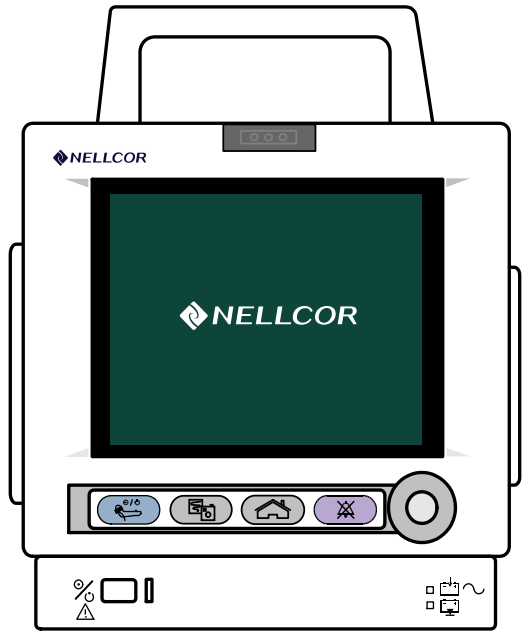
NELLCOR

OxiMax N 5500

Patient Monitor Service Manual



SERVICE MANUAL

For N5500 Patient Monitor

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Notice

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Revision/Printing History

The documentation printing date and part number indicate its current edition. The printing date changes when a new edition is printed in accordance with the revision history of the documentation. Minor corrections and updates which are incorporated at reprint do not cause the date to change. The document part number changes when extensive technical changes are incorporated.

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Section 1: Introduction

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: Explosion hazard. Do not use the N5500 in the presence of flammable anesthetics or gases.

WARNING: Do not spray, pour, or spill any liquid on the N5500, its accessories, connectors, switches, or openings in the chassis.

WARNING: Do not immerse the N5500 or its accessories in liquid or clean with caustic or abrasive cleaners.

WARNING: Ensure that conductive portions of the electrodes, leads, and cable do not come into contact with any other conductive parts.

WARNING: Before attempting to open or disassemble the N5500, disconnect the power cord from the N5500

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

WARNING: The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the N5500 patient monitor.

WARNING: Do not silence the N5500 audible alarm or decrease its volume if patient safety could be compromised.

WARNING: During the safety test, AC mains voltage will be present on the applied part terminals. Exercise caution to avoid electrical shock hazard.

WARNING: Do not place the N5500 into operation after repair or maintenance has been performed, until all Performance Tests and Safety Tests listed in section 3 of this service manual have been performed. Failure to perform all tests could result in erroneous monitor readings.

WARNING: High voltage is generated by the LCD backlight driver. Exercise caution when operating monitor with covers open..

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 N5500 monitor.

CAUTION: Observe ESD (electrostatic discharge) precautions when working within the unit and/or when disassembling and reassembling the N5500 patient monitor and when handling any of the components of the N5500 patient monitor.

CAUTION: When reassembling the N5500, over-tightening could strip out the screw holes in the cases, rendering it unusable.

CAUTION: If any problem with N5500 built in an optional printer, check a printer's door is closed well. Operating error may be caused if the cover is not closed correctly.

CAUTION: If internal battery cable has been disconnected, pay particular attention to polarity of the cable before reattaching. If battery cable polarity is reversed, it is likely that circuit damage will occur.

CAUTION: Ferrite Cores are used for electromagnetic compatibility. Please do not remove Ferrite Cores while disassembling or reassembling, otherwise the monitor can be affected by electromagnetic interference and measure inaccurate data to be displayed or stored.

CAUTION: When reassembling, never forget that one of four screws on the back bracket must be connected to green ground cable of the power inlet. This method is for protecting dormant electrical shock hazards to operator or service engineer.

1.1 Manual Overview

This manual contains information for servicing the N5500 patient monitor.
The monitor subsequently referred to as N5500 throughout this manual. Only qualified service personnel should service this product. Before servicing the N5500, read the operator's manual carefully for a thorough understanding of safe operation.

Read and understand all safety warnings and service notes printed in this service manual and the operator's manual part number MDR05002-A7008.

1.2 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 N5500 operator's manual part number MDR05002-A7008.
To understand the various Nellcor sensors, ECG leads, blood pressure cuffs, and temperature probes that work with the monitor, refer to the individual directions for use that accompany these accessories.

1.3 Description of the N5500 Patient Monitor

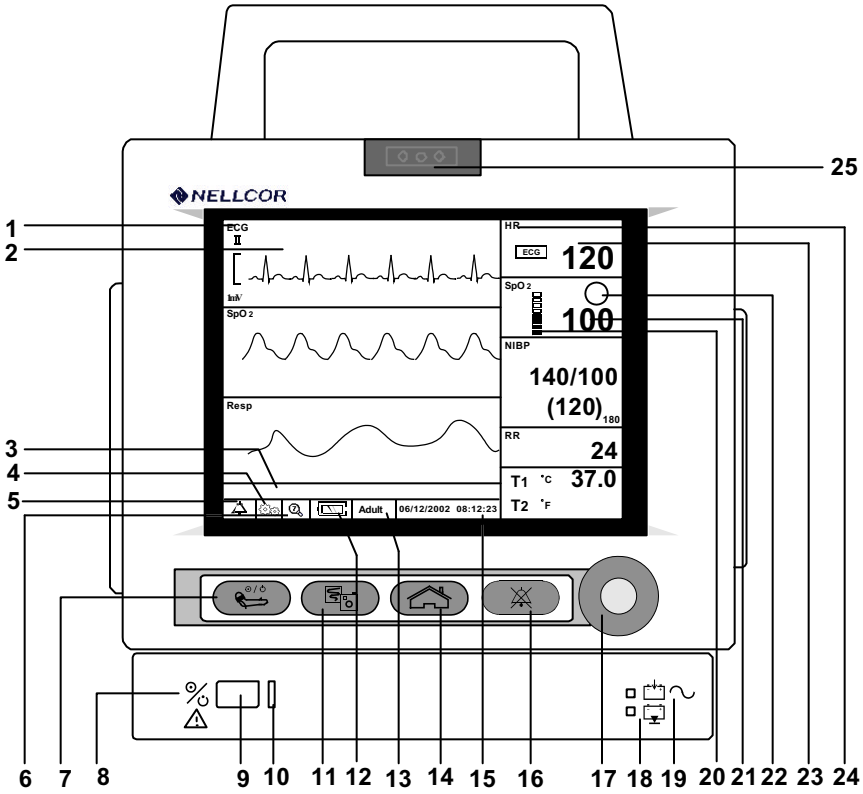
The purpose and function of the Nellcor N5500 patient monitor is to monitor ECG, heart rate, noninvasive blood pressure (systolic, diastolic, and mean arterial pressures), functional arterial oxygen saturation, respiration, and temperature for adult, pediatric and neonate patients in all hospital areas and hospital-type facilities. It may be used during hospital transport and in mobile, land-based environments, such as ambulances, within the specification of the environmental characteristics. It is not intended for home use. Monitor users should be skilled at the level of qualified health care professionals, such as a technician, doctor, nurse or medical specialist.

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-acutecenters.

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

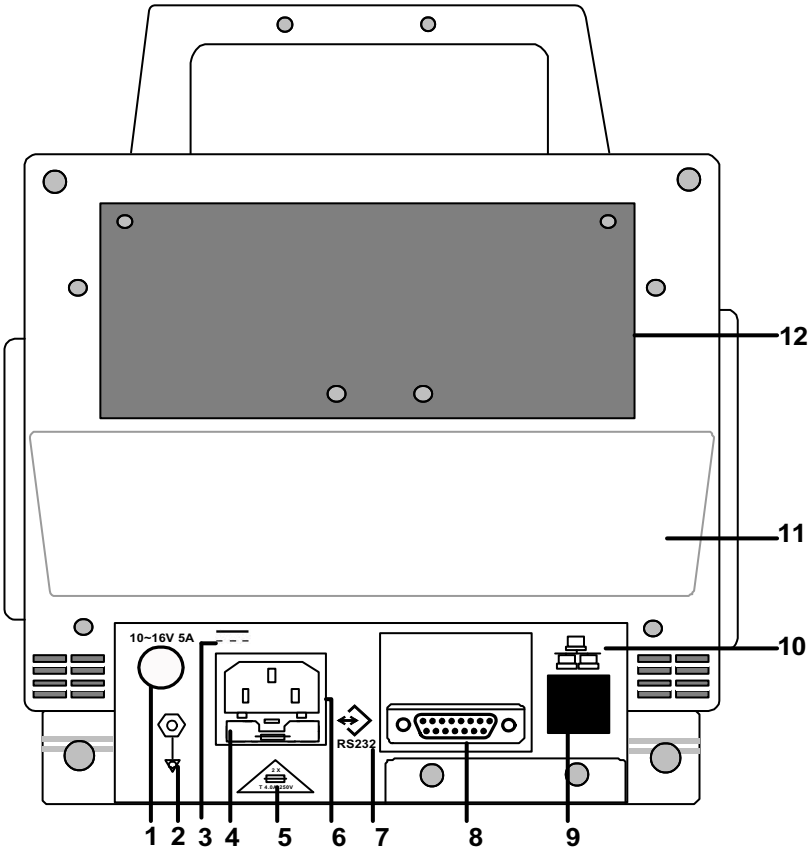
The physical and operational characteristics of the monitor are described in the operator's manual and in the **Specifications** section of this manual.

Figure 1 and 2 identify the displays, controls, indicators and symbols of the front and rear panels.



1. Waveform Display Icon
2. Graphic Frame
3. Message Frame
4. Set-up Icon
5. Alarm/Limits Icon
6. Big Numbers Icon
7. NIBP Start/Stop Switch
8. Power On/Off Icon
9. Power On/Off Button
10. Power On/Off Indicator
11. Record Switch
12. Battery Icon
13. Patient Mode Display
14. Home Switch
15. Date and Time Display
16. Alarm Silence/Suspend Switch
17. Knob Switch
18. Low Battery Indicator
19. Battery Charging/ AC Power Indicator
20. Pulse Amplitude Indicator
21. Numeric Value Display
22. SatSeconds Indicator
23. Numeric Frame
24. Numeric Display Icon
25. Alarm Indicator

Figure 1. N5500 Front Panel

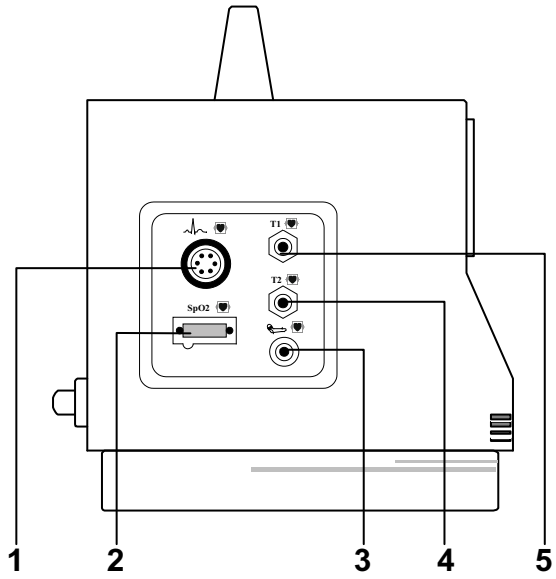


1. External DC Power Connector
2. Equipotential Terminal (Ground)
3. External DC Power Symbol
4. Fuse Holder
5. Fuse Replacement (Fuse Label)
6. AC Power Connector
7. Data Interface Symbol
8. Data Port Connector
9. Network Connector
10. Network Symbol
11. Product Label
12. Heat Sink

Figure 2. N5500 Rear Panel

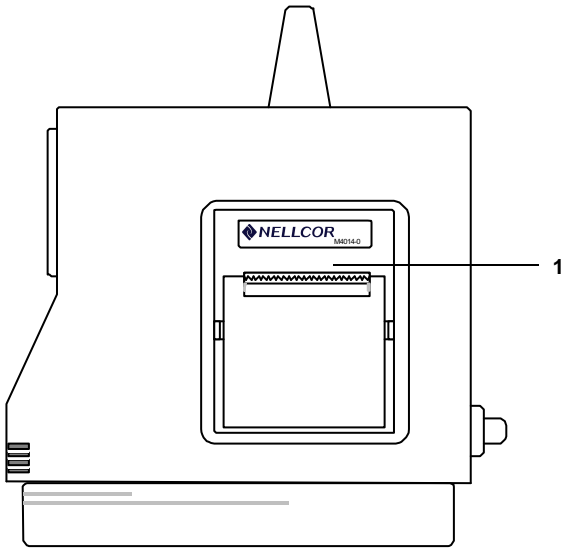
The N5500 patient monitor has a color liquid crystal display (LCD). The Numeric frames on the screen contain five numeric values are displayed. The Graphic Frames contain three equally sized graphic frames in which real-time physiological waveforms, graphical trend, or tabular trend data are displayed.

Controlling is accomplished by using the knob to interact with the appropriate area or icon on the screen.



1 ECG/Respiration Connector
2 SpO_2 Connector
3 NIBP Connector
4 Temperature Connector (T2)
5 Temperature Connector (T1)

Figure 3. N5500 Right Side Panel



1 Optional thermal printer or Printer cover

Figure 4. N5500 Left Side Panel

Section 2: Routine Maintenance

WARNING: Do not spray or pour any liquid on the monitor or its accessories. Do not immerse the N5500 or its accessories in liquid or clean with caustic or abrasive cleaners.

2.1 Cleaning

To clean the N5500, dampen a cloth with a commercial, nonabrasive cleaner and wipe the exterior surfaces lightly.

CAUTION: Do not allow any liquids to come in contact with the power connector or switches or to penetrate connectors or openings in the instrument.

Note: For cables, sensors and cuffs, follow the cleaning instructions in the directions for use that accompany these accessories.
Note: If liquid is spilled on the monitor, clean and dry thoroughly before reuse.
Note: If in doubt about monitor safety, refer the unit to qualified service personnel.

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

- The N5500 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 top, bottom, and front surfaces of the monitor lightly.

2.2 Periodic Safety and Functional Checks

The N5500 requires no routine service or calibration other than cleaning and battery maintenance. The following performance verification tests may be used following repair or during routine maintenance (if required by your local institution).

1. Inspect the exterior of the N5500 for damage.

2. Inspect labels for legibility. If the labels are not legible, contact Nellcor Technical Services Department or your local Nellcor representative.

3. Verify that the unit performs properly as described in **Performance Verification** section.

4. Perform the electrical safety tests detailed in **Performance Verification** section. If the unit fails these electrical safety tests, do not attempt to repair. Contact Nellcor Technical Services Department or your local Nellcor representative.

2.3 Functional Checks

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

1. If the monitor has been visibly damaged or subjected to mechanical shock (for example, if dropped), perform the performance tests as described in **Performance Verification** section.

2. Perform the electrical safety tests as described in **Safety Tests** section. If the unit fails these electrical safety tests, refer to **Troubleshooting** section.

3. Inspect the fuses for proper value and rating (qty 2, 4.0 A, 250 volts).

2.4 Batteries

If the N5500 has not been used for a long period of time, the battery will need charging. To charge the battery, connect the N5500 to an AC outlet as described in Paragraph 3.3.1 in this service manual or the **Battery Operation** section of the operator's manual.

Nellcor recommends replacing the instrument's battery every 2 years. When the N5500 is going to be stored for 2 months or more, it is recommended to remove the battery prior to storage. To replace or remove the battery, refer to **Disassembly Guide**.

Note: Storing the N5500 for a long period without charging the battery may degrade the battery capacity. The battery may require a full charge/discharge cycle to restore normal capacity. Nellcor recommends that the N5500's sealed, Ni-MH batteries be replaced at 2-year intervals. Refer to **Disassembly Guide** Section.

Note: The battery cannot be charged by an external DC power source.

2.5 Environmental Protection

Follow local governing ordinances and recycling plans regarding disposal or recycling batteries and other device components.

Section 3: Performance Verification

3.1 Introduction

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing the N5500 covers. 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 N5500 fails to perform as specified in any test, repairs must be made to correct the problem before the monitor is returned to the user.

3.2 Equipment Needed

Table 1 lists the equipment required for performance verification.

Table 1. Required Test Equipments

Equipment	Description
Digital multimeter (DMM)	Fluke Model 87 or equivalent
ECG cable for 3-leadwires	MDEC No.2
ECG cable for 5-leadwires (optional)	MDEC No.4
ECG leads	MDEL series (MDEL-3S, MDEL-3G)
ECG leads (optional)	MDEL series (MDEL-5S, MDEL-5G)
NIBP hose	Colin Hose No.1EM/No.3EM
NIBP cuff	Colin Cuff series
Pulse oximetry cable	DOC-10
OxiMax Durasensor® oxygen transducer	DS-100A
OxiMax oxygen transducer	MAX-A
Temperature probes	Monotherm™
SpO_2 simulator	Nellcor SRC-MAX simulator
ECG simulator	METRON PS-420 or equivalent
NIBP simulator	Bio-Tek “BP Pump 2” or equivalent
Respiration simulator	METRON PS-420 or equivalent
Temperature simulator	medSim 300 or equivalent
Safety analyzer	METRON QA-90 or equivalent
Data interface cable	RS-232 cable
Stopwatch	Manual or electronic

3.3 Performance Tests

The battery charge and battery performance test should be performed before monitor repairs whenever the battery is suspected as being a source of the problems. All other tests may be used following repairs or during routine maintenance (if required by your local institution). Before performing the battery performance test, ensure that the battery is fully charged. This section is written using Nellcor factory-set power-up defaults. If your institution has preconfigured custom defaults, those values will be displayed.

3.3.1 Battery Charge

1. Connect monitor to AC power source using proper power cord.

2. Verify AC Power indicator is lit.

3. Charge battery fully for at least 18 hours.

4. The only way to check for a full charge is to perform the procedure in paragraph 3.3.2 “Battery Performance Test.”

Note: The battery may require a complete charge/discharge cycle to restore its normal capacity, depending on its previous usage.

3.3.2 Battery Performance Test

1. The N5500 monitor is specified to typically operate on battery power a minimum of 1 hour, at 25°C, with no printing, and one NIBP measurement every 5 minutes. Before performing this test, ensure that the battery is fully charged (paragraph 3.3.1).

2. Ensure monitor is not connected to AC power.

3. With N5500 turned off, press Power On/Off switch and verify battery icon appears at bottom of display after power-on self-test is completed. Boxes in battery icon should all be filled, indicating battery is charged.

4. Connect *Nellcor* SRC-MAX SpO_2 simulator to monitor via DOC-10 sensor cable.

5. Connect NIBP simulator to monitor via Colin-NO.EM hose.

6. Set SRC-MAX as follows: SpO_2 of 75% and pulse rate of 60 bpm.

7. Set NIBP simulator to simulate pressure setting of 120/80 mmHg and heart rate of 80 bpm.

8. Verify monitor is responding to SpO_2 simulator signal and audible alarm is sounding. Use knob to select SpO_2 Menu and silence SpO_2 audible alarm (SpO_2 alarm suspend condition).

9. Use knob to select NIBP Menu and set Automatic Mode Interval to 5 minutes. Initial NIBP measurement will be automatically taken in 5 minutes, then subsequent NIBP measurements will be taken for 5 minutes, Automatic Mode Interval (from one measurement completes to the next measurement starts).

10. N5500 monitor must operate for 1 hour with a full-charged battery. N5500 monitor must operate for at least 5 minutes before monitor automatically powers down due to low battery condition.

11. Verify low battery alarm occurs and the low battery indicator is lit about 5 minutes before battery fully discharges.

12. Allow monitor to operate until it automatically powers down due to low battery condition. Verify high priority alarm occurs 15 seconds before monitor automatically shuts down.

13. If monitor passes this test, immediately recharge battery (3.3.1 Battery Charge).

3.3.3 Power-On Self-Test

1. Connect monitor to AC power source and verify AC Power indicator is lit.

2. Observe monitor front panel. With monitor off, press Power On/Off switch. Monitor must perform the following sequence.
   a. Monitor emits three consecutively higher pitched beeps.
   b. Nellcor logo appears for a few seconds, with version numbers of the software displayed in lower left corner of display.
   c. Alarm Indicator (red) on the top of the front panel, AC power indicator (green) and Low battery indicator (green) on the right bottom of the front panel are illuminated.
   d. Upon successful completion of power-on self-test, display will be in normal monitoring screen configuration.

Note: Power-on self-test takes approximately 3 seconds to complete.

Note: No vital signs numeric values or waveforms will be displayed.

3.3.4 General Operation Tests

3.3.4.1 Alarms and Alarm Silence

1. Press monitor Power On/Off switch to turn monitor on.

2. Connect SRC-MAX SpO_2 simulator to sensor input cable and connect cable to monitor.

3. Set SRC-MAX as follows: SpO_2 of 75% and pulse rate of 60 bpm.

4. Verify following monitor reaction:

   a. Pulse bar begins to track artificial pulse signal from SRC-MAX.
   b. After about 10 to 20 seconds, monitor displays saturation and pulse rate as specified by simulator. Verify values are within following tolerances:
      - Tolerance of Oxygen Saturation : ±2 % SpO_2
      - Tolerance of Pulse Rate : ±3 bpm
   c. Audible alarm sounds and "Low SpO_2 limits violated" message will be displayed and % SpO_2 numeric area will flash, indicating the parameter has violated default alarm limits.

5. Press Alarm silence/suspend switch on monitor front panel. Audible alarm is temporarily silenced.

6. Verify the following:
   a. An audible alarm remains silenced.
   b. Alarm silence icon appears in each numeric frame on display.
   c. %SpO_2 display continues flashing.
   d. Audible alarm returns in approximately 60 seconds.

3.3.4.2 QRS Volume Control

1. Press monitor Power On/Off switch to turn monitor on.

2. Connect SRC-MAX SpO_2 simulator to sensor input cable and connect cable to monitor.

3. Set SRC-MAX as follows: SpO_2 of 75% and pulse rate of 60 bpm.

4. Verify SpO_2 and pulse rate values are correctly displayed.

5. Press Alarm silence/suspend switch on front panel of the monitor to temporarily silence audible alarm.

6. Verify heart rate tone source, found in ECG Menu, is set to "SpO_2".

7. Select Setup icon on the screen to display Set-up menu.

8. Rotate knob to highlight QRS volume on Set-up menu and press knob to adjust QRS volume.

9. Set QRS volume 1 to 7 and return to the monitoring screen. Verify beeping pulse rate tone increases.

10. Set QRS volume 7 to 1 and return to the monitoring screen. Verify beeping pulse rate tone decreases.

11. Set QRS volume to Off and return to the monitoring screen. Verify beeping pulse rate tone is no longer audible.

12. Return QRS volume to a comfortable level.

3.3.4.3 LED Excitation Test

This procedure uses normal system components to test circuit operation. A *Nellcor OxiMax* oxygen transducer, 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. Press the Power On/Off switch to turn the monitor on.

3. Connect DOC-10 pulse oximetry cable to the monitor.

4. Connect a MAX-A sensor to the pulse oximetry cable.

5. Leave the sensor open with the LEDs and photo detector visible.

6. After monitor completes its normal power-up sequence, verify that the sensor LED is brightly lit.

7. Slowly move sensor LED in proximity of photodetector element of the sensor (close the sensor slowly). Verify; as LED approaches the optical sensor, that the LED intensity decreases.

8. Open the sensor and notice that the LED intensity increases.

9. Repeat step 7 and intensity will again decrease. This variation is an indication that the microprocessor is in proper control of LED intensity.

10. Press the Power On/Off switch to turn the N5500 monitor off.

3.3.4.4 Restoring Power-On Default Settings

The following test procedures will verify that alarms are activated at the level of factory default alarm limits and that any changed settings are saved and in effect when the user changes alarm limit settings and saves the current settings as a power default.

1. Turn the monitor on at the factory default settings.

2. Select Alarm/limits icon to display Alarm/limits menu. Alarm/limits menu appears.

3. Verify alarm limits are set to as shown in Table 2.

4. Change Patient mode Adult to Pediatric/Neonatal, then verify alarm limits are set to as shown in Table 2.

Table 2. Parameter Alarm Limit Factory Defaults

Factory Defaults	Adult	Pediatric	Neonatal
Heart Rate Alarm Upper Limits	120 BPM	160 BPM	200 BPM
Heart Rate Alarm Lower Limits	50 BPM	75 BPM	100 BPM
NIBP SYS Alarm Upper Limits	160 mmHg	120 mmHg	90 mmHg
NIBP SYS Alarm Lower Limits	90 mmHg	70 mmHg	40 mmHg
NIBP DIA Alarm Upper Limits	90 mmHg	70 mmHg	60 mmHg
NIBP DIA Alarm Lower Limits	50 mmHg	40 mmHg	20 mmHg
NIBP MAP Alarm Upper Limits	110 mmHg	90 mmHg	70 mmHg
NIBP MAP Alarm Lower Limits	60 mmHg	50 mmHg	30 mmHg
%SpO_2 Alarm Upper Limits	100 %	100 %	95 %
%SpO_2 Alarm Lower Limits	90 %	90 %	80 %
RR Alarm Upper Limits	30 BPM	30 BPM	100 BPM
RR Alarm Lower Limits	8 BPM	8 BPM	30 BPM
T1/T2 Alarm Upper Limits	39.0º C (102.2º F)	39.0º C (102.2º F)	39.0º C (102.2º F)
T1/T2 Alarm Lower Limits	36.0º C (96.8º F)	36.0º C (96.8º F)	36.0º C (96.8º F)

5. Change alarm limit value via Alarm/limits menu.

6. Save the current changed alarm limit values as a power on default setting via Service menu (see **Service Menu and Factory Defaults** section). Turn off the monitor.

7. Press Power On/Off switch to turn on the monitor.

8. Verify alarm limits are set to the current changed alarm limit values.

3.3.4.5 Printer Testing (Option)

If an optional printer is installed in the N5500 monitor, the following test procedures will verify the printer performance.

1. Turn the monitor on.

2. Connect all the necessary parameter simulator to the monitor.

3. Select Set-up icon to display Set-up menu. Set-up menu appears.

4. Test #1: One-shot printing
   - i. Set Print mode to One-shot.
   - ii. Press Record switch when all the parameter signals display normally.
   - iii. Verify the parameter values and waveforms are printed out for 20 seconds.

5. Test #2: Continuous printing
   - i. Set Print mode to Continuous.
   - ii. Press Record switch when all the parameter signals display normally.
   - iii. Verify the parameter values and waveforms are printed out continuously.
   - iv. Verify printing stops with pressing Record switch again.

6. Test #3: Print speed
   - i. Set Print speed to 25 mm/s.
   - ii. Press Record switch when all the parameter signals display normally.
   - iii. Verify the parameter values and waveforms are printed out with 25 mm/s.
   - iv. Verify printing stops with pressing Record switch again.
   - v. Set Print speed to 50 mm/s.
   - vi. Press Record switch when all the parameter signals display normally.
   - vii. Verify the parameter values and waveforms are printed out with 50 mm/s.
   - viii. Verify printing stops with pressing Record switch again.

7. Test #4: Print-on-alarm
   - i. Select Alarm/limits icon to display alarm/limits menu. Alarm/limits menu appears.
   - ii. Set Print-on-alarm to ON in the Alarm/limits menu.
   - iii. Set Hear rate of ECG simulator to 30 bpm.
   - iv. Verify Heart rate low limits violated alarm is activated and the parameter values and waveforms are printed out.

Note: If no printer is installed in the N5500 monitor, Print mode and Print speed will not display in the Set-up menu.

Note: If there is no printer paper left or printer paper places improperly, the monitor will display an error message and activate low priority alarm.

Note: If an optional printer connection is improper, the monitor will display an error message and activate low priority alarm.

3.3.4.6 Serial Interface Test

Perform the following procedure to test the serial port. The serial connector is Dsub-15, located on the monitor's rear panel, identified with the data interface symbol (RS-232).

1. Connect a serial cable between the N5500 monitor and PC COM1.

2. Run "DSUB15 Test.exe" on PC.

3. Set "BAUDRATE" to cbr57600.

4. Set "HEX" to Hex.

5. Press the OPEN button.

6. Turn the N5500 monitor on, then enter the service code, 916, in order. The monitor is now set up to "Central Monitoring System (CMS)" mode.

7. Verify that first two transferred numbers are 55 and 01.

8. Press the CLOSE button to exit the program.

9. Enter the service code, 900, in order to exit CMS mode.

3.3.4.7 Network Test

Perform the following procedure to test the Network. The Network connector is located on the monitor's rear panel, identified with the Network symbol.

1. Connect a network line to the N5500 monitor, then turn the N5500 monitor on.

2. Run "RJ45 Test.exe" on PC connected the network line using the same gateway as the N5500.

3. Press the PROBE button.

4. Verify that the number of N5500 connections to PC found is correct.

5. Press the EXIT button to close "RJ45 Test.exe".

CAUTION: Do not change any other settings of the test programs while performing the serial test and the Network test.

3.3.5 Measurement Parameter Operation Tests

3.3.5.1 ECG Operation with an ECG Simulator

1. Press Power On/Off switch to turn monitor on.

2. Connect ECG leads to appropriate jacks on ECG simulator.

3. Connect leads to MDEC ECG cable.

4. Connect MDEC to ECG input port on N5500.

5. Set ECG simulator as follows:
   - Heart rate: 30 bpm
   - Amplitude: 1 millivolt
   - Lead select: II
   - Normal sinus rhythm
   - Adult mode

6. After normal power-up sequence, verify the following monitor reactions:
   a. After about 15 seconds, monitor displays a heart rate of 30 ±3 bpm.
   b. Verify audible alarm will sound, "Low heart rate limits violated" message will display and heart rate display will flash, indicating heart rate is below default low alarm limit (medium priority alarm).

7. Increase heart rate setting on ECG simulator to 240 bpm.
   a. After about 15 seconds, verify monitor displays heart rate of 240 ±3 bpm.
   b. Verify audible alarm will sound, "High heart rate limits violated" message will display and heart rate display will flash, indicating heart rate is above default high alarm limit (medium priority alarm).

8. Decrease heart rate setting on ECG simulator to 120 bpm.
   a. After about 15 seconds, verify monitor displays heart rate of 120 ±3 bpm.

9. Disconnect LL lead from ECG simulator.
   a. Verify "ECG Leads Off" alarm message appears, three dashes are displayed in HR(heart rate) display, and low priority audible alarm sounds.
   b. Reconnect LL lead to ECG simulator. Verify "ECG Leads Off" alarm message no longer appears and audible alarm is silenced.
   c. Repeat this test for LA and RA leads.

10. Connect all the leads to the monitor.
    a. Select ECG menu and set ECG Lead selection to Lead I.
    b. Verify the lead selection.
    c. Repeat step 10-a for all the ECG Lead selections.

11. Set ECG Lead selection to Lead II.

12. Change ECG waveform size to all the selectable sizes and verify an appropriate size of the waveform displays

13. Disconnect 3 ECG leads and connect 5 ECG leads.

14. Set ECG cable type to "5 Leads" via Set-up Menu.

15. Repeat step 9 to 12.

16. Turn the monitor off.

Note: The accuracy of N5500 ECG measurements is ±3 bpm. In the procedure, add the tolerance of the simulator to the acceptable range of readings.

3.3.5.2 Pneumatic System Operation with NIBP simulator

These tests verify the functionality of the N5500 pneumatic system. The Bio-Tek simulator or any equivalent NIBP simulator is required to perform these tests. Each of the tests must be performed to verify pneumatic system functionality.

The N5500 must be placed in ***NIBP Test Mode***. For a detailed explanation of the NIBP Test Mode, refer to **Service Menu and Factory Default Settings** section**.**

Note: Before accessing the NIBP Test mode, ensure that current patient mode is proper for the Pneumatic system to be test. You can set Patient mode; Adult/Pediatric or Neonatal via Set-up menu.

Note: In the NIBP Test Mode, no function switch will have no effect except the knob. All the tests will start to be performed by pressing or rotating the knob. If you would like to stop the test during test progressing, press the knob.

1. Turn on Bio-Tek simulator and press "Pressure Test" button to place simulator in test mode.

2. Connect simulator hose to NIBP connector on N5500.

3. Place N5500 in NIBP Test Mode with NIBP Test screen active. (See Table 10)

3.3.5.2.1 Pressure Sensor Accuracy Test

The pressure sensor accuracy test verifies the pressure accuracy of the N5500 pressure sensor.

1. Ensure Bio-Tek simulator is in Static pressure test mode.

2. NIBP Test screen is active on N5500, then select "Pressure Sensor Accuracy Test" by the knob.

3. Press Select button on simulator until simulator displays "Pressure Source Set Test Pressure". Adjust pressure on the simulator for 250, 150, 50 and 0 mmHg.

4. Press Start Pump button on simulator. The simulator will begin to pressurize. Allow 15-20 seconds for pressure to stabilize.

5. The current pressure in mmHg will be displayed on both the simulator and N5500 displays. Ensure N5500 pressure sensor accuracy meets the performance standard of ANSI/AAMI SP-10:1992+A1:1996 (within the specification by more than ±3 mmHg or 2 percent of reading, whichever is greater) to successfully complete the test.

3.3.5.2.2 Over Pressure Test

The over-pressure test verifies the functionality of the over-pressure relief system.

1. Ensure Bio-Tek simulator is in Pressure relief test mode.

2. Ensure NIBP Test screen is active on N5500, then select "Over Pressure Test" by the knob.

3. Press Start Test button on simulator. The simulator will pressurize the system until the monitor's over-pressure relief system activates.

4. Ensure the monitor activates over-pressure relief system at the point of protection pressure.

Note: The test will have been successfully completed if the simulator displays a pressure reading, approximately, of 320±10 mmHg in adult/pediatric mode and 160±5 mmHg in neonatal mode. However, the motor's inflation pressure speed may cause a slight difference between over-pressure relief values in test and the specified relief values.

3.3.5.2.3 Air Leakage Test

The air leakage test verifies the integrity of the pneumatic system.

1. Ensure the monitor is set up with Rigid cuff can.

2. Ensure NIBP Test screen is active on N5500, then select "Air Leakage Test" by the knob.

3. The N5500 displays pressure of approximately 290 mmHg automatically.

4. The test result displays at the test completion. The initial pressure value at 1 minute is displayed after the test start and the air leakage value at further 3 minutes after the 1 minute elapsed.

Note: The test will have been successfully completed if the pressure has dropped by 6 mmHg, or less, during the 1-minute period.

3.3.5.2.4 Inflation Time Measurement

The inflation time test verifies the inflation time of the N5500.

1. Ensure the monitor is set up with Rigid cuff can.

2. Ensure NIBP Test screen is active on N5500, then select "Inflation Time Measurement" by the knob.

3. The N5500 displays pressure of approximately 290 mmHg automatically and measures inflation time in seconds.

4. The test result displays at the test completion.

Note: The test will have been successfully completed if the inflation time is 4.0 to 7.5 seconds (to 250 mmHg).

3.3.5.2.5 Deflation Rate Measurement

The deflation time test verifies the deflation rate of the N5500.

1. Ensure the monitor is set up with Rigid cuff can.

2. Ensure NIBP Test screen is active on N5500, then select "Deflation Rate Test" by the knob.

3. The N5500 displays pressure of approximately 290 mmHg automatically, then measures deflation rate during reducing the pressure.

4. The test result displays 4 parts (from 260-180mmHg, 180-100mmHg, 100-60mmHg and 60-30 mmHg) at the test completion.

5. Confirm the result is within the specification.
   - 260-180mmHg : 4.8 ~ 6.0 mmHg/s
   - 180-100mmHg : 4.8 ~ 6.0 mmHg/s
   - 100-60mmHg: 3.5 ~ 5.0 mmHg/s
   - 60-30 mmHg : 2.8 ~ 4.2 mmHg/s

3.3.5.3 Pulse Oximetry Operation with SpO_2 simulator

1. Connect the monitor to an AC power source.

2. Turn on the monitor by pressing the Power On/Off switch.

3. Connect the DOC-10 pulse oximetry cable after the monitor completes POST.

4. Connect the SRC-MAX simulator to the other end of the DOC-10 cable.

5. The monitor will:
   - be in SpO_2 alarm
   - display an SpO_2 of 75 (Test pass criteria is 73 to 77 % SpO_2)
   - display a pulse rate of 60 (Test pass criteria is 57 to 63 bpm)
   - display low level modulation

6. Test #1: SpO_2
   i. Press the SRC-MAX % SpO_2 selection button. The SRC-MAX % SpO_2 90 LED will light.
   ii. The monitor will display three dashes until the SRC-MAX stabilizes at 90 % SpO_2. The test pass criteria is 88 to 92 % SpO_2.
   iii. The monitor will display:
   - 90 % SpO_2
   - 60 bpm
   - no alarm

7. Test #2: Pulse rate (bpm)
   i. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 200 LED will light:
   ii. The monitor will increase to 200 bpm. The test pass criteria is 197 to 203 BPM.
   iii. The monitor will display:
   - 90 % SpO_2
   - 200 bpm
   -alarm: "High heart rate limits violated" message will display and heart rate display will flash, indicating pulse rate is above default high alarm limit (medium priority alarm).
   iv. Press the SRC-MAX PULSE RATE selection button. The SRC-MAX PULSE RATE 60 LED will light.
   v. The monitor will decrease to 60 and stabilize at 60 bpm. The test pass criteria is 57 to 63 bpm.
   vi. The monitor will display:
   - 90 % SpO_2
   - 60 bpm
   - no alarm
   - low level modulation

8. Test #3: Modulation Level
    i. Press the SRC-MAX %MODULATION selection button. The SRC-MAX %MODULATION LED will light.
    ii. The monitor waveform display will spike and stabilizes at a higher modulation level.
    iii. The monitor will display:
    - 90 % SpO_2
    - 60 bpm
    - no alarm
    iv. Disconnect all equipments and turn off the monitor.

3.3.5.4 Respiration Operation with a Respiration Simulator

1. Press Power On/Off switch to turn monitor on.

2. Connect ECG leads to appropriate jacks on respiration simulator.

3. Connect ECG leads to MDEC ECG cable.

4. Connect MDEC to ECG input port on N5500.

5. Set simulator for respiration rate of 120 breaths per minute.

6. After normal power-up sequence, verify the following monitor reactions:
    a. Monitor displays respiration rate of 120 ±3 breaths per minute.
    b. Audible alarm will sound, "High respiration rate limits violated" message will display and respiration rate display will flash, indicating respiration rate is above default high alarm limits. (medium priority alarm)

7. Decrease respiration rate setting on respiration simulator to 20 breaths per minute.
    a. Verify monitor displays respiration rate of 20 ±3 breaths per minute.

Note: The accuracy of N5500 ECG measurements is ±3 breaths per minute. In the procedure below, add the tolerance of the simulator to the acceptable range of readings.

3.3.5.5 Temperature Operation with a Temperature Simulator

1. Press Power On/Off switch to turn monitor on.

2. connect temperature probe (supplied with the temperature simulator) to appropriate connector on temperature simulator.

3. Connect temperature probe to temperature input port on N5500.

4. Set temperature simulator as follows:
   - Temperature: 37°C (98.0°F)
   - Probe type: Monotherm™ Temperature Probes (Probe accuracy: ±0.1°C)

5. After normal power-up sequence, verify temperature reads 37°C ±0.1°C (98.6°F ±0.2°F if Fahrenheit is selected as temperature units).

6. Turn monitor off.

Note: The accuracy of N5500 temperature measurements is ±0.1°C (±0.2°F) in the range of 25°C to 45°C and ±0.2°C in the range of 15° C to less than 25° C as specified in **Specification** section. In the procedure above, add the tolerance of the simulator and the probe to the acceptable range of readings.

3.4 Safety Tests

N5500 safety tests meet the standards of, and are performed in accordance with, IEC 60601-1, Clause 19 (Second Edition, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03), EN60601-1 for instruments classified as Class I and Type CF.

3.4.1 Protective Earth Continuity

This test checks the integrity of the power cord ground wire from the AC plug to the instrument chassis ground. The current used for this test is less than or equal to 4 Volts RMS, 50 to 60 Hz, and 25 Amperes.

1. Connect the monitor AC mains plug to the analyzer as recommended by the analyzer operating instructions.

2. Connect the analyzer resistance input lead to the equipotential terminal (ground lug) on the rear of the instrument. Verify that the analyzer indicates 100 milliohms or less.

3.4.2 Electrical Leakage

The following tests verify the electrical leakage of the monitor.

3.4.2.1 Earth Leakage Current

This test is in compliance with IEC60601-1 earth leakage current. The applied voltage for IEC60601-1 the voltage is 264 Volts AC, 50 to 60 Hz. All measurements shall be made with the power switch in both “On” and “Off” positions.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.

2. Perform test as recommended by analyzer operating instructions.

Table 3. Earth Leakage Current Values

Test Condition	Allowable Leakage Current (microamps)
Normal polarity	500
Normal polarity; Neutral open	1000
Reverse polarity	500
Reverse polarity; Neutral open	1000

Note: Earth leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in Table 3.

3.4.2.2 Enclosure Leakage Current

This test is in compliance with IEC60601-1 enclosure leakage current. This test is for ungrounded enclosure current, measured between enclosure parts and earth. The applied voltage for IEC60601-1 the applied voltage is 264 Volts AC at 50 to 60 Hz.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.

2. Place a 200 cm^2 foil in contact with the instrument case making sure the foil is not in contact with any metal parts of the enclosure that may be grounded.

3. Measure the leakage current between the foil and earth.

Note: The analyzer leakage current indication must note exceed the values listed in Table 4.

Table 4. Enclosure Leakage Current

AC Line Cord	Neutral Line Wire	Power Line Ground Wire	Allowable Leakage Current (microamps)
Closed	Closed	Closed	100
Closed	Closed	Open	500
Closed	Open	Closed	500
Open	Closed	Closed	500
Open	Open	Closed	500
Open	Closed	Open	500

3.4.2.3 Patient Leakage Current

This test measures patient leakage current in accordance with IEC60601-1, clause 19, for Class I, Type CF equipment. Patient leakage current in this test is measured from any individual patient connection to earth (power ground).

1. Configure the electrical safety analyzer as recommended by the analyzer operating instructions.

2. Connect the monitor's AC mains power cord to the analyzer as recommended by the analyzer operating instructions.

3. Connect the ECG test cable between the ECG connector on the N5500 and the appropriate input connector on the analyzer.

4. Turn on the N5500.

5. Perform the patient leakage current test as recommended by the analyzer operating instructions.

6. Repeat the patient leakage current test for the SpO_2 and temperature patient connections, using the appropriate test cables.

Note: Patient leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in Table 5.

Note: This test requires a test cable for each patient connector. For example, the ECG test cable consists of the ECG cable connector, with all conductors shorted together, connected to a test lead from the electrical safety analyzer. Test cables for SpO_2 and temperature can be configured in a similar manner, by wrapping each sensor end individually with aluminum foil filled with conductive gel (only enough gel to ensure conductivity). Attach a wire to the foil that is connected to a test lead from the electrical safety analyzer.

Table 5. Patient Leakage Current Values

Test Condition	Allowable Leakage Current (microamps)
Normal polarity	10
Normal polarity; Neutral open	50
Normal polarity; Earth open	10
Reverse polarity	50
Reverse polarity; Neutral open	50
Reverse polarity; Earth open	50

3.4.2.4 Patient Leakage Current - (Mains Voltage on the Applied Part)

WARNING: AC mains voltage will be present on the applied part terminals during this test. Exercise caution to avoid electrical shock hazard.

WARNING: Do not touch the patient leads clips or the simulator parts connected to patient leads during this test as an electrical shock will occur.

This test measures patient leakage current in accordance with IEC60601-1, clause 19, for Class I, type CF equipment. In this test, 110% of mains voltage is applied between each patient connection and earth (power ground). Patient leakage current is then measured from any individual patient connection to earth.

Note: Keep the patient test cable length as short as possible during the leakage test.

Note: This test requires the same test cables for each patient connector as described in 3.4.2.3 Patient Leakage Current.

1. Configure electrical safety analyzer as recommended by analyzer operating instructions.

2. Connect monitor's AC mains power cord to analyzer as recommended by analyzer operating instructions.

3. Connect ECG test cable between ECG connector on N5500 and appropriate input connector on analyzer.

4. Turn on N5500.

5. Perform test as recommended by analyzer operating instructions.

6. Repeat test for SpO_2 and temperature patient connections, using appropriate test cables.

Note: Patient leakage current is measured with normal and reverse mains polarity. For each condition, the measured leakage current must not exceed that indicated in Table 6.

Table 6. Patient Leakage Current Values–Mains Voltage on Applied Part

Test Condition	Allowable Leakage Current (microamps)
Normal polarity	50
Reverse polarity	50

3.4.2.5 Patient Auxiliary Current

This test measures patient auxiliary current in accordance with IEC60601-1, clause 19, for Class I, type CF equipment. The applied voltage for IEC60601-1 the voltage is 264 volts, 50 to 60 Hz. Patient auxiliary current is measured between each ECG test lead and between each sensor connection for all possible connections.

Note: Keep the patient test cable length as short as possible during the leakage test.
Note: This test requires the same test cables for each patient connector as described in 3.4.2.3 Patient Leakage Current.

1. Configure the electrical safety analyzer as recommended by the electrical analyzer's operating instructions.

2. Connect the monitor's AC mains power cord to the electrical analyzer as recommended by the electrical analyzer's operating instructions.

3. Connect the patient test lead combination in table 7 to the appropriate input connector on the electrical analyzer.

4. Turn on the N5500.

5. Perform patient auxiliary current test per table 8 as recommended by electrical analyzer's operating instructions.

6. Repeat the patient auxiliary current test for each test lead combination as listed in Table 7 and measure each patient auxiliary current.

Table 7. Test Lead Combinations

First Test Lead	Second Test Lead
ECG #1 (LA)	ECG #3 (RA)
ECG #1 (LA)	ECG # 2 (LL)
ECG #2 (LL)	ECG #3 (RA)
ECG #1 (LA)	Temperature 1/2
ECG #2 (LL)	Temperature 1/2
ECG #3 (RA)	Temperature 1/2
ECG #1 (LA)	SpO_2
ECG #2 (LL)	SpO_2
ECG #3 (RA)	SpO_2
Temperature 1/2	SpO_2

Table 8. Allowable Leakage Current

Polarity	Neutral Line Wire	Power Line Ground Wire	Allowable Leakage Current (microamps)
Normal	Closed	Normal	10
Normal	Open	Normal	50
Normal	Closed	Open	50
Reversed	Closed	Normal	10
Reversed	Open	Normal	50
Reversed	Closed	Open	50

Section 4: Service menu and Factory Default Settings

4.1 Introduction

This section discusses use of the Service menu to configure Power-on default settings, Alarm Suspend, Alarm Silence Period, Audible Alarm Type, AC Line Frequency, Language selections, NIBP Test Mode access, and System Information to obtain service-related information about the monitor. Also this section explains briefly the factory default settings and Demo mode.

4.2 Service Menu

The purpose of the Service menu (Figure 6, Table 9) is to allow the authorized user to create a Power-on default for each setting in the N5500. Power on defaults are the settings in effect each time the N5500 is powered on. Once the Service menu is entered, physiological monitoring is terminated. The screen layouts do not display any information associated with normal monitoring operation. Use the following procedure to configure the Service Menu for the N5500 monitor (also see **Using the Monitor** section, page 35 of the operator's manual):

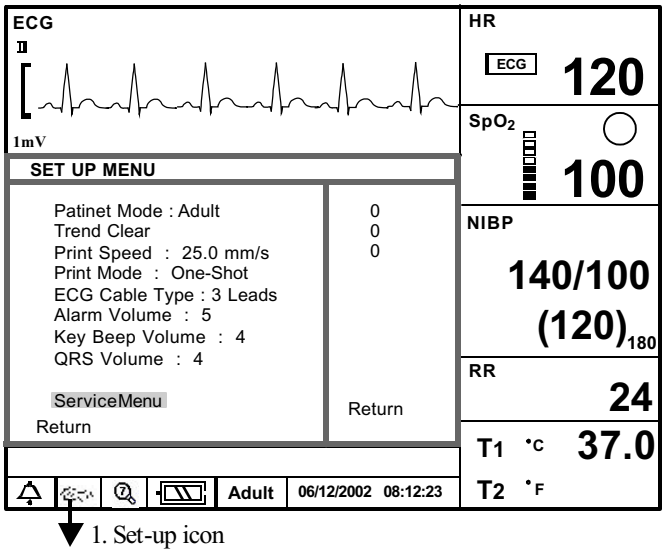


Figure 5. The access of Service Menu via Set-up menu

1. Set N5500 to normal monitoring mode.

2. Rotate the knob to highlight the ***Set-up icon***. (Set-up icon located on the bottom of

the screen display). Press the knob. Set-up menu displays.

3. Rotate the knob to highlight Service Menu in the Set-up menu, and then press the knob to access the Service Menu.

4. Three digits displays in the Level 2 Menu as shown in Figure 5.

   Note: The access code is **4**, **0**, **2**. It is set at the factory and may not be changed.

5. Rotate the knob to highlight the top of the digits. Press the knob to enter the access code. The digit turns yellow. This indicates that it is ready to rotate the knob in order to change the digit.

6. Rotate the knob until "4" appears, then press the knob.

7. Repeat step 5-6 to enter all the access code "**4**" "**0**" "**2**".

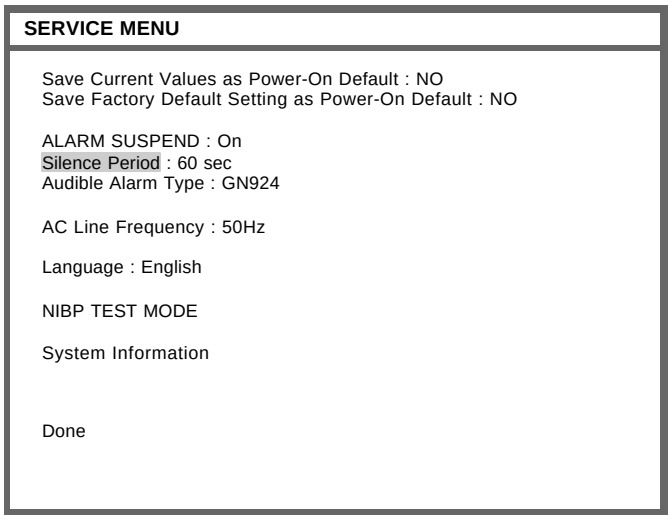


Figure 6. Service Menu

8. The Service Menu will now be present. The available Service Menu items are explained in Figure 6 and Table 9. Make changes to these menu items as desired by rotating and pressing the knob.

9. Select "YES" on "Save Current Values as Power-On Default" if any changes of the setting become power-on defaults.

   Note: Select "YES" on "Save Factory Default Setting as Power-On Default", then the monitor will set back to Factory default settings as power-on defaults.

10. Select "Done". The Notice screen will be present.

11. Turn the monitor off, then power the monitor on again.

Note: The monitor must be powered off upon selecting "Done" to save any changes into the monitor, and then the changes made to the Power on defaults will be in effect next time the unit is powered up.

Note: If you do not select "YES" on save current values or back to factory defaults as power-on default, the monitor will not save any changes and it will be automatically powered off upon selecting "Done" to exit Service menu screen.

Table 9. Service menu

Menu Item	Response
Save Current Values as Power-On Default	YES, NO
Save Factory Default Setting as Power-On Default	YES, NO
Alarm Suspend	On, Off
Alarm Silence Period	30, 60, 90, 120, 180 sec
Audible Alarm Type	GN924, IEC60601-1-8
AC Line Frequency	50Hz, 60Hz
Language	Chinese, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Norwegian, Polish, Portuguese, Russian, Spanish, Swedish
NIBP Test Mode	Activate NIBP Test Mode screen (see Table 11)
System Information	Activate System Information screen (see Table 12)
Done	The monitor will be powered off upon selecting "Done", then any changes will be in effect next time the unit is powered up.

Save Current Values as Power-On Default

The current N5500 settings become the power-up defaults next time the unit is powered up.

Save Factory Default Setting as Power-On Default

The N5500 factory default settings become the power-up defaults next time the unit is powered up. See section 4.4 Factory Default Settings and Table 12.

Alarm Suspend

If "On" is chosen, the monitor may be able to invoke the Alarm Suspend mode by pressing and holding the ***Alarm silence/suspend switch*** for 2 seconds. Some institutions may wish to prevent Alarm Suspend from being invoked. If so, "Off" should be selected. In this case, Alarm Suspend via the corresponding ***numeric parameter menus*** or the ***alarm/limits menu*** is also prevented from being invoked.

Alarm Silence Period

Pressing the ***Alarm silence/suspend switch*** temporarily silences alarms for the time indicated in the Silence Period.

Audible Alarm Type

GN924 or IEC60601-1-8

The N5500 has two different audible alarm types, called GN924 and IEC60601-1-8. They have different tone pitch and on-off beep patterns. (Refer to Alarms and Limits section in the operator's manual)

AC Line Frequency

50 Hz or 60Hz

The monitor is designed for supporting AC line frequency both 50 Hz and 60 Hz. Select either 50Hz or 60 Hz frequency for an appropriate AC line.

Language

The language selected will be used for all the text shown on the display; the selected language will be effective the next time the monitor is powered up.

Note : If an unfamiliar language is chosen, the user may find it difficult to operate the monitor.

NIBP Test Mode

WARNING: A blood pressure cuff, connected to the monitor, should never be applied to a human subject while the monitor is in NIBP test Mode, as injury could result.

NIBP Test Mode provides to facilitate performing verification testing for the NIBP subsystem. Typically, when these tests are performed, the pneumatic system is connected to an NIBP simulator or a Rigid cuff can as a closed reference volume. For the detailed test procedures in this mode, refer to the **Performance Test** section.

The NIBP Tests are described in Table 10. When any of NIBP tests is initiated, "Test in Progress" message will appears on the right of the top screen during the test.

In the NIBP Test Mode, no function switch will have no effect except the knob. All the tests will start to be performed by pressing or rotating the knob. If you would like to stop the test during test progressing, press the knob.

Note: If any further NIBP test is not selected to be performed after a test is completed, a notice screen will display in approximately 10 minutes.

Table 10. NIBP Test Mode

Tests	Description
Pressure Sensor Accuracy Test	Verifies that the pneumatic pressure sensor accuracy is within the specification.
Over Pressure Test	Verifies that the valve will open and the pump will be disabled if system pressure reaches the over-pressure protection point (320±10 mmHg in adult/pediatric mode, 160±5 mmHg in neonatal mode).
Air Leakage Test	Verifies that the pneumatic pressure air leakage is within a pressure drop of 6 mmHg/min.
Inflation Time Measurement	Verifies that the pneumatic pressure inflation is at the time of 4.0 to 7.5 seconds (to 250 mmHg)
Deflation Rate Measurement	Verifies that the proportional valve will open and bleed off pressure at the rate of 2.8 to 6.0 mmHg/second (260mmHg – 30mmHg).
Return	Exits NIBP Test Mode screen immediately, returns to Service Menu.

System Information

This screen displays several system-related items:

Table 11. System Information

System Information	Description
Monitor On Time	Displays the number of hours, rounded to the nearest hour, that the monitor has been operational.
Recorder On Time	Displays the number of hours, rounded to the nearest hour, that the Recorder has been operational.
Battery Deep Discharges	Displays the number of deep-discharge cycles seen by the battery. The monitor records a deep discharge cycle when the battery voltage reaches the voltage at which a "Deadly Low Battery" alarm is issued.
System Software Version	Displays the revision level of the system software. The revision level is also shown on the LCD as part of the Copyright screen.

Note: The values of Monitor On Time, Recorder On Time and Battery Deep Discharges may not be reset, but they will be reset to zero when a new Main PCB assembly is installed.

CMS (Central Monitoring System)

The N5500 monitor has a capability of transferring patient data to Central Monitoring System (CMS) for N5500. For more information, refer to the CMS instructions for use.

4.3 Demo Mode

The purpose of Demo mode is to show a visual presentation demonstrating how the N5500 monitor works. The following procedure is set to Demo mode.

1. Turn the N5500 monitor on.

2. Rotate the knob to highlight the Set-up icon, then press the knob. Set-up menu displays.

3. Rotate the knob to highlight Service Menu in the Set-up menu (see Figure 5), and then press the knob to enter the Demo access code for Demo mode.

4. Three digits displays in the Level 2 Menu as shown in Figure 5.

5. Rotate the knob to highlight the top of the digits. Press the knob to enter the Demo access code, "**3**" "**1**" "**4**" in this order.

6. The monitor is now set to Demo mode, and demonstrates a typical monitoring screen.

4.4 Factory Default Settings

Factory default settings are divided into three groups, adult, pediatric and neonatal as described in Table 12.

The parameters of the N5500 monitor are preset to "Adult" monitoring mode. Alarm limits settings will be automatically changed to the default settings for each patient mode as the mode is changed to Adult, Pediatric or Neonatal mode.

Table 12. Factory Default Settings for the N5500

Parameter	Factory Defaults		
	Adult	Pediatric	Neonatal
Monitoring Mode	Adult	Pediatric	Neonatal
NIBP Initial Cuff Inflation	180 mmHg	180 mmHg	120 mmHg
NIBP Auto Mode Interval	OFF	OFF	OFF
NIBP SYS Alarm Upper Limits	160 mmHg	120 mmHg	90 mmHg
NIBP SYS Alarm Lower Limits	90 mmHg	70 mmHg	40 mmHg
NIBP DIA Alarm Upper Limits	90 mmHg	70 mmHg	60 mmHg
NIBP DIA Alarm Lower Limits	50 mmHg	40 mmHg	20 mmHg
NIBP MAP Alarm Upper Limits	110 mmHg	90 mmHg	70 mmHg
NIBP MAP Alarm Lower Limits	60 mmHg	50 mmHg	30 mmHg
ECG Size	10.0 mm/mV	10.0 mm/mV	10.0 mm/mV
ECG Filter Mode	Monitor	Monitor	Monitor
ECG Pacer Detect	OFF	OFF	OFF
ECG Sweep Speed	25.0 mm/s	25.0 mm/s	25.0 mm/s

Parameter	Factory Defaults		
	Adult	**Pediatric**	**Neonatal**
Heart Rate Tone Source	ECG	ECG	ECG
Heart Rate Alarm Upper Limits	120 BPM	160 BPM	200 BPM
Heart Rate Alarm Lower Limits	50 BPM	75 BPM	100 BPM
C-Lock	OFF	OFF	OFF
Satseconds Value	OFF	OFF	OFF
SpO2 In-Sensor Type	%SpO2	%SpO2	%SpO2
SpO2 Sweep Speed	25.0 mm/s	25.0 mm/s	25.0 mm/s
%SpO2 Alarm Upper Limits	100 %	100 %	95 %
%SpO2 Alarm Lower Limits	90 %	90 %	80 %
Respiration On/Off	ON	ON	ON
Respiration Size	Size Level 3	Size Level 3	Size Level 3
Respiration Sweep Speed	12.5 mm/s	12.5 mm/s	12.5 mm/s
RR Alarm Upper Limits	30 BPM	30 BPM	100 BPM
RR Alarm Lower Limits	8 BPM	8 BPM	30 BPM
Temperature Unit T1	° C	° C	° C
Temperature Unit T2	° C	° C	° C
T1 Alarm Upper Limits	39.0 °C (102.2 °F)	39.0 °C (102.2 °F)	39.0 °C (102.2 °F)
T1 Alarm Lower Limits	36.0 °C (96.8 °F)	36.0 °C (96.8 °F)	36.0 °C (96.8 °F)
T2 Alarm Upper Limits	39.0 °C (102.2 °F)	39.0 °C (102.2 °F)	39.0 °C (102.2 °F)
T2 Alarm Lower Limits	36.0 °C (96.8 °F)	36.0 °C (96.8 °F)	36.0 °C (96.8 °F)
Print-On-Alarm	OFF	OFF	OFF
Alarm Suspend Initiation	OFF	OFF	OFF
Alarm Suspend Access	ON	ON	ON
Alarm Silence Period	60 seconds	60 seconds	60 seconds
Audible Alarm Type	GN 924	GN 924	GN 924
ECG Cable Type	3 leads	3 leads	3 leads
Alarm Volume	5	5	5
Key Beep Volume	4	4	4
QRS Volume	4	4	4
Tabular Trend Time Interval	20 seconds	20 seconds	20 seconds
AC Line Frequency	50 Hz	50 Hz	50 Hz
Print mode**	One-Shot	One-Shot	One-Shot
Print Speed**	25.0 mm/s	25.0 mm/s	25.0 mm/s
Language	English	English	English

Note: Asterisks (**) by a parameter in the above table indicate the print settings in which an optional thermal printer installed.

Note: The factory default value of "AC Line Frequency" is preset to 60 Hz for the N5500 software version 1.00, 1.01, 1.02 and 1.03 only. Check your N5500 monitor for the software version installed.

Section 5: Troubleshooting

5.1 Introduction

This section explains how to troubleshoot the N5500 if problems arise.
Tables are supplied that list possible monitor difficulties, along with probable causes, and recommended actions to correct the difficulty.

5.2 How to Use This Section

Use this section in conjunction with **Performance Verification** section and **Spare Parts** section. To remove and replace a part you suspect is defective, follow the instructions in **Disassembly Guide** section.

5.3 Who Should Perform Repairs

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

5.4 Replacement Level Supported

The replacement level supported for this product is to the printed circuit board (PCB assembly) and major subassembly level. Once you isolate a suspected PCB assembly, follow the procedures in **Disassembly Guide** section, to replace the PCB assembly with a known good PCB assembly. 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 assembly with the suspected malfunctioning PCB assembly (the original PCB assembly that was installed when you started troubleshooting) and continue troubleshooting as directed in this section.

Obtaining Replacement Parts
Nellcor 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 listed in **Spare Parts** section.

5.5 Troubleshooting Guide

Problems with the N5500 are separated into the categories in Table 13. Refer to the paragraph indicated for further troubleshooting instructions in this section.

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

All of the categories in Table 13 are discussed in the following paragraphs.

Table 13. Problem Categories

Problem Area	Refer to Paragraph
1. Power ▪ No power-up ▪ Fails power-on self-test ▪ Powers down without apparent cause	5.5.1 Power
2. Display ▪ Display does not respond properly	5.5.2 Display
3. Switches/Knob ▪ Monitor does not respond properly to switches	5.5.3 Switches/Knobs
4. Alarms/Audible Tones ▪ Alarms are generated without apparent cause ▪ Tones do not sound properly	5.5.4 Alarms/Audible Tones
5. Operational Performance ▪ Displays appear to be operational, but monitor shows no readings ▪ Suspect readings ▪ Printer not responding	5.5.5 Operational Performance
6. Error Codes ▪ Error code displays on the screen	5.5.6 Error Codes

5.5.1 Power

Power problems are related to AC and/or DC. Table 14 lists recommended actions to address power problems.

Table 14. Power Problems

Symptom	Recommended Action
1. When AC power cord is connected to the N5500, AC power indicator on the front panel is not lit.	1. Ensure power cord is plugged into appropriate AC outlet of voltage and frequency. 2. Replace Power Supply assembly. 3. Ensure Power Switch PCB is plugged into Main PCB assembly. If connection is good, replace Power Switch PCB
2. The N5500 fails to power-up when the Power On/Off switch is pressed.	1.Ensure power cord is plugged into operational AC outlet of appropriate voltage and frequency. Ensure AC power indicator is lit. If indicator is not lit, replace Power Supply assembly. 2.Check fuses located on Power Supply assembly above AC inlet receptacle. Replace fuses if necessary. 3.Inside monitor, check main flat cable and ensure that it is connected to Main PCB assembly and Rear communication PCB assembly. 4.Inside monitor, check SMPS to Rear communication board DC wire connected to SMPS and Rear communication PCB. 5.Ensure Power Switch PCB is plugged into Main PCB assembly. If connection is good, replace Power Switch PCB. 6.If the problem persists, replace Main PCB assembly. 7.If the problem persists, replace Power switch PCB.
3. The N5500 turns on, then sounds an alarm and shuts off and no error code is displayed.	1. If problem persists, replace Main PCB assembly.
4. The N5500 does not operate when disconnected from AC power	1. The battery may be discharged. To recharge the battery, refer to section 3.3.1 Battery Charge. Note: DC power should not charge the battery. 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. 2. If problem persists, replace battery fuse on Power Supply.
5. Battery does not charge	1. If the battery fails to hold a charge, replace the battery as indicated in Battery Replacement 2. Open the monitor as described in Disassembly Guide. Verify the power supply's LED while on AC. While charging battery, the red LED is lit until battery charging is completed, then the green LED is lit. Replace the power supply if the LEDs are not lit.

5.5.2 Display

Table 15 lists symptoms of problems relating to non-functioning displays, and recommended actions. If the action requires replacement of a PCB assembly or module, refer to Disassembly Guide.

Table 15. Display

Symptom	Recommended Action
1. LCD screen is totally black after system powers-up.	1. Ensure backlight wire is connected to backlight inverter. 2. Ensure backlight inverter wire is connected to Main PCB assembly. 3. Ensure Booting Mode Selector is set to ' NORMAL' . 4. If the problem persists, replace LCD cable. 5. If the problem persists, replace backlight inverter. 6. If the problem persists, replace Main PCB assembly. 7. If the problem persists, replace LCD panel.
2. LCD screen is illuminated, but no data is visible after system powers-up.	1. Ensure backlight wire is connected to Main PCB assembly and backlight inverter. 2. Ensure LCD cable is connected to Main PCB assembly and LCD panel. 3. If the problem persists, replace LCD cable. 4. If the problem persists, replace Main PCB assembly. 5. If the problem persists, replace backlight inverter. 6. If the problem persists, replace LCD panel.
3. LCD screen has data, but is not illuminated after system powers-up.	1. Ensure backlight wire is connected to Main PCB assembly and backlight inverter. 2. Ensure LCD cable is connected to Main PCB assembly and LCD panel. 3. If the problem persists, replace Main PCB assembly. 4. If the problem persists, replace backlight inverter. 5. If the problem persists, replace LCD panel.
4. Display values are missing or erratic	1. If the measurement cables are connected, ensure that the cables are properly connected. 2. If the problem persists, replace the measurement cables. 3. If the problem persists, replace LCD cable. 4. If the problem still persists, replace Main PCB assembly. 5. If the problem still persists, replace ECG PCB assembly. 6. If the problem still persists, replace SpO_2 PCB assembly.
5. Display pixels do not light.	1. Check the connection of Main PCB assembly. 2. If the problem persists, replace LCD cable. 3. If the problem still persists, replace Main PCB assembly. 4. If the problem still persists, replace LCD panel.

5.5.3 Switches/Knobs

Table 16 lists symptoms of problems and recommended actions to address problems with the knob and front panel switches.

Table 16. Switches/Knob Problems

Symptom	Recommended Action
1. N5500 fails to power-up when Power On/Off switch is pressed.	1. Take steps as noted in paragraph 5.5.1.
2. N5500 powers-up, but some or one of the other switches respond.	1. Ensure Function switch PCB is plugged into Main PCB assembly. If connection is good, change Function switch PCB. 2. If problem persists, change Main PCB assembly.
3. When knob is rotated, no highlight appears on display screen, and/or monitor does not respond to knob presses.	1. Ensure encoder wire is plugged into Main PCB assembly. If connection is good, change encoder. 2. If problem persists, replace Main PCB assembly.

5.5.4 Alarms/Audible Tones

Table 17 lists symptoms of problems and recommended actions to address problems with the display and audible tones.

Table 17. Alarms/Audible Tones Problems

Symptom	Recommended Action
1. Alarm sounds for no apparent reason	1. Moisture or spilt liquids can cause an alarm not to sound. Allow the monitor to dry thoroughly before using 2. If the problem persists, replace Main PCB assembly.
2. Audible alarm does not sound.	1. Check alarm silence status. 2. Verify alarm volume setting in Set-up menu. 3. Check 50 pi speaker connection. Ensure 50 pi speaker wire is connected to rear communication PCB. 4. If problem persists, replace 50 pi speaker assembly. 5. Check the flat cable between main PCB and rear communication PCB. 6. If problem persists, replace Main PCB assembly. 7. If problem persists, replace rear communication PCB.
3. N5500 responds to switch press, but key press tone fails to sound.	1. Check Key Beep volume setting in Set-up menu. 2. Ensure 30 pi speaker wire is connected to rear communication PCB. 3. If problem persists, replace 30 pi speaker assembly. 4. Check the flat cable between Main PCB and rear communication PCB. 5. If problem persists, replace Main PCB assembly. 6. If problem persists, replace rear communication PCB.

5.5.5 Operational Performance

Table 18 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.

Table 18. Operational Performance Problems

Symptom	Recommended Action
1. Monitor appears to be operational, but physiological values are suspect or nonexistent.	1. Replace each patient cable (or hose) with a known serviceable cable. 2. Ensure internal ECG, temperature, and SpO_2 cables are connected to main PCB assembly. Ensure hoses in pneumatic system are properly connected, and NIBP pump motor is connected to power supply PCB assembly. 3. If problem persists, replace main PCB assembly.
2. Printer paper will not advance.	1. Open printer door and check paper is present. 2. If problem persists, ensure printer wire is connected to SpO_2 PCB assembly. 3. If problem persists, replace printer.
3. Printer paper will advance, but paper remains blank when printing should be present.	1. Open printer door and check paper is oriented correctly. 2. If problem persists, replace printer.

5.5.6 Error Codes

When the N5500 detects an error condition, the monitor will attempt to show an error code on the display screen.

If such an error occurs during monitoring operation, the monitor will sound a low-priority alarm. Audible alarm can be terminated by pressing Alarm silence/suspend switch, but it depends on error codes and conditions.

Table 19 provides a complete list of error codes and problem identification.

If an error code occurs, take the following actions:

1. Turn monitor off, then on again.

Note: If error code still appears, take monitor out of service and contact Nellcor Technical Services or your local Nellcor representative for advice on remedial action.

Table 19. Technical Error Codes

Error Codes	Explanation
EEE001	SpO_2 module RAM error
EEE002	SpO_2 module ROM/code integrity error
EEE003	SpO_2 module Bad CRC in communications
EEE004	SpO_2 module Bad communication message
EEE005	$SpO_2$2 module Communication error, incorrect value
EEE006	SpO_2 module Calibration (offset) failure
EEE009	SpO_2 module Syntax communication error
EEE010	SpO_2 module Sensor error
EEE012	SpO_2 module other hardware problem
EEE017	SpO_2 module Indicator that sensor appears defective
EEE050	SpO_2 module Intermittent error
EEE051	SpO_2 module DigiCAL communication error
EEE255	SpO_2 module Invalid jumper selection
EEE256	SpO_2 module Beginning of Packet missing
EEE257	SpO_2 module Packet Start (SID) missing
EEE258	SpO_2 module Packet Length error
EEE259	SpO_2 module Message Length error
EEE260	SpO_2 module Packet contains unsupported Key
EEE261	SpO_2 module Packet CRC error
EEE262	SpO_2 module End of Packet missing
EEE263	SpO_2 module Packet contains undefined Key
EEE267	SpO_2 module Corrupted variable
EEE265	SpO_2 module Memory overflow
EEE266	SpO_2 module Bad Pointer
EEE267	SpO_2 module Parameter Value out-of-range
EEE268	SpO_2 module Reset detected
EEE269	SpO_2 module Unexpected value
EEE270	SpO_2 module Time out
EEE271	SpO_2 module Not ready/Not initialized
EEE272	SpO_2 module Double fault
EEE273	SpO_2 module Data out of range error
EEE274	SpO_2 module Incompatible digical sensor
EEE275	SpO_2 module Incorrect registration number
EEE275	SpO_2 module Sensor read failure
EEE277	SpO_2 module Sensor signature verification fails
EEE281	SpO_2 module Overflow/Underflow
EEE282	SpO_2 module Sensor activation failure
EEE283	SpO_2 module Sensor write failure
EEE284	SpO_2 module Both HW and SW ECG triggers received
EEE285	SpO_2 module Host attempted read or close of sensor trend before successful open
EEE286	SpO_2 module Host attempted redundant open of sensor trend

Error Codes	Explanation
EEE287	SpO_2 module Sensor trend data unavailable for reading by Host
EEE288	SpO_2 module No more sensor trend data available for reading by Host
EEE289	SpO_2 module Sensor Private label/Host sensor Key incompatible
EEE700	NIBP module RAM error
EEE701	NIBP module ROM error
EEE702	NIBP module Different mode settings between the monitor and the module, i.e. Adult mode is set in the N5500 during Neonatal mode set in the NIBP module
EEE703	NIBP module Improper reset response
EEE704	NIBP module Busy response
EEE705	NIBP module Single failure message
EEE706	NIBP module Zero pressurization message
EEE707	NIBP module No initialization
EEE708	NIBP module error*
EEE801	Analog system ECG&Respiration module error*
EEE802	Analog system Temperature module error*
EEE803	Analog system error*
EEE804	Analog system SpO_2 module communication error*
EEE901	ARM Exception – Undefined instruction trap*
EEE902	ARM Exception – Software interrupt*
EEE903	ARM Exception – Prefetch abort*
EEE904	ARM Exception – Data abort*
EEE905	Printer communication error*
EEE906	Battery status checking error*
EEE907	RTC error*

Note: An asterisk (*) by an error code explanation in the above table indicates that an audible alarm occurred by the error code cannot be silenced by pressing Alarm silence/suspend switch.

Section 6: Disassembly Guide

WARNING: Performance Verification. Do not place the N5500 into operation after repair or maintenance has been performed, until all Performance Tests and Safety Tests listed in Section 3 of this service manual have been performed. Failure to perform all tests could result in erroneous monitor readings.

WARNING: Before attempting to open or disassemble the N5500, disconnect the power cord from the N5500.

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.

6.1 General

This section describes disassembly procedures detailed disassembly instructions and accompanied by illustrations. Disassembly Sequence Flow Chart that is used to access replaceable parts of the N5500 is illustrated in Figure 7. The boxes on the flow chart represent the various components or sub-assemblies. A complete listing of the available spare parts and part numbers is in **Spare Parts** section. Follow the reverse sequence of the disassembly procedures for reassembly.

The N5500 can be disassembled down to all major component parts, including:

- PCB assemblies
- acquisition modules, SMPS & LCD
- battery
- cables
- brackets & cases
- printer

The following tools are required:

- small, Phillips-head (+) screwdriver
- medium, Phillips-head (+) screwdriver
- needle-nose pliers

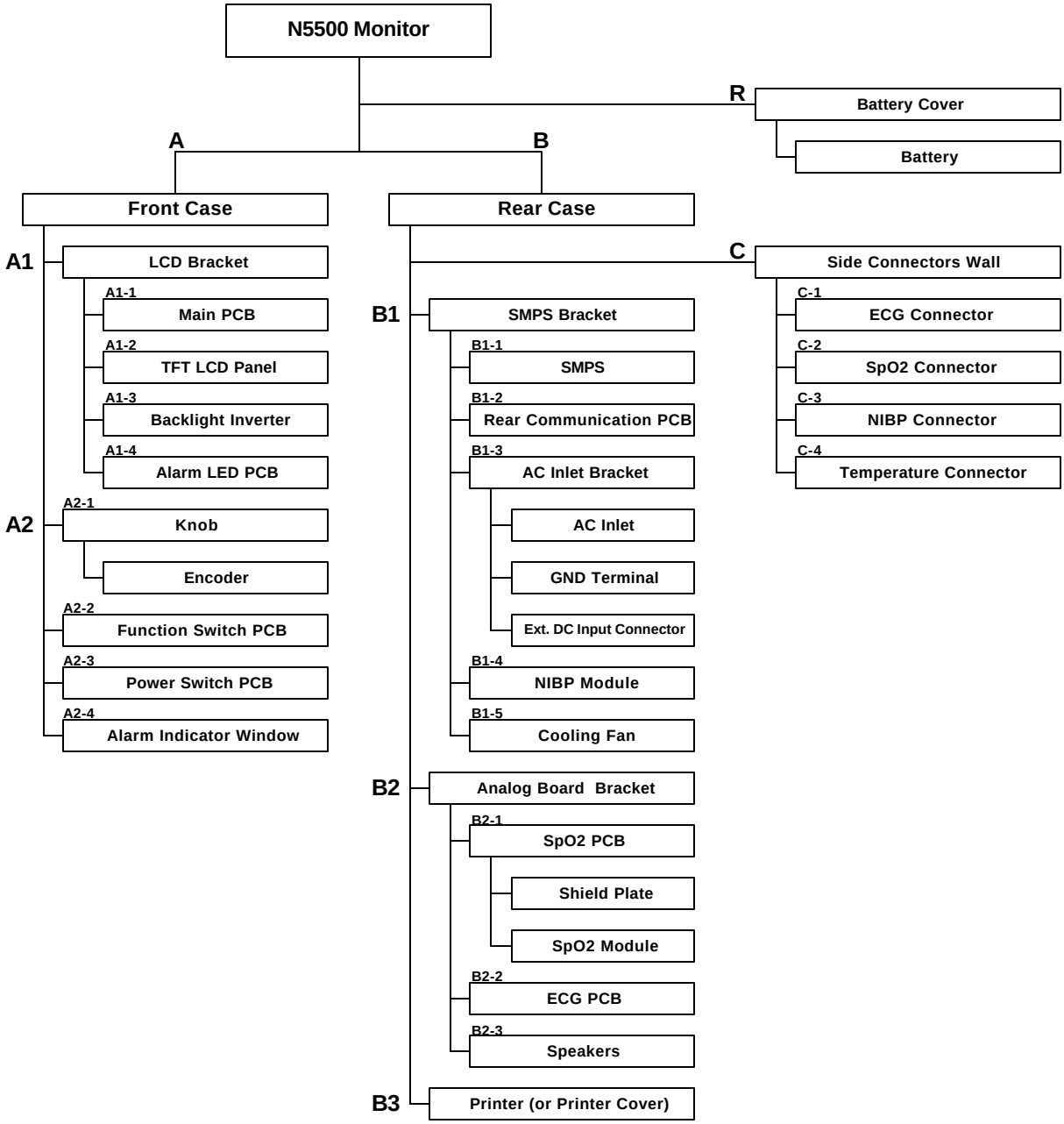


Figure 7. Disassembly Sequence Flow Chart

6.2 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, to replace the PCB with a known good PCB. Check to see if the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started trouble shooting) and continue troubleshooting as detected in this section.

6.3 Prior to Disassembly

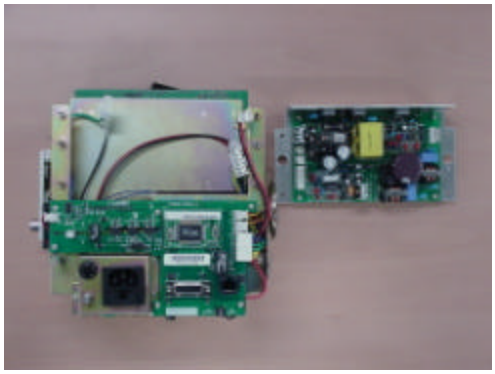
1. Turn the N5500 off by pressing the Power On/Off switch.

2. Disconnect the monitor from the AC power source

6.4 Fuse Replacement

This section describes the fuse replacement without disassembling the main case of the monitor.

AC Inlet Fuse Replacement	
	a. Push the fuse socket latch of the AC inlet slightly down.
	b. Pull the socket out from the inlet.

	c. Remove a fuse from the socket, then replace a new fuse (250V/4A).
Battery Fuse or External DC Fuse Replacement	
	a. Step B2-1, SMPS disassembly
	b. Ensure a blown fuse F1: External DC Fuse (250V/6.3A) F2: Battery Fuse (250V/6.3A)
	c. Replace a new fuse (250V/6.3A), then reassembly the SMPS in following the reverse sequence of the fuse replacement instructions.

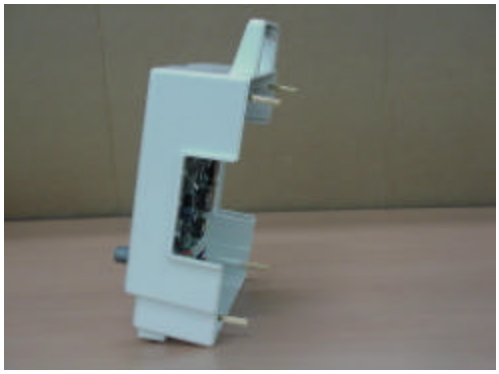
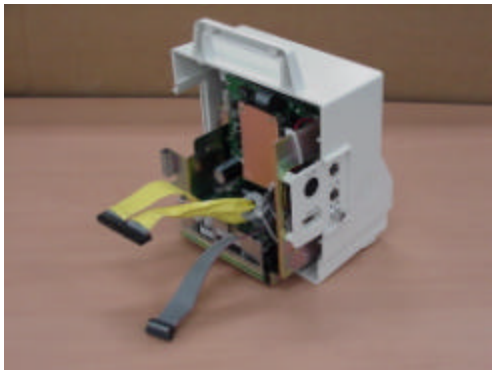
6.5 Battery Disassembly

This section describes the steps to remove the battery from the N5500 for replacement without disassembling the main case of the monitor

R. Battery Disassembly	
	a. Remove 2 screws on the lower part of the rear case, holding the Battery cover to the rear case.
	b. Remove the Battery cover. c. Disconnect the Battery wire.
	d. Remove the Battery.

6.6 Monitor Disassembly

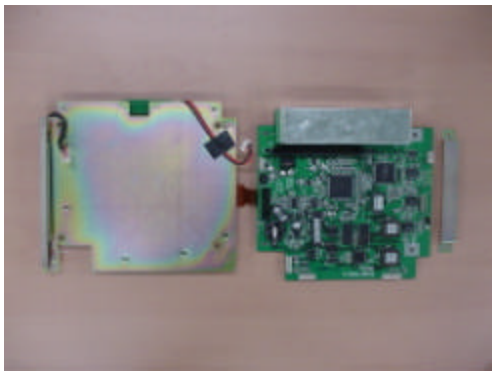
This section describes the steps to separate the front and rear case assemblies.

Before the steps A and B;	
	a. Remove the monitor's 6 screws.
	b. Separate the front case from the rear case. c. Turn down the grabbers of the Main board cable connector on the Main PCB to disconnect the Main board cable from the Main PCB. d. Disconnect the NIBP cable from the Main PCB.
 	

6.7 Front Case Disassembly Procedures

This section describes the items that may be removed on the front case assembly.

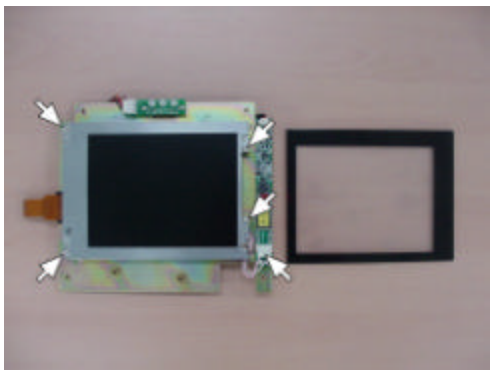
A. Front Case Disassembly	
A1. To remove the LCD Bracket from the front case	
	a. Disconnect the Encoder wire, the Function switch board wire and the Power switch board wire from the Main PCB. b. Remove 4 corner screws on the LCD Bracket.
	c. Remove the LCD Bracket from the front case.
A1-1. Main PCB Disassembly	
	a. Disconnect the Inverter wire and the LED Board wire from the Main PCB. b. Remove 4 screws on the Main PCB. c. Remove the Bridge bracket from the Main PCB. d. Remove the LCD cable from the Main PCB.



CAUTION:
Be careful of disconnecting the LCD cable because the LCD connector cover is weak.

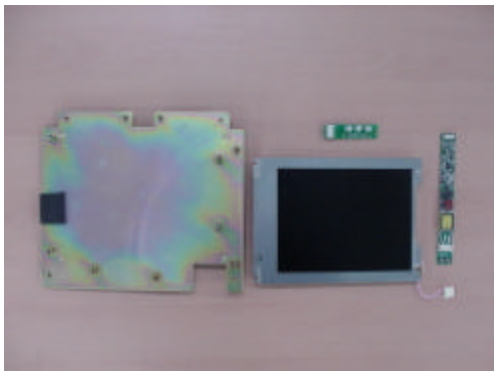
A1-2. TFT LCD Panel Disassembly

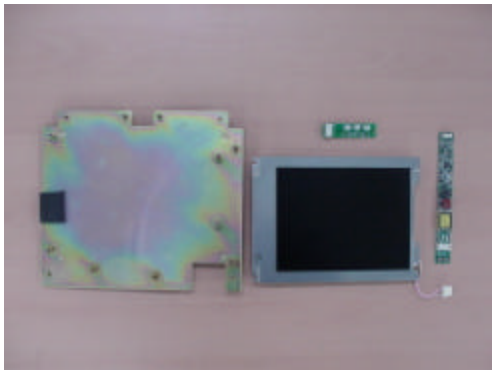
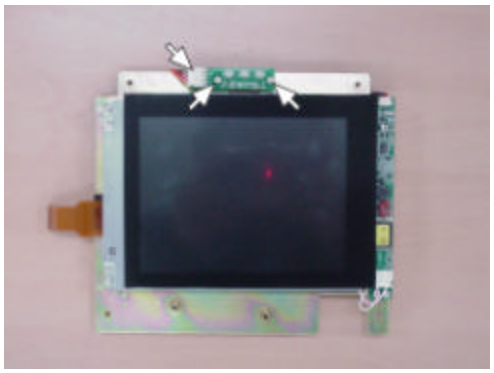
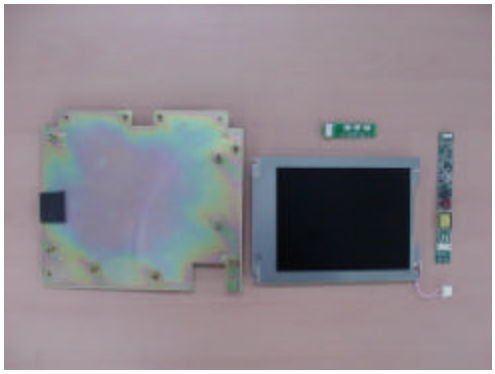
a. Remove the LCD window from the LCD panel.

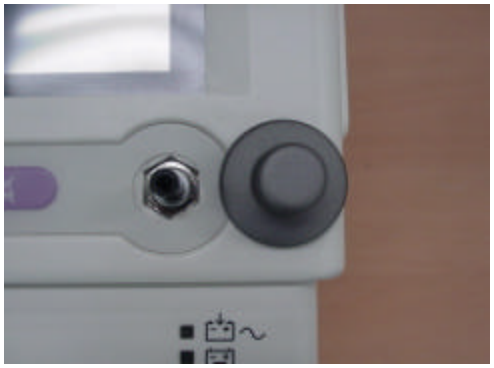
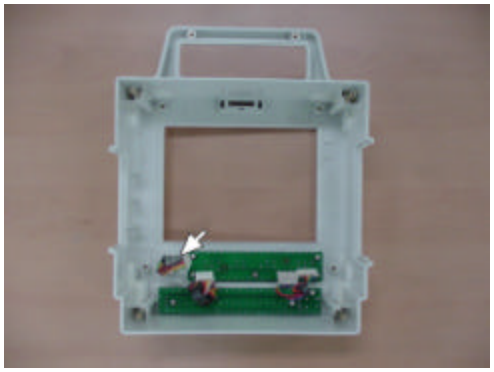
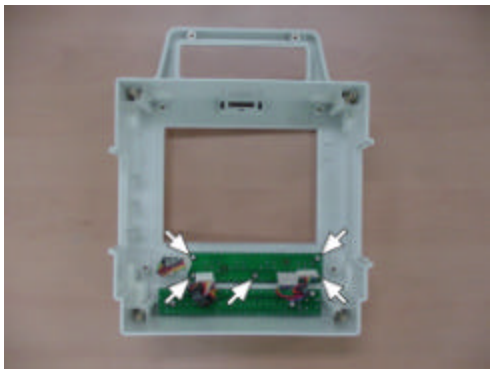
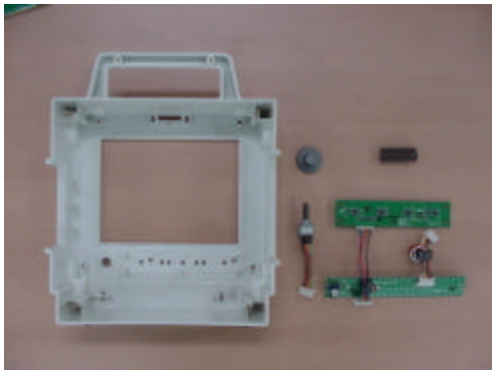


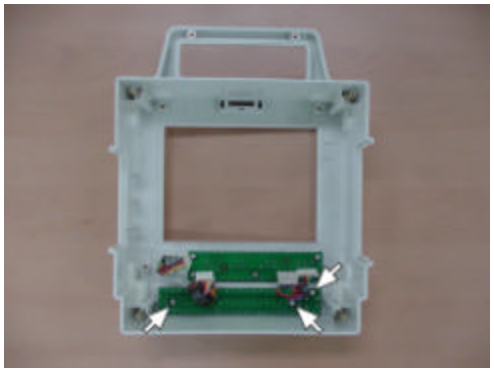
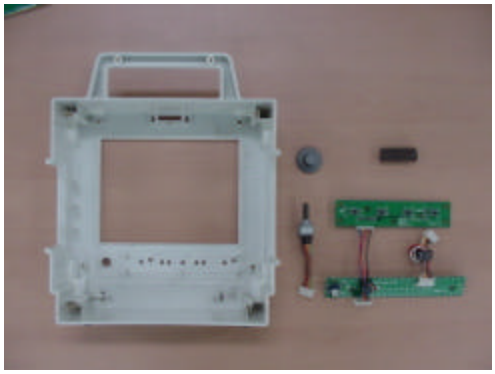
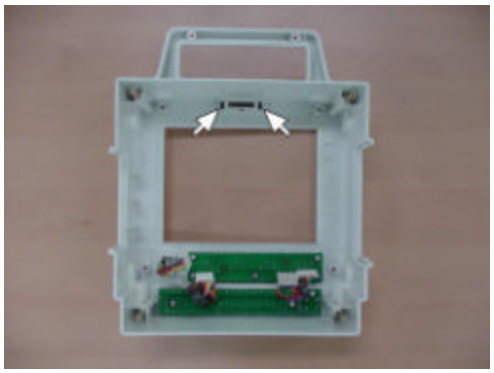
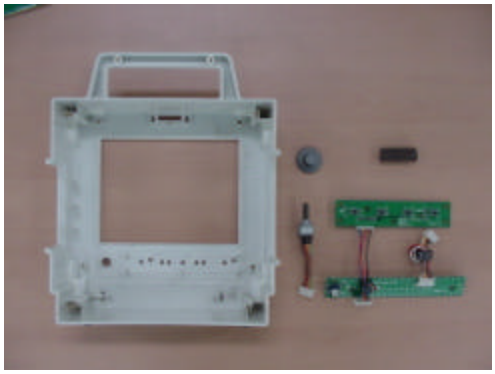
b. Disconnect the LCD backlight wire from the LCD panel.

c. Remove 4 screws on the LCD panel.



A1-3. LCD Backlight Inverter Disassembly	
	a. Disconnect the LCD backlight wire and the Inverter wire from the Backlight inverter. b. Remove 3 screws on the Backlight inverter
	
A1-4. Alarm LED PCB Disassembly	
	a. Disconnect the Alarm LED board wire from the Alarm LED PCB. b. Remove 2 screws on the Alarm LED PCB.
	

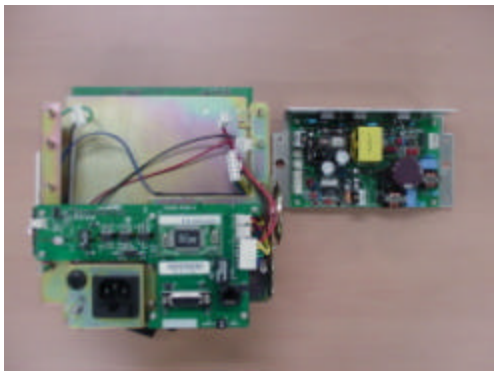
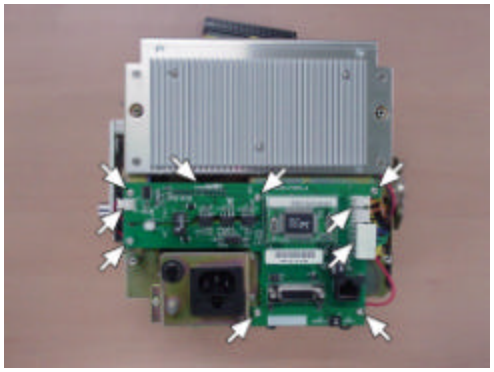
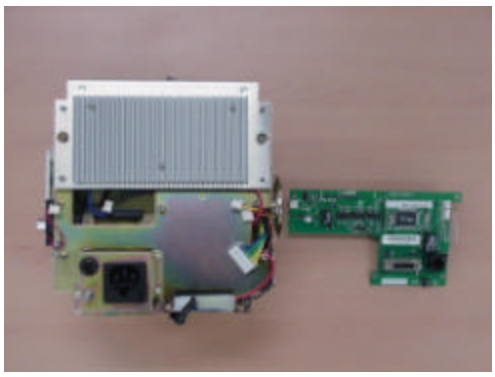
A2-1. Knob, Encoder Disassembly	
	a. Pull the Knob straight out from the front case. **CAUTION:** Be careful when pulling the Knob because the Encoder may be damaged.
	b. Turn the Encoder to the left in order to remove the Encoder from the front case.
A2-2. Function Switch PCB Disassembly	
	a. Remove 5 screws on the Function switch PCB.
	

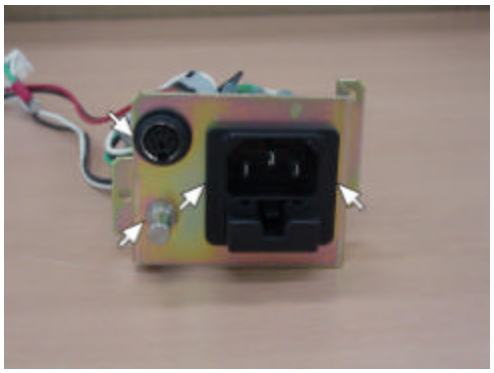
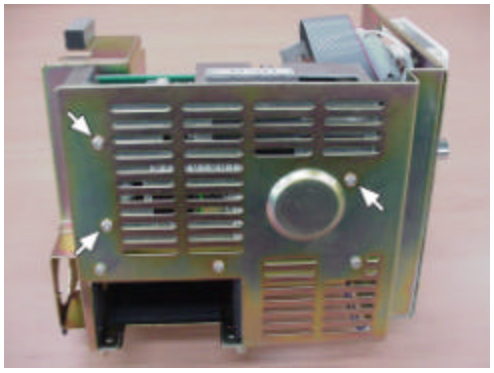
A2-3. Power Switch PCB Disassembly	
	a. Remove 3 screws on the Power switch PCB.
	
A2-4. Alarm Indicator Window Disassembly	
	a. Push the latches slightly to remove the Alarm indicator window.
	

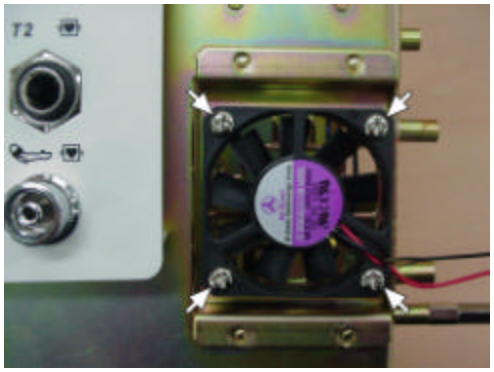
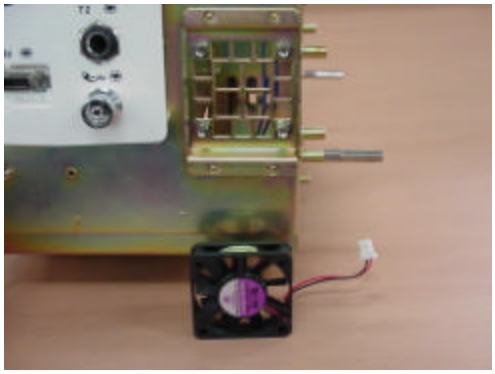
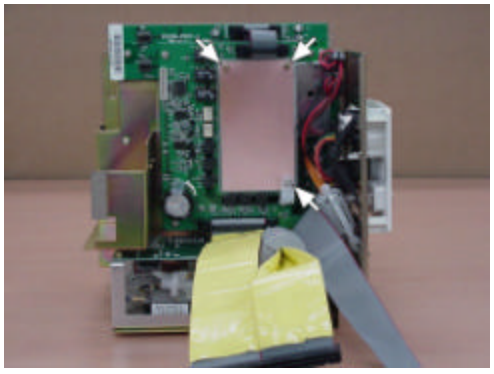
6.8 Rear Case Disassembly Procedures

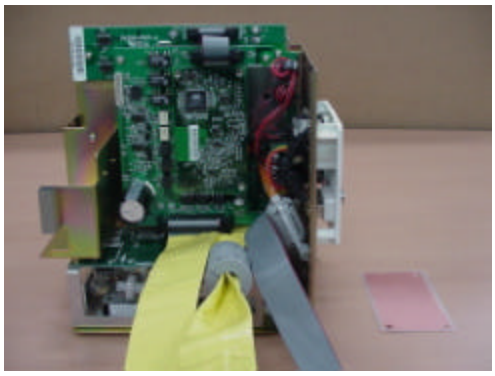
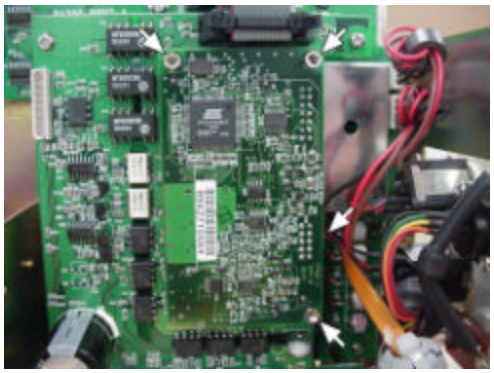
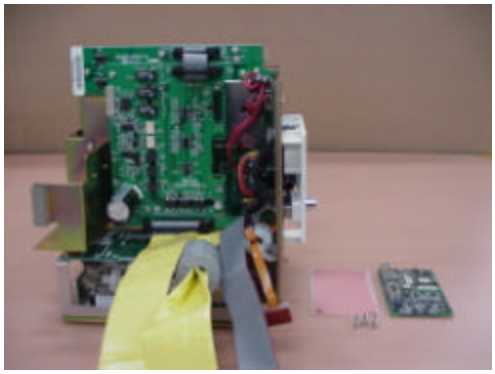
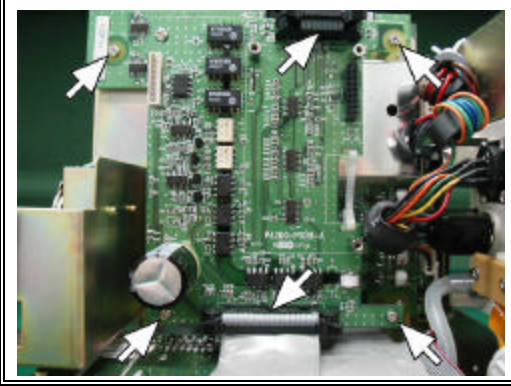
This section describes the steps to disassemble the rear case assembly.

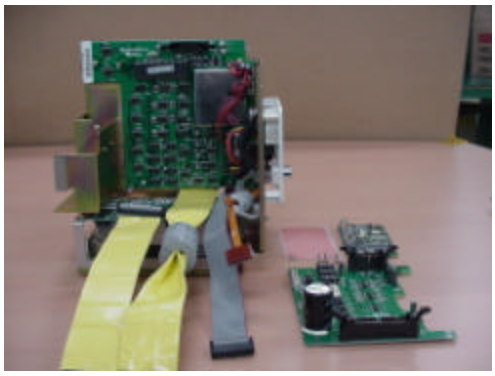
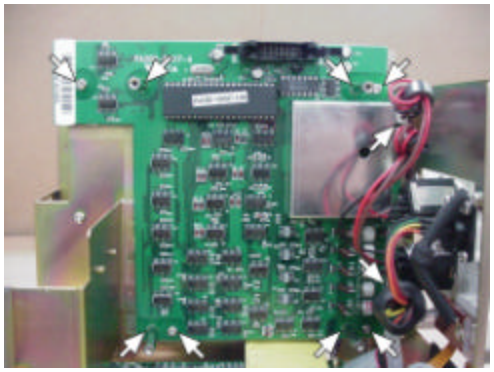
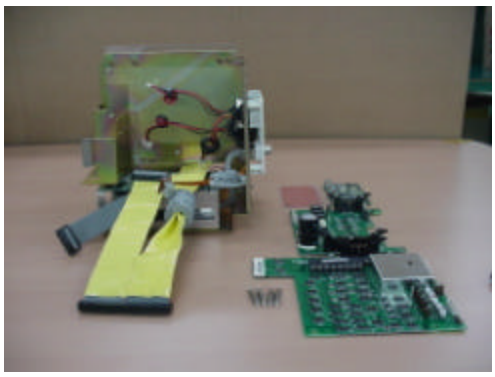
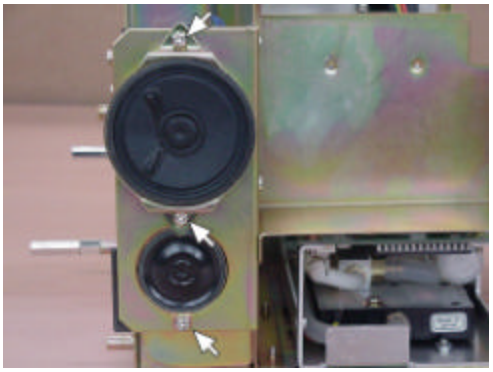
B. Rear Case Disassembly	
B1. SMPS Bracket Disassembly	
	a. Remove 4 screws and washers on the rear case.
	b. Separate the rear case from the rear case assembly.
B1-1. SMPS Disassembly	
	a. Remove 4 corner screws on the SMPS. b. Disconnect the AC inlet wire and the SMPS to Rear board DC wire, the Battery wire and the External DC input wire from the SMPS.

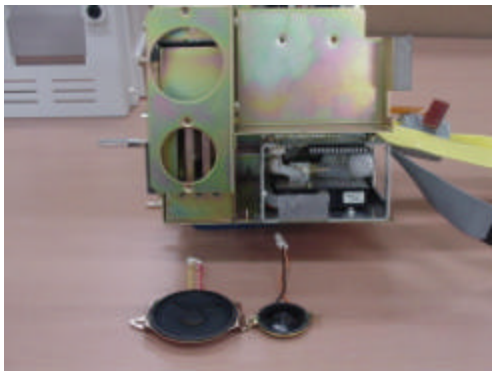
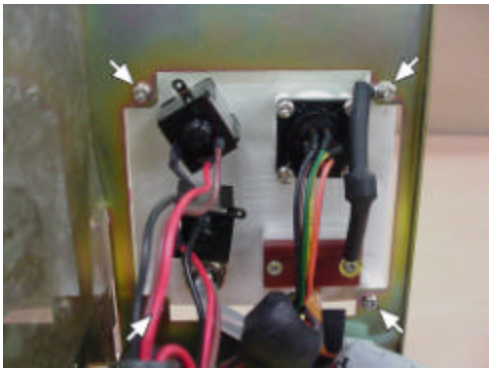
	
B1-2. Rear Communication PCB Disassembly	
	a. Remove 6 screws on the Rear communication PCB. b. Disconnect the Main board cable, the SMPS to Rear board DC wire, the Speaker wires and the Fan wire from the Rear communication PCB.
	
B1-3. AC Inlet Bracket Disassembly	
	a. Remove 3 screws on the AC inlet bracket.

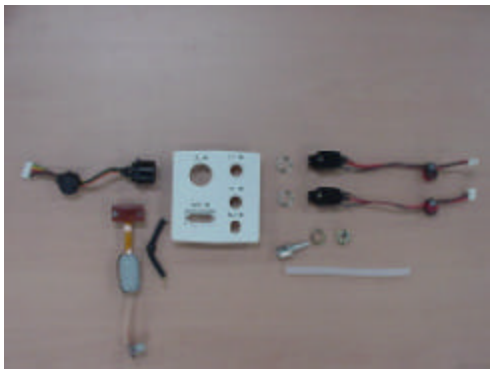
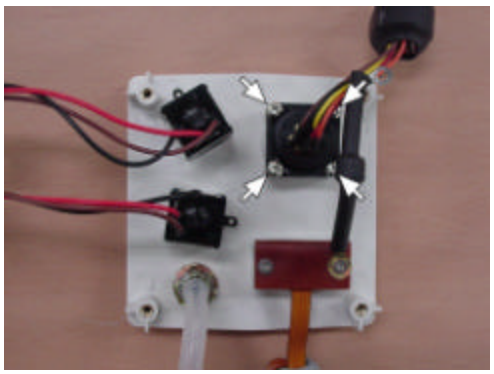
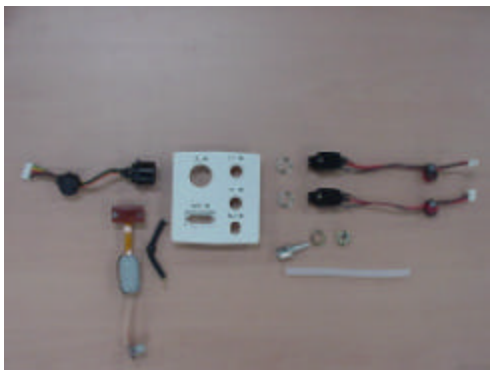
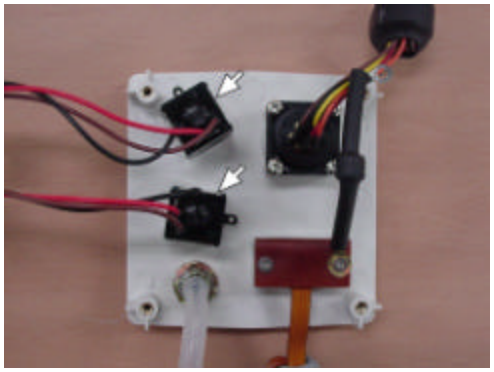
	b. A nut is firmly on the back of the External DC input connector. Turn the nut to the left in order to remove it. A nut is firmly on the back of the GND terminal. Turn the nut to the left in order to remove it. c. Push both side of the latches on the AC inlet slightly to remove the AC inlet.
	
B1-4. NIBP Module Disassembly	
	a. Remove 3 screws on the SMPS bracket.
	b. Remove the NIBP hose from the NIBP module. c. Remove the NIBP module from the SMPS bracket.

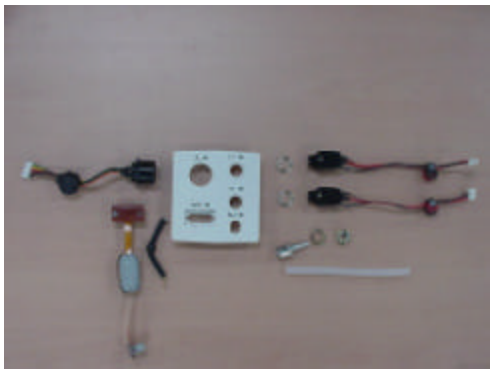
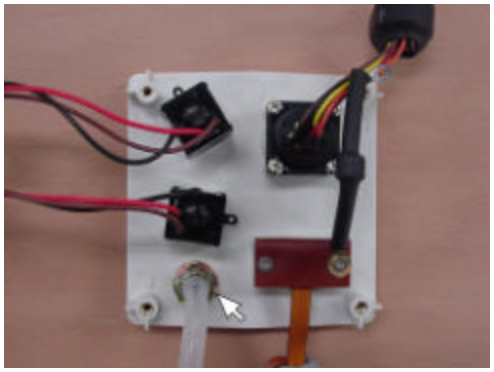
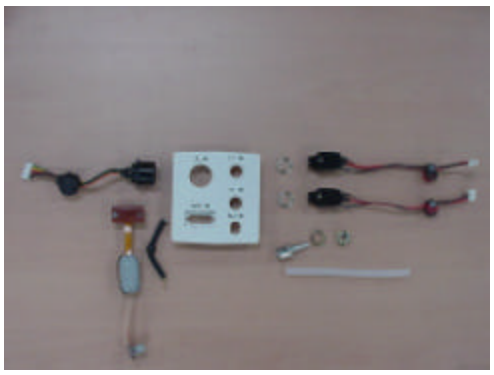
B1-5. Cooling Fan Disassembly	
	a. Remove 4 corner screws on the cooling fan.
	b. Remove the cooling fan from the SMPS bracket.
B2. Analog Bracket Disassembly	
B2-1. SpO_2 module and SpO2 PCB Disassembly	
	a. Remove 3 screws on the Shield plate.

	b. Remove the Shield plate from the SpO_2 module.
	c. Remove 3 PCB supporters on the SpO_2 module. d. Remove the PI cable from the SpO_2 module.
	e. Remove the SpO_2 module
	f. Turn down the grabbers of the Main board cable connector and the Analog board cable connector on the rear PCB. g. Disconnect the Main board cable and the Analog board cable.

	h. Remove the SpO_2 PCB.
B2-2. ECG PCB Disassembly	
	a. Disconnect the ECG wire and the Temperature wires from the ECG PCB. b. Remove 4 corner screws on the ECG PCB. c. Remove the PCB supporters on the ECG PCB.
	d. Remove the ECG PCB.
B2-3. Speakers Disassembly	
	a. Remove 2 screws on both side of each speaker.

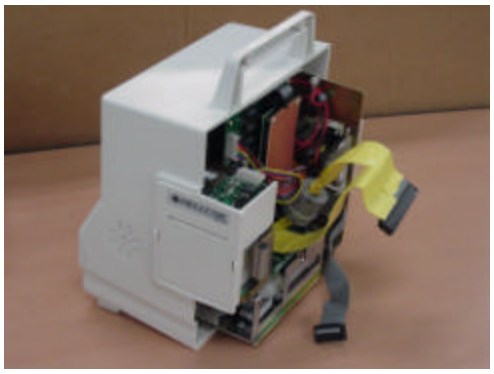
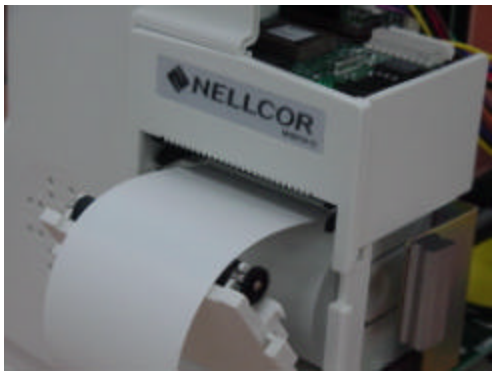
	b. Remove the speakers from the Analog Board bracket.
C. Side Connectors Wall Disassembly	
	a. After the SMPS bracket and the Analog Boards are disassembled, as described in B1 and B2, remove 4 corner screws fastening the Side connectors wall to the SMPS bracket. b. Remove the Arrester Wire.
	c. Remove the Side connectors wall.
C-1. SpO_2 Connector Disassembly	
	a. Remove 2 screws on both side of the SpO_2 connector.

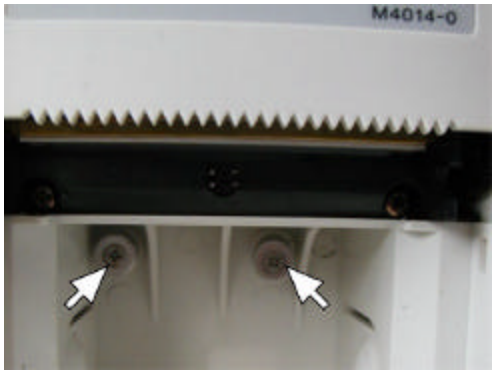
	b. Remove the SpO_2 connector from the Side connectors wall.
C-2. ECG Connector Disassembly	
	a. Remove 4 corner screws on the ECG connector.
	b. Remove the ECG connector from the Side connectors wall.
C-3. Temperature Connector Disassembly	
	a. Turn the Temperature connector to the left. Remove the Temperature connector from the Side connectors wall.

	
C-4. NIBP Connector Disassembly	
	a. Remove the NIBP hose from the NIBP connector. b. Turn to the left a nut fastening the NIBP connector.
	c. Remove the NIBP connector from the Side connectors wall.

6.9 Optional Printer Assembly/Disassembly Procedures

This section describes the steps that may remove an optional printer in the N5500. If you would like to install a printer, follow the reverse sequence of the procedures.

B3. Printer Disassembly	
	The rear case separated from the front case
	a. Disconnect the printer wire from the SpO_2 PCB and the Printer.
	b. Open the printer door and remove print paper.

B3. Printer Disassembly	
	c. Remove 2 screws inside the Printer door.
	d. Remove the Printer.

Section 7: Spare Parts

WARNING: Follow local government ordinances and recycle instructions regarding disposal or recycling of device components, including batteries.

7.1 Introduction

Spare parts, along with part numbers, are shown in Table 20. “Item No.” corresponds to the circled callout numbers in Figure 8.

7.2 Obtaining Replacement Parts

Nellcor Technical Service 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.

7.3 Parts List

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

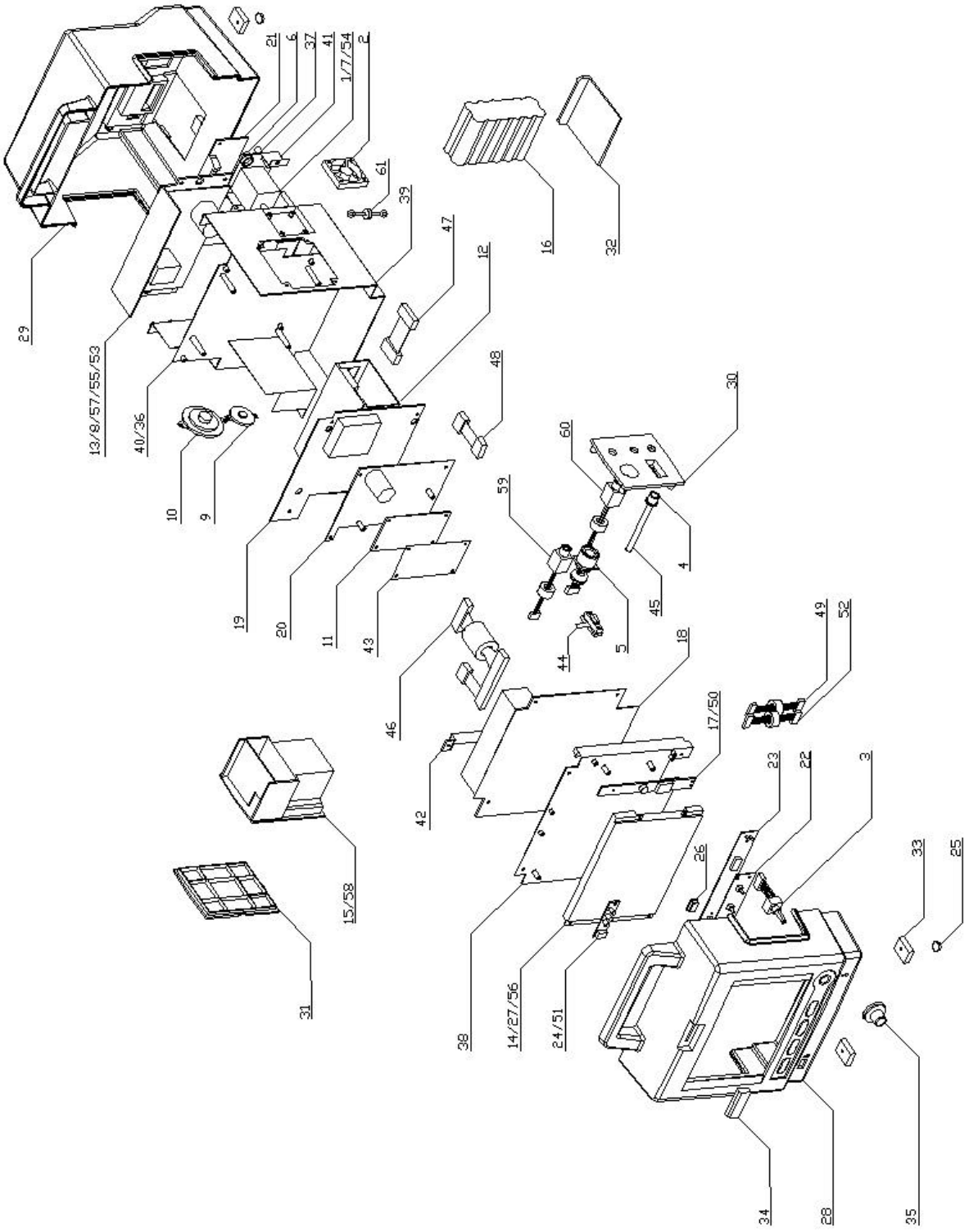


Figure 8. N5500 Exploded View

Table 20. N5500 Parts List

Item	Part Code	Description
1	E0001-0	Power Entry
2	E2006-0	Cooling Fan
3	E3006-0	Optical Encoder
4	E4074-0	Colin NIBP Connector
5	E4076-0	ECG Connector
6	E4077-0	External DC Input Connector
7	E8004-0	AC Inlet Fuse (250V/ T4A)
8	E8005-0	Battery Fuse (250V/ T6.3A)
9	E9004-0	Speaker 30pi
10	E9003-0	Speaker 50pi
11	M0001-0	NELLCOR SpO_2 Module
12	M0003-0	Colin NIBP Module
13	M2005-0	SMPS
14	M4012-0	LCD (6.4" TFT)
15	M4014-0	Printer
16	M6005-0	Battery
17	M8001-0	Backlight Inverter
18	P1016-0	Main Board
19	P1017-0	ECG Board
20	P1018-0	SpO_2 Board
21	P1019-0	Rear Communication Board
22	P1020-0	Function S/W Board
23	P1021-0	Power S/W Board
24	P1022-0	Alarm LED Board
25	S9000-0	Rubber Foot
26	T0015-0	Power On/Off Switch
27	T0055-0	LCD Window
28	T0056-0	Front Case
29	T0057-0	Rear Case
30	T0058-0	Side Connectors Wall
31	T0059-0	Printer Cover
32	T0060-0	Battery Cover
33	T0061-0	Foot
34	T0062-0	Alarm Indicator Window
35	T0063-0	Knob
36	T3029-0	Insulation
37	T4003-0	Ground Terminal
38	T4081-0	LCD Bracket
39	T4082-0	SMPS Bracket

Item	Part Code	Description
40	T4083-0	Analog BD Bracket
41	T4084-0	AC Inlet Bracket
42	T4085-0	Bridge Bracket
43	T4086-0	Shield Plate
44	W0019-0	PI Cable
45	W0062-0	Colin Inner Hose
46	W0064-0	Main BD Cable
47	W0065-0	NIBP Cable
48	W0066-0	Analog BD Cable
49	W0067-0	Function SW BD Wire
50	W0068-0	Backlight Inverter Wire
51	W0069-0	LED BD Wire
52	W0071-0	Power SW BD Wire
53	W0073-0	External DC Input Wire
54	W0074-0	AC Inlet Wire
55	W0075-0	Battery Wire
56	W0076-0	LCD Cable
57	W0077-0	SMPS to Rear BD DC Wire
58	W0078-0	Printer Wire
59	E4075-0	Temperature Connector, 3P
60	E4092-0	Temperature Connector, 4P
61	W0082-0	Arrester Wire

Section 8: Packing For Shipment

8.1 General Instructions

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

Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by the Nellcor warranty. If the original shipping carton is not available, use another suitable carton; North American customers may call Nellcor Technical Services to obtain a shipping carton.
Prior to shipping the monitor, contact your supplier or the local Nellcor office (Technical Services Department) for a returned goods authorization (RGA) number. Mark the shipping carton and any shipping documents with the returned goods authorization number.

Pack 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 N5500 by any method that provides proof of delivery.

8.2 Returning the N5500

Contact Nellcor Technical Services Department or your local Nellcor representative for shipping instructions, including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Nellcor Technical Services Department, it is not necessary to return the sensor or other accessory items with the monitor. Pack the N5500 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.

8.3 Repacking In Original Carton

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

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

2. Place in shipping carton and seal carton with packaging tape.

3. Label carton with shipping address, return address and RGA number, if applicable.

8.4 Repacking In a Different Carton

If the original carton is not available, use the following procedure to pack the N5500:

1. Place the monitor in a plastic bag.

2. Locate a corrugated cardboard shipping carton with at least 200 pounds per square inch (psi) bursting strength.

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.

Section 9: Specification

9.1 Display

Screen Size	130.56 mm × 97.92 mm (6.425 inch)
Screen Type/Color	Liquid Crystal Display (LCD) Color, Cold Cathode Fluorescent Backlit
Resolution	640 × 480 pixel
Number of traces	3 Waveforms (Maximum)

9.2 Controls

Standard	Trim Knob control; 5 soft switches (Power On/Off, NIBP start/stop, Record, Home, Alarm Silence/Suspend)

9.3 Alarms

Categories	Patient Status and System Status
Priorities	Low, Medium, and High Priorities
Notification	Audible and Visual
Setting	Default and Individual

9.4 Physical

Instrument	
Dimensions	230×230×275 (mm) (W×D×H) including a handle and excluding options and accessories
Weight	5.0 (kg) excluding options and accessories
Printer (Optional)	
Type	Thermal
Weight	0.4 (kg)
Resolution	200 dpi (8 dot/mm)
Number of channels	1 to 2 channels
Paper Width	50 mm
Paper Speeds	25.0 mm/s and 50.0 mm/s

9.5 Electrical

Instrument	
Power Requirements	AC Mains 100Vac to 240Vac, 50 Hz/60 Hz, 63 to 110 VA, 1A Max
Fuses	qty 2, 4.0 A, 250 volts, slow-blow, IEC (5×20 mm)
Battery	
The battery provides 1 hour of battery operation when fully charged with no printing and one NIBP measurement per 5 minutes at typical 25° C.	
Type	NI-MH
Voltage/Capacity	14.4 V/ 3.6 Ampere-Hours
Recharge	14 hours with N5500 turned off 18 hours with N5500 operating
Shelf Life	2 months, new fully charged battery
Complies with	91/157/EEC

9.6 Environmental Conditions

Operation	
Temperature	5° C to 40° C
Humidity	15 % RH to 95% RH, non-condensing
Altitude	0 ft to 10,000 ft (0 m to 3,048 m)
Transport and Storage (not in shipping container)	
Temperature	– 20 ° C to 50 ° C
Humidity	15 % RH to 95% RH, non-condensing
Altitude	– 1,280 ft to 15,000 ft (– 390 m to 4,572 m)
Transport and Storage (in shipping container)	
Temperature	– 20° C to 60° C
Humidity	15 % RH to 95% RH, non-condensing
Altitude	– 1,280 ft to 15,000 ft (– 390 m to 4,572 m)

Note: The system may not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity range.

9.7 Measurement Parameters

ECG

Heart Rate	
Measurement Range	20 BPM to 250 BPM
Accuracy	±3 BPM or ±5%, whichever is greater
ECG (Electrocardiograph)	
Leads	3 / 5 Lead, user selectable I, II, III, V, aVR, aVL, aVF
Lead Off Detection	Detected and displayed
Input	
Input Dynamic Range	±5 mV AC, ±300 mV DC
Voltage Range	±0.5 mV to ±5 mV
Signal Width	40ms to 120ms (Q to S)
ECG (Electrocardiograph)	
Output	
Frequency Response (Bandwidth)	
Low Extend	0.05 Hz to 40 Hz
Filter	0.5 Hz to 30 Hz
Monitor	0.5 Hz to 40 Hz
ECG Size (sensitivity)	1.25, 1.7, 2.5, 5.0, 7.5, 10.0, 15.0, 20.0 *(mm per 1mV)*
Display Sweep Speeds	12.5 mm/sec, 25.0 mm/sec, and 50.0 mm/sec
Pacemaker Detection	Indicator on waveform display (user selectable)
Defibrillator Discharge Recovery	< 5 sec per IEC601-2-27

Respiration rate

Technique	Trans-thoracic impedance
Range	3 breaths/min to 120 breaths/min
Accuracy	±3 breaths/min
Leads	RA to LA
Display Sweep Speeds	6.25 mm/s, 12.5 mm/s, 25.0 mm/s
Lead Off Condition	Detected and displayed

NIBP

Pulse Rate	
Pulse Rate Range	Adult/Pediatric 30 BPM to 180 BPM Neonatal 30 BPM to 240 BPM
Pulse Rate Accuracy	±2 BPM or ±2%, whichever is greater
NIBP (Non-Invasive Blood Pressure)	
Technique	Oscillometric Measurement
Measurement modes	AUTO, MANUAL and STAT
AUTO Mode	Automatic BP measurements at intervals of 1, 3, 5, 10, 15, 30, 60, and 90 minutes
MANUAL Mode	Single measurement initiated by *NIBP Start/Stop switch*
STAT Mode	Series of consecutive measurements for 5 minutes
NIBP pressure measuring range	
Systolic pressure range	Adult/Pediatric: 60 mmHg to 250 mmHg Neonatal: 40 mmHg to 130 mmHg
Diastolic pressure range	Adult/Pediatric: 40 mmHg to 220 mmHg Neonatal: 20 mmHg to 90 mmHg
Mean pressure range	Adult/Pediatric: 45 mmHg to 235 mmHg Neonatal: 35 mmHg to 105 mmHg
Pressure Display Range	Adult/Pediatric: 10 mmHg to 300 mmHg Neonatal: 5 mmHg to 150 mmHg
Pressure Display Accuracy	Mean error and standard deviation per ANSI/AAMI SP10:1992+A1:1996
Pressure Sensor Accuracy	±3 mmHg or ±2% of reading, whichever is greater, per ANSI/AAMI SP10:1992+A1:1996
Initial Cuff Inflation	Adult/Pediatric: 100, 120, 140, 160, 180, 200, 220, 240, 260, 280 mmHg Neonatal: 50, 60, 70, 80, 90, 100, 110, 120, 130, 140 mmHg
Subsequent cuff inflation	Prev SYS +50 mmHg AUTO Mode (for Adult) Prev SYS +30 mmHg AUTO Mode (for Neonatal)
Automatic cuff deflation	Measurement time exceeding 180s in adult/pediatric (90s in neonatal) or maximum pressure value exceeding 300 mmHg in adult/pediatric (150 mmHg in neonatal).
Overpressure protector	320 ±10 mmHg for Adult/Pediatric 160 ±5 mmHg for neonatal
Standards	Meets performance standards of ANSI/AAMI SP10:1992+A1:1996

Note: Systolic and diastolic blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or automated sphygmomanometers.

SpO_2

%Saturation	
Range	1% to 100%
Low Perfusion	0.03% to 20%
Accuracy	Without Motion-Adults[1] 70% to 100% ±2 digits Without Motion-Neonate[1] 70% to 100% ±3 digits 1% to 69% unspecified With Motion[2] -Adults/Neonate 70% to 100% ±3 digits Low Perfusion[3] 70% to 100% ±2 digits 1% to 69% unspecified
Display Sweep Speeds	12.5 mm/sec, 25.0 mm/sec, and 50.0 mm/sec
Pulse Rate	
Range	20 BPM to 250 BPM
Accuracy	Without Motion[3] 20 BPM to 250 BPM ±3 digits With Motion normal physiologic range (55 to 125 BPM) ±5 digits Low Perfusion[3] 20 BPM to 250 BPM ±3 digits

[1]Adult specification are shown for OxiMax MAX-A and MAX-N sensors with the N5500. Neonate specifications are shown for OxiMax MAX-N sensors with the N5500. Saturation accuracy will vary by sensor type.

[2]Applicability(accuracy with motion): OxiMax sensors.

[3]Specification applies to monitor performance and was validated with Biotek and Nellcor simulators

Temperature

Probe Type	Thermistor probe (Monotherm™ temperature probes)
Parameter displayed	T1, T2
Range	15° C to 45° C
Display Accuracy	±0.1° C (25° C to 45° C) ±0.2° C (15° C to less than 25° C)
Probe Accuracy	±0.1° C

9.8 Trends

Types	Graphical and Tabular
Memory Storage	24 hours, nonvolatile, 20 seconds data interval
Graphical Format	One graph for all parameters Also user-selectable each parameter to be desired
Display Range	2 hours
Tabular Format	One table for all variables. 18 rows (date, parameter labels, and 16 variable rows)
Display Time Interval	20 sec, 1 min, 2 min, 3 min, 5 min, 10 min, 15 min, 20 min

9.9 Compliance

Item	Compliant with
Classification	Class I (on AC power) Internally powered (on battery power)
Type of protection	Type CF – Applied part
Mode of operation	Continuous
Resistant to liquid	Class IPX1 Drip-proof equipment
General Safety	IEC60601-1:1998+A1:1991+A2:1995 General requirements for Safety and Essential Performance
	IEC60601-2-49:2001 Particular requirements for the Safety of Multifunction patient equipment
	IEC60601-1-1:2000 Safety requirements for medical electrical systems
Alarms	EN475:1995 Electrically – generated alarm signals
	IEC60601-1-8:2001 Draft Alarm systems requirements, tests and guidances in medical electrical equipments systems
Electrocardiograph	IEC60601-2-27:1994 Particular requirements for the safety of Electrocardiographic monitoring equipment
	AAMI EC53:1995+A1:1998 ECG cables and leadwires
Non-invasive Blood Pressure	AAMI SP10:1992+A1:1996 Electronic or Automated Sphygmomanometers
	EN1060-1:1995 Non-invasive sphygmomanometers
	EN1060-3:1997 Supplementary requirements for electrical-mechanical blood pressure measuring systems
	IEC60601-2-30:1999 Particular requirements for the Safety, including essential performance, of automatic cycling indirect blood pressure monitoring equipment
Oxygen saturation	EN865:1997 Pulse oximeters, Particular requirements
	ASTM F 1415:1992 Standard specification for Pulse oximeters
	ISO9919:1992 Pulse oximeters for medical use-requirements
	ISO/W 9919:2001 Draft Basic safety & essential performance of Pulse oximeter for medical use
Temperature monitoring	EN12470-4:2001 Performance of Electrical Thermometers for continuous Measurement

Item	Compliant with
Electromagnetic Compatibility	IEC 60601-1, sub clause 36, IEC/ IEC60601-1-2:1993 Electromagnetic compatibility-requirements & test
	IEC61000-3-2 Harmonic Emmision
	IEC61000-3-3 Voltage Fluctations/Fliker Emission
	IEC61000-4-2 Electrostatic Discharge
	IEC61000-4-3 Radiated RF electromagnetic field
	IEC61000-4-4 Electrical fast transient/burst
	IEC61000-4-5 Surge current
	CISPR 11 (EN55011) RF Emissions Group 1, Class B
Reliability	IEC60068-2-6, IEC60068-2-34 Environmental testing -Vibration
	IEC60068-2-27 Environmental testing - Shock
Labeling	EN1041:1998 Information supplied by the manufacturer with medical devices
Marking	IEC 60878, EN 980, ISO 7000, EN 60417-1, EN 60417-2
button spacing	ISO 7250

Section 10: System Processing Description

10.1 System Overview

The N5500 patient monitor is a multi-function monitor for use on adult, pediatric and neonatal patients; ECG, heart rate, non invasive blood pressures, arterial oxygen saturation, pulse rate, respiration rate and temperature.
In addition to monitoring and displaying the status of these physiological parameters, the instrument performs various microprocessor-programmed analytical functions;

- Creating both visual and audible alarm signals when settable limits are violated;
- Creating and displaying warning/error messages when conditions are detected that would degrade or prevent valid measurements;
- Creating and displaying graphical or tabular trend data;
- Providing input to an optional recorder for printout of current or tabular trend data.

The monitor is essentially a battery-powered instrument. An internal charging unit is designed to accept only an AC line voltage.

10.2 System Block Diagram

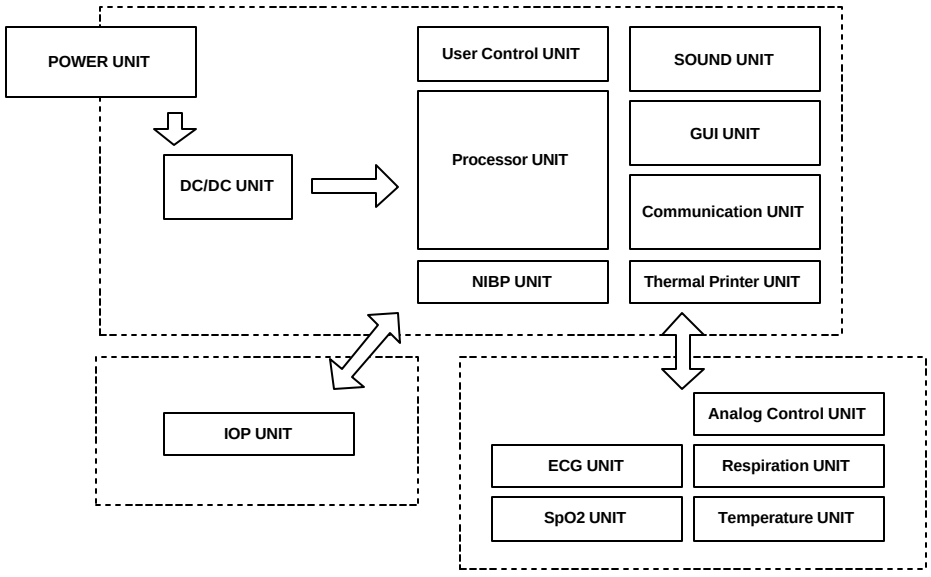


Figure 9. N5500 System Block Diagram 1

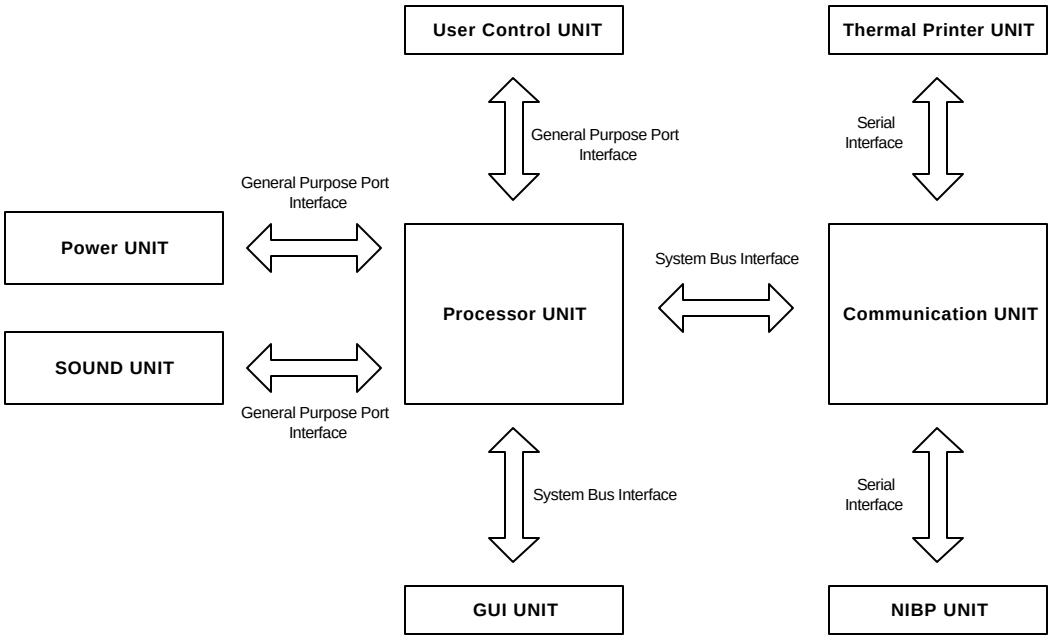


Figure 10. N5500 System Block Diagram 2

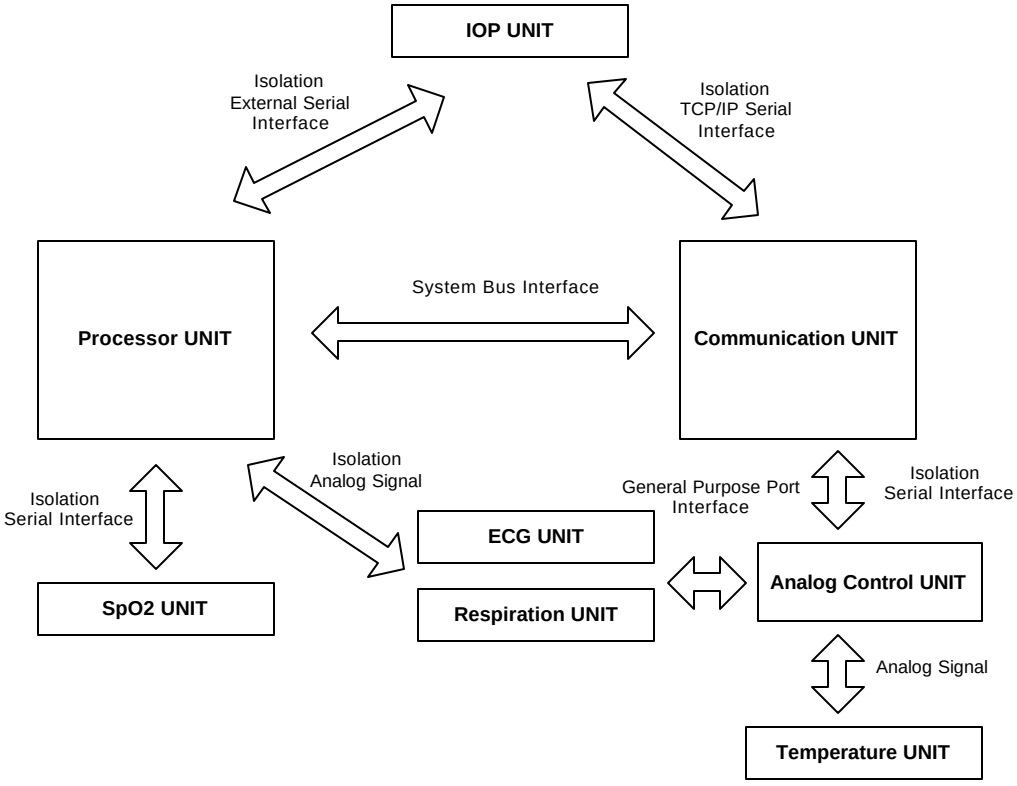


Figure 11. N5500 System Block Diagram 3

Technical Information, N5500

Unit Description

- **Power unit :** consists of power entry module, SMPS, battery charger, battery, external DC input and DC/DC unit.

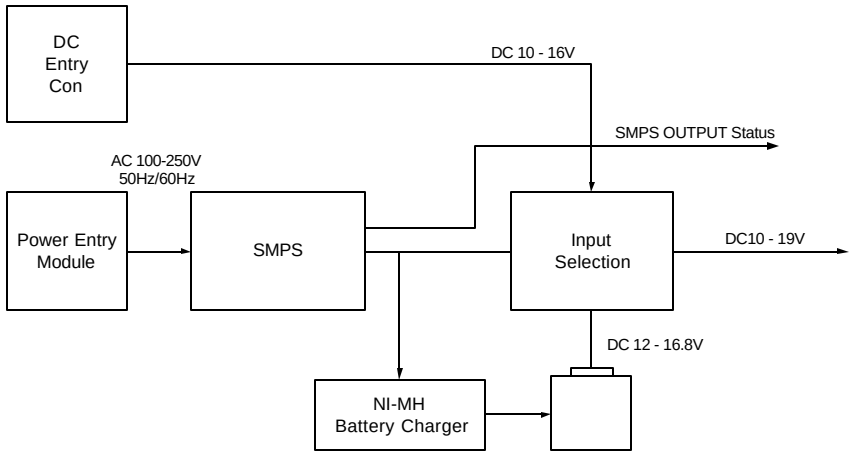


Figure 12. Power Unit Block Diagram

- **Processor unit :** consists of Samsung S3C44B0X CPU, SDRSM, Boot ROM and Flash.

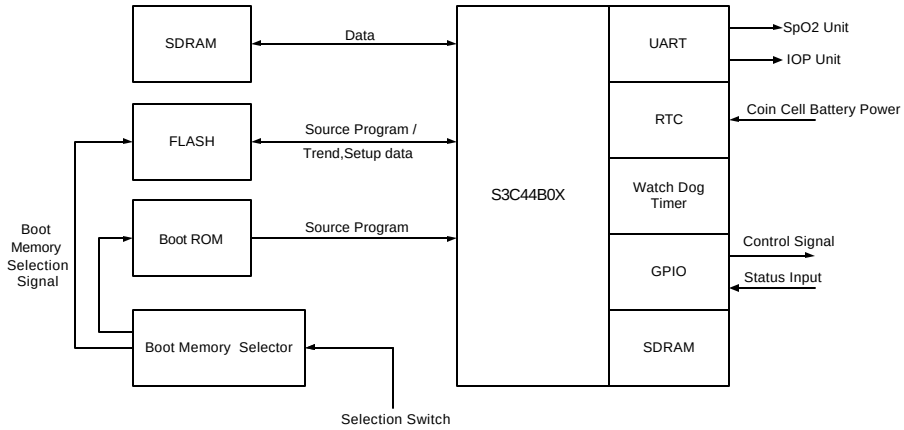


Figure 13. Process Unit Block Diagram

- **User-control unit :** consists of 1 power on/off switch, 4 functional switch, optical encoder, power on indicator LED, AC power indicator LED and low battery indicator LED.

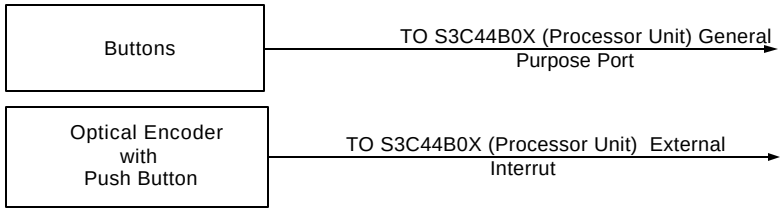


Figure 14. User-Control Unit Block Diagram

- **Sound unit :** consists of 8bit PIC micom, 2-channel amplifiers and speaker.

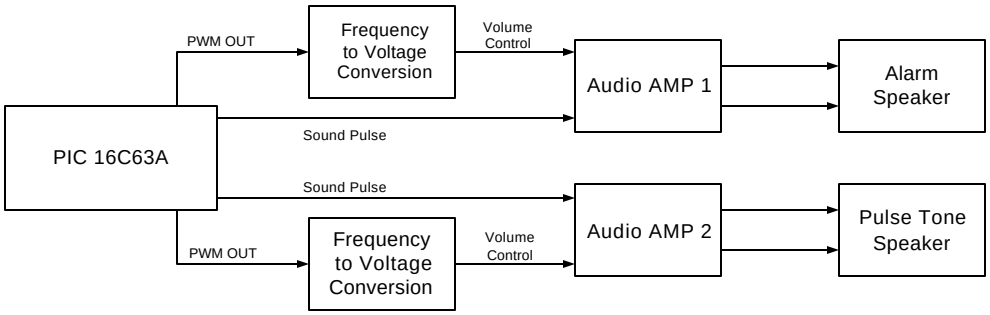


Figure 15. Sound Unit Block Diagram

- **Communication unit :** 4-channel UART

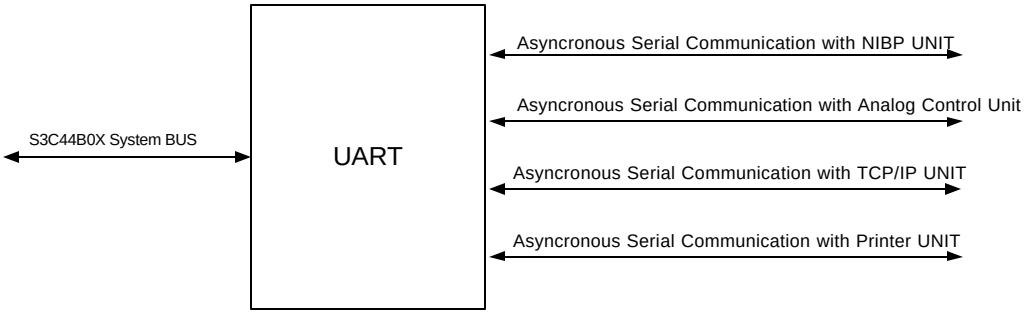


Figure 16. Communication Unit Block Diagram

- **GUI (graphic user interface) unit :** consists of TFT LCD, inverter for backlit and internal video controller.

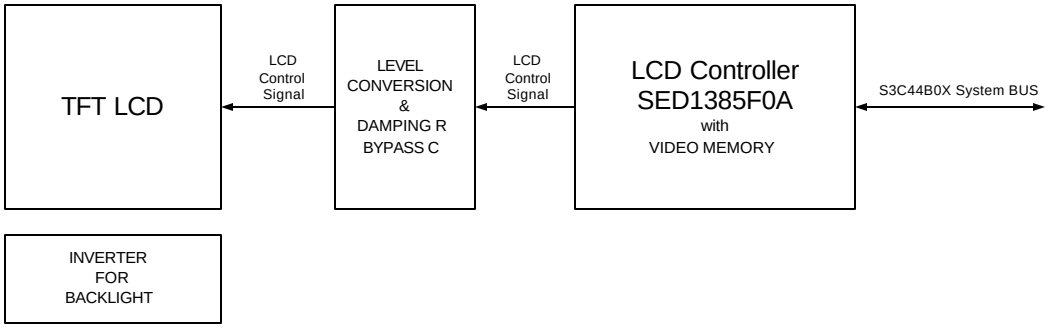


Figure 17. GUI Unit Block Diagram

- **Thermal Printer unit :** prints data records.

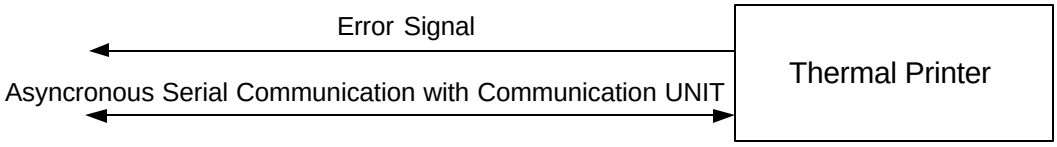


Figure 18. Thermal Printer Unit Block Diagram

- **NIBP unit :** measures non-invasive blood pressure data.

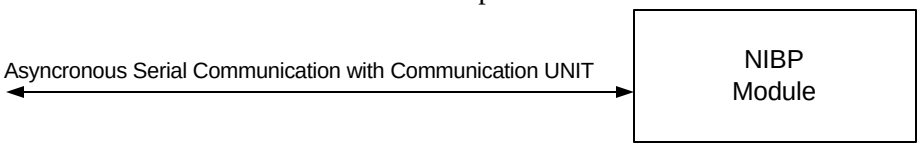


Figure 19. NIBP Unit Block Diagram

- **ECG unit :** measures electrocardiographic waveform data.

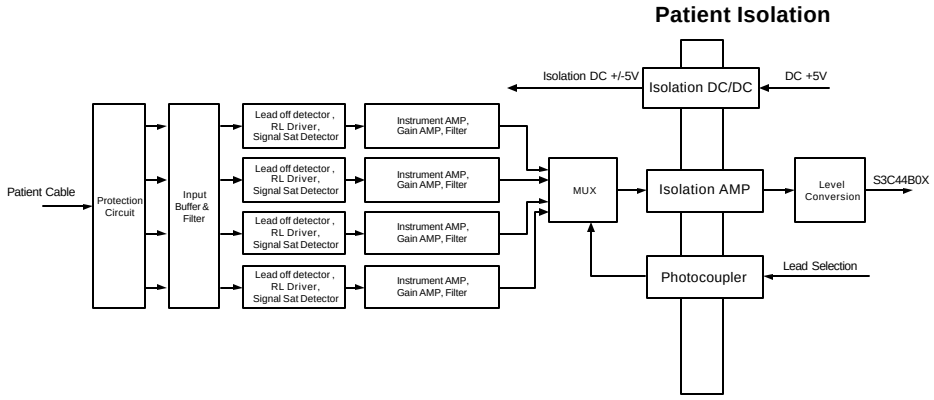


Figure 20. ECG Unit Block Diagram

- **Respiration unit :** measures respiration rate data.

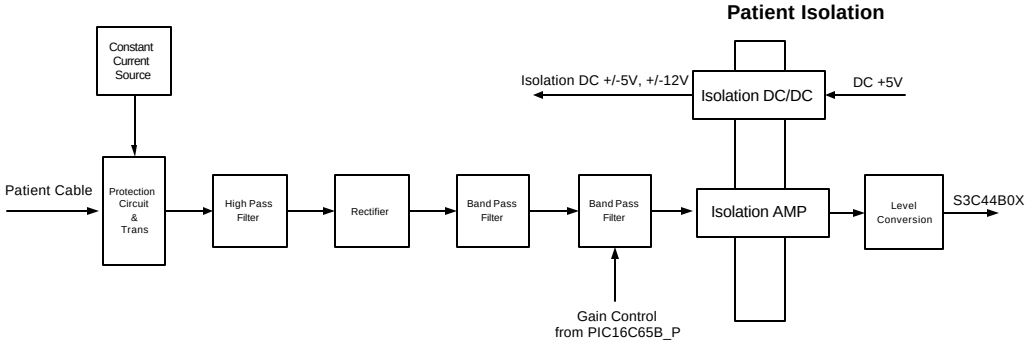


Figure 21. Respiration Unit Block Diagram

- **SpO2 unit :** measures oxygen saturation data.

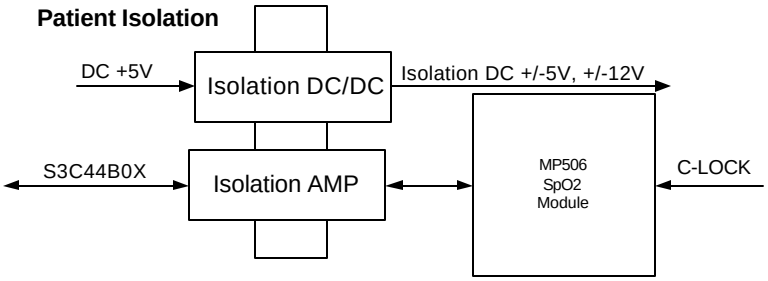


Figure 22. SpO2 Unit Block Diagram

- **Temperature unit :** measures temperature data.

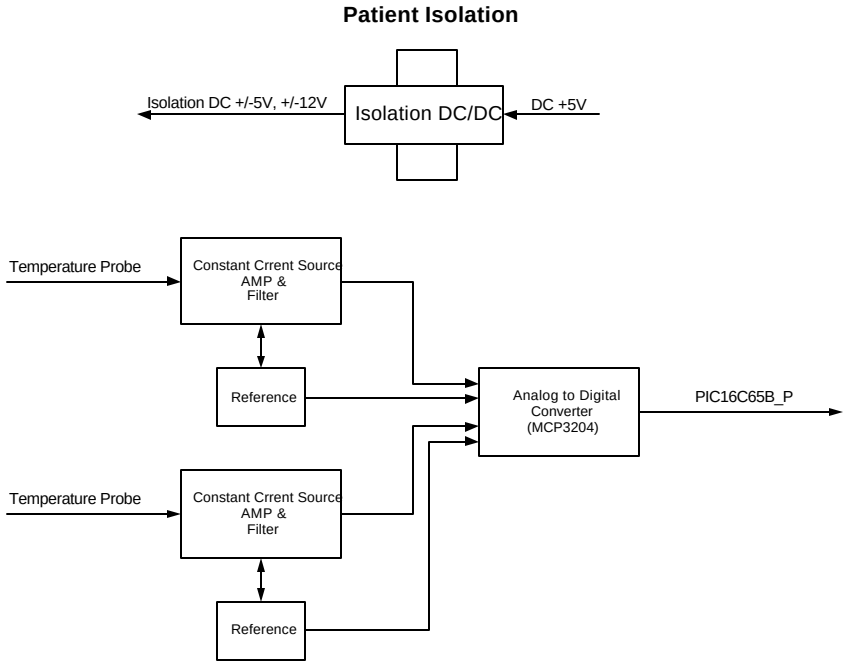


Figure 23. Temperature Unit Block Diagram

- **Analog control unit:** analog circuit control, PIC16C65 – selection of ECG channels and filter, size adjustment, verification of lead off, QRS, heart rate, etc.

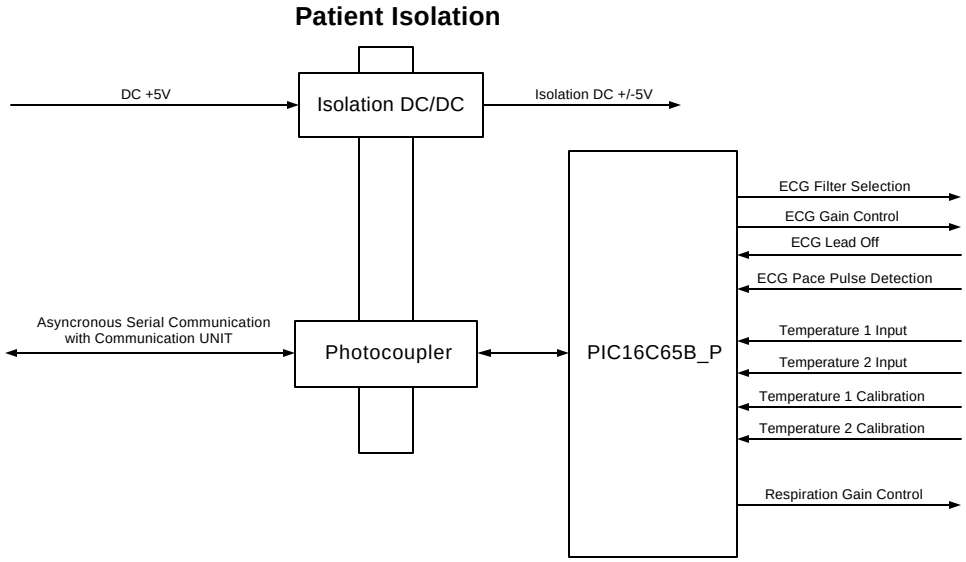


Figure 24. Analog Control Unit Block Diagram

External Interface

- **TCP/IP** : Network connector
- **Serial I/O** : a female 15 pin sub-miniature D shell connector

10.3 ECG Processing

The measurement of the skin surfaces electrocardiogram is based on the electrical signals on the skin surface, produced as the heart muscle contracts and relaxes. The signals are detected by electrodes placed on the patient body. The information on heart activity carried by these signals varies with the placing of the electrodes.

The technique used in ECG senses the varying potential difference between two points at the skin surface which respond to the chemical actions of the muscular activity of the heart.

Three electrodes are attached to the patient's right arm (RA), left arm (LA) and left leg (LL). The varying potentials at these locations are cable-connected to the ECG circuit inputs where they are conditioned, and the difference of potential between two selected leads is digitized before transmitting through opto-isolators to the processor. The processor-installed algorithms operate on the signals to develop drivers for the graphic display and to compute the heart rate in beats per minute (bpm).

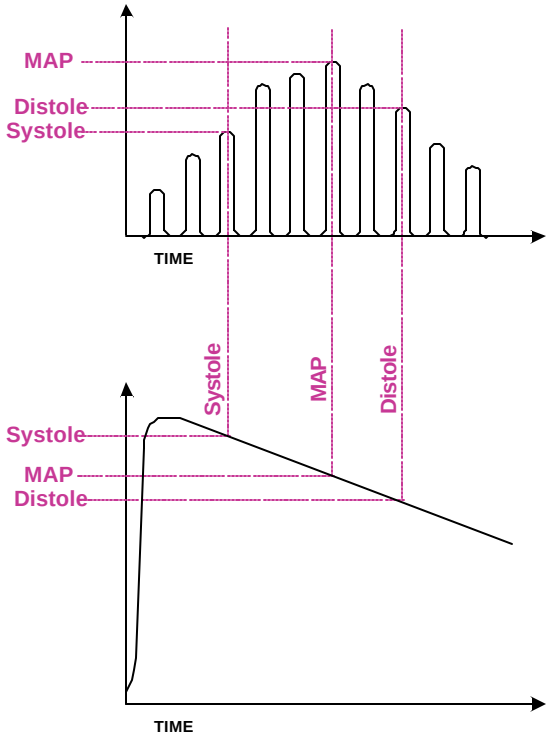
In addition to the acquisition of the QRS waveform complex, the ECG input and subsequent signal processing computing circuitry perform a number of other functions:

- They detect a lead-off condition if one of the electrode connections is disrupted.
- They detect the presence of pacemaker signals within the QRS waveform complex of the ECG.

10.4 NIBP Processing

Overview

The oscillometric technique does not use Korotkoff sounds to determine blood pressure. The oscillometric technique monitors the changes in cuff pressure caused by the flow of blood through the artery. The monitor inflates the cuff to a pressure that occludes the artery. Even when the artery is occluded, the pumping of the heart against the artery can cause small pressure pulses in the cuff baseline pressure. The monitor lowers cuff pressure at a controlled rate. As the cuff pressure goes down, blood starts to flow through the artery. The increasing blood flow causes the amplitude of the pressure pulses in the cuff to increase. These pressure pulses continue to increase in amplitude with decreasing cuff pressure until they reach a maximum amplitude at which point they begin to decrease with decreasing cuff pressure. The cuff pressure at which the pulse amplitude is the greatest is known as Mean Arterial Pressure(MAP). The manner in which the pulse amplitudes vary is often referred to as the pulse envelope. The envelope is an imaginary line that connects the peak of each pressure pulse and forms an outline. The shape of the envelope is observed by the monitor using a variety of techniques to determine the diastolic and systolic blood pressure.



Oscillometric Response (Pressure Pulses)

Cuff Pressure

Overall Accuracy Discussion

Overall system accuracy shall be determined by considering various influences of the pressure sensor accuracy, motion artifacts, other artifact created by pressure valve, technical errors of electrical components, and the origin error of oscillometric method. The origin error of oscillometric comes from the basic theory of that the MAP is determined by the pulse. Therefore, there might be an error of the time between two pulses. In another words, the greatest amplitude point of pulses could not represent the MAP point exactly.

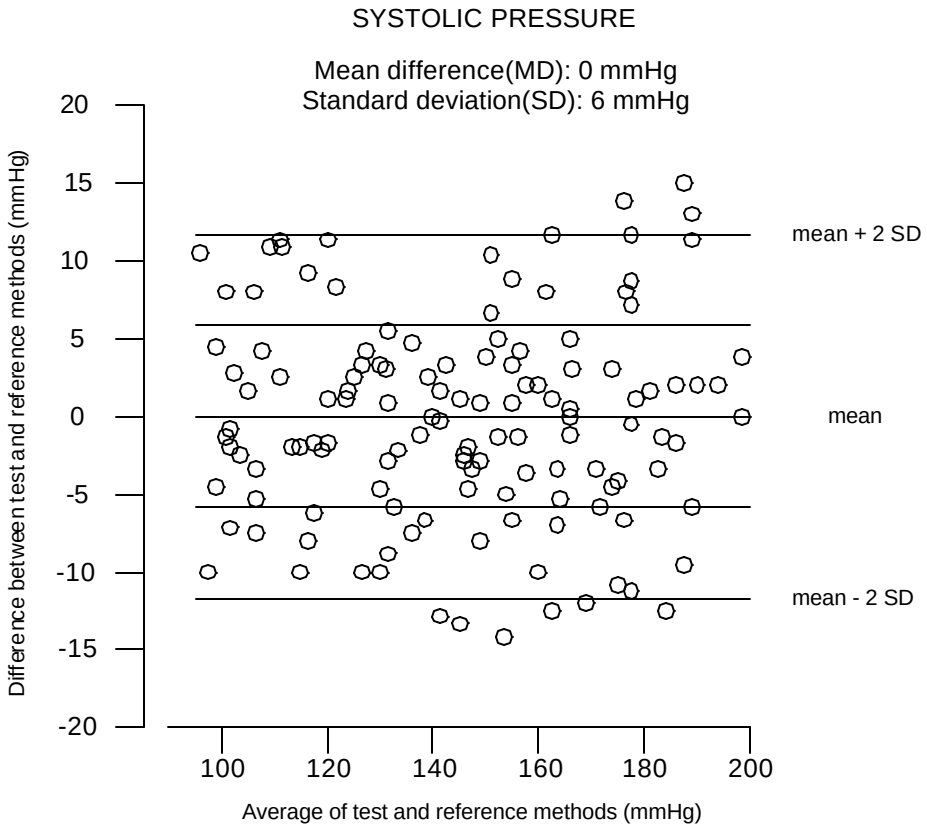
On clinical trial perspective, overall system accuracy is not easy to be determined. The clinical trial test protocols have been tried and have been described in many treatises, and international standards. So, there are many methods to determine the overall system accuracy of Automated Sphygmomanometer using the oscillometric method. But, there are no absolute test protocols to determine the overall system accuracy of the Automated Sphygmomanometer using oscillometric method. Normally, the Gold standards of Blood pressure for the reference are the intra-arterial pressure and the auscultatory method.

The popular standard for the overall system accuracy is AAMI, SP-10 1992; 1996 (Electronic or automated sphygmomanometers).
The main test conditions are as follow:

A. Data comparing the Intra-arterial or the auscultatory by the clinical experts with the automated sphygmomanometer.

B. For data collection and the data analysis, Bland-Altman Plot is used.
C. On the systolic, diastolic, and MAP, the Deltas of all measurements shall be met under +/- 5mmHg of mean difference (MD), and +/- 8mmHg of standard deviation (SD).

(Delta = Intra-arterial or Auscultatory – Automated sphygmomanometer)



(EXAMPLE) Agreement between test and reference methods for systolic pressure. Hypothetical data

10.5 SpO_2 Processing

Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photodetector. 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 systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement (SpO_2). Because a measurement of SpO_2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). The monitor determines SpO_2 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 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 monitor 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 monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (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.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the sensor's red LED to accurately measure SpO_2. During manufacturing, the mean wavelength of the red LED is encoded in a resistor in the sensor.

During monitoring, the instrument's software reads this resistor value and selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO_2. This resistor value is read when the monitor turned on, periodically thereafter, and each time a new sensor is connected. Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Measured versus Calculated Saturation

The measured SpO_2 value from an oximeter may differ from the saturation value that is calculated from a blood gas partial pressure of oxygen (PO_2). This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation: pH, temperature, partial pressure of carbon dioxide (PCO_2), 2, 3-DPG, and fetal hemoglobin.

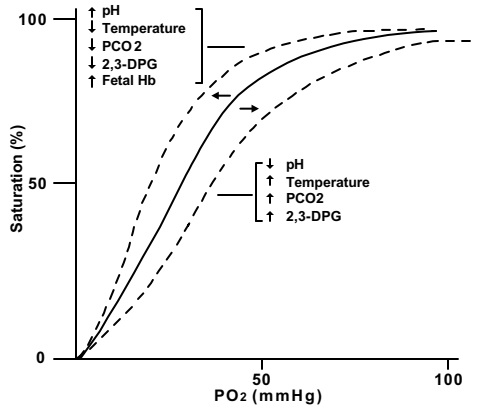


Figure 25. Oxyhemoglobin Dissociation Curve

Functional versus Fractional Saturation

This monitor 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 hemoglobin. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

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

OxiMax Technology

The N5500 SpO_2 monitoring is designed to use Nellcor *OXIMAX* brand sensors, which integrate the *OXIMAX* technology. These sensors can be identified by their deep blue plug color. All *OXIMAX* sensors contain a memory chip carrying information about the sensor which the monitor needs for correct operation, including the sensor's calibration data, model type, troubleshooting codes, and error detection data. This unique oximetry architecture enables several new features with the N5500. When an *OXIMAX* sensor is connected to the N5500, the monitor will first read the information in the sensor memory chip, check it to make sure that there are no errors, and then load the data to begin monitoring. The monitor containing OxiMax Technology uses calibration data contained in the sensor in calculating the patient' s SpO_2.

10.6 Respiration Processing

The N5500 respiration monitoring is designed to use the variation of this thoracic impedance. The chest contains various materials, ranging from bone to air. Each of these materials has different electrical properties and is located in a different portion of the chest. The materials of the chest vary in electrical resistivity (the amount of electrical resistance between opposite faces of a cube of that material), which is an important determinant of electrical impedance in the body.

Two of the major components of the chest, blood and air, are at opposite ends of the scale. Furthermore, the volume of each of these materials varies with time over the cardiac and breathing cycles. The variation of the thoracic impedance is caused by the difference between air and blood in the thoracic impedance. Blood has relatively low resistivity, which varies over the cardiac cycle owing to changing blood volumes in the heart and in the vascular compartment. Air, on the other hand, has high electrical resistivity and hence impedance, and it undergoes wide volume changes in the lungs during normal breathing. i.e. the impedance of blood is 150 ohm/cm and the one of air is 5000 ohm/cm.

The patient's respiration is detected by using two of the three leads of the ECG electrodes (RA and LA, or RA and LL) and cable. The electrical impedance between a

pair of electrodes is determined by dividing the voltage difference between the two electrodes by the current that passes between them. When the electrodes are placed on the actual structure, respective structures change.

A low-level excitation signal is applied to these leads, and the variation of the thoracic impedance caused by the breathing is sensed and processed for display and measurement. This variation is processed to the voltage value for the measurement.
In order to transfer the thoracic impedance by a transformer, it is used a minimum constant current of the sine wave carrier signal. The transferred thoracic impedance is changed to the voltage signal by using bridge circuit and differential amplifier. Then, ECG signal is removed by filter, and carrier frequency is removed by full wave rectifier and filter in order to extract only thoracic impedance in amplifying at the definite level of signal. This extracted thoracic impedance signal is used to measure the respiration by digital signal processing.

10.7 Temperature Processing

Measurement of patient temperature is accomplished by processing the signal from a probe containing a resistor whose resistance is temperature dependent. The class of such components is called thermistor.

Temperature measurement used by N5500 patient monitoring system is based on a thermistor whose resistance is inversely proportional to its temperature. By measuring the thermistor's resistance, its temperature can be calculated. The resistance of the thermistor is measured by passing a current through it and measuring the voltage developed across it.

The N5500 patient monitor is designed to accept the signals from electrically isolated a range of temperature probes from the Monotherm™ range. The probes may be used for skin or rectal temperature measurement. Probes are furnished with a standard 10-feet lead; extension leads are available. The signal from the probe is conditioned by the monitor input circuitry, processed, and used to drive the numeric display.

N5500 Service Manual
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Part Number: MDR05002-A7009-0
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