

Sensitest Pulse Oximeter Sensor Tester

Operating Manual

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UNPACKING INSTRUCTIONS:

Package Contents:

Sensitest SpO₂ Sensor Tester Battery: 9V NEDA 1604 Operating Manual

The Sensitest SpO_2 Sensor Tester is powered by a 9V alkaline battery (included). To install the battery, see section 3.3 of this Manual.

To order this manual, use Part Number 6100-020

Revision	Revision History Description	Date
F	Warranty revised to 2 years.	2008-Oct-08
G	 Warranty revised to 5 years Updated Corporate Address Expansion Box discontinued 	2012-Mar-08
Н	- Updated Corporate Address	2014-Nov-04

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Our routine method of shipment is via common carrier. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim.

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Please note only serialized products (products labelled with a distinct serial number) and accessories are eligible for partial refund and/or credit. Non-serialized parts and accessory items (cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. In order to receive a partial refund/credit, the product must not have been damaged, and must be returned complete (meaning all manuals, cables, accessories, etc.) within 90 days of original purchase and in "as new" and resalable condition. The *Return Protedure* must be followed.

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This instrument was thoroughly tested and inspected and found to meet DSI's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Research Council of Canada (NRC) and/or the National Institute of Standards and Technology (NIST). Devices for which there are no NRC/NIST calibration standards are measured against in-house performance standards using accepted test procedures.

Warranty

Warranty and Product Support

Datrend Systems Inc. ("DSI") warrants this instrument to be free from defects in materials and workmanship under normal use and service for five (5) years from the date of original purchase. During the warranty period DSI will, at our option, either repair or replace a product at no charge that proves to be defective; provided you return the product (shipping, duty, brokerage and taxes prepaid) to DSI. Any and all transportation charges incurred are the responsibility of the purchaser and are not included within this warranty. This warranty extends only to the original purchaser and does not cover normal wear and tear or damage from abuse, neglect, accident or misuse, or as the result of service or modification by other than DSI. IN NO EVENT SHALL DATREND SYSTEMS INC. BE LIABLE FOR CONSEQUENTIAL DAMAGES.

No warranty shall apply when damage is caused by any of the following:

- Power failure, surges, or spikes,
- Damage in transit or when moving the instrument,
- Accident, alteration, abuse or misuse of the instrument,
- Fire, water damage, theft, war, riot, hostility, acts of God, such as hurricanes, floods, etc.

Only serialized products (those items bearing a distinct serial number tag) and their accessory items are covered under this warranty. PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and non-serialized modules are not covered under this warranty.

This warranty gives you specific legal rights and you may have other rights, which vary from province to province, state to state, or country to country. This warranty is limited to repairing the instrument to DSI's specifications.

When you return an instrument to DSI for service, repair or calibration, we recommend shipment using the original shipping foam and container. If the original packing materials are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industrial-approved, shock-absorbent material all around the instrument.

DSI will not be responsible for lost shipments or instruments received in damaged condition due to improper packaging or handling. All warranty claim shipments must be made on a prepaid basis (freight, duty, brokerage, and taxes). No returns will be accepted without a Return Materials Authorization ("RMA) number. Please contact Datrend (see Chapter 7) to obtain an RMA number and receive help with shipping/customs documentation.

Recalibration of instruments, which have a recommended annual calibration frequency, is not covered under the warranty.

Warranty Disclaimer

Should you elect to have your instrument serviced by someone other than DSI, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to DSI for service, especially during the original warranty period. In all cases, breaking the tamper-resistant Quality Seal should be avoided at all cost, as this seal is the key to your original instrument warranty. In the event that the seal must be broken to gain internal access to the instrument (e.g., in the case of a customer-installed firmware upgrade), you must first contact DSI at 1-800-667-6557. You will be required to provide us with the serial number for your instrument as well as a valid reason for breaking the Quality Seal. You should break this seal only after you have received factory authorization. Do not break the Quality Seal before you have contacted us! Following these steps will help ensure that you will retain the original warranty on your instrument without interruption.

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Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. DSI will not be responsible for any injuries sustained due to unauthorized equipment modifications.

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Specifications

This chapter provides the specifications of the **Sensitest** Pulse Oximeter Sensor Tester.

1. SPECIFICATIONS

Sensor Interfaces

Sensitest provides standard interfaces for Nellcor[®] and Ohmeda sensors. Up to three additional sensor modules may be optionally installed to accommodate most major manufacturers of pulse oximeters.

Test Modes

MODE 1	Continuity test of red LED, infrared LED and photodiode circuits of sensor. Captures and displays intermittent short/open circuit conditions.	
MODE 2	Displays photodiode response to red and infrared LEDs as two bar graphs with numeric readouts ranging from zero to 99.	
Test Current		
MODE 1	LEDs: 2.0 mA Photodiode: 0.5 mA	
MODE 2	LEDs: 2.0 mA Photodiode: N/A	

Measurement Rate

MODE 1	125 Hz
MODE 2	4 Hz

User Interface

- 20 character X 2 line LCD
- Low battery LED indicator
- Piezo audio indicator
- POWER and MODE switches

Power Supply

- Standard 9V alkaline battery (NEDA 1604)
- Battery life: 100 hours

Dimensions

18 cm X 13 cm X 5 cm (7" X 5" X 2")

Weight

0.4 kg (0.88 lb.)

Optional Adaptors

Adaptor modules are available for most major makes. Maximum number of internal modules is three.

Overview

Chapter

This chapter provides an overview of the **Sensitest** Pulse Oximeter Sensor Tester.

2. GENERAL DESCRIPTION

The **Sensitest** SpO_2 Sensor Tester ("**Sensitest**") is a portable, battery-powered instrument for testing the electrical and optical function of pulse oximeter sensors. The standard model **Sensitest** provides connectors for testing Nellcor[®] and Ohmeda sensors, with additional makes accommodated by optional connector modules which may be installed on the right panel of the instrument.

The **Sensitest** provides two modes of operation, selectable by the front panel MODE switch. In MODE 1, the **Sensitest** checks the continuity of the red LED, infrared LED and photodiode circuits of the sensor by applying a test current to each circuit and measuring the resulting voltage across the circuit. The **Sensitest** interprets the voltages and displays "OK" on the LCD for voltages within the normal range. For voltages outside the normal range, the **Sensitest** indicates the respective circuit is open or shorted, or that one wire is shorted to another wire in the sensor cable. The circuit continuities are measured and displayed on the LCD at a rate of 125 times per second.

MODE 1 provides a *glitch capture* feature for detecting intermittent short or open circuit conditions in a faulty sensor. If the **Sensitest** detects one or more of the diode circuits changes from the "OK" condition to any other state, the **Sensitest** will emit a brief alarm tone and will freeze the LCD display for one second. This allows defective sensors to be diagnosed by flexing the sensor cable until the intermittent short or open circuit is "captured" by the **Sensitest**.

In MODE 2, the **Sensitest** measures and displays the photodiode's response to light emitted by the red and infrared LEDs of the sensor. The photodiode response to each LED is displayed as a bar graph across the LCD, and also as a numeric readout ranging from zero to 99 full scale. The units of measure are arbitrary as MODE 2 is intended for comparing sensors of the same make and model to one another, rather than providing an absolute figure of merit for a specific sensor.

MODE 2 is useful for comparing the optical sensitivity of sensors under test to a "reference sensor" which is known to be in good working order, such as a new sensor which has not seen clinical use. Note, for a valid comparison, sensors under test must be of the same make and type as the "reference sensor". *MODE 2 is <u>not intended</u> for comparing the optical sensitivity of one sensor make to another, or for comparing the sensitivity of reusable sensors to disposable sensors.*



Operation

This chapter explains how to power-up and operate the **Sensitest** Pulse Oximeter Sensor Tester.

3. OPERATION

3.1 Mode 1 Operation (Continuity)

- <u>NOTE</u>: If you have just unpacked the **Sensitest**, you must first install the 9V battery (included). See section 3.3 for battery installation instructions.
 - 1. Switch the **Sensitest** ON using the front panel POWER switch.
 - 2. If the front panel LOW BAT light is lit, see Section 3.3 for battery replacement instructions.
 - 3. Upon powering up, the **Sensitest** will display its software version and will conduct a self-test. After the self-test is completed, set the front panel MODE switch to the "1" position (MODE 1). With no sensor connected to the **Sensitest**, the LCD should indicate that all three diode circuits are open as shown in **Figure 1**.



Figure 1 - No Sensor Connected; all diode circuits open.

4. Connect a pulse oximeter sensor to the **Sensitest**. The LCD should indicate that the red LED circuit (RED), the infrared LED circuit (IR) and the photodiode circuit (PHOTOD) of the sensor are "OK" if the sensor is electrically functional, as shown in **Figure 2**.



Figure 2 - Red LED (RED), infrared LED (IR), and photodiode (PHOTOD) circuits of sensor functional ("OK").

NOTE: Connect only one sensor at a time to the **Sensitest**. Connecting more than one sensor will produce erroneous results.

TABLE 1 lists the diode test currents and voltage ranges corresponding to the "OK" conditions shown in **Figure 2** above.

CIRCUIT	Test Current	"OK" Voltage Range
Red LED	2.0 mA	1.16 to 2.09 V
Infrared LED	2.0 mA	0.60 to 1.41 V
Photodiode	500 uA	0.40 to 0.80 V

TABLE 1: Voltage Ranges for a Functioning Sensor

5. If the sensor has an electrical fault in one of the diodes or in the cable, the **Sensitest** will display the fault condition under the respective RED, IR or PHOTOD designator on the LCD. The fault conditions displayed are as follows:

OPEN	LED or photodiode is open circuit
SHORT	LED or photodiode is shorted
S/GND	LED cathode is shorted to cable shield or braid (i.e. "ground")
S/PHD	LED cathode is shorted to photodiode anode
S/CA	Photodiode is shorted to LED

Note, if the status of one of the LEDs is displayed as "S/GND" then the status of the other LED is indicated as "-----", since its status cannot be reliably determined in this case. Similarly, if one of the LEDs has a "S/PHD" fault, the status for the alternate LED and photodiode are both displayed as "-----".

6. To diagnose intermittent sensor faults, work the sensor and flex the sensor cable while observing the **Sensitest** display. If an intermittent fault condition is detected, the **Sensitest** will emit an audio "chirp", and will freeze the fault condition on the LCD for one second. Continue flexing the cable and sensor until a consistent fault is determined.

In MODE 1, the **Sensitest** measures and displays the sensor continuity 125 times per second, allowing intermittent short and open circuits to be readily "captured".

 Illustrations of electrical fault conditions for sensors incorporating the "Nellcor[®] wiring" configuration, and for sensors incorporating the "Ohmeda wiring" configuration, are shown with the corresponding MODE 1 displays in Figure 3 through Figure 6.

(Note that manufacturers using the "Nellcor[®] wiring" configuration for their sensors include Nellcor[®], Nonin, BCI International, Hewlett-Packard, Datex (SAS-F), Invivo Research and others. Manufacturers using the "Ohmeda wiring" configuration for their sensors include Ohmeda, Novametrix, SpaceLabs, Nihon Kohden and others.)







Figure 4 - Photodiode open circuit.



Figure 5 - Infrared LED shorted to cable shield.

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Figure 6 - Red LED Shorted to photodiode anode.

 Additional fault conditions which are relevant to sensors having the Ohmeda wiring configuration are illustrated in Figure 7 to Figure 9, along with the corresponding MODE 1 displays. Note that the Sensitest indicates the red and infrared LEDs as "OPEN" for both fault conditions shown in Figure 9. For the case where the common anode lead is open circuit, the

condition is indicated correctly. However, the **Sensitest** is unable to distinguish this fault from a short between the common anode lead and the cable shield. In both cases, however, the fault is localized to the common anode wire of the sensor cable.



Figure 7 - Omeda LED cathodes shorted together.



Figure 8 - Omeda photodiode shorted to LED common anode. Note that for some sensors, this particular fault may be indicated on the LCD as illustrated in Figure 9.



- Figure 9 Ohmeda common anode lead open circuit; Ohmeda common anode lead shorted to cable shield.
 - 9. When finished testing, disconnect the sensor from the **Sensitest** and switch the POWER to OFF to conserve battery power.

3.2 Mode 2 Operation (Sensitivity)

1. If the **Sensitest** is not already powered up, switch the instrument ON and connect the sensor to be tested.

NOTE: Connect only one sensor at a time to the **Sensitest**. Connecting more than one sensor will produce erroneous results.

Set the front panel MODE switch to the "2" position (MODE
 The photodiode's response to light emitted by the red LED (RED) and the infrared LED (IR) will be shown on the LCD, as illustrated in the example of Figure 10.



Figure 10 - Example of MODE 2 display.

As shown above, the response to each LED is indicated both as a bar graph and as a corresponding numeric value ranging from zero to 99 in arbitrary units of measure.

- 3. Note that if no sensor is connected to the **Sensitest**, both MODE 2 bar graphs will indicate zero response. If one of the LEDs in the sensor is open or short circuited, the bar graph for the faulty LED will similarly indicate zero. Switch the **Sensitest** to MODE 1 to diagnose the sensor fault in this case.
- 4. When testing flexible or disposable sensors, orient the sensor so that the photodiode opposes the LEDs of the sensor. Do not insert your finger or other object between the photodiode and LEDs when testing in MODE 2 as this will weaken the signal and adversely affect the response.

- 5. With some sensors, especially flexible and disposable sensors, it may be necessary to cover the sensor with your hand to shield it from strong sources of ambient light to prevent interference on the MODE 2 display.
- 6. Although it is impossible to completely generalize the readings obtained in MODE 2, for many sensors the infrared LED will show a stronger response than the red LED. Infrared readings in the 70 to 99 range are typical, with the red response being typically in the 50 to 80 range.

A higher response indicates an optically brighter LED, or conversely, a more optically sensitive photodiode. Squeezing the sensor so that the photodiode is moved closer to the LEDs will of course increase the response for both red and infrared.

- 7. MODE 2 is most useful when it is used to compare similar sensors *relatively*. Use a sensor known to be in good working condition, such as a new sensor which has not been used clinically, to obtain a "baseline standard" response. Then, measure MODE 2 responses of sensors having the same make and type as the "good sensor" to determine the relative brightness of the sensor LEDs, or the relative sensitivity of the photo diodes.
- 8. Do not attempt to use MODE 2 to compare the responses obtained from sensors of differing make (e.g. Nellcor[®] vs. Hewlett-Packard). Such comparisons are meaningless as each manufacturer's pulse oximeter is designed to accommodate the characteristics of the LEDs and photodiode which are incorporated into the manufacturer's sensor.

Similarly, it is not advisable to compare MODE 2 responses of disposable and reusable sensors, or sensors intended for different sites of application, even if they are supplied by the same pulse oximeter manufacturer.

However, MODE 2 may be useful in comparing sensors from the original manufacturer of the pulse oximetry product with "replacement sensors" supplied by an alternate, third-party manufacturer. Similarly, "reconditioned" or repaired sensors returned from a third-party service provider may be checked against a newer sensor using MODE 2. In either of these cases, use MODE 2 to compare only those sensors having the same intended clinical use (e.g. same application site).

9. When finished testing, disconnect the sensor from the **Sensitest** and switch the POWER to OFF to conserve battery power.

3.3 Battery Installation and LCD Contrast Adjustment

The **Sensitest** is powered by a standard 9V alkaline battery (9V NEDA 1604). As the power consumed by the **Sensitest** is low, a quality alkaline battery will provide over 100 hours of continuous operation.

Once the LOW BAT light on the front panel is illuminated, the **Sensitest** will provide another two hours of operation, approximately. The battery should be replaced soon after the LOW BAT light is activated, otherwise the instrument may produce unpredictable results.

The **Sensitest** is shipped without the battery installed. Follow these instructions to install or replace the battery and adjust the LCD contrast, if necessary.

- 1. Ensure the **Sensitest** POWER is switched OFF.
- 2. Locate the battery compartment on the left panel of the instrument (see **Figure 11**). Open the battery door by pressing up on the door catch and simultaneously pulling the door outwards.
- 3. Install or exchange the battery with 9V NEDA 1604. Observe polarity of the battery snap connections.
- 4. Switch the power ON to confirm the instrument is operational, and the LOW BAT light is now off.
- 5. The LCD contrast adjustment is accessed via a hole in the battery compartment (see **Figure 11**). Use a small screwdriver or electronic adjustment tool to adjust the LCD to the desired level of contrast, if necessary.
- 6. Switch the **Sensitest** OFF, install the battery in the compartment and replace the battery compartment door.



Figure 11 - Battery installation and LCD contrast adjustment.

3.4 Optional Connector Module Installation

To allow testing of additional sensor makes other than Nellcor[®] and Ohmeda, DSI provides optional connector modules for installation in the **Sensitest**. Up to three such connector modules may be installed in the instrument in place of the right panel. Modules are available for most of the major pulse oximeter manufacturers. If more than three additional modules are required, please refer to Section ?.

To install a connector module, it is necessary for a qualified technician to open the **Sensitest** and connect the module (or modules) to the main circuit board inside. Provided the installation instructions given below are followed, this will not void any existing warranty on the unit.

- 1. Ensure that the **Sensitest** POWER is switched OFF before opening the unit.
- 2. Lay the **Sensitest** on its front panel. Remove the six #6 screws which secure the rear cover of the enclosure, then remove the cover.
- 3. If no connector modules have been previously installed in the Sensitest, remove the black plastic side panel on your left (the one without the battery compartment). This panel will not be used once connector modules have been installed in the Sensitest.

If one or two connector modules are already installed in the unit, note that each new connector module will take the place of one of the small blank panels currently installed. Take care not to lose the smaller, triangular shaped pieces which form part of the side of the instrument enclosure.

4. Install the new connector module(s) according to Figure 12.



Figure 12 - Installation of connector module.

The connector module may be located at any of the three possible locations on the side of the enclosure, and may be connected to any of the three MOLEX connectors located on the left side of the **Sensitest** circuit board, as shown in **Figure 12**.

- 5. Replace the triangular shaped end pieces at top and bottom on the left, and install one or two of the rectangular pieces provided to occupy the positions of unused connector locations, if necessary.
- 6. Mate the rear cover to the **Sensitest** enclosure, ensuring that the installed module(s) and blank panel(s) seat in the groove of the rear cover. Replace the rear cover of the instrument using the six #6 screws.

Note:

There are four standoffs installed into the rear cover of the **Sensitest**. These standoffs provide mechanical support for the circuit board inside the unit and *must* be left in place.

3.5 Adapter Cable Fabrication

As an alternative to DSI connector modules, or to allow testing of sensors for which no module is currently provided, it may be possible for the user to fabricate an adaptor cable for interfacing either the Nellcor input or the Ohmeda input on the **Sensitest** front panel to the sensor to be tested.

Before attempting to fabricate adaptor cables, the user must be certain that wiring information for the sensor to be tested is

accurate. Significant differences exist in sensor wiring conventions between manufacturers, and also between sensors supplied by *the same manufacturer*. For any given manufacturer, earlier model sensors may also have different internal wiring than newer models. Note that the use of adaptor cables or adaptor modules not supplied by DSI may invalidate the **Sensitest** warranty.

In general, many pulse oximeter sensors may be classified into one of two possible wiring configurations, as illustrated in **Figure 13**.



Figure 13 - Nellcor[®] and Ohmeda "wiring styles" for pulse oximeter sensors.

For the Nellcor[®] wiring style, the red and infrared LEDs are connected in antiparallel. Examples of sensors having the Nellcor configuration include Nellcor[®], Nonin, BCI International, Hewlett-Packard, Datex (SAS-F), Invivo Research and others.

For the Ohmeda wiring style, the red and infrared LEDs are independent with a common connection at the anode. Examples of sensors having the Ohmeda configuration include Ohmeda, Novametrix, SpaceLabs, Nihon Kohden and others.

To create an adaptor cable for the **Sensitest**, the procedure is generally as follows:

- From the service manual for the pulse oximeter, find or determine the schematic diagram for the sensor to be tested. Ensure that the schematic diagram agrees with the manufacturer's part number or model number for the sensor. Also beware of wiring variations introduced by sensor *extension cables*, if the manufacturer supplies such extensions for connecting the sensor to the input of the pulse oximeter.
- 2. Source the mating connector for the sensor. Such connectors are usually obtainable from the pulse oximeter manufacturer.
- 3. Based on the sensor schematic, decide whether to interface the sensor to the **Sensitest** via the front panel Nellcor connector (anti-parallel LEDs), or via the Ohmeda connector (common anode LEDs).

Adaptor cables for the Nellcor input will require a standard DB-9 male at the **Sensitest** end. Adaptor cables for the Ohmeda input will require the following connector at the **Sensitest** end:

Part no. D02PB906MSTH, manufactured by Hypertronics Corp., Hudson MA, Tel. 800-225-9228 or 978-568-0451.

4. The pin-out of the Sensitest Nellcor input is shown in Figure 14, and the pin-out of the Ohmeda input is shown in Figure 15. Note that the Sensitest circuit ground (GND) is internally connected to the cable shield and to the photodiode cathode for both Nellcor[®] and Ohmeda inputs.

Based on the schematics of **Figure 14** and **Figure 15**, determine the adaptor cable wiring so the appropriate diode is connected to the correct pin of the **Sensitest** front panel connector. An example of a cable for adapting the **Sensitest** Nellcor input to a sensor for a Hewlett-Packard pulse oximeter (M1020A) is given in **Figure 16**.



Figure 14 - Nellcor[®] pin-out.



Figure 15 - Omeda pin-out.



Figure 16 - Adaptor cable for connecting **Sensitest** Nellcor[®] input to sensor for Hewlett-Packard M1020A ("Merlin").



4. CALIBRATION

Sensitest does not require calibration. If desired, performance can be verified by connecting a known good sensor to the **Sensitest**.

If repair service is required, contact DSI Customer Service at 1-800-667-6557 (604-291-7747 Outside North America), or <u>customerservice@datrend.com</u> about the authorized service facility nearest your location.

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