Patient Monitor BP-S510

Service Manual

Part Number: A7086 Rev.XC3 (1731071A)
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Directive

- Copyright law allows no part of this instruction manual to be reproduced without permission.
- The content of this manual are subject to change without notice.
- The contents of this manual should be correct. If, for some reason, there are any questionable points, please do not hesitate to contact our service center.
- The manual will be replaced if any pages are missing or collation is incorrect.

Warranty

- Please contact your local distributor about the warranty period.
- Device failure or damage related to the following situations during the guarantee period is not covered by this warranty:
  - Installation, transfer installation, maintenance and repairs by any person other than an authorized Omron Healthcare Co., Ltd. employee or technician specified by Omron Healthcare Co., Ltd..
  - Damage sustained to the Omron Healthcare product(s) caused by product(s) from another company excluding products delivered by Omron Healthcare Co., Ltd.
  - Damage – caused by mishandling and/or misuse – is the responsibility of the user.
  - Maintenance and repairs utilizing maintenance components that are not specified by Omron Healthcare Co., Ltd.
  - Device modifications or use of accessories not recommended by Omron Healthcare Co., Ltd.
  - Damage caused by accidents or natural disasters (earthquakes, flooding, etc.).
  - Damage resulting from usage where caution statements and operating instructions shown in this manual have not been followed.
  - Damage due to neglect of specified maintenance checks.
- This warranty only covers the hardware of the BP-S510. The warranty does not cover the following selections:
  - Whatever damage or loss results from the attachment of accessories or their operation.
  - In the event of a defect in the product, contact our sales outlet or EU representative as noted on the back cover.

- The BP-S510 conforms to the EMC standard IEC60601-1-2.
  Note that mobile phones should not be used in the vicinity of the BP-S510.

Note, however, any device not complying to the EMC standard that is used with the BP-S510 renders the BP-S510 as non-compliable to the EMC standard.

Revision History

Product brand names shown in this manual are likely to be the trademark or registered trademark of the company concerned.

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SAFETY INFORMATION

General Safety Information

This section contains important safety information related to general use of the BP-S510 multi-parameter patient monitor. Other important safety information appears throughout the manual. The BP-S510 will be referred to as the monitor throughout this manual.

Important! Before use, carefully read this manual, accessory directions for use, all precautionary information and specifications.

Warnings

Warnings are identified by the WARNING symbol shown above.

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

	**WARNING: Explosion hazard. Do not use the monitor in the presence of flammable anesthetics or gases.**
	**WARNING: Do not spray, pour, or spill any liquid on the monitor, its accessories, connectors, switches, or openings in the chassis.**
	**WARNING: Do not immerse the monitor 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 monitor, disconnect the power cord from the monitor.**
	**WARNING: Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a monitor with a broken display panel.**
	**WARNING: The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the monitor.**
	**WARNING: Do not silence the monitor audible alarm or decrease its volume if patient safety could be compromised.**
	**WARNING: During the safety test, AC main voltage will be present on the applied part terminals, Exercise caution to avoid electrical shock hazard.**
	**WARNING: Do not place the monitor into operation after repair or maintenance has been performed, until all Performance Tests and Safety Tests listed in Performance Verification section 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.

Caution statements identify conditions or practices that could result in damage to the equipment or other property.

- **CAUTION: Observe ESD (electrostatic discharge) precautions when working within the unit and/or when disassembling and reassembling the monitor and when handling any of the components of the monitor.**
- **CAUTION: When reassembling the monitor, over-tightening could strip out the screw holes in the cases, rendering it unusable.**
- **CAUTION: If any problem with the monitor built in an optional recorder, check a recorder'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: For continued protection against risk of fire, replace only with same type and rating of fuse.**

Manual Overview

This manual contains information for servicing the BP-S510 monitor.
The monitor subsequently referred to as the monitor throughout this manual. Only qualified service personnel should service this product. Before servicing the monitor, 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 A7072

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 monitor operator's manual part number A7072
To understand the various SpO_2 sensors, ECG leads, blood pressure cuffs, temperature probes, IIBP transducer and CO_2 accessories that work with the monitor, refer to the individual directions for use that accompany these accessories.

Intended Use for the BP-S510 Monitor

The BP-S510 is intended to be used to monitor electrocardiography, heart rate, noninvasive blood pressure (systolic, diastolic and mean arterial pressures), functional arterial oxygen saturation, pulse rate, respiration, temperature, invasive blood pressure and capnography for adult and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist.

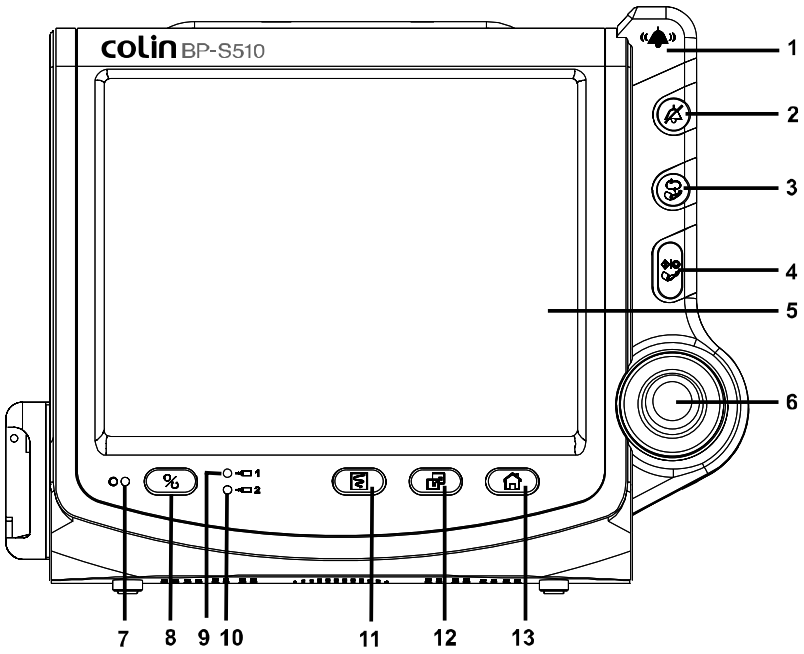
Note: Hospital use typically includes such areas as general care floors, operating rooms, special procedure areas, intensive and critical care area, within the hospital. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgical centers, and sub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

Identifying the BP-S510 monitor Configurations

The following table identities BP-S510 monitor configurations and how they are indicated. The model-option number and serial number are located on the back of the monitor.
All information in this manual, including the illustrations, is based on a monitor configured with Capnography ($EtCO_2$ and $InCO_2$), IBP and recorder. If the relevant functions do not exist, please verify your unit configuration.

Configuration	REF No.	Description
BP-S510	112580	Standard (ECG, NIBP, SpO_2, 2-channel Temperature, Respiration)
BP-S510P	112581	Standard + Recorder
BP-S510C	112582	Standard + Capnography
BP-S510PC	112583	Standard + Capnography + Recorder
S510-IBP	131324	2-channel IBP module

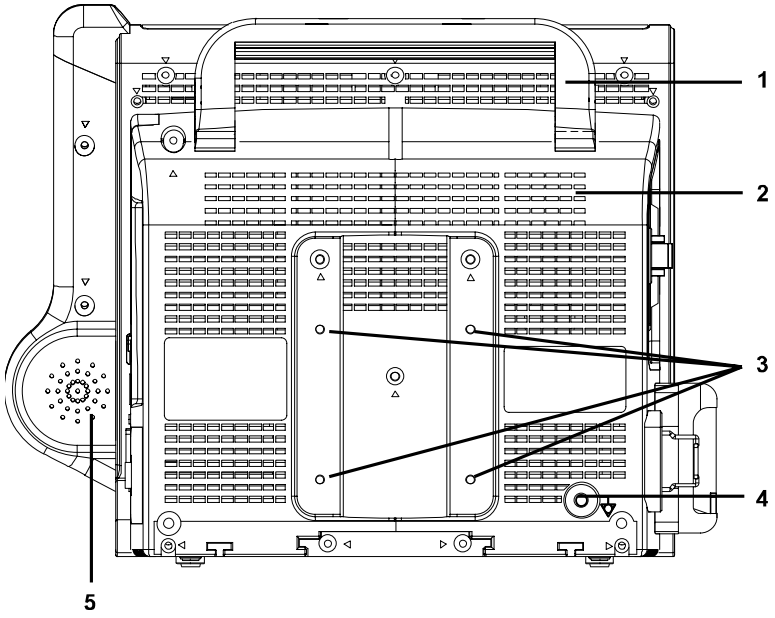
Front Panel Components



1 Visual alarm indicator
2 Alarm silence button
3 NIBP interval button
4 NIBP start/stop button
5 LCD
6 Jog dial
7 Power on indicator
8 Power on/off button
9 Battery charging indicator 1
10 Battery charging indicator 2
11 Record button
12 Trend button
13 Home button

Figure 1. Front Panel Components

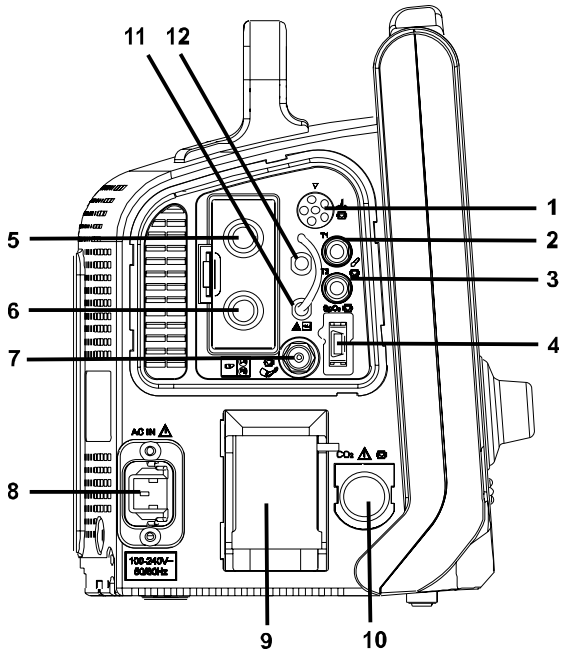
Rear Panel Components



1 Handle
2 Ventilators
3 VESA connector holes
4 Equipotential terminal
5 Speaker

Figure 2. Rear Panel Components

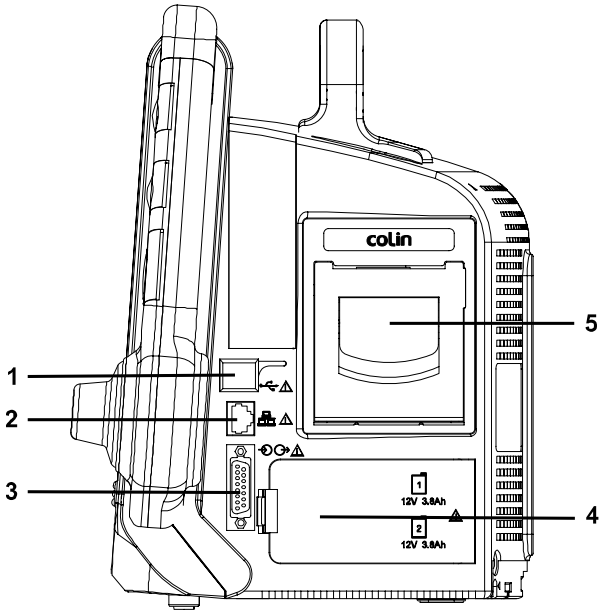
Left Panel Components



1	ECG connector	7	NIBP connector
2	Temperature channel 1	8	AC power connector
3	Temperature channel 2	9	Water trap (option)
4	SpO_2 connector	10	CO_2 connector (option)
5	IBP channel 1 (option)	11	CO_2 filter (option)
6	IBP channel 2 (option)	12	CO_2 exhaust port (option)

Figure 3. Left Panel Components

Right Panel Components



1 USB port
2 LAN port
3 RS-232 port
4 Battery cover
5 Recorder (option)

Figure 4. Right Panel Components

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ROUTINE MAINTENANCE

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

Cleaning

The monitor may be surface-cleaned by using a soft cloth dampened with either a commercial, nonabrasive cleaner or one of the solution listed in the below. Lightly wipe the top, bottom and front surfaces of the monitor lightly.

- 70% Isopropyl alcohol
- 10% Chlorine bleach solution

For cables, sensors, cuffs, transducer and probes, follow cleaning instructions in the directions for use shipped with those components.

Avoid spilling liquid on the monitor, especially in connector areas. If liquid is accidentally spilled on the monitor, clean and dry thoroughly before reuse. If in doubt about monitor safety, refer the unit to qualified service personnel for checking.

Periodic Safety and Functional Checks

The following performance verification tests may be used following repair or during routine maintenance (if required by your local institution). The following checks should be performed at least every year by qualified service personnel.

1. Inspect labels for legibility. If the labels are not legible, contact your local supplier.
2. 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. If the unit fails these performance tests, refer to **Troubleshooting** section.
3. Perform the electrical safety tests described in **Performance Verification** section. If the unit fails these electrical safety tests, do not attempt to repair. Contact your local supplier.
4. Inspect the fuses for proper value and rating.
   qty 2, 6.3 A, 250 volts for AC mains

Batteries

If the monitor has not been used for a long period of time, more than 2 months, the battery will need charging. To charge the battery, connect the monitor to an AC outlet as described in **Battery Charge** paragraph in this service manual or the **Battery Operation** section of the operator's manual.

Note: Storing the monitor 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. Omron Healthcare recommends that the monitor's sealed, Ni-MH batteries be replaced at 2 year intervals. Refer to **Disassembly Guide** section.

CAUTION: If the monitor is to be stored for a period of 2 months or longer, it is recommended to notify service personnel to remove the battery from the monitor prior to storage. To replace or remove the battery, refer to Disassembly Guide section. Recharging the battery is strongly recommended when the battery has not been recharged for 2 or more months.

CAUTION: If the battery shows any signs of damage, leakage, or cracking, it must be replaced immediately.

CAUTION: Discarded battery may explode during incineration. Recycle used batteries properly. Do not dispose of batteries in refuse containers.

Environmental Protection

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

Note: The monitor should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

Note: The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.

Note: For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the monitor.

PERFORMANCE VERIFICATION

General

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

Required Equipment

Table 1 lists the equipment required for performance verifications.

Table 1. Required Equipment

Equipment	Description
Digital multimeter (DMM)	Fluke Model 87 or equivalent
ECG cable	ECG cable No.8
ECG 3 lead wires	ECG 3 lead wires No.5
ECG 5 lead wires	ECG 5 lead wires No.6 (optional)
NIBP cuff for neonatal	NIBP cuff No.11 (3cm)
NIBP cuff for adult	NIBP cuff No.3 (12cm)
NIBP cuff hose for neonatal	NIBP cuff hose No.3 (3.5m)
NIBP cuff hose for adult	NIBP cuff hose No.1 (3.5m)
NIBP rigid PVC vessel	9 cm diameter
NIBP rigid PVC vessel	5 cm diameter
SpO_2 extension cable	DOC-10
SpO_2 sensor (durable)	DS-100A
Temperature probes	YSI-400 series
IBP extension cable	IBP extension cable
ECG simulator	Metron PS-420 or equivalent
SpO_2 simulator	Nellcor SRC-MAX simulator
NIBP simulator	Bio-Tek BP Pump 2 or equivalent
Sphygmomanometer small	Common used sphygmomanometer
Y tube	Omron Y tube
Cuff joint	Omron cuff joint
Inflation bulb	Omron inflation bulb
Temperature simulator	Metron PS-420 or equivalent
IBP simulator	Metron PS-420 or equivalent
IBP test cable	Omron IBP test cable
CO_2 gas flow meter	STEC SEF-21A or equivalent
Safety analyzer	Metron QA-90 or equivalent
Data interface cable	RS-232 cable
LAN cable	Common used LAN cable
USB memory	Common used USB memory
Stopwatch	Manual or electronic

Note: The sphygmomanometer small shall be calibrated periodically. The correct value can not be found if the sphygmomanometer has not been calibrated.

Note: Contact your local supplier for pricing and ordering information.

System Tests

The monitor must be placed in the service menu. For a detailed explanation to access the service menu, refer to **Service Menu and Factory Default Settings** section**.**

1. Rotate the jog dial to select ***System Test*** in the service menu, and then press the jog dial.

Switch/LED Test

This tests the buttons, jog dial and the visual alarm indicator.

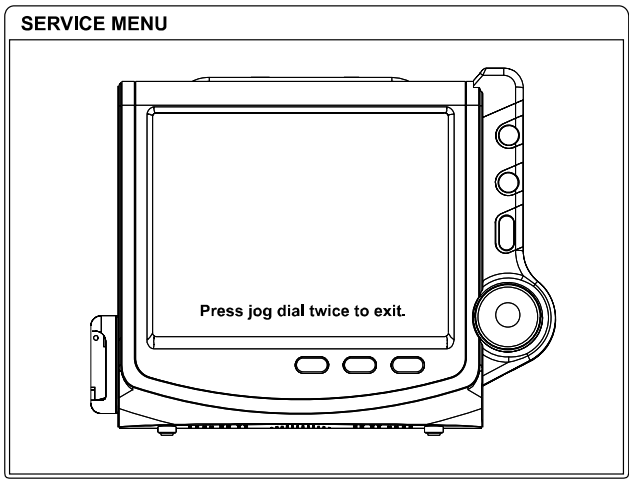


Figure 5. Switch/LED Test

1. Select ***Switch/LED Test*** in the system test. The image screen will appear as Figure 5.
2. Verify that the alarm visual indicator flashes with red and yellow.
3. Press all the buttons one by one, except for the power on/off button.
   When a button is pressed, the same button on the image screen will turn blue.
   For example, when the jog dial is pressed, the jog dial on the screen turns blue.
   When the jog dial is rotated, the sign indicating the rotate direction will appear.
4. After finishing the test, press the jog dial twice to exit.

Pass/Fail Results

If a pressed button turns blue on the screen, the button is in a normal state.

LCD Test

This tests the LCD display.

1. Select ***LCD Test*** in the system test.
2. The screen color will change over the following sequence:
   Red → Green → Blue → White → Black … every two seconds
3. After testing the test, press jog dial twice to exit.

Pass/Fail Results

When the color of the test screen changes in the order from Red, Green, Blue, White to Black, the LCD display is in a normal state.

Alarm Audible Test

This tests the alarm tones by displaying the level of the alarm tone on the screen.

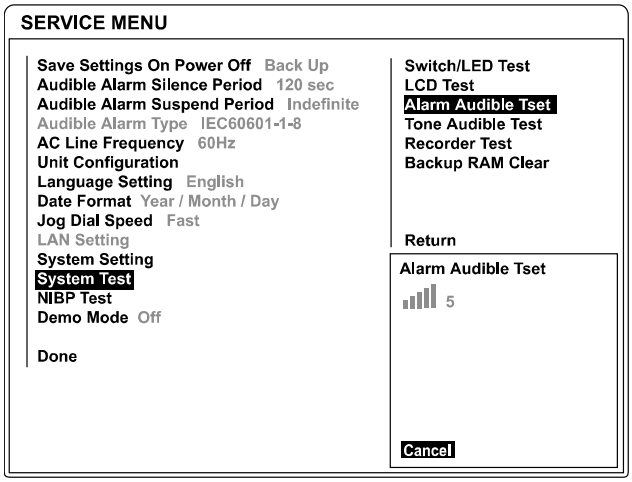


Figure 6. Alarm Audible Test

1. Select ***Alarm Audible Test*** in the system test.
2. The level of the alarm tone will appear on the screen as the alarm tone sounds. Then, the level goes up gradually. When the tone reaches the maximum level 8, it returns to the minimum level 1.
3. After finishing the test, press the jog dial to select ***Cancel***. The menu box will disappear.

Pass/Fail Results

When the alarm tone changes to eight steps, the alarm tone is in a normal state.

Tone Audible Test

This tests HR/PR tones, key beeps and completion sounds.

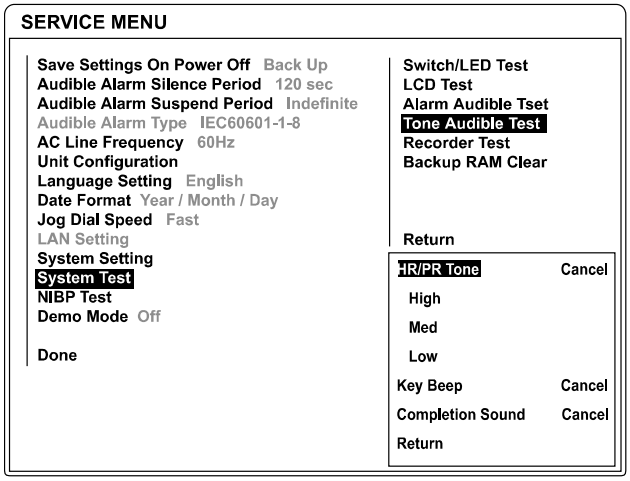


Figure 7. Tone Audible Test

1. Select ***Tone Audible Test*** in the system test.
2. Rotate the jog dial to select ***HR/PR Tone***.
   The HR/PR tone sounds intermittently as the level goes up gradually. When the tone reaches the maximum level 7, it returns to the minimum 1.
   When the tone returns to the minimum, the pitch will change automatically.
   There are three pitches – High, Med and Low.
3. Press ***Cancel*** to finish the test.
4. Rotate the jog dial to select ***Key Beep*** or ***Completion Sound.***
5. Verify that ***Key Beep*** or ***Completion sound*** sounds properly.
6. After finishing the test, press the jog dial to select ***Cancel***. The menu box will disappear.

Pass/Fail Results

When the HR/PR tone changes to seven steps and the pitch changes to three steps, the HR/PR tone is normally set.
When the key beep changes to seven steps, the key beep is normally set.
When the completion sound is heard, it is normally set.

Recorder Test

This tests the printing condition.

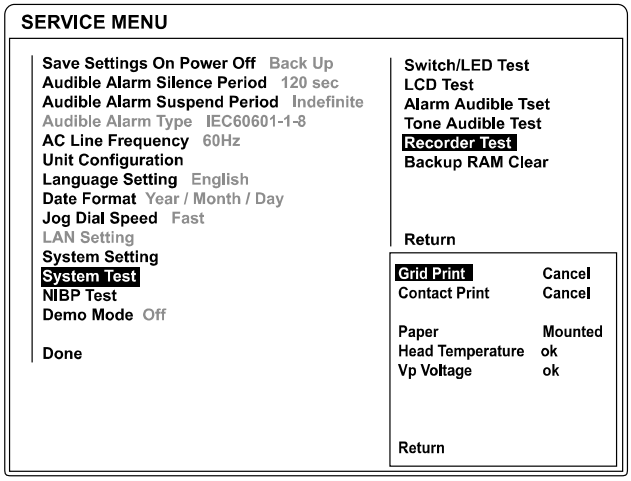


Figure 8. Recorder Test

1. Select ***Recorder Test*** in the system test.
   The recorder condition is displayed as follows:
   Paper: The " Mounted" sign appears when the paper is installed properly. If the paper runs out or the printer door is open, "empty" sign will appear in red.
   Head Temperature: The "OK" sign appears when the head temperature is normal. If the head temperature is abnormal, the "error" sign appears.
   Vp Voltage: The "OK" sign appears when the voltage is normal. If the voltage is abnormal, the "error" sign appears.
2. Select ***Grid Print***. Verify that printing can be done without meandering.
3. After checking, select ***Cancel*** to stop printing.
4. Select ***Contact Print.*** Verify that printing can be done at an equal density.
5. After checking, select ***Cancel*** to stop printing.

Pass/Fail Results

When the printed line is free from meandering on unevenness in density, the printing function is normal.

Backup RAM Clear

When ***Backup RAM Clear*** is set to ***Yes***, all settings of the monitor including the service settings return to the factory defaults from the next cycle.

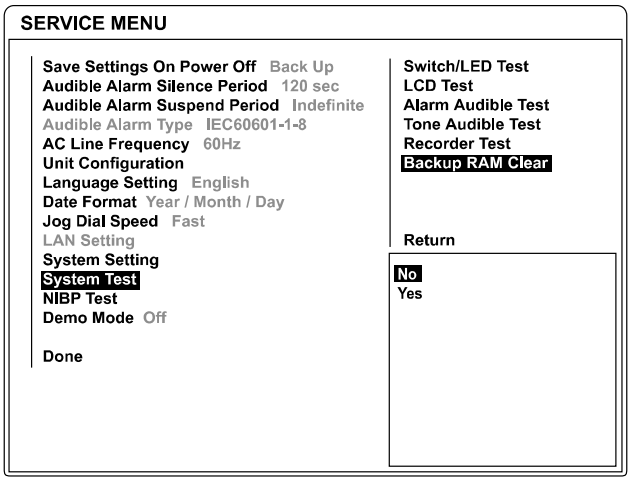


Figure 9. Backup RAM Clear

Note: Set the monitor to appropriate AC line frequency (50Hz or 60Hz) again after Back Up RAM clearance.

Performance Tests

The battery charge and battery discharge 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 discharge test, ensure that the battery is fully charged. This section is written using **factory defaults** as power-up. If your institution has preconfigured custom defaults, those values will be displayed.

Power

1. Connect the monitor to AC power source using proper power cord.
2. Verify that ***Battery charging indicator*** is lit.
3. Press ***Power on/off button***.
4. Verify that the monitor is turned on and that ***Power on indicator*** is lit.
5. After the monitor operates in normal mode, disconnect the power cord.
6. Verify that ***Battery status icon*** appears on the screen instead of lighting Battery charging indicator.
7. Press ***Power on/off button*** over 1 second, and then verify that the monitor is turned off.

Battery Charge

1. Connect the monitor to AC power source using proper power cord.
2. Verify that ***Battery charging indicator*** is lit with orange.
3. Charge the battery fully until ***Battery charging indicator 1 and 2*** are changed to green. It will be take about 12 hours.
4. To check for a full charge, perform the procedure in paragraph "**Battery Discharge**".

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

Battery Discharge

1. Disconnect the power cord from the monitor with a fully charge battery.
2. Turn on the monitor by pressing ***Power on/off button.***
3. Verify that ***Battery status icon*** appears at bottom of the screen after power-on self-test is completed. The bar in battery status icon should be filled, indicating battery is charged.
4. Connect the SpO_2 simulator to monitor via the SpO2 extension cable.
5. Connect the NIBP simulator to the monitor via NIBP cuff hose.
6. Set the SpO_2 simulator as follows: SpO_2 of 95% and pulse rate of 60bpm.
7. Set the NIBP simulator to simulate pressure setting of 120/80 mmHg and heart rate of 80 bpm.
8. Set ***NIBP auto mode interval*** to 5 minutes.
9. The monitor must operate for 1 hour with a fully charged battery. The monitor must operate for at least 15 minutes before the monitor powers down due to the low battery condition.
10. Verify that the low priority alarm occurs and the alarm message "***System: Low battery***" is displayed about 15 minutes before battery fully discharges.

11. Allow monitor to operate until it automatically powers down due to the low battery condition. Verify that the high priority alarm occurs and the alarm message "***System: Critically low-battery condition***" is displayed about 5 minutes before the monitor automatically shuts down.

12. If the monitor passes this test, immediately recharge the battery. (paragraph "**Battery Charge**")

Power-On Self-Test (POST)

1. Connect the monitor to AC power source and verify that ***Battery charging indicator*** is lit.

2. Observe the monitor's LCD screen. With the monitor off, press ***Power on/off button***. The monitor must perform the following sequence.

    a. The monitor progresses the checksum for the flash memory and displays the bar while the checksum is proceeding.

    b. After the checksum for flash memory is completed, the copyright screen appears and all indicators are lit for a few seconds. The copyright screen displays the company logo, the version of system and the current time.

    c. Then the monitor performs the power-on self-test (POST).

    d. Upon successful completion of power-on self-test (POST), the post pass tone sounds and the monitor will be in normal monitoring screen.

Note: Power-on self-test (POST) including the checksum for the flash memory takes approximately 13 seconds to complete.

Note: If an error condition occurs during the POST, the monitor will be display an error message.

Note: During the POST, the integrity of all programming is checked first. If software testing is successful, hardware tests are initiated. If all testing is successful, the monitor is ready for use. If an error message is displayed during the POST, please refer to **Troubleshooting** section.

General Operation Tests

Alarms and Alarm Silence

1. Connect the monitor to an AC power source.
2. Press ***Power on/off button*** to turn on the monitor.
3. Connect the SpO_2 simulator to the SpO_2 extension cable and connect the cable to the monitor.
4. Set the SpO_2 simulator as follows: SpO_2 of 75% and pulse rate of 60bpm.
5. Verify following the monitor reaction:
    a. The pulse amplitude indicator begins to track artificial pulse signal from the SpO_2 simulator.
    b. After about 10 to 20 seconds, the monitor displays oxygen saturation and pulse rate as specified by simulator. Verify values are within following tolerances:
        - Tolerance of Oxygen Saturation : ±2 %
        - Tolerance of Pulse Rate : ±3 bpm
    c. Audible alarm sounds and "***SpO_2: Lower limit violated***" message will be displayed and %SpO_2 numerical area will flash, indicating the parameter has violated default alarm limits. (High priority alarm)
6. Press ***Alarm silence button*** on the monitor's front panel. Audible alarm will be temporarily silenced.
7. Verify the following:
    a. An audible alarm remains silenced.
    b. ***Alarm silence icon*** appears in SpO_2 numerical area on the screen.
    c. %SpO_2 display continues flashing.
    d. Audible alarm returns in approximately 120 seconds.

HR/PR Tone Volume Control

1. Press ***Power on/off button*** to turn on the monitor.
2. Connect the SpO_2 simulator to SpO_2 extension cable and connect the cable to the monitor.
3. Set the SpO_2 simulator as follows: SpO_2 of 75% and pulse rate of 60bpm.
4. Verify %SpO_2 and pulse rate values are correctly displayed.
5. Press ***Alarm silence button*** on front panel of the monitor to temporarily silence audible alarm.
6. Select ***Setup icon*** to display ***Setup menu***.
7. Select ***HR/PR tone Volume*** in ***Setup menu***.
8. Set HR/PR tone volume level 1 to level 7 and return to the monitoring screen. Verify beeping pulse rate tone increases.
9. Set HR/PR tone volume level 7 to level 1 and return to the monitoring screen. Verify beeping pulse rate tone decreases.

10. Set HR/PR tone volume to ***Off*** and return to the monitoring screen. Verify beeping pulse rate tone is no longer audible.

11. Return HR/PR tone volume to a comfortable level.

Sensor LED Excitation Test

This procedure uses normal system components to test circuit operation. An SpO_2 sensor, *DS-100A* 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 button*** to turn on the monitor.
3. Connect the SpO_2 extension cable to the monitor.
4. Connect the SpO_2 sensor to the SpO_2 extension cable.
5. Leave the sensor open with the LEDs and photo detector visible.
6. After the 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 ***Power on/off button*** to turn off the monitor.

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.

Table 2. Parameter Alarm Limit Factory Defaults

Factory Defaults	Adult	Neonatal
HR/PR Upper Alarm Limits	180 bpm (beats per minute)	200 bpm
HR/PR Lower Alarm Limits	40 bpm	50 bpm
NIBP SYS Upper Alarm Limits	200mmHg	130 mmHg
NIBP SYS Lower Alarm Limits	70 mmHg	50 mmHg
NIBP DIA Upper Alarm Limits	160 mmHg	100 mmHg
NIBP DIA Lower Alarm Limits	30 mmHg	10 mmHg
NIBP MAP Upper Alarm Limits	180 mmHg	110 mmHg
NIBP MAP Lower Alarm Limits	40 mmHg	20 mmHg
%SpO_2 Upper Alarm Limits	100 %	100 %
%SpO_2 Lower Alarm Limits	90 %	85 %
RESP Upper Alarm Limits	30 bpm (breaths per minute)	50 bpm
RESP Lower Alarm Limits	0 bpm	0 bpm
TEMP1, 2 Upper Alarm Limits	38.0°C (100.4°F)	39.0°C (102.2°F)
TEMP1, 2 Lower Alarm Limits	14.5°C (58.1°F)	14.5°C (58.1°F)
$EtCO_2$ Upper Alarm Limits	80mmHg	80mmHg
$EtCO_2$ Lower Alarm Limits	0mmHg	0mmHg
$InCO_2$ Upper Alarm Limits	20mmHg	20mmHg

Factory Defaults	Adult	Neonatal
InCO_2 Lower Alarm Limits	0mmHg	0mmHg
IBP1 SYS Upper Alarm Limits	200 mmHg	130 mmHg
IBP1 SYS Lower Alarm Limits	70 mmHg	50 mmHg
IBP1 DIA Upper Alarm Limits	160 mmHg	100 mmHg
IBP1 DIA Lower Alarm Limits	30 mmHg	10 mmHg
IBP1 MEAN Upper Alarm Limits	180 mmHg	110 mmHg
IBP1 MEAN Lower Alarm Limits	40 mmHg	20 mmHg
IBP2 SYS Upper Alarm Limits	200 mmHg	130 mmHg
IBP2 SYS Lower Alarm Limits	70 mmHg	50 mmHg
IBP2 DIA Upper Alarm Limits	160 mmHg	100 mmHg
IBP2 DIA Lower Alarm Limits	30 mmHg	10mmHg
IBP2 MEAN Upper Alarm Limits	180 mmHg	110 mmHg
IBP2 MEAN Lower Alarm Limits	40 mmHg	20 mmHg

1. Turn on the monitor at the factory default settings.
2. Select ***Alarm limits icon*** to display ***Alarm limits menu***.
3. Verify that alarm limits are set to as shown in Table 2.
4. Change ***Patient mode*** in the setup menu Adult to Neonatal, then verify that alarm limits are set to as shown in Table 2.
5. Change alarm limit value via ***Alarm limits menu***.
6. Save the 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 button*** to turn on the monitor.
8. Verify alarm limits are set to the changed alarm limit values.

Recorder Test (Option)

If Recorder option is installed in the monitor, the following test procedures will verify the recorder performance.

1. Connect the monitor to an AC power source.
2. Press ***Power on/off button*** to turn on the monitor.
3. Connect all necessary simulators to the monitor.
4. Select ***Setup icon*** on the screen to display ***Setup menu***.
5. Test #1: 20 sec printing
    a. Set Wave record time to ***20 sec*** via setup menu.
    b. Press ***Record button*** when all the parameter signals display normally.
    c. Verify that the parameter values and waveforms are printed out for 20 seconds.
6. Test #2: Continuous printing
    a. Set Wave record time to ***Continuous*** via setup menu
    b. Press ***Record button*** when all the parameter signals display normally.
    c. Verify the parameter values and waveforms are printed out continuously.
    d. Verify printing stops with pressing ***Record button*** again.

7. Test #3: Record speed
    a. Set ***Record speed*** to 25 mm/s.
    b. Press ***Record button*** when all the parameter signals display normally.
    c. Verify the parameter values and waveforms are printed out with 25 mm/s.
    d. Set ***Record speed*** to 50 mm/s.
    e. Press ***Record button*** when all the parameter signals display normally.
    f. Verify that the parameter values and waveforms are printed out with 50 mm/s.
8. Test #4: Wave Record Select
    a. Set Wave Record Select to ***ECG1+ECG2*** via Setup menu.
    b. Press ***Record button*** when all the parameter signals display normally.
    c. Verify the two ECG waveforms are printed out.
    d. Repeat this test for other selections.
9. Test #5: Record on Alarm
    a. Set Record on Alarm to ***ON*** via Setup menu.
    b. Set Heart rate of ECG simulator to 30 bpm.
    c. Verify "***HR: Lower limit violated***" alarm is activated and the parameter values and waveforms are printed out.
10. Test#6: Auto List Record
    a. Set Auto list record to ***ON*** via Setup menu.
    b. Set Save time interval to ***0.5 minutes*** via Tabular trend menu.
    c. Verify that the monitor automatically prints out the data after stored 8 data in the trend memory.

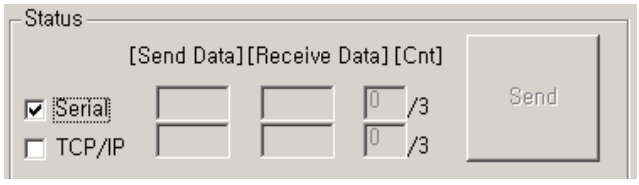
Note: If no recorder is installed in the monitor, the record setup menus will be grayed out in ***Setup menu.***

Note: If there is no recorder paper left or recorder paper places improperly, the monitor will display an informative message.

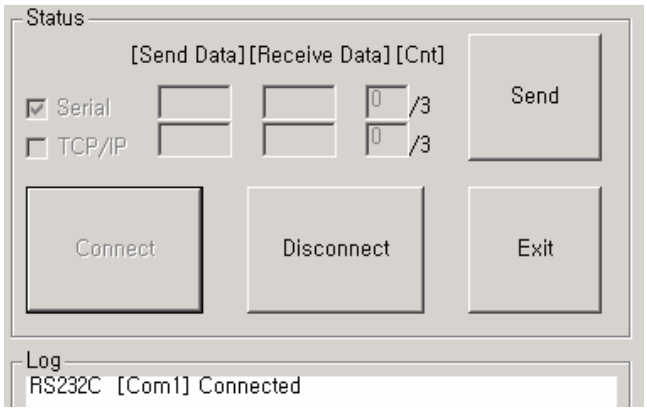
Serial Interface Test

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

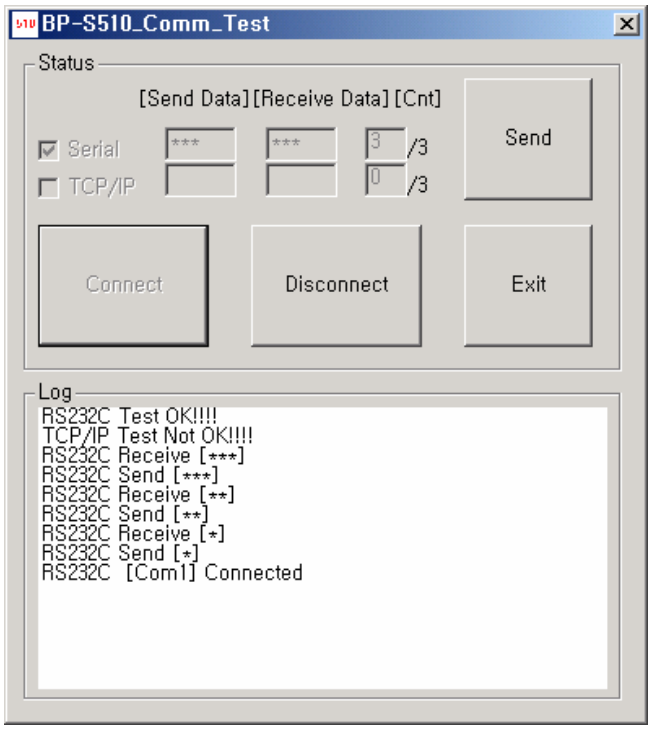
1. Turn on the monitor, and select the service menu via the setup menu.
2. Enter the service code, **6**, **1**, **6**, in order.
3. Connect the serial interface cable between the monitor and PC COM1 port.
4. Run "BP-S510_Comm_Test.exe" on PC.
5. Click ***Serial*** on the left side of dialog box for the serial interface test.



6. Click ***Connect***, then verify that log message “RS232C [Com1] Connected” appears on the PC.



7. Click ***Send***, then verify the followings:
   - The monitor displays three dashes (-) with the beep sound.
   - The log message “RS232 Test OK!!!” appears on the PC.



8. Click ***Disconnect*** to stop the serial interface test.

Network Test

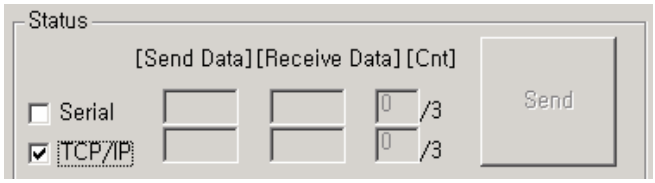
Perform the following procedure to test the Network. The Network connector is located on the monitor's right panel, identified with the Network symbol.

Prior to the network test, configure the network setting on PC with the followings.

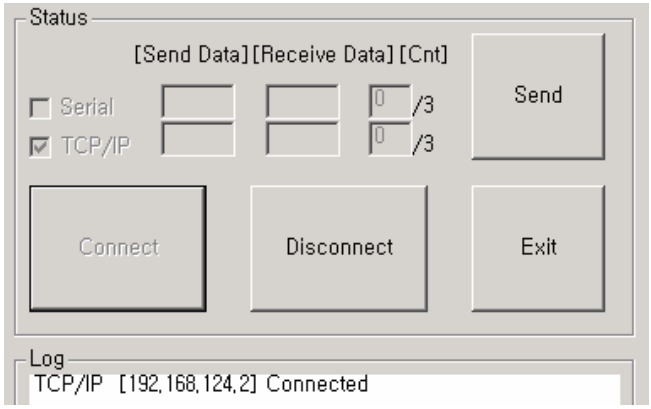
- IP address 192.168.124.1.
- Gateway 192.168. 124. 254.
- Subnet Mask 255.255.255.0.

When completed the network setting on the PC properly, follow the below test procedure.

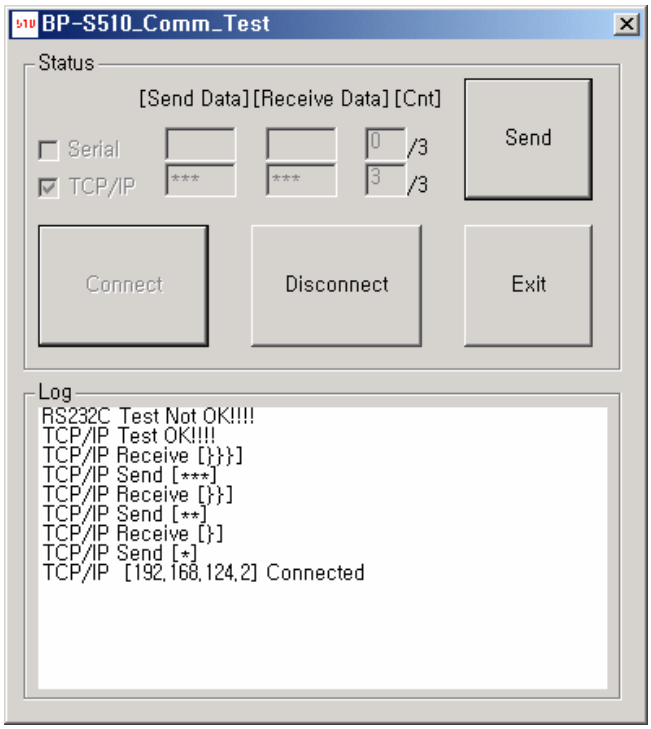
1. Turn on the monitor, and select the service menu via the setup menu.
2. Enter the service code, **6**, **1**, **6**, in order.
3. Connect a network line to the monitor. (Do not connect PC to the monitor directly)
4. Run "BP-S510_Comm_Test.exe" on PC.
5. Click **TCP/IP** on the left side of the dialog box for the network test.



6. Click ***Connect***, then verify that log message "TCP/IP [192.168.124.2] Connected" appears on the PC.



7. Click ***Send***, then verify the followings:
   - The monitor displays three dashes (-) with the beep sound.
   - The log message “TCP/IP Test OK!!!” appears on the PC.



8. Click ***Disconnect*** to stop the network test.

USB Interface Test

Perform the following procedure to test the USB port. The USB connector is located on the monitor’s right panel, identified with the USB interface symbol.

1. Copy the file named “BP-S510_USB_Test.muf” to USB memory’s root directory.
2. Connect the USB memory to the monitor,
3. Turn on the monitor, and select the service menu via the setup menu.
4. Enter the service code, **6**, **1**, **6**, in order..
5. After a few seconds, verify that the monitor displays “OK” with the beep sound.

Note: Do not change the file name, “BP-S510_USB_Test.muf” for the USB connection test.

Note: For a detailed explanation to access the service menu, refer to **Service Menu and Factory Default Settings** section.

Measurement Parameter Operation Tests

ECG Operation

1. Press ***Power on/off button*** to turn on the monitor.
2. Connect the ECG 3 lead wires to appropriate jacks on the ECG simulator.
3. Connect lead wires to the ECG cable.
4. Connect ECG cable to the ECG connector on the monitor's left panel.
5. Set the 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 that the following monitor reactions:
   a. After about 15 seconds, the monitor displays a heart rate of 30 ± 3 bpm.
   b. Verify that audible alarm sounds and that "***HR: Lower limit violated***" message displays on the message area.
   c. Verify that the HR/PR numerical area flashes and that the heart rate is below default lower alarm limit (high priority alarm).
7. Increase the heart rate setting on the ECG simulator to 240 bpm.
   a. After about 15 seconds, verify that the monitor displays heart rate of 240 ± 3 bpm.
   b. Verify that audible alarm sounds and that "***HR: Upper limit violated***" message displays
   c. Verify that the HR/PR numerical area flashes and that the heart rate is above default upper alarm limit (high priority alarm).
8. Decrease the heart rate setting on the ECG simulator to 120 bpm.
   a. After about 15 seconds, verify the monitor displays heart rate of 120 ± 3 bpm.
9. Disconnect the LL lead from the ECG simulator.
   a. Verify that the "***ECG: Check ECG leads & electrodes***" message appears, that three dashes are displayed in the HR/PR numerical area, and that medium priority alarm sounds.
   b. Reconnect the LL lead to the ECG simulator. Verify that "***ECG: Check ECG leads & electrodes***" message no longer appears and that the audible alarm is stopped.
   c. Repeat this test for the LA and the RA leads.
10. Connect all the leads to the monitor.
    a. Select ***ECG waveform menu*** and set ***Lead select*** to Lead I.
    b. Verify that the lead selection is displayed on the ECG waveform area.
    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 that an appropriate size is displayed on the ECG waveform area.

13. Set the ***ECG cable select*** to ***Auto*** via ECG waveform menu.
14. Verify that ***Lead Select*** in ECG waveform menu displays ***I, II, III***.
15. Disconnect 3 ECG leads and connect 5 ECG leads.
16. Verify that ***Lead Select*** in ECG waveform menu displays ***I, II, III. aVR, aVL, aVF, V (Chest Lead)***.
17. Repeat step 9 to 12.
18. Turn off the monitor.

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

NIBP Operation

The monitor must be placed in the service menu. For a detailed explanation to access the service menu, refer to **Service Menu and Factory Default Settings** section**.**

1. Rotate the jog dial to select ***NIBP Test*** in the service menu, and then press the jog dial.

Note: **Inflation Speed Test, Initial Deflation Test (I), Initial Deflation Test (II), Deflation Speed Test and Offset Test are intended for factory use only.**

Pressure Sensor Accuracy Test

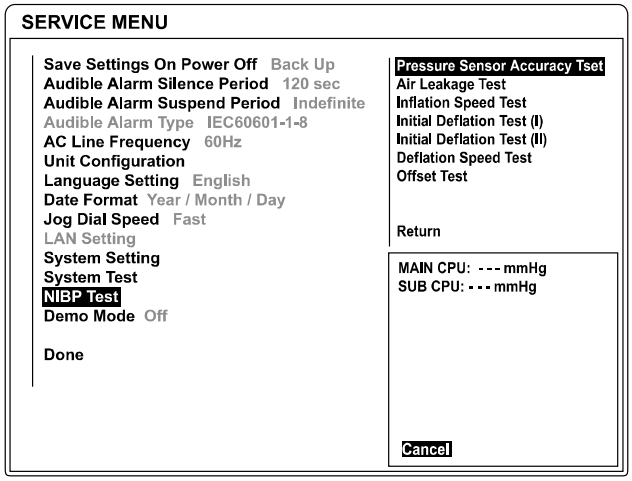


Figure 10. Pressure Sensor Accuracy Test

1. Connect the NIBP cuff hose to the NIBP connector on the monitor's left panel.
2. Connect the other end of the NIBP cuff hose to the Y tube via the cuff joint.
3. Connect the sphygmomanometer and the Inflation bulb to the Y tube.
4. Select ***Pressure Sensor Accuracy Test***, and then press the jog dial.
5. Raise the pressure of the sphygmomanometer to 0, 50, 100 and 200 mmHg by pumping the inflation bulb and compare the pressure of the sphygmomanometer with the pressure displayed by the monitor.

   If air leakage disables accurate comparison of the above pressures, eliminate the cause of air leakage.
6. After finishing the test, press the jog dial to select ***Cancel***. The menu box will disappear. If ***Cancel*** is selected during the test progressing, the test will stop and the menu box will disappear.

Pass/Fail Results

The difference between the sphygmomanometer's and the monitor's readings are as follows:

Sphygmomanometer	Monitor's Readings
0 mmHg	±0 mmHg
50 mmHg	50±6 mmHg
100 mmHg	100±6 mmHg
200 mmHg	200±6 mmHg

Air Leakage Test

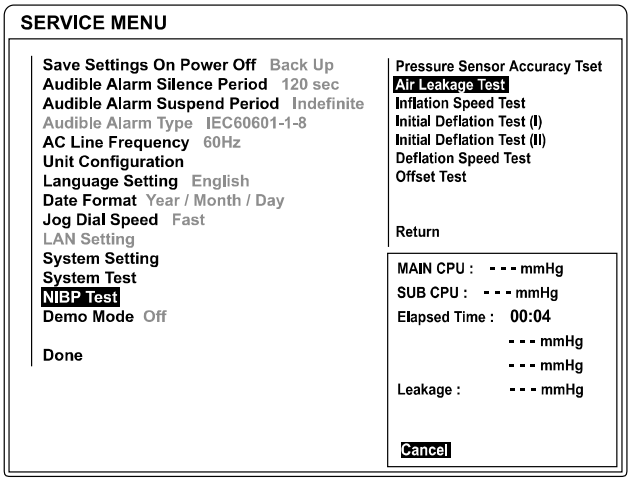


Figure 11. Air Leakage Test

1. Place the adult cuff with a rigid PVC vessel (5 cm diameter).
2. Connect the cuff to the NIBP connector on the monitor's left panel via NIBP cuff hose.
3. Select ***Air Leakage Test***, and then press the jog dial.
4. The result will be displayed in four minutes.
5. After finishing the test, press the jog dial to select ***Cancel***. The menu box will disappear. If ***Cancel*** is selected during the test progressing, the test will stop and the menu box will disappear.

Pass/Fail Results

It passes if the leak value is less than 12mmHg/3minutes.

Pulse Oximetry Operation

1. Connect the monitor to an AC power source.
2. Turn on the monitor by pressing the ***Power on/off button***.
3. Connect the SpO_2 extension cable to SpO_2 connector on the monitor's left panel after the monitor completes POST.
4. Connect the SpO_2 simulator to the other end of the SpO_2 extension 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
   a. Press the ***% SpO_2 selection button*** on the SpO_2 simulator. The PULSE RATE 90 LED will light:
   b. The monitor will display three dashes until the the SpO_2 simulator stabilizes at 90 %SpO_2. The test pass criteria is 88 to 92 % SpO_2.
   c. The monitor will display: - 90 % SpO_2
      - 60 bpm
      - no alarm
7. Test #2: Pulse rate (bpm)
   a. Press the ***PULSE RATE selection button*** on the SpO_2 simulator. The PULSE RATE 200 LED will light:
   b. The monitor will increase to 200 bpm. The test pass criteria is 197 to 203 bpm.
   c. The monitor will display:
      - 90 % SpO_2
      - 200 bpm
      - alarm: "***PR (SpO_2): Upper limit violated***" message will display and the HR/PR area will flash, indicating pulse rate is above default upper alarm limit (High priority alarm).
   d. Press the ***SRC-MAX PULSE RATE selection button*** on the SpO_2 simulator. The PULSE RATE 60 LED will light.
   e. The monitor will decrease to 60 and stabilize at 60 bpm. The test pass criteria is 57 to 63 bpm.
   f. The monitor will display:
      - 90 % SpO_2
      - 60 bpm
      - no alarm
      - low level modulation
8. Test #3: Modulation Level
   a. Press the ***%MODULATION selection button*** on the SpO_2 simulator. The %MODULATION LED will light.
   b. The monitor's waveform area will spike and stabilizes at a higher modulation level.

c. he monitor will display:
- 90 % SpO_2
- 60 bpm
- no alarm

d. Disconnect all equipments and turn off the monitor.

Respiration Operation

1. Press ***Power on/off button*** to turn on the monitor.
2. Connect ECG lead wires to an appropriate jack on the respiration simulator.
3. Connect ECG lead wires to the ECG cable.
4. Connect the ECG cable to the ECG connector on the monitor's left panel.
5. Set the respiration simulator to 120 breaths per minute.
6. After the normal power-up sequence, verify the following reactions:
    a. The monitor displays respiration rate of 120 ±3 breaths per minute.
    b. Audible alarm will sound, "***Resp: Upper limit violated***" message will display and the Respiration numerical area will flash, indicating a respiration rate is above default upper alarm limits. (high priority alarm)
7. Decrease the respiration rate setting on the respiration simulator to 20 breaths per minute.
    a. Verify that the monitor displays the respiration rate of 20 ±3 breaths per minute.

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

Temperature Operation

1. Press ***Power on/off button*** to turn on the monitor.
2. Connect the temperature probe (supplied with the temperature simulator) to an appropriate jack on the temperature simulator.
3. Connect the temperature probe to the temperature connector on the monitor's left panel.
4. Set the temperature simulator as follows:
    - Temperature: 37°C (98.0°F)
    - Probe type: YSI-400 series Temperature Probes (Probe accuracy: ±0.1°C)
5. After the normal power-up sequence, verify that the temperature reads 37°C ±0.1°C (98.6°F ±0.2°F if Fahrenheit is selected for the temperature unit).
6. Turn off the monitor.

Note: The accuracy of 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. In the procedure above, add the tolerance of the simulator and the probe to the acceptable range of readings.

IBP Operation

1. Connect the monitor to an AC power source.
2. Turn on the monitor by pressing the ***Power on/off button.***
3. Connect the IBP test cable to the IBP simulator, then turn on the IBP simulator.
4. Press ***6, zero button*** on the IBP simulator, then press ***enter*** button on the IBP simulator.
5. Connect the other end of IBP test cables to IBP channel 1 and 2 connectors on the monitor's left panel after completed the POST.
6. The monitor will display IBP waveform's baseline on the screen.
7. Select IBP waveform menu or IBP menu, then set ***Pressure Zero Setting***, to ***Yes*** to perform the zero calibration.
8. If zero calibration is successful, the monitor will display the value "0" on the IBP numerical area.
9. Press the ***5, wavef button*** on the IBP simulator, then press ***enter*** button on the IBP simulator.
10. The monitor will:
    - display IBP waveform on the screen.
    - display systolic, mean, diastolic measurement values on the IBP numerical area.

Note: Initial values of IBP simulator are systolic 120mmHg, diastolic 80mmHg at channel 1, systolic 120mmHg, diastolic 0mmHg at channel 2.

CO_2 Operation

2. Connect the monitor to an AC power source. Turn on the monitor.
3. Rotate the jog dial to highlight CO_2 numerical area and then press the jog dial to display the CO_2 menu.
4. Verifying that ***Capno Measurement*** is set to ***On*** in CO_2 menu.
5. Test #1: Display Accuracy
    a. Connect the 10% calibration gas cylinder with the valve to the sampling tube connected to the water trap of the monitor.
    b. After passed the warm up time (about 3 minutes), repeat 3 or 4 times turning on and off the valve of the gas cylinder with the interval of 1 to 2 seconds.
    c. Verifying that the monitor displays 76mmHg ± 2mmHg in CO_2 numerical area.
6. Test #2: Flow Rate
    a. Connect the flow meter to the sampling tube connected to the monitor.
    b. Connect a sampling tube to the other side of the flow meter and make the other side of the sampling tube open.
    c. Verify that the flow rate is between 150 ± 2mmHg.
7. Test #3: Water Trap
    a. Check that the module does not indicate a "Water trap full" message when a clean water trap is installed. If this is correct, remove the water bottle and block the path between the water trap LED and detector.
    b. Verify that a "water trap full" message appears.
8. Test #4: Occlusion
    a. Block the sample input. The module should enter the "occlusion" state. Verify that it does correctly enter this occlusion state.
    b. Unblock the input. Verify that after the modules occlusion sequence of high flow rates and valve actuations the occlusion message disappears and the module restores normal function.

Safety Tests

The monitor 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.

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 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.

Electrical Leakage

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 the test as recommended by analyzer operating instructions.

Table 3. Earth Leakage Current Values

Test Condition	Allowable Leakage Current (microamps)
Normal Condition (NC)	500
SFC Open Supply (SFC OS)	1000
Normal Condition RM (NCRM)	500
SFC Open Supply RM (SFC OSRM)	1000

SFC: Single Fault Condition / RM: Reverse Mains/Lines Voltage

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.

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 200cm^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 not exceed the values listed in Table 9.

Table 4. Enclosure Leakage Current

Test Condition	Allowable Leakage Current (microamps)
Normal Condition (NC)	100
SFC Open Supply (OS)	500
SFC Open Earth (SFC OE)	500
Normal Condition RM (NCRM)	100
SFC Open Supply RM (SFC OSRM)	500
SFC Open Earth RM (SFC OERM)	500

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 monitor and the appropriate input connector on the analyzer.
4. Turn on the monitor.
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 Condition (NC)	10
SFC Open Supply (OS)	50
SFC Open Earth (SFC OE)	50
Normal Condition RM (NCRM)	10
SFC Open Supply RM (SFC OSRM)	50
SRC Open Earth RM (SFC OERM)	50

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 paragraph "**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 the monitor and the appropriate input connector on the analyzer.
4. Turn on the monitor.
5. Perform the test as recommended by the analyzer operating instructions.
6. Repeat the test for SpO_2 and temperature patient connections, using the 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 (SFC)	50
Reverse polarity (SFCRM)	50

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 paragraph "**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 monitor.
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 #2 (LL)
ECG #1 (LA)	ECG # 3 (RA)
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
ECG #1 (LA)	IBP
ECG #2 (LL)	IBP
ECG #3 (RA)	IBP
SpO_2	IBP
Temperature 1/2	IBP
Temperature 1/2	SpO_2

Table 8. Allowable Leakage Current

Test Condition	Allowable Leakage Current (microamps)
Normal Condition (NC)	10
SFC Open Supply (OS)	50
SFC Open Earth (SFC OE)	50
Normal Condition RM (NCRM)	10
SFC Open Supply RM (SFC OSRM)	50
SRC Open Earth RM (SFC OERM)	50

Verification Check Sheet

Record the results of the performance verification on the sheet.

Model Name		Serial No.		Date		Tester	

PERFORMANCE TEST			
ITEMS	**RESULTS**	**REMARKS**	
Power	Pass / Fail		
Battery charge	Pass / Fail		
Battery discharge	Pass / Fail		
Power-on self-test (POST)	Pass / Fail		
Alarms and alarm silence	Pass / Fail		
HR/PR tone volume control	Pass / Fail		
Sensor LED excitation test	Pass / Fail		
Restoring power-on default settings	Pass / Fail		
Recorder test (option)	-		
- 20 sec printing	Pass / Fail		
- Continuous printing	Pass / Fail		
- Record speed	Pass / Fail		
- Wave record select	Pass / Fail		
- Record on alarm	Pass / Fail		
- Auto list record	Pass / Fail		
Serial interface test	Pass / Fail		
Network test	Pass / Fail		
USB interface test	Pass / Fail		
ECG operation	-		
- 30 ±.3 bpm (High priority alarm condition)	Pass / Fail	Value:	bpm
- 240 ±.3 bpm (High priority alarm condition)	Pass / Fail	Value:	bpm
- 120±.3 bpm (Normal condition)	Pass / Fail	Value:	bpm
- ECG lead off (LL)	Pass / Fail		
- ECG lead off (LA)	Pass / Fail		
- ECG lead off (RA)	Pass / Fail		
NIBP operation			
- Pressure sensor accuracy test 0 ±.0 mmHg	Pass / Fail	Value:	mmHg
- Pressure sensor accuracy test 50 ±.6 mmHg			
- Pressure sensor accuracy test 100 ±.6 mmHg	Pass / Fail	Value:	mmHg
- Pressure sensor accuracy test 200 ±.6 mmHg	Pass / Fail	Value:	mmHg
- Air leakage test 12mmHg/3minutes	Pass / Fail	Value:	mmHg
Pulse oximetry operation	-		
- SpO2 90 ± 2 %	Pass / Fail	Value:	%
- Pulse rate 60 ± 3 bpm	Pass / Fail	Value:	bpm
- Modulation level	Pass / Fail		
Respiration operation	Pass / Fail		
Temperature operation	Pass / Fail		
IBP operation	Pass / Fail		
CO_2 operation	-		
- Display accuracy	Pass / Fail		
- Flow rate	Pass / Fail		
- Water trap	Pass / Fail		
- Occlusion	Pass / Fail		
SYSTEM TEST			
Switch/LED test	Pass / Fail		
LCD test	Pass / Fail		
Alarm audible test	Pass / Fail		
Tone audible test	Pass / Fail		
Recorder test	Pass / Fail		

SAFETY TEST			
TEST CONDITIONS	**LIMIT (uA)**	**RESULTS**	**REMARKS**
Earth leakage current (NC)	500	Pass / Fail	Value: uA
Earth leakage current (SFC OS)	1000	Pass / Fail	Value: uA
Earth leakage current (NCRM)	500	Pass / Fail	Value: uA
Earth leakage current (SFC OSRM)	1000	Pass / Fail	Value: uA
Enclosure leakage current (NC)	100	Pass / Fail	Value: uA
Enclosure leakage current (OS)	500	Pass / Fail	Value: uA
Enclosure leakage current (SFC OE)	500	Pass / Fail	Value: uA
Enclosure leakage current (NCRM)	100	Pass / Fail	Value: uA
Enclosure leakage current (SFC OSRM)	500	Pass / Fail	Value: uA
Enclosure leakage current (SFC OERM)	500	Pass / Fail	Value: uA
Patient leakage current (NC)	10	Pass / Fail	Value: uA
Patient leakage current (OS)	50	Pass / Fail	Value: uA
Patient leakage current (SFC OE)	50	Pass / Fail	Value: uA
Patient leakage current (NCRM)	10	Pass / Fail	Value: uA
Patient leakage current (SFC OSRM)	50	Pass / Fail	Value: uA
Patient leakage current (SFC OERM)	50	Pass / Fail	Value: uA
Mains voltage on applied part (SFC)	50	Pass / Fail	Value: uA
Mains voltage on applied part (SFCRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP2 (NC)	10	Pass / Fail	Value: uA

SAFETY TEST			
TEST CONDITIONS	**LIMIT (uA)**	**RESULTS**	**REMARKS**
Patient auxiliary current ECG RA-TEMP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-IBP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-IBP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-IBP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP1 (SFC OE)	50	Pass / Fail	Value: uA

SAFETY TEST			
TEST CONDITIONS	**LIMIT (uA)**	**RESULTS**	**REMARKS**
Patient auxiliary current SpO_2-IBP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current SpO_2-IBP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-IBP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP1-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP1 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP1 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP1 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP1 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP1 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP1 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-IBP2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP2-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA

Remarks

NC:	Normal Condition
NCRM:	Normal Condition Reverse
SFC:	Single Fault Condition
OS:	Single Fault Condition (Open Line/Neutral)
OSRM:	Single Fault Condition (Open Line/Neutral) Reverse
OE:	Single Fault Condition (Open Earth)
OERM:	Single Fault Condition (Open Earth) Reverse

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SERVICE MENU AND FACTORY DEFAULT

General

This section discusses use of the Service menu to configure 'Save setting on Power off', 'Audible Alarm Silence Period', 'Audible Alarm Suspend Period', 'Audible Alarm Type', 'AC Line Frequency', 'Unit Configuration', 'Language Setting', 'Date Format', 'Jog Dial Speed', 'System Setting', 'System Test', 'NIBP Test' and 'Demo Mode'. Also, this section explains briefly the factory default settings.

Service Menu

The purpose of the Service menu (Figure 12, Table 9) is to allow the authorized user to create a Power-on default for the settings in effect each time the monitor 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 monitor (also see **Using the Monitor** section of the operator's manual):

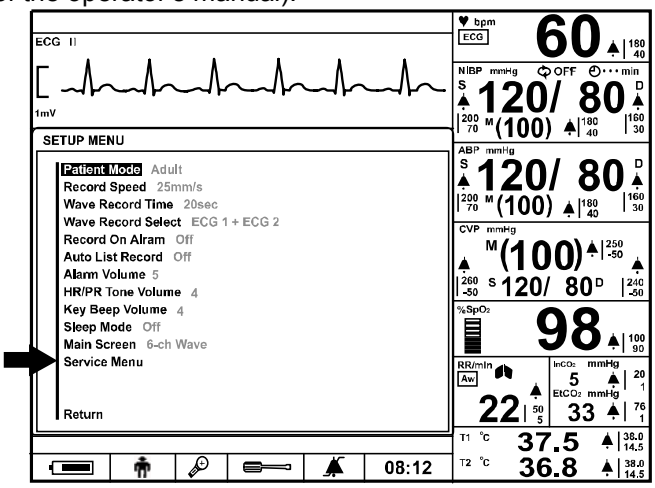

Figure 12. The access of Service Menu via Set-up menu

1. Set the monitor to normal monitoring mode.
2. Rotate the jog dial to highlight the ***Setup icon*** located on the bottom of the screen, and then press the jog dial. ***Setup menu*** displays.
3. Rotate the jog dial to highlight ***Service Menu*** in ***Setup menu***, and then press the jog dial to access the ***Service Menu***.
4. Three digits are displayed in the Level 2 Menu as shown in Figure 12.

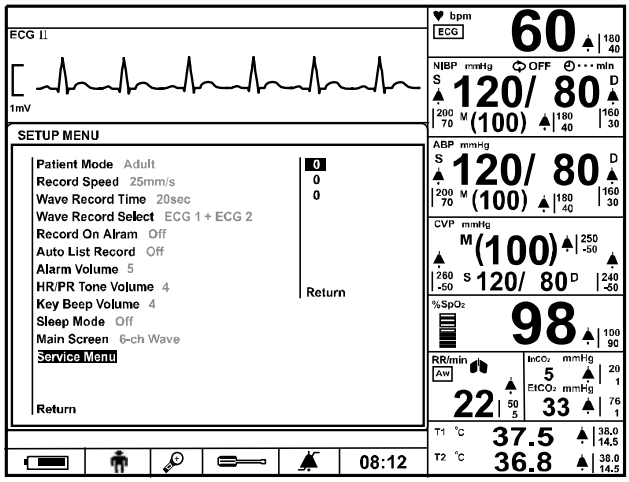

Figure 13. Entering the pass code

Note: The access code is **6, 0, 6**. It is set at the factory and may not be changed.

5. Rotate the jog dial to highlight the top of the digits. Press the jog dial to enter ***Pass code***.
6. Rotate the jog dial until "6" appears, then press the jog dial.
7. Repeat step 5-6 to enter all the access code "**6**""**0** "**6**".

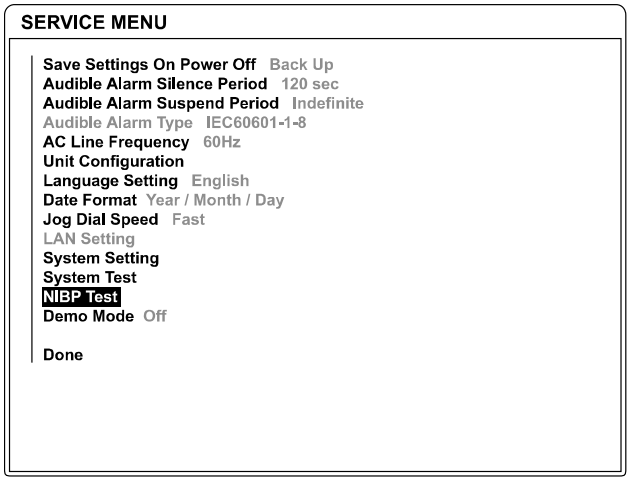

Figure 14. Service Menu

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 jog dial.
9. Select "Done". The monitor will present the message "All changes made to the power-up defaults will be in effect the next time the monitor is turned on:" before turned off.
10. Turn off the monitor, and then turn on the monitor 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 monitor is powered up.

Table 9. Service menu

Level 1 Menu	Level 2 Menu	Level 3 Menu
Save settings on Power off	Custom	
	Back Up	
	Default	
Audible Alarm Silence Period	30, 60 90, 120 seconds	
Audible Alarm Suspend Period	Off, 10, 20, 30, 60 minutes, Indefinite	
Audible Alarm Type	IEC60601-1-8	
AC Line Frequency	50Hz, 60Hz	
Unit Configuration	NIBP	mmHg, kPa
	IBP	mmHg, kPa
	CO_2	mmHg, %, kPa
	Temperature	°C, °F
Language Setting	한국어 (Korean), 中文 (Chinese), Dansk (Danish), Nederlands (Dutch), English, Français (French), Deutsch (German), Italiano (Italian), 日本語 (Japanese), Português (Portuguese), Español (Spanish), Svenska (Swedish)	
Date Format	Year/Month/Day, Month/Day/Year, Day/Month/Year	
Jog Dial Speed	Fast, Normal	
LAN Setting	For future release	
System Setting	Monitor On Time	
	Recorder On Time	
	Battery Deep Discharges	
	System Software Version	
	Module Version	
	Print value of configuration	
	Tone Set (Detail)	
System Test	Switch/LED Test	
	LCD Test	
	Alarm Audible Test	
	Tone Audible Test	
	Recorder Test	
	Backup RAM Clear	
NIBP Test	Pressure Sensor Accuracy Test	
	Air Leakage Test	
	Inflation Speed Test	
	Initial Deflation Test (I)	
	Initial Deflation Test (II)	
	Deflations Speed Test	
	Offset Test	
Demo Mode	On, Off	
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 settings on Power off

If the save settings on power off is set to ***Custom***, the monitor does not save the settings when the monitor is power off. Therefore, the first settings when the monitor is powered up become the power-up defaults in the next power-on cycling.
If the save settings on power off is set to ***Back Up***, the monitor saves the current settings when the monitor is powered off. The saved settings become the power-on defaults in the next power-on cycling.
If the save settings on power off is set to ***Default***, the factory default settings become the power-up defaults in the next power-on cycling.

Audible Alarm Silence Period

Pressing ***Alarm silence button*** temporarily silences alarms for the period selected in the service menu. The factory default of alarm silence period is 120 seconds.

Audible Alarm Suspend Period

If ***Audible Alarm suspend period*** is set to other than ***Off*** or ***Indefinite***, the audible alarm is not activated for the time interval by pressing and holding the ***Alarm silence button*** for 2 seconds. If ***Off*** is selected, the audible alarm suspension is not allowed to activate. If ***Indefinite*** is selected, the audible alarm suspension continues until canceled. (inhibition)

Audible Alarm Type

The monitor has an audible alarm type in accordance with IEC60601-1-8.

Table 10. Audible Alarm Characteristics

Alarm Category	Tone Pitch	Beep Rate
High priority	High	10 beeps in 10 seconds
Medium priority	Medium	3 beeps in 16 seconds

AC Line Frequency

The monitor supports ***AC line frequency*** both 50 Hz and 60 Hz. Select either ***50Hz*** or ***60 Hz*** for an appropriate AC line.

Unit Configuration

The unit configuration of each parameter can be set in the service menu.

Language Setting

The selected language will be used for all the text shown on the display; and it will be effective from the next powered up.

Date Format

The date format is selectable; Year/Month/Day, Month/Day/Year, Day/Month/Year

Jog Dial Speed

The jog dial speed is selectable; Fast, Normal

System Setting

This menu displays the information for system settings.

Monitor On Time
This menu displays the number of hours, minutes and seconds, rounded to the nearest hour that the monitor has been operational. The term that the monitor is in the service mode is not included.

Recorder On Time
This menu displays the number of hours, minutes and seconds, rounded to the nearest hour that the Recorder has been operational.

Battery Deep Discharges
This menu displays the number of deep-discharge cycles seen by the battery. The monitor records a deep discharge cycle when the monitor is automatically turned off after a “Critically Low Battery” alarm is issued.

System Software Version
This menu displays the revision level of the system software. The revision level is also shown on the LCD as part of the Copyright screen.

Module Version
This menu displays information for each module or board version.

Print Value of Configuration
This menu is used to print out the set values. This function is useful when collecting a wrong value.

Tone Set (Detail)
This menu used to set the HR/PR tone with High, Medium, Low or SpO_2.

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 CPU module is installed.

System Test

These menus provide to facilitate performing verification testing for the overall system. For a detailed procedure, refer to **Performance Verification** section**.**

Table 11. System Test

Tests	Description
Switch/LED Test	tests the buttons, jog dial and visual alarm indicator.
LCD Test	tests the LCD display.
Alarm Audible Test	tests the alarm tones.
Tone audible Test	tests the HR/PR tones, the key beeps and the completion sounds.
Recorder Test	tests the printing condition.
Backup RAM Clear	is used to set the factory defaults.

NIBP Test

These menus provide to facilitate performing verification testing for the NIBP subsystem. For a detailed procedure, refer to **Performance Verification** section**.**

Table 12. NIBP Test

Tests	Description
Pressure Sensor Accuracy Test	verifies that the pneumatic pressure sensor accuracy is within the specification.
Air Leakage Test	verifies that the pneumatic pressure air leakage is within a pressure drop of 3 mmHg/min.
Inflation Speed Test	is intended for factory use only.
Initial Deflation Test (I)	is intended for factory use only.
Initial Deflation Test (II)	is intended for factory use only.
Deflation Speed Test	is intended for factory use only.
Offset Test	is intended for factory use only.
Return	returns to Service Menu after the test completed.

Demo Mode

The purpose of Demo Mode is to show a visual presentation demonstrating how the monitor works.

Factory Default Settings

Factory default settings are divided into adult and neonatal as described in Table 13.

The patient mode is preset to “Adult” mode. Alarm limits will be automatically changed to the default settings for each patient mode as the mode is changed to Adult or Neonatal mode.

Table 13. Factory Default Settings

Parameter	Ranges/Selections	Factory Defaults	
		Adult	Neonatal
ECG			
ECG Cable Select	3 Leads, 5 Leads, AUTO	AUTO	AUTO
ECG Lead Select	I, II, III, aVR, aVL, aVF, V(Chest Lead)	-	-
ECG Size (mm/mV)	×1/4, ×1/2, ×1, ×1.5, ×2	×1	×1
ECG Filter Mode	Monitor, Low Extend, Filter, Respiration Rejection	Monitor	Monitor
ECG Pacer Detect	On, Off	Off	Off
ECG Sweep Speed	12.5, 25.0, 50.0 mm/s	25.0 mm/s	25.0 mm/s
HR/PR Source	AUTO, HR, PR	AUTO	AUTO
HR/PR Upper Alarm Limits	35 to 305 bpm (Adult/Neo) (5 bpm steps)	180 bpm	200 bpm
HR/PR Lower Alarm Limits	30 to 300 bpm (Adult/Neo) (5 bpm steps)	40 bpm	50 bpm
NIBP			
NIBP Initial Cuff Inflation	120, 140, 160, 180, 200, 220mmHg (Adult) (16.0, 18.7, 21.3, 24.0, 26.7, 29.3, kPa) 80, 100, 120, 140 mmHg (Neo) (9.3, 12.0, 14.7, 16.0, 18.7 kPa)	180 mmHg 24.0 kPa	120 mmHg 16.0 kPa
BP On Alarm	On, Off	Off	Off
Smart Clock	On, Off	On	On
Smart Inflation	On, Off	On	On
Completion Sound	On, Off	On	On
NIBP Automatic Mode Interval	Off, Cont, 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45, 60, 90,120 ,180 minutes	Off	Off
NIBP SYS Upper Alarm Limits	60 to 260 mmHg (Adult), 40 to 130 mmHg (Neo) 8.0 to 34.7 kPa (Adult), 5.3 to 17.3 kPa (Neo) (10 mmHg / 1.3 kPa steps)	200 mmHg 26.7 kPa	130 mmHg 17.3 kPa
NIBP SYS Lower Alarm Limits	50 to 250 mmHg (Adult), 30 to 120 mmHg (Neo) 6.7 to 33.3 kPa (Adult), 4.0to 16.0 kPa (Neo) (10 mmHg / 1.3 kPa steps)	70 mmHg 9.3 kPa	50 mmHg 6.7 kPa
NIBP DIA Upper Alarm Limits	40 to 210 mmHg (Adult), 20 to 100 mmHg (Neo) 5.3 to 28.0 kPa (Adult), 2.7 to 13.3 kPa (Adult) (10 mmHg / 1.3 kPa steps)	160 mmHg 21.3 kPa	100 mmHg 13.3 kPa
NIBP DIA Lower Alarm Limits	30 to 200 mmHg (Adult), 10 to 90 mmHg (Neo) 4.0 to 26.7 kPa (Adult), 1.3 to 12.0 kPa (Neo) (10 mmHg / 1.3 kPa steps)	30 mmHg 4.0 kPa	10 mmHg 1.3 kPa
NIBP MAP Upper Alarm Limits	50 to 240 mmHg (Adult), 30 to 110 mmHg (Neo) 6.7 to 32.0 kPa (Adult), 4.0 to 14.7 kPa (Neo) (10 mmHg / 1.3 kPa steps)	180 mmHg 24.0 kPa	110 mmHg 14.6 kPa
NIBP MAP Lower Alarm Limits	40 to 230 mmHg (Adult), 20 to 100 mmHg (Neo) 5.3 to 30.7 kPa (Adult), 2.7 to 13.3 kPa (Neo) (10 mmHg / 1.3 kPa steps)	40 mmHg 5.3 kPa	20 mmHg 2.7 kPa
IBP			
IBP Sweep Speed	12.5, 25.0, 50.0 mm/s	25.0 mm/s	25.0 mm/s
Pressure Zero Setting	Yes, No	No	No
P1 Label	P1, ABP	ABP	ABP

Parameter	Ranges/Selections	Factory Defaults	
		Adult	Neonatal
P1 Scale	0~50, 0~100, 0~200, 0~300, AUTO	AUTO	AUTO
P1 SYS Upper Alarm Limits	-50 to 260 mmHg (Adult/Neo) (10 mmHg steps) -6.7 to 34.7 kPa (Adult/Neo) (1.3 kPa steps)	200 mmHg 26.7 kPa	130 mmHg 17.3 kPa
P1 SYS Lower Alarm Limits	-60 to 250 mmHg (Adult/Neo) (10 mmHg steps) -8.0 to 33.3 kPa (Adult/Neo) (1.3 kPa steps)	70 mmHg 9.3 kPa	50 mmHg 6.7 kPa
P1 DIA Upper Alarm Limits	-50 to 260 mmHg (Adult/Neo) (10 mmHg steps) -6.7 to 34.7 kPa (Adult/Neo) (1.3 kPa steps)	160 mmHg 21.3 kPa	100 mmHg 13.3 kPa
P1 DIA Lower Alarm Limits	-60 to 250 mmHg (Adult/Neo) (10 mmHg steps) -8.0 to 33.3 kPa (Adult/Neo) (1.3 kPa steps)	30 mmHg 4.0 kPa	10 mmHg 1.3 kPa
P1 MEAN Upper Alarm Limits	-50 to 260 mmHg (Adult/Neo) (10 mmHg steps) -6.7 to 34.7 kPa (Adult/Neo) (1.3 kPa steps)	180 mmHg 24.0 kPa	110 mmHg 14.7 kPa
P1 MEAN Lower Alarm Limits	-60 to 250 mmHg (Adult/Neo) (10 mmHg steps) -8.0 to 33.3 kPa (Adult/Neo) (1.3 kPa steps)	40 mmHg 5.3 kPa	20 mmHg 2.7 kPa
P2 Label	P2, CVP, PAP, LAP	CVP	CVP
P2 Scale	0~20, 0~50, 0~100, 0~200, 0~300, AUTO	AUTO	AUTO
P2 SYS Upper Alarm Limits	-50 to 260 mmHg (Adult/Neo) (10 mmHg steps) -6.7 to 34.7 kPa (Adult/Neo) (1.3 kPa steps)	200 mmHg	130 mmHg
P2 SYS Lower Alarm Limits	-60 to 250 mmHg (Adult/Neo) (10 mmHg steps) -8.0 to 33.3 kPa (Adult/Neo) (1.3 kPa steps)	70 mmHg 9.3 kPa	50 mmHg 6.7 kPa
P2 DIA Upper Alarm Limits	-50 to 260 mmHg (Adult/Neo) (10 mmHg steps) -6.7 to 34.7 kPa (Adult/Neo) (1.3 kPa steps)	160 mmHg 21.3 kPa	100 mmHg 13.3 kPa
P2 DIA Lower Alarm Limits	-60 to 250 mmHg (Adult/Neo) (10 mmHg steps) -8.0 to 33.3 kPa (Adult/Neo) (1.3 kPa steps)	30 mmHg 4.0 kPa	10 mmHg 1.3 kPa
P2 MEAN Upper Alarm Limits	-50 to 260 mmHg (Adult/Neo) (10 mmHg steps) -6.7 to 34.7 kPa (Adult/Neo) (1.3 kPa steps)	180 mmHg 24.0 kPa	110 mmHg 14.7 kPa
P2 MEAN Lower Alarm Limits	-60 to 250 mmHg (Adult/Neo) (10 mmHg steps) -8.0 to 33.3 kPa (Adult/Neo) (1.3 kPa steps)	40 mmHg 5.3 kPa	20 mmHg 2.7 kPa
SpO_2			
C-Lock	On, Off	Off	Off
PLETH Sweep Speed	12.5, 25.0, 50.0 mm/s	25.0 mm/s	25.0 mm/s
%SpO_2 Upper Alarm Limits	70 to 100 % (Adult/Neo) (1 % steps)	100 %	100 %
%SpO_2 Lower Alarm Limits	69 to 99 % (Adult/Neo) (1 % steps)	90 %	85 %
Respiration			
Apnea Time Setting	Off, 20, 30, 40, 50, 60 sec, Step 60, Step 90	30 sec	30 sec
Respiration/Apnea	Off, AUTO, awRR, imRR	AUTO	AUTO
Respiration Size	×1/4, ×1/2, ×1, ×1.5, ×2	×1	×1
Respiration Sweep Speed	6.25, 12.5, 25.0 mm/s	12.5 mm/s	12.5 mm/s
RR Upper Alarm Limits	5 to 155 bpm (5 bpm steps)	30 bpm	50 bpm
RR Lower Alarm Limits	0 to 150 bpm (5 bpm steps)	0 bpm	0 bpm
Capnography			
CAPNO Sweep Speed	6.25, 12.5, 25.0 mm/s	12.5 mm/s	12.5 mm/s
Scale	0~40, 0~60, 0~80, AUTO	AUTO	AUTO
Capno Measurement	On, Off	On	On
Calibration	Yes, No	No	No
$EtCO_2$ Upper Alarm Limits	2 to 80 mmHg (Adult/Neo) (2 mmHg steps) 0.3 to 10.7 kPa (Adult/Neo) (0.3 kPa steps) 0.3 to 10.5 % (Adult/Neo) (0.3 % steps)	80 mmHg 10.7 kPa 10.5 %	80 mmHg 10.7 kPa 10.5 %
$EtCO_2$ Lower Alarm Limits	0 to 78 mmHg (Adult/Neo) (2 mmHg steps) 0 to 10.4 kPa (Adult/Neo) (0.3 kPa steps) 0 to 10.3 % (Adult/Neo) (0.3 % steps)	0 mmHg 0 kPa 0 %	0 mmHg 0 kPa 0 %
$InCO_2$ Upper Alarm Limits	2 to 20 mmHg (Adult/Neo) (2 mmHg steps) 0.3 to 2.7 mmHg (Adult/Neo) (0.3 kPa steps) 0.3 to 2.6 % (Adult/Neo) (0.3 % steps)	20 mmHg 2.7 kPa 2.6 %	20 mmHg 2.7 kPa 2.6 %

Parameter	Ranges/Selections	Factory Defaults	
		Adult	Neonatal
$InCO_2$ Lower Alarm Limits	0 to 18 mmHg (Adult/Neo) (2 mmHg steps) 0 to 2.4 kPa (Adult/Neo) (0.3 kPa steps) 0 to 2.3 % (Adult/Neo) (0.3 % steps)	0 mmHg 0 kPa 0 %	0 mmHg 0 kPa 0 %
Temperature			
T1, T2 Upper Alarm Limits	15.0 to 45.5 °C (Adult/Neo) (0.5º C steps) 59.0 to 113.9 °F (Adult/Neo) (0.1°F steps)	38.0 °C (100.4 º F)	39.0 °C (102.2 º F)
T1, T2 Lower Alarm Limits	14.5 to 45.0 °C (Adult/Neo) (0.5º C steps) 58.1 to 113.0 °F (Adult/Neo) (0.1°F steps)	14.5 °F (58.1 °F)	14.5 °F (58.1 °F)
Others			
Patient Mode	Adult, Neonatal	Adult	
Record Speed**	25.0 mm/s, 50.0 mm/s	25.0 mm/s	
Wave Record Time**	20 sec, Continuous (10sec delay)	20 sec	
Wave Record Select**	ECG1 + ECG2, PLETH, RESP, IBP1, IBP2 or CAPNO	ECG1 + PLETH	
Record on Alarm**	On, Off	Off	
Auto List Record**	On, Off	Off	
Alarm Volume	1, 2, 3, 4, 5, 6, 7, 8	5	
HR/PR tone Volume	Off, 1, 2, 3, 4, 5, 6, 7	4	
Key Beep Volume	Off, 1, 2, 3, 4, 5, 6, 7	4	
Sleep Mode	Off, 10, 20, 30 min	Off	
Main Screen	4ch-wave, 6ch-wave, Big Number	-	
Alarm Limits Display	On, Off	On	
Auto Alarm	On, Off	Off	
Auto Alarm Setting (Upper)	+10 to +50%	+40%	
Auto Alarm Setting (Lower)	-50 to -10%	-20%	
Save Time Interval	Off, 0.5,1,2,2.5,5,10,15,20,30,60,120 min	Off	
Graphical Display On/Off	On/Off for each parameter	On	
Save Setting on Power Off*	Custom, Back up, Default	Back up	
Audible Alarm Silence Period*	30, 60, 90, 120 sec	120 sec	
Audible Alarm Suspend Period*	Off, 10, 20, 30, 60 min, Indefinite (Alarm Inhibition)	Indefinite	
AC Line Frequency*	50, 60 Hz	60 Hz	
NIBP Unit*	mmHg, kPa	mmHg	
IBP Unit*	mmHg, kPa	mmHg	
CO_2 Unit*`	mmHg, %, kPa	mmHg	
Temperature Unit*	°C , °F	°C	
HR/PR Tone Set*	High, Med, Low, SpO_2	High	
Date Format*	year/month/day, month/day/year, day/month/year	year/month/day	
Jog Dial Speed*	Fast, Normal	Normal	
Demo Mode*	On, Off	Off	
Language*	한국어 (Korean), 中文 (Chinese), Dansk (Danish), Nederlands (Dutch), English, Français (French), Deutsch (German), Italiano (Italian), 日本語 (Japanese), Português (Portuguese), Español (Spanish), Svenska (Swedish)	English	

Note: An asterisk (*) by a parameter in the above table indicates that the parameter can only be changed by authorized personnel as described in the service manual

Note: Asterisks (**) by a parameter in the above table indicate the settings only when an optional recorder is installed in the monitor.

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FIRMWARE DOWNLOAD

General

This section is for the purpose for reloading Firmware into the monitor when the possibility of corrupted Firmware exists, or updating Firmware with a new system revision (system/device version). Call your local supplier for the latest version of Firmware utility required.

Equipment Needed

Table 14 lists the equipment required for Firmware download.

Table 14. Required Equipments for Firmware Download

Equipment	Description
Firmware Download Tool	USB Memory with BP-S510 Field Utility (firmware downloading software)

How to Download

1. Turn off the monitor.
2. Turn on the monitor by pressing the **Power on/off button**.
3. The monitor displays the bar while the checksum for the flash memory is in progress
4. Press ***NIBP start/stop button*** and ***NIBP interval*** simultaneously before filled the bar completely.
5. The monitor will display the firmware upgrade screen as shown below figure 15.

Figure 15. Firmware downloading display

6. Connect USB memory to the USB port on the right panel of the monitor.
7. **BP-S510 Field Utility** will be run automatically. It will take about 5 minutes.

8. Three bars on the screen indicate the progress status for the downloading.

   “T” displays the transferring status from the USB memory to the monitor.

   “D” displays the deleting status of the flash memory.

   “W” displays the writing status of the flash memory.

9. When three bars are filled, the completion code will be displayed in the box located on the center of the screen as shown Figure 16. Refer to Table 15.

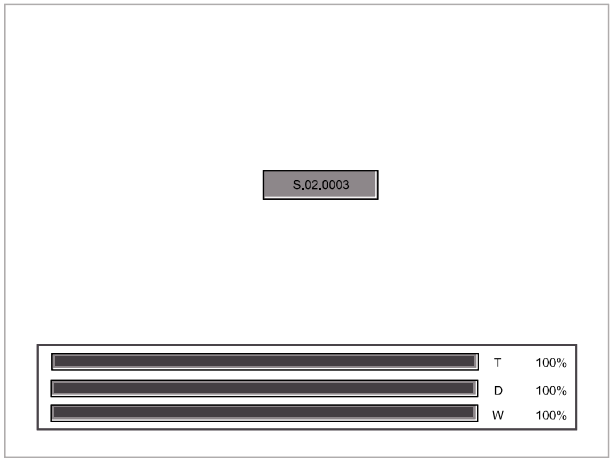

Figure 16. Firmware downloading completion

Table 15. Completion codes

Code	Description
I.00.0001	USB is not connected
S.00.0001	Find USB
S.01.0001	Boot download & fusing complete
S.02.0001	Main download & fusing complete

Note: If any problem during Firmware downloading, the error code will be displayed in the box located on the center of the screen. Refer to Firmware Download in **Troubleshooting** section.

10. After completion of downloading, turn off the monitor.
11. Disconnect the USB memory from the monitor.
12. After a few seconds, turn on the monitor again.
13. Check the system version indicated on the copyright screen.

Note: You can check the boot version on the bar while the monitor performs the checksum for the memory.

14. Perform the tests specified in **Performance Verification** section.

Note: When a new firmware downloading is completed, the monitor still keeps the previous settings.

Note: If any problem occurs during Firmware downloading, refer to Firmware Download in **Troubleshooting** section.

TROULBESHOOTING

General

This section provides information that can be helpful in troubleshooting the BP-S510 monitor.

How to Use This Section

If the Unit is not functioning property, please check on the following item, before calling for repair service. Use this section in conjunction with **Performance Verification** section and **Spare Parts** section. To remove and replace a part suspected the trouble, follow the instructions in **Disassembly Guide** section.

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 your local supplier.

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
Omron Healthcare provides technical assistance information and replacement parts. To obtain replacement parts, contact your local supplier. Refer to the part names and part numbers listed in **Spare Parts** section.

Troubleshooting Guide

Problems with the monitor are separated into the categories for further troubleshooting instructions.

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 your local supplier.

Table 16. Problem Categories

Categories	Symptoms
1. Power	1.1: AC Power is on but Battery indicator is not lighting. 1.2: Monitor does not power up though the button is pressed. 1.3: Monitor shuts off automatically after power on. 1.4: Monitor does not power on with battery. 1.5: Monitor makes buzzer sound when turning on the monitor.
2. Display	2.1: The LCD display is blacked up after completed the POST. 2.2: LCD is illuminated but no data is visible. 2.3: Some pixels are not lighting.
3. Sound	3.1: Audible alarm not sound. 3.2: The key press tone fails to sound.
4. Jog dial and Buttons	4.1: One or some buttons does not respond. 4.2: The Jog Dial rotates, but no responds from the LCD display.
5. NIBP	5.1: The cuff does not inflate. 5.2: Error Message C11 or E03. 5.3: The NIBP value is not reliable.
6. SpO_2	6.1: The SpO_2 sensor does not light. 6.2: Sensor is lighting but no display on SpO_2 window.
7. CO_2	7.1: CO_2 module does not operate. 7.2: CO_2 module fails to calibration.
8. Temperature	8.1: TEMP {1 or 2} : Internal Error is displayed.
9. Respiration	9.1: Respiration (imRR) gets too much noise or cannot measure the Respiration (imRR). 9.2: Respiration is not displayed. 9.3: Does not measure Respiration (awRR).
10. Firmware download	Error Code displayed.
11. Technical alarm condition	Alarm message or error code displayed.

1. Power

Power problems are related to AC and/or Battery as follows. If the action requires replacement of the components, refer to **Disassembly Guide** section.

CAUTION: Electrical shock hazard. Disconnect a power cord from the monitor before attempting to open or disassemble the monitor.

Symptom 1.1: AC Power is on but Battery charging indicator is not lighting.

Cause	Check	Action	Remark
Power cord is not connected to the AC	AC power cord is properly connected to the AC outlet.	Re-connect AC connection or replace the AC power cord.	
Battery is not installed.	Battery is installed.	Install the battery.	
SMPS is malfunctioning	Charging voltage.	Replace the SMPS	
Front key board is malfunctioning.	Front key board or Front key wire.	Replace the front key board or the front key wire.	

Symptom 1.2: Monitor does not power up though the button is pressed.

Cause	Check	Action	Remark
SMPS is malfunctioning	Charging voltage.	Replace the SMPS	
Fuse of SMPS is burnt out.	Check the fuse of SMPS.	Replace the fuse or SMPS.	
Hub board is malfunctioning.	Connection between SMPS and Main Board.	Replace the hub board.	
Front key board is malfunctioning.	Front key board or Front key wire.	Replace the front key board or front key wire.	
Main board is malfunctioning.	-	Replace the main Board.	

Symptom 1.3: Monitor shuts off automatically after power on.

Cause	Check	Action	Remark
Main board is malfunctioning.	-	Replace the main board.	

Symptom 1.4: Monitor does not power on with battery.

Cause	Check	Action	Remark
Battery is not installed.	Battery is installed.	Pull out and re-install the battery.	
Battery is totally discharged.	Battery voltage.	Recharge the battery for 12 hours. Replace the battery.	
SMPS does not recharge the battery	Charging voltage of the SMPS	Replace the SMPS.	
Hub board is malfunctioning	Connection between the SMPS and the main Board.	Replace the hub board.	
Main board is malfunctioning.	-	Replace the main Board.	

Symptom 1.5: Monitor makes buzzer sound when turning on the monitor.

Cause	Check	Action	Remark
Hub board, Main board, SMPS or NIBP module are not assembled properly	Assemble between the boards	Reassemble the boards Replace the hub board. Replace the NIBP module. Replace the main board. Replace the SMPS.	

2. Display

Symptom 2.1: The LCD display is blacked up after normal POST.

2.2: LCD is illuminated but no data is visible.

2.3: Some pixels are not lighting.

Cause	Check	Action	Remark
LCD cable is loose.	LCD cable connection between Front assembly and Main board.	Reconnect the cable or replace the cable.	
Inverter wire is loose.	Inverter wire connection between Front assembly and Main board.	Reconnect the cable or replace the cable.	
LCD is malfunctioning	-	Replace the LCD.	

Symptom 2.4: Display values are missing or erratic.

Cause	Check	Action	Remark
Measurement Cables are not properly connected.	Each parameter cable connection. Zeroing the IBP Warming up the CO_2 module CO_2 calibration.	Replace the each cable. Replace the relevant parameter cables. Replace the relevant board or modules. Replace the Main board.	

3. Sound

Symptom 3.1: Audible alarm not sound.

Cause	Check	Action	Remark
Alarm silence is activated.	Alarm Silence button	Cancel the alarm silence condition.	
Speaker is faulty or wire is loose.	Speaker wire connection between speaker and Side Key Board.	Reconnect the wire or replace the speaker	
16pin cable between Side Key Board and Main board is loose.	Check the cable connection.	Replace the cable or replace the 16 pin cable.	
Main board is malfunctioning.	-	Replace the main board.	

Symptom 3.2: The key press tone fails to sound.

Cause	Check	Action	Remark
Beep volume is set to zero.	Key beep volume in Setup menu.	Increase the key beep volume in Setup menu.	
Speaker is faulty or wire is loose.	Speaker wire connection between speaker and Side Key Board.	Reconnect the wire or replace the speaker	
16 pin cable between Side key board and Main board is loose.	Check the cable connection.	Replace the cable or replace the 16 pin cable.	
Main board is malfunctioning.	-	Replace the main board.	

4. Jog Dial and Button problems

Symptom 4.1: One or some buttons does not respond.

Cause	Check	Action	Remark
Side key board or Front Key board is malfunctioning.	-	Replace the relevant board.	
Front key wire is loose.	Cable connection.	Reconnect the cable or replace the cables.	
Main board is malfunctioning.	-	Replace the main Board.	

Symptom 4.2: The Jog Dial rotates, but no responds from the LCD display.

Cause	Check	Action	Remark
The 16 pin cable is loose.	Cable connection between the boards.	Reconnect the cable or replace it.	
Side key board is malfunctioning.	-	Replace the side key Board.	
Main board is malfunctioning.	-	Replace the main Board.	

5. NIBP

Symptom 5.1: The cuff does not inflate.

Cause	Check	Action	Remark
Cuff or Cuff hose is folded.	Cuff and hose connection.	Unfold the cuff or cuff hose.	
NIBP tube inside of the monitor is blocked or kinked.	NIBP tube of the monitor inside.	Unfold the NIBP tube.	
NIBP module is malfunctioning.	-	Replace the NIBP module.	
Main board is malfunctioning.	-	Replace the main board.	

Symptom 5.2: Error Message C11 or E03

Cause	Check	Action	Remark
NIBP tube is disconnected.	The connection of NIBP tube.	Re-connect the NIBP tube. If the problem persists, replace the NIBP module.	

Symptom 5.3: The NIBP value is not reliable.

Cause	Check	Action	Remark
NIBP module is malfunctioning.	Sensor accuracy test, Air leakage test and Over-pressure test	Replace the NIBP module.	

6. SpO_2

Symptom 6.1: The SpO_2 sensor does not light.

Cause	Check	Action	Remark
The connection between SpO_2 sensor and extension cable is loose.	Connection between sensor and extension cable.	Reconnect them.	
SpO_2 module does not work.	-	Replace the SpO_2 module.	
Main board is malfunctioning.	-	Replace the Main Board.	

Symptom 6.2: Sensor is lighting but no display on SpO2 window.

Cause	Check	Action	Remark
SpO_2 module does not work.	-	Replace the SpO_2 module.	
Main board is malfunctioning.	-	Replace the main board.	

7. CO_2

Symptom 7.1: CO_2 module does not operate.

7.2: CO_2 module fails to calibration.

Cause	Check	Action	Remark
Measurement cables were not properly connected.	Cable connection of each point.	Re-set up the cable connections or replace the CO_2 accessories.	
CO_2 module does not operate.	-	Replace the CO_2 module.	
Main board is malfunctioning.	-	Replace the main board.	

8. Temperature

Symptom 8.1: TEMP {1 or 2} : Internal Error is displayed.

Cause	Check	Action	Remark
Temperature reset does not work.	-	Replace the main board.	

9. Respiration

Symptom 9.1: Respiration (imRR) gets too much noise or cannot measure the Respiration.

9.2: Respiration is not displayed.

Cause	Check	Action	Remark
ECG accessories are improperly connected or electrode is contaminated.	Accessory connection and electrode.	Replace the accessories or electrode.	
ECG board is malfunctioning.	-	Replace the ECG board.	
Main board is malfunctioning.	-	Replace the main board.	

Symptom 9.3 : Monitor does not measure Respiration (awRR).

Cause	Check	Action	Remark
CO_2 module is malfunctioning.	-	Replace the CO_2 module.	
Main board is malfunctioning.	-	Replace the main board.	

10. Firmware Download

If the error code appears during the firmware downloading, take the following action.

Note: If the alarm message still appears, take monitor out of service and contact your local supplier for advice on remedial action.

Table 17. Firmware Downloading Error Codes

Code	Description	Action
E.00.0001	USB is not used.	Check your USB memory.
E.00.0002	Section.muf file not found or break.	Check your USB memory.
E.00.0003	Ver.muf file not found or break.	Check your USB memory.
E.00.0004	Update.muf file not found or break.	Check your USB memory.
E.00.0005	Binary file not found or break.	Check your USB memory.
E.01.0003	Boot download failed.	Try downloading again.
E.02.0003	Main download failed.	Try downloading again.
E.01.0005	Burn boot failed.	Try downloading again.
E.02.0005	Burn main failed.	Try downloading again.
E.01.0007	Boot section different.	Try downloading again.
E.02.0007	Main section different.	Try downloading again.
E.91.Block No.	Boot section check error.	Contact your local supplier.
E.92.Block No.	Main section check error.	Try downloading again.

10. Technical Alarm Condition

When the monitor detects the technical alarm condition, the monitor will display the alarm message on the screen.

If the alarm message occurs, follow the check items in the below table to remove the alarm condition after checking the alarm message in the alarm message area or informative message area.

Table 18. Alarm Messages and Check Items

Alarm Messages	Check Items
NIBP: Check cuff (C11)	Cuff pressure did not increase enough even after activating the pump for more than 30 seconds (adult). There is a possibility that a cuff hose is disconnected, or a cuff may not be wrapped around an arm. Check cuff and cuff hose. This error possibly occurs in case of large cuffs that are wrapped around loosely. When the error still occurs even after checking above, there is a possible air leakage from a ruptured cuff. Replace it with a new one.
NIBP: Check cuff / Patient (C12)	Blood pressure could not be measured even after cuff pressure decreased. It is possibly because pulse was not strong enough for measurement, or because change of pulse amplitude could not be obtained. Check whether cuffs are not wrapped around thick clothing. After wrapping cuffs around property, measure again. When the error occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Cuff excessive artifact (C13)	Measurement failed because of patient movement during measurement. Tell the patient to stay still, then, measure again. When it occurs in the initial measurement in continuous mode, the

Alarm Messages	Check Items
	second measurement will start unless Stop button is pressed.
NIBP: Cuff insufficient pressure (C14)	Measurement failed because of insufficient pressurizing. There is a possibility that standard cuff pressure might be detected wrongly due to noises, motion artifact or external vibration. Check whether cuffs are not wrapped around thick clothing, whether the patient is moving and whether cuffs are free from outside vibrations, then, measure again. When it occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Cuff irregular pulses (C15)	Blood pressure could not be measured because oscillation graph was not normal. There is a possibility that motion artifact or vibration from outside might interrupt the measurement. Check whether the patient stays still and cuffs are free from external vibration, then, measure again. When it occurs in the initial measurement in continuous mode, the second measurement is continued unless Stop button is pressed.
NIBP: Cuff motion artifact (C16)	Blood pressure could not be measured because noises interrupted pulse waveform signal. Check for motion artifacts, or external vibration and then, measure again. When it occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Cuff time-out (C17)	Measurement was preventively stopped because measurement time exceeded 160 seconds (adult), There is a possibility that blood pressure might be repeatedly measured due to insufficient pressurizing caused by calcified pseudohypertension.
NIBP: Cuff time-out, over 160 pulses (C18)	Pulse waveform signal more than 160 beats are detected during measurement. There is possibility that noises might interrupt signal. Motion artifact or external vibrations possibly affected cuffs. Check for patient movement and if the cuff is free from stays still and cuffs are free from outside vibration, then, measure again.
NIBP: Cuff pressure failure (C19)	Cuff pressure exceeded more than 300 mmHg (adult) during measurement. There is a possibility that the patient moved during measurement or strong pressure from outside might be added to cuffs. Considering above, measure again.
NIBP: Cuff weak pulse (C20)	Amplitude of pulse obtained from cuffs are too weak. This error possibly occurs when cuffs are wrapped around loosely in ASO patients or when cuffs are wrapped around thick clothing. Wrap cuffs around properly, then, measure again.
NIBP: Check cuff, hose and mode (C21)	Patient to be measured, and cuff size used, do not match. This error may occur if the blood pressure measurement mode setting is incorrect, if the cuff has been wrapped tightly in the adult mode, loosely in the neonatal mode or if the arm has been bent during measurement. Check the measurement mode setting and application of the cuff, and measure again.
NIBP: Internal error (E03)	NIBP module error BPM pressure sensor fault. Pump operated for ten seconds, however pressure does not change. Check the connection of the cuff hose.
NIBP: Internal error (E07)	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local supplier.
NIBP: Internal error (E08)	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local supplier.

Alarm Messages	Check Items
NIBP: Internal error (E09)	NIBP module error Fault detected in accordance with safety monitoring to BPM IEC standards. The pressure inside the cuff reaches the standard pressure. Standard pressure Adult: 320mmHg Neonatal: 157mmHg
NIBP: Internal error (ROM)	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local suppler.
NIBP: Internal error (RAM)	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local suppler.
NIBP: Internal error (COM)	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local suppler.
ECG: Internal error.	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local suppler.
RESP: Internal error.	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local suppler.
{label}: Loss of pulse.	Check the condition of the patient and fitting of the transducer and cable, and measure again.
IBP: Internal error.	Verify that the IBP module is correctly installed after the BP-S510 is powered off. If the problem persists, reboot the monitor.
SpO_2: Loss of pulse.	Signal obtained from sensor is weak. SpO_2 could not be measured. There may be a problem with fitting of the SpO_2 sensor, or blood flow at the sensor site may be unsatisfactory. Check the condition of the patient and fitting of the sensor, and measure again.
SpO_2: Internal error.	A problem with the SpO_2 measurement has been detected. The SpO2 measurement function does not operate. If switching power OFF/ON has no effect it is possible that a fault has occurred. Stop using the monitor immediately and contact qualified service personnel or your local supplier.
TEMP*{n}*: Internal error.	An internal circuit fault has been detected. If switching power OFF/ON has no effect it is possible that a fault has occurred in the monitor. Cease use immediately.
CAPNO: Internal error.	A problem with the capnography measurement function has been detected. The capnography measurement function does not operate. If switching power OFF/ON has no effect it is possible that a fault has occurred. Cease use immediately.
CAPNO: Sensor error.	The connector may be damaged or a fault may have occurred within the gas unit or main unit. Cease use immediately.
SYSTEM: Critically low-battery condition.	Connect the AC power cord of the monitor to the AC main to recharge the battery.
SYSTEM: Real time clock error.	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local supplier.
SYSTEM: WDT error.	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local supplier.
SYSTEM: RAM error.	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local supplier.
SYSTEM: Failure.	Reboot the monitor. If the problem persists, cease use immediately and contact qualified service personnel or your local supplier.
ECG : Check ECG leads & electrodes.	ECG error is detected, Electrodes or lead wires may not be correctly attached or a circuit is possibly saturated due to offset voltage. Check whether electrodes are correctly attached and electrodes are new and wet. Confirm the patient's skin is clean.
{label}: Cable/Sensor disconnected.	Cable not connected to the main unit. If connected, the cable may be damaged. Replace with a new cable. If replacing the cable has

Alarm Messages	Check Items
	no effect the problem may be within the device. In this case, cease use immediately.
SpO_2: Check probe.	Sensor is not in contact with patient. SpO_2 could not be measured. Fit the sensor correctly to the patient, and measure again.
TEMP*{n}*: Temperature probe disconnected.	Sensor not connected to the main unit. If connected, the cable may be damaged. Replace with a new cable. If replacing the cable has no effect the problem may be within the device. In this case, cease use immediately.
CAPNO: Occlusion.	Check the patient condition.
CAPNO: Water trap full.	Disconnect the sampling tubing from the water trap and replace the water trap with a new one.
ECG: Signal saturation.	Decrease the ECG size via the setup menu.
RESP: Check Resp leads & electrodes.	Electrodes or lead wires may not be correctly attached or a circuit is possibly saturated due to offset voltage. Check whether electrodes are correctly attached and electrodes are new and wet. Confirm the patient's skin is clean.
{label}: Unable to zero calibration.	Could not zero calibrate pressure. Check that the transducer is open to the atmosphere, and check the three-way tap. As it is also possible that the measured pressure incorporates noise, check the measurement circuit.
{label}: Out of range.	A value outside the measurement range was obtained. As the transducer has been subject to abnormal pressure, check the measurement circuit.
SpO_2: Check sensor.	Sensor not connected. If connected, the cable or connector may be damaged. Replace with a new cable. If replacing the cable has no effect the problem may be within the device. In this case, cease use immediately.
SpO_2: Sensor failure.	A problem with the SpO_2 sensor has been detected. The SpO_2 measurement function does not operate. The possible cause is a connection failure of the SpO_2 sensor and the extension cable, or a failure of the sensor or cable. Reconnect the sensor and extension cable or replace them with new ones. If the problem doesn't clear up after carrying out the remedies above or switching power OFF/ON, a grave fault can develop, Cease the use of the sensor immediately.
SpO_2: Module reset.	A problem with the SpO_2 measurement has been detected. The SpO_2 measurement function does not operate. If switching power OFF/ON has no effect it is possible that a fault has occurred. Cease use immediately.
TEMP*{n}*: Out of range.	A measure reading outside the measurement range was obtained. It is possible that the temperature in the vicinity of the sensor is extremely low (less than 15.0°C) or extremely high (more than 45.0°C). Adjust the ambient temperature and measure again.
CAPNO: Zero calibration range error	Try again the gas calibration.
CAPNO: Zero calibration signal unstable error	Try again the gas calibration.
CAPNO: High calibration range error	Try again the gas calibration.
CAPNO: High calibration signal unstable error	Try again the gas calibration.
SYSTEM: Low battery.	Plug the AC power cord to the AC main to recharge the battery.
NIBP: Retry, Check cuff/Patient (C12)	Blood pressure could not be measured even after cuff pressure decreased. It is possibly because pulse was not strong enough for

Alarm Messages	Check Items
	measurement, or because change of pulse amplitude could not be obtained. Check whether cuffs are not wrapped around thick clothing. After wrapping cuffs around properly, measure again. When the error occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Retry, Cuff excessive artifact (C13)	Measurement failed because of patient movement during measurement. Tell the patient to stay still, then, measure again. When it occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Retry, Cuff insufficient pressure (C14)	Measurement failed because of insufficient pressurizing. There is a possibility that standard cuff pressure might be detected wrongly due to noise, patient movement or external vibrations. Check whether cuffs are not wrapped around thick clothing, whether the patient is moving and whether there is external vibration. When it occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Retry, Cuff irregular pulses (C15)	Blood pressure could not be measured because oscillation graph was not normal. There is a possibility that patient movement or external vibration interrupted the measurement. Check whether a patient stays still and cuffs are free from outside vibrations, then, measure again. When it occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Retry, Cuff motion artifact (C16)	Blood pressure could not be measured because noises interrupted pulse waveform signal. There is a possibility that patient movement or external vibration interrupted the measurement. Confirm the patient is not moving and the cuff is free of external vibration, then, measure again. When it occurs in the initial measurement in continuous mode, the second measurement will start unless Stop button is pressed.
NIBP: Retry, Cuff time-out, over 160 pulses (C18)	Pulse waveform signal more than 160 beats are detected during measurement. There is a possibility that noise, patient movement or external vibrations. Confirm the patient is not moving and the cuff is free of external vibration, then, measure again.
NIBP: Retry, Cuff pressure failure (C19)	Cuff pressure exceeded more than 300mmHg during measurement. There is a possibility that the patient moved during measurement or strong pressure from outside might be added to cuffs. Considering above, measure again.
NIBP: Retry, Check cuff, hose and mode (C21)	Patient to be measured, and cuff size used, do not match. This error may occur if the blood pressure measurement mode setting is incorrect, if the cuff has been applied tightly in the adult mode loosely in the neonatal mode or if the arm has been bent during measurement. Check the measurement mode setting and application of the cuff, and measure again.
{label}: No zero reading.	Perform the pressure zero setting.
SpO_2: Motion artifact.	SpO2 could not be measured due to signal noise thought to be due to body movement. Ensure that the patient remains at rest, and measure again.
SYSTEM: No recorder paper.	In case the recorder door is open, close the door. In case the recorder paper is empty, insert new paper and close the door.
SYSTEM: Abnormally shut down last time.	The monitor has been abnormally shut down last time. When power is lost for less than 30 seconds, the monitor will preserve the current settings and trend data restored

Alarm Messages	Check Items
	automatically before the power loss. However, if the power loss is over 30 seconds, the monitor will be back to the previous user settings (or the factory default settings) as per the 'save settings on power off' in the service menu. Contact qualified personnel in your facility or your local supplier.
SYSTEM: No recorder installed.	The recorder is not installed in your monitor. If required, contact your local supplier.

Note: If the alarm message still appears, contact your local supplier for advice on remedial action.

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DISASSEMBLY GUIDE

WARNING: Performance Verification. Do not place the monitor into operation after repair or maintenance has been performed, until all Performance Tests and Safety Tests listed in Performance Verification section 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 monitor, disconnect the power cord from the monitor.

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.

General

This section describes disassembly procedures with detailed disassembly instructions and illustrations. Disassembly Sequence Flow Chart that is used to access replaceable parts of the monitor is illustrated in Figure 17. 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 monitor can be disassembled down to all major component parts, including:

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

The following tools are required:

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

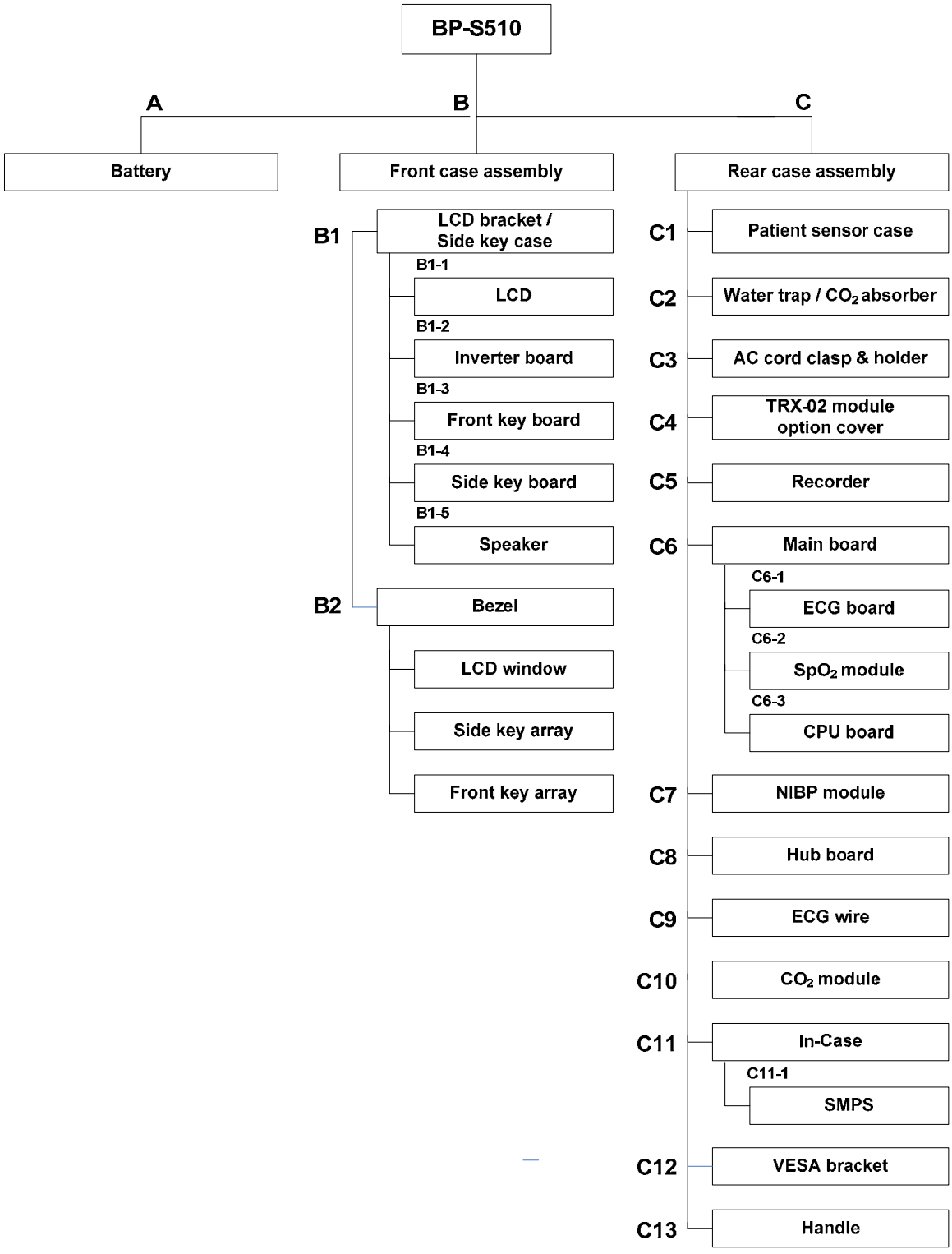

Figure 17. Disassembly Sequence Flow Chart

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.

Prior to Disassembly

1. Turn off the monitor by pressing ***Power on/off button***.
2. Disconnect the monitor from the AC power source.

Fuse Replacement

CAUTION: For continued protection against risk of fire, replace only with same type and rating of fuse.

1. After step C11-1, remove 2 AC main fuses (F1, F2: 250V/6.3A) out of the socket if required. SMPS disassembly.
2. Remove 2 battery fuses (F3, F4: 250V/6.3A) out of the socket if required.
3. Replace (a) new fuse(s).
4. Reassembly the monitor.

Battery Replacement (A)

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

1. Release a lock and remove the battery cover (ST0139).
2. Carefully remove the battery and then, replace a new battery (SM6010).
3. Put on the battery cover.

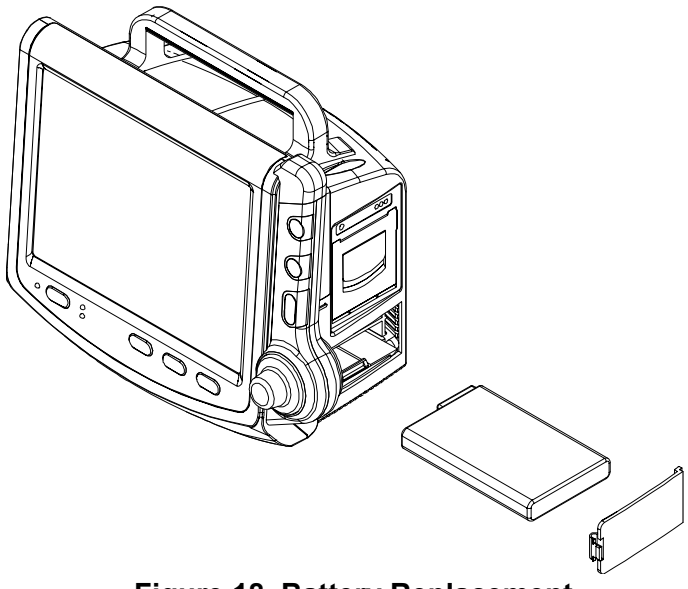

Figure 18. Battery Replacement

Monitor Disassembly

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

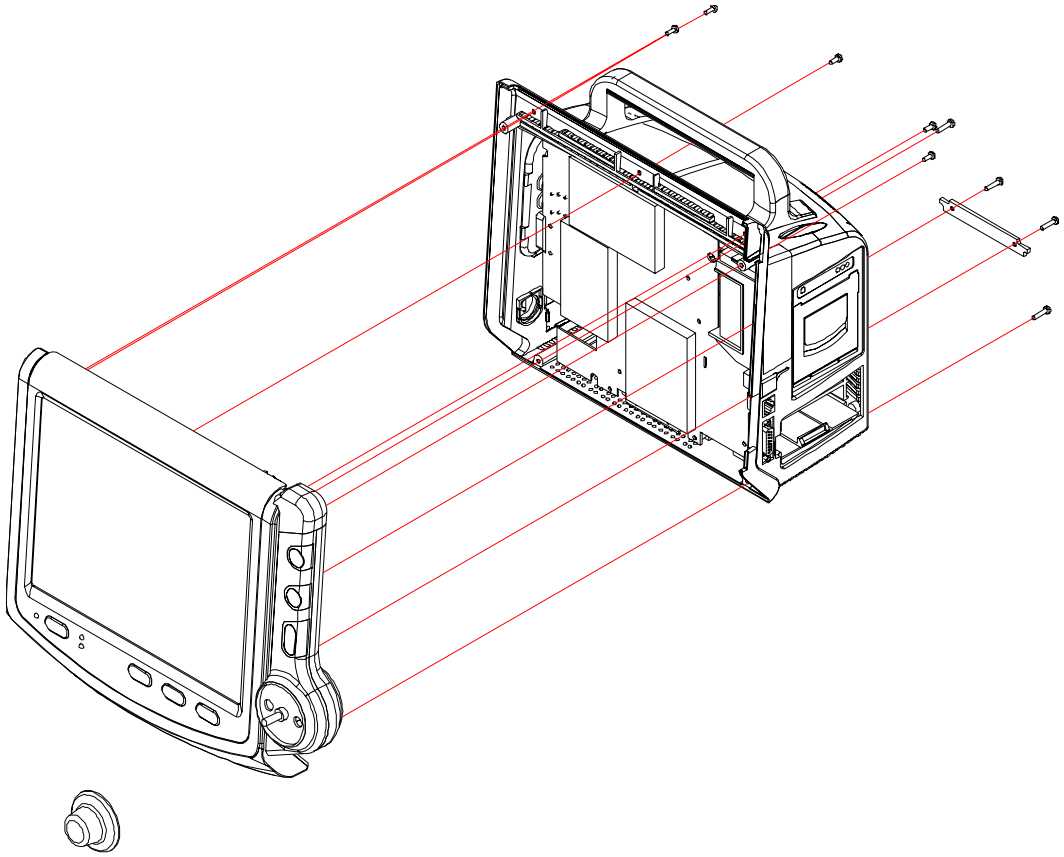

Figure 19. Monitor Disassembly

Table 19. Part Descriptions – Front Case and Rear Case Assembly

Part Codes	Descriptions	Qty
-	Front case assembly (A)	1
-	Rear case assembly (B)	1
ST0140	Knob (Jog dial)	1
ST0148	Gas module cover	1

Before the steps B and C

1. Pull the knob (jog dial) straight out to separate from the monitor.
2. Remove 3 flat-head screws (3 x 4), 3 round-head screws (3 x 6) and 2 flat-head screws (3 x 11) on the rear case.
3. Separate the front case from the rear case.
4. Disconnect the LCD wire, the front key wire, the side key wire and inverter wire from the main board.
5. Remove 2 flat-head screws (3 x 11) on the gas module cover
6. Seperate the gas module cover form the rear case.

Front Case Disassembly (B)

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

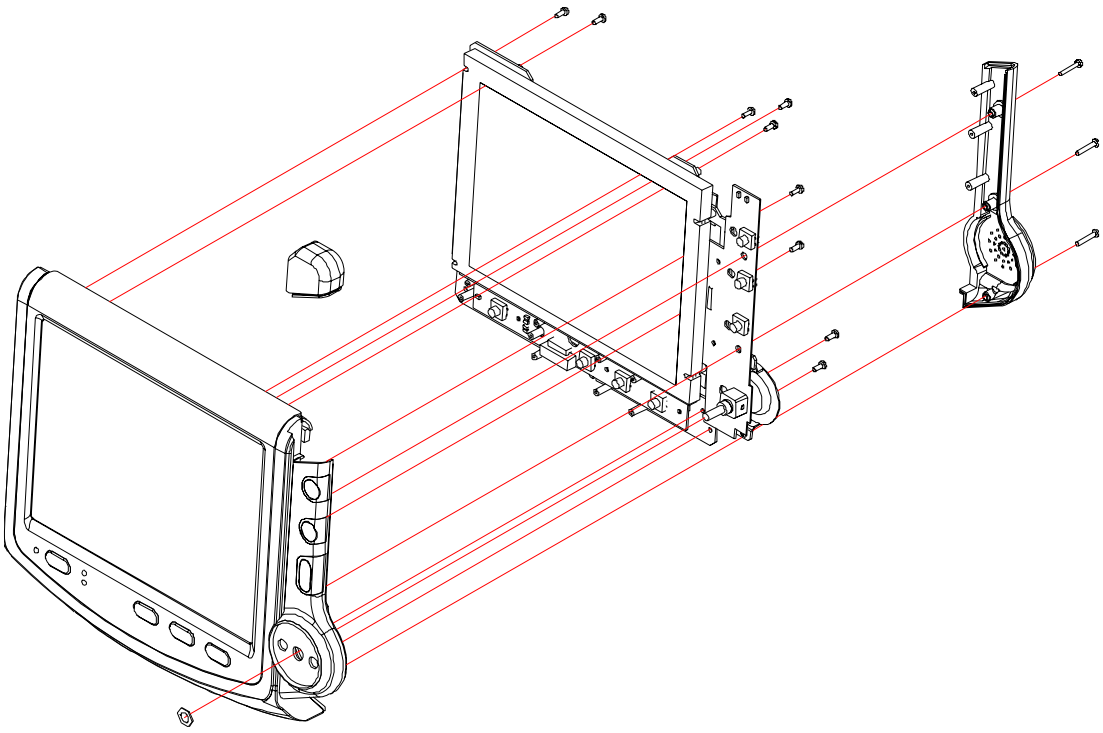

Figure 20. Front Case Disassembly – LCD Bracket, Side Key Case

Table 20. Part Descriptions – LCD Bracket, Side Key Case

Part Codes	Descriptions	Qty
ST0136	Side key case	1
ST4118	LCD bracket	1
ST0160	Alarm LED reflector	1

B1. LCD bracket and Side Key Case disassembly

1. Remove 3 flat-head screws (3 x 18) on the side key case.
2. Separate the side key case from the front case assembly.
3. Remove 9 round-head screws (3 x 6) on the LCD bracket.
4. Separate the LCD bracket from the front case assembly.
5. Separate the alarm LED reflector from the front case assembly.

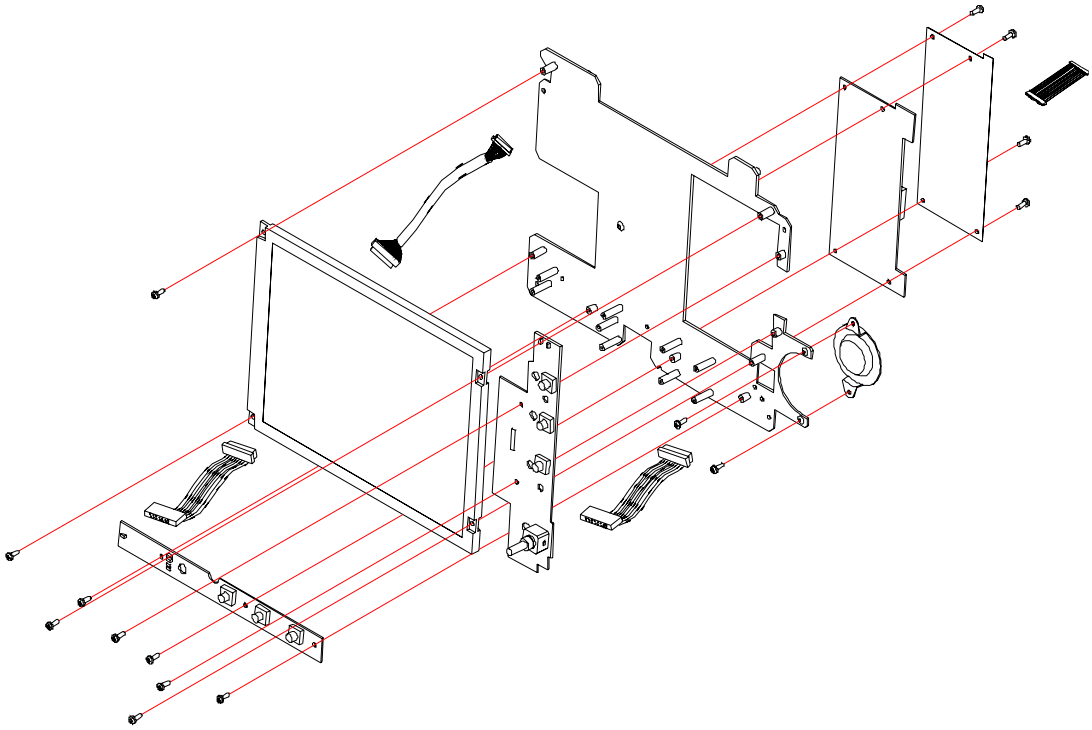

Figure 21. Front Case Disassembly – LCD, Insulation, Inverter Board, Front Key Board, Side Key Board, Speaker

Table 21. Part Descriptions – LCD, Insulation, Inverter Board, Front Key Board, Side Key Board, Speaker

Part Codes	Descriptions	Qty
SW0147 / SW0148	LCD wire (20 / 21 pin)	1/2
SM4024 / SM4028	LCD	1/2
SW0143	Inverter wire (12 pin)	1
ST3034	Insulation	1
SP1065	Inverter board	1
SW0141	Front key wire (14 pin)	1
SP1064	Front key board	1
SW0140	Side key wire (16 pin)	1
XP1063	Side key board	1
SE9010	Speaker	1

B1-1.LCD disassembly

1. After step B1, remove 4 round-head screws (3 x 6) on the LCD.
2. Disconnect the LCD wire from the LCD.
3. Separate the LCD from the LCD bracket.

B1-2.Insulation and Inverter board disassembly

1. After step B1, remove 4 round-head screws (3 x 6) screws on the Insulation and the Inverter board.
2. Disconnect the Inverter wire from the Inverter board.
3. Separate the insulation and the Inverter board from the LCD bracket.

B1-3.Front key board disassembly

1. After step B1, disconnect the front key wire from the front key board.
2. Remove 3 round-head screws (3 x 6) on the front key board.
3. Separate the front key board from the LCD bracket.

B1-4.Side key board disassembly

1. After step B1, disconnect the side key wire from the side key board.
2. Remove 2 round-head screws (3 x 6) on the side key board.
3. Separate the side key board from the LCD bracket.

B1-5.Speaker disassembly

1. After step B1, remove 2 round-head screws ((3 x 4) on the speaker.
2. Separate the speaker from the LCD bracket.

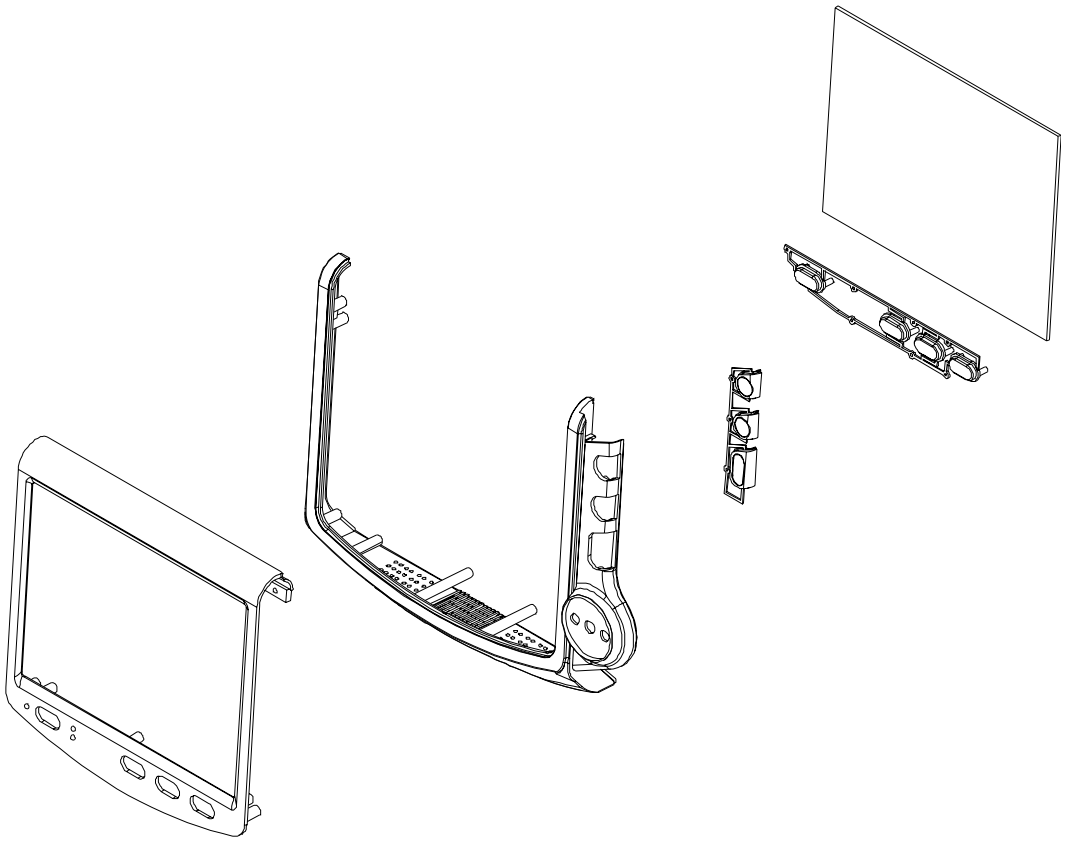

Figure 22. Front Case Disassembly – Bezel, LCD Window, Front Key Array, Side Key Array

Table 22. Part Descriptions – Bezel, LCD Window, Front Key Array, Side Key Array

Part Codes	Descriptions	Qty
XT0132	Front case assembly	1
XT0135	Bezel assembly	1
ST0159	LCD window	1
ST0141	Front key array	1
ST0142	Side key array	1

B2. Bezel disassembly

1. Separate the side key array and the front key array from the bezel assembly.
2. Separate the LCD window from the bezel assembly.
3. Separate the bezel from the front case assembly.

Rear Case Disassembly (C)

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

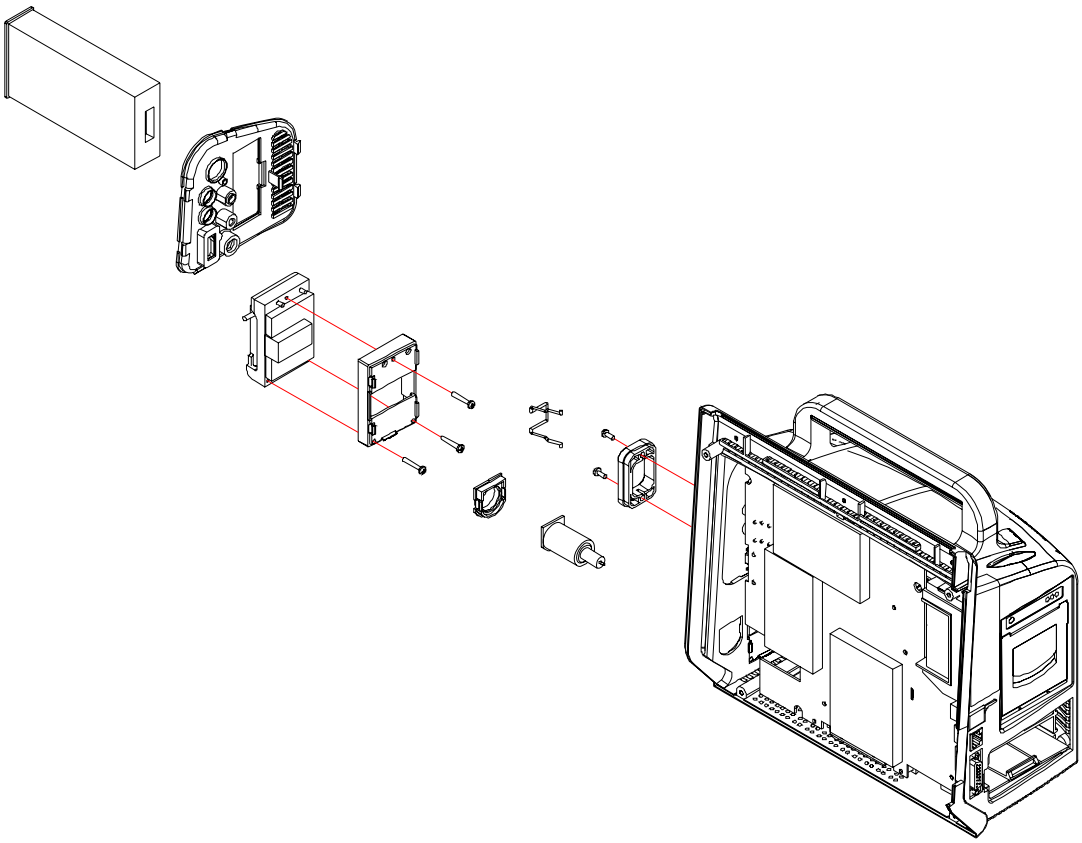

Figure 23. Rear Case Disassembly – Patient Sensor Case, Water Trap, CO_2 Absorber & Holder, AC Cord Clasp & Holder

Table 23. Part Descriptions – Patient Sensor Case, Water Trap, CO_2 Absorber & Holder, AC Cord Clasp & Holder

Part Codes	Descriptions	Qty
-	IBP module	1
ST0154	Patient sensor case (with CO_2 option)	1
ST0137	Patient sensor case (without CO_2 option)	1
ST0143	AC cord clasp holder	1
ST4124	AC cord clasp	1
ST0156	CO_2 absorber holder	1

C1. Patient Sensor Case disassembly

1. Pull the IBP module out to separate form the rear case assembly.
2. Disconnect the tubes connected to each connector.
3. Separate the patient sensor case from the rear case assembly

C2.Water Trap and CO_2 Absorber disassembly

1. Separate the tubes connected to the water trap and CO_2 absorber.
2. Separate the water trap and CO_2 absorber from the rear case assembly.
3. Remove 3 tapping screw (3 x 20) from the water trap holder.
4. Separate the water trap holder from the water trap.

Note: The water trap, water trap holder and CO_2 absorber is included in the CO_2 assembly. (XM0008).

C3. AC Cord Clasp & Holder and CO_2 Absorber Holder disassembly

5. Separate the AC cord clasp from the rear case assembly.
6. Remove 2 flat-head screw (4 x 10) from the AC cord clasp holder.
7. Separate the AC cord clasp holder from the rear case assembly.
8. Separate the CO_2 absorber holder from the CO_2 absorber.

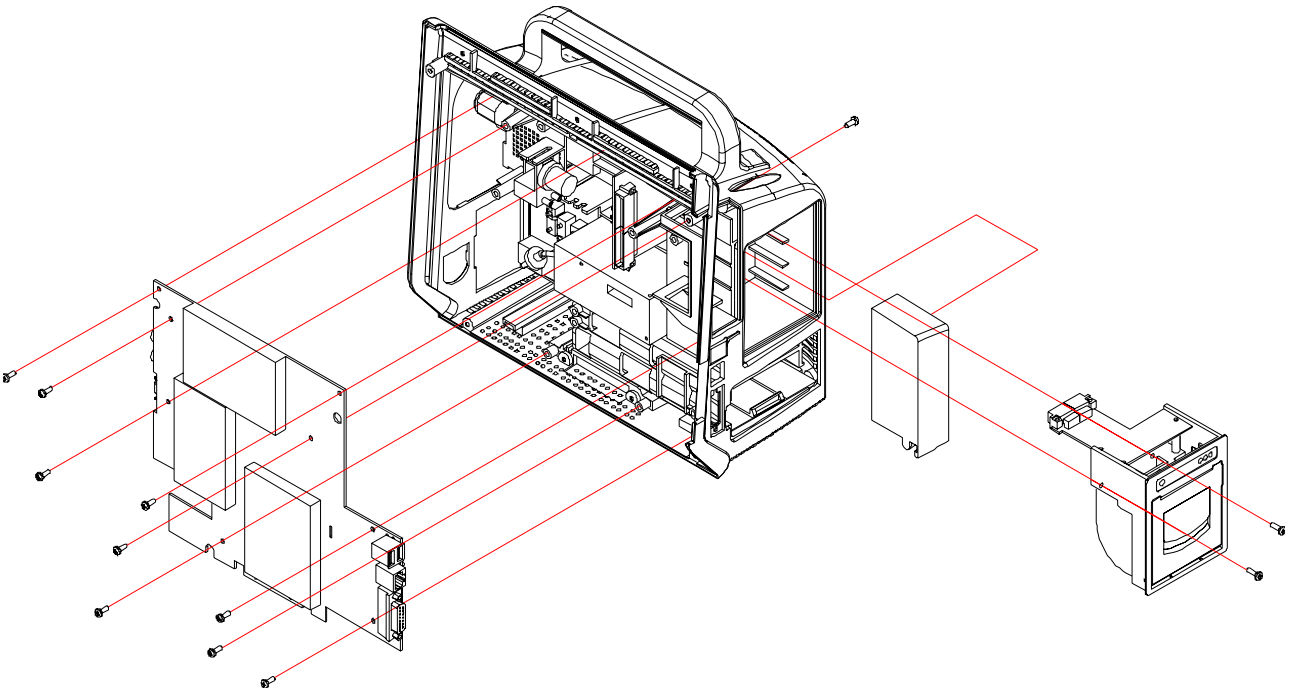

Figure 24. Rear Case Disassembly – TRX-02 Module Option Cover, Recorder, Main Board

Table 24. Part Descriptions – TRX-02 Module Option Cover, Recorder, Main Board

Part Codes	Descriptions	Qty
ST0147	TRX-02 module option cover	1
XM4020	Recorder module	1
ST0145	Recorder option cover	
SP1059	Main board	1

C4. TRX-02 module option cover disassembly

1. Remove 1 round-head screw (3 x 6) on the rear case assembly.
2. Separate the TRX-02 module option cover form the rear case assembly.

C5.Recorder disassembly

1. Remove 2 round-head screws (3 x 6) on the recorder.
2. Open the recorder door.
3. Pull out the recorder to remove from the rear case assembly.

*If no print option in, remove 2 screws on the recorder option cover, and then remove the recorder option cover.

C6.Main Board disassembly

1. Remove the ECG wire, TRX-02 and CO_2 wire from the man board.
2. Remove 5 screws on the main board.
3. Remove the main board from the rear case assembly.

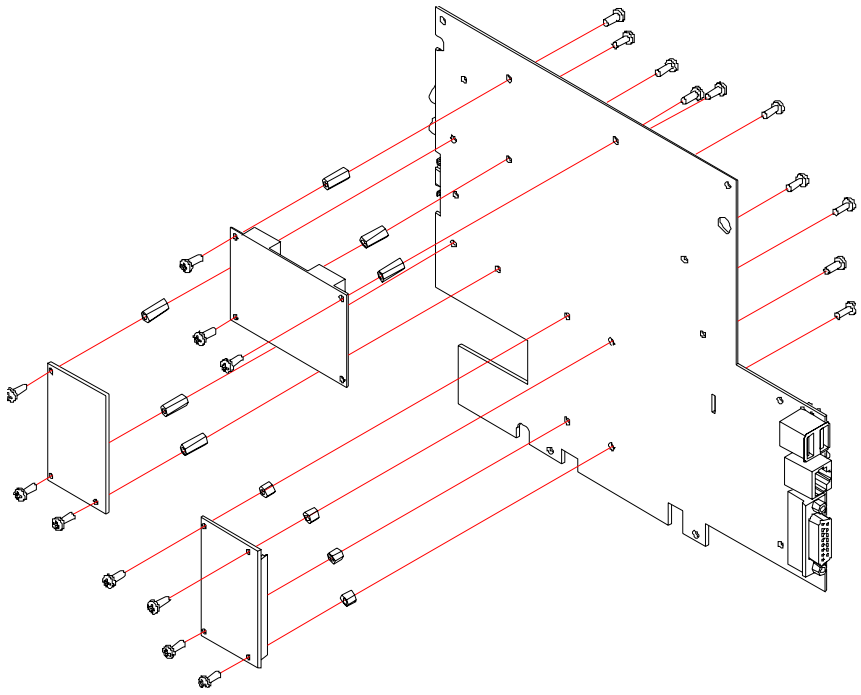

Figure 25. Rear Case Disassembly – ECG Board, SpO_2 Module, CPU Module

Table 25. Part Descriptions – ECG Board, SpO_2 Module, CPU Module

Part Codes	Descriptions	Qty
SP1061	ECG board	1
-	SpO_2 module	1
SP1062	CPU module	1

C6-1.ECG Board disassembly

1. After step C8, remove 6 round-head screws (3 x 6) on the ECG board and the main board to remove 3 supporters fastening the ECG board.
2. Separate the ECG board from the main board.

C6-2.SpO_2 module disassembly

1. After step C8, remove 6 round-head screws (3 x 6) on the SpO_2 module and the main board to remove 3 supporters fastening the SpO_2 module.
2. Remove the SpO_2 module from the main board.

C6-3.CPU module disassembly

1. After step C8, remove 8 round-head screws (3 x 4) on the CPU module and the main board to remove 4 supporters fastening the CPU module.
2. Remove the CPU module from the main board.

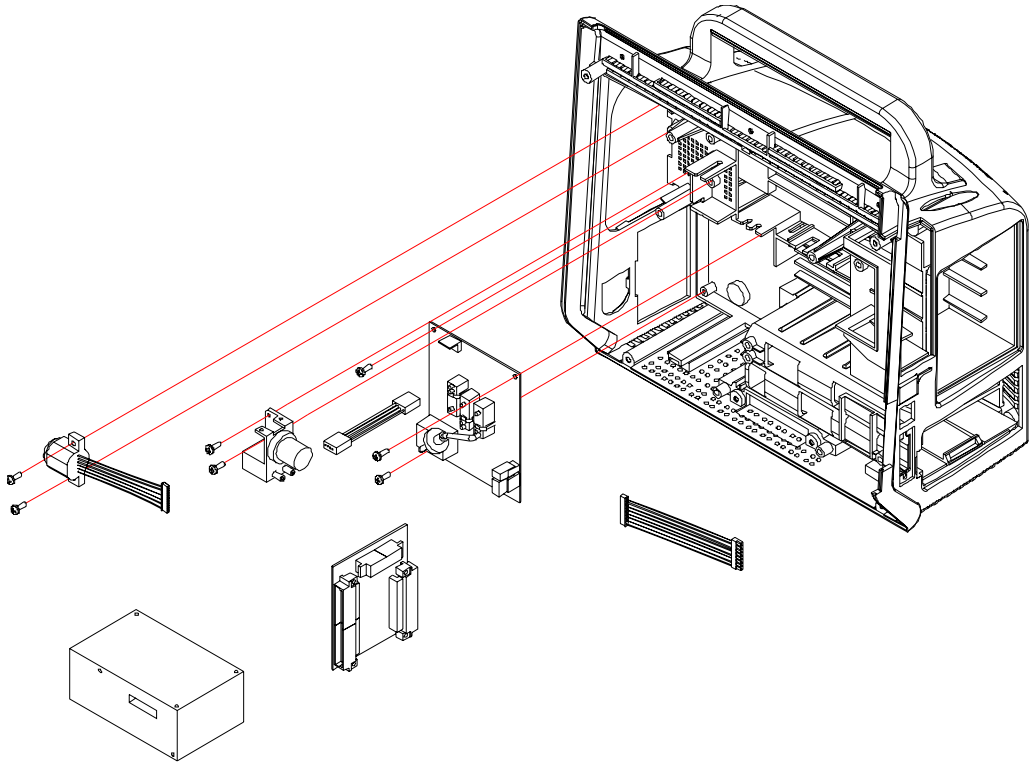

Figure 26. Rear Case Disassembly – NIBP Module, Hub Board, ECG Wire, CO_2 Module

Table 26. Part Descriptions – NIBP Module, Hub Board, ECG Wire, CO_2 Module

Part Codes	Descriptions	Qty
-	NIBP module	1
SP1060	Hub board	1
XM0008	$EtCO_2$ assembly	1
SW0144	ECG wire (12 pin)	1
SW0142	TRX-02 wire (8 pin)	1
SW0146	CO_2 wire (4 pin)	1

C7.NIBP module disassembly

1. Separate the NIBP module from the rear case assembly.

C8.Hub Board disassembly

1. Remove the hub board from the rear case assembly.

C9.ECG Wire disassembly

1. Remove 2 round-head screws (3 x 6) on the ECG wire.
2. Separate the ECG wire from the in-case assembly.

C10.CO_2 Module disassembly

1. Remove 3 round-head screws (2 x 5) on the CO_2 board and 2 round-head screws (2 x 5) on the CO_2 pump.
2. Remove the CO_2 board and CO_2 pump from the in-case assembly.

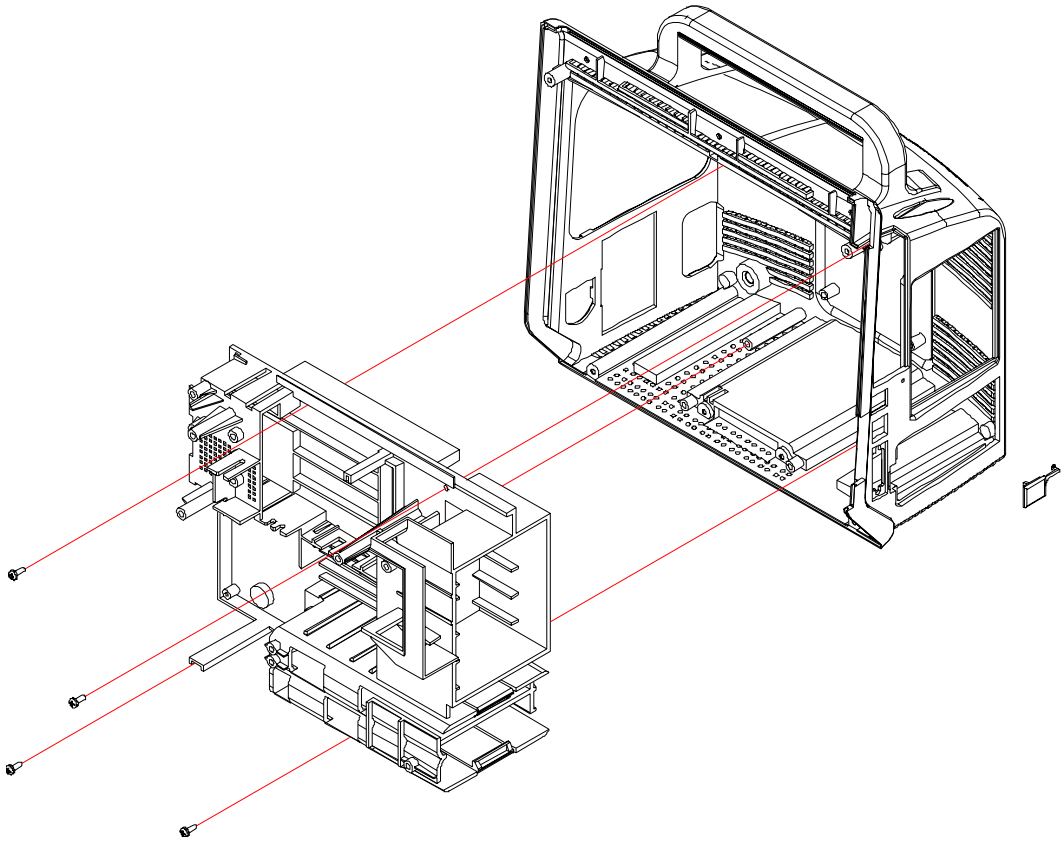

Figure 27. Rear Case Disassembly – In-Case

Table 27. Part Descriptions – In Case

Part Codes	Descriptions	Qty
XT0134	In-case assembly	1

C11.In-Case disassembly

1. Remove 4 round-head screws (3 x 6) on the in-case assembly.
2. Separate the in-case from the rear case assembly.

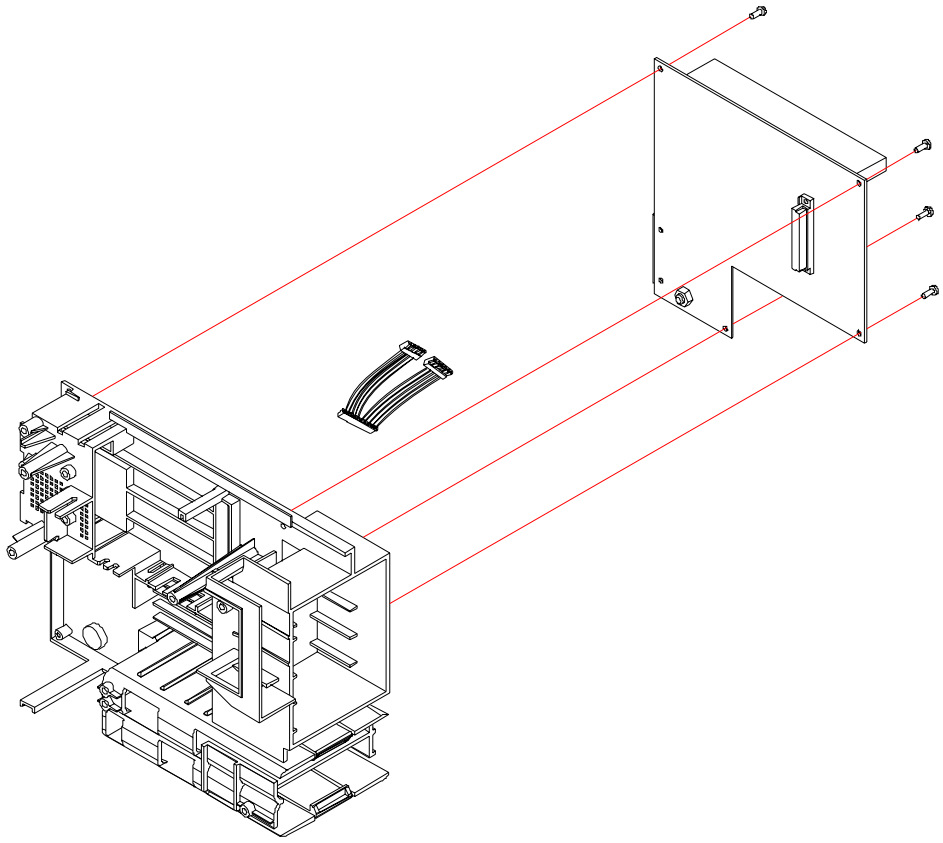

Figure 28. Rear Case Disassembly – SMPS

Table 28. Part Descriptions – SMPS

Part Codes	Descriptions	Qty
XM2018	SMPS assembly	1
SW0145	Battery connector wire (10 / 5 + 6 pin)	1

C11-1.SMPS disassembly

1. Remove 4 round-head screws (3 x 6) on the SMPS assembly.
2. Remove the SMPS assembly from the in-case assembly.
3. Separate the battery connector wire from the SMPS assembly.

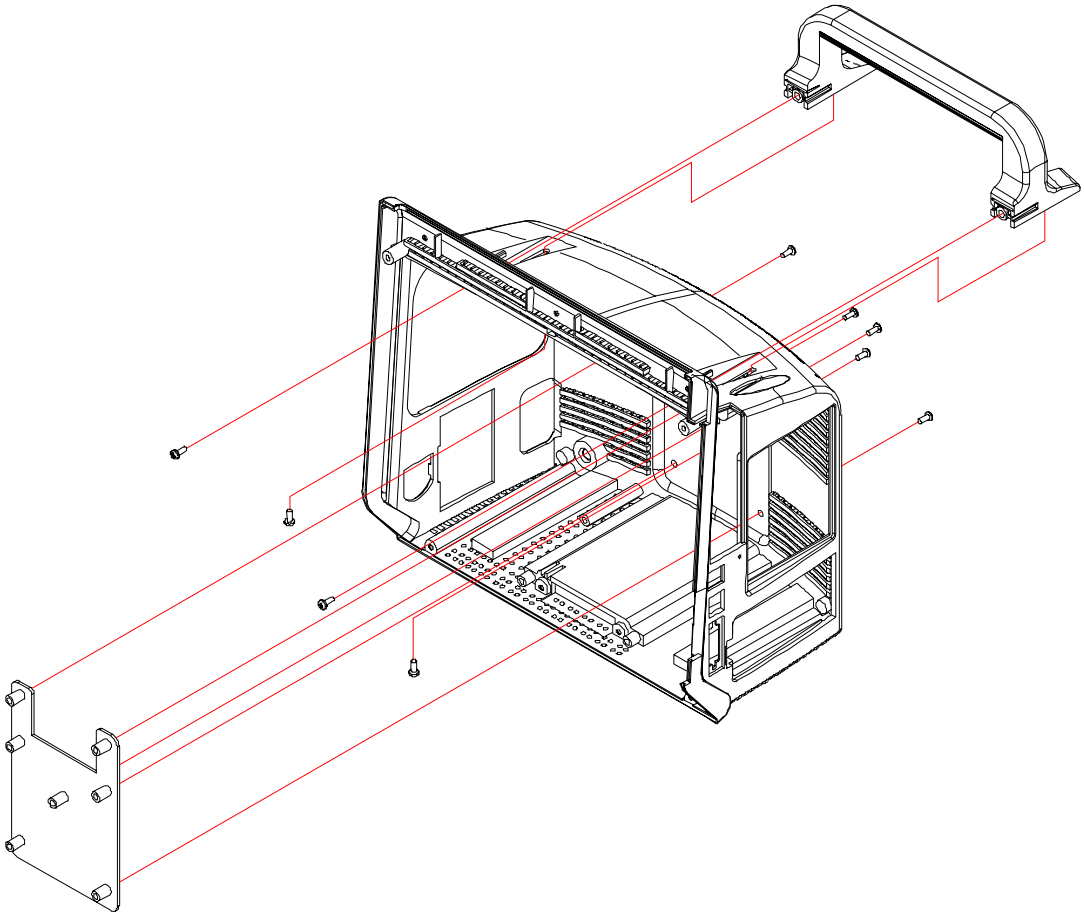

Figure 29. Rear Case Disassembly – VESA Bracket, Handle

Table 29. Part Descriptions – VESA Bracket, Handle

Part Codes	Descriptions	Qty
XT0133	Rear case assembly	1
ST4119	VESA bracket	1
XT0138	Handle assembly	1

C12. VESA Bracket disassembly

1. Remove 5 flat-head screws (4 x 10) on the VESA bracket.
2. Remove the VESA bracket from the rear case assembly.

C13. Handle disassembly

1. Remove 4 round-head screws (4 x 6) on the handle assembly.
2. Remove the handle from the rear case assembly.
3. Remove the handle rubber from the handle assembly.

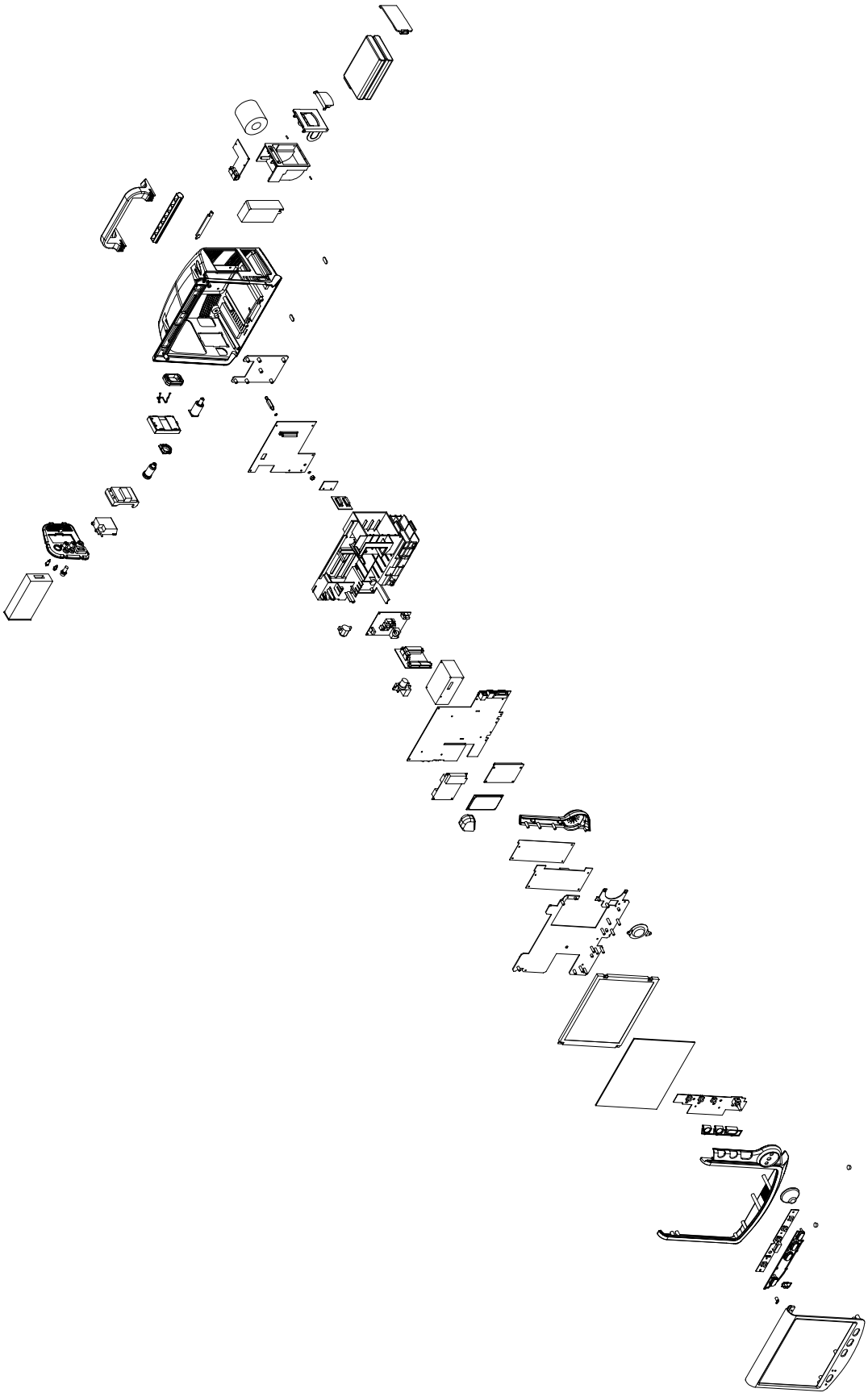

Figure 30. BP-S510 Exploded View

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SPARE PARTS

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

General

Spare parts, along with part numbers, are shown in Table 30. “Item No.” corresponds to the circled callout numbers in Figure 31.

Obtaining Replacement Parts

Omron Healthcare provides technical assistance information and replacement parts. To obtain replacement parts, contact your local supplier. Refer to parts by the part names and part numbers.

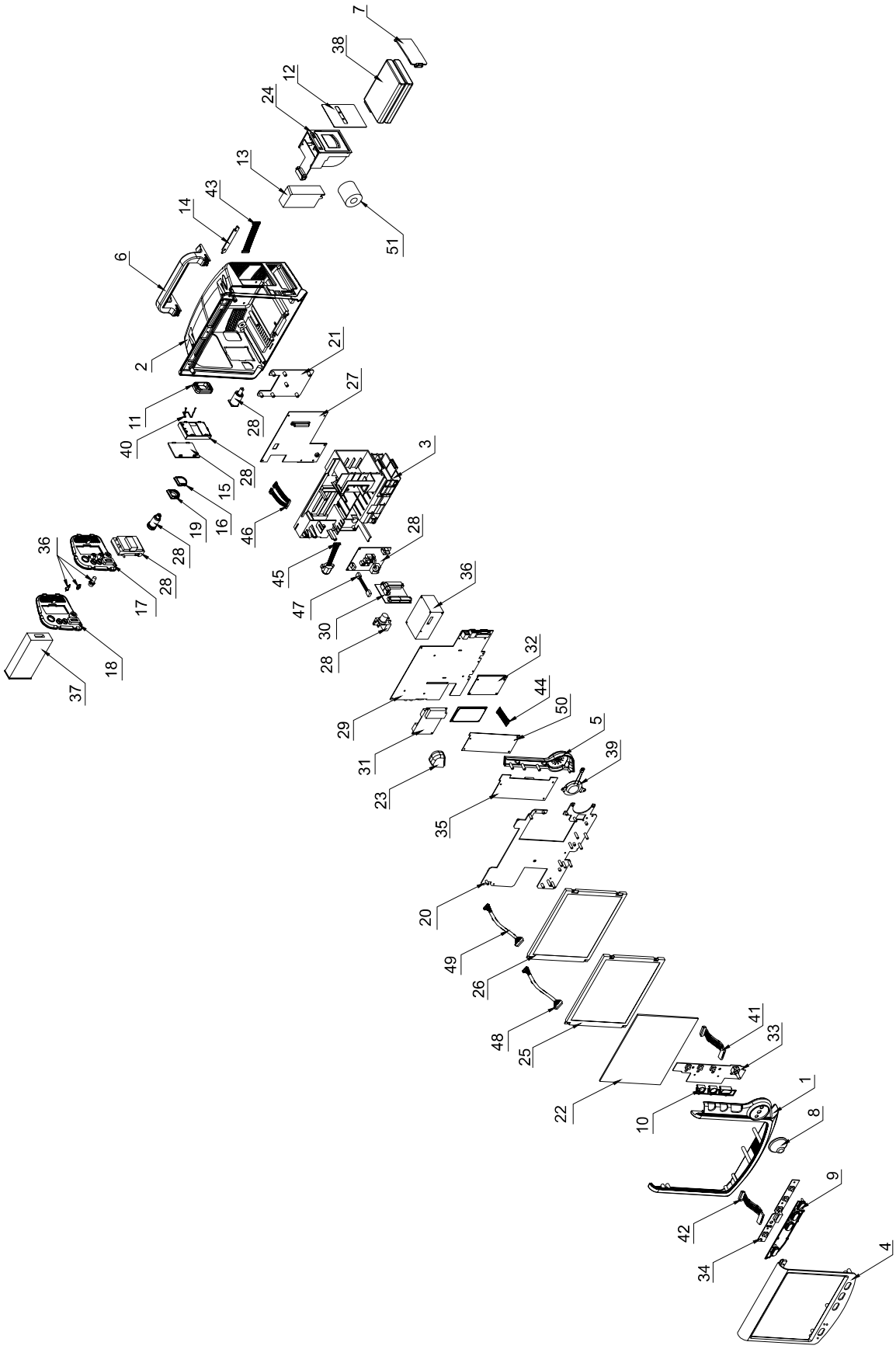

Figure 31. BP-S510 Exploded View – Spare Parts

Table 30. Spare Part List

Item	Part Code	Description
1	XT0132	Front case assembly
2	XT0133	Rear case assembly
3	XT0134	In-case assembly
4	XT0135	Bezel assembly
5	ST0136	Side key case
6	XT0138	Handle assembly
7	ST0139	Battery cover
8	ST0140	Knob (jog dial)
9	ST0141	Front key array
10	ST0142	Side key array
11	ST0143	AC cord clasp holder
12	ST0145	Recorder option cover
13	ST0147	TRX02 module option cover
14	ST0148	Gas module cover
15	ST0149	Water trap module option cover
16	ST0150	CO_2 absorber option cover
17	ST0154	Patient sensor case ($EtCO_2$ option)
18	ST0137	Patient sensor case (without $EtCO_2$ option)
19	ST0156	CO_2 absorber holder
20	ST4118	LCD bracket
21	ST4119	VESA bracket
22	ST0159	LCD window
23	ST0160	Alarm LED reflector
24	XM4020	Recorder module
25	SM4024	LCD (Mitsubishi)
26	SM4028	LCD (AUO)
27	XM2018	SMPS assembly
28	XM0008	CO_2 assembly
29	SP1059	Main board
30	SP1060	Hub board
31	SP1061	ECG board
32	SP1062	CPU module
33	XP1063	Side key board
34	SP1064	Front key board
35	SP1065	Inverter board
36	-	NIBP module
37	-	IBP module
38	SM6010	Battery
39	SE9010	Speaker
40	ST4124	AC cord clasp
41	SW0140	Side key wire
42	SW0141	Front key wire
43	SW0142	TRX02 wire
44	SW0143	Inverter wire

Item	Part Code	Description
45	SW0144	ECG wire
46	SW0145	Battery connector wire
47	SW0146	CO_2 wire
48	SW0147	LCD wire for Mitsubishi
49	SW0148	LCD wire for AUO
50	ST3034	Insulation
51	SA0062	Paper (50mm)
-	SB0042	Product Label
-	SB0047	Printer Label
-	SA7072	Operation Manual
-	SA7086	Service Manual

Note: You can use the assembly kit (SS8001) supplied by the manufacturer for screws, washers and supporters. Contact your local supplier for more information.

PACKING FOR SHIPMENT

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 Omron Healthcare warranty. If the original shipping carton is not available, use another suitable carton;

Returning the BP-S510 monitor

Pack the monitor 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.

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 and return address.

Repacking In a Different Carton

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

1. Place the monitor in a protective plastic bag against shock.
2. Locate a corrugated cardboard shipping carton with at least 20 kg/m^2 bursting strength.
3. Fill the bottom of the carton with at least 7 cm 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 and return address.

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SPECIFICATION

Display

Screen Size	10.4” measured diagonally across the TFT-LCD screen
Screen Type/Color	Liquid Crystal Display (LCD) Color, Cold Cathode Fluorescent Backlit
Resolution	800 × 600 pixel
Number of traces	4 or 6 waveforms

Controls

Standard	Jog dial control; 7 soft buttons (NIBP start/stop, Home, NIBP interval, Alarm silence, Trend, Record, Power on/off)

Alarms

Categories	Patient Status and System Status
Priorities	Low, Medium and High Priorities
Notification	Audible and Visual
Setting	Default and Individual
Alarm Volume Level	45 to 85 dB

Physical Characteristics and Recorder

Instrument		
Dimensions	360 × 280 × 215 (mm) (W×H×D) including a handle and excluding options and accessories	
Weight	5.5 kg excluding optional configurations and accessories	
Degree of protection against electric shock	ECG:	Type CF with defibrillator protection
	IBP(P1-P2):	Type CF with defibrillator protection
	NIBP:	Type CF with defibrillator protection
	SpO_2:	Type CF with defibrillator protection
	Temperature (T1-T2):	Type CF with defibrillator protection
	Gas(CO_2):	Type CF with defibrillator protection
Mode of Operation	Continuous	
Classification:	Class IIb (MDD Annex IX Rule10:MEDDEV 2.4/1 Rev.8)	

Recorder (Optional)	
Type	Thermal
Weight	150 g
Resolution	8 dot/mm
Number of channels	1 to 2 channels
Paper Type	Thermal
Paper Width	50 mm
Paper Speeds	25.0 mm/s and 50.0 mm/s

Electrical

Instrument	
Power Requirements	AC Mains 100-240V~50/60 Hz, 0.5-1.3A
Fuses	q'ty 2, T6.3 A, 250 volts, (time-lag), IEC (5×20 mm)
Battery	
A battery typically provides operating time of 1 hour when fully charged with no printing, no external communication, no audible alarm sound and one NIBP measurement per 5 minutes at 25°C.	
Type	Ni-MH
Voltage/Capacity	12 V/ 3.8 Ampere-Hours
Recharge	Over 12 hours with monitor turned on/off
Shelf Life	2 years, new battery fully-charged
Compliance	91/157/EEC

Environmental Conditions

Operation	
Temperature	10°C to 40°C (50°F to 104°F)
Humidity	15 % RH to 90% RH, non-condensing
Altitude	500hPa to 1060hPa
Transport and Storage (in shipping container)	
Temperature	−20°C to 60°C (−4°F to 140°F)
Humidity	15 % RH to 95% RH, non-condensing
Altitude	500hPa to 1060hPa
Note: The system may not meet its performance specifications if stored or used outside the specified temperature and humidity range.	

Measurement Parameters

ECG

Heart Rate	
Measurement Range	20 bpm ~ 250 bpm
Accuracy	±3 bpm or ±5% whichever is greater
Average Response Time	5 seconds (from 80 to120 bpm) 9 seconds (from 80 to 40 bpm)
Tall T-wave Rejection Capability	maximum T-wave amplitude 1.8 mV

ECG (Electrocardiograph)	
Leads	3 / 5 Lead Lead I, II, III, aVR, aVL, aVF, V (Chest Lead)
Lead Off Detection	Detected and displayed
Input	
Input Dynamic Range	±5 mV AC, ±300 mV DC
Voltage range	±0.5 mV ~ ±5 mV
Signal Width	40 ms ~ 120 ms (Q to S)
Output	
Frequency Response (Bandwidth)	
Low Extend	0.05 Hz ~ 40 Hz
Filter	0.5 Hz ~ 30 Hz
Monitor	0.5 Hz ~ 40 Hz
Respiration Rejection	1 Hz ~ 40 Hz
ECG Size	×1/4, ×1/2, ×1, ×1.5, ×2
Display Sweep Speeds	12.5 mm/sec, 25.0 mm/sec, and 50.0 mm/sec
Defibrillator Discharge Recovery	<5 sec per IEC60601-2-27

Respiration

im RR	
Technique	Trans-thoracic impedance
Range	0, 3 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

aw RR (Option)	
Technique	Nondispersive Infrared Spectroscopy
Range	0 to 120 breaths/min
Accuracy	±1 breath/min
Display Sweep Speeds	6.25 mm/s, 12.5 mm/s, 25.0 mm/s

Pulse Rate	
Pulse Rate Range	Adult 40 bpm ~ 200 bpm Neonatal 40 bpm ~ 240 bpm
Pulse Rate Accuracy	±2 bpm or ±2%, whichever is greater
NIBP (Non-Invasive Blood Pressure)	
Technique	Oscillometric Measurement
Measurement modes	MANUAL, AUTO and CONT
MANUAL Mode	Single measurement initiated by *NIBP Start/Stop switch*
AUTO Mode	Automatic BP measurements at intervals of 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45, 60, 90, 120, or 180 minutes
CONT Mode	Series of consecutive measurements for 5 minutes
NIBP pressure measuring range	
Systolic pressure range	Adult 60 mmHg ~ 250 mmHg Neonatal 40 mmHg ~ 120 mmHg
Diastolic pressure range	Adult 40 mmHg ~ 200 mmHg Neonatal 20 mmHg ~ 90 mmHg
MAP pressure range	Adult 45 mmHg ~ 235 mmHg Neonatal 30 mmHg ~ 100 mmHg
NIBP Accuracy	Mean error and standard deviation per ANSI/AAMI SP10:2002
Pressure Display Range	10 mmHg ~ 300 mmHg
Pressure Display Accuracy	±3mmHg
Initial Cuff Inflation	Adult 120, 140, 160, 180, 200, 220, mmHg (16.0, 18.7, 21.3, 24.0, 26.7, 29.3, kPa) Neonatal 80, 100, 120, 140 mmHg (9.3, 12.0, 14.7, 16.0, 18.7 kPa)
Automatic cuff deflation	Measurement time exceeding 180s in adult/pediatric (90s in neonatal) or maximum pressure value exceeding 300 mmHg in adult (150 mmHg in neonatal).
Overpressure protector	300 ±10 mmHg for Adult 150 ±5 mmHg for neonatal

SpO_2

Pulse Rate		
Range	20 bpm ~ 250 bpm	
Accuracy	Without Interference	20 bpm ~ 250 bpm ±3 digits
	Low Perfusion	20 bpm ~ 250 bpm ±3 digits
SpO_2		
Range	1% to 100%	
Low Perfusion	0.03% to 20%	
Accuracy	Without Interference-Adult	
		70% ~ 100% ±2 digits
		1% ~ 69% unspecified
	Without Interference-Neonate	
		70% ~ 100% ±3 digits
		1% ~ 69% unspecified
	Low Perfusion	70% ~ 100% ±2 digits
		1% ~ 69% unspecified
Display Sweep Speeds	12.5 mm/sec, 25.0 mm/sec and 50.0 mm/sec	

Neonatal specifications are shown for neonatal sensors with the monitor. Saturation accuracy will vary by sensor type as specified by the manufacturer.

Note: The wavelength range of the light emitted are near 660 nm and 890 nm with the energy not exceeding 15mW.

Temperature

Probe Type	Thermistor probe YSI 400 series
Parameter displayed	T1, T2
Range	15°C ~ 45°C (59°F to 113°F)
Display Accuracy	±0.1°C (25°C to 45°C) or ±0.2°F (77°F to 113°F) ±0.2°C (15°C to less than 25°C) or ±0.4°F (59°F to less than 77°F)
Probe Accuracy	±0.1°C (±0.2°F)

IBP

Pulse Rate	
Range	20 bpm ~ 250 bpm
Accuracy	±1% or ± 1 beat
IBP	
Parameter displayed	P1, ABP P2 , ABP, CVP, PAP, LAP
Pressure measuring range	-50 mmHg ~ 300 mmHg
Input Impedance	More than 1 M ohm
Transducer driving voltage	DC 5V
Transducer input sensitivity	5uV/V/mmHg
Zero calibration range	± 100mmHg
Zero calibration accuracy	Less than ±1mmHg
Frequency characteristics	dc to 25Hz
Pressure display accuracy	Monitor: Less than ±3mmHg
Scale	P1 0~50, 0~100, 0~200, 0~300, AUTO P2 0~20, 0~50, 0~100, 0~200, 0~300, AUTO
Display Sweep Speeds	12.5 mm/sec, 25.0 mm/sec, and 50.0 mm/sec

Capnography

Parameter displayed	$EtCO_2$, $InCO_2$
Range	0 mmHg ~ 100 mmHg; 0 kPa ~ 13.3 kPa; 0 % ~10 % CO_2 STPD (standard temperature and pressure dry)
Accuracy	±2mmHg or ±4%, whichever is greater
Stability	< 0.3 % (vol) CO_2 /24hrs
Rise Time	400 ms (average)
Delay Time	1.8 (average)
System Response	2.1 (average)
Warm up time	3 minutes average
Display Sweep Speeds	6.25mm/sec, 12.5 mm/sec and 25.0 mm/sec

Trends

Types	Graphical and Tabular
Nonvolatile memory	saves total 1500 data saves at selected time interval saves alarm condition & error events saves NIBP Measuremets
Graphical Format	Total 2 graphs a graph for NIBP, P1/P2, SpO_2, T1/T2 parameters a graph for HR/PR, Resp, $EtCO_2$ parameters User-selectable each parameter to be desired
Tabular Format	One table for all parameters
Display	8 lists
Save Time Interval	30sec or 1, 2, 2.5, 5, 10, 15, 20, 30, 60 or 120 minutes

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
Degree of protection	IP21 (provided by enclosures)
General	93/42/EEC Directives for medical devices
	21CFR820 Code of Federal Regulations
	2002/96/EC Waste electrical and electronic equipment Directive(WEEE)
	91/157/EEC Battery Declaration Directive
	93/86/EEC Battery Disposal Directive
	ISO9001:2000 Quality Management Systems - Requirements
	ISO13485:2003 Quality Systems– Medical Devices –Particular requirements for the application of ISO9001
	ISO14971:2000 Risk analysis managements – medical devices
	IEC60601-1:1988+A1:1991+A2:1995 General requirements for Safety and Essential Performance
	IEC60529:2001 Degree of Protection Provided by Enclosures (IP21)
	EN ISO14155-1:2003 Clinical investigation of medical devices for human subjects – part 1: General requirements
	AAMI HE48:1993 Human factors engineering guidelines and preferred practices for the design of medical devices
	IEC60601-1-1:2000 Safety requirements for medical electrical systems
	IEC60601-1-4:2000 Particular requirements for programmable medical systems
	IEC60601-1-6:2004 Medical electrical equipment Part 1-6: General requirements for safety Collateral Standard: Usability
	ISO10993-1:2003 Biological evaluation of medical devices – Part 1: Evaluation and testing
	IEC60601-2-49:2001 Particular requirements for multifunction patient monitoring equipment
Alarms	IEC60601-1-8:2003 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 EC13:2002 Cardiac monitors, heart rate meters and alarms
	AAMI EC53:1995+A1:1998 ECG cable and leads
Non-invasive Blood Pressure	AAMI SP10:2002+A1:2003 Electronic or Automated Sphygmomanometers
	EN1060-1:1995+A1:2002 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
	ISO9919:2005 Basic safety & essential performance of Pulse oximeter for medical use
Temperature monitoring	EN12470-4:2000 Performance of Electrical Thermometers for continuous Measurement

Item	Compliant with
Invasive Blood Pressure	IEC60601-2-34:2000 Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
Capnography	EN864:1996 Capnometers for use with humans-Particular requirements
	ISO9918:1993 Capnometers for use with humans-Requirements
	ISO21647:2004 Particular requirements for the basic safety and essential performance of respiratory gas monitors
Electromagnetic Compatibility	IEC60601-1, sub clause 36, IEC/ IEC60601-1-2:2001+A1:2004 Electromagnetic compatibility-requirements & test
	IEC61000-3-2:2005 Harmonic Emission Ed 3.0
	IEC61000-3-3:2005 Voltage Fluctuations/Flicker Emission Ed 1.2
	IEC61000-4-2:2001 Electrostatic Discharge Ed 1.2
	IEC61000-4-3:2002 Radiated RF electromagnetic field Ed 2.1
	IEC61000-4-4:2004 Electrical fast transient/burst Ed 2.0
	IEC61000-4-5:2005 Surge current Ed 2.0
	IEC61000-4-6:2004 Conducted disturbances, induced by RF field Ed 2.1
	IEC61000-4-8:2001 Power frequency (50/60Hz) magnetic field Ed 1.1
	IEC61000-4-11:2004 Voltage dips, short interruption and voltage variation on power supply input lines Ed 2.0
	CISPR 11:1997 (EN55011:1998) Limits and methods of measurement of radio disturbance characteristics of industrial scientific and medical (ISM) radio-frequency equipment RF Emissions Group 1, Class B
Package	ISTA (Procedure 1A, 1994 Rev.) Pre-Shipment Test Procedures (Package)
Reliability	IEC60068-2-27:1987 Environmental testing – Shock
	IEC60068-2-6:1995 Environmental testing –Vibration
	IEC60068-2-64:1993 Environmental testing: vibration, broad-band random (digital control) and guidance
Labeling	EN1041:1998 Information supplied by the manufacturer with medical devices
Marking	IEC /TR60878:2003 Graphical symbols for electrical equipment in medical practice
	EN980:2003 Graphical symbols for use in the labeling of medical devices
	ISO7000:2004 Graphical symbols for use on equipment-index and synopsis
	EN60417-1:1999 Graphical symbols for use on equipment-overview and application
	EN60417-2:1999 Graphical symbols for use on equipment-symbol originals
	EN50419:2005 Marking of electrical and electronic equipment in accordance with article II (2) of directive 2002/96/EC (WEEE)

SYSTEM PROCESSING

System Overview

The BP-S510 monitor is a multi-function monitor for use on adult and neonatal patients; ECG, heart rate, non invasive blood pressures, arterial oxygen saturation, pulse rate, respiration rate, temperature, invasive blood pressure and capnography.
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 data or stored trend data.

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

System Block Diagram

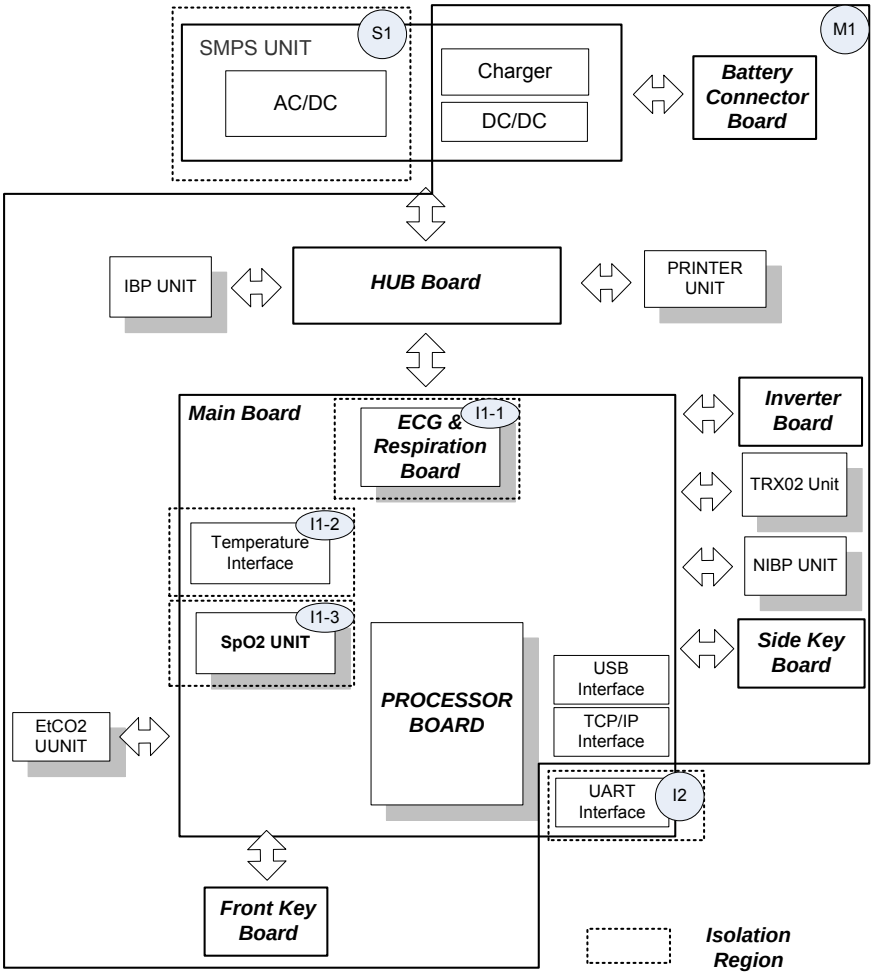


Figure 32. System Block Diagram

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

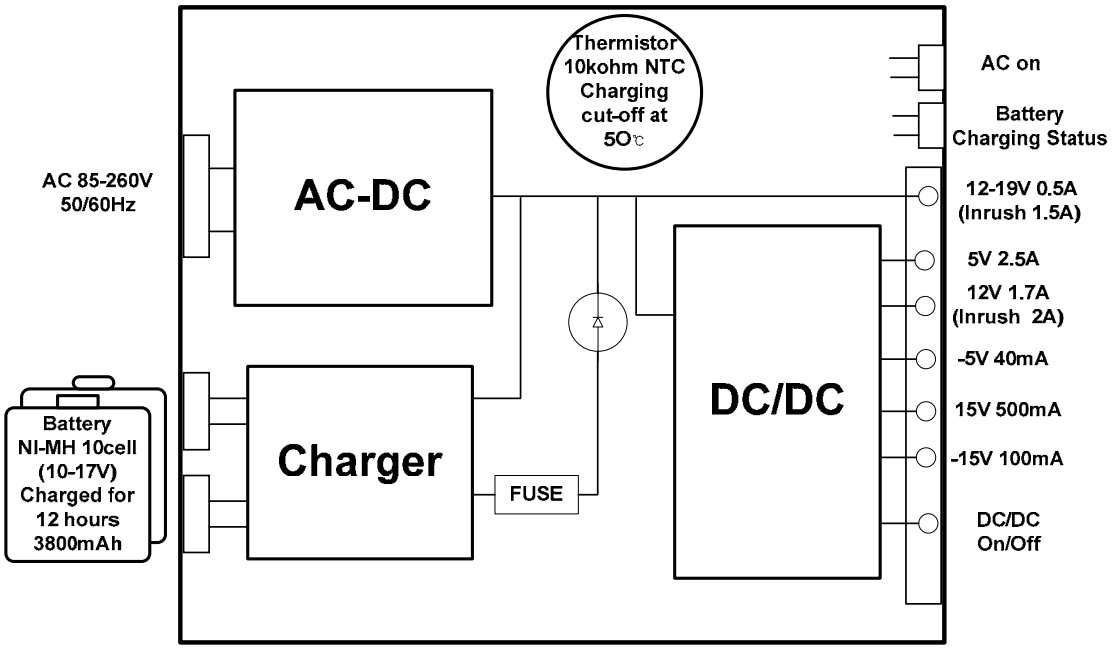


Figure 33. Power Unit Block Diagram

- **Processor unit:** consists of Samsung S3C2440 CPU, SDRAM, Boot ROM and Flash.

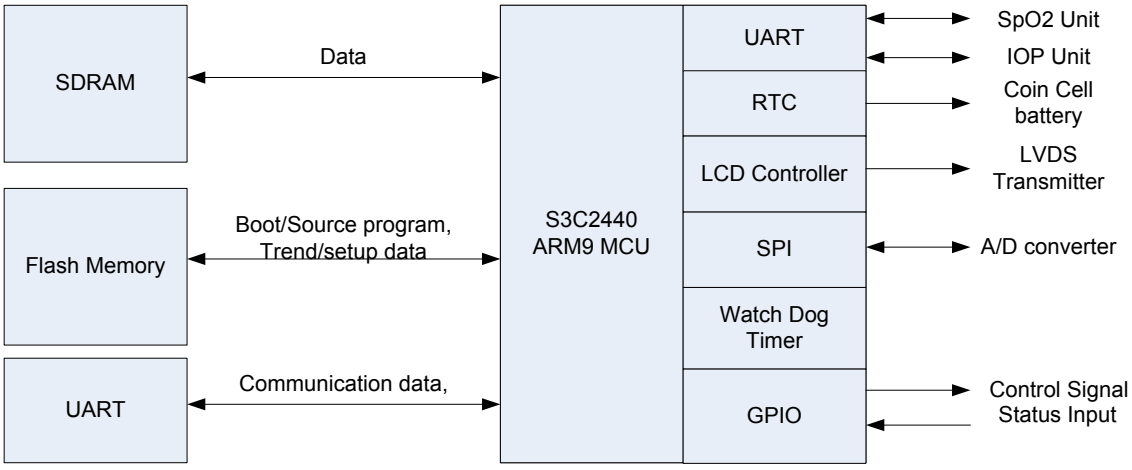


Figure 34. Process Unit Block Diagram

- **User-control unit:** consists of jog dial, 6 functional button, optical encoder, power on indicator LED, Battery charging indicator LED and battery charging status indicator LED.

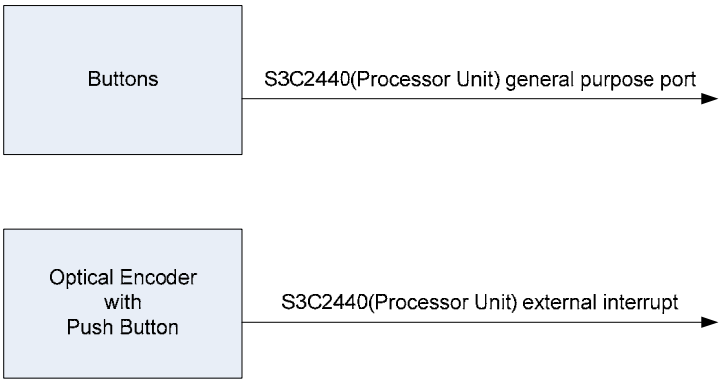


Figure 35. User-Control Unit Block Diagram

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

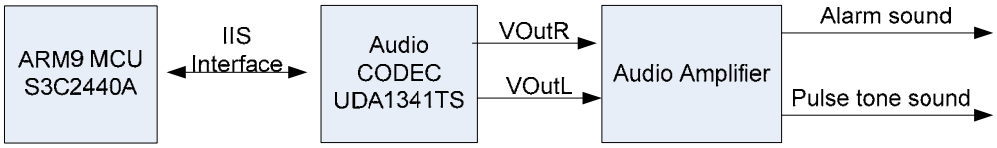


Figure 36. Sound Unit Block Diagram

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

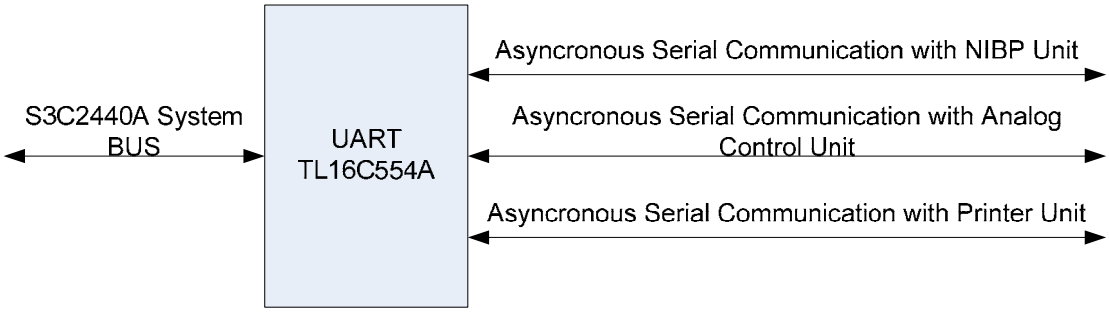


Figure 37. Communication Unit Block Diagram

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

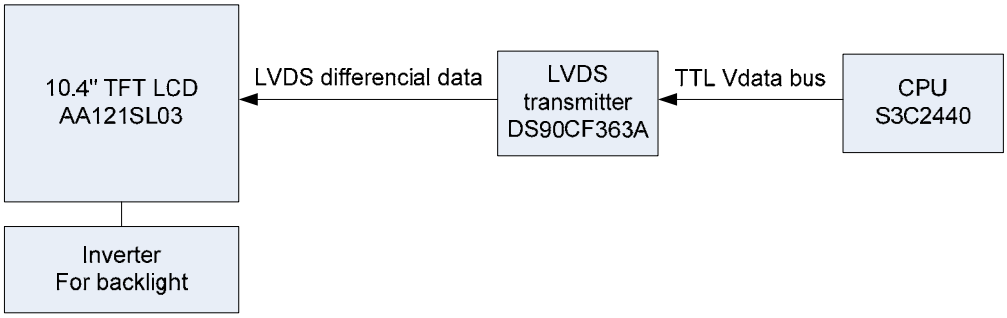


Figure 38. GUI Unit Block Diagram

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

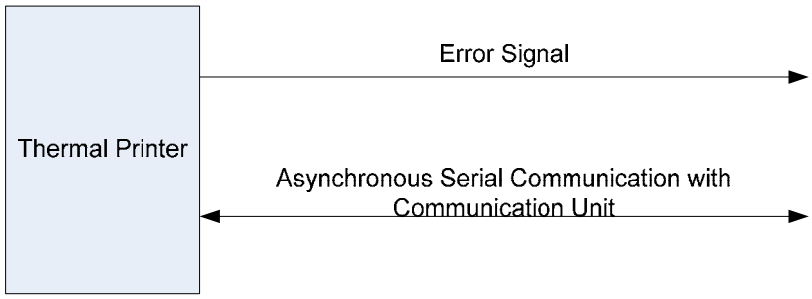


Figure 39. Thermal Recorder Unit Block Diagram

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

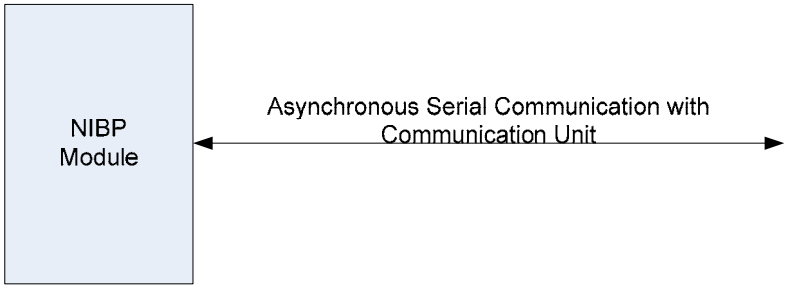


Figure 40. NIBP Unit Block Diagram

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

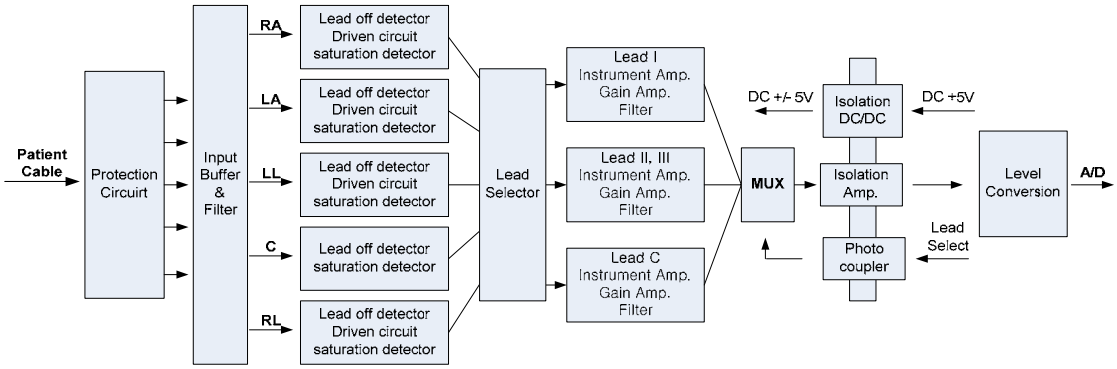


Figure 41. ECG Unit Block Diagram

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

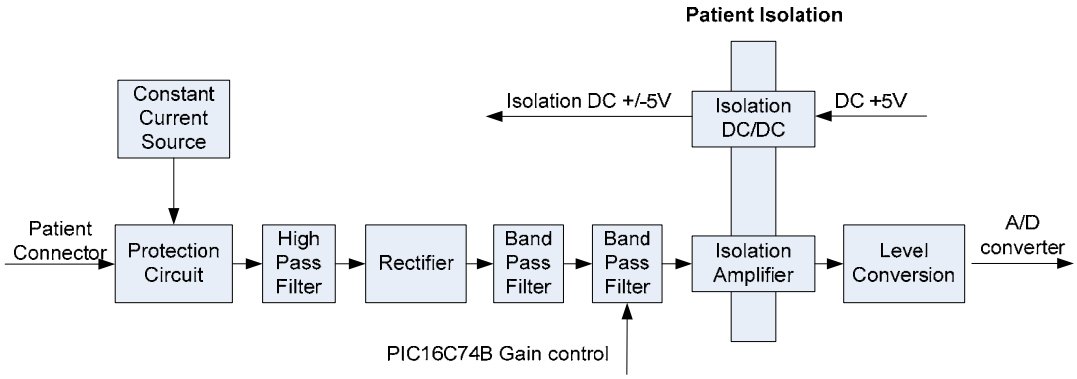


Figure 42. Respiration Unit Block Diagram

- **SpO_2 unit:** measures oxygen saturation data.

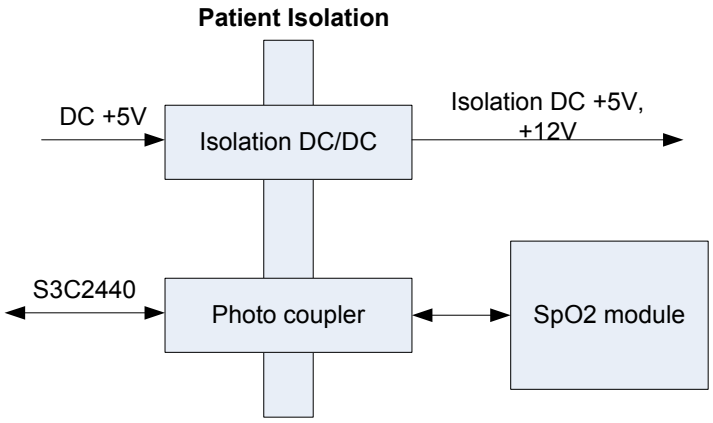


Figure 43. SpO_2 Unit Block Diagram

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

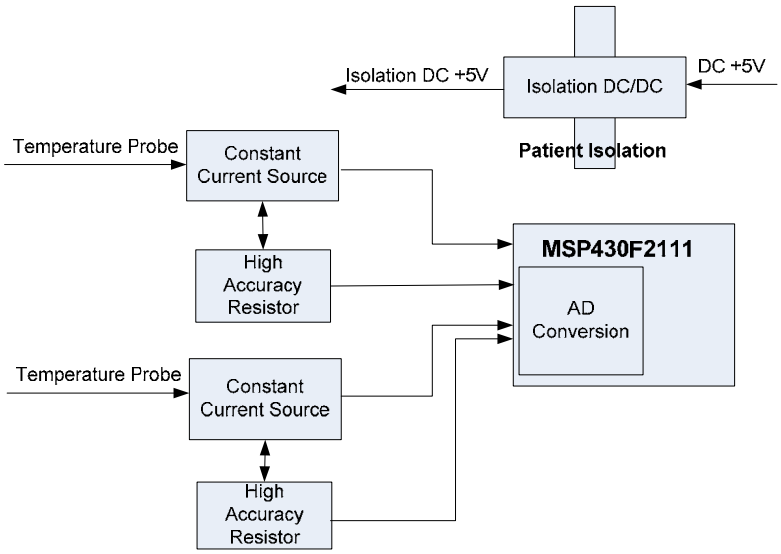


Figure 44. Temperature Unit Block Diagram

- **IBP unit:** measures invasive blood pressure data.

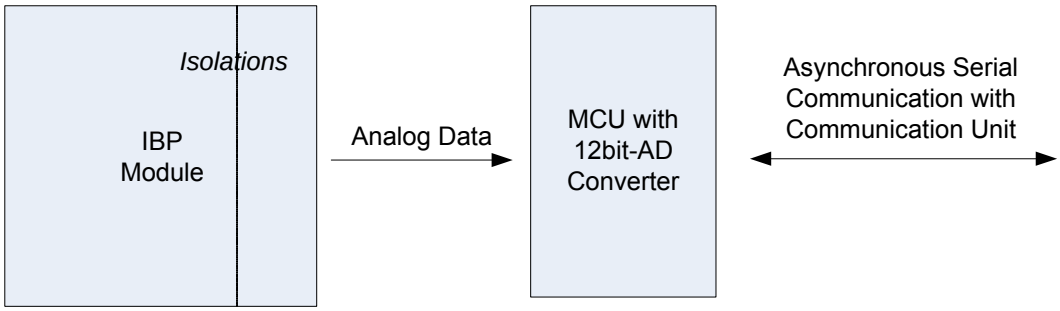


Figure 45. IBP Unit Block Diagram

- **CO_2 unit:** measures CO_2 data

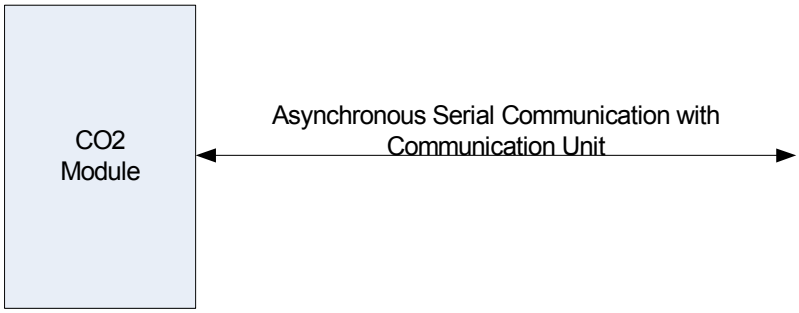


Figure 46. CO_2 Unit Block Diagram

- **TRX-02 unit:** wireless communication

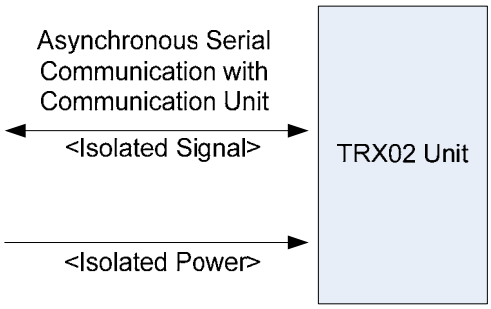


Figure 47. TRX-02 Unit Block Diagram

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).

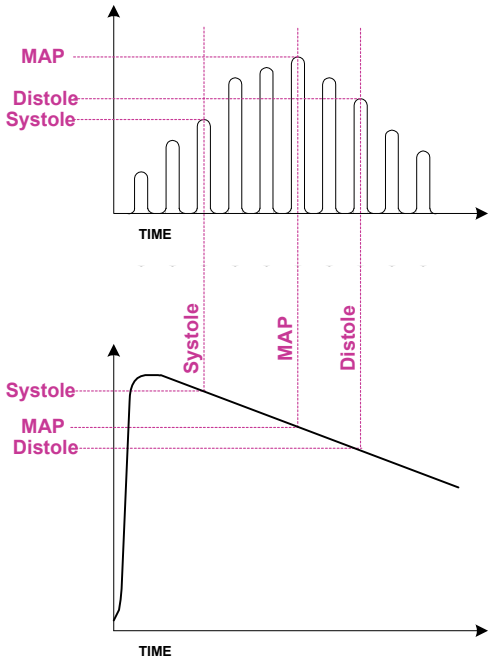
In addition to the acquisition of the QRS waveform complex, the ECG input and subsequent signal processing computing circuitry perform a number of other functions:

- 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.

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.

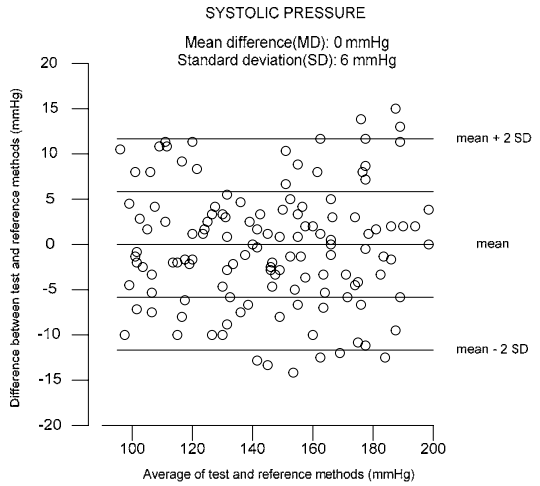
On clinical trial perspective, overall system accuracy is not easy to be determined. The clinical trial test protocols have been tried and have been described in many treatises, and international standards. So, there are many methods to determine the overall system accuracy of Automated Sphygmomanometer 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-10:2002+A1:2003 (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

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 SpO_2 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 SpO_2 sensor's red LED to accurately measure SpO_2. During monitoring, the instrument's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO_2.

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 (PO2). This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO2 and saturation: pH, temperature, partial pressure of carbon dioxide (PCO_2), 2, 3-DPG, and fetal hemoglobin.

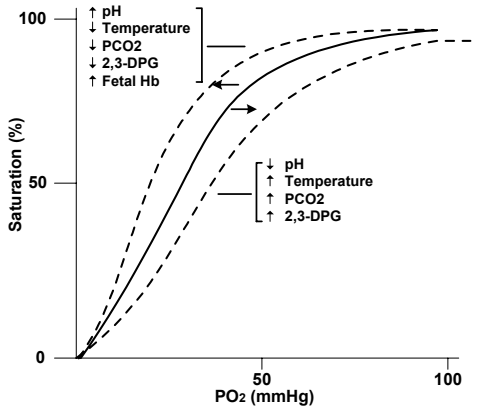


Figure 48. Oxyhemoglobin Dissociation Curve

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:

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

SpO_2 Accuracy

The saturation (SpO2) accuracy specification and/or pulse rate (PR) performance were analyzed by comparative oximetry performance (COPS) tests between BP-S510 SpO2 module and MP506 module with the same version of the oximetry algorithm from Nellcor. This was to demonstrate that the performance of BP-S510 SpO2 module was equivalent to that of MP506, which had been validated during both standard motion, combined motion and cold-induced peripheral vasoconstriction (low perfusion) conditions by direct comparison to measurements of arterial oxygen saturation (SaO2) obtained from arterial blood samples analyzed with Instrumentation Laboratory (IL) CO-Oximeters under Nellcor's clinical protocol, Invasive Controlled Hypoxia Studies.

Respiration Processing

The 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.

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 the BP-S510 monitor 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 BP-S510 monitor is designed to accept the signals from electrically isolated a range of temperature probes from YSI-400 series. 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.

Invasive Blood Pressure Processing

The pressure transducer is connected to a pressure line which, by means of a catheter is invasively connected to the patients blood stream. The force of movement of the blood in the patients vessels in transported by the fluid column n the pressure line to the transducer. This movement cause an electrical signal to be generated which is then amplified to display the pressure wave and the numeric for the systolic, diastolic and mean pressure values.

The blood pressure is influenced by the respiratory system. This occurs in spontaneous breathing patients, but is ore apparent in positive pressure ventilated patients. To reduce this respiration artifact the module uses a variable weight filter technique in the processing of the pressure values.

Capnography Processing

The capnography parameter provides the continuous, non-invasive monitoring of sidestream end-tidal carbon dioxide ($EtCO_2$), inspired carbon dioxide ($InCO_2$), and respiration rate (RR). The measured values for capnography ($EtCO_2$, $InCO_2$ and RR) are displayed in the CO_2 parameter box and a CO_2 waveform can be continuously displayed. Nitrous oxide compensation is selectable.