


Smart Check[®]

Cushion Monitoring Device

Operation Manual



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Warning

Indicates that not following the specified procedure could lead to potentially hazardous conditions resulting in serious injury.

Caution

Indicates that not following the specified procedure could lead to potentially hazardous conditions resulting in minor to moderate injury or damage to the equipment or other property.

















Incident Reporting

In the event of a serious incident or injury, contact Customer Support.

Contents

Intended Use	2
Important Safety Information	
Parts Detail	3
Specifications	
Overview	
Smart Setup Instructions	4
Check Instructions	5
Disconnection, Storage and Transport	
Optional Setup Instructions	6
Hand Check Guide	7
Hard Reset Instructions	
Troubleshooting	
Cleaning and Disinfecting	8
Maintenance	
Disposal and Recycling	
Electromagnetic Compatibility (EMC)	9
Limited Warranty	
Español	10
Français	19
Português	28

Symbols Glossary

	Manufacturer		Medical Device		Model number
	Date of manufacture		Serial number		Quantity
	Consult instructions for use	IP54	Ingress Protection: Dust and Splashing Water		Atmospheric Pressure Limitation
	IEC 60601-1: Type BF Applied Part		Keep dry.		Humidity Limitation (relative, non-condensing)
	Do not discard in household trash.		User identification		Temperature Limit
	Low battery: amber light		Choking hazard		

Please Note

Supplier: This manual must be given to the user of this product.

Operator (Individual or Caregiver): Before using this product, read the instructions and save for future reference.

Products may be covered by one or more U.S. and foreign patents and trademarks, including Hybrid Elite®, ROHO®, Sensor Ready®, shape fitting technology®, Smart Check® and SR™.

Product information is changed as needed; current product information is available at permobil.com. Contact Customer Support for previous versions of product information.

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Intended Use

Smart Check Cushion Monitoring Device (Smart Check) is a cushion feedback system that is intended to assist the user by saving an inflation range during cushion setup. During subsequent inflation level checks, Smart Check is intended to indicate whether adjustments are needed to remain in the saved range.

Smart Check must be connected to a ROHO Single Compartment Cushion with Sensor Ready Technology (Sensor Ready Cushion) or a ROHO Hybrid Elite SR Cushion (Hybrid Elite SR).



A clinician who is experienced in seating and positioning should determine whether the product is appropriate for the individual's particular seating needs. The product's intended use statement alone should not be relied upon to make that determination.

The medical products featured in this document are intended to be only one part of an overall care regimen that includes all seating and mobility equipment and therapeutic interventions. A clinician who is experienced in seating and positioning should identify this care regimen after evaluating the individual's physical needs and overall medical condition.


A clinician should also evaluate for visual, reading, and cognitive impairment to determine the need for caregiver assistance or the need for other assistive technology, such as large-print instructions, to ensure proper product use.

Read this instruction manual carefully and completely before using the product, to ensure proper use of this device.

Important Safety Information

Warnings:

- All aspects of Smart Check use described in this manual can be performed by the individual or by a caregiver. If you are unable to perform any tasks described in this manual, seek assistance.
- Use of this device does not eliminate routine inspection of the product and all normal activities associated with skin and soft tissue protection (weight shifts, skin inspection, overall skin care, etc.)
- DO NOT use a cushion, cover, or hand pump other than those compatible with Smart Check (see "Product Specifications"). Use of a non-compatible cushion or cover may interfere with the accuracy of Smart Check functions and reduce or eliminate the benefits of the cushion, increasing the risk to skin and other soft tissue. Using a cushion that is not compatible may also result in damage to Smart Check and will void the warranty.
- DO NOT use an underinflated or overinflated cushion because 1) the product benefits will be reduced or eliminated, resulting in an increased risk to skin and other soft tissue, and 2) the individual may become unstable and vulnerable to falling. Carefully follow all instructions, including those provided with the cushion. If the cushion does not appear to be holding air, or if you are not able to inflate or deflate the cushion, see "Troubleshooting" in the manual provided with the cushion. Immediately contact the equipment provider, distributor or Customer Support if the problem persists.
- Check inflation frequently, at least once a day, using the Smart Check or a hand check.
- Confirm that Smart Check is not pressing against your body.
- DO NOT modify Smart Check or any component. Doing so may result in damage to the product and will void the warranty.
- The cushion MUST be properly sized to the user. IF IT IS NOT, Smart Check may not find the individual's inflation range during Smart Setup, reducing or eliminating the benefits of the cushion and increasing the risk to skin and other soft tissue.
- If your cushion feels unstable during Smart Setup, perform a Hard Reset and then repeat Smart Setup. If you still feel unstable, perform an Optional Setup and consult with a healthcare provider.

 **Warning:** KEEP BATTERIES OUT OF REACH OF CHILDREN AND ANY INDIVIDUALS WHO HAVE A TENDENCY TO PLACE INEDIBLE OBJECTS IN THEIR MOUTHS. Swallowing or inhalation may lead to serious injury or death. IMMEDIATELY seek emergency medical assistance.

Warnings:

- Set up your cushion in the usual environmental conditions. Perform Check when environmental conditions, including temperature and altitude, change significantly.
- DO NOT use in the presence of flammable anesthetics and/or in an oxygen-rich environment. Doing so will increase the risk of fire or explosion.
- BURN HAZARD: If ambient temperature exceeds 47°C (117°F), DO NOT maintain contact with product surface for more than ten (10) minutes. DO NOT expose the product to high heat, open flames, or hot ashes. Testing or certification claims, including for flammability, may no longer apply to this device when it is combined with other products or materials. Check testing and certification claims for all products used in combination with this device.
- USE CAUTION when in presence of children to avoid a strangulation hazard. Detach Smart Check when not in use and store in a safe and accessible location.

Cautions:

- Daily: Inspect Smart Check quick disconnect, tubing, and device housing for wear or breakage, and to ensure inter-component attachment. DO NOT continue to use Smart Check if any part is damaged or cannot be attached securely. Periodically, Smart Check should be inspected by a qualified technician.
- DO NOT submerge Smart Check in liquid, as it will damage the device.
- Protect Smart Check from blunt force shocks that may cause damage and/or breakage.
- DO NOT use the inflation valve, quick disconnect, or any Smart Check component as a handle for carrying or for pulling the cushion.
- Prolonged exposure to ozone may degrade some of the materials used in the manufacture of this product, affect the performance of this product, and void the product warranty.
- Prolonged exposure to UV light / sunlight may cause product labels to fade.



Parts Detail

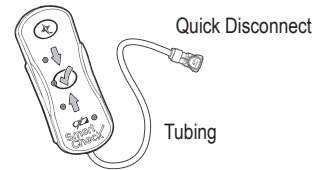
Package Contents: Smart Check, storage case, operation manual, limited warranty supplement

To order replacement parts, contact the equipment provider or Customer Support.

*Refer to instructions for faceplate details.

 Refer also to the instructions provided with the cushion.

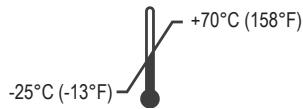
Smart Check Faceplate*



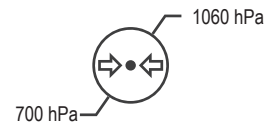
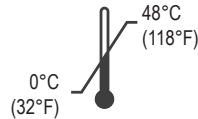
Storage Case

Specifications

Storage Conditions



Operating Conditions



Altitude Limitation (above sea level): Lower -410 m (-1,350 ft.) ; Upper 3185 m (10,450 ft)

Materials:

Smart Check: polycarbonate with polyester faceplate; Storage Case: polystyrene; Tubing: polyurethane; Quick Disconnect: acetal

Expected Service Life: 5 years

Batteries: one (1) year typical operating time

This product complies with RoHS2.

Smart Check is a type BF Applied Part. Smart Check has been tested and complies with IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11; certified to CAN/CSA Standard C22.2 No. 60601-1. Electromagnetic interference is not caused by Smart Check and does not interfere with Smart Check.

Smart Check is an IP54-rated device (protected from dust and splashing water).

Products and Accessories

Compatible with Smart Check:

Note: Not available in all markets. Contact Customer Support.

ROHO Covers: Standard, Heavy Duty and Hybrid Elite

ROHO Cushions: Sensor Ready and Hybrid Elite SR

ROHO Hand Pump

Overview

This page explains how to use Smart Check to find, save, and check your cushion inflation setting. Read this overview and all instructions before using Smart Check.

Warnings:

- Perform Setup (either Smart Setup or Optional Setup) when using Smart Check for the first time.
- Perform Smart Setup or Optional Setup again if the following changes occur: 1) a different individual is using Smart Check; 2) a different chair or a different cushion is being used; or 3) the individual experiences physiological changes (for example, weight loss or weight gain).

Proper Cushion Inflation Setting:

- sink down into the cushion and
- "float" above the cushion base.



Smart Setup:

To use Smart Check to perform a Smart Setup: First, follow the "Smart Setup Instructions": Smart Check will find and save your cushion inflation setting for you. Then, follow the "Check Instructions": when you press the Check Button, Smart Check will tell you if you need to adjust your cushion.

Optional Setup:

Optional Setup is an alternative to Smart Setup. Optional Setup may be preferred in the following situations:

- A qualified seating specialist has determined an alternate immersion and envelopment level for the individual.
- The individual must accommodate needs (such as severe asymmetrical posture) that are beyond the immersion and envelopment setting found by Smart Check during Smart Setup.
- The cushion is being used on an upholstered surface (such as a Captain's Seat).

To use Smart Check to perform the Optional Setup: First, find your preferred cushion inflation setting without using Smart Check; follow the instructions provided with the cushion. Then, follow the "Optional Setup Instructions" in this manual, using Smart Check to save your inflation setting. Finally, follow the "Check Instructions" in this manual. When you press the Check Button, Smart Check will tell you if you need to adjust your cushion.

Smart Setup Instructions

Smart Check will find and save the inflation setting for you, on your cushion, in your chair.

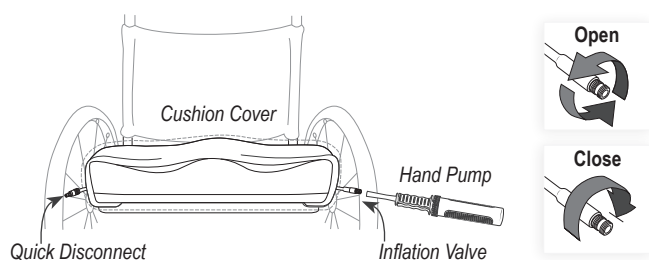
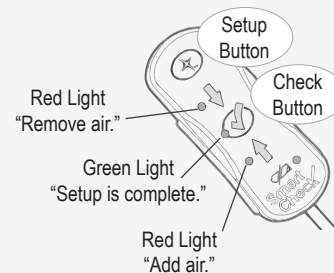
Note: Results may vary based on body type.

⚠ Warnings:

- Perform the following steps in the usual environmental conditions.
- The cushion **MUST** be overinflated to start Smart Setup. You may temporarily feel unstable; if so, proceed with caution.
- The individual **MUST** be seated on the cushion in the chair before using Smart Check.

Note: The Hybrid Elite SR Cushion is shown in all cushion images on this page.

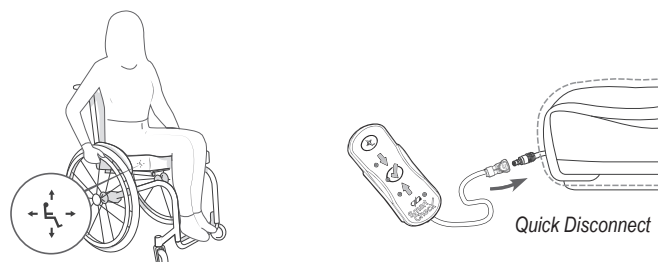
Symbols and Lights for Smart Setup



1. Place and inflate the cushion:

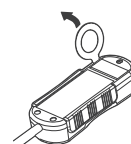
If a cushion cover is used, place the cover on the cushion before inflating.

- Place the cushion in the chair.
- Slide the hand pump nozzle over the inflation valve. Open the inflation valve, at least one full rotation.
- Inflate until all of the air cells feel firm. Close the inflation valve until it comes to a stop. Remove the hand pump.



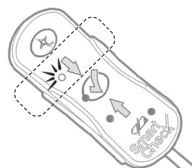
2. Transfer and attach Smart Check:

- Sit in the chair in your usual position. Pull to remove the tab (first-time use only).
- Make sure the inflation valve is closed. Attach Smart Check to the cushion. You will hear a "click" when the connection is secure.



Note: When Smart Check is attached to the cushion, close the zipper as completely as possible. Before removing the cover, remove Smart Check, if it is attached to the cushion.

⚠ IMPORTANT! If you are performing a new Setup, the Smart Check setting must first be cleared; see "Hard Reset Instructions."



3. Perform the Check step:

- Press the Check Button (✓).
- When you see the red down arrow light (↓), proceed to step 4.

IMPORTANT! IF YOU SEE THE RED UP ARROW LIGHT (↑) when you press the Check Button, more air may be needed. Follow these steps: Make sure the quick disconnect is securely attached. Then, open the inflation valve; add more air; close the inflation valve. Press the Check Button (✓) again. Repeat until you see the red down arrow light (↓), and then proceed to step 4.

4. Perform the Setup step:

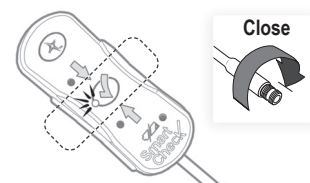
- Press (but do not hold) the Setup Button. The red down arrow light (↓) will now **flash**.
 - Open the inflation valve, release air (approximately 30 to 60 seconds)*, and wait for the flashing green light. See step 5.
- If the red down arrow light (↓) stops flashing before you have opened the valve, go back to step 3.

***To ensure an accurate reading:** Remain still and avoid restricting air flow while you release air from the cushion.

5. Finish:

- When you see the flashing green light, close the inflation valve. The green light means that Setup is complete.
- Your cushion is now set up. Next: See "Check Instructions."

⚠ **Warnings:** Store Smart Check in a safe, accessible location. See "Disconnection, Storage and Transport." • Confirm that Smart Check is not pressing against your body.



Check Instructions

Perform a Check after completing Setup (Smart Setup or Optional Setup).

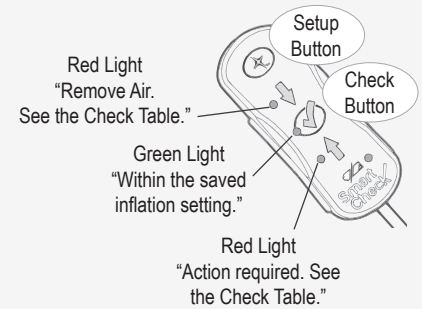
Warnings:

- Perform a Check frequently, at least once a day!
- The cover used during Setup must be the same cover used during Check.
- Perform a Check when there is a significant change in altitude.

How to Perform a Check:


1. You should be in your usual sitting position.
2. Press the Check Button.
3. Refer to the Check Table below.



Symbols and Lights for Check





Check Table

Notes: After you perform a Check, you may choose to perform a Hand Check to become familiar with your inflation range. See the "Hand Check Guide." • You may be able to add or remove a small amount of air and still be at your cushion inflation setting. Smart Check saves your cushion inflation setting with some room for adjustment.

Light	Status	Action
	The cushion is within the saved inflation setting.	No further action is required.

Light	Possible Causes	Action
	Your weight may be unevenly distributed	Perform a weight shift to circulate air in the cushion, then press the Check Button to get a new reading.
	The quick disconnect is not securely attached to the cushion.	Make sure the connection is secure, then press the Check Button to get a new reading. See "Troubleshooting" in this manual.
	The cushion needs more air.	Open the valve and add more air to the cushion (6 to 10 pumps). Close the valve. Press the Check Button to get a new reading. Repeat as needed.  Warning: If you are unable to make adjustments on your own, discontinue use until assistance is available.
	The cushion or the quick disconnect on the cushion has a slow leak.	See "Troubleshooting" in the manual provided with the Sensor Ready Cushion or the Hybrid Elite Cushion, or contact Customer Support.

Light	Cause	Action
	The cushion has too much air.	Open the valve and remove air from the cushion until you see the green light. Close the valve.  Warning: If you are unable to perform this task, seek assistance.

Disconnection, Storage and Transport

To Disconnect Smart Check from the Cushion: Press down on the gray latch, then separate.

Storage or Transport: Disconnect Smart Check from the cushion. Clean and disinfect the product. When not in use, place Smart Check in a safe, accessible location (for example, the storage case provided with Smart Check), to protect the device from moisture, contaminants and damage. After storing or transporting, inspect the product to ensure it was not damaged (see "Troubleshooting"), and follow the instructions for product use.



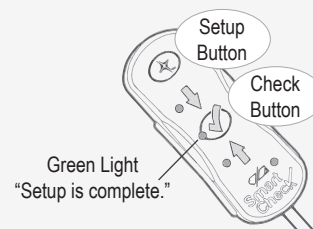
Optional Setup Instructions

Optional Setup is an alternative to Smart Setup that records your preferred cushion inflation setting. See "Overview" for more information.

⚠ Warnings:

- Optional Setup should not be used if the individual weighs less than 90 lbs. (40 kg).
- It is recommended that a qualified seating specialist be consulted when saving a preferred cushion inflation setting with Optional Setup.
- Perform the following steps in the usual environmental conditions.

Symbols and Lights for Optional Setup

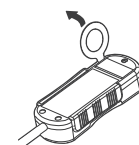


Part One: Adjust Your Cushion Without Smart Check

1. Perform a Hard Reset. See "Hard Reset Instructions."

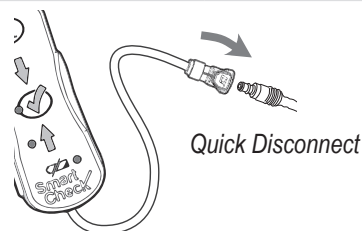
Note: For first-time use, remove the battery pull tab.

2. Inflate the cushion and place it in the chair. Sit on the cushion in your usual position.
3. Adjust the cushion; see the instructions provided with the cushion.
4. Perform a hand check to confirm immersion and envelopment. (See the "Hand Check Guide" in this manual.)



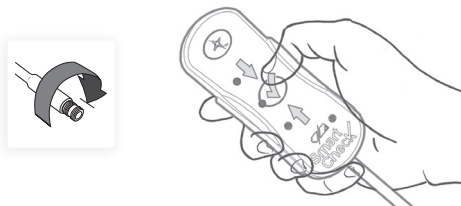
Part Two: Save Your Setting With Smart Check

5. Make sure Smart Check is attached to the cushion. You will hear a "click" when the connection is secure.



6. Make sure the inflation valve is closed.

7. Press the Check Button (✓) to activate Smart Check. You will see either a red up arrow (↑) or a red down arrow (↓) light. **DO NOT add or remove air.**



8. Press and hold the Setup Button for four (4) seconds until you see a green light. Your cushion is now set up. Next: See "Check Instructions."

The green light means that your preferred cushion inflation setting has been saved. The green light DOES NOT indicate a Proper Cushion Inflation Setting (see "Overview" for more information).



⚠ **Warnings:** Store Smart Check in a safe, accessible location. See "Disconnection, Storage and Transport." • Confirm that Smart Check is not pressing against your body.

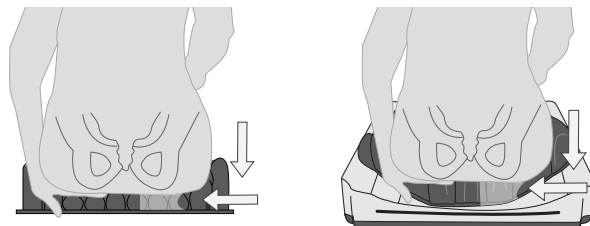
Hand Check Guide


Use this guide to adjust your cushion during Optional Setup.

A hand check is also recommended after performing Smart Setup so you will have a reference point if you need to adjust your cushion without Smart Check (for example, if the device has been misplaced).

 Before you perform a hand check, refer to “Important Safety Information” and read the warning about using an under-inflated cushion or an over-inflated cushion.

1. Place your hand between yourself and the cushion. Feel for the lowest bony prominence. You should be able to slightly move your fingertips.
2. If it feels like the cushion has too much air or not enough air, adjust as needed and see “Check Instructions” and “Overview.”



 **Warning:** Make sure that there is at least a ½ in. (1.5 cm) of air supporting the individual's bony prominences.

Hard Reset Instructions

Before you perform a new Setup, you must clear the setting on Smart Check by performing a Hard Reset.

Note: Smart Check may be attached or detached when performing the Hard Reset.

1. Make sure there are no steady or flashing lights. If there is a steady or flashing light, wait until it goes out before proceeding.
2. Simultaneously press and hold both the Check Button and the Setup Button for five (5) seconds. Each of the lights will flash one time, indicating that your previous setting has been removed.
3. After the Hard Reset is complete, follow all setup instructions as indicated in this manual. (See “Smart Setup” or “Optional Setup.”)



Troubleshooting

For additional assistance, contact the equipment provider, distributor, or Customer Support.

Problem	Action
No lights are displayed on Smart Check after you press the Check Button.	Make sure the pull tab has been removed from the battery compartment. Confirm the battery type and battery orientation. Replace the batteries if needed. See “Maintenance.” Contact Customer Support if the issue continues.
Smart Setup: After you press the Check Button, Smart Check still displays the red “add air”(↑) light, but you have confirmed that the cushion is overinflated and that the quick disconnect is securely attached.	Inspect the O-ring on the cushion's quick disconnect for wear or damage. If damage is found, contact Customer Support. Inspect the cushion for a slow leak. See “Troubleshooting” in the manual provided with the cushion.
Optional Setup: You do not see a green light after pressing and holding the Setup Button for four (4) seconds.	Repeat Part 2 of “Optional Setup Instructions.” If you still do not see a green light, note that Optional Setup may not be compatible with your physical needs or preferences. Refer to the “Overview” and “Smart Setup Instructions,” or contact your clinician or Customer Support.
Assistance is needed to use or maintain Smart Check; you encounter unexpected problems; or a component is damaged.	Contact Customer Support.

Cleaning and Disinfecting

⚠ Warnings:

- Cleaning and disinfecting are separate processes. Cleaning must precede disinfection. Before use by a different individual, clean, disinfect, and check product for proper functioning. When used by the same individual, clean and disinfect the product regularly and when it becomes soiled.
- Follow safety guidelines on cleaning and disinfecting product labels.
- Smart Check should not be cleaned with acetone, MEK, toluene, or adhesive removers.

⚠ **Sterilization:** Smart Check is not packaged in a sterile condition, nor is it intended or required to be sterilized prior to use. High temperatures accelerate aging and cause damage to the product assembly.



Warning: DO NOT immerse Smart Check in liquid.

To Clean: Wipe Smart Check with mild detergent and a clean, soft cloth or a sponge. Air dry.



To Disinfect: Wipe Smart Check with bleach-free disinfecting wipe. Air dry.



Care Symbols Glossary:



Wipe with a damp cloth.



Do not bleach.



Dry flat.

Maintenance

⚠ **Warning:** DO NOT perform maintenance on Smart Check while it is in use. Doing so may result in improper functioning.

Daily: Inspect Smart Check quick disconnect, tubing, and device housing for wear or breakage, and to ensure inter-component attachment. DO NOT continue to use Smart Check if any part is damaged or cannot be attached securely. Periodically, Smart Check should be inspected by a qualified technician.

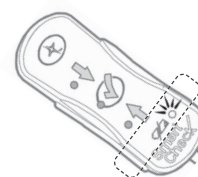
Battery Replacement

The low-battery light means the batteries should be replaced. Follow the instructions below.

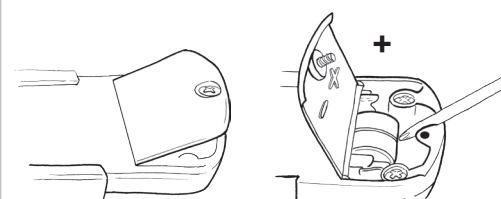
Notes: Smart Check will remember your saved setting after battery replacement. • To preserve battery life, Smart Check automatically goes into "sleep" mode when not in use. • Expected service life of batteries: one (1) year.

1. Detach Smart Check from the cushion at the quick disconnect.
2. Use a Phillips head screwdriver with a non-conductive handle to loosen the screw and open the battery door.
3. Use the screwdriver to release the batteries.
4. Refer to "+" and insert two (2) new 1.5 volt alkaline button cell batteries (LR44, A76, AG13 or equivalent).
5. Close the battery door.
6. Tighten the screw.

⚠ **Caution:** If the screw is not tightened completely, the batteries may be exposed to moisture, resulting in product damage.



Low-Battery Light



⚠ **Warning:** KEEP BATTERIES OUT OF REACH OF CHILDREN AND ANY INDIVIDUALS WHO HAVE A TENDENCY TO PLACE INEDIBLE OBJECTS IN THEIR MOUTHS. Swallowing or inhalation may lead to serious injury or death. IMMEDIATELY seek emergency medical assistance.



Disposal and Recycling

Disposal: Dispose of the product and/or components in accordance with the applicable regulations in your jurisdiction, (including electronic waste disposal). At the end of its useful life, treat as healthcare waste and dispose of according to local healthcare-waste guidelines. DO NOT INCINERATE.

Recycling: Contact a local recycling agency to determine recycling options for the product.



Electromagnetic Compatibility (EMC)

Install and operate the device according to the EMC information presented in this section.

The device is designed to function under a wide range of environmental conditions without compromise to Safety or Essential Performance.



Warnings:

- Proper use of this device depends on careful reading of all instructions and labels.
- DO NOT modify the device or any components.
- An internal battery is used for normal operation of this device. To avoid abnormal operation of this device, do not place the device next to or beneath other equipment; or, if such placement is necessary, verify normal operation of this device and the other equipment.
- Use of accessories or components other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device, which may result in abnormal operation.
- Performance of this device may degrade if any part of the device is used closer than 12 in. (30cm) to portable RF communications equipment (including peripherals such as antenna cables and external antennas). Placement closer than 12 in. (30cm) is neither specified nor permitted for this device.

Declaration of compliance to IEC 60601-1-2: Ed. 4.0 (2014): The device has been tested to verify essential performance in the presence of electromagnetic disturbances as outlined in the summary of tests below.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic environment – guidance
Radiated RF emissions - CISPR 11	Group 1 Class B	According to CISPR 11 group 1, Class B.
Conducted RF emissions - CISPR 11	N/A	This equipment/system is suitable for use in healthcare professional and home health care establishments and uses only RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions - IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Electromagnetic Immunity

Immunity Test Levels – Enclosure Port

Phenomenon	Basic EMC Standard	Immunity Test Levels – Home Healthcare Environment			
Electrostatic Discharge	IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV contact discharges ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharges			
Radiated RF EM Fields	IEC 61000-4-3	10 V/m; 80 MHz – 2.7 GHz; 80% 1 kHz amplitude modulation			
Proximity Fields from RF Wireless Communications Equipment	IEC 61000-4-3	Frequency (MHz)	Modulation	Level (V/m)	Distance (m)
		385	18Hz PM 50%	27	0.3
		450	FM ± 5 kHz dev, 1kHz (or 18Hz PM 50%)	28	0.3
		710	217Hz PM 50%	9	0.3
		745	217Hz PM 50%	9	0.3
		780	217Hz PM 50%	9	0.3
		810	18Hz PM 50%	28	0.3
		870	18Hz PM 50%	28	0.3
		930	18Hz PM 50%	28	0.3
		1720	217Hz PM 50%	28	0.3
		1845	217Hz PM 50%	28	0.3
		1970	217Hz PM 50%	28	0.3
		2450	217Hz PM 50%	28	0.3
		5240	217Hz PM 50%	9	0.3
		5500	217Hz PM 50%	9	0.3
		5785	217Hz PM 50%	9	0.3
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m; 50 Hz and 60 Hz			

Immunity Test Levels – Input A.C. Power Port – N/A

Immunity Test Levels – Patient Coupling Port – N/A

Immunity Test Levels – Signal Input / Output Parts Port – N/A

Associated cables – none

Notice: No deviations from the collateral standard IEC 60601-1-2:2014 were performed.

Notice: All necessary instruction for maintaining compliance can be found in the safety and maintenance sections in this manual. No further steps are required.

Limited Warranty

Limited Warranty Term: 24 months from the date the product was originally purchased. See also the Limited Warranty supplement provided with your product, or contact Customer Support.