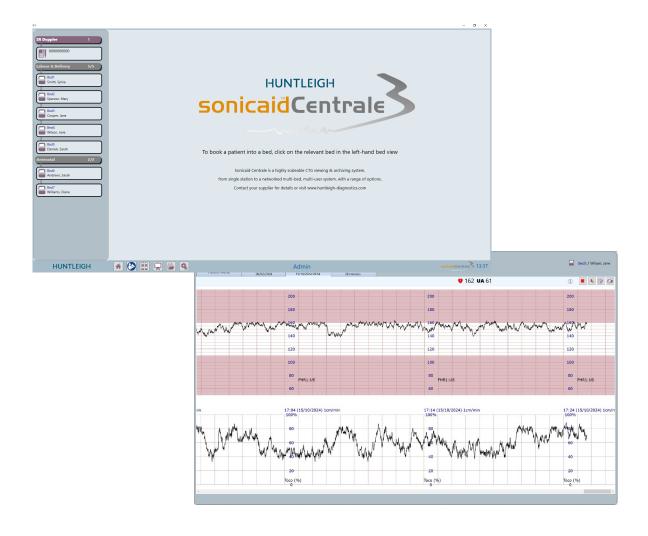
# Instructions for Use Sonicaid® Centrale

CardioTocoGraph (CTG) Viewing & Archiving System – Version 3





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### 1 Introduction

Sonicaid Centrale is a full specification CardioTocoGraph (CTG) viewing & archiving system. Traces are automatically saved to the patient's record and are quick and easy to retrieve for case review.

The system provides the following key functions:

- Single bed live CTG view
- Multi-bed CTG view
- Patient management
- Automatic trace archiving
- Trace retrieval for review
- User configurable CTG alerts
- Optional CTG analysis

- Supports STAN fetal monitors
- Optional security and audit
- Optional Partogram
- Optional GDT
- Optional SR Doppler connection
- · Optional chalkboard

### 1.1 Intended use

Sonicaid Centrale is intended for use by healthcare professionals for the centralised monitoring of physiological parameters in pregnant women and fetuses. It provides viewing, analysis & archiving of data sourced from fetal monitors.

### 1.2 Contra-indications

Sonicaid Centrale is not intended to provide a primary fetal monitoring function. Its use is secondary to the fetal monitor(s) and must not be relied on to alert users to potential problems, clinical issues or clinical management of the pregnancy. Clinicians retain full responsibility for all aspects of pregnancy management and for correct and effective use of the fetal monitor in the patient environment.

The alert functions are provided simply to alert users to FHR data which is outside user-set rate and time limits. They must not be relied on to alert users to problems like loss of contact or to clinical conditions such as tachycardia or bradycardia.

### 1.3 Clinical Benefit

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

# 1.4 Fetal monitoring connections

Sonicaid Centrale is able to detect fetal monitors which implement Philips, Huntleigh, Sonicaid or Neoventa STAN RS232 protocols (see table of compatible fetal monitors below). When Centrale detects the monitor it can accept its data and identify the fetal monitor manufacturer and model.

Centrale supports only those features that are part of the fetal monitors with the abovementioned protocols. If you have a fetal monitor that measures parameters other than those supported by these serial protocols, Centrale cannot display them.

If a third party manufacturer claims compliance with any of the above mentioned protocols, responsibility for compliance lies with that manufacturer.

Sonicaid Centrale compatible Huntleigh fetal monitors			
Sonicaid Team3	Sonicaid Team & Team Duo		
Sonicaid FM820, FM830, FM840, FM820E & FM830E	Sonicaid BD4000 & BD4002		
Sonicaid SRX, SRXR, SR2, SR2R, SR3 & SR3R			

**Note**: Other fetal monitors may be compatible, please contact your local sales representative for further compatibility options.

# 1.5 Cautions & warnings

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### Warning - Cybersecurity

Connecting Centrale to an IT network must be carried out by a qualified network administrator.

### Warning - Cybersecurity



Ports 9090 through 9095 of the patient monitoring network must be protected from public network traffic by means of an adequate configured firewall.

### Warning - Cybersecurity



HL7 should only be configured for use on a secure internal network for hospital information systems by a qualified network administrator.

### Warning - Cybersecurity



Centrale should only be installed on a server which is in a secure location at a hospital site, and only accessible by hospital IT personnel.

### Warning - Cybersecurity



Only devices which are configured to be on the same private subnet as the Centrale server shall be able to connect to the Centrale system.

### 3<sup>rd</sup> Party Software



Sonicaid Centrale is designed to run on a dedicated PC/server. Under no circumstances must any 3<sup>rd</sup> party software be installed on the system without prior approval, in writing, from Huntleigh Healthcare. In the event of unauthorised software being installed, Huntleigh Healthcare cannot be held responsible for resulting data corruption, misrepresentation, loss or any other failing of the system.



While remote access clients may have 3<sup>rd</sup> party software installed, it is recommended that running multiple applications concurrently should be avoided, or kept to a minimum. If system resources are overloaded, data may be lost or corrupted. Huntleigh Healthcare cannot accept liability for any such loss or resultant problems or outcomes.

### System back-up



As with any software system, crashes may occur at any time, and may result in loss or corruption of clinical data. Similarly, hardware failures may result in loss or corruption of data. While every effort is made to minimise this risk, it is strongly recommended that back-up protection measures are employed in line with industry standard practice. Huntleigh Healthcare cannot accept liability for any loss of data, corruption or other loss relating to data back-up failure or loss through any other causes.



### **Clinical management**

Sonicaid Centrale is not a diagnostic tool – it simply presents information. As with any computer / software system, bugs or faults may result in incorrect information being displayed. If any doubt as to fetal or maternal condition arises through using the Sonicaid Centrale system, alternative measures must be undertaken immediately to ensure appropriate clinical management



### **System Security**

In the event of unauthorised access ('hacking') into the system or through any other malicious actions, data may be lost or corrupted. The system has no protection against unauthorised access. Users should take appropriate local measures to limit access to authorised users only.



### **Data protection & patient confidentiality**

Due to the flexible, user configurable nature of Sonicaid Centrale, the system administrator is responsible for ensuring compliance with any local, national or other regulatory requirements relating to patient information, the storing, displaying and archiving of such data, and access to such data.



### **Data integrity**

At all times, clinicians must retain full responsibility for appropriate management of any situation. Sonicaid Centrale is designed as an information system intended to present information to assist clinicians in delivering the highest possible standard of care, not to replace established clinical practice. All users are responsible for ensuring the accuracy of entered data, and for confirming that it has been correctly logged.



### Date / Time

All actions, traces, data entry, etc. are time stamped using the server system clock. If the system clock is incorrectly set, the logged times will reflect this error. The user is responsible for checking that the date & time are correct – this is shown in the bottom right-hand corner of the screen at all times. If the time is incorrect, advise the system administrator immediately.



### **Patient details**

Any patient names, demographic or other data appearing in this document are for demonstration purposes only and are purely fictitious. Any similarity this data may have to any real person is purely coincidental.



### System operation

The system is designed for continuous operation and should therefore never be switched off during normal use.



### CTG analysis (option)

This document only describes the operation of the analysis function. It does not include the clinical application which is beyond the scope of this document. It is essential that all users of the analysis option are fully trained on its use and application. This function is an aid to CTG trace interpretation to inform the clinician. It does not diagnose fetal condition and does not replace the need for expert trace interpretation & effective management of the pregnancy. It is only approved for use from 26 weeks to term, prior to the onset of labour, and is not for use during labour. Visit <a href="https://www.huntleigh-diagnostics.com">www.huntleigh-diagnostics.com</a> for further information on the CTG analysis.



### Potential loss of clinical data

Installing Sonicaid Centrale on laptops or other mobile devices is not recommended. If used, power saving actions relating to lid closure, & inactivity timeout functions (standby / sleep / hibernation) must be disabled & mains power must be used at all times. Failure to disable such features, or battery operation, may result in irretrievable loss of clinical data. The use of laptops or other mobile devices as extra client/viewing terminals is acceptable. However, it is recommended that the above features are disabled on clients as well, to ensure continuity of operation. Desktop PCs must also have any sleep / hibernation / standby functions disabled to avoid data loss.

The use of screen savers is acceptable. However, users must be aware that when these are active, update of live data is suspended. Screen savers which superimpose on, but do not obscure, the trace view (e.g. MS Windows "Bubbles") may cause confusion as the Sonicaid Centrale view can still be seen but will not be updated. However, no data is lost in screen saver mode & the view will be updated as soon as the screen saver is deactivated.



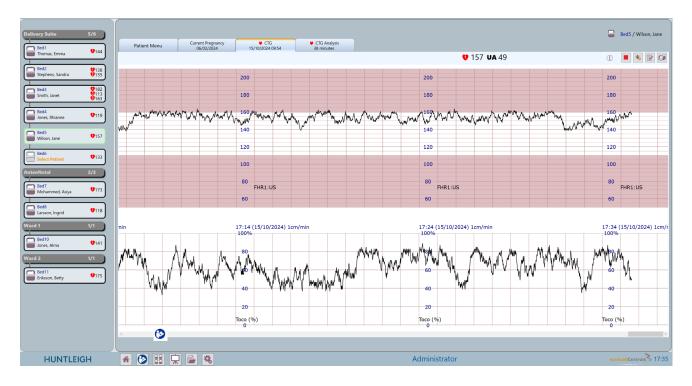
System snapshots or volume shadow copies must not be taken while the Centrale services are running.

Product Labelling				
<b>C €</b> 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)			
•••	Legal Manufacturer in association with the CE mark in Europe ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden			
Manufactured By		Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk		
$\triangle$	Warning	DI	Device Identification code	
MD	Medical Device	23	Cardboard packaging can be recycled.	
REF	Catalogue Number			

# 2 Getting started

# 2.1 Screen layout

The screen is divided into two areas, as shown below:

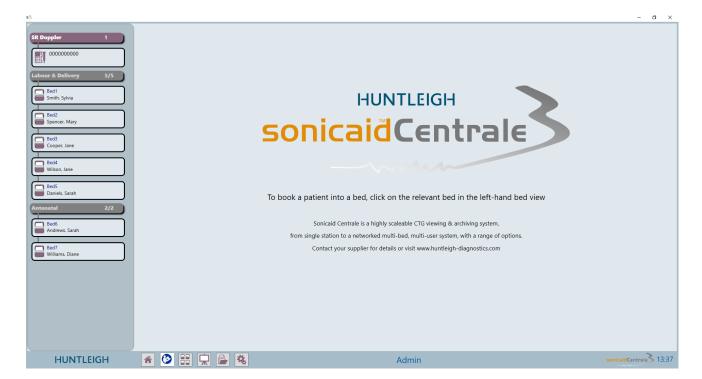


- The left hand view displays bed group(s), listing the beds contained within the system.
- The right hand view will contain one of the following at any one time
  - o Home page
  - Single trace view
  - o Multi trace view
  - Patient record view
  - Analysis results view (where option installed)
  - Analysis trend view (where option installed)
  - Chalkboard (where option installed)
  - SR Doppler (where option installed)
  - Security and audit (where option installed)
  - GDT (where option installed)
  - o Partogram (where option installed)

# 3 System operation

Starting the Sonicaid Centrale application will show the 'Home page' as displayed below.

# 3.1 Home page



Note: this screen may vary in different markets

# 3.1.1 To return to the home page



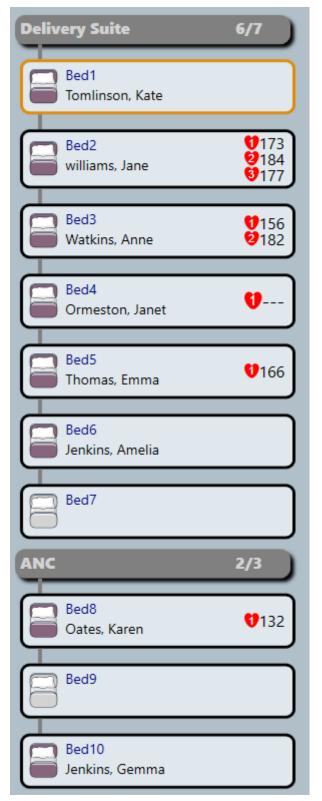
Click to return to the home page.

### 3.1.2 Help



Click for 'Instructions for use'

# 3.2 Bed & bed group functions



The left-hand column shows all the beds in the system, organised into bed groups.

Click on a bed to admit a patient or view a CTG trace.

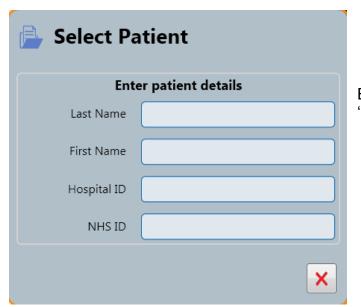
The bed group shows the group name and number of occupied beds / total beds in the group.

Click to maximise or minimise the beds in this group. This turns yellow when any alert is active in this bed group.

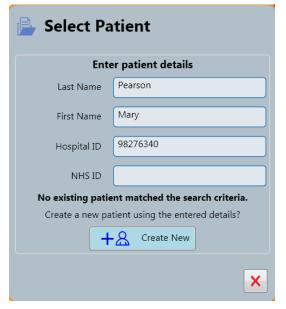
# 3.3 Adding a new patient:



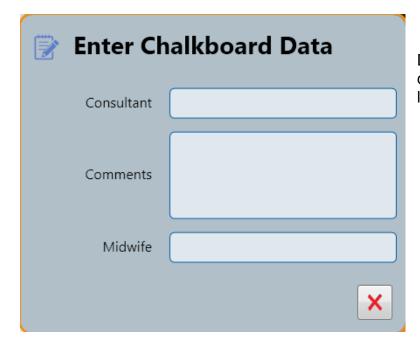
Select a bed.



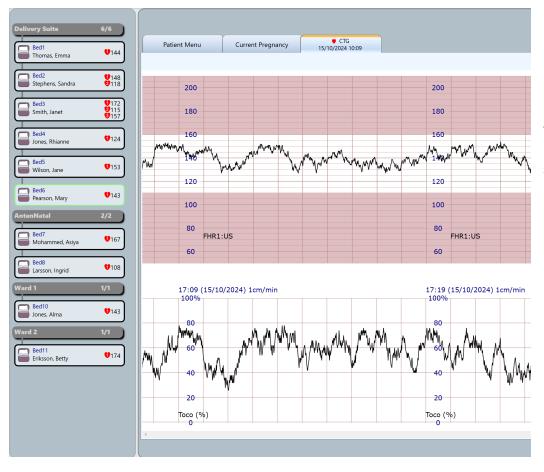
Enter 'Last name', 'First name' and 'Hospital ID'.



As the patient details do not match an existing patient within the system, a 'Create new' patient button appears. Pressing this button adds the new patient details to the system and displays the chalkboard entry view.

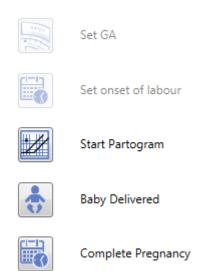


Details can be added to the chalkboard at this point and/or at a later date.

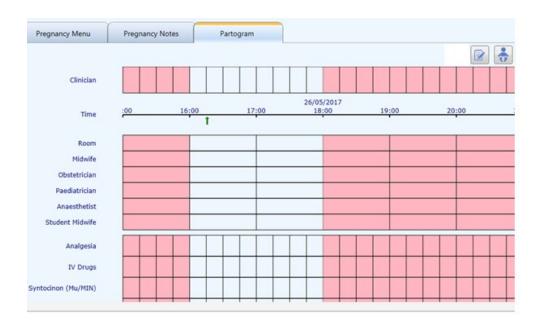


The patient is booked into the selected bed.

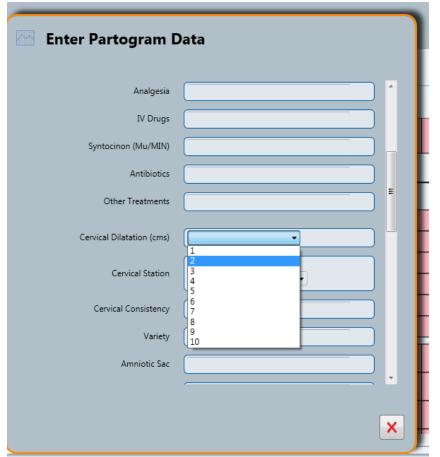
# 3.4 Partogram (optional feature)



Once the **GA** and **onset of labour** buttons have been clicked and data entered, "Start Partogram" can be selected using the partogram button as shown.



Click on the notepad icon and move the time line to where you want to enter the details.



This allows data to be entered, either from a drop down box or plain text.

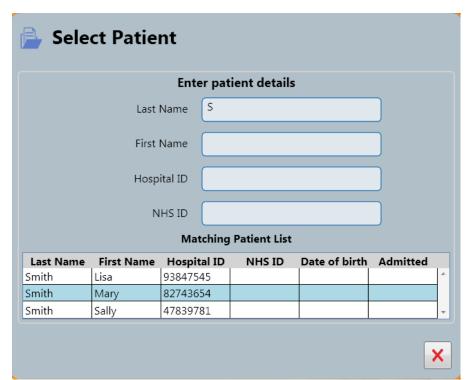


Select to set the baby delivered time and details.

# 3.5 Admit an existing patient



Select a bed.



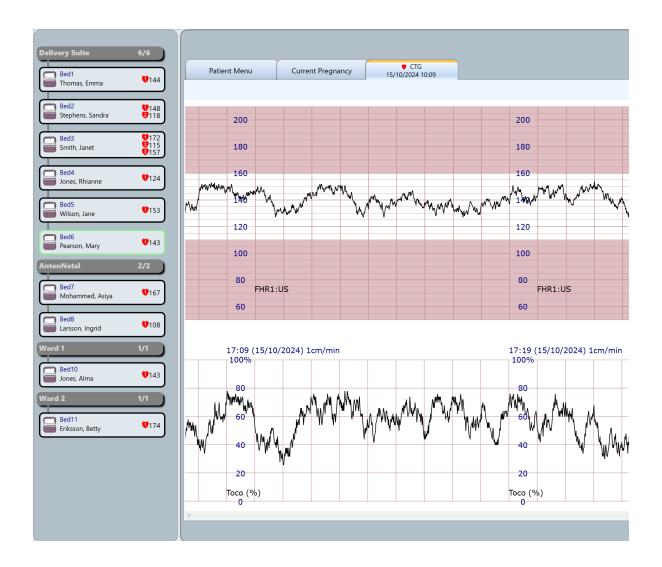
Enter patient details, matching patients will be displayed as you type.

Then click on the correct patient name in the 'Matching Patient List' and click on the 'button, or double click on the patient name.

IMPORTANT: Always check that the patient I.D. is correct – this is the only unique identifier, as there may be more than one patient in the database with the same name.

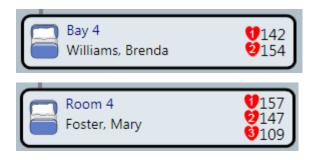


The bed symbol changes from light grey to dark grey indicating that the patient is now admitted to the bed.





Bed frame showing bed name, patient name and the heart rate data from the CTG. The bed frame border colour changes to green to show that this is the currently selected bed.

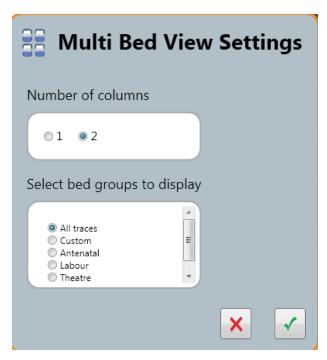


Bed frame showing twin and triplets heart rates.

### 3.6 Multi-bed view



Pressing this button displays the multi-bed view settings screen

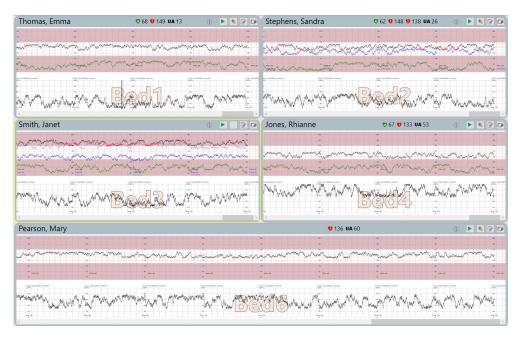


Select the number of columns view required (1 or 2).

Select the bed groups to display. This section allows the user to select specific beds to display in the multi bed view window. There are three options available.

- 1 The user can select all traces to display all beds with live CTG traces associated.
- 2 The user can select a specific bed group. All beds with live CTG traces associated with them within the selected group will be displayed.
- 3 The user can select 'custom'. A mixture of beds with live CTG traces associated with them can be selected from across all the bed groups.

The multi-bed view displays all beds with active traces.



The icons in the header bar for each trace operate in the same way as in single trace view. To select the single trace view for one of the traces, double click on the trace.

# 3.7 Reviewing stored patient data



Review stored patient data for a patient not currently booked into any bed.

# 3.8 Starting a CTG trace



Check that the fetal monitor is connected to the wall connection point.

Start monitoring the patient. This will automatically start the trace recording session.



If a trace is completed without admitting a patient, the trace will be unallocated. Refer to PRMT Tool section.

# 3.9 Stopping a CTG trace



Switch the fetal monitor off. After a short delay the CTG will close.

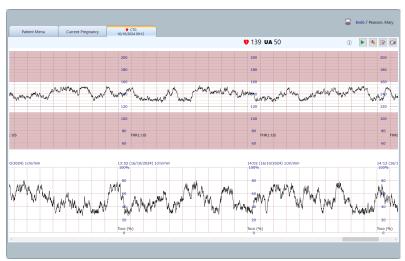


If the patient has left the bed, then you must remember to discharge the patient on the system.



If a new trace is started on a new patient, without first discharging the previous patient, the trace will be assigned to the previous patient. Refer to PRMT Tool section.

# 3.10 Single trace view



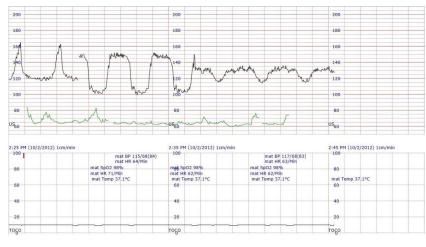
This is the default single patient view



Tab shows a patient name.



### 3.10.1 Trace details



The chart speed can be set to 1, 2 or 3cm/min.

FHR vertical scaling can be set to 20bpm/cm, over the range 50-210bpm, or 30bpm, range 30-240bpm.

TOCO scale covers the range 0 to 100% for external TOCO and 0 to 100mmHg for IUP monitoring.

When available, maternal heart rate (MHR) will be plotted in green on the FHR scale. All other maternal parameters will be displayed on the contractions scale.

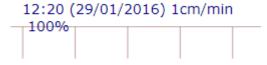
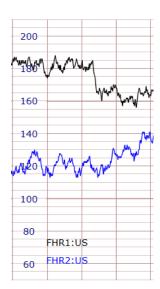
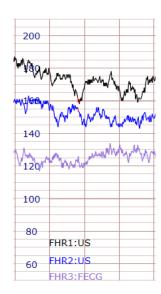


Chart date & time are displayed at fixed intervals between the FHR & TOCO scales. The interval is 10 minutes when the chart speed is set to 1cm/min.

- 80		
	FHR1:US	
+	FHR2:US	
60	THIXZ.UU	
	FHR3:FECG	

The FHR mode is annotated towards the bottom of the FHR chart as 'US' or 'FECG'.



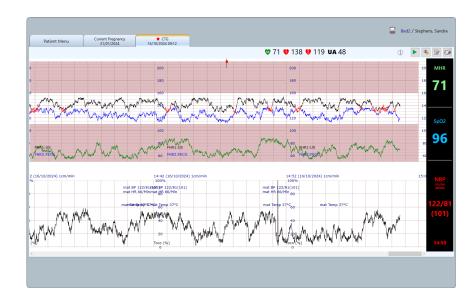


Twins FHR traces are presented in black and blue. For triplets, a third FHR is added to the trace, coloured purple.

### 3.10.2 Maternal Vital Signs View

There will be the option to activate a large, independent Maternal Vital Signs view in the Single and Multibed display. This will give the user better visibility of maternal observations.

### 3.10.2.1 Maternal vital signs activated in Single bed view



### 3.10.2.2 Maternal vital signs activated in Multi bed view

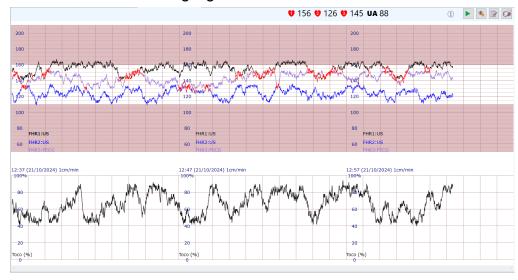


The default setting for the Maternal Vital Signs View will be OFF. Navigate to settings and check the Enabled box to activate the Maternal Vital Signs View.

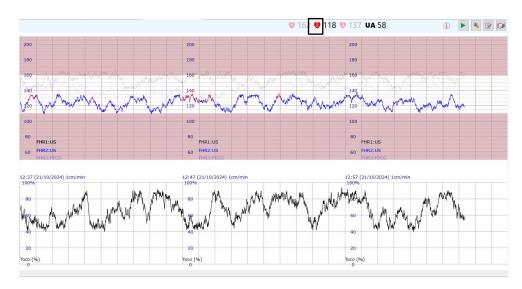


### 3.10.3 Twin and Triplet Fade out Function

Introducing the new enhanced Twin and Triplet Fade out Function. When monitoring Twins or Triplets Sonicaid Centrale does not Offset the Fetal Heart in the same way as the Fetal Monitor. The Fetal Heart Rates of both/all Fetuses are presented as they are with any coincidence in values highlighted in Red.

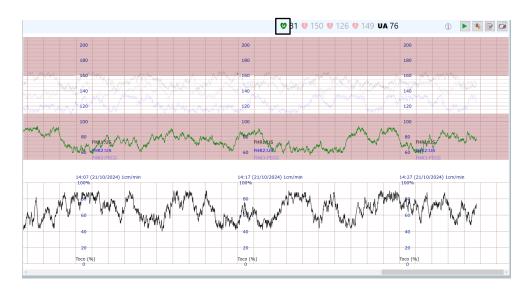


In order to view one Fetal Heart trace clearly, click on the heart of the fetus you want to view at the top of the trace.

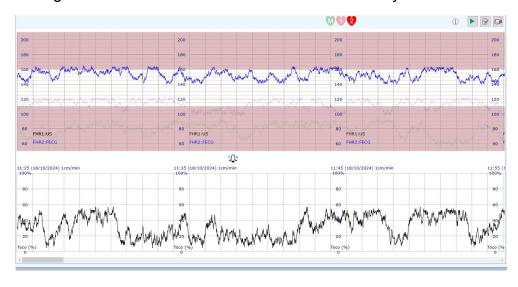


Now only the selected FHR will be in view with any other faded out in the background to enable easier interpretation.

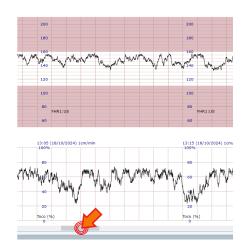
The Maternal Heart Rate can also be highlighted by clicking on the Green Heart at the top of the trace.



Fading out FHR on a stored trace works the same way.



### 3.10.4 Trace scrolling



Click & drag the scroll bar below the trace. This function is also available in multi-bed view for each trace.

After 1 minute, the trace will automatically scroll back to its current point.

#### 3.10.5 **Alerts**

Note that these alerts operate independently of the local alert system of each connected fetal monitor and the settings may be different.

These alerts are not clinical alerts, they are user alerts.



Although it has become standard practice in the industry to refer to these as, for example 'Tachycardia alarm', implying by its name some clinical significance, this is not the case. They do not interpret the FHR data in any way, they simply draw the user's attention to the fact that the FHR has been outside a user defined range for a user defined period of time.

Additionally, the Low & High FHR alerts make limited allowance for loss of signal & transient returns to rates within the user set limits. However, the presence of signal loss or transient returns to rates within the user set limits may result in these alerts not triggering.

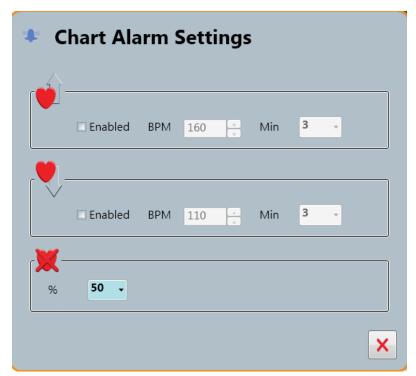
In the event of an alert, it remains the responsibility of the user to determine what has caused the alert, whether there is any clinical risk, and to ensure appropriate management.

Alerts can be disabled by the user, or the audio can be turned down or off.

The alerts in this product are provided as an adjunct to good clinical practice in checking the patient & reviewing the trace on a regular basis & must not be relied on to detect abnormalities in the trace.



Click to check or change alert settings.



The system includes alerts for the following:

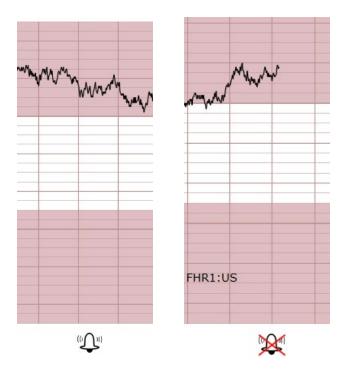
High FHR alert - alerts to FHR above the set threshold for a set time period.

Low FHR alert - alerts to FHR below the set threshold for a set time period.

Loss of signal alert - alerts to loss of FHR signal over a set percentage of a set time period. The system also includes a cross-

channel alert. This alerts users to conditions where the heart rate is the same (or similar) on any 2 heart rate channels (FHR1, FHR2, MHR).

Note that the cross-channel alert cannot be adjusted and is permanently enabled.



Alert threshold settings are shown on the chart by a change in background colour.

Alerts are indicated on the chart:

(\***O**\*)

Indicates an alert event.

Indicates alert event acknowledged

Hover over the icon to show further details of the alert.

If an alert is active on a bed, the heart symbol and the FHR data will flash

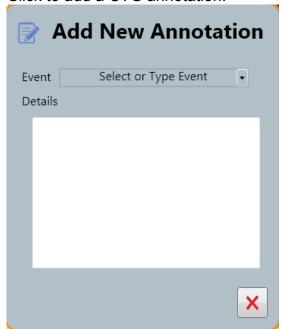


Yellow bell indicates active alert, click on it to acknowledge the alert.

### 3.10.6 Adding a trace annotation



Click to add a CTG annotation.



There are 3 data fields:

- Event: Click on the drop-down box for a predefined list of annotations.
   Alternatively, simply type free text into this field.
- 2. **Details**: Type details into this field.



An annotation is shown on the CTG. If this is on a stored trace, the mark will be grey instead of yellow.

Hover over the annotation to view the details.

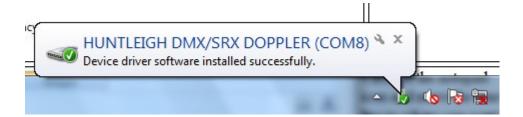
### 3.10.7 Printing a trace



Click to print the CTG.

The last page of a print-out shows a list of all annotation details.

### 3.10.8 Connecting SR series Doppler – optional



If non-rechargeable batteries are being used on the device, check the Doppler has had the battery type configured appropriately so as not to charge a non-rechargeable battery Connect the SR Doppler using a micro USB cable to the USB connection on the workstation.

The first time this is connected the device driver will be loaded



Switch on the Doppler, the 'SR Doppler' icon will appear showing the serial number at the top of the left hand side.



Click on the 'SR Doppler' icon to access stored and real time records

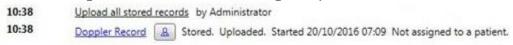
Click Associate this session with a bed' if a patient you are recording is already in a bed but does not have a CTG connected. This will start a real time recording from the SR Doppler and allocate to the patient.

Click 'Reset this session' to start new recording

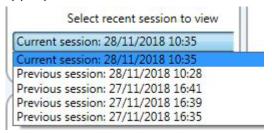


Upload all stored records - check Doppler is in the default numbers display mode

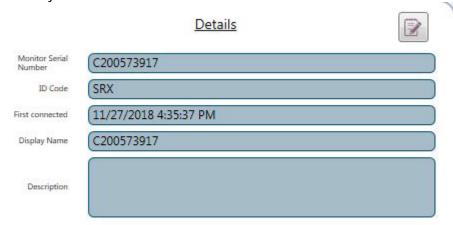
Select 'upload all stored records', click 'Doppler Record' to open saved recordings and the icon to the right to allocate the recording to a patient



From the drop down box select the connection session and allocate recordings to the patients as appropriate



Details of the Doppler will be shown, clicking the 'Details' icon will allow you to change the name displayed and enter a description for the device. This is stored against the device ID on the system and shown when it is connected.



### 3.10.9 CTG analysis (optional feature)

The ante

### **CTG Analysis Intended Use**

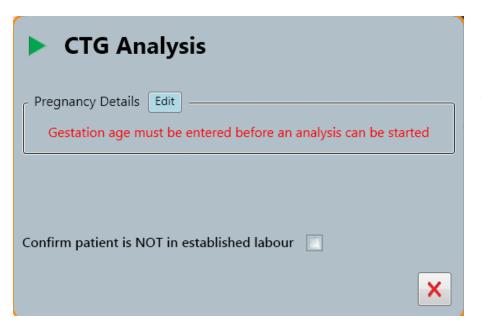
The intended use of the CTG analysis option is for the computerised analysis of antepartum cardiotocograms in pregnancies from 26 weeks gestation onwards (32 weeks in the USA). It can be used on women who are experiencing Braxton-

Hicks contractions but is not intended for use in established labour as the fetus is then exposed to additional factors such as labour contractions, pharmacological agents, and epidural anaesthesia.

The analysis provided is intended as an adjunct to - and not a replacement for - the clinician's visual assessment of a cardiotocogram. As such, this CTG analysis is an aid to clinical management but not a diagnosis, which remains the responsibility of an appropriately qualified clinician. Indeed, both the clinician's visual assessment of a cardiotocogram and the analysis provided by this software should be considered within the context of a full clinical assessment before decisions are made regarding management. Such an assessment may include further tests such as umbilical blood flow velocity waveforms or biophysical profiling.

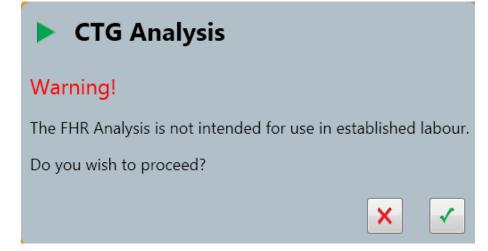


Click to start a CTG analysis.



Enter the gestational age (GA).

Click '√' to confirm that the patient is NOT in established labour.



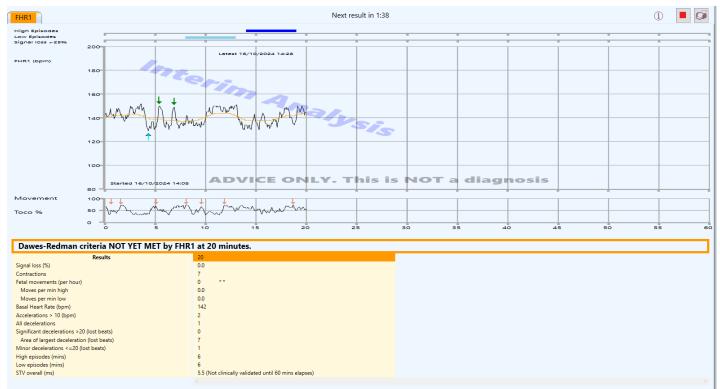
Should you choose to proceed with a CTG analysis while the patient is in labour, you MUST NOT rely on the analysis result



Indicates the start point of the analysis.



Indicates the end point of the analysis



If analysis results are not ready the screen will show "Awaiting results". The first result will be displayed after 10 minutes of good quality trace. This is updated every 2 minutes up to a maximum of 60 minutes.

The screen shows a compressed CTG with analysis results below.

Dawes-Redman criteria NOT MET by FHR1 at 12 minutes.

Dawes-Redman criteria NOT YET MET by FHR1 at 12 minutes.

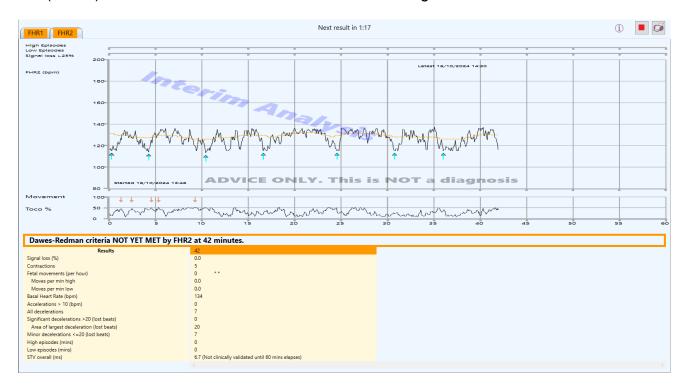
Dawes-Redman criteria MET by FHR1 at 12 minutes.

There are 3 possible outcomes as per these examples. Refer to the clinical training material for further information on understanding these outcomes.

### Criteria not met because:

- No moves and less than 3 accelerations
- Baseline fitting is uncertain

Where criteria is not met, or not yet met, moving the mouse pointer over the coloured result bar (above) will show the reasons for the criteria not being met.



For twins analyses click the tabs to switch between each fetus' analysis.

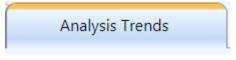
The tabs are colour coded in the same way as the results, indicating whether the latest result meets the criteria or not.



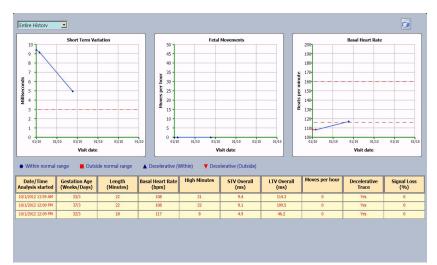
Click to print the analysis.



Click to stop a live analysis.



Click to select the trend view.



The trend view presents graphic plots of 3 key analysis parameters against time:

- STV
- **Fetal Movements**
- Basal heart rate

A minimum of 3 sets of traces and analyses are required to activate this function.

Note: Trends are not available for twins.



Click to select time period for the trend view.



Click to print the trend view.

#### 3.10.10 STAN



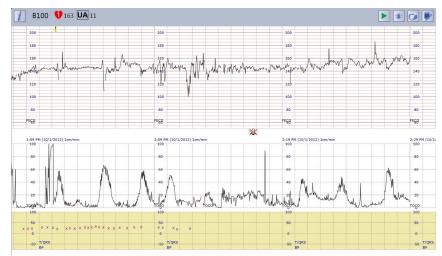
### STAN monitoring

The STAN functionality is an aid to clinical management but not a diagnosis, which remains the responsibility of an appropriately qualified clinician. Sonicaid Centrale is merely presenting data from the STAN monitor, and therefore, any clinical significance of the data is down to the user, who should refer to the STAN

documentation and Neoventa's guidelines.



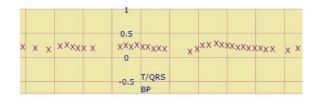
It is essential that users of this system are fully trained in using ST analysis and in understanding and interpreting such data. Huntleigh accept no responsibility for this & users are referred to Neoventa for all support in relation to this analysis.



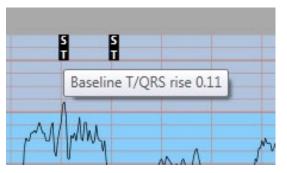
This option allows Sonicaid Centrale to receive ST analysis data from Neoventa STAN® fetal monitors when connected.

This data is displayed with the CTG trace & is archived as part of the CTG trace record.

NOTE: The scaling of the STAN area of the trace screen is different from that of a STAN monitor. Users who are familiar with STAN should be aware that data will be scaled differently on Sonicaid Centrale and could give the impression that the ST rise is lower than it actually is.



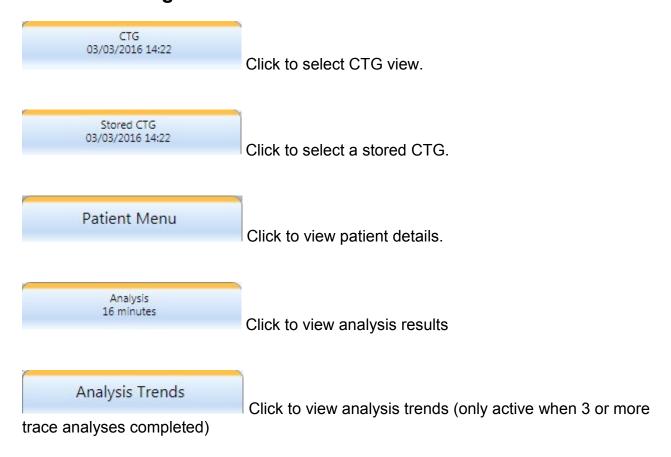
The t/qrs ratio data associated with the ST analysis is displayed on a separate chart below the contractions chart in the CTG trace view.



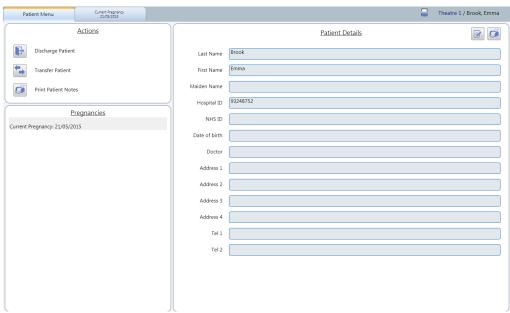
ST events are displayed at the top of the FHR scale.

Hover over the ST event mark to display additional information relating to the ST event.

# 3.11 Switching views

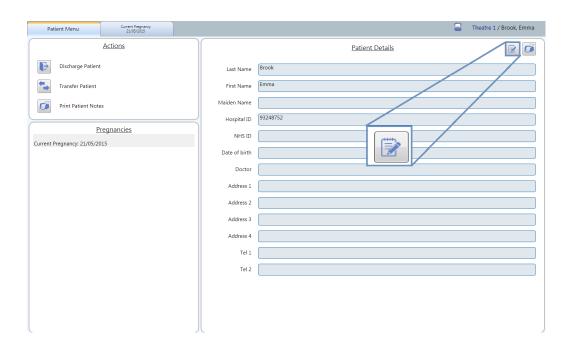


# 3.12 Patient details view



This view shows all activity associated with the patient.

# 3.12.1 Editing patient details

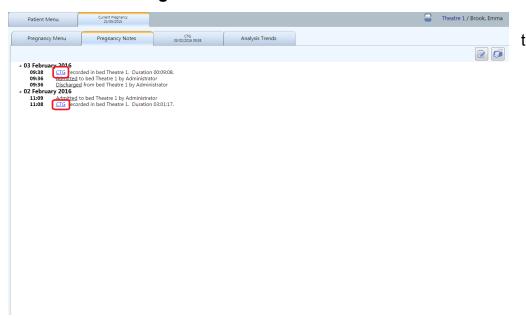


Press the edit details button.



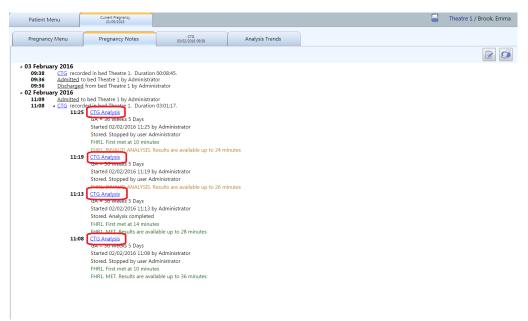
Edit details as required.

### 3.12.2 Retrieving stored CTGs



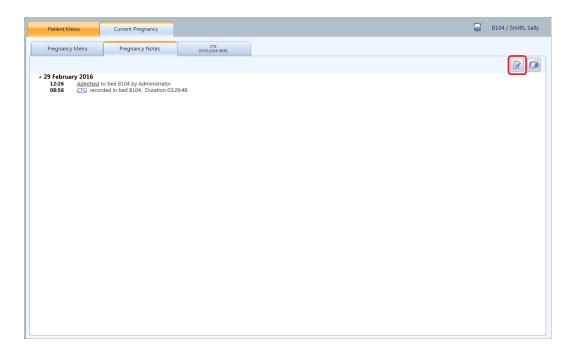
Click on the trace to be retrieved

# 3.12.3 Retrieving stored analysis results

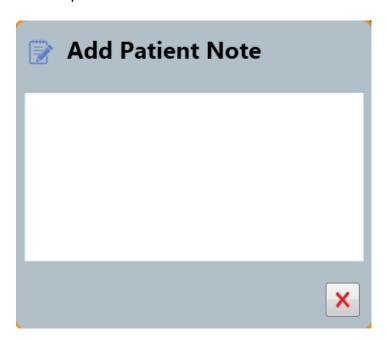


Click to expand the CTG details and click on the analysis to be reviewed.

# 3.12.4 Adding patient notes



# To add patient notes

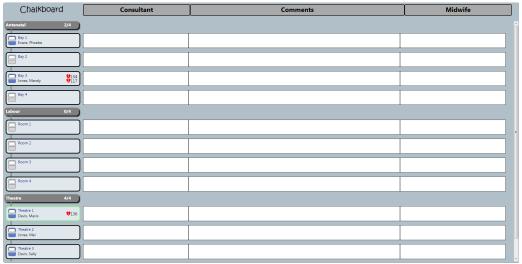


Type notes as required

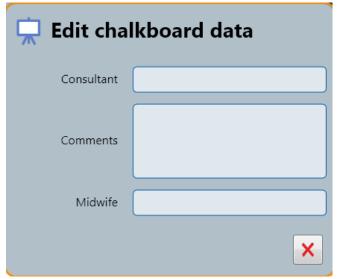
## 3.12.5 Chalkboard (optional feature)



Click to open the chalkboard.



The chalkboard provides an overview of the current status of all beds. Each bed has a chalkboard entry associated against it. To add or edit chalkboard data, click on the desired chalkboard field.



Enter or edit data in the chalkboard data view.

If a bed has no patient associated to it, chalkboard data cannot be added to that entry.

## 3.12.6 Discharging a patient



Click to discharge a patient from a bed.

The system can be configured to automatically discharge a patient after a CTG has been switched off. After the CTG has been switched off the bed will be shown in orange until the patient is discharged.

## 3.12.7 Settings, Audit and Admin

The settings available to change for a user will depend on the user access level.



Select the 'settings, audit and admin' button.

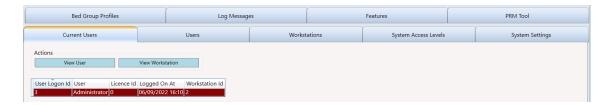


Four buttons appear:

- Admin access.
- User settings.
- System audit.
- · GDT settings.



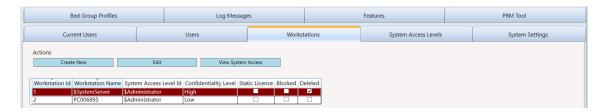
Admin access.



Current user: A list of current users logged on to the system.



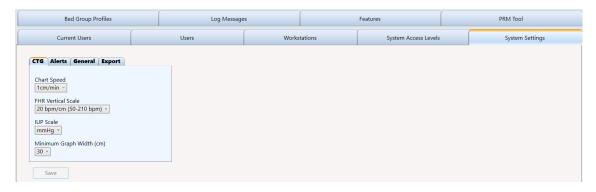
Users: A list of current users and their user access levels.



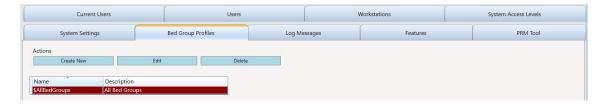
Workstations: A list of workstations which have access to the system.



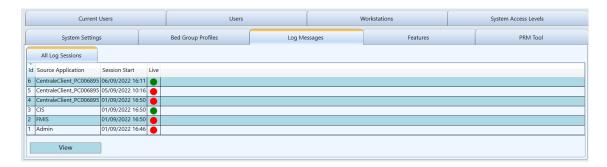
System access levels: Create and edit system access levels.



System settings: System wide CTG settings and general settings.



Bed group profile: Create new and edit existing bed group profiles.



Log messages: Displays any errors that have occurred.



Features: Displays all features available and which ones have been licensed



### User settings.

Allows the logged on user to set specific CTG settings and which bed group profile they wish to use (if any).



### System audit.

A comprehensive audit of all user transactions



### GDT settings.

Enable GDT. Setup incoming and outgoing GDT file locations. Select which file format extension is to be used

## 4 PRM Tool

The Patient Record Maintenance Tool (PRMT) is used to manage CTG traces (recorded from CTG machines or SR Dopplers), which have been allocated to the wrong patient or left un-allocated, unless the system has been configured to start saving data once the patient has been allocated to the bed.

When a trace is moved, any analysis sessions or annotations that are marked on the trace will move along with the trace.

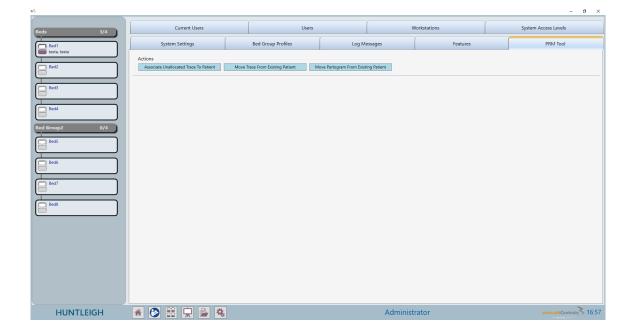
The PRM tool is built into the client application within the administrator tab, and all actions carried out using this tool are audited if the security & audit option has been purchased. Access to the PRM tool is controlled by user access levels (if Security & audit option purchased), where only users with appropriate access rights have access.

Changes made to patient record(s) are updated in real time and do not require any other interaction.

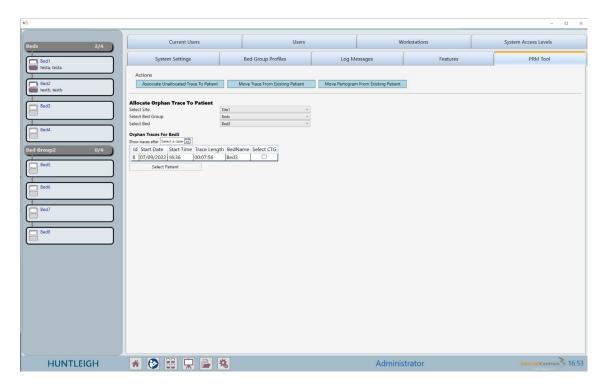
## 4.1 Allocating unallocated traces

If a CTG is switched off before the trace has been allocated to a patient, it can be restored to a patient record using the PRM tool.

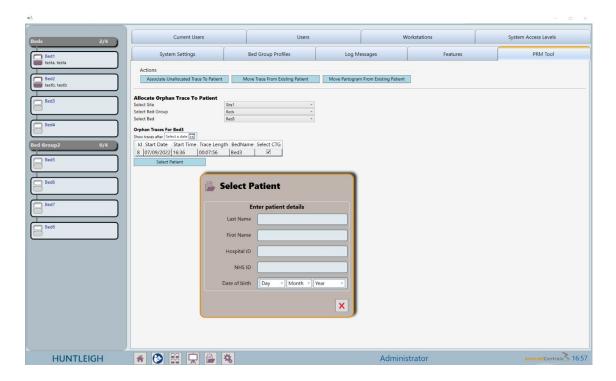
The tool is accessed from the administrator window and the tool should be selected as below.



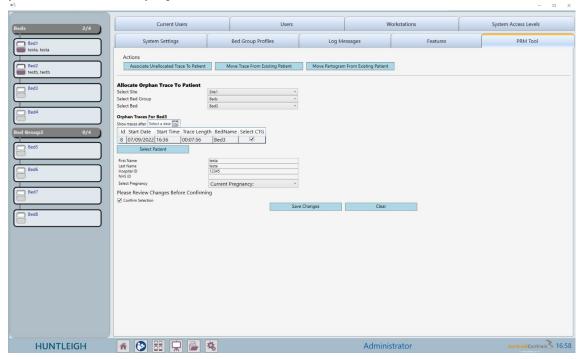
To allocate an unallocated trace select the first action 'Associate Unallocated Trace to Patient'.



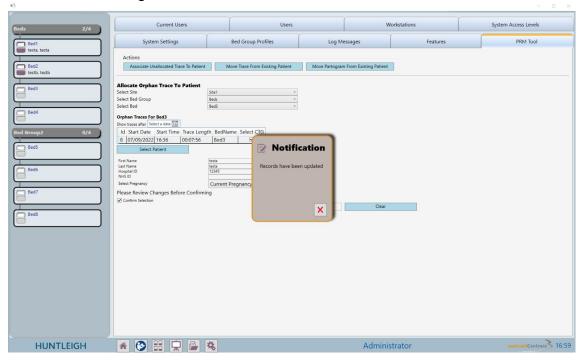
Select the site, bed group and bed to show unallocated traces that are available; these can be filtered by using the date filter.



Enter the patient details for the patient this trace is to be allocated to and select the patient from the displayed list.



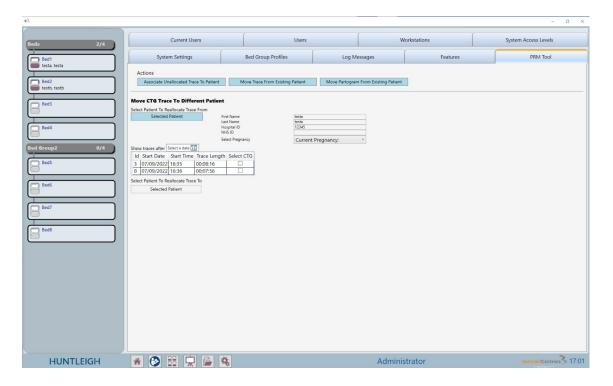
Select the pregnancy this record relates to. Tick the box to confirm selections and select 'Save Changes'.



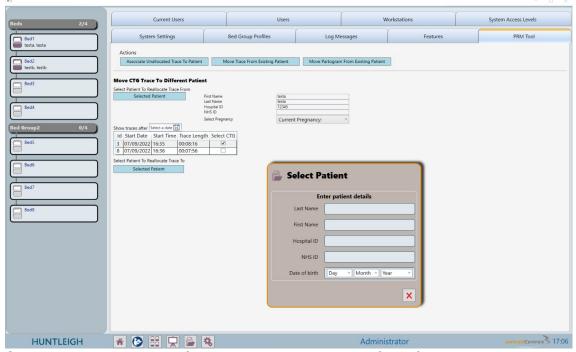
The trace allocation will then be shown in the patient notes against the date & time it was originally recorded

16:36 CTG Stored. recorded in Bed1. Duration 00:07:56. Trace Reallocated

# 4.2 Move trace from Existing Patient

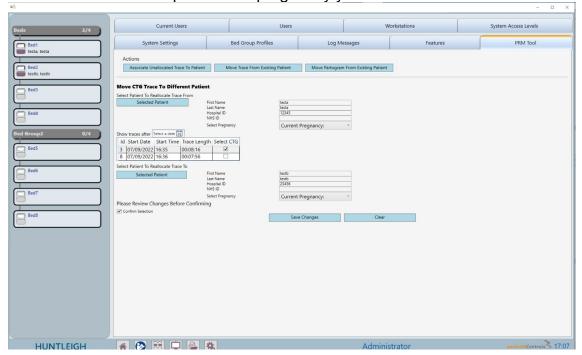


Select the 'Move trace from Existing Patient,' enter the patient name and select from the list.

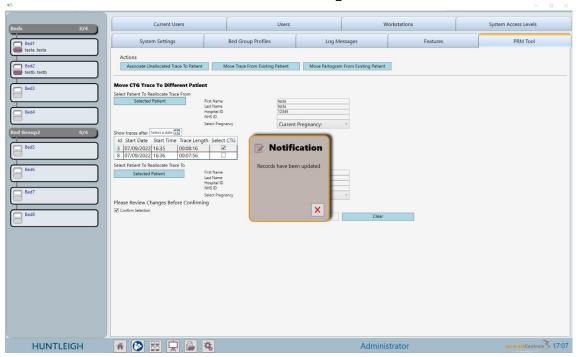


Select the required trace from the list using the date filter if appropriate and pregnancy (current or previous ones).

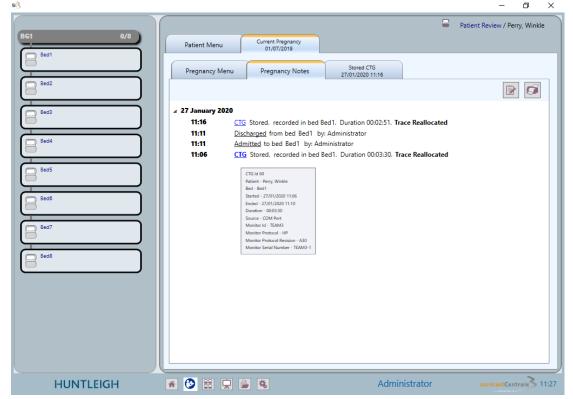
Enter the details of the patient and pregnancy you wish to move the trace to.



Select Confirm Selection and then 'Save Changes'.



Confirmation of the trace move is shown and the trace shown in the patient record below.



When hovering the mouse over the 'Trace reallocated' text further details are shown in the notes list.

09:14 CTG Stored. recorded in bed Bed4. Duration 00:05:04. Trace Reallocated

Trace moved from Jane Jenkins NHS ID: Hospital ID: 456464

# 5 Trouble-shooting

Due to the nature of the system, it is not possible to cover all possible areas of trouble-shooting in this manual. This section includes first-line trouble-shooting relating primarily to difficulties in using the system. For more in-depth system support refer to your system administrator.

Problem	Possible solutions / explanations
Screen is blank	-Check screen connected to mains power.
	-Check power is switched on at mains socket
	-Check screen on/off switch is On. On most screens there is a small green or amber light – confirm that this is lit.
	-Blank screensaver may have been activated – move/click mouse or enter
	keystroke on keyboard to re-activate screen
	-Computer may have been switched off.
Not receiving data	-Check CTG is switched on and working (note – CTG printer does not need
from CTG	to be running)
	-Check CTG is connected to wall socket in room – check cable connectors
	are secure
	-Book patient into bed – traces cannot be viewed until this is done
Unable to annotate	-Traces can only be annotated within the timeframe of the trace, not on the
trace	blank grid area to the right of the trace.

System not responding	Check connections between the computer, keyboard, mouse and the network socket.
	Refer to your administrator – the server may need to be shut-down and restarted – do NOT attempt to do this unless authorised and trained.
All access terminals shut-down and not responding	Power cut – the main server will be supported for a short time by the UPS (depending on model) – typically about 10-15 minutes. After this, if power is not restored, the server will be shut-down. When power is subsequently restored, the whole system will need to be re-started – contact your administrator or IT department If power is restored before the server shuts down, simply re-start all access terminals.
Mouse / Keyboard not responding	Check cable and connection
Print-outs not printing	Check printer is switched on, is 'On-line' and has sufficient paper loaded. For ink-jet printers, ink cartridge may need replacing – refer to printer manual for details.  For laser printers, toner may need replacing – refer to printer manual for details.
System error message appears on screen	During system maintenance, while shutting down or re-starting the system, error messages may appear – these will normally clear themselves after a short delay. If the message does not clear after ~1 minute, contact your system administrator or first line support team.

# 6 System maintenance

### 6.1 General maintenance

The only scheduled maintenance required is to back up the database. This is subject to local policy and is normally managed by your IT department. Contact your system administrator or IT department for details.

IMPORTANT: In the event of hardware failure, software bugs or other system related problems, disk storage overflow, etc., data may be lost at any time. Note that data may also be lost in the event of network issues and other infrastructure issues which are managed by and remain the responsibility of the customer. The customer is responsible for ensuring that regular back-ups of the database are kept in accordance with established industry practice, local protocols and guidelines. Failure to do so may result in total loss of all patient information, CTG trace records, etc.

Huntleigh Healthcare cannot, under any circumstances, accept any responsibility for loss of, or corruption of, any stored data relating to Sonicaid Centrale. Such data is the property of the customer who is solely responsible for protecting it.

No other maintenance is required, other than cleaning and checking for damage. This can be included in your routine local equipment maintenance programmes.

If you have maintenance contract cover, contact your system administrator or supplier for details. Note that this does not include data back-up which at all times remains the responsibility of the customer.

# 7 Service support

First-line support is provided by your local super-user or local IT support. For service support & details of maintenance contracts, contact your supplier.

### 7.1 Licence renewal

The use of this software is controlled by a licence key. To extend or renew your licence, or to add software options, refer to the installation instructions supplied with the product. Contact your supplier for further information on options, upgrades & support.

As part of the ongoing development programme, the company reserves the right to modify specifications and materials of the Sonicaid Centrale without notice.

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If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

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ArjoHuntleigh AB Hans Michelsensgatan 10 211 20 Malmö, Sweden



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