

Smart CheckTM

by ROHO[®]

Operation Manual



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

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

s h a p e f i t t i n g t e c h n o l o g y[®]

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ROHO.com

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ROHO, Inc. has a policy of continual product improvement and reserves the right to amend this document.

Intended Use

Smart Check™ by ROHO® (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).



Important Safety Information

- Read this instruction manual carefully and completely before using the product.
- ROHO medical products are intended to be part of an overall care regimen. ROHO, Inc. recommends that a clinician make product recommendations based upon an evaluation of the individual's medical and therapeutic needs and overall condition (for example, potential allergic reactions). 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.)

Warnings

- **DO NOT** use an under-inflated cushion or an over-inflated cushion because the product benefits will be reduced or eliminated, resulting in an increased risk to skin and other soft tissue. If the cushion does not appear to be holding air, or if you are not able to inflate or deflate the cushion, see the TROUBLESHOOTING section of the manual that was provided with the cushion. Immediately contact your clinical caregiver, distributor, or ROHO, Inc. if the problem persists.
- Check inflation frequently, at least once a day, using the Smart Check or a hand check.
- 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). Before performing a new Setup, you must clear your Smart Check setting; see HARD RESET INSTRUCTIONS.
- **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.
- **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.

Important Safety Information, Continued

Warnings, Continued

- Using an accessory (for example, a pump or a cushion cover) other than those provided by ROHO, Inc., may be unsafe and could void the product warranty.
- **DO NOT** modify Smart Check or any components. Doing so may result in damage to the product and will void the warranty.
- **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.
- 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.
- 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.
- 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.
- **BURN HAZARD:** If ambient temperature exceeds 47°C (117°F), **DO NOT** maintain contact with product surface for more than ten (10) minutes.
- Smart Check **MUST** be used **ONLY** with a compatible ROHO cushion cover. Use of a different cover may interfere with the accuracy of Smart Check functions.
- **DO NOT** perform maintenance on Smart Check while it is in use. Doing so may result in improper functioning.
- Set up your cushion in the usual environmental conditions. Perform Check when environmental conditions, including temperature and altitude, change significantly.

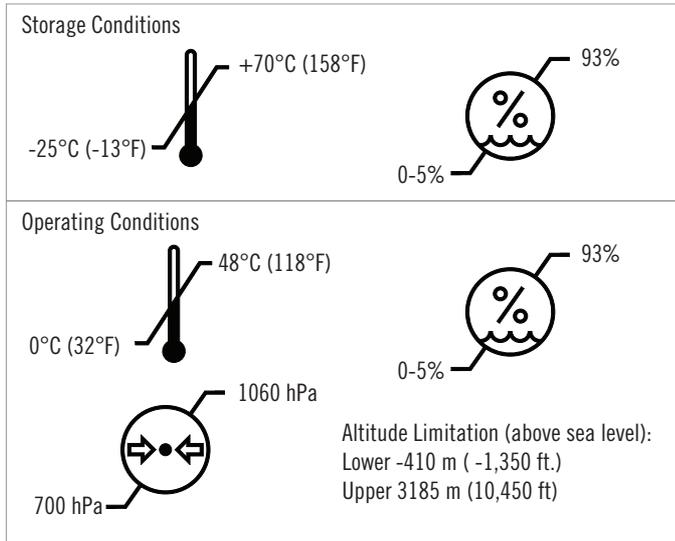
Cautions

- 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. ROHO, Inc. recommends that Smart Check be inspected periodically 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** expose the product to high heat, open flames, or hot ashes.
- **DO NOT** use the inflation valve or any Smart Check components 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.

Legend

Warning		Temperature Limit	
Refer to instructions for use.		Humidity Limitation (relative, non-condensing)	
Manufacturing location		Atmospheric Pressure Limitation	
Keep dry.		Choking hazard	
Wipe by hand.		Do not discard in household trash.	 
Air dry.		User identification	
Do not use bleach.		IEC 60601-1: Type BF Applied Part	
Low battery: amber light			

Specifications



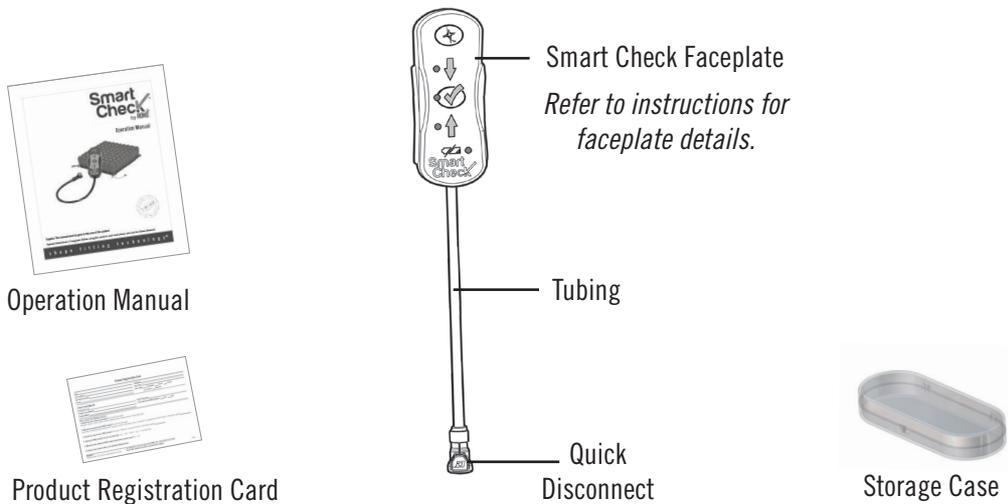
- Smart Check: polycarbonate with polyester faceplate
- Storage Case: polystyrene
- Tubing: polyurethane
- Quick Disconnect: acetal
- This product complies with RoHS2.
- Smart Check is a type BF Applied Part. Smart Check has been tested and complies with IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-11; 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.
- Expected Service Life: 5 years
- Batteries: one (1) year typical operating time
- Smart Check is an IP54-rated device (protected from dust and splashing water).

Parts Detail

Package Contents: Smart Check™ by ROHO®, Smart Check instructions, registration card, storage case

Product Registration: Mail the enclosed product registration or register your product at ROHO.com.

 For information about your cushion, refer to the *ROHO® Single Compartment Cushion with Sensor Ready™ Technology Operation Manual*.



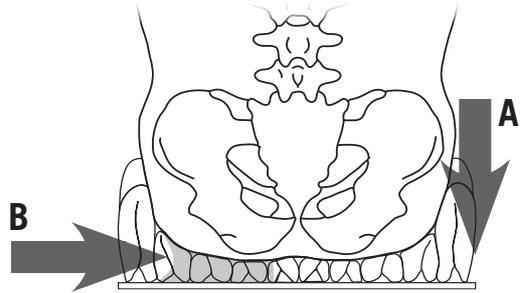
Overview

This page explains how to use Smart Check to find, save, and check your cushion inflation setting. Please read before using Smart Check.

Smart Setup and Check:

1. Follow the SMART SETUP INSTRUCTIONS. Smart Check will find and save your cushion inflation setting for you.
2. Follow the CHECK INSTRUCTIONS. When you press the Check Button, Smart Check will tell you if you need to adjust your cushion.

Proper Cushion Inflation Setting: **A**) sink down into the cushion and **B**) “float” above the cushion base.



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).

Warnings:

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

Optional Setup (and Check)

1. Find your preferred cushion inflation setting without using Smart Check. (Follow the *ROHO® Single Compartment Cushion with Sensor Ready™ Technology Operation Manual*.)
2. Follow the OPTIONAL SETUP INSTRUCTIONS, using Smart Check to save your inflation setting.
3. Follow the CHECK INSTRUCTIONS. When you press the Check Button, Smart Check will tell you if you need to adjust your cushion.

IMPORTANT!

- 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). Before performing a new Setup, you must clear your Smart Check setting; see HARD RESET INSTRUCTIONS.
- Perform a Check frequently, at least once a day!

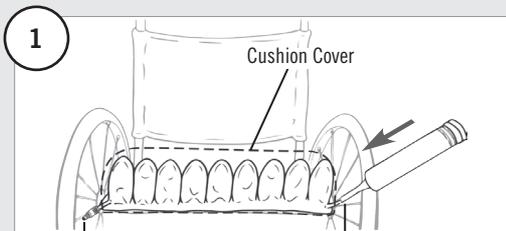
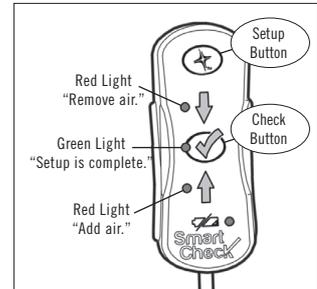
Smart Setup Instructions

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.



- 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.

Symbols and Lights for Smart Setup

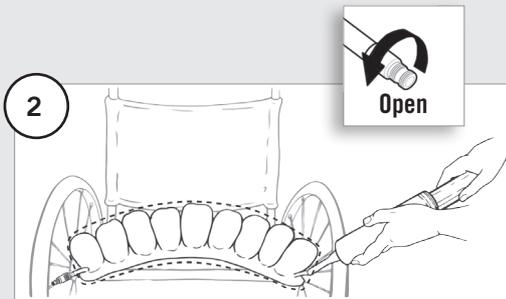


Quick Disconnect

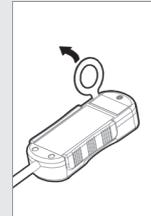
Inflation Valve

1. Place the cushion in the chair. Place the nozzle of the pump over the inflation valve.

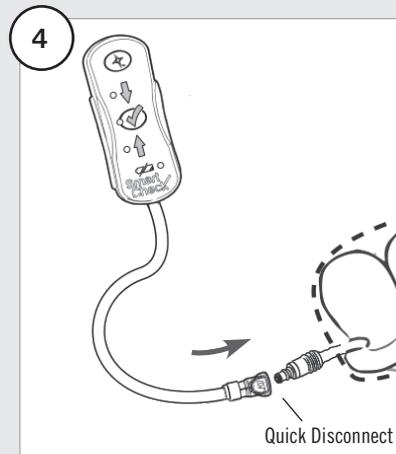
If a cushion cover is used, place the cover on the cushion before inflating.



2. Open the inflation valve. Overinflate the cushion until it bulges. Close the inflation valve. Remove the pump.



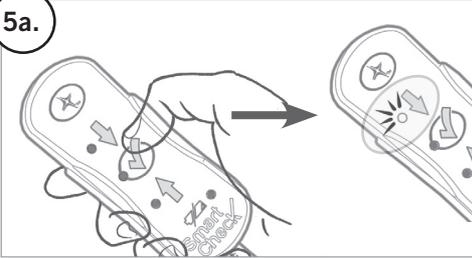
3. Sit in the chair in your usual position. Pull to remove the tab (*first-time use only*).



4. Make sure the inflation valve is closed. Attach Smart Check to the cushion. You will hear a "click" when the connection is secure.

Smart Setup Instructions, Continued

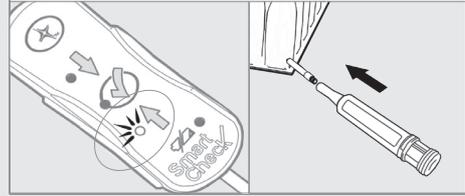
5a.



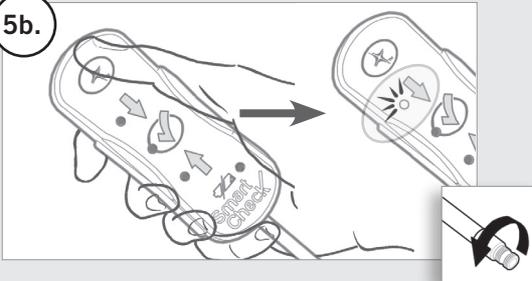
5a. Press the Check ✓ Button.
When you see the red down arrow ↓ light,
proceed to step 5b.

NOTE: If you see the red up arrow ↑ light
when you press the Check Button:

1) Make sure the quick disconnect is securely
attached, and 2) Open the inflation valve,
add more air, close the inflation valve,
and press the Check ✓ Button again. *Repeat until
you see the red down arrow light.*



5b.



5b. 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.

If the red down arrow ↓ light stops flashing before you
have opened the valve, go back to 5a.

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

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.)



Store Smart Check in a safe and accessible location. See DISCONNECTION AND STORAGE instructions.

Check Instructions

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

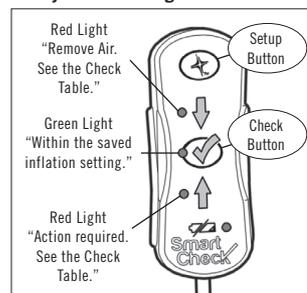
How to Perform a Check:

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



- Perform a Check frequently, at least once a day!
- If a cover was used while setting up the cushion, the same cover must be used during Check.
- Perform a Check when there is a significant change in altitude.

Symbols and Lights for Check



Check Table

NOTE: 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.

NOTE: 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.

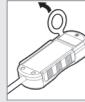
Light	Status	Action
	The cushion is within the saved inflation setting.	No further action is required.
Light	Possible Causes	Action
	Your weight may be unevenly distributed.	Perform a weight shift to circulate air in the cushion, then press the Check Button to get a new reading.
	The quick disconnect 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. 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 <i>ROHO® Single Compartment Cushion with Sensor Ready™ Technology Operation Manual</i> or contact Customer Care.
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. If you are unable to perform this task, seek assistance.

Optional Setup Instructions

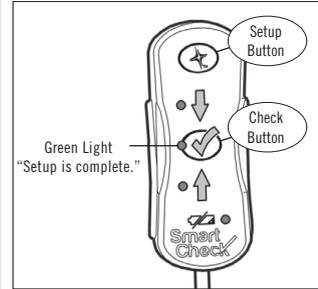
Optional Setup is an alternative to Smart Setup that records your preferred cushion inflation setting. See OVERVIEW for more information.

Part One: Adjust Your Cushion Without Smart Check

1. Perform a Hard Reset. See HARD RESET INSTRUCTIONS.
2. Inflate the cushion and place it in the chair. Sit on the cushion in your usual position. Adjust the cushion by following the CUSHION ADJUSTMENT instructions in the *ROHO® Single Compartment Cushion with Sensor Ready™ Technology Operation Manual*.
3. Perform a hand check to confirm immersion and envelopment. (See the HAND CHECK GUIDE in this manual.)



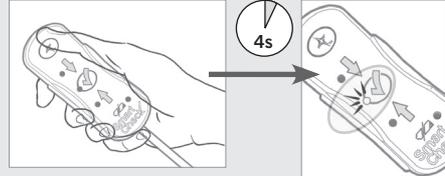
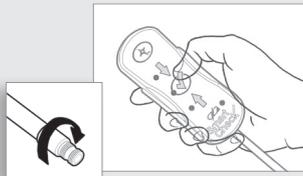
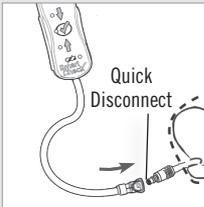
Symbols and Lights for Optional Setup



Part Two: Save your Setting with Smart Check



- 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.



4. Make sure Smart Check is attached to your cushion. You will hear a “click” when the connection is secure.
5. Make sure the inflation valve is closed. Press the Check ✓ Button to activate Smart Check. You will see either a ↑ or a ↓ red light. **DO NOT** add or remove air.
6. Press and hold the Setup Button for four (4) seconds until you see a green light. 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.



Store Smart Check in a safe and accessible location. See DISCONNECTION AND STORAGE instructions.

Your cushion is now set up. (Next: See CHECK INSTRUCTIONS.)

Hand Check Guide

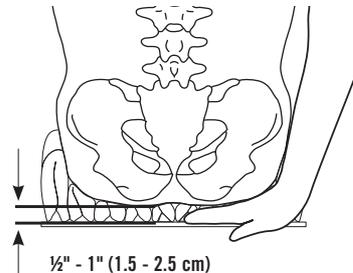
Use this guide to adjust your cushion during Optional Setup.

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. The recommended distance between the individual and the seating surface is ½ - 1 inch (1.5 cm to 2.5 cm).
2. If it feels like the cushion has too much air or not enough air, adjust as needed and see CHECK INSTRUCTIONS and OVERVIEW.

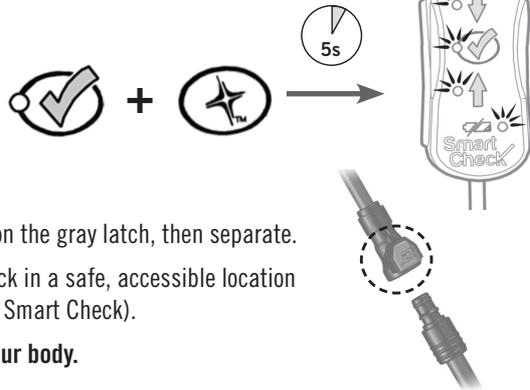


Hard Reset Instructions

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.
2. Simultaneously press and hold 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.



Disconnection and Storage

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

To Store Smart Check: You may detach and store Smart Check in a safe, accessible location when not in use (for example, the storage case provided with Smart Check).

 **Confirm that Smart Check is not pressing against your body.**

Troubleshooting	
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. Contact Customer Care 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 Care. Inspect the cushion for a slow leak. See TROUBLESHOOTING in the <i>ROHO® Single Compartment Cushion with Sensor Ready™ Technology Operation Manual</i> .
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 Care.
You require assistance with the use or maintenance of Smart Check or you encounter unexpected problems.	Contact Customer Care.

Limited Warranty

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

Cleaning and Disinfecting



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



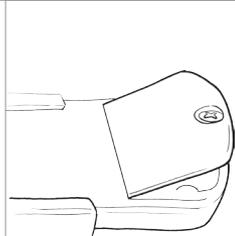
Sterilization: Smart Check is not packaged in a sterile condition, nor is it intended or required to be sterilized prior to use. High temperatures accelerate aging and cause damage to the product assembly.

Battery Replacement

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



- 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, AG13 or equivalent).
5. Close the battery door.
6. Tighten the screw. **NOTE:** If the screw is not tightened completely, the batteries may be exposed to moisture, resulting in product damage.



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

Dispose of the product and/or components in accordance with the applicable regulations in your jurisdiction, (including electronic waste disposal). **DO NOT INCINERATE.**





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The Quality Management System of
ROHO, Inc. is certified to
ISO 9001:2008 and ISO 13485:2003.

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