HUNTLEIGH

SC300

Anwendungshinweise

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Οδηγίες χρήσης

Anwendungshinweise

Spot Check Vital Signs Monitor

Notice

Warranty

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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

Table of Contents

1. General Safety Information

This section contains important safety information related to general use of the Smartsigns® Compact 300 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 / Cautions

General warning / caution

Refer to Instructions for Use

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

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 anaesthetics 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 the accessories instructions 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: Do not connect more than one patient to the monitor.

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

CAUTION: Exercise care for the safe and effective use of Smartsigns® Compact 300 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 Service Department.

2. Introduction

WARNING: The Smartsigns® Compact 300 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® Compact 300 vital signs monitor. The Smartsigns® Compact 300 is available in the following configurations:

Config.	Features
SC300	NiBP, Pulse & SpO2
SC300T	NiBP, Pulse, SpO2 & Temperature
SC300N	NiBP, Pulse & SpO2 (NELLCOR)
SC300NT	NiBP, Pulse, SpO2 (NELLCOR) & Temperature

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, SpO_2 and Temperature options. If your monitor configuration lacks any of these options, certain information in this manual does not apply.

2.1 Features of the Smartsigns® Compact 300

Physical

The Smartsigns Compact 300 series is a small lightweight SPOT check vital signs monitor. It measures 130mm x 125mm x 299 mm and weighs 1.25 Kg. The integrated carry handle allows the unit to be hand carried between locations.

Electrical

The monitor is powered either by the local mains supply (100 – 240 VAC 50/60Hz) or an internal 2200 mAh lithium Ion battery.
The internal batteries are charged whenever the SC300 is connected to the local supply.

Display

The monitor uses a 6” LED type of numerical display to display patient and system status.

Auxiliary Outputs

The monitor provides an RS-232 I/O facility on the rear of the unit, this is used for software upgrades.

2.2 Intended Use

The Smartsigns Compact 300 Series is intended for use by trained healthcare professional in healthcare settings to monitor physiologic status of Adult, Paediatric and Neonatal patients.
Physiologic measurements include:

- Non invasive blood pressure (NiBP)
- Pulse oximetry
- Pulse rate
- Temperature

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, 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 monitor.

2.3 About This Manual

This manual explains how to set up and use the Smartsigns® Compact 300 vital signs monitor. Important safety information relating to general use of the monitor appears before this introduction. Other important safety information is located throughout the text where applicable.

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

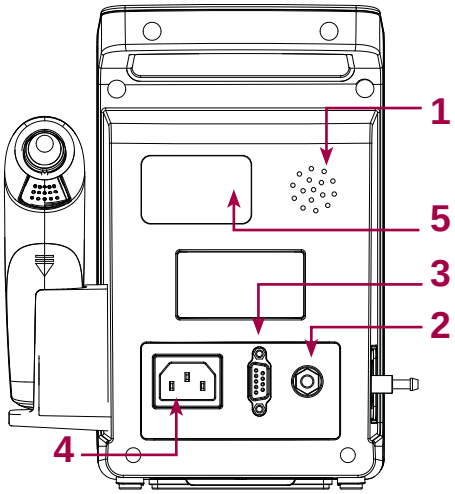
This manual is compatible with units fitted with Version 3.0 software and above.

3. Description of Controls, Indicators, Symbols and Displays

3.1 Identification of Front Panel Controls and Symbols

1	Carry handle
2	Display
3	ON / OFF
4	**Battery Indicator** • ON: Monitor is connected to the AC power source • OFF: Battery is fully charged • FLASHING: The battery is charging. • FLASHING RED: Low battery indication **AC Power Indicator** • ON: Monitor is connected to AC power • OFF: Monitor is not connected to AC power
5	Return
6	Patient group selection
7	Start / Stop NiBP
8	Wireless infrared thermometer

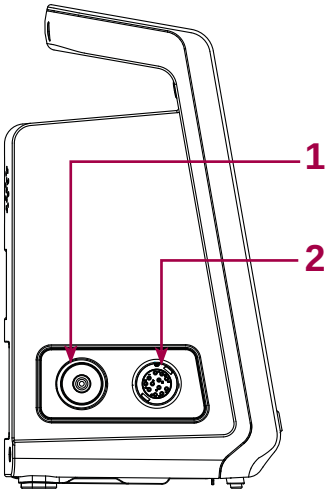
3.2 Identification of rear panel controls



1	Loudspeaker
2	Equipotential post
3	RS232 Service port
4	AC Power connector
5	Product identification label

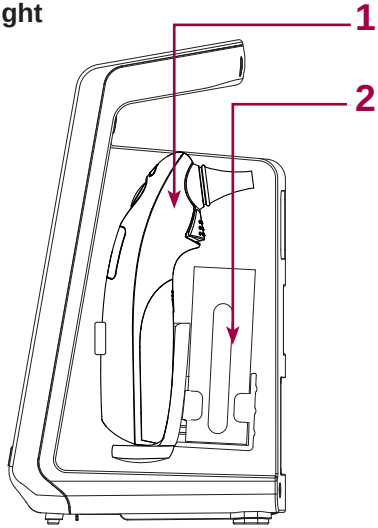
3.3 Identification of Side panel controls

Left



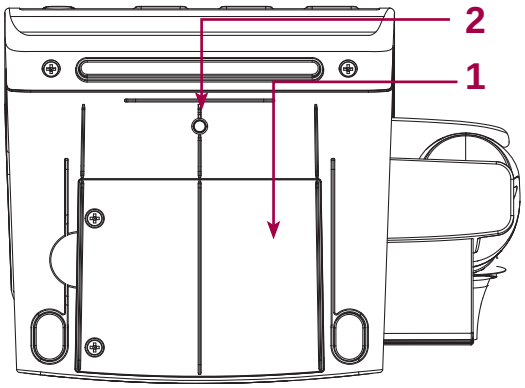
1	NiBP connector
2	SpO2 connector

Right



1	Wireless Infra red thermometer IRT10 (option)
2	Thermometer lenses (option)

3.4 Identification of Underside



1	Battery compartment
2	Adaptor plate fixing point

The internal battery is accessed through the compartment located on the underside of the unit.

A fixing kit is available for the unit. It is attached using a single point fixing.

3.5 Description of Symbols/ Indicators

The symbols and Indicators are described as follows:

Symbols	Description
	Attention, consult accompanying documents.
	Patient type: Adult
	Patient type: Paediatric
	Patient type: Neonatal
	Start / Stop Non-invasive blood pressure measurement
	Type BF – Defibrillator proof
	Equipotentiality
	On/Off/Standby

Symbols	Description
	Battery charging indicator lamp
	AC power(AC)
	Input/output
	Refer to instructions for use
IPX1	Protection against vertically falling water drops
	Date of manufacture
SN	Serial number
CE 0088	Conformité Européenne Complies with medical device directive 93/42/ EEC
	Disposal instructions
	Manufacturer
	This way Up
	Fragile – Handle with care
	Limit of stacking layers
	Keep dry

3.6 Description of Controls

Controls	Description
	**ON/OFF/STANDBY Key** • Press this button to start the system – the system status indicator will illuminate green. • When in measurement mode, press this button to enter standby mode – the system indicator changes to amber. • To switch OFF, press and hold this button for 2s.
	**Return key** Error code clearance • Press this key to clear any error code which may be displayed when in measurement mode. Save measurement • Press this key to save measurement to memory Memory re-call • Press and hold this key for 2s to access stored measurements in the memory Pulse tone enable / disable • Press and hold this key for 4s to enable the pulse tone setting (on / off) Maintenance mode selection • Press this key within 10s of power up to enter the maintenance mode.
	**Patient Group select key** Patient selection • Press this key to select the relevant patient group.
	**Start/Stop NIBP Measurement** • Press this key to initiate a blood pressure measurement, If the button is pressed during a measurement, the measurement will stop.

4. Setting up the Monitor

WARNING: The Smartsigns® Compact 300 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® Compact 300 vital signs monitor, SpO2 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.

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

CAUTION: If the Smartsigns® Compact 300 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® Compact 300 vital signs monitor is shipped in one carton. Examine the carton carefully for evidence of damage. Contact Huntleigh Healthcare Ltd Service 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.

4.2 List of Components

Quantity	Item
1	Smartsigns Compact 300 Spot Check Vital Signs Monitor
1	NiBP Cuff Adult (25 – 35 cm)
1	NiBP hose
1	SpO2 sensor
1	Wireless thermometer (Optional)
1	Thermometer lenses - pack 20 pcs (Optional)
1	Operator's manual
1	Power cord (country specific)
1	Grounding wire

A range of accessories are available for the Smartsigns Compact 300 series, please contact your distributor or the customer services Department for more information.

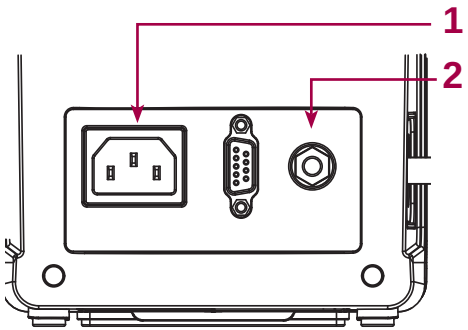
4.3 Power Cable Connections

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 in the specified voltage and frequent range (100 – 240 VAC, 50-60 Hz).



1	AC inlet
2	Equipotential point

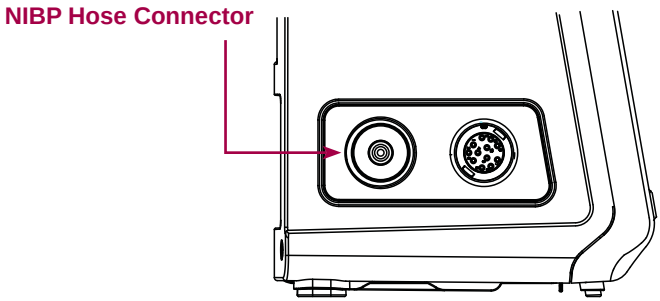
1. Connect the female connector end of the AC power cord to the monitor rear panel connector.
2. Plug the male connector end of the AC power cord into a suitably grounded AC outlet.
3. Verify that the Charging/AC Indicator is lit.
4. If necessary, connect the grounding wire. Connect the grounding wire 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.

4.4 Connecting Accessories

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.

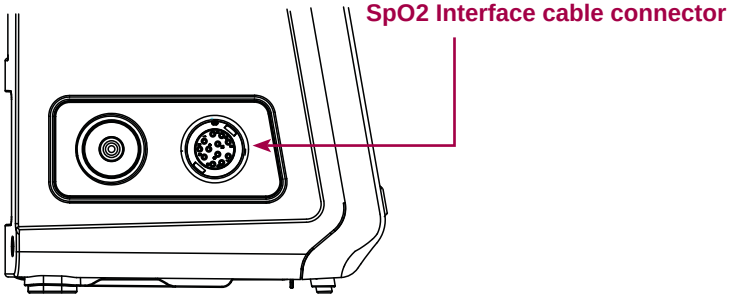
Note: For the safety of patients, and to ensure the best product performance and accuracy, use accessories provided with the Smartsigns® Compact 300 only, or accessories recommended by Huntleigh Healthcare Ltd Service Department.

NIBP Hoses and Cuffs



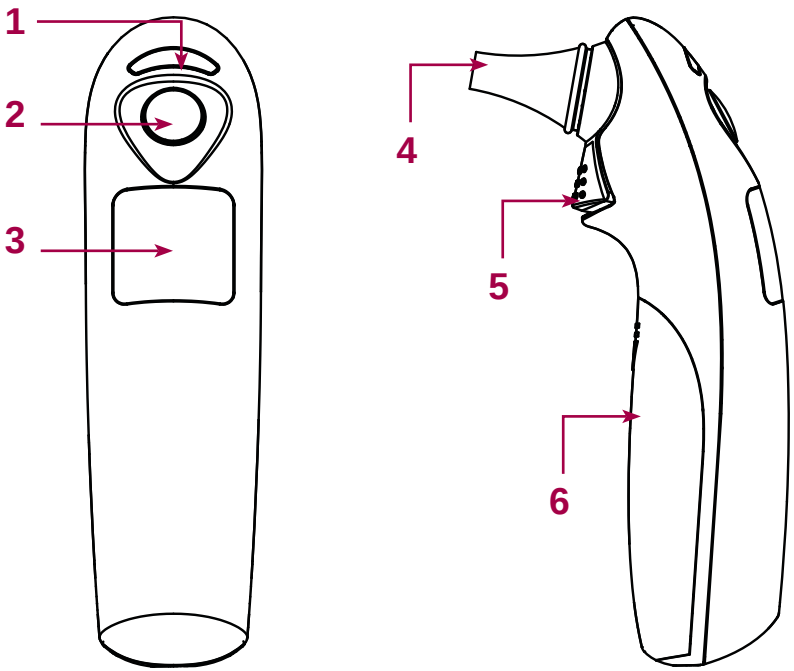
1. Select the appropriate size cuff for the patient and apply the cuff to the selected site.
2. Connect the hose to the NiBP connector on the side of the unit.

SpO2 Cables and Sensors



1. Select an appropriate sensor for the patient and desired application.
2. Apply the sensor to the selected site.
3. Connect the SpO2 sensor to the side of the unit.

Wireless thermometer (Option)



1	Status indicator
2	Start measurement
3	Display
4	Infra red sensor
5	Lense ejector
6	Battery compartment

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® Compact 300 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: 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.

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.

5.1 Installing the Battery pack

The monitor has an internal Lithium Ion rechargeable battery which can power the unit when an AC power source is not available.

Turn the monitor OFF, disconnect the power cord and any accessory.

Place the monitor on a surface and place upright with the base exposed.

Unscrew the battery cover, offer the battery into the battery compartment making sure the positive and negative terminals are connected correctly.

Replace the battery cover and secure, turn the monitor upright.

5.2 Operating on Battery Power

With the SpO2 sensor connected and NiBP measurements taken at 10 minute intervals, the operating time for a fully charged battery pack is typically not less than 12 hours.

When connected to the AC power supply, the battery is automatically charged.

The battery icon shown on the screen will indicate the battery status:

Battery indicator	Status
	Battery is fully charged
	Battery is charged but not at maximum level
	Battery requires recharging

If the battery symbol flashes, it indicates that the battery needs to be charged immediately. The flashing symbol is also accompanied with an audible alert.

5.3 Charging a low battery

Connect the monitor to the local AC supply, charging is automatic.

During the charging process, the battery charging indicator lamp illuminates green.

On reaching full capacity the battery charging indicator lamp will extinguish.

The typical charging time of the lithium-ion battery is:

- With the monitor switched OFF, the recharge time is less than 3 hours.
- With the monitor switched ON, the recharge time is no longer than 5.5 hours.

5.4 Battery Using Guidance

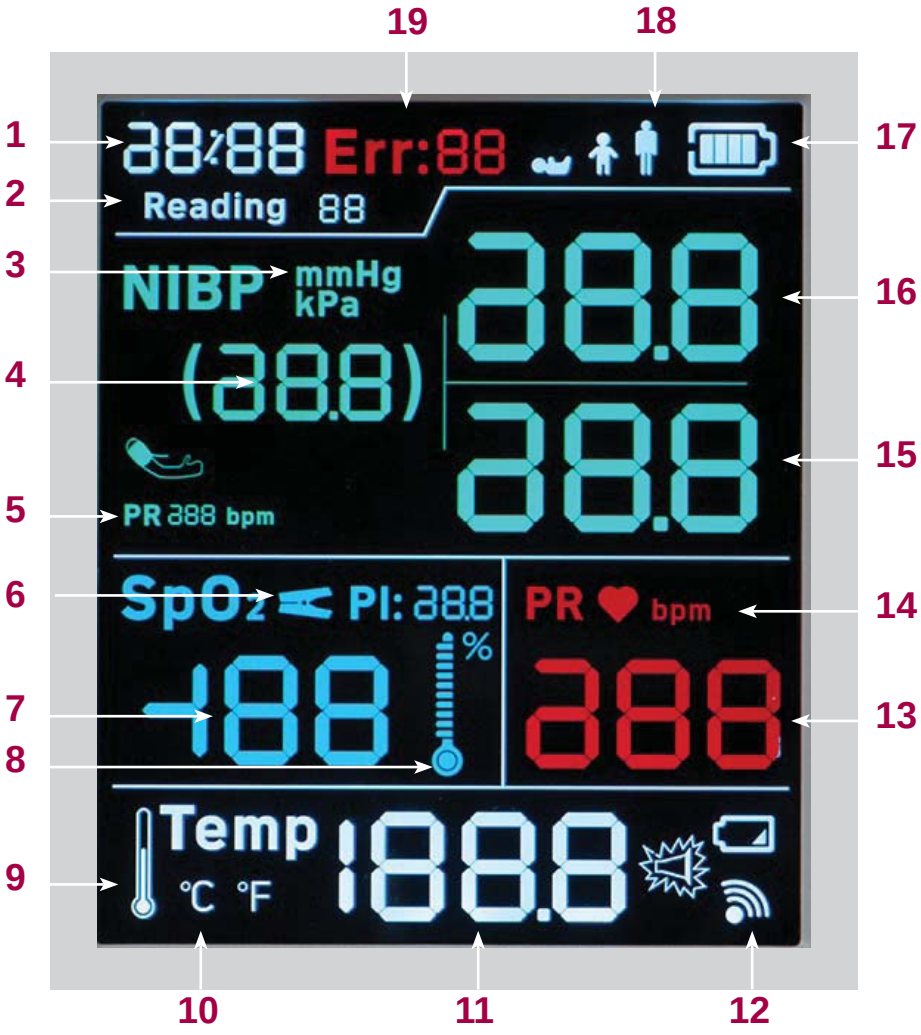
Life expectancy of the battery depends on how frequent and how long it is used. For a properly maintained and stored lithium-ion battery, its service life is approximately 3 years.

With more frequent and aggressive use, the life expectancy can be less.

We recommend replacing lithium-ion batteries every 3 years.

6. System Display

The display is organised into a series of zones



Item	Description
1	System time Set the time - Year, Month, Date, Hour, Minute
2	Patient measurement data review 50 sets data can be stored in the monitor
3	NIBP measurement units mmHg or kPa.
4	MAP - Mean arterial blood pressure reading
5	Pulse rate – derived from NiBP measurement
6	SpO2 sensor status: Own brand SpO2: • Icon flash: Poor finger connection, or sensor is disconnected Nellcor SpO2 • Icon off: Probe is off • Icon flash: Poor finger connection or sensor is disconnected
7	SpO2 measurement
8	Relative indication of signal strength
9	Temperature measurement
10	Temperature units (ºC or ºF)
11	Temperature reading
12	Wireless connection indicator – temperature sensor ON: Temperature sensor paired OFF: Temperature sensor NOT paired
13	Pulse rate – derived from the SpO2 sensor
14	Pulse rate symbol
15	Diastolic blood pressure measurement
16	Systolic blood pressure measurement
17	Battery indicator.
18	Patient type (neonate, paediatric, adult)
19	Error code

7. Using the Monitor

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® Compact 300 is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

WARNING: The Smartsigns® Compact 300 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.

7.1 Turning the Monitor ON

Before using the Smartsigns® Compact 300, 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 haemoglobin, arterial dyes, low perfusion, dark pigment, and externally applied colouring agents such as nail polish, dye, or pigmented cream.

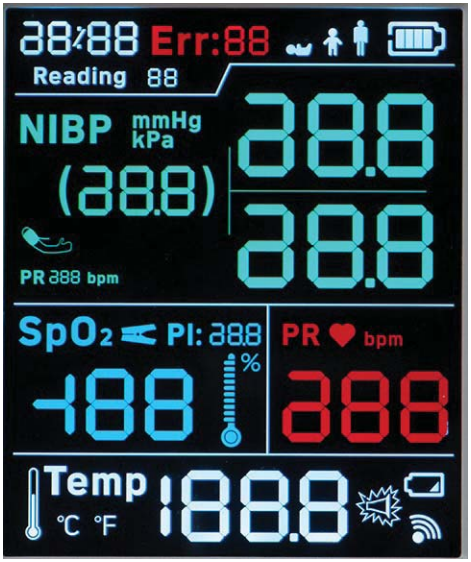
Note: The parameters may be set on an individual basis, by the clinician, and these settings will remain in effect until the monitor is turned off.

7.2 Performing Power On and Self-Test (POST)

CAUTION: The Smartsigns® Compact 300 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 Service Department.

1. Turn the monitor ON by pressing the ON/OFF/STAND BY button.
2. The monitor automatically starts the Power On Self Test (POST), which tests the system integrity.
3. Verify that the monitor sounds a confirmation tone during power up and each section of the display is illuminated.



Power On Self Test

4. Should the system detect an internal problem, the system will display an error code on the display. Contact a qualified service person
5. Upon completion of the POST, the monitor will enter the MEASUREMENT MODE.

7.3 Turning the Monitor OFF

To switch the system OFF, follow the steps blow,

1. Ensure the monitoring session has finished.
2. Disconnect all accessories from the patient.
3. Press and hold the ON/OFF/STAND BY key for 2s, the system will shut down.

8. System Settings

The Smartsigns Compact 300 Series provides multiple working modes for its users

- Measurement mode – Take measurements
- Review mode – View saved measurements
- Parameter setting mode – Set pulse tone ON or OFF
- Maintenance mode – Adjust system settings
- Standby mode - Sleep

Each mode offers different facilities and access to different settings.

8.1 Measuring Mode

After the initial startup, the system defaults to the measurement mode.

From here the user can undertake a series of measurements.

1. Press  to start the NIBP measurement.
2. Apply the SpO2 sensor to the patient, after a short period, the SpO2 measurement will be displayed on the screen.
3. Apply a new infrared lens cover to the tip of the Thermometer, temperature measurements can now be made
4. After making a measurement, data will be displayed in the corresponding area on the display.
5. Press  to save the measurement to memory.
6. After measuring one or multiple parameters, data will be automatically saved if there is no additional measurement made within 2 minutes.

8.2 Review Mode

In the measuring mode, press  for 2s to enter review mode; in this mode, up to 50 sets measurement data can be reviewed. Measurements are stored in date and time order.

1. Press  to cycle through the stored measurements, the oldest measurement will be displayed first.
2. Press  to return to the measurement mode.

This monitor saves up to 50 measurements.

8.3 Pulse Tone Setting

1. In the measuring mode, press and hold  for 4s to enter the pulse tone setting.
2. The PR value will flash
3. Press  to switch pulse sound on or off.
4. Press  to save the setting and return to the measurement mode.

8.4 Standby Mode

Press  to enter the standby mode.

The monitor will automatically enter the standby mode if there is no activity for 10 minutes.

The monitor will automatically shut down if it remains in standby mode for more than 30 minutes

When the unit is in standby mode, the display will be switched off and the ON/OFF/STANDBY key backlight will be illuminated amber.

8.5 Exiting Standby Mode

To exit the standby mode, press any key. Additionally, the system will automatically exit standby if:

1. The monitor receives an input from the SpO2 sensor.
2. The power is too low ()
3. Receives a temperature measurement

8.6 Maintenance Mode

The maintenance mode is intended for use of a biomedical technician or suitably qualified person. It is unlikely that healthcare professionals or clinicians would need to access this mode.

To enter the maintenance mode, press the key within 10s of switching the system ON.

The system will display the firmware revision in each of the corresponding sections of the display.

In this mode, the user can access the flowing settings:

a) NIBP units of measure

b) Temp units of measure

c) System date & time

d) NIBP leak test

e) NIBP pressure test

f) Display brightness

g) Restoration of the factory default settings.

Having made a change, Press and hold to shut the monitor down. The new settings will take effect when the monitor is restarted.

NIBP Units Setting

Enter the maintenance mode;

1. Press or to alternate between mmHg or kPa.
2. Make the selection and press and hold to shut the monitor down or to move to the next setting.

Temp Units Setting

Enter the maintenance mode;

1. Press and switch to the TEMP unit setting area
2. Press or to switch between ºC or ºF
3. Make the selection and press and hold to shut the monitor down or to move to the next setting.

System Date & Time Setting

Enter the maintenance mode;

Year

1. Press  twice to enter the ” year” setting area;
2. Press  to increase the value
3. Press  to decrease the value

Month/Day

1. Press  to enter the ”Month” setting
2. Press  to increase the value
3. Press  to decrease the value
4. Press  to enter the ”Day” setting
5. Press  to increase the value
3. Press  to decrease the value

Hour/Minute

1. Press  to enter the ”Hour” setting
2. Press  to increase the value
3. Press  to decrease the value
4. Press  to enter the ”Minute” setting
5. Press  to increase the value
3. Press  to decrease the value

Having made the selection, press  to exit the date and time setting.

NIBP Module Testing

 ***This adjustment is reserved for service personnel***

Enter the maintenance mode.

1. Press  until the PR bpm display begins to flash
2. Press  to switch between the leak test or pressure test

   “150” selects the NIBP leak test;
   “250” selects the NIBP pressure testing.
3. Press  to start each test.

Brightness Adjust

This adjustment is reserved for service personnel

Enter the maintenance mode

1. Press  repeatedly until the brightness adjustment setting begins to flash.
2. Press  or  to adjust the display brightness – 05 being maximum brightness.

Restoring Factory Default settings

This adjustment is reserved for service personnel

Enter the maintenance mode;

1. Press  repeatedly until 00 is displayed in the PR bpm area.
2. Although the factory default settings cannot be changed, the user can assign a different configuration to the local default settings.
3. To restore the configuration to the default factory settings, press  to select 00.

The factory default settings are:

Unit	Default setting
NiBP units	mmHg
Temperature Units	ºC
Patient Type	Adult
Beep Tone	ON

9. NIBP Monitoring

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 Service Department. Using other cuffs or hoses may result in inaccuracies.

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.

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® Compact 300 readings for patient assessment.

The Smartsigns® Compact 300 is not intended for diagnostic treatment. To ensure patient safety, use other diagnosis equipment.

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.

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.

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

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

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.

As with all automatically inflatable blood pressure devices, continual cuff measurements can cause injury to the patient being monitored.

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.

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

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

Do not touch the monitor when a defibrillator is being discharged (electrified), as doing so may cause electric shock.

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.

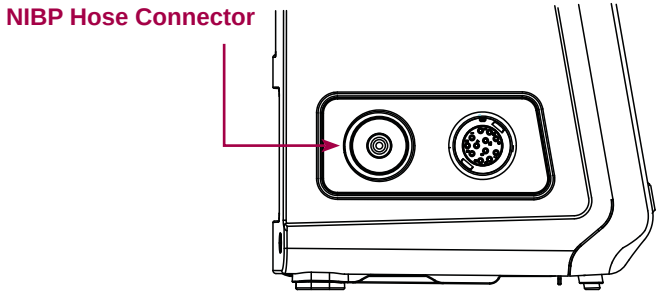
9.1 General

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

9.2 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 Service Department.

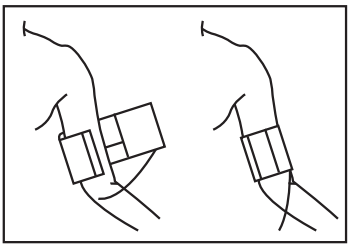
1. Measure the patient's limb and select the proper size cuff. As a general rule, cuff width should span approximately two-thirds of the distance between the patient's elbow and shoulder.

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

3. Connect a cuff to the 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.



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.

Size	Limb Circumference	Cuff width	Hose length
Neonate 1	3.1 - 5.7 cm	2.5 cm	3m
Neonate 2	4.3 - 8.0 cm	3.2 cm	
Neonate 3	5.8 - 10.9 cm	4.3 cm	
Neonate 4	7.1 - 13.1 cm	5.1 cm	
Infant	10 - 19 cm	8 cm	
Paediatric	18 - 26 cm	10.6 cm	
Adult	25 - 35 cm	14 cm	
Adult	33 - 47 cm	17 cm	
Adult	46 - 66 cm	21 cm	

9.3 Starting / Stopping Measurements

Press the  key on the monitor's front panel to initiate a measurement.

As soon as the measurement has started, the MAP area of the display will show the cuff pressure.

The system will inflate the cuff to the appropriate default target pressure.

The default target pressure of this monitor is:

- Adult: 160mmHg
- Child: 120mmHg
- Neonate: 100mmHg

After a short period, the measurement will be displayed on the screen.

The pulse rate will be shown below the NiBP measurement.

If there is any doubt concerning the NIBP measurement, an alternative method should be used.

10. SpO2/Pulse Rate Monitoring

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.

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.

Pulse oximetry readings and pulse signal can be affected by certain ambient environmental conditions, sensor application errors, and certain patient conditions.

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

Inaccurate measurements may be caused by:

- ***incorrect sensor application or use***
- ***significant levels of dysfunctional haemoglobin (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 anaemia, or hypothermia***
- ***there is arterial occlusion proximal to the sensor the patient is in cardiac arrest or is in shock***

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 SpO2 sensor is attached***

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

The sensor disconnect error indicates 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.

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.

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.

10.1 General Principles of Measuring SpO_2 Plethysmography Parameter

Oxygen saturation in capillary blood is measured by a method called pulse oximetry (SpO_2). It is a continuous, non-invasive method of determining the amount of oxygen attached to the haemoglobin in red blood cells (oxyhaemoglobin). It is an estimation of arterial oxygen saturation.

The traditional method relies on the concept of passing red and infra-red light into the capillary bed and measuring the changes due to the absorption during the pulsatile cycle. Both red and infra red sensors with specific wave lengths serve as the light source for the light transfer, whereas a photodiode serves are the receptor.

The Smartisgns Compact 300 series uses technologies from two different providers:

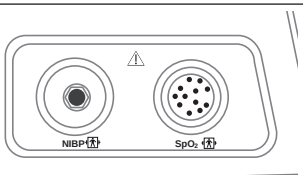
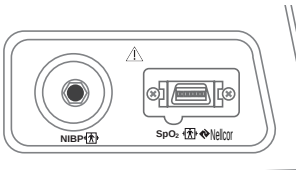
Technology	Red wavelength (nm)	Infra Red wavelength (nm)
Own brand	660	905
Nellcor	660	890

Sensors are designed for specific patient groups and sites, therefore, when considering the sensor, consider the patients weight, activity, expected levels of perfusion and environment.

To optimise the SpO_2 measurement, apply it as directed and pay particular attention to all warnings and cautions

10.2 Identifying the SpO_2 Module

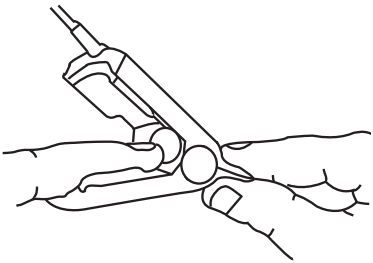
To identify which SpO2 module is incorporated into your product, refer to the identification on the side of the unit:

	**Own brand SpO2 module**
	**Nellcor Oximax SpO2**

NOTE: The SpO2 sensors are NOT interchangeable between the different technologies.

10.3 Setup Connections

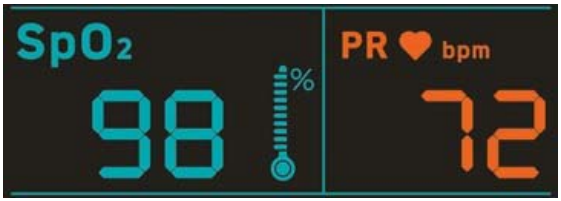
Carefully apply the sensor to the patient's finger as described in the sensor directions for use.



Insert the interface cable into the socket marked SpO2 on the monitor.

Turn the monitor ON, the measurements will appear on the SpO2 and PR area of the display after a short period.

10.4 SpO2 and Pulse Rate Display



SpO2 (Arterial oxygen saturation):	The percentage of oxyhaemoglobin to total haemoglobin.
Bar graph:	Relative strength of the pulse.
PR - Pulse rate:	Pulse or heart rate derived from SpO2 signal source.
PR symbol:	Heart beat

11. Temperature Monitoring

The Thermometer must be calibrated at least once every two years, contact your service personnel when calibration is necessary

Use only specified protective lense covers

The protective lense cover is single-use. Repeated use might give rise to cross infection.

The protective lense cover must be used when measuring, if not, it might cause cross infection or inaccurate readings.

Before use, check whether the cover is free from damage, if not, don't use.

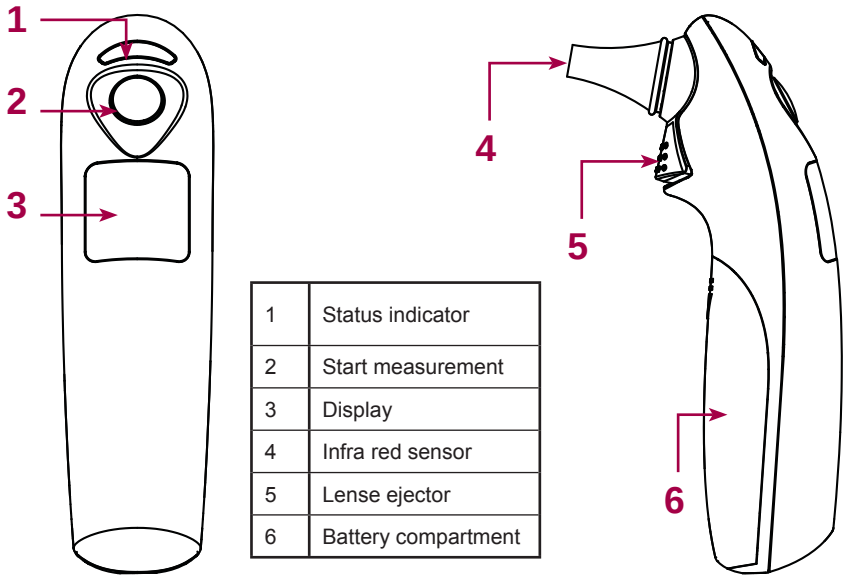
Handle the thermometer with care, it should be stored in the cradle when not in use.

Discard the protective lense cover in accordance with the local regulations.

During the monitoring process, the temperature measuring instrument will automatically check itself once per hour. Self-checking will last 2 seconds, and will not affect the normal working of the temperature monitor.

Temperature measurements are obtained from a wireless infrared ear thermometer. Measurements are sent via a wireless connection established between the thermometer and the main unit.
Both items (Thermometer and unit) must be paired to enable wireless data transfer.

11.1 Description of the Thermometer IRT10



1	Status indicator
2	Start measurement
3	Display
4	Infra red sensor
5	Lense ejector
6	Battery compartment

11.2 Thermometer Display

Key	Function / Display
	Battery status
	Lense filter status
	Wireless status
	Scale ºC or ºF
	Measurement

11.3 Main Unit Display

Key	Function / Display
	Temperature logo
	Scale ºC or ºF
	Measurement
	Wireless status

11.4 Pairing the Thermometer and Main Unit

1. Make sure the main unit and ear thermometer are both switched OFF.
2. Press and hold the “ejector key” on the thermometer and switch it ON.
3. The thermometer display will alternate between ºC and ºF and then display “SE”.
4. When “SE” is displayed, release the ejector button and switch the main unit ON.
5. Pairing will be established when the icon is displayed on the host unit.
6. If pairing has failed, no icon will be displayed.

11.5 Temp Measurement

1. Install a new protective lense cover to the thermometer.
2. Place the ear thermometer in the correct position and press the measurement key.
3. After approximately two seconds, the sensor emits a short “tone” indicating that the measurement is complete.
4. Remove the thermometer.
5. The measurement will be shown on the thermometer’s screen, it will be automatically transferred to the monitor.

6. Press the eject key to remove the disposable lens.
7. Place the lens in the appropriate waste collection point and replace the thermometer onto the unit

12. 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.

12.1 General

Follow local governing ordinance and recycling instructions regarding the disposal or recycling of end of life use of Smartsigns® Compact 300 and accessories. Otherwise environment or people may be harmed from improper disposal of battery or accessories.

12.2 Returning the Smartsigns® Compact 300 and System Components

Contact Huntleigh Healthcare Ltd Service Department for shipping instructions including a Returned Goods Authorization (RGA) number. Pack the Smartsigns® Compact 300 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® Compact 300 by any shipping method that provides proof of delivery.

12.3 Service

The Smartsigns® Compact 300 requires no routine service other than cleaning or battery maintenance that is mandated by the user's institution. For more information, refer to Smartsigns® Compact 300 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 Service Department.

If the institution's service personnel cannot correct problems, the Smartsigns® Compact 300 should be returned to Huntleigh Healthcare Ltd for service. Contact Huntleigh Healthcare Ltd Service Department for return instructions.

12.4 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.

12.5 Cleaning

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

- The Smartsigns® Compact 300 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.

12.6 Battery maintenance

If the Smartsigns® Compact 300 vital signs monitor has not been used 2 months, the battery will need charging. To charge the battery, connect the Smartsigns® Compact 300 to an AC power source as described in the Battery Operation section.

Note: Storing the Smartsigns® Compact 300 for a long period without charging the battery may degrade the battery capacity.

CAUTION: If the Smartsigns® Compact 300 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.

13. 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® Compact 300, its accessories, connectors, switches, or openings in the chassis.

13.1 General

If the Smartsigns® Compact 300 is unable to perform any of its monitoring functions because of the loss of software control or a hardware malfunction, an error code is presented.
In the unlikely event of the unit developing a fault, fault codes will be shown in the corresponding area and the related parameters will flash on the screen

Code	Description	Cause	Solution
01	The communication of SpO2 module has stopped	There is a problem with SpO2 module	Contact service personnel or biomedical engineer.
02	Unrecognised probe	The probe can't be recognized by SpO2 module	Check the connection between probe and host, if the alarm still can't be cancelled, contact service personnel or biomedical engineer.
03	Weak signal	The signal is too weak	Check patient's vital signs, and change the measurement site.
04	Too much light	SpO2 probe is too loose	Check and connect the SpO2 probe again, ensure the stable
05	SpO2 board fault	There is a problem with the module	Do not use and contact service personnel.
06	PI too low	The SpO2 signal is too weak.	Check the patient's condition and change the application site.
07	Probe fault	There is a problem with the probe	Do not use the probe and contact service personnel
08	Interference	The signal has been interfered by motion or noise	Check for any possible sources of signal noise from the area around the sensor and check the patient for excess motion
10	Loose cuff	The NIBP cuff is not properly connected	Check and connect the cuff again.
11	Air leak	The NIBP cuff is not properly connected or there is a leak in the airway	Check the connection or use a new cuff, if the problem persists, contact service personnel.

Code	Description	Cause	Solution
12	Air pressure Err	The pressure is not stable, such as hose entanglement	Check the connection or use a new cuff. If the problem persists, contact service personnel.
13	NIBP weak signal	The cuff is loose or the signal is weak	Check the patient type setting and the connection or replace a cuff. If the error persists, contact service personnel
14	NIBP over range	The measured value is not within the specified range	Contact service personnel
15	NIBP excessive motion	Arm motion	Check the patient's condition and reduce the motion
16	NIBP over voltage protective	the airway may be occluded	Check the airway and the patient's condition. If the error persists, contact service personnel
17	NIBP air leak	There is a leak in airway	Check and replace the parts that cause the leak. If the error persists, contact service personnel
18	NIBP system error	There is a problem with the system of pressure pump	Do not use the NIBP module and contact service personnel
19	NIBP time-out	The measurement time exceeds 120s in adult/ child mode or 90s in neonate mode	Check the patient type setting and connection. If needed, replace a cuff, if the error persists, contact service personnel
20	NIBP signal saturated	Excess motion	Reduce the motion and measure again
21	NIBP self-test error	There is a problem with the sensor or other hardware	Do not use the NIBP module and contact service personnel
22	NIBP communication error	There is a problem with the NIBP module or host	Restart the monitor, if the error persists, contact service personnel
23	NIBP cuff type wrong	The cuff doesn't match the patient type	Replace a cuff and measure
30	Ear thermometer communication error	The battery is too low or there is a problem with the communication module	Replace a battery, and restart the monitor,if the error persists, contact service personnel
46	Low battery	The battery terminal voltage is too low	Connect the monitor to an AC power source and allow the batteries to charge.
47	12V too high	There is a problem with the system power supply	Restart the monitor. If the error persists, contact service personnel
48	12V too low		
49	5V too high		
50	5V too low		

Serviceable error codes and other error codes are listed in the Smartsigns® Compact 300 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 Service Department, make sure that the battery is charged, and that all power connections are correctly made.

Temperature Module

Problem	Possible Cause	Servicing Method
Er0	Wireless module failure	Contact service personnel
Wireless transmission failure	Thermometer is far away from the receiving device	Keep ear thermometer within 10M of main unit.
	Thermometer does not connect to the main unit or Main unit is switched OFF	Pair again and ensure the receiving device is on.
	Wireless transmission function is damaged	Contact service personnel

13.2 Corrective Action

If you experience a problem while using the Smartsigns® Compact 300 and are unable to correct it, contact qualified service personnel or Huntleigh Healthcare Ltd Service Department.

The Smartsigns® Compact 300 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® Compact 300; contact qualified service personnel or Huntleigh Healthcare Ltd Service 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,

13.3 Obtaining Technical Assistance

For technical information and assistance, or to order a service manual, call Huntleigh Healthcare Ltd Service Department. The service manual includes information required by qualified service personnel when servicing the Smartsigns® Compact 300.

When calling the Huntleigh Healthcare Ltd Service Department, you may be asked to tell the representative the software version number of your Smartsigns® Compact 300. Qualified service personnel or Huntleigh Healthcare Ltd Service Department may help you check the software version installed in your monitor.

14. Electromagnetic Compatibility

Make sure the environment in which Smartsigns® Compact 300 is installed is not subject to strong sources of electromagnetic interference (e.g. radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, complies with EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering
- Plugging the equipment into a different outlet so that the devices are on different branch circuits

WARNING: The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Smartsigns® Compact 300 as replacement parts for internal components, may result in increased emissions or decreased immunity of the Smartsigns® Compact 300.

WARNING: The Smartsigns® Compact 300 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Smartsigns® Compact 300 should be observed to verify normal operation in the configuration in which it will be used

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Smartsigns® Compact 300 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The Smartsigns® Compact 300 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartsigns® Compact 300 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The Smartsigns® Compact 300 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Smartsigns® Compact 300 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Smartsigns® Compact 300 is intended for use in the electromagnetic environment specified below. The customer or the user of the Smartsigns® Compact 300 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Smartsigns® Compact 300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz outside ISM bands[a] 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands	3V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of the equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz, to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Smartsigns® Compact 300 is used exceeds the applicable RF compliance level above, the Smartsigns® Compact 300 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® Compact 300.

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

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Smartsigns® Compact 300 intended for use in the electromagnetic environment specified below. The customer or the user of the Smartsigns® Compact 300 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_r (>95 % dip in U_r) for 0,5 cycles 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 s	<5 % U_r (>95 % dip in U_r) for 0,5 cycles 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 s	Mains power quality should be that of a typical commercial of hospital environment. If the user of the Smartsigns® Compact 300 requires continued operation during power mains interruptions, it is recommended that the Smartsigns® Compact 300 is powered from an uninterruptible power supply or battery, by specifying the battery option at time of purchase.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_r is the a.c. mains voltage prior to the application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the Smartsigns® Compact 300

The Smartsigns® Compact 300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. the customer or user of the Smartsigns® Compact 300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Smartsigns® Compact 300 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15. Specifications

15.1 Equipment Classification

Type of protection against electric shock.	Class 1 with internal power
Degree of protection against electric shock 	BF
Mode of operation.	Continuous
Degree of protection against harmful ingress of particles and/or water.	IPX1
Degree of safety of application in the presence of a flammable anaesthetic	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE

15.2 Standards

MDD 93/42/EEC	**EN ISO13485:2012+AC2012**
EN ISO14971: 2012	**EN 60601-1: 2006/ AC:2013**
EN 60601-1-2: 2007/AC:2010	**EN60601-1-6:2010**
EN 980:2008	**EN 1041: 2008**
EN ISO10993-1:2009	**EN ISO10993-5:2009**
EN ISO 10993-10:2010	**EN 1060-1:1995+A2:2009**
EN 1060-3:1997+A2:2009	**EN 1060-4:2004**
EN ISO 80601-2-30:2009+A1:2013	**EN ISO 80601-2-61:2011**
EN 62366:2008	**EN62304:2006**

15.3 General

Display	100mm x 120mm
RS-232	
Equipotential socket	
Loud speaker	
Size	Width 125mm, Height 299mm, Depth 130mm
Weight	1.25Kg including battery (weight of battery:0.25Kg)
Service Life	7 years

15.4 Electrical

AC Power	
Voltage	100-240 VAC
Frequency	50Hz/60Hz
Input current	0.3-0.15A
Battery	
Type	2200 mAh, 11.1V Lithium Ion
Charging Time	When monitor is OFF, the charging time will be no longer than 3 hours When monitor is ON, the charging time will be no longer than 5.5 hours.
Endurance time	12 hours fully charged Low battery alarm is sounded 5 minutes before shut down.
Battery Specifications (IRT10 ear thermometer)	2 x Type LR03 AAA1.5VDC

15.5 Environmental

Operation	
Temperature	0 °C to 40 °C without ear thermometer) 15 °C to 36 °C (with ear thermometer)
Humidity	93% non-condensing (without thermometer) ≤93% non-condensing (with thermometer)
Altitude	700 hPa to 1060hPa
Transport and Storage	
Temperature	–20 °C to 60 °C (Packed)
Humidity	≤93% 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.

15.6 Measurement Parameters

NIBP

Measurement method	Oscillometric	
Parameter display	Systolic pressure, diastolic blood, mean pressure and pulse	
Range of measurement for adult	systolic pressure	40-270mmHg (5.3-36kPa)
	diastolic pressure	10-215mmHg (1.3-28.7kPa)
	mean pressure	20-235mmHg (2.7-31.3kPa)
Range of measurement for child	systolic pressure	40-200mmHg (5.3-26.7kPa)
	diastolic pressure	10-150mmHg (1.3-20kPa)
	mean pressure	20-165mmHg (2.7-22kPa)
Range of measurement for neonate	systolic pressure	40-135mmHg (5.3-18kPa)
	diastolic pressure	10-100mmHg (1.3-13.3kPa)
	mean pressure	20-110mmHg (2.7-14.7kPa)
Resolution	1mmHg (0.1kPa)	
The measurement range and accuracy of static pressure	0 mmHg (0 kPa) to 300 mmHg (40.0 kPa) to ±3 mmHg (±0.4 kPa)	
Accuracy	±5mmHg	

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.

SpO_2

Range and accuracy (70% to 100%*)		
Own Brand	0% to 100%	±2% (measured without motion in adult/child mode) ±3% (measured without motion in adult/child mode)
Nellcor Module	0% to 100%	±2% (measured without motion in adult/child mode) ±3% (measured without motion in neonate mode)
Resolution	1%	

** Accuracy 0% to 69% - not specified*

Temperature

Probe Type	Thermistor probe
Range	34° C to 42.2° C (93.2° F to 107.6°F)
Display Accuracy	36° C to 42° C : ±0.2° C (±0.4° F) 20° C to 34° C : ±0.3° C (±0.5° F)
Resolution	0.1°C
Standards	ASTM E1112-00:2000, EN12470-3 and EN12470-4

Pulse Rate

Range and accuracy			
Own Brand	25bpm -250bpm	1bmp	±1bmp
Nellcor Module	20bpm-300bpm	1bpm	±3bpm (20bpm to 250bpm) Not specified (251bpm to 300bpm)
NIBP Module	40bpm-240bpm	1bpm	±3bpm or ±3%(MAX)

16. Accessories

Please use accessory models designated by the manufacturer. Using accessories of other models may cause damage to this monitor

Disposable accessories can be used only once; their repeated using may result in performance deterioration or cross infection

Check the accessories and their packages for any signs of damage. Do not use them if any damage is observed

Disposing of single use accessories shall be handled in accordance with the local protocol after use.

Item	Part No
Own brand SpO2	
12 Pin Adult re-useable SpO2 sensor 10ft	**ACC VSM 289**
12 Pin to DB9F Extension cable 8ft	**ACC VSM 290**
Adult reusable SpO2 sensor (DB9F) 3ft	**ACC VSM 291**
Neonate / Paediatric Wrap sensor (DB9F) 3ft	**ACC VSM 292**
NELLCOR OXIMAX SpO2	
NELLCOR Reusable Extension cable/DOC-10,10ft	**ACC VSM 251**
Adult Nellcor Reusable SpO2 Sensor/DS-100A,3ft	**ACC VSM 252**
NELLCOR Reusable Type Y SpO2 Sensor/Dura-Y D-YS,3ft	**ACC VSM 255**
Neo Disposable Nellcor SPO2 Probe(MAX-N),3ft	**ACC VSM 256**
Ped Disposable Nellcor SPO2 Probe(MAX-P),3ft	**ACC VSM 257**
NiBP	
Infant NIBP Cuff 6-11cm	**ACC VSM 273**
Infant NIBP Cuff 10-19cm	**ACC VSM 274**
Paediatric NIBP Cuff 18-26cm	**ACC VSM 275**
Adult NIBP Cuff 20-38cm	**ACC VSM 276**
Adult NIBP Cuff 25-35cm	**ACC VSM 277**
Adult NIBP Cuff 33-47cm	**ACC VSM 278**
Adult NIBP Cuff 46-66cm	**ACC VSM 279**
Neo Disposable NIBP Cuff #1 / 3.0-5.5cm	**ACC VSM 280**
Neo Disposable NIBP Cuff #2 / 4.0-7.6cm	**ACC VSM 281**
Neo Disposable NIBP Cuff #3 / 5.6-10.6cm	**ACC VSM 282**
Neo Disposable NIBP Cuff #4 / 7.0-12.8cm	**ACC VSM 283**
NIBP hose /3M	**ACC VSM 284**

Temperature	
Lens filter 200 pcs (10 boxes)	**ACC VSM 293**
Lens filter 800 pcs (40 boxes)	**ACC VSM 286**
Lens filter 8,000 pcs (400 boxes)	**ACC VSM 287**
Hardware	
Mobile stand	**ACC VSM 153**
Wall mount	**ACC VSM 157**
Utility hook	**ACC VSM 187**
Utility basket	**ACC VSM 189**
Fixing / mounting kit	**ACC VSM 288**
IV Pole clamp	**ACC VSM 294**

17. 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.

17.1 Service Returns

If for any reason the Smartsigns Compact 300 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:-

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

Tel:	+44 (0)29 20485885
Fax:	+44 (0)29 20492520
Email:	sales@huntleigh-diagnostics.co.uk
	service@huntleigh-diagnostics.co.uk
	www.huntleigh-diagnostics.com

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The Smartsigns® Compact 300 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 ...performance for life

Huntleigh Healthcare Ltd. - Diagnostic Products Division
35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom
T: +44 (0)29 20485885 **F:** +44 (0)29 20492520 **E:** sales@huntleigh-diagnostics.co.uk
W: www.huntleigh-diagnostics.com

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Registered No: 942245 England & Wales. Registered Office:
ArjoHuntleigh House, Houghton Hall Business Park, Houghton Regis, Bedfordshire, LU5 5XF

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