

SmartSat™
Pulse Oximetry Analyzer

Operation Manual

Notices

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In the interest of continued product improvement, all specifications are subject to change without notice.

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Revision History

Warranty Service & Shipping Instructions

Warranty Service

All repairs on products under warranty must be performed or approved in writing by Clinical Dynamics Service personnel. *Unauthorized repairs will void the warranty.*

Assistance

If the product fails to function properly, or if assistance, service or spare parts are required, contact Clinical Dynamics Customer Service at 800 247-6427 or visit our web site, www.clinicaldynamics.com and select the SERVICE Key to fill out a Request for Calibration/Service Form. After this form has been submitted, a Clinical Dynamics' Service Representative will contact you to help solve your problem. Before contacting Clinical Dynamics, please attempt to duplicate the problem and to check all accessories to ensure that they are not the cause of the problem. Prior to calling please be prepared to provide:

1. Product Name, Model Number, Serial Number and Software version.
2. Complete description of the problem including the conditions under which the problem occurred. Ideally, a written problem description would be provided, allowing for more efficient handling of your initial service request and the subsequent diagnosis and remedy of the problem.
3. Your institution's complete name and address. Please also provide a contact name and phone number.
4. A purchase order number if the product needs non-warranty service or you are ordering spare parts.

Returning a Product for Service

Contact Clinical Dynamics Customer Service at 800 247-6427 and provide the information listed above under Assistance. If it is determined that you need to ship the unit back, it is highly recommended that you pack the product in its original shipping carton and packing materials, provided that they are still useable. If the original packaging is not available, select a sturdy corrugated carton large enough to hold whatever items you are returning, *and also to allow 4 to 6 inches of packing material on all sides of the items*. Whether you use the original packaging or an appropriate substitute, please follow these packing instructions:

1. Remove all hoses, cables, power cords and any other accessories from the instrument and, if possible.
Note: if you are using substitute packaging, it is essential that you seal the instrument in a clean, static free plastic bag or in clean bubble wrap in order to prevent packing material from entering the product.
2. Pack only the accessories you are requested to return; place them in a separate bag.
3. If you are using substitute packaging, create a foundation of 4 to 6 inches of packing material (either bubble wrap or packing "peanuts") at the bottom of the carton.
4. Insert the instrument and the accessory bag into the shipping carton.
5. If you are using substitute packaging, fill the 4 sides and the top of the carton with 4 to 6 inches of packing material (either bubble wrap or packing "peanuts"). Ensure that the instrument and accessory bag are held firmly in place by the packing material.
6. Please place paperwork such as the purchase order, contact info and reasons for return in the top of the carton.
7. Close the carton and securely seal it with tape; since in most cases the carton will have been previously used, it may be necessary to reinforce the original tape on the bottom of the carton.
8. Ship the product via whatever carrier (UPS, FedEx, etc.) is most convenient. However, please be aware that, depending on where you are shipping from, standard UPS ground shipping could take as long as 7 business days. Unless other arrangements are made, Clinical Dynamics will return the repaired product to you via UPS.
9. Shipping insurance is optional. Claims for damage to the product during shipping must be initiated by the shipper.

Additional Instructions for International Shipments

Customers outside the United States must include a "pro-forma invoice" for customs purposes as part of their shipping documents. It is imperative that the name of the product appears exactly as follows:

SmartArm Test Equipment

Or

SmartSat Test Equipment

The use of any other product name could add unnecessary delays when shipping internationally.

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Warranty

Clinical Dynamics Corporation (CDC) warrants to the purchaser that the **SmartSat Pulse Oximetry Analyzer** shall be free from defects in material and workmanship for 3 years for U.S. customers and 1 year for international Customers. CDC's sole obligation with respect to any such defect is limited to the repair with new or remanufactured parts, or at CDC's option, replacement of the **SmartSat**, or refund of the purchase price.

This warranty is made on the condition that prompt notification of a defect is given to CDC within the warranty period. CDC shall have the sole right to determine whether a defect exists.

This warranty extends to the original purchaser only. This warranty does not apply to a **SmartSat** that has its tamper seals removed or cut, altered, subjected to misuse, negligence, unauthorized repair, or accident, or operated other than in accordance with the instructions.

This warranty represents the exclusive obligation of CDC and the exclusive remedy of the purchaser regarding defects in a **SmartSat**. **This warranty is given in lieu of any expressed or implied warranties, including the warranty of merchantability or fitness for a particular purpose, which warranties are disclaimed. No person is authorized to modify, in any manner, CDC's obligation described above.**

CDC shall not, in any case, be liable for special, incidental, or consequential damages arising from breach of warranty, breach of contract, negligence or any other legal theory.

Precautions

To maintain battery life, it is recommended that the battery be cycled (discharged and fully recharged) after every 30 hours of use. This will provide optimum battery performance throughout the life of the battery.

For optimum **SmartSat** performance, it is recommended that the **SmartSat** be allowed to "warm up" for 5 minutes before use.

For accurate results, it is recommended that you use the oximeter interface cables provided with the **SmartSat**. If you should damage or misplace these cables, please contact the factory for replacement. Use of cables other than those provided by Clinical Dynamics may result in inaccurate test results.

Section 1. Introduction

General

The **SmartSat** *Pulse Oximetry Analyzer* is the first test system available to test both the probe and pulse oximeter independently. This method allows the user to diagnose problems to either the probe or pulse oximeter. The **SmartSat** has two probe test modes and a SpO2 simulator mode with user programmable Auto Sequences for automated testing.

The first probe test is the Probe Continuity Test. This tests the probe for opens, shorts, and intermittent probe problems. The Probe Continuity Test provides an electrical integrity test of the probe.

The second probe test is the Probe Sensitivity Test. This tests the sensitivity of the RED and IR LEDS and the ratio of the Red to IR sensitivity. This test is valuable for testing a probe during its functional life. The user can then determine if the probe is within an acceptable sensitivity range.

The SpO2 Simulator tests the pulse oximeter through a complete range. The full featured SpO2 simulator provides the following features: Oxygen Saturation; Pulse Rate; R-Curves for testing pulse oximeters and user programmable Auto Sequences for automated testing.

In addition to these testing features, the **SmartSat** incorporates a high-resolution graphic display, an internal battery, built in probe test ports and a compact, lightweight enclosure.

Intended Audience

The Operation Manual is intended for end users of the **SmartSat** *Pulse Oximetry Analyzer*. It contains installation and operation instructions, applications notes, performance limitations and routine performance verification procedures. To achieve satisfactory results, it is imperative that the operator read this manual thoroughly before attempting to use the **SmartSat**.

Documentation Comments

Clinical Dynamics has attempted to present all information as clearly and error-free as possible. However, if you detect any errors or omissions, or wish to suggest improvements to the manual, please mail, fax or email your comments to:

Clinical Dynamics Corporation
10 Capital Drive
Wallingford, CT 06492
Attn: Sales Department

Fax: (203) 269-3402
Email: sales@clinicaldynamics.com

Section 2. Product Description

Overview

SmartSat Pulse Oximetry Analyzer is a state-of-the-art instrument designed to provide accurate and reliable performance. The following list presents some of the more salient features of the **SmartSat**.

- Standardized scientific procedure for electronically testing pulse oximeters.
- The first available Probe Analyzer for probe testing. The Probe Analyzer has two tests: The Probe Continuity Test and The Probe Sensitivity Test.
- Full featured SpO2 Simulator: Oxygen Saturation and Pulse Rate; Ambient Light; Pulse Modulation Simulation and user programmable Auto Sequences to automate common test procedures.
- Internal Battery allows testing in remote sites such as ICU, OR and other patient floors.
- 320 x 240 high resolution graphic display allows visualization of waveforms.

Section 2. Product Description

Section 3. Physical Description

The **SmartSat** Pulse Oximetry Analyzer is a microprocessor controlled patient simulator and probe analyzer housed in a compact (8 x 8 x 5 inch) and portable (6 pounds with battery) aluminum case. Performance and technical specifications are listed below.

SpO₂ Simulator

Oxygen Saturation (SpO₂)

- Range: 0-100%
- Resolution: 1%
- Accuracy: $\pm 0.5\%$ from 70-100%
 $\pm 1\%$ from 50-69%

R-Curves

- Preset manufacturer's R-curves: BCI, Criticare, Criticare SPOT, Datascope, Datex, Hewlett-Packard, Masimo, Nellcor, Nihon Kohden, Nonin, Novamatrix, Ohmeda and Sensormedics(contact the factory for availability of others)

Pulse Rate

- Range: 20-300 bpm
- Resolution: 1 bpm
- Accuracy: ± 1 from 20-199 bpm
 ± 2 from 200-300 bpm

Pulse Modulation

- Range: 0.10-20% of nominal amplitude
- Resolution: 1%
- Accuracy: $\pm 1\%$

Probe Analyzer

Probe Continuity Test

Simultaneous Channels:

- 2 for Nellcor style probes: LED & photodiode circuits
- 3 for Ohmeda style probes: Red LED, IR LED, and photodiode circuits

Probe Connection

- Integral connectors for Nellcor & Ohmeda probes
- Adapters available for other manufacturer's probes

General

Display

- Type: backlit graphics LCD (Liquid Crystal Display)
- Resolution: 320h X 240w, 0.36mm dot pitch
- Control: contrast adjustment

Serial Interface

- Type: RS232C, 9 pin D-connector, DCE
- Baud Rate: 1200 bps for Remote Control
- Mode: Remote Control

Printer Interface

- Type: Centronics type connector, 25 pin

Battery

- Type: Nickel Metal Hydride (NimH)
- Voltage: 19.2V
- Capacity: 2.1 Amp-Hour (Approximately 5 to 6 Hours operating Time)
- Charge time: 18 Hours

External Power Supply

- Type: Desk-mount linear
- Input: 120 VAC, 60Hz or 230 VAC, 50Hz or 100 VAC, 60 Hz
- output: 24VDC, 500mA, 6 foot cable
- Safety Agency Approvals: UL, CSA, CE, TUV

Physical

- Case: Aluminum, non skid feet, carry handle
- Dimensions: 8" wide, 8" deep, 5" high
- Weight: 6 pounds (including battery)

Section 4. Installation & Operation

Unpacking

The **SmartSat**, manual, and accessories are shipped in one carton. Please note cables may be different, depending on what cables were ordered with **SmartSat**. Inspect the carton carefully for any signs of damage. Remove the **SmartSat** from the carton and inspect the **SmartSat**. Retain all shipping materials for inspection by the carrier in case of shipping damage or for reshipment. The original carton and packing materials are to be used when the unit is shipped back to Clinical Dynamics for annual calibration.

Contents Checklist

QTY.	Checklist
1	SmartSat <i>Pulse oximetry Analyzer</i>
1	Operation Manual
1	Service Manual
1	Nellcor SpO2 Simulation Cable
1	Ohmeda SpO2 Simulation Cable
1	External AC Adapter
1	Detachable Power Cord (US)
1	Foam Insert Set

Missing Items

If an item is missing or damaged, call Customer Service, (203) 269-0090.

Indications and Contradictions

The **SmartSat** *Pulse Oximetry Analyzer* is intended for testing pulse oximeters and pulse oximeter probes. The device is not designed, sold, or intended for use except as indicated.

The **SmartSat** *Pulse Oximetry Analyzer* is not to be used on patients either directly or indirectly.

Installation and Initial Setup

If there is no apparent damage to the **SmartSat**, follow these steps.

With **SmartSat** power off:

1. Connect the Power Cord to the AC Adapter. Plug in the Power Cord to an electrical outlet.
2. Connect the External AC Adapter to the **SmartSat**. When done properly, the green light on the DC power jack will light up. If no power source is available, the internal battery may be used to power the **SmartSat**(the system battery may not be fully charged prior to delivery it is recommended that you charge the battery for 18 hours before use).

Operating Procedures

The following sections describe the basic operations of the **SmartSat**.

Power-on Procedure

1. Push the Red Power Button to turn on the **SmartSat**. The system will initially display a power up screen.
2. The **SmartSat** will then momentarily perform a self-test and proceed to the Main Menu.

Initial Configuration

The **SmartSat** is configured for testing Nellcor pulse oximeters on power-up. The **SmartSat** may be changed to other brands of pulse oximeters in the SpO2 Simulation and Probe Testing Menus. The modes of operation from each menu are described in the following sections. Note: That pressing the PREV key stores the current settings as power-up defaults. To connect **SmartSat** to the pulse oximeter and to test the pulse oximeter probe:

1. Disconnect the probe from the pulse oximeter. Connect the probe to the appropriate Probe Analyzer Port or Probe Analyzer Cable connected through the ohmeda Probe Analyzer Port.
2. Select the appropriate simulator cable for testing. Connect the simulator cable to the SpO2 Simulator Port using the end with the 9-pin female D shell connector.
3. Next, connect the other end of the oximeter test cable to the probe connection site. The **SmartSat** is now ready to the pulse oximeter and pulse oximeter probe. Please refer to the modes of operation beginning on the following page.

The SmartSat Main Menu

The **SmartSat** Main Menu will be displayed following power-up of the system.

Oximeter		OXYGEN SAT (SpO2 %)	PULSE RATE (BPM)	PulseMod		
Nellcor		100	75	5.00%		
-DataLog-						
Probe Continuity						
LED	Open				
	Good				
	Short				
PHOTO	Open				
	Good				
	Short				
SglSwp						
SpO2sim	Probe-C	Probe-S	Setup	BatChck		
F1	F2	F3	F4	F5	MORE	PREV
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The main display is subdivided into three major windows:

1. Upper window (SpO2 Simulator)
2. Middle window (Graphic Display Measurements)
3. Bottom window (Control Panel Soft-keys)

The SpO2 Simulator features include:

- Oximeter Selection
- Oxygen Saturation (SpO2) ; range 0 to 100%
- Pulse Rate ; range 20-300 bpm
- Pulse Modulation; range 0.10-20%
- Programmable Auto Sequences

The SpO2 Simulator window has 4 main features. The Oximeter field displays the pulse oximeter being tested. The OXYGEN SAT field displays the oxygen saturation simulated. The PULSE RATE field selects the pulse rate simulated. The PulseMod field selects the perfusion of the pulse.

The Graphic Display Measurement (middle) window displays:

- Nellcor and other Two Trace type LED and Photo-diode continuity tracing
- Ohmeda and other Three Trace type RED, IR and Photo-diode continuity tracing
- Programmable Auto Sequences
- Advanced Simulation Features: Arrhythmia, Motion Artifact and Ambient Light, Set Up

Section 4. Installation & Operation

Control Panel Options:

Soft-keys can be utilized to navigate through screens to control all **SmartSat** features. From the main menu, the following options are available:

- F1 (SpO2Sim) accesses the SpO2 Simulator Menu.
- F2 (Probe-C) activates the probe continuity test
- F3 (Probe-S) activates the probe sensitivity feature.
- F4 (Setup) changes basic setup features.
- F5 (BatChk) Displays Battery Voltage
- MORE - advances the system to the next lower level in the menu tree. If there is no lower level the key will be inactive.
- PREV - returns **SmartSat** to the previous menu and saves any changes made to **SmartSat**

The SpO2 Simulator Menu

Purpose of SpO2 Simulator Menu: Used on a routine basis for preventive maintenance, quality assurance, trouble shooting and repair of pulse oximeters.

From the main menu, Press F1 (SpO2Sim) to enter the SpO2 Simulator menu. The PREV key will return the system to the main menu.

		OXYGEN SAT (SPO2 %)	PULSE RATE (BPM)			
Oximeter		100	75	PulseMod		
Nellcor				5.00%		
-DataLog-						
Probe Continuity						
L E D	Open				
	Good				
	Short				
P H O T O	Open				
	Good				
	Short				
SglSwp						
Manual	AutoSeq					
F1	F2	F3	F4	F5	MORE	PREV
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

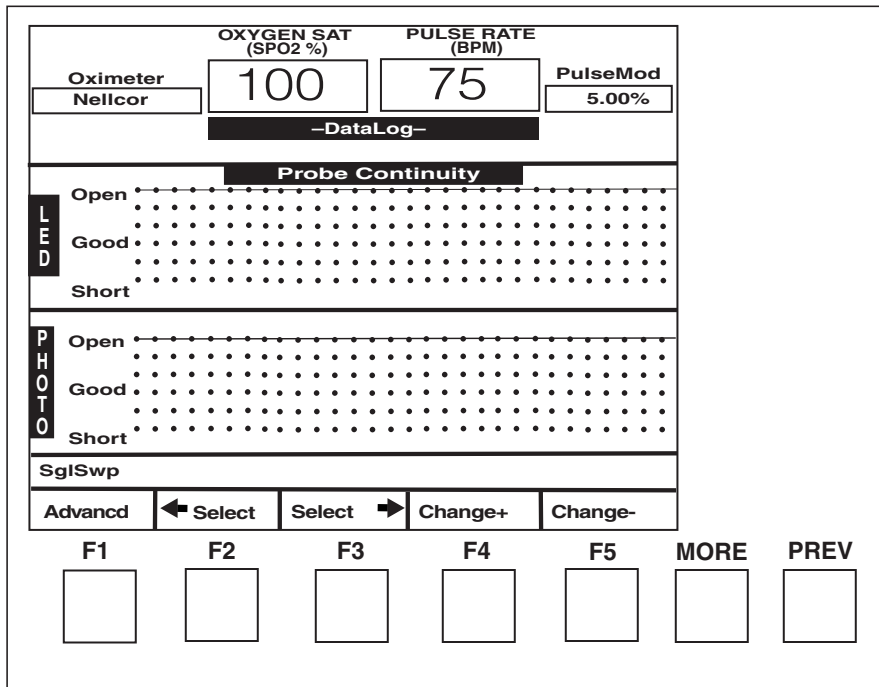
From the SpO2 Simulator Menu the following options are available:

- F1 (Manual) enters the SpO2 Simulator manual test mode
- F2 (AutoSeq) enters the programmable Auto Sequences Directory
- F3, F4 and F5 are not used on this screen.
- PREV - will step back in the menu tree to the main menu.
- MORE is not used on this screen.

The SpO2 Simulator Menu, Manual Mode

Purpose of SpO2 Simulator Menu, Manual Mode: Used on a routine basis for preventive maintenance, quality assurance, trouble shooting and repair of pulse oximeters.

From the SpO2 Simulator Menu, Press F1 (Manual) to enter the SpO2 Simulator menu, manual mode. The PREV key will return the system to the main menu.



From the SpO2 Simulator Menu, Manual Mode, the following options are available:

- F1 (Advancd) introduces simulation features such as Arrhythmias, Motion Artifact and Ambient Light Simulation. Note: When this is pressed, the Probe Continuity Test Window will be replaced with the Advanced Simulation Mode Screen and return when you utilize the Probe Continuity Test, described in detail on the following page.
- F2 (Select) scrolls cursor upward through the selectable parameters.
- F3 (Select) scrolls cursor downward through the selectable parameters.
- F4 (Change+) changes parameter upward.
- F5 (Change-) changes parameter downward.
- PREV - will step back in the menu tree to the main menu.
- MORE is not used on this screen.

The SpO2 Simulation Menu, Advanced Simulation Mode

Purpose of the SpO2 Simulator Menu's Advanced Simulation Mode: The advanced simulation features can be used for preventative maintenance, quality assurance, trouble shooting and repair of pulse oximeters and pre-purchase evaluations of pulse oximeters.

From the SpO2 Simulator Menu, Manual Mode, Press F1 (Advancd) to enter the SpO2 Simulator Menu, Advanced Simulation Mode.

Oximeter		OXYGEN SAT (SpO2 %)	PULSE RATE (BPM)	PulseMod		
Nellcor		100	75	5.00%		
-DataLog-						
Arrhythmia: Off Motion Artifact: 0 Ambient Light DC Level: 5 AC Level: 0 Frequency: Off						
Standrd	↑ Select	Select ↓	Change+	Change-		
F1	F2	F3	F4	F5	MORE	PREV
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

From the SpO2 Simulator Menu, Advanced Simulation Mode, the following options are available:

- F1 (Standrd) returns **SmartSat** to standard SpO2 Simulation.
- F2 (Select) scrolls cursor upward through the selectable parameters.
- F3 (Select) scrolls cursor downward through the selectable parameters.
- F4 (Change+) changes parameter upward.
- F5 (Change-) changes parameter downward.
- MORE is not used on this screen.
- PREV will return the system to first screen in the SpO2 Simulation Mode.

The SpO2 Simulation Programmable Auto Sequences Directory

Purpose of Programmable Auto Sequences Directory: Used on a routine basis for preventive maintenance and quality assurance, trouble shooting and repair of pulse oximeters. Each selectable brand of pulse oximeter is represented by an auto sequence test. These can be modified and saved for special testing needs.

From the SpO2 Simulator Menu, selecting F2 (AutoSeq) will place you in the Programmable Auto Sequences Directory screen. From the Programmable Auto Sequences Directory, the following options are available:

Oximeter	OXYGEN SAT (SPO2 %)	PULSE RATE (BPM)	PulseMod			
Nellcor	100	75	5.00%			
-DataLog-						
Programmable AutoSequence Directory						
BCI : 58 - 100	MASIMO	OHMEDA				
CRITICARE	NELLCOR	OHMD: 50 - 81				
CSI SPOT	NELL: 50 - 81	SENSORMEDX				
DATASCOPE	NELLOxiMAX	TREND LOOP				
DATEX	NONIN	4 POINTS				
HP	NOVAMETRIX	PR: 40 - 200				
Select ↑	Select ↓	Program	Run			
F1	F2	F3	F4	F5	MORE	PREV
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

- F1 (Select) scrolls cursor upward through the auto sequences.
- F2 (Select) scrolls cursor downward through the auto sequences.
- F3 is not used on this screen.
- F4 (Program) modifies auto sequences.
- F5 (Run) selects auto sequence, then press F1 (Start/Stop) to start the auto sequence.
- MORE is not used on this screen.
- PREV - will return SmartSat to the previous screen, pressing PREV multiple times will return SmartSat to the Main Menu.

The SpO2 Simulation Programmable Auto Sequences Directory, Program Mode

Purpose of Programmable Auto Sequences Directory, Program Mode: User can modify and save each auto sequence test for their specific testing requirements.

From the SpO2 Simulation Programmable Auto Sequences Directory, pressing F4 (Program) will place you in the Programmable Auto Sequences Directory, Program Mode screen.

OXYGEN SAT (SpO2 %)		PULSE RATE (BPM)		PulseMod	
Oximeter Nellcor	100	75		5.00%	
-DataLog-					
AutoSeq: Nellcor			Oximeter: Nellcor		
Step	Time	Mod	SpO2	Rate	
1	20s	5.00	100	70	
2	20s	5.00	99	70	
3	20s	5.00	98	70	
4	20s	5.00	97	70	
5	20s	5.00	96	70	
6	20s	5.00	95	70	
7	20s	5.00	94	70	
8	20s	5.00	93	70	
9	20s	5.00	92	70	
10	20s	5.00	91	70	
SelectMode: Step ↑ ↓ (Use MORE to change)					
← Char	Char →	Select <>	Change+	Change -	
F1	F2	F3	F4	F5	MORE
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

From the Programmable Auto Sequences Screen, Program Mode, the following options are available:

- F1 (<Char) scrolls cursor upward through each character. F1 becomes (Select?) when the cursor is in oximeter:_____ or in the autosequence itself.
- F2 (Char>) scrolls cursor downward through each character. F2 becomes (Select?) when the cursor is in oximeter:_____ or in the autosequence itself.
- F3 (Select <>) scrolls cursor between.
- F4 (Change+) changes the highlighted character and field.
- F5 (Change-) selects auto sequence, then press F1 (Start/Stop) to start the auto sequence.
- MORE is not used on this screen.
- PREV - will return **SmartSat** to the previous screen, and save any changes made to the programmable autosequence.

The SpO2 Simulation Programmable Auto Sequences Directory, Run Mode

Purpose of Programmable Auto Sequences Directory, Run Mode: Starts the selected autosequence test for their specific testing requirements.

	OXYGEN SAT (SPO2 %)	PULSE RATE (BPM)	
Oximeter Nellcor	100	75	PulseMod 5.00%
-DataLog-			
AutoSeq: Nellcor		Oximeter: Nellcor	
Step	Time	Mod	SpO2 Rate
1	20s	5.00	100 70
2	20s	5.00	99 70
3	20s	5.00	98 70
4	20s	5.00	97 70
5	20s	5.00	96 70
6	20s	5.00	95 70
7	20s	5.00	94 70
8	20s	5.00	93 70
9	20s	5.00	92 70
10	20s	5.00	91 70
Start			
F1	F2	F3	F4
F5	MORE	PREV	

From the SpO2 Simulation Programmable Auto Sequences Directory, select the desired autosequence and press F5 (Run).

From the Programmable Auto Sequences Directory, Run Mode, the following options are available:

- F1 (Start) starts the selected autosequence test. Press F1 (Stop) to stop test. This switch will toggle between Start/Stop.
- F2 not used in this screen.
- F3 not used in this screen.
- F4 not used in this screen.
- F5 is not used in this screen.
- MORE is not used on this screen.
- PREV - will return **SmartSat** to the previous screen. Note: You must stop the autosequence by pressing the F1 (Stop) key otherwise the autosequence will continue to run until completed. This allows the user to perform probe testing concurrently with simulation.

Note: When using autosequences, the programmed oximeter type will take precedence and change the oximeter selection displayed at the upper left when the test starts.

The Probe Continuity Test Menu

Purpose of Probe Continuity Test: Confirms proper electrical and insulation properties within the pulse oximeter probe. In an intact/normal probe the continuity trace will sweep across the screen within the GOOD zone. If an open or short connection is detected the trace will shift in the appropriate direction. When the probe is being tested, the cabling should be gently wiggled as a stress test to check for intermittent abnormal electrical connections. This is useful for intermittent problems, isolating the problems and ruling out human error.

From the main menu, Press F2(Probe-C) to enter the Probe Continuity Test screen. The PREV key will return the system to the main menu.

Oximeter		OXYGEN SAT (SPO ₂ %)	PULSE RATE (BPM)	PulseMod		
Nellcor		100	75	5.00%		
-DataLog-						
Probe Continuity						
LED	Open				
	Good				
	Short				
PHOTO	Open				
	Good				
	Short				
SglSwp						
Oximtr+	Oximtr -	SwpMode	Center	Reset		
F1	F2	F3	F4	F5	MORE	PREV
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

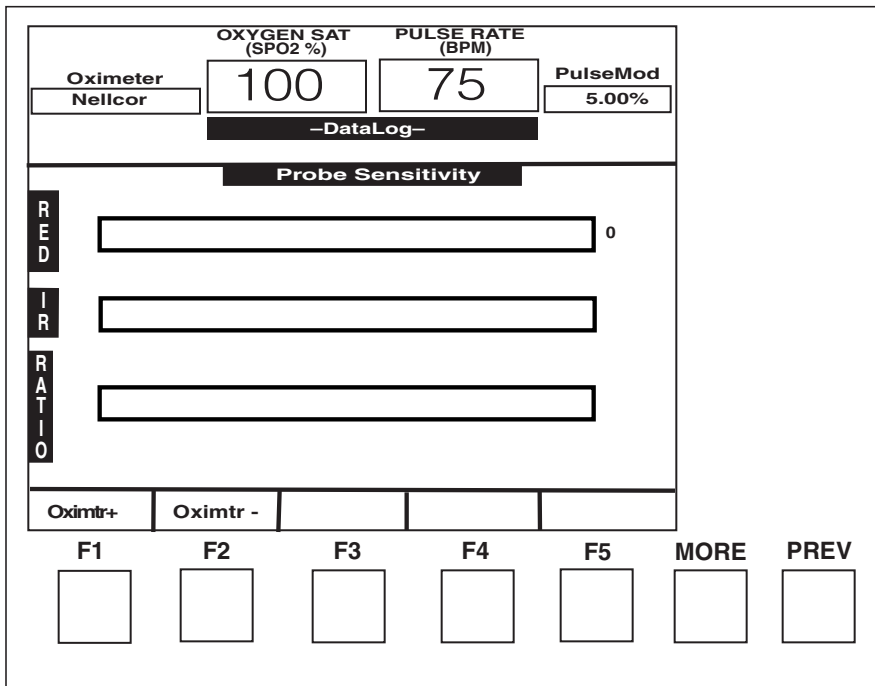
From the Probe Continuity Test Menu, the following options are available:

- F1 (oximtr+) scrolls upward through the brands of oximeter probes
- F2 (oximtr-) scrolls downward through the brands of oximeter probes
- F3 (SwpMode) toggles between Single Sweep and Repetitive Sweep test modes. Single Sweep stops sweeping on any fault while Repetitive Sweep tests continuously.
- F4 (Center) Centers the baseline waveform on the Good levels on the display and displays the baseline LED and PhotoDiode voltage drops.
- F5 - Reset will restart the trigger function.
- PREV - returns the user to the main menu.
- MORE - currently not utilized.

The Probe Sensitivity Test Menu

Purpose of Probe Sensitivity Test: Determines if the sensory diodes are receiving the appropriate signals. In some cases, cleaning the surface of the LED and sensor lens with a solvent solution will improve probe performance. on the following page, there are some reference values for the Probe Sensitivity Test.

From the main menu, press F3 (Probe-S) to enter the Probe Sensitivity Test Menu. The PREV key will return the system to the main menu.



From the Probe Sensitivity Test menu, the following options are available:

- F1 (Oximtr+) scrolls upward through the brands of oximeter probes.
- F2 (Oximtr-) scrolls downward through the brands of oximeter probes
- F3 , F4 & F5 not currently utilized.
- PREV returns user to the main menu.
- MORE not used in this screen.

Probe Sensitivity Test: Reference Values

The values labeled "Typical" in the table below were obtained by averaging the readings obtained by performing the **SmartSat's** Probe Sensitivity test on a large number of good pulse oximeter probes. The values labeled "Typical Range" are values at which, when the "probe under test" measures outside this range, it should be considered suspect. Since the pulse oximeter manufacturers have thus far declined to provide absolute limits for these ranges, we can not positively state that probes that exceed these limits are "bad." However, we can state that they deviate significantly from the "typical" probes of that make and model. In general, when evaluating probes using the Probe Sensitivity test, if you obtain a reading outside the limits, you should take into account other factors. For example, multiple readings (such as Red and Ratio) outside the limits or an out-of-limit reading on a probe that is old or looks worn, is probably an indication of a probe that may malfunction under certain clinical conditions.

Probe	Red Typical	Red Typical Range	IR Typical	IR Typical Range	Ratio Typical	Ratio Typical Range
Nellcor DS-100A	158	>79	262	>196	60	30 to 90
Ohmeda Clip Tip	168	>168	268	>244	63	40 to 100

The Setup Menu

Allows configuration of Key Beep (on/off), selection of Remote Control or Datalog for the RS-232 port and enter information which will print on a datalogged test report.

Oximeter Nellcor		OXYGEN SAT (SPO2 %) 100	PULSE RATE (BPM) 75	PulseMod 5.00%		
-DataLog-						
Key Beep: On Serial Port: DataLog Printing Stored Printing: Off Work Order #: _____ Oximeter # : _____ Date: __ - __ -02 Tested By: _____						
Select ↑	Select ↓		Change+	Change -		
F1	F2	F3	F4	F5	MORE	PREV
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

From the Setup Menu the following options are available:

- F1 (Select) scrolls cursor upward through the selectable parameters.
- F2 (Select) scrolls cursor downward through the selectable parameters.
- F3 is blank when Key Beep and Serial Port parameters are selected. F3 becomes F3 (Char) when Work Order, Oximeter, Date and Tested By parameters are selected.
- F4 (Change+) changes parameter upward.
- F5 (Change-) changes parameter downward.
- MORE is not used on this screen.
- PREV will return user to the main menu.

The Battery Check Menu

Purpose of the **SmartSat's** Battery Check Menu: Displays **SmartSat's** battery voltage.

From the Main Menu, Press F5 (BatChk) to enter **SmartSat's** Battery Check Menu.

Oximeter Nellcor		OXYGEN SAT (SpO2 %) 100	PULSE RATE (BPM) 75	PulseMod 5.00%		
-DataLog-						
Probe Continuity						
I D E A	Open				
	Good				
	Short				
P H O T O	Open				
	Good				
	Short				
SgISwp		Bat:19.82V (19.00V=LoBat)				
SpO2sim	Probe-C	Probe-S	Setup	BatChck		
F1	F2	F3	F4	F5	MORE	PREV
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

From the Battery Check Menu all Main Menu options are available:

- F1 is not used on this screen.
- F2 is not used on this screen.
- F3 is not used on this screen.
- F4 is not used on this screen.
- F5 (BatChck) displays current battery voltage. Pressing it will turn off/on the battery indicator.
- MORE returns user to the main menu.
- PREV returns user to the main menu.

Note:

1. When connected to the external power supply, the value displayed is the power supply voltage, not the battery voltage.
2. "Low Battery" indicator comes on at approximately 19V as the remaining battery life approaches 1 hour.
3. **SmartSat** will shut off when the battery discharges to approximately 16V.

Section 5. Frequently Asked Questions

Q: How do I test my probes with the SmartSat?

A: Simply connect a Nellcor, BCI, Nonin or Ohmeda probe into the Nellcor or Ohmeda Probe Analyzer ports on the side of the **SmartSat**. For other brands of probes, use the appropriate Probe Analyzer Cable and connect it into the Ohmeda Probe Analyzer port. Then connect the probe to the Probe Analyzer cable to test the probe.

Q: Why does the SmartSat test the probe and oximeter independently?

A: During the extensive market research when developing **SmartSat**, we found that over 96% of all oximetry problems occur within the probe. **SmartSat** is a "True Test Standard" utilized by major pulse oximetry manufacturers for electrically testing the functional accuracy of pulse oximeters. With both a SpO2 simulator and Probe Analyzer in one test system, problems are correctly identified and can be repaired. There is no guesswork involved.

Q: What types of probes can be tested?

A: All types of probes (except MRI probes) can be tested with **SmartSat**:

1. Adult size permanent probes
2. Adult size disposable probes
3. Neonate size permanent probes
4. Neonate size disposable probes

Q: How does the Probe Continuity Test work?

A: The Probe Continuity Test completely checks each probe for open, short, and intermittent failures. The probe can be tested correctly throughout its useful life cycle.

Q: I am using the Probe Sensitivity Test and when I open the finger probe or hold it towards the light, my readings are affected. Why does this happen?

A: When the probe is opened, it separates the LED's and the Photodiode paths. The farther the Photodiode is from the LED's, the less red and infrared light reaches the Photodiode, which affects the readings.

Section 5. Frequently Asked Questions

Q: What pulse oximeters does SmartSat test?

A: **SmartSat** works with the following pulse oximeters; BCI, Criticare, Criticare SPOT, Datascope, Datex, Hewlett-Packard, Masimo, Nellcor, Nihon Kohden, Nonin, Novamatrix, Ohmeda and Sensormedics.

Q: How did Clinical Dynamics Corporation obtain the R-Curves?

A: Our engineers obtained the information from and worked with each manufacturer to assure a "True Test Standard" for testing pulse oximeters. We thank those manufacturers for their help. Because of our relationships with these manufacturers through non-disclosures and supplier agreements, we are assured future compatibility by these manufacturers using **SmartSats** for testing their pulse oximeters throughout their organizations.

Section 6. Pulse Oximeter Compatibility Chart

The following manufacturers use **Nellcor™** technology with their systems:

- | | |
|----------------------------|------------------------------|
| 1. Philips Medical Systems | 13. Marquette (Eagle) |
| 2. Atom Medical Corp. | 14. MDE |
| 3. Baxter Healthcare Corp. | 15. Mennen Medical |
| 4. Century Medical Inc. | 16. Drager |
| 5. Colin | 17. Respiroinics |
| 6. GEMedical Services | 18. CAS Medical Systems |
| 7. Welch Allyn | 19. Zoll |
| 8. Datascope | 20. Siemens |
| 9. Drager | 21. Sleeptrace/Areca Science |
| 10. Edentec | 22. SpaceLabs |
| 11. Fukuda Denshi | 23. Synetics |
| 12. Ivy Biomedical Systems | 24. Schiller |

The following manufacturers use **Masimo®** technology with their systems:

- | | |
|---------------------------|----------------------------|
| 1. Ohmeda-Medical | 15. Critikon |
| 2. Drager | 16. Ivy Biomedical Systems |
| 3. Welch Allyn | 17. Medtronic |
| 4. Atom Medical | 18. Respiroinics |
| 4. Alaris Medical Systems | 19. SS Corpulus |
| 6. Bitmos | 20. Getemed |
| 7. Invivo Research | 21. Graseby |
| 8. MDE | 22. Kohken Medical |
| 9. Mennen Medical | 23. Mindray |
| 10. Datascope | 24. Schiller |
| 11. GE Medical Systems | 25. Stephan |
| 12. Zoll | 26. CAS Medical Systems |
| 13. Colin | 27. Nascor Neonatal |
| 14. Allegiance | 28. Hill-Rom |

Section 6. Pulse Oximeter Compatibility Chart

Section 7: Remote Control, Version 0.4

Remote control of the **SmartSat** by a host computer is possible via an RS-232 serial port located on its right panel. This RS-232 port, a 9-pin female D-shell, is configured as a "DCE," allowing direct connection to the serial port on IBM-compatible computers. Therefore, to connect the **SmartSat** to an IBM-compatible PC, a standard cable, rather than a null modem cable, should be used. (A CGA video monitor extension cable, readily available in computer stores and mail-order catalogs, can be used. Alternatively, Clinical Dynamics can supply the appropriate cable.)

The serial port on the host computer should be configured with the following communications parameters:

Baud Rate:	1200 baud
Data Bits:	8
Stop Bits:	1
Parity:	None

The **SmartSat**'s communication protocol is essentially an all-ASCII, all-uppercase format. (The only exceptions are messages that contain waveform datapoints in binary code.) An ASCII format facilitates using popular PC communications software such as Windows Terminal, ProComm or Crosstalk as a "control console" to interact with the **SmartSat**. Before developing the remote control software for use in your application, it is recommended that the programmer familiarize themselves with the communications protocol using PC communications software.

To send remote control commands using the Windows 3.11 Terminal program:

- Select the -Communications option under the Settings pulldown menu and set the following:

Baud Rate:	1200 baud
Data Bits:	8
Stop Bits:	1
Parity:	None

- Then select the -Terminal Preferences option under the Settings pulldown menu and set the following:

Enable "Local Echo" under "Terminal Modes"
Enable "Outbound" under "CR->CR/LF"

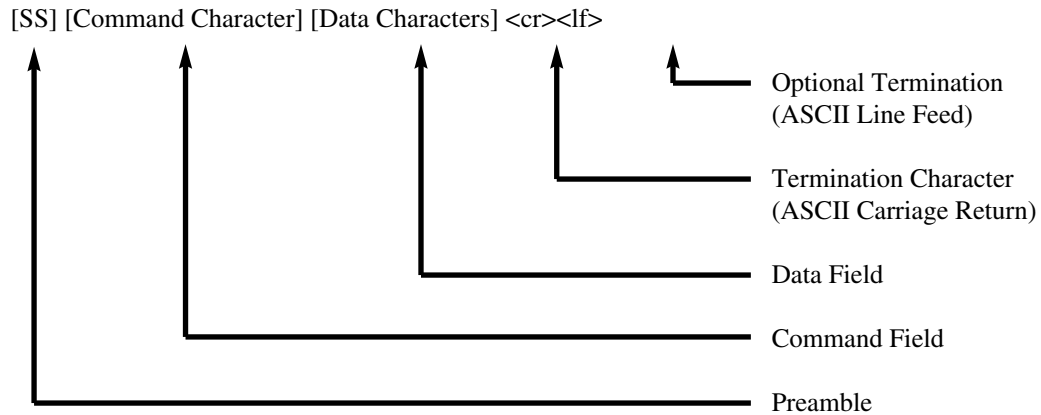
Communication between the **SmartSat** and the host device consists of two categories:

- 1) Command messages sent by the host to the **SmartSat**
- 2) Response messages sent by the **SmartSat** to the host

The following pages describe the command messages and response messages in detail.

Please note that if the terminal is receiving repeated strings of "SRP" it is because the **SmartSat** RS-232 port is set to "DataLog" not "Remote Control" This can be changed via the "Advanced" settings on the **SmartSat**.

Generic *Command Message* Format



Note: Brackets are for documentation only and are not part of the command format.

As shown above, host command messages consist of four (4) fields:

1. Preamble: [SS]
2. Command Field: a single *uppercase* letter (described below)
3. Data Field: 0 or more bytes (command dependent)
4. Termination Character: <cr> (i.e., hexadecimal “0d”, the ASCII carriage return control code)
5. **Optional** Termination Character: <lf> (i.e., hexadecimal “0f”, the ASCII line feed control code); Note use this character to improve readability of commands and responses when controlling the **SmartSat** using PC communications software.

A checksum is not used because it is awkward to generate and transmit checksums with an ASCII terminal. Message integrity checking is achieved via a structured message format; limit tests for all transmitted data; and command and data acknowledgment.

See the attached table for a list of commands and the associated data field contents.

Generic *Response Message Format*

<cr><lf>[SyntaxError]<cr><lf>

As The **SmartSat** receives and parses the incoming command message, if it encounters an illegal command syntax, it will generate a "SyntaxError" response.

[DataError]<cr><lf>

If the **SmartSat** encounters an illegal data value, it will generate a "DataError" response.

[SS] [Command Character] [=] [Data Characters] <cr><lf>

After receipt of a valid command and valid data, and after the **SmartSat** has successfully executed the command, it will acknowledge that fact to the host by echoing the preamble and command field followed by an "=" sign, the data field and the termination character.

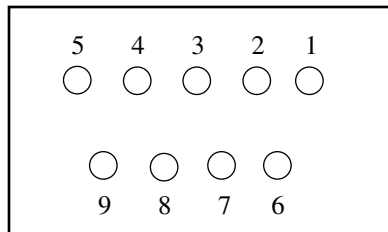
Section 7. Remote Control, Version 0.3

Command	Description	Data Field Range	Example
K	Locks front panel keypad	0 = Unlock 1 = Lock	S S K 0 <cr> S S K 1 <cr>
S	Sets SpO ₂ value	000 to 100	S S S 0 9 1 <cr>
R	Sets Pulse Rate value	020 to 300	S S R 0 7 5 <cr>
O	Sets Oximeter Type	B=BCI C=Criticare P=CSI Spot D=Datascope X=Datex H=HP M=Masimo N=Nellcor Q=N. OxiMax K=NihonKohden Z=Nonin V=Novamatrix O=Ohmeda S=Sensormedics	S S 0 B <cr>
A	Sets Pulse Modulation value scaled at 001=0.05%	000 to 200 Max setting is 200=10.00%	S S A 1 1 0 <cr>
D	Sets DC Level of Ambient Light	000 to 255	S S D 1 0 0 <cr>

Reserved commands for future use:

Command	Description	Data Field Range	Example
T	IR Tissue Transmissivity Red Tissue Transmissivity is set to 0.5 IR Tissue Transmissivity	000 to 255	<i>not yet implemented</i>
F	Sets Frequency of Ambient Light (Flicker Frequency)	0=Off 1= 60 Hz 2=120Hz 3=121Hz 4= 50 Hz 5=100Hz 6=101Hz	<i>not yet implemented</i>
L	Sets AC Level of Ambient Light (Flicker Level)	0 to 255	<i>not yet implemented</i>

SmartSat RS-232 Serial Communications Pin Assignments



9 Pin D-Type Female Connector

<u>Pin</u>	<u>Signal</u>
------------	---------------

- | | |
|---|--|
| 1 | (Not Used) |
| 2 | Rx (Receive Data, Input to SmartSat) |
| 3 | Tx (Transmit Data, Output from SmartSat) |
| 4 | DTR (Data Terminal Ready, Input to SmartSat) |
| 5 | GND (Signal Ground) |
| 6 | DSR (Data Set Ready, Output from SmartSat) |
| 7 | (Not Used) |
| 8 | DSR (Data Set Ready, Output from SmartSat) |
| 9 | (Not Used) |