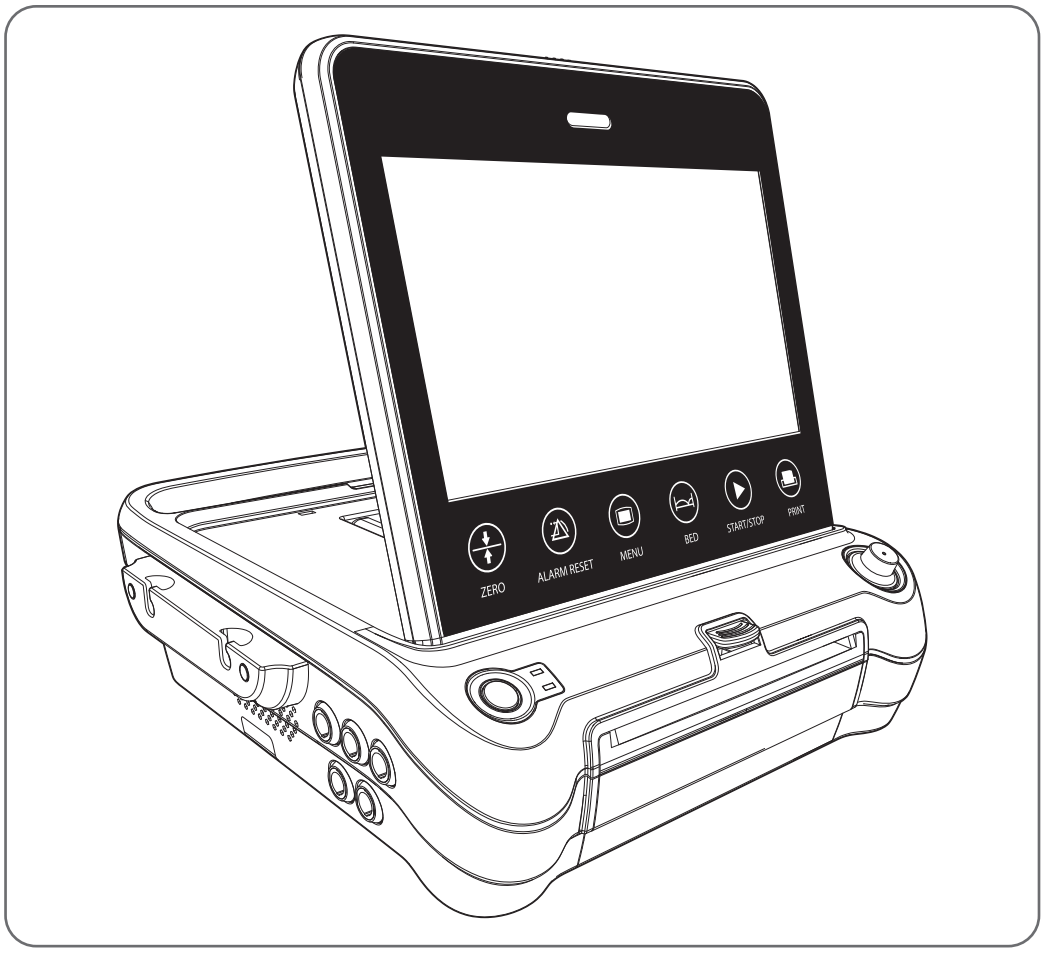
Fetal Monitor
SRF618B6

Instructions for Use



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The Sunray B6 Fetal Monitor - SRF618B6 - is a Programmable Electrical Medical System as defined by IEC/EN60601-1: 2005, for which this manual applies.

Content

1 Introduction

1.1 Intended use

The Sunray B6 Fetal Monitor is intended for non-invasive monitoring of the physiological parameters of pregnant women during antepartum testing, labor and delivery. It is intended for continuous and auscultatory monitoring of uterine activity (UA), fetal movements (FM), and fetal heart rate (FHR) of single fetuses, twins, and triplets.

It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. It is not intended for home use.

In addition, for host systems with non-interruptible power supply/battery feature, it is intended for use in indoor transport situations in healthcare facilities.

The nonstress test function is intended for pregnant women from the 28th week of gestation.

Short term variation (STV) is intended for use as decision support during antenatal screening in fetal assessment for fetuses of low gestation (w 26-32) and when there are doubts regarding the short term variation no matter gestation in the third trimester.

1.2 Intended use environment

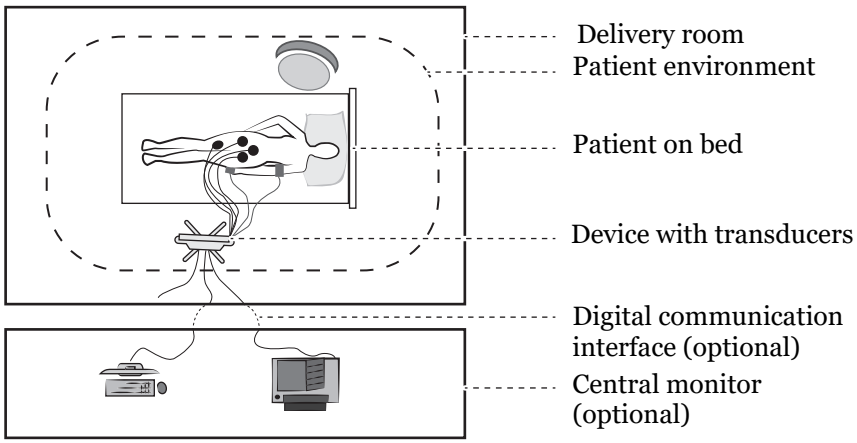


Figure 1:1 Intended use environment

Operator can be anywhere.

1.3 Contraindications

The Sunray B6 Fetal Monitor is *not* intended for:

- use during defibrillation, electro-surgery, or magnetic resonance imaging (MRI),
- monitoring of neonates, or
- patients requiring immediate delivery as in the following situations:
  - conditions that preclude vaginal delivery such as documented or suspected placenta previa,
  - cord prolapse, scar rupture and ablatio placentae, or
  - need for immediate delivery unrelated to fetal heart rate, such as active maternal or fetal bleeding.

1.4 Warranty

Guangzhou Sunray Medical Apparatus Co., Ltd. guarantees that this instrument will not have any quality problem in term of materials and technology within the warranty period promised by our company. If the purchased product has a quality problem of this kind, please inform our company. Our company will provide a warranty for the user free of charge, and will repair or replace a product that is proved to be defective. Please see the “Stipulations for Warranty” specified on the warranty card for details.

The warranty is void in cases of:

a) damage caused by mishandling during shipping;

b) subsequent damage caused by improper use or maintenance;

c) damage caused by alteration or repair by anyone not authorized by Sunray;

d) damage caused by accidents;

e) replacement or removal of serial number label and manufacture label.

If a product covered by warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, Sunray Medical will, at its discretion, repair or replace the defective part(s) free of charge. Sunray Medical will not provide a substitute product for use while the defective product is being repaired.

The designed service life of this product is 7 years. This company will provide repair service for the user within the term of the service life.

Consumables such as printer paper, ultrasound gel, and printer cartridges are not covered by warranty.

1.5 Overview of SRF618B6

This user manual is written to cover a complete system configuration. The table below defines functions and capabilities that are optional at time of purchase.

Model	Wireless transducers	Monitoring twin FHR	Monitoring triplet FHR	Built-in battery
SRF618B6	Optional	Optional	Optional	Optional

1.5.1 Front view

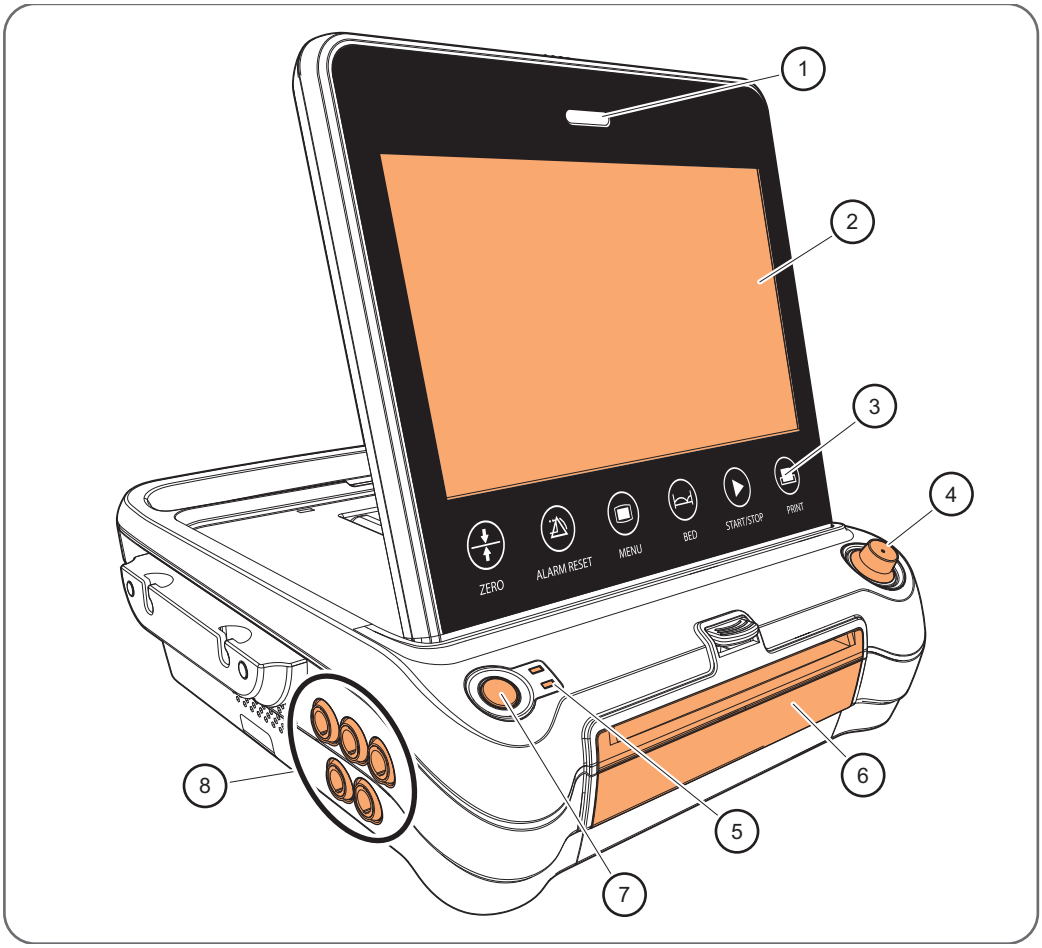


Figure 1:2 Main unit front view

Pos	Component
1	Alarm indicator
2	Main screen
3	Touch keys
4	Control knob
5	Mains power and system battery charging indicator
6	Paper tray
7	Power ON/OFF button
8	Patient connectors

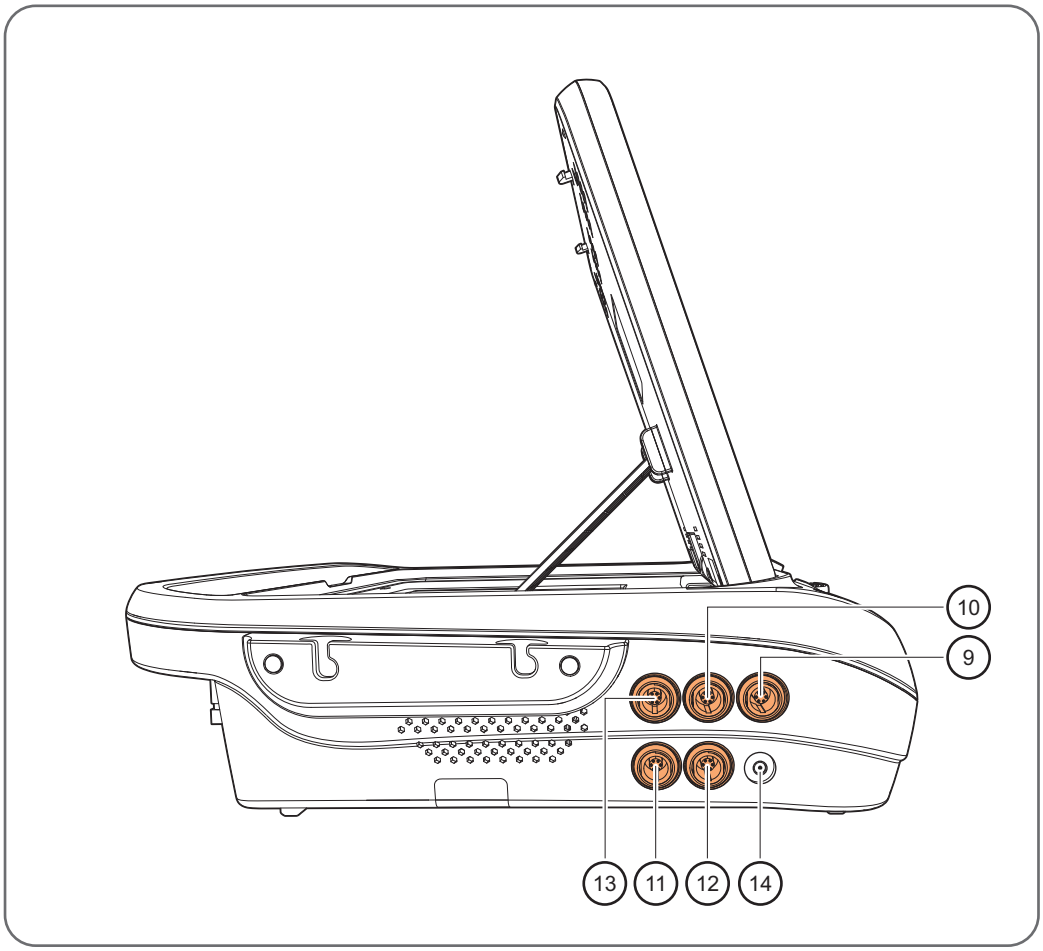


Figure 1:3 Main unit left side view

Pos	Component
9	Ultrasound FHR1 connector
10	Ultrasound FHR2 connector
11	Fetal movement marker connector
12	TOCO connector
13	Ultrasound FHR3 connector (optional)
14	For future use

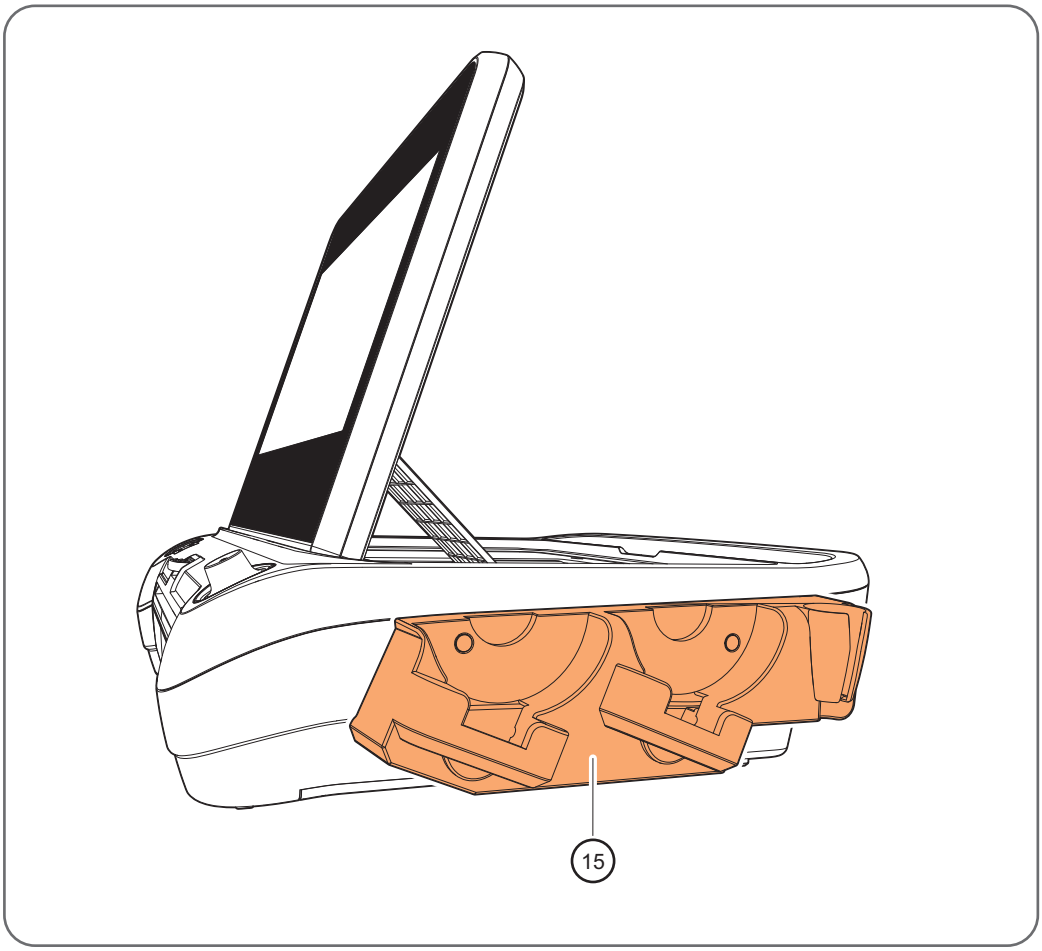


Figure 1:4 Main unit right side view

Pos	Component
15	Charging rack for wireless transducers (optional)

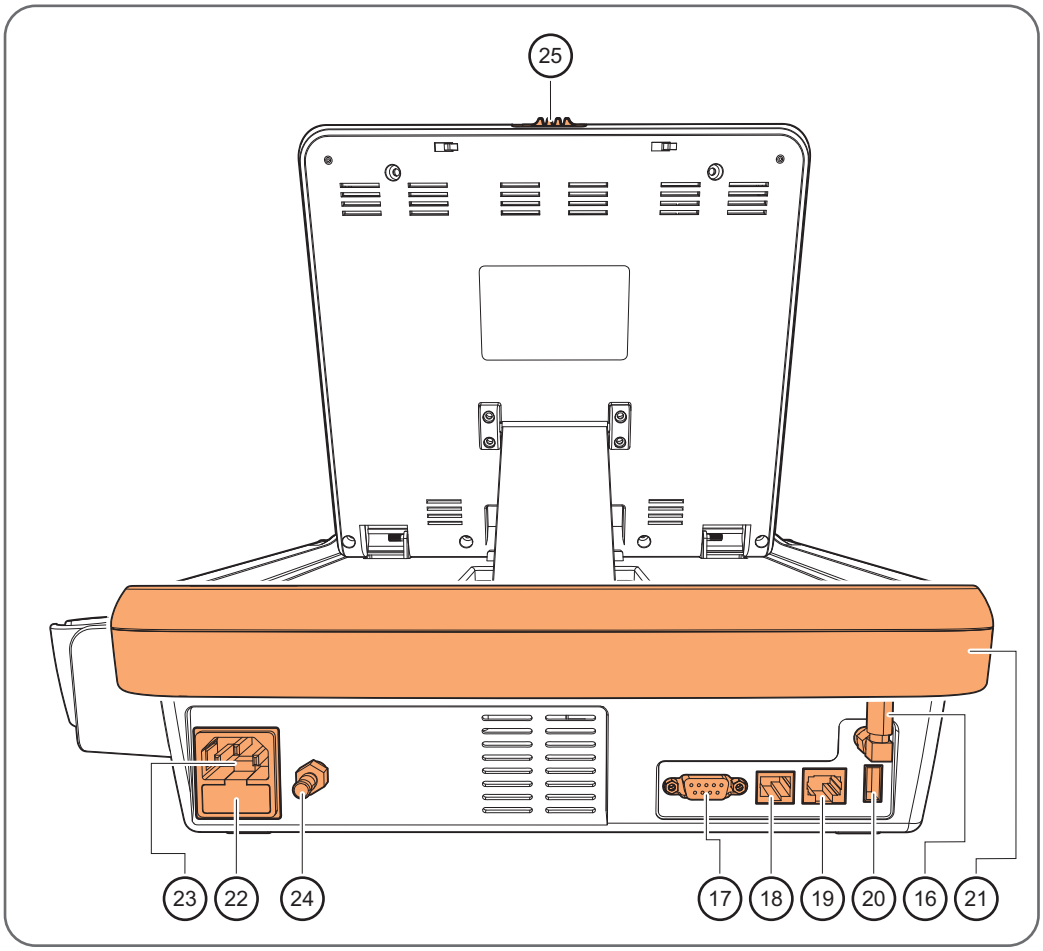


Figure 1:5 Main unit rear view

Pos	Component
16	Antenna interface for wireless transducers
17	RS-232 interface connector
18	RS-485 interface connector
19	Ethernet interface connector
20	USB interface connector
21	Carrying handle
22	Fuse holder
23	Mains power connector
24	Potential equalization conductor
25	Tilt lock for screen

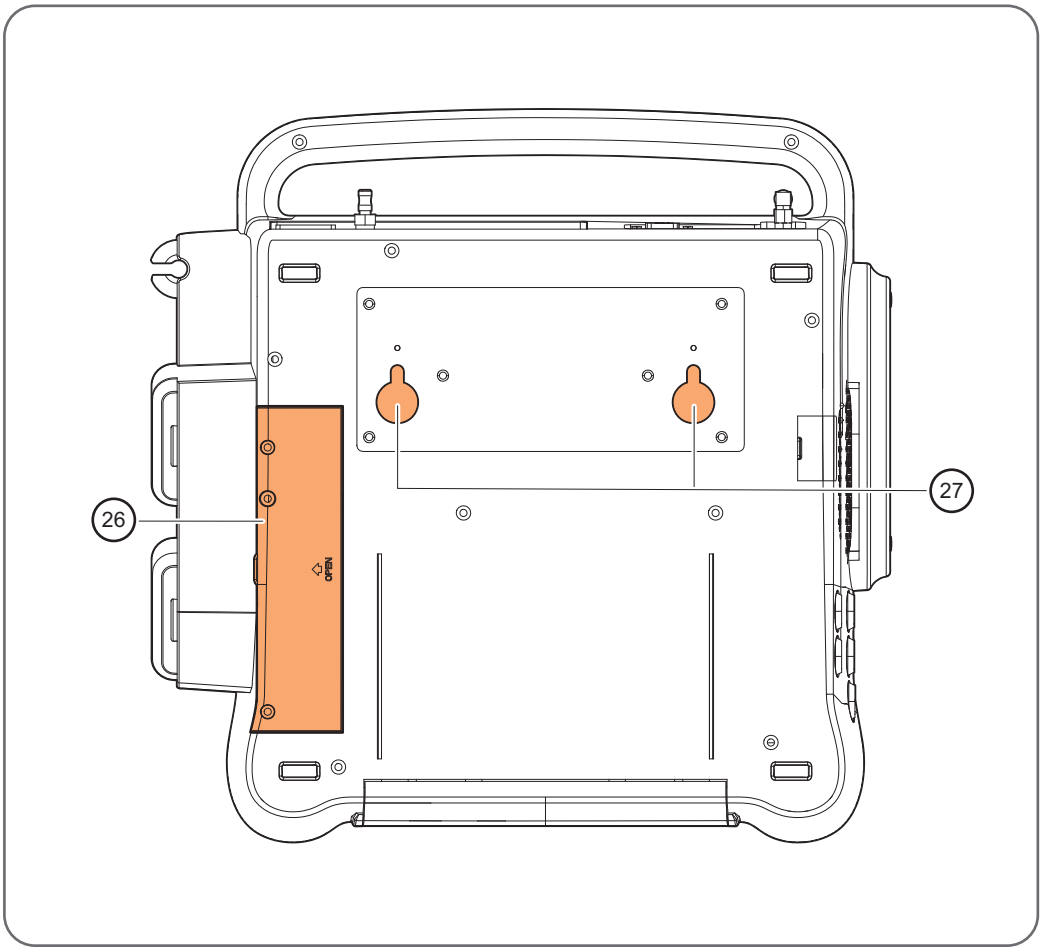


Figure 1:6 Main unit bottom view

Pos	Component
26	Battery compartment
27	Wall mount and trolley attachment points

1.5.2 Touch keys and control knob

Caution!
Avoid violent operations such as continuously pressing the touch keys or control knob.

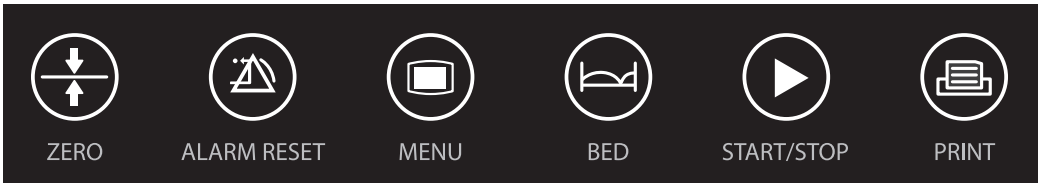


Figure 1:7 Touch key bar located below the main screen

Label	Name	Function
ZERO	Zero TOCO	Sets the current TOCO contraction value as reference baseline.
ALARM RESET	Alarm silence	Silences audible alarm signal generation for currently active alarm conditions.
MENU	Menu access	Enters the main setup menu, including the fetal settings, maternal settings and system settings.
BED	Bed toggle	Enters the quick settings menu.
START/ STOP	Start/Stop recording	Starts and stops the recording mode.
PRINT	Printer start/stop	Starts and stops the printing function.

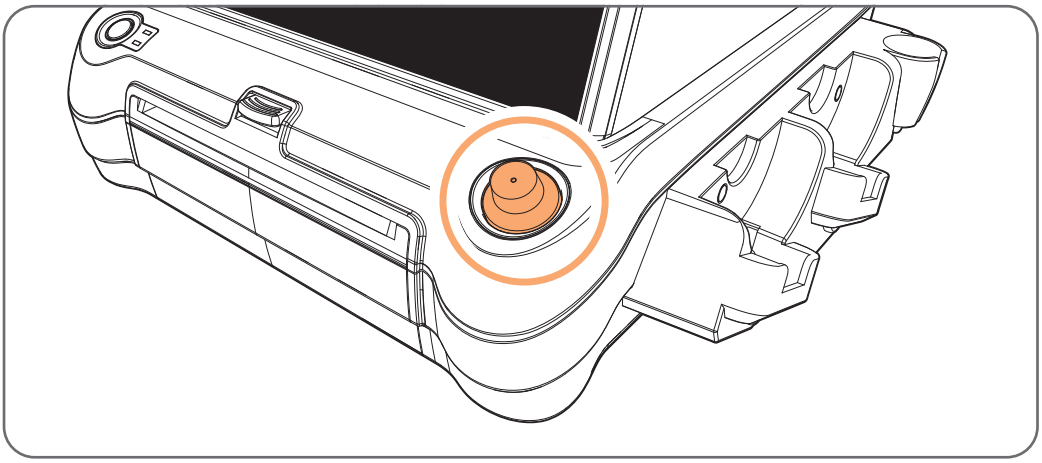


Figure 1:8 Control knob

The control knob is used for navigating the main screen, i.e. accessing menu buttons, adjusting sound volume, changing settings etc.

- To scroll, change focus or increase / decrease values, rotate the control knob clockwise / counter clockwise.
- To select an item that is in focus, button or value, press and release the control knob.

1.5.3 Accessories

Caution!

Only connect sensors and transducers that are listed as compatible. See further “Compatible devices” on page 101.

Sensors and transducers are connected to the main unit via the connectors on the left and right side panels. Each accessory has a tab on the connector housing to ensure proper insertion.

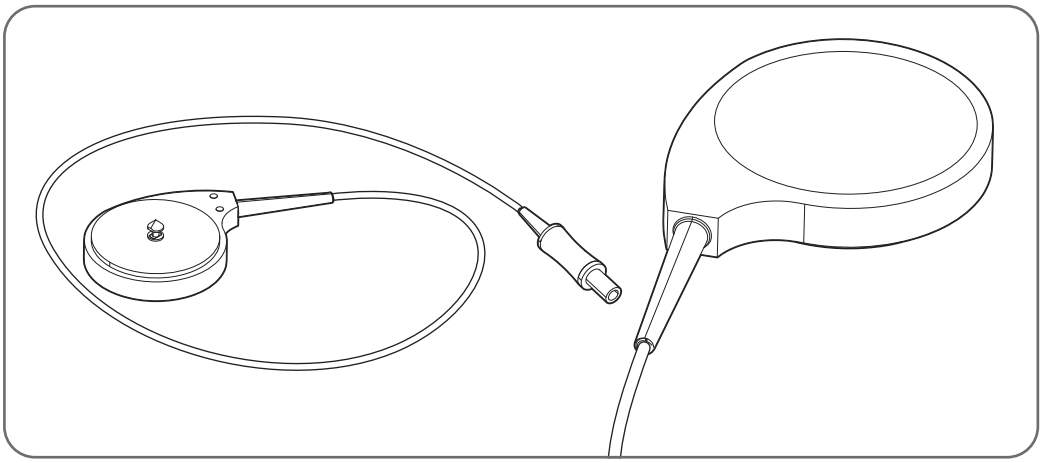


Figure 1:9 Wired ultrasound transducer for recording of fetal heart rate

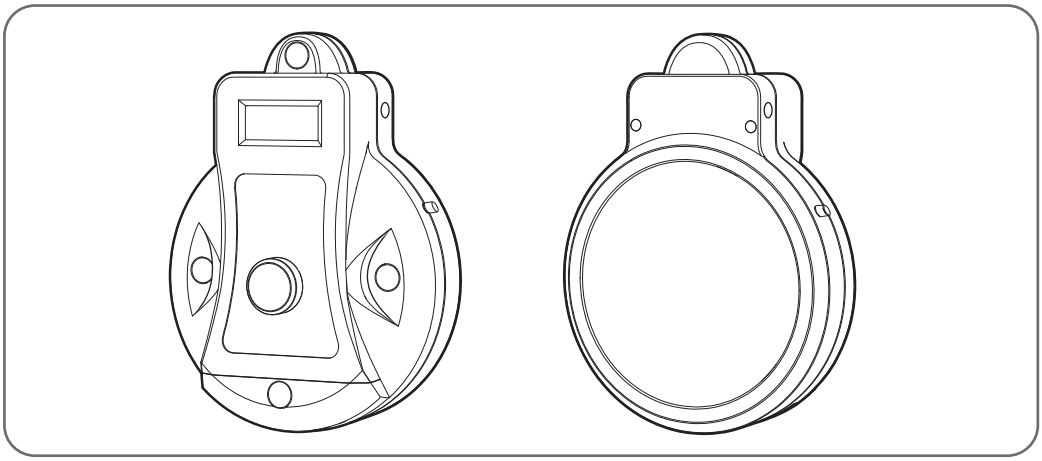


Figure 1:10 Wireless ultrasound transducer for recording of fetal heart rate

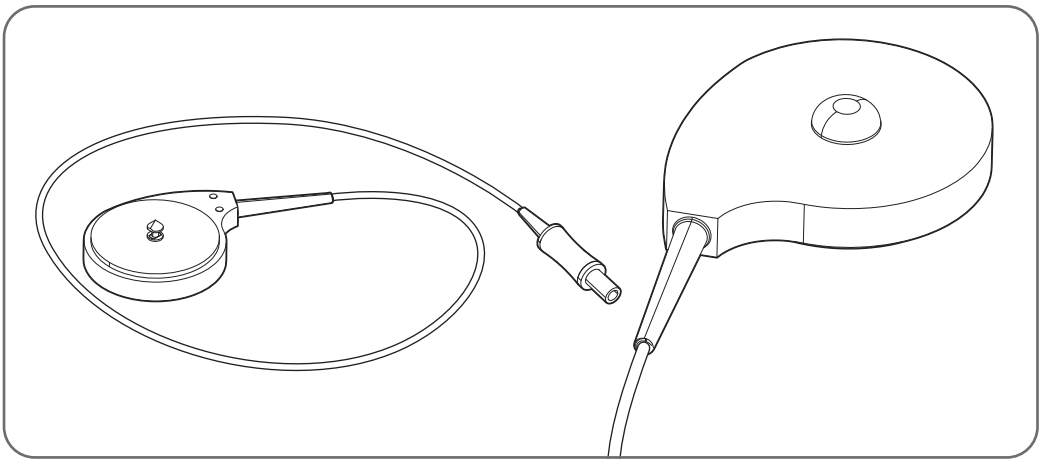


Figure 1:11 Wired TOCO transducer for recording uterine contractions

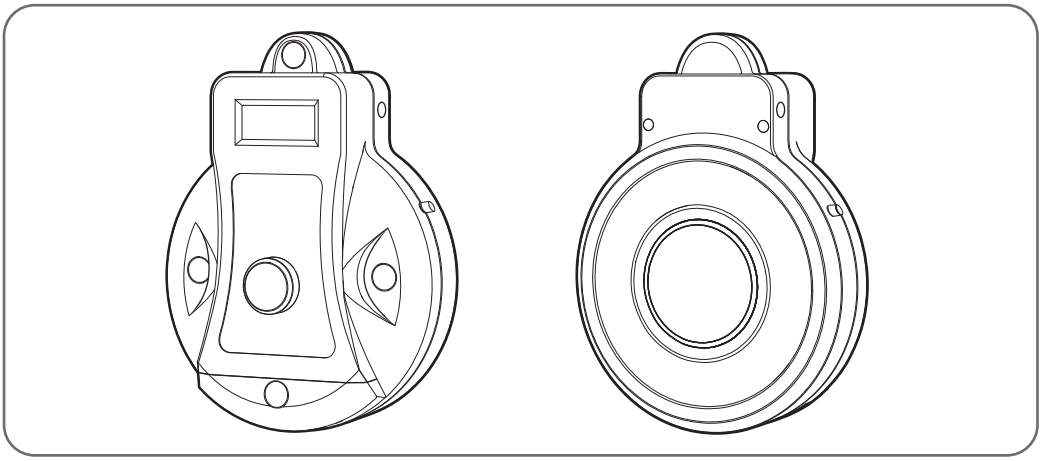


Figure 1:12 Wireless TOCO transducer for recording uterine contractions

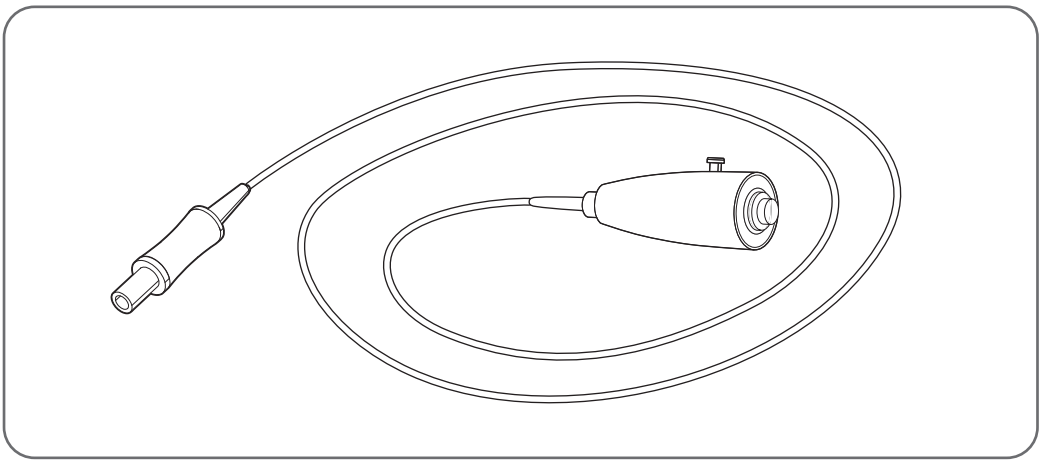


Figure 1:13 Wired fetal movement marker for manual registration of fetal movements

Accessory or spare part	Part number
Wired ultrasound transducer	P1221-05032
Wireless FHR1 ultrasound transducer (2.4GHz. Only for use with 2.4GHz charging rack.)	P1271-05021
Wired TOCO transducer	P1224-05042 P1224-05048
Wireless TOCO transducer (2.4GHz. Only for use with 2.4GHz charging rack.)	P1271-02055
Wired fetal movement marker	P1221-12003
Wireless fetal movement marker	P1271-12006
Transducer belt	P2224-08001
Aquasonic coupling gel	P7001-00030
Printer paper with 50-210 bpm HR range and 20 bpm/cm scaling	P8105-00003
Printer paper with 30-240 bpm HR range and 30 bpm/cm scaling (USA)	P8105-00004
Power cord	P5301-00001
Fuse T2AL250V	P4904-00004
Rechargeable system battery (lithium-ion)	P4901-01016
Rechargeable battery for wireless transducer (lithium-polymer)	P4901-01030

1.5.4 User interface overview

The main screen of the monitor displays numbers, traces, menus and monitor status information. Three different background color themes can be configured, black, green or pink.

The appearance may vary depending on which options are installed and which functions are in use.

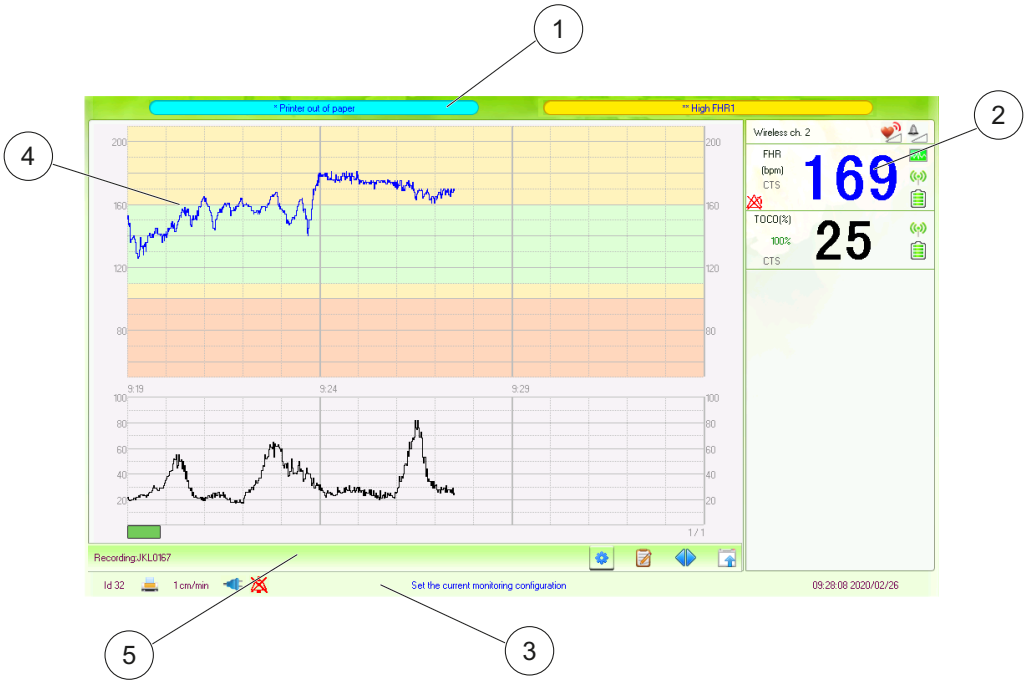
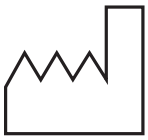
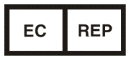


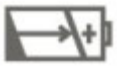
Figure 1:14 Main screen

Label	Name	Function
1.	Alarm field	Display area for visual alarm signals, showing currently active alarm conditions. Physiological alarms are displayed on the left and technical alarms to the right.
2.	Fetal numeric field	a) Wireless channel indicator b) FHR sound volume indicator c) Audible alarm sound volume indicator d) Current FHR value for respective twin e) FHR signal quality. When the quality is poor, the indicator turns gray. f) Transmission quality for wireless transducers. When the quality is poor, the indicator turns gray. g) Battery charge indicator for wireless transducers. h) Offset level (+20 or -20) applied to twin/triplet FHR in CTG trace. i) Current uterine pressure.
3.	Status field	a) Bed number, used for device recognition in Sunray CMS. If Sunray CMS is not configured, this position is left blank. b) Printer status indicator as printing, printer error (printer symbol is crossed through) or idle mode (printer symbol is gray). c) Horizontal resolution of the CTG trace on screen. d) Power status indicator. e) Alarm status indicator. f) System feedback information. g) Central monitoring status indicator. h) System time and date.
4.	CTG trace	Display of heart rate and uterine activity trend during monitoring or while reviewing recordings. The vertical resolution is configurable to 50-210bpm@20bpm/cm (international standard) or 30-240bpm@30bpm/min (US standard). The horizontal resolution is configurable to 1, 2 and 3 cm/min. The pattern color of the fetal heart rate area can be adapted to different CTG classification guidelines, see “System settings of clinical significance” on page 103. Recording ID is shown in the top left corner.
5.	Shortcut / Recording menu	a) Patient name and ID. b) Control to change view mode. c) Control to view event log. d) Control to scroll CTG trace. e) Control to open tools submenu, accessing functions to input patient information, review event log and review automated CTG analysis. f) Control to access quick settings menu.

1.6 Markings and identification

1.6.1 Product identification labels

Symbol	Denomination	Description
	Manufacturer name, address	
	Date of manufacture	
	EC REP	Authorized representative in the European Community
	Catalogue number / model/ type ref.	
	Serial number	Indicates serial number that is unique for each individual main unit.
	Batch code	
	Consult instructions for use	Signifies that the instructions for use must be read.
	Consult instructions for use	Indicates need for the operator to consult the instructions for use.
	IP-classification	Symbol marked on any device with protected enclosure according to IEC 60529.
	CE mark	Confirms the device is CE-marked towards MDD, 93/42/EEC.

Symbol	Denomination	Description
	WEEE mark	Indicates separate collection for waste electrical and electronic equipment.
	Type B applied part	Suitable for external application to the patient.
	Power indicator	Indicates device is connected to mains supply.
	Battery charging indicator	Indicates system battery is charging.
	AC supply	Alternating current supply voltage.
	Protective ground	Identifies the protective ground terminal of the device.
	General warning sign	The related hazard is clarified in text at each symbol when appearing on the device or instruction. The hazards are also explained in the instructions for use.
	Potential equalization conductor	Can be used for connection to external earth bar if local regulations prescribe all touchable metal parts to be earthed.
	Power ON/OFF	Identifies the power ON/OFF switch.
	USB port	Non-isolated USB. For removable storage devices. Note that only devices powered by the USB port should be used. Devices supplied by other cabling must not be connected unless medical-grade supplied. Total current must not exceed 0.5A.

Symbol	Denomination	Description
NET	Ethernet port	Connection to hospital intranet. Isolated
RS-232	Serial RS-232 port	Identifies the RS-232 serial communication port. Isolated.
RS-485	Serial RS-485 port	Identifies the RS-485 serial communication port. Isolated.

2 Safety

2.1 Local regulations

Always follow the instructions in this document, unless local regulations state otherwise.

2.2 Target group

The user profile may vary over different regions. Typical users are:

- midwives,
- specialists in obstetrics and gynecology, and
- obstetrical nurses on a labour ward.

Users are required to have sufficient skills in the language in which this user manual is written, to ensure that these and other instructions can be understood and complied with.

For further information regarding education and training, contact Sunray Medical or your local distributor.

2.3 Safety symbols

The instructions contain three symbols which, together with text, indicate to the user that there are risks involved.

The symbols are displayed to the left of the text. Three different symbols are used to indicate the degree of danger:

Warning!
This symbol indicates that there is a potential hazard that could result in death or injury.

Caution!
This symbol indicates that there is a potential hazard that could result in minor or moderate injury, equipment damage, extra work or unexpected results.

Tip!
This symbol indicates information that makes the handling of the installation easier or offers a possible operational technical advantage.

2.4 Equipment handling

Warning!
To avoid patient injury, place the monitor in a position that ensures it cannot accidentally fall on the patient.

Warning!
Overloading or improper use of mounting solutions, such as a trolley or a wall arm, may cause serious injury to anyone hit by falling equipment.

Warning!
If your unit is mounted on a wall arm with a spring setting, make sure the spring is set correctly to prevent the arm from rebounding when releasing the locking screw and thereby hitting the user.

Caution!
Never lift a unit by its cables as this can damage the equipment.

Caution!
Keep the unit dry from moisture and clean from dust as this can damage the equipment. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

Caution!
Avoid vibrations and high temperatures as this can damage the equipment.

Caution!
When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.

Caution!
Please place the monitor on a level and stable supporting plane. Enough space should be left around the monitor so as to guarantee normal ventilation.

2.5 Ground connection

Warning!
To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth.

2.5.1 Potential equalization conductor

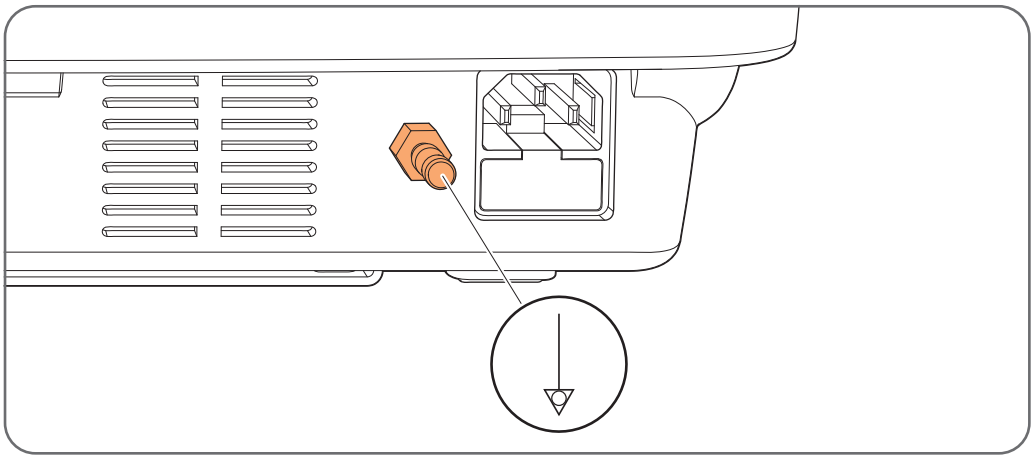


Figure 2:15 Potential equalization conductor

The main unit is equipped with an optional connection to an earth reference bar for equipotential bonding. The connector fulfills requirements in IEC/EN 60601-1 clause 8.6.7.

2.6 Electrical safety

Warning!
Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

Warning!

No unauthorized modification of this monitor is permitted.

Warning!

The monitor is *not* intended for use during defibrillation. Defibrillation during labour and delivery is contraindicated and may cause permanent injury to the unborn child.

Warning!

The monitor is *not* intended for use during MRI. Remove all transducers, sensors, and accessories before performing MRI, otherwise harm to the patient or the user may result.

Warning!

The monitor is *not* intended for use during electrosurgery. Remove all transducers, sensors, and accessories before performing electrosurgery, otherwise harm to the patient or the user may result.

Warning!

To avoid electrical shock, do not use the wired transducers to monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where the mother is immersed in water.

Warning!

Note that if the patient is connected to more than one piece of equipment, the sum of their leakage current components may exceed permitted limits, even if the individual leakage currents are below the permitted limit.

Caution!

Connecting electrical equipment to a multi-socket outlet effectively leads to creating a medical electrical system, and can result in a reduced level of safety.

Caution!

In case of accidental wetting of the main unit, interrupt the power, disconnect from patient and contact a qualified technician.

Caution!

Ensure positioning of the equipment allows easy disconnection from the mains supply.

Caution!
Avoid touching the patient when you are accessing mounting solutions or any cabling other than the patient sensors.

2.7 Environmental conditions

The Sunray B6 Fetal Monitor should only be used under the following operating conditions:

- Ambient temperature: +5°C to +40°C
- Relative humidity: < 90% (no condensation)
- Atmospheric pressure: 860 hPa to 1060 hPa

Sunray B6 Fetal Monitor may be used in a normal hospital environment, and is approved under EN60601- 1-2 as regards electromagnetic interference (EMI) and radio transmitters.

As with other medical electrical devices, the Sunray B6 Fetal Monitor needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these instructions for use and SRF618B6 Service Manual.

2.8 Electromagnetic interference

Caution!
Radio transmission equipment, mobile telephones, magnetic resonance imaging (MRI) machines etc. may affect the functioning of the device and must not be used in its proximity. Particular care must be observed during the use of strong emission sources such as electrocautery, to prevent electrocautery cables etc. being laid over or near the device.

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

Caution!
The monitor has a protective earth conductor which is needed for EMC purposes. Always use the supplied power cord with the three-prong plug to connect the monitor to AC mains. Never adapt the three-prong plug from the power supply to fit a two-slot outlet.

Caution!

The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

Caution!

Disconnect transducers that are not in use from the main unit. Otherwise, the transducers may be affected by ambient interference and generate false output data.

The device and its accessories listed in section “Compatible devices” on page 101, comply with EMC standard IEC 60601-1-2:2014.

The system can be susceptible to interference from continuous, repetitive, power line bursts, and other RF energy sources, even if the other equipment is compliant with EN 60601-1-2 emission requirements. Examples of other sources of RF interference are other medical electrical devices, cellular products, information technology equipment, and radio/television transmissions. Fetal parameters, especially ultrasound, are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

Before taking the device into use in a new setting, assess the electromagnetic compatibility of the device with surrounding equipment.

2.9 Connection of external equipment

External equipment intended for connection to signal inputs, signal outputs or other sockets, must comply with the requirements of applicable IEC/EN standards (e.g. IEC/EN 60950 for IT equipment and the IEC/EN 60601 series for medical electrical equipment). In addition, all such combinations (systems) must comply with the requirements of IEC/EN 60601-1, clause 16, Medical Electrical Systems.

Warning!

Equipment that does not comply with the requirement of IEC/EN 60601 must be kept at least 1.5 m away from the patient or the surface on which the patient is lying.

All persons who connect external equipment to signal inputs, signal outputs or other sockets have created a system, and are therefore responsible for ensuring that the system complies with the requirements of IEC/EN 60601-1. When in doubt, consult qualified medical technicians or Sunray Medical.

Warning!
Do not touch the leads of external connectors, e.g. the connector from a central monitoring system, while connecting it to the main unit.

2.10 Disposal

To avoid contaminating personnel, environment or other equipment, before disposing of medical equipment at the end of its useful life, make sure it has been properly disinfected and decontaminated, in accordance with your country's laws and regulations.

Do not dispose of electrical and electronic equipment as unsorted municipal waste. Collect it separately, so that it can be safely and properly reused, treated, recycled, or recovered. This applies to the main unit, cables and accessories for multiple use.

Equipment intended for single use, such as skin electrodes, should be disposed of properly as medical waste in accordance with your country's regulations.

3 Operating the device

3.1 Starting a recording

Warning!
Before being taken into use for the first time, the system must be installed by qualified personnel according to SRF618B6 Service Manual.

Warning!
When running the system from an internal battery, pay attention to the battery indicator on the screen. If the battery runs low, connect the main unit to mains power, to prevent the system from shutting down.

Caution!
When starting to monitor a new patient, ensure that you are not continuing the recording from the previous patient, as this may lead to an incorrect assessment of the patients' condition.

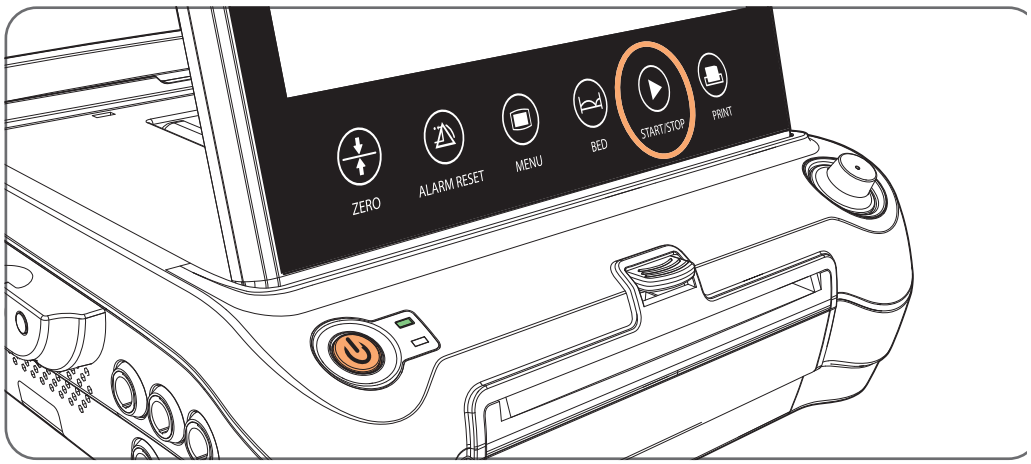


Figure 3:16 Power on button and "START/STOP" touch key

1. Push the power button on the front of the main unit. The main screen will appear within seconds.

2. If a previous recording exist that was paused less than 2 hours earlier, a dialog will be presented providing the possibility to continue the paused recording. If there is no paused recording, a watermark in the CTG trace area of the screen will indicate that the monitor is in *idle* mode.

3. Press and hold the "START/STOP" touch key. A recording is started and the *idle* watermark in the CTG trace area is removed. You are now ready to start monitoring the patient.

4. If you wish to print the recording continuously on thermal paper, ensure there is paper in the tray and press the “PRINT” touch key. Select the option “Print continuously”.

Tip!

Each recording is automatically assigned a Recording ID. This ID consists of the “Machine Name” + four digits and is visible in the field above the CTG trace. You can verify that a recording is ongoing by a recording ID being assigned, and that there is no *idle* or *stopped* watermark in the CTG trace window.

Tip!

Sunray Medical recommends always keeping the main unit connected to mains power. This will prevent undesirable draining of the battery.

3.2 Ending or pausing a recording

Caution!

Do not press the power button continuously. Allow at least 10 seconds between switching the monitor off and on.

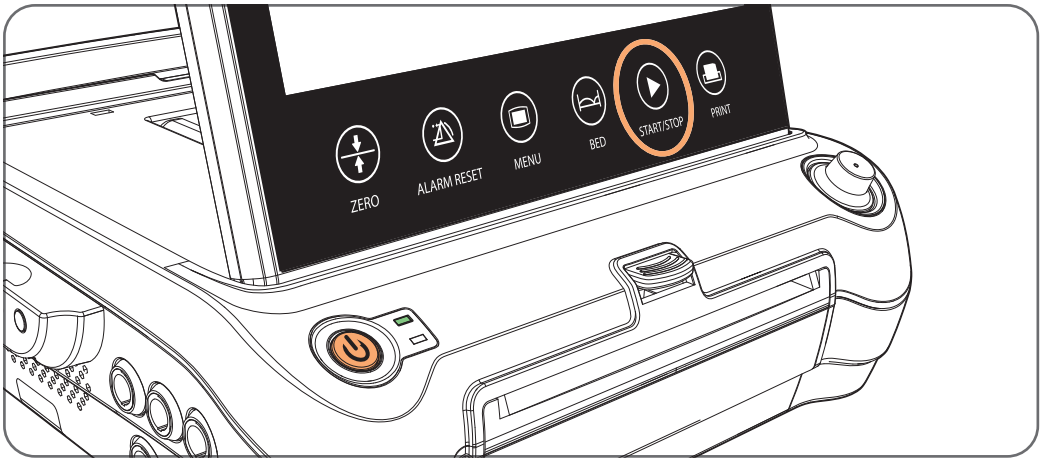


Figure 3:17 “START/STOP” touch key

1. During recording, press and hold the “START/STOP” touch key. A dialog will appear asking you whether you want to pause the ongoing recording or to end it permanently.

2. If you choose to pause the recording, a dialog will be presented providing you the option to continue the paused recording or to end it. You can either keep the system in this state, or you can power off the system until you wish to continue with the recording.

3. If you choose to end the recording instead, this will be indicated by a *stopped* watermark in the CTG trace.

4. To print the ended recording on paper, press the “PRINT” touch key. Select the option “Print all”.

5. To power off the main unit, hold down the power button for three seconds.

6. You can also choose to start another recording. To do this hold down the “START/ STOP” touch key again.

3.3 Quick settings

Caution!

The settings made in the quick settings dialog apply to the present recording only. The settings are set to their values in the system settings when the next recording is started.

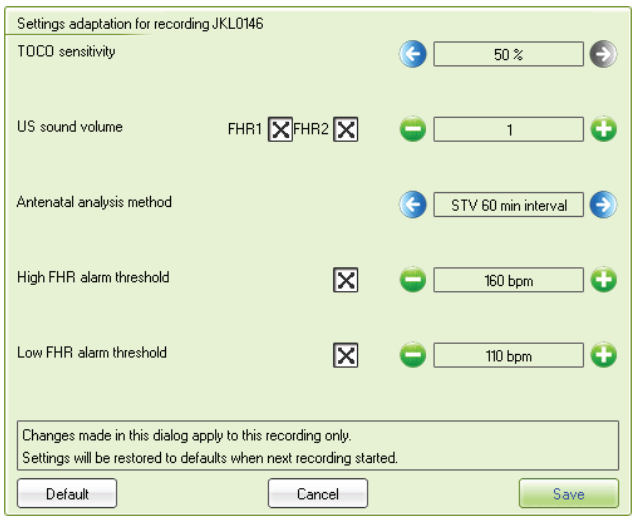


Figure 3:18 Quick settings screen

1. Press the “BED” touch key. The quick settings screen is displayed.

2. Select setting by ticking the corresponding box.

3. Change the settings by pressing the “+” and “-” buttons.

4. Press “Default” to set all settings to their default values.

5. Press “Save” to save the settings or “Cancel” to discard the changes and exit the quick settings.

3.4 Entering patient information

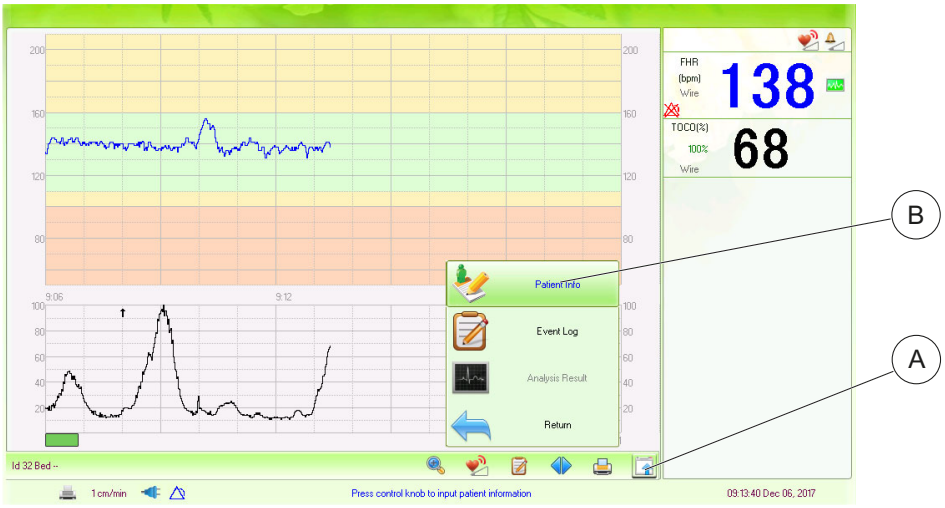


Figure 3:19 Accessing the patient information input dialog

1. During recording or before starting a new recording, rotate the control knob to select the “Tools” menu button (A). Then select the “Patient Info” menu item (B) to enter the Patient Information input dialog.

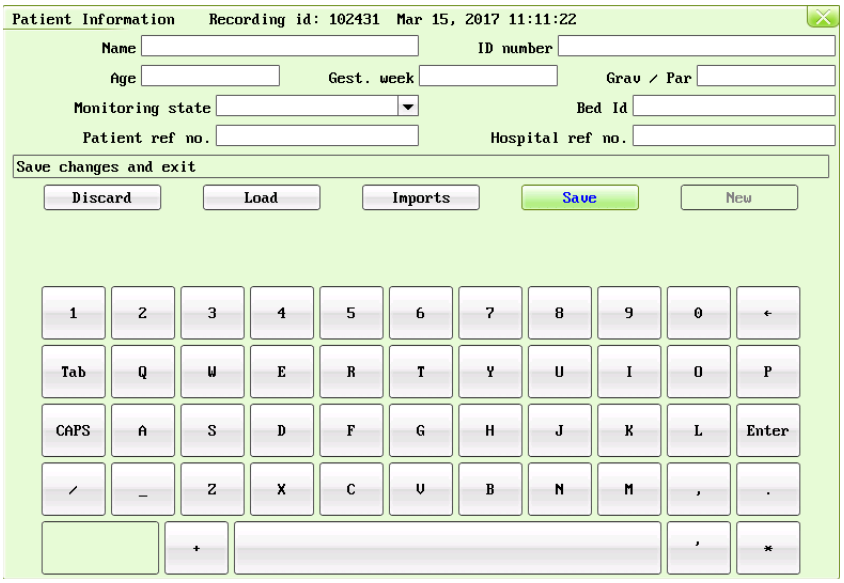


Figure 3:20 Manual entry of patient information using on-screen keyboard

2. To enter the patient information manually, use the on-screen keyboard and control knob to enter patient's name, age, the gestational week, gravidity/parity information, etc. Press “Enter” after you are done with each text field.

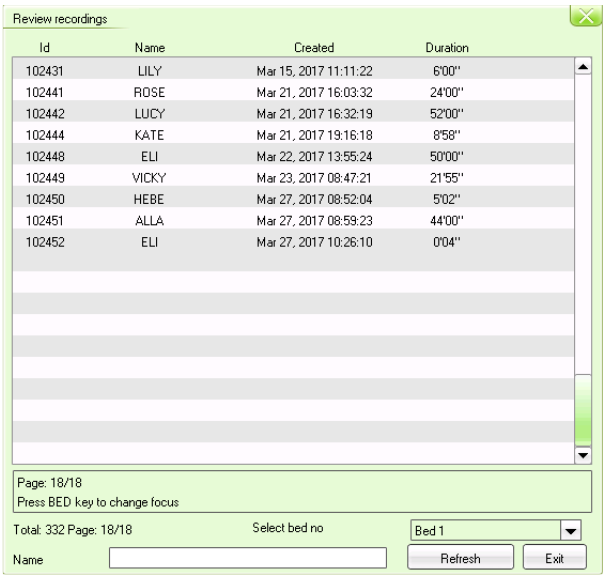


Figure 3:21 Loading patient information from a previous recording file

3. Alternatively, you can load patient information from a previous recording file. To do this, select the “Load” button, and then select the recording from which you wish to copy the patient information.

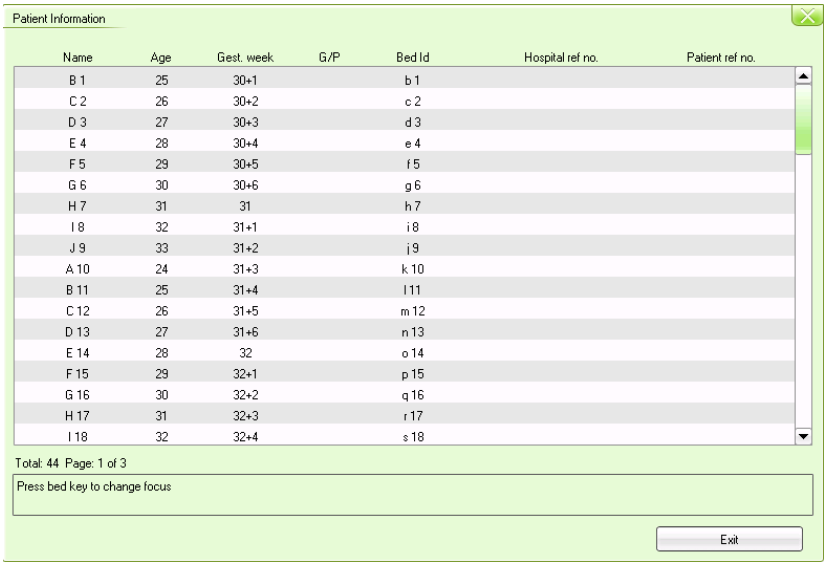


Figure 3:22 Importing patient information from insight software

4. A third alternative is to import the patient information from the PC insight software. To do this, select the “Preset” button, and then the preset list from which you wish to copy patient information. To import the preset list, select the preset function of the PC insight software according to its user manual.

5. When you are done, select “Save” to store the information and then “Exit” to the monitoring view.

3.5 Entering annotations

The annotations function allows you to record text information relating to a recording, to be stored as part of recording data.

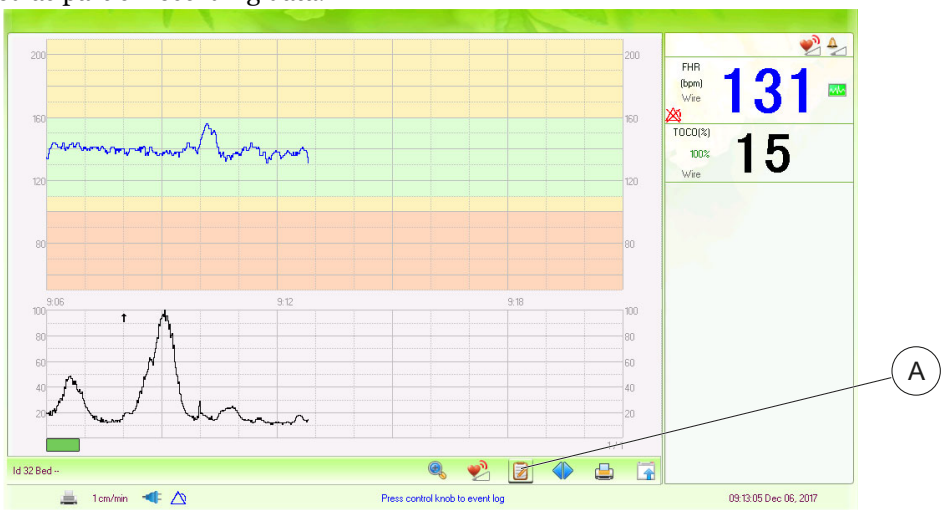


Figure 3:23 Opening the event log

1. During recording, rotate the control knob to select the “Event log” menu button (A). This will open the event log window.

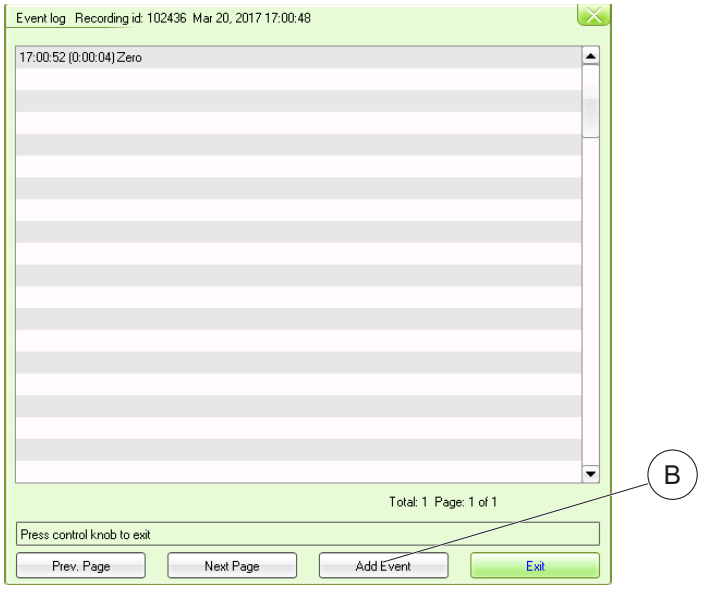


Figure 3:24 Opening the “Add event” menu

2. Select “Add Event” (B) to enter the “Add Event” menu.

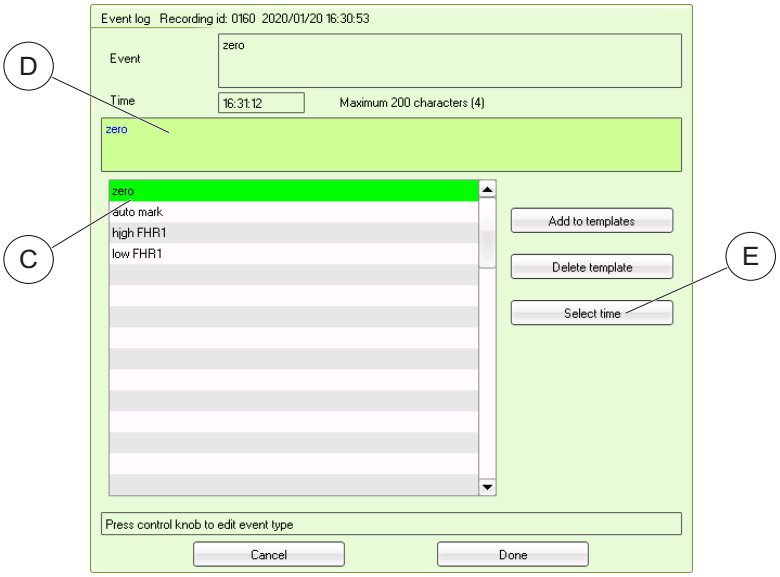


Figure 3:25 Selecting annotation template

3. Use the control knob to select the appropriate annotation template (C).

4. If there is no suitable template available, switch to the text edit field (D) by turning and pushing the control knob or using the touch screen. Then enter a suitable text using the on-screen keyboard.

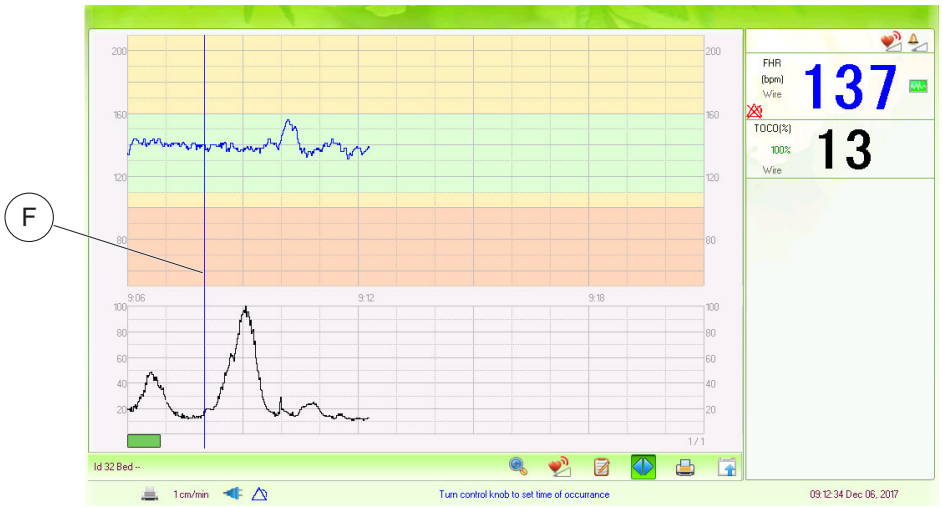


Figure 3:26 Selecting event occurrence

5. If you wish to back-date the annotation, select the “Select Time” button (E) to specify where in the recording the event occurred. Then rotate the control knob and move to the page where the event occurred, and press the control knob. Then move the blue marker (F) to highlight the exact point in time where the event occurred, and press the control knob again. After you have specified annotation text and time, select “Done” to add the annotation to the log.

6. If you do not wish to back-date the annotation, just select ‘Done’ to add the annotation to the log dated with current time.

3.6 Reviewing the CTG trace

The CTG trace window allows the clinician to interpret the fetal heart rate and maternal contractions, classify the CTG and ultimately determine the condition of the fetus.

Tip!

To aid the operator in classifying the baseline of the fetal heart rate, the CTG trace can be configured to show different background colors for different heart rate levels. Make sure that the setting matches your local guidelines for baseline classification.

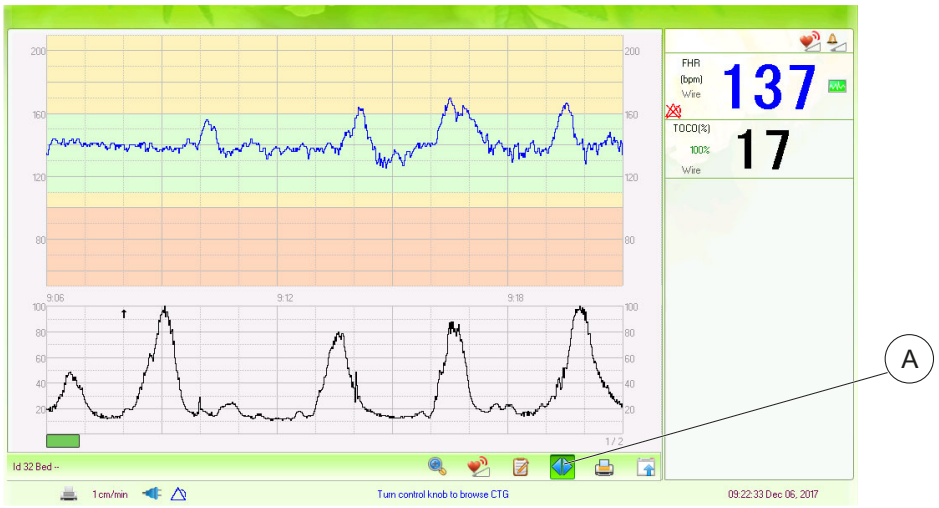


Figure 3:27 Scroll CTG window

1. Select the “Scroll” menu button (A) either by using the touch screen or by operating the control knob. This will activate the scroll mode.

2. You can now scroll the CTG trace back and forth, page by page, by turning the control knob or a swiping movement left or right on the touch screen.

Tip!

To scroll several pages in one go, just twist the control knob several clicks at once.

3. To exit the scroll mode, select the “Scroll” menu button again.

Figure 3:28 CTG trace window

Pos	Measured value	Appearance
1.	Fetal heart rate from FHR1	Solid line, blue
2.	Fetal heart rate from FHR2	Solid line, purple
3.	Fetal heart rate from FHR3	Solid line, brown
4.	Uterine activity from TOCO	Solid line, black
5.	Fetal movement recorded with fetal movement marker	Downward arrow with 'M' character, gray
6.	Fetal movement recorded with ultrasound transducer	Upward arrow with "U1"/"U2"/"U3" indication, gray
7.	Fetal movement recorded with TOCO transducer	Upward arrow with 'T' character, gray
8.	Event log marker	Upward arrow, gray
9.	Timestamp	-

3.7 Reviewing the event log

The event log is a summary of alarm conditions and annotations that has taken place during the recording, helping the clinician to overview the clinical picture. It is accessible during an ongoing recording, and when reviewing a previous

recording.

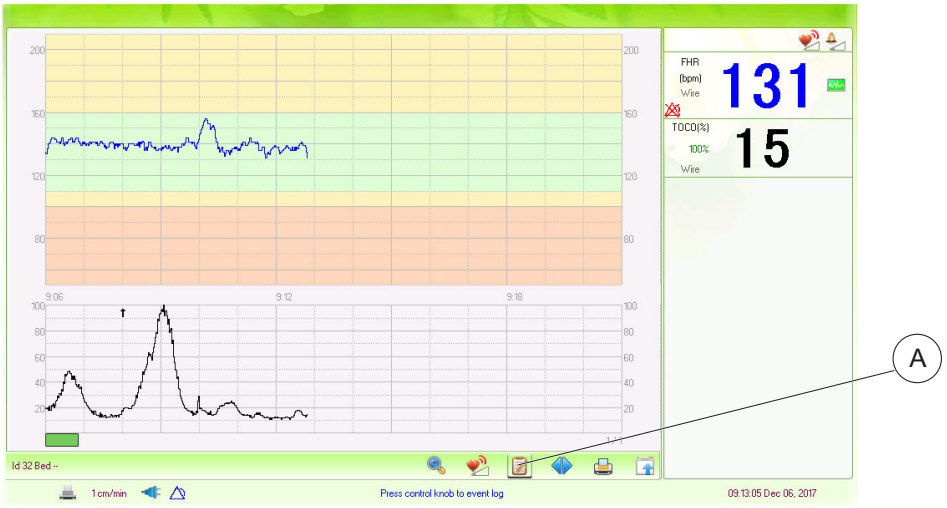


Figure 3:29 Accessing the event log window

1. Use the control knob to select the “Event Log” menu button (A).
2. You can now review the list of alarm conditions and annotations page by page by turning the control knob.
3. To exit the event log, select the “Exit” button and push the control knob again.

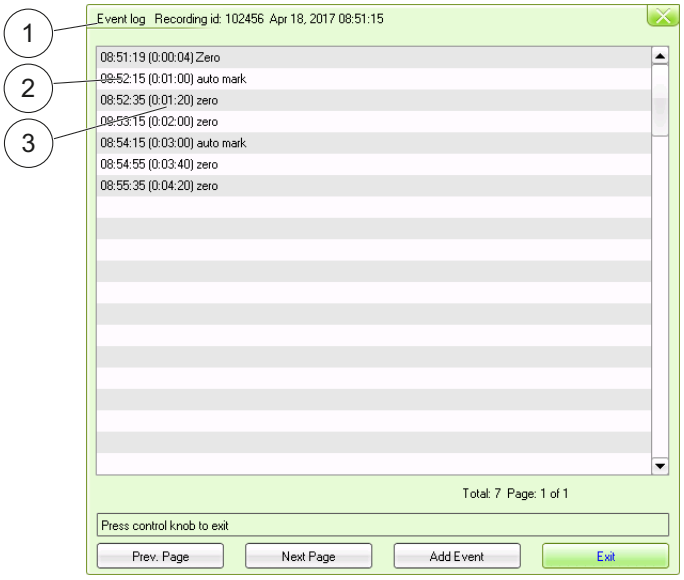


Figure 3:30 Event log window

Pos	Description
1	Recording identifier
2	Alarm conditions
3	Annotations

3.8 Working with alarms

Caution!

Do not base patient monitoring solely on the alarm system. Absence of alarm triggering events does not imply the wellbeing of the mother or fetus. The alarm system does not replace personal surveillance and clinical examination of your patient.

Caution!

When an alarm occurs, always check the patient's condition first.

3.8.1 Alarm system overview

Figure 3:31 Alarm system overview

Pos	Description
1	Currently active alarm conditions
2	Audible alarm signal sound volume indicator
3	Alarm signal inactivation indicator
4	Alarm reset control
5	Indicators for individually inactivated alarms

Alarms, grouped as physiological alarms and technical alarms, are visually displayed in the alarm field on the screen. Depending on how your system is configured, alarms can also be presented as audible signals.

In terms of severity, alarm conditions are divided into three priority levels: high, medium and low. For each presented alarm, the priority is indicated as:

Alarm priority	Backgr. color	Symbol	Audible tone (if configured)
High	Red, flashing	***	DO-DO-DO--DO-DO---DO-DO-DO--DO-DO, 14 second interval
Medium	Yellow, flashing	**	DO-DO-DO, 20 second interval
Low	Cyan blue, not flashing	*	DO-DO, 25 second interval

***High priority alarms represent conditions that potentially require intervention to avoid serious patient injury or death.

**Medium priority alarms represent conditions that potentially require intervention to avoid patient injury.

*Low priority alarms represent conditions that the operator needs to be aware of as monitoring continues.

The alarm priorities are preset, and cannot be changed.

If several alarm conditions are active at the same time, the audible alarm signal will reflect the alarm condition of highest priority.

An auditory alarm signal will sound until the triggering conditions cease, or the operator activates the alarm reset key. The sound pressure range for audible alarm signals is 45dB ~ 85dB, depending on the configured alarm sound level.

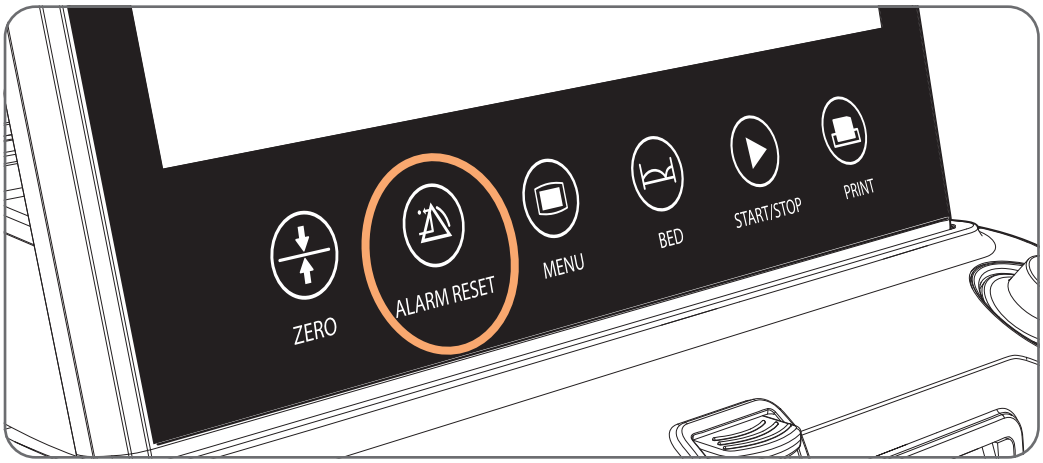


Figure 3:32 “ALARM RESET” touch key

After the alarm reset key has been activated, audible alarm signals will only be generated for subsequent alarm conditions.

Visual alarm signals remain on the screen as long as the triggering condition persist.

All alarm conditions are stored within the system, and can be reviewed in the event log, see section “Reviewing the event log” on page 42. After intentional or accidental power loss, the event log can be reviewed by bringing up the previous recording.

Tip!
Units with an installed system battery will be unaffected by temporary power loss.

3.8.2 Physiological alarms

Physiological alarms indicate a vital sign exceeding its configured threshold. Alarm thresholds can be adjusted, and the alarms can be disabled. See further "System settings of clinical significance" on page 103.

Caution!
Potential hazards may arise if alarms have differently configured settings on different monitors in the same delivery ward. At the start of a new recording, review the alarm settings and ensure the alarm settings are appropriate for your patient.

Caution!
Setting alarm limits to extreme values may trigger alarms too often or too seldom, rendering your alarm system useless.

Message	Condition	Priority	Delay*	Alarm expires
High FHR1/2/3	When the fetal heart rate has been higher than the configured threshold for a certain time. (Threshold and interval configurable.)	Medium	Equal to configured interval.	**
Low FHR1/2/3	When the fetal heart rate has been lower than the configured threshold for a certain time. (Threshold and interval configurable.)	Medium	Equal to configured interval.	**
High MHR	When the maternal heart rate measured with MECG leadset has been higher than the configured threshold for a certain time. (Threshold and interval configurable.)	Medium	Equal to configured interval.	**
Low MHR	When the maternal heart rate measured with MECG leadset has been lower than the configured threshold for a certain time. (Threshold and interval configurable.)	Medium	Equal to configured interval.	**

*Delay from physiological condition to alarm signal being generated.
**The alarm signal expires when triggering condition is no longer fulfilled.

3.8.3 Technical alarms

A technical alarm indicates that patient monitoring may be compromised due to a technical circumstance. The following technical alarm conditions generate alarm signals.

Alarm message	Alarm condition	Priority	Delay*	Alarm expires
FHR1/2/3 and FHR1/2/3 coincide	When two fetal heart rates coincide, suggesting that both sensors monitor the same fetus.	Low	60 s	**
FHR1/2/3 Transducer disconnected	When ultrasound transducer is disconnected from patient or monitor.	Low	None	**
Wireless FHR 1/2: No wireless signal	Communication problem with wireless ultrasound transducer.	Low	< 3 s	**
Wireless TOCO: No signal	Communication problem with wireless TOCO transducer.	Low	< 3 s	**
FHR1/2 Transducer Low Battery	Low battery power for cordless wireless ultrasound transducer.	Low	< 3 s	**
TOCO Transducer Low Battery	Low battery power for wireless TOCO transducer.	Low	< 3 s	**
Low system battery	System battery voltage is too low, system will be automatically powered off within 10 min unless power cord is connected.	Medium	> 10 min before system is automatically shut down.	When system reconnected to mains.
Printer tray open	Paper tray is not closed.	Low	None	**
Printer out of paper	There is no paper in the printer paper tray.	Low	None	**
Unknown printer error	Internal error in printer module.	Low	None	After system restart, if condition no longer exists.
Fetal module error	Internal error in fetal parameter module.	High	None	After system restart, if condition no longer exists.
CMS offline	Connection to the central monitoring system or the STN Stream server has stopped working.	Low	None	**

*Delay from technical condition to alarm signal being generated.

**The alarm signal expires when triggering condition is no longer fulfilled.

3.8.4 Preparations for use

Caution!

Ensure that the alarm system is configured so that alarm signals are perceivable by the operator. Depending on your environment, you may wish to enable audible alarm signals, and select an appropriate audible alarm sound level.

Caution!

If audible alarm signaling is configured, you should regularly confirm the operation of the audible alarm signal by performing a loudspeaker test as described in “Performing functional check” on page 79.

Review the alarm settings to verify that the alarm system is configured appropriately for the patient you intend to monitor and the location where the monitor is placed.

Tip!

Some alarm settings can be changed in the quick settings dialog. Note that the settings made in the quick settings dialog apply to the present recording only.

1. Fetal alarms may need to be adapted depending on the fetus’ onset conditions, e.g. gestational age and heart rate baseline level.
2. Use of audible alarm and sound level may need to be adapted to the monitoring type, e.g. antenatal testing or intrapartum recording, and where the clinicians are expected to be during the recording.
3. If you are uncertain on how well the alarm signal can be perceived, perform an alarm test by stimulating a signal that is higher than the upper threshold or lower than the lower threshold of a configured level alarm.

Tip!

If you wish, you can configure the audible alarm signal to be generated on only ‘High’ or ‘High and medium’ priority alarm conditions, using the ‘Audible alarm signal conditions’ setting. See further “System settings” on page 104.

3.8.5 Monitoring with alarms

During monitoring, make sure there is at least one physician in the area where the alarm sound can be heard or the alarm messages can be seen, so necessary measures can be taken when an emergency occurs.

When the monitor gives out an alarm and catches your attention, you should:

1. Check the patient's condition.
2. Identify the cause of the alarm.
3. Silence the alarm if necessary.

4. Check if the alarm is terminated when the alarm condition is solved.

5. Consider if the alarm limits should be changed. Some settings can be changed in the quick settings dialog.

When the monitored physiological parameter comes back within the threshold range or if the technical condition does not exist any longer, the monitor will stop signaling the alarm.

3.9 Working with wireless transducers

The Sunray B6 Fetal Monitor can be equipped with capability for wireless monitoring using two Ultrasound transducers and one TOCO transducer. If needed, you can mix the usage of wired and wireless transducer, for example by using a wireless ultrasound transducer for twin one and a wired for twin two, etc.
For specific instructions on how to set up patient monitoring with wireless transducers, see “Monitoring fetal heart rate with ultrasound transducers” on page 65 and “Monitoring uterine activity with TOCO transducer” on page 70 respectively.

Caution!
The wireless ultrasound and TOCO transducers are suitable for use when the patient is taking shower, but are not intended for underwater monitoring.

Caution!
Avoid the use of pulsating water jets while monitoring, as these can result in an incorrect or artificial heart rate being recorded.

Caution!
Before taking a new wireless system in use, make sure it does not interfere with other Sunray Medical monitors on the ward by ensuring that a unique wireless channel number is configured for each device.

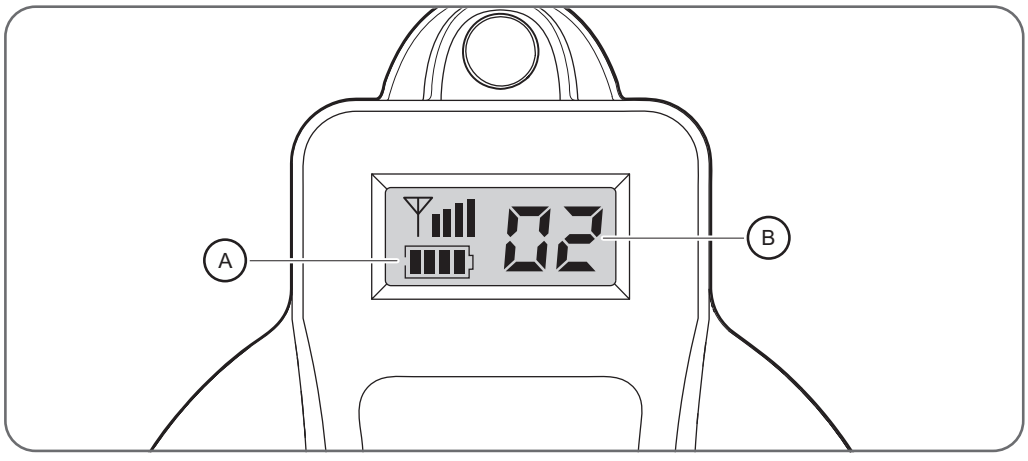


Figure 3:33 Display and markings for wireless monitoring of ultrasound FHR and TOCO.

1. When taking a wireless transducer out of the charging rack, confirm that the battery power (A) is sufficient for the monitoring you intend, and that the transducer communicates with the main unit, either by comparing the wireless channel number (B) on the transducer with the one displayed on the screen, or by simulating fetal heart movements and making sure it is reflected on the screen and/or loudspeaker.

2. If you experience problems with monitoring quality:

   a) Check the positioning of the transducers and tightness of the transducer belts. Transducer and/or fetus may have moved.

   b) Confirm that battery levels are sufficient.

   c) Confirm that the patient is within range of the main unit and not moving excessively. Monitoring quality cannot be guaranteed while the patient is e.g. walking.

   d) Confirm that the antennas on the rear side of the main unit are properly tightened.

   e) Confirm that no other Sunray monitors at the ward are configured with the same wireless channel number.

Tip!

If a wireless transducer is out of communication range from the main unit for more than two minutes, it will automatically shut down to save battery power. To reactivate the transducer, simply place it back into the charging rack for a short moment.

3. If any of the wireless transducers run out of battery, you can switch to a wired transducer simply by connecting one to the appropriate port. Do not forget to put the wireless one back in the charging rack after cleaning.

4. Alternatively, you can replace the wireless transducer with one from another unit:

   a) To do this, first place the depleted transducer in the charging rack of the other unit (which must be powered on). Confirm that the wireless channel number on the transducer display is updated by comparing it to the one on the screen (see Figure 3:35 on page 54).

   b) Then place the charged transducer from the other unit on the charging rack for the unit you are using to monitor your patient. Confirm that the wireless channel number on the transducer display is updated by comparing it to the one on the screen (see Figure 3:35 on page 54).

   c) You can now use the charged transducer to monitor your patient.

Tip!

To make sure that you always have charged transducers when you need them for monitoring, keep the main unit power cord connected to the mains between use.

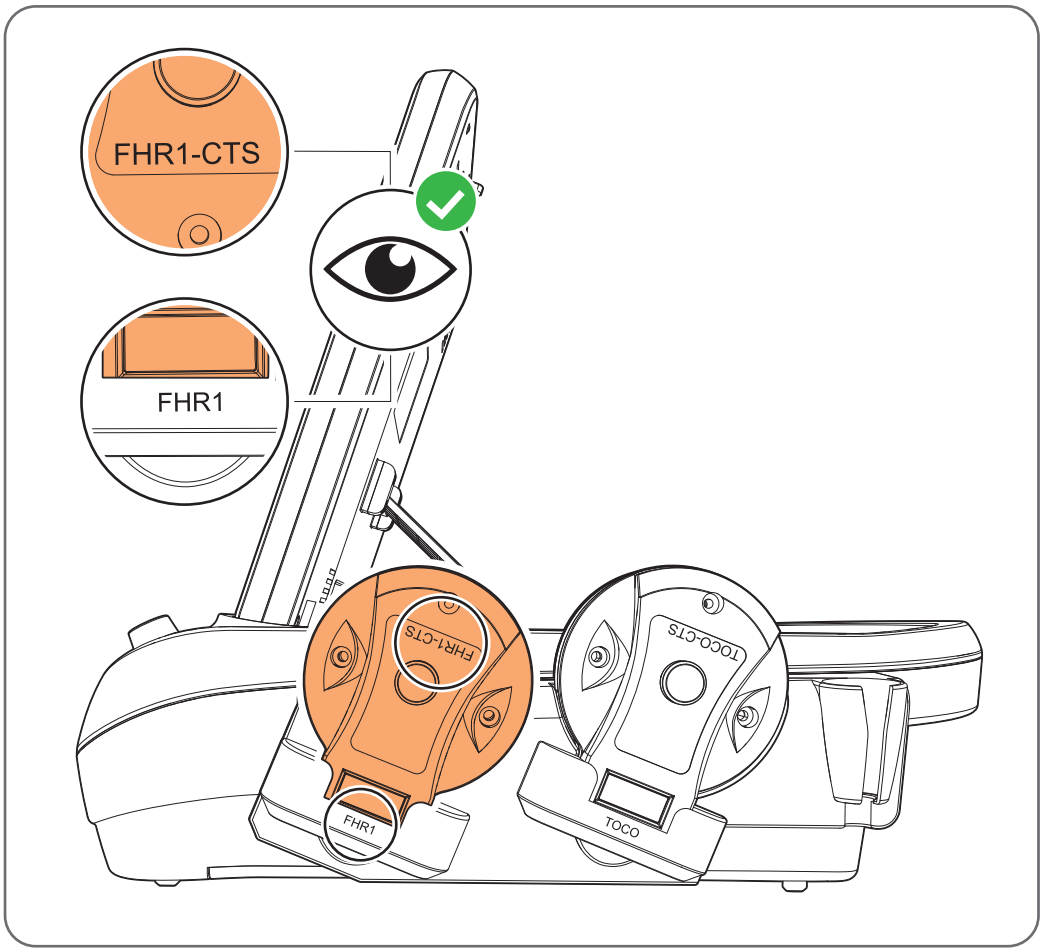


Figure 3:34 Charging rack with wireless transducers, placed in the right hand side of the main unit

5. When placing wireless transducers back in the charging rack of the other main unit, make sure they are properly cleaned before placing them in the intended compartment.

3.10 Automated CTG analysis

The automated CTG analysis allows the clinician to assess the condition of the fetus based on a number of predefined parameters and scores, calculated by the system. The following CTG analysis methods are supported.

a) NST - nonstress test. (See further “Publications on NST - Nonstress test” on page 119.)

b) CST - contraction stress test. (See further “Publications on CST - Contraction stress test” on page 120.)

c) Fischer’s analysis. (See further “Publications on Fischer’s analysis” on page 118.)

d) Krebs’ analysis. (See further “Publications on Krebs’ analysis” on page 119.)

e) STV analysis. (See further “Publications on STV” on page 118.)

Warning!

The automated CTG analysis functions are only intended for antenatal use, i.e. surveillance of pregnancies. They are not intended for intrapartum use, i.e. not for use during delivery.

Caution!

The automated CTG analysis functions are intended to support the physicians in interpreting the CTG. Conclusions should be drawn on the basis of the physicians' diagnosis.

Caution!

The automated CTG analysis functions calculate a number of scores derived from the monitored fetal heart rate, tocography and recorded fetal movements. It is the responsibility of the clinician to do the diagnostic interpretation of these and other data.

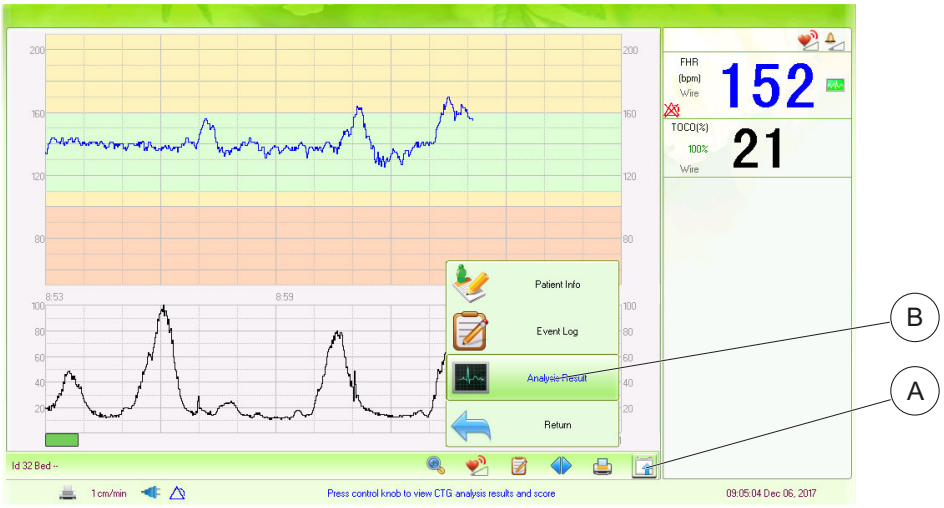


Figure 3:35 Accessing the automated CTG analysis function

1. Make sure your system is configured for the test that you intend running, STV, NST, CST, Fischer or Krebs.

2. Rotate the control knob and select the “Tools” menu button (A) and then the “Analysis Result” menu item (B) to enter the automated CTG analysis function.

   Note: The automated CTG analysis requires at least ten minutes of fetal heart rate data to be able to carry out the calculations.

3. While the analysis is running (10 to 60 minutes depending on configured interval), the monitor will continuously update the CTG analysis results on a two minute basis.

4. After the analysis has ended, you can choose to print the CTG trace together with the analysis results by selecting the “Print” button.

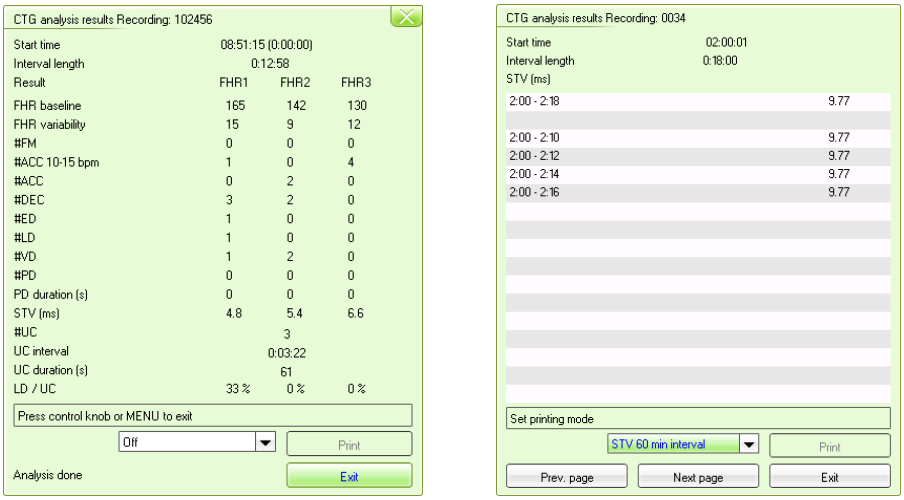


Figure 3:36 CTG analysis results

Tip!

If you are using the system in both antenatal and intrapartum recordings, it is recommended to keep the STV function disabled by default, and enable it when needed, to prevent STV values to be recorded in the event log during intrapartum recording. This is achieved by setting “Print CTG parameters” to “Off”, and when STV analysis is indicated, changing the analysis method from “Off” to “STV 60 min interval” in the “Quick settings” menu.

Tip!

- With STV analysis, the short term variation is calculated using a sliding window of 60 minutes
- With Fischer’s analysis, the short term variation (STV) is calculated using a sliding window of 20 minutes.
- With Krebs’ analysis, the short term variation (STV) is calculated using a sliding window of 30 minutes.

Parameter	Description
Start time	The relative start time of the analysis.
Interval length	The analyzed monitoring interval length (10 to 60 minutes).
FHR Baseline	Average fetal heart rate when not influenced by fetal movement or contractions.
FHR Variability	Estimated average long term variation (LTV) of the fetal heart rate when the fetal heart rate is at the baseline, measured in bpm.
#FM	Number of fetal movements registered with fetal movement marker or via transducers by automatic fetal movement detection.
#ACC	Number of accelerations with amplitude larger than 10 bpm lasting more than 10 seconds, and accelerations with amplitude larger than 15 bpm lasting more than 15 seconds.
#DEC	Total number of decelerations.
#ED	Number of early decelerations.
#LD	Number of late decelerations.
#VD	Number of variable decelerations.

Parameter	Description
#PD	Number of prolonged decelerations.
PD Duration (s)	Average duration time of prolonged decelerations.
STV (ms)	Estimated short term variation, measured in milliseconds.
#UC	Number of uterine contractions.
UC interval	Average contraction interval (peak-to-peak).
UC duration (s)	Average contraction duration in seconds.
LD / UC	Ratio of late decelerations.

3.11 Printing on paper

The Sunray B6 Fetal Monitor has a built-in thermal printer with capability for both continuous and retrospective printing.

3.11.1 Printer overview

Figure 3:37 View of printer with associated controls

Pos	Part	Description
1	Print key	Used for starting and stopping continuous printout.
2	Printer status indicator	Printer status indicator as printing, printer error (printer symbol is crossed through) or idle mode (printer symbol is gray).
3	Paper outlet	-
4	Technical alarms	Indicates inability to print, e.g. out-of-paper or tray open condition.
5	Button for opening paper tray	Used for opening of the paper tray.

3.11.2 Printout overview

Caution!

If there is any discrepancy between the display and the printout, base assessment on the printout.

Caution!

If the data is doubtful, clinicians should make diagnoses based on the real condition.

Tip!

When working with printouts, be aware that since the pixel resolution is higher on paper than on the screen, the granularity of the fetal heart rate trace will also be higher. However, this will not affect the classification of variability.

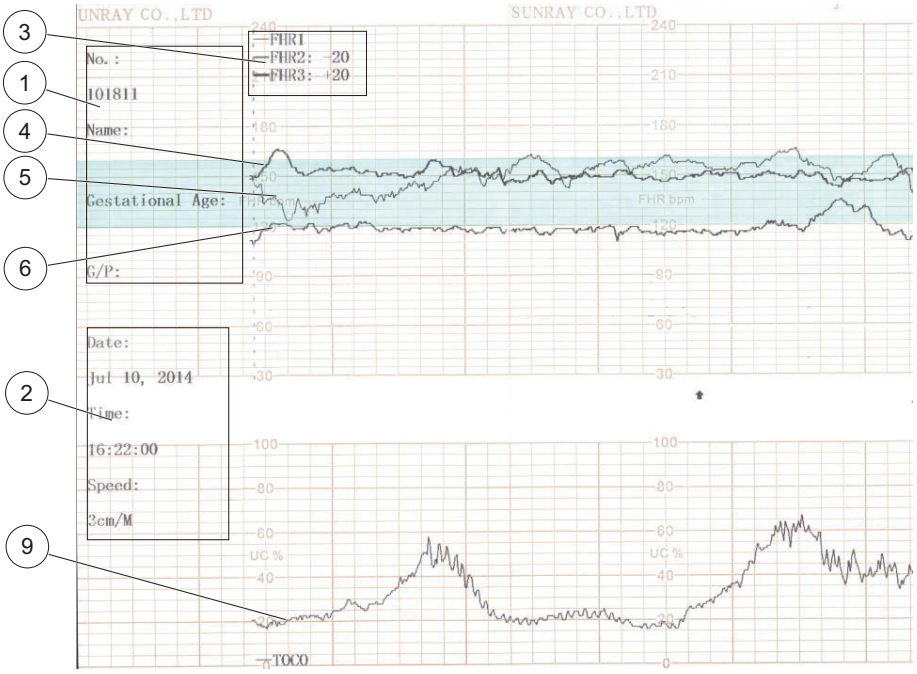


Figure 3:38 Example of printout with traces

Pos	Data	Description
1	Patient information	Patient information list, including the ID, name etc.
2	Recording Information	A list of current date, time, print speed
3	HR trace legend	Defines line thickness and configured twin separation offset used for heart rate traces
4	FHR3 trace	FHR3 is drawn with thick line.
5	FHR1 trace	FHR1 is drawn with medium thick line.
6	FHR2 trace	FHR2 is drawn with thin line.
9	TOCO trace	Drawn with medium thick line.

3.11.3 Preparing for printing

Caution!
Different paper speed settings cause different FHR trace appearance on the printout. To avoid misinterpretation, we recommend setting all monitors on the ward to the same paper speed.

1. Make sure there is enough printer paper for the recording you wish to print. If needed, load new paper according to “Loading paper” on page 65.
2. Ensure the printer settings match the recording you wish to make, including the “Printing timeout” setting which will automatically stop the printing after the specified time.

Tip!
You can set the offset of the FHR2 and FHR3 traces to separate the three FHR traces on the screen and the recorder paper.

3.11.4 Continuous printing during recording

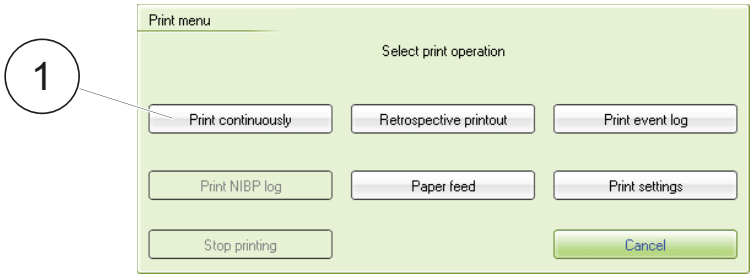


Figure 3:39 Print menu, continuous printing

1. After a recording is started, press the “PRINT” touch key and select “Print continuously” from the print menu.
2. The printer will now start printing the trace up until current time, and then continue printing until the recording is ended, or the printer timeout is reached.
3. If you want to cancel the printing, press the “PRINT” touch key and select “Stop printing” from the print menu.
4. If you want to print the event log or feed paper, press the “PRINT” touch key and select desired option from the print menu.

Tip!
When the printer runs out of paper, a technical alarm will be shown on the screen.

3.11.5 Retrospective printing during or after recording

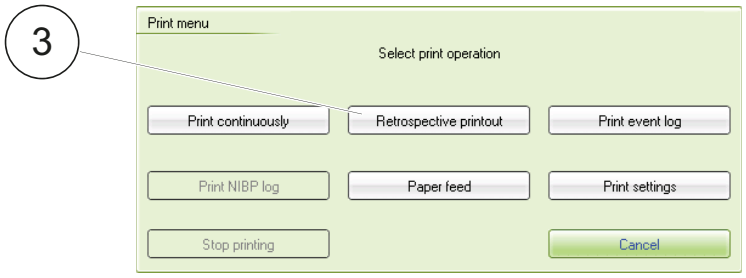


Figure 3:40 Print menu, retrospective printing

To retrospectively print a segment of a recording:

1. Ensure the recording you wish to print is displayed on the screen. If needed, open it by using the review recordings menu option.

2. Ensure the printer is not already occupied with printing another trace.

3. Press the “PRINT” touch key and select “Retrospective printing” (or “Print segment”) from the print menu.

4. Rotate the control knob to select the page where you want to start the printing. Push the control knob. A blue line will now appear in the trace (A). Press the control knob to select the start point. The blue line will now turn to red (B).

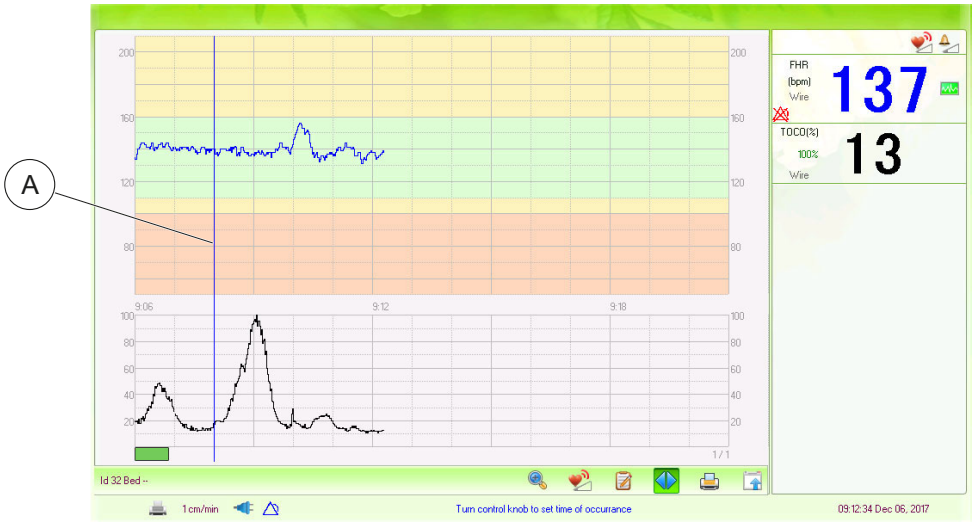


Figure 3:41 Selecting start of printout range

5. Rotate the control knob to select the page where you want to finish the printing. Push the control knob. A blue line will appear in the trace (C). Press the control knob to select the end point. The blue line will now turn to red and the printing will start.

Figure 3:42 Selecting end of printout range

6. If you want to cancel the printing, press the “PRINT” touch key and select “Stop printing” from the print menu.

3.11.6 Loading paper

Caution!

Use only printer paper with the same HR Scale as the scale set on the screen. Use of printer paper with incorrect scaling can result in incorrect assessment of the CTG trace. You can verify compatibility of the paper by performing a test printout from the “Printer Settings” menu.

Caution!

Only use printer paper provided by Sunray Medical. Paper provided by third party manufacturers may have different width and grid layouts, causing risk of incorrect CTG trace assessment.

Tip!

Thermal printer paper should be stored in a cool, dark and dry environment.

The printer can be loaded with one pack of paper at a time. One pack consists of 150 connected sheets of paper and will be sufficient for 25 hours with a printing speed of 1 cm per minute.

The last five pages in the pack have a special marking to draw the attention of the operator to the fact that the paper is about to run out.

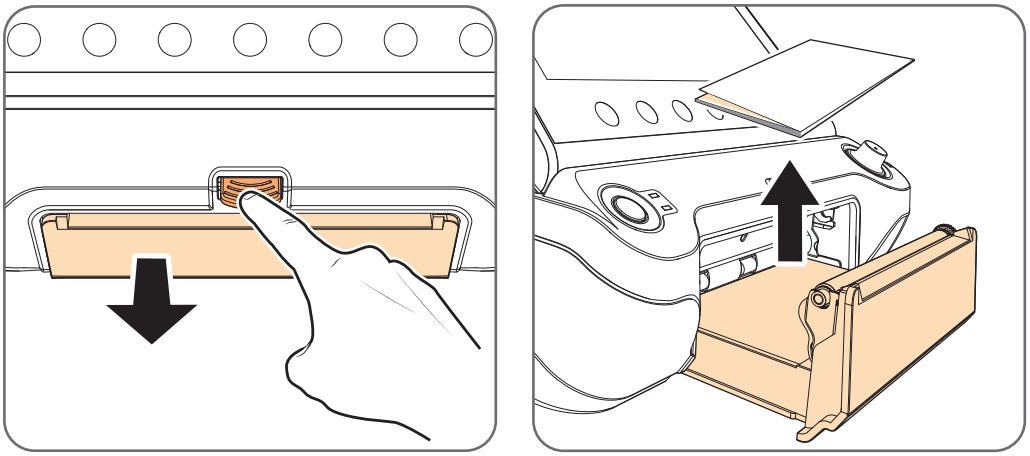


Figure 3:43 Procedure to load paper

1. To load paper, first press the button that opens the paper tray.
2. Remove any paper that is left over from the previous pack. Only one pack of paper fits into the printer.

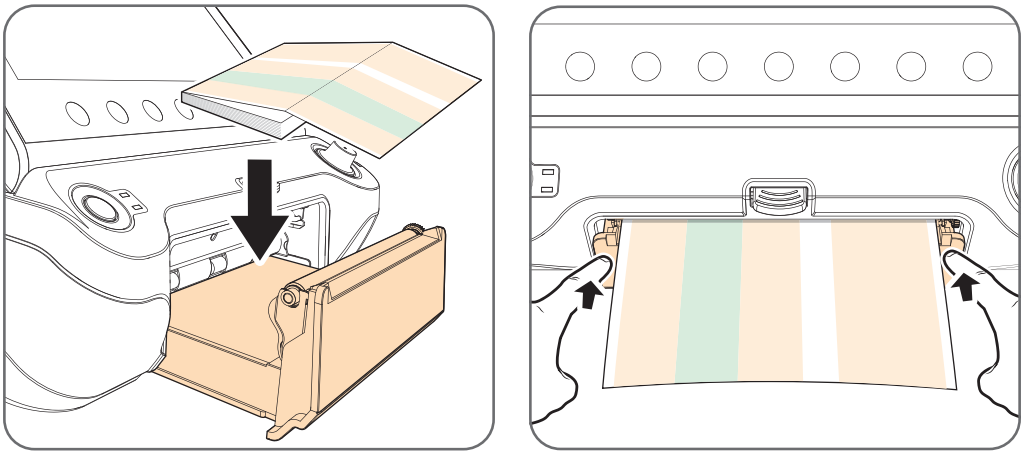


Figure 3:44 Procedure to load paper

3. Open a new pack of thermal paper. Unfold the top page of the stack, place the stack with the heart rate grid upper section to the left, and then slide the paper into the paper tray. Pull the top page of the loading paper out of the tray.
4. Push the paper tray all the way in. The tray must be in the closed position for the printer to function.
5. The printer is now ready for use.

3.12 Managing stored recordings

For each completed recording, a separate recording file containing measurement data, annotations and patient information is recorded and stored within the main unit. The

file is intended for retrospective purposes, and can be brought up for review on the screen, printed on paper or exported to a USB storage device.

The storage capacity in the monitor is approximately 500 recordings depending on recording length and content.

When the storage reaches the maximum capacity, the system will delete the oldest recordings automatically to create space for new recordings.

Tip!
A password can be set to prevent unauthorized access to stored recordings.

3.12.1 Reviewing a stored recording

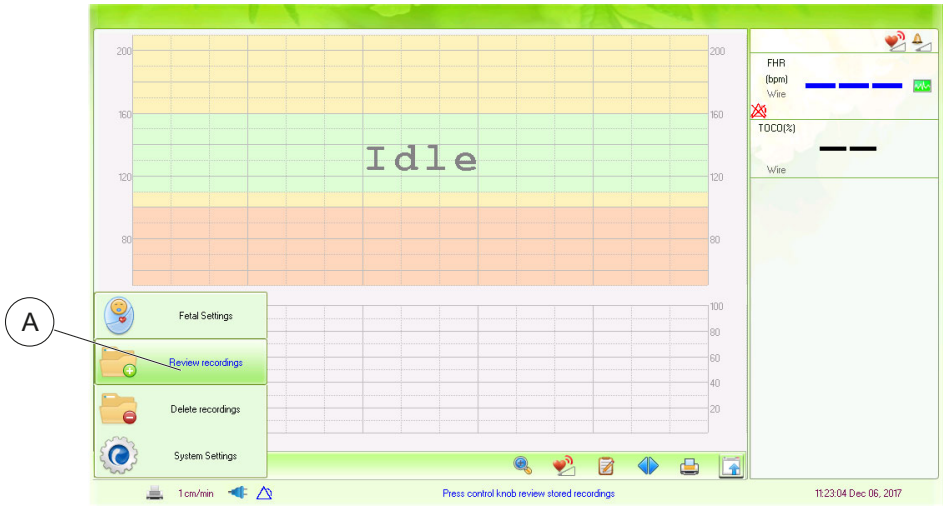


Figure 3:45 "Review recordings" menu option

1. Press the "MENU" touch key to open the system menu, and then select "Review recordings" (A). Note that the possibility to review a previous recording is only accessible while no other recording is ongoing, so you will have to end any ongoing recordings first.

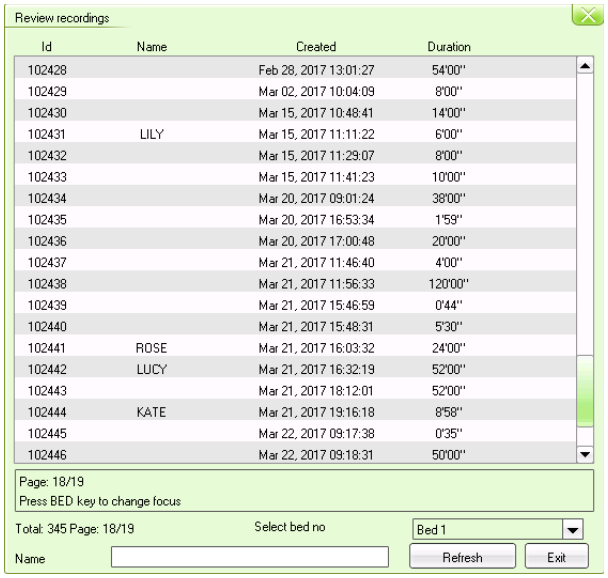


Figure 3:46 Selecting recording for review

2. Rotate the control knob to highlight the recording you wish to review, and press the knob to confirm. The recording is now displayed, allowing you to analyze the CTG trace, review events and alarms, and to retrospectively print the recording.

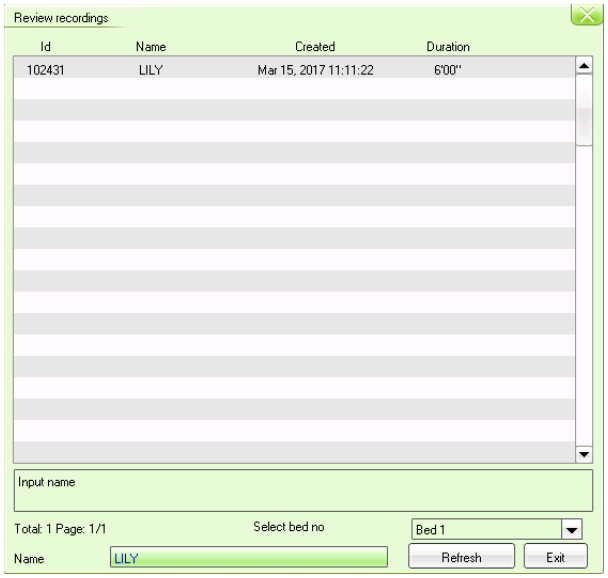


Figure 3:47 Procedure for filtering list of recordings based on patient name

3. Alternatively, you can search for a specific recording based on the patient's name. To do this, enter the patient's first and/or last name in the "Name" edit fields, and then press "Refresh" to update the list.

3.12.2 Archiving stored recordings to USB

1. Connect a USB storage device with sufficient storage capacity to the USB connector at the rear side of the main unit. Also make sure the storage device is not write-protected.

2. Press the “MENU” touch key to open the system menu, and select “Export Recordings”.

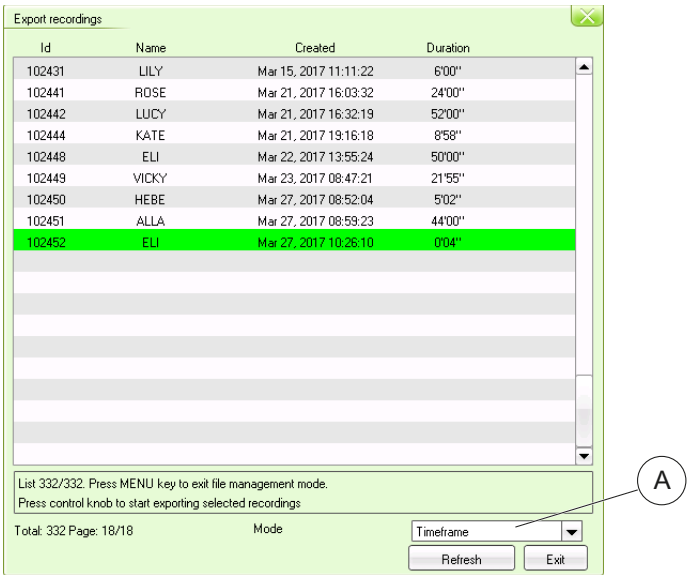


Figure 3:48 Selecting recording(s) for export to USB

3. To export multiple recordings in one step, first ensure that the “Mode” field (A) is set to “Timeframe”. Rotate and press the control knob to select the first recording in the sequence to be exported. Then rotate and press the control knob to select the last recording to be exported. A confirmation dialog will ask you to confirm the selected interval before copying the recording files to the USB storage device.

4. To export a single recording, first change the “Mode” field (A) from “Timeframe” to “Single”. Then rotate and press the control knob to select the single recording you wish to export. A confirmation dialog will ask you to confirm before copying the file.

5. Select “Exit” to return to the main screen.

6. Remove the USB storage device from the main unit.

3.12.3 Deleting stored recordings

1. Press the “MENU” touch key to open the system menu, and then select “Delete Recordings”.

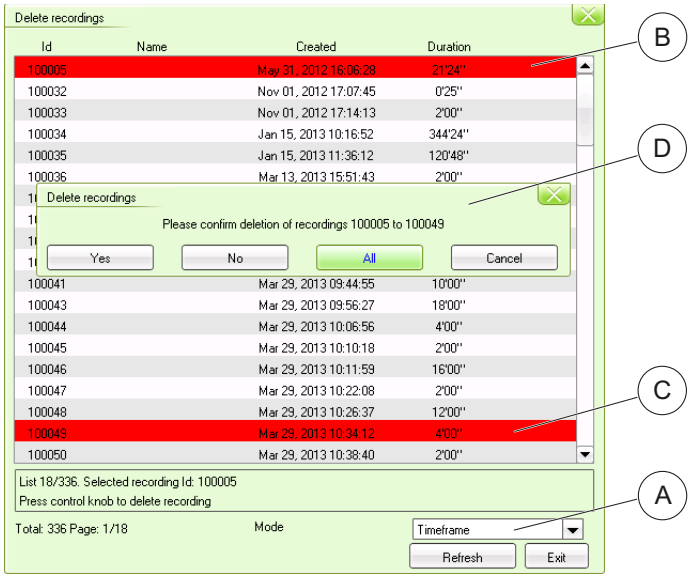


Figure 3:49 Selecting multiple recordings for deletion

2. To delete multiple recordings in one step, first ensure that the “Mode” field (A) is set to “Timeframe”. Rotate and press the control knob to select the first recording in the sequence to be deleted (B). Then rotate and press the control knob to select the last recording to be deleted (C). A confirmation dialog (D) will ask you to confirm the selected range before deleting the files.

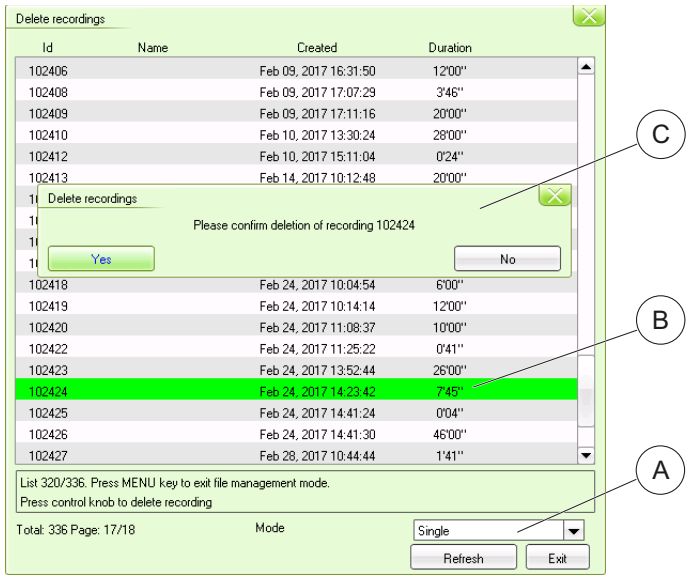


Figure 3:50 Selecting single recording to delete

3. To delete a single recording, first change the “Mode” field (A) from “Timeframe” to “Single”. Then rotate and press the control knob to select the single recording (B) you wish to delete. A confirmation dialog (C) will ask you to confirm before deleting the file.

4. Select “Exit” to return to the main screen.

4 Monitoring

4.1 Monitoring fetal heart rate with ultrasound transducers

4.1.1 Prerequisites

Accessories
Ultrasound transducer (wired or wireless)
Ultrasound gel
Transducer belt or elastic tubular net

4.1.2 Setting up

Caution!

- During ultrasound recording, maternal heart rate may be picked up accidentally. Regularly check that the ultrasound transducer is monitoring the fetus.
- During ultrasound recording in twin and triplet pregnancies, the other twins heart rates may be picked up accidentally. Regularly check that the ultrasound transducer is monitoring the intended twin.
- Exercise of clinical judgment in the monitoring of low-risk patients to avoid unnecessary insonation.

1. Ensure the power is switched on and a recording is started.
2. If you wish to record fetal movements using the ultrasound transducer, ensure the “AFM operation mode” setting in the “Fetal Settings” menu is set to “FHR or “Both”.

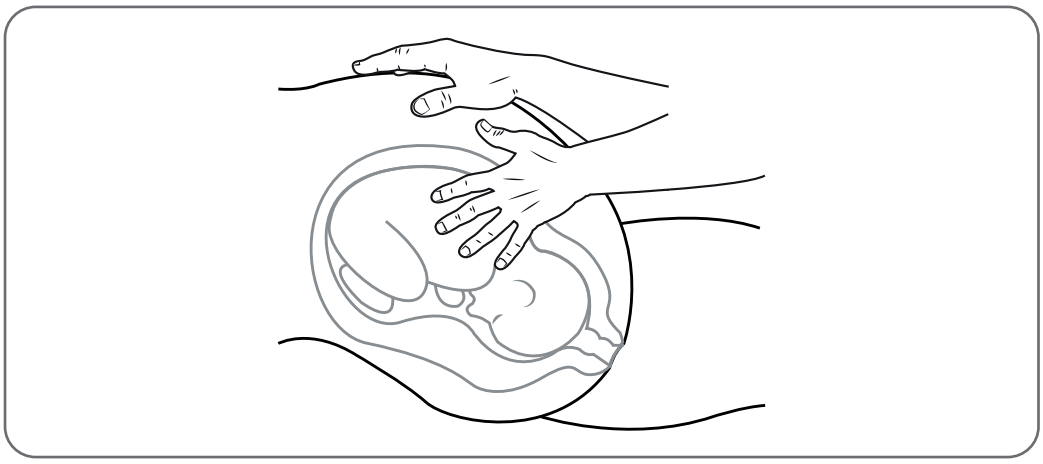


Figure 4:50 Palpation to locate the back of the fetus

3. Identify the back of the fetus (palpation).

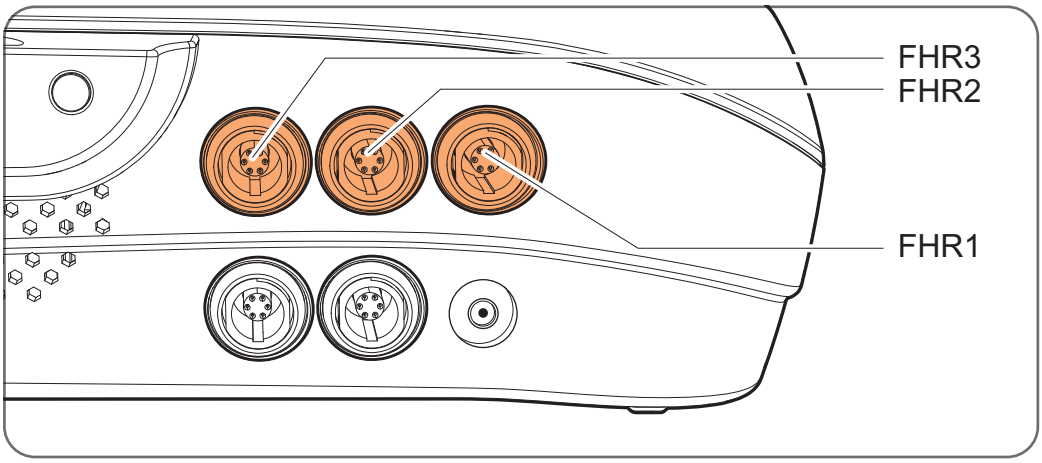


Figure 4:51 The FHR1, FHR2 and FHR3 connectors for wired operation on the sides of the main unit

4. To set up for monitoring with wired ultrasound transducer, connect the ultrasound transducer to the appropriate connector, FHR1 (for fetus 1), FHR2 (for fetus 2) or FHR3 (for fetus 3), on the main unit.

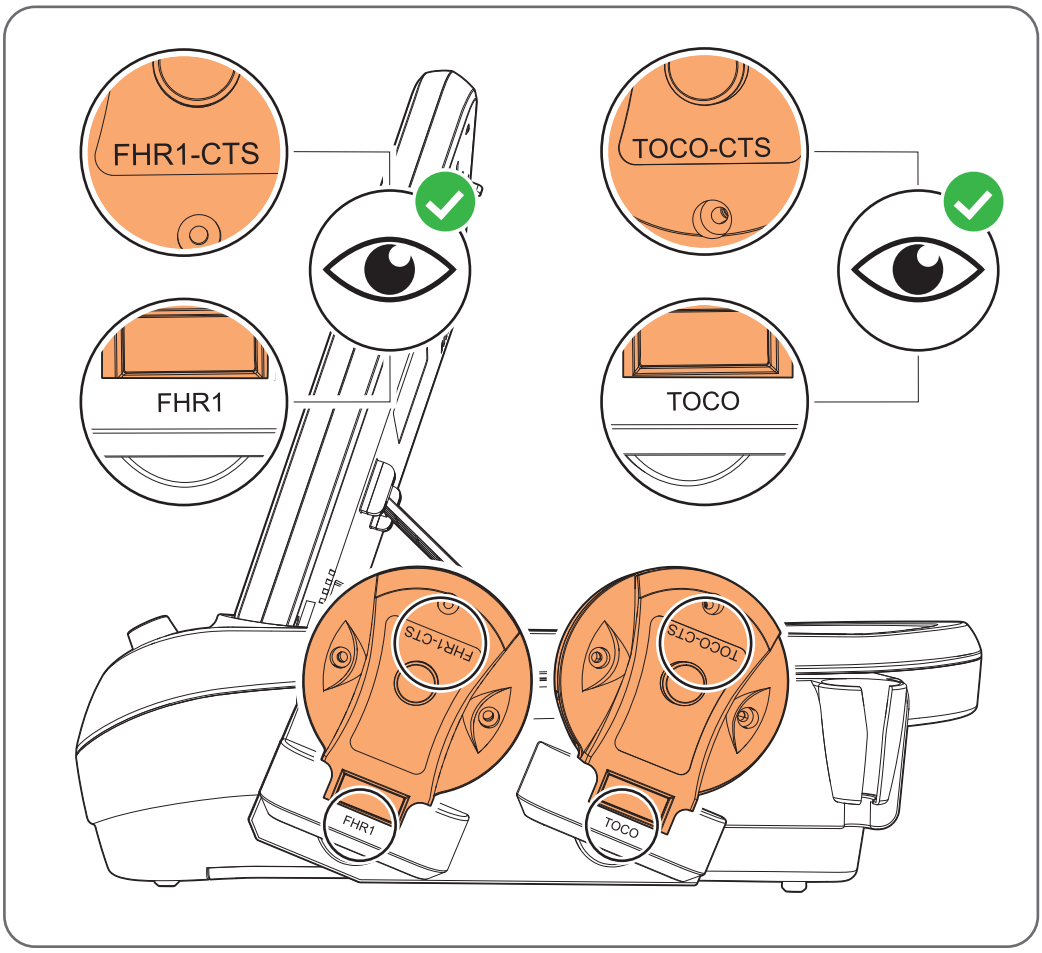


Figure 4:52 The wireless FHR1 ultrasound transducer in the charging rack

5. Alternatively, to set up for monitoring with wireless ultrasound transducer, lift the appropriate transducer FHR1 (for fetus 1) from the charging rack. Ensure that the transducer battery is sufficiently charged for the intended monitoring session. Also

verify that the wireless transducer is communicating with the main unit by follow the instructions in “Working with wireless transducers” on page 49.

Tip!

If the transducer battery is not sufficiently charged, you can use a wired transducer instead, or take a charged transducer from another unit. To pair a transducer from another unit with the unit you are using for monitoring your patient, follow the instructions in “Working with wireless transducers” on page 49.

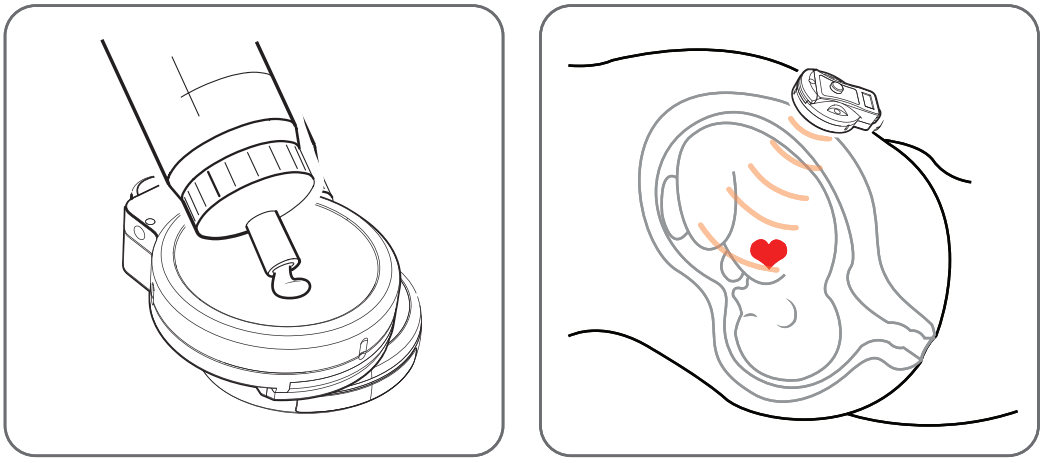


Figure 4:53 Application of ultrasound transducer

6. Apply ultrasound gel on the ultrasound transducer. Do not use excessive amount of gel. The ultrasound transducer can glide out of position.

7. Place the transducer on the maternal abdomen with the flat surface against the skin. Direct the transducer towards the fetal heart.

8. Moving the ultrasound transducer over the skin, locate the position where the audible feedback from the fetal heart is strongest.

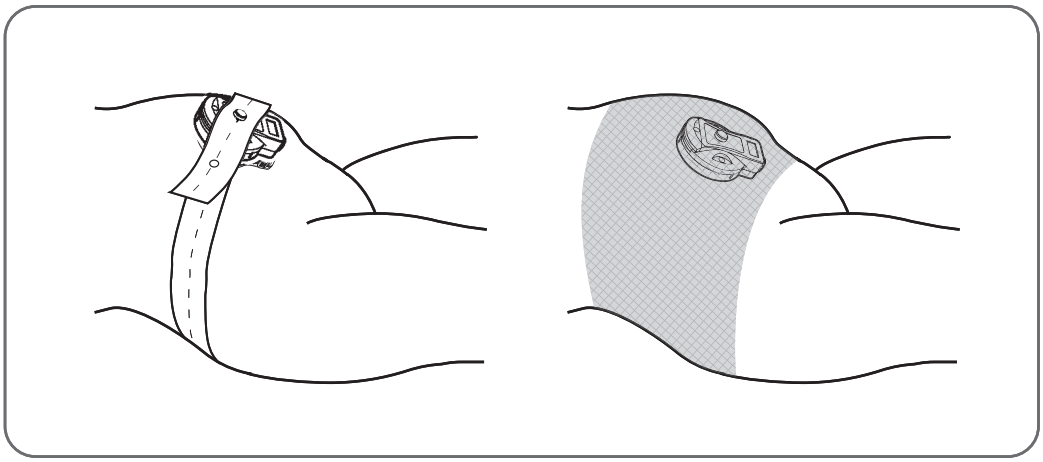


Figure 4:54 Ultrasound transducer secured with belt or tubular net

9. Use a transducer belt or an elastic tubular net to secure the ultrasound transducer on the maternal abdomen.

Tip!

Elastic tubular net is often considered more comfortable, especially for obese patients.

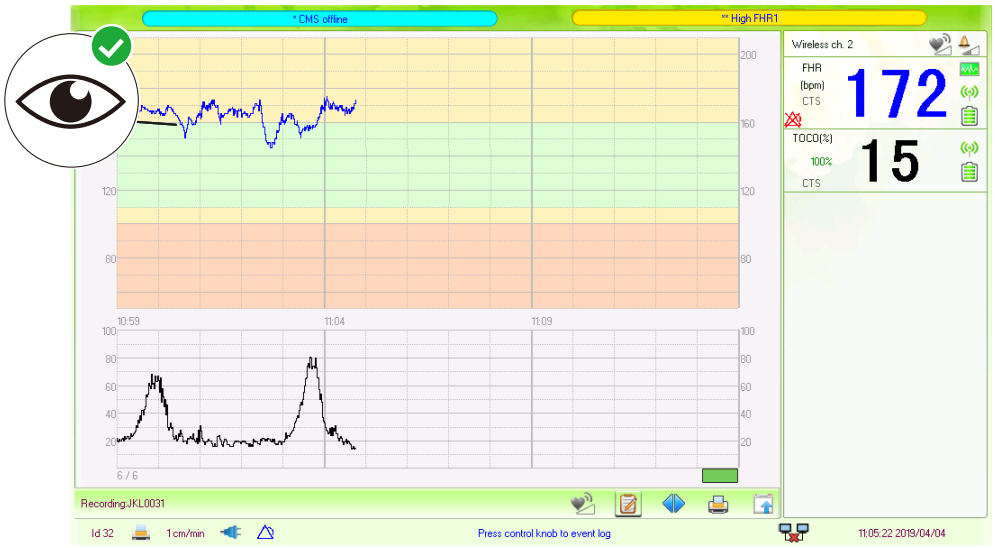


Figure 4:55 Verifying ultrasound recording quality

10. Verify that you have a good signal, that you are not accidentally recording the maternal heart rate, heart rate of twin, or half the fetal heart rate.

Tip!

- During ultrasound recording, the transducer may have to be relocated as the fetus may be moving and descend in the pelvis.
- If difficult to make contact with fetal heart beat, perform sonography.
- If both wired and wireless ultrasound transducer is connected for the same twin, the wired transducer will take precedence over the wireless.

4.1.3 Presentation

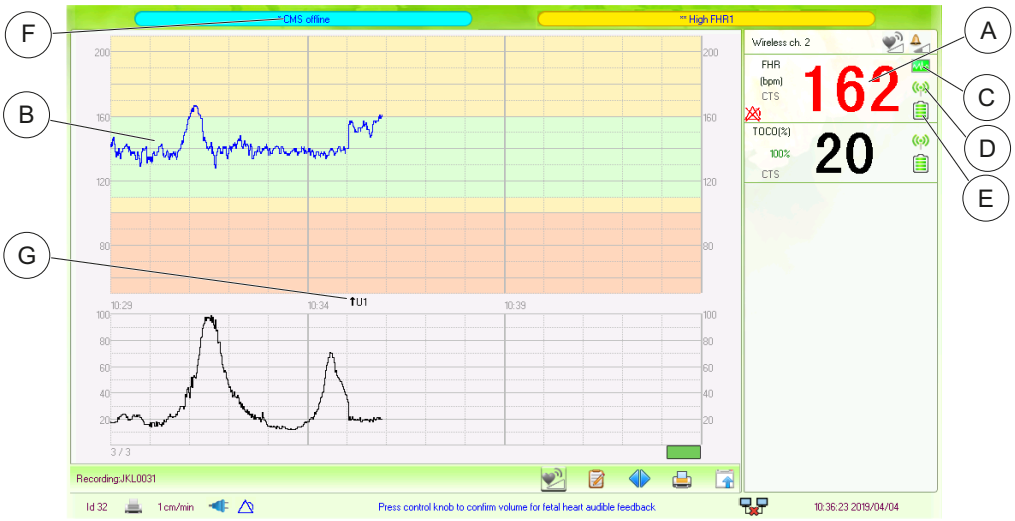


Figure 4:56 Presentation of ultrasound FHR

Pos	Description
A	Heart rate value (bpm)
B	Heart rate trace
C	Signal quality indicator
D	Transmission quality for wireless transducer
E	Battery charge status for wireless transducer
F	Alarms related to ultrasound FHR monitoring
G	Fetal movement recorded with the ultrasound transducer

4.1.4 Alarms

Name	Type
High/Low FHR	Physiological alarm
FHR1/2/3 and FHR1/2/3 coincide	Technical alarm
FHR1/2/3 Transducer disconnected	Technical alarm

4.2 Monitoring uterine activity with TOCO transducer

4.2.1 Prerequisites

Accessories
TOCO transducer (wired or wireless)
Transducer belt or elastic tubular net

4.2.2 Setting up

1. Ensure the power is switched on and a recording is started.
2. If you wish to record fetal movements using the TOCO transducer, ensure the “AFM operation mode” setting in the “Fetal Settings” menu is set to “TOCO or “Both”.

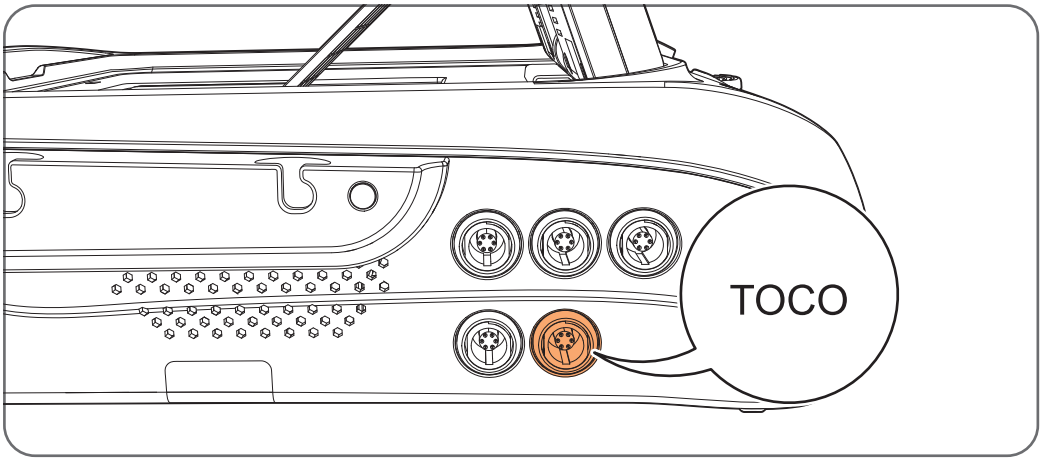


Figure 4:57 The TOCO connector for wired operation on the right side of the main unit

3. To prepare for monitoring with wired TOCO transducer, connect the TOCO transducer to the corresponding connector on the main unit.

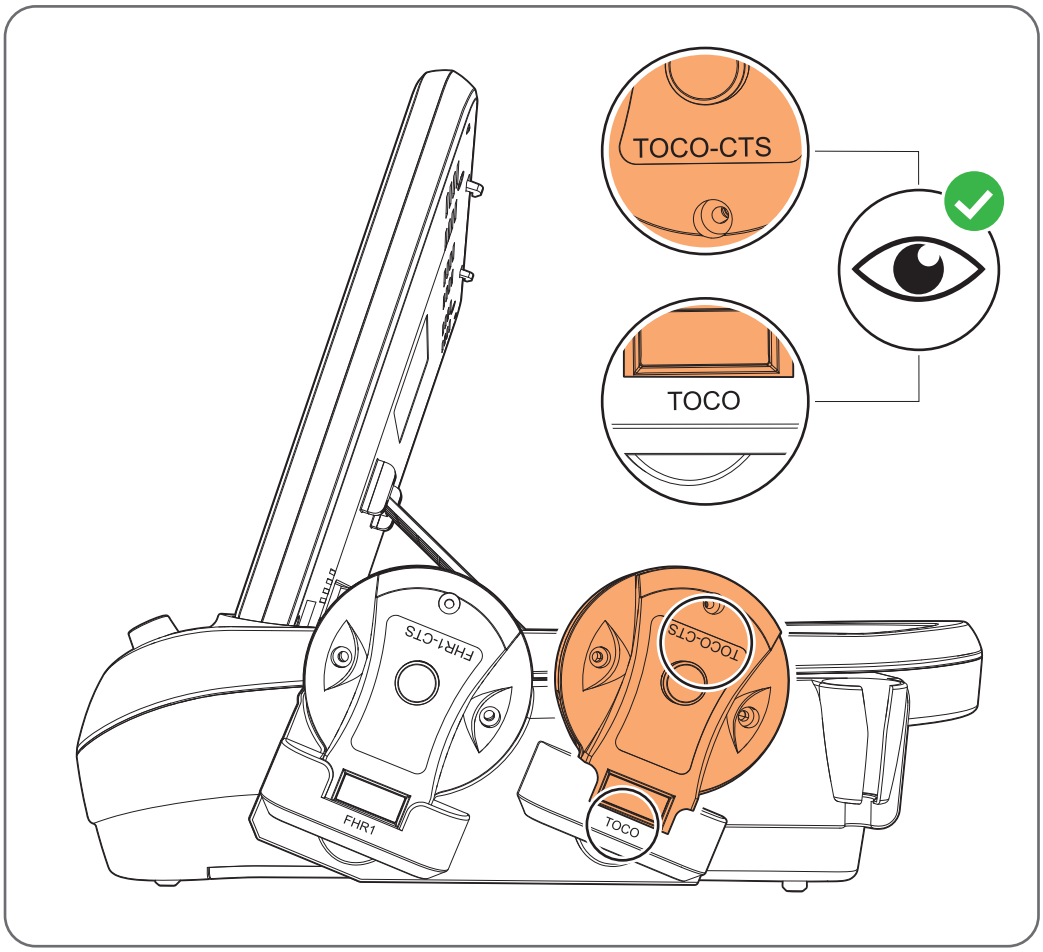


Figure 4:58 Wireless TOCO transducer in charging rack

4. Alternatively, to prepare for monitoring with wireless TOCO transducer, lift the wireless TOCO from the charging rack and ensure that the transducer's battery is sufficiently charged for the intended monitoring session. Also verify that the wireless transducer is communicating with the main unit. See further instructions in "Working with wireless transducers" on page 49.

Tip!

If the transducer battery is not sufficiently charged, you can use a wired transducer instead, or take a charged transducer from another unit. To pair a transducer from another unit with the unit you are using for monitoring your patient, follow the instructions in "Working with wireless transducers" on page 49.

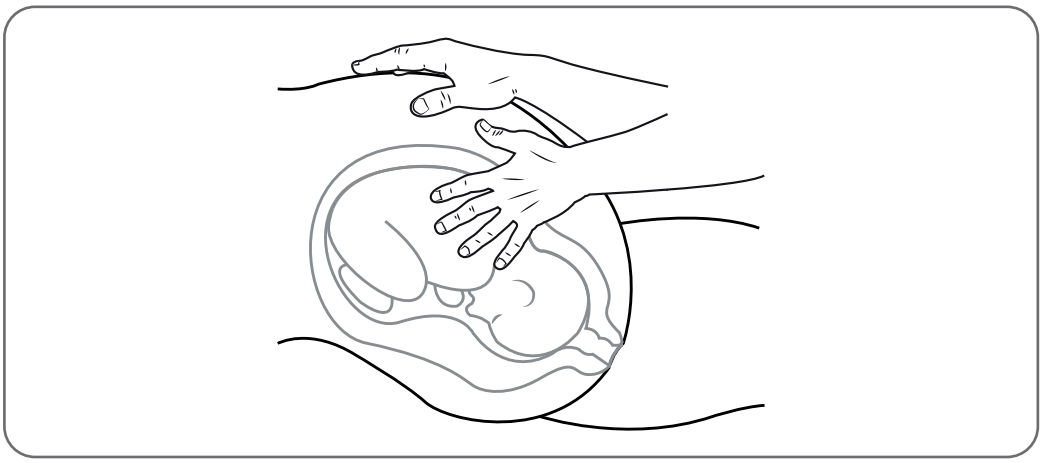


Figure 4:59 Palpation to locate best placement for TOCO transducer

5. Identify the upper part of the fundus (palpation) to locate best placement.

6. Place the TOCO transducer over the fundus. Do *not* use ultrasound gel with the TOCO transducer.

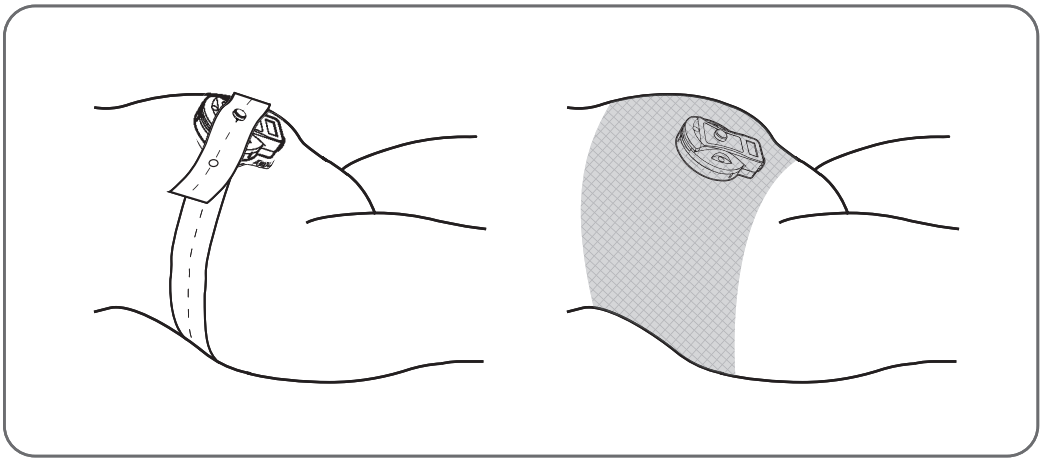


Figure 4:60 TOCO transducer secured with belt or tubular net

7. Use a transducer belt or an elastic tubular net to secure the TOCO transducer over the fundus.

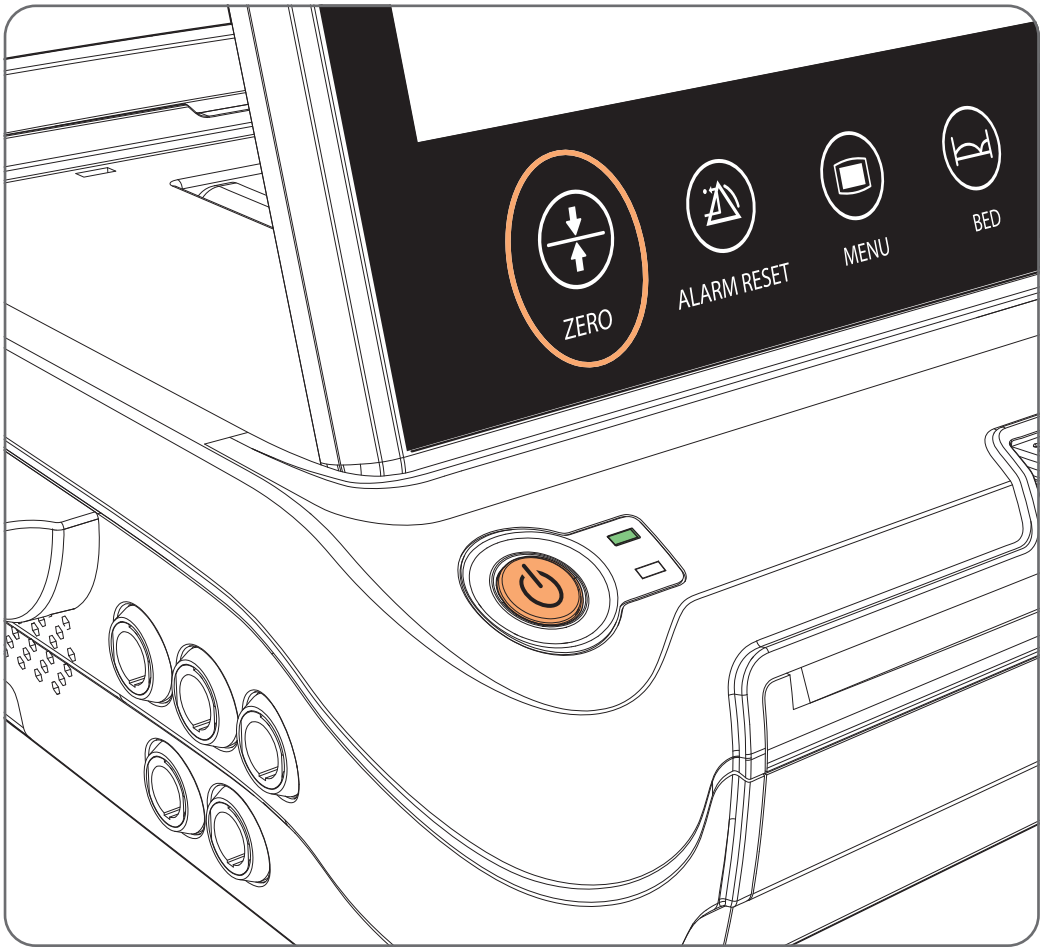


Figure 4:61 Zero TOCO functions using the “ZERO” touch key

8. To zero the TOCO signal, press the “ZERO” touch key between contractions.

9. Await the first contraction and verify that it is clearly defined in the trace.

Tip!

- During TOCO recording, the transducer may have to be relocated as the fetus may be moving and descend in the pelvis.
- If needed, you can adjust the sensitivity of the TOCO recording by changing the “TOCO sensitivity” setting in “Fetal Settings”.

4.2.3 Presentation

Figure 4:62 Presentation of uterine activity recorded with TOCO transducer

Pos	Description
A	TOCO value (%)
B	TOCO trace
C	Fetal movement recorded with the TOCO transducer

4.2.4 Alarms

Name	Type
> 5 UC in 10 mins	Physiological alarm

4.3 Monitoring fetal movements using the fetal movement marker

4.3.1 Prerequisites

Accessories
Fetal movement marker (wired or wireless)

4.3.2 Setting up

1. Ensure the power is switched on and a recording is started.

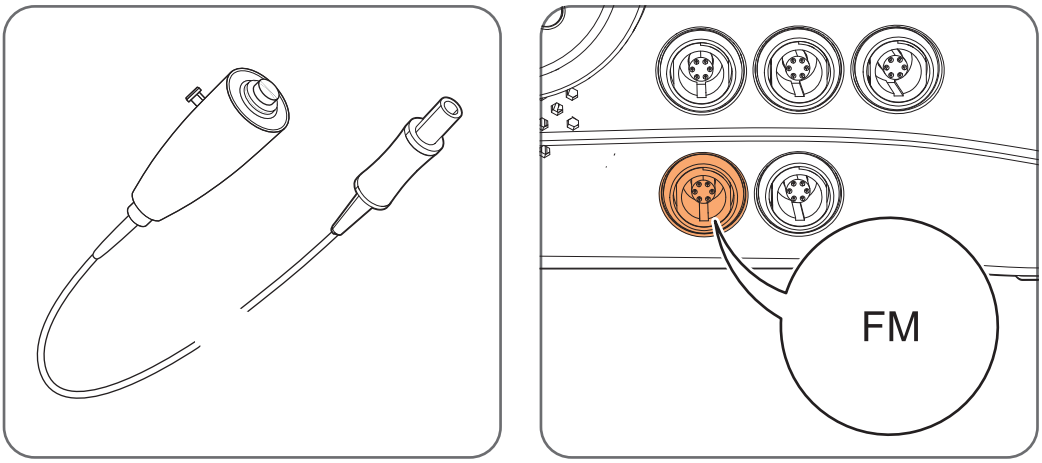


Figure 4:63 The fetal movement marker connector for wired operation on the right side of the main unit

2. To prepare for using the wired fetal movement marker, connect it to the corresponding connector on the main unit.

Figure 4:64 Fetal movement marker operated by the mother

3. Let the patient hold the (wired or wireless) marker in her hand; ask her to press the button when she feels a fetal movement.

Tip!

Multiple fetal movement marker actuations within 5 seconds are counted as one movement only.

4.3.3 Presentation

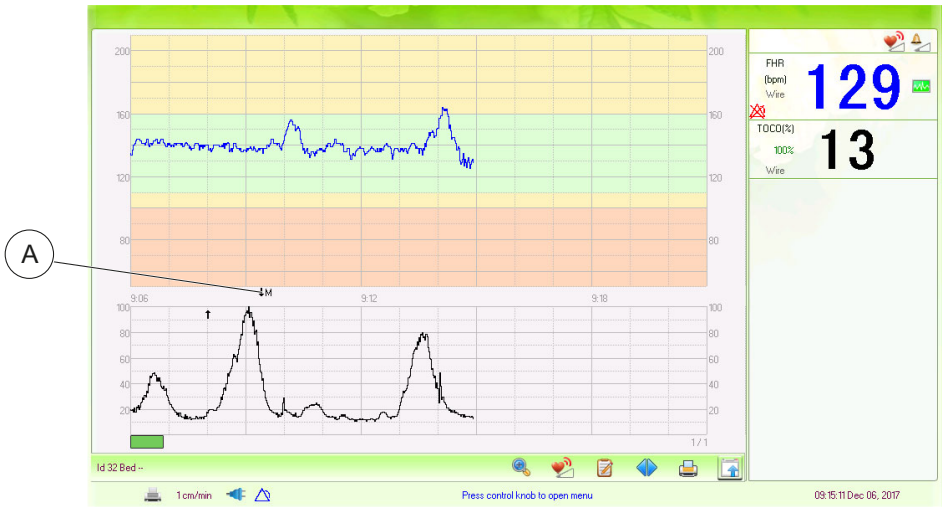


Figure 4:65 Presentation of fetal movement indications on the main screen

Pos	Description
A	Fetal movement marker in CTG trace

5 Maintenance

5.1 Intervals

After each use

Remove transducers from the patient; wipe remaining gel off the patient and the transducer with a clean soft cloth or tissue.

Wait for the paper printout to stop and then tear it off along the perforation.

In case of repeated signal problems

Inspect transducers, cables and connectors to check for cracks or other damage. If damage is suspected, perform appropriate function test described later in this section.

Every 6 months

For units with installed system battery option, make sure that the batteries are fully recharged at least every 6 months.

Every 12 months

The system should be inspected by qualified technicians every 12 months.

Caution!

- For units with installed battery option, make sure that the batteries are fully recharged at least every 6 months.
- The repair of the instrument must be conducted by technical personnel authorized by the manufacturer.

5.2 Inspecting and cleaning the equipment

Caution!

- To avoid cross-contamination between patients, it is recommended that transducers and cables are cleaned and disinfected after each use, before they are put back to storage.
- The manufacturer has no responsibility for the effectiveness of listed chemical agents against infectious diseases. Consult infectious disease experts in your hospital if needed.
- Do not use strong solvents such as acetone.
- Never use abrasives such as steel wool or metal polish.

Task interval

Between each use.

Conditions

Comply with hospital guidelines and local regulations.

Accessories
Any of the following detergents: • Mild soap solution • Isopropanol 70% • Ethanol 70%
Soft cloth

5.2.1 Cleaning the main unit

Caution!

- Unplug the monitor from mains power and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.
- Avoid pouring liquids on the monitor while cleaning.
- Do not spray directly on the main unit.
- Do not allow any remaining solution on the surface of the monitor.

1. Inspect the main unit, power cable and system interface cables for cracks and damage. If damage is suspected, contact qualified service personnel.

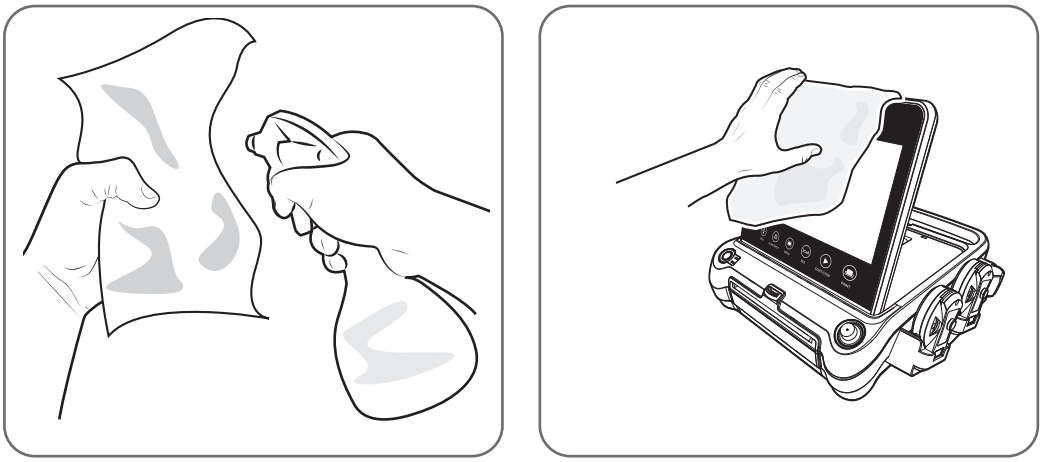


Figure 5:66 Cleaning the main unit

2. Clean all external surfaces of the main unit using a cloth and any of the above listed detergents.

3. Let air-dry or wipe the remaining moisture with a soft dry cloth. Also ensure that there are no residues of cleaning detergent or water in the wireless transducer charging rack.

5.2.2 Cleaning the transducers

Caution!
Unplug transducers and sensors from the main unit before cleaning.

1. Inspect the transducers and their cables for cracks and damages. If damages are suspected, contact qualified service personnel.

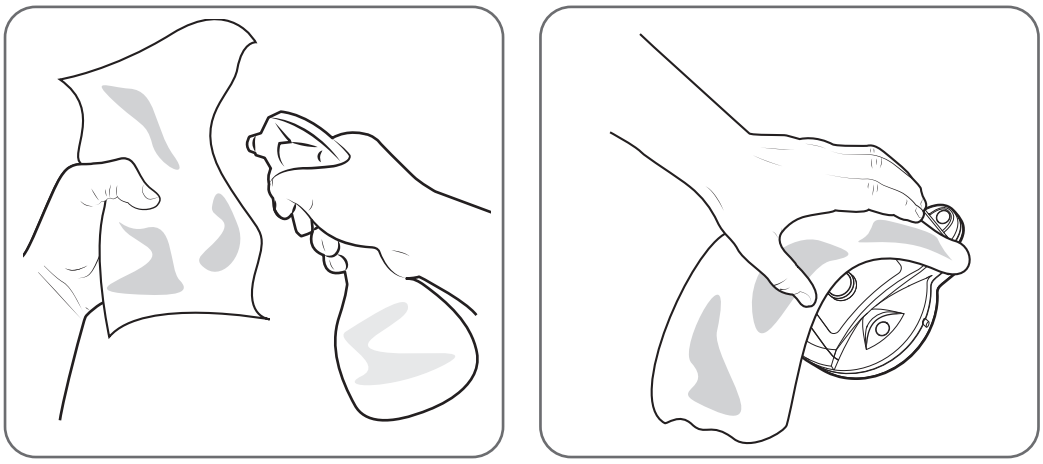


Figure 5:67 Cleaning transducers

2. Clean the external surfaces using a cloth and any of the above listed detergents.
3. Let air-dry or wipe the remaining moisture with a soft dry cloth.

5.3 Performing functional check

Task interval
Daily.

Conditions
No special conditions needed for completion of this task.

Accessories
Depending on scope of test and configuration: • Computer connected to the hospital intranet for testing network connectivity.

5.3.1 Main unit and printer

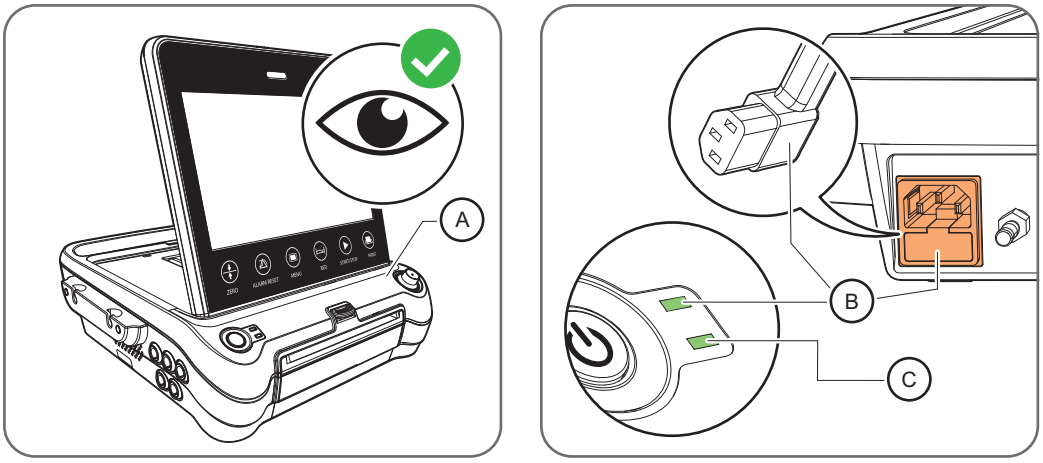


Figure 5:68 Inspecting main unit and printer

1. Inspect the main unit (A) and make sure that it is not damaged or dirty.
2. If operating from mains power, make sure the mains cable (B) is connected. If operating from internal battery, make sure that it is fully charged (C) before use.
3. Power on the main unit using the power button on the left side.
4. Verify that the monitor starts up without any error messages.

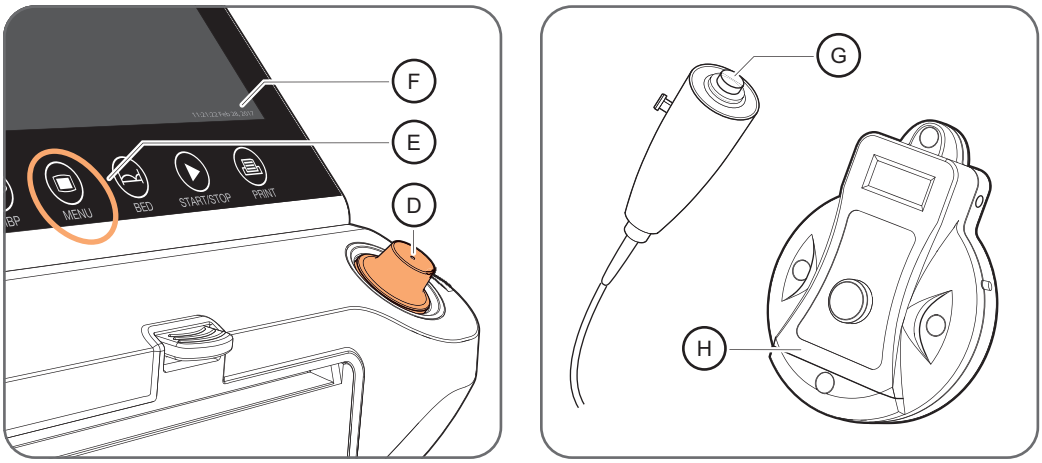


Figure 5:69

5. Turn the control knob (D) left and right to confirm that it is working. Highlight the display mode menu option and push the control knob to confirm that the knob (D) is working.
6. Select the “MENU” touch key (E) to confirm that the touch key bar is working. Select the “MENU” touch key (E) again to hide the system menu.
7. Verify that the time and date displayed in the lower right corner (F) of the screen is set correctly.

8. Verify the loudspeaker function, e.g. by connecting a fetal movement marker and pushing the button (G), or connecting an ultrasound transducer (H) and simulate fetal heart activity.

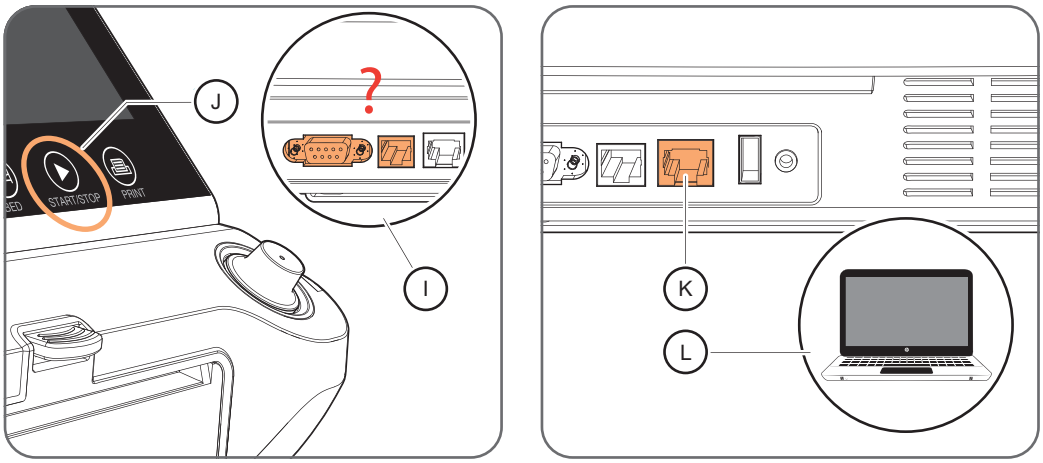


Figure 5:70

9. If communication with a central monitoring system is configured, check that the cable (I) is connected and then start a recording by holding the “START/STOP” touch key (J). Verify that the new recording is displayed on your central monitoring system.

10. If IP network communication has been configured, make sure that the cable (K) is connected and then verify the connectivity by making a ICMP (“ping”) request against the configured IP address, from another computer (L) on the network.

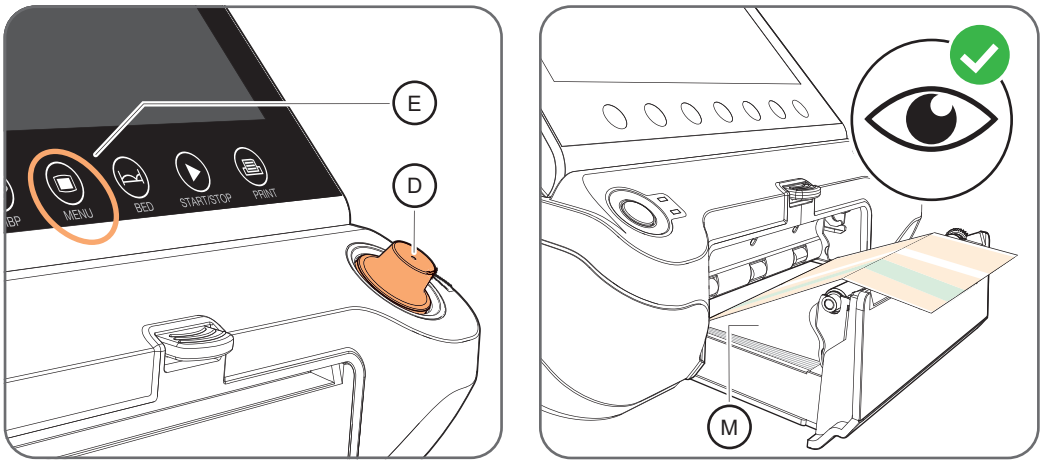


Figure 5:71

11. Hold the “MENU” touch key (E) and then use the control knob (D) to enter the system settings dialog. Then select “Printer Settings”. Make sure there is paper in the printer paper drawer (M) and then select the “Print Test Page” button. Verify that a test printout is generated, that the printed text and lines have sufficient contrast against the paper, and that the paper scaling matches the scaling of the CTG trace on the screen.

5.3.2 Wired TOCO transducer

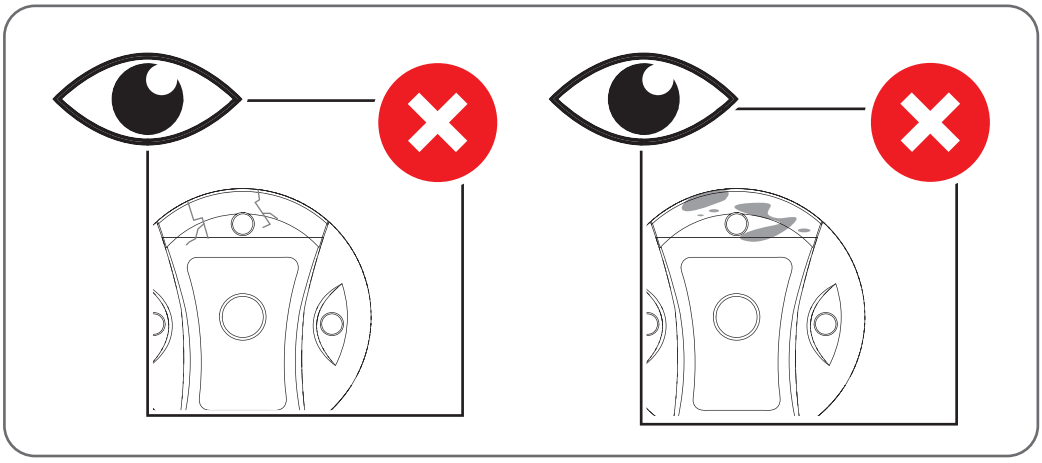


Figure 5:72 Inspecting the wired TOCO transducer

1. Inspect the TOCO transducer, the cable and the connector and make sure it is not damaged.

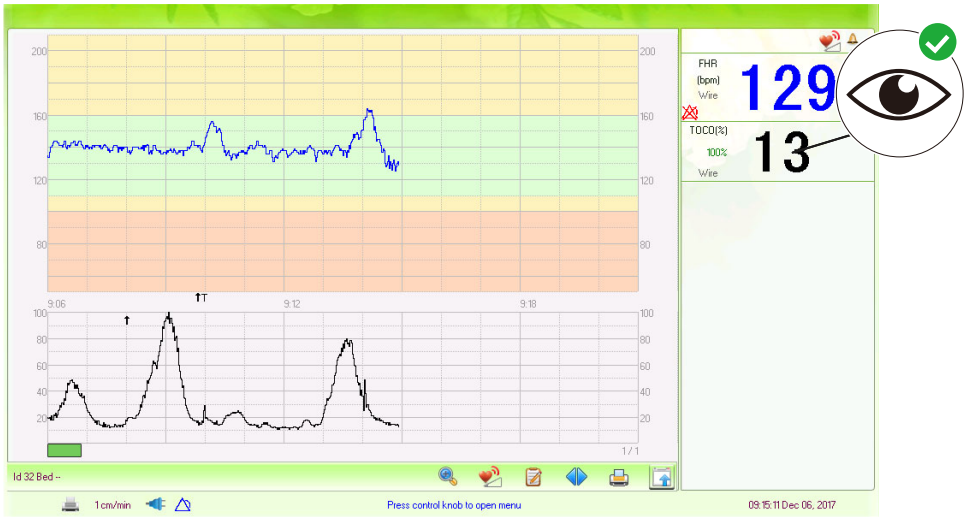


Figure 5:73 Verify that a TOCO value appears on the display

2. Connect the TOCO transducer to the corresponding connector on the main unit. Verify that a TOCO value appears on the display.

3. Apply pressure to the sensor area and check that the TOCO value on the display increases accordingly.

4. Release pressure and check that the TOCO value decreases.

5.3.3 Wired ultrasound transducer

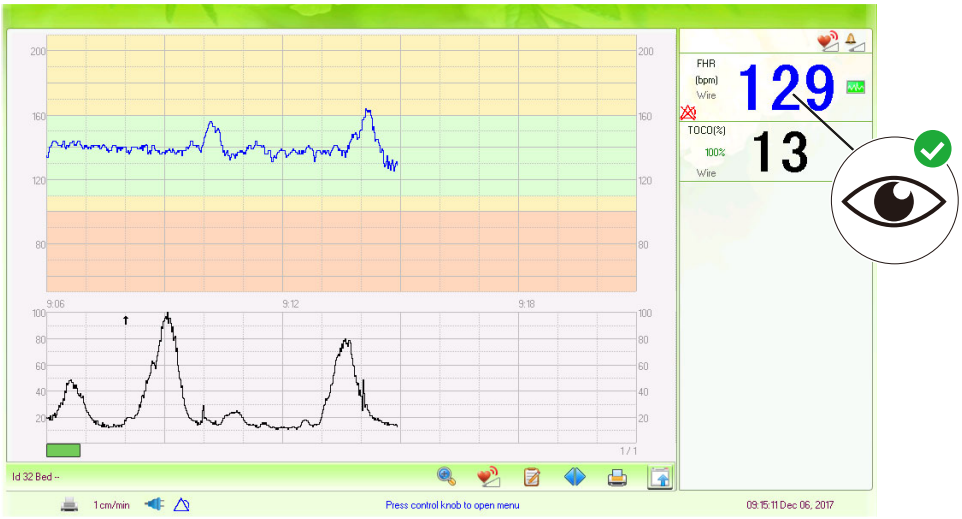


Figure 5:74 Verify that an FHR1 value appears on the display

1. Connect a wired ultrasound transducer to the FHR1 connector on the main unit. Verify that an FHR1 field appears on the display.

2. Move the transducer up and down over a flat surface. A whistling sound should be heard when the transducer is moved at a speed of approximately 10 cm/s.

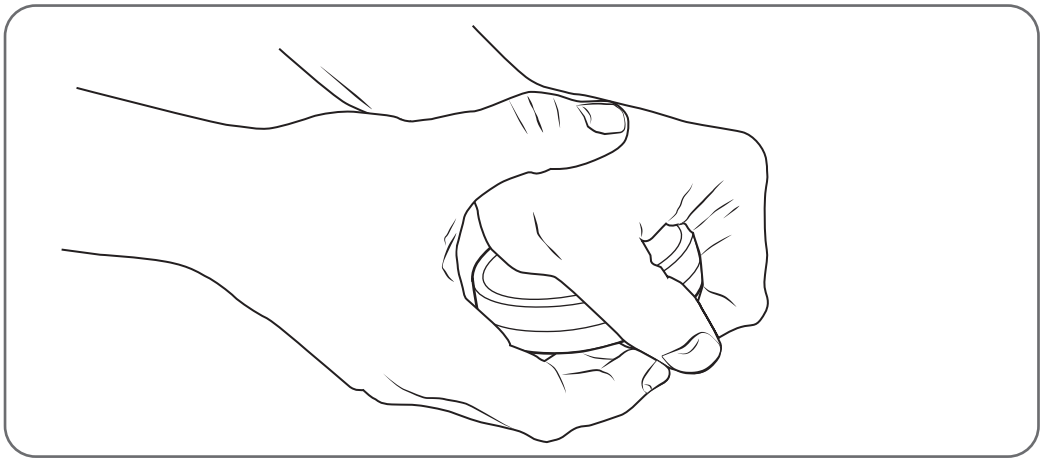


Figure 5:75 Simulating fetal heart movements

3. Hold the transducer sensor side in the hand with the palm of the hand against the sensor area. Strike the soft area of muscle between your thumb and index finger at a regular interval. A corresponding sound should be heard and the corresponding heart rate frequency be visible on the display.

4. Repeat the test for the FHR2 connector, and FHR3 if available.

5.3.4 Wireless TOCO transducer

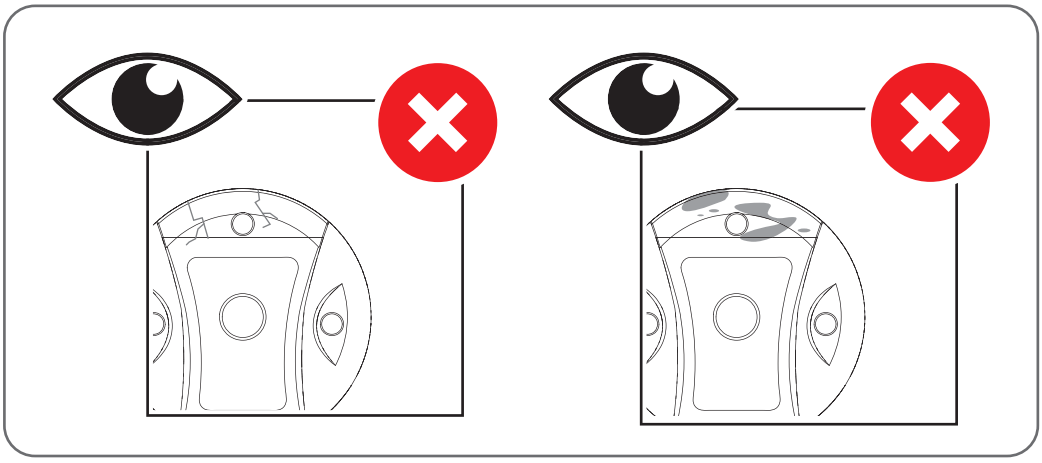


Figure 5:76 Inspecting the wireless TOCO transducer

1. Remove the TOCO transducer from the charging rack. Inspect it and make sure it is not damaged.

2. While the transducer is still out of the charging rack, verify that the display does not indicate ‘ON’. If the display indicates ‘ON’, this indicates that there is another transducer nearby is configured to communicate on the same wireless channel.

3. Check that the battery is sufficiently charged.

4. Check that the signal strength indicator is at its maximum.

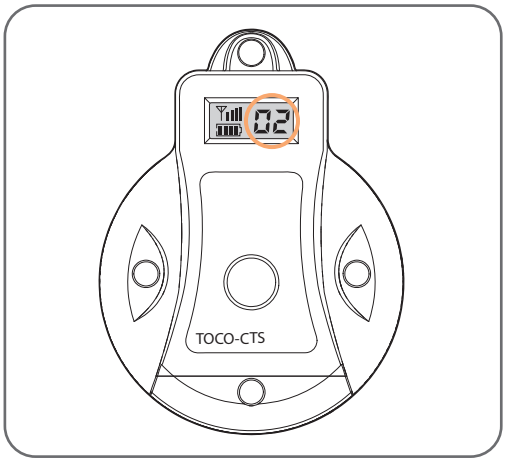


Figure 5:77 Verify that the wireless channel numbers on display and transducer match

5. Verify that the wireless channel number visible on the transducer display matches the wireless channel number shown on the main unit screen.

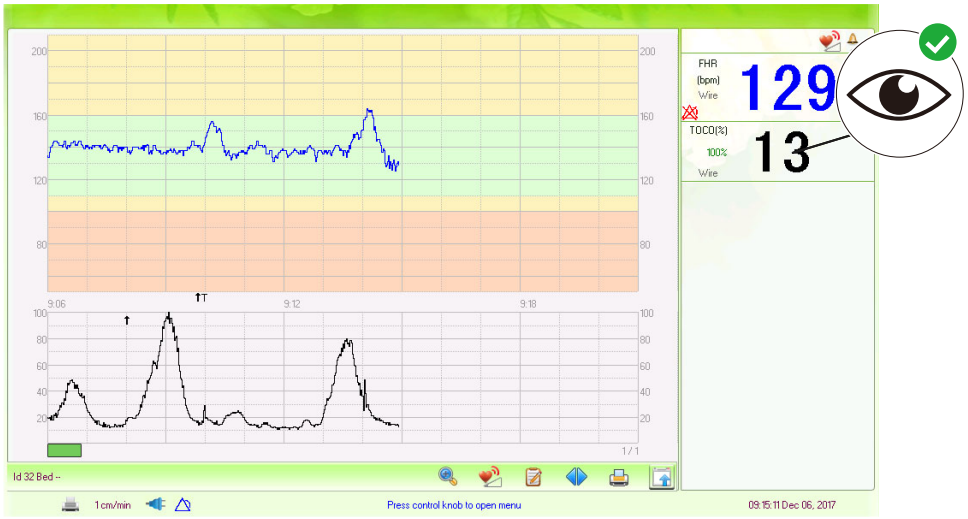


Figure 5:78 Verify that a TOCO value appears on the display

6. Verify that a TOCO value appears on the display.

7. Apply pressure to the sensor area and verify that the TOCO value on the display increases accordingly.

8. Release pressure and verify that the TOCO value decreases.

5.3.5 Wireless ultrasound transducer

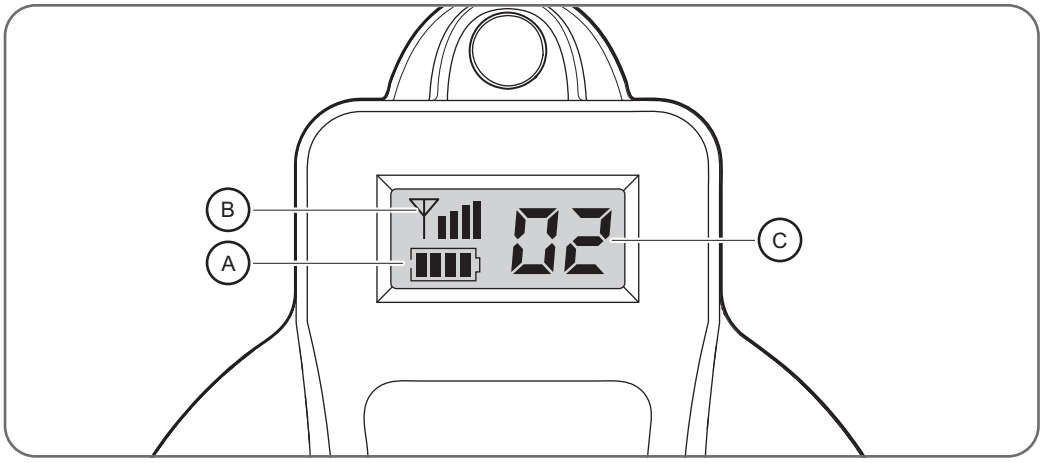


Figure 5:79 Inspecting a wireless ultrasound transducer

1. Remove the ultrasound transducer (FHR1) from the charging rack. Inspect it and make sure it is not damaged.

2. While the transducer is still out of the charging rack, verify that the display does not indicate 'ON'. If the display indicates 'ON', this indicates that there is another transducer nearby is configured to communicate on the same wireless channel.

3. Check that the battery (A) is sufficiently charged.

4. Check that the signal strength indicator (B) is at its maximum.

5. Verify that the wireless channel number (C) visible on the transducer display matches the wireless channel number shown on the main unit screen.

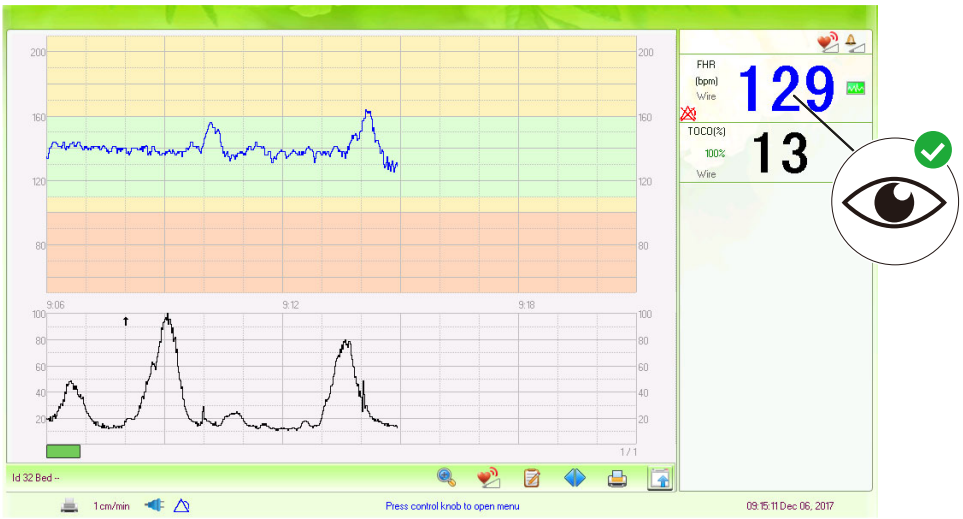


Figure 5:80 Verify that an FHR1 value appears on the display

6. Verify that the corresponding FHR indicator (FHR1) appears on the display.

7. Hold the transducer over a flat surface, with the sensor area in parallel with and facing the flat surface, and move the transducer up and down. A whistling sound should be heard at a speed of approximately 10 cm/s.

8. Hold the transducer sensor side in the hand with the palm of the hand against the sensor area. Tap with a regular rhythm on the top of the hand. A corresponding sound should be heard and the tapping frequency (heart beat value) be visible on the display.

5.3.6 Wired fetal movement marker

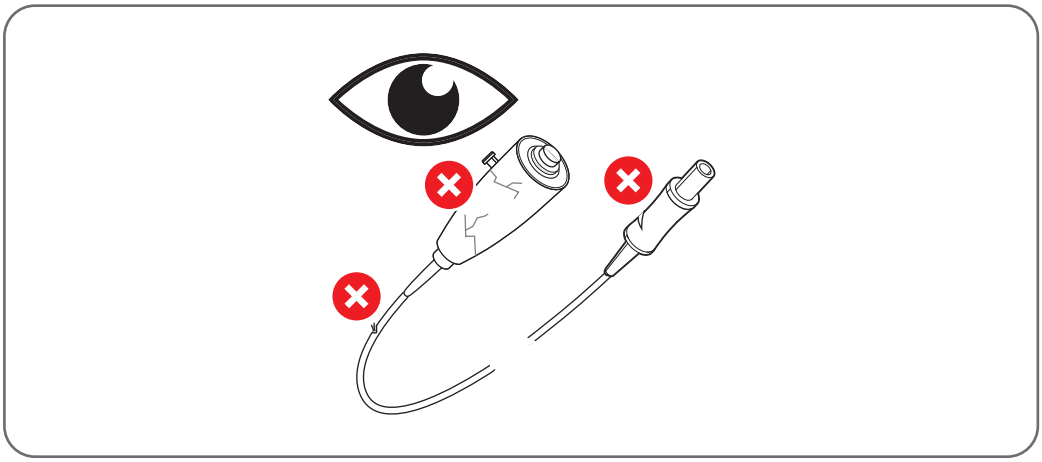


Figure 5:81 Inspecting the wired fetal movement marker

1. Inspect the fetal movement marker, its cable and connector and make sure they are not damaged. Connect it to the corresponding connector on the main unit.

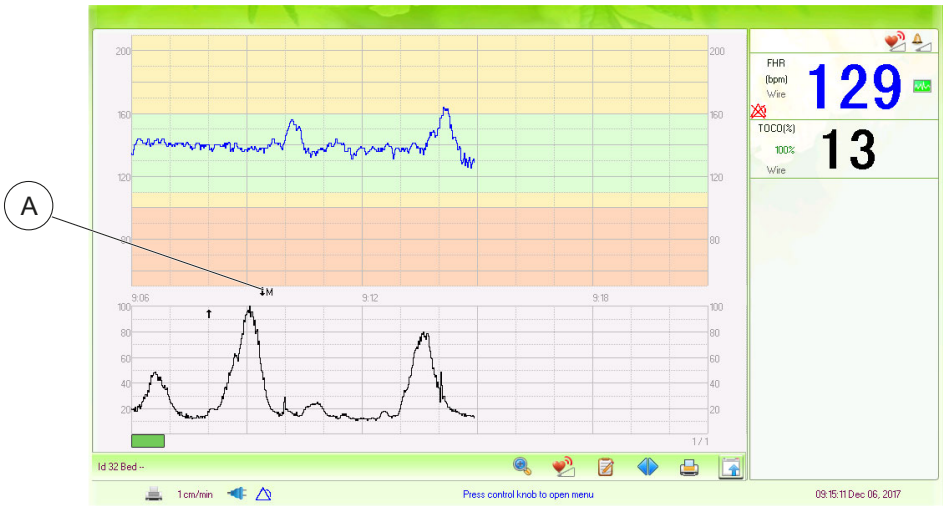


Figure 5:82 Fetal movement mark on screen

2. Start a recording and then push the fetal movement marker actuation button. Verify that an audible indication is generated and that a corresponding marker (A) is presented in the CTG trace on the screen.

5.3.7 Wireless fetal movement marker

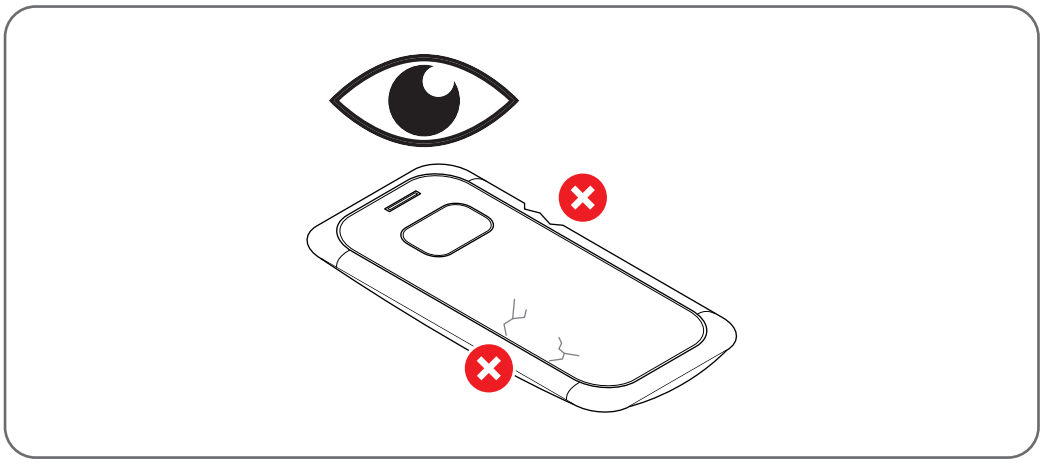


Figure 5:83 Inspecting the wireless fetal movement marker

1. Inspect the fetal movement marker and make sure that it has no cracks or damage.

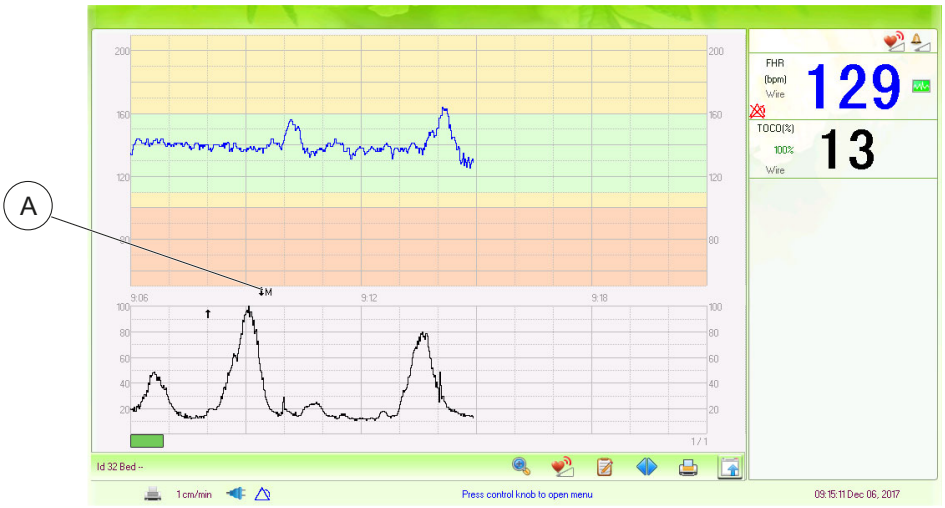


Figure 5:84 Fetal movement mark on screen

2. Start a recording. Verify that the fetal movement marker has remaining battery power by pushing its actuation button, and ensuring that the green LED on the enclosure is lit as you do so.

3. Verify communication with the main unit by pushing the actuation button again and ensuring an audible indication is generated by the main unit, and that a corresponding marker (A) is presented in the CTG trace on the screen.

5.4 Setting system date and time

1. Ensure the power is switched on. Do not start a recording yet as it is not possible to change the system time while a recording is ongoing.

2. Hold the “MENU” touch key and then select “System Settings”.

3. Select “Time Settings”.

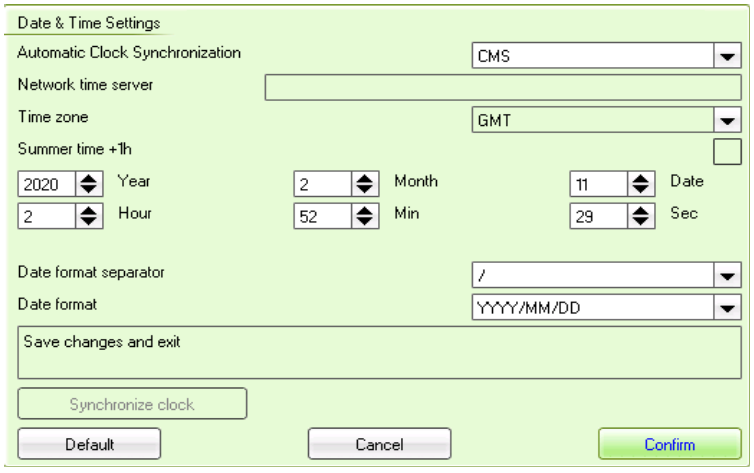


Figure 5:85 Use the control knob to adjust the time and date digits

4. To set the time manually, use the control knob to adjust the time and date digits and then select “Confirm” to save.

Tip!

The system can be configured for automatic synchronization of system time against your central monitoring system or a network time server supporting NTP/SNTP.

5. To set up the system to synchronize the clock against your central monitoring system, make sure the ‘Automatic Clock Synchronization’ setting set to ‘CMS’. The system will now update the clock automatically when the central monitoring systems sends an updated time stamp, provided that this function is supported by your CMS.

6. To set up the system to synchronize the clock against a network time server, make sure the ‘Automatic Clock Synchronization’ setting set to ‘Network server’, and that you have an active network connection. Then configure the IP address of the network time server you wish to use using the ‘Network time server’ setting. Make sure the ‘Time zone’ setting matches your location. If your location is currently using daylight savings time, make sure the ‘Summer time +1h’ setting is enabled. The system will now update the clock automatically with regular intervals. You can also make an immediate synchronization by using the ‘Synchronize clock’ button.

6 Troubleshooting

Area of concern	Problem	Potential cause	Solution
Main unit.	Screen is black, power indicator is off.	Power cable is loose.	Ensure the power cable is fully seated in the socket.
		The fuse has blown.	Replace the fuse.
		The battery has run out of power.	Connect to mains power supply.
	Loudspeaker noise.	Sound volume configured too high.	Turn down the volume.
		Interference by mobile phone or other electromagnetic interference source.	Power off or move the interference source.
			Move the unit to a place with less interference.
	Message ‘reindex files’ displayed during startup.	Device was not shut down properly and recordings index has become invalid.	Enter the ‘Review recordings’ functions and select the ‘Refresh’ button.
	Cannot access ‘Export recordings’ menu	USB disk not connected	Make sure the USB disk is attached to the USB connector
		Incompatible USB disk	Try using another USB storage device with FAT16 or FAT32 filesystem.
Printer.	Paper jam.	Paper not positioned correctly in paper tray.	Open the paper tray and reposition the paper.
		Paper is damp.	Replace with dry paper.
	Printer does not work.	Printout is not started.	Press the “PRINT” touch key.
		Printer is out of paper.	Load paper.
		The paper tray is not closed.	Push the paper tray until both left and right hand latches are locked.
		Printer failure.	Contact service personnel.
	Faint trace or no trace.	Low quality paper.	Use paper recommended by manufacturer.
		Adjustment nuts of the print head are unbalanced.	Contact service personnel.

Area of concern	Problem	Potential cause	Solution
Wireless monitoring.	No indication of wireless transducer being connected.	Low battery.	Charge the transducer before use.
		Transducer is broken.	Replace the transducer.
	Bad reception of wireless signal.	Multiple systems configured to use the same wireless channel.	Configure systems to use different wireless channels.
		The distance between patient and system is too long.	Move patient and system closer.
		Problems with wireless antennas.	Ensure the antennas on the rear side of the main unit undamaged and well tightened.
		Strong influence from electromagnetical interference.	Identify and remove the source of the electromagnetical interference.
	Transducer battery depleted too quickly.	Battery worn out.	Replace the battery with a new.
		Insufficient charging between use.	Make sure the transducer is sufficiently charged between use.
	Transducer display is blinking 'ON' while transducer is out of the charging rack.	Multiple systems configured to use the same wireless channel.	Configure systems to use different wireless channels.
Central monitoring	Recording not visible in central monitoring system.	Central monitoring communication not configured	Review 'CMS Settings' configuration
		CMS cable not connected	Connect CMS cable to 'RS-232- connector on the rear side of the main unit, and make sure it is connected to the applicable wall connector. Ensure the CMS status symbol becomes green.
	Crossed over CMS symbol on screen, or 'CMS offline' alarm	CMS cable not connected	Connect CMS cable to 'RS-232- connector on the rear side of the main unit, and make sure it is connected to the applicable wall connector. Ensure the CMS status symbol becomes green.

Area of concern	Problem	Potential cause	Solution
STAN Viewer Live and network archiving	Recording not visible on STAN Viewer Live	STN Stream server communication not configured	Review 'Network Settings' configuration
		Network cable not connected	Connect network cable to rear side of the main unit, and make sure it is connected to the applicable wall connector. Ensure the network status symbol becomes green.
		Recording was ended more than 2 hours ago	STAN Viewer Live only support review of ongoing and recent recordings.
		Server problem	Ensure the server is running.
			Consult STN Stream Server / STAN Viewer Live installation manuals.
	Recording not stored to network archive	STN Stream server communication not configured	Review 'Network Settings' configuration
		Network cable not connected	Connect network cable to rear side of the main unit, and make sure it is connected to the applicable wall connector. Ensure the network status symbol becomes green.
		Server problem	Ensure the server is running.
			Consult STN Stream Server installation manual.

Area of concern	Problem	Potential cause	Solution
Ultrasound FHR monitoring.	Poor trace quality.	Fetus or transducer has moved.	Reposition the transducer. If needed, perform palpation.
		Loose belt.	Tighten the belt or use elastic tubular net.
		Superfluous ultrasound gel.	Wipe off superfluous ultrasound gel.
		Frequent fetal movements.	Wait out fetal movements.
		Maternal movement.	Ask the patient to be still.
		Inadequate ultrasound gel, or gel has dried out.	Apply more gel.
	Unintentional recording of maternal pulse.	Transducer receives pulses from maternal blood vessels stronger than the fetal heart beats.	Direct transducer away from maternal arteries.
			Direct the transducer more precisely towards the fetal heart. Perform palpation if needed.
	Recording of half the fetal heart rate.	Transducer not directed sufficient towards the fetal heart, making the recording sensitive to maternal breathing.	Direct the transducer more precisely towards the fetal heart.
TOCO monitoring.	Poor trace quality or fluctuating TOCO baseline.	The belt is too tight or too loose.	Adjust the belt tightness.
		The belt has no elasticity.	Replace the belt.
		Maternal movement.	Ask the patient to be still.
		Frequent fetal movements.	Wait out fetal movements.
	TOCO reading exceeds range.	The body pressure from uterus to TOCO transducer is higher than the average numeric.	Adjust TOCO sensitivity setting.

7 Specifications

7.1 Safety classifications

MDD classification:		
Class IIa		

Type of protection against electric shock:		
Class I equipment with internal power supply		

Degree of protection against electric shock:		
Wired ultrasound transducers, TOCO transducer and fetal movement marker	Type B	

Degree of protection against harmful ingress of water		
Main Unit	IPXX	May be wiped with moistened cloth.
Wireless ultrasound transducers (2.4GHz), Wireless TOCO transducer (2.4GHz)	IP68	Suitable for use when patient is taking a shower, but not intended for underwater monitoring.
Wired ultrasound transducers	IP68	Not intended for underwater use.
Wired TOCO transducer	IPX4	May be rinsed under running water.
Wired and wireless fetal movement marker	-	May be rinsed under running water.

Equipment type
Portable

Mode of operation
Continuous

EMC
Group I Class A

Caution!

The IP68 classification of wired ultrasound transducers only applies for cleaning. The wired transducers are not intended for underwater use.

Caution!

The 2.4GHz wireless ultrasound and TOCO transducers are suitable for use when the patient is taking a shower, but are not intended for underwater monitoring.

Caution!

The equipment must NOT be used in the presence of flammable anaesthetic mixture with air or with oxygen or with nitrous dioxide.

7.2 Main unit

Physical Characteristics	
Dimensions (width x depth x height):	360 x 356 x 114 mm
Weight:	5.0 kg

Power	
Operating voltage:	100-240 VAC
Line frequency:	50/60 Hz
Power consumption (maximum):	100 VA

Battery (optional)	
Type:	Rechargeable lithium-ion battery
Nominal voltage:	11.1 V
Nominal capacity:	4000 mAh
Operating time (new battery, fully charged, printer inactive)	2 hours - 4 hours depending on configuration
Charging time (when monitor is powered off)	4 hours
Charge mode:	Constant current/ constant voltage (CC-CV)
Charge current (Standard):	0.2 C (780 mA)
Charge voltage (Standard):	12±0.1 V
Maximum continuous charge current:	2000 mA

Operation environment	
Operating temperature:	+5°C to +40°C
Relative Humidity:	< 90 % (non-condensing)
Atmospheric pressure range:	860 hPa to 1060 hPa

Transport and storage environment	
Transport (inside packing) or storage (outside packing)	
Temperature range:	-20°C to +55°C
Relative humidity range:	< 90 % (non-condensing)
Atmospheric pressure range:	860 hPa to 1060 hPa

Display	
10.2” LCD with 1024x600 pixel resolution displaying the following output data.	
Numerics field:	Triple fetal heart rate, ultrasound (bpm) Contraction, TOCO (relative units)
CTG trace, up to 15 min visible, scrollable:	Triple fetal heart rate, ultrasound (bpm) Contraction, TOCO (relative units) Fetal movement indications

Display	
CTG trace, horizontal resolution:	1, 2 or 3 cm/min
CTG trace, FHR range:	50 - 210 bpm@ 20 bpm/cm, or 30 - 240 bpm@ 30 bpm/cm
CTG trace, UA range:	0 - 100 units (TOCO)

Audible Indicators	
Fetal heart beat:	Doppler-shift audio from ultrasound transducers
Audible alarm signal:	Configurable melody and volume
Fetal movement marker:	Notification

Data Storage
Internal storage of each individual recording
Possibility of archiving stored recordings to USB storage devices and network servers

7.3 Recording

US Recording	
Technique:	Ultrasonic pulse doppler
Ultrasonic operating frequency:	0.8 MHz - 5.0 MHz
Centre frequency:	2.0 MHz
Intensity:	<10 mW/cm^2
Average intensity at peak time (spatial-peak temporal-average intensity - LSPTA):	<100 mW/cm^2
Offset from nominal frequency 2 MHz:	±10%
Negative peak sound pressure (peak-rarefactional acoustic pressure - PR):	<1 MPa
FHR range:	30 - 240 bpm
FHR accuracy:	±1 bpm
Thermal indices and mechanical index are below 1.0	

TOCO Recording	
Output range:	0-100 units
Sensitivity:	0.2 units/g
Manual output offset:	0, 5, 10, 15 or 20 configurable
Resolution:	1 unit
Accuracy:	±10% of display

Fetal Movement Recording	
Manually operated	Hand-held button
Automatic, from ultrasound transducer (configurable)	Based on fetal heart rate, where an acceleration of 15 to 40 bpm above baseline lasting at least 10 seconds is recorded as a fetal movement
Automatic, from TOCO transducer (configurable)	Based on uterine activity trace, where a peak of at least 10 units above baseline with a duration of minimum 8 seconds and maximum 16 seconds is recorded as a fetal movement

7.4 Printer

Recorder specification	
Printing method:	Thermal sensitive dot line
Effective printing width:	144 mm
Printing Speed, real-time recording:	1, 2 or 3 cm/min, configurable
Printing Speed, retrospective printing:	Up to 50 mm/sec
Paper width:	156 mm

Recorder specification	
Recorded Information:	FHR1, FHR2 and FHR3 trace/marks, TOCO trace, Fetal movement mark, Time & date, Printing speed, Patient Name & ID, FHR2 and FHR3 Offset
Printer head temperature detection:	Thermistor
Out-of-paper detection:	Photo interrupter Watermark notification on last 5 paper sheets

7.5 Wireless subsystem

Communication	
Transmission frequency:	2.4 GHz
Whereof FHR1 channels 2 to 15 (configurable):	2.405 to 2.470 in steps of 0.005 (GHz)
Whereof TOCO channels 2 to 15 (configurable):	2.413 to 2.478 in steps of 0.005 (GHz)
Receiver bandwidth:	1 MHz
Modulation technique:	GFSK
Effective radiated power:	0 dBm
Effective communication range:	> 10 m
Communication range in air:	> 20 m

Batteries	
Type:	Rechargeable lithium-polymer
Continuous working time: (new battery, fully charged)	8 hours
Charging time:	4 hours - 5 hours
Nominal capacity:	1150 mAh
Nominal voltage:	3.7 V
Charge mode:	Constant current / constant voltage (CC-CV)
Charge current (standard):	0.2 C (230 mA)
Charge voltage (standard):	5 ± 0.1 V
Maximum continuous charge current:	1150 mA

7.6 Compatible devices

7.6.1 TOCO, ultrasound and fetal movement marker accessories

Part number	Description
P1221-05032	Wired ultrasound transducer
P1271-05043 P1271-05021	Wireless FHR1 ultrasound transducer (2.4GHz)
P1271-05022	Wireless FHR2 ultrasound transducer (2.4GHz)
P1224-05040 P1224-05042 P1224-05048	Wired TOCO transducer
P1271-02055	Wireless TOCO transducer (2.4GHz)
P1221-12003	Wired fetal movement marker

Part number	Description
P4907-00012 P1271-12006	Wireless fetal movement marker
P2224-08001	Transducer belt
P7001-00030	Aquasonic coupling gel

7.6.2

7.6.3 Printer paper

Part number	Description
P8105-00003	Printer paper with 50-210bpm range with 20 bpm/cm scaling
P8105-00004	Printer paper with 30-240bpm range 30 bpm/cm scaling (USA)

7.6.4 Mounting equipment

Part number	Description
P1263-12005 P2228-16001 P1422-12003	Trolley
P1263-12003	Wall arm
P5301-00011 P5301-00001	Power cord
P4904-00004	Mains fuse T2AL250V

7.6.5 Batteries

Part number	Description
P4901-01016	Rechargeable system lithium-ion battery
P4901-01013 P4901-01030	Rechargeable lithium-polymer battery for wireless FHR1 and TOCO transducer

7.6.6 Monitoring and archiving systems

System type	Description	Compatible brands
Central monitoring systems	Central monitoring systems communicating according to HP publication M13509014L. RS-232 or ethernet connection possible.	A list of compatible brands is not provided. When connecting, the organization performing the installation is responsible for confirming compatibility between SRF618B6 and the central monitoring system.

7.7 System settings of clinical significance

7.7.1 System settings

Setting name	Description	Options/ Constraints	Factory default	Comment
Machine name	The first three letters of this string is used as prefix when naming recordings.	Text string	-	To avoid confusion if there are more than one STAN unit on the ward, make sure this is set differently on the different units.
Language	Language used on screen and printouts	Chinese English Spanish French Portuguese Polish Russian Italian German Danish Swedish Finnish Norwegian Dutch Czech	English	
Screen color theme	Color theme used for screen	Classic Black Fresh Green Warm Pink	Classic Black	
Audible alarm signal conditions	Defines which alarm condition priorities should generate an audible alarm signal	Audio off, High, High and medium, High, medium and low	Audio off	Password protected
Alarm Volume	Sound level for audible alarms	1, 2, 3, 4	2	Password protected
Allow alarm inactivation	Which types of changes the user is allowed to make to the alarm system during recording.	No changes allowed Threshold changes allowed All changes allowed	All changes allowed	Password protected
Maximum recording time	Maximum recording time in minutes	10 to 1440 in steps of 5	1440	When the recording reaches the maximum recording time, the recording is automatically stopped
Menu timeout	Time of inactivity until the screen resets to default, in seconds	10 to 60 in steps of 2 0 inactivates the timeout function	20	Applies to screen menus
Screen brightness	Level of light emitted from the main unit screen	1 to 8	4	
Keyboard timeout	Time of user inactivity before the touch key bar is locked, in minutes	Off, 1, 2, 5	Off	To unlock the touch key bar, hold down the “MENU” key for three seconds
Key sound	Whether to generate sound feedback when using touch keys and control knob	On Off	On	
Screen font name	Font used for presenting text on screen and printouts	System Courier Sans Serif Terminal Tahoma Arial Times New Roman Poland Russian Courier	Sans Serif	All fonts may not be available for all language settings

Setting name	Description	Options/ Constraints	Factory default	Comment
Password protect recordings	Whether password is required to review and delete recordings	On Off	Off	
Printer Settings				
Printout reference	Title text on printouts, for reference purposes	Text string	-	Can be used to identify e.g. the hospital or ward
Printing timeout	Time until continuous printout is automatically paused	Off 10, 20, 30, 40, 50, 60, 120	Off	
Print CTG parameters	Default CTG analysis method at start of recording	Off Fischer NST CST Krebs STV 60 min interval	Off	
Print CTG analysis score	Whether to print calculated score from automated CTG analysis function on continuous printout	On Off	Off	
STV log interval	Interval with which calculated STV values are recorded in the event log	Off, 2, 10	10	
Line style	Whether to print heart rate traces on printout in a smoothed fashion	Smoothed trace True trace	True trace	
Gestational age format	Format to use when printing gestational age	XX+X XX-X	XX+X	
CMS Settings				
Machine id	Id number used when setting the ethernet Id (MAC address) of the system.	1 to 200	32	If devices are used connected to an ethernet network, this number must be set to be unique within the ward.
Bed id	Id number used for identifying the bed on Sunray CMS	1 to 200	32	Should be set to a unique number within the ward. Only applicable if Sunray CMS is configured.
Network	Supported hardware version environment for Sunray CMS	Version 2 Version 1	Version 2	Only applicable if Sunray CMS is configured.
CMS Protocol	Which protocol to use for CMS communication on RS-232 port	Off Philips A20 Philips A30 STAN R1B Sunray ATS	Off	Select STAN R1B if your CMS supports the STAN protocol. Philips A20 is recommended if your system does not support the STAN protocol. Philips A30 is recommended for triplet monitoring, but may not be available with all CMS.
CMS Media	Whether to transmit data to CMS using RS-232 serial communication or ethernet network.	RS-232 Ethernet	RS-232	CMS Media is enabled only if CMS Protocol is set to any of the Philips or STAN protocols. Settings CMS Server Address and CMS Server Port are enabled if set to Ethernet
CMS Server IP address	IP address to use when communicating with CMS using ethernet network.	Text string	-	

Setting name	Description	Options/ Constraints	Factory default	Comment
CMS Server port	Port number to use when communicating with CMS using ethernet network.	Text string	0	
CMS Auto	Whether to start sending data to Philips/STAN CMS independent of server control	On Off	Off	Only applicable if Philips A20/A30 is configured
Send FHR signal	Whether to send the fetal heart rate to Sunray CMS also when recording is in idle mode	On Off	Off	Only applicable if Sunray CMS is configured.
Time Settings				
Automatic clock synchronization	Whether to automatically synchronize system clock, and against what source	Off CMS Network server	CMS	
Time zone	Local time zone	GMT -12 to GMT +12	GMT	Only applicable if network time synchronization is configured.
Summer time +1h	Whether daylight savings time is currently to be applied	On Off	Off	Only applicable if network time synchronization is configured.
Network time server	IP address of NTP/SNTP server to use for network time synchronization	Text string	-	Only applicable if network time synchronization is configured.
Date format separator	Character used for separating year, month and date when displaying date on screen and printouts	'/', '-', '.'	'/'	
Date format	Format used when displaying date on screen and printouts	Month DD, YYYY, DD Month, YYYY, D/M/YYYY, DD/MM/YYYY, M/D/YYYY, MM/DD/YYYY, YYYY/M/D, YYYY/MM/DD	YYYY/MM/DD	
Network Settings				
Use DHCP	Whether to enable dynamic IP configuration using DHCP (dynamic host configuration protocol)	Yes No	No	
Local IP	Defines a static IP address in the form that the system uses for identifying itself on an IP network	IPv4 format	-	
Subnet mask	Defines the network subnet mask to use when addressing other devices on the network	IPv4 format	255.255.255.0	Only applicable if local IP address is configured.
Gateway address	Defines the gateway that the system may need to reach systems outside the local area network, e.g. a network time server	IPv4 format	-	Only applicable if local IP address is configured.

Setting name	Description	Options/ Constraints	Factory default	Comment
STN Stream server	Whether to transmit recording data to a n STN Stream server	On Off	Off	The STN Stream server is needed to enable network archiving of recordings in STN file format and/or Stan Viewer Live.
STN Stream Server IP	IP address of the STN Stream server	IPv4 format		Only applicable if STN Stream server address is configured.
STN Stream Server Port no	Port to use for connecting to the STN Stream server	Text string	11000	Only applicable if STN Stream server address is configured.

7.7.2 Fetal settings

Setting name	Description	Options/ Constraints	Factory default	Comment
HR Grid Range	Defines HR scaling in CTG grid on screen and printout	50-210 30-240	50-210	Password protected
FHR Grid color	Defines the background colors of the CTG grid on screen	Per alarm thresholds NICE 1999/BJOG 2007 FIGO 1992/NICE 2007 FIGO 2015 SFOG 2017	Per alarm thresholds	
FHR1 Transducer mode	Defines the priority between wired and wireless transducers.	Wired Wireless	Wireless	
Display Speed	Defines horizontal scaling in CTG grid on screen and printouts	1 cm/min 2cm /min 3cm/min	1cm/min	Password protected
FHR Trace Separation	Defined whether FHR2 and FHR3 shall be displayed with -20 resp. +20 bpm offset on screen and printout	Off FHR2 -20, FHR3 +20 FHR2 +20, FHR3 -20	Off	FHR2 -20, FHR3 +20 is common practice in China, while FHR2 +20, FHR3 -20 is common practice in Europe
US sound volume	Default sound volume for audible feedback from ultrasound transducers.	Off 1 to 16	4	
Fetal Alarms	Defines whether alarm signals shall be generated for high/low fetal heart rate for FHR1	On Off	Off	
Transducer disconnection alarm	Defines whether alarm signals shall be generated when FHR and TOCO transducers are disconnected	On Off	Off	Configurable only if “Fetal Alarm” set to “On”
FHR2 level alarms	Defines whether alarm signals shall be generated for high/low fetal heart rate for FHR2	On Off	Off	Configurable only if “Fetal Alarm” set to “On”
FHR3 level alarms	Defines whether alarm signals shall be generated for high/low fetal heart rate for FHR3	On Off	Off	Configurable only if “Fetal Alarm” set to “On”
High FHR alarm threshold	Threshold for High FHR level alarm (bpm)	111 to 210	160	Password protected Configurable only if “Fetal Alarm” set to “On” Cannot be set below “Low FHR alarm threshold”
Low FHR alarm threshold	Threshold for Low FHR level alarm (bpm)	50 to 159	110	Password protected Configurable only if “Fetal Alarm” set to “On” Cannot be set above “High FHR alarm threshold”
High FHR alarm delay	Delay time for generating High FHR level alarm (seconds)	0 to 300 in steps of 5	300	Configurable only if “Fetal Alarm” set to “On”
Low FHR alarm delay	Delay time for generating Low FHR level alarm (seconds)	0 to 300 in steps of 5	240	Configurable only if “Fetal Alarm” set to “On”
TOCO Sensitivity	Amplification level (relative units)	50%, 100%, 200%	100%	
TOCO baseline level	Baseline level applied after “Zero Toco”	0, 5, 10, 15, 20	20	

Setting name	Description	Options/ Constraints	Factory default	Comment
AFM operation mode	Operation mode for automatic fetal movement detection	Off, TOCO, FHR, Both	Off	
AFM to Sunray CMS	Defines whether fetal movements detected with the automatic fetal movement detection function shall be transmitted to Sunray CMS	On Off	Off	Only applicable if Sunray CMS is used on the ward
Wireless communication channel	Channel number used for wireless communication between the main unit and the wireless transducers	2 to 15	-	Must be configured differently on different units on the ward, to avoid interference

7.8 Standards compliance

Reference	Name
IEC 60601-1:2005 + A1:2012	General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-8:2006 + A1:2012	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-37:2007	Particular requirements for the basic safety and essential performance of ultrasonic diagnostic and monitoring equipment
EN 300 220-2, V3.1.1	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1 000 MHz; Part 2: Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU for non specific radio equipment

8 Appendix

8.1 Contact information

Contact information for qualified installation staff and technical support:

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8.2 Abbreviations

The abbreviations used in this manual and their full names are listed below.

Abbreviation	Full Description
AC	Alternating Current
CMS	Central Monitoring System
CST	Contraction Stress Test
CTG	Cardiotocography
FHR	Fetal Heat Rate
FM	Fetal Movement
HR	Heart Rate
LCD	Liquid Crystal Display
MRI	Magnetic Resonance Imaging
NST	Nonstress Test
NTP	Network Time Protocol
STN	File format used for retrospective review of recording files produced by this fetal monitor
SVL	STAN Viewer Live, a software tool for reviewing the ongoing recording from a remote location

Abbreviation	Full Description
TOCO	Tocodynamometer
UA	Uterine Activity (TOCO)
US	Ultrasound (Transducer)

8.3 Electromagnetic emissions and immunity

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their systems. Immunity is defined in the standard as the ability of a system to perform without degradation in the presence of an electromagnetic disturbance.

8.3.1 Electromagnetic emissions - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration: electromagnetic emissions		
Emissions test	**Compliance**	**Avoiding Electromagnetic Interference**
Radio Frequency (RF) emissions: CISPR 11	Group 1	The SRF618B6 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission: CISPR 11	Class A	The SRF618B6 is suitable for use in all establishments, but if used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, whatever additional measures are necessary.
Harmonic emissions: IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions: IEC 61000-3-3	Complies	

8.3.2 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The SRF618B6 is intended for use in the electromagnetic environment specified below. The customer or user of the Sunray B6 Fetal Monitor should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be covered with wood, concrete or ceramic tiles. If floor are covered with a synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100kHz repetition frequency	±2 kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral ±2 kV line(s) to earth	±1 kV line(s) and neutral ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT , 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT,1 cycle, 0°; 70 % UT, 25 and 30 cycle, 0°; 0 % UT voltage interruption, 250/300 cycle.	0% UT , 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT,1 cycle, 0°; 70 % UT, 25 and 30 cycle, 0°; 0 % UT voltage interruption, 250/300 cycle.	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The SRF618B6 is intended for use in the electromagnetic environment specified below. The customer or user of the Sunray B6 Fetal Monitor should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz - 80 MHz; 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Low Frequency Therapeutic Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1{,}2\sqrt{P}$ (80 MHz - 800 MHz) resp. $d = 2{,}3\sqrt{P}$ (800 MHz - 2.7 GHz), where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1] should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Low Frequency Therapeutic Device is used exceeds the applicable RF compliance level above, the Low Frequency Therapeutic Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Low Frequency Therapeutic Device.

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

Guidance and manufacturer's declaration - electromagnetic immunity			
The SRF618B6 is intended for use in the electromagnetic environment specified below. The customer or user of the Sunray B6 Fetal Monitor should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
IMMUNITY to proximity fields from RF wireless communications equipment IEC 61000-4-3	Tested as specified in "Test specifications" on page 117	Tested as specified in "Test specifications" on page 117	The ENCLOSURE PORT of SRF618B6 shall be tested as specified in "Test specifications" on page 117 using the test methods specified in IEC 61000-4-3. The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $$E = \left[\frac{6}{d}\right]\sqrt{P}$$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. If the SRF618B6 complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS. $$d = \left[\frac{7}{3}\right]\sqrt{P}$$

8.3.3 Recommended separation distance

Recommended separation distances between portable and mobile RF communications equipment and the Low Frequency Therapeutic Device

The SRF618B6 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Sunray B6 Fetal Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sunray B6 Fetal Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

8.3.4 Test specifications

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0.3	27
450	430-470	GMRS460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz 2	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMT	Pulse modulation b) 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/ n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the SRF618B6may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

8.4 Scientific references

8.4.1 Publications on STV

The details of the underlying algorithms are described in the literature listed below and the current product matches the published method descriptions, but we here provide an overview. The input is the RR intervals, i.e. the time between consecutive R peaks. To avoid the risk of analysing false heart beat detections the input signal is filtered to remove suspected artifacts.
The filtered intervals are averaged over 3.75 s epochs, and the difference between consecutive epoch averages constitute the core of the algorithms. The epoch difference is averaged over each minute and the number finally presented by the monitor (the STV value) is the mean minute average over the entire recording.
The analysis starts when there have been five detected heart beats within one minute and the first result is presented 10 minutes thereafter. This value will be updated every two minutes.
Decelerations will obviously affect the epoch difference. Therefore these are detected, and minutes which include any part of a deceleration are not included in the total mean. The deceleration detection algorithm is also based on the original algorithms described in the literature.

Short-term variation in abnormal antenatal fetal heart rate records.
Street P., Dawes G.S., Moulden M., Redman C.W.G.
American journal of obstetrics and gynecology, vol 165, p. 515-523, 1991

Computerized Analysis of the Fetal Heart Rate.
Farmakides G., Weiner Z.
Clinical obstetrics and Gynecology, vol 38 (1), p. 112-120, 1995

A computer system for the numerical analysis of nonstress tests.
Pardey J., Moulden M., Redman C.W.G.
Am J Obstet Gynecol, vol 186 (5), p.1095-1103, 2002

Baseline in human fetal heart rate records.
Dawes G.S., Houghton C.R.S, Redman C.W.G.
British journal of obstetrics and gynaecology, vol 89 (4), p.270-275, 1982

8.4.2 Publications on Fischer's analysis

The implementation of Fisher's analysis in the Sunray B6 Fetal Monitor follows the publications listed below.

Kardiotokographie-Praxis.
Klaus Goeschen, Eckhard Koepcke (ed.)
Georg Thieme Verlag, 2003.

Ein Vorschlag zur Beurteilung des antepartualen Kardiotokogrammes (A suggestion for the evaluation of the antepartal cardiotocogram).
Fischer, W. M., Stude, I., Brandt, H.
Z. Geburtshilfe Perinatol. 1976 Apr;180(2):117-23.

Kardiotokographie. Diagnostische Methoden in der Perinatologie.
Fischer, W.M. (ed.), Berg, D., Brandt, H., Ekert, W.D.
Georg Thieme Verlag, Stuttgart. ISBN 978-3135068039.

Kardiotokographie: Lehrbuch u. Atlas
Fischer, W.M. (ed.)
Georg Thieme Verlag, Stuttgart. ISBN 978-3135068015.

8.4.3 Publications on Krebs' analysis

The implementation of Krebs' analysis in the Sunray B6 Fetal Monitor follows the publications listed below.

Clinical application of a scoring system for evaluation of antepartum fetal heart rate monitoring.
Krebs HB, Petres RE.
Am J Obstet Gynecol. 1978 Apr 1;130(7):765-72.

II. Multifactorial analysis of intrapartum fetal heart rate tracings.
Krebs HB, Petres RE, Dunn LJ, Jordaan HV, Segreti A.
Am J Obstet Gynecol. 1979 Apr 1;133(7):773-80.

Intrapartum fetal heart rate monitoring. IV. Observations on elective and nonelective fetal heart rate monitoring.
Krebs HB, Petres RE, Dunn LJ, Segreti A.
Am J Obstet Gynecol. 1980 Sep 15;138(2):213-9.

Intrapartum fetal heart rate monitoring. VI. Prognostic significance of accelerations.
Krebs HB, Petres RE, Dunn LJ, Smith PJ.
Am J Obstet Gynecol. 1982 Feb 1;142(3):297-305.

Intrapartum fetal heart rate monitoring. VIII. Atypical variable decelerations.
Krebs HB, Petres RE, Dunn LJ.
Am J Obstet Gynecol. 1983 Feb 1;145(3):297-305.

8.4.4 Publications on NST - Nonstress test

The implementation of NST in the Sunray B6 Fetal Monitor follows the publications listed below.

Pregnancy outcome in the patient with a nonreactive nonstress test and a positive contraction stress test.

Slomka C, Phelan JP.
Am J Obstet Gynecol. 1981 Jan;139(1):11-5.

The nonstress test: a review of 3,000 tests.
Phelan JP.
Am J Obstet Gynecol. 1981 Jan;139(1):7-10.

Fetal heart rate decelerations during a nonstress test.
Phelan JP, Lewis PE Jr.
Obstet Gynecol. 1981 Feb;57(2):228-32.

A computer system for the numerical analysis of nonstress tests.
Pardey J, Moulden M, Redman CW.
Am J Obstet Gynecol 186:1095-1103, 2002.

8.4.5 Publications on CST - Contraction stress test

The implementation of CST in Sunray B6 Fetal Monitor follows the publications listed below.

Antepartum fetal heart rate testing. II. Intrapartum fetal heart rate observation and newborn outcome following a positive contraction stress test.
Gauthier RJ, Evertson LR, Paul RH.
Am J Obstet Gynecol. 1979 Jan 1;133(1):34-9.

The contraction stress test.
Lagrew DC Jr.
Clin Obstet Gynecol. 1995 Mar;38(1):11-25. Review.

Antepartum fetal heart testing: a clinical appraisal.
Goldkrand JW, Benjamin DS.
Obstet Gynecol. 1984 Jan;63(1):48-51.

Fetal breathing movements and the abnormal contraction stress test.
Manning FA, Platt LD.
Am J Obstet Gynecol. 1979 Mar 15;133(6):590-3.

8.5 EU Declaration of Conformity

Declaration of Conformity - RED Directive

Manufacturer Name:	Guangzhou Sunray Medical Apparatus Co.,Ltd
Address:	38 Gaoke Road, Gaotang Industry District, GuangShanEr Road, 510520,Guangzhou, PEOPLE'S REPUBLIC OF CHINA
EU Representative Name:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestrasse 80, 20537 Hamburg Germany
Radio Equipment Name:	Fetal Monitor
Model:	SRF618B6
Radio Equipment Description:	The radio equipment can be equipped with capability for wireless monitoring using wireless Ultrasound transducer, TOCO transducer and fetal movement marker.

We declare under our sole responsibility that the radio equipment described above is in conformity with the Radio Equipment Directive 2014/53/EU. The following harmonized standards are those which the product applies.

EN 300 440-2,V2.1.1	Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1,V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-3,V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 300 220-1 V3.1.1	Short Range Devices (SRD) operating in the frequency range 25 MHz to 1000MHz; Part 1: Technical characteristics and methods of measurement
EN 300 220-2 V3.1.1	Short Range Devices(SRD) operating in the frequency range 25 MHz to 1000 MHz; Part 2: Harmonised Standards covering the essential requirements of article 3.2 of Directive 2014/53/EU for non specific radio equipment
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10MHz~ 300GHz)

Signed by: Liu Li Jun

Position:Management Representative of manufacturer

CE 0123

Sunray

Manufacturer

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