ENGLISH

User Manual

CE
0088

Medical Devices Directive 93/42/EEC

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 of the Smartsigns® range without notice.

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1. Introduction

Before using this equipment, please study this manual carefully and familiarise yourself with the controls, display features and operating techniques.

The ***Smartsigns® Assist*** is a portable mains / battery operated Vital Signs monitoring system which is suitable for use on human patients, one at a time.

1.1 Recommended Clinical Applications

The ***Smartsigns® Assist*** is intended for monitoring of blood pressure, pulse rate, temperature, breathing rates and oxygen saturation of adult, paediatric and neonatal patient groups.

2. Accessories

Each system is supplied with the following standard accessories:-

Description	Qty
ECG / Respiration cable	1
Re-useable Adult NiBP cuff	1
NiBP Hose	1
Re-useable Adult SpO2 sensor	1
SpO2 Extension cable	1
Oral temperature probe	1
Temperature probe covers (pack of 25)	1
Power pack	1
Power cord	1
User manual	1

A wide range of accessories is available for the ***Smartsigns®*** range and can be ordered from your supplier or by contacting Huntleigh Healthcare Diagnostic Products Division directly.

3. Warnings

Do not use this equipment in the presence of flammable gases.

Do not immerse any part of the equipment in any liquids.

Do not use solvent cleaner on any part of the system.

Do not use high temperature sterilising or E-beam / gamma sterilisation processes.

Do not attempt to use alternative universal power adaptors with the system. The universal power adaptor supplied with the system is the only one certified for use with the ***Smartsigns® Assist*** range.

This product contains sensitive electronics; strong radio frequency fields could interfere with the operation of the system. In the event where this occurs, we suggest that the source of interference is identified and the equipment is used 'out of range'.

Do not destroy packing, either retain for future use or return to supplier.

Only use recommended patient applied leads / cables and accessories.

The ***Smartsigns® Assist*** can be connected to the public mains supply, however, any doubt concerning the integrity of the earth conductor, the equipment must be operated from its internal power source.

DO NOT use during MRI scanning, induced current could cause harm (burns) to the patient.

Observe extreme caution when using a defibrillator on a patient. Do not touch any part of the patient or equipment during defibrillation.

If any doubt exists concerning the use of this equipment, an alternative method should be used.

4. Symbols

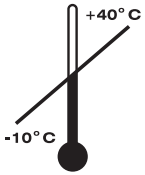
Symbol	Description
	Type CF equipment (defibrillator protected)
	Attention - consult accompanying documents
	ON, OFF / Stand by
	Direct Current
	Alternating current
	Nurse Call output
	Printer interface
	Serial data output
	VGA output

The following symbols are used on the outer packing and are concerned with protection from mechanical and environmental hazards: -

Fragile equipment

Do not use hooks

Keep Dry 90% Rh



Storage temperature
-10°C to +40°C

This way up

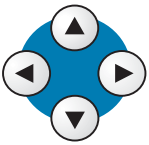
5. System Controls

5.1 Front Panel

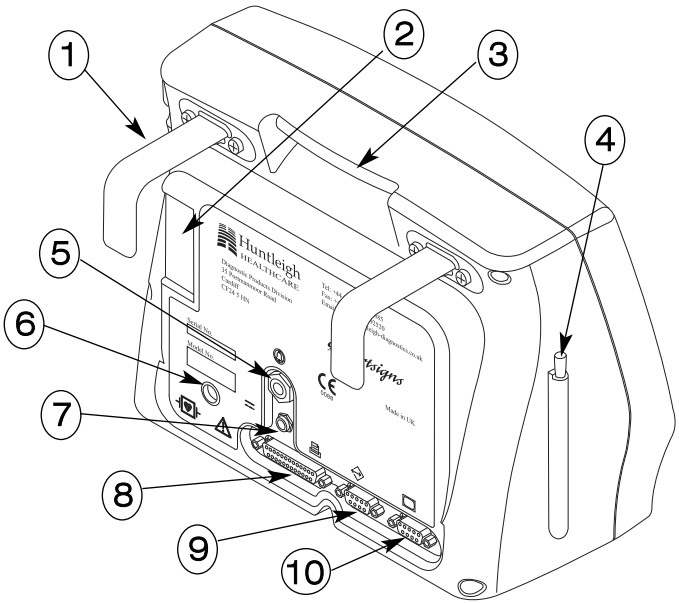
The following section describes the front and rear panel controls and facilities.

Key	Description
1	Colour graphic display with integrated touch screen
2	Temperature probe holder
3	ECG input
4	NiBP input
5	SpO2 input
6	Temperature input

5.1.1 Controls & Indicators

Symbol	Function
	ON, OFF / Stand by
	External dc supply is connected to the system.
	Battery status LED
	Start BP measurement
	Alarm suspend
	Accept selection / setting
	Cancel selection / setting
	Cursor / navigation keys
	On line HELP
	System settings: - • Volume control Up / Down • Screen brilliance • Screen contrast NOTE - Press the  button to sequence through the options, and adjust the setting with the up / down keys.

5.2 Rear Panel



Key	Description
1	Removable bed hooks (2)
2	Smartcard interface
3	Integral handle
4	Stylus
5	Nurse call output
6	Bracket fixing
7	DC input
8	Parallel printer interface
9	Serial output
10	VGA output

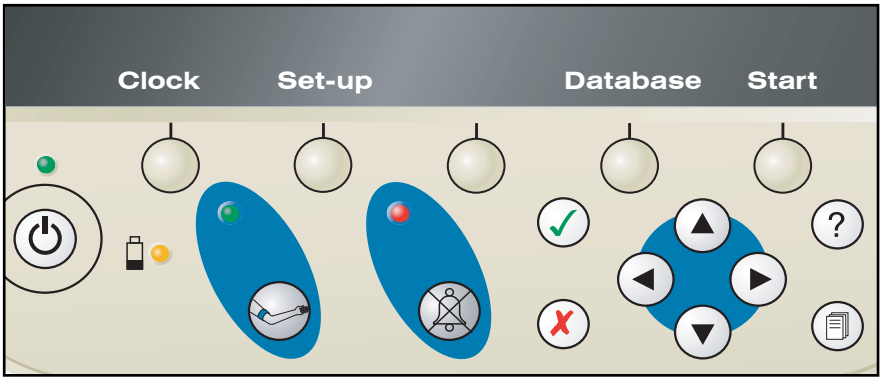
5.3 Switching On

Connect the power supply to the DC input on the rear of the unit marked ⎓ .

Attach the power cord to the power supply and connect it to a hospital grade AC outlet and switch ON.

The green LED mounted on the front of the unit will illuminate. Switch the unit ON using the ON/OFF STANDBY button.

The system will sound a short audible tone, perform a self test and display the opening screen.



Press CLOCK and follow the on screen instructions to reset the system clock.

Press SET-UP to display the system set-up options.

Press DATABASE to access the system's database.

Press START to display the application screen.

If the system does not produce the audible tone on power up, contact your service department immediately.

5.4 Charging the battery

Battery charging is automatic and occurs when the external power supply is connected to the system.

90% capacity is achieved after approximately 1.5 hours charging. Full capacity is achieved after a 16 hour charge cycle.

Battery level is indicated by a graphical symbol on the main screen.
When the battery level reduces to 15% capacity, an audible tone is produced - **the user must charge the battery immediately.**

When operating from it's internal battery pack, the amber battery status LED will be illuminated.

DO NOT incinerate the battery pack as they may explode, follow your local protocols for safe disposal.

6. Operating Modes

The system can operate in one of three modes: -

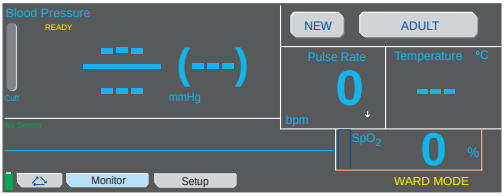
- Ward mode
- Observation mode
- Monitoring mode

6.1 Ward Mode

This mode should be selected where the basic 'spot checking' of the patient's vital signs are being undertaken and is intended for use on multiple patients.

Ward mode provides the user with a NiBP, Temperature and an SpO2 monitoring capability.

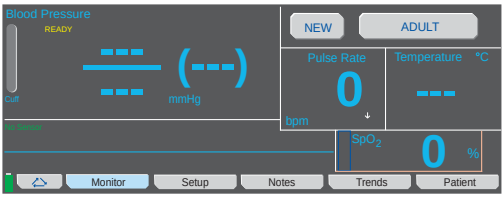
Patient status is displayed numerically on the system's screen along with the SpO2 waveform.



6.2 Observation Mode

This mode is usually selected for medium to long term monitoring of single patients

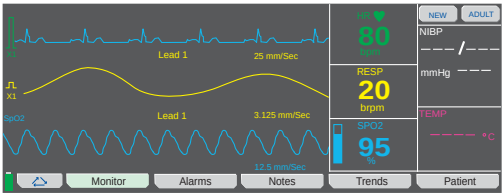
Observation Mode (OBS) provides the same monitoring capability as Ward mode but includes automatic annotation facility combined with a storage and trend capability and full function alarms.



6.3 Monitoring Mode

This mode is selected where long term monitoring is required.

Monitoring Mode provides the user with a NiBP, ECG, Respiration, SpO2 and Temperature monitoring capability.



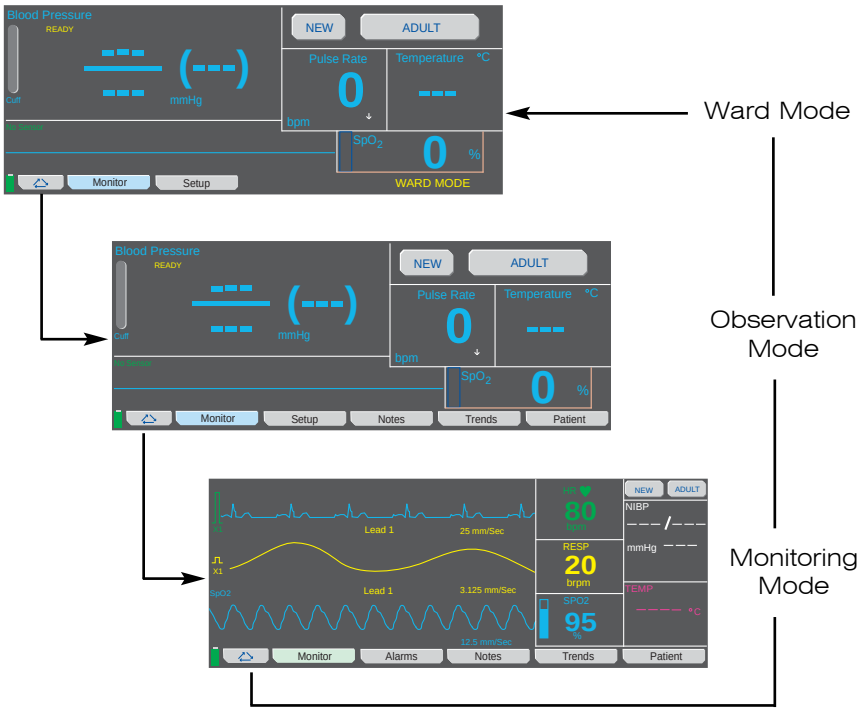
Information is displayed in a conventional format with waveforms for the ECG, Respiration and SpO2 signals.

This mode provides advanced features such as: -

- Automatic annotation.
- Numerical trend.
- Patient data storage and retrieval
- Full function alarms

6.4 Switching between modes

Press the mode button  to switch between modes: -



6.4.1 Selecting stand by or switching the unit OFF

Press the ⏻ button and select either: -

STANDBY to place into standby mode.

POWER OFF to switch the system OFF.

Or CANCEL to return to the application screen.

To restart the system from STAND BY, press the ⏻ button.

7. Patient Group Selection

Patient group must be checked and adjusted (if necessary) *before* the start of any monitoring session.

Press the ADULT (paediatric or neonatal) area of the screen to sequence through the patient groups.

Selecting a particular patient group sets the appropriate operating modality including alarm settings, target inflation pressures and signal processing techniques.

7.1 Registering a Patient

This facility is not available in WARD MODE.

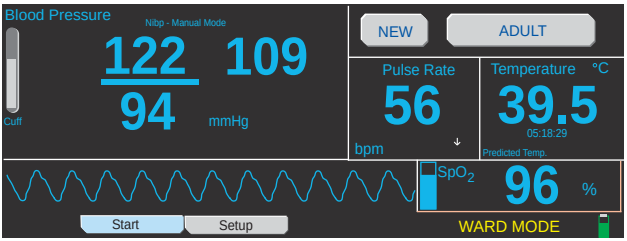
7.2 Discharging a Patient

Pressing the NEW TAB area of the screen discharges the patient from the system.

In WARD MODE, pressing the NEW TAB clears the screen of any previous readings.

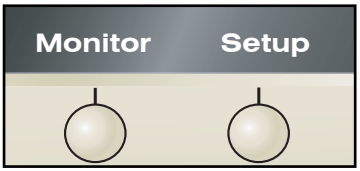
8. Screen layout - Ward Mode

The application screen is organised into a series of 'active zones'.



Using the touch screen, the *on screen* tabs or the programmable soft keys, the user can access the WARD MODE set-up options.

8.1 Soft key descriptions



8.1.1 Monitor

Pressing MONITOR returns the system to the WARD MODE application screen.

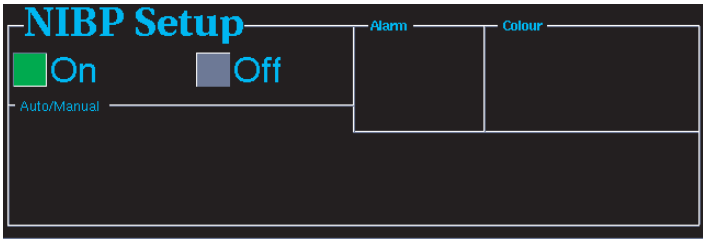
8.1.2 Setup

Pressing SET-UP will display the following set-up options:-

- NiBP
- Pulse
- TEMP
- SpO2

8.1.3 NiBP Set-up Options

Pressing the **NiBP** button displays the NiBP set-up options:-



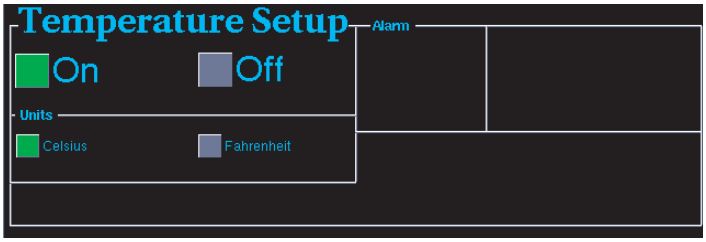
ON - switches the NiBP facility ON.

OFF - switches the NiBP facility OFF.

Press MONITOR to return to the application screen.

8.1.4 Temperature Set-up options

Pressing **TEMP** displays the temperature set-up option: -



ON - switches the TEMPERATURE facility ON

OFF - switches the TEMPERATURE facility OFF.

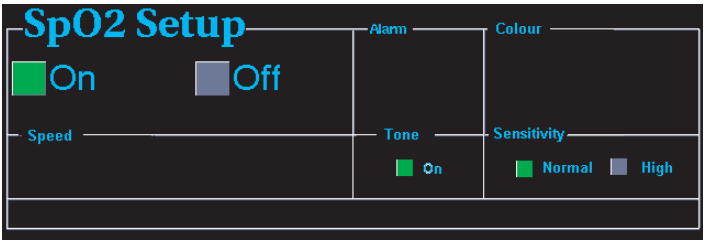
Celsius - selects °C scale

Fahrenheit - selects °F scale

Press MONITOR to return to the application screen.

8.1.5 SpO2 Set-up Options

Pressing **SpO2** displays the following set-up options: -



ON- switches the SpO2 facility ON.

OFF - switches the SpO2 facility OFF.

TONE - enables / disables the pulse tone

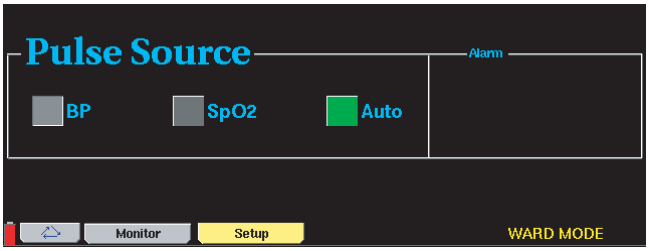
SENSITIVITY - sets NORMAL or HIGH sensitivity

Press MONITOR to return to the application screen.

8.1.6 Pulse Source Set-up Options

The system can derive the pulse rate from either the SpO2 sensor (primary source) or the BP cuff (secondary source).

Pressing **Pulse** displays the following set-up options: -



BP - selects the BP cuff.

SpO2 - selects the SpO2 sensor.

Auto - selects automatic source (BP cuff or SpO2 sensor).

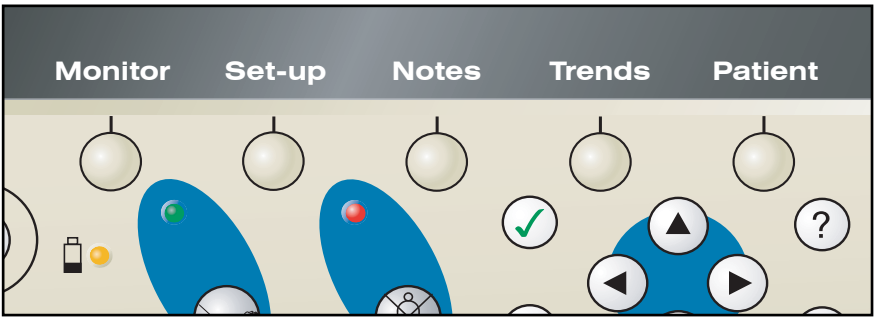
Press MONITOR to return to the application screen.

9. Screen Layout - Observation Mode

The OBSERVATION Mode operates in the same way as WARD mode but provides the operator with integrated note facility access to the patient database and user programmable alarms.

All patient measurements are stored in the systems internal memory and can be reviewed on screen at any time.

9.1 Soft key descriptions



9.2 Monitor

Pressing MONITOR returns the system to the OBSERVATION MODE application screen.

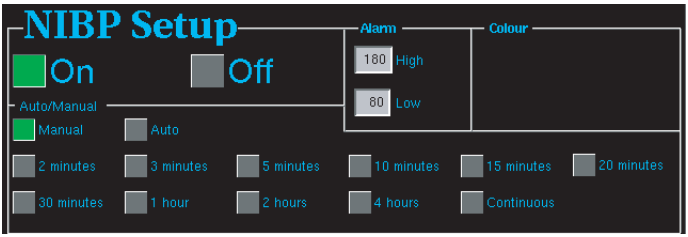
9.3 Set-up Options

Pressing SET-UP will display the following set-up options:-

- NiBP
- Pulse
- TEMP
- Alarms
- SpO2

9.3.1 NiBP

Pressing the NiBP button displays the NiBP set-up options:-



ON - switches the NiBP facility ON.

OFF - switches the NiBP facility OFF.

Auto - selects automatic BP mode.

Manual - selects manual BP mode.

NOTE : When the Automatic measurement mode is selected, the user can make measurements every 2, 3, 5, 10, 15, 20, 30, 60 mins, 2hr, 4hrs or make Continuous measurements.

If continuous measurement is selected, the system makes repeated blood pressure measurements over a 5-minute period. The cycle will not start until the cuff pressure has reduced to 10mmHg.

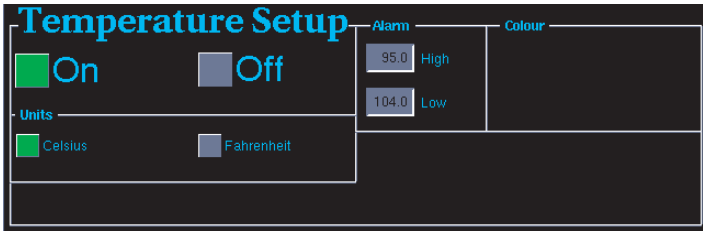
All Automatic BP measurements are initiated from the start / stop button mounted on the front panel.

ALARM - Pressing any of the alarm settings will display the alarm set-up screen. See section 9.3.5 for specific details.

Press MONITOR to return to the application screen.

9.3.2 Temperature

Pressing **TEMP** displays the temperature set-up option: -



ON- switches the TEMPERATURE facility ON

OFF - switches the TEMPERATURE facility OFF.

Celsius - selects °C scale

Fahrenheit - selects °F scale

ALARM - Pressing any of the alarm settings will display the alarm set-up screen. See section 9.3.5 for details.

Press MONITOR to return to the application screen.

9.3.3 SpO2

Pressing **SpO2** displays the following set-up options: -

ON- switches the SpO2 facility ON.

OFF - switches the SpO2 facility OFF.

TONE - enable / disable the pulse tone

SENSITIVITY - sets NORMAL or HIGH sensitivity

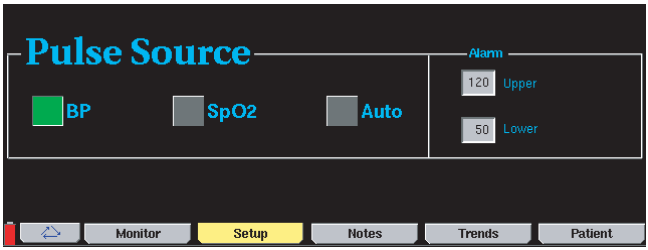
ALARM - Pressing either of the alarm settings will display the alarm set-up screen. See section 9.3.5 for specific detail.

Press MONITOR to return to the application screen.

9.3.4 Pulse Source

The system can derive the pulse rate from either the SpO2 sensor (primary source) or the BP cuff (secondary source).

Pressing **Pulse** displays the following set-up options: -



BP - selects the BP cuff as the source for pulse rate determination.

SpO2 - selects the SpO2 sensor as the source for pulse rate determination.

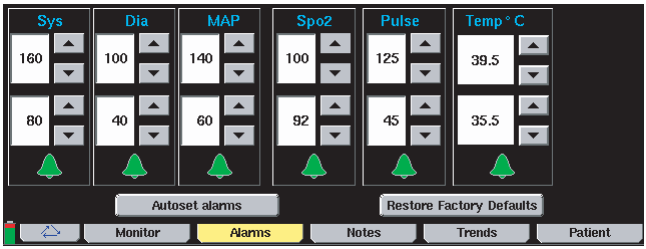
AUTO - selects automatic source (BP cuff or SpO2 sensor).

ALARM - Pressing either of the alarm settings will display the alarm set-up screen. See section 9.3.5 for specific detail.

Press MONITOR to return to the application screen.

9.3.5 Alarms

Pressing any of the alarm setting options will display the alarm set-up screen: -



Use the ▲▼ keys to adjust the limits as necessary.

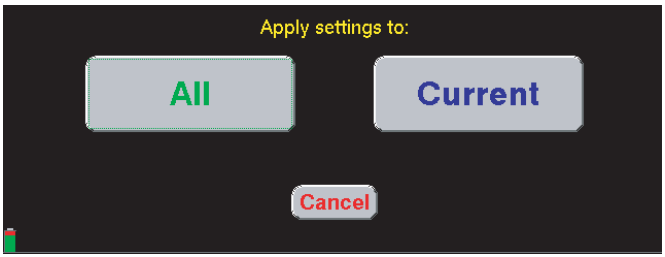
Press AUTOSET to select the AUTO SET facility.

Press RESTORE FACTORY DEFAULTS to restore factory settings.

Any of the alarms can be disabled by pressing the alarm symbol

ENABLED DISABLED

Press MONITOR, the system will display the following screen before returning to the main application screen: -



Press ALL to save the settings.

Press CURRENT to apply the settings to the current session only.

Press CANCEL to cancel selection.

9.4 Notes

The user can add notes to the monitoring session at any time.

Pressing the NOTES Tab or soft-key will display the QWERTY screen.

The user can create their own note or select from a series of pre-loaded messages by pressing the key ▼ opposite the text box on the screen.

The system will display the list of pre loaded messages.

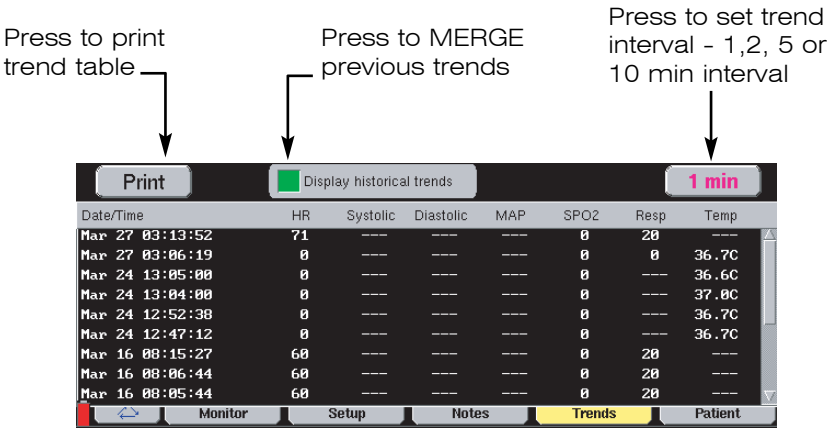
Use the ▲▼ keys to scroll the list and use the touchscreen to select as appropriate.

Press ✓ to confirm the selection.

The system will return to the application screen.

9.5 Trends

Pressing the TREND button will display the trend screen.



The trend intervals can be set to 1,2, 5, or 10 minute periods and are displayed as a series of rows and columns.

New data enters the screen from the top.

The right side of the screen contains a scroll bar, use the stylus to move the bar down to display the previous set of readings; move the bar up to return to the latest readings.

Press PRINT to print the trend report.

Press MONITOR to return to the application screen.

9.6 Patient

Pressing the PATIENT Tab displays the patient registration screen.

If the patient's name is to appear on any printed report, the patient must be registered onto the system.

Enter the patient's Surname or Ref number, or alternatively, press the  key to display the contents of the system's database.

Use the ▲▼ keys to scroll the list.

If the patient's details appear on the list, highlight it and press ✓ to accept.

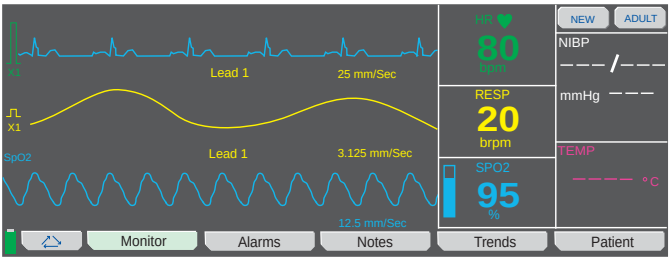
The system will display the patient details, check and press ✓ to confirm the selection

The system will return to the application screen.

Alternatively, if the patient's details are not displayed, complete the registration process by pressing the new patient TAB (soft key 4) and follow the on screen instructions.

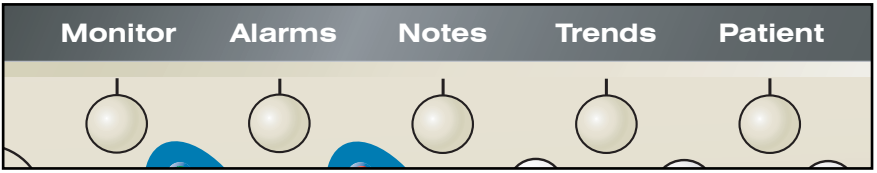
10. Screen layout - Monitoring Mode

The *Monitoring* screen displays the ECG, respiration and pulse oximetry waveforms as well as the standard numerical data.



To modify or change any of the parameters, touch any part of the screen area to display the set-up options.

10.1 Soft key descriptions



10.2 Monitor

Pressing MONITOR returns the system to the application screen.

10.3 Alarms

See section 9.3.5

10.4 Notes

See section 9.4

10.5 Trends

See section 9.5

10.6 Patient

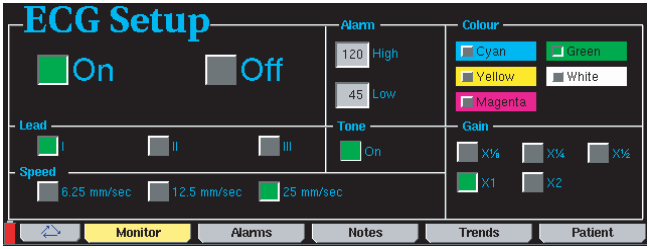
See section 9.6

10.7 Set-up options

To modify or change any of the parameters, touch any part of the screen area to display the set-up options.

10.7.1 ECG

Press the ECG waveform area to display the ECG set-up screen.



From this screen the user can select or change any of the following settings: -

ON - Switches the ECG channel ON

OFF - Switches the ECG channel OFF

LEAD - Selects lead I, II, or III

SPEED - Selects 6.25, 12.5 or 25mm/sec

GAIN - Selects X1/8, X1/4, X1/2, X1, X2

TONE - Switches the ECG beep tone ON / OFF

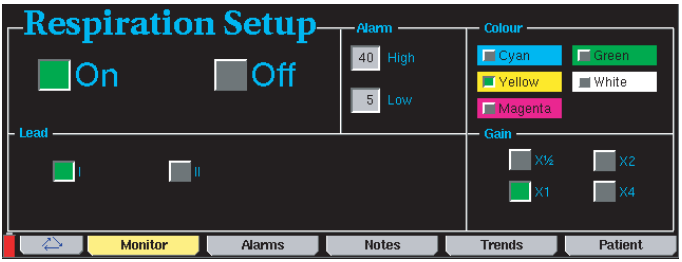
COLOUR - Change the colour of waveform, Cyan, Green, Yellow, White and Magenta

ALARM - Pressing either of the alarm settings will display the alarm set-up screen - See section 9.3.5.

Adjust the settings as required and press MONITOR to save and return to the application screen.

10.7.2 Respiration

Press the RESPIRATION waveform area to display the Respiration set-up screen.



From this screen the user can adjust any of the following settings: -

ON - Switches the RESPIRATION channel ON

OFF - Switches the RESPIRATION channel OFF

LEAD - Selects lead I or II configuration

GAIN - Selects X1/2, X1, X2, X4

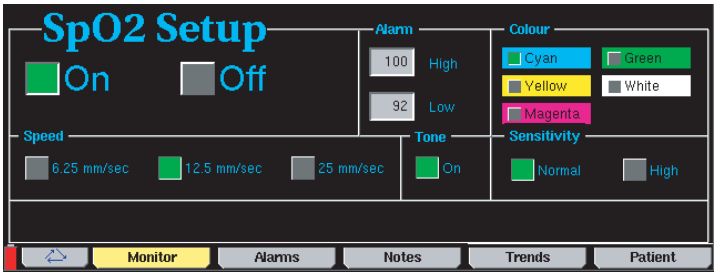
COLOUR - Change the colour of waveform, Cyan, Green, Yellow, White and Magenta

ALARM - Pressing either of the alarm settings will automatically display the alarm set-up screen - See section 9.3.5.

Adjust the setting as required and press MONITOR to save and return to the monitoring screen.

10.7.3 SpO2

Press the SpO2 waveform area to display the SpO2 set-up screen.



From this screen the user can adjust any of the following settings: -

ON - Switches the SpO2 channel ON

OFF - Switches the SpO2 channel OFF

Speed - Selects 6.25, 12.5 or 25mm/sec

Tone - Switches the beep tone ON / OFF

Sensitivity - Selects normal or high sensitivity

Colour - Change the colour of waveform, Cyan, Green, Yellow, White and Magenta

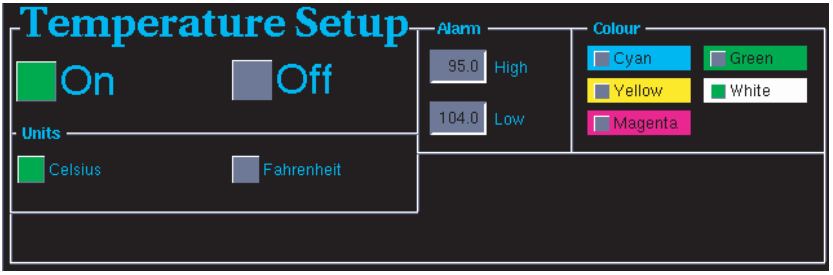
Alarm - Pressing either of the alarm settings will display the alarm set-up screen - See section 9.3.5.

Adjust the setting as required and press MONITOR to save and return to the application screen.

10.7.4 Temperature

Press the Temperature area of the screen to display the Temperature set-up screen.

From this screen the user can adjust any of the following settings: -



ON - Switches the channel ON

OFF - Switches the channel OFF

UNITS - Selects °C or °F

COLOUR - Change the colour of the display, Cyan, Green, Yellow, White and Magenta.

ALARM - Pressing either of the alarm settings will display the alarm set-up screen - See section 9.3.5

Adjust the setting as required and press MONITOR to save and return to the application screen.

10.7.5 NiBP

See section 9.3.1

11. ECG Monitoring

IMPORTANT: *Always set the patient group before starting a procedure, and ensure that there are sufficient consumables available for the monitoring session.*

NOTE - *This facility is not available in either WARD or OBSERVATION modes.*

11.1 Warnings

Check all cables before operation.

All ECG cables, including fly leadsets, must be *"straight through"* type. (i.e. they must not contain resistors).

Only use the patient cables supplied with the system.

DO NOT connect any NON-ISOLATED accessories to the system when connected to a patient.

The system provides an isolated circuit for the ECG capability, ensure that the conductive parts of the ECG patient cable do not contact any other conducting parts including ground.

Total leakage currents of the system must not exceed the limits specified by IEC 60601-2-27:1994

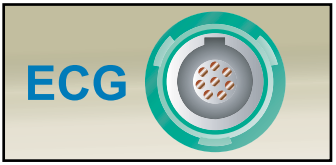
When using ES equipment, do not place the ECG electrodes near the grounding plate of the ES equipment.

If the patient has a pacemaker, a qualified healthcare professional must supervise the procedure at all times. The rate meter may count the 'pacer' rate during an arrest or arrhythmia - in this situation, DO NOT rely upon the system's alarms.

Check the expiry date of the ECG electrodes, if the date has expired, discard the electrodes.

11.2 Monitor Connections

Connect the patient cable to the front panel socket.



11.3 Patient preparation / connection

Connect the ECG electrodes to the lead wires before attaching to the patient.

For optimum performance, we recommend using high quality silver / silver chloride electrodes.

Prepare the electrode site by cleaning with an alcohol swab.

Remove any hair from the electrode site.

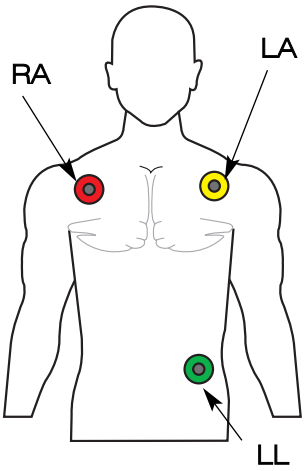
11.4 Adult Electrode Placement

Place the electrodes into positions shown.

Place the Red electrode RA below the right clavicle.

Place the Yellow electrode LA below the left clavicle.

Place the Green electrode LL under the 6th rib on the lower left area of the abdomen.



Connect the lead wires to the patient cable.

Do not allow the ECG cable to place stress on to the ECG electrodes, as this will produce poor quality recordings.

The ECG waveform will now be displayed on the screen.

11.5 Neonatal Electrode Placement

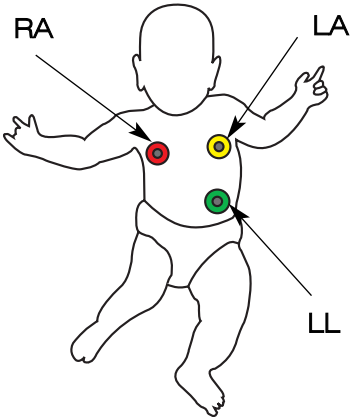
Place the electrodes into positions shown.

Place the Red electrode RA under the right clavicle.

Place the Yellow electrode LA under the left clavicle.

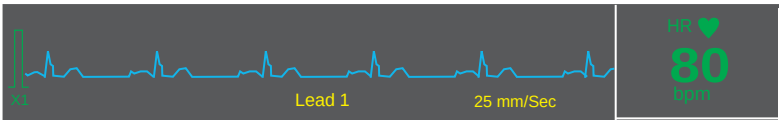
Place the Green electrode LL under the 6th rib on the lower left of the abdomen.

Connect the lead wires to the patient cable.



11.6 The ECG Waveform

The ECG waveform is displayed on the upper part of the screen with the HR and pulse display appearing along side.



The flashing symbol ♥ is synchronised with each detected heartbeat.

Press the key and ▲▼ keys to set the appropriate volume level.

11.7 Error Messages

Error Message	Cause	Corrective action
ASYSTOLE	System does not detect an ECG signal	Attend to patient
LEAD OFF	The ECG leads becomes detached from the patient.	Check and replace leads
PACER	System has detected pacing pulses	Close observation of the patient is required

12. Respiration Monitoring

IMPORTANT: *Always set the patient group before starting a procedure, and ensure that there are sufficient consumables available for the monitoring session.*

NOTE - *This facility is not available in either WARD or OBSERVATION modes.*

12.1 Warnings

The system uses the ECG patient cable and electrode positions to determine the respiration rates (RR). Take the same precautions as for ECG monitoring.

All ECG cables, including fly leadsets, must be *"straight through"* type. (i.e. they must not contain resistors).

Only use the patient cables supplied with the system.

12.2 Monitor Connections

Follow the same connections as ECG monitoring.

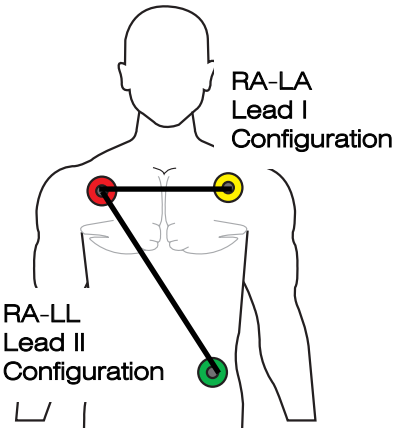
12.3 Patient preparation / connection

Follow the same patient preparation as for ECG monitoring.

12.4 Respiration Measurement

The system uses a transthoracic method to determine the respiration rate.

This method is particularly useful as it detects changes in impedance between the RA and LL electrodes (lead II selection) caused by the movement of the chest.



NOTE: Some patient groups may require lead I selection.

12.5 The Respiration Waveform

The respiration waveform is displayed in the central part of the screen with the RR appearing along side it.

12.6 Error Messages

The following section provides the user with a description of ERROR massages, which may be displayed during Respiration measurement.

Error Message	Cause	Corrective action
LEAD OFF	Lead disconnected from patient	Reconnect lead
APN	No respiration detected by the system	Attend to patient

13. Blood Pressure Monitoring

The system measures systolic (Sys), diastolic (Dia) and mean arterial blood pressure (MAP) using an Oscillometric technique.

13.1 Patient Groups

The NiBP facility can measure blood pressure in three patient groups. The groups are defined below according to the amendment to ANSI/AAMI SP10-1996: -

- **Neonatal** - intended for infants 28 days or less of age if born at term (37 weeks gestation or more); otherwise, up to 44 gestational weeks.
- **Paediatric** - Intended for larger infants and children from 29 days to 18 years in paediatric care.
- **Adult** - Intended for persons greater than 18 years of age.

Group	Systolic	Diastolic	Mean	Pulse Rate
Adult	30 - 260	20 - 235	20 - 255	30 - 220
Paediatric	30 - 160	15 - 130	15 - 140	30 - 220
Neonatal	25 - 120	10 - 105	10 - 110	30 - 220

13.2 Warnings

Always select the correct size cuff for accurate measurement. Do not over tighten the cuff.

Do not place the cuff on a limb, which is being used for the delivery of intravenous infusion or therapy.

Do not place the cuff on the same limb, which is being used for Sats measurement.

Do not place the cuff over clothing.

Do not kink or compromise the hose.

Prolonged inflation and measurement cycling may cause Ischemia or neuropathy; regularly check the cuff position and level of comfort. If continuous monitoring is being undertaken , check the patients extremity for signs of impeded blood flow.

The unit will operate normally when attached to a patient who may be connected to a defibrillator. The unit is protected against defibrillator discharge.

13.3 Cuff selection

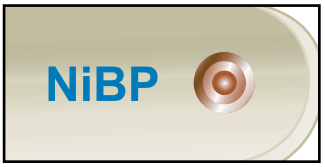
The following chart can be used as a guide to aid cuff selection: -

Re-useable cuffs		
Cuff type	Range Cm	Part No.
Infant	10 - 19	ACC VSM 51
Child / small adult	18 - 26	ACC VSM 52
Adult	25 - 35	ACC VSM 53
Large arm	33 - 47	ACC VSM 54
Thigh	44 - 66	ACC VSM 55
Disposable cuffs		
Cuff Type	Range	Part No.
Neonate 1*	3 - 6	ACC VSM 56
Neonate 2*	4 - 8	ACC VSM 57
Neonate 3*	6 - 11	ACC VSM 58
Neonate 4*	7 - 13	ACC VSM 59
Neonate 5*	8 - 15	ACC VSM 60
Infant	8 - 15	ACC VSM 61

Disposable cuffs		
Cuff Type	Range	Part No.
Child	12 - 19	ACC VSM 62
Small adult	17 - 25	ACC VSM 63
Adult	23 - 33	ACC VSM 64
Large arm	31 - 40	ACC VSM 65
Thigh	38 - 50	ACC VSM 66
Blood Pressure Hoses		
4' Straight		ACC VSM 46
10' Straight		ACC VSM 47
10' Coiled		ACC VSM 48
4' Straight Neonate		ACC VSM 49
4' Coiled		ACC VSM 50
* Must use NiBP hose # ACC VSM 49 for neonates		

13.4 Monitor Connections

Connect the NiBP hose to the front panel socket marked NIBP and connect the Cuff to the free end of the hose.

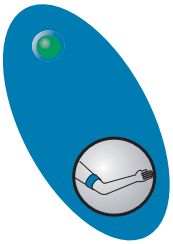


13.5 Patient preparation / connection

Carefully wrap the appropriate sized cuff around the measurement site.

Adults / Paediatric patients	Upper arm or ankle.
Neonatal patients	Upper arm or thigh.

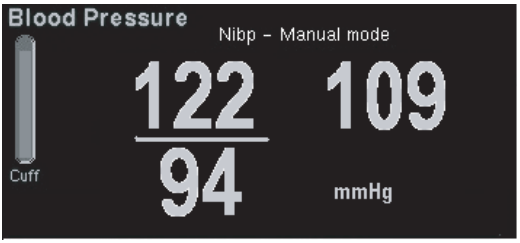
13.6 Manual BP Measurements



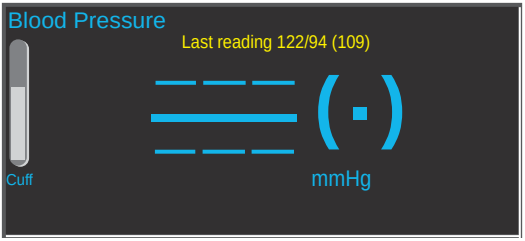
Press the START NiBP button to start a measurement.
The green LED will illuminate.

The cuff pressure graphic will change as the cuff pressure increases (not available in Monitoring mode).

When the measurement is complete, the system will sound a tone and display the SYS /DIA and MAP readings on the screen (Ward / Observation screen shown).



The measurement is displayed for two minutes and then transferred to the last reading section of the display



(NOTE: This facility is not available in MONITORING mode).

13.7 Automatic BP Measurements

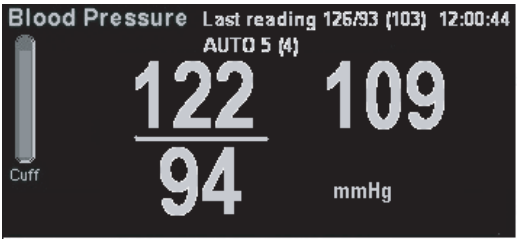
NOTE The system must be set to AUTO mode to be able to make automatic BP measurements.

See section 9.1.3 for AUTO mode set-up options.

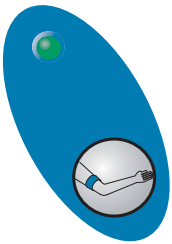
Press the START NiBP button to start a measurement. The green LED will illuminate.

When the system has completed an automatic measurement, the system sounds a tone and displays a status message which indicates the measurement mode, time period between measurements and the elapsed time.

E.g. AUTO 5 (4) indicates that the system is set to make automatic measurements every 5 minutes and that 4 minutes have elapsed since the last reading.



13.8 Cancelling a BP Measurement



Measurements can be cancelled at any time by pressing the NiBP start / stop key.

13.9 NiBP Error Messages

Error Message	Cause	Corrective action
Air Leak	Loose connections or damaged cuffs	Check hose, cuff connections & cuffs for leaks
Cuff not connected	Cuff not connected to the system	Fit cuff
Kinked Hose Overpressure	NiBP hose kinked Internal pressure valve tripped	Straighten hose Power cycle unit
Weak Pulses	Patient condition / cuff placement	Check patient condition
Excessive patient motion	Patient not at rest	Restrict patient movement
No Pulses detected	Patient condition / cuff placement	Check patient condition
Valid BP not found	System unable to complete measurement	Retry measurement
Kinked or neonatal hose	High pressure detected	Check hose and fit the correct type of cuff

13.10 Cleaning the NiBP cuffs

Gently wipe the cuff with a cloth dampened with a suitable cleaning solution. Thoroughly wipe off excess cleaning solutions.

Do not allow water to enter into the cuff.

Approved cleaning solutions include: -

Common hospital disinfectants including, Clorox®, liquid bleach (1:10 solution of Clorox® /water), isopropyl alcohol. Lysol® solution, Phisorex®, Quatricide®, Virex® and Vesphene®.

13.11 Cleaning the NiBP Tubing

Gently wipe the cuff with a cloth dampened with a suitable cleaning solution (mild detergent solution).

Thoroughly wipe off excess cleaning solutions.

DO NOT use any of the following cleaning solutions as they may cause permanent damage to the hose assembly: -

Butyl alcohol, Denatured ethanol, Freon™, Mild chlorine bleach solution, Isopropyl alcohol, Trichloroethane, Trichloroethylene, Acetone, Vesphene II, Enviroquat®, Staphene®, Misty®, Glutaraldehyde.

14. SpO2 Monitoring

14.1 Warnings

The Dolphin™ oximetry sensors are indicated for use in continuous non-invasive monitoring of arterial oxygen saturation and pulse rate determination.

Use only Dolphin™ oximetry sensors with this range of monitoring systems. Using other sensors with this system may cause patient injury, inaccurate reading or damage to the system.

Check the sensor at least every 4 to 8 hours and reposition every 24 hours.

Avoid applying the senor to oedematous or fragile tissue.

Excessive patient movement, ambient light, electromagnetic interference, dysfunctional haemoglobin, low perfusion, intra-vascular dyes, nail polish or long or artificial nails may affect the performance of the sensor and present inaccurate results.

Do not use the sensor if it is damaged, the sensor is contraindicated if the patient exhibits any reaction to the application of adhesive tape.

Note - The material used in the manufacture of the sensor contain no natural latex protein.

DO NOT use this equipment in an MRI environment.

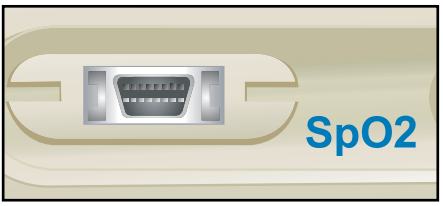
A range of sensors are available for use on the Smartsigns® series, the following table details the sensor type and the appropriate patient group: -

Sensor type	Patient group	Part No.
Dolphin 210	Adult re-useable sensor	ACC VSM 07
DD520*	Disposable adult sensor	ACC VSM 08
DD560	Disposable Infant / Neonatal sensor	ACC VSM 09
DD 320	Adult multi site Y sensor	ACC VSM 84
DD 360	Neonate multi site Y sensor	ACC VSM 85

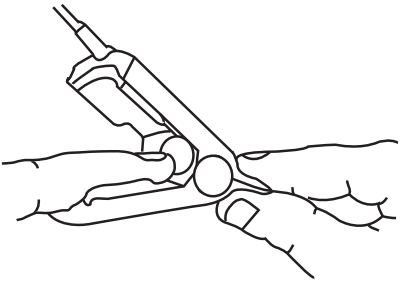
** The DD520 sensor (Adult / Paediatric model) can be used on adult and paediatric patients who are > 30 KG.*

14.2 Monitor Connections

Connect the sensor to the extension cable, and connect the assembly to the to the front panel socket marked SpO2.



14.3 Patient preparation / connection



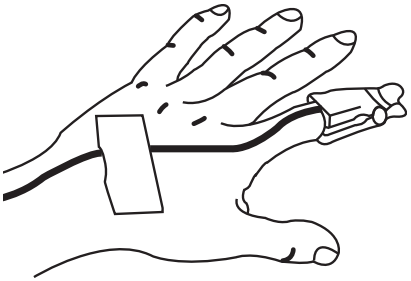
Insert the patient's digit to the sensor.

The preferred digit is the index finger (adult).

The digit is correctly inserted when the tip of the finger touches the rear of the guideposts.

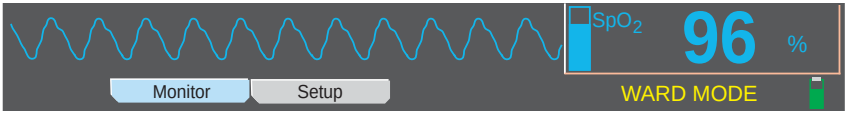
Ensure the sensor cable extends along the top of the patient's hand. Tape the cable in place if necessary.

After a short while, the system will display the saturation waveform and saturation level (%).



14.4 The SpO2 Waveform

The SpO2 waveform is displayed on the lower part of the screen with the saturation level appearing along side it.



The 'pleth' bar graph provides the operator with an indication of signal quality.

Press the  key and the up / down keys to set the appropriate volume level.

The beep tone is synchronised with the pulse rate and alters frequency according to the saturation level - the higher the saturation level, the higher the pitch.

14.5 SpO2 Error messages

The following section provides the user with a description of ERROR messages, which may be displayed during SpO2 measurement.

Error Message	Cause	Corrective action
No sensor	No sensor connected to system	Connect the sensor to the system
Sensor OFF patient	Sensor detached from patient	Re apply sensor to patient
Sensor defective	System detected a defective sensor	Replace sensor
Low perfusion	Patient perfusion is too low	Check patient status and patient connection
Pulse search	Hardware is being adjusted for best signal	Change site or sensor
Too much ambient light	Excessive light for the sensor to function	Reduce the ambient level around the patient
Insufficient signal	Patient perfusion is too low	Check patient status and patient connection

14.6 Cleaning the sensor

 *Remove the sensor and cable from the unit before cleaning.*

Always clean the sensor between use and patients; wipe the sensor surfaces with a soft cloth moistened with warm water, mild soap solution or isopropyl alcohol.

Contact Huntleigh Healthcare for additional cleaning details.

15. Temperature Measurement

NOTE: The temperature measurement should only be used with adult and paediatric patients (age 3 and above).

Always use a new probe cover between measurements.

Oral measurements are displayed within 4 seconds.

Axillary measurements are displayed within 16 seconds.

15.1 Monitor Connections

Connect the temperature probe to the front panel socket marked TEMP and place the sensor into its holder on the side of the unit.

Temperature measurements start automatically when the sensor is removed from its holder.

Hold the probe by its handle and withdraw the sensor from its holder,

Carefully slide the tip into a new probe cover until it 'snap fits' into position.

DO NOT touch the tip or the ejector button.

15.2 Oral Temperature Measurements

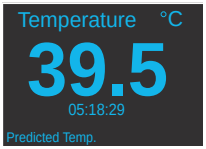
NOTE - The Oral temperature probe is colour coded BLUE.

Carefully insert the probe tip into the patient's opened mouth, near either of the sublingual pockets.

Hold the probe in position throughout the measurement.

When the measurement is complete, the system will sound an audible 'tone' and display the measurement on the screen.

Each temperature measurement is time stamped.



After completing the measurement, carefully remove the probe from the patient's mouth and eject the probe cover by pressing the eject button.

Replace the temperature probe into its holder. Wait at least five seconds before making the next measurement.

Follow local instructions regarding disposing of the used probe cover.

15.3 Axillary Temperature Measurement

Axillary measurements are accurate only for children under the age of four.

Ensure the Oral probe is connected to the system.

Hold the probe by its handle and withdraw the sensor from its holder.

Carefully slide the tip into a new probe cover.

DO NOT touch the tip of the sensor.

Lift the patient's arm and place the probe tip into position. The correct position is as high as possible in the axilla.

Position the patient's arm at their side so that the probe is held in position throughout the measurement cycle.

If necessary, hold the probe in position throughout the measurement.

When the system has completed the measurement, the system will sound an audible tone and display the measurement on the screen.

After completing the measurement, carefully remove the probe and eject the probe cover by pressing the eject button.

Replace the temperature probe into its holder.

Follow local instructions regarding disposing of the used probe cover.

15.4 Temperature Error Messages

The following section provides the user with a description of ERROR messages, which may be displayed during Temperature measurement.

Error Message	Cause	Corrective action
No sensor	Sensor not detected	Connect sensor to unit
Time out	Predictive time exceeds 60 sec	Replace sensor in holder and restart the measurement
Loss of contact	Sensor moved	Replace sensor in holder and restart the measurement

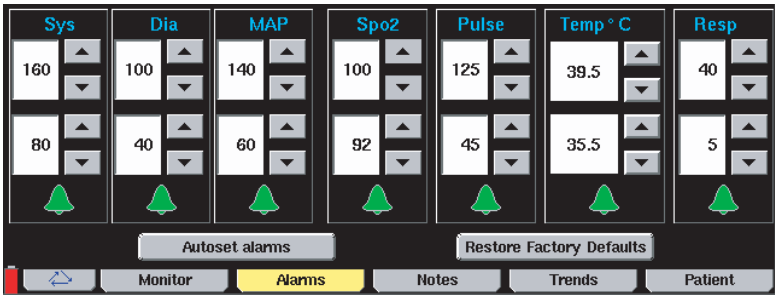
16. Alarms

Alarms are available in the OBSERVATION and MONITORING modes only and are applied to the following parameters: -

- Pulse rate / Heart rate
- Respiration rate (MONITORING mode only)
- Blood pressure - SYS, DIA and MAP
- O2 Saturation level
- Temperature

To change any of the settings, press the ALARM Tab or appropriate soft key or the alarm section of the set-up screens.

The system will display the ALARM set-up screen.



Use the ▲▼ area of the screen to adjust the setting as necessary.

The AUTOSET facility allows the user to customise the alarm settings for the patient. When a stable waveform or reading has been established, pressing AUTO SET sets the following limits: -

- NIBP +/- 20% of current or last measurement.
- Heart rate / pulse rate +/- 30% of current / last reading.
- Temperature +/- 3% of current / last reading.

Press MONITOR to confirm selection and return to the application screen.

16.1 Adjusting The Audible Level Of The Alarms

The audible levels can be adjusted by pressing the  key and the ▲▼ keys as appropriate.

16.2 Alarm priorities

The alarms are classified according to their severity - high, medium or low priority.

16.2.1 High priority signal - warning signal

A high priority alarm indicates that an ***immediate*** operator response is required. The high priority alarm is both audible and visual. The high priority alarm is repeated every 10 seconds.

16.2.2 Medium priority signal - cautionary signal

The medium priority alarm is a signal indicating that a ***prompt*** operator response is required. The medium priority alarm is both audible and visual. The medium priority signal is repeated every 25 seconds.

16.2.3 Low priority signal - attention signal

The low priority alarm indicates that operator ***awareness*** is required. The low priority alarm comprises of a ***continuously*** displayed visual indication.

The following table describes the priority of the various alarms: -

Alarm type	Priority Level		
	High	Medium	Low
ECG			
Asystole	■		
Alarm limit exceeded	■		
Pacer detected	■		
Lead off		■	

Alarm type	Priority Level		
	High	Medium	Low
Respiration			
Alarm limit exceeded	■		
Apnoea	■		
Lead off		■	
NiBP			
Alarm limit exceeded	■		
Over pressure	■		
Loose cuff		■	
BP Pulse too low		■	
Air leak		■	
SpO2			
Alarm limit exceeded	■		
Low perfusion	■		
Sensor defective		■	
Too much ambient light		■	
Insufficient signal		■	
Too much ambient light		■	
Insufficient signal		■	
Pulse search			■
No sensor			■

Alarm type	Priority Level		
	High	Medium	Low
Temperature			
Alarm limit exceeded	■		
Time out		■	
Loss of contact		■	
No probe			■
General			
Battery Low			■

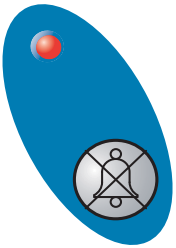
16.3 Alarm Ranges

The following table provides a list of the ranges and the default settings: -.

Parameter		Adult	Paediatric	Neonatal
Heart rate				
Heart rate BPM	High	60 - 250 (120)	100 - 300 (120)	100 - 300 (180)
	Low	30 - 120 (45)	30 - 150 (50)	30 - 200 (80)
NiBP				
Systolic mmHg	High	70 - 240 (160)	40 - 180 (160)	40 - 180 (120)
	Low	50 - 150 (80)	15 - 130 (80)	15 - 130 (60)
Diastolic mmHg	High	40 - 130 (100)	50 - 100 (100)	50 - 100 (60)
	Low	30 - 120 (40)	10 - 50 (40)	10 - 50 (30)

Parameter	Adult	Paediatric	Neonatal
Spo2 (% saturation)			
High	80 -100 (100)		
Low	80 - 99 (92)		
Temperature			
High °C or °F	35 - 43 or 95 - 110 (39.5)		
Low °C or °F	26 - 38 or 80 - 100 (35.5)		
Respiration			
High RPM	10 - 100 (40)	15 - 150 (40)	30 - 200 (60)
Low RPM	5 - 30 (5)	5 - 40 (5)	5 - 50 (5)

16.4 Suspending the alarms



The operator can suspend an alarm by pressing the status box on the display or the ALARM SUSPEND button on the unit front panel.

The alarms will remain suspended for 2 minutes unless a further alarm violation occurs.

17. Care of your equipment

Although the *Smartsigns® Assist* is robust and has been designed to withstand normal clinical use, the unit contains delicate components and accessories, which should be handled and treated with care.

We recommend that the system is included into an annual calibration / maintenance programme where the accuracy of the system is checked against the manufacturers' specifications.

If any part of the system appears to be damaged, the system should be returned to your service centre for repair.

The system, excluding the display, can be wiped with a soft disposable cloth dampened with a mild detergent and warm water solution, avoid the electrical contacts and connectors. Do not allow any fluid to seep into the system.

Ensure the unit is completely dry before use.

The display can be wiped with a soft dry tissue.

18. Disinfecting

The accessories can be disinfected if required as per local infection control policies or wiped with a wipe or swab dampened with Isopropyl alcohol 70% w/v.

Phenolic, detergent based disinfectants containing cationic surfactants, ammonia based compounds, or antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the system, as permanent damage will result.

19. Trouble Shooting

The following table is intended to help the user in the event of encountering problems: -

Problem	Cause	Solution
System will not switch ON	Batteries discharged No power connected to system	Charge batteries Connect power
Unit 'beeps' continuously	Low battery condition	Charge batteries
Touch screen does not respond	Touch screen requires calibration	Recalibrate touch screen
NiBP Measurements		
Cuff does not inflate	Cuff inflate period greater than 45 seconds	Check cuff and tube for leaks
Cuff does not fully deflate	Check connections for obstructions	Remove obstructions
Overpressure in Cuff	Excessive patient movement	Ensure patient is resting
No pulse rate detected	Facility turned OFF in software	Turn facility ON
	Poor site of BP cuff	Reposition cuff
ECG Monitoring		
No ECG complex displayed on the screen	ECG switched OFF Poor electrode contact	Switch ON Re position electrode(s)
ECG complex too large or too small	Incorrect ECG gain setting	Adjust gain setting in set up
	Incorrect lead selection	Select alternative lead (I, II or III)

Problem	Cause	Solution
	RESP Monitoring	
No RESP complex displayed on the screen	RESP switched OFF Poor electrode contact	Switch ON Re position electrode(s) or try selecting alternative lead selection (I orII)
RESP complex too large or too small	Incorrect RESP gain setting	Adjust gain setting in set up
SpO2 Monitoring		
No SpO2 trace set-up Poor trace	Trace disabled in set-up screen Low perfused site Poor fitting sensor	Switch trace ON in Re-position sensor Re-position sensor
	Too much ambient light	Remove or reduce light
No Beep tone	Beep tone turned OFF in software	Set beep tone ON
Temperature Monitoring		
No temperature measurement	Facility turned off in set-up Sensor 'timed out'	Turn ON facility Replace sensor to unit to reset timer and start the measurement again
Temperature displayed in the wrong scale	Poor sensor site Incorrect set-up	Re-position sensor Modify scale setting in software
Printing		
No reports can be printed	Incorrect print set-up	Modify print output in set-up

If trouble persists, consult your service centre or Huntleigh Healthcare Diagnostic Products Division using the contact details at the rear of this manual.

20. Warranty & service

Huntleigh Healthcare Diagnostic Products Divisions' standard terms and conditions apply to all sales. Copies are available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

If for any reason the system 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 - Assist'.

For further details, refer to NHS document HSG(93)26 (UK only). Huntleigh Healthcare reserve the right to return product that does not contain a decontamination certificate.

A service manual is available for the system and contains service information, parts lists and faultfinding guidelines.

The service manual can be obtained by contacting your local supplier or: -

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

Tel: +44 (0) 29 20496793 - Service (24hr answer machine)
Tel: +44 (0) 29 20485885
Fax: +44 (0) 29 20492520

Email: sales@huntleigh-diagnostics.co.uk

service@huntleigh-diagnostics.co.uk

21. Technical Data

Physical	
Size	93 x 380 x 250mm
Weight	3.2 Kg
Environmental	
Operating temperature	+10°C to +30°C
Storage temperature	-10°C to +40°C
Atmospheric pressure range	700hpa to 1060hpa
Relative humidity	90% non condensing
Electrical	
NiMH battery pack	12V @ 4A/Hr
Fuse type / rating	Internal thermal fuse 70°C (Resettable)
	Internal T3.5A (Resettable)
Regulatory compliance	
Complies with	EN60601-1: 1990
	UL2601-1
	CSA22.2 No 601-1
EN60601-1 Classification	
Type of protection against electric shock	Class 1 (when operated via supplied PSU) internally powered
Degree of protection against electric shock	Type CF 

EN60601-1 Classification	
Degree of protection against ingress of liquids	IPX0
Degree of safety in presence of flammable gases	Not suitable for use in the presence of flammable gases
Mode of operation	Continuous
Power adaptor	
Input voltage	100 - 240VAC
Input frequency	50 - 60 Hz
Inrush current	<16A
Input current	0.34 - 0.62A
Output voltage	20V DC
Output current	Regulated to 2A max
Operating temperature	+10°C to +30°C
Storage temperature	-10°C to +40°C
Degree of protection against the ingress of fluid	IP40
Mode of operation	Continuous
Degree of protection presence of flammable anaesthetics	Not suitable for use in the presence of flammable anaesthetics
Dimensions	134mm x 55mm x 80mm

Safety	
Earth leakage current	<0.5mA
Patient leakage current	<10μA DC, <100μA AC
Protection class	Class 1
Safety standards	EN60601-1, UL2601-1

NiBP	
Method	Oscillometric technique
Accuracy	Meets ANSI/AMMI SP10-1996
Patient groups	Adult, Paediatric and Neonate
Operating mode	Manual or automatic modes
Automatic cycle	Continuous, 2, 3, 5, 10, 15, 20, 30, 60, 120 minutes and 4 hrs
Cuff type	Full range of reusable and disposable 'latex free' cuffs
Hose type	Reusable type, 10' long
Pulse rate range	30 - 240 bpm
Accuracy	Meets ANSI/AMMI SP10-1996

	Default cuff inflation target pressure	Maximum cuff inflation target pressure	Over pressure limit
Adult	160mmHg	270mmHg	280mmHg
Paediatric	120mmHg	170mmHg	200mmHg
Neonate	90mmHg	132mmHg	141mmHg

SpO2	
Sensor type	Adult reusable sensor using dual LED and digital signal processing technology
LED Wavelength	Red 660 ± 2nm IR 905 ± 10nm
Extension cable	2.4M
SpO2 Range (Functional)	0% to 100%
Resolution	0.1%
SpO2 and Pulse rate accuracy	
SpO2 (Functional)	No motion and normal perfusion
Adult Paediatric >30 Kg	70 - 100 ± 2 % 0 - 69 Unspecified
Pulse rate (bpm)	No motion and normal perfusion
Adult Paediatric >30 Kg	30 - 240 bpm (Adult Paediatric and Neonatal) ± 3 bpm
SpO2 (Functional)	Motion or low perfusion <0.2%
Adult Paediatric >30 Kg	70 - 100 ±3% 0 - 69 unspecified
Pulse rate (bpm)	Motion or Low perfusion <0.2%
Adult Paediatric >30 Kg	30 - 240 ± 5 bpm

Temperature	
Method	Microprocessor and thermistor based system designed for Oral, Axillary and Rectal temperature measurements
Operating modes	Predictive
Oral probe ID	Blue with 4' cable
Rectal probe ID	Red with 4' cable
Measurement Times predictive	
Oral predictive	4 secs
Paediatric Axillary	8 to 16 secs
Rectal	15 secs
Accuracy	+/-0.36°C (+/-0.2°F)
Ambient temperature range	16 to 40°C (60.8°F to 104°F)
Patient temperature range	28.9°C to 42.2°C (84°F to 108°F)
Predict temperature range	34.5°C to 42.2°C (94°F to 108°F)

ECG	
Classification	Type CF
Defibrillator protection	Yes
No of leads	I, II and III

ECG	
Lead type	Zero ohm, 3 lead with detachable chest leads terminated with 'pinch clip' electrodes
Bandwidth	0.7Hz to 30Hz
Input impedance	>10MΩ
Gain	Satisfies EC13
Max input offset voltage	+/- 300mV
CMMR	140dB
Input signal range	0.15mV to 5mV
Heart rate range	20 to 350bpm
Resolution	1bpm
Accuracy	+/- 1bpm

Respiration	
Method	Impedance technique via ECG electrode placement. System incorporates advanced adaptive cardio artefact rejection filter
Leads	Lead II default Lead I user selectable
Range	0 to 180 Breaths per min
Accuracy	+/- 2 Breaths per min
Bandwidth	0.5 to 3Hz
High impedance indication	