Koya™

Dayspring™

Upper Extremity

Directions for Use

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Getting Started with Dayspring™

Read this entire guide before using your device.

The Dayspring wearable compression system is designed for the treatment of lymphedema, chronic edema and venous insufficiency. The system can be used in a home or clinic setting and is designed to allow you to be mobile during treatment.

The optional Koya app allows you to work with your provider to individualize your treatment settings and track your usage.

Contact Koya Medical

- By Phone: **+1-415-209-5035**
  Monday – Friday between 8 am - 6 pm PST
- By Email: **support@koyamedical.com**

Indications for Use

U.S. Federal Law restricts this device to sale by or on the order of a licensed healthcare professional.

Please read the instructions for use before using the device.

Consult your physician or healthcare provider for recommendations regarding your therapy, treatment duration and frequency. Use this product only in the manner consistent with directions provided.

The Dayspring system is a prescription-only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision for the treatment of the following:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time

The Dayspring system is developed on a wearable compression technology platform, which is designed to provide mobility to the user.

Contraindications and Warnings

The Dayspring system should not be used if you have one or more of the following conditions:

- Pulmonary edema
- Thrombophlebitis
- Congestive heart failure
- Deep vein thrombosis
- Episodes of pulmonary embolism
- Infections and inflammations
- Acute cancer
- Uncontrolled systemic disease
- Conditions in which increased venous and lymphatic return is undesirable

⚠ WARNING: Risk of Electric Shock

- Do not attempt to open, tamper, disassemble, or service the device. Such attempts could result in damage to the product.
- Do not touch metal contacts on the connectors.
- Do not use the device near water, while bathing or in wet environment.
- Unplug the charger when not in use.

WARNING: Risk of Personal Injury

- Always use the provided Liner when using this device.
- Only apply the device in a manner consistent with the directions in this document.
- Do not use the device while driving, operating machinery, or during any activity which may put the device user at undue risk of injury.
- Persistent use of the device in the presence of skin irritation may cause injury.
- Keep all components away from wet and hot surfaces.
- Strangulation hazard: Cables should never be placed near or around children or around a person's neck.
- Do not use the device if it is not working properly, if it is damaged, or dropped in water.
- Do not place device within reach of children.
- Do not use the device outside of the specified temperature, humidity and atmospheric pressure ranges.

CAUTION: Risk of Device Damage

- Do not attempt to bend your elbow more than 20 degrees when wearing the device.
- Do not use devices that can generate high heat such as irons or blow dryers near the Dayspring system.
- Do not attempt to wash the Dayspring garment.
- Do not place objects more than 5 pounds on the carrying case.

Introduction

Dayspring is a programmable, calibrated, wearable active compression system designed to stimulate the body's lymphatic system and provide you with mobility and portability while helping you manage your chronic condition.

The system is comprised of a Controller and a segmented Garment with multiple, programmable compression segments. When properly used, the Dayspring system creates a calibrated pressure gradient and compresses sequentially in a wrist to shoulder (distal to proximal) direction to help you move and drain excess lymph fluid.

Your Dayspring system comes with the following:

- One Directions for Use
- One Quick Start Guide
- One Programmable Controller
- One Segmented Garment, sized to measure
- Accessories (two Gauntlets, two Liners, and one Charging Cable)
- An optional Koya app, which can be downloaded from the Apple App Store or Google Play Store
- One Carrying Case

For the most up to date directions for use, visit **www.koyamedical.com/dayspring-directions**

Setup

Charging the Controller

1. Before using the system for the first time, fully charge the Controller. A full charge takes approximately three hours. The battery indicator light on the Controller will flash orange when charging and turn green when fully charged.

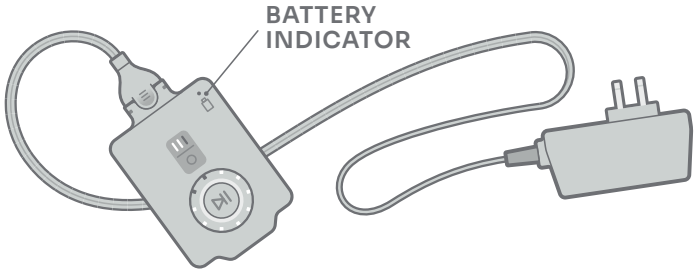


Figure 1. Controller with the Charging Cable.

Note: The Controller will be in a deep sleep mode and you must charge it prior to first use.

Wearing the Liner and Gauntlet

2. Slide your arm through the Liner and pull it up towards your shoulder to make sure it's completely unwrapped and smooth. Next, put on the Gauntlet as shown below.

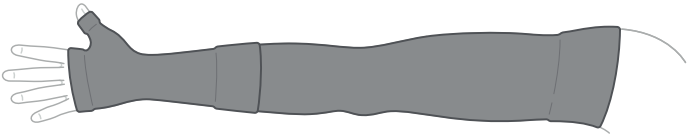


Figure 2. Gauntlet and Liner worn on the hand and arm.

Donning the Garment

3. Use the adjustable straps to form a loose cone shape. Make sure the smaller wrist end of the cone is facing away from you. Slide your arm through the cone. The Garment should cover your arm completely. Adjust the straps to ensure a snug, tight but comfortable fit from the wrist up to the arm. Make sure there are no major gaps in the garment and adjust as necessary. Depending on your specific garment size you may have up to 7 straps.

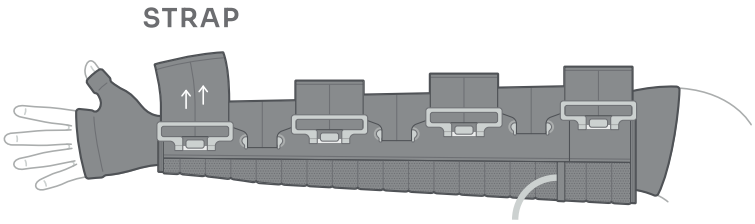


Figure 3. Adjust straps to ensure a snug fit.

Connecting the Garment to Controller

4. Connect the Garment to the Controller as shown below.

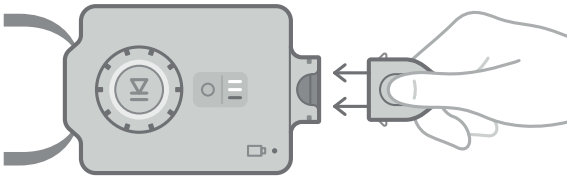


Figure 4. Connecting Garment to Controller.

Treatment

Selecting Treatment Pressure

5. Press the intensity button underneath the pressure bars to toggle between pre-programmed treatment pressure settings. A single lit bar indicates low pressure, a double bar indicates medium pressure (default), and a triple bar indicates high pressure.

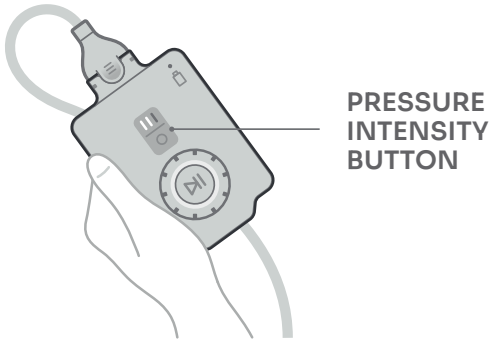


Figure 5. Toggle between pressure settings with intensity button.

Starting Treatment

6. Press the play/pause button once to start treatment. An illuminated light ring will appear - indicating that the treatment has started and is delivering active compression therapy. Each session is automatically set to stop after sixty (60) minutes. The light ring will count down to reflect how much time is remaining.

Figure 6. Press play/pause button to start treatment.

At the start of each session, there is a preparation phase so your limb is ready to receive treatment. This option is turned on by default. Use the Koya app to toggle this option.

Pausing and Resuming Treatment

When a treatment session is active, press the play/pause button to pause the treatment at any time. While treatment is paused, treatment pressure settings can be changed by pressing the intensity button. Press play/pause again to resume treatment.

The system will remain paused for a maximum of ten (10) minutes before turning the system off.

Note: Perform the treatment for at least sixty (60) minutes a day or as prescribed by your healthcare provider.

Completing Treatment

Each session will automatically end after sixty (60) minutes. Towards the end of treatment the Controller will vibrate to indicate five (5) minutes remain. To manually end treatment, at any time, press and hold the play/pause button for three (3) seconds.

Once complete, disconnect the Controller from the Garment. To remove the Garment, loosen all straps and slide the Garment off your arm. You can also detach the fastners to help remove the Garment if needed.

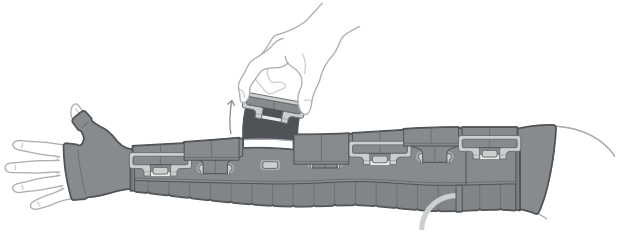
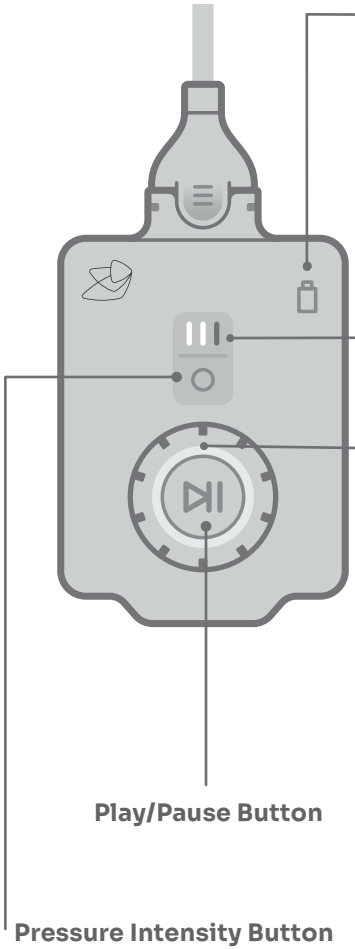


Figure 7. If needed, detach fasteners to remove Garment.

Finish the doffing process by removing the Gauntlet and Liner. Charge the Controller as needed. When not in use, store components of the Dayspring system in the provided carrying case.

Custom Treatment Option and Controller Indicators Summary



Play/Pause Button

Pressure Intensity Button

Battery Indicator

- Green: Fully charged
- Orange: Low battery
- Flashing Orange: Charging or critical low battery

Pressure Intensity Bars

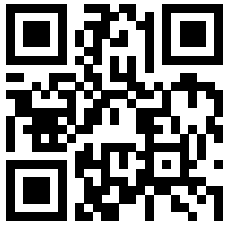
- 1 Bar: Low Pressure
- 2 Bars: Medium Pressure
- 3 Bars: High Pressure
- Middle Bar Only: Custom settings activated through Koya App*

Status Indicator

- Light ring counts down the time remaining in treatment
- Light ring flashes when treatment is paused
- Single blue light means Dayspring is ready to pair to the Koya App via Bluetooth
- Single flashing orange light appears when the Garment is not connected
- Single flashing red light appears when there's a system error (See Troubleshooting)

*To reset pressure settings if custom pressure settings are used, hold the pressure intensity button for two (2) seconds until the middle light bar disappears, or you can turn off the custom pressure settings using the Koya App.

Koya App



The Koya App delivers a personalized experience that lets you and your clinician customize your Dayspring system's pressure settings, check your battery life, review your treatment progress, and ensure that your Dayspring device's firmware is always up to date. The app can be downloaded from the Apple App Store or Google Play Store, or by scanning this QR Code.

Connecting to App

To connect the Dayspring system to the Koya App, turn on Bluetooth and WiFi connectivity on your mobile device. Press and hold the intensity button on the Controller until a blue light appears. Once the blue light appears, open the Koya App and follow the prompts on the screen.

Connected Features

The Koya App is the ideal companion to help you customize your treatment and stay current with the latest device updates.

- Customize pressure settings
- Start, pause and stop treatment
- Track session duration
- View treatment history and your own usage patterns
- Check battery life
- Update to the latest firmware

Updating Firmware

The Koya app also allows you to have the latest firmware on your device so you can ensure the Dayspring system is always up to date. To update the system's firmware, launch the Koya app and tap on the menu button located on the top right of the treatment screen. From the main menu, select "Support", tap "Firmware" and "Update".

Cleaning & Care

Before cleaning, ensure the Controller is turned off and disconnected from the Garment and Charging Cable. To clean, wipe the Controller and Garment with a clean damp cloth or an alcohol wipe.

After cleaning, visually check neither component is soiled or damaged. Allow the surfaces to fully dry before starting treatment. Repeat cleaning steps as necessary.

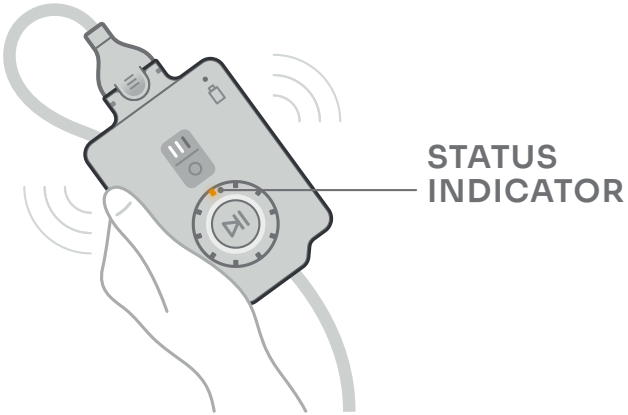
Hand or machine wash the Liner and Gauntlet with like colors. Only use warm water and mild detergent. Lay flat to dry. Do not wring, iron, dry clean or bleach. Clean them at least once a week, or as needed.

Handle the Dayspring system with care. When not in use, store components of the Dayspring system in the provided carrying case. Store the system in a clean, cool, and dry location. Avoid exposure to extreme temperatures and humidity.

Troubleshooting

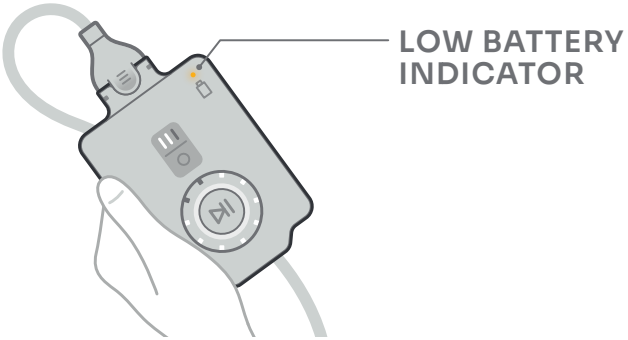
Garment Not Detected:

If you attempt to start treatment but the Garment is not properly attached to the Controller, the status indicator light will flash orange and the Controller will vibrate. Ensure the Garment is properly attached to the Controller prior to starting treatment.



Low Battery:

If the battery level becomes low during treatment, the battery indicator light on the Controller will turn orange. After treatment has ended make sure to fully charge the Controller.

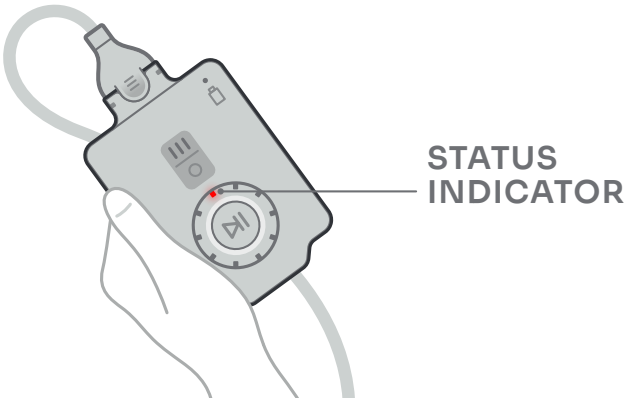


Critical Low Battery:

If the battery level is critically low, the battery indicator light will flash orange and the Controller will vibrate if you attempt to use it. Connect the Controller to the Charging Cable and recharge the battery to full before using the device again.

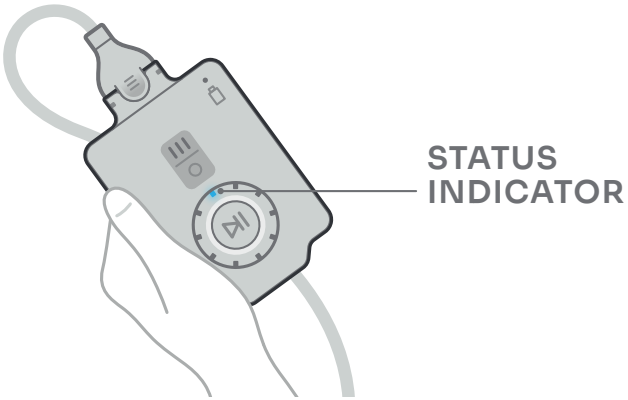
System Error:

If the status indicator light flashes red, please contact Koya Medical for assistance.



Bluetooth:

If you are having difficulty with the Bluetooth connection between your smartphone and the Controller, reset the connection by going to the Bluetooth settings on your phone and tapping “Forget” the Koya device. Press and hold the intensity button on the Controller for two (2) seconds until a blue light appears on the status indicator. Once the blue light appears, open the Koya app and follow the prompts on the screen.



Expected Service Life

The Dayspring system has an operational life of three (3) years.

Potential Complications & Adverse Events

If you experience any pain or adverse reactions from using Dayspring, stop using the device and consult with your healthcare provider immediately. For other questions or concerns about the Dayspring system or to contact the manufacturer, Koya Medical.

Please call:
+1-415-209-5035
Monday – Friday between 8 am - 6 pm PST

Send an email to:
support@koyamedical.com

Product Registration

Register your product to receive up to date information on your system.
Visit **www.koyamedical.com/register**

Warranty Information

Koya Medical warrants to the original purchaser of the Dayspring device that your device is free from defects in materials and workmanship for one (1) year from the date of original purchase. This warranty extends to only the original purchaser and is not transferable. Keep your invoice or receipt safe as this is your proof of purchase and the date marked on it shall be deemed the date of purchase. If during this one (1) year period, the Dayspring device does not function properly because of a defect in materials or workmanship, Koya will repair or replace it with a new device or equivalent product free of charge. The warranty of the replacement Dayspring device will expire on the date of the original warranty expiration. The purchaser's exclusive remedy with respect to the Dayspring device shall be replacement. This warranty covers the original purchaser and cannot be transferred with sale or other transfer of the Dayspring device to any other person or entity.

EXCLUSIONS
This warranty does not apply if the Dayspring device has been:

- Changed or modified by any person or entity other than Koya Medical.
- Serviced or repaired by any person or entity other than Koya Medical.

- Damaged by an act of God, external causes, misuse, abuse, negligence, accident, wear and tear, unreasonable use, use not in accordance with product instructions, failure to perform required maintenance, involvement of parts or components not supplied by Koya Medical or by other causes unrelated to defective materials or workmanship.

No Other Warranty

Unless modified in writing and signed by both parties, this warranty is understood to be the complete and exclusive agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this agreement. No employee of Koya Medical or any other party is authorized to make any warranty in addition to those made in this warranty.

FCC Compliance

This device contains FCC ID: 2AA9B10. This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can

radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Bluetooth® Trademark

The Bluetooth word, mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Koya Medical is under license. Other trademarks and trade names are those of respective owners.

Technical Information

Charging Cable	Input	Voltage 90 ~ 264 VAC Current: 800mA Frequency: 50/60Hz
	Output	Voltage 18.0 VDC Current: 2000mA
Controller	Input	Voltage 18.0 VDC Current: 2000mA
	Output	Voltage 25.0 VDC Current: 3000mA

Additional Technical Information

Garment Material:
Polyester/Spandex blend

Operating Temperature:
5 °C to 30 °C
41°F to 86 °F

Transport & Storage Temperature:
-20 °C to 60 °C
-4 °F to 186 °F

Relative Humidity:
15% to 95%

Atmospheric Pressure:
70 to 106 kPa

Protection Against Fluid Ingress
IP22

Applied Part
B

Manufacturer Information:
Koya Medical
2461 Peralta Street
Oakland, CA 94607
+1-415-209-5035

support@koyamedical.com

EMC Safety Information

Electromagnetic Compatibility

The Dayspring system has been tested for immunity to electrostatic discharge, radio frequency interference, proximity RF fields from wireless equipment, and power frequency magnetic fields as specified in the table below. Emissions of energy are not likely to cause interference with nearby electrical equipment.

Guidance and Manufacturer's Declaration – Emissions Medical Equipment and Medical Systems

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

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Dayspring System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Dayspring System is suitable for use in all establishments, including domestic establishments and those 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 fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Emissions Medical Equipment and Medical Systems

The Dayspring System contains a fully certified Bluetooth transmitter module. This device complies with Part 15 of the FCC Rules. Operation of the Bluetooth transceiver is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received.

Specification	Description
Standard	Bluetooth® 5 LE
ISM Frequency Band	2.360 – 2.500 GHz
Channels	0-39
Transmit Power	Bluetooth® 5 LE
Modulation Method	+4 dBm
Max Data Rate	2 Mbps

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Immunity Test
ESD IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV I/Os	± 2 kV Mains ± 1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV Mains ± 2 kV Common	± 1 kV Mains ± 2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropouts IEC 61000-4-11	> 95% Dip for 0.5 cycle > 95% Dip for 0.5 cycle 30% Dip for 25 cycle > 95% Dip for 300 cycles	> 95% Dip for 0.5 cycle > 95% Dip for 0.5 cycle 30% Dip for 25 cycle > 95% Dip for 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dayspring System requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency 50/60 Hz 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 commercial or hospital environment.
Conducted RF IEC 61000-4-6	3V 0.15 MHz-80MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	3V 0.15 MHz-80MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	Home Healthcare Environment Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	

Label Symbols

	Caution
	Do not use if damaged.
	Type B Applied Part
	Serial Number
	Important information is found in instructions.
	Indicates the temperature limits to which the medical device can be safely exposed.
IP22	Controller and garment are protected against solid foreign objects greater than 12.5 mm. Protection against vertically falling water drops when enclosure tilted up to 15°.
	Do not wash.
	Do not tumble dry.
	Name of Manufacture
	Date of Manufacture (YYYY-MM-DD)
	Catalogue Number
	Lot Number
	Indicates the humidity limits to which the medical device can be safely exposed.
	Product not to be disposed of in normal waste stream.
	Federal law restricts this device to sale by or on the order of a healthcare provider or properly licensed practitioner.
	Bluetooth trademark
	Do not iron.
	Nonionizing electromagnetic radiation
	Do not dry clean.

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