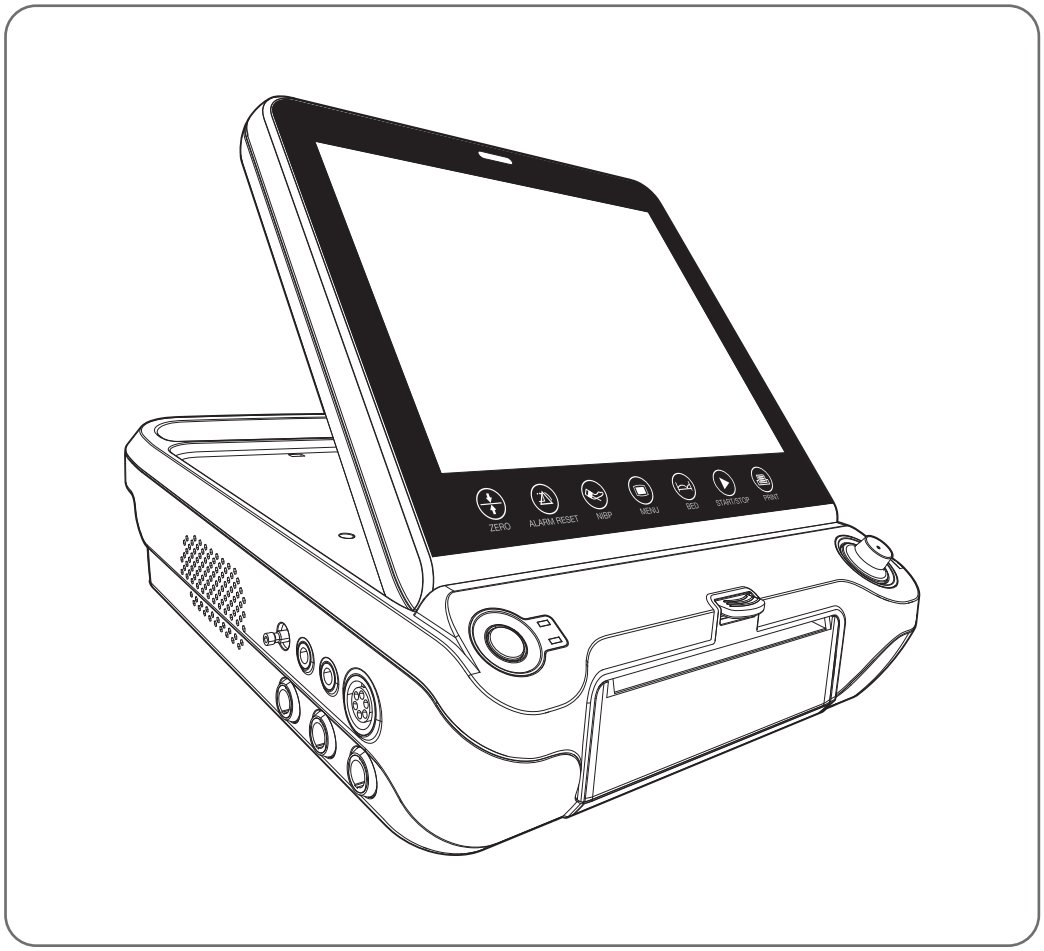
stan S41

Maternal and Fetal Monitor
SRF618X9

Service Manual



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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.

Contents

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.

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.

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.

1.2 Intended use environment

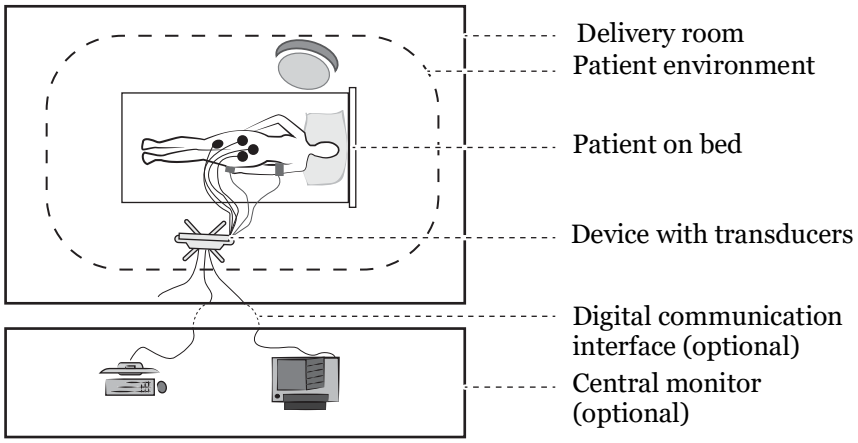


Figure 1:1 Intended use environment

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.

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 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

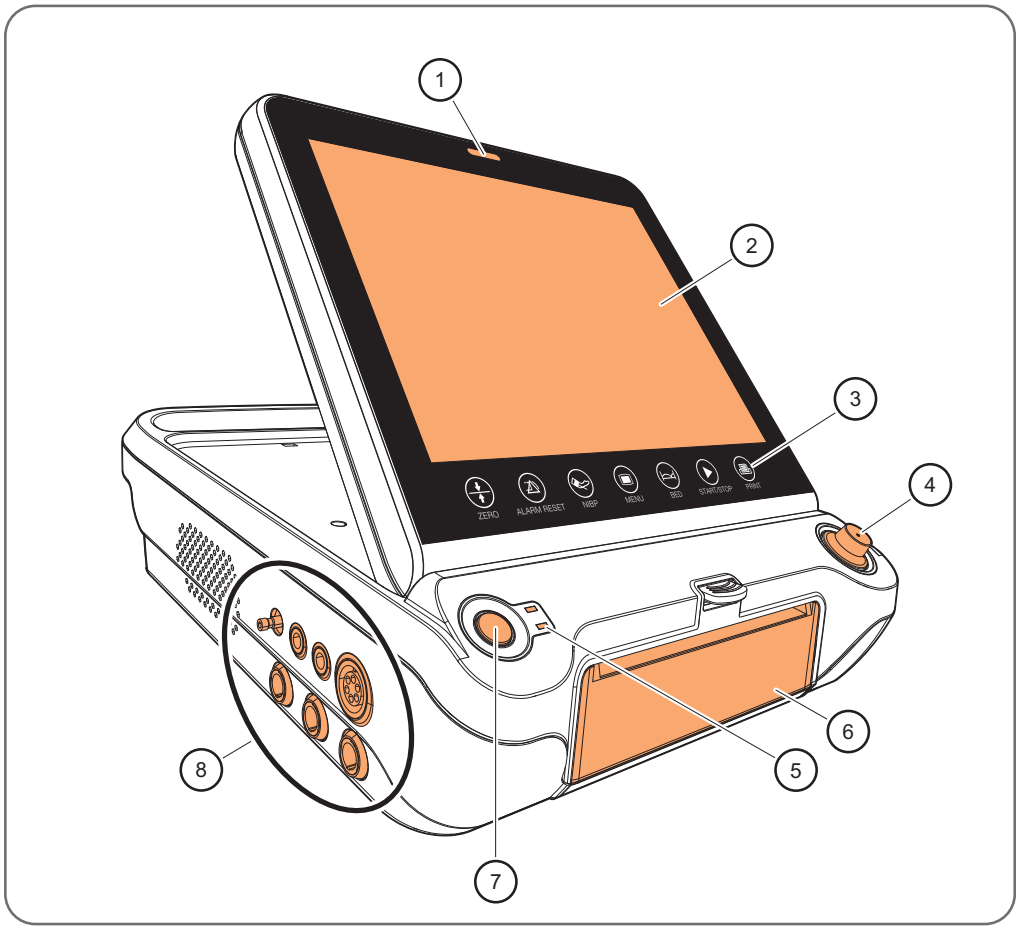


Figure 1:2 Main unit front view

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

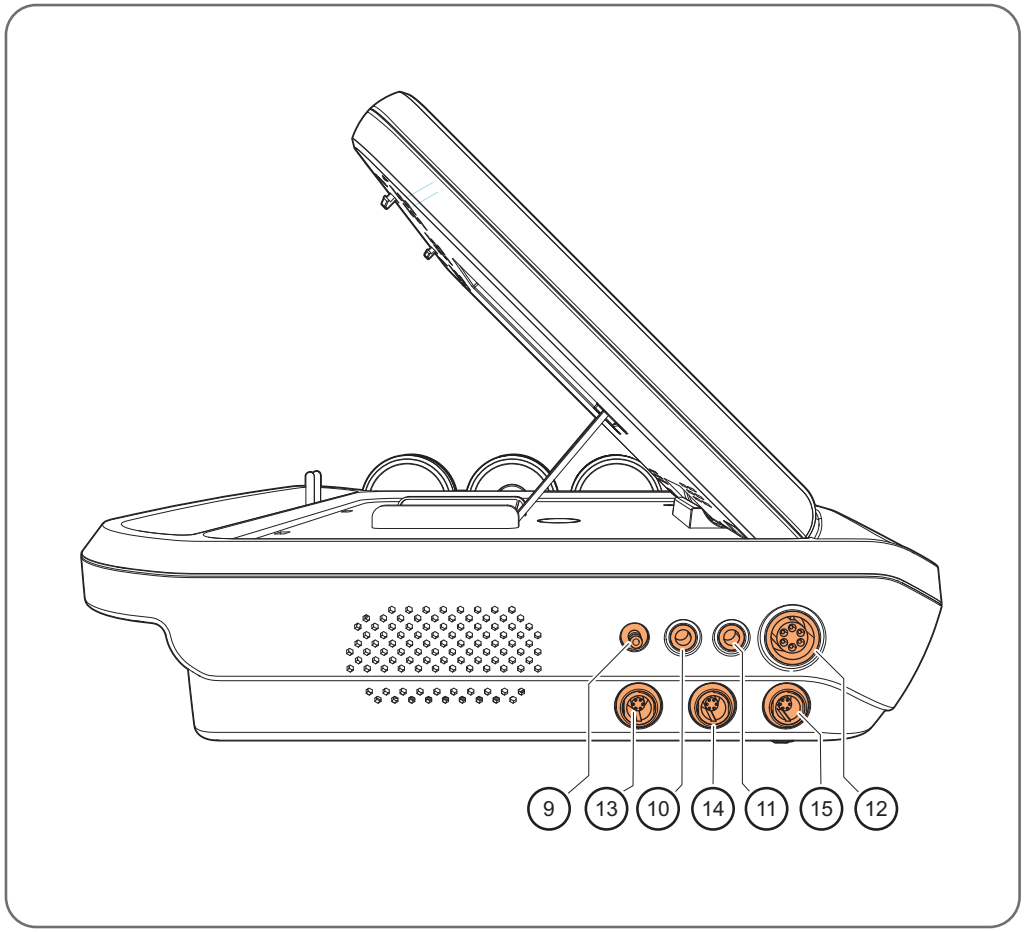


Figure 1:3 Main unit left side view

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)

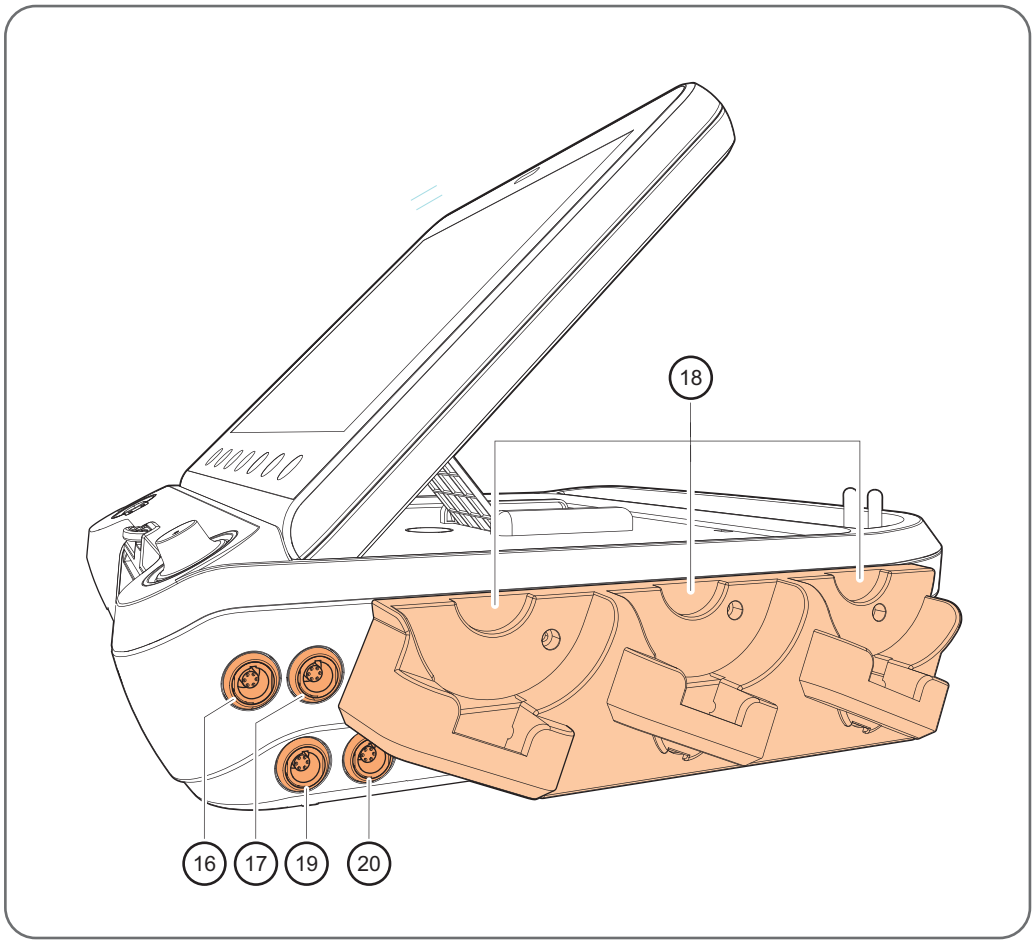


Figure 1:4 Main unit right side view

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

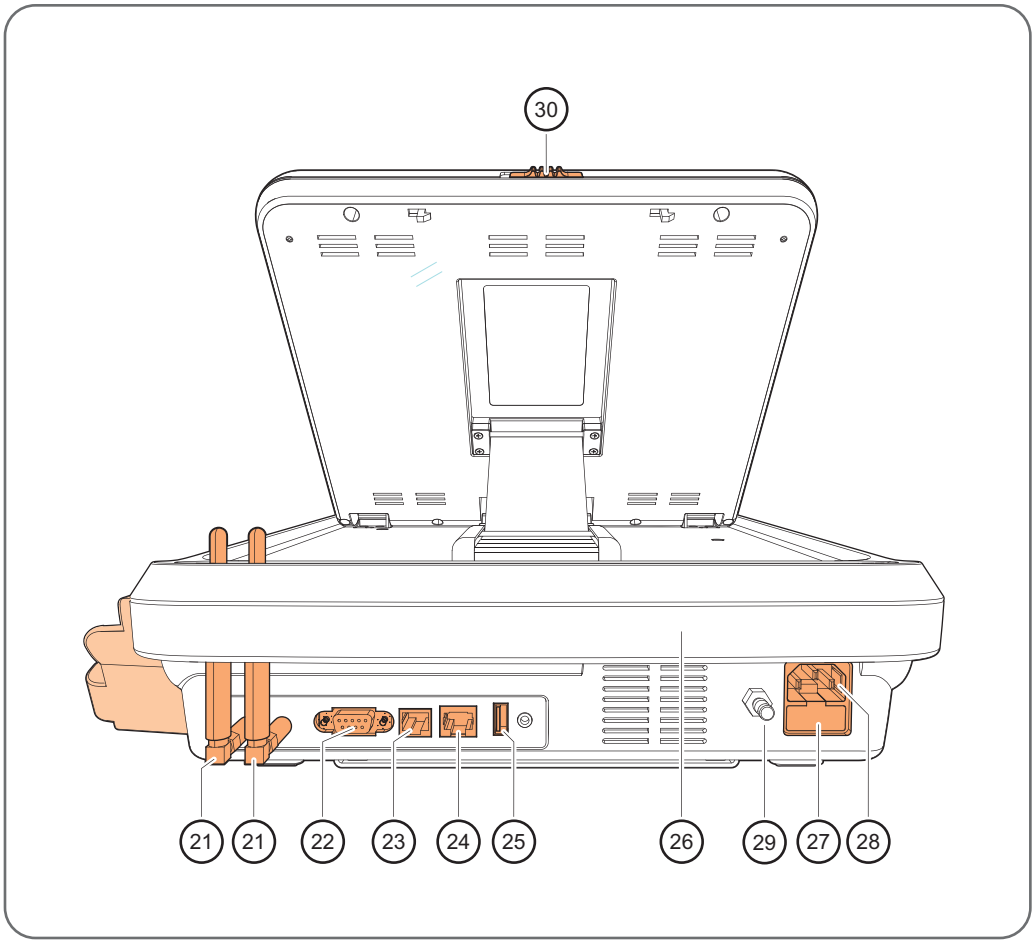


Figure 1:5 Main unit rear view

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

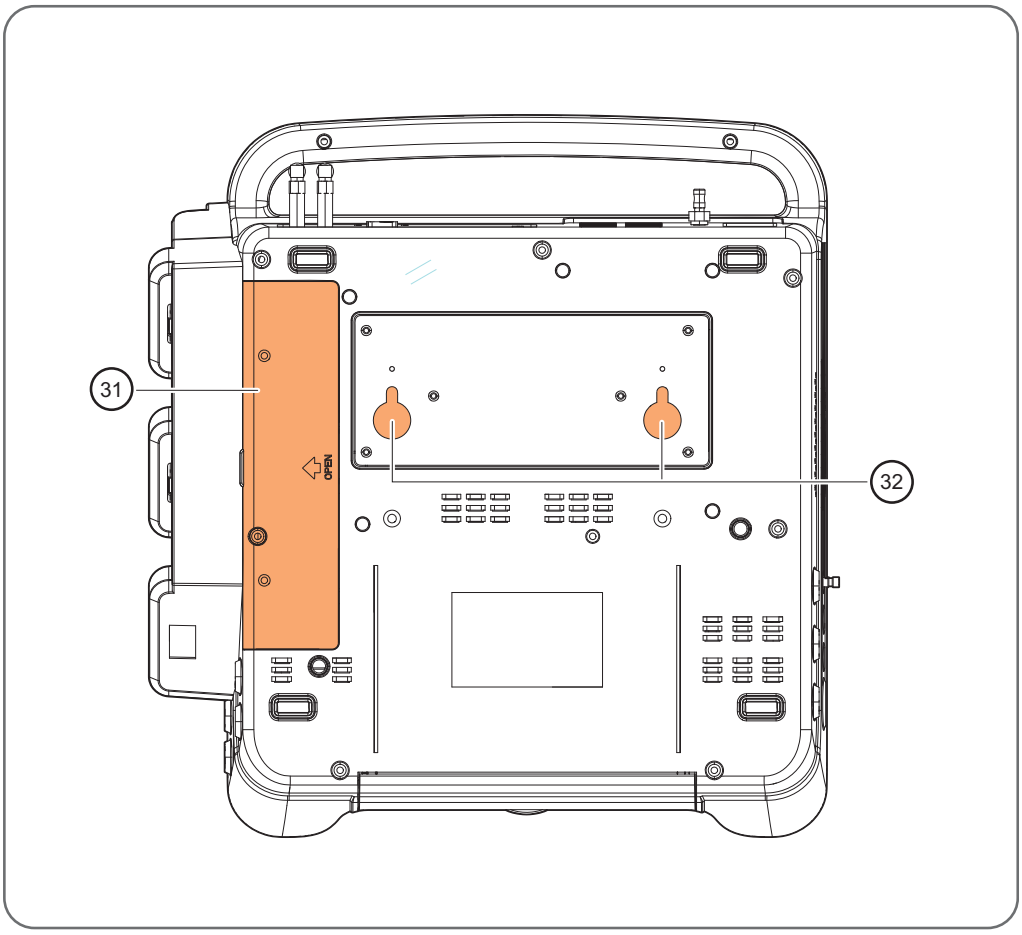


Figure 1:6 Main unit bottom view

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.

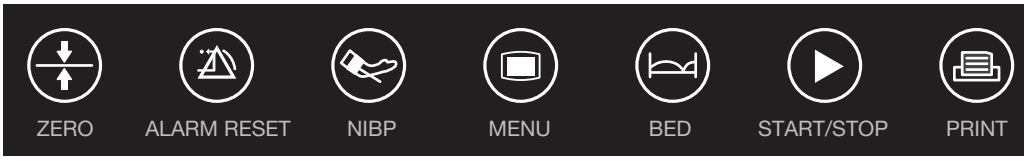


Figure 1:7 Touch key bar located below the main screen

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	Access to quick settings menu.
START/ STOP	Start/Stop recording	Starts and stops the recording mode.
PRINT	Printer start/stop	Starts and stops the printing function.

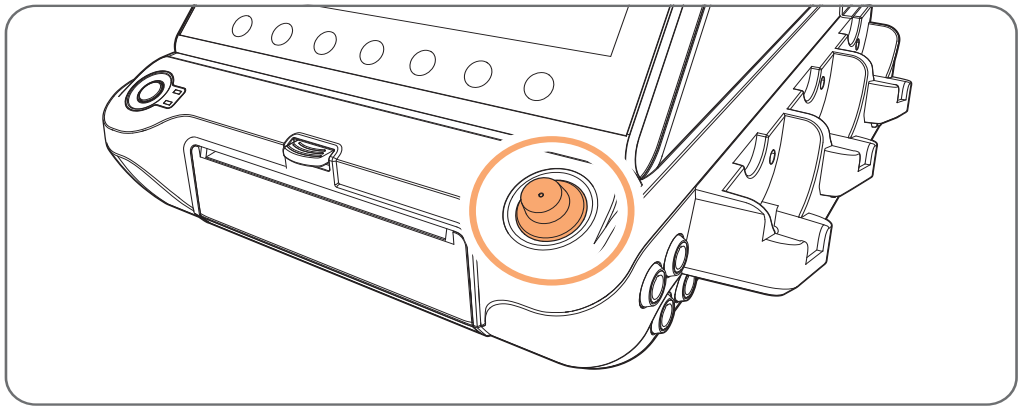


Figure 1:8 Control knob

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 111.

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.

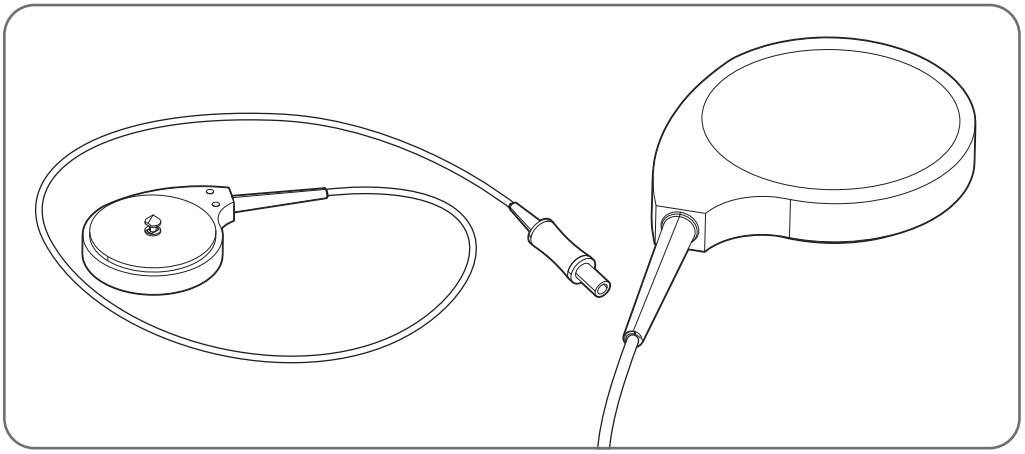


Figure 1:9 Wired ultrasound transducer for recording of fetal heart rate

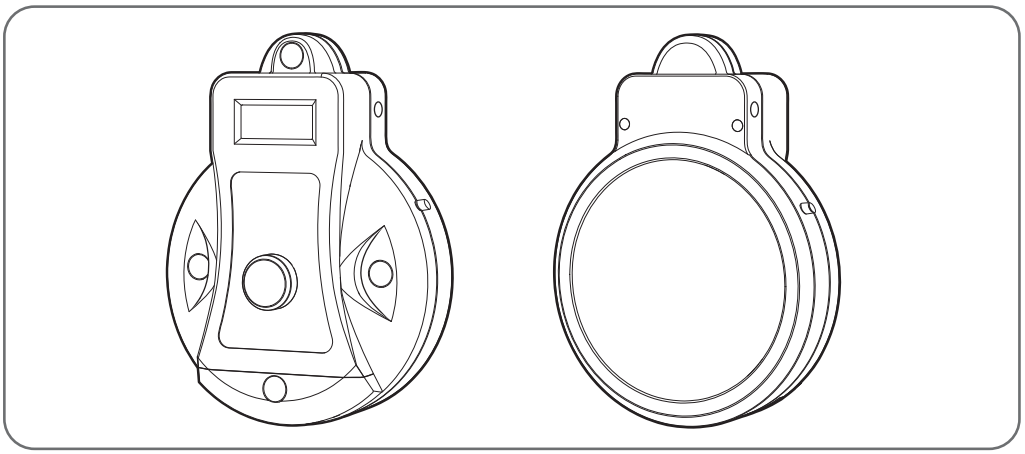


Figure 1:10 Wireless ultrasound transducer for recording of fetal heart rate

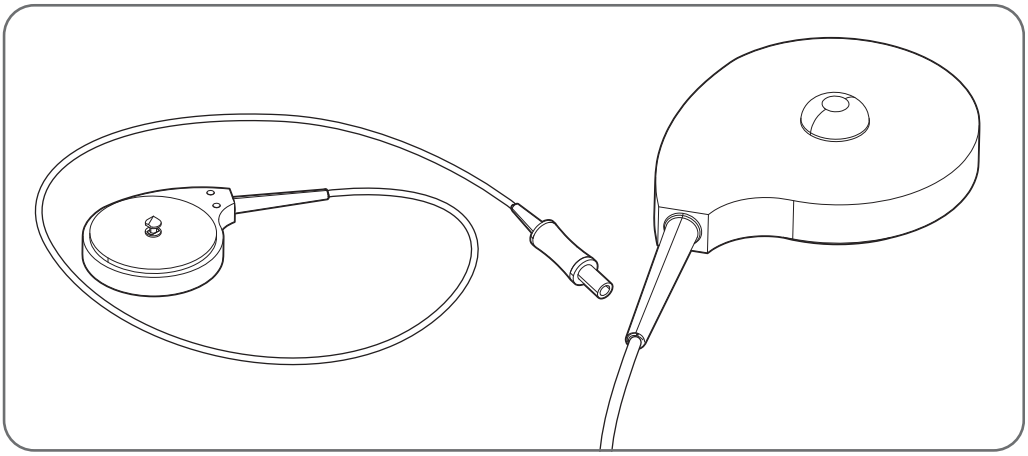


Figure 1:11 Wired TOCO transducer for recording uterine contractions

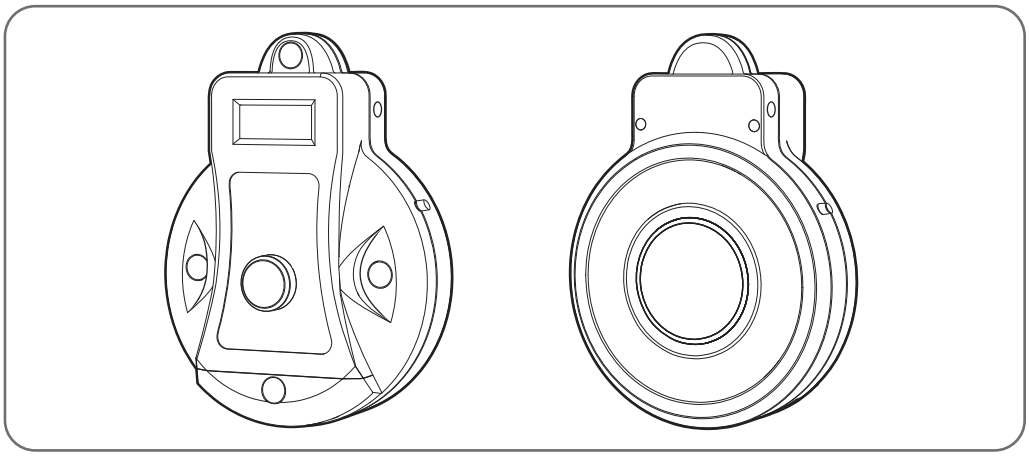


Figure 1:12 Wireless TOCO transducer for recording uterine contractions

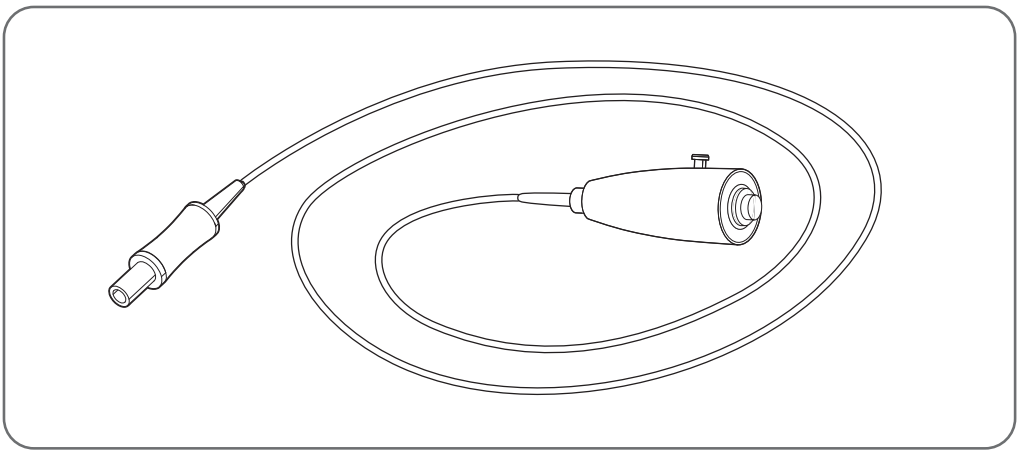


Figure 1:13 Wired fetal movement marker for manual registration of fetal movements

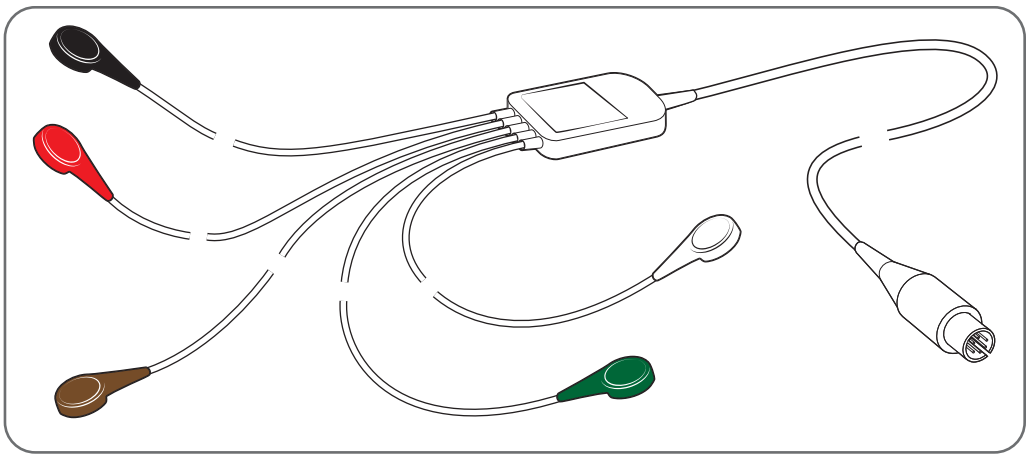


Figure 1:14 5-leadwire MECG leadset for recording of maternal ECG, heart rate and respiratory rate

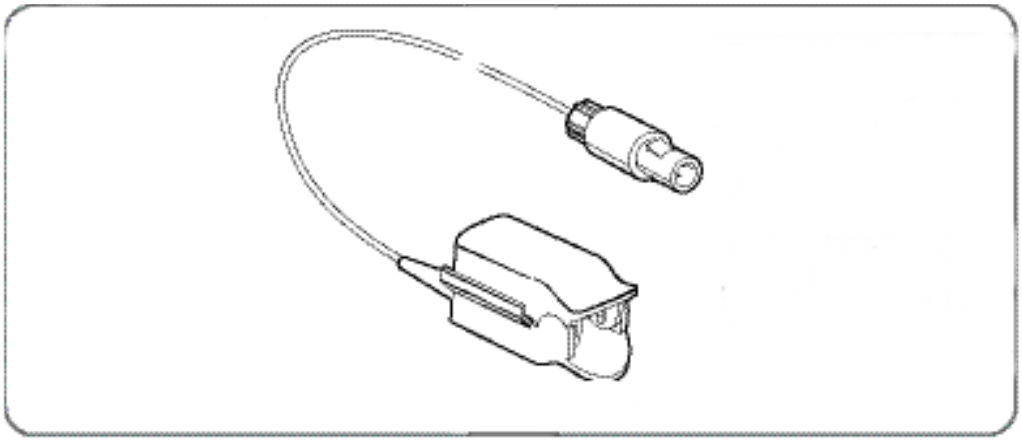


Figure 1:15 MSpO2 sensor for recording of maternal pulse and oxygen saturation

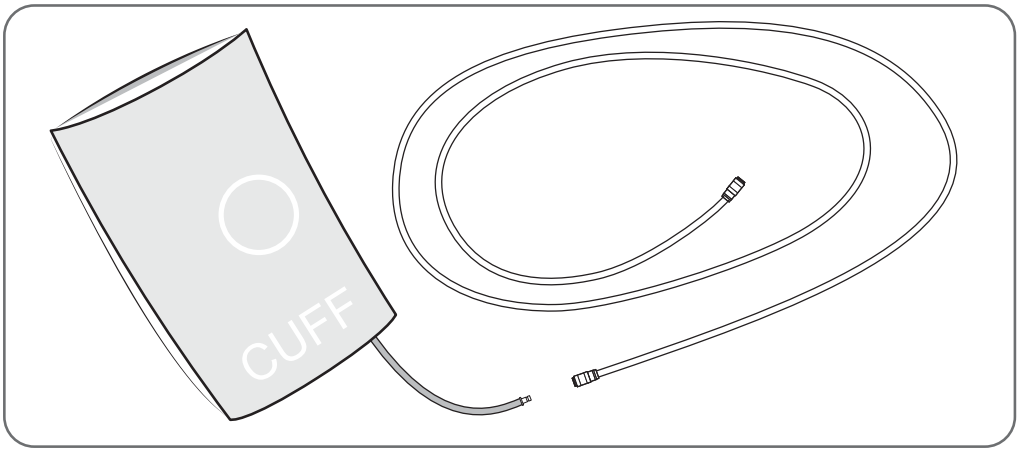


Figure 1:16 NIBP cuff for non-invasive measurement of maternal blood pressure

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
Wired TOCO transducer	P1224-05052
Wireless FHR2 ultrasound transducer (2.4GHz. Only for use with 2.4GHz charging rack.)	P1271-05042
Wireless FHR1 ultrasound transducer (433MHz, for underwater monitoring. Only for use with 433MHz charging rack.)	P1271-05050
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)

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 Koala	IPC-5065 (Clinical Innovations)
Koala IUP catheter	IPC-5000 (Clinical Innovations)
IUP adapter cable for IntranPlus	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)
5-leadwire MECG leadset cable	P9001-00477
3-leadwire MECG leadset cable	P9001-00478
Disposable ECG electrode for MECG recording	P7001-00296
MSpO2 clip	P7002-00008
MSpO2 extension cable	P9001-00501
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 (US)	P8105-00004
Power cord	P5301-00001
Fuse T2AH250V	P4904-00010
Rechargeable system battery (lithium-ion)	P4910-00015

Rechargeable battery for wireless transducer (lithium-polymer)	P4901-07006

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.

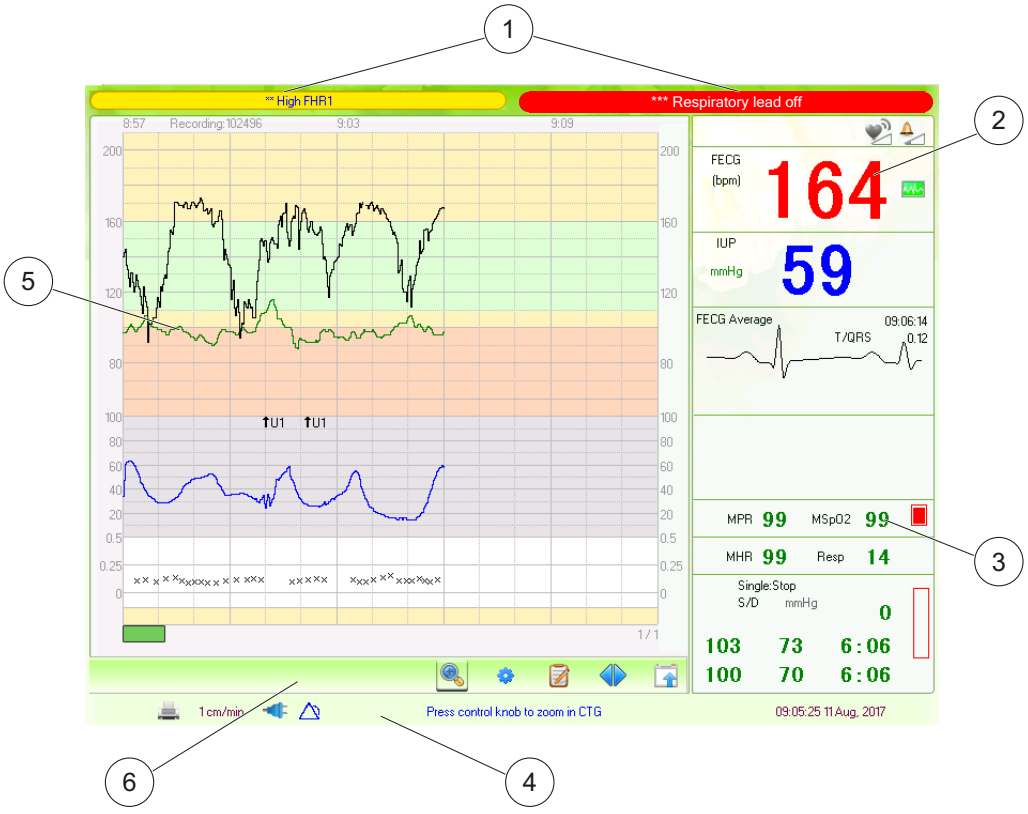


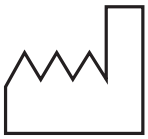
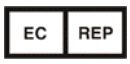
Figure 1:17 Main screen

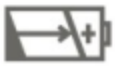
Label	Name	Function
1	Alarm field	Display area for visual alarm signals, showing currently active alarm conditions. Physiological alarms are displayed on the left and technical alarms to the right.
2	Fetal numeric field	a) Wireless channel indicator b) FHR sound volume indicator c) Audible alarm sound 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.
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) Printer status indicator as printing, printer error (printer symbol is crossed through) or idle mode (printer symbol is gray). b) Horizontal resolution of the CTG trace on screen. c) Power status indicator. d) Alarm status indicator. e) System feedback information. f) Central monitoring status indicator. g) 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 “Fetal settings” on page 121.
6	Shortcut / Recording menu	a) Patient name. b) Control to change view mode. c) Control to view event log. d) Control to scroll CTG trace. e) Control to print CTG trace segment. f) Control to open tools submenu, accessing functions to input patient information, review event log and review automated CTG analysis.

1.6 Markings and identification

1.6.1 Product identification labels

Symbol	Denomination	Description
	Manufacturer name, address	
	Date of manufacture	
	EU representative	
	Catalogue number / model/ type ref.	
	Serial number	Indicates serial number that is unique for each individual SRF618K9 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.
IPNN	IP-classification	Symbol marked on any device with protected enclosure according to IEC 60529.

Symbol	Denomination	Description
	CE mark	Confirms the device is CE-marked towards MDD, 93/42/EEC.
	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.

Symbol	Denomination	Description
	Power ON/OFF	Identifies the power ON/OFF switch.
	USB port	Non-isolated USB. For removable storage devices. Note that only devices powered by the USB port should be used. Devices supplied by other cabling must not be connected unless medical-grade supplied. Total current must not exceed 0.5A.
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

Warning!
Do not modify this equipment without authorization of the manufacturer.

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

- Technically qualified personnel of the hospital
- Authorized technical personnel at 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

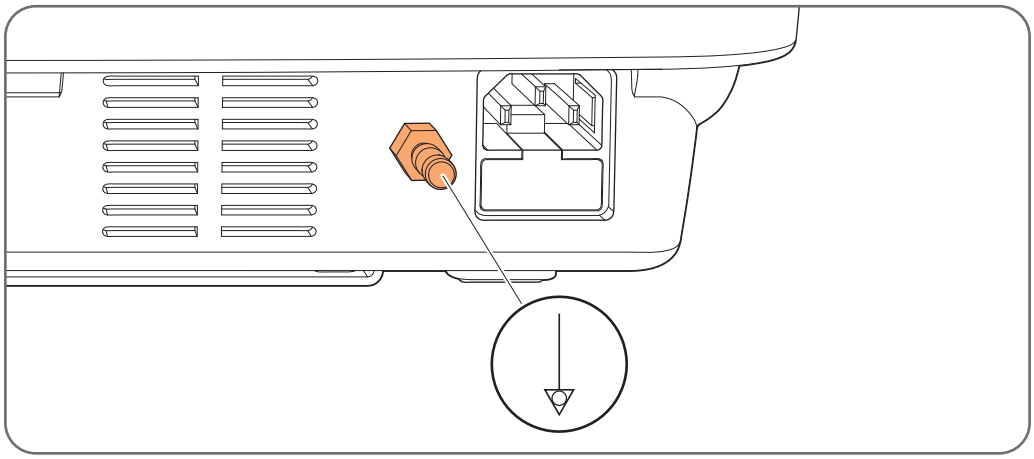


Figure 2:18 Potential equalization conductor

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 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 this service manual and STAN S41 Instructions For Use.

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 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.

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.

The device and its accessories listed in section “Compatible devices” on page 111, 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.
d

3 Installation

3.1 Unpacking

Prerequisites

The STAN S41 is to be operated in a climatic environment (temp etc.) expected for medical devices in such facilities. Comply with local regulations.

1. Before opening, inspect the packaging and ensure it has not been damaged during transport.

2. Unpack and check that all equipment is included as specified on the delivery note. The packing is specially designed for the equipment and is approved for world-wide air transportations. All packing material is possible to recycle, but is recommended to be stored if transportation is required in the future.

3. Task completed.

3.2 Mounting

3.2.1 Attaching to Mounting Solution

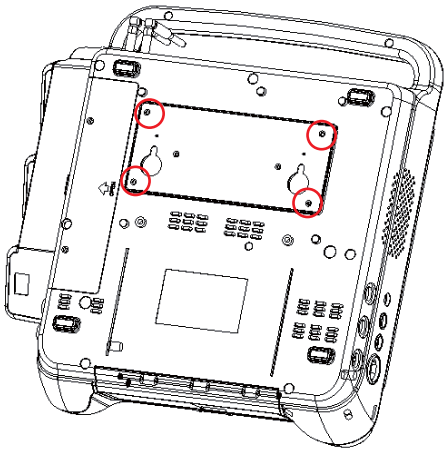


Figure 3:19

1. Mount STAN S41 with any compatible mounting equipment using the sheet metal parts on the rear side.

    - Always follow the manufacturer's instructions.
    - Recommended insertion depth is 8mm, screw dimension M3.

3.2.2 Mounting antennas

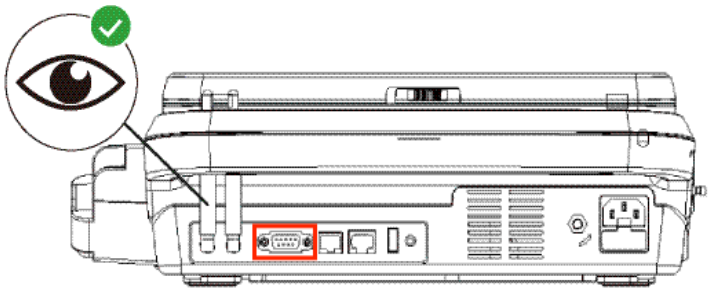


Figure 3:20

1. If the STAN S41 is equipped with wireless transducers, ensure antennas are mounted correctly to make sure the wireless communication between main unit and wireless transducer is good.

    - Always follow the manufacturer's instructions.
    - Ensure there are two antennas. The first is used for FHR1 and TOCO communication and the second for FHR2 communication.
    - Check and make sure the type of the antenna is correct. 433MHz antenna is suitable for under water monitoring transducers, 2.4GHz antenna is suitable for 2.4GHz transducers.
    - Inspect that the antennas are intact.
    - Screw the antennas to the connector tightly.
    - Adjust the antennas to upright position.
    - Position the main unit appropriately to prevent damage to the antennas.

Warning!
Ensure that the maximum load is not exceeded for the complete mounting solution.

Warning!
Ensure that the correct screw length is used for the application.

Tip!
When mounting the STAN S41 Trolley, routing of cables is easier before the trolley's column has been attached to the trolley's base.

Tip!
The main unit batteries are sufficiently charged at delivery. Additional charging of batteries is not necessary before starting the unit for the first time.

3.3 Cabling

3.3.1 Power Supply Cabling

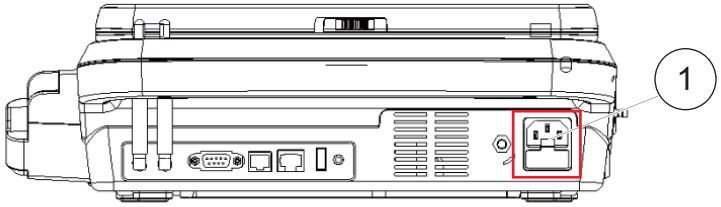


Figure 3:21

1. Connection to the mains supply with the pinout of the main unit power supply cable.
2. Task completed.

3.3.2 CMS Cabling

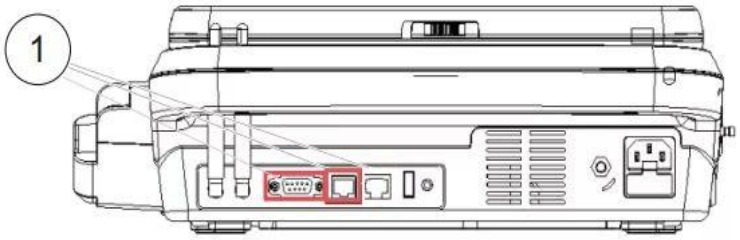


Figure 3:22

1. Connection to Central Monitoring systems with communication in accordance with the network cable or using RS232.
2. Task completed.

3.4 Configuration

3.4.1 Configuring Language

1. Ensure the power is switched on.

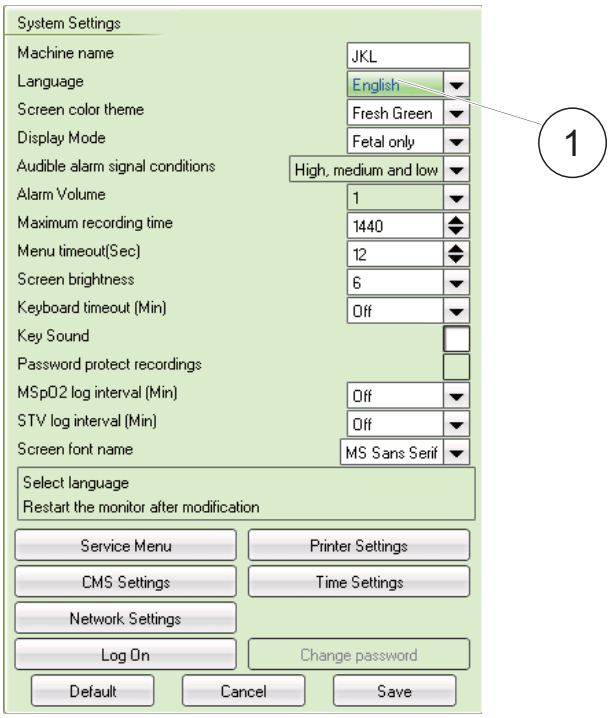


Figure 3:23

2. Tap the MENU and select System Settings.
3. Select Language and Save to store the changes.
4. Task completed.

3.4.2 Setting Time and Date

1. Ensure the power is switched on.

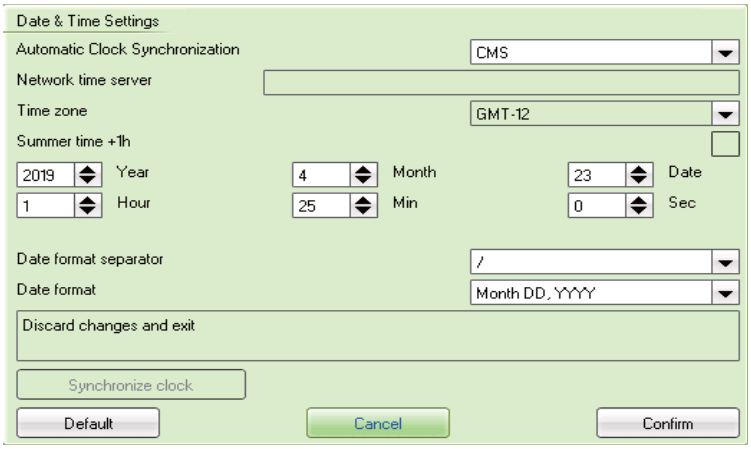


Figure 3:24

2. Tap the MENU and select System Settings.
3. Select Time Settings.
4. Update the date and time and select Save to store the changes.
5. Task completed.

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.

6. 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.
7. 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.

3.4.3 Configuring Network

1. Ensure the power is switched on.

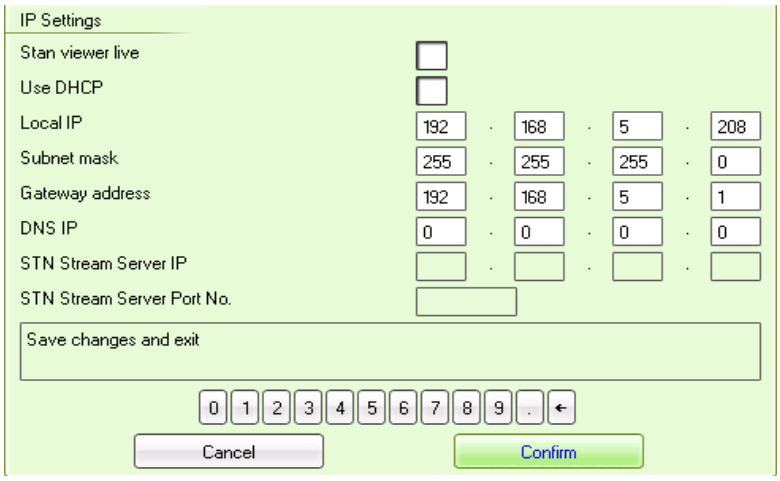


Figure 3:25

2. Tap the MENU and System Settings.
3. Select Network Settings.
4. Either configure a static IP address with subnet mask, or select to use DHCP.
5. If not using DHCP, configure Gateway address and DNS server address if needed
6. Select Save to store the changes.

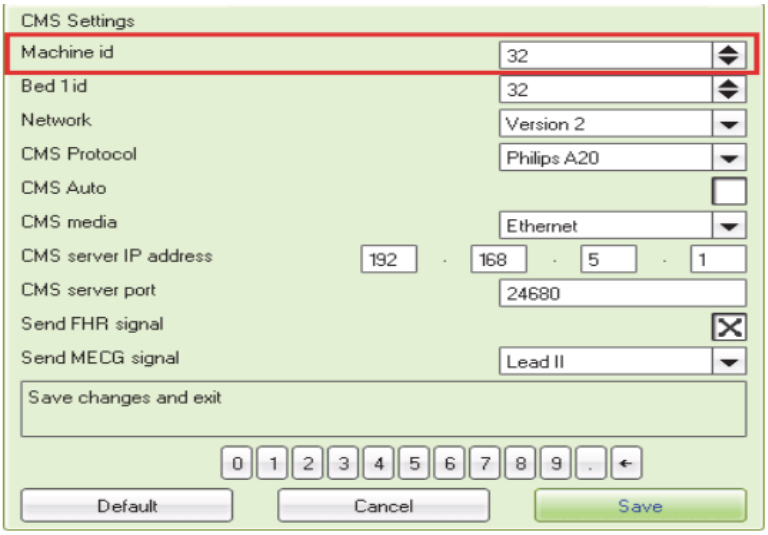


Figure 3:26

7. Tap the MENU and System Settings.
8. Select CMS Settings.
9. Set the unique Machine id. and select Save to store the changes.

10. Task completed.

Caution!

The Machine id of each STAN S41 in the same LAN should be unique. The machine ID setting will impact the MAC address of STAN S41. If two or more STAN S41 units in the same LAN have the same Machine id, it will induce the Ethernet connection error.

3.4.4 Configuring Printer

1. Ensure the power is switched on.

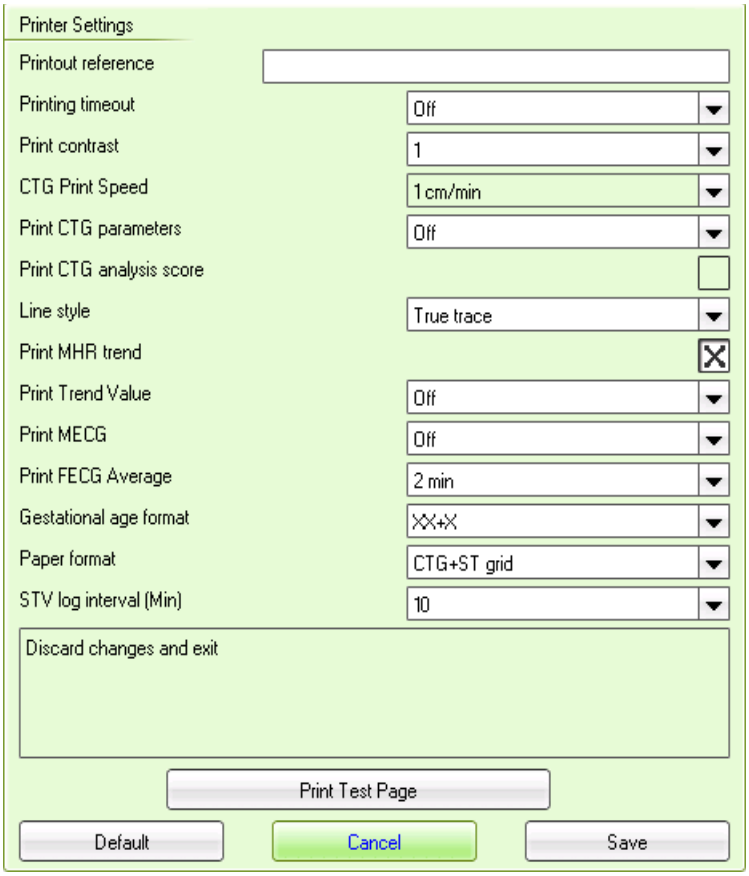


Figure 3:27

2. Tap the MENU and System Settings.
3. Select Print Settings.
4. Set the setting about CTG and ECG and select Save to store the changes.
5. Task completed.

3.4.5 Configuring Central Monitoring System

1. Ensure the power is switched on.

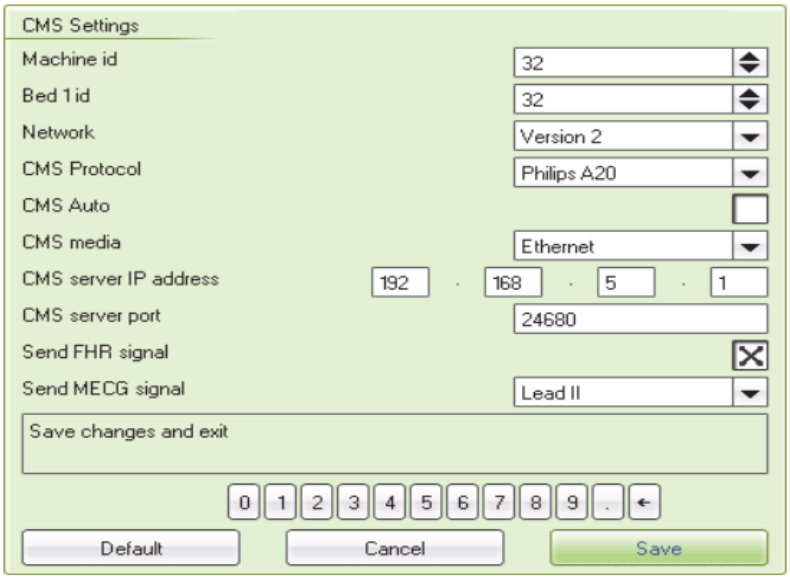


Figure 3:28

2. Tap the MENU and System Settings.
3. Select CMS Settings.
4. For sending data to a central monitoring system (CMS) configure CMS protocol and CMS media as appropriate.
5. Select Save to store the changes.
6. Task completed.

Tip!

Although the normal connection to CMS is via RS-232 serial communication, the device can also connect with CMS using wired Ethernet, provided that this is supported by the CMS.

3.4.6 Configuring Alarms

1. Ensure the power is switched on

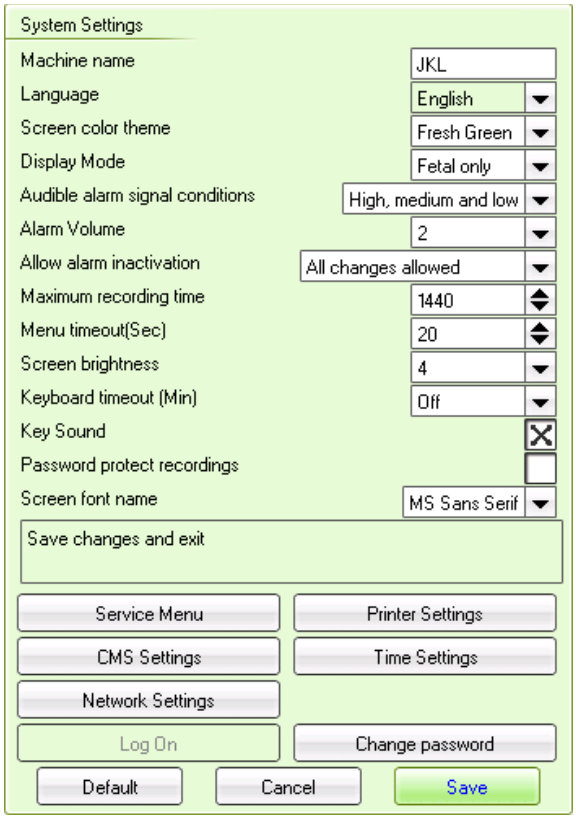


Figure 3:29

2. Tap the MENU.
3. Select System Settings and Log On with the password (default “888888”).
4. For generating audible alarm, configure Audible alarm signal conditions, Alarm volume and Allow alarm inactivation as appropriate.

5. Select Save to store the changes..

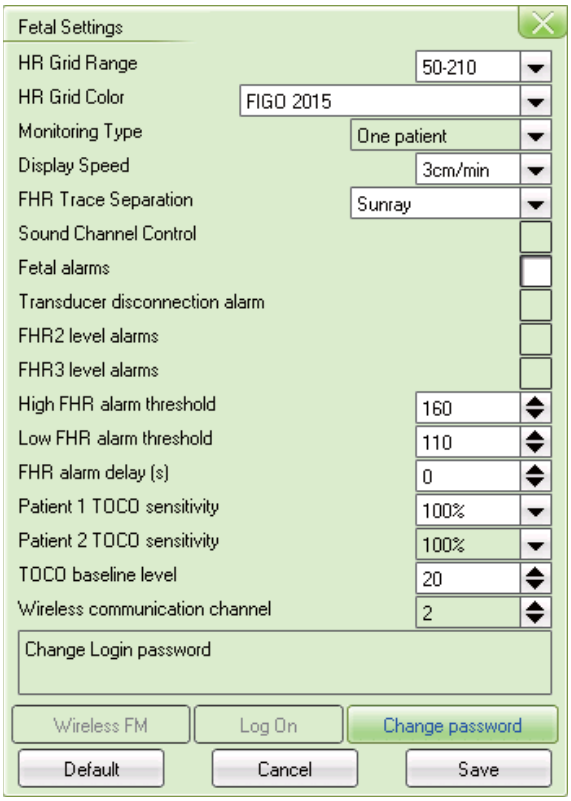


Figure 3:30

6. Tap the MENU.
7. Select Fetal Settings and Log On with the password (default “888888”）.
8. Set the alarm threshold of the FHR.
9. If using FHR2, select FHR2 level alarms if needed.
10. Select Save to store the changes.
11. Task completed.

3.4.7 Configuring Wireless FM

1. Ensure the power is switched on.

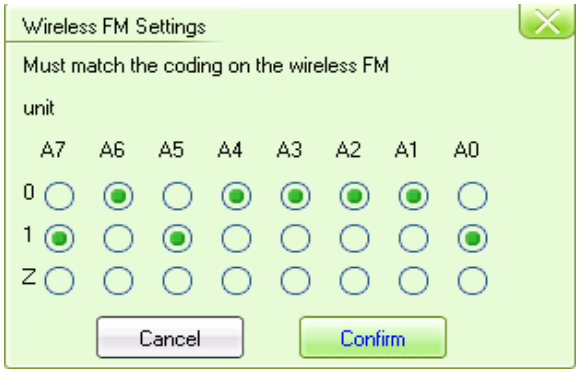


Figure 3:31

2. Tap the MENU.
3. Select Fetal Settings and Wireless FM.
4. Set the coding mark of the Wireless FM according the Note in battery lid of Wireless FM marker.
5. Select Save to store the changes.
6. Task completed.

3.5 Functional Test

3.5.1 Main unit test

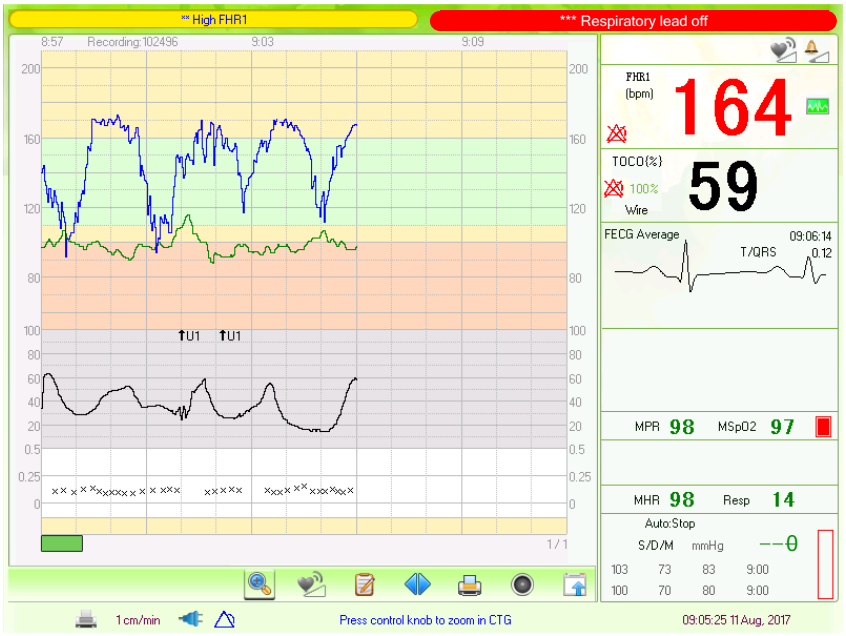


Figure 3:32

1. Ensure the power is switched on.
2. Hold the START/STOP touch key to start monitoring.
3. Connect an ultrasound transducer and move it up and down with the sensor area facing a flat surface.
    - A whistling sound should be heard when the transducer is moved at a speed of approximately 10cm/s.
4. Apply pressure to the sensor area and check that the TOCO value on the display increases accordingly.
5. Hold the PRINT touch key to print the trace.
6. Task complete.

3.5.2 NIBP test

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

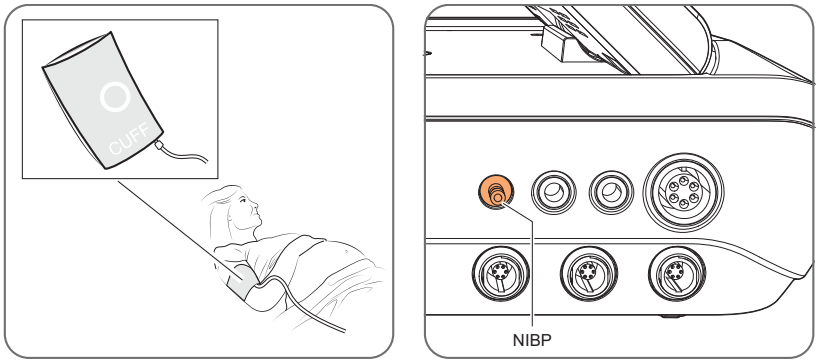


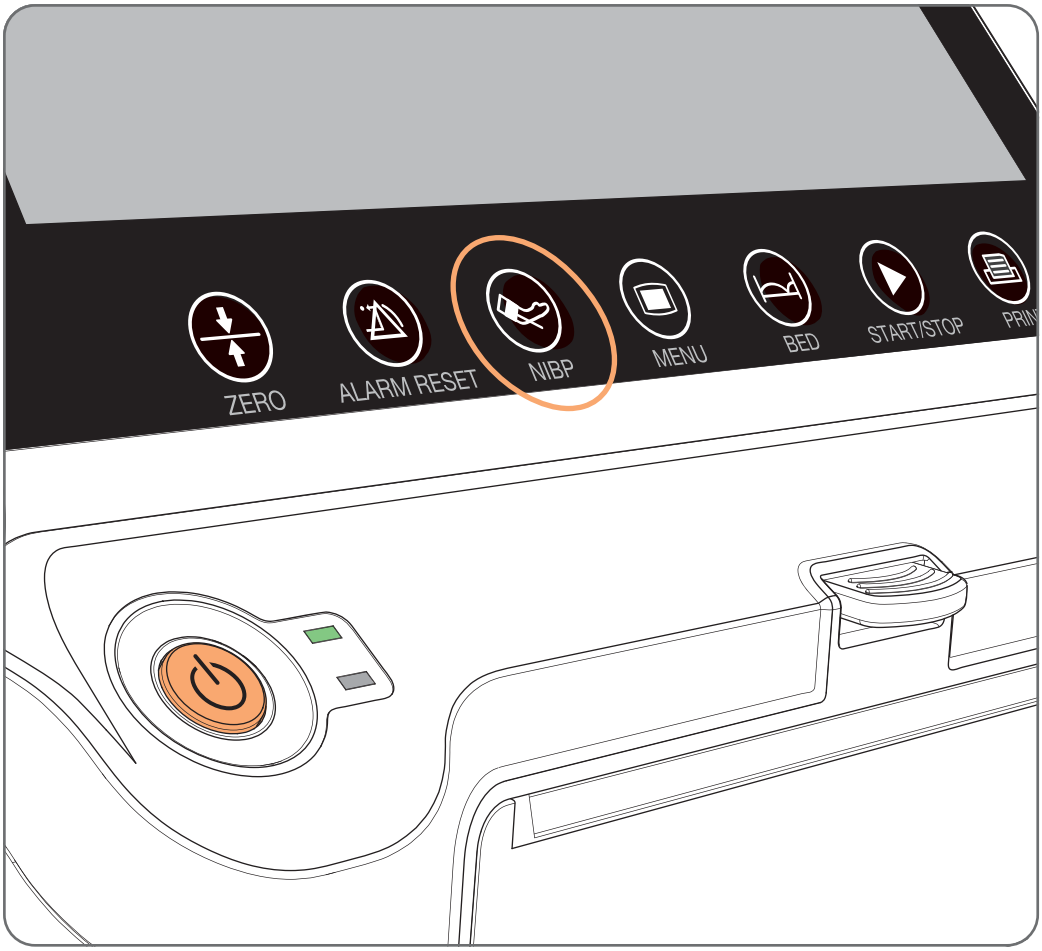
Figure 3:33 Location of the NIBP connector on the left side of the main unit

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

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

Tip!

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.


ZERO
ALARM RESET
NIBP
MENU
BED
START/STOP

4 Functional Description

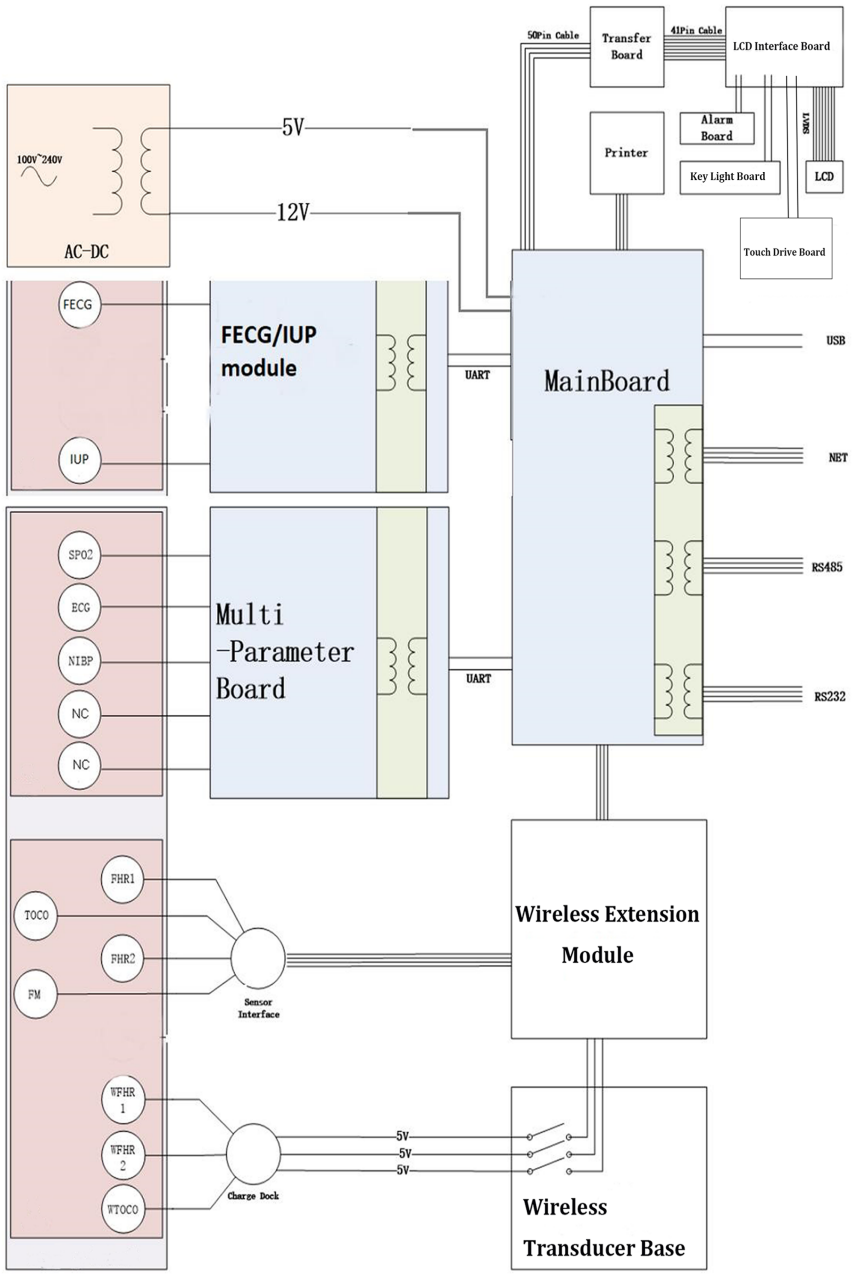


Figure 4:34

The STAN S41 comprises a Main unit and several transducers (US, TOCO, Fetal movement, etc.) In addition a printer and a charging station may be connected as well as touch key and storage devices. It is also possible to connect to central monitoring system. There is also a built-in non invasive blood pressure unit (NIBP).

4.1 Main Unit

There are additional circuit boards in the main unit.

- Main Board: The main software and the fetal algorithm are running in the Main Board.
- Power Board: Supply the power to the main unit.
- Multi-Parameter Board: Process the data from the Multi-Parameter transducers and sent to Main Board.
- Transfer Board: Transfer the signal of the LCD interface board, on/off switch and the knob to the Main Board.
- LCD Interface Board: Transfer to display and supply the power to the screen.
- Alarm Board: Red and yellow light is shown during active alarm.
- RF External Board: Supply the port to connect to the wireless transducer.
- Hall Interface: Manage the power and the channels of the wireless transducer and the ID of the wireless transducer.

In addition there are also the following modules:

- A system battery
- On-off switch
- Speaker
- Printer

4.2 Transducers

4.2.1 General

The transducers enclosure are glued and are not possible to open. There are no serviceable parts within any of the transducers.

4.2.2 US (Ultrasound)

This transducer uses piezo crystals and Doppler effect measurement to detect the fetal heart rate. All analog and digital electronics resides within the transducer together with a high performance micro-controller with communication functionality.

4.2.3 TOCO

This transducer uses a pressure sensor to measure the contractions. The transducer includes all necessary analog and digital electronics as well as a high performance micro-controller with measurement communication functionality.

4.2.4 Fetal Movement

This transducer uses a code to send the Fetal Movement to the unit.

4.2.5 MSpO2

This transducer uses an external MSpO2 sensor to measure the oxygen concentration as well as the mother's pulse. The transducer includes all necessary analog and digital electronics as well as a high performance micro-controller.

4.2.6 NIBP

This function uses a compatible blood pressure cuff to an arm, wait until the measurement has been completed and a reasonable NIBP result is shown on the display. The pressure of the cuff is released after the measurement has been completed.

4.2.7 MECG and respiratory rate

This transducer have 5 leadwires called RA,LA, RL, LL and V. Choose flat area to place electrodes. Attach the skin electrodes to the MECG leadwire cable. Attach the electrodes to the patient. 3-leadwire mode, 5-leadwire mode, MECG waveform can be displayed if you select different leads.

5 Repair

Warning!
Always take precautions against electrostatic discharge before opening/disassembling STAN S41 Main Unit.

Caution!
To preserve the sealing of the wireless transducers, maintaining their IP68 classification, only technicians authorized by the manufacturer are allowed to open the body of a wireless transducer.

Tip!
For instructions regarding testing and checking of STAN S41 equipment, see section 6 Maintenance.

Tip!
If requested, Sunray Medical can supply descriptions, assembly instructions, calibration instructions etc., that will assist technical personnel to exchange spare parts.

5.1 Repair philosophy

Spare part listed in this service manual are supplied by Sunray Medical or local representatives.

The instructions for the exchangeable parts are also included in this document.
If a part is not listed with part number nor has an instruction, it is not considered an exchangeable part.

Please contact Sunray Medical or your local representative for more information.

5.2 Disassembling Main Unit

Task interval
When called for upon due to repair or troubleshooting purposes

Time Elapse
10 min

Conditions
No specific conditions is needed for completion of this task.

Spare parts
No spare parts needed for completion of this task.

Tools
Screwdriver Phillips 2

5.2.1 Instructions

1. Disconnect the STAN S41 main unit from power.
2. Place the STAN S41 with screen down on a non-scratching surface.

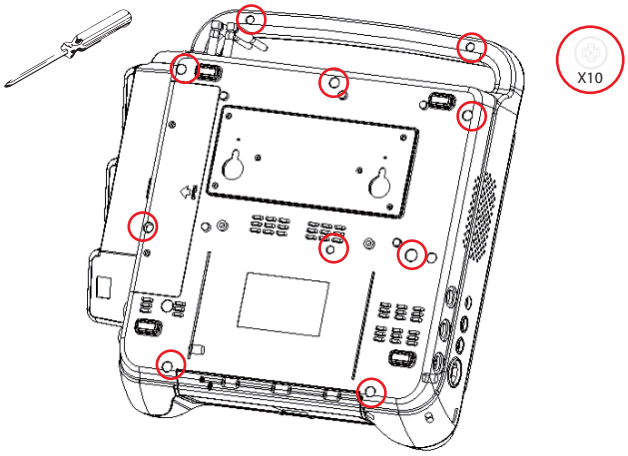


Figure 5:35

3. Remove the 10 screws with a Phillips screwdriver.

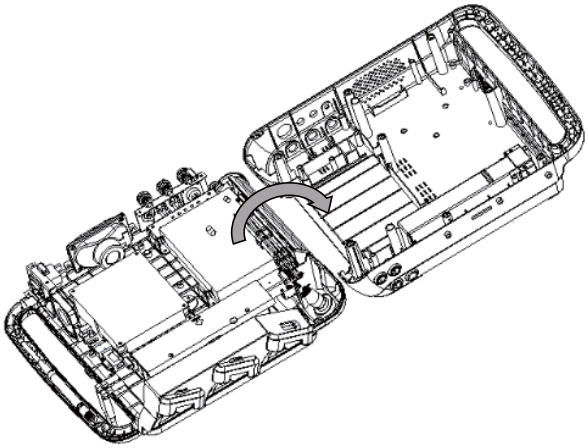


Figure 5:36

4. Carefully fold down the rear part of the main unit.
5. Task completed.

5.3 Reassembling Main Unit

Task interval
When called for upon due to repair or troubleshooting purposes

Time Elapse
10 min

Conditions
No specific conditions is needed for completion of this task.

Spare parts
No spare parts needed for completion of this task.

Tools
Screwdriver Phillips 2

5.3.1 Instructions

1. Place the STAN S41 screen down on a non-scratching surface.
2. Make sure the cables between the two parts are placed in a suitable ‘clip’.

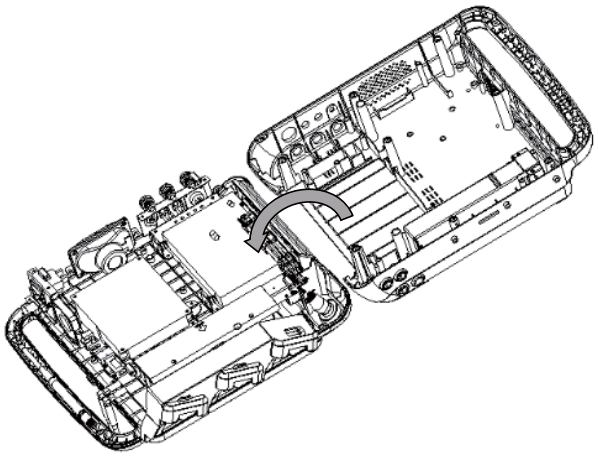


Figure 5:37

3. Carefully mount the rear part of the main unit back to its original position.

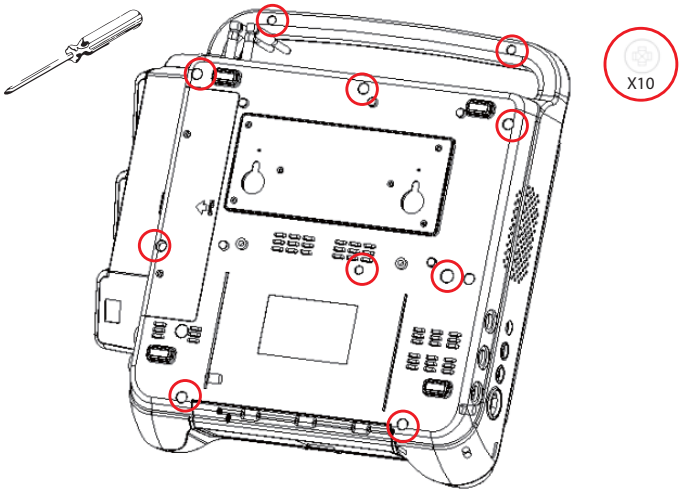


Figure 5:38

4. Fasten the 10 screws with a Phillips screwdriver.
5. Connect main unit to power.
6. Task completed.

5.4 Replacing the system battery

Task interval
24 Months

Time Elapse
10 min

Conditions
No specific conditions is needed for completion of this task.

Spare parts
Replacement battery pack.

Tools
Screwdriver Phillips 2

5.4.1 Instructions

Warning!
Make sure that the replacement battery is not damaged before installation.

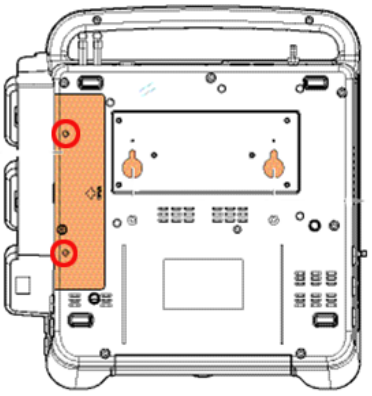


Figure 5:39

1. Loosen the two screws for the battery compartment lid.
2. Unplug the installed battery and remove it.
3. Connect the new battery and place it in the compartment.
4. Fasten the two screws for the battery compartment lid.
5. Dispose of the old battery accordeing to local regulations.
6. Task completed.

5.5 Replacing the batteries in wireless transducers

Task interval
24 Months

Time Elapse
10 min

Conditions
No specific conditions is needed for completion of this task.

Spare parts
Replacement battery pack.

Tools
Screwdriver Phillips 2

5.5.1 Instructions

Warning!
Make sure that the replacement battery is not damaged before installation.

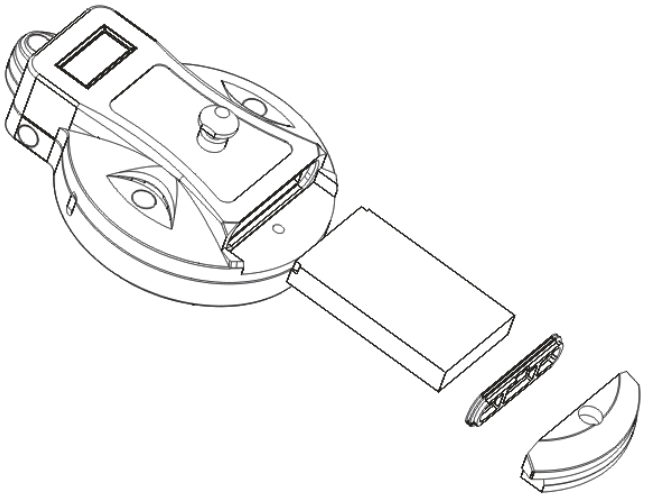


Figure 5:40

1. Remove the transducer from the charging rack.
2. Loosen the screw holding the battery cap.
3. Remove the battery cap.
4. Remove the battery.
5. Note the polarity and install the new battery.
6. Fasten the screw holding the battery cap.
7. Task completed.

6 Maintenance

6.1 Maintenance Inspection

6.1.1 Visual Inspection

Prior to using the monitor every time, do the following inspections:

- Check the monitor and accessories to see if there is any visible evidence of damage that may affect patient safety. Pay special attention to cracks on the transducers and cables before immersing them into fluid.
- Check all the outer cables, power socket and power cables.
- Check if the monitor functions properly.
- If any damage is detected, stop using the monitor on the patient. Replace the damaged part(s) or contact the manufacturer for service before reusing it.

6.1.2 Routine Inspection

The overall check of the monitor, including safety check and function check, must be performed by qualified personnel every 6 to 12 months, and each time after service. The equipment must undergo periodic electric safety testing to ensure proper patient isolation from leakage currents. This must include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

6.1.3 Mechanical Inspection

Make sure all exposed screws are tight.
Check the external cables for splits, cracks or signs of twisting.
Replace any cable that shows serious damage.
Pay particular attention to the supply socket.

Warning!
Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

Caution!
Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.

6.1.4 Software Version Inspection

During maintenance and repair operations on Stan S41, it is essential to ensure that the device is running the latest software version. Please contact your local representative for information about the latest release of the Stan S41 software.

6.2 Maintaining the Battery

It is required to follow the instructions in this service manual during installation, storage and maintenance of the battery.
When the battery is charged, used or stored, keep it away from objects or materials with static electric charges.
The recommended charge temperature range is from 0 °C (+32 °F) to +40 °C (+104 °F). Do not exceed this range.
The recommended charge temperature range for wireless transducers batteries is from 0 °C(+32 °F) to +45°C(113°F)
Do not exceed this range.
When not using the equipment for an extended period, remove the battery from the monitor and store it in a place with low humidity and low temperature.
Batteries wear out over time. If the operating time from battery is much shorter than usual, the battery is worn out and should be replaced.

6.3 Intervals

After each use

Remove transducers or 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 and the wireless transducers batteries, 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.

Every 24 months

The system battery and the wireless transducers batteries should be replaced by qualified technicians every 24 months.

The internal dust of the main unit should be cleaned by qualified technicians every 24 months. After maintenance, make sure that the overall check of the monitor, including safety check and function check are performed.

Caution!

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

Caution!

The repair of the instrument must be performed by qualified personnel.

6.4 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

6.4.1 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.

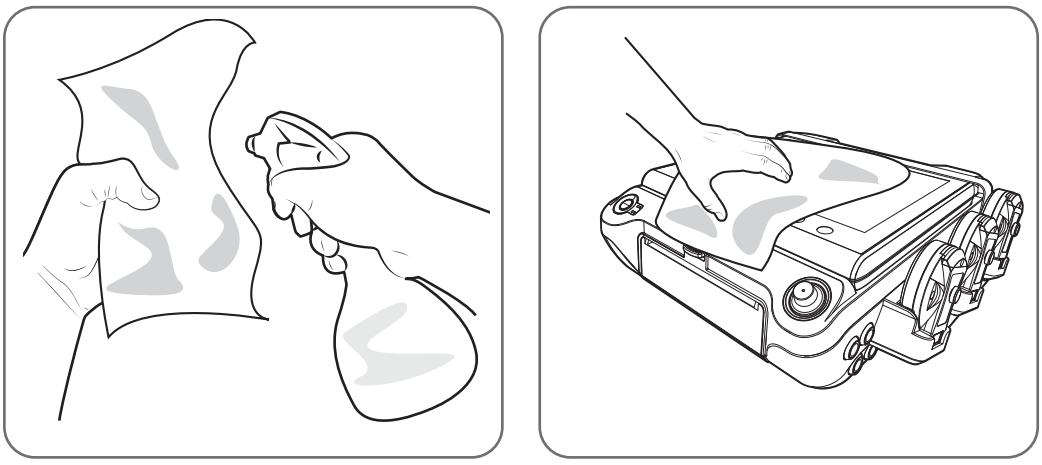


Figure 6:41 Cleaning the main unit

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.

6.4.2 Clean the transducers

Caution!

Unplug transducers and sensors from the main unit before cleaning.

1. Inspect the transducers, sensors, ECG leadsets and their cables for crack and damages. If damages are suspected, contact qualified service personnel.

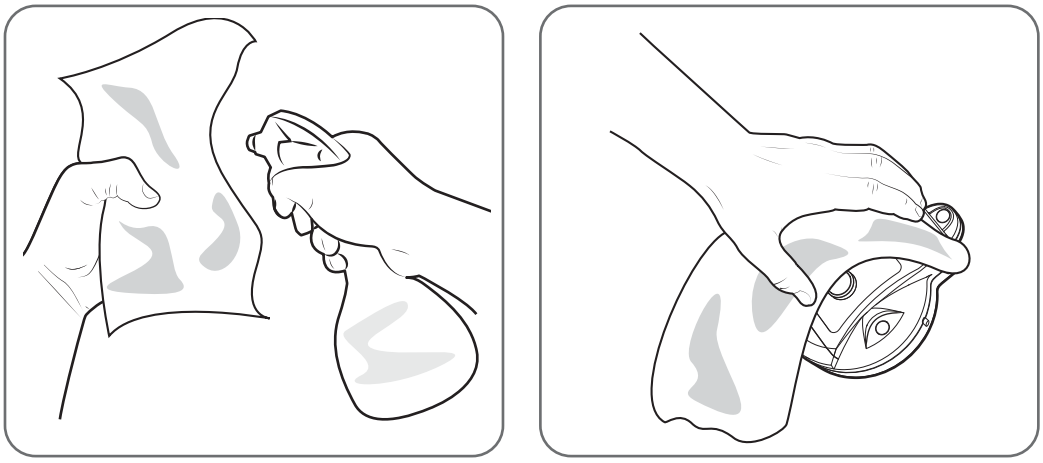


Figure 6:42 Cleaning transducers

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

6.4.3 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 6:43 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.

6.5 Performing functional check

Task interval
Daily, every 12 months or after repair.

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.

6.5.1 Main unit and printer

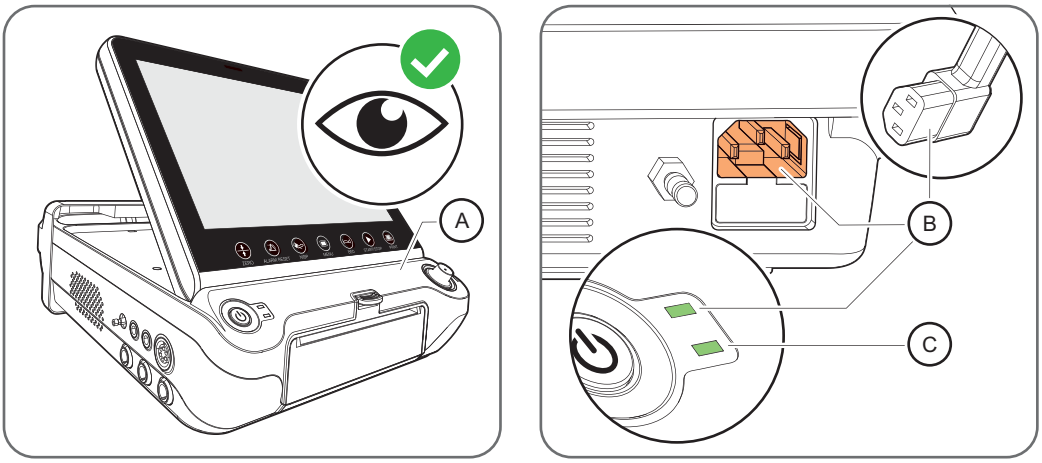


Figure 6:44 Inspecting main unit and printer

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.

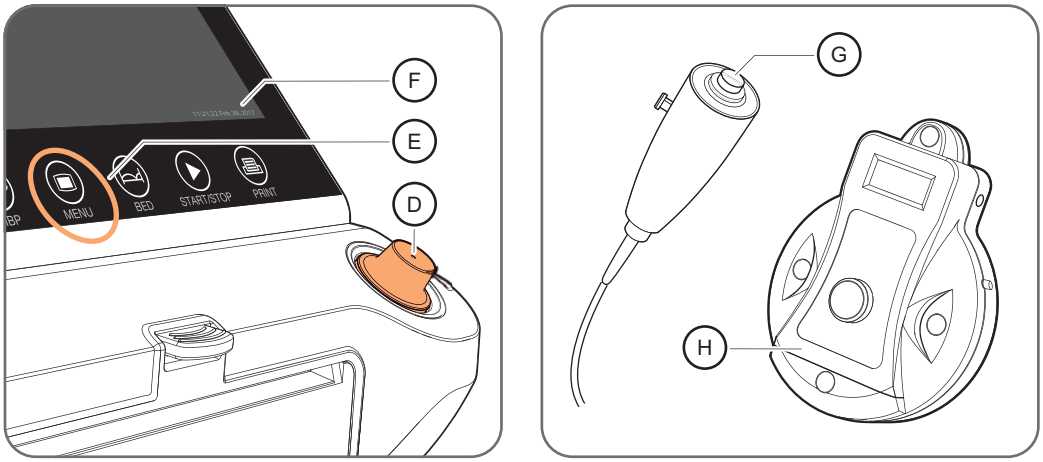


Figure 6:45

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.

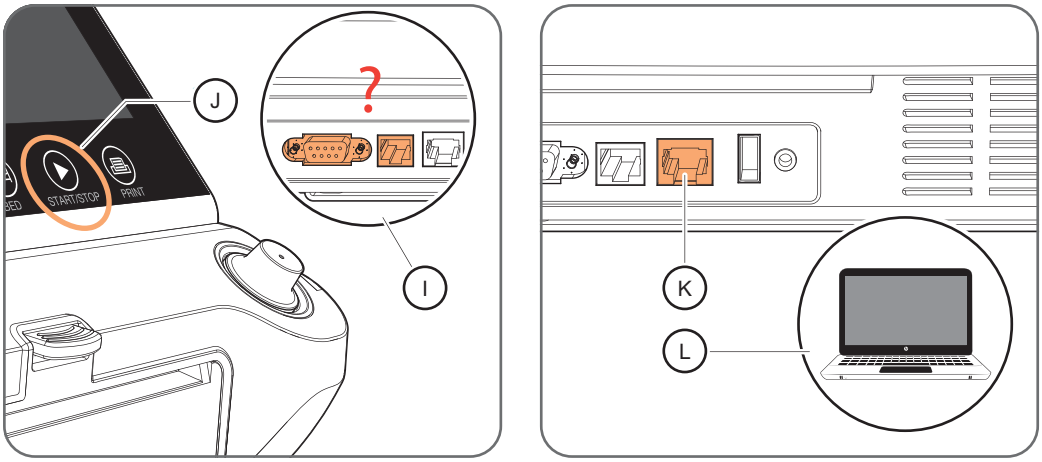


Figure 6:46

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.

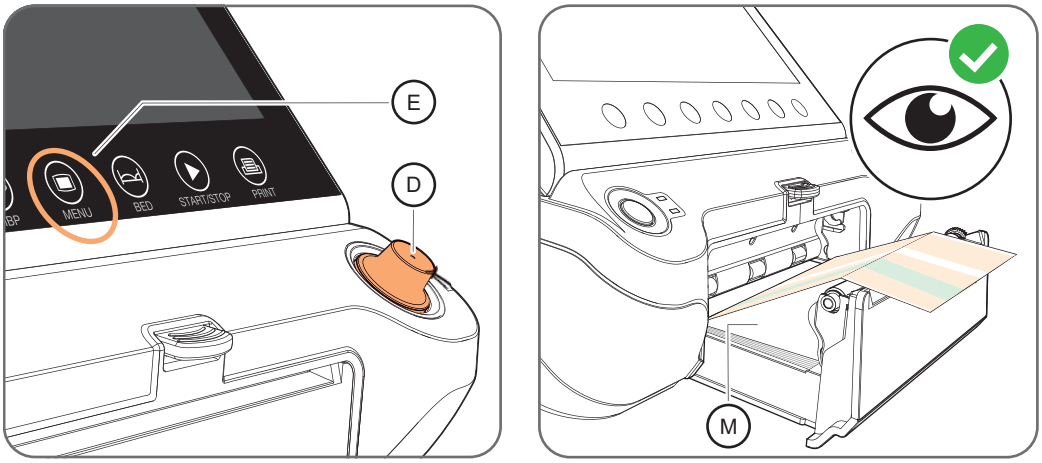


Figure 6:47

11. Hold the “MENU” touch key (E) and then use the control knob (D) to enter the system setting 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.

6.5.2 Wired TOCO transducer

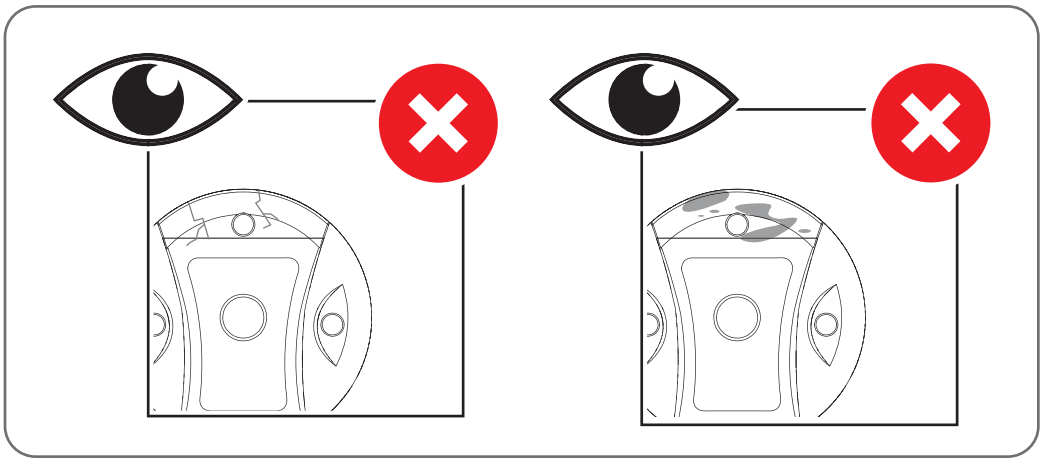


Figure 6:48 Inspecting the wired TOCO transducer

1. Tested parameters

Pressure values(g)	Output TOCO value
50	14-18 (relative baseline reference)
100	30-36 (relative baseline reference)
200	60-72 (relative baseline reference)
300	92-100 (relative baseline reference)

2. Setting to be used

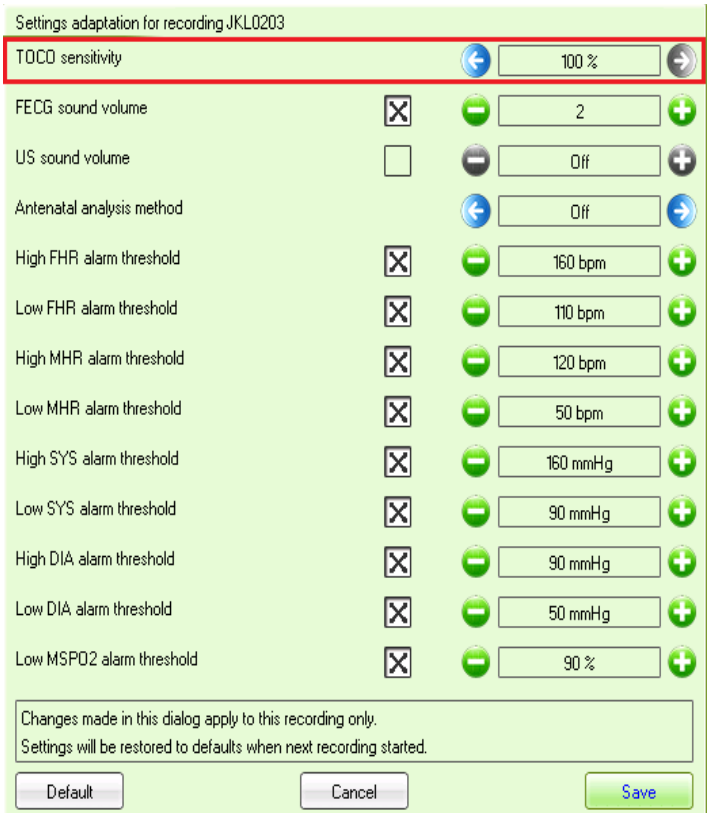


Figure 6:49 Set the TOCO sensitivity in Quick settings dialog

a) TOCO sensitivity: 100%

3. Test methods

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

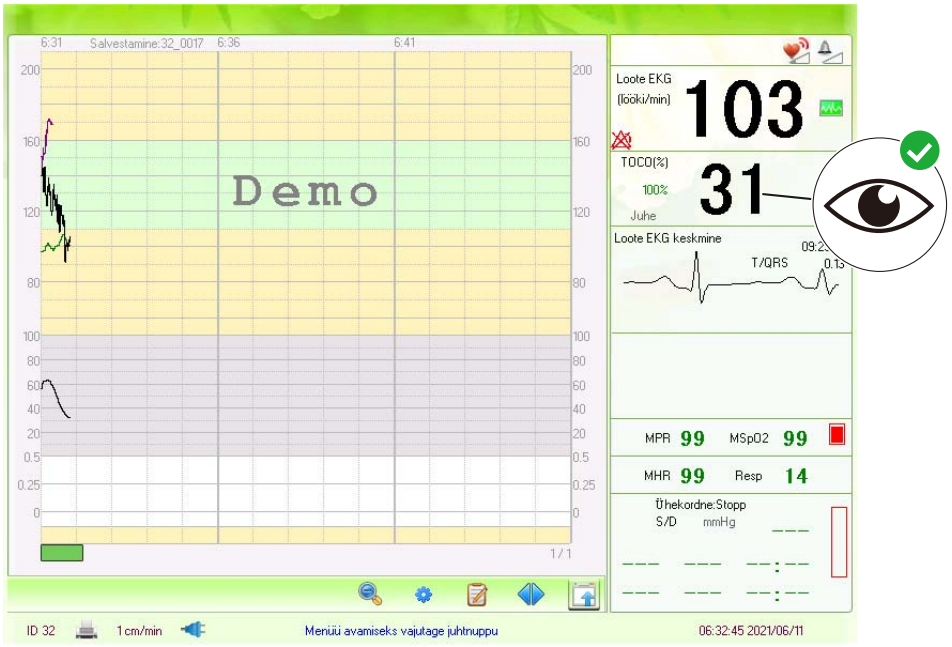


Figure 6:50 Verify that a TOCO value appears on the display

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

Figure 6:51 Imply the preload and the weights in the sensor area

c) Lay the TOCO transducer flat with the button facing up.

d) Apply pressure to the sensor area with preload (20g-50g), Then press the “ZERO” touch key to set the TOCO reference.

e) Apply pressure to the sensor area with weights (100g) and verify that the TOCO value on the display increases accordingly.

f) Release pressure and verify that the TOCO value decreases.

6.5.3 Wired Ultrasound transducer

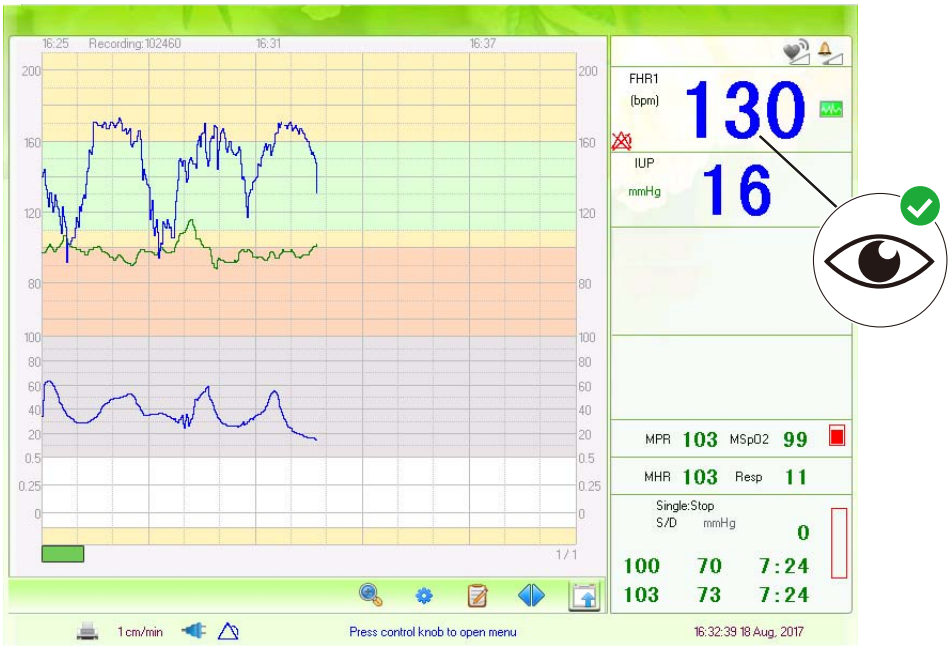


Figure 6:52 Verify that an FHR1 value appears on the display

1. Tested parameters: 30bpm/min, 120bpm/min, 240bpm/min.
2. Accepted tolerances: ±1bpm/min.
3. Test methods
   a) Connect a wired ultrasound transducer to the FHR1 connector on the main unit. Verify that an FHR1 field appears on the display.
   b) Turn the fetal heart simulator on.
   c) Place the FHR probe on the fetal heart simulator.
   d) Start monitoring and a corresponding sound should be heard and the tapping frequency (heart beat value) be visible on the display.

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

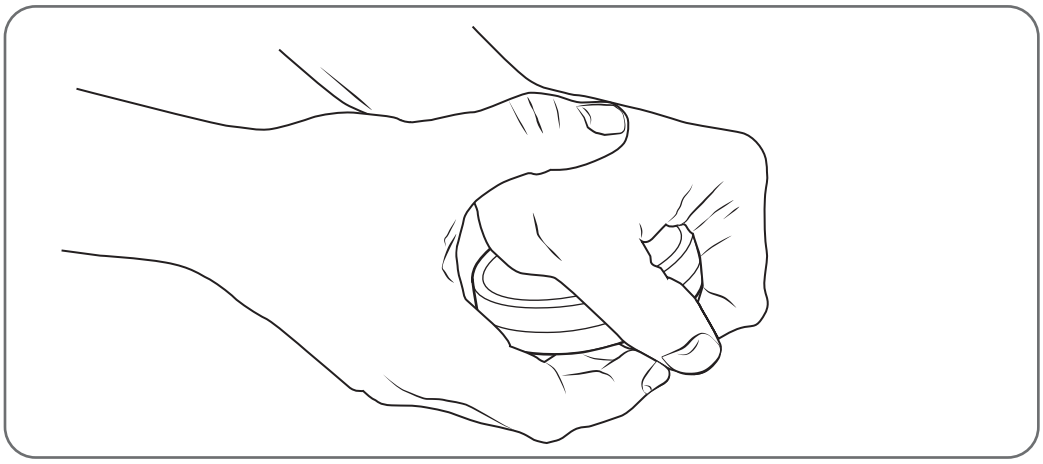


Figure 6:53 Simulating fetal heart movements

6.5.4 Wireless TOCO transducer

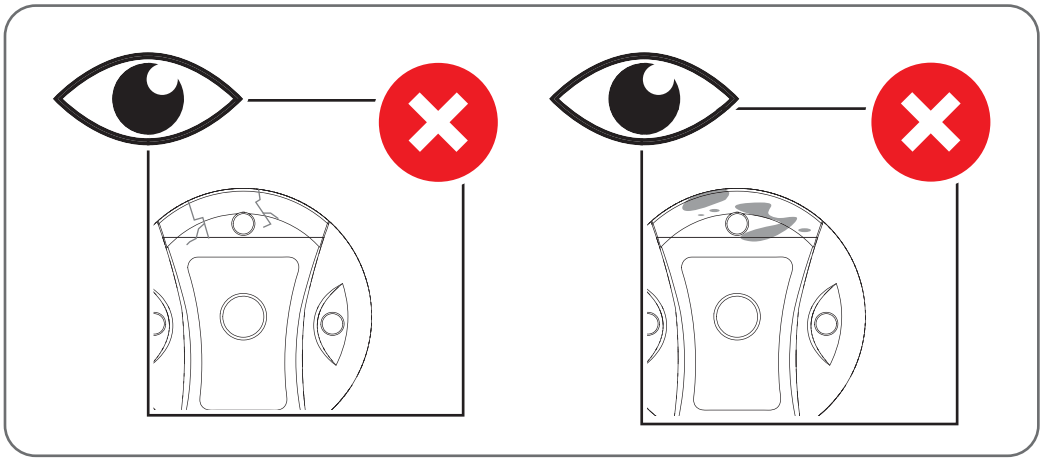


Figure 6:54 Inspecting the wireless TOCO transducer

1. Tested parameters

Pressure values(g)	Output TOCO value
50	14-18 (relative baseline reference)
100	30-36 (relative baseline reference)
200	60-72 (relative baseline reference)
300	92-100 (relative baseline reference)

2. Settings to be used

   a) TOCO sensitivity: 100%

3. Test methods

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

b) 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 nearby transducer placing on the charging rack is configured to communicate on the same wireless channel.

c) Verify that the battery is sufficiently charged.

d) Verify that the signal strength indicator is at its maximum.

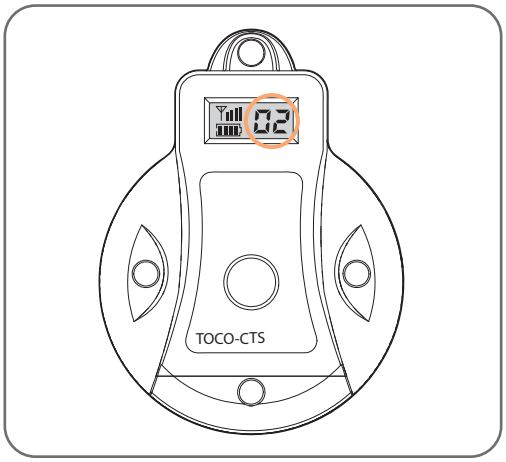


Figure 6:55 Verify that the wireless channel numbers on display and transducer match

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

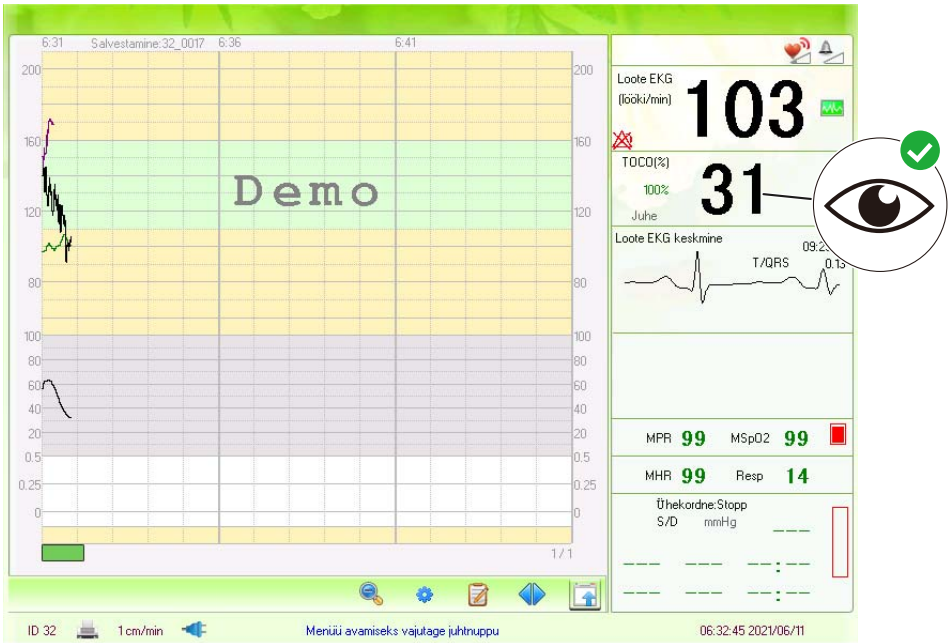


Figure 6:56 Verify that a TOCO value appears on the display

f) Lay the TOCO transducer flat with the button facing up.

g) Apply pressure to the sensor area with preload (20g-50g), then press the “ZERO” touch key to set the TOCO reference.

h) Apply pressure to the sensor area with weights (100g) and verify that the TOCO value on the display increases accordingly.

i) Release pressure and verify that the TOCO value decreases.

6.5.5 Wireless Ultrasound transducer

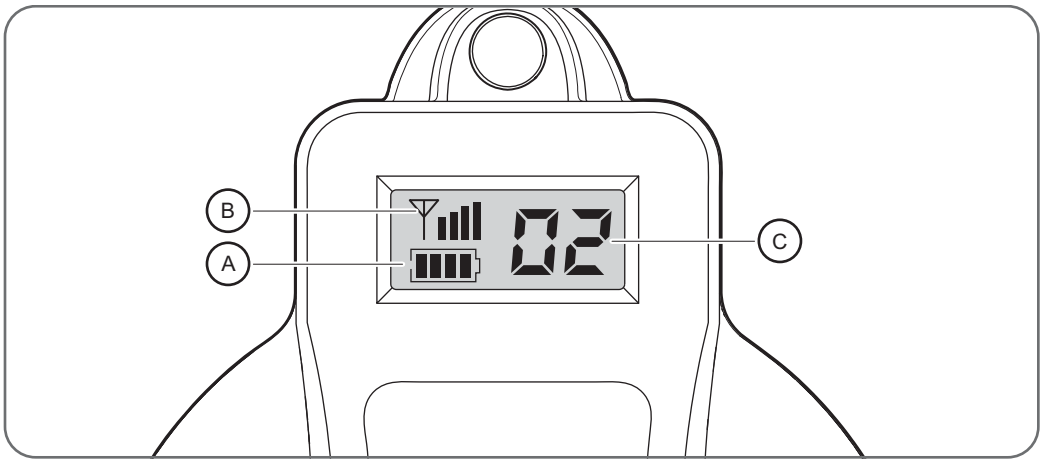


Figure 6:57 Inspecting a wireless ultrasound transducer

1. Tested parameters: 30bpm/min, 120bpm/min, 240bpm/min.
2. Accepted tolerances: ±1bpm/min.
3. Test methods

   a) Remove the ultrasound transducer (FHR1 or FHR2) from the charging rack. Inspect it and make sure it is not damaged.

   b) 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 nearby transducer placing on the charging rack is configured to communicate on the same wireless channel.

   c) Verify that the battery (A) is sufficiently charged.

   d) Verify that the signal strength indicator (B) is at its maximum.

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

Figure 6:58 Verify that an FHR1/FHR2 value appears on the display

f) Turn the fetal heart simulator on.

g) Place the FHR probe on the fetal heart simulator.

h) Start monitoring and a corresponding sound should be heard and the tapping frequency (heart beat value) be visible on the display.

6.5.6 FECG

1. Tested parameters: 30bpm/min, 120bpm/min, 240bpm/min.

FECG values(bpm)	Accepted tolerances
30~180	±1bpm/min
180~240	±2bpm/min

2. Test methods

a) Cut off the hub from a scalp electrode, remove the insulation of the outmost 10mm from the leads.

b) Attach spiral lead to RA, the reference plate lead to LA and skin electrode connector to LL of an ECG simulator.

c) Insert the scalp electrode connector to the FECG legplate.

d) Connect the FECG legplate connector to the main unit

e) Start a new recording.

f) Adjust the heart rate frequency of the Vital Signs Simulator to 30 BPM, 120 BPM and 240 BPM one by one, tested with FECG probes and check the display number to find whether it is in the right range.

6.5.7 IUP

1. Tested parameters: 25mmHg, 50mmHg, 100mmHg.
2. Accepted tolerances: 1mmHg or ±5%, the larger one
3. Test methods
   a) Connect S41 to a calibrated manometer, IUP catheter+IUP adapter cable and membrane pump. Increase pressure and verify that the value on the screen corresponds to the value on the manometer.

6.5.8 NIBP function

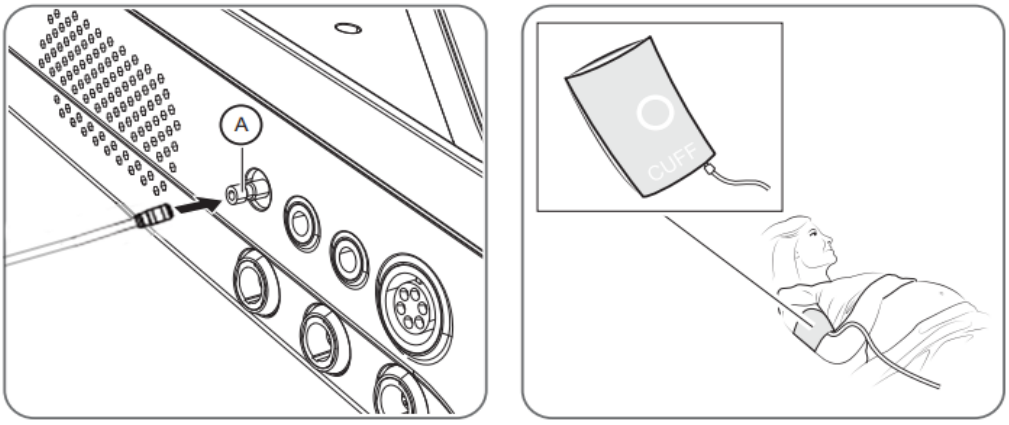


Figure 6:59 Inspecting the NIBP cuff and hose

1. Tested parameters

SYS/DIA/MAP (mmHg)
120/80/93

2. Accepted tolerances: ±8mmHg
3. Test methods
   a) Inspect the NIBP cuff and hose for cracks and damage.
   b) Connect a compatible blood pressure cuff to the NIBP connector (A) on the side of the main unit.
   c) Connect vital signs simulator to the monitor through cuff and simulated arm, set the vital simulator into: (SYS/DIA/MAP):(120/80/93)mmHg.

d) Wait until the measurement has been completed and verify that a NIBP result within tolerances is shown on the display.

e) 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.

4. Leakage test

a) Inspect the NIBP cuff and hose for cracks and damage.

b) Connect a compatible blood pressure cuff and simulated arm to the NIBP connector (A) on the side of the main unit.

c) Ensure the power is switched on and start a recording.

d) Tap the MENU

e) Select Maternal Settings and NIBP Settings.

f) Log On with the Password (default“888888”).

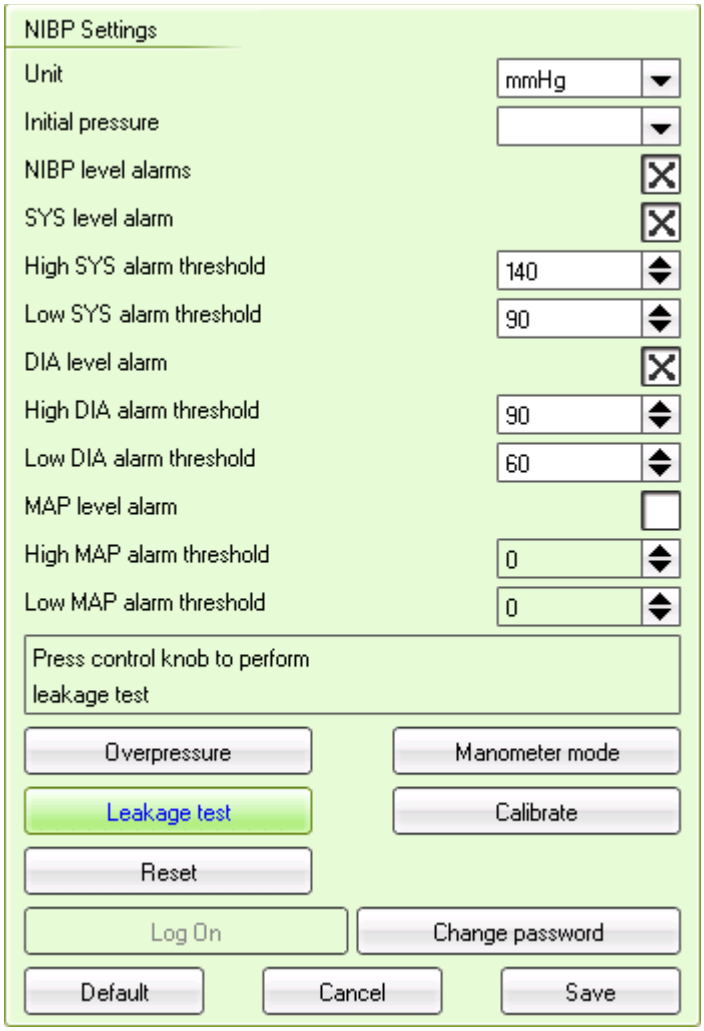


Figure 6:60 Trigger the Leakage test in the NIBP Settings

g) Select the “Leakage test”, S41 will run the test automatically.

h) When the pressure is stable, disconnect the cuff from S41.

i) Verify that the pressure of the cuff is released after the measurement has been completed.

j) The alarm "NIBP air leakage" shall be displayed as visual and audible alarm.

5. Overpressure test

a) Inspect the NIBP cuff and hose for cracks and damage.

b) Connect a compatible blood pressure cuff and simulated arm to the NIBP connector (A) on the side of the main unit.

c) Connect vital signs simulator to the monitor with cuff, manual pump and simulated arm, set the vital simulator into Overpressure test mode.

d) Ensure the power is switched on and start a recording.

e) Tap the MENU

f) Select Maternal Settings and NIBP Settings.

g) Log On with the Password (default“888888”).

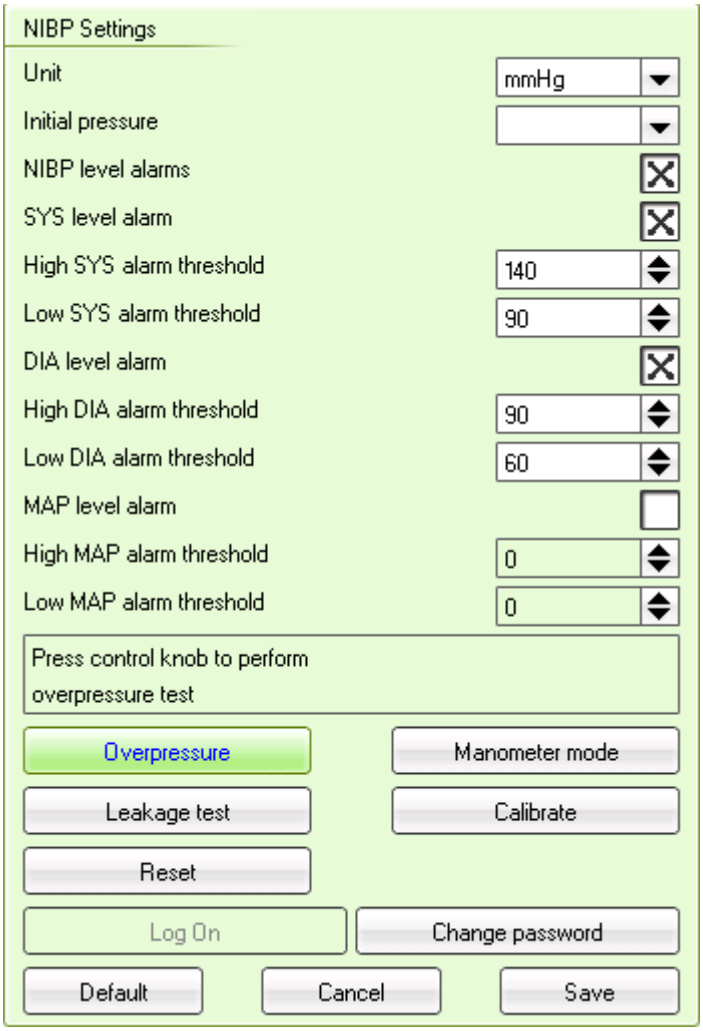


Figure 6:61 Trigger the Overpressure test in the NIBP Settings

h) Select the “Overpressure”, trigger the test process in simulator simultaneously.

i) Increase pressure to 301-320±5mmHg and verify that the module automatically releases pressure within 15s (over 325 mmHg it shall release immediately) .

j) Verify that the pressure of the cuff is released after the measurement has been completed.

6. Manometer mode test

a) Accepted tolerances: ±3mmHg

b) Inspect the NIBP cuff and hose for cracks and damage.

c) Connect a compatible blood pressure cuff and simulated arm to the NIBP connector (A) on the side of the main unit.

d) Connect vital signs simulator to the monitor through cuff and simulated arm, set the vital simulator into Manometer test mode.

e) Ensure the power is switched on and start a recording.

f) Tap the MENU

g) Select Maternal Settings and NIBP Settings.

h) Log On with the Password (default“888888”).

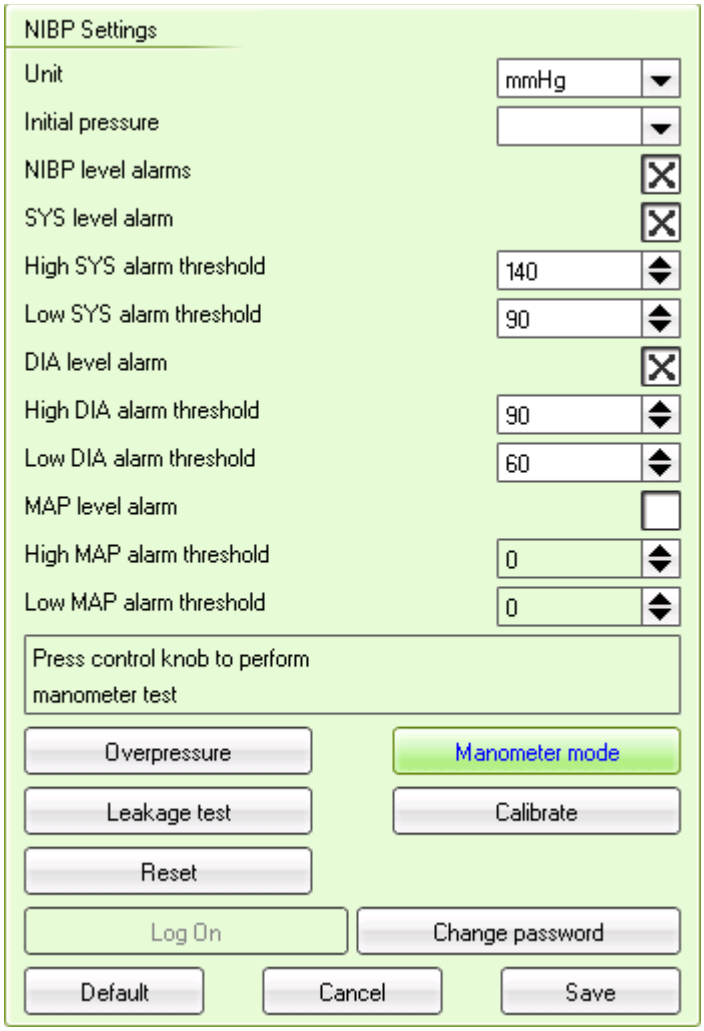


Figure 6:62 Trigger the Manometer mode test in the NIBP Settings

i) Select the “Manometer mode”, trigger the test process in simulator simultaneously.

j) Wait until the test has been completed and verify that a reasonable NIBP result is shown on the display, the accepted tolerances: ±3mmHg.

k) Verify that the pressure of the cuff is released after the measurement has been completed

7. NIBP Function calibration(available from software version 1.7.3.20190408.T and later)

   a) Accepted tolerances: ±3mmHg

   b) Inspect the NIBP cuff and hose for cracks and damage.

   c) Connect a compatible blood pressure cuff and simulated arm to the NIBP connector (A) on the side of the main unit.

   d) Connect vital signs simulator to the monitor through cuff and simulated arm.

   e) Ensure the power is switched on and start a recording.

   f) Tap the MENU

   g) Select Maternal Settings and NIBP Settings.

   h) Log On with the Password (default“888888”).

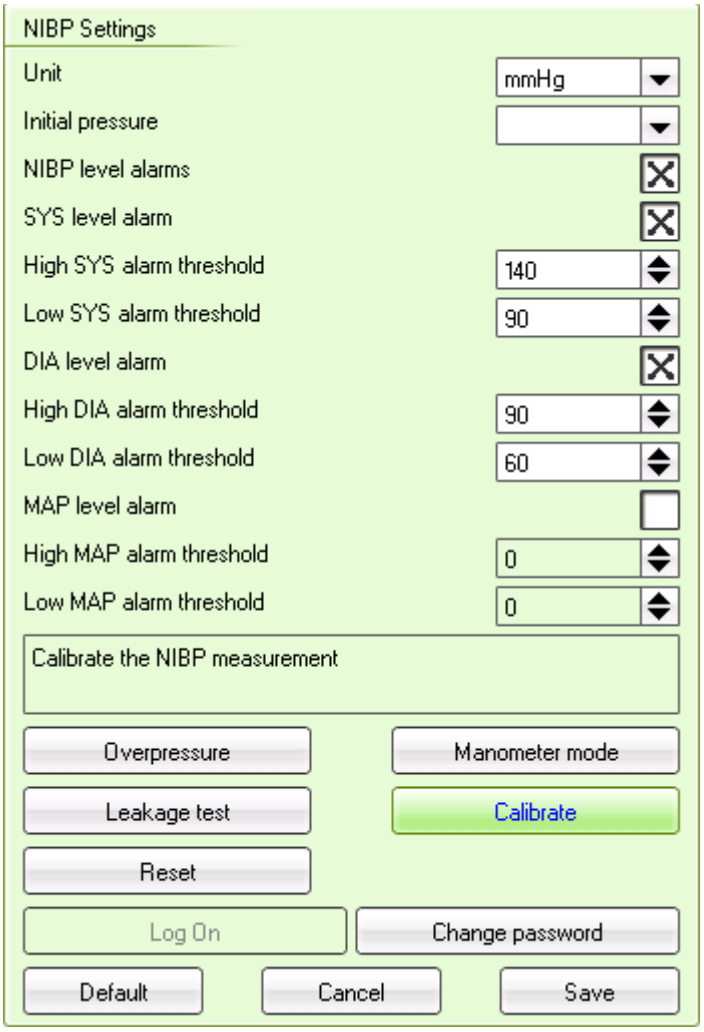


Figure 6:63 Start the Calibration function in the NIBP Settings

i) Select the “Calibrate” , and apply a pressure of 200mmHg.

j) Wait until the pressure has been relatively stable, select the “read pressure” and verify that a reasonable NIBP result is shown on the display, the accepted tolerances: ±3mmHg.

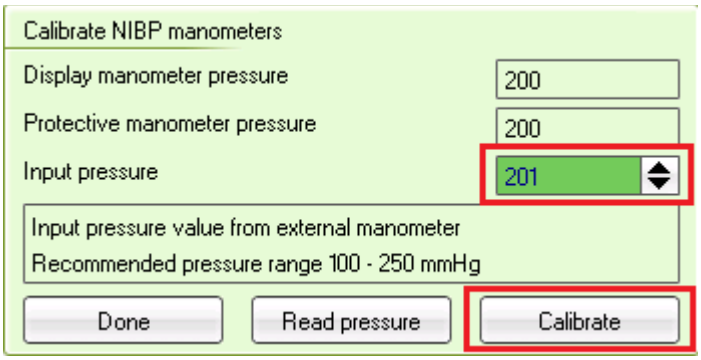


Figure 6:64 Manometer calibration

k) If the NIBP result overpass the tolerances, select the “Input pressure” and input the real-time pressure from the simulator, select the “Calibrate” for con-

firm.Select the “read pressure” again and verify that a reasonable NIBP result is shown on the display, the accepted tolerances: ±3mmHg.

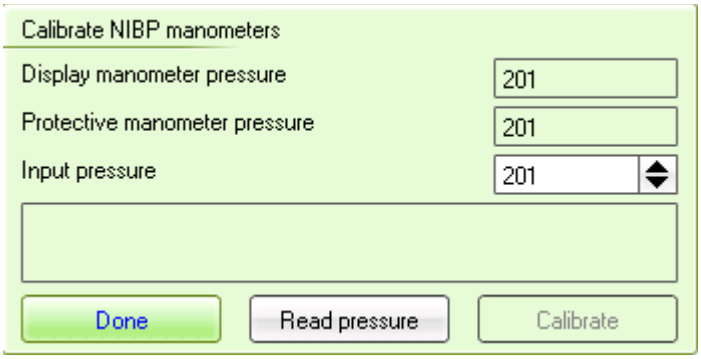
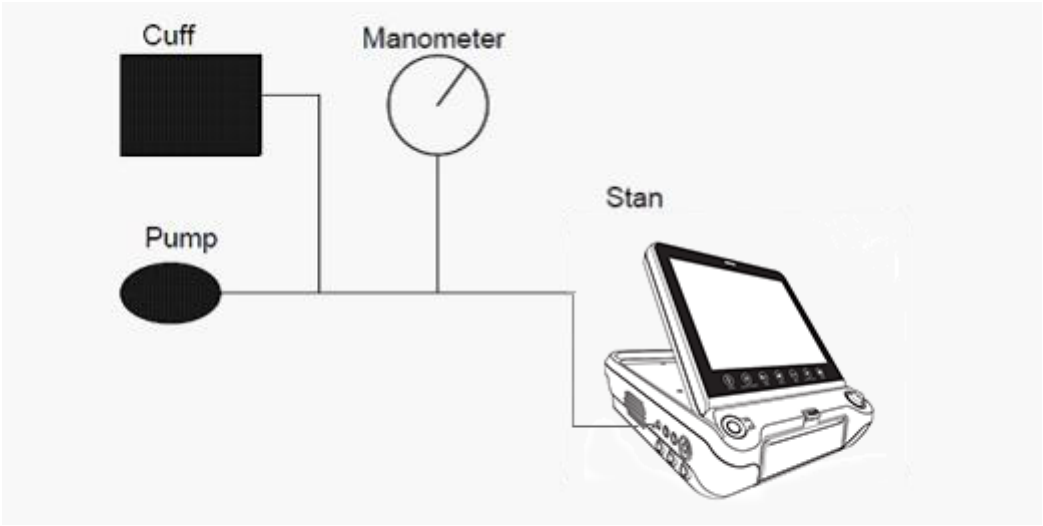


Figure 6:65 Verifying manometer calibration

l) Select “Done” to finish the NIBP function Calibration.Verify that the pressure of the cuff is released after the measurement has been completed.

Tip!

If you don’t have the test simulator, you can perform an Overpressure test and Manometer mode test with the Calibrated Manometer and Pump as the following instruction showed.



6.5.9 MSpO2 function

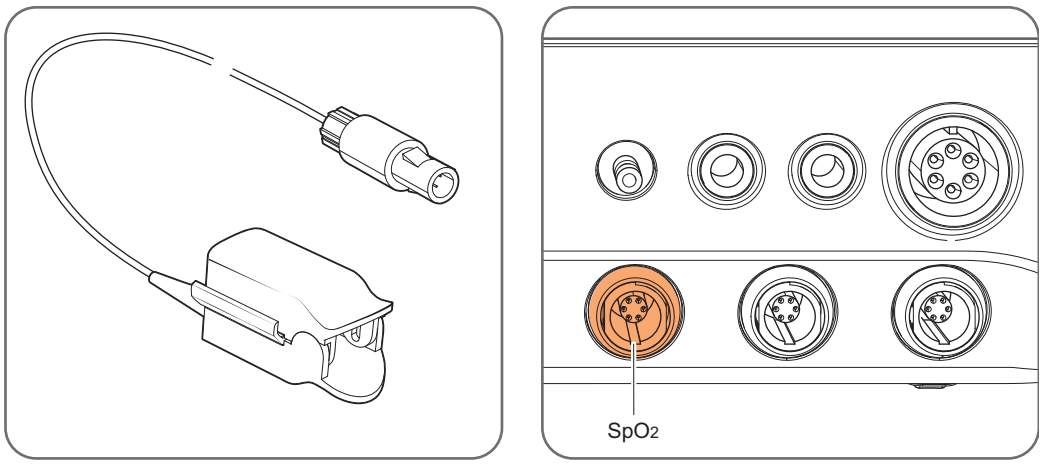


Figure 6:66 Inspecting the MSpO2 sensor and cable

1. Tested range: 30%-100%.
2. Tested parameters: 85%,100%.
3. Accepted tolerance: ≤2 units (70%-100%).
4. Settings to be used: PR=80bpm.
5. Test methods

    a) Inspect the MSpO2 Sensor, its cable and connector and make sure it is not damaged.

    b) Connect the MSpO2 Sensor to the corresponding connector on the main unit.

    c) Select the SpO2 function in the vital simulator, switch multi-parameter or maternal interface mode, connect the monitor SpO2 probe to the vital simulator, it shall displays normal SpO2 values, pulse and waveform.

    d) Clamp the finger probe of monitor to the vital simulator.Set the SpO2 of simulator to 85% and 100% separately, compare the errors.

6.5.10 MECG function

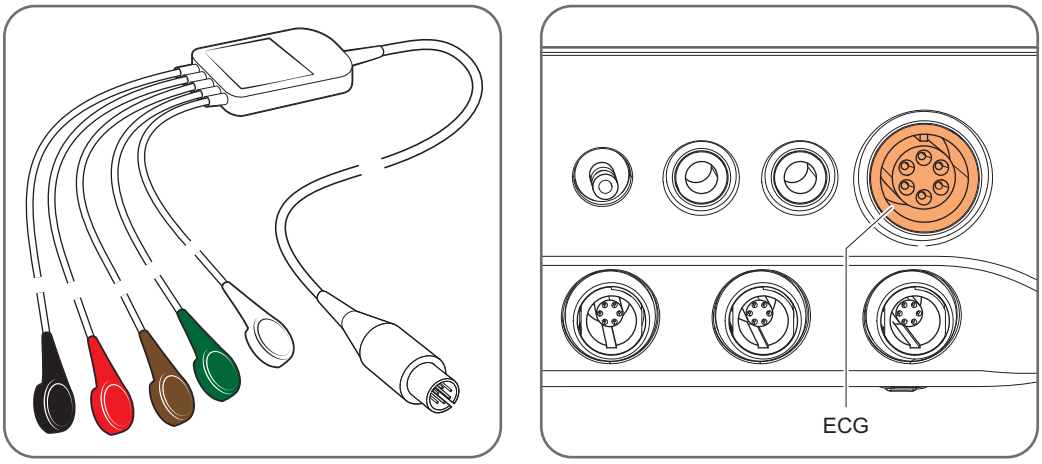


Figure 6:67 Inspect the MECG cable

1. Tested parameters: 30bpm, 150bpm, 300bpm.
2. Accepted tolerances: ±1bpm or ≤±1%, the large one.
3. Test methods
   a) Inspect the 3-lead or 5-lead MECG leadwire cable for cracks and damage. Make sure that the corresponding leadset type is selected in MECG Settings.
   b) Connect the leadwires to the corresponding 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 of another human subject. Be careful to follow the preparation procedures described in STAN S41 Instructions for Use.

   c) Open the MECG view mode by selecting the “View mode” menu button and verify that each head displays the appropriate signal.
   d) Set the HR into 30, 150, 300 times/min.Record the results and compare the errors.
   e) Disconnect each ECG leadwire separately and verify that a corresponding lead-off technical alarm is displayed.

6.5.11 Respiratory rate function

1. Tested parameters: 10rpm, 100rpm.
2. Accepted tolerances: ±2rpm.
3. Test methods

Set Resp rate(RR) of vital simulator into 10 and 100rpm, record the test result and compare the errors.

6.5.12 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.

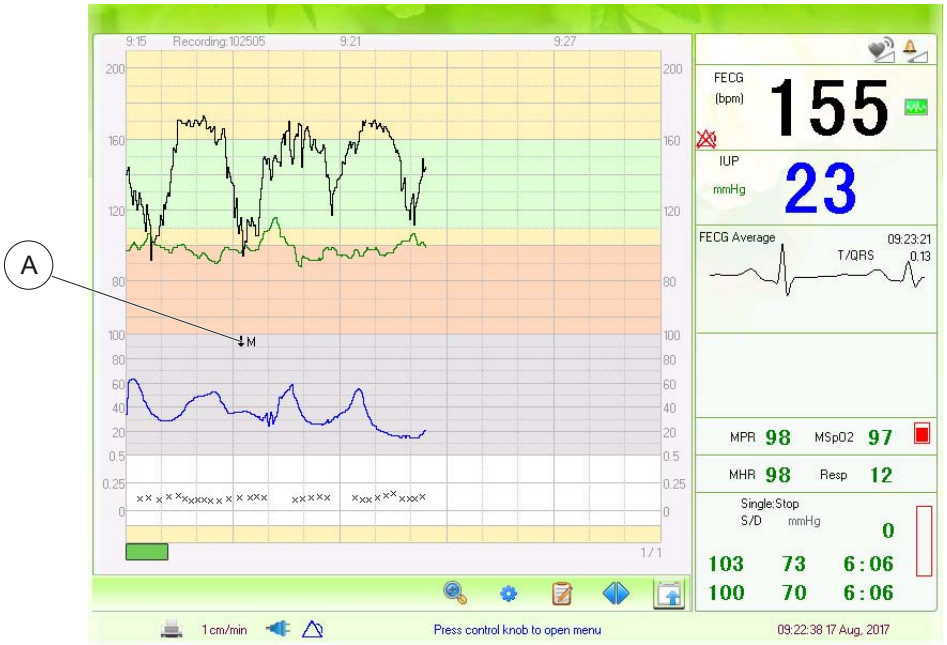


Figure 6:68 Fetal movement mark on screen

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 is presented in the CTG trace on the screen.

6.5.13 Wireless fetal movement marker

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

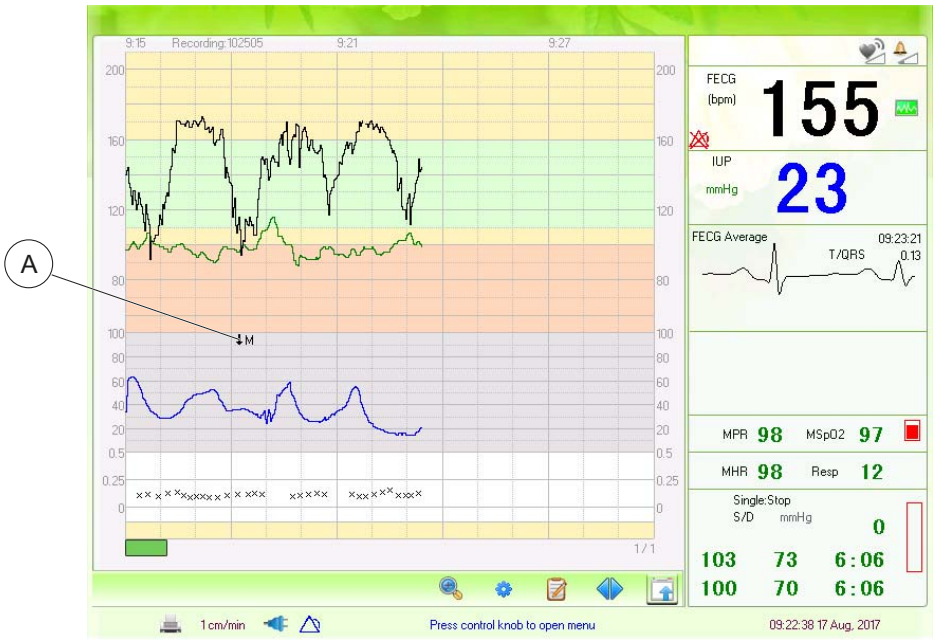


Figure 6:69 Fetal movement mark on screen

2. Start a recording.Verify that the fetal movement marker has remaining battery power by pushing its actuation button, and ensuring that the blue 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 is presented in the CTG trace on the screen.

6.6 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”.

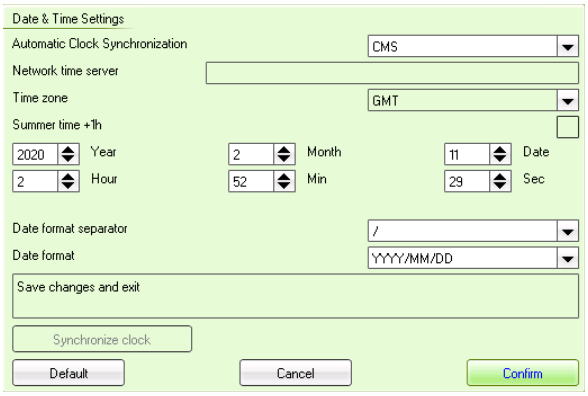


Figure 6:70 Use the control knob to adjust the time and date digits

4. 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.

6.7 Exporting logs 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 system log" or "Export FECG log" in the menu.

7 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.
		Thermal print head is dirty.	Clean the print head with alcohol and a cotton swab.

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 and of correct type (433MHz vs. 2.4GHz).
		Strong influence from electromagnetical interference.	Identify and remove the source of the electromagnetical interference.
		Incorrect transducer version 433MHz vs. 2.4GHz.	Use correct transducer type.
	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.	Another nearby transducer placed on the charging rack is configured to use the same wireless channel.	Configure systems to use different wireless channels.

Area of concern	Problem	Potential cause	Solution
Central monitoring	Recording not visible in central monitoring system.	Central monitoring communication not configured	Review 'CMS Settings' configuration
		CMS cable not connected	Ensure that CMS protocol is activated in the CMS settings, either Philips A20 or STAN R1B. Make sure a recording is started.Make sure to use correct cable for the corresponding CMS. Try a null modem adapter to verify.
	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	Make sure all S41 units have a unique Machine ID.
		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” and “Check Skin” technical alarm.	Patient not connected.	Check legplate, scalp and skin electrode.
		Signal quality problems.	Check skin and scalp electrode; if necessary reapply.
	“Check Skin” 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” technical alarm.	Loose or unconnected scalp electrode or electrode applied through membranes.	"Apply fresh single packed skin electrode."
	“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.

8 Specifications

8.1 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, Wireless TOCO transducers	IP68	Suitable for use when patient is taking shower, but not intended for use in bath.
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, fetal movement marker (wired and wireless), 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 wire connected 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.

8.2 Main unit

Physical Characteristics	
Dimensions (width x depth x height):	365x 385 x 118 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:	5200mAh	4500mAh
Operating time (new battery, fully charged, printer inactive)	>3hours	>2hours
Charging time (when monitor is powered off)	<6hours	<6.5hours
Charge mode:	Constant current/ constant voltage (CC-CV)	Constant current/ constant voltage (CC-CV)
Charge current (Standard):	0.2C (1040mA)	0.2C (900mA)
Charge voltage (Standard):	12.6V	12.6V
Maximum continuous charge current:	2500mA	2250mA

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

8.3 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	

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:	Manual, Automatic, STAT (short term automatic mode)
Range, pSYS:	40-270 mmHg

Maternal NIBP Recording	
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
Lead off detection:	All electrodes individually except RL
Pacemaker pulse rejection capability:	None
Transients when monitor is separated from mains:	None

MECG Recording	
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%)

8.4 Thermal recorder

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 75 mm/sec
Paper width:	156 mm
Recorded Information:	FHR1, FHR2 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

8.5 Wireless subsystem

Communication	
Transmission frequency:	2.4 GHz ISM
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

8.6 Compatible devices

8.6.1 TOCO, ultrasound and fetal movement marker accessories

Part number	Description
P1221-05038 P1221-05037 P1221-05032	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)
P1224-05052 P1224-05048 P1224-05042 P1224-05040	Wired TOCO transducer
P1271-05044 P1271-02055	Wireless TOCO transducer(2.4GHz)
P1271-05052	Wireless TOCO transducer (433MHz, for underwater use)
P1221-12035 P1221-12003	Wired fetal movement marker
P1271-12006 P4907-00012	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

8.6.2 FECG and IUP consumables and accessories

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

8.6.3 NIBP cuffs and hose

Part number	Description
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)
P9001-00506	Adult NIBP cuff (thigh perimeter 42 cm - 54 cm)
P9001-00473	Adult NIBP cuff (upper arm perimeter 25 cm-35 cm)
P9001-00108	Adult NIBP cuff
P9001-00474	Adult NIBP cuff (upper arm perimeter 33 cm-47 cm)
P9001-00482	Adult NIBP cuff (thigh perimeter 46 cm-66 cm)
P9001-00485	NIBP cuff extension hose (3.0m)
P9001-00472	NIBP cuff extension hose (2.0m)

8.6.4 MSpO2 sensors and cables

Part number	Description
P7002-00008	MSpO2 sensor
P7002-00006	MSpO2 sensor
P9001-00140	MSpO2 sensor
P9001-00501	MSpO2 extension cable

8.6.5 MECG consumables and accessories

Part number	Description
P9001-00477	5-leadwire MECG cable
P9001-00401	5-leadwire MECG cable
P9001-00201	5-leadwire MECG cable
P9001-00478	3-leadwire MECG cable
P5300-00004	3-leadwire MECG cable
P7001-00296	Disposable ECG electrode
P7001-00295	Disposable ECG electrode

8.6.6 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 (US)

8.6.7 Mounting equipment

Part number	Description
P2228-16001 P1422-12003	Trolley
P1263-12003	Wall arm
P5301-00011 P5301-00001	Power cord (3.0m) Power cord (2.0m)
P4904-00010 P4904-00004	Mains fuse T2AH250V Mains fuse T2AL250V

8.6.8 Batteries

Part number	Description
P4910-00015 P4910-00006 P4901-01014	Rechargeable system lithium-ion battery(5200 mAH) Rechargeable system lithium-ion battery (4500 mAH) Rechargeable system lithium-ion battery (4000 mAH)
P4901-07006 P4901-01013 P4901-01030	Rechargeable lithium-polymer battery for wireless FHR1, FHR2 and TOCO transducer Rechargeable lithium-polymer battery for wireless FHR1, FHR2 and TOCO transducer Rechargeable lithium-polymer battery for wireless FHR1, FHR2 and TOCO transducer

8.6.9 Monitoring and archiving systems

System type	Description	Compatible brands
Central monitoring systems	Central monitoring systems communicating according to HP publication M13509014L using RS-232.	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.	See http://www.neoventa.com/support/cms-with-st/ for an up-to-date list of compatible systems.

8.6.10 Training materials and clinical guidelines

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.

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.

8.7 System settings of clinical significance

8.7.1 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	Off, 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	
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
Touch key lock	Whether to activate the touch key lock when holding down the MENU button	On Off	Off	
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	
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	Whether to print calculated output parameters from the automated CTG analysis function on continuous printout	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	2	
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 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 MHR	Whether to print maternal heart rate as a trace on printout	On Off	On	
Print FECG Averages	Interval with which to print FECG average waveforms 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	Grid type on paper installed in the printer.	CTG-only grid CTG+ST grid	CTG+ST grid	The configuration of this setting must match the paper type available at the ward.
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	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 CMS independent of server control	On Off	Off	Only applicable if Philips CMS is configured
Time Settings				
Automatic clock synchronization	Whether to automatically synchronize system clock, and against what source	Off CMS Network server	CMS	
Time zone	Local time zone	GMT -12 to GMT +12	GMT	Only applicable if network time synchronization is configured.
Summer time +1h	Whether daylight savings time is currently to be applied	On Off	Off	Only applicable if network time synchronization is configured.
Network time server	IP address of NTP/SNTP server to use for network time synchronization	Text string	-	Only applicable if network time synchronization is configured.
Date format separator	Character used for separating year, month and date when displaying date on screen and printouts	'/', '-', '.'	'/'	
Date format	Format used when displaying date on screen and printouts	Month DD, YYYY, DD Month, YYYY, D/M/YYYY, DD/MM/YYYY, M/D/YYYY, MM/DD/YYYY, YYYY/M/D, YYYY/MM/DD	YYYY/MM/DD	
Network Settings				
Use DHCP	Whether to enable dynamic IP configuration using DHCP (dynamic host configuration protocol)	Yes No	No	
Local IP	Defines a static IP address in the form that the system uses for identifying itself on an IP network	IPv4 format	-	

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.

8.7.2 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	
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 FHR1 and FHR2 shall be displayed with -20 resp. +20 bpm offset on screen and printout	Off FHR1 -20, FHR2 +20 FHR1 +20, FHR2 -20	Off	FHR1 +20, FHR2 -20 is common practice in Europe, while FHR1 -20, FHR2 +20 is common practice in China
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”
FHR alarm delay(s)	Delay time for generating High / Low FHR level alarms (seconds)	0 to 300 in steps of 5	5	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 only showed if AFM is activated under hardware settings
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	Setting only showed if AFM is activated under hardware settings

Setting name	Description	Options/ Constraints	Factory default	Comment
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	
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	

8.7.3 Maternal settings

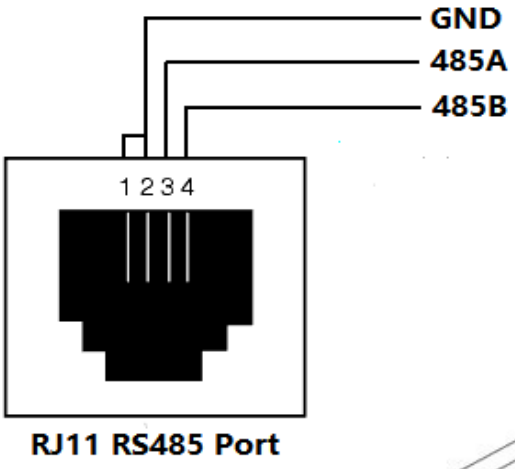
Setting name	Description	Options/ Constraints	Factory default	Comment
MECG Settings				
Leadset type	Type of leadset cable used for MECG monitoring	5 leadwires 3 leadwires	3 leadwires	
5-leadwire mode	Default lead presented in user interface when using 5-leadwire cable	I, II, III, aVR, aVL, aVF, Vx	II	
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	
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 Trend	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 sensitivity	Select the respiration sensitivity	1, 2, 3, 4, 5	2	
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 150	30	Cannot be set below “Low Resp alarm threshold”
Low Resp alarm threshold	Lower alarm threshold for RR level alarm	0 - 149	8	Cannot be set above “High Resp alarm threshold”

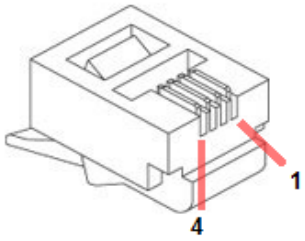
Setting name	Description	Options/ Constraints	Factory default	Comment
Apnea alarm (s)	Time between last calculated RR value until generation of apnea alarm (seconds)	Off, 10 to 40	10	Password protected
MSpO2 Settings				
MSpO2 Alarm	Whether to generate level alarms for oxygen saturation and pulse rate calculated from MSpO2 signal	On Off	On	
Low MSpO2 alarm threshold	Lower alarm threshold for MSpO2 oxygen saturation level alarm	90-99	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	
Initial Pressure	Initial inflation pressure at start of NIBP measurement	100 to 300 mmHg	160	Should be set slightly higher than anticipated systolic pressure
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	On	
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”
Display MAP	Whether to display the MAP value of NIBP measurements on screen and printouts.	Yes No	No	

8.8 Standards compliance

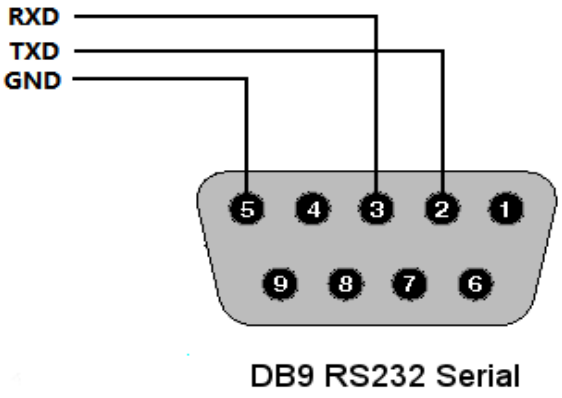
Reference	Name
IEC 60601-1:2005 + A1:2012+A2:2020	General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements 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

8.9 Pinout information of RS-485/RS-232/NET interface



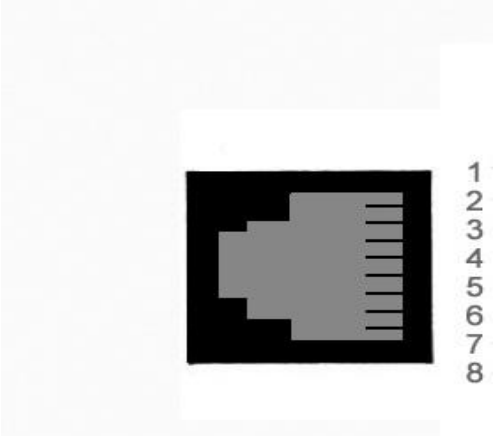


Pinout Number	Definition
1	ISO-GND
2	ISO-GND
3	485A
4	485B



Pinout Number	Definition
1	NC
2	ISO-TXD
3	ISO-RXD
4	NC
5	ISO-GND

Pinout Number	Definition
6	NC
7	NC
8	NC
9	NC



Pinout Number	Definition
1	TX+
2	TX–
3	RX+
4	NC
5	NC
6	RX-
7	NC
8	NC

9 Spare Parts

9.1 Spare Parts List

Device	Part no
RS485 Connection Cable	P1211-03005
S41 upper case	P2263-04050
S41 lower case	P2263-04067
2.4GHz Wireless Module for FHR1	P1263-02068
2.4GHz Wireless Module for FHR2	P1263-02069
433MHz Wireless Module for FHR1	P1802-00130
433MHz Wireless Module for FHR2	P1802-00220
LCD screen interface board	P1263-02074
Wireless Extension Module	P1802-00222
LCD Screen	P4630-00019
Rotating Shuttle	P4801-08011
2.4GHz Omnidirectional antenna	P4908-00007
433MHz Omnidirectional antenna	P4980-00010
Fuse T2AL250V	P4904-00004
Main Board	P1263-02039 P1263-02076
Printer module_V3	P4909-03006
Power supply module	P4902-07005
Multi-parameters board	P9001-00022
Rechargeable lithium-polymer battery for wireless FHR1, FHR2 and TOCO transducer	P4901-07006
Button Cell	P4901-03011
Rechargeable system lithium-ion battery	P4910-00015

10 Appendix

10.1 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

10.2 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
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)

10.3 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.

10.3.1 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	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

10.3.2 Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity test	**IEC 60601 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 100 kHz repetition frequency	±2 kV power supply lines ±1 kV signal input/output 100 kHz 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 (50/ 60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC 61000-4-6	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 (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 b) 18 Hz	27	27
	450	430-470	GMRS460, FRS 460	FM c) ± 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				
	Test frequency	**Modulation**	**IEC 60601-1-2 Test Level** (V/m)	**Compliance level** (V/m)
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	30 kHz	CW	8	Not Applicable
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	Pulse modulation 50 kHz	7.5	7.5

CE 0123

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