INSTRUCTIONS FOR USE

SC300

Vital Signs Monitor

781301EN-13 12/2021

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Notice

Warranty

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Revision History

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

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: This instrument can only be connected to a power socket with protective earth.

WARNING: Do not position the equipment or the power cord to make it difficult to operate the power plug, which is used to isolate the equipment electrically from the mains supply.

WARNING: Do not make contact with the signal Input/Output ports and the patient simultaneously.

WARNING: After defibrillation the monitor will resume normal operation within 10 seconds.

WARNING: There is no alarm system in the monitor, it only provides fault codes for reference. The monitor is not suitable for continuous monitoring. Please pay attention to the patient to avoid a deterioration in the patient's condition.

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.

1.2 Service Life

This has been defined as the minimum time period during which the device is expected to remain safe and suitable to meet its intended use, and all risk control measures remain effective. Huntleigh Healthcare Ltd's commitment is that the expected service life for this Device has been defined as 7 years.

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 Vital Signs Monitor. It measures 130mm x 125mm x 219 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.

Note: It is recommended that the operator is positioned about 1 metre from the monitor during normal use.

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.

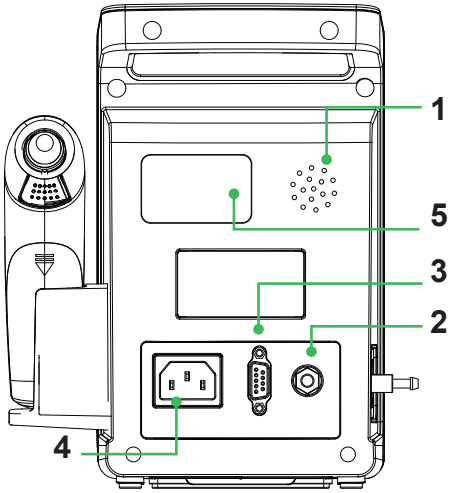
This manual is compatible with units fitted with Version 2.0 software and above.

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: Battery is being charged, or fully charged • OFF: Battery is not fitted or faulty • FLASHING: Mains Supply is disconnected, Monitor running on battery power. **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

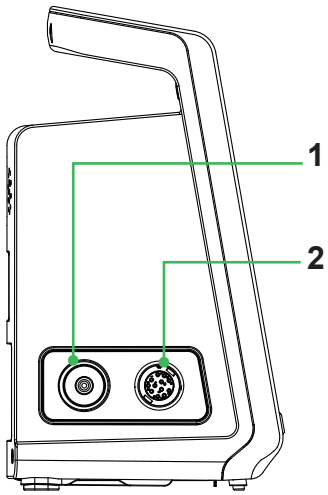
3.2 Identification of rear panel controls



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

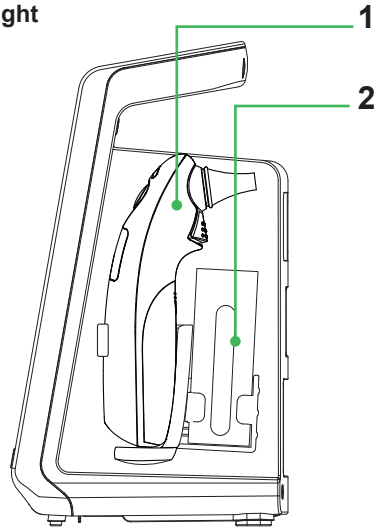
3.3 Identification of Side panel controls

Left



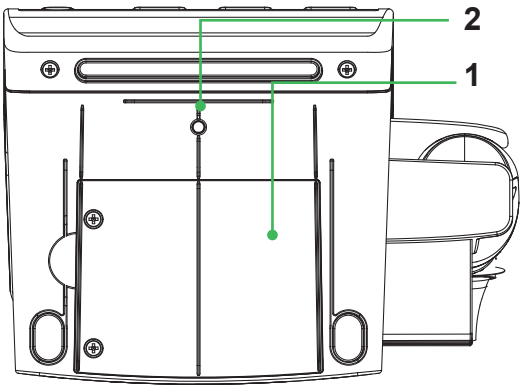
1	NiBP connector
2	SpO2 connector

Right



1	Wireless Infrared thermometer IRT10 (option)
2	Thermometer probe cover (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
	Patient type: Adult
	Patient type: Paediatric
	Patient type: Neonatal
	Start / Stop Non-invasive blood pressure measurement
	Type BF – Defibrillator proof
	Equipotentiality
	On/Off/Standby
	Battery charging indicator lamp

Symbols	Description
	AC power(AC)
	Input/output
	Refer to instructions for use
IPX1	Protection against vertically falling water drops
RX Only	Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.
CE 2797	This symbol signifies that this product complies with the essential requirements of the Medical Device Directive (93/42/EEC) - Medical Device Regulation (EU/2017/745)
	This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.
Manufactured By:	**Huntleigh Healthcare Ltd.** 35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk www.huntleigh-diagnostics.com
	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden

	General Warning		Attention, consult accompanying documents.
	This way Up		Fragile – Handle with care
	Limit of stacking layers		Keep dry
	No alarm system	REF	Reference Number
SN	Serial Number (Date of manufacture is included in SN)	DI	Device Identifier
MD	Medical Device		

3.6 Description of Controls

Controls	Description
	**ON/OFF/STANDBY Key** • Press this button to start the system – the system status indicator will illuminate white. • When in measurement mode, press this button to enter standby mode – the system indicator flashes. • 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 temperature , altitude or 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 Vital Signs Monitor
1	NiBP Cuff Adult (25 – 35 cm)
1	NiBP hose
1	SpO2 sensor
1	Wireless thermometer (Optional)
1	Thermometer probe cover - 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.

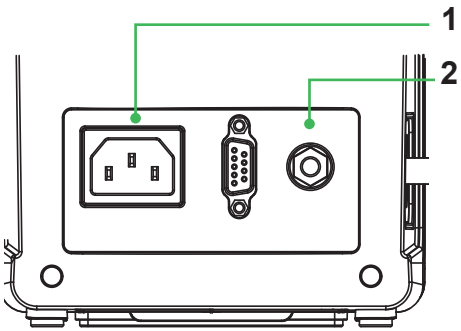
4.3 Power Cable Connections

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

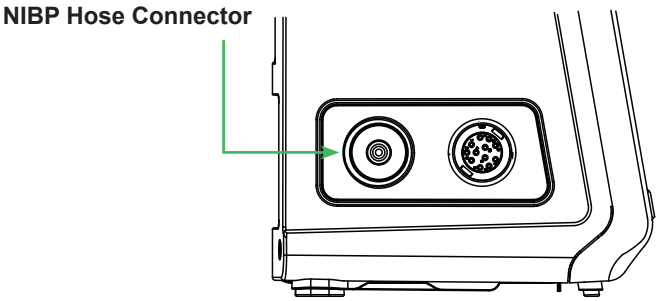
1. Connect the female connector end of the AC power cord to the monitor rear panel connector.
2. Plug the male connector end of the AC power cord into a suitably grounded AC outlet.
3. Verify that the Charging/AC Indicator is lit.
4. If necessary, connect the grounding wire. Connect the grounding wire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

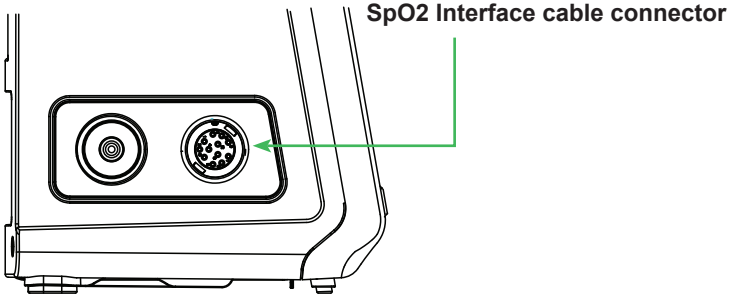
Note: For the safety of patients, and to ensure the best product performance and accuracy, use accessories provided with the Smartsigns® Compact 300 only, or accessories recommended by Huntleigh Healthcare Ltd Service Department.

NIBP Hoses and Cuffs



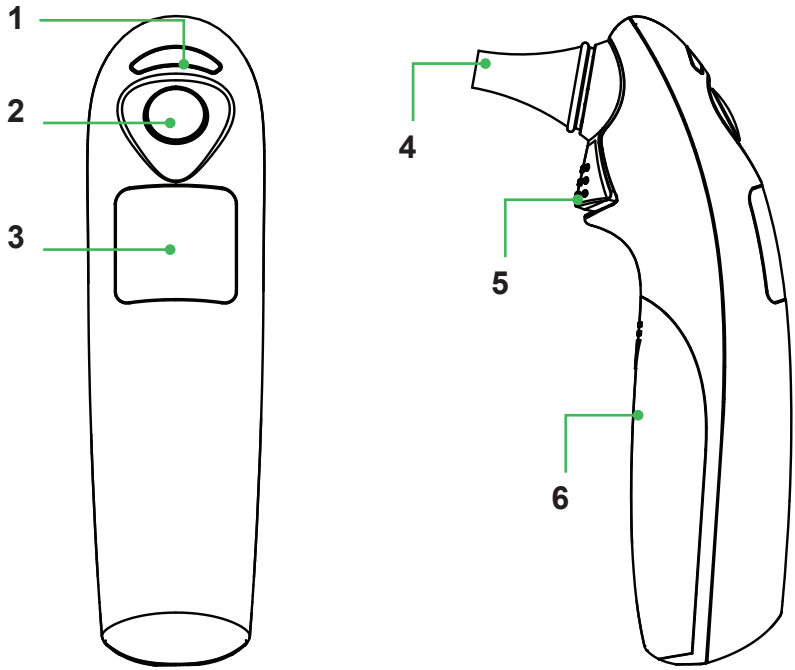
1. Select the appropriate size cuff for the patient and apply the cuff to the selected site.
2. Connect the hose to the NiBP connector on the side of the unit.

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	Infrared sensor
5	Probe cover 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 NiBP measurements taken at 15 minute intervals, the operating time for a fully charged battery pack is nominally 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 white.

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

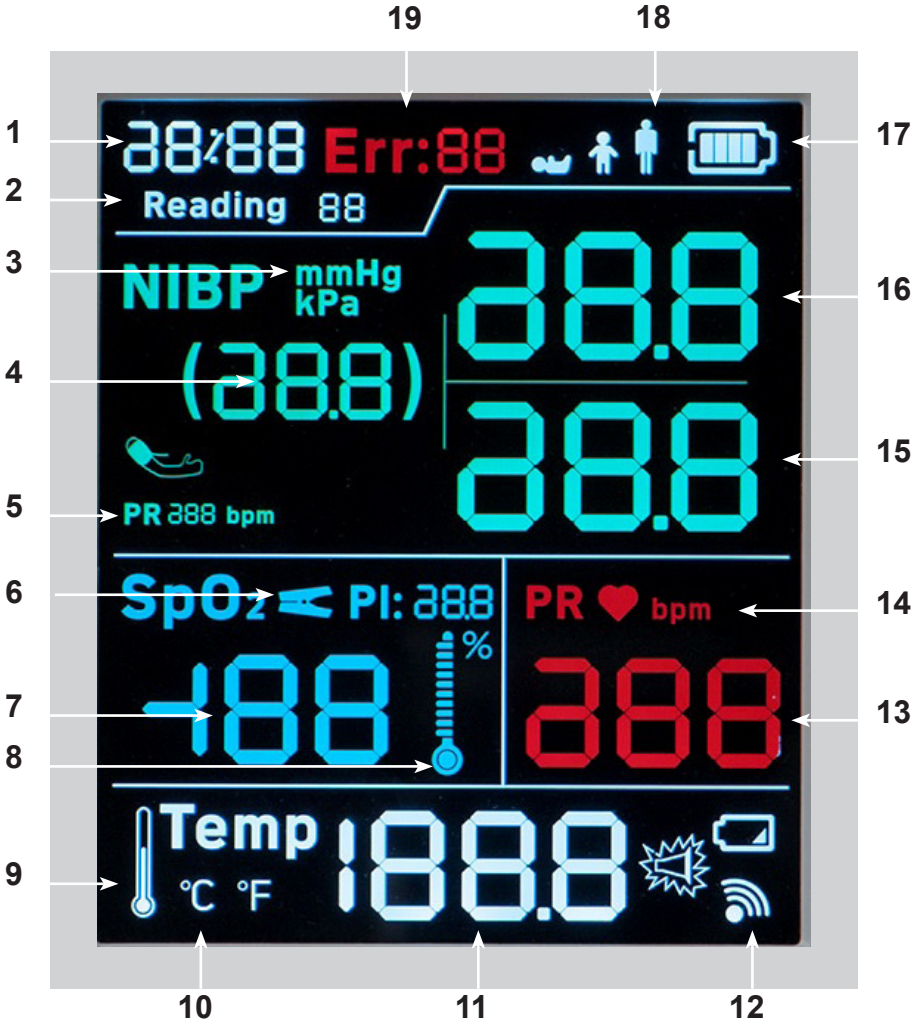
Life expectancy of the battery depends on how frequent and how long it is used. For a properly maintained and stored lithium-ion battery, its service life is approximately 3 years.

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 (Rotating digits is searching for a pulse).
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.

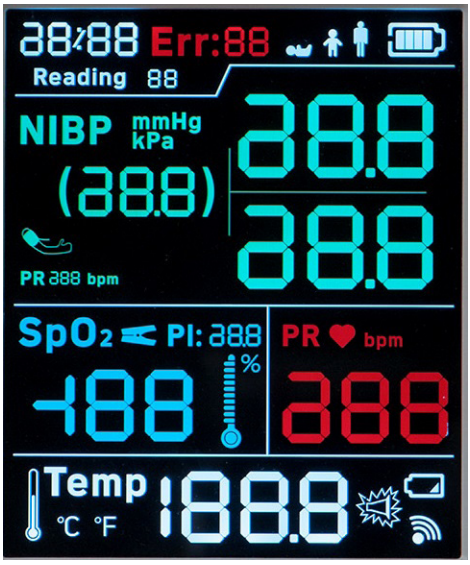
Note: The parameters may be set on an individual basis, by the clinician, and these settings will remain in effect until the monitor is turned off.

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 probe 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

When in measurement mode , press  to enter standby mode - the system indicator flashes.

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 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.

Continual cycling of the BP cuff may in extreme situations cause harm to the patient. Assess the advantages of frequent measurements in particular the use of CO mode against the potential risk of injury.

Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected

Do not place the cuff over a wound as this can cause further injury.

Do not use the NIBP cuff on a limb being used for intravenous infusion or any area where circulation is compromised or has the potential to be compromised.

Do not apply the NIBP cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, as it could cause temporary interference to blood flow and result in injury to the patient.

Do not place the NIBP cuff on a limb on the same side as a mastectomy.

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.

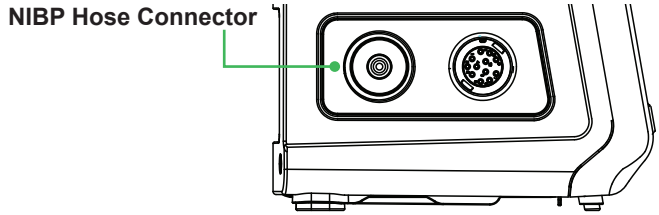
Note: **This equipment is suitable for use in the presence of electrosurgery.**

Note: **The monitor can be used for NIBP measurements on Adult, Paediatric and Neonate patient**

Note: **The SC300 Automated Sphygmomanometer is NOT intended for use with pregnant (including pre-eclamptic) patients.**

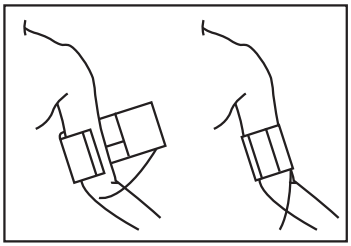
Note: **The SC300 Automated Sphygmomanometer effectiveness has not been established in pregnant (including pre-eclamptic) patients.**

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 ajor 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	
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	3m
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.

9.4 Automatic Measurements

Using the front panel keypad, users can set the unit to deliver automatic cyclic NiBP measurements – this interval can be set to 2, 3, 4, 5, 10, 15, 20, 25, 30, 60 or CO (continuous STAT measurements).

Setting the Auto NiBP time interval

From the main application screen, press and hold the NiBP START / STOP button for 2s to enter the AUTO NiBP mode.

The CLOCK will change from the current time (Hours & minutes) and display the AUTO interval setting (00:02 default setting).

As soon as the interval is displayed, release the button.

Press the NIBP START / STOP button to cycle through the interval options.

2 → 3 → 4 → 5→ 10 → 15 → 20 → 25 → 30 → 60 → CO (STAT mode)

From here the user will be able to set the time interval (minutes) : 2, 3, 4, 5, 10, 15, 20, 25, 30, 60 and CO (CO = continuous sequential measurements for 5 minute period equivalent to STAT mode).

Select the desired interval.

NOTE: When the system is set to CO mode, the system will take sequential measurements in a 5 minute period. After the 5 minute STAT period has elapsed, the system will automatically revert back to manual mode.

Saving the Auto NiBP time interval

To SAVE the NiBP interval setting, press the RETURN button  once.

The interval is “locked” into the system and displayed in the clock area of the display.

Starting the AUTOMATIC NiBP Measurement

Press the NIBP START / STOP button  to begin the sequence of measurements.

The cuff will begin to inflate and the interval time will change to a countdown timer counting down to the start of the next measurement.

When the timer reaches 00:00, the next measurement begins automatically.

The SC300 will remain in this mode until the user forces a STOP or switches the unit OFF.

Stopping the AUTOMATIC NiBP Measurement

PRESS and HOLD the NIBP START / STOP button  to stop the automatic interval.

The SC300 will automatically return to manual mode.

Or

Switch the system OFF.

The next time the system is powered up, it will be in MANUAL mode.

Recalling SAVED measurements

Press and HOLD the SAVE button  for 2s.

Use the patient group selection  to cycle up through the saved measurements.

Use the NIBP START / STOP  to cycle down through the saved measurements.

9.5 Hypersensitive Patients

In order to obtain accurate blood pressure measurement for a hypersensitive patient, please refer to the following:

1. During the measurement, the patient should be relaxed.
2. 5 minutes should elapse before the first reading is taken.
3. The patient position should be:
   a) Comfortably seated
   b) Legs uncrossed
   c) Feet flat on the floor
   d) Back and arm supported
   e) Middle of the CUFF at the level of the right atrium of the heart.

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.

SpO2 settling time: Allow the system to stabilise before recording the patient's SpO2 and PR values.

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 ardiac 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.

Skin irritations or lacerations may occur as a result of the sensor being attached to one location for too long. To avoid skin irritations and lacerations periodically inspect the sensor application site and change the application site at least once every two hours.

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

The Maximum available output power is 4mW

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 SpO_2 Accuracy Test

Warning: A functional tester cannot be used to assess the accuracy of a pulse oximeter probe.

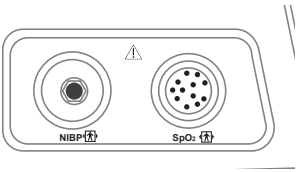
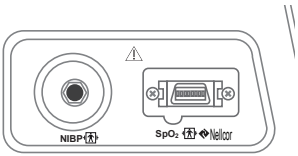
The recommended method of determining the SpO2 accuracy of the monitor is to compare it's SpO2 readings with the readings of a CO-oximeter.

10.3 PR Accuracy Determination

The reference method for the computation of Pulse Rate accuracy is electronic pulse simulator.

10.4 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:

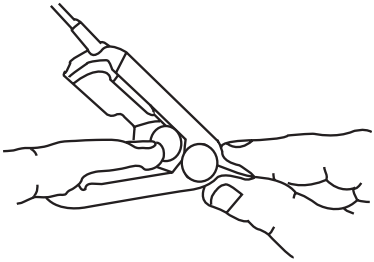
	**Own brand SpO2 module**
	**Nellcor Oximax SpO2**

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

10.5 Setup Connections

Adult SpO_2 Sensor

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

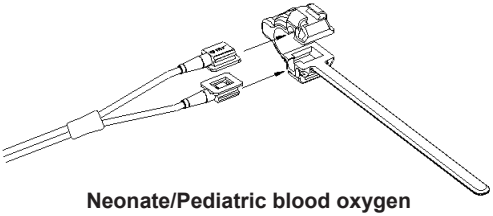


Insert the interface cable into the socket marked SpO2 on the monitor.

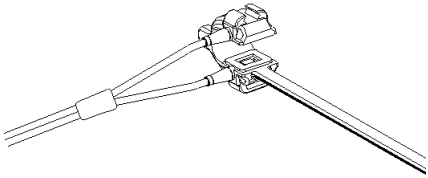
Turn the monitor ON, the measurements will appear on the SpO2 and PR area of the display after a short period.

Neonate/Pediatric wrap SpO_2 sensor

Neonate/Pediatric wrap oxygen sensor consists of the Y-shaped blood-oxygen sensor and wrap. Insert the LED side of the Y-shaped sensor in the upper groove of the sheath, and respectively the photo detector side of the sensor within the lower groove (See Figures below).



Neonate/Pediatric blood oxygen sensor wrap (1)



Neonate/Pediatric blood oxygen sensor wrap (2)

Neonate/Pediatric blood oxygen sensor wrap (3)

10.6 SpO2 and Pulse Rate Display

SpO2 (Arterial oxygen saturation):	The percentage of oxyhaemoglobin to the sum of oxyhaemoglobin and deoxyhaemoglobin (functional arterial oxygen saturation).
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 calibration of the Thermometer should be checked at least once every two years.

Use only specified protective probe covers

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

The protective probe 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.

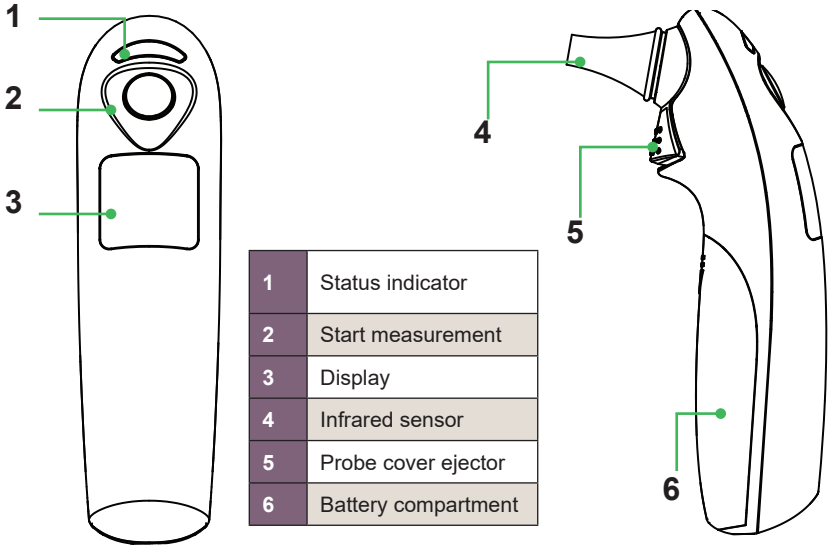
Handle the thermometer with care, it should be stored in the cradle when not in use.

Discard the protective probe 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	Infrared sensor
5	Probe cover ejector
6	Battery compartment

11.2 Thermometer Display

Key	Function / Display
	Battery status
	Probe cover status
	Wireless status
	Scale ºC or ºF
	Measurement

11.3 Main Unit Display

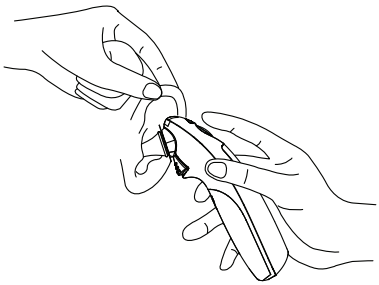
Key	Function / Display
	Temperature logo
	Scale ºC or ºF
	Measurement
	Wireless status

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 probe cover to the thermometer.
2. When correctly fitted, the icon changes to .
3. Momentarily press the on standby button on the temperature probe to switch the device on, 2 short beeps will be emitted from the probe.
4. Position the patient with their head moved to one side, gently pull the ear backward to straighten the ear canal. Gently insert the tip of the temperature probe fully into the ear, ensuring the ear canal is fully sealed.



5. Press and hold down the on/standby button on for 1 second, continue to hold the probe in place until a short beep is heard from the probe when the measurement is complete.
6. Remove the thermometer and read the temperature.
7. The temperature will be displayed on the temperature probe and monitor.

8. Upon completion press the eject key to remove the probe cover.
9. Place the probe cover in the appropriate waste collection point and replace the thermometer back into its holder

NOTE
The temperature probe will automatically power off after 60 seconds of inactivity.

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 and Disinfection

Materials and methods listed in this section are recommended by the Company for cleaning and disinfecting the system.

Any damage arising from the use of non-recognised materials and methods will not be covered under the terms of the warranty.

The Company will not assume liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, consult your infection control department or an epidemiologist in your institution.

Also consider any local policies that may be applicable.

Cleaning and Disinfecting the Monitor

WARNING: Only use detergents and disinfectants recommended in this Instruction Manual; use of other detergents and disinfectants may result in damage to the device and accessories or safety risks.

WARNING: Before cleaning the monitor, power off and disconnect it from the AC power supply.

WARNING: Never use EtO (ethylene oxide) to disinfect the monitor.

WARNING: Always wipe off disinfectant using a clean damp cloth.

WARNING: Do not mix detergents; hazardous gases may be generated.

WARNING: Do Not reuse disposable or single use accessories.

WARNING: To protect the environment, disposable accessories must be recycled or disposed in accordance with local policies.

WARNING: After cleaning, if a sensor cable is damaged or shows any evidence of ageing, it should be replaced with a new cable.

WARNING: Do not perform high-temperature or E beam/gamma sterilisation on the product or any of its accessories. This may cause damage which could result in harm.

CAUTION: Do not allow any fluid to enter the products and do not immerse in any solution. Contact your maintenance department if any fluid enters the unit.

To prevent potential cross infection, we recommend cleaning the external surfaces of the system between patients.

Switch the system OFF, disconnect from the local main supply and remove all sensors.

Use a soft cloth dampened with either a commercial or non-abrasive cleaner, lightly wipe the housing and display.

Where necessary, use a soft dry cloth to remove any residual detergent or cleaner and allow to dry in a well ventilated area before reconnecting the sensor and the local main supply.

Cleaning and disinfecting SpO_2 sensors

Follow the instructions provided by the sensor manufacturer.

Cleaning and Disinfecting BP cuffs

WARNING: Do not squeeze the rubber hose on the cuff.

WARNING: Do not allow fluid to pass into the bladder during the cleaning process.

WARNING: Do not dry clean the cuff.

WARNING: The single use cuff may be cleaned with soap for infection control purposes.

NOTE: Long term use of disinfectants may result in discolouration of the cuff.

The BP cuffs are manufactured from two piece construction, the internal bladder and the external cuff. Prior to cleaning, the bladder must be removed, the cuff can be hand or machine washed with warm water and a mild detergent. The bladder can be washed in water. Allow both items to air dry before re-assembly.

The Cuff can be disinfected using a damp cloth with 70% ethanol or 70% Isopropanol.

Cleaning and Disinfecting Thermometer

The probe tip is the most delicate part of the thermometer. It has to be clean and intact to ensure accurate readings.

Gently wipe the surface of the probe tip with a cotton swab or soft cloth moistened with alcohol.

After the alcohol has completely dried, fit a new probe cover and take a temperature measurement.

If the probe tip is damaged, please contact your service agent.

Use a soft, dry cloth to clean the thermometer display and exterior.

Do not use abrasive cleaners.

Never submerge the thermometer in water or any other liquid.

Store thermometer and probe covers in a dry location free from dust and contamination and away from direct sunlight.

Precautions

After cleaning check the system, if there is any evidence of damage, do not use.

If it is necessary to return the system to Huntleigh for repair, clean the device thoroughly and follow the instruction in the maintenance section:

- Never allow any liquid to flow into the housing.
- Never pour liquid onto any part or accessory.
- Never soak the system in a liquid.
- Do not use any abrasive material, bleach or strong solvent as this will cause permanent damage.

Recommended detergents

Item	Detergent	Disinfectant
Monitor housing	Isopropyl alcohol (70%) Hydrogen peroxide (2.7%~3.3%)	Isopropyl alcohol (70%) Glutaraldehyde solution (2%) Sodium hypochlorite (2.5%)
Power cord		
SpO2 sensors – reusable	Alcohol free hand soap Sodium Hypochlorite (2.5%) (bleaching powder containing chlorine, 3% aqueous solution) Hydrogen peroxide (2.7%~3.3%)	Isopropyl alcohol (70%) Glutaraldehyde solution (2%) Sodium hypochlorite (2.5%)
SpO2 sensors – single use	Single use – dispose after use	
NiBP cuffs – reusable	Bladder: warm water Cuff: damp cloth 70% ethanol or 70% Isopropanol	
NiBP cuffs – single use	Single use – dispose after use	

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

WARNING: The replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a hazard.

WARNING: The replacement of lithium batteries or fuel cells incorrectly would result in an unacceptable risk.

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 sensor 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 sensor is too loose	Reposition SpO2 sensor.
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	Sensor fault	There is a problem with the sensor	Do not use the sensor 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
09	No pulse detected	SpO2 sensor cannot detect pulse signal	Probe loose or faulty
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
27	Systolic pressure out of range	The measured value is outside the specified range	Incorrect patient group set or wrong size cuff
28	Mean pressure out of range	The measured value is outside the specified range	Incorrect patient group set or wrong size cuff
29	Diastolic pressure out of range	The measured value is outside the specified range	Incorrect patient group set or wrong size cuff
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

Code	Description	Cause	Solution
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		
51	Unable to obtain SpO2 data	Sp02 module can not calculate SpO2 value	Faulty SpO2 module
52	Unable to obtain PR data	Sp02 module can not calculate PR value	Faulty SpO2 module

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: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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 ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Declaration - electromagnetic emission	
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**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies

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**
Conducted RF IEC 61000-4-6	3V 0.15 MHz to 80MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V

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**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
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
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE U_r is the a.c. mains voltage prior to the application of the test level.		

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	**IEC60601 test level**				**Compliance level**
	Test frequency	**Modulation**	**Maximum power**	**Immunity level**	
Radiated RF IEC61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

15. Specifications

15.1 Equipment Classification

Type of protection against electric shock.	Class 1 with internal power
Degree of protection against electric shock 	BF defibrillation proof applied parts : NIBP, SpO_2 BF non-defibrillation proof applied part : TEMP
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 size	100mm x 120mm
Rear output ports	RS-232, Equipotential socket
Audible tone	Internal Loudspeaker
Size	Width 125mm, Height 219mm, 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
Rated Input power	35VA
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	5°C to 40°C (without ear thermometer) 15°C to 36°C (with ear thermometer)
Humidity	93% non-condensing (without thermometer) ≤85% non-condensing (with thermometer)
Altitude	700 hPa to 1060hPa
Transport and Storage	
Temperature	–20 °C to 60 °C (without ear thermometer) –20 °C to 55 °C (with ear thermometer)
Humidity	≤93% non-condensing (without ear thermometer) ≤85% non-condensing (with ear thermometer)
Altitude	700hPa to 1060hPa
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 270 mmHg (36.0 kPa) to ±3 mmHg (±0.4 kPa)		
Accuracy	±5mmHg		
Automatic Intervals	2, 3, 4, 5, 10, 15, 20, 25, 30, 60 or CO measurement intervals		
Overpressure protection	Range	Adult	297mmHg
		Pediatric	240mmHg
		Neonate	147mmHg
	Tolerance	±3mmHg	

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 neonate mode)
Nellcor Module	0% to 100%	±2% (measured without motion in adult/child mode) ±3% (measured without motion in neonate mode)
Resolution	1%	
Data averaging and other signal proccessing time	2 seconds	
Data update time	8 seconds	

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

Temperature

Probe Type	Tympanic Infrared
Range	35° C to 42° C (95° F to 107.6°F)
Accuracy	±0.2° C (±0.4° F)
Resolution	0.1°C (0.1° F)
Standards	ASTM E1112-00:2000, EN12470-3 and EN12470-4

Pulse Rate

Range and accuracy			
Own Brand	20bpm -250bpm	1bpm	±2bmp
Nellcor Module	25bpm-250bpm	1bpm	±3bpm
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

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

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 309**
Adult Nellcor Reusable SpO2 Sensor/DS-100A,3ft	**ACC VSM 310**
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	
Probe cover 200 pcs (10 boxes)	**ACC VSM 293**
Probe cover 800 pcs (40 boxes)	**ACC VSM 286**
Probe cover 8,000 pcs (400 boxes)	**ACC VSM 287**
Hardware	
Mobile stand	**ACC VSM 153**
Wall mount	**ACC VSM 154**
Utility hook	**ACC VSM 187**
Utility basket	**ACC VSM 189**
Fixing / mounting kit	**ACC VSM 288**
IV Pole clamp	**ACC VSM 294**

17. End of Life Disposal

This symbol signifies that this product, including its accessories and consumables is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.

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.

18.1 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

This section is only applicable to United Kingdom (UK) market when UK marking is applied to the Arjo medical device labelling.

UK Symbol:

UK CA 0086	UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) Figures indicate UK Approval Body supervision.

UK Responsible Person & UK Importer:

Arjo (UK) Ltd., ArjoHuntleigh House, Houghton Regis. LU5 5XF

Is the appointed UK Responsible Person as defined in UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

For Northern Ireland (NI) CE marking will still apply until further amendment to applicable regulations.

1001071-2

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.
In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

Manufactured in the UK by Huntleigh Healthcare Ltd on behalf of;

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www.huntleigh-healthcare.us/

A Member of the Arjo Family

As our policy is one of continuous improvement, we reserve the right to modify designs without prior notice.

HUNTLEIGH

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