INSTRUCTIONS FOR USE

Team3 USA

Fetal Monitor

777732-6 2025-10

HUNTLEIGH

A MEMBER OF THE ARJO FAMILY

Table of Contents

1. Safety

- **We recommend that exposure to ultrasound should be kept As Low As Reasonably Achievable - (ALARA guidelines). This is considered to be good practice and should be observed at all times. For further clinical information, see “Appendix 3, Ultrasound Safety Considerations” on page 90.**
- **Team3 provides just one indicator of fetal condition. This should be assessed as part of an holistic approach to obstetric care together with other factors. A complete assessment must be made before taking appropriate action. If there is any doubt concerning the accuracy of any measurement, an alternative method should be used.**

Symbols

General Warning	Refer to Instructions for Use	Attention, consult accompanying documents / Instructions for Use

Rx Only	Caution: Federal law restricts this device to sale by, or on the order of a licensed healthcare practitioner.

1.1 Warnings

- **Do not use in the presence of flammable gases or in oxygen rich environments.**
- **Do not sterilize the product or its accessories. The product will be damaged, and there is a risk of patient and user harm.**
- **Keep dry, do not immerse Team3 in liquid. Ultrasound and Toco transducers are IPX7 rated. Team3 with wired transducers is not intended for use in water birth situations.**
- **Always fit Protective cover to protect against fluid ingress when moving Team3 by hand or on a trolley.**
- **Do not use in the sterile field unless additional barrier precautions are taken.**
- **Use only recommended accessories listed in this manual.**
- **Do not dispose of batteries in fire as this can cause them to explode.**
- **The optional Lithium battery pack is a service replaceable item. Replacement by inadequately trained personnel could result in a hazard.**
- **Do not use with defibrillators. Ensure that all Team3 leads and applied parts are removed from the patient before applying Defibrillation.**
- **Team3 series monitors are not intended for use with patients fitted with cardiac pacemakers.**
- **Do not use with electrosurgical devices.**
- **Team3 can be isolated from the AC mains supply by removing the IEC mains inlet connector. Ensure that this is fully accessible at all times.**
- **Team3 is a Class 1 product that relies for safety on its protective earth. Ensure it is connected to a suitably earthed AC mains supply.**
- **Do not use in the home environment.**
- **Do not use the Team3 in vehicles or in aircraft.**
- **If this product is connected to another item of electrical equipment, ensure that the system is fully compliant with IEC60601-1.**
- **This product contains sensitive electronics, therefore, strong radio frequency fields could possibly interfere with it. This may be indicated by unusual sounds from the loudspeaker. We recommend that the source of interference is identified and eliminated.**
- **Do not expose to excessive heat, including prolonged exposure to sunlight.**
- **This equipment must not be modified.**
- **This equipment is for use only by suitably qualified healthcare practitioners.**
- **When configuring the system, consider and minimise the risk of persons tripping over cables.**

- **Do not use during magnetic resonance imaging (MRI) scanning.**
- **Do not use if there is any damage to the unit or its accessories.**
- **The use of the Team3 is restricted to one patient at a time.**
- **As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **Do not place the fetal monitor or accessories in any position that might cause it to fall on the patient.**
- **To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.**
- **Do not start or operate the fetal monitor unless the setup was verified to be correct.**
- **Avoid placing the device on surfaces with visible liquid spills.**
- **Do not place the fetal monitor where the controls can be changed by the patient.**
- **Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.**
- **The risk of cyber attack on the fetal monitor is negligible. Refer to section 1.2 Personal Cybersecurity Information below.**
- **The emissions characteristics of this equipment make it suitable for use in individual areas and hospitals (CISPR 11 Class A). If it is used in a residential environment, (for which CISRR 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 re-locating or re-orienting the equipment.**
- **When monitoring the fetal heart rate using an external ultrasound transducer, the fetal heart rate may sometimes be falsely reported. This is characteristic of ultrasound monitoring and can have a number of causes, including inadvertent monitoring of the maternal heartrate or signal artefact (see section 6.3).**

1.2 Personal & Cybersecurity Information

1.2.1 Personal Security Information

The Team3 Fetal Monitor 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 comprehensive security strategies to comply with local regulations and to protect the information and systems from internal and external security threats.
To ensure the patients' safety and protect their personal health information, the user should implement practices or measures that include:

- Physical safeguards - Security measures to ensure that unauthorised personnel do not have access to the monitor.
- Operational safeguards - Security measures during operation.
- Administrative safeguards - Security measures in management.
- The device should be used in isolation and not connected to any external system.
- If an external connection is deemed necessary, the host system should follow the security requirements of the Healthcare professionals (HCPs) IT administrators and local policy and should include:
  - ◊ Protected from unmanaged network traffic by way of a correctly configured firewall
  - ◊ The use of an up to date Anti-Virus software
  - ◊ Up-to-date operating system
- Patient data – Healthcare professionals (HCPs) should be made aware that the transfer of data from the Team3 to any generic PC, laptop or system and the subsequent annotation of such data with patient identifiable information such as hospital number, name, data of birth etc. will require that the data is encrypted at the time of annotation, a separate encryption method will also be required for transmission of said data.

CAUTION:

- **The operation of the monitor shall be restricted to authorised personnel only. Assign only staff with a specific role the right to use the monitor.**
- **Protect patients' sensitive information while using the monitor in public places. For information displayed on the monitor or saved in the monitor, please pay attention to personal information protection.**
- **In use, to prevent unauthorised interaction with the monitor, it is recommended that the screen is locked should the monitor be left unattended for any prolonged period. Refer to the IFU for instructions on how to lock the display screen.**
- **It is recommended that default passwords referenced in the IFU are changed from time to by authorised personnel to reduce the risk of unauthorised access.**
- **Protect all the passwords for prevention of unauthorised changes to the monitors, and to protect unauthorised access to patient records**

1.2.2 Interfaces & Connection to authorised external devices

Ensure that the monitor is connected only to devices authorised/approved by Huntleigh Healthcare. Users should operate all Huntleigh deployed and supported monitors within Huntleigh authorized specifications. (Refer to the Fetal monitor rear panel illustration in section 3.2 for details of the location of the following connectors):

(9) RJ45 Connector

The RJ45 connector is not functional. It is not intended for connection to hospital networks or any external equipment.

(8) USB Connector x 2

The USB connector is provided to facilitate the export of patient records from the monitor's internal memory to a USB flash drive. Access to patient records and the export facility is restricted to authorized personnel only and is password protected.
Note: Anti-virus measures such as USB device virus scanning should be carried out prior to using any recommended USB flash drive.

(4) RS232/CRS

The RS232/CRS connector allows connectivity to an external Central Record System as described in Section 11. It streams CTG data in RS232 serial format utilising a HP50 protocol.
No patient data is transmitted by the Fetal Monitor through this connection.

(5) Wireless Telemetry

The Wireless Telemetry connector supports connectivity to the Sonicaid Telemetry unit. Analogue waveforms and digital data is streamed from the wireless system to the Fetal Monitor via a bespoke cable assembly. This port provides data input only.

1.3 Infection Control

Single use transducer belts are for single patient use only and must not be re-used.
For other single use accessories refer to the user instructions supplied with them.

1.4 Patient Applied Parts

As defined in IEC60601-1, the patient applied parts of the Team3 Fetal Monitor are the:

- TOCO Transducer
- NIBP Cuff
- Patient Event Marker
- Ultrasound Transducer
- $MSpO_2$ Sensor

2. Introduction

The Team3A fetal/maternal monitor is intended for antepartum use.

The following features are standard on all models:

- Triple channel ultrasound fetal heart rate detection with audio.
- External monitoring of maternal contractions
- Maternally sensed fetal movements
- Automatic detection of fetal movement
- Color 8.4” touchscreen display
- Connections to an authorised CRS system via serial port
- USB - for trace storage, upgrading and configuration
- **DAWES REDMAN™** analysis

The following options are available for all models:

- Integral rechargeable battery
- Maternal Non-Invasive Blood Pressure
- Maternal pulse oximetry ($MSpO_2$)
- Maternal pulse rate (MPR) derived from MSpO2 or NiBP

Note
This IFU relates to software; v21.2.

2.1 Intended Use and Indications

The Sonicaid Team3 Antepartum fetal monitor (Team3 fetal monitor) is indicated for use by trained healthcare professionals in non-invasive monitoring of physiological parameters in pregnant women and fetuses, during the antepartum period of pregnancy. The Team3 fetal monitor is intended for pregnant women with singleton or twin pregnancies from the 28th week of gestation, through to term and delivery. In cases of triplet, the Team3 fetal monitor is intended for use from 30th week of gestation through 35 weeks gestation . The devices are intended for use in clinical and hospital-type facilities.

Sonicaid Team3 Antepartum is suitable for use when there is a need to monitor the following physiological applications:

- Single, twin or triplet fetal heart rates by means of ultrasound
- Uterine activity - externally sensed
- Manual fetal movement detection - maternally identified using the event marker
- Automatic fetal movement detection (defaults to OFF / Not for use in twin or triplet pregnancies).
- Maternal pulse rate (MPR) and oxygen saturation via pulse oximetry
- Maternal non-invasive blood pressure.
- The **DAWES REDMAN** EFM analysis output - advises whether a number of defined criteria indicative of a normal EFM record has been met for singleton pregnancies but not for triplet pregnancies. It provides nonspecific analysis in twin pregnancies due to nonspecific fetal movement input

2.2 Clinical Benefit

Provides the healthcare practitioner with valuable data for the assessment of fetal well-being.

2.3 Contraindications

This device is contraindicated for patients fitted with pacemakers.

2.4 Confirming Fetal Life Before Use

Fetal heart rate detection by the monitor may not always indicate that the fetus is alive. Confirm fetal life prior to monitoring, by measuring the fetal heart rate through auscultation, using a Pinard stethoscope or Doppler ultrasound device, and palpate the maternal pulse to ensure that the fetus is the signal source for the recorded heart rate.

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.

2.5.1 Contents

Standard - All models

Item	Item	Item
1 x Team3	1 x Ultrasound Transducer	1 x Toco transducer
1 x Event marker	1 x Pack of standard paper*	1 x 250ml Ultrasound Gel
Quick Start Guide	1 x Instructions for Use	2 x Transducer belt
1 x Power Cord		

Blood Pressure Option

Item	Item	Item
1 x Medium Cuff	1 x Large Cuff	1 x Connecting Hose

MSpO2 Option

Item	Item
1 x Interface lead	1 x Finger sensor (type depends on option selected with order)

Note
All Team3 models are twins capable as standard but are supplied with 1x US transducer. For twins or triplets, if this option is installed, order extra US transducers separately as required.

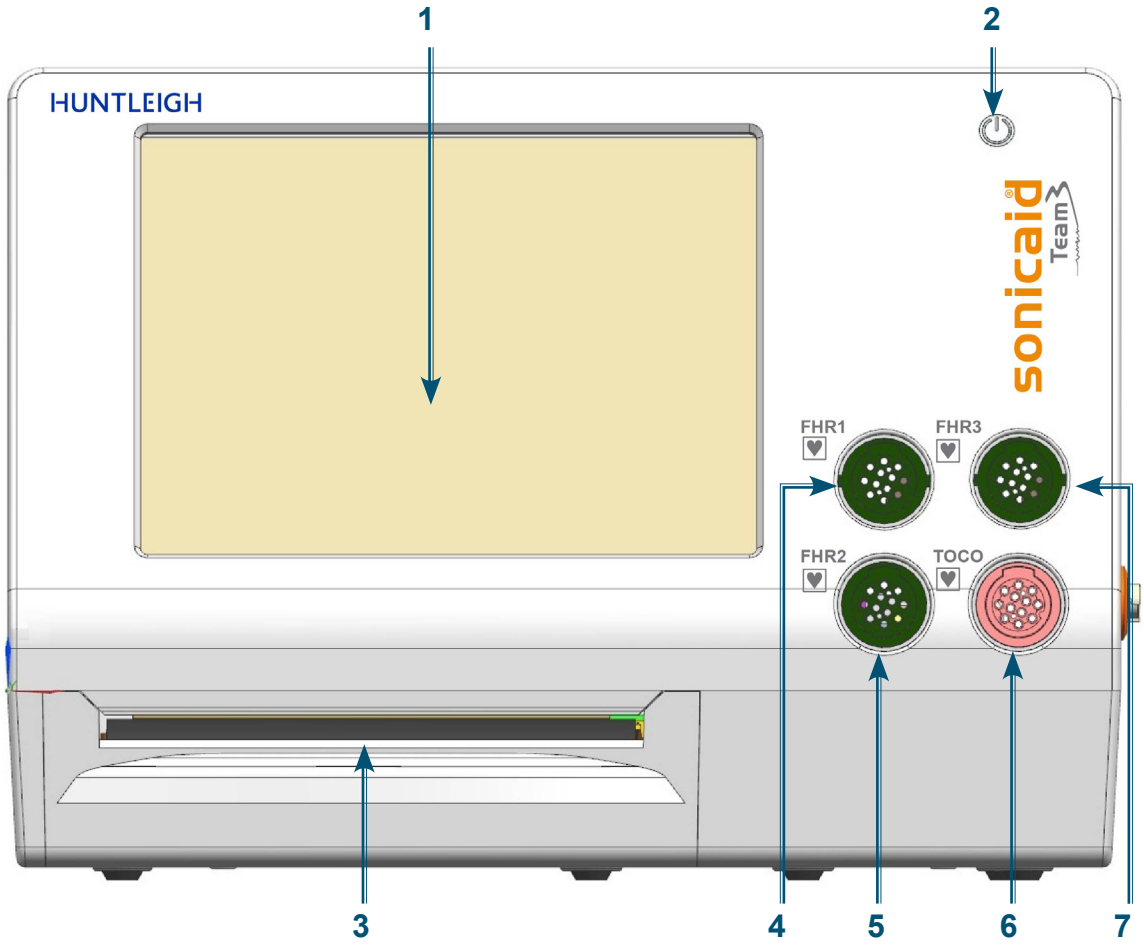
2.6 Operator Positioning

Team3 can be comfortably operated from a standing or seated position in front of the unit.

3. Product Identification

Safety and performance are only assured when used in conjunction with the correct types of transducer. Do not attempt to connect any devices via these sockets other than those supplied or recommended by Huntleigh.

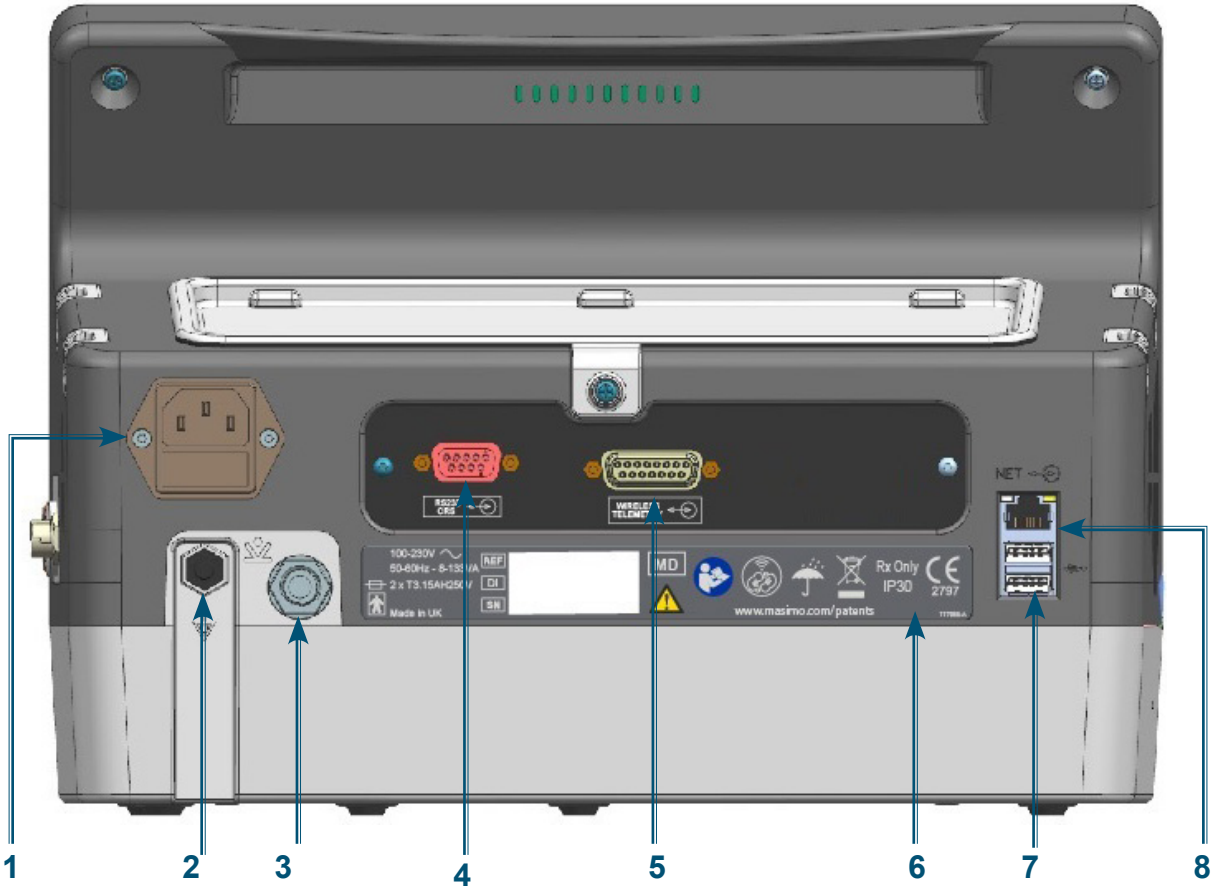
3.1 Front Panel



1	Touchscreen	5	FHR2 US socket
2	On/Off Button	6	TOCO Transducer socket
3	Printer *	7	FHR3 US socket *
4	FHR1 US socket		

** Depending on model/options purchased.*

3.2 Rear Panel

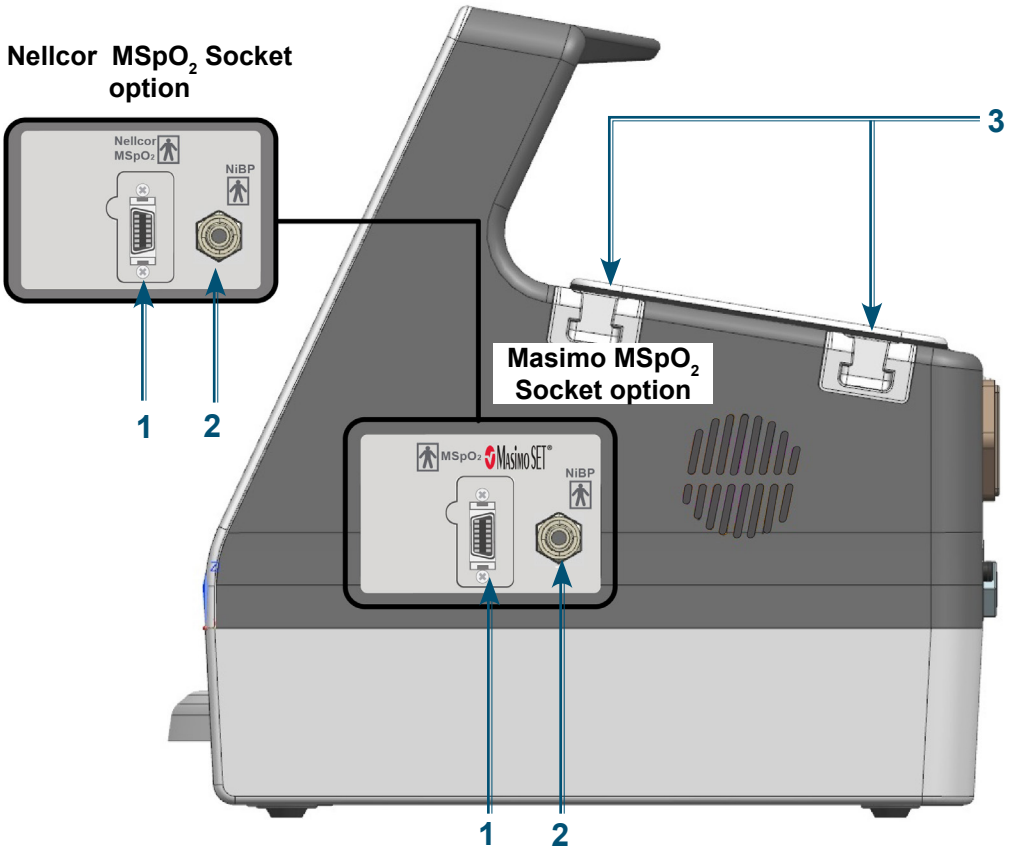


1	Mains Socket	5	Wireless Telemetry Socket
2	Equipotential earth point	7	Rating Label
3	Fetal Event Marker Socket	8	USB Port x 2
4	RS232/CRS Socket	9	Ethernet Port *

** Not enabled - future upgrade.*

3.3 Base Panel Label

3.4 Side Panel



1	Maternal NIBP *	2	Maternal SpO_2 *	3	Transducer storage

** Depending on model/options purchased.*

3.5 Product Labelling

Note: Product labelling should be read from a distance no greater than 0.5m.			
	Applied parts (Ultrasound Probes / TOCO) are type CF		Applied parts (Maternal NIBP/$MSpO_2$/fetal event marker) are type BF
	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.		
CLASSIFIED c UL us 25EA	MEDICAL — PATIENT-MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601- 1:14, IEC 60601-1-6, CAN/CSA-C22.2 No. 60601-1-6, IEC 60601-1- 8 CAN/CSA-C22.2 No. 60601-1-8, IEC 80601-2-30, CAN/CSA-C22.2 No. 80601-2-30, IEC 60601-2-37, CAN/CSA-C22.2 No. 80601-2-61, IEC 80601-2-49, ISO 80601-2-61		
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 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		
	Warning		Attention, consult accompanying documents / Instructions for Use
~	Alternating current (AC)		On/Standby
DI	Device Identifier	MD	Medical Device
SN	Serial Number	REF	Reference Number
	Protective Earth		Date of Manufacture
	Keep Dry		Do not use hook
	Fragile		Cardboard packaging can be recycled.
40°C -10°C	Temperature Limitations	93%	Limits of Relative Humidity
PVC	Does not contain PVC	LATEX	Not made with natural rubber latex.
YYYY-MM	Use By		Do Not Reuse
	Fetal Event Marker		Equipotential Earth
	Limits of Atmospheric Pressure	IP30	Protected against ingress of solid foreign objects >2.5mm diameter. Not protected against ingress of water.
	USB Port	NET	Ethernet Port
	RoHS Compliant (RoHS - Restriction of Hazardous Substances)	4	Max stack x 4 identical boxes
	This side up		Wireless Telemetry Ready

4. Setup

4.1 System Connection

WARNING: These requirements must be met when a Team3 is connected to any other electrical equipment, such as a PC.

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

2 Anyone who connects additional equipment to signal input or signal output parts of the system is configuring a medical system, and is therefore responsible for ensuring that the system complies with the requirements of IEC60601-1. If there is any doubt as to whether your system complies, consult the technical service department or your local Huntleigh representative.

3 If non-medical equipment (e.g. the PC or 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 via Huntleigh sales agents.

4 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 4mm2 56/28AWG yellow and green earth wire, connected to the Equipotential Earth Point point at the installation. At no point 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 Probe/Sensor/Cuff Connection

Ensure all probe/sensor leads are fully inserted into the appropriate socket.

Do not remove any cables by pulling on the lead.

4.3 Loading Paper

Refer to Section 9.6 - Loading Printer Paper

4.4 Handling and Mounting

Cart

If the unit is moved regularly, for maximum safety it is recommended that it is mounted on the purpose-designed cart, which is available as an accessory. Follow the instructions provided with the cart regarding assembly and proper mounting of the Team3.

- **If the Team3 is being used on a cart, make sure the cart brakes are applied, except when the cart is being moved.**
- **Team3 should not be used whilst being moved between locations.**
- **Take care to ensure that trailing transducer cables and other connecting leads do not present trip hazards that could lead to the equipment falling. Always store unused transducers correctly.**
- **Do not attempt to move the cart, or use the Team3, without ensuring that the unit and all transducers and cables are secured.**
- **Keep hands clear of the cart wheels while the cart is in motion. Do not attempt to free trapped cables without stopping the cart and applying the brakes.**
- **When moving Team3, either by hand or when cart mounted, the protective cover with a minimum of IPX2 should be fitted to prevent ingress of fluids which may be encountered during transit. A suitable cover is available as an accessory.**

Wall bracket

If the unit is seldom moved, a purpose-designed bracket is available as an accessory to allow the Team3 to be wall mounted with maximum safety. Follow the instructions provided with the bracket regarding assembly and proper mounting of the Team3.

- **Brackets must be installed by trained personnel using fixings appropriate for the wall construction and load. Carry out load tests before use.**
- **Ensure that the Team3 is securely fitted to the bracket using the correct adaptor plate and screws as described in the instructions supplied with the bracket.**
- **Choose the location carefully to prevent possibility of users, patients or passers-by striking the unit, causing injury.**

5. Operation

5.1 Switching the Unit ON

Connect the monitor to the local mains supply. The unit will automatically power up.

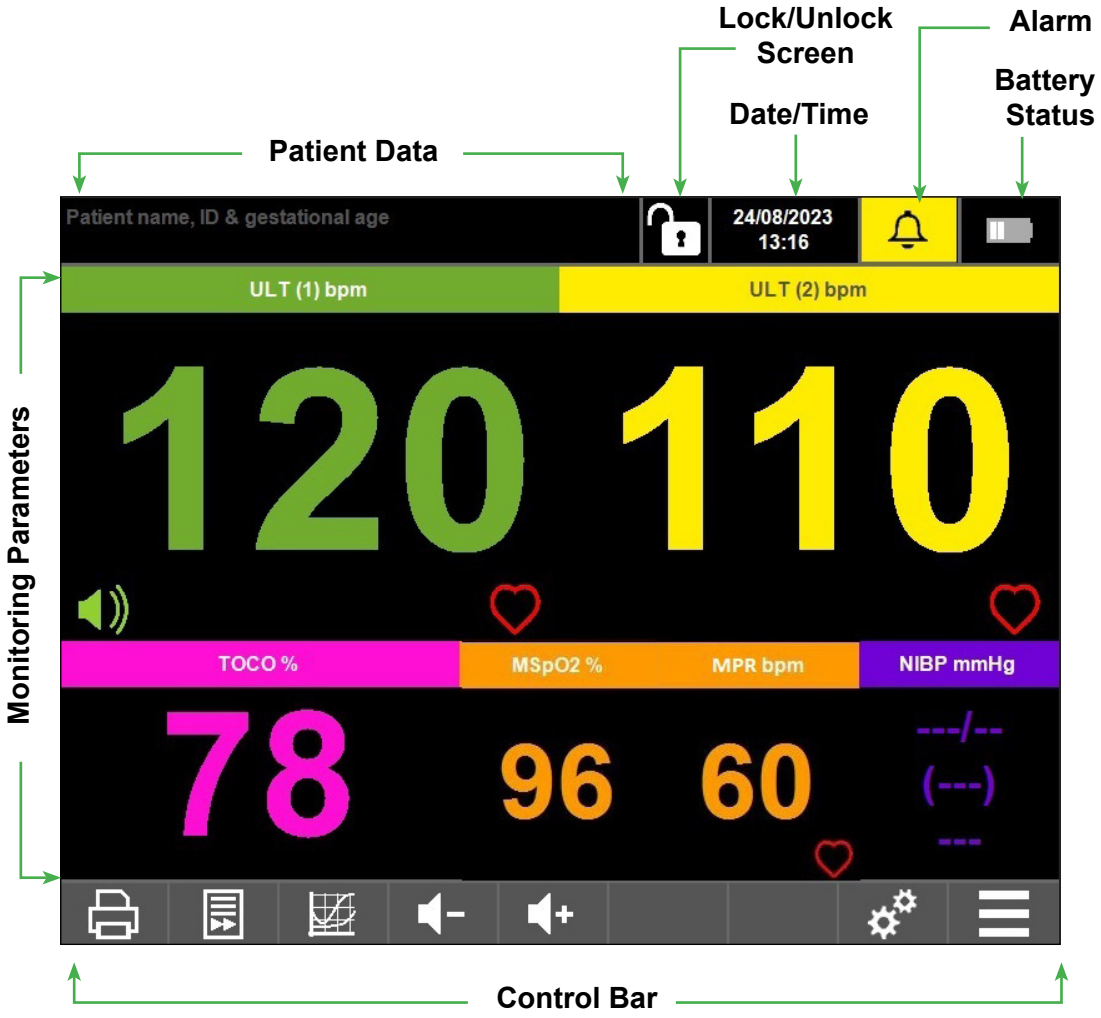
If the unit is in off/standby mode with power already applied, press and hold ⏻ for approximately 2 seconds to switch on. A short tone will be heard.

The unit will briefly display a splash screen, then continue to the Application Screen.

5.2 Application Screen

The application screen will be displayed and automatically configured according to the options / modules fitted to the unit. The screen is arranged into a series of waveforms and numerical indicators. All functions are accessed via the touchscreen, either through the Control Bar Menus located across the bottom of the screen or by touching each application.

Note that some applications require you to touch and hold on the relevant area.



5.2.1 Patient database

The Team3 is not an archiving system. The patient database is intended for short term trace storage and review only. For long term storage, it is recommended an authorised CRS system is used.

Note: Patient Data entered will automatically be deleted when Print/Record is stopped.

Data stored on the Team3 can be exported using the export facility within the Recordings Manager to move selected traces from the Team3 onto a USB drive.

The operator can search for, and view a previously stored trace in the View menu. Refer to section 5.3.8 for full details.

There is an upper limit of 200 stored live recordings after which time, the Team3 will automatically delete the oldest recording.

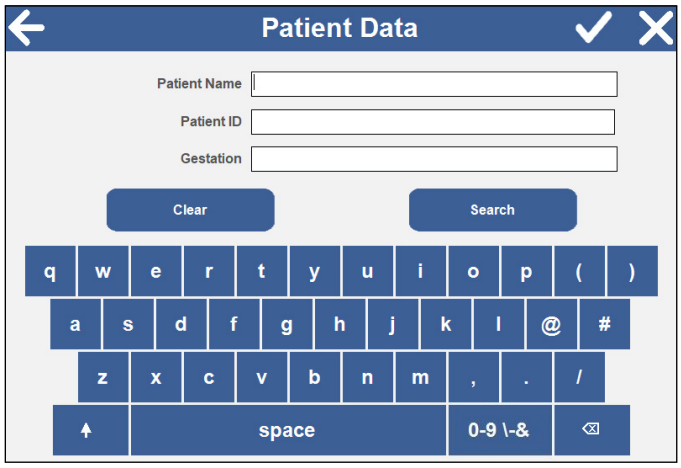
5.2.2 Entering Patient Data

Touch and hold the Patient Data region in the top left corner of the screen to enter the Patient Data screen.

Note
If you cannot access the Patient Data screen, this function may be disabled - refer to section 14.5 for details.

This screen allows the operator to enter the patient's name, ID number, navigate to the 'Set Gestational Age' screen and search for previous patients

Touch and hold the Patient Data region in the top left corner of the screen to enter the Patient Data screen.



Enter Patient Name and Patient ID using the on-screen keyboard.

Touch Clear to remove any details from the form.

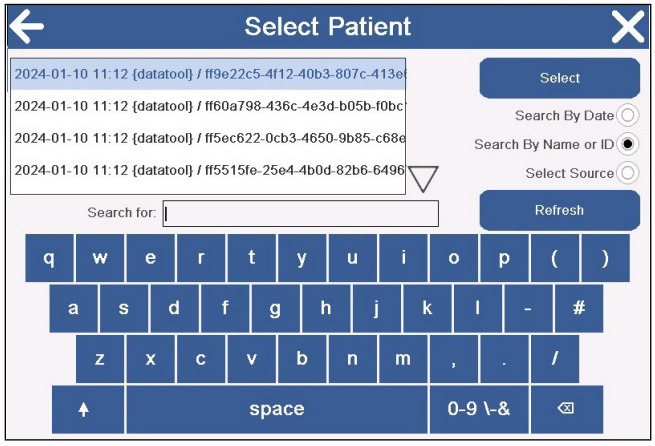
Touch Search to view the Search screen which allows the operator to select the Patient Data of a mother who has been previously monitored.

Note: To search for patient records stored in the fetal monitor, enter passcode 9 8 7 6 5 after touching Search.

Touch the 'Gestation' box to enter the 'Set Gestational Age' screen.

Touch ✓ to return to the Monitoring screen with the details on this form.

Searching for Patient Names



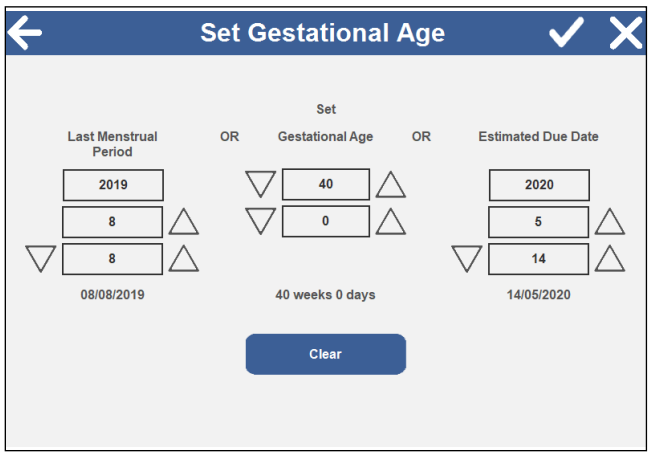
The operator can search for a patient either by date, Patient Name / ID or from an external USB device.

(The Select source option will only appear if there is a USB deviice inserted.)

Touch Refresh to check if any USB devices with exported recordings are connected.

Touch the patient required and touch Select to return to the Monitoring screen with the details of this patient in the Patient Data region.

Setting Gestational Age



The Set Gestation dialogue allows the operator to change any one of:

- Last menstrual period date
- Gestational age
- Estimated due date

Based on the current date, changing any one of these will automatically update the other two.

Touch any up or down arrow icon to change the values. The maximum value of gestation age is set at 44 weeks.

Touch ← to return to the Patient Data screen with the current value of gestational age.

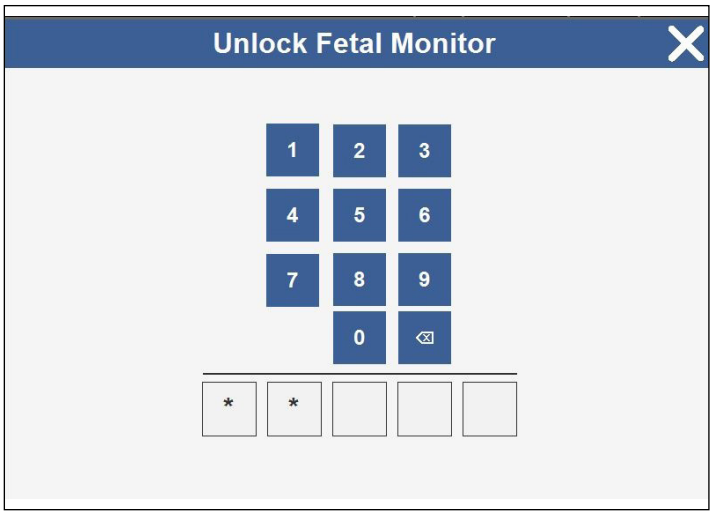
Touch Clear to reset the GA values to zero.

Touch ✓ to return to the Patient Data screen with a cleared value of gestational age.

5.2.3 Lock / Unlock Screen

Touch to access the Lock Screen.

Touch Lock to lock screen or to exit with out locking.

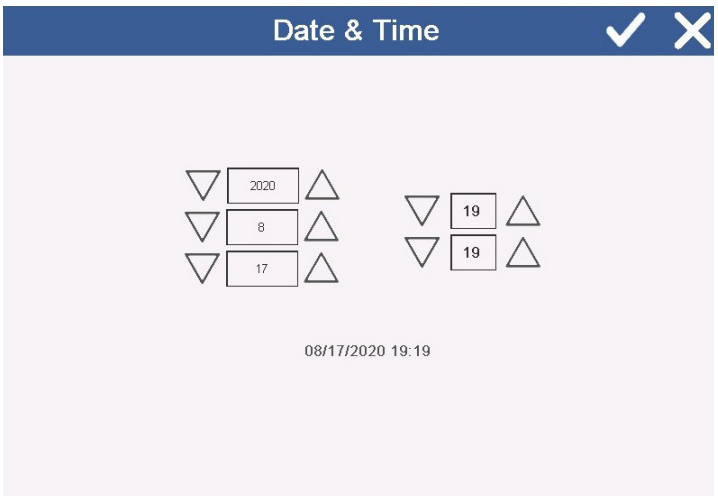


Touch to unlock the screen.

The operator will need to enter a 5 digit code via the touchscreen, (default code 0 0 1 2 3), to unlock the screen.

5.2.4 Date / Time

Touch and hold the Date/Time area of the screen to enter the Data and Time screen. (Note: This screen can also be accessed via the Settings Menu.)

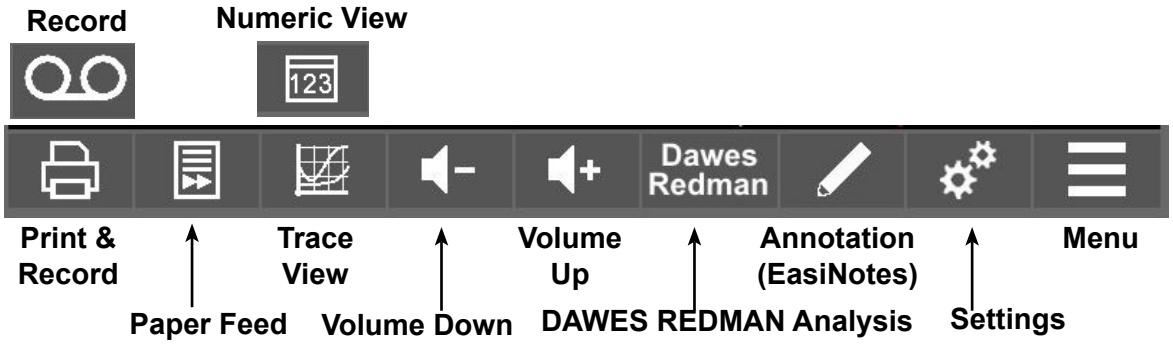


Use the arrows to set the current date and time.

Press to confirm

5.3 Control Bar

Displayed along the bottom of the screen is the control bar. Functions depend on the options / modules installed and the operating mode of the unit.



5.3.1 Record / Print

	Touch to print or record.*
	Indicates printing or recording is active. Touch to cancel printing or recording. All printed data is also recorded. The recorded data can be reviewed when required. **Note: Patient Data entered will automatically be deleted when Print/Record is stopped.**
	Annotation Icon appears in the control bar when printing or recording is active. (See Annotation - below).

5.3.2 Paper Feed

	Touch and hold to feed the paper through printer.* ** If option installed.*

5.3.3 Numeric / Trace View

	Touch to toggle between displaying the data in numeric or trace format.

5.3.4 Volume Up/Down

	Touch to decrease or increase the volume.

5.3.5 DAWES REDMAN Analysis

	This icon is only visible if the gestational age has been set and Team3 is running **DAWES REDMAN** analysis. (If **DAWES REDMAN** is enabled).

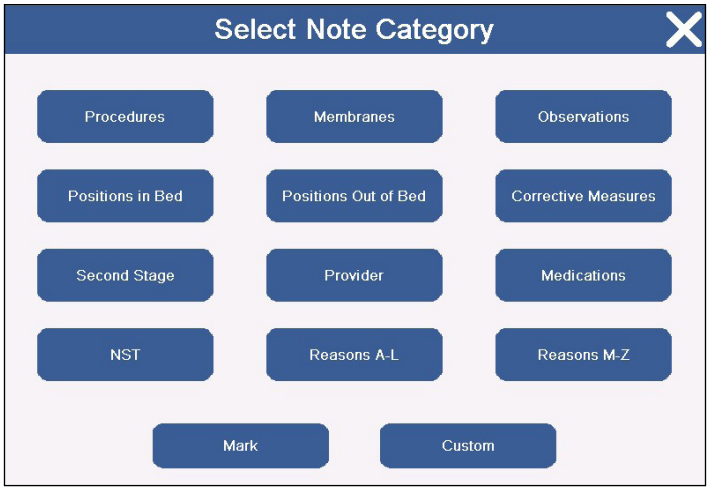
5.3.6 Annotation - EasiNotes

	Annotation Icon appears in the control bar when printing or recording is active. This feature allows the operator to add a pre-stored note to the printout or recorded file. Touch to access the Annotation menu.

5.3.7 PDF

	
	PDF icon is only visible when reviewing a stored trace with a USB (8GB) plugged into the rear of the fetal monitor. Touch to store a PDF copy of the trace onto the USB

Annotation Main Menu



Touch each note category to access the sub menu options available.

Note

- **The Easinote sub-system is very flexible allowing up to 12 groups of 12 notes to be configured on Team3.**
- **The "Mark" button allows users to print a blank annotation field on the trace for adding a hand written note.**
- **Refer to Sections 14.5 and 14.6 for details on how to access the Settings Management feature to customise and translate notes.**
- **The "Custom" button allows users to type custom notes using an on-screen keyboard - click on the "Send" button to output the message.**

Annotation Sub Menu

Touch any of the options to add the note to the recording/printing data.

The selected note will appear on the printed / recorded data.

5.3.8 Settings Menu

Touch  on the control bar to view the Settings menu. This menu allows users to configure the Team3 settings to be specific to the patient. The settings remain in effect until the monitor is powered off, unless they are saved as defaults.

To save new settings as defaults, make the desired changes, then navigate to Settings Management and select Save Local Settings.

The following diagram shows how to navigate to all menu options available from the Settings menu. Touch any button to view the sub menu options available for it. Each sub menu is described on the following pages.

The images show the default settings for each option.The menu options shown will be model dependent and vary depending on sensors and accessories attached.

Settings	Clinical	TOCO
	System	Sound
		Non Stress Test
		Background Colour
		Date & Time
		Printer Illumination
		CRS

- Trace Offsets
- Alarm
  - FHR
  - TOCO
  - MSpO2
  - MPR
  - NIBP
  - Alarm Volume
- Analysis Settings
- Secure Settings (passcode 12345)
  - Service (passcode 55555)
    - Licensing
      - Manometer
      - NIBP Calibration
      - Contacts
      - Recordings Manager
    - Set Language
    - Hospital Name
    - Demonstration
    - Version Information
    - Regional Settings
    - Clinical Settings
    - Patient Data
    - Trace & Printer Settings
      - Trace Speed & Scale
      - Printer Paper
    - Lock Codes
      - Secure Settings Code
      - Unlock Code
      - Service Code
      - Patient Data Code
    - Settings Management
    - NIBP Protocol

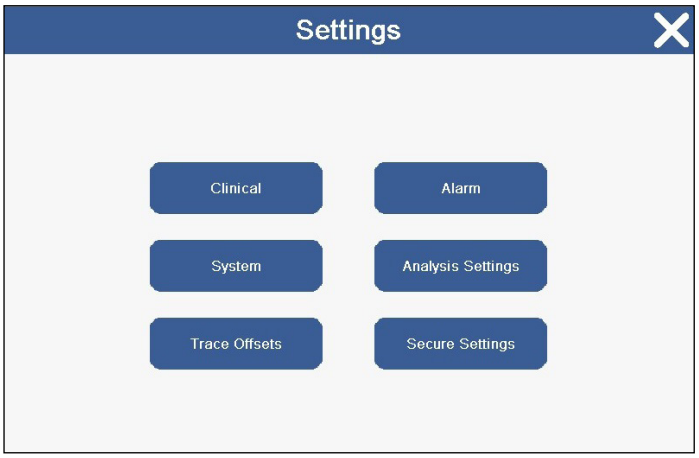
Touch ✓ or ← to return to previous page. ✓ accepts data and ← does not. ✗ returns to Main Application screen.

For all Menu and sub menu screens the options are selected/deselected by touching on the icons as follows:

☐	**Option disabled**	☑	**Option enabled**
○	**Option not selected**	◉	**Option selected**
△	**Increases selection**	▽	**Decreases selection**

Settings Main Menu

Touch each category to access the sub menu options available.

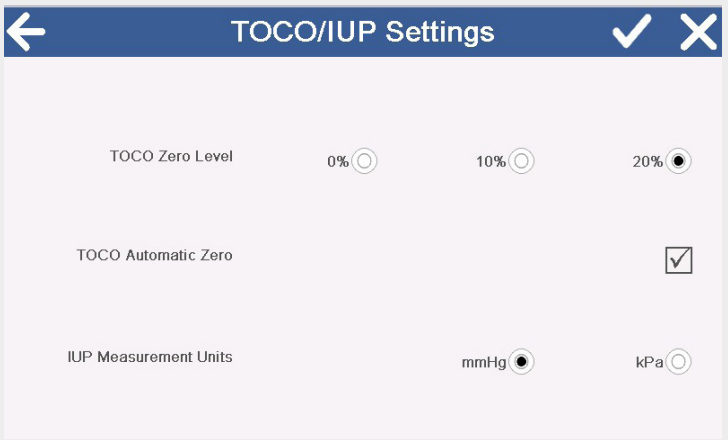


Note

- **The Trace Offsets sub menu is only available if not printing or recording.**
- **The Trace Offsets sub menu is only visible when ultrasound transducers are plugged into the FHR1 and FHR2 sockets on the front of the unit.**
- **Team3 will return all settings to Default levels when switched off. Default settings can be customised - refer to Section 14.5.**
- **If the mains supply is interrupted for more than 30 seconds when no backup battery is provided, the Team3 shall revert to Default settings.**

Settings Sub Menus

Clinical Settings Sub Menu



System

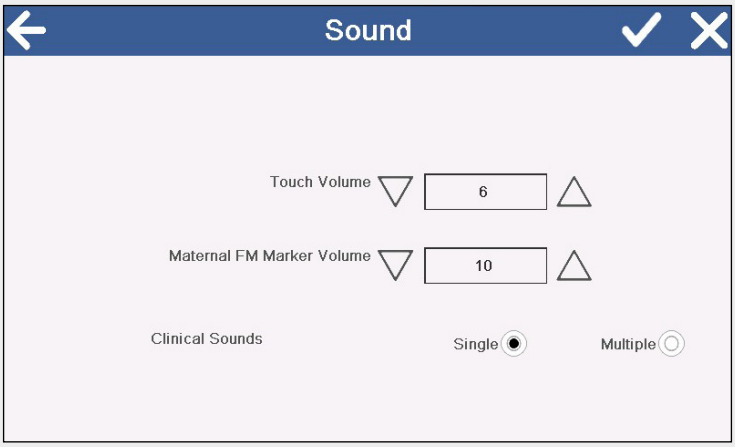
Note
Date & Time and Recording limits settings not available when printing/recording.

System Settings Sub Menu

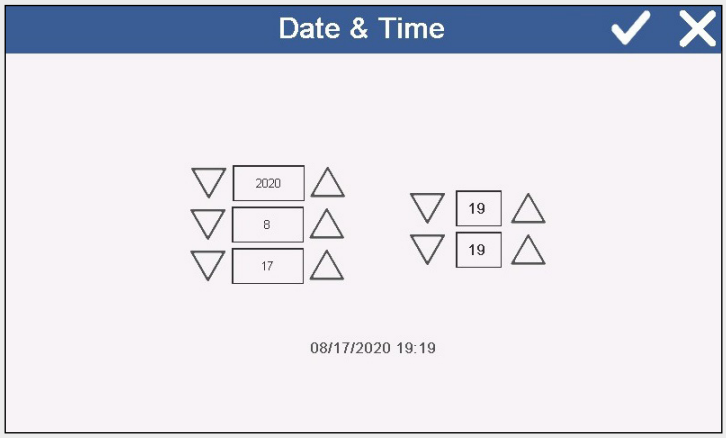
Sound

Note
Does not set Alarm Volume or volume of heart sounds.

Note
The "Clinical Sounds" option buttons allow listening of just one sound channel or multiple sounds.

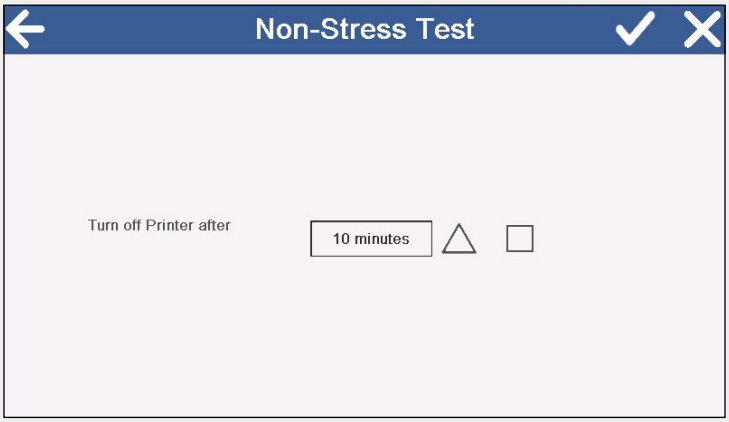


Date & Time

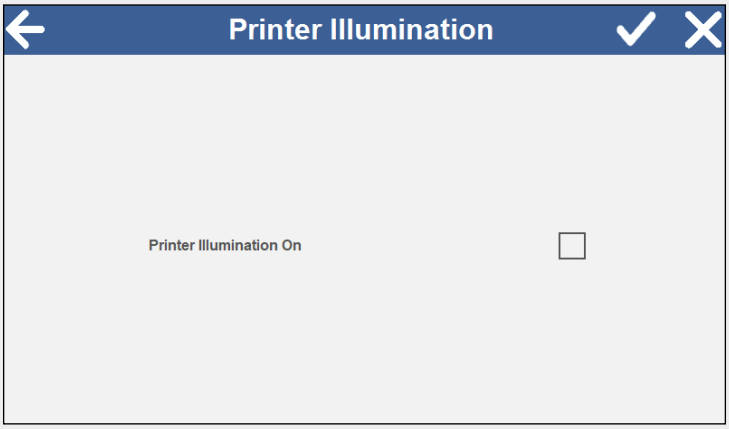


Non-Stress Test

If enabled, printing / recording stops after this time has elapsed.

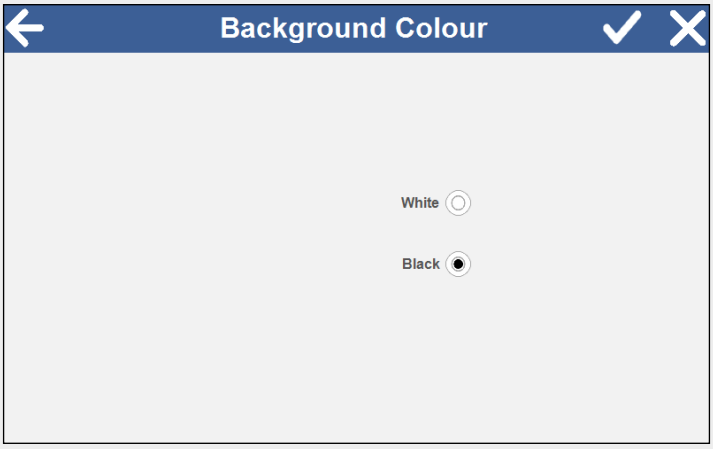


Printer Illumination



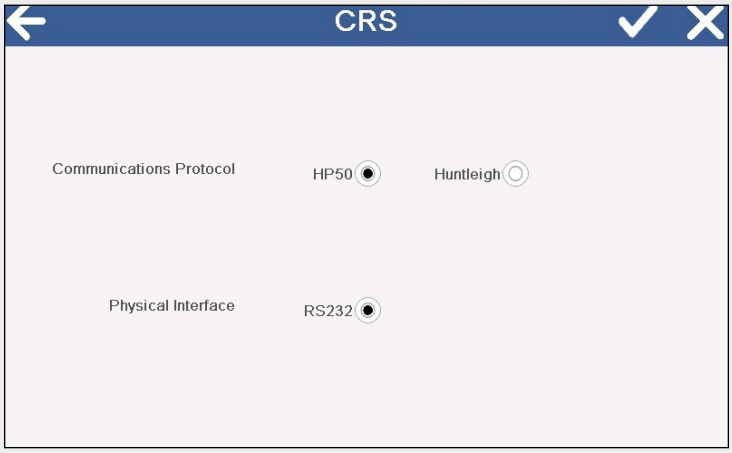
Background Colour

In this screen, the operator can change the background colour of the screen to suit their preference or ambient light levels.



CRS

In this screen select HP50 for all authorised third party Clinical Records Systems (CRS).
Refer to Section 11.

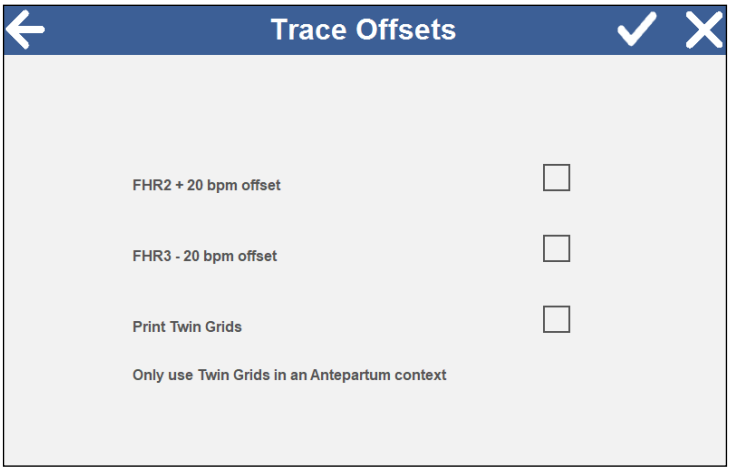


Trace Offsets

When monitoring twins or triplets, this option offsets each trace by 20 bpm to make viewing clearer.

Note
The Trace Offsets option is only available when two or more US transducers are connected.

Note
Print Twin Grids not accessible when printing or recording enabled.



Alarm

WARNING : Ensure that ALARM LIMITS are set to realistic values. Use of extreme values can render the ALARM SYSTEM useless.

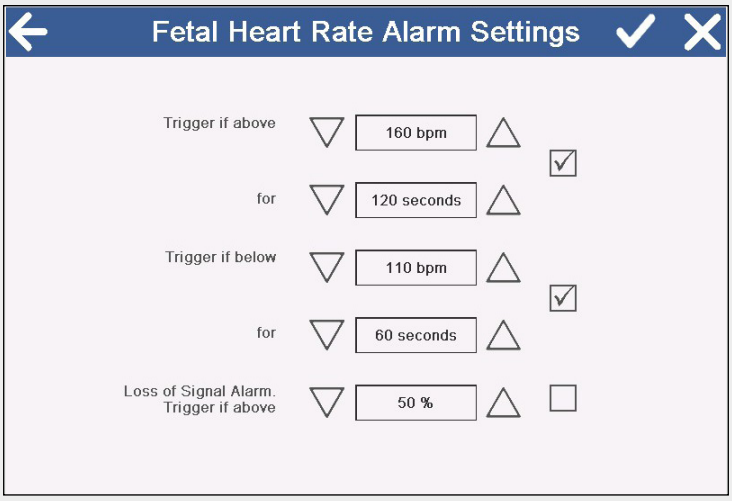
Alarm Settings Sub Menu

Touch each check box to enable / disable each alarm.

If selected a ✓ will appear in the box.

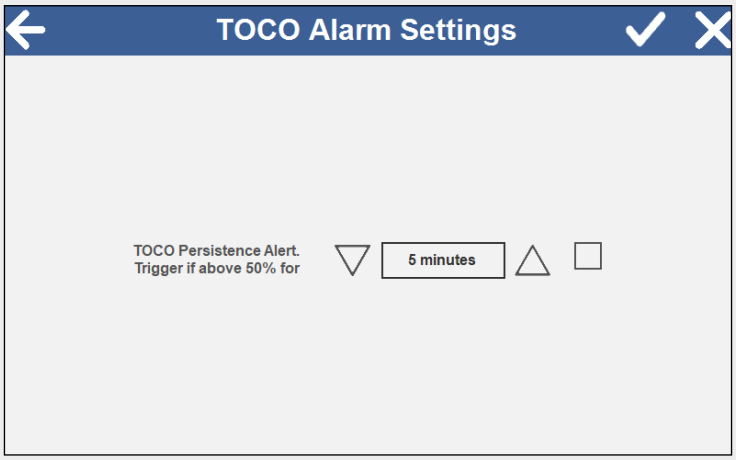
Touch △ ▽ to set each trigger threshold.

FHR



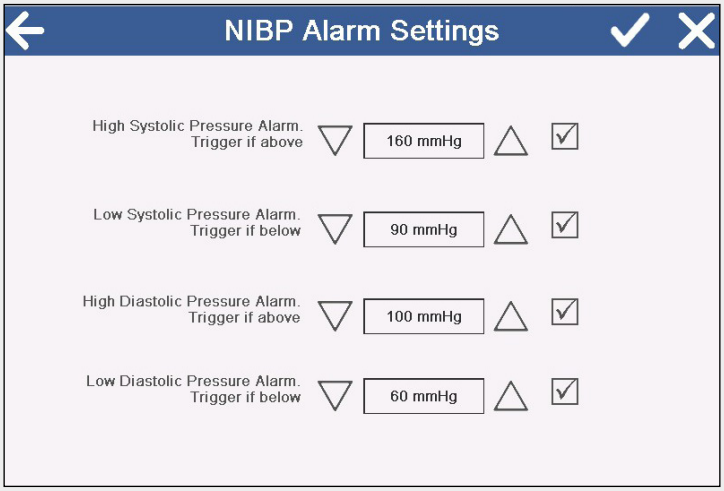
TOCO

TPA - TOCO
Persistence Alert



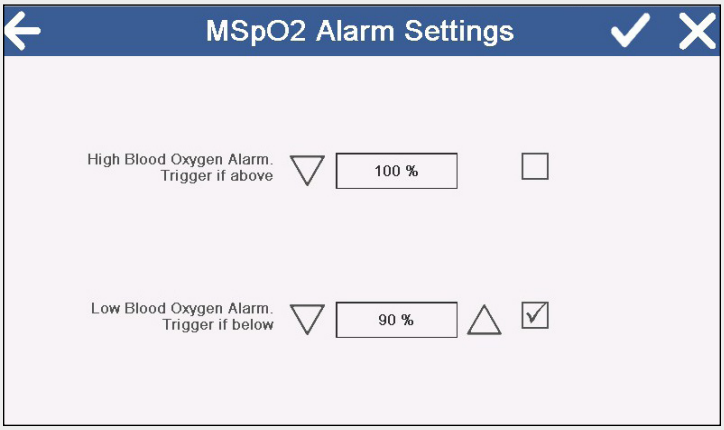
NIBP

Note
Only available if NIBP option fitted.



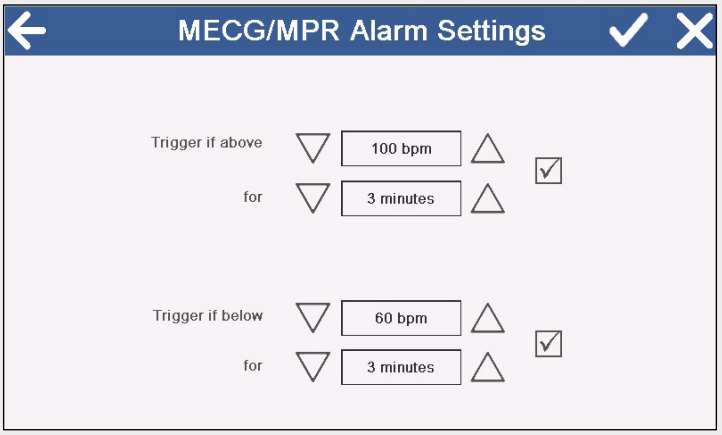
MSpO2

Note
Only available if $MSpO_2$ option fitted.



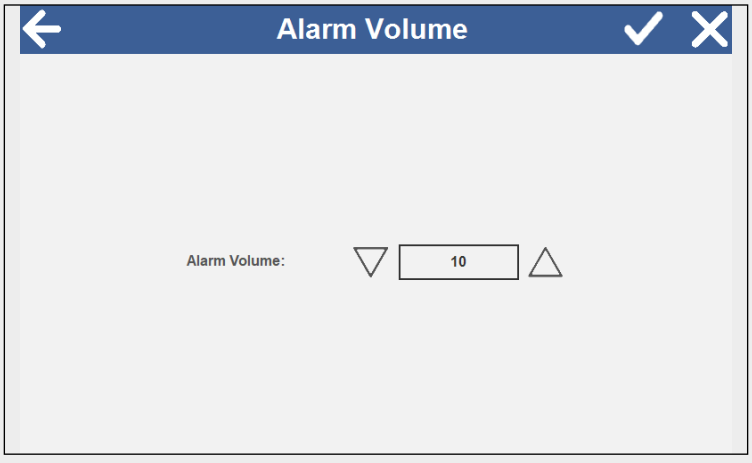
MPR

Note
Only available i if MSpO2 option fitted in Team3A.



Alarm Volume

Note
This sets the volume level for alarm sounds. This is independent of the user set volume level for normal audio sounds. Alarm volume cannot be set to zero.



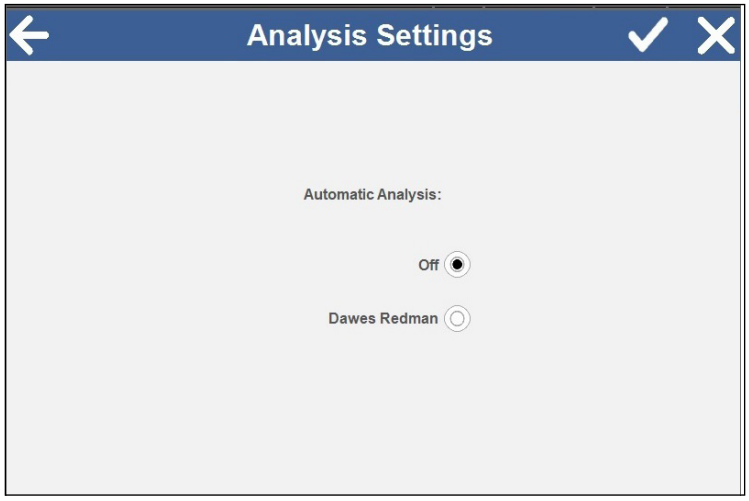
Analysis Settings

Note
Options in this screen depend on the licensed features. Antepartum units will start up with Dawes Redman off.

Select '**DAWES REDMAN**' to enable the analysis.

Touch the checkmark at the top of the screen to accept the settings.

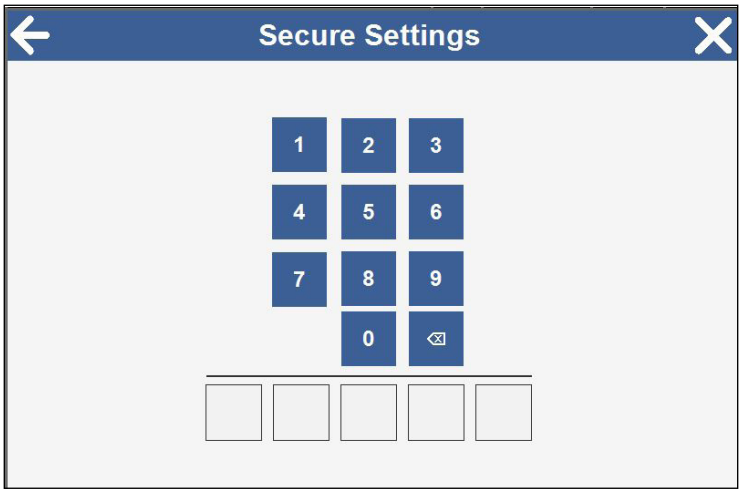
Note
To set the default to always be ON for Dawes Redman, access the Secure Settings area (Settings Management) and save as new default.



Secure Settings

The operator will need to enter a 5 digit code (default
1 2 3 4 5) to enter the secure area.

Note
Refer to Section 14.5 and also the Service manual.



5.3.9 View Menu

Touch the icon to access the View Menu settings.

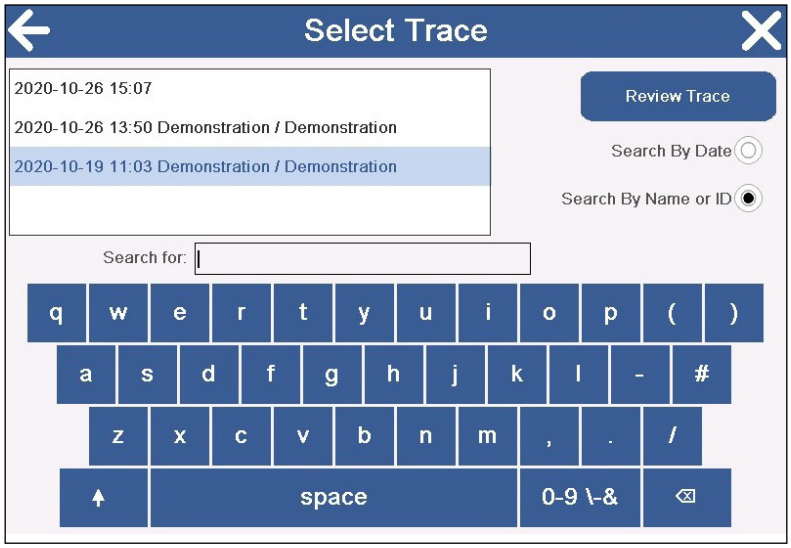
Touch each category to access the sub menu options available.

Review Trace

This screen allows the operator to select a previous trace to review.

A passcode is required in order to view patient records.

The default passcode is 98765.



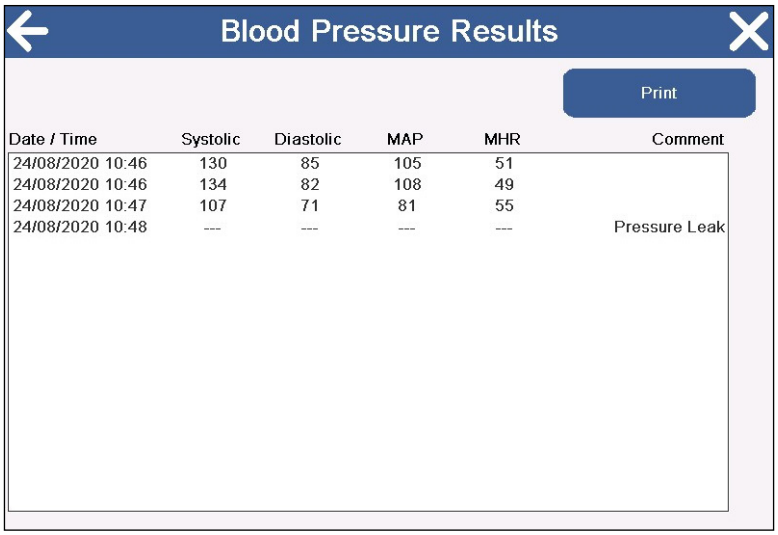
he operator can choose to search for the CTG trace by either date or Patient Name / ID.
Select source will only appear if there is a USB drive inserted. This function will enable the user to review a previously exported trace.
To review a previously exported trace:
Insert USB drive into the back of the Team3 to enable the option to review patient data.
Touch Refresh to check if any USB devices with exported recordings are connected.
Click on the Select Source radio button to display all traces that have been saved to the USB drive.
Touch the CTG trace required and touch Review CTG. The selected trace will now be displayed on the application screen.
You can scroll through the trace by touching and moving the thick grey scroll bar on the screen. The trace view updates when you release the scroll bar.

If a printer is fitted, press  to print the trace.

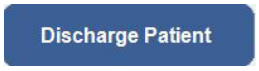
Review Mode Sub Menu

When the monitor is in review mode, touching this button on the control bar will display a Review menu.

Discharge Patient	Starts a new monitoring session with a new patient.

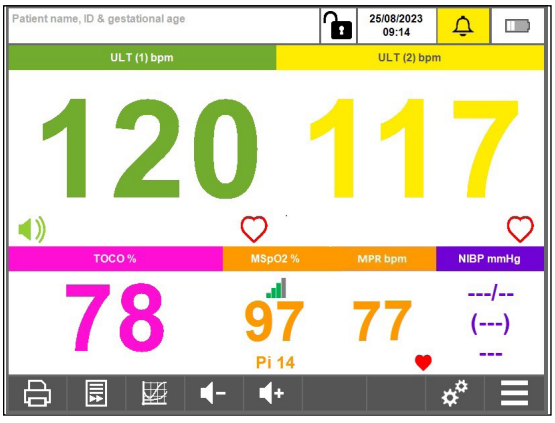
New Trace	Starts a new monitoring session with the selected patient.
Blood Pressure Readings Displays Blood Pressure results screen. Touch the "Print" button to print out the results.	

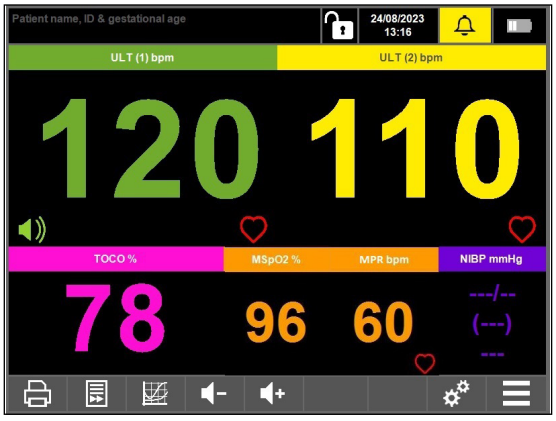
USB to Store Trace (PDF) to USB Drive (8GB max)

1. Select View Menu  .
2. Review Trace  .
3. Enter PIN code to enable access to stored traces. (PIN code : 98765).
4. Select trace from list by using the arrow to scroll through the traces  ,
5. Insert USB into USB drive in the rear panel of the fetal monitor.
6. Select View Menu and then select Discharge Patient  .
8. Remove USB from the fetal monitor to enable trace to be shared on a PC.

5.4 Monitoring Parameters

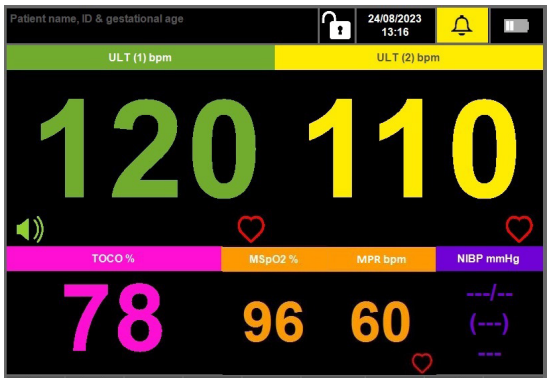
You can configure the screen to display a white or black background. (Refer to ‘Settings’).



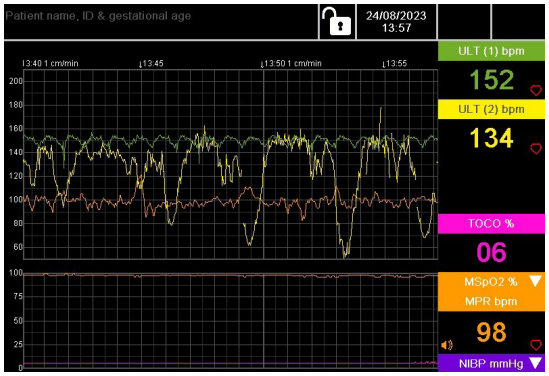


The application screen can be displayed in either Numeric or Trace format.

Touch  or  to toggle between displaying the data in numeric or trace format.



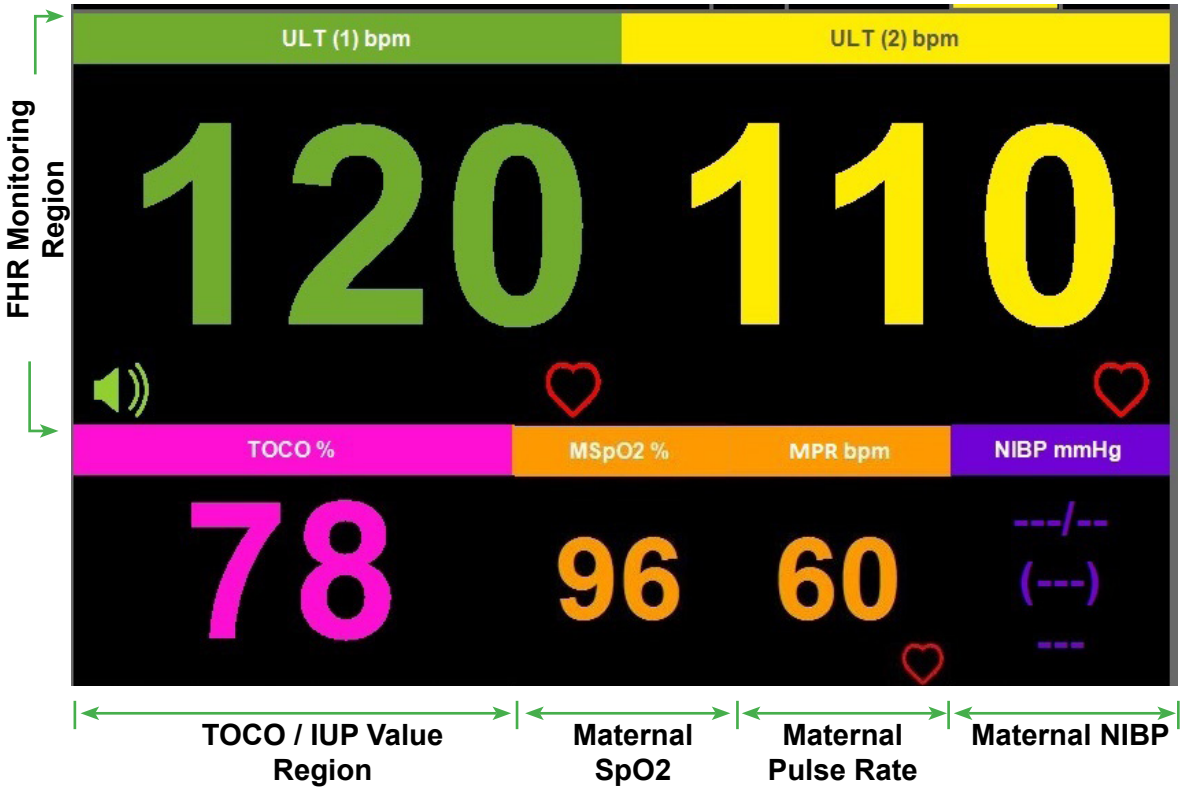
Numeric format



Trace format

5.4.1 Numeric Format

The numeric data screen increases the size of the numeric data and removes the traces. This is useful when operators are not in direct attendance as the numbers can be seen from a distance.
The display is split into regions, its configuration is dependent on whatever sensors/probes are attached.



Audio
Audio can only be enabled on one channel at a time.
Touch and hold on any FHR or MHR region of the screen to select audio for that channel. A speaker symbol  will appear on the channel if audio is enabled.

To turn the audio off, touch the region displaying the speaker symbol.

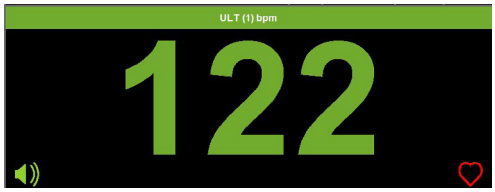
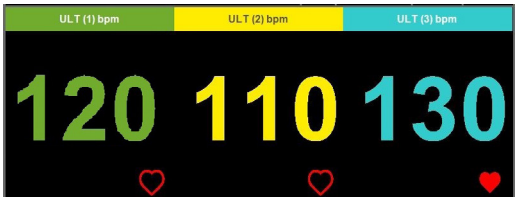
Fetal Heart Rate Signal Confidence
The heart rate is depicted by a flashing heart symbol on the bottom right corner of each region. The color of this heart denotes the HR confidence, it is not an indicator of signal strength.

Red - High

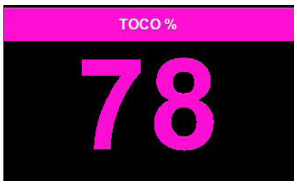
Amber - Moderate

Yellow - Low
If the heart symbol is displayed in outline only and no FHR is displayed, the Team3 cannot detect the fetal heartbeat.

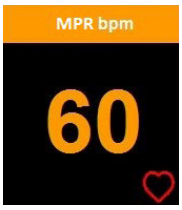
5.4.2 FHR Monitoring

	**Singleton Monitoring** In singleton monitoring, the FHR in displayed in large digits in the top centre region. Display shows FHR via wired ultrasound transducer with audio.
	**Twins Monitoring** In twins monitoring, the FHR display region is split to display the two separate Fetal Heart rates, both using wired ultrasound. Audio is enabled for channel 1 only.
	**Triplet Monitoring** In triplet monitoring, the FHR display region is split to display the three separate Fetal Heart rates. Display shows triplets' FHR, channels 1 ,2 and 3 from wired ultrasound. Audio is turned off in this display example.

5.4.3 TOCO

	**TOCO** The TOCO region shows TOCO measurements in progress. Touch and hold on the TOCO region to Zero the TOCO.

5.4.4 $MSpO_2$ / MPR

	**MPR** If the MECG lead is not in use, the MPR measured by $MSpO_2$ will be displayed.

MSpO2

There are two types of $MSpO_2$ sensor, Nellcor and Massimo, the following table describes the differences between the two.

Nellcor

The $MSpO_2$ region shows the probe plugged in and measuring oxygenation. Nellcor supports the following symbols:

 **- Interference**

 **- No finger inserted**

 **- Pulse search/no pulse detected**

Masimo

Numeric View

Trace View

Diagnostics Screen (For details see Appendix 5 sections Perfusion Index and Siq Bar Graph)

The Masimo SpO2 display's supports the following:

- Perfusion Index Indicator (Pi)
- Siq Bar Graph.
- These can be enabled or disabled (see Clinical Settings)

Technical Alarms (For details see Appendix 5 section Masimo Technical Alarms)

Two types of technical alarms are supported for Masimo:

- Blocking Technical Alarms - The SpO2 probe is unusable and measurements cannot be made (e.g. sensor expired).
- Informative Technical Alarms - The reading may be compromised unless action is taken (e.g. Too much ambient Light).

Sensor Off Patient (For details see Appendix 5 Section Sensor Off Patient)

- If the sensor is either removed or falls off a patient following a valid SpO2 reading an Informative Technical Alarm will occur.
- If the sensor is either removed or falls off a patient and no valid SpO2 reading has been detected, an Informative Message will occur.

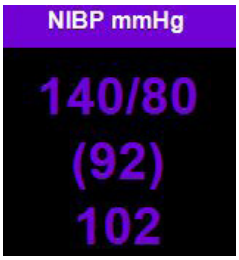
Informative User Messages (For details see Appendix 5 Informative User Messages)

- Informative messages provide feedback to the user for messages which may assist with device usage (e.g. searching for pulse)

Sensor or Cable expired or Near Expiry (For details see Appendix 5 Sensor or Cable Expiry)

- The Masimo SpO2 module monitors the usage of both cables and sensors. Feedback will be provided when either a cable or sensor are near expiration or expired

5.4.4 Maternal NIBP



The NIBP region shows a measurement having been made.

Touch and hold the NIBP region to access the NIBP menu.

Refer to 'Maternal Blood Pressure' Section 7.3 for instructions on performing maternal blood pressure.

5.4.5 Trace Format

The graphical trace screen emphasizes the display of data in graphical form, with numeric data shown on the right hand side.

Only one of $MSpO_2$, NIBP and MPR can be expanded at any one time.

Touch ▼ to expand each measurement.

Annotations and Clinical Events are printed vertically in the TOCO / $MSpO_2$ region of the trace screen.

5.5 Switching the Unit OFF

Press and hold ⏻ to switch the unit Off. A confirmation screen will be displayed.

Touch Power Off to turn off the Team3 or touch ✕ to return to the last screen.

Alternatively, continued holding of the off button for ~15s will switch the unit off directly from any machine state.

5.6 Auto Restart

In the unlikely event that Team3 operation is interrupted, the monitor will automatically restart.

Following a restart, all previously configured settings and operating modes will be retained and the monitoring function will resume as normal.

5.7 Battery Charging

5.7.1 The unit is switched OFF

If the following conditions are all true,

- The unit is switched OFF
- The unit is connected to the mains supply
- The battery option is installed
- The battery is not fully charged

then the On/Off button will illuminate green  and flash, indicating that the battery is charging. Otherwise the indicator will be OFF.

5.7.2 The unit is switched ON

Battery status when the Team3 is NOT plugged into mains supply		
Battery is fully charged.		Battery level is low and requires charging.

Battery status when the Team3 is plugged into mains supply and charging		
Battery is fully charged.		Battery level is low but Team3 is charging.

Note

- **Typical charge time to 90% capacity from discharged is 3 hours.**
- **With Battery supply, monitoring a single ultrasound channel at 25% volume and no printing, Team3 can operate for a minimum of 4 hours.**

6. Monitoring Fetal Parameters

6.1 Preliminary

Ensure that the transducers and transducer belts are clean and ready for use. In particular, check the transducers for cracks or signs of damage. See also cleaning instructions in Section 13.

1. Switch on Team3.
2. Check the printer (If fitted). Ensure there is sufficient paper.
3. Check the printer setup (FHR offsets, Twins/Triplets grids).
4. Enter patient details, if required.
5. To use the **DAWES REDMAN** CTG analysis, the gestational age must be entered before starting the printer / recorder

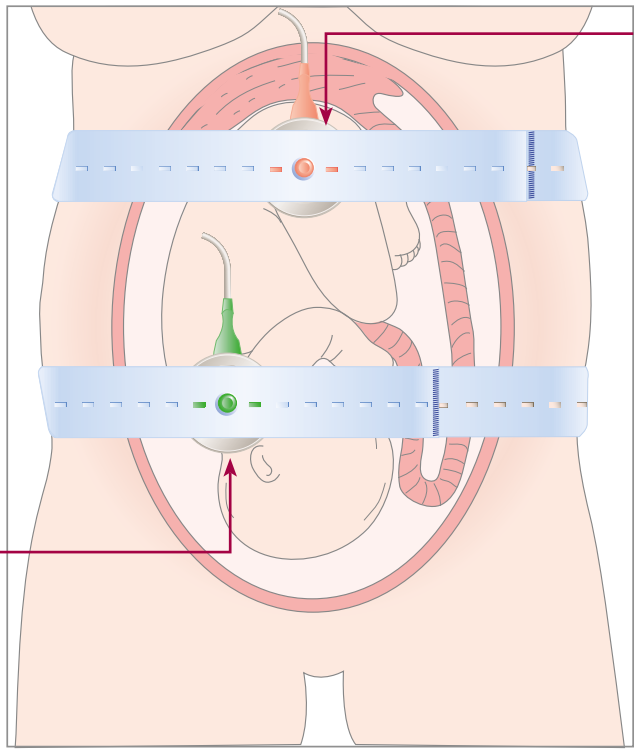
6.2 Ultrasound Monitoring

1. Connect the green transducer to the green socket marked FHR1 on Team3. On the main screen, the ULT1 region becomes active.
2. Palpate the abdomen to determine fetal lie and position.
3. Make the patient comfortable in a semi-recumbent or sitting position. Place the belt around the abdomen, and secure over transducer button.

Transducer and belt attachment

4. Apply Aquasonic coupling gel liberally to the face of the transducer. Position the transducer on the abdomen over the fetal site. Move it slowly until the characteristic hoof-beat sound of the fetal heart is heard.
5. When a good signal is being obtained, Team3 displays the FHR. Check that the fetal heart pulse lamp flashes with each fetal heartbeat, and that the FHR is different from the maternal pulse rate taken at the mother's wrist (or by alternative means). Make a note of the maternal pulse on the chart paper.
6. Connect the fetal event marker to the socket on the rear panel. Explain to the mother how and when to use it. Note that a timeout between presses prevents markers being generated continuously.
7. Adjust the sound level with the volume controls on the touchscreen.
8. To start printing/recording, press the printer/recorder on/off button on the touchscreen.

Hints on Monitoring



Transducer positioning for Ultrasound monitoring

- Make sure the transducer is placed in the optimum position. Avoid positions with strong placental sounds (swishing) or the fetal cord pulse at the same rate as the fetal heart.
- If the fetus is in the Occiput Anterior presentation and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus.
- It is not possible to monitor the fetal heart rate unless an audible fetal heart signal is present. It is important to distinguish the fetal pulse from the maternal pulse. To do this, feel the mother's pulse during the examination, or monitor Maternal HR with $MSpO_2$.

6.3 False recording of FHR

⚠ **When monitoring the fetal heart rate using an external ultrasound transducer, the fetal heart rate may sometimes be falsely reported. This is characteristic of ultrasound monitoring and can have a number of causes, including:**

- **Inadvertent monitoring of the maternal heart rate; whereby the transducer picks up stronger signals from the pulsations of the maternal vessels, particularly in the second stage of labor (when the fetal head and heart is lower within the birth canal);**
- **Signal artefact, such as double-counting or half-counting, whereby the recorded fetal heart rate suddenly appears suspiciously higher or suspiciously lower than the audio signal coming from the monitor's loudspeaker.**

Note: If you have reason to doubt the reliability of the fetal heart rate and/or maternal heart rate, always confirm by independent means.

How to minimise the chances of double rating, half rating or other types of artefact occurring

1. Palpate the maternal pulse for one minute simultaneously and record it on the printed output. Check that the maternal rate is different from the displayed fetal rate.
2. Recording a signal for maternal MECG/$MSpO_2$ will help to identify any cross-correlation between maternal and fetal heart rates.

6.4 Twins/Triplets Ultrasound Monitoring

Use the same procedure as for singleton monitoring, using multiple transducers.

1. Connect the green transducers to the green sockets marked FHR1/FHR2/FHR3 on Team3. On the main screen, the ULT1/2/3 regions become active.
2. Palpate the abdomen and ascertain the lie of each fetus.
3. Place the ultrasound transducers on the patient's abdomen in the optimum positions. Use the ULT1 transducer to monitor the first, presenting fetus. Make the transducers secure with belts.
4. To hear the audio signal for each fetus, press the relevant area of screen. The Audio symbol shows which is the active audio channel.
5. Check that the two /three heart rates are different.

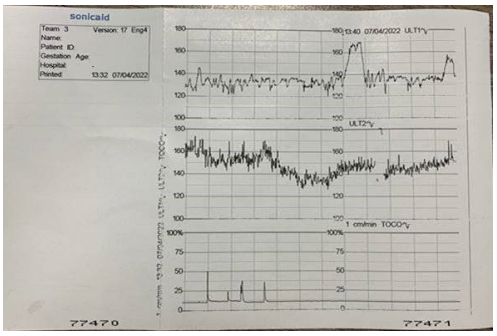
   If the heart rates appear similar check the positions of the transducers.
6. Connect the fetal event marker to the socket on the rear panel. Explain to the mother how and when to use it.
7. Refer to Settings Menu - Print Settings if printer offsets* are required on the traces.

***Note: Once selected, printer offset options remains active until de- selected by the user or the unit is switched off.**

Note: In multiple pregnancies, the manually activated event marker does not allow to determine which fetus is deemed to move.

When interpreting a trace to which the +20bpm or -20bpm offsets have been applied, the interpreter must subtract or add these offsets (20 bpm) from the displayed baseline rate to determine true baseline rate – failure to do so may result in misinterpretation of the trace & inappropriate clinical management. The ULT2 +20/ ULT3 -20 flags are printed at regular intervals as a reminder.

6.4.1 Print Twins Grids



Enabling the print twin grids setting allows twin FHR's to be simultaneously printed in separate grids on the same page of the print-out. (Settings >Trace Offsets>Print Twins Grids).

Print Twin Grids is recommended for antepartum use only.

7. Monitoring Maternal Parameters

7.1 Contractions (using TOCO transducer)

Use only TOCO transducers supplied with the Team3, or listed in the Accessories.

1. Ensure that the TOCO transducer and belt are clean and ready for use. In particular, check the transducer for cracks or signs of damage. See also cleaning instructions in Section 13.
2. Connect the TOCO transducer to the pink socket on Team3.
3. Place the belt round the abdomen, and secure it over the transducer button so that it is retained on the midline over the fundus of the uterus.
4. DO NOT USE COUPLING GEL. Wipe off any gel present on abdomen around this area.
5. Contractions activity is measured as a % of full scale deflection. Touch & hold the TOCO region of the screen to zero the contractions to the set % level (0, 10, 20% - see settings). If enabled, an auto-zero function will activate if the trace has been flat for 3+ minutes.

Check the baseline periodically and re-zero the TOCO if necessary.

7.2 Fetal Movement Event Marker

Fetal movement events can be captured in 2 ways, automatic and manual.

7.2.1 Automatic Fetal Movement Event Marker

The function, when monitoring twins or triplets, can be enabled, however it will not indicate what fetus made the movement.

Automatic Fetal Movement is not indicated for use during labor.

Please be aware Automatic Fetal Movement Markers in the absence of fetal life may be a result of:

- **Movement of the deceased fetus during or following maternal movement.**
- **Movement of the deceased fetus during or following maternal abdominal examination.**
- **Movement of the ultrasound transducer.**
- **The ultrasound transducer detecting a maternal movement, such as the mother coughing or crying.**

Fetal movement events are recorded automatically when this mode is selected, and an appropriate detection level is set. Refer to section 14.5 - Secure Settings - Clinical Settings Sub Menu to activate Automatic Fetal Movement option.

Note: The Automatic Fetal Movement Marker function is defaulted to OFF . If a user wants this function activated, they will need to turn it on behind a password protected screen.

A triangular marker is automatically printed at the top of the fetal heart rate grid.

 - Automatic Fetal Movement Marker

7.2.2 Manual Fetal Movement Event Marker

The Fetal Movement Event Marker is a pushbutton switch fitted with a captive cable and connector which is supplied as standard. It is plugged into the socket on the rear of the unit. The switch allows maternally sensed fetal movements to be recorded.

Note: The manual Fetal Event Marker is indicated for use in antepartum.
Note: The function, when monitoring twins or triplets, will not indicate what fetus made the movement.

Use only Fetal Event Marker switch supplied with the Team3, or listed in the Accessories. Do not connect any other item of equipment to the Fetal Event Marker socket.

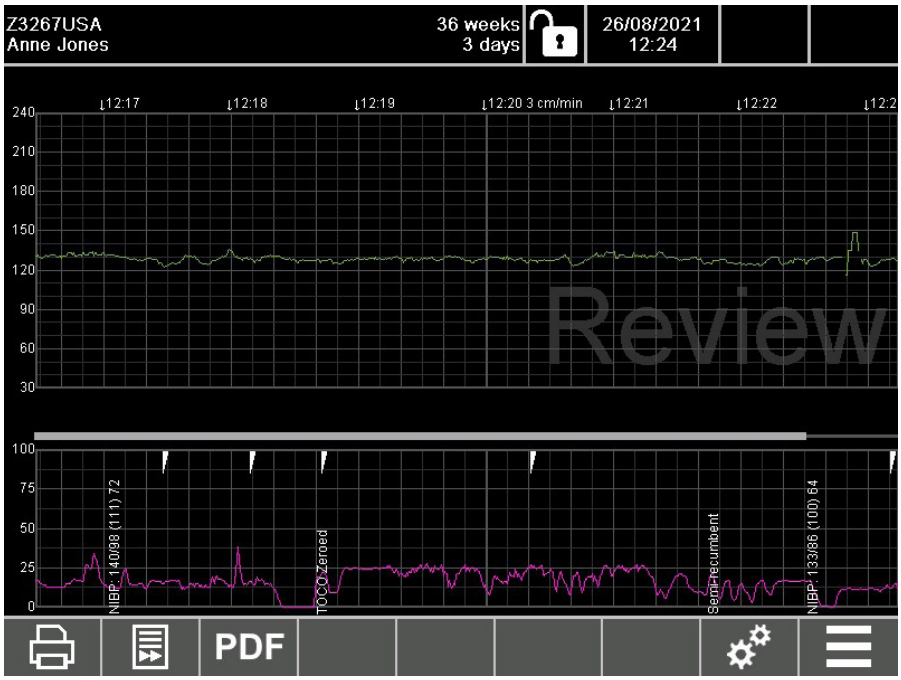
Before use, inspect the Fetal Event Marker switch and connecting cable assembly, ensuring that it is clean and undamaged. See Section 13 for cleaning procedures.

The Fetal Event Marker must be kept dry. Do not immerse or use in the presence of liquids.

1. Connect the event marker to the jack socket on the rear of Team3 ( ).
2. Give the event marker to the mother. Tell her to press the button every time she feels a fetal movement.

A triangular event mark is printed at the top of the TOCO grid.

- Manual Fetal Movement Marker



Note: Team3 can record both Manual and Automatic Fetal Movements simultaneously.

7.3 Maternal Blood Pressure

Team3 can measure the mother's systolic and diastolic blood pressure, mean arterial pressure, and the average pulse rate during the measurement. Measurements can be made manually or automatically (at an interval defined by the user).
An alarm is triggered if the mother's blood pressure goes above or below certain limits. The alarm can be switched off if preferred.

In countries where mean arterial pressure is not used, the value may be disabled on the Team3 printout and display.

Attaching the cuff

The correct selection, & positioning, of cuffs is of paramount importance in ensuring reliable BP readings.

Cuff size

It is essential to ensure that the cuff size is matched to the patient's arm circumference. Two cuff sizes are supplied as standard with the Team3 blood pressure option:

- Medium cuff – covering arm circumferences from 24-32cm
- Large cuff – covering circumferences from 32-42cm

While the above should cover the vast majority of patients, other cuff sizes are available as optional accessories.

Use of an incorrectly sized cuff may result in errors in the BP measurement.

Cuff positioning

To ensure accurate measurement, the cuff must be positioned correctly. It is positioned on the upper arm, and can be applied over light clothing. Any tight, thick or constrictive clothing should be removed.

The cuff must be applied with the hose coming out at the bottom of the cuff, not the top, and should be level with the heart.

When fitting the cuff, note the position of the 'Artery marker' printed on the cuff. Do NOT rely on the hose as the artery position marker.

Other considerations

There are many other factors which can effect BP measuremen.

Key issues that affect accuracy of BP measurements:

- The patient should be relaxed & rested – minimum 5 minutes before commencing measurement
- The patient should not smoke, exercise or consume caffeine for 30 minutes before the test
- The patient should be sitting upright & comfortably with the arm raised to the level of the heart, suitably supported – it should not be held in position by the patient
- The patient should not move or speak during the test
- The cuff must be of the correct size & correctly positioned as detailed above – do NOT rely on the hose as the artery position marker

A conventional sphygmomanometer uses a fundamentally different method of measuring BP based on auscultation. This is generally recognised as the gold standard in non-invasive BP measurement and it is recommended that local protocols are in place for this method to be used for diagnosing/confirming hypertension.

Measurement Limitations

NIBP readings can be affected by the position of the patient, their physiological condition, the measurement site, and physical exercise. Thus a clinician must determine the clinical significance of the NIBP information.

The measurement may be inaccurate or impossible:

- with excessive and continuous patient movement such as shivering or convulsions
- if a regular arterial pressure pulse is hard to detect with cardiac arrhythmias
- with rapid blood pressure changes
- with severe shock or hypothermia that reduces blood flow to the peripheries
- with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery
- on an edematous extremity.

Suspect Hypertensive Patients

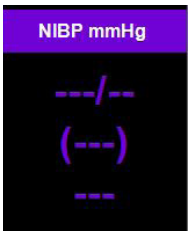
To make a measurement for use in the diagnosis of hypertension, follow the steps below:

1 Ensure the patient is comfortably seated, with their legs uncrossed, feet flat on the floor and back and arm supported.

2 Ask the patient to relax and not talk before and during the measurement.

3 If possible, wait 5 minutes before making the first measurement.

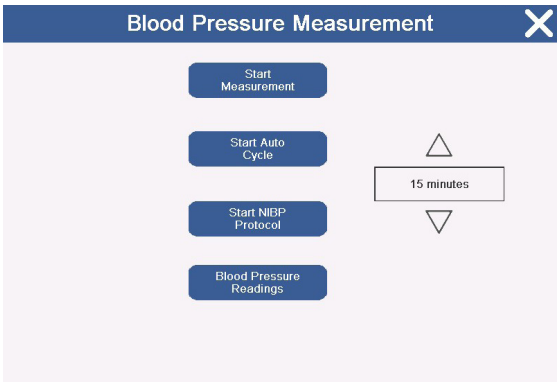
7.3.1 Taking BP measurements



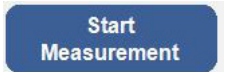
Attach the correct size cuff to the mother.

Touch and hold the NIBP region to access the NIBP menu.

You can select either manual mode or automatic mode:



Manual NIBP

Touch 

to start a manual NIBP reading.
Once completed, the reading will be displayed in the NIBP region.

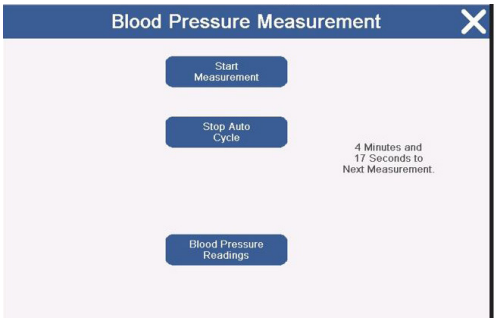
Automatic NIBP

To set an automatic measurement, touch △ ▽ to set the interval between measurements.

Touch Start Auto Cycle to start the measurement. Once completed, the reading will be displayed. A clock symbol will be shown in the NIBP region. An NIBP reading will automatically be taken at the determined interval.

In this screen, you can see a countdown timer indicating when the next blood pressure is due.

To cancel automatic NIPB readings, touch and hold the NIBP region to access the NIBP menu and touch Stop Auto Cycle .



NIBP Protocol

Select Start NIBP Protocol to start the sequential NIBP protocol as follows:

1. BP every 5 minutes times 12 measurements then
2. BP every 15 minutes times 4 measurements then xcvb
3. BP every 30 minutes times 4 measurements then
4. BP hourly forever until turned off

During the protocol, a clock symbol will be displayed in the NIBP region. An NIBP reading will be taken at each point in the protocol and the blood pressure will be displayed.
To cancel the NIBP protocol, touch and hold the NIBP region to access the NIBP menu and touch Stop NIBP Protocol .

Note: The latest measurement results are displayed continuously until a repeat measurement is made or for a period set by the user in the system settings. Refer to section 14.5.

- **To stop the measurement, touch and hold the NIBP region. Touch Stop Measurement to stop the measurement.**
- **To avoid harming the patient, clinical judgement should be used to determine whether unattended blood pressure measurements are appropriate, particularly in the range 1 to 5 minutes.**

Failed measurements (manual and automatic)

When an NIBP measurement fails:

- The NIBP display shows **---/--.**

- **Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal colour, warmth and sensitivity. If the skin quality changes or if the extremity circulation is being affected, move the cuff to another arm or stop the blood pressure measurements immediately. Check more frequently when making automatic measurements**
- **Always use the correct size of cuff. Do not use any cuffs other than those licensed for use with the Team3.**
- **The blood pressure cuff must be properly positioned to ensure blood pressure accuracy and patient safety. Wrapping the cuff too loosely (preventing proper inflation) may result in inaccurate NIBP readings.**
- **For maternal use only; do not use on neonates.**

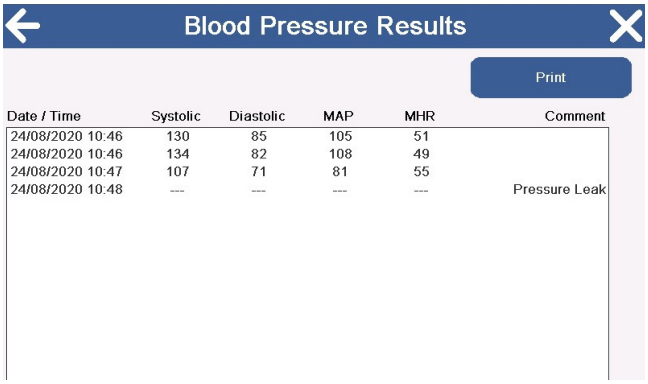
- **Safety mechanisms are incorporated to prevent over-inflation, or extended period inflation. However, patients should be advised to summon assistance if any discomfort results from the use of the NIBP function, and its use discontinued.**
- **Note that, as with all auto-BP measurement systems, results may vary from one make to another, and from measurements based on using a manual sphygmomanometer. Readings are also subject to the well documented "white coat effect" & patients should be rested for a minimum of 5 minutes before measurements are taken. It is recommended that BP readings are confirmed using a manual sphygmomanometer before diagnosing clinical hyper- / hypo- tensive conditions requiring treatment.**
- **Avoid taking measurements during contractions as this may affect the reading.**
- **Frequent measurements may cause blood flow interference and injure the patient.**
- **To prevent further injury, do not place the cuff on any wound.**
- **Do not place the blood pressure cuff on a limb under intravenous infusion, intravenous therapy or arteriovenous shunt, or the transient blood flow interference will injure the patient.**
- **Do not place the cuff on the arm at the same side as mastectomy, or lymph node clearance.**
- **NIBP readings may be inaccurate for patients experiencing moderate to severe arrhythmia.**
- **The increasing cuff pressure may cause transient function failure to other monitoring equipment used on the same limb.**
- **Patient injury risk. Any external compression of the blood pressure hose or cuff may cause patient injury, system errors, or inaccurate measurements.**
- **Patient injury risk. Never install Luer Lock connectors on Team3 blood pressure cuff tubing. Using these connectors on blood pressure cuff tubing creates the risk of mistakenly connecting this tubing to a patient's intravenous line and introducing air into the patient's circulatory system.**
- **Ensure the inflation tube connecting the blood pressure cuff to the Monitor is not obstructed or tangled.**
- **Extremes of temperature, humidity and altitude outside limits specified for Team3 can affect results.**

Reviewing BP Results

Touch and hold the NIBP region to access the NIBP menu.

Touch Blood Pressure Readings to show the BP results screen. The NIBP results will de displayed.

Touch △ ▽ to scroll through the results.



Note: BP results can be printed in review mode - see section 5.3.8.

7.4 Maternal Oximetry

Team3 can measure the mother's blood oxygen saturation and pulse rate. An alarm sounds (if enabled), if the mother's oxygen saturation drops below the set level, or if her pulse rate goes above or below certain limits.

Recommended for best practice:

- **Unplug SPO2 sensors when not in use; leaving SpO2 sensors plugged in can impact the Team3's performance**
- **Do not clip the SpO2 sensor to anything other than the mother.**

7.4.1 Procedure

Note: If using the Sonicaid Wireless Transducer System FTS3 or Freedom SF1, you will need to view the Version screen (See 15.5 Secure Settings) to determine if you can use SpO2 and wireless transducers at the same time on your Team3. Mainboard versions less than 5 cannot support concurrent use of Freedom and SpO2.

1. Connect the maternal oximetry sensor to the maternal oximetry cable.
2. Connect the oximetry cable to the Team3 connector. Ensure that the connector key on the oximeter lead is correctly aligned with the $MSpO_2$ socket keyway on the Team3 connector. Push the connector straight in until it locks. Do not twist.
3. Attach the sensor to the mother. See the instructions supplied with the sensor.
4. When it finds a signal, the results will be displayed in the $MSpO_2$ / MPR bpm region of the screen.

Note: If monitoring MECG, the MECG heart rate overrides the pulse rate from the oximeter.

5. Adjust the alarm limits and alarm volume, if necessary. See Section 8.

Disconnecting the oximetry sensor

To disconnect the oximetry sensor, grip the outer part of the connector and pull to release the locking catches.

- **Do not try to disconnect the oximetry module by pulling on the lead. This will be unsuccessful, and the connector may be damaged.**
- **Do not use any maternal oximetry sensors other than those approved for use with the Team3. Use of incompatible sensors or connecting cables could result in patient harm.**
- **Use only Sonicaid connecting cables.**
- **Use only Masimo compatible RD SET MD14-05 5 ft. cable on fetal monitors fitted with Masimo MSpO2 .**
- **Use only Nellcor compatible DOC 10 connecting cables on fetal monitors fitted with Nellcor MSpO2 .**
- **Remove any nail varnish and artificial fingernails before use as they are likely to affect the readings. Nail varnish remover contains acetone. Contact with acetone will damage the maternal oximetry sensor.**
- **Relocate the sensor periodically (at least every 4 hours) and monitor skin integrity. If the mother experiences discomfort due to the oximetry sensor, discontinue use immediately.**
- **A poor $MSpO_2$ signal may prevent the FHR cross-checking from functioning. If a good MPR indication cannot be obtained other methods must be used to prevent accidental interpretation of MPR as FHR.**
- **Inspect $MSpO_2$ sensor for damage before use.**
- **Check $MSpO_2$ signal quality regularly to ensure that no deterioration has occurred.**
- **Do not use the $MSpO_2$ sensor on the same arm as the NIBP cuff.**

- **Nellcor (Rectangular Socket) - Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Covidien Nellcor™ monitoring systems, sensors, and cables. Reference the individual testing device's operator's manual for the procedures specific to the model of tester used. While such devices may be useful for verifying that the sensor, cabling, and monitoring system are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO_2 measurements.**

Further information

The following information and warnings are supplied in accordance with the requirements of ISO 9919:

1. The Team3 $MSpO_2$ system is calibrated to display functional oxygen saturation.
2. The range of peak wavelengths and maximum optical power outputs for the approved pulse oximeter probes are as follows:

Probe Type	Peak Wavelengths	Optical Power Output
Masimo RD SET DCI (4050)	660nm (red light) and 940nm (infrared light)	<15mW
Nellcor DS100A	660 and 890nm nom.	<15mW

3. The function or accuracy of the $MSpO_2$ system may be affected by the following:
   - Incorrect sensor position.
   - Presence of an arterial catheter, blood pressure cuff, or intravascular line on the same limb.
   - Ambient light.
   - Excessive patient movement.
   - Intravascular dyes or externally applied colouring such as nail polish, dye or pigmented cream. Artificial fingernails.
4. Displayed ranges: $MSpO_2$ and pulse ranges are as shown in section 15.
5. Data update period: 1 second
   Heart rate averaging: 8 beats
   Alarm latency: < 1 second
6. Alarm limits: See Section 15- Specifications.
7. Compatible probe types: Nellcor Durasensor DS-100A , Masimo RD SET DCI (4050)
8. Recommended maximum application time: 4 hours
9. Probe temperatures >41°C – Specific instructions: Not applicable
10. Probe temperatures >41°C – Operator sequence of actions: Not applicable
11. Probe temperatures >41°C – Maximum temperature: Not applicable
12. Probe temperatures >41°C – Age restriction: Not applicable
13. Biocompatibility: Refer to probe manufacturer for full details.
14. Sterility: Not applicable. Probes are not supplied pre- sterilised.
15. Caution notes: See above for cautions regarding use of compatibl sensors and connecting cables.
16. Patient population: For use on maternal patients only.

    Applied body part: Any well-perfused finger that fits comfortably in the sensor Index finger preferred.

    Application: For occasional use on maternal patients within a fixed healthcare facility.

Note
For further clinical information/studies/reports please refer to Appendix 4 - MSpO2 Addition Clinical Information.

Note:
- **On fetal monitors fitted with Masimo MSpO2 : For further clinical information, see “Appendix 5 Maternal SpO2 Additional Masimo Information”.**
- **On fetal monitors fitted with Nellcor MSpO2 : For further clinical information, see “Appendix 4 Maternal SpO2 Additional Nellcor Clinical Information”.**

Note:

- **Use of non-Masimo SpO2 sensors/cables with Team3: If using any SpO2 sensor or connecting cable other than Masimo, the customer acknowledges that Huntleigh makes no representation as to the accuracy of the measurement of SpO2.**
- **Use of non-Nellcor SpO2 sensors/cables with Team3: If using any SpO2 sensor or connecting cable other than Nellcor, the customer acknowledges that Huntleigh makes no representation as to the accuracy of the measurement of SpO2.**

Nellcor Clinical Evaluation report summary:

The following summary describes the demographic information of the subjects enrolled into the study for all other sensors (listed in Table A-1): A total of 11 subjects were analyzed. There were 4 (36.4%) males and 7 (63.6%) female subjects enrolled into the study. The mean age of study participants was 30.36 ± 7.85 years, with a range of 22 to 46 years of age. Three subjects had dark pigmentation (dark olive to extremely dark). Weight ranged from 58.4 kg to 114.4 kg, and height ranged from 159 cm to 187 cm.

A_{RMS} (Accuracy root mean square) is used to describe the accuracy of pulse oximetry, which is affected by both bias and precision. Both SpO2 and pulse rate meet the acceptance criteria for the D100A sensor during non-motion conditions.

(≤ 3.0% using 411 data points, over 70-100% saturation, and ≤3.0% using 444 data points for BMP).

8. Alarms

8.1 What is meant by an alarm

There are 2 types of alarm on Team3; Technical Alarms and Clinical Alarms. Technical alarms are displayed with a blue bell icon and clinical alarms are displayed with a yellow bell icon . Both alarms will have different sounds. Technical alarms will not print.
During most monitoring sessions things occur which are to some extent unexpected or outside normal routine. These are referred to collectively as alarms, even though many of them are not in the least alarming.

These alarms must not be relied on to detect pathological heart rate patterns.

- **Team3 must be printing / recording for alarms to be active.**
- **All alarms have Medium priority.**

8.2 What is seen and heard

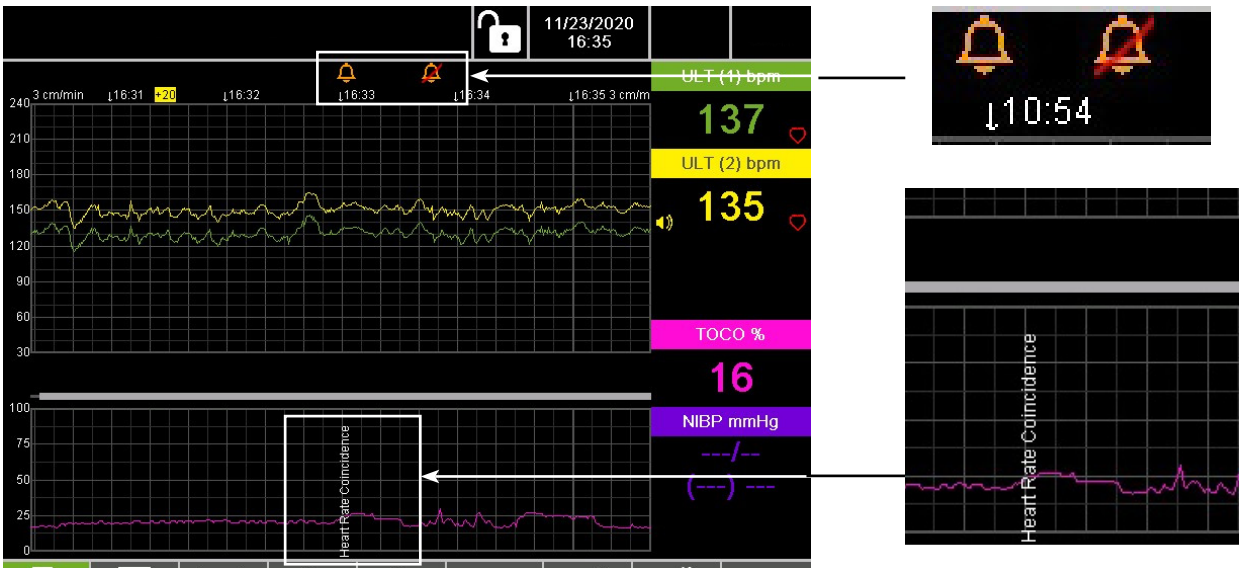
When the Team3 enters an alarm condition, an alarm sounds, will appear at the top of the screen and the associated alarm regions will flash.

An alarm indicator will be printed on the trace screen identifying the time of the alarm . An alarm condition will be printed on the TOCO region of the screen.

The alarm will continue to sound until the operator acknowledges the alarm.

Touch to acknowledge the alarm and turn off the audible and visual indicators.

An alarm acknowledgement indicator will be printed on the trace screen identifying the time of the alarm acknowledge .



Printed Indicators

- Fetal alarms
- Maternal alarms

ULT1 and ULT2 Fetal High Heart Rate	Maternal Systolic High Alarm
ULT1 and ULT2 Fetal Low Heart Rate	Maternal Systolic Low Alarm

ULT1 and ULT2 Fetal Signal Loss	Maternal Diastolic High Alarm
Maternal High Heart Rate	Maternal Diastolic Low Alarm
Maternal Low Heart Rate	Toco Persistence Alert
Maternal Low O_2 Saturation Alarm	
Maternal High O_2 Saturation Alarm	

8.3 Responding to alarms

Type of alarm	Recommended user response
Signal outside range	Acknowledge alarm Responsible clinician to decide what action to take
Loss of signal	Acknowledge alarm, if appropriate For FHR: reposition the transducer For other parameters: check transducer attachment and connections
Fetal Cross Channel	Re-position transducers if required.

8.4 Controlling alarms

There are four ways of controlling alarms:

- Acknowledge (i.e. silence) it when it occurs.
- Switch it off, so that it is never triggered.
- Alter thresholds so that it occurs more frequently or less frequently.
- Alter the volume of the audio alarm.

Switching alarms off, changing thresholds or volume
See Section 5.3.7 - Settings - Alarm Settings.

Note: To test the alarms, run Demo mode (see section 14.5) and wait until an alarm is triggered. All Alarms are of Medium priority and so any input will provide confirmation of a working Alarm system.

8.5 Nellcor SpO2 technical alarms (Nellcor SpO2 option only)

The following technical alarms may be displayed:

MSpO2 Extended updates

Indicates maternal heart rate measurement has been static for 25+ seconds. If triggered, the displayed MPR is invalid. Re-position the sensor (try a different finger) .

MSpO2 Pulse Timeout

Indicates that the pulse signal has been lost. Re-position the sensor (try a different finger) .

Sensor fault

Indicates sensor is faulty - check cable connections or try another sensor and/or sensor interface cable.

SpO2 fault

Indicates an internal SpO2 module fault - service repair required.

Note
To test the alarms, it will be necessary to simulate alarm conditions using external input means. For FHR alarms, this can be done simply and quickly just by stroking the face of a connected Ultrasound transducer by hand, varying the rate to trigger high and low rate alarms accordingly.

9. Printing

9.1 Introduction

Team3 incorporates a thermal printing system for use with continuous fan-fold thermal paper. It is virtually silent, rendering it unobtrusive in operation.

9.2 Paper options

The printing system is optimised for use with plain Sonicaid thermal print paper, although alternative paper trays are available as accessories to facilitate the use of Philips or GE/Corometrics paper. Note that the printout options available with alternative paper types may be restricted due to difference in size compared to the Sonicaid paper.

Standard thermal print paper fades over a period of time – typically up to 5 years depending on storage conditions. If it is necessary to guarantee a longer storage time for paper traces, the use of Architrace paper is recommended. This has a 25 year rated lifetime. Alternatively, consider the use of Central Monitoring Software which allow traces to be stored and archived electronically.

9.3 Paper care and handling

To preserve the life of the paper, both before and after printing, it should be stored indoors at a temperature of 18-25°C, and with a relative humidity of 40-60%.
Do not expose to UV light sources such as direct sunlight or fluorescent lighting.
Do not allow the paper to come into contact with the following:

- Carbon and carbonless forms
- Wet-type diazo copy paper
- Chart papers or adhesives containing Tributyl-phosphate
- Dibutyl-phosphate or other organic solvents
- Envelopes or folders composed of plastics containing plasticizers
- Solvents or solvent-containing products, which include Alcohol, Ketones, Esters, Ethers or derivates from this chemical group
- Petroleum solvents like Gasoline, Toluene or Benzene
- Greasy substances like Lanolin (e.g. Hand-lotion), Lard, Butter Oil or Vegetable Oil.
- Any heat source.

9.4 Print speed and duration

Print speed is selectable at 1, 2 or 3 cm/minute according to user preference or local clinical practice. Total running times with a standard 45m pack of Sonicaid paper are as follows:

Speed	Running Time
1cm/minute	75 hours
2cm/minute	37.5 hours
3cm/minute	25 hours

Note
The Print Speed can only be changed through the Secure Settings menu. (See Section 14.5).

9.5 Changing paper packs

Paper packs generally have a pre-printed colored marker to alert the user that the paper is about to reach the end of its duration. With the Sonicaid paper this starts at approximately 1 metre before the end of the pack, giving 30-100 minutes notice of paper end. Use this time to unwrap and prepare a new pack ready for printing.

When the paper end is reached, the printer will stop. The printer icon on the control bar will change to  . Print information will be stored in memory for up to 100 hours to allow the paper pack to be changed. Follow the procedure described below for changing the paper pack.

Once a new pack of paper has been installed and the paper tray pushed home, print icon will return to  and the stored data will be printed at a quick rate until the buffer is empty. Then it will revert to printing live data.

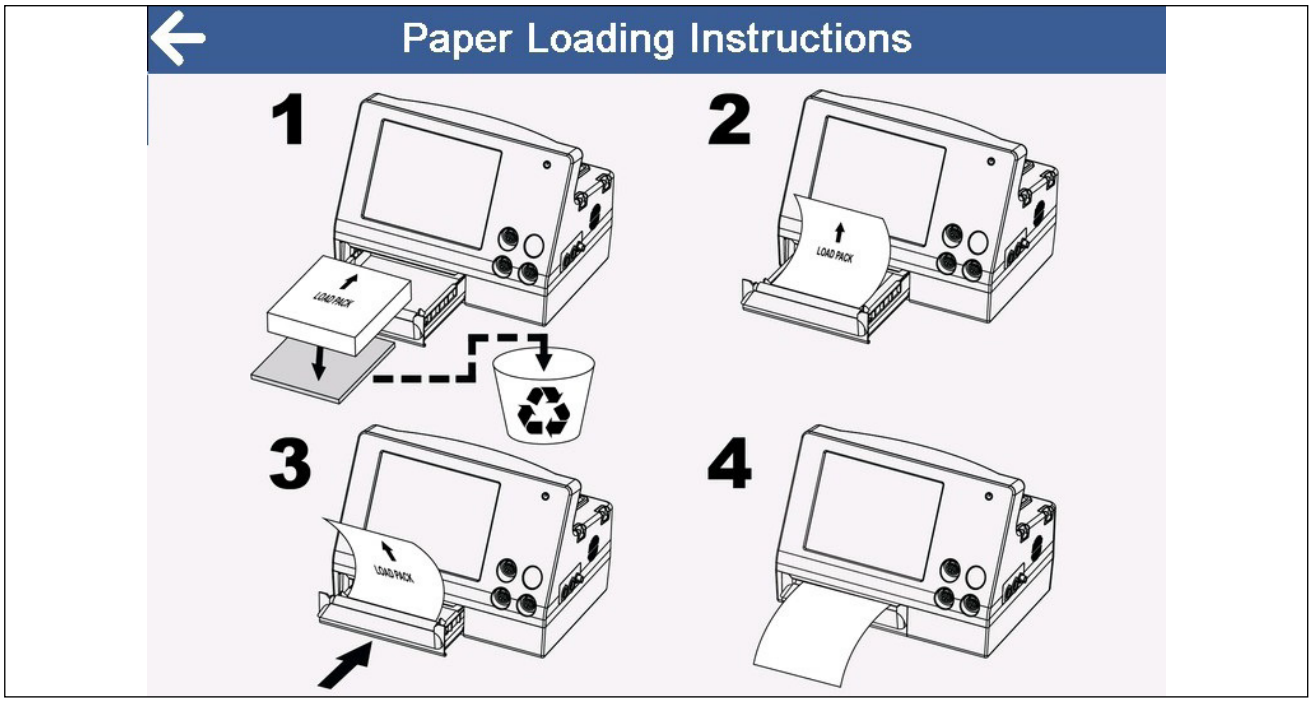
Finally, ensure that at least one fresh pack of paper is available to replace the old one when it comes to an end.

The printer buffer is cleared if the unit is turned off, or in the event of a power failure.

To avoid contact with sharp edges, do not insert hands inside printer aperture.

9.6 Loading printer paper

When the printer tray is opened, a help screen displaying the following diagram is shown. The screen may be closed by closing the paper tray or bypassed using the back button  .

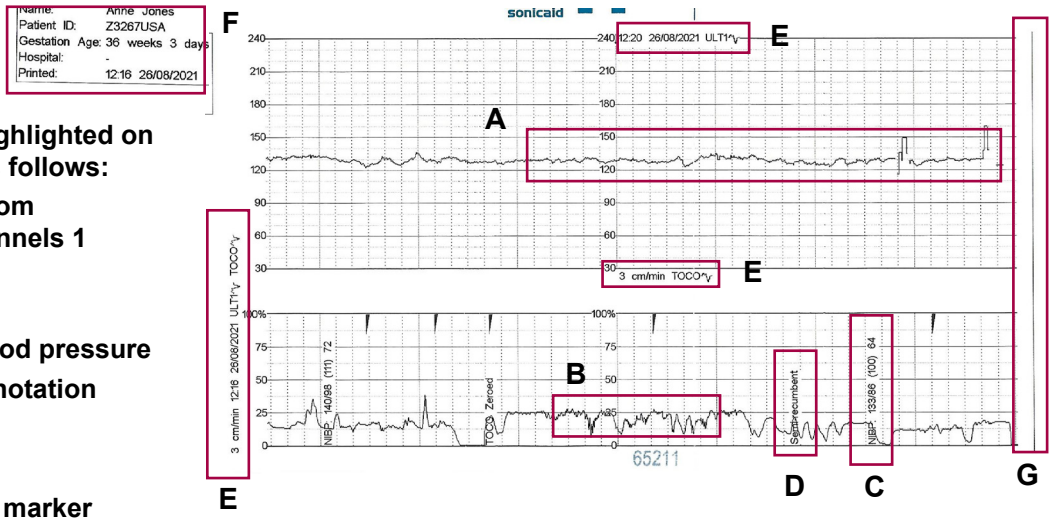


Note: Ensure the paper remains centrally aligned while closing the drawer.

IMPORTANT: As paper tracks through a printer mechanism it will move from side to side due to variations in paper and printer mechanism alignment. This is an unavoidable feature of all printers of this type, as used in all makes of fetal monitors. With plain paper, where the grid is printed at the same time as the trace data, any alignment error is eliminated, ensuring 100% print accuracy. With pre-printed paper, this error cannot be eliminated and will result in alignment errors between the trace and the grid.

9.8 Sample Trace (Sonicaid paper)

The illustration below is of an actual CTG chart.



The features highlighted on the chart are as follows:

A. FHR trace from ultrasound channels 1 and 2

B. TOCO trace

C. Maternal blood pressure

D. Easinote annotation

E. Legends

F. Header

G. End of trace marker

9.9 Turning off the printer

9.9.1 Normal recording

Touch the Green printer button  . The button will flash while the printer's buffers are cleared and become grey when the printing has stopped.

Touch the Green printer unavailable button  . If the paper has run out, the following screen will appear.

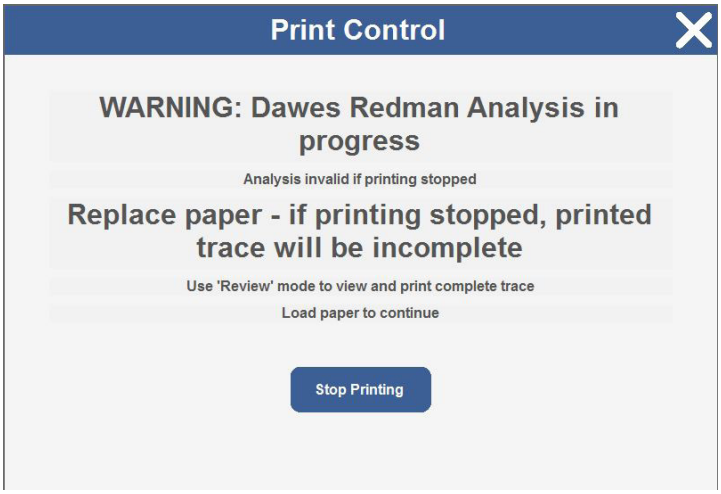
Touch  to stop the recording or  to cancel. If cancelling, replenish the paper to continue

9.9.2 Stopping the printer while DAWES REDMAN analysis is running

If the **DAWES REDMAN** CTG analysis has not yet met the criteria, stopping the printer will result in the analysis being invalidated.

Touch the Green printer button  . The following screen will appear.

If the paper has run out, touch the Green printer unavailable button  . The following screen appears.



Touch  to stop the analysis or  to cancel.

9.9.3 Stopping the printer while print timer running

If the print timer is available this will show as an overlay on the print button  .
When the printer is active this will show as follows  .

If you attempt to stop the printer before the print timer expires, the following screen will be displayed.

Touch  to stop the printing or  to cancel.

10. DAWES REDMAN Antepartum Analysis

10.1 Overview

DAWES REDMAN analysis is a software option available with all Team3 antepartum monitors. The software tests fetal heart rate parameters against the criteria which define a normal record in single pregnancies for antepartum testing. The output for twins is nonspecific since each twin's fetal movement may not be certain at the time of maternal annotation with the manual marker. This analysis cannot be used in triplet pregnancies.
The **DAWES REDMAN** criteria have been developed by Dawes, Redman et al at Oxford University and the CTG analysis provides an objective measurement of a range of trace features that have been trained within an algorithm derived from the Oxford database. The analysis report output will contain the messages 'Dawes-Redman Criteria Met', 'Dawes-Redman CTG analysis invalid' or 'Dawes-Redman Criteria Not Met'. For further details on the training and use of this EFM analysis algorithm, visit www.dawes-redman.com.
DAWES REDMAN analysis can be used on women who are experiencing Braxton-Hicks contractions but it is not intended for use in latent or established labour.
As such, **DAWES REDMAN** analysis is not a diagnostic tool, but an aid to clinical management when a Fetal Heart Rate tracing is being interpreted by a qualified physician.
Indeed, both the physician's visual assessment of the trace and the analysis provided by **DAWES REDMAN** should be considered within the context of a full clinical assessment before decisions are made regarding clinical management.
High quality fetal heart rate continuous tracing and maternal annotation input of fetal movements is needed for the **DAWES REDMAN** EFM analysis to provide a usable output.
The analysis integrated into Team3 is a full implementation of version 1.0.0.8 of **DAWES REDMAN** EFM analysis .

IMPORTANT
Interpretation and diagnosis of the Trace record remain the responsibility of the appropriately qualified medical staff.

⚠ **The DAWES REDMAN analysis is not valid during latent or established labor.**

⚠ **DAWES REDMAN analysis does not support triplets. If a third US transducer is connected, DAWES REDMAN is automatically disabled.**

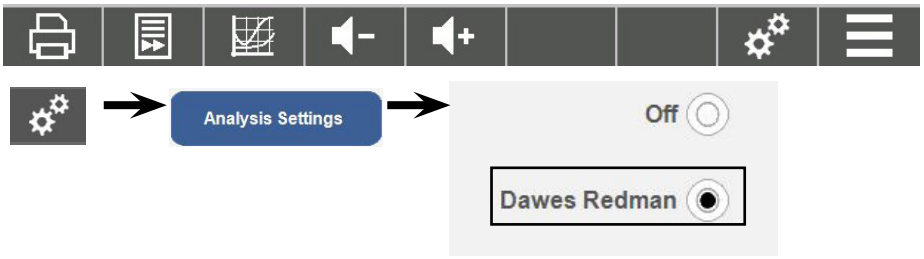
10.2 Using DAWES REDMAN Analysis

Note
- **Ensure that the manual fetal movement event marker is plugged in and working.**
- **DAWES REDMAN analysis does not take account of automated fetal movements.**
- **DAWES REDMAN analysis is OFF by default on Antepartum monitors.**

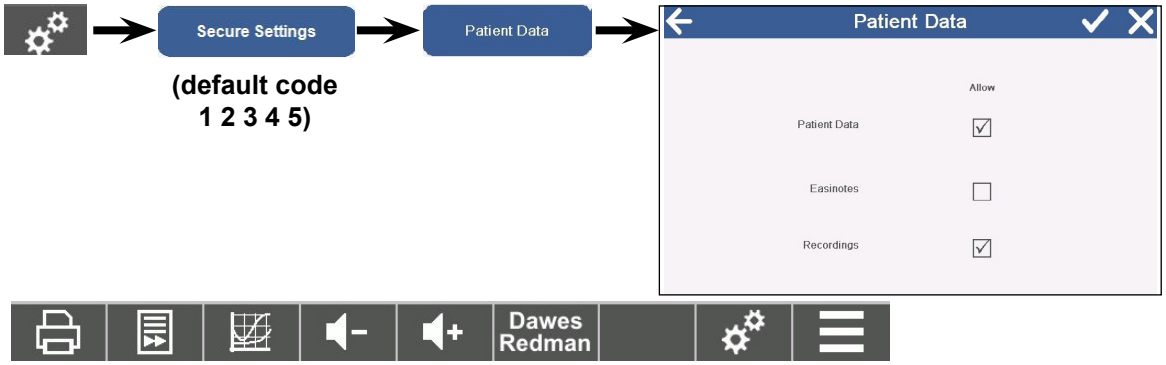
The first analysis result is reported after 10 minutes of good quality Trace data. It is then updated every 2 minutes, up to a maximum of 60 minutes.
The analysis can be stopped once the criteria have been met. Team3 produces a report of the analysis results at the end of the trace. Abnormalities are highlighted. If the analysis is not stopped, it is possible for the results to change to CRITERIA NOT MET.

Starting DAWES REDMAN analysis

Dawes Redman must be enabled in Analysis Settings in order for the **DAWES REDMAN** analysis button to be displayed.



Patient data and Recordings in the Secure Settings menu must also be enabled as shown below.

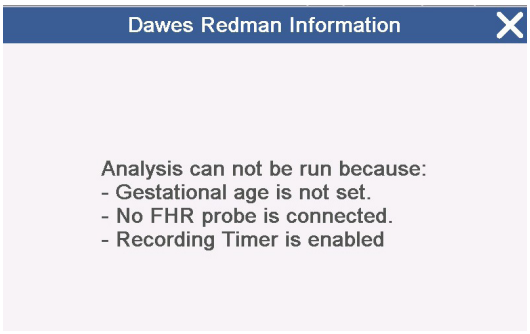


(default code 1 2 3 4 5)

Note

- **Ensure only 1x ultrasound transducer is plugged in unless monitoring twins. If a second ultrasound transducer is left plugged in, but not used, this will affect the analysis.**
- **Ensure gestation age is set in Patient Details.**

Failure to follow all of these instructions will bring up a warning message when the **DAWES REDMAN** button is pressed. See below a full lis t of all possible reasons why the **DAWES REDMAN** analysis cannot be started and the corresponding screen.



- **Gestational age is not set.**
- **No FHR probe is connected.**
- **Recording Timer is enabled.**
- **Invalid probes connected.**
- **Analysis does not support triplets.**
- **Analysis is not indicated for use with FECG.**

Start the printer or recording to start analysis. The Trace will contain the message '**DAWES REDMAN** Started' and the **DAWES REDMAN** button will turn Light Purple.

Analysis Button	Description
	The **DAWES REDMAN** analysis has not been enabled in Analysis Settings.
Dawes Redman	The **DAWES REDMAN** analysis cannot be started due to one of several reasons.
Dawes Redman	The **DAWES REDMAN** analysis can be started.
Dawes Redman	Prior to 10 minutes the **DAWES REDMAN** button will be Light Purple.
Dawes Redman	Between 10 and 60 minutes, if the Criteria are not yet met, the **DAWES REDMAN** button will be Dark purple.
Dawes Redman	After 60 minutes, if the Criteria are not met, the **DAWES REDMAN** button will be Cyan.
Dawes Redman	Between 10 and 60 minutes, if the Criteria are met, the **DAWES REDMAN** button will be Green.

Analysis stops at 60 minutes and after printing the table of results, monitoring of the fetus and the mother continues.
If the Green, Dark Purple or Cyan **DAWES REDMAN** button is pressed, Team3 will display the results from the last analysis calculation.

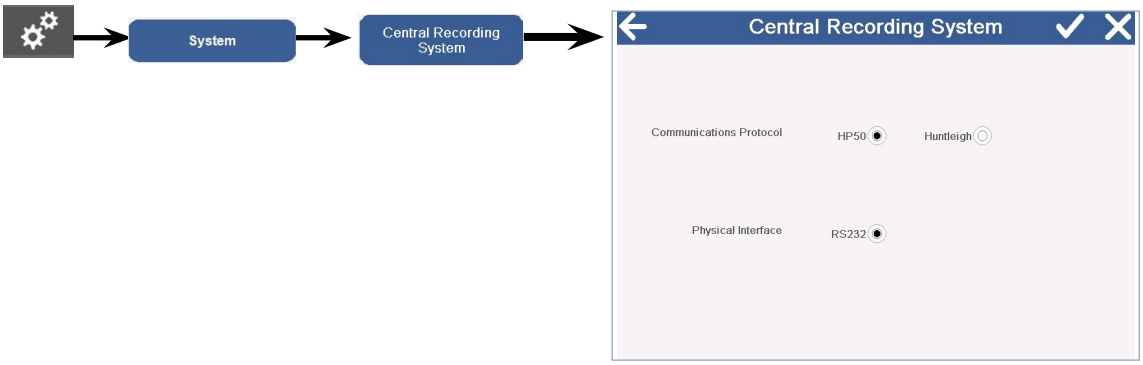
11. Using Team3 with a Clinical Records System

Team3 can be connected to authorised CRS systems:

Central monitoring systems using the industry standard HP50 / Philips communications protocol A.03.00 should work with Team3. Contact Huntleigh Healthcare for details.

11.1 Connecting Team 3 to authorised CRS software

1. Connect the CRS software lead to the RS232 connector on the rear of Team3.
2. Refer to the connection instructions supplied with your OEM CRS system.
3. Select the relevant communication protocol in the Central Monitoring Screen.



12. Trouble Shooting

This section gives some of the more common problems encountered during use together with possible causes. If the problem cannot be located after consulting the table in this section, the Team3 should be switched off, disconnected from mains power source and a qualified technician should be consulted.
Before attempting trouble-shooting, verify that the power cable is properly connected to both the Team3 and the mains power source.

12.1 Essential Performance

If you lose essential performance, refer to the table in Appendix 2: Manufacturer's Performance Criteria Specification.

12.2 FHR

SYMPTOM	POSSIBLE CAUSE / REMEDY
No FHR signal displayed	Check Team3 is switched on. Check the FHR transducer is connected.
High % signal loss	Check transducer placement. Check the transducer is not damaged. Consider switching from Ultrasound to FECG.
No FHR trace printed	Check Print button has been pressed. Check there is paper in the paper tray. Check paper tray is fully pushed in.
Only one trace (twins/tripets) OR Traces superimposed (twins/triplets)	Check 'Printer Offsets' in Printer setup. See Section 5.3.7
No beep when button pressed.	Check sound setting. See section 5.3.7.
Alarm not working	Alarm may be turned off. See Section 5.3.7 Team3 not printing/recording.

12.3 Oximetry

SYMPTOM	POSSIBLE CAUSE / REMEDY
No signal appears when the oximetry sensor is connected OR Signal disappears after some time of monitoring	Check that cable is properly connected to monitor. Check connections between cable and sensor. Check finger properly inserted. Nail varnish can interfere with readings – try own finger.

12.4 Fetal event marker

SYMPTOM	POSSIBLE CAUSE / REMEDY
No mark appears on the trace when the mother presses the event marker.	Check event marker is connected Check enough time has elapsed since button last pressed.
Team3 does not beep when the mother presses the event marker	Check event marker is connected Check sound setting. See section 5.3.7.

12.5 Maternal blood pressure

SYMPTOM	POSSIBLE CAUSE / REMEDY
No reading reported.	Check cuff and hose, then try another measurement.

12.6 Printing

SYMPTOM	POSSIBLE CAUSE / REMEDY
Paper runs out	A colored stripe will appear when the paper pack nears its end (Sonicaid paper). Once the paper has expired, the printer icon on the control bar will change to  . Print information will be stored in memory for up to 100 hours to allow the paper pack to be changed.
Poor print quality	1. Make sure the correct paper is loaded. 2. Make sure the paper is loaded correctly. 3. Make sure the paper tray is fully pushed in. 4. Try printing again. 5. If there is no improvement, clean the print head. See Section 14.
Printer stops working	Check paper supply and feed. If not successful, swap unit out. Trace data is stored in memory.

12.7 General

SYMPTOM	POSSIBLE CAUSE / REMEDY
Unit locks up, is unresponsive or is unable to switch off	Maintain contact on the on/off sense button until the unit shuts down - this may take 15-20 seconds.

In the unlikely event that Team3 operation is interrupted, the monitor will automatically restart.

Following a restart, all previously configured settings and operating modes will be retained and the monitoring function will resume as normal.

If multiple restarts occur, the monitor will perform a full reset. In this event, the display will go blank, closely followed by a splash screen whilst the monitor reboots.

This may take up to 40 seconds after which the monitoring function will resume as normal.

If this is deemed inconvenient, please contact your supplier.

13. Care and Cleaning

13.1 General Care

All Huntleigh products have been designed to withstand normal clinical use, however they can contain delicate components, for example the ultrasound transducer, which should be handled and treated with care.

Periodically, and whenever the integrity of the system is in doubt, carry out a check of all functions as described in the relevant section of the IFU. If there are any defects to the housing contact Huntleigh or your distributor for repair or to order a replacement.

Please ensure that you check with your facility's local infection control policy and medical equipment cleaning procedures.

Observe warnings and guidance on cleaning fluid labelling regarding use and personal protective equipment (PPE).

Always switch off the monitor and disconnect from the AC supply before cleaning and disinfecting.

Do not use abrasive cloths or cleaners.

Do not use automatic washers or autoclaves.

Do not use phenolic detergent based disinfectants, solutions containing cationic surfactants, ammonia-based compounds, perfumes or antiseptic solutions such as Sterisol or Hibiscrub.

If detergent or disinfectant wipes are used ensure that excess solution is squeezed from the wipe prior to use.

Do not allow any fluid to enter the products and do not immerse in any solution.

Always wipe off disinfectant using a cloth dampened with clean water.

13.2 General Cleaning and Disinfecting

Always keep the external surfaces clean and free of dirt and fluids using a clean dry cloth.

1. Wipe any fluids from the surface of the product using a clean dry cloth.
2. Wipe with a cloth dampened in 70% Isopropyl Alcohol.
3. Completely dry with a clean, dry lint free cloth.
4. If the product has been contaminated use the methods described for patient applied parts.

13.3 Cleaning and Disinfecting Patient Applied Parts

Clean the applied parts before examining a patient using low risk cleaning method below.
Following patient examination, clean and/or disinfect the applied parts by the appropriate method based upon the level of cross contamination risk, as defined below:

Risk	Definitions	Procedure
Low	Normal use or low risk situations include patients having intact skin and no known infection and the probes have not been contaminated with blood.	1. Remove soiling, wipe with a mild neutral detergent and then wipe with a cloth dampened in water. 2. Completely dry with a clean lint free cloth.
Medium	The patient has a known infection, skin is not intact, the part is heavily soiled.	1. Follow low risk procedure then wipe with a cloth dampened in Sodium Hypochlorite (1,000ppm). 2. After two minutes wipe with a cloth dampened in water and then dry with a clean lint free cloth.
High	This procedure should only be used when the part has been contaminated by blood.	1. Follow low risk procedure then wipe with a cloth dampened in Sodium Hypochlorite (10,000ppm). 2. After two minutes wipe with a cloth dampened in water and then dry with a clean lint free cloth.

WARNING
Repeated and unnecessary use of concentrated solutions will result in damage to the product. Do not allow Sodium Hypochlorite solutions to come into contact with metal parts.

The use of disinfectant materials, other than those listed, is the responsibility of the user for their efficacy and compatibility with the device.

Approved Products	✓	DO NOT USE	✗
LINGET ANIOS		**SURFA'SAVE**	
WIP'ANIOS Excel		**Surfanios Premium**	
Clinell Alcohol Wipes (Red)			
Clinell Alcohol Wipes Plus+ (Red)			
Clinell Universal Wipes (Green)			
Clinell Universal Spray (Green)			
Clinell Detergent Range (Yellow)			

WARNING
After using chemicals ALWAYS rinse off / remove the chemical with absorbent material, dampened in clean water and dry with a clean cloth.

13.4 NIBP Cuff and Maternal Oximetry Sensor

For cleaning and disinfection, refer to instructions supplied by the manufacturer.

13.5 Transducer Belts

Re-useable belts can be hand-washed at 40°C maximum using a washing powder or mild detergent solution following the detergent manufacturer's guidance. Rinse with clean water and dry without using heat.

14. Maintenance

Warning
It is very important that all instructions in the Maintenance section are followed carefully.

13.1 User maintenance

The checks below can be performed by any user of the equipment.

Mechanical inspection

Every three months:

1. Inspect the AC supply cable, transducers, and all other assemblies and connectors for loose or broken parts, or any other damage.
2. Pay particular attention to the AC supply socket.
3. Look carefully for cracks which may allow the ingress of liquids or gels.
4. Replace any broken or damaged transducers or cables.
5. If there is damage to the main Team3 unit, contact your local Huntleigh Healthcare Ltd representative.

Cleaning the print head on the printer

1. Pull the paper tray out as far as it will go.
2. Remove the paper pack.
3. Using a lint-free cloth and pure alcohol, wipe along the full width of the print head, which is beneath the plastic edge of the paper compartment.
4. Replace the paper tray and paper pack.

Check NIBP cuffs and hose

Once a month:

1. Check the NIBP hose. Straighten out any kinks and distortions.
2. Check the cuff(s) for wear and damage.

Check oximetry sensor

Once a month:

Check the oximetry sensor for any signs of wear or damage.

If damage is identified do not use the device. Contact the manufacturer for more information.

14.2 Technical maintenance

Refer to your Service department for details of technical maintenance and support.

14.3 Corrective maintenance

All corrective maintenance must be performed by qualified engineers approved by Huntleigh Healthcare Ltd.

The Sonicaid Team3 Service Manual (order part number 777490) is designed as an aid to engineers in maintenance and service of repairable parts.

14.4 Servicing

Servicing should be performed only by Huntleigh Healthcare Ltd or their appointed service agent. If you have difficulty obtaining service for Team3, contact Huntleigh Healthcare Ltd.

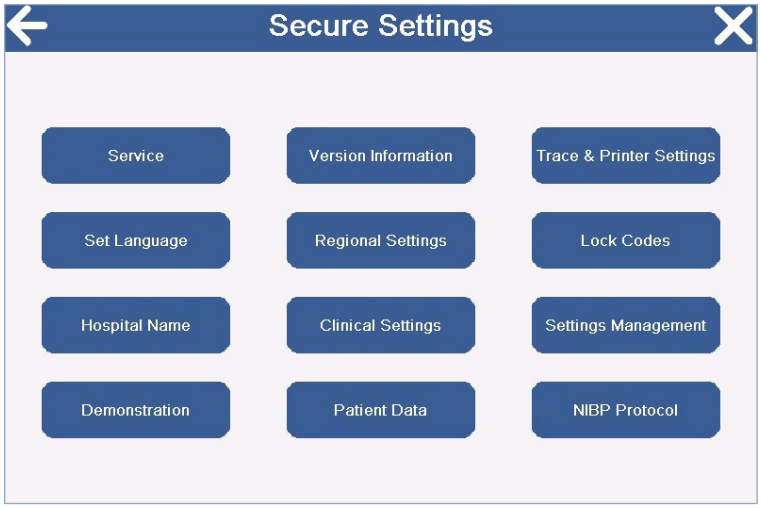
WARNING
Servicing cannot be performed while the unit is in use.

14.5 Secure Settings

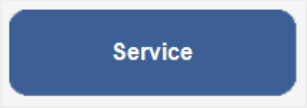
WARNING
The Secure Settings menus should be accessed by authorised personnel only.

Touch  to access the Settings menu.

The operator will need to enter a 5 digit code via the touchscreen, (default code 1 2 3 4 5) , to enter the Secure Settings Menu.

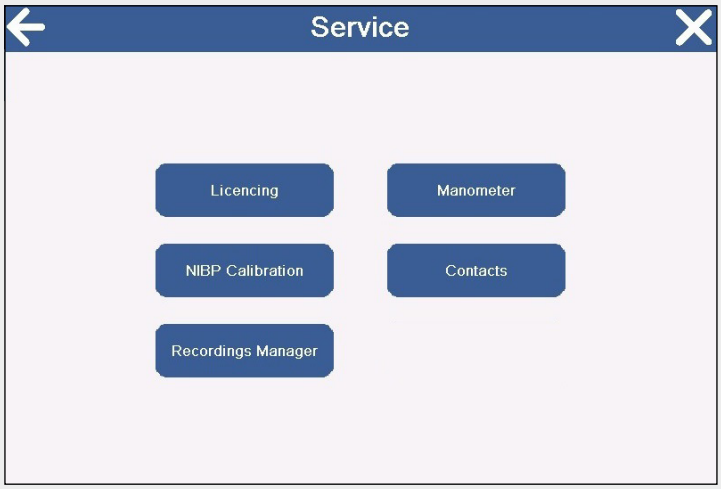


Service Sub Menu



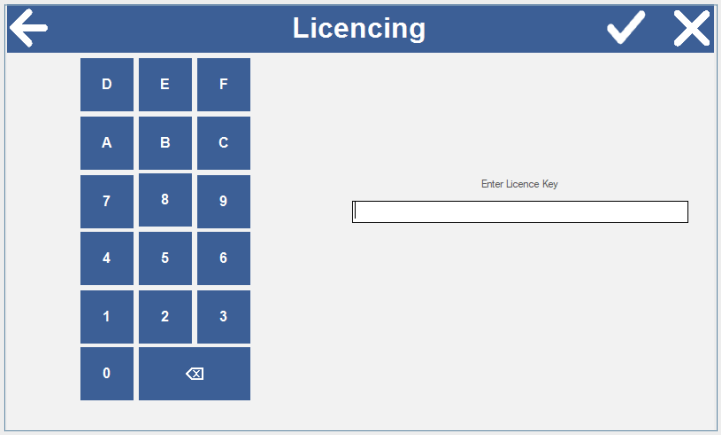
Service menu options are for use by trained biomedical staff only.

Enter a 5 digit code via the touchscreen,
(default code 5 5 5 5 5),
to enter the Service Menu.



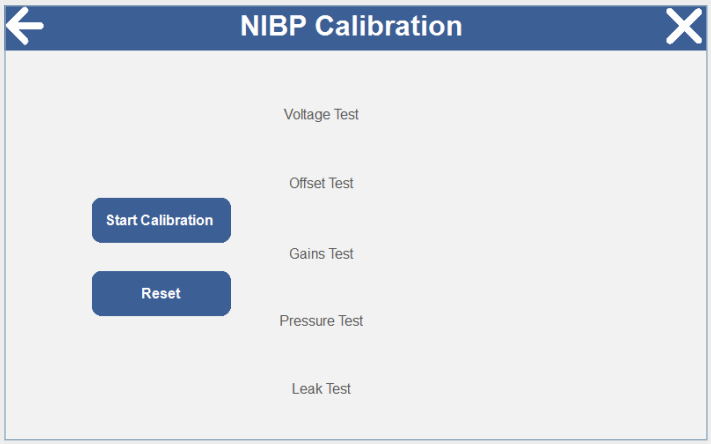
Licencing

For service use only. Allows additional features to be enabled with a valid license key.



NIBP Calibration

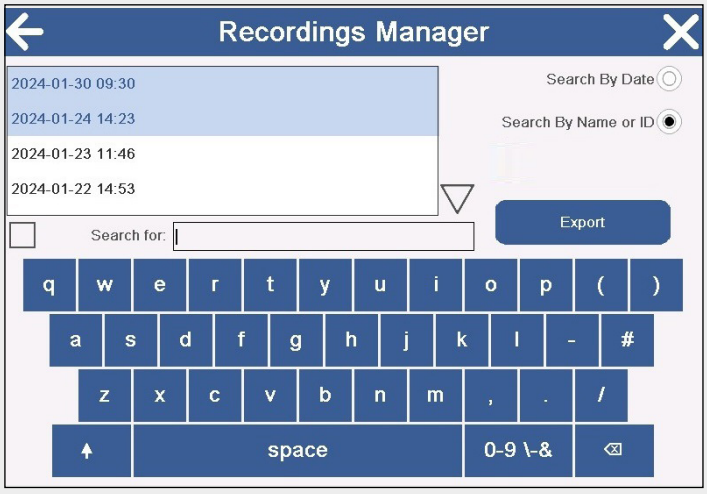
For service use only. Allows qualified biomedical engineers to calibrate the fetal monitor's NIBP system.



Recordings Manager

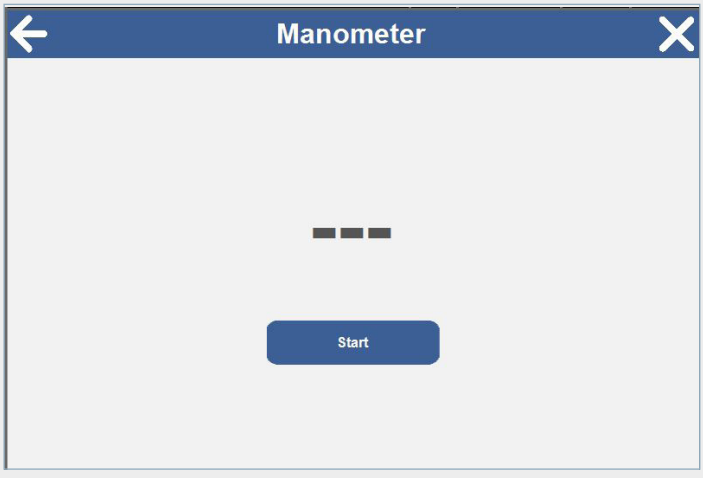
This button is only available once traces are selected. Select each trace to Archive/Export.

Export - The Export button allows traces to be moved from internal Team3 storage to a USB drive and kept for future viewing if required. Exporting traces from Team3 to a USB drive deletes the selected traces from the Team3. The USB drive capacity requirement is 8GB and the recommended suppliers are Transcend and SanDisk.

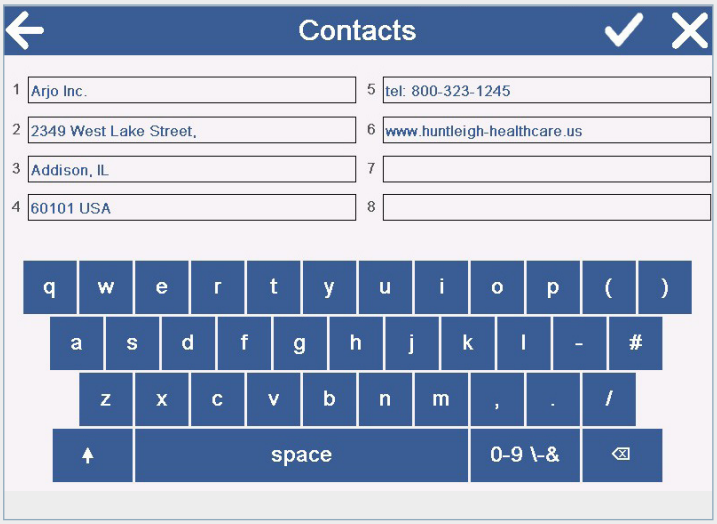


Manometer

For service use only. Allows qualified biomedical engineers to perform tests related to NIBP measurement.

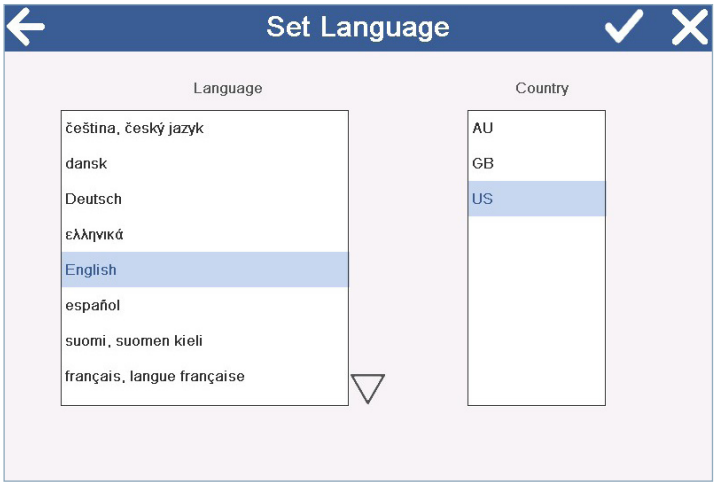


Contacts

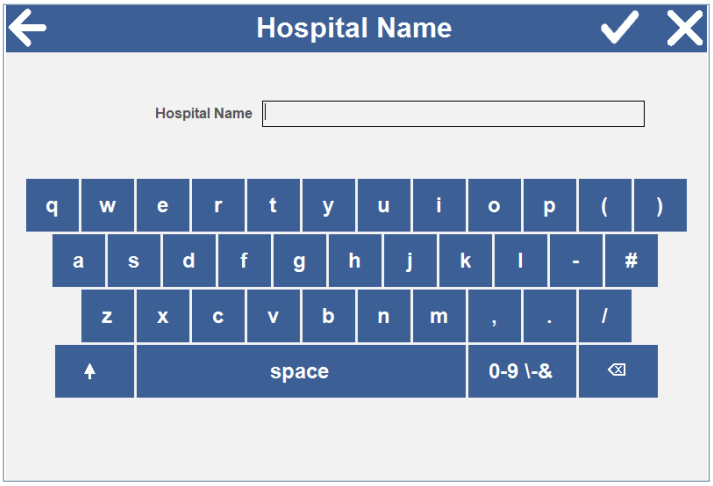


Set Language

The unit will request a power down when the language has been changed and ✓ is touched.



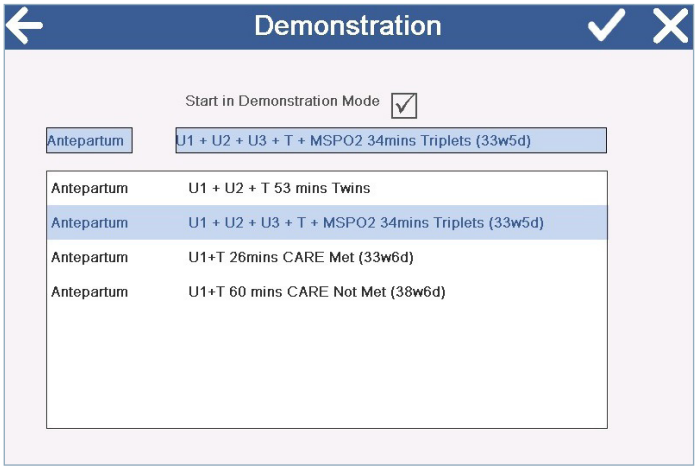
Hospital Name



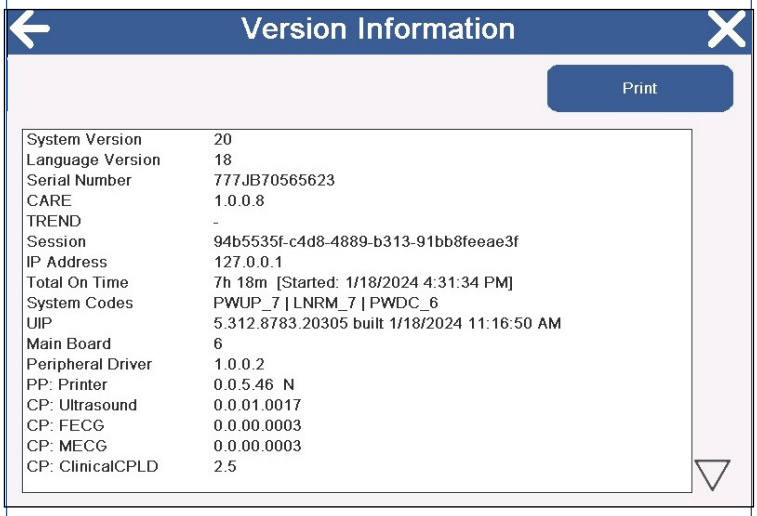
Demonstration

Allows the system to be used in demonstration mode. Plays a previously recorded Trace in a continuous loop until this dialogue used to turn it off. Requires the power to be cycled off and on.

Click on one of the demo traces - this will enable an antepartum demo mode. Switch
unit off/on to activate.
Alternatively, selecting the tick box will run an intrapartum demo mode.
To disable demo mode switch the unit off/on.

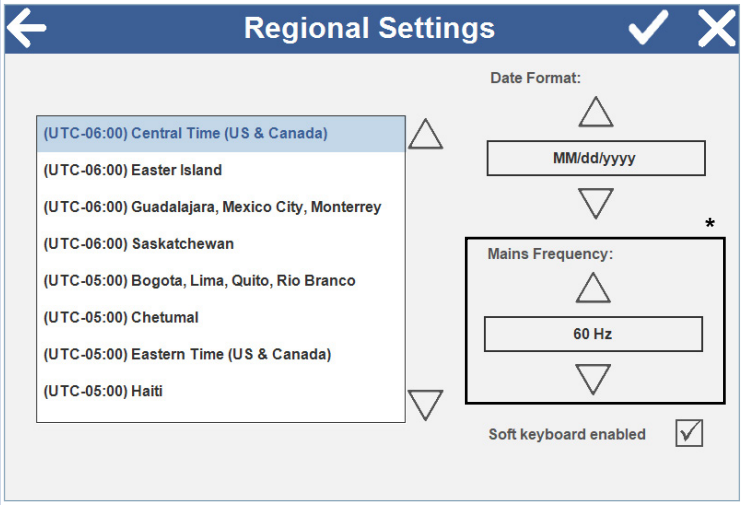


Version Information



Regional Settings

Changing the timezone allows for daylight savings to be implemented. The unit will request a power down when ✓ is touched.



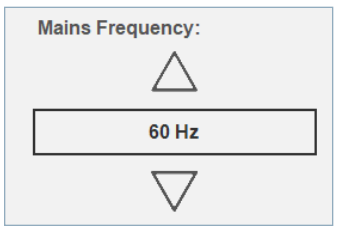
* Mains Frequency Setting

The default setting for the mains frequency on this product is 50Hz.

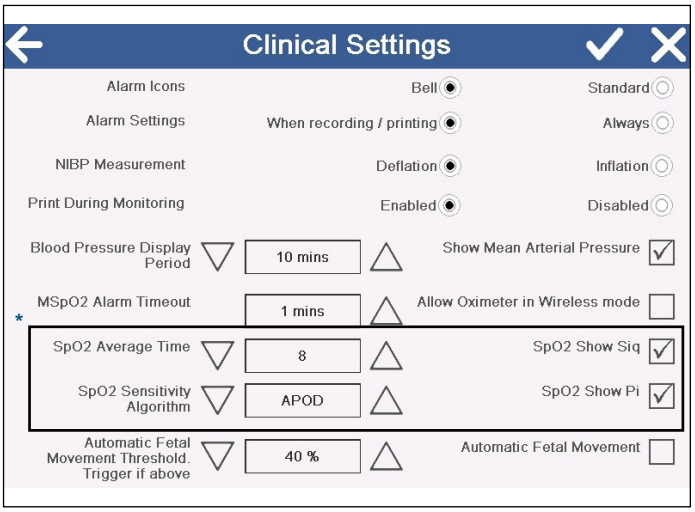
Touch △ ▽ to select required frequency.

Touch ✓ to confirm.

*** Note: The Mains Frequency for the US is 60 Hz. Do not change this setting.**



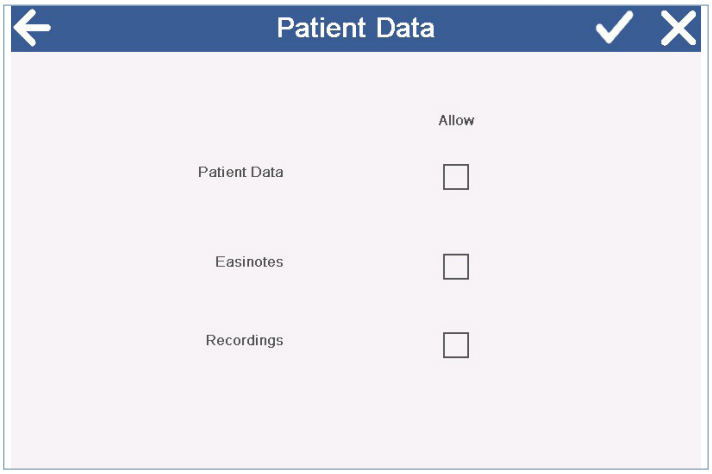
Clinical Settings



The clinical settings screen allows authorised users to change the following (the factory default settings are shown):

- The alarm icon type displayed on screen
- Whether to record alarms only when recording/printing
- Whether to measure NIBP during Inflation or Deflation
- How long to display the previous blood pressure reading
- Whether to include Mean Arterial Pressure (MAP) on the blood pressure display
- Print During Monitoring - Enable(default) or Disable. When disabled, the print Icon on the diagnostic screen will be replaced with a record Icon. No printing will occur when recording. Printing will still be available in sub menus where applicable e.g. printing a pre-recorded trace
- The timeout period for the Msp02 alarm
- Whether to allow oximetry in wireless mode
- * Masimo SpO2 Only – Adjust the sensitivity averaging time (for details see Appendix 5 Averaging Time)
- * Masimo SpO2 Only – Adjust the sensitivity algorithm setting (for details see Appendix5 Sensitivity Algorithm)
- * Masimo SpO2 Only – Enable or Disable the Siq bar graph on the main display (for details see Appendix 5 Siq Bar Graph)
- * Masimo SpO2 Only – Enable or disable the Pi Indication on the main display (for details see Appendix 5 Perfusion Index)
- Sets the sensitivity threshold for the automatic Fetal movement and enables or disables the feature. Use △ or ▽ to set the threshold as required. The required threshold may depend on whether the trace is showing a high incidence of artefact. It is recommended to set the threshold between 40-60%.

Patient Data



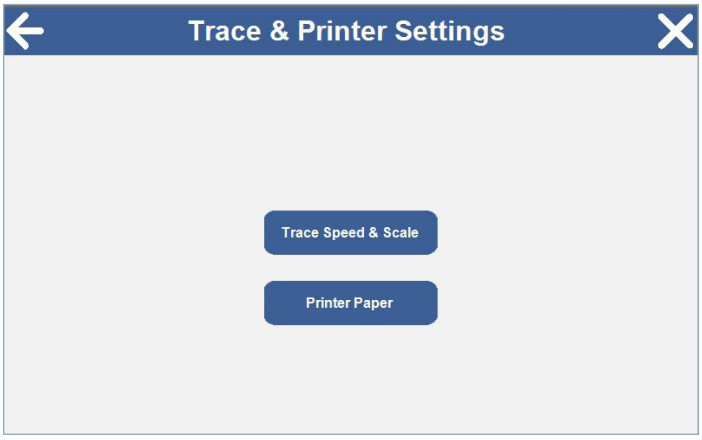
Allows these functions to be enabled/disabled.

- Patient Data: Allows entry of patient identification data into the monitor. The patient's ID appears at the top of the monitoring screen and on the paper printouts and stored recordings (if Recordings is also enabled).
- Easinotes: Allows the user to add annotations to the tracing when the fetal monitor is printing/ recording, using the Annotations icon to view the EasiNotes selection screens.
- Recordings: The fetal monitor records the patients' traces while they are being printed. Recorded traces can be viewed later if desired.

Note: If 'Recordings' is not checked, the traces can still be printed, but they will not be stored in the monitor for review.

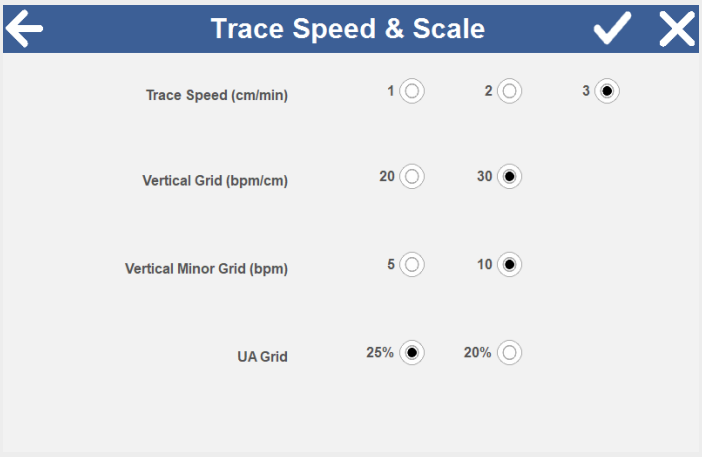
Trace & Printer Settings

This button is not available while printing is in progress.



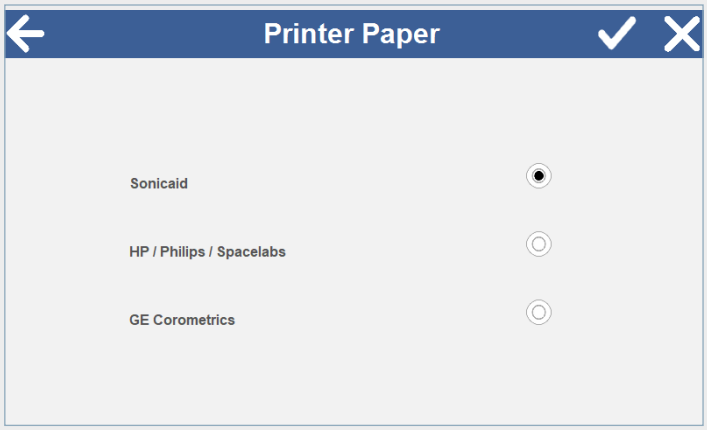
Trace and Printer Settings Sub Menu

Trace Speed & Scale

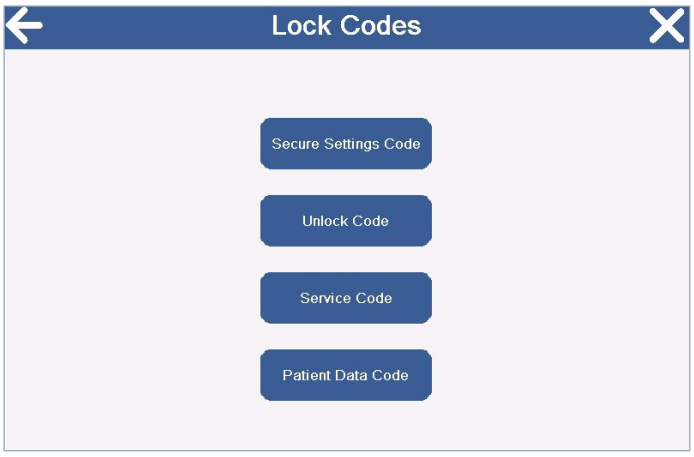


Printer Paper

Non-Sonicaid papers require a non-standard paper tray to be fitted



Lock Codes



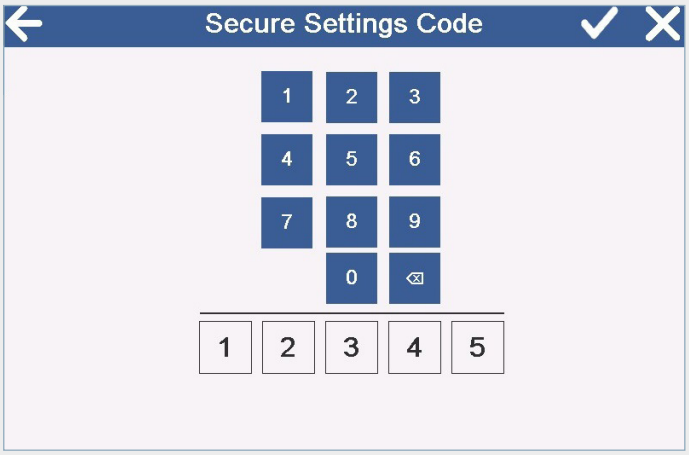
Lock Codes Sub Menu

Secure Settings Code

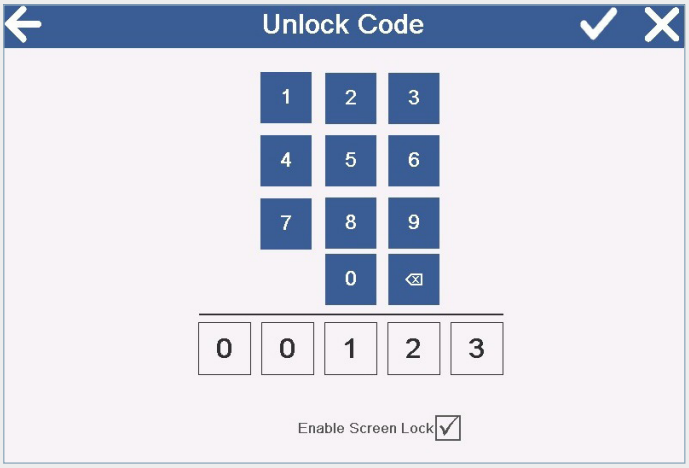
Allows the lock codes to be changed to values other than the factory settings:

- Secure Settings Code: 12345
- Unlock Code: 00123
- Service Code: 55555
- Patient Data Code: 98765

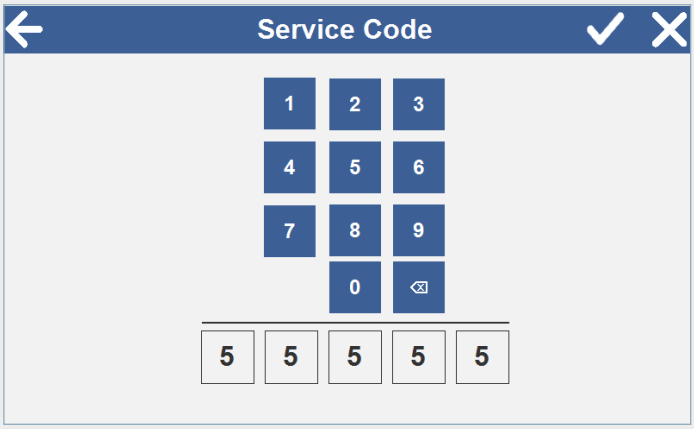
Note: It is the hospital's responsibility to keep track of any lock code changes. Forgotten or lost codes cannot be reset.



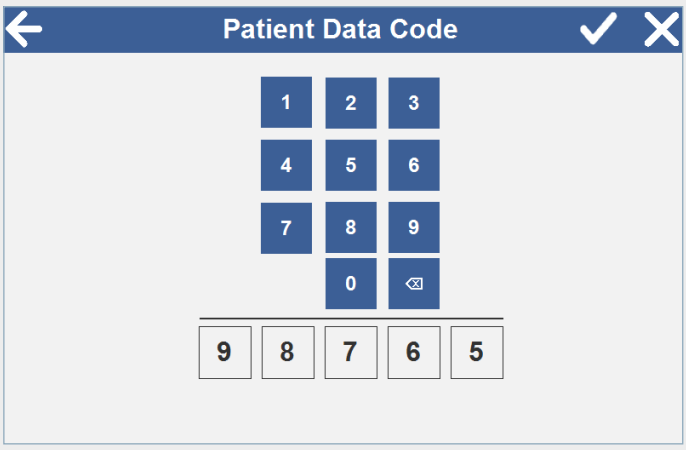
Unlock Code



Service Code



Patient Data Code



Settings Management

Save New Defaults = Fix all current settings as defaults.

Restore Factory Settings = Reverts any changes made in the 'Save New Defaults' setting back to their original factory defaults. Select 'Save new defaults' to make these changes permanent.

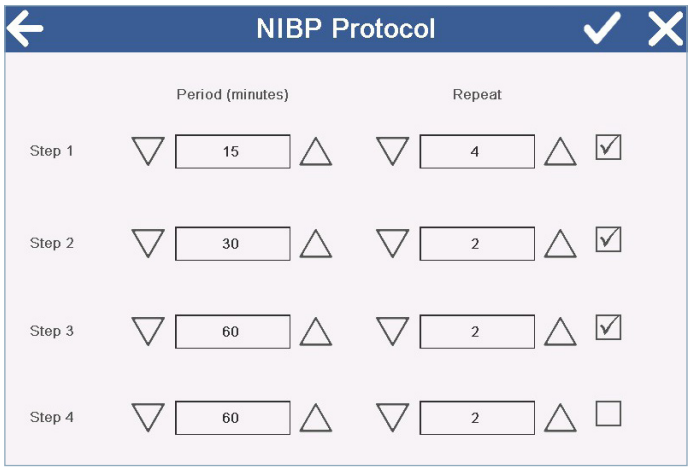
Imports and Exports allow transfer to and from Team3 via USB Flash Drive.*

Note: Do NOT transfer settings files from one monitor to another if the software versions are not the same.

Note: Import/Export buttons are only displayed when a USB Flash Drive is installed.
***A software tool is available from your supplier to support the Easinote function. See section 14.6.**

NIBP Protocol

Allows NiBP protocol details to be customised.



14.6 Customising Easinotes

WARNING
The Secure Settings menus should be accessed by authorised personnel only.

The Easinote sub-system is very flexible allowing up to 12 groups of 12 notes to be configured on Team3. Refer to Section 14.5 for details on how to change the Language and to access the Settings Management feature.

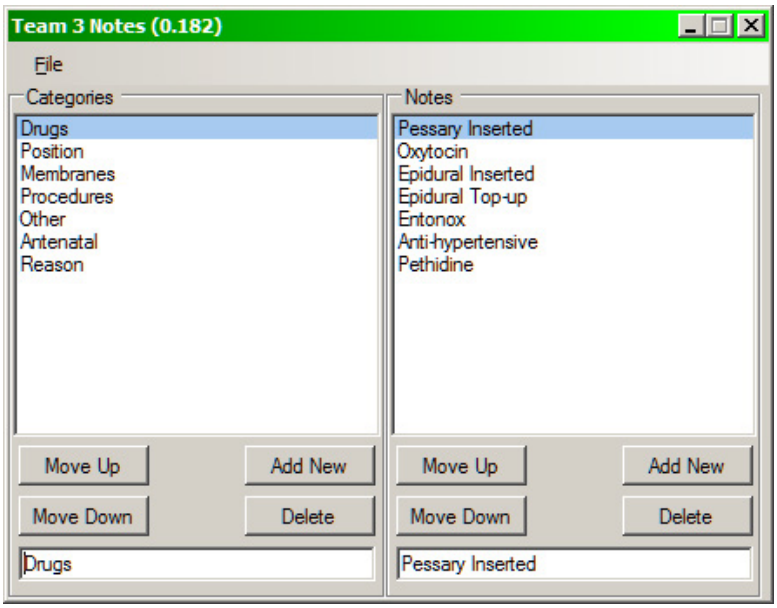
Exporting Easinotes

1. With Team3 switched on, plug a USB flash drive into one of the Team3 USB sockets.
2. Set up Team3 to operate in the language of your choice. This will ensure that the Easinote file to be exported is saved with the other files for that language. It is important to remember that each language has its own Easinotes file so Easinotes will change with Language selection.
3. Enter the Settings Management screen.
4. Touch the Export EasiNotes button to copy the current language Easinotes to the USB Flash Drive.
5. Exit the menu and remove the USB flash drive.

Customising Easinotes

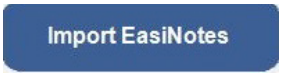
1. Contact Huntleigh Service and get a link to download the Easinotes Editing tool.
2. Install the tool and run it. (See image below).
3. Open the Easinotes.hcf file on the USB Flash Drive, exported from your Team3.
4. On the left of the tool is shown each of the Categories (See section 5.3.6.).

   The buttons below allow new categories to be created, other categories to be deleted and their relative positions changed in the list.



5. On the right of the tool is shown each of the notes for the selected Category. The buttons below allow new notes to be created, other notes to be deleted and their relative positions changed in the list.
6. At the bottom of the tool, the 2 text boxes allow the selected Category or Note to be edited. These text boxes allow text in any Windows language to be used, so for instance, a full set of French notes could be assembled.
7. When editing is complete, save your work, overwriting the original file.

Importing Easinotes

1. With Team3 switched on, plug the USB flash drive containing your edited Easinotes.hcf file into one of the Team3 USB sockets.
2. Team3 must already be set up to operate in the language of your choice. This will ensure that the Easinote file to be imported is saved with the other files for that language.
3. Enter the Settings Management screen.
4. Touch the 

button to copy the Easinotes file from the USB Flash Drive.
5. Exit the menu and remove the USB flash drive.
6. If possible, send the Easinotes.hcf file that you are now using to Huntleigh so that it can be included in later software releases.

15. Specifications

15.1 Equipment Classification

Protection against electric shock.	Class 1
Applied Parts	Type CF - Ultrasound Probes /TOCO/ FECG  Type BF - Maternal NIBP/MSpO2/fetal event marker 
Mode of operation.	Continuous
Degree of protection against harmful ingress of particles and/or water.	Main Unit : IP30 when Fixed or Stationary. IP32 with protective cover used when moving product Ultrasound and Toco: IPX7 Other transducers : Not protected
Suitability for use in an oxygen rich environment.	Not suitable

15.2 General

Rated Supply Voltage	100-230V AC
Fuse Type	2 x T3.15AH 250V
Power Input	50-60Hz 8-133VA
Battery (optional)	14.4V Lithium Ion Battery Pack
Real time clock battery	Panasonic CR2032/BN 3V lithium
Size	Width 318mm, Height 230mm, Depth 237mm
Weight	5.7Kg (with Printer)
Service Life	7 years

15.3 Environmental

Operating		**Storage**
+10°C to +40°C	**Temperature range**	-10°C to +40°C
10% to 90% (non condensing)	**Relative Humidity**	93% maximum
86 kPa to 106 kPa	**Pressure**	86 kPa to 106 kPa

15.4 Transducers

Ultrasound

Range	30 to 240 bpm
Accuracy	± 1 bpm over the range 100-180 bpm ± 2 bpm outside range
Alarms	High: 150-200 bpm Low: 50-120 bpm Signal Loss: % loss in last 5 minutes
Mode	Directional pulsed Doppler Repetition rate 3.0kHz
Frequency	1.0MHz (green)
P–	<30kPa
Iob	<1mW/cm2
Ispta	<3mW/cm2
Resolution	16 bits
Safety	Type CF protection
Ingress Protection	IPX7
Standards	IEC60601-2-37 (Thermal Indices (TI) and Mechanical Index (MI) are <1.0 for all device settings)

Uterine activity (external TOCO)

Range	0-100 relative units
Sensitivity	80% (±5%) scale reading equivalent to 100g
Offset range	±100g
Auto zero	Manual and auto zero facility
Safety	Type CF protection
Ingress Protection	IPX7

Alarm characteristics

Alarm Sound Pressure Levels at 1m	Minimum 53db(A) Default 75db(A) Maximum 92db(A)
Alarm tone	3 pulses Pulse frequency = 311Hz Pulse duration = 170ms Rise time = 17ms Fall time = 28ms Inter pulse gap = 160ms Pulse amplitudes within 10% of each other Inter burst interval between 2.5s and 30s

Maternal blood pressure

Method	Oscillometric		
Pressure Range	0-300mmHg		
Measurement ranges	Systolic 25-280 mmHg Diastolic 10-220 mmHg Pulse 30-240 bpm		
Accuracy	**Measurement during deflation**	**Measurement during inflation, IMT**	**Required according to international standards**
Pressure transducer accuracy	±1 mmHg	±1 mmHg	max. ±3 mmHg
Measurement accuracy mean deviation	<1.7 mmHg	<1.19 mmHg	max. ±5 mmHg
Measurement accuracy standard deviation	<5.6 mmHg	<3.48 mmHg	max. 8 mmHg
Modes	Manual or automatic User-selectable interval in Auto Mode: 1, 2, 3, 5, 10, 15, 20, 30, 45, 60, 90 or 120 minutes		
Record / display	On-screen display and printed record of: ● Systolic blood pressure ● Diastolic blood pressure ● Pulse rate ● Mean arterial pressure		
Alarms	Systolic High: 100-180mmHg Systolic Low: 50-150mmHg Diastolic High: 70-130mmHg Diastolic Low: 40-120mmHg		
Safety	Type B protection Hardware and software controls to limit: ● Inflation (max. 300 mmHg) ● Measurement time (max. 90 s)		
Standards	EN 1060-3 EN 1060-4 EN 80601-2-30 ANSI/AAMI SP-10 The sphygmomanometer was clinically investigated according to the requirements of ISO 81060-2		

Maternal Oximetry

Module	Masimo	NELLCOR (Rectangular Socket)
Sensor types	The Masimo SPO_2 option is supplied with a Masimo 4050 DCI Adult finger sensor.	NELLCOR OxiMax-compatible sensors, identifiable by the deep lavender/blue (or white) color of their plug. The Nellcor SPO_2 option is supplied with a Nellcor DS-100A sensor.
Saturation range	1-100% $MSpO_2$	1-100% $MSpO_2$
Saturation accuracy	±1SD of normal distribution, within ranges: • 70-100%: ±2 digits displayed • 0-69%: unspecified	±1SD of normal distribution, within ranges: • 70-100%: ±2 digits displayed • 0-69%: unspecified
Pulse rate range	20-250 bpm	20-250 bpm
Pulse rate accuracy	±3 digits	±3 digits
Record/display	• On-screen display and printed record of: • Maternal % SpO2 • Heart rate • Signal IQ • Perfusion index *Refer to Appendix 5 for additional messages*	On-screen display and printed record of: • Maternal % SpO_2 • Heart rate
Safety	Type BF protection	Type BF protection
Alarms	Low saturation: 85-99% MSpO2 High saturation: 86-100% MSpO2 *Refer to Appendix 5 for additional alarms*	Low saturation: 85-99% $MSpO_2$ High saturation: 86-100% $MSpO_2$
Standards	ISO 9919	ISO 9919

15.5 Printer

Print head	128mm thick film
Resolution	8 dots per mm
Printer speeds	1, 2, or 3cm per minute (user selectable) 10 cm per minute fast forward
Paper	Plain thermal paper, z-fold, 45m length
FHR scales	30–240 bpm or 50–210 bpm (user selectable)
Annotation	• Hospital name, time, date, paper speed, monitoring modes, signal loss • Mother's name and ID number (optional)

15.6 Connections *

Front Panel

FHR1	1.0MHz ultrasound transducer
FHR2	1.0MHz ultrasound transducer
FHR3	1.0MHz ultrasound transducer
TOCO	Toco transducer

** Depending on model*

Side Panel

MSpO$_2$	Maternal pulse oximetry
NIBP	Maternal non-invasive blood pressure

Rear Panel

Mains Inlet	Mains power
Fetal Event Marker socket	¼ inch jack plug connection
Equipotential Earth Point	Provides common earthing point for connected equipment
RS232	Central Record System (CRS)
Auxiliary	Wireless telemetry system
USB Ports	External Keyboard, Barcode Reader, Touchscreen, Upgrader Memory Stick
Ethernet Port	Future CRS

Interfaces

Telemetry	Sonicaid Wireless Telemetry
System	Authorised CRS systems

15.7 Display

Technology	TFT Liquid Crystal Display (LCD)
Size	8.4" diagonal
Resolution	SVGA, 800 x 600
Viewing Angle	170°

Data display

ULT1, ULT2, ULT3	Fetal heart rate (30–240 bpm) Pulse rate and confidence indicator
TOCO	0–100 (relative units)
MSpO$_2$	Oxygen saturation Pulse rate
NIBP	Systolic and diastolic pressures Pulse rate MAP

15.8 Default Settings

Alarms

Loss of Signal	50%
Fetal Heart Rate	High - 160bpm for 3 minutes ON Low - 110bpm for 3 minutes ON
Toco Persistance Alert	50% for 5 minutes OFF
Maternal Heart Rate	High - 100bpm for 3 minutes OFF Low - 60bpm for 3 minutes OFF
Maternal Systolic Pressure	High -140mmHg OFF Low - 90mmHg OFF
Maternal Diastolic Pressure	High - 90mmHg OFF Low - 60mmHg OFF
Maternal Low Blood Saturation	94% OFF

Automatic Analysis

DAWES REDMAN	OFF

Audio

FHR	6 (out of 20)
Touch	6 (out of 20)
Alarms	10 (out of 20)
Fetal Movement	10 (out of 20)
Communications protocol	HP50 over RS232
Automatic Movement Detect	40% OFF

NIBP

Auto Enable	OFF
Repeat Interval	5 minutes

Printer

Vertical scale	20 bpm/cm
Minor Vertical Scale	10 bpm
Speed	1 cm/min
Twins Print Grid	OFF
FHR2 Offset	OFF
FHR3 Offset	OFF
Paper Type	Sonicaid

Timer

Non Stress Test Timer Period	10 minutes OFF

View

Start Screen	Numeric
Background color	Black

Uterine Activity

Toco Zero Level	10%
Toco Auto Zero	ON

Miscellaneous

Screen Lock Code	00123
Screen Lock Enabled	ON
Mains Frequency	50Hz
Alarm Icons	Bell
Date Format	dd/MM/yyyy
MSpO$_2$ Alarm Timeout	1 minute
NIBP Valid Period	10 minutes
Show Mean Arterial Pressure	ON
Secure Settings Code	12345
Keyboard	ON
Language	en-US

EasiNotes (Optional Feature)

If the EasiNotes annotation feature is enabled and the fetal monitor is printing, , the following EasiNotes are available to users by touching the Annotations icon in the control bar on the main monitoring screen: The EasiNotes are broken into 12 categories as listed below. Users can also enter custom notes up to 70 characters long as well as place mark on the tracing at a user-specified point.

Procedures	Membranes	Observations
Cervical Exam	Intact	Denies Contractions
Oxygen On	Bulging	Vaginal Bleeding
Urinary Catheter	Leaking	Emesis
Cervical Catheter	SROM	Thrashing
IUPC Inserted	AROM	Shaking
FSE Applied	Clear Fluid	Hyperventilating
Amnioinfusion Started	Meconium Present	
Bedside Ultrasound	Bloody	
Cesarean Prep	Purulent	
Position in Bed	**Position Out of Bed**	**Corrective Measures**
Left Side	Ambulating	Position Change
Right Side	Birthing Ball	IV Rate Increase
Supine	Up to Bathroom	Pitocin Off
Semi-Fowlers	Up to Chair	Epidural Infusion Off
On Bedpan	Up to Shower	Oxygen On
Sitting		Cervical Exam
Peanut Ball		Altered Breathing
Lithotomy		Altered Pushing
Trendelenburg		Called for Assistance
		Physician Notified
		Resident Notified
		Midwife Notified

Second Stage	Provider	Medications
Laboring Down	Physician Notified	Pitocin
Pushing	Resident Notified	Epidural Initiated
Descent with Pushing	Midwife Notified	Analgesic/Sedative
Perineal Bulging	RN at Bedside	Antibiotic
Rectal Bulging	Physician at Bedside	Anticonvulsant
Crowning	Resident at Bedside	Antiemetic/Antacid
Head Delivered	Midwife at Bedside	Antihypertensive
NSVD		Cervical Ripening
Precipitous Delivery		Insulin
Vacuum Delivery		Nitrous Oxide
Forceps Delivery		Respiratory/Asthma
Cesarean Delivery		Uterine Stimulant
NST	**Reasons A - L**	**Reasons M - Z**
Initiated	Antenatal Testing	MVI
Completed	Bleeding	NST
Reactive	Chronic Hypertension	Observation
Non-Reactive	Decreased FM	Other
Equivocal	Diabetes	Placenta Abruption
Acoustic Stimulation	Eclampsia	Placenta Previa
Manual Stimulation	Fall	Post Dates
Provider Notified	Gestational Diabetes	Preeclampsia
Decreased FM	Gestational Hypertension	ROM
	Hyperemesis	Scheduled Cesarean
	Induction of Labor	UTI
	Labor	Other
Custom		
Users can enter custom notes of up to 70 characters, including spaces and punctuation.		
Mark		
Places a mark on the maternal tracing when selected.		

15.9 General Standards

IEC60601-1	**ISO 15223-1**	**JIS T 0601-1**
ANSI/AAMI ES60601-1	**IEC60601-2-49**	**IEC60601-1-2**
CAN/CSA C22.2 No 60601-1	**IEC62304**	

16. Accessories

Use only recommended accessories listed in this manual or in the Accessories and Consumables catalogue.

Please refer to the Accessories & Consumables catalogue included with the monitor for further details of products available for use with the Team3. See www.huntleigh-diagnostics.com for Sonicaid Fetal Monitoring Accessories & Consumables Catalogue (LIT 751348). The latest issue of this catalogue is available on request from local Huntleigh representatives. Available accessories, consumables and spares include:

Accessories

Item	Part No
Cart	**ACC-OBS-072**
Wall mounting Bracket	**ACC-OBS-076**
NIBP Cuff (Various Sizes) *	**-**
Patient Event Marker	**SP 7775-6901**
Ultrasound, TOCO and MSpO2 Transducers Transducers *	**-**
Service Manual	**777490**
Team3 Protective cover	**ACC-OBS-088**

Consumables

Item	Part No
Aquasonic Gel (various Sizes) *	**-**
Sonicaid Paper packs * (standard - box 20)	**ACC-321414**
Transducer Belts *	**-**

** See Accessories and Consumables catalogue for full range of options.*

17. Warranty & Service

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

Service Returns

If for any reason the Team3 has to be returned, please:

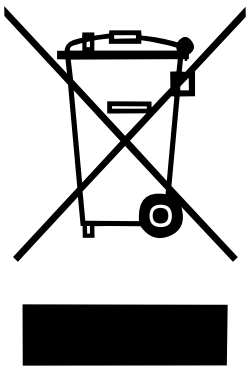
- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package ‘Service Department ‘

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

Service Department.
12625 Wetmore Rd,
San Antonio, TX 78247,
United States

Phone: +1 (800) 323 1245

18. 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.

Appendix 1 Electromagnetic Compatibility

Make sure the environment in which Team3 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 Team3 as replacement parts for internal components, may result in increased emissions or decreased immunity of the Team3.

WARNING: The Team3 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Team3 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 Team3 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The Team3 is intended for use in the electromagnetic environment specified below. The customer or the user of the Team3 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The Team3 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 Team3 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Team3 is intended for use in the electromagnetic environment specified below. The customer or the user of the Team3 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Proximity Immunity Compliance Information			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
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz outside ISM bandsa 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands	3V	
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	80MHz to 800MHz 800MHz to 2.5GHz
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, b should be less than the compliance level in each frequency range c. 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.			
b 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 Team3 is used exceeds the applicable RF compliance level above, the Team3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Team3. c Over the frequency range 150kHz to 80kHz, field strengths should be less than 3V/m.			

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Team3 is intended for use in the electromagnetic environment specified below. The customer or the user of the Team3 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 % Ur (>95 % dip in Ur) for 0,5 cycles 40 % Ur (60 % dip in Ur) for 5 cycles 70 % Ur (30 % dip in Ur) for 25 cycles <5 % Ur (>95 % dip in Ur) for 5 s	<5 % Ur (>95 % dip in Ur) for 0,5 cycles 40 % Ur (60 % dip in Ur) for 5 cycles 70 % Ur (30 % dip in Ur) for 25 cycles <5 % Ur (>95 % dip in Ur) for 5 s	Mains power quality should be that of a typical commercial of hospital environment. If the user of the Team3 requires continued operation during power mains interruptions, it is recommended that the Team3 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 Ur is the a.c. mains voltage prior to the application of the test level.			

Appendix 2 Manufacturer's Performance Criteria Specification

Below are comprehensive Essential Performance definition tables. The definitions apply to the intrapartum model fitted with all available options which also covers ante-partum functionality. Relevant particular standards provide the source material for the requirements in these tables.

Particular Standards

The following particular standards are referenced:

Standard	Description	Standard	Description	Standard	Description
IEC 60601-2-37	Ultrasound	IEC 80601-2-61	SPO2	IEC 60601-2-49	Multi-parameter
IEC 60601-2-30	NIBP	IEC 60601-2-27*	MECG		

** not applied in full, as this channel is used only to obtain the maternal heat rate, which is used to validate the calculated ultrasound derived fetal heat rate*

IEC 60601-2-37 Ultrasound	
EP Requirement	**Sub clause detail**
Displayed value error	Free from error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis Free from the display of incorrect numerical values associated with the diagnosis to be performed
Ultrasound output	Free from the production of unintended or excessive ultrasound output
Transducer temperature	Free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature

IEC 60601-2-30 NIBP	
EP Requirement	**Sub clause detail**
Error magnitude	Error over full operating environmental conditions is ± 3 mmHg or 2% of reading maximum
Reproducibility	Reproducibility shall be less than 3 mmHg (0,4 kPa).
Mains power interruption	Mains on/off behaviour – either continue as before or stop with Technical Alarm. Cuff deflation to < 15mm Hg shall be completed in less than 30s, and no result shall be displayed.
Measurement outside specified range	If measurement result is outside specified range – Technical Alarm produced
High / low pressure alarms	Medium priority alarms for high and low systolic, diastolic or mean arterial pressure are included.

IEC 80601-2-61 SPO2	
EP Requirement	**Sub clause detail**
Oxygen saturation	SpO2 accuracy is within 4%RMS over range from 70 to 100% Medium priority alarms for low saturation level and high or low heart rate included
Pulse rate	Pulse rate accuracy is within ± 5 bpm (or ± 2 %)
Mains power failure	Performance is unaffected, provided unit has not switched off
Data update period	Less than 30 s (typically 1 s)
Signal inadequacy indication	If heart rate is static for 25+ seconds or if signal is lost
Detection of probe and cable extender faults	Display shows --/--- if cable faults are present

IEC 60601-2-27 MECG	
EP Requirement	**Sub clause detail**
Heart rate range and accuracy	Range is 30 to 200 bpm minimum Accuracy is within 10% or 5 bpm whichever is greater
Maternal heart rate alarms	Heart rate alarms shall activate within specified delay time

IEC 60601-2-49 Multi Parameter	
EP Requirement	**Sub clause detail**
Display of all monitored physiological parameters and visual alarm signals	Must continue to perform within specification
Alarm conditions and priority	Alarm functions as defined in IFU section 8. All Alarms are medium priority
Indication of validity of measurements	SPO2 Technical alarms for static rate or lost signal

Appendix 3 Ultrasound Safety Considerations

General

Diagnostic ultrasound has been in use for over 35 years with no confirmed adverse effects on patients or instrument operators at the intensities typical of present diagnostic instruments. However, available data are not wholly conclusive, and the possibility remains that biological effects may be identified in the future. Because fetal tissue could be more sensitive to biological effects by reason of rapid cell division, it is particularly desirable that ultrasound exposure of pregnant subjects be kept to a minimum.
Medical and scientific authorities therefore recommend that ultrasound procedures be performed in accordance with the “ALARA” principle, which states that the energy delivered to the patient should always be kept As Low As Reasonably Achievable.
The transmitted acoustic power of the Sonicaid Team3 fetal monitor is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring that each examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.

Acoustic output data for the transducers for use with the Sonicaid Team3 fetal monitors is summarized in the following tables. The values given are based on measurements in water using a calibrated hydrophone and are stated as the estimated de-rated intensities. The de-rated intensity constitutes the most biologically relevant parameter available, since true determinations of the actual absorbed dose in tissue would require invasive measurement techniques. The de-rated intensity is, therefore, calculated mathematically using a de-rating factor consisting of a constant (the assumed attenuation coefficient) and allowing for the frequency of the transducer and the distance from the transducer face to the measurement hydrophone.
The calculated de-rated intensity values for the Sonicaid Team3 fetal monitors compare very favourably with previously reported acoustic safety data for Doppler ultrasound instruments and are appropriate for all clinical applications recommended in this manual.

At present, there is a clear consensus that the benefits to patients of prudent use of diagnostic ultrasound outweigh the risks that may be present. See:

a) Report No. 24, National Council on Radiation and Protection: biological effects of ultrasound, clinical effects and observations.
b) Ziskin M.C., in World Policies on the Use of Diagnostic Ultrasound in Obstetrics: The American Institute of Ultrasound Policy and Statement on Safety. Ultrasound in Medicine and Biology 12: 711-714, 1986.

Acoustic Output

The ultrasound transducer used with the Sonicaid Team3 fetal monitors has a single mode of operation, with fixed acoustic output parameters that are not user adjustable.

Acoustic Output Reporting Table for Track 1 – Non-Auto-scanning Mode Sonicaid Team3 Operating Mode: PWD Application(s): Fetal Monitoring					
Acoustic Output			**MI**	**$I_{SPTA.3}$ (mW/cm²)**	**$I_{SPPA.3}$ (mW/cm²)**
Global Maximum Value*			0.013	1.2 (Note 1)	5.8 (Note 1)
Associated Acoustic Parameters	Pr.3 (MPa)		0.013		
	Wo total (mW)			2.5mW	2.5mW
	fc (MHz)		1.0	1.0	1.0
	Z_{sp} (cm)		2.4	2.4	2.4
	Beam Dimensions	x_{-6} (cm)		0.066	0.066
		y_{-6} (cm)		0.067	0.067
	PD (µS)		70		70
	PRF (Hz)		3000		3000
	Overall EBD (cm2) (all eight crystals)			7.95	

Definition of Terms

$I_{SPTA.3}$ The de-rated spatial peak temporal average intensity
$I_{SPPA.3}$ The de-rated spatial peak pulse average intensity
I_{SATA} The spatial average temporal average intensity
MI The mechanical index
Pr.3 The de-rated peak negative pressure
Wo The ultrasonic power
fc The acoustic centre frequency
Z_{sp} The axial distance at which the reported parameter is measured
X_{-6} Y_{-6} respectively the in-plane (azimuth) and out-of-plane (elevation) -6dB dimensions in the x-y plane where Zsp is found
PD Pulse duration
PRF Pulse repetition frequency
EBD Entrance beam dimensions for the azimuth and elevation planes

Additional Information

Parameter	Value	Uncertainty
I_{SATA} @ transducer face	0.30 mW/cm2 Note 1	±24%

Note 1: 'In-situ' de-rating of 0.3dB/cm/MHz has been applied in order to derive de-rated values.

Uncertainties

The reported uncertainties are based on standard uncertainties multiplied by a coverage factor k = 2 providing a level of confidence of approximately 95%.

Acoustic Parameter	Uncertainty	Acoustic Parameter	Uncertainty
Power	±28%	Intensity	±20%
Pressure	±10%	Centre Frequency	±10%

Thermal and mechanical indices are below 1 under all circumstances.
Measurements were made by the National Physical Laboratory, Teddington, Middlesex, UK in accordance with NEMA UD-2.

Appendix 4 Maternal SpO2 Additional Nellcor Clinical Information

Nellcor Theory of Operation

Overview

This chapter explains the theory behind operations of the Nellcor™ Portable SpO_2 Patient Monitoring System.

Theoretical Principles

The monitoring system uses pulse oximetry to measure functional oxygen saturation in the blood. Pulse oximetry works by applying a Nellcor™ sensor to a pulsating arteriolar vascular bed, such as a finger or toe. The sensor contains a dual light source and a photodetector.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO2). Ambient conditions, sensor application, and patient conditions can influence the ability of the monitoring system to accurately measure SpO2.

Pulse oximetry is based on two principles: oxyhemoglobin and deoxyhemoglobin. differ in their absorption of red and infrared light (measured using spectrophotometry), and the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (registered using plethysmography).

A monitoring system determines SpO2 by passing red and infrared light into an

arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the sensor serve as light sources; a photo diode serves as the photo detector.

Since oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation.

The monitoring system uses the pulsatile nature of arterial flow to identify the oxygen saturation of arterial hemoglobin. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitoring system bases its SpO2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, a monitoring system must know the mean wavelength of the sensor's red LED to accurately measure SpO2.

During monitoring, the monitoring system’s software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO2.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Note: During certain automatic calibration functions, the monitoring system may briefly display a flat line on the plethysmographic waveform. This is a normal operation and does not require any user intervention.

Functional Testers and Patient Simulators

Some models of commercially available bench top functional testers and patient simulators can be used to verify the proper functionality of Covidien Nellcor™ monitoring systems, sensors, and cables. Reference the individual testing device's operator's manual for the procedures specific to the model of tester used. While such devices may be useful for verifying that the sensor, cabling, and monitoring system are functional, they are incapable of providing the data required to properly evaluate the accuracy of a system's SpO2 measurements. Fully evaluating the accuracy of the SpO2 measurements requires, at a minimum, accommodating the wavelength characteristics of the sensor and reproducing the complex optical interaction of the sensor and the patient’s tissue.

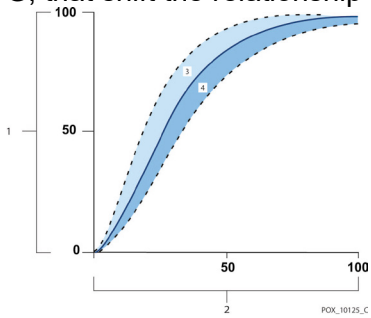
These capabilities are beyond the scope of known bench top testers. SpO2 measurement accuracy can only be evaluated in vivo by comparing monitoring system readings with values traceable to SaO2 measurements obtained from simultaneously sampled arterial blood using a laboratory CO-oximeter.
Many functional testers and patient simulators have been designed to interface with the monitoring system's expected calibration curves and may be suitable for use with monitoring systems and/or sensors. Not all such devices, however, are adapted for use with the OxiMax™ digital calibration system.
While this will not affect use of the simulator for verifying system functionality, displayed SpO2 measurement values may differ from the setting of the test device. For a properly functioning monitoring system, this difference will be reproducible over time and from monitoring system to monitoring system within the performance specifications of the test device.

Unique Technologies
Functional versus Fractional Saturation
This monitoring system measures functional saturation where oxygenated hemoglobin is expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482, report fractional saturation where oxygenated hemoglobin is expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobins. To compare functional saturation measurements to those from a monitoring system that measures fractional saturation, fractional measurements must be converted using the listed equation.

$$\Phi = \frac{\phi}{100 - (\eta + \Lambda)} \times 100$$

Φ	functional saturation	η	%carboxyhemoglobin
ϕ	fractional saturation	Λ	%methemoglobin

Measured versus Calculated Saturation
When calculating saturation from a blood gas partial pressure of oxygen (PO2), the calculated value may differ from the SpO2 measurement of a monitoring system. This usually occurs when saturation calculations exclude corrections for the effects of variables such as pH, temperature, the partial pressure of carbon dioxide (PCO2), and 2,3-DPG, that shift the relationship between PO2 and SpO2.



1	% Saturation Axis
2	PO2 (mmHg) Axis
3	Increased pH; Decreased temperature, PCO2, and 2,3-DPG
4	Decreased pH; Increased temperature, PCO2, and 2,3-DPG

Data Update Period, Data Averaging, and Signal Processing

The advanced signal processing of the OxiMax™ algorithm automatically extends the amount of data required for measuring SpO2 and pulse rate depending on the measurement conditions. The OxiMax™ algorithm automatically extends the dynamic averaging time required beyond seven (7) seconds during degraded or difficult measurement conditions caused by low perfusion, signal artifact, ambient light, electrocautery, other interference, or a combination of these factors, which results in an increase in the dynamic averaging.
If the resulting dynamic averaging time exceeds 20 seconds for SpO2, the monitoring system displays the pulse search indicator while continuing to update SpO2 and pulse rate values every second. If the dynamic averaging time exceeds 25 seconds, a low-priority Extended Update alarm also appears.
As such measurement conditions extend, the amount of data required may continue to increase. If the dynamic averaging time reaches 40 seconds, and/or 50 seconds for pulse rate, the monitoring system display a Pulse Timeout alarm and reports a zero saturation indicating a loss-of-pulse condition.

System Features

Nellcor™ Sensor Technology

Use Nellcor™ sensors, which are specifically designed for use with the monitoring system. Identify Nellcor™ sensors by the Nellcor™ logo on the plug. All Nellcor™ sensors contain a memory chip carrying information about the sensor which the monitoring system needs for correct operation, including the sensor's calibration data, model type, troubleshooting codes, and error detection data.
This unique oximetry architecture enables several new features.
Any monitoring system containing OxiMax technology uses calibration data contained in the sensor in calculating the patient's SpO2. With sensor calibration, the accuracy of many sensors is improved, since the calibration coefficients can be tailored to each sensor.
Contact Covidien or a local Covidien representative for a Nellcor™ Oxygen Saturation Accuracy Specification Grid listing all of the sensors used with the monitoring system. Covidien retains a soft copy at www.covidien.com.

Clinical studies report

This appendix contains data from clinical studies conducted for the Nellcor™ sensors used with the Nellcor™ portable SpO2 patient monitoring system.
One (1) prospective, controlled hypoxia clinical study was conducted to demonstrate the accuracy of Nellcor™ sensors when used in conjunction with the Nellcor™ portable SpO2 patient monitoring system. The study was performed with healthy volunteers at a single clinical laboratory.
Accuracy was established by comparison to CO-oximetry.

Methods

Data from 11 healthy volunteers were included in the analysis. Sensors were rotated on digits and brow to provide a balanced study design. SpO2 values were continuously recorded from each instrument while inspired oxygen was controlled to produce five steady state plateaus at target saturations of approximately 98, 90, 80, 70 and 60%. Six arterial samples were taken 20 seconds apart at each plateau resulting in a total of approximately 30 samples per subject. Each arterial sample was drawn over two respiratory cycles (approximately 10 seconds) while SpO2 data were simultaneously collected and marked for direct comparison to CO2. Each arterial sample was analyzed by at least two of the three IL CO-oximeters and a mean SaO2 was calculated for each
sample. End tidal CO2, respiratory rate, and respiratory pattern were continuously monitored throughout the study.

Study Population

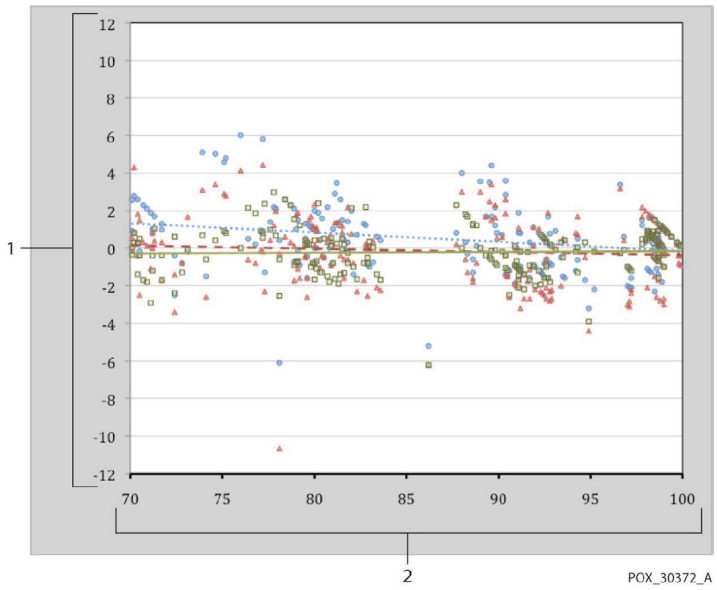
Type	Class	Total
Gender	Male	5
	Female	6
Race	Caucasian	8
	Hispanic	2
	African American	1
	Asian	0
Age	-	19-48
Weight	-	108-250
Skin pigment	Very Light	2
	Olive	5
	Dark olive/Medium black	3
	Extremely dark/Blue black	1

Table A-1. Demographic Data
Study Results

Accuracy was calculated using the root mean square difference (RMSD).

SpO2 Decade	MAX-A		MAX-N		MAX-FAST	
	Data points	Arms	Data points	Arms	Data points	Arms
60-70	75	3.05	71	2.89	71	2.22
70-80	55	2.35	55	2.32	55	1.28
80-90	48	1.84	48	1.73	48	1.48
90-100	117	1.23	117	1.68	117	0.98

Table A-2. SpO2 Accuracy for Nellcor™ Sensors vs. CO-oximeters
Figure A-1. Modified Bland-Altman Plot



1	Test Sensor; Avg CO-oximeter value 70-100% SpO2	2	Avg CO-oximeter value 70-100% SpO2
●	Oximetry board with MAX-A sensor	·····	Trendline of MAX-A sensor
▲	Oximetry board with MAX-N sensor	- - -	Trendline of MAX-N sensor
■	Oximetry board with MAX-FAST sensor	———	Trendline of MAX-FAST sensor

Adverse Events or Deviations

The study was conducted as expected with no adverse events and no deviations from the protocol.

Conclusion

The pooled results indicate that for a saturation range of 60-80% for SpO2, the acceptance criterion was met for the monitoring system when tested with MAX-A, MAX-N and MAX-FAST sensors. The pooled results indicate that for a saturation range of 70-100% for SpO2, the acceptance criterion was met.

Appendix 5 Maternal SpO_2 Additional Masimo Information

5.1 Technical Information

Perfusion Index (Pi)

The Perfusion Index (Pi) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Pi thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.

The perfusion index assists clinicians in determining optimal placement of the SpO2 sensor. This parameter is also useful as a troubleshooting tool by helping a clinician rule out whether a questionable value may be due to low perfusion and/or a low signal to noise condition. Clinicians use Pi to quickly identify the optimal site to place the sensor. Higher Pi values reflect stronger pleth signals which facilitate more consistent measurements.

An added benefit is that changes in perfusion can be an indicator to the clinician of important changes in the patient's physiological status.

The Pi value from the board is encoded within a data range of 0.000% to 20.000%. It is recommended to round the Pi value to the hundredths place digit for a value of 0.02% to 0.99%, round to the tenths place digit for values between 1% and 9.9% and use whole numbers for values between 10% and 20%.

Siq Bar Graph

Provides an assessment of the confidence in the measurement displayed.

Sensitivity Algorithm

The sensitivity mode setting allows the clinician to adapt the SpO2 measurement sensitivity to the patient's level of SpO2 signal strength and quality at the measurement site. Table 122 below provides an overview of the three distinct sensitivity modes.

Sensitivity Mode	Use Case
Normal	Patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).
Adaptive Probe Off Detection (APOD) (Default)	Patients who have a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.
Maximum (MAX) **Note: Maximum setting will not be persisted between power cycles.**	Patients with weak signals (high ambient noise and/or patients with low perfusion) or when a "low perfusion" message displays in APOD or normal mode. It is recommended for use during procedures or when clinician and patient contact is continuous such as in higher acuity settings. It is not recommended for care areas where patients are not monitored visually, such as general wards. Max sensitivity is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

Averaging Time

Length of time over which the system calculates the average of all data points, can be:
2-4, 4-6, 8, 10, 12, 14, or 16 seconds (default 8S).

Masimo Technical Alarms

Technical Alarms indicate an issue with the SpO2 sensor which is either effecting or preventing a measurement being made. Technical alarms fall into two Categories:

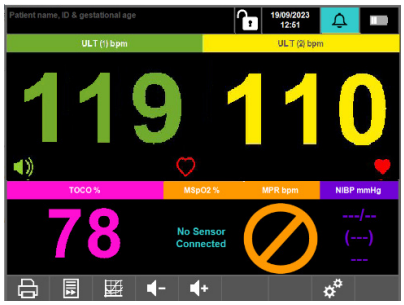
- Blocking Technical Alarms
- Informative Technical Alarms

Blocking Technical Alarms

Alarms where the SpO2 probe is unusable and measurements cannot be made.

- The Technical Alarm will sound
- Blocked Icons will flash alternately with the Alarm Reason in the MPR and SpO2 windows
- The Alarm Indicator Icon and Alarm reason will flash Blue
- The Alarm can be cancelled by pressing the Alarm Icon
- Once Cancelled both Blocked Icons will remain on screen
- Pressing on Blocked Icon will show the Blocked Reason
- Blocking technical alarms are defined in Appendix 5 User Alarms and Messages

The example shown is for No Sensor Connected in Numeric View.



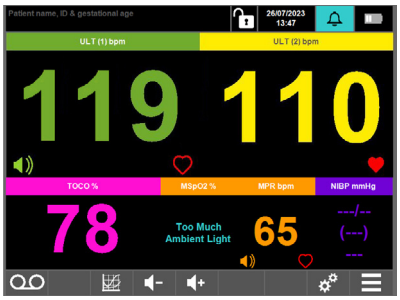
If the Alarm is cancelled, the flashing sequence will stop and the blocked Icons will remain.

Informative Technical Alarms

Alarms where the reading may be compromised unless action is taken. Readings are still presented on the diagnostics screen whilst the alarm is active.

- The Technical Alarm will sound
- SpO2 and MPR Readings will flash alternately with the Alarm Reason
- The Alarm Indicator Icon and Alarm reason will flash Blue
- The Alarm can be cancelled by pressing the Alarm Icon
- Informative technical alarms are defined in Appendix 5 User Alarms and Messages

The example shown is for Too Much Ambient Light in Numeric View

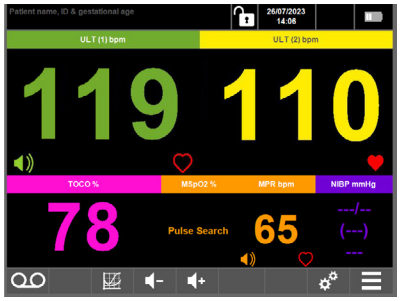


Informative User Messages

Informative user messages provide feedback to the user for messages which may assist with device usage.

- The Message will alternate between MSpO2 and MPR and the current reading
- Informative messages will be the same color as the SpO2 area (orange)
- Informative messages are defined in Appendix 5 User Alarms and Messages.

The example shown is for Pulse Search in Numeric View.



Sensor or Cable Expiry

The Masimo protocol indicates if certain sensors/cables are either Near expiry or expired.
Expiry can be one of the following:

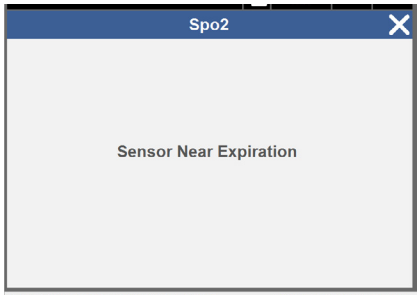
- Near Expiration – given well in advance of an item expiring, the item can still be used
  - Unit Idle
  - Unit Recording/Printing
- Expired – The item will have to be replaced
  - Sensor On Patient
  - Sensor Off Patient

Near Expiration

- If a “Near expiration” message is received the “Near expiration” window (opposite) will be displayed under the following conditions:
  - Unit Idle – Message will be displayed
  - Unit recording and/or Printing – Message will not be displayed (the message will be displayed once recording/printing has ended).

Near Expiration messages and associated items are defined in Appendix 5 User Alarms and Messages

The example shown is for Sensor Near expiration

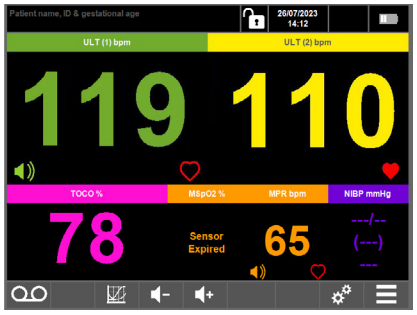


Expired - with MSpO2 Sensor On Patient

- If the expiry message is received with the finger inserted the monitoring session will continue and an “Informative User Message” will be displayed, it will alternate with the current reading.
- This will allow the current measuring session to continue.

Near Expiration messages and associated items are defined in Appendix 5 User Alarms and Messages

The example shown is for Sensor expired in Numeric View.

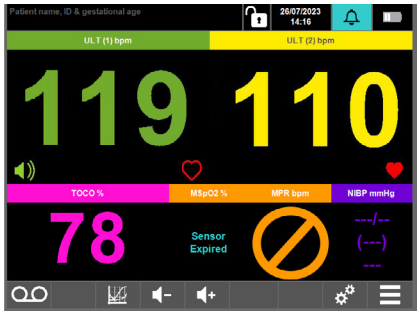


Expired - with MSpO2 Sensor Off Patient

- If the expiry message is received with the finger NOT inserted a Blocking Technical Alarm will be displayed, the message will alternate with the blocked Icon.
- This will Block any further use of this sensor.
- This alarm can be cancelled in which case both SpO2 and MPR windows will show the Blocked Icon.
- As with other Blocking alarms, if one of the Blocked Icons is pressed after the alarm has been cancelled the blocked reason will be displayed.

Near Expiration messages and associated items are defined in Appendix 5 User Alarms and Messages

The example shown is for Sensor expired.



Sensor Off Patient

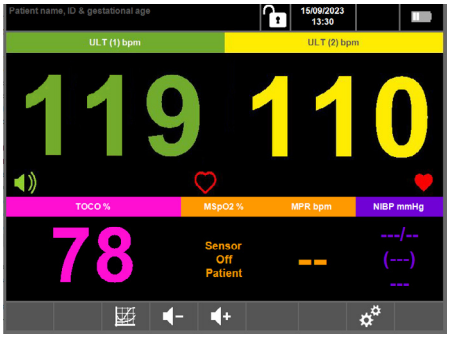
The following scenarios are supported:

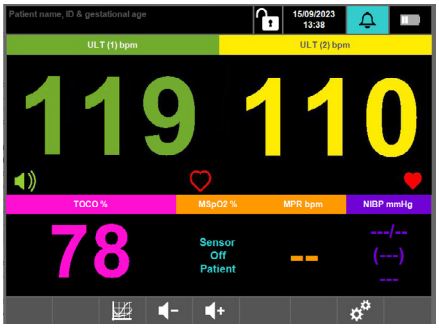
Expiry can be one of the following:

- Sensor either removed or falls off patient
  - Scenario 1 – Before valid SpO2 Data has been received
  - Scenario 2 – After valid SpO2 Data has been received

Scenario 1 – Before valid SpO2 Data has been received

- The message “Sensor Off Patient” will be displayed as an “informative user message” i.e. there will be no alarm
- The Message will alternate between MSpO2 and MPR.



Scenario 2 – After valid SpO2 Data has been received • The message “Sensor Off Patient” will be displayed as an “informative technical alarm”. • The Message will alternate between MSpO2 and MPR.	

User Alarms and Messages

The following table lists the Masimo Alarms/Messages against the corresponding Alarm/Message Category:

Category	Message/Alarm	
Blocking Technical Alarms	• Cable Expired (**with** Sensor Off Patient, No Sensor Connected, or No Adhesive Sensor) **(Replace Cable)** • Incompatible Cable • Defective Cable **(Replace Cable)** • Sensor Expired (**with** Sensor Off Patient or No Adhesive Sensor) **(Replace Sensor)** • Incompatible Sensor • Defective Sensor • Adhesive Sensor Expired (**with** Sensor Off Patient) **(Replace Adhesive Sensor)** • Incompatible Adhesive Sensor • Unrecognized Adhesive Sensor **(Replace Adhesive Sensor)** • Check Sensor Connection	• Cable Expired (**without** Sensor Off Patient, No Sensor Connected, or No Adhesive Sensor) • Unrecognized Cable **(Replace Cable)** • No Sensor Connected • Sensor Expired (**without** Sensor Off Patient or No Adhesive Sensor) • Unrecognized Sensor • Check Cable and Sensor Fault • No Adhesive Sensor **(No Adhesive Sensor Connected)** • Adhesive Sensor Expired (**without** Sensor Off Patient) **(Replace Adhesive Sensor Next Patient)** • Defective Adhesive Sensor **(Replace Adhesive Sensor)**
Informative User Messages	• Low Signal IQ • Sensor Initializing • Pulse Search	• Interference Detected • Low Perfusion Index • Low Sensor Battery
Informative Technical Alarms	• Too Much Ambient Light	• Sensor Off Patient
No MspO2 Connected	• No Cable Connected	
Near Expiration	• Cable Near Expiration • Adhesive Sensor Near Expiration	• Sensor Near Expiration
Not Applicable	• Demo Mode	• SpO2 Only Mode

5.2 Clinical Information

Sp02 General Description

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor is connected to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two ways: l) as a percent value for arterial oxygen saturation (Sp02), and, 2) as a pulse rate (PR).

General: The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

Technologies

Masimo Signal Extraction Technology (SET®)

Masimo Signal Extraction Technology's signal processing differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise).

Masimo SET® pulse oximetry utilizes parallel engines and adaptive filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET® signal processing algorithm, Discrete Saturation Transform® (DST®), in parallel with Fast Saturation Transform (FST®), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

Principles of Operation

Pulse oximetry is governed by the following principles:

Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), and methemoglobin (blood with oxidized hemoglobin content) species differ in their absorption of visible and infrared light.

The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

PO2 General Warnings and Notes

WARNING: Inaccurate SpO2 readings may be caused by:

- **Improper sensor application and placement**
- **Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.**
- **Elevated levels of bilirubin**
- **Elevated levels of dyshemoglobin**
- **Vasospastic disease, such as Raynaud's, and peripheral vascular disease**
- **Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.**
- **Hypocapnic or hypercapnic conditions**
- **Severe anemia**
- **Very low arterial perfusion**
- **Extreme motion artefact**
- **Abnormal venous pulsation or venous constriction**
- **Severe vasoconstriction or hypothermia**
- **Arterial catheters and intra-aortic balloon**
- **Intravascular dyes, such as indocyanine green or methylene blue**
- **Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.**
- **Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.**
- **Skin color disorders**

WARNING

- **Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.**
- **Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.**
- **Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.**
- **The Fetal monitor is not an apnea monitor.**
- **The pulse oximeter should not be used for arrhythmia analysis.**
- **SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).**
- **If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.**
- **If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.**
- **Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayedon the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.**
- **To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.**
- **Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.**

WARNING

- **Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.**
- **To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.**

Notes:

- **A functional tester cannot be used to assess the accuracy of the pulse oximeter.**
- **High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.**
- **When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.**
- **Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).**
- **Cables and sensors are provided with X-Cal technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.**

Specifications

Saturation (% Sp02)	1-100%	
Pulse rate range	20-240 bpm	
Perfusion	0.02% - 20%	
Saturation Accuracy (% Sp02) - During No Motion Conditions	**Adults, Pediatrics:** • 100%: ±2 digits • 0-69%:unspecified	**Neonates:** • 100%: ±3 digits • 0-69%: unspecified
Saturation Accuracy (% Sp02) - During Motion Conditions	**Adults, Pediatrics:** • 100%: ±3 digits • 0-69%:unspecified	**Neonates:** • 100%: ±2 digits • 0-69%: unspecified
Pulse Rate (bpm) - During No Motion Conditions	**Adults, Pediatrics, Neonates:** 25 to 240 ± 3 digits	
Pulse Rate (bpm) - During Motion Conditions	**Adults, Pediatrics, Neonates:** 25 to 240 ± 5 digits	
Resolution	Saturation (% Sp02) Pulse Rate (bpm)	
Low Perfusion Performance	> 0.02% Pulse Amplitude Saturation (% Sp02) ± 2 digits % Transmission > 5% Pulse Rate ± 3 digits	

Patient Cables

The table below provides basic specifications of compatible Masimo LNOP, RD, LNC, and M-LNC patient cables, adapters, and extensions.

Part Number	Receptacle or Part Description	Sensor Interface	Model Description	Length	GTIN (Global Trade Item Number)
4080	14 pin Mini-D	RD	RD SET MD14-05	5 ft.	00843997009751

RD SET Sensors (for use with compatible RD patient cable)

The table below provides basic specifications of compatible Masimo LNOP, RD, LNC, and M-LNC patient cables, adapters, and extensions.

		RDSET Reusable					SpO2 Accuracy (%)		PR Accuracy (bpm)		Low Perfusion Accuracy (No Motion)	
P/N	Sensor	Desc-ription	GTIN	Application Site	510K	Weight Range (kg)	No Motion	Motion	No Motion	Motion	SpO2 (%)	PR (bpm)
4050	DCI	Adult Finger	00843-99700-9843	Finger or Toe	K180046	> 30	± 2	± 3	±3	± 5	± 2	± 3

Radiant Power of Light for LNOP, RD SET, LNCS, and M-LNCS Sensors

Radiant Power at 50 mA pulsed
□ ▯15mW

Nominal Wavelengths

Masimo oximetry sensors use light emitting diodes (LED's) which operate at the following wavelengths (except TC-I, TF-I, and TFA-1 sensor types as specified in their respective columns below.)

LED	General	TC-I	TF-I	TFA-1
	Nominal Wavelength	Nominal Wavelength	Nominal Wavelength	Nominal Wavelength
Red	660 nm	653 nm	660 nm	653 nm
Infrared	905 nm	880 nm	880 nm	905 nm

5 Non-Medical Device Accessories (Masimo Testers)§

The following testers can be used to verify the general functionality of Masimo devices or devices containing Masimo SET pulse oximetry. Refer to the tables below for various testers and their test parameter specifications.

Oximeter Testers

The Masimo Tester is used to verify the general functionality of Masimo devices or devices containing Masimo SET® pulse oximetry. The Tester is available in configurations which allow a connection to Masimo SET devices as well as connections via Masimo patient cables.

		Test Parameter Specifications	
Tester PN	Connector Type	SpO2 (%)	Pulse Rate (bpm)
1593	Direct Connect (14-Pin)	81 ± 3	61 ± 1
2367	LNCS (9-Pin)		
4249	RD		

Compatibility

[1] The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.

[3] The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[4] See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.

[5] The TC-I sensor is contraindicated for patients with pierced ears at the measuring site.

[6] The TF-I sensor must be removed and repositioned to a different monitoring site at least every 2 hours. If extended monitoring is required, use of a single patient adhesive digit sensor is recommended.

[7] The TF-I, TC-I, and DBI sensors were not validated under motion conditions.

[8] The Trauma and Newborn sensors are for use only with instruments containing Masimo SET oximetry (Version 4.1.0.1 or higher) or monitors licensed to use specialty sensors.

[9] Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.

[10] Masimo M-LNCS, LNOP, RD, and LNCS sensors, cables, and adapters have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS 9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.

[11] For M-LNCS Blue, LNOP Blue is the predicate. Masimo SET technology with LNOP Blue sensors have been validated for no motion accuracy in human blood studies on neonatal, infant and pediatric patients with congenital cyanotic cardiac lesions in the range of 60%-100% SpO2 against a laboratory co-oximeter. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

[12] The presented 510(k) reference is based on the specific FDA clearance for the specific Masimo technology board cleared with the compatible Masimo sensor. The 510(k) reference may vary for the Masimo sensor depending on the pulse oximetry technology (i.e. Masimo SET, Masimo rainbow SET, Philips FAST, Nellcor).

[13] Masimo accessories are designed and verified by Masimo to be compatible for use with Masimo technology integrated into OEM devices. Please refer to the OEM device manufacturer for a list of Masimo accessories and features/parameters which are currently available for use with the OEM device.

5.3 TRADEMARKS, LEGENDS AND LOGOS

Grant by Masimo. Masimo hereby grants to Huntleigh a non-exclusive license to use the Masimo Licensed Trademarks with the Licensed Devices for identification purposes and for publicity and promotional purposes when it is advertising Licensed Devices.

No Implied License; Non-Authorized Accessories. Huntleigh agrees to include the following legend on the exterior of Licensed Devices:

“NO IMPLIED LICENSE: Possession of this device does not convey any express or implied license to use the device with unauthorized sensors or cables that would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.”

“NON-AUTHORIZED ACCESSORIES: Masimo technology is designed to operate together with Masimo cables, sensors and accessories as an integrated system. When any component of the system is compromised, erroneous measurements can occur. Accordingly, the use of unauthorized sensors or accessories, such as third-party reprocessed or copycat sensors can yield unreliable results when used with a Masimo device. The performance of Masimo technology is not validated when used with any unauthorized sensor or accessory.”

5.4 END-USER LICENSE AGREEMENT

THIS DOCUMENT IS A LEGAL AGREEMENT BETWEEN YOU (“PURCHASER”) AND HUNTLEIGH. IF YOU DO NOT AGREE TO THE TERMS OF THIS AGREEMENT, PROMPTLY RETURN THE ENTIRE PACKAGE, INCLUDING ALL ACCESSORIES, IN THEIR ORIGINAL PACKAGE, WITH YOUR SALES RECEIPT TO HUNTLEIGH FOR A FULL REFUND.

a. Grant of License. In consideration of payment of the license fee, which is part of the price paid for this product, Huntleigh grants to Purchaser a nonexclusive, nontransferable license, without right to sublicense, to use the copy of the incorporated software/firmware, and documentation in connection with Purchaser’s use of Masimo products for their labeled purpose. Huntleigh reserves all rights not expressly granted to Purchaser.

b. Ownership of Software/Firmware. Title to, ownership of, and all rights and interests in, any Masimo software and/or firmware and the documentation, and all copies thereof, remain at all times vested in Masimo Corporation, licensor to Huntleigh, and they do not pass to Purchaser.

c. Assignment. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise, without Huntleigh’s prior written consent; any attempt without such consent, to assign any rights, duties or obligations arising hereunder shall be void.

d. Copy Restrictions. The software/firmware, mask works, circuit board layouts, and accompanying written materials are copyrighted. Unauthorized copying of the software, including software that has been modified, merged, or included with other software, or other written materials is expressly forbidden. You may be held legally responsible for any copyright infringement that is cause or incurred by your failure to abide by the terms of this license. Nothing in this license provides any rights beyond those provided by 17 U.S.C. §117.

e. Use Restriction. As the Purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not electronically transfer the software/firmware from the products to any other device. You may not disclose, publish, translate, release distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble, or create derivative works based on the Masimo product, the software/firmware, or the written materials without the prior written consent of Masimo. Masimo sensors that are designated for single use are licensed under Masimo patents for use on a single patient only, and are not sold. Possession of a Masimo device does not convey any express or implied license to use the device with unauthorized sensors or cables that would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to the device. There is no license, implied or otherwise, that would allow use of single use Masimo Sensors beyond their intended single use. After use of single use Masimo sensors, there is no further license granted by Masimo to use the sensors and they must be discarded.

f. Non-Authorized Accessories. Masimo technology is designed to operate together with Masimo devices, cables, sensors, and accessories as an integrated system. When any component of the system is compromised, erroneous measurements can occur. Accordingly, the use of unauthorized cables, sensors, or accessories, such as third-party reprocessed or copycat sensors, can yield unreliable results when used with a Masimo device. The performance of Masimo technology is not validated when used with any unauthorized cable, sensor, or accessory.

g. Transfer Restrictions. The software/firmware is licensed to the Purchaser and may not be transferred to anyone, except other end-users, without the prior written consent of Huntleigh. In no event may you transfer, assign, rent, lease, sell, or otherwise dispose of the software/firmware or the products on a temporary basis.

h. Beneficiary. Masimo Corporation is a Beneficiary of this Agreement and has the right to enforce its provisions.

U.S. Government Rights: If you are acquiring software (including the related documentation) on behalf of any part of the United States Government, the following provisions apply: the software is deemed to be “commercial software” and “commercial computer software documentation,” respectively pursuant to DFAR Section 227.7202 FAR 12.212, as applicable. Any use, modification, reproduction, release, performance, display or disclosure of the software (including the related documentation) by the U.S. Government or any of its agencies shall be governed solely by the terms of this Agreement and shall be prohibited except to the extent expressly permitted by the terms of this agreement.

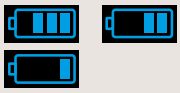
Appendix 6
Sonicaid Wireless Transducer System

Please refer to the IFU supplied with the Sonicaid Wireless Transducer System for detailed instructions on the use, care and maintenance before connecting and using the equipment.

Connecting the Sonicaid Wireless Transducer System

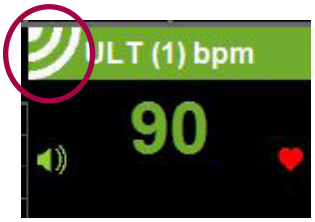
1. FTS-3 should be placed on a flat surface. Alternatively, it can be installed on a Huntleigh approved trolley.
2. Connect the power cable from a suitable wall socket to the mains connector on the rear panel.
3. Plug the end of the interface cable supplied into the 15-way ‘D’ socket on the rear panel.
4. Plug the other end of the interface cable supplied into the 15-way ‘D’ socket on the rear panel of the Team3.

5. Before operating, ensure the wireless transducers are docked into the docking slot and fully charged.

Battery indicator	Status
	Full charging icon: fully charged.
	Increasing charging icon: charging
	No charging icon: the transducer is not placed in the docking slot correctly.
	If the screen displays ERROR, it indicates that the transducer is not connected well or you have placed a transducer from another system by mistake.

Using the Sonicaid wireless transducer system

1. Switch on the Sonicaid wireless transducer system.
2. Check that the wireless transducers are fully charged.
3. Examine the mother, and establish the best position for the transducers.
4. Take out the transducer from the docking slot of the base station and it will power on automatically.
5. The wireless connection indicator is on, and it indicates the transducer is taken out.



6. Place the transducers on the patient.

- **Note**
- **A complete charging process takes approximately 3.5 hours.**
- **The transducer screen displays the signal strength, battery level and working channel.**
- **After the wireless transducer is successfully connected to the base station, it will also display the transducer type. All the indicators are green.**
- **If the transducer is not successfully connected, it will power off automatically.**
- **If you want to power off the transducer, put it back in the docking slot.**
- **If the transducer connects to the base station successfully, the wireless connection indicator, (see 5 above), is always on. Do not put back the inactivated transducer in the docking slot.**
- **The US-T transducer taken up first displays US1 on the screen, and the one taken up later displays US2. Please do not take two US transducers simultaneously, wait 2 seconds to take the other one. Restart the transducers if you take up two US-T transducers at the same time by mistake.**
- **Apply coupling gel to the US-T transducer before use and move the transducer to get the desired fetal heart and belt it to the belly.**
- **Underwater monitoring requires less coupling gel or no coupling gel. The TOCO-T transducer transducer can be applied to the belly directly without coupling gel.**
- **To disable wireless operation and return to wired transducer monitoring, dock the wireless transducers back into the docking slots in the base station.**

Ending Monitoring

Once monitoring is complete and the wireless transducers and base station have been cleaned, dock the wireless transducers into the docking slots in the base station, so they are easily located when you want to use the system again, and so the transducer batteries can be charged.

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;

ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö, Sweden

CE 2797

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

Distributed in the USA by:
Arjo Inc.
2349 West Lake Street, Suite 250
Addison, IL 60101
T: 800-323-1245
www.huntleigh-healthcare.us

1001057-3

www.huntleigh-diagnostics.com/

www.huntleigh-healthcare.us/

A Member of the Arjo Family

HUNTLEIGH

1001048-3