INSTRUCTIONS FOR USE

Team3 USA

Fetal Monitor

777732-4 10/2024

HUNTLEIGH

A MEMBER OF THE ARJO FAMILY

Table of Contents

1. Safety

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

Symbols

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

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

1.1 Warnings

- **Do not use in the presence of flammable gases or in oxygen rich environments.**
- **Do not sterilize the product or its accessories. The product will be damaged, and there is a risk of patient and user harm.**
- **Keep dry, do not immerse Team3 in liquid. Ultrasound and Toco transducers are IPX7 rated. Team3 with wired transducers is not intended for use in water birth situations.**
- **Always fit Protective cover to protect against fluid ingress when moving Team3 by hand or on a trolley.**
- **Do not use in the sterile field unless additional barrier precautions are taken.**
- **Use only recommended accessories listed in this manual.**
- **Do not dispose of batteries in fire as this can cause them to explode.**
- **The optional Lithium battery pack is a service replaceable item. Replacement by inadequately trained personnel could result in a hazard.**
- **Do not use with defibrillators. Ensure that all Team3 leads and applied parts are removed from the patient before applying Defibrillation.**
- **Team3 series monitors are not intended for use with patients fitted with cardiac pacemakers.**
- **Do not use with electrosurgical devices.**
- **Team3 can be isolated from the AC mains supply by removing the IEC mains inlet connector. Ensure that this is fully accessible at all times.**
- **Team3 is a Class 1 product that relies for safety on its protective earth. Ensure it is connected to a suitably earthed AC mains supply.**
- **Do not use in the home environment.**
- **Do not use the Team3 in vehicles or in aircraft.**
- **If this product is connected to another item of electrical equipment, ensure that the system is fully compliant with IEC60601-1:2005.**
- **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.**
- **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.**

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 IEC60601-1:2012, the patient applied parts of the Team3 Fetal Monitor are the:

- TOCO Transducer
- Ultrasound Transducer
- Patient Event Marker
- NIBP Cuff

2. Introduction

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

The following features are standard on all models:

- Dual channel ultrasound fetal heart rate detection with audio.
- External monitoring of maternal contractions
- Maternally sensed fetal movements
- Automatic detection of fetal movement
- Color 8.4” touchscreen display
- Connections to Sonicaid Reporter software via serial port
- USB - for trace storage, upgrading and configuration

The following options are available for all models:

- Integral rechargeable battery
- Maternal Non-Invasive Blood Pressure

Note
This IFU relates to software; v20.

2.1 Intended Use and Indications

The Sonicaid Team3 Antepartum fetal monitor (Team3 fetal monitor) is indicated for use by trained healthcare professionals in non-invasive monitoring of physiological parameters in pregnant women and fetuses, during the antepartum period of pregnancy. The Team3 fetal monitor is intended for pregnant women from the 26th week of gestation, through to term. The devices are intended for use in clinical and hospital-type facilities.

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

- Single or twin fetal heart rates by means of ultrasound
- Uterine activity - externally sensed
- Fetal movement - maternally sensed and externally via ultrasound.
- Maternal pulse rate
- Maternal non-invasive blood pressure.

2.2 Contraindications

This device is contraindicated for patients fitted with pacemakers.

2.3 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.

2.3.1 Contents

Standard - All models

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

Blood Pressure Option

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

Note
All Team3 models are twins capable as standard but are supplied with 1x US transducer. For twins, an extra US transducer is required to be ordered seperately.

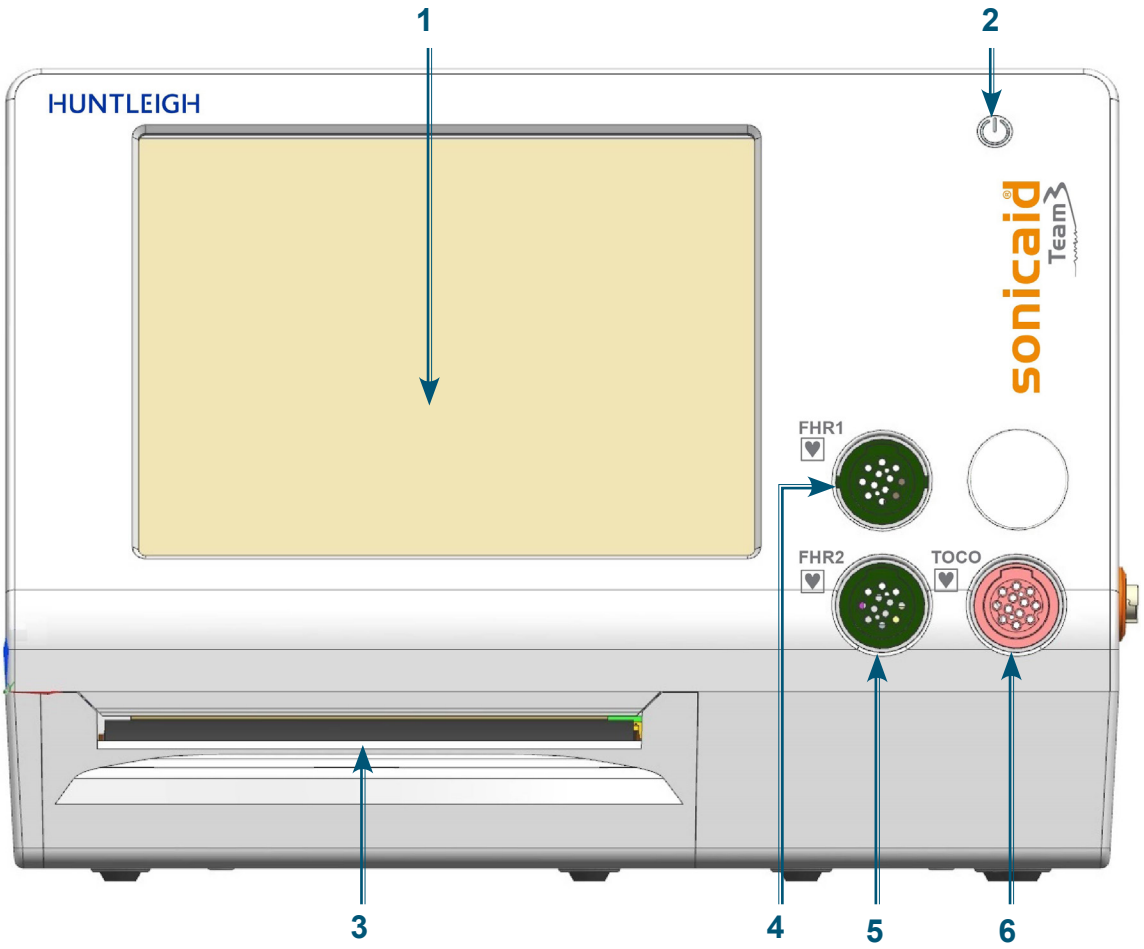
2.4 Operator Positioning

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.

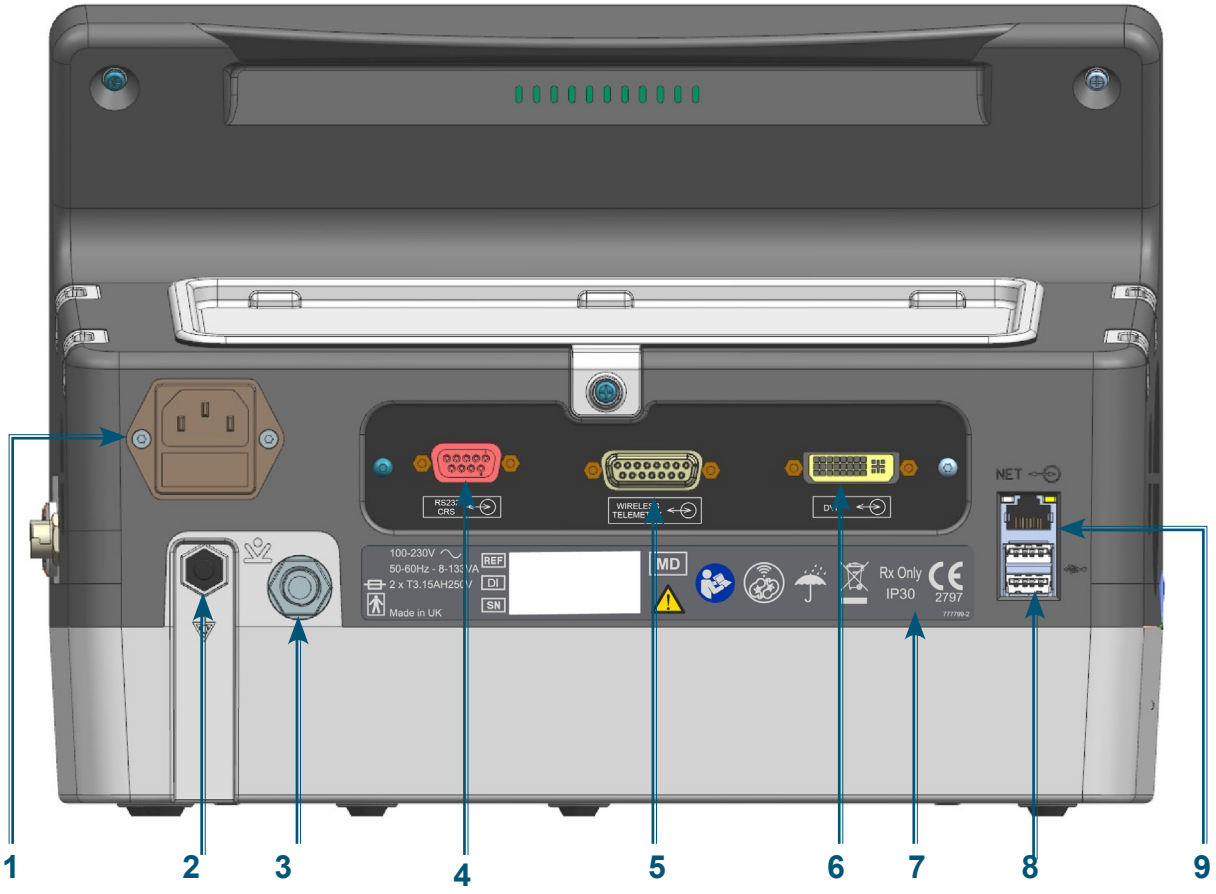
3.1 Front Panel



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

** Depending on model/options purchased.*

3.2 Rear Panel

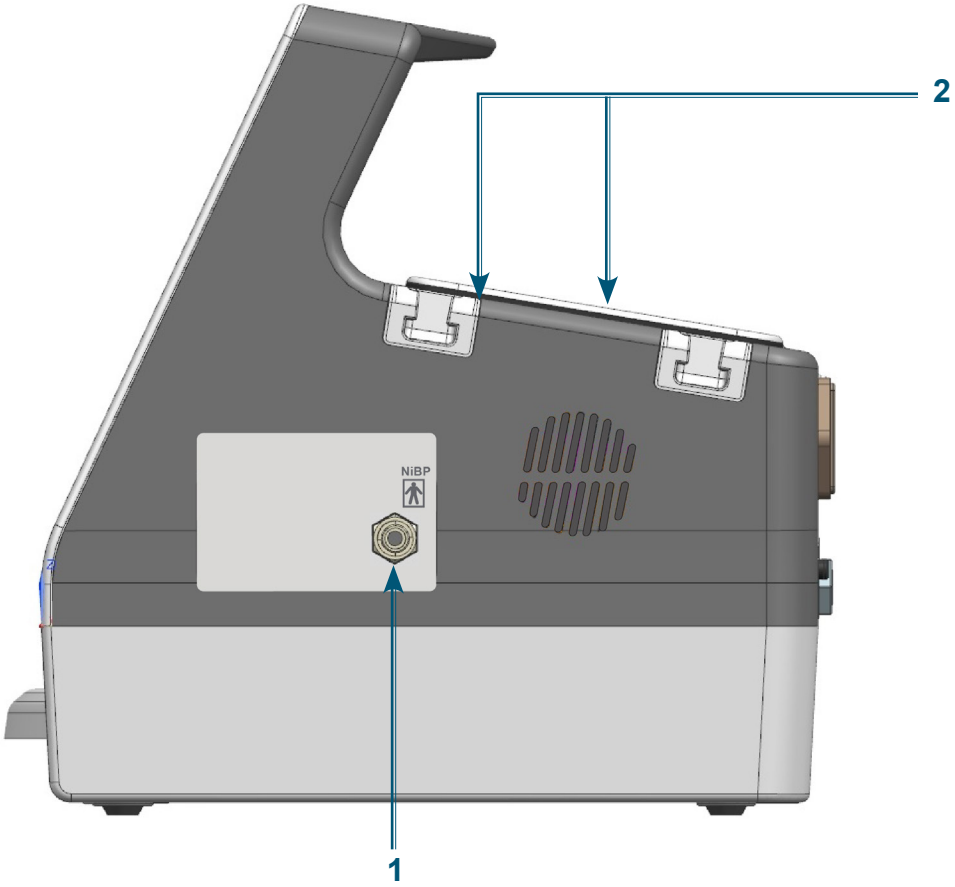


1	Mains Socket	6	DVI Socket *
2	Equipotential earth point	7	Rating Label
3	Fetal Event Marker Socket	8	USB Port x 2
4	RS232/CRS Socket	9	Ethernet Port **
5	Wireless Telemetry Socket		

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

3.3 Base Panel Label

3.4 Side Panel



1	Maternal NIBP *	2	Transducer storage

** Depending on model/options purchased.*

3.5 Product Labelling

Note: Product labelling should be read from a distance no greater than 0.5m.			
	Applied parts (Ultrasound Probes / TOCO) are type CF*		Applied parts (Maternal NIBP/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.		
 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)		
Manufactured By:	**Huntleigh Healthcare Ltd.** 35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk www.huntleigh-diagnostics.com		

	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden		
	Warning		Attention, consult accompanying documents / Instructions for Use
~	Alternating current (AC)		On/Standby
DI	Device Identifier	MD	Medical Device
SN	Serial Number	REF	Reference Number
	Protective Earth		Date of Manufacture
	Keep Dry		Do not use hook
	Fragile		Cardboard packaging can be recycled.
40°C -10°C	Temperature Limitations	93%	Limits of Relative Humidity
PVC	Does not contain PVC	LATEX	Not made with natural rubber latex.
YYYY-MM	Use By		Do Not Reuse
	Fetal Event Marker		Equipotential Earth
	Limits of Atmospheric Pressure	IP30	Protected against ingress of solid foreign objects >2.5mm diameter. Not protected against ingress of water.
	USB Port	NET	Ethernet Port
	RoHS Compliant (RoHS - Restriction of Hazardous Substances)	4	Max stack x 4 identical boxes
	This side up		Wireless Telemetry Ready

** 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 point at the installation. At no point should a patient be connected directly to Earth. All external earth connections should be visually inspected to ensure that all cables and connections are of good condition. Earth bonding checks should be carried out with a suitable portable appliance tester. The Impedance between the protective earth and Equipotential earth at the installation shall not exceed 0.1Ω

4.2 Probe/Sensor/Cuff Connection

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

Do not remove any cables by pulling on the lead.

4.3 Loading Paper

Refer to Section 9.6 - Loading Printer Paper

4.4 Handling and Mounting

Cart

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

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

Wall bracket

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

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

5. Operation

5.1 Switching the Unit ON

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

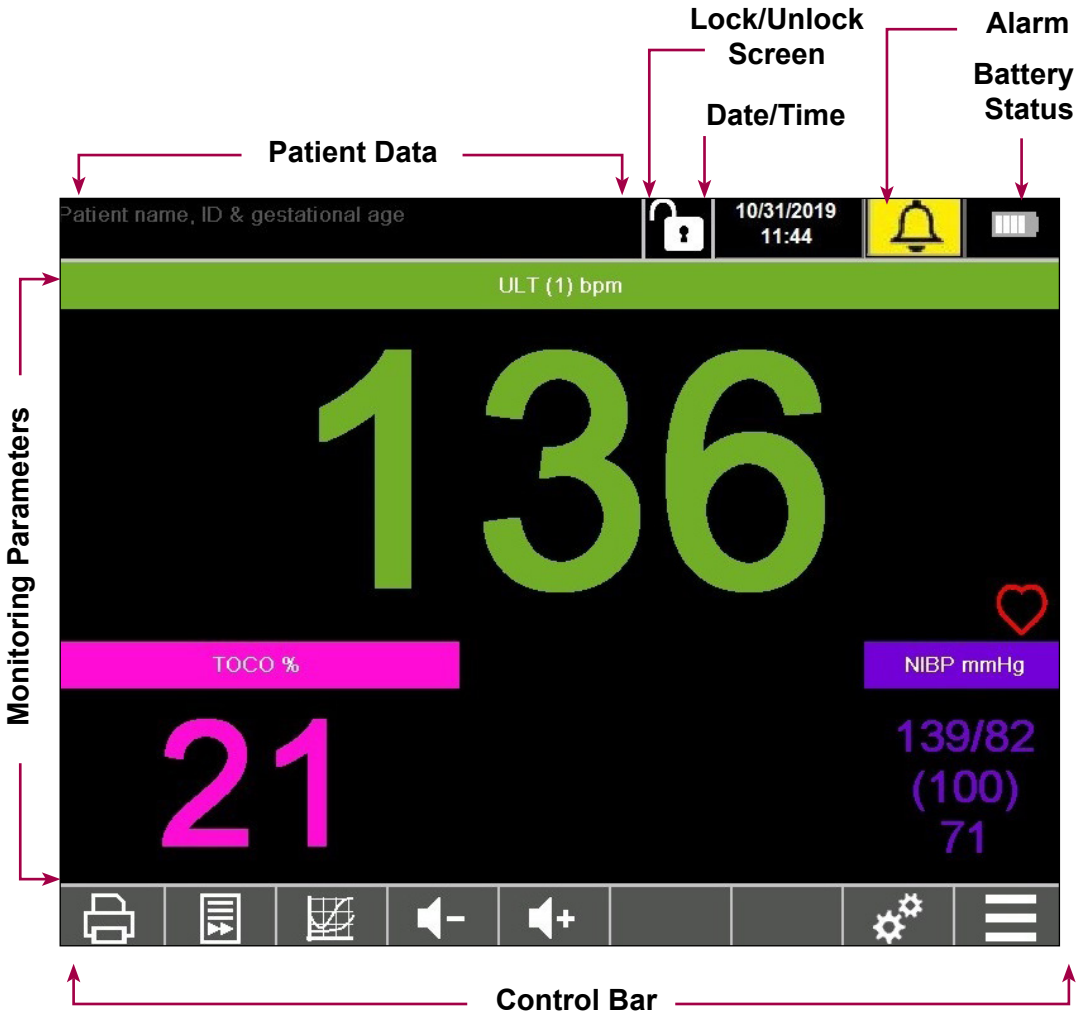
If the unit is in off/standby mode with power already applied, press and hold ⏻ for approximately 2 seconds to switch on. A short tone will be heard.

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

5.2 Application Screen

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

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



5.2.1 Patient database

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

To archive or export the patient database we recommend:

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

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

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.

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

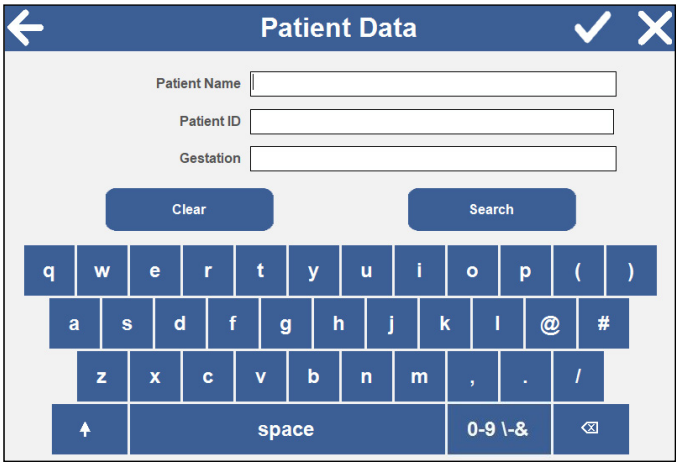
5.2.2 Entering Patient Data

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

Note
If you cannot access the Patient Data screen, this function may be disabled - refer to section 13.5 for details.

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

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



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

Touch Clear to remove any details from the form.

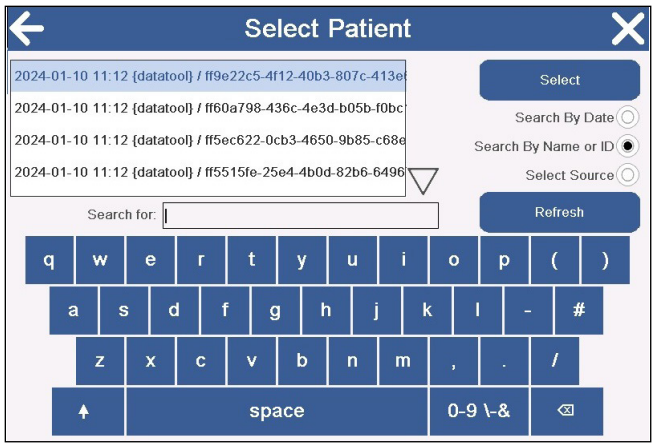
Touch Search to view the Search screen which allows the operator to select the Patient Data of a mother who has been previously monitored.

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

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

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

Searching for Patient Names



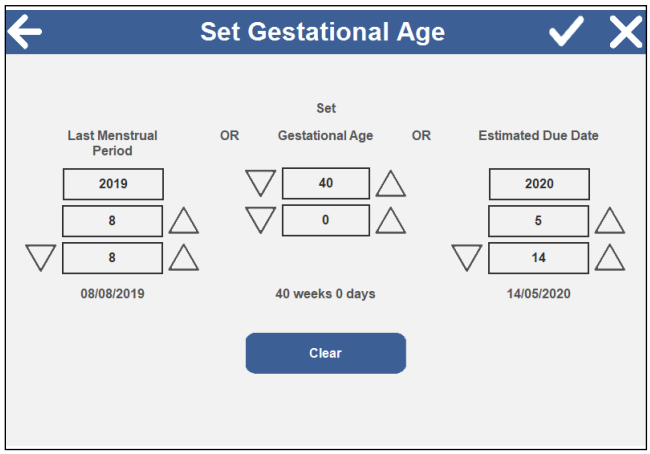
The operator can search for a patient either by date, Patient Name / ID or from an external USB device.

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

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

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

Setting Gestational Age



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

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

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

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

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

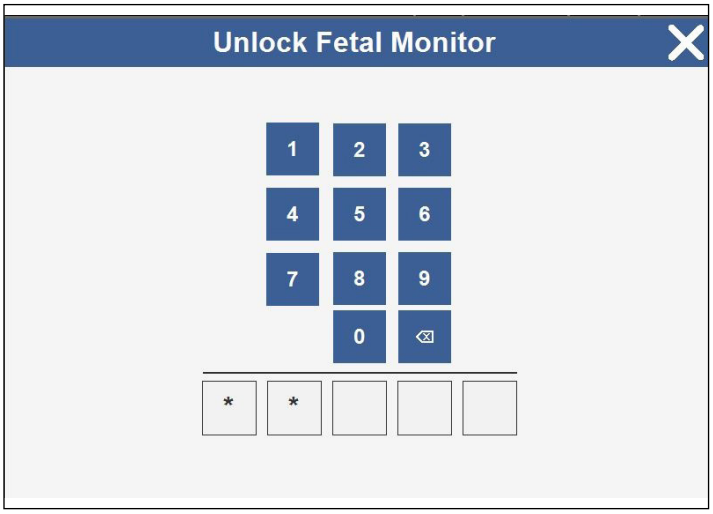
Touch Clear to reset the GA values to zero.

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

5.2.3 Lock / Unlock Screen

Touch to access the Lock Screen.

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

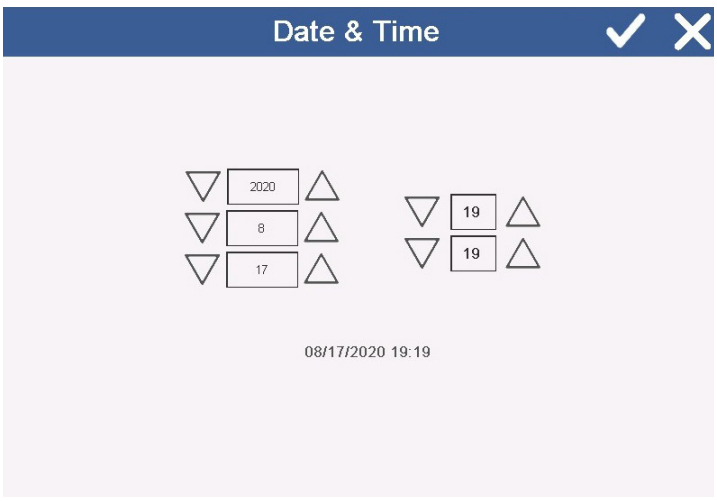


Touch to unlock the screen.

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

5.2.4 Date / Time

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

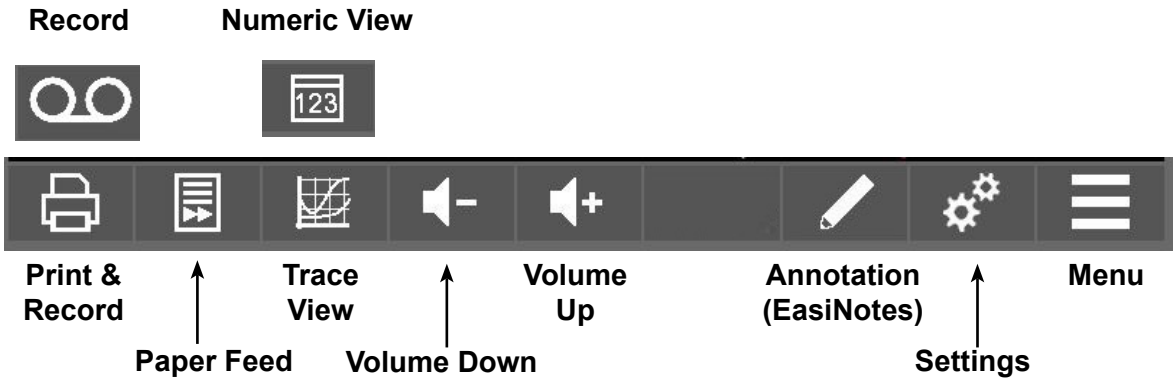


Use the arrows to set the current date and time.

Press to confirm

5.3 Control Bar

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



5.3.1 Record / Print

	Touch to print or record.*
	Indicates printing or recording is active. Touch to cancel printing or recording. All printed data is also recorded. The recorded data can be reviewed when required.
	Annotation Icon appears in the control bar when printing or recording is active. (See Annotation - below).

** If option(s) installed.*

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 Annotation - EasiNotes

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

5.3.6 PDF

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

Annotation Main Menu

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

Note

- **The Easinote sub-system is very flexible allowing up to 12 groups of 12 notes to be configured on Team3.**
- **The "Mark" button allows users to print a blank annotation field on the trace for adding a hand written note.**
- **Refer to Sections 13.5 and 13.6 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.The menu options shown will be model dependent and vary depending on sensors and accessories attached.

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

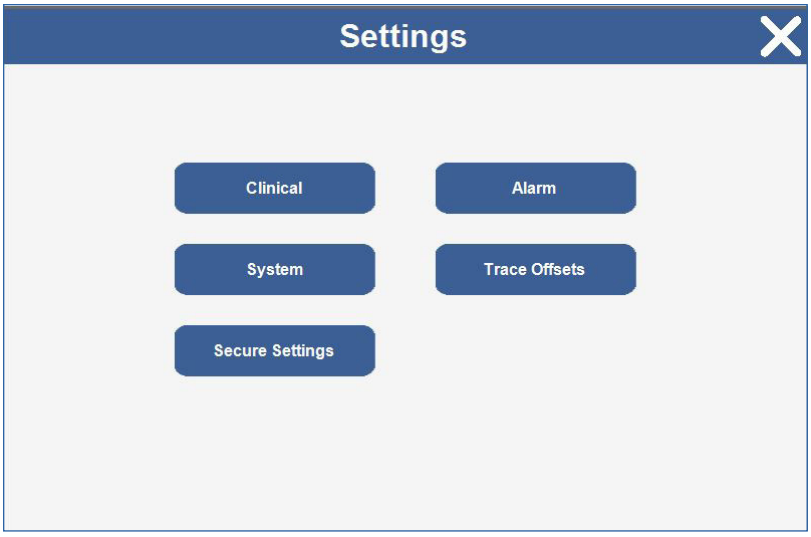
	CRS	
Trace Offsets		
Alarm	FHR	
	TOCO	
	NIBP	
	Alarm Volume	
Secure Settings	Service	Licensing
(passcode 12345)	(passcode 55555)	Manometer
		NIBP Calibration
		Contacts
		Recordings Manager
		Archive Manager
	Set Language	
	Hospital Name	
	Demonstration	
	Version Information	
	Regional Settings	
	Clinical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

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

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

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

Settings Main Menu



Touch each category to access the sub menu options available.

Note

- **The Trace Offsets sub menu is only available if not printing or recording.**
- **The Trace Offsets sub menu is only visible when ultrasound transducers are plugged into the FHR1 and FHR2 sockets on the front of the unit.**
- **Team3 will return all settings to Default levels when switched off. Default settings can be customised - refer to Section 13.5.**
- **If the mains supply is interrupted for more than 30 seconds when no backup battery is provided, the Team3 shall revert to Default settings.**

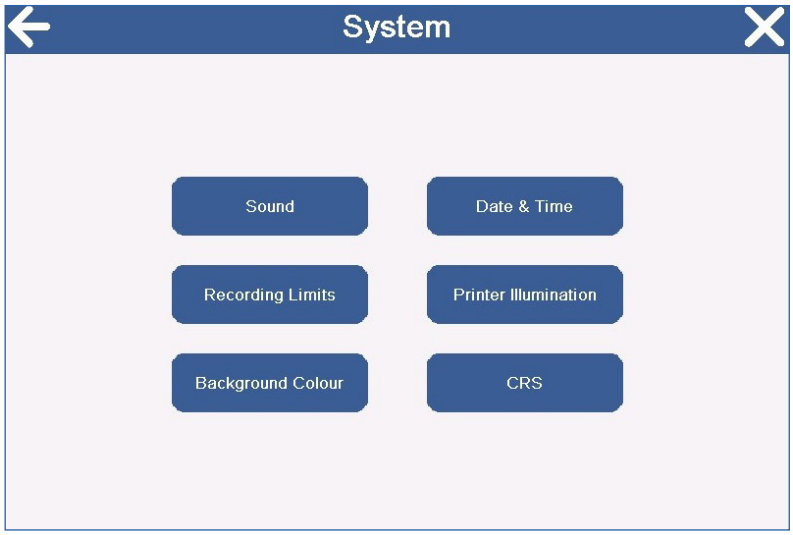
Settings Sub Menus

Clinical Settings Sub Menu

TOCO

System

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

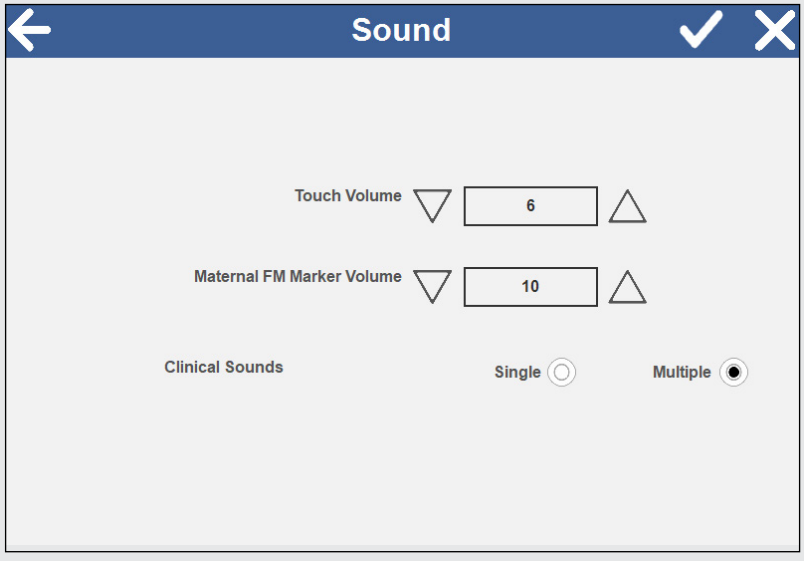


System Settings Sub Menu

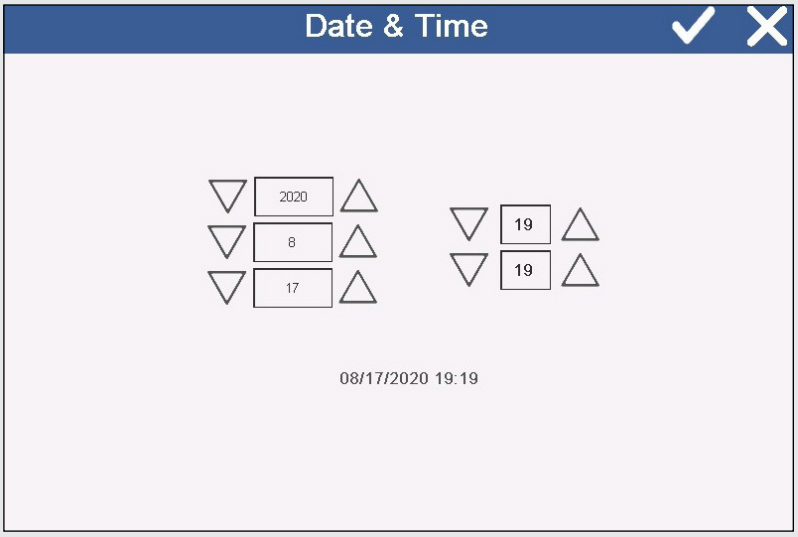
Sound

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.

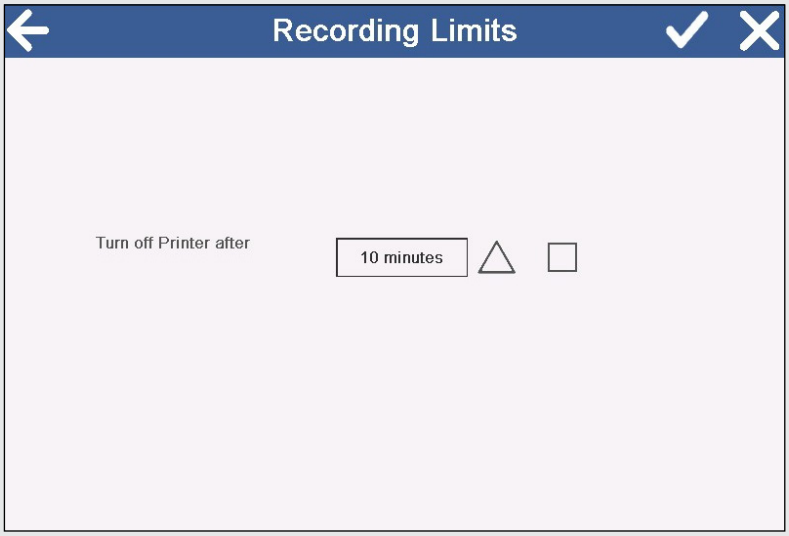


Date & Time

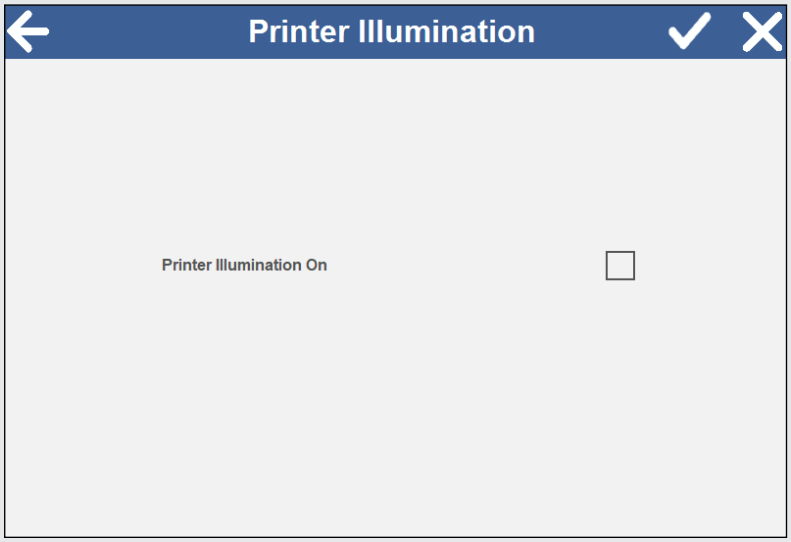


Recording Limits

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

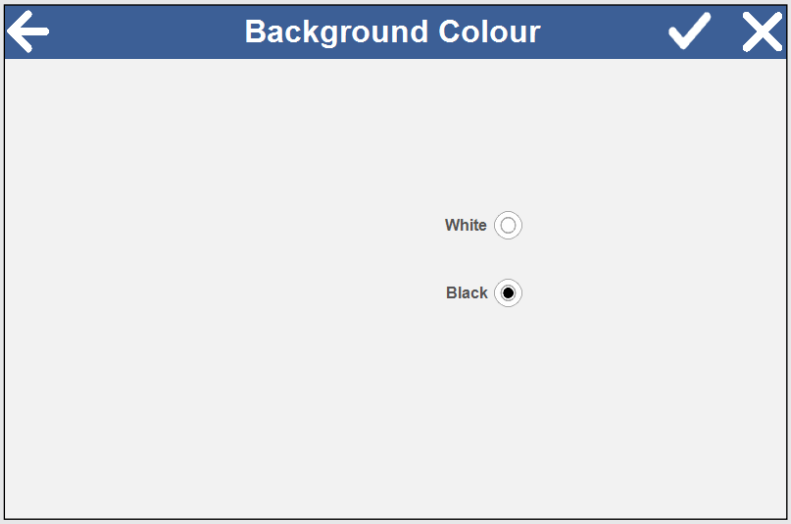


Printer Illumination



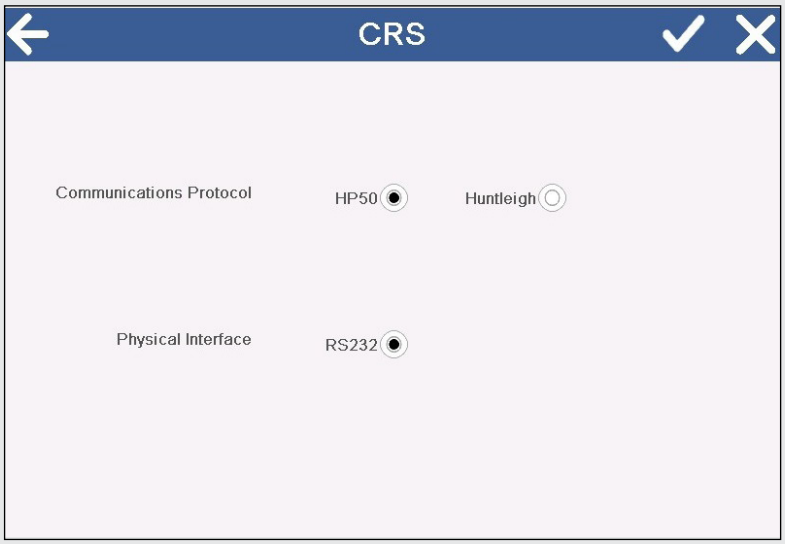
Background Colour

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



CRS

In this screen select HP50 for all third party Clinical Records Systems (CRS), as well as Sonicaid Centrale. Select Huntleigh for use with Sonicaid Reporter.

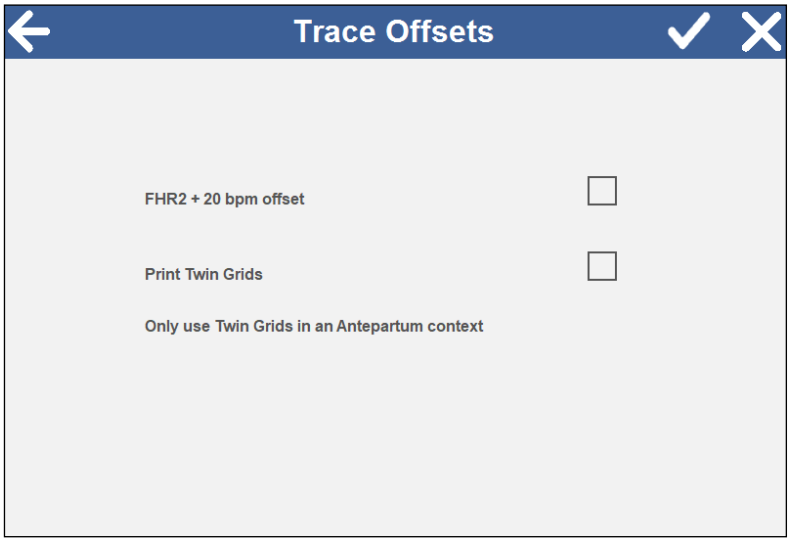


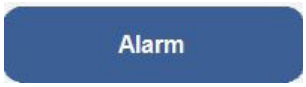
Trace Offsets

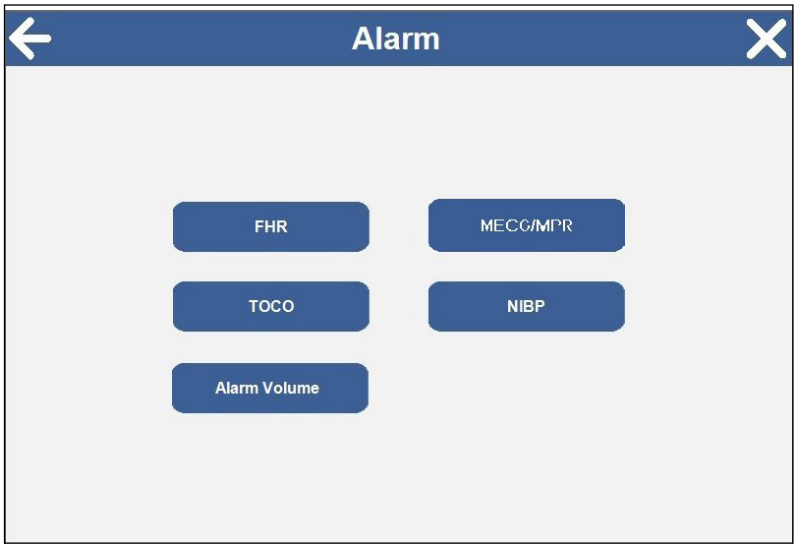
When monitoring twins or triplets, this option offsets each trace by 20 bpm to make viewing clearer.

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

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







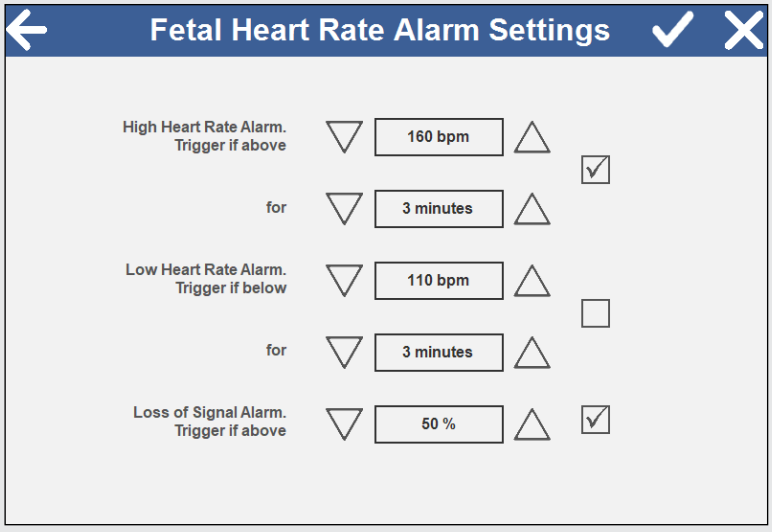
WARNING
Ensure that ALARM LIMITS are set to realistic values. Use of extreme values can render the ALARM SYSTEM useless.

Alarm Settings Sub Menu

Touch each check box to enable / disable each alarm.

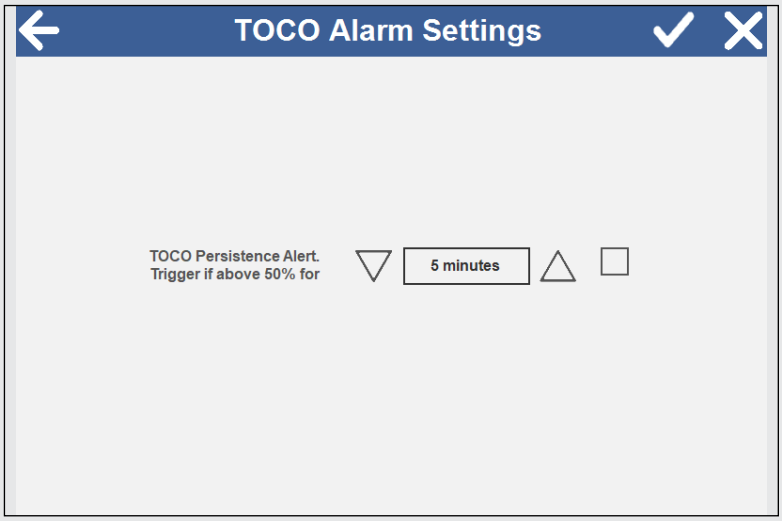
If selected a ✓ will appear in the box.

Touch △ ▽ to set each trigger threshold.



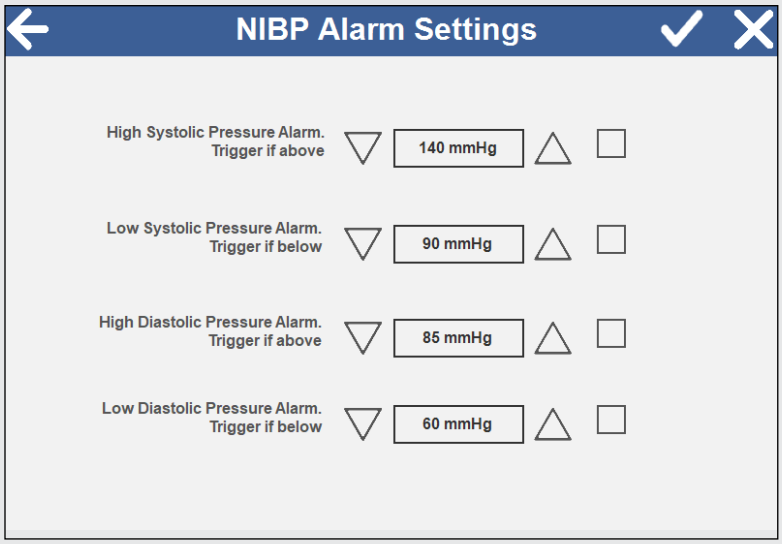
TOCO

TPA - TOCO
Persistence Alert



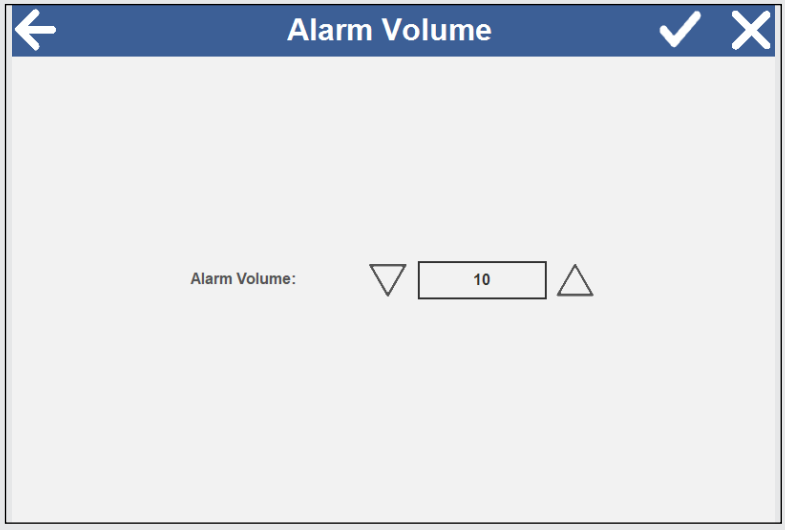
NIBP

Note
Only available if NIBP option fitted.



Alarm Volume

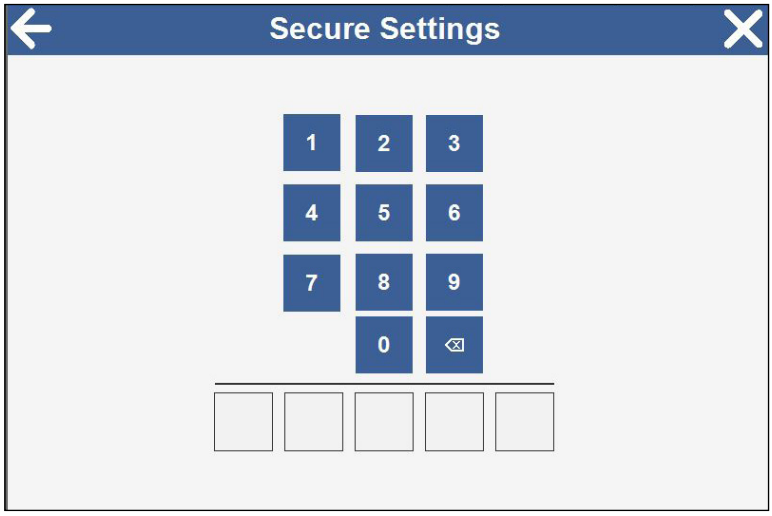
Note
This sets the volume level for alarm sounds. This is independent of the user set volume level for normal audio sounds. Alarm volume cannot be set to zero.



Secure Settings

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

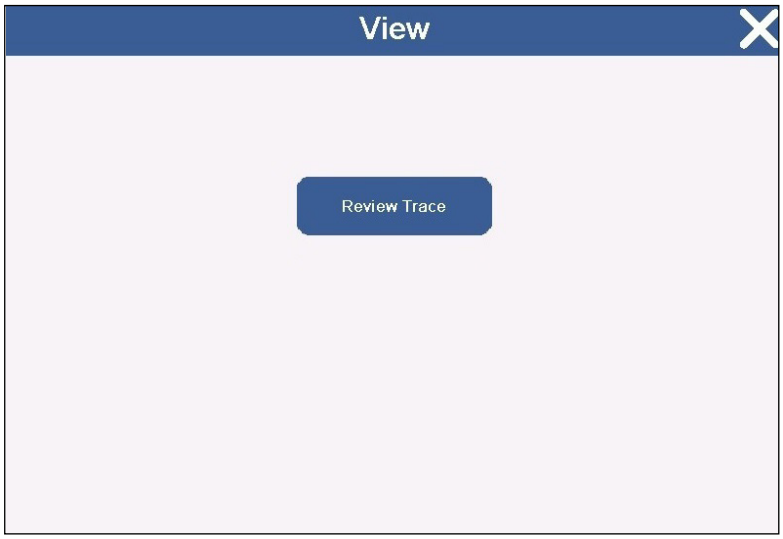
Note
Refer to Section 13.5 and also the Service manual.



5.3.8 View Menu

Touch the icon to access the View Menu settings.

Touch each category to access the sub menu options available.

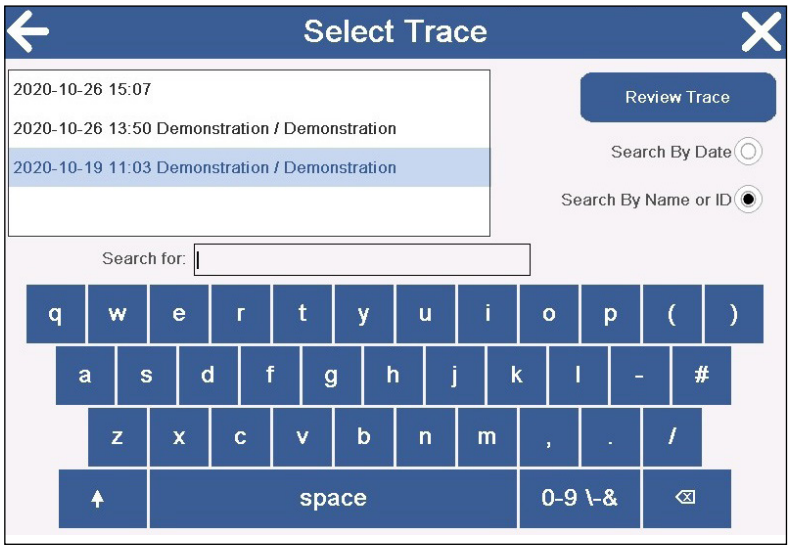


Review Trace

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

A passcode is required in order to view patient records.

The default passcode is 98765.



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

Touch the trace required and touch 

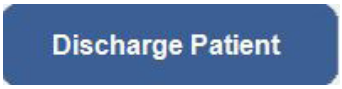
. The selected trace will now be displayed on the application screen.

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.

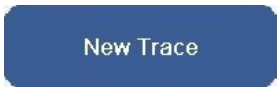
If a printer is fitted, press  to print the trace.

Review Mode Sub Menu

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



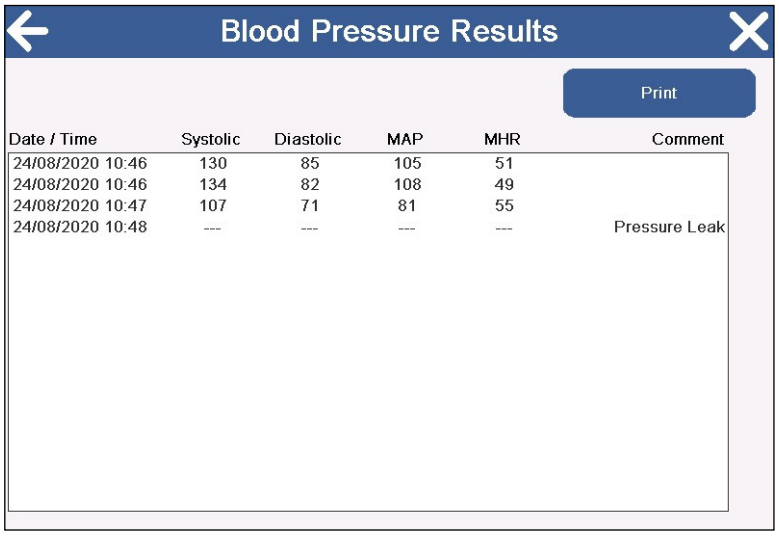
Starts a new monitoring session with a new patient.



Starts a new monitoring session with the selected patient.

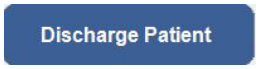
Displays Blood Pressure results screen.

Touch the "Print" button to print out the results.



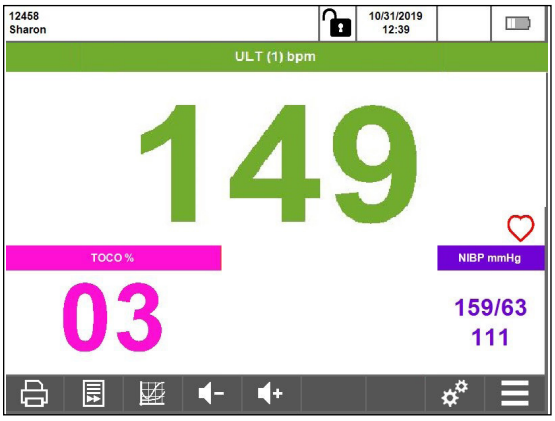
U

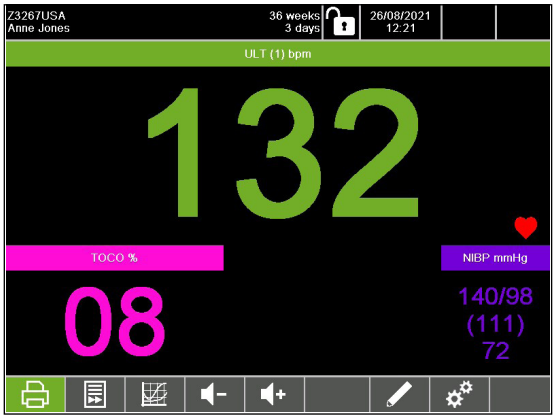
SB to Store Trace (PDF) to USB Drive (8GB max)

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

5.4 Monitoring Parameters

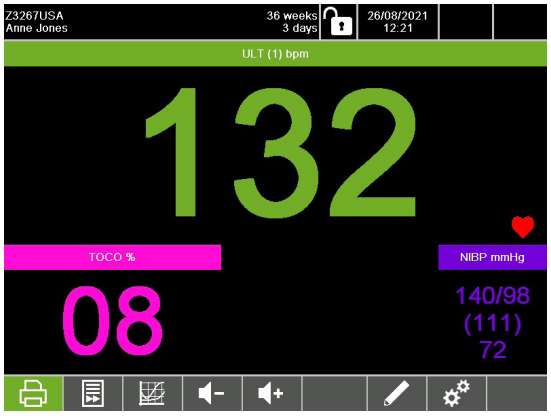
You can configure the screen to display a white or black background. (Refer to 'Settings').



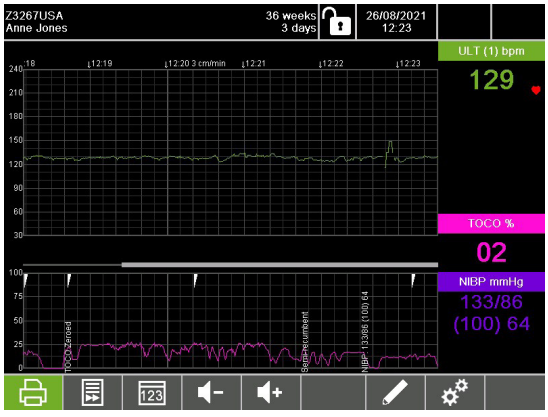


The application screen can be displayed in either Numeric or Trace format.

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



Numeric format

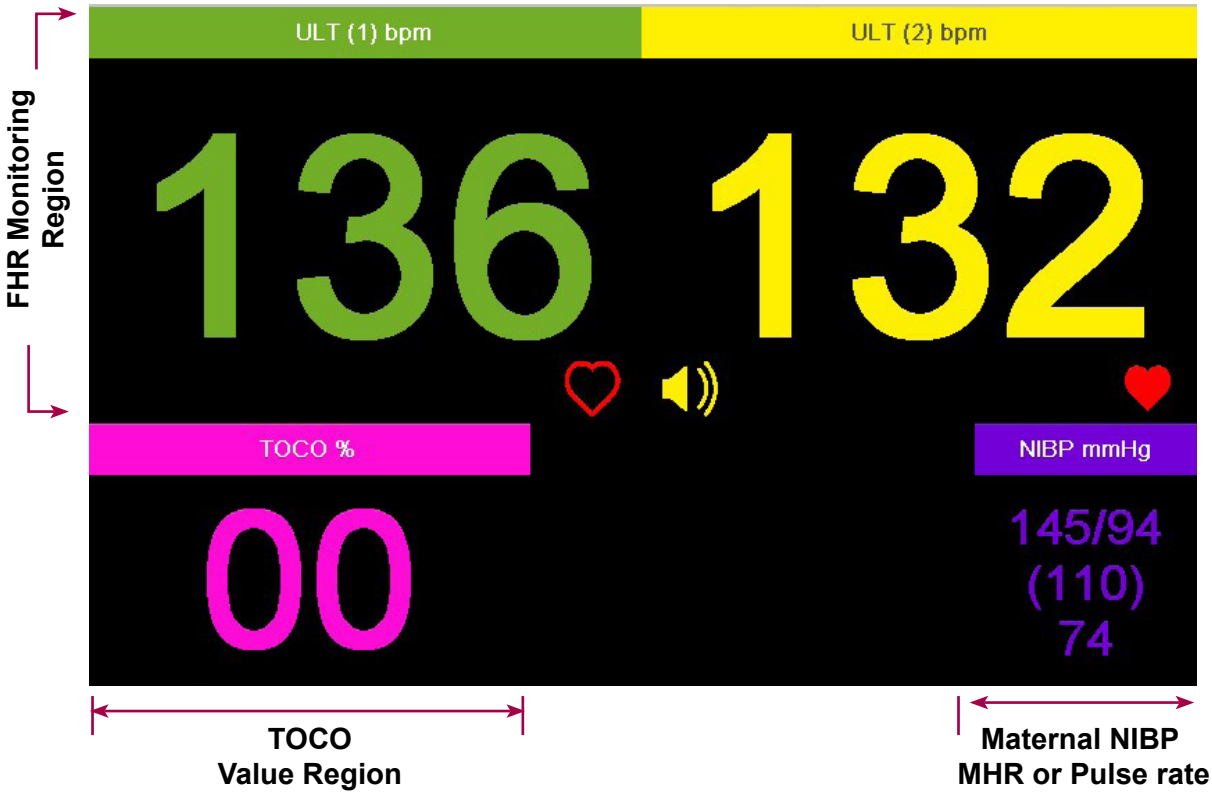


Trace format

5.4.1 Numeric Format

The numeric data screen increases the size of the numeric data and removes the traces. This is useful when operators are not in direct attendance as the numbers can be seen from a distance.

The display is split into regions, its configuration is dependent on whatever sensors/probes are attached.



Audio

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

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

Fetal Heart Rate Signal Confidence

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

 Red - High

 Amber - Moderate

 Yellow - Low

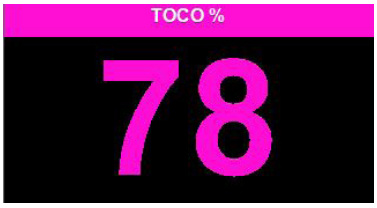
If the heart symbol is displayed in outline only and no FHR is displayed, the Team3 cannot detect the fetal heartbeat.

5.4.2 FHR Monitoring

Singleton Monitoring
In singleton monitoring, the FHR in displayed in large digits in the top centre region. Display shows FHR via wired ultrasound transducer with audio.

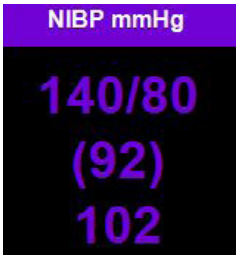
Twins Monitoring
In twins monitoring, the FHR display region is split to display the two separate Fetal Heart rates, both using wired ultrasound. Audio is enabled for channel 1 only.

5.4.3 TOCO



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

5.4.4 Maternal NIBP



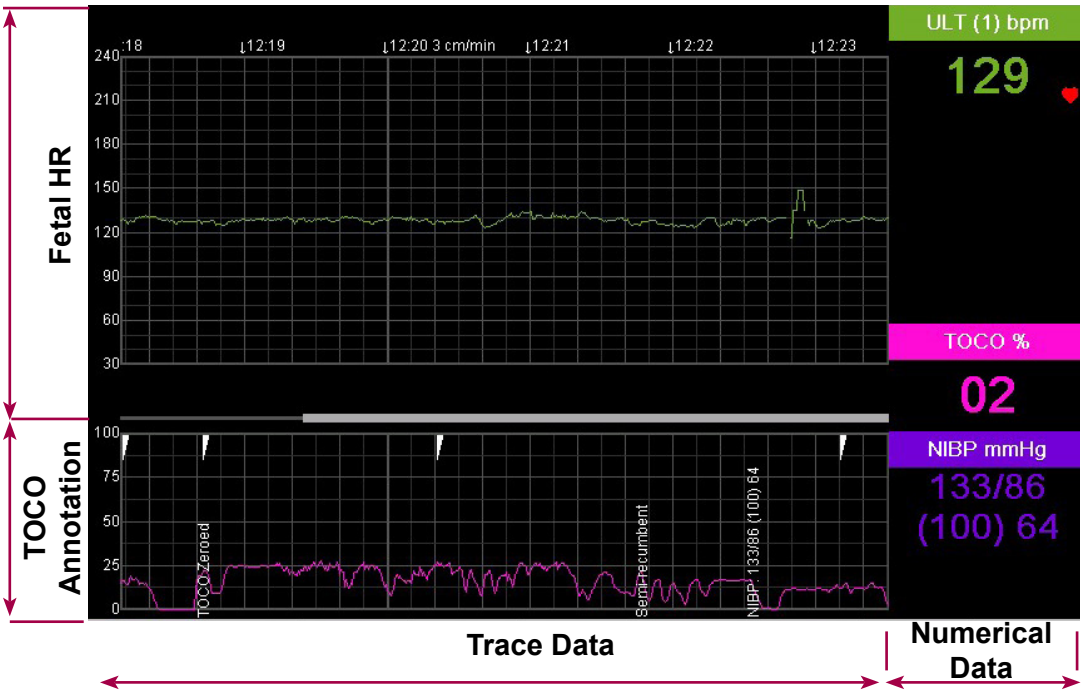
The NIBP region shows a measurement having been made.

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.

5.4.5 Trace Format

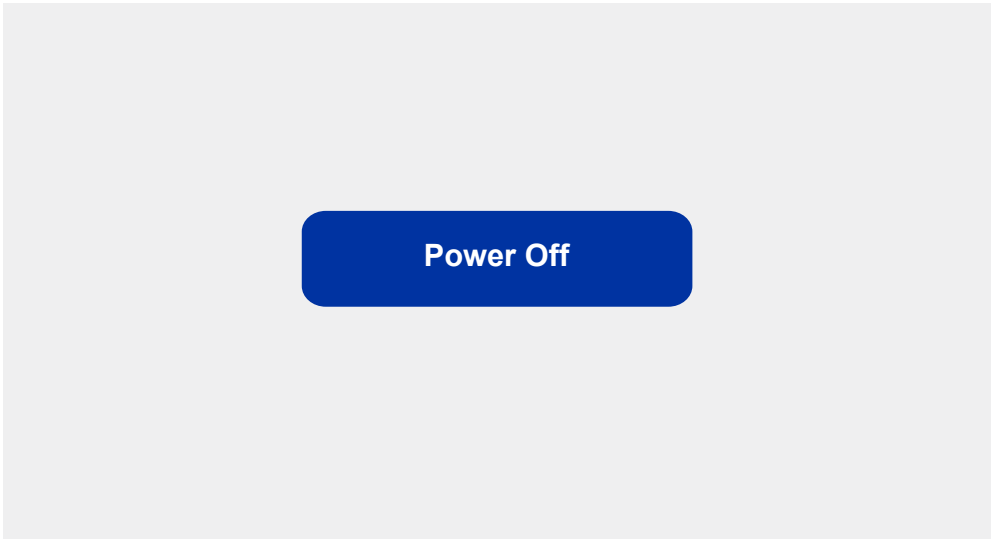
The graphical trace screen emphasizes the display of data in graphical form, with numeric data shown on the right hand side.



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

5.5 Switching the Unit OFF

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



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

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

5.6 Auto Restart

In the unlikely event that Team3 operation is interrupted, the monitor will automatically restart.
Following a restart, all previously configured settings and operating modes will be retained and the monitoring function will resume as normal.

5.7 Battery Charging

5.7.1 The unit is switched OFF

f the following conditions are all true,

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

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

5.7.2 The unit is switched ON

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

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

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

6. Monitoring Fetal Parameters

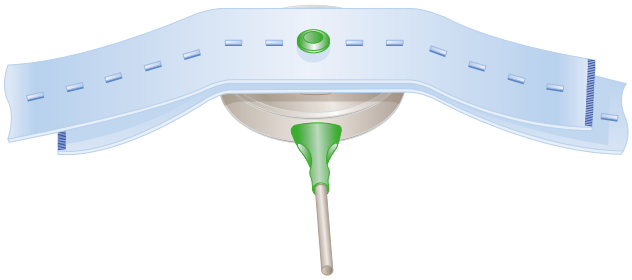
6.1 Preliminary

Ensure that the transducers and transducer belts are clean and ready for use. In particular, check the transducers for cracks or signs of damage. See also cleaning instructions in Section 14.

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.

6.2 Ultrasound Monitoring

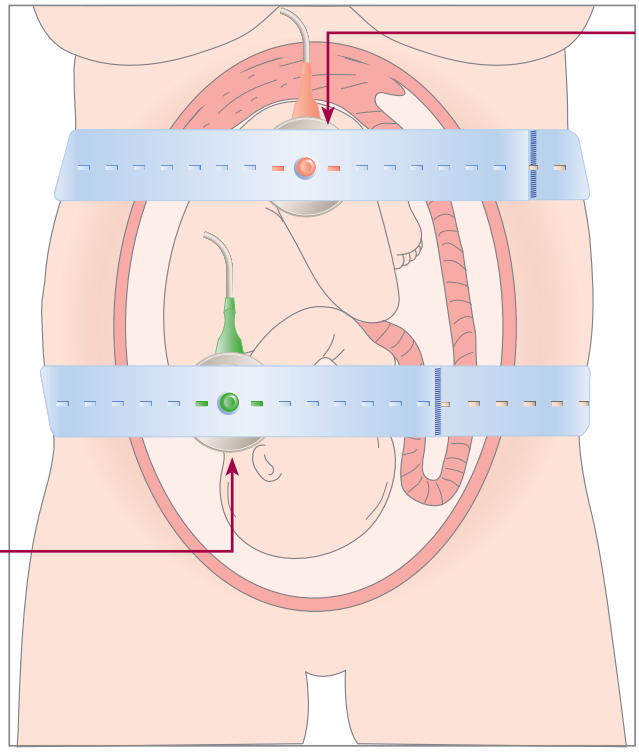
1. Connect the green transducer to the green socket marked FHR1 on Team3. On the main screen, the ULT1 region becomes active.
2. Palpate the abdomen to determine fetal lie and position.
3. Make the patient comfortable in a semi-recumbent or sitting position. Place the belt around the abdomen, and secure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



Transducer and belt attachment

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

Hints on Monitoring



Transducer positioning for Ultrasound monitoring

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

6.3 False recording of FHR

When monitoring FHR, the heart rate may be falsely reported. This can have a number of causes including double-rating or half rating, and is characteristic of ultrasound fetal monitoring. Another cause may be detection of maternal signals, (particularly in the absence of fetal signals). Doubling of the maternal rate can result in a trace looking like a fetal trace.

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. Listen to the Audio signal. The 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.
3. Repeat any of 1 to 3 if half rating or double rating or other artefact is suspected.

6.4 Twins Ultrasound Monitoring

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

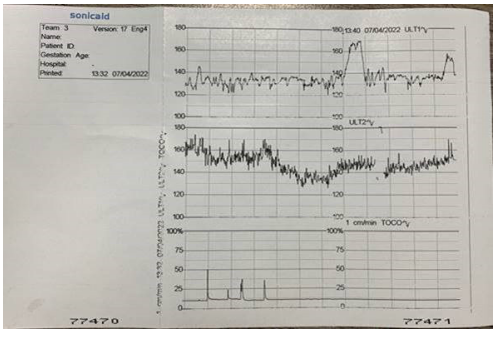
1. Connect the green transducers to the green sockets marked FHR1/FHR2 on Team3. On the main screen, the ULT1/2 regions become active.
2. Palpate the abdomen and ascertain the lie of each fetus.
3. Place the ultrasound transducers on the patient's abdomen in the optimum positions. Use the ULT1 transducer 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 heart rates are different.

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

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

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

6.4.1 Print Twins Grids



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

Print Twin Grids is recommended for antepartum use only.

7. Monitoring Maternal Parameters

7.1 Contractions (using TOCO transducer)

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

1. Ensure that the TOCO transducer and belt are clean and ready for use. In particular, check the transducer for cracks or signs of damage. See also cleaning instructions in Section 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 & hold the TOCO region of the screen to zero the contractions to the set % level (0, 10, 20% - see settings). If enabled, an auto-zero function will activate if the trace has been flat for 3+ minutes.

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

7.2 Fetal Movement Event Marker

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

7.2.1 Automatic Fetal Movement Event Marker

This function is not recommended for use when monitoring twins as it is not possible to associate a movement event with a specific fetus.

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 13.5 - Secure Settings - 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

7.2.2 Manual Fetal Movement Event Marker

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

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.

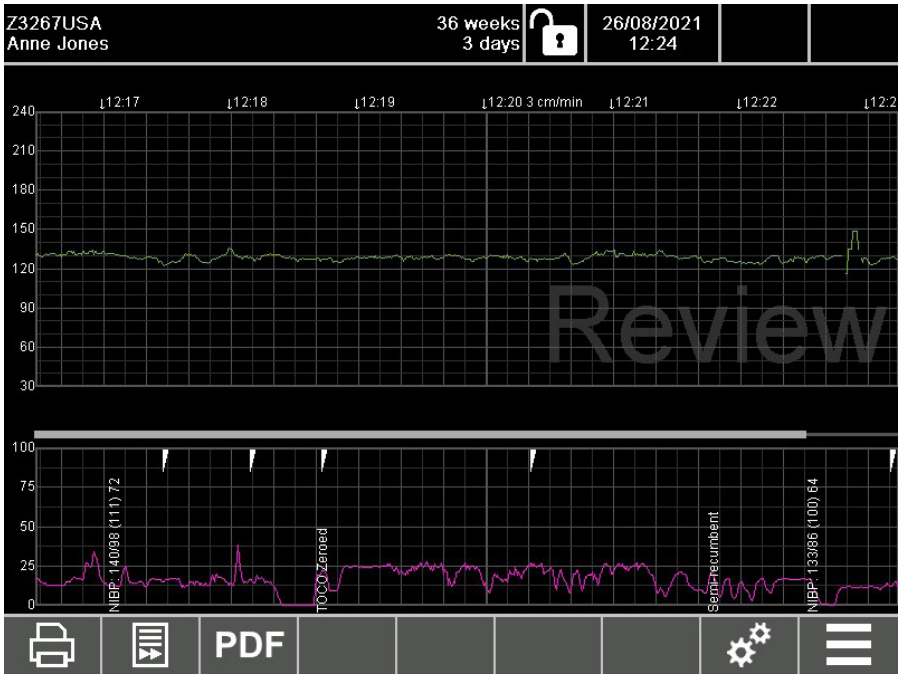
Before use, inspect the Fetal Event Marker switch and connecting cable assembly, ensuring that it is clean and undamaged. See Section 15 for cleaning procedures.

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.

7.3 Maternal Blood Pressure

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

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

Attaching the cuff

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

Cuff size

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

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

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

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

Cuff positioning

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

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

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

Other considerations

There are many other factors which can effect BP measuremen.

Key issues that affect accuracy of BP measurements:

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

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

Measurement Limitations

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

The measurement may be inaccurate or impossible:

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

Suspect Hypertensive Patients

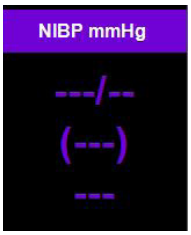
To make a measurement for use in the diagnosis of hypertension, follow the steps below:

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

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

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

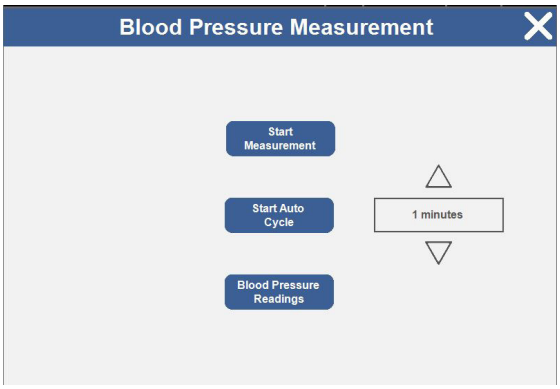
7.3.1 Taking BP measurements



Attach the correct size cuff to the mother.

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

You can select either manual mode or automatic mode:



Manual NIBP

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

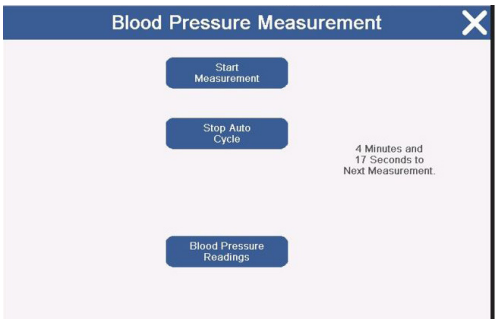
Automatic NIBP

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.

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



To cancel automatic NIPB readings, touch and hold the NIBP region to access the NIBP menu and touch 

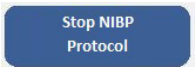
.

NIBP Protocol

Select 

to start the sequential NIBP protocol as follows:

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

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

.

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 13.5.

- **To stop the measurement, touch and hold the NIBP region. Touch  to stop the measurement.**

- **To avoid harming the patient, clinical judgement should be used to determine whether unattended blood pressure measurements are appropriate, particularly in the range 1 to 5 minutes.**

Failed measurements (manual and automatic)

When an NIBP measurement fails:

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

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

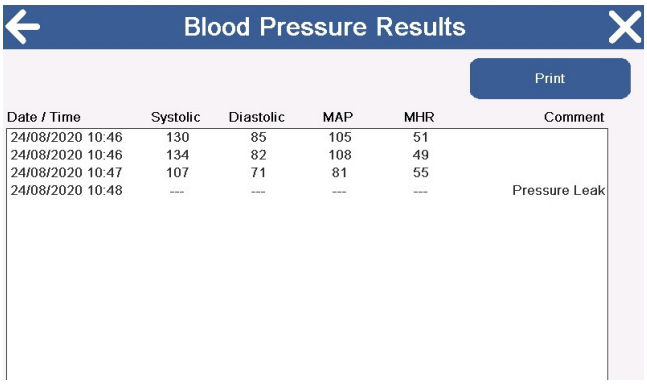
- **Safety mechanisms are incorporated to prevent over-inflation, or extended period inflation. However, patients should be advised to summon assistance if any discomfort results from the use of the NIBP function, and its use discontinued.**
- **Note that, as with all auto-BP measurement systems, results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

Reviewing BP Results

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

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

Touch △ ▽ to scroll through the results.



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

8. Alarms

8.1 What is meant by an alarm

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

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

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

8.2 What is seen and heard

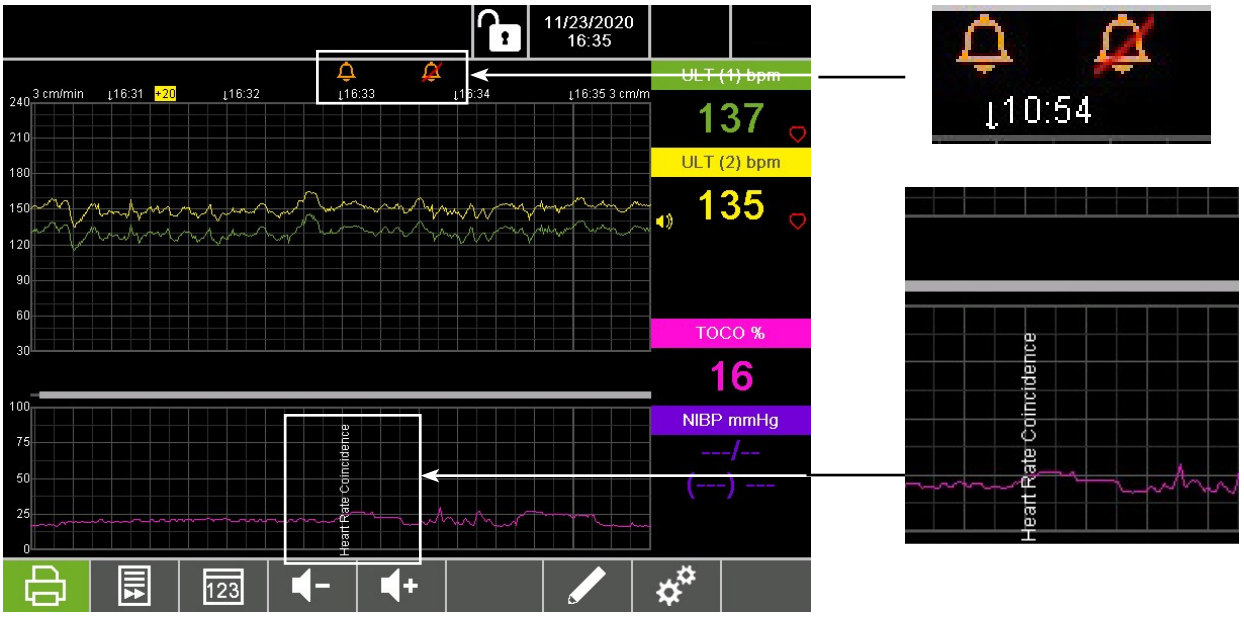
When the Team3 enters an alarm condition, an alarm sounds, will appear at the top of the screen and the associated alarm regions will flash.

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

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

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

An alarm acknowledgement indicator will be printed on the trace screen identifying the time of the alarm acknowledge . Alarm(s) Acknowledged will be printed on the TOCO region of the screen.



Printed Indicators

- Fetal alarms
- Maternal alarms

ULT1 and ULT2 Fetal High Heart Rate
ULT1 and ULT2 Fetal Low Heart Rate
ULT1 and ULT2 Fetal Signal Loss
Maternal High Heart Rate
Maternal Low Heart Rate
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.

Note: To test the alarms, run Demo mode (see section 13.5) and wait until an alarm is triggered. All Alarms are of Medium priority and so any input will provide confirmation of a working Alarm system.

9. Printing

9.1 Introduction

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

9.2 Paper options

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

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

9.3 Paper care and handling

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

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

9.4 Print speed and duration

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

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

Note
The Print Speed can only be changed through the Secure Settings menu. (See Section 13.5).

9.5 Changing paper packs

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

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

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

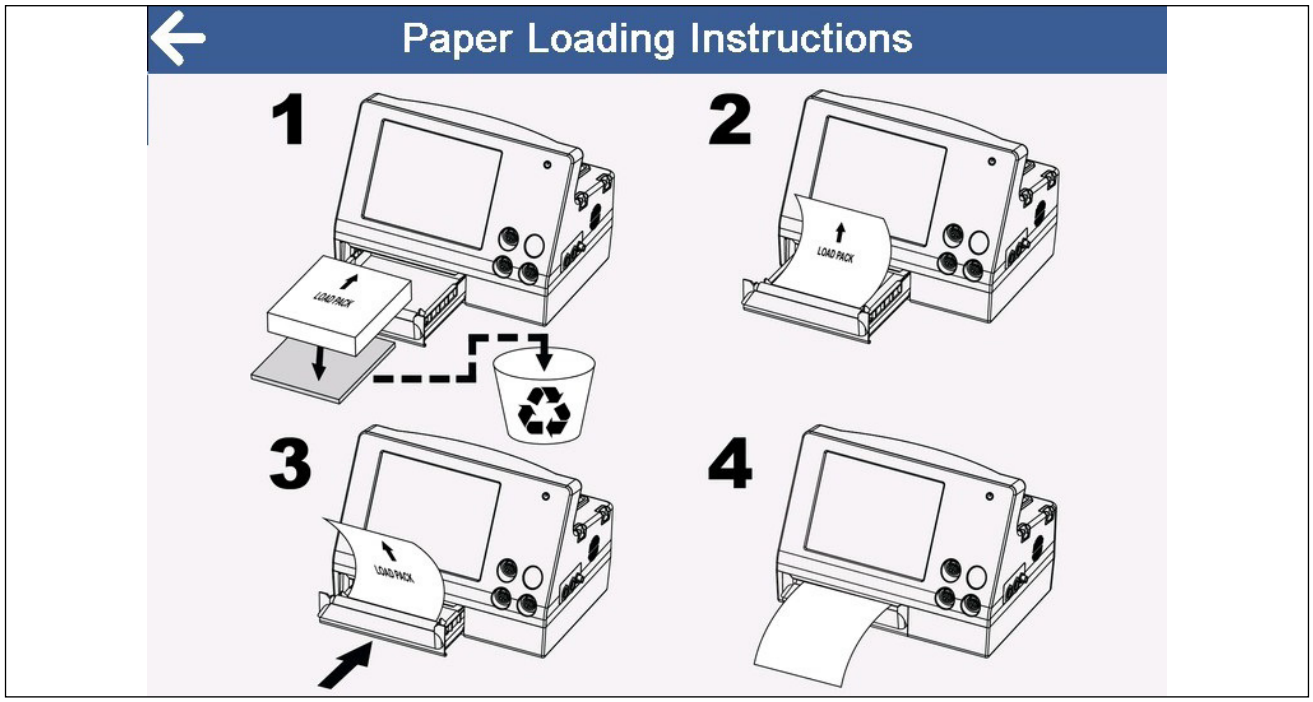
Finally, ensure that at least one fresh pack of paper is available to replace the old one when it comes to an end.

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

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

9.6 Loading printer paper

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

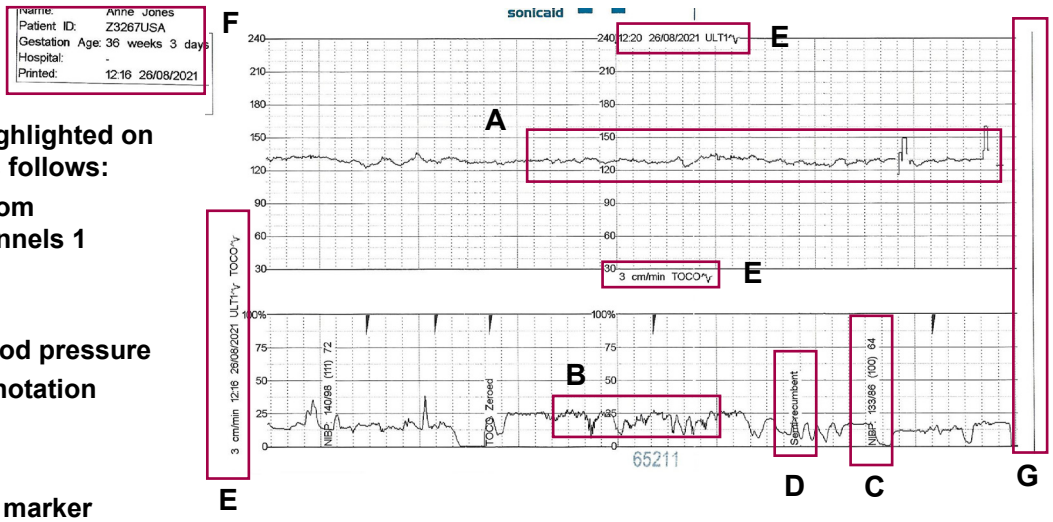


Note: Ensure the paper remains centrally aligned while closing the drawer.

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

9.8 Sample Trace (Sonicaid paper)

The illustration below is of an actual CTG chart.



The features highlighted on the chart are as follows:

A. FHR trace from ultrasound channels 1 and 2

B. TOCO trace

C. Maternal blood pressure

D. Easinote annotation

E. Legends

F. Header

G. End of trace marker

9.9 Turning off the printer

9.9.1 Normal recording

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

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

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

9.9.2 Stopping the printer while print timer running

If the print timer is available this will show as an overlay on the print button  .

When the printer is active this will show as follows  .

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

Touch  to stop the printing or  to cancel.

10. Using Team3 with Sonicaid Reporter

The Team3 can be connected to PC-based Sonicaid Reporter software:

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.

10.1 Connecting Team3 to Sonicaid Reporter software

1. Connect the Sonicaid Reporter connecting lead to the RS232 connector on the rear of Team3.
2. Refer to the connection instructions supplied with your Sonicaid Reporter software.

11. 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.

11.1 Essential Performance

If you lose essential performance, refer to the table on page 98, Manufacturer's Performance Criteria Specification.

11.2 FHR

SYMPTOM	POSSIBLE CAUSE / REMEDY
No FHR signal displayed	Check Team3 is switched on. Check the FHR transducer is connected.
High % signal loss	Check transducer placement. Check the transducer is not damaged. Consider switching from Ultrasound to FECG.
No FHR trace printed	Check Print button has been pressed. Check there is paper in the paper tray. Check paper tray is fully pushed in.
Only one trace (twins) 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.

11.3 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.

11.4 Maternal blood pressure

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

11.5 Printing

SYMPTOM	POSSIBLE CAUSE / REMEDY
Paper runs out	A colored stripe will appear when the paper pack nears its end (Sonicaid paper). Once the paper has expired, the printer icon on the control bar will change to  . Print information will be stored in memory for up to 100 hours to allow the paper pack to be changed.
Poor print quality	1. Make sure the correct paper is loaded. 2. Make sure the paper is loaded correctly. 3. Make sure the paper tray is fully pushed in. 4. Try printing again. 5. If there is no improvement, clean the print head. See Section 13.
Printer stops working	Check paper supply and feed. If not successful, swap unit out. Trace data is stored in memory.

11.6 General

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

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

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

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

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

If this is deemed inconvenient, please contact your supplier.

12. Care and Cleaning

12.1 General Care

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

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

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

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

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

Do not use abrasive cloths or cleaners.

Do not use automatic washers or autoclaves.

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

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

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

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

12.2 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.

12.3 Cleaning and Disinfecting Patient Applied Parts

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

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

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

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

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

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

12.4 NIBP Cuff

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

12.5 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.

13. Maintenance

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

13.1 User maintenance

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

Mechanical inspection

Every three months:

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

Cleaning the print head on the printer

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

Check NIBP cuffs and hose

Once a month:

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

13.2 Technical maintenance

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

13.3 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.

13.4 Servicing

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

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

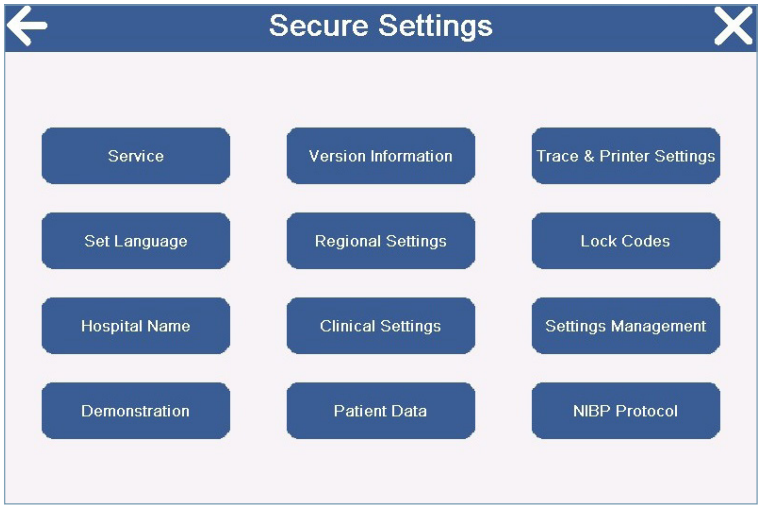
13.5 Secure Settings

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

Touch  to access the Settings menu.

Secure Settings

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.

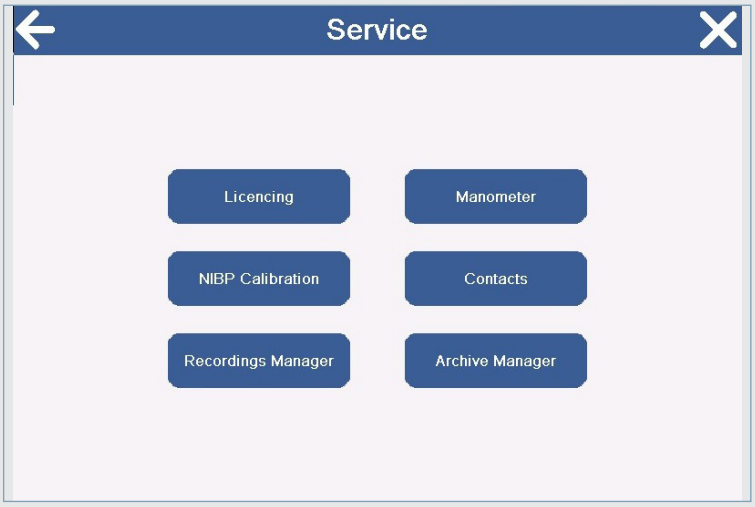


Service Sub Menu

Service

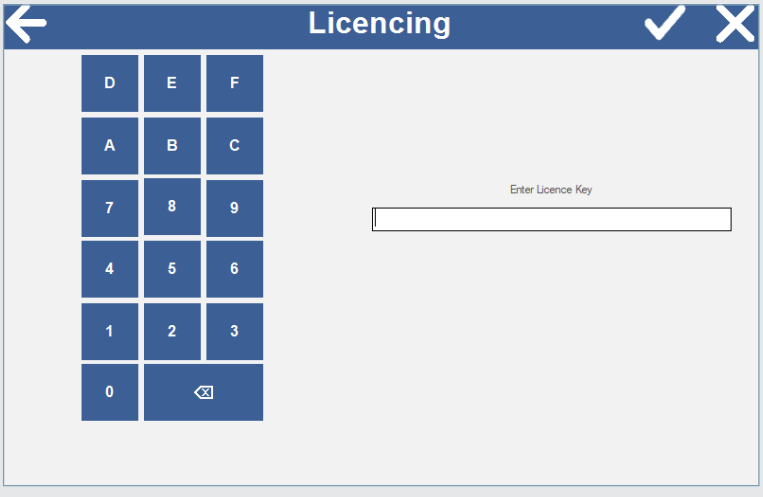
Service menu options are for use by trained biomedical staff only.

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



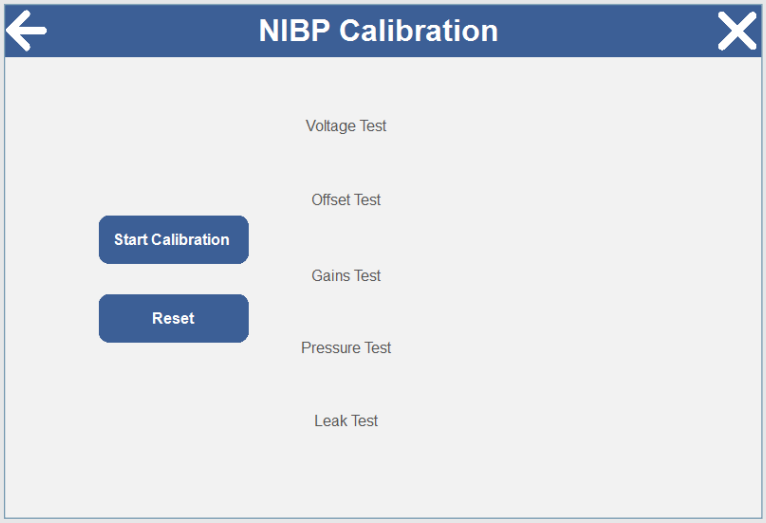
Licencing

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.

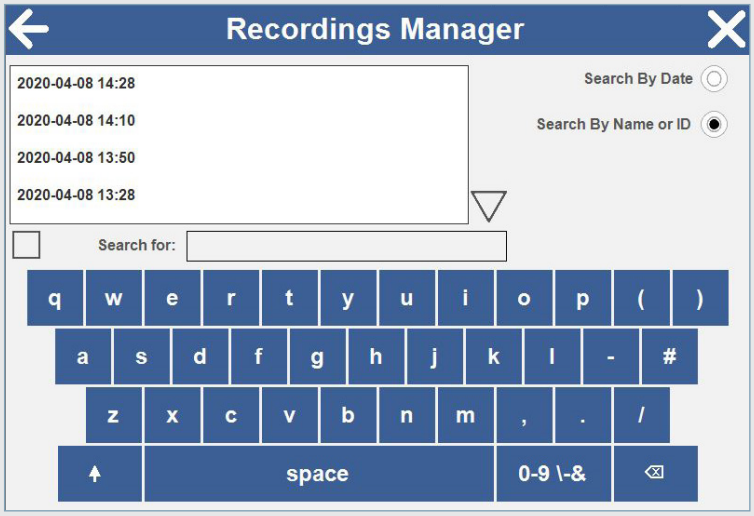


Recordings Manager

These buttons are only available once traces are selected. Select each trace to Archive/ Export.

Archive - The Archive button allows traces to be moved from the live database to the internal archive database.

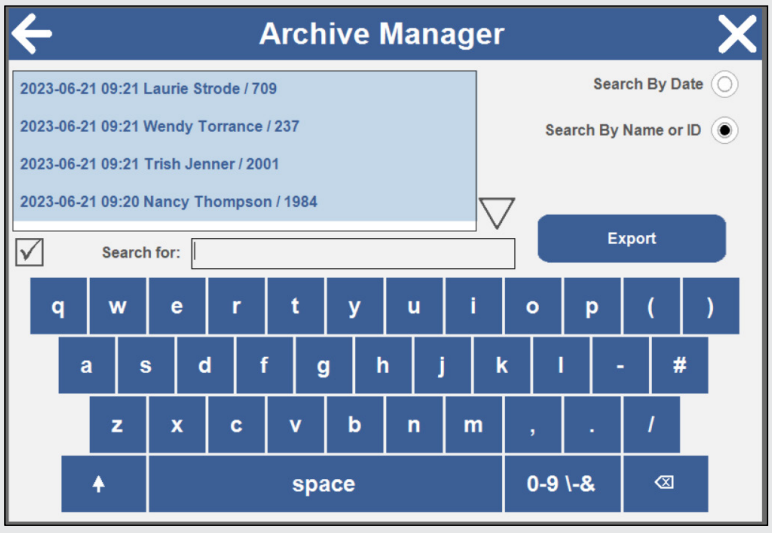
Export - The Export button allows traces to be moved from internal Team3 storage to a USB drive and kept for future viewing if required. Exporting traces from Team3 to a USB drive deletes the selected traces from the Team3. The USB drive capacity requirement is 8GB and the recommended suppliers are Transcend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



Archive Manager

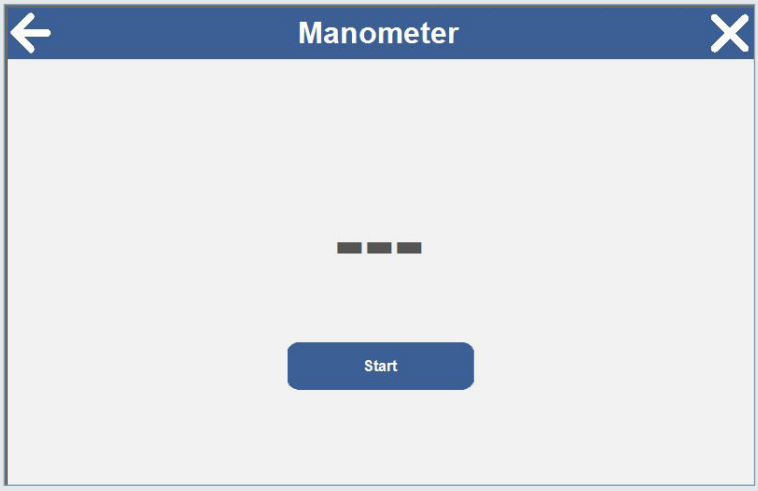
The Export button is only available if traces have been archived from the Recordings Manager screen. Select each trace to Export.

Export - Export button – refer to Recordings Manager.

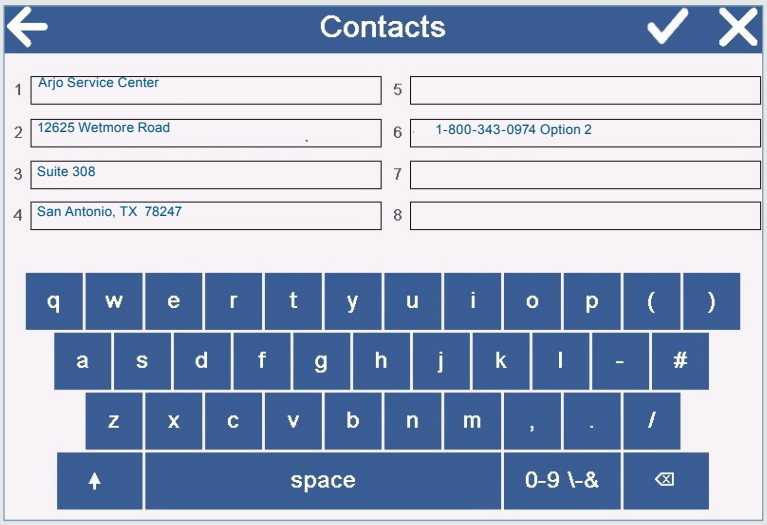


Manometer

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

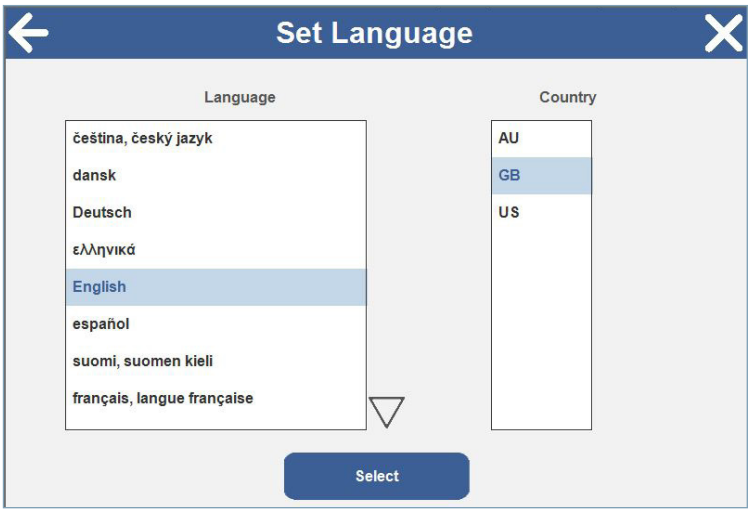


Contacts

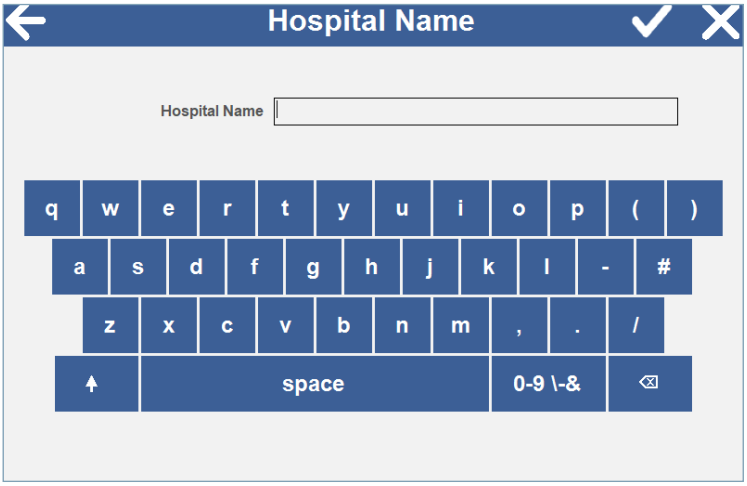


Set Language

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

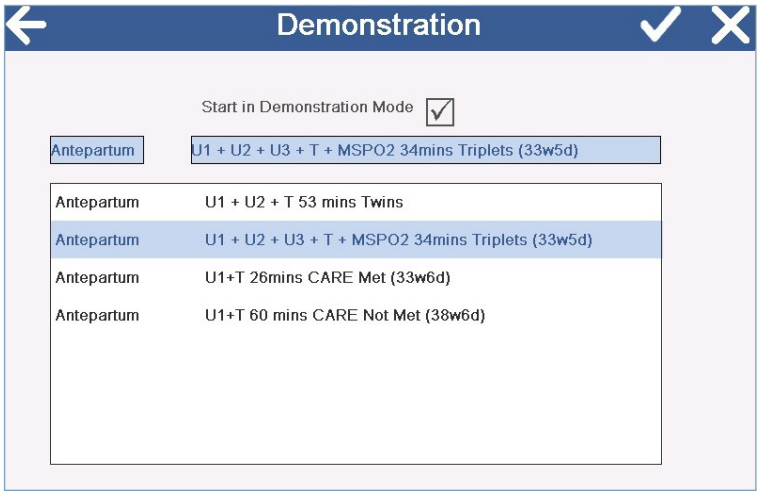


Hospital Name



Demonstration

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

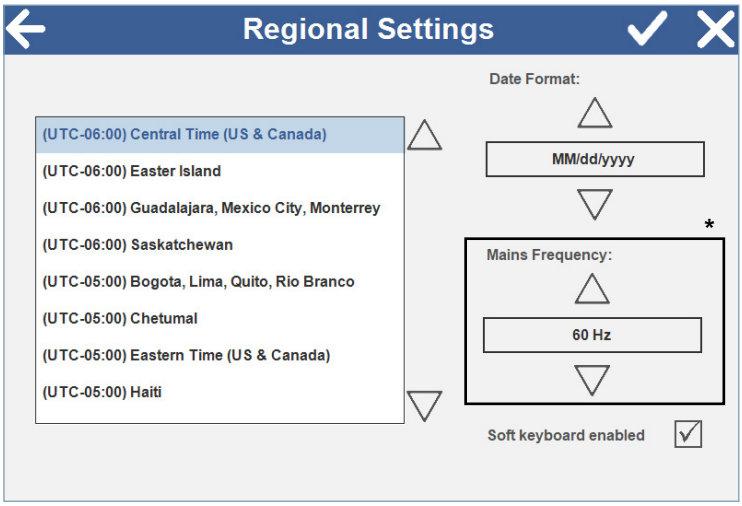


Click on one of the demo traces - this will enable an antepartum demo mode. Switch unit off/on to activate.
Alternatively, selecting the tick box will run an intrapartum demo mode.
To disable demo mode switch the unit off/on.

Version Information

Regional Settings

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



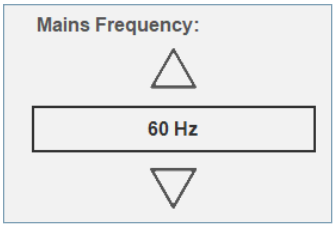
* Mains Frequency Setting

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

Touch △ ▽ to select required frequency.

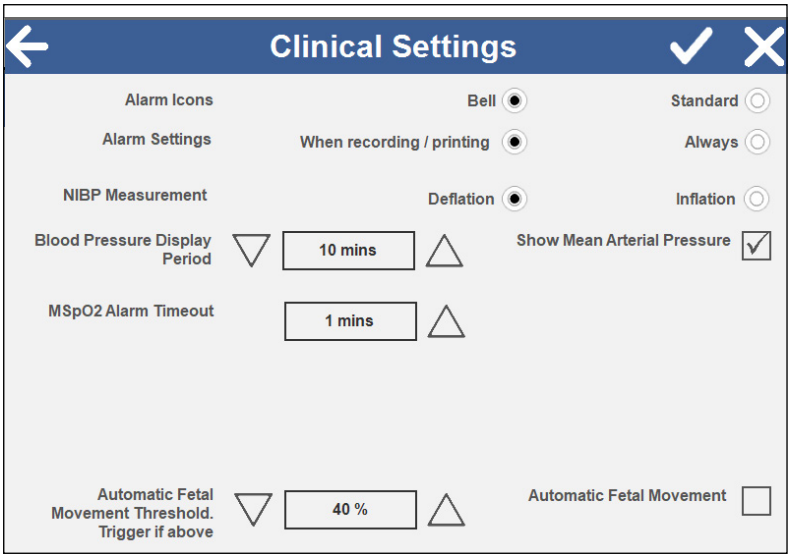
Touch ✓ to confirm.

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



Clinical Settings

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

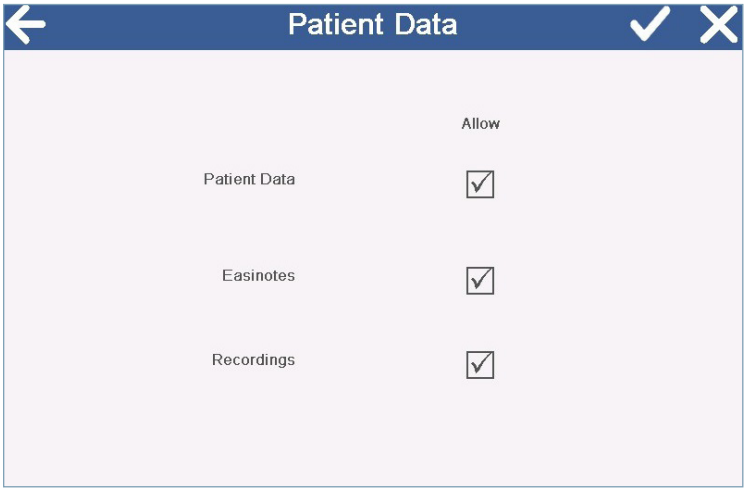


- The alarm icon type displayed on screen
- Whether to record alarms only when recording/printing
- Whether to measure NIBP during Inflation or Deflation
- How long to display the previous blood pressure reading
- Whether to include Mean Arterial Pressure (MAP) on the blood pressure display
- The timeout period for the Msp02 alarm
- Whether to allow oximetry in wireless mode
- Sets the sensitivity threshold for the automatic Fetal movement and enables or disables the feature. Use △ or ▽ to set the threshold as required. The required threshold may depend on whether the trace is showing a high incidence of artefact. It is recommended to set the threshold between 40-60%.

Patient Data

Allows these functions to be enabled/disabled.

- Patient Data: Allows entry of patient identification data into the monitor. The patient's ID appears at the top of the monitoring screen and on the paper printouts and stored recordings (if Recordings is also enabled).

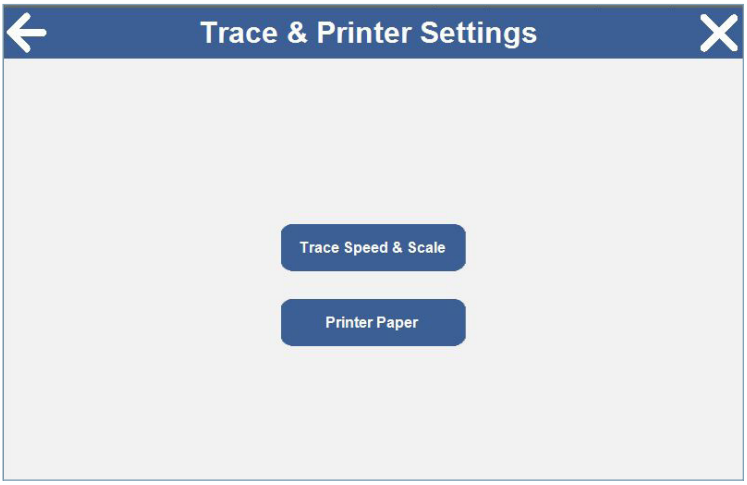


- Easinotes: Allows the user to add annotations to the tracing when the fetal monitor is printing/ recording, using the Annotations icon to view the EasiNotes selection screens.
- Recordings: The fetal monitor records the patients' traces while they are being printed. Recorded traces can be archived or viewed later if desired.

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

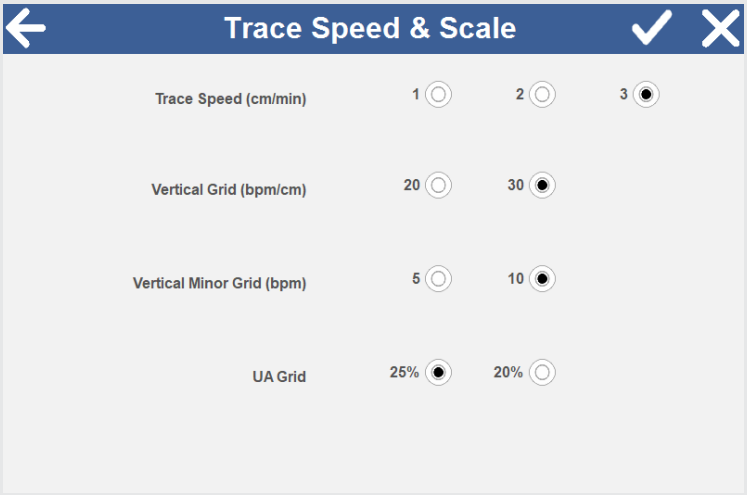
Trace & Printer Settings

This button is not available while printing is in progress.



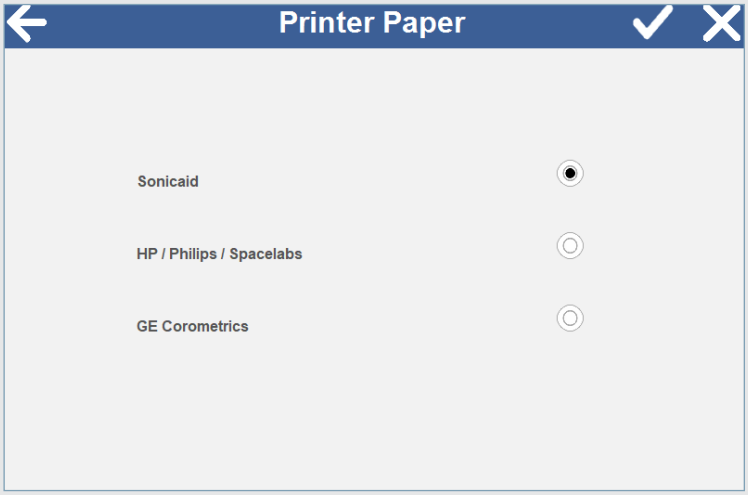
Trace and Printer Settings Sub Menu

Trace Speed & Scale

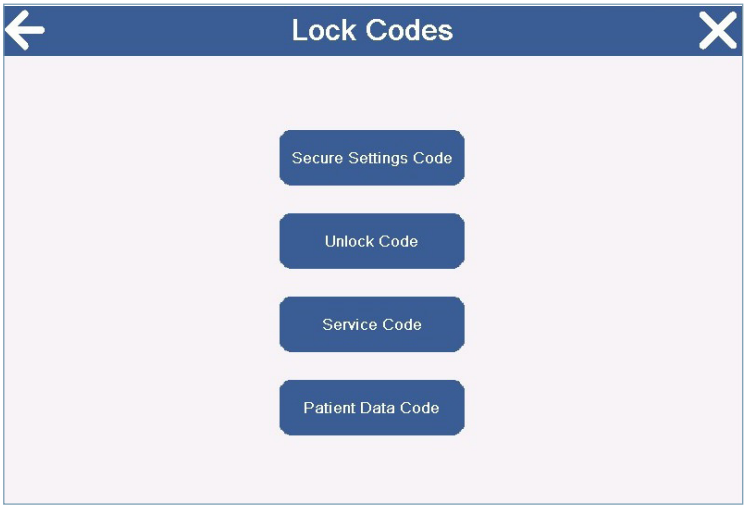


Printer Paper

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



Lock Codes



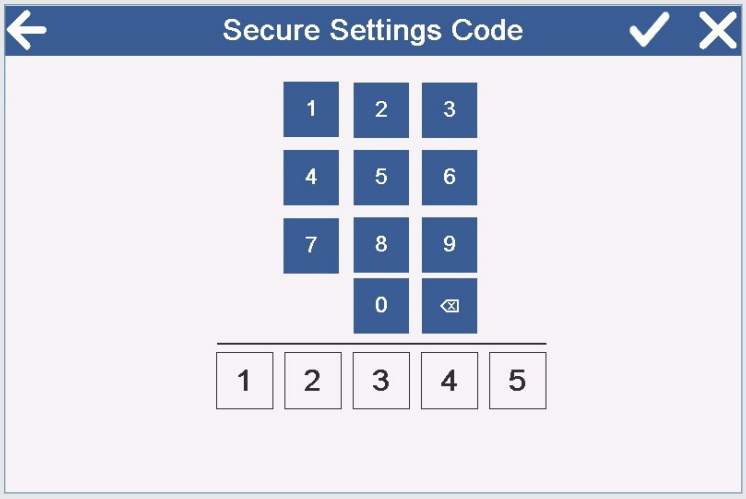
Lock Codes Sub Menu

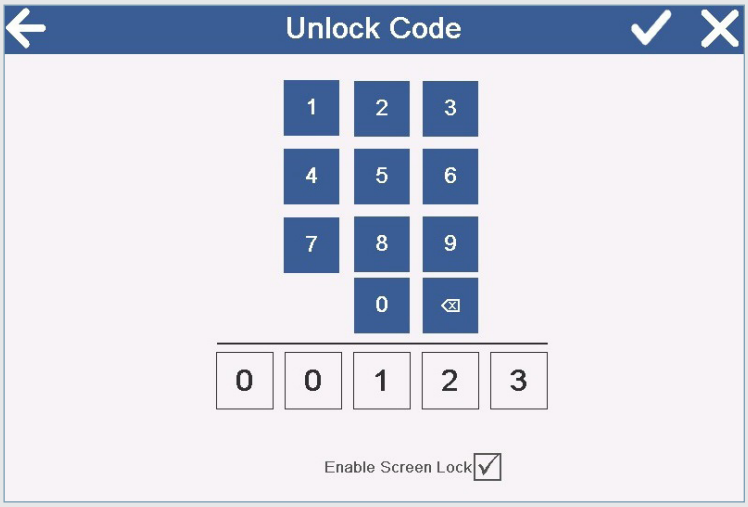
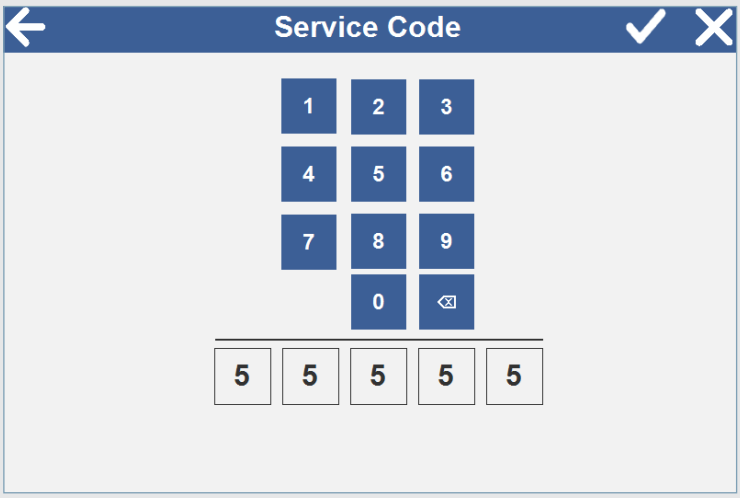
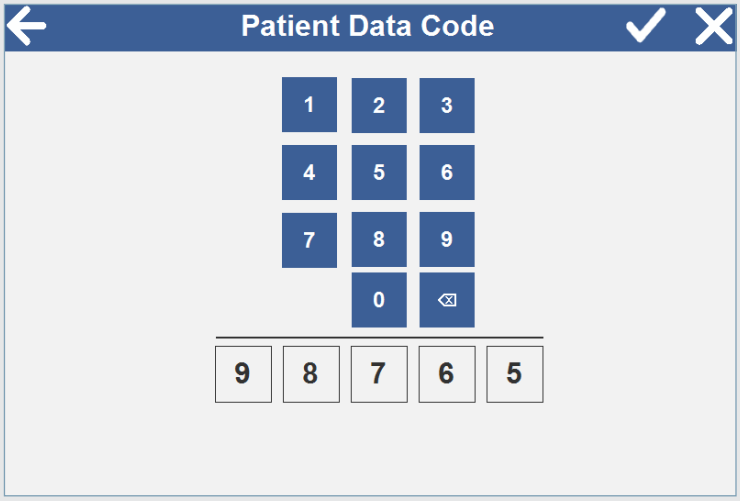
Secure Settings Code

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

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

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



Unlock Code	
Service Code	
Patient Data Code	

Settings Management

Save New Defaults = Fix all current settings as defaults.

Restore Factory Settings = Overwrite all current settings with the stored defaults.

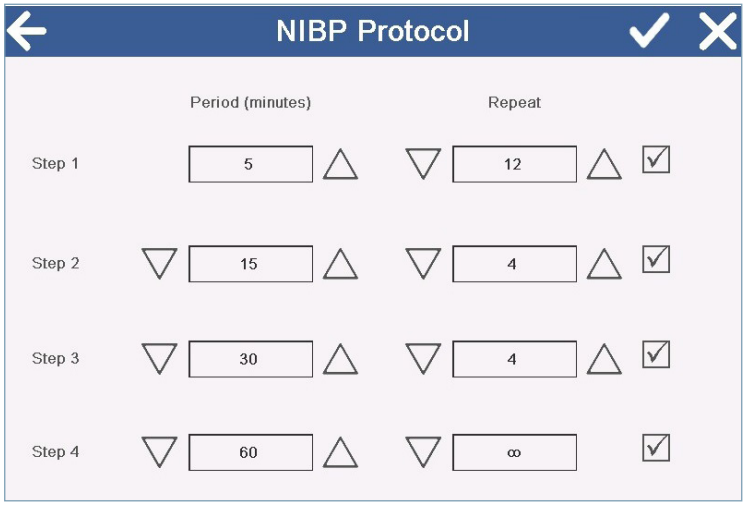
Imports and Exports allow transfer to and from Team3 via USB Flash Drive.*

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

Note: Import/Export buttons are only displayed when a USB Flash Drive is installed.
***A software tool is available from your supplier to support the Easinote function. See section 13.6.**

NIBP Protocol

Allows NiBP protocol details to be customised.



13.6 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 13.5 for details on how to change the Language and to access the Settings Management feature.

Exporting Easinotes

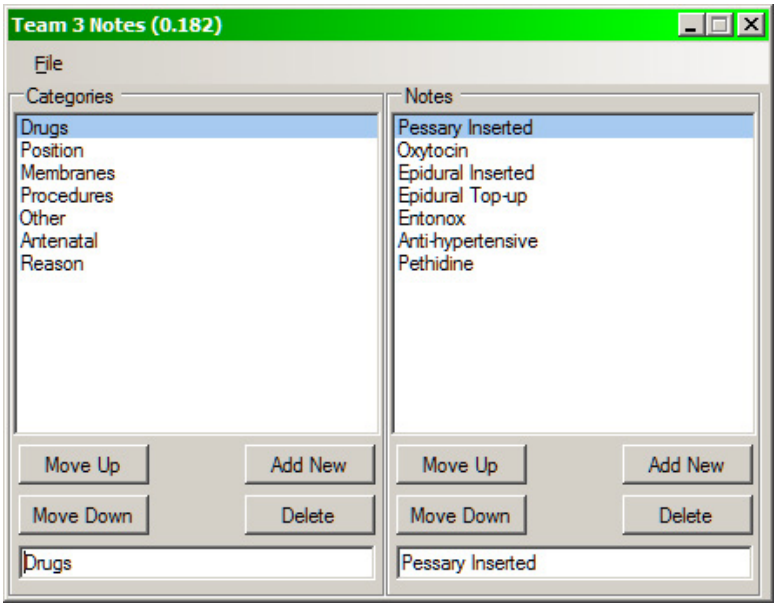
1. With Team3 switched on, plug a USB flash drive into one of the Team3 USB sockets.
2. Set up Team3 to operate in the language of your choice. This will ensure that the Easinote file to be exported is saved with the other files for that language. It is important to remember that each language has its 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 Import EasiNotes 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.

14. Specifications

14.1 Equipment Classification

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

14.2 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

14.3 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

14.4 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)

Uterine activity (external TOCO)

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

Alarm characteristics

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

Maternal blood pressure

Method	Oscillometric		
Pressure Range	0-300mmHg		
Measurement ranges	Systolic 25-280 mmHg Diastolic 10-220 mmHg Pulse 30-240 bpm		
Accuracy	**Measurement during deflation**	**Measurement during inflation, IMT**	**Required according to international standards**
Pressure transducer accuracy	±1 mmHg	±1 mmHg	max. ±3 mmHg
Measurement accuracy mean deviation	<1.7 mmHg	<1.19 mmHg	max. ±5 mmHg
Measurement accuracy standard deviation	<5.6 mmHg	<3.48 mmHg	max. 8 mmHg
Modes	Manual or automatic User-selectable interval in Auto Mode: 1, 2, 3, 5, 10, 15, 20, 30, 45, 60, 90 or 120 minutes		
Record / display	On-screen display and printed record of: ● Systolic blood pressure ● Diastolic blood pressure ● Pulse rate ● Mean arterial pressure		
Alarms	Systolic High: 100-180mmHg Systolic Low: 50-150mmHg Diastolic High: 70-130mmHg Diastolic Low: 40-120mmHg		
Safety	Type B protection Hardware and software controls to limit: ● Inflation (max. 300 mmHg) ● Measurement time (max. 90 s)		
Standards	EN 1060-3 EN 1060-4 EN 80601-2-30 ANSI/AAMI SP-10 The sphygmomanometer was clinically investigated according to the requirements of ISO 81060-2: 2013		

15.5 Printer

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

14.6 Connections *

Front Panel

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

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

System	Sonicaid Reporter

** Depending on model*

14.7 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
TOCO	0–100 (relative units)
NIBP	Systolic and diastolic pressures Pulse rate MAP

14.8 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

Audio

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

NIBP

Auto Enable	OFF
Repeat Interval	5 minutes

Printer

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

Timer

Non Stress Test Timer Period	10 minutes OFF

View

Start Screen	Numeric
Background color	Black

Uterine Activity

Toco Zero Level	10%
Toco Auto Zero	ON

Miscellaneous

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

14.9 General Standards

IEC60601-1: 2005 + A1:2012	**ISO15223-1:2012**
ANSI/AAMI ES60601-1:2005 + A1:2012	**IEC60601-2-49:2018**
CAN/CSA C22.2 No 60601-1:14	**IEC62304**
JIS T 0601-1:2012	**IEC60601-1-2: 2014**

15. Accessories

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

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

Accessories

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

Consumables

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

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

16. Warranty & Service

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

Service Returns

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

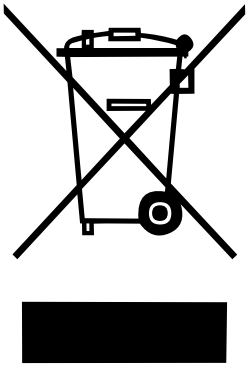
- Clean the product following the instructions in this manual.
- Pack it in suitable packing.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department '

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

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

Phone: +1 (800) 323 1245

17. End of Life Disposal



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

Appendix 1 Electromagnetic Compatibility

Make sure the environment in which Team3 is installed is not subject to strong sources of electromagnetic interference (e.g. radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, complies with EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering
- Plugging the equipment into a different outlet so that the devices are on different branch circuits

WARNING: The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Team3 as replacement parts for internal components, may result in increased emissions or decreased immunity of the Team3.

WARNING: The Team3 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Team3 should be observed to verify normal operation in the configuration in which it will be used

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Team3 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The Team3 is intended for use in the electromagnetic environment specified below. The customer or the user of the Team3 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	The Team3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Team3 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Team3 is intended for use in the electromagnetic environment specified below. The customer or the user of the Team3 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Proximity Immunity Compliance Information			a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz, to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz outside ISM bandsa 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands	3V	
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	80MHz to 800MHz 800MHz to 2.5GHz
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, b should be less than the compliance level in each frequency range c. Interference may occur in the vicinity of the equipment marked with the following symbol:
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
b Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Team3 is used exceeds the applicable RF compliance level above, the Team3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Team3. c Over the frequency range 150kHz to 80kHz, field strengths should be less than 3V/m.			

Guidance and Manufacturer's declaration - electromagnetic immunity			
The Team3 is intended for use in the electromagnetic environment specified below. The customer or the user of the Team3 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % Ur (>95 % dip in Ur) for 0,5 cycles 40 % Ur (60 % dip in Ur) for 5 cycles 70 % Ur (30 % dip in Ur) for 25 cycles <5 % Ur (>95 % dip in Ur) for 5 s	<5 % Ur (>95 % dip in Ur) for 0,5 cycles 40 % Ur (60 % dip in Ur) for 5 cycles 70 % Ur (30 % dip in Ur) for 25 cycles <5 % Ur (>95 % dip in Ur) for 5 s	Mains power quality should be that of a typical commercial of hospital environment. If the user of the Team3 requires continued operation during power mains interruptions, it is recommended that the Team3 is powered from an uninterruptible power supply or battery, by specifying the battery option at time of purchase.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE Ur is the a.c. mains voltage prior to the application of the test level.			

Appendix 2 Manufacturer's Performance Criteria Specification

Below are comprehensive Essential Performance definition tables 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	Standard	Description	Standard	Description
IEC 60601-2-37	Ultrasound	IEC 80601-2-61	SPO2	IEC 60601-2-49	Multi-parameter
IEC 60601-2-30	NIBP	IEC 60601-2-27*	MECG		

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

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

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

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

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

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

Appendix 3 Ultrasound Safety Considerations

General

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

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

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

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

Acoustic Output

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

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

Definition of Terms

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

Additional Information

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

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

Uncertainties

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

Acoustic Parameter	Uncertainty
Power	±28%
Pressure	±10%
Intensity	±20%
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).

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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