NONIN

Operator's Manual

CO-Pilot™

Model H500

Wireless Handheld Multi-Parameter System

CE 0123

English

Rx Only	**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Follow Instructions for Use.

Nonin® reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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CE 0123

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Indications for Use

The Nonin Medical CO-Pilot™ Wireless Handheld Multi-Parameter System (Model H500), is intended for noninvasive measuring of functional oxygen saturation of arterial hemoglobin (%SpO_2), pulse rate, carboxyhemoglobin saturation (%COHb), methemoglobin saturation (%MetHb), and cerebral or somatic hemoglobin oxygen saturation (%rSO_2). This device is not meant for the sole use of clinical decision making; it must be used in conjunction with additional methods of assessing clinical signs and symptoms.

- For %SpO_2 and pulse rate, the CO-Pilot System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients who are well or poorly perfused, during both motion and non-motion conditions in professional healthcare facilities, mobile, and EMS settings.
- For %rSO_2, the CO-Pilot System is intended for spot-checking and/or measuring during clinician assessment of adult, pediatric, infant, and neonate patients in professional healthcare facilities, mobile, and EMS settings.
- For %COHb and %MetHb, the CO-Pilot System is intended for spot-checking, multiple spot-checks to observe change, and/or measuring during clinician assessment of adult and pediatric patients in professional healthcare facilities, mobile, and EMS settings.

Refer to the applicable sensor Instructions for Use (IFU) for sensor indications for use and accuracy claims.

Warnings

This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
Oximetry functions are disabled after critical battery is reached.
This device is only defibrillation proof when used with Nonin-specified cables and accessories. To avoid patient injury, only use Nonin-specified cables and accessories (see *Accessories*).
Use only Nonin-branded signal processors, sensors, and accessories, otherwise patient injury can result. These sensors are manufactured to meet the accuracy specifications for this device. Using other manufacturers' sensors can result in improper oximeter performance.
Inspect the sensor application site in accordance with the sensor instructions for use to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor may vary due to medical status or skin condition.

Warnings (Continued)

Avoid excessive pressure to the sensor application site as this may cause damage to the skin beneath the sensor.
Always inspect the device before use. Do not use a damaged device or sensor. Before using any sensor, carefully read the sensor instructions for use, which contains sensor application information for each sensor.
To prevent improper performance and/or patient injury, verify compatibility of the display, signal processor, sensor(s), and accessories before use.
No modifications to this device are allowed as it may affect device performance.
Protect from exposure to water or any other liquid, with or without AC power.
As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or tripping.
Do not use this device in an magnetic resonance (MR) environment.
Explosion Hazard: Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases.
Use the CO-Pilot display only within its designated range (See *Specifications* section) from display to signal processor. Moving outside this range may cause missing or lost data.
This device turns off after approximately 30 minutes when the low battery indicator appears.
If this device is used adjacent to or stacked with other equipment, the device should be observed carefully to verify normal operation.
The use of signal processors, sensors, accessories, and cables other than those listed in the *Parts and Accessories List* may result in increased electromagnetic emission and/or decreased immunity of this device.
This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Attempted repair will damage the device and void the warranty.
The device must be able to measure the pulse properly to obtain an accurate measurement. Verify that nothing is hindering the pulse measurement before relying on the measurement.
Operation of this device below the minimum amplitude of 0.3% modulation may cause inaccurate results for SpO_2.
Portable and mobile RF communications equipment can affect medical electrical equipment.
Do not use the signal processor or display while charging. Charging is an operator function. To ensure patient safety, the system is not to be in contact with the patient during charging.

Warnings (Continued)

Use the CO-Pilot only with power supply supplied by Nonin Medical.
To ensure patient safety, the D-HH is not to be in contact with the patient.
Refer to the applicable sensor Instructions for Use (IFU) for additional warnings and cautions.

Cautions

When using this device in an operating room, it must remain outside the sterile field.
This equipment complies with IEC 60601-1-2 for electromagnetic compatibility (EMC) for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information specified in this manual.
The CO-Pilot is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the United States FCC. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This device has been shown to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.
Factors that may degrade oximeter performance include the following: - excessive ambient light - excessive motion - electrosurgical interference - moisture in the sensor - improperly applied sensor - blood flow restrictors (arterial catheters, blood pressure cuffs, infusion lines, etc.) - incorrect sensor type - poor pulse quality - venous pulsations - anemia or low hemoglobin concentrations - cardiovascular dyes - dysfunctional hemoglobin - artificial nails or fingernail polish - residue (e.g., dried blood, dirt, grease, oil) in the light path
Batteries are a fire hazard if damaged. Do not damage, mishandle, disassemble, service, or replace with non-specified components.
Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.

⚠ *Cautions (Continued)*

Do not apply sensor over open wound, incision, or compromised skin. Inspect the sensor site prior to applying the sensor.
Inspect the sensor application site in accordance with the sensor instructions for use to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor may vary due to medical status or skin condition.
Do not autoclave, sterilize, immerse, or spray this device with liquid or use caustic or abrasive cleaning agents. Do not use cleaning agents or cleaning products that contain ammonium chloride.
Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device. If you are unsure how to reach your distributor, please call Nonin for your distributor's contact information.
A functional tester can only be used to assess the performance of the SpO_2-only sensors.
If this device fails to respond as described, discontinue use until the situation is corrected by qualified technical professionals.
For measurement, the device may not work when circulation is reduced. Warm or rub the finger, or reposition the device.
In some circumstances, the device may interpret motion as good pulse quality during measurement. Minimize patient motion as much as possible.
Do not simultaneously touch the accessible connector pins and the patient.
The device has been designed for use within the specified accuracy ranges. Use outside of these ranges has not been tested and may result in improper oximeter performance.
All parts and accessories connected to the serial port of this device must be certified according to at least IEC Standard EN 60950, IEC 62368-1, or UL 1950 for data processing equipment.
Ensure time and date value is correct.
Implants may affect performance.
Refer to the applicable sensor Instructions for Use (IFU) for additional warnings and cautions.

Declaration of Conformity with FCC and Canadian Ministry of Health Rules for Electromagnetic Compatibility

- Nonin Medical, Inc., of 13700 1st Avenue North, Plymouth, Minnesota, 55441, declares under its sole responsibility that the CO-Pilot, to which this declaration relates, comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- Ministry of Health (Canada), Safety Code 6: standards include a substantial safety margin designed to ensure the safety of all persons, regardless of age and health. The exposure standard for wireless mobile phones employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures: (1) Reorient or relocate the receiving antenna, (2) Increase the distance between the equipment and the receiver, (3) Connect the equipment to an outlet on a circuit different from the outlet where the receiver is connected, or (4) Consult the dealer or an experienced radio/TV technician for assistance.

The CO-Pilot is designed and manufactured to not exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This EUT has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.

The FCC requires the user to be notified that any changes or modifications to this device that are not expressly approved by Nonin Medical, Inc. may void the user's authority to operate the equipment.

NOTE: No modifications to this device are allowed that in any way affect or alter its antenna or antenna configuration.

System Symbols

This chapter describes the symbols that are found on the CO-Pilot System components and packaging. Detailed information about functional symbols can be found in "System Components and Set Up" section on page 18.

Table 1. *Labeling and Packaging Symbols*

Symbol	Description
	CAUTION!
	Authorized Representative in the European Community.
	Follow instructions for use.
CE 0123	CE Marking indicating conformance to all applicable directives, including EC Directive No. 93/42/EEC concerning medical devices.
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1, UL 60601-1 and CAN/CSA-C22.2 No. 601.1.
IP33	Enclosure Degree of Ingress Protection: D-HH, SP-BLE: IP33
	Class II, Double Insulated
	Serial Number
	Direct Current
	Defibrillation Proof Type BF Applied Part (patient isolation from electric shock when connected to a signal processor.)
	Indicates separate collection for waste electrical and electronic equipment (WEEE).
	Non-ionizing electromagnetic radiation. Equipment includes RF transmitters. Interference may occur in the vicinity of equipment marked with this symbol.
	Do Not Discard
	Lot Number
	Catalogue Number

Table 1. *Labeling and Packaging Symbols* ***(Continued)***

Symbol	Description
QTY	Quantity
	Date of Manufacture
	Manufacturer
	Storage/Shipping Temperature Range
	Handle With Care.
	Keep Dry
	Storage/Shipping Humidity Range
	Not an Alarm System
Li-ion Battery	Lithium-ion Polymer Battery
MD	Medical Device
BDA	Bluetooth Device Address

Table 2. *Power Supply Labeling and Packaging Symbols*

Symbol	Description
	BSMI Mark, Taiwan
	Federal Communications Commission
	PSE Mark, Japan
	RCM Tick Mark, Australia and New Zealand
	Medical Power Supply Certification

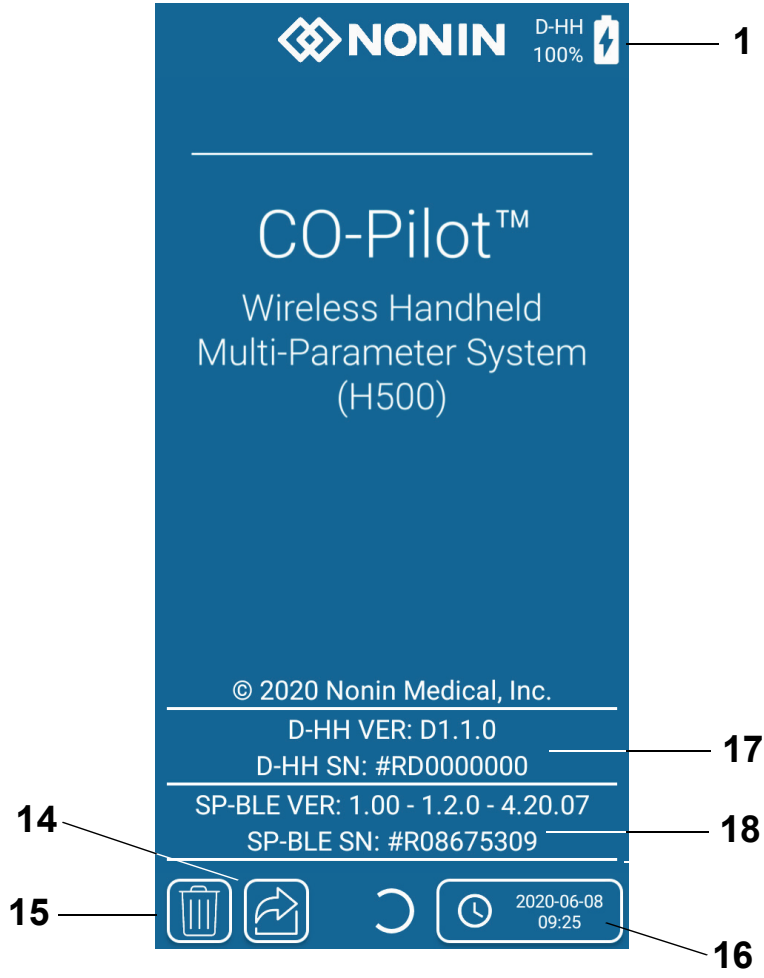
Table 2. *Power Supply Labeling and Packaging Symbols* ***(Continued)***

Symbol	Description
	UL Safety Mark for united States and Canada
	CE Marking indicating conformance to all applicable directives
	Indoor Use Only
	Class II, Double Insulated

Display Screens and Symbols

Refer to the following Table for definitions to the numbered items associated with **Figures 1-3**.

Start-Up



CO-Met

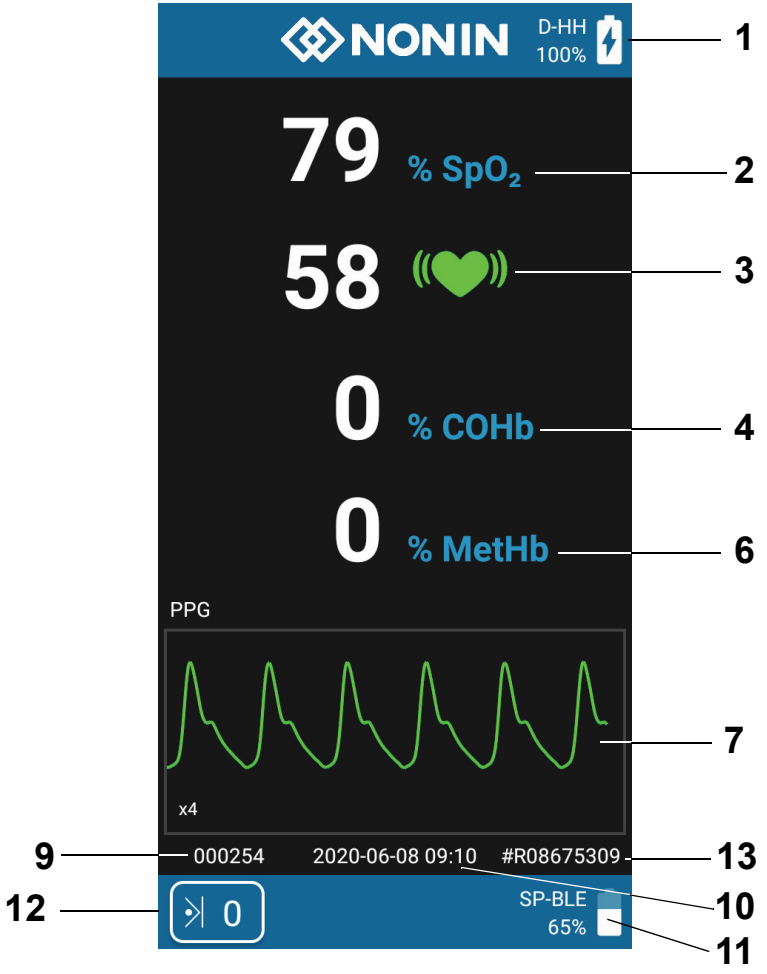


Figure 1. *CO-Met Measurement Screen, CO-Met Enabled*

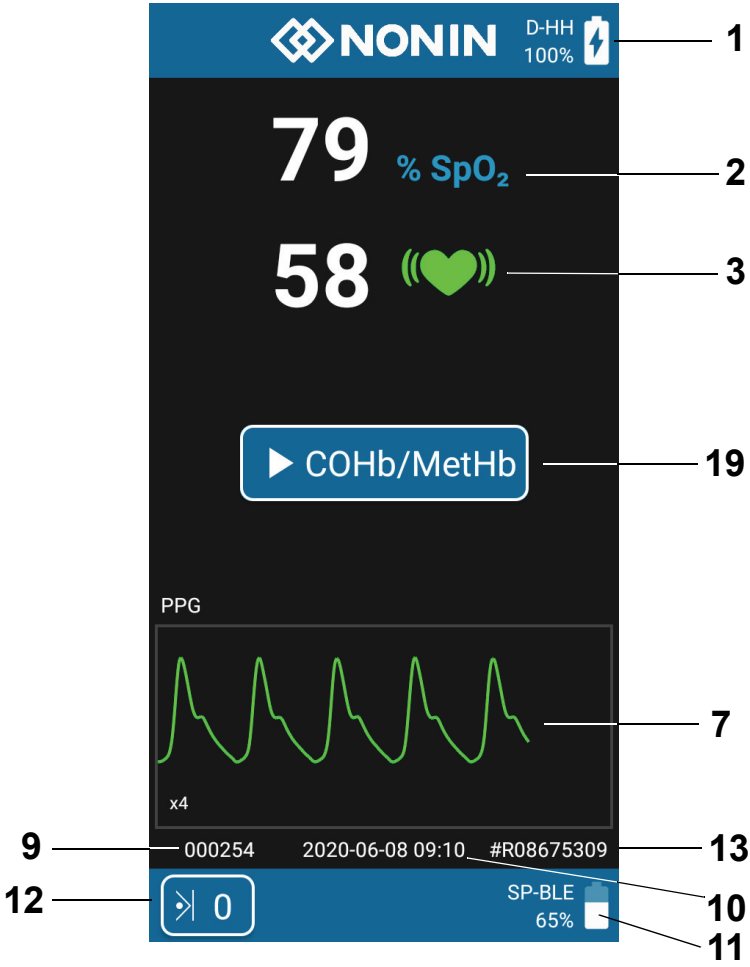


Figure 2. *CO-Met Measurement Screen, CO-Met Disabled*

Pulse Oximetry

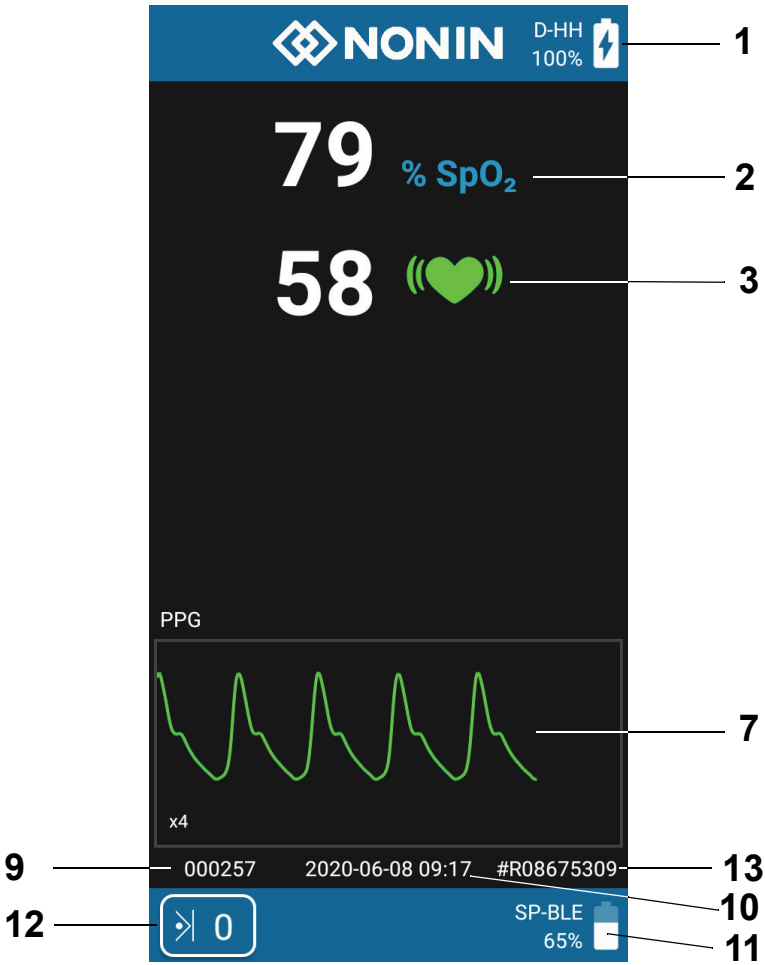


Figure 3. *SpO_2 Measurement Screen*

Cerebral and Tissue Oximetry

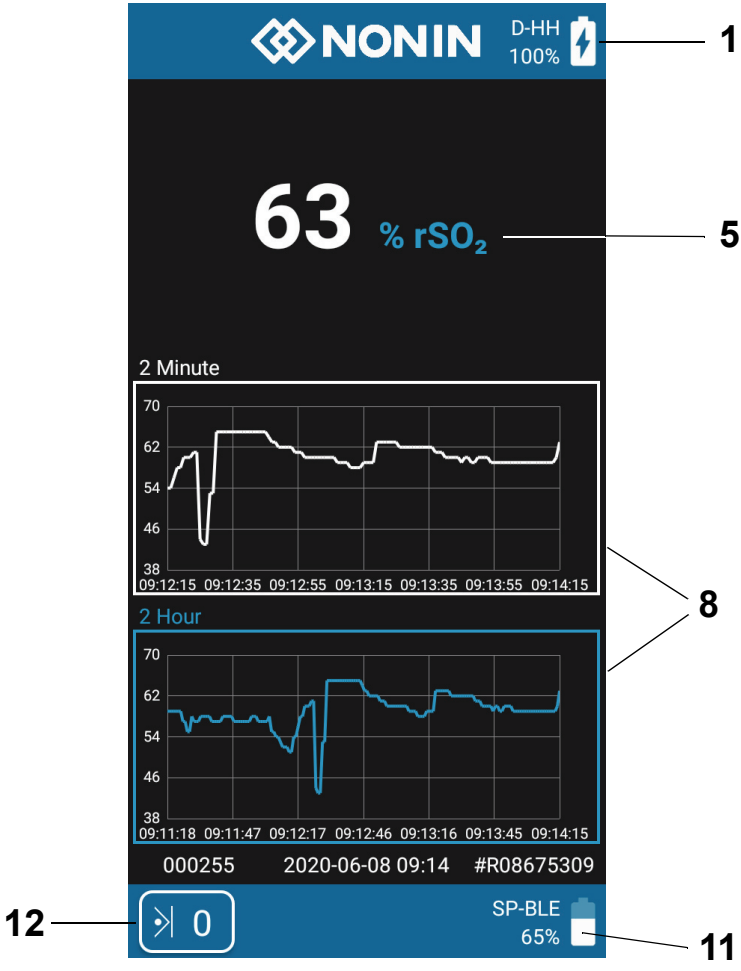


Figure 4. *rSO_2 Measurement Screen*

Table 3. *CO-Pilot Measurement Screen Symbols and Indicators*

No.	Symbol	Description
1		**Display Battery Indicator** The display battery indicator shows the approximate percentage of battery life remaining on the display. For signal processor battery information see item number **11**.  Approximate Battery Percentage  Charging  Critical Battery
2	$\%SpO_2$	**Percent Functional Hemoglobin Oxygen Saturation** Displays dashes until the reading is valid. $\%SpO_2$ data displays from 0 to 100% when a signal processor receives an adequate signal from an attached sensor.
3		**Pulse Rate** Displays dashes until the reading is valid. Pulse Rate data displays from 18 to 321 BPM when a signal processor receives an adequate signal from an attached sensor. The symbol will change color based on the pulse signal quality, see "Determining Pulse Signal Quality" section on page 25.
4	%COHb	**Percent Carboxyhemoglobin** Displays dashes until the reading is valid. %COHb data displays from 0 to 99% when a signal processor receives an adequate signal from an attached sensor.
5	rSO_2	**Cerebral and Tissue Hemoglobin Oxygen Saturation** **NOTE:** *$\%rSO_2$ displays when an absolute cerebral and tissue sensor is attached to a signal processor.* $\%rSO_2$ displays from 0 to 100% when a signal processor receives an adequate signal from an attached cerebral and tissue sensor.

Table 3. *CO-Pilot Measurement Screen Symbols and Indicators*

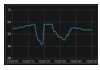
No.	Symbol	Description
6	%MetHb	**Percent Methemoglobin** Displays dashes until the reading is valid. %MetHb data displays from 0 to 99% when a signal processor receives an adequate signal from an attached sensor.
7		**Pulse Waveform, Photoplethysmogram** The plethysmogram is normalized and the scale is automatically determined by the system.
8		**RSO_2 Histogram** Trend graph of the rSO_2 measurements for a 2-minute time scale and a 2-hour time scale.
9	EXAMPLE: 000016	**Session ID** Unique identifier for recorded data file.
10	EXAMPLE: 2019-08-28 06:32	**Date and Time** The date and time display in 24-hour clock format (yyyy-mm-dd hh:mm). To set the date and/or time, see "Setting Date and Time" section on page 36.
11		**Signal Processor Battery Indicator** The indicator shows the approximate percentage of battery life remaining on the signal processor.  Approximate Battery Percentage  Charging  Critical Battery
12		**Event Marker** Displays current event mark number. *Single Press*: Places an event mark with the indicated number into the data file. *Hold Press*: Creates a new data file for the current session.
13	EXAMPLE: #SN05555554	**Signal Processor Serial Number** Unique identification number for signal processor.

Table 3. *CO-Pilot Measurement Screen Symbols and Indicators*

No.	Symbol	Description
14		**File Transfer** Used to download data from D-HH device.
15		**File Delete** Used to delete data from D-HH device.  Confirms request to delete all files.  Cancels request to delete all files; returns to previous screen.
16		**Clock** The date and time display in 24-hour clock format (yyyy-mm-dd hh:mm). Pressing this button allows for setting of the date and/or time, see "Setting Date and Time" section on page 36".
17		**D-HH Device and Software** Provides the serial number and software revision for the D-HH.
18		**SP-BLE Device and Software** Provides the serial number and software revision for the SP-BLE.
19		**Enable/Disable CO-Met** When shown, COHb and MetHb measurements will not be displayed or saved. The user must enable measurement of COHb and MetHb by pressing the button. The measurement of COHb and MetHb must be re-enabled each time the display goes to standby.

System Components and Set Up

NOTES:

- Before using the system, please review all warnings and cautions.
- Before using the system for the first time, the battery should be charged fully.
- Additional, but recommended, set-up tasks include: setting the clock.

Unpacking

Carefully remove the system components and accessories from the shipping carton. Inspect all components for damage. Compare the packing list with the accessories received to make sure the shipment is complete.

The standard system configuration includes these non-sterile components:

- D-HH, Nonin CO-Pilot handheld display
- SP-BLE, Nonin CO-Pilot Signal Processor, Bluetooth Low Energy
- H500-CC, Nonin CO-Pilot System Carrying Case
- Power Supply (quantity 2).
- SenSmart® 8330AA Multi-Sensing Sensor
- USB Flash Drive
- Data Download Cable
- Operator's Manual
- Quick Start Guide

For a list of accessories, see "Parts and Accessories" section on page 40.

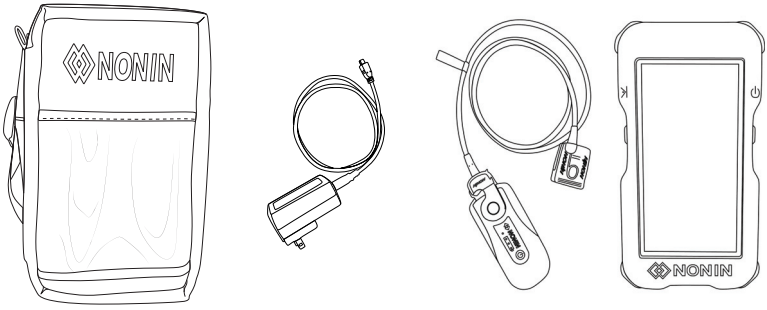


Figure 5. *Unpacking the CO-Pilot System*

System Configuration

CO-Pilot System in Carry Case with Finger clip sensor attached

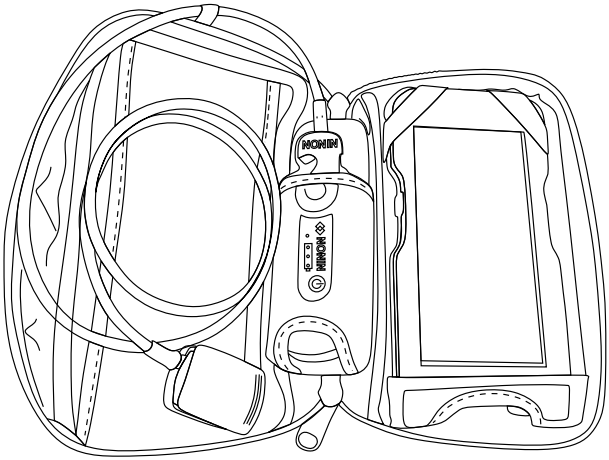


Figure 6. *System Set Up*

System Display

The system display allows the user to view %COHb, %MetHb, $\%SpO_2$, and pulse rate data. See below for display features and descriptions.

For cleaning instructions, refer to "Care and Maintenance" section on page 38.

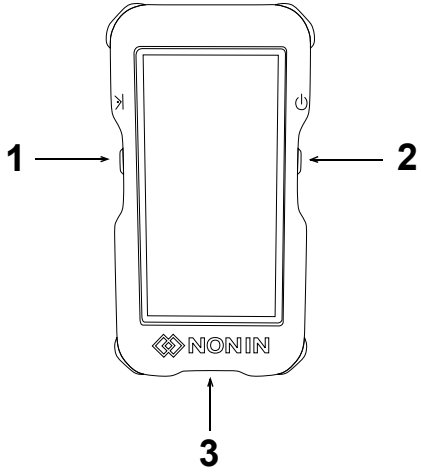


Figure 7. *D-HH Display*

Table 4. *D-HH Features*

No.	Description
1	**Event Mark Button** *Single Press*: Places an event mark with the indicated number into the data file. *Hold Press*: Creates a new data file for the current session.
2	**On/Off, Sleep Button** • ***On*** – Pressing this button once turns on the display. Each time the display is turned on, it activates the signal processor. • ***Sleep***– Quickly press the On/Off button to turn both display and signal processor off. • ***Off (Long-Term Storage Mode)*** – For information on putting display into long-term storage mode, see "Placing Device in Long-Term Storage Mode" section on page 28.
3	**Display Charging Port/Download Port** See "Charging the System" section on page 27 for charging instructions and battery life information.

Signal Processor (SP-BLE)

The signal processor calculates all measurements and sends to paired display through a Bluetooth Low Energy (BLE) wireless connection.

Signal processor requires a sensor to be connected to the sensor connection port to take a measurement. See "Connect/Disconnect a Sensor to the Signal Processor" section on page 22 for sensor connection instructions.

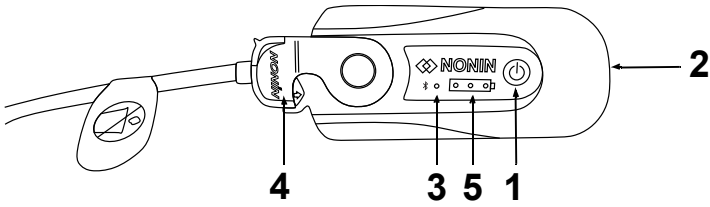


Figure 8. *SP-BLE Signal Processor*

Table 5. *SP-BLE Features*

No.	Symbol	Description
1		**On/Off Button** • ***On*** – Press and hold power button. • ***Off (Long-Term Storage Mode)*** – For information on putting signal processor into long-term storage mode, see "Placing Device in Long-Term Storage Mode" section on page 28.
2	NA	**Signal Processor Charging Port**
3		**Bluetooth Indicator** Bluetooth indicator LED flashes blue when signal processor is ready for a connection to display and solid blue when a connection has been made.
4	NA	**Sensor Connection Port**
5		**Signal Processor Battery Indicator** Shows the current battery status of the signal processor. For more information on signal processor battery, see "Charging the System" section on page 27.

Connect/Disconnect a Sensor to the Signal Processor

1. To connect:
   a. Flip the clear lock on the signal processor back to expose the connection port (**Figure 9.A**).
   b. Insert the sensor connector into the signal processor connection port (**Figure 9.B**).
   c. Flip the lock over the sensor connector and click it into place (**Figure 9.C**).

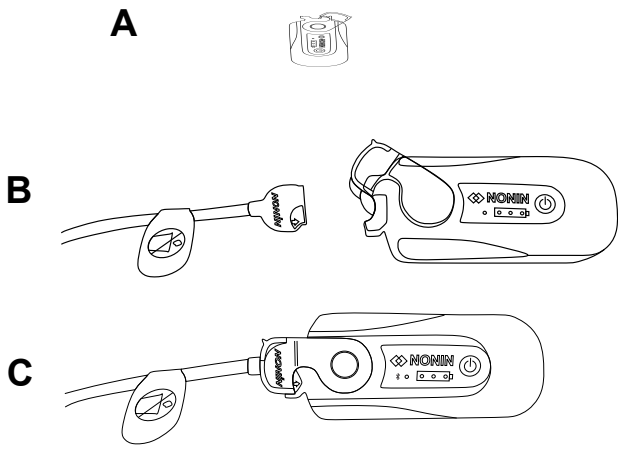


Figure 9. *Connect Sensor to Signal Processor*

2. To disconnect:
   a. Flip the clear lock on the signal processor back to disengage the lock from the connector.
   b. Grasp the connector and remove the sensor from the signal processor.

Replacing the Lock on the Signal Processor

NOTE: Replacement locks may be ordered if the lock is lost or damaged.

1. Align the lock hinge with the connector end of the signal processor. (**Figure 10.A**).

2. Gently spread the lock hinge so it fits over the end of the signal processor.
3. Click the lock into place (**Figure 10.B**).

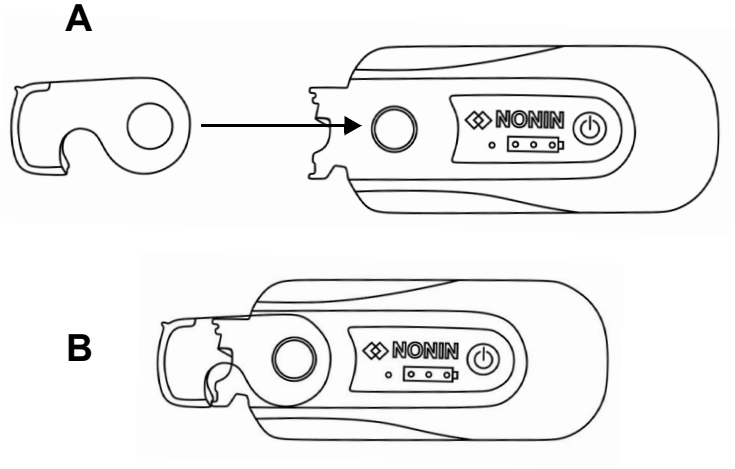


Figure 10. *Signal Processor Lock Replacement*

Sensors

Detailed information regarding specific sensor use (e.g., patient population, body/tissue, application, connecting the sensor to the system) can be found in the respective sensor instructions for use.

For a list of compatible sensors, refer to the "Parts and Accessories" section on page 40.

System Operation

CAUTION: Between patients, start a new patient record. This can be accomplished either by placing the CO-Pilot System into Sleep Mode or by pressing and holding the event mark button.

WARNING: This device is intended only as an adjunct device in patient assessment. It should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

WARNING: As with all medical equipment, carefully route patient cables and connections to reduce the possibility of entanglement, strangulation, or tripping.

Initial System Set-Up

Follow the below steps when setting up the system for the first time.

1. Fully charge display and signal processor per instructions in "Charging the System" section on page 27.
2. Press and hold the **On/Off** button on signal processor until all three green LEDs blink on and Blue Bluetooth LED begins to blink.
3. Press and hold the **On/Off, Sleep** button on display until screen turns on.
4. It is recommended to set Date and Time following “Setting Date and Time” instructions in "Setting Date and Time" section on page 36 upon initial setup of device.
5. Connect sensor to signal processor and engage sensor lock.
6. Observe display during start-up to ensure screen is working and expected parameters are indicated.
7. System is now ready to take a measurement or to be turned off for future use.

Start-up Sequence

Each time the display is turned on, it performs a brief start-up sequence.

1. Press **On/Off, Sleep** button on display.
2. The display lights up and displays the welcome screen.
3. Display will automatically connect to signal processor.
4. Sensor and signal processor turn on.

5. Once display has connected to signal processor, measurement screen will display. The system is now ready to take a measurement.

NOTE: If the sensor does not turn on, ensure sensor is plugged into the signal processor. If the sensor still does not turn on, press and hold down the **On/Off** button on the signal processor.

Taking a Measurement

1. Prepare the system for measurement by following the steps in the previous section, “Start-up Sequence”.
2. Place the sensor on the patient according to sensor instructions.
3. Take measurement.
4. When operation is complete, briefly press the **On/Off, Sleep** button on display to end session and turn off the device. Signal processor will turn off automatically.

During patient measurements the D-HH and SP-BLE may reach temperatures of up to 47 degrees Celsius when operated inside of the carrying case, which is safe for contact with healthy adult skin for up to 10 minutes. Allow the D-HH and SP-BLE to cool prior to skin contact of greater than 10 minutes.

During patient measurements the D-HH and SP-BLE may reach temperatures of up to 43 degrees Celsius when operated outside of the carrying case, which is safe for contact with healthy adult skin (no time restriction).

Determining Pulse Signal Quality

The pulse signal quality can be determined by the color of the pulse waveform displayed on the display. This pulse waveform changes colors to alert you to changes in pulse quality that may affect the readings:

- **Green** Pulse Waveform indicates a good pulse signal.
- **Yellow** Pulse waveform indicates a marginal pulse signal.
- **Red** Pulse Waveform indicates an inadequate pulse signal.

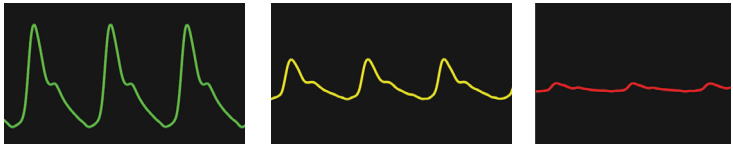


Figure 11. *Pulse Signal Quality*

Event Marking

NOTE: New patient record can be started when the event mark button is held for more than 0.5 seconds. Between patients, turn the display off. When the device is turned on, the display begins a new patient record.

After turning on the system and applying the sensor to the patient:

1. Press the event mark button to place an event mark in the recorded data
2. Verify the event mark on screen increased by '1'. The event marker icon number will increment with each mark event.

Pressing the event marker icon below will place an event number in the data file:

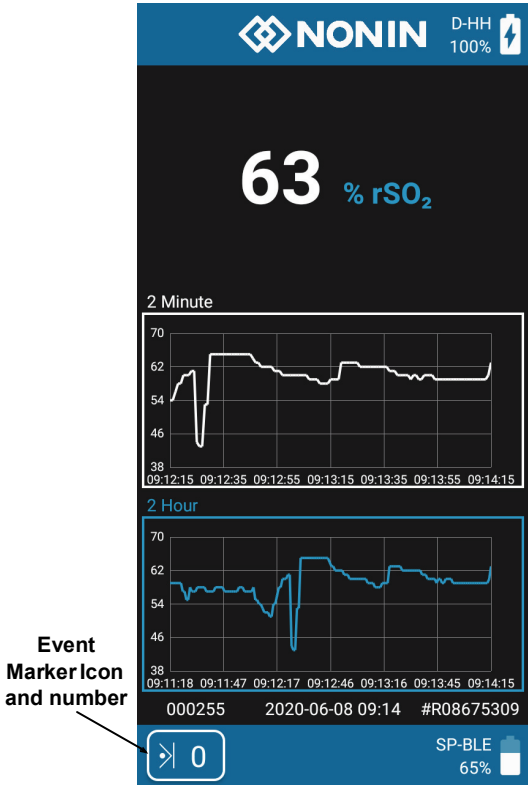


Figure 12. *Event Marking*

Charging the System

WARNING: Do not use the signal processor or display while charging. Charging is an operator function. To ensure patient safety, the system is not to be in contact with the patient during charging.

CAUTION: Charging signal processor at temperatures below 0 degrees °C (32 degrees °F) will decrease battery life. Do not charge signal processor at temperatures below 0 °C (32 °F).

Display and signal processor must both be charged to use system.

1. Charge the display and signal processor using the provided Nonin power supplies.
2. Insert power supply into respective display and signal processor charging ports.

During patient measurements the D-HH and SP-BLE may reach temperatures of up to 57 degrees Celsius when charged inside of the carrying case, which is safe for contact with healthy adult skin for up to 1 minute. Allow the D-HH and SP-BLE to cool prior to skin contact of greater than 1 minute.

During charging the D-HH and SP-BLE may reach temperatures of up to 48 degrees Celsius when charged outside of the carrying case, which is safe for contact with healthy adult skin for up to 10 minutes. Allow the D-HH and SP-BLE to cool prior to skin contact of greater than 10 minutes.

SP-BLE Battery Indication	Battery Level
1 blinking green light	Critical to Low (0-19%)
1 green light lit, 1 blinking green light	Medium (20-59%)
2 green lights lit, 1 blinking green light	High (60-99%)
3 green lights are lit	Full (100%)

Battery

For more information, see the “Internal Power” section in "Specifications" section on page 55.

CAUTIONS:

- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Batteries are a fire hazard if damaged. Do not damage, mishandle, disassemble, service, or replace with non-specified components.
- Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.

Signal Processor Battery Status: Discharge

To check battery status on signal processor,

1. Quickly press the On/Off button on signal processor.
2. Battery indicator lights will light indicating current battery status.

SP-BLE Battery Indication	Battery Level
3 green lights are lit	High (60-100%)
2 green lights are lit	Medium (20-59%)
1 green light is lit	Low (5-19%), charge SP
1 green light is blinking	Critical (0-4%), charge SP
No lights	Depleted or Off

Signal processor battery status can also be found on the display screen as shown in *Symbol 11* of **Figure 3.**

Placing Device in Long-Term Storage Mode

When not using device daily or for storing for long periods of time, battery life can be extended by placing the system into Long-Term Storage Mode.

1. Press and hold On/Off, Sleep button on display until screen prompt appears
2. Choose “Power Off” on screen. Screen will go black. Display is now in Long-Term Storage Mode.

3. Press and hold the On/Off button on the signal processor until all signal processor lights flash simultaneously. Signal processor is now in Long-Term Storage Mode.

To take system out of Long-Term Storage mode for use, follow steps 2-5 in "Initial System Set-Up" section on page 24.

Data Download

Session data can be downloaded from the display onto a memory stick.

NOTE: Data can only be downloaded via download cable and memory stick. Data cannot be downloaded directly from device by use of included charging cable.

1. Plug USB memory stick into download cable and insert data download cable connector into the charging port of display.
2. On display start-up screen tap the file transfer icon to start the data download process as shown below.

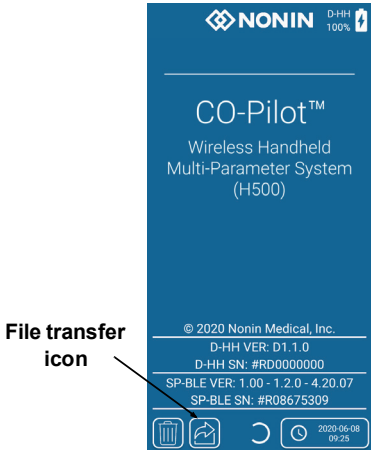


Figure 13. *Start-Up Screen - Select Transfer Icon*

NOTE: If using the same USB memory stick, the display may automatically return to the file location used for the last data download.

3. Display will show Data Download Screen 1. Tap menu icon in upper left of screen:

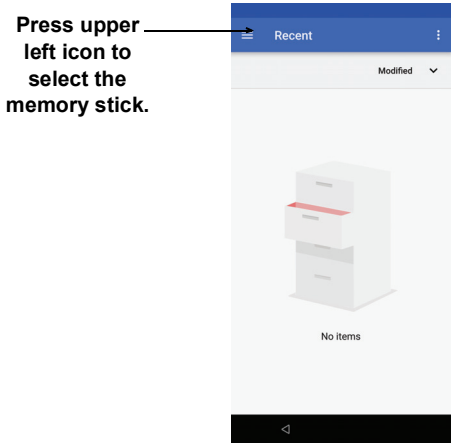


Figure 14. *Data Download Screen 1- Select Menu Icon*

4. Select memory stick location by selecting the USB memory stick in menu:

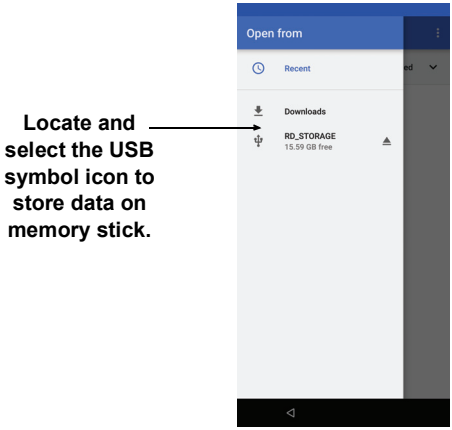


Figure 15. *Data Download Screen 2- Memory Stick Location*

5. Choose the desired storage location and press SELECT. Data download will begin automatically once files are selected:

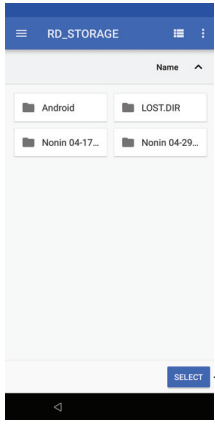


Figure 16. *Data Download Screen 3- Select Files to Transfer*

6. Data transfer is successful if the File Transfer icon has been replaced with the Confirm icon, shown as a check mark in **Figure 17**.

Figure 17. *Data Transfer Successful*

To view downloaded files:

1. Disconnect memory stick from data download cable.
2. Connect memory stick to computer USB port.
3. Open desired file using a spreadsheet program (e.g. Microsoft Excel).

Session Number:	6					
Start Date:	2019-09-18					
Serial Number:	R05555554					
Sensor Type:	Regional					
Time	Data Point	Mark	rSO2 (%)	Hbl (%)	Poor Signal Quality	Reserved
8:29:08	0					
8:29:09	1		--	--	1	00-5e
8:29:10	2		--	--	1	00-56
8:29:11	3		--	--	1	00-7e
8:29:12	4		--	--	1	00-5e
8:29:13	5		--	--	1	00-56
8:29:15	6		--	--	1	00-56
8:29:15	7		--	--	1	00-16
8:29:17	8	1	--	--	1	00-7e
8:29:17	9		--	--	1	00-56
8:29:18	10		--	--	1	00-16
8:29:19	11	2	--	--	1	00-56
8:29:20	12		--	--	1	00-56
8:29:21	13		--	--	1	00-0e
8:29:22	14		--	--	1	00-04
8:29:23	15		--	--	1	00-04
8:29:24	16		--	--	1	00-04
8:29:25	17		--	--	0	00-00
8:29:26	18		71	0.88	0	00-00
8:29:27	19		71	0.88	0	00-00
8:29:28	20		71	0.88	0	00-00
8:29:29	21		70	0.88	0	00-00
8:29:30	22		70	0.88	1	00-5c
8:29:31	23		70	0.88	1	00-14

Figure 18. *Download Data Files*

NOTE: The time data is intended to be in a HH:mm:ss format. Opening the downloaded data files in a spreadsheet program may cause the time data to be formatted inconsistently. To confirm that the time data is formatted as intended, ensure the file name's time value (HH-mm-ss) matches the first time of the data (HH:mm:ss). It may be necessary to reformat the time data to a HH:mm:ss format to present the data as intended.

Data Delete

Session data can be deleted from the D-HH device by following the steps below.

1. On display start-up screen tap the File Delete icon to start the data delete process as shown below.

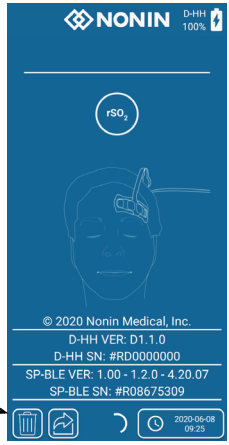


Figure 19. *Start-Up Screen - Select File Delete Icon*

2. Tapping the File Delete icon **once** will cause the Delete button and File Transfer button to be replaced by the ‘check mark’ and ‘X’ icons shown in **Figure 20**.

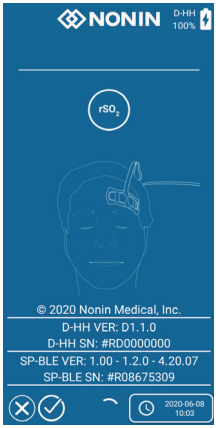


Figure 20. *Start-Up Screen - Select File Delete Confirm icon*

3. Pressing the 'Check Mark' icon will delete all files on the D-HH device and pressing the 'X' will return to the previous screen (*Start-Up Screen - Select File Delete Icon*).

NOTE: Once files have been deleted, they cannot be recovered.

Setting Date and Time

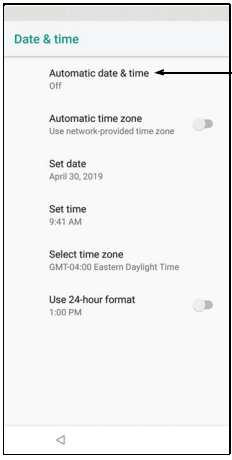
Date and time must be set manually.

To set data and time:

1. Turn on the display to show Start-Up screen.
2. Tap the date and time button.

Figure 21. *Start-Up Screen - Setting Date and Time*

3. Date and Time screen will appear (**Figure 22.**) Select “Set date” and enter the appropriate date.
4. Select “Set time” and enter the appropriate time.



Select:

- Manually set the date.
- Manually set the time.

Make sure the following are set:

- Automatic = OFF
- Automatic time zone = disabled

NOTE: The display is not a mobile device; there is no way for display to use automatic time zone.

Figure 22. *Date and Time Screen - Settings*

Care and Maintenance

The advanced digital circuitry within the CO-Pilot system components requires no calibration or periodic maintenance.

Do not attempt to open the case of any of the system components or repair the electronics. Opening the case will damage the component and void the warranty. If the device or system is not functioning properly, see "Troubleshooting" section on page 43.

The Oxitest Plus 7 (software rev. 2.5 or greater) by Datrend Systems, Inc. can be used to verify operation of the pulse oximeter. The Oxitest cannot be used to verify COHb, MetHb, or rSO_2 values.

CAUTIONS:

- Follow local, state and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Batteries are a fire hazard if damaged. Do not damage, mishandle, disassemble, service, or replace with non-specified components.
- Do not charge Li-Ion batteries at a temperature of 0 °C (32 °F) or less as this may result in significantly reduced battery life.

Cleaning Instructions

The following cleaning instructions apply to the display and signal processor.

1. Wipe the component with a soft cloth dampened with a cleaning solution, taking care to avoid liquid entering open connectors (leave reusable sensors connected to the signal processor; ensure display charging port cover is fully inserted; do not use excessive liquid). Do not use any cleaning solution other than those listed below, as permanent damage could result.
2. Allow to air-dry.

Approved cleaning chemicals:

- Isopropyl alcohol
- Ammonium chloride
- 10% bleach/90% water solution

The following cleaning instructions apply to the carrying case.

- Clean with a mild detergent (see note) in warm water. Allow to air dry. Do not machine wash or dry.

NOTE: To clean washable surfaces, use in a solution of warm water and detergent. Mild detergents, such as hand and dish-washing liquid detergents, dissolve dirt and grease.

WARNING: Protect from exposure to water or any other liquid, with or without AC power.

CAUTION: Do not place the device in liquid or clean it with any cleaning solutions that are not listed in this operator's manual.

CAUTION: Use a detergent that is safe for skin and washable surfaces. Most detergents can be high sudsing, so use sparingly. Wipe with a damp, detergent-free cloth to remove residue.

Parts and Accessories

WARNING: Use the CO-Pilot only with power supply supplied by Nonin Medical.

For more information about Nonin parts and accessories, visit www.nonin.com or contact Nonin Medical.

Model	Description
Power Supply	
Power Supply	Medical Grade, 15W
Instructions for Use	
CO-Pilot Manual	Operator's Manual for the CO-Pilot system
Display	
D-HH	CO-Pilot System display
Signal Processors and Accessories	
SP-BLE	Signal processor for use with the CO-Pilot System
SP-BLE-SL	Signal processor sensor lock, 2-pack
Cables and Other Accessories	
H500-CC	Carrying case
INT-100	Intermediate Cable **NOTE**: For use with 8204CA only.
H500-DK	Data download kit, includes data download cable and USB flash drive

Compatible Sensors

The following Nonin sensors are compatible for use with the CO-Pilot System.

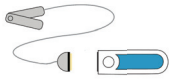
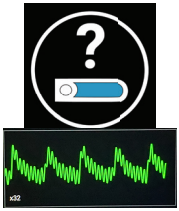
Model	Description
8100A Series	**Reusable, Finger Clip Pulse Oximeter Sensor** **8100AA:** Measures SpO_2 and pulse rate of adult and pediatric patients (> 30 kg /66 lb) who are well or poorly perfused, during both motion and non-motion conditions. **8100AP:** Measures SpO_2 and pulse rate of pediatric patients (8 – 60 kg / 18 – 132 lb) who are well or poorly perfused, during both motion and non-motion conditions.
8100S Series	**Reusable, Soft Pulse Oximeter Sensor** **8100SL:** Measures SpO_2 and pulse rate of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions, with digit height (thickness) of 12.5 – 25.5 mm (0.5 – 1.0 in.). **8100SM:** Measures SpO_2 and pulse rate of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions, with digit height (thickness) of 10 – 19 mm (0.4 – 0.75 in.). **8100SS:** Measures SpO_2 and pulse rate of adult and pediatric patients who are well or poorly perfused, during both motion and non-motion conditions, with digit height (thickness) of 7.5 – 12.5 mm (0.3 – 0.5 in.).
8100Q2	**Reusable Ear Clip Pulse Oximeter Sensor** Measures SpO_2 and pulse rate of adult and pediatric patients (>40 kg / 88 lb) who are well or poorly perfused, during non-motion conditions.
8004CA	**Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor** Measures rSO_2 of adult and pediatric patients weighing ≥ 88 pounds (40 kilograms).
8004CB	**Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor** Measures rSO_2 of neonate, infant, and pediatric patients weighing ≤ 88 pounds (40 kilograms).
8004CB-NA	**Non-Adhesive, Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor** Measures rSO_2 of neonate, infant, and pediatric patients weighing ≤ 88 pounds (40 kilograms).

Model	Description
8204CA	**Single-Patient Use, Non-Sterile, Disposable Regional Oximetry Sensor** Measures rSO_2 of adult and pediatric patients weighing ≥ 88 pounds (40 kilograms).
8330AA	**Multi-Sensing Reusable Finger Clip Sensor** Measures SpO_2, COHb, MetHb and pulse rate of adult and pediatric patients (> 66 lbs/30 kg).

WARNING: The use of signal processors, sensors, accessories, and cables other than those in the Parts and Accessories List may or will result in increased electromagnetic emission and/or decreased immunity of this device.

WARNING: Use only Nonin-branded oximeter sensors. These sensors are manufactured to meet the accuracy specifications for Nonin oximeters. Using other manufacturers' sensors can result in improper oximeter performance.

Troubleshooting

Error Icon/ Description	Problem	Possible Solution
	Sensor not plugged into signal processor.	Plug sensor into signal processor and engage sensor lock.
	Display cannot connect to signal processor.	Check that the signal processor is charged and turned on. Charge signal processor if necessary. Ensure that the display and signal processor are within the specified operating range and free of obstructions or interference sources. Contact Nonin if signal processor is charged and turned on and an error persists.
	Sensor Fault	Connect new sensor to signal processor
	Inadequate Signal.	Check sensor placement on patient and adjust as needed. Potentially try a different digit. Check for and limit excessive patient motion. Check for potential interfering devices and increase separation distance.
	Error Code	Refer to error code on display and reference below for solution.
Display is black/ inactive.	Display is turned off or battery is depleted.	Try turning the display on or connect power supply to display.

Error Icon/ Description	Problem	Possible Solution
	Signal processor is charging. Measurements are not available while the signal processor is charging.	Disconnect the signal processor from the power supply.
Signal processor has no lights on/ inactive.	Signal processor is long-term storage (off) mode or battery is depleted.	Try turning the signal processor on or connect the power supply to signal processor.
NA	Device is not charging.	Ensure that the charging port is free of any contaminants and the power supply plug is fully inserted
	Noisy Waveform (PPG)	Check sensor placement on patient and adjust as needed. Potentially try a different digit. Check for and limit excessive patient motion. Check for potential interfering devices and increase separation distance.

If these solutions do not correct the problem, please contact Nonin Technical Service. See Service and Support section for contact information.

Error Codes

Certain operation conditions may cause error codes to pop-up on screen. These error codes are detailed below:

Error Code	Possible Cause	Possible Solution
COM-01	Wireless connection setup failed. Connection may have taken too long to open.	Attempt connection again. If problem persists, contact Nonin.
COM-02	Wireless connection rejected, likely due to pairing mismatch.	Contact Nonin.
COM-03	Wireless connection failed security authentication.	Attempt connection again. If problem persists, contact Nonin.
OXI-01	SP-BLE is not sending critical data.	Attempt connection again. Power the device off and then on. If problem persists, contact Nonin.
OXI-02	SP-BLE internal error.	Power the device off and then on. If problem persists, contact Nonin.
OXI-03	SP-BLE gas gauge failure.	Power the device off and then on. If problem persists, contact Nonin.
MEM-01	Application configuration failure.	Contact Nonin.
MEM-02	Failure during file transfer. OTG cable may have been bumped during file transfer.	Attempt connection again. If problem persists, contact Nonin.
MEM-03	Failure during file deletion.	Attempt connection again. If problem persists, contact Nonin.
MEM-04	Failure creating study file.	Attempt connection again. If problem persists, contact Nonin.

Service, Support, and Warranty

Service and Support

A return authorization number is required before returning any product to Nonin. To obtain this return authorization number, contact Nonin Technical Service:

Nonin Medical, Inc.
13700 1st Avenue North
Plymouth, Minnesota 55441 USA

(800) 356-8874 (USA and Canada)
+1 (763) 553-9968 (outside USA and Canada)
Fax: +1 (763) 553-7807
E-mail: technicalservice@nonin.com

Nonin Medical B.V.
Doctor Paul Janssenweg 150
5026 RH Tilburg
The Netherlands
+31 (0)13 45 87 130
E-mail: technicalserviceintl@nonin.com

www.nonin.com

WARNING: This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.

Warranty

For warranty information, please refer to: **http://www.nonin.com/warranty/**

Technical Information

NOTE: This product complies with ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

CAUTION: A functional tester cannot be used to assess the accuracy of the display, signal processor or sensor.

CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.

Essential Performance

Essential performance of the CO-Pilot™ Wireless Handheld Multi-Parameter System includes providing accurate measurements within claimed tolerances or giving indication of abnormal operation.

Manufacturer's Declaration

Refer to the following tables for specific information regarding this device's compliance to IEC 60601-1-2.

Table 6. *Electromagnetic Emissions*

Emissions Test	Compliance	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.		
RF Emissions CISPR 11	Group 2	This device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 7. *Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	±5% U_T (>95% dip in U_T) for 0.5 cycle ±40% U_T (60% dip in U_T) for 5 cycles ±70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 8. *Recommended Separation Distances*

This table details the recommended separation distances between portable and mobile RF communications equipment and this device.

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

	Separation Distance According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Equipment Response Time

If the SpO_2 signal from the sensor is inadequate, the last measured values freeze for 10 seconds and are then replaced with dashes.

SpO_2 Values	Response	Latency
Fast Averaged SpO_2	3 second or faster exponential time constant	2 beats

Pulse Rate Values	Response	Latency
Fast Averaged Pulse Rate	3 second or faster exponential time constant	2 beats

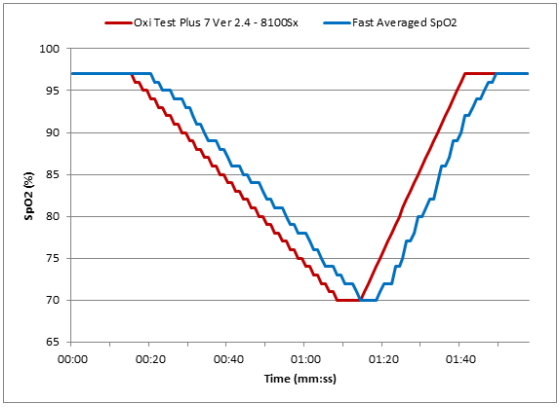
Equipment Delays	Delay
Display Update Delay	1.5 – 2.5 seconds*

*Wireless communications can be delayed when in environments with high radio interference.

Example – SpO_2 Exponential Averaging

SpO_2 decreases 1.0% every 2 seconds (5% over 10 seconds)

Pulse Rate = 75 BPM



Specific to this example:

- The response of the SpO_2 average is 6 seconds.

Testing Summary

COHb/MetHb Principles of Operation

An oximeter is a non-invasive device that passes several colors of light (from red to infrared) through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well- oxygenated blood is bright red, while poorly oxygenated blood is dark red. The presence of COHb and MetHb causes other color differences sensed only in the infrared. The oximeter analyzes the color fluctuations caused by heart pulses so it can cancel out steady conditions (e.g., steady venous blood flow, skin thickness, bone, fingernails, etc.). The light emissions of the sensor are measured in every color and then stored in the sensor's embedded memory so light color caused by manufacturing variations are canceled. With the patient in a steady state and the sensor light emissions canceled out, the oximeter can estimate SpO_2, COHb, and MetHb. The mathematics are fixed in the oximeter hardware and software; therefore, no field calibration is needed. There are no adjustable parts within the oximeter that affect the calibration. Nonin oximeters are calibrated to closely approximate functional oxygen saturation, COHb fraction, and MetHb fraction values.

COHb Accuracy Testing

COHb accuracy testing was conducted at an independent research laboratory on healthy, male and female, non-smoking, light to dark-skinned subjects that were 18 years of age and older. The measured carboxyhemoglobin value (%COHb) of the sensors was compared to simultaneous arterial blood samples as assessed by co-oximetry. The accuracy of the sensors in comparison to the co-oximeter samples measured over the COHb range of 0-15% with 95 – 100% SaO_2. Accuracy data was calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment-Particular requirements for basic safety and essential performance of pulse oximeter equipment.

MetHb Accuracy Testing

MetHb accuracy testing was conducted at an independent research laboratory on healthy, male and female, non-smoking, light to dark-skinned subjects that were 18 years of age and older. The measured methemoglobin value (%MetHb) of the sensors was compared to simultaneous arterial blood samples as assessed by co-oximetry. The accuracy of the sensors in comparison to the co-oximeter samples measured over the MetHb range of 0 – 15% with 95 – 100% SaO_2. Accuracy data was calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment-Particular requirements for basic safety and essential performance of pulse oximeter equipment.

SpO_2 Principles of Operation

Pulse oximetry is a non-invasive method that passes red and infrared light through perfused tissue and detects the fluctuating signals caused by arterial pulses. Well-oxygenated blood is bright red, while poorly oxygenated blood is dark red. The pulse oximeter determines functional oxygen saturation of arterial hemoglobin (SpO_2) from this color difference by measuring the ratio of absorbed red and infrared light as the volume fluctuates with each pulse.

SpO_2 Accuracy Testing

During motion and non-motion conditions at an independent research laboratory, SpO2 accuracy testing was conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that were 18 years of age and older. The measured arterial hemoglobin saturation value (SpO2) of the sensors was 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 SpO_2 range of 70 – 100%. Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

SpO_2 Accuracy Testing in Presence of COHb and MetHb

During non-motion conditions at an independent research laboratory, SpO_2 accuracy testing in the presence of COHb and MetHb was conducted during induced hypoxia studies on healthy, male and female, non-smoking, light- to dark-skinned subjects that were 18 years of age and older.

The measured arterial hemoglobin saturation value (SpO_2) of the sensors was compared to arterial hemoglobin oxygen (SaO_2) 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 SpO_2 range of 80 – 100%, range 0 – 15% COHb and SpO_2 range of 80 – 100%, range 0 – 15% MetHb.

Accuracy data was calculated using the root-mean-squared (A_{rms} value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Pulse Rate Accuracy Testing

This test measured pulse rate oximeter accuracy with and without motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 80601-2-61 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Accuracy Testing

This test uses an SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 80601-2-61 for pulse rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

rSO_2 Principles of Operation

Regional oximetry uses calculations based on the Beer-Lambert law or Beer's law, to determine cerebral and tissue oxygenation. The Beer-Lambert law relates the absorption of light to the properties of the material through which the light is traveling. The law states that there is a logarithmic relationship between the concentration of compounds and the transmission of light through it. By utilizing wavelengths of light that are absorbed by the compounds to be measured, the concentration of the compounds can be determined. For cerebral and tissue oximetry, the compounds of interest are hemoglobin, deoxygenated hemoglobin, and tissue.

The oximetry sensors use a proprietary, patented arrangement of light emitters (LEDs) and light detectors (photodiodes). This arrangement effectively provides a "deep tissue" absorption measurement focused on the cerebrum. The absorption measurement is largely unaffected by surface or near-surface features, irregularities, or substances.

rSO_2 Accuracy Testing

At an independent research laboratory, rSO_2 accuracy testing was conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects that were 18 years of age and older. The measured cerebral and tissue hemoglobin saturation value (rSO_2) of the sensors was compared to arterial/venous hemoglobin oxygen ($SavO_2$) value, determined from venous and arterial blood samples. The model used for blood in the brain was 70% venous and 30% arterial, which is applicable under normocapnic conditions. The venous blood was drawn from the right jugular bulb. The accuracy of the sensors in comparison to the blood gas analyzer samples measured over the rSO_2 range of 45 – 100%. Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-2-61, Medical Electrical Equipment—Particular requirements for basic safety and essential performance of pulse oximeter equipment.

Specifications

CAUTION: The device has been designed for use within the specified ranges. Use outside of these ranges has not been tested and may result in improper oximeter performance.

%COHb Display Range:	0 to 99%
%MetHb Display Range:	0 to 99%
%SpO_2 Display Ranges:	0 to 100%
%rSO_2 Display Range:	0 to 100%
Pulse Rate Display Range:	18 to 321 beats per minute (BPM)
Sensor Accuracy:	Refer to the sensor Instructions for Use (IFU) for accuracy data.
Measurement Wavelengths and Output Power [a]:	Refer to sensor IFU for details.
Memory:	Minimum 280 hours
Temperature:	
Operating:	0 ºC to 40 ºC (32 ºF to 104 ºF)
Transient Operating[b]:	-20 ºC to 50 ºC (-4 ºF to 122 ºF)
Storage/Transportation:	-40 ºC to 70 ºC (-40ºF to 158 ºF)
Humidity:	
Operating:	15% to 93% noncondensing
Transient Operating[b]:	15% to 90% noncondensing
Storage/Transportation:	Up to 93% noncondensing
Altitude:	
Operating:	0 to 4,000 meters (13,123 feet)
Atmospheric Pressure:	443 to 795 mmHg (590 to 1060 hPA)

Power Requirements (Mains):	100–240 VAC 50–60 Hz
Internal Power:	
D-HH Battery:	3.8 volt Li-ion battery, 3600 mAh
SP-BLE Battery:	3.7 volt Li-ion battery, 1260 mAh
Battery Capacity*:	Approximately 10 hours continuous operation *From a fully charged new battery measuring SpO_2, PR, COHb, and MetHb.
Battery Capacity Following Storage:	
Standby State for 1 Week:	Approximately 4 hours continuous operation*
Off State for 1 Month:	Approximately 8 hours continuous operation* *From a fully charged new battery measuring SpO_2, PR, COHb, and MetHb.
Charging Time*:	Approximately 9 hours *From critical battery level

a. This information is especially useful for clinicians performing photodynamic therapy.

b. The system will operate for a minimum of 20 minutes when exposed to the extreme environmental operating conditions.

Dimensions:	
D-HH:	97 mm W x 178 mm H x 21 mm D 3.8 in. W x 7.0 in. H x 0.8 in. D
SP-BLE:	23 mm H x 28 mm W x 89 mm L 0.9 in. H x 1.1 in. W x 3.5 in. L
Weight:	
D-HH:	330 grams (11.6 ounces)
SP-BLE:	90 grams (3.2 ounces)
Warranty:	
D-HH Display, SP-BLE Signal Processor:	2 years
Battery:	1 year

Classification per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL60601-1:	
Type of Protection:	Internally powered (on battery power). Class II with AC adapter.
Mode of Operation:	Continuous
Enclosure Degree of Ingress Protection:	
D-HH, SP-BLE:	IP33

Bluetooth Low Energy

Overview

Bluetooth Low Energy technology allows wireless communication between electronic devices. The technology is based on a radio link that offers fast and reliable data transmissions. Bluetooth Low Energy uses a license-free, globally available frequency range in the ISM band—intended to ensure communication compatibility worldwide.

The CO-Pilot System uses Bluetooth Low Energy to transmit data between the display and the signal processor.

Specifications

Operation	Bluetooth Low Energy
Bluetooth Compliance	Version 4.2
Transmission Power	< 8 dBm
Operating Distance	9.1 meters (30 feet), line-of-sight
Antenna Type	Internal

Quality of Service (QoS) Requirements

The CO-Pilot System requires an uninterrupted Bluetooth Low Energy connection to function properly. To achieve this level of QoS, ensure that both the display and signal processor are within operating distance of each other and are separated from potentially interfering devices or objects.

Communication Disruption

If the wireless communication between the display and the signal processor is disrupted, the display presents an error icon (refer to the *Troubleshooting* section). When this occurs, the display automatically attempts to re-establish the connection, and no additional action is required.

If encountering a communication disruption, first ensure that the display and signal processor are within their specified operating distance. Then, reposition the devices to minimize the obstructions between them while also separating the devices from nearby obstructions such as solid walls, floors, etc.

Interference from nearby wireless devices can also cause communication disruptions. If experiencing disruption when the display and signal processor are within range and have a clear line-of-sight, scan the environment for devices potentially interfering and move the CO-Pilot System away according to the following table:

Interfering Device Type	Transmission Power (W)	Separate Distance (m)
Wi-Fi	10	1.60
	1	0.51
	0.1	0.16
	0.01	0.05
Cellular	10	0.81
	1	0.26
	0.1	0.08
	0.01	0.03

The transmission power of a typical Wi-Fi router is about 0.1 Watts, and the transmission power of a typical cellular phone is about 0.5 Watts.

Security

The display and signal processor are paired during manufacturing which allows the devices to securely communicate via an encrypted Bluetooth Low Energy connection. This exclusive encrypted connection to each other secures the system from other devices by rejecting connection requests.

The communication between the display and the signal processor is protected from eavesdropping through the pairing and encryption security mechanisms built into Bluetooth Low Energy.

As such, upon delivery of the CO-Pilot System, there is no user action required to establish cybersecurity.