Hillrom™

Welch Allyn®
Spot Vital Signs 4400

Instructions for use – Addendum
Hillrom Extended Care Solution

Software version 1.X

For information about any product, contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/.

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This manual applies to # 901057 Vital Signs Device.

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Contents

Introduction

The purpose of this Instructions for use (IFU) addendum is to describe features of the Welch Allyn® Spot Vital Signs 4400 (device) configured for home use. A more complete description of the Spot 4400 is available on the CD accompanying the device, part number 419833. The addendum does not repeat details already presented in that IFU but focuses narrowly on the at-home configuration--on the amendments and modifications that pertain to at-home use. It describes how an at-home configuration and setup is different from Spot 4400 devices used inside medical facilities. It also includes many warnings and cautions targeting home users, informing them how best to protect themselves, members of their household, and also the device.

This addendum complements the Quick Reference, a pamphlet patients receive and review with a clinician before taking the device home. The Hillrom Connected Care resource page also provides access to videos and other literature related this at-home platform. Scan the code below to go to that site.

Modifications to FDA cleared Intended use (modifications are underlined)

The Welch Allyn® Spot Vital Signs 4400 (device) is intended to be used by patients to initiate spot-check/single measurement of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and body temperature in oral and axillary modes of adult and pediatric patients greater than 12 years of age under the direction of clinicians or other medical professionals. The intended use locations for patients to be measured are in the home environment. Patient vitals captured on the device will be sent to a software designed to collect and transmit health information.

The Hillrom Connected Care Platform solution is not intended for use in the diagnosis, cure, treatment, or prevention of disease. It is not intended as a substitute for medical care by a healthcare provider. It is not intended for emergency use or real-time monitoring.

Contraindications

- The device is not intended for use on neonates.

- The device is not intended for unattended monitoring.
- The device is not intended for patient transport.
- The device is not intended to be used in a carrying case.

For contraindications of SpO2 sensors, consult the sensor manufacturer's directions for use.

FDA guidance

The FDA issued Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. During this emergency and while the policy is in effect, the FDA does not intend to object to limited modifications to indications, claims, functionality, hardware, or software of cleared non-invasive remote monitoring devices that are used to support patient monitoring without prior submission of a 510(K) where the modifications do not create an undue risk. Based on this guidance, Hillrom has released the Welch Allyn Spot Vital Signs 4400 Device for use in the home with Hillrom Connex software.

When the device is used in the home, it is not intended for use in the diagnosis, cure, treatment or prevention of disease on its own. It is not intended as a substitute for medical care by a healthcare provider. It is not intended for emergency use or real-time monitoring.

Device performance

Validation of the integration of the Bluetooth radio, the home user screen and power cord into the Welch Allyn® Spot Vital Signs 4400 device was completed through software verification testing and design validation of the changes to the user interface, power cord and Bluetooth® radio, and IFU. The Spot 4400 device has been tested and shown to comply with IEC 60601-1 Edition 3.1, IEC 60601-1-2 4th Edition and IEC 60601-1-11 2nd edition. A Risk assessment has been performed according to ISO 14971. Any identified hazards have been found to be acceptable.

Potential risks

See the Instructions for use included on the enclosed CD, this Addendum, and the Quick reference for a complete list of Warnings and Cautions.

For further information on the Hillrom Welch Allyn® Spot 4400 Home, including the Instructions for use, this Addendum, and the Quick reference, visit hillrom.com.

Symbols and definitions

Documentation symbols

For information on the origin of these symbols, see the Welch Allyn symbols glossary: http://www.welchallyn.com/symbolsglossary.

	**WARNING** The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning statements appear with a grey background in a black and white document.
	**CAUTION** The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data. This definition applies to both yellow and black and white symbols.
	Follow instructions/directions for use (IFU) -- mandatory action. A copy of the IFU is available on this website. A printed copy of the IFU can be ordered from Welch Allyn for delivery within 7 calendar days.

Power symbols

	Stand-by		Direct current (DC)
	Power plug		Battery absent or faulty
	Alternating Current power present, battery fully charged		Battery charge level
	Alternating Current power present, battery is charging		Battery

	Alternating current (AC)		Rechargeable battery
	Rated power input, DC		Rated power input, AC
Li-ion	Lithium-ion battery		

Connectivity symbols

	USB		Bluetooth Low Energy technology

Miscellaneous symbols

	Manufacturer		Defibrillation-proof Type BF applied parts
	Reorder Number		Serial Number
	Product Identifier		Recyclable
	Do not reuse, Single use device		Separate collection of Electrical and Electronic Equipment. Do not dispose as unsorted municipal waste.
IP22	IP = International Protection Marking 2 = Ingress against solid foreign objects 2 = Protected against vertically falling water drops when enclosure tilted up to 15°		Call for maintenance
	This way up		Fragile

	Stacking limit by number		This device has no alarms.
	Temperature limit		Global Trade Item Number
	Humidity limitation		Keep dry
	Maximum safe working load limits		Mass in kilograms (kg)
	Atmospheric pressure limitation		Non-ionizing electromagnetic radiation
	Time required to complete a process, like charging a battery (2 hours)		Intertek Testing Laboratories Approved (ETL)

Screen symbol

	Process indicator for activities like acquiring measurements and connecting to a laptop or an iPhone		NIBP (blood pressure) or Start BP

About warnings and cautions

Warning and caution statements can appear on the device, on the packaging, on the shipping container, or in this document.

The device is safe for patients and clinicians when used in accordance with the instructions and the warning and caution statements presented in this manual.

Before using the device, familiarize yourself with the sections of this instructions for use that pertain to your use of the device.

WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.

CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of patient data.

General warnings and cautions

NOTE This section presents only new warnings and cautions or those that have been modified from the most recently released Instructions for use (IFU) to address the at-home user. See the IFU on the enclosed CD for a full listing of warnings and cautions for clinical versus at-home users.

WARNING Safety and inaccurate measurement risk. Use and store the device in an environment that avoid hazards and prevents device damage.

- Do not place or operate the device in direct sunlight.
- Do not operate the device outdoors.
- If the device gets wet during transport, allow it to dry before use.
- Keep the device away from pets and children.
- Keep the device away from heat sources (fireplaces, ovens, etc.).
- Keep the device away from sources of dust or lint (clothes dryers, home fans, etc.).
- Keep the device away from moisture-producing devices (humidifiers, nebulizers, vaporizers, etc.).

WARNING Safety risk. The device does not have a protective earth (grounded) terminal. Stop using the device if you observe arcing or sparks at the outlet.

WARNING Strangulation risk. Do not allow children or pets to touch or play with device cords, cables, or tubing that could get wrapped around their necks.

WARNING Choking risk. An oral probe cover enters your mouth when taking oral temperatures. When inserting the probe tip inside the mouth, ensure that the probe cover remains on the probe tip to avoid the risk of choking on the probe cover. When using on children or vulnerable people, the Spot 4400 device must only be used with special care and under permanent supervision. When used on adults, caution should be taken.

WARNING Choking risk. The Bluetooth dongle should never be placed in the mouth as it poses a choking risk.

WARNING Patient injury risk. Wash your hands frequently, and especially before and after touching the device, to reduce cross-contamination and the spread of infection.

WARNING Personal injury risk. Do not place the device anywhere that it might fall on you and hurt you.

WARNING Patient injury and inaccurate measurement risk. Do not operate the device while it is being carried or transported.

WARNING Patient injury and inaccurate measurement risk. Do not modify or alter the device in any way. Modification may affect performance, safety, and accuracy.

WARNING Patient injury and inaccurate measurement risk. Use only the App and device software provided with the Extended Care Solution. Using any other software violates the safety, effectiveness, and design controls of this medical device.

WARNING Personal injury risk. The power cord plug is the disconnect device used to isolate this equipment from supply mains. Position the equipment so that it is not difficult to reach or disconnect the plug.

WARNING Inaccurate measurement risk. Dust and particle ingress can affect the accuracy of blood pressure measurements. Use the device in clean environments to ensure measurement accuracy. If you notice dust or lint build-up on the device's vent openings, have the device inspected and cleaned by a qualified service technician.

WARNING Welch Allyn is not responsible for the integrity of a facility's power. If the integrity of a facility's power is in doubt, always operate the device on battery power alone when it is attached to a patient.

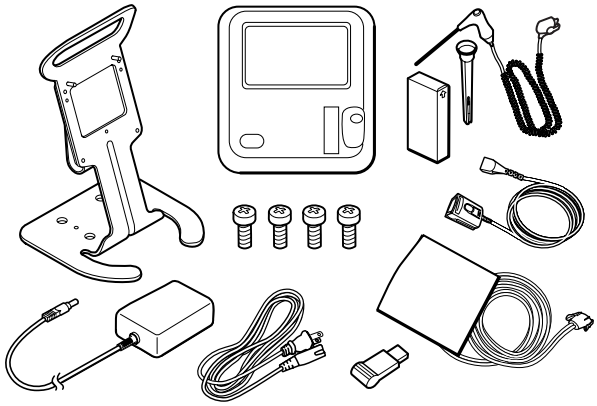
CAUTION Use only a Class II AC power cord to charge the power source for the device.

CAUTION To ensure that the system meets its performance specifications, store and use the system in an environment that maintains the specified temperature and humidity ranges (see Environmental specifications).

Device setup and basic operation

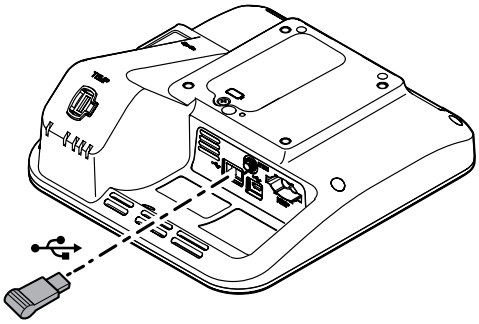
The medical facility is responsible for assembling the device before the patient takes it home. If any connectors or cables come loose and the patient needs help to reconnect them, consult the Setup section of the complete IFU (on CD) for instructions. The health care provider or medical facility is the point of contact for technical problems.

Pictured below are the Spot 4400 device, the stand plus hardware, and most accessories that comprise the 4400-RPMKIT: power supply and power cord, thermometer probe and probe well, probe covers, Nonin SpO2 sensor and cable, Bluetooth Low Energy dongle, and blood pressure hose. Missing from this illustration is the EcoCuff blood pressure cuff, which appears on the cover of this IFU Addendum next to the fully assembled device.



Connect the Bluetooth Low Energy dongle

1. On the rear of the device, align the Bluetooth Low Energy dongle with the USB port.
2. Insert the dongle, pressing firmly until the dongle is seated.



Power

The Power button ⏻, located on the lower-left corner of the device, performs multiple functions.

- Powers up the device
- Wakes the device from Sleep mode
- Opens a pop-up dialog with controls to power down, enter Sleep mode, or cancel

CAUTION Do not use a long press of the Power button to power down the device when it is functioning normally. You will lose configuration settings. Touch the **Settings** > **Device** tab to power down the device.

The LED in the center of the power plug symbol indicates the battery charging status.

- Green indicates that AC power is present and that the battery is fully charged.
- Amber indicates that AC power is present and that the battery is charging.

NOTE You may operate the device while the battery is charging.

NOTE The time from powering on the device until it is ready for use is approximately 40 seconds.

Device warm up and cool down

If the device has been stored below -4°F (-20°C) or above 122°F (50°C), allow the device to warm up or cool down in a room temperature environment of 50°F– 90°F for 4 hours before powering on the device.

Power up the device

The device runs a brief diagnostic self-test each time it powers up. If an issue occurs, the error message appears in the Status area.

WARNING To ensure patient safety, listen for an audible indicator and watch for visual messages at power-up at least once daily. Correct any system errors before using the device. In addition to the audible indicator, the screen Status area displays icons and messages that help you to distinguish any actions, if needed.

WARNING Always observe the device during power-up. If any display fails to illuminate properly, or if a system fault code or message displays, inform qualified service personnel immediately, or call your nearest Hillrom Customer Service or Technical Support facility. Do not use the device until the problem is corrected.

CAUTION Always use the device with an adequately charged and properly functioning battery.

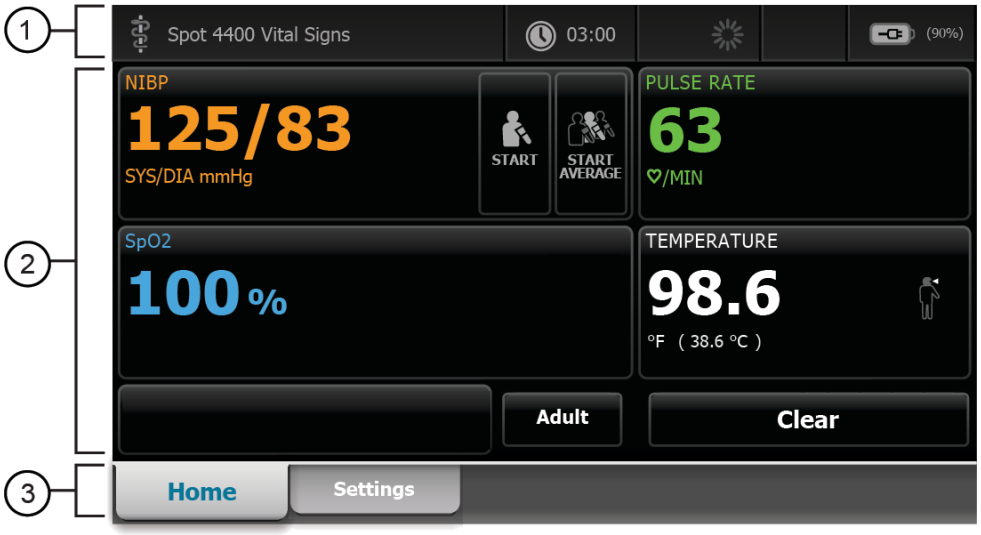
Press ⏻ to power up the device.

The power LED flashes until the device displays the brand logo and a power-up tone sounds. This process takes about 40 seconds. On initial power-up, the device prompts you to set the language, date, and time.

Primary screens

The device has primary screens and pop-up screens.

The primary screens have three sections:



	Item	Description
1	Status	Status area appears at the top of the screen and includes information regarding system-wide features.
2	Content	The Content area displays information determined by the primary — or global — navigation tab chosen at the bottom of the screen. The content area also might have vertical tabs on the left side of the screen that relate to the primary navigation tab chosen. It also can display summary information on current vital signs.
3	Primary navigation	The primary navigation tabs appear at the bottom of the screen.

Battery status

The battery status indicator displays the state of the battery.

The battery status is represented by icons in the upper-right corner of the device display. The status represents several possible situations.

- The device is connected to a power source and the battery is charging or is fully charged. The estimated charge rate is displayed as a percentage of capacity.
- The device is not connected to a power source and is running on battery power. The estimated charge time remaining is shown by a series of 0–4 bars and hours/minutes:
- The device is connected to a power source but the battery does not maintain a charge (or has been removed).

Icon	Description
	4 bars: Running on battery, battery charge is high; 76% - 100%; display time remaining (HH:MM)
	3 bars: Running on battery, battery charge is medium; 51% - 75%; display time remaining (HH:MM)
	2 bars: Running on battery, battery charge is low; 26% - 50%; display time remaining (HH:MM)
	1 bar: Running on battery, battery charge is very low; 11% - 25%; display time remaining (HH:MM)
	0 bars: Running on battery, battery charge is very low; 0% - 10% Display time remaining (HH:MM)

When the battery is not being recharged and power becomes low, a notification appears in the Status area.

NOTE Monitor the remaining battery charge in the battery status indicator and plug the device into a power outlet as soon as you are able.

If the notification is dismissed or if you take no action to charge the battery, a non-dismissible notification appears and sounds when battery power is critically low. Plug the device into a power outlet immediately to prevent the device from powering down.

Information and error messages

NOTE This device has no alarms.

When the device detects certain events, a notification appears in the Device Status area at the top of the screen. Below are the notification types.

- Information messages, which appear on a blue background.
- Error messages, which appear on a white background.

You can dismiss a notification by touching the message on the screen or, for some notifications, you can wait for the notification to time out. Some notifications are not dismissable and will persist as long as the applicable condition remains.

Refer to the Troubleshooting section for a complete list of information and error messages.

Caring for the Spot 4400 and accessories

While the Spot 4400 is in a patient's home, the patient is responsible for protecting the device from damage and for completing cleaning and disinfection tasks.

WARNING Electric shock hazard. Do not open the device or attempt repairs. The device has no user-serviceable internal parts. Only perform routine cleaning and disinfection specifically described in the Quick Reference.

Protecting the equipment

- Make sure the Spot 4400 is on a level surface where it won't be knocked over or damaged.
- Make sure the hoses, cables, and power cord do not cause a trip hazard.
- Keep the Spot 4400 and iPhone away from pets and children who may damage the equipment.

Cleaning and disinfection

Hillrom recommends you clean and disinfect the unit with Clorox disinfecting wipes when visibly soiled, prior to use on another person, and as instructed per facility protocol.

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.

Disinfecting 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 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. Do not clean or disinfect the EcoCuff blood pressure cuff. Replace it if soiled.
5. Remove the oximetry finger sensor for separate cleaning instructions according to the manufacturer's Instructions for use, which are provided.

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

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 visible 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.

Troubleshooting

This section presents tables of notification and error messages to help you troubleshoot issues on the device. Only the new content related to the at-home configuration is presented here.

To use these tables, locate the message that displays on the device in the left column of the table. The remainder of the row explains possible causes and suggests actions that can resolve the issue.

NOTE Instructions to "Call for service" in troubleshooting tables mean that you should contact qualified service personnel in your facility to investigate the issue. For issues with the device and its operation, contact Hillrom Technical Support at hillrom.com/en-us/about-us/locations/.

Communications messages

Bluetooth LE (BLE)

Bluetooth messages apply to Home Mode only.

Message	Possible cause	Suggested action
Bluetooth hardware error. 074010	Device detected a Bluetooth hardware and is not functional	Reboot device. If problem persists replace Bluetooth radio. If problem still present, replace main PCBA.
Bluetooth power on check failure. 074020	Device cannot detect a functional Bluetooth module.	Replace Bluetooth radio. If problem still present, replace main PCBA.
Bluetooth device successfully connected. 074030	Bluetooth connected	No action required.
Bluetooth device disconnected. 074040	Bluetooth not connected	Bluetooth client dropped the connection.
Bluetooth device not detected on startup in Home Mode. 074050	Bluetooth LE adapter not found on startup	Insert or replace the Bluetooth LE adapter.

Specifications

Physical specifications

Protection classifications, all device configurations	
Characteristic	**Specification**
Electrical rating	100 – 240 V AC, 50 – 60 Hz, 1.2A – 0.5 A
Duty cycle	Continuous operation
Design life	
Spot 4400 device	5 years (maintaining safety and performance)
Battery	300 full charge / discharge cycles
Nonin SpO2 sensor	1 year per manufacturer specifications
SureTemp temperature probe	1 year
Bluetooth dongle	5 years per manufacturer specification
EcoCuff	200 inflation cycles (single patient use)
Power supply	250,000 hours per manufacturer specifications
Shelf life	
Battery	Up to 1 year before installation
Other device components	None
Type of protection against electric shock	Class II internally powered
Degree of protection against electric shock, for parts applied to patients	Type BF defibrillator proof IEC EN 60601-1, 2nd and 3rd Editions
Recovery time following defibrillator discharge	Less than or equal to 15 seconds

Protection classifications, all device configurations	
Flammable anesthetics	**WARNING** Not suitable for use with flammable anesthetics.
Degree of protection provided by the enclosure with respect to harmful ingress of liquids	**IP22** Protected from ingress against solid foreign objects and against vertically falling water drops when enclosure tilted up to 15°
Height	10.1 in. (25.7 cm)
Width	9.3 in. (23.6 cm)
Depth	4.9 in. (12.4 cm)
Weight (including battery)	3.8 lb (1.7 kg)
Graphical display resolution	
Dimensional outline	6.5 in. (W) x 4.1 in. (H) x 0.13 in. (D) (164.9 mm [H] x 103.8 mm [W] x 3.40 mm [D])
Active area	6.1 in. (W) x 3.4 in. (H) (154.08 mm [W] x 85.92 mm [H])
Resolution	800 x 480 pixels

Environmental specifications

Operating temperature	50°F to 104°F (10°C to 40°C)
Operating altitude	-1250 to 10,000 ft. (-381 m to 3,048 m)
Operating humidity	15% to 90% noncondensing
Storage/Transport temperature	-4°F to 122°F (-20°C to 50°C)
Storage/Transport humidity	15% to 95% noncondensing

Configuration options

The at-home model of the Spot 4400 is available in a single configuration.

Model	Description
44WT-H	Nonin SpO2, SureTemp, NIBP, Bluetooth radio

Standards and compliance

General compliance and standards

The device complies with the following standards:

21 CFR Subchapter H – Medical Devices – US Food and Drug Administration
IATA DGR – International Air Transport Association Dangerous Goods Regulation
United Nations ST/SG/AC.10/11 – Manual of Tests and Criteria, Part III, Sub-Section 38.3
AAMI TIR69: 2017 – Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems
ANSI/IEEE C63.27: 2017 – American National Standard for Evaluation of Wireless Coexistence
AS/NZS IEC 60601-1
ASTM D 4332, E 1104
ASTM E 1112-00 (2018) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
CAN/CSA C22.2 NO.60601-1[1] CAN/CSA-C22.2 NO.60601-1-2
EN/IEC 60601-1, 60601-1-2, 60601-2-30, 62304, 80601-2-30, 62366, 60601-1-6, 60601-1-11
EN/ISO 13485, 14971, 80601-2-56, 80601-2-61, 81060-2
ISTA 2A
AAMI ES60601-1

NOTE All standards are used with their current amendments upon product release.

Storage and disposal

Home users should follow these steps to properly return the Spot 4400 and return or dispose of its accessories.

1. Follow the instructions in *Prepare the Spot 4400 for cleaning and disinfection* to clean and disinfect the device and accessories.
2. After cleaning and disinfecting the device and accessories, pack the Spot 4400, the stand, the thermometer, and the SpO2 sensor in the same box used to deliver the device to the home.
3. Dispose of all probe covers and blood pressure cuffs, even if you didn't use them. Do not return them to the medical facility.
4. Close the box tightly to enable safe return to the medical facility. If a shipping label was provided, you can return the device at a FedEx store in your area.

Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertain to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact Hillrom Technical Support for guidance on safe disposal protocols.

For more specific disposal or compliance information, see www.welchallyn.com/weee, or contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/.

Guidance and manufacturer's declaration

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. This device complies with IEC 60601-1-2:2014/EN 60601-2-1:2015.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in these tables and in the *Instructions for use*.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the device in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using the device in extremely close proximity to other equipment.

NOTE The Spot Vital Signs 4400 device has essential performance requirements associated with blood pressure measurement, oxygen saturation, and temperature measurement. In the presence of EM disturbances, the device displays an error code. Once the EM disturbances stop, the Spot Vital Signs 4400 device self-recovers and performs as intended.

WARNING Use only accessories and cables Welch Allyn recommends for use with the Spot Vital Signs 4400 device. Accessories and cables not recommended by Welch Allyn may affect the EMC emissions or immunity.

WARNING Maintain minimum separation distance of 12 inches (30 cm) between any part of the Spot Vital Signs 4400 device and portable RF communication equipment (including peripherals such as antenna cables and external antennas). Performance of the Spot Vital Signs 4400 device might degrade if proper distance is not maintained.

WARNING The use of the Spot Vital Signs 4400 device adjacent to or stacked with other equipment or medical electrical systems should be avoided because it could result in improper operation. If such use is necessary, the Spot Vital Signs 4400 and other equipment should be observed to verify that they are operating normally.

Emissions and immunity information

Electromagnetic emissions

The Spot 4400 device is intended for use in the electromagnetic environment specified below. The customer or user of the Spot 4400 device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Spot 4400 device 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.
Conducted and RF emissions CISPR 11	Class B	The emission characteristics of the Spot 4400 make it 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	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

The Spot 4400 device is intended for use in the electromagnetic environment specified below. The customer or the user of the Spot 4400 device should assure that 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	±8 kV contact ±15 kV air	±8 kV ±15 kV	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	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input/ output lines	±1 kV	
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line- to -line	±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
	±0.5 kV, ±1 kV, ±2 kV Line-to-ground	±2 kV	
Voltage dips, short interruptions and	100 % U_T; 0.5 cycle	0 % U_T; 0.5 cycle	Mains power quality should be that of a typical commercial or hospital

Electromagnetic immunity

voltage variations on power supply input lines IEC 61000-4-11	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°		environment. If the user of the Spot 4400 device requires continued operation during power mains interruptions, it is recommended that the Spot 4400 device be be powered from an uninterruptible power supply or a battery.
	100 % U_T; 1 cycle	0 % U_T; 1 cycle	
	70 % U_T; 25/30 cycles Single phase: at 0°	70 % U_T; 25/30 cycles	
	0 % U_T; 250/300 cycle	0 %U_T; 250/300 cycle	
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.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Electromagnetic immunity

The Spot 4400 device is intended for use in the electromagnetic environment specified below. The customer or the user of the Spot 4400 device should assure that 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 Spot 4400 device, 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 Vrms 150 kHz to 80 MHz	3 Vrms	$d = [\frac{3.5}{V_1}]\sqrt{P}$
	6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz.	6Vrms .	$d = [\frac{12}{V_2}]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/M, 80 MHz to 2.7 GHz	3 V/M	$d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz

Electromagnetic immunity				
			where *P* is the maximum output power rating of the transmitter in watts (W) and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note1: At 80 MHz and 800 MHz, 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.

Note 3: The device was tested to AIM 7351731 Rev 2.00: 2017-02-23 standard. The device passed all testing according to the standard. Test results are available by request.

[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 Spot 4400 device is used exceeds the applicable RF compliance level above, the Spot 4400 device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Spot 4400 device.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Spot 4400 device

The Spot 4400 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Spot 4400 device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Spot 4400 device as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)			
Rated max. output power of transmitter (W)	**150 kHz to 80 MHz outside ISM bands** $d = [\frac{3.5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2.7 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.37	0.63	0.38	0.73
1	1.17	2.00	1.20	2.30
10	3.69	6.32	3.79	7.27

Recommended separation distances between portable and mobile RF communications equipment and the Spot 4400 device

100	11.67	20.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance*d* in meters (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.

Test specifications for enclosure port immunity to RF wireless communications equipment

Test frequency (MHz)	Band [a] MHz	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation [b]	0.2	0.3	9

Test specifications for enclosure port immunity to RF wireless communications equipment		
5500	217 Hz	
5785		

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 percent duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 percent pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Accessories

Part number	Description
4400-HPS	Power supply for home use
PWCD-H	Line cord B, North America home use
4400-BLE	Bluetooth Low Energy dongle for home use
02895-000-NCE	Welch Allyn Oral Temperature Probe and Well Assembly for Monitors; 9.0 ft/2.7 m Cord; Blue
20500-251N-NCE	SureTemp probe covers (250 covers/25 box)

Service protection plans

Part number	Description
S1-4400-BPI-1	4400 SmartCare Protection BPI 1YR
S1-4400-BPI-3	4400 SmartCare Protection BPI 3YR

Literature/Documentation

Part number	Description
772265	Hillrom Connected Care Platform Quick Reference

Material No. 772263

Hillrom