INSTRUCTIONS FOR USE

Team3

Fetal Monitor

ENGLISH

777919-1 08/2022

HUNTLEIGH
A MEMBER OF THE ARJO FAMILY

Team3 – English

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.**
- **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

1.1 Warnings

- **Do not use in the presence of flammable gases or in oxygen rich environments.**
- **Do not sterilise 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 IEC60601-1:2005.**
- **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.**
- **The risk of cyber attack on the fetal monitor is negligible. No special means are required to secure the device or its updates.**
- **Monitoring MECG allows a check to be made that the fetal heart rate being recorded does in fact belong to the fetus and not the mother. MECG is not provided as a diagnostic ECG function and is therefore not designed to meet all of the requirements of IEC 60601-2-27.**
- **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 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.

1.3 Patient Applied Parts

As defined in IEC60601-1:2005, the patient applied parts of the Team3 Fetal Monitor are the:

- TOCO Transducer
- Ultrasound Transducer
- Patient Event Marker
- NIBP Cuff
- $MSpO_2$ Sensor
- MECG Electrodes
- Fetal ECG Electrodes
- FECG leg plate lead
- FECG reference electrode pad

1.4 Service Life

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

2. Introduction

The Team3 series of fetal/maternal monitors are intended for antepartum (Team3A) and intrapartum use (Team3I).

The following features are standard on all models (Team3A and Team3I):

- Dual channel ultrasound fetal heart rate detection with audio.
- External monitoring of maternal contractions
- Maternally sensed fetal movements
- Automatic detection of fetal movement
- Colour 8.4” touchscreen display
- Connections to Central Record System via serial port
- Connection to Sonicaid wireless telemetry
- USB - for upgrading and configuration

The following options are available for all models:

- Dawes-Redman Analysis *
- Triplets
- eCTG models (No printer)
- Integral rechargeable battery
- DVI video output
- Paper tray insert for pre-printed paper
- Maternal Non-Invasive Blood Pressure
- Maternal pulse oximetry ($MSpO_2$)
- Maternal heart rate derived from MSpO2 or NiBP

Team3I has in addition the following as standard:

- Fetal ECG (FECG) **
- Maternal ECG (MECG) ***
- Intra-uterine pressure ***

Team3I additional options:

- Labour Trend function *

Note: This IFU relates to Version 17 software and above.

** Not available in all markets*
*** Electrodes/sensors supplied separately*
**** Interface cables and Electrodes/sensors supplied separately*

2.1 Intended Use and Indications

The Team3 fetal monitors are indicated for use by trained healthcare professionals in non-invasive and invasive monitoring of physiological parameters in pregnant women and fetuses, during the intrapartum and antepartum periods of pregnancy. The devices are intended for use in clinical and hospital-type facilities.

Monitoring using ultrasound is recommended from the 26th week of gestation for routine fetal monitoring.

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
- Fetal movement - maternally sensed and externally via ultrasound.
- Maternal heart rate and oxygen saturation via pulse oximetry
- Maternal non-invasive blood pressure.

Sonicaid Team3 Intrapartum 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 and/or FECG
- Maternal heart rate via ECG electrodes
- Uterine activity - externally or internally sensed
- Fetal movement - maternally sensed and externally via ultrasound
- Maternal heart rate and oxygen saturation via pulse oximetry
- Maternal non-invasive blood pressure.

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.
The Team3 system is not intended for use in intensive care units, operating rooms or in transport monitoring applications.

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		

** except where Philips/GE paper insert option installed*

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)

Standard - Team3l

Item
1 x FECG lead (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.

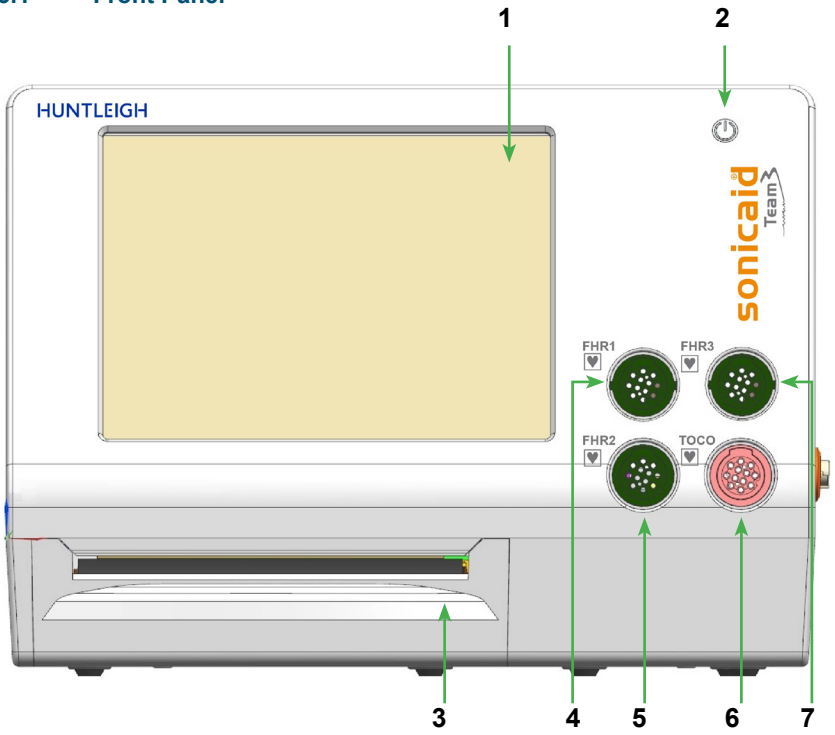
2.6 Operator Positioning

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.

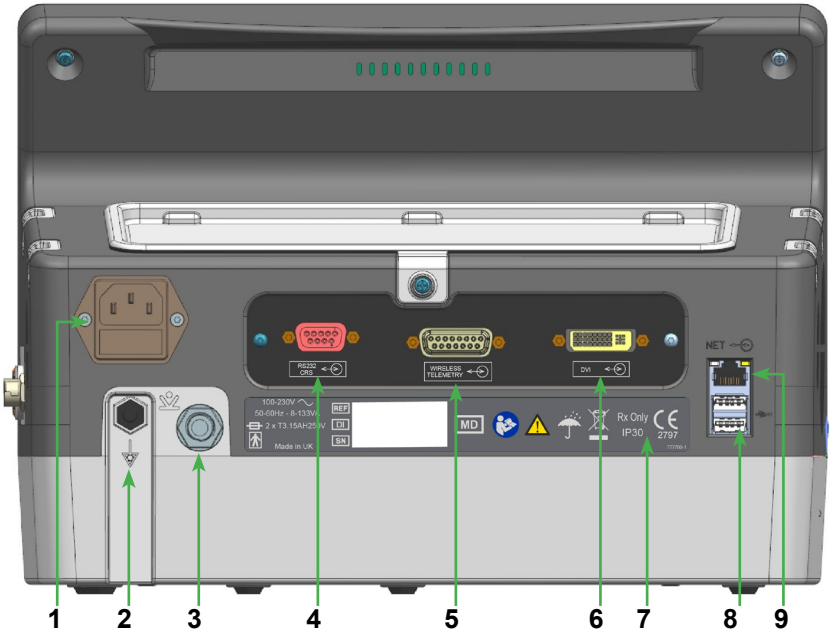
3.1 Front Panel



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

** Depending on model/options purchased.*

3.2 Rear Panel

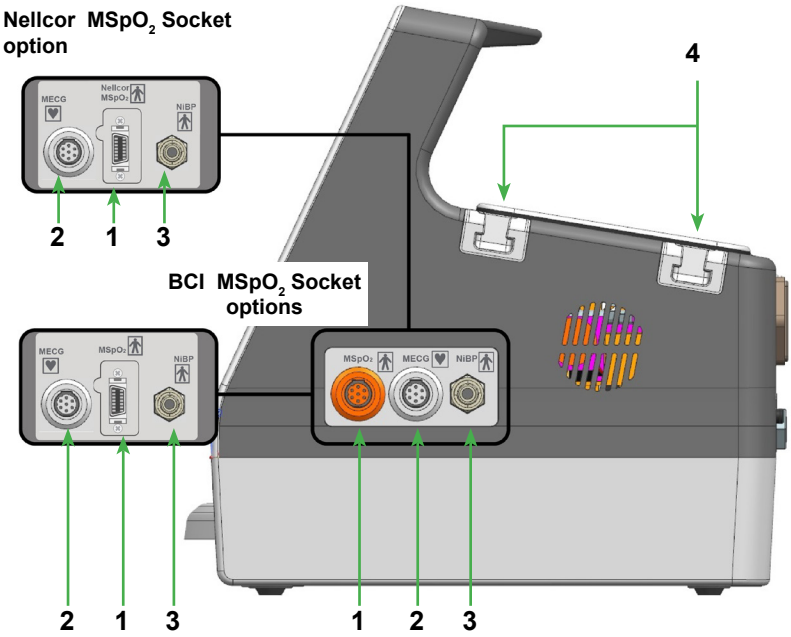


1	Mains Socket	6	DVI Socket *
2	Equipotential earth point	7	Rating Label
3	Fetal Event Marker Socket	8	USB Port x 2
4	RS232/CRS Socket	9	Ethernet Port **
5	Wireless Telemetry Socket		

** Depending on model/options purchased.*
*** Not enabled - future upgrade.*

3.3 Base Panel Label

3.4 Side Panel



1	Maternal SpO_2 *	3	Maternal NIBP *
2	Maternal ECG *	4	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/ FECG/ MECG) 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 ES60601-1:2005 + A1:2012, CAN/CSA C22.2 No. 60601-1:14, IEC 60601-1-6:2010 (ed.3) + A1:2013, CAN/CSA-C22.2 No. 60601-1-6:2011 + A1:2015, IEC 60601-1- 8:2006 (ed.2) + Am.1:2012, CAN/CSA-C22.2 No. 60601-1-8:2008 + A1:2014, IEC 80601-2-30:2009 (ed.1) + A1:2013, CAN/CSA-C22.2 No. 80601-2-30:2010, IEC 60601-2-37 (ed.2), Am1, CAN/CSA-C22.2 No. 80601-2-61:2014, IEC 80601-2-49: 2018, ISO 80601-2-61:2011 (ed.1)		
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)		

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	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.
	Temperature Limitations		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		

** As defined by IEC60601-1*

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 IEC60601-1:2005; clause 16. 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 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.

4.1.1 DVI output (option)

The DVI output allows an external display monitor (must support 800x600 resolution) to be connected to Team3 using a standard DVI cable. Additionally, if the external display is a touch screen, a second cable from the display can be plugged into one of the USB ports. This allows Team3 to be controlled from the external display monitor. The integral screen remains active in this mode as a display but the touch function is disabled.

The external display monitor must either be medical grade, or additional electrical isolation measures must be taken to ensure that the system complies with the relevant electrical / safety standards.

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

Trolley

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

- **If the Team3 is being used on a trolley, make sure the trolley brakes are applied, except when the trolley 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 trolley, or use the Team3, without ensuring that the unit and all transducers and cables are secured.**
- **Keep hands clear of the trolley wheels while the trolley is in motion. Do not attempt to free trapped cables without stopping the trolley and applying the brakes.**
- **When moving Team3, either by hand or when trolley 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

If the DVI option is installed and an external touchscreen is connected, the external screen must be powered on before either applying mains power to Team3, or turning it on.

In this mode, all references to the touchscreen control of Team3 in this manual refer to the external touchscreen. The touch function of the integral screen is disabled in this mode.

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

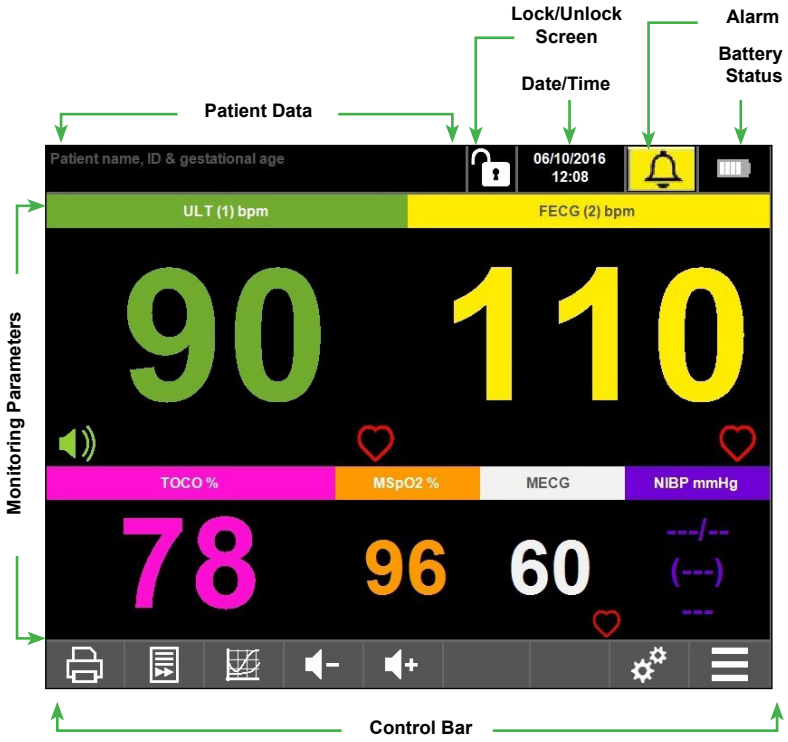
If the unit is in off/standby mode with power already applied, touch and hold for approximately 2 seconds to switch on. A short tone will be heard.

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 patient database is intended for short term trace storage and review only. For long term storage, it is recommended that our Sonicaid FetalCare or Sonicaid Centrale CTG viewing and archiving system is used.

Traces are automatically stored to the Team3 database whenever a trace is printed or recorded. Note that traces viewed on screen before starting the printer or the recording are NOT saved.

The database capacity is ~3.5GB. In typical use, this should store up to 2 years of traces in an intrapartum setting, more in an antepartum setting.

When the database is ~85% full, a message will prompt the user to archive traces >1 year old. This message is repeated each time the unit is switched on until this is done. After 7 days, if still not done, the system will force archiving. Traces are archived to a USB memory stick via one of the 2x USB ports on the rear panel.

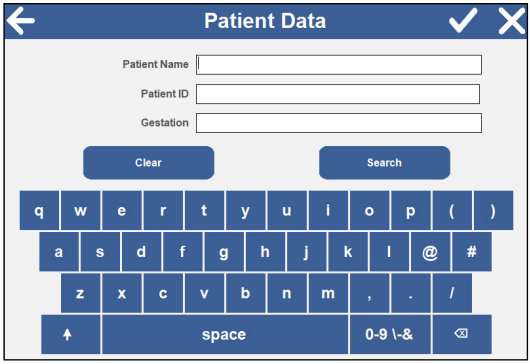
There is also an internal archive facility, using the "Recordings Manager" to move selected traces to the Archive memory, and the "Archive Manager" to restore traces to the live database. Note that this does not increase the overall database capacity, but in large databases, this does speed up access to traces in the live database for review. Refer to section 16.5.

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 16.5 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.



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

Touch Clear to remove any details from the form.

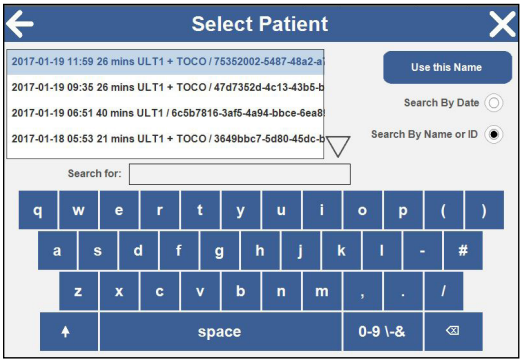
Touch Search to view the Search screen which allows the operator to select the Patient Data of a mother who has been previously monitored.

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.

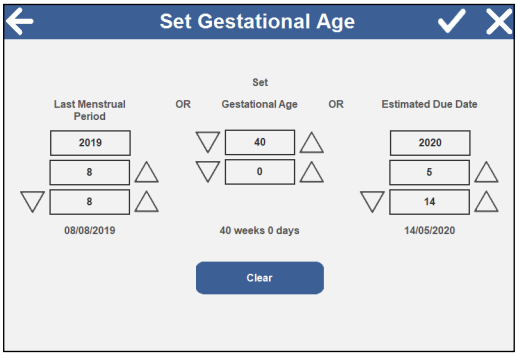
Searching for Patient Names



Touch 

to return to the Monitoring screen with the details of this patient in the Patient Data region.

Setting Gestational Age

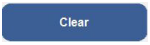


The Set Gestation dialogue allows the operator to change any one of:

- 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.

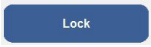
Touch 

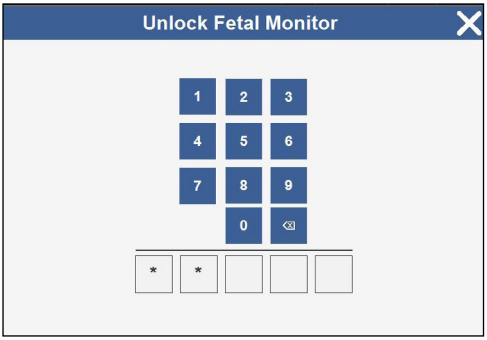
to reset the GA values to zero.

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

5.2.2 Lock / Unlock Screen

Touch  to access the Lock Screen.

Touch  to lock screen or  to exit with out locking.

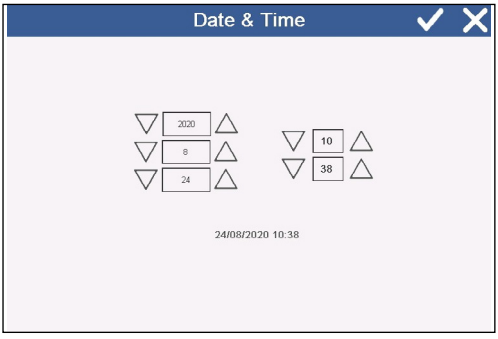


Touch  to unlock the screen.

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

5.2.3 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.)

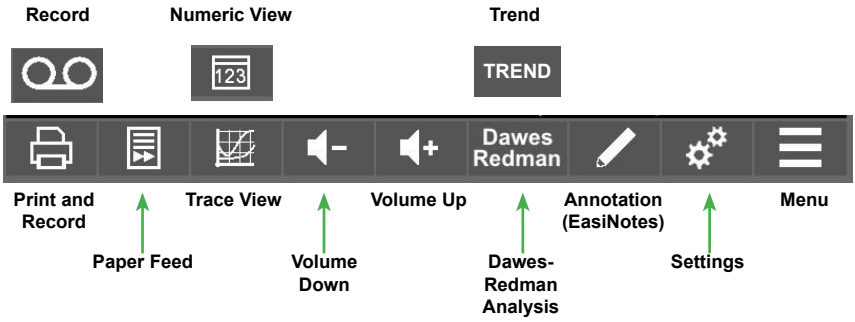


Use the  arrows to set the current date and time.

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 Print / Record

See Section 9 - Printing for details.

	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.
	Annotation Icon appears in the control bar when printing or recording is active. (See Annotation - below).

** on eCTG models with no printer.*

5.3.2 Paper Feed

	Touch and hold to feed the paper through printer.*

** If option(s) 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 / Trend function

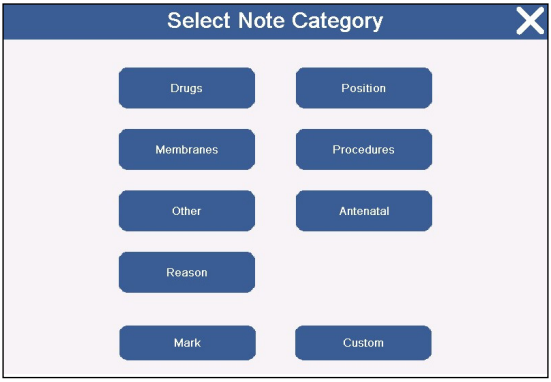
Dawes Redman TREND	The icons are only visible if the gestational age has been set and Team3 is running Sonicaid Trend or Dawes-Redman analysis.*

** If option(s) installed.*

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.

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 16.5 and 16.6 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.**

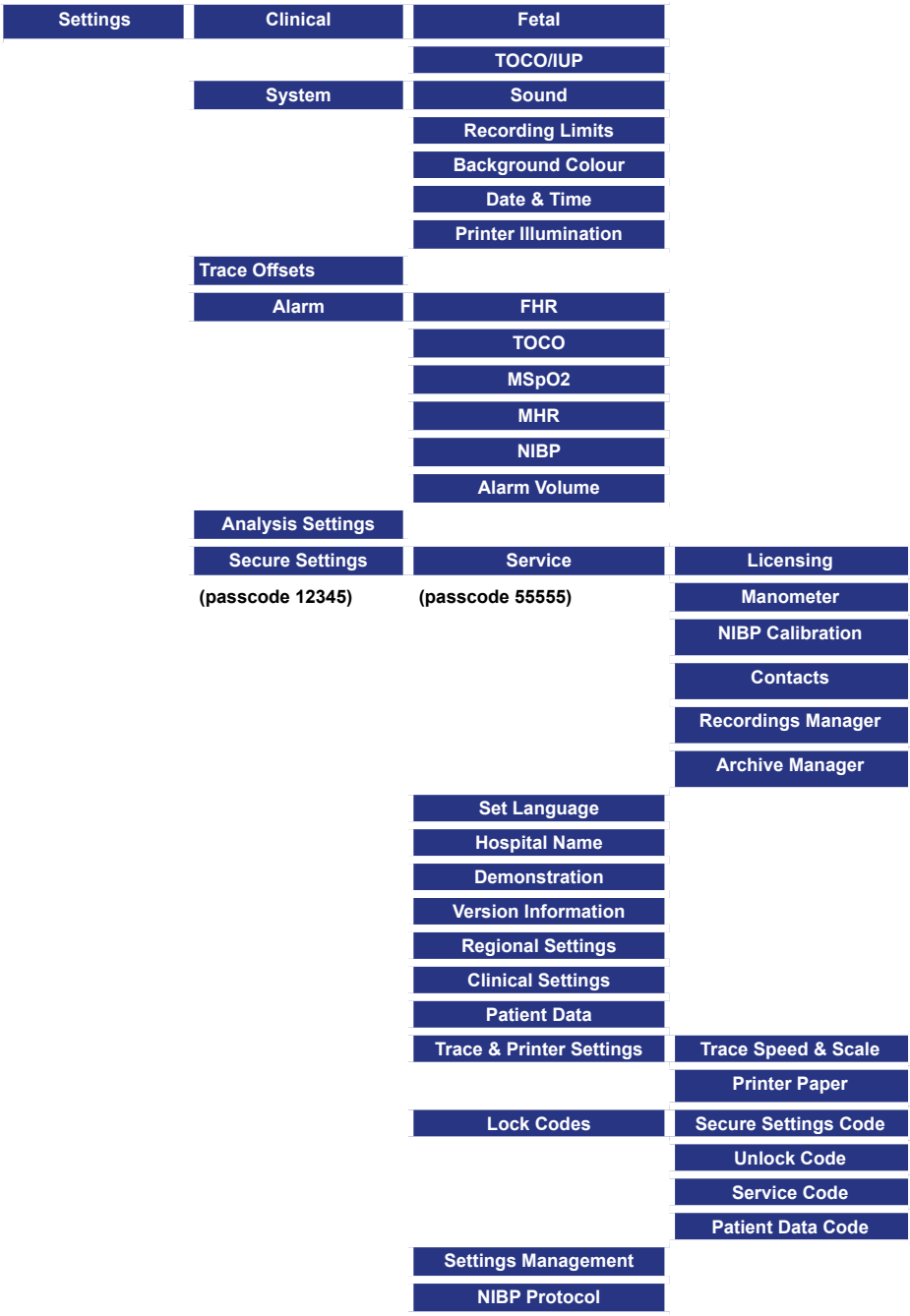
Annotation Sub Menu

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

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

5.3.7 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.

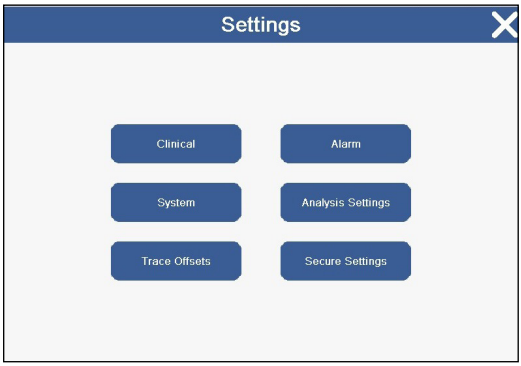


Touch or to return to previous page. accepts data and does not. returns to Main Application screen.

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.

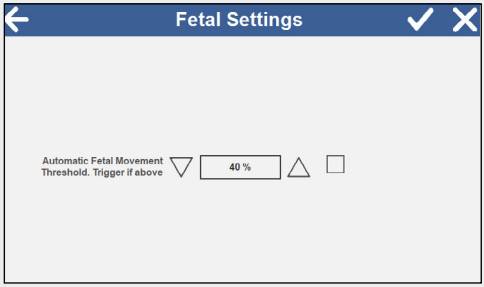
Note

- **The Trace Offsets sub menu is only available if not printing or recording.**
- **Team3 will return all settings to Default levels when switched off. Default settings can be customised - refer to Section 16.5.**
- **If the mains supply is interrupted for more than 30 seconds when no backup battery is provided, t he Team3 shall revert to Default settings.**

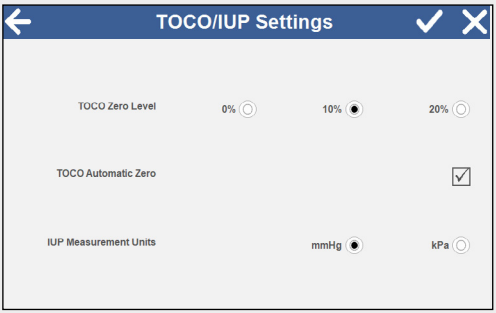
Settings Sub Menus

Clinical Settings Sub Menu

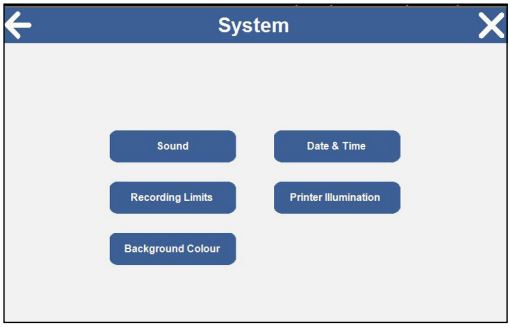
Fetal



TOCO/IUP



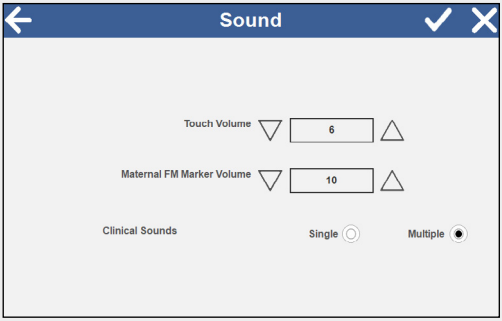
System



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

System Settings Sub Menu

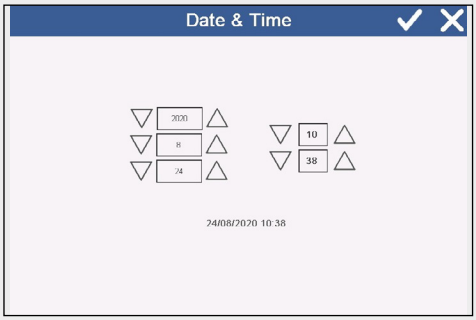
Sound



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

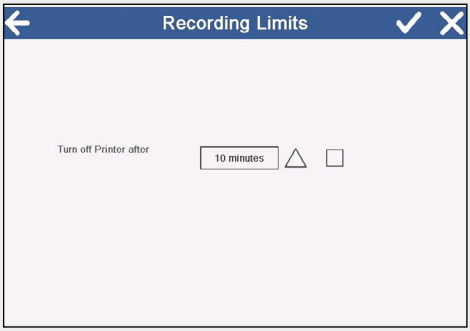
Note
The "Clinical Sounds" option buttons allow listening of just one sound channel or multiple sounds.

Date & Time

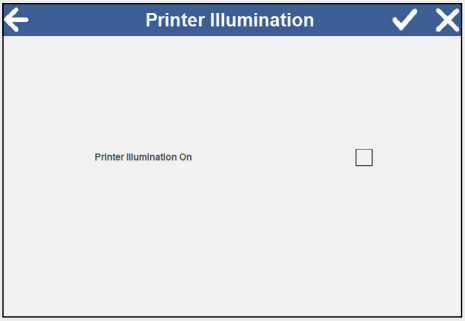


Recording Limits

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

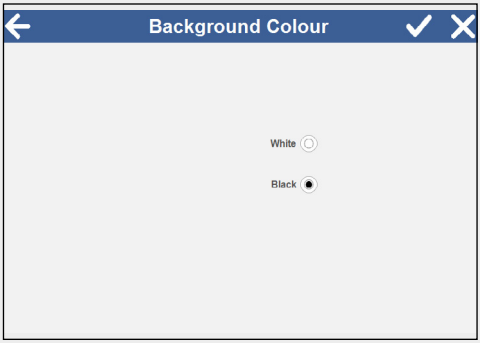


Printer Illumination



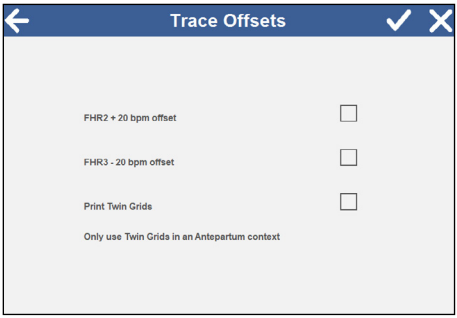
Background Colour

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



Trace Offsets

Note
Print Twin Grids not accessible when printing or recording.



Alarm

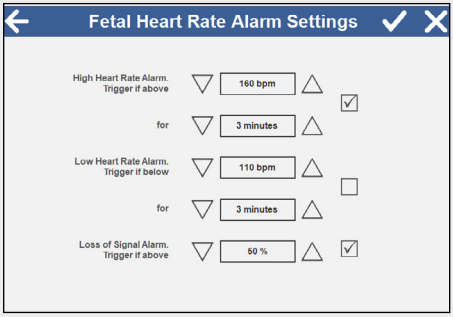
WARNING
Ensure that ALARM LIMITS are set to realistic values. Use of extreme values can render the ALARM SYSTEM useless.

Alarm Settings Sub Menu

Touch each check box to enable / disable each alarm. If selected a ✓ will appear in the box.

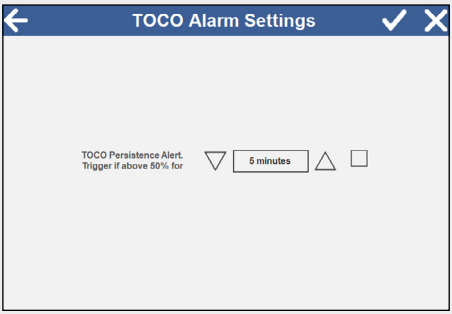
Touch △ ▽ to set each trigger threshold.

FHR



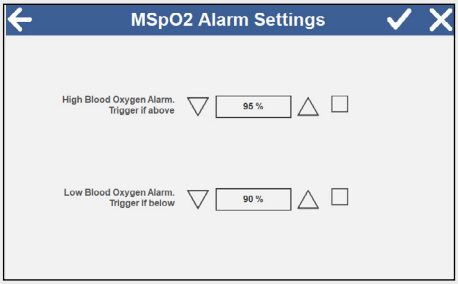
TOCO

TPA - TOCO
Persistence Alert



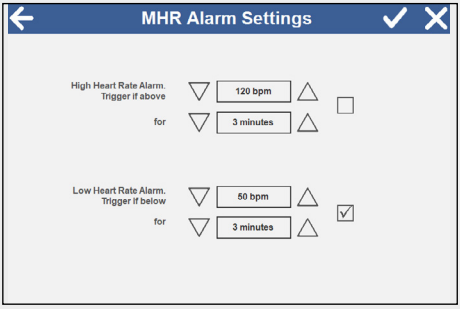
MSpO2

Note
Only available if $MSpO_2$ option fitted.



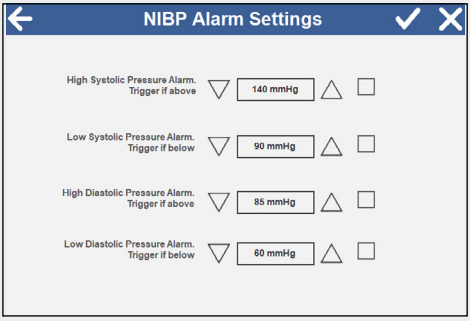
MHR

Note
Only available in Team3I models or if MSpO2 option fitted in Team3A.



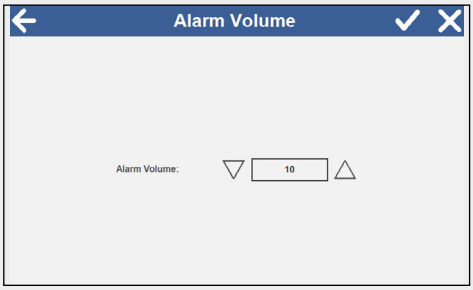
NIBP

Note
Only available if NIBP option fitted.



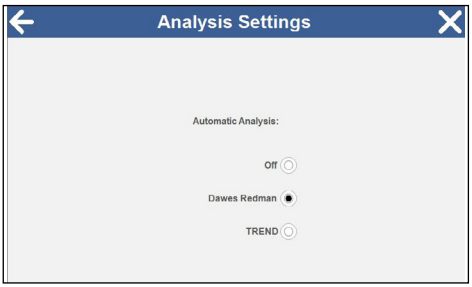
Alarm Volume

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

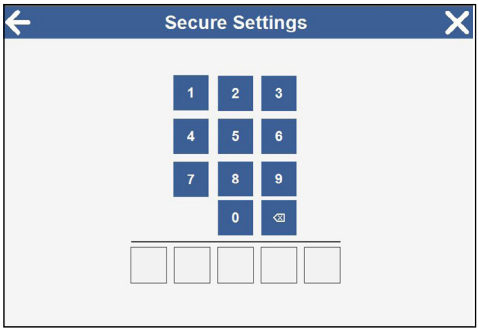
Note
Options in this screen depend on the licensed features. Intrapartum units will start up with Trend and Antepartum units will start up with Dawes Redman. The defaults can be changed in the Secure Settings area.



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 16.5 and also the Service manual.



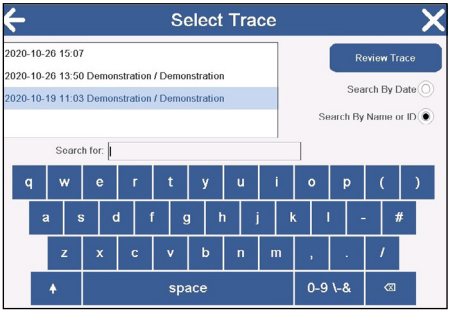
5.3.8 View Menu

Touch the icon to access the View Menu settings.

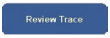
Touch each category to access the sub menu options available.

Note: FECG, MECG sub menu buttons will only be displayed in Intrapartum models and only if probes are attached.

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



The operator can choose to search for the CTG trace either by date or Patient Name / ID.

Touch the CTG trace required and touch 

. The selected trace will now be displayed on the application screen.

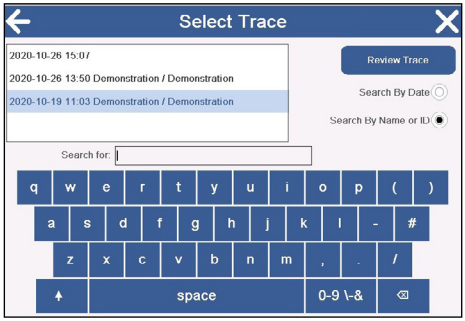
You can scroll through the trace by touching and moving the thick grey scroll bar on the screen. The trace view updates when you release the scroll bar.

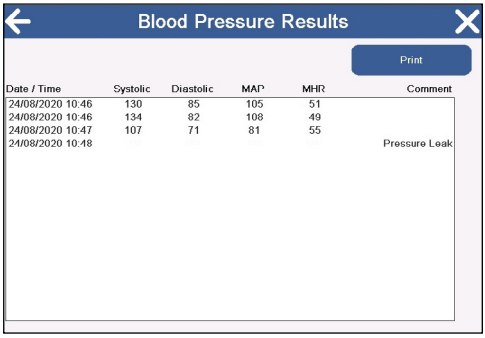
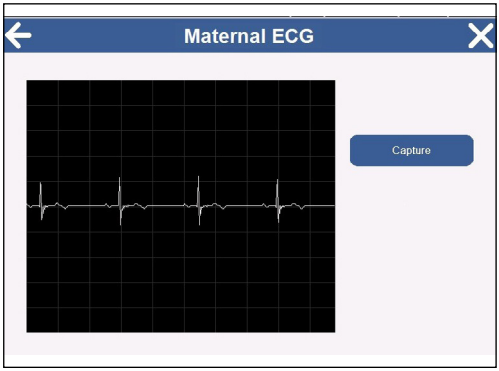
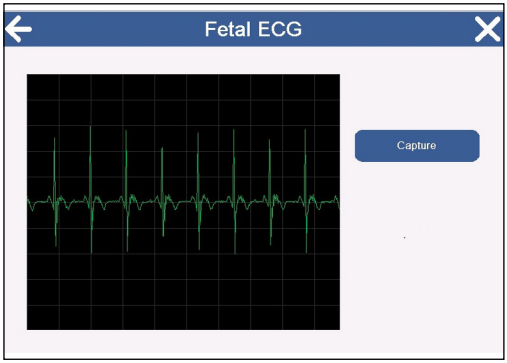
If a printer is fitted, press  to print the trace.

Review Mode Sub Menu

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

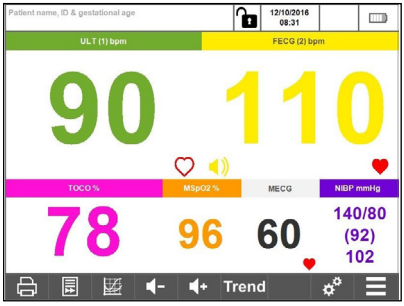
Navigates to the Select CTG trace screen.

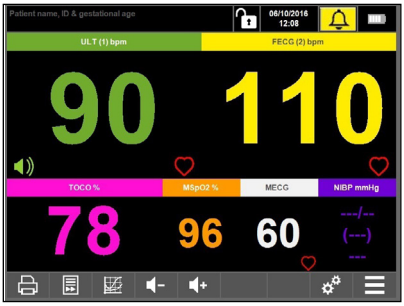


Discharge Patient	Starts a new monitoring session with a new patient.
New Trace	Starts a new monitoring session with the selected patient.
Blood Pressure Readings Displays Blood Pressure results screen. Touch the "Print" button to print out the results.	
MECG FECG The MECG/ FECG screens display a trace from any ECG probe (Fetal or maternal) that is plugged in. Touch Capture to freeze the screen to view the trace. Touch Run to restart the trace.	 

5.4 Monitoring Parameters

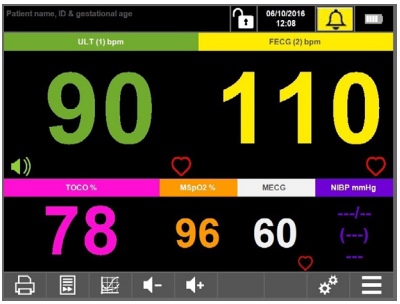
You can configure the screen to display a white or black background. (Refer to ‘Settings’).



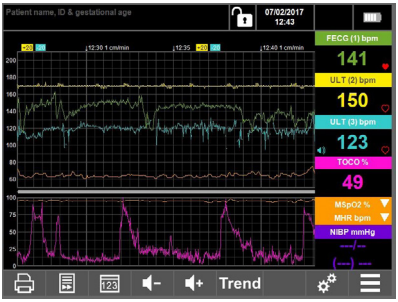


The application screen can be displayed in either Numeric or Trace format.

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



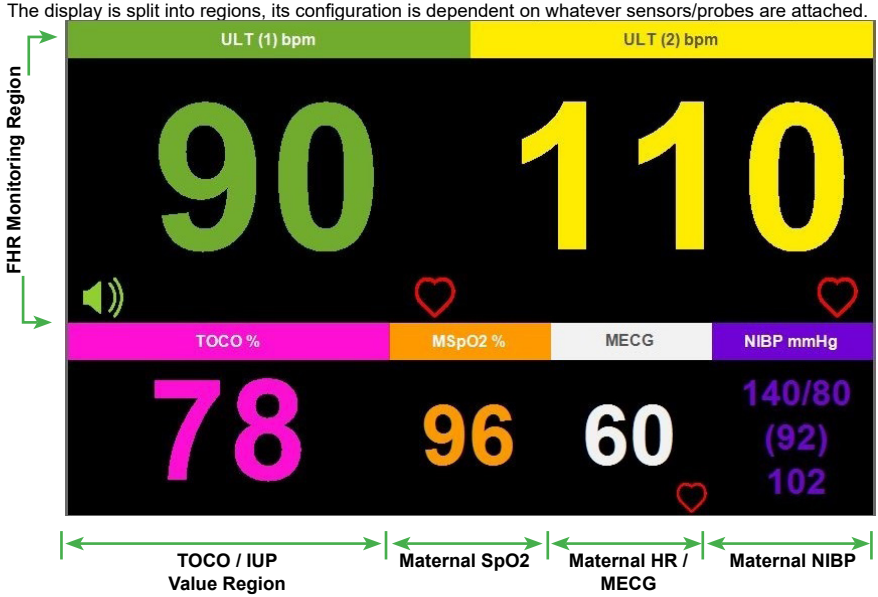
Numeric format



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 be configured for a single channel or multiple simultaneous channels - refer to section 5.3.7.
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 colour of this heart denotes the HR confidence, it is not an indicator of signal strength.

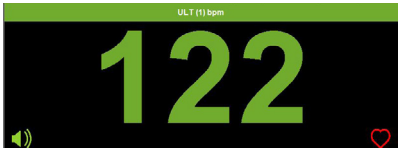
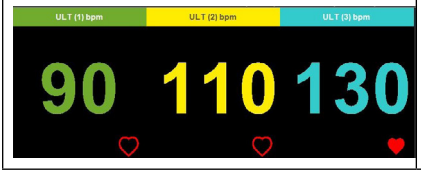
 Red - High

 Amber - Moderate

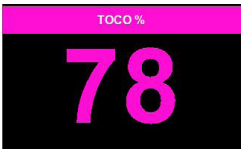
 Yellow - Low

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 /IUP

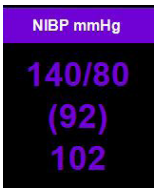
	**TOCO** The TOCO region shows TOCO measurements in progress. Touch and hold on the TOCO region to Zero the TOCO.
	**IUP *** The TOCO region shows IUP measurements in progress. Touch and hold on the TOCO region to Zero the IUP. Refer to instructions supplied with the IUP sensor for correct zeroing.

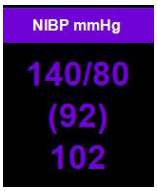
5.4.4 $MSpO_2$ / MHR / MECG

	**MSpO2** The $MSpO_2$ region shows the probe plugged in and measuring oxygenation. **MECG *** The MECG region shows maternal heart rate.
	**MSpO2 / MHR** If the MECG lead is not in use, the MHR measured by $MSpO_2$ will be displayed.

** Intrapartum Model only*

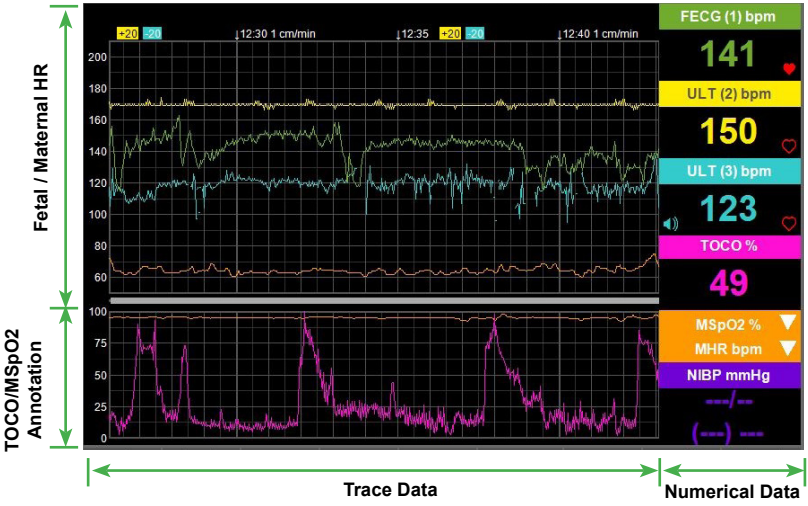
5.4.5 Maternal NIBP

	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 7.5 for instructions on performing maternal blood pressure.

	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 7.5 for instructions on performing maternal blood pressure.

5.4.6 Trace Format

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



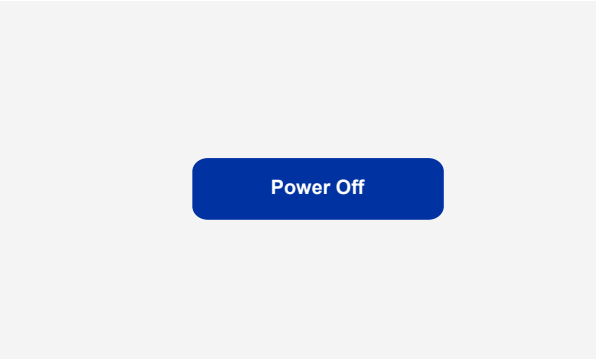
Only one of $MSpO_2$, NIBP and MECG / MHR can be expanded at any one time.

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

Touch 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 touch on the off button for ~15-20s will switch the unit off directly from any machine state.

5.6 Battery Charging

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.

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 15.

1. Switch on Team3.
2. Check the printer (If fitted). Ensure there is sufficient paper.
3. Check the printer setup (FHR offsets, Twins 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

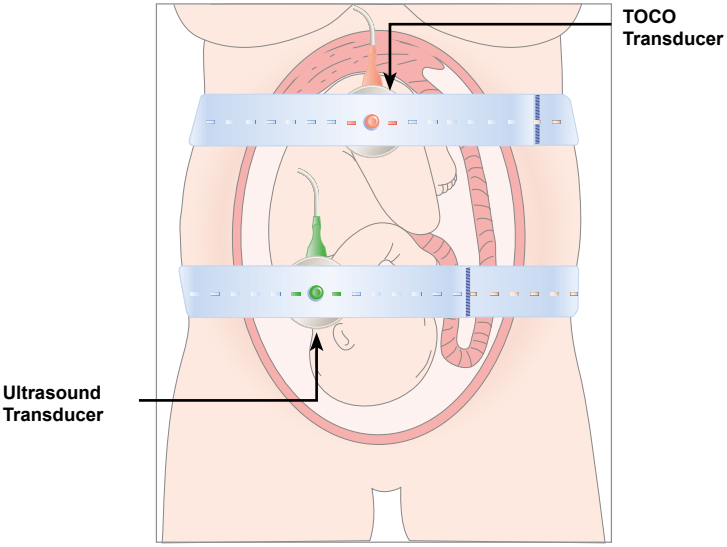
1 Connect the green transducer to the green socket marked FHR1 on Team3. On the main screen, the ULT1 region becomes active.

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.

Note
The printed trace, and the trace saved to the patient database, will only show trace data from the point when the printer is started. Any on-screen trace data prior to this will be discarded.



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 MECG or $MSpO_2$.

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 ransducer picks up stronger signals from the pulsations of the maternal vessels, particularly in the second stage of labour (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.

3. When using ultrasound, listen to the Audio signal. The Doppler audio sound will always reflect the true rate of the detected signal and cannot be affected by double rating or half rating. Fetal heart sound should be like a galloping horse, not a swishing sound from maternal vessels.
4. Repeat any of 1 to 3 if half rating or double rating or other artefact is suspected
5. Re-positioning the Ultrasound transducer to ensure clear heart valve sounds are heard will ensure best performance.

Note: **Disconnect all non-used ultrasound transducers as interference can result in an artificial trace when the transducer is not applied to the patient.**

6.4 Twins / Triplets Ultrasound Monitoring

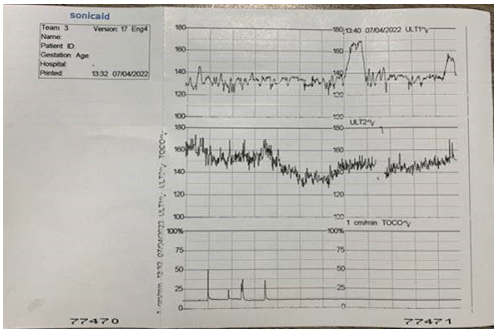
Use the same procedure as for singleton monitoring, using multiple transducers.

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. f 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, this offset option remains active until de- selected by the user or the unit is switched off. (Subject to locally set default settings).**

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 and 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.

6.5 Fetal ECG (Team3I models only- using a Fetal ECG electrode)

Connection

An FECG transducer can be connected via any of the green sockets on the front of the monitor (FHR1, FHR2, FHR3).

Note:
Only one FECG transducer can be connected at a time. If more than one FECG transducer is connected, the following screen will be displayed:

It is possible to monitor FECG for a fetus independently of the ultrasound monitoring. The FECG channel can be used simultaneously with the two ultrasound channels for triplet monitoring.

- **Always check electrodes and their packaging before use.**
- **Use only FECG electrodes supplied with the Team3, or listed in the Accessories and Consumables brochure.**

Monitoring procedure using Safelinc™ / Qwik Connect™ electrodes

Follow the instructions for use supplied with the fetal ECG electrode

1. Attach the FECG lead to the mother's leg, using the adhesive electrode pad.
2. Attach the FECG electrode to the fetal presenting part.
3. Connect the FECG electrode to the FECG lead.
4. Allow a few minutes for the signal to stabilise and a clear fetal heart rate to be displayed. The confidence indicator should be a red heart.
5. Adjust the volume control as necessary.

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 15.
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 and 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 Contractions (using IUP transducer)

- **Use only IUP transducer types supplied with the Team3, or listed in the Accessories.**
- **Always check transducers and their packaging before use to ensure that there is no damage and that sterility has not been compromised.**
- **Follow the manufacturers' instructions for correct use.**
- **Do not connect IUP transducers to Team3 Antepartum models as they are not compatible.**

1. Connect the IUP connecting lead to the pink socket on Team3.
2. Check IUP units of measurement (mmHg or kPa). Change, if required (See Section 5.3 - Settings Menu).
3. Insert the catheter as described in the instructions supplied with it.
4. Zero the transducer as described in the instructions supplied with it. Touch and hold the IUP region of the screen to zero the IUP.
5. To confirm placement and function of the transducer, ask the patient to cough. A spike should be observed in the contractions measurement.

7.3 Fetal Movement Event Marker

When monitoring twins, this function will indicate movement of either twin - it is not possible to associate a movement event with a specific fetus.

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

7.3.1 Automatic Fetal Movement Event Marker

Automatic Fetal Movement is not indicated for use during labour.

Fetal movement events are recorded automatically when this mode is selected, and an appropriate detection level is set. Refer to section 5.3.7 - Settings Menu - Clinical Settings Sub Menu to activate Automatic Fetal Movement option.

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

- Automatic Fetal Movement Marker

Please be aware Automatic Fetal Movement Marker's 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.

7.3.2 Manual Fetal Movement Event Marker

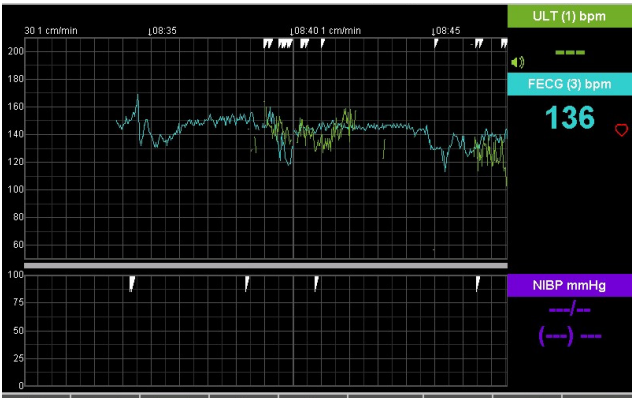
The Fetal Movement Event Marker is a pushbutton switch fitted with a captive cable and connector which is supplied as standard. It is plugged into the socket on the rear of the unit. The switch allows maternally sensed fetal movements to be recorded.

- **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 15 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.**

7.4 Maternal ECG (MECG)

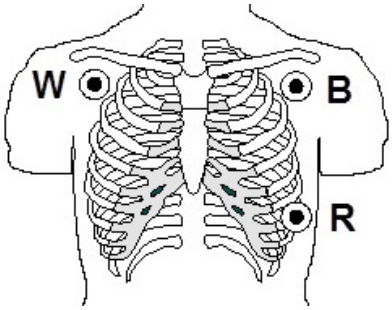
Monitoring MECG allows a check to be made that the fetal heart rate being recorded does in fact belong to the fetus and not the mother.

MECG is not provided as a diagnostic ECG function and is therefore not designed to meet all of the requirements of IEC 60601-2-27.

MECG monitoring procedure

1. Use self-adhesive disposable electrodes. Placement of the electrodes is not critical, though it is a good idea to have the lower electrode placed clear of the diaphragm, as the muscles here are very active in contraction.

   A recommended arrangement might be:



2. Connect the MECG lead (white) to the MECG socket on the side of Team3.
3. Clip the three flying leads of the MECG lead to the electrodes. They are colour-coded white, black and red (W, B and R in the diagram above).
4. Allow a few minutes for the signal to stabilise and a clear maternal heart rate to be displayed. Check the signal visually by displaying the MECG waveform (Press ☰ > MECG).

7.4.1 Fetal Cross Channel

The monitor's 'Fetal Cross-channel' detection technology can help by continuously monitoring the maternal pulse and fetal heart rate by detecting when the same heart rate is being recorded.

Either MECG or SPO2 finger sensor can be used to derive the maternal pulse.

If the maternal and/or fetal heart rates appear similar an alarm will sound and 'FETAL CROSS CHANNEL' will be printed.

If you have reason to doubt the reliability of the fetal heart rate, always confirm by independent means.

- **A poor MECG/SPO2 signal will prevent the FHR cross-channel from functioning. If a good MECG/SPO2 signal cannot be obtained, other methods must be used to ensure FHR integrity so as to prevent accidental interpretation of MHR as FHR.**
- **Check MECG/SPO2 signal quality regularly to ensure that no deterioration has occurred.**
- **The Team3l MECG function is not intended for diagnostic use - where maternal cardiac monitoring is required appropriate diagnostic patient monitoring equipment must be used.**
- **Ensure that any loose conductive parts of electrodes and associated connectors for applied parts including the neutral electrode do not contact any other conductive parts including earth.**

7.5 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, and 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 (colour: blue)
- Large cuff – covering circumferences from 32-42cm (colour: grey)

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

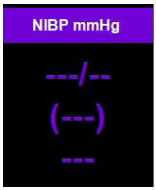
There are many other factors which can effect BP measurement and reflect best practice against national and international guidelines.

Key issues that affect accuracy of BP measurements:

- The patient should be relaxed and rested – minimum 3 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 and 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 and 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.

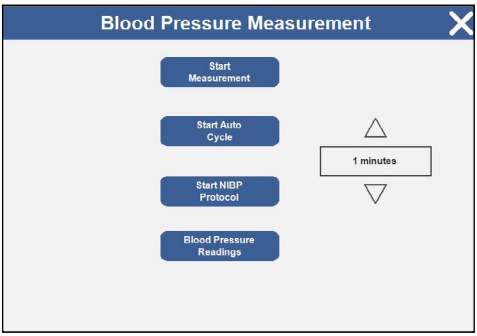
7.5.1 Taking BP measurements



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 Start Measurement 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. 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
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 16.5.**
- **The above default protocol can be customised. Refer to section 16.5.**

- **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 **---/--.**

- **Always use the correct size of cuff. Do not use any cuffs other than those licensed for use with the Team3.**
- **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" and patients should be rested for a minimum of 3 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.**
- **The increasing cuff pressure may cause transient function failure to other monitoring equipment used on the same limb.**
- **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.**

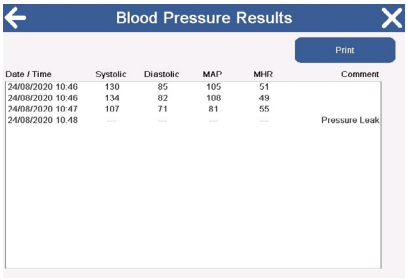
Reviewing BP Results

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

Touch 

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.

7.6 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.

7.6.1 Procedure

Note
If using the Freedom SF1, you will need to view the Version screen (See 16.5 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 $MSpO_2$ / MHR 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.**
- **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 MHR indication cannot be obtained other methods must be used to prevent accidental interpretation of MHR 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.**
- **BCI (Round/Rectangular Socket) - A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor. To check the function of the device, an optional Oximeter/ECG Patient Simulator is available as an accessory (Smiths Medical PM, Inc. Cat# 1606). The simulator attaches to the Oximeter in place of the sensor or patient cable. It provides a known $\%SpO_2$ and pulse rate signal to the Oximeter, allowing the Oximeters performance to be checked.**
- **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 9919:2005 clause 6.8.2 (aa):

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
BCI 3444	660±3nm and 905±10nm	1.8 and 2.0mW typ.
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 17.

5. Data update period: 1 second
   Heart rate averaging: 8 beats
   Alarm latency: < 1 second
6. Alarm limits: See Section 17- Specifications.
7. Compatible probe types: BCI (Smiths Medical) Adult Comfort Clip 3444
   Nellcor Durasensor DS-100A
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 5 - MSpO2 Addition Clinical Information.

BCI Clinical Eval. report:

This study was a descriptive, cross-sectional investigation of healthy, human subjects comparing four Model 31400 Pulse Oximeter Modules (Board 31402B2) determined oxygen saturation (SpO_2) values during motion (test condition) to CO-oximeter determined functional oxygen saturation (SaO_2) values (reference condition). Two additional Model 31400 Pulse Oximeter Modules (Board 31402B2) which were not subjected to motion were used as a control and to determine stable plateaus in the oxygen saturation readings.
Two Model 31400 Pulse Oximeter Modules (Board 31402B2) using Nellcor™ DS-100A sensors also not subjected to motion were (one old style – gray connector and one new style – blue connector) tested.
The study was conducted at oxygen concentrations that targeted an even distribution over the SaO_2 range of 70% to 100%-SaO_2.

Ten adult, volunteer subjects participated in this trial. They varied in age from 20 to 39 (mean 25.9) years. Two Black or African American, seven White
subjects and one subject who did not indicate a race were enrolled. Eight subjects described themselves ethnically as non- Hispanic or non-Latino and two as Hispanic or Latino. There were five female and five male subjects in this trial.

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

The alarms in Team3 are intended to alert users to monitoring data which fall outside user set levels/timings for each type of alarm.
They are not intended to alert users to clinical conditions or pathology. They must not be relied on for this, which remains the responsibility of the user.

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

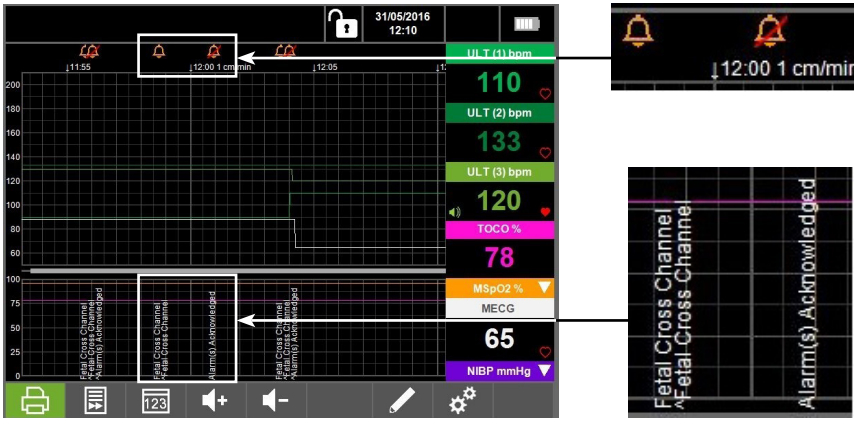
- **Team3 must be printing / recording for alarms to be active.**
- **All alarms have Medium priority.**

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  . Alarm(s) Acknowledged will be printed on the TOCO region of the screen.



Printed Indicators

• Fetal alarms
• Maternal alarms

FECG, ULT1, ULT2 and ULT3 Fetal High Heart Rate
FECG, ULT1, ULT2 and ULT3 Fetal Low Heart Rate
FECG, ULT1, ULT2 and ULT3 Fetal Signal Loss
Maternal High Heart Rate
Maternal Low Heart Rate
Maternal Low O_2 Saturation Alarm
Maternal High O_2 Saturation Alarm

Maternal Systolic High Alarm
Maternal Systolic Low Alarm
Maternal Diastolic High Alarm
Maternal Diastolic Low Alarm
Toco Persistence Alert
Alarm(s) Acknowledged

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.

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 MHR 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, such as Sonicaid Centrale, Fetalcare or Obstetric Archive, 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 16.5).

9.5 Changing paper packs

Paper packs generally have a pre-printed coloured 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.

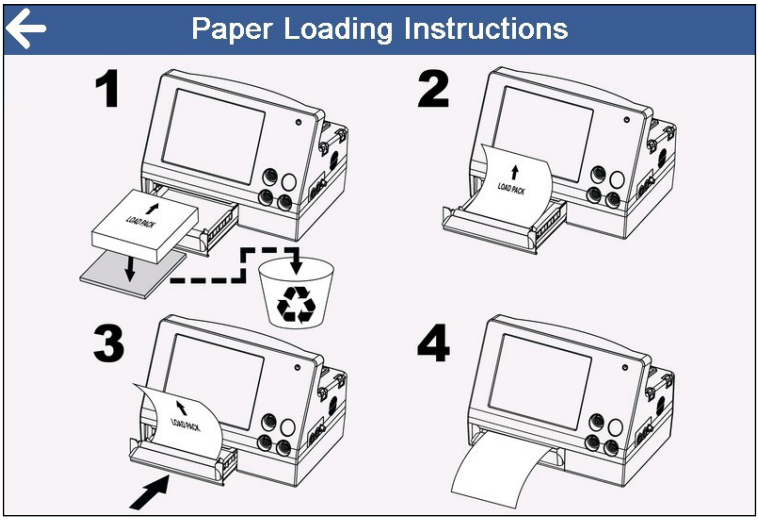
Once a new pack of paper has been installed and the paper tray pushed home, the print icon will return to and the stored data will be printed at a quick rate until the buffer is empty. Then it will revert to printing live data.

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.

The screen automatically returns to normal operation when the tray is closed but this is not an indicator that the tray is FULLY closed. Always ensure it is fully closed by checking that the front face of the paper tray is flush with the front face of the surrounding case.

9.7 Using non-Sonicaid paper

We strongly recommend the use of standard Huntleigh paper. There are many advantages to our plain paper including:

- 100% trace registration accuracy
- No risk if inserted the wrong way up (this can result in mis-interpretation and poor outcomes
- Pack size is 3x length of GE/Philips packs - less likely to run out during a labour and requires less frequent replacement
- High quality copying for case review, referral, training and legal cases (pre-printed colour grids may not copy clearly)
- High quality paper . Note there are many suppliers of cheap paper – these can result in image drop out, reduced storage life, increased print-head wear and accumulation of debris on the head.

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.
However, it is recognised that some users will have a preference for pre-printed paper. This section details the procedure for using such papers. Users must be aware of, and accept, the limitations as detailed above in using such paper.

The following actions are necessary in order to use the Team3 with non-Sonicaid paper:

- Change the paper tray, following the instructions supplied with the tray.
- Change the Team3 paper settings (See Section 16.5).

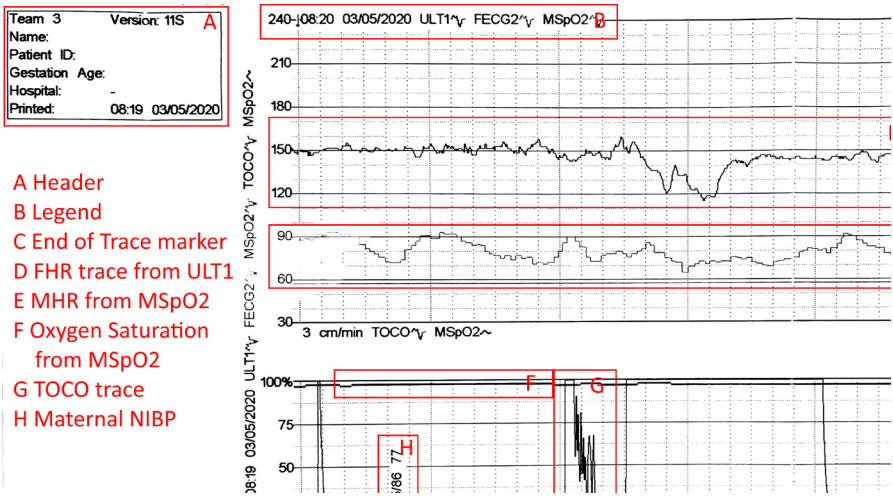
Note: The use of pre-printed graticuled paper disables 'twins side-by- side' trace printout.

The following alternative paper trays are available as accessories:

- Philips paper tray
- GE Corometrics paper tray

9.8 Sample Trace (Sonicaid paper)

The illustration below is of an actual CTG chart.



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.

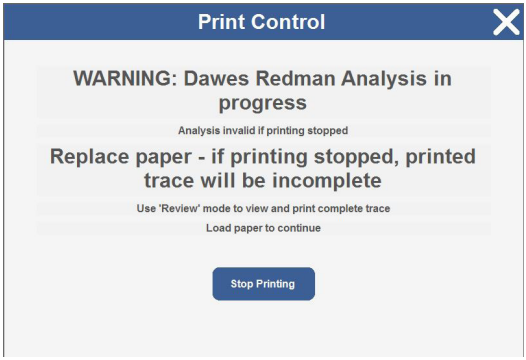
Touch  to stop the recording or  to cancel. If cancelling, replenish the paper to continue

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 Stop Printing 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 Stop Printing to stop the printing or  to cancel.

10. Sonicaid Trend

10.1 Introduction

Sonicaid Trend is a software option available with all Team3 series monitors. It measures fetal heart rate parameters at regular intervals, and describes the trace in a way that is quantitative and not qualitative. Trend is not intended as a replacement for skilled visual interpretation of the trace, but it does help long-term changes in the fetal heart rate pattern to be assessed.

Note: Sonicaid Trend is ON by default on Intrapartum monitors (Team3I).

- **Caution: Trend is valid only during the first stage of labour.**
- **The trace Trend data provided by the Sonicaid Trend is intended to assist, not to replace, the physician's visual assessment of a trace.**

No guidelines on interpretation or limits of normality are provided, but the clinician can use the numeric values to identify and quantify the relative changes in fetal heart rate parameters over a period of time.

Numerical description of the trace allows direct comparison between traces. It also provides training support for trace interpretation, and readily available data for clinical research projects.

IMPORTANT

Trend provides numeric and objective trending information on key FHR trace parameters only. It does not provide any form of trace interpretation. Interpretation and diagnosis of the record remain the responsibility of the appropriately qualified medical staff.

10.2 Sonicaid Trend

Trend measurements are performed at 15 minutes, and every 15 minutes thereafter. It fits a baseline using the last 60 minutes of fetal heart data collected, then calculates the following parameters:

- Baseline heart rate (bpm) for the last 60 minutes
- Baseline heart rate (bpm) for the last 15 minutes
- Deceleration size (beats) for the last 60 minutes
- Deceleration size (beats) for the last 15 minutes
- Short term variation(ms) for the last 60 minutes

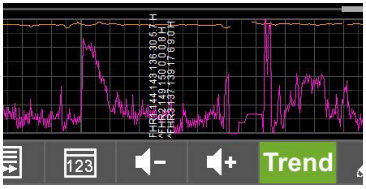
Confidence Indicator

Trend provides a confidence indicator showing the reliability of the baseline fit, and hence the fetal rate parameters. Confidence is shown as High, Medium or Low (H, M or L).

If the confidence indicator is Medium or High, the results reliably reflect the fetal heart rate pattern. If the confidence indicator is Low, interpret the results in relation to the appearance of the trace. Use them only if they are considered to be a sensible reflection of the visually assessed pattern.

10.3 Sonicaid Trend results

Printed and Displayed Results



The parameter values and confidence indicator are printed on the contractions section of the trace.

60 minute values are available after the first hour. Until then the results show 'NA'.

Signal Loss

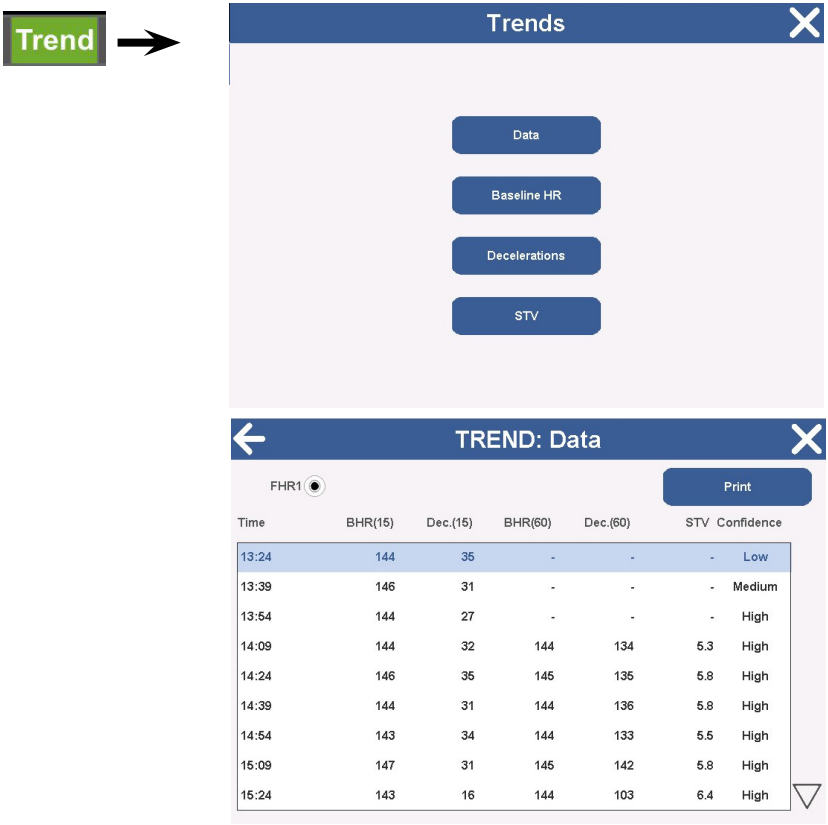
If signal loss is >50%, the results will show ‘SL’.

10.4 Viewing Sonicaid Trend data

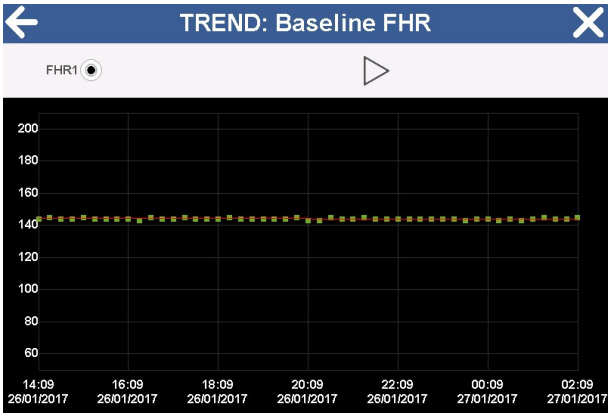
When Printing, Recording or Viewing a CTG

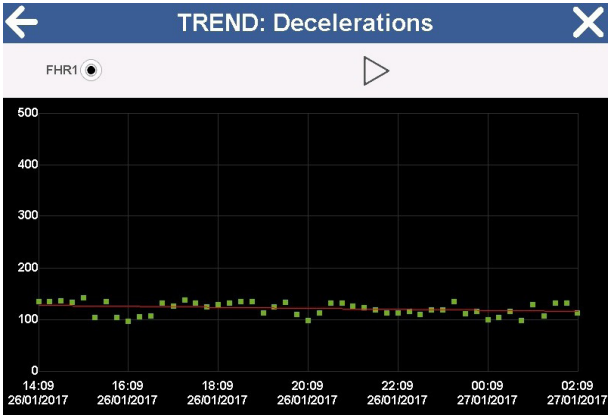
If Trend results are available in any of these modes of operation, the Trend button in the Control Bar will appear Green. Touching this button will display Trend Results associated with the CTG.
TREND data can be viewed either in numeric table form or in graph views.

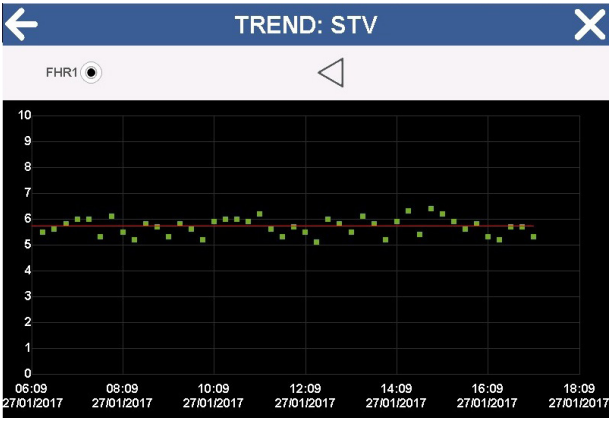
The graph views are particularly powerful in alerting clinicians to long term trends which are easily missed and can highlight significant clinical issues - an application note further detailing this function is available from your supplier.



Time	BHR(15)	Dec.(15)	BHR(60)	Dec.(60)	STV	Confidence
13:24	144	35	-	-	-	Low
13:39	146	31	-	-	-	Medium
13:54	144	27	-	-	-	High
14:09	144	32	144	134	5.3	High
14:24	146	35	145	135	5.8	High
14:39	144	31	144	136	5.8	High
14:54	143	34	144	133	5.5	High
15:09	147	31	145	142	5.8	High
15:24	143	16	144	103	6.4	High


TREND: Baseline FHR
FHR1
200
180
160
140
120
100
80
60
14:09 26/01/2017
16:09 26/01/2017
18:09 26/01/2017
20:09 26/01/2017
22:09 26/01/2017
00:09 27/01/2017
02:09 27/01/2017


TREND: Decelerations
FHR1
500
400
300
200
100
0
14:09 26/01/2017
16:09 26/01/2017
18:09 26/01/2017
20:09 26/01/2017
22:09 26/01/2017
00:09 27/01/2017
02:09 27/01/2017


TREND: STV
FHR1
10
9
8
7
6
5
4
3
2
1
0
06:09 27/01/2017
08:09 27/01/2017
10:09 27/01/2017
12:09 27/01/2017
14:09 27/01/2017
16:09 27/01/2017
18:09 27/01/2017

11. Dawes-Redman Antepartum Analysis

11.1 Intended Use

The intended use of Dawes-Redman analysis is to analyse clinically indicated antepartum CTGs in pregnancies from 26 weeks gestation onwards. It can be used on women who are experiencing Braxton-Hicks contractions but it is not intended for use in latent or established labour as the fetus is then exposed to additional factors such as labour contractions, pharmacological agents and epidural anaesthesia.

The analysis provided by Dawes-Redman is intended to assist, not to replace the physicians's visual assessment of a trace.

As such, Dawes-Redman analysis is not a diagnosis, but an aid to clinical management. Diagnosis remains the responsibility of an appropriately 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 management. Such a clinical assessment may include further tests such as umbilical blood flow velocity waveforms or biophysical profiling.

11.2 Overview

Dawes-Redman analysis is a software option available with all Team3 series monitors. The software tests fetal heart rate parameters against the criteria which define a normal record. Abnormalities are highlighted.

The analysis integrated into Team3 is a full implementation of the latest, most powerful, version of the world-renowned Dawes-Redman CTG analysis.

IMPORTANT

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

The Dawes-Redman analysis is not valid during latent or established labour.

11.3 The Dawes-Redman Criteria

The Dawes-Redman criteria have been developed by Dawes, Redman et al at Oxford University over many years based on a growing database - the largest of its type in the world. It is a unique evidence based approach to CTG interpretation designed to replace the traditional visual interpretation based on highly subjective opinion, which is subject to high inter- and intra-observer variation. Studies have shown that this subjective process is associated with poor outcomes.

The Dawes-Redman CTG analysis replaces this with objective measurement of a wide range of trace features, which are then checked against a powerful algorithm derived from the large Oxford database. The analysis report states whether the criteria have met, or not met, the criteria. For further details on the clinical application of the analysis, contact your supplier.

11.4 Dawes-Redman Analysis

Note

- **Ensure that the manual patient event marker is plugged in and working.**
- **Dawes-Redman analysis does not take account of automated fetal movements.**
- **Dawes-Redman analysis is ON by default on Antepartum monitors (Team3A).**

The first analysis result is reported after 10 minutes of good quality CTG data. It is then repeated every 2 minutes, up to a maximum of 60 minutes. The analysis fits a baseline to the fetal heart rate data collected so far, and from this measures accelerations and decelerations. Short-term variation is calculated, and episodes of high and low variation looked for.

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. As more data is received, a subsequent analysis may re-fit the baseline so that, for example, an episode of high variation is no longer above the first centile.

Twin and Triplet traces

Dawes-Redman analysis does not take account of fetal movement when analysing twins.

Dawes-Redman analysis on triplets is planned for a future software upgrade.

The system then compares the calculated results with the Dawes-Redman criteria.

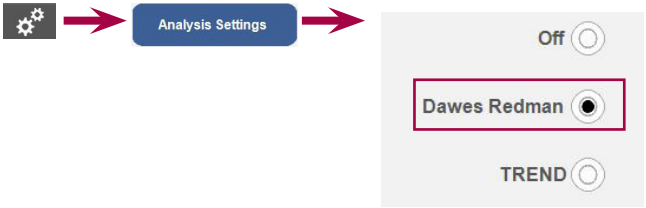
- If the analysis is stopped prior to 10 minutes, there are no analysis results.
- If the analysis is stopped between 10 and 60 minutes and the Criteria are MET, the system prints and displays the message Dawes-Redman Criteria Met as well as all of the measurement parameters.
- If the analysis is stopped between 10 and 60 minutes and the Criteria are NOT YET MET, the system prints and displays the message, Dawes-Redman analysis invalid because Analysis stopped prematurely. The measurement parameters are also available.
- If the analysis continues for a full 60 minutes and the Criteria are still NOT MET, the system prints and displays the message, Dawes-Redman Criteria Not Met with the Reasons for the failure to meet the criteria. The measurement parameters are also available.
- Analysis does not continue past 60 minutes.

11.5 Using Dawes-Redman analysis

Starting Dawes-Redman analysis

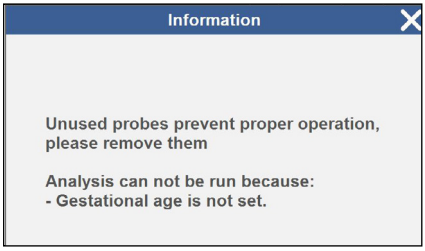
Before setting up Dawes-Redman analysis, the button will be grey with a ‘Not Available’ symbol in red.

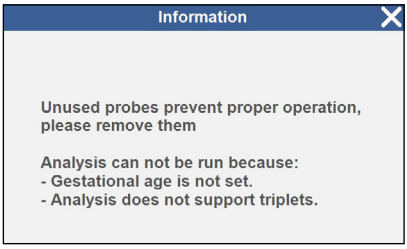
To remove the symbol and make analysis available, ensure Dawes-Redman is enabled on the Settings -> Analysis page.



- 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.

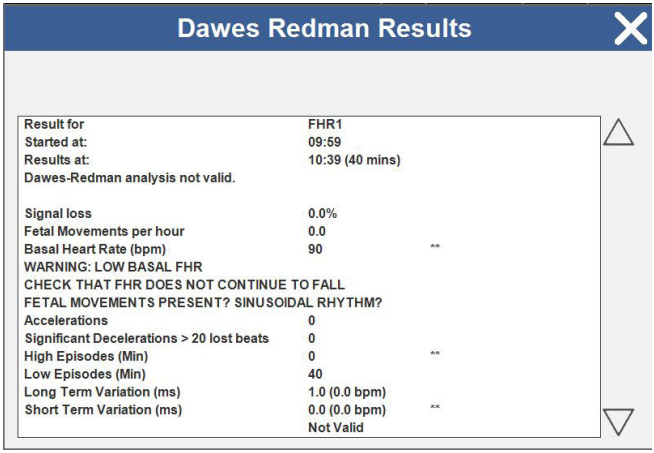




Start the printer or recording to start analysis. The CTG will contain the message ‘Dawes-Redman Started’ and the Dawes-Redman button will turn Light Purple.

While printing or recording

- Prior to 10 minutes the Dawes-Redman button will be Light Purple.
- Between 10 and 60 minutes, if the Criteria are not yet met, the Dawes-Redman button will be Dark Purple.
- Between 10 and 60 minutes, if the Criteria are met, the Dawes-Redman button will be Green.
- After 60 minutes, if the Criteria are not met, the Dawes-Redman button will be Cyan.
- 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.



While reviewing a CTG with analysis results

- If the Criteria are Met, the Dawes-Redman button will be Green.
- If the Criteria are Not Met, the Dawes-Redman button will be Cyan.
- If the Green Dawes-Redman button is pressed, Team3 will display the results from the last analysis calculation.
- If the Cyan Dawes-Redman button is pressed, the Team3 will display the results from the last analysis calculation.
- If the button is cyan, the trace should be continued until the button turns green (criteria met) or for 60 minutes, after which the analysis will automatically stop.
- If the trace is stopped before the criteria have been met, and before 60 minutes, this will invalidate the analysis.

Stopping Dawes-Redman analysis

Stop recording or printing to stop analysis. The CTG will contain the messages ‘Dawes-Redman Criteria Met’, Dawes-Redman CTG analysis invalid' or ‘Dawes-Redman Criteria Not Met’.

11.6 Dawes-Redman Analysis report

When the analysis is stopped, the printer produces a report of the analysis results at the end of the trace. The report shows:

- Values for the calculated parameters
- When the Dawes-Redman criteria were first met
- Whether the Dawes-Redman criteria were met at the time the analysis was stopped
- Abnormalities

CARE result for	FHR1
Started at:4	11.08 AM
Stopped at:	12.08 PM (60 mins)
Dawes-Redman criteria met at	60 minutes
Signal Loss	0.0%
Fetal Movements per hour	0.0
Basal Heart Rate (bpm)	140
Accelerations	8
Decelerations > 20 lost beats	8
High Episodes (Min)	14
Low Episodes (Min)	0
Short Term Variatio (ms)	6.4 (2.2 bpm)

Dawes-Redman analysis is not valid during labour.
This is NOT A DIAGNOSIS.

Team3 shows the last calculated values for

- **Signal Loss**
- **Fetal movements per hour**
- **Basal heart rate**
- **Accelerations**
- **Decelerations**
- **High episodes**
- **Low episodes**
- **Short term variation**

Reasons for not meeting the criteria

If the criteria were not met, the reasons are included in the printout. Possible reasons are:

Reason
Basal heart rate outside normal range
Large decelerations
No episodes of high variation
No movements and fewer than 3 accelerations
Baseline fitting is uncertain
Short-term variation is less than 3ms
Possible error at the end of the record
Deceleration at the end of the record
High-frequency sinusoidal rhythm
Suspected sinusoidal rhythm
Long-term variation in high episodes below acceptable level
No accelerations

Abnormalities

Double asterisks indicate that the criteria have not been met due to one or more of the following conditions:

- Fetal heart rate < 116 bpm or > 160 bpm on a record of less than 30 minutes
- Decelerations > 100 lost beats (> 20 lost beats on a record of less than 30 minutes)
- No moves and fewer than 3 accelerations
- No episodes of high variation
- Short term variation < 3ms
- No accelerations **and**
  either < 21 movements per hour
  or long term variation in episodes of high variation below the tenth centile
- Long term variation in episodes of high variation below the first centile

A single asterisk indicates one of the following conditions:

- Short term variation < 4ms, but ≥ 3 ms
- Basal heart rate < 116 bpm or > 160 bpm on a record ≥ 30 minutes
- Decelerations present, but not meeting the criteria for size of record length

A single asterisk does not necessarily mean that the record cannot pass the criteria. If all other parameters are normal at the 30 minute point, the abnormality could be within acceptable limits to meet the analysis criteria.

Basal heart rate warnings

A basal heart rate of 115 bpm or lower triggers a printed warning:

WARNING: LOW BASAL FHR
CHECK THAT FHR DOES NOT CONTINUE TO FALL
FETAL MOVEMENTS PRESENT? SINUSOIDAL RHYTHM?

12. Using Team3 with a CRS System

The Team3 can be connected to the following PC-based Central Record Systems:

- Sonicaid FetalCare
- Sonicaid Centrale

The Team3 has been validated for use with the listed Huntleigh Software systems. Other manufacturers' systems using the industry standard HP50 / Philips communications protocol should also work but may not have been validated - contact Huntleigh for details.

12.1 Connecting Team3 to Sonicaid FetalCare and Sonicaid Centrale

1. Connect the Sonicaid FetalCare connecting lead to the RS232 connector on the rear of Team3.
2. Refer to the connection instructions supplied with your Huntleigh or other CRS system.

13. 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.

13.1 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) OR Traces superimposed (twins)	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.

13.2 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.

13.3 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.

13.4 Maternal blood pressure

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

13.5 Printing

SYMPTOM	POSSIBLE CAUSE / REMEDY
Paper runs out	A coloured 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 16.
Printer stops working	Check paper supply and feed. If not successful, swap unit out. Trace data is stored in memory.

13.6 General

SYMPTOM	POSSIBLE CAUSE / REMEDY
Unable to switch unit off	Maintain contact on the on/off sense button until the unit shuts down - this may take 15-20 seconds.

14. Care and Cleaning

14.1 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.

WARNING

- **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.**

14.2 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.

14.3 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)			

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

14.4 NIBP Cuff and Maternal Oximetry Sensor

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

14.5 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.

Single use disposable belts are designed for single patient use only and should not be washed. These are distinguished from re-useable belts by colour (white) and include orange SONICAID branding.

15. Maintenance

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

15.1 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.

15.2 Technical maintenance

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

15.3 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.

15.4 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.

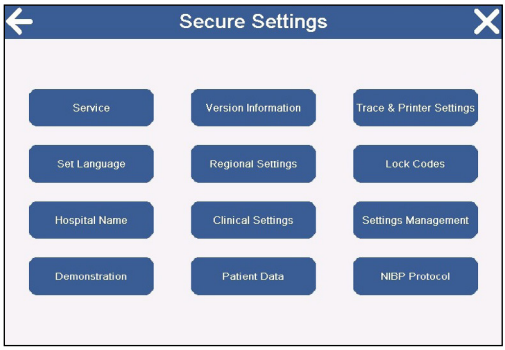
WARNING
Do not attempt service while the fetal monitor is in use.

15.5 Secure Settings

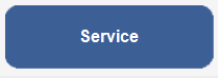
WARNING
The Secure Settings menus should be accessed by authorised personnel only.

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.

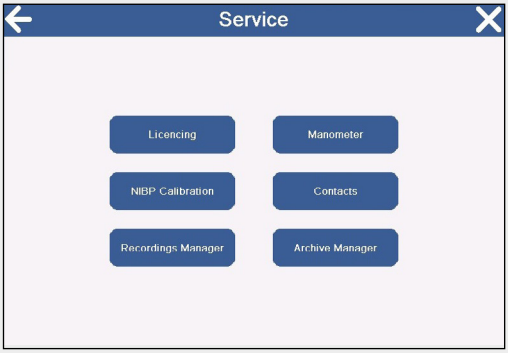


Service Sub Menu



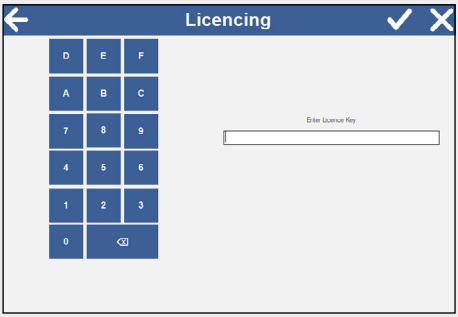
Service menu options are for use by trained biomedical staff only.

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



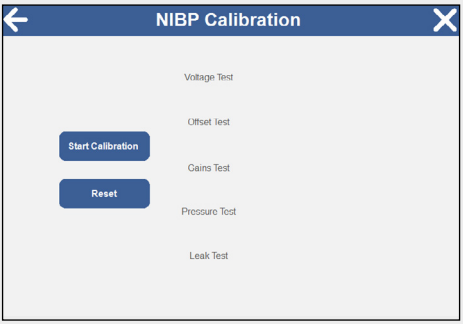
Licencing

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



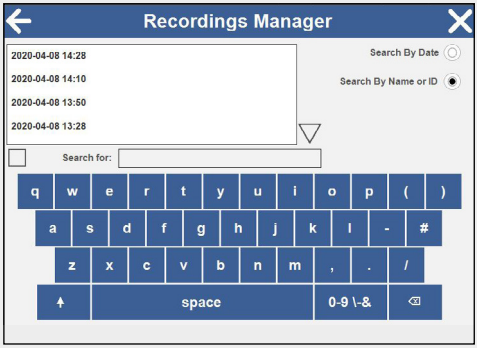
NIBP Calibration

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



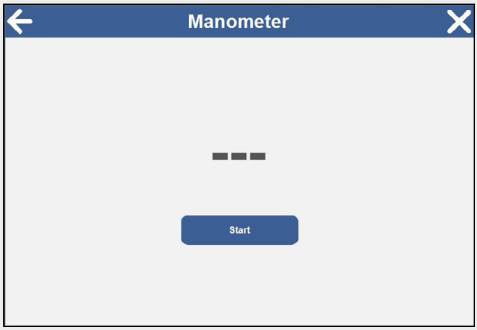
Recordings Manager

Recordings Manager allows trace records to be moved to the internal archive database.

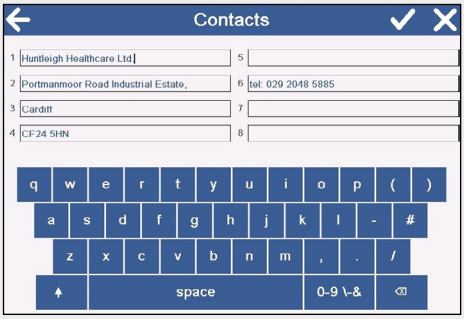


Manometer

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



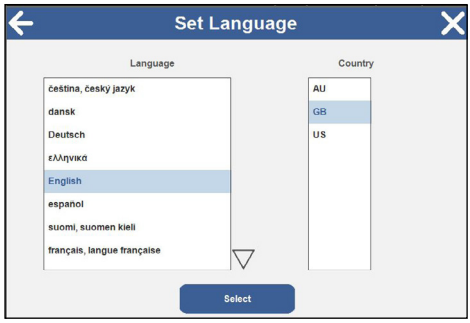
Contacts



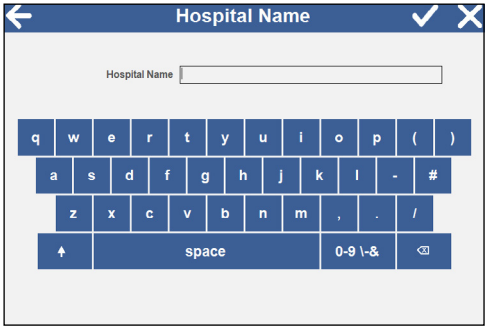
Archive Manager

Archive Manager allows trace records from the internal archive to be transferred back into the live database.

Set Language

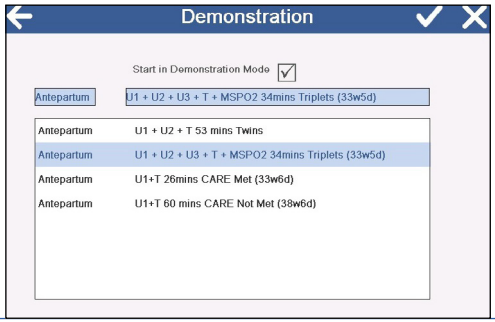


Hospital Name



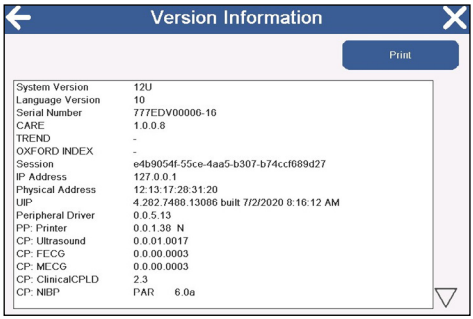
Demonstration

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



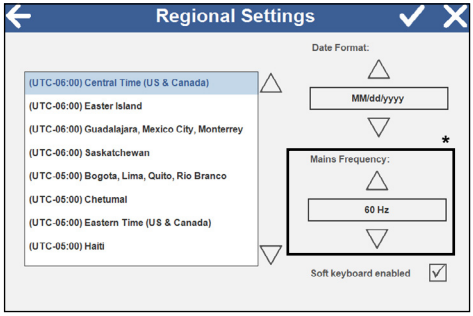
Click on one of the demo traces - this will enable an antepartum demo mode. Switch unit off/on to activate.
Alternatively, selecting the tick box will run an intrapartum demo mode.
To disable demo mode switch the unit off/on.

Version Information



Regional Settings

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

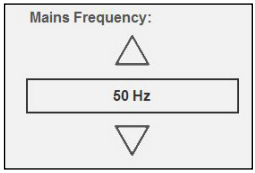


*** Mains Frequency Setting**

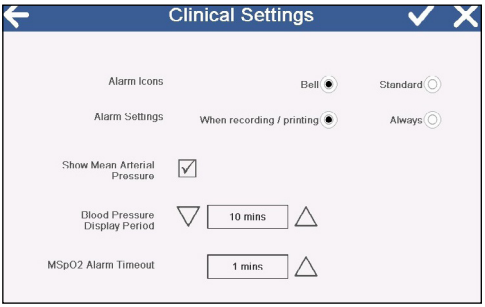
The default setting for the mains frequency on this product is 50Hz.

Touch △ ▽ to select required frequency.

Touch ✓ to confirm.

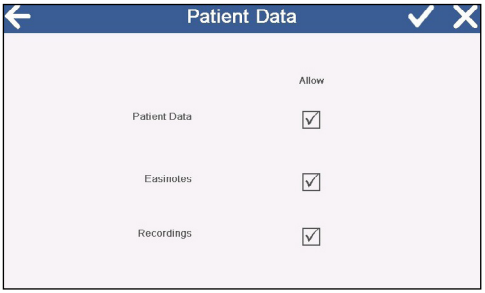


Clinical Settings



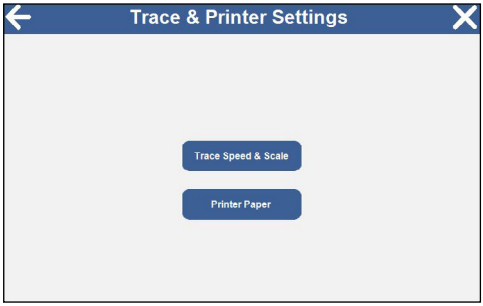
Patient Data

Allows these functions to be enabled/ disabled.



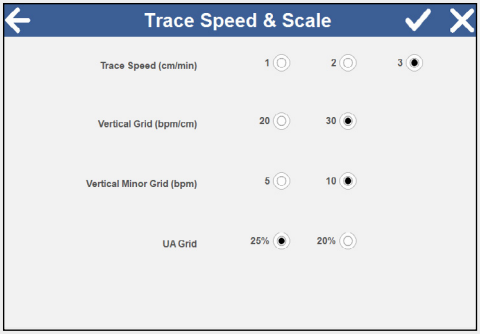
Trace & Printer Settings

This button is not available while printing is in progress.



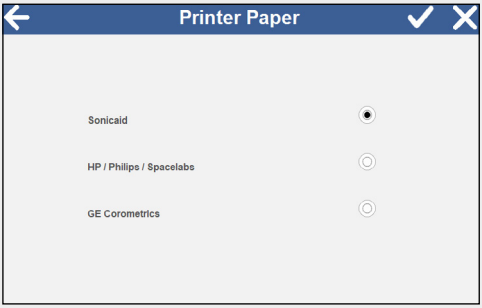
Trace and Printer Settings Sub Menu

Trace Speed & Scale

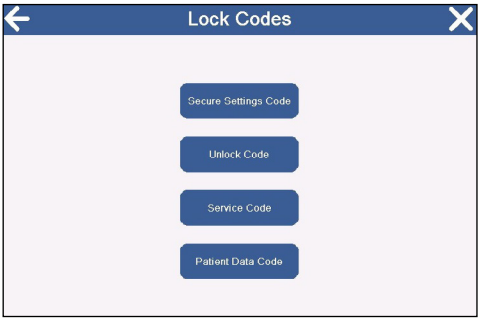


Printer Paper

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

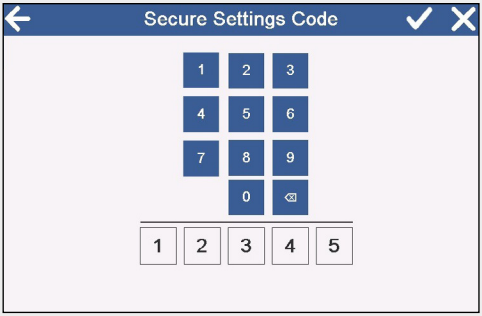


Lock Codes

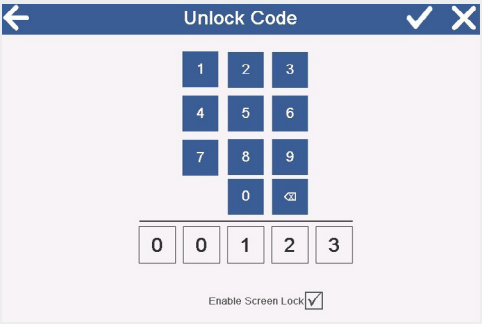


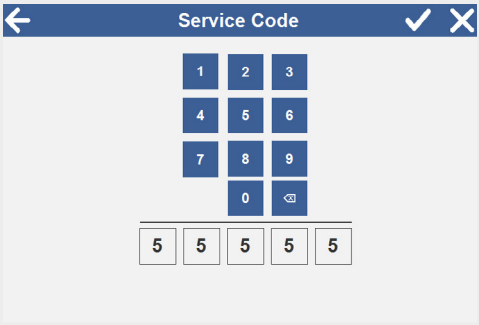
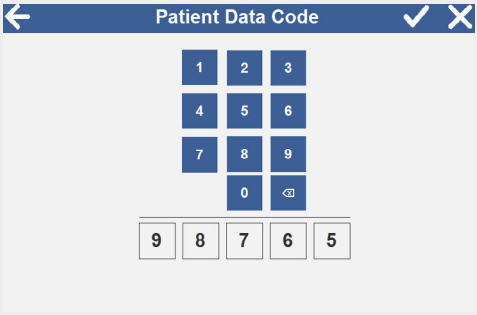
Lock Codes Sub Menu

Secure Settings Code



Unlock Code



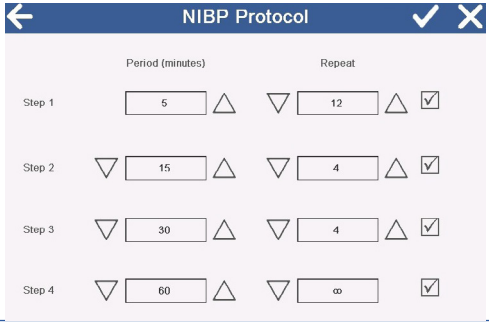
Service Code	
Patient Data Code	
Settings Management Save Local Settings = Fix all current settings as defaults. Apply Defaults = Overwrite all current settings with the stored defaults. Imports and Exports allow transfer to and from Team3 via USB Flash Drive.*	

Note

- **Do NOT transfer settings files from one monitor to another if the software versions are not the same.**
- **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 16.6.**

NIBP Protocol

Allows NiBP protocol details to be customised.



15.6 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 16.5 for details on how to change the Language and to access the Settings Management feature.

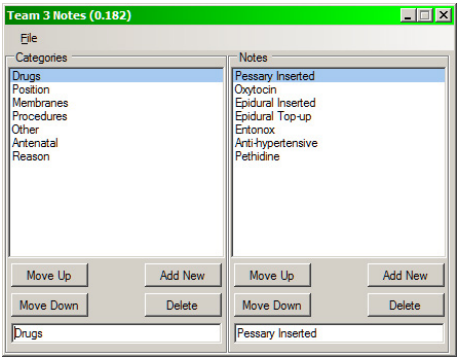
Exporting Easinotes

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.

16. Specifications

16.1 Equipment Classification

Protection against electric shock.	Class 1
Applied Parts	Type CF - Ultrasound Probes /TOCO/ FECG/MECG  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

16.2 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

16.3 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

16.4 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 : 2007 (Thermal Indices (TI) and Mechanical Index (MI) are <1.0 for all device settings)

FECG

Range	30 to 240 bpm
Accuracy	± 1 bpm over the range 100-180 bpm ± 2 bpm outside range
Alarms	As Ultrasound Leads off alarm
Input impedance	10M Ohm
Input range	30µV to 500µV peak to peak
DC offset	±2V common mode ±300mV differential
Common mode range	±20V @ mains frequency
Noise	<10µV peak-to-peak referred to input
Safety	Type CF protection

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

Uterine activity (internal IUP)

Transducers	Intran Plus 400 / Koala® IPC5000C Or as detailed in the current Team3 Accessories and Consumables Brochure
Pressure range	0-100 mmHg/0-13.3 kPa (user selectable)
Sensitivity	5µV/V/mmHg
Accuracy	±5%
Safety	Type CF protection

MECG

Range	30-240 bpm
Accuracy	±1 bpm
Alarms - High and Low Rate Signal Loss	High: 60-160 bpm Low: 30-90 bpm Leads off alarm
Input Range	500µV to 5mV peak to peak
Safety	Type CF protection
Maximum update rate for displayed heartrate	80-120 bpm: 2 secs 80-40 bpm: 4 secs
Heartrate calculation	Calculated from the mean of a maximum of 4 beat intervals. The display update rate is 4Hz.
Standards	MECG is not provided as a diagnostic ECG function and is therefore not designed to meet all of the requirements of IEC 60601-2-27. Monitoring MECG allows a check to be made that the fetal heart rate being recorded does in fact belong to the fetus and not the mother

Maternal oximetry

Module	**BCI (Round / Rectangular Socket)**	**NELLCOR (Rectangular Socket)**
Sensor types	**BCI (Smiths Industries) 3444 / NELLCOR DS100A Finger Sensor** Or as detailed in the current Team3 Accessories and Consumables Brochure	**NELLCOR DS100A** Or as detailed in the current Team3 Accessories and Consumables Brochure
Saturation range	0-99% MSpO2	1-100% MSpO2
Saturation accuracy	±1SD of normal distribution, within ranges: 70-100% +/-4% measurement capability 70-99% +/- 2 digits displayed 0–69% unspecified	±1SD of normal distribution, within ranges: 70-100% +/- 2 digits displayed 0–69% unspecified
Pulse rate range	30-240 bpm	20-250 bpm
Pulse rate accuracy	±2 bpm or ±2%, whichever is greater	+/- 3 digits
Record/display	On-screen display and printed record of: Maternal % SpO2 Heart rate	
Safety	Type BF protection	
Alarms	Low saturation: 85-99% MSpO2 Signal loss	
Standards	ISO9919 : 2005	

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: 2013		

16.5 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)

16.6 Connections *

Front Panel

FHR1	1.0MHz ultrasound transducer / fetal ECG lead
FHR2	1.0MHz ultrasound transducer / fetal ECG lead
FHR3	1.0MHz ultrasound transducer / fetal ECG lead
TOCO	Toco transducer/IUP lead **

Side Panel

MSpO$_2$	Maternal pulse oximetry
NIBP	Maternal non-invasive blood pressure
MECG	Maternal Electrocardiograph using ECG electrodes

Rear Panel

IEC-320 C14 chassis plug	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
DVI Socket	External display
USB Ports	External Keyboard, Barcode Reader, Touchscreen, Upgrader Memory Stick
Ethernet Port	Future CRS

Interfaces

Telemetry	Sonicaid Wireless Telemetry
System	Sonicaid Centrale Sonicaid Fetalcare

** Depending on model*
*** Intrapartum Model only*

16.7 Display

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

Data display

ULT1, ULT2	Fetal heart rate (30–240 bpm) Pulse rate and confidence indicator
FECG	Fetal heart rate (30–240 bpm) Pulse rate
MECG	Maternal heart rate (30–240 bpm) Pulse rate
TOCO	0–100 (relative units)
IUP	0–100mmHg or 0–13.3 kPa
MSpO$_2$	Oxygen saturation Pulse rate
NIBP	Systolic and diastolic pressures Pulse rate MAP

16.8 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 - a licence key can be purchased to activate this
TREND	OFF - a licence key can be purchased to activate this

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

View

Start Screen	Numeric
Background colour	Black

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

Uterine Activity

Toco Zero Level	10%
Toco Auto Zero	ON
IUP Units	mmHg

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-GB

16.9 General Standards

IEC60601-1: 2005 + A1:2012	**ISO15223-1:2012**
ANSI/AAMI ES60601-1:2005	**IEC60601-2-49:2011**
CAN/CSA C22.2 No 601.1-M90 (R2005)	**IEC62304**
JIS T 0601-1:2012	
IEC60601-1-2: 2007	

17. Accessories

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

Please refer to the Accessories and Consumables catalogue included with the monitor for further details of products available for use with the Team3. The latest issue of this catalogue is available on request from local Huntleigh representatives. Available accessories, consumables and spares include:

Accessories

Item	Part No
Team3 PAPER TRAY – Phillips	ACC-OBS-077
Team3 PAPER TRAY – Corometrics (GE)	ACC-OBS-078
Team3 PAPER TRAY – Huntleigh	ACC-OBS-079
Trolley	ACC-OBS-072
Wall mounting Bracket	ACC-OBS-076
FECG Connecting Leads *	-
MECG Connecting Lead	ACC-OBS-070
IUP Catheter Connecting Lead *	-
NIBP Cuff (Various Sizes) *	-
Patient Event Marker	SP 7775-6901
Ultrasound, TOCO and MSpO2 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-8400-8003
Transducer Belts *	-
Fetal ECG Electrodes and Leg Plates *	-
Maternal ECG Electrodes (box 300)	ACC-OBS-027
Disposable IUP Catheter Transducer *	-

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

18. Warranty and 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 ‘

For further details, refer to NHS document HSG(93)26 (UK only).

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

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

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

Appendix 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.**
- **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**
- **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**
			Portable and mobile RF communications equipment should be used no closer to any part of the Team3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz outside ISM bands[a] 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands	3V	$d = 1.2\sqrt{P}$ 150 KHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of the equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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

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

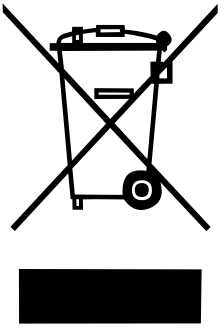
[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters,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

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

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Team3 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 % U_r (>95 % dip in U_r) for 0,5 cycles 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 s	<5 % U_r (>95 % dip in U_r) for 0,5 cycles 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 s	Mains power quality should be that of a typical commercial of hospital environment. If the user of the 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 U_r is the a.c. mains voltage prior to the application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the Team3			
The Team3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. the customer or user of the Team3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Team3 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 2 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 3 Manufacturer's Essential Performance Criteria Specification

Below are comprehensive Essential Performance definition tables for inclusion in the Team 3 fetal monitor IFU. 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
IEC 60601-2-37	Ultrasound
IEC 60601-2-30	NIBP
IEC 80601-2-61	SPO2
IEC 60601-2-27*	MECG
IEC 60601-2-49	Multi-parameter

** 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 4 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 (2004).

Appendix 5 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

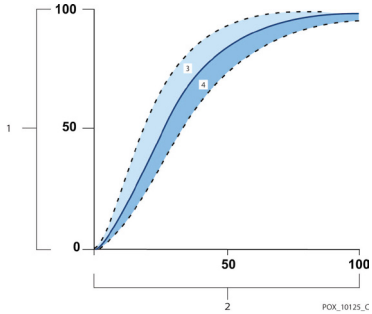
This monitoring system measures functional saturation where oxygenated hemoglobin is expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as 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
ϕ fractional saturation
η %carboxyhemoglobin
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	Caucasion	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

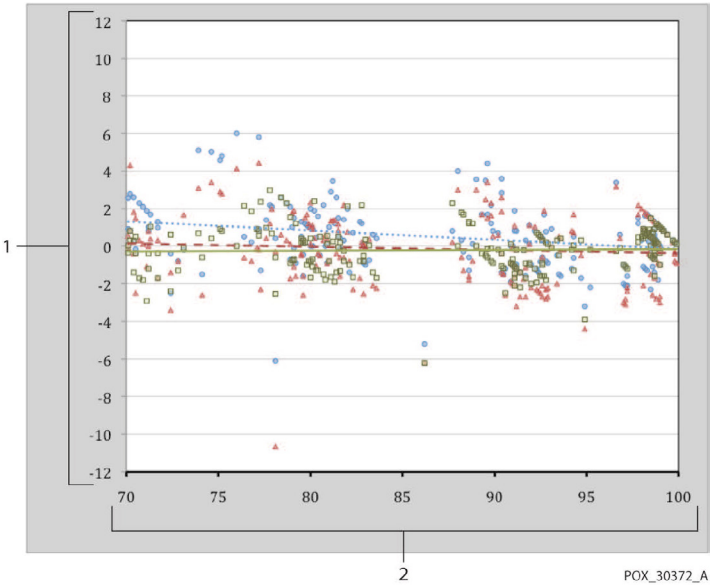
Table A-1. Demographic Data

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.

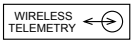
Appendix 6 Sonicaid Wireless Telemetry

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

Connecting the Sonicaid Freedom telemetry unit

1. If Sonicaid Freedom is mounted on the Team3 trolley, the aerial must be mounted on Team3 using the SF1 Freedom Antenna Fixing Kit. Full instructions are provided with the kit. Contact your local sales representative for details.

   If it is not mounted on the Team3 trolley, ensure the Sonicaid Freedom is securely located on a suitable flat surface and connect the aerial directly to the Sonicaid Freedom rear panel socket, ensuring it is kept vertical during use.
2. Connect the power cable from a suitable wall socket to the mains connector on the rear panel.
3. Plug the end of the data cable labelled Freedom into the 15-way ‘D’ socket on the rear panel.
4. Plug the other end of the cable labelled CTG into the 15-way ‘D’ socket on the rear panel of the Team3.

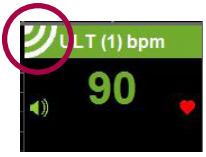
   

5. Before operating, ensure the transducers are plugged in and fully charged (takes 3 to 4 hours).

Using the telemetry unit

1. Switch on the telemetry unit.
2. Check that the transmitter is fully charged.
3. Examine the mother, and establish the best position for the transducers.
4. Attach the transducers securely to the mother.

Note
When the wireless transducers are undocked from the receiving station, a symbol will be shown on the ULT1/TOCO channel to indicate wireless monitoring.



To disable wireless operation and return to wired transducer monitoring, dock the wireless transducer back into the receiver charging bays.

You will need to view the Version screen (See 16.5 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.

To prevent equipment damage and possible personal injury, do not position the receiver on top of the Team3. A trolley mounting bracket is available to mount the telemetry unit on the Team3 trolley.

Appendix 7
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.

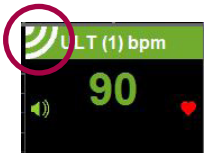
   

5. Before operating, ensure the wireless transducers are docked into the docking slot and fully charged.

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 and TOCO-E transducer can be applied to the belly directly without coupling gel.**
- **The TOCO-E transducer monitors DECG or MHR only when it is connected with the DECG or MECG cable. If the TOCO-E transducer is not connected with the DECG or MECG cable, it only monitors TOCO. Besides, the DECG cable and the MECG cable cannot be connected to the TOCO-E transducer at the same time.**
- **When using the TOCO-E transducer to monitor DECG or MHR, it is recommended that the DECG cable or the MECG cable be kept straight to avoid damage to the TOCO-E transducer's interface caused by twisted cable.**
- **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.

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

UK Symbol:

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

UK Responsible Person & UK Importer:

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

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

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

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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.

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