HUNTLEIGH

Anwendungshinweise

Kullanım Talimatları

Brugsvejledning

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Οδηγίες χρήσης

Anwendungshinweise

smartsigns® LitePlus

Notice

Warranty

The information contained in this document is subject to change without notice.
Huntleigh Healthcare Ltd makes no warranty of any kind with regard to this material, including, but not limited to, the implied warranties or merchantability and fitness for a particular purpose. Huntleigh Healthcare Ltd shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

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.

Contents

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1. General Safety Information

This section contains important safety information related to general use of the Smartsigns® Liteplus vital signs monitor. Other important safety information appears throughout the manual

Important! Before using this equipment, please study this manual carefully and familiarise yourself with the controls, display features and operating techniques. Ensure each user fully understands the safety and operation of the unit, as misuse may cause damage to the unit or injury to the user or patient.

1.1 Warnings

Warnings are identified by the WARNING symbol shown and alert you to potential hazards.

WARNING: In the USA, do not connect to an electrical outlet controlled by a wall switch as the device may be accidentally turned off.

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

WARNING: Do not disconnect a power cord before the system shuts down as monitor settings may be lost.

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

WARNING: Do not touch the monitor when a defibrillator is being discharged (electrified), as doing so may cause electric shock. NIBP monitoring only in this monitor is protected against the discharge of a defibrillator. The other functions (SPO2, TEMP) are not protected. Please be sure of no other patient connections, except NIPB, before using the defibrillator.

WARNING: If the monitor does not shut down properly, the settings return to factory defaults.

WARNING: Check the equipment prior to use and ensure its safe and proper use.

WARNING: Do not autoclave the monitor.

WARNING: Explosion hazard. Do not use the unit in the presence of flammable anesthetics or gases. Do not operate in a hyperbaric chamber, in oxygen-enriched environments, or in any other potentially explosive environment.

WARNING: Before use, carefully read sensor or probe directions for use, including all warnings, cautions, and instructions.

WARNING: Do not use damaged cuffs, sensors and other cables. Do not immerse cuffs, sensors and other cables completely in water, solvents, or cleaning solutions as the connectors are not waterproof. Do not sterilize cuffs, sensors and other cables by irradiation, steam, or ethylene oxide. Refer to each cleaning instructions in the directions for use.

WARNING: If the battery shows any signs of damage, leakage, or cracking, it must be replaced immediately, by a qualified service person, and only with a battery approved by the manufacturer.

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

WARNING: The measurement of vital signs can be affected by patient conditions, motions, sensors, environmental condition and electromagnetic external condition.

WARNING: It is possible that any radio frequency transmitting equipment and other sources of electrical noise such as cellular phones, due to close proximity or strength of a source, may result in disruption of performance.

WARNING: To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

WARNING: Disconnect the monitor and sensors during magnetic resonance imaging (MRI) scanning. Use during MRI could cause burns or adversely affect the MRI image or the monitor's accuracy. Also, to avoid burns, remove the sensors from the patient before conducting MRI.

WARNING: During prolonged and continuous SpO_2 monitoring, check the sensor site at least once every 4 hours. Inspect the patient's skin integrity and circulation, and relocate the sensor if necessary. Tissue damage can result from improper or prolonged sensor attachment.

WARNING: Do not lift the monitor by a sensor cable or a power cord because the cable could disconnect from the monitor, causing the monitor to drop on the patient.

WARNING: The unit may not operate effectively on patients who are experiencing convulsions or tremors.

WARNING: To avoid burns, the temperature probe must remain in the probe well when turning the monitor on or off.

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

1.2 Cautions

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

CAUTION: Alert you to exercise care necessary for the safe and effective use of Smartsigns® Liteplus monitor. Inaccurate data may be measured if operated or stored at conditions outside the stated ranges, or subjected to excessive shock or dropping.

CAUTION: Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked 'Hospital Only' or 'Hospital Grade'.

CAUTION: The accuracy of the monitor may degrade if the monitor is connected to secondary I/O devices when the monitor is not connected to earth reference.

CAUTION: Never place fluids on the monitor. In case of fluid spilling on the monitor, disconnect power cord, wipe clean immediately and have the monitor serviced to ensure that no hazard exists.

CAUTION: The monitor may display error codes when outside of the measurable range occur.

CAUTION: Accessory equipment connected to the monitor'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 IEC60601-1-1 and the electromagnetic compatibility standard IEC60601-1-2. If in doubt, contact Huntleigh Healthcare Technical Services Department.

2. Introduction

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

This manual contains information about the Smartsigns® Liteplus vital signs monitor. The Smartsigns® Liteplus is available in the following configurations:

Config.	Features
NB	Standard (NIBP + Pulse Rate + Ni-MH Battery)
NSB	Standard + SpO_2
NTB	Standard + Temperature
NSTB	Standard + SpO_2 + Temperature
NPB	Standard + Printer
NSPB	Standard + SpO_2 + Printer
NTPB	Standard + Temperature+ Printer
NSTPB	Standard + SpO_2 + Temperature + Printer

Note: Refer to Specification Section for more information about each configuration.

All information in this manual, including the illustrations, are based on a monitor configured with the NIBP, Temperature, SpO_2, and Printer options. If your monitor configuration lacks any of these options, certain information in this manual does not apply.

2.1 Features of the Smartsigns® Liteplus

Physical

The Smartsigns® Liteplus vital signs monitor is a lightweight and compact vital signs monitor measuring 130×180×284 (mm) (H×D×W) and weighing 2.7 kg. Its carrying handle is designed for instrument transport while battery-powered monitoring.

Electrical

The monitor is powered by a Ni-MH type of internal battery pack. The batteries are continuously recharged when AC power (100-240 VAC, 50-60 Hz) is connected to the monitor. Details are described in the Battery Operation section.

Display

The monitor has an LED display which shows numeric patient information as well as alphanumeric status conditions and error codes.

Auxiliary Outputs

The monitor provides RS-232 I/O port for software upgrade or nurse call system. Refer to the RS-232 Interface section for additional information.

2.2 Intended Use

The purpose and function of the Huntleigh Healthcare Smartsigns® Liteplus vital signs monitor is to monitor non-invasive blood pressure (systolic, diastolic, and mean arterial pressures), functional arterial oxygen saturation, pulse rate for adult, pediatric and neonate patients and temperature for adult and pediatric patients in all hospital areas and hospital-type facilities. It may be used during hospital transport and in mobile, land-based environments, such as ambulances, within the specification of the environmental characteristics.

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

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

Note: The medically skilled and trained user can be clinicians like doctors and nurses who know how to take and interpret a patient's vital signs. These clinicians must take direct responsibility for the patient's life. This can include care-givers or medically trained interpreters who are authorised under the appropriate clinical facility procedures to support patient care. Any inappropriate setting, especially the alarm limit or alarm notification settings, can lead to a hazardous situation that injures, harms or threatens the patient's life. This equipment should only be operated by trained users who can adjust the settings of the patient monitor.

2.3 About This Manual

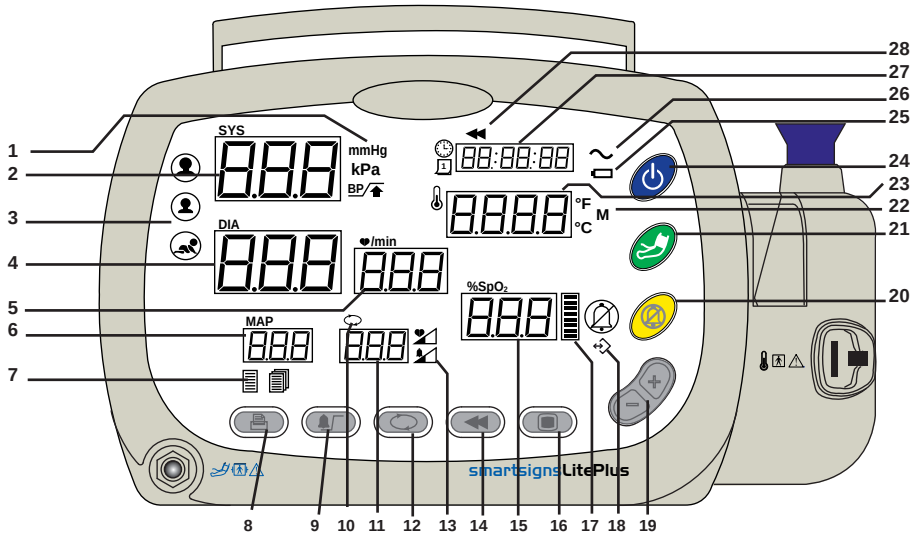
This manual explains how to set up and use the Smartsigns® Liteplus vital signs monitor. Important safety information relating to general use of the monitors appears before this introduction. Other important safety information is located throughout the text where applicable.

All users should read this manual thoroughly. More experienced users of the Smartsigns® Liteplus will be able to go to the topics for the information they require.

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

3. Description of Controls, Indicators, Symbols and Displays

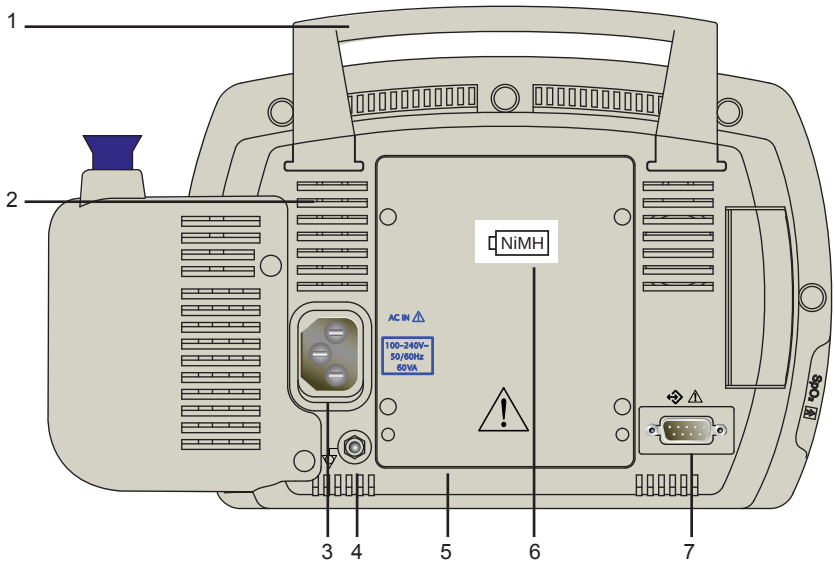
3.1 Identification of Front Panel Controls and Symbols



1	Blood Pressure Unit Indicators	15	%SpO2 Display
2	Systolic Blood Pressure Display	16	Mode Button
3	Patient Type Indicators	17	Pulse Amplitude Indicator
4	Diastolic Blood Pressure Display	18	Alarm Silence Indicator
5	Pulse Rate Display	19	Up/Down Selection Button
6	MAP (Mean Arterial Pressure) Display	20	Alarm silence button
7	Print Setting Indicators	21	NIBP start/stop button
8	Print Button	22	Temperature Unit/Mode Indicators
9	Alarm Button	23	Temperature Display
10	Auto Indicator	24	Power Button
11	Auto Cycle Display	25	Battery Indicator
12	Auto Button	26	Charging/AC in Indicator
13	Pulse Tone/Alarm Volume Setting Indicators	27	Time Display
14	Review Button	28	Review Indicator

Figure 1. Front Panel Controls and Symbols

3.2 Identification of Rear Panel Components and Symbols



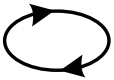
1	Handle	4	Equipotential (Ground)
2	Air Ventilator	5	Battery Cover (Replacement)
3	AC Power Connector	6	Battery Label
7	RS-232 Data Interface		

Figure 2. Rear Panel Components and Symbols

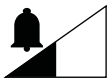
3.3 Description of Symbols/ Indicators

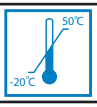
The symbols and Indicators are described as follows:

Table 1. Display Symbols/Indicators

Symbols	Description
	Attention, consult accompanying documents.
	Type BF applied part
	Type BF – Defibrillator proof
	Equipotentiality
	Data interface
	**Review Indicator** is lit when the user select the Review button to see the patient history.
	**Auto Indicator** is on whenever NIBP automatic timed cycles are enabled.
	**Charging/AC in Indicator** is on whenever AC power is present from the wall (even if the monitor is off and is not under battery charging). The Charging/AC in indicator flashes while the battery is charging, and then remains illuminated once the battery is maintained with a trickle charge.

Symbols	Description
	**Battery Indicator** indicates the state of the battery. This indicator is on when the monitor uses battery power. This indicator will be flashing when the battery needs charging. It is not reset unless AC power cord has been plugged in for battery charging.
	**Alarm Silence Indicator** is on continuously whenever the unit is in Alarm Silence mode.
°F	**Temperature in degrees Fahrenheit** is configured to display temperature in degrees Fahrenheit.
°C	**Temperature in degrees Celsius** is configured to display temperature in degrees Celsius.
M	**Temperature in Monitor mode** is configured to take temperature in the monitor mode. This indicator is off when the temperature is being taken using the predictive method.
	**Patient type: Adult** is on when the Patient type is adult.
	**Patient type: Paediatric** is on when the Patient type is paediatric.
	**Patient type: Neonatal** is on when the Patient type is neonatal.
mmHg	**NIBP unit: mmHg** is on when the NIBP unit setting is mmHg.
kPa	**NIBP unit: kPa** is on when the NIBP unit setting is kPa.

Symbols	Description
	**Target Pressure Setting Indicator** is flashing when the NIBP target inflation pressure is under the setting for NIBP measurement.
	**Time Indicator** is on when the actual time is displayed on the time/date numeric display area. It is flashing when it is selected to set the time in configuration mode.
	**Date Indicator** is on when the actual date is displayed on the time/date numeric display area. It is flashing when it is selected to set the date in configuration mode.
	**Manual Print Indicator** is on when the print setting is set to Manual Print.
	**Stream Print Indicator** is on when the print setting is set to Stream Print.
	**Pulse Tone Volume Setting indicator** is flashing when the pulse tone volume setting is selected in setting mode.
	**Alarm Volume Setting Indicator** is flashing when the alarm volume setting is selected in setting mode.
	**Network Indicator** is flashing when the monitor is set to software upgrade mode.
	AC Power Rating Input
	Disposal Instructions

Symbols	Description
	Manufacturer
	Date of Manufacture
CE 0088	CE Mark
	UL Mark
IPX2	Dust and Water Resistance
REF	Reference Number
SN	Serial Number
  	Environmental shipping / storage temperature limitations
	Fragile - Handle with Care
	This Way Up
	Keep Dry

3.4 Description of Controls

Table 2. Controls

Controls	Description
	**Power Button** turns the monitor on or off when pressed for over 1 second.
	**NIBP start/stop button** initiates NIBP measurement when pressed. If the NIBP start/stop button is pressed again during the measurement, it will cancel the current reading.
	**Alarm Silence Button** allows you to silence a patient alarm temporarily and also is used to acknowledge (cancel) other non-patient alarms.
	**Up/Down Selection Buttons** allows you to select items within a particular settable feature in several different modes. If the Up or Down selection button is pressed and held, the unit will scroll through the available selections as if the button is being pressed repeatedly while the button is held in.
	**Print Button (Option)** sends the data to the printer and prints current onscreen readings if a printer is installed in the monitor. Pressing the Print button during print-out stops printing.
	**Review Button** allows the user to review or to erase measurement data in the memory. If pressed and held for more than 3 seconds, the monitor will erase the data.
	**Auto Button** puts the monitor in Auto interval selection mode, allowing the user to take automatic blood pressures at a selected increment.
	**Alarm Button** puts the monitor into Alarm Set mode, allowing the user to set alarm limits for Systolic, Diastolic, MAP, Pulse rate and SpO_2.
	**Mode Button** puts the monitor into the Settings or Configuration mode. Once the monitor is in one of these modes, the Mode button will be used to cycle through the configuration options of the specific menu mode.

4. Setting up the Monitor

WARNING: The Smartsigns® Liteplus is a prescription device and is to be operated by qualified personnel only. It is designed for use by medical clinicians. Although this document might illustrate medical monitoring techniques, the monitor must be used only by trained clinicians who know how to take and interpret a patient's vital signs.

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

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

WARNING: To ensure patient safety, do not place the monitor in any position that might cause it to fall on the patient.

WARNING: Do not lift the monitor by the sensor cables or power cord because the cable could disconnect from the monitor, causing the monitor to drop on the patient.

WARNING: Disconnect the monitor and sensors/cables during magnetic resonance imaging (MRI) scanning. Using the monitor during MRI may cause burns or adversely affect the MRI image or the monitor's accuracy.

WARNING: To ensure accurate performance or prevent device failure do not subject the monitor to extreme moisture, such as direct exposure to rain. Such exposure may cause inaccurate performance or device failure

WARNING: Do not use the Smartsigns® Liteplus vital signs monitor, SpO_2 sensors, temperature probes or connectors that appear damaged.

WARNING: Discarded battery may explode during incineration. Follow local government ordinances and recycle instructions regarding disposal or recycling of device components, including batteries.

WARNING: Do not touch the monitor when a defibrillator is being discharged (electrified), as doing so may cause electric shock. NIBP monitoring only in this monitor is protected against the discharge of a defibrillator. The other functions (SPO2, TEMP) are not protected. Please be sure of no other patient connections, except NIPB, before using the defibrillator.

WARNING: Ensure that the speaker is clear of any obstruction. Failure to do so could result in an inaudible alarm tone.

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

CAUTION: Recycle used batteries properly. Do not dispose of batteries in refuse containers.

4.1 Unpacking and Inspection

The Smartsigns® Liteplus vital signs monitor is shipped in one carton. Examine the carton carefully for evidence of damage. Contact Huntleigh Healthcare Ltd Technical Services Department immediately if any damage is discovered. Return all packing material and monitor. Refer to the Maintenance section for instructions on returning damaged items.

Set the monitor to the user's intended position where the user can easily recognise the visual and audible monitoring conditions. Normally it is recommended to set at a distance of 1 metre from the user. Also, the viewpoint is at any point within the base of a cone by an angle of 30° to the centre of the monitoring display.

4.2 List of Components

Quantity	Item
1	Smartsigns® Liteplus Vital signs monitor
1	NIBP Cuff adult (23 - 33 cm)
1	NIBP Cuff small adult (17 - 25 cm)
1	NIBP Cuff child (12 - 19 cm)
1	NIBP Hose adult/paediatric
1	Temperature Probe with Temperature option configured
1	Temperature Probe Cover with Temperature option configured
1	SpO_2 Sensor with SpO_2 option configured
1	Pulse Oximetry Cable with SpO_2 option configured
1	Operator's Manual
1	Power Cord (applicable to country of sale)
1 pack	Printer Paper with Printer option configured

A range of additional accessories are available for the Smartsigns® Liteplus. Please contact the Customer Services Department for more information.

4.3 Power Cable Connections

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

CAUTION: For the safety of patients, use only a Huntleigh Healthcare Ltd supplied power cord. Using a non approved power cord can damage the monitor, and will void the product warranty. If in doubt about the integrity of the AC power source, the monitor must be operated from its internal battery.

AC Power

Ensure that the AC outlet is properly grounded and that it is the specified voltage and frequency (100-240 VAC, 50-60 Hz).

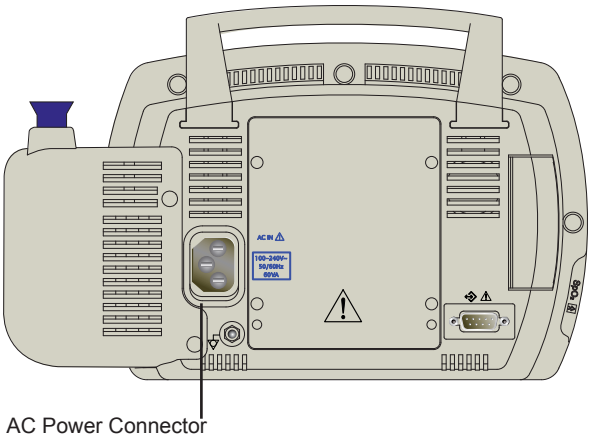


Figure 3. AC Power Connection

1. Connect the female connector end of the AC power cord to the monitor rear panel connector.
2. Plug the male connector end of the AC power cord into a properly grounded AC outlet.
3. Verify that the Charging/AC in Indicator is lit. This indicator will be flashing if the battery needs charging.
4. If necessary, connect the grounding wire. Connect the grounding wire connector to the equipotential terminal on the rear panel. Attach the clip end of the grounding wire to the medical equipment grounding terminal on the wall.

Note: If the Charging/AC in Indicator is not lit, check:

- the power cord
- the AC power inlet

4.4 Measurement Cable Connections

WARNING: Do not lift the monitor by the sensor cables, or power cord because the cable could disconnect from the monitor, causing the monitor to drop on the patient.

NIBP Hoses and Cuffs

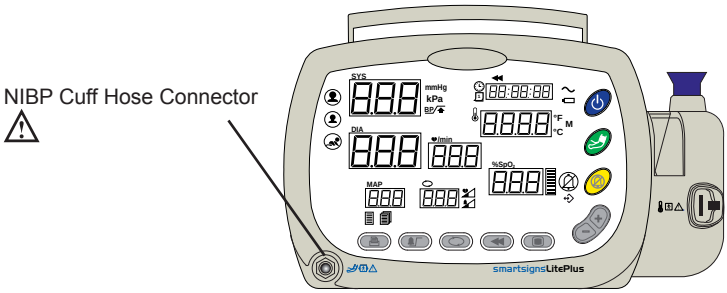


Figure 4. NIBP Cable Connections

1. Select the appropriate size cuff for the patient (Refer to the NIBP Monitoring section) and apply the cuff to the selected site.
2. Connect the hose to the right panel NIBP connector (see Figure 4).

Note: For the safety of patients, and to ensure the best product performance and accuracy, use only a cuff and a hose provided with the Smartsigns® Liteplus, or a cuff and hose recommended by Huntleigh Healthcare Ltd Technical Services.

4.5 SpO2 Cables and Sensors

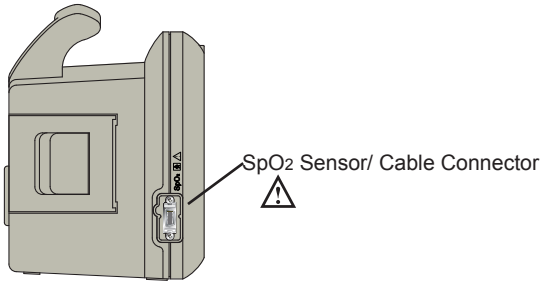


Figure 5. SpO2 Sensor/Cable Connections

1. Select an appropriate sensor for the patient and desired application.
2. Apply the sensor to the selected site.
3. Connect the sensor to the cable.
4. Connect the cable to the right panel SpO2 connector (see Figure 5).

Note: For the safety of patients, and to ensure the best product performance and accuracy, use only Huntleigh Healthcare Ltd provided tsensor pulse oximetry cables and SpO_2 sensors.

4.6 Temperature Probes

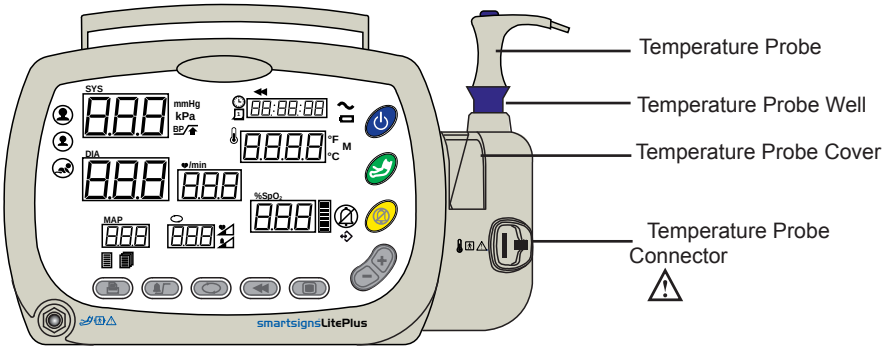


Figure 6. Temperature Probe Connections

1. Insert the plug into the compatible jack on the monitor right panel.

Note: For the safety of patients, and to ensure the best product performance and accuracy, use only Huntleigh Healthcare Ltd provided temperature probes (see Figure 6).

Note: The temperature probes are available from Huntleigh Healthcare Ltd sales department. For the safety of patients, and to ensure the best product performance and accuracy, use only temperature probes that have passed the recommended biocompatibility testing in compliance with ISO10993-1.

5. Battery Operation

WARNING: Dispose of Battery in accordance with local requirements and regulation. Follow local instructions regarding disposal or recycling of batteries.

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

CAUTION: Measured or displayed data may not be assured in the low battery or the critical low battery condition.

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

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 of internal battery if necessary.

5.1 Operating on Battery Power

The monitor has an internal battery that can be used to power the monitor during transport or when AC power source is not available.

Table 3. Front Panel Indications in accordance with power operation

Condition			Indicators
Monitor	**AC Power**	**Battery**	
No operation	Connected	Full charged	‘Charging/AC in’ on
No operation	Connected	Charging	‘Charging/AC in’ flashing
Operation	Connected	Full charged	‘Charging/AC in’ on
Operation	Connected	Charging	‘Charging/AC in’ flashing
Operation	Disconnected	Normal battery status	‘Battery’ on
Operation	Disconnected	Low battery status	‘Battery’ flashing

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

A new, fully charged battery will provide the following operating times under each condition:

Table 4. Operating time in accordance with battery conditions

Type	Conditions	Operating Time
NI-MH	without any measurement and printing at 25°C	10 hours
	with an NIBP measurement per 15 minutes, continuous SpO_2 measurement and no printing	8 hours

5.2 Charging a Low Battery

1. Connect the monitor to AC power in order to charge a low or dead battery. (see 'Setting up the Monitor' section)

Note: A full charge of a depleted Ni-MH battery takes approximately 8 hours while the monitor is turned off.

5.3 Low Battery Indication

The Battery Indicator flashes when the remaining battery power is only enough for about 10 minutes of operation. The monitor will also sound an audible alarm. This will inhibit the monitor from printing. This audible alarm can be silenced by pressing the Alarm silence button. Connecting the monitor to AC power will terminate the alarm.

A battery status of approximately 3-minutes operation will inhibit the monitor from taking NIBP inflation.

After a critical low battery alarm sounds for about 5 seconds, the monitor will automatically shut down. You should connect the monitor to an AC power source to avoid any loss of monitor settings and trend data.

6. Using the Monitor

WARNING: To avoid burns, the probe must remain in the probe well when turning the monitor on or off.

WARNING: If the POST (power on self-test) is not completed successfully, do not use the monitor.

WARNING: Ensure that the speaker is clear of any obstructions. Failure to do so could result in an inaudible alarm tone.

WARNING: Disconnect the monitor and sensors/cables during magnetic resonance imaging (MRI) scanning. Using the monitor during MRI may cause burns or adversely affect the MRI image or the monitor's accuracy.

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

WARNING: The Smartsigns® Liteplus is a prescription device and is to be operated by qualified personnel only. It is designed for use by medical clinicians. Although this document might illustrate medical monitoring techniques, the monitor must be used only by trained clinicians who know how to take and interpret a patient's vital signs.

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

6.1 Turning on the Monitor

Before using the Smartsigns® Liteplus, verify that the monitor is working properly and is safe to use. Proper working condition will be verified each time the monitor is turned on as described in the following procedure.

Note: Physiological conditions, medical procedures, or external agents that may interfere with the monitor's ability to detect and display measurements, include dysfunctional hemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied coloring agents such as nail polish, dye, or pigmented cream.

Note: The parameters may be set on an individual basis, by the clinician, and these settings will remain in effect until the monitor is turned off.

6.2 Performing Power On and Self-Test (POST)

CAUTION: The Smartsigns® Liteplus automatically starts the Power-On-Self-Test, which tests the monitor circuitry and functions. During POST (immediately after power-up), confirm that all display segments and indicators are illuminated and the power on beep tone sounds.

CAUTION: If any indicator or display element does not light, or the speaker does not sound, do not use the monitor. Contact qualified service personnel or Huntleigh Healthcare Ltd Technical Service Department.

1. Turn on the monitor ON by pressing the Power button.
2. The monitor automatically starts the Power On Self Test (POST), which tests monitor circuitry and functions.
3. Ensure the monitor sounds the power-on beep tones, and all displays and indicators are illuminated for 3 seconds.

CAUTION: The power-on beep tones will not be heard if Sound mode is set to 3 (Mute) via Service mode. It may cause the hazard that speaker failure cannot be detected during the POST. This hazard must be ackknowledged to the operator before sound mode is set to 3 (Mute) in risk control point of view

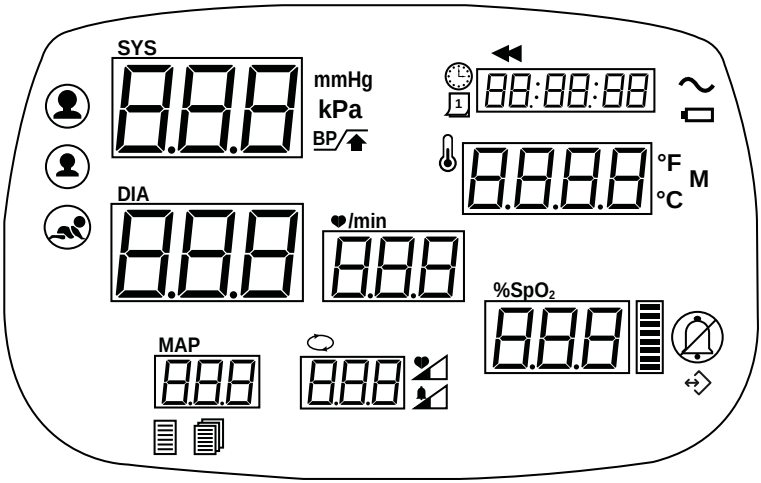


Figure 7. Power On Self Test

4. If the Smartsigns® Liteplus detects an internal problem during POST, the monitor will display an error code. Contact qualified service personnel or Huntleigh Healthcare Ltd Technical Services Department.
5. Upon successful completion of the POST, the monitor enters Normal mode.

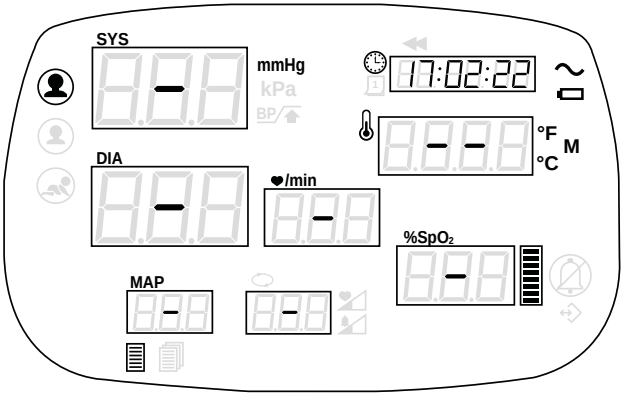


Figure 8. Normal Mode Before Measurement

Note: If the segment of 'SYS', 'DIA' and 'MAP' displays is blinking, do not use the monitor and contact qualified service personnel or Huntleigh Healthcare Ltd Technical Services Department because this symptom indicates that an internal problem may occur.

6.3 Setting Date and Time

This procedure will enable you to set current date and time of the monitor.

Note: The date format may be selected either 'year/month/day' or 'day/ month/ year' via Service mode.

With the monitor in the normal monitoring mode:

1. Press and hold the Mode button for 3 seconds until the monitor enters Configuration mode.
2. Press the Mode button twice until the Time indicator and Hour set are flashing. Set current time to increment Hour up and down between 0 and 23, using the Up/Down (+/-) selection buttons.
3. Press the Mode button until the Time indicator and Minute set are flashing. Set current minute between 00 and 59, using the Up/Down (+/-) selection buttons.
4. Press the Mode button until the Time indicator and Second set are flashing. Set current second between 00 and 59, using the Up/Down (+/-) selection buttons.
5. Press the Mode button until the Date indicator and Year set are flashing. Set current year, using the Up/Down (+/-) selection buttons.

6. Press the Mode button until the Date indicator and Month set are flashing. Set current month, using the Up/Down (+/-) selection buttons.

7. Press the Mode button until the Date indicator and Day set are flashing. Set current day, using the Up/Down (+/-) selection buttons.

8. Pressing buttons other than the Mode button also returns to normal operation. If there is no activity for 5 seconds, the monitor will return to normal operation.

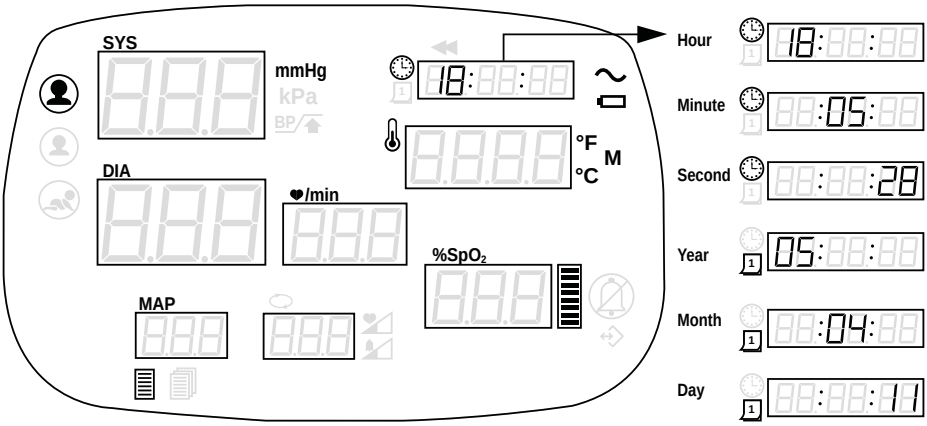


Figure 9. Date and Time Setting

6.4 Setting Patient Type

This procedure will allow you to select Patient Type: Adult, Pediatric or Neonatal.

With the monitor in the normal monitoring mode:

1. Press the Mode button until the Patient type indicators are on (a selected Patient type indicator is shown flashing).
2. Select a desired patient type, using the Up/Down (+/-) selection buttons.
3. Press any other button to return to normal operation. If there is no activity for 3 seconds, the monitor will return to normal operation.

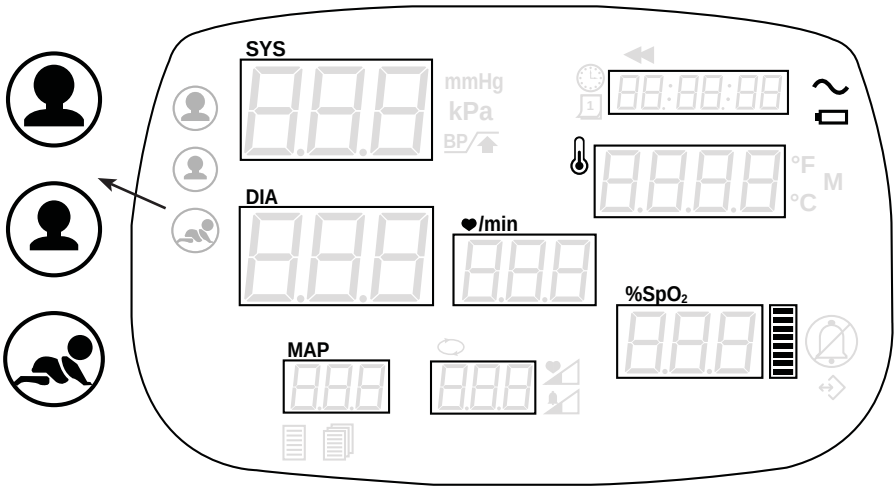


Figure 10. Patient Type Setting

6.5 Setting NIBP Units

This procedure will allow you to select a NIBP measurement unit either mmHg or kPa.

With the monitor in the normal monitoring mode:

1. Press and hold the Mode button for 3 seconds or more until the monitor enters Configuration mode. Once the monitor is in the Configuration mode, current NIBP unit is flashing on the display.

2. Select a NIBP unit either mmHg or kPa, using the Up/Down (+/-) selection buttons.

3. Press any other button to return to normal operation. If there is no activity for 3 seconds, the monitor will return to normal operation.

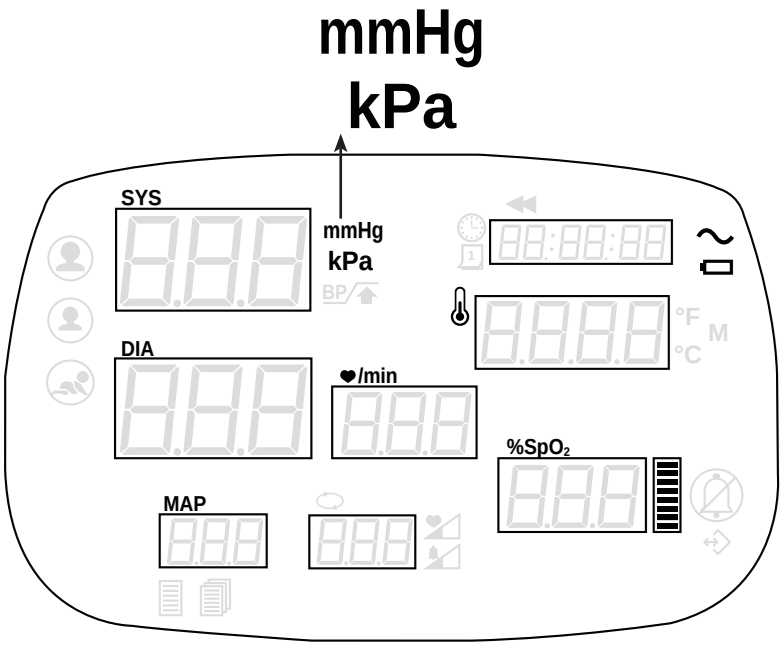


Figure 11. NIBP Units Setting

6.6 Setting Temperature Units and Modes

This procedure will allow you to set temperature type and measurement units, providing the monitor has the temperature option. You can display the temperature measurement in either Celsius (°C) or Fahrenheit (°F). Also you may select whether to use Monitor mode or Predictive mode for taking temperatures. For more information, refer to Temperature Monitoring section of this manual.

With the monitor in the normal monitoring mode:

1. Press the Mode button until the Temperature units and modes are on (a selected unit/mode is shown flashing).

2. Select desired temperature unit and mode, using the Up/Down (+/-) selection buttons.

   Fahrenheit Predictive (°F) Fahrenheit Monitored (°F M)

   Celsius Predictive (°C) Celsius Monitored (°C M)

3. Press any other button to return to normal operation. If there is no activity for 3 seconds, the monitor will return to normal operation.

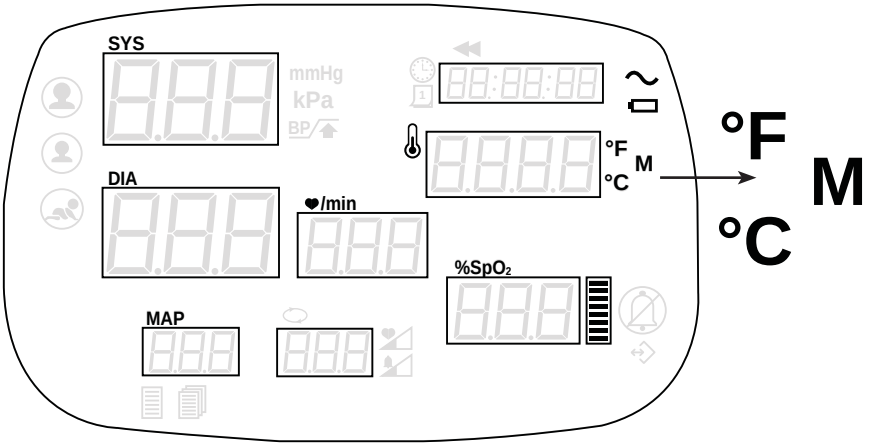


Figure 12. Temperature Units and Modes Setting

6.7 Setting Pulse Tone Volume

This procedure will enable you to set Pulse Tone Volume.

With the monitor in the normal monitoring mode:

1. Press the Mode button until the Pulse Tone Volume setting indicator and current pulse tone volume are displayed.

2. Select a level of pulse tone volume between 0 and 8, using the Up/Down (+/-) selection buttons.

3. Press any other button to return to normal operation. If there is no activity for 3 seconds, the monitor will return to normal operation.

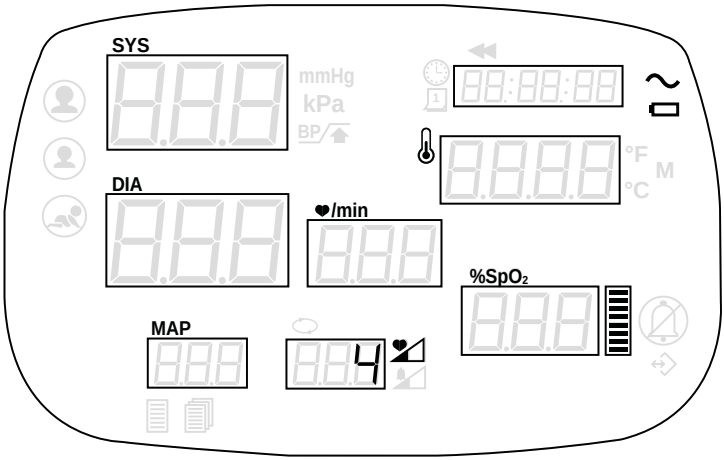


Figure 13. Pulse Tone Volume Setting

6.8 Setting Alarm Volume

This procedure will enable you to set audible Alarm Volume.

With the monitor in the normal monitoring mode:

1. Press the Mode button until the Alarm Volume setting indicator and current alarm volume are displayed.

2. Select a level of alarm volume between 1 and 8, using the Up/Down (+/-) selection buttons.

3. Press any other button to return to normal operation. If there is no activity for 3 seconds, the monitor will return to normal operation.

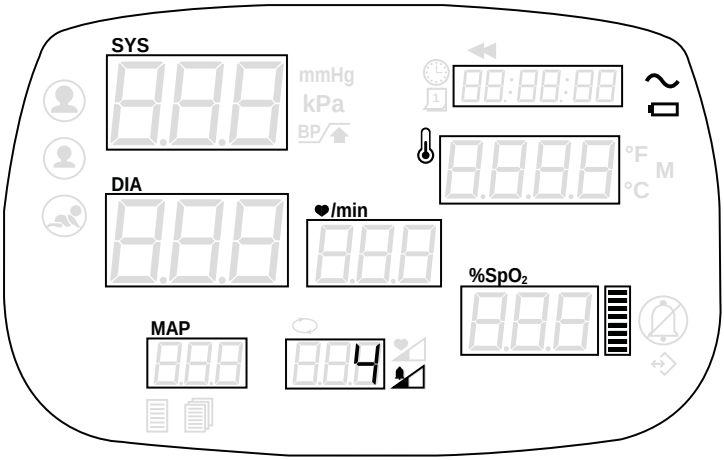


Figure 14. Alarm Volume Setting

6.9 Resetting to Factory Defaults

Following procedure will allow you to reset the monitor operating parameters to the factory default settings.

With the monitor powered off:

1. Simultaneously press the Power button and the NIBP start/stop button.
2. The monitor runs a self-test and then displays the current monitor software version.
3. Press the Mode button until " DEFAULT RESET=NO" is displayed.
4. To leave the settings unchanged, select 'NO' using only the Down (-) selection button.

   To reset the operating parameters to the factory default values, select 'YES' using only the Up (+) selection button. The monitor immediately resets to the defaults and the confirmation tone sounds.
5. To return to normal operation, turn the monitor off; then restart.

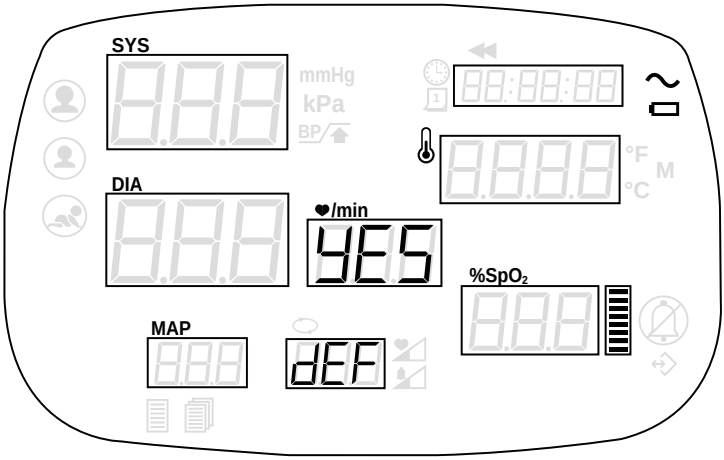


Figure 15. Factory Defaults Setting

7. NIBP Monitoring

WARNINGS: For the safety of patients, and to ensure the best product performance and accuracy, use only the cuffs and the hose provided with the monitor, or recommended by Huntleigh Healthcare Ltd Technical Services. Using other cuffs or hoses may result in inaccuracies.

WARNING: Inaccurate measurements may be caused by incorrect cuff application or use, such as placing the cuff too loosely on the patient, using the incorrect cuff size, or not placing the cuff at the same level as the heart, leaky cuff or hose, and excessive patient motion.

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

WARNING: The Smartsigns® Liteplus is not intended for diagnostic treatment. To ensure patient safety, use other diagnosis equipments.

WARNING: The monitor displays results of the last blood pressure measurement until another measurement starts. If a patient's condition changes during the time interval between measurements, the monitor will not detect the change or indicate an alarm condition.

WARNING: Any excessive patient motion may cause inaccurate measurements of non-invasive blood pressure. Make sure there is no patient motion affected to blood pressure measurements.

WARNING: The blood pressure cuff should not be applied to the same extremity as the one to which an SpO_2 sensor is attached, since cuff inflation will disrupt SpO_2 monitoring and lead to nuisance alarms.

WARNING: Check the patient's limb on which the cuff is applied to assure that circulation is not constricted. Constriction of circulation is indicated by discoloration of the extremity. This check should be performed at the clinician's discretion at regular intervals based on the circumstances of the specific situation.

WARNING: In some cases, rapid, prolonged cycling of an oscillometric, noninvasive blood pressure monitor cuff has been associated with any or all of the following: ischemia, purpura, or neuropathy. Apply the oscillometric cuff appropriately, according to instructions, and check the cuff site and cuffed extremity regularly when blood pressure is measured at frequent intervals or over extended periods of time.

WARNING: Never place the cuff on extremity being used for intravenous infusion or any area where circulation is compromised or has the potential to be compromised. Never fit NIBP system with Luer Lock adapters that can be connected to IBP or injection systems.

WARNING: As with all automatically inflatable blood pressure devices, continual cuff measurements can cause injury to the patient being monitored. Weigh the advantages of frequent measurement and/or use of STAT mode against the risk of injury.

WARNING: During use on patients, ensure that heavy objects are not placed on the hose. Avoid crimping or undue bending, twisting, or entanglement of the hose.

WARNING: Never use an adult or pediatric monitor setting or cuff for an NIBP measurement on a neonatal patient. Adult and pediatric inflation limits can be excessive for neonatal patients, even if a neonatal cuff is used.

WARNING: NIBP readings may be inaccurate for patients experiencing moderate to severe arrhythmia.

WARNING: Do not touch the monitor when a defibrillator is being discharged (electrified), as doing so may cause electric shock. NIBP monitoring only in this monitor is protected against the discharge of a defibrillator. The other functions (SPO2, TEMP) are not protected. Please be sure of no other patient connections, except NIPB, before using the defibrillator.

Note: A patient's vital signs may vary during administration of agents affecting the cardiovascular system, such as those used to raise or lower blood pressure or raise or lower heart rate.

Note: Blood pressure measurements can be affected by the position of the patient, the patient's physiological condition, and other factors.

7.1 General

NIBP processing by the monitor uses the oscillometric measuring technique. A motorized pump inflates the cuff to initially block the flow of blood in the extremity. Then, under monitor control, the pressure in the cuff is gradually reduced, while a pressure transducer detects air pressure and transmits a signal to the NIBP circuitry.

When the cuff pressure is still above systolic pressure, small pulses or oscillations in the cuff pressure begin to be sensed by the transducer. As the cuff continues to deflate, oscillation amplitude increases to a maximum and then decreases. When maximum oscillation amplitude occurs, the cuff pressure at that time is measured as mean arterial pressure (MAP). The systolic and diastolic pressures are calculated based on analysis of the oscillation amplitude profile.

Note: This equipment is suitable for use in the presence of electrosurgery

7.2 Setup Connections

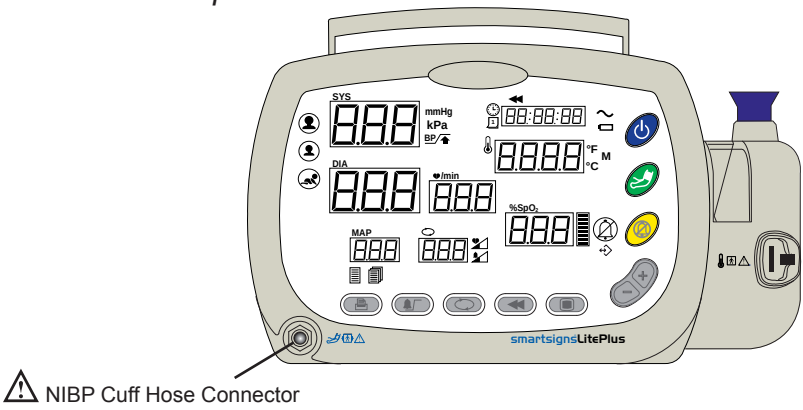


Figure 16. NIBP Setup Connections

For the safety of patients, and to ensure the best product performance and accuracy, use only the cuffs and the hose provided with the monitor or recommended by Huntleigh Healthcare Ltd Technical Services.

1. Measure the patient's limb and select the proper size cuff. As a general rule, cuff width should span approximately two-thirds of the distance between the patient's elbow and shoulder.

2. Connect the hose to the bottom of left corner of the monitor as shown Figure 16. Push until you hear a click, indicating that the connection is secure.

3. Connect a cuff to the cuff hose and push until you hear a click, indicating that the connection is secure.

4. Wrap the cuff around a bare arm or around an arm covered in thin clothing. Thick clothing or a rolled up sleeve will cause a major discrepancy in the blood pressure reading.

5. Wrap the cuff around the patient's arm so that the centre of the cuff's rubber bladder sits on the artery of the upper arm. The hose should be brought out from the peripheral side without bending. (The Brachial artery is located on the inside of the patient's upper arm.) At this time, check that the index line on the edge of the cuff sits inside the range. Use a different size cuff if the index line is outside of the range, as this will cause a major discrepancy in blood pressure readings.

CAUTION: The adult cuff should be wrapped around the arm tightly enough so that only two fingers can be inserted under it, above and below the cuff.

6. Maintain the height of the cuff-wrapped upper arm artery to that of the heart's right ventricle during measurement.

7. Follow the cuff directions for use when applying the cuff to the arm.

Table 5. Cuff Size

Patient Group Setting	Cuff	Hose	Circumference Range
Neonate	Neonate (single use)	Neonatal Hose	3 - 6cm
			4 - 8cm
			6 - 11cm
			7 - 13cm
			8 - 15cm
Paediatric	Infant APC	Adult Hose	8 - 13cm
	Child APC		12 - 19cm
Adult	Small Adult APC		19 - 25cm
	Adult APC		23 - 33cm
	Large Adult APC		31 - 40cm
	Thigh APC		38 - 50cm

7.3 NIBP Measurement Modes

Blood pressure measurements can be made in three modes:

- MANUAL mode - One measurement of each systolic/diastolic/mean arterial pressure.
- Automatic (AUTO) mode - Measurements at preset intervals.
- STAT mode - As many measurements as possible within a 5-minute period.

7.4 Description of NIBP Operation

Setting Initial Inflation Pressure

With the monitor in the normal monitoring mode:

1. Press the Mode button twice until current NIBP target inflation is displayed.
2. Change NIBP target inflation to be desired, using the Up/Down (+/-) selection buttons.
3. Press any other button to return to normal operation. If there is no activity for 3 seconds, the monitor will return to normal operation.

The numeric display in the lower right corner of the NIBP frame indicates the setting of the initial inflation pressure. The initial inflation pressure can be set from 120 to 260 mmHg for adult (120 to 170 mmHg for pediatric, 80 to 140 mmHg for neonatal), in intervals of 10 or 20mmHg. You may select an initial cuff inflation pressure. This is particularly important with children, since an initial cuff inflation pressure of factory default, 160 mmHg for adult (120 mmHg for pediatric, 90 mmHg for neonatal) may be uncomfortable, and is typically higher than it needs to be.

When NIBP Smart Inflation is set to OFF via Service Mode: in MANUAL mode the cuff pressure is inflated until the inflation value selected by user, In AUTO/STAT Mode, the cuff pressure is inflated until the inflation value selected by user in initial measurement and, from the next measurement, the inflation value for Adult and Pediatric patients will be last Systolic BP value + 50mmHg and the inflation value for Neonatal patients will be last systolic BP value + 30mmHg.

When NIBP Smart Inflation is set to ON via Service Mode: in MANUAL mode, the suitable inflation value for the Adult and Pediatric patient is automatically calculated during the inflation, and the inflation value for the Neonatal patient is initial inflation value selected by the user. In AUTO/STAT mode, the suitable inflation value for the Adult and Pediatric patient is automatically calculated during the inflation in initial measurement and, from the next measurement, the inflation value will be last systolic BP value +50mmHg. Also, the inflation value for the Neonatal patient is initial inflation value selected by user in initial measurement and, from the next measurement, the inflation value for Neonatal patient will be last systolic value +30mmHg.

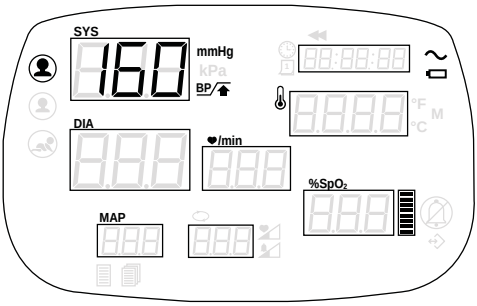


Figure 17. Initial Inflation Pressure

Initiating MANUAL mode of NIBP operation

1. Press the NIBP start/stop button.

A single blood pressure measurement will be made. As soon as an NIBP measurement begins, the SYS display shows the current cuff pressure.

Systolic, diastolic, and MAP values are presented when the measurement is completed. The measurements remain in the numeric display for 2 minutes or until another NIBP cycle begins.

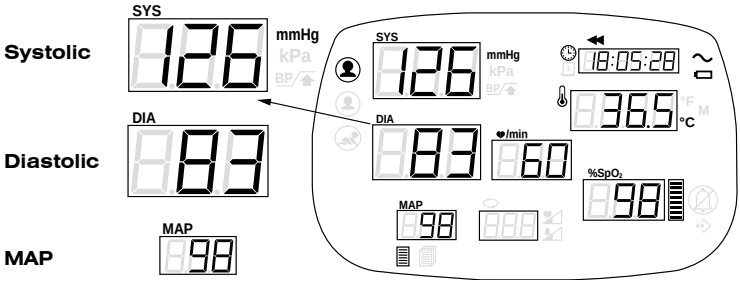


Figure 18. Manual mode of NIBP operation

Initiating AUTO mode of NIBP operation

1. Press the Auto button. The latest selected interval is displayed.

2. Press the Up/Down (+/-) selection buttons to cycle through the options, which include (-), STAT, and a range of intervals:1, 2, 3, 4, 5, 10, 15, 30, 45, 60, 90, 120, and 240 minutes for taking automatic blood pressures. The dash (-) indicate that automatic measurement is turned off.

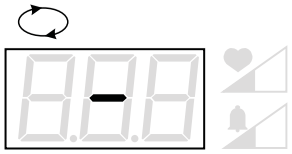


Figure 19. Indication of Auto Mode Turn-Off

Upon selection, automatic measurement is activated and the initial measurement will be made immediately after you select an interval.

The AUTO indicator is flashing when s selected for the automatic mode interval. After the first cycle, the cuff target pressure is not used; rather, the cuff inflates to a pressure level 20~30 mmHg above the previous systolic reading.

The automatic NIBP cycles continue until one of the following occurs:

- The monitor reaches the 5-minute limit for a STAT measurement.
- The monitor halts because the NIBP start/stop button is pressed.
- The monitor halts because the Auto button is pressed.
- The monitor halts because of an alarm, alert, or error condition.
- The AUTO cycle is changed to '-'.

Note: During Auto mode, if an NIBP limit violation alarm occurs, this alarm disables any automatic NIBP measurement until the alarm is released.

Figure 20. Auto Mode Setting (i.e.) – 15 minute Period

Note: The interval is the time from the beginning of one measurement cycle to the beginning of the next measurement cycle.

Note: The selected interval is displayed on the Auto cycle display. The countdown timer for initiating next measurement is displayed on the Time display.

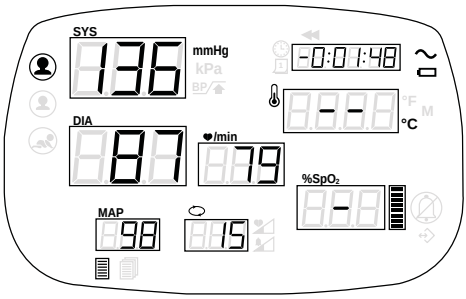


Figure 21. Auto Mode of Measurement

Initiating STAT mode of NIBP operation

1. Press the Auto button. The latest selected interval is displayed.

2. Press the Up/Down (+/-) selection buttons to set STAT.
   Upon selection, automatic measurement is activated and the initial measurement will be made in 3 seconds after you select an interval.

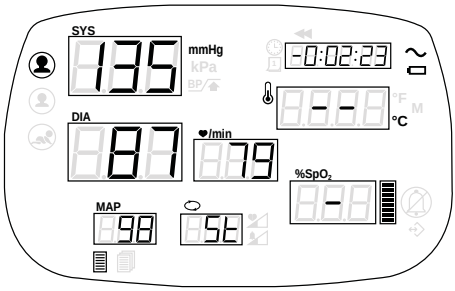


Figure 22. STAT Mode Setting

With the selected interval STAT, the monitor takes repeated NIBP measurements for 5 minutes. Current cuff pressures are not dynamically displayed during a STAT reading. The measurement displays the NIBP reading from the previous cycle until the current cycle finishes. (Before the first cycle finishes, the display appears blank.)

Note: During STAT mode, if an alarm, alert, or error condition occurs, the STAT measurement will be terminated.

Stopping Blood Pressure Measurements

1. Press the NIBP start/stop button at any time that you wish to stop the current measurement and deflate the cuff. If AUTO or Stat mode is underway, the mode including interval time will be reset.

Note: During AUTO mode, pressing the NIBP start/stop button at the time before the next auto measurement starts will cancel the AUTO mode and will be made a single blood pressure measurement (MANUAL mode).

8. SpO2/Pulse Rate Monitoring

WARNING: Tissue damage can be caused by incorrect application or use of an SpO_2 sensor, for example by wrapping the sensor too tightly or by applying supplemental tape. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity and 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: Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

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

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**
- **the patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia**
- **there is arterial occlusion proximal to the sensor the patient is in cardiac arrest or is in shock**

WARNING: Loss of pulse signal can occur in any of the following situations:

- **the sensor is too tight**
- **there is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight**
- **a blood pressure cuff is inflated on the same extremity as the one to which an SpO_2 sensor is attached**

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

CAUTION: The sensor disconnect error 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: Inaccurate readings could result if a sensor is used incorrectly. Before using a sensor, carefully read and understand the sensor directions for use. Periodically check to see the sensor remains properly positioned on the patient and that skin integrity is acceptable. Refer to sensor directions for use.

CAUTION: To ensure the best product performance and accuracy, use only Huntleigh Healthcare Ltd provided SpO_2 sensors for SpO_2 measurements. Other SpO_2 sensors may cause improper performance.

8.1 General

The Smartsigns® Liteplus uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying an OXIMAX sensor to a pulsating arteriolar vascular bed. SpO_2 and Pulse rate is updated every second. The OXIMAX sensor contains a dual light source and photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2). Because a measurement of SpO_2 is dependent upon light from the OXIMAX sensor, excessive ambient light can interfere with this measurement.

8.2 Setup Connections

Use only provided sensor pulse oximetry cables and SpO_2 sensors with the monitor.

Biocompatibility testing has been conducted on sensors in compliance with ISO10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing. The sensors have passed the recommended biocompatibility testing and are therefore in compliance with ISO10993-1.

When selecting a sensor, consider patient's weight and activity, adequacy of perfusion, availability of sensor sites, need for sterility, and anticipated duration of monitoring. For more information, refer to Table 6, or contact to Huntleigh Healthcare Ltd sales department.

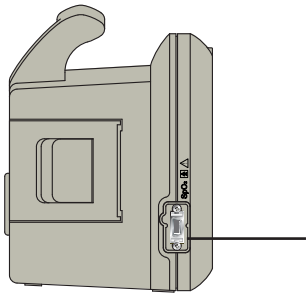


Figure 23. SpO_2 Setup Connections

1. Observe all warnings and cautions in the directions for use.

2. Carefully apply the sensor to the patient, as described in the sensor directions for use. The sensor may be connected directly to the connector. Typically, however, it is more convenient to connect the sensor to the monitor by using an SpO_2 pulse oximetry cable.

Table 6. SpO_2 Sensors

Sensor	Model	Patient Size
OXIMAX Durasensor ® Oxygen transducer (Reusable, non-sterile)	DS-100A	>40 kg
OXIMAX oxygen transducer (Sterile, single-use only)	MAX-N	<3 or >40 kg
OXIMAX oxygen transducer (Sterile, single-use only)	MAX-A	>30 kg
OXIMAX Oxyband ® Oxygen transducer (Reusable, non-sterile)	OXI-P/I	3 kg to 30 kg
OXIMAX adhesive reflectance oxygen transducer	MAX-FAST	>40 kg

8.3 Description of Pulse Rate Operation

The monitor displays the pulse rate during SpO2 measurements. It displays NIBP pulse information only if no SpO2 reading is available.

During the measurement period, the pulse amplitude indicator rises and falls in rhythm with the monitored pulse rate. The pulse amplitude indicator is a segmented display showing the relative strength of the detected pulse. As the detected pulse becomes stronger, more bars light with each pulse.

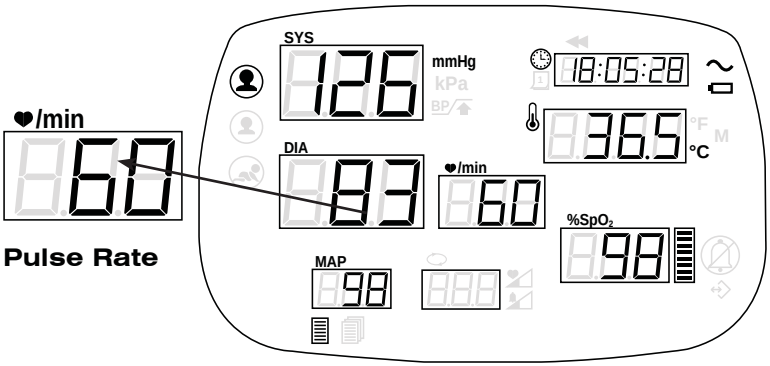


Figure 24. Pulse Rate Operation

8.4 Description of SpO2 Operation

SpO2 Operation

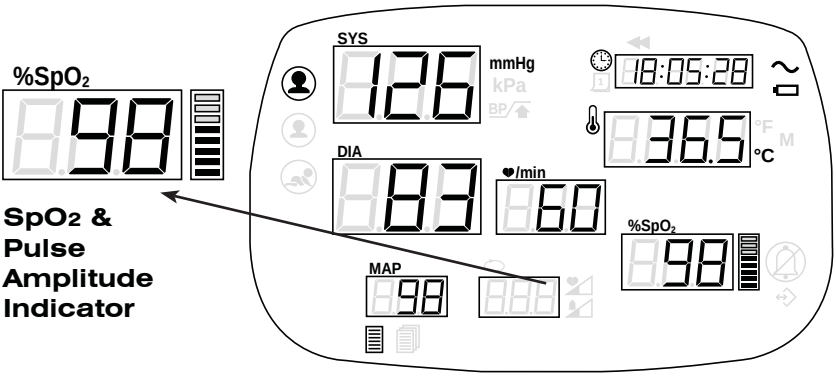


Figure 25. SpO2 Operation

Functional versus Fractional Saturation

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

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

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO_2), the calculated value may differ from the SpO_2 measurement of the monitor. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and pH, temperature, the partial pressure of carbon dioxide (PCO_2), 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 660nm and 890nm 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.

Adjusting Pulse Tone Volume from SpO_2 signal

For the setting the pulse tone volume, refer to section 6.7, of this manual.

1. Press the Mode button until the Pulse Tone Volume setting indicator and current pulse tone volume are displayed.

2. Select a level of pulse tone volume between 0 and 8, using the Up/Down (+/-) selection buttons.

9. Temperature Monitoring

WARNING: To avoid burns, the probe must remain in the probe well when turning the monitor on or off.

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

WARNING: To ensure patient safety and to obtain accurate and reliable temperature results, read this section thoroughly before using the temperature instrument.

WARNING: To limit patient cross-contamination, use only manufacturer's recommended single-use disposable probe covers. The use of any other probe cover, or the failure to use a probe cover, can endanger patients in the electrical risk point of view and produce inaccurate temperature measurements.

WARNING: Never re-use a probe cover. Discard, without using it, any probe cover that makes contact with any heat source (including hands and fingers) prior to use.

WARNING: Use of a probe at the wrong site produces inaccurate measurements and can cause patient injury.

WARNING: Use extreme caution when taking rectal temperatures on children. Insert the probe tip only 3/8-inch (~1 cm) to avoid risk of bowel perforation.

WARNING: The thermometer consists of high-quality precision parts. Protect it from severe impact or shock. Do not use the thermometer if you notice any signs of damage to the probe or the instrument.

WARNING: Do not use the temperature instrument for any purpose other than those described in this document. Doing so will invalidate the product warranty.

WARNING: The probe must remain in steady contact with the sublingual pocket throughout the measurement period; otherwise, the monitor fails to accurately predict the temperature.

WARNING: Never insert the probe, without disregarding a used probe cover, into the probe well to keep the probe well clean (decontaminated). Remove a used probe cover or replace a probe cover whenever the probe needs to be returned to the probe well.

WARNING: Never wipe the inside of the probe well with water-damped cloth during the cleaning. It may cause any electrical risks.

9.1 General

This section applies if the monitor is configured with the temperature option.

Measurement of patient temperature is accomplished by processing the signal from a probe containing a resistance element whose impedance is temperature dependent. These devices are called thermistors. The signal from the probe is conditioned by the monitor input circuitry, processed, and the measured values are shown in the numeric frame.

9.2 Setup Connections

WARNING: To limit patient cross-contamination, use only manufacturer's recommended single-use disposable probe covers. The use of any other probe cover, or the failure to use a probe cover, can endanger patients in the electrical risk point of view and produce inaccurate temperature measurements.

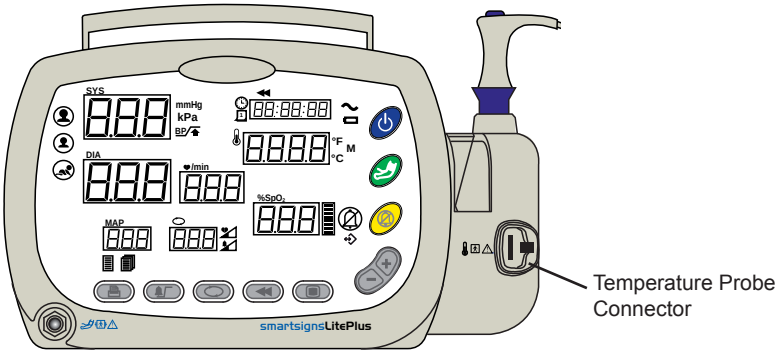


Figure 26. Temperature Setup Connections

Follow the directions for use accompanying the temperature probe.

Note: Use only provided temperature probes which have passed the recommended biocompatibility testing in compliance with ISO10993-1.

Note: If temperature probes are not readily available, contact Huntleigh Healthcare Ltd sales department. To avoid nuisance limit alarms,the probe should be affixed to the patient before connecting to the monitor's right panel connector.

9.3 Temperature Measurement Modes

Temperature measurements can be made in two modes:

- **PREDICTIVE mode**

is a one-time measurement that takes only a few seconds. It results in a single temperature reading which is displayed at the end of the brief measurement period.

- **MONITORED mode**

is a continuous measurement over an indefinite period. The current temperature displayed dynamically throughout the measurement period.

9.4 Description of Temperature Operation

Setting the Temperature Measurement Mode

For the setting the Temperature measurement mode, refer to section 6.6 of this manual.

1. Press the Mode button until the Temperature units and modes are on (a selected unit/mode is shown flashing).

2. Select desired temperature unit and mode, using the Up/Down (+/-) selection buttons.

Note: If there is no activity for 3 seconds, the monitor will return to normal operation.

Table 7. Indication of Temperature Measurement Mode

Indication	Temperature Mode
°C	Celsius Predictive
°C M	Celsius Monitored
°F	Fahrenheit Predictive
°F M	Fahrenheit Monitored

Taking a Predictive Measurement

To take a predictive temperature (Celsius Predictive or Fahrenheit Predictive indicator shall be on), follow these steps:

Note: Verify that the temperature measurement type is set to predictive. (Indicator 'M' is not illuminated.)

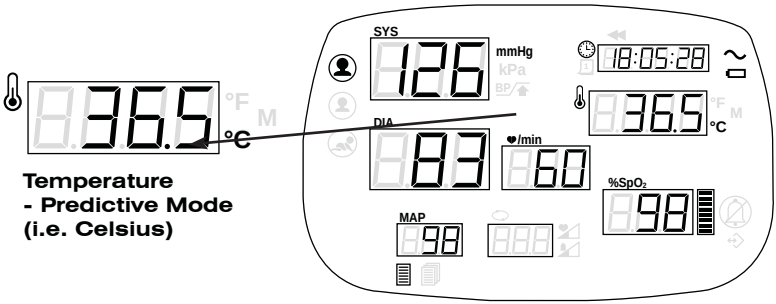


Figure 27. Temperature – Predictive Mode

Oral Measurement

1. Remove the temperature probe from the probe well. The temperature probe runs a self-test, displaying '888.8' for a few seconds. When it is ready for use, verify "OrL" appears in the temperature display. If not, press the Up/Down (+/-) selection buttons to select Oral or Axillary.

2. Put a new probe cover on the probe tip. Verify that the cover locks into position.

3. Insert the tip of the probe into the mouth—under the tongue and against a sublingual pocket.

4. Hold the probe in place until the measurement is complete.
   When the temperature prediction is complete (usually about 10 seconds later), the monitor briefly sounds a tone and displays the temperature reading, which persists for one minute.

Note: Use only a blue-capped probe for oral temperatures.

Note: The probe must remain in steady contact with the sublingual pocket throughout the measurement period; otherwise, the monitor fails to accurately predict the temperature.

Note: During the measurement period, the temperature window displays a "walking box"—a box with the sides illuminated sequentially. When the measurement is complete, the monitor sounds a tone and displays the measurement in the temperature window.

5. Eject the probe cover by pressing the ejection button, and hygienically dispose of it.

6. Return the probe into the probe well.

If the monitor cannot make a predicted measurement, it takes a monitored temperature. (See “Taking a Monitored Measurement” on page 52.)

Possible reasons for a failure to predict are the following:

- The measured temperature is too high or
- The ambient temperature too low or
- The temperature measurement varies too much during the prediction period.

If a probe position error occurs during the temperature determination, the temperature displays “P”.

Axillary Measurement

1. Remove the temperature probe from the probe well. The temperature probe runs a self-test, displaying ‘888.8’ for a few seconds. When it is ready for use, verify “ALY” appears in the temperature display. If not, press the Up/Down (+/-) selection buttons to select Oral or Axillary.

2. Put a new probe cover on the probe tip. Verify that the cover locks into position.

Note: Use only a blue-capped probe for axillary temperatures.

Note: During the measurement period, the temperature window displays a “walking box”—a box with the sides illuminated sequentially. When the measurement is complete, the monitor sounds a tone and displays the measurement in the temperature window.

Note: Be sure that nothing touches the probe tip before you place it in the axillary measurement site. If the probe tip is moved after it first makes contact, the measurement is unreliable.

3. Lift the patient’s arm to fully expose the axilla.

4. Place the probe tip as high as possible in the axilla, and then bring the patient’s arm down to make maximum contact with the probe tip. Hold the patient’s arm in this position, keeping the patient as still as possible, for the duration of the measurement.
   When the temperature prediction is complete (usually about 10 seconds later), the monitor briefly sounds a tone and displays the temperature reading, which persists for one minute.

5. Eject the probe cover by pressing the ejection button, and hygienically dispose of it.

6. Return the probe into the probe well.

If the monitor cannot make a predicted measurement, it takes a monitored temperature. (See “Taking a Monitored Measurement” section.)

Possible reasons for a failure to predict are the following:

- The measured temperature is too high or
- The ambient temperature too low or
- The temperature measurement varies too much during the prediction period.

Be sure that the probe tip is fully covered by the axilla and the arm, and that it is not touching any clothing.

If a probe position error occurs during the temperature determination, the temperature displays “P”.

Rectal Measurement

1. Remove the temperature probe from the probe well.
   The temperature probe runs a self-test, displaying ‘888.8’ for a few seconds. When it is ready for use, the monitor clears the temperature display. “rEC” appears in the temperature display.

2. Load a probe cover onto the probe.

3. Apply a thin coat of water-based lubricant to the probe tip.

4. Separate the patient’s buttocks with one hand.

5. Insert the probe tip 1 centimeter (3/8-inch) inside the rectal sphincter. Tilt the probe slightly to ensure good tissue contact, and keep the buttocks separated throughout the duration of the measurement.
   When the temperature prediction is complete (usually about 10 seconds later), the monitor briefly sounds a tone and displays the temperature reading, which persists for one minute.

Note: Use only a red-capped probe for rectal temperatures.

Note: During the measurement period, the temperature window displays a “walking box”—a box with the sides illuminated sequentially. When the measurement is complete, the monitor sounds a tone and displays the measurement in the temperature window.

6. Remove the probe.

7. Eject the probe cover by pressing the ejection button, and hygienically dispose of it.

8. Return the probe into the probe well.

If a probe position error occurs during the temperature determination, the temperature displays “P”.

Taking a Monitored Measurement

To take a monitored temperature (Celsius Monitored or Fahrenheit Monitored indicator shall be on), the procedures for monitored and predictive temperature measurements are the same, with the following exceptions:

For monitored measurements:

- The monitor must be set to take a monitored temperature.
- The monitor displays the temperature continuously.
- The measurement continues until the probe is replaced in the probe well.

Note: Verify that the temperature measurement type is set to monitored.

If the measured temperature remains below the minimum measurable temperature for 5 minutes, the temperature cycle is terminated and the temperature display goes blank. To reactivate the probe, insert it into the probe well, discarding the used probe cover, and extract it again, loading a new probe cover.

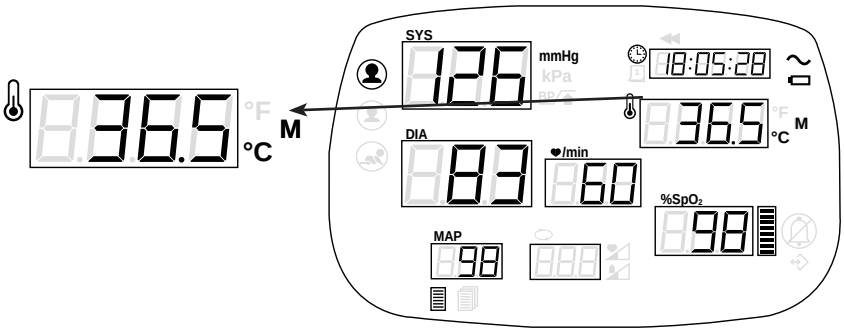


Figure 28. Temperature – Monitored Mode

Note: The monitor only displays 26°C to 43°C (80°F to 110°F). If the reading is over 43°C (110°F) or under 26°C (80°F), the monitor will display as follows.

Figure 29. Example display of over 43°C or under 26°C

Probe Decontamination Procedure

1. Turn the monitor off.
2. Unplug the latching probe connector from the monitor.
3. Remove the probe from the probe well.
4. Remove the probe well from the monitor.
5. Clean the probe and the inner and outer surface of the probe well by swabbing with a cloth dampened with 70% isopropyl alcohol or a 10% solution of chlorine bleach.

Note: Do not immerse or soak the probe in any type of fluid.

Note: Do not autoclave the probe or probe well.

Note: Do not use steam, heat, or gas sterilisation of the probe or probe well.

Note: Do not use hard or sharp objects to clean the probe well. These can damage the probe well, which could cause the unit to fail.

6. Thoroughly dry all surfaces before reassembling the instrument.
7. Re-install the probe well into the monitor.
8. Insert the probe into the probe well.
9. Reconnect the probe latching connector to the monitor, making sure that the connector snaps into place.

10. Alarms And Limits

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

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

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

WARNING: If different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre, a potential hazard can exist.

CAUTION: For patient safety, all alarms are reset to the factory default levels whenever the patient type is changed. This means that you must either accept the default alarm limits or set new limits every time you change patient type.

CAUTION: The high alarm limit for any vital sign is always higher than the low alarm limit for the same vital sign. For example, the alarm limit for systolic high is always higher than the alarm limit for systolic low.

Note: For adjusting alarm volume, you may refer to section 6.8, of this manual. Alarm volume is set to '4' as a factory default.

10.1 General

When the monitor detects certain conditions that require user attention, such as out-of-limit vital signs, the monitor enters an alarm state. The monitor response is indicated by visual and audible indication

Table 8. Alarm Indication

Alarm Condition	Alarm Indication
Battery Failure Loss of Pulse	Presenting appropriate error codes and sounding audible alarms. *Note: In case of loss of pulse alarm, error code (E44) is flashing*
Limit violation	Flashing the violating value in the appropriate display and sounding audible alarms.
Other system or measurement error	Presenting appropriate error codes and sounding audible alarms if available.

10.2 Setting Alarm Limits

CAUTION: Do not set the alarm limit to extreme values that can cause the alarm to become useless.

During patient monitoring, an alarm occurs when a measurement falls outside the programmed alarm limit. Alarms can be set or turned off for the following vital signs:

- Systolic high and Systolic low alarm limits
- Diastolic high and Diastolic low alarm limits
- MAP high and MAP low alarm limits
- Pulse rate high and Pulse rate low alarm limits
- SpO_2 high and SpO_2 low alarm limits

The range of high and low alarm limits for each vital sign is shown here:

Table 9. Range of Alarm Limits (Defaults)

Parameter	Low Limit, Default	High Limit, Default	Resolution
Systolic (mmHg)			
Neonatal	40 to 115, 50	45 to 120, 100	5 mmHg (0.7 kPa)
Pediatric	60 to 155, 75	65 to 160, 145	5 mmHg (0.7 kPa)
Adult	60 to 245, 75	65 to 250, 220	5 mmHg (0.7 kPa)
Diastolic (mmHg)			
Neonatal	20 to 85, 30	25 to 90, 70	5 mmHg (0.7 kPa)
Pediatric	40 to 125, 50	45 to 130, 100	5 mmHg (0.7 kPa)
Adult	40 to 195, 50	45 to 200, 110	5 mmHg (0.7 kPa)
MAP (mmHg)			
Neonatal	30 to 95, 40	35 to 100, 80	5 mmHg (0.7 kPa)
Pediatric	45 to 135, 60	50 to 140, 110	5 mmHg (0.7 kPa)
Adult	45 to 230, 60	50 to 235, 120	5 mmHg (0.7 kPa)
PR (bpm)			
Neonatal	25 to 295, 100	30 to 300, 200	5 bpm
Pediatric	25 to 295, 50	30 to 300, 150	5 bpm
Adult	25 to 295, 50	30 to 300, 120	5 bpm
SpO_2 %			
Neonatal	50 to 98, 85	52 to 100, 98	1%
Pediatric	50 to 98, 90	52 to 100, 100	1%
Adult	50 to 98, 90	52 to 100, 100	1%

NIBP Alarm Limits

Alarm Limits determine the high and low points of patient data at which the monitor will sound an alarm.

Systolic high and low alarm limits

With the monitor in the normal monitoring mode:

1. Press the Alarm button until Systolic high alarm limit is displayed.
2. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.
3. Press the Alarm button once again until Systolic low alarm limit is displayed.
4. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.

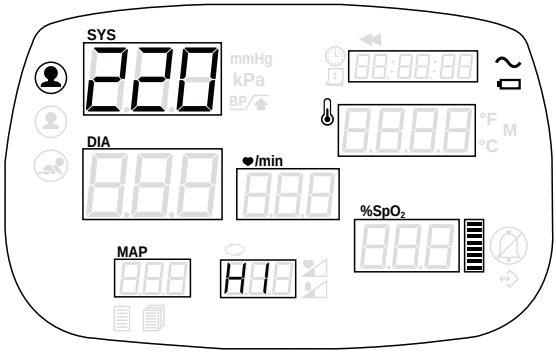


Figure 30. Systolic High Alarm Limit Setting

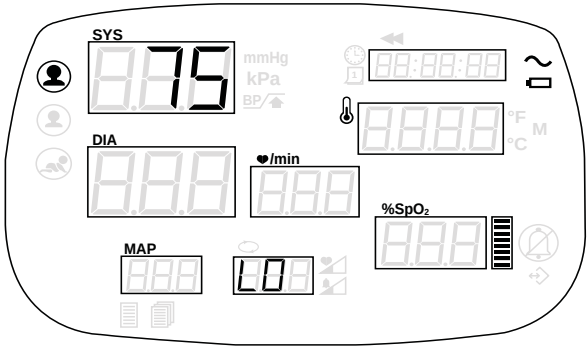


Figure 31. Systolic Low Alarm Limit Setting

Diastolic high and low alarm limits

With the monitor in the normal monitoring mode:

1. Press the Alarm button until Diastolic high alarm limit is displayed.
2. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.
3. Press the Alarm button once again until Diastolic low alarm limit is displayed.
4. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.

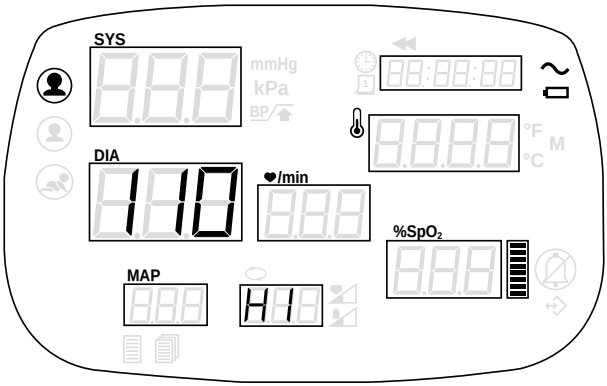


Figure 32. Diastolic High Alarm Limit Setting

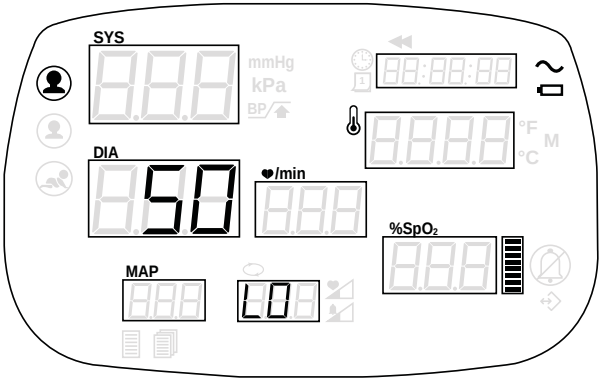


Figure 33. Diastolic Low Alarm Limit Setting

MAP high and low alarm limits

With the monitor in the normal monitoring mode:

1. Press the Alarm button until MAP high alarm limit is displayed.
2. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.
3. Press the Alarm button once again until MAP low alarm limit is displayed.
4. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.

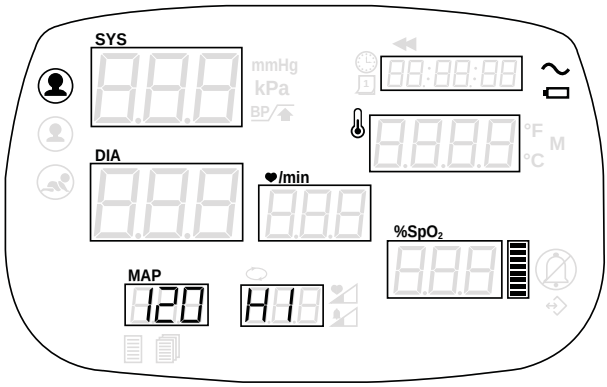


Figure 34. MAP High Alarm Limit Setting

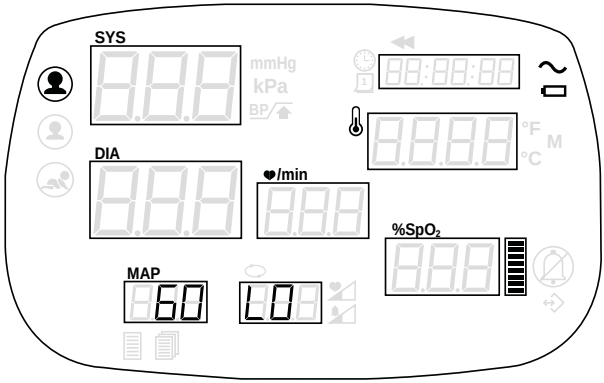


Figure 35. MAP Low Alarm Limit Setting

Pulse Rate Alarm Limits

Alarm Limits determine the high and low points of patient data at which the monitor will sound an alarm.

With the monitor in the normal monitoring mode:

1. Press the Alarm button until Pulse rate high alarm limit is displayed.
2. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.
3. Press the Alarm button once again until Pulse rate low alarm limit is displayed.
4. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.

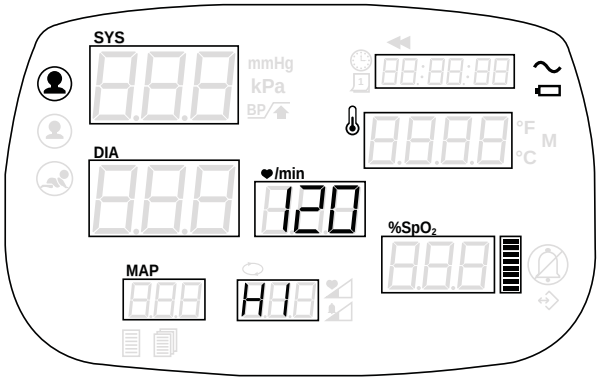


Figure 36. Pulse Rate High Alarm Limit Setting

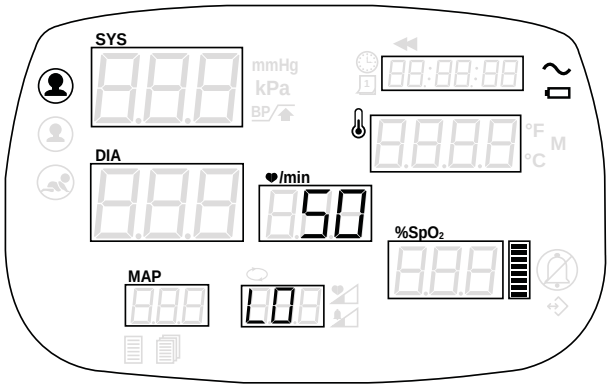


Figure 37. Pulse Rate Low Alarm Limit Setting

SpO_2 Alarm Limits

Alarm Limits determine the high and low points of patient data at which the monitor will sound an alarm.

With the monitor in the normal monitoring mode:

1. Press the Alarm button until SpO_2 high alarm limit is displayed.
2. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.
3. Press the Alarm button once again until SpO_2 low alarm limit is displayed.
4. Leave the limit unchanged or press the Up/Down (+/-) selection buttons as needed to change the limit to another value.

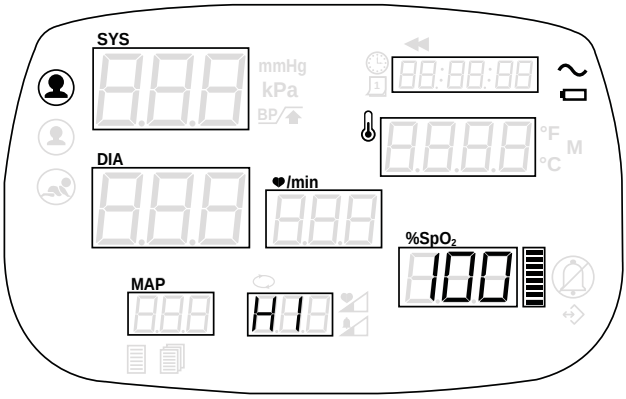


Figure 38. SpO_2 High Alarm Limit Setting

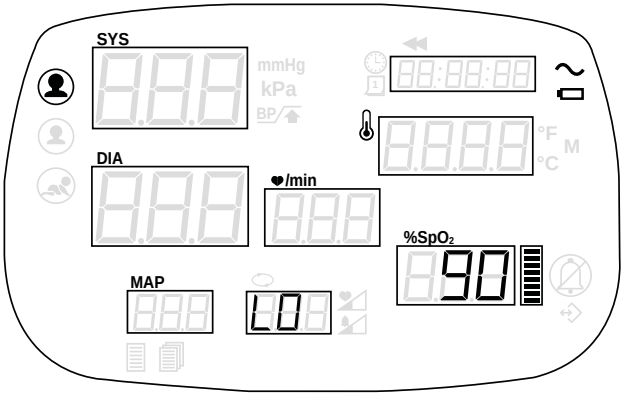


Figure 39. SpO_2 Low Alarm Limit Setting

10.3 Alarm Silence

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

Press the *Alarm Silence Button* on the front panel. This action temporarily silences all audible alarms for 90 seconds. Alarm Silence Indicator lights during a temporary silence period.

1. Press the Alarm Silence Button to immediately silence the alarm tone. (Alarm silence period default-90 seconds later, the alarm resumes if the alarm condition has not been corrected.)

2. Check the patient and provide appropriate care.

If the Alarm Silence Button is pressed during the alarm silence, the alarm silence is ended and the audible alarms are re-enabled.

Note: Visual indications of an alarm condition cannot be turned off. For example, if the %SpO_2 low alarm limit is exceeded, the audible alarm can be silenced for the alarm silence period, but the %SpO_2 value will continue to flash.

Note: Low Battery alarm cannot be silenced while running on battery power. Connecting the monitor to AC power will silence the alarm. If a sensor disconnect alarm is occurred, the alarm can be released by pressing the Alarm Silence Button.

Note: The alarms can be cancelled by pressing the Alarm silence button, but battery failure, loss of pulse and limit violation alarms cannot be released until the alarm condition is terminated.

10.4 Verifying Visual and Audible Alarm Indication

If the monitor fails to perform as specified in this test, contact qualified service personnel for assistance.

You can verify the alarm operation for all parameters like NIBP, SpO_2 and Temp, by following the procedures below.

1. Connect the monitor to an AC power source.
2. Press the Power Button to turn on the monitor.
3. Connect the simulator to the sensor input cable and connect cable to monitor.
4. Set the simulator to a smaller value than the lower alarm limit on the monitor.
5. Verify the following reaction:
   a. The monitor begins to track the physiological signal from the simulator.
   b. After about 10 to 20 seconds, the monitor displays the value measured as specified by the simulator. Verify values are within the tolerances specified in the **Specification** section for each parameter (NIBP, SpO_2, Temp).
   c. The violating value in the appropriate display flashes and the audible alarm sounds.

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

11. Reviewing Patient Data

11.1 General

You can review stored patient data either by viewing it on the monitor or by printing it. The monitor stores 200 measurements. After 200 measurements are reached, the oldest stored measurement will be deleted and replaced with a new measurement. 24-hour old measurements will also be automatically deleted. Data is recorded when patient measurement completes or an alarm condition occurs.

Pressing the Review button while the monitor is in Normal mode or Auto mode will enter Review mode. This will cause the monitor to display the most recent data set. If SpO_2 data or temperature data is available when the NIBP cycle completes, that information will be included in the record and will display in Review mode.

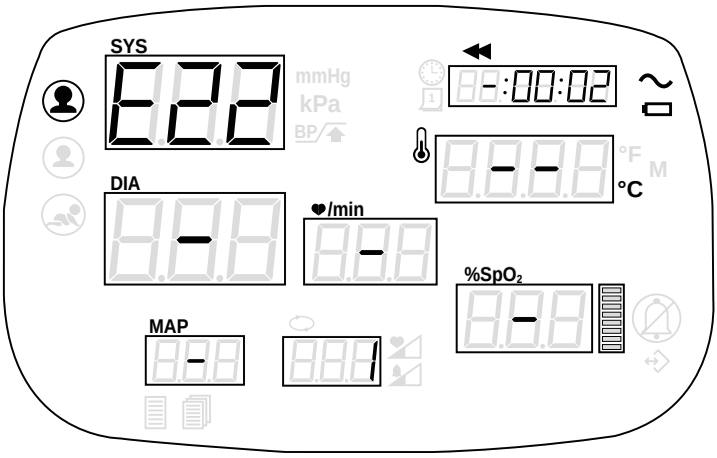
11.2 Displaying Stored Patient Data

1. Press the Review button to display the newest stored set of patient vital-signs data.

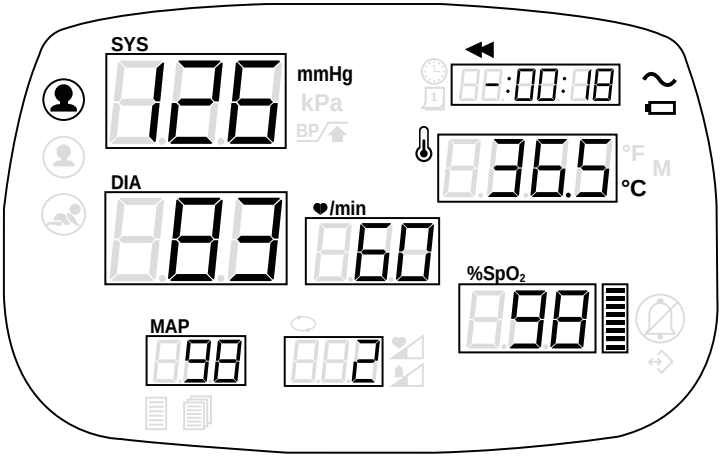
   - The monitor interrupts the dynamic display of any current vital-sign measurement.
   - The most current set of stored data including NIBP, SpO_2, Pulse rate and Temperature with a data-set sequence number and the time and date of the displayed reading during a patient data review, if available, displays on entry into Review mode.
   - The next most recent stored data sets display wrapping from the first stored data set to the last by pressing the Review button subsequently.
   - In Review mode, the readings show time of reading in minus time, for example, (-0:05) is 5 minutes ago, (-2:45) is 2 hour 45 minutes ago

2. Press the Up/Down (+/-) selection button to cycle forward or backward (scroll) through the stored measurement data sets. (The monitor stores 200 measurement cycles.)

3. To stop reviewing data and return to normal operation, press any button other than the Review button or the Up/Down (+/-) selection button.



Data #1 Display: Data stored at an error occurred 2 minutes ago



Data #2 Display: Data stored at the measurement completed 18 minutes ago

Figure 40. Stored Patient Data Display

Note: 5 seconds of operator inactivity will exit Review mode and return to Normal mode.

11.3 Printing Stored Patient Data (Optional Printer Installed)

You can print vital-signs measurement data each time the monitor completes a measurement cycle (stream printing), or you can store patient data and print all of it at one time (batch printing). For information on setting the printer for stream printing or batch printing, see section 12 “Printing”.

Follow the instructions to print stored data if an optional printer is installed.

1. Press Print button when the monitor is in Review mode to display stored data on the screen.

- If the monitor is not printing, press the Print button to start printing.
- If the monitor is printing, press the Print button to stop printing.

Note: The print button is not enabled during an NIBP cycle.

11.4 Erasing Patient Data

All patient vital-signs data is stored even the monitor is powered off, however 24-hour old data will be removed. You can also erase patient data when you change the time and date settings and at any time during normal monitor operation.

Erasing Data During Normal Operation

To erase patient data during normal operation;

1. Press and hold the Review button for 3 seconds to erase data in the memory. After data cleared, the monitor returns to normal operation.

12. Printing

12.1 General

This section applies if the monitor is configured with the printer option.

When the optional printer is installed, the monitor allows the user to print in Manual mode or Stream mode. The type is determined by the Print setting in Configuration mode.

Manual Mode

The monitor prints out current measurement data (Real-time printing) or stored patient data on the screen (Batch printing). Manual print indicator is on.

Stream Mode

The monitor automatically prints out patient measurement data: as NIBP measurement or Temperature predictive measurement completes. Also in Stream mode, the monitor automatically prints out the measurement data when an alarm condition occurs. When the Print button is pressed at Stream mode, the monitor prints out current measurement data. Stream print indicator is on.

12.2 Selecting Manual or Stream Printing type

This procedure will allow you to select Print mode either Manual or Stream.

With the monitor in the normal monitoring mode:

1. Press and hold the Mode button for 3 seconds or more until the monitor enters Configuration mode.
2. Press the Mode button once again until either Manual Print or Stream Print indicator is flashing on the display.
3. Press the Up/Down (+/-) selection button to alternate between Manual Print and Stream Print and display. A selected type indicator will be flashing on the display.
4. To set the displayed printing method and return to normal operation, press any other key. If there is no activity for 5 seconds, the monitor will return to normal operation.

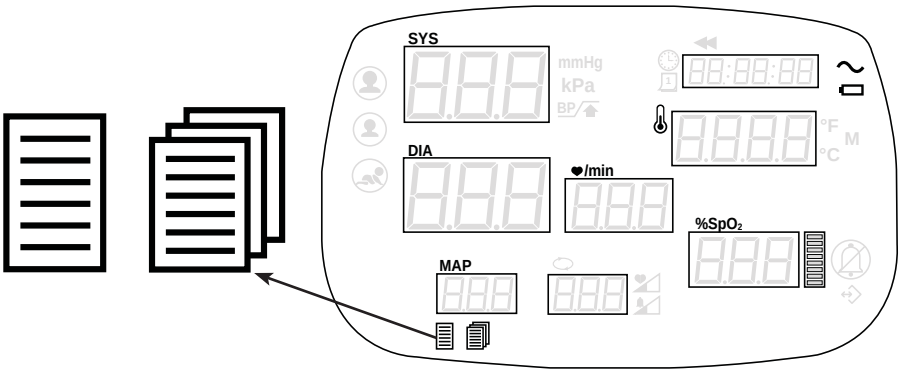


Figure 41. Printing Type Setting

12.3 Printing Patient Data (Manual Mode)

You can print vital-signs measurement data each time you press the Print button (Manual printing), or you can store patient data and print all of it at one time (Batch printing).

Follow the instructions to print stored data if an optional printer is installed.

1. Press Print button when the monitor is in Normal or Review mode.
    - If the monitor is not printing, press the Print button to start printing.
    - If the monitor is printing, press the Print button to stop printing.

Note: The print button is not enabled during an NIBP cycle.

Note: The monitor sounds an invalid button tone when the printer door opens or when paper runs out.

12.4 Print Out Configuration

Print Out includes information as follows:

- Header: Time, Date, Measurement Parameters and Parameter units
- Measurement data and/or error codes

Real Time Print Out at Manual and Stream Modes

Patient Name:
Patient ID:
Physician:
Comments:

TIME	SYS	DIA	MAP	HR	O_2	TEMP
	- -	mmHg	- -	BPM	%	°C
17:26 26-Mar-2004						
17:26	127	84	98	68	98	36.1

Figure 42. Real-Time Printing

Stored Data Print Out

Patient Name:
Patient ID:
Physician:
Comments:

TIME	SYS	DIA	MAP	HR	O_2	TEMP
	- -	mmHg	- -	BPM	%	°C
17:20 26-Mar-2004						
17:19	126	83	98	60	98	36.5
17:15	123	82	97	62	98	36.5
17:14	E22	-	-	-	-	-

Figure 43. Stored Data Printing (Batch Printing)

Note: The date format shown in the printout may be selected either 'year/month/day' or 'day/month/year' via Service mode.

Stream Print Out at Alarm Condition

Patient Name:
Patient ID:
Physician:
Comments:

TIME	SYS	DIA	MAP	HR	O_2	TEMP
	- -	mmHg	- -	BPM	%	°C
17:52 26-Mar-2004						
17:52	127	84	98	200↑	75	36.1

Figure 44. Stream Printing at Alarm Condition

System Information Print out

If the Print button is pressed while the monitor is in Service mode, (accessed by authorized personnel only), the monitor prints out the internal settings of the monitor as shown in Figure 45.

17:52	26-Mar-2004
Patient type:	Adult
NIBP target press (mmHg):	160
NIBP auto interval:	15
NIBP units:	mmHg
NIBP Smart Inflation	Off
Temperature mode:	Predict
Temperature units:	°F
Print mode:	Manual
Night panel:	Off
Nurse call state	Normal open
Date format	Y-M-D
Sound mode	Full
Pulse tone volume:	4
Alarm tone volume:	4
Alarm limit settings	
High Sys (mmHg)	220
Low Sys (mmHg)	75
High Dia (mmHg)	110
Low Dia (mmHg)	35
High MAP (mmHg)	120
Low MAP (mmHg)	50
High HR (BPM)	120
Low HR (BPM)	50
High SpO_2 (%)	100
Low SpO_2 (%)	90
Total cycles:	6
Total runtime:	2
Software versions:	
Units:	3.00
NIBP:	1.01
SpO_2:	1.90
Temp:	1.2

Figure 45. System Information Printing

13. RS232 Interface

13.1 Overview

The Smartsigns® Liteplus monitor provides RS-232 I/O port for software upgrade or nurse call system. The 9-pin connector mounted on the rear panel provides an access port for a serial interface. RS-232 I/O port is intended only for connection to specified equipment in accordance with compliance requirements.

13.2 Cable Connection

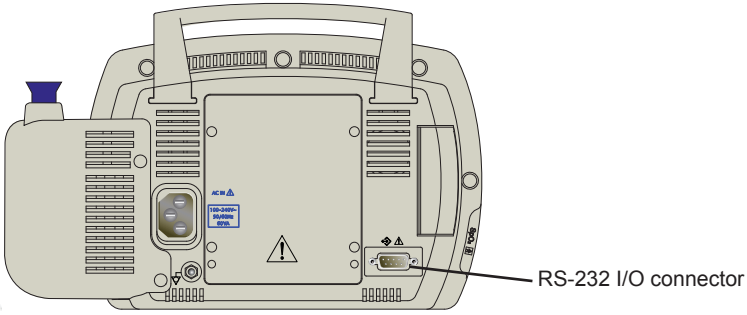


Figure 46. RS-232 I/O connector

The Pin layouts (as viewed from the rear panel of the monitor) are illustrated below.

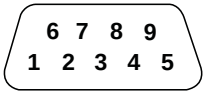


Figure 47. Data Port Pin Layout

Table 10. RS-232 Serial Interface Connections

Pin #	Signal
1	+5V (Use for Software Upgrade)
2	RxD_232 (RS-232 Input)
3	TxD_232 (RS-232 Output)
4	DTR (Use for Software Upgrade)
5	Signal ground (Isolated from Earth ground)
6	DSR (Use for Software Upgrade)
7	Nurse call A
8	Nurse call B
9	SMODE (Use for Software Upgrade)

13.3 Nurse Call Interface

WARNING: Although the Nurse Call option enables remote notification of an alarm condition, it is not intended to replace appropriate bedside patient surveillance by trained clinicians.

The monitor can be connected to a Nurse Call system through a customized cable that connects to the Nurse Call connector. When the cable is connected and operational, the monitor immediately notifies the Nurse Call system when a patient alarm occurs.

The Nurse Call function specification is as follows:

- Switch current: 1 A maximum
- Switch voltage: 30 Vac/dc maximum
- Isolation: 1500 Vrms
- Alarm relay: Normal open (default)

Note: The alarm relay may be selected either 'Normal Open' or 'Normal Close' via Service mode.

14. Maintenance

WARNING: Only qualified service personnel should remove the cover. There are no internal user-serviceable parts.

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

CAUTION: Unplug the power cord from the monitor before cleaning the monitor.

14.1 General

Follow local governing ordinance and recycling instructions regarding the disposal or recycling of end of life use of Smartsigns® Liteplus and accessories. Otherwise environment or people may be harmed from improper disposal of battery or accessories.

14.2 Returning the Smartsigns® Liteplus and System Components

Contact Huntleigh Healthcare Ltd Technical Services Department for shipping instructions including a Returned Goods Authorization (RGA) number. Pack the Smartsigns® Liteplus monitor with sensors, cables 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 monitor during shipping. Return the Smartsigns® Liteplus by any shipping method that provides proof of delivery.

14.3 Service

The Smartsigns® Liteplus requires no routine service other than cleaning or battery maintenance that is mandated by the user's institution. For more information, refer to Smartsigns® Liteplus service manual. Qualified service personnel in the user's institution should perform periodic inspections of the monitor. If service is necessary, contact qualified service personnel or Huntleigh Healthcare Ltd Technical Services Department.

If the institution's service personnel cannot correct problems, the Smartsigns® Liteplus should be returned to Huntleigh Healthcare Ltd for service. Contact Huntleigh Healthcare Ltd Technical Services Department for return instructions.

14.4 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 safety relevant labels for legibility.

14.5 Cleaning

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

- The Smartsigns® Liteplus may be surface-cleaned by using a soft cloth dampened with either a commercial or nonabrasive cleaner, and lightly wiping the top, bottom, and front surfaces of the monitor lightly.

For sensors and probes follow cleaning, disinfecting and/or sterilizing instructions in the directions for use shipped with those components.

Never allow any liquid substance to enter any monitor connector. If a connector does come in contact with a liquid substance accidentally, clean and dry thoroughly before reuse. If in doubt about monitor safety, refer the unit to qualified service personnel.

14.6 Battery maintenance

If the Smartsigns® Liteplus vital signs monitor has not been used 2 months, the battery will need charging. To charge the battery, connect the Smartsigns® Liteplus to an AC power source as described in the Battery Operation section.

Note: Storing the Smartsigns® Liteplus for a long period without charging the battery may degrade the battery capacity. A full charge of a depleted Ni-MH battery takes approximately 8 hours while the monitor is switched off.

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

CAUTION: If the battery shows any signs of damage, leakage, or cracking, it must be replaced immediately, by a qualified service person, and only with a battery approved by the manufacturer.

CAUTION: Discarded battery may explode during incineration. Follow local government ordinances and recycle instructions regarding disposal or recycling of device components, including batteries.

CAUTION: Recycle used batteries properly. Do not dispose of batteries in refuse containers.

14.7 Replacement of Printer Paper

1. Open the door by pulling the latch on the printer slightly. The door should tilt open.
2. Reach in and remove the spent paper core by pulling it over gently with your thumb and index finger.
3. Place a new paper roll. Orient the paper roll.
4. Pull the paper towards you until approximately 2 inches (5.08 cm) of paper have been unrolled.
5. Align the paper with the pinch roller attached to the printer door.
6. Close the printer door.

Note: To ensure that the paper is aligned in the slot and has not been pinched in the door, pull the loose edge until a few inches of paper is showing. If the paper will not move, open the door and return to alignment step 5.

Note: The monitor sounds an invalid button tone when the printer door opens or when paper runs out.

15. 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 monitor is functioning correctly.

WARNING: Only qualified service personnel should remove the cover. There are no user-serviceable parts inside.

CAUTION: Do not spray, pour, or spill any liquid on the Smartsigns® Liteplus, its accessories, connectors, switches, or openings in the chassis.

15.1 General

If the Smartsigns® Liteplus is unable to perform any of its monitoring functions because of the loss of software control or a detected hardware malfunction, an error code is presented.

Table 11. Error Codes

Error Codes	Description
E01	Battery failure
E02	Abnormally shutdown last time
E09	System error (malfunction)
E21	Air leakage
E22	Cuff not detected
E23	Kinked or neonate hose
E24	Cuff too large for neonate
E25	Overpressure condition
E26	Motion artifact
E27	Weak pulse or no pulse detected
E28	Valid BP not found
E29	NIBP module error (malfunction)
E41	Sensor off
E42	Sensor disconnected
E43	Bad sensor
E44	Loss of pulse
E49	SpO_2 module error (malfunction)
"P"	Loss of tissue contact
E62	Probe disconnected
E63	Probe error
E64	Probe heated too high
E65	Ambient temperature out of range
E69	Temperature module error (malfunction)

Serviceable error codes and other error codes are listed in the Smartsigns® Liteplus service manual. If the monitor continues to present an error code, call the Huntleigh Healthcare Ltd technical representative and report the error code number. You will be advised of the remedial action to be taken. Before calling the Huntleigh Healthcare Ltd Technical Services Department, make sure that the battery is charged, and that all power connections are correctly made.

15.2 Corrective Action

If you experience a problem while using the Smartsigns® Liteplus and are unable to correct it, contact qualified service personnel or Huntleigh Healthcare Ltd Technical Services Department.

The Smartsigns® Liteplus service manual, which is for user by qualified service personnel, provides additional troubleshooting information.

Following is a list of possible errors and suggestions for correcting them.

1. **There is no response to the Power On/Off switch.**

    - A fuse may be blown. Notify service personnel to check and, if necessary, replace the fuse.

    - If operating on battery power, the battery may be missing or discharged. If the battery is discharged, charge the battery, see Battery Operation section.

2. **The monitor display does not function properly and the power- on beep tones do not sound during the power-on self-test.**

    - Do not use the Smartsigns® Liteplus; contact qualified service personnel or Huntleigh Healthcare Ltd Technical Services Department.

3. **The monitor is operating on battery power, even though it is connected to AC.**

    - Make sure that the power cord is properly connected to the Smartsigns® Liteplus.

    - Check to see if power is available to other equipment on the same AC circuit.

    - The monitor will be operated from its internal battery if in doubt about the integrity of the AC power source,

15.3 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 Smartsigns® Liteplus can cause inaccurate measurement readings. Do not rely entirely on the Smartsigns® Liteplus readings for patient assessment.

WARNING: It is possible that any radio frequency transmitting equipment and other sources of electrical noise such as cellular phones, due to close proximity or strength of a source, may result in disruption of performance of the Smartsigns® Liteplus.

WARNING: It is possible, although unlikely, that large equipment using a switching relay for its power on/off may result in disruption of performance of the Smartsigns® Liteplus when the large equipment powers on or off. Do not place the Smartsigns® Liteplus to monitor in such environments.

CAUTION: 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 electromagnetic noise in health care environments (for example; electrosurgical unit, 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 result in disruption of performance of this device.

CAUTION: The Smartsigns® Liteplus 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 monitor may not seem to operate correctly.

CAUTION: Disruption may be evidenced by erratic readings, cessation of operation, or other incorrect functioning.

If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions taken to eliminate the source:

- 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.

If assistance is required, contact Huntleigh Healthcare Ltd Technical Services Department.

15.4 Obtaining Technical Assistance

For technical information and assistance, or to order a service manual, call Huntleigh Healthcare Ltd Technical Services Department. The service manual includes information required by qualified service personnel when servicing the Smartsigns® Liteplus.

When calling the Huntleigh Healthcare Ltd Technical Services Department, you may be asked to tell the representative the software version number of your Smartsigns® Liteplus. Qualified service personnel or Huntleigh Healthcare Ltd Technical Services Department may help you check the software version installed in your monitor.

16. Factory Defaults

16.1 General

The Smartsigns® Liteplus is shipped with factory default settings. You may change the default settings to desired values as described in 'Using the Monitor' and 'Alarm and Limits' sections of this manual. When you turn the monitor off properly with the change of the default setting, the changed settings will be saved and they will be power-on default settings for next power-on. If you want the power-on setting back to factory defaults, refer to section 6 of this manual ('Using the Monitor')

16.2 Parameter Ranges and Default Settings

Table 12. Parameter Ranges and Factory Defaults

Parameter		Ranges		Defaults
Systolic (mmHg) Alarm Limits	Neonatal	Low: 40 to 115	High: 45 to 120	50, 100
	Pediatric	Low: 60 to 155	High: 65 to 160	75, 145
	Adult	Low: 60 to 245	High: 65 to 250	75, 220
Diastolic (mmHg) Alarm Limits	Neonatal	Low: 20 to 85	High: 25 to 90	30, 70
	Pediatric	Low: 40 to 125	High: 45 to 130	50, 100
	Adult	Low: 40 to 195	High: 45 to 200	50, 110
MAP (mmHg) Alarm Limits	Neonatal	Low: 30 to 95	High: 35 to 100	40, 80
	Pediatric	Low: 45 to 135	High: 50 to 140	60, 110
	Adult	Low: 45 to 230	High: 50 to 235	60, 120
PR (bpm) Alarm Limits	Neonatal	Low: 25 to 295	High: 30 to 300	100, 200
	Pediatric	Low: 25 to 295	High: 30 to 300	50, 150
	Adult	Low: 25 to 295	High: 30 to 300	50, 120
SpO_2 % Alarm Limits	Neonatal	Low: 50 to 98	High: 52 to 100	85, 98
	Pediatric	Low: 50 to 98	High: 52 to 100	90, 100
	Adult	Low: 50 to 98	High: 52 to 100	90, 100
Patient Type		Adult, Pediatric, Neonatal		Adult
NIBP Units		mmHg, kPa		mmHg
NIBP Auto Interval		Off, STAT, 1, 2, 3, 4, 5, 10, 15, 30, 45, 60, 90, 120, 240		15
Temperature Units/Modes		°C, °F, °C M, °F M		°F
Pulse Tone Volume		0 to 8		4
Alarm Volume		1 to 8		4
Night Panel		On, Off		Off
Nurse call state		Normal Open, Normal Close		Normal Open
Date format		Y-M-D, D-M-Y		Y-M-D
Sound mode		Full, Mid, Mute		Full
Print Control		Manual, Stream		Manual
NIBP Smart Inflation		On/Off		Off

17. Specifications

17.1 Physical

Instrument	
Dimensions	130×180×284 (mm)
Weight	2.7 (kg)

17.2 Electrical

AC Power	
Power	100Vac to 240Vac, 50 Hz/60 Hz,60 VA
Battery	
Type	Ni-MH
Voltage/Capacity	Ni-MH : 8.4 V/ 7.6 Ampere-Hours
Charging Time	Ni-MH : 8 Hours
Shelf Life	2 years, new fully charged battery
Complies with	91/157/EEC, 93/86/EEC and 2006/66/EC

17.3 Environmental

Operation	
Temperature	10 °C (50 °F) to 40 °C (104 °F)
Humidity	15 % RH to 95% RH, non-condensing
Altitude	700 hPa to 1060hPa
Transport and Storage	
Temperature	–20 °C (-4 °F) to 50 °C (122 °F)
Humidity	15 % RH to 95% RH, non-condensing
Altitude	500 hPa to 1060 hPa

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

17.4 Measurement Parameters

NIBP

Pulse Rate	
Pulse Rate Range	Adult/Pediatric 40 BPM to 200 BPM Neonatal 40 BPM to 240 BPM
Pulse Rate Accuracy	±2 BPM or ±2%, whichever is greater
NIBP (Non-Invasive Blood Pressure)	
Technique	Oscillometric Measurement
Measurement modes	AUTO, MANUAL and STAT
AUTO Mode	Automatic NIBP measurements at intervals of 1, 2, 3, 4, 5, 10, 15, 30, 45, 60, 90, 120, and 240 minutes
MANUAL Mode	Single measurement initiated by NIBP Start/Stop switch
STAT Mode	Series of consecutive measurements for 5 minutes
NIBP pressure measurement range	
Systolic pressure range	Adult: 60 mmHg to 250 mmHg (8 kPa to 33.3 kPa) Pediatric: 60 mmHg to 250 mmHg (8 kPa to 33.3 kPa) Neonatal: 40 mmHg to 120 mmHg (5.3 kPa to 16.0 kPa)
Diastolic pressure range	Adult: 40 mmHg to 200 mmHg (5.3 kPa to 26.7 kPa) Pediatric: 40 mmHg to 200 mmHg (5.3 kPa to 26.7 kPa) Neonatal: 20mmHg to 90 mmHg (2.7 kPa to 12.0 kPa)
Mean pressure range	Adult: 45 mmHg to 235 mmHg (6 kPa to 31.3 kPa) Pediatric: 45 mmHg to 235 mmHg (6 kPa to 31.3 kPa) Neonatal: 30 mmHg to 100 mmHg (4 kPa to 13.3 kPa)
Pressure Display Accuracy	Meets ANSI/AAMI SP10:2002+A1:2003
Cuff Pressure Range	0 to 300 mmHg (0 to 40 kPa)
Initial Cuff Inflation	Adult: - 120, 140, 160 (default), 180, 200, 220, 240, 260 mmHg (15.9, 18.6, 21.2 (default), 23.9, 26.6, 29.2, 31.9, 34.5 kPa) Pediatric: - 120 (default), 130, 140, 150, 160, 170mmHg (15.9 (default), 17.2, 18.6, 19.9, 21.2, 22.6 kPa) Neonatal: - 80, 90 (default), 100, 110, 120, 130, 140 mmHg (10.6, 11.9 (default), 13.3, 14.6, 15.9, 17.5, 18.6 kPa)
Overpressure protector	Adult/Pediatric 300 mmHg (N.C.), 330 mmHg (S.F.C.) Neonatal 150 mmHg (N.C.), 165 mmHg (S.F.C.)
Standards	ANSI/AAMI SP10:2002+A1:2003, IEC60601-2-30:1999 EN1060-1:1995, EN1060-3:1997 and EN1060-4:2004.

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

SpO2/Pulse Rate

%Saturation	
Range	1% to 100%
Low Perfusion	0.03% to 20%
Accuracy	Without Interference -Adults 70% to 100% ±2 digits 1% to 69% unspecified Without Interference-Neonate[1] 70% to 100% ±3 digits 1% to 69% unspecified Low Perfusion[2] 70% to 100% ±2 digits 1% to 69% unspecified
Pulse Rate	
Range	20 BPM to 300 BPM
Accuracy	Without Interference[2] 20 BPM to 300 BPM ±3 digits Low Perfusion[2] 20 BPM to 300 BPM ±3 digits
Standards	ISO9919:2005

[1]Neonate specifications are shown for neonate sensors with the Smartsigns® Liteplus. Saturation accuracy will vary by sensor type recommended by the manufacturer.
[2]Specification applies to monitor performance and was validated with Biotek and Nellcor simulators

Temperature

Probe Type	Thermistor probe
Range	26° C to 43° C (80° F to 110°F)
Display Accuracy	±0.1° C (±0.2° F)
Measurement units	° C, ° F
Measurement modes	Predictive, Monitored
Predictive Mode	One-time measurement in a single temperature reading which is displayed at the end of the brief measurement period
Monitored Mode	Continuous measurement over an indefinite period.
Standards	ASTM E1112-00:2000, EN12470-3 and EN12470-4

Printer

Type	Thermal
Resolution	8 (dots/mm)
Printing speed	45 (mm/s)
Paper width	57 (mm)

17.5 Compliance

Item	Compliant with
Classification	Class I (on AC power) and Internally powered (on battery power) Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
Mode of operation	Continuous
Type of protection	Type BF – Applied parts (NIBP Defibrillation-proof applied parts)
General Safety	93/42/EEC Medical Device Directive
	US FDA 21 CFR 820 Code of federal regulations, Quality system regulation
	91/157/EEC Battery Declaration Directive
	93/86/EEC Battery Disposal Directive
	2006/66/EC Battery directive
	2002/96/EC waste electrical and electronic equipment (WEEE)
	ISO13485:2003 Quality Systems - Medical devices - Requirements for regulating purposes
	IEC60601-1:1998+A1:1991+A2:1995 General requirements for safety of medical electrical equipment

Item	Compliant with
General Safety	IEC60529 Degree of protection provided by enclosures water ingress testing (IPX2)
	EN ISO14155-1:2003 Clinical Investigation of Medical Devices for Human Subjects-part 1: General Requirement
	AAMI HE48:1993 Human factors engineering guidelines and preferred practices for the design of medical devices
	IEC60601-2-49:2001 - Particular requirements for the safety of Multifunction patient monitoring equipment
	IEC60601-1-1:2000 Collateral standard for medical electrical systems
	IEC60601-1-4:2000 Collateral standard for Programable medical systems
	IEC60601-1-6:2004 Collateral standard for Usability
	ISO14971:2000+A1:2003 Application of risk management to Medical devices
	ISO10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing
Alarms	IEC60601-1-8:2003 Alarm systems requirements, tests and guidances in medical electrical equipments systems
Non-invasive blood pressure	AAMI SP10:2002+A1:2003 Electronic or Automated Sphygmomanometers
	EN1060-1:1995 Non-invasive sphygmomanometers
	EN1060-3:1997 Supplementary requirements for electrical-mechanical blood pressure measuring systems
	EN1060-4:2004 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
	IEC60601-2-30:1999 Particular requirements for the Safety, including essential performance, of automatic cycling indirect blood pressure monitoring equipment
Oxygen saturation	ISO9919:2005 Pulse oximeters, Particular requirements
Temperature monitoring	ASTM E1112-00:2000 - Electronic thermometer for intermittent determination of patient temperature
	EN12470-3 Clinical thermometers - Part 3: Performance of compact electrical thermometers (non predictive/predictive) with maximum device
	EN12470-4 Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement
Electromagnetic Compatibility	IEC 60601-1, sub clause 36, and IEC60601-1-2:2001+ A1:2004 Electromagnetic compatibility-requirements & test
	IEC61000-3-2:2005 Harmonic Emission

Item	Compliant with
Electromagnetic Compatibility	IEC61000-3-3:2005 Voltage Fluctuations/Flicker Emission
	IEC61000-4-2:2001 Electrostatic Discharge (ESD)
	IEC61000-4-3:2006 Radiated RF electromagnetic field
	IEC61000-4-4:2004 Electrical fast Transient/Burst (EFT)
	IEC61000-4-5:2005 Surge current
	IEC61000-4-6:2006 Conducted disturbances, induced by RF field
	IEC61000-4-8:2001 Power frequency (50/60H) Magnetic field
	IEC61000-4-11:2004 Voltage dips, short interruptions, and voltage variation on power supply input lines
	CISPR 11, EN55011 RF emissions Group 1, Class B Limits and methods of measurement of radio disturbance characteristics of industrial scientific and medical (ISM) radio-frequency equipment.
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)
Package	ISTA: Pre-Shipment Test Procedures (Procedure 1A, 2001 Rev.)
	ASTM D4169:2005 Standard practice for performance testing of shipping containers and system
	IEC 60068-1:1988 Environmental testing, Part 1: General guidelines
Reliability	IEC60068-2-27 Environmental testing - Shock
	IEC60068-2-6:1995 Environmental testing –Vibration (sinusoidal)
	IEC60068-2-64:1993, Broadband random (Digital Control) and Guidance

17.6 Manufacturer's Declaration

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

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

Table 13. Electromagnetic Emissions (IEC60601-1-2)

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

Table 14. 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

Immunity Test	IEC60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
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 Smartsigns® Liteplus requires continued operation during power mains interruption, it is recommended that the Smartsigns® Liteplus 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	
	<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 Smartsigns® Liteplus 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 15. Electromagnetic Immunity (IEC60601-1-2)

Immunity Test	IEC60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Potable and mobile RF communications equipment should be used no closer to any part of the Smartsigns® Liteplus , including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.			
Radiated RF IEC 61000-4-3	3 V/m 80 MHz ~ 800 MHz	3 V/m	distance = 1.2 √Power 80 MHz ~ 800 MHz
	3 V/m 800 MHz ~ 2.5 GHz	3 V/m	distance = 2.3 √Power 800 MHz to 2.5 GHz
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz ~ 80 MHz	3 Vrms	distance = 1.2 √Power 150 kHz to 80 MHz
Note: 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 survey 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 Smartsigns® Liteplus is used exceeds the applicable RF compliance level above, the Smartsigns® Liteplus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Smartsigns® Liteplus. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
 Interference may occur in the vicinity of equipment marked with the following symbol:			

Table 16. Recommended Separation Distances

Frequency of Transmitter	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
Equation	d = 1.2 √P	d = 1.2 √P	d = 2.3 √P
Rated Maximum Output Power of Transmitter in Watts	Separation Distance in Meters	Separation Distance in Meters	Separation Distance in Meters
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 separation distance can be estimated using the equation in the corresponding column, where P is the maximum output [power rating of the transmitter in watts (W)] according to the transmitter manufacturer.

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

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

Table 17. Cables (IEC60601-1-2)

Cables and Sensors	Maximum Length	Complies with
Pulse oximetry cable	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
Software download cable, RS-232 serial, 9 pin "D"	10 ft. (3 m)	
Non-terminated cable, RS-232, 9 pin "D"	10 ft. (3 m)	
Reusable SpO_2 sensor	3 ft (0.91 m)	

18. Warranty & Service

Huntleigh Healthcare Diagnostic Products Division standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

Service Returns

If for any reason the Smartsigns Liteplus® has to be returned, please:

- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department '

For further details, refer to NHS document HSG(93)26 (UK only).

Huntleigh Diagnostics reserve the right to return product that does not contain a decontamination certificate.

A service manual is available for the Smartsigns® series. It contains service information, parts lists and fault finding guidelines. The service manual can be obtained by contacting your local supplier or:-

Customer Care Department.
Huntleigh Healthcare, Diagnostic Products Division,
35, Portmanmoor Rd.,
Cardiff. CF24 5HN
United Kingdom.

Tel: +44 (0)29 20496793 - Service (24hr answer machine)
Tel: +44 (0)29 20485885
Fax: +44 (0)29 20492520
Email: sales@huntleigh-diagnostics.co.uk
cardiff.service@huntleigh-diagnostics.co.uk

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The Smartsigns® LitePlus is in conformity with the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and has been subject to the conformity assurance procedures laid down by the Council Directive.

Manufactured in the UK by Huntleigh Healthcare Ltd.
As part of the ongoing development programme the company reserves the right to modify specifications and materials without notice.

HUNTLEIGH ...with people in mind

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