

sonicaid[®]

FetalCare

Instructions for use

Document No. 775300-EN-8
06/2020

1	Introduction	3
1.1	Intended use	3
1.2	Contra-indications	3
1.3	Precautions & warnings	4
1.4	Service Life	6
2	Getting started	7
2.1	Screen layout	7
3	System operation	8
3.1	Home page	8
3.1.1	To return to the home page	8
3.1.2	Help	8
3.2	Bed & bed group functions	9
3.3	Adding a new patient:	9
3.4	Admit an existing patient	10
3.5	Multi-bed view	11
3.6	Reviewing stored patient data	12
3.7	Starting a CTG trace	12
3.8	Stopping a CTG trace	12
3.9	Single trace view	13
3.9.1	Trace details	14
3.9.2	Trace scrolling	15
3.9.3	Alerts	15
3.9.4	Adding a trace annotation	18
3.9.5	Printing a trace	18
3.9.6	Connecting SR series Doppler – optional	19
3.9.7	CTG analysis (optional feature)	20
3.9.8	STAN	25
3.10	Switching views	27
3.11	Patient details view	27
3.11.1	Retrieving stored CTGs	28
3.11.2	Retrieving stored analysis results	29
	Click to expand the CTG details and click on the analysis to be reviewed.	29
3.11.3	Adding patient notes	29
3.12	Discharging a patient	30
3.13	Settings, Audit and Admin	30
3.14	System Settings	31
3.15	Log Messages	32
4	PRMT Tool	33
4.1	Allocating unallocated traces	33
4.2	Move trace from Existing Patient	36
5	Trouble-shooting	39
6	System maintenance	40
6.1	General maintenance	40
7	Service support	40
7.1	Licence renewal	40

1 Introduction

Sonicaid Fetalcare 3 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

1.1 Intended use

Sonicaid Fetalcare 3 is not a stand-alone medical device – it can only be used as part of a networked CTG system when connected to one or more fetal monitors.

It supports a range of makes/models of fetal monitor and can support up to 8 bed connections. Equally, there is no guarantee as to how many the system can support, as this will be determined by other factors such as server resource, network capacity and other local infrastructure limitations which are beyond our control.

Its primary intended uses include:

- Collection of real-time data from one or more fetal monitors.
- Displaying CTG traces.
- Archiving of CTG traces and associated data.
- Retrieval of archived traces and associated data for review.
- Alert functions relating to fetal parameters.
- Optional Dawes/Redman CTG analysis.
- STAN fetal monitors.
- Managing patients, entering notes, adding annotations and printing.

1.2 Contra-indications

Sonicaid Fetalcare 3 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 Precautions & warnings



3rd Party Software

Sonicaid Fetalcare 3 is designed to run on a dedicated PC/server. Under no circumstances must any 3rd 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 3rd 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 Fetalcare 3 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 Fetalcare 3 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 Fetalcare 3, 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 Fetalcare 3 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 www.huntleigh-diagnostics.com for further information on the CTG analysis.

**Potential loss of clinical data**

Installing FC3 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 (eg. MS Windows “Bubbles”) may cause confusion as the FC3 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.

Product Labelling			
	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		Device Identification code
	Medical Device		Cardboard packaging can be recycled.
	Catalogue Number		

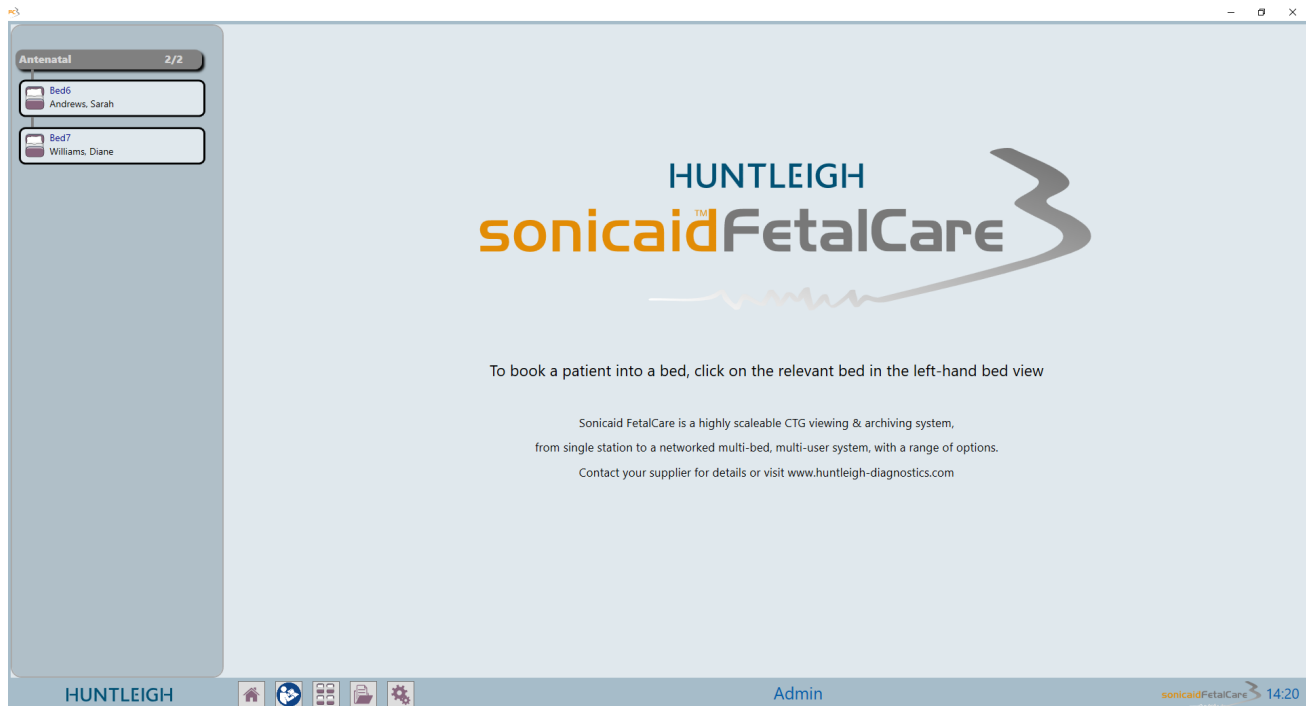
1.4 Service Life

Huntleigh Healthcare state that the lifetime of the Sonicaid Fetalcare (HD775) product range is for as long as it is compatible with the available software and hardware systems. Therefore a definitive lifetime cannot be given. The intended service life for the device is at least 7 years.

2 Getting started

2.1 Screen layout

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

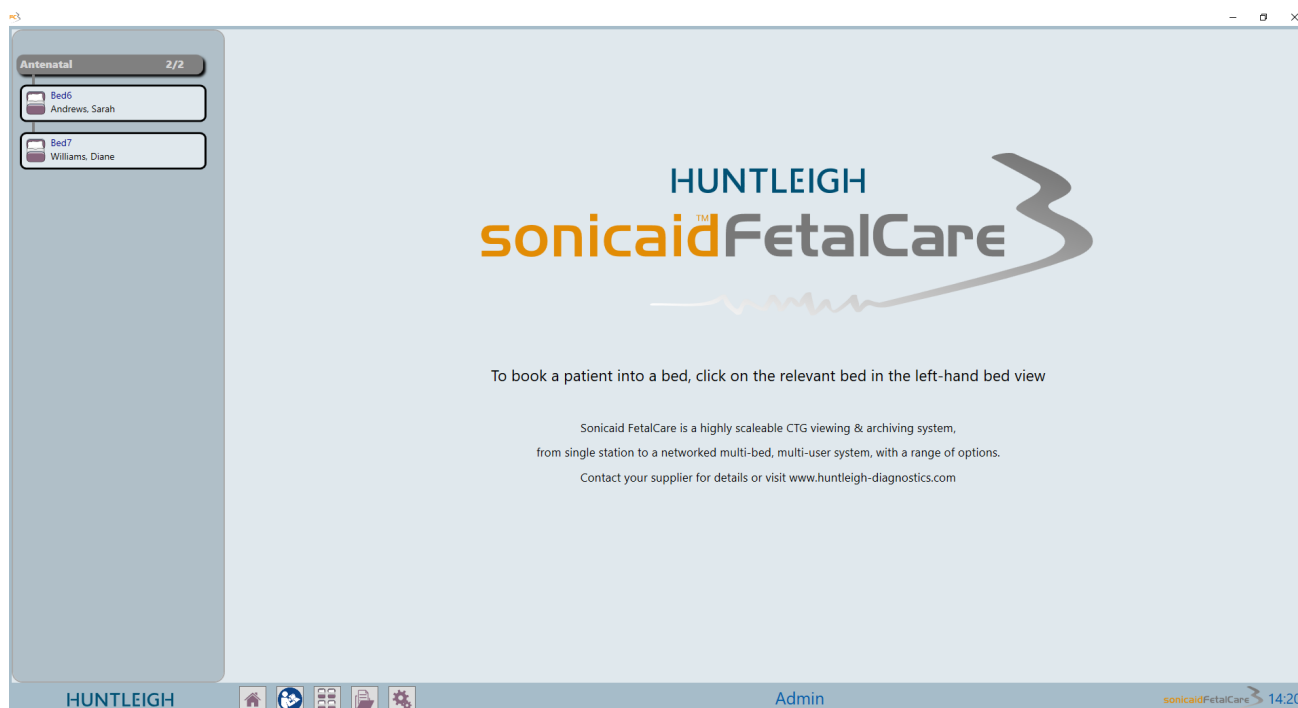


- The left hand view, lists the beds contained within the system.
- The right hand view will contain one of the following at any one time
 - Home page
 - Single trace view
 - Multi trace view
 - Patient record view
 - Analysis results view (where option installed)
 - Analysis trend view (where option installed)
 - Optional SR Doppler connection
 - GDT (where option installed)

3 System operation

Starting the Sonicaid Fetalcare 3 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



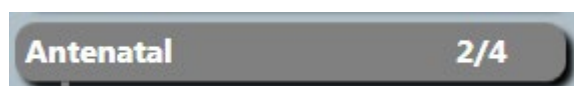
Click for 'Instructions for use'

3.2 Bed & bed group functions



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

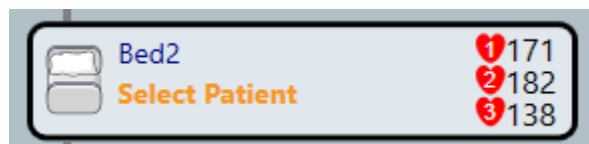
Click on a bed to admit a patient or view a CTG trace.



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:

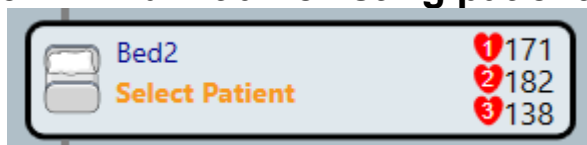


Select a bed.

A screenshot of the 'Select Patient' dialog box. It has a title bar with a folder icon and the text 'Select Patient'. Below the title bar is a section titled 'Enter patient details' which contains four text input fields: 'Last Name', 'First Name', 'Hospital ID', and 'NHS ID'. At the bottom right of the dialog box is a red 'X' button.

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

3.4 Admit an existing patient



Select a bed.

Select Patient

Enter patient details

Last Name

First Name

Hospital ID

NHS ID

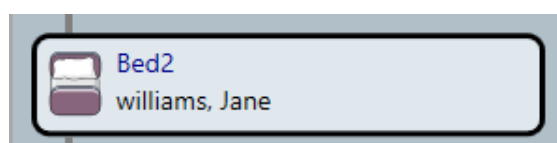
Matching Patient List

Last Name	First Name	Hospital ID	NHS ID	Date of birth	Admitted
Smith	Lisa	93847545			
Smith	Mary	82743654			
Smith	Sally	47839781			

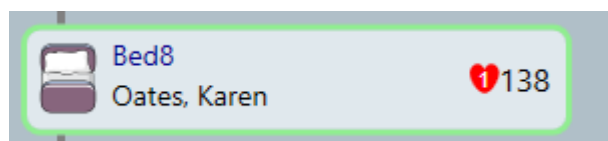
Enter patient details, matching patients will be displayed as you type.

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

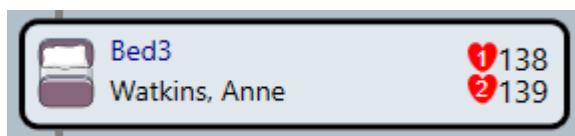
IMPORTANT: Always check that the patient I.D. is correct – this is the only unique identifier, as there may be more than one patient in the database with the same name.



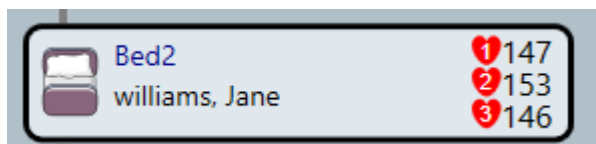
The bed symbol changes from light grey to dark grey, indicating that the patient is now admitted to the bed.



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.



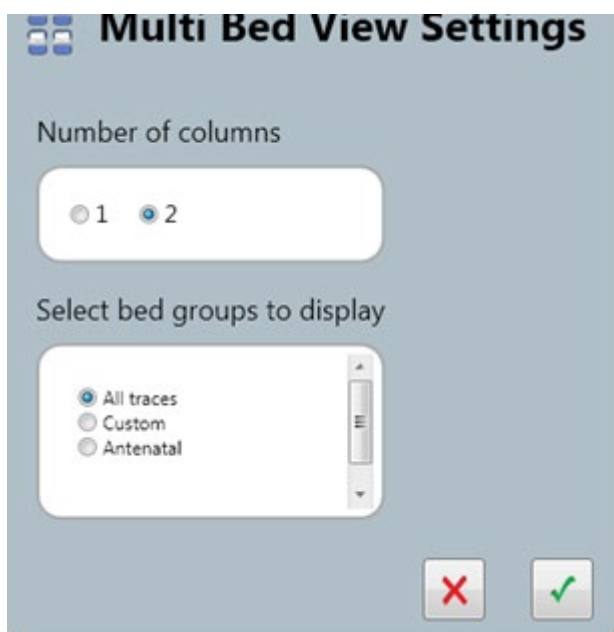
Bed frame showing twin and triplets heart rates.



3.5 Multi-bed view



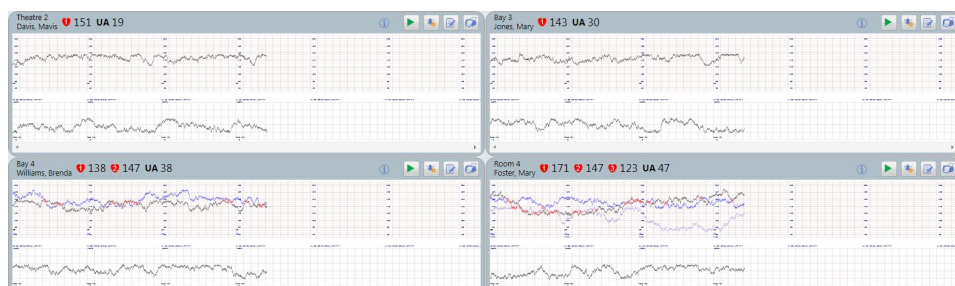
Pressing this button displays the multi-bed view settings screen



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.

3.6 Reviewing stored patient data



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

3.7 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. See PRMT tool section

3.8 Stopping a CTG trace



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

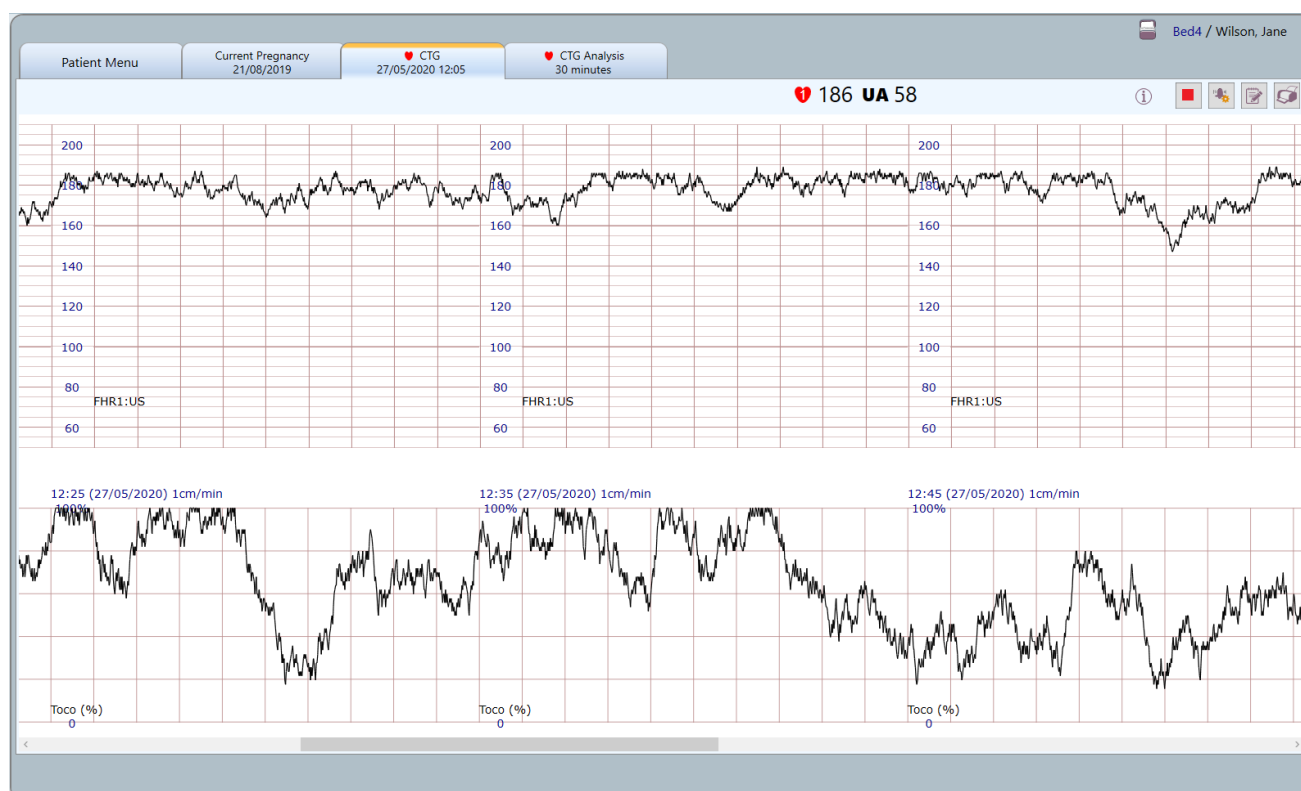


If the patient has left the bed, then you must remember to discharge the patient on the system.



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. See PRMT tool section.

3.9 Single trace view

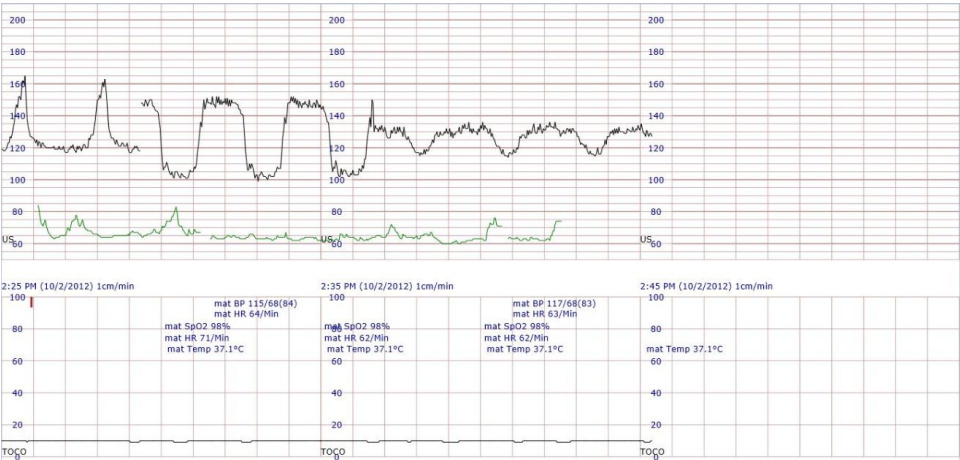


This is the default single patient view.

 154 UA 45

Shows bed name and FHR data.

3.9.1 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.

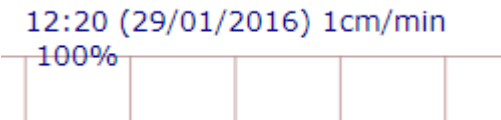
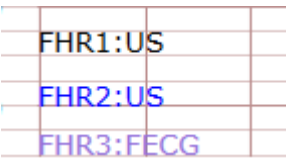
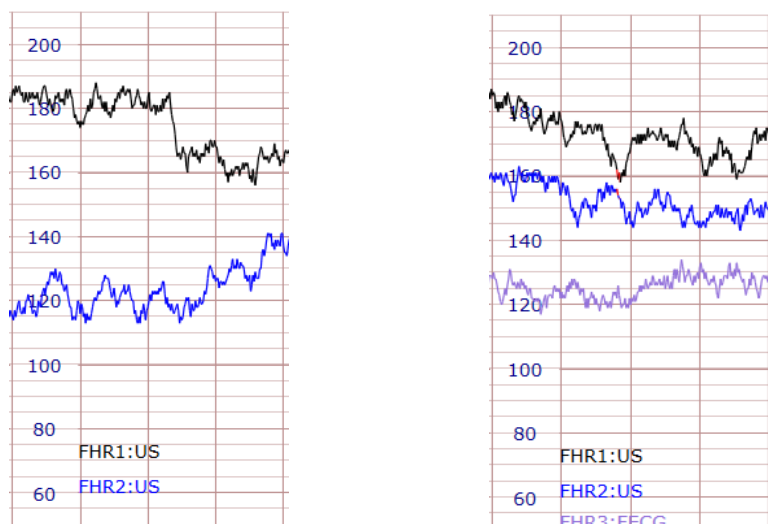


Chart date & time are displayed at fixed intervals between the FHR & TOCO scales. The interval is 10 minutes when the chart speed is set to 1cm/min.

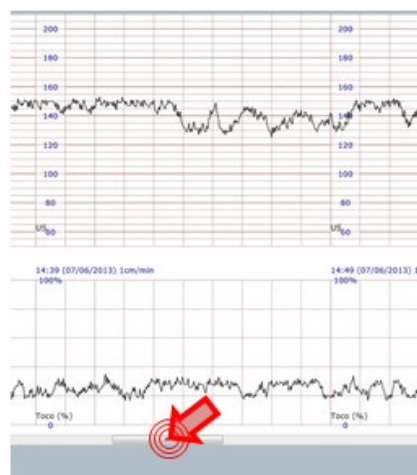


The FHR mode is annotated towards the bottom of the FHR chart as 'US' or 'FECG'.



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

3.9.2 Trace scrolling



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

3.9.3 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.

Chart Alarm Settings

☒ Enabled BPM 160 Min 3

☒ Enabled BPM 110 Min 3

% 50

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:



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.

3.9.4 Adding a trace annotation



Click to add a CTG annotation.

There are 3 data fields:

1. **Event:** Click on the drop-down box for a pre-defined list of annotations. Alternatively, simply type free text into this field.
2. **Details:** Type details into this field.
3. **Author:** Enter your name.



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

Hover over the annotation to view the details.

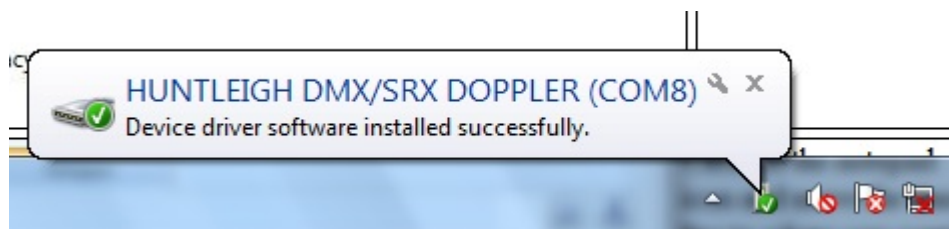
3.9.5 Printing a trace



Click to print the CTG.

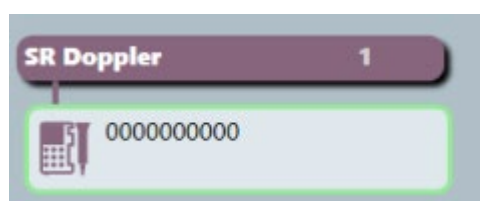
The last page of a print-out shows a list of all annotation details.

3.9.6 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' button to access stored 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.

10:38 Upload all stored records by Administrator
10:38 Doppler Record  Stored. Uploaded. Started 20/10/2016 07:09 Not assigned to a patient.

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

Select recent session to view

- Current session: 28/11/2018 10:35
- Current session: 28/11/2018 10:35
- Previous session: 28/11/2018 10:28
- Previous session: 27/11/2018 16:41
- Previous session: 27/11/2018 16:39
- Previous session: 27/11/2018 16:35

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.

Details 

Monitor Serial Number	C200573917
ID Code	SRX
First connected	11/27/2018 4:35:37 PM
Display Name	C200573917
Description	

3.9.7 CTG analysis (optional feature)



CTG Analysis Intended Use

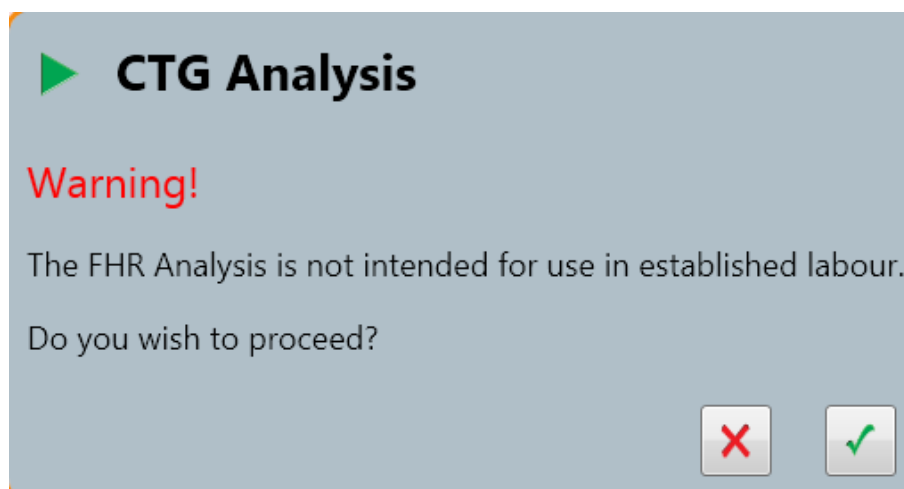
The intended use of the CTG analysis option is for the computerised analysis of antepartum cardiotocograms in pregnancies from 26 weeks gestation onwards (32 weeks in the USA). It can be used on women who are experiencing Braxton-Hicks contractions but is not intended for use in established labour as 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.

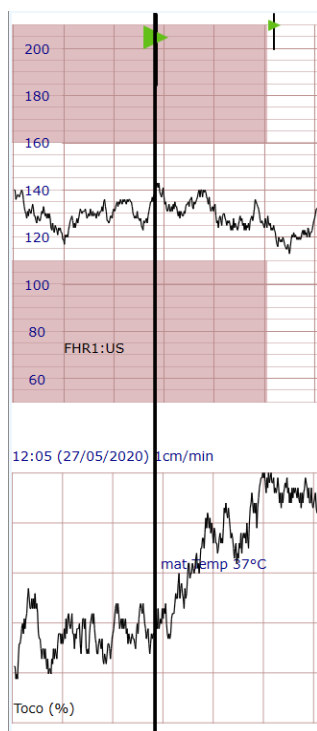


Click to start a CTG analysis.

Enter the gestational age (GA).

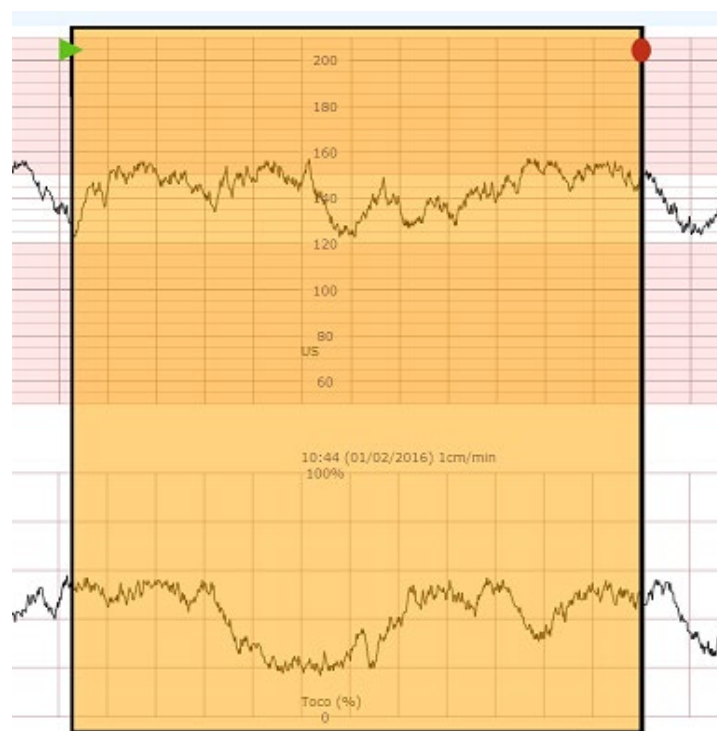


Should you choose to proceed with a CTG analysis while the patient is in labour, you **MUST NOT** rely on the analysis result.



For 'One Mark' analysis, place the vertical marker at the desired start point and click.

Note that there may be up to 10 minutes delay before any analysis results become available.



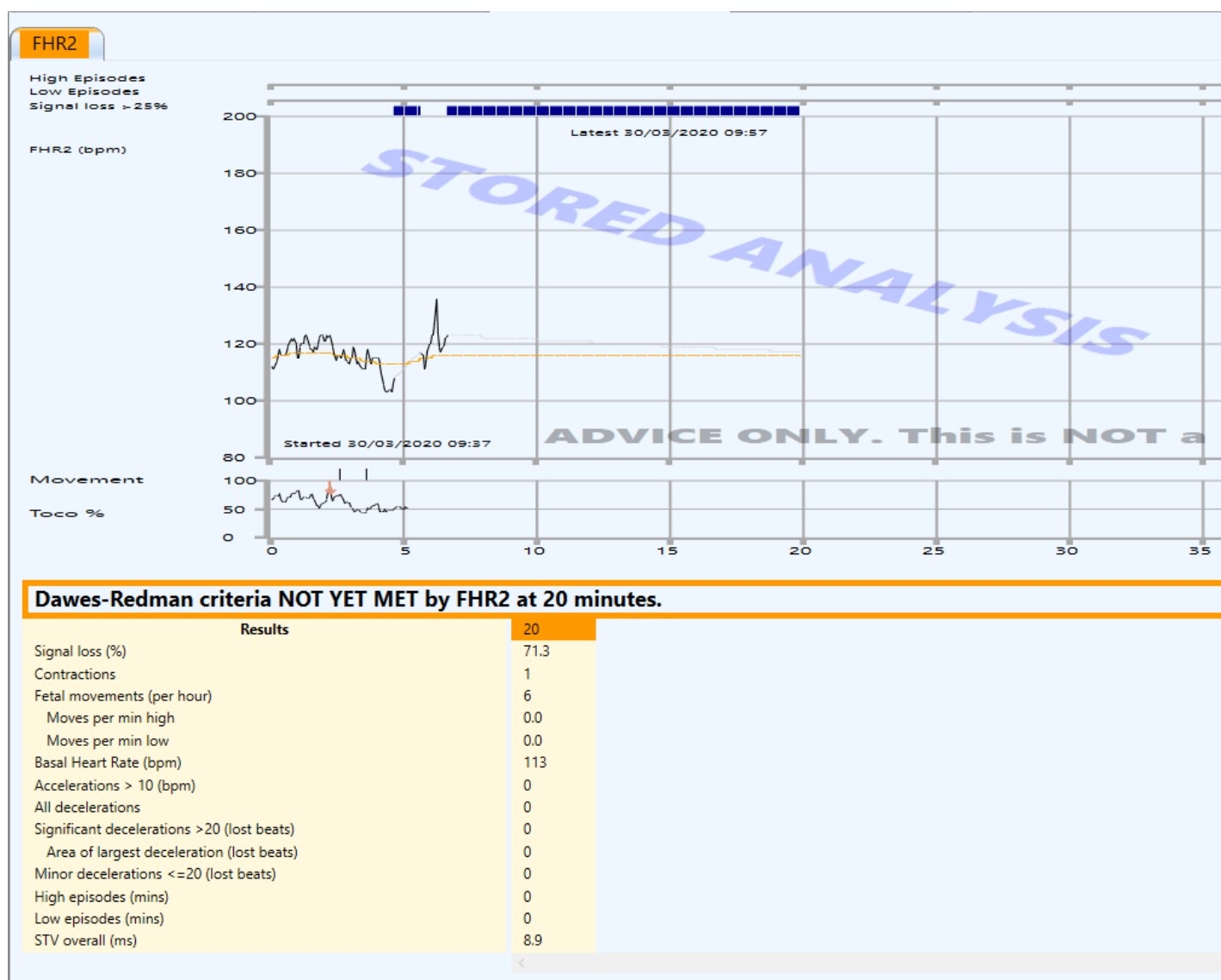
For 'Two Mark' analysis, place the first vertical marker at the desired start point and click. Move to the desired end point and click to place the second marker, which will move in 2 minute steps.



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.

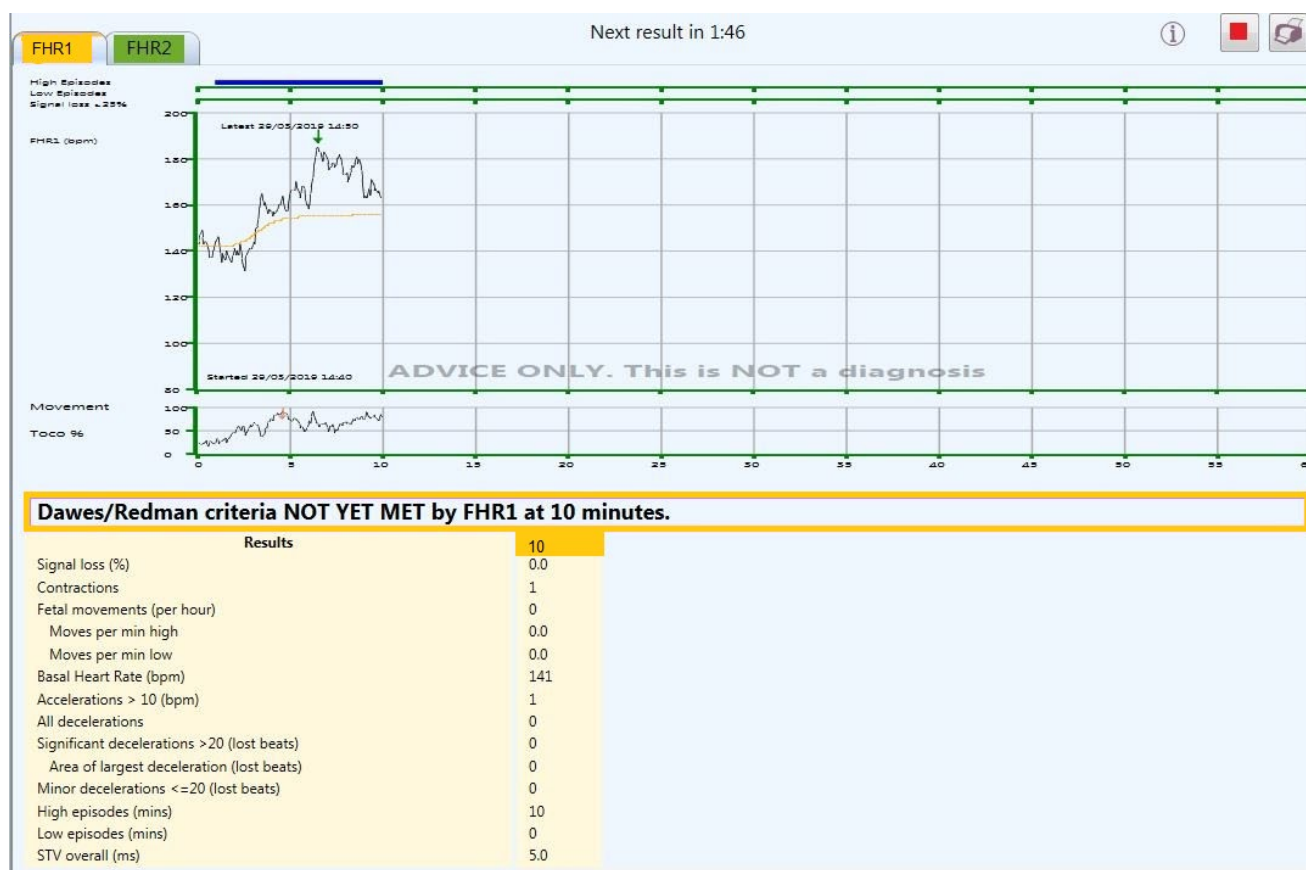
Dawes-Redman criteria MET by FHR1 at 12 minutes.

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

Analysis Trends

Click to select the trend view

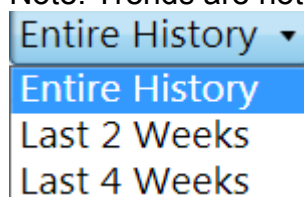


The trend view presents graphic plots of 3 key analysis parameters against time:

- 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.

3.9.8 STAN

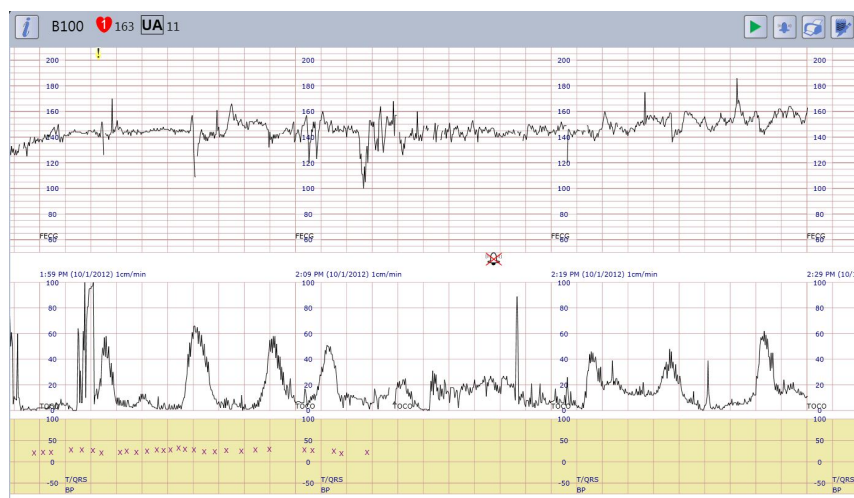


STAN monitoring

The STAN functionality is an aid to clinical management but not a diagnosis, which remains the responsibility of an appropriately qualified clinician. Sonicaid Fetalcare 3 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.



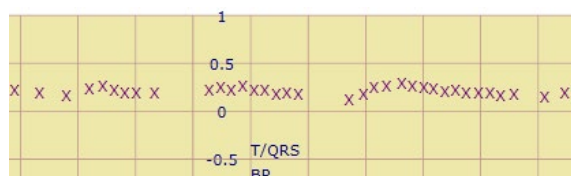
It is essential that users of this system are fully trained in using ST analysis and in understanding and interpreting such data. Huntleigh accept no responsibility for this & users are referred to Neoventa for all support in relation to this analysis.



This option allows Sonicaid Fetalcare 3 to receive ST analysis data from Neovanta 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 Fetalcare 3 and could give the impression that the ST rise is lower than it actually is.



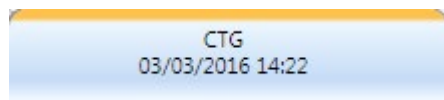
The t/qrs ratio data associated with the ST analysis is displayed on a separate chart below the contractions chart in the CTG trace view



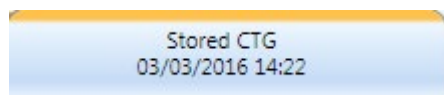
ST events are displayed at the top of the FHR scale.

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

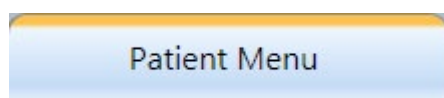
3.10 Switching views



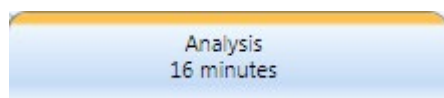
Click to select CTG view.



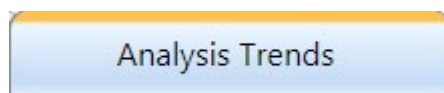
Click to select a stored CTG.



Click to view patient details



Click to view analysis results



Click to view analysis trends (only active when 3 or more trace analyses completed)

3.11 Patient details view

A screenshot of the 'Patient Menu' view. The top bar shows 'Patient Menu', 'Current Pregnancy 21/05/2015', and 'Theatre 1 / Brook, Emma'. The main area is divided into two panels. The left panel has two sections: 'Actions' with buttons for 'Discharge Patient', 'Transfer Patient', and 'Print Patient Notes'; and 'Pregnancies' with a sub-header 'Current Pregnancy: 21/05/2015'. The right panel is titled 'Patient Details' and contains a form with fields for: Last Name (Brook), First Name (Emma), Maiden Name, Hospital ID (93248752), NHS ID, Date of birth, Doctor, Address 1, Address 2, Address 3, Address 4, Tel 1, and Tel 2.

This view shows all activity associated with the patient.

Editing patient details

Patient Menu

Current Pregnancy
21/05/2015

Theatre 1 / Brook, Emma

Actions

Discharge Patient

Transfer Patient

Print Patient Notes

Pregnancies

Current Pregnancy: 21/05/2015

Patient Details

Last Name

Brook

First Name

Emma

Maiden Name

Hospital ID

93248752

NHS ID

Date of birth

Doctor

Address 1

Address 2

Address 3

Address 4

Tel 1

Tel 2

Press the edit details button.

3.11.1 Retrieving stored CTGs

Patient Menu

Current Pregnancy
21/05/2015

Theatre 1 / Brook, Emma

Pregnancy Menu

Pregnancy Notes

CTG
03/02/2016 09:38

Analysis Trends

03 February 2016

09:38

CTG

recorded in bed Theatre 1. Duration 00:09:08.

09:36

Admitted to bed Theatre 1 by Administrator

09:36

Discharged from bed Theatre 1 by Administrator

02 February 2016

11:09

Admitted to bed Theatre 1 by Administrator

11:08

CTG

recorded in bed Theatre 1. Duration 03:01:17.

Click on the trace to be retrieved.

3.11.2 Retrieving stored analysis results

The screenshot displays the 'Pregnancy Notes' tab for a patient named Brook, Emma, in Theatre 1. The interface shows a list of events for 03 February 2016. Key events include:

- 09:38 CTG recorded in bed Theatre 1. Duration 00:08:45.
- 09:36 Admitted to bed Theatre 1 by Administrator
- 09:36 Discharged from bed Theatre 1 by Administrator
- 11:09 Admitted to bed Theatre 1 by Administrator
- 11:08 CTG recorded in bed Theatre 1. Duration 03:01:17.

Below these events, there are three 'CTG Analysis' entries, each with a red box around the text 'CTG Analysis':

- 11:25 CTG Analysis: GA = 36 Weeks 5 Days. Started 02/02/2016 11:25 by Administrator. Stored. Stopped by user Administrator. FHR1. First met at 10 minutes. FHR1. INTRAUTERINE ANALYSIS. Results are available up to 24 minutes.
- 11:19 CTG Analysis: GA = 36 Weeks 5 Days. Started 02/02/2016 11:19 by Administrator. Stored. Stopped by user Administrator. FHR1. INTRAUTERINE ANALYSIS. Results are available up to 26 minutes.
- 11:13 CTG Analysis: GA = 36 Weeks 5 Days. Started 02/02/2016 11:13 by Administrator. Stored. Analysis completed. FHR1. First met at 14 minutes. FHR1. MET. Results are available up to 28 minutes.
- 11:08 CTG Analysis: GA = 36 Weeks 5 Days. Started 02/02/2016 11:08 by Administrator. Stored. Stopped by user Administrator. FHR1. First met at 10 minutes. FHR1. MET. Results are available up to 36 minutes.

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

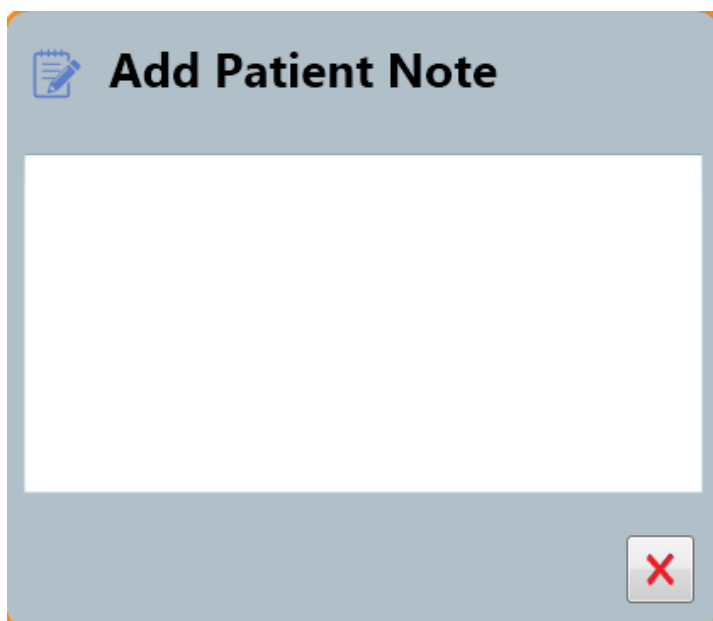
3.11.3 Adding patient notes

The screenshot displays the 'Pregnancy Notes' tab for a patient named Sally, Smith, in B104. The interface shows a list of events for 29 February 2016:

- 12:26 Admitted to bed B104 by Administrator
- 08:56 CTG recorded in bed B104. Duration 03:29:48.

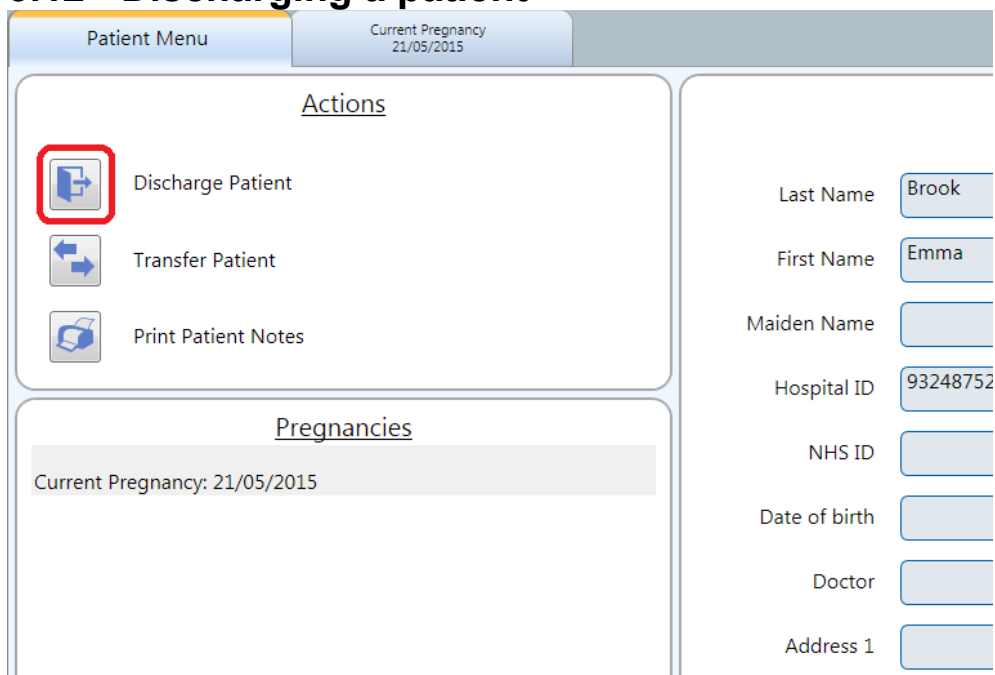
A red box highlights the 'Add Note' icon (a document with a pencil) in the top right corner of the notes area.

To add patient notes

A dialog box titled "Add Patient Note" with a notepad icon. It features a large white text area for typing notes and a red "X" button in the bottom right corner for closing the dialog.

Type notes as required

3.12 Discharging a patient

The "Patient Menu" interface shows a header with "Patient Menu" and "Current Pregnancy 21/05/2015". The main area is divided into two sections: "Actions" and "Pregnancies". In the "Actions" section, the "Discharge Patient" button (with a right-pointing arrow icon) is highlighted with a red square. Other buttons include "Transfer Patient" (with a double arrow icon) and "Print Patient Notes" (with a printer icon). The "Pregnancies" section shows "Current Pregnancy: 21/05/2015". To the right, a form contains fields for "Last Name" (filled with "Brook"), "First Name" (filled with "Emma"), "Maiden Name", "Hospital ID" (filled with "93248752"), "NHS ID", "Date of birth", "Doctor", and "Address 1".

Click to discharge a patient from a bed

3.13 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.

GDT settings.



Admin access

3.14 System Settings

The System Settings page allows the user to change the chart speed and grid used on the system as well as the general settings below;

System Settings
Log Messages
PRM Tool

CTG Settings
General Settings

Hospital name

Doctor name on printout ☒

Start CTG on empty bed ☒

Save

3.15 Log Messages

The log messages are used for fault funding and list any messages in connection with the FetalCare services. Each time the services are restarted a new log entry is created.

System Settings			
Log Messages			
PRM Tool			
All Log Sessions			
Id	Source Application	Session Start	Live
16	CentraleClient_LAPTOP-TH750N09	08/04/2020 11:55	●
15	Admin	08/04/2020 08:59	●
14	CentraleClient_LAPTOP-TH750N09	08/04/2020 08:42	●
13	CIS	08/04/2020 08:42	●
12	FMIS	27/03/2020 14:23	●
11	Admin	27/03/2020 12:28	●
10	Admin	27/03/2020 12:19	●
9	CentraleClient_LAPTOP-TH750N09	27/03/2020 12:18	●
8	CIS	27/03/2020 12:18	●
7	FMIS	27/03/2020 12:18	●
6	CentraleClient_LAPTOP-TH750N09	27/03/2020 12:16	●
5	CentraleClient_LAPTOP-TH750N09	27/03/2020 10:48	●
4	CIS	27/03/2020 10:48	●
3	FMIS	27/03/2020 10:48	●
2	Admin	27/03/2020 10:47	●
1	FMIS	27/03/2020 10:47	●
View			

4 PRMT 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.

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.

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, unless the system has been configured to start saving data once the patient has been allocated to the bed.

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

The screenshot displays the PRM Tool interface within an application window. At the top, there are three tabs: 'System Settings', 'Log Messages', and 'PRM Tool', with the 'PRM Tool' tab being the active one. Below the tabs, there is a section titled 'Actions' containing two buttons: 'Associate Unallocated Trace To Patient' and 'Move Trace From Existing Patient'. Below this, there is a section titled 'Allocate Orphan Trace To Patient' which includes three dropdown menus labeled 'Select Site', 'Select Bed Group', and 'Select Bed'.

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

Actions
 Associate Unallocated Trace To Patient Move Trace From Existing Patient

Allocate Orphan Trace To Patient

Select Site: Site1
 Select Bed Group: BG1
 Select Bed: Bed1

Orphan Traces For Bed1

Show traces after: Select a date: 15

Id	Start Date	Start Time	Trace Length	BedName	Select CTG
59	27/01/2020	10:25	00:04:15	Bed1	☐

Select Patient

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

Select Patient

Enter patient details

Last Name:
 First Name:
 Hospital ID:
 NHS ID:

Background Screen:

Actions
 Associate Trace To Patient Move Trace From Existing Patient

Allocate Orphan Trace To Patient

Select Site: Site1
 Select Bed Group: BG1
 Select Bed: Bed1

Show traces after: 27/01/2020 15

Id	Start Date	Start Time	Trace Length	BedName	Select CTG
59	27/01/2020	10:25	00:04:15	Bed1	☒

Select Patient

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

Actions

Associate Unallocated Trace To Patient

Move Trace From Existing Patient

Allocate Orphan Trace To Patient

Select Site

Site1

Select Bed Group

BG1

Select Bed

Bed1

Orphan Traces For Bed1

Show traces after

27/01/2020

15:28

Id	Start Date	Start Time	Trace Length	BedName	Select CTG
59	27/01/2020	10:25	00:04:15	Bed1	☒

Select Patient

First Name

gH

Last Name

gH

Hospital ID

gH

NHS ID

Select Pregnancy

Current Pregnancy

Please Review Changes Before Confirming

☒ Confirm Selection

Save Changes

Clear

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

Actions

Associate Unallocated Trace To Patient

Move Trace From Existing Patient

Allocate Orphan Trace To Patient

Select Site

Select Bed Group

Select Bed

Orphan Traces For Bed1

Show traces after

27/01/2020

15:28

Id	Start Date	Start Time	Trace Length	BedName	Select CTG
59	27/01/2020	10:25	00:04:15	Bed1	☒

Select Patient

First Name

gH

Last Name

gH

Hospital ID

gH

NHS ID

Select Pregnancy

Current Pregnancy

Please Review Changes Before Confirming

☒ Confirm Selection

Save Changes

Clear

Notification

Records have been updated successfully

☒

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

10:43 [CTG](#) Stored. recorded in bed Bed7. Duration 01:47:21. **Trace Reallocated**

Trace was an orphan trace previously

4.2 Move trace from Existing Patient

Actions

Associate Unallocated Trace To Patient Move Trace From Existing Patient

Move CTG Trace To Different Patient

Select Patient To Reallocate Trace From

Selected Patient

First Name: Fe
 Last Name: Ge
 Hospital ID: 123
 NHS ID:
 Select Pregnancy: Current Pregnancy: 24(0)

Show traces after: Select a date: 15

Id	Start Date	Start Time	Trace Length	Select CTG
1	27/01/2020	09:12	00:24:03	☐

Select Patient To Reallocate Trace To

Selected Patient

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

System Settings Bed Group Profiles Log Messages Features

Current Users PRM Tool Users Machines System Access Levels

Actions

Associate Unallocated Trace To Patient Move Trace From Existing Patient

Move CTG Trace To Different Patient

Select Patient To Reallocate Trace From

Selected Patient

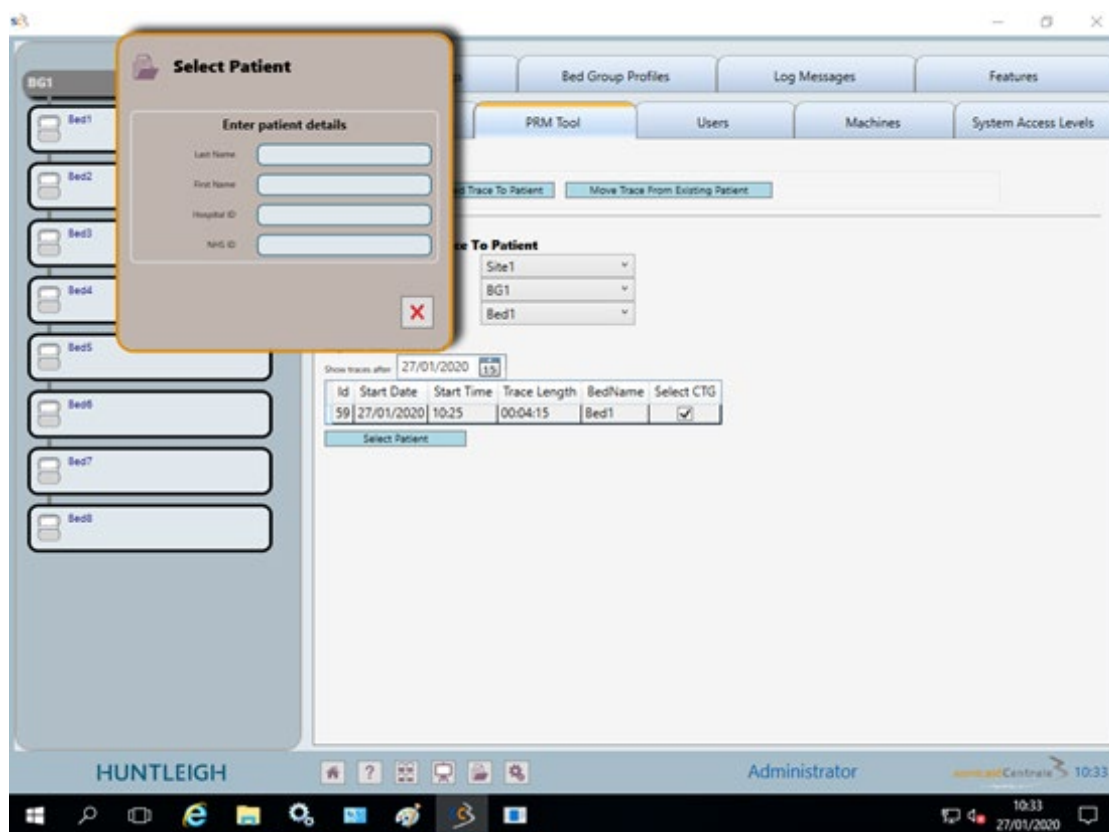
First Name: Fe
 Last Name: Ge
 Hospital ID: 123
 NHS ID:
 Select Pregnancy: Current Pregnancy: 24(0)

Show traces after: Select a date: 15

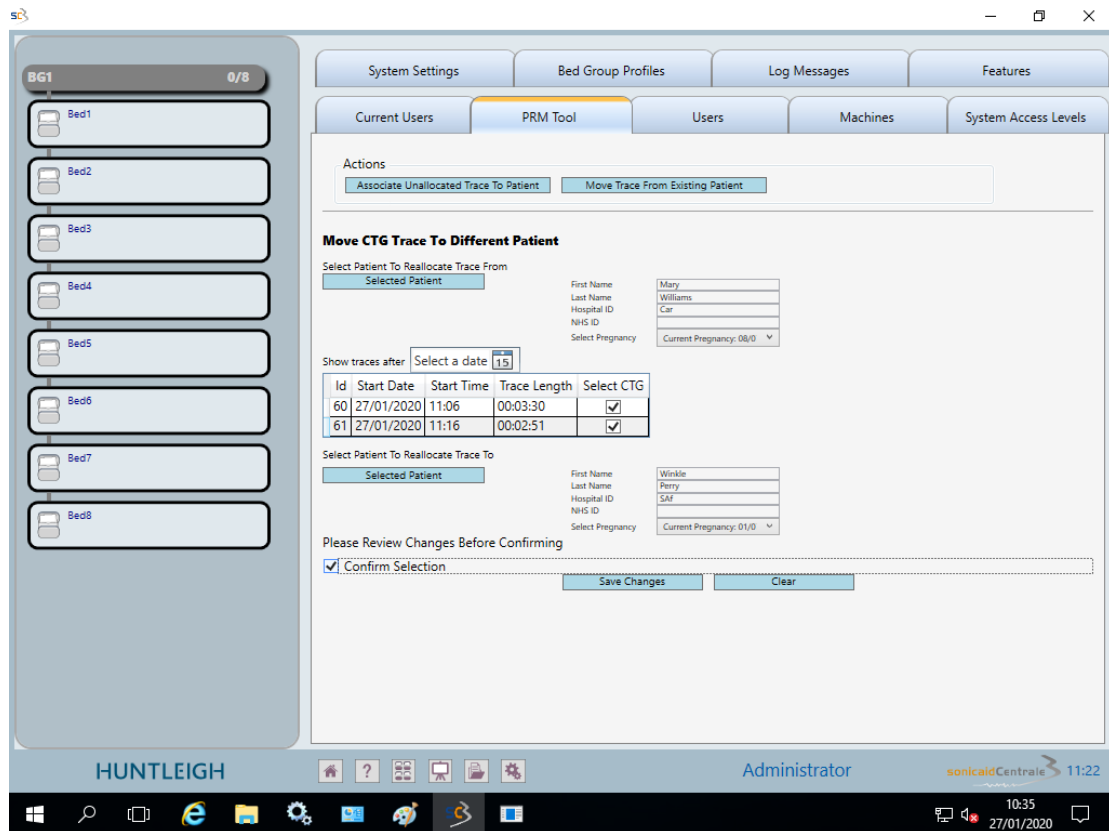
Id	Start Date	Start Time	Trace Length	Select CTG
2	27/01/2020	09:12	00:10:11	☐
3	27/01/2020	09:12	00:02:15	☐
4	27/01/2020	09:13	00:02:57	☐
5	27/01/2020	09:13	00:01:02	☐
6	27/01/2020	09:14	00:00:34	☐
7	27/01/2020	09:15	00:00:11	☐
8	27/01/2020	09:16	00:04:31	☐
9	27/01/2020	09:17	00:05:12	☐
10	27/01/2020	09:17	00:01:49	☐
11	27/01/2020	09:17	00:23:39	☐
12	27/01/2020	09:18	00:00:35	☐
13	27/01/2020	09:20	00:01:47	☐
14	27/01/2020	09:20	00:00:47	☐
15	27/01/2020	09:23	00:00:11	☐
16	27/01/2020	09:23	00:18:15	☐
17	27/01/2020	09:23	00:18:03	☐
18	27/01/2020	09:24	00:17:11	☐
19	27/01/2020	09:24	00:16:16	☐

HUNTLEIGH Administrator 10:57 27/01/2020

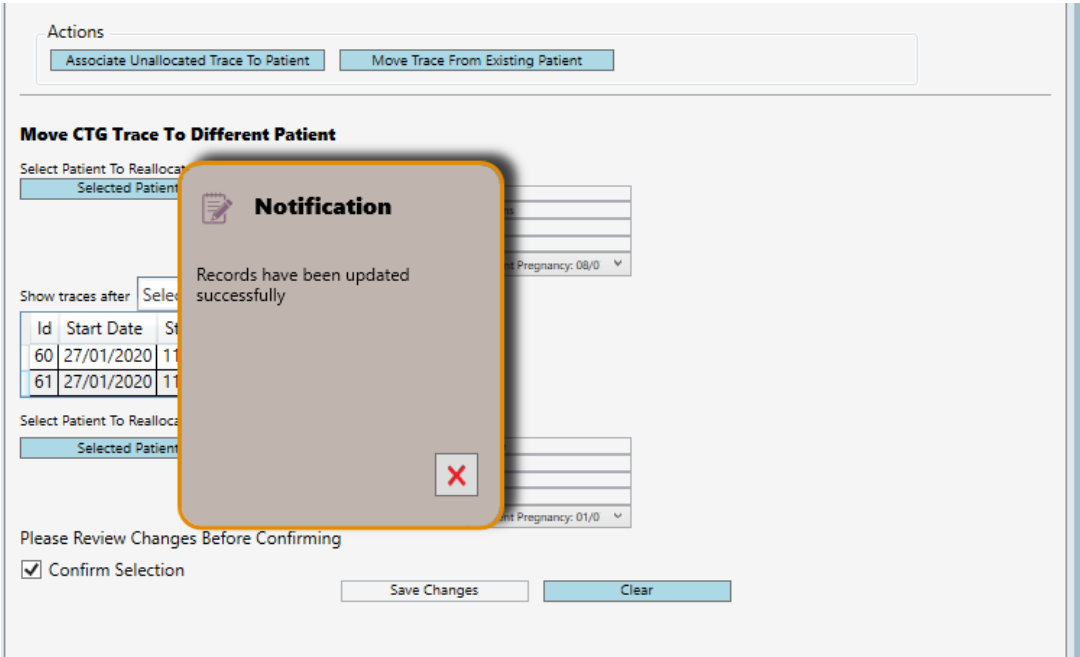
Select the required trace from the list using the date filter if appropriate and pregnancy (current or previous ones).



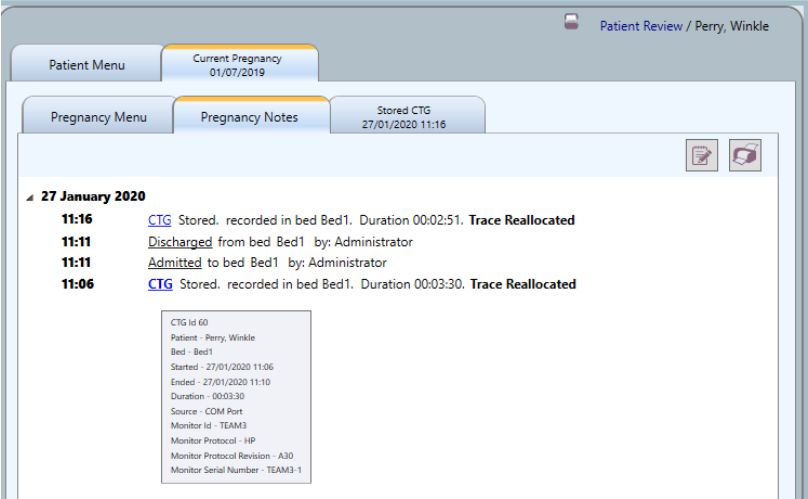
Enter the details of the patient and pregnancy you wish to move the trace to



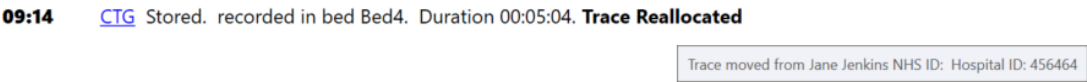
Select Confirm Selection and then ‘Save Changes’



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



5 Troubleshooting

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 from CTG	-Check CTG is switched on and working (note – CTG printer does not need 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 trace	-Traces can only be annotated within the timeframe of the trace, not on the 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 re-started – 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 Fetalcare 3. 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 Fetalcare 3 without notice.

Huntleigh Healthcare Ltd Sonicaid, Huntleigh and 'H' logo are registered trademarks of Huntleigh Technology Ltd.

©Huntleigh Healthcare Ltd. 2016

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

Manufactured and distributed 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

Registered No: 942245 England & Wales. Registered Office:
ArjoHuntleigh House, Houghton Hall Business Park, Houghton Regis, Bedfordshire, LU5 5XF
©Huntleigh Healthcare Limited 2016

A Member of the Arjo Family

® and ™ are trademarks of Huntleigh Technology Limited

As our policy is one of continuous improvement, we reserve the right to modify designs without prior notice.

HUNTLEIGH

AW:: 1001048-1

06/2020