Overview

This Quick Reference guides patients through the vitals capture process after initial setup and training in the hospital or clinic.

Welch Allyn Spot Vital Signs 4400 Device

Hillrom Connex Portal

Hillrom Connex App

Modifications to FDA cleared Intended use (Spot 4400) (modifications are underlined)

Intended use (Spot 4400)

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.

Modifications to Hillrom Connex App Intended use (modifications are underlined)

Intended use (Hillrom Connex App)

The Hillrom™ Connex® software is designed to collect, track, trend, and retrospectively transmit health information (e.g., blood pressure, SpO2, temperature, and pulse rate) from commercially available wireless FDA cleared medical in-home devices, and health and wellness devices, to an online (cloud) database. With user's consent, this information will be shared with a health care provider. The Hillrom Connex software 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 health care provider. It is not intended for emergency use or real-time monitoring.

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, the Addendum, and this 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, Addendum, and this Quick reference, visit hillrom.com.

Attention health care providers

To help patients with first-time setup of their iPhones, including pairing the iPhone with the Welch Allyn Spot Vital Signs 4400, go to page 15 of this Quick Reference.

Set up the Spot Vital Signs 4400 device and accessories

- Make sure the Spot 4400 is on a level surface where it won't be knocked over or damaged.
- Plug the Spot 4400 into an AC outlet.
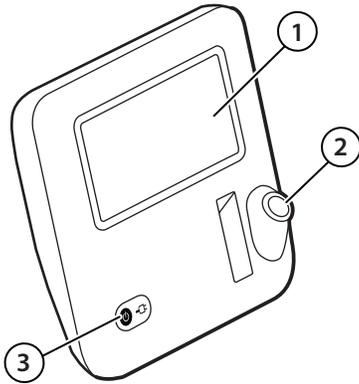 A green indicator light on the front of the unit and on the power brick light up.

⚠ **CAUTION** Do not use an extension cord to power the Spot 4400.

📖 **NOTE** The Spot 4400 includes a separate power supply unit as part of the Medical Electrical (ME) Equipment.

- Never move the Spot 4400 by pulling on any of the cords. This may cause the device to tip over or damage the cord.
- Never pull on the power cord when disconnecting the cord from the mains outlet. When disconnecting the power cord, always grasp the plug and pull the plug from the outlet.
- Keep the cord away from liquids, heat, and sharp edges.
- Make sure the hoses, cables, and power cord do not cause a trip hazard.
- Keep the Spot 4400 away from pets and children who may damage the equipment or suffer physical injury from falling equipment.

Controls, indicators, and connectors

1	LCD screen	7" color touchscreen
2	Thermometer probe well	Houses the SureTemp probe
3	Power button	• Powers on the device • Provides power options • Wakes up device from sleep mode
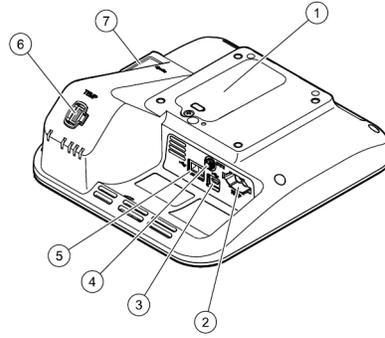
1	Battery compartment (behind stand)	Houses the battery
2	NIBP (blood pressure)	Connects the blood pressure hose to the Spot 4400
3	USB port	Provides a connection to an external computer or for the Bluetooth dongle
4	Power connection	Connects the power adapter to the device
5	USB port	Provides a connection to an external computer or for the Bluetooth dongle.
6	Thermometer	Connects the SureTemp probe to the device
7	SpO2 (pulse)	Connects the SpO2 sensor to the device

Screen indicators

1	Status	Includes battery status indicator
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

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 plugged in and is running on battery power. The estimated remaining battery time is shown as a percentage and a series of bars.
- The device is connected to a power source but the battery does not maintain a charge.

Bars	Description
▮▮▮▮	Running on battery, battery charge is high; 76% - 100%.
▮▮▮	Running on battery, battery charge is medium; 51% - 75%.
▮▮	Running on battery, battery charge is low; 26% - 50%.
▮	Running on battery, battery charge is very low; 11% - 25%.
▯	Running on battery, battery charge is very low; 0% - 10%.

When the battery is not being recharged and power becomes low, a notification appears in the Battery status indicator. Plug the device into a power outlet immediately to prevent the device from powering down.

Symbols in the Connex App

✳	Bluetooth	➕	Add
⚙	Settings menu, Advanced menu	♡	Pulse
⏰	Reminders	👤	Account
📱	Devices	🩺	Followers
i	About	?	Help
‹	Back	›	Move forward, Next

Power up the Spot 4400

Press the power button.

⏻ The power LED flashes until the device displays the brand logo and a power-up tone sounds.

When the device is on, the power button opens a dialog with controls to power down, enter sleep mode, or cancel out of the power menu. A blue light also appears on the Bluetooth dongle.

⚠ **WARNING** 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.

⚠ **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. Tap the **Settings** > **Device** tab to power down the device.

Start Vitals Capture

Launch the Hillrom Connex App on your phone

1. Tap the **Hillrom Connex** app on your phone 🏠.

2. Tap **New Vitals** to begin capturing your health information.
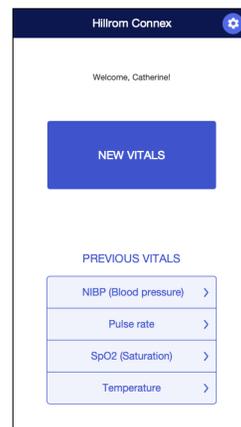
Capture NIBP/Blood pressure

NOTE If you have a cuff already wrapped and sized for your arm, just slide it onto your arm and skip the first 4 steps and start with step 5. Otherwise, follow each step in this section.

1. Put the blood pressure cuff on your bare upper arm.
2. Place the artery marker (**1**) over your brachial artery.
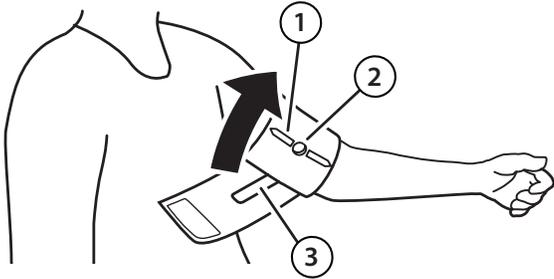
3. Apply the cuff snugly, allowing room for no more than two fingers underneath.
4. Wrap the Velcro, leaving the hose port (**2**) poking through the window (**3**).
5. Attach the blood pressure hose by pinching the connector sides and snapping it into the port.
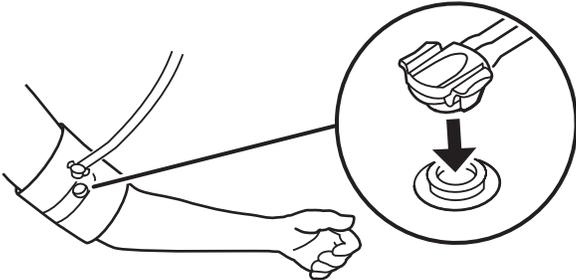
6. Take your blood pressure using the following guidelines for an accurate blood pressure.
   - Sit quietly for a few minutes.
   - Make sure your back and feet are supported and keep your legs uncrossed.
   - Keep your upper arm at heart level with the lower arm supported, i.e., resting on a table.
   - Keep your arm still during the measurement cycle.
7. On the Spot 4400, tap either **Start** or **Start Average** , as directed by your health care provider.
   Once the blood pressure cuff has deflated, the capture is complete.

Capture SpO2/Saturation and pulse rate

1. Clean the application site (ring finger, middle finger, or index finger of the opposite arm from where you placed the blood pressure cuff) for the SpO2 sensor. Remove anything, such as nail polish, that could interfere with sensor operation.

2. Put the SpO2 sensor on your finger, aligning your fingernail with the graphic on the top of the sensor.
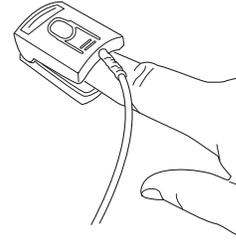
   Keep your arm at heart level.
3. Once the SpO2 reading is achieved on the Spot 4400, remove the SpO2 clip from your finger.
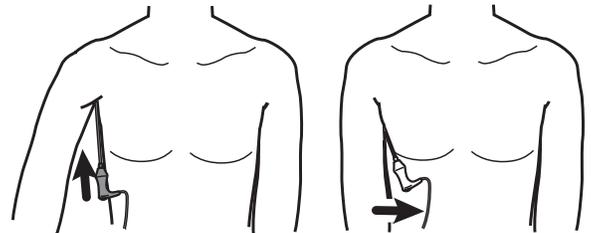
Capture temperature

NOTE Temperatures should not be taken within 20 minutes of strenuous exercise, ingesting hot or cold liquids, eating, chewing gum or mints, brushing teeth, or smoking.

1. Remove the temperature probe from the probe well.
   The device sounds a tone as it enters the ready state.
2. Insert the probe into a new probe cover and press the probe handle down firmly.
   - For an oral temperature, hold the probe tip in place under your tongue as shown below.

   - For an axillary temperature, hold your arm up and place the probe tip as high as possible in your armpit. Hold your arm snugly at your side while taking your temperature.

The device sounds a tone when the final temperature is obtained (in approximately 6 to 15 seconds).
3. Remove the probe and firmly press the eject button on the top of the probe to release the probe cover.
4. Dispose of the probe cover properly.
5. Return the probe to the probe well.

NOTE Your phone must have an internet connection and the **Hillrom Connex** App must be open to transmit your vitals to your health care provider.

Save and transmit vitals

1. Observe all completed vitals measurements on the Spot 4400.

2. On your phone, tap **Save** to transmit your vitals to your health care provider.

Review vitals

You can review your previous vitals (Blood pressure, Pulse rate, SpO2, or Temperature) and the last time your vitals data was sent to your health care provider.

1. Tap the **Hillrom Connex** app on your phone .
2. Tap any of the previous vital measurements to display them by date and timestamp.
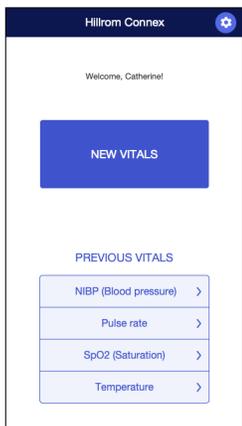
3. On the Home screen, tap the in the upper right corner.

   The *Settings* screen appears.

4. Tap your name in the header.
5. View the date and time of the **Last sync** to see the last time your vitals data was sent to your health care provider.

Delete vitals

You do not need to delete any vitals, but you can if you wish.

1. On the Hillrom Connex App, tap a previous vitals measurement.
2. Swipe the vitals record you want to delete.
3. Tap the **Delete** button.

Set up reminders

1. If you are not already logged in, open the Hillrom Connex App.
2. On the Home screen, tap the in the upper right corner.

   The *Settings* screen appears.

3. Tap **Reminders**.
   The *Reminders* screen appears. (**No reminders set** appears if you haven't set any reminders.)
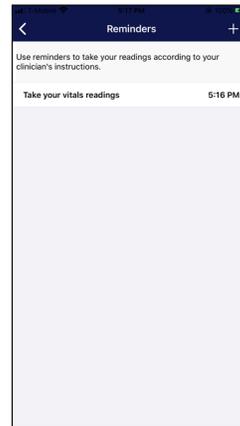
4. Tap the on the top right of the screen.

   The *Reminder* screen appears.

5. Tap the *Time* field and then use the clock tool to set the reminder time.
6. Tap **Save** to save the reminder or **Cancel** to reject it.

Cleaning and disinfection instructions

⚠️ **WARNING** Electric shock hazard. Before cleaning and disinfecting the device, disconnect the AC power cord from the mains outlet and the power source.
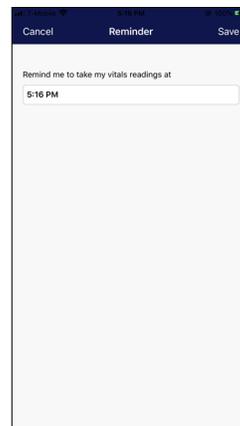
⚠️ **WARNING** Electric shock hazard. DO NOT immerse the device or accessories. The device and the accessories are not heat-resistant.

⚠️ **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.*

Prepare the Spot 4400 for 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 by your health care provider.

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 if soiled.
5. Remove the oximetry finger sensor for separate cleaning according to the manufacturer's instructions for use, which are provided.

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 thermometer probe and wipe entire probe.
4. Wipe cords, cables and stand (if present).
5. Discard any used wipe(s).
6. Wash 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 cord, cables and stand (if present). Make sure all wiped surfaces remain visibly wet for 4 minutes.
4. Discard any used wipe(s).
5. Wash hands thoroughly.

Questions?

Consult Help in the Hillrom Connex App under **Settings > Help.** If the Help does not answer questions about the device or the Connex App operation, contact Hillrom Technical Support at hillrom.com/en-us/about-us/locations/.

Warnings and Cautions

Warning and caution statements can appear on the device, on the packaging, and in this document. These statements are all about safety and avoiding risks of injury and equipment damage. This long list covers general use of the device, actions you should take, and actions you should avoid to protect yourself and get accurate vitals measurements.

Take some time to read over this list to avoid harm and have the best results with your device.

⚠️ **WARNING** The warning statements identify conditions or practices that could lead to illness, injury, or death.

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

General warnings and cautions

⚠️ **WARNING** Safety and inaccurate measurement risk. Use and store the device in a clean environment that avoids 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.).

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

⚠ **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** 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** Patient injury and inaccurate measurement risk. Do not operate the device while it is being carried or while moving it from one location to another.

⚠ **WARNING** Patient injury and inaccurate measurement risk. Do not change the device in any way. Changes may affect performance, safety, and accuracy.

⚠ **WARNING** Patient injury risk. Many factors can affect the accuracy and performance of the device. Your health care provider will let you know if your vital signs seem inaccurate and you need to do something different.

⚠ **WARNING** Personal injury risk. The power cord plug connects and disconnects the device from AC power. Make sure you can reach the outlet easily to plug in and unplug the device.

⚠ **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** Patient injury risk. Damaged cords, cables, and accessories can affect your safety. Never lift the device by the power supply cord or accessory cables. Inspect the power cord, blood pressure cuff, SpO2 cable, and other accessories for wear or damage. Replace as necessary.

⚠ **WARNING** Patient injury risk. Make sure the blood pressure hose has no kinks or sharp bends. The cuff and hose should not be pressed or pinched. Any of these problems may cause injury, system errors, or inaccurate measurements.

⚠ **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** Patient injury risk. Do not place the device anywhere that it might fall on you and hurt you.

⚠ **WARNING** Equipment failure and patient injury risk. Do not cover the air intake or exhaust vents on the rear and base of the device. Covering these vents could cause the device to overheat.

⚠ **WARNING** Equipment damage and personal injury risk. No modifications to the device are allowed by anyone other than a qualified Welch Allyn service representative. Modification of the device could be hazardous to patients and personnel.

⚠ **WARNING** Fire and explosion hazard. Do not operate the device in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide; in oxygen-enriched environments; or in any other potentially explosive environment.

⚠ **WARNING** Electric shock hazard. Do not open the device for any reason. Only perform cleaning and disinfection as described in this document.

⚠ **WARNING** Electric shock hazard. Do not insert anything into the ports or connectors on this device besides the accessories that came with the device.

⚠ **WARNING** Explosion or contamination hazard. Improper disposal of batteries may create an explosion or contamination hazard. Never put batteries in the trash. Always recycle batteries according to local regulations.

⚠ **WARNING** Use the device only as described in this document.

⚠ **WARNING** Inaccurate measurement risk. Do not expose to temperatures higher than 122º F (50º C).

⚠ **WARNING** Inaccurate measurement risk. Do not use the device if you are experiencing convulsions or tremors.

⚠ **WARNING** Liquids can damage electronics inside the device. Prevent liquids from spilling on the device. If liquids are spilled on the device:
1. Power down the device.
2. Disconnect the power plug.
3. Dry off excess liquid from the device.

   📓 **NOTE** If liquids possibly entered the device, do not use it again and contact your health care provider.

4. Reconnect the power plug.
5. Power on the device and verify that the device functions normally before using it.

⚠ **WARNING** The device might not function properly if dropped or damaged. Protect it from severe impact and shock. Do not use the device if you notice any signs of damage. Report any damage immediately to your health care provider.

WARNING Patient safety risk. Inaccurate measurement risk. Use only Hillrom- or Welch Allyn-approved accessories, and use them according to the manufacturer's directions for use.

WARNING Hillrom is not responsible for the integrity of your power supply. If the integrity of your power supply is in doubt, always operate the device on battery power alone when taking vitals measurements.

WARNING Electromagnetic interference risk. Avoid using the Spot 4400 device next to or stacked with other equipment or medical electrical systems. If such use is necessary, observe the Spot 4400 and other equipment to make sure they are operating normally.

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

WARNING Using accessories, transducers, and cables other than those specified may result in degraded electromagnetic compatibility performance, or increased emissions of this device.

WARNING Patient harm and equipment damage risk. Carefully route cords and cables to reduce the possibility of entanglement.

WARNING Strangulation risk. The cords and cables can wrap around your neck. When used on children or vulnerable people, the Spot 4400 device accessories must only be applied with special care and under permanent supervision. When used on adults, caution should be taken.

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. Small parts, such as the Bluetooth dongle, should never be placed in the mouth as they pose a choking risk.

CAUTION Before disassembling the device or installing options, disconnect from the device, power it down, and disconnect the AC power cord and any attached accessories (for example, SpO2 sensors, blood pressure hoses and cuffs, and temperature probes) from the device.

CAUTION United States Federal law restricts this device to sale, distribution, or use by or on the order of a physician or licensed health care professional.

CAUTION Electromagnetic interference risk. The device complies with applicable domestic and international standards for electromagnetic interference. These standards are intended to minimize medical equipment electromagnetic interference. Although this device is not expected to present problems to other compliant equipment or be affected by other compliant devices, interference issues still may occur. As a precaution, avoid using the device in close proximity to other equipment. In the event that equipment interference is observed, relocate the equipment as necessary or consult manufacturer's directions for use.

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

CAUTION If the touchscreen is not responding properly, refer to the troubleshooting section. If the problem cannot be resolved, discontinue using the device and contact your health care provider or Hillrom technical support.

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.

NIBP (blood pressure) warnings and cautions

WARNING Patient injury risk. If you had a mastectomy or lymph node clearance under one arm, place the blood pressure cuff on the other arm.

WARNING Do not apply cuff to areas where your skin is delicate or damaged, as this can cause further injury. Check the cuff site frequently for irritation.

WARNING Patient injury risk. Inaccurate measurement risk. Do not place the cuff where it can disturb proper circulation or where circulation is already compromised. Do not place the cuff on any extremity used for intravenous infusions. Do not place the cuff on any limb used for intravascular access or therapy, or that has an arterio-vascular (A-V) shunt. Watch your arms for anything that looks abnormal while using the device to take vital signs measurements.

WARNING Patient injury risk. Too frequent blood pressure measurements can result in blood flow interference. Follow the frequency measurement as prescribed by your health care provider.

WARNING Use only blood pressure cuffs and hoses supplied with the device to ensure safe and accurate NIBP measurements.

WARNING NIBP readings may be inaccurate for patients with certain conditions, such as moderate to severe arrhythmia, arterial sclerosis, poor perfusion, diabetes, pregnancy, pre-eclampsia, and renal diseases.

WARNING Inaccurate measurement risk. Pulse rate measurements generated through the blood pressure cuff or through SpO2 might not be as accurate as heart rate measurements from an ECG or taken by your health care provider.

WARNING Inaccurate measurement risk. Ensure an airtight seal at all connection points before use. Excessive leaking may affect readings.

WARNING Inaccurate measurement risk. Minimize blood pressure cuff movement and arm motion during readings. Excessive movement may alter readings.

WARNING Inaccurate measurement risk. Properly position the blood pressure cuff to ensure blood pressure accuracy.

WARNING Inaccurate measurement risk. For accurate readings, only use the blood pressure cuff when the artery index marker falls within the printed range indicated on the cuff.

WARNING The blood pressure cuff must be properly positioned to ensure blood pressure accuracy and safety. Wrapping the cuff too loosely (preventing proper inflation) may result in inaccurate readings.

CAUTION If a site other than the bare upper arm is used, the blood pressure measurement may be inaccurate.

CAUTION Correct sizing of the blood pressure cuff is important for accurate blood pressure readings. A cuff that is too small might provide false high readings, while a cuff that is too large might provide false low readings.

Temperature warnings and cautions

WARNING Patient injury risk. Do not exceed the recommended temperature measurement duration. Continuous measurement duration of 3 minutes at an oral site and 5 minutes at an axillary site are recommended for accurate measurement. Do not continuously measure beyond 10 minutes in either mode.

WARNING Patient injury risk. Always take a temperature measurement with a single-use probe cover securely attached. Failure to use a probe cover can cause cross-contamination and inaccurate temperature readings.

WARNING Patient injury risk. Inaccurate measurement risk. Do not use the thermometer if you notice any signs of damage to the probe or the instrument. If the thermometer probe is dropped or damaged, remove it from service and contact your health care provider.

WARNING Inaccurate measurement risk. Always take an axillary temperature with direct contact between the probe cover and the skin. Carefully place the probe, avoiding contact with other objects or material.

CAUTION Inaccurate measurement risk. Activities such as strenuous exercise, ingesting hot or cold liquids, eating, chewing gum or mints, brushing teeth, or smoking may affect oral temperature measurements for up to 20 minutes.

CAUTION Probe covers are disposable, nonsterilized, and single-use. Ensure that probe covers are disposed of properly.

SpO2 warnings and cautions

WARNING The accuracy of SpO2 measurements can be affected by any of the following:
- sensor not at heart level
- blood pressure cuffs, infusion lines, etc.
- moisture in the sensor
- improperly applied sensor
- residue (e.g. dried blood, dirt, grease, oil) on the finger
- artificial nails
- fingernail polish
- poor pulse quality
- anemia
- room brightness
- excessive motion
- high carbon monoxide levels

WARNING Patient injury risk. Inaccurate measurement risk. Do not use the SpO2 finger clip sensor and the blood pressure cuff on the same arm at the same time. The SpO2 reading could be inaccurate, or you might not capture SpO2 at all.

WARNING Inaccurate measurement risk. Severe anemia may cause inaccurate SpO2 readings.

WARNING Inaccurate measurement risk. Misapplied sensors or sensors that become partially dislodged may cause inaccurate SpO2 readings.

WARNING Inaccurate measurement risk. Venous congestion may cause inaccurate reading of actual arterial oxygen saturation. The sensor should not be below the level of your heart (e.g. your arm dangles toward the floor as you take a reading while in bed).

WARNING High-intensity extreme lights, such as pulsating strobe lights, directed on the SpO2 sensor may interfere with its ability to obtain vital sign readings.

WARNING Patient injury risk. The SpO2 sensor and cable are intended only for connection to pulse oximetry equipment. Do not attempt to connect these cables to a PC or any similar device. Always follow the manufacturer's directions for care and use of the sensor.

WARNING Patient injury risk. Incorrect SpO2 sensor application, or excessive pressure or duration of sensor use can cause tissue damage. Inspect the sensor site periodically.

CAUTION Exercise caution when applying an SpO2 sensor to a damaged or injured finger.

CAUTION Do not modify or alter the SpO2 sensor in any way. Alterations or modification may affect performance and/or accuracy.

Troubleshooting

Issue	Probable cause	Suggested action
Bluetooth hardware error. 074010	Device detected a Bluetooth hardware and is not functional.	Contact your health care provider or Hillrom Technical Support.
Bluetooth power on check failure. 074020	Device cannot detect a functional Bluetooth module.	
Bluetooth device successfully connected. 074030	Bluetooth connected	No action required.
Bluetooth device disconnected. 74040	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	Contact your health care provider or Hillrom Technical Support.
I cannot pair the Spot 4400 with my phone OR A "Connection failed" message appears when I try to pair	Bluetooth is not active on the phone	Open Bluetooth settings on the phone and turn on Bluetooth.
	You tried to pair the device with your phone using the phone's Bluetooth settings	Once the phone's Bluetooth is turned on, pair the device and the phone using the Hillrom Connex App.
	The Spot 4400 is too far away from your phone	Move the phone closer to the device. The phone should be no more than 5 feet away from the Spot 4400.
	The initial Bluetooth pairing is no longer functioning	1. Delete the Spot 4400 from the Hillrom Connex App. 2. Re-pair the Spot 4400 with your phone using the Hillrom Connex App.
		1. Delete the pairing to the Spot 4400 from the iOS settings. 2. Re-pair the Spot 4400 with your phone.
	The Bluetooth dongle is loose	1. Power down the Spot 4400. 2. Unplug the Bluetooth dongle in the back of the Spot 4400 and plug it back in. 3. Delete the pairing to the Spot 4400 from the iOS settings. 4. Re-pair the Spot 4400 with your phone.
I forgot my password OR Login failed	Varies	Tap **Forgot password?** on the Hillrom Connex App *Login* screen. Follow the instructions to reset your password.

Issue	Probable cause	Suggested action
I did not receive a password reset email	Your email address is not established in the Hillrom Connex system	Make sure that the email address used to request the password reset is the same as the address used to sign up for the Hillrom Connex App. You might need to confirm your email address with your health care provider.
	A different or incorrect email address was used to sign you up	

📖 **NOTE** If the wrong email address was used to sign you up, your health care provider will have to sign you up again. No patient email addresses can be edited in the Hillrom Connex system.

Issue	Probable cause	Suggested action
The Spot 4400 screen is dark	Device is not on	1. Plug in the Spot 4400 and charge it. 2. Press the power button a bit longer and wait for two beeps.
The Spot 4400 turned itself off	Normal operation	Use the power button to turn on the device.
The Hillrom Connex App collected the readings but did not send them to my health care provider	The smartphone's WiFi connection is out of range or failed transmission	Refer to the smartphone manual. Set your smartphone to the correct transmission mode.
	The smartphone is out of cellular range or failed transmission	Refer to the smartphone manual. Relocate the smartphone. If it is out of WiFi range, switch to cellular.
	The cellular connection has been turned off on the smartphone	Refer to the smartphone manual. Relocate the smartphone. If it is out of cellular range, switch to WiFi.
	The Hillrom Connex App was closed before the data was sent.	Make sure the smartphone is connected to either a WiFi or a cellular connection and open the Hillrom Connex App.
How do I know my data is going to my health care provider?	Varies	In the Hillrom Connex App, go to **Settings** > **Account**, and look at the *Last Sync* time and date. If it is old, make sure the smartphone is connected to either a WiFi or cellular connection, and open the Hillrom Connex App.
I'm not sure my readings were saved	Varies	In the Hillrom Connex App, select one of the *Previous Vitals* options and check the date and time of the readings.

Issue	Probable cause	Suggested action
My Hillrom Connex App is not working properly	The smartphone or app is in a bad state	Close and reopen the Hillrom Connex App.
		Refer to the smartphone manual. Restart the smartphone.
		Uninstall and re-install the Hillrom Connex App, following your phone's manual.
My temperature does not stay on the screen when I return the probe to the probe well.	The thermometer is in Direct mode (indicated by a snail icon on the screen).	Return the probe to the probe well and try again.
		The thermometer is too warm. Return the probe to the probe well and try again in a few minutes.
		The ambient temperature is too warm, preventing the probe from reaching a predictive mode-ready state. Open the Connex App and select **New Vitals** to see the temperature appear in the app. Allow the temperature reading to stabilize and press **Save**.
No data transferred from the device to the Hillrom Connex App	Bluetooth for the device is not properly turned on, connected, or programmed	Make sure Bluetooth is properly programmed.
		Open the Hillrom Connex App before taking vitals readings.
I can't read an SpO2	The clip is not on properly or the fingernail is not clean	Reposition the clip.
		Use your index finger on your left hand.
		Make sure your fingernail polish is removed.
I can't read a temperature	Varies	Consult the Welch Allyn Spot 4400 Instructions for Use under **Settings** > **Help** > **Take an oral temperature**.
I've run out of probe covers	Varies	Call your health care provider.
My blood pressure cuff gets too painful	Cuff is too tight	Always stop a blood pressure reading if the pressure is too much. Undo the Velcro on the cuff and reapply as instructed.
		Consult Help in the Hillrom Connex App under **Settings** > **Help** > **Take a blood pressure**.

Issue	Probable cause	Suggested action
System setup or maintenance questions	If the Connex App Help does not answer questions about the device or the Connex App operation, contact Hillrom Technical Support.	
Unexpected operation or events		
The device malfunctions		

NOTE The Hillrom Connex App must be open to successfully capture readings from the device.

For more information

Scan the following code to go to the Hillrom Extended Care Solution resource page.

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Health Care Provider Instructions

Before the patient arrives

1. Assemble equipment (see 772264, Welch Allyn Spot 4400 Assembly Instructions).
2. Set up the patient in the Hillrom Connex Portal (see 800267324, Hillrom Connex Portal Instructions for Use) on the Hillrom Extended Care Solution resource page.

3. Send an email to the patient with the temporary password.

During the patient visit

1. Review the Quick Reference with the patient.
2. Instruct the patient to enable Bluetooth on the their iPhone.
3. Assist the patient as needed with the following steps on their iPhone.
   a. Go to the App Store and download the **Hillrom Connex App** .
   b. Accept the Terms and Conditions.
   c. Enter email address.
   d. Confirm the demographics.
   e. Save the new account.
      An email is sent with login credentials.
   f. Follow the instructions in the email and/or any additional setup steps.

The account is ready to take the first measurement.

Reminders

Demonstrate how to set up reminders on the iPhone (see page 3).

Demonstrate vitals capture

1. Walk through the instructions for capturing vitals (pages 2 and 3) with the patient.
2. Perform a vitals capture with the patient.
   a. Tap **New Vitals** to begin capturing the patient's health information.
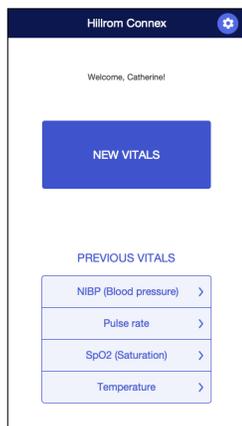
   b. If this is the first time the application is attempting to pair with the Spot 4400, a **Pairing Request** message appears.
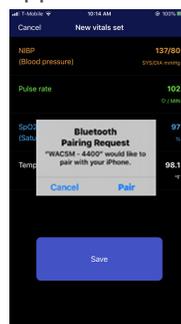
   c. Tap **Pair**.
      A successful pairing message appears on the Spot 4400.

      When the first vitals measurement is taken, the Hillrom Connex App automatically pairs the phone to the Spot 4400.
3. Complete the vitals capture instruction as shown on page 3.

Review

1. Walk through the instructions for reviewing vitals (page 2) with the patient.
2. Instruct the patient on what to do if there's a problem.
   a. Show how to access **Help**. On the Home screen, tap the in the upper right corner.

      The *Settings* screen appears.
3. Show the patient the **Troubleshooting** section on page 10.
4. Review the care and cleaning of the Spot 4400 and accessories (page 6).
5. Provide contact information and other notes for patient below.

Health care provider contact information/notes

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