Operating Instructions

Datascope
Duo™

mindray™
NORTH AMERICA

mindray
NORTH AMERICA

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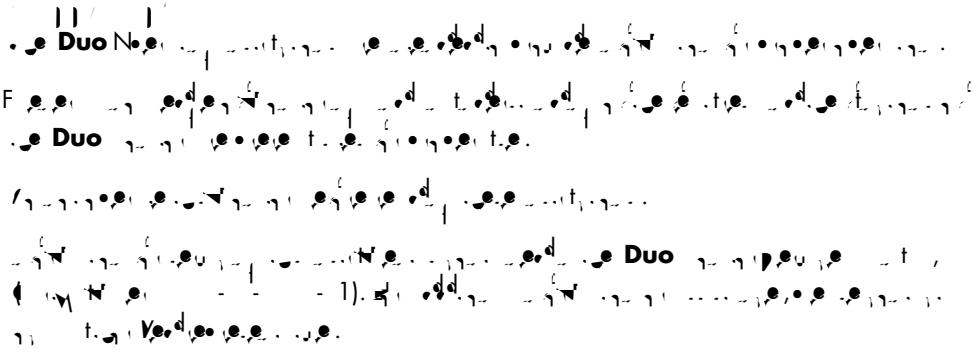
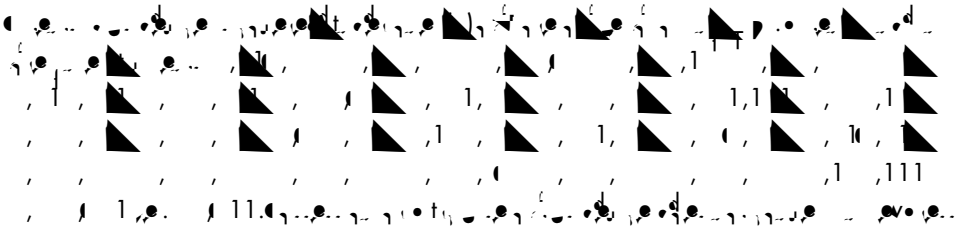
Navigator™ is a U.S. trademark of Mindray DS USA, Inc.

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

Nellcor® and OxiMax® are U.S. registered trademarks of Nellcor Puritan Bennett Inc.



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.**



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.

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.

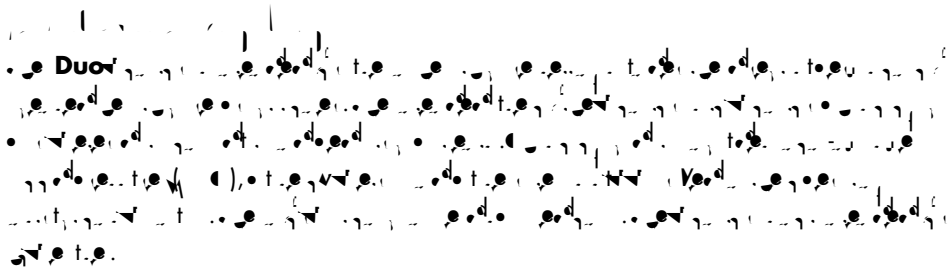
CAUTION: Remove the battery prior to shipping the Duo.

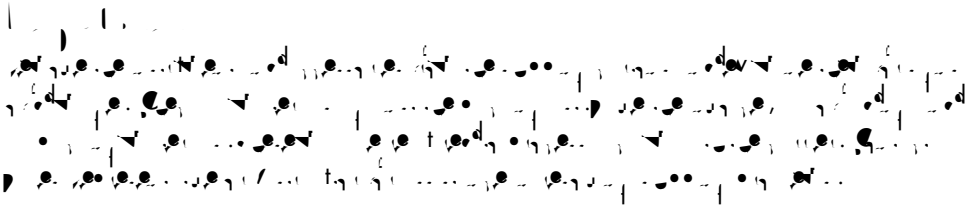
NOTE: **Potential hazards due to errors in software or hardware have been minimized by actions taken in accordance with IEC 60601-1-4.**

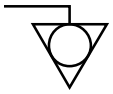
NOTE: **Information codes and error codes with corresponding explanations are provided to assist in the identification and correction of problems that may occur with the monitor.**

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.**





SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
			
			
			

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1.0 General Product Description

1.1

1.2

1.2.1

Duo

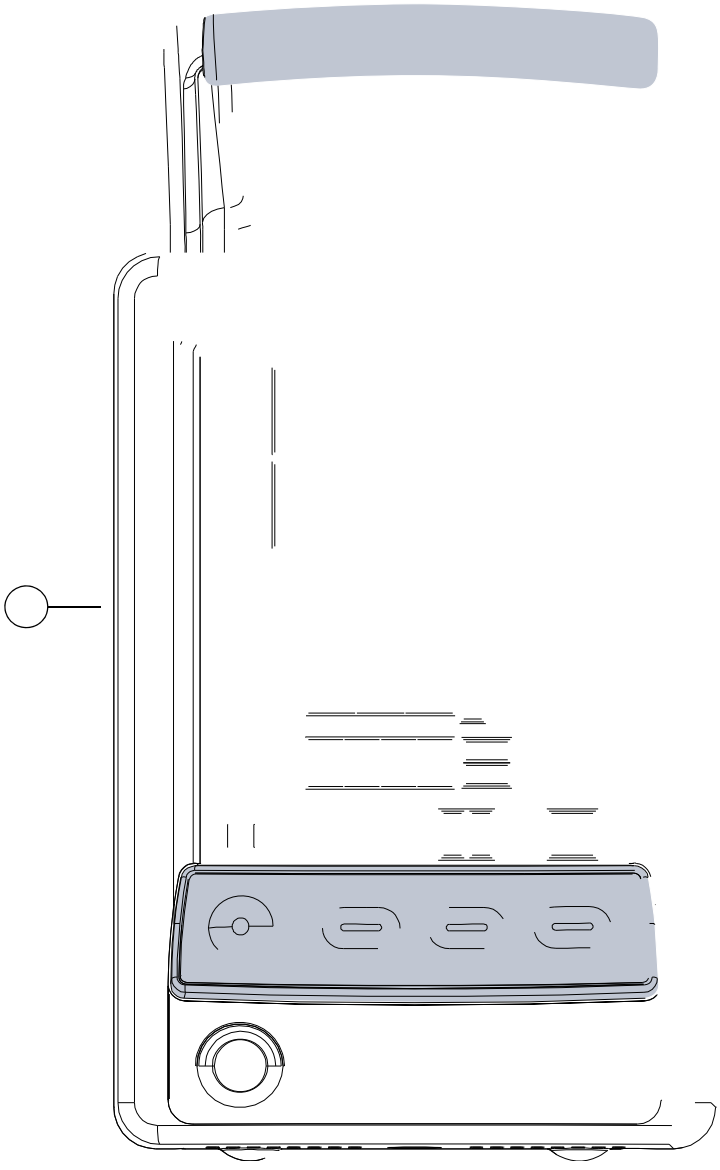


FIGURE 1-1

1. Digital Display

Duo

Parameter Tiles

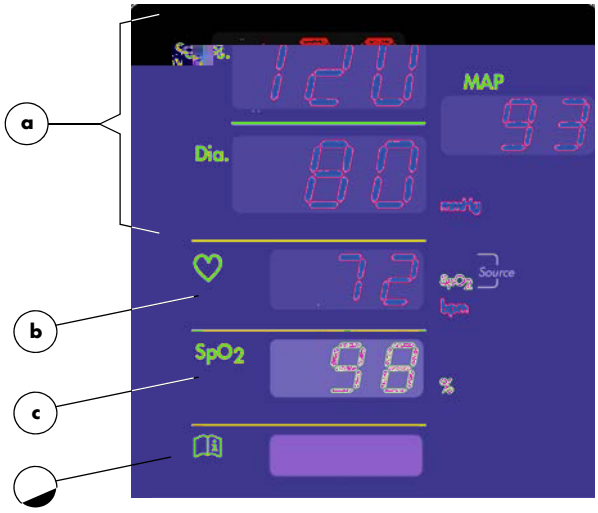


FIGURE 1-2

a. NIBP

Sys., **Dia.**, **MAP** **mmHg**, **kPa**.

b. Pulse Rate

NIBP **SpO2** **bpm**.

c. SpO2

SpO2 **%**.

d. Information Codes

LED Indicators

FIGURE 1-3

a. Battery Charging

b. AC Power

c. Patient Size

Adult

d. NIBP Start/Stop

Sys.

2. Keypad

Duo

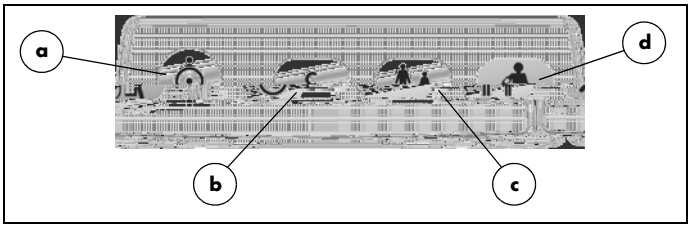


FIGURE 1-4

a. Power ON/OFF

Duo

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

Duo

b. Clear/Next Patient

c. Patient Size

Adult, **Pediatric**.

Duo

d. NIBP Start/Stop

3. Connector Panel

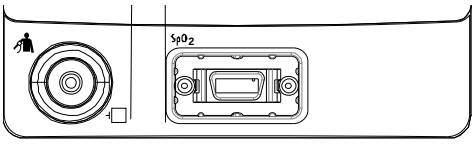


FIGURE 1-5

a. NIBP Pneumatic Fitting

Duo.

b. SpO_2 Receptacle (optional)

Duo.

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

1.2.2

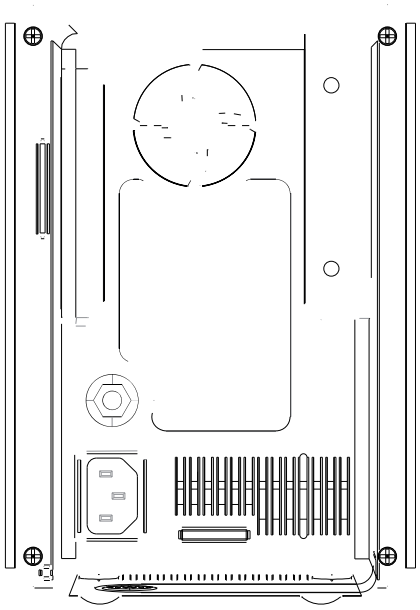


FIGURE 1-6

1. Serial Port

2. Equipotential Lug

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

3. AC Receptacle

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

1.2.3

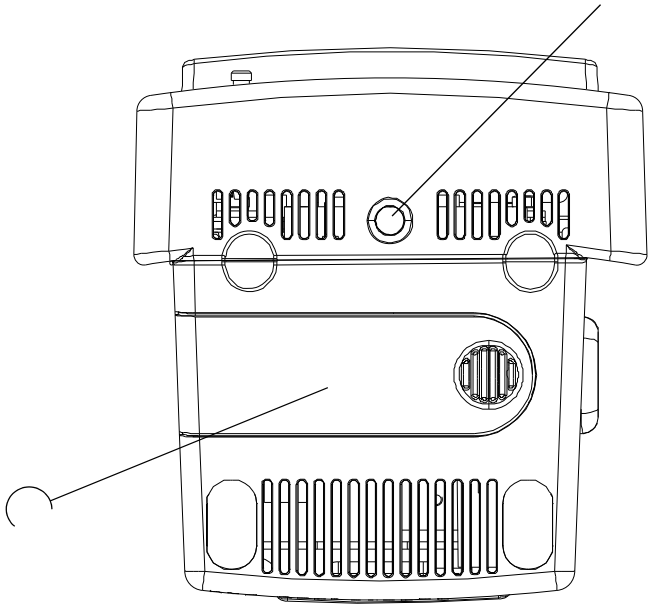


FIGURE 1-7

a. Mounting Nut

b. Battery Compartment

2.0 *Operation*

2.1

Duo

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

2.1.1

Duo.

2.1.2

Duo **Duo**

Duo

Duo

Duo

EVENT	TIME PERIOD TO ENTER STANDBY MODE

Power ON/OFF

Duo

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

Duo

Duo

Duo

2.1.4

Duo.

2.2

Duo.

1. **Duo**
2.

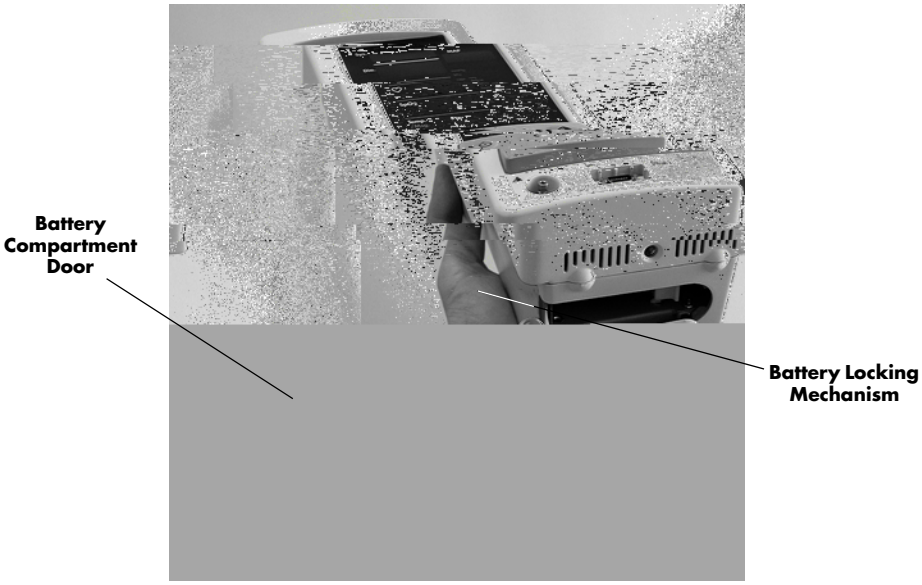


FIGURE 2-1

FIGURE 2-2

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

3.

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

4. **Duo** **Power ON/OFF** **Duo**

2.2.1

Duo (%)

mmHg **kPa**.

mmHg.

2.3

Duo.

2.3.1

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.

Duo

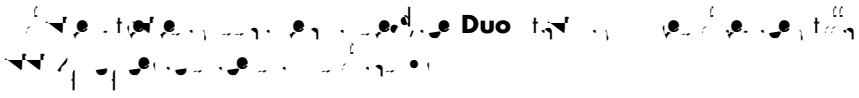
NIBP Start/Stop **Duo**

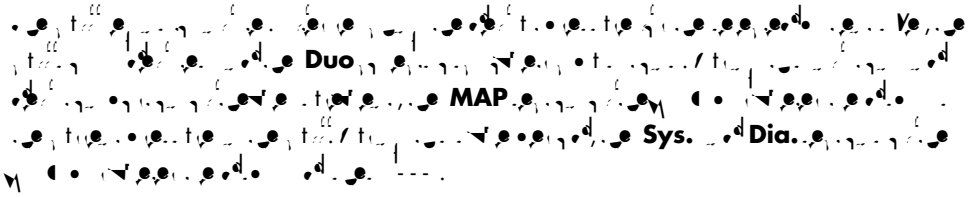
PATIENT SIZE SETTING	DEFAULT CUFF INFLATION PRESSURE

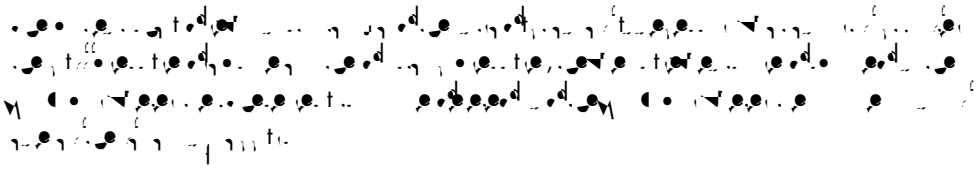
Duo

Duo,

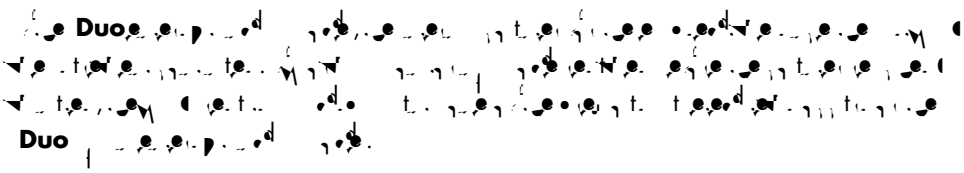
MAP





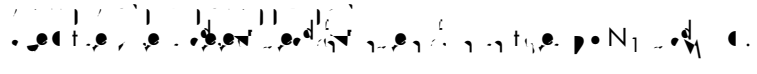


- **Clear/Next Patient**
- **Duo**

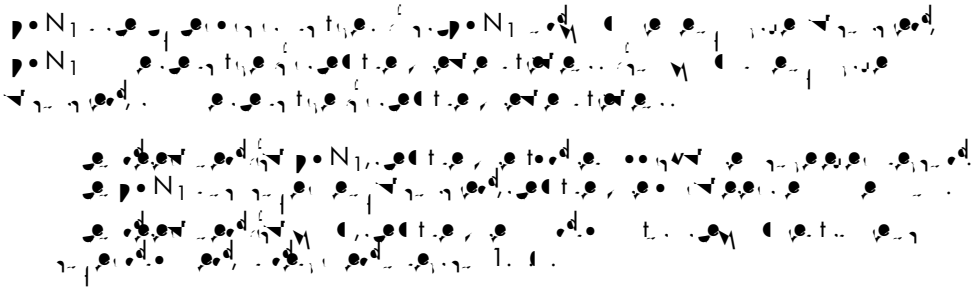


NOTE: **Pressing the NIBP Start/Stop key while the NIBP measurement is in progress will stop the measurement and deflate the cuff.**

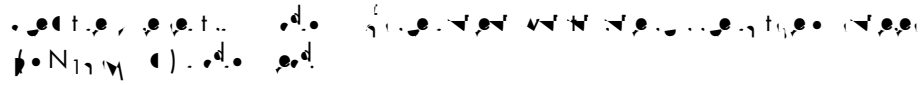
2.3.2



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

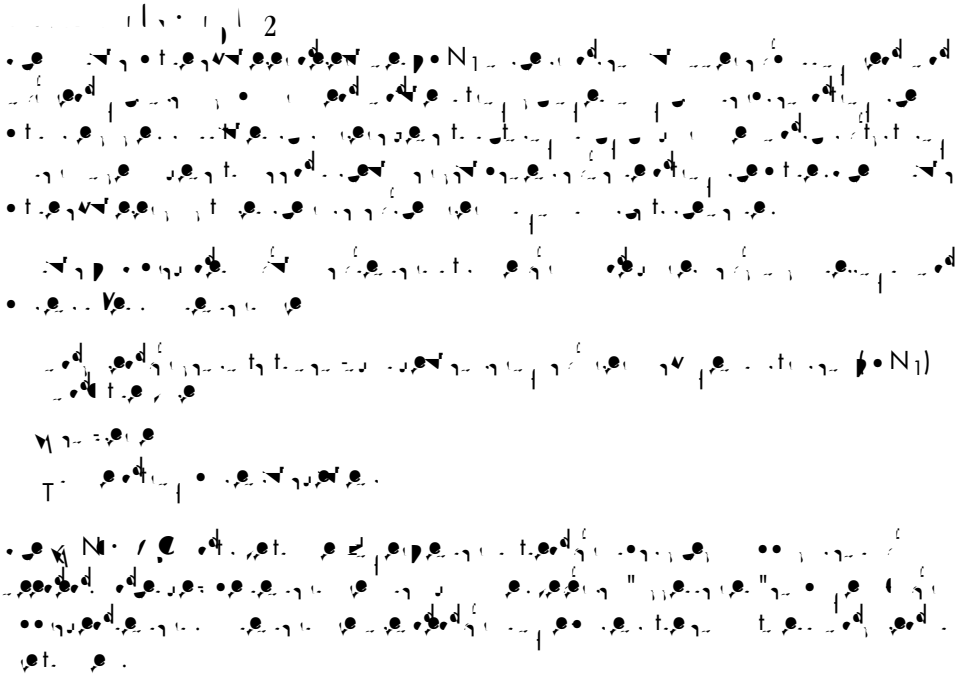


NOTE: **Pulse Rate from NIBP is a static value since NIBP is a static, one-time measurement.**



2.3.3

2.3.3.1



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.**

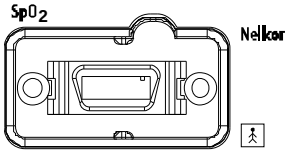
1.
2.
3.

2.3.3.2

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

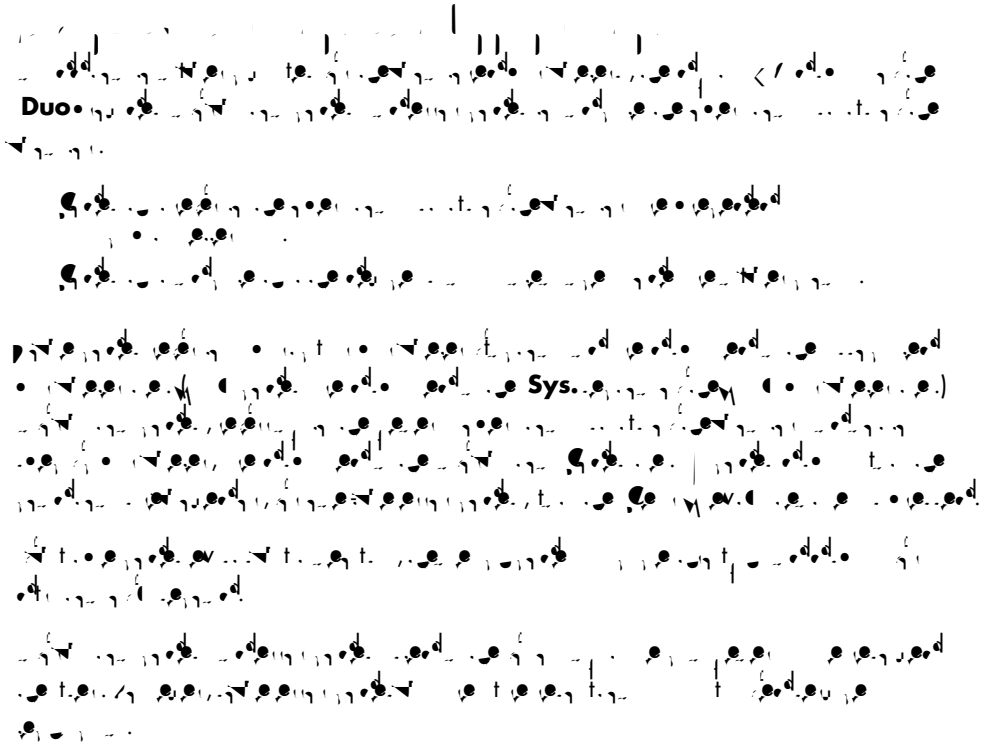
NOTE: **Refer to instructions included with each SpO_2 sensor and cable for proper placement and use.**

1.
2.
3.
4.



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



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

MESSAGE TYPE	CODE	DESCRIPTION	REASON
	1		
	1		
	11		
	1		
	1		
	1		

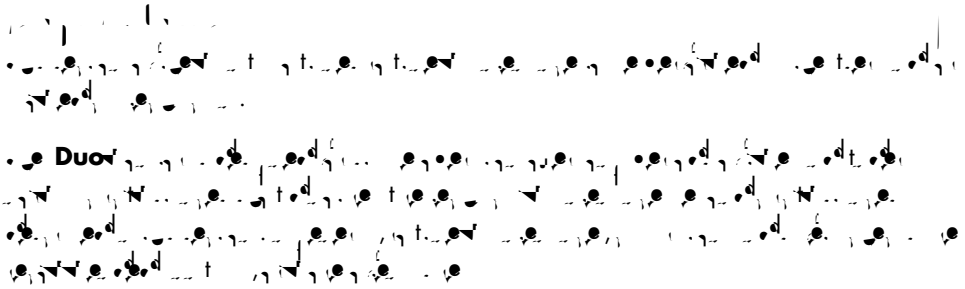
MESSAGE TYPE	CODE	DESCRIPTION	REASON

2.4.2

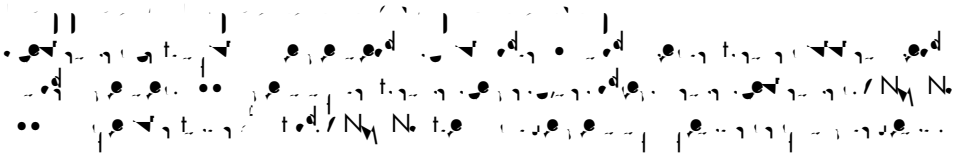
MESSAGE TYPE	CODE	DESCRIPTION	REASON
	1		

3.0 User Maintenance

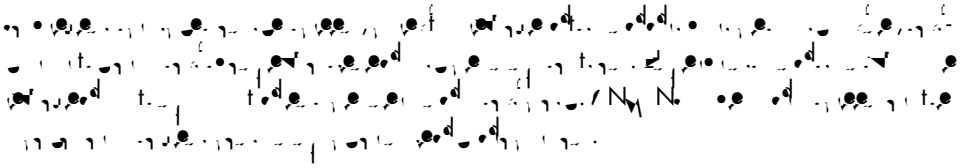
3.1



3.2

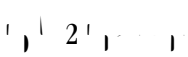


WARNING: Do not clean the monitor while it is ON and/or connected to AC power.



3.3

3.3.1



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

1.

2.

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

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

3.3.2.1

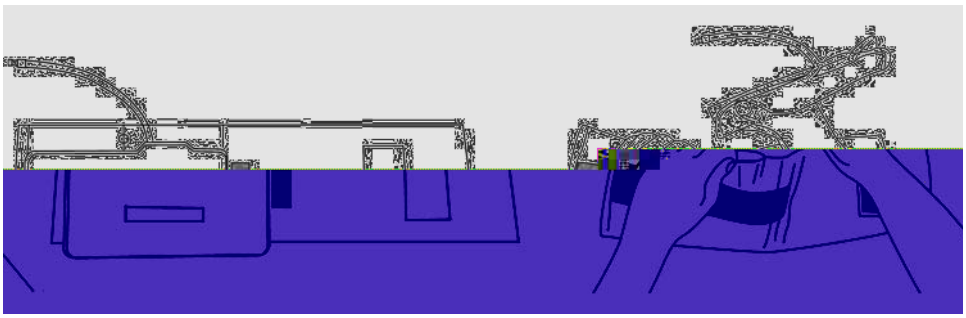
Cleaning

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

Disinfection

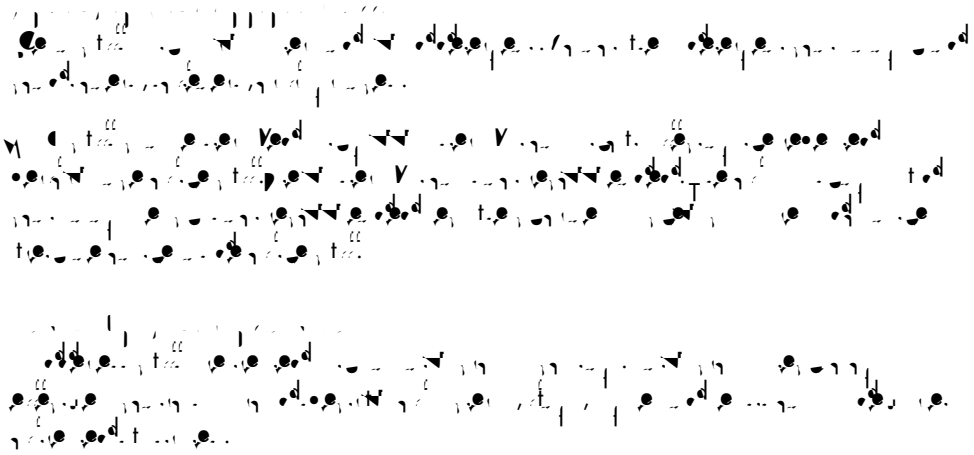
NOTE: **Prolonged use of disinfectant may cause discoloration of the cuff.**

1.
2.
3.
4.

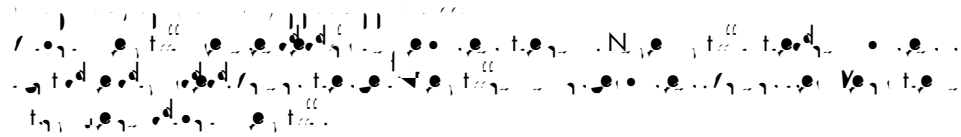


CAUTION: **Do not dry clean the cuff.**
Do not press the cuff with a hot iron.
Do not use detergent and disinfectant other than fresh water or 70% isopropanol.
Clean and disinfect the cuff according to the instructions.

3.3.2.2



3.3.2.3



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

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

1.

2.

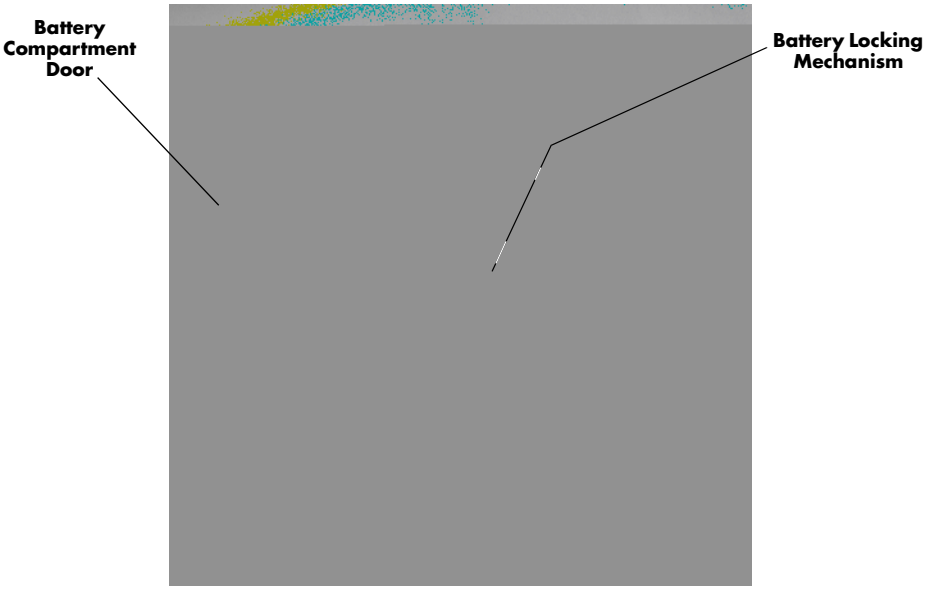


FIGURE 3-1

3.

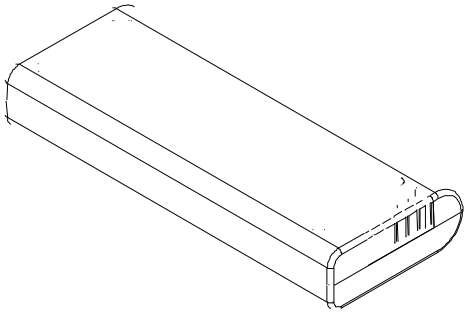


FIGURE 3-2

4.

5.

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.

Duo

4.0 *Accessories*

4.1

0020-00-0123-01

DESCRIPTION	PART NUMBERS
(1)	- - - 1
(1)	- - - 1
( )	(1- (- 1

4.2

4.2.1

DESCRIPTION	PART NUMBERS
[illegible]	[illegible]
[illegible]	[illegible]

DESCRIPTION	PART NUMBERS
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]

DESCRIPTION	PART NUMBERS
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]

4.2.2

DESCRIPTION	PATIENT SIZE	PART NUMBERS

DESCRIPTION	PART NUMBER

DESCRIPTION	PART NUMBER

** Sensors must be reordered through Nellcor.*

4.2.3

DESCRIPTIONS	PART NUMBER

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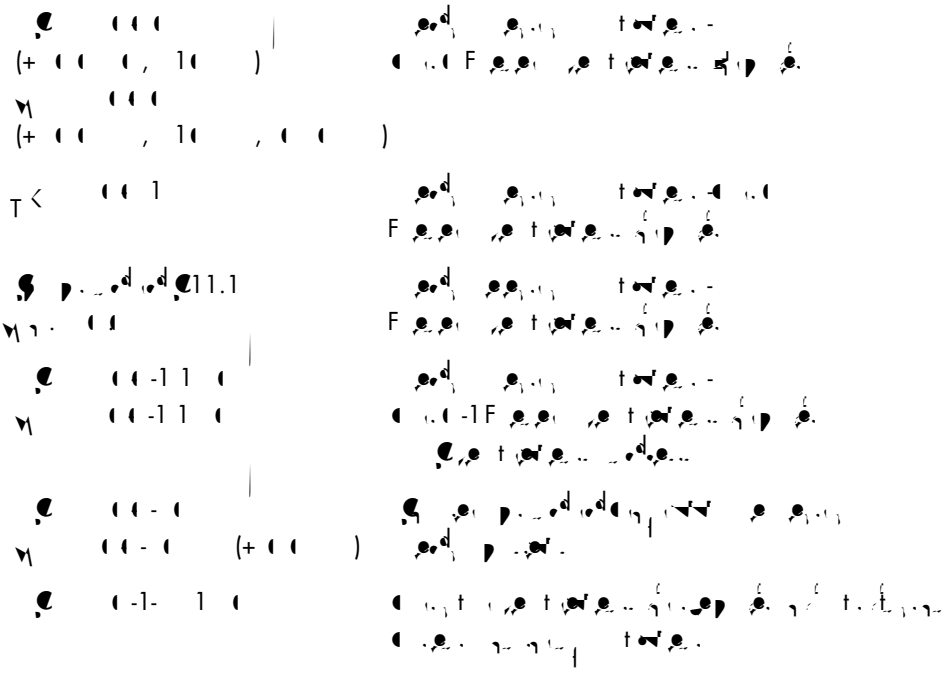
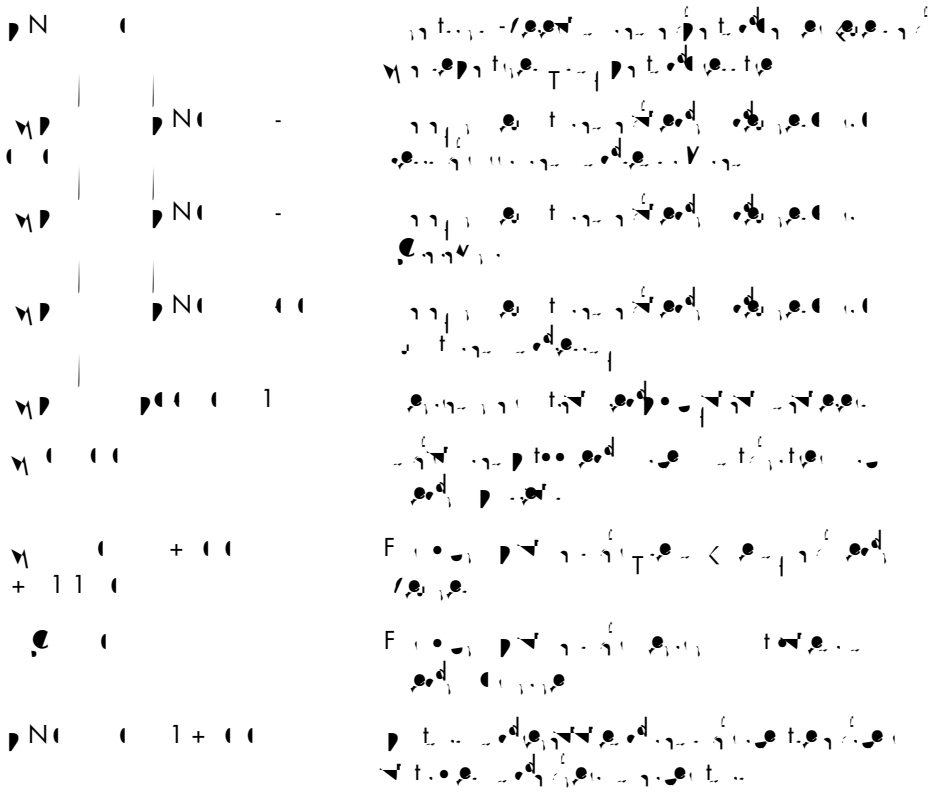
5.0 *Appendix*

5.1

5.1.1





5.1.5

5.2

5.2.1

5.2.2

*

	ADULT MODE	PEDIATRIC MODE

5.2.3

*

	ADULT MODE	PEDIATRIC MODE

* 1, *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

1

5.2.5

	ADULT MODE	PEDIATRIC MODE

5.2.6

5.2.6.1

ADULT MODE	PEDIATRIC MODE

ADULT MODE	PEDIATRIC MODE

5.2.6.2

5.2.6.3

5.2.6.4

5.2.6.5

5.2.6.6

PATIENT SIZE	PRESSURE INCREMENT (DEPENDING ON ALGORITHM)	DEFAULT START PRESSURE

5.2.6.7

5.2.7

5.2.7.1

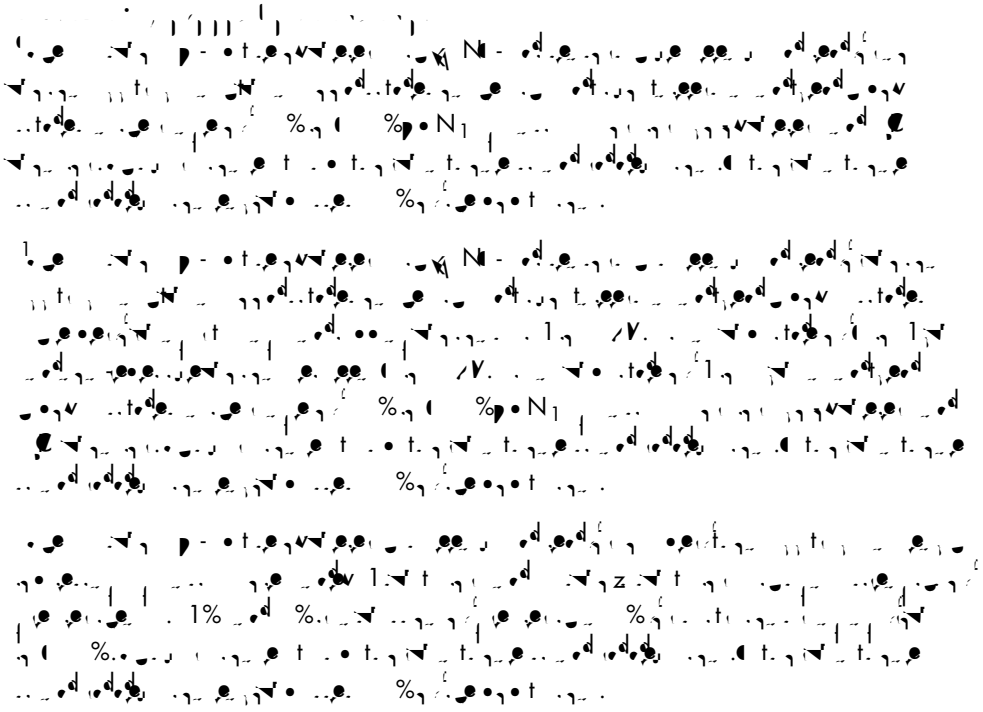
5.2.7.2

PATIENT SIZE	SATURATION RANGE	
	70% to 100%	0 – 69%

PATIENT SIZE	SATURATION RANGE	
	70% to 100%	0 – 69%

LOW PERFUSION CONDITIONS			
PULSE AMPLITUDE	% TRANSMISSION	SATURATION ACCURACY	PULSE RATE ACCURACY
1%	%		

PATIENT SIZE	PULSE RATE RANGE	ACCURACY	
		NO MOTION CONDITIONS	DURING MOTION CONDITIONS



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

	%
	%

SENSOR	ACCURACY
	%
	%
	%
	%

	/V.

RANGE	ACCURACY

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

5.2.8.1

1.

2.

5.2.9

(+ %)

(+ -)

5.2.10

5.2.10.1 0146-00-0079

5.2.11

5.2.11.1

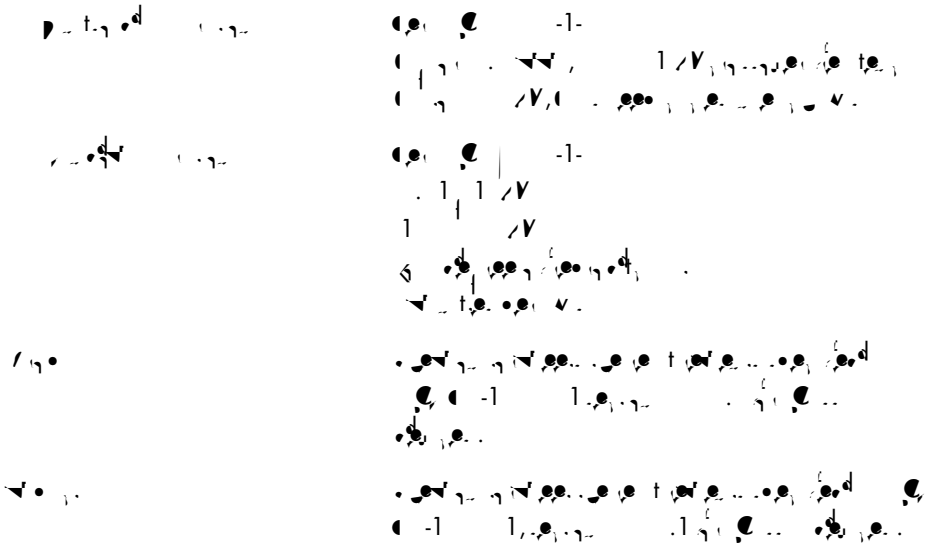
5.2.11.2

5.2.12

Duo

Duo

5.2.13



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

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE

TABLE 5-2

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE

TABLE 5-2

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

Duo

Duo

IMMUNITY TEST	**IEC 60601 TEST LEVEL**		
	% T T (% T •)	% T T (% T •)	**Duo**
	% T • (% T •)	% T • (% T •)	**Duo**
	% T • (% T •)	% T • (% T •)	
	% T • (% T •)	% T • (% T •)	
(/V)			

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

TABLE 5-3

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

Duo

Duo

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
			Duo
			Recommended separation distance
			$d = 1.1 \sqrt{P}$
			$d = 1.1 \sqrt{P}$
			$d = 1.1 \sqrt{P}$
			P ( ) d).

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

Duo

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**
	$d = [3.5/V_1]\sqrt{P}$	$d = [3.5/E_1]\sqrt{P}$	$d = [7/E_1]\sqrt{P}$
.(	1	1	.1
1	.	.	.
(	(.1	(.1	1.
(	.	.	.
(	(1	(1	1

Duo

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

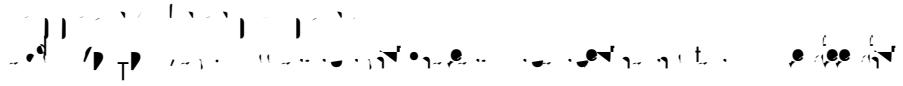
NOTE: **These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**

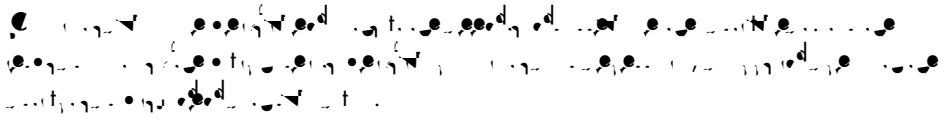
NOTE: **The Duo is intended for use in the electromagnetic environment specified below. The customer or the user of the Duo should assure that it is used in such an environment.**

Duo

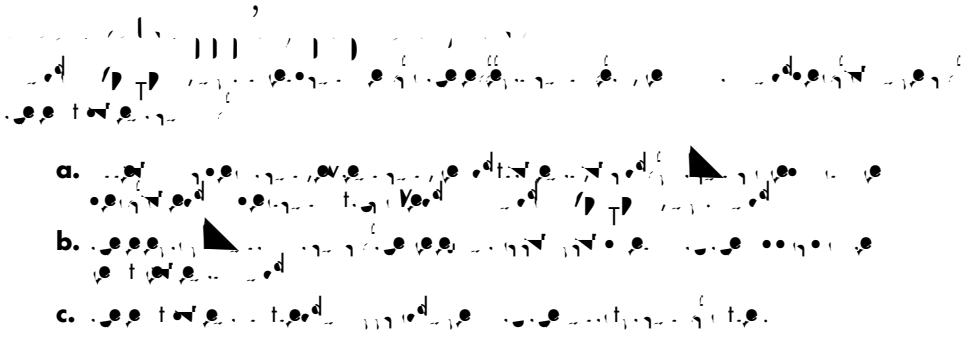
NOTE: **Mains power quality should be that of a typical commercial or hospital environment. If the user of the Duo requires continued operation during power mains interruptions, it is recommended that the Duo be powered from an uninterruptible power supply or a battery.**

5.3





5.4



a.

b.

c.

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]