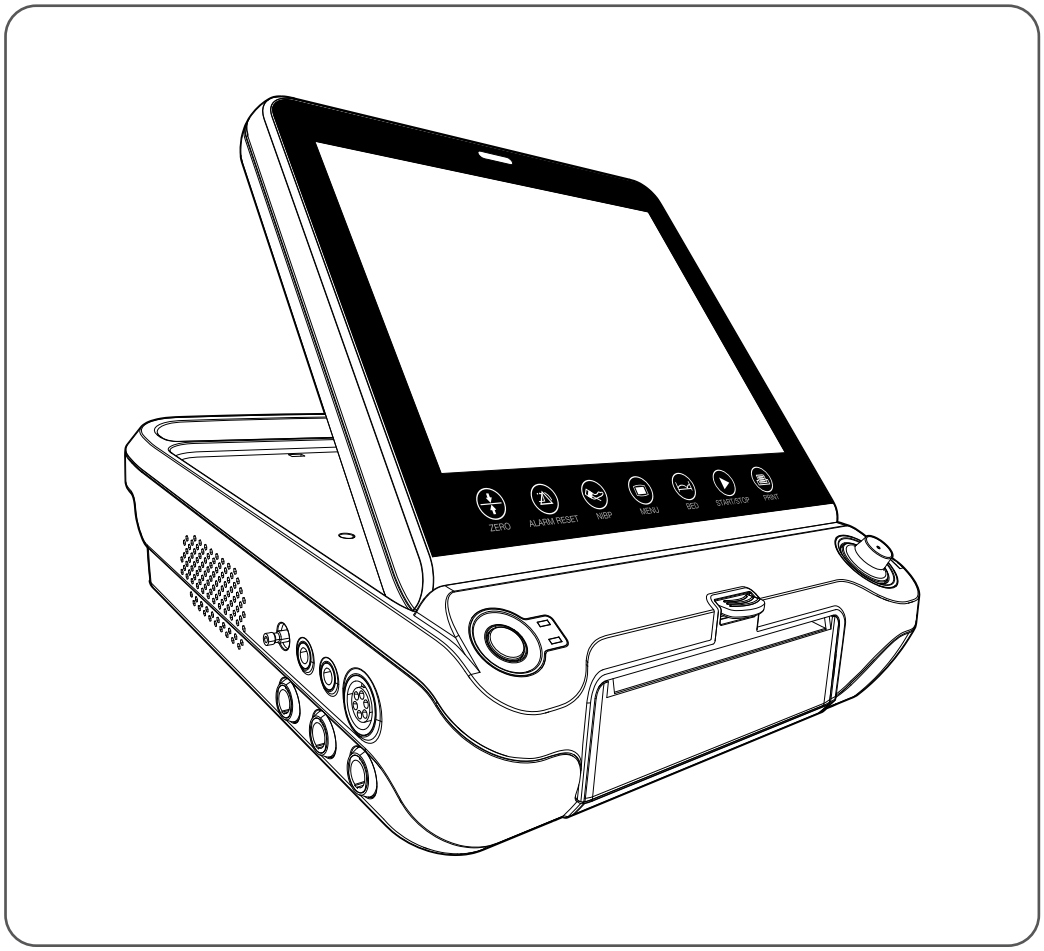
stan S41

Maternal and Fetal Monitor
SRF618X9

Instructions for Use



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The STAN S41 Maternal and Fetal Monitor - SRF618X9 - 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 STAN S41 Maternal and 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 maternal ECG, maternal non-invasive blood pressure (NIBP), maternal oxygen saturation (MSpO2), maternal respiration rate (Resp), uterine activity (UA), fetal movements (FM), and fetal heart rate (FHR) of single fetuses and twins.

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 FECG function (optional) is intended for internal monitoring of fetal heart rate (FHR) by the use of a fetal scalp electrode, during labor.

The fetal ST analysis function (optional) is intended for monitoring of the fetal heart activity during labor, from the 36th week of gestation.

The IUP function (optional) is intended for internal monitoring of uterine activity (UA) by the use of an intra-uterine pressure catheter (IUPC), during labor.

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

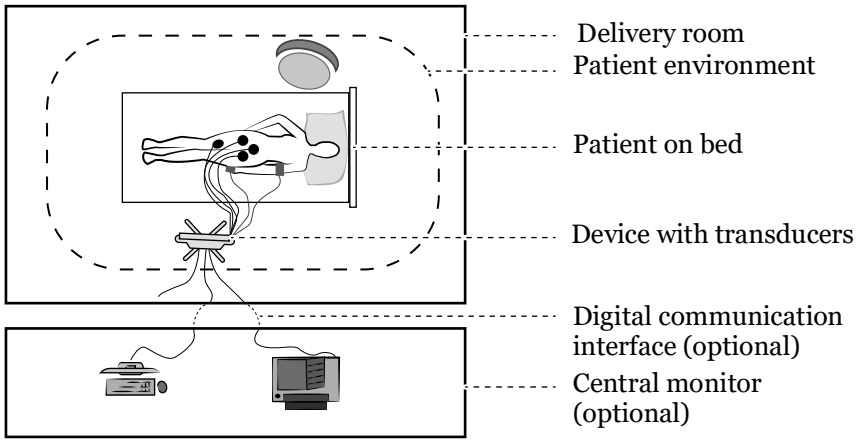


Figure 1:1 Intended use environment

Operator can be anywhere.

1.3 Contraindications

The STAN S41 Maternal and Fetal Monitor is *not* intended for:

- use during defibrillation, electro-surgery, or magnetic resonance imaging (MRI),
- ECG measurements on patients connected to external electrical stimulators or with cardiac pacemakers,
- 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.

In addition, the FECG function (optional) is *not* intended for fetal heart rate monitoring or fetal ST analysis on patients for whom use of a fetal spiral electrode is contra-indicated.

In addition, the fetal ST analysis function (optional) is *not* intended for:

- Fetal ST analysis on pregnant mothers with a gestational age less than 36 weeks, on twin/triplet fetuses, for presentation other than vertex or before amniotic membranes are ruptured,

- fetal ST analysis on fetuses that do not have a stable baseline and normal variability at onset of recording,
- fetal ST analysis when managing clinician is not trained in fetal ST analysis,
- fetal ECG monitoring on patients connected to external electrical stimulators such as TENS, or with cardiac pacemakers, or
- use in the presence of flammable anaesthetics, such as flammable anaesthetic mixture with air, oxygen or nitrous dioxide.

In addition, the IUP function (optional) is *not* intended for intra-uterine pressure monitoring on patients for whom use of an IUPC is contra-indicated.

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 10 years. This company will provide repair service for the user within the term of the service life.

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

1.5 Overview of STAN S41

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 US and TOCO	Wireless US and TOCO for underwater monitoring	FECG and IUP	Fetal ST analysis	Built-in battery
SRF618X9	Optional	Optional	Optional	Optional	Optional

1.5.1 Front view

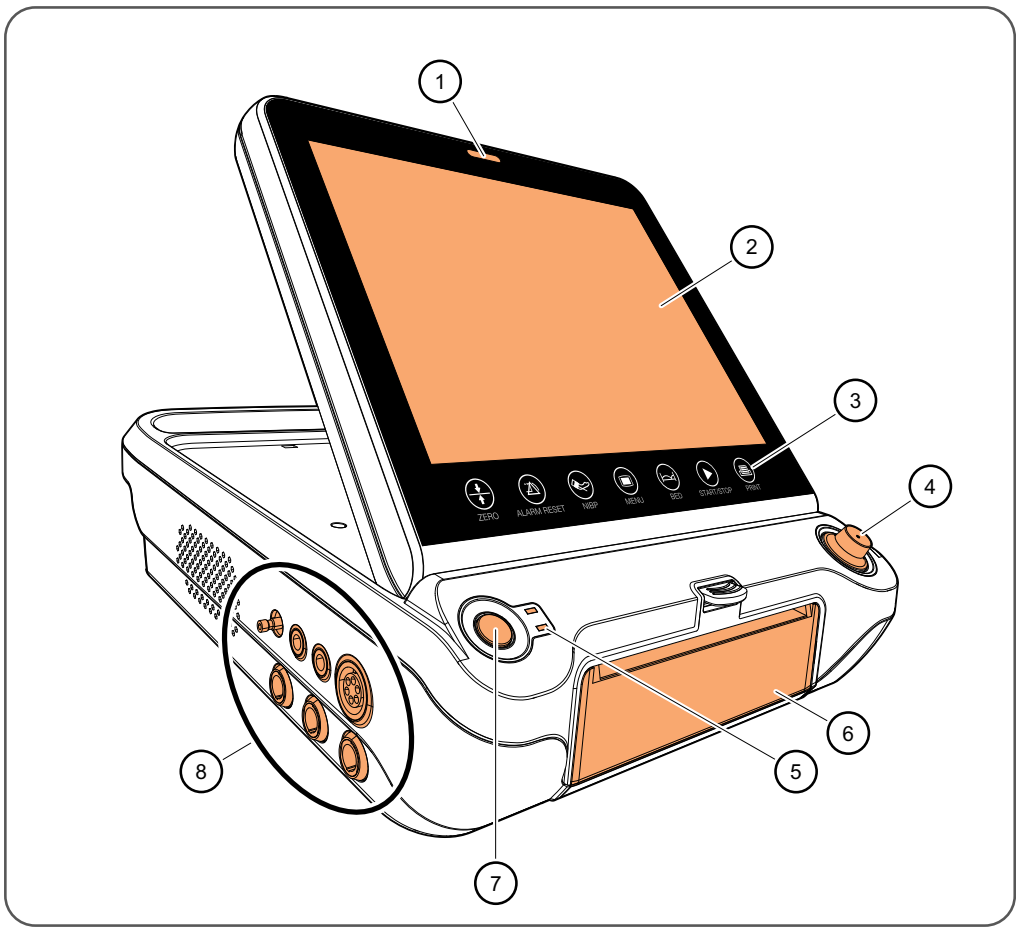


Figure 1:2 Main unit front view

Pos	Component
1	Alarm indicator
2	Main screen
3	Touch keys
4	Control knob
5	Mains power and system battery charging indicator

Pos	Component
6	Paper tray
7	Power ON/OFF button
8	Patient connectors

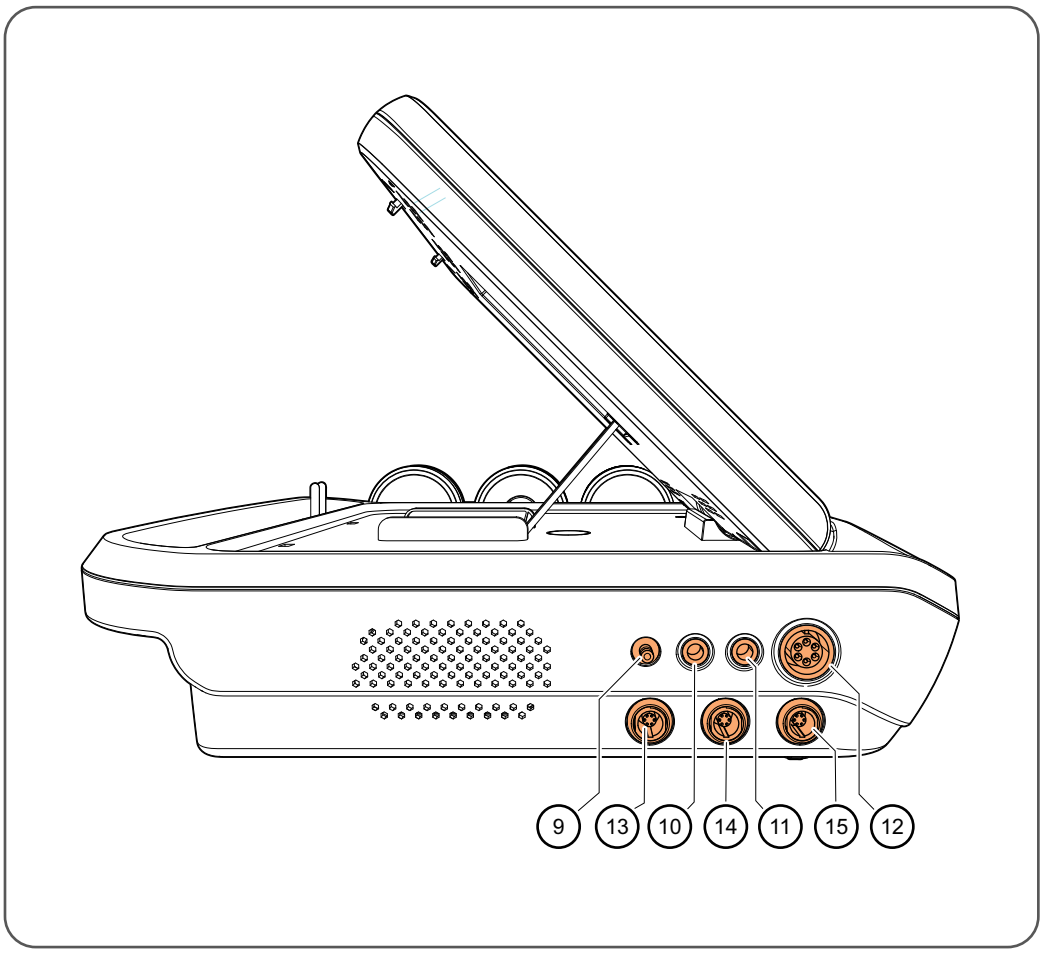


Figure 1:3 Main unit left side view

Pos	Component
9	NIBP connector
10	For future use
11	For future use
12	MECG connector
13	MSpO2 connector
14	IUP connector (optional)
15	FECG connector (optional)

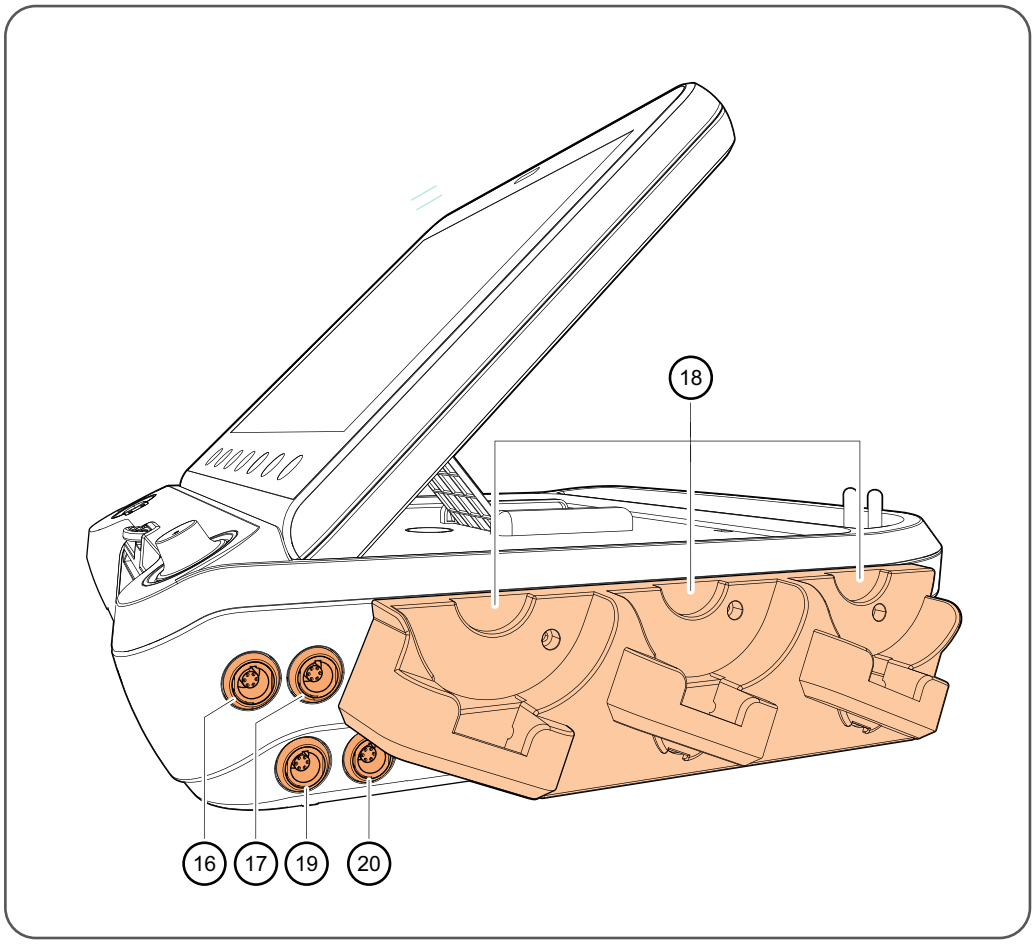


Figure 1:4 Main unit right side view

Pos	Component
16	Ultrasound FHR1 connector
17	TOCO connector
18	Charging rack for wireless transducers (optional)
19	Fetal movement marker connector
20	Ultrasound FHR2 connector

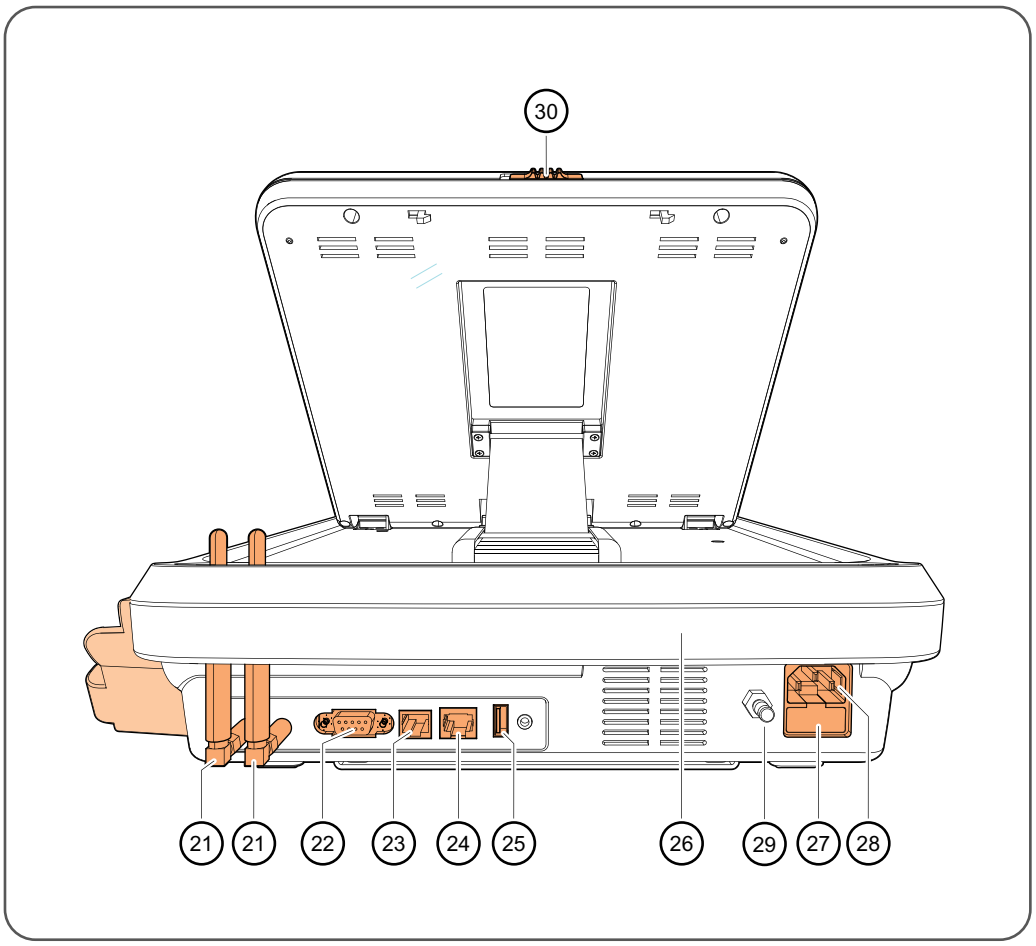


Figure 1:5 Main unit rear view

Pos	Component
21	Antenna interface for wireless transducers
22	RS-232 interface connector
23	RS-485 interface connector
24	Ethernet interface connector
25	USB interface connector
26	Carrying handle
27	Fuse holder
28	Mains power connector
29	Potential equalization conductor
30	Tilt lock for screen

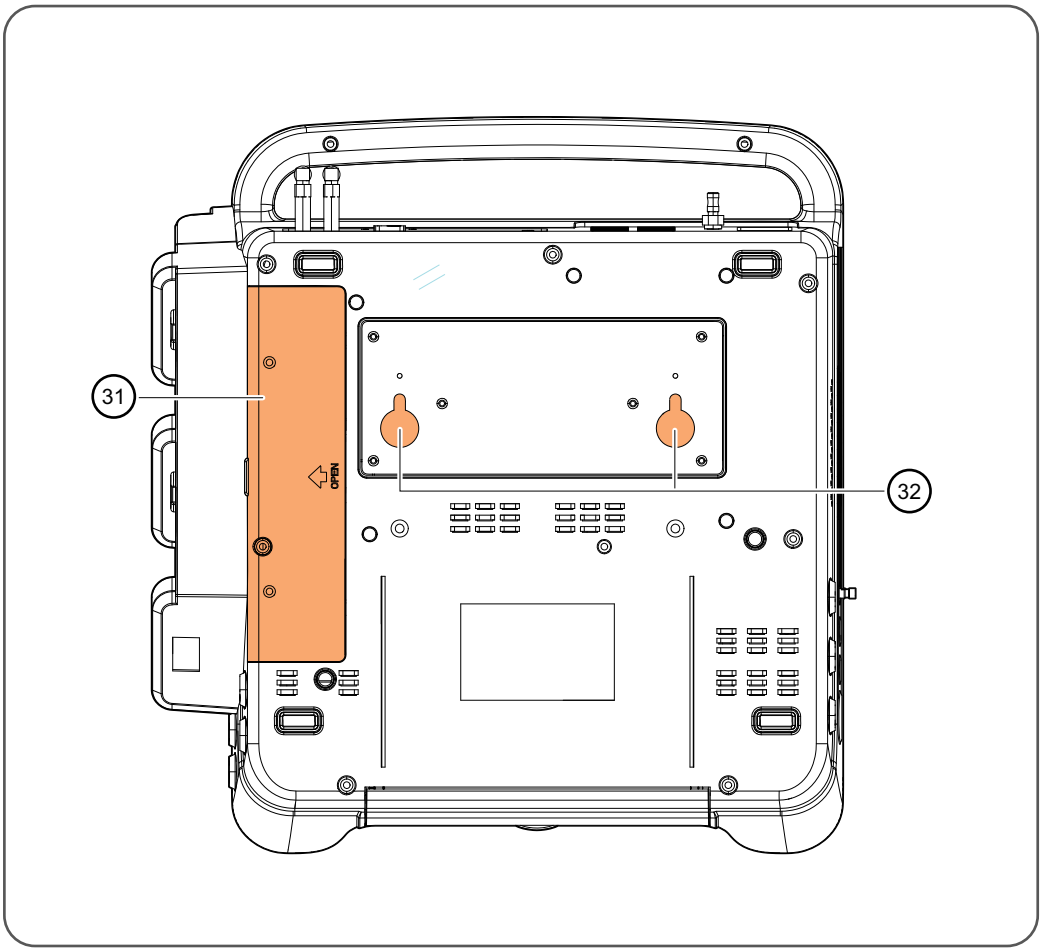


Figure 1:6 Main unit bottom view

Pos	Component
31	Battery compartment
32	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.

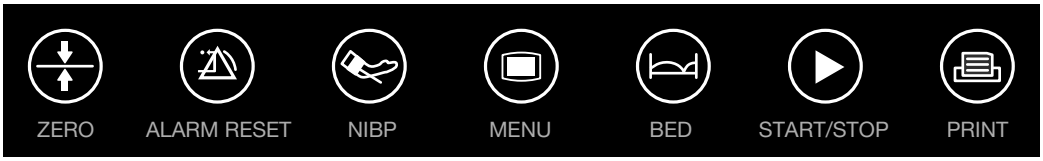


Figure 1:7 Touch key bar located below the main screen

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.
NIBP	Start/Stop NIBP	Opens the NIBP measurement menu. During an ongoing measurement, selecting this key will cancel the ongoing measurement and deflate the cuff.
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.

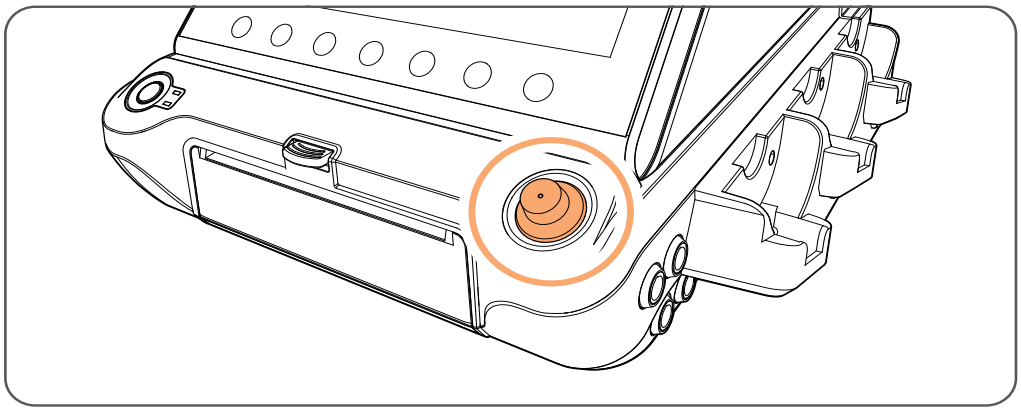


Figure 1:8 Control knob

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 155.

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.

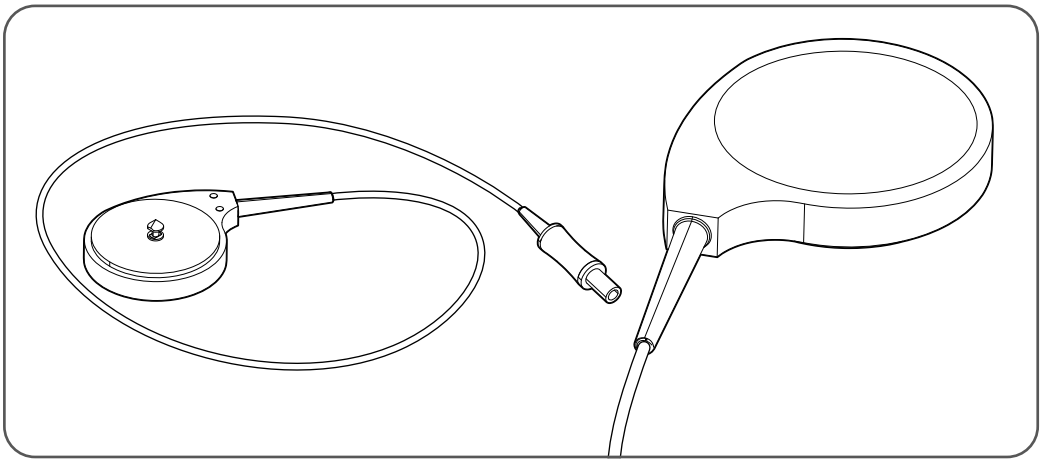


Figure 1:9 Wired ultrasound transducer for recording of fetal heart rate

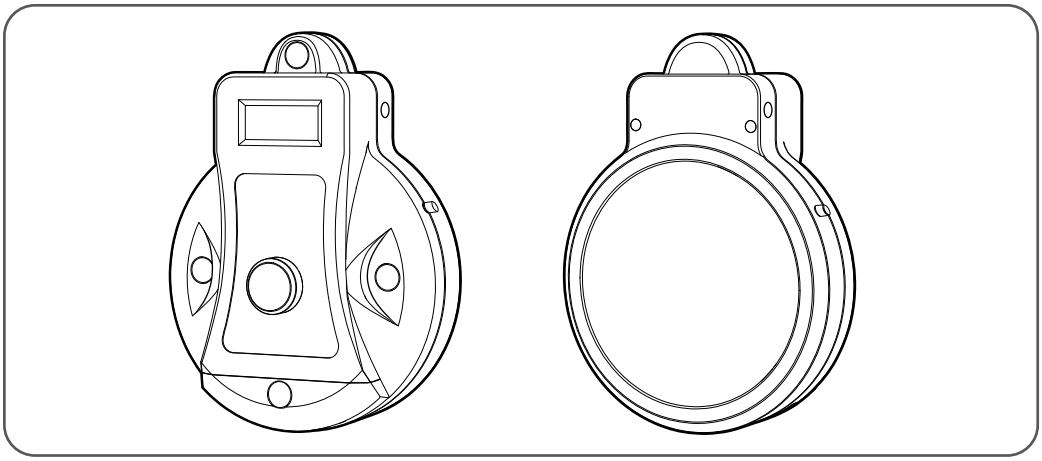


Figure 1:10 Wireless ultrasound transducer for recording of fetal heart rate

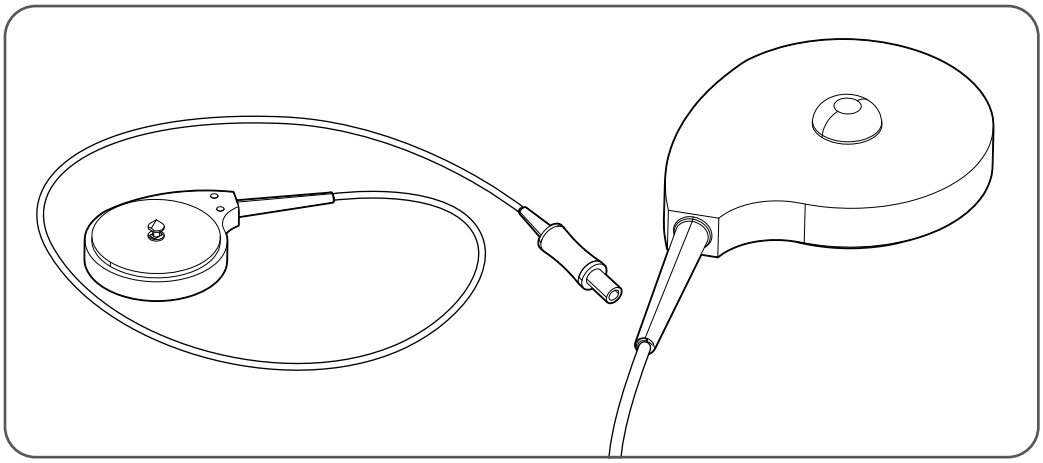


Figure 1:11 Wired TOCO transducer for recording uterine contractions

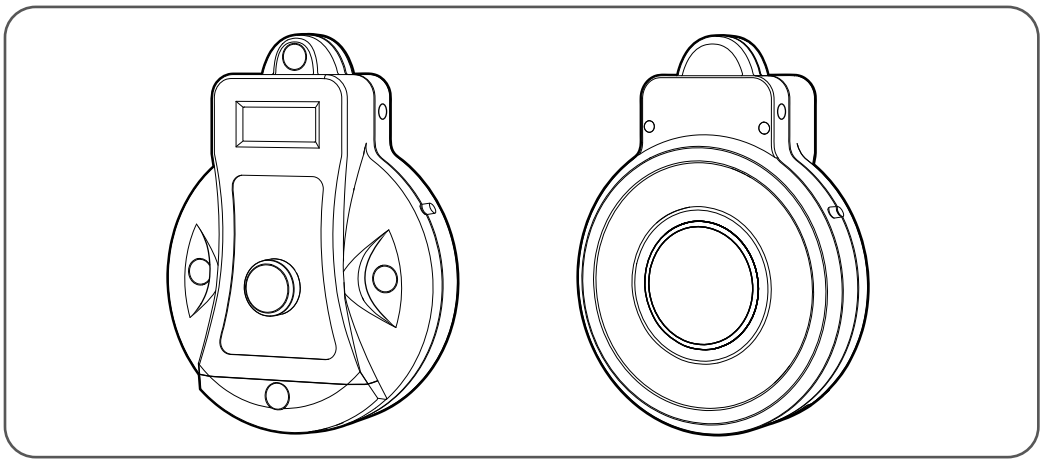


Figure 1:12 Wireless TOCO transducer for recording uterine contractions

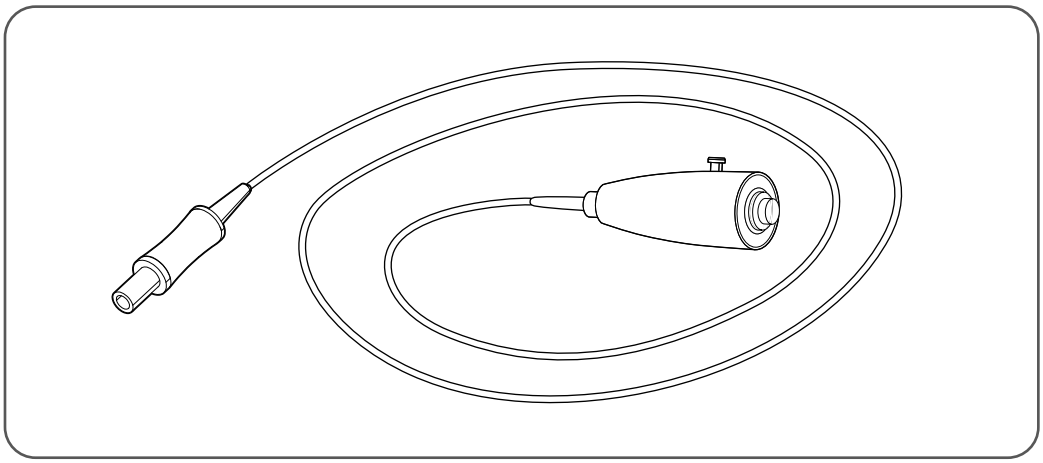


Figure 1:13 Wired fetal movement marker for manual registration of fetal movements

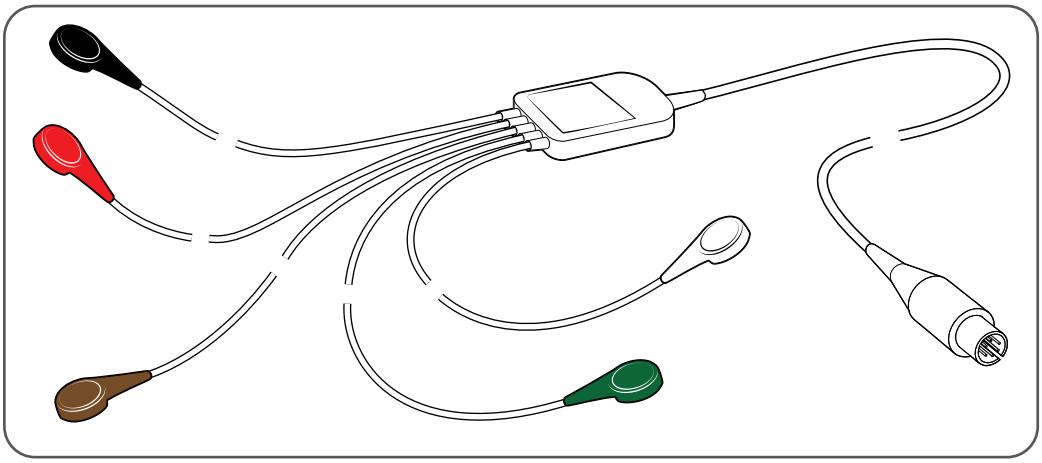


Figure 1:14 5-leadwire MECG leadset for recording of maternal ECG, heart rate and respiratory rate

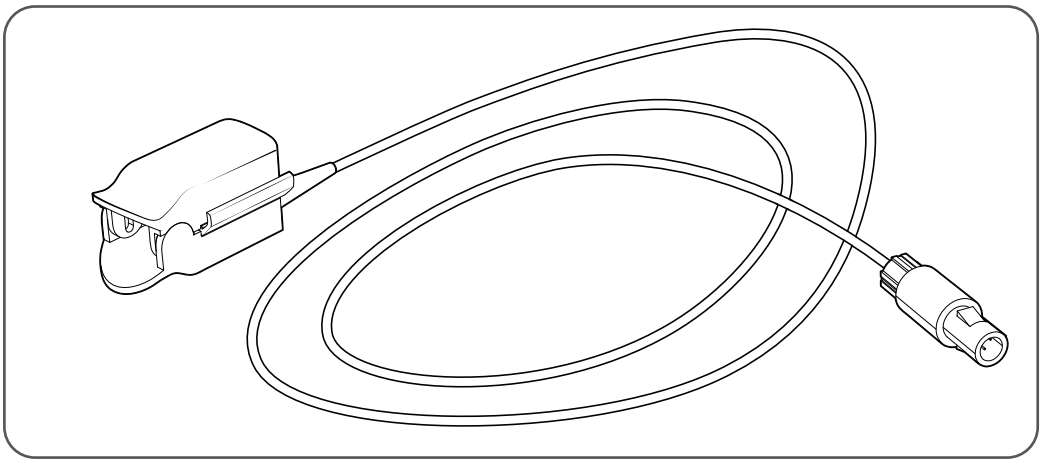


Figure 1:15 MSpO2 sensor for recording of maternal pulse and oxygen saturation

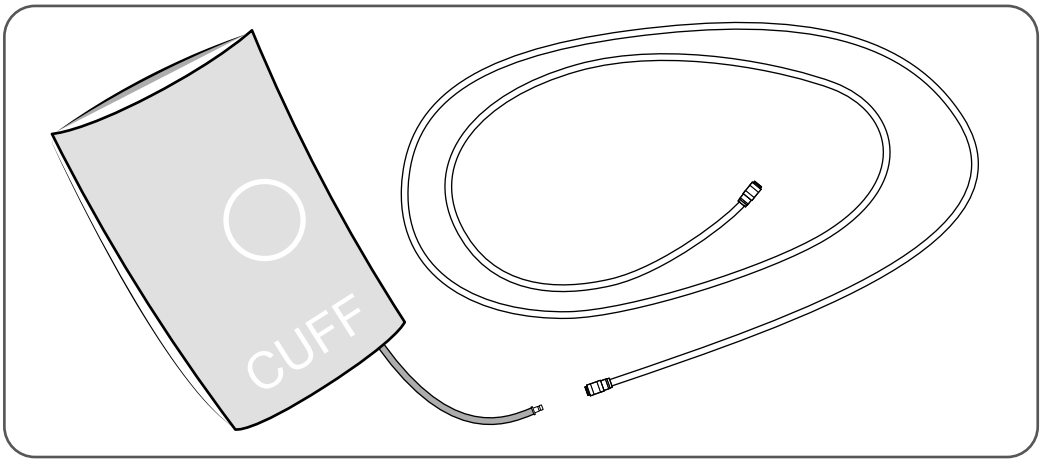


Figure 1:16 NIBP cuff for non-invasive measurement of maternal blood pressure

Accessory or spare part	Part number
Wired ultrasound transducer	P1221-05038
Wireless FHR1 ultrasound transducer (2.4GHz. Only for use with 2.4GHz charging rack.)	P1271-05043
Wireless FHR1 ultrasound transducer (433MHz, for underwater monitoring. Only for use with 433MHz charging rack.)	P1271-05050
Wireless FHR2 ultrasound transducer (2.4GHz. Only for use with 2.4GHz charging rack.)	P1271-05042
Wireless FHR2 ultrasound transducer (433MHz, for underwater monitoring. Only for use with 433MHz charging rack.)	P1271-05051
FECG legplate for Goldtrace	P1263-03024
Goldtrace fetal spiral electrode	CNS000004 (Neoventa Medical)
Single-packed skin electrode suitable for fetal ST analysis	CNS000003 (Neoventa Medical)
Wired TOCO transducer	P1224-05052
Wireless TOCO transducer (2.4GHz. Only for use with 2.4GHz charging rack.)	P1271-05044
Wireless TOCO transducer (433MHz, for underwater monitoring. Only for use with 433MHz charging rack.)	P1271-05052
IUP adapter cable for Clinical Innovations/Koala	IPC-5065 (Clinical Innovations)
Koala IUP catheter	IPC-5000 (Clinical Innovations)
IUP adapter cable for Utah Medical/Intran	P1263-03027
IntranPlus IUP catheters	IUP-400, IUP-450 IUP-500, IUP-550 (Utah Medical)
Wired fetal movement marker	P1221-12035
Transducer belt	P2224-08001
Transducer belt - 5 cm wide	CNS000107 (Neoventa Medical)
Transducer belt - 10 cm wide	CNS000108 (Neoventa Medical)
Legplate belt	CNS000106 (Neoventa Medical)
Aquasonic coupling gel	P7001-00030
5-leadwire MECG leadset cable	P9001-00201
3-leadwire MECG leadset cable	P9001-00478
Disposable ECG electrode for MECG recording	P7001-00296
MSpO2 sensor	P7002-00008
MSpO2 extension cable (also require P7002-00008 for use)	P9001-00501

Accessory or spare part	Part number
Adult NIBP cuff (upper arm perimeter 20.5 cm - 28 cm)	P9001-00503
Adult NIBP cuff (upper arm perimeter 27 cm-35 cm)	P9001-00504
Adult NIBP cuff (upper arm perimeter 34 cm-43 cm)	P9001-00505
Adult NIBP cuff (thigh perimeter 42 cm-54 cm)	P9001-00506
NIBP cuff extension hose	P9001-00485
Printer paper with CTG+ST analysis grid, with 50-210 bpm HR range and 20 bpm/cm scaling,	P8105-00063
Printer paper with CTG-only grid, with 50-210 bpm HR range and 20 bpm/cm scaling	P8105-00003
Printer paper with CTG-only grid, with 30-240 bpm HR range and 30 bpm/cm scaling (USA)	P8105-00004
Power cord	P5301-00001
Fuse T2AH250V	P4940-00010
Rechargeable system battery (lithium-ion)	P4910-00015
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.

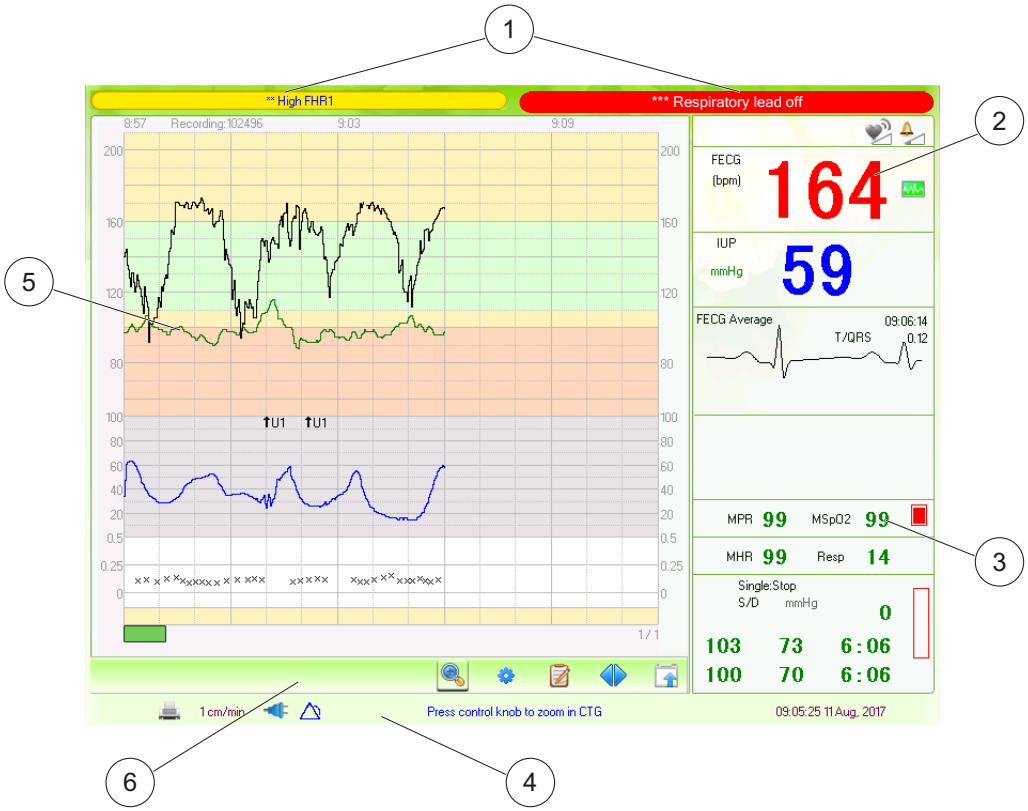


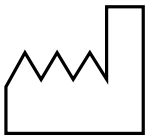
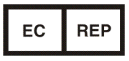
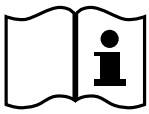
Figure 1:17 Main screen

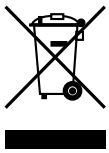
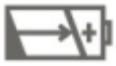
Label	Name	Function
1.	Alarm field	Display area for visual alarm signals, showing currently active alarm conditions. Physiological alarms are displayed on the left and technical alarms to the right.
2.	Fetal numeric field	a) Wireless channel indicator b) FHR sound volume indicator c) Audible alarm sound 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 FHR in CTG trace. i) Current uterine pressure. j) FECG Average waveform with current T/QRS ratio and BP indicator.
3.	Maternal numeric field	a) Current maternal oxygen saturation and pulse measured from MSpO2 sensor b) Maternal blood pressure measured with NIBP cuff. c) Current maternal heart rate and respiratory rate measured with MECG leadset.

Label	Name	Function
4.	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.
5.	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 “Training materials and clinical guidelines” on page 159. Recording ID is shown in the top left corner.
6.	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 SRF618X9 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 CF Applied Part	Suitable for external and internal application to the patient including direct cardiac application.
	Defibrillation-proof type CF applied part	Suitable for external and internal application to the patient including direct cardiac application.
	Defibrillation-proof type BF 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.

Symbol	Denomination	Description
	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.
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

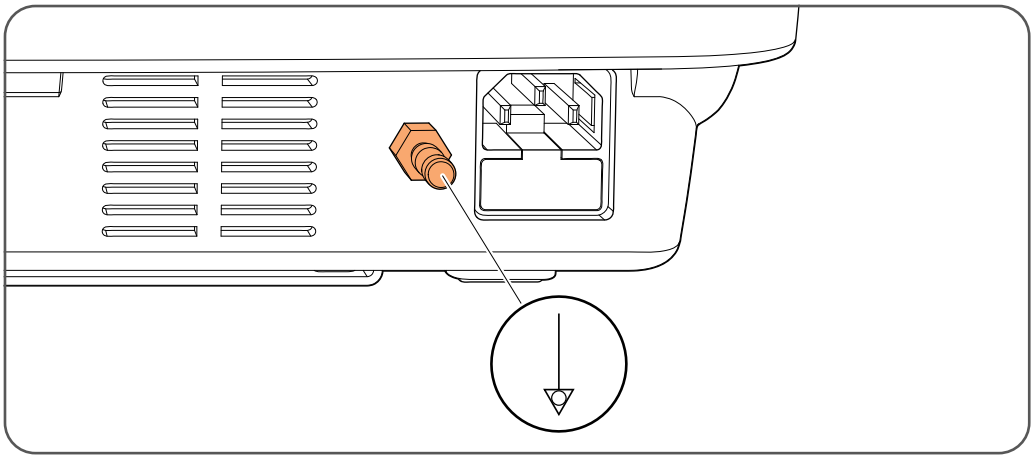


Figure 2:18 Potential equalization conductor

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!

Avoid contact between the skin or scalp electrode contacts and earth or any electrically conductive object.

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 STAN S41 Maternal and 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

STAN S41 Maternal and 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 STAN S41 Maternal and 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 STAN S41 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 155, comply with EMC standard IEC 60601-1-2:2014+A1:2020.

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 STAN S41 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.

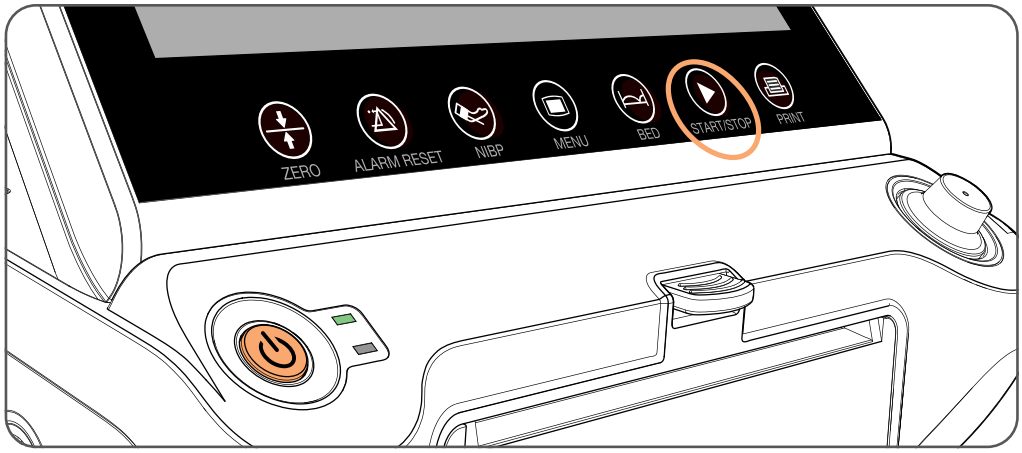


Figure 3:19 Power on button and "START/STOP" touch key

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 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.

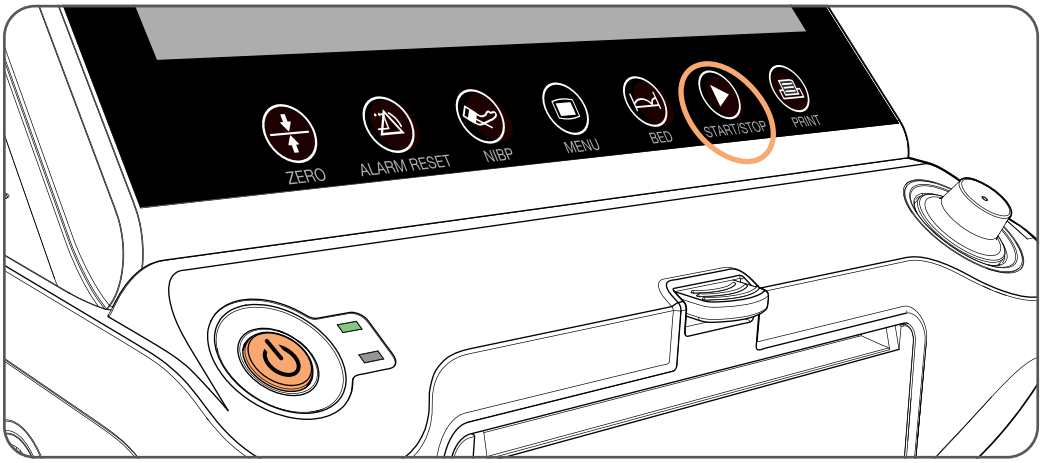


Figure 3:20 “START/STOP” touch key

1. During recording, press 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.

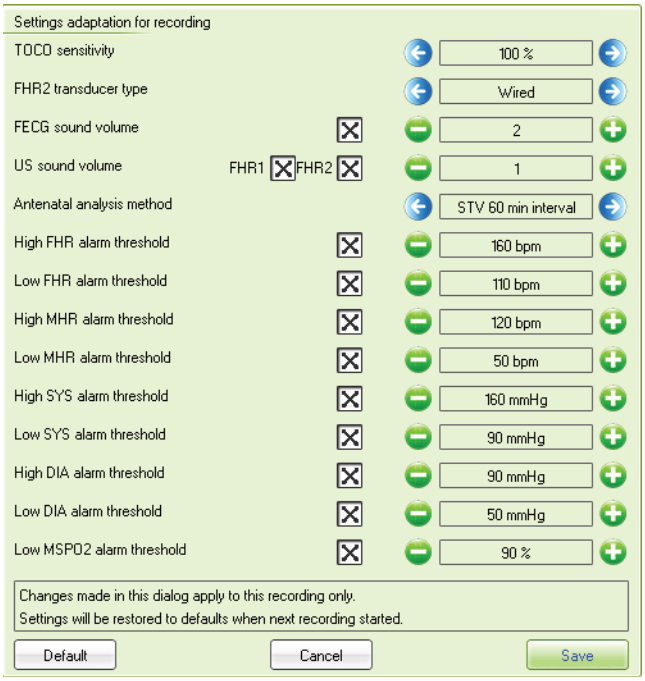


Figure 3:21 Quick settings screen

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

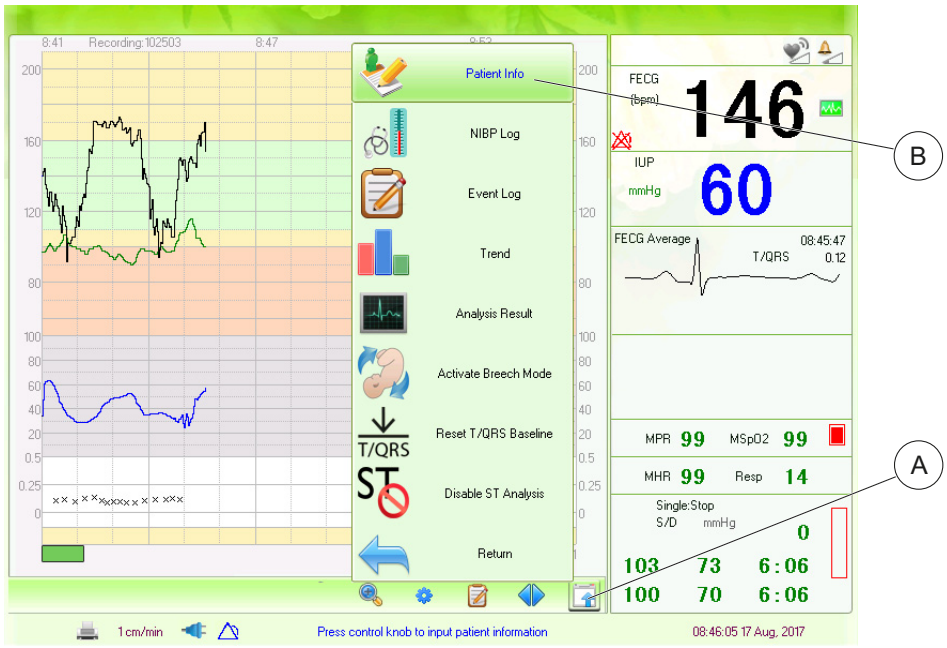


Figure 3:22 Accessing the patient information input dialog

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.

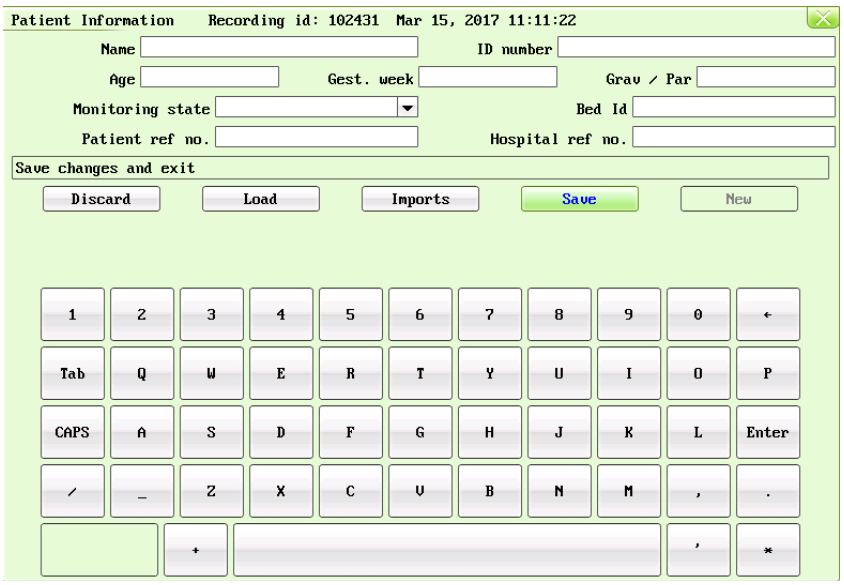


Figure 3:23 Manual entry of patient information using on-screen keyboard

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.

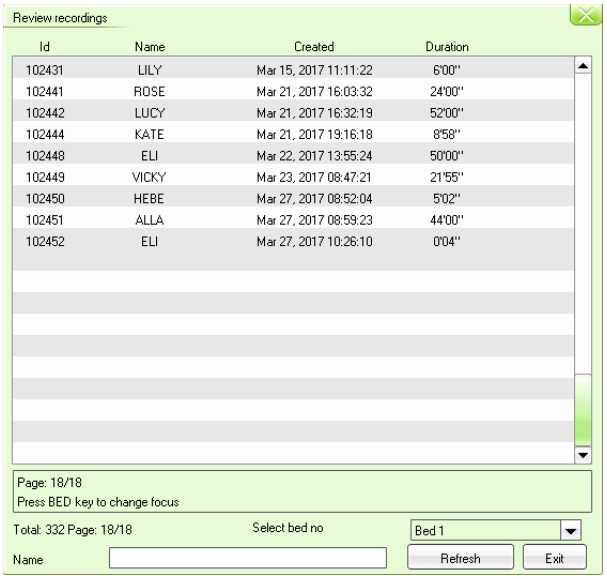


Figure 3:24 Loading patient information from a previous recording file

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.

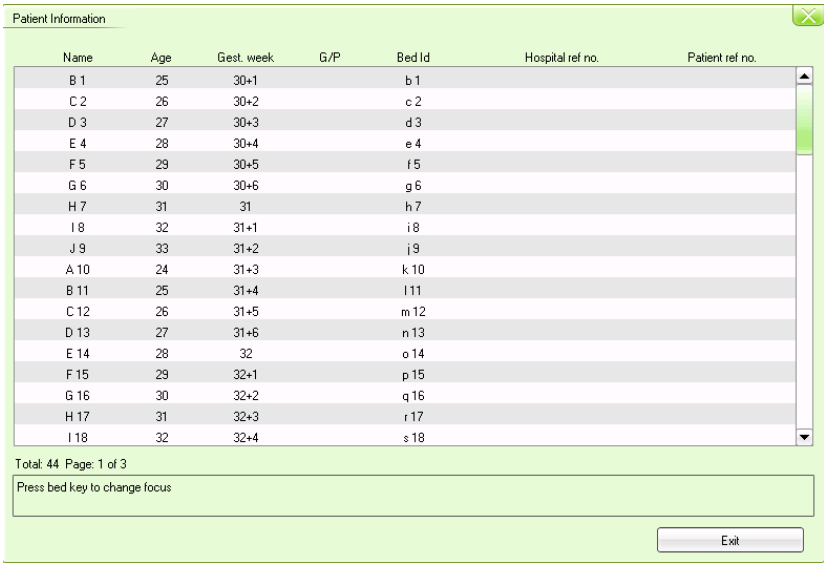


Figure 3:25 Importing patient information from insight software

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.

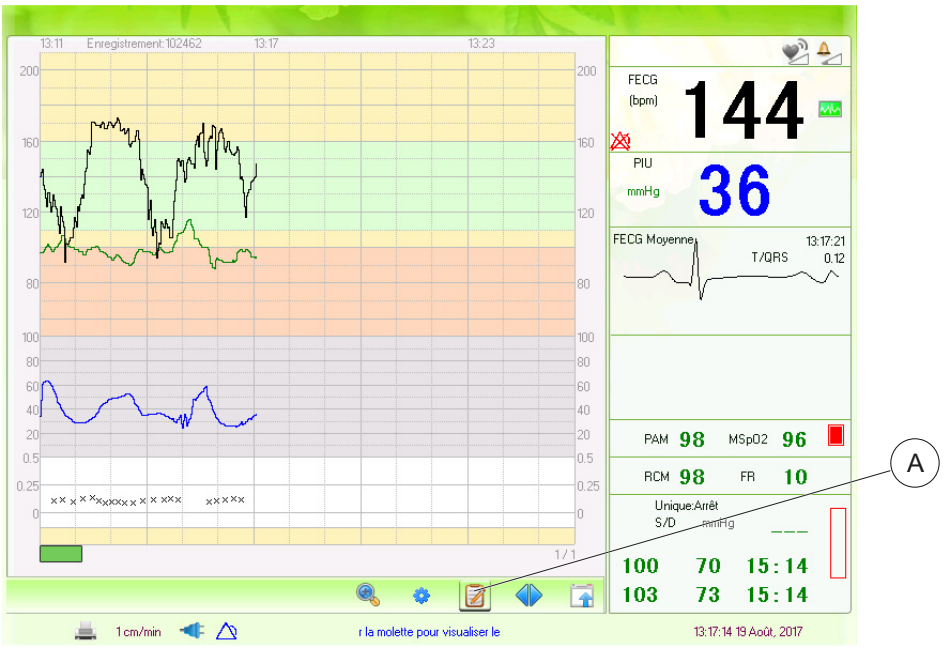


Figure 3:26 Opening the event log

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

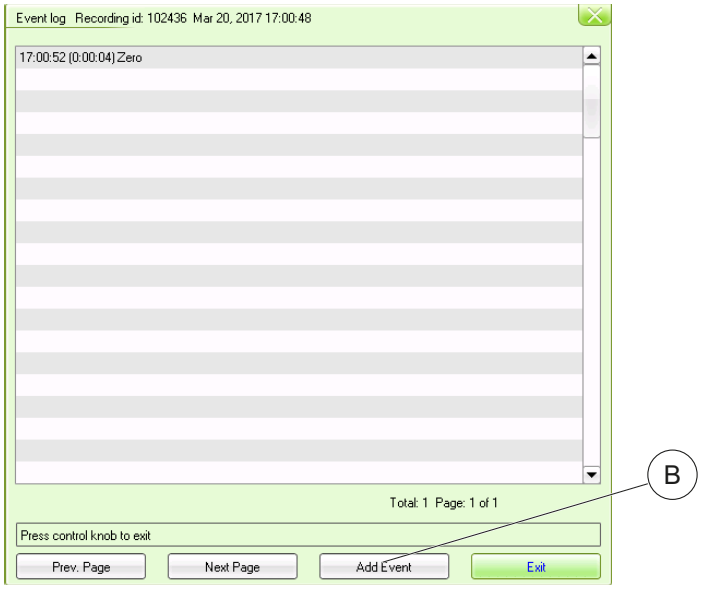


Figure 3:27 Opening the “Add event” menu

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

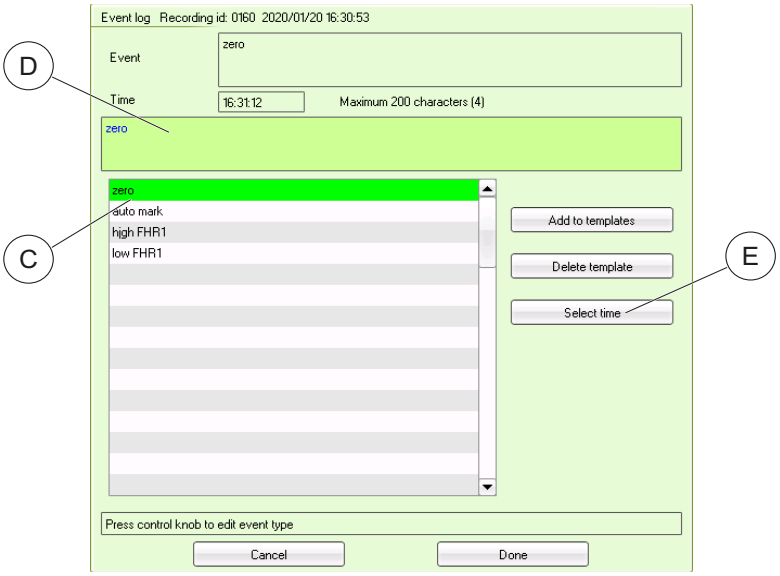


Figure 3:28 Selecting annotation template

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.

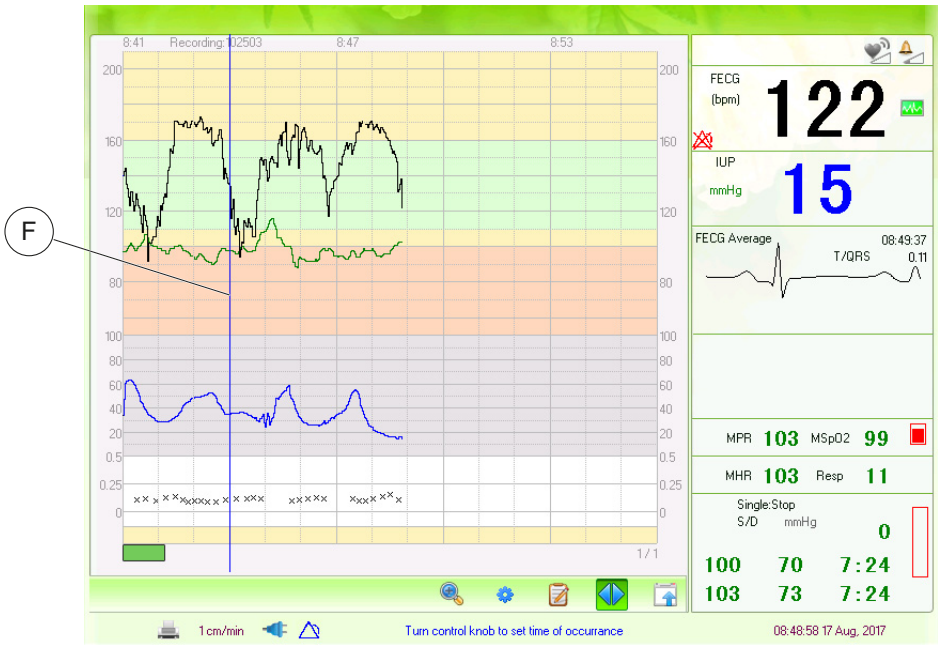


Figure 3:29 Selecting event occurrence

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.

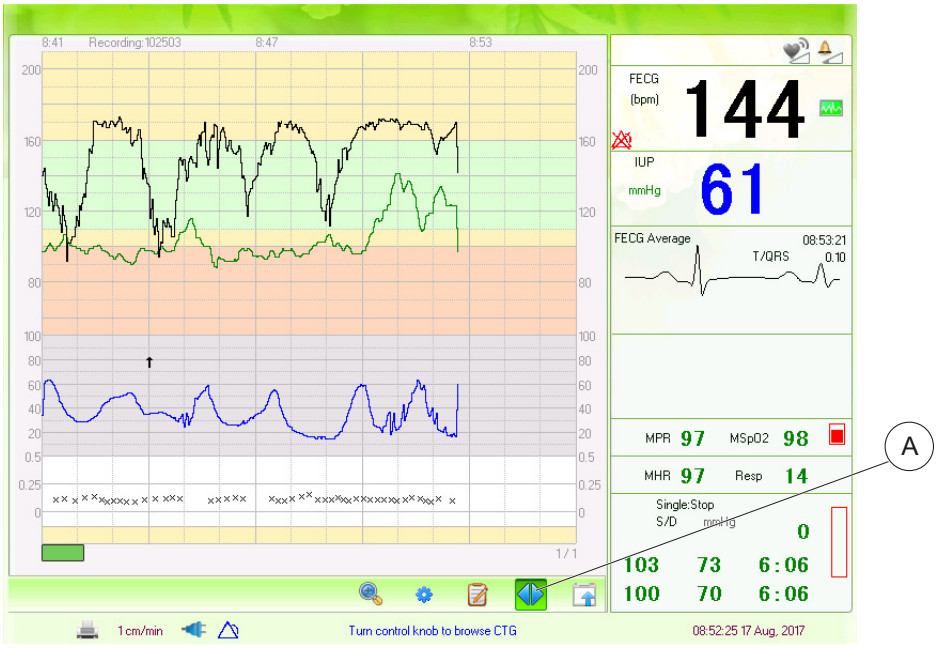


Figure 3:30 Scroll CTG window

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.

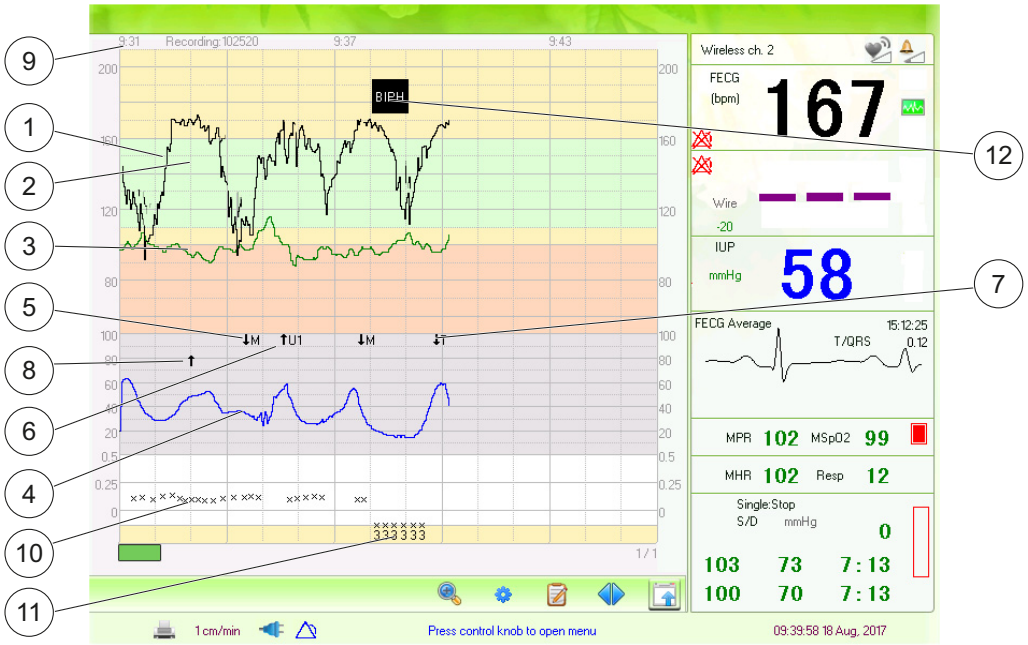


Figure 3:31 CTG trace window

Pos	Measured value	Appearance
1.	Fetal heart rate from FHR1, or fetal heart rate from scalp electrode	Solid line, blue, solid line, black
2.	Fetal heart rate from FHR2	Solid line, purple
3.	Maternal pulse from MSpO2 and MECG	Solid line, green
4.	Uterine activity from TOCO, or uterine activity from IUP	Solid line, black, solid line, blue
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" indication, gray
7.	Fetal movement recorded with TOCO transducer	Upward arrow with 'T' character, gray
8.	Event log marker	Upward arrow, gray
9.	Timestamp	-
10.	T/QRS ratio	Crossmark, black
11.	Indicator for biphasic ST waveform	"1" / "2" /"3" indication, black
12.	ST event	Descriptive text, white on black background

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.

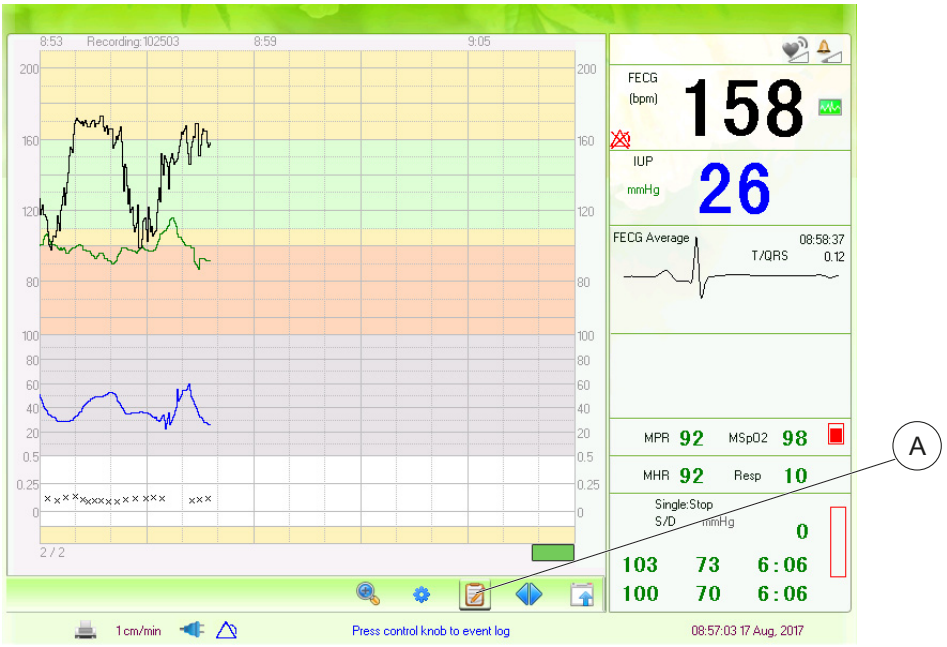


Figure 3:32 Accessing the event log window

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.

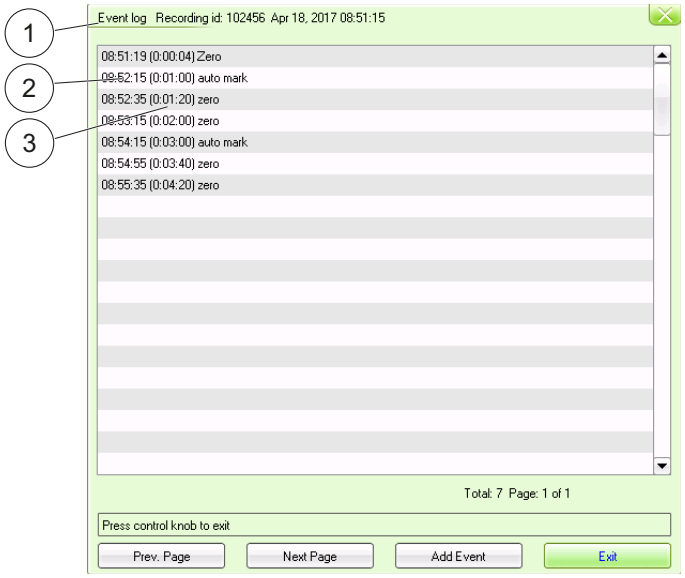


Figure 3:33 Event log window

Pos	Description
1	Recording identifier
2	Alarm conditions
3	Annotations

3.8 Reviewing the NIBP log

The NIBP log is a summary of NIBP measurements that have been taken 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 3:34 Accessing the NIBP log window

1. Use the control knob to select the “Tools” menu button (A). Then select the “NIBP Log” menu item (B) to enter the NIBP log.

2. You can now review the list of NIBP measurements page by page by turning the control knob.

3. To exit the NIBP log, select the “Exit” button and push the control knob again.

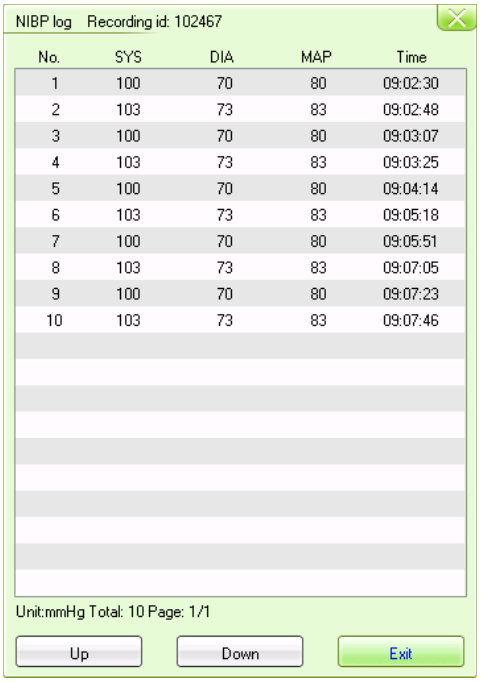


Figure 3:35 NIBP log window

3.9 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.

3.9.1 Alarm system overview

Figure 3:36 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.

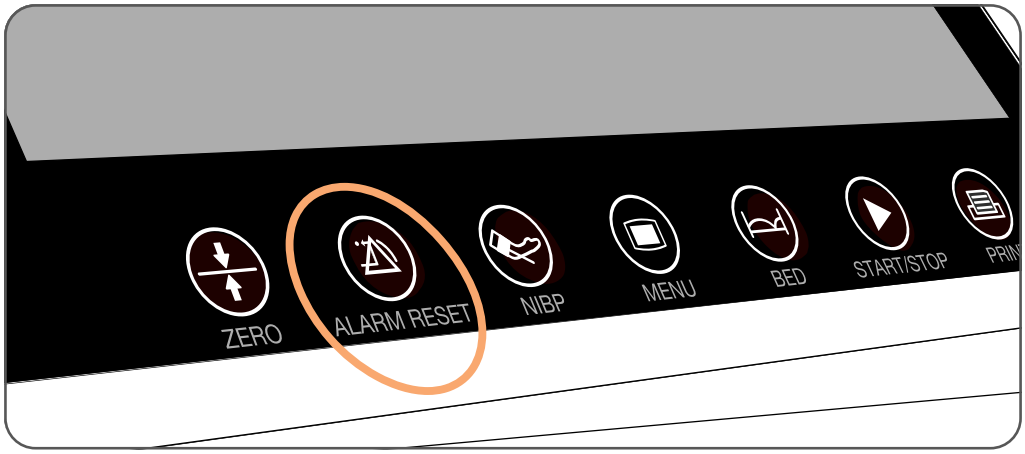


Figure 3:37 “ALARM RESET” touch key

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 43. 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.

3.9.2 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 161.

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
Baseline T/QRS rise	T/QRS baseline level has increased with more than 0.05, compared with previous 180 minutes.	Medium	5 to 10 minutes depending on signal quality.	Does not expire.
Episodic T/QRS rise	T/QRS has temporarily increased over the baseline level by more than 0.10.	Medium	10 seconds to 2 minutes depending on heart rate and signal quality.	Does not expire.
Biphasic ST	The ST slope in the FECG waveform has been biphasic grade 2 or 3 for three consecutive FECG averages.	Medium	15 seconds to 3 minutes depending on heart rate and signal quality.	Does not expire.
High FHR1/2	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	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.	**

*Delay from physiological condition to alarm signal being generated.

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

Message	Condition	Priority	Delay*	Alarm expires
> 5 UC in 10 mins	When there has been five or more uterine contractions during the previous ten minutes.	Low	< 125 s	**
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.	**
Maternal Cardiac Standstill	Cardiac standstill	High	< 10 s	**
High RR	When the respiratory rate measured with MECG leadset is higher than upper alarm threshold	Medium	< 3 s	**
Low RR	When the respiratory rate measured with MECG leadset is lower than lower alarm threshold	Medium	< 3 s	**
Maternal Asphyxia	Respiration cannot be detected within configured interval.	High	Equal to configured interval.	**
Low MSpO2	When the maternal oxygenation is lower than lower alarm threshold	Medium	None	**
High maternal pulse rate	When the maternal pulse rate measured with SpO2 sensor has been higher 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.

Message	Condition	Priority	Delay*	Alarm expires
Low maternal pulse rate	When the maternal pulse rate measured with SpO2 sensor has been lower than the configured threshold for a certain time. (Threshold and interval configurable.)	Medium	Equal to configured interval.	**
High SYS/DIA/MAP	When the systolic BP, diastolic BP or MAP is higher than respective configured alarm threshold.	Medium	Depends on selected measurement interval.	At next measurement where condition no longer fulfilled.
Low SYS/DIA/MAP	When the systolic BP, diastolic BP or MAP is lower than respective configured alarm threshold.	Medium	Depends on selected measurement interval.	At next measurement where condition no longer fulfilled.
*Delay from physiological condition to alarm signal being generated. **The alarm signal expires when triggering condition is no longer fulfilled.				

3.9.3 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.

Caution!

The technical alarm that warns for coinciding fetal and maternal heart rates, does only work when a maternal heart rate is recorded with either the maternal SpO2 sensor or MECG.

Alarm message	Alarm condition	Priority	Delay*	Alarm expires
FHR1/2 and FHR1/2 coincide	When two fetal heart rates coincide, suggesting that both sensors monitor the same fetus.	Low	60 s	**
FHR1/2 and MHR coincide	When fetal heart rate and maternal pulse coincide, suggesting that the fetal sensor may be monitoring the mother.	Low	60 s	**
Breech presentation?	Continuous presence of negative P-waves in the recorded FECG waveform during cephalic mode recording.	Low	2 to 10 minutes depending on heart rate and signal quality.	**
Cephalic presentation?	Continuous presence of negative P-waves in the recorded FECG waveform during breech mode recording.	Low	2 to 10 minutes depending on heart rate and signal quality.	**
*Delay from technical condition to alarm signal being generated. **The alarm signal expires when triggering condition is no longer fulfilled.				

Alarm message	Alarm condition	Priority	Delay*	Alarm expires
ST signal loss	No T/QRS ratios calculated for 90 seconds.	Low	90 s	**
T/QRS baseline missing	The ST analysis function does not yet have sufficient data to calculate T/QRS baseline rise or Episodic T/QRS rise alarms.	Low	None	**
Check skin electrode	Connection with skin electrode not sufficient to detect FECG heart rate.	Low	< 5 s	**
Check scalp electrode	Connection with scalp electrode not sufficient to detect FECG heart rate.	Low	< 5 s	**
ST Disabled: Noisy Signal	FECG signal too disturbed by artifacts to perform ST analysis.	Low	10 - 60 s	**
ST Disabled: Weak Signal	FECG signal too weak to perform ST analysis.	Low	10 - 60 s	**
ST Disabled: Signal Interference	Suspected interference from other equipment. ST analysis cannot be performed.	Low	10 - 60 s	**
Recording will stop at XX:XX	A recording exceeds 23 hours.	Low	None	Does not expire
FHR1/2 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	**
Leads RA/LA/LL/V Off Leads R/L/F/C Off	MECG lead is detached from patient or MECG leadset cable is detached from main unit.	Low	None	**
ECG I/II/V: Polarized	Cardiograph polarization.	Low	None	**
Respiratory lead off	Respiration lead is detached from patient or MECG leadset cable is detached from main unit.	Low	None	**
MSpO2 Sensor Off	MSpO2 sensor is detached from patient or main unit.	Low	None	**
MSpO2: Pulse not found	Pulse oximeter cannot determine the pulse.	High	< 30 s	**

*Delay from technical condition to alarm signal being generated.

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

Alarm message	Alarm condition	Priority	Delay*	Alarm expires
NIBP selftest failure	Failure in sensor or other hardware.	Medium	None	After “Reset” button in NIBP settings menu. is activated, if condition no longer persists.
Loose NIBP Cuff	NIBP measurement failed due to a cuff-related problem. Check size, positioning and snugness of the cuff. Check that patient is not moving excessively, or is wearing clothing where the cuff is being applied.	Low	None	After next measurement, if condition no longer exists.
NIBP Air Leakage	Air leakage in solenoid valve, hose or cuff.	Low	None	After next measurement, if condition no longer exists.
NIBP: Air pressure error	Stable cuff pressure cannot be maintained. Check integrity of hose and cuff.	Low	None	After next measurement, if condition no longer exists.
Weak NIBP Signal	NIBP module cannot sense the patient pulse. Check snugness of cuff.	Low	None	After next measurement, if condition no longer exists.
NIBP measurement out of range	Blood pressure above or below guaranteed measurement range.	Low	None	After next measurement, if condition no longer exists.
NIBP excessive movements	Patient moves frequently during measurement, or has an uneven pulse such as arrhythmia.	Low	None	After next measurement, if condition no longer exists.
NIBP overpressure	Cuff pressure exceeds safety limit, 315±10 mmHg.	High	None	After next measurement, if condition no longer exists.
NIBP signal saturated	NIBP sensor signal is saturated.	Low	None	After next measurement, if condition no longer exists.
NIBP air system leakage	Air leakage suspected while performing leakage test.	Low	None	After next measurement, if condition no longer exists.

*Delay from technical condition to alarm signal being generated.

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

Alarm message	Alarm condition	Priority	Delay*	Alarm expires
NIBP module failure	Internal error in NIBP module.	Medium	None	After “Reset” button in NIBP settings menu. is activated, if condition no longer persist
NIBP measurement timeout	Measurement time exceeds 120 seconds.	Medium	None	After next measurement, if condition no longer exists.
NIBP incorrect cuff type	Cuff measurement error.	Low	None	After next measurement, if condition no longer exists.
NIBP cuff timeout	Cuff pressure constantly higher than 12 mmHg during 170 or more seconds.	High	None	After next measurement, if condition no longer exists.
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.
Maternal module error	Internal error in maternal parameter module.	High	< 10 s	After system restart, if condition no longer exists.
FECG module error	FECG module communication error.	High	< 10 s	After system restart, if condition no longer exists.

*Delay from technical condition to alarm signal being generated.

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

Alarm message	Alarm condition	Priority	Delay*	Alarm expires
FECG module disconnected	Internal error in FECG module.	High	< 10 s	After system restart, if condition no longer exists.
Filesystem error	Some or all of the data in the recording cannot be archived properly at the start of a recording.	High	None	**
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.

3.9.4 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 123.

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. Maternal alarms may need to be adapted to the mother’s health situation and onset conditions. NIBP alarms often need to be adapted individually to the normality values of each patient.

3. 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.

4. 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 161.

3.9.5 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.

3.10 Working with wireless transducers

The STAN S41 Maternal and 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.

There are two different wireless transducer subsystems, one operating on the 2.4GHz frequency band and one operating on the 433MHz frequency band. Only the 433MHz variants of the wireless FHR and TOCO transducers (white enclosure) can be used for underwater monitoring.

As the transmission of the wireless signal from the transducer to the monitor is significantly attenuated by water, it may be necessary to move the main unit closer to the

bathtub. Also note that bathtubs with metal walls may further reduce the operating range.

Tip!

Remember to zero the TOCO baseline a few minutes after the patient has entered or left the bathtub. The TOCO baseline may become affected by the temperature change when moving the TOCO transducer into or out of the water.

For specific instructions on how to set up patient monitoring with wireless transducers, see “Monitoring fetal heart rate with ultrasound transducers” on page 75 and “Monitoring uterine activity with TOCO transducer” on page 94 respectively.

Caution!

The 2.4GHz wireless ultrasound and TOCO transducers are suitable for use when the patient is taking shower, but are not intended for underwater monitoring. Use the 433MHz wireless ultrasound and TOCO transducers 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.

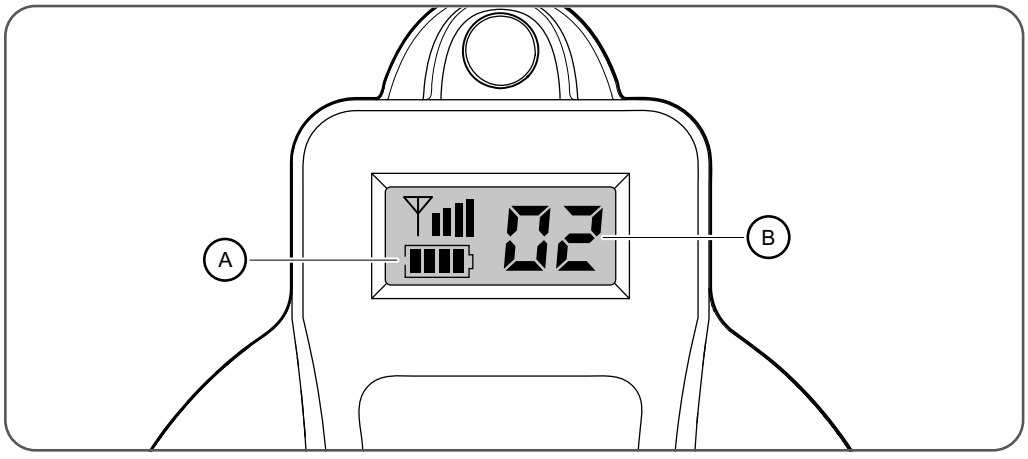


Figure 3:38 Display and markings for wireless monitoring of ultrasound FHR and TOCO.

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. For FHR2, you also need to switch the FHR2 transducer type from wireless to wired by following the instructions in “Quick settings” on page 37. 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 3:38 on page 57).

   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 3:38 on page 57).

   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.

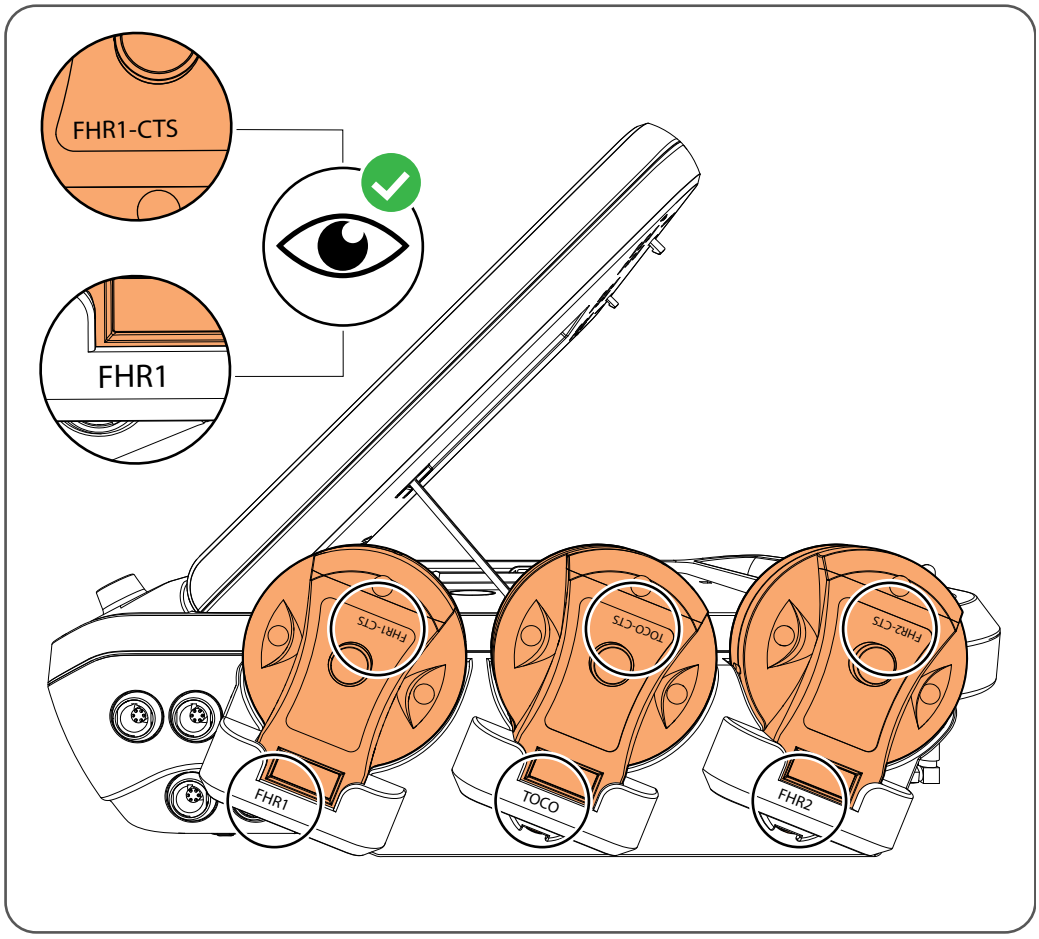


Figure 3:39 Charging rack with wireless transducers, placed in the right hand side of the main unit

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.

Caution!

Make sure the wireless transducers are placed in the correct charging rack. The 433MHz transducers cannot be charged in a 2.4GHz charging rack or vice versa.

3.11 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 177.)

b) CST - contraction stress test. (See further “Publications on CST - Contraction stress test” on page 178.)

c) Fischer’s analysis. (See further “Publications on Fischer’s analysis” on page 176.)

d) Krebs’ analysis. (See further “Publications on Krebs’ analysis” on page 177.)

e) STV analysis. (See further “Publications on STV” on page 176.)

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.

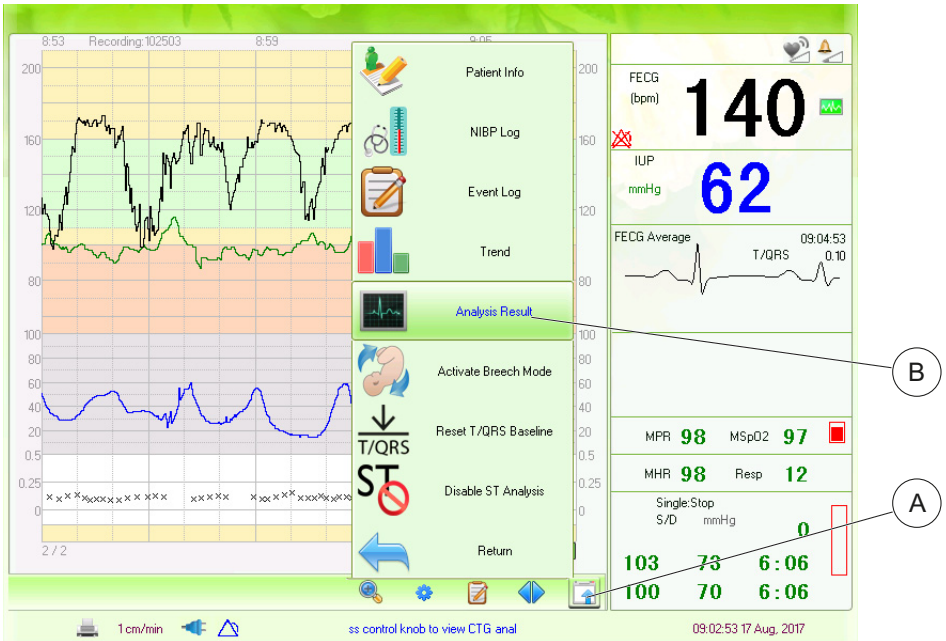


Figure 3:40 Accessing the automated CTG analysis function

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.

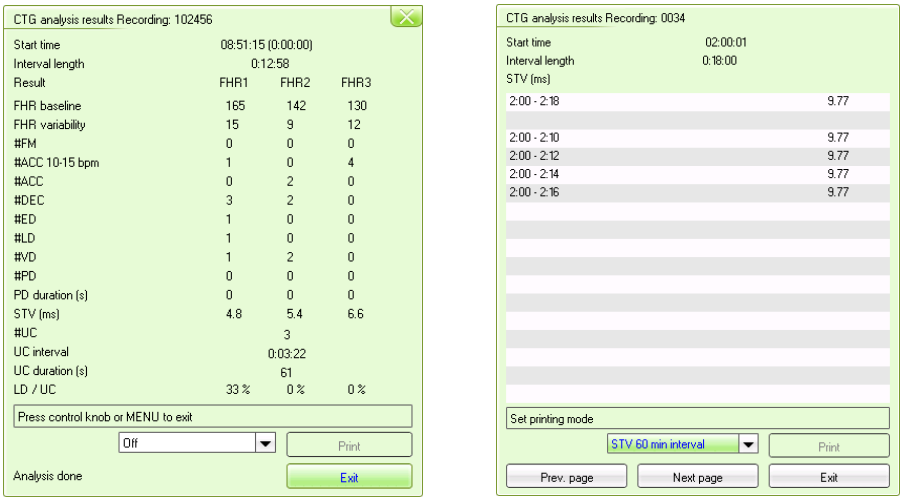


Figure 3:41 CTG analysis results

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.

Parameter	Description
#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.
#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.

3.12 Printing on paper

The STAN S41 Maternal and Fetal Monitor has a built-in thermal printer with capability for both continuous and retrospective printing.

3.12.1 Printer overview

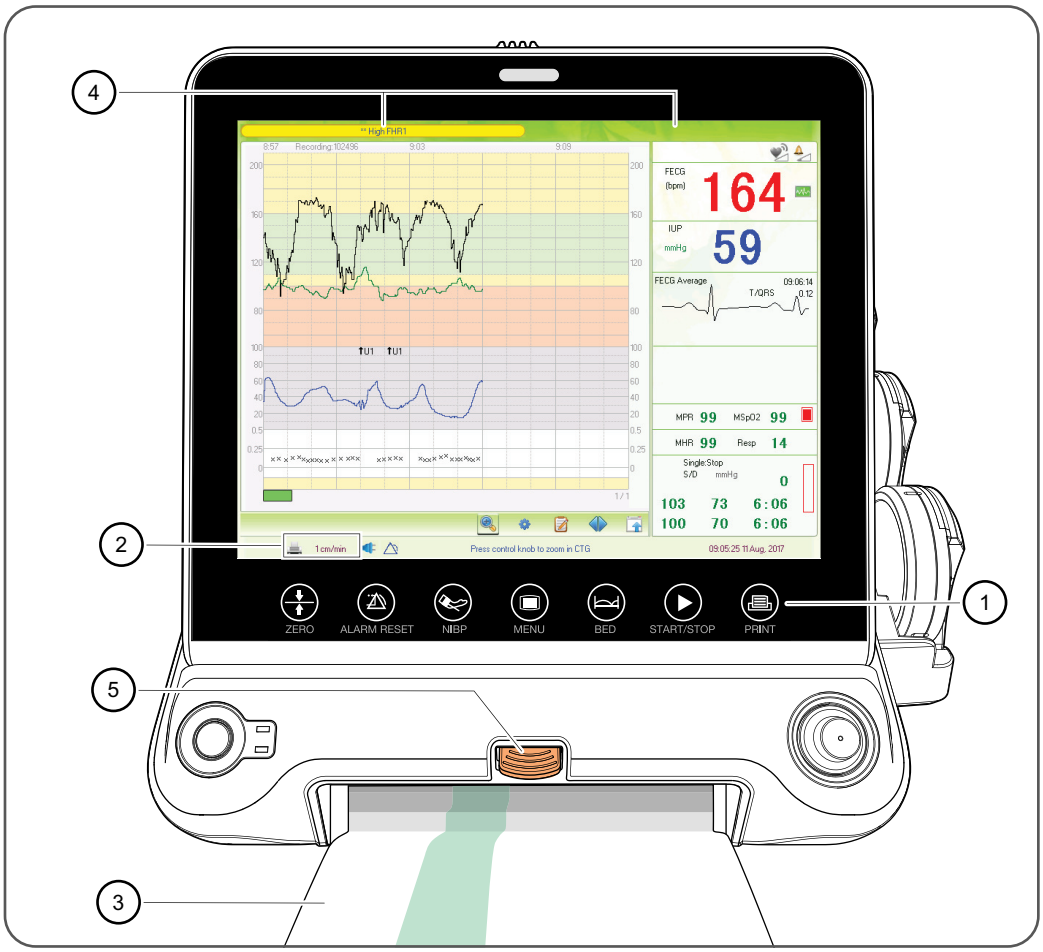


Figure 3:42 View of printer with associated controls

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.

3.12.2 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.

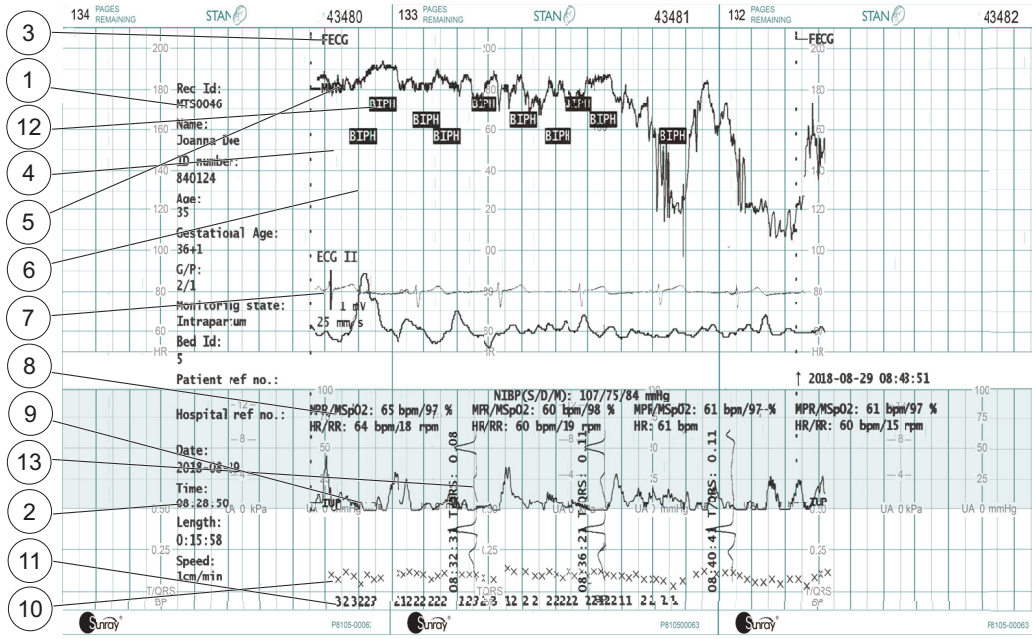


Figure 3:43 Example of printout with traces

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	N/A	N/A
5	FHR1 trace	FHR1 is drawn with medium thick line.
6	FHR2 trace	FHR2 is drawn with thin line.
7	MECG trace	Snapshot of MECG trace.

Pos	Data	Description
8	Maternal monitoring data	Summary of maternal monitoring data including pulse/heart rate, respiratory rate and oxygenation.
9	TOCO or IUP trace	Drawn with medium thick line.
10	T/QRS ratio	Crossmark.
11	Indicators for biphasic ST waveform	“1” / “2” /”3” indication, black.
12	ST events	Descriptive text, white on black background.
13	FECG average waveforms	Printed with 2 minute intervals.

3.12.3 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 68.

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 trace to separate the two FHR traces on the screen and the recorder paper.

3.12.4 Continuous printing during recording

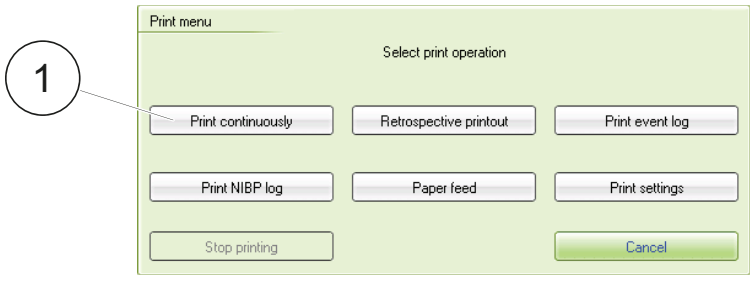


Figure 3:44 Print menu, continuous printing

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, NIBP 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.

3.12.5 Retrospective printing during or after recording

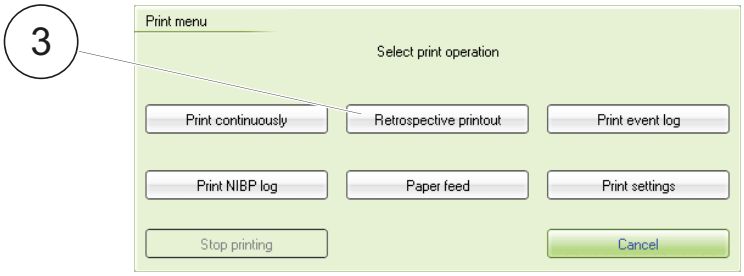


Figure 3:45 Print menu, retrospective printing

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).

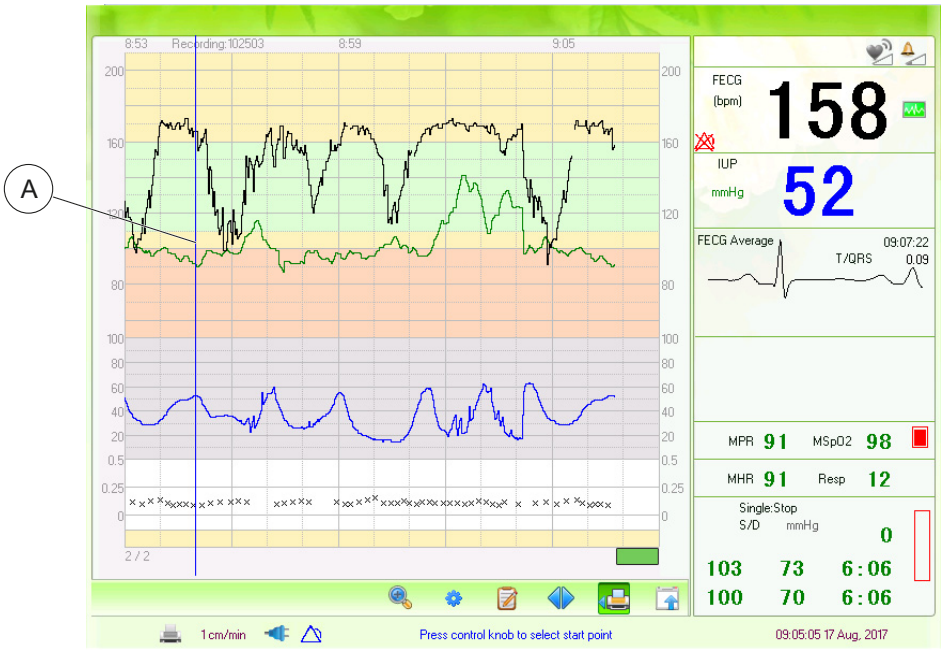


Figure 3:46 Selecting start of printout range

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.

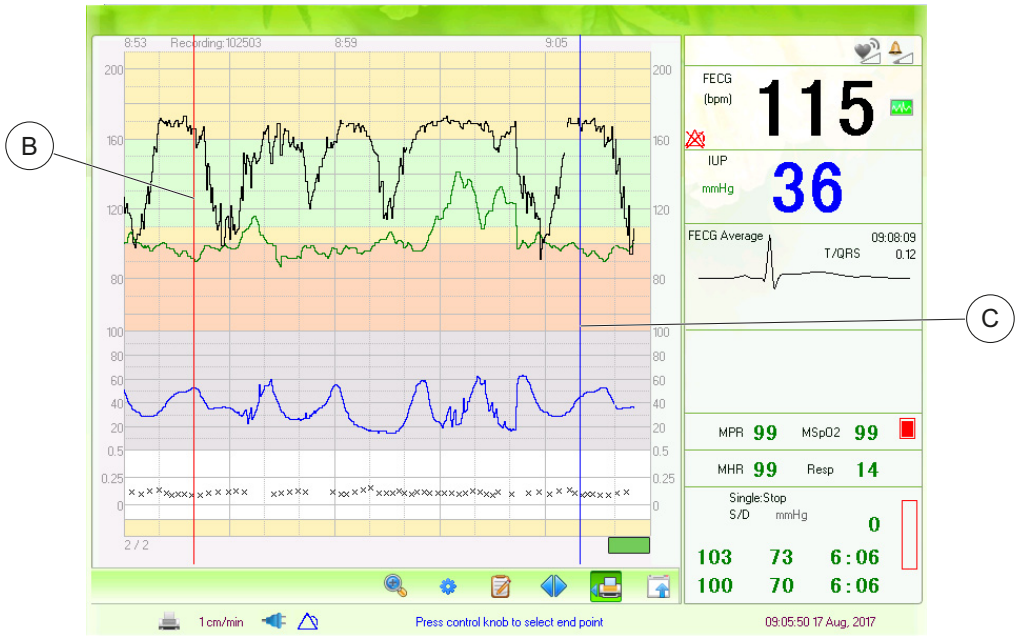


Figure 3:47 Selecting end of printout range

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

3.12.6 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.

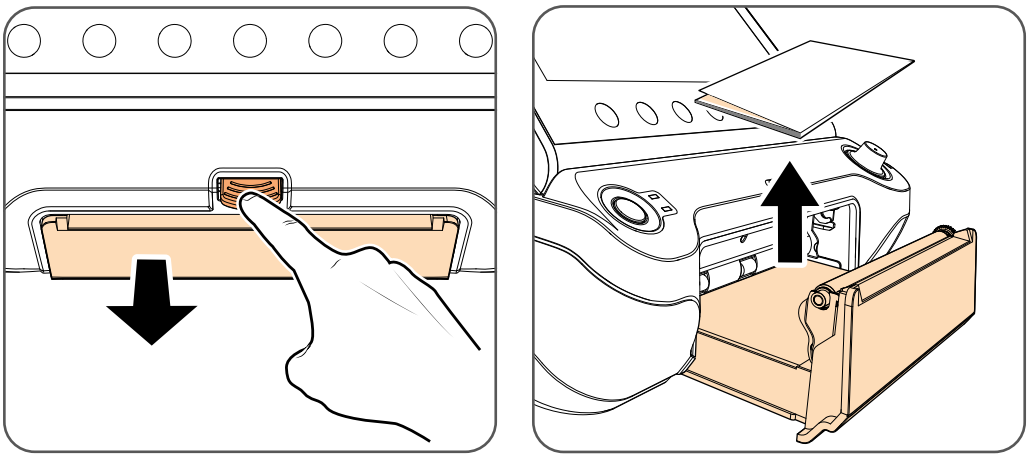


Figure 3:48 Procedure to load paper

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.

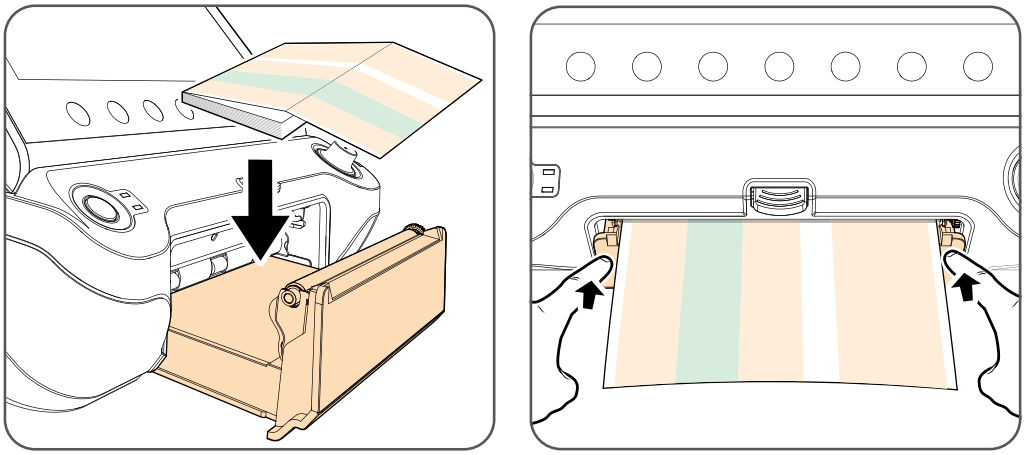


Figure 3:49 Procedure to load paper

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.

3.13 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.

With storage in STN file format, the storage capacity in the monitor is approximately 20 to 50 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.

3.13.1 Reviewing a stored recording

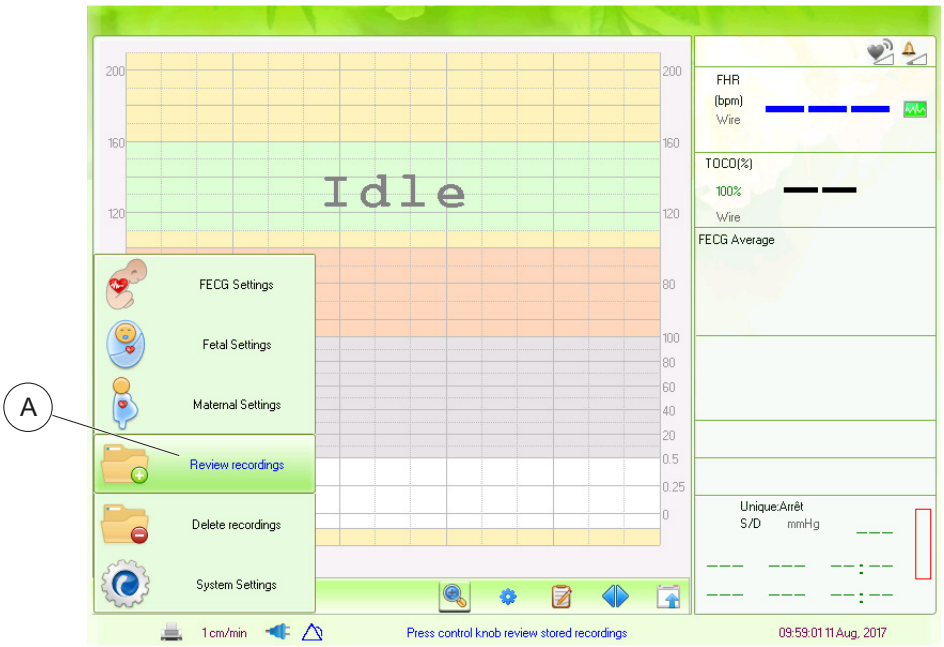


Figure 3:50 "Review recordings" menu option

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.

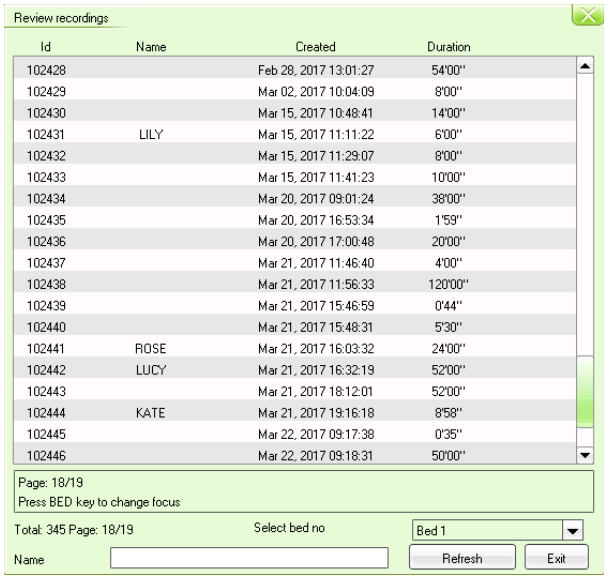


Figure 3:51 Selecting recording for review

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.

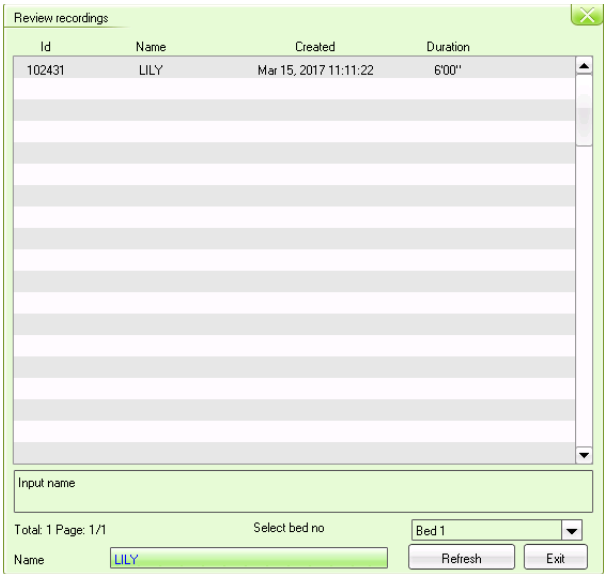


Figure 3:52 Procedure for filtering list of recordings based on patient name

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.

3.13.2 Archiving stored recordings to USB

1. Make sure the S41 is switched off. 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. Switch on the S41, and select "Export Recordings" in the menu.

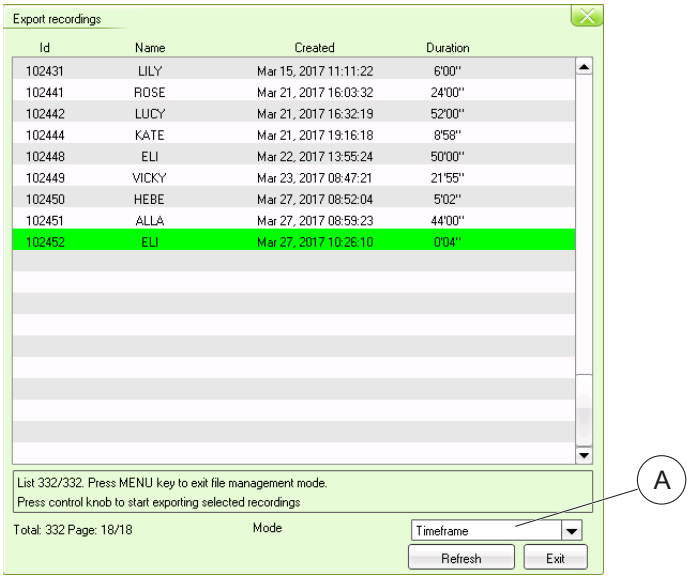


Figure 3:53 Selecting recording(s) for export to USB

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.

Tip!
Recordings can also be automatically stored to a network file server.

3.13.3 Deleting stored recordings

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

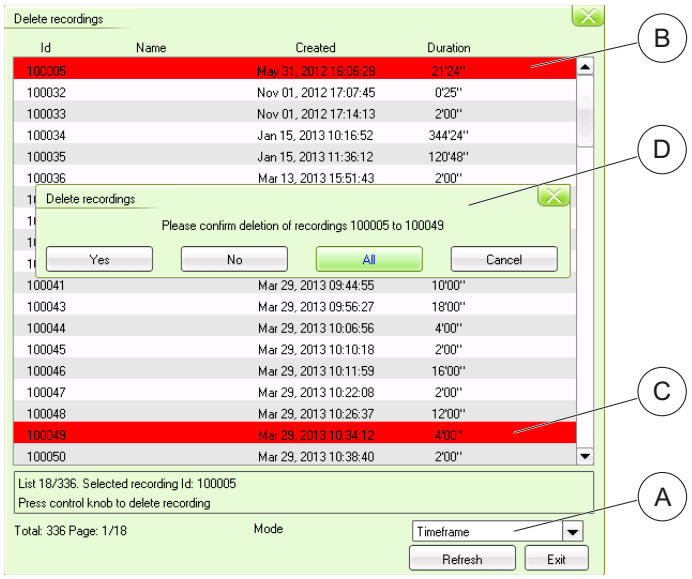


Figure 3:54 Selecting multiple recordings for deletion

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.

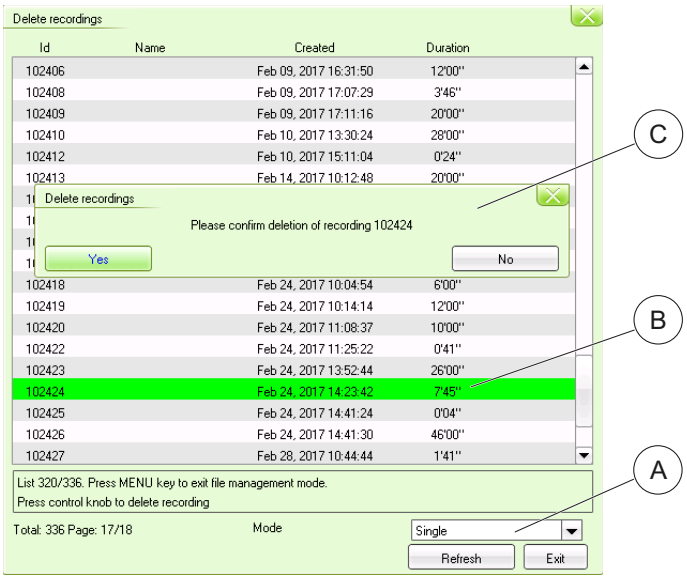


Figure 3:55 Selecting single recording to delete

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 pregnancies, the other twins heart rate 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”.

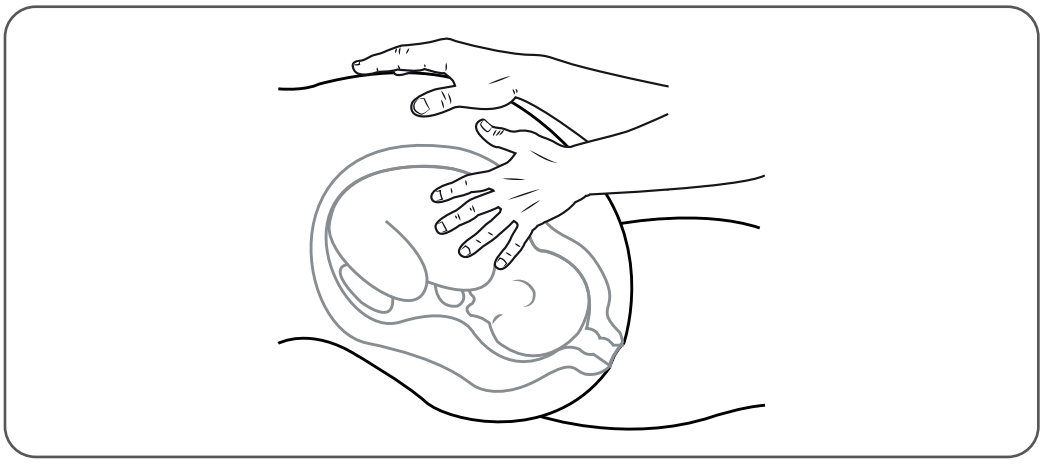


Figure 4:56 Palpation to locate the back of the fetus

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

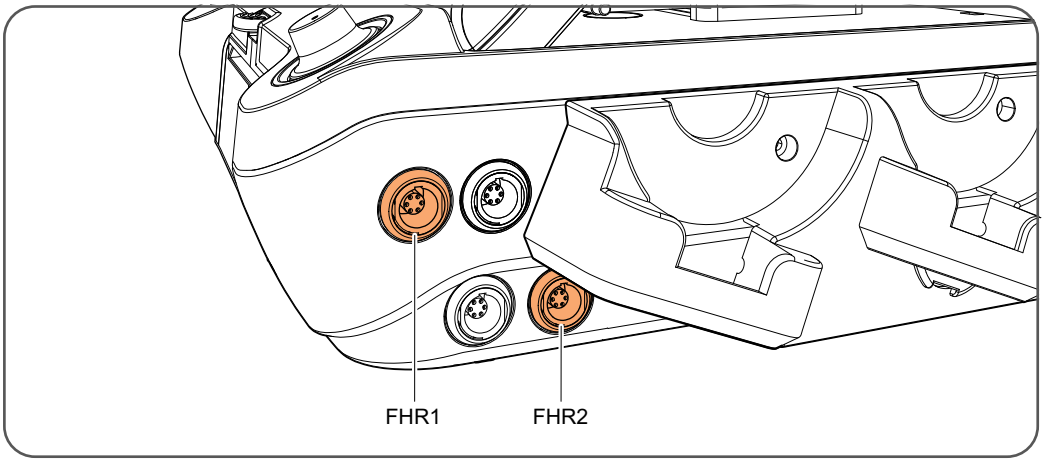


Figure 4:57 The FHR1 and FHR2 connectors for wired operation on the sides of the main unit

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), on the main unit.

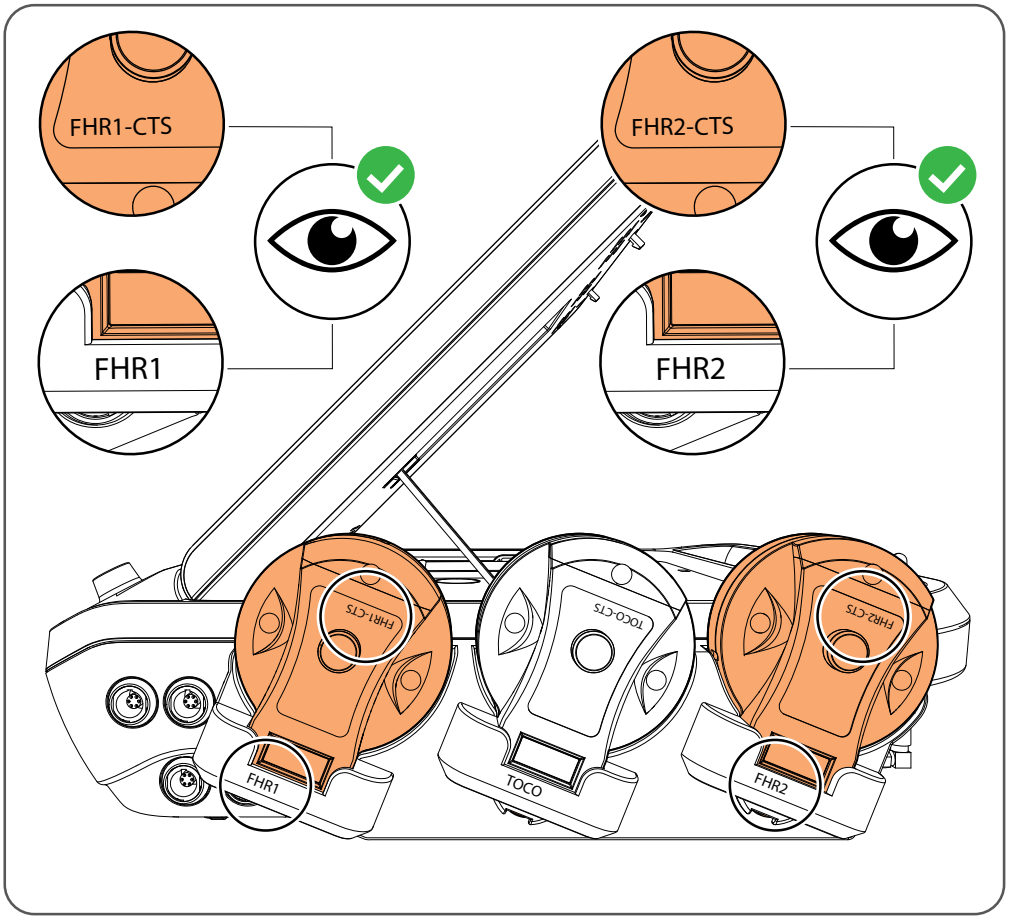


Figure 4:58 The wireless FHR1 and FHR2 ultrasound transducers in the charging rack

5. Alternatively, to set up for monitoring with wireless ultrasound transducer, lift the appropriate transducer FHR1 (for fetus 1) or FHR2 (for fetus 2) 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 56.

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 56.
- For FHR1, the system is capable of automatically switching between wireless and wired transducer. However for FHR2, you need to manually switch between wired and wireless transducer by following the instructions in “Quick settings” on page 37.

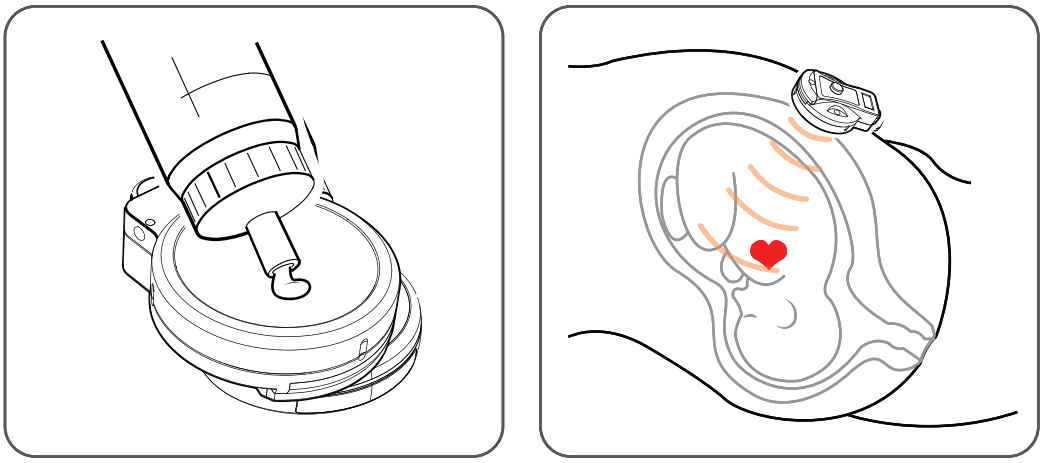


Figure 4:59 Application of ultrasound transducer

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.

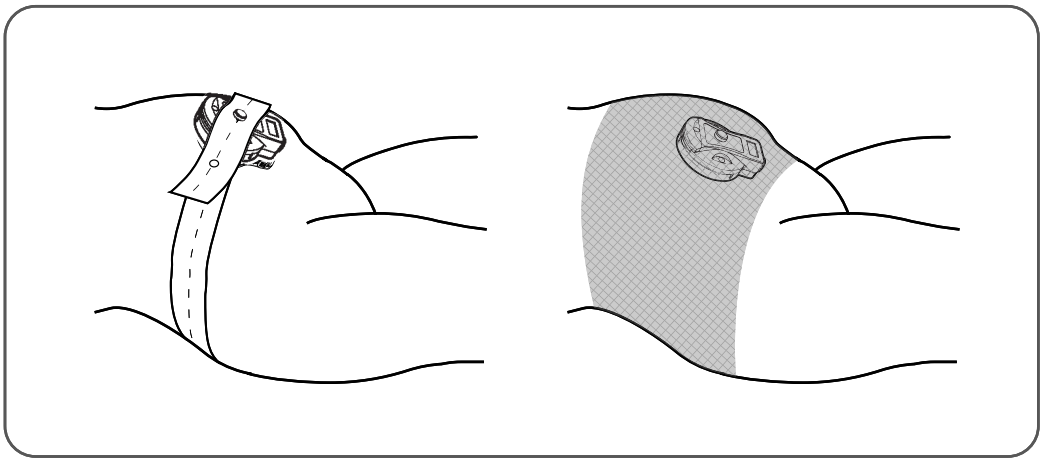


Figure 4:60 Ultrasound transducer secured with belt or tubular net

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.

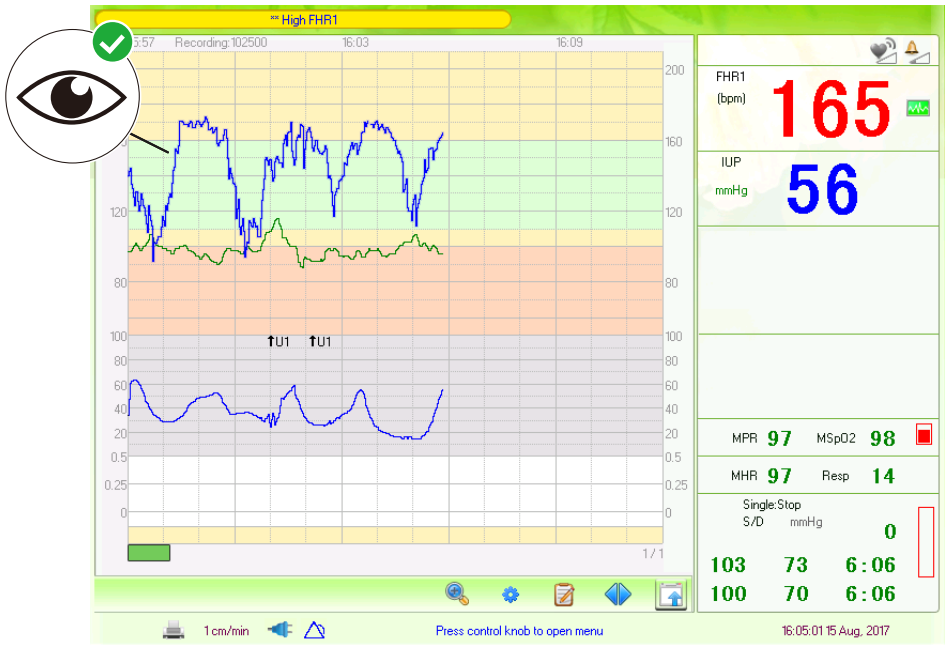


Figure 4:61 Verifying ultrasound recording quality

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

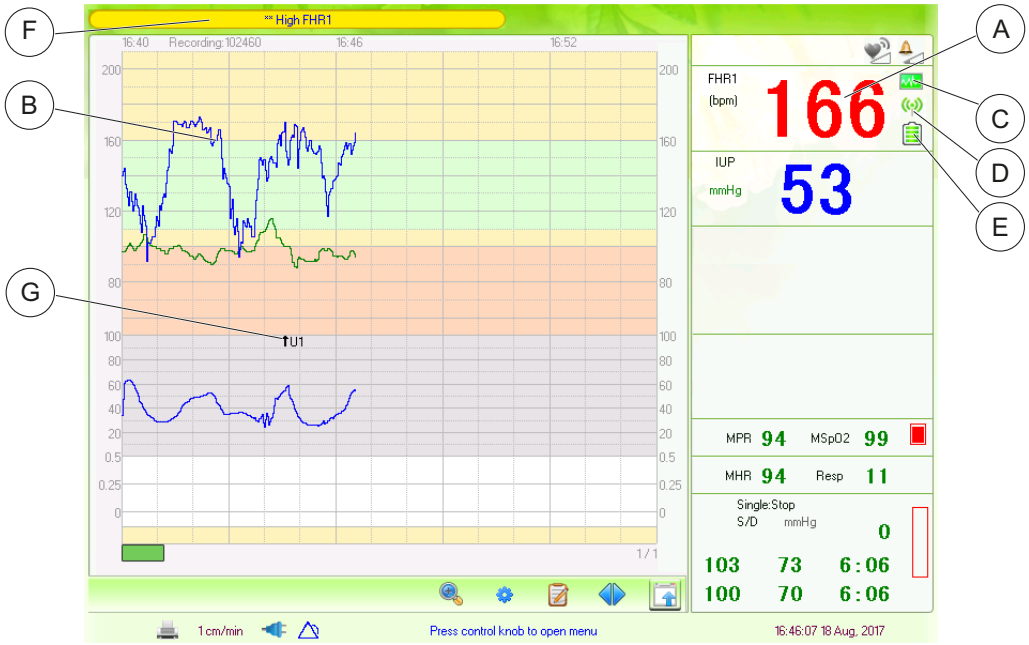


Figure 4:62 Presentation of ultrasound FHR

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 and FHR1/2 coincide	Technical alarm
FHR1/2 and MHR coincide	Technical alarm
FHR1/2 Transducer disconnected	Technical alarm

4.2 Monitoring fetal heart rate with scalp electrode

This section applies to systems with FECG option installed.

4.2.1 Prerequisites

Accessories
Fetal scalp electrode of recommended type (FSE)
Single-packed skin electrode of recommended type
FECG legplate
Legplate belt (only needed for legplates with a belt knob)
Abrasive patch and alcohol for skin preparation

4.2.2 Setting up

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

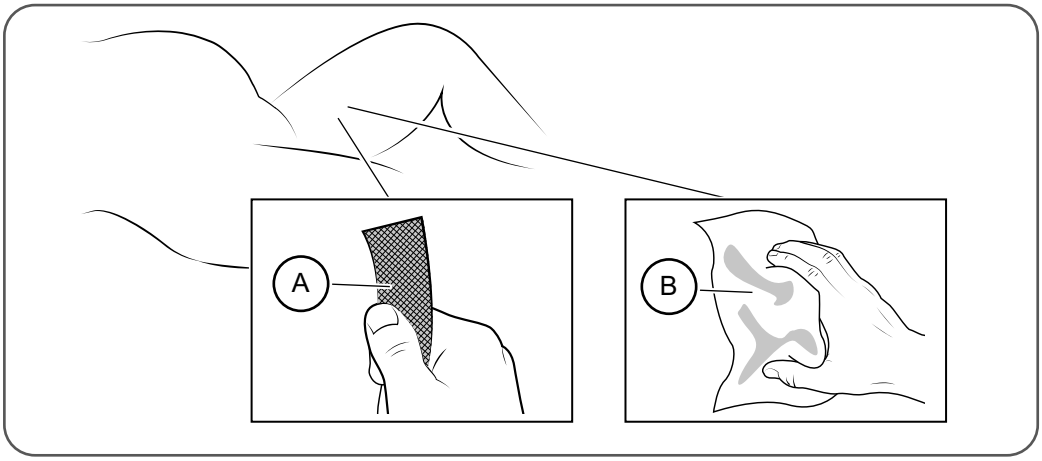


Figure 4:63 Prepare skin area

2. Abrade the thigh with abrasive patch (A) close to the inguinal canal. Avoid positioning the skin electrode over the thigh muscle, as tension of the thigh muscle during contractions may interfere with the FECG signal acquisition.

3. Wipe the skin with alcohol (B) and let dry.

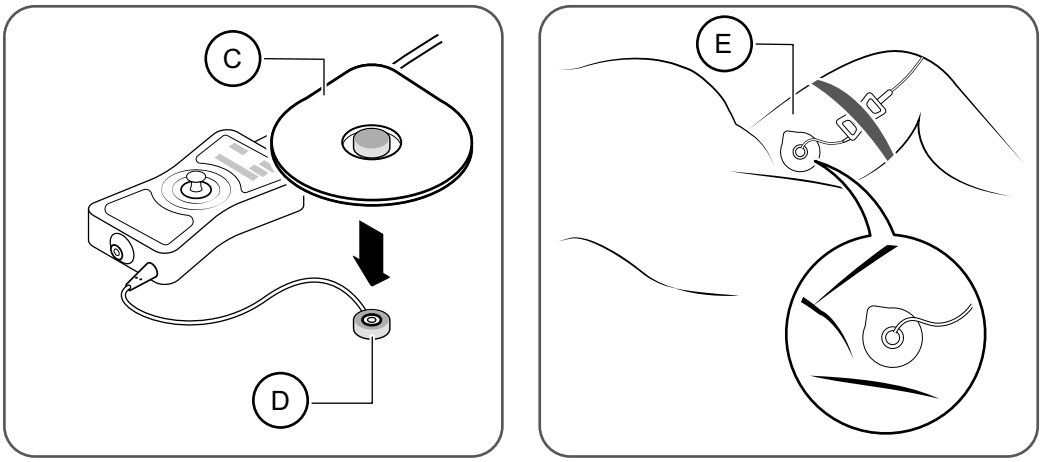


Figure 4:64 Attach skin electrode and legplate

4. Attach the skin electrode (C) to the legplate (D).

Tip!

For optimum signal quality, use single-packed skin electrodes of the recommended brand. The contact gel of a skin electrode dry out within days if left in e.g. an opened container.

5. Apply the skin electrode with the attached legplate close to the inguinal canal (E).
6. If you are using a reusable legplate with a belt knob, secure the legplate with the legplate belt.
7. Open the package of the fetal scalp electrode.

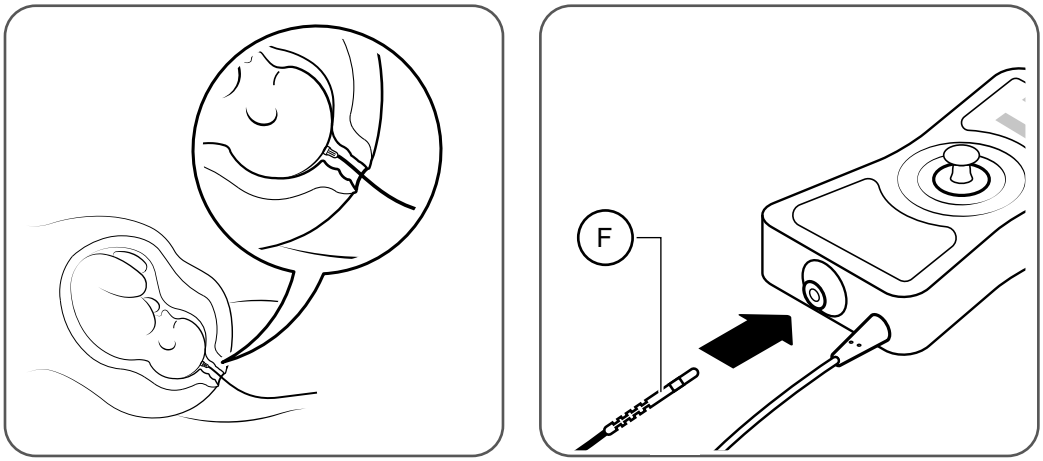


Figure 4:65 Attach the FECG connector on the same side of the main unit as the legplate connector.

8. Apply the fetal scalp electrode according to manufacturer's instructions.

Tip!

For optimum FECG signal quality, the spiral must be fully rotated into the fetal scalp. This is achieved if the drive tube springs back slightly after you release it.

9. Wipe off any visible mucous or show from the wires so it is not pushed into the legplate. Then connect the fetal scalp electrode wires (F) to the legplate.

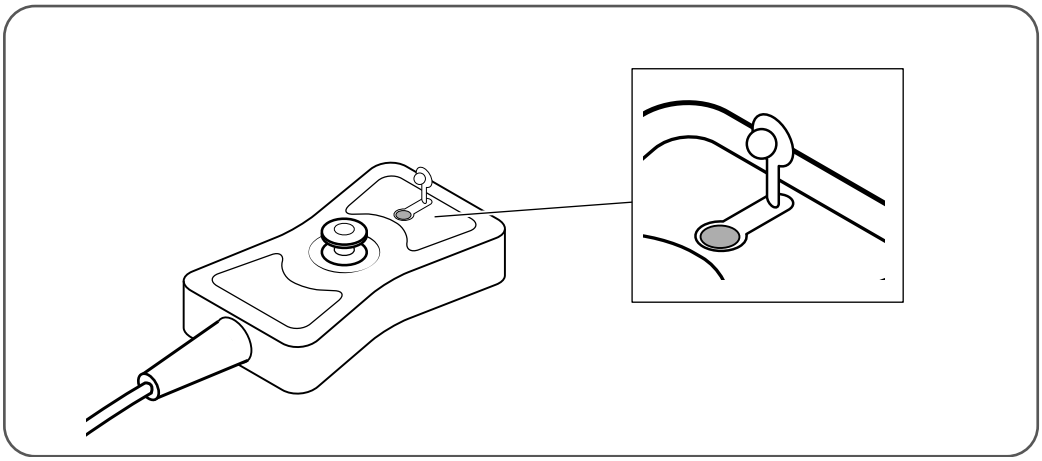


Figure 4:66 Flushport of the FECG legplate

Tip!

If mucous or show gets into the connector on the reusable legplate, clean the connector by flushing with a syringe filled with saline or water through the flush port on the legplate.

10. Connect the legplate to the fetal monitor.

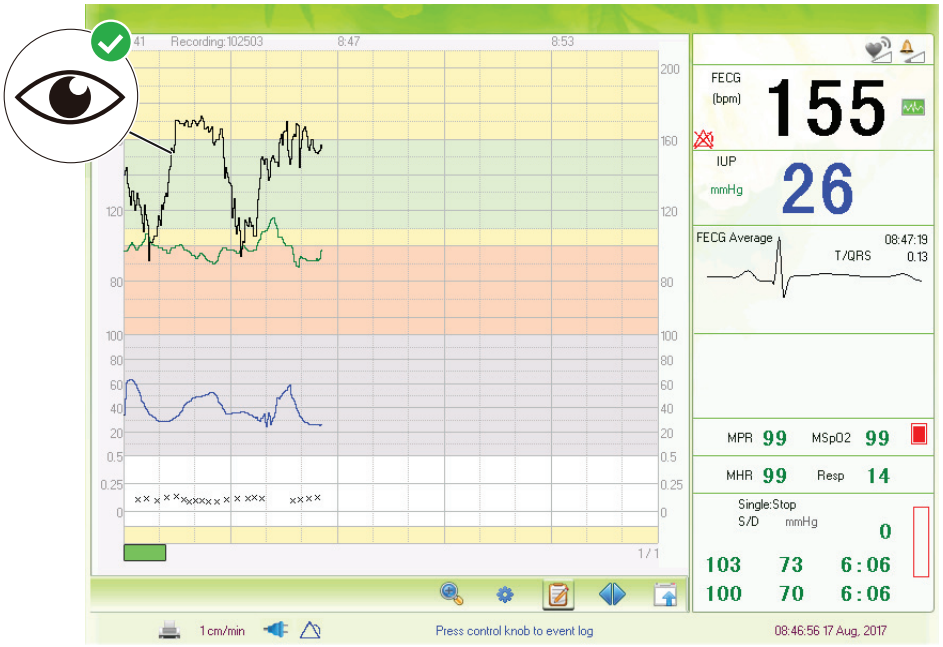


Figure 4:67 Verify availability of FHR

11. Verify that no technical alarms applicable to FECG monitoring is displayed on the screen, and that the monitor starts presenting fetal heart rate.

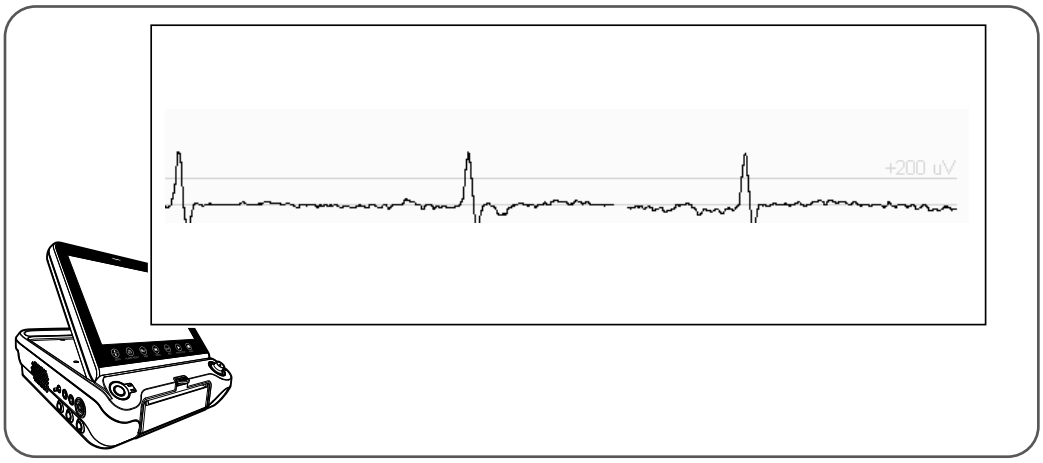


Figure 4:68 "Fetal and FECG" viewmode

12. If you are monitoring with ST analysis of the fetal ECG, verify by carefully studying the FECG signal in the "Fetal and FECG" viewmode to ensure that:

    - The signal quality is adequate.
    - The mother's ECG and heart rate are not being recorded.
    - The breech mode function is activated in case of breech presentation (and not activated in cephalic presentation).
    - There are no cardiac malformations or arrhythmias that may distort the FECG average or the heart rate calculation.

4.2.3 Presentation

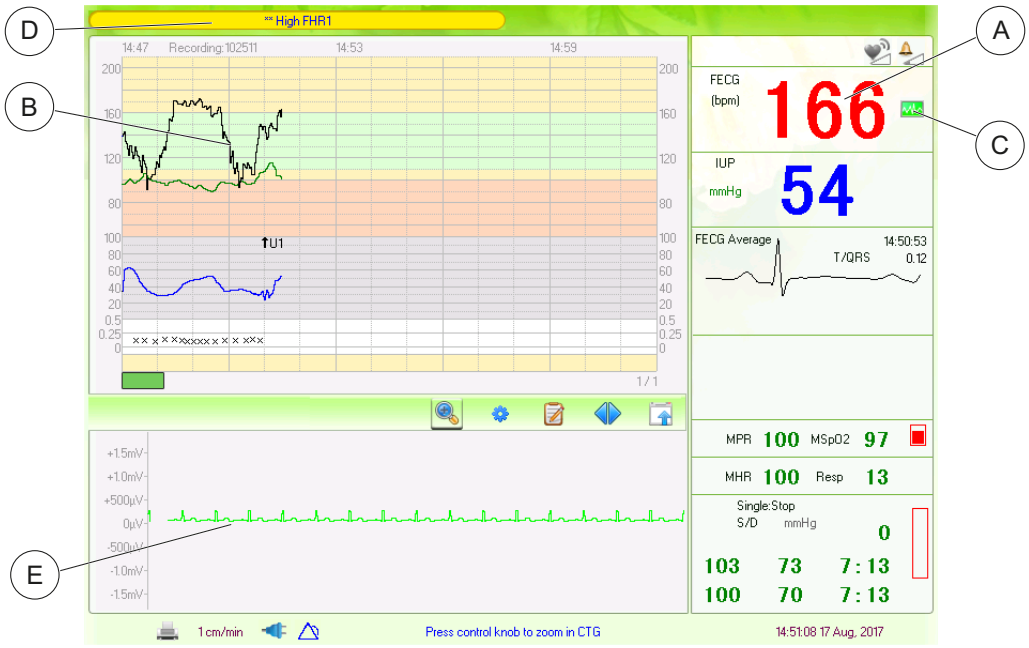


Figure 4:69 Presentation of FECG FHR

Pos	Description
A	Fetal heart rate value (bpm)
B	Fetal heart rate trace
C	Signal quality indicator
D	Alarms related to FECG HR monitoring
E	Current FECG signal

4.2.4 Alarms

Name	Type
High/Low FHR	Physiological alarm
Check skin electrode	Technical alarm
Check scalp electrode	Technical alarm
FHR1/2 and FHR1/2 coincide	Technical alarm
FHR1/2 and MHR coincide	Technical alarm
FHR1/2 Transducer disconnected	Technical alarm

4.3 Monitoring with fetal ST analysis

This section applies to systems with the ST analysis option installed.

Warning!
Read all instructions, including “Indications for Use”, “Contraindications”, Warnings, Cautions and “Signal Quality” prior to use. Failure to follow these instructions may result in serious patient injury.

Warning!

- Intrapartum management of the fetus is a complex process that uses a variety of maternal and fetal considerations in the formulation of clinical decisions. The STAN Clinical Guidelines are recommendations that are based on extensive clinical investigation and subsequent prospective clinical use. STAN Clinical Guidelines are not a substitute for individualised clinical assessment and decision-making for each patient.
- ST analysis is adjunct to fetal heart rate monitoring and should not be used exclusively to make patient management decisions. There are situations in which the fetus is experiencing hypoxia but an ST event may not be detected. These include the following:
  - Cases with loss of variability - preterminal heart rate traces
  - Preexisting hypoxia
  - Inadequate time to obtain baseline T/QRS
  - Poor ST signal quality

  If there is reason to believe that any of the above applies base clinical decision making on available data, e.g. FHR.
- Central monitoring systems connected to STAN can display FHR and uterine activity tracings, but may not support the display of fetal ST analysis data. In this case ST information including events and signal quality information will not be available on the centralized monitoring system. Failure to regularly check the STAN monitor and event log for important ST information directly, especially during periods of fetal heart rate abnormality, may lead to important information being missed and injury to the patient.
- Do not rely solely on the appearance of an ST event flag to signal the need for obstetrical intervention. If you suspect, on the basis of FHR-only and/or clinical data that the fetus is experiencing severe hypoxia, you should manage the patient accordingly despite the absence of an ST event flag.
- When ST analysis data has not been available for >4 minutes and efforts to readjust the fetal scalp electrode and the monitor fail to restore the signal, base clinical management on available data, e.g., FHR. Gaps in T/QRS ratios longer than 4 minutes may lead to important ST information (ST Events) being missed.
- Fetal ECG is similar to, but not the same as adult ECG. Fetal heart pathology, such as hypoplastic left ventricle, can not be diagnosed from the fetal ECG signal. Even if the fetal ECG pattern appears normal, it can not be assumed that the fetal heart is normal. STAN S41 is not a substitute for a fetal echocardiography exam.
- Before a T/QRS baseline has been established, STAN will be presenting T/QRS ratios but may not be ready to detect ST events. Follow the instructions in this chapter.

4.3.1 Prerequisites

- The operator is trained in fetal surveillance and interpretation of CTG.
- The operator has appropriate training in fetal monitoring with ST analysis.
- Clinical guidelines for monitoring CTG with fetal ST analysis.
- Indications for use of fetal ST analysis fulfilled, without any contraindication present. At start ST analysis needs a stable FHR baseline and normal variability.
- Monitor is powered on and set up for monitoring of fetal heart rate with scalp electrode, according to previous section.

The operator must receive specialized training in the use and interpretation of the STAN S41 Maternal and Fetal Monitor's ST analysis feature, to ensure proper performance and safe use of this device. Available training for the STAN device, ST analysis and related interpretation is described on www.neoventa.com under "Support" and under "Neoventa Academy" and description of device functionality is available for downloading.

4.3.2 Setting up

Caution!

If ST analysis is used, the monitoring should start during 1st stage of labour, and the fetus should not be compromised. Application of the STAN Clinical Guidelines requires adequate signal quality and an initial period of stable fetal conditions.

Caution!

Do not attempt to rupture amniotic membranes with the scalp electrode. Contact between the electrode and membrane fragments could result in a distorted FECG average waveform, which can cause incorrect ST analysis.

Caution!

The ST analysis feature is an adjunct to conventional fetal heart monitoring, and should not be used as a substitute for clinical interpretation of FHR.

Caution!

The safety and effectiveness of ST analysis has not been systematically evaluated in the following situations:

- Premature fetus (less than 36 gestational weeks)
- Twin pregnancy
- Breech presentation

1. Apply the fetal scalp electrode, see section "Monitoring fetal heart rate with scalp electrode" on page 79. Ensure that amniotic membranes have fully receded from where the scalp electrode has been applied.

2. Verify that the fetal heart rate has a stable baseline and normal variability. When fetal asphyxia has been severe and long lasting, the ST waveform returns towards normal, reflecting a markedly reduced ability by the fetus to respond. A change over time cannot be expected, therefore reliance on ST analysis in this situation may lead to serious adverse neonatal outcome.

3. Before relying on ST analysis data, verify that the FECG complex is of a normal appearance, by observing the raw FECG signal in "Fetal and FECG" viewmode.

    - In the event of a constant, non-fluctuating fetal heart rate, ensure that no other device is interfering with the FECG signal.

    - If the ECG waveform is inverted (P-wave and R-peak are negative), the scalp electrode may be applied on a fetus in breech position. If this is the case and

you wish to continue monitoring with ST analysis, use the breech mode function.

- Inspect the R-peak. If R-peaks are splitted (or notched) signal averaging and ST analysis may become inaccurate.

Tip!

- In case of a contraindication, limitation or other circumstance that constrain you from using the ST analysis, you can deactivate the ST analysis during the remainder of the recording by selecting “Deactivate ST analysis” in the “Tools” menu. Note that if you choose to re-activate the ST analysis after it has been deactivated, the T/QRS baseline will be reset.
- In case the ST analysis has been performed on a non-representative ECG signal such as interfering equipment, you can reset the T/QRS baseline by selecting “Reset T/QRS baseline” in the “Tools” menu. Note that this action will restart the ST analysis and should therefore only be performed in stable fetal conditions.

Caution!

For monitoring twin 2 with scalp electrode after twin 1 has been delivered, it is recommended to deactivate the ST analysis, as ST analysis should not be started after active or involuntary pushing. If you still choose to continue with ST analysis, use the “Reset T/QRS Baseline” function to prevent the T/QRS baseline from twin 1 to affect the ST analysis of twin 2.

4. Ensure that the quality of the FECG signal is sufficient for ST analysis:
   - FECG heart indicator at level 3 or 4.
   - T/QRS ratios should appear regularly in the T/QRS area of the CTG trace.
   - There should be no technical alarms related to FECG recording in alarms field, such as *ST Disabled: Weak Signal* or *ST Disabled: Noisy Signal*.
   - If there are no T/QRS ratios during contractions, the skin electrode may be attached to low on the maternal thigh. Consider replacing it with a new electrode, closer to the inguinal canal.
5. Before the system can detect *Baseline T/QRS rises* and E*pisodic T/QRS rises*, it has to establish a T/QRS baseline. This is indicated in the event log by the message *T/QRS baseline established*. In normal conditions, this should occur within 5-10 minutes.
6. During recording, continuously assess the signal quality. If there are periods of > 4 minutes without T/QRS ratios, you may miss *Episodic T/QRS rises* and *Biphasic ST* events. In the event of signal quality problems, the following corrective action should be taken:
   - Open the “Fetal and FECG” viewmode and review the appearance of the FECG signal.
   - Check legplate and make sure it makes good contact with both the skin and scalp electrode.
   - Check/apply a new skin electrode.

- Check/apply a new scalp electrode.

4.3.3 Presentation

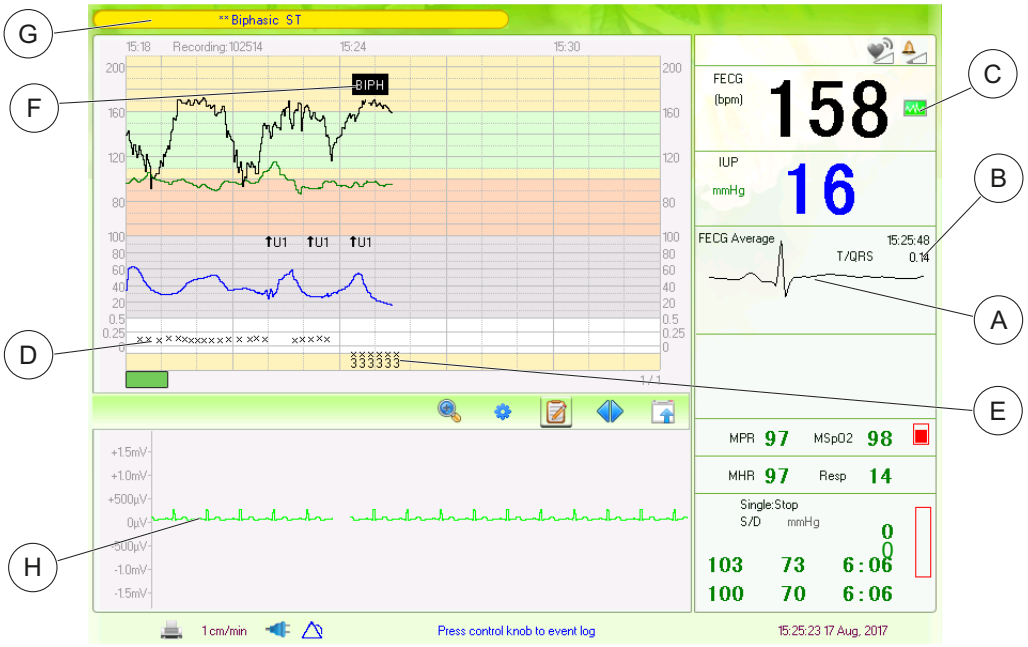


Figure 4:70 Presentation of ST analysis information

Pos	Description
A	Current FECG average waveform
B	Current T/QRS ratio
C	Signal quality indicator
D	T/QRS trace (crosses)
E	Indicators of biphasic ST waveform
F	ST event indicators
G	Alarms related to ST analysis
H	Current FECG signal

4.3.4 Alarms

Name	Type
Biphasic ST	Physiological alarm
T/QRS baseline rise	Physiological alarm
Episodic T/QRS rise	Physiological alarm
ST Signal Loss	Technical alarm
ST Disabled: Noisy signal	Technical alarm
ST Disabled: Weak signal	Technical alarm
ST Disabled: Signal interference	Technical alarm
T/QRS Baseline established	Information signal
T/QRS Baseline missing	Technical alarm

Detection of *Episodic T/QRS rises* requires an initial baseline of 10 T/QRS ratios, and detection of *T/QRS baseline rises* requires an initial baseline of 20 T/QRS ratios. While these baselines are being determined, the *T/QRS Baseline not yet established* technical alarm is displayed.

4.3.5 Potential root causes of inadequate ST signal quality

Factor	Description
Skin electrode quality	There are large variations in the quality of available skin electrodes. It is recommended to use only high quality, single packed skin electrodes are used when monitoring with STAN S41, see further “Compatible devices” on page 155.
Skin electrode age/dryness	It is very important that skin electrodes are fresh. The electrode gel will dry out if the bag is not sealed properly and affect the performance of the electrode. Single-packed skin electrodes are preferable.
Poor skin preparation	Some electrodes will provide up to 1000 times’ increased electrical resistance if there is no skin preparation prior to application, resulting in a poor ST signal quality. An abrasive surface is included with the recommended skin electrodes.
Scalp electrode quality	Use only scalp electrodes listed as compatible when monitoring with fetal ST analysis, see further “Compatible devices” on page 155.
Scalp electrode application	It is very important that the application is performed correctly. Do not use the scalp electrode to rupture the membranes, as membrane material can affect the electrode performance. Use only recommended single spiral scalp electrodes and rotate at least 360° for proper attachment. For more information, see the instructions included with the disposable pack.
Legplate problem	The cables can be internally damaged, which is not visible from the outside. If the cables are damaged, you may still have a CTG-recording but no T/ QRS ratios.

4.3.6 Assessing the ST signal quality

In signal mode, the QRS complex of the fetal ECG should be clearly visible, and it should be possible to identify a positive P-wave.

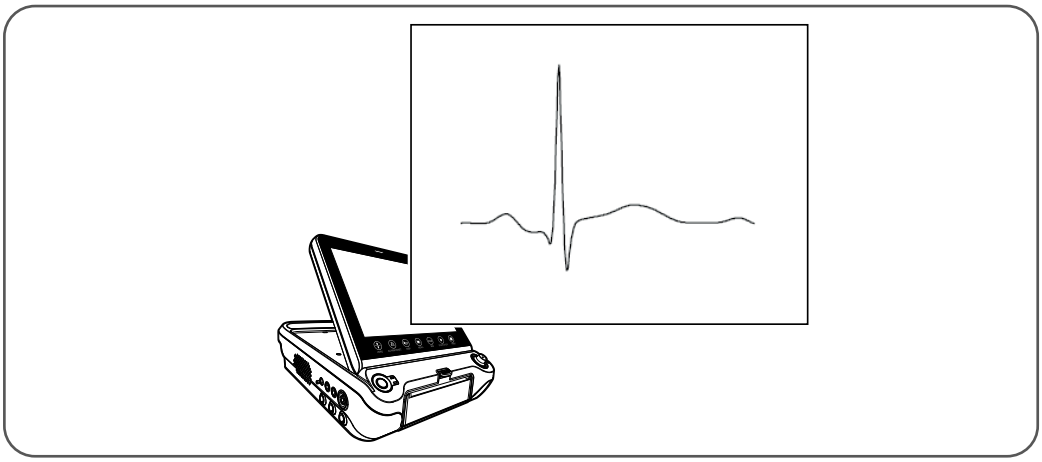


Figure 4:71 FECG Average window with clearly identifiable ECG complex and positive P-wave

The FECG average window should present a clearly identifiable ECG complex.

If the ST signal is of poor quality, one or more of the following may be observed when inspecting the signal in the “Fetal and FECG” viewmode:

- Difficult to identify QRS complexes
- Low amplitude of the T/QRS complexes
- Fluctuating FECG baseline
- “Noisy” FECG (ST) signal
- Maternal ECG complexes interfering with the FECG signal

As soon as poor ST signal quality is detected by STAN S41, the monitor will display an ST disabled technical alarm, accompanied by one or both of the messages Check skin and Check scalp.

If no T/QRS ratios have been plotted for more than 90 seconds, an ST signal loss event will be recorded in the event log. The ST signal loss event will be closed when a minimum of 5 T/QRS ratios have been plotted over a period of 2 minutes.

At the start of a recording, pay special attention to the “Fetal and FECG” viewmode and the event log, and inspect the FECG signal in the “Fetal and FECG” viewmode. If an ST signal loss event is active in the event log, adequate measures should be taken to improve the signal quality.

4.3.7 Reduced number of T/QRS ratios

Signal quality is of vital importance, to ensure correct information to the operator.

ST signal quality may deteriorate for a short period of time due to the electrical noise introduced by active movements of the mother. Short-time loss of T/QRS ratios may also be caused by maneuvers involving the area where the scalp electrode is applied, such as vaginal examinations or fetal scalp blood sampling. Usually, in such situations, the ST signal quality and the T/QRS ratios will recover spontaneously. If the ST signal does not recover, adequate measures should be taken, see further “General guidance on improving the signal quality” in table below.

If the ST signal quality deteriorates gradually with no signs of recovery, this usually indicates a loosening of the skin or scalp electrode. Other causes may be fetus- and/or mother-related, such as: scalp edema or the scalp electrode is in close proximity of the vaginal wall. Adequate measures should be taken in order to improve the ST signal quality, including the application of new electrodes, see further “General guidance on improving the signal quality” in table below.

NOTE: Reduced numbers of T/QRS ratios are normally observed during decelerations with marked loss of beats or during periods of bradycardia, even in presence of good signal quality.

Recommendations	
General guidance on improving the signal quality:	Inspect the FECG signal in the “Fetal and FECG” viewmode and make sure a normal fetal ECG complex is recorded. Observe appearance of the complexes, amplitude, and level of noise.
	Make sure the skin electrode is properly applied: skin prepared as recommended, skin electrode is well-attached and not placed over the thigh muscle. A poorly attached skin electrode will increase susceptibility to electrical noise. If necessary, apply a new skin electrode. The adhesion of the skin electrode to the skin may deteriorate over time due to movements and sweating, therefore in prolonged labours you may need to apply a new skin electrode.
	If necessary, apply a new scalp electrode. A loose scalp electrode usually causes low amplitude FECG complexes and poor ST signal quality.
If the CTG pattern is classified as normal and the signal recovers:	Continue monitoring with STAN S41 according to the Clinical Guidelines.
If the CTG pattern is classified as normal and the ST signal does not recover:	It is the individual clinician’s decision for how long signal recovery attempts should continue. If the fetal heart rate (FHR) becomes intermediary or abnormal (non-reassuring), see below.
If the CTG pattern is classified as intermediary or abnormal (non-reassuring) and the ST signal recovers immediately with no gaps in T/QRS ratios longer than 4 minutes:	Be aware that gaps in T/ QRS ratios longer than 4 minutes may lead to important ST information (ST Events) being missed.
If the CTG pattern is classified as intermediary or abnormal (non-reassuring) and the ST signal cannot be recovered, consider basing the clinical decision on available data e.g. FHR information:	Be aware that gaps in T/ QRS ratios longer than 4 minutes may lead to important ST information (ST Events) being missed.
If the CTG pattern is classified as preterminal:	Immediate intervention is indicated, according to the Clinical Guidelines.

4.3.8 Breech Presentation

Warning!

- ST analysis has not been evaluated to date in breech deliveries, in clinical studies. Accordingly, its safety and effectiveness in breech deliveries is unknown. However, the monitor is capable of monitoring breech deliveries, so the below general points apply to this situation.
- Attachment of a fetal scalp electrode to breech will result in an inverted fetal ECG pattern. The STAN S41 monitor is equipped with a breech mode function that should be activated if there is a clear indication for attempted vaginal breech delivery by a clinician with requisite skills.
- In the event of breech presentation, the breech mode function should be activated. If not, STAN S41 may display wrong T/QRS ratios and detect false biphasic ST potentially resulting in harm to the fetus and mother.

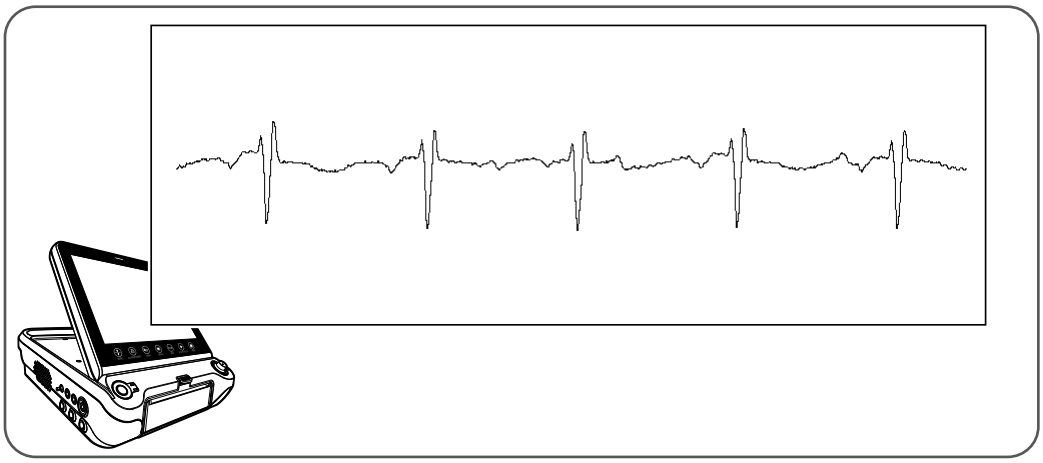


Figure 4:72 Upside down FECG signal in breech presentation

When monitoring during a breech presentation, the scalp electrode is applied in such a way that the FECG will be upside down compared with a cephalic presentation. This is most obvious from the fact that the initial ECG waveform component (P-wave) is negative. If STAN S41 is operating with an ECG that is recorded upside down, false biphasic ST may be detected. When the scalp electrode is applied in a breech presentation, the breech mode should be activated. STAN S41 will then invert the FECG and analyze it in the normal way.

STAN S41 will provide a technical alarm if FECG complexes with negative P-waves are recorded continuously for 3 minutes. This situation would appear when the breech mode function is set incorrectly (not activated during a breech presentation or activated during a cephalic presentation).

NOTE: Occasionally, negative P-waves may be observed during periods of severe bradycardia.

4.3.9 Atypical FECG complexes

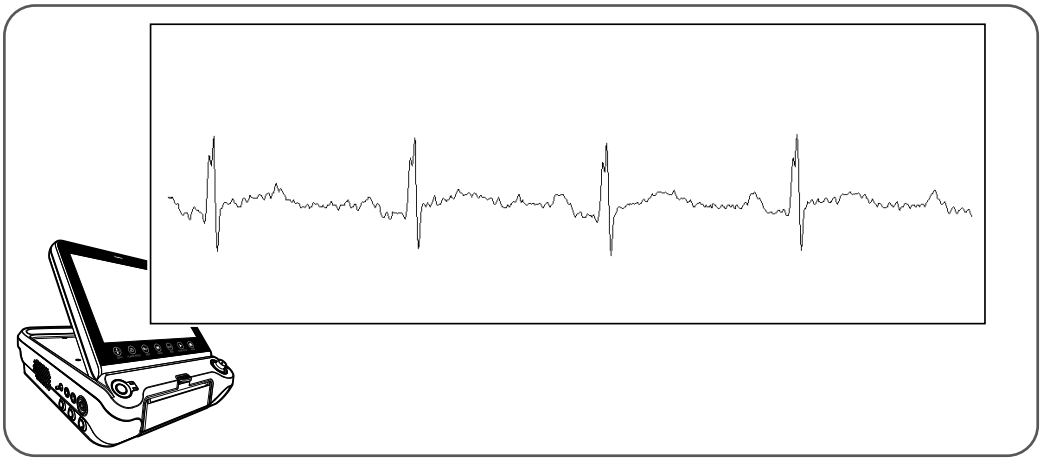


Figure 4:73 FECG with split R-peaks

The ECG complexes may be atypical in a variety of ways. If R-peaks are splitted (or notched) signal averaging and ST analysis may become inaccurate.

4.4 Monitoring uterine activity with TOCO transducer

4.4.1 Prerequisites

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

4.4.2 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”.

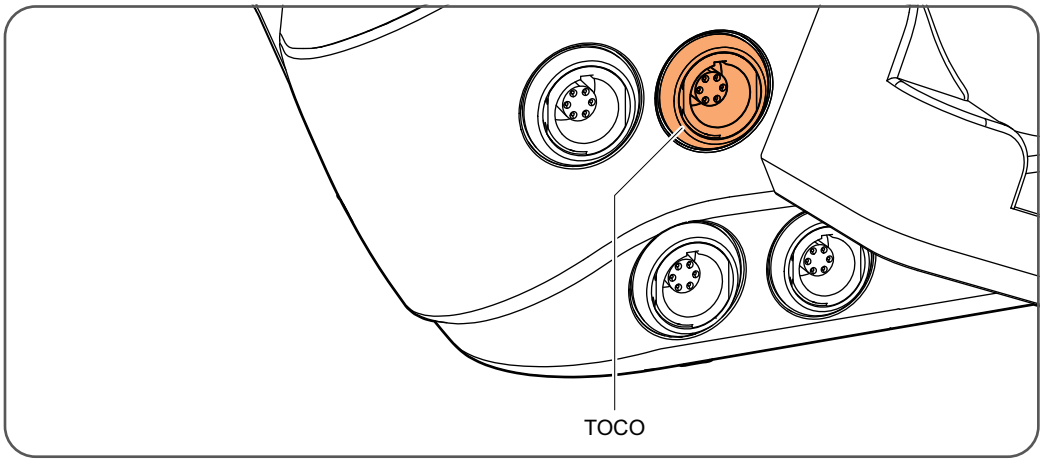


Figure 4:74 The TOCO connector for wired operation on the right side of the main unit

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

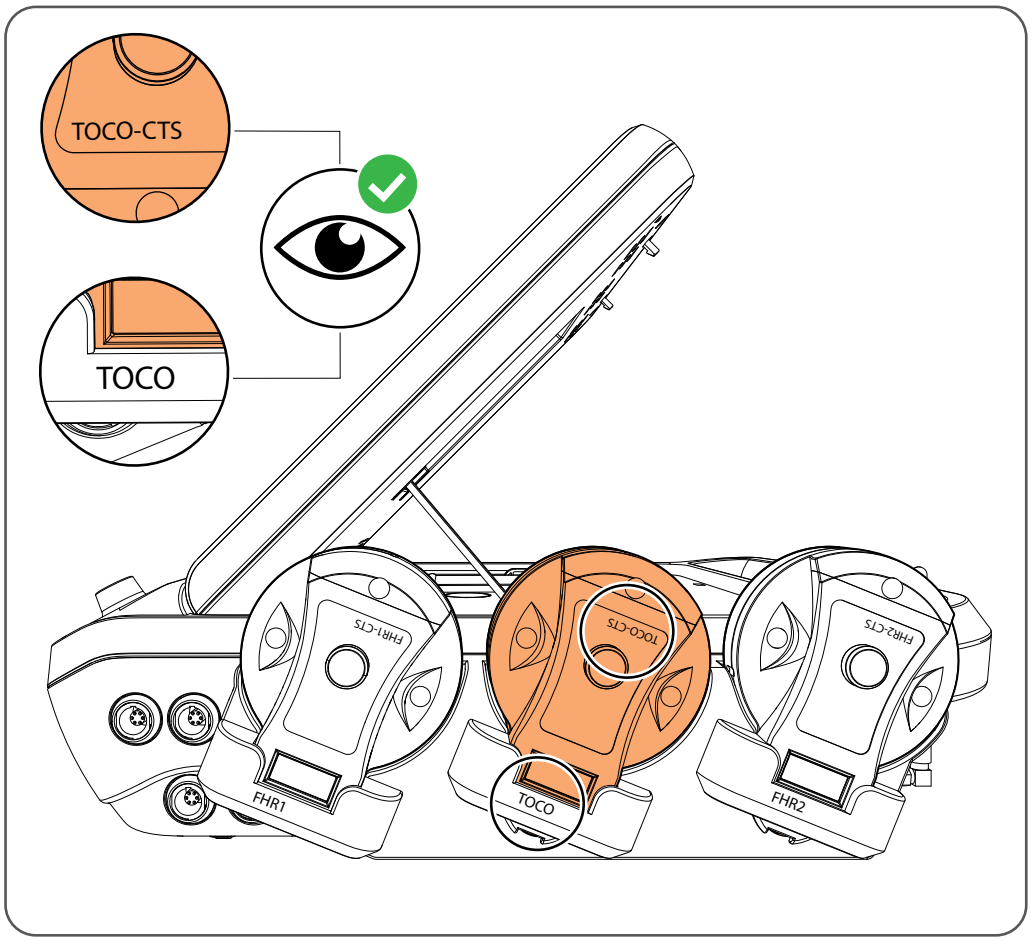


Figure 4:75 Wireless TOCO transducer in charging rack

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 56.

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 56.

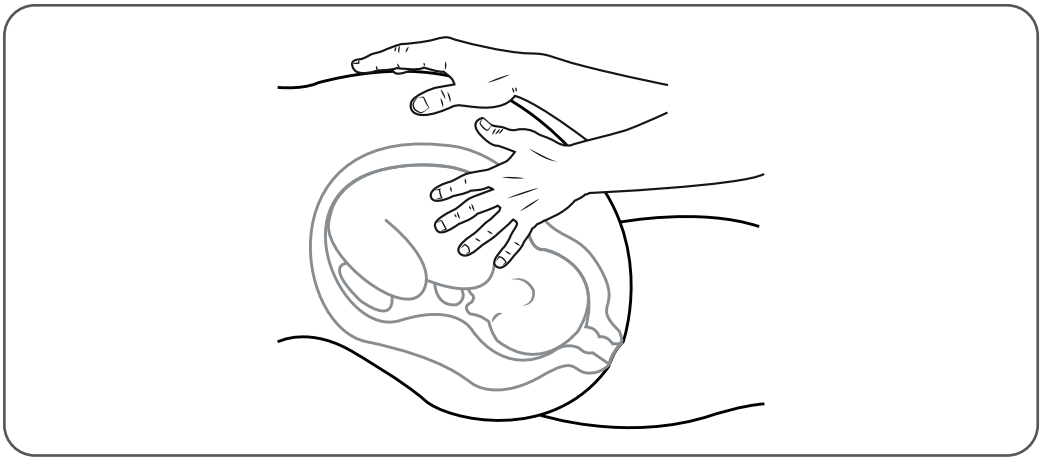


Figure 4:76 Palpation to locate best placement for TOCO transducer

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.

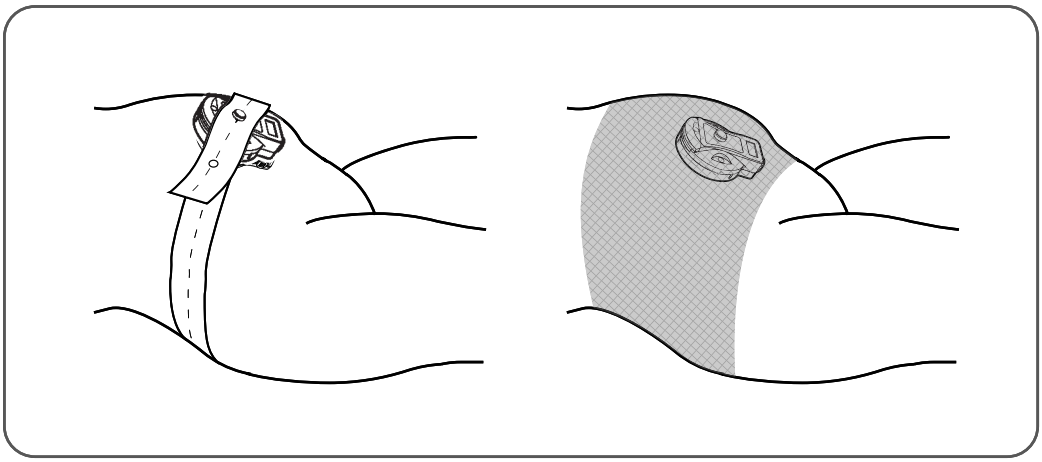


Figure 4:77 TOCO transducer secured with belt or tubular net

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

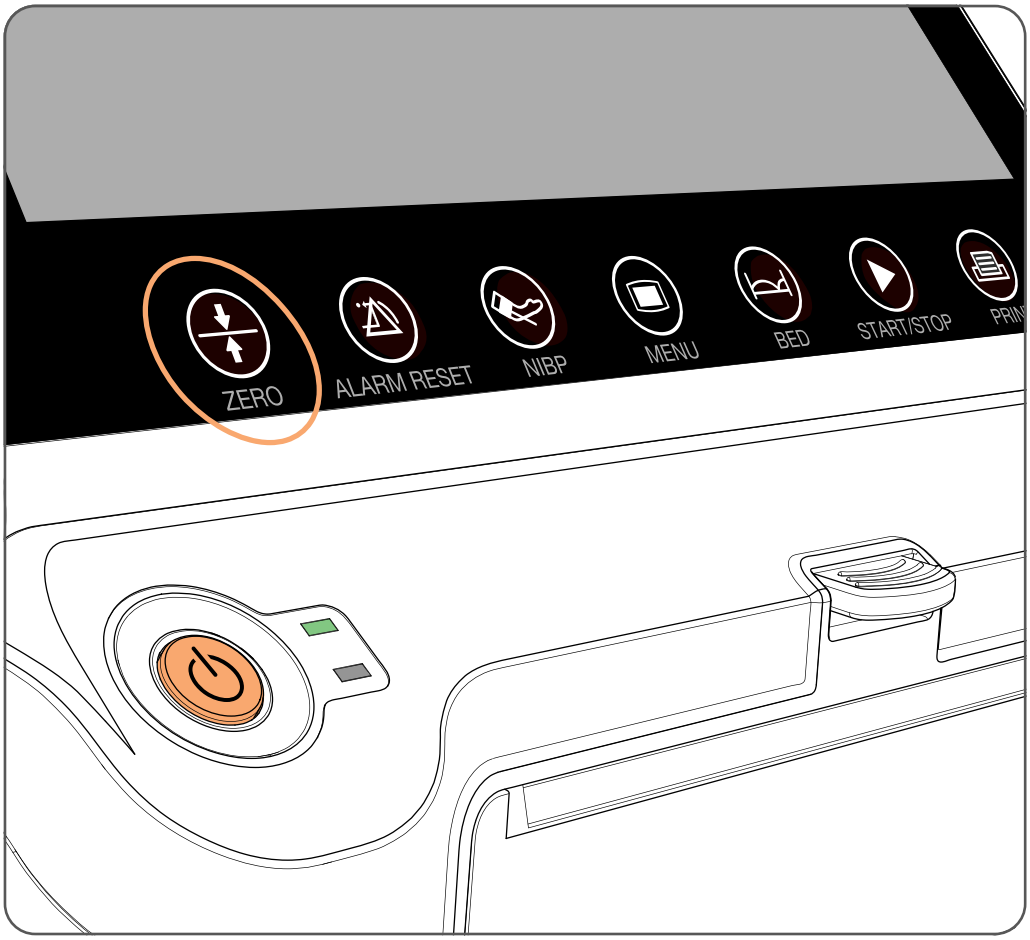


Figure 4:78 Zero TOCO functions using the “ZERO” touch key

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”.

4.4.3 Presentation

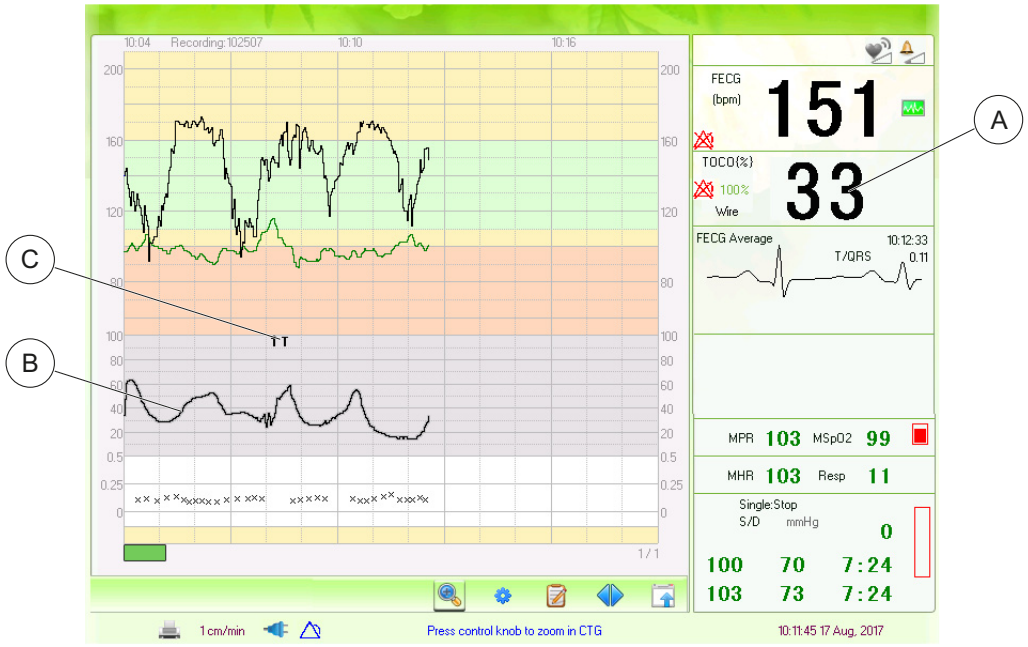


Figure 4:79 Presentation of uterine activity recorded with TOCO transducer

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

4.4.4 Alarms

Name	Type
> 5 UC in 10 mins	Physiological alarm

4.5 Monitoring uterine activity with IUP catheter

This section applies to systems with IUP option installed.

4.5.1 Prerequisites

Accessories
Sterile IUP catheter of compatible brand and type
IUP adapter cable for selected brand

4.5.2 Setting up

Caution!
Only use the zero IUP control when the catheter tip is in atmosphere pressure.
Follow the IUP catheter instructions for zeroing.

1. Follow the instructions for the IUP catheter and insert it into the uterus.
2. Connect the IUP catheter to the IUP adapter cable using the interconnection cable.
3. Connect the IUP adapter cable to the fetal monitor.
4. Zero the IUP by using the Zero IUP control on the fetal monitor, following the conditions for zeroing described on the IUP instructions for use.
5. Await the first contraction and verify that it is clearly defined in the trace.

4.5.3 Presentation

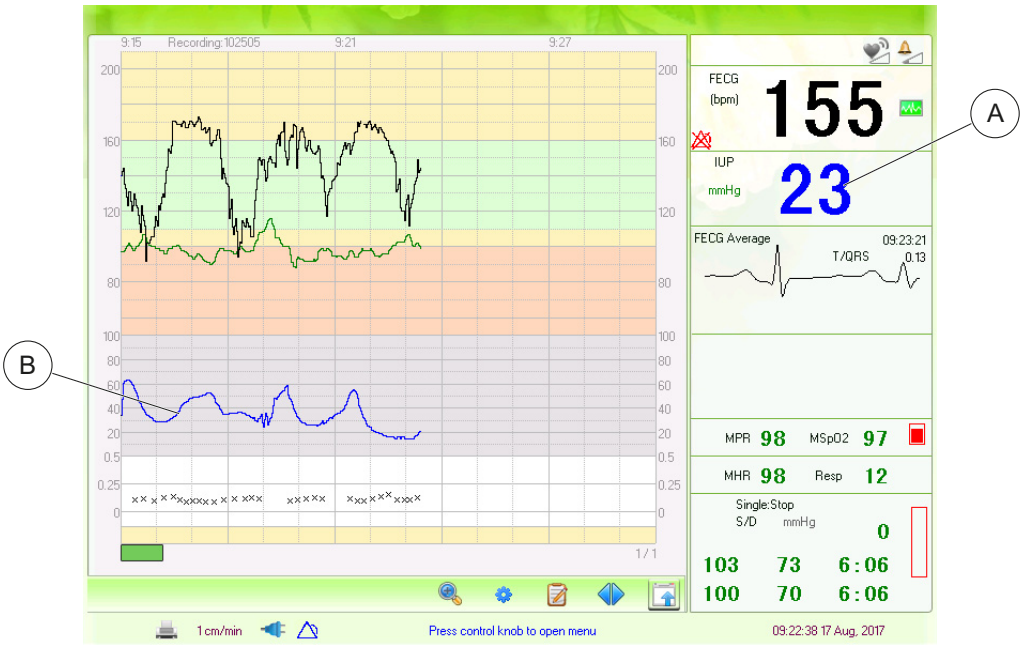


Figure 4:80 Presentation of uterine activity recorded with IUP catheter

Pos	Description
A	IUP value (mmHg)
B	IUP trace

4.5.4 Alarms

Name	Type
> 5 UC in 10 mins	Physiological alarm

4.6 Monitoring fetal movements using the fetal movement marker

4.6.1 Prerequisites

Accessories
Fetal movement marker (wired or wireless)

4.6.2 Setting up

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

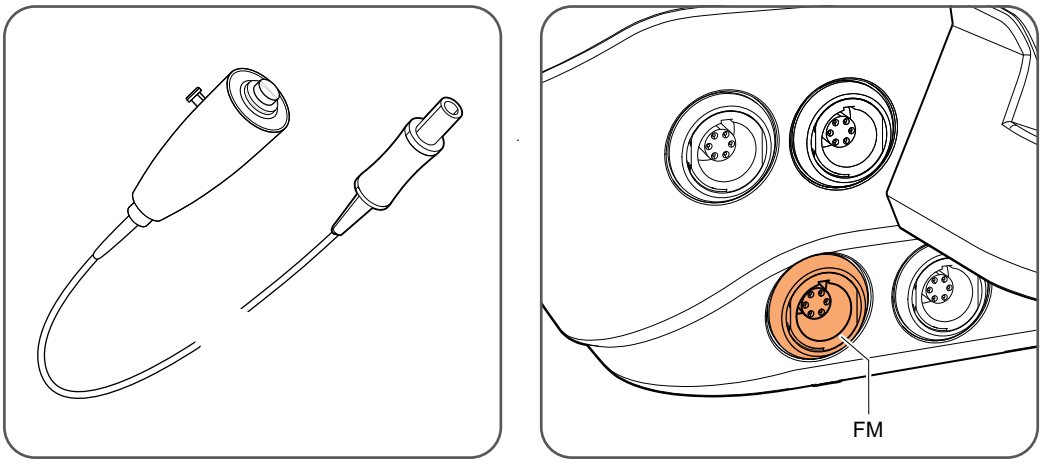


Figure 4:81 The fetal movement marker connector for wired operation on the right side of the main unit

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

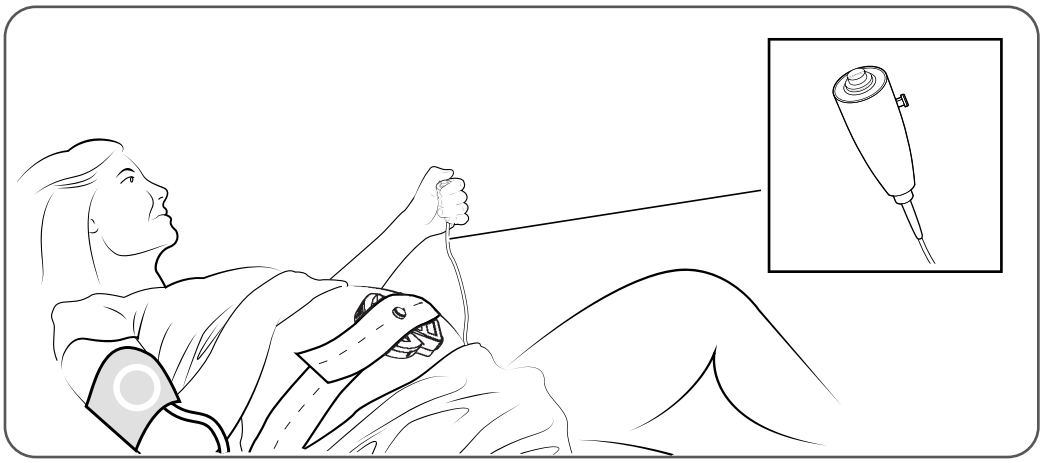


Figure 4:82 Fetal movement marker operated by the mother

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.

4.6.3 Presentation

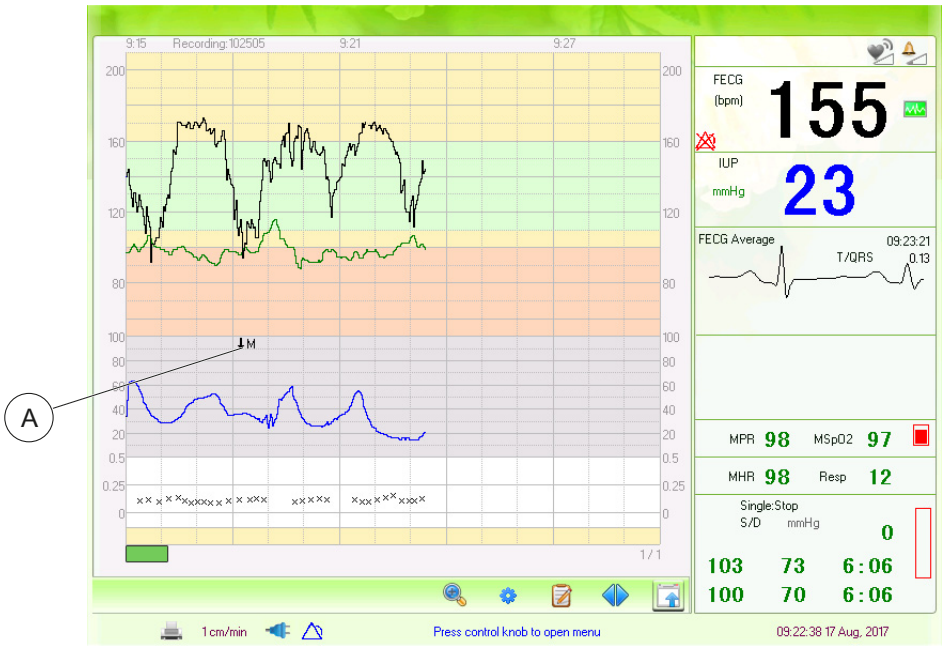


Figure 4:83 Presentation of fetal movement indications on the main screen

Pos	Description
A	Fetal movement marker in CTG trace

4.7 Monitoring maternal blood pressure (NIBP)

4.7.1 Prerequisites

Accessories
NIBP cuff of appropriate size

4.7.2 Warnings

Warning!

- Frequent measurements can cause injury to the mother due to blood flow interference.
- Do not apply NIBP cuff over wound. This can cause further injury.
- The NIBP measurement function in the STAN S41 Maternal and Fetal Monitor should only be used on the mother. Do not apply the cuff on neonates or children.
- Do not use the cuff on a limb with an intravenous infusion or arterial catheter in place.
- Do not apply the cuff on areas where skin damage has occurred or is expected to occur.
- Check the patient frequently to ensure the NIBP cuff is not causing prolonged impairment of the patient's circulation.
- Use clinical judgment to decide whether to perform frequent unattended blood pressure measurements. Patients with severe blood clotting disorders may present the risk of hematoma in the limb fitted with the cuff.
- Do not perform NIBP measurements on an arm if there is lymphedema or risk for lymphedema in that limb.
- For patients who have had a mastectomy, do not apply cuff on the involved arm.
- Prevent the cuff hose from becoming kinked as pressure may remain in cuff after measurement, potentially causing injury to the patient due to blood flow interference.

4.7.3 Setting up

Caution!

- Use only cuffs and accessories listed as compatible.
- Ensure the use of correct sized cuff.
- Apply the cuff correctly and avoid compression or restriction of the hose.
- Do not use the NIBP measurement function if it has not been calibrated correctly.
- Blood pressure measurements may temporarily affect other medical equipment applied to the same arm.

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

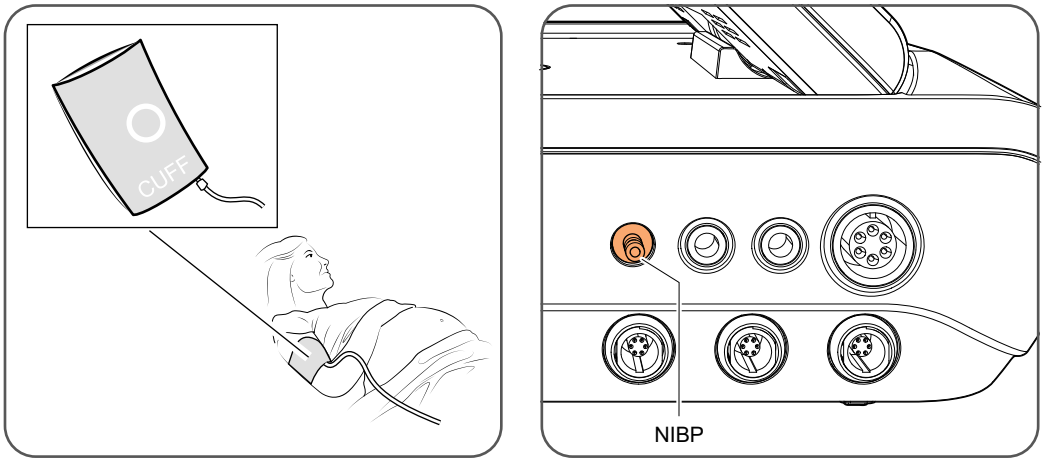


Figure 4:84 Location of the NIBP connector on the left side of the main unit

2. Connect the NIBP cuff to the corresponding connector on the main unit.

3. Apply the NIBP cuff around the mother's bare arm with the text facing outward. Centre the artery symbol on the cuff directly over the brachial artery.

   While tightening the cuff, verify that you have selected the correct size by making sure the "index" marker on the cuff is within the "range" marking. If not, select another cuff size.

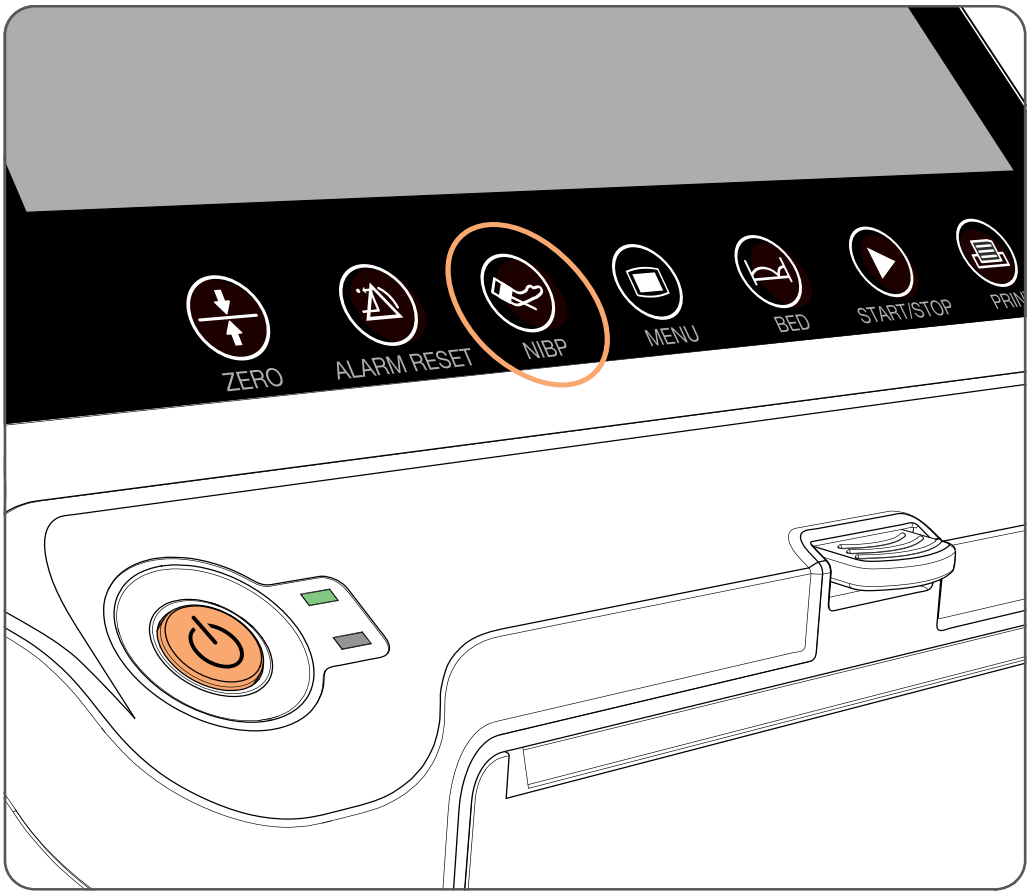


Figure 4:85 Location of NIBP touch key on front side of main unit

4. Press the “NIBP” touch key to open the NIBP mode menu. Then select the preferred operating mode:
   - “Single” takes one single blood-pressure measurement.
   - “Auto” initiates a measurement cycle with a specified measurement-to-measurement interval.
   - “STAT” - short term automatic mode - starts a series of measurements where the monitor performs as many as it can during 5 minutes.
5. You can always stop an ongoing measurement by pressing the “NIBP” touch key again. This operation also ends the “STAT” mode.

Tip!

For optimum measuring accuracy:

- Let the mother relax for at least 5 min prior to the first measurement.
- Keep the cuffed arm in extension, with the cuff in level with the heart, during the entire measurement.
- During the entire measurement, it is important for correct measurements that the mother is relaxed and comfortably seated with support for arm and back, her legs are not crossed, and that she does not talk.
- The hose should not be twisted or kinked.
- The blood pressure estimates can be affected by extreme temperature, humidity, and altitude, see “Environmental conditions” on page 31.
- There may be single readings which are not correct. Therefore, when unexpected values occur, perform additional readings to verify the result.

Caution!

NIBP measurements during uterine contractions may cause discomfort for the mother, and may not be accurate. It is advised to stop or postpone any measurements while a uterine contraction is ongoing.

4.7.4 Presentation

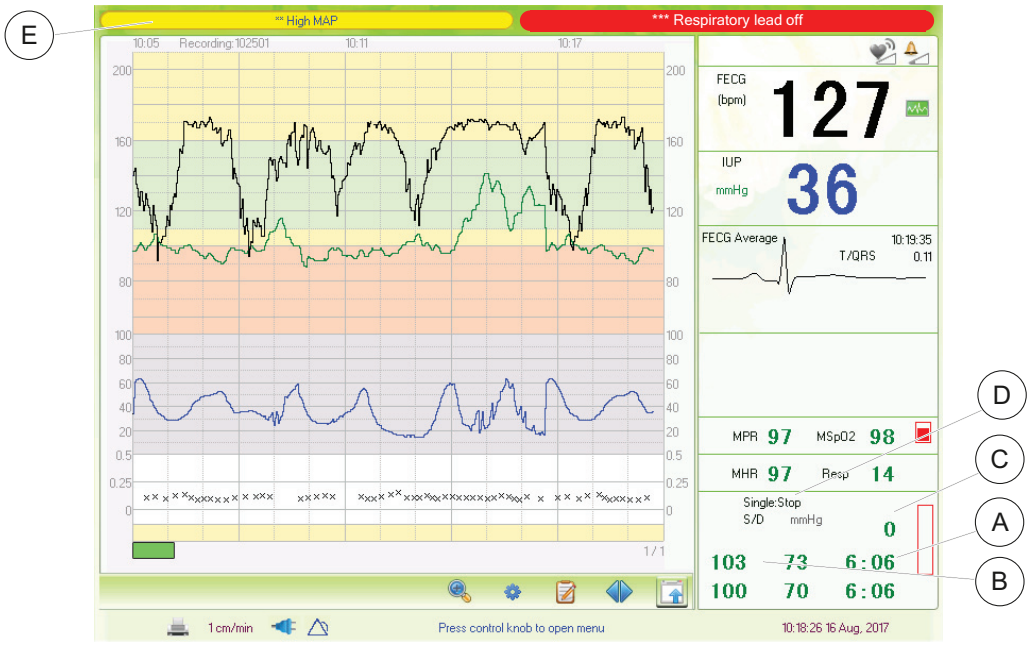


Figure 4:86 Presentation of NIBP measurements on the main screen

Pos	Description
A	Timestamps for the two last completed measurements
B	Systolic, diastolic and mean arterial pressure from two last completed measurements
C	Current cuff pressure
D	Measurement status. Time to next automatic measurement, if “Auto” mode selected
E	Alarms related to NIBP measurements

Tip!

In the NIBP settings tick the check box “Display MAP” to display the MAP values of NIBP measurements on screen and printouts.

4.7.5 Alarms

Name	Type
High/Low NIBP	Physiological alarm
NIBP selftest failure	Technical alarm
Loose NIBP Cuff	Technical alarm
NIBP Air Leakage	Technical alarm
NIBP: Air pressure error	Technical alarm
Weak NIBP Signal	Technical alarm

Name	Type
NIBP measurement out of range	Technical alarm
NIBP excessive movements	Technical alarm
NIBP overpressure	Technical alarm
NIBP signal saturated	Technical alarm
NIBP air system leakage	Technical alarm
NIBP module failure	Technical alarm
NIBP measurement timeout	Technical alarm
NIBP incorrect cuff type	Technical alarm
NIBP cuff timeout	Technical alarm

4.7.6 Limitations

Measurements may be impossible or inaccurate in following situations:

- If the patient moves excessively and/or continuously.
- If a regular arterial pulse is hard to detect.
- On patients with cardiac arrhythmias.
- When rapid blood pressure changes occur.
- In patients with severe shock or hypothermia that reduces blood flow to the periphery.
- In obese patients, where the thick layer of fat surrounding the limbs dampens the oscillations coming from the artery.
- On an oedematous extremity.
- During uterine contractions.

4.8 Monitoring maternal oxygen saturation and pulse with pulse oximeter

4.8.1 Prerequisites

Accessories
Reusable MSpO2 sensor

4.8.2 Warnings

Warning!

- The MSpO2 monitoring with the STAN S41 Maternal and Fetal Monitor should only be used on the mother. Do not apply the sensor on neonates or children.
- Do not apply the sensor too tight, as pressure necrosis may occur.
- Do not keep the sensor on the same location for more than 4 hours, as skin irritation may occur.
- Do not use the STAN S41 Maternal and Fetal Monitor together with defibrillators, electro-surgical equipment or MRI. Such use is contraindicated.
- No alarms are generated if mains supply is interrupted or the monitor is accidentally turned off during monitoring.

4.8.3 Setting up

Caution!

- Use only sensors and extension cables listed as compatible, see section 7.6.4 MSpO2 sensors and cables. Use of incompatible components can result in degraded performance.
- Inspect the application place every 2-4 hours, or according to hospital procedures.
- Do not put tape over the MSpO2 sensor housing. If the sensor needs to be secured, place tape over the sensor cable instead.
- Do not autoclave the sensor or immerse it in liquid.
- If the sensor is damaged in any way, stop using it immediately.
- Do not connect several extension cables in serial, as this can result in degraded performance.

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

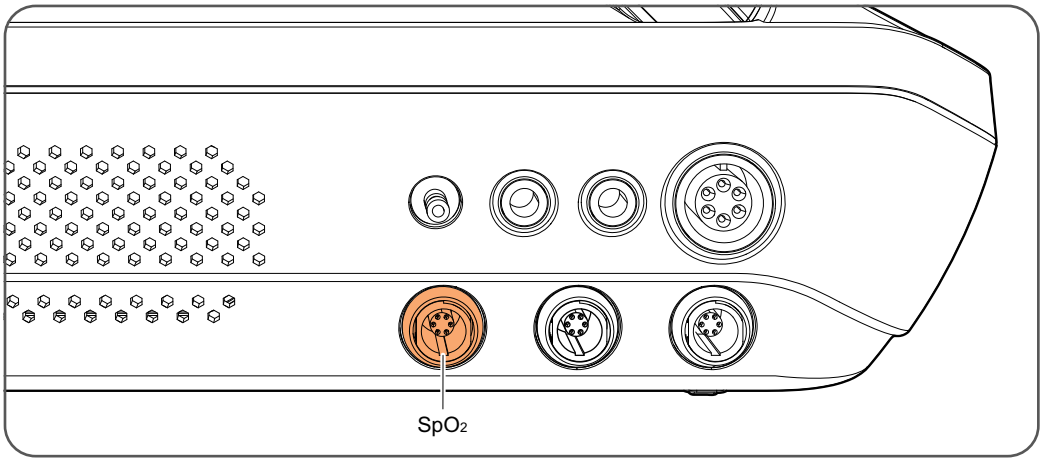


Figure 4:87 Location of the SpO2 connector on the left side of the main unit

2. Connect the MSpO2 sensor to the corresponding connector on the main unit.

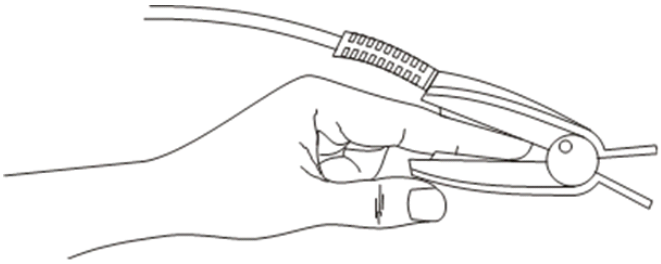


Figure 4:88 MSpO2 sensor positioning on index finger

3. Apply the MSpO2 sensor on the patient's index finger with the nail marking facing the nail side.

Caution!

- Nail polish may interfere with pulse oximeter signal strength.
- If possible, avoid placing the sensor on the same extremity as the blood pressure cuff, arterial catheter or intravenous infusion.

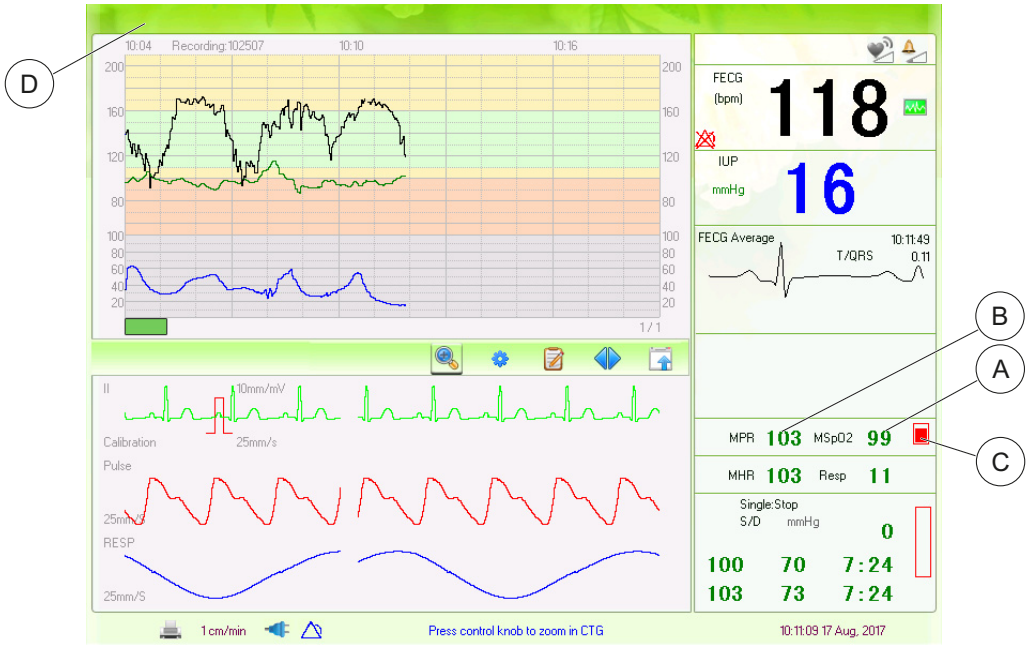


Figure 4:89 MSpO2 signal quality indicators on main screen

4. Verify that you have adequate signal by ensuring that:

   a) The MSpO2 field shows a saturation value (A) and a maternal pulse value (B).

   b) The plethysmographic pulse bar (C) reaches at least 50% during pulses.

   c) There are no technical alarms (D) related to MSpO2 monitoring.

4.8.4 Presentation

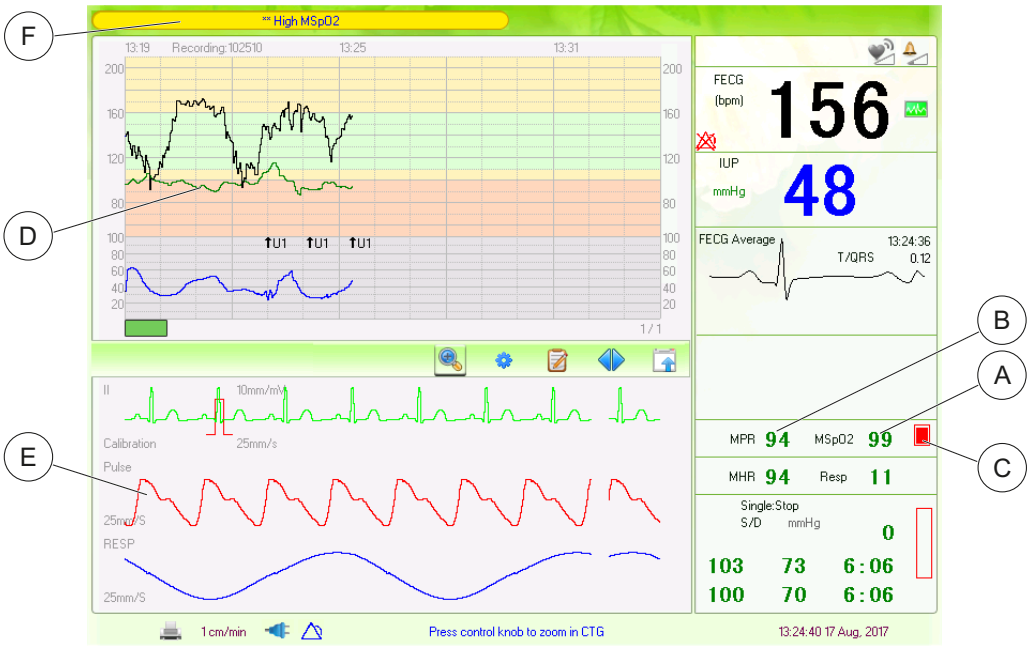


Figure 4:90 Presentation of maternal pulse and oxygen saturation from the SpO2 sensor on the main screen

Pos	Description
A	Maternal oxygen saturation (%)
B	Maternal pulse (bpm)
C	Plethysmographic pulse bar, indicating input signal quality on beat-to-beat basis
D	Maternal pulse trace (bpm)
E	MSpO2 pulse waveform
F	Alarms related to MSpO2 monitoring

Tip!

To eliminate the risk of confusion between the maternal and fetal heart rate traces, regularly check that the fetal and maternal heart rate traces in the CTG window do not coincide.

4.8.5 Alarms

Name	Type
High/Low MSpO2	Physiological alarm
High/Low MPR	Physiological alarm
FHR1/2 and MHR coincide	Technical alarm
MSpO2 Sensor Off	Technical alarm
MSpO2: Pulse not found	Technical alarm

4.8.6 Limitations

Measurement may be impossible or inaccurate:

- If the MSpO2 sensor is applied incorrectly, too loose or too tight.
- If the sensor is subject to direct light or strong ambient light, infrared and UV light. If necessary, shield the sensor with a surgical towel.
- In cases of intravascular dyes or dysfunctional haemoglobin.
- When the patient wears nail polish or artificial fingernails.
- When patient is moving excessively.
- If the blood perfusion is low in the extremity on which the sensor is applied.

4.9 Monitoring maternal ECG and respiratory rate

4.9.1 Prerequisites

Accessories
3- or 5-leadwire MECG cable
Compatible skin electrodes
Conductive electrode gel if needed

4.9.2 Warnings

Warning!

- The MECG monitoring function presents a continuous waveform representing the patient's cardiac electric activity, allowing assessment of the current physiological state. Only proper connection of ECG cables can ensure a satisfactory measurement.
- When connecting the leadwire cable and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes are securely attached to the patient.
- Verify lead off detection before start of monitoring, e.g. by disconnecting the ECG leadwire cable from the main unit, and ensuring that ECG lead off technical alarms are presented.
- All skin electrodes should be of the same manufacture/material. Use only electrodes and cables listed as compatible in section “MECG consumables and accessories” on page 157, i.e. silver-silver chloride (Ag-AgCl) ECG electrodes and cables meeting AAMI standards.

Caution!

- Different types of electrodes may produce different offset voltage. Only use skin electrodes listed as compatible when using the monitor for MECG monitoring.
- Although the monitor is protected against defibrillation effects, defibrillation of the patient is contraindicated while connected to the STAN S41 Maternal and Fetal Monitor.
- The monitor does not have capability of detecting or rejecting pacemaker pulse, nor does it provide a pulse to synchronize a defibrillator discharge.
- The monitor can be set up to generate alarm signals for high maternal heart rate. Note that this is not equivalent to alarms for tachycardia.

4.9.3 Setting up

Caution!

Regularly inspect whether the skin is irritated from attachment of cardiograph electrodes, if so, replace with new electrodes or change their sites every 24 hours.

1. Ensure the power is switched on and a recording is started.
2. Confirm that the alarm settings are appropriate for your patient.
3. Choose flat area to place electrodes. Prepare each site for skin electrode attachment:

a) Consider shaving hair from skin at chosen sites.

b) Gently rub skin surfaces at sites to remove dead skin cells.

c) Thoroughly cleanse the site with a mild soap and water solution (do not use alcohol as this will increase skin impedance).

d) Let the skin dry before applying the electrodes.

4. Attach the skin electrodes to the MECG leadwire cable.

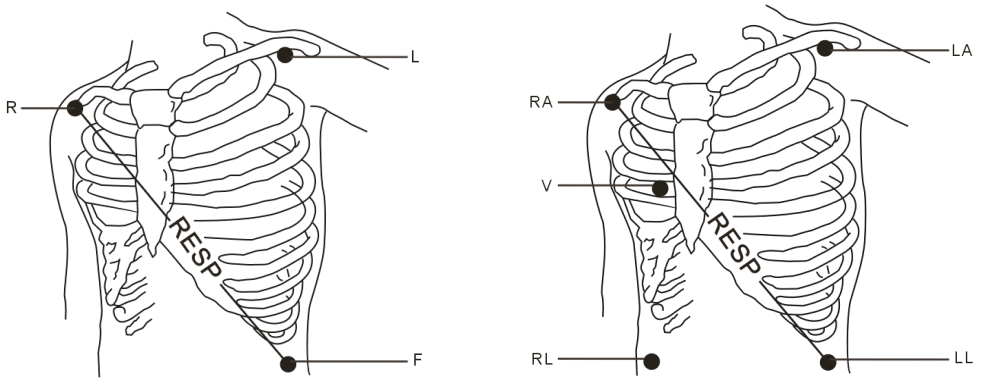


Figure 4:91 Electrode placement for 3- resp 5-leadwire mode

5. Attach the electrodes to the patient. See section “Electrode placement” on page 116 for a detailed guide to where electrodes shall be placed.

6. If needed, conductive electrode gel can be applied to the electrodes to improve the skin conductance.

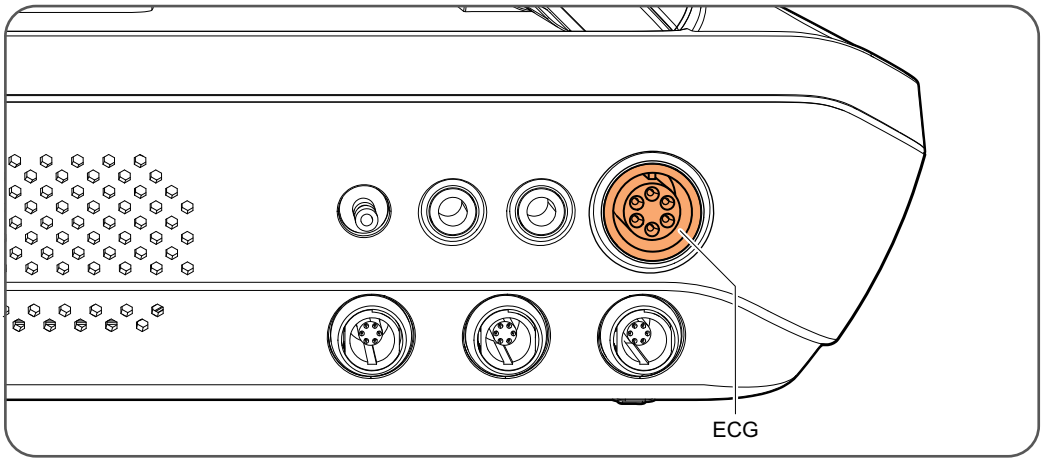


Figure 4:92 Location of the ECG connector on the left side of the main unit

7. Connect MECG leadwire cable to the ECG connector of the main unit.

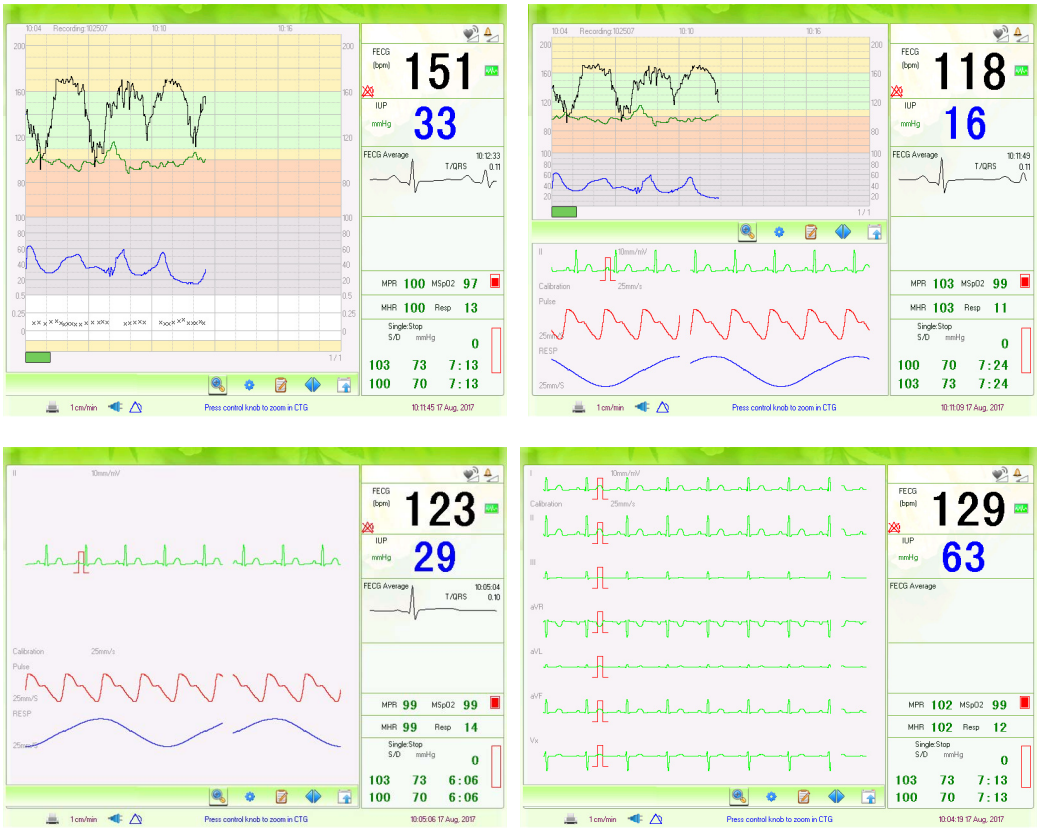


Figure 4:93 View modes “Fetal only”, “Fetal and Maternal”, “Maternal only” and “7 MECG lead waveforms”

8. Configure the appropriate view mode by changing the “Display Mode” system setting, to either “Fetal only”, “Fetal and Maternal”, “Maternal only” and “7 MECG lead waveforms”.

9. If you select the maternal view mode, select which lead you wish to have presented as MECG source in the “MECG Settings”. For 3-leadwire mode, you can select MECG source as leads I, II and III, and for 5-leadwire mode, you can select MECG source as leads I, II, III, AVR, AVL, AVF, and V. If the MECG waveform appears inaccurate, switch MECG source to another lead.

10. If needed, change the display amplification of the MECG signal by altering the MECG gain setting.

Caution!

- When recording MECG, the maternal respiratory rate is automatically calculated from ECG Lead II (also referred to as “respiratory lead”). To avoid incorrect calculation of respiratory rate, avoid placing the respiratory lead electrodes RA and LL over the liver area and the ventricles.
- Do not rely on respiratory monitoring on patients that move a lot, as this can generate false alarms.
- To ensure patient safety, all leads must be attached to the patient.

11. Verify that you have an adequate signal. Confirm that the MECG signal contains repetitive QRS waveforms, is free from noise and other artifacts, and that a maternal

heart rate value is displayed. Allow for a 20-second monitor stabilization period before testing.

4.9.4 Presentation

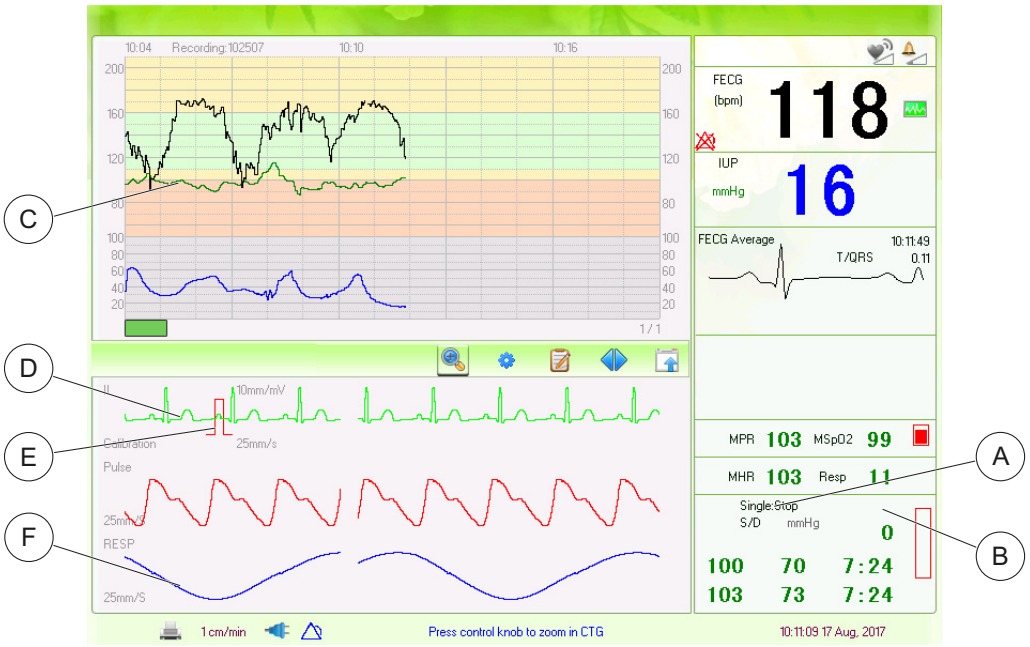


Figure 4:94 Presentation of MECG, MHR and maternal respiratory rate from MECG electrodes

Pos	Description
A	Maternal heart rate*
B	Respiratory rate
C	Maternal heart rate trend
D	MECG waveform (lead configurable)
E	Signal amplitude indicator for calibration purposes
F	Respiratory waveform
*The heart rate display is updated with an interval of 1 s. The response time for a change in heart rate is less than 10 s.	

Tip!
To eliminate the risk of confusion between the maternal and fetal heart rate traces, the maternal heart rate trend is always drawn in green.

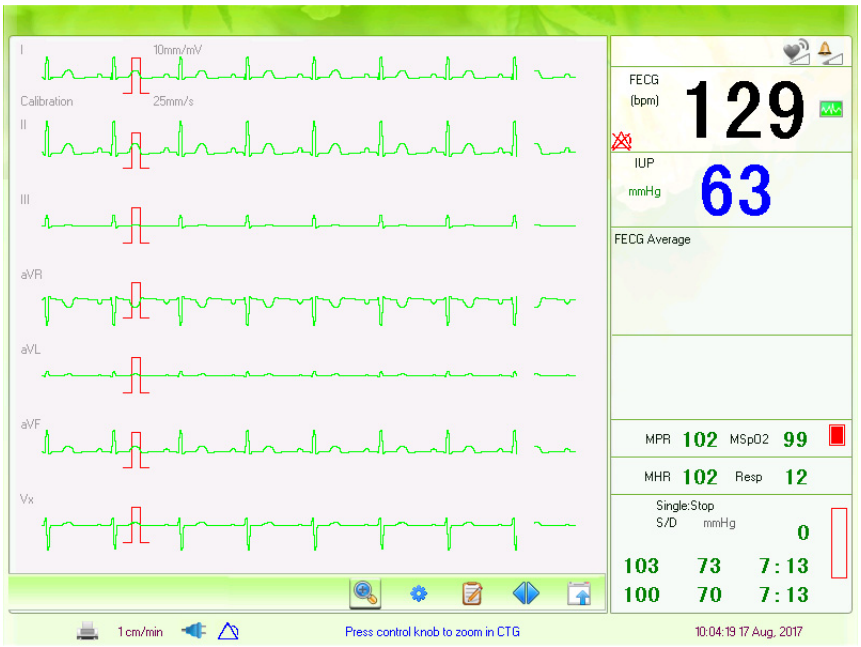


Figure 4:95 "7 MECG lead waveforms" view mode

4.9.5 Alarms and events

Name	Type
High MHR	Physiological alarm
Low MHR	Physiological alarm
Maternal Cardiac Standstill	Physiological alarm
High RR	Physiological alarm
Low RR	Physiological alarm
Maternal Asphyxia	Physiological alarm
FHR1/2 and MHR coincide	Technical alarm
Leads RA/LA/LL/V Off, or Leads R/L/F/C Off	Technical alarm
ECG I/II/V: Polarized	Technical alarm
Respiratory lead off	Technical alarm

4.9.6 Electrode placement

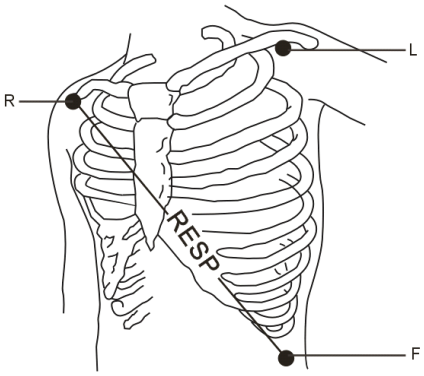


Figure 4:96 3-Leadwire electrode placement by European naming standard.

Electrode placement for 3-leadwire MECG cable				
American Standard (AHA)		**European Standard (IEC)**		
Label	**Color**	**Label**	**Color**	**Position**
RA	White	R	Red	Near the right shoulder, directly below the clavicle.
LA	Black	L	Yellow	Near the left shoulder, directly below the clavicle.
LL	Red	F	Green	On the left hypogastrium.

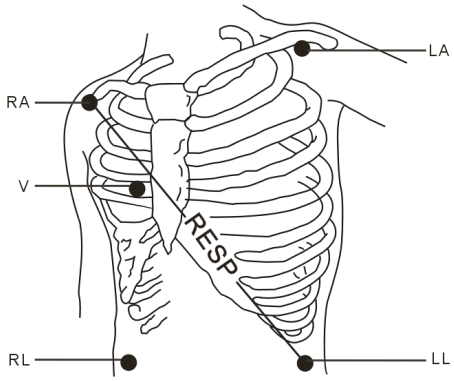


Figure 4:97 5-Leadwire electrode placement by European naming standard.

Electrode placement for 5-leadwire MECG cable				
American Standard (AHA)		**European Standard (IEC)**		
Label	**Color**	**Label**	**Color**	**Position**
RA	White	R	Red	Near the right shoulder, directly below the clavicle.
LA	Black	L	Yellow	Near the left shoulder, directly below the clavicle.

Electrode placement for 5-leadwire MECG cable				
American Standard (AHA)		**European Standard (IEC)**		
Label	**Color**	**Label**	**Color**	**Position**
RL	Green	N	Black	On the right hypogastrium.
LL	Red	F	Green	On the left hypogastrium.
V	Brown	C	White	On the chest.

5 Maintenance

5.1 Intervals

After each use

Remove transducers and electrodes 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.

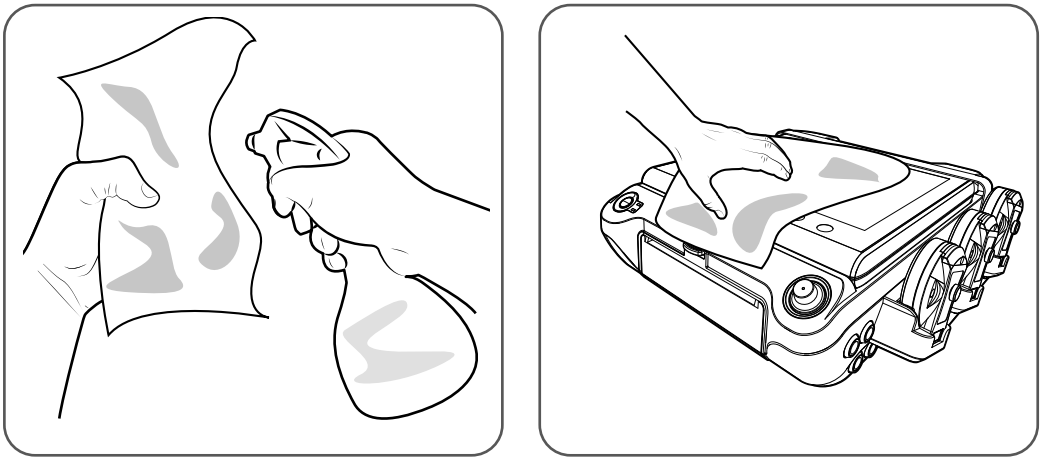


Figure 5:98 Cleaning the main unit

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, sensors, ECG leadsets and their cables for cracks and damages. If damages are suspected, contact qualified service personnel.

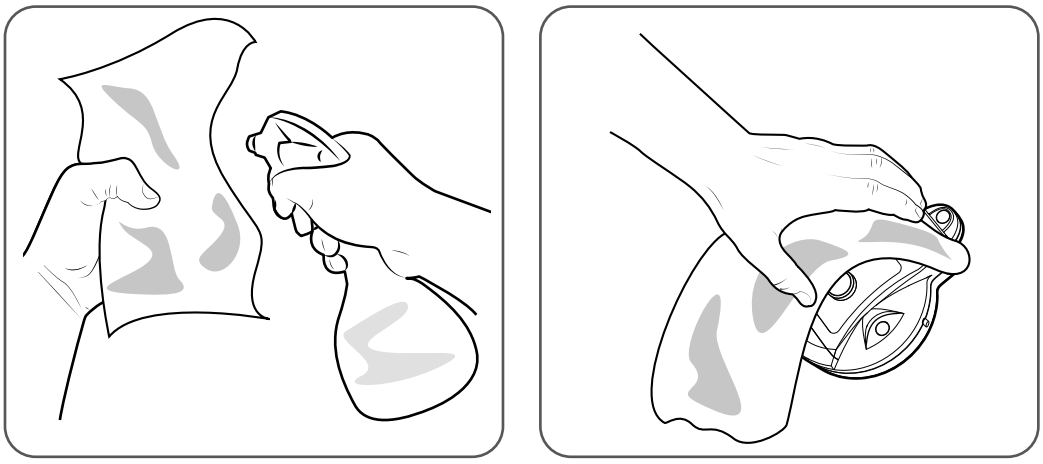


Figure 5:99 Cleaning transducers

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

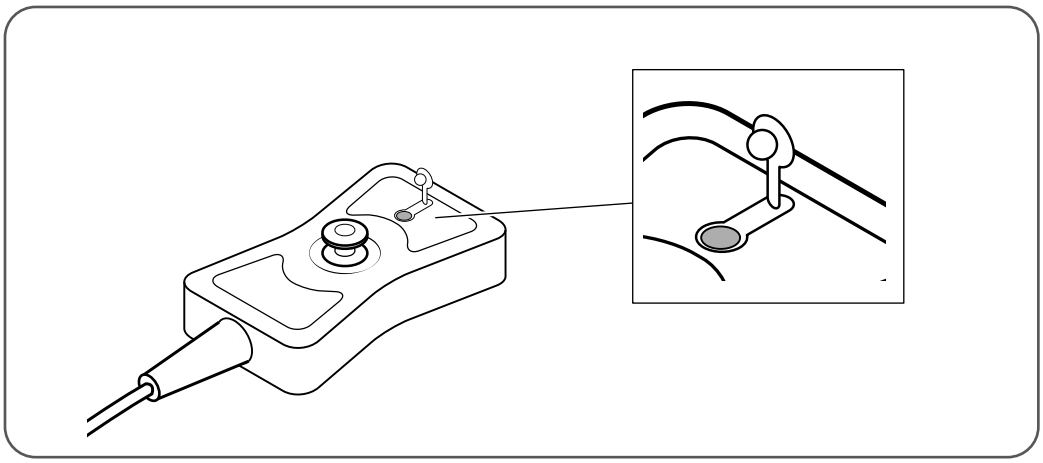


Figure 5:100 Flushport of the reusable FECG legplate

3. Inspect the scalp electrode connector on the reusable FECG legplate. If mucus or show has been pushed into the connector, flush the flushport with a syringe filled with saline or water.

4. Let air-dry or wipe the remaining moisture with a soft dry cloth.

5.2.3 Cleaning the NIBP cuff and hose

Caution!

- Cleaning liquid allowed to seep into the hose or bladder of a reusable NIBP cuff will cause damage to the monitor.
- Avoid squeezing the rubber tube of the NIBP cuff.
- Do not dry-clean the NIBP cuff.
- Only clean the outer surface of the NIBP connectors and make sure no liquid goes into the connector.

1. Inspect the NIBP hose for cracks and damage. If damage is suspected, contact qualified service personnel.

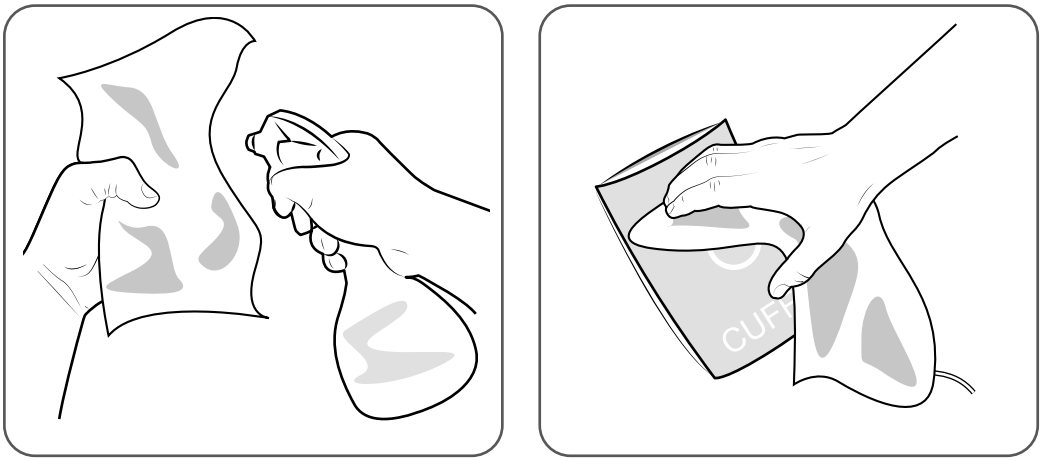


Figure 5:101 Cleaning the NIBP cuff and hose

2. Clean the surfaces of the cuff and hose using a cloth and any of the recommended detergents.

3. Let air-dry or wipe the remaining moisture with a soft dry cloth.

4. The cuff can also be machine-washed. Note however that this will reduce the lifetime of the cuff. Remove the latex rubber bag before washing, and close the Velcro fastening. Allow the cuff to dry thoroughly after washing; then reinsert the rubber bag.

Tip!

To replace the rubber bag in the cuff, first place the bag on the top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the complete cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

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. • Rigid and durable cylinder such as a metal water bottle for performing NIBP leakage test. • Adult ECG simulator for testing integrity of MECG leadset cable.

5.3.1 Main unit and printer

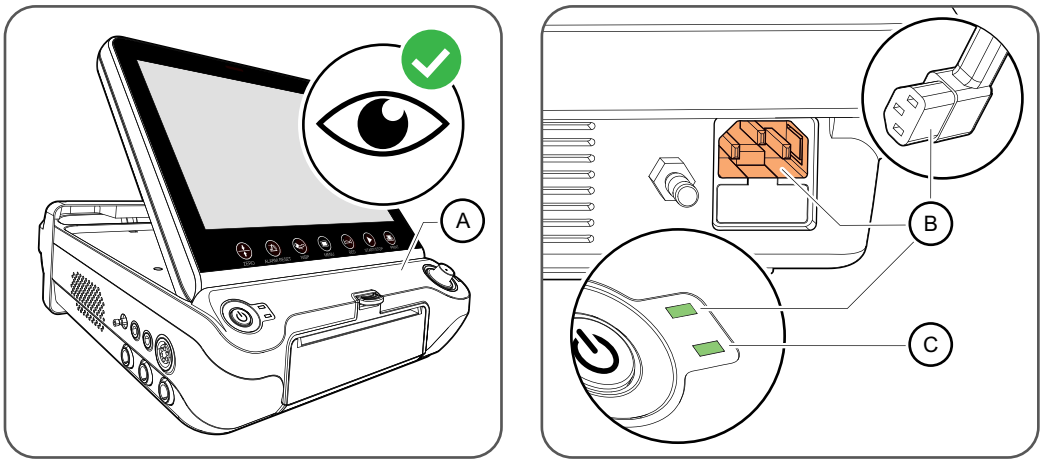


Figure 5:102 Inspecting main unit and printer

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.

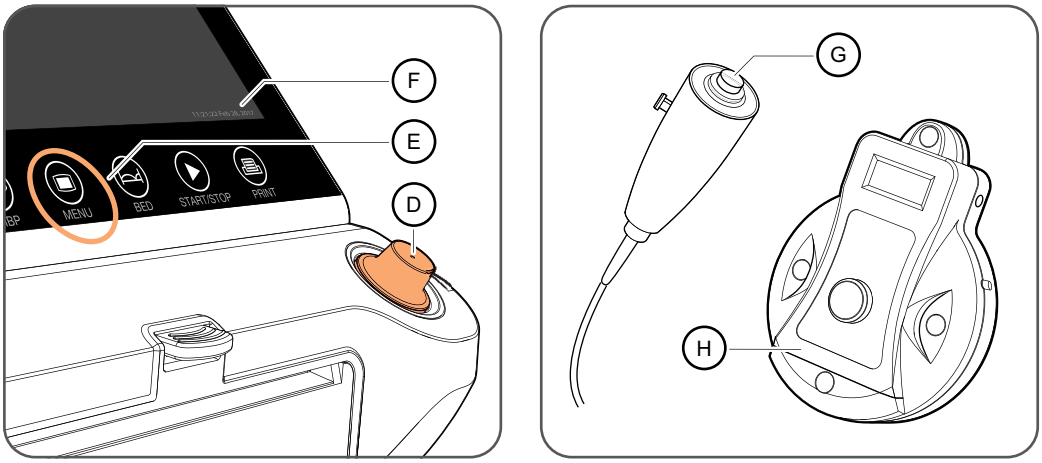


Figure 5:103

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.

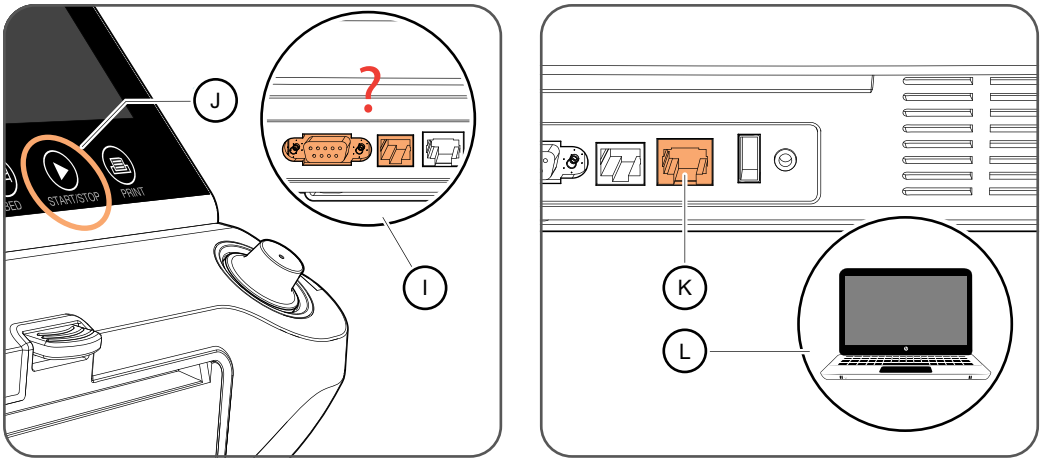


Figure 5:104

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.

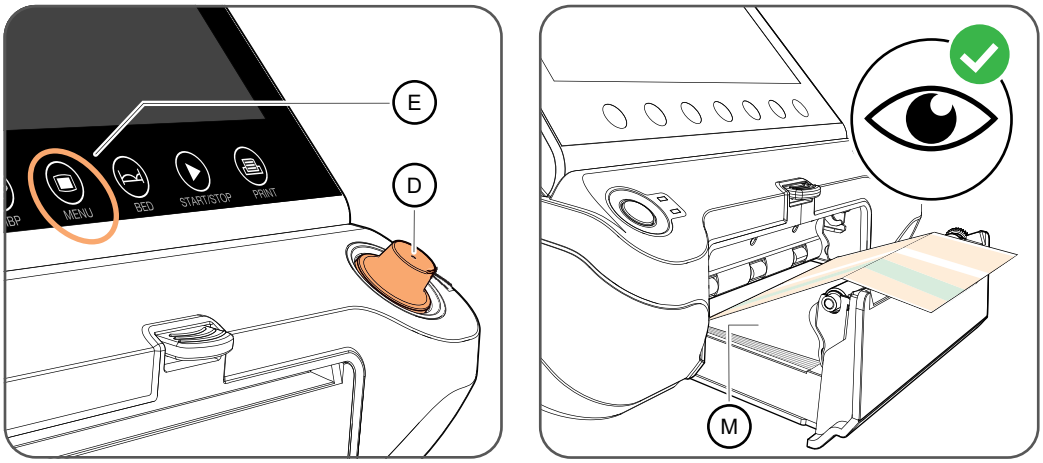


Figure 5:105

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

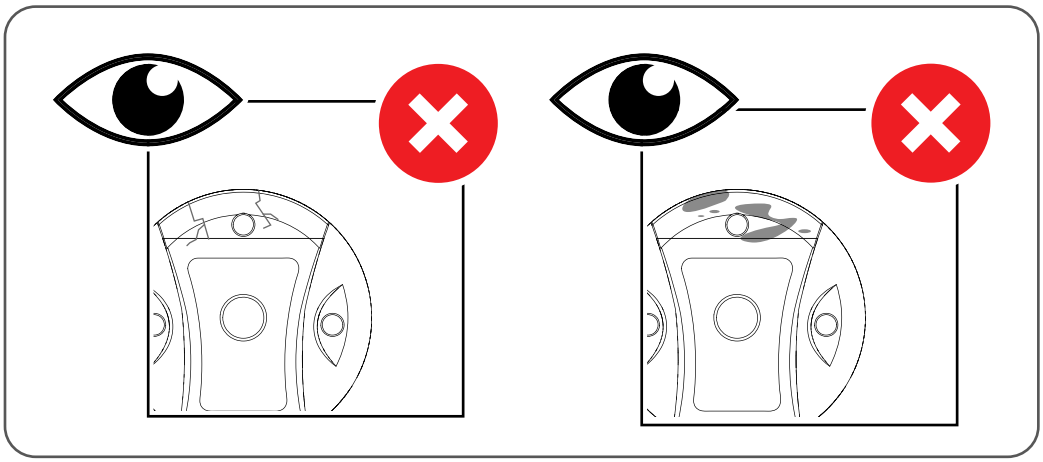


Figure 5:106 Inspecting the wired TOCO transducer

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

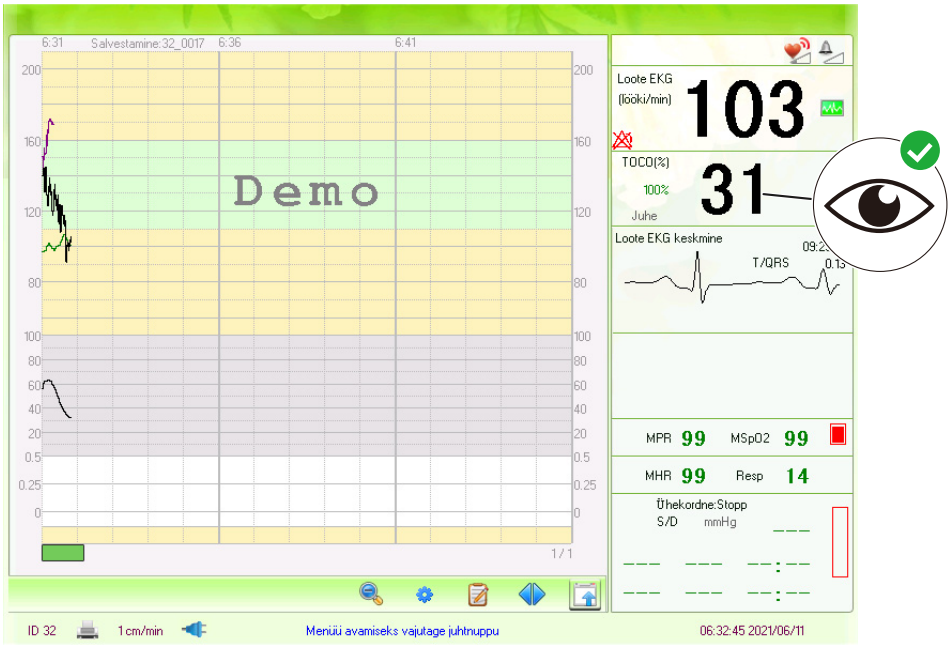


Figure 5:107 Verify that a TOCO value appears on the display

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

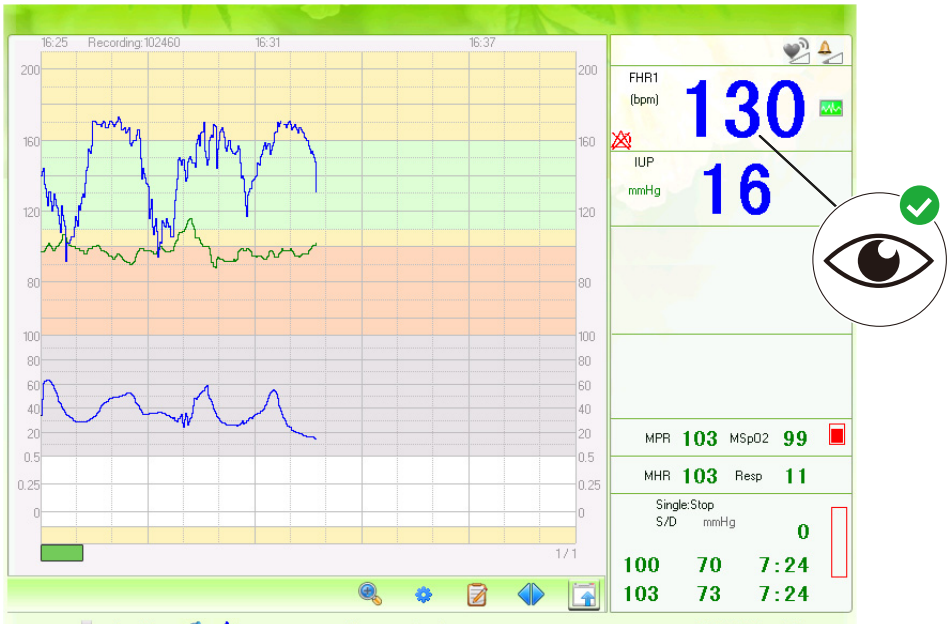


Figure 5:108 Verify that an FHR1 value appears on the display

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.

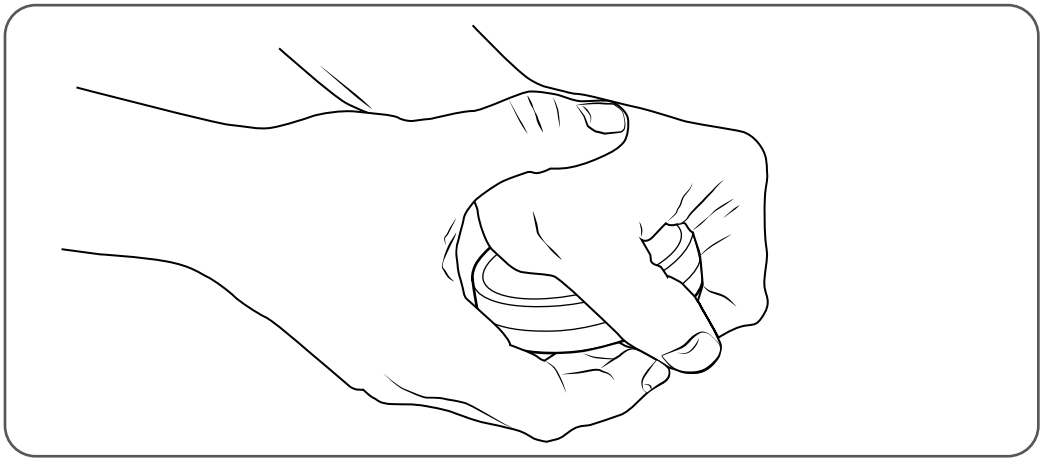


Figure 5:109 Simulating fetal heart movements

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.

5.3.4 Wireless TOCO transducer

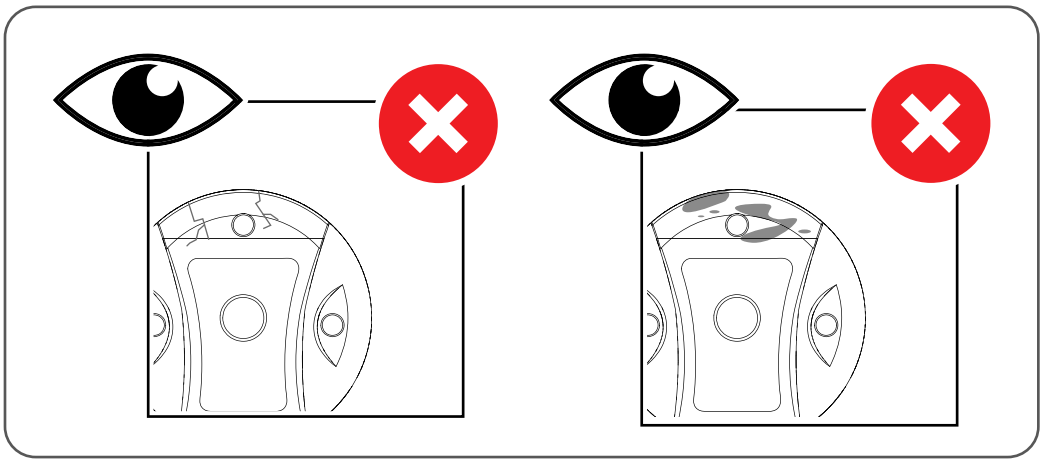


Figure 5:110 Inspecting the wireless TOCO transducer

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.

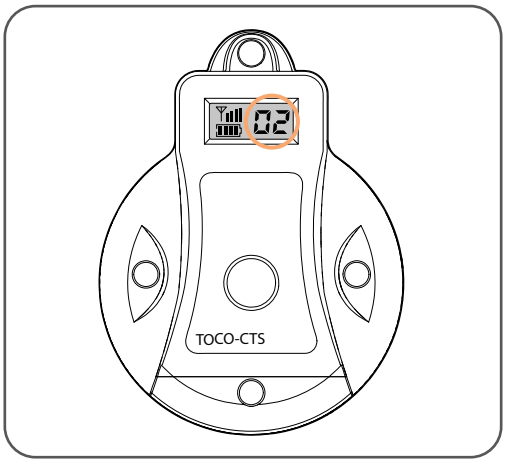


Figure 5:111 Verify that the wireless channel numbers on display and transducer match

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

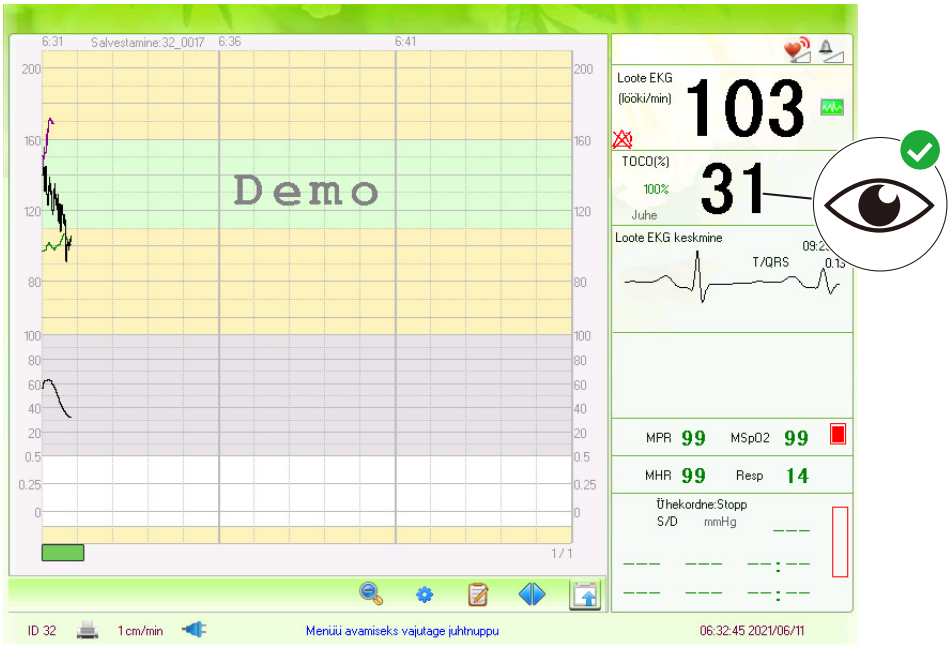


Figure 5:112 Verify that a TOCO value appears on the display

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

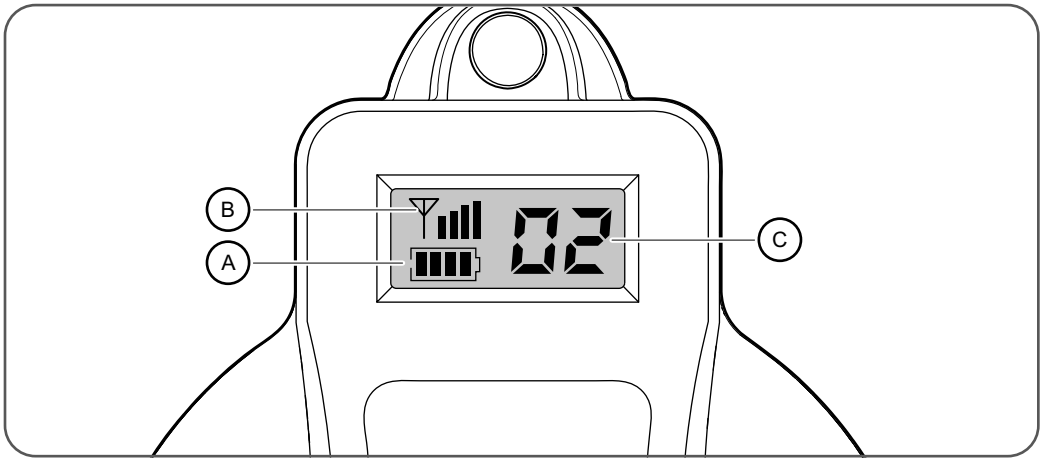


Figure 5:113 Inspecting a wireless ultrasound transducer

1. Remove the ultrasound transducer (FHR1 or FHR2) 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.

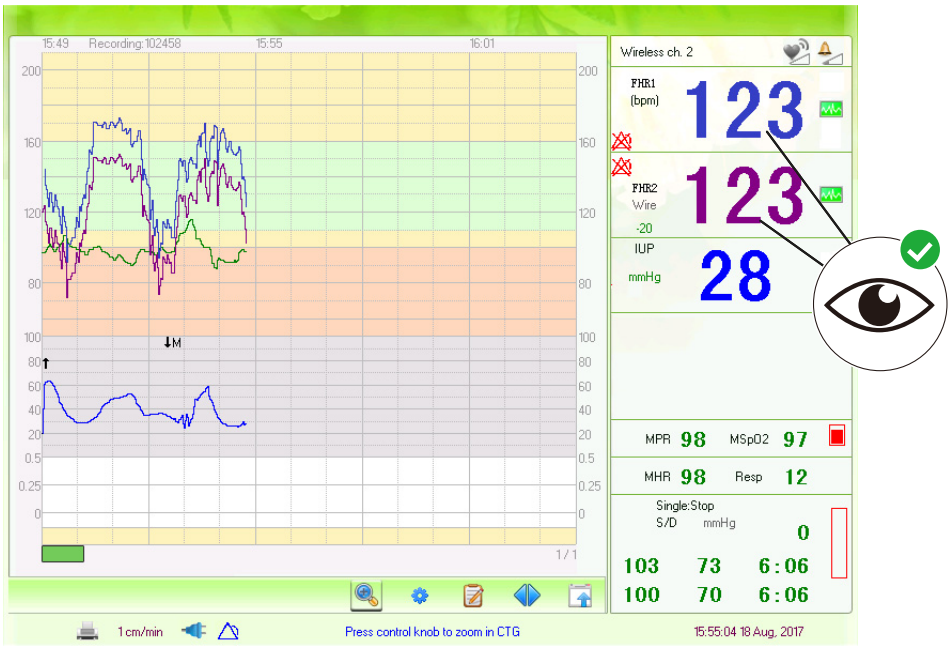


Figure 5:114 Verify that an FHR1/FHR2 value appears on the display

6. Verify that the corresponding FHR indicator (FHR1 or FHR2) 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 FECG function

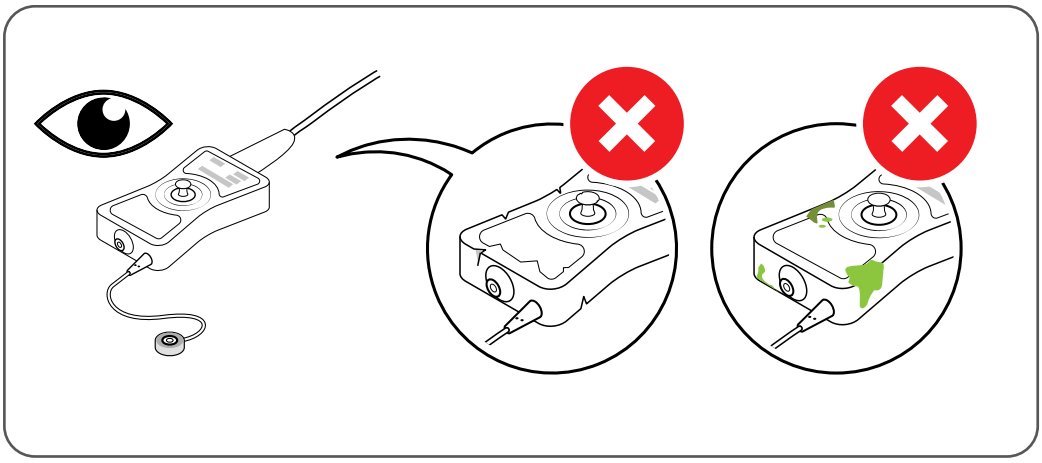


Figure 5:115 Inspect the FECG legplate

1. Inspect the FECG legplate for cracks and damage.

2. Inspect the scalp electrode connector.

3. Connect the leads to the scalp, scalp ref and skin outlets of a fetal ECG simulator. (To be able to connect to the scalp electrode connector, you may need to cut and strip the wires of a scalp electrode.) If you do not have a fetal ECG simulator available, you can connect to the RA, LA and LL (R, L, F) outlets of an adult ECG simulator. Power on the ECG simulator and start a suitable simulation.

Tip!

Alternatively, if you do not have an ECG simulator available, you can test on yourself or another human subject. Be careful to follow the preparation procedures described in the section “Monitoring maternal ECG and respiratory rate” on page 111.

4. Open the “Fetal and FECG” viewmode by selecting the “Viewmode” menu button and verify that each lead displays the appropriate signal.

5. Disconnect each FECG leadwire separately and verify that a corresponding lead-off technical alarm is displayed.

5.3.7 IUP function

1. Inspect the IUP adapter cable for cracks and damage.
2. Connect the IUP adapter cable to the “IUP” connector on the main unit. Verify that “IUP” is indicated on the display.
3. Select the “ZERO” touch key and verify that the value is set to “0”.

5.3.8 NIBP function

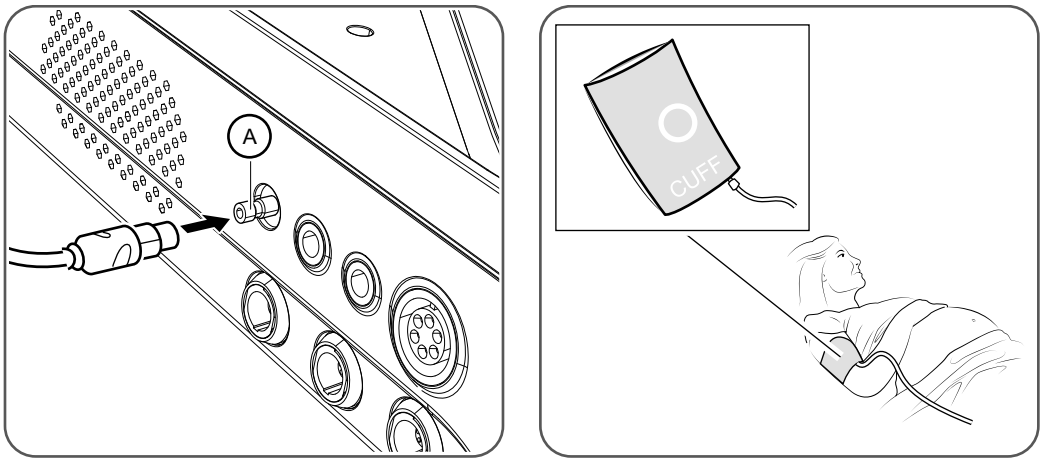


Figure 5:116 Inspecting the NIBP cuff and hose

1. Inspect the NIBP cuff and hose for cracks and damage.
2. Connect a compatible blood pressure cuff to the NIBP connector (A) on the side of the main unit.
3. Apply the cuff to an arm and start an NIBP measurement by holding the “NIBP” touch key and select “Single”.
4. Wait until the measurement has been completed and verify that a reasonable NIBP result is shown on the display.
5. Verify that the pressure of the cuff is released after the measurement has been completed.

Tip!

If you suspect that the cuff or hose is leaking, you can perform an automated leakage test. This is accessible through the “NIBP Settings” menu.

5.3.9 MSpO2 function

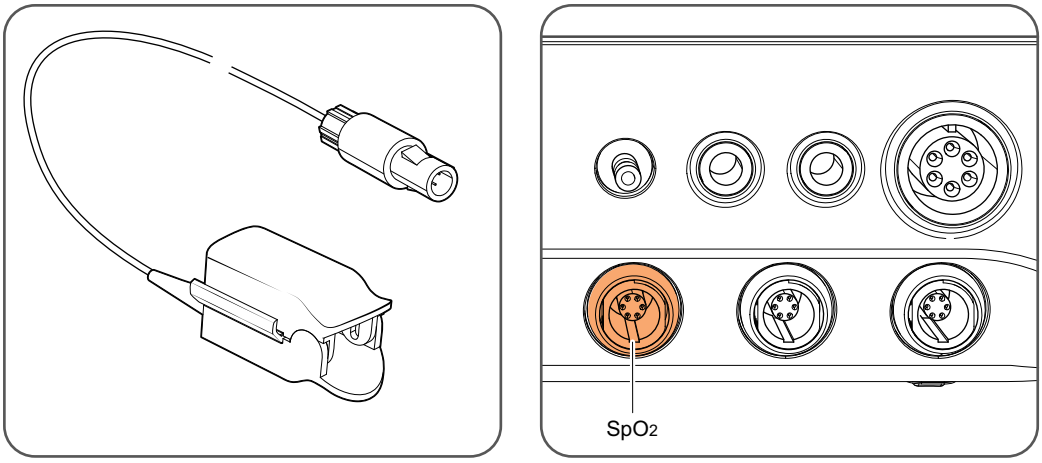


Figure 5:117 Inspecting the MSpO2 sensor and cable

1. Inspect the MSpO2 Sensor, its cable and connector and make sure it is not damaged.
2. Connect the MSpO2 Sensor to the corresponding connector on the main unit.
3. Apply the sensor to a finger. Verify that reasonable values for saturation and heart rate are shown on the display.

5.3.10 MECG and respiratory rate function

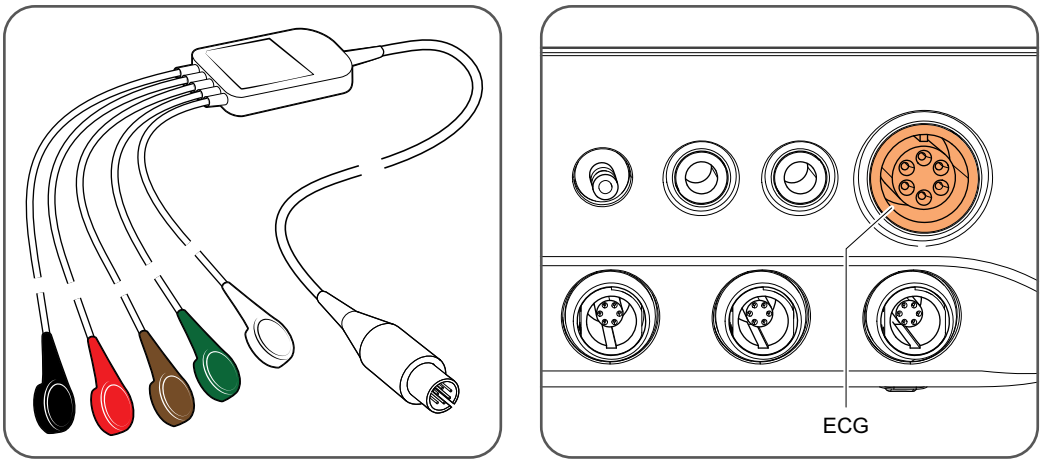


Figure 5:118 Inspect the MECG leadwire cable

1. Inspect the MECG leadwire cable for cracks and damage.

2. Connect the leadwires to the RA, LA, RL, LL and V outlets of an adult ECG simulator. (Depending on model, these can also be named R, L, N, F, C.) Power on the ECG simulator and start a suitable simulation.

Tip!

Alternatively, if you do not have an ECG simulator available, you can test on yourself or another human subject. Be careful to follow the preparation procedures described in the section “Monitoring maternal ECG and respiratory rate” on page 111.

3. Open the MECG view mode by selecting the “View mode” menu button and verify that each lead displays the appropriate signal.

4. Disconnect each ECG leadwire separately and verify that a corresponding lead-off technical alarm is displayed.

5.3.11 Wired fetal movement marker

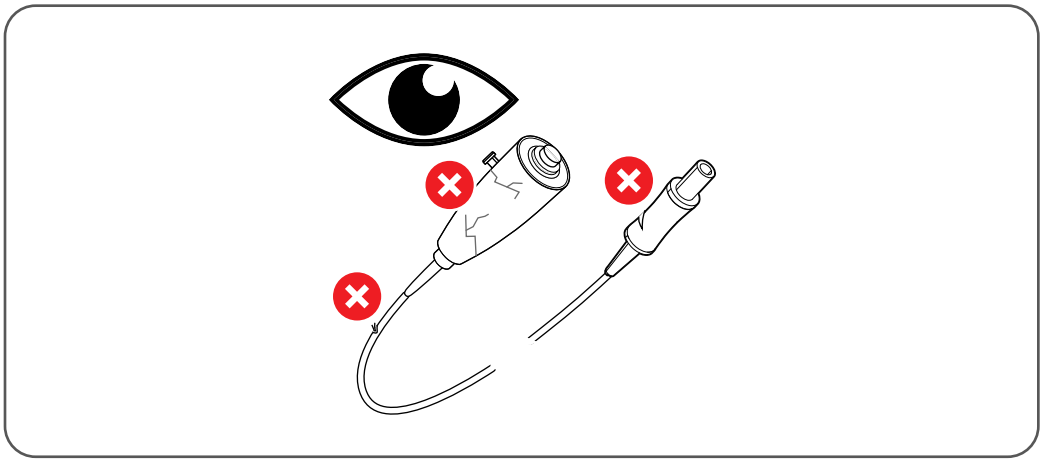


Figure 5:119 Inspecting the wired fetal movement marker

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.

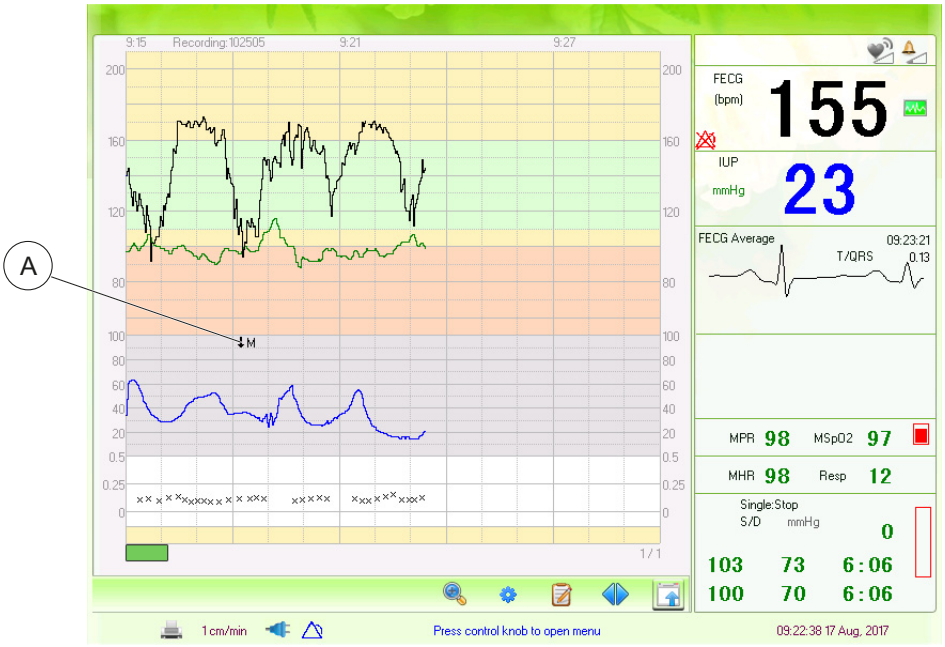


Figure 5:120 Fetal movement mark on screen

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.

5.3.12 Wireless fetal movement marker

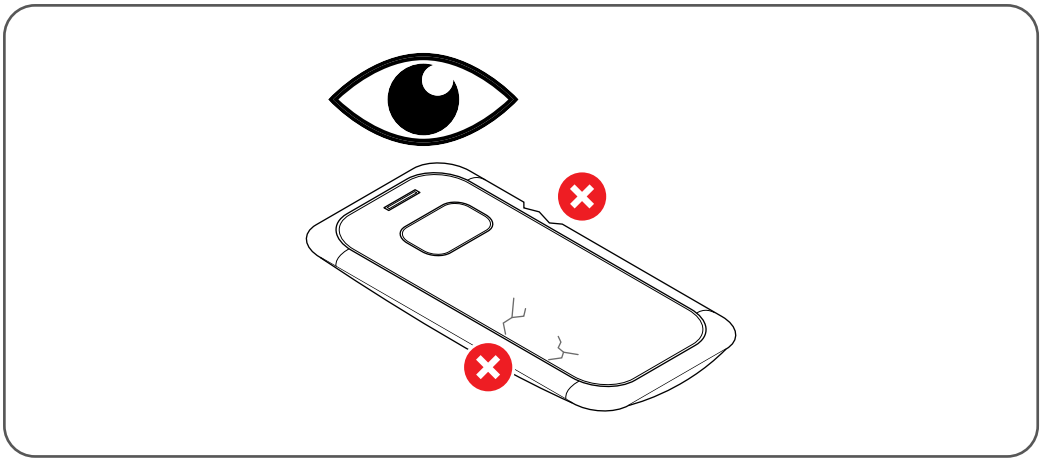


Figure 5:121 Inspecting the wireless fetal movement marker

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

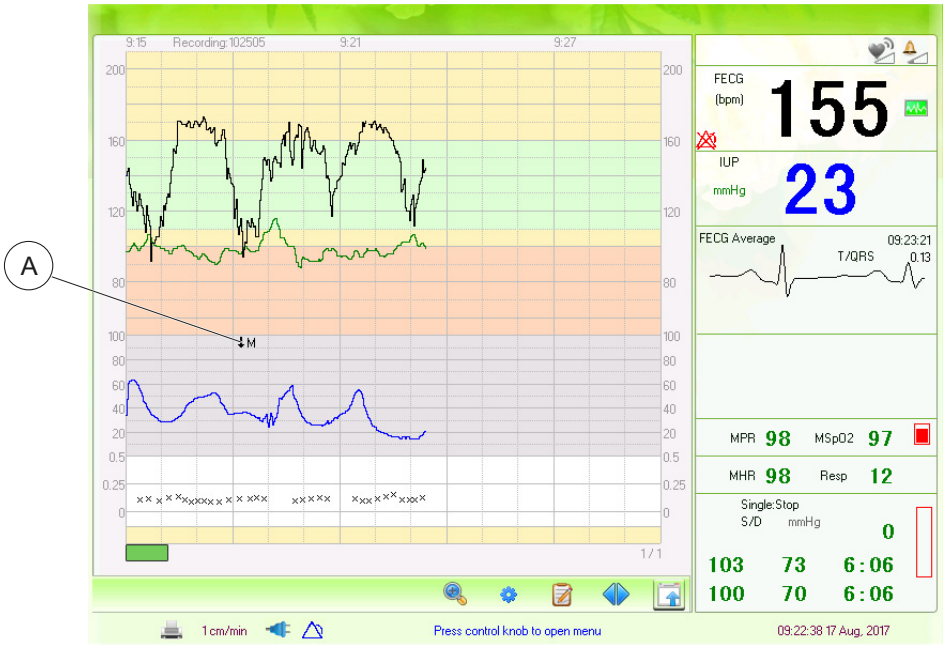


Figure 5:122 Fetal movement mark on screen

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”.

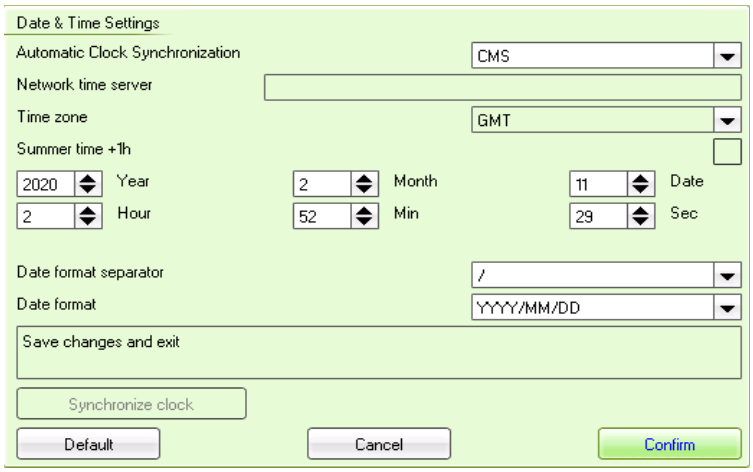


Figure 5:123 Use the control knob to adjust the time and date digits

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.

Area of concern	Problem	Potential cause	Solution
FECG monitoring	Both “Check Scalp electrode” and “Check Skin electrode” technical alarm.	Patient not connected.	Check legplate, scalp and skin electrode.
		Signal quality problems.	Check skin and scalp electrode; if necessary reapply.
	“Check Skin electrode” technical alarm.	Inadequate skin preparation.	Prepare the skin properly, by rubbing gently with sandpaper and apply a new skin electrode.
		Loose or unconnected skin electrode.	Check skin electrode; reapply if necessary.
		Skin electrode too dry.	Apply fresh skin electrode from sealed bag.
	“Check Scalp electrode” technical alarm.	Loose or unconnected scalp electrode or electrode applied through membranes.	Check scalp electrode; reapply if necessary.
	“ST disabled: Weak signal” technical alarm.	Scalp electrode not properly attached or applied through fetal membranes.	Check scalp electrode; reapply if necessary.
		Loose skin electrode.	Check skin electrode; reapply if necessary.
		Skin electrode too dry.	Apply fresh skin electrode from sealed bag.
	“ST disabled: Noisy signal” technical alarm.	Interference with electrical noise from TENS equipment.	Disconnect TENS equipment.
		Interference with myoelectric activity (muscle noise) from the tensed maternal thigh.	Apply a new skin electrode away from the muscle.
	“ST disabled: Signal interference” technical alarm.	Interference with electrical noise from TENS equipment.	Disconnect TENS equipment.
	“Breech presentation?” technical alarm.	Undiagnosed breech position.	Confirm fetal presentation. Activate breech mode if applicable.
	“Cephalic presentation?” technical alarm.	Breech mode enabled by mistake.	Disable breech mode.
		Incorrect diagnose of breech presentation.	Confirm fetal presentation and, if applicable, disable breech mode.

Area of concern	Problem	Potential cause	Solution
FECG monitoring (cont.)	Poor quality of the fetal heart rate trace.	Loose scalp electrode or applied through fetal membranes.	Check scalp electrode; reapply if necessary.
	Poor quality of the ST data.	Loose skin electrode.	Check skin electrode; reapply if necessary.
		Skin electrode too dry.	Apply fresh skin electrode from sealed bag.
	Poor quality of ST data during contractions.	Interference with muscle noise.	Apply a new skin electrode away from the muscle.
	Repeated signal problems.	Mucous gathered in scalp electrode connector of the reusable legplate.	Clean legplate connector by flushing saline water through the legplate flush port. (See cleaning instructions.)
		Damaged legplate.	Perform legplate check according to instructions in Service Manual.
IUP monitoring	Poor signal quality, or no deflection at all.	Transducer cable damaged.	Carry out functional test or contact technical personnel.
	Readings too high	Baseline zeroing not performed.	Carry out zero IUP procedure according to IUPC manufacturer instructions.

Area of concern	Problem	Potential cause	Solution
MECG monitoring.	Poor trace quality.	Insufficient preparation of skin sites.	Repeat preparation of skin sites.
		Skin electrode gel has dried out.	Replace with fresh electrodes from unopened package. Check expiry date.
		Corroded skin electrode connectors on leadwire cable.	Remove corrosion or replace leadwire cable.
		MECG cable is loose.	Ensure the ECG cable is fully seated into the socket.
	External signal interference.	Main power socket has no ground wire.	Connect to power socket with standard ground wire.
		Strong source of interference in surrounding environment.	Remove the source of interference.
			Consider connecting the potential equalization conductor to a ground source.
	Unexpected reading.	Incorrect electrode placement.	Check the positioning of the electrodes.

Area of concern	Problem	Potential cause	Solution
NIBP monitoring.	Measurement fails.	The NIBP cuff is not wrapped tight enough around the patient's arm.	Check that the cuff is sufficiently wrapped around the patient's arm. Ensure that the cuff size is appropriate for the patient.
		Cuff incorrectly positioned or applied over clothes	Reposition cuff over patient’s bare arm, arrow over the brachial artery, and repeat measurement.
		Pressure inside cuff exceeds 300mmHg, releasing the overpressure safety valve.	Ensure cuff is not squeezed or pressed together and repeat measurement.
		Air leakage	Perform leakage test. Replace cuff and hose if needed.
	The cuff does not inflate.	The cuff hose is kinked.	Extend the hose to remove the kink.
		Blocked valves or pneumatics.	Contact service personnel.
	Incorrect reading.	Limitations in technology compared to manual measurements.	Repeat measurement.
		Patient movements interfering with measurement.	Repeat measurement.
		Patient is exhausted, emotionally stressed, affected by caffeine, in need to empty bowels, etc.	Resolve the condition if possible, and repeat measurement.
MSpO2 monitoring.	No reading.	Loose sensor or improper placement of the sensor.	Reposition the sensor.
		Inappropriate application site (e.g. too thick, too thin, deeply pigmented, or otherwise too deeply colored to permit appropriate light transmission.	Apply the sensor on a different site.

7 Specifications

7.1 Safety classifications

MDD classification:
Class IIb

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 BF, defibrillation-proof
FECG, IUP	Type CF
MSpO2, NIBP, MECG	Type CF, defibrillation-proof

Protection for defibrillation effect and restoration after defibrillation
<5 seconds

Degree of protection against harmful ingress of water		
Main Unit	IPX1	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.
Wireless ultrasound transducers (433MHz), Wireless TOCO transducer (433MHz)	IP68	Intended for underwater use.
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 wiped with moistened cloth.
NIBP cuffs, MSpO2 sensor, MECG leadset cable, FECG legplate, IUP adapter cable	-	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. The 433MHz wireless ultrasound and TOCO transducers are intended for underwater use.

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):	230 x 340 x 270 mm
Weight:	6.5 kg

Power	
Operating voltage:	100-240 VAC
Line frequency:	50/60 Hz
Power consumption (maximum):	120 VA

Battery (optional)		
Article number	P4919-00015	P4910-00006
Type	Rechargeable Lithium-ion Battery	Rechargeable Lithium-ion Battery
Nominal voltage	11.1 V	11.1 V
Nominal capacity	5200 mAh	4500 mAh
Operating time (new battery, fully charged, printer inactive)	>3 hours	>2 hours
Charging time (when monitor is powered off)	<6 hour	<6.5 hour
Charge mode	Constant current/ constant voltage (CC-CV	Constant current/ constant voltage (CC-CV
Charge current (Standard)	0.2 C (1040 mA)	0.2 C (900 mA)
Charge voltage (Standard)	12.6V	12.6V
Maximum continuous charge current	2500 mA	2250 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	
12.1” LCD with 800x600 pixel resolution displaying the following output data.	
Numerics field:	Triple fetal heart rate, FECG and/or ultrasound (bpm) Contraction, TOCO (relative units) or IUP (mmHg) T/QRS ratio, FECG Average waveform and biphasic ST indicator NIBP (SYS/DIA/MAP, mmHg or kPa) Maternal oxygen saturation, oximeter (%) Maternal pulse rate, oximeter (bpm) Maternal heart rate, MECG (bpm) Maternal respiratory rate, MECG (rpm)
CTG trace, up to 15 min visible, scrollable:	Triple fetal heart rate, FECG and/or ultrasound (bpm) Contraction, TOCO (relative units) or IUP (mmHg) Fetal movement indications
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) 0 - 100 mmHg (IUP)
Realtime traces:	FECG waveform MECG lead waveforms Respiratory waveform SpO2 waveform

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	
Number of crystals	12

FECG Recording	
Frontend performance:	
Maximum electrode potential difference:	±0.75 VDC
Input range:	±10 mV
Input bandwidth:	1.5 to 100 Hz (-3dB)
Mains frequency rejection:	>40dB
FHR detection:	
FHR sensitivity (detected beats):	50 µV (min QRS peak ampl)
FHR range:	30 - 240 bpm
FHR accuracy:	±1 bpm (30 - 180 bpm) ±2 bpm (180 - 240 bpm)
Fetal ST analysis:	
Beats per FECG Average:	30
Sensitivity, normal R-peak:	100 µV p-p (min QRS amplitude)
Sensitivity, notched R-peak:	200 µV p-p (min QRS amplitude)
T/QRS ratio range:	-0.30 to +0.90
T/QRS ratio accuracy:	±0.02
Indication of biphasic ST segment:	Graded 0, 1, 2 and 3
Detection of T/QRS baseline rises:	Rises of 0.06, 0.09, 0.11, 0.13 etc within a timeframe of 180 minutes
Detection of episodic T/QRS rises:	Rises of > 0.10 units
Detection of significant biphasic ST waveform:	Sequences of at least three consecutive BP2/ BP3s

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

IUP Recording	
Frontend performance:	
Bandwidth:	DC to 0.7 Hz (-3dB) (-40dB at 2.3 Hz)
Recording:	
Range:	0-100 mmHg (0-13.33 kPa)
Resolution:	1 mmHg
Accuracy:	±5% of displayed value

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

Maternal Pulse Oximetry Recording	
Technique:	Digital oximeter technology
MSpO2 range:	30 - 100%
MSpO2 resolution:	1%
MSpO2 accuracy:	±2% (70% - 100% range) (reference method: CO-oximeter)
Average SpO2 calculation time:	16s
Pulse rate range:	25-250 bpm
Pulse rate resolution:	1 bpm
Pulse rate accuracy:	±2 bpm
Wavelengths:	670 & 910 nm (Information about the wavelength range can be especially useful to clinicians.)
Optical output power:	< 0.75 W

Maternal NIBP Recording	
Technique:	Oscillometric
Measurement modes:	Single, Automatic, STAT (short term automatic mode)
Range, pSYS:	40-270 mmHg
Range, pDIA:	10-210 mmHg
Range, MAP:	20-230 mmHg
NIBP accuracy:	Average deviation < ±5 mmHg Standard deviation < ±8 mmHg Static pressure ±3 mmHg (static)
Cuff pressure range:	0-300 mmHg (safety pressure valve releases at > 300 mmHg)
Auto air discharging for cuff:	When measurement time exceeds 120 seconds, at power off, or when cuff pressure exceeds over-pressure protection at 300 mmHg
Average air charging time for cuff:	< 40 s
Total measurement time:	20 - 45 s typical, depending on heart rate and movement interference
Time interval for automatic mode:	2, 5, 10, 15, 30 min selectable

MECG Recording	
Input method:	3- or 5-leadwire mode, configurable
Lead selection:	I, II, III, aVR, aVL, aVF, V (5-leadwire mode) I, II, III (3-leadwire mode)
Differential input impedance:	>= 5.0 Mohm
Input circuit current:	< 0.1 µA
Baseline recovery time:	<= 3 seconds (monitoring mode)
Protection for defibrillation effect and restoration after defibrillation:	< 5 seconds
Restore time of electrode polarization after defibrillation:	ECG waveform will recover to the baseline in 10 seconds
Input range:	± 6.0 mV
Common-mode rejection ratio (CMRR):	Diagnosis mode: >90 dB Monitor mode: >115 dB HARDEST mode: 110 dB Operation mode: >110 dB
Frequency response:	Diagnosis mode: 0.05 - 130 Hz Monitor mode: 0.5 - 40 Hz HARDEST mode: 5 - 20 Hz Operation mode: 1 - 25 Hz
Noise level:	<=30 µVpp RTI (reduced to input)
Calibration signal:	1 mV ±5%
Protection:	Isolation withstanding 4000 V @ 50/60 Hz
Patient leakage current:	<10 µA

MECG Recording	
Lead off detection:	All electrodes individually except RL
Pacemaker pulse rejection capability:	None
Transients when monitor is separated from mains:	None
Display gain:	2.5, 5, 10, 20, 40 mm/mV, adjustable
Display time base:	12.5 mm/s, 25 mm/s, 50 mm/s, adjustable
Display aspect ratio:	1:20 to 3.2:1 depending on display gain and time base setting
Maximum electrode potential difference	±500 mVDC
Auxiliary output	None
Synchronizing pulse for cardioversion:	None
MHR range:	15 - 300 bpm
MHR resolution:	1 bpm
MHR accuracy:	±1% or ±1 bpm, whichever is higher
MHR detection sensitivity:	>=0.20 mVpp
Rejection capability for high T wave:	0 - 1 mV T-wave amplitude
MHR step response:	6-10 s (80 - 120 bpm and 80 - 40 bpm)
MHR averaging:	Every 4 pulses
MHR accuracy in cases of ventricular bigeminy:	If all QRS wave groups are calculated, HR is 80 bpm; if only larger R wave or S wave is calculated, HR is 40 bpm.
MHR accuracy in cases of slow alternating ventricular bigeminy:	If all QRS wave groups are calculated, HR is 60 bpm; if only larger wave is calculated, HR is 30 bpm.
MHR accuracy in cases of rapid alternating ventricular bigeminy:	If all QRS wave groups are calculated, HR is 120 bpm.
MHR accuracy in cases of bidirectional systoles:	If all QRS wave groups are calculated, HR is 90 bpm; if only larger wave is calculated, HR is 45 bpm.

Respiratory Recording	
Technique:	Impedance based, measured between MECG leadwires RA-LL (R-F)
Detection sensitivity:	0.2 - 3 ohms
Baseline impedance range:	500 - 2000 ohms (50 - 120 kHz excitation frequency)
RR range:	0 - 120 rpm
RR resolution:	1 rpm
RR accuracy:	±2 rpm
Current applied to patient for respiration sensing, leads-off detection, and active noise suppression:	< 300 µA, 65 kHz (±10%)

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
Recorded Information:	FHR1, and FHR 2 trace/marks, TOCO and IUP trace, T/QRS trace, FECG average waveforms, biphasic ST indicators, ST event indicators, Fetal movement mark, Time & date, Printing speed, Patient Name & ID, FHR2 Offset, MHR, MSpO2
Printer head temperature detection:	Thermistor
Out-of-paper detection:	Photo interrupter Watermark notification on last 5 paper sheets

7.5 Wireless subsystem

Communication (2.4 GHz version)	
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

Communication (433 MHz version)	
Transmission frequency:	433 MHz
Whereof FHR1 channels 2 to 15 (configurable):	433.1 MHz to 434.4 MHz in steps of 0.1 (MHz)
Whereof TOCO channels 2 to 15 (configurable):	433.1 MHz to 434.4 MHz in steps of 0.1 (MHz)
Receiver bandwidth:	0.1 MHz
Modulation technique:	GFSK

Communication (433 MHz version)	
Effective radiated power:	14 dB
Effective communication range (general):	> 10 m
Effective communication range (under water):	> 5 m
Communication range in air (line of sight):	70 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 P1221-05037 P1221-05038	Wired ultrasound transducer
P1271-05043 P1271-05038 P1271-05021	Wireless FHR1 ultrasound transducer (2.4GHz)
P1271-05050	Wireless FHR1 ultrasound transducer (433MHz, for underwater use)
P1271-05042 P1271-05022	Wireless FHR2 ultrasound transducer (2.4GHz)
P1271-05051	Wireless FHR2 ultrasound transducer (433MHz, for underwater use)
P1224-05040 P1224-05042 P1224-05048 P1224-05052	Wired TOCO transducer
P1271-05044 P1271-02055	Wireless TOCO transducer (2.4GHz)
P1271-05052	Wireless TOCO transducer (433MHz, for underwater use)
P1221-12003 P1221-12035	Wired fetal movement marker
P4907-00012 P1271-12006	Wireless fetal movement marker
P2224-08001	Transducer belt
CNS000107 (Neoventa Medical)	Transducer belt
CNS000108 (Neoventa Medical)	Transducer belt - 10 cm wide, suitable for high BMI patients
P7001-00030	Aquasonic coupling gel

7.6.2 FECG and IUP consumables and accessories

Part number	Description
P1263-03024	FECG legplate for Goldtrace
CNS000004 (Neoventa Medical)	Goldtrace fetal spiral electrode
CNS000003 (Neoventa Medical)	Single-packed skin electrode suitable for fetal ST analysis
CNS000106 (Neoventa Medical)	Legplate belt suitable for tightening the reusable legplate to the maternal thigh
IPC-5065 (Clinical Innovations)	IUP adapter cable for Clinical Innovations/Koala
IPC-5000 (Clinical Innovations)	Koala IUP catheter
P1263-03027	IUP adapter cable for Utah Medical/Intran
IUP-400 IUP-450 IUP-500 IUP-550 (Utah Medical)	IntranPlus IUP catheters

7.6.3 NIBP cuffs and hose

Part number	Description
P9001-00473 P9001-00108	Adult NIBP cuff (upper arm perimeter 25 cm-35 cm)
P9001-00474	Adult NIBP cuff (upper arm perimeter 33 cm-47 cm)
P9001-00503	Adult NIBP cuff (upper arm perimeter 20.5 cm-28 cm)
P9001-00504	Adult NIBP cuff (upper arm perimeter 27 cm-35 cm)
P9001-00505	Adult NIBP cuff (upper arm perimeter 34 cm-43 cm)
P9001-00482	Adult NIBP cuff (thigh perimeter 46 cm-66 cm)
P9001-00506	Adult NIBP cuff (thigh perimeter 42 cm-54 cm)
P9001-00485	NIBP cuff extension hose (3.0 m)
P9001-00472 P9001-00403 P9001-00109	NIBP cuff extension hose (2.0 m)

7.6.4 MSpO2 sensors and cables

Part number	Description
P7002-00008	MSpO2 sensor
P9001-00501 P9001-00484	MSpO2 extension cable (also require P7002-00008 for use)

7.6.5 MECG consumables and accessories

Part number	Description
P9001-00401 P9001-00201	5-leadwire MECG cable
P9001-00478 P5300-00004	3-leadwire MECG cable
P7001-00296 P7001-00295	Disposable ECG electrode

7.6.6 Printer paper

Part number	Description
P8105-00063	Printer paper for ST analysis with 50-210 bpm @ 20 bpm/cm scaling
P8105-00003	Printer paper with CTG-only grid, 50-210bpm range with 20 bpm/cm scaling
P8105-00004	Printer paper with CTG-only grid, 30-240bpm range 30 bpm/cm scaling (USA)

7.6.7 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
P4940-00010	Mains fuse T2AH250V

7.6.8 Batteries

Part number	Description
P4901-01014 P4910-00006 P4901-00015	Rechargeable system lithium-ion battery
P4901-01013 P4901-01030	Rechargeable lithium-polymer battery for wireless FHR1, FHR2 and TOCO transducer

7.6.9 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 STAN S41 Maternal and Fetal Monitor and the central monitoring system.
Central monitoring systems compatible with fetal ST analysis	Central monitoring systems capable of communicating ST information according to Neoventa STAN protocol. RS-232 or ethernet connection possible.	See www.neoventa.com/support/cms-with-st/ for an up-to-date list of compatible systems.

7.6.10 Training materials and clinical guidelines

Neoventa Medical part number	Product	Description
TRM100300/C	Web based CTG training - hospital or individual license	Web-based training in CTG interpretation. Includes access to online training material and certification test for hospital staff. Hospital is provided with an administrator login for creating and managing individual accounts for hospital staff members. After passed certification test, each student receives a certificate in electronic format.
TRM100300	Web based training in ST analysis - hospital or individual license	Web-based training in fetal ST analysis. Includes access to online training material and certification test for hospital staff. Individual certificates are provided in electronic format. Hospital receives an administrator login for creating and managing individual accounts for hospital staff members.

Neoventa Medical part number	Product	Description
CLD300201	Green book part I	The Physiology of Fetal Surveillance, The Green Book of Neoventa Part 1. Educational book with basic physiology, CTG physiology, CTG interpretation, FECG physiology, ST analysis and assessment of the newborn child.
CLD300230	Green book part II	Fetal Surveillance and assessments of fetal reactions, The Green Book of Neoventa Part II. Educational book includes both user aspects from published studies to a set of 63 authentic index cases, to illustrate the physiology and further understanding to fetal reactions during the process of being born.
CLD300200/7 - Russian CLD300200/31 - Dutch CLD300200/33 - French CLD300200/34 - Spanish CLD300200/44 - UK English CLD300200/45 - Danish CLD300200/46 - Swedish CLD300200/47 - Norwegian CLD300200/48 - Polish CLD300200/49 - German CLD300200/351 - Portuguese CLD300200/358 - Finnish CLD300200/372 - Estonian	Clinical guidelines for ST analysis	Clinical guideline card for ST analysis following applicable regional recommendations.

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	
Display Mode	Default display mode at power on	Fetal only Fetal and Maternal Maternal only 7 MECG lead waveforms	Fetal only	
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
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	
Touch key lock	Whether to activate the touch key lock when holding down the MENU button	On Off	Off	
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	

Setting name	Description	Options/ Constraints	Factory default	Comment
Auto start recording	Whether to start recording immediately after power on	On Off	Off	
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
Auto start printing	Whether to start printing immediately when a new recording starts, or a paused recording is continued	On Off	Off	
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	
Print NIBP	Whether to print NIBP measurements on printout	On Off	On	
Print MHR trend	Whether to print maternal heart rate as a trace on printout	On Off	On	
Print Trend value	Time interval for printing maternal parameter values on printout, in minutes	Off, 5, 10, 15, 20, 30, 40, 50, 60	Off	
Print MECG	Whether to print MECG waveforms on printouts	On Off	Off	
Print FECG Average	Whether and how often to print the FECG average waveform on printouts	Off 2 min 4 min 5 min	2 min	
Gestational age format	Format to use when printing gestational age	XX+X XX-X	XX+X	
Paper format	Format of paper installed in the printer paper tray	CTG-only grid CTG+ST grid	CTG+ST grid	This setting must match the preprinted grid of the thermal paper available at the ward. See further “Printer paper” on page 157
CMS Settings				
Machine id	Id number used when setting the ethernet Id (MAC address) of the system.	1 to 99	32	If devices are used connected to an ethernet network, this number must be set to be unique within the ward.

Setting name	Description	Options/ Constraints	Factory default	Comment
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	-	
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
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	-	

Setting name	Description	Options/ Constraints	Factory default	Comment
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.
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	
FHR2 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 shall be displayed with -20 resp. +20 bpm offset on screen and printout	Off FHR2 -20 FHR2 +20	Off	FHR2 -20 is common practice in China, while FHR2 +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 and FECG	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”
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	
AFM operation mode	Operation mode for automatic fetal movement detection	Off, TOCO, FHR, Both	Off	

Setting name	Description	Options/ Constraints	Factory default	Comment
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
FECG Settings:				
Mains frequency	Defines the frequency for which the power line interference removal filter shall be optimized	50Hz, 60Hz	50Hz	Set this equal to the mains supply alternating current frequency in your country
Display speed (mm/s)	Display speed for the FECG signal in the “Fetal and FECG” viewmode	12.5, 25, 50	25	
Gain (mm/mV)	Display amplification for the FECG signal in the “Fetal and FECG” viewmode	5, 12.5, 25, 50, 100	50	
Transducer disconnection alarm	Defines whether alarm signals shall be generated when FECG and IUP transducers are disconnected	On Off	Off	Configurable only if “Fetal Alarm” set to “On”
Default ST mode	Default activation state for fetal ST analysis function when starting a new recording	On, Off	On	Configurable only if the ST analysis option is installed
FECG sound volume	Default sound volume for audible feedback from FECG HR detection.	Off 1 to 16	4	

7.7.3 Maternal settings

Setting name	Description	Options/ Constraints	Factory default	Comment
MECG Settings				
Leadset type	Type of leadset cable used for MECG monitoring	5 leadwires 3 leadwires	3 leadwires	
5-leadwire mode	Default lead presented in user interface when using 5-leadwire cable	I, II, III, aVR, aVL, aVF, Vx	II	
3-leadwire mode	Default lead presented in user interface when using 3-leadwire cable	I, II, III	II	
Speed (mm/s)	Horizontal display resolution for presenting MECG signals on screen	12.5, 25, 50	25	
MECG Alarm	Whether to generate level alarms for MHR calculated from MECG signal	On Off	On	
High MHR alarm threshold	Upper alarm threshold for MECG HR level alarms	16 to 300	120	Cannot be set below “Low MHR alarm threshold”
Low MHR alarm threshold	Lower alarm threshold for MECG HR level alarms	15 to 299	50	Cannot be set above “High MHR alarm threshold”
Gain (mm/mV)	Display amplification for presenting MECG signals on screen	2.5, 5, 10, 20, 40	10	
Operating Mode	Defines the clinical setting for which signal interference removal filters shall be optimized	Diagnosis Surgery Monitor Hardest	Monitor	
Mains filter frequency	Defines the frequency for which the power line interference removal filter shall be optimized	Off, 50Hz, 60Hz	50Hz	It is recommended to set this equal to the mains supply alternating current frequency in your country
Scale indicator	Whether to display scale indicator for MECG signals on screen	On Off	On	
Leads Standard	Defines which ECG leads naming convention to use on screen and printouts	European USA	European	
Pacing Alarm	Whether to generate an alarm signal at suspected pacemaker activity	On Off	Off	
Display MHR	Whether to display MHR as a trace in CTG trend on screen	On Off	On	
Resp Settings				
Display amplification	Display amplification for presenting respiratory lead signal on screen	0.25, 0.5, 1, 2, 4	1	
Respiration alarms on/off	Whether to generate level alarms for respiratory rate (RR) calculated from MECG signal	On Off	On	
High Resp alarm threshold	Upper alarm threshold for RR level alarm	1 to 120	30	Cannot be set below “Low Resp alarm threshold”
Low Resp alarm threshold	Lower alarm threshold for RR level alarm	0 - 119	8	Cannot be set above “High Resp alarm threshold”

Setting name	Description	Options/ Constraints	Factory default	Comment
Apnea alarm (s)	Time between last calculated RR value until generation of apnea alarm (seconds)	Off, 10 to 40	10	Password protected
MSpO2 Settings				
MSpO2 Alarm	Whether to generate level alarms for oxygen saturation and pulse rate calculated from MSpO2 signal	On Off	On	
Low MSpO2 alarm threshold	Lower alarm threshold for MSpO2 oxygen saturation level alarm	90 to 99	90	
High MPR alarm threshold	Upper alarm threshold for MSpO2 pulse rate level alarm	16 to 300	120	Cannot be set below “Low MPR alarm threshold”
Low MPR alarm threshold	Lower alarm threshold for MSpO2 pulse rate level alarm	15 to 299	50	Cannot be set above “High MPR alarm threshold”
MSpO2 log interval	Interval with which recorded oxygen saturation is recorded in the event log	Off, 5, 15, 30, 60	Off	
NIBP Settings				
Unit	Display unit for NIBP	mmHg, kPa	mmHg	
Pressure	Initial inflation pressure at start of NIBP measurement	100 to 300 mmHg	160	Should be set slightly higher than anticipated systolic pressure
Display MAP	Whether to display the MAP value of NIBP measurements on screen and printouts.	Yes No	No	
NIBP Level alarms	Whether to generate NIBP level alarms	On Off	On	
SYS Level alarm	Whether to generate NIBP level alarms based on systolic pressure (SYS)	On Off	On	
High SYS alarm threshold	Upper alarm threshold for systolic NIBP level alarm	41 to 280	160	Cannot be set below “Low SYS alarm threshold”
Low SYS alarm threshold	Lower alarm threshold for systolic NIBP level alarm	40 to 279	90	Cannot be set above “High SYS alarm threshold”
DIA Level alarm	Whether to generate NIBP level alarms based on diastolic pressure (DIA)	On Off	On	
High DIA alarm threshold	Upper alarm threshold for diastolic NIBP level alarm	11 to 210	90	Cannot be set below “Low DIA alarm threshold”
Low DIA alarm threshold	Lower alarm threshold for diastolic NIBP level alarm	10 to 219	50	Cannot be set above “High DIA alarm threshold”
MAP Level alarm	Whether to generate NIBP level alarms based on mean arterial pressure (MAP)	On Off	Off	
High MAP alarm threshold	Upper alarm threshold for MAP level alarm	21 to 240	110	Cannot be set below “Low MAP alarm threshold”
Low MAP alarm threshold	Lower alarm threshold for MAP level alarm	20 to 239	60	Cannot be set above “High MAP alarm threshold”

7.8 Standards compliance

Reference	Name
IEC 60601-1:2005+A1:2012+A2:2020	General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020	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+A2:2020	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 60601-2-27:2011	Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30:2018	Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-37:2007+A1:2015	Particular requirements for the basic safety and essential performance of ultrasonic diagnostic and monitoring equipment
IEC 60601-2-49:2018	Particular requirements for the safety of multifunction patient monitoring equipment
ISO 80601-2-61:2017+COR1:2018	Particular requirements for the basic safety and essential performance of pulse oximeter equipment
EN 1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009	Non-invasive sphygmomanometers. General requirements
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:

Neoventa Medical AB
Phone: +46 31 7583212
E-mail: ts@neoventa.com

Guangzhou Sunray Medical Apparatus Co., Ltd.
Phone: +86 20 87570362
E-mail: techsupport@sunray.cn

8.2 Abbreviations

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

Abbreviation	Full Description
AC	Alternating Current
BIPH	Biphasic ST waveform
CMS	Central Monitoring System
CST	Contraction Stress Test
CTG	Cardiotocography
ECG	Electrocardiogram
FECG	Fetal ECG
FHR	Fetal Heat Rate
FM	Fetal Movement
HR	Heart Rate
IUP	Intra-uterine pressure
LCD	Liquid Crystal Display
MECG	Maternal ECG
MRI	Magnetic Resonance Imaging
NIBP	Non-invasive Blood Pressure

Abbreviation	Full Description
NST	Nonstress Test
NTP	Network Time Protocol
PR	Pulse Rate
RESP	Respiration
RR	Respiration Rate
SpO2	Saturation Pulse Oxygen
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
TOCO	Tocodynamometer
T/QRS	T-wave height normalized against amplitude of QRS complex, expressed in percent
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**
RF emissions: CISPR 11	Group 1
RF emission: CISPR 11	Class A
Harmonic emissions: IEC 61000-3-2	N/A
Voltage fluctuations/ flicker emissions: IEC 61000-3-3	N/A

8.3.2 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100kHz repetition frequency	±2 kV power supply lines ±1 kV signal input/output 100kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode
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 and 70% UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250/300 cycle.	0% UT; 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT; 1 cycle and 70% UT; 25/30 cycles; Single phase: at 0°. 0% UT; 250/300 cycle.
Power frequency magnetic field IEC 61000-4-8	30 A/m 50/60Hz	30 A/m 50/60Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 2Hz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 2Hz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 2Hz	3 V/m 80 MHz – 2.7 GHz 80% AM at 2Hz
NOTE: UT is the AC mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test frequency (MHz)	**Band a) (MHz)**	**Service**	**Modulation**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance level (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430-470	GMRS460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800-960	GSM 800/ 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Guidance and manufacturer's declaration - electromagnetic immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test Frequency**	**Modulation**	**IEC 60601-1-2 Test Level (A/m)**	**Compliance Level (A/m)**
	30 kHz	CW	8	N/A
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	Pulse modulation 50 kHz	7.5	7.5

8.4 Scientific references

8.4.1 Publications on fetal ST analysis

For a complete and up-to-date list if articles in fetal ST analysis, including abstracts, please see http://www.neoventa.com/st-analysis-clinical-bibliography.

2001 - Amer-Wahlin et al.
Amer-Wahlin et al. Cardiotocography only versus cardiotocography plus ST analysis of fetal electrocardiogram for intrapartum fetal monitoring: a Swedish randomised controlled trial. Lancet. 2001;358(9281):534-8.

2014 - Olofsson et al.
A critical appraisal of the evidence for using cardiotocography plus ECG ST interval analysis for fetal surveillance in labor. Part I: the randomized controlled trials. Acta Obstet Gynecol Scand 2014; 93:556-569.

2014 - Olofsson et al.
Olofsson et al. A critical appraisal of the evidence for using cardiotocography plus ECG ST interval analysis for fetal surveillance in labor. Part II: the meta-analyses. ACTA Obstet Gynecol Scand 2014; 93:571-586.

2015 - Amer-Wåhlin and Kwee
Amer-Wahlin and Kwee. Combined cardiotocographic and ST event analysis: A review. Best Pract Res Clin Obstet Gynaecol. 2015 Jun 23. pii: S1521-6934(15)00107-8. doi: 10.1016/j.bpobgyn.2015.05.007. Epub ahead of print

2016 - Blix et al.
Blix E, Brurberg KG, Reierth E, Reinar LM, Øian P. ST waveform analysis versus cardiotocography alone for intrapartum fetal monitoring: a systematic review and meta-analysis of randomized trials. Acta Obstet Gynecol Scand 2016; 95:16-27.

2016 - van 't Hooft et al.
Van 't Hooft et al. ST-analysis in electronic foetal monitoring is cost-effective from both the maternal and neonatal perspective. J Matern Fetal Neonatal Med. 2016 Jan 14:1-6. (Epub ahead of print)

2016 - Vayssière et al.
Vayssière et al. (2016) Is STAN monitoring associated with a significant decrease in metabolic acidosis at birth compared with cardiotocography alone? Review of the three meta-analyses that included the recent US trial. Acta Obstet Gynecol Scand. 2016 June 6. doi: DOI: 10.1111/aogs.12923.

2017 - Chandraharan
Chandraharan STAN a friend or a foe? J Matern Fetal Neonatal Med. 2017 Jan 23:1-8. doi: 10.1080/14767058.2016.1276559.

8.4.2 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

8.4.3 Publications on Fischer's analysis

The implementation of Fisher's analysis in the STAN S41 Maternal and 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.

8.4.4 Publications on Krebs' analysis

The implementation of Krebs' analysis in the STAN S41 Maternal and 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.

8.4.5 Publications on NST - Nonstress test

The implementation of NST in the STAN S41 Maternal and 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.

8.4.6 Publications on CST - Contraction stress test

The implementation of CST in STAN S41 Maternal and 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:	Maternal and Fetal Monitor
Model:	SRF618X9 - STAN S41
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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