Hillrom™

# Welch Allyn®
# Spot Vital Signs 4400


## Instructions for use

### Software version 1.X

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This manual applies to # 901057 Vital Signs Device.

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153 USA

CE 0297

Authorized Australian Sponsor
Welch Allyn Australia Pty. Ltd.
1 Baxter Drive
Old Toongabbie NSW 2146
Australia

EC REP and EU IMPORTER
Welch Allyn Limited
Navan Business Park
Dublin Road
Navan, Co. Meath
C15 AW22
Ireland

hillrom.com

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

EAC

Authorized Representative for
Kazakhstan
TOO Orthodox Pharm
Uly Dala Avenue 7/4, apt 136
Nur-Sultan 010000 Kazakhstan

Hillrom™

# Contents

# Introduction

This manual describes the capabilities and operation of the Welch Allyn® Spot Vital Signs 4400 (device). The information, including the illustrations, pertains to a device configured with noninvasive blood pressure (NIBP), body temperature, pulse oximetry (SpO2), and pulse rate. If your device configuration lacks any of these options, some information in this manual might not apply.

Before using the device, read the sections of the manual that pertain to your use of the device.

## Intended use

The Welch Allyn Spot Vital Signs 4400 (device) is intended to be used by medical professionals for operator initiated spot-check/single measurement of noninvasive blood pressure, pulse rate, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO2), and body temperature in oral, rectal and axillary modes of adult and pediatric patients down to 29 days of age. The intended use locations for patients to be measured are physician's offices, general hospital and alternate care environments.

## Contraindications

This device is not intended to be used:

- for use on neonates.
- for unattended monitoring.
- for patient transport.
- for use in the home healthcare environment.

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

# Symbols and definitions

## Documentation symbols

For information on the origin of these symbols, see the Welch Allyn symbols glossary: https://www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80022/80022945LITPDF.pdf.

| | |
|---|---|
|  | **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. |
|   | Follow instructions/directions for use (IFU) -- mandatory action.<br>A copy of the IFU is available on this website.<br>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 |

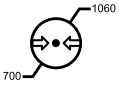
| | | | |
|---|---|---|---|
|  | Alternating current (AC) |  | Rechargeable battery |
|  | Rated power input, DC |  | Rated power input, AC |
| **Li-ion** | Lithium-ion battery |  | Protective Earth (PE) |

## Connectivity symbols

| | |
|---|---|
|  | USB |

## 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. |
| IPX2 | IP = International Protection Marking<br>X = No object ingress rating<br>2 = Protected against vertically falling water drops when enclosure tilted up to 15° |  | Call for maintenance |
|  | This way up |  | Fragile |

| | | | |
|---|---|---|---|
| EC REP | Authorized Representative in the European Community | | This device has no alarms. |
|  | Temperature limit | GTIN | Global Trade Item Number |
|  | Stacking limit by number |  | Keep dry |
|  | Humidity limitation |  | Atmospheric pressure limitation |
| MD | Medical Device | $R_x$ ONLY | Prescription only or "For Use by or on the order of a licensed medical professional" |
|  | Non-ionizing electromagnetic radiation | | |

# Mobile stand symbols

| | | | |
|---|---|---|---|
|  | Maximum safe working load limits |  | Mass in kilograms (kg) |
|  | **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. | | |

# Screen symbol

| | |
|---|---|
|  | Process indicator for activities like acquiring measurements and connecting to a laptop |

# 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

**WARNING** Patient injury risk. Many environmental variables, including patient physiology and clinical application, can affect the accuracy and performance of the device. Therefore, you must verify all vital signs information, especially NIBP and SpO2, before treating the patient. If there is any question about the accuracy of a measurement, verify the measurement using another clinically accepted method.

**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** Patient injury risk. Damaged cords, cables, and accessories can affect patient and operator safety. Never lift the device by the power supply cord or patient connections. Routinely inspect the AC power cord, blood pressure cuff, SpO2 cable, and other accessories for strain relief wear, fraying, or other damage. Replace as necessary.

**WARNING** Patient injury risk. During defibrillation, keep discharge paddles away from device sensors and other conductive parts in contact with the patient.

**WARNING** Patient injury risk. Any external compression of the blood pressure hose or cuff or kinked tubing may cause patient injury, system errors, or inaccurate measurements.

**WARNING** Patient injury risk. Wash hands to reduce the risk of cross-contamination and nosocomial infection.

**WARNING** Patient injury risk. Do not place the device in any position that might cause it to fall on the patient.

**WARNING** Patient injury risk. Do not place the cuff on the arm on the same side of a mastectomy or lymph node clearance. If necessary, use the femoral artery in the thigh to take a measurement.

**WARNING** Patient injury risk. Inaccurate measurement risk. Do not place the cuff where it can disturb proper circulation. Do not place the cuff on any area where circulation is compromised or on any extremity used for intravenous infusions. Do not place the cuff on any limb where intravascular access or therapy, or an arterio-vascular (A-V) shunt is present. Observe the limb concerned to ensure that operation of the device does not result in prolonged impairment of circulation.

**WARNING** Patient injury risk. Inaccurate measurement risk. Do not use an SpO2 finger clip sensor and a blood pressure cuff simultaneously on the same limb. Doing so may cause a temporary loss of pulsatile flow, resulting in either no reading or an inaccurate SpO2 or pulse rate until the flow returns.

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

**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 overheating of the device.

**WARNING** This equipment is not suitable for use in the presence of electro-surgery.

**WARNING** For operator and patient safety, peripheral equipment and accessories that can come in direct patient contact must comply with all applicable safety, EMC, and regulatory requirements.

**WARNING** Equipment damage and personal injury risk. When transporting the device on a mobile stand, properly secure all patient cables and cords to keep them clear of the wheels and to minimize trip hazards.

**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. This equipment must only be connected to a supply mains with protective earth.

**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 maintenance procedures specifically described in this manual while the device is not in use on a patient. Inspection and servicing of internal parts shall only be performed by qualified service personnel.

**WARNING** Electric shock hazard. All signal input and output (I/O) connectors are intended for connection of only devices complying with IEC 60601-1, or other IEC standards (for example, IEC 60950), as applicable to the device. Connecting additional devices to the device may increase chassis or patient leakage currents. Measure the leakage currents to confirm that no electric shock hazard exists.

**WARNING** Explosion or contamination hazard. Improper disposal of batteries may create an explosion or contamination hazard. Never dispose of batteries in refuse containers. Always recycle batteries according to local regulations.

**WARNING** Use the device only as described in this instructions for use. Do not use the device on patients as described in the Contraindications.

**WARNING** Inaccurate measurement risk. The device is not intended for use during patient transport outside of the medical facility. Do not use the device to take measurements on any patient in transit.

**WARNING** Inaccurate measurement risk. Do not connect more than one patient to a 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** Inaccurate measurement risk. Do not expose to temperatures higher than 122º F (50º C).

**WARNING** Inaccurate measurement risk. Do not use the device on patients who are on heart-lung machines.

**WARNING** Inaccurate measurement risk. Do not use the device on patients who 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. Remove battery pack from the device.
4. Dry off excess liquid from the device.

   **NOTE** If liquids possibly entered the device, remove the device from use until it has been properly dried, inspected, and tested by qualified service personnel.

5. Reinstall battery pack.
6. Reconnect the power plug.
7. Power on the device and verify that the device functions normally before using it.

**WARNING** The device may 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. Qualified service personnel must check any device that is dropped or damaged for proper operation before putting the device back into use.

**WARNING** Defective batteries can damage the device. If the battery shows any signs of damage or cracking, it must be replaced immediately and only with a battery approved by Welch Allyn.

**WARNING** Personal injury risk. Improper handling of the battery can lead to heat generation, smoke, explosion or fire. Do not short-circuit, crush, incinerate, or disassemble the battery. Never dispose of batteries in refuse containers. Always recycle batteries according to national or local regulations.

**WARNING** Use only Welch Allyn approved accessories, and use them according to the manufacturer's directions for use. Using unapproved accessories with the device can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

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

**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.

**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** Use of accessories, transducers, and cables other than those specified may result in degraded electromagnetic compatibility performance of this device.

**WARNING** Use of accessories, transducers, and cables other than those specified may result in increased emissions or decreased immunity of the device.

**WARNING** Patient harm and equipment damage risk. Carefully route patient cords and cables to reduce the possibility of patient entanglement. When transporting the Spot Vital Signs device on a mobile stand, properly secure all patient cords and cables to keep them clear of the wheels and to minimize trip hazards.

**WARNING** Strangulation risk. The cords and cables can wrap around the patient's neck. When used on children or vulnerable patient populations, the Spot Vital Signs 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 the patient's mouth when taking oral temperatures. When inserting the probe tip inside the mouth of a patient, ensure that the probe cover remains on the probe tip to avoid the risk of the patient choking on the probe cover. When using on children or vulnerable patient populations, the Spot Vital Signs 4400 device must only be used with special care and under permanent supervision. When used on adults, caution should be taken.

**WARNING** Verify the patient vitals data for each entry on the Spot Vital Signs 4400 device before transferring patient records.

**CAUTION** This device is not intended for use in the home healthcare environment.

**CAUTION** Do not operate the device in the presence of magnetic resonance imaging (MRI) or hyperbaric chambers.

**CAUTION** Electric shock hazard. Do not sterilize the device. Sterilizing the device could damage 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 healthcare 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** Do not move the stand while the power source is plugged into the mains outlet.

**CAUTION** Do not sterilize the device. Sterilizing the device could harm the device.

**CAUTION** Use only a Class I (grounded) AC power cord to charge the power source for the device.

**CAUTION** Never move the device or mobile stand 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 attachment plug. Keep the cord away from liquids, heat, and sharp edges. Replace the power cord if the strain relief, cord insulation, or metal prongs are damaged or begin to separate from the attachment plug.

**CAUTION** Do not exceed the maximum weight limits for your mobile stand with basket or bins. See the "Specifications" section for the basket/bins and mobile stand maximum weight limits.

**CAUTION** Use only the Welch Allyn USB client cable to connect a laptop computer to the USB client port. Any laptop connected to the device must be running on a battery, a 60601-1 compliant power supply, or a 60601-1 compliant isolation transformer.

**CAUTION** If the touchscreen is not responding properly, refer to the troubleshooting section. If the problem cannot be resolved, discontinue use of the device and contact an authorized Welch Allyn service center or qualified service personnel.

**CAUTION** If the device stops operating within its design specifications, remove it from service and have it inspected by a qualified service person.

## Residual risk information

This product complies with relevant electro-magnetic interference, mechanical safety, performance, and biocompatibility standards. However, the product cannot completely eliminate potential patient or user harm from the following:

- Harm or device damage associated with electro-magnetic interference,
- Harm from mechanical hazards,
- Harm from device, function, or parameter unavailability,
- Harm from misuse error, such as inadequate cleaning, and/or
- Harm from device exposure to biological triggers that may result in a severe systemic allergic reaction.

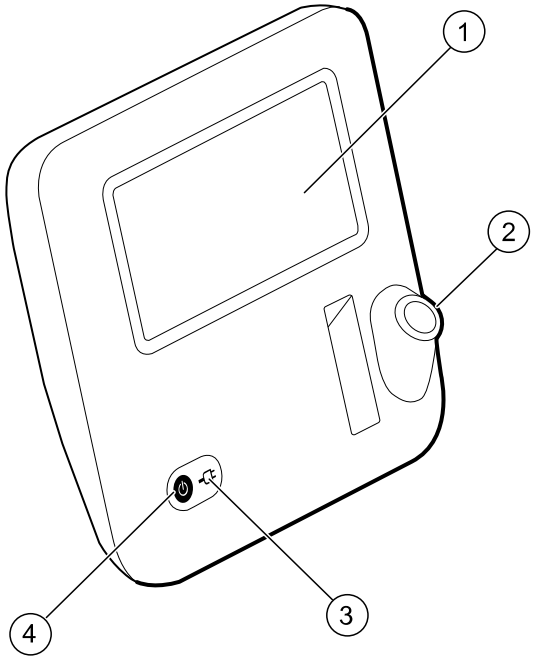
## Adverse event reporting statement (notice to users and/or patients)

Notice to Users and/or Patients in EU: Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

# Controls, indicators, and connectors

**NOTE** Your model might not contain all of these features.

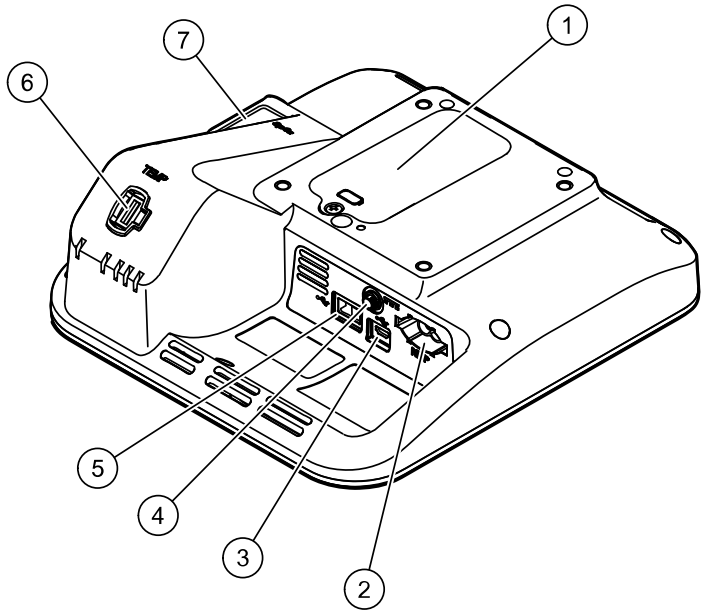
**Front-Left view**




| No. | Feature | Description |
|---|---|---|
| 1 | LCD screen | 7" color touchscreen provides a graphical user interface |
| 2 | Thermometry probe well | Houses the SureTemp probe on the device |
| 3 | Battery charge and power-up status indicator | The LED indicates the charging and power-up status when connected to AC power:<br>• Green: The battery is charged<br>• Amber: The battery is charging<br>• Flashing: The device is powering up |

| No. | Feature | Description |
|---|---|---|
| 4 | Power button | Blue button on lower-left corner of the device:<br>• Powers on the device<br>• Provides power options for the device<br>• Wakes up the device from Sleep mode |

**Back-Bottom-Left view**




| No. | Feature | Description |
|---|---|---|
| 1 | Battery compartment (behind cover) | Houses the battery (captive screw secures cover to device) |
| 2 | NIBP | Connects the NIBP hose to the device |
| 3 | USB client port | Provides a connection to an external computer for testing, software upgrades, and connectivity |
| 4 | Power connection | Connects the power adapter to the device |
| 5 | USB port | Connects a USB drive to the device for saving log files |
| 6 | Thermometry | Connects the SureTemp probe to the device |
| 7 | SpO2 | Connects the SpO2 sensor to the device |

# Setup

## Supplies and accessories

For a list of all approved supplies and accessories, see "Approved Accessories" in the Appendix.

**WARNING** Patient injury risk. Clean all accessories, including cables and tubes, before storing the accessories on the device or cart. This helps reduce the risk of cross contamination and nosocomial infection. Refer to 'Clean the equipment' in "Maintenance and service" for directions.

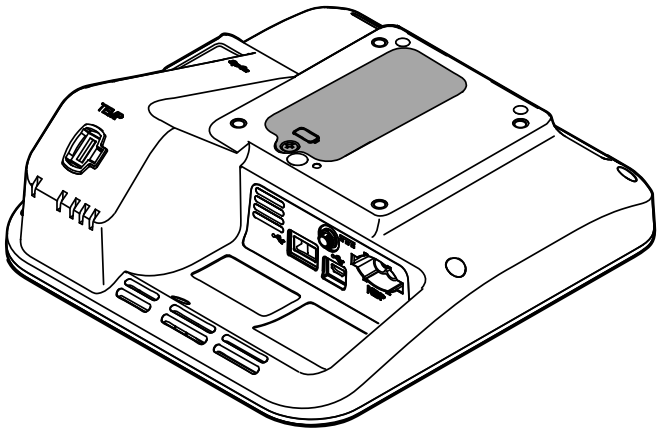
## Connect the battery

This procedure applies to first-time setup of the device. The battery is inserted in the battery compartment when you receive a new device. However, it is not connected.

**WARNING** Personal injury risk. Improper handling of the battery can lead to heat generation, smoke, explosion, or fire. Do not short-circuit, crush, incinerate, or disassemble the battery. Never dispose of batteries in refuse containers. Always recycle batteries according to national or local regulations.

**WARNING** Use only Welch Allyn approved accessories, and use them according to the manufacturer's directions for use. Using unapproved accessories with the device can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

1. Set the device on a flat surface with the screen facing downward to access the battery cover.



2. Locate the battery cover, indicated by on the back of the device.
3. Using a double-slotted screwdriver, loosen the captive screw at the base of the battery cover, and then remove the cover.
4. Remove the battery to access the battery connection port on the device.
5. Insert the battery connector into the battery connection port on the device.
6. Insert the battery into the battery compartment.
7. Replace the battery cover, and then tighten the captive screw at the bottom of the battery cover.

**NOTE** Do not over-tighten the screw.

# Mount the device

The Spot Vital Signs 4400 device can be mounted on either the mobile stand, desk stand, or wall mount. Follow the assembly instructions or instructions for use included with your device.

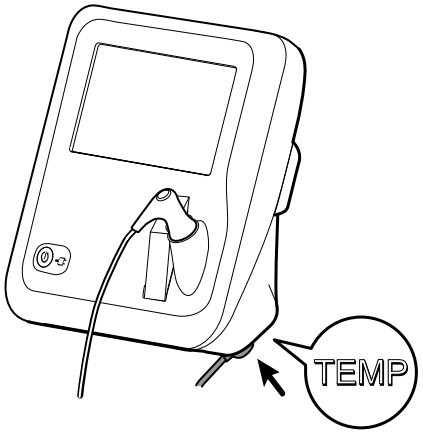
## Connect AC power to a power source

You can use the device with power from the mains outlet. Battery power can be used after charging the battery.

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

# Attach the temperature probe

1. Insert the probe well into the front of the device.
2. Insert the SureTemp probe into the probe well.
3. Attach the SureTemp probe connector to the bottom of the device.




4. In the compartment to the left of the probe well, insert a Welch Allyn probe cover carton.

# Connect the NIBP hose

1. Place your thumb and forefinger on the hose connector spring tabs and squeeze firmly.
2. Align the hose connector with the hose connector port on the bottom of the device.
3. Insert the hose connector, pressing firmly until both of the spring tabs click into place.

# Disconnect the NIBP hose

1. Place your thumb and forefinger on the hose connector spring tabs.

   **NOTE** Always grasp the hose by the connector spring tabs. Do not pull on the hose itself.

2. Squeeze the spring tabs firmly and pull until the connector releases.

# Connect the SpO2 cable

**WARNING** Patient injury risk. Do not use a damaged sensor or pulse oximetry cable or a sensor with exposed electrical or optical components.

1. On the rear of the device, align the SpO2 cable connector with the cable connector port.
2. Insert the cable connector, pressing firmly until the connector is seated.

# Disconnect AC power

**CAUTION** Never move the device or mobile stand 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 attachment plug. Keep the cord away from liquids, heat, and sharp edges. Replace the power cord if the strain relief, cord insulation, or metal prongs are damaged or begin to separate from the attachment plug.

Grasp the power line plug and pull the plug from the mains outlet.

# Startup

## 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.

### Power up the device

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

**CAUTION** Use only a Class I (grounded) AC power cord to charge the battery for this device.

Press ⏻ to power up the device.

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

### Set the date and time

1. Touch the **Settings** tab.
2. Touch the **Date / Time** vertical tab.
3. Touch either the ▲ or ▼ keys or the key pad, set the date and time.

**NOTE** The date and time stamps on saved patient measurements will adjust when you change the date and time settings.

### Change the language

Refer to "Advanced Settings" in the *Service manual* for instructions on how to change the language.

## Power down the device

When the device is functioning normally, use this method to power down. This method retains patient measurements in the device memory for a maximum of 24 hours. Saved measurements are available for recall or electronic transmission to the network. This method also ensures that any configuration settings you have changed and saved will be maintained at the next startup.

1. Do one of the following to access the power menu:
   - Briefly press ⏻.
   - Touch **Settings** > **Device** > **Power down**.

   If there is no system message, a dialog box appears with options to Power down, Sleep, and Cancel.
2. Touch **Power down**.

   The device clears all data onscreen and performs a complete software shutdown.

## Reset the device

Reset the device only when the device becomes unresponsive. Patient data and configuration settings will be cleared from device memory.

1. Press and hold ⏻, located on the lower-left corner of the device.
2. If there is a prompt with options to Power down, Sleep, or Cancel, continue to press ⏻ for several seconds.

   The device powers down. Patient data and configuration settings are cleared from device memory.
3. Press ⏻ to power up the device.

## Sleep mode

The device enters sleep mode after a period of inactivity. You can also manually put the device into sleep mode.

Different types of inactivity have different time delays:

- When a configurable amount of time has passed since the last screen press
- The sensor modules are not being used to capture vitals

Two actions wake the device from sleep mode:

- The power button is pressed.
- The screen is tapped.

### Enter Sleep mode

1. Press .

   If there is no system message, a dialog box appears with options to Power down, Sleep, and Cancel.

2. Touch **Sleep.**

   The device enters Sleep mode. The battery continues to charge in sleep mode.

To wake the device from sleep mode, press the power button or tap the screen.

## Common screen functionality

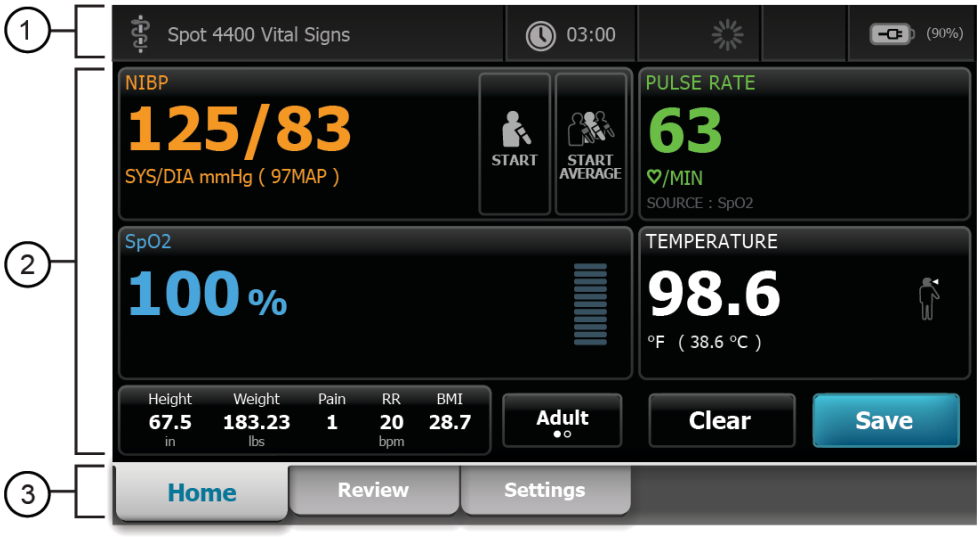
Many parameter areas on the screen allow you to enter data. Touch an icon to perform the function noted.

| Icon | Description |
|---|---|
|  | **Numeric keypad** for entering numeric information. |
|  | **Back key** to delete data starting at the right side of the data being entered. |
|   | **Next key** captures the data entered, clears the data field, and advances to the next data field for data entry. |
|   | **OK key** captures entered data and closes keypad or keyboard being used to enter data. |
|   | **Cancel key** closes the keypad or keyboard without capturing entered data. |

## 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).

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

| Bars | Description |
|---|---|
| 0 | 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.

# Pop-up screens

When a pop-up screen appears, you cannot access any buttons or controls on the screen behind the pop-up. The specified action on the pop-up screen must be accomplished or, if allowed, actively dismissed or canceled, before other screens become active.

There are instances when multiple, layered pop-up screens occur. In these instances, only the top pop-up screen is accessible. The specified action on the top pop-up screen must be accomplished or, if allowed, actively dismissed or canceled, before the pop-up screen behind becomes active.

# Navigation

There are four types of navigation in the device:

- Primary tabs
- Vertical tabs
- Command buttons
- Shortcuts

## Primary tabs

The primary tabs at the bottom of the screen enable you to switch between tabs and change the controls in the content area on the device. The tab you choose determines what information appears on the screen. The three primary tabs are:

- Home
- Review
- Settings

## Vertical tabs

The vertical tabs on the left side of the screen enable you to navigate to additional areas of a primary tab. The vertical tabs displayed are determined by the primary tab chosen.

## Command buttons

Command buttons, such as the Height or Weight buttons, enable you to navigate and perform actions.

## Shortcuts

Shortcuts provide an efficient means of navigation. For example, touching the battery area in the status bar enables you to navigate to Settings [**Settings > Device > Date/Time**] and displays more information about that portion of the device.

## Home tab

The Home tab displays patient information:

- Status area, including notifications and battery status
- Patient type
- NIBP
- SpO2
- Pulse rate
- Temperature
- Action area, including Clear and Save
- Additional parameters

## Review tab

The Review tab displays saved patient data, including core vital signs and additional parameters. Each row of data shows the date and time at which the data were saved. The Review tab also provides the option to delete patient data.

**NOTE** Patient data will be deleted after 24 hours, or after the device is reset.

# Settings tab

The Settings tab enables you to edit certain device functions. It contains vertical navigation tabs:

- Averaging
- Date / Time
- Device
- Advanced

## Adjust screen brightness

The screen can be adjusted to 10 levels of brightness. Adjust screen brightness in the Device tab in Settings.

1. On the Settings tab, touch **Device**.
2. In the Brightness area, touch ▲ or ▼ to brighten or dim the screen.

# Patient vitals

## NIBP

Located in the upper-left corner of the Home tab, the NIBP frame contains data and features relevant to noninvasive blood pressure measurement.

**WARNING** Patient injury risk. Do not install luer connectors on blood pressure tubing. Using luer connectors in manual or automated blood pressure systems creates the risk of inadvertent connection to intravenous (IV) tubing, which can introduce air into the patient's circulatory system.

**WARNING** Patient injury risk. Any external compression of the blood pressure hose or cuff or kinked tubing may cause patient injury, system errors, or inaccurate measurements.

**WARNING** Patient injury risk. Too frequent measurements can result in blood flow interference. Measurement frequency is at the discretion of the trained clinician using the equipment.

**WARNING** Patient injury risk. The decision to use the device on pregnant or pre-eclamptic patients is at the discretion of the trained clinician using the equipment.

**WARNING** Use only blood pressure cuffs and hoses listed as approved accessories to ensure safe and accurate NIBP measurements.

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

**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 are subject to artifact and might not be as accurate as heart rate measurements generated through ECG or through manual palpation.

**WARNING** Patient injury risk. Inaccurate measurement risk. Do not place the cuff where it can disturb proper circulation. Do not place the cuff on any area where circulation is compromised or on any extremity used for intravenous infusions. Do not place the cuff on any limb where intravascular access or therapy, or an arterio-vascular (A-V) shunt is present. Observe the limb concerned to ensure that operation of the device does not result in prolonged impairment of circulation.

**WARNING** Patient injury risk. Inaccurate measurement risk. Do not use an SpO2 finger clip sensor and a blood pressure cuff simultaneously on the same limb. Doing so may cause a temporary loss of pulsatile flow, resulting in either no reading or an inaccurate SpO2 or pulse rate until the flow returns.

**WARNING** Patient injury risk. Do not place the cuff on the arm on the same side of a mastectomy or lymph node clearance. If necessary, use the femoral artery in the thigh to take a measurement.

**WARNING** Possible measurement error. Use only Welch Allyn blood pressure cuffs and accessories; substitution may result in measurement error.

**WARNING** Inaccurate measurement risk. Do not use the device or accessories in environments affected by extremes of temperature, humidity, or altitude. See "Environmental specifications" for acceptable operating conditions.

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

**WARNING** Inaccurate measurement risk. Minimize 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. Only use the cuff when the artery index marker falls within the printed range indicated on the cuff; otherwise, erroneous readings will result.

# NIBP measurements

At the start of a measurement, the device inflates the cuff to the appropriate level. In the NIBP frame, the systolic display shows the cuff inflation pressure while the blood pressure measurement is in progress.

**NOTE** The Pediatric mode gives you the option of setting a lower initial inflation pressure when using the StepBP deflation and not SureBP.

The device measures blood pressure as the cuff is inflating. If patient movement, excessive noise, or an arrhythmia prevent the device from determining the blood pressure while the cuff is inflating, the device attempts to measure the blood pressure while deflating the cuff.

## NIBP measurement display

When the measurement is complete, the NIBP frame displays the measurement until you save it, or until you start another NIBP measurement. If any NIBP measurement is out of range or cannot be determined, the NIBP frame shows a "++" or "- -" in front of the measurement. All other NIBP parameters display no values.

The frame can display systolic and diastolic measurements, and MAP calculations. Touch the NIBP frame to toggle between SYS/DIA and MAP views.You can configure the default view in Advanced settings.

# Cuff selection guidelines

Properly measure the arm to determine the appropriate cuff size.

## Measuring guidelines

- Measure the circumference of the patient's bare upper arm, midway between the elbow and shoulder.
- If the circumference of the patient's arm falls between two cuff sizes, use the larger cuff size.
- When the cuff is wrapped around the patient's arm, verify that the artery index marker lies somewhere between the two range markings on the cuff.

## One-piece cuff measurements

| Cuff Size | Circumference (cm) | Circumference (in) |
|---|---|---|
| Infant | 9.0 – 13.0 | 3.5 – 5.1 |
| Small child | 12.0 – 16.0 | 4.7 – 6.3 |
| Child | 15.0 – 21.0 | 5.9 – 8.3 |
| Small adult | 20.0 – 26.0 | 7.9 – 10.2 |
| Adult | 25.0 – 34.0 | 9.8 – 13.4 |
| Large adult | 32.0 – 43.0 | 12.6 – 16.9 |
| Thigh | 40.0 – 55.0 | 15.7 – 21.7 |

# Position the cuff

**NOTE** The device and cuffs were validated using the bare upper arm site.

**WARNING** Patient injury risk. Inaccurate measurement risk. Do not place the cuff where it can disturb proper circulation. Do not place the cuff on any area where circulation is compromised or on any extremity used for intravenous infusions. Do not place the cuff on any limb where intravascular access or therapy, or an arterio-vascular (A-V) shunt is present. Observe the limb concerned to ensure that operation of the device does not result in prolonged impairment of circulation.

**WARNING** Patient injury risk. Inaccurate measurement risk. Do not use an SpO2 finger clip sensor and a blood pressure cuff simultaneously on the same limb. Doing so may cause a temporary loss of pulsatile flow, resulting in either no reading or an inaccurate SpO2 or pulse rate until the flow returns.

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

**CAUTION** If a site other than the bare upper arm is used, the blood pressure measurements may be different. It is important to document the alternate site on the patient record.

Before positioning the cuff, ensure that you have selected the appropriate cuff size.

The device uses the oscillometric method to determine blood pressure; therefore, if the cuff extends to the antecubital fossa (bend in the elbow), you can still acquire an accurate blood pressure reading.

1. Check the cuff for residual air from a previous measurement. Squeeze the cuff as needed to completely deflate the cuff.
2. Position the cuff on the patient's bare upper arm midway between the shoulder and the elbow.
3. Wrap the cuff snugly so that there is room for no more than two fingers between the cuff and the patient's bare upper arm.
4. Position the alignment mark on the cuff directly over the brachial artery.
5. Ensure that the blood pressure tubing has no kinks or twists.

**NOTE** In situations where you cannot position the cuff level with the heart, you should adjust the measurements as follows for greater accuracy. For each inch (2.54 cm) that the cuff is above the level of the heart, add 1.8 mmHg to the displayed reading. For each inch (2.54 cm) that the cuff is below the level of the heart, subtract 1.8 mmHg from the displayed reading. It is important to document the adjustment on the patient record.

**NOTE** For additional guidance addressing best practices for taking blood pressure measurements, see Tips for Taking Accurate Blood Pressure Readings on the Hillrom website.

## Obtain a single NIBP measurement

**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.

**CAUTION** To minimize inaccurate measurement, limit patient movement during an NIBP measurement cycle.

Before you begin, select the appropriate cuff size and properly position it around the patient's bare upper arm. Ensure that the patient is comfortably seated, legs are uncrossed, feet are flat on the floor, back and arm are supported, and the cuff is level with the patient's heart.

To obtain an accurate resting blood pressure reading, wait 5 minutes to begin this procedure.

1. Optionally, touch the NIBP frame to change between SYS/DIA and MAP views.
2. If necessary, touch **Adult** to change the mode to Pediatric.
3. Touch **START** to begin a single measurement.

   A STOP button appears. NIBP always displays the current cuff pressure. When complete, the NIBP measurement will continue to be displayed until you save it or you start another NIBP measurement.

## Cancel an NIBP measurement

In the NIBP parameter, touch **STOP**.

The device cancels the NIBP measurement and an information message appears informing you that the NIBP reading was stopped and that no reading was captured.

# Averaging

The Averaging program enables you to record the patient's average NIBP readings over a set period of time.

## Start Averaging

The averaging program takes consecutive NIBP measurements within a configurable amount of time. When the program is complete, the average measurement is displayed on the Home tab.

**NOTE** You can configure NIBP Averaging program settings in Advanced settings.

1. Place the proper cuff around the patient's bare upper arm.
2. On the Home tab, touch **START AVERAGE**.

   After a short delay, the first measurement begins. Each measurement is displayed in the history list.
3. If necessary, touch **Skip** to stop the current measurement.

   When touched, the current measurement stops and a countdown timer starts. Once the timer ends, the measurement is recaptured. The averaging program continues as normal.
4. If necessary, touch **Cancel** to stop Averaging. If measurements were taken, you must choose to save or discard the data.
   - To save a single measurement, select the measurement and touch **Save**.
   - To save multiple measurements, select the measurements and touch **Average**. Then touch **Save** on the Home tab.
5. When the program is complete, touch **Save** to save the patient data, or touch **Clear** to discard the data.

**NOTE** Patient data will be deleted after 24 hours, or after the device is reset.

# Temperature

## General temperature warnings and cautions

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

**WARNING** Patient injury risk: The decision to use this device with children, or pregnant or nursing women is at the discretion of the trained clinician using the equipment.

**WARNING** Inaccurate measurement risk. To ensure optimal accuracy, always confirm that the correct mode and site are selected.

**WARNING** Patient injury risk. Do not exceed the recommended temperature measurement durations in Direct mode. Continuous measurement durations of 3 minutes at the oral and rectal sites and 5 minutes at the axillary site are recommended for accurate measurement. Do not continuously measure beyond 10 minutes in any 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 patient cross-contamination and inaccurate temperature readings.

**WARNING** Patient injury risk. Probe covers are single-use. Reusing a probe cover can cause patient cross-contamination.

**WARNING** Patient injury risk. Always remain with patient while measuring temperature.

**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 have it inspected by a qualified service person.

# Temperature frame

From the temperature frame you can measure patient temperature.

Located in the lower right corner of the Home tab, the temperature frame contains data and features relevant to temperature measurement.

## Temperature measurement display

The frame displays the temperature in Celsius and Fahrenheit. You can configure the default view in Advanced settings.

## Site selection

Remove the temperature probe and touch the **Temperature site control** to toggle between sites.

| Icon | Description |
|---|---|
|  | Pediatric axillary |
|  | Adult axillary |

| Icon | Description |
|---|---|
|  | Oral |
|  | Rectal. Devices configured with the temperature module and the red rectal probe well and probe default to the rectal mode. |

### Temperature buttons

The button on the right side of the frame enables you to use Direct mode.

| Icon | Button name | Description |
|---|---|---|
|  | Direct mode | Touch the button to enter Direct mode. |

## SureTemp® Plus temperature module

The temperature module uses a thermistor thermometer design and a predictive algorithm to calculate patient temperatures in the Predictive mode.

**WARNING** Patient injury risk. Do not exceed the recommended temperature measurement durations in Direct mode. Continuous measurement durations of 3 minutes at the oral and rectal sites and 5 minutes at the axillary site are recommended for accurate measurement. Do not continuously measure beyond 10 minutes in any mode.

**WARNING** Patient injury risk. Inaccurate measurement risk. Oral/axillary probes (blue ejection button at top of probe) and blue removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red removable probe wells are used for taking rectal temperatures only. Use of the incorrect removable probe well could result in patient cross-contamination. Use of the probe at the wrong site will result in temperature errors.

**WARNING** Patient injury risk. When taking rectal temperatures, insert the probe tip a maximum of 5/8 inch (approximately 1.5 cm) inside the rectum of adults and a maximum of 3/8 inch (approximately 1 cm) inside the rectum of children to avoid the risk of bowel perforation.

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

**WARNING** Patient injury risk. Always take a temperature measurement with a Welch Allyn single-use probe cover securely attached. Failure to use a probe cover can cause patient discomfort from a heated probe, patient cross-contamination, and inaccurate temperature readings.

**WARNING** Inaccurate measurement risk. To ensure optimal accuracy, always confirm that the correct mode and site are selected.

**WARNING** Never use a damaged temperature probe. The thermometer consists of high-quality precision parts and should be protected from severe impact or shock. Do not use the thermometer if you notice any signs of damage to the probe or device. If the thermometer probe is dropped or damaged, remove it from use and have it inspected by qualified service personnel.

**WARNING** Inaccurate measurement risk. For rectal measurements, apply a thin layer of lubricant to probe cover, if necessary, for patient comfort. Use of excessive lubricant may affect reading accuracy.

**CAUTION** Inaccurate measurement risk. Patient 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** Inaccurate measurement risk. Always use new probe covers taken from the device's probe cover box holder to ensure accurate temperature measurements. Probe covers taken from other places or that haven't stabilized in temperature may result in inaccurate temperature measurements.

**CAUTION** Probe covers are disposable, nonsterilized, and single-use. Probes are also nonsterilized. Do not autoclave probes and probe covers. Ensure that probe covers are disposed of according to facility requirements or local regulations.

## Temperature mode selection

The device takes a patient temperature in either Predictive (Normal) or Direct mode. The default setting is the Predictive mode.

### Predictive mode

Predictive mode is a one-time measurement that takes a temperature in approximately 6-15 seconds. Removing the probe from the probe well, loading a probe cover, and holding the probe tip in place at the measurement site initiates a Predictive mode measurement. The device sounds a tone to indicate the end of a predictive measurement.

### Direct mode

Direct mode provides continual temperature measurements. For oral and rectal measurements, it is recommended to measure temperature until the temperature stabilizes or for 3 minutes. For axillary measurements, it is recommended to measure temperature until the temperature stabilizes or for 5 minutes. The device changes to Direct mode approximately 60 seconds after the probe is removed from the probe well.

**CAUTION** The device does not retain Direct mode temperatures in memory. For temperature measurements that are within normal range, it is important to note the temperature before removing the thermometer probe from the measurement site and then manually record it in the patient record. Once the temperature probe is returned to the well, the temperature measurement is removed from the Home tab.

After 10 minutes of using the Direct mode, the device stops updating the measurement, generates a notification, and clears the measurement.

## Take a temperature in the Predictive mode

**WARNING** Inaccurate measurement risk. To ensure optimal accuracy, always confirm that the correct mode and site are selected.

**CAUTION** Probe covers are disposable, nonsterilized, and single-use. Probes are also nonsterilized. Do not autoclave probes and probe covers. Ensure that probe covers are disposed of according to facility requirements or local regulations.

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.
3. Touch **Temperature site control** to select the measurement site: oral, pediatric axillary, adult axillary, or rectal.
4. Hold the probe tip in place at the measurement site.

   While the measurement is being obtained, the temperature frame displays the process indicator.

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

   The temperature frame continues to display the temperature in degrees Fahrenheit and degrees Celsius until the measurement is saved, cleared, or a new temperature measurement begins.

## Take a temperature in the Direct mode

Direct mode displays the temperature of the probe as long as the probe tip remains in place at the measurement site and remains within the operating patient temperature range. The patient's measured temperature will reach equilibrium in approximately 3 minutes at the oral and rectal measurement sites and approximately 5 minutes at the axillary site.

The device enters Direct mode by the following methods.

- After you complete a Predictive mode measurement, touch  to change from Predictive to Direct mode. The temperature frame in the lower-left corner changes to "MODE: Direct..." as it switches to the Direct mode.
- Remove the probe from the probe well, load a probe cover, select a temperature site, and expose the probe to ambient air for more than 60 seconds. The temperature frame changes to "MODE: Direct...".

- If you have a patient whose body temperature is below the normal temperature range and you follow the previous step, the probe sensor identifies this condition and turns off the probe preheater in order to accommodate the lower body temperature measurement.

**WARNING** Inaccurate measurement risk. To ensure optimal accuracy, always confirm that the correct mode and site are selected.

**WARNING** Patient injury risk. Do not exceed the recommended temperature measurement durations in Direct mode. Continuous measurement durations of 3 minutes at the oral and rectal sites and 5 minutes at the axillary site are recommended for accurate measurement. Do not continuously measure beyond 10 minutes in any mode.

**CAUTION** Probe covers are disposable, nonsterilized, and single-use. Probes are also nonsterilized. Do not autoclave probes and probe covers. Ensure that probe covers are disposed of according to facility requirements or local regulations.

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.
3. Touch **Temperature site control** to select the measurement site: oral, pediatric axillary, adult axillary, or rectal.

   The temperature frame changes to Direct mode approximately 60 seconds after the probe is removed from the probe well.

   The device sounds a tone to indicate the start of a Direct mode measurement.
4. Hold the probe tip in place at the oral or rectal measurement site for a total of 3 minutes and at the axillary site for 5 minutes.
5. While the measurements are being obtained, the temperature frame displays the patient's continuous temperature measurements in degrees Fahrenheit and degrees Celsius.

**NOTE** The device does not retain Direct mode temperatures in memory. Therefore, it is important to note the temperature before removing the probe from the measurement site and then manually record it in the patient record.

6. Remove the probe after the temperature measurement is obtained and firmly press the eject button on the top of the probe to release the probe cover.
7. Return the probe to the probe well to continue taking temperatures in the Predictive mode.

# SpO2

The SpO2 equipment is calibrated to display functional oxygen saturation of arteriolar hemoglobin, and measures the pulse rate in a patient through a pulse oximeter. The SpO2 sensors provided by Nonin for use with the device have been tested for biocompatibility in accordance with ISO 10993-1.

For signal processing and other specifications, refer to the manufacturer's directions for use.

## SpO2 frame

The SpO2 frame displays data and the controls used in pulse oximetry measurements.

The frame provides a numeric view and a waveform view of SpO2 data. You can toggle between views by touching the left side of the frame.

The SpO2 frame remains blank if no SpO2 measurement has been acquired.

### SpO2 numeric view

The numeric view indicates the SpO2 saturation percentage and the pulse amplitude. The SpO2 saturation is displayed as a percentage between 0 and 100%. The SpO2 reading is updated and refreshed each second, ± 0.5 seconds.

The pulse amplitude bar indicates the pulse beat and shows the relative pulse strength. More bars illuminate as the detected pulse gets stronger.

**NOTE** Absence of activity of the pulse amplitude bar indicates that the sensor is not applied to a patient or the sensor is defective. Refer to the Troubleshooting section for a complete list of information and error messages.

### SpO2 waveform view

The SpO2 waveform updates in real-time. For additional specifications, refer to the sensor manufacturer's directions for use.

## Measure SpO2 and pulse rate

The SpO2 equipment is calibrated to display oxygen saturation and pulse rate. The SpO2 saturation is displayed as a percentage range from 0 to 100%. The oxygen saturation and pulse rate are updated and refreshed each second, ± 0.5 seconds.

**WARNING** Inaccurate measurement risk. Severe anemia may cause erroneous SpO2 readings.

**WARNING** Inaccurate measurement risk. The pulse oximeter can be used during defibrillation, but the readings may be inaccurate for up to 20 seconds.

**WARNING** Inaccurate measurement risk. Misapplied sensors or sensors that become partially dislodged may cause either over or under reading of actual arterial oxygen saturation.

**WARNING** Inaccurate measurement risk. Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from the measurement site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a bed with arm dangling to the floor).

**WARNING** Inaccurate measurement risk. Use only Nonin sensors and accessories on Nonin-equipped devices.

**WARNING** Inaccurate measurement risk. Patient injury risk. Verify sensor, cable, and pulse oximeter compatibility before use.

**WARNING** Patient injury risk. Do not attempt to reprocess, recondition, or recycle any sensors or patient cables. Doing so might damage electrical components.

**WARNING** Patient injury risk. The pulse oximeter is NOT intended for use as an apnea device.

**WARNING** Patient injury risk. Do not use tape to secure the finger clip sensor to the site; this can restrict blood flow and cause inaccurate readings. Use of additional tape can cause skin damage or damage the sensor.

**WARNING** When using the flex sensor, always use new tape to secure the sensor to the measurement site. Flex sensor tape is single-use only.

**WARNING** Unless otherwise specified, do not sterilize sensors or patient cables by irradiation, steam, autoclave or ethylene oxide.

**WARNING** Patient injury risk. Loss of pulse signal can occur when the patient has severe anemia or hypothermia.

**WARNING** SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

**WARNING** High-intensity extreme lights, such as pulsating strobe lights, directed on the sensor may not allow the pulse oximeter to obtain vital sign readings.

**WARNING** Use the pulse oximeter as an early warning device. As you observe a trend toward patient hypoxemia, use laboratory instruments to analyze blood samples to better understand the patient's condition.

**WARNING** The accuracy of SpO2 measurements can be affected by any of the following:

- excessive ambient light
- excessive motion
- electrosurgical interference
- arterial catheters, blood pressure cuffs, infusion lines, etc.
- moisture in the sensor
- improperly applied sensor
- carboxyhemoglobin
- residue (e.g. dried blood, dirt, grease, oil) in the light path
- artificial nails
- incorrect sensor type
- poor pulse quality
- venous pulsations
- anemia or low hemoglobin concentrations
- cardiovascular dyes
- sensor not at heart level
- dysfunctional hemoglobin
- fingernail polish

**CAUTION** If using pulse oximetry during full body irradiation, keep the sensor out of the irradiation field. If the sensor is exposed to the irradiation, the reading might be inaccurate or the unit might read zero for the duration of the active irradiation period.

**CAUTION** Exercise caution when applying a sensor to a site with compromised skin integrity. Applying tape or pressure to such a site may reduce circulation and/or cause further skin deterioration.

**CAUTION** If the Low Perfusion message is frequently displayed, find a better perfused measuring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

**CAUTION** Circulation distal to the sensor site should be checked routinely.

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

This device can be used with Nonin finger clip sensors, or with Nonin flex sensors and tape. Before you begin this procedure, consult the manufacturer's directions for use for selecting the correct sensor type.

**NOTE** Observe all warnings and cautions in the sensor manufacturer's directions for use, and always follow the manufacturer's directions for care and use of the sensor.

**NOTE** If a sterile sensor is required, select a sensor that has been validated for sterilization, and follow the sensor manufacturer's directions for sterilizing the sensor.

**NOTE** Do not use flex sensors on patients who have allergic reactions to the adhesive.

To take an SpO2 measurement:

1. Verify that the sensor cable is connected to the device.

   **WARNING** Patient injury risk. The sensor and extension 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.

2. Clean the application site. Remove anything, such as nail polish, that could interfere with sensor operation.
3. Attach the sensor to the patient according to the manufacturer's directions for use, observing all warnings and cautions.

   **NOTE** Place the sensor and the NIBP cuff on different limbs to reduce unnecessary errors when you measure these parameters at the same time.

4. Confirm that the device displays SpO2 and pulse rate data within 6 seconds after connecting the sensor to the patient.

   **WARNING** Patient injury risk. Incorrect sensor application, or excessive pressure or duration of sensor use can cause tissue damage. Inspect the sensor site periodically as directed in the sensor manufacturer's instructions.

While SpO2 is being measured, the displayed pulse rate is acquired from the sensor. If SpO2 is not available, the pulse rate is acquired from NIBP. The device identifies SpO2 or NIBP as the pulse rate source.

**NOTE** Do not use the device for continuous SpO2 monitoring. Once a measurement is obtained, remove the sensor from the patient.

# Enter vitals measurements manually

1. Press and hold a frame, such as **NIBP**.

   A pop-up dialog box appears. If additional parameters are enabled, these are displayed on the right.
2. On the left, touch an empty field and enter the measurement.
3. Touch **OK.**
4. When you are finished entering vitals measurements manually, touch **OK** to return to the Home tab.

   The measurements appear on the Home tab. The frame displays "SOURCE: Manual" to indicate that a measurement was entered manually.

# Additional parameters

Additional parameters are core measurements that you can enter physically on the device, such as height, weight, respiration, and pain.

**NOTE** Body mass index (BMI) is automatically calculated when height and weight are entered.

## Enter additional parameters

1. On the Home tab, touch the **Additional Parameters** frame.

   A pop-up dialog appears. Additional parameters are displayed on the right.
2. Using either the keypad or ▲ or ▼, manually enter the patient height, weight, respiration rate, or pain level.

   If height and weight are entered, BMI will be automatically calculated and displayed on the Home tab.
3. Touch **OK** to close the keypad dialog.
4. When you are finished entering patient information, touch **OK**.
5. Touch **Save** to save the data.

**NOTE** Patient data will be deleted after 24 hours, or after the device is reset.

# Save patient data

You can save vitals measurements and additional parameters to the device. The saved data is accessible from the Review tab for up to 24 hours.

1. Collect all vitals measurements and enter additional parameters as needed.
2. From the Home tab, touch **Save**.

   The device sounds two audible indicators and the notification "Save Successful" appears at the top of the screen.
3. Touch the **Review** tab to verify that settings were saved.

   The patient data appears on a row with the date and time at which you saved the data.

**NOTE** Patient data will be deleted after 24 hours, or after the device is reset.

# Advanced settings

Consult the *Spot Vital Signs 4400 Service manual* for Advanced settings.

# Maintenance and service

## Perform periodic checks

1. Verify the following at least daily:
   - The audio tone, especially at startup
   - The touchscreen alignment
   - The date
   - The time
2. Visually inspect the following at least weekly:
   - The device for any damage or contamination
   - All cables, cords, and connector ends for damage or contamination
   - All mechanical parts, including covers, for integrity
   - All safety-related labeling for legibility and adhesion to the device
   - All accessories (cuffs, tubing, probes, sensors) for wear or damage
   - Documentation for current revision of the device
3. Visually inspect the following at least monthly:
   - The mobile stand wheels for wear and faulty operation
   - The mounting screws on wall units or stands for looseness and wear

Update settings, replace items, or call for service as necessary, based on results from a visual inspection. Do not use the device if you see any signs of damage. Qualified service personnel must check any device that is damaged for proper operation before putting the device back into operation.

## Recommended service intervals

To confirm that the device is functioning within design specifications, perform periodic service as indicated in the following table. The device has no specific use time limitation. The device may remain in service until repair is required or operation indicates that it is out of calibration.

Customers who have the Standard unlicensed edition of the Welch Allyn Service Tool can perform the basic functional verification procedures referenced in the table. Refer to the *Spot Vital Signs 4400 Service manual* for instructions.

| Component | Service interval | Service procedure |
|---|---|---|
| NIBP module | Annually | Basic functional verification |
| SpO2 module | Annually | Basic functional verification |

| Component | Service interval | Service procedure |
|---|---|---|
| SureTemp Plus | Annually | Basic functional verification |
| Battery | Semi-annually[1] | Replace the battery |

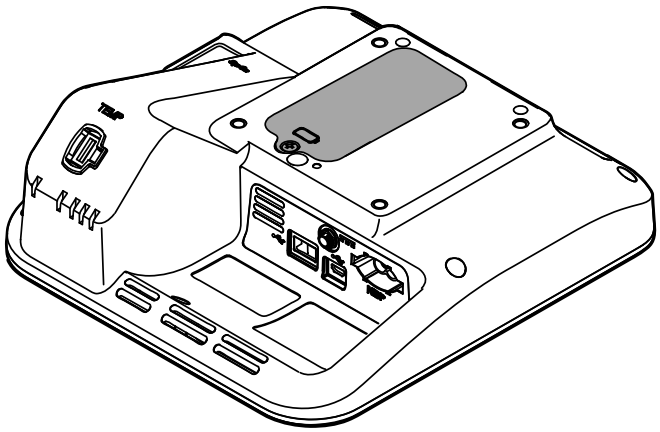
[1] Battery performance is a function of clinical use and charge/discharge patterns. Welch Allyn recommends replacing the battery after six months or when its remaining capacity no longer meets workflow requirements.

# Replace the device battery

**WARNING** Personal injury risk. Improper handling of the battery can lead to heat generation, smoke, explosion or fire. Do not short-circuit, crush, incinerate, or disassemble the battery. Never dispose of batteries in refuse containers. Always recycle batteries according to national or local regulations.

**WARNING** Use only Welch Allyn approved accessories, and use them according to the manufacturer's directions for use. Using unapproved accessories with the device can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

1. Set the device on a flat surface with the screen facing downward to access the battery cover.



2. Locate the battery cover, indicated by .
3. Using a double-slotted screwdriver, loosen the captive screw at the base of the battery cover, and then remove the cover.
4. Remove the old battery from the battery compartment.
5. Disconnect the battery connector from the battery connection port on the device.
6. Insert the battery connector for the new battery into the battery connection port on the device.
7. Insert the new battery into the battery compartment.
8. Replace the battery cover, and then tighten the captive screw at the bottom of the battery cover.

**NOTE** Do not overtighten the screw.

# Cleaning requirements

This section presents procedures for cleaning the device (including the device, stand, accessories, and accessory basket and bins).

Welch Allyn has validated these instructions to be capable of preparing your device and above accessories for re-use. Clean on a routine basis according to your facility's protocols and standards or local regulations.

**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.

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

**WARNING** Electric shock hazard. DO NOT immerse or autoclave 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.

**CAUTION** Do not sterilize the device. Sterilizing the device could harm the device.

If liquids are spilled on the device:

1. Power down the device.
2. Disconnect the power cord from the mains outlet and the power source.
3. Remove battery pack from the device.
4. Dry off excess liquid from the device.

   **NOTE** If liquids possibly entered the device, remove the device from use until it has been properly dried, inspected, and tested by qualified service personnel.

5. Reinstall battery pack.
6. Reconnect the power cord.
7. Power on the device and verify that the device functions normally before using it.

## Prepare to clean the equipment

**CAUTION** Some cleaning agents are not appropriate for all components of the device. Use only approved cleaning agents, and observe restrictions noted for some components in the following table. Using unapproved cleaning agents may cause damage to components.

**CAUTION** Do not use bleach solutions of any kind when cleaning metal electrical contacts. They will damage the device.

Select a cleaning agent from the following table.

**Section 1. Approved for all device components (device, stand, accessory basket and bins)**

| Cleaning agent | Additional information |
|---|---|
| Accel INTERVention | |
| Accel TB | |
| CaviWipes | |
| Clinell® Universal Wipes | |
| Oxivier TB | |
| Sani-Cloth® Plus | |
| Super Sani-Cloth® | |
| 70 percent isopropyl alcohol solution | Applied to a clean cloth |
| Cleancide | |
| Clorox HealthCare Bleach Germicidal Cleaner | |
| Super HDQ® L10 | Dilution rate of ½ oz per gallon of water (1:256) applied to a clean cloth |
| Tuffie5 Cleaning Wipes | |
| Virex II (256) | Dilution rate of ½ oz per gallon of water (1:256) applied to a clean cloth |
| Not all disinfectants listed above may be approved for sales in your country. Always refer to your country specific registration approvals or listings for disinfectants. | |

**Section 2. Not approved for cleaning the display**

| Cleaning agent | Additional information |
|---|---|
| 10 percent bleach solution | (.5% - 1% sodium hypochlorite) applied to a clean cloth |
| Clorox HealthCare Bleach Germicidal Cleaner | |
| Sani-Cloth® Bleach | |
| Not all disinfectants listed above may be approved for sales in your country. Always refer to your country specific registration approvals or listings for disinfectants. | |

## Remove liquid spills from the device

Liquids can damage electronics inside the device. Follow these steps if liquids spill on the device.

1. Power down the device.
2. Disconnect the power cord from the mains outlet and the power source.

3. Remove battery pack from the device.
4. Dry excess liquid from the device.
5. Reinstall battery pack.
6. Reconnect the power cord.
7. Power on the device and verify that the device functions normally before using it.

If liquids possibly entered the device, remove the device from use until it has been properly dried, inspected, and tested by qualified service personnel.

## Clean the equipment

Follow the cleaning agent manufacturer's instructions to prepare solution, if applicable, and clean all exposed surfaces of the device, accessory bin(s) and basket, cords and cables, and stand. Wipe all surfaces until no visible soil remains. Change the wipe or cloth throughout the cleaning procedure as needed.

**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 maintenance procedures specifically described in this manual. Inspection and servicing of internal parts shall only be performed by qualified service personnel.

**CAUTION** Sterilizing the device could damage the device.

1. Disconnect the AC power cord from the mains outlet.
2. Wipe the top of the device.
3. Wipe the sides, front, and rear of the device.
4. Avoid residual film buildup on the LCD screen. After cleaning, wipe the LCD screen with a clean cloth dampened with water, and then wipe the screen dry with a dry clean cloth.
5. Wipe the bottom of device.
6. Wipe the accessory bins or basket.
7. Wipe the AC power cord.
8. Wipe the stand from top to bottom.

## Dry the equipment

1. Allow all components except the LCD screen to air dry.
2. Wipe the LCD screen dry with a clean cloth.

## Store the device

Store the device according to facility guidelines to keep the device clean, dry, and ready for service.

## Cleaning accessories

Accessories include components like blood pressure cuffs and hoses, SpO2 sensors and cables, and thermometers. Follow accessory manufacturer’s instructions for cleaning.

For cleaning the wallboard and VESA mount use only 70 percent isopropyl alcohol solution applied to a clean cloth.

For cleaning the mobile stand use only 70% isopropyl alcohol solution applied to a clean cloth.

Follow the cleaning agent manufacturer's instructions to prepare a solution, if applicable, and clean all exposed surfaces of the desk stand. Wipe all surfaces until no visible soil remains. Change the wipe or cloth throughout the cleaning procedure as needed.

# Troubleshooting

This section presents tables of notification and error messages to help you troubleshoot issues on the device.

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 the following tables mean that you should contact qualified service personnel in your facility to investigate the issue.

## NIBP messages

| Message | Possible cause | Suggested action |
|---|---|---|
| User cancelled NIBP reading. | The NIBP measurement was cancelled by user | Clear the message and retry NIBP. |
| NIBP not functional. 050002 | The NIBP measurement is not available | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to determine NIBP; check connections; limit patient movement. 050003 | The NIBP measurement may be inaccurate, patient motion occurred, or the settings for patient readings obtain might not be accurate | Make sure the NIBP settings/patient mode is appropriate. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to determine NIBP; check connections; limit patient movement. 050004 | Excessive artifact, no blood pressure parameters could be calculated | Unable to determine blood pressure. Check connections; restrict patient movement. If problem persists, have the device inspected by a qualified service technician. |
| Unable to determine NIBP; check inflation settings. 050005 | Low inflation on blood pressure measurement attempt | Make sure the NIBP settings/patient mode is appropriate. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to determine NIBP; check connections and tubing for kinks. 050006 | The NIBP tubing has a kink, or there is a NIBP transducer calibration failure | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Unable to determine NIBP; check connections; limit patient movement. 050007 | The blood pressure measurement dumped too soon | Make sure the NIBP settings/patient mode is appropriate. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to determine NIBP; check connections; limit patient movement. 050008 | There were not enough steps on the measurement attempt | Unable to determine blood pressure. Check connections; restrict patient movement. |
| Unable to determine NIBP; check inflation settings. 050009 | There is invalid patient information for the selected mode | Make sure the NIBP settings/patient mode is appropriate. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to determine NIBP; check connections; limit patient movement. 05000A | The re-inflation was too late on the measurement attempt | Unable to determine blood pressure. Check connections; restrict patient movement. |
| Unable to determine NIBP; check inflation settings. 05000B | There were many re-inflate attempts on the measurement attempt | Unable to determine blood pressure. Check connections; restrict patient movement. |
| Unable to determine NIBP; check connections and tubing for kinks. 05000C | Couldn't bleed pressure below safe venous return pressure | Unable to release cuff pressure. Check tubing for kinks and connection integrity. |
| NIBP air leak; check cuff and tubing connections. 05000D | Air leak in cuff or tubing | Leak was detected in BP cycle. Check the tubing and connections. |
| Unable to determine NIBP; check connections; limit patient movement. 05000F | Auto Zero check failure | The NIBP pressure is not stable and the transducer zero value cannot be set. If problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050105 | WACP message CRC mismatch on NIBP module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050201 | This message is not implemented by the NIBP module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050202 | This message is not supported by the NIBP module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050203 | The NIBP module has run out of memory | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050205 | The NIBP module has received a invalid parameter | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050206 | The parameter provided by the NIBP module is outside of the | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| | allowable range for the specified message | |
| NIBP not functional. 050207 | The NIBP module message requires an object, but did not contain one | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050208 | The NIBP module object provided with the message could not be deserialized | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050209 | The NIBP module object could not be serialized | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05020A | The NIBP module message is performing a request or action when the module state prohibits the request or action. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not calibrated. 050503 | Factory EEPROM checksum error on NIBP. Units internal configuration was corrupted | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050504 | User EEPROM checksum error. Configuration data which can be set in the user's configuration menu was damaged or lost on NIBP | Calibrate the NIBP Module. If problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050505 | Post failure of A/D convertor | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not calibrated. Calibrate the module. 050509 | NIBP module calibration failure, the calibration signature is zero | Calibrate the NIBP module. |
| Invalid algorithm. Select correct algorithm and retry. 050512 | Invalid NIBP Algorithm. NIBP component software tried to configure the sensor in an illegal manner | Verify the algorithm. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050513 | Invalid NIBP initiation code | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Invalid patient mode. Select correct patient mode and retry. 050514 | Invalid patient mode on NIBP. The NIBP component software tried to configure the sensor in an illegal manner | Verify correct patient mode. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050515 | Invalid module configuration for NIBP | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050516 | NIBP module malfunction | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Ambient temperature out of range. Clear error and retry. 050517 | Ambient temp out of range on NIBP | Restore device to normal temperature ranges and try again. |
| Low battery. Plug into outlet. 050518 | The NIBP module power rail is too low | Plug device into an AC outlet to charge the battery. |
| Battery overcharged. Disconnect from outlet. 050519 | The NIBP module power rail is too high. NIBP was calibrated without A/C connected or battery too low. | Battery is overcharged. Remove from charging source. Charge battery and initialize NIBP module and recalibrate with A/C connected. |
| NIBP not calibrated. Calibrate the module. 050601 | NIBP failed to load safety processors calibration record from EEPROM | Calibrate the NIBP module. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050602 | NIBP safety processor failed ROM checksum | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not calibrated. Calibrate the module. 050603 | NIBP safety processor not calibrated, missing calibration signature | Calibrate the NIBP module. If the problem persists, have the device inspected by a qualified service technician. |
| Cuff pressure limits exceeded. 050604 | NIBP system failure. Overpressure | Restrict patient movement. |
| Premature auto cycle skipped. 050605 | NIBP auto cycle skipped, SVRP requirement not satisfied | Cuff pressure is not below safety return pressure long enough to allow a cycle to occur. |
| Cuff pressure too high. Clear error to retry. 050606 | NIBP cuff pressure above SVRP for too long | Verify cuff connections. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050607 | NIBP cannot clear the failsafe errors | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050608 | NIBP safety processor has stopped responding | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Stat mode requested too soon. Clear to retry. 050609 | NIBP excessive stat mode time. The time between readings is less than one minute and the readings plus time between readings result in the device taking over 15 minutes to complete the averaging cycle. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to determine NIBP; check connections and tubing for kinks. 05060A | NIBP transducers are not matched | The transducer are above 5 mmHg and the difference in pressure is greater than 40 mmHg. Check cuff for pinched or obstructed tubing. If the problem persists, have the |

| Message | Possible cause | Suggested action |
|---|---|---|
| | | device inspected by a qualified service technician. |
| NIBP not calibrated. Calibrate the module. 05060B | Factory EEPROM checksum error on NIBP. Units internal configuration was corrupted | Calibrate the NIBP module. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05060C | NIBP command not implemented | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05060D | NIBP wrong data count | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05060E | NIBP data range error | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05060F | NIBP no POST error to clear | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050610 | NIBP cannot clear this POST error | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050611 | NIBP command not command type | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050612 | NIBP communication timeout | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician.. |
| NIBP not functional. 050613 | NIBP response header wrong | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050614 | NIBP response checksum wrong | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050615 | Too much NIBP data was received | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050616 | NIBP FPROM erase error | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 050617 | NIBP FPROM programming error | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| NIBP not functional. 050618 | Invalid NIBP target pressure | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Check cuff inflation settings. | Cuff inflation target was overridden due to max pressure being too low | Change cuff inflation target or maximum pressure so that the cuff inflation target is at least 20 mmHg lower than maximum pressure. |
| NIBP not functional. 05FF01 | Unrecognized WACP parameter received from sensor | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF02 | Timeout waiting for sensor response | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF03 | Error deserializing the WACP message received from the sensor | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF04 | WACP stack send message failure | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF05 | Timeout waiting for asynchronous sensor message | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF06 | One or more undetermined numerics when reading status indicates OK | Check connections. Restrict patient movement. |
| NIBP not functional. 05FF07 | Unrecognized sensor reading status code | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF08 | Sensor power up failure | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF09 | WACP rendezvous failure | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF0A | Application firmware retrieval error during POST | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF0B | Upgrade .pim file is corrupt | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF0C | Configured upgrade firmware directory cannot be accessed | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| NIBP not functional. 05FF0E | The NIBP sensor unexpectedly reset | Clear the error and try again |

| Message | Possible cause | Suggested action |
|---|---|---|
| NIBP not functional. 05FF0F | The NIBP sensor firmware failed to upgrade | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

# SpO2 messages

## General SpO2 messages

| Message | Possible cause | Suggested action |
|---|---|---|
| SpO2 not functional. 044800 | SpO2 not functional | Internal hardware malfunction in SpO2 module. If the problem persists, have the device inspected by a qualified service technician. |
| SpO2 rebooting. 044900 | The SpO2 module is not responding. | Informational error. The host software is attempting to clear an error by rebooting the SpO2 module. No action required. |
| SpO2 rebooting. 044901 | The SpO2 module stopped sending data | Informational error. The host software is attempting to clear an error by rebooting the SpO2 module. No action required. |
| SpO2 rebooting. 044902 | SpO2 received a packet with bad CRC from module | Informational error. The host has received a packet with bad CRC from the SpO2 module. The packet in question is ignored. No action required. |
| SpO2 rebooting. 044903 | The SpO2 power on self test failed | Internal hardware malfunction in SpO2 module. If the problem persists, have the device inspected by a qualified service technician. |
| SpO2 rebooting. 044904 | The SpO2 power on self test timed out | Internal hardware malfunction in SpO2 module. If the problem persists, have the device inspected by a qualified service technician. |

## Nonin messages

| Message | Possible cause | Suggested action |
|---|---|---|
| Sensor not connected. Clear to retry. 040100 | The SpO2 sensor is not connected | Connect SpO2 sensor, if the problem is still present, replace the SpO2 cable. If the problem is still present, verify the module functionality by replacing the sensor with an applicable SpO2 tester. If the message persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| SpO2 interference detected. Clear to retry. 040400 | The SpO2 interference detected. | Reapply the sensor to the patient. If the problem is still present, replace the SpO2 sensor. If the problem is still present, replace the cable. If the problem is still present, verify module functionality by replacing the sensor with an applicable SpO2 tester. If the message persists, have the device inspected by a qualified service technician. |
| Low perfusion index. Clear to retry. 040500 | SpO2 marginal pulse quality or artifact | Reapply the sensor to the patient. If the problem is still present, replace the SpO2 sensor. If the problem is still present, replace the cable. If the problem is still present, verify module functionality by replacing the sensor with an applicable SpO2 tester. If the message persists, have the device inspected by a qualified service technician. |

# Temperature messages

| Message | Possible cause | Suggested action |
|---|---|---|
| Temperature not functional. 030105 | WACP message CRC mismatch on temperature module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030201 | This message is not implemented by the temperature module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030202 | This message is not supported by the temperature module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030203 | The temperature module has run out of memory. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030204 | No parameter provided for the specified message. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030205 | The temperature module received an invalid parameter | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030206 | The parameter provided by the temperature module is outside of the allowable range for the specified message. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Temperature not functional. 030207 | The temperature module message requires an object, but did not contain one. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030208 | The temperature module object provided with the message could not be deserialized. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030209 | The temperature module object could not be serialized. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03020A | The temperature module message is performing a request/action when the module state prohibits the request/action. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03020B | The temperature module requested item is not currently available due to the module state. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030503 | The temperature module factory settings, and calibration information is corrupt. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030504 | The temperature module user settings are corrupt. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030509 | The temperature module calibration is not set. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03050C | The temperature module error log is corrupt. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030516 | A hardware malfunction on the temperature module has been detected. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030518 | The temperature module power rail is too low. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030519 | The temperature module power rail is too high. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to detect new temperature. Retry measurement. 03051A | The temperature module reference voltage circuit was detected to be | Probe malfunction. If problem persists, replace probe. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| | under voltage or unstable. | |
| Ambient temperature out of range. Clear to retry. 030801 | The temperature module measurement is below the allowable temperature values and beyond the low ambient or patient limits. | Verify conditions are greater than 50 °F or 10 °C. If conditions are valid and the problem persists, replace the probe. If the problem persists, have the device inspected by a qualified service technician. |
| Ambient temperature out of range. Clear to retry. 030802 | The temperature module measurement is above the allowable temperature values and beyond the high ambient or patient limits. | Verify conditions are less than 104 °F or 40 °C. If conditions are valid and the problem persists, replace the probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030803 | The temperature module internal calibration resistor (RCAL) on the board is damaged or contaminated (pulse too long). | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030804 | The temperature module internal calibration resistor (RCAL) on the board is damaged or contaminated (pulse too short). | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030805 | The temperature module internal circuit validation resistor (PTB) on the board is damaged (value is over). | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030806 | The temperature module internal circuit validation resistor (PTB) on the board is damaged (value is under). | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Ambient temperature out of range. Clear to retry. 030807 | The temperature module A/D measurement timed out | Verify conditions are greater than 50 °F or 10 °C. If conditions are valid and the problem persists, replace the probe. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. 030808 | The temperature module probe was not characterized/calibrated | Probe malfunction. Replace the probe. If the problem persists, have the device inspected by a qualified service technician. |
| Insert correct color-coded probe well. 030809 | The temperature module is missing the probe well | Insert the probe well |
| Temperature not functional. 03080A | The temperature module has a problem saving to the device EEPROM in biotech mode | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Temperature not functional. 03080B | The temperature module error detection mechanism detected an error | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. 03080C | The temperature module probe error detection mechanism detected an error | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03080D | The temperature module log error detection mechanism detected an error | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03080E | The temperature module calibration error detection mechanism detected an error | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Connect temperature probe. 03080F | The temperature module detected no probe connected | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. 030810 | The temperature module cannot read the probe EEPROM correctly or the probe left the factory without being tested. | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030811 | The temperature module has an invalid events index | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030812 | There is a problem reading the temperature module EEPROM or saving to the device EEPROM in biotech mode. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. Code 030813 | The temperature module has a problem reading the probe EEPROM. | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030814 | The temperature module TEMP CONFIG ACQUIRE FAILURE | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030815 | The temperature module TEMP CONFIG RELEASE FAILURE | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030816 | The temperature module TEMP CONFIG INVALID PTR FAILURE | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Temperature not functional. 030817 | EEPROM not initialized | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to detect new temperature. Retry measurement. 030818 | The temperature module heater indicates on when turned off. | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Unable to detect new temperature. Retry measurement. 030819 | The temperature module heater indicates off when turned on. | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03081A | The temperature module HTR_Q is on and HTRC is off but still has voltage. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03081B | The temperature module HTR_Q is tri-stated with HTRC enabled and has heater power. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03081C | The temperature module turned Q&C on and the heater voltage is not high enough. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03081D | The temperature module heater hardware failsafe should have turned off but did not. | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. 03081E | The temperature module probe is above 112°F or 43.3°C. | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. 03081F | The temperature module has excessive heater energy | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030820 | The temperature module host interface error | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Ambient temperature out of range. Clear to retry. 030821 | The temperature module over ambient 45 °C temp | Verify conditions are less than 104 °F or 40 °C. If conditions are valid and the problem persists, replace the probe. If the problem persists, have the device inspected by a qualified service technician. |
| Ambient temperature out of range. Clear to retry. 030822 | The temperature module under ambient temp | Verify conditions are greater than 50 F or 10°C. If conditions are valid and the problem persists, replace the probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030823 | The temperature module has an invalid SureTemp algorithm | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Temperature not functional. 030824 | The temperature module is over max battery volts | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030825 | The temperature module is under min battery volts | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030826 | The temperature module battery volts not set | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030827 | The temperature module predict algorithm is not set | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 030828 | The temperature module ambient temp is not set | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. 030829 | The temperature module has a non-responsive probe. The thermistor has pulled away from the tip or the heater is broken. | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Replace temperature probe. 03082A | The temperature module is experiencing bad probe gain | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03082B | The temperature module has a bad probe response value | Probe malfunction. Replace probe. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03C800 | The temperature module is not functional | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03C900 | Unable to deserialize messages from the temperature module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03CA00 | Unsupported message received from the Temperature module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03CB00 | Unable to send message to the Temperature module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03CC00 | Temperature module communication times out | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |
| Temperature not functional. 03CD00 | Failed to upgrade the temperature module | Internal malfunction. If the problem persists, have the device inspected by a qualified service technician. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Temperature not functional. 03CE00 | Unable to read PIM file | Retry the device update. |
| Temperature not functional. 03CE01 | Upgrade file directory could not be accessed | Retry the device update |
| Direct mode reading timed out | Direct mode reading times out | Direction mode reading times out |
| Tissue contact lost. | Lost tissue contact while attempting to acquire a temperature measurement or acquired measurement was performed with limited tissue contact. | Check the tissue contact and try the measurement again. |
| Temperature module reset. 03D000 | Temperature sensor reset unexpectedly | None |

# Patient data messages

| Message | Possible cause | Suggested action |
|---|---|---|
| Database schema out of data; recreating. | The database was cleared due to a schema update | Information status message; press OK button to dismiss. |
| Database is unreadable during startup; recreating. 1F0001 | The database was unreadable during startup | Press OK button to dismiss. |
| Error accessing PDM database; restarting PDM. 1F0002 | Database corrupted when device is in operation | Press OK button to dismiss. |
| Maximum number of patient records + Oldest record overwritten. | Data was deleted as it contained more than 50 records | Information status message; press OK button to dismiss. |
| No data saved. | A manual save is not allowed | Information status message; press OK button to dismiss. |
| Save successful. | A manual record was saved | Information status message; press OK button to dismiss. |

# System messages

| Message | Possible cause | Suggested action |
|---|---|---|
| 000001 | System failure | Restart the device |

| Message | Possible cause | Suggested action |
|---|---|---|
| 000002 | System failure | Restart the device |
| 000003 | System failure | Restart the device |
| 000004 | System failure | Restart the device |
| 000005 | System failure | Restart the device |
| 000006 | System failure | Restart the device |
| Internal hardware failure. | The root file system is corrupted; restart not possible | Restart the device. If the problem persists, replace the main PCBA. |
| Internal hardware failure. 140100 | EEPROM access failed. The device boot is possible, but wired communications are disabled | Reprogram the EEPROM. If the problem persists replace the main PCBA. |
| Internal hardware failure. | SPL memory test failure, the device will sound an SOS pattern | Restart the device. If the problem persists, replace the main PCBA. |
| Internal hardware failure. 1C1000 | The device PIC communications never starts or quits. The communication won't reasonably recover at startup or during operation | Restart the device. If the problem persists, replace the main PCBA. |
| Low battery 30 minutes or less remaining. 1C1005 | The battery power is low | Connect the power supply to AC power to charge the device. |
| Low battery 5 minutes or less remaining. 1C1006 | The battery power is extremely low | Connect the power supply to AC power to charge the device. |
| Battery is critically low; plug into outlet. Device is shutting down. 1C1007 | The battery power is critically low | Connect the power supply to AC power to charge the device. |
| Update unsuccessful. Reboot and retry. 1C1008 | The software update failed | Restart the device. If the problem is still present, replace the main PCBA. |
| Host battery not charging. 1C100A | The host battery is not charging | Restart the device. If the problem is still present, check cable connections. If the problem is still present, perform functional checks for host. If the problem is still present, replace battery. If the problem persists, replace the main PCBA. |
| Factory default settings now active. 3A0001 | The factory configuration settings are active | The device has been configured to factory defaults, any user settings have been reset. |
| Internal hardware failure. Device will shut down. 1C100D | Power supply issue. The PMIC is too hot | Check the operating environment temperature. Allow the device to cool down before operating again. If the problem is still present, check the cable connections. If the problem is still present, perform functional checks for host. If the problem is still present, replace the battery. If the problem is still present, replace the main PCBA. |

| Message | Possible cause | Suggested action |
|---|---|---|
| Input voltage too low. Device will shut down. 1C100C | Power supply issue. The PMIC input voltage is too low | Check the operating environment temperature. Allow the device to cool down before operating again. If the problem is still present, check the cable connections. If the problem is still present, perform functional checks for host. If the problem is still present, replace the battery. If the problem is still present, replace the main PCBA. |
| Unexpected restart occurred. 1C1012 | The device unexpectedly restarted | Continue normal operation |
| Device battery is not installed. 1C100E | There is no battery in the device | Check the device for a battery and install one if it is missing. If the problem is still present, perform diagnostic checks on the device. If the problem persists, replace the main PCBA. |
| Advanced settings unavailable. | The advanced settings are unavailable because the device is not in an idle state | Confirm that no sensors are attached to the device and there is no unsaved data. |
| Software upgrade is downloading. Do not shutdown. | Cannot power down device as software install is in progress | N/A |
| Save not successful. | The device configuration or logs were not saved to the USB device | Information status message; press OK button to dismiss |
| Save successful. | The device configuration or logs were saved to the USB device | Information status message; press OK button to dismiss |
| Send successful. | Data was successfully sent over USB. | N/A |

# Power messages

| Message | Possible cause | Suggested action |
|---|---|---|
| Device is operating in battery mode | A/C power cord has been disconnected | None |
| Sleep mode is unavailable. An NIBP averaging program is in progress. | Sleep mode is not allowed when intervals are in progress | Stop any active averaging programs or enter sleep mode when averaging is complete. |
| Sleep mode is unavailable. An error is active. | Sleep mode is not available when errors are active | Clear all active errors. |
| Sleep mode is not available. Unsaved readings are present. | Sleep mode is not allowed with unsaved readings | Save or clear readings. |

# Software update messages

| Message | Possible cause | Suggested action |
|---|---|---|
| Software Update: Manifest transfer timed out. Verify connection and retry. | The manifest file transfer timed out or connection was lost during download | Verify the connection and retry. |
| Software Update: Package file transfer timed out. Verify connection and retry | The package file transfer timed out or connection was lost during download | Verify the connection and retry. |
| Software Update: Invalid token file. | There was an invalid token file | Verify and update the token file. |
| Software Update: Unable to find manifest file on server. | Unable to find manifest file on server | Verify the manifest file is on the server. |
| Software Update: Unable to verify manifest file signature. | Unable to verify manifest file signature | Regenerate the software package and retry. |
| Software Update: Package file corrupted. Regenerate package and retry. | The package file is corrupt, does not have expected SHA256 hash | Regenerate the software package and retry. |
| Software Update: Unable to find package file. | The package file cannot be found | Verify the package file is on the server. |
| Software Update: Installation failed. Reboot and retry. | At least one of the sub systems failed to install | Restart the device. |
| Software Update: Upgrade unsuccessful. Insufficient disk space. | The partition is running out of space | Free up adequate space needed to perform the upgrade. |
| Software Update: Update unsuccessful. Incompatible firmware. | The current firmware version is too low to install update | Try to update to an earlier software package. |
| Software Update: SWUP internal error | SWUP NIBP is not functional | SWUP internal error. |
| Software Update: Manager internal error | The Software Update manager is not functional | Software Update Manager internal error. |

# Specifications

## Physical specifications

| Protection classifications, all device configurations | |
|---|---|
| **Characteristic** | **Specification** |
| Electrical rating | Power supply model: FW8031M/DT/15<br>Input: 100 – 240 V AC, 50 – 60 Hz, 0.6 A – 0.3 A<br>Output: 15 V DC, 2.0 A |
| Duty cycle | Continuous operation |
| Type of protection against electric shock | Class I internally powered |
| Degree of protection against electric shock, for parts applied to patients | Type BF defibrillator proof<br>IEC EN 60601-1, 2nd and 3rd Editions |
| Recovery time following defibrillator discharge | Less than or equal to 15 seconds |
| Flammable anesthetics | **WARNING** Not suitable for use with flammable anesthetics. |
| Degree of protection provided by the enclosure with respect to harmful ingress of liquids | IPX2 Protected 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] ) |

| Protection classifications, all device configurations | |
|---|---|
| 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 |
| Pixel arrangement | RGB (red, green, blue) |
| Pixel size | 63.2 µm (W) x 179 µm (H) |
| Luminance | 530 cd/m2 |

## Battery specifications

| 2 Cell battery specifications | Hours of use |
|---|---|
| Ambulatory care continuous 12 minute cycles - 40 patient cycles | 8 |

## Mobile stand specifications

| Mobile stand | Basket/bins maximum weight limit | Mobile stand maximum weight limit |
|---|---|---|
| 4400-MBS | 2.0 lb /0.9 kg | 22 lb /10 kg |

## NIBP specifications

| NIBP specifications | |
|---|---|
| Cuff pressure range | Meets or exceeds IEC/ISO 80601-2-30 standards for cuff pressure range |
| Systolic range | Adult: 30 to 260 mmHg (StepBP, SureBP)<br>Pediatric: 30 to 260 mmHg (StepBP, SureBP) |
| Diastolic range | Adult: 20 to 220 mmHg (StepBP, SureBP)<br>Pediatric: 20 to 220 mmHg (StepBP, SureBP) |
| Cuff Inflation Target | Adult:160 mmHg (StepBP)<br>Pediatric: 140 mmHg (StepBP) |
| Maximum Target Pressure | Adult: 280 mmHg (StepBP, SureBP)<br>Pediatric: 280 mmHg (StepBP, SureBP) |

| NIBP specifications | |
|---|---|
| Blood pressure determination time | Typical: 15 seconds<br>Maximum: 150 seconds |
| Blood pressure accuracy | Meets or exceeds ANSI.AAMI SP10:2002 standards for noninvasive blood pressure accuracy (±5 mmHg mean error, 8 mmHg standard deviation) |
| Mean Arterial Pressure (MAP) range<br>The formula used to calculate MAP yields an approximate value. | Adult: 23 to 230 mmHg (StepBP, SureBP)<br>Pediatric: 23 to 230 mmHg (StepBP, SureBP) |
| Pulse rate range (using blood pressure determination) | Adult: 30 to 200 bpm (StepBP, SureBP)<br>Pediatric: 30 to 200 bpm (StepBP, SureBP) |
| Pulse rate accuracy (using blood pressure determination) | ±5.0% (±3 bpm) |
| Overpressure cutoff | Adult: 300 mmHg ±15 mmHg<br>Pediatric: 300 mmHg ±15 mmHg |

# SureTemp Plus temperature module specifications

| SureTemp Plus temperature module specifications | |
|---|---|
| Temperature range (all measurement sites) | 80 °F to 110 °F (26.7 °C to 43.3 °C) |
| Calibration accuracy | ±0.2 °F (±0.1 °C) (Direct mode) |

| Laboratory accuracy | | |
|---|---|---|
| **Temperature measurement range** | **Ambient**<br>64.4 °F (18 °C) to 82.4 °F (28 °C) | **Ambient**<br>50 °F (10 °C) to 64.4 °F (18 °C) or 82.4 °F (28 °C) to 113 °F (40 °C) |
| Less than 95.9 °F (35.5 °C) | ±0.36 °F (±0.2 °C) | ±0.36 °F (±0.2 °C) |
| 95.9 °F (35.5 °C) to less than 96.4 °F (35.8 °C) | ±0.18 °F (±0.1 °C) | ±0.36 °F (±0.2 °C) |
| 96.4 °F (35.8 °C) to less than 98.0 °F (37.0 °C) | ±0.18 °F (±0.1 °C) | ±0.3 °F (±0.2 °C) |
| 98.0 °F (37.0 °C) to 102.0 °F (39.0 °C) | ±0.18 °F (±0.1 °C) | ±0.2 °F (±0.1 °C) |
| Greater than 102.0 °F (39.0 °C) to 106.0 °F (41.0 °C) | ±0.18 °F (±0.1 °C) | ±0.3 °F (±0.2 °C) |

| Laboratory accuracy | | |
|---|---|---|
| Greater than 106.0 °F (41.0 °C) to 107.6 °F (42.0 °C) | ±0.18 °F (±0.1 °C) | ±0.36 °F (±0.2 °C) |
| Greater than 107.6 °F (42.0 °C) | ±0.36 °F (±0.2 °C) | ±0.36 °F (±0.2 °C) |

### Thermometry clinical accuracy validation

For a copy of our Clinical Validation Study, please contact Hillrom Customer Care.

## SpO2 specifications

Refer to sensor manufacturer's directions for use for additional information.

**WARNING** Functional testers cannot be used to assess the accuracy of a pulse oximeter device.

While functional testers may be useful for verifying that the pulse oximeter sensor, cabling, and device are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO2 measurements. Fully evaluating the accuracy of the SpO2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient's tissue. These capabilities are beyond the scope of known bench-top testers. SpO2 measurement accuracy can only be evaluated in vivo by comparing pulse oximeter readings with SaO2 measurements obtained from simultaneously sampled arterial blood made using a laboratory CO-oximeter.

**NOTE** Contact the sensor manufacturer for further SpO2 clinical testing information.

**NOTE** Refer to sensor manufacturers' directions for use for further accuracy information.

| SpO2 specifications | |
|---|---|
| SpO2 performance measurement range | 1 to 100% |
| **Nonin sensor accuracy guide** | SpO2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the sensors is compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO2 range of 70 – 100%. Accuracy data is calculated using the root-mean-squared ($A_{rms}$ value) for all subjects, per ISO 9919:2005, Standard Specification for Pulse Oximeters for Accuracy. |
| Pulse rate | 18 to 300 bpm: ± 3 digits |

| SpO2 specifications | |
|---|---|
| | Low perfusion (40 to 240 bpm): ± 3 digits |
| Saturation<br><br>**NOTE** Saturation accuracy varies by sensor type. | 70% to 100%<br>**Adult/Pediatrics**<br>**No Motion**<br>Finger Clip: ± 2 digits<br>Flex: ± 3 digits<br>**Motion**<br>Finger Clip: ± 2 digits<br>Flex: ± 3 digits<br>**Low Perfusion**<br>All Sensors: ± 2 digits |

# Environmental specifications

| | |
|---|---|
| Operating temperature | 50 °F to 104 °F (10 °C to 40 °C) |
| Storage/Transport temperature | -4 °F to 122 °F (-20 °C to 50 °C) |
| Storage/Transport/Operating altitude and atmospheric pressure | -1250 to 10,000 ft. (-381 m to 3,048 m)<br>70 kPA to 106 kPA |
| Operating humidity | 15% to 90% noncondensing |
| Storage/Transport humidity | 15% to 95% noncondensing |

# Manufacture date: how to decode serial numbers

The Serial number (SN) of a device reveals many details about its manufacture. The last four digits of the device SN reveal the device's date of manufacture.

SN: XXXX####WWYY
where
XXXX = Manufacturing plant
#### = Sequential number of manufacture
WW = Week of manufacture
YY = Year of manufacture

# Calibration

The device has no specific use time limitation. The device may remain in service until repair is required or operation indicates that it is out of calibration. However, if an error code appears on the device, have the device inspected by a qualified service technician and stop using the device.

See the *Welch Allyn Spot Vitals Signs 400 Service manual* for recommended service intervals. Accuracy checks and calibration are only recommended if the device case is opened or if issues are suspected. In cases where the device case is opened or if issues are suspected, send the device in for repair.

Calibration is not required annually.

# Standards and compliance

## General compliance and standards

The device complies with the following standards:
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
EN/ISO 13485, 14971, 80601-2-56, 80601-2-61, 81060-2
ISTA 2A
AAMI ES60601-1[1]

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

## Storage and disposal

Disposal must be in accordance with the following steps:

1. Follow the instructions in this manual in the section *Prepare to clean the equipment*.
2. Segregate material in preparation for the recycling process:
    - Components are to be disassembled and recycled based on type of material:
        - Plastic to be recycled as plastic waste
        - Metal to be recycled as metals
            - Includes loose components containing more than 90% metal by weight
            - Includes screws and fasteners
        - Electronic components, including the power cord, to be disassembled and recycled as Waste of Electrical and Electronic Equipment (WEEE)
        - Batteries to be dismantled from the device and recycled as per WEEE

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

For information about electromagnetic compatibility (EMC), see the Hillrom website:

https://www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80025/80025125LITPDF.pdf

You can order a printed copy of the Emissions and immunity information from Hillrom for delivery within 7 calendar days.

# Appendix

## Approved accessories

The following tables list approved device accessories and applied parts. For information about options, upgrades, and licenses, refer to the service manual.

**WARNING** Use only Welch Allyn approved accessories and applied parts, and use them according to the manufacturer's instructions for use. Using unapproved accessories with the device or applied parts can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

### Accessories

#### Blood pressure accessories (latex-free)

| Part number | Model | Description |
|---|---|---|
| 4500-34 | BP | Fast BP hose w Fport, 5 ft |
| 4500-35 | BP | Fast BP hose w Fport, 10 ft |
| 5200-08 | | Calibration "T" connector |

#### Nonin pulse oximetry

| Part number | Model | Description |
|---|---|---|
| 6083-001 | | 1m Nonin Extension Cable |
| 6083-003 | | 3m Nonin Extension Cable |

#### SureTemp Plus thermometry

| Part number | Description |
|---|---|
| 02895-000 | Oral probe and well kit (9ft. / 2.7M) |

| Part number | Description |
|---|---|
| 02895-100 | Rectal probe and well kit (9ft. / 2.7M) |
| 02894-0000 | Oral probe well (blue) |
| 02894-1000 | Rectal probe well (red) |
| 05031-110 | SureTemp Plus Disposable probe covers (10,000 covers, packaged 25/box) |
| 05031-101 | SureTemp Plus Disposable probe covers (1,000 covers, packaged 25/box) |
| 06138-000 | Temperature calibration key |
| 01802-110 | 9600 Plus Calibration Tester |

## Mounting options

| Part number | Description |
|---|---|
| 4400-DST | Desktop Stand - portable stand with cuff and cord management |
| 4400-MBS | Spot Vital Signs 4400 Mobile Stand |
| 77794-M4400 | Wall Mount system for 4400 with GS 777 |
| 77794-2M4400 | Wall Mount system for 4400 with GS 777 and PANOPTIC |

## Miscellaneous items

| Part number | Description |
|---|---|
| 106275 | USB cable for wired connectivity |
| PWCD-B | Line cord B, North America |
| PWCD-2 | Line cord 2, Europe |
| PWCD-4 | Line cord 4, United Kingdom |
| PWCD-6 | Line cord 6, Australia/New Zealand |
| PWCD-66 | Line cord 6, Australia/New Zealand —Orange |
| PWCD-3 | Line cord 3, Israel |
| PWCD-Y | Line cord Y, Italy |
| 4400-PS | Spot Vital Signs 4400 power supply |

| Part number | Description |
|---|---|
| BATT22 | Spot Vital Signs 4400 2 cell Lithium-ion battery |

## SmartCare protection plans

| Part number | Description |
|---|---|
| S1-4400-PRO-1 | 4400 SmartCare Protection 1YR |
| S1-4400-PRO-3 | 4400 SmartCare Protection 3YR |
| S1-4400-PRO-PS | 4400 SmartCare Protection 3YR POS |

## SmartCare protection plus plans

SmartCare protection plus plans include onsite repair.

| Part number | Description |
|---|---|
| S9-4400-PROPLUS-1 | 4400 SmartCare Protection Plus 1YR |
| S9-4400-PROPLUS-3 | 4400 SmartCare Protection Plus 3YR |
| S9-4400-PROPLUS-PS | 4400 SmartCare Protection Plus 3YR POS |

## SmartCare biomed plans

| Part number | Description |
|---|---|
| S1-4400 | 4400, Comprehensive partnership program point of sale |
| S1-4400-2 | 4400, Comprehensive partnership program 1 year renewal |
| S1-4400-5 | 4400, Comprehensive partnership program, 5 years |
| S1-4400-C | 4400, Comprehensive partnership program, 1 years + Calibration |
| S1-4400-2C | 4400, Comprehensive partnership program, 2 years + Calibration |
| S1-4400-5C | 4400, Comprehensive partnership program, 5 years + Calibration |

## Literature/Documentation

| Part number | Description |
|---|---|
| 107241 | Spot Vital Signs 4400 CD Kit (*Instructions for use* and *Quick reference*) |

# Applied parts

## FlexiPort cuffs

**NOTE** Some model numbers and product features described in this publication might not be available in your country. For the latest information about products and features, please contact Hillrom Customer Care.

| Part number | Model | Description |
|---|---|---|
| REUSE-06 | Reusable | Cuff, Welch Allyn, reusable, small infant |
| REUSE-07 | Reusable | Cuff, Welch Allyn, reusable, infant |
| REUSE-08 | Reusable | Cuff, Welch Allyn, reusable, sm child |
| REUSE-09 | Reusable | Cuff, Welch Allyn, reusable, child |
| REUSE-10 | Reusable | Cuff, Welch Allyn, reusable, sm adult |
| REUSE-11 | Reusable | Cuff, Welch Allyn, reusable, adult |
| REUSE-11L | Reusable | Cuff, Welch Allyn, reusable adult long |
| REUSE-12 | Reusable | Cuff, Welch Allyn, reusable, lg adult |
| REUSE-12L | Reusable | Cuff, Welch Allyn, reusable, lg adult long |
| REUSE-13 | Reusable | Cuff, Welch Allyn, reusable, thigh |
| SOFT-08 | Disposable | Cuff, Welch Allyn, small child |
| SOFT-09 | Disposable | Cuff, Welch Allyn, child |
| SOFT-10 | Disposable | Cuff, Welch Allyn, small adult |
| SOFT-11 | Disposable | Cuff, Welch Allyn, adult |
| SOFT-11L | Disposable | Cuff, Welch Allyn, adult long |
| SOFT-12 | Disposable | Cuff, Welch Allyn, lg adult |
| SOFT-12L | Disposable | Cuff, Welch Allyn, lg adult long |
| SOFT-13 | Disposable | Cuff, Welch Allyn, thigh |

| Part number | Model | Description |
|---|---|---|
| REUSE-06-ML | Reusable | Cuff, Welch Allyn, reusable, small infant, ML |
| REUSE-07-ML | Reusable | Cuff, Welch Allyn, reusable, infant, ML |
| REUSE-08-ML | Reusable | Cuff, Welch Allyn, reusable, sm child, ML |
| REUSE-09-ML | Reusable | Cuff, Welch Allyn, reusable, child, ML |
| REUSE-10-ML | Reusable | Cuff, Welch Allyn, reusable, sm adult, ML |
| REUSE-11-ML | Reusable | Cuff, Welch Allyn, reusable, adult, ML |
| REUSE-11L-ML | Reusable | Cuff, Welch Allyn, reusable adult long, ML |
| REUSE-12-ML | Reusable | Cuff, Welch Allyn, reusable, lg adult, ML |
| REUSE-12L-ML | Reusable | Cuff, Welch Allyn, reusable, lg adult long, ML |
| REUSE-13-ML | Reusable | Cuff, Welch Allyn, reusable, thigh, ML |
| SOFT-08-ML | Disposable | Cuff, Welch Allyn, small child, ML |
| SOFT-09-ML | Disposable | Cuff, Welch Allyn, child, ML |
| SOFT-10-ML | Disposable | Cuff, Welch Allyn, small adult, ML |
| SOFT-11-ML | Disposable | Cuff, Welch Allyn, adult, ML |
| SOFT-11L-ML | Disposable | Cuff, Welch Allyn, adult long, ML |
| SOFT-12-ML | Disposable | Cuff, Welch Allyn, lg adult, ML |
| SOFT-12L-ML | Disposable | Cuff, Welch Allyn, lg adult long, ML |
| SOFT-13-ML | Disposable | Cuff, Welch Allyn, thigh, ML |
| ECOCUFF-09 | Disposable | EcoCuff, Child, 1521 cm |
| ECOCUFF-10 | Disposable | EcoCuff, Small Adult, 2028 cm |
| ECOCUFF-11 | Disposable | EcoCuff, Adult, 2738 cm |
| ECOCUFF-12 | Disposable | EcoCuff, Large Adult, 3345 cm |

## Nonin pulse oximetry

| Part number | Description |
|---|---|
| 3278-010 | 8000AP Nonin SpO2 sensor, adult, 2m |
| 2360-010 | 8000AP Nonin SpO2 sensor, pediatric, 2m |
| 4774-000 | 8008JFW Nonin infant replacement wraps 25/pack |

| Part number | Description |
|---|---|
| 0740-000 | 8008J Nonin infant flex sensor with 25 wraps |
| 0741-000 | 8000J Nonin adult flex sensor with 25 wraps |
| 4097-000 | 8000JFW Nonin adult replacement wraps 25/pack |

## SureTemp Plus thermometry

| Part number | Description |
|---|---|
| 02895-000 | Oral probe and well kit (9ft. / 2.7M) |
| 02895-100 | Rectal probe and well kit (9ft. / 2.7M) |
| 05031-101 | SureTemp Plus Disposable probe covers (1,000 covers, packaged 25/box) |
| 05031-110 | SureTemp PlusDisposable probe covers (10,000 covers, packaged 25/box) |

# Warranty

Welch Allyn warrants the product to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for the period of two years from the date of purchase from Welch Allyn or its authorized distributors or agents.

The warranty period shall start on the date of purchase. The date of purchase is: 1) the invoiced ship date if the device was purchased directly from Welch Allyn, 2) the date specified during product registration, 3) the date of purchase of the product from a Welch Allyn authorized distributor as documented from a receipt from said distributor.

This warranty does not cover damage caused by 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Welch Allyn, and 4) accidents.

The product warranty is also subject to the following terms and limitations: Accessories are not covered by the warranty. Refer to the directions for use provided with individual accessories for warranty information.

Shipping cost to return a device to a Welch Allyn Service center is not included.

A service notification number must be obtained from Welch Allyn prior to returning any products or accessories to Welch Allyn's designated service centers for repair. To obtain a service notification number, contact Welch Allyn Technical Support.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. WELCH ALLYN'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. WELCH ALLYN IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.