



Hillrom Extended Care Solution – Between Patient Inspection (BPI) Process

REF 772267 DIR 80026727 Ver. C
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(91)772267

Introduction

This document provides instructions for cleaning, disinfecting, completing an inventory and inspection of returned items, and replenishing disposable stock related to the Welch Allyn Spot Vital Signs 4400 (“device”) and the Hillrom Extended Care Solution.

NOTE EcoCuffs are disposable and for single-patient-use only. EcoCuffs should be discarded after single-patient-use. They cannot be cleaned or disinfected. If the device was returned with EcoCuffs, discard them regardless of whether opened or not.

Warnings

A warning statement in this instruction identifies a condition or practice which, if not corrected or discontinued immediately, could lead to injury, illness, or death.

WARNING Patient injury risk. Clean all accessories, including cables and tubes, before storing the accessories on the device or stand. This helps reduce the risk of cross contamination and nosocomial infection.

Cleaning and disinfection

As a general safety precaution, the device must undergo cleaning and disinfection/decontamination before being prescribed to another patient or before returning for service, repair, inspection, or disposal. Cleaning is an essential prerequisite for effective disinfection/decontamination.

WARNING Electric shock hazard. Before cleaning and disinfecting the device, disconnect the AC power cord from the mains outlet and the power source.

WARNING Electric shock hazard. DO NOT immerse the device or accessories. The device and the accessories are not heat-resistant.

WARNING Liquids can damage electronics inside the device. Prevent liquids from spilling on the device.

Cleaning refers to the removal of germs, dirt, and impurities from surfaces. It does not kill germs, but by removing them, it lowers their numbers and the risk of spreading infection.

Disinfection refers to using chemicals, for example, EPA registered disinfectants, to kill germs on surfaces. This process does not necessarily clean dirty surfaces or remove germs, but by killing germs on a surface after cleaning, it can further lower the risk of spreading infection.¹

NOTE For facilities that do not have established cleaning and disinfection processes in place, Hillrom recommends the following procedure.

NOTE See the device Instructions for use for additional approved cleaning products.

Prepare the Spot 4400 for cleaning and disinfection

1. Unplug the device from the electrical mains outlet.
2. Use as many Clorox disinfecting wipes as necessary to ensure the wipe remains wet, but not dripping during both the cleaning and disinfection steps.
3. Follow the directions on the Clorox disinfecting wipes manufacturing label.
4. Remove the oximetry finger sensor for separate cleaning instructions according to the manufacturer’s Instructions for use.

Step 1: Cleaning

1. Remove the wipe from the Clorox disinfecting wipes container.
2. Wipe all surfaces of the device, including the top, sides, front, rear, and bottom of the device. Use as many wipes as needed to wipe all surfaces.
3. Remove the thermometer probe and then wipe the entire probe.
4. Wipe cords, cables, and stand.
5. Discard any used wipe(s).
6. Wash your hands thoroughly.

Step 2: Disinfection

1. Using a new Clorox disinfecting wipe, wipe down all surfaces of the device, including the top, sides, front, thermometer probe, rear, and bottom of the device.
2. Use enough wipes for all treated surfaces to remain visibly wet for 4 minutes. Reapply disinfectant as needed to keep the area visibly wet.
3. Wipe cords, cables, and stand. Make sure all wiped surfaces remain visibly wet for 4 minutes.
4. Discard any used wipe(s).
5. Wash your hands thoroughly.

Inventory accessories and replace as needed

- SureTemp Plus probe - (part #: 02895-000-NCE)
- NIBP tubing - (part #: 4500-34)
- Nonin SpO2 sensor - (part #: 3278-010)
- Power supply - (part #: 4400-HPS)
- Stand - (part #: 4400-DST)
- Battery - (part #: BATT22)
- Power cord - (part #: PWCD-H Line cord B, North America home use)
- Bluetooth dongle - (part #: 4400-BLE)
- Screw kit - (part#: 410350)

Complete a physical inspection

Check for the following types of damage:

- Device: cracks, legible labels, visible distortion or discoloring of the display when powered on.
- Stand: physical damage (bent, missing screws, missing feet)
- SureTemp Plus temperature probe: visible cracks in probe housing or wire insulation, bare wiring or visible internal wiring damage
- Nonin SpO2 finger sensor: visible cracks in sensor housing or wire insulation, screws
- Power supply: visible cracks in the housing or wire insulation, bare or visible internal wiring

1. Disinfection for Households. Interim Recommendations for U.S. Households with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19).

Complete a system inspection

Attach all accessories, power on the device, and perform the checks described in this section.



NOTE To access the device Service manual for more information, follow this link to the Spot 4400 documents page: <https://www.welchallyn.com/en/products/categories/patient-monitoring/vital-signs-devices/spot-vital-signs-4400-device/documents.html>



NOTE No error(s) = PASS for all system checks.

Device powers on to home display with no errors

If errors, check the Symptoms and solutions table listed in the Service manual and follow recommended guidance. Replace accessory as directed.

Start blood pressure check

If errors, check Symptoms and Solutions Table listed in the Service Manual and follow recommended guidance. Replace accessory as directed.

Stop blood pressure check

If errors, check Symptoms and Solutions Table listed in the Service Manual and follow recommended guidance. Replace accessory as directed.



NOTE An information message, “User canceled NIBP reading.” will appear when you stop a blood pressure measurement. This is not an error.

Remove temperature probe from well check

If errors, check Symptoms and Solutions Table listed in the Service manual and follow recommended guidance. Replace accessory as directed.



NOTE The IFU CD includes a link to the Service manual, which is available on the Hillrom website.

SpO2 tile check

If errors, check Symptoms and Solutions Table listed in the Service Manual and follow recommended guidance. Replace accessory as directed.

Battery power check

Unplug the device from AC power. Device can be powered on, battery indicator shows battery level, and device can be powered down. If the device does not power on with the battery, plug the device in and charge the battery for 30 minutes. Check battery power again.

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Bluetooth radio dongle check

The Bluetooth radio dongle flashes when connected. Replace dongle if not showing as connected.

AC power indicators check

Power indicator on display indicates that the power supply is plugged in and that the battery is charging or fully charged. If not, replace power supply if needed.

After completing all system checks...

Power off the device and detach all accessories.

Replenish stock of disposables

- Probe covers qty. 250 (part #: 20500-251N-NCE)
- Pack 4 EcoCuffs: qty. 2 size 11 (part #: ECOCUFF-11), qty. 2 size 12 (part #: ECOCUFF-12)
- FlexiPort® EcoCuff™ Directions for Use (part #: 722328) or download from this link: <https://www.welchallyn.com/content/dam/welchallyn/documents/sap-documents/LIT/80019/80019369LITPDF.pdf>
- Nonin® SpO2 Instructions for Use – download from this link: <https://www.nonin.com/wp-content/uploads/Operators-Manual-8000A.pdf>
- Welch Allyn Spot Vital Signs 4400 Instructions for Use Addendum (part #: 772263)
- Welch Allyn® Spot Vital Signs® 4400 Assembly Instructions – 4400-RPMKIT (part #: 772264)
- Hillrom Extended Care Solution – Quick Reference (part #: 772265)
- Hillrom Extended Care Solution Clinical Training Checklist for At-Home Patient Vitals Capture (part #: 772266)
- CD, IFU, SPOT 4400 1.X (part #: 419833)



NOTE Facilities have the option of printing documents as needed or ordering from Hillrom.

Use the “4400-H Between Patient Inspection Form” on the next page to document inspection activities and confirm completion.



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4400-H Between Patient Inspection Form

Date: _____	Manufacturer: _____
Serial Number: _____	Model: _____

	PASSED	N/A	REMARKS/COMMENTS
Cleaned			
4400 Device			
4400 Accessories			
Inventory Accessories/Parts – Replace if missing			
SureTemp Plus Probe / Well **			
Nonin SpO2 Sensor **			
NIBP tubing**			
Power Supply **			
Stand **			
Power Cord **			
Bluetooth Dongle **			
Physical Inspection			
4400 Device *			
Stand **			
SureTemp Plus Probe & Well **			
Nonin SpO2 Sensor **			
Power Supply / Cord **			
System Inspection (no errors)			
Device Power-On *			
Blood Pressure Start *			
Blood Pressure Stop			
Temperature Probe / Well			
SpO2 Function Tile			
Bluetooth Radio Dongle			
Power Supply *			
Battery *			
Replenish stock of disposables (probe covers, EcoCuffs, transport box, literature)			
Probe Covers			
EcoCuffs			
Transport box			
Literature (4 items): 772263, 772264, 772265, and CD 419833			

***Repair if not PASSED **Replace if not PASSED**

BPI COMPLETION CONFIRMATION	
By signing this form, I declare that all of the steps in the BPI instruction have been completed.	
Start Time / Day:	
Stop Time / Day:	
Signature:	
Printed Name:	
Date:	
Employee Number (if applicable)	

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