LUCON P30

Pulse Oximeter

Operator's Manual

MEDIANA

OPERATOR'S MANUAL

P30 Pulse Oximeter

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P30 Operator's Manual
Revised Date: 1008
Part Number-Revision: A7133-XA
Printed in Korea

CE
0434

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Revision History

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

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Safety Information

General Safety Information

This section contains important safety information related to general use of the P30 hand-helded pulse oximeter. Other important safety information appears throughout the manual. The P30 pulse oximeter will be referred to as the P30 or the unit throughout this manual.

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

Warnings

Warnings are identified by the WARNING symbol shown above.

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

WARNING: As with any medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING: The unit has protection from defibrillators and electrosurgical units. It may remain attached to the patient during defibrillation or while an electrosurgical unit is in use, but the readings may be inaccurate during use and shortly thereafter. During defibrillation, make sure that defibrillator paddles do not contact cables or any other conductive parts, in contact with the patient.

WARNING: Inspect the unit and all accessories before use to make sure there are no signs of physical damage or improper function. Do not use the unit or any accessory if damaged.

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

WARNING: The unit is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: The measured values of the unit can be affected by patient conditions, motion, sensors, environmental conditions, and nearby electromagnetic external conditions.

WARNING: The unit is intended to be used in a hospital and hospital facilities environment by trained medical personnel.

WARNING: It is possible that noises beyond guaranteed from immunity requirements of IEC60601-1-2, any radio frequency transmitting equipment and other sources of electrical noise such as cellular phones, can result in disruption of the unit operation. Refer to the *Manufacturer's declaration* section.

WARNING: To ensure patient safety, do not place the unit in any location that

could allow it to fall on the patient.

WARNING: Always disconnect the unit and sensors during magnetic resonance imaging (MRI) scanning. Attempting to use the unit during MRI could cause burns or adversely affect the MRI image or the unit's accuracy. To avoid burns, remove the unit sensors from the patient before conducting MRI.

WARNING: Never lift the unit by the sensor cable or any other accessory. Such accessories could detach, causing the unit to fall on the patient.

WARNING: Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a unit with a broken display panel.

WARNING: Any connections between this unit and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so could result in unsafe leakage current and grounding conditions.

WARNING: For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.

WARNING: Do not connect more than one unit to a patient.

WARNING: Do not touch signal input, signal output or other connectors, and the patient simultaneously.

Cautions

Cautions are identified by the CAUTION symbol shown above.

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

CAUTION: The unit may not operate properly if it is operated or stored at conditions outside the ranges stated in this manual, or subjected to excessive shock or dropping.

CAUTION: Never place fluids on the unit. If fluid spills on the unit, remove batteries, wipe dry immediately, and have the unit serviced to make sure that no hazard exists.

CAUTION: When connecting the unit to any instrument, verify proper operation before clinical use. Both the unit and the instrument connected to it must be connected to a grounded outlet.

CAUTION: Accessory equipment connected to the unit's data interface must be certified according to IEC60950 for data-processing equipment or IEC60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC60601-1-1 system requirements. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of IEC 60601-1-1 and the electromagnetic compatibility system standard IEC60601-1-2. If in doubt, consult Mediana Technical Support Representative.

CAUTION: Risk of explosion if battery is replaced by an incorrect type.

CAUTION: Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.

CAUTION: This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures

- **Reorient or relocate the receiving device.**
- **Increase the separation between the equipment.**
- **Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.**
- **Consult the manufacturer or field service technician for help.**

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Introduction

WARNING: Patient conditions may result in erroneous readings. If the measurements are suspect, verify the reading using another clinically accepted measurement method.

Intended Use for the P30 pulse oximeter

The P30 pulse oximeter is intended to be used to monitor functional arterial oxygen saturation (SpO_2) and pulse rate in all areas of a hospital, hospital-type facilities, intra-hospital transport and home environments. Users should be skilled at the level of a technician, doctor, nurse or medical specialist.

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

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

About This Manual

This manual explains how to set up and use the pulse oximeter.

Read the entire manual including the *Safety Information* section, before you operate the unit.

Features for the P30 pulse oximeter

Physical/Mechanical

The P30 is a lightweight, compact hand-helded pulse oximeter, which can be operated with alkaline batteries.

Electrical

The P30 pulse oximeter is powered by three alkaline batteries only. It is typically provides 8 hours of monitoring. Refer to the **Battery Operation** section for details.

Display

The monitoring screen shows numeric information by a 7-segment LCD as well as alarm conditions by indicators.

Auxiliary Outputs

The unit provides the data port. Refer to the **Using the Data Port** section for details.

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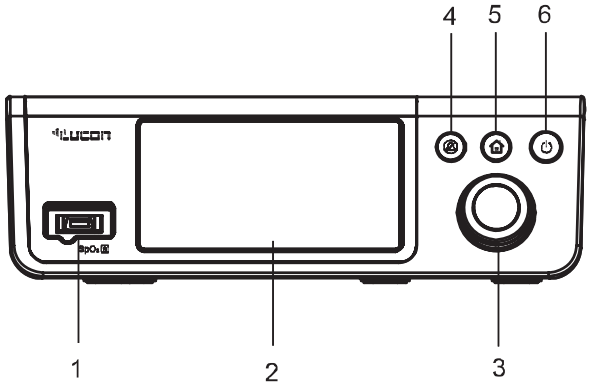
Description of the P30

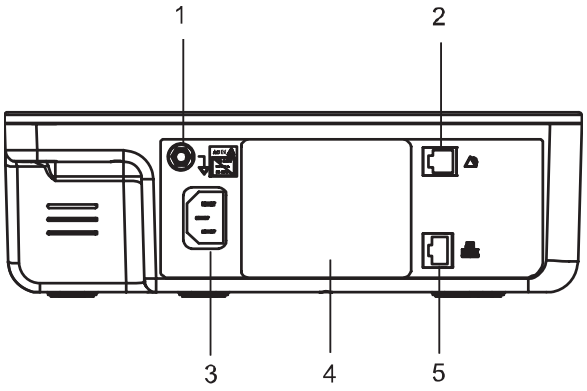
Front Panel Controls



1 SpO_2 connector
2 LCD
3 Jog dial
4 Alarm stop button
5 Home butten
6 Power button

Figure 1. Front Panel Controls

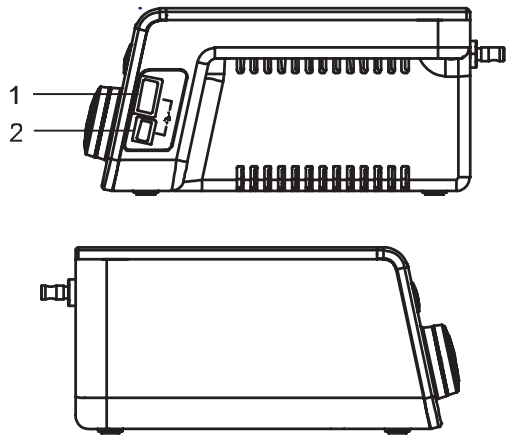
Rear Panel Components



1 Equipotential terminal
2 Nurse call port
3 AC power connector
4 Battery cover
5 LAN port

Figure 2. Rear Panel Components

Right and Left Panel Components



1 USB port (USB A type)
2 USB port (mini USB B type)

Figure 3. Right and Left Panel Components

Table 1. Button Symbols

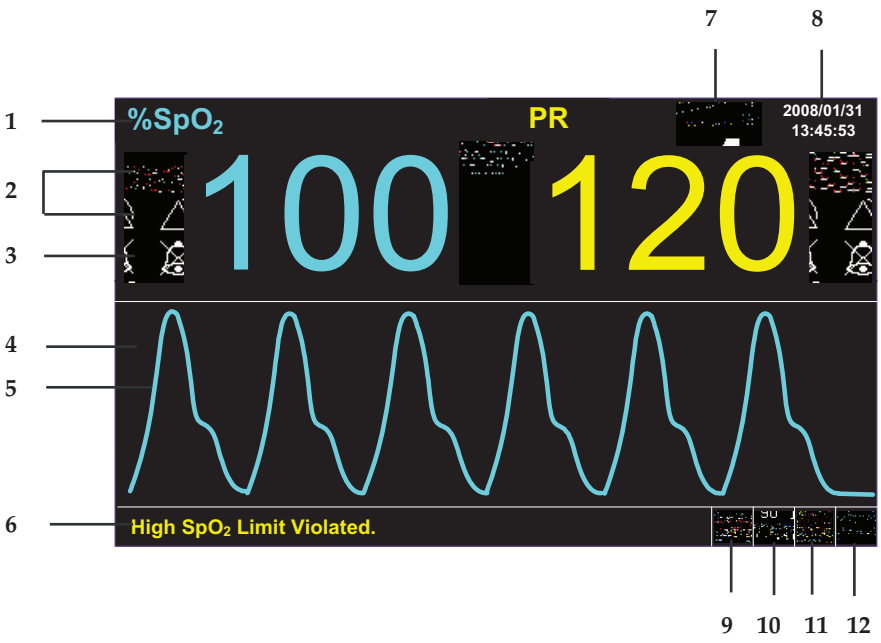
Symbols	Description
	**Power on/off button** turns the unit on or off.
	**Silence button** toggles between disabling and re-enabling the audible alarm or pulse beep tone and is used to return to the previous screen.
	**Home Button** exits a menu displayed on the screen and goes to the main screen.

Table 2. Panel and Label Symbols

Symbols	Description
	Battery charging indicator
	Power on indicator
	Interference indicator Appears on the screen when the sensor detects the presence of artifact.
	Finger off indicator Appears on the screen when the sensor is not on the patient.
	Sensor off indicator Appears on the screen when the sensor is not connected to the unit.
	Sensor failure indicator Appears on the screen when the sensor is invalid.
	Type BF Applied part - Defibrillation proof-
	EU representative
	Attention, consult accompanying documents
	CE mark
	Dust and water resistance
	Crossed-out wheeled bin
	Manufacturer
	Date of manufacture

Symbols	Description
REF	Reference number
SN	Serial number
	Environmental shipping/storage altitude limitations
	Environmental shipping/storage humidity limitations
	Environmental shipping/storage temperature limitations
	Fragile –Handle with care
	This way up
	Keep dry
	Attention: consult Accompanying documents

Displays



1	Title of numeric parameter	7	Battery status icon
2	Alarm icon	8	Time display
3	Alarm limit values	9	Patient mode icon
4	Waveform	10	Alarm limits menu icon
5	Waveform area	11	Sound menu icon
6	Informative message area	12	Setup menu icon

Figure 4. Displays

Table 3. Display Symbols

Symbols	Description	Symbols	Description
	Battery status icon		Alarm limits menu icon
	Audible Alarm Active icon		Patient mode: Adult
	Audible Alarm silence icon		Patient mode: Pediatric
	Audible Alarm suspend icon		Patient mode: Neonatal
	Audible Alarm inhibition icon		Setup menu icon
	Alarm limit values		Sound menu icon
	Pulse amplitude indicator	2008/01/31 13:45:53	Time display

Table 4. Display Symbols

Function	Color
SpO_2 Waveform	Cyan
Pulse Rate	Yellow
SpO_2	Cyan
General background	Black
Informative message	Black background, Green font
Low priority alarm message	Black background, Yellow font
Medium priority alarm message	Black background, Yellow font
High priority alarm message	Black background, Red font
Battery status icon (normal)	Green
Battery status icon (low battery)	Yellow or Red (refer to Table 7)

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Setting up the P30

WARNING: To ensure accurate performance and prevent device failure, do not expose the unit to extreme moisture, including direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Refer to *Specification* section.

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

WARNING: Make sure that the speaker is not obstructed. Failure to do so could result in an inaudible alarm tone.

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

Unpacking and Inspection

The unit is shipped in one carton. Examine the carton carefully for evidence of damage. Contact Mediana Technical Support Representative immediately if any damage is discovered. Return all packing material and unit. Refer to the **Maintenance** section for instructions on returning damaged items.

Note: Refer to **Performance Verification** section in the service manual for the detailed information.

List of Components

Items	**Quantity**
P30 pulse oximeter	1
SpO_2 reusable sensor	1
AAA alkaline battery	3
Operator's Manual	1
Optional Items	
SpO_2 disposable sensor for adult	-
SpO_2 disposable sensor for neonate	-
RS-232 interface cable	-
Service Manual	-

Note: Optional items may be ordered if needed. Contact Mediana Technical Support Representative for pricing and ordering information.

Power Cable Connections

WARNING: Do not connect to an electrical outlet controlled by a wall switch because the device may be accidentally turned off.

CAUTION: If the integrity of the AC power source is in doubt, the monitor must be operated from its internal battery.

AC Power

Make sure that the AC outlet is properly grounded and supplies the specified voltage and frequency (100-240V~ 50-60 Hz).

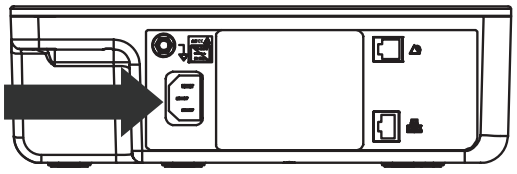

Figure 5. AC power

1. Connect the female connector end of the AC power cord to mains connector on the monitor's rear panel.
2. Plug the male connector end of the AC power cord into a properly grounded mains outlet.
3. If necessary, connect grounding wire. Connect the grounding wire connector to the equipotential terminal on the rear panel. Now attach the clip end of the grounding wire to the medical equipment grounding terminal on the wall.
4. Verify that the ***Battery Charging Indicator*** on the monitor's front panel is lit.

Note: Even if the monitor is not turned on, the ***Battery Charging Indicator*** is lit when the AC power cord is connected into a mains outlet.

Note: If the ***Battery Charging Indicator*** is not lit, check:

- the power cord
- the AC power inlet
- the power/ mains outlet
- No Battery

If the ***Battery Charging Indicator*** still is not lit although no problem is found, contact qualified service personnel or your local supplier for assistance.

Sensor Connection

WARNING: For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.

Note: Both frequent checks by the operator on say a daily basis and more comprehensive technical checks less frequently are covered by this requirement in order to detect mechanical damage and damage to cables, etc.

1. Select an appropriate sensor for the patient and desired application.

   When selecting a sensor, consider the patient's weight and activity, adequacy of perfusion, availability of sensor sites, need for sterility, and anticipated duration of monitoring. Refer to Table 5.

2. Carefully apply the sensor to the patient, as described in the sensor directions for use. Observe all warnings and cautions in the directions for use.
3. Connect the sensor to the sensor port on the top of the unit. (see Figure 1).

Note: If the sensor is not connected firmly, the unit could lose signal from patient.

Note: Refer to directions for use to make sure the proper placement for various types of SpO_2 sensor.

Note: Periodically check to see that the sensor remains properly positioned on the patient and that skin integrity is acceptable. Refer to the sensor directions for use.

Table 5. SpO_2 Sensors

Sensor	Model	Patient Size
OXIMAX oxygen transducer (Sterile, single-use only)	MAX-N MAX-A	<3 or >40 kg >30 kg
OXIMAX Durasensor ® Oxygen transducer (Reusable, non-sterile)	DS-100A	>40 kg

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Battery Operation

CAUTION: Recharging the battery is strongly recommended when it has not been fully recharged for 2 or more months.

CAUTION: When the voltage of the battery is very low, it is a possibility of not operating.

Note: It is recommended that the monitor remain connected to AC power source when not in use. This will ensure a fully charged battery whenever it is needed.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter. It is recommended for service personnel to check periodically or replace the internal battery if necessary.

Operating the P30 on Battery Power

The P30 has an internal battery that can be used to power the monitor when AC power source is not available. The battery status icon appears on the screen when the monitor is on battery power.

1. Turn off the P30.
2. Remove the battery cover.
3. Insert the battery into the main unit carefully.

Table 6. Front Panel Indications for Power Source

Power Connections	Front Panel Indications
AC source	Battery status icon disappears on the screen.
Battery	Battery status icon appears on the screen.

The monitor cannot operate with a fully discharged battery. Before turning on the monitor with a battery that has been completely discharged, first plug the monitor into an AC outlet to charge the battery for a minimum of 3 minutes. The monitor may then be powered on.

A new, fully charged optional battery will provide 4, 8 or 12 hour(s) monitoring operation under the following conditions:

- No audible alarm condition
- No external communication operating
- Ambient temperature at 25°C

Note: Three types of battery are available as the optional items.

Battery Status Indication

When operating on batteries, the battery status icon in the lower part of the display indicates the battery charge condition. See Table 7.

Table 7. The Monitor Battery Status Icon

Battery Status Icons	Battery Status Icon Color
	Green (constant)
	Yellow (constant) ≤ 15 minutes
	Red (flashing) ≤ 5 minutes

A low priority alarm occurs when the remaining battery power is only enough for 15 minutes of operation. The alarm message ***'Low Battery'*** appears on the screen and the visual alarm indicator is lit with yellow.

This alarm cannot be silenced while running on battery power. Connecting the monitor to AC power will silence the alarm.

A high priority alarm occurs for about 5 minutes before the monitor shuts off. The alarm message '***Critically Low-Battery Condition***' will appear and the visual alarm indicator will flash with red. After that, the monitor will automatically shut down. Connect the monitor to an AC power source to avoid any loss of trend data or settings.

Low Battery Indication

1. Connect the monitor to AC power source to charge a low or depleted battery (see the **Setting up the Monitor** section).
2. Verify that the ***Battery Charging Indicator*** is lit with orange.

Table 8. Front Panel Indications for Battery Status

Battery status	Battery charging indicator
Full charged	Green
Charging	Orange
Not installed	OFF

Note: Even if the monitor is turned off, the ***Battery Charging Indicator*** is lit while the battery is recharged.

Note: A full charge of a depleted battery takes over 6 hours per battery.

Using the P30

WARNING: Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the unit can cause inaccurate measurement readings. Do not rely entirely on the unit's readings for patient assessment.

WARNING: For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.

WARNING: Tissue damage can be caused by incorrect application or use of an SpO_2 sensor. Harm can be caused, for example, by wrapping the sensor too tightly, by applying supplemental tape, or by leaving a sensor on too long in one place. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity, correct positioning, and adhesion of the sensor.

WARNING: Do not use damaged SpO_2 sensors. Do not use an SpO_2 sensor with exposed optical components. Do not immerse sensor completely in water, solvents, or cleaning solutions because the sensor and connectors are not waterproof. Do not sterilize SpO_2 sensors by irradiation, steam or ethylene oxide. Refer to the cleaning instructions in the directions for use for reusable SpO_2 sensors.

WARNING: Inaccurate measurements may be caused by:

- **incorrect sensor application or use**
- **significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin)**
- **intravascular 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 direct sunlight**
- **excessive patient movement**
- **high-frequency electrosurgical interference and defibrillators**
- **venous pulsations**
- **placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line**
- **patient conditions such as hypotension, severe vasoconstriction, severe anemia, hypothermia, cardiac arrest, or shock**
- **arterial occlusion proximal to the sensor**
- **environmental conditions**
- **unspecified length of the pulse oximetry cable**

WARNING: Do not attach any cable to the sensor port connector that is intended for computer use.

CAUTION: The sensor disconnect error message and associated alarm indicate the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, pulse oximetry cable or both.

CAUTION: Reusable sensors may be used on the same site for a maximum of 4 hours, provided the site is inspected routinely to ensure skin integrity and correct positioning.

Turning on the P30

Before using the P30 in a clinical setting, confirm that the unit is working properly and is safe to use as described below.

CAUTION: If any indicator or display element does not light, or the speaker does not sound, do not use the P30. Instead, contact qualified service personnel.

1. Turn on the P30 by pressing ***Power on/off button*** on the right of the unit for over one second.
2. The software version is displayed and the SpO_2 alarm indicator and the Pulse rate alarm indicator are lit for approximately 2 seconds.

Figure 6. Start up screen

Note: The software version shown above is only a sample.

3. The P30 sounds the power-on beep tone.

Setting Basic Setup Parameters

This procedure will allow you to set Patient Mode, New Patient, Brightness, Sleep Mode, Date Time.

Rotate the jog dial to highlight the Setup Menu Icon. Press the jog dial to display the setup menu.

Table 9. Setup Menu

Level 1 Menu	Level 2 Menu or Response
SETUP MENU	
Patient Mode	Adult, Pediatric, Neonatal
New Patient	Yes, No
Brightness	1, 2, 3, 4, 5
Sleep Mode	OFF, 10, 20, 30 min
Date Time	Year/Month/Data/Hour/Minute
Return	

Setting Sound

This procedure will allow you to set Beep Volume, Button Volume, Alarm Volume.

Rotate the jog dial to highlight the Sound Menu Icon. Press the jog dial to display the setup menu.

Table 10. Sound Menu

Level 1 Menu	Level 2 Menu or Response
SETUP MENU	
Beep Volume	1, 2, 3, 4, 5, 6, 7
Button Volume	1, 2, 3, 4, 5, 6, 7
Alarm Volume	1, 2, 3, 4, 5, 6, 7
Return	

SpO_2 and Pulse Rate Menu

Table 11. Waveform Menu

Level 1 Menu	Level 2 Menu or Response
Waveform MENU	
Sweep Speed	6.25 mm/s, 12.5 mm/s, 25.0 mm/s
Tabular Trend	
Graphical Trend	
Return	

Sweep Speed

The user-selectable Sweep Speed determines the speed at which the SpO_2 waveform trace moves across the screen. ***Sweep Speed*** can be selected from 6.25 mm/s, 12.5 mm/s and 25.0 mm/s, and the SpO_2 waveform is synchronized with the ECG waveform.

Table 12. SpO_2 Menu

Level 1 Menu	Level 2 Menu or Response
SpO_2 MENU	
(Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(SpO_2 Alarm Inhibition)	On, Off
Return	

SpO_2 Alarm Inhibition

When the SpO_2 alarm inhibition is set to ***On***, the audible alarm for SpO_2 limit violation is inhibited.

Table 13. Pulse Rate Menu

Level 1 Menu	Level 2 Menu or Response
Pulse Rate MENU	
(Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(PR Alarm Inhibition)	On, Off
Return	

PR Alarm Inhibition

When the PR alarm inhibition is set to ***On***, the audible alarm for PR limit violation is inhibited.

Alarms and Limits

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

WARNING: Each time the unit is used, check alarm limits to make sure that they are appropriate for the patient being monitored.

General

When the unit detects certain conditions that require user attention, the unit enters an alarm state.

Note: The audible and visual alarms on the unit, used in conjunction with clinical signs and symptoms, are the primary source for notifying medical personnel that a patient alarm condition exists.

Alarm Priority and Messages

There are three possible priorities for visual and audible alarms: High, Medium, and Low. Refer to **Troubleshooting** section for the recommended actions.

Table 14. Alarm Messages

Priority	Condition	Messages
High	Loss of Pulse from SpO2	SpO2 Loss of Pulse
	Critically Low-Battery condition	Critically Low-Battery condition
Medium	High/Low Pulse Rate limits violated	High Pulse Rate limits violated
		Low Pulse Rate limits violated
	High/Low SpO2 limits violated	High SpO2 limits violated
		Low SpO2 limits violated
Low	SpO2 – Technical Error Messages Note: All SpO2 Error Codes have corresponding recovery code. Errors will be handled by its recovery code. The following messages are the results of all recovery codes.	SpO2 Error - EEE001 ~ SpO2 Error: EEE511
		SpO2 Module Reset
		Reconnect / Replace SpO2 sensor
		Reposition / Replace SpO2 sensor
		Replace SpO2 sensor
	SpO2 Cable/Sensor Disconnect	SpO2 Cable/Sensor Disconnect
	Sensor Off from SpO2 Sensor	SpO2 Sensor Off
	Low Battery	Low Battery
	Technical System Error	EEE 700 ~
Informative	SpO2 Sensor Adjust Condition	SpO2 Weak pulse
		SpO2 Weak signal
		SpO2 Motion Interference
		SpO2 Excess Infrared light
		SpO2 Electrical/Optical Interference
		High Pulse Amplitude
	SpO2 Sensor Adjust Messages	SpO2 Sensor: Alternate site?
		SpO2 Sensor: Cover sensor site?
		SpO2 Sensor: Ear/Forehead sensor?
		SpO2 Sensor: Nasal/Ear sensor?

Priority	Condition	Messages
Informative	SpO2 Sensor Adjust Messages	SpO2 Sensor: OxiMax adhesive sensor?
		SpO2 Sensor: Secure cable
		SpO2 Sensor: Headband
		SpO2 Sensor: Warm site
		SpO2 Sensor: Bandage assembly
		SpO2 Sensor: Nail polish
		SpO2 Sensor: Sensor too tight?
		SpO2 Sensor: Reposition sensor
		SpO2 Sensor: Isolate interference source
		SpO2 Sensor: Clean sensor site
	SpO2 Pulse search	SpO2 Pulse search
	Abnormally shut down last time	Abnormally shut down last time
	Exit Scrolling in Trend Screens	Press Knob to Exit Scroll
	Exit Graphical Trend Screen	Press Home switch to Exit Graphical trend
	Exit Tabular Trend Screen	Press Home switch to Exit Tabular trend
	Alarm suspend	Alarm suspend
	Alarm inhibition	Alarm inhibition

Note: Informative conditions indicate a system condition that needs to be corrected.

Visual Alarm Indication

Table 15. Visual Alarm Characteristics

Alarm Condition	Color	Flashing Rate
High priority	Red	5 flashes in 3 seconds (approximately 1.7Hz)
Medium priority	Yellow	5 flashes in 8 seconds (approximately 0.6Hz)
Low priority	Yellow	Always on (non-flashing)

Note: SpO2 alarm indicator and Pulse rate alarm indicator on the front panel respond with the flashing rates described in Table 15 when an alarm occurs.

Audible Alarm Indication

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

The audible alarm has different tone pitch and on-off beep patterns for each alarm priority.

Table 16. Audible Alarm Characteristics

Alarm Category	Tone Pitch	Beep Rate
High priority	~976 Hz	10 beeps in 15 sec
Medium priority	~697 Hz	3 beeps in 15 sec
Low priority	~488 Hz	1 beeps in 30 sec

Setting Alarm Limit

WARNING: Each time the unit is used, check alarm limits to make sure that they are appropriate for the patient being monitored.

You can change alarm limits from default values, if necessary. These changes remain in effect until they are modified again, or until the unit is turned off.

Setting Alarm Limits via Alarm Limits Menu

1. Rotate the jog dial to highlight the ***Alarm Limits Icon*** on the lower of the screen, then press the jog dial to display the ***Alarm Limits Menu.***
2. Press the jog dial to select ***Alarm Limits***. The monitor will display all alarm limits that are currently in effect for all monitored parameters. Select the alarm limits to set.

Table 17. Alarm Limits Menu

Level 1 Menu	Level 2 Menu or Response
ALARM LIMITS MENU	
Print on Alarm	On, Off
Alarm Limits	PR, SpO_2,
	Alarm Inhibition for each parameter
Alarm Limits Display	On, Off
Return	

Alarm Limits Ranges

Table 18 describes the possible alarm limits. The unit is shipped with factory default settings.

Table 18. Alarm Limits Ranges

Parameters	High limit, Default	Low limit, Default	Resolution
Pulse Rate (BPM)	31 to 250, 170 (Adult/Pediatric), 190 (Neonatal)	30 to 249, 40 (Adult/Pediatric), 90 (Neonatal)	1 BPM
SpO_2 (%)	21 to 100, 100 (Adult/Pediatric), 95 (Neonatal)	20 to 99 , 95 (Adult/Pediatric), 80 (Neonatal)	1 %

Verifying Visual and Audible Alarm Indication

If the unit fails to perform as specified in this test, contact qualified service personnel or your local supplier for assistance.

1. Press ***Power on/off button*** to turn on the unit.
2. Connect the simulator to sensor input cable and connect cable to unit.
3. Set the simulator to smaller value than the %SpO_2 lower alarm limit on the unit.
4. Verify following the unit reaction:
    a. The pulse oximeter begins to track the physiological signal from the simulator.
    b. After about 10 to 20 seconds, the unit displays the value measured as specified by simulator. Verify values are within the tolerances specified in **Specification** section for each parameter
    c. Audible alarm sounds.
    d. %SpO2 alarm indicator on the front panel flashes.

Note: The maximum mean time of the alarm delay is less than 10 seconds other than specified in this manual.

Audible Alarm Silence

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

When an alarm occurs, you can silence the audible alarm for the audible alarm silence period (30, 60, 90 or 120 seconds) selected via service menu. However, visual alarms continue during this time. The factory default for audible alarm silence period is 60 seconds.

To silence an audible alarm:

1. Press the ***Alarm Stop Button*** to immediately silence the alarm tone. The alarm resumes after the audible alarm silence period if the alarm condition has not been corrected.

2. Check the patient and provide appropriate care.

During the audible alarm silence period, you can press the ***Alarm Stop Button*** again to re-enable the audible alarm tones. Also, if another alarm occurs during the audible alarm silence period, the audible alarm tones will be automatically re-enabled.

Note: The audible alarms caused by some technical errors may be canceled by pressing the ***Alarm Stop Button***. However, battery failure and physiological alarms cannot be canceled until the alarm condition is corrected.

Audible Alarm Suspend/Inhibition

WARNING: If an alarm condition occurs while in the Alarm Suspend state, the only alarm indication on the monitor will be visual displays related to the alarm condition.

There are two modes to disable the audible alarm.

1. Audible Alarm Suspend Mode
2. Audible Alarm Inhibition Mode

To initiate an audible alarm suspend or inhibition:

1. To initiate an audible alarm suspend or inhibition, press the ***Alarm Stop Button*** and hold it for at least 2 seconds.
2. To cancel an audible alarm suspend or inhibition condition, press the ***Alarm Stop Button*** for 2 seconds again.

Note: You may disable limit violation alarms of each vital sign via the ***PR or SpO2, Alarm Limits menus***.

This action disables audible alarms for a user-defined ***Alarm Suspension Period*** (10, 20, 30 or 60 minutes) selected via the Service Menu.

If Alarm Suspension Period is set to ***10, 20, 30*** or ***60*** minutes, the audible alarm is not activated for the specified time interval and the message ***"Audible alarm suspended"*** is displayed.

If ***OFF*** is selected, the audible alarm suspend or inhibition is not allowed to activate.

If ***Indefinite*** is selected, the audible alarm is inhibited and the message ***"Audible alarm inhibited"*** is displayed. The alarm inhibition state will be terminated by pressing the ***Alarm Stop Button*** for at least 2 seconds.

In the alarm inhibition state, an ***Alarm Reminder Tone*** will sound at the preset interval to remind the user that the audible alarm is inhibited.
The preset interval for an ***Alarm Reminder Tone*** can be set to ***OFF***, ***3*** or ***10 minutes*** via the Service Menu. If ***OFF*** is selected, the ***Reminder Tone*** will be disabled.

Note: The periods can only be changed by authorized personnel via the *Service Menu*.

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Maintenance

WARNING: The cover should be removed only by qualified service personnel. There are no internal user-replaceable parts except for the battery.

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

WARNING: Remove batteries from the unit before cleaning the unit.

Recycling and Disposal

When the unit, battery, or accessories reach the end of useful life, recycle or dispose of the equipment according to appropriate local and regional regulations.

Returning the P30 and System Components

Contact Mediana Technical Support Representative for shipping instructions including a Returned Goods Authorization (RGA) number. Pack the unit with sensors, cable or other accessory items in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect the unit during shipping. Ship the unit according to instructions received from Mediana..

Service

The unit requires no routine service other than cleaning, battery maintenance, and service activity which is mandated by the user's institution. For more information, refer to the service manual. Qualified service personnel in the user's institution should perform periodic inspections of the unit. If service is necessary, contact qualified service personnel or Mediana Technical Support Representative.

Periodic Safety Checks

It is recommended that the following checks be performed every 24 months.

- Inspect the equipment for mechanical and functional damage.
- Inspect the external safety labels for legibility.

Cleaning

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

- Quatemary Ammonium
- Alcohol-70% Isopropyl
- 10% Chlorine bleach solution
- PDI Sani-System

For sensors, follow cleaning instructions in the directions for use shipped with those components.

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

Battery Maintenance

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

Note: The battery should be removed from the unit if placed in storage or will not be used for a long period.

Troubleshooting

WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the unit is functioning correctly.

WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside except for the battery.

General

If the unit detects an error, it can display an error code. The error codes are listed in the service manual. If an error code is displayed, write down the code and contact your service department. Before calling Mediana Technical Support Representative, make sure that the battery is charged and that all power connections are in place.

Corrective Action

If you experience a problem while using the unit and are unable to correct it, contact qualified service personnel or Mediana Technical Support Representative. The service manual provides additional troubleshooting information for qualified personnel.

Following is a list of possible errors and suggestions for corrective action.

1. There is no response to the Power button.

- The battery may be missing or the polarity may be not placed properly. (see **Battery Operation** section).

2. The unit screen does not function properly and the power-on beep tones do not sound.

- Do not use the unit; contact qualified service personnel or Mediana Technical Support Representative.

3. When the alarm condition occurs, check the following items.

- Follow the check item in the below table to remove the alarm condition

EMI (Electromagnetic Interference)

WARNING: Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the unit can cause inaccurate measurement readings. Do not rely entirely on the unit readings for patient assessment.

WARNING: It is possible that any radio frequency transmitting equipment and other nearby sources of electrical noise may result in disruption in the unit operation.

WARNING: It is possible, although unlikely, that large equipment using a switching relay for its power on/off may affect unit operation. Do not operate the unit in such environments.

This device has been tested and found to comply with the limits for medical devices to the IEC60601-1-2, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments (such as electrosurgical equipment, defibrillator, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may affect the unit operation.

WARNING: The unit is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the unit may not seem to operate correctly.

Monitor disruption may be indicated by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site to determine the source of this disruption. Try the following actions to see if they eliminate the disruption:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this equipment.

The unit generates, uses, and can radiate radio frequency energy. If the unit is not installed and used in accordance with these instructions, the unit may cause harmful interference with other devices in the vicinity.

If assistance is required, contact Mediana Technical Support Representative.

Obtaining Technical Assistance

For technical information and assistance, or to order the service manual, call Mediana Technical Support Representative. The service manual provides information required by qualified service personnel when servicing the unit.

When calling Mediana Technical Support Representative, you may be asked to provide the software version number of your unit. The software version is displayed when unit power is first applied.

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Technical Information

Principles of Operation

The unit uses pulse oximetry to measure functional oxygen saturation in the blood. Because a measurement of SpO_2 is dependent upon light from the SpO_2 sensor, excessive ambient light can interfere with this measurement. SpO_2 and Pulse rate is updated every second.

Functional versus Fractional Saturation
This unit measures functional saturation — oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation — oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

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

Measured versus Calculated Saturation
When saturation is calculated from a blood gas partial pressure of oxygen (PO2), the calculated value may differ from the SpO2 measurement of the unit. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO2 and pH, temperature, the partial pressure of carbon dioxide (PCO2), 2, 3-DPG, and fetal hemoglobin.

Automatic Calibration
Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the *OXIMAX* sensor's red LED to accurately measure SpO_2. The wavelength range of the light emitted are near 660 nm and 890 nm with the energy not exceeding 15 mW. During monitoring, the instrument's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO_2.
Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Factory Default Settings

The P30 is shipped with factory default settings. Authorized personnel can use the procedures described in the service manual to change default settings.

Table 19. Parameter Ranges and Factory Defaults

Parameters	Ranges/Selections	Factory Defaults
Pulse Rate High Alarm Limits	31 to 250 bpm (1bpm steps)	170 bpm (Adult/Pediatric) 190 bpm (Neonatal)
Pulse Rate Low Alarm Limits	30 to 249 bpm (1bpm steps)	40 bpm (Adult/Pediatric) 90 bpm (Neonatal)
% SpO_2 Upper Alarm Limits	21 to 100 % (1 % steps)	100 %(Adult/Pediatric) 95% (Neonatal)
% SpO_2 Lower Alarm Limits	20 to 99 % (1 % steps)	85 %(Adult/Pediatric) 80% (Neonatal)
Sweep Speed	6.25, 12.5, 25.0 mm/s	12.5 mm/s
%SpO2 Limit Alarm Inhibition	On, Off	Off
PR Limit Alarm Inhibition	On, Off	Off
Patient Mode	Adult, Pediatric, Neonatal	Adult
Brightness	1,2,3,4,5	5
Sleep Mode	Off, 10, 20, 30 min	Off
Alarm Limits Display	On, Off	Off
Beep Volume	1,2,3,4,5,6,7	4
Button Volume	1,2,3,4,5,6,7	4
Alarm Volume	1,2,3,4,5,6,7	4

Specification

Display

Screen Size	32.2 mm × 40.3 mm
Screen Type	3 digit 7-segment / 8-segment LCD TN, Positive mode

Controls

Standard	3 soft buttons (Power, Alarm stop, Home) Jog dial

Alarms

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

Physical Characteristics

Instrument	
Dimensions	24 × 8 × 15 (mm) (W×H×D) excluding accessories
Weight	1.1kg excluding accessories

Electrical

Battery	
Three new batteries typically provide 4, 8 or 12 hours of monitoring with no external communication, no audible alarm sound and 25°C.	
Type	Li-ion
Voltage/Capacity	11.1 V

Environmental Conditions

Operation	
Temperature	10°C to 45°C (50°F to 113°F)
Humidity	15 % RH to 95% RH, non-condensing
Altitude	-390~3,012m
Transport and Storage (in shipping container)	
Temperature	−20°C to 70°C (−4°F to 158°F)
Humidity	15 % RH to 95% RH, non-condensing
Altitude	-390~5,574m
Note: The system may not meet its performance specifications if stored or used outside the specified temperature and humidity range.	

Performance

%Saturation		
Range	0% to 99%	
Accuracy	without interference	70% to 100% ±2 %
Pulse Rate		
Range	30 BPM to 254 BPM	
Accuracy	without interference	30bpm to 254bpm ±2 bpm

Compliance

Item	Compliant with
Classification	Internally powered
Type of protection	Type BF – Applied part
Mode of operation	Continuous
Degree of protection	Class IPX1 Drip-proof equipment
General	93/42/EEC Directives for medical devices
	21CFR820 Code of Federal Regulations 2002/96/EC Waste electrical and electronic equipment Directive.
	91/157/EEC Battery Declaration Directive
	93/86/EEC Battery Disposal Directive
	2006/66/EC Battery Directive
	EN ISO13485:2003 Quality Systems– Medical Devices –Particular requirements for the application of ISO9001
	EN ISO14971:2007 Risk analysis managements – medical devices
	EN 60601-1:1996 General requirements for Safety and Essential Performance
	EN60529:1992 Degree of Protection Provided by Enclosures Water Ingress Testing (IPX1)
	EN ISO14155-1:2003 Clinical investigation of medical devices for human subjects – part 1: General requirements
	AAMI HE48:1993 Human factors engineering guidelines and preferred practices for the design of medical devices
	EN60601-1-1:2001 Safety requirements for medical electrical systems
	EN60601-1-4:1996+A1:1999 Particular requirements for programmable medical systems
	EN60601-1-6:2004 Medical electrical equipment Part 1-6: General requirements for safety Collateral Standard: Usability
	EN ISO10993-1:2003 Biological evaluation of medical devices – Part 1: Evaluation and testing
	EN ISO10993-5:1999 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
	EN ISO10993-10:2002+A1:2006 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
Alarms	EN60601-1-8:2004 Alarm systems requirements, tests and guidances in medical electrical equipments systems
Oxygen saturation	EN ISO9919:2005 Basic safety & essential performance of Pulse oximeter for medical use

Item	Compliant with
Electromagnetic Compatibility	IEC60601-1, sub clause 36, IEC/ EN60601-1-2:2001 Electromagnetic compatibility-requirements & test
	EN61000-3-2:2006 Harmonic Emission Ed 3.0
	EN61000-3-3:1995+A1:2001+A2:2005 Voltage Fluctuations/Flicker Emission Ed 1.2
	EN61000-4-2:1995+A1:1998+A2:2001 Electrostatic Discharge Ed 1.2
	EN61000-4-3:2006 Radiated RF electromagnetic field Ed 2.1
	EN61000-4-4:2004 Electrical fast transient/burst Ed 2.0
	EN61000-4-5:2006 Surge current Ed 2.0
	EN61000-4-6:2007 Conducted disturbances, induced by RF field Ed 2.1
	EN61000-4-8:1993+A1:2001 Power frequency (50/60Hz) magnetic field Ed 1.1
	EN61000-4-11:2004 Voltage dips, short interruption and voltage variation on power supply input lines Ed 2.0
	CISPR11:1997 (EN55011:2007) RF Emissions Group 1, Class B
Package	ISTA: (Procedure 1A, 2001) Pre-Shipment Test Procedures (Package)
	ASTM D4169:2005 Standard Practice for Performance Testing of Shipping Containers and System
	EN60068-1:1994 Environmental Testing, Part 1: General Guidelines
Reliability	EN60068-2-6:1995 Environmental testing - vibration (sinusoidal)
	EN60068-2-64:1994 Environmental testing - vibration, broad-band random (digital control) and guidance
	EN60068-2-27:1993 Environmental testing - Shock
Labeling	EN1041:1998 Information supplied by the manufacturer with medical devices
Marking	IEC/TR60878:2003 Graphical symbols for electrical equipment in medical practice
	EN980:2003 Graphical symbols for use in the labeling of medical devices
	ISO7000:2004 Graphical symbols for use on equipment-index and synopsis
	EN60417-1:1999 Graphical symbols for use on equipment-overview and application
	EN60417-2:1999 Graphical symbols for use on equipment-symbol originals
	EN50419:2005 Marking of electrical and electronic equipment in accordance with article II (2) of directive 2002/96/EC (WEEE)

Manufacturer's Declaration

WARNING: For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the P30.

The P30 is suitable for use in the specified electromagnetic environment. The customer and/or user of the P30 should assure that it is used in an electromagnetic environment as described below;

Table 20. Electromagnetic Emissions (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	The P30 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The P30 is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emission IEC 61000-3-3	Complies	

Table 21. Electromagnetic Immunity (IEC60601-1-2)

Immunity Test	IEC60601-1-2 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	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric 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 and/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 and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply	<5 % U T (>95 % dip in UT) for 0.5 cycle	<5 % U T (>95 % dip in U T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the P30 requires continued operation during power mains interruption, it is recommended that the P30 be powered from an uninterruptible power supply or battery.
IEC 61000-4-11	40 % U T (60 % dip in UT) for 5 cycles	40 % U T (60 % dip in U T) for 5 cycles	
	70 % U T (30 % dip in UT) for 25 cycles	70 % U T (30 % dip in UT) for 25 cycles	

Immunity Test	IEC60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
	<5 % U T (95 % dip in UT) for 5 sec.	<5 % U T (95 % dip in UT) for 5 sec.	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	It may be necessary to position the P30 further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note: UT is the AC mains voltage prior to application of the test level.			

Table 22. Electromagnetic Immunity (IEC60601-1-2)

Immunity Test	IEC60601 test level	Compliance level	Electromagnetic environment guidance
The P30 is intended for use in the electromagnetic environment specified below. The customer or the user of the P30 should assure that it is used in such an environment.			
			Potable and mobile RF communications equipment should be used no closer to any part of the P30 including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz ~ 80 MHz	3 Vrms	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz ~ 800 MHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
	3 V/m 800 MHz ~ 2.5 GHz	3 V/m	$d = 2.3 \sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters as deter-mined 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 he 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.			

Immunity Test	IEC60601 test level	Compliance level	Electromagnetic environment guidance
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 P30 is used exceeds the applicable RF compliance level above, the P30 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the P30. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the P30. (IEC60601-1-2)

Table 23. Recommended Separation Distances

Recommended separation distance between Portable and mobile RF communications equipment and the P30			
The P30 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of he P30 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the P30 as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter in watt	**Separation distance according to frequency of transmitter in meter**		
	150 kHz to MHz $d = 1.2\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1.2\sqrt{P}$	***800 MHz to 2.5GHz*** $d = 2.3\sqrt{P}$
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 metres (m) can be estimated 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 80MHz and 800MHz, 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.			

Table 24. Cables (IEC60601-1-2)

Cables and Sensors	Maximum Length	Complies with
Non-terminated cable, RS-232, 9 pin "D"	10 ft. (3 m)	-RF emissions, CISPR 11, Class B/ Group 1 -Harmonic emissions, IEC 61000-3-2 -Voltage fluctuations/flicker emission, IEC 61000-3-3 -Electrostatic discharge (ESD), IEC 61000-4-2 -Electric fast transient/burst, IEC61000-4-4 -Surge, IE 61000-4-5 -Conducted RF IEC 61000-4-6 -Radiated RF, IEC 61000-4-3
Reusable SpO_2 sensor	3 ft (0.91 m)	

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Part Number: A7133-XA
Revised Date: 1008
Printed in Korea

CE
0434