual** on the top menu bar.



# 7. Tap Start.

## NOTE:

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



- 8. To pause therapy, do these:
  - a. Tap **Pause** during therapy.



b. Tap **Resume** to start the therapy.



c. If the therapy has been paused for 8 minutes, a pop-up screen will show to allow you to choose to Stop or Resume the therapy. Tap **Stop** or **Resume**.



d. If Stop is selected, an Incomplete Therapy screen will show. Tap **Stop** or **Resume**.



9. When the therapy session is complete, the Therapy Complete screen will show. Press **Done** to return to the Main screen.



#### NOTES:

- The Monarch™ Airway Clearance System will dim the screen after 3 minutes of no active therapy or inputs. The system will completely shut down after 10 minutes on battery power.
- If the Monarch System is powered by the AC/DC power adapter, the device will not shutdown.

## Run Program Mode—Therapy 1 and Therapy 2

# **Using the Pendant**

- 1. See "Program Therapy Mode" on page 33 to set up and save a therapy program as prescribed by a physician.
- Select Therapy 1 or Therapy 2, and press the Center button.



To start the therapy, select **Start**, and press the **Center** button.

#### Notes:

- The total therapy time shows on the pendant. The timer will countdown during the therapy session.
- The therapy settings can be adjusted while a therapy session is in progress.
- 4. To pause therapy, do these:
  - a. Select **Pause**, and press the **Center** button.





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



c. If the therapy has been paused for 8 minutes, this screen will show. Use the Up and Down navigation buttons to select Stop or Resume, and press the Center button.



 If Stop is selected, an Incomplete Therapy screen will show. Use the Up and Down navigation buttons to select Stop or Resume, and press the Center button.



 The cough timer screen will show at each cough interval. Either wait for the timer to run out of time, or select **Resume** and press the **Center** button to continue with your therapy session.



7. When the therapy is complete, the Therapy Complete screen will show. Press the **Center** button to return to the Main screen.



# **Using the Mobile App**

- 1. Press and hold the power button on the pendant for 5 seconds.
- 2. From your mobile device, tap the Monarch app to open the app.
- 3. Tap **Request Control**.

#### NOTE:

The Monarch app will automatically pair with the Monarch garment during the first two minutes after the Monarch garment is powered on.

After the first two minutes, the Monarch garment must be manually paired with the Monarch app by going into the pendant menu. See "Manage Bluetooth® Connections" on page 67.



4. From the **pendant**, select **Allow**, and press the **Center** button.



# 5. Tap **Go to Therapy**.

#### NOTE:

The pendant screen will show a message that your mobile device is controlling the Monarch garment.



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



# 7. Tap Start.

#### NOTE:

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



#### NOTE:

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

- 8. To pause the therapy, do these:
  - You can pause during the therapy by tapping Pause.



b. Tap **Resume** to start the therapy.



c. If the therapy has been paused for 8 minutes, this screen will show. Tap **Stop or Resume**.



 The cough timer screen will show at each cough interval. Either wait for the timer to run out of time, or select Resume to continue with your therapy session.



 If Stop is selected, an Incomplete Therapy screen will show. Tap Stop or Resume to continue.



11. When the therapy session is complete, the Therapy Complete screen will show. Press **Done** to return to the Main screen.



## **NOTES:**

- The Monarch™ Airway Clearance System will dim the screen after 3 minutes of no active therapy or inputs. The system will completely shut down after 10 minutes on battery power.
- If the Monarch System is powered by the AC/DC power adapter, the device will not shutdown.

## **Isolate PODS**

# **Using the Pendant**

 From the Main screen, select Menu, and press the Center button.



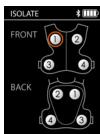
2. Select the **Therapy Settings** menu.



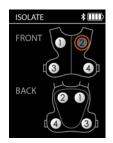
 Use the **Down** navigation button to select the ISOLATE PODS menu. Press the **Center** button to view the ISOLATE PODS screen.



4. Use the Navigation button to select different PODs. A colored circle around the POD shows which POD is selected. Select the POD that is to be turned on or off.



Press the **Center** button to turn the POD on or off



#### NOTE:

White indicates that the POD will be active. Gray indicates that the POD is off. A defective POD is shown with a red cross icon.



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

## NOTE:

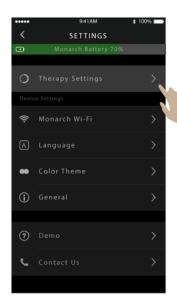
The system will not allow all PODs to be in inactive. At least one POD must be active for the Monarch System to deliver therapy.

# Using the Mobile App

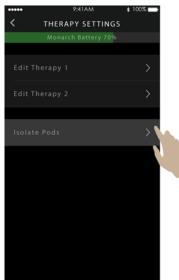
 Tap the **Settings** icon on the top right of the app.



# 2. Tap Therapy Settings.



# 3. Tap Isolate Pods.



4. Tap on the POD(s) to be turned on or off.

## NOTE:

A **green** checked POD means the POD is **active**.

A **gray** POD means the POD is **inactive**.

A **red** POD means a **defective** POD which does not function.



- 5. Swipe from right to left to see the other side of the garment.
- 6. Tap **Save**, on the top right, to save the changes or tap **Cancel**, on the top left, to discard the changes.

#### NOTE:

The system will not allow all PODs to be inactive. At least one POD must be active for the Monarch System to deliver therapy.

## **DEVICE INFORMATION**

## **USING THE PENDANT**

 From the Main screen, select Menu, and press the Center button.



2. Select the **Device Information** menu.



3. Select the **General** menu.



4. Select the **Software Information** menu.



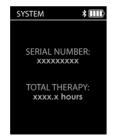
- 5. The following general information will show:
  - MCB (Master Control Board) APP Software
  - MCB BL (bootloader) Software
  - Pendant APP Software
  - Pendant Software



Press the **Back** button to return to the previous screen or select the **System Information** menu.



- 7. The following general information will show:
  - Serial Number
  - Total Therapy Hours



 Press the **Back** button to return to the previous screen, or select the **System Clock and Date** menu.



 The time and date information will show. Time is in 24 hour format. Date is in MM/DD/YYYY format.

#### NOTE:

The clock and date will be set at Hill-Rom before shipment and will show the current Coordinated Universal Time (UTC) to correctly synchronize the use data with the VisiView™ Health Portal. The time and date cannot be adjusted by the user, only viewed for confirmation of the settings.



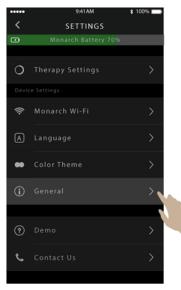
Press the **Back** button on the pendant to return to the previous screen.

## **USING THE MOBILE APP**

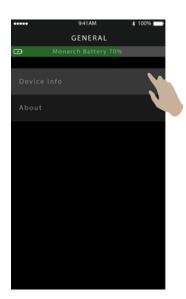
1. Tap the **Settings** icon on the top right of the app.



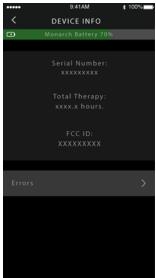
2. Tap **General**.



3. Tap Device Info.



- 4. The following information will show for Device Info:
  - Serial Number
  - Total Therapy hours for this Monarch device
  - FCC ID

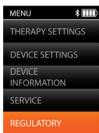


## REGULATORY

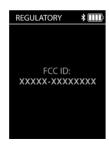
 From the Main screen, select Menu, and press the Center button.



Select the Regulatory menu, and press the Center button.



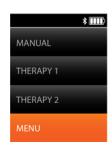
3. View the regulatory information. Press the **Back** button to return to the previous screen.



## SET THE LANGUAGE

#### USING THE PENDANT

 From the Main screen, select Menu, and press the Center button.



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



Select the Language menu, and press the Center button.



4. Use **Up** or **Down** navigation buttons to select the language you want shown on the Monarch pendant, and press the **Center** button.



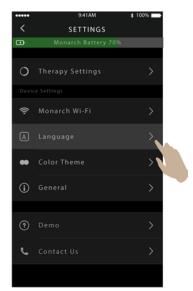
5. Press the **Back** button to return to the previous screen.

#### USING THE MOBILE APP

1. Tap the **Settings** icon on the top right of the app.



## 2. Tap Language.



 Tap the Language you want shown on the Monarch app and pendant.

#### NOTE:

A check by the language shows the active language.

 Tap Save, on the top right, to save the changes, or tap Cancel, on the top left, to discard the changes.



#### MANAGE BLUETOOTH® CONNECTIONS

## TURN BLUETOOTH® ON OR OFF

 From the Main screen, select Menu, and press the Center button.



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



Select the Wireless menu, and press the Center button.



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



#### **CONNECT DEVICE**

 Select the **Device List** menu. The Monarch System will automatically start scanning for Bluetooth® enabled devices.



 A list of Paired Devices and Other mobile devices available will show.



 Use the navigation buttons to select the mobile device to connect to from either the Paired list or Other list.



8. Press the **Center** button to confirm the mobile device selected.

#### NOTE:

If the device was previously paired, an option to Connect or Delete will show.



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



10. Once Paired, the device will show under Paired.



## **DELETE A PAIRED DEVICE**

#### NOTE:

The mobile device's Bluetooth® must be enabled in order to delete a device from the of Paired Devices on the pendant.

- 1. Do Step 1 through Step 6 of "Manage Bluetooth® Connections" on page 67.
- Select the device to delete, and press the Center button.



3. Select **Delete**, and press the **Center** button.



The device will no longer be listed under Paired Devices.



4. 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

 From the Main screen, select Menu, and press the Center button.



Select **Device Settings**, and press the **Center** button.



3. Select **Wireless**, and press the **Center** button.



 Select the WiFi feature. Use the Left and Right navigation buttons to turn on or off the WiFi feature.



Select **Network 2** for your primary WiFi connection.



- Use the navigation buttons on the pendant to select the letter or number to enter your network password. Click **SHOW TEXT** to view the password.
- Press the **Center** button to accept each character.



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



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



## LTE

 From the Main screen, select Menu, and press the Center button.



Select Device Settings, and press the Center button.



3. Select Wireless, and press the Center button.



 Select the LTE feature. Use the Left and Right navigation buttons to turn on or off the LTE feature.



The LTE Status information screen shows:

- Carrier Name
- Mobile Equipment Identifier (MEID)
- SIM card ID



## **CHANGE COLOR THEMES**

## **USING THE PENDANT**

 From the Main screen, select Menu and press the Center button.



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



Select the Color Themes menu, and press the Center button.



 Select the desired color, and press the Center button.

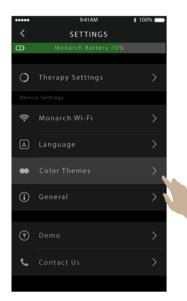


## **USING THE MOBILE APP**

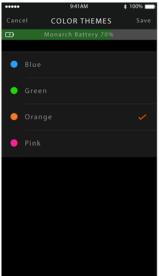
1. Tap the **Settings** icon on the top right of the app.



2. Tap Color Themes.



- 3. Tap the color you want.
- Tap **Save** to save the changes, or tap Cancel to discard the changes.



#### **CLEANING**



#### **WARNING:**

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.
- Do not expose the unit to excessive moisture.
- Use cleaning products in accordance with the manufacturer's instructions.
- 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.



## **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 to wipe clean the garment with the 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 VEST SHELL

To remove difficult spots or stains, 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 vest shell monthly or when visibly soiled.

#### NOTE:

Only the Vest Shell can be machine washed. The Shoulder Strap Pads, Backpack Cover, and POD Covers should be wiped clean with an approved cleaner

- 1. Remove the Vest Shell from the Garment.
- 2. Fasten all the hook and loop fastener 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.

## SUPPORT

## **USING THE PENDANT**

 From the Main screen, select Menu and press the Center button.



Select the **Device Information** menu, and press the **Center** button.



3. Select the **Support** menu.



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

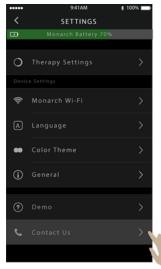


## **USING THE MOBILE APP**

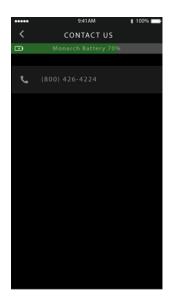
1. Tap the **Settings** icon on the top right of the app.



2. Tap Contact Us.



3. Tap the phone number to place a call.



## **ERRORS**

1. From the **Main** screen, select **Menu** and press the **Center** button.



2. Select the **Device Information** menu, and press the **Center** button.



Select Errors to review system error codes, and press the Center button.



4. Select **Reset** to remove the error information, and press the **Center** button.



5. Select **No** or **Yes** to reset the error list, and press the **Center** button.



Once **Yes** is selected, the pendant will show no errors.

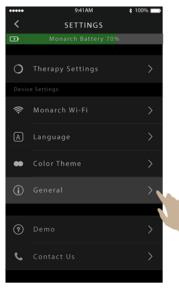


## **USING THE MOBILE APP**

1. Tap the **Settings** icon on the top right of the app.



2. Tap **General**.



3. Tap **Device Info**.



4. Tap **Errors** to view a list of errors.



5. Tap **Reset** to clear the error list.



- 6. Tap **Yes** to clear the error list.
- 7. Tap the back arrow to return to the previous screen.

## NOTE:

The reset of errors will erase the current list being shown on the pendant. The system will continue to store errors collected on the device even though they are not viewable on the pendant.

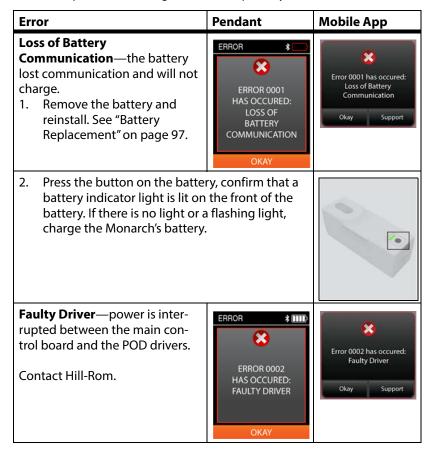


#### **CRITICAL ERRORS**

#### NOTE:

If the solution is to contact Hill-Rom or the solution provided does not resolve the error, 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.respiratorycare.hill-rom.com.



Error	Pendant	Mobile App
Loss of Communication—the pendant lost communication with the main control board.  Contact Hill-Rom.	ERROR \$ III)  ERROR 0003 HAS OCCURED: LOSS OF COMMUNICATION  OKAY	Error 0003 has occured: Loss of Communication Okay Support
Product Overheat—the temperature exceeds the garments operating temperature.  Press Okay to terminate the therapy to allow the Monarch garment to cool for 15 minutes.	ERROR \$ IIII)  ERROR 0004  HAS OCCURED: PRODUCT OVERHEAT PLEASE RUN THERAPY ONLY AFTER 15 MIN  OKAY	Error 0004 has occured: Product overheat please run device after 15min Okay

## **CAUTION ERRORS**

## NOTE:

If the solution is to contact Hill-Rom or the solution provided does not resolve the error, 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.respiratorycare.hill-rom.com

Error	Pendant	Mobile App
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 at least one of the PODs is working.	WARNING \$ IIID  FRONT POD 2 IS NOT WORKING	Front Pod 2 is not working  Okay Support
Contact Hill-Rom.	OKAY	

Error	Pendant	Mobile App
Battery under 25%—the battery charge is less than 25%. Charge the battery or use the AC/DC power adapter to plug into a wall outlet. Or, you may continue the therapy with the understanding that the battery charge may run out before the therapy set time.	YOU MAY NOT BE ABLE TO COMPLETE YOUR THERAPY  START BACK	Monarch Battery Under 25% You may not be able to complete your therapy  Back Start
<b>Low battery</b> —plug the system into power.	LOW BATTERY! PLEASE CHARGE YOUR DEVICE OKAY	Monarch Battery Low! Your therapy may get interrupted Please charge your Monarch soon Okay
<b>POD Isolation</b> —one POD must be active for therapy.	WARNING * IIID  YOU CAN NOT ISOLATE ALL THE PODS  OKAY	You cannot isolate all the pods Okay
Stuck button—make sure that a button is not accidentally being pressed during startup or for an extended period of time. Put the pendant in its holder to prevent any accidental contact.	WARNING * IIII)  STUCK BUTTON  OKAY	Not applicable

Error	Pendant	Mobile App
<b>WiFi</b> —reconnect to the WiFi communication, see "WiFi" on page 70.	WARNING \$ IIID  LOSS OF COMMUNICATION WITH WIFI MODULE  OKAY	Loss of WIFI Communication
<b>Bluetooth</b> ®—reconnect to the Bluetooth® communication, see "Manage Bluetooth® Connections" on page 67.	WARNING \$ IIID  LOSS OF COMMUNICATION WITH BLUETOOTH MODULE  OKAY	Loss of Bluetooth Communication
LTE Communication—move to a location where the LTE signal strength increases. Make sure that you have LTE access at this time and that the device is correctly configured for the LTE.	WARNING * III)  LOSS OF COMMUNICATION WITH LITE MODULE  OKAY	Loss of LTE Communication
1. Remove the battery, and then install the battery. See "Battery Replacement" on page 97.	WARNING \$ IIID  LOSS OF BATTERY COMMUNICATION  OKAY	Loss of Battery Communication

Error	Pendant	Mobile App
2. Press the button on the batter battery indicator light is lit on battery. If there is no light or a plug the unit into power.		
<b>Data storage</b> —contact Hill-Rom.	WARNING * IIII)  DATA STORAGE CORRUPTION  OKAY	Data storage Corruption  Okay
Unauthorized USB—remove the unauthorized USB device from Monarch device.	WARNING \$ IIID  UNAUTHORIZED USB DEVICE DETECTED  OKAY	Unauthorized USD device detected Okay
<b>Maximum Therapy</b> —sixty minutes is the maximum therapy time allowed per therapy session.	WARNING * IIID  YOU CAN ONLY SET THE MAXIMUM THERAPY OF 60 MINS  OKAY	You can only set the maximum therapy of 60 mins

#### **Pendant Error** Mobile App WIFI Router—check the router WARNING \* ..... cables and reconnect with the WIFI router, see "WiFi" on page 70. Monarch is unable to MONARCH connect to WIFI router IS UNABLE TO CONNECT TO Okay WIFI ROUTER

#### **SERVICE**

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 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.



#### **WARNING:**

Only authorized person should service the Monarch™ Airway Clearance System. Service by unauthorized persons 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.respiratorycare.hill-rom.com.

#### **EXPECTED LIFE**

The expected service life for the Monarch 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 Monarch garment.

#### NOTE:

For proper disposal, make sure to follow your local, state, or country electronic and battery regulations to safely discard or recycle the 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 The serial number can be found via the pendant (see "Device Information" on page 59), or the serial number can be found on the product identification label. The product identification label is under the backpack cover just over the battery compartment.

#### NOTE:

The serial number of the Monarch™ Airway Clearance System may be found on the inside of the front cover of this User Manual. If the serial number is not there, the user can record it there for easy reference.

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 persons should service the Monarch™ Airway Clearance System, Model 1000. Service by unauthorized persons 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**

- Make sure the DC connector from the AC/DC power adapter is securely plugged into the charging port on the bottom of the Monarch™ garment. Make sure the battery is fully charged and is properly seated in 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) DOES NOT ACTIVATE**

- Use the pendant to get to the Isolate PODS screen (see "Isolate PODS" on page 56). 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 the fit of garment, refer to "Garment Fitting" on page 20.

#### STORAGE AND HANDLING

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

- 1. Place the garment in the carry case.
- Insert the AC/DC power adapter, power cord, battery, and other accessories into the compartments above the garment in the carry case.
- 3. Close the carry case to secure the garment inside.

## SHIPPING THE UNIT



#### **WARNING:**

To help prevent injury and/or equipment damage, obey these:

- Do not ship the battery with over a 30% charge.
- Do not store the battery at temperatures above 140°F (60°C), such as inside of a car on a hot day or in direct sunlight.



#### **CAUTION:**

If shipping is required, the original packing material provides the best protection for The Monarch™ Airway Clearance System. Retain the original packing 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	Shoulder pads
	195499	Back cover
	198221	POD cover
	M07774	POD cover (set of 4)
	198457S	Pendant clip
	198413S	Panel hinge kit

Symbol	Part Number	Description
	198683	Washable vest shell, orange
	198684	Washable vest shell, blue
	198685	Washable vest shell, green
	198686	Washable vest shell, pink
	198687	Washable vest shell, red
~	198678	Battery access panel, green
	198679	Battery access panel, red
	198680	Battery access panel, pink
	198681	Battery access panel, blue
MA.	198682	Battery access panel, orange
	194566S	Battery
	198656	Carry case
	195500	AC/DC power adapter

Symbol	Part Number	Description
	M07437	Power cord, NA_Canada (NEMA1-15P)

#### **BATTERY REPLACEMENT**

## **NOTES:**

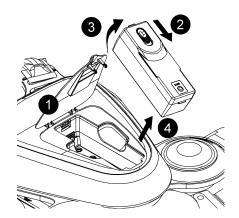
- Consult your local regulations to safely discard or recycle the battery.
- Do not return the battery unless specifically requested by customer service.
- Remove the battery before you return the main garment for repairs.



## **WARNING:**

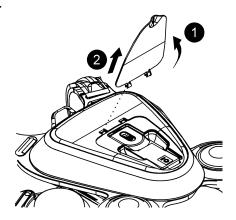
Do not ship the battery with over a 30% charge or injury and/or equipment damage may occur.

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



## **BATTERY ACCESS PANEL REPLACEMENT**

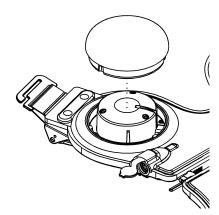
- 1. Lift the battery access panel.
- Hold the battery access panel close to the hinges, and slowly pull the access panel away from the backpack to remove the hinges from the backpack.
- Hold the new battery access panel with the logo facing away from the backpack.
- Insert the left hinge of the access panel on to the backpack until it clicks, and then insert the right hinge until it clicks.



5. Press on the access panel until it clicks closed.

### **POD COVER REPLACEMENT**

- Lay the garment on a flat surface.
- Unzip the garment, and open it so that you can get access to the inside of it.
- From the inside of the garment, hold the POD cover with one hand, and gently squeeze the cover while you pull it straight away from the garment to remove the cover.



- 4. Hold the new POD cover so that the larger recess in the inner cover aligns with its mate on the internal ring of the POD. The three outer recesses should align with their respective screws.
- 5. Press the POD cover gently into the POD ring and over the POD. Press the cover fully in position such that all sides of the cover touch the garment.

#### SHOULDER PAD REPLACEMENT

- Disengage the shoulder pad's hook and loop fastener, and then remove the pad from the garment.
- Put the new pad into position on the garment, and firmly press the shoulder pad together to engage the hook and loop fastener.



## **BACKPACK ELASTIC COVER REPLACEMENT**

- 1. Lay the garment on a flat surface.
- Remove the battery access panel. See "Battery Access Panel Replacement" on page 98.
- 3. Start at the bottom of the backpack, and lift the elastic skirt out from under the edge of the backpack.
  - Continue up both sides of the backpack elastic cover to fully remove it from the backpack.



4. Align the new cover with the backpack, and then do the removal procedure in reverse order. Make sure that the stretchable skirt is secured completely around the edge of the backpack.

## **VFST SHELL REPLACEMENT**

See "Attaching the Vest Shell" on page 19.

## **AC/DC POWER ADAPTER**

Only use a Hill-Rom approved Monarch  $^{\mathsf{m}}$  power adapter as the AC/DC adapter.



### **SPECIFICATIONS**

Feature	Dimension
Monarch™ weight (with battery)	13.2 lb (6 kg)
Size guide	Fits mid chest circumference of 22" to 50" (55.9 cm to 127 cm)
Base garment	EVA foam
Garment shell	Polyester
Electrical Requirements	Nominal voltage: 24 V 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: 2700 mAh
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)	
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 a secondary control for the device. The Monarch™ Airway Clearance System also features an optional WiFi module to export device use data in home care environments.

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

Feature	Dimension	
LTE 4G (Optional Configuration	ion)	
Technology	FDD-LTE 3G PP Rel. 9+	
LTE Band Designation	Band 4, 13	
Power Class	3	
Transmit Power	23 dBm typical	
Receive Sensitivity	Min -93 dBm	
Data Rates	DL 10Mbps, UL 5Mbps	
Antenna	Internal/built-in	
Cat	1	
IP Services	TCP	

### **Classification and Standards**

	ı		
Technical and Quality Assur-	ANSI/AAMI ES60601-1		
ance	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	Class II (double insulation)		
Electric Shock			
Classification According to Directive 93/42/EEC: Ila			
Degree of Protection Against Ingress of Water: IP42			
Maximum Sound Pressure	65 dBA		
Level			
<b>Not</b> 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.

#### **Electromagnetic Compatibility Guidance**

The Monarch™ Airway Clearance System is suitable for the electromagnetic environment settings specified in the tables that follow.



#### 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-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctua- tions/ 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 Dis- charge	± 8kV Contact Discharge ± 15kV Air Dis- charge	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 health- care 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 environ- ment.
Voltage Dips, Short Interrup- tions, and Volt- age Variations On Power Sup- ply 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; 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°	Mains power quality should be of a typical home healthcare environment. If the user of the Monarch™ Airway Clearance System requires continued operation it is recommended that the Monarch™ Airway Clearance System uninterruptedly power supply or a battery.
	0% UT; 250/300 cycle	0% UT; 250/300 cycle	

# **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
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 health- care environment.

Note: U<sub>T</sub> 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
			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.
			Recommended separation distance:
Conducted RF IEC 61000- 4-6	3 V/m 150 kHz to 80 MHz	3 V/m	$d = 1.2 \sqrt{P}$

### **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	
Radiated RF IEC 61000- 4-3	10 V/m 80 MHz to 2.7 GHz	3 V/m	80 MHz to 800 MHz $d = 1.2 \ \sqrt{P}$	
			800 MHz to 2.7 GHz $d = 2.33\sqrt{P}$	
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation in meters (m).	
			Field strengths from fixed RF transmit- ters, as determined by an electromag- netic site survey, should be less than the compliance level in each frequency range.	
			Interference may occur in the vicinity of equipment marked with the following symbol.	
			$((\overset{\bullet}{\blacktriangle}))$	

Note 1: At 80 MHZ and 800 MHz, the higher the 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 PMACS1 is used exceeds the applicable RF compliance level above, the PMACS1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PMACS1.

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 Systemprevent 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 80 MHz to 800 800 MHz to 2.7 GHz 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  $\mathbf{d}$  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.

Specifications

### **NOTES:**

# Hill-Rom.