INSTRUCTIONS FOR USE

SC500

Vital Signs Monitor

787302EN-4 03/2022

HUNTLEIGH

A MEMBER OF THE ARJO FAMILY

WARNING
To avoid injury, always read this Instructions for use and accompanied documents before using the product.

WARNING
The SC500 Vital Signs Monitor should only be used for the purposes specified in these instructions for use. Any other use is prohibited.

Mandatory to read the Instructions for use.

Please Note:
These Instructions For Use apply to the SC500 Vital Signs Monitors (all variants).

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)

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

Table of Contents

1. Safety Instructions

Symbols

General Warning
Attention, consult this manual. Refer to safety section.

Refer to Instructions for Use.

Attention, consult accompanying documents / Instructions for Use.

1.1 Warnings

WARNING
This equipment is for use only by suitably qualified healthcare practitioners.

WARNING
Do not use in the presence of flammable gases, pharmaceuticals in aerosols or in oxygen rich environments.

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

WARNING
The monitor is a Class 1 device which relies on the earth connection to maintain safety. Ensure it is connected to a suitably earthed AC mains supply.

WARNING
Do not use if there is any damage to the unit or its accessories.

WARNING
To avoid accidental disconnection, route all cables in a way to prevent a tripping hazard. Secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.

WARNING
Alarm upper and lower limits should be set depending on the patient. Do not rely exclusively on the audible alarm system.

WARNING
If this product is connected to another item of electrical equipment, ensure that the system is fully compliant with IEC60601-1.

WARNING
Do not use the SC500 in vehicles or in aircraft.

WARNING
This equipment must not be modified.

WARNING
During defibrillation, the operator should not come into contact with the patient, the monitor or the supporting table; otherwise serious injury or death could result.

WARNING
Connect only Items that have been specified as part of the Medical Electrical system or have been specified as being compatible with the Medical Electrical system.

WARNING
This unit is not MRI compatible and must not be used in an MRI environment.

WARNING
Do not make contact with exposed metal parts and the patient simultaneously.

WARNING
PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter ALARM SIGNALS. Keep pacemaker PATIENTS under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument

WARNING
This product contains sensitive electronics, therefore, strong radio frequency fields could possibly interfere with it. This may be indicated as a disturbance on the physiological waveform. We recommend that the source of interference is identified and eliminated.

WARNING
Mains isolation is achieved by disconnecting the mains connector to the rear of the SC500 or unplugging from the mains supply.

WARNING
If a loss of power poses an unacceptable risk to the patient the SC500 must be connected to an appropriate mains power source.

WARNING
Do not position the Medical Equipment such that it makes it difficult to disconnect the supply.

WARNING
The internal battery must be used if the integrity of the protective earth conductor or protective earthing system is in doubt.

CAUTION
The SC500 is restricted to single patient use.

CAUTION
Use only recommended accessories listed in this manual.

CAUTION
Do not expose to excessive heat, including prolonged exposure to sunlight.

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

NOTE
This IFU is based on the maximum configuration. Some content and displays may not be applicable to your monitor.

NOTE
After defibrillation, the electrocardiogram (ECG) waveform will recover within 5s, other parameters will recover within 10s

1.2 Infection Control

The system uses a mixture of reusable and single use accessories, refer to section 24 for specific details.

1.3 Patient Applied Parts

As defined in IEC60601-1:2005, the patient applied parts of the Smartsigns® Compact 500 Vital Signs Monitor are:-

- ECG Cable
- Blood Pressure cuff
- SpO2 Sensor
- Temperature sensor

2. Introduction

The Huntleigh Smartsigns® SC500 is a high performance Vital Signs monitor which is capable of performing short, medium and long term monitoring of Adult, Paediatric and Neonate patients for use in a variety of low and mid acuity healthcare settings.

The SC500 can monitor the following parameters:

- ECG
- Oxygen Saturation
- Non-invasive Blood Pressure
- Body Temperature (Tympanic measurement)

2.1 Intended Use

The Smartsigns Compact 500 Series is intended for use by trained healthcare professionals in healthcare settings to monitor physiologic status of Adult, Paediatric and Neonatal patients.

NOTE
Spot monitoring mode is not intended for continuous patient monitoring.

NOTE
The SC500 is not intended for use in the emergency medical services environment, for example ambulance or paramedic services.

2.2 Contra-Indications

The device is not intended for use outside a Healthcare facility.

No absolute contraindications exist for ECG monitoring, however, clinicians should be aware of situations developing as a result of certain allergies caused by sensitivity to adhesives used to fix electrodes onto the skin.

Pulse oximetry is contra indicated for use on active patients or for prolonged use. To prevent tissue damage, sensor position should be checked every 2 hours (as indicated by circulatory status and or skin integrity) and repositioned every 4 hours.

When using wrap type of sensors, do not apply tape to close the sensor, venous pulsation may compromise measurements.

Prolonged use and frequent BP determination can lead to venous pooling and or congestion, avoid continuous long term measurements on high risk patients.

2.3 Personal Security Information

The SC500 operates in an environment where personal and sensitive data is available, whilst the system offers various levels of access, it is the responsibility of the institution to develop and implement appropriate security measures to comply with local regulations and safeguard personal data.

2.4 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.

2.5 Unpacking / Preliminary Checks

We recommend that a thorough visual inspection is made immediately the unit is received. Should any damage be evident or any parts missing, ensure that Huntleigh Healthcare Ltd is informed at once.

Each configuration is supplied with a patient group specific (ADU, PED or NEO) starter pack of accessories, these include:

SC500 Base configuration	**Each base configuration is supplied with:** 1 x NiBP cuff set (3) - ADU, PED or NEO 1 x NiBP Hose (3M) 1 x Huntleigh SpO2 sensor - ADU, PED or NEO 1 x Huntleigh SpO2 Interface Cable(**) 1 x Grounding cable 1 x Power cord 1 x Instructions for use
Option 1	**ECG** Supplied with: 1 x 3 Way ECG cable (IEC) - ADU / PED Or 1 x 3 Way Yolk with 1 x pack of pre wired NEO electrodes.
Option 2	**Nellcor Oximax SpO2** Supplied with 1 x Nellcor SPO2 Interface cable 1 x Nellcor SpO2 sensor - ADU, PED or NEO
Option 3	**Tympanic Temperature** Supplied with: 1 x Tympanic thermometer (wireless) 1 x Pack of 20 Thermometer probe covers
Option 4	**Printer** Supplied with: Integrated recorder 1 x Roll paper

(**) Huntleigh SPO2 Interface cable is provided when the PED or NEO patient groups are specified.

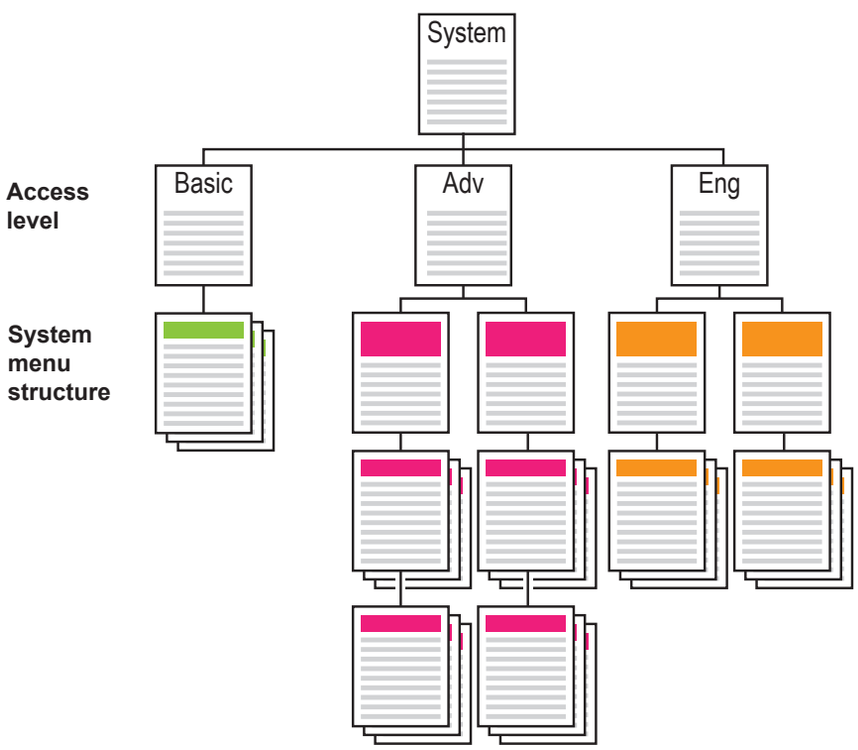
2.6 Basic operation and Controls

System management and controls are affected through a hierarchical menu structure with three levels of access control - Basic, Advanced and Engineer.

Each level provides access to certain features and functionality described in the table below:

Access level	Description	Functionality	Access to patient records	Protection method
Basic	Normal use	User interface and controls only	No	None
Advanced	User maintenance	Full system administration	Yes	Password *
Engineer	Factory maintenance	Engineering functionality – establishing and uploading specific profiles, adjustment of local default settings, system calibration etc.	No	Password *

* Refer to your technical support department for password information.



The flexibility of the system means that the operator can access the same control from different areas of the system, for example, menus and system sub menu control can be accessed through:

- Physiological waveform
- Numerical area of the screen
- Soft keys

2.6.1 Operator Position

The operator should be positioned in-front of the SC500 for optimal viewing of the display and touchscreen operation.

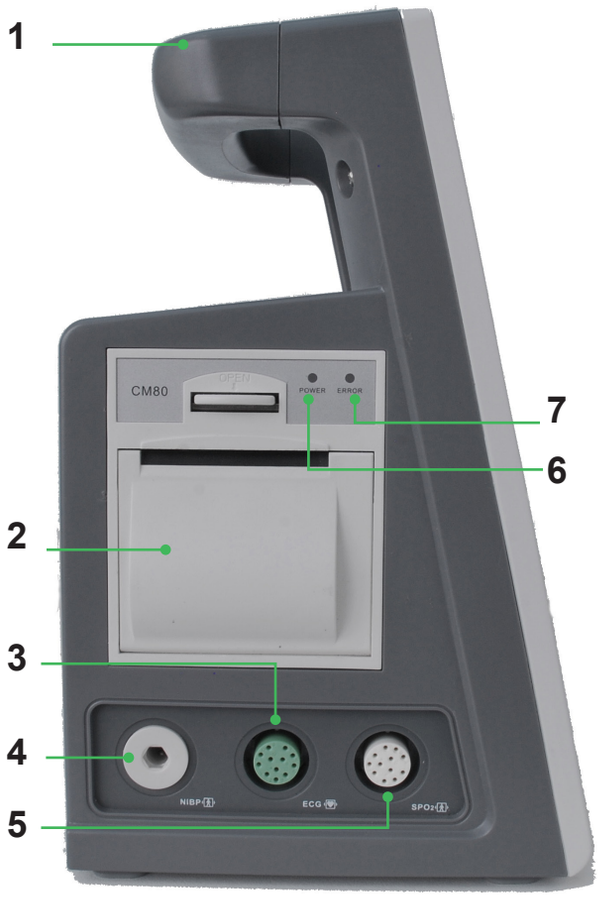
3. Product Identification

WARNING
Safety and performance can only be assured when the system is used in conjunction with the correct type of accessory. Do not attempt to use any accessory other than those supplied or recommended by Huntleigh.

3.1 Front Panel

1	**Touchscreen**
2	**Wireless Infrared thermometer (IRT10)**
3	**AC power indicator** ◊ On: The monitor is connected to AC power. ◊ Off: The monitor is not connected to AC power.
4	**Battery indicator** ◊ On: The monitor is equipped with a battery and is connected to AC power. ◊ Off: battery is fully charged, is not installed or malfunction. ◊ Flashing: The monitor is running on battery power.
5	**NIBP Start/Stop Button**
6	**Alarm indicator (left indicator is for physiological alarm and the right indicator is for technical alarm).**

3.2 Left Side Panel



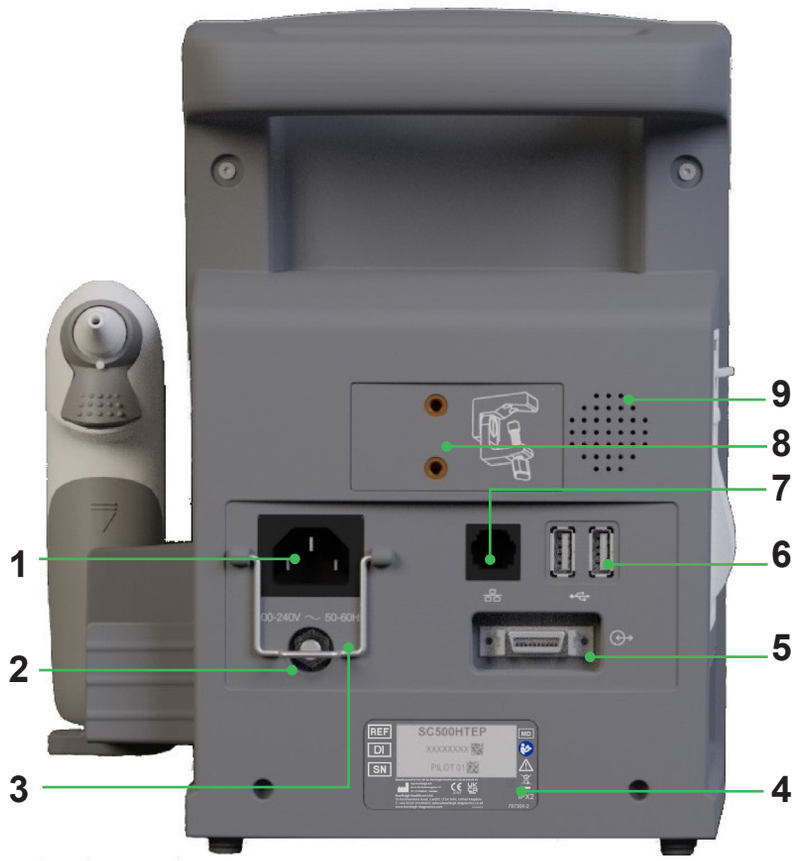
1	Carry Handle
2	Internal thermal recorder
3	ECG cable connector
4	NIBP connector
5	HUNTLEIGH SpO2 connector*
6	Recorder power indicator
7	Recorder error indicator

** Depending on model/options purchased.*

3.3 Right Side Panel

1	On/Off
2	Wireless Infrared thermometer (IRT10) Holder
3	Thermometer probe cover holder

3.4 Rear Panel



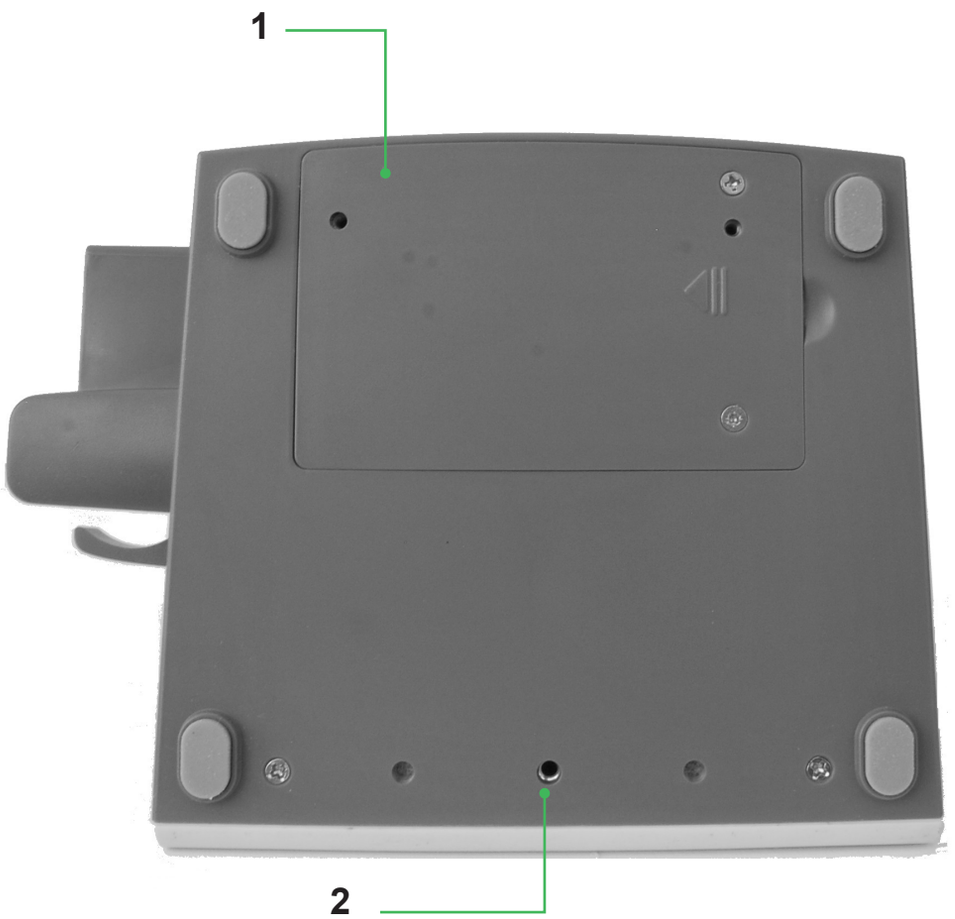
1	Mains socket	6	USB Port x 2
2	Equipotential earth point	7	Ethernet port
3	IEC Mains cable retaining clip	8	IV Pole attachment
4	Product identification label	9	Loudspeaker
5	Multifunctional Interface *		

WARNING
If this product is connected to another item of electrical equipment, ensure that the system is fully compliant with IEC60601-1.

WARNING
The ear thermometer supplied with this monitor can only communicate with an appropriate Huntleigh monitor.

NOTE
Lift the IEC Mains cable retaining clip, fully insert the connector before lowering the clip fully over the connector.

3.5 Base



1	Battery Compartment
2	Roll stand adapter plate fixing screw location

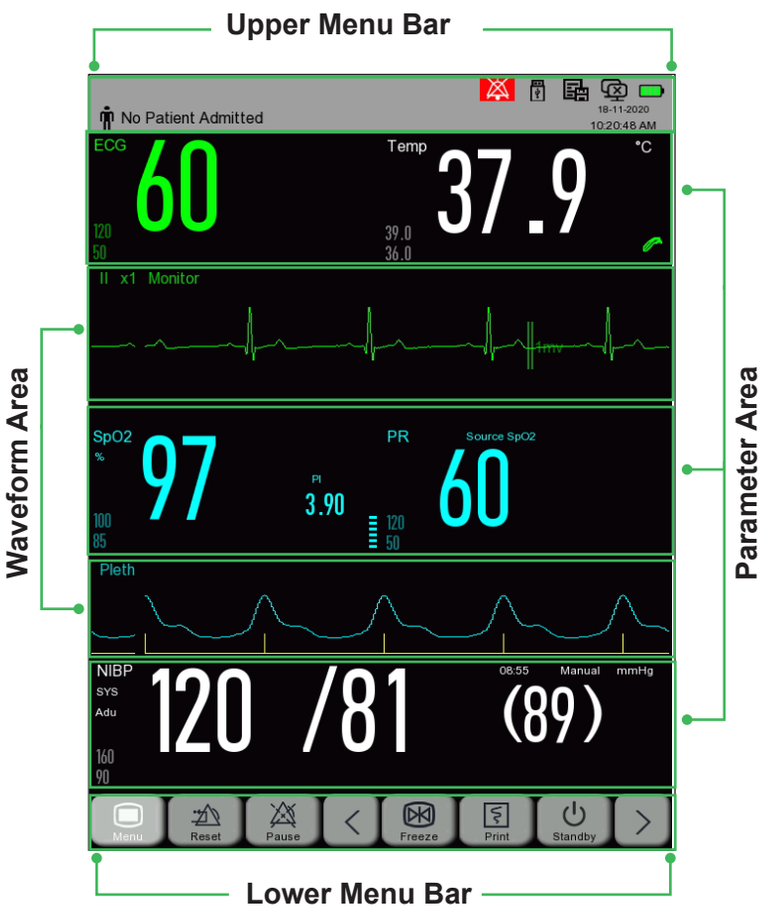
3.6 Display

This monitor uses a backlit colour LCD display with integrated touch screen.

Physiological parameters, waveforms, alarm messages, date and time, network connection status, battery level and other messages are displayed simultaneously.

The screen is divided into four areas:

- Waveform area
- Parameter area
- Upper menu bar
- Lower menu bar



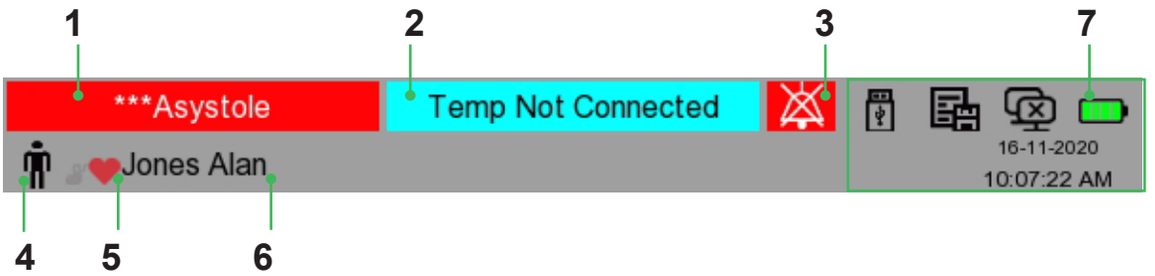
3.6.1 Waveform Area

- 2 waveforms can be displayed, along with the respective identification
- Touch a waveform to display the corresponding setup menu.

3.6.2 Parameter Area

- Displays measured parameters
- Parameters are displayed in the same colour as their waveform
- Touch a parameter to display the corresponding setup menu

3.6.3 Upper Menu Bar



1	**Physiological Alarm Status**
2	**Technical Alarm Menu**
3	**Alarm Status identification**
4	**Patient group identification**
5	**Pacer Status identification**
6	**Patient Name**
7	**Monitor setup area: USB drive status, SD card status, Central Monitoring System (CMS) status, Battery status, Date and Time**

	CMS enabled		**CMS disabled**
	SD card inserted		**SD card not inserted**
	Battery status		**USB flash drive connected**

The UPPER menu bar includes the following indicators, from left to right:

1. Physiological alarm status:
   Displays the active physiological alarm messages.
2. Technical alarm message:
   Displays technical alarm status.
3. Alarm Status indicator:
   Indicates the status of the Auditory alarm system
   - Alarm Pause
   - Alarm Off
4. Patient data:-
   - Patient name
   - Patient Group
   - Pacemaker Status.
5. Date and Time.

3.6.4 Lower menu bar

The lower menu bar contains the shortcut keys or smart keys. The presentation will depend upon the configuration of the monitor.

1	**Scroll left to show more shortcut keys**
2	**Scroll right to show more shortcut keys**

3.7 Product Labelling

Symbol Explanation			
	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.		
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)		
RX Only	Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.		
IPX2	Protection against vertically dripping when the device is tilted at an angle up to 15° from its normal position.		
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		
	CF Applied parts, with defibrillation proof function		BF Applied parts, with defibrillation proof function
	Warning		Attention, consult accompanying documents / Instructions for Use
~	Alternating current (AC)		On/Off
DI	Device Identifier	REF	Reference Number
SN	Serial Number (Date of manufacture is included in SN)	MD	Medical Device
	USB Port		Multi-function Interface
	Network Interface		Ethernet Port
	Keep Dry		Equipotential Earth
	Fragile		Do not use hook
	Temperature Limits		Cardboard packaging can be recycled.
PVC	Does not contain PVC		Humidity Limitations
YYYY-MM	Use By	LATEX	Not made with natural rubber latex.
	Atmospheric Pressure Limits		Do Not Reuse
4	Max stack of x 4 identical boxes		This way up

** As defined by IEC60601-1.*

4. System Setup

4.1 System Connection

WARNING
These requirements must be met when the device is connected to any other electrical equipment.

Non-medical equipment must comply with the relevant IEC or ISO safety standard. For Information Technology equipment, this standard is IEC950/ EN60950.

If non-medical equipment (e.g. printer) with enclosure leakage currents greater than those allowed by IEC60601-1 is to be used in the patient environment (within 1.5m of the patient), the enclosure leakage currents must be brought within the limits laid down by IEC60601-1. This may be achieved by using a medical grade isolating transformer. Suitable types are available from Huntleigh.

An Equipotential earth point is provided on the rear of the monitor for connection to a recommended earth point at the installation.
The earth wire should be run separately from any mains or current carrying cables and should be kept as short as possible. Connection is achieved using a DIN 42801 type female terminal terminated onto 4mm^2 56/28AWG yellow and green earth wire, connected to the Equipotential Earth Point at the installation.
Under no circumstances should a patient be connected directly to Earth. All external earth connections should be visually inspected to ensure that all cables and connections are of good condition. Earth bonding checks should be carried out with a suitable portable appliance tester. The Impedance between the protective earth and Equipotential earth at the installation shall not exceed 0.1Ω.

4.2 Patient Connections

CAUTION
Do not remove any cables by pulling on the lead.

Ensure all patient cables, sensors and hoses are fully inserted into the appropriate socket.

4.3 Handling and Mounting

Mobile Stand

WARNING
If the product is being used on a trolley, make sure the trolley brakes are applied when stationary.

WARNING
Take care to ensure that trailing cables and other connecting leads do not present trip hazards that could lead to the equipment falling. Always store accessories correctly.

WARNING
Do not attempt to move the trolley, or use the system, without ensuring that the unit and all cables are secured.

WARNING
Keep hands clear of the trolley wheels while the trolley is in motion. Do not attempt to free trapped cables without stopping the trolley and applying the brakes.

Follow the instructions provided with the mobile stand regarding assembly and proper mounting of the product.

Wall mount

WARNING
Brackets must be installed by trained personnel using fixings appropriate for the wall construction and load. Carry out load tests before use.

WARNING
Ensure that the product is securely fitted to the bracket using the correct adaptor plate and screws as described in the instructions supplied with the bracket.

WARNING
Choose the location carefully to prevent possibility of users, patients or passers-by striking the unit, causing injury.

Follow the instructions provided with the wall mount bracket regarding assembly and proper mounting of the product.

5. Operation

5.1 Switching the Unit ON

WARNING
If an error message is displayed, do not use the monitor. Disconnect from the mains supply and contact your service department.

NOTE
The system will sound an alarm if it detects a problem during the start up process.

Connect the monitor to the local mains supply.

Press and hold for approximately 2 seconds to switch the unit on.

After a short period, the unit will display a welcome screen, perform a self test, then continue to the default setting for monitoring the patient. The application screen will be displayed and configured according to the options fitted to the unit.

5.2 Shortcut keys

Touch each key on the lower menu bar to activate the corresponding function.

Use the left/right arrows to access additional shortcut keys.

5.3 Standby Mode

Press the Standby [Standby] shortcut key to place the monitor into standby mode. In standby mode:

- There are no alarms or waveforms on the screen.
- Patient data is not saved during a Standby period.
- [Press any key to exit standby mode] is shown on the screen.

Press any key to exit the standby mode.

5.4 Touchscreen Lock

To disable the touch screen, press and hold the Main Menu Button Menu for 2 seconds. The button will change to Menu and a message will be displayed on screen.

Press and hold Menu to unlock the touchscreen.

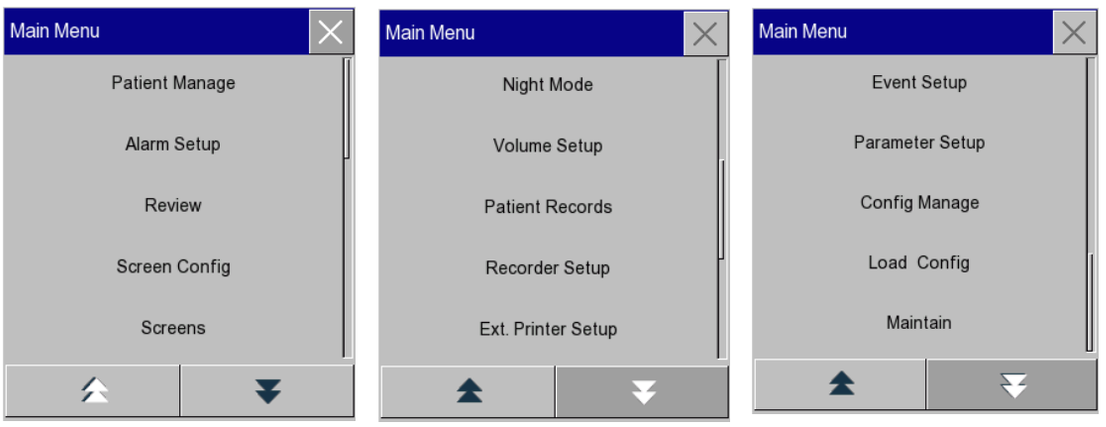
5.5 Switching the Unit OFF

Press and hold for approximately 2 seconds to switch the unit off.

5.6 Main Menu

5.6.1 General Setup

Press the Menu key on the screen or the button on the front panel to enter the Main Menu window. Some menu options will be detailed in the relevant sections in this IFU.



Use the and keys to scroll through the menu options. Pressing each option will display the corresponding sub menu.

Press to exit the menu.

5.6.1.1 Patient Manage

See Section 7.

5.6.1.2 Alarm Setup

See Section 9.

5.6.1.3 Review

See Section 15.

5.6.1.4 Screen Config

Brightness

The user can adjust the brightness of the display.

Enter [Main Menu] → [Screen Config] → [Brightness].

Select the appropriate brightness level between 10 (the darkest) ~100 (the brightest).

Press to save and exit.

Privacy Mode

In Privacy Mode, the monitoring data is not displayed on the screen. It can be activated only under CMS (Central Monitoring System) monitoring. To activate privacy mode:

Enter [Main Menu] → [Screen Config] → [Privacy Mode].

When privacy mode is activated:

The message [In monitoring...press any key to exit privacy mode!] is shown on the monitor screen.

The monitoring continues normally but the patient data can only be viewed on the work station.

Alarms can still be triggered, alarm sounds and indicators are provided at the bed side and the work station.

System sounds are muted, such as QRS and beat sounds as well as various prompt tones.

The monitor exits from the privacy mode in any of the following conditions:

- You press any key (except Power key).
- The monitor is disconnected from the CMS.
- Battery level runs low

5.6.1.5 Screens

See Section 8.

5.6.1.6 Night Mode

The monitor provides a night mode facility:

To activate night mode:

Enter [Main Menu] → [Night Mode].

The [Night Mode Setup] window pops up. Slide the cursor to the ON position. The following options are available:

Set up [Alm Vol], [QRS Vol], [Key Vol] and [Brightness].

Press ☒ to save and exit.

To exit night mode:

Enter [Main Menu] → [Night Mode].

The [Night Mode Setup] window pops up. Select [Night Mode].

The warning message [Exit Night Mode?] is displayed. Select [Yes] to exit night mode.

Press ☒ to return to the main application screen.

5.6.1.7 Volume Setup

This setting controls the Alarm, QRS and Pulse volume levels.

Select the [Volume Setup] shortcut key, or enter [Main Menu] → [Volume Setup].

Select [Alm Vol] : Set the level between 2 (the lowest volume, which depends on the setting of the Minimum Alarm Volume) and 10 (the loudest volume). See the 'Alarms' Section 9 for more details;

Select [QRS/Beat Volume]: Sets the appropriate volume within 0~10;

Press ☒ to save and exit.

5.6.1.8 Patient Records

See Section 7

5.6.1.9 Recorder Setup

See Section 17.

5.6.1.11 External Printer Setup

See Section18.

5.6.1.12 Event Setup

Event setup involves saving waveforms for manually triggered events. During patient monitoring, the occurrence of some events may have certain impact on the patient. Users can select waveforms for manually triggered events in the [Mark Event] settings. When an event is triggered, the monitor will mark it and save the corresponding waveforms. The event can be recalled later to analyse its impact.

The steps are described below:

Enter [Main Menu] → [Event Setup].

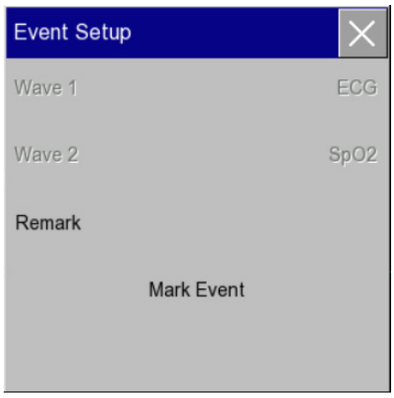
Waveforms are fixed to ECG (Currently selected lead) wave 1 and SPO2 wave 2

Enter remarks in the Remark area, if necessary.

Select [Mark Event]. [Manual Trigger Successful] will be shown at the bottom left of the screen

To review a manually triggered event, enter [Main Menu] → [Review] → [Alarm Event Review] or touch 

→[Alarm Event Review].



5.6.1.13 Parameter Setup

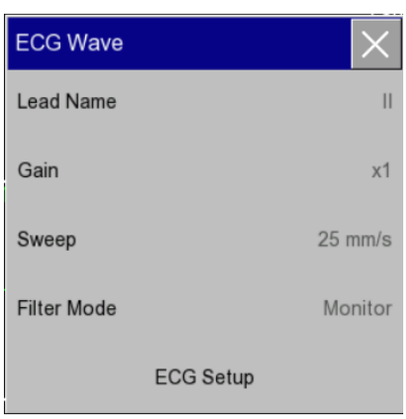
Adjustments to each of the parameters can be accessed using any the following methods:

- Waveform Area
- Parameter Area
- Short cut key

Using ECG as an example:

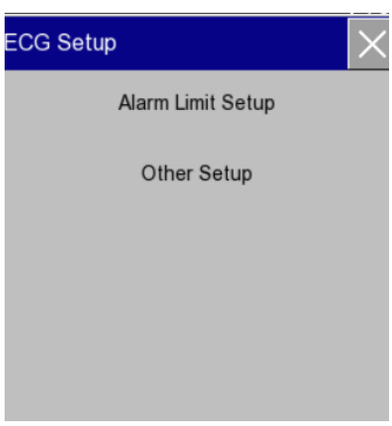
Waveform Area

Press the ECG waveform to display the [ECG Wave] set up options:



Parameter Area

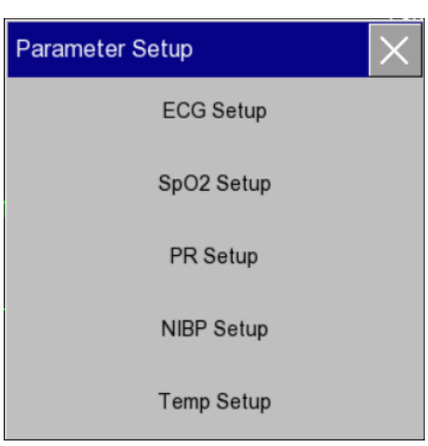
Press the ECG parameter area to display the [ECG set up] options:

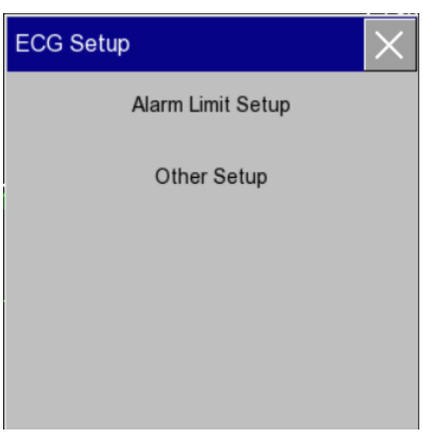


Shortcut Key

If the lower menu bar has been configured with the parameter Setup short cut key 

, press this key to display the [Parameter Setup]:





5.6.1.14 Configuration Management

See Section 6.

5.6.1.15 Load Configuration

See Section 6.

5.6.2 Maintain Menu

Some monitor settings are found in a secure menu.

To access this menu, the operator must enter a 4 digit password. (Refer to your technical support team for the password code).

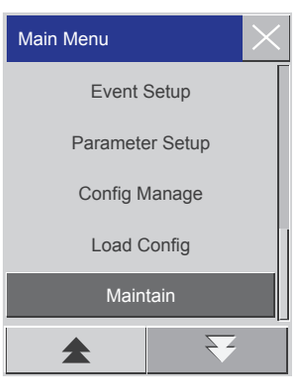
5.6.2.1 USER Maintain Menu

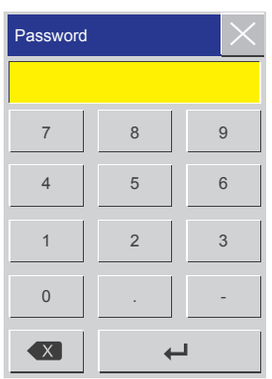
CAUTION
The USER maintain menus are password protected and should only be accessed by authorised personnel. Changes in this area could impact on system operability and limit certain functionality.

Enter the Main Menu and scroll down to the Maintain option.

Press to select.

Enter the 4 digit passcode and press Enter ↵ to confirm selection.
The extended set up options are now accessible.





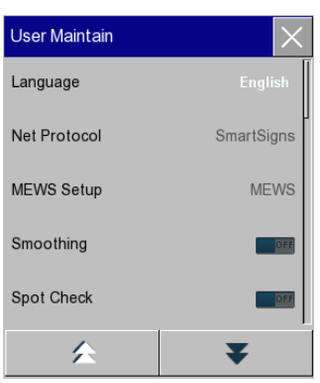
5.6.2.2 Language Setup

The monitor supports several languages, to set the language, follow the steps below:-

Enter [Maintain] → [Password]→ [Language].

Select the relevant language.

Press [Yes] to confirm.



5.6.2.3 Smoothing

The visual presentation of the waveform can be enhanced by the application of a smoothing feature.

Waveform smoothing can be set ON or OFF.

Select [Smoothing] and select [On] or [Off].

Press ☒ to save selection.

5.6.2.4 Network Protocol

To facilitate data transfer between the monitor and the central nurses system, the appropriate network protocol must be established. Refer to your technical support department for relevant information.

Select [Net Protocol], select [Huntleigh], [Huntleigh OEM] or [HL7].

Make selection and press ☒ to save selection.

> ⚠ **Warning - Cybersecurity**
> **Connecting the SC500 to an IT network must be carried out by a qualified network administrator.**

> ⚠ **Warning - Cybersecurity**
> **Ports 23 and 8821 of the patient monitoring network must be protected from public network traffic by means of an adequate configured firewall.**

> ⚠ **Warning - Cybersecurity**
> **HL7 should only be configured for use on a secure internal network for Hospital information systems by a qualified network administrator.**

5.6.2.5 Spot Mode

Spot mode can be set ON or OFF.

Select [Spot Mode] and select [On] or [Off].

Press ☒ to save selection.

For further information see section 8.4

5.6.2.6 Wave Fill Setup

The user can customise the appearance of the SPO2 waveform.

Select [Wave Fill Setup], Select [SpO2] to toggle wave fill on/off.

Press ☒ to save selection.

5.6.2.7 Time Setup

The system clock can be set up to reflect the current time zone.

Select [Time Setup] and make adjustments to [Year], [Month], [Day], [Hour], [Min], [Second], [Date Format] and [Time Format].

Press ✔ to confirm selection, changes become effective immediately.

5.6.2.8 Alarm Setup

See Section 10.

5.6.2.9 Touchscreen Calibrate

The touchscreen can be re-calibrated by the user.

Select [Touchscreen Calibrate] and follow the on-screen instructions.

5.6.2.10 Module Colour

Different colours can be assigned to the different modules.

Select [Module Colour], select the required parameter [ECG] and select the required colour from the colour palette.

Press ☒ to save selection.

5.6.2.11 Units Setup

The user has the facility to change or standardise on the range of units of measure.

Select [Units Setup] and select the parameter to be changed (height, Weight, Pressure, Temperature, pressure units), make selection and press ☒ to save changes.

5.6.2.12 Nurse Call Setup

See Section 19.

5.6.2.13 Module Setup

With the exception of the SPO2 function, modules can be enabled and disabled.

Select [Module setup], select appropriate module and select [On or Off].

Press ☒ to save selection.

5.6.2.14 Monitor Info.

It may be necessary to inspect the monitors' software status,

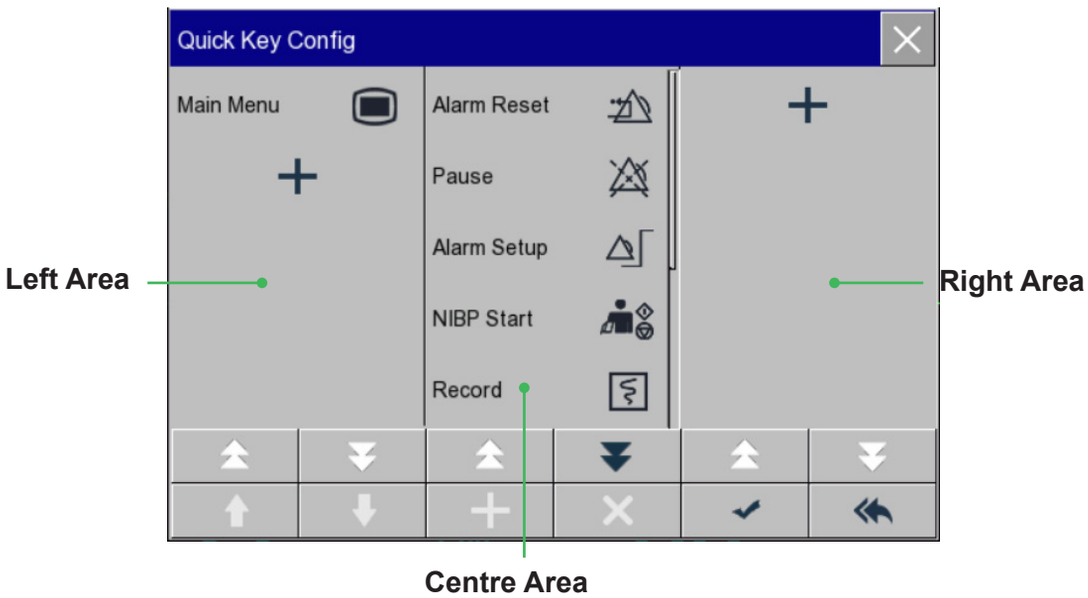
Monitor information contains the following information:-

- Operating system software version, NK Version
- Software Version
- Compile time
- Configuration code
- Device Serial Number

To access monitor information, select [Monitor info] and read the information displayed on the screen.

5.6.2.15 Quick Key Config.

Shortcut keys can be added or removed from the lower menu bar.
Enter [Maintain] → [Quick Key Config] to open the menu, as shown in the figure below:



Three shortcut key areas are represented on the left, middle and right sections of the lower menu bar. Press + to open the [Quick key] menu. Select the shortcut keys you want to add. After you have added the shortcut key press ✔ to confirm.

Quick Key Config screen Symbol Explanation			
▲▼	Page up/down to show the hidden shortcut keys.	✕	Delete a shortcut key
▲ ▼	Move up/down a shortcut key.	↩	Restore factory default quick key settings

5.6.2.16 Wave Save

See section 15.2.

5.6.2.17 ECG Calibrate

The user can check the integrity of the ECG channel by applying a calibration signal to the system.
Select [ECG Calibrate], the system will automatically apply a 1mV calibration signal to the ECG channel.

5.6.2.18 NIBP Verify

Refer to your technical Service Manual for details.

5.6.2.19 Leakage Test

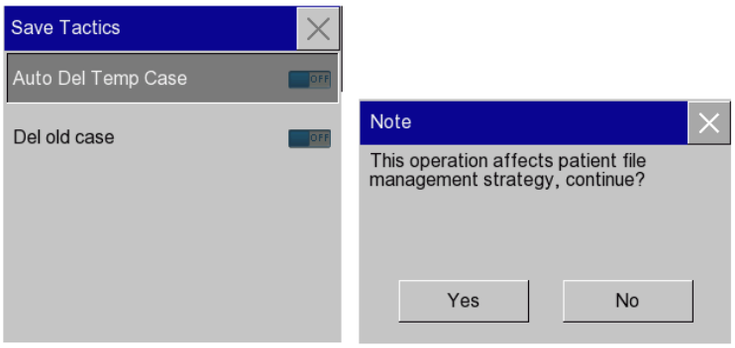
Refer to your technical Service Manual for details.

5.6.2.20 Format SD Card

See Section 19.4.

5.6.2.21 Save Tactics

The Save Tactics and Del old case functions are intended to support the patient management function, it allows the user to automatically delete any temporary or old files which the system creates during the patient ADMIT process.



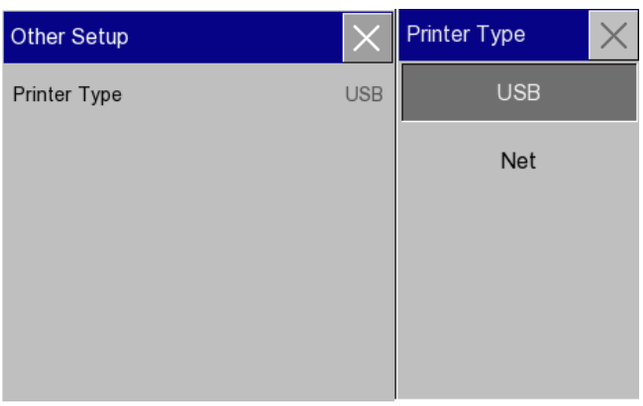
5.6.2.22 Other Setup

The Other setup option allows the user to setup the printer type.

Printer Type

The monitor can support A4 format printer either through its USB connection or via a network port.

Select [Other Setup], [Printer Type] and select [USB] or [Net] as appropriate.



5.6.2.23 Set User Password

Accessing the Set User Password will open a passcode entry window, entering a 4 digit passcode and selecting enter will change the current user password.

To change the passcode back repeat as above or contact your engineering support team.

5.6.2.24 DEMO

This monitor incorporates a demonstration mode, this is particularly useful for training purposes.

From the user maintain menu:

- select [DEMO]
- The system will automatically display the demonstration feature.
- To switch the DEMO mode off

Either

- Switch the monitor off

or

- Select [Main menu], [Maintain], enter password and select [Exit DEMO]

6. Configuration Management

WARNING
The Configuration Management menus are password protected and should only be accessed by authorised personnel.

6.1 Overview

WARNING
Care should be taken when importing USER configurations not to inadvertently overwrite a configuration for another department.

WARNING
It must be noted that within a configuration, users can apply an additional level of adjustment and customisation during the monitoring session, these will not be saved when the patient is discharged or the system is switched off. In this case, the system will return to its default profile / configuration.

WARNING
Users can swap between configurations but should be aware of the impact the changes will have on the patient being monitored.

WARNING
When switching between profiles, the system will adopt default settings, in all cases check the patient group, paced setting and alarm settings are appropriate for the patient being monitored.

Understanding the SC500's configuration management capability is essential to ensure safe and practical monitoring is delivered at all times.

The monitor supports the customisation of the user configuration, this allows you to adapt the monitor to meet the requirements of your clinical settings and or environment.

This functionality is defined by the following features:

Screen settings defined by the appearance and layout of the screen

Measurement settings defined by the alarm limits and associated parameters

Monitor settings defined by system settings such as volume, display brightness, event capture and report style.

In addition to the options listed above, the user has the capability to develop and apply three customised user configurations to each department.

Default Configuration	• Adult • Paediatric • Neonate
User Configuration	USER Config 1
	USER Config 2
	USER Config 3
Export	All configuration files present on the SC500 are EXPORTED
Import	All configuration files on the USB flash drive are IMPORTED

6.2 Managing Configurations

The configuration management option is a protected area of the system and can only be accessed using a password. This feature should only be accessed by suitably qualified personnel. Adjustments applied from this area are significant.

6.2.1 Restoring Factory Dafaults

In certain circumstances it may be necessary to restore factory defaults.

To restore factory defaults, select [Main Menu], [Config Manage], enter password and select [Restore Factory Defaults]. The system will restore factory default settings.

Press ☒ to return to the previous screen.

6.2.2 Creating and Saving a User Configuration

The operator can create up to three USER configurations.

Having made the adjustments (parameters, alarm limits etc), select [Main Menu], [Config Manage], enter password and select [Save As User Config].

Using the on screen keyboard, allocate a name for the configuration.

Press the return key to confirm.

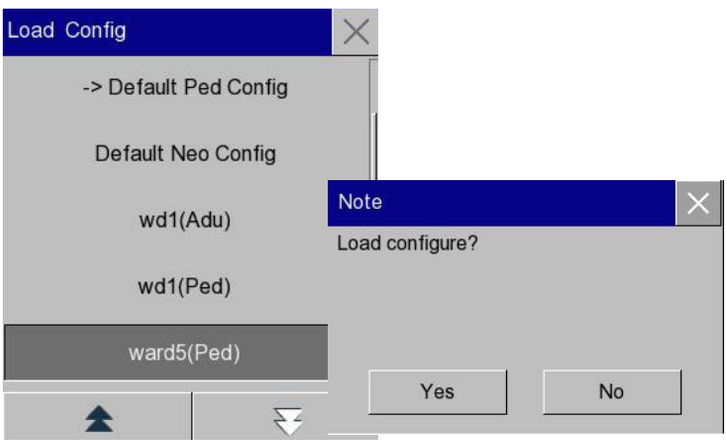
The configuration will be automatically added to the configuration list.

6.2.3 Loading a configuration

To load a new configuration, select [Main Menu], [Config Manage], enter password and select [Load Config].

The system will display the contents of the configuration list, make the necessary selection. A check box will be displayed, select [Yes] to load or [No] to return to the previous screen.

The configuration will be automatically loaded and the system will return to the monitoring screen.



6.2.4 Deleting a configuration

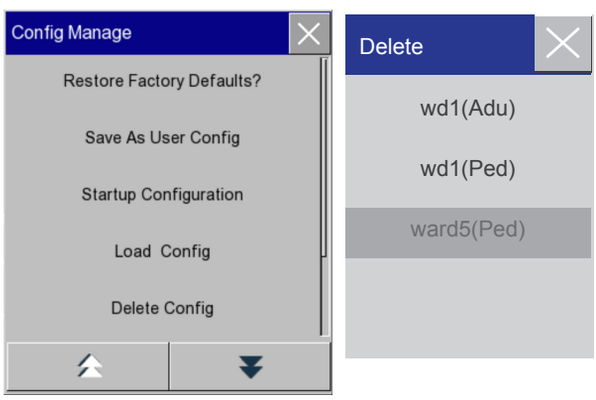
In certain circumstances it may be necessary to delete a configuration.

To delete a configuration, select [Main Menu], [Config Manage], enter password and select [Delete Config].

The system will display the contents of the configuration list, make the necessary selection.

The configuration will be deleted automatically.

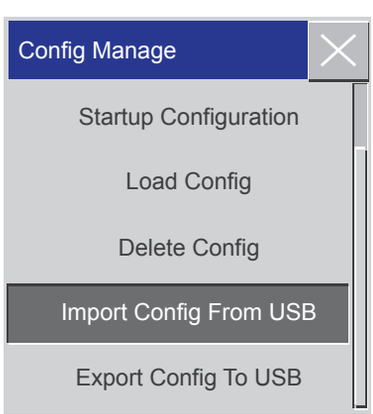
Press ☒ to return to the previous screen.



6.2.5 Importing a Configuration from USB

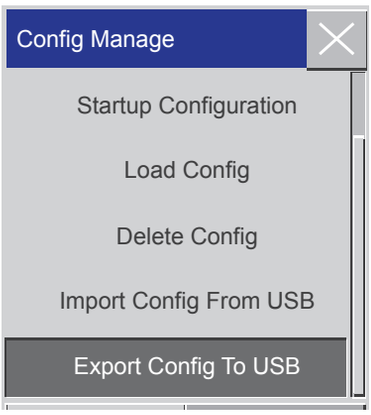
The systems flexibility allows configurations to be shared between devices, to do this it is necessary to IMPORT a configuration from a flash memory card connected to the USB port.

To import a configuration from the USB port, select [Main Menu], [Config Manage], enter password and select [Import Config From USB].



6.2.6 Exporting a Configuration to USB

Configurations can be saved and exported to a flash memory card connected to the systems USB port.



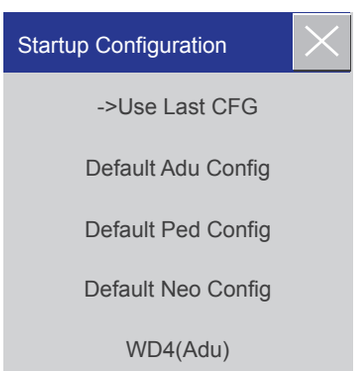
NOTE
When exporting a configuration to a USB drive, do not remove the USB drive until the export process is completed in order to prevent data corruption.

6.2.7 Startup Configuration

The start up configuration can be selected from any of the following:-

- Use Last CFG (Use last configuration)
- Default Adult Config
- Default Ped Config
- Default Neo Config
- Custom Config 1
- Custom Config 2
- Custom Config 3

In [Config Manage] menu, enter [Configuration on Startup] and select from [Use Last CFG], [Default Adu Config], [Default Ped Config], [Default Neo Config] or user-defined configuration.



7. Patient Management

7.1 Patient concepts

WARNING
Always perform a discharge function to close the current monitoring session. Discharging the patient re-sets the equipment's default settings.

Patients must be identified to the system so that data can be assigned correctly, they must be ADMITTED to the monitor to facilitate certain functionality associated with the monitoring session.

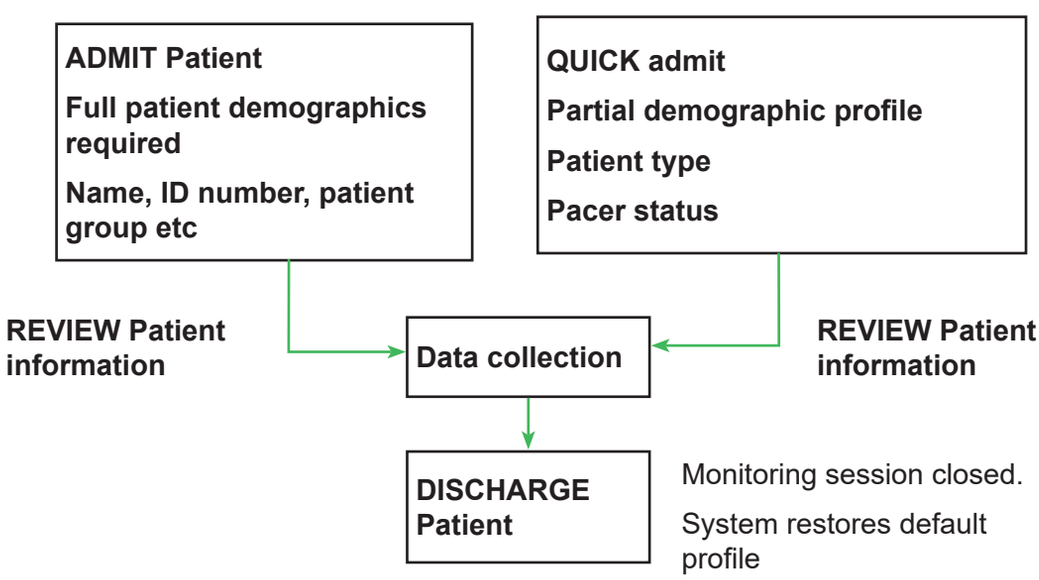
ADMITTING a patient initiates specific algorithms which are used to calculate measurements as well as applying specific alarm limits.

When a patient is DISCHARGED, the collection of data ends and is passed to the patient's data file, the equipment default values are reset.

It is important to develop a standardised approach to the management of patients to ensure that the integrity of patient data and system functionality is maintained.

Failure to manage the patient through the ADMIT and DISCHARGE process may result in the loss of important information or it being incorrectly assigned.

The flexibility of the PATIENT MANAGEMENT function allows you to perform a QUICK ADMIT, full ADMIT, review PATIENT INFORMATION and close the session through the DISCHARGE function.

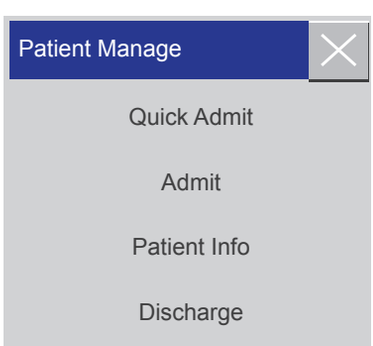


You can access the [Patient Manage] menu in three ways:

Enter [Main Menu] and select [Patient Manage];

Click the [Patient Manage] shortcut key on the lower menu bar;

Click in the patient info area on the upper menu bar.



The system displays and stores data as soon as the patient is connected to the system. This lets the user monitor a patient who is not yet admitted onto the system.

7.2 Quick Admit

The QUICK ADMIT process requires you to enter a minimum set of information:

Select [Main Menu], [Patient Manage], [Quick Admit].

A warning check box appears, select [YES] to discharge the current patient and apply the data to a new patient, or [NO] to return to the previous screen.

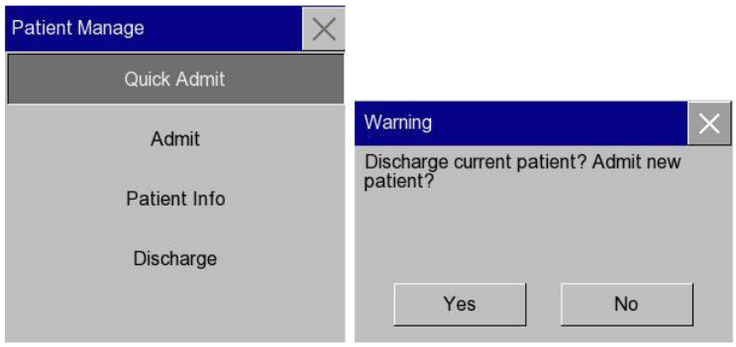
Where applicable, select Patient Type [ADU], [PED] or [NEO]

Set the Pacer status [ON] or [OFF].

All captured data will be associated to the NEW patient.

Close the window to return to the main monitoring screen.

The patient is now admitted onto the system.



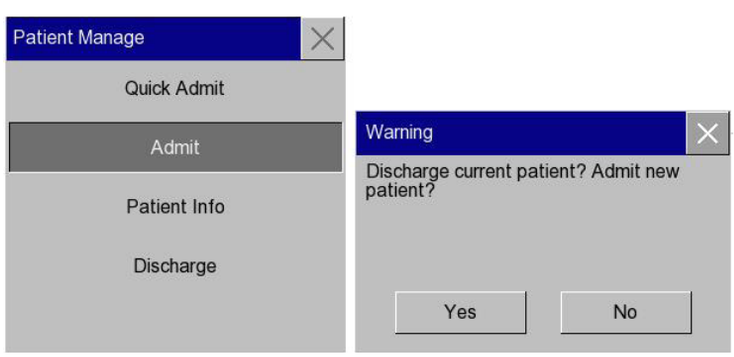
7.3 Admitting a Patient

WARNING
The monitor assigns a default setting to both [Pat Type] and [Pace]. Make sure the data in the Patient Information area are consistent with the patient's details.

WARNING
When the patient type is changed, the system will load the factory default configuration. Verify the alarm limits to ensure that these alarm limits suit your patient.

Select [Main Menu], [Patient Manage], [Admit].

A warning check box appears, select [YES] to discharge the current patient and apply the data to a new patient, or [NO] to return to the previous screen.

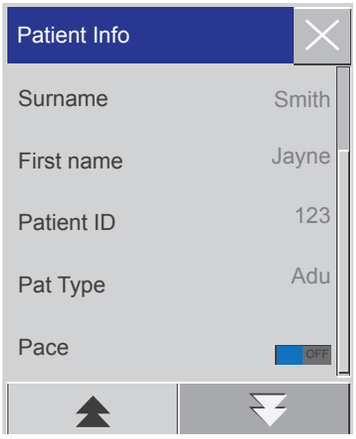


The Patient Information menu will be displayed, the user should complete as much of this information as possible – Surname, First name, Patient ID, Patient Type, Pacer Status, Sex, Date of Birth, Height, Weight, Blood Group.

Pay particular attention to the Patient Type and Pacer Status settings.

All captured data will be associated to the NEW patient.

Close the window to return to the main monitoring screen.



- [Pat Type]: the options include [ADU] (Adult), [PED] (Pediatric), [NEO] (Neonatal). It is essential to select the correct patient type, as it determines the algorithm used to calculate and process the patient data, as well as applying certain alarm limits.
- [Pace]: This setting determines whether the monitor displays pacemaker pulse. When [Pace] is set to "ON" and pacemaker signal is detected, a symbol will be shown above the ECG waveform, and will be shown at the upper right corner of the message prompt area.

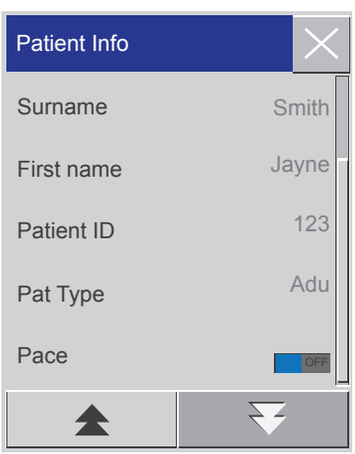
7.4 Patient Information

It is possible to review patient information.

Select [Main Menu], [Patient Manage], [Patient Info]

The patient information window will be displayed.

Scroll through the list paying particular attention to the PATIENT TYPE and PACE settings.



7.5 Managing Patient Records

WARNING
Patient Records are password protected and should be accessed by authorised personnel only.

NOTE
In the event of a power failure, alarm events are saved in the patient file.

NOTE
Patient alarm messages, physiological and technical alarms are saved in the patient file.

NOTE
When exporting data to a USB drive, do not remove the USB drive until the export process is completed in order to prevent data corruption.

NOTE
When the monitor is shut down, the data applicable to the monitoring session is automatically saved. On startup, the system creates a new session.

You can review, delete and export archived patient files, however, patient files can only be archived if the monitor is fitted with an SD card.

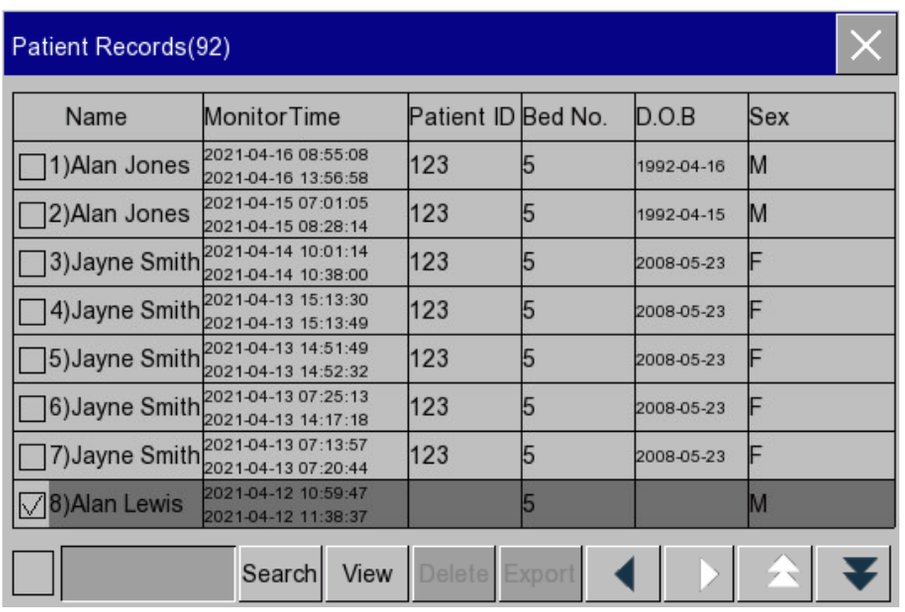
Query	Enter the patient name in the field at the lower left corner of the [Pat File Manage] window and click [Query] to search for the patient's file.
View	Select the patient info bar you want to review. Click [View] to open [Review] menu, in which you can view [Patient Info], [Trend Review], [NIBP Review], [Alarm Event Review] and [Wave Review].
Delete	Delete the selected patient file.
Export	Export the selected patient file to a USB flash drive or PC.

The operating steps for Patient Records are described below:

Enter [Main Menu] → [Patient Records], and enter the password.

Enter a patient name in the input field at the lower left corner of the window.

Click [Search] to the show the patient files found.



If multiple patient files are available, click the keys to select the one you want to view; click the keys to show more patient information.

You can [View], [Delete] and [Export] the selected patient file.

When you check the selection box at the lower left corner, all patient files will be selected. At this time, you can click [Delete] to delete all patient files.

You can export patient files following these steps:

- If a single patient file is selected, select [Export] to open the [Data Export] menu.

  Set the [Start Time] and [End Time].

  Select [File Format]: options are .bin, .txt or .xls.

  Select [Export Media]: options are USB or FTP.

USB: Export to a USB flash drive.

FTP: Export to a FTP server via wired network.

Select [Data Export] to start export. When it is finished, the prompt message [Data export succeeded, please restart.] will be shown.

- If multiple patient files are selected, operational steps are the same with those for single patient file except that [Start Time] and [End Time] cannot be set.

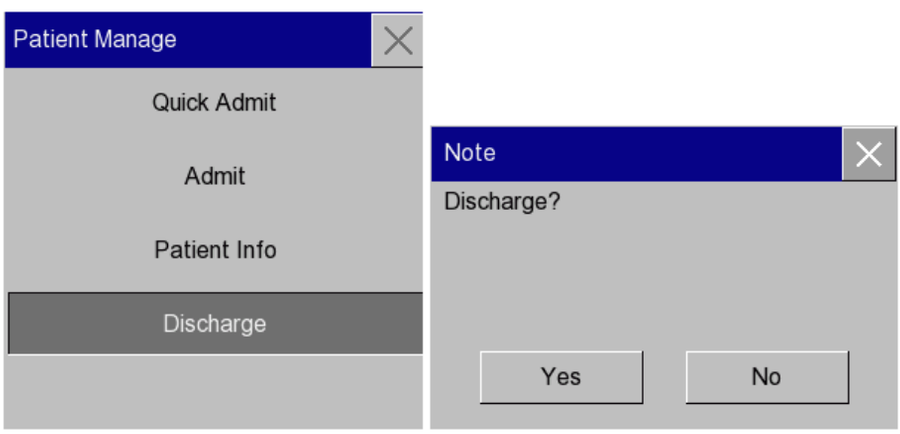
7.6 Discharge

WARNING
After the patient is discharged, [Pace] will default to OFF.

To discharge a patient from the monitor:

Enter [Patient Manage] → [Discharge].

The system will display a prompt message [Discharge?].



- [Yes]: Discharges the patient. The patient data will be archived automatically.
- [No]: Cancels the discharge operation.

8. User Interface

The monitor provides users with multiple interface options in the form of screens or displays:

- Standard display
- List view
- Spot Mode

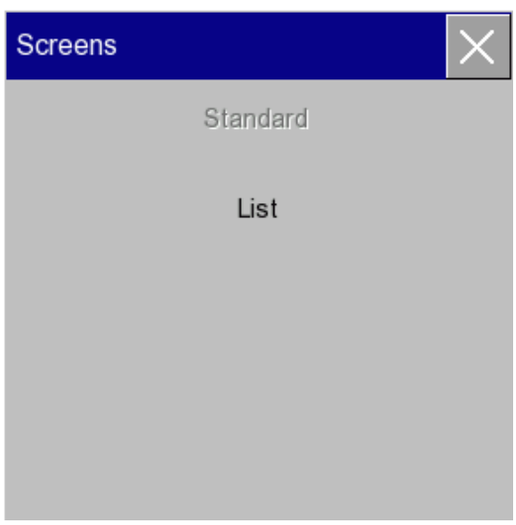
Each display option will be dependent on the monitor configuration and can be customised to match the environment.

To select the appropriate interface:

Select the 

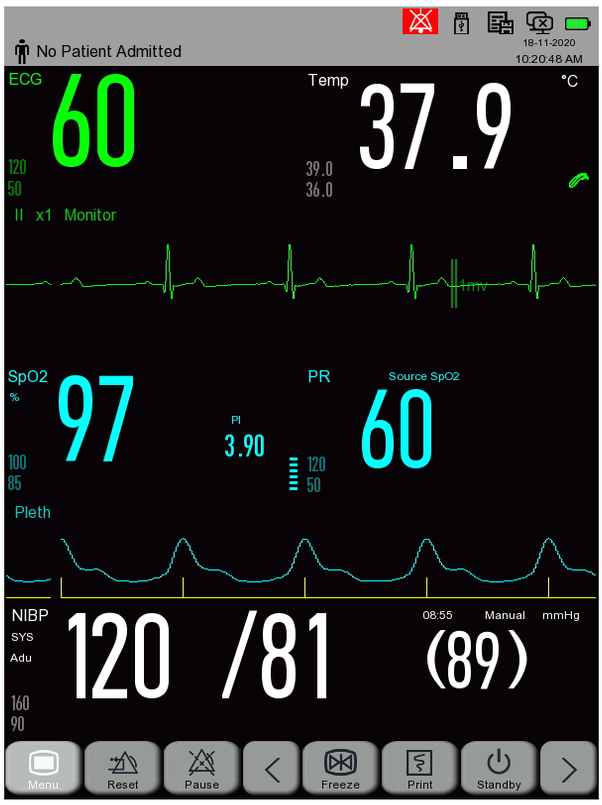
[Screens] smart key, or select [Screens] under [Main Menu].

In the [Screens] menu, select the desired interface.



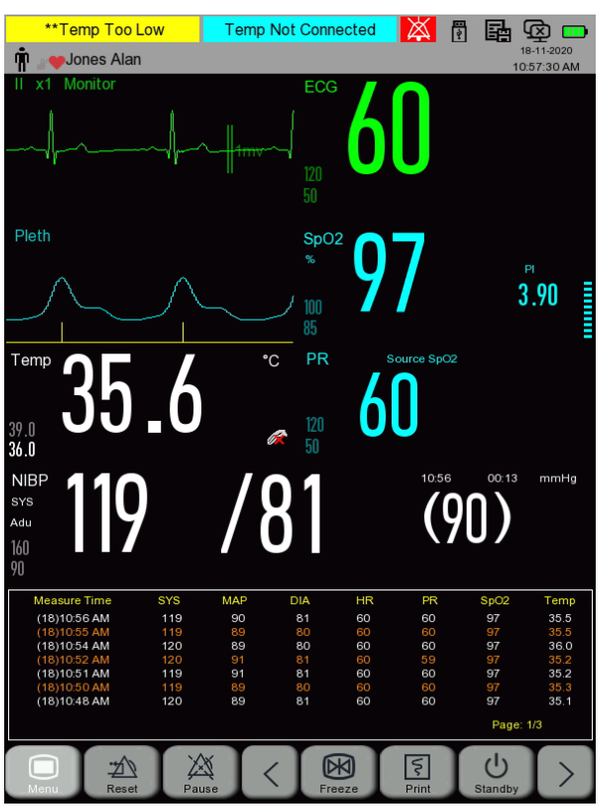
8.1 Standard Display

The monitor displays the Standard interface by default. The Standard interface can display 2 waveforms and up to 5 data channels.



8.2 List View

The List View presents a combination of up to 5 parameters together with a summary of the trended data shown in tabular format in the lower area of the display.



8.3 Customising the Interface

The user can make changes to the appearance of each of the screens, changes can be applied to:

- Waveform sweep speed
- Waveform type
- Colour of the waveform and parameter
- Position and visibility of the parameter

8.3.1 Setting the waveform sweep speed

1. In the Standard display, select the waveform. Using the SpO2 waveform as an example: Select the SpO2 wave → [Sweep].

2. Select the appropriate sweep speed.

8.3.2 Setting the waveform style

This feature is password protected and can only be accessed by the ADVANCED user level.

8.3.3 Setting the module colour

This feature is password protected and can only be accessed by the ADVANCED user level.

8.3.4 Waveform Fill feature

This feature is password protected and can only be accessed by the ADVANCED user level.

8.3.5 Changing the Displayed modules

This feature is password protected and can only be accessed by the ADVANCED user level.

9. SPOT Check Mode

WARNING
Audible and Visual Physiological Alarms are not supported in Spot Check mode.

WARNING
By default the Technical alarm volume is muted in Spot Check Mode, Visual alarms only.

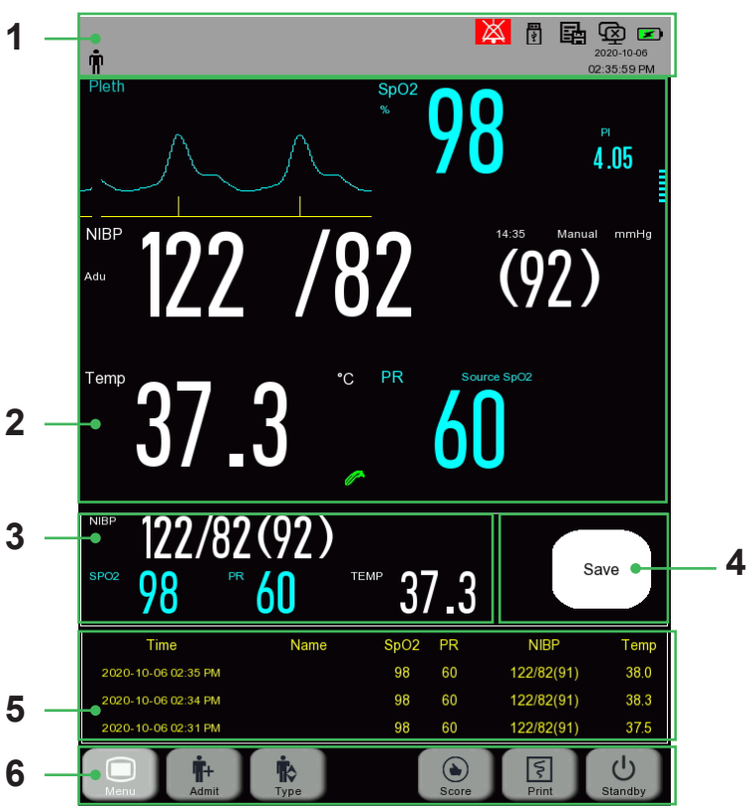
SPOT Check Mode provides reduced functionality designed for quick verification of patient status, measurements include:-

- Oxygen saturation
- Pulse rate
- Non invasive blood pressure
- Temperature (Tympanic)

NOTE
The ECG function is not supported when the SC500 is configured in spot mode.

9.1 Spot Check Mode – Display Layout

The Spot Check screen display is arranged as follows:



1	Upper Menu Bar	4	Save button
2	Parameter and Waveform Area	5	Spot Check trends
3	Data to be Saved	6	Lower Menu Bar

9.1.1 Upper Menu Bar

The upper menu bar displays the patient group, date & time and technical status of the system.

9.1.2 Parameter and Waveform Area

The parameter and waveform area of the Spot Check Mode displays the following information:

- Plethysmogram
- Oxygen saturation level
- Blood pressure
- Temperature
- Pulse rate

9.1.3 Spot Check List preview

This area displays the most recent session Spot Check patient record

Press on the area to display the Spot Mode Check List.

If the SC500 is shutdown or switched to Standard Mode, Spot Mode data is erased.

Time	Name	SpO2	PR	NIBP	Temp
18-11-2020 11:12 AM		97	60	119/80(89)	37.9
18-11-2020 11:11 AM		97	60	119/81(90)	35.3
18-11-2020 11:08 AM		97	60	119/81(90)	35.7

9.1.4 Save Button

Spot Check Mode records are saved to the Spot Check list. Saved records are only available until the system is either rebooted or the system is switched to continuous monitoring mode, no patient data is permanently stored in spot monitoring mode .

9.1.5 Manual input Data

Enabling- Input Data Display

When enabled this provides additional input fields these fields allow the user to manually input patient relevant information such as:

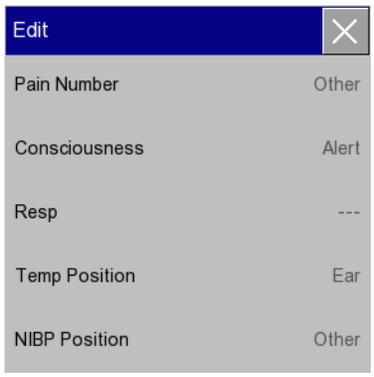
- Pain Number
- Consciousness
- RESP
- Temp position
- NIBP position

This information is then stored with the patient parameter spot data.

Pain Number	Consciousness	Resp	Temp Position	NIBP Position
Other	Alert	---	Ear	Other

Press the Manual Input Data area in the Spot Check interface, the below input menu will open.

Select any of the desired fields to manually input details and values.



Press enter on the input field to save the details and values then X to close the menu.

This data is saved in the Spot Check List patient records when the save key is pressed.

Upon selecting save, the inputted details and values will revert to default values.

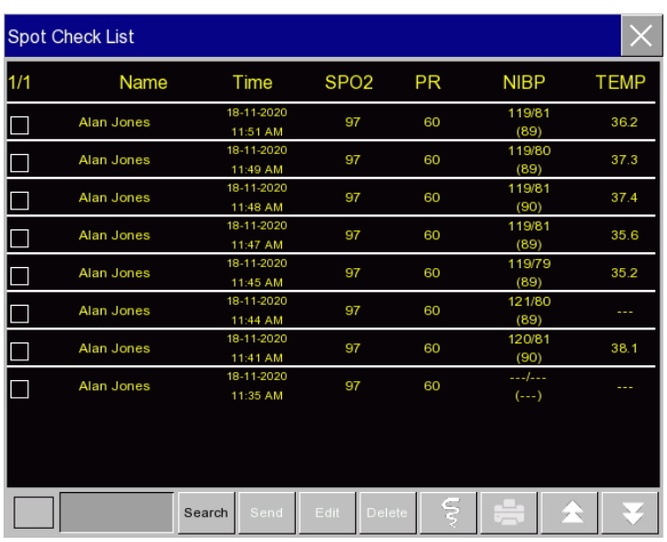
9.2 Spot Check List

The Spot Check List displays the most recent spot mode patient records stored on the system in reverse chronological order.

9.2.1 Spot Check List:-Patient Records

Selecting the Spot Check List preview area opens the Spot Check List as shown below.

Each data point represents the stable values of measurement stored manually or automatically
Data is saved to the list manually or automatic on completion of an NIBP measurement.



Patient Records can be selected for:-

Spot Check List:-Search

Spot Check List records can be searched for partial or full patient name

Select the search button entering the search criteria and press enter.

Spot Check list:-Edit

Individual records can be selected and edited.
Including the following information :

- Surname, Patient Surname
- First Name, Patient First Name
- Sys, Systolic pressure value.
- DIA, Diastolic pressure value.
- MAP, Mean Average Pressure value.
- SpO2, Saturation value.
- Pulse rate, SPO2 or NIBP Pulse Rate value.
- Temp, Tympanic Temperature Measurement value.
- Pain Number, Pain Score index 1-10
- Consciousness, Record the consciousness of the patient, Options include:-
  - ◊ Alert
  - ◊ Confused
  - ◊ Reacts to Voice
  - ◊ reacts to pain
  - ◊ Unresponsive

- Temp Position, Records the location of the temperature measurement site, options include:-
  - ◊ Ear
  - ◊ Mouth
  - ◊ Anus
  - ◊ Armpit
  - ◊ Other

- NIBP Position, records the location of the NIBP pressure measurement options include :-
  - ◊ Left Calf
  - ◊ Right Calf
  - ◊ Left Wrist
  - ◊ Right Wrist
  - ◊ Other

Spot Check list:-Delete
Individual or multiple patient records can be selected for permanent deletion from the system.

Spot Check list:-Record
Individual or multiple patient records can be selected for output on the integrated thermal recorder (if installed).

Spot Check list:-Print
Individual or multiple patient records can be selected for output on the externally connected printer.

Automatic Data Save
During normal Spot monitoring upon the completion of an NIBP measurement, a Patient record is automatically stored.

9.3 Lower Menu Bar

The Lower Menu Bar displays the spot mode quick keys.

1	**Main Menu**	4	**Score**
2	**Admit/Discharge**	5	**Record**
3	**Patient Type**	6	**Standby**

9.3.1 Main Menu

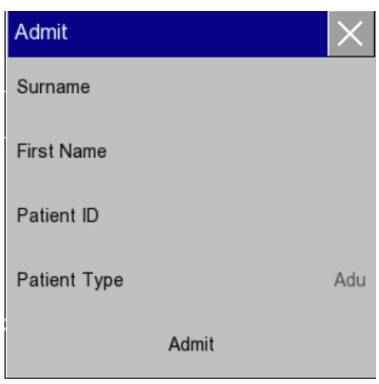
See section 5.6.

9.3.2 Admitting a patient (SPOT Check)

Press the ADMIT button  to display the input form. Enter the Patients surname, first name, ID and patient group.

Press ADMIT to save the information and to accept the patient onto the system.

When a patient is admitted on to the system the Admit button will change to  selecting this key will discharge the currently admitted patient and open the admit patient input form.



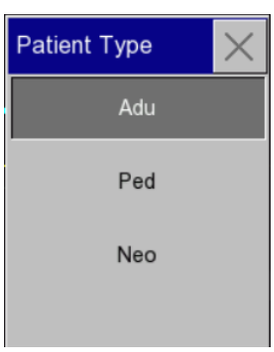
Power off discharge

When the SC500 is powered off in Spot mode, admitted patients are automatically discharged.

9.3.3 Patient Group Selection

Press the Patient type softkey  to display the patient group options.

Make the necessary selection and press  to save the data.



9.3.4 NIBP Start Stop

See section 14.5.

9.3.5 Score

The score button opens the score calculator.

This calculator can be configured to MEWS or NEWS2 scoring system.

Please refer to section 16 for specific details.

9.3.6 Record

Pressing the record button 

will start the MEWS or NEWS2 recorded output on internal thermal recorder if available.

9.3.7 Standby

See section 5.3.

10. Alarms

WARNING
The use of different alarm configurations on different monitors in the same area may result in danger to the patient.

WARNING
Audible Alarms are disabled in SPOT mode, only visual technical alarms are supported.

Alarms are dynamic and respond to the physiological status of the patient, the information in this section applies to all measurements; however, certain measurements have specific characteristics which are detailed in their respective sections.

The monitor uses a range of methods to alert the user of an alarm condition:

- Visual indication
- Audible alert
- On screen status message
- Flashing parameter

NOTE
The system is supplied with a set of default settings, see section 25 for details.

10.1 Alarm Classification

Alarms are classified into two groups.

Physiological alarm- are patient specific and are generated when a parameter exceeds or violates a specific threshold.

Physiological alarms are supported by a visual indicator (alarm indicator and flashing parameter) and an alarm status message.

Technical alarm - technical alarms or system error messages are triggered when the system detects a technical malfunction or INOP condition. An example of an INOP condition is ECG lead off or SpO2 sensor fault. See Section 27 for further details.

Technical alarms are also supported with a similar type of visual indicator and status message.

NOTE
System messages may not be associated with the patient's vital signs, however, they could impact on the operation of the system.

Alarms can also be assigned different levels of priority e.g. High, medium or low.

	Physiological alarm	Technical alarm
High-level alarm	The patient is in life-threatening, imminent danger (e.g., asystole) and emergency treatment should be carried out.	Serious device failure or mis-operation (e.g., low battery) may result in failure to monitor the critical conditions of the patient, which will threaten his/her life.
Medium-level alarm	Abnormality is detected in the patient's vital signs; treatment measures should be taken promptly.	Some device failures or mis-operation may not endanger the patient's safety, but will affect normal monitoring of vital physiological parameters.
Low-level alarm	Abnormality is detected in the patient's vital signs; treatment may be necessary.	Some device failure or mis-operation may result in certain malfunctions, but will not endanger the patient's safety

To aid the identification, each priority is assigned a different colour:

- Red High priority, potentially life threatening e.g. asystole
- Yellow Medium priority, lower priority e.g. respiration alarm violation
- Cyan Low priority e.g. most INOP situations

When an alarm is generated, the monitor will use the following methods to alert the user:

- Visual alarm
- Audible alarm
- Status message
- Flashing parameter

Technical alarms for sensor, probe or modules that are intentionally disconnected by the operator can be reset by pressing the alarm reset key.

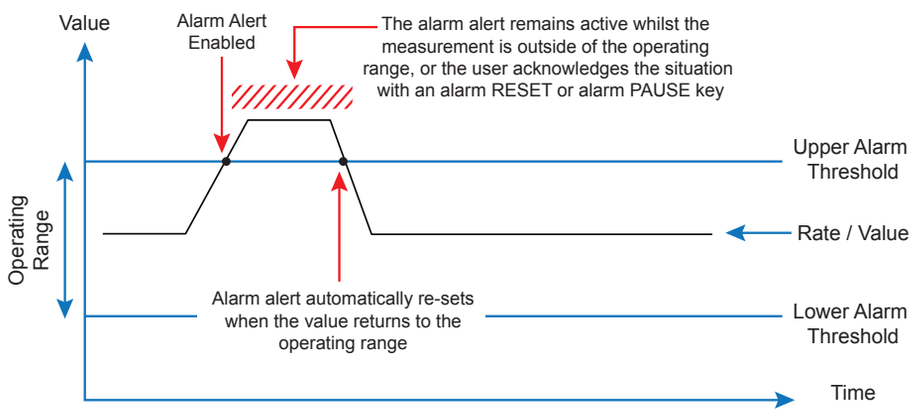
10.2 Alarm Types

Both models supports latching and non-latching alarm functionality, the functionality differs and is described below:

NOTE
The latching functionality is not applied to Technical Alarms.

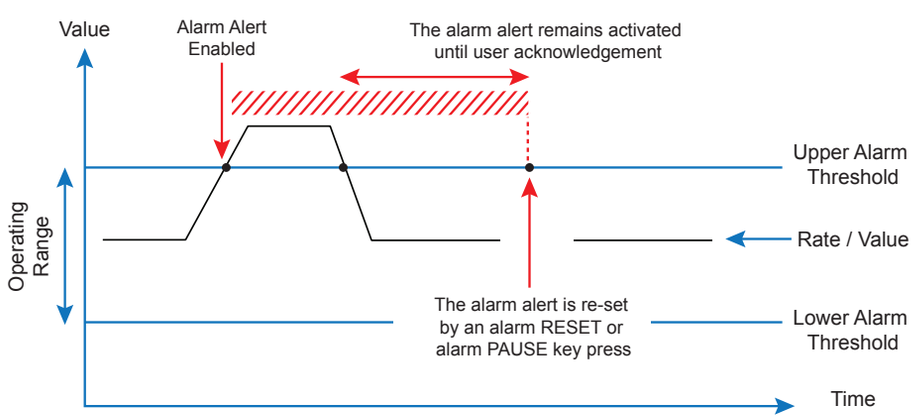
10.2.1 Non Latching Alarms

In an alarm condition, the audible and visual alert automatically resets itself if the parameter returns to the operating range. This applies to both upper and lower threshold settings.



10.2.2 Latching Alarms

In an alarm condition, latching alarms remain activated when the alarm condition returns to the normal The alarm will remain active until the user intervenes with an alarm RESET or an alarm PAUSE key press. Latching alarms remain activated until user intervention has occurred.



10.3 Visual alarm indication

There are two alarm indicators mounted on the upper left corner of the monitor, these are linked to the alarm type and alarm priority; as a consequence, both illuminate with different colours and flash at different frequencies.

Physiological Alarm:

High	Red (left indicator), flashing
Medium	Yellow (left indictor), flashing
Low	Yellow (left indictor), continuous

Technical Alarm:

High	Red (left indicator), flashing
Medium	Yellow (left indictor), flashing
Low	Cyan (right indictor), continuous

10.4 Alarm tones

WARNING
Both the bedside monitor and the CMS are provided with an audible alarm function.

WARNING
When the monitor is connected to the CMS, all alarm limits are synchronised. If an alarm delay is enabled at the bedside, the CMS alarm will also be delayed.

WARNING
When multiple alarms of different levels are generated simultaneously, the monitor will prioritise the highest priority alarm.

CAUTION
Alarms can be paused and reset at the CMS terminal.

CAUTION
Alarms can be enabled and disabled at the CMS terminal.

CAUTION
Critical alarms such as Asystole take priority over all high priority alarm conditions.

The audible alarm tone is linked to the severity level:.

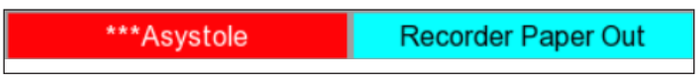
High	Beep Beep Beep - - Beep Beep - - Beep Beep Beep - - Beep Beep
Medium	Beep – Beep – Beep
Low	Beep

10.5 Alarm status messages

Colour coded status messages are shown in the alarm area in the upper menu area of the screen.

Markers are added to the status messages which are linked to the severity:

Priority	Colour	Marker
High	Red	***
Medium	Yellow	**
Low	Yellow – physiological Cyan – technical	*



Example Showing Red High Priority Alarm and Cyan low priority Technical alarm

Example showing Low priority Physiological alarm and Low Priority Technical alarm

10.5.1 Parameter indication

When a parameter exceeds an alarm limit, the parameter and the corresponding alarm value will flash once per second.

10.5.2 Multiple alarms

If more than one alarm is activated, alarm status messages are shown in succession and the system will generate an audible tone according to the highest priority.

10.6 Setting alarm limits

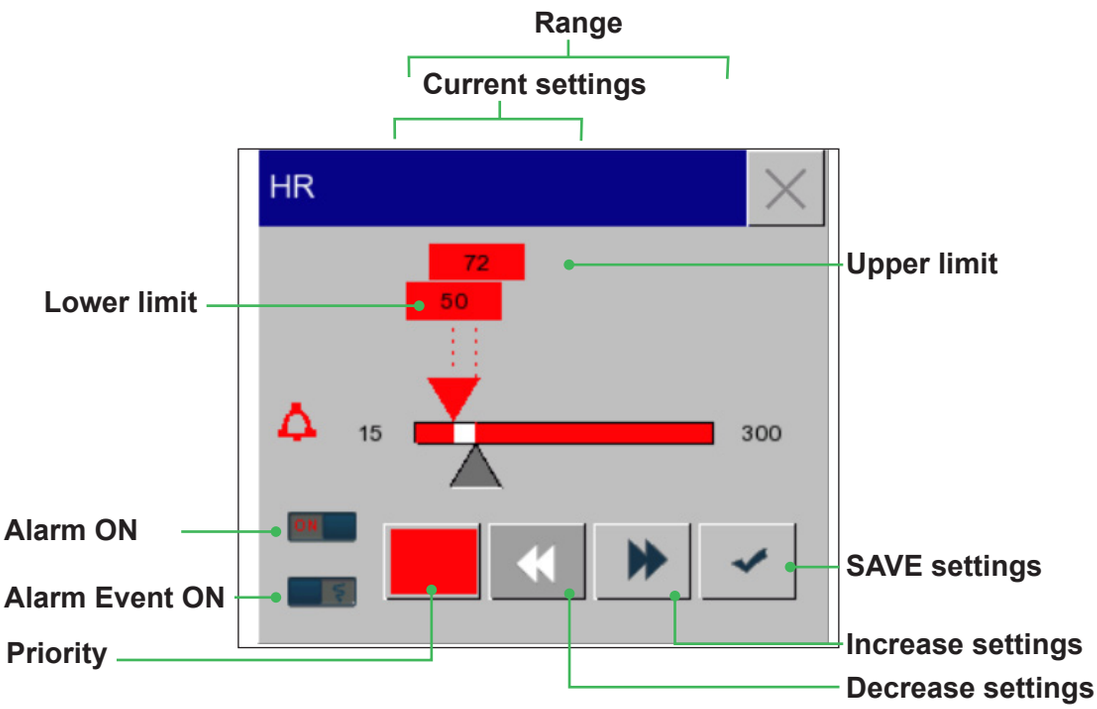
The monitor provides users with a method of alarm adjustment. Users can establish individual limits as well as establishing different priorities for each parameter.

10.6.1 Setting alarm limits and priorities

To change the alarm settings and or priority, select [Main MENU], [Alarm Setup], [Alarm Limit Setup].

Use the ▼ key to scroll down the list and select the particular parameter.

Using HR as an example, the HR lower limit set to 50 BPM and HR upper limit set to 120 BPM.



Select the limit to change, use the ◄►keys or use the touch screen to move the cursor to the new setting.

Should you need to assign a different priority level, select the priority box and toggle through the options – Red High priority, Yellow medium priority and Cyan low priority.

Press ✔ to save settings and close.

Press ☒ to abandon the changes (revert to previous settings) and close

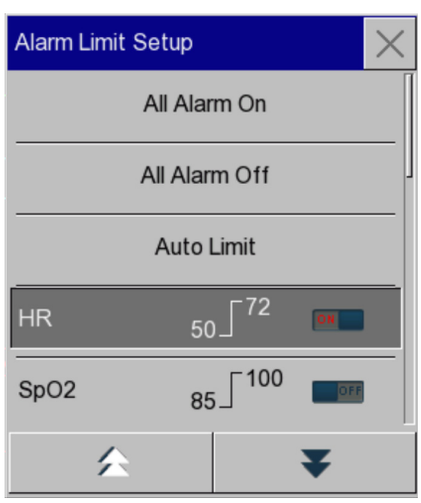
10.3.1 Viewing all alarm limits

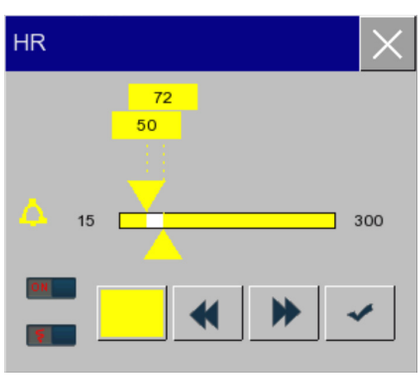
The alarm limit window will list the alarm priority and limits for each of the parameters.

Select [Main MENU], [Alarm Setup], [Alarm Limit Setup] to display the following screen:

Use the ▼ key to scroll down the list.

Using HR as an example, the HR lower limit set to 50 BPM and HR upper limit set to 72 BPM.





10.6.3 Setting Alarm AUTO limits

WARNING
Do not set alarm limits to extreme values, as the alarm system may be rendered ineffective.

WARNING
When setting upper and lower alarm limits, make sure the patient type is correct (ADU, PED or NEO).

WARNING
If you have set up the upper and lower alarm limits manually, the monitor will display these alarm limits instead of the default alarm limits of the system.

WARNING
In the event of unexpected total power loss, the equipment will retain the user adjusted alarm limits for a period of 120 seconds after which the system will revert to the selected limits specific to that configuration.

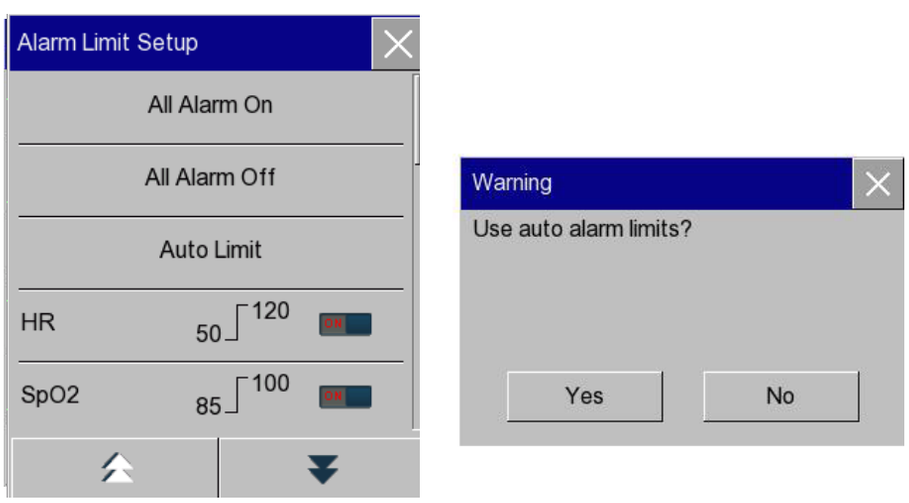
WARNING
If the alarm function is set to "OFF", the monitor cannot trigger an alarm when there is an alarm condition. The operator should use this function with caution.

The monitor is capable of assigning AUTO limits to certain parameters, these will be automatically applied to operate within predefined limits.

The Auto Limit function applies predefined upper and lower alarm limits to baseline parameter values:

- HR HR-10 BPM and HR+12 or [maxHR-minHR]/2
- SpO2 -2% and +5% or [max%-min%]/2
- NiBP (Sys, Map & Dia) +/- 20mmHg
- Temp +/- 1°C
- PR (SpO2 & NIBP) +/- 5 Bpm

Select [Main MENU], [Alarm Limit Setup], [Auto Alarm Limit], a warning check box will appear, confirm selection as necessary.



10.6.4 Switching ON alarm limits

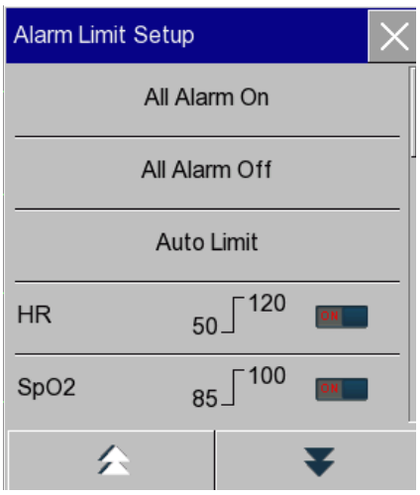
Alarms can be switched ON individually or as a group.

Select [Main MENU], [Alarm Setup], [Alarm limit setup]

Select [All Alarms ON]

ALL alarms will be switched ON

Alarms can be switched OFF individually or as a group.



10.6.5 Switching OFF individual alarms

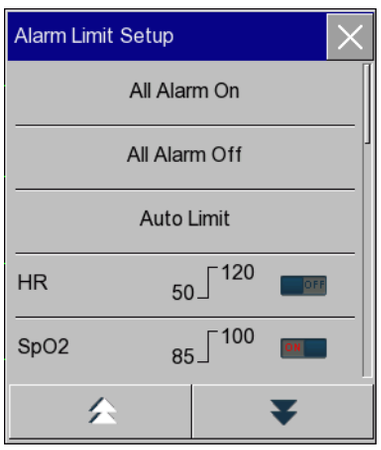
Using ECG as an example, select the ECG parameter.

Select [Alarm Limit Setup]

Slide the HR toggle to the OFF position.

When the alarm is switched OFF, a symbol

( ) appears in the corresponding area of the parameter section



10.6.6 Switching OFF all alarms

Select [Main MENU], [Alarm Setup], [Alarm limit setup]

Select [All Alarms OFF]

ALL alarms will be disabled.

10.6.7 Setting the Alarm OFF reminder

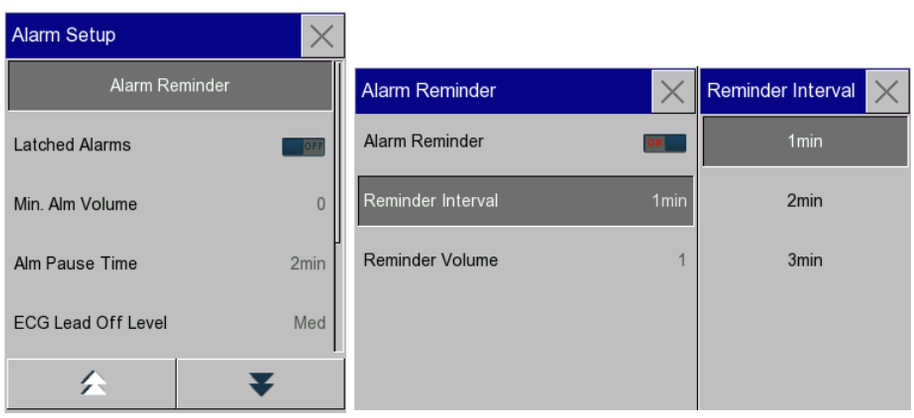
When the alarm volume is set to 0 or switched OFF, the monitor is able to produce a periodic audible reminder which reminds the user that the alarms are disabled.

This feature can only be accessed through the maintenance menu (password required).

Select [Maintain], [enter password], [Alarm Reminder]

Select [ON].

The user has the option to adjust the reminder interval [1, 2 or 3 minutes] and the level of audible alert [1 to 10].



10.6.8 Pausing the Alarms

Users can pause the alarms by pressing the Pause soft key 

.

10.6.9 Defining the Alarm Pause period

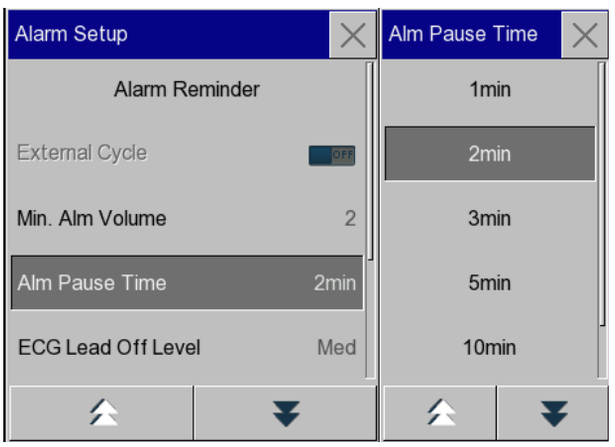
Users can specify the alarm PAUSE period (1, 2, 3, 5, 10 or 15mins).

This feature is accessed through the maintenance menu (password protected).

Select [Main Menu], [Maintain], [enter password], [Alarm Reminder], [Alm Pause Time]

Select [1 minute], [2 Minutes], [3 Minutes], [5 Minutes], [10 Minutes] or [15 Minutes].

Make the appropriate selection and press ☒ to save and exit.



10.7 Setting the alarm volume

WARNING
The audible alarm level, which may be less than the ambient levels, could impact on the identification of an alarm condition.

WARNING
Setting the alarm Volume to minimum (0) will disable the audible output (visual alarms will remain active).

WARNING
Do not rely exclusively on the audible alarm system.
The operator should pay close attention to the patient's status.

NOTE
The maximum alarm volume is 10.

To adjust the alarm volume setting, enter [Main Menu] → [Volume Setup] and select [Alarm Volume].

Set the volume within the range of X - 10 where X represents the lowest volume setting and 10 represents the maximum setting.

Slide the cursor to the required position and press ✔ to save the setting.

10.7.1 Setting the minimum alarm volume

NOTE
The audible level of the alarm is ≤85 dB.

NOTE
This function is password protected and should only be adjusted by your biomedical engineering team.

To set the minimum alarm volume, enter [Main Menu], [Maintain], [Enter password], [Alarm Setup], [Min alm Volume], use the cursor to set the required level.

Press ✔ to save and exit.

NOTE: If the alarm volume setting is set to 0, the  symbol will displayed in the upper menu bar.

10.8 Alarm events

The system is capable of recording USER events associated with alarm conditions such as:

- Alarm pause
- Alarm reset / acknowledgement
- Alarm threshold triggered (upper and lower limits

10.8.1 Setting alarm events

The system is capable of automatically capturing events generated by an alarm.

These can be automatically printed on the integrated recorder.

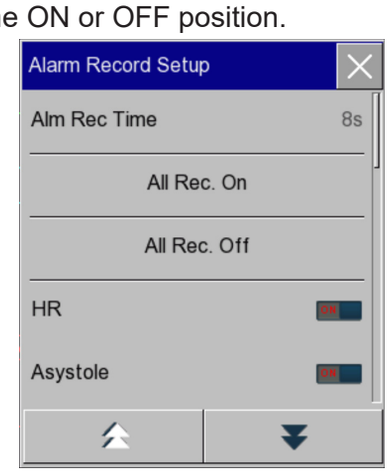
Select [Main Menu], [Alarm Set-up], [Alarm Record Setup].

Select the [Alm Rec Time], [8s] or [16s].

To turn ALL event capture ON, select [ALL Rec ON].

To turn ALL event capture OFF, select [ALL Rec OFF].

In addition to the global control, individual parameters can be adjusted accordingly, simply slide the parameter switch to the ON or OFF position.



10.9 Alarm System Self-test

At startup, the alarm system will perform self-test of the alarm indicators and sound.

◊ The red and yellow alarm indicators illuminate for 1s in turn.
◊ At the same time, the alarm system sounds an audible "beep" .

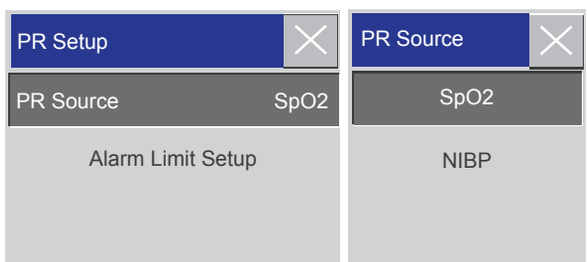
11. Pulse Rate Setup

11.1 Overview

The monitor is able to derive the Pulse Rate from a range of different physiological sources. In all cases the colour of the Pulse Rate parameter will be consistent with the source.

11.2 PR Source

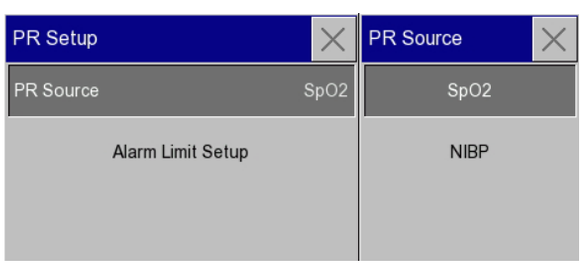
Select the PR parameter area to enter the Setup menu, where you can set PR Source.



SpO2	Display the pulse rate value from SpO2.
NIBP	Display the pulse rate value from NIBP.

11.3 PR Alarm Limit Setup

Select the PR parameter area to display the PR set up options.

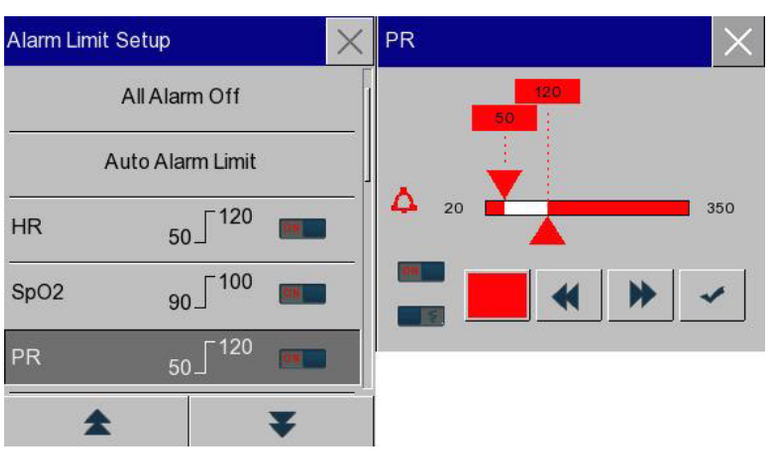


Select [Alarm Limit Setup] .

PR alarm limits can be adjusted using the ◄►keys or the touch screen.

Priority level adjustment is achieved by selecting the priority box and toggling through the options –

- Red High priority
- Yellow medium priority
- Cyan low priority



Press ✔ to save settings.

12. ECG Monitoring

12.1 Precautions

WARNING
During defibrillation, the operator should not come into contact with the patient or device.

WARNING
The SC500 should not be used with 5 or 12 lead patient cables, the use of such cables may lead to increased ECG noise, incorrect heart rate meter and deformation of the ECG trace.

WARNING
Only 3 lead ECG cable assemblies supplied by Huntleigh are approved for use with this monitor.

WARNING
Check for skin irritation at the ECG electrode site. If there is any sign of irritation, replace the electrode or change its position.

WARNING
When connecting the electrodes or patient cable, ensure that the associated connectors and applied parts do not contact any other conductive parts including earth.

WARNING
Interference from instruments near the patient and/or ESU interference could cause problems with the ECG performance.

WARNING
Avoid placing the ECG electrodes or cable near the grounding plate of the High Frequency (HF) Surgical Equipment, to reduce the hazard of burns in the event of a defect in the neutral connection of the HF surgical equipment .

WARNING
Do not expose the monitor to X-ray and high-intensity magnetic fields.

WARNING
Patients with a pacemaker must be observed continuously because the heart rate from the pacemaker may still register in the case of a cardiac arrest or certain arrhythmias. Do not rely on alarms.

NOTE
If the ECG electrode is correctly placed and the ECG wave is still inaccurate, please replace the patient leads.

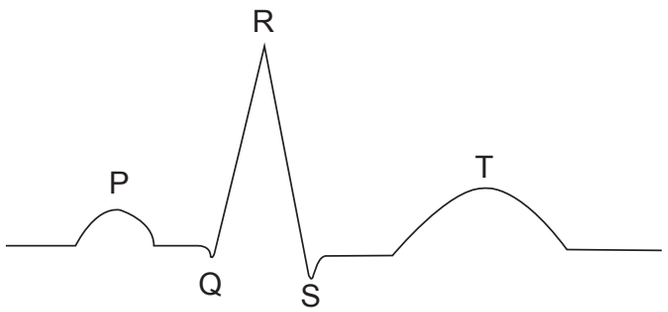
NOTE
To protect the environment, please recycle and treat used electrodes appropriately.

12.2 Introduction

The electrocardiogram (ECG) detects and measures the electrical activity of the patient's heart and displays it on the monitor screen as a physiological waveform supported by numerics. This device has a 3 lead monitoring capability.

The system uses Primary Lead selection to calculate HR.

Successful ECG monitoring should be based on waveforms which exhibit the following characteristics:



- The QRS should be either above or below the baseline, it should never be bi-phasic.
- The QRS complex should be tall and narrow
- The P waves and T waves should be less than 0.2mV

12.3 Working with Paced Patients

Working with paced patients presents various challenges when monitoring their ECG. It is important to enable the PACE status for PACED patients.

All pacemaker pulses are rejected by software regardless of the PACE On/Off status.

When managing patients through ADMIT and QUICK ADMIT function, always verify the PACER status of the patient and set the monitor accordingly.

Always pay close attention to PACED patients ensuring that the detected paced pulse is displayed correctly.

12.3.1 Pacemaker Detection – Enabled

When PACE status is ON (enabled);

- Pacemaker pulse rejection prevents the pacer pulses being counted as extra QRS beats.
- Pacer pulse markers are displayed on the ECG waveform.
- The PACED identification is displayed alongside the patient group.

12.3.1 Pacemaker Detection – Enabled

When PACE is set to OFF (Disabled);

- PACER markers are not shown on the ECG waveform.
- The PACED identification is not displayed alongside the patient group.

12.4 Monitoring Steps

12.4.1 Skin preparation for electrode placement

1. Identify the correct electrode sites avoiding damaged or abnormal areas of skin
2. Where necessary, shave the electrode site.
3. Thoroughly clean the skin with soap and water.(Do not use ether or pure alcohol, these substances can increase the resistance of the skin).
4. Dry the skin thoroughly

12.4.2 Connecting the ECG Cable

1. Connect the chest leads to the electrodes.
2. If you are not using pre- gelled electrodes, apply the conductive gel.
3. Place electrodes in the correct position on the patient
4. Connect the patient cable to the ECG socket on the patient monitor

After a short while, the monitor will display the ECG wave and Heart Rate.

12.4.3 ECG lead identification and placement

Adopting a standardised approach to ECG monitoring is very important in obtaining optimised ECG signals to assist with the diagnosis and management of cardiac patients, different leads in different positions can be used. Correct lead placement is essential for accurate diagnosis, the QRS complex can be affected if the electrode (or lead set) is incorrectly positioned. .

Monitoring leads

Lead set	Leads available
3 Lead system	I, II, III

The identification of the ECG electrodes differ according to certain standards, the table below defines the label and colour code according to the AAMI and IEC standards:

3 Lead system

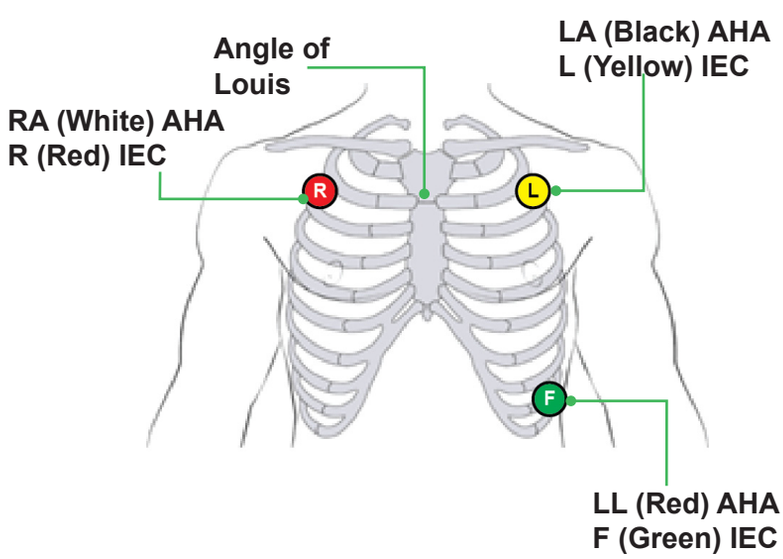
Electrode label		Electrode colour	
AAMI	IEC	AAMI	IEC
RA	R	White	Red
LA	L	Black	Yellow
LL	F	Red	Green

12.4.3.1 Standard 3 Lead placement (IEC)

Red electrode (R) — Place it below the clavicle, near the right shoulder.

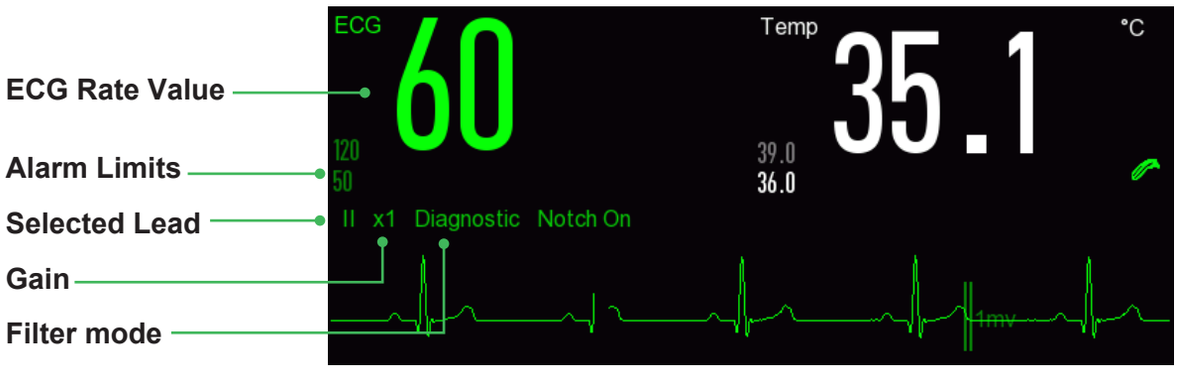
Yellow electrode (L) — Place it below the clavicle, near the left shoulder.

Green electrode (F) — Place it at the left lower abdomen.



12.5 ECG Display

One ECG wave can be displayed on the system's display, the actual configuration is defined by the settings in the ECG waveform menu.



12.6 ECG Setup

12.6.1 Lead Setup

The monitor provides users with a 3 lead ECG capability.

Lead selection option:

- Lead I
- Lead II (Default)
- Lead III

12.6.2 Setting the waveform Gain

If the ECG waveform is too small or appears to be clipped, it is possible to change the size of the waveform.

Select the ECG wave to enter the ECG Wave setup menu, select Gain and choose one of the following options

- ×0.125
- ×0.25
- ×0.5
- ×1 (Default)
- ×2
- ×4

Changing the size of the waveform only affects the physical appearance, it does not change the signal detection or subsequent analysis.

The 1mV CAL reference mark allows you to make a comparison with a reference point.

12.6.3 Setting the ECG Sweep Speed

Select the ECG waveform to enter the ECG Wave setup menu → [Sweep] and choose one of the flowing options.

- 6.25 mm/s
- 12.5 mm/s
- 25 mm/s (Default)
- 50 mm/s

12.6.4 Setting the ECG filter

To ensure optimum levels of performance, the monitor is equipped with two different types of filter, the filter setting should match the monitoring environment.

- MON – MONITORING filter to be used in general monitoring settings (Default).
- DIA – DIAGNOSTIC filter to be used when diagnostic quality is required.

Select the ECG wave to enter the [ECG Wave] menu → [Filter Mode] → [Diagnostic] or [Monitor].

12.6.5 Notch Filter Setting

The 50/60Hz notch filter removes any potential interference associated with the line frequency.

The notch filter can be set ON/OFF.

When the ECG filter is set to MONITOR, the notch filter setting is automatically set to ON.

When the ECG filter is set to DIAGNOSTIC, the notch filter can be switched ON or OFF.

With the Diagnostic filter enabled perform the following steps to disable the notch filter:-

- Select the ECG parameter area to enter the Setup menu → [Other Setup]
- Select Notch filter [On]: 50/60Hz Notch filter is enabled
- Select Notch filter [Off]: 50/60Hz Notch filter is disabled.

13. SpO_2 Monitoring

13.1 Overview

WARNING
Injected dyes such as Methylene Blue or intravascular dyshemoglobins such as carboxyhemoglobin (COHb) and methemoglobin (MetHb) may lead to inaccurate measurements.

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

The monitor can be supplied with two types of SpO2 technology; whilst the sensors are not interchangeable, they both operate using the same basic principles.

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 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 as the receptor.

The Smartisgns Compact 500 series uses technologies from two different providers:

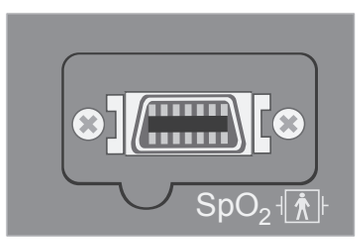
- Huntleigh SpO2
- Nellcor™ Oximax.

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 as directed by the accompanying IFU and pay particular attention to all warnings and cautions

13.1.1 Identification of SpO2 technology

The SpO2 technology is pre-configured before the Monitor is delivered. You can identify it based on the connector type:

Huntleigh SpO2 Technology		**Nellcor™ Oximax SpO2 Technology**	

It is useful for the clinician to know the wavelength range and maximum optical output power of the sensor for the purpose of photodynamic therapy.

Technology	Red wavelength (nm)	Infra Red wavelength (nm)	Maximum optical output
Huntleigh SpO2	660	905	15mW
Nellcor™ Oximax	660	900	15mW

13.2 Safety

WARNING
The monitor is only compatible with SpO2 sensors approved by Huntleigh. Before monitoring the patient, please check if the sensor and extension cord are compatible with the Monitor. Incompatible accessories may reduce the performance of the Monitor.

WARNING
Before monitoring the patient, check the sensor for damage. If the SpO2 sensor or its packaging appear to be damaged, do not use it, return it to the manufacturer.

WARNING
Check the patient's skin every two hours to ensure good skin quality and colour. In case of any skin change, move the sensor to another part. Relocate the sensor at least every 4 hours. If the patient experiences any discomfort, discontinue use immediately.

WARNING
Do not place the SpO2 sensor on a limb which is supporting an IV system.

WARNING
Misapplication of a pulse oximeter probe with excessive pressure for prolonged periods can induce pressure injury.

WARNING
The operator is responsible for verifying the compatibility of the monitor, probe and cable before use, or patient injury can result.

WARNING
Do not use the equipment in an MRI environment.

WARNING
High oxygen levels may predispose a premature infant to retrolental fibroplasia.
If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off.
Transcutaneous pO2 monitoring is recommended for premature infants receiving supplemental oxygen.

NOTE
The SC500 provides a normalised plethysmogram with Performance Indicator (P.I.) for both Huntleigh and Nellcor technology.

NOTE
The SC500 is calibrated to display functional oxygen saturation

The following factors may affect the SpO2 measurement:

- Incorrect sensor placement.
- Presence of intravenous dyes.
- Excessive patient movement.
- Ambient optical radiation.
- Improper operating temperature (environment).
- Sensor applied to a limb fitted with blood pressure cuff or intravenous set.
- Patients presenting with ductus arteriosus and or cardiac arrhythmias.

- Low perfusion or poor circulation at the sensor site.
- Shock, anaemia, hypothermia and vasoconstrictors may reduce blood flow.
- High frequency radio interference whether from the host of from adjacent equipment.

13.3 Accuracy verification

13.3.1 SpO2 Accuracy

WARNING
Functional Testers cannot be used to assess SpO2 accuracy

13.3.2 PR Accuracy

The accuracy of the SpO2 PR can be verified by comparing it with the patient's heart rate derived from the ECG electrode placement.

13.4 SpO2 Waveform (Huntleigh)

The Pleth Wave is automatically scaled to fit the space on the screen. It is not proportional to the pulse volume or signal quality.

The Perfusion Index has a range 0.05% to 20%, the higher the value, the better the perfusion.

The SQI represents signal quality, the higher the vertical bar the better the quality of the signal.

The Pleth Bar provides a visual indication of arterial pulsatility.

Pressing the Pleth Wave will display the waveform setup, whilst pressing the numerical area will display the extended set up options.

13.5 SpO2 Setup (Huntleigh)

The user can make changes to the SpO2 set up by selecting either the waveform area or the parameter area.

Select the SpO2 waveform to adjust the waveform sweep speed [6.25], [12.5], [25], [50mm/s] or access the SpO2 setup options.

13.5.1 Sweep speed

Select the waveform area to display the Pleth Wave set up options, select [SWEEP], [6.25mm/s], [12.5mm/s], [25mm/s], or [50mm/s].

Make selection and press ☒ to confirm selection.

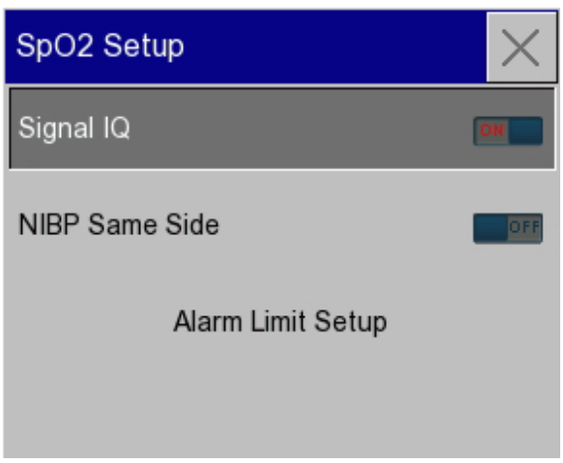
13.5.2 Signal IQ

The SpO2 measurement is supported by Signal IQ, this can be enabled or disabled as required.

When enabled the Signal IQ provides a graphical representation of the non-normalised plethysmograph amplitude, this is used to determine the quality of the SPO2 signal.

Select the waveform area to display the set up options, select [SpO2 Setup], [Signal IQ], [ON/OFF] as required

Make selection and press ☒ to confirm selection.



13.5.3 NiBP same side

In situations where the SpO2 sensor has to be applied to the same arm where a blood pressure cuff is applied, the NiBP SAME SIDE function is recommended as it applies a specific algorithm for processing the SpO2 signals.

Select the waveform area or the SpO2 parameter to display the set up options, set [NiBP Same side ON / OFF] as required.

Make selection and press ☒ to confirm selection.

13.5.4 Alarm set up

The SpO2 channel is equipped with a comprehensive alarm functionality. Select the waveform area or the SpO2 parameter to display the set up options, select [SpO2 setup].

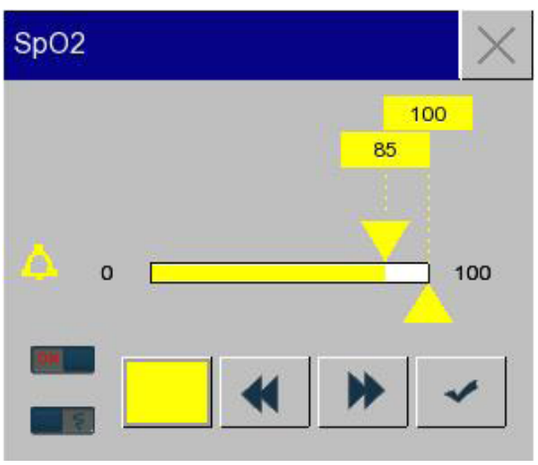
Select [Alarm Limit Setup], select [SpO2].

Select the limit to change, use the ◄►keys or the touch screen to slide the cursor to the new setting.

Should you need to assign a different priority level, select the priority box and toggle through the options – Red High priority, Yellow medium priority and Cyan low priority.

Press ✔ to save settings.

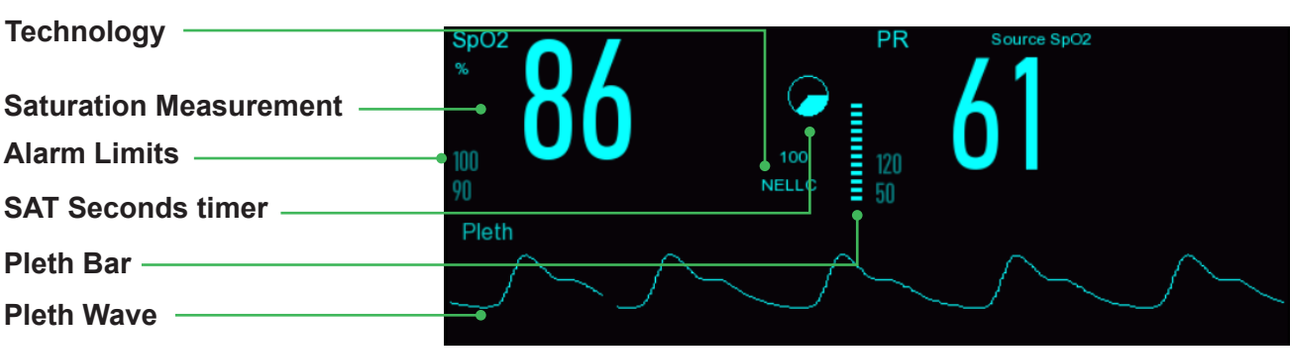
See Section 10 for more details.



13.6 SpO2 Waveform (Nellcor Oximax)

The Pleth Wave is automatically scaled to fit the space on the screen. It is not proportional to the pulse volume or signal quality.

The SAT Second timer displays the SAT Second setting.



13.7 SpO2 Setup (Nellcor Oximax)

Setting up the Nellcor Oximax SpO2 measurements is almost identical to those steps described in the previous sections, however, the Oximax option includes a proprietary SAT Second alarm management feature.

SAT Second alarms are designed to reduce the number of false SpO2 alarms, it is user adjustable and uses a combination of ALARM THRESHOLD and TIME DURATION. The SAT Seconds alarm is a value set to 10, 25, 50 or 100s by the user.

The algorithm calculates the duration of the event multiplied by the number of percentage points the SpO2 falls outside the saturation alarm threshold, see examples below:

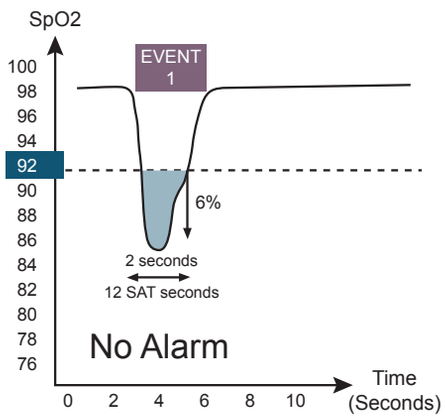
Example 1

- SAT Second alarm set to 25s.
- Low SpO2 level set to 92%

Scenario: The patient's SpO2 drops to 86% for a time duration of 2s before the saturation returns above the low alarm limit of 92%.

Calculation: 6% drop x 2 Seconds = 12 SAT Seconds

Because the SAT Second alarm is set to 25s, and the SAT Second value is 12 SAT Seconds, no alarm will be generated.



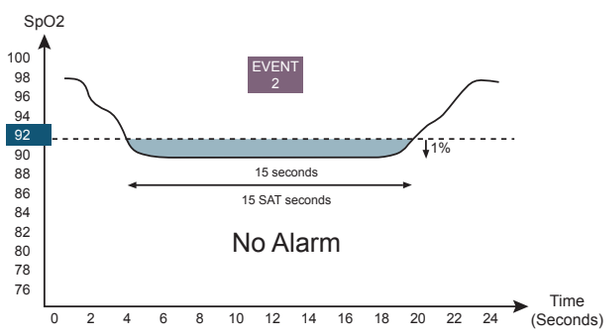
Example 2

- SAT Second alarm set to 25s.
- Low SpO2 level set to 92%

Scenario: The patient's SpO2 drops to 91% for a time duration of 15s before the saturation returns above the low alarm limit of 92%. E.g.

Calculation: 1% drop x 15 Seconds = 15 SAT Seconds

Because the SAT Second alarm is set to 25s and the SAT Second value is 15 SAT Seconds, no alarm will be generated.



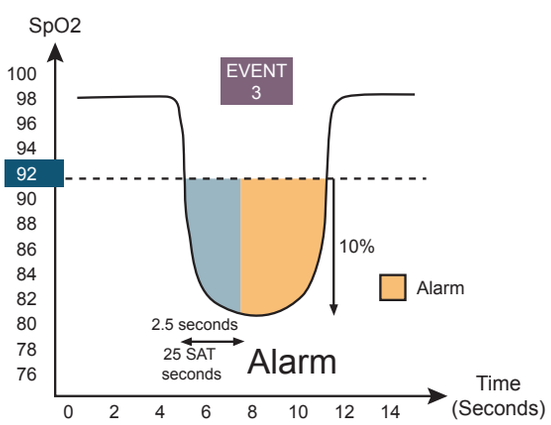
Example 3

- SAT Second alarm set to 25s.
- Low SpO2 level set to 92%

Scenario: The patient's SpO2 drops to 82% for a time duration of 5s before the saturation returns above the low alarm limit of 92%. E.g.

Calculation: 10% drop x 5 Seconds = 50 SAT Seconds

Because the SAT Second alarm is set to 25s, an alarm would be generated 2.5s into the event because the SAT Seconds (50s) exceeds the 25s setting.



13.8 SpO2 Monitoring Steps

WARNING
Follow the instructions for use supplied with the SpO2 sensor for correct placement.

The monitor will accept signals from a range of different SpO2 sensors e.g., traditional finger sensors, soft tip sensors or wrap type of sensor. Refer to the instructions for use which accompany the sensor for indications for use and any contra indications.

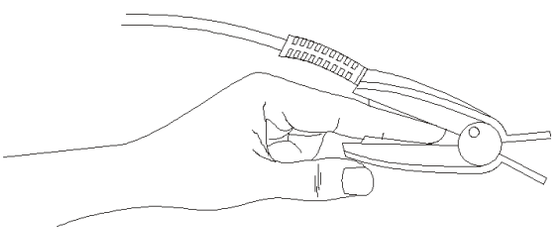
Some sensors will connect directly to the monitor, whilst others require the use of an interface cable.

Monitoring Adult and Paediatric patients

Connect the SpO2 sensor directly to the monitor or via the extension cable.

Apply the sensor to the patient's finger

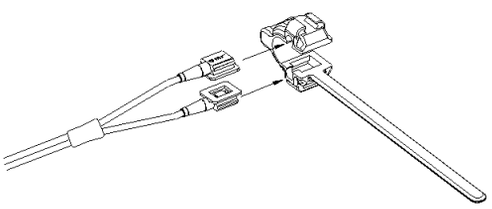
After a short period the SpO2 waveform will appear on the display.

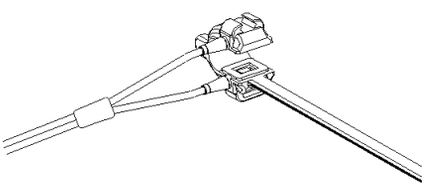


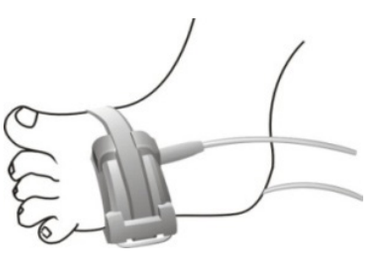
Monitoring Neonate patients:

The measurement for neonates is almost the same as that for the Adult and Paediatric groups, however, the sensor is of a different construction.

The Neonate sensor usually consists of a Y shape or wrap type of sensor which may be applied to the foot or hand.







To achieve best results, follow the instructions for use which accompany the particular sensor.

14. NIBP Monitoring

14.1 Overview

The SC500 NIBP is intended to give a medical indication of Systolic, Diastolic, Mean Arterial blood pressure and pulse rate for Adult, Neonatal and Paediatric patients, for the detection of high and low blood pressure.

The SC500 Automated Sphygmomanometer is NOT intended for use with pregnant, including pre-eclamptic, patients.

The SC500 Automated Sphygmomanometer effectiveness has not been established in pregnant (including pre-eclamptic) patients.

The NIBP function uses the oscillometric technique. A pump inflates the cuff to initially occlude the flow of blood, then under controlled conditions, the pressure in the cuff is gradually reduced.

When the cuff pressure is above systolic pressure, small pulses or oscillations begin to be sensed by the transducer. As the cuff continues to deflate, the 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 the analysis of the oscillation amplitude profile.

14.2 Safety

WARNING
Inspect the cuff tubing and connections for kinks and obstructions before use to prevent accidental continuous CUFF pressure, this will obstruct blood flow that could lead to possible injury to the patient.

WARNING
Select the correct patient group before measurement. Do not apply the higher adult settings to pediatric or neonatal patients; this may lead to patient injury

WARNING
Do not perform the NIBP measurement on a patient with sickle cell disease.

WARNING
Unattended automatic measurement - Clinical judgement must be used to decide whether to perform frequent unattended BP measurements on patients with severe blood clotting disorders due to the elevated risk of haematoma in the limb with the cuff.

WARNING
Automated Sphygmomanometers must be checked on a regular basis as prolonged impairment of circulation may result in injury to the patient.

WARNING
Pressurisation of the BP cuff can temporarily cause loss of function of other Medical Equipment used on the same limb.

WARNING
Avoid connecting the NIBP cuff to the patient during times of high frequency electro surgery.

WARNING
Do not place the cuff on the arm at the same side as mastectomy.

WARNING
Do not place the CUFF on a limb where intra-vascular access or therapy, or an arterio-venous (A-V) shunt is present. Pressurisation of the cuff will temporarily interfere with blood flow that may result in injury to the patient.

WARNING
Do not place the cuff on any wound.

CAUTION
Operating outside the specified environmental conditions for temperature, relative humidity and pressure may result in accurate NIBP readings

14.3 NIBP 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.

Measure the patient's limb and select the proper size cuff. As a general rule, the cuff should encompass 80-100% of the limb circumference.

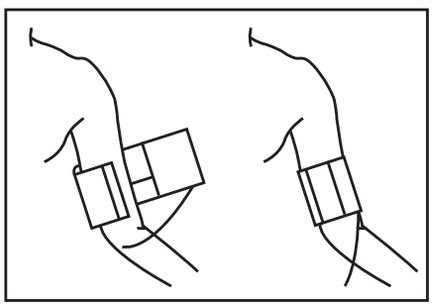
Connect the hose to the NIBP Hose connector as shown. Push until you hear a click.

14.3.1 NiBP Cuff selection and application

WARNING
Use of an incorrectly sized cuff or a misaligned cuff may result in errors in the BP measurement.

NOTE
The following instructions apply to upper arm measurements, the same precautions should be adopted if other sites are being used.

Follow the application instructions for use to ensure the correct size of cuff for the patient. Failure to do so will adversely affect the accuracy of the measurement.



Place the open cuff around the upper arm.

Align the artery marker with the brachial artery.

Wrap the cuff around the arm ensuring that the INDEX marker falls between the RANGE indicator.

The cuff should be wrapped snugly around the arm, check by placing two fingers between the arm and inner surface of the cuff.

The patient should either be laying on their back or seated in a chair with back and arm support, legs uncrossed and their feet flat on the floor, with the centre line of the cuff at the level of the right atrium of the heart.

Failure to follow these steps may result in incorrect measurements.

14.3.2 Limitations of measurement

NiBP measurements are affected by several influences, patient compliance, position, physiological status and measurements site. In these situations, the HCP should determine the clinical significance of NiBP information.

Measurements will be adversely affected with heart rates of less than 40 BPM and heart rates greater than 240 BPM.

Measurements are also affected by:

- Excessive patient movement
- Cardiac arrhythmias
- Rapid changes in blood pressure
- Patient presenting with shock or hypothermia
- Patient presents with large oedematous limbs so as to affect the arterial oscillations

Consider delaying a blood pressure measurement if the patient has:

- **Smoked** - Smoking within 30 minutes of an NIBP measurement procedure can elevate the blood pressure readings.
- **Exercised** - Exercising before NIBP measurements can lower blood pressure readings.
- **Consumed caffeinated products or other stimulants** - Caffeine or other stimulants taken before the NIBP measurements can raise blood pressure reading.

Other Considerations

There are many factors which can affect BP measurements, if any doubt exists, seek an alternative method and or refer to your local protocol for guidance.

Cuff Height adjustment

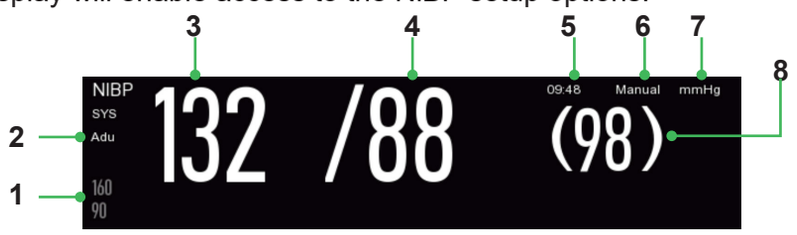
The NIBP cuff must be placed on a limb level with the patients heart.
If the cuff cannot be placed on a limb that is level with the patients heart the following height adjustment must be used add 0.75mmHg (0.1kPa) for each centimeter higher add 1.9mmHg per inch (0.25kPa)

14.3.3 NIBP Display

The NIBP measurements are displayed in the parameter area. The figure below is for reference only.

The actual display interface of the Monitor may be slightly different from this figure.

Accessing the NiBP display will enable access to the NiBP setup options.



1	**Alarm limit**	5	**Time of the measurement**
2	**Patient type: ADU, PED or NEO.**	6	**Measurement mode: auto, manual or Stat**
3	**Systolic pressure**	7	**Pressure unit: mmhg or kPa**
4	**Diastolic pressure**	8	**Mean pressure**

During NIBP measurement the display area shows the real-time cuff pressure as shown below

14.4 NIBP Setup

Press the NiBP area to display the set up options.

The User can access the following settings:

- Set the measurement mode – Manual or automatic
- Adjust the initial cuff target pressure
- Adjust alarm limits
- Enable STAT measurements
- Reset the NiBP module

Extended set up options include (Other Setup):

- ◊ Set venous puncture cuff pressure
- ◊ Start Assisted Venous Puncture process
- ◊ Enable dynamic NiBP analysis

14.4.1 Patient Type

The PATIENT TYPE is set during the PATIENT ADMIT process.

Check the correct patient type appears in the NiBP parameter area.

Failure to set the correct patient group will deliver incorrect measurements.

14.4.2 Measurement Modes

The monitor is capable of delivering three types of NiBP measurement:

- Manual measurements are made on demand
- Automatic measurements are made at predefined periods (1 min to 480 mins)
- STAT sequential measurements are made during a 5 minute period (use only with supervised patients)

14.4.2.1 Manual Mode

Press the NiBP parameter to display the set up options, press [Measurement Mode], [Manual], make the selection and press X to save and exit.

14.4.2.2 Automatic Mode

Press the NiBP parameter to display the set up options, press [Measurement Mode], [Auto], select the measurement period [1, 2, 2.5, 3, 10, 15, 20, 30, 45, 60, 120, 240 or 480min] make the selection and press X to save and exit.

14.4.2.3 STAT Mode

Press the NiBP parameter to display the set up options, select [STAT].

The STAT sequence of measurements will start immediately.

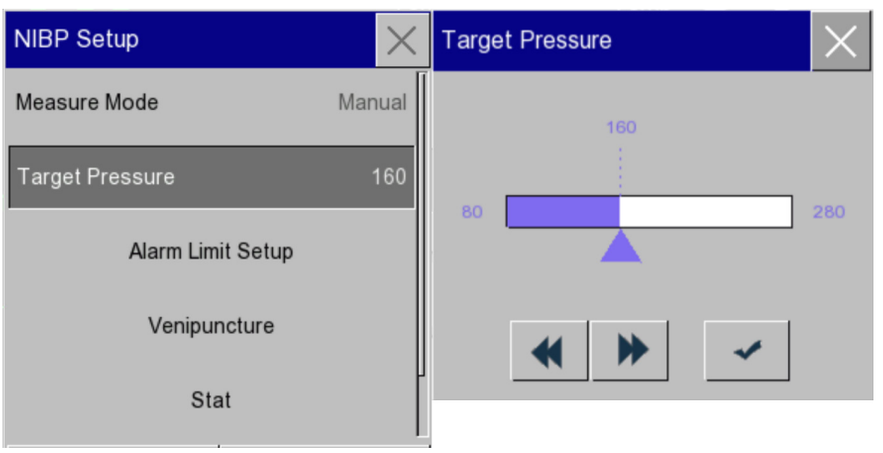
The sequence will continue until the 5 minute period has elapsed.

14.4.3 Target Pressure

The TARGET PRESSURE is patient group specific, the following default settings are applied:

- Adult 160 mmHg (range 80-240 mmHg)
- Paediatric 120 mmHg (range 80-200 mmHg)
- Neonate 100 mmHg (range 60-120 mmHg)

The user can adjust the initial cuff target pressure, press the NiBP parameter to display the set up options, press [Target Pressure], use the ⬅➡ keys to set the desired setting.

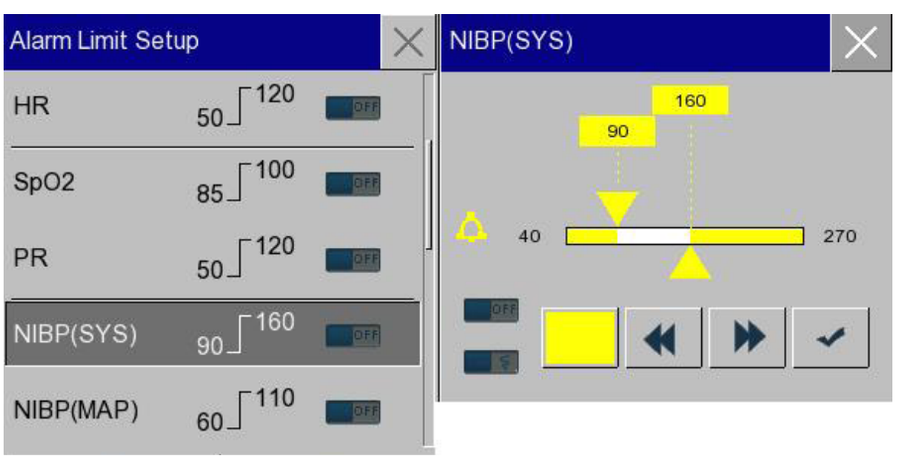


Press ✔ to save and exit.

14.4.4 Alarm Limit Setup

Alarm limits can be applied to the SYSTOLIC, DIASTOLIC and MAP measurements.

Press the NiBP parameter to display the set up options, select [Alarm Limit Setup], select [NIBP (SYS)], [NIBP (MAP)], [NIBP (DIA)].



Select the limit to change, use the ⬅➡ keys or the touch screen to drag the cursor to the new setting.

Should you need to assign a different priority level, select the priority box and toggle through the options – Red High priority, Yellow medium priority and Cyan low priority.

Press ✔ to save settings.

See section 10 for more details.

14.4.5 STAT measurements

See section 14.4.2.3

14.4.6 Reset Module

In the unlikely event that the NiBP module 'locks up' pressing the RESET key resets the module and re-established communication with the host.

14.4.7 Other Setup (EXTENDED Options)

An extended set of options are provided by the OTHER SETUP menu, these cover the assisted venous puncture mode and NiBP analysis feature.

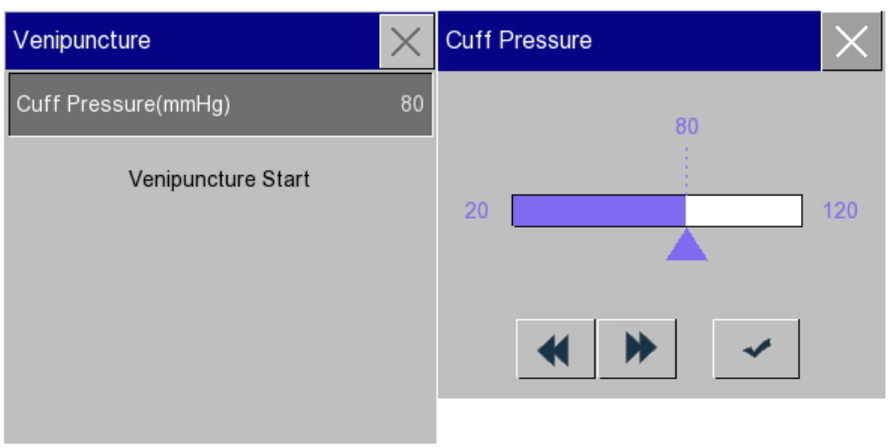
The Assisted Venipuncture Mode is used to support the drawing of blood samples. This function generates sub diastolic pressure which creates a short term venous occlusion allowing the drawing off of a sample.

14.4.7.1 Venous Cuff Pressure (mmHg)

The VENIPUNCTURE cuff pressure is patient group specific, the following default settings are applied:

- Adult 80 mmHg (range 20-120 mmHg)
- Paediatric 60 mmHg (range 20-80 mmHg)
- Neonate 40 mmHg (range 20-50 mmHg)

The user can adjust the cuff pressure. Press the NiBP parameter to display the set up options, press [Other Setup], [Cuff Pressure (mmHg)] use the ◄► keys to set the desired setting.



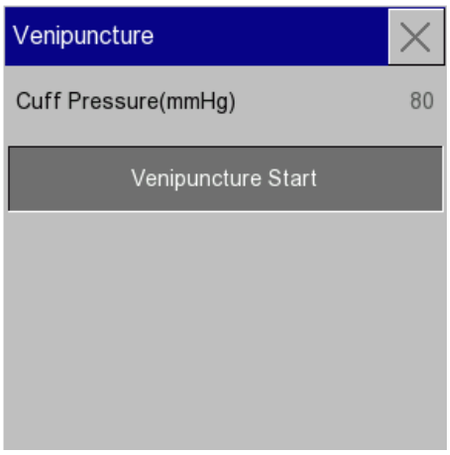
Press ✔ to save and exit.

14.4.7.2 Venipuncture Start

With the NiBP cuff applied to the correct position, press the NiBP parameter to display the set up options, select [Venipuncture] to display the venipuncture setup options.

With the NiBP cuff applied to the correct position,

Select [Venipuncture Start].



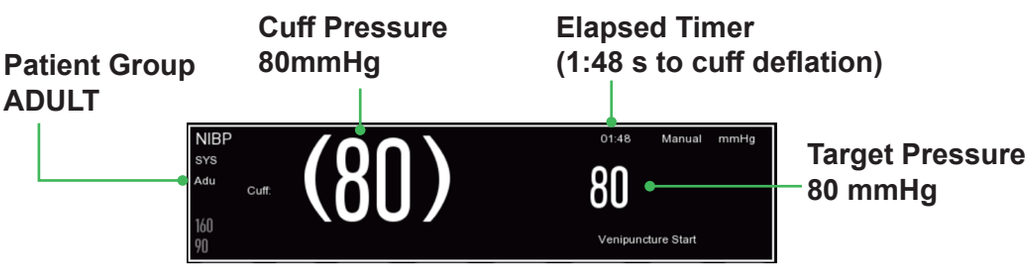
The cuff will automatically inflate to the target pressure and hold it for a set period allowing sufficient time to draw a sample.

The Cuff will hold the target pressure for:

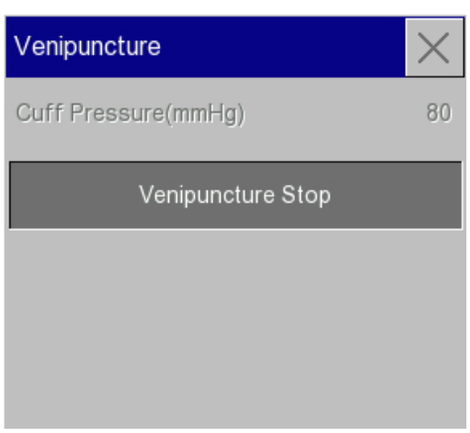
- Adult 170 seconds
- Paediatric 170 seconds
- Neonate 85 seconds

After which the system automatically deflates the cuff.

During the procedure, the NiBP area will display the elapsed time, cuff pressure and target pressure.



The user can wait until the timer has elapsed or force a stop by pressing the VENOUS PUNCTURE STOP tab



The cuff will deflate under controlled conditions.

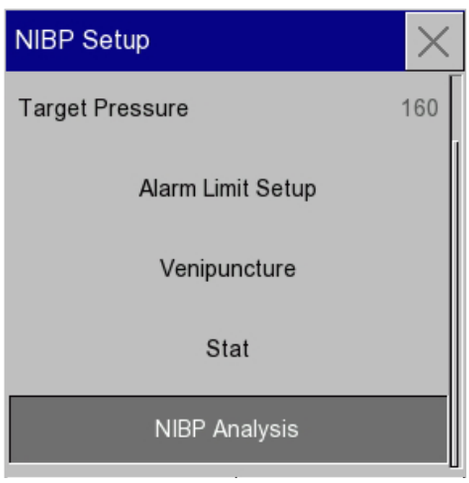
NOTE
Performing a venous puncture with the unit set to AUTO mode will suspend the timed measurements for the duration of the venepuncture and a further period of 3 minutes afterwards.

14.4.7.3 NiBP Analysis

The NiBP ANALYSIS feature allows you to display and compare the patient's BP measurements with user definable limits.

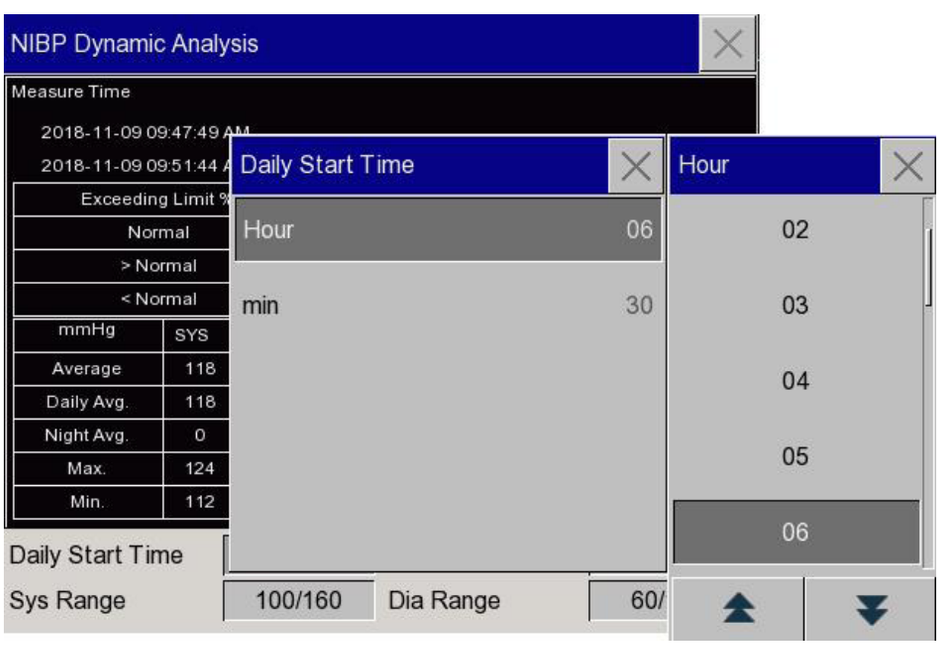
Users can specify the time period as well as defining specific limits – these may be patient specific or established in line with local protocol or clinical settings.

- Daily start time Start period of analysis
- Daily end time End period of analysis
- Systolic Range Systolic range – High and Low
- Diastolic Range Diastolic range – High and Low



Setting Daily Start time

To set the DAILY START time, press the NiBP parameter area of the screen to display the NiBP Set up options, use the ⬆⬇ keys scroll down to [Other setup], select [NiBP Analysis], [Daily Start Time].



Use the ⬆⬇ keys to set the relevant start time.

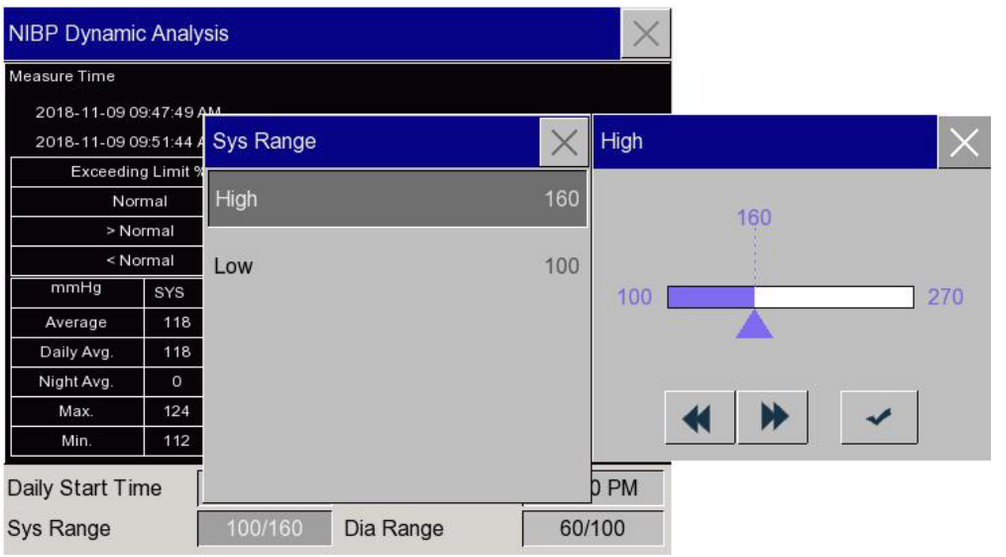
Press ☒ to save and return to previous menu.

Setting Daily End time

This is identical to the previous section.

Setting Systolic Range

To set the SYSTOLIC RANGE, press the NiBP parameter area of the screen to display the NiBP Set up options, use the ↑↓ keys scroll down to [Other setup], select [NiBP Analysis], [Sys Range].



Select [High] and use the ← → keys to set the appropriate level.

Select [Low} and use the ← → keys to set the appropriate level.

Press the ✓ key to save the settings.

Press ☒ to return to previous menu.

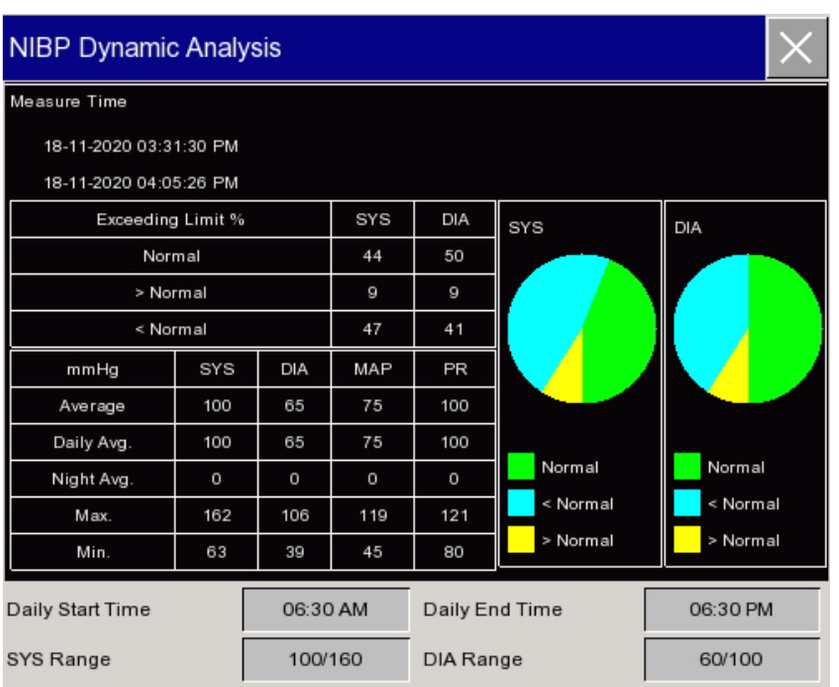
Setting Diastolic Range

This is identical to the previous section.

14.4.7.4 Dynamic Analysis Trend

In line with the user defined settings, the analysis will automatically calculate and display the following information:

- Measurement period – start and end times
- Number of measurements (%) classified as NORMAL
- Number of measurements (%) classified as > NORMAL
- Number of measurements (%) classified as <NORMAL

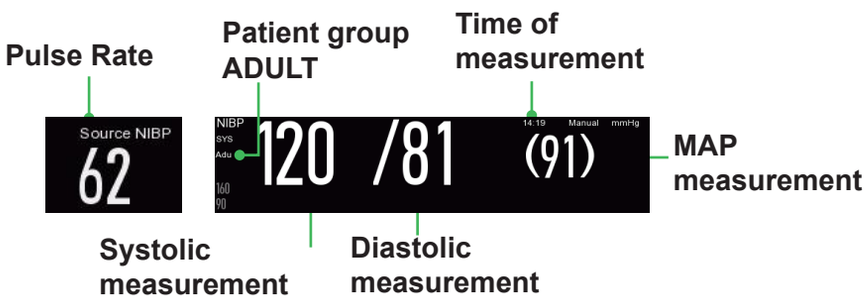


14.5 Start / Stop Manual BP Measurement

To start a manual measurement, press the NiBP start / stop button .

The cuff will inflate to the target pressure and measure the BP during the controlled deflation of the cuff.

The measurement will be displayed:



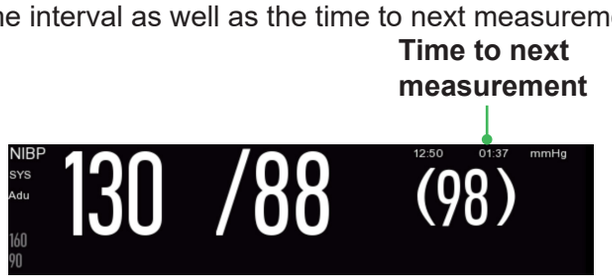
The measurement can be terminated at any point during the measurement cycle, by pressing the NiBP start / stop button .

14.6 Start / Stop Automatic BP measurement

NOTE
If you have any doubt about the reading accuracy, check the patient's vital signs with an alternative method.

Starting and stopping the AUTOMATIC sequence is very similar to the previous steps, however, the automatic sequence will continue until it is stopped by the operator.

The display will identify the time interval as well as the time to next measurement



To stop the sequence of measurements, press the NiBP start / stop button .

When the AUTO sequence is terminated, the system will revert to MANUAL mode.

15. Temperature Monitoring

15.1 Overview

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.

15.2 Safety

WARNING
The calibration of the Thermometer should be checked at least once every twelve months.

WARNING
Use only specified Probe covers

WARNING
The Probe cover is single-use. Repeated use might give rise to cross infection.

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

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

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

WARNING
The operator is responsible for checking the compatibility of the thermometer probe cover before use.

WARNING
Incompatible lens covers can result in degraded performance

WARNING
Operating outside the specified environmental conditions for temperature, relative humidity and pressure may result inaccurate Temperature readings

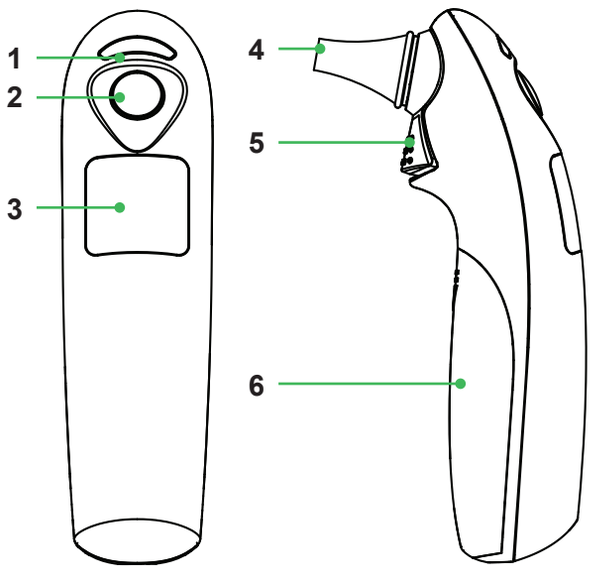
WARNING
Discard the protective lens cover in accordance with the local regulations.

NOTE
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.

NOTE
The thermometer automatically conducts self-test every hour during temperature measurement. Self-test lasts for 2 seconds and does not affect the normal operation of the thermometer.

NOTE
The disposable temperature probe should only be used once.

15.3 Description of the Thermometer IRT10



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

15.3.1 Thermometer Display

Key	Function / Display
	Battery status
	Probe cover status
	Wireless status
°C °F	Scale ºC or ºF
188.8	Measurement

15.3.2 Pairing the Thermometer and Main Unit

1. With the temperature probe switched off, press and hold the “Probe Cover Eject” button, and at the same time press the “Temp Measure” button to turn the power on. When the temperature displays the characters SE (after the °C and °F characters are displayed twice alternately), release the “Probe Cover Eject Button” and within 10 seconds press the Temperature Parameter area on the monitor screen, and select Connect Thermometer.

2. Wireless connection/transmission status:

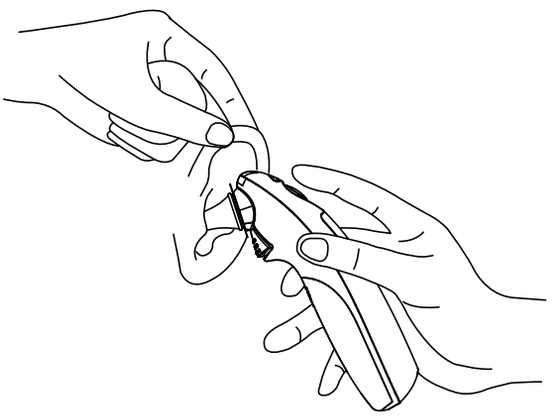
3. When the wireless connection is successful, the icon is displayed.

4. When the wireless transmission is successful, the icon does not flash

5. When the wireless connection has failed, the icon is displayed.

15.3.3 Measuring Temperature

1. Install a new probe cover to the thermometer.
2. Momentarily press the on standby button on the temperature probe to switch the device on, 2 short beeps will be emitted from the probe.
3. 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.



4. 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.
5. Remove the thermometer and read the temperature.
6. The temperature will be displayed on the temperature probe and SC500 display.
7. Upon completion press the eject key to remove the probe cover.
8. Place the probe cover in the appropriate waste collection point and replace the thermometer back into it's holder.

NOTE
The temperature probe will automatically power off after 60 seconds of in activity, if the battery becomes exhausted and the probe shuts down in less than 60 seconds the patient monitor will display probe not connected.
Manually powering off the device within 60 seconds will also trigger the “Temp Not connected” technical alarm.

15.3.4 Wireless Transmission Function

Temperature measurements are transmitted wirelessly to a paired patient monitor.

Common faults and troubleshooting methods

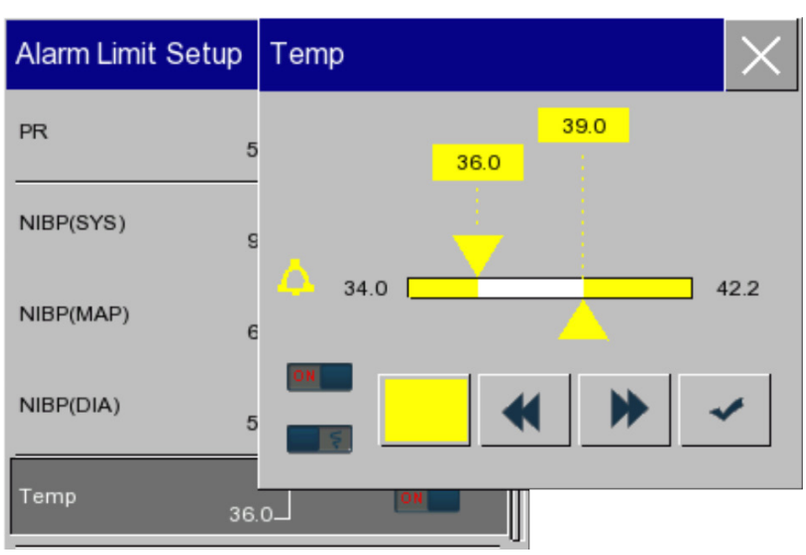
Faults	Possible causes	Troubleshooting methods
Er0	Wireless module does not work	Contact your supplier for assistance
Wireless transmission failed	The infrared in-ear thermometer is too far away from the receiving instrument	Please keep the distance between the thermometer and the receiving instrument within 10M and ensure there is no obstruction.
	The infrared in-ear thermometer is not connected to any receiving instrument, or the receiving instrument is in power off or standby state.	Conduct wireless connection pairing again and make sure the receiving instrument is turned on
	Wireless transmission still fails	Contact supplier for assistance

15.4 Temperature Display

The temperature measurement is displayed on the screen, pressing this area will enable access to the [TEMP Setup] menu.

15.4.1 Alarm settings

Select the TEMP display, select [Alarm Limit Setup], and select [Temp]



Select the limit to change, use the ◄► keys or the touch screen to move the cursor to the new setting.

Should you need to assign a different priority level, select the priority box and toggle through the options – Red High priority, Yellow medium priority and Cyan low priority.

Press ☒ to save settings and exit.

16. Score Calculator

16.1 Introduction

There are two early warning scoring functions supported by the SC500; they are:

MEWS – Modified Early Warning Score

NEWS2 – National Early Warning Scoring System

NEWS2 is the latest version of the National Early Warning Score (NEWS), first produced in 2012 and updated in December 2017, which advocates a system to standardise the assessment and response to acute illness.

Reproduced from: Royal College of Physicians. National Early Warning Score (NEWS) 2: Standardising the assessment of acute-illness severity in the NHS.

Both MEWS and NEWS2 are early warning scoring tools used to aid the recognition of deteriorating patients, it uses a scoring system based on a specific set of physiological parameters which are taken when recording routine patient observations.

16.2 Safety

WARNING
The scoring systems are intended to be used by healthcare professionals only

WARNING
The scores are for reference and should not be used alone for diagnostic purposes.

WARNING
The scoring systems are not for use with pregnant patients or those under the age of 16 years.

WARNING
It is important to follow local protocols and policies regarding the use and selection of MEWS or NEWS2 methods

16.3 MEWS (Modified Early Warning Score)

The MEWS scoring system calculates and displays an aggregated score as an output based on the following five parameters:

- Pulse rate
- Systolic BP
- Respiration rate
- Temperature
- AVPU (alert, reacting to voice, reacting to pain or unresponsive)

16.4 NEWS2 (National Early Warning Score)

The NEWS2 scoring system calculates and displays an aggregated score as an output based on the following eight parameters:

- Pulse rate
- Systolic BP
- Respiration rate
- Temperature
- SpO2 (1)
- SpO2 (2)
- Air / Oxygen
- ACVPU (Alert, Confusion, Voice, Pain, Unresponsive.)

16.5 Switching between MEWS and NEWS2

Switching between the two systems should only be performed by qualified personnel.

This function is password protected and accessed through the MAIN menu.

Select the MENU soft key, select [MAINTAIN], enter the password and select MEWS Setup [MEWS or NEWS2].

The selected scoring system is displayed for reference.

MEWS

Param.	Score							
	3	2	1	0	1	2	3	Units
HR		<=40	41-50	51-100	101-110	111-129	>=130	BPM
Sys	<=70	71-80	81-100	101-199		>=200		mmHg
Resp		<9		9-14	15-20	21-29	>=30	Br/m
Temp		<35		35-38.4		>=38.5		°C
AVPU				A	V	P	U	AVPU

Mews thresholds cannot be user defined

NEWS2

Param.	Score							
	3	2	1	0	1	2	3	Units
PR	<=40		41-50	51-90	91-110	111-130	>=131	ppm
Sys	<=90	91-100	101-110	111-219			>=220	mmHg
Resp	<=8		9-11	12-20		21-24	>=25	Br/m
Temp	<=35.0		35.1-36.0	36.1-38.0	38.1-39.0	>=39.1		°C
SPO2(1)	<=91	92-93	94-95	>=96				
SPO2(2)	<=83	84-85	86-87	88-92*	93-94**	95-96**	>=97**	
Air/Oxygen		Oxygen		Air				
ACVPU				A			C,V,P,U	ACVPU

*>=93 on air

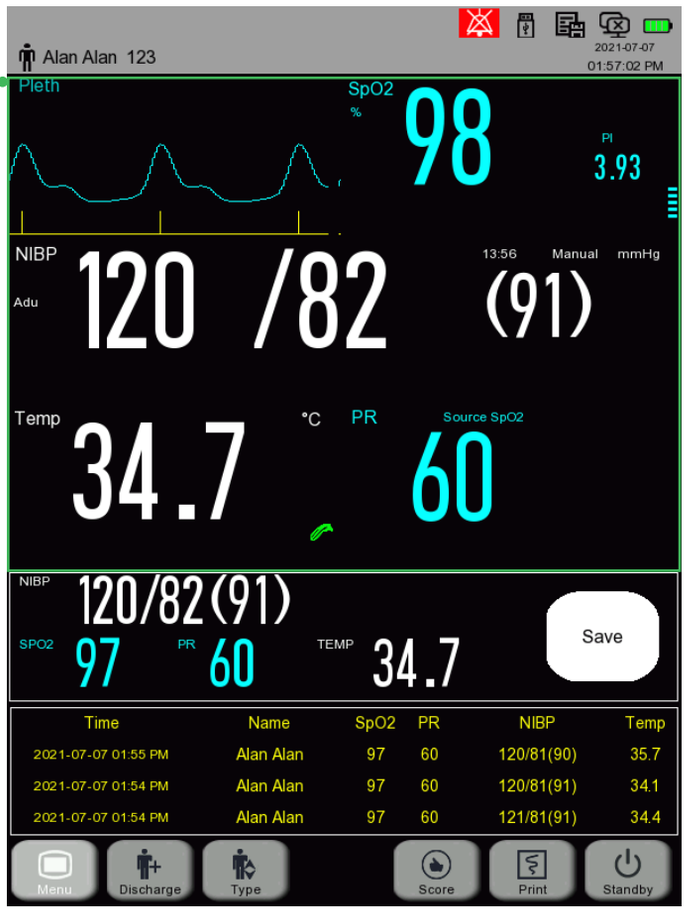
**On Oxygen Please refer to the IFU for further guidance

Press ☒ to close and save selection.

The early warning scoring systems use the physiological data captured by the SC500 as the basis for each calculation and as a general rule, the higher the score, the more abnormal the observation.

Real time physiological measurements

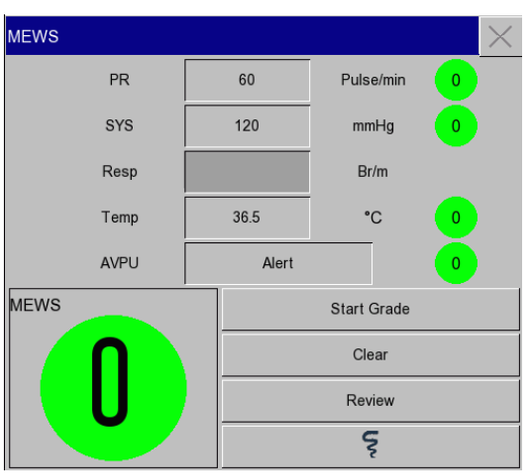
SpO2, NiBP, Temp & Pulse



16.6 MEWS System

16.6.1 Entering the MEWS calculation screen

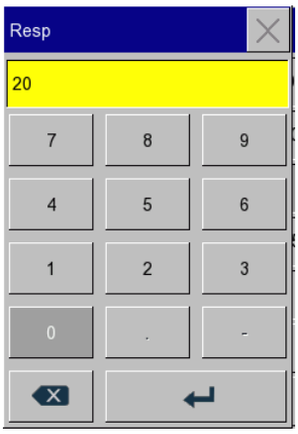
Having captured a series of measurements on the SPOT display, press the SCORE soft key to display the MEWS calculation window.



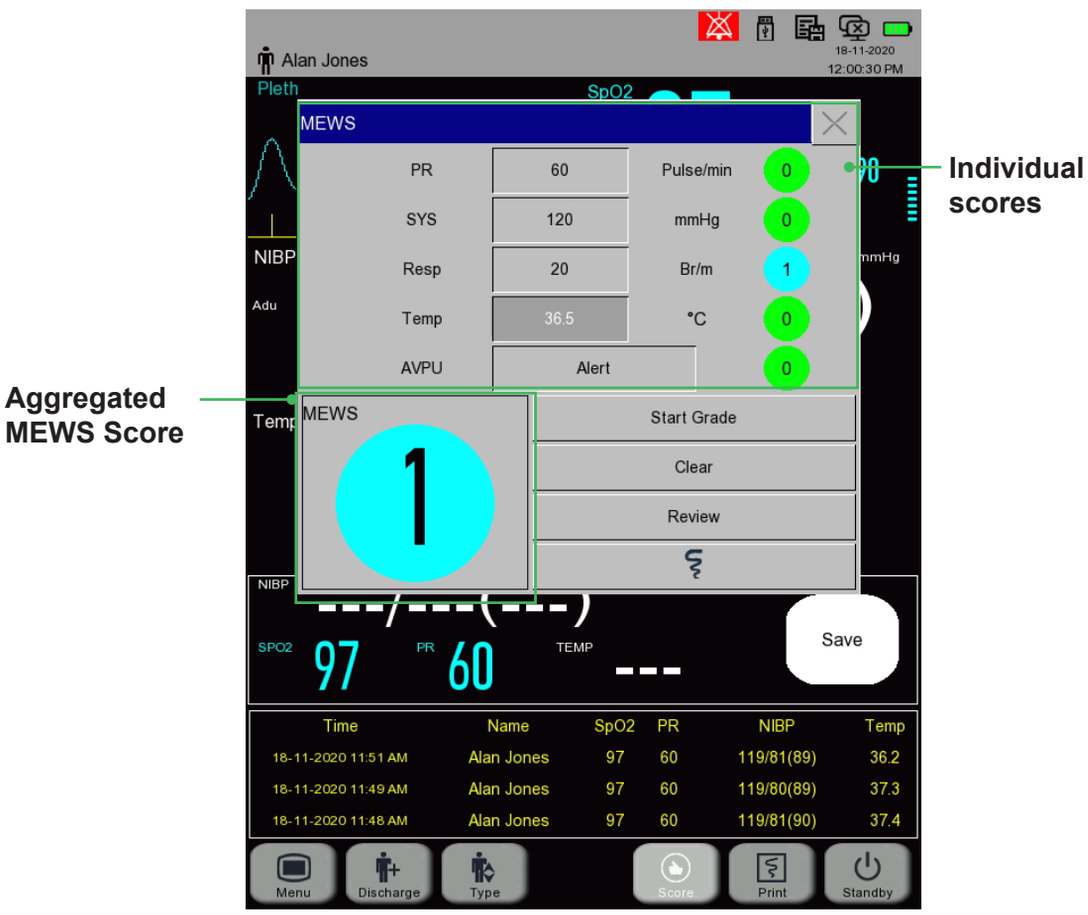
Some of the fields (PR, SYS and TEMP) will be automatically populated with data copied from the application screen:

Where there are blank entries, for example (RESP), press the RESP field to display the data entry menu.

Using the on screen keypad, enter the values as appropriate.



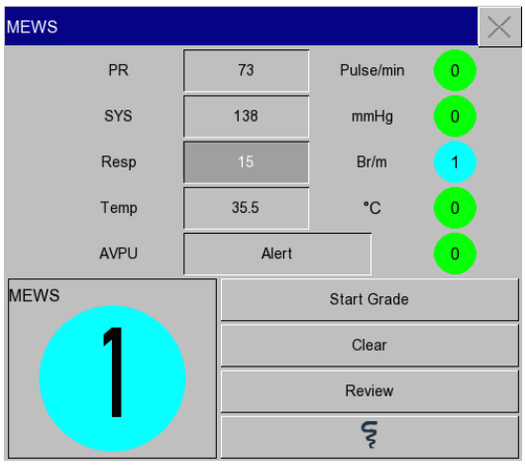
The input variables (PR, SYS, Resp, Temp & AVPU) are now complete, press the START GRADE soft key, the system will automatically calculate and display the corresponding aggregated MEWS score (1).



16.6.2 Saving, reviewing, clearing and printing the MEWS Score

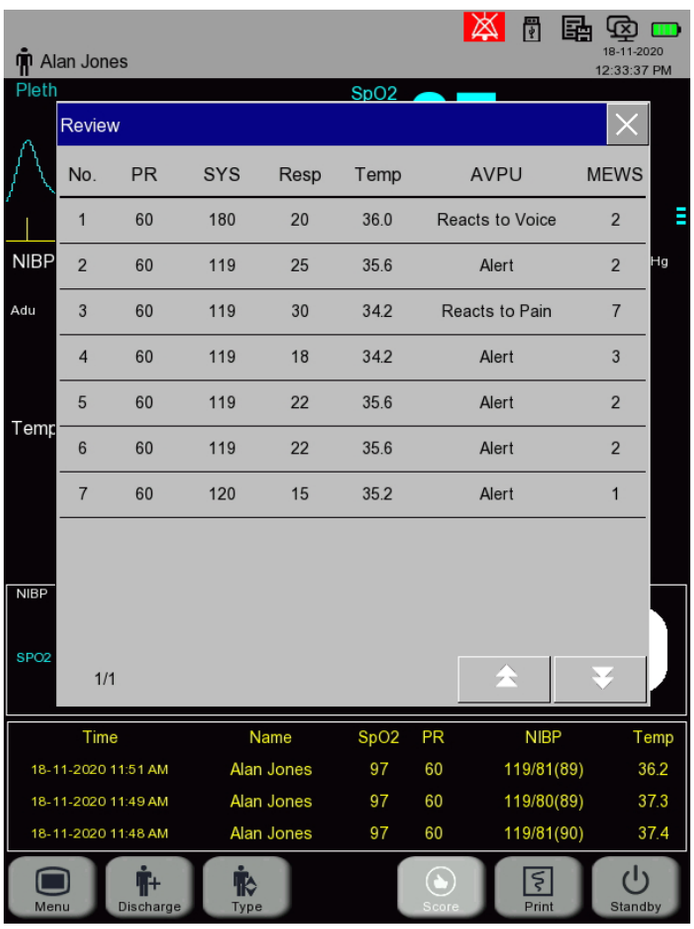
Scores can be saved to the system's memory for review and analysis.

Press the START GRADE area of the MEWS calculation menu to save the aggregated score.



To clear the MEWS calculator, press CLEAR to erase the contents and scores.

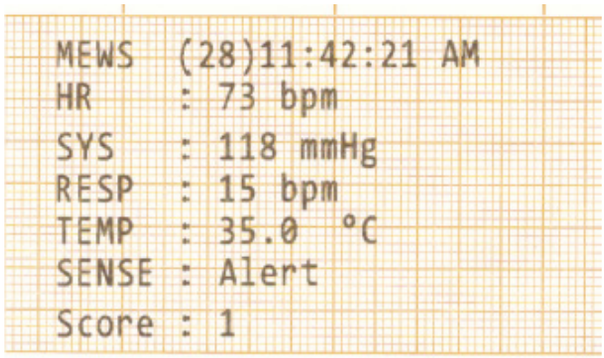
To review the saved scores, press the REVIEW button on the MEWS calculation menu. Calculations will be displayed in tabular format with the latest calculation appearing at the top of the list.



If the SC500 is fitted with an integrated printer, it is possible to produce a printout of the MEWS calculation.

From the MEWS calculation menu, press the PRINTER soft key.

The integrated printer will produce a short chart strip as shown:



16.7 NEWS2 System

The NEWS2 system differs from the MEWS system in that it uses eight parameters to calculate a score.

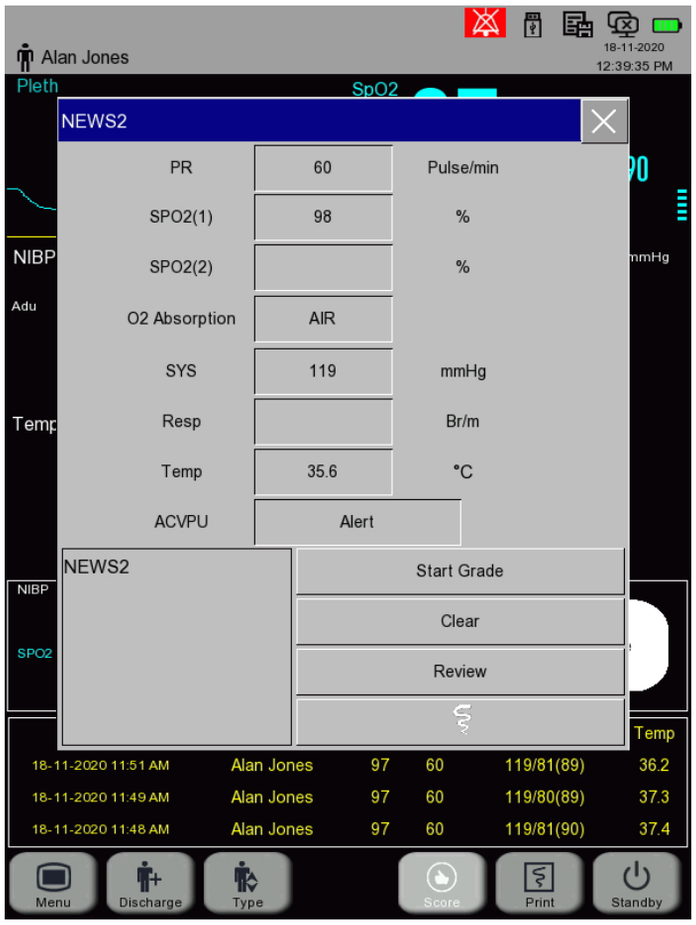
Physiological parameter	Score 3	2	1	0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO_2 Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO_2 Scale 2 (%)	≤83	84–85	86–87	88–92 ≥93 on air	93–94 on oxygen	95–96 on oxygen	≥97 on oxygen
Air or oxygen?		Oxygen		Air			
Systolic blood pressure (mmHg)	≤90	91–100	101–110	111–219			≥220
Pulse (per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Consciousness				Alert			CVPU
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	

Image courtesy of Royal College of Physicians. National Early Warning Score (NEWS).

NOTE
The SPO2(2) value should only be used under the direct guidance of a medical professional for hypercapnic and COPD patients.

16.7.1 Entering the NEWS2 calculation screen

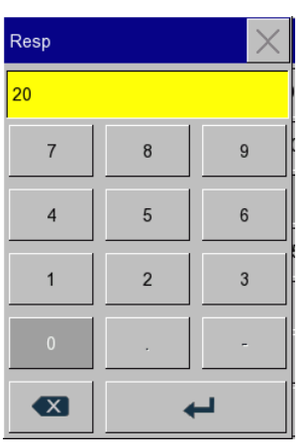
Having captured a series of measurements on the SPOT display, press the SCORE soft key to display the NEWS2 calculation window.



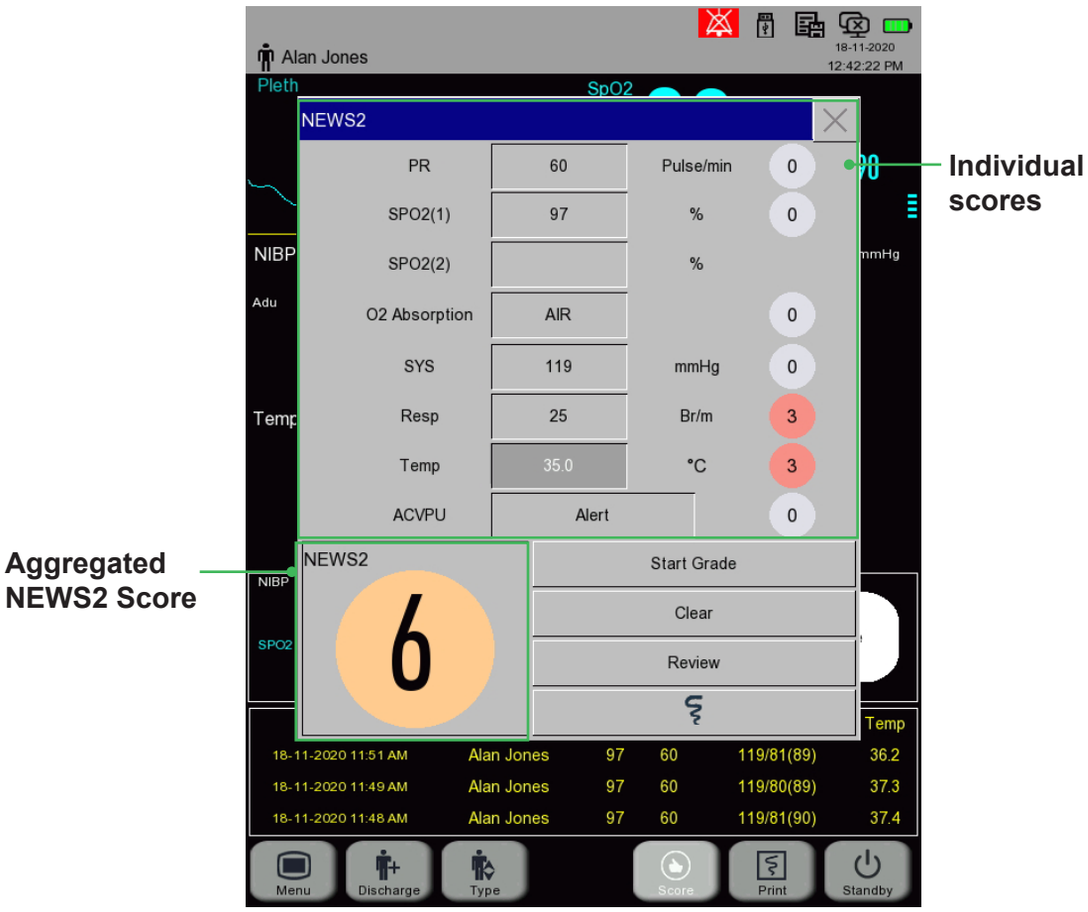
Some of the fields (PR, SpO2(1), O2 Absorption, SYS, TEMP and ACVPU) will be automatically populated with data copied from the application screen.

Where there are blank entries, for example (RESP), press the RESP field to display the data entry menu.

Using the on screen keypad, enter the value as appropriate.



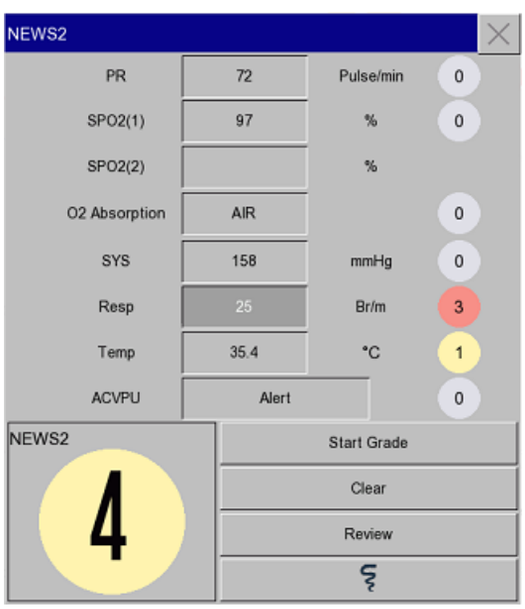
The input variables are now complete and the system will automatically calculate and display the corresponding aggregated NEWS2 score (6).



16.7.2 Saving, reviewing, clearing and printing the NEWS2 Score

Scores can be saved to the system's memory for review and analysis.

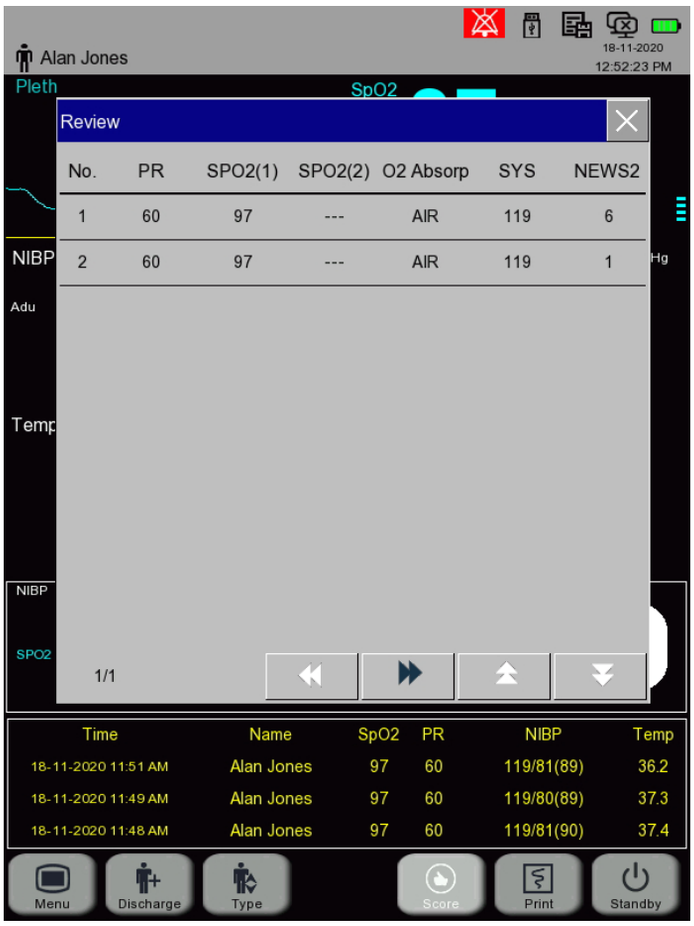
Press the START GRADE area of the NEWS2 calculation menu to save the aggregated score



To clear the NEWS2 calculator, press CLEAR to erase the contents and scores.

To review the saved scores, press the REVIEW area of the NEWS2 calculation menu.

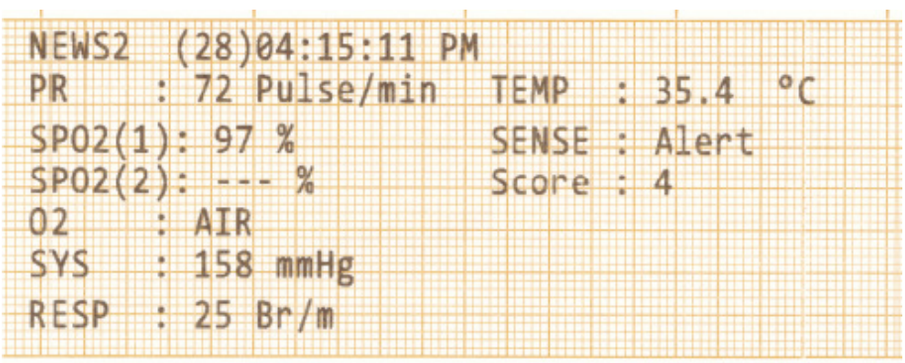
Calculations will be displayed in tabular format with the latest calculation appearing at the top of the list. Use the left and right scroll keys to view all saved values.



If the SC500 is fitted with an integrated printer, it is possible to produce a printout of the MEWS calculation.

From the MEWS calculation menu, press the PRINTER soft key.

The integrated printer will produce a short chart strip as shown:



17. Managing Data

17.1 Overview

The system provides the user with up to 120 hours of stored data, this comprises 5,000 NiBP measurements, 200 alarm events and up to 48 hours of waveform storage.

This information is patient specific and is collected throughout the monitoring session, it can be displayed in graphical and or tabular formats. All information is stored in the patient database.

17.2 Waveforms

NOTE
Changes to this function can only be accessed when NO patient is admitted onto the system.

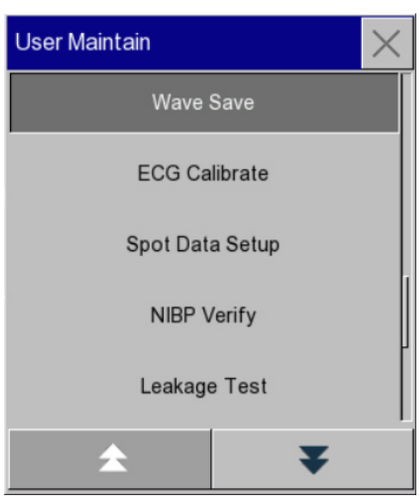
The system must be configured to SAVE waveforms, prior to ADMITTING a patient onto the system.

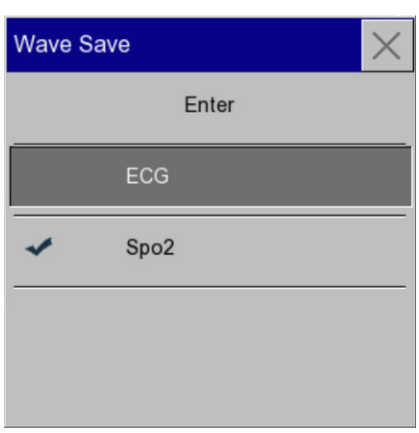
This cannot be altered after a patient has been admitted and is associated with a particular profile.

This feature can only be accessed through the ADVANCED access level and is protected by a password.

Select [Main Menu], [Maintain], enter [password] to display the ADVANCED setup menu. Scroll down the list and select [Wave Save].

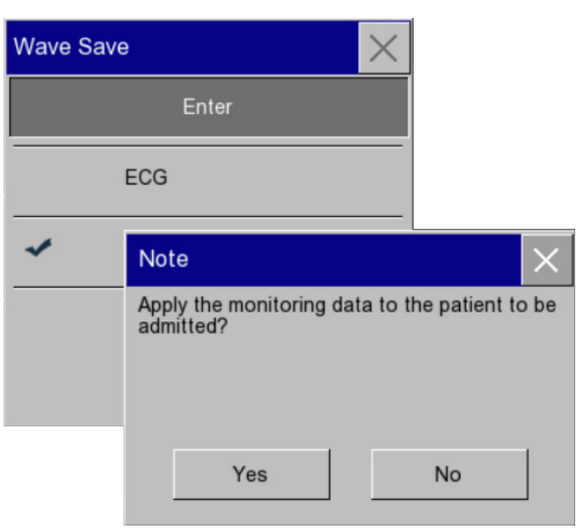
Select the waves to be saved by selecting either ECG, SPO_2 or Both, press enter to save the selection





Upon selecting Enter the following note will be displayed.

Selecting yes will confirm the current setting and admit a new blank patient profile..

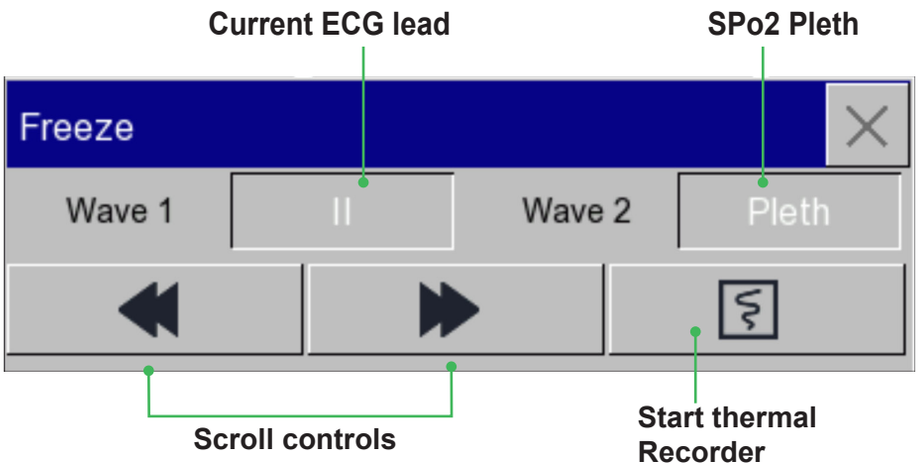


17.3 Waveform Freeze

Users have the ability to FREEZE waveforms on the display.

Press the FREEZE soft key  to display the main controls.

As there are only 2 parameters with supporting waveforms, wave 1 is fixed to ECG (selected Lead), wave 2 is allocated to the Pleth waveform (unless the SC500 is not fitted with the ECG option, then wave 1 is allocated to the pleth with wave 2 disabled).

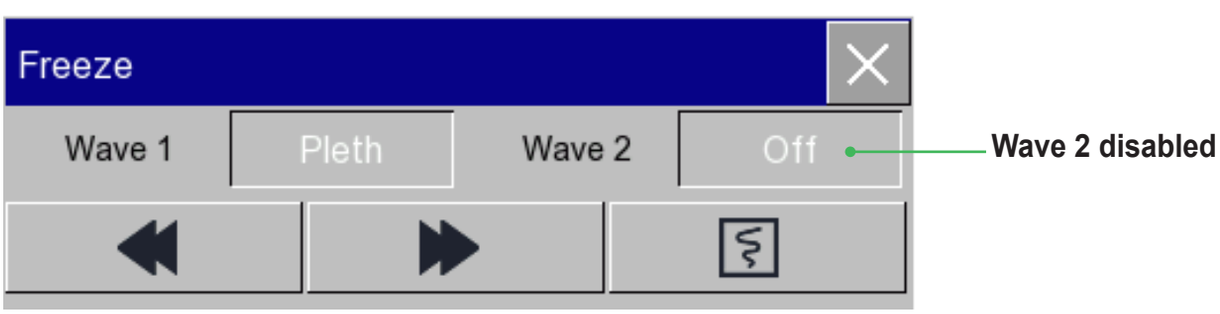


Use the  controls to scroll back and forth the saved waves.

Press the print key  to produce a chart strip of the selected waveforms.

Press  to exit.

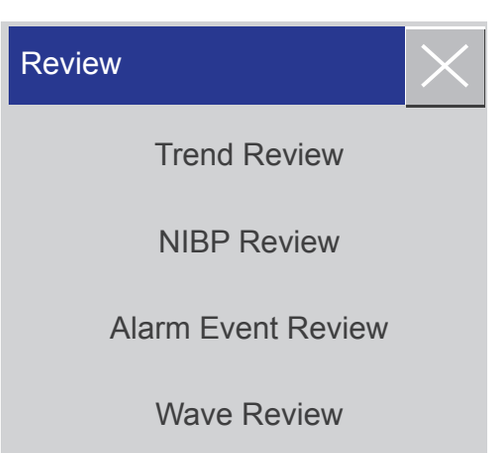
The image below gives an example of the SC500 Freeze window on an SC500 with no ECG fitted.



17.4 Review

The REVIEW information is patient specific which is collected over a period of time, it can be presented in either a graphical or tabular format.

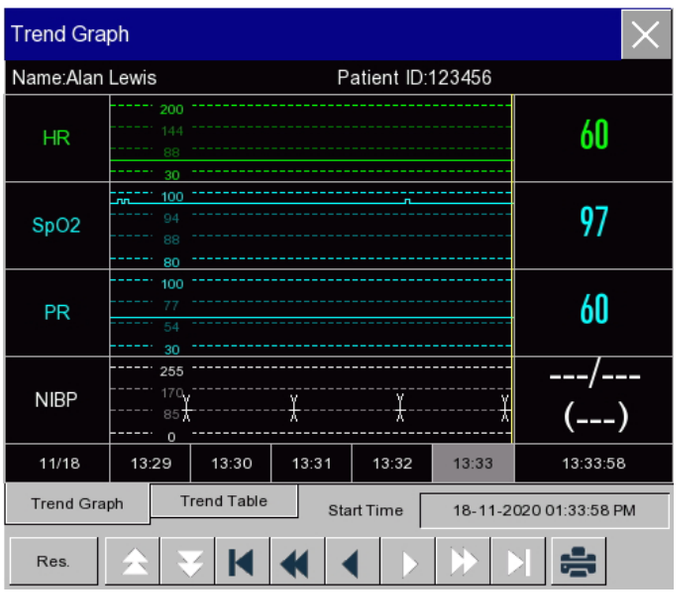
To access the trend data, press [Main Menu], [Review] to display the following options:



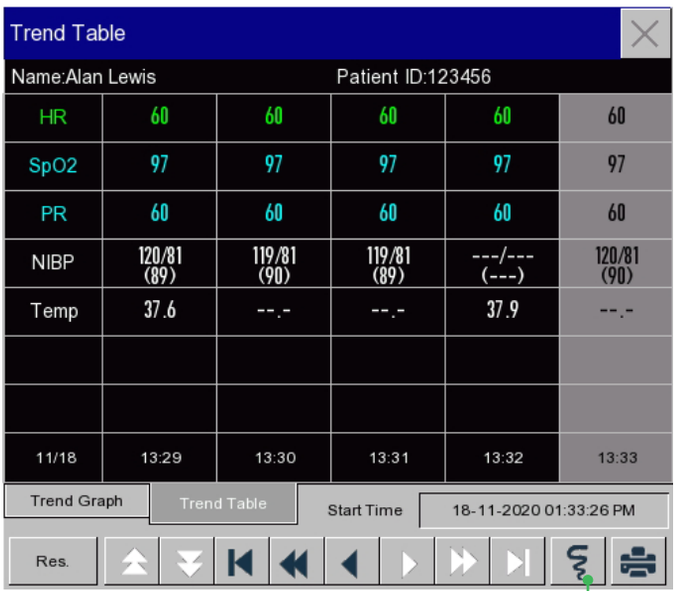
17.4.1 Trend Review

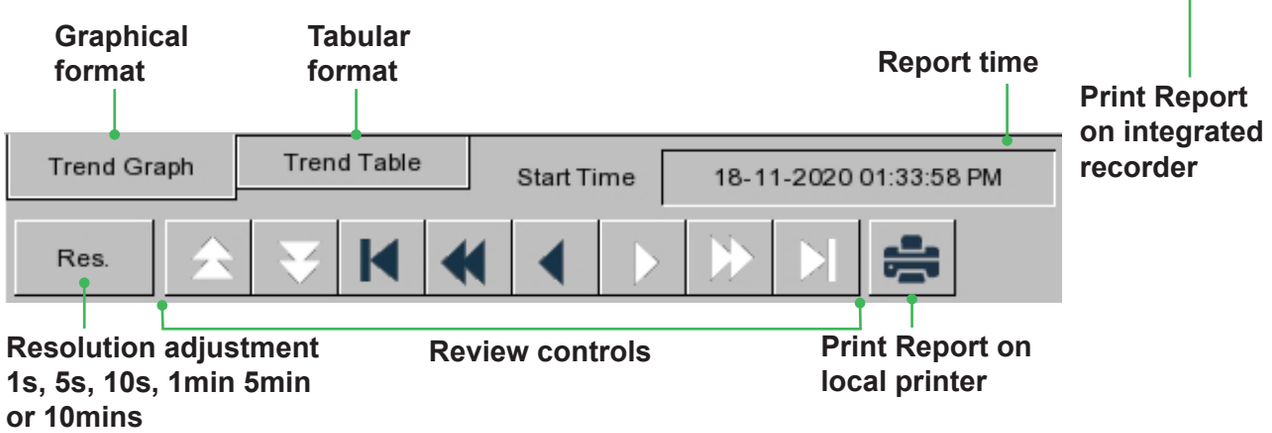
Press [Trend Review] to display the trend table, this can be presented in either graphical or tabular format.

Graphical format



Tabular format





Trend Review Symbol Explanation	
▲▼	Page up and down to view other parameter trend graphs not shown in the current view.
◀▶	Move the cursor left or right by one step to view along the timeline of trend database.
◀◀ ▶▶	Move the cursor left or right by one page to view along the timeline of trend database.
⏮ ⏭	Jump to the start point or end point of the trend database to view the earliest or latest trend info saved.

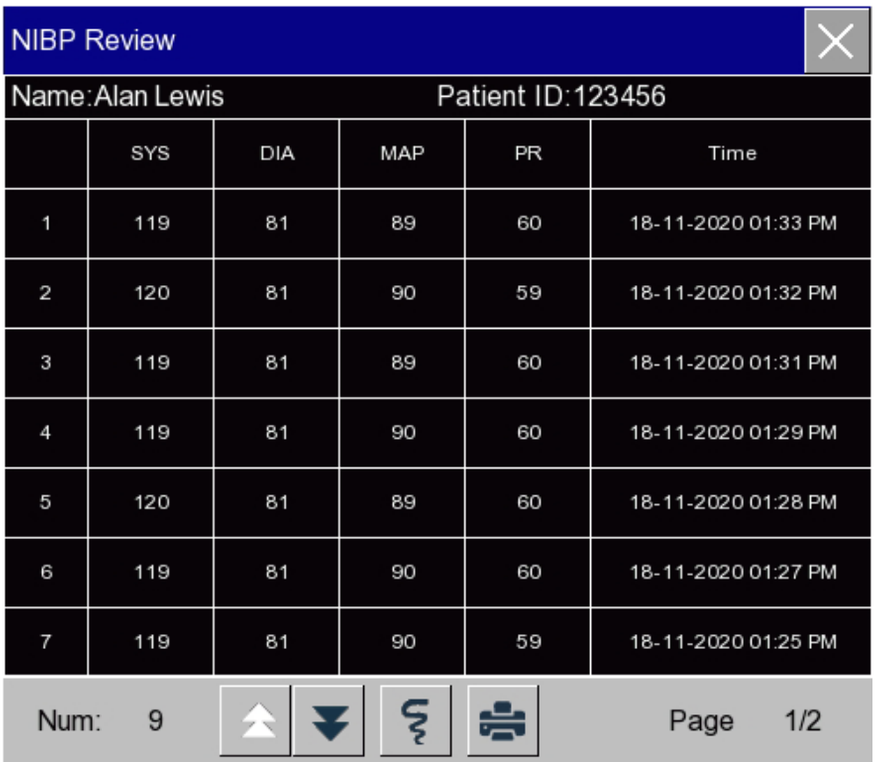
New data will appear from the right hand side of both reports.

Using the review controls, users have the ability to look back through the report.

Both trend tables are dynamic and reflect the system configuration. The graphical trend cannot be printed on the integrated printer, these reports can only be printed on a local printer via the USB connection.

17.4.2 NiBP Review

Press [NiBP Review] to display list of NiBP measurements. These will be listed in order with the oldest measurement at the top of the list.



	SYS	DIA	MAP	PR	Time
1	119	81	89	60	18-11-2020 01:33 PM
2	120	81	90	59	18-11-2020 01:32 PM
3	119	81	89	60	18-11-2020 01:31 PM
4	119	81	90	60	18-11-2020 01:29 PM
5	120	81	89	60	18-11-2020 01:28 PM
6	119	81	90	60	18-11-2020 01:27 PM
7	119	81	90	59	18-11-2020 01:25 PM

17.4.3 Alarm Event Review

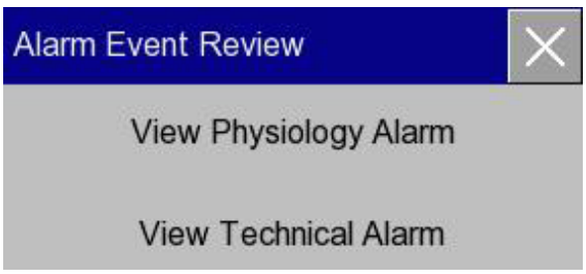
WARNING
Only current physiological and technical info can be displayed. When the unit is restarted, the alarm event file is cleared.

WARNING
When the alarm list exceeds 200 entries, the oldest event will be deleted.

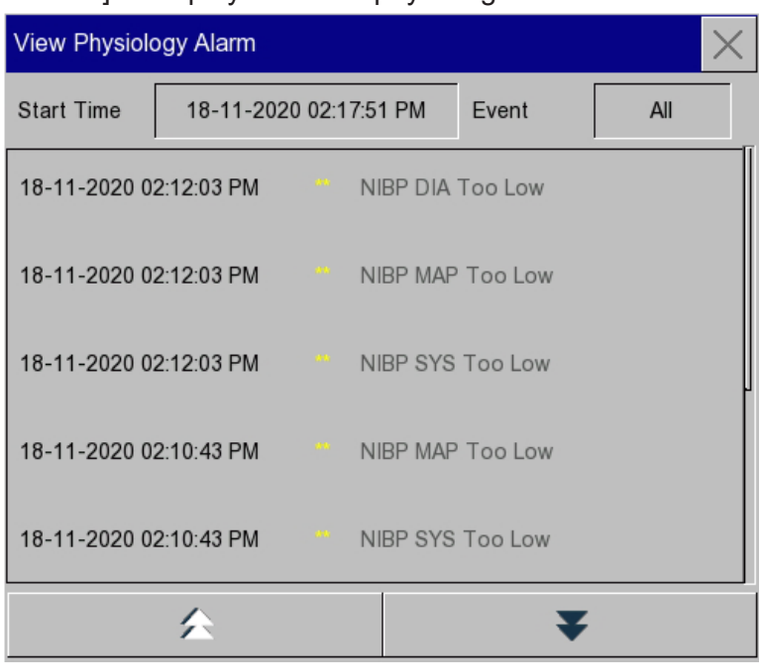
WARNING
Power loss events are not recorded in the Physiological or Technical alarm log.
The event will be evident by the ending of the current data set and the start of a new patient data set for the admitted patient.

NOTE
The Technical alarm can be viewed only, it cannot be printed.

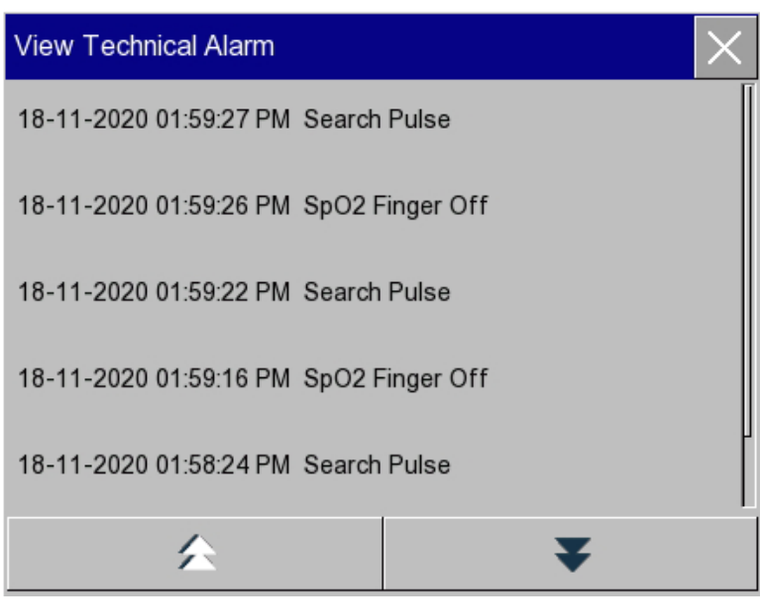
Press [Alarm Event Review] to display list of Alarm messages. There are two options, PHYSIOLOGICAL and TECHNICAL.



Press [View Physiological Alarm] to display the list of physiological alarms



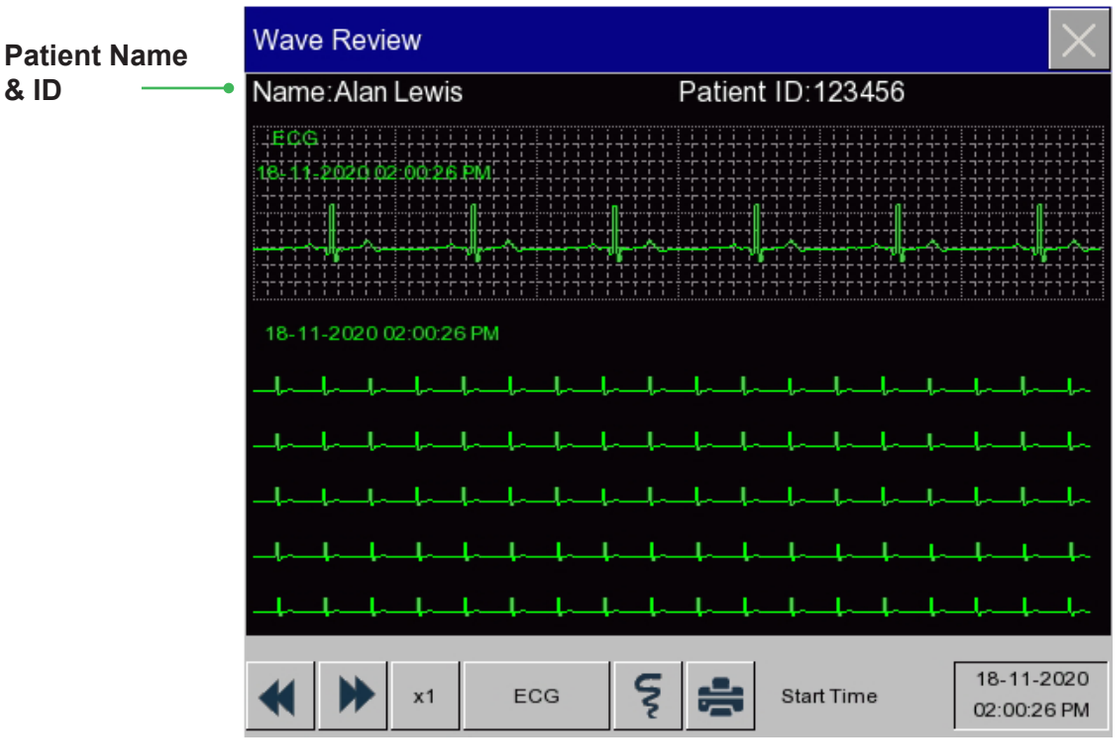
Press [View Technical Alarm] to display the list of technical alarms



Press  to close the window.

17.4.4 Waveform Review

Press [Wave Review] to display the saved waveforms.



Waveform Review Symbol Explanation	
	Page up and down
x1	Waveform gain; select this button to choose the appropriate gain.
I	Waveform identification; select the waveform to be viewed.
2018-10-06 07:50:58	Start time of waveform view.
	Print waveform.
	Print waveform via USB printer.

Users can print any of the saved waveforms.

Examples

ECG Wave Review:

Before admitting a patient, enter the [Wave Save] interface under [User Maintain]; select the waveform to be saved.

In the [Review] menu, select [Wave Review].

In the [Wave Review] window, select the parameter to be reviewed.

Use to view waveform.

Select to enter the [Record Setup] menu. After setting the record start time in this menu, select [Record] to record the waveform.

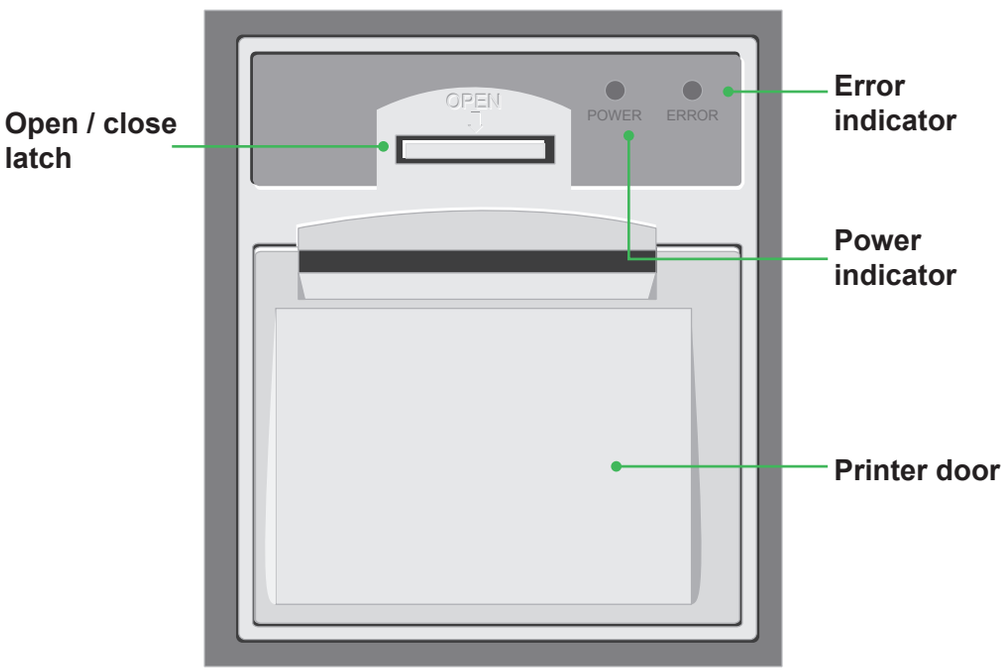
Select to set and print a wave review report. See the "Print Setup" chapter for details.

Press to exit the [Wave Review] window.

18. Recorder

18.1 Description of Recorder

The optional integrated recorder can print a combination of numerical data as well as up to three user defined physiological waveforms.



Recorder

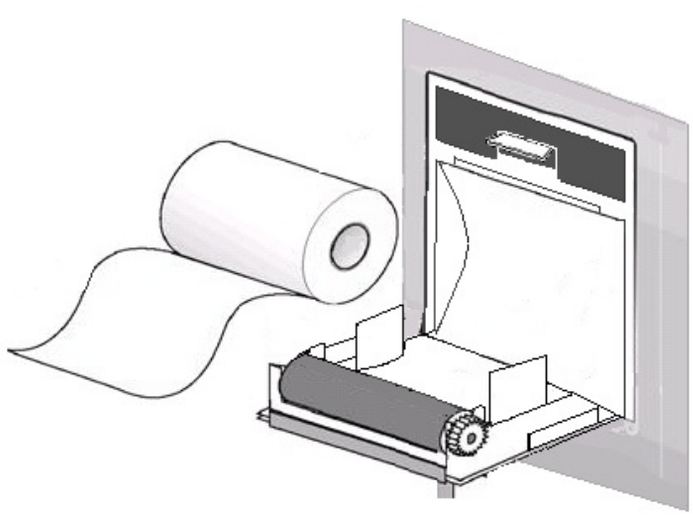
18.2 Loading paper

Press the latch and pull the door open.

Remove the empty paper core.

Load the new roll into the compartment, with the thermo sensitive side (grid or shiny side) upper most. Pull the free end up and over the edge of the printer door. At least 25mm of paper should extend over over the roller.

Close the door firmly.



To test if the paper is loaded correctly, start a recording. If the recorder fails to print, re-load paper and repeat the process

CAUTION
To prevent damage to the print head, take care when loading the paper.

CAUTION
Do not pull on the paper whilst printing as you may damage the recorder.

CAUTION
Ensure the recorder door remains shut except for paper change or troubleshooting.

18.3 Recordings

Recordings are divided into the following types according to the method in which they were produced or triggered

- Real time record or printout triggered manually
- Automatic timed record or printout triggered by the recorder interval setting
- Alarm record or printout triggered by a physiological parameter exceeding a specific limit

A recorded output can also be generated by the following functionality:

- Waveform freeze function
- Event detection:
  - Alarm
  - Manually triggered event
  - Trend summary

18.3.1 Setting up the Recorder

Before any records or printouts can be generated, the recorder has to be set up.

Select [Main Menu], [Recorder Setup] to display the set up options.

From this menu, the operator can make the following adjustments:

- Record wave 1 – specify the waveform to be printed in position 1
- Record wave 2 – specify the waveform to be printed in position 2
- Page speed – 25 or 50mm/s
- Record duration – record length 4s, 8s, 16s, 32s or continuous
- Record interval – Off, 1 hr, 2hrs, 3hrs, 4hrs,
- Grid – Printing of background grid

Recorded Waves (1 or 2)

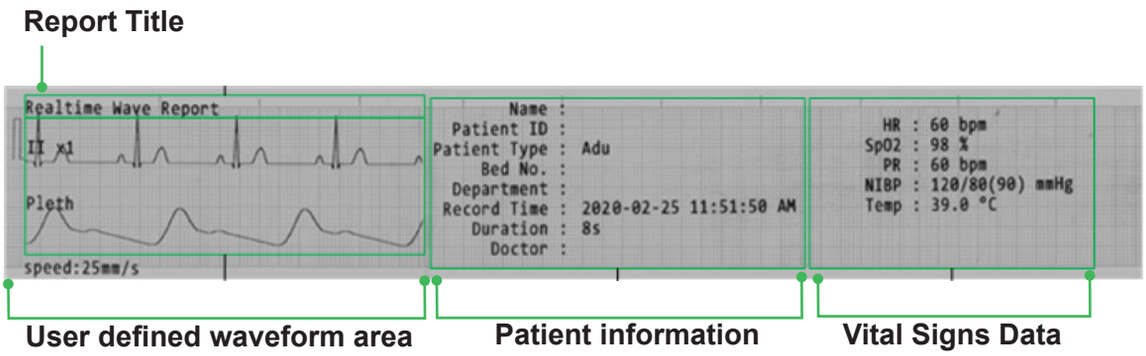
The recorded output has predefined waves as shown below these cannot be changed

Wave 1 ECG (Current Selected Lead)

Wave 2 SPO2

Press  to save and exit.

Sample Recorded Output



18.4 Manual Operation

NOTE
A manual recording can be initiated by pressing the relevant soft key.

To initiate a manual record, press the  softkey.

The recorder will stop automatically when the record is complete.

18.5 Automatic Operation

Automatic records or printouts are controlled by the programmable timer, event capture or alarm records settings. The recorder will automatically start and stop the process according to the set up conditions.

18.6 Recorder maintenance

18.6.1 Clearing paper jam

If chart paper becomes jammed in the mechanism, open the recorder door and refit following the instructions in section 17.2.

18.6.2 Cleaning

NOTE
Do not use any materials (e.g., abrasive paper) that can damage the recorder.

NOTE
Do not apply excessive force to the thermal print head.

From time to time, it may be necessary to clean the thermal print head.

Open the recorder door, remove the paper roll, using a cotton bud impregnated with a small amount of alcohol, gently wipe the underside of the print head.

Allow the alcohol to dry, reload the chart roll and close the recorder door.

19. External Printing

19.1 External printer specification

NOTE
For instructions on the printer, please see the documentation supplied by the manufacturer.

The system can output A4 format patient reports via the USB connected printer. The monitor supports the following types of printer:

- HP laserJet 1505n monochrome laser printer
- HP laserJet P2035n laser printer
- HP laserJet P4015n laser printer
- HP laserJet 1606dn laser printer
- Lenovo LJ2650DN laser printer
- Lenovo LJ4600DN laser printer

Report specification:

- Paper size: A4
- Resolution: 300dpi
- Single/double-sided report

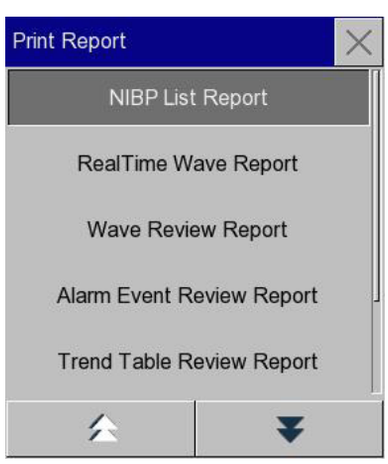
19.2 Report Printing

The system can generate reports which details the following:

- List of NiBP measurements
- Real time waveforms
- Review of saved waveform
- Alarm events
- Trends – tabular or graphical

The reports are patient specific

To print any of the reports, select [Main Menu], [Ext Printer Setup], [Print Report], make the appropriate selection.



Each report has a sub menu associated with its functionality, for example, the user can define a specific time period for the report and or the type of waveform to be printed.

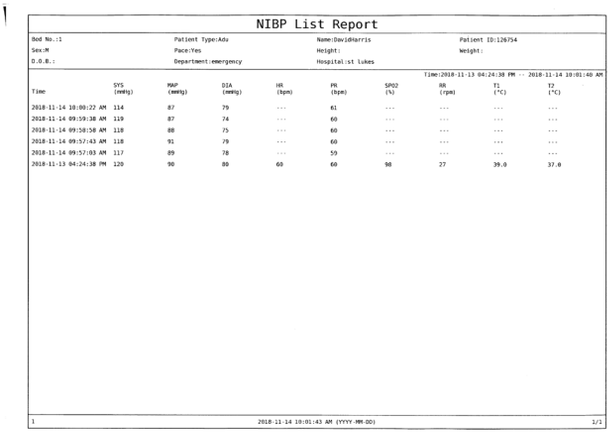
In each case follow the instructions in each sub menu.

19.2.1 NiBP List report

The NiBP report lists all BP measurements that are associated with the patient being monitored.

Select [Main Menu], [Ext Printer Setup], [Print Report], [NiBP List].

- Start Time, this can be any time since the patient was admitted.
- Set the period, this is the amount of time before the start time to include in the report.
  - ◊ 30mins
  - ◊ 1hr
  - ◊ 2hrs
  - ◊ 3hrs
  - ◊ 6hrs
  - ◊ 12hrs
  - ◊ 24hrs
  - ◊ 48hrs
  - ◊ 72 hrs
  - ◊ 96hr
  - ◊ ALL, all of the saved measurements will be printed.


NIBP List Report

Bed No.:1 Patient Type:Adu Name:DavidHarris Patient ID:126754
Sex:M Pace:Yes Height: Weight:
D.O.B.: Department:emergency Hospital:st lukes

Time:2018-11-13 04:24:38 PM -: 2018-11-14 10:01:40 AM

Time	SYS (mmHg)	MAP (mmHg)	DIA (mmHg)	HR (bpm)	PR (bpm)	SPO2 (%)	RR (rpm)	T1 (°C)	T2 (°C)
2018-11-14 10:00:22 AM	114	87	79	---	61	---	---	---	---
2018-11-14 09:59:38 AM	119	87	74	---	60	---	---	---	---
2018-11-14 09:58:58 AM	118	88	75	---	60	---	---	---	---
2018-11-14 09:57:43 AM	118	91	79	---	60	---	---	---	---
2018-11-14 09:57:03 AM	117	89	78	---	59	---	---	---	---
2018-11-13 04:24:38 PM	120	90	80	60	60	98	27	39.0	37.0

1 2018-11-14 10:01:43 AM (YYYY-MM-DD) 1/1

Example, the start time is set to 8:30am the period is set to 2 hours.

All NIBP readings 2 hours before 8:30am are included on the printed report.

Press [Print] to start printing.

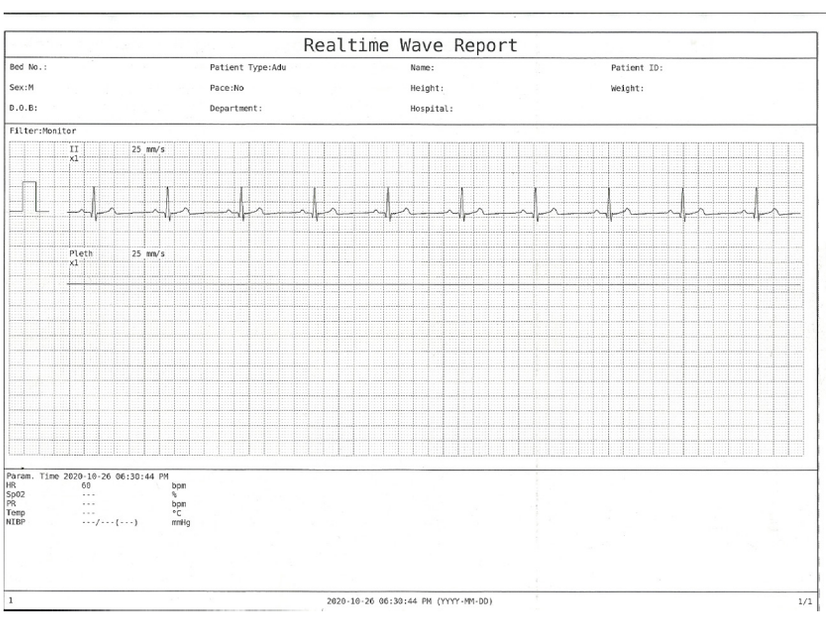
19.2.2 Real Time Waveform report

The real time waveform report captures waveforms which are currently being displayed on the screen.

Select [Main Menu], [Ext Printer Setup], [Print Report], [Real Time Wave Report].

- Set the sweep speed.
  - ◊ [12.5]
  - ◊ [25]
  - ◊ [50mm/s]
- Select the waveforms to be printed – this is dynamic and determined by the layout of the display

Press [Print] to start printing.


Realtime Wave Report

Bed No.: Patient Type:Adu Name: Patient ID:
Sex:M Pace:No Height: Weight:
D.O.B: Department: Hospital:

Filter:Monitor

II x1 25 mm/s

Pleth x1 25 mm/s

Param. Time 2020-10-26 06:30:44 PM

HR	60	bpm
SpO2	---	%
PR	---	bpm
Temp	---	°C
NIBP	---/---(---)	mmHg

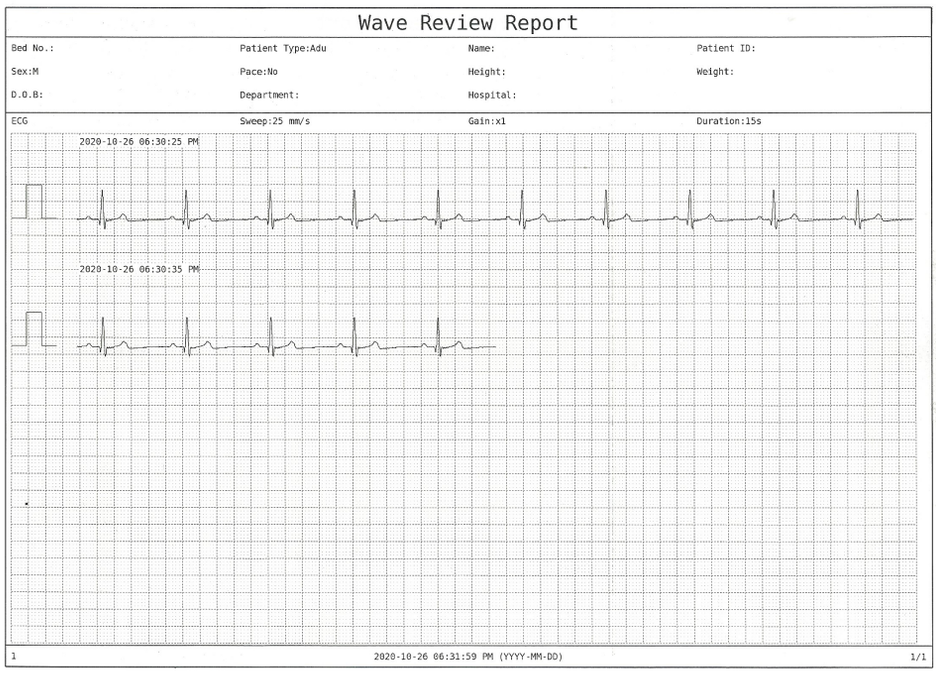
1 2020-10-26 06:30:44 PM (YYYY-MM-DD) 1/1

19.2.3 Wave Review report

The wave review report provides a short snap shot of current waveforms.

Select [Main Menu], [Ext Printer Setup], [Print Report], [Wave Review Report].

- Start time
- Duration
  - ◊ 15s
  - ◊ 30s
  - ◊ 45s
  - ◊ 60s
  - ◊ 75s
  - ◊ 90s
- Set the sweep speed
  - ◊ 6.25
  - ◊ 12.5
  - ◊ 25
  - ◊ 50 mm/s
- Set the gain
  - ◊ X1
  - ◊ x2
- Set the wave
  - ◊ ECG
  - ◊ Pleth



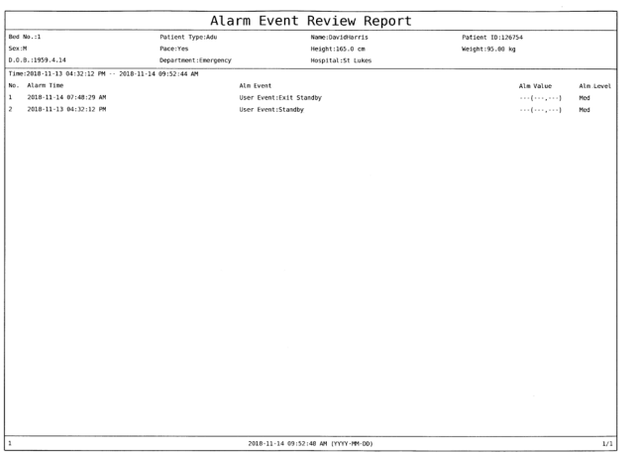
Press [Print] to start printing.

19.2.4 Alarm event report

The alarm event report prints a comprehensive list of all alarm events (physiological and technical). The report provides a summary of:
Alarm time
Alarm description
Alarm value (if physiological)
Alarm type (Low medium or high priority status)

Select [Main Menu], [Ext Printer Setup], [Print Report], [Alarm Event Report].

- Set the start time for the report, this can be any time since the patient was admitted.
- Set the period, this is the amount of time before the start time to include in the report.
  - ◊ 30mins
  - ◊ 1hr
  - ◊ 2hrs
  - ◊ 3hrs
  - ◊ 6hrs
  - ◊ 12hrs
  - ◊ 24hrs
  - ◊ 48hrs
  - ◊ 72 hrs
  - ◊ 96hr
  - ◊ Auto
  - ◊ ALL, all of the saved measurements will be printed.


Alarm Event Review Report

Bed No.:1 Patient Type:Adu Name:DavidHarris Patient ID:126754
Sex:M Pace:Yes Height:165.0 cm Weight:95.00 kg
D.O.B.:1959.4.14 Department:Emergency Hospital:St Lukes

Time:2018-11-13 04:32:12 PM -- 2018-11-14 09:52:44 AM

No.	Alarm Time	Alm Event	Alm Value	Alm Level
1	2018-11-14 07:48:29 AM	User Event:Exit Standby	---(---,---)	Med
2	2018-11-13 04:32:12 PM	User Event:Standby	---(---,---)	Med

1 2018-11-14 09:52:48 AM (YYYY-MM-DD) 1/1

Example, the start time is set to 8:30am the period is set to 2 hours.

All alarm events 2 hours before 8:30am are included on the printed report

.Press [Print] to start printing.

19.2.5 Trend Table Review Report

The trend report provides a summary of the physiological parameters associated with the current patient.

Select [Main Menu], [Ext Printer Setup], [Print Report], [Tabular Trend Report].

Trend Table Review Report

Bed No.:1	Patient Type:Adu	Name:DavidHarris	Patient ID:126754
Sex:M	Pace:Yes	Height:165.0 cm	Weight:95.00 kg
D.O.B.:1959.4.14	Department:Emergency	Hospital:St Lukes	

Time	11-14 09:30:00 AM	11-14 09:00:00 AM	11-14 08:30:00 AM	11-14 08:00:00 AM	11-14 07:30:00 AM	11-14 07:00:00 AM	11-14 06:30:00 AM	11-14 06:00:00 AM
HR(bpm)	60	60	60	60	---	---	---	---
RR(rpm)	27	27	27	27	---	---	---	---
SpO2(%)	98	98	98	98	---	---	---	---
PR(bpm)	60	60	60	60	---	---	---	---

1 2018-11-14 09:53:31 AM (YYYY-MM-DD) 1/1

- Start Time, this can be any time since the patient was admitted.
- Period, this is the amount of time before the start time to include in the report.
  - ◊ 30mins
  - ◊ 1hr
  - ◊ 2hrs
  - ◊ 3hrs
  - ◊ 6hrs
  - ◊ 12hrs
  - ◊ 24hrs
  - ◊ 48hrs
  - ◊ 72 hrs
  - ◊ 96hr
  - ◊ Auto
  - ◊ ALL, all of the saved events will be printed.
- Res. (Resolution of the report)
  - ◊ 30s
  - ◊ 1min
  - ◊ 5mins
  - ◊ 10mins
  - ◊ 15mins
  - ◊ 30mins
  - ◊ 1 hr
  - ◊ 2hrs
  - ◊ 3 hrs.
  - ◊ Auto
- Type Priority
  - ◊ Parameter
  - ◊ Time
- Parameter

o HR (If ECG fitted)

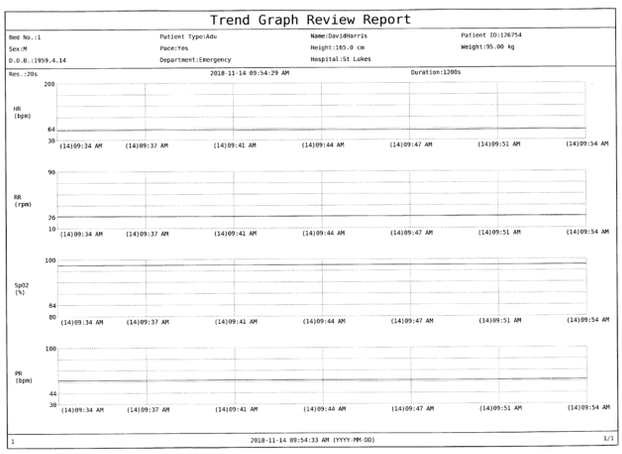
  - ◊ SPO2
  - ◊ PR
  - ◊ NIBP
  - ◊ TEMP

Press [Print] to start printing

19.2.6 Trend Graph Review Report

The graphical report provides a summary of the physiological parameters associated with the current patient.

Select [Main Menu], [Ext Printer Setup], [Print Report], [Graphical Trend Report].



- Start Time, this can be any time since the patient was admitted.
- Period, this is the amount of time before the start time to include in the report.
  - ◊ 30mins
  - ◊ 1hr
  - ◊ 2hrs
  - ◊ 3hrs
  - ◊ 6hrs
  - ◊ 12hrs
  - ◊ 24hrs
  - ◊ 48hrs
  - ◊ 72 hrs
  - ◊ 96hr
  - ◊ Auto
  - ◊ ALL, all of the saved events will be printed.
- Res. (Resolution of the report)
  - ◊ 30s
  - ◊ 1min
  - ◊ 5mins
  - ◊ 10mins
  - ◊ 15mins
  - ◊ 30mins
  - ◊ 1 hr
  - ◊ 2hrs
  - ◊ 3 hrs.
  - ◊ Auto
- • Type Priority
  - ◊ Parameter
  - ◊ Time
- • Parameter
  - ◊ HR (If ECG fitted)
  - ◊ SPO2
  - ◊ PR
  - ◊ NIBP
  - ◊ TEMP

Press [Print] to start printing.

19.2.7 Cancelling a report

To cancel a report, select [Main Menu], [Ext Printer Setup], [Print Report], select report being printed and select [Cancel].

19.3 Printer Error Messages

A limited number of error messages will be displayed in the system status area of the display, a more detailed list will be displayed on the printer itself.

20. Extended Functionality

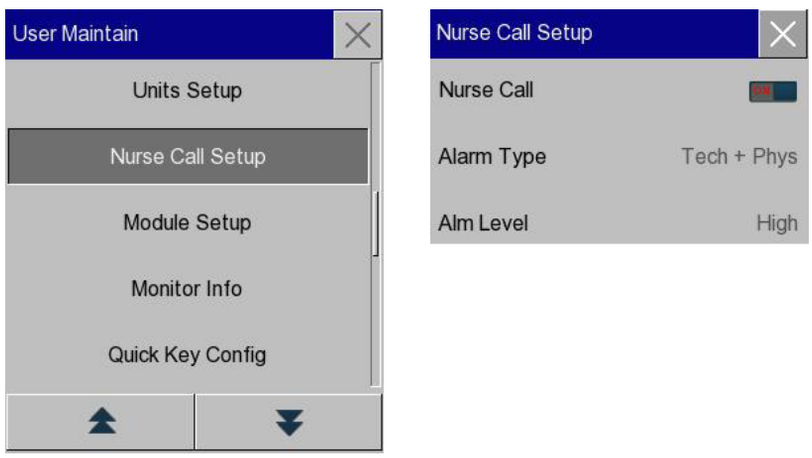
WARNING
Some functions are password protected and should only be accessed by authorised personnel.

20.1 Nurse Call

The nurse call feature allows the system to alert caregivers of an alarm condition.

This feature should only be accessed by the engineering team during installation and commissioning.

To set up the Nurse Call function, select [Main Menu], [Maintain], enter password, select [Nurse Call Setup].



From here the user can enable / disable the Nurse Call function, specify the alarm type and priority.

To switch the nurse call ON, slide the cursor to the ON position.

To set the Alarm Type, press [Alarm Type] and make the necessary selection [Physiological], [Technical] or [Both].

To set the Alarm level (priority), press [Alarm Level] and make the necessary selection [High], [Medium + High] or [Low + Medium + High].

Press X to save the selection and exit.

20.2 Central Monitoring System Interface

The system can be connected to a Huntleigh Central Monitoring System via a wired connection.

Refer to CMS installation manual for configuration details.

20.3 Formatting SD card

The internal SD card is used to store patient records.

A patient record includes:-

- Patient Info
- Trend Review data
- NIBP Review Data
- Alarm Event Review Data
- Wave Review Data
- Wave Save data (when enabled)

This data is stored for every patient admitted on to the device.

Formatting the SD card will erase all patient related data!

DO NOT USE THIS FUNCTION WHILST MONITORING A PATIENT.

When transferring data to and from the system, it may be necessary to FORMAT the SD card.

This function should be used with caution. During the formatting process, ALL data on the card will be erased.

This function can only be performed through the ENGINEERING and ADMINISTRATIVE access level.

Select [Main Menu], [Maintain] , enter password, select [Format SD Card].

A dialogue box appears, press [Accept] to continue. The process will start automatically.

Upon completion, the monitor will restart automatically.

21. Battery

21.1 Introduction

WARNING
Improper replacement of the lithium battery could result in unacceptable risks.

WARNING
Battery replacement should be carried out by suitably qualified personnel.

WARNING
Please keep the battery out of the reach of children.

WARNING
Battery electrolyte is hazardous. If the battery electrolyte comes into contact with your skin or enters your eyes, please wash with clean water immediately and seek medical attention.

WARNING
If the equipment is to be left unused for a long period of time, disconnect the battery

The monitor is equipped with a built-in rechargeable battery. When AC power supply is connected, the battery is charged automatically. In the event of unexpected power outage, the system will automatically use the battery to power the system. When operating on battery power, the battery LED will flash. System operation will not be affected.

The battery display indicates the following conditions:-

Battery Symbol	Explanation
	battery level is full.
	battery level is not full.
	battery level is low and charging should be considered.
	battery is being charged.
	absence or damaged battery.

21.2 Battery installation

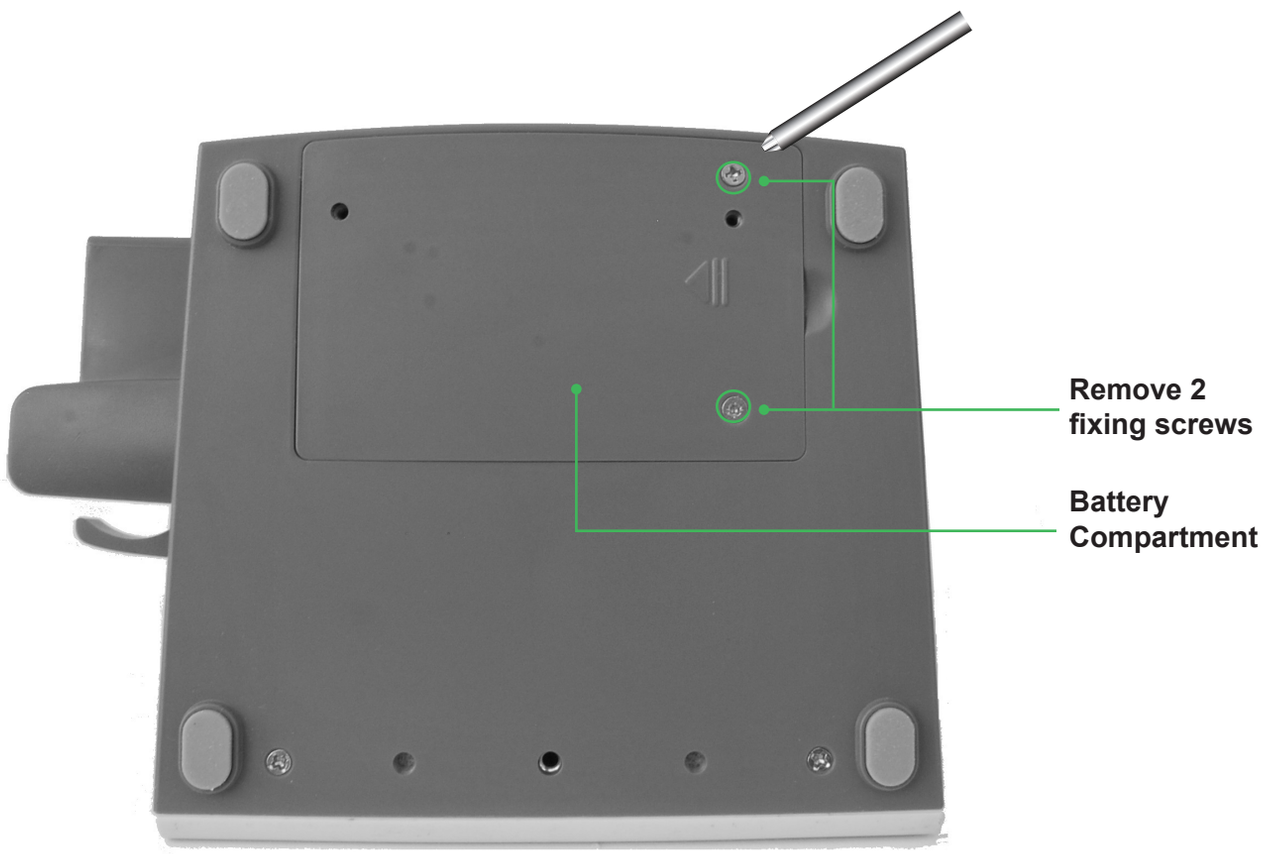
WARNING
Only use batteries approved by Huntleigh.

WARNING
Do not remove the battery if the system is switched ON.

Steps for installation or replacement of the battery:

Switch off the monitor; disconnect the power cord and all accessories.

Place the monitor with its back facing upward, locate the battery compartment.



Remove the two fixing screws with a screwdriver.

Install the battery into the battery compartment paying attention to the connections.

Tighten the screws and perform a functional test, (refer to Service Manual).

21.3 Battery optimisation

NOTE
In order to prolong the service life of the rechargeable battery, if the battery is stored for a long period of time, it is recommended that the battery is charged every three months to prevent battery deterioration.

NOTE:
The run time of the battery depends on the configuration and operation of the device. For example, frequent NIBP measurement will reduce the run time.

1) Optimising Battery Performance

Ensure that the battery has undergone at least two complete optimisation cycles before the unit is used on battery supply.

[A complete optimisation period means uninterrupted charging until the battery is fully charged, and discharging until the monitor shuts down automatically].

When optimising the battery, please ensure the following:

- Disconnect the monitor from the patient.
- Connect to the local mains power for a period of time no less than 6 hours with the device switched off.
- Ensure the AC Mains Power Indicator and Battery Indicator are illuminated.
- After approximately 6 hours, disconnect the AC power supply
- Turn the device on, run the device on battery until the system shuts down automatically.
- Repeat the charge and discharge cycle for a second time
- Battery optimisation is complete.

2) Check Battery Performance

The battery life will vary depending on storage, operating conditions, frequency of discharging and operating time.

Battery performance will degrade for prolonged periods of no use.

Steps for checking the battery:

- Inspect the battery for signs of damage.
- Check the battery icon, if the  is displayed, the battery is damaged or there is no battery connected.
- Check whether the battery can be charged normally when connected to AC power supply.
- Disconnect the monitor from the patient.
- Connect to the local mains power for a period of time no less than 6 hours with the device switched off.

Following the charge cycle

- Disconnect the AC power supply
- Record the start time
- Turn the device on, run the device on battery until the system shuts down automatically.
- Record the end time of the discharge cycle

The length of discharging time reflects the performance of the battery.

When the discharging time reduces to less than 50% of the original value, replace the battery.

21.4 Battery Recycling

WARNING
Do not disassemble, short-circuit or place the battery in fire as explosion, leakage of hazardous gas or other hazards may occur.

If the battery is damaged, depleted or not holding sufficient charge the battery should be replaced by service personnel in accordance with the guidelines in the service manual.

22. Cleaning

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.

22.1 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 a recommended detergent or disinfectant, 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.

22.2 Cleaning and Disinfecting ECG cables

Use a soft cloth, dampened with a recommended detergent or disinfectant, wipe down the entire length of the patient cable and fly leads.

Use a soft dry cloth to wipe off excess cleaning agent.

Place the accessories in a cool, ventilated environment to dry.

Do not immerse contacts in cleaning solution.

22.3 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.

22.4 Cleaning and disinfecting SpO2 sensors

Follow the instructions provided by the sensor manufacturer.

22.5 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 lens filter 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 the thermometer and lens filters in a dry location free from dust and contamination and away from direct sunlight.

22.6 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 instructions 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:

<table>
<tr><th>Item</th><th>Detergent</th><th>Disinfectant</th></tr>
<tr><td>Display screen</td><td>Ethanol (75%±5)
Isopropyl alcohol (70%)</td><td>Ethanol (75%±5)
Isopropyl alcohol (70%)</td></tr>
<tr><td>Monitor housing</td><td rowspan="3">Ethanol (75%±5)
Isopropyl alcohol (70%)</td><td rowspan="3">Isopropyl alcohol (70%)
Glutaraldehyde solution (2%)
Sodium hypochlorite (2.5%
Hydrogen peroxide (2.7% ~ 3.3%)</td></tr>
<tr><td>Power cord</td></tr>
<tr><td>ECG patient cable</td></tr>
<tr><td>ECG electrodes</td><td>Single use – dispose after use</td><td></td></tr>
<tr><td>SpO2 sensors – reusable</td><td>Alcohol free hand soap,
Sodium hypochlorite (2.5%)
Hydrogen peroxide(2.7% ~ 3.3%)</td><td>Isopropanol (70%)
Glutaraldehyde solution (2%),
Sodium hypochlorite (2.5%)</td></tr>
<tr><td>SpO2 sensors – single use</td><td colspan="2">Single use – dispose after use</td></tr>
<tr><td>Temperature sensor</td><td>Alcohol free hand soap,
Sodium hypochlorite (2.5%)
Hydrogen peroxide (2.7% ~ 3.3%)</td><td>Isopropanol (70%)
Glutaraldehyde solution (2%),
Sodium hypochlorite (2.5%)</td></tr>
<tr><td>NiBP cuffs – reusable</td><td colspan="2">Bladder: warm water
Cuff: damp cloth 70% ethanol or 70% Isopropanol</td></tr>
<tr><td>NiBP cuffs – single use</td><td colspan="2">Single use – dispose after use</td></tr>
</table>

23. Maintenance

WARNING
It is very important that all instructions in the Maintenance section are followed carefully.

WARNING
Servicing cannot be performed while the unit is in use.

23.1 User maintenance Daily Checks

1. Check the touch screen for scratches and cracks that may prevent normal use or impair the visibility of the display.
2. Check the device casing for cracks deformation and any signs of fluid ingress or leakage.
3. Check the installation or location meets the environmental requirements and ingress protection.
4. Visually check all transducers cables and accessories for any signs of damage and replace accordingly.
5. Visually check AC supply cable, transducers, and all other assemblies and connectors for loose, broken parts or any other damage.
6. Pay particular attention to the AC supply socket.
7. If there is damage to the main SC500 unit, contact your local Huntleigh Healthcare Ltd representative.
8. Switch the device on and check that the device operates normally, the alarm self-test is performed at boot up and the device is able to run on its internal battery
9. Ensure the time and date are set correctly.

23.2 Scheduled Technical maintenance

We recommend that the SC500 is included into an annual maintenance schedule, details of these checks can be found in the supporting service manual.

Refer to your Service department for details of technical maintenance and support

23.3 Corrective maintenance

All corrective maintenance must be performed by qualified engineers approved by Huntleigh Healthcare Ltd.

The SC500 Service Manual (order part number 787337) is designed as an aid to engineers in maintenance and service of repairable parts.

23.4 Servicing

Servicing should be performed only by Huntleigh Healthcare Ltd or their appointed service agent. If you have difficulty obtaining service for SC500, contact Huntleigh Healthcare Ltd.

24. Technical Specifications

Equipment Classification	
Type of protection against electric shock.	Internally powered equipment
Degree of protection against electric shock ⚠	Type CF with defib protection - ECG 
	Type BF with defib protection - NiBP, Temp, SpO2 
Mode of operation.	Continuous
MDD/MDR Classification	Class IIb
Ingress Protection	IPX2 Patient Monitor, IPX0 for the temperature probe
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

General	
Rated supply voltage	100 – 240 VAC
Supply frequency	50Hz / 60Hz
Power input	45VA
Internal Battery	Lithium Ion 11.1V 4400mAh
Size	164mm (L) x 150mm (W) x 245mm (H)
Weight	≤2.5Kg battery and temperature probe not included
Service life	7 years

Environmental		
	Operating	**Storage**
Temperature	0 ° C ~ 40 ° C (without IRT10) 15 ° C ~ 36 ° C (with IRT10)	-20 to +60°C (without IRT10) -20 to +55°C (with IRT10)
Relative humidity	≤ 93% Non-condensing without IRT10 ≤ 85% Non-condensing with IRT10	≤ 93% Non-condensing without IRT10 ≤ 85% Non-condensing with IRT10
Pressure	700mb to 1060mb	700mb to 1060mb

Main Battery	
Battery Specification	11.1V 4400mAh, rechargeable lithium-ion battery, providing continuous sustainable power supply for at least 8 hours under full charge and normal use. With +5%, -10% relative error (built-in battery).
Charging time	Power off state:5.5 hours from depletion to 90% charge in normal use Power on state:10.5 hours from depletion to 90% charge in normal use (apply semi-charge mode in power on state)
Power off delay	**20-30min (from the first low battery alarm)**

Display	
Size	**8”**
Type	Colour TFT
Resolution	**600 x 800 pixels**
Maximum number of waveforms	2
Control	Integrated touchscreen
Number and types of screens (user interface)	Standard screen List view Spot Check

Data Storage	
Short trends	1hr trend, (1s resolution)
Long trends	120hr trend, (1min resolution)
Trend capacity	120hr (graphical and tabular)
Alarm events	200 events first in first out rolling buffer
NIBP measurements	5,000 groups
Waveforms	24hr single lead ECG and SP02 waveforms

ECG		
3 Lead	RA, LA, LL	
Lead designation	I, II, III	
Maximum number of waveforms on display	1	
Sweep Speed	6.25, 12.5, 25 and 50 mm/s	
QRS amplitude range	0.5mV to 5mV	
QRS pulse width (Adult)	70 to 120ms	
QRS pulse width (Neonate / Paediatric)	40 to 120ms	
Heart rate range	Adult	Neonate / Paediatric
	15 to 300 BPM	15 to 350 BPM
Accuracy	±1% or ±1 BPM	
Resolution	1 BPM	
Sensitivity	≥ 200μV peak	
Tall T wave rejection	1.2 mV	
Filtering Characteristics	Monitoring mode	0.5Hz to 40Hz (-3dB to +0.4dB)
	Diagnostic mode	0.05Hz to 150Hz (-3dB to +0.4dB)
Input Impedance	≥ 5MΩ	
CMMR (dB)	Diagnostic >90dB Monitoring >105dB	
Electrode offset voltage	±300mV	
Input dynamic range	DC bias voltage up to ±750mV	
Lead-off detection current	DC current <0.1μA	
System noise	≤25μVP-P	
Calibration voltage	1 mV, error range ±5%	
Input signal range	±5mV	
Pacemaker Detection/Rejection without overshoot.	Amplitude: ±2mV to ± 700mV Pulse Width: 0.1ms to 2.0ms	
HR Calculation	If the last 3 RR intervals are greater than 1200ms, the last 4 RR intervals are averaged for the HR calculation. Otherwise the last 12 RR intervals (with the longest and shortest intervals excluded) are averaged for the HR calculation.	
Response time of HR meter to change in heart rate	80bpm to 120bpm or from 80bpm to 40bpm, less than 10s.	

Heart rate meter accuracy and response to arrhythmia	
Ventricular bigeminy	80±1bpm
Slow alternating ventricular bigeminy	60±1bpm
Rapid alternating ventricular bigeminy	120±1bpm
Bidirectional systoles	90±2bpm

Time to alarm for Tachycardia	
Figure 4 a) @ 1mV	<10s
Figure 4 a) @ 0.5mV	<10s
Figure 4 a) @ 2mV	<10s
Figure 4 b) @ 1mV	<10s
Figure 4 b) @ 0.5mV	<10s
Figure 4 b) @ 2mV	<10s

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 Paediatric	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 300mmHg (40.0 kPa)	
Accuracy (Static pressure Accuracy)	±3mmHg (±0.67 kPa)	
Automatic Intervals SC500	1, 2, 2.5, 3, 10, 15, 20, 30, 45, 60, 120, 240, 480 minutes and STAT	
Overpressure protection	Adult 297mmHg	
	Paediatric 240mmHg	
	Neonate 147mmHg	
Over pressure protection tolerance	Tolerance	±3mmHg (±0.4 kPa)
Maximum measurement duration	Adult/Paediatric	120 seconds
	Neonatal	85 seconds

Venipuncture inflation mode		
Inflation pressure	Adult	20 to 120mmHg (3 to 16kPa)
	Paediatric	20 to 80mmHg (3 to 11kPa)
	Neonate	20 to 50mmHg (3 to 7kPa)
Automatic deflate after	Adult	170s
	Paediatric	170s
	Neonate	85s

SpO2		
Display Range	0% to 100%*	
Own Brand Accuracy	70% to 100%	±2% (measured without motion in adult/child mode)
		±3% (measured without motion in neonate mode)
Nellcor Accuracy	70% to 100%	±2% (measured without motion in adult/child mode)
		±3% (measured without motion in neonate mode)
Resolution	1%	±3BPM (25 to 250BPM)
Data averaging and other signal processing time	12 seconds	
Data update time	2 seconds	

**Accuracy in the range of 0% to 69% is undefined*

Pulse Rate - Range and Accuracy		
Own Brand	20bpm ~ 250bpm	±2bpm
Nellcor Module	25bpm ~ 250bpm	±3bpm
	251bpm ~300bpm	Undefined
NIBP Module	40bpm ~ 240bpm	±3bpm or ±3%(MAX)
Resolution (All Modules)	1bpm	

NOTE
SPO2 Accuracy measurements are statistically distributed Only about two thirds of measurements can be expected to fall within specified accuracy of the value measured by a CO-OXIMETER.

Temperature	
Probe Type	Tympanic Infrared
Measurement Range	34°C to 42.2°C (93.2°F to 108°F)
Accuracy Range	35°C to 42°C (95°F to 107.6°F)
Accuracy	±0.2° C (±0.4° F) (without sensor error); Other range ±0.3°C (±0.5°F)
Resolution	0.1°C (0.1° F)
Measurement Interval	≥12s
Measurement Duration	<4 seconds
Units	°C ,°F
Standards	ASTM E1112-00:2000, EN12470-3 and EN12470-4

IRT10 Thermometer Battery	
Battery specification	3V (2 AAA alkaline batteries)
Power off delay	The in-ear thermometer automatically powers off after 60±10 seconds from the end of temperature measurement.

Recorder (Internal Printer)	
Number of channels	Two
Paper width	50mm
Record width	48mm
Paper speed	25 or 50mm/s
Waveform settings	8s, 16, 32s
Alarm trigger	Automatic pre and post trigger capture

Input / Output	
Multi-function port	Includes nurse call
Nurse call	Nurse call relay contacts (2A, 30VDC)
USB	Data transfer, external printer
Alarm Indicators	Red, Yellow, Cyan
Alarm Level	85db max

Standards	
ISO 13485:2016	Medical devices quality management systems
ISO 14971:2019	Application of risk management to medical devices
IEC 60601-1:2012 (reprint)	General requirements for basic safety and essential performance
IEC 60601-1-2:2014	General requirements for basic safety and essential performance, collateral standard, EMC requirements and test
IEC 60601-1-6:2012+A1:2013	General requirements for basic safety and essential performance - usability
IEC 60601-1-8:2006+A1:2012	General requirements for basic safety and essential performance, collateral standard general requirements tests and guidance for alarm systems in medical devices and medical electrical systems
IEC 60601-2-27:2011	Particular requirements for the basic safety and essential performance of ECG monitoring equipment
IEC 80601-2-30:2009+A1:2013	Basic safety and essential performance of automated sphygmomanometers
IEC 80601-2-49:2018	Basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-56:2017+A1:2018	Particular requirements for basic safety and essential performance of clinical thermometers for body temperature
ISO 80601-2-61:2011	Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN 1060-1:1995+A2:2009	Non-invasive sphygmomanometers, general requirements
EN 1060-3:1997+A2:2009	Non-invasive sphygmomanometers, supplementary requirements electro-mechanical blood pressure measuring systems
IEC 62366-1:2015	Application of usability engineering to medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
ISO 15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied, general requirements
IEC 62304:2006+A1:2015	Medical device software – software life cycle process
ISO 10993-1:2018	Biological evaluation and testing of medical devices
ISO 10993-5:2009	Biological evaluation and testing of medical devices, tests for cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

25. System Alarm Messages

Each physiological or technical alarm message is listed in this section, the appearance on the monitor will be dependent on the monitor configurations

25.1 Physiological Alarm Messages

Source	Default Level	Selectable level	Condition	Indication
ECG				
HR too high	Medium	High, medium	Value exceeded	Yellow alarm
HR too low	Medium	High, medium	Value dropped	Yellow alarm
Asystole	High	High	Arrhythmia detected	Red alarm
Noise signal	Medium	High, medium		
SpO2				
SpO2 too high	High	High, medium	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit.	Red alarm
SpO2 too low	High	High, medium		
PR too high	High	High, medium, low		
PR too low	High	High, medium, low		
Pulse Not Found	High	High	No pulse detected	Red alarm
NIBP				
SYS/MAP/DIA too high	Medium	High, medium	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit	Yellow alarm
SYS/MAP/DIA too low	Medium	High, medium		
Temp				
Temp too high	Medium	High, medium, low	The measured value is greater than the upper alarm limit or smaller than the lower alarm limit	Yellow alarm
Temp too low	Medium	High, medium, low		

25.2 Technical Alarm Messages

Source	Message	Alarm level	Condition	Solution
XX	XX Init err	High	Error X occurs in the XX module initializing process	Restart the Monitor to try again. If the error still exists, contact Huntleigh for service
	XX comm stop	High	The XX module fails to communicate with the main system.	
	XX comm err	High	The XX module fails to communicate normally with the main system.	
XX	XX alm lmt err	Low	The alarm limit of parameter XX has accidentally changed	Contact Huntleigh for service.
XX	XX over-range	Low	The measured value of parameter XX goes beyond the specified measurement range	
ECG	ECG lead off	Low	The ECG lead is connected unreliably.	Check if the ECG lead YY is connected properly
	ECG noise	Low	The ECG signal contains strong interfering signal	Check if the ECG lead is connected properly and if the patient performs any major movement.
SpO2	SpO2 finger off	Low	The SpO2 sensor is disconnected from the finger.	Check if the SpO2 sensor is connected properly
	SpO2 no sensor	Low	The SpO2 sensor is connected unreliably	
	SPO2 Saturation not Found	Low		
	SpO2 sensor off	Low		
	NELLC error, resetting	Low	There is a Nellcor module error. The system is resetting	If system resetting fails, or the error still exists after you restart the Monitor, please contact Huntleigh for service
	Search pulse	Low	The SpO2 sensor is connected unreliably or the patient moves his/her arm	Check the patient's condition and if the SpO2 sensor is connected properly
	SpO2 Out Of Range	Low	The measured value goes beyond the specified measurement range.	Follow the specified measurement range
	SpO2 Low signal	Low	Peripheral Circulation	Change sensor position
Temp	Temp Not Connected	Low	The wireless temperature probe has disconnected from the monitor.	Turn on temperature probe, check and replace batteries if required.
	Temp Out of Range	Low	The measured temperature exceeds the specified temperature range of the wireless tympanic temperature probe.	Repeat temperature measurement, replace tympanic cover. Use another device to confirm temperature reading

NIBP	NIBP self-test error	High	An error occured during the initialisation process	Enable the reset function in the NIBP menu. If the error still exists, contact us for service.
	NIBP comm error	High	The NiBP communication port has a fault	
	NIBP Init Err	High		
	Loose cuff	Low	The BP cuff is not applied correctly	Reconnect the BP cuff.
NIBP	Pneumatic leak	Low	Air leak in the system	Check the connection condition of each part or replace the NIBP cuff. If the fault still exists, contact service.
	Pressure over range	Low	An error occurs in the measurement process.	
	Air leak	Low	Air leak in the system	
	Weak signal	Low	An error occurs in the measurement process.	Check if the selected patient type is correct. Check the connection condition of each part or replace the NIBP cuff. If the fault still exists, contact service
	Cuff type error	Low	The NIBP cuff is incompatible with the selected patient type	
	Excessive motion	Low	The patient moves his/her arm.	Check the patient's condition and the connection condition of each part, and then try the measurement again. If the fault still exists, contact service
	Signal saturated	Low	An error occurs in the measurement process.	
	NIBP system failure	Low		
	NIBP measure timeout	Low		
	NIBP measure failed	Low		
	Over pressure	Low	BP hose may be twisted	Check the patient's condition and if the air circuit is unobstructed, and then try the measurement again. If the fault still exists, contact service.
	NIBP reset error	Low	Illegal reset occurs in the NIBP measurement process	Check if the NIBP air circuit is blocked and then try the measurement again. If the error still exists, contact Huntleigh for service.
	Low Signal Quality (SQI<15%)	Low	Poor Signal	
Other alarms	Low battery	Medium	The battery power is low	Connect the Monitor to the AC power supply to charge the battery. If the fault still exists after 6-hour charging, contact us for service
	Countdown to Shutdown (in xxS)	High	The battery power is so low that the system is forced to shut down	Connect the Monitor to the AC power supply to charge the battery

25.3 System Prompt Messages

System prompt messages do not have an alarm status. They provide feedback to the user of specific conditions.

NIBP Alarm Message	
Message	**Message Description**
Please start	General NIBP standby status message
Manual measure...	Manual Measurement mode, Measurement in progress
Auto measuring...	Automatic Measurement mode, Measurement in progress
Stat measurement	Continuous Measurement mode, Measurement in progress
Measure stopped	NIBP Measurement manually cancelled
Over pressure	NIBP over pressure detected, measurement cancelled
Leakage testing...	Pneumatic Circuit leakage test in progress
Leakage test stopped	Pneumatic Circuit leakage test manually cancelled
Calibrating...	
Calibrate stopped	
Resetting...	NIBP circuit reset in progress
Reset failed	NIBP circuit reset failed to complete
Reset for error	NIBP reset, NIBP errors occurred during reset
Venipuncture start	NIBP Venipuncture Started
Venipuncture stop	NIBP Venipuncture Stopped
Module resetting...	
ECG Calibrating	1mV ECG Calibration pulse enabled.

Other Prompt Messages	Alarm Message
Alarm Off	All Physiological alarms are disabled
Screen is Locked! Long Press Man Menu to Unlock!	Touch screen Locked
IP conflict	Another device on the network has the same IP address
Import Successful	Import configuration files from USB successful
Import Failed	Import configuration files from USB Failed
Loading config successfully	Configuration loaded successfully
Load Config Fail	Configuration Failed to load
Delete config succeed	Deletion of the configuration was successful
Delete Config Fail	Deletion of the configuration Failed
Sampling	Data Acquisition enabled, Sampling in progress
Relearn	ECG Relearn in progress
Demo Mode	Demonstration mode enabled

26. Default Configuration

The Default configuration settings are list below.

Standard users cannot change the default configurations,

Depending on the system configuration some settings can be altered and saved as user configurations.

26.1 General Configuration

Alarm

Item	Default Setting
Alarm volume	2
Alarm recording time	8s

Waveform/ parameter colour

Item	Default Setting
ECG	Green
SPO2	Cyan
NIBP	White
TEMP	White

Review

Item	Default Setting
Trend graph resolution	1s
Trend table resolution	1 min

Layout

Item		Default Setting
Screen Select		Standard
Quick key		Default: main menu – alarm reset – NIBP start – screens – review – alarm setup – standby
Waveform sequence on standard screen	1	ECG1 (where fitted)
	2	SpO2
Parameter sequence in Spot mode	Parameter 1	SPO2
	Parameter 2	NIBP
	Parameter 3	Temp
	Parameter 4	PR (SPO2 or NIBP)

Event Setup

Item	Default Setting
Waveform 1	II
Waveform 2	SpO2

Record

Item	Default Setting
Waveform 1	ECG (Current Selected lead)
Waveform 2	SPO2
Waveform record output speed	25 mm/s
RT record time	8s
Timed record interval	Off
Grid	On

Maintenance

Item		Default Setting
Wave mode		Mono
Wave Line		Thin
Analog out		Off
Alarm setup	Alarm mute	Off
	Reminder interval	1Min
	Reminder volume	1
	Min. Alarm volume	2
	Alarm pause time	2 min
	Alarm Delay	Not allowed
Nurse call	Nurse Call switch	Off
	Alarm level	High
	Alarm type	Technical and Physiological

26.2 Default Alarm Limits

Item		Default Setting
HR	ADU	50 --- 120
	PED	75 --- 160
	NEO	100 --- 200
SpO2	ADU	85 --- 100
	PED	
	NEO	
PR	ADU	50 --- 120
	PED	75 --- 160
	NEO	100 --- 200
SYS(NIBP)	ADU	90 --- 160
	PED	70 --- 120 0---4
	NEO	40 --- 90
MAP(NIBP)	ADU	60 --- 110
	PED	50 --- 90
	NEO	25 --- 70
DIA(NIBP)	ADU	50 --- 90
	PED	40 --- 70
	NEO	20 --- 60
TEMP	ADU	Low 36, High 39
	PED	Low 36, High 39
	NEO	Low 36, High 39

Arrhythmia Type	Alarm Limit Range		Default	Step	Unit	Priority
	From	To				
Asystole	**Fixed**		**<14**	**-**	**Bpm**	**High**

26.3 Parameter Default Configuration

Default ECG Settings

Item	Default Setting
Lead name	II
Gain	x 1
Sweep	25 mm/s
Channel format	1
Filter Mode	Monitor
Lead type	3 Lead
Calculate lead	II
HR Source	ECG
Alarm	On
Alarm record	Off
Alarm level	Medium
Notch filter	On (50/60Hz)
Smart lead off	Off

Default SpO2 Settings – Huntleigh

Item		Default Setting
Sweep		25 mm/s
Signal IQ		On
NIBP Same Side		Off
Alarm		On
Alarm record		Off
Alarm level		High
SpO2 Alarm limits	ADU	(90 --- 100)
	PED	
	NEO	(90 -- 100)

Default SpO2 Settings – Nellcor

Item		Default Setting
Sweep		12.5mm/s
Sat-Second		50s
Signal IQ		On
Alarm		On
Alarm record		Off
Alarm level		High
SpO2 Alarm limits	ADU	(85 --- 100)
	PED	
	NEO	(85 --- 100)

Default PR Settings

Item	Default Setting
Alarm	On
Alarm record	Off
PR source	SpO2
Alarm level	High

Default NIBP Settings

Item		Default Setting
Patient type		ADU
Measure Mode		Manual
Interval		1min
Alarm		On
Alarm record		Off
Alarm level		Medium
Initial pressure	ADU	160
	PED	120
	NEO	100

Default Temp Settings

Item		Default Setting
Alarm		On
Alarm record		Off
Alarm level		Medium
Alarm limit	ADU	36.0°C - 39.0°C
	PED	
	NEO	

27. Electromagnetic Compatibility

Make sure the environment in which SC500 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 SC500 as replacement parts for internal components, may result in increased emissions or decreased immunity of the SC500.

WARNING
The SC500 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the SC500 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 SC500 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The SC500 is intended for use in the electromagnetic environment specified below. The customer or the user of the SC500 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The SC500 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 SC500 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	

NOTE
The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and Manufacturer's declaration - electromagnetic immunity			
The SC500 is intended for use in the electromagnetic environment specified below. The customer or the user of the SC500 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 SC500, 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 SC500 is used exceeds the applicable RF compliance level above, the SC500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SC500.

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

Guidance and Manufacturer's declaration - electromagnetic immunity			
The SC500 intended for use in the electromagnetic environment specified below. The customer or the user of the SC500 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 SC500 requires continued operation during power mains interruptions, it is recommended that the SC500 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 SC500

The SC500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the SC500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SC500 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.

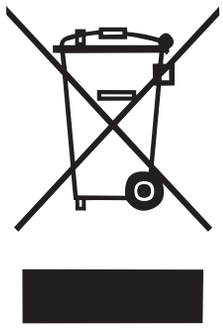
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

28. Toxic/Hazardous Substances/Elements

Material used in the SC500 Patient monitor or accessories that patients or users will come into contact with has passed biocompatibility testing and is verified to to ISO 10993-1.

Component		Pb	Hg	Cd	Cr(V1)	PBB	PBDE
Housing	Front Housing	O	O	O	O	O	O
	Rear housing	O	O	O	O	O	O
	Keys	O	O	O	O	O	O
	Facing	O	O	O	O	O	O
	Labels	O	O	O	O	O	O
Display	Display	X	X	X	X	X	X
Main Unit	Hardware	O	O	O	X	O	O
	Internal wires	O	O	O	O	O	O
	PCBA	X	O	O	O	O	O
Packing	Packing materials	X	X	O	O	X	X
General components	Connectors	O	O	O	X	O	O
	Power cord	O	O	O	O	O	O
Battery	Lithium battery	X	X	X	X	X	X
Accessories	ECG	X	O	O	O	O	O
	SpO2	X	O	O	O	O	O
	Temp	X	O	O	O	O	O
	NIBP	X	O	O	O	O	O
Note	O: Such hazardous/toxic substance contained in all homogeneous materials of such component falls within the content limit specified in SJ/T11363-2006.						
	×: Such hazardous/toxic substance contained in one or more homogeneous materials of such component goes beyond the content limit specified in SJ/T11363-2006.						

29. 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.

30. Warranty & Service

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

Service Returns

If for any reason the SC500 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 Healthcare Ltd reserve the right to return product that does not contain a decontamination certificate.

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

Appendix A Accessories

This section lists the approved accessories for use with the SC500.

These items can be sourced through your supplier or directly with HUNTLEIGH.

WARNING
To maintain system integrity and performance, only use HUNTLEIGH approved items.

WARNING
Never re-use single use items, reuse may compromise device functionality and patient safety.

WARNING
If any accessory packaging is damaged, do not use the item and contact the supplier.

WARNING
The use of incompatible Pulse oximeter probes and probe cable extenders, can result in degraded performance.

WARNING
Do not use SpO2 Sensors in the sterile field unless additional barrier precautions are taken.

WARNING
Electrode choice is based on clinical preference and/or application.

WARNING
The operator is responsible for ensuring that the device operates correctly on the chosen ECG electrode.

NOTE
Huntleigh recommend the use of commonly available pre-gelled electrodes.

Certain items such as ECG cables provide particular levels of protection. Do not use compatible cables otherwise leakage current and defibrillator protection may be compromised.

Recommended accessories

ECG Cables		
Order Code	**Description**	**Pack size**
ACC VSM 300	3 Way ECG Cable (IEC)	1
ACC VSM 303	3 Way Neonatal trunk	1
ACC VSM 201	Prewired Neonatal ECG electrodes (3)	40

Temperature Lens covers		
Order Code	**Description**	**Pack size**
ACC VSM 293	Lens filter 200 pcs (10 boxes)	1
ACC VSM 286	Lens filter 800 pcs (40 boxes)	1
ACC VSM 287	Lens filter 8,000 pcs (400 boxes)	1

SpO2 Sensors (Huntleigh technology)				
Order Code	**Description**	**Location**	**Weight**	**Pack size**
ACC VSM 289	Adult Reusable SpO2 Finger sensor, 10ft	Finger clip	>30kg	1
ACC VSM 290	SpO2 Extension Cable, 8ft	N/A	N/A	1
ACC VSM 291	Adult Reusable SpO2 Finger sensor, 3ft	Finger clip	>30kg	1
ACC VSM 292	Neo/Ped Reusable SpO2 Wrap Sensor, 3ft	Wrap Sensor	>3kg	1
ACC VSM 304	Neonatal disposable SPO2 sensor	Foot	>3kg	1
ACC VSM 305	Adult Reusable soft tip sensor	Finger	>40kg	1
ACC VSM 306	Paediatric Reusable soft tip sensor	Finger	15-40kg	1
ACC VSM 307	Infant Reusable soft tip sensor	Finger	3-15kg	1
ACC VSM 308	Neonatal Reusable silicone wrap sensor	Finger/Foot	1-3kg	1

SpO2 Sensors (Compatible Nellcor Oximax technology)				
Order Code	**Description**	**Location**	**Weight**	**Pack size**
ACC VSM 309	DOC10 Compatible Extension cable	N/A	N/A	1
ACC VSM 310	DS100A Compatible Reusable Sensor	Finger	>40kg	1
ACC VSM 311	Adult/Neonate disposable SpO2 sensor	Finger/Foot	>40kg/<3kg	24/box
ACC VSM 312	Paediatric disposable SpO2 sensor	Finger	15-40kg	24/box
ACC VSM 313	Adult disposable SpO2 sensor	Finger	>40kg	24/box
ACC VSM 314	Adult Reusable soft tip sensor	Finger	>40kg	1
ACC VSM 315	Paediatric Reusable soft tip sensor	Finger	15-40kg	1
ACC VSM 316	Infant Reusable soft tip sensor	Finger	3-15kg	1
ACC VSM 317	Adult/Neonatal Reusable silicone wrap sensor	Finger/Foot	>40kg/<3kg	1

NiBP Cuffs and hoses		
Order Code	**Description**	**Pack size**
ACC VSM 277	Adult NIBP Cuff 25-35CM	1
ACC VSM 275	Ped NIBP Cuff 18-26CM	1
ACC VSM 274	Inf NIBP Cuff 10-19CM	1
ACC VSM 273	Inf NIBP Cuff 6-11CM	1
ACC VSM 279	Adult NIBP Cuff 46-66CM	1
ACC VSM 276	Adult NIBP Cuff 20-28CM	1
ACC VSM 278	Adult NIBP Cuff 33-47CM	1
ACC VSM 284	NiBP Hose 3M	1
ACC VSM 318	Adult single use cuff 45 - 56cm (5 pcs)	5
ACC VSM 319	Adult single use cuff 36.5 - 46cm (5 pcs)	5
ACC VSM 320	Adult single use cuff 27.5 - 36.5cm (5 pcs)	5
ACC VSM 321	Adult single use cuff 20.5 - 28.5cm (5 pcs)	5
ACC VSM 322	Paediatric single use cuff 13.8 - 21.5cm (5 pcs)	5
ACC VSM 323	Infant single use cuff 9 - 14.8cm (5 pcs)	5
ACC VSM 280	Disposable #1 Neo Cuff (3 - 5CM)	1
ACC VSM 281	Disposable #2 Neo Cuff (4~7.6CM)	1
ACC VSM 282	Disposable #3 Neo Cuff (5.6~10.6CM)	1
ACC VSM 283	Disposable #4 Neo Cuff (7.0~12.8CM)	1

Hardware		
Order Code	**Description**	**Pack size**
ACC VSM 347	Printer Paper 50mm*20m (with grid)	1
ACC VSM 153	Roll stand	1
ACC VSM 154	Wall mount	1
ACC VSM 187	Utility hook	1
ACC VSM 189	3.5" Utility basket	1
ACC VSM 348	Earth cable	1
ACC VSM 249	IV Pole clamp	1
ACC-VSM-353	Fixing/Mounting kit	1

Appendix B Clinical Evaluation

SpO2 Summary Report

SpO2 Test model: Huntleigh Blood Oxygen Saturation Module (27 subjects) Third Party Blood Oxygen Saturation Module (27 subjects) Nellcor Blood Oxygen Saturation Module (26 subjects)

Clinical subjects:

Test subjects; 60 adults and paediatrics and 20 infants and newborn subjects participated in this trial. The adults and paediatrics varied in age from 3 to 76 years old (mean 43.7). The infants and newborn varied in age from 0.25 to 730 days (mean 170.8). There were 46 males and 34 females subjects in this trial. All the people were Chinese, skin type was yellow.

Health of test Subjects

All subjects needed their vital signs monitoring due to the illness or injury.

Test Method

The oxygen saturation probe of the test instrument was placed on the hands or feet of the test subjects with the oxygen saturation values displayed on the test unit.

Simultaneously arterial blood of the test subjects were collected and analysed for arterial blood gas.

NIBP Summary Report

Test Subjects; 60 adults and paediatrics and 20 infants and newborn subjects participated in this trial. The adults and paediatrics varied in age from 3 to 76 years old (mean 43.7). The infants and newborn varied in age from 0.25 to 730 days (mean 170.8). There were 46 males and 34 females subjects in this trial.

Health of test Subjects

All subjects needed their vital signs monitoring due to the illness or injury.

Test method

The circumference of the biceps were measured on test subjects to select the correct NIBP cuff.

The Invasive blood pressure and non-invasive blood pressure comparison method using a contrast unit for comparison

The test instrument was set up for non-invasive measurements and the contrast unit set up for invasive blood pressure measurement and the results of both units recorded simultaneously.

The invasive blood pressure and non-invasive blood pressure are measured on the same side of the test subject.

Measurements were taken every 10 minutes with systolic, diastolic and mean blood pressure values recorded as a result, 10 groups of data pairs were obtained.

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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