# **NELLCOR**

# OxiMax N-595

Pulse Oximeter Service Manual



This ISM device complies with Canadian ICES-001.

Cet appareil ISM est conforme à la norme NMB-001 Canada.

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## **Warnings**



Warnings are identified by the WARNING symbol shown above.

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.



WARNING: The sensor extrapolates from the date and time provided by the N-595 when recording the sensor event record to the sensor. The accuracy of the date/time is the responsibility of the N-595. It is recommended that the N-595 user set the time/date to the correct value before a sensor event record-enabled sensor is connected, and that this date/time not be changed while the sensor remains connected. Since a sensor with sensor event record data can be transported from one monitor to another, having discrepancies in the date/time between monitors and the sensor event record data will affect the order the sensor event record data appears. To eliminate this possible problem, all monitors within an institution should be set to the same time.



WARNING: Explosion hazard. Do not use the N-595 pulse oximeter in the presence of flammable anesthetics.



WARNING: Do not spray, pour, or spill any liquid on the N-595, its accessories, connectors, switches, or openings in the chassis.



WARNING: Before attempting to open or disassemble the N-595, disconnect the power cord from the N-595.



WARNING: The LCD panel contains toxic chemicals. Do not ingest chemicals from a broken LCD panel.



WARNING: The use of accessories, *OxI-MAX* sensors, and cables other than those specified may result in increased emission and/or decreased immunity of the N-595 pulse oximeter.



WARNING: Do not silence the N-595 audible alarm or decrease its volume if patient safety could be compromised.

# Cautions



Cautions are identified by the CAUTION symbol shown above.

Cautions alert the user to exercise care necessary for the safe and effective use of the N-595 pulse oximeter.



**Caution: Observe ESD (electrostatic discharge) precautions when working within the unit.** 

Caution: Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the N-595 and when handling any of the components of the N-595.



Caution: When reassembling the N-595, tighten the screws that hold the cases together to a maximum of 10 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.



Caution: When installing the Power Supply or the User Interface PCB, tighten the seven screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the bottom case, rendering it unusable.

## **Manual Overview**

This manual contains information for servicing the Nellcor model N-595 pulse oximeter. Only qualified service personnel should service this product. Before servicing the N-595, read the operator's manual carefully for a thorough understanding of safe operation of the N-595.



WARNING: Explosion hazard. Do not use the N-595 pulse oximeter in the presence of flammable anesthetics.

## **Description of N-595 Monitor**

The N-595 Monitor is intended for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate. The N-595 is intended for use with neonatal, pediatric, and adult patients during both no-motion and motion conditions and for patients who are well or poorly perfused, in hospitals, hospital-type facilities, intra-hospital transport, and home environments. For prescription use only.

Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

Home Care use is defined as managed/used by a lay person (parent or other similar non-critical caregiver) in the home environment.

Use with any particular patient requires the selection of an appropriate *OxI-MAX* oxygen sensor as described in the N-595 Operator's Manual.

Motion performance claims are applicable to models MAX-A, MAX-AL, MAX-P, MAX-N, and MAX-I Nellcor *OxiMax*<sup>TM</sup> oximetry sensors.

Through the use of the four softkeys, the operator can access trend information, select an alarm limit to be changed, choose the language to be used, adjust the internal time clock, and change communications protocol. The N-595 can operate on AC power or on an internal battery. The controls and indicators for the N-595 are illustrated and identified in Figure 1 and Figure 2.

#### **Front Panel**



Figure 1: N-595 Front Panel

**Rear Panel** 



Figure 2: N-595 Rear Panel

#### Softkey Menu

The N-595 hierarchy is outlined below. The user chooses the type of trend data to view by selecting either Monitor trend or Sensor trend data in the Trend menu. Sensor sub-menu choices differ depending on what type of in-sensor data is stored in the sensor chip, such as, event or loop.

The menu structure includes BACK softkey options that allow the user to move back to the previous menu level without exiting the Trend menu entirely. Trend data must be compiled on entry/reentry to the Trends menu. When the softkeys are available, both BACK and EXIT options are available. The BACK softkey goes to the previous level and the EXIT softkey goes to the main menu. If only one space is available the BACK Softkey is included, this may require going back one or two levels to get to an EXIT softkey.

The BACK and EXIT softkeys are positioned on the right-most softkeys, respectively.

The below menu structure identifies:

- **BOLDFACE TYPE** softkey title as displayed on the monitor
- <u>Underlined Text</u> description of the softkey menu item
- Italicized Text the destination of the BACK and EXIT softkeys

(Main Menu) LIMITS (Limits Menu) - SELECT

- SELE
- ADULT
- EXIT (to Main menu)

TREND (Trend Menu)

- MON (Monitor Menu)
- VIEW (Monitor Trend View Menu)
- - DUAL
- - SPO2
- - PULSE
- NEXT (<u>History/Amplitude Menu</u>)
  - - HIST (Delete/Print2 Menu)
- DELETE (delete Trends)
  DELETE (delete Trends)
   - - "DELETE TRENDS"
   - - YES (return to Main menu)
   - - NO (back to Delete/Print menu)
   - PRINT
   - BACT (back to Hist/Amp menu)
  - - **EXIT** (to Main menu)
- - - **AMP** (Amplitude Menu)
  - - BACK (back to Hist/Amp menu)
  - - EXIT (to Main menu)
  - - BACK (back to Monitor Trend View menu)
- - **EXIT** (to Main menu)

-	-	<b>ZOOM</b> (Monitor Trend Zoom Menu)
_	_	- TIME (for current view cycle through 18h 36h 12h 8h 1h 2h 1h
-	-	
		<i>30m</i> , <i>15m</i> , <i>40s</i> , <i>20s</i> )
-	-	- SCALE (for current view, cycle through $\pm 5$ , $\pm 10$ , $\pm 15$ , $\pm 20$ , $\pm 25$ ,
		$\pm 30, \pm 35, \pm 40$ and $\pm 50$ of the max and min. values under the
		cursor default to 10 to 100 if there is no data point under the
		cursor)
-	-	- <b>AUTO</b> (based on all of the graphed trend data: maximum value,
		rounded up to nearest multiple of 10, minimum value, rounded
		down to nearest multiple of 10 minus 10)
_	_	- BACK (back to Monitor menu)
-	-	- BRCK (back to Monitol Menu)
-	-	NEXT (Delete/Print'i Menu)
-	-	- DELETE
-	-	"DELETE TRENDS?"
-	-	YES (to Main menu)
_	_	- $ NO$ (back to Delete/Print1 menu)
-	-	
-	-	- PRINI
-	-	- BACK (back to Monitor menu)
-	-	- EXIT (to Main menu)
-	-	BACK (back to Trend menu)
	e El	NSOD (Songer/Event Menu)
-	SE	
	(IT E	event data is in the sensor, the following menu, the Screen will remain in
		the appropriate state until the next menu selection is made)
-	-	<b>GRAPH</b> (Graph Menu) (display events #1-N, in inverse chronological
		order: un/down also scroll through events in order)
		(about providuo graph, antworkilable when there is a providuo
-	-	
		graph)
-	-	<ul> <li>&gt; (show next graph, only available when there is a next graph)</li> </ul>
-	-	- PRINT
-	-	- BACK (back to Sensor menu)
-	-	
-	-	<ul> <li>A (show previous table, only available when there is a previous</li> </ul>
		graph; bottom/top line repeats in new table)
-	-	<ul> <li>v (show next table, only available when there is a next graph;</li> </ul>
		hottom/ton line repeats in new table)
-	-	
-	-	- BACK (back to Sensor menu)
-	-	- EXIT (to Main menu)
	(Se	nsor/Loop Menu) (If continuous-Loop data is in the sensor, the following
	4	will be displayed)
		VIEW (Senser Trend View Menu)
-	-	
-	-	- DUAL (shows SP02+BPM)
-	-	- SPO2
-	-	- PULSE
_	_	<b>ZOOM</b> (cycle through 2h 1h 30m and 15m for current view)
	_	
-	-	
-	-	BACK (to Trend menu)
-	EX	IT (to Main menu)
SET	UΡ	(Setup Monitor Menu)
-		W (Setup View Menu)
	• • •	
-	-	
-	-	BLIP
-	-	BACK (back to Setup menu)
-	-	EXIT (to Main menu)

- SENSOR (Setup Sensor Menu)

- DATA (On-screen options for SENSOR-R (Write-once Sensor) sensor are: "SPO2, SPO2+BPM, DEFAULT." On-screen options for SENSOR-RW (rewritable sensor) are: "SPO2, SPO2+BPM, DEFAULT." SELECT toggles SENSOR-R or SENSOR-RW sensor type; up/down keys scroll through options in order.) The SENSOR-R feature supports all of the current OxIMax sensors.
- - SELECT

-

- - **BACK** (back to Setup Sensor menu)
- - **EXIT** (to Main menu)
- MSG (Sensor Set Message Menu)
- - BACK (back to Setup Sensor menu)
- - EXIT (to Main menu)
- NEXT (Clock/Language Menu)
- - CLOCK (Clock Menu)
- - SET (Clock Set Menu)
- - SELECT (press select to toggle through hours, minutes, seconds, month, day, year; use up/down buttons to set each selection)
- - BACK (back to Clock/Language menu)
- - **EXIT** (to Main menu)
- LANG (Language Setup Menu) (use up/down buttons to toggle though languages)
- - **BACK** (back to Clock/Language menu)
- - NEXT (Communication/Nurse Call Menu)
  - - COMM (Communication Port Configuration Menu)
- - SELECT
  - - **BACK** (back to Communication/Language menu)
- - **EXIT** (to Main menu)
  - NCALL (Nurse Call Menu)
  - - NORM +
  - - NORM -
    - - **BACK** (back to Communication/Nurse Call menu)
    - - EXIT (to Main menu)
  - - NEXT (Analog/Mode Menu)
  - - ANALOG (Analog Voltage Select Menu)
  - - - 0 VOLT
  - - - 1 VOLT
  - - - STEP
    - - **BACK** (back to Analog/Mode menu)
- - - **MODE** (Mode Menu)
  - - BACK (back to Analog/Mode menu)
  - - - EXIT (to Main menu)
  - - BACK (back to Communication/Nurse Call menu)
- - - **EXIT** (to Main menu)
  - - **BACK** (back to Clock/Language menu)
- - **BACK** (back to Setup menu)
- **EXIT** (to Main menu)

LIGHT (Turns the display backlight on or off)

## **Related Documents**

To perform test and troubleshooting procedures and to understand the principles of operation and circuit analysis sections of this manual, you must know how to operate the monitor. Refer to the N-595 operator's manual. To understand the various Nellcor approved *OxI-MAX* sensors that work with the monitor, refer to the individual *OxI-MAX* sensor's directions for use.

The latest version of the operator's manual and the service manual are posted on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv\_Supp/ProductManuals.html

Spare Parts and Accessories are posted on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv\_Supp/Apartweb/main/PartAcceMenu.html

# Cleaning



WARNING: Do not spray, pour, or spill any liquid on the N-595, its accessories, connectors, switches, or openings in the chassis.

For surface-cleaning and disinfecting follow your institution's procedures or:

- The N-595 may be *surface-cleaned* by using a soft cloth dampened with either a commercial, nonabrasive cleaner or a solution of 70% alcohol in water, and lightly wiping the surfaces of the monitor.
- The N-595 may be *disinfected* using a soft cloth saturated with a 10% solution of chlorine bleach in tap water.

Before attempting to clean an SpO2 *Oxi-Max* sensor, read the directions for use enclosed with the *Oxi-Max* sensor. Each sensor model has cleaning instructions specific to that sensor.

## **Periodic Safety Checks**

The N-595 requires no calibration.

The battery should be replaced at least every 2 years. See *Battery Replacement* on page 67.

The following checks should be performed at least every 24 months by a qualified service technician.

- 1. Inspect the equipment for mechanical and functional damage.
- 2. Inspect safety labels for legibility. If the labels are damaged, contact Nellcor's Technical Services Department, 1.800.635.5267, or your local Nellcor representative.

# **Functional Checks**

If the monitor has been visibly damaged or subjected to mechanical shock (for example, if dropped), immediately perform the performance tests. See *Performance Tests* on page 11.

The following checks should be performed at least every 2 years by a qualified service technician.

- 1. Perform the electrical safety tests detailed in *Safety Tests* on page 33. If the unit fails these electrical safety tests, refer to *Troubleshooting* on page 51.
- 2. Inspect the fuses for proper value and rating (F1 & F2 = 0.5 amp, 250 volts).

#### **Battery**

Nellcor recommends replacing the instrument's battery every 2 years. When the N-595 is going to be stored for 3 months or more, remove the battery prior to storage. To replace or remove the battery, refer to *Disassembly Guide* on page 63.

If the N-595 has been stored for more than 30 days, charge the battery as described in *Battery Charge* on page 12. A fully discharged battery requires 14 hours with the monitor turned off, or 18 hours if it is in use, to receive a full charge. The battery is being charged whenever the instrument is plugged into AC.

Note: If power stored in the battery is too low, the unit will not operate even when plugged into AC. If this occurs, leave the unit plugged in to allow the battery to charge as described in *Battery Charge* on page 12. After approximately 10 minutes, the battery should have enough charge to allow the unit to operate on AC.

## Introduction

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing the N-595 cover. All tests except the battery charge and battery performance tests must be performed as the last operation before the monitor is returned to the user.

If the N-595 fails to perform as specified in any test, repairs must be made to correct the problem before the monitor is returned to the user.

# **Equipment Needed**

Equipment	Description
Digital Multimeter (DMM)	Fluke Model 87 or equivalent
Durasensor <sup>®</sup> OXI-MAX oxygen sensor	DS-100A
OXIMAX oxygen sensor	MAX-A
Safety Analyzer	Must meet current AAMI ESI/1993 & IEC 60601-1/1998 specifications
Pulse oximetry cable	DOC-10
Data interface cable	EIA-232 cable (optional)
Stopwatch	Manual or electronic
Nellcor model SRC-MAX Tester	Provides testing for DigiCal compatible Monitors

#### **Table 1: Equipment Needed**

## **Performance Tests**

The battery charge procedure should be performed before monitor repairs whenever possible.

Note: This section is written using Nellcor factory-set defaults. If your institution has pre configured custom defaults, those values will be displayed. Factory defaults can be restored (see *Reset Softkey* on page 40).

#### **Battery Charge**

Perform the following procedure to fully charge the battery.

- 1. Connect the monitor to an AC power source.
- Verify that the monitor is off and that the AC Power/Battery Charging ● 
  <sup>1</sup>→ 2. indicator is lit.
  - 3. Charge the battery for at least 14 hours with the monitor turned off or 18 hours with the monitor turned on.

#### **Power-Up Performance**

The power-up performance tests verify the following monitor functions:

- Power-On Self-Test on page 12
- Power-On Defaults and Alarm Range Limits on page 13

# Power-On Self-Test

- 1. Connect the monitor to an AC power source.
- $rac{1}{2}$ . Verify that the monitor is off and that the AC Power/Battery Charging indicator is lit.
  - 3. Do not connect any cables to the monitor.



- Turn on the N-595 by pressing the ON/STANDBY button. Observe the 4. monitor front panel. The monitor must perform the following:
  - Within 2 seconds all LEDs are illuminated, all pixels on the LCD display • are illuminated, and the backlight comes on.
  - The indicators remain lighted. •
  - The LCD display shows NELLCOR and the software version of the N-595.

Note: The software "Version" displayed in the example below is X.X.X.The actual software version will be displayed on your monitor.



- A 1-second beep sounds, indicating proper operation of the speaker, and all indicators turn off except the AC Power/Battery Charging indicator and the LCD screen.
- The N-595 begins normal operation.

#### PLETH VIEW:



#### **BLIP (MAGNIFIED) VIEW**



#### Power-On Defaults and Alarm Range Limits

- Note: When observing or changing alarm limits, a time-out is in effect (approximately 10 seconds). If no action is taken within the time-out, the monitor automatically returns to the monitoring display.
- Note: The descriptions that follow are based on the assumption that Pleth view is the view that has been selected.

The steps for changing an alarm limit are the same if the view being used is Blip (Magnified) view.

Note: Power-on defaults will be the factory-set defaults or the defaults set by your institution.



1. Turn on the N-595 by pressing the ON/STANDBY button.



2. Press the LIMITS softkey. Verify that the monitor emits a single beep and the pleth view is replaced with a display of the alarm limits. The upper alarm limit for %SpO2 will indicate an alarm limit of "100" (or institutional default setting) inside a box.





- 3. Press and hold the ADJUST DOWN button. Verify that the boxed number for %SpO2 upper alarm limit reduces to a minimum of "86."
- Note: A decimal point in the display indicates that the alarm limits have been changed from factory default values.
- **SELECT** 4. Press the SELECT softkey. Verify that the monitor emits a single beep and the box moves to the %SpO<sub>2</sub> lower alarm limit of "85" (or your institutional default setting).

	• NELLCO	JR			N-090	
)	AD UPPER LOWER SAT-S	ULT LIM %SPO2 86 85 0FF	ITS BPM 170 40	%SP02 BPM	100 110	
w .	SELECT	NEO	ADULT	EXIT		-
. 38	$\bigcirc$	$\bigcirc$	$\bigcirc$	$\bigcirc$	( <b>0</b> )	-



5. Press and hold the ADJUST DOWN button and verify that the %SpO2 lower alarm limit display reduces to a minimum of "20."

6. Press and hold the ADJUST UP button and verify that the %SpO2 lower alarm limit display cannot be raised past the upper alarm limit setting of "85."

- **EXIT** 7. Press the EXIT softkey.

8. Press the LIMITS softkey

**SELECT** 9. Press the SELECT softkey three times. Verify that the monitor emits a beep after each keystroke. The Pulse upper alarm limit should be "170" and should be boxed.

• NELLCO	DR			N-595
AD UPPER LOWER SAT-S	0LT LIM %SP02 86 85 0FF	ITS BPM 170 40	%SP02 BPM	100 110
SELECT	NEO	ADULT	EXIT	
	$\bigcirc$	0		0



10. Press and hold the ADJUST DOWN button.

11. Verify that the minimum displayed value is "41" for the BPM upper alarm limit.

**EXIT** 12. Press the EXIT softkey.

1

LIMITS

13. Press the LIMITS softkey.

SELECT

14. Press the SELECT softkey four times. Verify that the pulse rate lower alarm limit display indicates an alarm limit of "40" and is boxed.

ADULT LIMITS %SP02 BPM UPPER 86 41 LOWER 85 40 BPM 110 SELECT NEO ADULT EXIT	♦ NE	LLCC	DR			N-595	
SELECT NEO ADULT EXIT	UPPE LOW	AD IR ER S	0LT LIMI %SP02 86 85 0FF	HTS BPM 41 40	%SP02 BPM	100 110	
	SEL	ECT	NEO	ADULT	EXIT		



- 15. Press and hold the ADJUST DOWN button. Verify that the boxed pulse rate lower alarm limit display reduces to a minimum of "30."
- 16. Press and hold the ADJUST UP button and verify that the boxed pulse rate lower alarm limit display cannot be adjusted above the pulse rate upper alarm limit of "40."
- **EXIT** 17. Press the EXIT softkey.
- LIMITS 18. Press the LIMITS softkey.
- **SELECT** 19. Press the SELECT softkey two times. Verify that *SatSeconds* SAT-S alarm is selected.

ADULT LIMITS %SP02 BPM UPPER 86 41 LOWER 85 40 BPM 110	NELLCO	OR			N-SR
Land Land	AD UPPER LOWER SAT-S	86 85 0FF	ITS BPM 41 40	%SP02 BPM	100 110
SELECT NEO ADULT EXIT	SELECT	NEO	ADULT	EXIT	



20. Press the ADJUST UP button repeatedly and verify that the *SatSeconds* alarm display cycles from OFF through 10, 25, 50, 100, OFF.

21. Press the ON/STANDBY button to turn the monitor off.

22. Press the ON/STANDBY button to turn the monitor back on.

- 23. Press the LIMITS softkey. Verify that the %SpO2 upper alarm limit display is boxed and indicates an alarm limit of "100."
  - 24. Verify that the %SpO2 lower alarm limit display is boxed and indicates an alarm limit of "85."
  - 25. Verify that the SatSeconds SAT-S alarm is set to OFF.
  - 26. Verify that the pulse rate upper alarm limit display is boxed and indicates an alarm limit of "170."
  - 27. Verify that the pulse rate lower alarm limit display is boxed and indicates an alarm limit of "40."



LIMITS

28. Press the ON/STANDBY button to turn the monitor off.

#### **Operational Setup**

Operational setup procedures verify and set up the following parameters.

- Alarms and Alarm Silence on page 18
- Alarm Volume Control on page 20
- Pulse Tone Volume Control on page 20
- Nurse Call on page 21
- Analog Output on page 22
- *Operation on Battery Power* on page 23

# Alarms and Alarm Silence



1. Sensor Port

- 1. Connect the DOC-10 monitor cable to the monitor sensor port.
- Connect the DS-100 Oxi-MAX sensor to the DOC-10 cable and your finger. 2.
- Press the ON/STANDBY button to turn the monitor on. 3.
- 4. Press the SETUP softkey. SETUP
- VIEW 5. Press the VIEW softkey.
- 6. Press the PLETH softkey. Verify that the %SpO2 and BPM indicate your PLETH SpO<sub>2</sub> and pulse rate.
- 7. Press the LIMITS softkey. LIMITS
- **SELECT** 8. Press the SELECT softkey to select SpO<sub>2</sub> lower alarm limit.
  - 9. Press the ADJUST UP button until the SpO2 lower alarm limit indicates 99.
- **SELECT** 10. Press the SELECT softkey three times to select pulse rate lower alarm limit.



- 11. Press the ADJUST UP button until the pulse rate lower alarm limit indicates 160.
- 12. Verify the following monitor reactions:

- The plethysmograph waveform tracks your pulse rate.
- The pulse tone is heard.
- Your SpO2 and pulse rate are flashing in the %SpO2 and BPM displays.
- The audible alarm sounds, indicating that both parameters have violated the alarm limits.



13. Press and hold the ALARM SILENCE button until the BPM display indicates "SEC." Continue to press the ALARM SILENCE button and press the ADJUST DOWN button until "60" is displayed in the %SpO2 display.



- 14. Press the ALARM SILENCE button.
- 15. With the monitor's alarm silenced, verify the following:
  - The alarm remains silenced for 60 seconds.



- The ALARM SILENCE indicator lights.
- The %SpO2 and BPM displays continue to flash.
- The pulse tone is still audible.
- The audible alarm returns in approximately 60 seconds.



16. Press and hold the ALARM SILENCE button until the BPM display indicates "SEC." Continue to press the ALARM SILENCE button and press the ADJUST DOWN button until "30" is displayed in the %SpO2 display.



17. Press the ADJUST UP button and verify that the displays indicate 60 SEC, 90 SEC, 120 SEC, and OFF. Release the ADJUST UP button when the display indicates "OFF."



- 18. Press and release the ALARM SILENCE button. Verify that the monitor's ALARM SILENCE indicator flashes.
- 19. Wait approximately 3 minutes. Verify that the monitor's alarm does not return. After 3 minutes, the monitor's alarm silence reminder beeps three times, and will continue to do so at approximately 3-minute intervals.

# Alarm Volume Control

After completing *Alarms and Alarm Silence* on page 18, perform the following procedure.



1. Press and hold the ALARM SILENCE button and verify the following:

- "OFF" is displayed for approximately 3 seconds.
- After 3 seconds, a steady tone is heard at the default alarm volume setting, the %SpO2 display indicates "VOL," and the BPM display indicates the default setting of 7.



2. While still pressing the ALARM SILENCE button, press the ADJUST DOWN button until an alarm volume setting of 1 is displayed. Verify that the volume of the alarm has decreased but is still audible.



3. Continue pressing the ALARM SILENCE button and press the ADJUST UP button to increase the alarm volume setting to a maximum value of 10. Verify that the volume increases.



Continue pressing the ALARM SILENCE button and press the ADJUST DOWN button until a comfortable audio level is attained.



5. Release the ALARM SILENCE button. The tone will stop.

## Pulse Tone Volume Control

After completing *Alarm Volume Control* on page 20, perform the following procedure.



1. Press the ADJUST UP button and verify that sound level of the beeping pulse tone volume increases.



Press the ADJUST DOWN button and verify that the sound level of the beeping pulse tone volume decreases until it is no longer audible.



3. Press the ADJUST UP button to return the beep volume to a comfortable level.

4. Remove the *OxI-MAX* sensor from your finger. Disconnect the DOC-10 monitor cable and the *OxI-MAX* sensor.

Nurse Call



1. Data Port Connector

9 10 11 12 13 14 15 1 2 3 4 5 6 7 8

1. Connect the negative lead of a voltmeter to pin 5 and positive lead to pin 11 of the data port connector (1) on the back of the monitor. Ensure that the audible alarm is not silenced or turned off.

- 2. Connect the SRC-MAX tester to the DOC-10 sensor cable.
- 3. Connect the DOC-10 sensor cable to the monitor SpO<sub>2</sub> connector.



Turn on the monitor and wait for the monitor to complete POST.

Note: The monitor should indicate a %SpO2 alarm of 75.

5. Verify an output voltage at pins 5 and 11 between +5 to +12 VDC.



- Press the ALARM SILENCE button. With no active audible alarm, the output voltage at pins 5 and 11 must be between -5 to -12 VDC. This verifies the RS-232 Nurse Call function.
- 7. With the instrument in an alarm condition, use a digital voltmeter (DVM) to verify that there is no continuity (1 megohms or greater) between pins 8 and 15 and that there is continuity (60 ohms or less) between pins 7 and 15.



8.

Press the SRC-MAX tester %SpO2 button to change the %SpO2 to 90.

9. Use a DVM to verify that there is continuity between pins 8 and 15 and that there is no continuity between pins 7 and 15. This verifies the solid state Nurse Call function.

# Analog Output

10 11 12 13 14 15

5 6

а

р

2 3



1 Data Port Connector

- 1. Connect the negative lead of a voltmeter to pin 10 and the positive to lead pin 6 of the data port connector (1) on the back of the monitor.
- **SETUP** 2. Press the SETUP softkey.
- **NEXT** 3. Press the NEXT softkey.
- **NEXT** 4. Press the NEXT softkey.
- **NEXT** 5. Press the NEXT softkey.
- **ANALOG** 6. Press the ANALOG softkey.
- **1 VOLT** 7. Press the 1 VOLT softkey.
  - 8. Verify that the monitor's output voltage is  $+1.0 \pm 0.025$  VDC. This verifies the analog SpO<sub>2</sub> function.
  - 9. Leave the negative lead connected to pin 10 and verify  $1.0 \pm 0.025$  VDC on pins 13 and 14. This verifies the monitor's BPM and Pleth function.

Note: If step 8 takes more than 2 minutes to complete, the analog output will time out. Repeat steps 2 through 6 to initiate the analog output.

- 10. Move the positive lead back to pin 6.
- **SETUP** 11. Press the SETUP softkey.
- **NEXT** 12. Press the NEXT softkey.
- **NEXT** 13. Press the NEXT softkey.
- **NEXT** 14. Press the NEXT softkey.
- **ANALOG** 15. Press the ANALOG softkey.
- **0 VOLT** 16. Press the 0 VOLT softkey.
  - 17. Verify that the monitor's output voltage is  $+0.0 \pm 0.025$  VDC.
  - 18. Leave the negative lead connected to pin 10 and verify  $0.0 \pm 0.025$  VDC on pins 13 and 14.
  - Note: If step 16 takes more than 2 minutes to complete, the analog output will time out. Repeat steps 10 through 14 to initiate the analog output.
  - 19. Disconnect the voltmeter from the instrument.

#### **Operation on Battery Power**

- 🖽 🗸
- 1. Disconnect the instrument from AC power and verify that the AC POWER indicator turns off.
  - 🔁 2. Verify that the monitor continues monitoring normally and that the LOW BATTERY indicator is not lit.

- Note: If the LOW BATTERY indicator is illuminated, perform *Battery Charge* on page 12.
- $rac{1}{2} \sim 3$ . Connect the monitor to AC power and verify that the AC POWER indicator turns on and that the instrument is monitoring normally.

#### **General Operation**

The following tests are an overall performance check of the system:

- *LED Excitation Test* on page 24.
- Operation with a Live Subject on page 25.



This procedure uses normal system components to test circuit operation. A Nellcor *OxtMax* oxygen sensor, model MAX-A, is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.



- 1. Connect the monitor to an AC power source.
- 2. Connect a DOC-10 pulse oximetry cable to the monitor sensor port.
- 3. Connect a MAX-A OxI-MAX sensor to the OXI-MAX sensor-input cable.



- 4. Press the ON/STANDBY button to turn the monitor on.
- 5. Leave the OxI-MAX sensor open with the LEDs and photo detector visible.

- 6. After the monitor completes its normal power-up sequence, verify that the *OxI-MAX* sensor LED is brightly lit.
- 7. Slowly move the *Oxt-MAX* sensor LED in proximity to the photo detector element of the *Oxt-MAX* sensor (close the *Oxt-MAX* sensor slowly). Verify, as the LED approaches the optical *OxtMAX* sensor, that the LED intensity decreases.
- 8. Open the OxIMAX sensor and notice that the LED intensity increases.
- 9. Repeat step 7 and the intensity will again decrease. This variation is an indication that the microprocessor is in proper control of LED intensity.



10. Press the ON/STANDBY button to turn the monitor off.

#### Operation with a Live Subject

Patient monitoring involves connecting the *OxiMax* sensor to a live subject for a qualitative test.



1 Sensor Port

- 1. Ensure that the monitor is connected to an AC power source.
- 2. Connect a DOC-10 pulse oximetry cable to the monitor sensor port.
- 3. Connect a Nellcor *OxiMax* MAX-A oxygen *OxiMax* sensor to the pulse oximetry cable.
- 4. Clip the MAX-A to the subject as recommended in the *OxiMax* sensor's directions for use.



- 5. Press the ON/STANDBY button to turn the monitor on and verify that the monitor is operating.
- 6. The monitor should stabilize on the subject's physiological signal in about 15 to 30 seconds. Verify that the oxygen saturation and pulse rate values are reasonable for the subject.

#### **Pulse Oximetry Functional Tests**

These tests utilize the pulse oximetry functional tester (Nellcor model SRC-MAX) to verify the performance of the N-595 monitor. See Figure 3.

All of these tests should be done in sequence.



Figure 3: SRC-MAX OxIMAX Oximetry Tester

# Introduction

The SRC-MAX functional tester allows qualified technicians to functionally test Nellcor *OxiMax* technology-based pulse oximeters and OEM *OxiMax* technology-based monitors. The technician must perform the test setup procedure before performing tests 1 through 4. The following is a brief description of each test:

- **Test Setup** This procedure establishes the baseline for all the other tests. The Test Setup procedure must be performed before performing any or all of the SRC-MAX tests.
- **Test 1: BPM** This procedure simulates an *OxiMax* sensor attached to a patient indicating 60 BPM and 200 BPM. The test setup procedure sets up Test 1 for 60 BPM.
- **Test 2: SpO2** This procedure simulates an *OxiMax* sensor attached to a patient, indicating 75 percent blood oxygen saturation and 90 percent blood oxygen saturation. The test setup procedure sets up Test 2 for 75 percent blood oxygen saturation.
- **Test 3: Modulation** This procedure simulates an *OxiMax* sensor attached to a patient indicating low and high pulse strength. The test setup procedure sets up Test 3 for low pulse strength.
- **Test 4: Light** This procedure simulates an *OxiMax* sensor attached to a patient indicating low and high light level passing through the patient at the sensor site. The test setup procedure sets up Test 4 for low light level.





1.Sensor Port

- 1. With the monitor turned off, connect the DOC-10 pulse oximetry cable to the sensor port.
- 2. Connect the SRC-MAX tester to the other end of the DOC-10 cable.



8. Turn on the monitor by pressing the ON/STANDBY button.

- 4. After the monitor completes POST, the monitor will:
  - be in SpO2 alarm
  - display an %SpO2 of 75 (pass criteria is 73 to 77 %SpO2 inclusive)
  - display a pulse rate of 60 (pass criteria is 57 to 63 BPM inclusive)
  - pulse amplitude indicator display low level modulation (low amplitude pulse amplitude indicator)



# Test #1: BPM



- 1. Press the SRC-MAX % Pulse Rate selection button. The SRC-MAX Pulse Rate 200 LED will light.
- 2. The monitor BPM will increase to 200 and stabilize at 200 BPM. The test pass criteria is 197 to 203 BPM inclusive.
- 3. The monitor will display:
  - 75 %SpO<sub>2</sub>
  - 200 BPM (pass criteria is 197 to 203 BPM inclusive)
  - alarm
  - pulse amplitude indicator low level modulation




- Press the SRC-MAX Pulse Rate select button. The SRC-MAX Pulse Rate 60 LED will light.
- 5. The monitor pulse rate will decrease to 60 and stabilize at 60 BPM. The test pass criteria is 57 to 63 BPM inclusive.
- 6. The monitor will display:
  - 75 %SpO<sub>2</sub>
  - 60 BPM (test pass criteria is 57 to 63 BPM inclusive)
  - alarm
  - pulse amplitude indicator low level modulation

## Test #2: SpO2



- 1. Press the SRC-MAX %SpO2 select button. The SRC-MAX %SpO2 90 LED will light.
- 2. The monitor will display three dashes until the SRC-MAX stabilizes at 90 %SpO2. The test pass criteria is 88 to 92 %SpO2 inclusive.

- 3. The monitor will display:
  - 90 % SpO<sub>2</sub> (pass criteria is 88 to 92 % SpO<sub>2</sub> inclusive)
  - 60 BPM
  - no alarm
  - pulse amplitude indicator low level modulation





- 4. Press the SRC-MAX %SpO2 select button. The SRC-MAX %SpO2 75 LED will light.
- 5. The monitor will display three dashes until the SRC-MAX stabilizes at 75 %SpO2. The test pass criteria is 73 to 77 %SpO2 inclusive.
- 6. The monitor will display:
  - 75 %SpO2 (pass criteria is 73 to 77 %SpO2 inclusive)
  - 60 BPM
  - alarm
  - pulse amplitude indicator low level modulation

## Test #3: Modulation Level



 Press the SRC-MAX % Modulation selection button. The SRC-MAX % Modulation LED will light. 2. The monitor pulse amplitude waveform will initially increase in amplitude and then stabilize.



- 3. The monitor will display:
  - 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive)
  - 60 BPM (test pass criteria is 57 to 63 BPM inclusive)
  - alarm
  - pulse amplitude indicator high level modulation
- 4. Perform *Test #1: BPM* on page 28. The pulse amplitude indicator should indicate high level modulation.
- 5. Perform *Test #2: SpO2* on page 29. The pulse amplitude indicator should indicate high level modulation.



- 7. The monitor pulse amplitude waveform will decrease in amplitude.



- 8. The monitor will display:
  - 75 % SpO<sub>2</sub>
  - 60 BPM
  - alarm
  - pulse amplitude indicator low level modulation
- 9. Perform *Test #1: BPM* on page 28. The pulse amplitue indicator should indicate low level modulation.
- 10. Perform *Test #2: SpO2* on page 29. The pulse amplitue indicator should indicate low level modulation.

Test #4: Light



- Press the SRC-MAX Light Level selection button. The SRC-MAX Light Level LED will light.
- 2. The monitor pulse amplitude waveform will initially increase in amplitude and then stabilize.



- 3. The monitor will display:
  - 75 %SpO2 (test pass criteria is 73 to 77 %SpO2 inclusive)
  - 60 BPM (test pass criteria is 57 to 63 BPM inclusive)
  - alarm
  - pulse amplitue indicator high level modulation

- 4. Perform *Test #1: BPM* on page 28. The pulse amplitue indicator should indicate high level modulation.
- 5. Perform *Test #2: SpO2* on page 29. The pulse amplitue indicator should indicate high level modulation.



- 7. The monitor pulse amplitude waveform will decrease in amplitude.
- 8. The monitor will display:
  - 75 %SpO<sub>2</sub>
  - 60 BPM
  - alarm
  - low level modulation
- 9. Perform *Test #1: BPM* on page 28. The pulse amplitue indicator should indicate low level modulation.
- 10. Perform *Test #2: SpO2* on page 29. The pulse amplitue indicator should indicate low level modulation.
- 11. Disconnect all equipment and turn off the monitor.

## **Safety Tests**

The N-595 safety tests meet the standards of, and are performed in accordance with, IEC 60601-1 (EN 60601-1, Amendment 1, Amendment 2,) and UL 2601-1, for instruments classified as Class 1 and TYPE BF and ANSI/AAMI Standard ES1.

Applicable tests for these standards are listed below. Technicians must be familiar with the Standards applicable to the technicians institution and country. Test equipment and its application must comply with the applicable standard.

• *Ground Integrity* on page 101 for test value.

- *Earth Leakage Current* on page 102 for test values.
- Enclosure Leakage Current on page 102 for test values.
- Patient Applied Risk Current on page 102 for test values.
- Patient Applied Risk Current on page 102 for test values.
- Note: **Patient Applied Risk Current** and **Patient Isolation Risk Current:** The leakage test lead from the test equipment must be connected to the N-595 SpO2 Sensor Port through the DOC-10 pulse oximetry cable using a male 9-pin "D" type connector that has all pins shorted together. During these tests the monitor will display "EEE 10," after the "Nellcor" screen.

## Introduction

This section discusses how to reconfigure power-on default values and access the service functions.

## **Power-On Settings**

The following paragraphs describe how to change power-on default settings.

By using softkeys as shown in Figure 1 on page 4, the user can change alarm limits, the type of display, baud rate, time and date, and trends to view.

Some values cannot be saved as power-on default values. An SpO2 lower alarm limit less than 80 will not be saved as a power-on default. Audible Alarm Off will not be accepted as a power-on default. An attempt to save either of these values as default will result in an invalid tone. These limits can be adjusted lower for the current patient, but they will be lost when the instrument is turned off.

A decimal point is added to the right of a display when the alarm limit for that display has been changed to a value that is not a power-on default value. If the new value is saved as a power-on default value, the decimal point will be removed. By using the service functions, changes can be saved as power-on default values.

## **Factory Default Settings**

Factory default settings are divided into two groups, adult and neonate. Default settings may be changed to institutional default settings; refer to *Setting Institutional Defaults (Sample)* on page 47.

#### **Neonate Default Settings**

Monitoring Mode	Setting		
Note: Bold entries are different than adult default settings.			
%SpO2 Lower Alarm Limit	80%		

#### **Table 2: Neonate Alarm Limit Factory Defaults**

	, 			
Monitoring Mode	Setting			
Note: Bold entries are different than adult default settings.				
%SpO2 Upper Alarm Limit	95%			
Alarm Silence Duration	60 seconds			
Alarm Silence Duration Off Setting	Disabled			
Alarm Silence Reminder	Enabled			
Alarm Volume	7 of 10			
Data Port Baud Rate	9600			
Data Port Protocol	ASCII			
Display Contrast	Midrange			
Display Format	Pleth			
OXIMAX Sensor Event Record Type	SpO2			
Language	English			
Nurse Call Polarity	Normally Low			
Pulse Beep Volume	4 of 10			
Pulse Rate Lower Alarm Limit	90 beats per minute			
Pulse Rate Upper Alarm Limit	190 beats per minute			
SatSeconds	Off			
Sensor Adjust Enabled	Yes			
Trend Display	%SpO2			

#### Table 2: Neonate Alarm Limit Factory Defaults

## **Adult Default Settings**

Monitoring Mode	Setting			
Note: Bold entries are different than neonate default settings.				
%SpO2 Lower Alarm Limit	85%			
%SpO2 Upper Alarm Limit	100%			
Alarm Silence Duration Off Setting	Disabled			
Alarm Silence Duration	60 seconds			
Alarm Silence Reminder	Enabled			
Alarm Volume	7 of 10			
Data Port Baud Rate	9600			
Data Port Protocol	ASCII			
Display Contrast	Midrange			
Display Format	Pleth			
OXIMAX Sensor Event Record Type	SpO2			
Language	English			
Nurse Call Polarity	Normally Low			
Pulse Beep Volume	4 of 10			
Pulse Rate Lower Alarm Limit	40 beats per minute			
inclusive	170 beats per minute			
SatSeconds	Off			
Sensor Adjust Enabled	Yes			
Trend Display	%SpO2			

#### Table 3: Adult Alarm Factory Defaults

## **Service Functions**

Service functions can be used to select institutional defaults and to access information about the patient or instrument. Only a Nellcor Customer Service Engineer should access some of the items available through the service functions. These items will be noted in the text that follows.

#### Accessing the Service Functions

All service functions are accessible when the DOC-10 pulse oximetry cable is disconnected from the monitor. Disconnect the *OxiMax* sensor from the MC-10 extension cable; or, disconnect the MC-10 extension cable from the instrument.



- 1. Turn on the N-595 by pressing the ON/STANDBY button.
- 2. Wait for monitor power-on self-test to complete.



3. Simultaneously press and hold the LIGHT softkey and the CONTRAST button until the service softkeys are displayed.



- Note: The service function is only accessible from the main menu display. The menu bar will change to the headings listed below.
- Note: If the above step is performed with a pulse oximetry cable connected, only the PARAM and EXIT softkeys appear on the screen.

The following list can be used as a quick reference showing how to reach different softkey functions. Items reached through the PARAM softkey can be accessed during normal operation. Functions provided by the PRINT and NEXT softkeys cannot be accessed when a pulse oximetry cable is connected to the instrument. Each of the various functions is described in the text that follows.

#### PARAM (Service Menu)

- RESET
- - RESET DEFAULTS?
- - YES (resets parameters to factory defaults, sounds three tones to indicate that defaults have reset)
- - NO (back to Service menu)
- SAVE
- - SAVE DEFAULTS?
  - YES (saves parameters as default settings, sounds three tones to indicate that defaults have been saved)
- - NO (back to Service menu)
- SENSOR (enables/disables sensor trend writing on rewritable sensors)
- - BACK (back to Service menu)

- EXIT (back to Main menu, sounds three tones to indicate that defaults have reset)
- BACK (back to Service menu)
- PRINT
- TREND
- ERRLOG
- INSTAT
- INFO
- NEXT
- **DOWNLD** (for downloading monitor software)
- ALARMS
- - SELECT
- ALLOW OFF? (<u>Allows alarms to be turned off</u>) (up/down buttons select Yes/No)
- - OFF REMINDER? (enables/disables Alarm Off reminder) (up/ down buttons select Yes/No)
- - BACK (back to Service menu)
- **NEXT** (back to Service menu)
- EXIT (back to Main menu)

#### **Exit Softkey**

EXIT

The EXIT softkey returns the monitor to the Main menu.

#### **Next Softkey**



There are not enough softkeys to display all of the options that are available at some levels of the menu. Pressing the NEXT softkey allows you to view additional options available at a given menu level.

#### Param Softkey Menu



When the PARAM softkey is pressed, the function of the softkeys changes as shown below. These options can be accessed without disconnecting the pulse oximetry cable from the instrument.



# Reset Softkey



SAVE

The RESET softkey can be used if any settings stored in memory have been changed from factory default values. If YES is pressed, the instrument sounds three tones and the settings return to factory default values. When NO is pressed, no changes are made to the settings stored in memory.

## Save Softkey

When adjustable values are changed from factory default, the SAVE softkey can be used to preserve the settings as institutional power-on default values. Pressing YES stores the current settings in memory. The instrument sounds three tones indicating that the changes have been saved as power-on default values. The new saved values will continue to be used through power-on and off cycles until they are changed and saved again, or until they are reset. If NO is pressed, the changed values will not be saved.

Note: An invalid tone indicates that a parameter value cannot be saved as a power-on default. See *Power-On Settings* on page 35. Along with the invalid tone, a message will be displayed indicating which parameter could not be saved as a power-on default.

## Sensor Softkey

SENSOR The SENSOR softkey enables/disables the Sensor Event Record function.

#### **Print Softkey Menu**



Accessing the PRINT softkey makes four printouts available. See *Data Port Interface Protocol* on page 105, for information about how to make connections to the data port and how data is presented in a printout. The appropriate printout can be selected by pressing the corresponding softkey. The softkey configuration that appears after the PRINT softkey has been pressed is shown below.



Up to 48 hours of trend data can be viewed on the printouts described below. When the monitor is turned on, trend data is recorded every 4 seconds. As an example, an instrument that is used 6 hours a week would take approximately 8 weeks to fill its memory.

Note: The two-letter codes and the symbols that occur in the printout are described in Table 19 on page 120.

Trend Softkey



A Trend printout will include all data recorded for up to 48 hours of monitoring since the last Delete Trends was performed. A new trend point is recorded every 4 seconds. The figure below is an example of a Trend printout.

N-595 VERSION X.X	X.X TREND	SpO2 Limit: 30-100	% PR Limit: 100-180BPM
ADULT	0SAT-S S	PO2 RESP MODE: I	NORMAL
TIME	%SpO	2 PR (bpm) PA	
12-FEB-02 14:00:00	100	120 220	
12-FEB-02 14:00:05	100	124 220	
12-FEB-02 14:00:10	100	190 220	
12-FEB-02 14:00:15	100	190 220	
12-FEB-02 18:00:43			
12-FEB-02 18:00:48			
N-595 VERSION X.X	X.X TREND	SpO2 Limit: 30-100	% PR Limit: 100-180BPM
ADULT	0SAT-S S	PO2 RESP MODE: I	NORMAL
TIME	%SpO	2 PR (bpm) PA	
12-FEB-02 18:00:53			
12-FEB-02 18:00:58			
12-FEB-02 18:01:03	98	100 140	
12-FEB-02 18:01:08	98	181* 190	
12-FEB-02 18:01:13	99	122 232	
Output Complete			

The first row of the printout includes information about the type of instrument delivering the information, the software level, type of printout, and alarm parameters. The second line lists the headings for the columns. These lines are printed out every 25 lines, or when a change to an alarm limit is made.

Patient data is represented with a date and time stamp for the data. In the example above, the "- - -" means that an OxIMAX sensor was connected but the signal quality of the data being received was too low for the monitor to interpret the data. Patient data that is outside of an alarm limit is marked with an asterisk (\*).

At the end of the printout "Output Complete" will be printed. This indicates that there was no corruption of data. If the Output Complete statement is not printed at the end of the printout, the data must be considered invalid.

# **ERRLOG Softkey**

This softkey is for Nellcor's Customer Service Engineering Only.



**ERRLOG** A list of all the errors recorded in memory can be obtained by pressing the ERRLOG softkey. The first line lists the type of instrument producing the printout, software level, type of printout, and the time of the printout. The second line of the printout consists of column headings. If nothing prints out, there have been no errors. An example of an Errlog printout is shown below.

N-595 VERSION	X.X.X.X		Error Log		Time:	14600:00:07
Time	Error	Task	Module	File	Line	Count
10713:21:03	269	6	24	1	764	1
00634:26:01	17	6	24	1	714	178
Output Complete						

# INSTAT Softkey

This softkey is for Nellcor's Customer Service Engineering Only.

DELETE

The DELETE softkey, described in the operator's manual, allows the user to delete the most recent trend data. The current trend data, along with the deleted trends, can be retrieved from the instrument through an Instat printout.

The oldest deleted trend is Trend 01 on the Instat printout. If a Trend 01 already exists in memory from an earlier Delete, the next deleted trend will become Trend 02. Every time DELETE is pressed, the number of existing trends will increase by 1. The current trend will have the largest trend number.

In the Instat printout below, line one is for instrument type, software revision level, type of printout, and alarm parameter settings. The second line contains the column headings. A trend point is recorded for every 4 seconds of instrument operation. Up to 48 hours of instrument operation data can be recorded.

If the final line on the printout shows "Output Complete," then the data has been successfully transmitted with no corruption. If there is no "Output Complete" line printed, the data should be considered invalid.

N-595 VERSION X.X.X.X Instat SpO2 Limit: 30-100% PR Limit: 100-180BPM
ADULT 0SAT-S SP02 RESP MODE: NORMAL
TIME Trend 01 %SpO2 BPM PA Status
12-FEB-02 14:00:00 SD
12-FEB-02 14:00:05 PS
12-FEB-02 14:00:10 100 120 220
12-FEB-02 14:00:15 100 120 220
N-595 VERSION X.X.X.X Instat SpO2 Limit: 80-100% PR Limit: 60-180BPM
ADULT 0SAT-S SP02 RESP MODE: NORMAL
TIME TREND 02 %SpO2 BPM PA Status
12-FEB-02 14:24:24 79* 58* 220 PS SL PL
12-FEB-02 14:24:29 79" 57" 220 PS SL PL
12-FEB-02 14: 24:29 0* 0* PS LP SL PL
N-595 VERSION X.X.X.X Instat SpO2 Limit: 80-100% PR Limit: 60-180BPM
ADULT 0SAT-S SP02 RESP MODE: NORMAL
TIME TREND 03 %SpO2 BPM PA Status
13-FEB-02 7:13:02 99 132* 220 PH
13-FEB-02 7:13:07 99 132* 220 PH
13-FEB-02 7:13:12 99 132* 220 PH
13-FEB-02 7:13:17 99 132* 220 PH
13-FEB-02 7:13:22 99 132* 220 PH
13-FEB-02 7:13:27 99 132* 220 PH
13-FEB-02 7:13:32 99 132* 220 PH
Output Complete

# INFO Softkey

This softkey is for Nellcor's Customer Service Engineering Only.

INFO

Pressing the INFO softkey produces a single line printout of instrument information as illustrated below. The data presented in the printout, going from left to right, is the instrument type (N-595), software version level, type of printout (INFO), CRC (Cyclic Redundancy Check) number, and ratio of current operating time to total operating time (the ratio itself has no units of measure).

N-595 Version XXXXXX INFO CRC:XXXX SEC: 123456789/987654321

#### **Next Softkey Menu**



Additional options can be accessed from the main Service Functions menu by pressing the NEXT softkey. When NEXT is pressed, the softkeys change to the functions shown below.



## **DOWNLD Softkey**

#### DOWNLD

When the DOWNLD softkey is selected, the instrument will display the revision of the Boot Code. To exit DOWNLD, cycle power to the instrument by pressing the ON/STANDBY button. Consult the Directions for Use (DFU) provided with any downloads or upgrades to the FLASH firmware.

When downloading new software via the data port, the baud rate is set at 19,200.





**ALARMS** Pressing the ALARMS softkey can change characteristics of the audible alarm. When the ALARMS softkey is pressed, the softkey's functions change as shown below.







The SELECT softkey is used to select what function of the audible alarm is going to be changed. A box can be cycled between two choices: ALLOW OFF and OFF REMINDER.

Use the following procedure to select and set the monitor's ALLOW OFF and OFF REMINDER:

- 1. Disconnect the OxIMAX sensor from the monitor.
- Note: If the OxiMax sensor is not disconnected, the only softkeys on the monitor's screen will be PARAM and EXIT.
- 2. Simultaneously press the LIGHT softkey and the CONTRAST softkey until the menu bar changes to the softkey headings shown below.





O

LIGHT

3. Press the NEXT softkey.

	NELLC	OR			N-595	
8 10 m				%SP02 BPM		
20	DOWNLD	ALARMS	NEXT	EXIT	3	-
-		$\bigcirc$	$\bigcirc$		$\bigcirc$	-



ALARMS 4. Press the ALARMS softkey.



SELECT 5. Use the SELECT softkey to toggle between ALLOW OFF? and OFF **REMINDER**?.

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6. Use the ADJUST UP or ADJUST DOWN button to change selected parameter.



7. Press the BACK softkey.

When ALLOW OFF is selected, a choice is given between allowing an audible Alarm Off or disabling the audible alarm OFF. Pressing the ADJUST UP or ADJUST DOWN button cycles between YES and NO. If YES is selected, the operator has the option of selecting AUDIBLE ALARM OFF. If NO is selected, the operator is not given the option of selecting AUDIBLE ALARM OFF as an alarm silence duration choice.

If the audible alarm is set to Off, a reminder tone can be sounded every 3 minutes to notify the user of this condition. The ADJUST UP and ADJUST DOWN buttons can be used to change the choice from YES to NO. Selecting YES enables the Reminder. Selecting NO disables the Reminder when the audible alarm is set to Off.

## **Setting Institutional Defaults (Sample)**

Power-up default values may be changed to institutional power-up default values. Set the desired limits in the normal operation mode and you will set the institutional defaults in the monitor's service mode. The following default values may be set:

- Alarm Silence Duration (30, 60, 90, 120 seconds)
- Alarms (Allow Off Yes/No)
- Off Reminder (Yes/No)
- Alarm Volume (1 to 10)
- Sensor Event Record Type (SpO<sub>2</sub>, SpO<sub>2</sub> + BPM, Default)
- Nurse Call Priority RS-232 (normally high, normally low)
- Pulse Beep Volume (0 to 10)
- Pulse Rate Upper Alarm Limit (lower limit plus 1 to 250 bpm)
- Pulse Rate Lower Alarm Limit (20 bpm to upper limit minus 1)
- SatSeconds (OFF, 10, 25, 50, 100)
- Sensor Adjust Enable (Yes/No)
- Data Port Baud Rate (2400, 9600, 19200)

- Data Port Mode (ASCII, OXINET, CLINICAL, GRAPH, AGILENT [Agilent HP monitor], SPACELB [SpaceLabs monitor], MARQ [GE Marquette monitor], DATEX [Datex-Ohmeda AS/3 monitor]). Available selections depend on the software installed in your N-595.
- SpO<sub>2</sub> Upper Alarm Limit (lower limit plus 1 to 100%)
- SpO<sub>2</sub> Lower Limit (80% to upper limit minus 1)

Use the following procedure to set institutional defaults.

- 1. Disconnect the OxIMAX sensor from monitor.
- Note: If the *OxiMax* sensor is not disconnected, the only softkeys on the screen will be PARAM and EXIT.
- 2. Set desired parameters to the institutional values. Refer to the N-595 Operator's Manual for the procedures to set the values.
- 3. Simultaneously press the LIGHT softkey and the CONTRAST button until the menu bar changes to the softkey headings shown below.



#### PARAM

O

LIGHT

4. Press the PARAM softkey.

	• NELLC	OR			N-595	
) ===				%SP02 BPM		
2	RESET	SAVE	SENSOR	BACK		-
ND-	( )	$\bigcirc$	$\bigcirc$	$\bigcirc$	( <b>0</b> )	-

<b> NELLCOR</b>	N-595
	%SP02 🕅
변~ 부 성 SAVE DEFAULTS? YES	BPM



6. Press the YES softkey. The monitor will sound three beeps indicating that defaults have been saved.

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## Introduction

This section explains how to troubleshoot the N-595 if problems arise. Tables list possible monitor difficulties, along with probable causes, and recommended actions to correct the difficulty.

## How To Use This Section

Use this section in conjunction with *Performance Verification* on page 11, and *Spare Parts* on page 81. To remove and replace a part you suspect is defective, follow the instructions in *Disassembly Guide* on page 63. The circuit analysis section in the *Technical Discussion* on page 125, offers information on how the monitor functions.

## **Who Should Perform Repairs**

Only qualified service personnel should open the monitor housing, remove and replace components, or make adjustments. If your medical facility does not have qualified service personnel, contact Nellcor's Technical Services or your local Nellcor representative.

## **Troubleshooting Guide**

Problems with the N-595 are categorized in Table 4. Refer to the paragraph indicated for further troubleshooting instructions.

Note: Taking the recommended actions discussed in this section will correct the majority of problems you may encounter. However, problems not covered here can be resolved by calling Nellcor's Technical Services or your local Nellcor representative.

Problem Area	Refer To
1. Power	Power on page 53
• No power-up on AC and/or DC	
• Fails power-on self-test	
• Powers down without apparent cause	
2. Buttons	Buttons on page 54
• Monitor does not respond properly to buttons being pressed	
3. Display/Alarms	Display/Alarms on page 55
• Display does not respond properly	
• Alarms and other tones do not sound properly or are generated without apparent cause	
4. Operational Performance	<i>Operational Performance</i> on
• Displays appear to be operational, but monitor shows no readings	page 50
Suspect readings	
5. Data Port	Data Port on page 57
• N-595 data port not functioning properly	

#### **Table 4: Problem Categories**

All of the problem areas in Table 4 on page 52 are discussed in the following paragraphs.

## Power

Power problems are related to AC and/or DC. Table 5 lists recommended actions to power problems.

Condition	Recommended Action
Battery Low indicator lights steadily while N-595 is connected to AC and battery is not discharged.	<ul> <li>Ensure that the N-595 is plugged into an operational AC outlet and the AC indicator is on.</li> <li>Check the fuses. The fuses are located in the Power Entry Module as indicated in <i>Fuse Replacement</i> on page 64. Replace if necessary.</li> <li>Open the monitor as described in <i>Monitor Disassembly</i> on page 65. Verify the power supply's output to the battery while on AC. Disconnect the battery leads from the battery and connect a DVM to them. The voltage measured should be 6.65 to 6.95 VDC and the current should be 320 to 480 mA. Replace power supply if above values are not met.</li> <li>Check the harness connection from the bottom enclosure to the User Interface PCB, as instructed in <i>User Interface PCB Removal/Replacement</i> on page 76. If the connection is good, replace the User Interface PCB.</li> </ul>
The N-595 generates an error code when disconnected from AC power.	The battery may be discharged. To recharge the battery, refer to <i>Battery Charge</i> on page 12. The monitor may be used with a less than fully charged battery but with a corresponding decrease in operating time from that charge. The battery may be defective.
Battery Low indicator on during DC operation and an alarm is sounding.	There are 15 or fewer minutes of usable charge left on the N-595 battery before the instrument shuts off. At this point, if possible, cease use of the N-595 on battery power, connect it to an AC source and allow it to recharge (approximately 14 hours). The N-595 may continue to be used while it is recharging. (A full recharge of the battery while the monitor is being used takes 18 hours.)

#### Table 5: Power Problems

Condition	Recommended Action
Battery does not charge.	<ul> <li>Replace battery if it is more than 2 years old.</li> <li>If the battery fails to hold a charge, replace the battery as indicated in <i>Battery Replacement</i> on page 67.</li> </ul>
	<ul> <li>Open the monitor as described in <i>Monitor</i> <i>Disassembly</i> on page 65. Verify the power supply's output to the battery while on AC. Disconnect the battery leads from the power supply and connect a DVM to them. The voltage measured should be 6.8 VDC ± 0.15 VDC and the current should be 400 mA ± 80 mA. Replace power supply if above values are not met.</li> </ul>

#### Table 5: Power Problems

#### **Buttons**

Table 6 lists symptoms of problems relating to non-responsive buttons and recommended actions. If the action requires replacement of a PCB, refer to *Disassembly Guide* on page 63.

Symptom	Recommended Action
The N-595 turns on but does not respond to some or all of the buttons.	• Replace the User Interface PCB. See <i>User</i> <i>Interface PCB Removal/Replacement</i> on page 76.
	• If the buttons still do not work, replace the Top case assembly. See <i>Top Case Assembly Removal/ Replacement</i> on page 80.

#### **Table 6: Button Problems**

## **Display/Alarms**

Table 7 lists symptoms of problems relating to non-functioning displays and audible tones or alarms, and recommended actions. If the action requires replacement of a PCB or module, refer to *Disassembly Guide* on page 63.

Symptom	Recommended Action
Display values are missing or erratic.	• If the <i>OXIMAX</i> sensor is connected, replace the pulse oximetry cable.
	• If the condition persists, replace the <i>OXIMAX</i> sensor.
	• If the condition still persists, replace the User Interface printed circuit board. See <i>User Interface</i> <i>PCB Removal/Replacement</i> on page 76.
Display pixels do not light.	• Check the connection between the User Interface PCB and the Display PCB.
	• If the condition does not change, replace the Display PCB. See <i>Display PCB Removal/ Replacement</i> on page 74.
	• If the condition still persists, replace the User Interface PCB. See <i>User Interface PCB Removal/</i> <i>Replacement</i> on page 76.
Alarm sounds for no apparent reason.	• Moisture or spilled liquids can cause an alarm to sound. Allow the monitor to dry thoroughly before using.
	• If the condition persists, replace the User Interface PCB. See User Interface PCB Removal/ Replacement on page 76.
Alarm does not sound.	Check alarm silence status.
	Check speaker connection.
	• Replace the speaker as described in <i>Alarm Speaker Removal/Replacement</i> on page 78.
	• If the condition persists, replace the User Interface PCB. See User Interface PCB Removal/ Replacement on page 76.

#### Table 7: Display/Alarms Problems

## **Operational Performance**

Table 8 lists symptoms of problems relating to operational performance (no error codes displayed) and recommended actions. If the action requires replacement of a PCB or module, refer to *Disassembly Guide* on page 63.

Symptom	Recommended Action
The Pulse Amplitude indicator seems to indicate a pulse, but the digital displays show zeroes.	<ul> <li>The <i>OXIMAX</i> sensor may be damaged; replace it.</li> <li>If the condition still persists, replace the User Interface PCB. See <i>User Interface PCB</i> <i>Removal/Replacement</i> on page 76.</li> </ul>
SpO2 or Pulse values change rapidly; Pulse Amplitude indicator is erratic.	<ul> <li>The OXIMAX sensor may be damp or may have been reused too many times. Replace it.</li> <li>An electrosurgical unit (ESU) may be interfering with performance: <ul> <li>Move the N-595 and its cables and OXIAX sensors as far from the ESU as possible.</li> <li>Plug the N-595 power supply and the ESU into different AC circuits.</li> <li>Move the ESU ground pad as close to the surgical site as possible and as far away from the OXIMAX sensor as possible.</li> </ul> </li> <li>Verify the performance with the procedures detailed in <i>Performance Verification</i> on page 11.</li> <li>If the condition still persists, replace the User Interface PCB. See User Interface PCB Removal/Replacement on page 76.</li> </ul>

#### **Table 8: Operational Performance Problems**

#### **Data Port**

Table 9 lists symptoms of problems relating to the data port and recommended actions. If the action requires replacement of the User Interface PCB, refer to *Disassembly Guide* on page 63.

Symptom	Recommended Action
No printout is being received.	• Confirm that printer is working through an alternate means.
	• The monitor's baud rate does not match the printer. Change the baud rate of the monitor following instructions in <i>Configuring the Data Port</i> on page 105.
	• If the condition still persists, replace the User Interface PCB. See <i>User Interface PCB Removal/</i> <i>Replacement</i> on page 76.
The RS-232 nurse call is not working.	• Verify that connections are made between pins 5 (GND) and 11 (nurse call) of the data port (Figure 16 on page 114).
	• Verify that the output voltage between ground pin 5 and pin 11 is -5 to -12 VDC (no alarm) and +5 to +12 VDC (during alarm) (Figure 16 on page 114).
	• If the condition still persists, replace the User Interface PCB. See <i>User Interface PCB Removal/</i> <i>Replacement</i> on page 76.

#### **Table 9: Data Port Problems**

## **Error Codes**

An error code is displayed when the N-595 detects a non-correctable failure. Table 10 provides a list of error codes for the N-595. When one of the following errors occurs:

- the N-595 sound a low priority alarm that cannot be silenced except by power-down
- measurements stop
- red "EEE" is displayed in the %SpO2 display area
- red error code is displayed in the left numeric display
- cycling the power clears the displayed error code

Table 10 provides a list of error codes for the N-595.

#### Table 10: Error Codes

Error Code	Meaning
1	SpO2 front end RAM error
2	SpO2 front end ROM/code integrity error.
3	SpO2 front end reported a bad CRC
4	SpO2 front end reported FSP message not allowed
5	SpO2 front end reported illegal value sent in FSP messageSpO2 front end
6	SpO2 front end reports calibration (offset) failure
9	SpO2 front end reported syntax error in FSP message
10	Over-current limit in SpO2 front end has tripped
11	SpO2 front end reports incorrect system voltage
12	SpO2 front end reports other hardware problem
14	SpO2 front end reports communication channel overflow
16	SpO2 front end reports watch dog time out
17	SpO2 front end reports that sensor appears defective
18	SpO2 front end reports internal register appears modified from expected value
19	SpO2 front end reports signal out-of-range
48	SpO2 front end reports spurious interrupt
49	SpO2 front end reports internal buffer overflow
50	SpO2 front end reports intermittent error
51	SpO2 front end reports digital communications error
52	SpO2 front end reports warmer error
53	Front end data not received
256	SpO2 back end reports beginning of packet missing
257	SpO2 back end reports packet start ID (SID) missing
258	SpO2 back end reports packet length error
259	SpO2 back end reports message length error
260	SpO2 back end reports packet contains unsupported Key
261	SpO2 back end reports packet CRC error
262	SpO2 back end reports end of packet missing
263	SpO2 back end reports packet contains undefined key

Meaning	
SpO2 back end reports corrupted variable	
SpO2 back end reports memory overflow	
SpO2 back end reports bad pointer	
SpO2 back end reports parameter value out-of-range	

#### Table 10: Error Codes

Error

Code	Meaning
264	SpO2 back end reports corrupted variable
265	SpO2 back end reports memory overflow
266	SpO2 back end reports bad pointer
267	SpO2 back end reports parameter value out-of-range
268	SpO2 back end reports reset detected
269	SpO2 back end reports unexpected value
270	SpO2 back end reports time-out
271	SpO2 back end reports not ready/not initialized
272	SpO2 back end reports double fault
273	SpO2 back end reports date out-of-range error
274	SpO2 back end reports incompatible software version
275	SpO2 back end reports incorrect registration number
276	SpO2 back end reports sensor read failure
277	SpO2 back end reports sensor signature verification fails
278	SpO2 back end reports warmed sensor temperature set point failure
279	SpO2 back end reports warmed sensor/SpO2 front end incompatible
280	SpO2 back end reports does not support feature required by sensor
281	SpO2 back end reports overflow/underflow
282	SpO2 back end reports sensor activation failure
512	General failure of UIF Module generic post
512	Dead battery/Missing battery
514	Real time clock is non-operational
515	Application code is not present in the flash
516	Invalid flash type
517	Serial clock line is not toggling or is toggling at an incorrect rate
518	Application program is corrupt
519	Invalid FE102 version
520	Error in the start up sequence
521	OS multitasking service failure
522	A state machine has received an unknown state transition

Table 10: Error Code	es
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Error Code	Meaning
523	The operation just attempted was not completed successfully - for example, Institutional Defaults could not be reset
524	An unexpected value was received - for example, an out-of-range parameter was passed to a function
525	EEPROM CRC failure
526	SpO2 module not responded
527	Institutional parameters lost - e.g. for UIF: Institutional EEPROM section CRC corrupt
528	Current settings lost - e.g. for UIF: Institutional EEPROM section CRC corrupt
529	Critical low battery
530	Low battery error
531	External watchdog failure
532	Power PC watchdog failure
533	Boot NVROM uninitialized error
534	Failed CRC check of application code in flash
535	Failed periodic ram CRC check on application code running in RAM
562	SpO <sub>2</sub> front end reset
563	SpO <sub>2</sub> reported error
564	Clinical mode was exited after input was received
565	Communication failures between software modules
566	Excessive resets before UIF runs
567	An unexpected interrupt has been asserted
568	General failure in UIF module generic post
569	BOOT application program is corrupt - CRC does not match
570	RTC was restarted
574	Excessive restarts within 1 minute

## **Other Messages**

In addition to the error codes listed in Table 10 on page 58, the following messages may be encountered:

Adjust Contrast Up, Down

When the user attempts to adjust the contrast of the display by pressing or pressing and holding the CONTRAST button.

#### Clock Sottings Los

Clock Settings Lost

If the N-595 detects that the real time clock has stopped running. This will usually occur when both battery and AC power are lost.

Data In OxiMax Sensor

When an *OxIMAx* sensor containing sensor event record data is connected to the N-595.

Data Type: SpO<sub>2</sub>

When a blank *OxIMAx* sensor is connected to a monitor with Data Type set to SpO<sub>2</sub>.

Data Type: Event/SpO2+BPM

When a blank OxiMax sensor is connected to a monitor with Data Type set to  $SpO_2 + BPM$ .

## Defaults Lost

If the N-595 detects that the power-on settings have been lost.

# Delete Trend?

When the user attempts to delete trend data from memory by pressing the DELETE softkey.

Invalid Blip Vol

When the user attempts to save current settings as power-on defaults and the blip volume is 0.



## Introduction

The N-595 can be disassembled down to all major component parts, including:

- PCBs
- battery
- cables
- chassis enclosures

The following tools are required:

- small, Phillips-head screwdriver
- medium, Phillips-head screwdriver
- small blade screwdriver
- needle-nose pliers or 1/4-inch socket
- torque wrench, 10 inch-pounds (1.13 Newton-meters)



WARNING: Before attempting to open or disassemble the N-595, disconnect the power cord from the N-595.



**Caution: Observe ESD (electrostatic discharge) precautions when working within the unit.** 

Note: Some spare parts have a business reply card attached. When you receive these spare parts, please fill out and return the card.

## **Replacement Level Supported**

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures in *Disassembly Guide* on page 63, to replace the PCB with a known good PCB. Check to see if the trouble symptom disappears and that the monitor passes all performance tests. If the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB)

that was installed when you started troubleshooting) and continue troubleshooting as directed in this section.

## **Prior to Disassembly**



- 1. Turn the N-595 off by pressing the ON/STANDBY button.
- 2. Disconnect the monitor from the AC power source.

## **Fuse Replacement**

- 1. Complete the procedure in paragraph *Prior to Disassembly* on page 64.
- 2. Disconnect the power cord from the back of the monitor.
- 3. Remove the fuse drawer from the power module by pressing down on the tab in the center and pulling out as shown in Figure 4.



Figure 4: Fuse Removal

4. Put two new, 5 x 20-mm, slow blow, 0.5-amp, 250-volt fuses in the drawer and reinsert the drawer in the power entry module.
## **Monitor Disassembly**

- 1. Complete the procedure in paragraph *Prior to Disassembly* on page 64.
- 2. Set the N-595 upside down, as shown in Figure 5.



Figure 5: Corner Screws

3. Remove the monitor's four corner screws.



# Caution: Observe ESD (electrostatic discharge) precautions when disassembling and reassembling the N-595 and when handling any of the components of the N-595.

- 4. Separate the monitor's top case from the bottom case of the monitor, being careful not to stress the wire harnesses between the cases. Place the two halves of the monitor on the table as shown in Figure 6.
- 5. Disconnect the monitor's Power Supply harness from J16 on the User Interface PCB.



Figure 6: Separating Case Halves

## **Monitor Assembly**

- 1. Connect the monitor's Power Supply to J16 on the User Interface PCB.
- 2. Place the monitor's top case over the bottom case, being careful to align the Display PCB, Power Entry Module, and the fan with the slots in the case halves.



Caution: When reassembling the N-595, tighten the screws that hold the cases together to a maximum of 10 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.

3. Install the four corner screws.

## **Battery Replacement**

#### Removal

- 1. Follow the procedure in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Remove the two screws from the battery bracket and lift the battery out of the bottom case as shown in Figure 7.
- 3. Be sure to note the polarity of the leads. Use needle-nose pliers to disconnect the leads from the battery.



Figure 7: Removing the Battery

4. The lead-acid battery is recyclable. Do not dispose of the battery by placing it in the regular trash. Dispose of the battery in accordance with local guidelines or return it to Nellcor's Technical Services for disposal.

## Replacement

- 5. Connect the leads to the battery. The red wire connects to the positive terminal, and the black wire connects to the negative terminal.
- 6. Insert the new battery into the bottom case with the negative terminal towards the outside of the monitor. Install the bracket and grounding lead with the two screws.
- 7. Complete the procedure in paragraph *Monitor Assembly* on page 66.
- 8. Turn the monitor on and verify proper operation.

## Power Entry Module (PEM) Removal/Replacement

#### Removal

- 1. Follow the procedure in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Push the top of the Power Entry Module (PEM) in from the outside of the case, and lift up.

3. Use needle-nose pliers to disconnect the leads from the PEM (see Figure 8).



Figure 8: Power Entry Module

#### Replacement

- 4. Reconnect the three power supply leads as indicated in Table 11 on page 71.
- 5. Install the PEM in the bottom case with the fuse drawer facing down. A tab in the bottom case holds the PEM in place. Insert the bottom wing of the PEM between the tab and the internal edge of the sidewall of the bottom case. Push the PEM down and towards the outside of the monitor until it clicks into place.
- 6. Complete the procedure in paragraph *Monitor Assembly* on page 66.

## **Power Supply Removal/Replacement**

#### Removal

- 1. Follow the procedure in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Push the top of the Power Entry Module (PEM) in from the outside of the case, and lift up.
- 3. Use needle-nose pliers to disconnect the leads from the PEM (see Figure 8).
- 4. Disconnect the fan wire harness from J1 on the Power Supply PCB (see Figure 9).
- 5. Use a 10-mm wrench to disconnect the Power Supply ground lead from the equipotential terminal (see Figure 8).
- 6. Remove the seven screws shown in Figure 9.

7. Lift the Power Supply out of the bottom case.



Figure 9: Power Supply

## Replacement

8. Reconnect the leads to the PEM following the instructions in Table 11, and Figure 8.

Wire Color / Label	Connect To
Green & Yellow	Equipotential Lug
Brown/Labeled "L"	"L" on the Power Entry Module
Blue/Labeled "N"	"N" on the Power Entry Module
Red/Labeled "+"	Positive Battery Terminal
Black/Labeled "-"	Negative Battery Terminal

## **Table 11: Power Supply Lead Connections**

9. Place the Power Supply in the bottom case.



Caution: When installing the Power Supply, tighten the seven screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the bottom case, rendering it unusable.

- 10. Install the seven screws in the Power Supply and tighten.
- 11. Connect the fan harness to J1 on the Power Supply.
- 12. Install the PEM in the bottom case with the fuse drawer facing down. A tab in the bottom case holds the PEM in place. Insert the bottom wing of the PEM between the tab and the internal edge of the sidewall of the bottom case. Push the PEM down and towards the outside of the monitor until it clicks into place.
- 13. Complete the replacement procedure in paragraph *Monitor Assembly* on page 66.

## **Cooling Fan Removal/Replacement**

#### Removal

- 1. Complete the procedure in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Disconnect the fan wire harness from J1 on the Power Supply PCB (see Figure 10).

3. Lift the cooling fan from the slots in the bottom case.



Figure 10: Cooling Fan

## Replacement

- 4. Connect the cooling fan wire harness to J1 on the Power Supply PCB.
- 5. Insert the cooling fan into the slots in the bottom case with the padded sides on the top and bottom and the fan's harness to the handle side of the case.
- 6. Complete procedure *Monitor Assembly* on page 66.

## **Display PCB Removal/Replacement**

#### Removal



WARNING: The LCD panel contains toxic chemicals. Do not ingest chemicals from a broken LCD panel.

- 1. Complete the procedures in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Disconnect the CCFL harness from J5 of the User Interface PCB. See Figure 11.
- 3. Use a small blade screwdriver to pry the clip from either edge of J13, then disconnect the Display PCB ribbon cable from the connector.
- 4. Separate the adhesive connection of the double-sided tape and lift the Display PCB up to remove it from the top case.

5. Remove and discard the used double-sided tape.



Figure 11: Display PCB

#### Replacement

- 6. Install new double-sided tape as shown in Figure 11.
- 7. Slide the Display PCB into the grooves in the top case. Check to make sure the Display PCB is firmly seated in the top case. Apply pressure between the top case and the display PCB to make good contact with the double-sided tape.
- 8. Connect the CCFL wire harness with two white wires to J5 of the User Interface PCB.

- 9. Connect the Display PCB ribbon cable to J13 of the User Interface PCB. Install the clip over the J5 connector.
- 10. Complete the procedure in paragraph Monitor Assembly on page 66.

## **User Interface PCB Removal/Replacement**

#### Removal

- 1. Complete the procedures in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Disconnect the CCFL harness (two white wires) from J5 of the User Interface PCB. See Figure 11.
- 3. Use a small blade screwdriver to pry the clip from either edge of J13, then disconnect the Display PCB ribbon cable from the connector.
- 4. Disconnect the keypad ribbon cable from connector J17 on the User Interface PCB (Figure 11). Lift up on the ribbon cable's outer shell until it clicks, then remove the cable from the connector.
- 5. Disconnect the speaker cable from J12 on the User Interface PCB.
- 6. Remove the five screws in the User Interface PCB (Figure 12 on page 77).

7. Remove the User Interface PCB from the top case.



Figure 12: User Interface PCB

#### Replacement



Caution: When installing the User Interface PCB, hand-tighten the five screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.

- 8. Place the User Interface PCB in the top case.
- 9. Install the five screws in the User Interface PCB.
- 10. Lift up on the outer shell of J17 (Figure 11) on the User Interface PCB until it clicks. Insert the keypad ribbon cable into J9 of the User Interface PCB. Slide the outer shell of J17 down until it locks in place.

- 11. Connect the speaker cable to J12 of the User Interface PCB.
- 12. Connect the CCFL wire harness with two white wires to J5 of the User Interface PCB.
- 13. Connect the Display PCB ribbon cable to J13 of the User Interface PCB. Install the clip over the J13 connector.
- 14. Complete the procedure in paragraph Monitor Assembly on page 66.

## Alarm Speaker Removal/Replacement

#### Removal

- 1. Complete the procedures in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Disconnect the speaker wire harness from J12 on the User Interface PCB (Figure 13).



3. Pull the holding clip back from the speaker and lift the speaker out of the top case.

Figure 13: Alarm Speaker

## Replacement

- 4. Pull the holding clip back, and insert the speaker into the top case.
- 5. Connect speaker wire harness to J12 on the User Interface PCB.
- 6. Complete the procedure in paragraph *Monitor Assembly* on page 66.

## **Top Case Assembly Removal/Replacement**

#### Removal

- 1. Complete the procedures in paragraphs *Prior to Disassembly* on page 64, and *Monitor Disassembly* on page 65.
- 2. Complete the procedural steps 1 through 6 in paragraph *User Interface PCB Removal/Replacement* on page 76.

#### Replacement



Caution: When installing the User Interface PCB, hand-tighten the five screws to a maximum of 4 inch-pounds. Over-tightening could strip out the screw holes in the top case, rendering it unusable.

3. Complete the procedural steps 8 through 14 in paragraph *User Interface PCB Removal/Replacement* on page 76.

## Introduction

The latest version of this manual is available on the Internet at:

http://www.mallinckrodt.com/respiratory/resp/Serv\_Supp/ProductManuals.html

Spare parts are shown in Table 12. Item numbers correspond to the callout numbers in Figure 14.

## **Obtaining Replacement Parts**

Nellcor's Technical Services provides technical assistance information and replacement parts. To obtain replacement parts, contact Nellcor or your local Nellcor representative. Refer to parts by the part names and part numbers.

Spare parts and accessories for the N-595 are listed on the Internet at:

http://mallinckrodt.com/respiratory/resp/Serv\_Supp/Apartweb/main/PartAcceMenu.html

## **Parts List**

Item	Description	Part Number
1	Top Case Assembly International (with Membrane Panel)	036652
1	Top Case Assembly U.S.A. (with Membrane Panel)	036657
2	Fuse Drawer	691500
3	Fuses	691032
4	Power Entry Module	691499
5	Cooling Fan	035469
6	Power Supply	SP036603/UT036603
7	Display PCB	SP902251
8	Battery	640119
9	Battery Bracket	035307
10	User Interface PCB	SP062315/UT062315
	Alarm Speaker (not shown)	036605
	Rubber Feet (not shown)	4-003818-00
	Power Cord U.S.A. (not shown)	071505
	Power Cord International (not shown)	901862
	Power Cord U.K. (not shown)	901863
	Tilt Stand (not shown)	891340
	GCX Mounting Kit (not shown)	035434

#### Table 12: Parts List

Figure 14 shows the N-595 expanded view with numbers relating to the spare parts list.



Figure 14: Exploded View

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## Introduction

To ship the monitor for any reason, follow the instructions in this section.

## **Returning the N-595**

Contact Nellcor's Technical Services Department or your local Nellcor representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor's Technical Services Department, it is not necessary to return the *OxiMax* sensor or other accessory items with the monitor. Pack the N-595 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it during shipping.

Return the N-595 by any shipping method that provides proof of delivery.

## **General Instructions**

Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by any applicable Nellcor warranty. If the original shipping carton is not available, use another suitable carton; North American customers may call Nellcor's Technical Services Department to obtain a shipping carton.

Prior to shipping the monitor, contact your supplier or local Nellcor office (Technical Services Department) for a returned goods authorization number. Mark the shipping carton and any shipping documents with the returned goods authorization (RGA) number. Return the N-595 by any method that provides proof of delivery.

## **Repacking in Original Carton**

If available, use the original carton and packing materials. See Figure 15. Pack the monitor as follows:

1. Place the monitor and, if necessary, accessory items in original packaging.



Figure 15: Packing

- 2. Place in shipping carton and seal carton with packing tape.
- 3. Label carton with shipping address, return address, and RGA number, if applicable.

## **Repacking in a Different Carton**

If the original carton is not available, use the following procedure to pack the N-595:

- 1. Place the monitor in a plastic bag.
- 2. Locate a corrugated cardboard shipping carton with a bursting strength of at least 200 pounds per square inch (psi).
- 3. Fill the bottom of the carton with at least 2 inches of packing material.
- 4. Place the bagged unit on the layer of packing material and fill the box completely with packing material.
- 5. Seal the carton with packing tape.
- 6. Label the carton with the shipping address, return address, and RGA number, if applicable.

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## Performance

#### **Measurement Range**

SpO2	1% to 100%
Pulse Rate	20 beats per minute (bpm) to 250 bpm
Perfusion Range	0.03% to 20%

#### **Accuracy and Motion Tolerance**

Saturation		
Without Motion - Adult <sup>1</sup>	70 to 100% ±2 digits	
Without Motion - Neonate <sup>1</sup>	70 to 100% ±3 digits	
With Motion - Adult and Neonate <sup>2</sup>	70 to 100% ±3 digits	
Low Perfusion <sup>3</sup>	70 to 100% ±2 digits	
Pulse Rate		
Without Motion <sup>1, 2, 3</sup>	20 to $250 \pm 3$ digits	
With Motion	normal physiologic range (e.g., 55 - 125 bpm) ± 5 digits	
Low Perfusion <sup>3</sup>	20 to $250 \pm 3$ digits	

<sup>1</sup> Adult specifications are shown for *OXIMAX* MAX-A and MAX-N sensors with the N-595. Neonate specifications are shown for *OXIMAX* MAX-N sensors with the N-595. Saturation accuracy will vary by the *OXIMAX* sensor type. Refer to the Sensor Accuracy Grid.

 $^2$  Applicability:  $\mathit{OxiMax}$  MAX-A, MAX-AL, MAX-P, MAX-I, and MAX-N sensors.

<sup>3</sup> Specification applies to monitor performance.

#### **Display Update Interval**

2 seconds

## **Electrical**

#### Instrument

Power Requirements	rated at 108 to 132 volts AC (nominal 120 VAC) or 200 to 240 volts AC (nominal 230 VAC), 20 volt/amps to be compliant with IEC 60601-1 sub-clause 10.2.2
Fuses	qty 2, 0.5 A, 250 volts, slow-blow, IEC (5 x 20 mm)

#### Battery

The battery provides at least 2 hours of battery life when new and fully charged with no alarms, no serial data, no analog output, no nurse call output, with backlight on while using a pulse simulator set for 224 bpm, high light and low modulation.

Туре	Lead acid
Voltage	6 Volts DC
Recharge	14 hours with N-595 turned off
	18 hours with N-595 operating
Shelf Life	2 months, new fully charged battery
	After 2 months storage the N-595 will run for 50% of stated battery life
Complies With	91/157/EEC

#### **OXIMAX Sensors**

## **Environmental Conditions**

## Operating

Temperature	5 °C to 40 °C (41 °F to 104 °F)
Altitude	-390 m to 3,012 m
	(-1,254 ft. to 9,882 ft.)
Atmospheric Pressure	70 kPa to 106 kPa
	(31.3 in. Hg to 20.6 in. Hg)

## Operating

Relative Humidity	15% to 95% non-condensing to be compliant with IEC 60601-1, sub-clause 44.5

#### Transport and Storage (not in shipping container)

Temperature	-20 °C to 60 °C
	(-4 °F to 140 °F)
Altitude	-390 m to 5,574 m
	(-1,254 ft. to 18,288 ft.)
Atmospheric Pressure	50 kPa to 106 kPa
	(31.3 in. Hg to 14.7 in. Hg)
Relative Humidity	15% to 95% non-condensing

#### **Transport and Storage (in shipping container)**

Temperature	-20 °C to 70 °C
	(-4 °F to 158 °F)
Altitude	-390 m to 5,574 m
	(-1,254 ft. to 18,288 ft.)
Atmospheric Pressure	50 kPa to 106 kPa
	(31.3 in. Hg to 14.7 in. Hg)
Relative Humidity	15% to 95% non-condensing

## **OXIMAX Sensor Power Dissipation**

Sensor	Dissipation
OxiMax MAX-N	52.5 mW
OxiMax MAX-I	52.5 mW
OxiMax MAX-P	52.5 mW
OxiMax MAX-A	52.5 mW
OxiMax MAX-AL	52.5 mW
OxiMax MAX-R	52.5 mW
OxIMAx Durasensor DS-100A	52.5 mW
OxiMax OxiCliq <sup>®</sup> P	52.5 mW
OxiMax OxiCliq N	52.5 mW

## **OxIMAX Sensor Power Dissipation**

Sensor	Dissipation
OxIMAX OxiCliq I	52.5 mW
OxiMax OxiCliq A	52.5 mW
<i>OxIMAx Dura-Y<sup>®</sup></i> D-YS	52.5 mW
OxiMax MAX-FAST	52.5 mW

## **Physical** Characteristics

Weight	5.8 lbs. (2.6 kg)
Dimensions	3.3 in. x 10.4 in. x 6.8 in. (8.4 cm x 26.4 cm x 17.3 cm)

# Compliance

Item	Compliant With
Equipment classification	Safety Standards: IEC 60601-1 (same as EN60601-1), CSA 601.1,
	UL 2601-1, EN865, EN/IEC 60601-1-2 (second edition)
Type of protection	Class 1 (on AC power)
	Internally powered (on battery power)
Degree of protection	Type BF - Applied part
Mode of operation	Continuous
N-595 resistant to liquid ingress	IEC 60601-1, sub-clause 44.6 for class IPX1 Drip-Proof equipment
Degree of Safety in presence of a flammable anaesthetic	UL 2601-1, sub-clause 5.5, Not suitable
Applied sensor label to indicate Type BF applied part	IEC 60601-1 Symbol 2 of Table DII of Appendix D
Equipotential lug symbol to indicate a potential equalization conductor	IEC 60601-1 Symbol 9 of Table DI of Appendix D
Attention symbol, consult accompanying documentation	IEC 60601-1 Symbols 14 of Table DI of Appendix D
External case made with non-conductive plastic	IEC 60601-1, sub-clause 16(a)
No holes in case top	IEC 60601-1, sub-clause 16(b)
115/230 voltage selector switch	IEC 60601-1, sub-clause 16(f)
Rigid case	IEC 60601-1, sub-clause 21(a)
Case mechanically strong	IEC 60601-1, sub-clause 21(b)
Case handle	IEC 60601-1, sub-clause 21(c)
N-595 resistant to rough handling	IEC 60601-1, sub-clause 21.6
N-595 tip/tilt test	IEC 60601-1, sub-clause 24.1
N-595 resistant to liquid ingress due to spills	IEC 60601-1, sub-clause 44.3 as modified by EN 865, clause 4
Environmental	IEC 60601-1, sub-clause 44.5
Cleaning	IEC 60601-1, sub-clause 44.7
Case surface made of non-toxic materials	IEC 60601-1, sub-clause 48
Case resistant to heat and fire	IEC 60601-1, sub-clause 59.2(b)

Item	Compliant With
N-595 power entry module fuse holder	IEC 60601-1, sub-clause 59.3
N-595 exterior markings	IEC 60601-1, sub-clause 6.1, 6.3, and 6.4; EN 865, clause 6
Front panel and case labeling	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2
N-595 button spacing	ISO 7250
Year of manufacture symbol	EN 980
Conductive coating and polymeric materials	UL 2601-1, clause 55
Operation during physical shock	IEC 60068-2-27 at 100 g
Operation during vibration	IEC 60068-2-6 and IEC 60068-2-34
Electromagnetic Compatibility	IEC 60601-1, sub clause 36, IEC/EN 60601-1-2 (second edition)
Radiated and conducted emissions	EN 55011, Group 1, Class B
Harmonic emissions	IEC 61000-3-2
Voltage fluctuations/flicker emissions	IEC 61000-3-3
Electrostatic discharge immunity	EN 61000-4-2, level 3 table top equipment
Radiated radio-frequency electromagnetic field immunity	IEC 61000-4-3 at 3V/m
Electrical fast transient/burst immunity	IEC 61000-4-4, level 3
Surge immunity	IEC 61000-4-5, level 3; FDA Reviewer's Guide
Conducted EMI susceptibility	IEC 61000-4-6 at 3 V/m
Power frequency magnetic fields	IEC 61000-4-8 at 3 V/m
Operation with line voltage variations	IEC 61000-4-11 for Table 7
Operation with electrical line voltage variations	FDA Reviewer's Guide
Radiated magnetic field emissions	RE 101/Army/7cm of MIL-STD-461E

## Manufacturer's Declaration



WARNING: The use of accessories, *OxiMax* sensors, and cables other than those specified may result in increased emission and/or decreased immunity of the N-595 pulse oximeter.

#### Table 13: Electromagnetic Emissions

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emission	Class B/ Group 1	The N-595 must emit electromagnetic energy in order to perform its intended
CISPR 11	1	function. Nearby electronic equipment may be affected.
RF emissions	Class B/ Group 1	The N-595 is suitable for use in all
CISPR 11	Gloup I	estaonsmients.
Harmonic emissions	Complies	
IEC 61000-3-2		
Voltage fluctuations/ flicker emission	Complies	
IEC 61000-3-3		

## Table 14: Electromagnetic Immunity

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the
IEC 61000-4-2	±8 kV air	±8 kV air	relative humidity should be at least 30 %.
Electric fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/or hospital environment
IEC 61000-4-4	±1 kV for input/ output lines	±1 kV for input/ output lines	
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial and/or hospital environment
IEC 61000-4-5			nospital environment
	±2 kV common mode	±2 kV common mode	

Note:  $U_T$  is the AC mains voltage prior to application of the test level.

## Table 14: Electromagnetic Immunity

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply	<5 % U <sub>T</sub> (>95 % dip in	<5 % U <sub>T</sub> (>95 % dip in	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the N-595
IEC 61000-4-11	40 % U <sub>T</sub>	40 % U <sub>T</sub>	operation during power mains interruption, it is recommended that the N-595 be powered from an uninterruptible power
	(60 % dip in U <sub>T</sub> ) for 5 cycles	(60 % dip in U <sub>T)</sub> for 5 cycles	supply or battery.
	70 % U <sub>T</sub>	70 % U <sub>T</sub>	
	(30 % dip in U <sub>T</sub> ) for 25 cycles	(30 % dip in U <sub>T)</sub> for 25 cycles	
	<5 % U <sub>T</sub>	<5 % U <sub>T</sub>	
	(95 % dip in U <sub>T</sub> ) for 5 sec.	(95 % dip in U <sub>T)</sub> for 5 sec.	
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the N-595 further from the sources of power frequency magnetic fields
IEC 61000-4-8			shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

**Note**:  $U_T$  is the AC mains voltage prior to application of the test level.

#### Table 15: Electromagnetic Immunity, Portable RF Equipment

The N-595 is suitable for use in the specified electromagnetic environment. The customer and/or user of the N-595 should assure that it is used in an electromagnetic environment as described below:

Immunity IEC 606 Test Test Lev	01-1-2 Compliance el Level	Electromagnetic Environment Guidance
-----------------------------------	-------------------------------	--

Portable and mobile RF communications equipment should be used no closer to any part of the N-595, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

		Recommended Separation Distance	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz 800 MHz	3 V/m	<i>distance</i> = $1.2\sqrt{Power}$ 80 MHz to 800 MHz
	3 V/m	3 V/m	$distance = 2.3 \sqrt{Power}$
	800 MHz		800 MHz to 2.5 GHz
	2.5 GHz		
Conducted RF	3 Vrms	3 Vrms	$distance = 1.2 \sqrt{Power}$
IEC 61000-4-6	150 kHz to		150 kHz to 80 MHz
	80 MHz		

**Note**: Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with survey accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the N-595 is used exceeds the applicable RF compliance level above, the N-595 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the N-595.

**Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Interference may occur in the vicinity of equipment marked with the following symbol:

((1:1))

#### **Table 16: Recommended Separation Distances**

Recommended Separation Distances between Portable and Mobile RF
Communications Equipment and the N-595 (IEC 60601-1-2)

Frequency of Transmitter	26 MHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated Maximum Output Power of Transmitter in Watts	Separation Distance in Meters	Separation Distance in Meters	Separation Distance in Meters
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where *P* is the maximum output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer.

**Note**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Cables and Sensors	Maximum Length	Complies With
DOC-10 pulse oximetry cable	10 ft. (3 m)	• RF emissions, CISPR 11, Class B/Group 1
Software download cable, RS-232 serial, 15 to 9 pin "D"	10 ft. (3 m)	<ul> <li>Harmonic emissions, IEC 61000-3-2</li> <li>Voltage fluctuations/flicker emission, UEC (1000-2-2)</li> </ul>
Non-terminated cable, RS-232/ Analog, 15 pin "D"	10 ft. (3 m)	<ul> <li>Electrostatic discharge (ESD), IEC 61000-4-2</li> </ul>
Oxinet hardwire cable	10 ft. (3 m)	• Electric fast transient/burst, IEC 61000-4-4
Printer cable, RS-232, 15 to 9 pin "D"	10 ft. (3 m)	• Surge, IEC 61000-4-5
HP Agilent interface cable	3.3 ft. (1 m)	<ul> <li>Conducted RF IEC 61000-4-6</li> <li>Radiated RF, IEC 61000-4-3</li> </ul>
GE Marquette interface cable	3.3 ft. (1 m)	
Datex-Ohmeda interface cable	3.3 ft. (1 m)	
Oxinet <sup>®</sup> II Data Cable	10 ft. (3 m)	
OXIMAX sensors:		• RF emissions, CISPR 11,
MAX-A	1.5 feet (0.5 m)	Class B/Group 1
MAX-AL	3 feet (0.9 m)	• Harmonic emissions, IEC 61000-3-2
MAX-I	1.5 feet (0.5 m)	• Voltage fluctuations/flicker emission,
MAX-N	1.5 feet (0.5 m)	IEC 61000-3-3
MAX-P	1.5 feet (0.5 m)	• Electrostatic discharge (ESD), IEC 61000-4-2
MAX-R	1.5 feet (0.5 m)	
OXIMAX Oxiband <sup>®</sup>	3 feet (0.9 m)	• Electric fast transient/burst, IEC 61000-4-4
sensors:		• Surge, IEC 61000-4-5
OXI-A/IN		• Conducted RF IEC 61000-4-6
υλι•ή/Ι		• Radiated RF, IEC 61000-4-3

## Table 17: Cables
Cables and Sensors	Maximum Length	Complies With
OxiMax Durasensor sensor	3 feet (0.9 m)	• RF emissions, CISPR 11, Class B/Group 1
DS-100A		• Harmonic emissions, IEC 61000-3-2
		• Voltage fluctuations/flicker emission, IEC 61000-3-3
		• Electrostatic discharge (ESD), IEC 61000-4-2
		• Electric fast transient/burst, IEC 61000-4-4
		• Surge, IEC 61000-4-5
		• Conducted RF IEC 61000-4-6
		• Radiated RF, IEC 61000-4-3
OXIMAX OxiCliq sensors:	OC-3 cable 3 feet (0.9 m)	• RF emissions, CISPR 11, Class B/Group 1
Р		• Harmonic emissions, IEC 61000-3-2
N I		• Voltage fluctuations/flicker emission, IEC 61000-3-3
А		• Electrostatic discharge (ESD),
<i>OXIMAX</i> <i>Dura-Y</i> sensors:	4 feet (1.2 m)	IEC 61000-4-2
D-YS		<ul> <li>Electric fast transient/burst, IEC 61000-4-4</li> </ul>
D-YSE		• Surge, IEC 61000-4-5
D-YSPD		Conducted RF IEC 61000-4-6
		• Radiated RF, IEC 61000-4-3

## Table 17: Cables

# Safety Tests

# **Ground Integrity**

100 milliohms or less

# Earth Leakage Current

AC Polarity	Line Cord	Neutral Cord	IEC 60601-1 AAMI/ ANSI-ES1	UL 2601-1
Normal	Closed	Closed	500 µA	300 µA
Reversed	Closed	Closed	500 µA	300 µA
Normal	Open	Closed	1000 µA	500 µA
Normal	Closed	Open	1000 µA	500 µA

# Enclosure Leakage Current

AC Line Polarity	Neutral Line Cord	Power Line Ground Cable	IEC 60601-1	AAMI/ANSI -ES1 UL 2601-1
Normal	Closed	Closed	100 µA	300 µA
Normal	Closed	Open	500 µA	300 µA
Normal	Open	Closed	100 µA	300 µA *
Reversed	Closed	Closed	500 µA	300 µA
Reversed	Open	Closed	500 µA	300 µA *
Reversed	Closed	Open	500 µA	300 µA
* ^ ^ \ / \ / \ \	ICI EC1 Jaco not		41 1:	•

\* AAMI/ANSI-ES1 does not include opening the line conductor.

# Patient Applied Risk Current

AC Line Polarity	Neutral Line	Power Line Ground Cable	IEC 60601-1 UL 2601-1	AAMI/ANSI-ES1
Normal	Closed	Closed	100 µA	10 µA **
Normal	Open	Closed	500 µA	50 µA **
Normal	Closed	Open	500 µA	50 µA **
Reversed	Closed	Closed	100 µA	10 µA **
Reversed	Open	Closed	500 µA	50 µA **

AC Line Polarity	Neutral Line	Power Line Ground Cable	IEC 60601-1 UL 2601-1	AAMI/ANSI-ES1
Reversed	Closed	Open	500 µA	50 µA **

 $\ast\ast$  These requirements are generally for IEC 60601-1 Class 1, TYPE-CF classified products.

## **Patient Isolation Risk Current**

AC Line Polarity	Neutral Line	Power Line Ground Cable	IEC 60601-1 UL 2601-1	AAMI/ ANSI-ES1
Normal	Closed	Closed	5 mA	50 µA ***
Reversed	Closed	Closed	5 mA	50 µA ***

\*\*\* These requirements are generally for IEC 60601-1 Class 1, TYPE-CF classified products.

## Introduction

When connected to the data port on the back of the N-595, printouts can be obtained or patient data can be communicated to a Nellcor Oxinet II monitoring system, Nellcor Intouch Remote Oximetry Notification System or personal computer (PC). Analog signals representing %SpO2, pulse rate, and pulse amplitude are also provided by the data port. A nurse call function is also available from the data port. Each of these is discussed in more detail in the paragraphs that follow.

The N-595 provides a bedside monitor interface for interfacing the N-595 with Agilent (HP), SpaceLabs, Marquette, and Datex monitors.

## **Configuring the Data Port**

Items pertaining to the data port can be adjusted by following the softkey map below. For a complete description of the softkeys, see the N-595 operator's manual.

SE	ΓUΡ	
-	NEX	КТ
-	-	LANG
-	-	- ENGLISH
-	-	- FRANCAIS
-	-	- DEUTSCH
-	-	- ITALIANO
-	-	- ESPAÑOL
-	-	- NEDERLANDS
-	-	- PORTUG
-	-	- SVERIGE
-	-	- BACK (back to Setup menu)
-	-	NEXT
-	-	- COMM
-	-	SELECT
		BAUD
		2400
		9600
		19200
		PROTOCOL
		ASCII
		OXINET
		CLINICAL
		GRAPH
		AGILENT (HP Agilent monitors)
		SPACELBS (Spacelabs monitors)
		MARQ (GE Marguette monitors)

DATEX (Dat	ex-Ohmeda AS/3 monitor)
------------	-------------------------

- - **BACK** (back to Setup menu)
  - - EXIT (back to Main menu)
- - NCALL (Nurse Call)
- - NORM +
- - NORM -
  - - **BACK** (back to Setup menu)
- - **EXIT** (back to Main menu)
- - NEXT
- - ANALOG
  - - - 0 VOLT
- - - 1 VOLT
  - - - STEP
  - - BACK (back to Setup menu)
    - - EXIT (back to Main menu)
- - BACK (back to Setup menu)
- - BACK (back to Setup menu)
- EXIT (back to Main menu)

## **Communication Baud Rate**

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-

The baud rate may need to be changed to match the abilities of the attached equipment. Perform the following procedure to change the baud rate to 2400, 9600, or 19200.

Note: When setting the communication protocol to AGILENT, SPACELBS, MARQ, or DATEX the communication baud rate is automatically set to the applicable baud rate.



- 1. Turn on the N-595 by pressing the ON/STANDBY button.
- **SETUP** 2. Press the SETUP softkey.
- **NEXT** 3. Press the NEXT softkey.
- **NEXT** 4. Press the NEXT softkey.

	SERIAL POR	RT SETUP	%SP02 4 00
	BAUD	9600	$\bigcup_{100}$ IUU.
	PROTOCOL	ASCII	врм 100.
_	SELECT	BACK	EXIT
6.	SELECT Use the ADJUST UP and A rate.	BACK	<b>EXIT</b> buttons to select the desir

### **Communication Protocol**

The COMM softkey is used to select from eight communication protocols supported by the data port. The selections are:

when performing this procedure because all settings will be saved as

• ASCII used for printouts

institutional default settings.

- OXINET to enable communication with Oxinet II
- CLINICAL intended for Nellcor use only
- GRAPH for graphic printouts
- AGILENT interfaces the N-595 with an Agilent (HP) monitor
- SPACELBS interfaces the N-595 with a SpaceLabs monitor
- MARQ interfaces the N-595 with a GE Marquette monitor
- DATEX interfaces the N-595 with a Datex-Ohmeda AS/3 monitor
- Note: Selecting AGILENT, SPACELBS, MARQ, or DATEX automatically sets the baud rate to the rate applicable for that protocol.

To change the communication protocol:





- 7. Use the ADJUST UP and ADJUST DOWN buttons to select the desired protocol.
- EXIT
- 8. Press the EXIT softkey set the protocol. The protocol setting will be in effect until the monitor is powered off.
  - Note: The protocol setup for the monitor may be saved as institutional default settings. See *Setting Institutional Defaults (Sample)* on page 47. Use care when performing this procedure because all settings will be saved as institutional default settings.

## **Language Selection**

Eight languages can be viewed on the screen and sent to the printer. The languages are ENGLISH, FRANCAIS (French), DEUTSCH (German), ITALIANO (Italian), ESPANOL (Spanish), NEDERLANDS (Dutch), PORTUG (Portuguese), and SVERIGE (Swedish).



1. Turn on the N-595 by pressing the ON/STANDBY button.





Use the ADJUST UP and ADJUST DOWN buttons to select the desired language.

BACK

6. Press the BACK softkey to save the language setting.

## **Nurse Call Setup**

The voltage polarity for the Nurse Call, available at pins 11 and 5, can be selected through the softkeys. NORM + sets the voltage to +5 VDC to +12 VDC and NORM - sets the voltage to -5 VDC to -12 VDC when there is no audible alarm. When an audible alarm occurs, these voltages switch polarity. This signal is available only if the instrument is operating on AC power. For more information, see *Nurse Call* on page 122.



1. Turn on the N-595 by pressing the ON/STANDBY button.



- 2. Press the SETUP softkey.
- **NEXT** 3. Press the NEXT softkey.
- **NEXT** 4. Press the NEXT softkey.



### **Analog Calibration Setup**

Analog calibration signals are provided to adjust a recorder to the output of the instrument. Selectable calibration signals are +1.0 VDC, 0.0 VDC, and Step. For more information on the analog signals see *Analog Output* on page 123.

1. Turn on the N-595 by pressing the ON/STANDBY button.



(%)

- 2. Press the SETUP softkey.
- **NEXT** 3. Press the NEXT softkey.
- **NEXT** 4. Press the NEXT softkey.
- **NEXT** 5. Press the NEXT softkey.
- **ANALOG** 6. Press the ANALOG softkey.

			%SP02	
			BPM	
0 VOLT	1 VOLT	STEP	BACK	

7. Press the 0 VOLT, 1 VOLT, or STEP softkey as required.

0 VOLT

1 VOLT

STEP

8. Press the BACK softkey.



## **Agilent (HP) Communications**

The N-595 sends SpO<sub>2</sub>, pulse rate, and alarm status data to the Agilent monitor.

The Agilent monitor requires an Agilent VueLink<sup>TM</sup> Aux Plus B interface module (A05 option) to interface with the N-595 pulse oximeter.

The RS-232 hardwire interface cable has a DB-15 connector for the N-595 and the applicable connector for the Agilent monitor. Nellcor cable part number 902256 is recommended for this interface.

A blank screen on the Agilent monitor will indicate corrupt data. The Agilent monitor will detect corrupt data in less than 100 milliseconds.

When the N-595 is in the Agilent mode of operation the interface baud rate is automatically set to 19,200 bits per second.



WARNING: Do not silence the N-595 audible alarm or decrease its volume if patient safety could be compromised.

The Agilent monitor only displays visual alarm indications for equipment interfaced through the Agilent VueLink<sup>TM</sup> Aux Plus B interface module. The N-595 monitor must be able to sound an audible alarm in order to maintain patient safety.

Note: The parameters setup for the Agilent bedside monitor interface may be saved as institutional default settings. See *Setting Institutional Defaults* (*Sample*) on page 47. Use care when performing this procedure because all settings will be saved as institutional default settings.

### **SpaceLabs Communications**

The N-595 sends SpO<sub>2</sub>, pulse rate, and alarm status data to the SpaceLabs monitor.

The SpaceLabs monitor requires a Universal *FlexPort*<sup>TM</sup> interface module to interface with the N-595 pulse oximeter.

Corrupt data will be indicated by a Communications Error displayed on the SpaceLabs monitor.

When the N-595 is in the SpaceLabs mode of operation the interface baud rate is automatically set to 9,600 bits per second.



WARNING: Do not silence the N-595 audible alarm or decrease its volume if patient safety could be compromised.

The SpaceLabs monitor provides both audible and visual alarm indications for equipment interfaced through the Universal FlexPort<sup>TM</sup> interface module. Silencing the N-595 alarms will also silence the SpaceLabs monitor alarms. The monitors must be able to sound an audible alarm in order to maintain patient safety.

Note: The parameters setup for the SpaceLabs bedside monitor interface may be saved as institutional default settings. See *Setting Institutional Defaults* (*Sample*) on page 47. Use care when performing this procedure because all settings will be saved as institutional default settings.

### **Marquette Communications**

The N-595 sends SpO<sub>2</sub>, pulse rate, and alarm status data to the Marquette monitor.

The Marquette monitor requires an Octanet<sup>TM</sup> interface module to interface with the N-595 pulse oximeter. The interface module comes with an interface cable, GE Marquette part number 417961-033, that connects to the Nellcor interface cable.

The RS-232 hardwire interface cable has a DB-15 connector for the N-595 and the applicable connector for the Marquette Octanet<sup>TM</sup> interface module cable. Nellcor cable part number 902254 is recommended for this interface.

Corrupt data will be indicated by a Communications Error displayed on the Marquette monitor.

When the N-595 is in the Marquette mode of operation the interface baud rate is automatically set to 9,600 bits per second.

The GE Marquette monitor only sounds audible alarms for equipment interfaced through the Octanet<sup>TM</sup> interface module. Silencing the N-595 audible alarm has no effect on the GE Marquette monitor sounding an alarm.

Note: The parameters setup for the Marquette bedside monitor interface may be saved as institutional default settings. See *Setting Institutional Defaults* (*Sample*) on page 47. Use care when performing this procedure because all settings will be saved as institutional default settings.

#### **Datex-Ohmeda Communications**

The Datex-Ohmeda monitor AS/3 must be configured for communications with the Nellcor N-200 monitor in order to communicate with the N-595 monitor.

Refer to the AS/3 operator's manual for instructions on configuring the AS/3 monitor.

The N-595 sends SpO<sub>2</sub>, pulse rate, and alarm status data to the Datex AS3 monitor.

The RS-232 hardwire interface cable has a DB-15 connector for the N-595 and the applicable connector for the Datex monitor. Nellcor cable part number 902255 is recommended for this interface.

Corrupt data will be indicated by a Communications Error displayed on the Datex monitor.

When the N-595 is in the Datex mode of operation the interface baud rate is automatically set to 2,400 bits per second.



WARNING: Do not silence the N-595 audible alarm or decrease its volume if patient safety could be compromised.

The Datex-Ohmeda monitor does not indicate audible or visual alarms for equipment interfaced. The N-595 monitor must be able to sound an audible alarm in order to maintain patient safety.

Note: The parameters setup for the Datex-Ohmeda bedside monitor interface may be saved as institutional default settings. See *Setting Institutional Defaults (Sample)* on page 47. Use care when performing this procedure because all settings will be saved as institutional default settings.

## **Connecting to the Data Port**

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Data is transmitted in the RS-232 format (pins 2, 3, and 5) or RS-422 (pins 1, 4, 9, and 12). RS-232 data can be transmitted a maximum of 25 feet, RS-422 data up to 4000 feet. The pin outs for the data port are illustrated in Figure 16.

Table	18:	Data	Port	Pin	Outs
-------	-----	------	------	-----	------

Pin	Signal
1	RXD+ (RS-422 positive input)
2	RXD_232 (RS-232 input)
3	TXD_232 (RS-232 output)
4	TXD+ (RS-422 positive output)
5	Signal Ground (isolated from earth ground)
6	AN_SpO2 (analog saturation output)
7	Normally Open (N.O.), Dry Contacts, for Nurse Call (N.O. with no audible alarm)

I

Pin	Signal
8	Normally Closed (N.C.), Dry Contacts, for Nurse Call (N.C. with no audible alarm)
9	RXD- (R-422 negative output)
10	Signal Ground (isolated from earth ground)
11	Nurse Call (RS-232 level output [-5 to -12 VDC with no audible alarm] [+5 to +12 VDC with audible alarm])
12	TXD- (RS-422 negative output)
13	AN_Pulse (analog pulse rate)
14	AN_Pleth (analog pleth waveform output)
15	Nurse Call Common for Dry Contacts

#### Table 18: Data Port Pin Outs

Note: When the instrument is turned off, the contact at pin 7 becomes closed and the contact at pin 8 becomes open.

The pin layout is illustrated in Figure 16 is viewed from the back of the monitor. An AMP connector is used to connect to the data port. Use AMP connector (AMP P/N 747538-1), ferrule (AMP P/N 1-747579-2), and compatible pins (AMP P/N 66570-2).

Figure 16: Data Port Pin Layout

When building an RS-422 cable, a resistor (120 ohms, 1/2 watt, 5%) must be added between pins 1 and 9 of the cable. The end of the cable with the resistor added must be plugged into the N-595. This resistor is not necessary for RS-232 cables.

The data cable must be shielded (example: Belden P/N 9616). Connectors at both ends of the data cable must have the shield terminated to the full 360 degrees of the connector's metal shell. If rough handling or sharp bends in the cable is anticipated, use a braided shield.

# **Communication With a PC**

Data can be sent from the N-595 to a PC by using a data cable with a Null modem connector installed between the instrument and the PC. Select the ASCII Comm protocol (see *Communication Protocol* on page 107). Data sent to the PC is serial, 8 data bits, no parity, 1 stop bit XON/XOFF flow control and is space delineated.

When the connection is made, real-time data will be sent to the PC. A new line of data will be sent every 2 seconds. The information presented will be the same as described in Real-Time Printouts later in this section.

Holding the Control key on the PC keyboard and pressing "C" twice can access an interactive mode. When the interactive mode has been accessed, real-time serial output is stopped and serial input is accepted. Printouts can be requested or the date and time can be adjusted via the PC. The PC monitor will display 5 options:

- 1. Dump Instrument Info
- 2. Set Date and Time
- 3. Dump Trend
- 4. Dump Error Log
- 5. Exit Interactive Mode

#### **Dump Instrument Info (Option 1)**

This allows Instrument Info to be printed or displayed on the PC screen. This option is intended for Nellcor's field service personnel. Instrument Info is a single line of data, which includes software version, CRC number, and total operating time.

#### Set Date and Time (Option 2)

When the instrument is shipped from the factory, the date and time are set to the time zone by the manufacturer. If the battery has been removed or disconnected, the time clock will not reflect the actual date and time. After battery power has been restored, it will be necessary to reset the date and time.

When option 2 has been selected, the date and time can be changed via the PC. The format for date and time is DD-MMM-YY HH:MM:SS. Move the cursor under the value to be changed and enter the new value.

#### Dump Trend (Option 3)

Selecting Dump Trend outputs current trend information. Up to 48 hours of trend information can be viewed. Information presented includes:

- instrument type
- software revision level
- printout type
- alarm limits
- date and time
- %SpO2
- pulse rate
- pulse amplitude.

### **Dump Error Log (Option 4)**

A list of all of the error codes in memory can be obtained by selecting option 4. The information that can be viewed includes instrument type, software revision level, printout type, time of printout, operating time of the recorded error, error number, task number, address, and count. This option is intended for Nellcor's field service personnel.

#### **Exit Interactive Mode (Option 5)**

Selecting option 5 exits the interactive mode and returns the data port to normal operation.

## Using Data on the PC

Data displayed on the PC screen can be captured for use in a word-processing spreadsheet.

Open a terminal program such as Hyper Terminal. Verify that the communications format is compatible with the data port of the N-595. If the communications format is compatible, real-time data will begin to be displayed on the PC. Capture the text to a file. Use Control C to stop data flow.

Import the data file into the spreadsheet. The data can now be manipulated by the commands of the spreadsheet. Some formatting of the data may be necessary.

# **Real-Time Printout**

When a real-time display or printout is being transmitted to a printer or PC, a new line of data is printed every 2 seconds. Every 25th line is a Column Heading line. A column heading line is also printed any time a value in the column heading line is changed. A real-time printout is shown in Figure 17.

Note: If the data output stops transmitting, turn the power off and back on again, or, if the monitor is connected to a PC, send an XON (Ctrl-q) to resume transmission.

N-595 VERSION 1.0.0	.0 CRC: X	xxx s	02 Limit: 85-1	100% PR L	imit: 40-170BPM
ADULT	0SAT-S	SP	02 RESP MOD	E: NORMAL	
TIME	%SpO2	BPM	PA S	Status	
13-FEB-02 14:00:05	100	120	50		
13-FEB-02 14:00:07	100	124	50		
13-FEB-02 14:00:09	100	190*	52	PH	
13-FEB-02 14:00:11	100	190*	50	PH	
13-FEB-02 14:00:13	100	190*	51	PH	
13-FEB-02 14:00:15	100	190*	50	PH	
13-FEB-02 14:00:17	100	190*	50	PH	
13-FEB-02 14:00:19	100	190*	51	PH	
13-FEB-02 14:00:21	100	190*	53	PH	LB
13-FEB-02 14:00:23	100	190*	50	PH	LB
13-FEB-02 14:00:25	100	090*	50	PH	LB
13-FEB-02 14:00:27			- 8	SD	LB
13-FEB-02 14:00:29			- 8	SD	LB
13-FEB-02 14:00:31			- 8	SD	
13-FEB-02 14:00:33			- 8	SD	
13-FEB-02 14:00:35			8	SD	
13-FEB-02 14:00:37			- 8	SD	
13-FEB-02 14:00:39			- 8	SD	
13-FEB-02 14:00:41			- 8	SD	
13-FEB-02 14:00:43			- 8	SD	
13-FEB-02 14:00:45			- 8	SD	
13-FEB-02 14:00:47			- 8	SD	
13-FEB-02 14:00:49			- 8	SD	
N-595 VERSION 1.0.0	0 CRC: X	xxx s	pO2 Limit: 85-1	100% PR L	imit: 40-1708PM
ADULT	0SAT-S	SP	O2 RESP MOD	E: NORMAL	
TIME	%SpO2	BPM	PA S	Status	
13-FEB-02 14:00:51			:	SD	
N-595 VERSION 1.0.0	.0 CRC: X	coox s	pO2 Limit: 80-1	100% PR L	imit: 40-1708PM
ADULT	0SAT-S	SP	O2 RESP MOD	E: NORMAL	
TIME	%SpO2	BPM	PA S	Status	
13-FEB-02 14:00:53	79*	59	50	SL PL	LB
13-FEB-02 14:00:55	79 <b>*</b>	59	50	PS SL PL	LB

Figure 17: Real-Time Printout

## **Column Heading**

To explain the printout, it is necessary to break it down to its key components. The first two lines of the chart are the Column Headings shown below. Every 25th line a Column Heading is printed. A column heading is also printed whenever a value of the Column Heading is changed. There are three Column Headings shown in Figure 17. The third Column Heading was printed because the SpO2 limits changed from 85-100% to 80-100%.

N-595	VERSION X.X.X.	CRC:	XXXX	SpO2 Lim	it: 70-100%	PR Limit:	60-160BPM
	ADULT	0SAT-S	s	PO2 RESP	MODE: NO	RMAL	
TIME		%SpO2	BPM	PA	Status		



N-595	VERSION X.X.X.	X CRC:	XXXX	SpO2 Lin	nit: 70-100%	PR Limit:	60-160BPM
	ADULT	0SAT-S	s	PO2 RES	P MODE: NO	RMAL	
TIME		%SpO2	BPM	PA	Status		

Data in the highlighted box above represents the source of the printout or display, in this case the N-595.

# Software Revision Level

 N-595
 VERSION X.X.X.X
 CRC: XXXX
 SpO2 Limit:
 70-100%
 PR Limit:
 60-160BPM

 ADULT
 0SAT-S
 SPO2 RESP MODE:
 NORMAL

 TIME
 %SpO2
 BPM
 PA
 Status

The next data field tells the user the software level (Version X.X.X.X) and a software verification number (CRC XXXX). Neither of these numbers should change during normal operation. The numbers will change if the monitor is serviced and receives a software upgrade.

# Alarm Limits

N-595	VERSION X.X.X.	X CRC:	XXXX	SpO2	Limit	70-100%	PR Limit:	60-160BPM
	ADULT	0SAT-S	1	SPO2 R	ESP	NODE: NOR	RMAL	
TIME		%SpO2	BPN	M PA		Status		

The last data field in the top line indicates the upper and the lower alarm limits for %SpO2 and for the pulse rate (PR). In the example above, the lower alarm limit

for SpO2 is 70% and the upper alarm limit is 100%. Pulse Rate alarm limits are 60 BPM (lower), and 160 BPM (upper).

Monitor Status

N-595	VERSION X.X.X.	X CRC:	xxxx	SpO2 Lin	nit: 70-100%	PR Limit:	60-160BPM
	ADULT	0SAT-S	s	PO2 RES	P MODE: NO	RMAL	
TIME		%SpO2	BPM	PA	Status		

The monitor status, ADULT or NEO (Neonate), is displayed on the second line of the heading.

# Column Headings

N-595	VERSION X.X.X	X CRC	XXXX	SpC2 Limit	70-100%	PR Limit	60-160B
	ADULT	0SAT-S	s	PO2 RESP	MODE: NOR	RMAL	
TIME		%SpO2	BPM	PA	Status		

Actual column headings are in the second row of the Column Heading. Patient data presented in the chart, from left to right, is the time that the line was obtained, the current %SpO<sub>2</sub> value being measured, the current Pulse Rate in beats per minute (BPM), the current Pulse Amplitude (PA), and the operating status of the N-595.

## **Patient Data and Operating Status**

Time

TIME		%SpO2	BPM	PA	Status	
12-NOV-00	14:00:05	100	190*	50		

The Time column represents the N-595 real-time clock.

# Patient Data

N-595 VERSION X.X.	X.X. CRC:	XXXXX	SpO2 Lin	nit: 70-100%	PR Limit	60-160BPM
ADULT	0SAT-S	S	PO2 RESP	MODE: NOR	MAL.	
TIME	%SpO2	BPM	PA	Status		
13-FEB-02 14:00:05	100	*190	50			

Patient data and the operating status of the unit are highlighted in the display above. Parameter values, at the time of the printout, are displayed directly beneath the heading for each parameter. In this example the %SpO2 is 100, and the pulse rate (BPM) is 190 beats per minute. The asterisk (\*) next to the 190 indicates that 190 beats per minute is outside of the alarm limits, indicated in the top row, for pulse rate. If no data for a parameter is available, three dashes (- - -) will be displayed in the printout.

Pulse Amplitude (PA) can range from 0 to 254. There are no alarm parameters for this value. It can be used for trending information and is an indication of a change in pulse volume, pulse strength, or circulation.

# Operating Status

XXX CRC:	xxxx s	ipO2 Lim	it: 70-100%	PR Limit:	60-160BPM
0SAT-S	SP	O2 RESP	MODE: NO	RMAL	
%SpO2	BPM	PA	Status		
100	*190	50		PH	
,	X.X.X CRC: 0SAT-S %SpO2 5 100	X.X.X CRC: XXXX 5 0SAT-S SP %SpO2 BPM 5 100 *190	X.X.X CRC: XXXX SpO2 Lim 0SAT-S SPO2 RESP %SpO2 BPM PA 5 100 *190 50	X.X.X CRC: XXXX SpO2 Limit: 70-100% 0SAT-S SPO2 RESP MODE: NO %SpO2 BPM PA Status 5 100 *190 50	X.X.X CRC: XXXX SpO2 Limit: 70-100% PR Limit: 0SAT-S SPO2 RESP MODE: NORMAL %SpO2 BPM PA Status 5 100 *190 50 PH

The Status column indicates alarm conditions and operating status of the N-595. In this example the PH means Pulse High. The status codes are listed in Table 19. As many as 4 codes can be displayed at one time in the Status column.

Table 19	Operating	Status	Codes
----------	-----------	--------	-------

Code	Meaning
AO	Alarm Off
AS	Alarm Silence
BU	Battery in Use
LB	Low Battery
LM	Loss of Pulse with Motion
LP	Loss of Pulse
МО	MOtion
PH	Pulse Rate Upper Limit Alarm
PL	Pulse Rate Lower Limit Alarm

Code	Meaning
PS	Pulse Search
SD	Sensor Disconnect
SH	Saturation Upper Limit Alarm
SL	Saturation Lower Limit Alarm
	No Data Available
*	Alarm Parameter Being Violated

Table 19: Operating Status (	Codes
------------------------------	-------

Note: A Sensor Disconnect will also cause three dashes (- - -) to be displayed in the patient data section of the printout.

## Trend Data Printout (ASCII Mode)

The format of data displayed when a trend printout is requested is similar to that of the real-time data. The only differences are that "TREND" is displayed in the top row instead of the "CRC:XXXX" software verification number, and there is no "Status" column (Figure 18).

Readings are displayed in 2-second intervals. The values on each row are an average for the 2-second period.

At the end of the printout, an "Output Complete" line indicates that the transmission was successful. If the "Output Complete" line is not present, the data should be considered invalid.

N-595 VE	RSION X.X.)	X TREN	b s	pO2 Limit: 70-100%	PR Limit: 60-160BPM
	ADULT	0SAT-S	SP	02 RESP MODE: NO	RMAL
TIME		%SpO2	BPM	PA	
12-FEB-02	14:00:05	100	120	150	
12-FEB-02	14:00:09	100	121	154	
12-FEB-02	14:00:13	100	120	150	
Output Cor	mplete				

Figure 18: Trend Data Printout (ASCII Mode)

## **Trend Printout (Graph Mode)**

The graph mode (Figure 19 and Figure 20) disables all printout functions except trend data. Trend printouts will be graphical if connected to a serial printer that

supports Epson ESC protocol. To print in the Graph mode the monitor protocol must be changed to GRAPH. See *Communication Protocol* on page 107.



Figure 19: Monitor Trend Data Printout (Graph Mode)



Figure 20: Sensor Event Record Printout (Graph Mode)

## **Nurse Call**

An RS-232 Nurse Call signal (pins 5 and 11) can be obtained by connecting to the data port. It is in the form of a positive or negative voltage chosen by the user.

The remote location will be signaled anytime there is an audible alarm. If the audible alarm has been set to Off or silenced, the Nurse Call function is also turned off.

Pin 11 on the data port is the RS-232 Nurse Call signal and pin 5 is ground (Table 20). When there is no audible alarm, the voltage between pins 10 and 11 will be -5 VDC to -12 VDC, or +5V DC to +12 VDC, depending on the option chosen via the softkeys (either NORM+ or NORM-). Whenever there is an audible alarm, the output between pins 5 and 11 will reverse polarity.

An internal Nurse Call relay (pins 7, 8, and 15) provides dry contacts that can be used to signal a remote alarm. Pin 15 is common, pin 7 is normally open (N.O.), and pin 8 is normally closed (N.C.). Table 20 shows the state of the contacts for

alarm and no alarm conditions, and for instrument off. Table 21 defines the ratings of the Nurse Call relay.

Pin	No Alarm or Alarm Silenced	Audible Alarm	Instrument Off
7 N.O.	Open	Closed	Closed
8 N.C.	Closed	Open	Open

 Table 20: Nurse Call Relay Pin States

.

#### Table 21: Rating of Nurse Call Relay

Maximum Input Voltage	30 VA or DC (polarity is not important)
Load Current	120 mA continuous (peak 300 mA @ 100 ms)
Minimum Resistance	26.5 ohms to 50.5 ohms (40.5 ohms typical) during alarms
Ground Reference	Isolated Ground
Electrical Isolation	1500 Volts

## **Analog Output**

Analog outputs are provided for Saturation, Pulse Rate, and a plethysmographic waveform.

The output voltage is 0.0 to +1.0 VDC for all three parameters. A 1.0 VDC output for saturation equals 100%; for pulse rate it equals 250 bpm; and for plethysmographic waveform, it equals 254 pulse amplitude units. The voltage will decrease as the values for these parameters decrease. If no data for a parameter is available, the output voltage for that parameter will be 1.0 VDC.

After the completion of power-on self-test (POST), the instrument will initiate an automatic three-step calibration signal. The calibration signal will begin at 0.0 VDC and hold that point for 15 seconds. It will then increase to 1.0 VDC and hold that value for 15 seconds. The third part of the calibration signal is a stair step signal. The stair step signal will start at 0.0 VDC and increase up to 1.0 VDC in 0.1 VDC increments. Each increment will be held for 1 second. Through use of the softkeys, the 0.0 VDC, 1.0 VDC, or stair step signal can be selected individually (see *Analog Output* on page 22).

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## **Oximetry Overview**

The N-595 uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an *OxiMax* sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The *OxiMax* sensor contains a dual light source and a photo detector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO<sub>2</sub>).

Because a measurement of SpO<sub>2</sub> is dependent upon light from the *OxiMax* sensor, excessive ambient light can interfere with this measurement.

Specific information about ambient conditions, *OxiMax* sensor application, and patient conditions is contained throughout this manual.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e., spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e., plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry *OxIMAx* sensor serve as light sources; a photo diode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the pulse oximeter uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

### **Functional versus Fractional Saturation**

This pulse oximeter measures functional saturation -- oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as

carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation -- oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

functional saturation =  $\frac{\text{fractional saturation}}{100 - (\% \text{ carboxyhemoglobin} + \% \text{ methemoglobin})} \times 100$ 

#### **Measured versus Calculated Saturation**

When saturation is calculated from a blood gas partial pressure of oxygen (PO<sub>2</sub>), the calculated value may differ from the SpO<sub>2</sub> measurement of a pulse oximeter. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO<sub>2</sub> and pH, temperature, the partial pressure of carbon dioxide (PCO<sub>2</sub>), 2,3-DPG, and fetal hemoglobin. See Figure 21.



Figure 21: Oxyhemoglobin Dissociation Curve

## SatSeconds Alarm Management

The N-595 utilizes Nellcor *SatSeconds* alarm management technique. *SatSeconds* is a function of the software within the N-595. With the *SatSeconds* technique, upper and lower alarm limits are set in the same way as traditional alarm management. The clinician also sets a *SatSeconds* limit that allows monitoring of %SpO2 below the selected lower alarm limit for a period of time before an audible alarm sounds. Refer to the N-595 Operator's manual for managing *SatSeconds*.

## **Reads Through Motion**

The N-595 takes advantage of increased micro processing power with advanced mathematical algorithms. Oxismart<sup>®</sup> XL advanced signal processing allows the N-595 to read through challenging motion conditions to deliver accurate saturation and pulse rate values. For a definition of motion, as applicable to the N-595, contact Nellcor's Technical Services Department.

## **OxiMax Technology**

The N-595 pulse oximeter is designed to use Nellcor brand *Ox1MAx* sensors containing *Ox1MAx* technology. These *Ox1MAx* sensors can be identified by the deep blue color of their plug. All *Ox1MAx*-compatible sensors contain a memory chip carrying information about the *Ox1MAx* sensor which the oximeter needs for correct operation, including the *Ox1MAx* sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the N-595.

When an *OxiMax*-compatible sensor is connected to the N-595, the pulse oximeter will first read the information in the *OxiMax* sensor memory chip, check it to make sure that there are no errors, and then load the data to begin monitoring. As the pulse oximeter reads the information, it flashes the *OxiMax* sensor model number on its display. This process takes a couple of seconds. Once the reading process is complete, the *OxiMax* sensor model number will stop flashing on the display, and then the N-595 will begin monitoring. The *OxiMax* sensor model number disappears after the pulse oximeter starts tracking the patient's SpO2 and pulse rate.

Pulse Oximeters containing *OxiMax* technology, including the N-595, use calibration data contained in the *OxiMax* sensor in calculating the patient's SpO2. By having the calibration in the *OxiMax* sensor, rather than the pulse oximeter, the accuracy of many *OxiMax* sensors can be improved, because the calibration coefficients can be tailored to each *OxiMax* sensor. Consult the accuracy card included with the pulse oximeter for specific accuracy information for the N-595 with different Nellcor approved *OxiMax* sensors.

The N-595 uses the information in the *Ox1Max*-compatible sensor to tailor troubleshooting messages for the clinician. The *Ox1Max* sensor contains coding that tells the pulse oximeter what kind of *Ox1Max* sensor is being used. When deciding what messages to display, the pulse oximeter takes into account the *Ox1Max* sensor type and recommended patient site for that model. The N-595 *Ox1Max* system therefore has an intelligent troubleshooting system.

## **Block Diagram Theory**



The monitor block diagram is shown in Figure 22.

Figure 22: Block Diagram

The N-595 main printed circuit board (PCB) consists of three main parts:

- The Secondary Input Port/Secondary Output Port (SIP/SOP)
- The FE-102 front end
- The User Interface (UIF).

The SIP/SOP and the FE-102 front end are both electrically isolated from the UIF. The FE-102 is electrically isolated to reduce capacitive coupling to earth ground and improve the FE-102's ability to read difficult patients. The SIP/SOP is isolated as mandated by regulations for patient safety.

The N-595 contains a microprocessor (Motorola MPC823 Power PC) and a microcontroller (Microchip PIC17C756). The microprocessor provides the bulk of the functionality in the pulse oximeter, acting as the master controller. The microcontroller controls the FE-102 analog front end. The two processors communicate by means of an asynchronous serial link between the two processors over an isolated barrier.

The microprocessor is responsible for interacting with the analog front end, and communicates with the front end through control signals. The microcontroller receives the analog voltages from the front end analog-to-digital (A/D) converters. The resultant data is used to calculate SpO2 and pulse rate values. The results are transmitted to the microprocessor via the serial link.

The primary responsibilities of the microprocessor are:

- Digital signal processing of the front end data.
- Display of the SpO<sub>2</sub> and pulse rate data, and all other display data including status light-emitting diodes (LEDs) on the membrane panel.
- User interface.
- Serial port communication through the SIP/SOP interface.
- Nurse call outputs.
- Analog outputs.
- Sound generation by generating the appropriate volume and frequency control settings for the speaker circuitry.
- Monitoring and controlling pulse oximeter power.
- Communicating with the real-time clock (RTC).
- Communicating with the electrically-erasable-programmable-read-only-memory (EEPROM).
- Trend data collection and storage.

Static random-access-memory (RAM) and FLASH read-only-memory (ROM) are provided for the microprocessor on the PCB. Two systems pulse oximeter integrated circuits (ICs) on the main PCB Vcc (+5 volts and +3.3 volts) power supply and provide watchdog timer. The system monitor will reset the entire PCB if the +5 volts is out of tolerance or the watchdog timer is not periodically reset by the software.

The FE-102 front end also contains a Static RAM, FLASH ROM, and a system monitor. The FE-102 front end's system monitor will reset just the FE-102 front end if the 5-volt VCCA is out of tolerance or the watchdog timer is not periodically reset by the software.

Power is supplied to the N-595 either from an AC connection (110 or 220 VAC) or from a 6-volt, 4 ampere-hour battery. The transition between power sources is invisible to the user, from AC power to battery power or from battery power to AC power. This allows functionality to remain during cases where AC power is lost or applied. The microprocessor monitors the battery voltage and shuts off the unit power supply if the battery voltage becomes too low to support N-595 functionality. The FE-102 front end power supply for the N-595 is an isolated switcher which generates +5 volts and  $\pm 12$  volts.

The patient is connected to the N-595 via an *Ox1Max* sensor and pulse oximetry cable. The SpO2 analog front end drives the *Ox1Max* sensor's LEDs, conditions the incoming signal, and provides adjustable gain status. The microprocessor measures the *Ox1Max* sensor's analog outputs and continually controls the gain stages and LED drive current to ensure that the signals are within the measurement range.

The N-595 has a 240 x 64 liquid-crystal display (LCD) which provides various display capabilities including numeric readouts for SpO2 and beats per minute (BPM) pulse rate, graphical pleth wave and pulse blip bar, menu selection elements, and status/error messages. There is also a membrane panel consisting of nine buttons and five LED indicators. The buttons allow the user to navigate through and input menu selections using the LCD and LED interfaces. The LED indicators provide feedback to the user on various N-595 and *Ox1MAx* sensor conditions. The N-595 contains a speaker for audio output.

The static RAM and the RTC for the microprocessor are powered whenever the N-595 has power, either AC power or battery power. This allows time and certain data to be maintained, even while the N-595 is turned off.


















PBCSL	_
SLOE	$\prec$
S_R/S_W	$\prec$
DSPLYCSL	$\prec$
VOL_D/A_CS	$\prec$

Figure 35 Main PCB Schematic Diagram (Sheet 8 of 13)



















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Healthcare

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