Operation/Service Manual

Datascope
Duo™

mindray™
NORTH AMERICA

Operating Instructions

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Duo™

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Navigator™ is a U.S. trademark of Mindray DS USA, Inc.

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Foreword

The **Duo** Operating Instructions are intended to provide information for proper operation.

General knowledge of monitoring and an understanding of the features and the functions of the **Duo** Monitor are prerequisites for proper use.

Do not operate this monitor before reading these instructions.

Information for servicing this instrument is contained in the **Duo** Monitor Service Manual, (Part Number 0070-00-0604-02). For additional information or assistance, please contact a local authorized representative.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician or other practitioner licensed by U.S. state law to use or order the use of this device.

Patents: This device is covered under one (1) of more of the following U.S. patents and any foreign equivalents 4,621,643; 4,700,708; 4,770,179; 4,869,254; 4,653,498; 4,928,692; 4,934,372; 5,078,136; 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,157,850; 6,206,830; 4,802,486; 5,351,685; 5,421,329; 5,485,847; 5,533,507; 5,577,500; 5,803,910; 5,853,364; 5,865,736; 6,263,222; 6,083,172 Re. 35,122. Possession or purchase of this device does not convey any express or implied license to use this device with replacement parts which would, alone, or in combination with this device, fall within the scope of one (1) or more of the patents related to this device.

Warnings, Precautions And Notes

Please read and adhere to all warnings, precautions and notes listed here and in the appropriate areas throughout this manual.

A **WARNING** is provided to alert the user to potential serious outcomes (death, injury, or serious adverse events) to the patient or the user.

A **CAUTION** is provided to alert the user to use special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients or users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Cautions are also provided to alert the user to adverse effects on this device of use or misuse and the care necessary to avoid such effects.

A **NOTE** is provided when additional general information is applicable.

Warnings

WARNING: The Duo monitor is not intended for unsupervised, continuous monitoring. It is for spot-check use only.

WARNING: Maintain extreme caution when a defibrillator is in use, avoiding contact with any part of the patient, table or monitor.

WARNING: Route cables neatly. Ensure cables, hoses, and wires are away from patient's neck to avoid strangulation. Keep floors and walkways free of cables to reduce the risk of tripping.

WARNING: This monitor is not intended for use in an MR environment.

WARNING: The Duo monitor is intended for hospital use under the direct supervision of a licensed health care practitioner.

WARNING: Do not clean the monitor while it is ON and/or connected to AC power.

WARNING: The Duo should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Duo should be observed to verify normal operation in the configuration in which it will be used.

WARNING: Operation of the Duo below the minimum amplitude or value of patient physiological signal may cause inaccurate results.

WARNING: Use of accessories, transducers, and cables other than those specified in the manual may result in increased Electromagnetic Emissions or decreased Electromagnetic Immunity of the Duo. It can also cause delayed recovery after the discharge of a cardiac defibrillator.

WARNING: Do not use a damaged or broken unit or accessory. Periodically, check all cables (e.g., AC line cord and patient connection cables) for damage that may occur through normal use. Replace cable if damaged in any way.

Precautions

CAUTION: **Do not place the SpO_2 sensor on an extremity with an invasive catheter or blood pressure cuff in place.**

CAUTION: **The use of portable and mobile RF communications equipment, in the proximity of the Duo, can affect the performance of this monitor.**

CAUTION: **Use only Mindray DS accessories with this product. For a comprehensive listing of Duo Accessories refer to section 4.0, "Accessories."**

CAUTION: **The patient size selection should be matched to the actual patient before monitoring begins.**

CAUTION: **Tissue damage or inaccurate measurement may be caused by incorrect SpO_2 sensor application or use, such as wrapping too tightly, applying supplemental tape, failing to inspect the sensor site periodically or failing to position appropriately. Carefully read the SpO_2 sensor directions and all precautionary information before use.**

CAUTION: **Excessive ambient light may cause inaccurate SpO_2 measurements. In such cases, cover the sensor site with opaque material.**

CAUTION: **The cuff must be properly applied to the patient's limb before inflating. If it is inflated without being securely wrapped, damage to the cuff can result.**

CAUTION: **This product contains natural rubber latex which may cause allergic reactions. This refers specifically to the large adult gray blood pressure cuff (0998-00-0003-35).**

CAUTION: **If the device is accidently saturated with any liquid, immediately discontinue use and contact service personnel.**

CAUTION: Inaccurate SpO_2 measurements may be caused by:

- **incorrect sensor application or use**
- **significant levels of dysfunctional hemoglobins, (e.g., carboxyhemoglobin or methemoglobin)**
- **intra-vascular dyes such as indocyanine green or methylene blue**
- **exposure to excessive illumination such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or excessive ambient light. In such cases, cover the sensor site with opaque material.**
- **excessive patient movement**
- **venous pulsations**
- **electro-surgical interference**
- **placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter or intra-vascular line.**
- **nail polish or fungus**

CAUTION: In certain situations in which perfusion and signal strength are low, such as in patients with thick or pigmented skin, inaccurately low SpO_2 readings will result. Verification of oxygenation should be made, especially in patients with chronic lung disease, before instituting any therapy or intervention.

CAUTION: Many patients suffer from poor peripheral perfusion due to hypothermia, hypovolemia, severe vasoconstriction, reduced cardiac output, etc. These symptoms may cause a loss in vital sign readings.

CAUTION: If the SpO_2 sensor or patient cable are damaged in any way, discontinue use immediately. To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize.

CAUTION: When applying the SpO_2 sensor to the patient, ensure proper positioning, alignment and skin integrity. Exercise extreme caution with poorly perfused patients.

CAUTION: When equipped with Masimo SpO_2, use only Masimo oxygen sensors and cables. Use of other oxygen sensors may cause improper oximeter performance.

CAUTION: When equipped with Nellcor SpO_2, use only Nellcor oxygen sensors and cables. Use of other oxygen sensors may cause improper oximeter performance.

CAUTION: Use only Mindray DS blood pressure cuffs and hoses with the Duo.

CAUTION: **A patient's skin is sometimes fragile (i.e., on pediatric and geriatric patients, or due to physiological conditions). In these cases, a longer duration between NIBP measurements should be considered to decrease the number of cuff inflations over a period of time. In extreme cases, a thin layer of soft roll or cotton padding may be applied to the limb in order to cushion the skin when the cuff is inflated. This may affect NIBP performance and should be used with caution.**

CAUTION: **Please consult a physician for interpretation of blood pressure measurements.**

CAUTION: **A blood pressure measurement can be affected by the position of the patient, and his/her physiological condition as well as other factors, such as patient movement.**

CAUTION: **Any condition that may affect the regularity and strength of arterial pressures (such as patient movement, cardiac arrhythmias, restriction of hose, etc.), will affect the accuracy and ability to measure the NIBP.**

CAUTION: **When cleaning SpO_2 sensors, do not use an excessive amount of liquid. Wipe the sensor surface with a soft cloth, dampened with a cleaning solution.**

CAUTION: **Do not subject the SpO_2 sensor to autoclaving.**

CAUTION: **Do not use SpO_2 sensors or cables that are damaged or have deteriorated.**

CAUTION: **Some disinfectants may cause skin irritation. Please rinse the NIBP cuffs thoroughly with water to remove any residual disinfectants.**

CAUTION: **Using dark colored soaps may stain the NIBP cuffs. Test a single cuff to ensure that no damage will occur.**

CAUTION: **Disposable NIBP cuffs can be cleaned using a mild soap solution and dried with a clean cloth.**

CAUTION: **Replace the Lithium Ion battery with part number 0146-00-0079 only.**

CAUTION: **Remove the battery if the Duo is not likely to be used for an extended period of time.**

CAUTION: **Remove the battery prior to shipping the Duo.**

CAUTION: **To avoid permanent damage, do not expose metal components (e.g., pins and sockets) to disinfectants, soaps or chemicals.**

CAUTION: **Only connect NIBP Luer fittings to Blood Pressure Cuff or Monitor.**

Notes

NOTE: **Potential hazards due to errors in software or hardware have been minimized by actions taken in accordance with IEC 60601-1-4.**

NOTE: **Information codes and error codes with corresponding explanations are provided to assist in the identification and correction of problems that may occur with the monitor.**

NOTE: **The comparison testing conducted via the auscultatory method used both Phase 4 and Phase 5 Korotkoff sounds. A report of the study finding for the auscultatory method is available by contacting Technical Support (201) 995-8116.**

NOTE: **The use of this equipment is restricted to one patient at a time.**

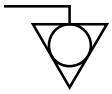
Indication for Use

The **Duo** monitor is intended for use in health care settings under the direct supervision of a licensed health care practitioner. The intended use of the monitor is to monitor physiologic parameter data on adult and pediatric patients. Physiologic data includes: non-invasive blood pressure (NIBP), pulse oximetry and pulse rate as summarized in the operating instructions manual. The information can be displayed only. The monitor is not intended for home use.

Unpacking

Remove the instrument and accessories from the shipping cartons and examine them for signs of damage. Check all materials against the packing list. Save the invoice, bill of lading and all packing materials. These may be required to process a claim with the carrier. Contact a Sales Representative or Distributor for assistance in resolving shipping problems.

Symbols

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Attention, Consult Accompanying Documents / Refer to Manual		Type BF Equipment
	Dangerous Voltage		Defibrillator Proof Type BF Equipment
	Equipotentiality		Battery Charging
	Alternating Current (AC)		NIBP
	ON/OFF (only for a part of the equipment)		Data Input/Output
	Patient Size (Adult/Pediatric)	C	Clear/Next Patient
	Non-ionizing electromagnetic radiation		Consult Operating Instructions

CE 0044 A symbol designating compliance of the **Duo** monitor with the Medical Device Directive (MDD) 93/42/EEC.

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1.0 General Product Description

1.1 Overview

The **Duo** is an NIBP spot-check monitor that is intended for use in health care settings on adult and pediatric patients requiring immediate and constant clinical supervision. Its design facilitates rapid, accurate NIBP measurement. The parameters that can be monitored with the **Duo** are: Non-Invasive Blood Pressure, Pulse Rate and SpO_2 (Optional).

The **Duo** can be powered by an AC connection or rechargeable Lithium Ion battery. Additionally, the unique carrying handle, light weight design and compact size, make **Duo** extremely portable.

The **Duo** can be carried by its handle, mounted on a rolling stand, or used as a tabletop device.

NOTE: **The Duo can be used in the presence of a defibrillator discharge and during electrosurgery.**

NOTE: **If it is stored or used outside of the specified environmental conditions, the Duo may not meet performance specifications (see the "Appendix" on page 5-1).**

1.2 Controls and Indicators

1.2.1 Front Panel

The **Duo** front panel is the main user interface, providing the digital LED display, keypad, and connector panel.

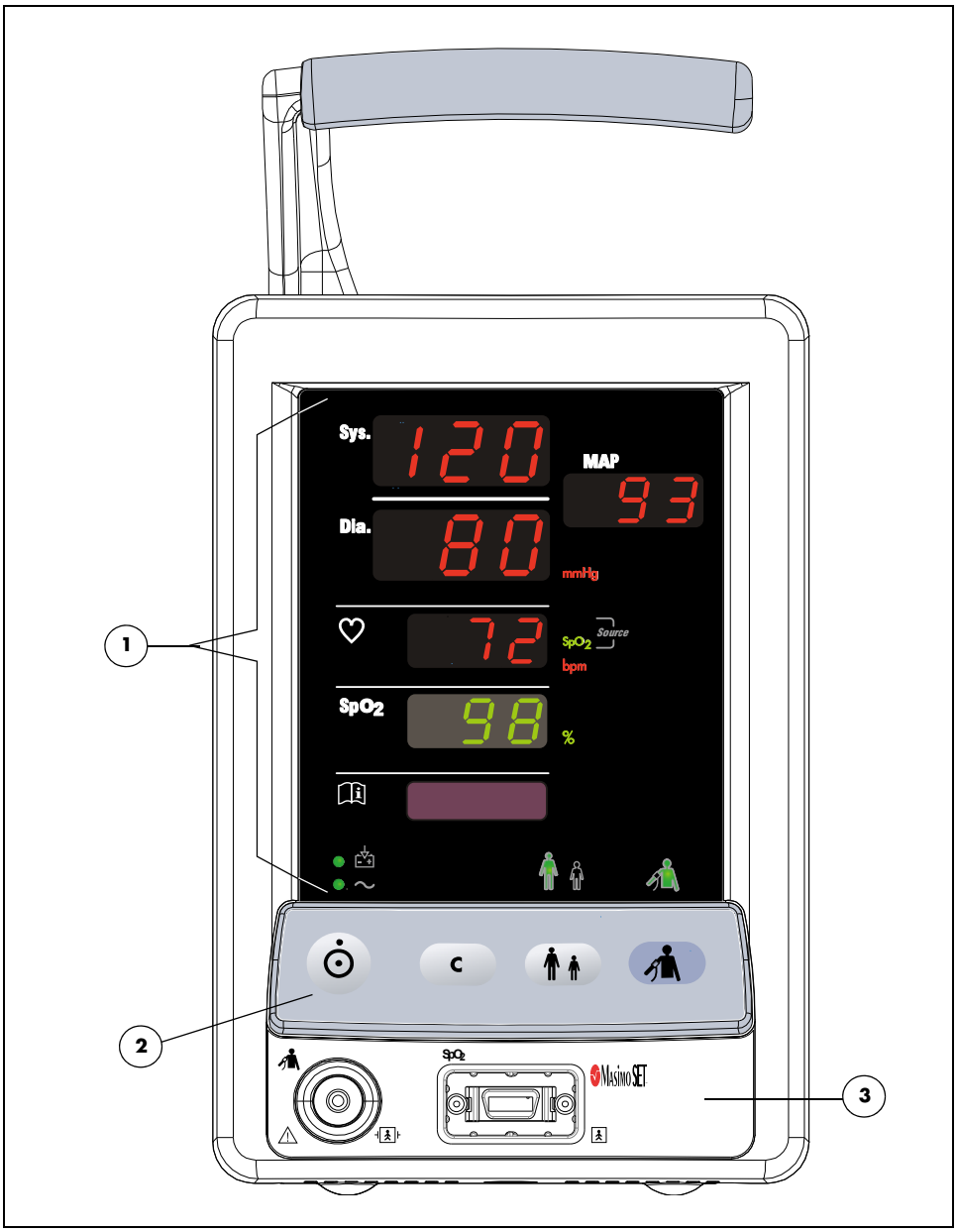


FIGURE 1-1 Front Panel

1. Digital Display

The **Duo** digital display features parameter tiles, numeric LEDs and LED indicators.

Parameter Tiles

The parameter tiles (shown in FIGURE 1-2) display the readings for the monitored parameters and also display information codes and error codes. When there is no measurement being determined and no code condition exists for a particular parameter, its associated tile will be blank.

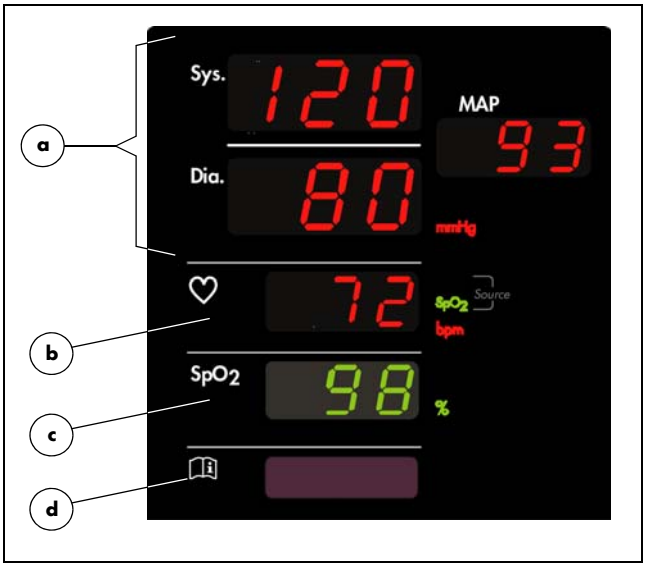


FIGURE 1-2 Parameter Tiles

a. NIBP

- The NIBP parameter tile is separated into three areas that are labeled as: **Sys.** (systolic), **Dia.** (diastolic) and **MAP** (mean arterial pressure). The LEDs are red.
- The labels for the unit of measure are **mmHg** or **kPa**.

b. Pulse Rate

- The Pulse Rate parameter tile is labeled with a heart symbol. ♡ The LEDs are red.
- The dual source labels are **NIBP** (red LED) and **SpO_2** (green LED).
- The label for the unit of measure is **bpm**.

c. SpO_2 (Optional)

- The SpO_2 parameter tile is labeled **SpO_2**. The LEDs are green.
- The label for the unit of measure is **%**.

d. Information Codes

- Information and error codes are displayed in the window.
- See section 2.4.1 for additional information.

LED Indicators

LED indicators (shown in FIGURE 1-3) illuminate green and are used to indicate the current status of the following: Battery Charging, AC Power, Patient Size and the NIBP function.

FIGURE 1-3 LED Indicators

a. Battery Charging

- If a battery is installed and AC power is being supplied to the monitor, the battery charging LED will illuminate to indicate that the battery is charging. The battery charging LED will illuminate regardless of whether the **Duo** is OFF or in normal monitoring mode.
- If a low battery condition exists, the battery charging LED will flash. When the LED begins flashing, the approximate remaining battery runtime is 10 – 20 minutes for the maximum load configuration of NIBP/SpO_2.

b. AC Power

- If AC power is being supplied to the monitor, the AC power LED will illuminate. The AC power LED will illuminate regardless of whether the **Duo** is OFF or in normal monitoring mode.

c. Patient Size

- The selected patient size LED will illuminate when the **Duo** is in normal monitoring mode. (In FIGURE 1-3, the **Adult** patient size LED is illuminated.)

d. NIBP Start/Stop

- If the **Duo** is in normal monitoring mode, and an NIBP measurement is in progress, the NIBP start/stop LED will illuminate. The NIBP start/stop LED will not be illuminated when the NIBP measurement is complete or has been stopped. A measurement can be manually stopped by the user or it can stop due to an error. NIBP error codes are displayed in the **Sys.** area of the NIBP parameter tile as described in section 2.4, “Information Codes and Error Codes”.

2. Keypad

The **Duo** keypad (shown in FIGURE 1-4) is used to initiate all functions. To confirm that a key has been successfully activated, two forms of feedback are provided. Manual feedback is provided in the form of a "click" that can be felt under the fingertip. Audible feedback is provided in the form of a single beep tone when the operation associated with that key is executed.

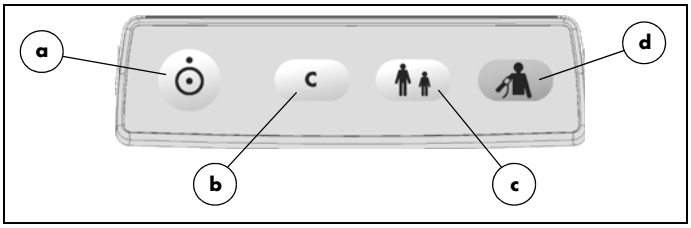


FIGURE 1-4 Keypad

a. Power ON/OFF

- This key is used to power the **Duo** ON or OFF. It is also used to exit standby mode and return to normal monitoring mode. The power OFF function features a time delay of two (2) seconds (minimum). When powering the **Duo** OFF, the user must depress the key for a minimum of 2 seconds.

NOTE: **If the Power ON/OFF key is depressed for less than two (2) seconds, the monitor will not power OFF.**

- When the **Duo** is powered OFF, all parameter data is permanently deleted.

b. Clear/Next Patient

- While in normal monitoring mode, this key is used to delete all data (including an NIBP E13 one-time information code) from the current display of the parameter tiles. When the data is deleted, the NIBP cuff inflation pressure is returned to the default value for the selected patient size.
- When a measurement for NIBP is currently in progress, this key is not active.

c. Patient Size

- This key is used to set the patient size to either **Adult** or **Pediatric**. While in normal monitoring mode, each press of this key toggles between the two sizes. When the **Duo** is powered OFF, the current patient size setting is maintained.
- When a measurement for NIBP is in progress, this key is not active.

d. NIBP Start/Stop

- This key is used to start an NIBP measurement and to stop an NIBP measurement that is already in progress.

3. Connector Panel

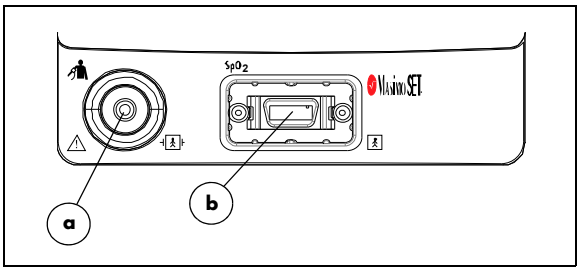


FIGURE 1-5 Connector Panel

a. NIBP Pneumatic Fitting

- This Rectus*, Quick-Connect pneumatic fitting is used to attach the NIBP hose to the **Duo**.

b. SpO_2 Receptacle (optional)

- This receptacle is used to attach the SpO_2 sensor to the **Duo**. The two versions of SpO_2 technology that are available for use with the DUO are Masimo® and Nellcor®.

* *Quick Connect Pneumatic Fittings available from Rectus-TEMA Corporation.*

1.2.2 Rear Panel

The rear panel provides a general information label, a serial port, an equipotential lug, an AC receptacle and a mounting alignment slot.

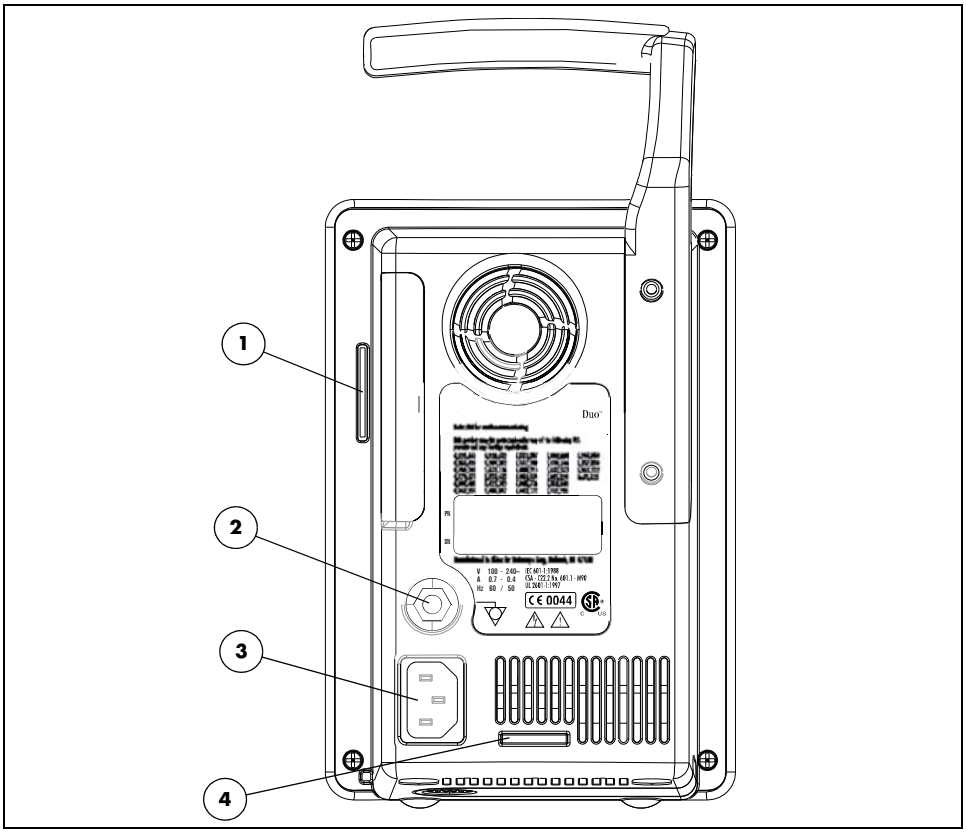


FIGURE 1-6 Rear Panel

1. Serial Port

This is used to connect optional modules.

2. Equipotential Lug

The equipotential lug provides equipotential grounding for hospital equipment.

NOTE: Ensure that when connecting external devices to the unit all equipotential terminals are connected.

3. AC Receptacle

This is the connector for the AC power cord.

NOTE: The power supply, and battery charger (if the battery is installed) are active any time AC power is supplied, regardless of whether the monitor is ON or OFF.

4. Mounting Alignment Slot

This is used to align the Duo with the mounting plate on the optional rolling stand.

1.2.3 Bottom Panel

The battery compartment and the mounting nut for the optional rolling stand are located on the bottom panel as shown in FIGURE 1-7.

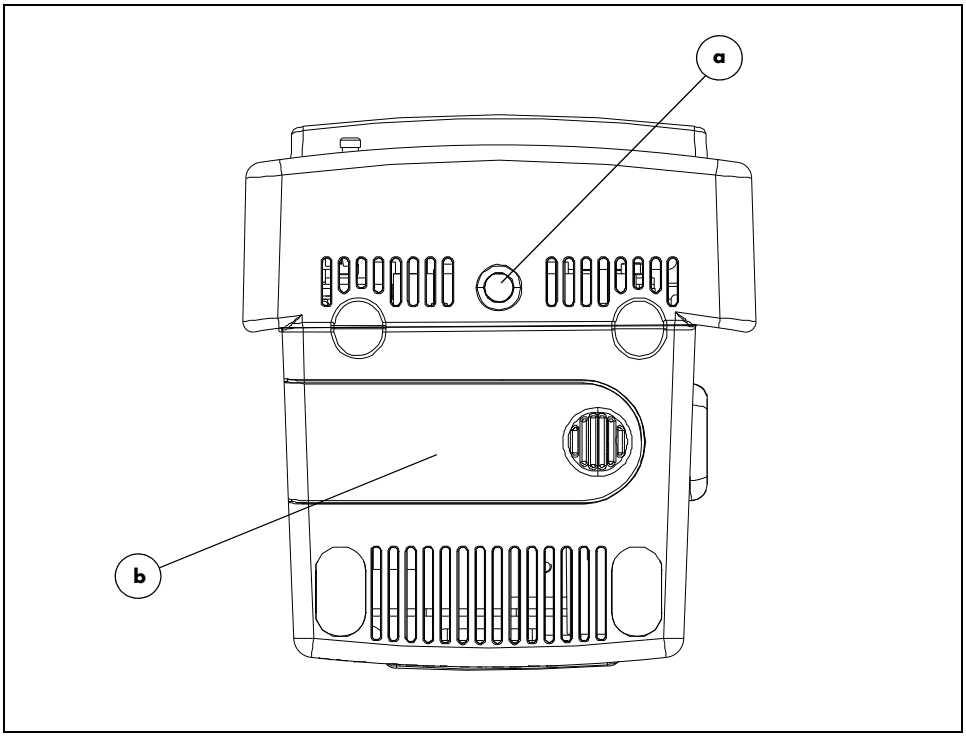


FIGURE 1-7 Bottom Panel

a. Mounting Nut

- The mounting nut secures the **Duo** to the optional rolling stand.

b. Battery Compartment

- The battery compartment houses one user-replaceable, rechargeable Lithium Ion battery. For ease of use, the door for the battery compartment is tethered to the bottom panel and features a molded finger grip.

2.0 *Operation*

2.1 Modes of Operation

The **Duo** functions in the following four (4) operating modes:

- **Normal Monitoring Mode**
- **Standby Mode**
- **Auto Shutoff Mode**
- **Maintenance Mode**

2.1.1 Normal Monitoring Mode

The Normal Monitoring Mode is the mode from which all monitoring functions are initiated during routine operation of the **Duo**.

2.1.2 Standby Mode

This feature is designed to save power while the **Duo** is running on battery power. The **Duo** can only enter Standby Mode from Normal Monitoring Mode and only while it is functioning on battery power. It cannot enter Standby Mode from Maintenance Mode or when it is connected to AC power. Changing the power source from battery to AC while in Standby Mode causes the **Duo** to automatically return to Normal Monitoring Mode. To indicate that the **Duo** has entered Standby Mode, the following will occur:

- The number eight (8) will display in the first LED position of the Information Codes tile and will then cycle through each of the three remaining LED positions of that tile.

When any of the events listed in the following table occur, an internal Standby Mode counter is reset to zero and started. The **Duo** enters Standby Mode after a preset time period for specific events as follows:

EVENT	TIME PERIOD TO ENTER STANDBY MODE
Switching from AC power to battery power	3 minutes
Any key press	3 minutes
The determination of an NIBP value	2 minutes
The acquisition point of SpO_2 data	3 minutes

In Standby Mode, the only key that is active is **Power ON/OFF**. When it is pressed for any duration of time, the **Duo** returns to Normal Monitoring Mode.

NOTE: The Duo cannot be powered OFF while in Standby Mode. It must return to Normal Monitoring Mode before it can be powered OFF.

2.1.3 Auto Shutoff Mode

This feature is also designed to save power while the **Duo** is operating from the internal battery. When the **Duo** has been in Standby Mode for 13 minutes, it will automatically power OFF. See the previous subsection for the conditions under which the **Duo** can enter Standby Mode.

2.1.4 Maintenance Mode

Maintenance Mode is a general reference to the following group of non-monitoring modes:

- Unit of Measure Mode
- Version Mode
- NIBP Calibration Mode
- NIBP Pneumatic Test Mode

Of the four (4) modes listed, only Unit of Measure Mode is intended for the clinician and is described in section 2.2.1. The remaining modes are strictly intended for the use of a biomedical technician or other qualified service person. If any of these modes is inadvertently entered, Normal Monitoring Mode can be reestablished by powering OFF and restarting the **Duo**.

2.2 Initial Set-Up

This section provides step-by-step instructions for initial set-up of the **Duo**.

1. Confirm that the proper voltage is available for connecting the **Duo** to AC power.

2. Install the battery as follows:

- Remove the battery compartment door (shown in FIGURE 2-1).

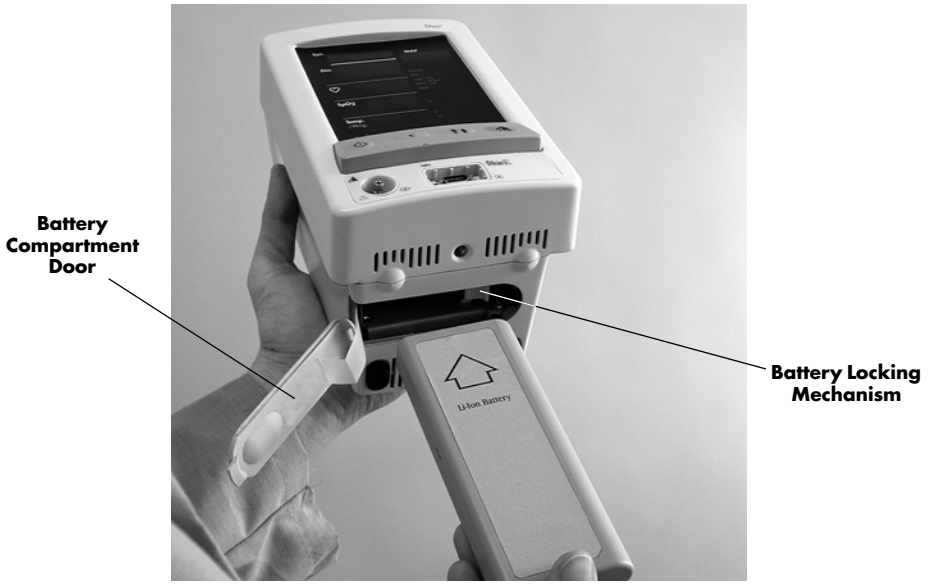


FIGURE 2-1 Battery Compartment

- The battery compartment is shaped so that the battery can only be inserted in the proper orientation. Disengage the battery locking mechanism by moving its plastic tab away from the center of the compartment (see FIGURE 2-1). Insert the new Lithium Ion battery with its contacts (shown in FIGURE 2-2) facing the rear of the compartment.

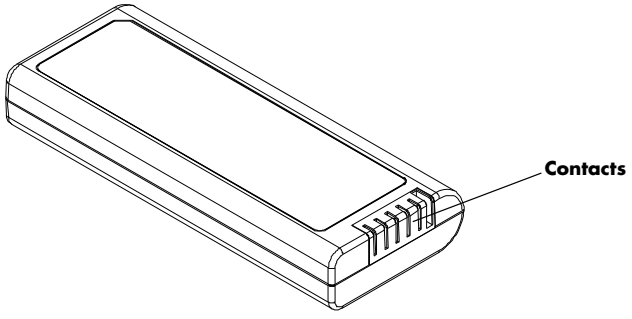


FIGURE 2-2 Lithium Ion Battery

- Ensure that the locking mechanism engages over the end of the battery by pressing the battery firmly into the compartment.
- Replace the battery compartment door.

NOTE: The Lithium Ion battery is shipped in a partially charged state and must be fully charged prior to its first use.

3. Charge the Lithium Ion battery as follows:

- Connect the AC power cord to the AC receptacle located on the rear panel.
- Plug the opposite end of the AC power cord into the appropriate AC outlet. The Battery Charging indicator will be illuminated on the front panel.
- Allow the battery to charge for a minimum of 4 hours.

NOTE: Optimum battery runtime is achieved after 3 charge/ discharge cycles.

4. Power ON the **Duo** by pressing the **Power ON/OFF** key. A single beep tone indicates that the **Duo** has successfully powered ON. An internal diagnostic test and an LED test are then executed. For the duration of the tests, all operational LEDs are displayed and the number "8" (plus any decimal LEDs) is displayed in the parameter tiles. When the tests are successfully complete, the following LEDs remain displayed:

- AC Power indicator (if AC power is present)
- Battery Charging indicator (if the battery is installed and AC power is present)
- Patient Size indicator (the current setting)
- Unit of Measure indicators (the most recent settings) for NIBP, Pulse Rate and SpO_2 (optional)

If any portion of the internal diagnostics test fails, error codes are displayed in specific parameter tiles as described in "Information Codes and Error Codes" on page 2-13.

2.2.1 Setting the Units of Measure (Units of Measure Mode)

The NIBP parameter has 2 choices for the unit of measure. This setting is maintained after the **Duo** is powered OFF. The units of measure for Pulse Rate (bpm) and SpO_2 (%) are not adjustable.

- The NIBP units of measure are **mmHg** and **kPa**.

The default setting is **mmHg**.

Use the following procedure to change the units of measure.

1. Ensure that the power to the **Duo** is OFF.
2. Press and hold the **Clear/Next Patient** key.
3. While continuing to hold the **Clear/Next Patient** key, press and hold the **Power ON/OFF** key for two (2) seconds until the **Duo** beeps.
4. Release both keys.
5. After an additional 2-second delay, the **Duo** will light the LED to show the currently stored setting of the NIBP unit of measure.
6. Press the **Clear/Next patient** key repeatedly until the desired NIBP (mmHg or kPa) unit of measure is showing.
7. Press the **Power ON/OFF** key for two (2) seconds to turn the **Duo** off and save the new settings.
8. You may then turn the **Duo** back on to resume normal operation.

NOTE: The Duo cannot be placed directly back into normal monitoring mode after setting the units of measure. It must first be powered OFF.

2.3 Routine Operation

This section provides guidelines and step-by-step instructions for the vital sign measurements that are routinely performed with the **Duo**.

2.3.1 NIBP Measurement

CAUTION: A patient's skin is sometimes fragile (i.e., on pediatric and geriatric patients, or due to physiological conditions). In these cases, a longer duration between NIBP measurements should be considered to decrease the number of cuff inflations over a period of time. In extreme cases, a thin layer of soft roll or cotton padding may be applied to the limb in order to cushion the skin when the cuff is inflated. This may affect NIBP performance and should be used with caution.

CAUTION: Please consult a physician for interpretation of blood pressure measurements.

CAUTION: A blood pressure measurement can be affected by the position of the patient, and his/her physiological condition as well as other factors, such as patient movement.

CAUTION: Any condition that may affect the regularity and strength of arterial pressures (such as patient movement, cardiac arrhythmias, restriction of hose, etc.), will affect the accuracy and ability to measure the NIBP.

The **Duo** utilizes the oscillometric method of measuring Non-Invasive Blood Pressure (NIBP). The measurement includes systolic (Sys.), diastolic (Dia.) and mean arterial pressure (MAP). There is no provision for interval measurement. Each measurement must be initiated by pressing the **NIBP Start/Stop** key while the **Duo** is in normal monitoring mode.

The initial default cuff inflation pressure is dependent on the patient size setting as follows:

PATIENT SIZE SETTING	DEFAULT CUFF INFLATION PRESSURE
Adult	178 ± 5 mmHg
Pediatric	133 ± 5 mmHg

If the **Duo** is in normal monitoring mode, then the selected NIBP unit of measure LED will be illuminated red, regardless of whether there is an NIBP value being displayed.

Upon power ON of the **Duo**, the NIBP unit of measure setting defaults to the most recent setting made in the Unit of Measure mode.

During the inflation and bleed portions of the NIBP measurement, the current cuff pressure displays in the **MAP** section of the NIBP parameter tile and updates approximately once every second.

After the first successful measurement, the subsequent inflation pressure for the same patient will be 50 ±10 mmHg above the previous systolic pressure measurement.

If a measurement cannot be obtained, the **Duo** automatically reinflates the cuff to 30 – 60 mmHg higher than the initial inflation pressure, but will not exceed the maximum cuff pressure listed in the "NIBP Sub-System Functional Requirements", section 5.2.6. This process will only repeat three times and then an associated error code will be displayed. Refer to "Information Codes and Error Codes" on page 2-13 for further information.

NOTE: Pressing the Clear/Next Patient key while there are no measurements in progress will reset the NIBP cuff inflation pressure to the default value for the selected patient size.

1. Select a blood pressure cuff that is appropriate for the size of the patient. Measure the circumference of the patient's limb for the best results.

NOTE: Using a correctly sized cuff, among other considerations, has a direct bearing on the accuracy of the obtained NIBP measurements. A cuff that is too narrow for the limb will result in erroneously high readings. Selection of the cuff size should be based on the circumference of the patient's limb. The design dimensions of the cuffs and their intended use are based on recommendations made by the American Heart Association.

CAUTION: Use only Mindray DS blood pressure cuffs and hoses with the Duo.

2. Attach the NIBP cuff to the NIBP extension hose.
3. Attach the NIBP extension hose to the NIBP pneumatic fitting on the **Duo**.
4. Apply the cuff to the patient as shown in FIGURE 2-3. Ensure that the cuff is deflated and lies directly against the patient's skin. The cuff should fit snugly. There should be no clothing between the patient's skin and the cuff.

CAUTION: The cuff must be properly applied to the patient's limb before inflating. If it is inflated without being securely wrapped, damage to the cuff can result.

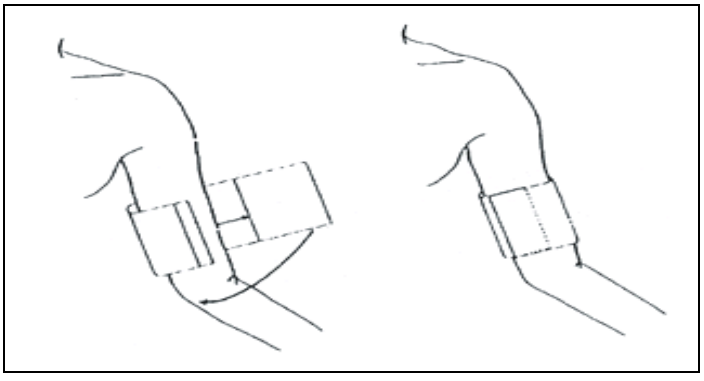


FIGURE 2-3 Application of the Blood Pressure Cuff

5. Ensure that the appropriate patient size has been selected on the **Duo**.
6. Press the **NIBP Start/Stop** key to begin the NIBP measurement.

The cuff begins to inflate. After reaching the default pressure for the selected patient size, the cuff slowly deflates and the **Duo** collects oscillometric pulsations. During this inflation and deflation portion of the measurement, the **MAP** section of the NIBP parameter tile displays the current pressure in the cuff. During this same period, the **Sys.** and **Dia.** sections of the NIBP parameter tile display dashes "- - -".

The patient should remain still to avoid the introduction of unnecessary motion artifact. After the cuff pressure drops below the diastolic pressure, the measurements are displayed in the NIBP parameter tile. These results will be deleted and the NIBP parameter tile will be blank if one of the following occurs:

- 15 minutes elapse since the last NIBP measurement
- The **Clear/Next Patient** key is pressed to clear the results
- The **Duo** is powered OFF

If the **Duo** enters Standby Mode, the internal counter for the elapsed time since the last NIBP measurement continues. If Normal Monitoring Mode resumes before the counter reaches 15 minutes, the NIBP results will display until one of the previous bulleted items occurs or the **Duo** again enters Standby Mode.

NOTE: Pressing the NIBP Start/Stop key while the NIBP measurement is in progress will stop the measurement and deflate the cuff.

2.3.2 Pulse Rate Measurement

The Pulse Rate is determined from one of two sources: SpO_2 and NIBP.

NOTE: If the optional SpO_2 is not purchased with the Duo, the Pulse Rate source will be NIBP by default.

SpO_2 is the higher priority source. If both SpO_2 and NIBP are being actively monitored, SpO_2 will be the source for the Pulse Rate measurement. If only NIBP is being actively monitored, it will be the source for the Pulse Rate measurement.

- When determined from SpO_2, the Pulse Rate updates approximately once every second. When SpO_2 is no longer being monitored, the Pulse Rate parameter tile will be blank.
- When determined from NIBP, the Pulse Rate will display until the NIBP results are no longer displayed, as described in section 2.3.1.

NOTE: Pulse Rate from NIBP is a static value since NIBP is a static, one-time measurement.

The Pulse Rate results will display for the same maximum time that the source parameter (SpO_2 or NIBP) is displayed.

2.3.3 SpO_2 Measurement (Optional)

Each of the following terms are associated with blood oxygenation: oxygen saturation, pulse oximetry, SpO_2 and plethysmography.

Oxygen saturation in capillary blood is measured by a method called pulse oximetry. Pulse oximetry is a continuous and non-invasive measurement of the amount of oxygen attached to the hemoglobin in red blood cells (also known as oxyhemoglobin saturation). SpO_2 is the estimation of arterial oxygen saturation. This term is used interchangeably with SaO_2. This value is displayed in the SpO_2 parameter tile.

Traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photo detector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This also assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts.

Performance Considerations

To ensure optimal SpO_2 measurement, use an appropriate sensor, apply it as directed, and observe all warnings and cautions. Sensors are designed for specific sites on patients with designated weight ranges. To select the appropriate sensor, consider the patient's weight, level of activity, adequacy of perfusion, available sensor sites and the sterility requirement.

If excessive ambient light is present, cover the sensor site with opaque material. Failure to do so may cause inaccurate measurements. Light sources that can affect performance include surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight.

In the event that a reading is unobtainable or inaccurate, consider the following:

- If the patient is poorly perfused, try applying the sensor to another site - such as a different finger or toe.
- Ensure that the sensor is properly aligned and securely applied.
- Use a new sensor.
- Move the sensor to a less active site.
- Use a type of sensor that tolerates some patient motion.
- Ensure that the sensor and site are clean/non-greasy. Nail polish and fungus should be removed.

Calibration

The oximetry sub-system incorporates automatic calibration mechanisms. No other calibration is required.

CAUTION: Do not place the SpO2 sensor on an extremity with an invasive catheter or blood pressure cuff in place.

CAUTION: Tissue damage or inaccurate measurement may be caused by incorrect SpO2 sensor application or use, such as wrapping too tightly, applying supplemental tape, failing to inspect the sensor site periodically or failing to position appropriately. Carefully read the SpO2 sensor directions and all precautionary information before use.

CAUTION: Inaccurate SpO2 measurements may be caused by:

- **incorrect sensor application or use**
- **significant levels of dysfunctional hemoglobins, (e.g., carboxyhemoglobin or methemoglobin)**
- **intra-vascular dyes such as indocyanine green or methylene blue**
- **exposure to excessive illumination such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or excessive ambient light. In such cases, cover the sensor site with opaque material.**
- **excessive patient movement**
- **venous pulsations**
- **electro-surgical interference**
- **placement of a sensor on an extremity that has a blood pressure cuff, arterial catheter or intra-vascular line.**
- **nail polish or fungus**

CAUTION: In certain situations in which perfusion and signal strength are low, such as in patients with thick or pigmented skin, inaccurately low SpO2 readings will result. Verification of oxygenation should be made, especially in patients with chronic lung disease, before instituting any therapy or intervention.

CAUTION: Many patients suffer from poor peripheral perfusion due to hypothermia, hypovolemia, severe vasoconstriction, reduced cardiac output, etc. These symptoms may cause a loss in vital sign readings.

CAUTION: If the SpO2 sensor or patient cable are damaged in any way, discontinue use immediately. To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize.

CAUTION: When applying the SpO2 sensor to the patient, ensure proper positioning, alignment and skin integrity. Exercise extreme caution with poorly perfused patients.

CAUTION: Excessive ambient light may cause inaccurate SpO2 measurements. In such cases, cover the sensor site with opaque material.

2.3.3.1 Masimo SET® SpO_2

The Masimo pulse oximeter determines SpO_2 in the traditional manner of passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. It assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. The Masimo pulse oximeter calculates the ratio of the arterial signals without the noise.

Masimo SET provides a family of sensors suitable for a wide variety of clinical settings and patient sizes. All sensors are:

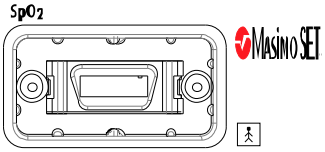
- Indicated for continuous non-invasive monitoring of arterial oxygen saturation (SpO_2) and Pulse Rate
- Non-sterile
- Usable during patient movement

The LNOP® DCI Adult Reusable Finger Sensor is used for “spot check” applications if needed. Adhesive-type sensors are also available. Refer to "Accessories" on page 4-1 for approved sensors. All sensors are intended for “single-patient use only” unless indicated as “reusable”.

CAUTION: When equipped with Masimo SpO2, use only Masimo oxygen sensors and cables. Use of other oxygen sensors may cause improper oximeter performance.

NOTE: Refer to instructions included with each SpO_2 sensor and cable for proper placement and use.

1. Select an SpO_2 sensor that is appropriate for the size of the patient.
2. Attach the SpO_2 sensor to the patient’s finger.
3. Orient the connector so that the Masimo SET logo is facing upward. Plug the connector into the SpO_2 receptacle on the front panel of the **Duo**. The SpO_2 measurement will display when the **Duo** detects that the sensor is connected to the patient.



These results are updated once every second and can display for a maximum of 2 minutes during continuous SpO_2 measurement.

NOTE: To disconnect the cable from the Duo, squeeze the tabs on the sides of the connector and then pull it straight out.

2.3.3.2 Nellcor® SpO_2

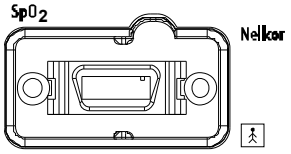
Nellcor provides a family of sensors suitable for a wide variety of clinical settings and patients. Specific sensors have been developed for a variety of patient sizes.

CAUTION: When equipped with Nellcor SpO2, use only Nellcor oxygen sensors and cables. Use of other oxygen sensors may cause improper oximeter performance.

The DS-100A Finger Clip Sensor is shipped with the Nellcor version of the **Duo**. This sensor is a combination sensor/cable/connector that attaches to the monitor.

NOTE: Refer to instructions included with each SpO_2 sensor and cable for proper placement and use.

1. Select an SpO_2 sensor that is appropriate for the size of the patient.
2. Attach the SpO_2 sensor to the patient's finger.
3. Attach the connector end of the SpO_2 sensor to the SpO_2 extension cable.
4. Plug the connector from the SpO_2 extension cable into the SpO_2 receptacle on the front panel of the **Duo**. The SpO_2 measurement will display when the **Duo** detects that the sensor is connected to the patient.



These results are updated once every second and can display for a maximum of 2 minutes during continuous SpO_2 measurement.

NOTE: To disconnect the cable from the Duo, squeeze the tabs on the sides of the connector and then pull it straight out.

2.4 Information Codes and Error Codes

In addition to numeric values for the monitored parameters, the digital LED display of the **Duo** provides information codes and error codes to indicate the operational status of the monitor.

- Codes that refer to the operational status of the monitor are preceded by a capital letter "E".
- Codes that indicate that the device is in Maintenance Mode are numeric only.

Some codes refer to a particular parameter function and are displayed in the associated parameter tile. (NIBP codes are displayed in the **Sys.** section of the NIBP parameter tile.) Information codes, referring to the general operational status of the monitor and not to a specific parameter, are displayed in the Information Codes tile. All codes display until the condition is removed or, for one-time error codes, until the Clear/Next Patient key is pressed.

If multiple codes exist simultaneously, then each code will cycle through and display for a duration of 1 second.

Information codes and error codes listed in the following table can generally be resolved by the user. However, some error codes may require resolution by a qualified service technician.

NOTE: Information codes and Error codes that are marked with an asterisk (*) are one-time codes that can be cleared from the display by pressing the Clear/Next Patient key.

2.4.1 Information Codes

MESSAGE TYPE	CODE	DESCRIPTION	REASON
NIBP	E03	*LOOSE CUFF	Cuff is not properly wrapped or no cuff is present.
	E06	SUCCESSFUL PNEUMATIC TEST	Indicates NIBP pneumatic test was successful.
	E07	PNEUMATIC TEST FAIL/PNEUMATIC LEAK	During pneumatic test, leak is detected.
	E08	*WEAK SIGNAL	Cuff is too loose or patient pulse is too weak.
	E09	*RANGE EXCEEDED	NIBP value exceeds the upper measurement limit.
	E10	EXCESSIVE MOTION SIGNAL SATURATED	Monitor is detecting too much motion and/or noise to obtain a reading.
	E11	*OVER PRESSURE	Pressure has exceeded the specified upper safety limit.
	E13	*NIBP TIME OUT	Measuring time has exceeded 120 seconds (adult/pediatric).
MASIMO SPO2	E20	SPO2 INTERFERENCE	Noise detected on the pulse signal prevents pulse discrimination.
	E21	SPO2 LOW PERFUSION	Patient perfusion is low.
	E22	SPO2 TOO MUCH LIGHT	There is too much ambient room light for the sensor to function properly.
	E23	SPO2 UNRECOGNIZED SENSOR	The sensor is not recognized by the monitor.
	E28	*SPO2 TIMEOUT	SpO2 has exceeded its maximum continuous measuring period of 2 minutes. The SpO2 data has been removed from the display.
	E29	SPO2 LOW SIGNAL IQ	Quality of signal is poor.
	E34	*PR EXCEED	PR value exceeds the measurement range.

MESSAGE TYPE	CODE	DESCRIPTION	REASON
NELLCOR SPO2	E40	SPO2 INTERFERENCE	Noise is detected on the pulse signal preventing pulse discrimination from the noise. The interference may be due to motion, excess infrared light or electrical/ optical interference.The message is removed when the noise is removed.
	E41	SPO2 CHECK SENSOR	The Nellcor module senses an unstable or illegal sensor. This may also be due to a poor connection or a bad sensor. The user is required to reconnect the same sensor or connect a new sensor. The message is removed once the Nellcor module clears the error.
	E43	SPO2 WEAK PULSE	A pulse rate can not be determined and all other measurement conditions are normal. The message is removed when a pulse is detected.
	E44	SPO2 WEAK SIGNAL	Noise is detected but a pulse rate can not be discriminated. The message is removed when a pulse is detected.
	E46	SPO2 MOTION	Motion is detected. The message is removed when No Pulse status is detected or when motion ceases.
	E47	*SPO2 TIMEOUT	SpO2 has been determined continuously for more than 2 minutes, so SpO2 data has timed out from the display.
	E34	PR EXCEED	PR value exceeds the measurement range.
GENERAL/ TECHNICAL	E501	BAT. VOLTAGE LOW	Battery voltage is low.

2.4.2 Error Codes

MESSAGE TYPE	CODE	DESCRIPTION	REASON
NIBP	E01	NIBP SELF TEST ERR	NIBP module hardware failure.
	E02	NIBP COMM ERR	Communication with NIBP module has failed.
	E04	AIR LEAK	Cuff, hose or connector is damaged. Internal leak.
	E05	AIR PRESSURE FAILURE	Stable pressure value is not available. (e.g., hoses are pinched or occluded)
	E12	NIBP SYSTEM FAILURE	Operation of blood pressure pump system failed.
	E14	*NIBP ILLEGALLY RESET	Unexpected NIBP reset.
	E15	NIBP RESET FAILED	NIBP reset failed.
	E16	*NIBP COMM CRC ERROR	NIBP Serial Communication failure
	E17	NIBP PATIENT SIZE CHANGE ERR	Attempt to change patient size failed
MASIMO SPO2	E24	SPO2 COMM ERROR	The monitor and the SpO2 modules are not communicating properly.
	E25	SPO2 BOARD FAULT	Masimo SET board failed to operate properly.
	E26	SPO2 SENSOR FAULT	Defective sensor.
NELLCOR SPO2	E42	SPO2 COMM ERROR	The front end module is having problems communicating (i.e., framing errors or bad checksums) with the Nellcor board.
	E45	SPO2 BOARD FAULT	The SpO2 board malfunctions.
GENERAL/ TECHNICAL	E504	KEYBOARD ERR1	Error with front panel keypad board.
	E505	MONITOR SHUTOFF FAILURE	Monitor cannot be turned off normally
	E506	SPO2 MODULE NOT RECOGNIZED	Monitor cannot communicate with the SpO2 module during self-test.

3.0 *User Maintenance*

3.1 Introduction

This section of the manual outlines routine maintenance to be performed by the user and/or biomedical technician.

The **Duo** monitor is designed for stable operation over long periods of time and under normal circumstances should not require technical maintenance beyond circumstances described in this section. In general, routine maintenance, calibration and safety checks are recommended annually, or more often as required by local statutory or hospital administration practice.

General Maintenance

Before using the **Duo**, perform the following general maintenance checks:

1. Perform a visual inspection of the exterior of the device, external cables, inserted modules and accessories. Replace damaged cables, modules and accessories as necessary.

NOTE: **If any damage is found on the exterior of the device, contact the biomedical engineer of the facility or Customer Service immediately.**

2. Verify that all device functions operate properly. If operating problems cannot be corrected, contact the Service Department at 1-800-288-2121 or (201) 995-8116 for assistance in determining the nearest field service location.

   Please be prepared to provide the instrument part number, the serial number, and a description of the problem with all requests for service.

3. Clean the device as needed as described in the following sections.

3.2 Care and Cleaning of the Monitor

The monitor housing may be cleaned with a mild soap and water solution or ammoniated window cleaner. Apply cleaning solution to the cloth, not directly onto the monitor. DO NOT apply large amounts of liquid. DO NOT use abrasive cleaning agents or organic solvents.

WARNING: Do not clean the monitor while it is ON and/or connected to AC power.

To prevent scratches on the screen, carefully remove dust and dirt particles with a fine, soft-hair brush or a soft sponge moistened with cleaning solution. Fingerprints and stains may be removed by using a liquid lens cleaner and a soft cloth. DO NOT wipe a dry screen or use alcohol or a solvent containing chlorinated hydrocarbon.

3.3 Care and Cleaning of Accessories

3.3.1 SpO_2 Sensors

NOTE: Refer to the individual instruction sheets that are packaged with each sensor.

1. Inspect the sensors and cables for damage on a daily basis. Replace as necessary.

2. Clean reusable sensors before and after each use as follows:

- Wipe the patient contact area using a soft cloth with a mild soap and water solution, or isopropyl alcohol. Hydrogen peroxide can be used to remove dried blood from all accessible surfaces.
- Clean the cable with a 3% hydrogen peroxide solution, isopropanol solution, or other active reagent. Do not subject the connector of the sensor to such a solution.
- Allow the sensor to completely dry before using.

CAUTION: When cleaning SpO2 sensors, do not use an excessive amount of liquid. Wipe the sensor surface with a soft cloth, dampened with a cleaning solution.

CAUTION: Do not subject the SpO2 sensor to autoclaving.

CAUTION: If the SpO2 sensor or patient cable are damaged in any way, discontinue use immediately. To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize.

CAUTION: Do not use SpO2 sensors or cables that are damaged or have deteriorated.

3.3.2 Care and Cleaning of Reusable Cuffs

NOTE: Accuracy of cuff-pressure transducers/indicators is to be verified at intervals specified by the manufacturer.

3.3.2.1 Reusable Cuffs with Bladders

Take out the bladder before cleaning and disinfecting the cuff.

Cleaning

The cuff can be hand washed or machine washed in warm water or with mild detergent. The bladder can be cleaned with a damp cloth. Air dry the cuff thoroughly after washing.

NOTE: Machine washing may shorten the service life of the cuff.

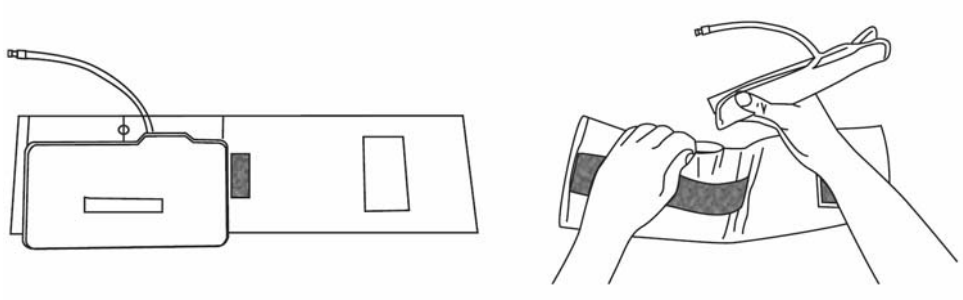
Disinfection

The cuff may be disinfected with a damp cloth with 70% isopropanol and water. It may also be disinfected with ultraviolet. The bladder can only be disinfected with ultraviolet.

NOTE: Prolonged use of disinfectant may cause discoloration of the cuff.

Replace the bladder after cleaning and disinfecting the cuff, as follows:

1. Place the bladder on the top of the cuff, as the figure shows.
2. Roll the bladder lengthwise and insert it into the large opening. See the figures below.
3. Hold the hose and the cuff and shake the complete cuff until the bladder is in position.
4. Thread the hose from inside the cuff, and out through the small hole under the internal flap.



CAUTION: Do not dry clean the cuff.
Do not press the cuff with a hot iron.
Do not use detergent and disinfectant other than fresh water or 70% isopropanol.
Clean and disinfect the cuff according to the instructions.

3.3.2.2 Reusable Bladderless Cuffs

Clean cuffs with warm water and a mild detergent. Do not use a detergent containing hand conditioners, softeners, or fragrances.

NIBP cuffs can be sterilized with gamma sterilization without affecting the repeated performance of the cuff. Steam sterilization is not recommended. Use of a washing liquid containing bleach is not recommended because chlorine will chemically break down the urethane on the inside of the cuff.

Antimicrobial Definition

Bladderless cuffs are treated with an antimicrobial coating. Antimicrobial technology effectively controls a broad spectrum of bacteria, fungi, algae and yeasts on a wide variety of treated substrates.

3.3.2.3 Disposable Blood Pressure Cuffs

Disposable cuffs are intended for single patient use only. Once a cuff is used on a patient it should be discarded. Do not use the same cuff on any other patient. Do not sterilize or use an autoclave on disposable cuffs.

NOTE: **Disposable cuffs can be cleaned using a mild soap solution and dried with a clean cloth. For Cuffs with bladders, remove bladder before cleaning.**

3.4 Battery Replacement and Maintenance

Battery Replacement

CAUTION: Replace the Lithium Ion battery with part number 0146-00-0079 only.

1. Remove the battery compartment door.
2. Disengage the battery locking mechanism by moving its plastic tab away from the edge of the battery (see 3-1). Remove the battery.

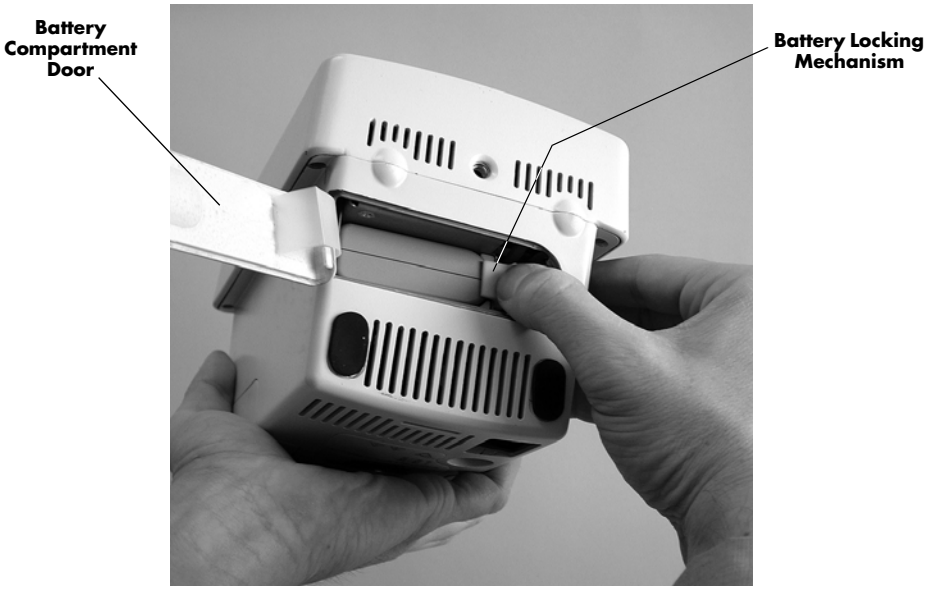


FIGURE 3-1 Battery Compartment

3. The battery compartment is shaped so that the battery can only be inserted in the proper orientation. Insert the new Lithium Ion battery with its contacts (shown in 3-2) facing the rear of the compartment.

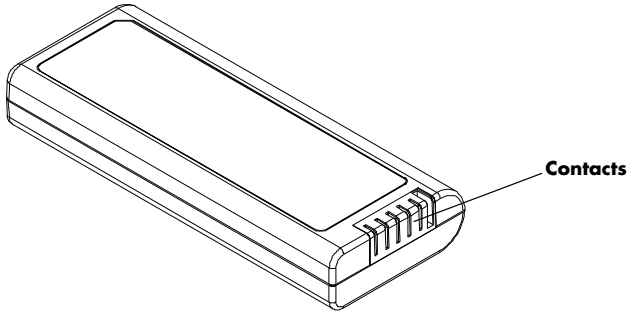


FIGURE 3-2 Lithium Ion Battery

4. Ensure that the locking mechanism engages over the end of the battery by pressing the battery firmly into the compartment.
5. Replace the battery compartment door.

Battery Maintenance and Disposal

CAUTION: Remove the battery if the Duo is not likely to be used for an extended period of time.

CAUTION: Remove the battery prior to shipping the Duo.

The **Duo** monitor uses a Lithium Ion battery. This type of battery may be subject to local regulations regarding disposal. At the end of battery life, dispose of the batteries in accordance with any local regulations.

4.0 *Accessories*

4.1 Standard Kits

Masimo SET® Adult/Ped Single-Patient Adhesive 0020-00-0123-01

DESCRIPTION	PART NUMBERS
(2) LNOP® Adt Adult Single-Patient Adhesive Finger Sensor	0600-00-0043-02
(2) LNOP® Pdt Pediatric Single-Patient Adhesive Finger Sensor	0600-00-0044-02
(1) Patient Cable, 12′ (3.7 m)	0012-00-1099-02

4.2 Optional Accessories

4.2.1 NIBP Accessories

Hoses

DESCRIPTION	PART NUMBERS
NIBP Hose, 5′ (1.5 m), Female Rectus/Female Rectus (for use with Reusable Cuffs and Adult/Child Disposable Cuffs)	0683-04-0003
NIBP Hose, 10′ (3.5 m), Female Rectus/Female Rectus (for use with Reusable Cuffs and Adult/Child Disposable Cuffs)	0683-04-0004

Reusable Cuffs - Quick-Connect

DESCRIPTION	PART NUMBERS
Reusable NIBP cuff, Child, 10 to 19cm, quick connect	0683-15-0001-01
Reusable NIBP cuff, Small Adult, 18 to 26cm, quick connect	0683-15-0002-01
Reusable NIBP cuff, Adult, 25 to 35 cm, quick connect	0683-15-0003-01
Reusable NIBP cuff, Large Adult, 33 to 47cm, quick connect	0683-15-0004-01
Reusable NIBP cuff, Thigh, 46 to 66cm, quick connect	0683-15-0005-01
Reusable NIBP Cuff, Adult Long, 25 – 35 cm, quick connect	0683-15-0006-01
Reusable NIBP Cuff, Large Adult Long, 33 - 47 cm, quick connect	0683-15-0007-01

Disposable Cuffs - Quick-Connect

DESCRIPTION	PART NUMBERS
Disposable NIBP cuff, Child, 10 to 19cm, quick connect, box of 10	0683-14-0001-01
Disposable NIBP cuff, Small Adult, 18 to 26cm, quick connect, box of 10	0683-14-0002-01
Disposable NIBP cuff, Adult, 25 to 35 cm, quick connect, box of 10	0683-14-0003-01
Disposable NIBP cuff, Large Adult, 33 to 47cm, quick connect, box of 10	0683-14-0004-01
Disposable NIBP cuff, Thigh, 46 to 66cm, quick connect, box of 5	0683-14-0005-01
Disposable NIBP Cuff, Adult Long, 25 – 35 cm, quick connect, box of 10	0683-14-0006-01
Disposable NIBP Cuff, Large Adult Long, 33 - 47 cm, quick connect, box of 10	0683-14-0007-01

4.2.2 SpO_2 Accessories

Masimo SET® Sensors

DESCRIPTION	PATIENT SIZE	PART NUMBERS
LNOP® Adt Adult Single Patient Adhesive Sensor (Box of 20)	> 30 kg	0600-00-0043-01
LNOP® Pdt Pediatric Single Patient Adhesive Sensor (Box of 20)	10 to 50 kg	0600-00-0044-01
LNOP® DCI Adult Reusable Finger Sensor	> 30 kg	0600-00-0047

Masimo SET® Cables and Accessories

DESCRIPTION	PART NUMBER
SpO_2 cable, PC08, 8′ (2.4 m)	0012-00-1099-01
SpO_2 cable, PC12, 12′ (3.7 m)	0012-00-1099-02
Clothing Clips (pkg of 5)	0600-00-0084

Nellcor® OxiMax® Cables and Accessories*

DESCRIPTION	PART NUMBER
Durasensor DS100A Adult Reusable Sensor	0600-00-0051
DOC-10 OxiMax® SpO_2 Cable	0012-00-1464

** Sensors must be reordered through Nellcor.*

4.2.3 Miscellaneous Accessories

DESCRIPTIONS	PART NUMBER
Battery, Lithium Ion	0146-00-0079
AC Power Cord, (110 Volt)	0012-25-0001
AC Power Cord, (220 Volt)	0012-25-0002
AC Power Cord, UK, (240 Volt)	0012-25-0003
Duo Rolling Stand Kit	DUOROLLSTD
Duo Mounting Bracket for rolling stand	0406-00-0857-01

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5.0 *Appendix*

5.1 Specifications

The **Duo** monitor complies with the following standards:

5.1.1 Safety Standards

IEC 60601-1:1988 (+ A1:1991, A2:1995)/ EN 60601-1:1990 (+ A1:1993, A2:1995, A13:1995)	Medical Electrical Equipment - Part 1: General Requirements For Safety
UL 60601-1:2003	Medical Electrical Equipment - Part 1 General Requirements for Safety
CSA Standard C22.2 No. 601.1M90	Medical electrical Equipment - General Requirements for Safety
IEC 60601-1-2:2001/ EN 60601-1-2:2001	Medical Electrical Equipment - Part 1-2: General Requirements for Safety: EMC Requirements and Tests
IEC 60601-1-4:1996/ EN60601-1-4:1996 (+A1:1999)	Collateral Standard: Programmable Electrical Medical Systems
IEC 60601-2-49:2001	Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment

5.1.2 Safety Designations

Type of protection against electric shock	Class 1 with internal electric power source. Where the integrity of the external protective earth (ground) in the installation or its conductors is in doubt, the equipment is operated from its internal electric power source (batteries).
Degree of protection against electric shock:	- NIBP - Type BF defibrillation protected - SpO_2 - Type BF - Monitor - Type B equipment
Supply Connection:	100 – 240 VAC (+/-10%) 50/60 Hz (+/-3 Hz) 0.7 – 0.4 Amps 7.2 VDC Internal Battery
Mode of Operation:	Continuous
Protection Against Hazards of Explosion:	Not protected (Ordinary)
Protection Against Ingress of Liquid's:	Not protected (Ordinary) - IPX0 per IEC 60529
Degree of electrical connection between equipment and patient:	Equipment designed for non-electrical connection to the patient
Degree of Mobility:	Transportable

5.1.3 Hazard Analysis (Risk Management)

EN ISO14971:2000	Medical Devices-Application of risk management analysis to medical devices

5.1.4 Performance/Accuracy

EN 865:1997	Pulse Oximeters - Particular Requirements
EN 1060-1:1995	Specification for Non-invasive Sphygmomanometers
EN 1060-3:1997	Non-invasive Sphygmomanometers, Supplementary Requirements for Electromechanical Blood Pressure Measuring Systems

ISO 3744:1994	Acoustics - Determination of Sound Power Levels of Noise Sources Using Sound Pressure
ANSI/AAMI/ISO 10993-10:1995	Biological evaluation of medical devices-Part 10: Tests for irritation and sensitization
ANSI/AAMI/ISO 10993-5	Biological evaluation of medical devices-Part 5: Cytotoxicity
ANSI/AAMI/ISO 10993-1:1997	Biological evaluation of medical devices-Part 1: Evaluation and testing
ANSI/AAMI SP-10:1992	Electronic or Automated Sphygmomanometers
EN 1041:1998	Information Supplied by the Manufacturer with Medical Systems
EN 980:1996 + A1:1999 + A2:2001	Graphical Symbols for Use in Labeling of Medical Devices
IEC 878:1998	Graphical Symbols for Electrical Equipment in Medical Practice
ISO 1000:1992 + A1:1998	SI units and recommendations for the use of their multiples and of certain other units

5.1.5 United States Food and Drug Administration Documents

Reviewer Guidance for Pre-market Notification Submission, November 1993 - draft Guidance

Non-Invasive Blood Pressure (NIBP) Monitor Guidance, March 10, 1997

Non-Invasive Pulse Oximeter General Guidance, draft, September 7, 1992

5.2 Patient Parameter Specifications

5.2.1 NIBP Sub-System Performance Characteristics

The NIBP function is capable of providing non-invasive systolic, diastolic and mean blood pressure measurements in Pediatric and Adult modes using a blood pressure cuff.

The NIBP function is in accordance with the requirements of EN 1060-1, EN 1060-3 and ANSI/AAMI SP-10:1992.

5.2.2 Systolic Pressure Measurement

Accuracy*: Mean error is less than +/-5 mmHg Standard Deviation is less than +/-8 mmHg

Range:

ADULT MODE	PEDIATRIC MODE
40 to 255 mmHg	40 to 200 mmHg

5.2.3 Diastolic Pressure Measurement

Accuracy*: Mean error is less than ±5 mmHg, Standard deviation is less than ±8 mmHg

Range:

ADULT MODE	PEDIATRIC MODE
10 to 210 mmHg	10 to 150 mmHg

* Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by ANSI/AAMI SP-10:1992, *Electronic or automated sphygmomanometers*.

NOTE: **Mean Arterial Pressure (MAP) is defined as:**
Mean Pressure 1 = Mean Pressure determined from the oscillometric profile
Mean Pressure 2 = (2*diastolic + systolic) / 3
Mean Pressure Displayed = (Mean Pressure 1 + Mean Pressure 2) / 2

5.2.4 Static Pressure Measurement

Range: 0 – 325 mmHg

Static Accuracy: ±3 mmHg over the entire range.

5.2.5 Pulse Rate from NIBP

Accuracy: ± 1 bpm

Resolution: 1 bpm

Range:

ADULT MODE	PEDIATRIC MODE
40 to 240 bpm	40 to 240 bpm

5.2.6 NIBP Sub-System Functional Requirements

5.2.6.1 Maximum Cuff Pressure

The software-controlled over-pressure monitor vents to atmosphere at the following pressures:

ADULT MODE	PEDIATRIC MODE
297 ±3 mmHg	243 ±3 mmHg

Under single-fault conditions, the hardware controlled over pressure mechanism vents the cuff to atmosphere so that the pressure in the cuff does not exceed the following:

ADULT MODE	PEDIATRIC MODE
300 (+10%) mmHg	300 (+10%) mmHg

5.2.6.2 Cuff Inflation

The inflation source is capable of supplying sufficient air to bring a volume of 500 cc to a pressure of 300 mmHg in no more than 20 seconds.

If the cuff is not inflated 5 mmHg within 18 seconds, the cuff is vented and the measurement is stopped.

5.2.6.3 Maximum Leakage

The maximum allowed pressure drop with the bleed valves closed is 6 mmHg in 60 seconds as measured with a 500 cc volume at differential pressures of 250 mmHg, 150 mmHg and 50 mmHg.

5.2.6.4 Vent Rate

A volume of 500 cc, when vented, is reduced from a pressure of 260 mmHg to a pressure of 15 mmHg in a maximum of 10 seconds.

5.2.6.5 Initial Conditions

An NIBP Zero is performed automatically before the NIBP can be initiated.

An NIBP measurement will not initiate until the unit has been powered on for 5 seconds, in order to allow time for the Zero.

5.2.6.6 NIBP Start Pressure Settings and Ranges

The Start Pressure is adjustable and is set to the following defaults:

PATIENT SIZE	PRESSURE INCREMENT (DEPENDING ON ALGORITHM)	DEFAULT START PRESSURE
Adult Mode	30 – 60 mmHg	178 ±5 mmHg
Pediatric Mode	30 – 60 mmHg	133 ±5 mmHg

5.2.6.7 NIBP Measurement Cycle

There is one mode of measurement operation: manual. The manual mode requires the operator to initiate the measurement cycle.

In the manual mode, the unit adjusts the inflation pressure according to the previous systolic pressure. After the first successful measurement is made, the subsequent inflation pressure becomes +50 ±10 mmHg above the previous systolic pressure measurement.

5.2.7 SpO_2 Performance Requirements

The **Duo** monitor is capable of providing SpO_2 functional saturation level measurements via an OEM Masimo MS-7 pulse oximeter, or an OEM Nellcor MP-506 pulse oximeter.

5.2.7.1 SpO_2 Agency Requirements

The SpO_2 function performs in accordance with the requirements of EN 865: 1997.

5.2.7.2 Masimo SpO_2 Performance Requirements

The Masimo MS-7 pulse-oximeter with SET technology is implemented.

SPO_2

Sensor Compatibility: Compatible with LNOP Series sensors.

Display Range: 1 – 100%

Resolution: 1%

Accuracy:

No motion conditions[1]

PATIENT SIZE	SATURATION RANGE	
	70% to 100%	**0 – 69%**
Adult Mode	±2 digits	unspecified
Pediatric Mode	±2 digits	unspecified

During motion conditions[2]

PATIENT SIZE	SATURATION RANGE	
	70% to 100%	**0 – 69%**
Adult Mode	±3 digits	unspecified
Pediatric Mode	±3 digits	unspecified

Response Time: 20 seconds to 95% of final step change of % SpO_2 value from 60 to 95% at 75 bpm. Post averaging time is set at 8 seconds.

Low Perfusion Performance[3]

LOW PERFUSION CONDITIONS			
PULSE AMPLITUDE	**% TRANSMISSION**	**SATURATION ACCURACY**	**PULSE RATE ACCURACY**
> 0.02%	> 5%	±2 digits	±3 digits

Pulse Rate

Resolution: 1 bpm

Update Rate: 1 Hz.

Range and Accuracy

PATIENT SIZE	PULSE RATE RANGE	ACCURACY	
		NO MOTION CONDITIONS[1]	**DURING MOTION CONDITIONS[2]**
Adult/Pediatric	25 – 240 bpm	±3 digits	±5 digits

Masimo® Reference Footnotes

[1]The Masimo MS-7 pulse oximeter with LNOP- Adt sensors have been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70% to 100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2]The Masimo MS-7 pulse oximeter with LNOP- Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz. At an amplitude of 1 to 2 cm and non-repetitive motion between 1 to 5 Hz. At an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70% to 100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[3]The Masimo MS-7 pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater then 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

NOTE: The sensor measurement wavelengths are nominally 660 nm for the red LED and 940 nm for the infrared LED. Maximum optical power output for LED is 4 mW.

5.2.7.3 Nellcor SpO_2 Performance Requirements

SpO_2

Sensor Compatibility: OxiMax series MAX-A, MAX-AL, MAX-P, MAX-FAST, MAX-R, OxiCliq A, OxiCliq P, D-YS, D-YSE, D-YSPD, DS-100A, OXI-A/N and OXI-P/I.

Display Range: 1 – 100%

Resolution: 1%

Saturation Accuracy:

SENSOR	ACCURACY
MAX-A, MAX-AL, MAX-P, MAX-I and MAX-FAST	70% to 100% ±2 digits Below 70% unspecified
OxiCliq A, OxiCliq P and OxiCliq I	70% to 100% ±2.5 digits Below 70% unspecified
D-YS, DS-100A, OXI-A/N and OXI-P/I	70% to 100% ±3 digits Below 70% unspecified
MAX-R, D-YSE and D-YSPD	70% to 100% ±3.5 digits Below 70% unspecified

Pulse Rate

Resolution: 1 bpm

Update Rate: 1 Hz.

Range and Accuracy

RANGE	ACCURACY
20 to 250 bpm	±3 bpm
251 to 300 bpm	Unspecified

NOTE: The sensor measurement wavelengths are nominally 660 nm for the red LED and 890 nm for the infrared LED. Maximum optical power output for LED is 4 mW.

5.2.8 Power Supply

5.2.8.1 Power Source

The **Duo** monitor auto-selects its power source from those available. The monitor uses the following priority in choosing the power source:

1. AC Mains Power
2. Internal battery power

The monitor operates from AC Mains power with or without the internal batteries installed.

5.2.9 AC Mains Power Source

Input Voltage:	100 – 240 VAC (+/-10%)
Line Frequency:	50/60 Hz (+/-3 Hz)
Current:	0.7 – 0.4 Amps

5.2.10 Battery Power

Time to Shutdown from Low Battery:	>10 minutes but < 20 minutes after indication, with 1 new, fully charged battery.

5.2.10.1 Lithium Ion Battery: P/N 0146-00-0079

The battery pack is 7.2 VDC, 6.6 Amp-hr.

The minimum Battery Run Time:	14.0 hours from one fully charged new battery at 25 °C with continuous SpO_2 measurement and NIBP measurements taken at 7 minute intervals.
	17.0 hours with NIBP only and measurements taken at 7 minute intervals.
	17.5 hours with continuous SpO_2 measurement and no NIBP measurements being taken.
The Battery Charge Time:	4.5 hours maximum.

5.2.11 Physical Characteristics

5.2.11.1 Maximum Size

130 mm maximum width

243 mm maximum height

140 mm maximum depth

5.2.11.2 Maximum Weight

1770 grams (3.9 pounds) maximum, without optional accessories

2088 grams (4.6 pounds) maximum, with 1 Lithium-ion battery, without optional accessories

5.2.12 Cooling Fan

The cooling fan operates when the **Duo** is running on AC power only and the internal temperature exceeds a pre-determined value. The fan does not operate when the **Duo** is running on battery power.

5.2.13 Environmental and Safety Characteristics

Storage Temperature:	-20 °C to +60 °C
Operating Temperature:	+5 °C to +40 °C
Storage Humidity:	10% to 95%, non-condensing
Operating Humidity:	15% to 95%, non-condensing
Storage Altitude:	(-1000 to 20,000 feet ASL) 1050 hPa to 466 hPa (788 mmHg to 349 mmHg)
Operating Altitude:	(-1000 to 9,889 feet ASL) 1050 hPa to 700 hPa (788 mmHg to 525 mmHg)
Shipping:	The monitor meets the requirements of ISTA shipping procedure 1A for containerized product, when packed in designated packaging.
Shock:	The monitor remains operational within specification after exposure to 15 g, 11 msec, half sine, shock pulse tested per IEC 60068-2-27.
Vibration:	The monitor remains operational within specification after exposure to the following Sinusoidal and Random Vibration (Reference FDA Reviewer Guidance for Pre-market Notification Submission, November 1993 - draft):

Sinusoidal Vibration:	Per IEC 60068-2-6 1 g or 0.07 mm, 57 – 62 Hz crossover frequency 10 to 500 Hz, 10 sweep cycles in each axis
Random Vibration:	Per IEC 60068-2-34 0.02 g2/Hz 20 – 500 Hz Low degree of reproducibility 9 minutes per axis
Drop:	The monitor meets the requirements specified by ECRI PB-296 892 section AIII 3.3 for Class 3 devices.
Impact:	The monitor meet the requirements specified by ECRI PB-296892, section AIII 3.2 for Class 3 devices.

Electromagnetic Compatibility

- The **Duo** meets the requirements of IEC 60601-1-2:2001/EN 60601-1-2:2001.

NOTE: The Duo needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

NOTE: Portable and mobile RF communications equipment can affect the Duo. See TABLE 5-1 through TABLE 5-4.

TABLE 5-1

GUIDANCE AND DECLARATION - ELECTROMAGNETIC EMISSIONS

The **Duo** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Duo** should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The **Duo** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The **Duo** is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

TABLE 5-2

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Duo** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Duo** should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

TABLE 5-2

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Duo** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Duo** should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% UT (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% UT (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Duo** requires continued operation during power mains interruptions, it is recommended that the **Duo** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T *is the A.C. mains voltage prior to application of the test level.*

TABLE 5-3

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Duo** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Duo** should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
			Portable and mobile RF communications equipment should be used no closer to any part of the **Duo**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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

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

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 5-4

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DUO

The **Duo** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **Duo** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **Duo** as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W (WATTS)	**SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER M (METERS)**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	D = 1.2 x $\sqrt{P}$	D = 1.2 x $\sqrt{P}$	D = 2.3 x $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

NOTE: The Duo is intended for use in the electromagnetic environment specified below. The customer or the user of the Duo should assure that it is used in such an environment.

- The **Duo** meets the additional electromagnetic compatibility requirements of the FDA Reviewer Guidance for Pre-market Notification Submission, November 1993 listed below:

AC Voltage Dropout: < 10 ms

NOTE: Mains power quality should be that of a typical commercial or hospital environment. If the user of the Duo requires continued operation during power mains interruptions, it is recommended that the Duo be powered from an uninterruptible power supply or a battery.

AC Slow Sags and Surge: 90 V to 150 V for 500 ms

AC Steady State Voltage: 95 – 132 V, AC/battery switching below 95 V

Quasi-static Fields: 500 – 2000 V/m sweep at 0.5 Hz sine

Magnetic Emissions: MIL-STD-461D, RE101, 30 Hz to 100 kHz @ 7 cm

5.3 Warranty Statements

Mindray DS USA, Inc. warrants that components within the monitor unit will be free from defects in workmanship and materials for the number of years shown on the invoice. Under this extended warranty, Mindray DS USA, Inc. will repair or replace any defective component at no charge for labor and/or materials. This extended warranty does not cover consumable items such as, but not limited to batteries, displays, external cables and sensors.

Recommended preventative maintenance, as prescribed in the Service Manual, is the responsibility of the user, and is not covered by this warranty.

Except as otherwise provided herein, the terms, conditions and limitations of Mindray DS USA, Inc.'s standard warranty will remain in effect.

USA, Canada, Mexico, and Puerto Rico

Mindray DS USA, Inc. warrants that its products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase except that disposable or one-time use products are warranted to be free from defects in workmanship and materials up to a date one year from the date of purchase or the date of first use, whichever is sooner. This warranty does not cover consumable items such as, but not limited to, batteries, external cables, sensors, cuffs, hoses, or mounts.

Mindray DS USA, Inc. will not be liable for any incidental, special, or consequential loss, damage, or expense directly or indirectly arising from the use of its products. Liability under this warranty and the buyer's exclusive remedy under this warranty is limited to servicing or replacing at Mindray DS USA, Inc.'s option at the factory or at an authorized Distributor, any product which will under normal use and service appear to the Company to have been defective in material or workmanship.

No agent, employee, or representative of Mindray DS USA, Inc. has any authority to bind Mindray DS USA, Inc. to any affirmation, representation, or warranty concerning its products, and any affirmation, representation or warranty made by any agent, employee, or representative will not be enforceable by buyer.

This warranty is expressly in lieu of any other express or implied warranties, including any implied warranty or merchantability or fitness, and of any other obligation on the part of the seller.

Damage to any product or parts through misuse, neglect, accident, or by affixing any non-standard accessory attachments or by any customer modification voids this warranty. Mindray DS USA, Inc. makes no warranty whatever in regard to trade accessories, such being subject to the warranty of their respective manufacturers.

A condition of this warranty is that this equipment or any accessories which are claimed to be defective be returned when authorized by Mindray DS USA, Inc., freight prepaid to Mindray DS USA, Inc., Mahwah, New Jersey 07430. Mindray DS USA, Inc. will not have any responsibility in the event of loss or damage in transit.

Calibration may be performed without the need to disassemble the instrument. It is the responsibility of the purchaser to perform calibration as necessary, in accordance with the instructions provided in this manual.

5.4 Manufacturer's Responsibility

Mindray DS USA, Inc. is responsible for the effects on safety, reliability and performance of the equipment only if:

a. assembly operations, extensions, readjustments, modifications or repairs are performed by persons authorized by Mindray DS USA, Inc.; and

b. the electrical installation of the relevant room complies with the appropriate requirements; and

c. the equipment is used in accordance with the instructions for use.

Service Manual

Datascope
Duo™

mindray™
NORTH AMERICA

Duo™ is a U.S. trademark of Mindray DS USA, Inc.

Navigator™ is a U.S. trademark of Mindray DS USA, Inc.

Masimo SET®, LNOP® and CleanShield® are U.S. registered trademarks of Masimo Corp.

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Foreword

This service manual gives a detailed description of the **Duo** Portable Patient Monitor, including circuit descriptions, test and calibration procedures, and spare parts listings. This manual is intended as a guide for technically qualified personnel during repair, testing, or calibration procedures.

Warnings, Precautions And Notes

Please read and adhere to all warnings, precautions, and notes listed here and in the appropriate areas throughout this manual.

A **WARNING** is provided to alert the user to potential serious outcomes (death, injury, or serious adverse events) to the patient or the user.

A **CAUTION** is provided to alert the user to use special care necessary for the safe and effective use of the device. They may include actions to be taken to avoid effects on patients or users that may not be potentially life threatening or result in serious injury, but about which the user should be aware. Cautions are also provided to alert the user to adverse effects on this device of use or misuse and the care necessary to avoid such effects.

A **NOTE** is provided when additional general information is applicable.

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1.0 *Theory of Operation*

1.1 Introduction

The **Duo** is a compact, lightweight, portable patient monitor intended for monitoring the following vital signs: blood pressure, SpO_2 (optional), and pulse rate on adult and pediatric patients. The **Duo** monitor can be powered by either the internal rechargeable Lithium-Ion battery or external 100~240 volt 50/60 Hz AC.

1.2 Hardware Overview

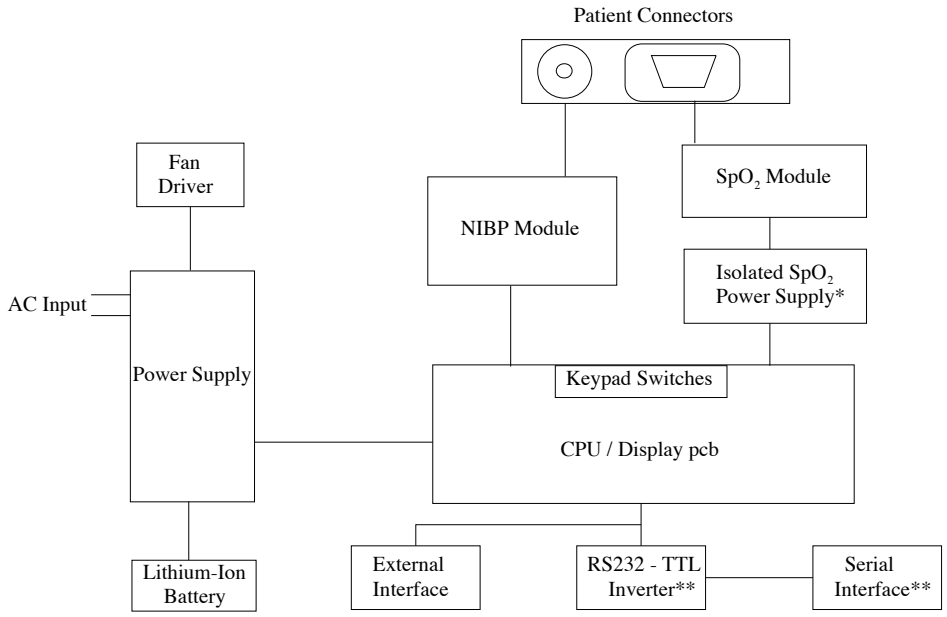

FIGURE 1-1 Interconnection Block diagram

* *The Isolated SpO_2 Power Supply is present with optional Masimo and Nellcor SpO_2 ONLY.*
** *The RS232 - TTL Inverter and Serial Interface Connector is used for software updates by Service*

1.2.1 Power Supply Board

Overview

The AC/DC converter transforms the AC input voltage (90 - 264 vac 50/60 Hz) to a DC voltage used to charge the internal Lithium-Ion battery and supply power to the +12 vdc and +3.3 vdc DC/DC converters. The battery charging circuit will actively charge the battery while the **Duo** is connected to an AC source. Battery charging takes place whether the monitor is on, off, or in use. The power supply will automatically switch to the internal battery if an AC source is not present.

NOTE: **The power supply board MUST be connected to a resistive load to operate properly and to avoid damage due to an over current condition.**

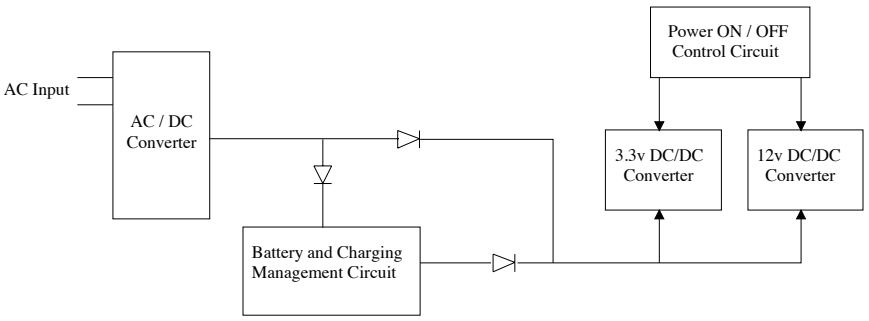

FIGURE 1-2 Power Supply Block Diagram

Power Supply Voltage Test Points:

Location	**Function**
Measure across C5	Primary Rectified Voltage (DC). Range: 105 - 374 volts.
C5 Negative Lead	Primary Ground.
Measure across Q1 pin1 and C5 Negative Lead	110k Hz Drive frequency.
Measure across C12	+10.5 vdc input for Fan Driver board.
C12 Negative Lead	Secondary Ground.
C47 Positive Lead	+5 vdc supply for Power On/Off Control.
C50 Positive Lead	+3.3 vdc output.
C68 Positive Lead	+12 vdc output.

1.2.2 Fan Driver Board Overview

The Fan Drive Board is active during the battery charging cycle. The Temperature Detector senses the temperature of the heat sink of the Secondary Rectifier diode and turns on the fan when the heat sink reaches a certain temperature.

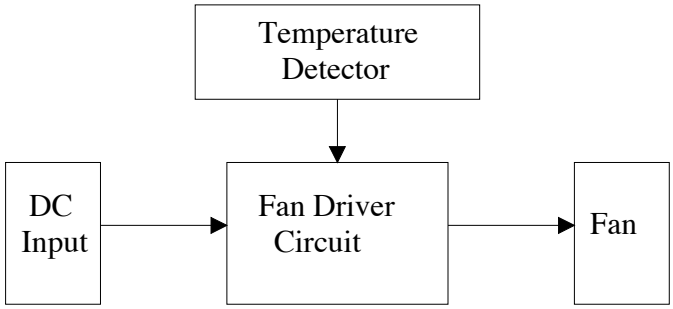

FIGURE 1-3 Fan Driver Block Diagram

Fan Driver Board Test Points

Location	Function
Measure across C202	+5 vdc Fan power.
C202 Negative Lead	Ground.
Measure between Q202 pin1 and Ground	Drive frequency when the Fan is activated.

1.2.3 CPU/Display Board Overview

The CPU/Display board controls the SpO_2 Module and NIBP Module through communications via UART devices. The CPU Board receives user commands from the Keypad. The power supply board provides +3.3 vdc and +12 vdc to the CPU board. These voltages are monitored by an A/D converter located on the CPU board. The CPU also controls an integral LED display array and indicator LEDs. The main processor has a built-in serial port that is used to load software. The processor also uses a FPGA to communicate with the NIBP Module, the optional SpO_2 module (SpO_2 presence is detected via a jumper on JP1) and to drive the LED arrays and indicators.

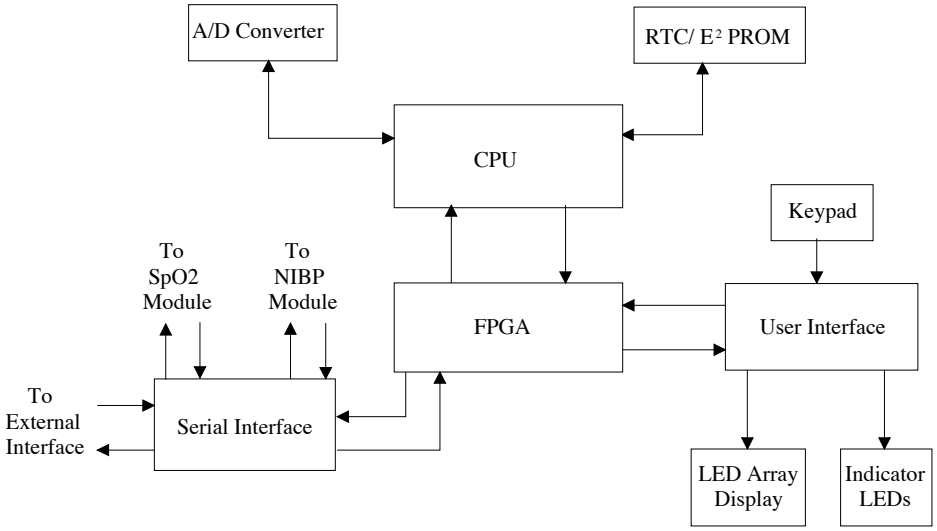

FIGURE 1-4 CPU/Display Board Block Diagram

CPU Board Test Points

Location	Function
VPP in	+12 vdc power supply
VDD in	+3.3 vdc power supply
BV	Battery voltage
5B in	+5 vdc power supply
ADV	+10.5 vdc ADV out
RST	CPU reset line
XT2	11.0592 MHz clock

1.2.4 NIBP Module Overview

The **Duo** monitor determines non-invasive blood pressure using the oscillometric method. The blood pressure cuff is inflated until the pressure in the cuff is sufficient to block blood flow in the brachial artery. As the cuff begins to deflate, blood beginning to flow through the artery will cause the artery to pulsate. These pulsations are transmitted through the blood pressure cuff and connecting hose to the pressure transducer in the NIBP module. The output of the pressure transducer is an analog pulsating signal. This signal is filtered by a high-pass filter and then amplified. The amplified analog signal is then converted to a digital signal. The digital signal is then processed to determine the systolic, diastolic, and mean pressures as well as heart rate.

1.2.5 SpO_2 Overview

Pulse oximetry (SpO_2) measurement is used to determine the oxygen saturation level of the patient's blood. The SpO_2 numeric display indicates the amount of hemoglobin that has bonded with oxygen molecules to form oxyhemoglobin. By analyzing the pulse in the fingertip using specified algorithm and consulting the clinical data table, we can obtain the SpO_2 value. The SpO_2 sensor consists of two LEDs (one red and one infrared) and a photodetector. The two LEDs are alternately lighted at a precise frequency. When the capillary vessels of the fingertip are filled, a certain amount of light from the LEDs is absorbed by blood in the capillaries. The remaining red and infrared light is then picked up by the photodetector. The photodetector detects the varying light intensity due to pulsations and transmits the changing light intensity in the form of changing electronic signals. The amount of light absorption is then compared to the known fixed LED output by the SpO_2 board. The pulse rate is counted and the SpO_2 value is determined by using an algorithm contained in the software on the SpO_2 board.

2.0 *Calibration and Performance Verification*

2.1 Introduction

The following procedures are provided to verify the proper operation of the **Duo** monitor. A menu driven interface is used to execute all verification tests. Performance tests should be performed at least once per year and after any preventive maintenance or repair has been performed.

2.2 Warnings and Guidelines

In the event that the instrument cover is removed, observe the following warnings and guidelines:

1. Do not short component leads together.
2. Perform all steps in the exact order they are given.
3. Use extreme care when reaching inside the opened instrument. Do not contact exposed metal parts that may become ''live''.
4. Read through each step in the procedure so it is understood prior to performing the step.

2.3 Test Equipment and Special Tools Required

- 0-300 mmHg Digital or Mercury manometer with bulb and valve
- 500 cc Test Chamber/Dummy Cuff. P/N 0138-00-0001-03
- DVM
- SpO_2 simulator
- NIBP simulator
- Safety Analyzer (Dempsey model 431 or equivalent)
- Oscilloscope
- Laptop or PC (software upgrade)

2.4 Calibration and System Checks

2.4.1 Device Appearance and Installation Checks

Inspect the **Duo** monitor to ensure that:

- The outer housing is clean and has no scratches or cracks
- When the device is gently shaken, there are no loose components
- All keys are smooth and free for operation
- Labels are complete, clean, and accurate
- All connectors/accessory modules are installed securely
  Ensure monitor is securely fastened to its rolling stand (if used)

2.4.2 Maintenance Functions/Non-Monitoring Modes

- When entering the maintenance functions/non-monitoring mode, the monitor will perform a self-test, however the verification of functional LEDs will not be displayed
- In the maintenance mode, the standby mode will not be active
- In the maintenance mode, the auto-shutoff will activate if no key is pressed for a period of 15 minutes.

2.4.3 Unit of Measure Mode

The unit of measure mode is used to change between mmHg and kPa. To access the Unit of Measure mode:

1. Turn the monitor off.
2. Simultaneously press and hold the **POWER** and **CLEAR** buttons.
3. Press the **CLEAR** button to cycle through the unit of measure choices.
4. Once the desired unit of measure is displayed, turn the **Duo** off to save that setting.

2.4.4 Software Version Mode

Use the following procedure to view the software version.

1. Ensure that the **Duo** is powered OFF.
2. Press and hold the **Patient Size** key.
3. While continuing to hold the **Patient Size** key, press and hold the **Power ON/OFF** key for two (2) seconds until the **Duo** beeps.
4. Release both keys.
5. After an additional 2-second delay, **Duo** will display "100" in the Pulse Rate tile and a number in the Information Codes tile.
6. Pressing the **Clear** key will cause the number displayed in the Pulse Rate tile to cycle through a sequence of four numbers indicating which software version is being displayed in the Information Codes tile as shown in the following table.

PULSE RATE TILE	INFORMATION CODES TILE SHOWS
100	Host Software Revision Level
200	NIBP Software Revision Level
300	SpO2 Software Revision Level

7. To return to normal operation, press the **Power ON/OFF** key for two (2) seconds to turn the **Duo** off.
8. You may then turn the **Duo** back on to resume normal operation.

NOTE: **The Duo cannot be placed directly back into normal monitoring mode from Software Version Mode. It must first be powered OFF.**

2.5 Safety Test

2.5.1 Test Equipment

- Safety Analyzer (Dempsey model 431 or equivalent)

2.5.2 Case Leakage

1. Plug the line cord of the unit into the safety analyzer.
2. Connect the case ground lead of the analyzer to the equipotential lug of the **Duo** monitor.
3. Perform the leakage tests under the following conditions:
   a. Case grounded:
      Normal polarity
      Normal polarity with open neutral
      Reverse polarity
   b. Case ungrounded:

      Normal polarity
      Normal polarity with open neutral
      Reverse polarity
4. Verify the current reading is <100 uA under normal operating conditions; <300 uA under single fault conditions for 120 VAC and <500 uA under single fault conditions for 230 VAC.

2.6 NIBP Calibration

2.6.1 Test Equipment

- NIBP simulator
- NIBP test chamber/dummy cuff
- Manometer with bulb

2.6.2 Test Procedure

2.6.2.1 Transducer Accuracy

1. Connect the 500 cc Test Chamber and calibrated manometer via a ''T'' fitting to the NIBP fitting on the **Duo** monitor under test.
2. Ensure the **Duo** is not turned on. Simultaneously, press and hold the **POWER** and **NIBP START/STOP** buttons.

   When the monitor enters the NIBP Calibration Mode, message code 525 will be displayed in the Information Codes window. Release the buttons simultaneously.
3. Momentarily press the **NIBP START/STOP** button to start the NIBP calibration. Vent the Test Chamber and verify the **Duo** and the manometer read zero. Using the bulb, pressurize the test chamber to 50 mmHg and verify the **Duo** reading agrees with the manometer +/- 3 mmHg. Using the bulb, increase the pressure to 200 mmHg and verify the **Duo** reading agrees with the manometer +/- 3 mmHg.

2.6.2.2 Pneumatic Leak Test

1. Connect the 500 cc test chamber to the NIBP fitting on the **Duo** monitor under test.
2. From the NIBP Calibration Mode (code 525) momentarily press the **CLEAR** button on the **Duo** keypad. The **Duo** will then switch to the Pneumatic Test Mode and will display message code 550 in the Information Codes window.
3. Momentarily press the **NIBP START/STOP** button to start the leak test. The **Duo** under test will automatically pressurize the test chamber to approximately 180 mmHg.
4. After approximately 20 seconds, the **Duo** under test will vent the pressure in the test chamber and display a message code E06 (Pass) or E07 (Fail) in the systolic window.

2.6.2.3 Dynamic Repeatability Test

1. Restart unit and allow it to enter normal operating mode.
2. Use polyurethane tubing to connect the **Duo** monitor to a calibrated NIBP simulator and the 500 cc test chamber/dummy cuff via a ''T'' fitting.
3. Select Adult patient size for both the **Duo** under test and the NIBP simulator.
4. Select a target simulated blood pressure within the ''normal'' range on the simulator.
5. Take 10 successive NIBP readings and compare the systolic, diastolic, mean and heart rate readings for consistency. Readings should not deviate more than +/- 5 mmHg for the NIBP readings and +/- 2 bpm or 2%, whichever is greater for heart rate.

NOTE: **The actual measured values displayed on the Duo monitor may not compare with the selected target pressure on the simulator. This test is intended to confirm the REPEATABILITY, not accuracy, of dynamic NIBP readings. Accuracy can only be confirmed by performing the NIBP Calibration outlined in section 2.6 of this manual.**

2.7 SpO_2 Verification

2.7.1 Test Equipment

- SpO_2 simulator

2.7.2 Test Procedure

1. Connect the appropriate SpO_2 probe connector to the **Duo** monitor.
2. Connect the SpO_2 probe to the SpO_2 simulator.
3. Set the simulator target values to:

   SpO_2 = 98%
   Pulse Rate = 70
4. Verify that the displayed SpO_2 and pulse rate values on the **Duo** monitor are +/- 2% of the simulator target values.
5. Change the simulator values.
6. Verify the displayed values on the **Duo** monitor are equal to the simulator values +/- 2%.

3.0 *Parts*

3.1 Introduction

This section contains exploded views of the **Duo** monitor, internal modules, and parts list.

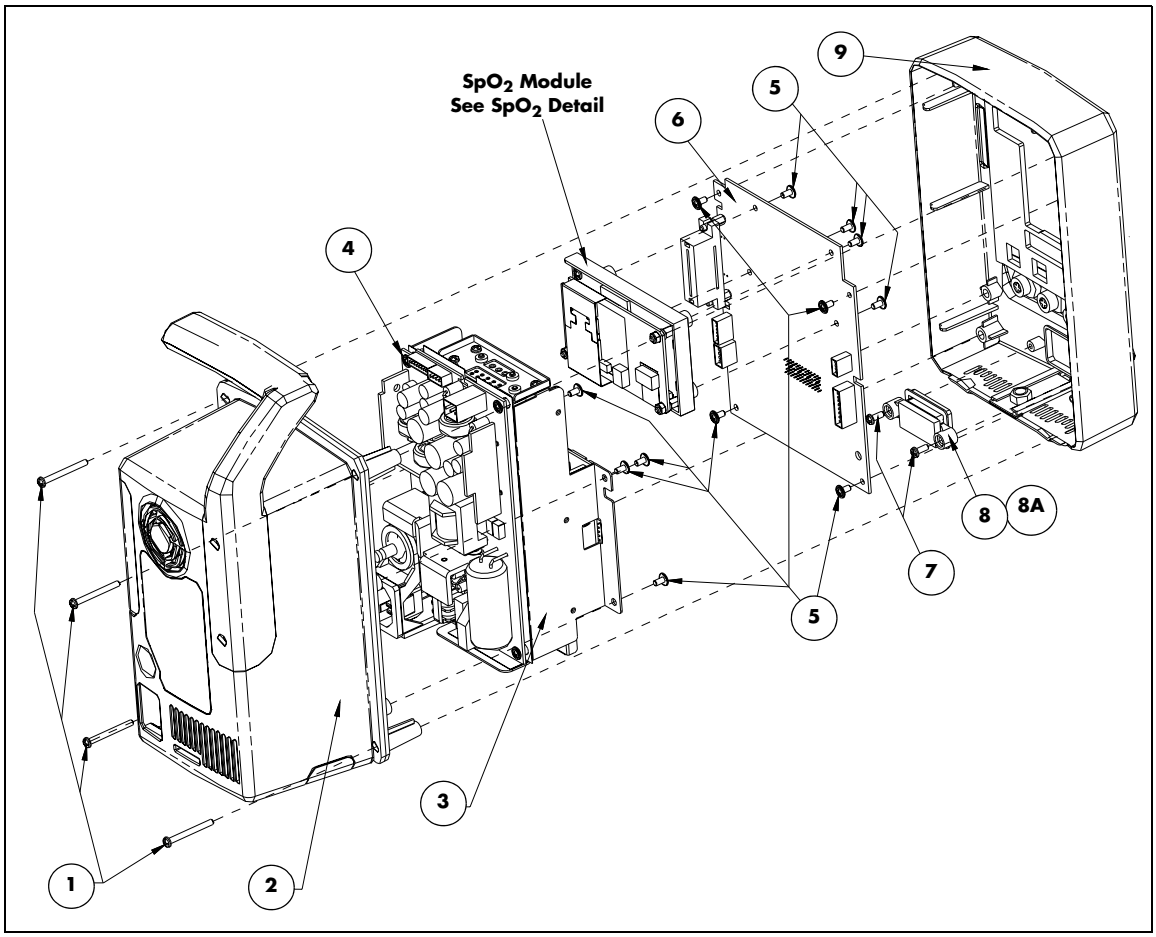

FIGURE 3-1 Duo Exploded View

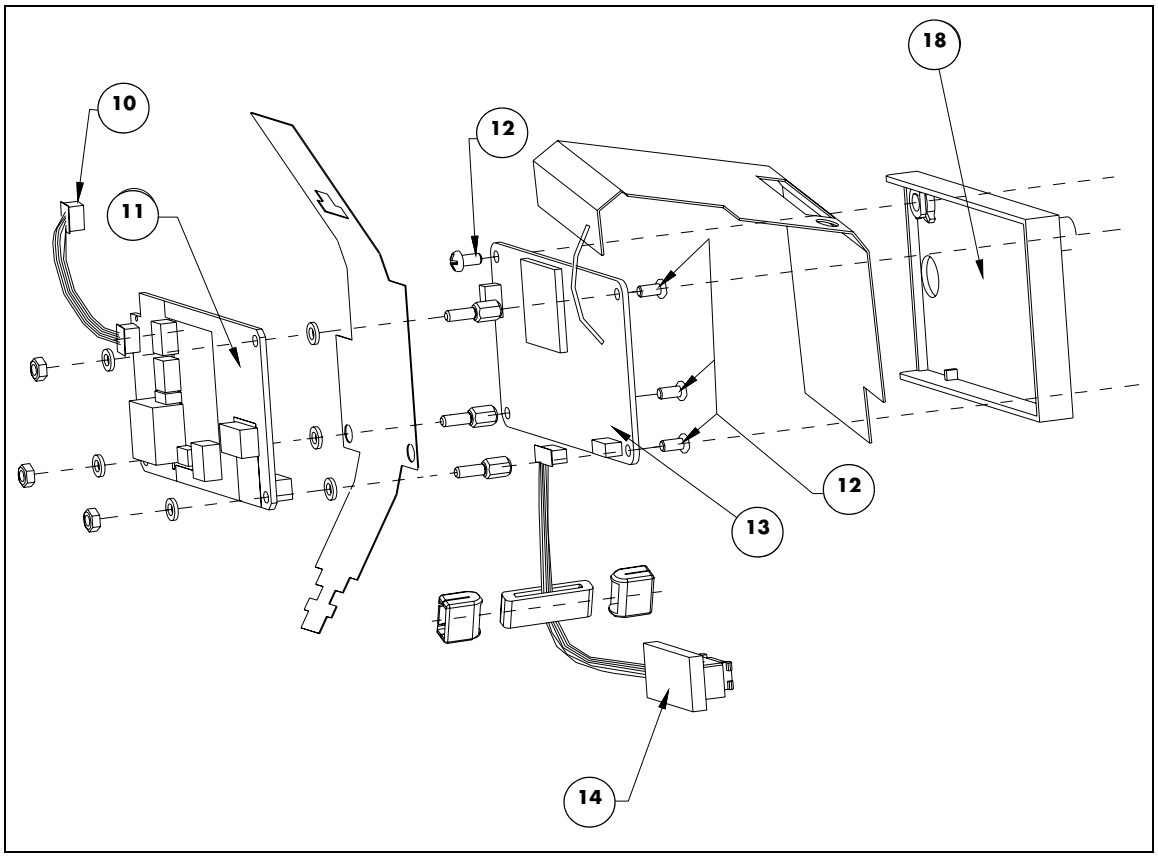

FIGURE 3-2 Masimo SpO_2 Detail

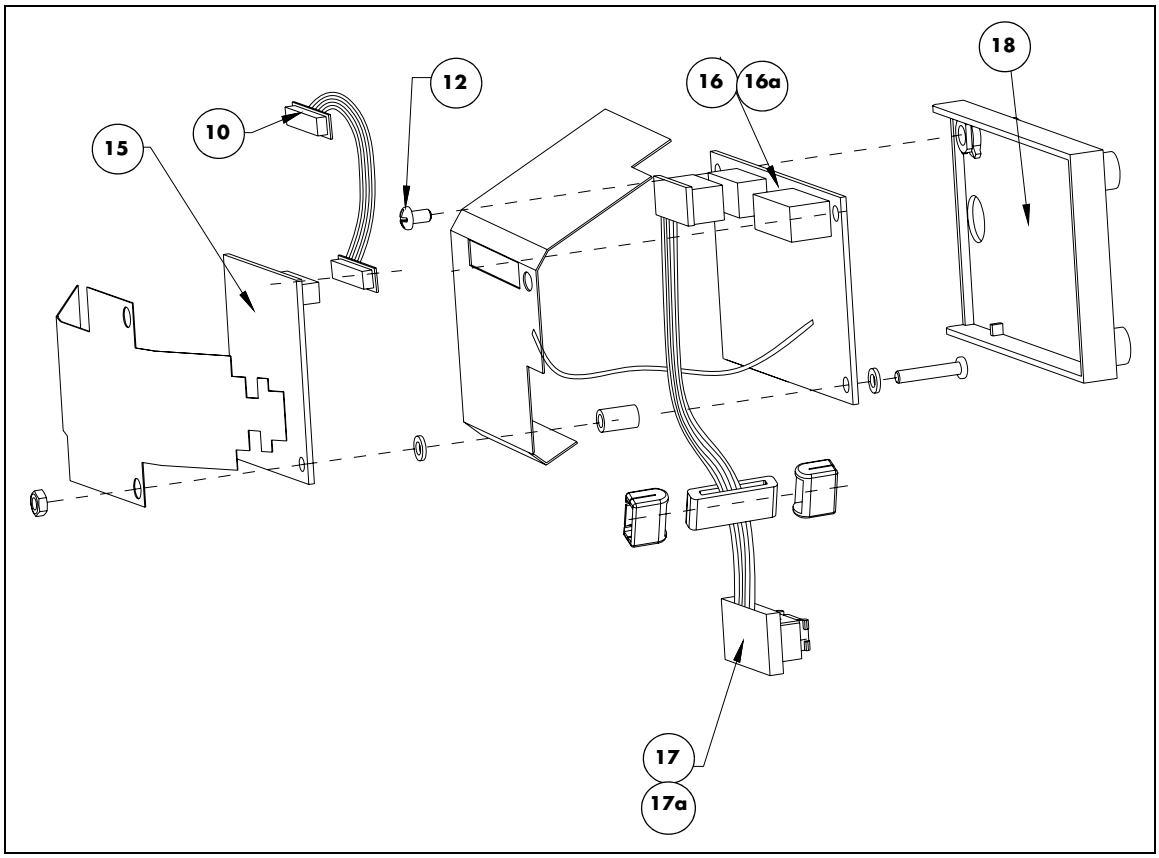

FIGURE 3-3 Nellcor SpO_2 Detail

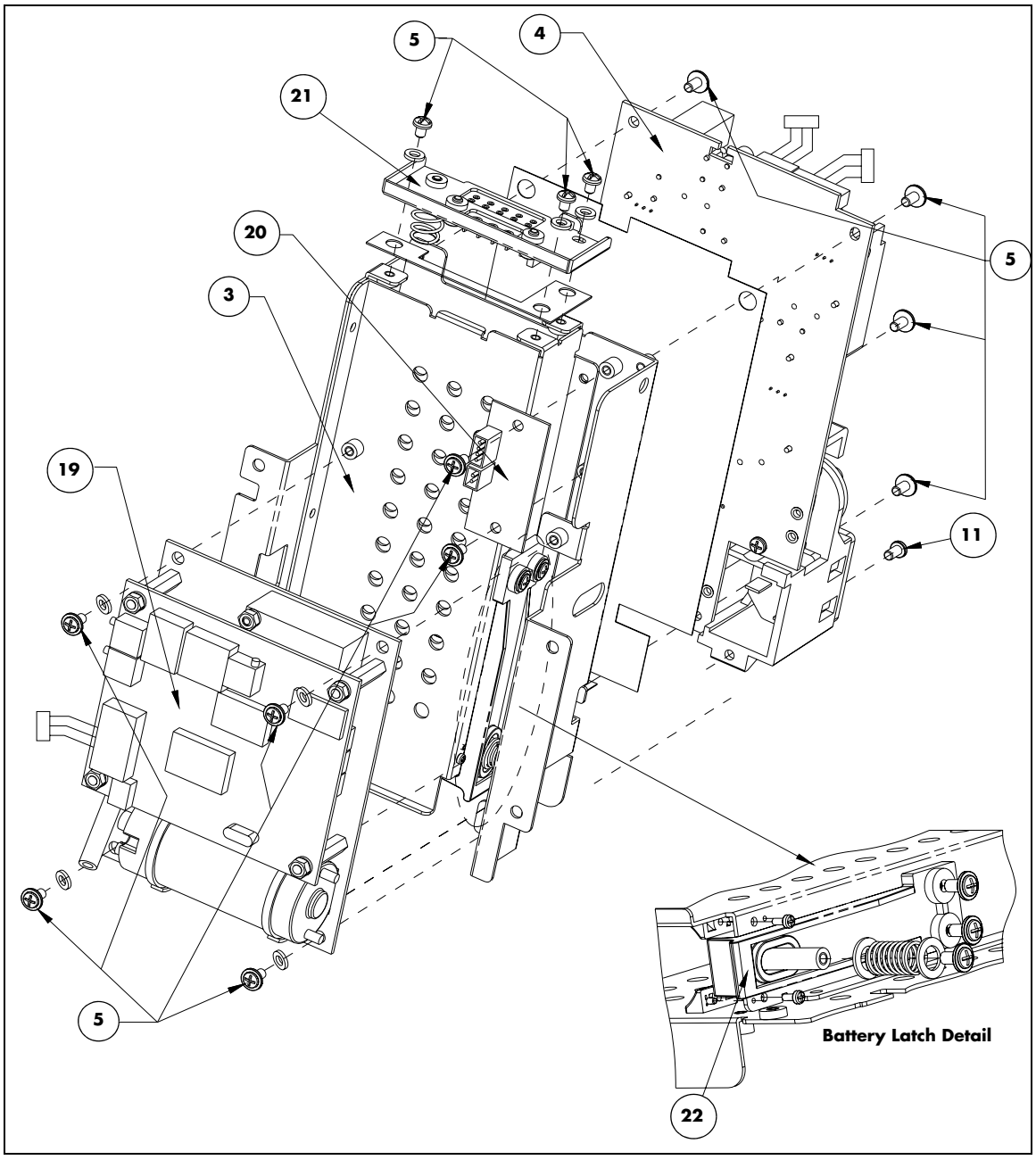

FIGURE 3-4 Main Frame

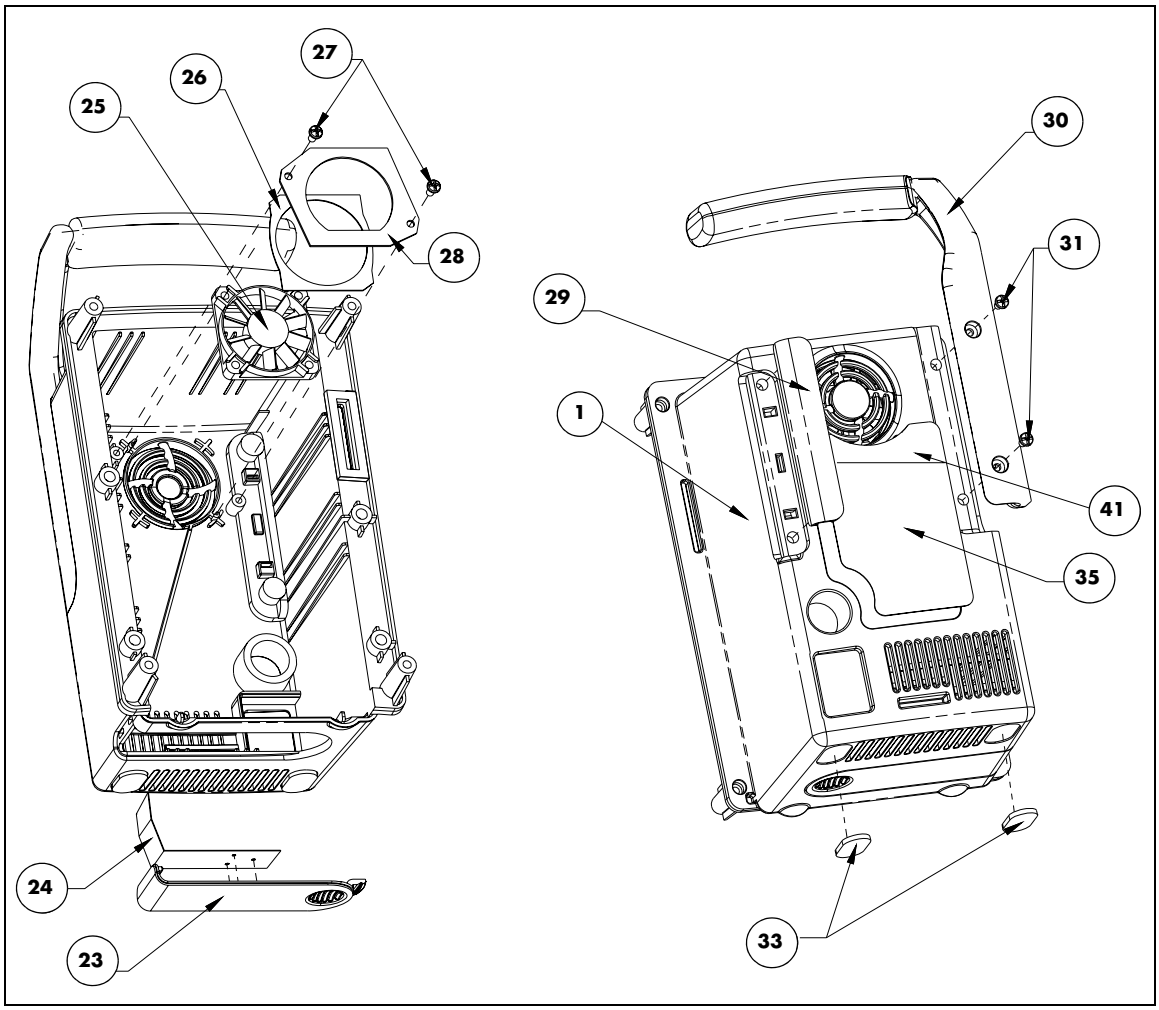

FIGURE 3-5 Rear Case Assembly

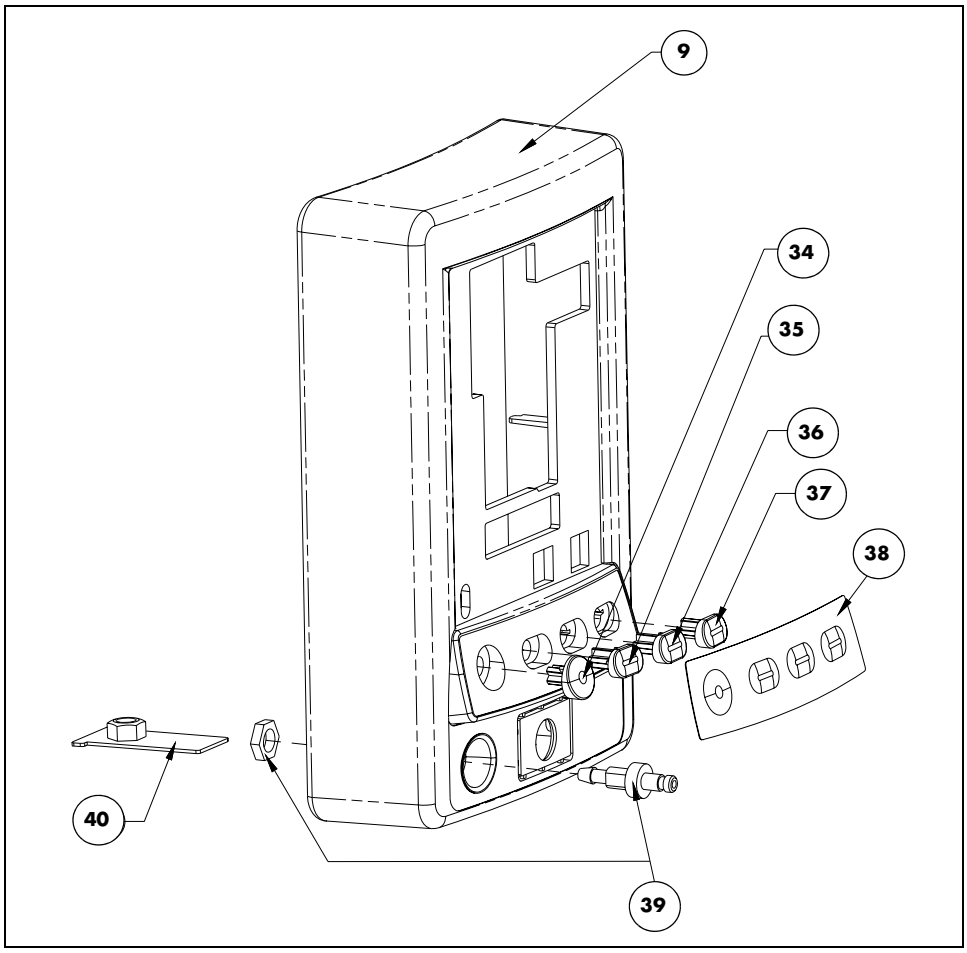

FIGURE 3-6 Front Case Assembly

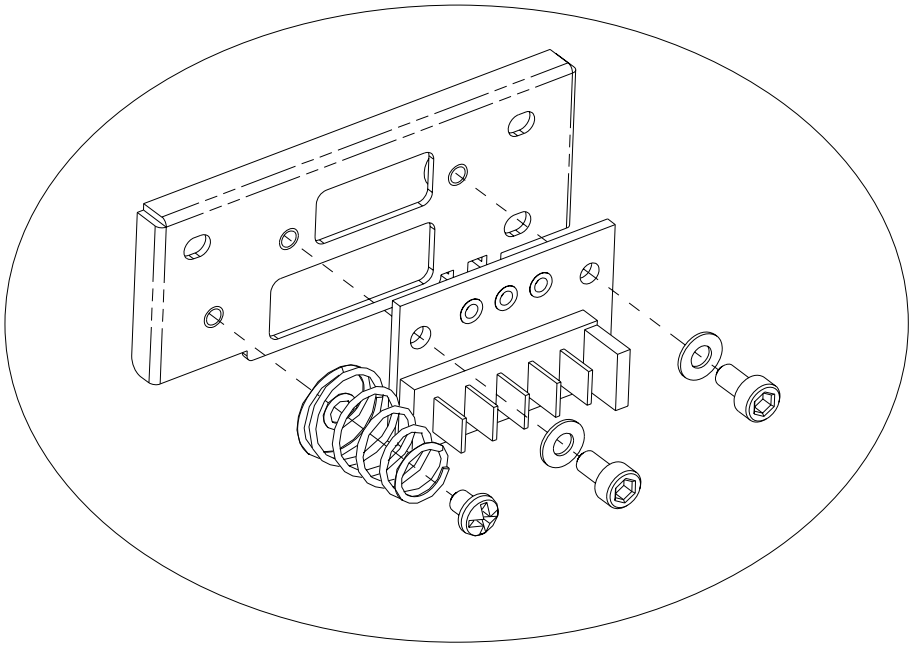

FIGURE 3-7 Battery Connector Assembly Detail

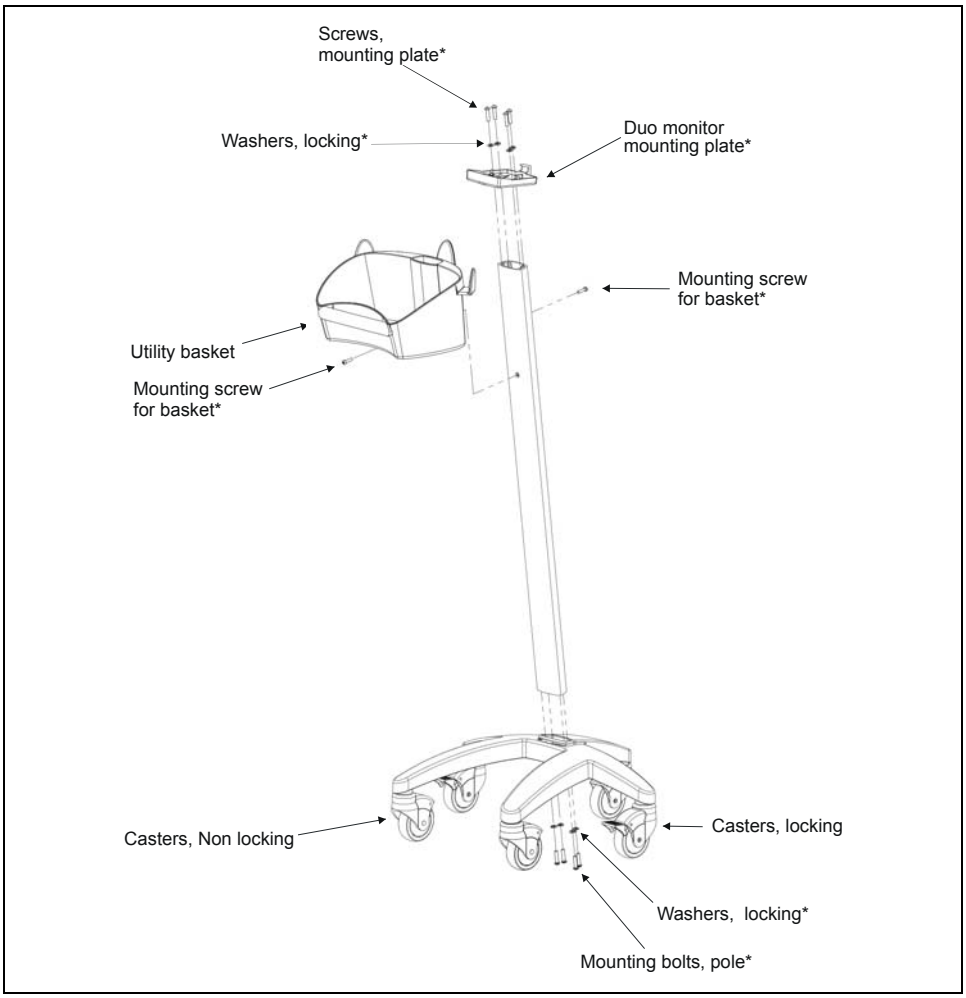

FIGURE 3-8 Duo Rolling Stand

Replacement Parts, Duo Rolling Stand

DESCRIPTION	PART NUMBER
Duo rolling stand, value	DUOROLLSTD
Duo monitor mounting kit	0406-00-0857-01
Casters, Non locking	0401-00-0045
Casters, Locking	0401-00-0046
Utility basket	0202-00-0166

* *Included in Duo monitor mounting kit*

3.2 Parts Listing

REF. NUMBER	PART NUMBER	DESCRIPTION
1	0211-00-0146	Housing Screw (metric panhead)
2	0380-00-0475	Rear Housing
3	0441-00-0107	Chassis
4	0671-00-0045	Power Supply Board
5	0211-00-0145	Metric Panhead Screw
6	0671-00-0044	CPU/Display Board
7	0213-00-0032	Self Tapping Screw
8	0380-00-0472	Nellcor Connector Shroud
8A	0380-00-0473	Masimo Connector Shroud
9	0380-00-0476	Front Housing
10	0012-00-1595	SpO_2 Power Cable
11	0671-00-0246	Masimo Isolated Power Board
12	0211-00-0143	Screw
13	0671-00-0243	Masimo SpO_2 Board
14	0012-00-1474	Masimo Flex Cable
15	0671-00-0247	Nellcor Isolated Power Board
16	0671-00-0242	Nellcor SpO_2 Board
16a	0671-00-0066	Nell-3 SpO_2 Board
17	0012-00-1457	Nellcor Flex Cable
17a	0012-00-1661	Nellcor Flex Cable
18	0386-00-0308	SpO_2 Mounting Plate
19	0104-00-0037	NIBP Module
20	0671-00-0063	Fan Driver Board
21	0671-00-0043	Battery Connector Board
22	0380-00-0481	Battery Latch
23	0380-00-0474	Battery Door
24	0346-00-0052	Battery Door Tether
25	0012-00-1592	Fan with cable
26	0348-00-0216	Fan Gasket
27	0213-00-4014	Screw
28	0386-00-0310	Fan Mounting Plate
29	0380-00-0471	Filler Panel
30	0367-00-0084	Handle
31	0211-00-0147	Handle Screw (metric panhead)
32	0334-00-1603-03	Rear Label, Lower, S/N
33	0348-00-0202	Foot
34	0380-00-0480-01	Power Switch Plunger
35	0380-00-0480-02	Clear Switch Plunger
36	0380-00-0480-03	Patient Size Switch Plunger
37	0380-00-0480-04	Start NIBP Switch Plunger

N/S - Not Shown

REF. NUMBER	PART NUMBER	DESCRIPTION
38	0330-00-0052	Keypad Overlay
39	0103-00-0411	Pneumatic Fitting
40	0386-00-0309	Mounting Plate
41	See table below	Rear Label, Upper
N/S	See table below	Display Overlay
N/S	See table below	Connector Label

N/S - Not Shown

Display Overlay

LANGUAGE	OPTION	PART NUMBER
English	NIBP Only	0330-00-0053-01
English	NIBP/SpO_2	0330-00-0053-11

Upper Rear Label

LANGUAGE	PART NUMBER
English	0334-00-1641-01

Connector Label

DESCRIPTION	PART NUMBER
No SpO_2	0334-00-1602-01
Masimo SpO_2	0334-00-1602-02
Nellcor SpO_2	0334-00-1602-04

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4.0 *Repair Information*

4.1 Introduction

This chapter of the **Duo** Service Manual provides the necessary technical information needed to perform repairs on the instrument. The most important prerequisites for effective troubleshooting are a thorough understanding of the instrument functions as well as an understanding of the theory of operation.

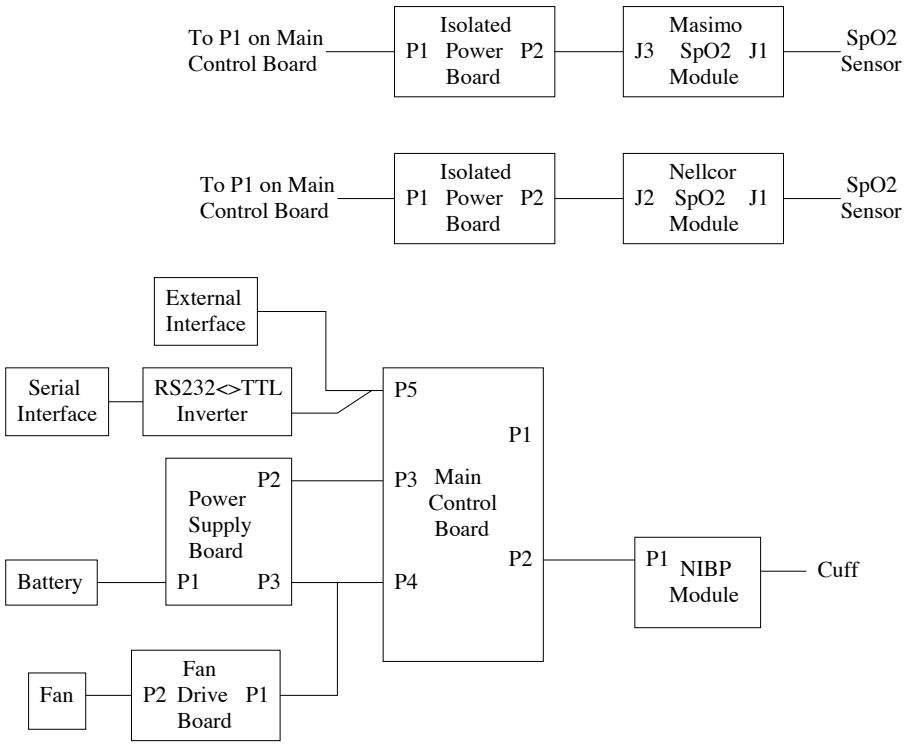

FIGURE 4-1 Module Interconnection

4.2 Troubleshooting Guide

Error Codes and Solutions

MESSAGE/ PROBLEM	REASON	SOLUTION
E01	NIBP Self Test Error	NIBP Module hardware failure
E02	NIBP Communications Error	Communications with NIBP Module have failed
E03	Loose Cuff	Cuff is not properly wrapped or no cuff is present
E04	Air Leak	Cuff, hose or connector is damaged, internal leak
E05	Air Pressure Failure	Stable pressure value is not available (e.g. hoses are pinched or occluded)
E06	Successful Pneumatic Test	Indicates NIBP pneumatic test was successful
E07	Pneumatic Test Failed/ Pneumatic Leak	Leak detected during the pneumatic test
E08	Weak Signal	Cuff is too loose or patient pulse is too weak
E09	Range Exceeded	NIBP value exceeds the upper measurement limit
E10	Excessive Motion Signal Saturated	Monitor is detecting too much motion and/or noise to obtain a reading
E11	Over Pressure	Pressure has exceeded the specified upper safety limit
E12	NIBP System Failure	Operation of blood pressure pump system has failed
E13	NIBP Time Out	Measuring time has exceeded 120 seconds
E14	NIBP Illegally Reset	Unexpected NIBP reset
E15	NIBP Reset Failed	NIBP reset failed
E16	NIBP Communications CRC Error	NIBP Serial Communication CRC failure
E17	NIBP Patient Size Change Error	Attempt to change Patient Size failed
E20	Masimo SpO_2 Interference	Noise detected on the pulse signal prevents pulse discrimination
E21	Masimo SpO_2 Low Perfusion	Patient perfusion is low
E22	Masimo SpO_2 Too Much Light	There is too much ambient room light for the sensor to function properly
E23	Masimo SpO_2 Unrecognized Sensor	The monitor does not recognize the sensor
E24	Masimo SpO_2 Communication Error	The monitor and the SpO_2 module are not communicating
E25	Masimo SpO_2 Board Fault	The Masimo SET board has failed to operate properly
E26	Masimo SpO_2 Sensor Fault	Defective sensor
E28	Masimo SpO_2 Timeout	SpO_2 data has been determined continuously for more than 2 minutes, so SpO_2 data has timed out from the display
E29	Masimo SpO_2 Low Signal IQ	The SpO_2 signal quality is poor

Error Codes and Solutions (Continued)

MESSAGE/ PROBLEM	REASON	SOLUTION
E34	Masimo SpO_2 Pulse Rate Exceeded	Pulse Rate value exceeds the measurement range
E34	Nellcor SpO_2 PR Exceeded	Pulse Rate value exceeds the measurement range
E40	Nellcor SpO_2 Interference	Noise is detected on the pulse signal, preventing pulse discrimination from the noise. The interference may be due to motion, excess infrared light or electrical/optical interference. The message is removed when the noise is removed
E41	Nellcor SpO_2 Check Sensor	The Nellcor module senses an unstable or illegal sensor. This may be due to a poor connection or a bad sensor. The user is required to reconnect the same sensor or connect a new sensor. The message will be removed once the Nellcor module clears the error
E42	Nellcor SpO_2 Communication Error	The front end module is having problems communicating (i.e.: framing errors or bad checksums) with the Nellcor module
E43	Nellcor SpO_2 Weak Pulse	A pulse rate can not be determined and all other measurement conditions are normal. The message is removed when a pulse is detected
E44	Nellcor SpO_2Weak Signal	Noise is detected but a pulse rate can not be discriminated. The message is removed when a pulse is detected
E45	Nellcor SpO_2 Board Fault	The SpO_2 board has malfunctioned
E46	Nellcor SpO_2 Motion	Motion is detected. The message is removed when No Pulse status is detected or when motion ceases
E47	Nellcor SpO_2 Timeout	SpO_2 data has been determined continuously for more than 2 minutes, so SpO_2 data has timed out from the display
E501	Unit Battery Voltage Low	Battery voltage is low
E504	Unit Keyboard Error 1	Error with front panel keypad board
E505	Monitor Shut Off Failure	Monitor cannot be turned off normally
E506	SpO_2 Module Not Recognized	Monitor cannot communicate with SpO_2 module during self-test

Monitor Failures

MESSAGE/ PROBLEM	REASON	SOLUTION
No display after power-on, power indicator does not light.	Bad line fuse	Replace fuse
	Bad power supply	Replace power supply
	Bad CPU/Display board	Replace CPU/Display board
NIBP or SpO_2 will not function.	CPU/Display board or module failure.	Isolate and replace defective board/module

Module Failures

MESSAGE/ PROBLEM	REASON	SOLUTION
NIBP cuff cannot be inflated.	Pinched or leaking hose or cuff	Check hose and cuff. Replace as needed
Intermittently won't take an NIBP reading.	Loose cuff or patient movement	Keep the patient quiet. Reapply cuff
NIBP readings inappropriately high or low for patient condition.	Incorrect cuff size. Incorrectly applied cuff	Use appropriate size cuff. Ensure correct cuff application
	NIBP module is out of calibration	Calibrate/replace NIBP module
No SpO_2 reading	SpO_2 sensor or cable damaged or disconnected	Check sensor placement and connection. Replace if damaged
	Sensor not on patient	
SpO_2 value is inaccurate	SpO_2 sensor or cable damaged or disconnected	Check sensor placement and connection. Replace if damaged
	Sensor not on patient	
	Coloring agent (dye) has been injected into patient	Retry after the coloring agent has dissipated
	Patient movement	Keep patient quiet
	Patient is cold	Warm patient and retry
	Patient is wearing nail polish	Remove nail polish

4.3 Disassembly Instructions

Before disassembling the unit, perform the following:

- Turn off the unit and remove the line cord
- Remove all cables and hoses
- Remove the battery
- Perform all maintenance on a properly grounded work station.

4.3.1 Tools Needed

- Phillips Screwdriver
- 5 mm nutdriver

4.3.2 Front Housing Removal

1. Remove four (4) 3 x 30 mm Phillips panhead machine screws from the corners of the Rear Housing.
2. Carefully separate the front and rear housings and disconnect the cables from the CPU/Display PCB connectors P02, P03 and P07. Disconnect the NIBP tubing from the front housing pressure fitting.

4.3.3 SpO_2 Interface Board Removal

1. Disconnect the cable from P01 on the CPU/Display pcb.
2. Remove three (3) 5mm hexnuts from their stand-offs on the SpO_2 pcb.
3. Lift the SpO_2 Interface pcb from the stand-offs.

4.3.4 SpO_2 Board Removal

1. Remove three (3) 5mm hex stand-offs from the SpO_2 Board.
2. Remove one (1) 3 x 6 mm Phillips panhead machine screw from the SpO_2 Board.
3. Lift the SpO_2 Board from the mounting bracket.

4.3.5 CPU/Display Board Removal

1. Remove four (4) 3 x 6 mm Phillips panhead machine screws from the corners of the CPU/Display Board.
2. Lift the CPU/Display Board from the Front Housing.

4.3.6 NIBP Module Removal

1. Remove four (4) 3 x 6 mm Phillips panhead machine screws from the corners of the NIBP module frame.
2. Lift the NIBP module from the battery housing frame.

4.3.7 Power Supply Removal

1. Remove the battery cable from P1 on the power supply PCB.
2. Remove four (4) 3 x 6 mm Phillips panhead machine screws from the corners of the power supply PCB.
3. Remove one (1) 3 x 6 mm Phillips panhead machine screw from the line power entry connector.
4. Slide the Power Supply pcb towards the bottom (open end) of the battery housing frame until it can go no farther.
5. Lift the power supply PCB from the battery housing frame. Use care to avoid breaking the positioning tab from the line power entry connector.

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