

DRAFT

USER MANUAL



STAN[®] S31 Fetal heart monitor

Table of contents

LIABILITY	1
Reservations.....	1
Warranty	1
Intended use	2
Indications for use.....	2
Contraindications for use	2
INTRODUCTION	3
SAFETY	5
Symbols	5
User requirements	5
Hazardous environments.....	5
Moisture	5
Electrical safety and EMC	6
Power source.....	6
Incorrect mains connection.....	6
Earth connection	6
Leakage current to patient.....	6
System combinations	7
Cables.....	7
Safety of patient and fetus	7
Electrodes.....	7
Data interpretation	8
EU declaration of conformity	8
GENERAL DESCRIPTION	9
System components	10
Operation modes	14
Event Log	16
USING THE SYSTEM	17
Environment.....	17
Customization	17
Calibration of touch screen	17
Handling.....	18

RECORDING	23
How to start a recording.....	23
Functions.....	25
MATERNAL PARAMETERS	31
STAN® VSM 21 vital sign monitor.....	31
FECG SIGNAL INSPECTION	35
Poor signal quality	35
Reduced amount of ST-datapoints.....	36
Breech presentation	37
Maternal ECG	38
Atypical FECG complexes	38
EVENT LOG	39
Review event log	39
Signal events.....	39
System events	40
ST events.....	40
User events.....	40
Maternal parameters	41
PRINTING ON PAPER	43
STAN® P 11 Thermal Recorder	43
Laser Printer.....	48
SERVICE FUNCTIONS	51
MAINTENANCE	53
Intervals	53
Cleaning.....	53
CLASSIFICATION	55
Protection against electric shock.....	55
Degree of protection against exposure to fluids	55
CONSUMABLES AND ACCESSORIES	57
STAN® TR 31	58

CONNECTION OF EXTERNAL EQUIPMENT
59

TROUBLESHOOTING **61**

General..... 61
Recording via FECG..... 61
Recording via TOCO or IUP 62
Recording via US1 or US2 63
System output signals 63
Thermal recorder failure 63
Laser printer failure 64

FUNCTIONAL TESTS **65**

STAN® T 31 TOCO..... 65
STAN® U31 US1 and STAN® U32 US2..... 65
3-lead FECG legplate 66

GENERAL **67**

Manufacturer..... 67
Other Manuals..... 67

APPENDIX.

Quick Reference Guide

DRAFT

LIABILITY

Neoventa Medical expects that when using the STAN® S31 fetal heart monitor,

- the equipment is used correctly, and
- the equipment is used in a suitable environment in conjunction with electrical installations approved for the purpose, and
- all repairs, adjustments or modifications are carried out by personnel authorised by Neoventa Medical

Reservations

Neoventa Medical will accept no responsibility if the product is used in a manner contrary to the manufacturer's intentions. This user manual provides no guarantee for such use.

The manual has been checked for accuracy. The instructions and specifications in the manual were applicable to the STAN® S31 fetal heart monitor at the time of printing. Subsequent models and manuals may be modified without prior notice.

Neoventa Medical accepts no responsibility for damage, caused directly or indirectly, arising from faults, omissions or any other deviations from intended use.

This user manual is protected under copyright legislation, and its contents may not be copied either in whole or in part without the prior written permission of Neoventa Medical.

This equipment may not be sold to persons other than physicians. It is designed to function in a hospital environment, not for home use.

If the equipment is to function correctly, it must be serviced and maintained by qualified technicians. Failure to do so may affect the functionality of the device, and may lead to injuries to patients and medical personnel.

Warranty

See separate warranty contract.

Intended use

The STAN® system is intended to be used in pregnancies at term (>36 completed gestational weeks) to improve the assessment of the fetal condition during labor as an adjunct to standard fetal heart rate monitoring.

Indications for use

Use of the STAN system is indicated when there is planned vaginal delivery and:

- there is a need for close fetal surveillance during labor, or
- there are maternal disorders and/or utero-placental dysfunction with potential adverse influence on fetal oxygen and nutritional supply, or
- there is deviation from the normal course of labor including induction/augmentation of labor.

Contraindications

Need for immediate delivery to avoid undue delay in situations such as:

- cord prolapse
- preterminal fetal heart rate changes
- marked fetal bleeding

Known maternal/fetal disorders when application of a fetal scalp electrode is contraindicated, such as:

- HIV
- Infectious hepatitis
- Active herpes zoster
- Known or suspected fetal coagulation disorder

INTRODUCTION

The STAN® S31 fetal heart monitor is a fetal monitoring system that continually monitors the heart rate and ECG of the fetus during labour by means of a scalp electrode, and the uterine activity of the mother through an external uterine activity transducer or internal pressure transducer. Unlike traditional EFM monitors, the STAN® S31 fetal heart monitor also employs a skin electrode attached to the mother's thigh, this electrode is essential in obtaining and displaying the fetal ECG wave-form. The STAN® S31 fetal heart monitor is also capable of measuring fetal heart rate by means of an ultrasound transducer. It is also possible to monitor one twin using fetal ECG and the other twin using the external ultrasound transducer. It is not possible to monitor twins simultaneously with fetal ECG. Dual ultrasound transducers also facilitate twin monitoring.

Data is displayed continuously on screen and also on paper if a thermal recorder is connected. Whereas external ultrasound recording only displays the fetal heart rate, internal recording using a scalp electrode can record and display the fetal ECG waveform. Using this information, the STAN® S31 calculates and displays a T/QRS ratio calculated from the fetal ECG complexes, and also indicates the incidence of “biphasic” ST waveforms. T/QRS ratio changes are constantly monitored and a message is printed in the event of any problem or significant event.

The STAN® S31 is a system in which patient transducers are directly connected to the Patient Interface Box (PIB) at the rear of the unit. Certain approved accessories, such as a thermal recorder, network printer and a keyboard, may also be connected.

The operator activates the various functions of the STAN® S31 fetal heart monitor by using its LCD touchscreen. By tapping the function buttons with the finger or a touchpen the user can activate functions and open menus.

SAFETY

Symbols



Warning symbol

This symbol means that the user must read the User Manual prior to activating the function. In this manual, it is used to highlight information to which extra attention should be paid.



High voltage

This symbol is used to indicate high-voltage components that will be exposed if the device is dismantled.

User requirements



The STAN® S31 fetal heart monitor should be operated only by personnel who have read this User Manual, and have been trained to operate the STAN® S31 fetal heart monitor according to the US Training Requirements. The operator must also be trained in how to interpret information as dictated by the manual, and must be competent to decide, while recording an ECG using the STAN® S31 fetal heart monitor, whether the signal has been generated by a maternal ECG complex or by a breech delivery.

Hazardous environments

The STAN® S31 fetal heart monitor is not shielded against electrocautery or defibrillators and must not be used together with or in proximity to flammable substances, e.g. anaesthetic gases. It should be used only in rooms that are relatively free of dust, moisture, vibrations and extreme temperatures. Neoventa Medical guarantees the functioning of the device only if it is used within the temperature range 40-104 degrees F.

Moisture

Make sure that the equipment and all its cables are dry when used. Condensation may occur if it is moved from one building to another. Should this be the case, dry the equipment thoroughly prior to mains connection.

Electrical safety and EMC

The STAN® S31 fetal heart monitor complies with the EN60601-1 electrical safety requirements and the EMC requirements in accordance with EN 60601-1-2.



Radio transmission equipment, mobile telephones 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. If in doubt, consult a qualified technician or the supplier.

Power source

The STAN® S31 fetal heart monitor must be used only with a power source of 100-240V 50/60 Hz. The mains cable has three conductors for connection to an earthed wall socket. The system must be connected to an outlet with proper protective earth wiring.

Incorrect mains connection

Check that the equipment is not connected to the mains by any component other than mains cable or approved trolley.

Earth connection

The STAN® S31 fetal heart monitor must have a protective earth connection. All forms of earth leakage represent a potential safety risk that may seriously injure patient and operator.

Leakage current to patient

Note that, if the patient is connected to more than one device, the sum of their leakage currents may exceed the allowed limit, even if the individual leakage currents are below the allowed limit.

System combinations

Please note that only system combinations as specified in this user manual are allowed. If other system combinations are required contact a qualified technician or the supplier.

Cables

Take care that the cables of the STAN® S31 are not damaged during use or storage. Transducers and other connectors may be damaged if trodden on. When connecting cables and transducers, make sure there is no risk of anyone stumbling or tripping over the cables, since the patient and fetus may be injured if the scalp electrode or skin electrodes are pulled off. Connect only the mains cable to the mains supply.

Safety of patient and fetus

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

Electrodes



Note that when used for internal recording the STAN® S31 is designed for use with disposable single-spiral electrodes. If other electrodes are used, the ECG signal from the scalp electrode may be of insufficient quality, resulting in a poor-quality recording that may lead to misinterpretation of data.

Neoventa Medical recommends that only the recommended electrodes and transducers are used.

During use of the STAN® S31 fetal heart monitor, the scalp electrode must at all times be properly attached to the fetus, so that good signal quality, facilitating correct data interpretation, may be obtained. If the electrodes or system cables are accidentally loosened, the fetus and mother may suffer physical injury as a result of data being unavailable to the operator.



The scalp electrode cables must be properly connected to ensure correct system function. Fix the scalp electrode in accordance with the instructions included with the disposable pack. After application the connector end must be fully inserted into the legplate. The legplate skin electrode cable must be connected only to the skin electrode. If the skin electrode is not connected, there is a risk that the mother's ECG will be recorded instead of that of the fetus. In order to avoid infection, only disposable electrodes of the recommended type should be used.

Please note, to ensure good signal quality during FECG recordings, the skin electrodes must always be stored in a sealed pouch to prevent the electrode gel from drying out. For best results, high quality single-packed electrodes should be used.

Please note the possibility of pick-up of interfering signals from other electronic equipment if no electrodes are connected to the legplate. This interference may in rare circumstances generate false fetal heart rate.

Data interpretation



Before commencing internal recording, the operator should verify that the ECG complex is of a normal appearance. Exercise particular care in the event of a constant heart rate, since this may be caused by another device interfering with the signal so that the system detects a “false” QRS complex. Check any warning messages that appear on screen - for example, if “Check Scalp” is displayed, make sure that the scalp electrode is securely attached to the scalp of the fetus.

The operator must be aware that abnormal ECG complexes may result in inaccuracies in ST analysis data. A diagnosis based on abnormal ECG complexes may result in incorrect assessment and treatment of the fetus. The operator must be capable of deciding whether it is the mother's ECG signal or a breech delivery that is being recorded. Failure to distinguish between the two may lead to fetal injury as a result of the interpretation of the wrong data.

Note that TENS (Transcutaneous Electronic Nerve Stimulation) must not be used during internal recording (FECG) with the STAN® S31 fetal heart monitor.



During external ultrasound recording it is essential to check that the fetal heart rate presented is not double or half the true heart rate. The operator should also make sure that the maternal heart rate is not erroneously recorded. During recording of twins the operator should check that the fetal heart rates presented are from different fetuses and not from the same source.

EU declaration of conformity

The STAN® S31 fetal heart monitor is CE-marked in accordance with the relevant EU directives. Neoventa Medical is responsible for the CE-marking of the equipment.



GENERAL DESCRIPTION

The STAN® S31 fetal heart monitor is a fetal monitoring system that continually monitors the heart rate and ECG (FECG) of the fetus during labour by means of a scalp electrode, and the uterine activity of the mother through an external uterine activity transducer (TOCO) or an intrauterine pressure (IUP) transducer. The STAN® S31 fetal heart monitor is also capable of measuring fetal heart rate by means of an ultrasound transducer (US). Dual ultrasound transducers facilitate twin monitoring.



Internal monitoring of fetal ECG (FECG) is achieved by means of a scalp electrode which may be attached to the defined presenting part of the fetus after rupture of the membranes. A skin electrode is applied to the inside of the mother's thigh close to the groin and connected to the skin electrode cable on the legplate. The legplate is fixed with an elastic band firmly around the mother's thigh, and the scalp electrode connector is then plugged in. The scalp electrode connector must be properly inserted to ensure correct system function.

Generally, internally recorded fetal ECG provides a more accurate value for the fetal heart rate, with true beat-to-beat measurements obtained from the RR interval between each individual ECG complex. Scalp electrode recording is the only possible method of obtaining a complete ECG waveform from the fetus, and this is essential for STAN®'s ST analysis.

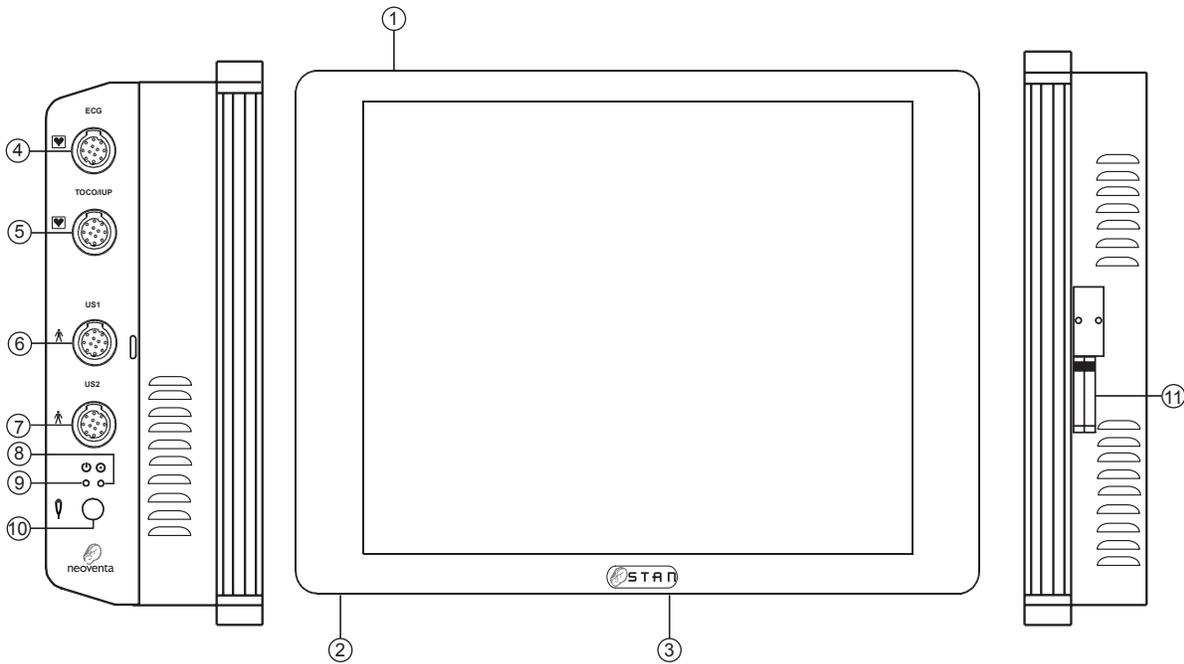
An ultrasound transducer (US) may be used for external monitoring. This method gives only a heart rate, and is usually not as precise in beat-to-beat terms as internal monitoring. The ultrasound transducer transmits a high frequency, but extremely low-strength sound impulse that is reflected back from the heart of the fetus. The monitor then calculates the heart rate from this echo and displays it on the screen. The transducer is fixed around the mother's abdomen with an elastic band. It must be directed towards the heart of the fetus in such a way that an optimum signal is obtained. Its positioning will need to be checked regularly.

For optimum monitoring during the second stage of labour, a scalp electrode should be attached as soon as possible.

Uterine activity is monitored externally using a transducer (TOCO), firmly attached by a separate elastic band, which detects pressure changes and provides a rough index of uterine activity. More accurate measurement can often be obtained through the use of an intrauterine pressure (IUP) transducer. This may be applied after the membranes have ruptured. The transducer is introduced into the cervix and located between the fetus and the wall of the uterus. It is then connected to the STAN® monitor via an adapter cable.

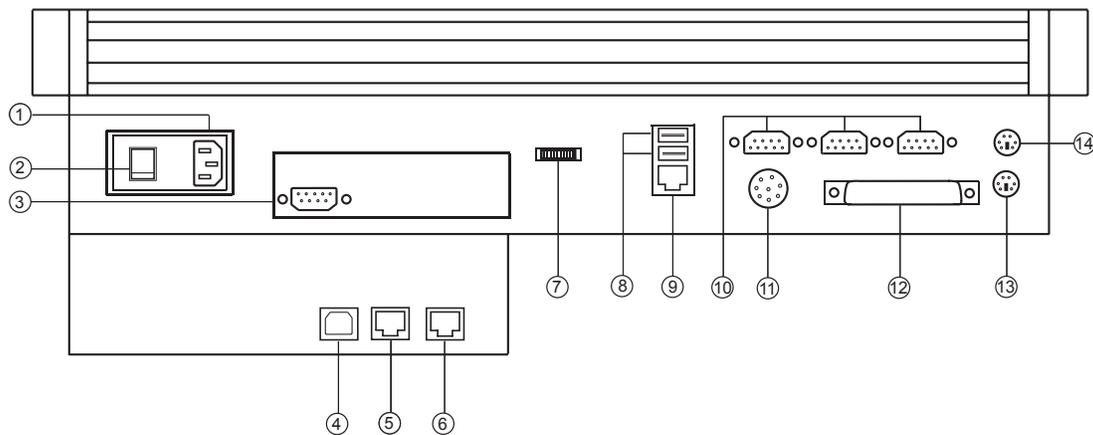
Twins may be monitored in two ways. Both may be monitored externally, by attaching the US1 transducer to the lower twin, and the US2 transducer to the upper one, or - after the membranes have ruptured - the lower twin may be monitored using FECG and the upper using US2. FECG and US1 cannot be used simultaneously. It is not possible to record both twins with FECG.

System components



1. Display unit
15" flat screen for data presentation.
2. Power switch
For turning the device on and off (located underneath).
3. Brightness control
For the adjustment of the display unit.
4. ECG (blue)
Input for legplates with scalp and skin electrode connectors.
5. TOCO/IUP (red)
Input for external uterine activity transducer or adapter cable for intrauterine pressure transducer.
6. US1 (green)
Input for external ultrasound transducer for heart rate measurement. This may be used in conjunction with US2 for recording twins. It cannot be used at the same time as FECCG.
7. US2 (yellow)
Input for external ultrasound transducer for heart rate measurement. This may be used in conjunction with US1 or FECCG for recording twins.
8. Activity LED (green)
Should begin to blink within 2 seconds of power on.

-  9. Power LED (green)
Should produce a green, constant light.
-  10. Event marker
For input from event marker cable
- 11. PC-card slot
Used for storage card

View from beneath

1. Mains input
For connection of 100-240 V 50/60 Hz mains cable.
2. Power switch
Power switch for turning the device on and off.
3. High speed serial port for patient interface box (Connect to (5) using cable CBL 103 003).
4. Patient Interface Box USB. Not Used.
5. Patient Interface Box high speed serial port (Connect to (3) using cable CBL 103 003).
6. Patient Interface Box external DC power input (5V DC) and analogue audio output (Connect to (11) using cable CBL 103 014).
7. Brightness control
For the adjustment of the display unit.
8. USB ports.
9. Network Port
Used for connection to Central Monitoring System and central printer, must only be used in conjunction with the ethernet (safety) isolation cable CNK 101 003.
10. Peripheral device connectors, COM1 for connection of Thermal Recorder, COM2 for connection to Central Monitoring System and COM3 for connection of Maternal Vital Signs Monitor.
Connect only approved peripheral devices.
11. Audio input/output and 5V 1A DC output (Connect to (6) using cable CBL 103014).
12. Port not used.
13. Mouse input (M/S)
For connection of mouse. Not used.

14. Keyboard input (K/B)
Use only approved keyboards.

All connectors that are not in use should be covered.

Operation modes

Three modes of operation are possible:

-Recording mode.

This is the mode used for recording data

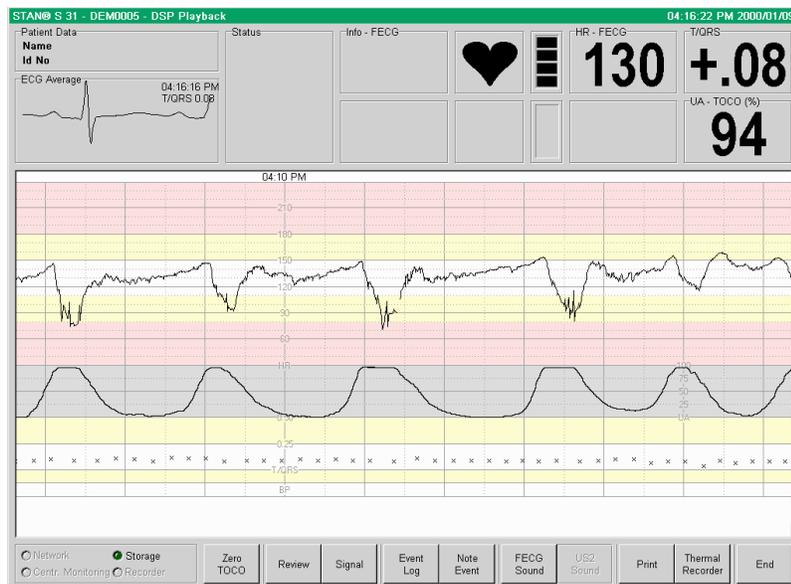
-Signal mode.

Used to check FECG signal quality

-Review mode.

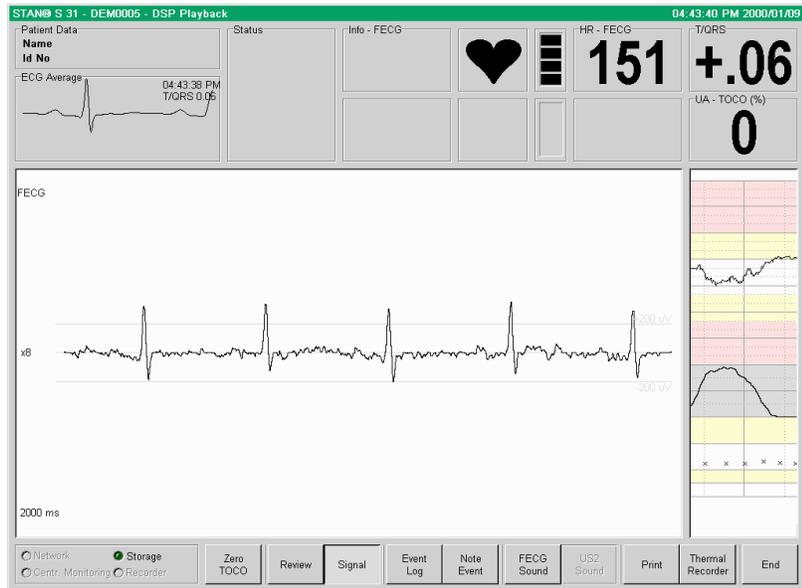
Used to review previously recorded data whilst recording

Recording mode (Live EFM Window)



This is the mode normally used in monitoring the fetus. At a recording speed of 3 cm/min, approximately 10 minutes of EFM and ST information will be displayed.

Signal mode (FECG Signal Window)



Signal mode may be used only in conjunction with internal recording by scalp electrode (FECG). When recording starts, the fetal ECG will automatically be displayed until a stable signal has been achieved, and the system will then switch to recording mode. The operator may at any time during recording return to signal mode to monitor the fetal ECG signal.

Review mode (EFM Scroll Window)



This mode permits review of the recording prior to that shown on screen in recording mode. To scroll through the recording, hold down and slide the scrollbar to the left or right with the finger/touchpen. To navigate with more precision, hold down and slide the actual EFM trace, or use the arrows on the ends of the scrollbar. The last few minutes of the ongoing recording always appears at the far right.



Note that if the window is moved fully to the right, the most recent part of the recording will appear in duplicate, both in the window on the extreme right showing the current recording and in the review window. It is important not to confuse these two windows when you analyse the curve. They should be viewed independently.

Event Log



The Event Log may be activated in all modes. It records information about various events, for more information see “EVENT LOG” on page 39

By pressing the Event Log button the Event Log can alternatively be shown or hidden. In review mode, move up and down in the Event Log by tapping the arrows in the event log window.

USING THE SYSTEM

Environment

The STAN® S31 fetal heart monitor should be used only under the following conditions:

- Ambient temperature: +50 degrees F to +104 degrees F.
- Relative humidity: 30% to 75% (no condensation).
- Atmospheric pressure: 700 hPa to 1060 hPa.



For more information see “SAFETY” on page 5.

The STAN® S31 fetal heart monitor may be used in a normal hospital environment, and is approved under EN60601-1-2 as regards electromagnetic interference (EMI) and radio transmitters.

Customization

Several functions in the software can be adjusted to the needs of the clinic. Adjustment is normally made by qualified technicians and is described in the service manual.

Before use, language, keyboard layout and machine name should be set. For further details, see STAN® S31 Service Manual (PRD 101 004).

The set-up menu can be accessed during startup, by touching the dialogue box “Set up menu” in the lower right corner.

Calibration of touchscreen

The touchscreen may need calibration for optimal precision of function buttons. The touchscreen calibration should be checked during yearly maintenance and if any problems with precision are encountered. Calibration of touchscreen is entered by touching the dialogue box “Calibration of touchscreen” during startup. For further information, see STAN® S31 Service Manual (PRD 101 004).

Handling

Power connection

Before use, the system must be connected to an earthed mains socket providing 100-240 VAC, 50/60 Hz, using the mains cable supplied or via an approved trolley or wall mount.

Note that the monitor is designed for use in an upright position and that there must be a clearance of at least 5 cm behind the rear panel of the main unit to permit adequate ventilation.



Power switch

To start the system, set the power switch located beneath the display unit to position 1 (see “System components” on page 10). Turn off the power by setting the switch to position 0.

For the system to function correctly, and no information lost, it is important that power is not interrupted until recording is complete and the system explicitly states that power may be switched off, see “End” on page 29.

Patient transducer connection

Connect the transducer by inserting the connector into the correct socket (see “System components” on page 10). The connectors are color coded. Check that the angle of the connector is correct. A degree of force will be required for insertion. Make sure that the correct transducer is connected to the correct socket according to the colour code on the connector or the text over the sockets and to the upper surface of the transducers. To disconnect, pull the connector straight out.

When recording twins, use either US1 and US2 (external recording) or FECG and US2 for internal recording of the lower fetus and external recording of the upper one. Note that FECG and US1 cannot be used simultaneously.

Connection of external equipment

External equipment such as keyboard, printer and network connections can be connected (see “CONNECTION OF EXTERNAL EQUIPMENT” on page 59).

Navigation

Function buttons and menus are operated through the LCD touchscreen. A function is activated by tapping a function button with the finger or a touchpen. Menus can be opened by pressing and holding the function button. Menu items are then selected by moving the finger or touchpen to the requested function and releasing.

Brightness control

This is to be found on beneath the display unit (see “System components” on page 10). Display unit brightness may be increased and decreased by turning to right or left. If the screen is completely black, check the adjustment of this control.

Data storage

All recordings are temporarily stored digitally on an internal flashdisk and transferred to a final storage media when possible. The disk has the capacity to store up to several hundred hours of data. There are different options for transfer of stored data.

1. Network storage
The S31 fetal heart monitor can connect to a network via ethernet. Once configured, the data will transfer automatically to a hospital server.
2. USB storage media
To transfer recordings to USB storage media when the STAN® is started, plug a *prepared* USB storage media into any of the two available USB connectors, see STAN® S31 Service Manual (PRD 101 004).

Please note that Neoventa Medical will accept no responsibility for electronic data archiving, and recommends that users develop a procedure for data archiving.



Data loss is possible if instructions are not correctly followed. For further details, see STAN® S31 Service Manual (PRD 101 004).

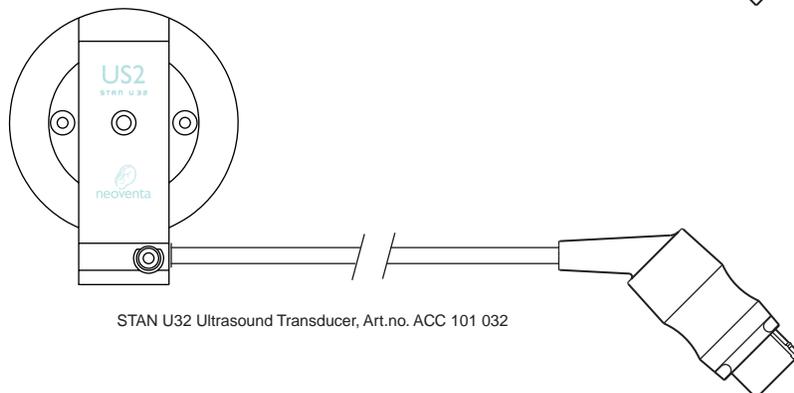
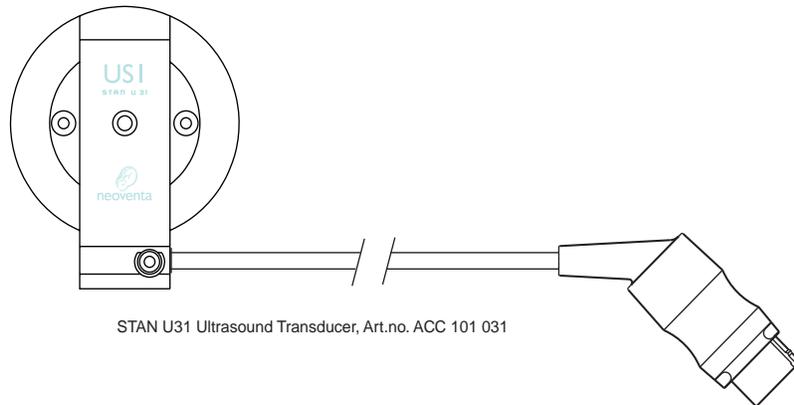
Recording time

Note that the maximum recording time is 48 hours. After 47 hours, the system will warn the operator that only 60 minutes of recording time remain, and recording will end after 48 hours. If the patient needs to be recorded for a longer period, recording must be terminated and a new recording begun.

Patient transducers

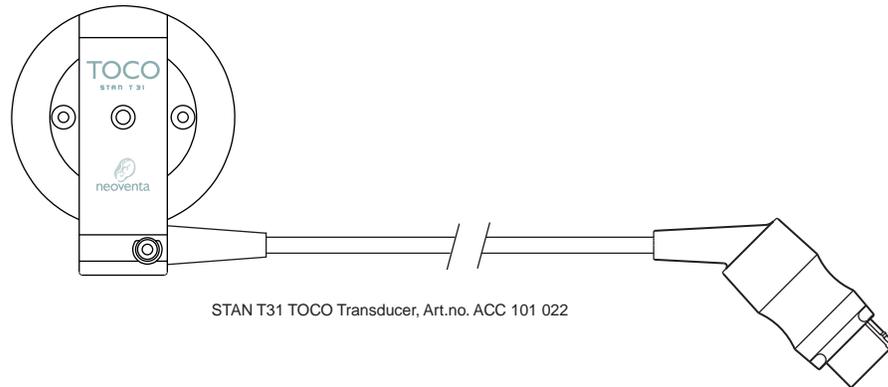
The transducers to be used should be connected to the Patient Interface Box (PIB) and correctly positioned on the patient. There are no restrictions regarding the order in which the device should be activated, and transducers attached.

U31 and U32 (UltraSound transducers)



The transducers are identified by the designations U31 and U32, and they are labelled “US1”(green connector) and “US2”(yellow connector) respectively. The optimum method of attachment is to stretch the elastic band around the mother's abdomen, identify the best position, adjust the band if necessary and then fix the transducer under the band. For optimum performance, the system should be operating while the best position is identified with the aid of the heart sounds from the speaker and the available heart rate indications. The transducer should be placed over the heart of the fetus.

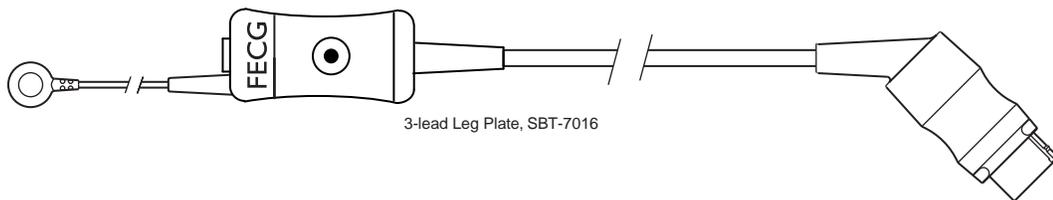
T31 TOCO (Uterine transducer)



STAN T31 TOCO Transducer, Art.no. ACC 101 022

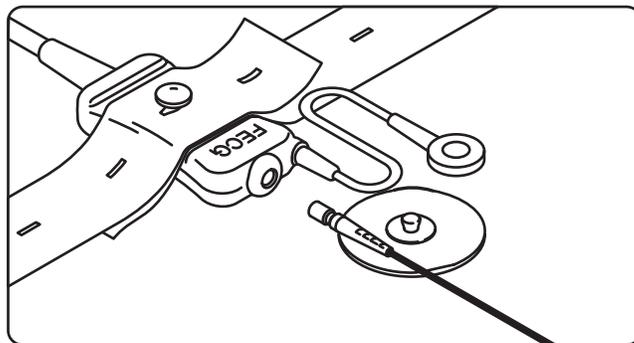
This transducer is identified by the designation T31, and is also labelled “TOCO” (red connector). The transducer is fixed with an elastic band. The transducer should be placed on the upper part of the abdomen over the maternal fundus. Tightening and loosening the elastic band will change the sensitivity.

F22 FECG Legplate SBT-7016 (Fetal ECG)



3-lead Leg Plate, SBT-7016

The legplate is identified by the marking SBT-7016, and is labelled “FECG” (blue connector).



During internal ECG recording, a skin electrode must be applied to the mother's groin, where there is relatively little musculature that might cause interference. Make sure to prepare the skin by rubbing with an abrasive device and wipe with an alcohol pad, in order to ensure good contact.

Attach the scalp electrode in accordance with the instructions included with the disposable pack. The legplate is secured firmly to the maternal thigh, by

wrapping elastic belt around and placing on top of connector through button holes on each end of belt. Connect skin electrode to the snap of the legplate and insert the male spiral electrode connector into the female legplate connector as shown. The scalp electrode must be properly attached to the fetus throughout the use of the STAN® S31 fetal heart monitor.

ST analysis requires good signal quality-more than may be required for EFM. Good signal quality is therefore essential. In some cases it may take up to 20 minutes before the contact surface between electrode and skin reaches an optimum state. If the electrodes or system cables are accidentally loosened, the fetus and mother may be injured as a result of data being unavailable to the operator.

The scalp electrode connectors must be properly inserted to ensure correct system function. The legplate skin electrode cable must be connected only to the skin electrode. In order to avoid infection, only disposable electrodes of the recommended type should be used. The scalp electrode application procedure is described in the directions included with the disposable pack.



Always disconnect the FECG cable from the main unit when it is not connected to a patient. Otherwise, the cable may be affected by ambient interference and generate false heart rate data.

Adapter cable for intrauterine pressure (IUP)

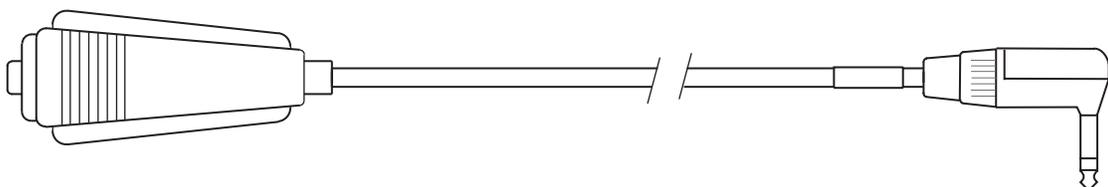
An IUP transducer for the measurement of intrauterine pressure may also be connected by using the IUP adapter cable and the recommended consumable.

Two different adapter cables are available:

- STAN® I 21 IUPT Adapter - for connection of Intran™ disposable IUP transducer from Utah Medical (marked ACC 101 004).
- STAN® I 22 IUPT Adapter - for connection of Koala™ disposable IUP transducer from Clinical Innovations (marked IPC-5060).

The IUP transducer application procedure is described in the directions included in the disposable pack.

Event marker



The event marker is connected to the socket on the patient interface box, and is normally used by the mother to record fetal movements. Each press by the mother inserts a vertical line marker in the uterine activity curve.

RECORDING

How to start a recording

Connecting the patient

Connect the transducer by inserting the connector into the correct socket (see “System components” on page 10). The connectors are color coded. Check that the angle of the connector is correct. A degree of force will be required for insertion. Make sure that the correct transducer is connected to the correct socket according to the colour code on the connector or the text over the sockets and to the upper surface of the transducers. To disconnect, pull the connector straight out. See also Quick Reference Guide.

In the case of internal scalp electrode recording (FECG), it is recommended that the skin and scalp electrodes are always applied before starting the system.

When recording twins, use either US1 and US2 (external recording) or FECG and US2 for internal recording of the lower fetus and external recording of the upper one. Note that FECG and US1 cannot be used simultaneously.

Starting the system

The system should be started by setting the power switch on the underside of the display unit to position 1. If the previous recording was properly concluded, the system will start immediately in signal mode for internal recording (FECG) and in recording mode for external monitoring (US). The system will automatically detect which transducers are connected and respond accordingly.

If the previous recording was not properly concluded and the system is restarted within two hours, the operator will be asked whether to continue the existing recording or start a new one. If the previous recording is to continue, the system will load it so that the entire recording can be analysed on screen. If the operator chooses to start a new recording, the previous recording will be terminated and a new one will be started.

When internal scalp electrode recording is performed, it is extremely important to study the signal carefully in signal mode to ensure that:

- the signal quality is adequate,
- the mother's ECG and heart rate are not being recorded,
- the correct “Breech mode” is set,
- there are no cardiac malformations or arrhythmias that may distort the ECG average or the heart rate calculation. See “FECG Signal Inspection” on page 35 for more information on how to recognize these ECGs.



It is important to make sure that the scalp or skin electrode is properly positioned, and relocate if necessary. If the fetus is dead, the mother's ECG may be recorded even if the scalp electrode is properly attached. In the event of breech presentation, the system's breech mode should be activated (see "Functions" on page 25). If not, the system may detect a false biphasic ST grade 3, potentially resulting in incorrect interpretation and potentially harm the fetus and mother.

In the event of cardiac malformations or arrhythmias, the greatest care should be taken, and the ECG average compared with the actual ECG in signal mode, so that any errors can be detected and the T/QRS determination and ST segment analysis can be checked. In arrhythmia, the heart rate pattern should be checked and external ultrasound monitoring considered.

Note that TENS must not be used during internal recording (FECG) with the STAN® S31 fetal heart monitor.



During external ultrasound recording it is essential to check that the fetal heart rate presented is not double or half the true heart rate. The operator should also make sure that the maternal heart rate is not erroneously recorded.

During recording of twins the operator should check that the fetal heart rates presented are from different fetuses and not from the same source. The system will warn the operator if heart rate from channel 1 and 2 coincides through a message in the status window and in the event log. Observe that if internal recording of the second twin is started after birth of the first baby, either a new recording must be started or the T/QRS baseline reset, see "Menu" on page 27.

Functions



1. Header: recording number.
A recording number is generated for each recording and displayed on screen. It also appears on printouts and is stored on disc.
2. Header: date and time
This shows the current date and time, updated every second.
3. Patient data
Patient data may be entered using the keyboard.
4. Status information
Provides information on system status and configuration and any warnings or error messages that affect the system.
5. Signal info 1 (upper) and 2 (lower)
Signal and warning information for channels 1 and 2.
6. Heartbeat indicator 1 (upper) and 2 (lower)
Indicates each detected beat (FECG) or twice a second (US) on channels 1 and 2 respectively. A small heart during FECG-recording indicates that the current heartbeat cannot be used for ST-analysis.
7. Signal quality 1 (upper) and 2 (lower)
Information on signal quality based on the previous ten seconds of the signal measured on channels 1 and 2 respectively. If the signal bar shows level 2 or less, measures for improving signal quality should be undertaken. Level 4 indicates optimal performance.
8. Heart rate 1 (upper) and 2 (lower)
Shows the current heart rate for the signal measured on channels 1 and

2 respectively. The header also indicates which signal is being measured.

9. T/QRS
Shows the current T/QRS ratio of the most recent ECG average, if fetal ECG is being measured.
10. Uterine activity
Shows current uterine activity and indicates whether this is being measured by an external TOCO transducer or an internal IUP transducer.
11. ECG average or maternal parameters
Shows the current ECG average with associated T/QRS ratio, biphasic indication and time (max. 20 seconds delay), if fetal ECG is being measured. The scaling of the ECG displayed indicates the signal amplitude.

If STAN® VSM 21 is connected maternal parameters may be shown in this window instead. The user can choose to view ECG-average window or Maternal-parameters window, by using the pop-up menu on the signal button.
12. EFM window: heart rate
Shows up to two heart rate patterns over time. If it is measured, maternal heart rate will also be displayed in EFM window.
13. EFM window: uterine activity
Shows uterine activity over time.
14. EFM window: T/QRS and BP
Displays T/QRS ratios and biphasic ST (BP) indications as a function of time.
15. Status indications
Shows the status of certain types of externally-connected equipment

Functioning: green diode, normal text.

Not installed: greyed-out diode, greyed-out text

Error: orange diode, strikethrough text
16. Basic menu
Displays the 10 menu buttons corresponding to the following possible states and functions:

Normal appearance: a button supports a function.
Button constantly depressed: shows whether a function or mode is active.
Button function not supported (text greyed out).
The basic functions of all buttons are activated by tapping the button it with a finger/touchpen on screen.
17. Pop-up menu
Several of the menu buttons include a pop-up menu that is activated by pressing and holding the button with the finger/touchpen. This facilitates further options for certain functions.

Menu

The menu may be activated as follows:

Function	Navigation/Operation
Basic function of selected menu button	Press and release function button with finger/touchpen
Additional features of selected menu button (shown in pop-up menu)	Press and hold function button with finger/touchpen
Activate menu items (selected as above) and leave pop-up menu	Press and release item text in pop-up menu with finger/touchpen

The following functions may be selected: (For a comprehensive description of all functions, please refer to STAN® S31 Reference Manual)

Button	Basic function	Menu function
1	Zero TOCO/Zero IUP output signal set to 5 or IUP output signal to 0.	Select TOCO sensitivity level. High sensitivity Normal sensitivity Low sensitivity
2	Review Two state function. When depressed, the system is in review mode (see “Review mode (EFM Scroll Window)” on page 15).	
3	Signal Two state function. When depressed, the system is in signal mode (see “Signal mode (FECG Signal Window)” on page 15).	Various adjustments that affect the ECG signal are possible as follows: Increase Increases displayed ECG signal amplitude. Decrease Decreases displayed ECG signal amplitude. Compress Decreases the time range displayed. Expand Increases the time range displayed. Maternal Vital Signs Data If activated, maternal parameters will be displayed on screen at the location of ECG average window. ECG average If activated during recording of maternal parameters, the ECG complex will be displayed. Breech Mode This should be activated only in the event of breech presentation.

Button	Basic function	Menu function
4	<p>Event Log</p> <p>Two state function. When depressed, the Event Log is displayed (see “Event Log” on page 16).</p>	<p>Various adjustments that affect the Event Log function are possible as follows:</p> <p>MSpO₂/MHR event</p> <p>Time interval for logging maternal parameters to the Event Log can be chosen.</p> <p>Manual logging of MSpO₂/MHR event.</p> <p>Reset T/QRS baseline</p> <p>To be used during twin recording, after birth of the first baby, if internal recording for the second twin is wanted.</p> <p>Disable ST</p> <p>If activated, ST will be disabled. For use on a premature fetus.</p>
5	<p>Note Event</p> <p>When activated a dialogue box is displayed in which text may be entered if a keyboard is in use.</p>	<p>Predefined Note Event</p> <p>There are 10 predefined Note Events. These may be selected, and will then be added in the Event Log.</p> <p>Enter Patient Data</p> <p>When activated a dialogue box is displayed in which patient data may be entered.</p>
6	<p>FECG Sound/US1 Sound</p> <p>Two state function. Sound is generated when depressed. If both FECG and US1 transducers are connected, the ECG will generate a beep.</p>	<p>The volume level is adjustable.</p> <p>Volume Level 5</p> <p>Volume Level 4</p> <p>Volume Level 3</p> <p>Volume Level 2</p> <p>Volume Level 1</p>
7	<p>US2 Sound</p> <p>Two state function. When depressed, sound is generated from the ultrasound transducer (US2).</p>	<p>The volume level is adjustable.</p> <p>Volume Level 5</p> <p>Volume Level 4</p> <p>Volume Level 3</p> <p>Volume Level 2</p> <p>Volume Level 1</p>
8	<p>Print/Abort Printing</p> <p>When activated a dialogue box is displayed in which printout can be sent to a laser printer.</p>	<p>Various adjustments that effect the recorder print-out are possible as follows:</p> <p>Signal report printout</p> <p>US2 + 20 bpm</p>

Button	Basic function	Menu function
9	Thermal Recorder Two state function. When depressed, the recorder is activated for continuous printing.	Various adjustments that effect the recorder print-out are possible as follows. Signal report printout US2 +20 bpm Calibration lines Print ECG average Print Event Log Feed Paper
10	End Activated to end the recording.	STAN® S31 System status.

If the text on the button is greyed out, the function is unavailable.

End

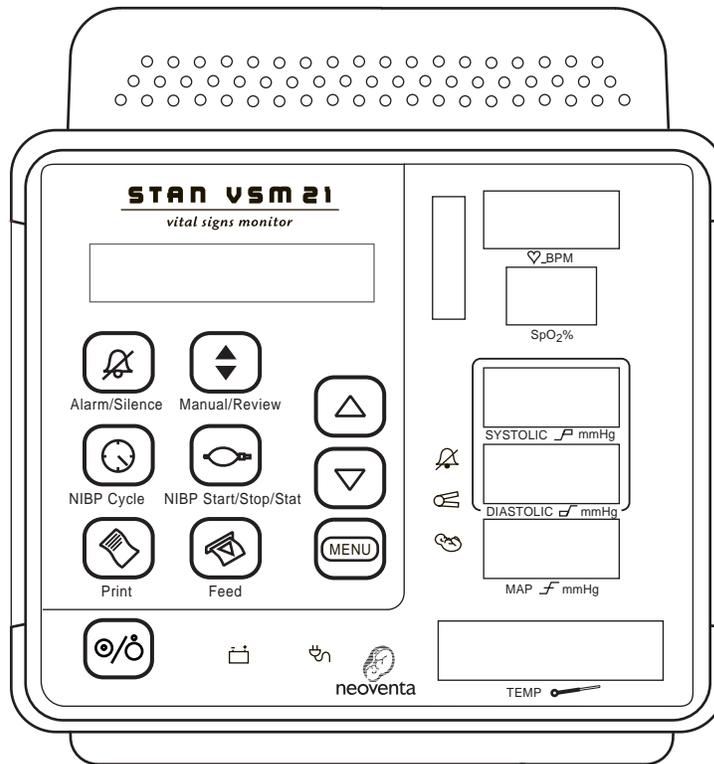
To end a recording (and prevent the loss of electronically stored data) the system should be closed down by using End menu button. When this function is activated, the recording will be stored on the internal disk. The mains power should under no circumstances be turned off during this transfer which normally only takes a few seconds.

If the system is not closed down using this procedure, there is a risk that up to a minute of data will be lost. Data will not be backed up before the system starts up next time.

If the system is to be moved to another room, or power needs to be turned off for some reason during a recording, the recording may be ended temporarily. If the system is restarted within two hours, the user will be asked whether recording is to continue (see “Starting the system” on page 23).

MATERNAL PARAMETERS

STAN® VSM 21 vital signs monitor



STAN® VSM 21 is a supervision monitor for monitoring maternal vital signs data.

- Temperature
- Blood Pressure (NIBP)
- Pulse rate
- Oxygen saturation SpO₂

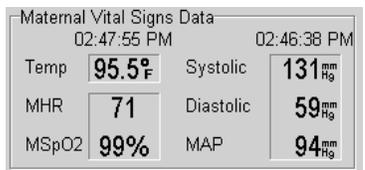
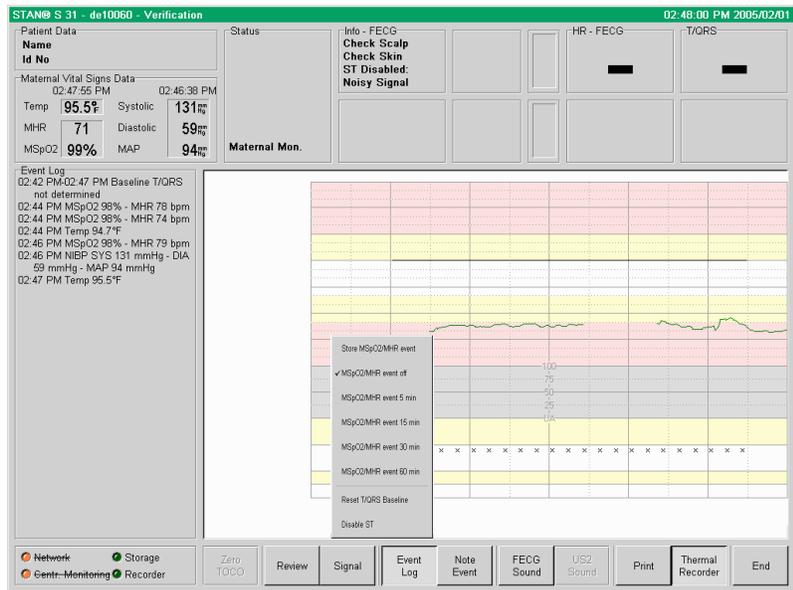
STAN® VSM 21 is equipped with a thermal printer which allows printing of vital signs and trend information.

See STAN® VSM 21 user manual for further information on handling.

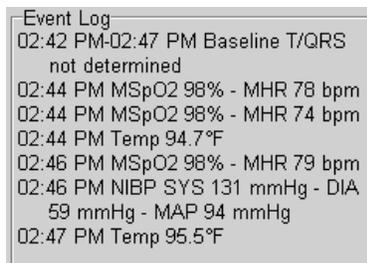
Connecting

STAN® VSM 21 is connected with the accompanying cable to the peripheral device socket beneath the display unit. The software must be adjusted for use together with the monitor. See STAN® S31 service manual for further information.

Display of Maternal parameters



All vital signs data are transferred automatically to the S31 system and presented on the screen as well as being stored for subsequent analysis and storage. The time of monitoring is to be found above the temperature and blood pressure data.



The monitoring of maternal vital signs data can create events in the event log.



In the menu “Event Log” it is possible to adjust how often the maternal vital signs data are to be automatically recorded in the event log. Choose the alternative “Store MSpO2/MHR event” to store the current maternal vital signs data immediately in the event log.



Note that if temperature measurement is not completed correctly, an incorrect value may be stored in the event log.

FECG Signal Inspection

Note that this section is relevant only to internal recording using a scalp electrode (FECG). In external monitoring using ultrasound (US), no FECG is obtained.



The easiest way of inspecting FECGs is to use signal mode. Generally, the user should look for ECG complexes that differ considerably from a normal ECG pattern. The average ECG that is usually visible on screen during internal recording (FECG) may under certain circumstances be misleading for the assessment of the abnormalities.

Poor signal quality

There are several factors that can contribute to a poor signal quality. The main factors are:

- Skin electrode quality. There are large variations in the quality of available skin electrodes. Only recommended skin electrodes should be used for STAN® monitoring.
- Skin electrode application. Skin preparation before application is of utmost importance. Some electrodes will provide up to 1000 times' increased electrical resistance if there is no skin preparation prior to application. An abrasive surface is included with the Neoventa-recommended skin electrodes.
- Skin electrode age/dryness. It is very important that skin electrodes used for STAN®-monitoring are fresh. The electrode gel will dry out if the bag is not sealed properly and affect the performance of the electrode. A single-packed electrode is preferable.
- Skin electrode position. It is important to place the skin electrode high up on the maternal thigh, close to the groin (inguinal canal), and NOT over the thigh muscle.
- Scalp electrode quality. Only electrodes recommended by Neoventa should be used for STAN®-monitoring.
- Scalp electrode application. It is very important that the application is performed correctly. The electrode should not be used to rupture the membranes as membrane material can affect the electrode performance. Only single spiral scalp electrodes are to be used and they should always be rotated at least 360° for proper attachment.
- For more information, see instruction included with the disposable package.
- Leg plate cable. The legplate cable can be damaged or deteriorate with ageing. The cables can be internally damaged which is not visible from the outside. If the cables are damaged the user may still have a EFM-recording but no ST information. The short skin electrode wire attachment can also become partially loose, leading to intermittent signal loss of ST data. According to the "Maintenance instructions" of the Service Manual (PRD 101 004) the legplate should be tested by a qualified technician every 12 months. The test should also be undertaken in case of repeated problems with the signal quality.

In Signal mode, the QRS complex of the ECG should always be clearly visible, and it must be easy to identify it visually in signal mode. If it is difficult to see the QRS complex, the signal is of poor quality and it may be necessary to relocate the scalp or skin electrode. A changing ECG signal may also be a sign of poor signal quality. In some situations, the maternal ECG signal is so strong it can interfere with and prevent the processing of fetal ECG. Low signal amplitude may also indicate that the electrodes may need to be reapplied. In such cases, the amplitude of the QRS complex is so low that signal noise may distort the ST analysis. The system will detect poor signal quality and display "ST Disabled", followed by one or both of the messages "Check skin" "Check scalp" in the signal information window.

Muscular noise may interfere with the signal for brief periods. This is normal, but if it persists action may need to be taken to improve signal quality.

Reduced number of ST-datapoints

Signal Quality is of vital importance, to ensure correct information to the user.

Sometimes, the signal quality deteriorates just for a short period of time, due to active movements of the mother and the electrical noise introduced by the muscle activity. Short-time loss of ST-information may also be caused by maneuvers involving the area where the scalp electrode is applied, such as vaginal examinations or FBS. Usually, in such situations, the signal quality and the ST-information will recover spontaneously. If not, adequate measures should be taken.*

If the signal quality deteriorates gradually and consistently during a recording, it usually means a loosening of the skin or scalp electrode. Other causes may be fetus- and/or mother-related, such as: scalp edema of the baby or the scalp electrode is in close proximity of the vaginal wall. The "FECG Info" window on the STAN® unit will recommend the user to check the skin electrode, the scalp electrode, or both. Adequate measures should then be taken in order to improve the signal quality*. A "Poor FECG signal quality" event will be opened in the Event log if no ST-datapoint has been plotted for more than 90 seconds.

Recommendations:

If the FHR is reassuring and;

- the signal quality recovers, continue STAN® monitoring according to guidelines
- the signal quality doesn't recover and the ST data continues to be missing, it is the individual clinician's decision for how long signal recovery attempts should continue. If signal doesn't recover and FHR becomes non-reassuring, please see below.

If the FHR is non-reassuring grade 1 and;

- the signal quality improves immediately with no ST-gaps longer than 4 minutes, continue STAN® monitoring according to the guidelines
- the signal quality can not be re-established and the ST information is not satisfactory, base the clinical decision on FHR data.

If FHR is non-reassuring grade 2 (preterminal):

-immediate intervention is indicated

***Guidance on improving the signal quality**

-Inspect the FECG signal window and make sure a "Fetal ECG" is what is recorded. Observe appearance of the complexes, amplitude, and level of noise.

-Make sure the skin electrode is properly applied: skin prepared as recommended, skin electrode is well-attached and not placed over muscle. A poorly attached skin electrode will increase susceptibility to electrical noise.

-If necessary change the scalp electrode. A loose scalp electrode usually causes low amplitude FECG complexes and poor signal quality.

Breech presentation

When recording during breech delivery, the scalp electrode is applied in such a way that the ECG will be upside down compared with a standard recording.

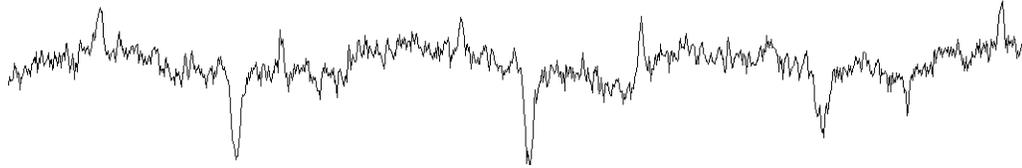


This is most obvious from the fact that the initial ECG waveform component (P-wave) is negative. If the system is operating with an ECG that is recorded upside-down, false biphasic ST grade 3 may be detected. When the scalp electrode is applied in breech presentation, the system's breech mode should be activated (see "Functions" on page 25). The system will then turn the ECG the right way up and analyse it in the normal way.

The system will provide a warning, in the Status window and in the Event Log, if ECG:s with continuous negative P-waves are recorded. This situation would appear if the ECG is recorded from an undiagnosed breech position or from a cephalic presentation when the breech mode has been erroneously activated.

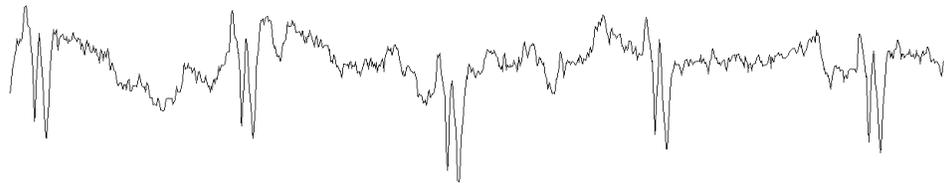
Maternal ECG

A maternal ECG obtained through an incorrectly located scalp electrode may be recognized by the absence of a P wave and a widened QRS complex.



Atypical FECG complexes

Fetal ECGs may be atypical in a variety of ways. If R-peaks are split, signal averaging and ST analysis may become inaccurate.



EVENT LOG

The event log can be alternately visible or hidden by pressing the Log function button. When the event log is hidden, more space is available on the screen to show the recording.



The log contains events even when hidden (see below). There is a risk of important information being missed when the event log is hidden, so it is recommended to keep it visible.

The Event log will become visible after an ST event.

Review event log

After a certain recording time the event log may contain more events than can possibly be shown on the screen at the same time. In “Review mode (EFM Scroll Window)” on page 15, review of earlier events in the event log can be examined by using the up/down (scrollbar) arrows in the event log window.

Signal events

The following signal events are logged in the event log:

1. Poor signal quality
When the signal quality is inadequate, this is automatically recorded in the Event Log together with the time the event was started and ended.
2. Breech mode
This is displayed when breech mode is activated. The system will provide a warning - “Breech presentation?”, if ECG:s with continuous negative P-waves are recorded for three minutes. This situation would appear if the ECG is recorded from an undiagnosed breech position. The system would also detect negative P-waves if the breech mode is erroneously activated during cephalic presentation. The system would then provide the message - “cephalic presentation?”.
3. Matching HR
The system will generate a warning if heart rate from US1 or FECG coincides with heart rate from US2.
4. Baseline T/QRS Reset
Message will appear if baseline T/QRS is reset, see “Functions” on page 25.
5. ST Manually disabled
If activated, see “Functions” on page 25, message will appear in event log.

6. ECG Signal interference
The system can detect disturbances generated from external equipment (for instance TENS). These disturbances can result in a distorted ECG signal and ST waveform analysis will then be blocked.

System events

One system event is recorded:

1. Recording paused
This is recorded when recording is temporarily ended, and will continue within two hours.

ST events

These events appear in the Event Log in bold script. Three different ST events are detected:

1. Episodic T/QRS rise
This is detected when the T/QRS ratios rise rapidly by more than 0,10 units from the T/QRS ratio baseline but return within 10 minutes.
2. Baseline T/QRS rise
The baseline is continuously calculated, the system will then continually compare the current baseline with the lowest detected during the last three hours, and report changes greater than 0,05 units.
3. Biphasic ST
This event occurs when the incidence of biphasic ST (types 2 and 3) is significant.



The system uses a strict quality criteria to detect these events. At the start of a recording, special attention should be paid to the log, and visual inspection of the FECG signal. If a “Poor Quality” event is active in the Event Log, adequate measures should be taken to improve the signal quality (by re-applying the electrodes if necessary) .

User events

These are events that the user enters through the keyboard, or selects from menu button 5 (Note Event).

Maternal parameters

If STAN® VSM 21 is connected maternal parameters can be automatically stored as events, see “MATERNAL PARAMETERS” on page 31.

PRINTING ON PAPER

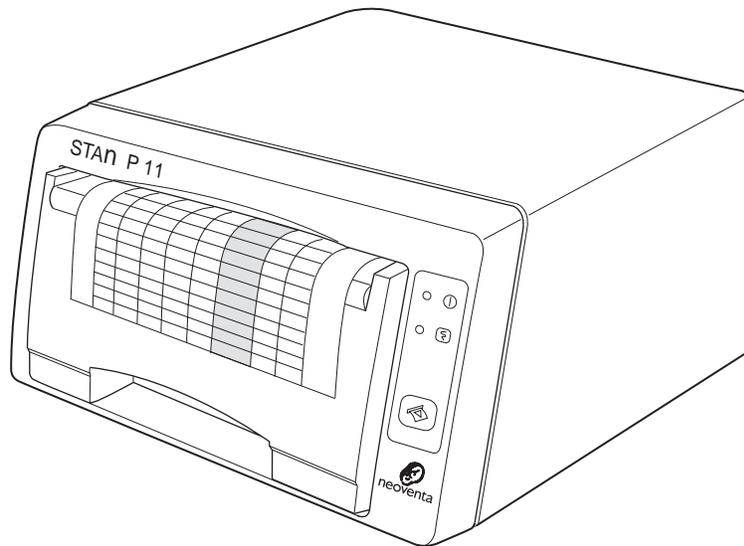
Two different printers can be connected to STAN® S31:

- STAN® P11 thermal recorder
The printer is placed on a trolley and prints continuously during recording on a paper strip.
- Laser printer
The laser printer can be connected through a local area network if it is placed outside the patient environment, at least 1.5 m. The printout is initiated by the user. It is also possible to print a report after recording has been carried out. The STAN® S31 fetal heart monitor does not support the use of a local laser printer.

Both types of printer are entirely controlled from STAN® S31 fetal heart monitor.

Adjustment of printer is normally carried out by qualified technicians and is described in the service manual.

STAN® P11 Thermal Recorder

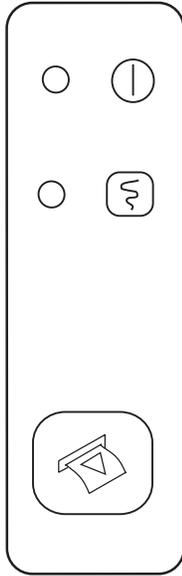


STAN® P11 is a printer for continuous on-line printing. It prints out similar information and at the same speed as the curves shown on the screen.

The printer may be turned off and on using Thermal recorder menu button. Possible printer problems (for example paper running out) are indicated in the status window.

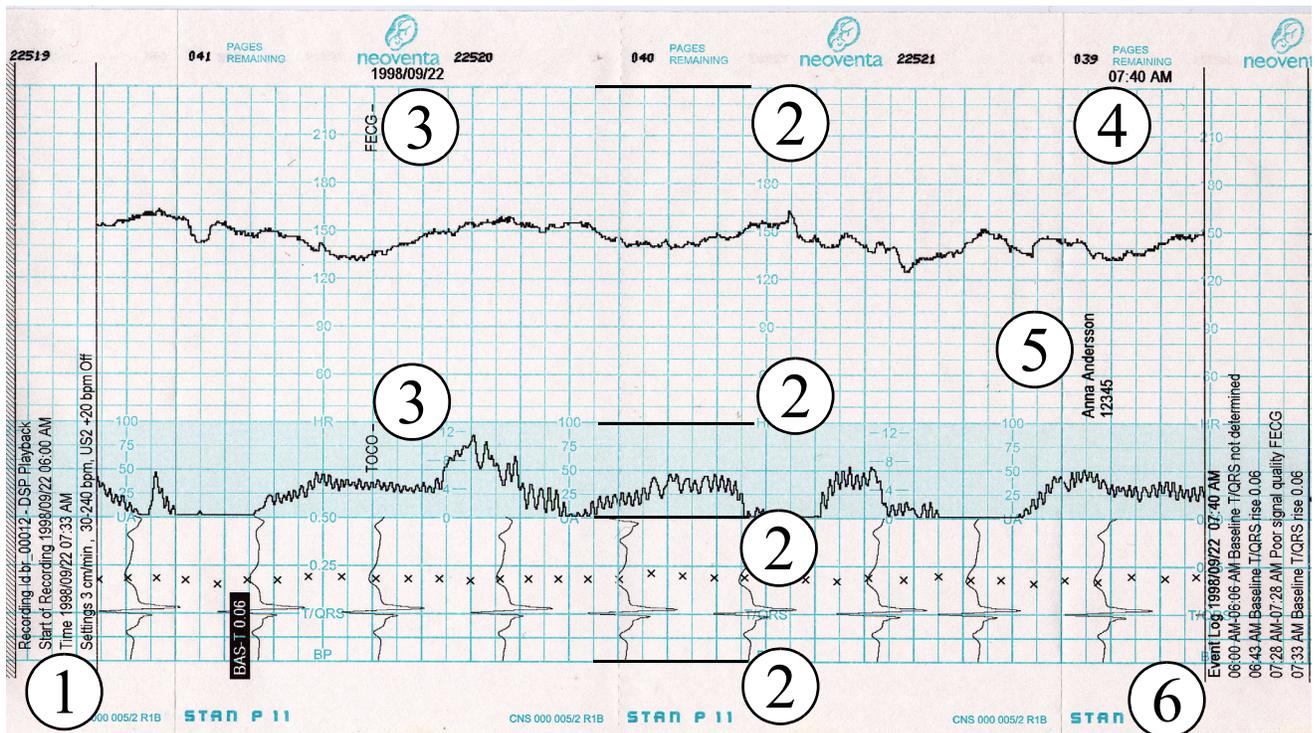
When the printer is activated it will print a short test printout. Then it is ready to start printing recording continuously.

Controls and indicators



- **Power-ON indicator**
The power-ON LED will be lit whenever the unit is connected to AC-line source and the AC mains switch on the rear of the recorder is set to position 1.
- **Printing indicator**
The indicator LED will be lit when printing is enabled or flashing when there is a printing problem (like paper-jam, out of paper or tray not properly closed)
- **Paper feed button**
This button is used to fast-forward the recorder paper. The recorder paper will be advanced at high speed by pressing and holding the button. The recorder will resume its original paper speed when the button is released.

The printout



1. **Header**
When printing starts, a header of text containing machine setting is printed, before actual recording starts to be printed.

2. Calibration lines
To ensure proper paper position, four calibration lines can be printed. This function can be switched on and off from the STAN® S31.
3. Transducer information
Transducer information for TOCO, IUP, FECG, US1 and US2 are written vertically each 30 minutes and when transducer configuration is changed.
4. Time and date
The time is printed each even ten minutes. The date is printed each 30 minutes.
5. Patient name and ID
Patient name and ID is written in the HR area each 30 minutes.
6. Event log
The event log is automatically printed after the end of the printout or via command from the STAN® S31.



Use only paper with the same scale as on the scale of STAN S31. During event log printing, or loading of paper, no traces will be printed. Only up to three minutes of traces could be recovered afterwards.

Events

The following events will be printed out on the paper.

SQ	Poor FECG signal quality	SQ is printed when it occurs, and every 10 min if it still remains.
EPI-T	Episodic T/QRS rise	EPI-T followed by a value is printed when it occurs.
BAS-T	Baseline T/QRS rise	BAS-T followed by a value is printed when it occurs.
BP	Biphasic ST	BP is printed when it occurs.
BM ON	Breech mode on	BM ON is printed when activated.
BM	Breech mode	BM is printed every 30 cm when active.
BM OFF	Breech mode off	BM OFF is printed when deactivated.
FECG + US2?	Matching heart rate FECG + US2	FECG + US2 is printed when heart rate is matching.
US1 + US2?	Matching heart rate US1 + US2	US1+US2 is printed when heart rate is matching.
BREECH?	Breech presentation?	BREECH? is printed when system identifies inverted ECG.

CEPH?	Cephalic presentation? CEPH? is printed when system identifies inverted ECG during breech mode.
SI	Signal Interference SI is printed when it occurs.
MD ON	ST Manually disabled MD ON printed when activated.
MD OFF	ST Manually disabled MD OFF is printed when deactivated.
BAS RESET	Baseline T/QRS Reset BAS RESET printed when activated.
+20 ON	US2 +20 bpm ON Printed when activated.
+20 OFF	US2 +20 bpm OFF Printed when deactivated.

Page numbering

Every sheet of the thermal paper has a unique sequential page number printed in the upper right corner. Number of pages remaining of the 160 sheets in a pack of paper is printed in the upper left corner.



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

Loading of paper

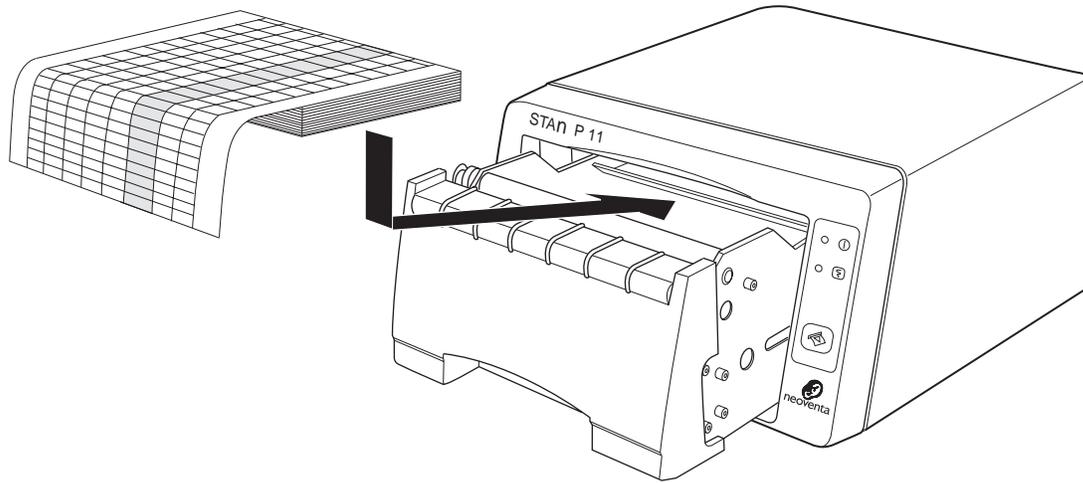
The printer is loaded with one pack of paper at a time. One pack contains 160 connected sheets of paper and is sufficient for 8 hours of printing with a speed of 3 cm per minute.

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

How to change the paper:

1. Pull out the paper tray
During the time that the paper tray is pulled out the printing is stopped.
2. Remove any paper that is left over from the former pack. Only one pack of paper fits into the printer.
3. Open a new package of thermal paper. See “CONSUMABLES AND ACCESSORIES” on page 57 for information on ordering thermal paper.

4. Place the pack of thermal paper with the printed side up as shown in the picture. Unfold a few of the uppermost sheets and let them hang down in front of the printer

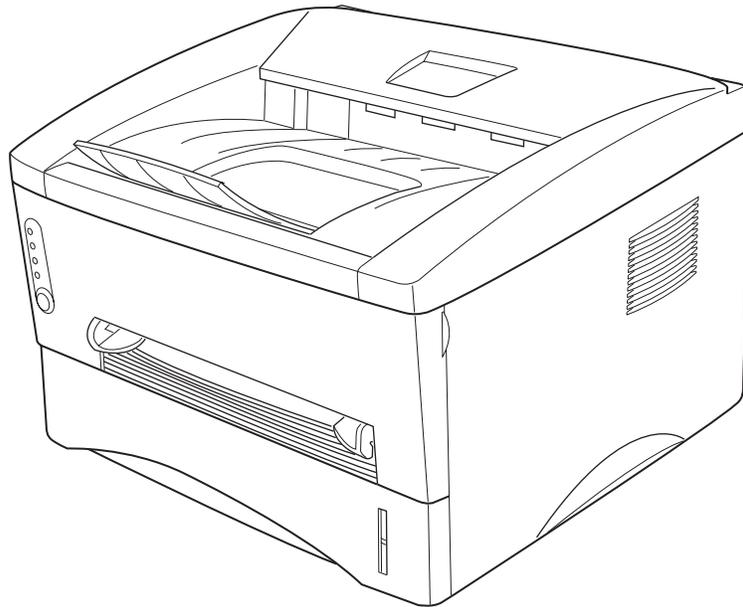


5. Push the paper tray all the way in.
The tray must be in the right position for the printer to function.
6. The printer is now ready for use.



Use only paper with the same scale as on the scale of STAN S31. During event log printing, or loading of paper, no traces will be printed. Only up to three minutes of traces could be recovered afterwards.

Laser Printer



This printer is placed outside the patient environment and connected to the STAN® S31 fetal heart monitor through a local area network.



Note that connection to laser printers must only be performed using the separation device CNK 101 003.

Recommended laser printer

See STAN® S31 Service manual for information about approved models and connections.

Page Printing

Printout from this printer is activated by the Print menu button. This printing is not continuous, but uses single A4 sheets.

The first part of the printout consists of the Event Log and a header containing information on:

- time and date when recording started
- recording identity
- patient name
- patient ID
- page number and total number of pages
- time and date of printing
- time and date of commencement of part included in printing
- time and date of conclusion of part included in printing
- time and heart rate scale used
- version number of system software.

The next part is the recording itself, and a smaller header showing parts of the information included in the first part of the printout. At a rate of 3 cm/

min, there is room for approximately 10 minutes of recording on one A4 sheet.

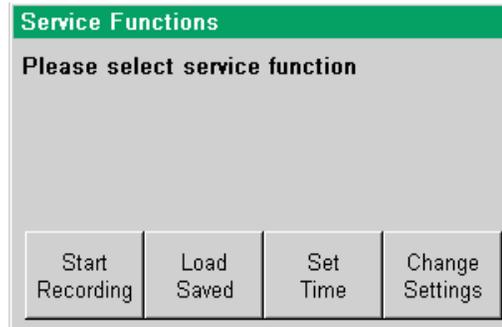


Where several systems are sharing a network printer, it is very important to check the page on which recording begins and ends, so that different recordings do not get mixed up.

SERVICE FUNCTIONS

During the startup procedure, a dialogue box “Service functions” will be displayed in the bottom right corner. By selecting this box with the finger or a touchpen, several options can be accessed.

In this mode, a menu with four different options is displayed:



1. Start Recording

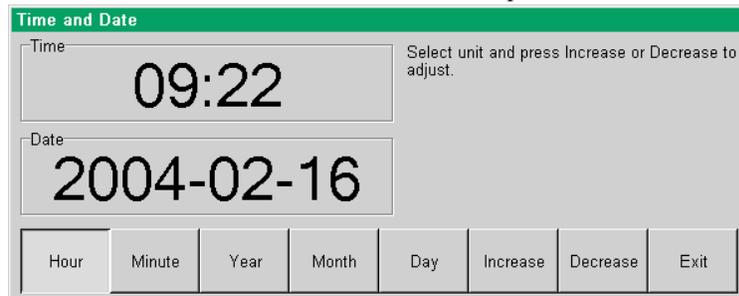
If this option is chosen, a recording will start in the normal way.

2. Load Saved

This function displays the recordings accessible on the internal disk, connected device or network. Individual recordings may be selected by using the arrows on the right side of the box. Selecting “OK” loads the selected recording, and this may be analysed in browse mode and printed to a network printer.

3. Set Time

If this function is activated, a dialogue box is displayed in which the time and date may be entered. Select the data requiring modification by touching the specific parameter button. Step up the selected time unit by pressing the increase button and step it down by pressing the decrease button. For example, if time is selected, one tap of the increase button will add one hour and one tap of the decrease button



will subtract one hour.

4. Change Settings

From the set-up menu a number of customer-specific parameters can be set. Select the “Change Settings” box to enter the function. A menu with different options is displayed. Before use, language, keyboard layout and machine name should be set. If the language parameter is changed, the system must be restarted for the parameter changes to have effect. The first three letters of the machine name parameter are used for deriving the names of the recordings made by the system. It is advised to set this parameter, so that recordings from different systems on the same ward won't be mixed with each other. Example

MLA, MLB, MLC etc. For further details, see STAN® S31 Service Manual (PRD 101 004).

MAINTENANCE

Intervals

After each use

Always clean transducers, cables and if necessary other parts (see “Cleaning” on page 53).

In case of repeated signal problems

Inspect transducers, cables and connectors to check for cracks or other damage. Leg plate cable should be tested according to instructions in STAN® S31 Service Manual (PRD 101 004)

Every 12 months

The system should be inspected by qualified technicians every 12 months (see also Service Manual, product no. PRD 101 004).

Cleaning

Display unit and Patient Interface Box

The display unit and the PIB should merely be wiped with a cloth moistened with a mild soap solution or 70% ethanol.

Take care not to scratch the monitor screen.

Accessories

The trolley, cables, transducer connectors etc. should merely be wiped with a cloth moistened with a mild soap solution or 70% ethanol.

Legplates may be cleaned with a moistened cloth of any of the following detergents:

- Alcohol-free hand-soap.
- 70% - 80% Isopropanol
- Sodium hypochlorite (bleach) solution 10% in water.
- Ethanol 70%
- Dilution of formaldehyde (3-6%)
- Cidex
- Cidex plus

Transducers may be cleaned with a moistened cloth, rinsed under running water or immersed in any of the following detergents:

- Mild soap/water.
- Dax disinfection 70%, ethanol denaturated with isopropanol and ethyl acetate
- 70% propanol/isopropanol.
- Chlorhexidine 5 mg/ml
- Cidex 2% (Sporicid).
- Virkon 1%

The temperature of the detergent should not exceed 113 degrees F. The transducers should not be subjected to temperatures in excess of 158 degrees F.

CLASSIFICATION

STAN® S31 fetal heart monitor is CE-marked as a class IIb medical device.

Protection against electric shock

Type of protection against electric shock - Class I

Degree of protection FECG connector - Type CF

Degree of protection TOCO/IUP connector - Type CF

Degree of protection US1 and US2 connector - Type B

Degree of protection against exposure to fluids

Main unit - May be wiped with moistened cloth

Legplate F22 (FECG) - May be rinsed under running water

Uterine transducer T 31 (TOCO) - May be rinsed under running water (IPX7)

Ultrasound transducers U 31 and U 32 - May be rinsed under running water (IPX7)

For more information about cleaning, sterilization and disinfection please refer to “Cleaning” on page 53.

CONSUMABLES AND ACCESSORIES

Spare parts are described in STAN® S31 service manual.

The following list specifies recommended consumables. Neovanta Medical guarantees the system function of the STAN® S31 fetal heart monitor system only if the recommended consumables are used.

Consumables

CNS 000 004	Goldtrace™ , Scalp Electrodes pack of 50
CNS 000 002	Skin Electrodes 30 pcs incl sandpaper
CNS 000 100/10	Belt Lock Knob 10 pcs.
CNS 000 101	Legplate Belt 15 m
CNS 000 102	Transducer Belt 15 m
CNS 000 005/2	Thermal Paper 30-240 bpm,40 pcs

Transducers

ACC 101 020	STAN® F22 , SBT 7016 Legplate (3-lead)
ACC 101 022	STAN® T 31 Toco Transducer
ACC 101 031	STAN® U 31 Ultrasound transducer 1
ACC 101 032	STAN® U 32 Ultrasound transducer 2
ACC 101 004	STAN® I 21 IUP adpt cable Utah Med
ACC 101 005	STAN® I 22 IUP adpt cable Koala
ACC 101 040	Event Marker

Accessories

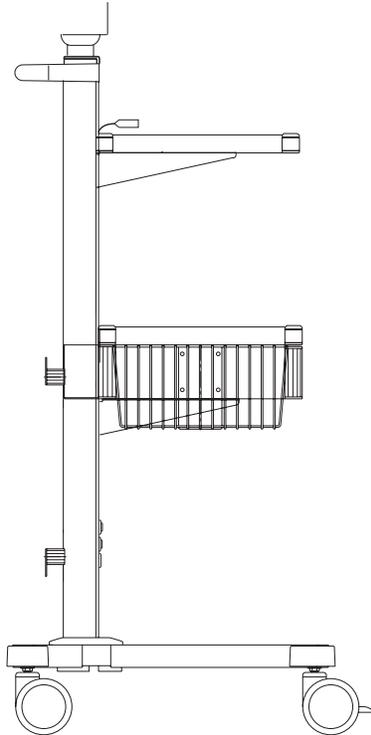
ACC 101 041/xx	STAN® K31 Keyboard
SBS 103 005/1	STAN® TR31 Trolley
PRN 000 005	STAN® P11 Thermal recorder
SYS 400 000	STAN® VSM21 Maternal Vital Signs Monitor
CBL 102 100/xx	STAN® S 31 Power Cord

Note: Item number may change without prior notice. Your local distributor will inform when this is the case.

STAN® TR 31

General description

The STAN® TR31 is a trolley specially designed for the STAN® S31. The trolley incorporates three electrical outlets to facilitate the use of thermal recorder or STAN® VSM 21 Vital signs monitor.



Safety

Note that no more than 10 kg should be placed on any shelf and that no more than 3 kg should be placed in the drawers. The maximum load for the trolley overall is 50 kg. Please note that the electrical outlets only should be used for P11 thermal recorder (SBS 000 005) or VSM21 vital signs monitor (SYS 400 000). Maximum allowed load on outlets are 10 A. Connecting other electrical equipment here may result in a safety hazard.



Use

The STAN® S 31 is secured to the trolley via a VESA mount on the back of the display unit. The lower shelf may be used for other electrical equipment that is classified as safe for medical use by EN 60601-1. If thermal recorder or vital signs monitor is connected, a jumper cordset (CBL 000 005) must be used.

CONNECTION OF EXTERNAL EQUIPMENT

External equipment intended for connection to signal inputs, signal outputs or other sockets must comply with the requirements of the relevant IEC standard (e.g. IEC 60950 in the case of IT equipment and the IEC/UL 60601 series for electrical medical-technical equipment). In addition, all such combinations (systems) must comply with the requirements of IEC 60601-1-1, Safety requirements for medical electrical systems.

Equipment that does not comply with the requirements of IEC 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 60601-1-1. When in doubt, consult qualified medical technicians or Neoventa Medical.

There are several types of connection for external equipment on the main unit (see “System components” on page 10). The following list specifies the items that may be connected to these connectors. Only specified equipment is supported, other connectors should be covered. Note that the three serial ports COM1, COM2 and COM3 have dedicated protocols. There is no safety risk if they are exchanged, but the software protocol is hardcoded.

Socket	Labelling	Permitted equipment
Serial port 1	COM1	STAN P11 Thermal recorder. Connect only by using cable CBL 103 011.
Serial port 2	COM2	Note that it is absolutely necessary to only connect to external equipment using cable CBL 103 012 and MSWC (CNK 300 000) as this is a non-floating connector. Supported systems are Milou (SYS 300 200) and Central Monitoring systems with communication accordance with a protocol specified in HP publication M13509014L using RS232.
		
Serial port 3	COM3	STAN VSM 21 Vital Signs Monitor. Connect only using cable CBL 103 010.

Socket	Labelling	Permitted equipment
Network port	LAN	Any of the two LAN ports can be used. Note that it is absolutely necessary to only connect to external network using cable adapter CNK 101 003. To that adapter a normal RJ-45 Ethernet cable can be connected for connection to network.



The only situation where CNK 101 003 may be omitted is if the device to be connected is a medical device classified for use within the patient environment, or if the device is a stand-alone unit supplied by a medical grade separation transformer. If uncertain, consult your local medical device responsible at the hospital.

There are currently three types of equipment that are supported via network connections: laser printers in network, laser printer via printer server, and monitoring/rectifying systems. In general the equipment connected must also be approved according to EN 60601, EN 60950 or equivalent. Currently supported network laser printers are those being in accordance with LPR (RFC 1079) and software protocol PCL 5. For further information, see STAN® S31 Service Manual (PRD 101 004).

TROUBLESHOOTING

The following list specifies a number of possible error situations and the probable cause.

General

Problem	Probable cause	Suggested action
System does not function. Screen black	Mains cable missing, or no power from mains outlet.	Connect mains cable to functioning mains outlet.
	Main unit turned off	Turn on power switch
	Fuses blown.	Contact technical personnel
	Monitor brightness on “dark” setting.	Adjust
	Internal error	Contact technical personnel.
Nothing but error message on screen.	Internal error	Contact technical personnel.
Keyboard does not work.	Internal error	Contact technical personnel.
No heart sound indications audible.	Transducers missing, or volume turned off or too low.	Check transducers and volume levels.
Error code displayed	Internal error	Contact technical personnel.

Recording via FECG

Problem	Probable cause	Suggested action
“Check scalp” displayed	Loose or unconnected scalp electrode or electrode applied through membranes	Check scalp electrode
“Check skin” displayed	Loose or unconnected skin electrode	Check skin electrode
	Skin electrode too dry	Apply fresh skin electrode from sealed bag
Both “Check scalp” and “Check skin” displayed	Patient not connected	Check legplate, scalp and skin electrode
	Signal quality problems	Check scalp and skin electrode, if necessary reapply

Problem	Probable cause	Suggested action
“ST disabled: Weak signal” displayed	Scalp electrode not properly attached or applied through fetal membranes	Check or reapply scalp electrode
	Loose skin electrode	Check skin electrode
	Skin electrode too dry	Apply fresh skin electrode from sealed bag
“ST disabled: Noisy signal” displayed	Interference with muscle noise	Apply a new skin electrode high up on the maternal thigh, close to the groin (inguinal canal), NOT over thigh muscle.
	Signal quality problems	Check skin and scalp electrode
“ST disabled: Signal interference displayed”	TENS equipment connected	Disconnect TENS equipment
	Other electrical noise from external equipment	Contact technical personnel
“Breech presentation?” displayed	Undiagnosed breech position	Check fetal position and if applicable, enable breech mode
“Cephalic presentation?” displayed	Breech mode function enabled by mistake	Disable breech mode
	Faulty diagnosed breech position	Check fetal position and if applicable, disable breech mode
Poor fetal heart rate quality	Loose scalp electrode or applied through fetal membranes	Check scalp electrode
Poor ST quality	Loose skin electrode	Check skin electrode
	Skin electrode too dry	Apply fresh skin electrode from sealed bag
Poor ST quality during contractions	Interference with muscle noise	Apply a new skin electrode away from thigh
“Matching HR: FECG+US2” displayed	Twin monitoring on the same fetus	Check vital signs and transducer positions
Repeated signal problems	Damaged legplate	Perform legplate check according to instructions in Service Manual

Recording via TOCO or IUP

Problem	Probable cause	Suggested action
Poor signal quality, or no deflection at all	Transducer cable damaged	Carry out functional test or contact technical personnel
Signal saturated on 100	“Zero TOCO” not activated	Activate “Zero TOCO”
	Too high sensitivity	Set lower sensitivity

Problem	Probable cause	Suggested action
Poor detection of contractions	Too high or too low sensitivity	Set sensitivity
	Inaccurate placement of transducer	Adjust placement and transducer belts

Recording via US1 or US2

Problem	Probable cause	Suggested action
No sound generated or HR values displayed	Transducer cable damaged	Carry out functional test or contact technical personnel
	Wrong position of transducer	Reposition transducer
“Matching HR: US1+US2” or “Matching HR: FECG+US2” displayed	Twin monitoring on same fetus	Check vital signs and transducer positions

System output signals

Problem	Probable cause	Suggested action
Miscellaneous		Contact technical personnel

Thermal recorder failure

Problem	Probable cause	Suggested action
No printout	Printer cable loose or damaged or communication problem	Check printer cable. Disconnect recorder from STAN® S31. Turn printer off and on. Connect it to STAN® S31 again.
Power indicator inactive	Fuses blown	Change fuses if needed. If repeated contact technical personnel.

Laser printer failure

Problem	Probable cause	Suggested action
No printout or "Check printer message"	Network cable loose or damaged	Check network cable
	Printer out of paper	Insert more paper
	Network problem	Contact technical personnel
Too dark printouts	Incorrect greyscale setting	Change greyscale settings
Too bright printouts	Incorrect greyscale settings	Change greyscale setting
	Printer running out of toner	Replace printer toner

FUNCTIONAL TESTS

This section describes some simple functional tests for transducers and input signals.

STAN® T 31 TOCO

Direction	Expected result
Connect uterine activity transducer to main unit.	“TOCO” should appear in the uterine activity window.
Activate “Zero TOCO”.	A value of 5 is displayed.
Apply slight pressure to transducer button.	Value should increase up to max. 100.

STAN® U31 US1 and STAN® U32 US2

Direction	Expected result
Connect ultrasound transducer to main unit (US1 or US2).	“US1” or “US2” should appear in the relevant Heart rate window.
Activate volume for correct transducer and set at high level. Move transducer up and down perpendicular to a flat surface, at different speeds, within an area 1-5 cm from the surface.	A whistling sound should be audible at certain speeds
Hold the transducer in the palm of the hand with the detector surface tight against the skin between thumb and forefinger. Knock in a regular pattern (several times a second) with the other side of the hand between thumb and forefinger.	A regular sound should be audible corresponding to the knocking frequency. If the knocking is relatively constant, it should be possible to calculate a heart rate value equivalent to the knocking frequency.

3-lead FECG legplate

Direction	Expected result
Connect FECG transducer to main unit .	“FECG” should appear in the FECG window.

For a more complete functional test consult technical personnel.

GENERAL

Manufacturer

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Other Manuals

STAN® S 31 fetal heart monitor Service Manual - PRD 101004



Quick Reference Guide

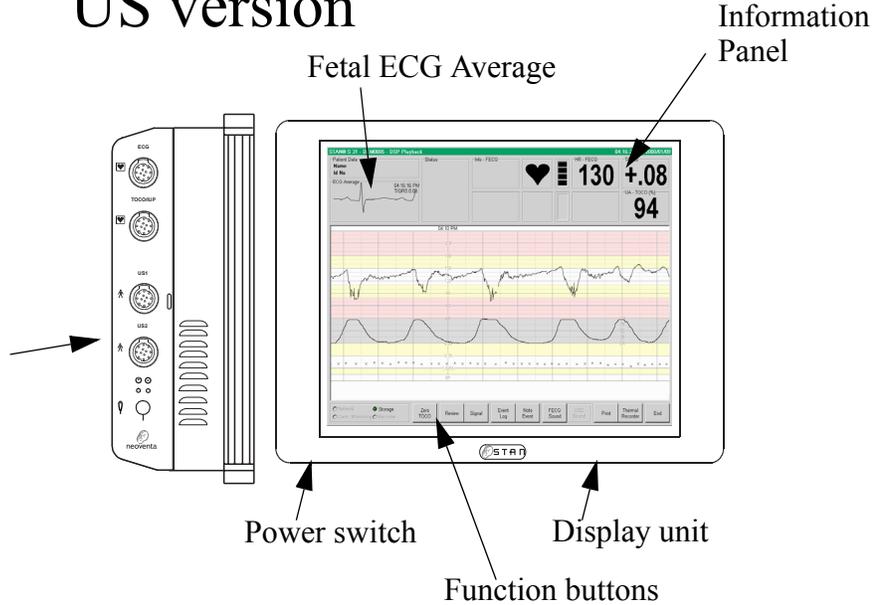
CE 0413

STAN[®] S31 fetal heart monitor, US version

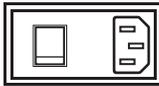


Please read the
STAN[®] S31 User Manual.

Patient
transducer
connectors



Power On/Off



The system is started by setting the power switch beneath the display unit to position 1.



End The system is closed down by using the “End” function button on the screen. When instructed on the screen, switch off the system by setting the power switch to position 0.

Temporary ending

The recording can be temporary ended. If the system is restarted within two hours, it will ask if to continue or start a new recording.

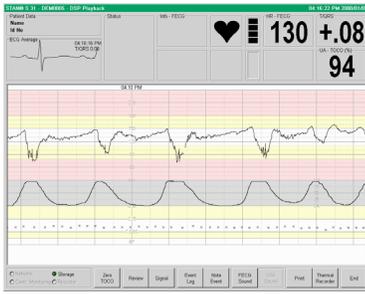
Fetal ECG analysis



In this document, this symbol indicates functions only activated when fetal ECG is recorded.

The system displays and analyses the waveform of the fetal ECG. The ECG can only be recorded through a single spiral scalp electrode.

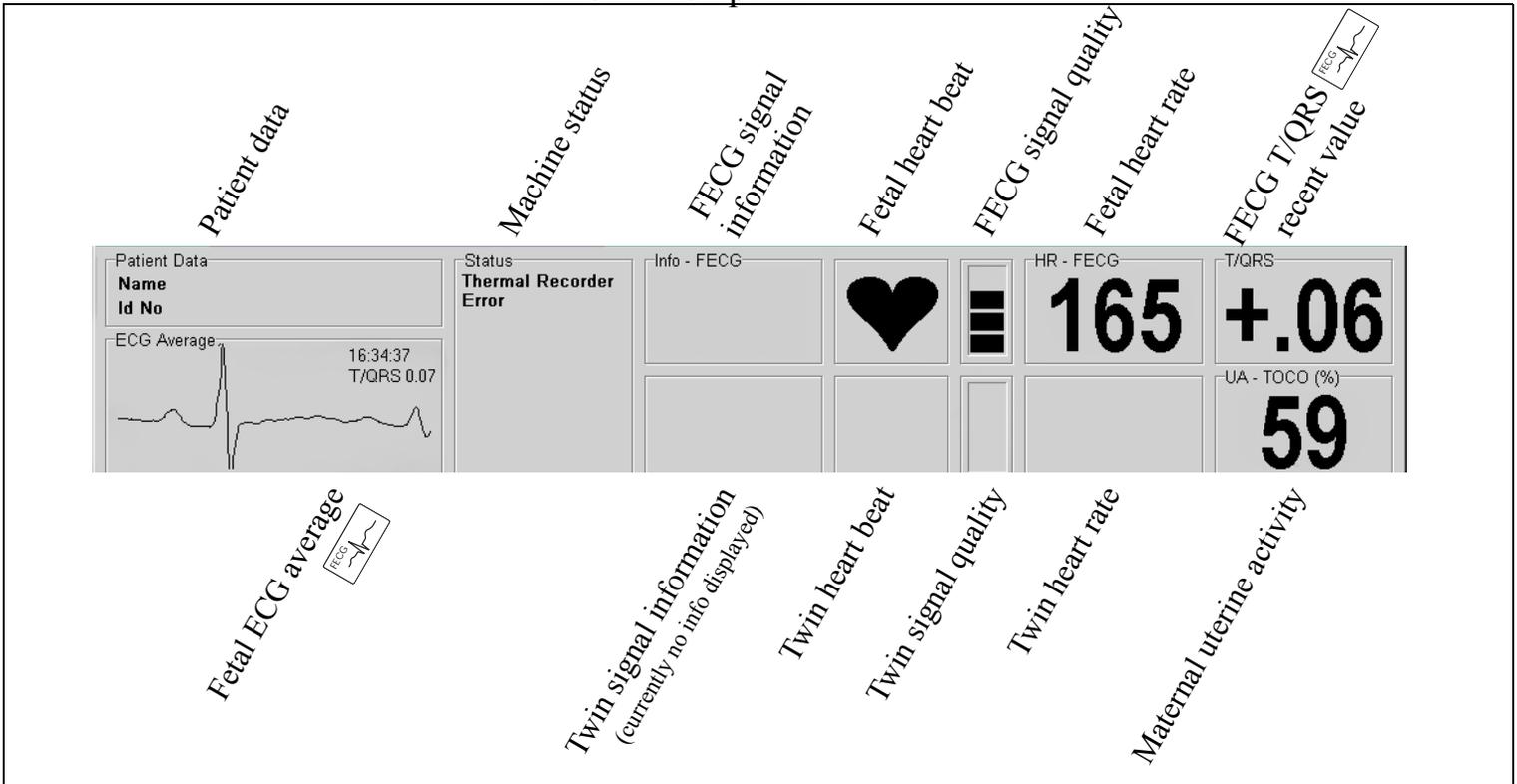
Screen layout



The display area is divided into three sections:

- Information Panel - instantaneous data
- Data presentation - trends, changes by time
- Function buttons - menus and system functions

Information panel



Function buttons

Function buttons are located at the bottom row of the display. Depressed button indicate activated function. Shaded (grey) buttons or text indicate unusable function.



Navigation

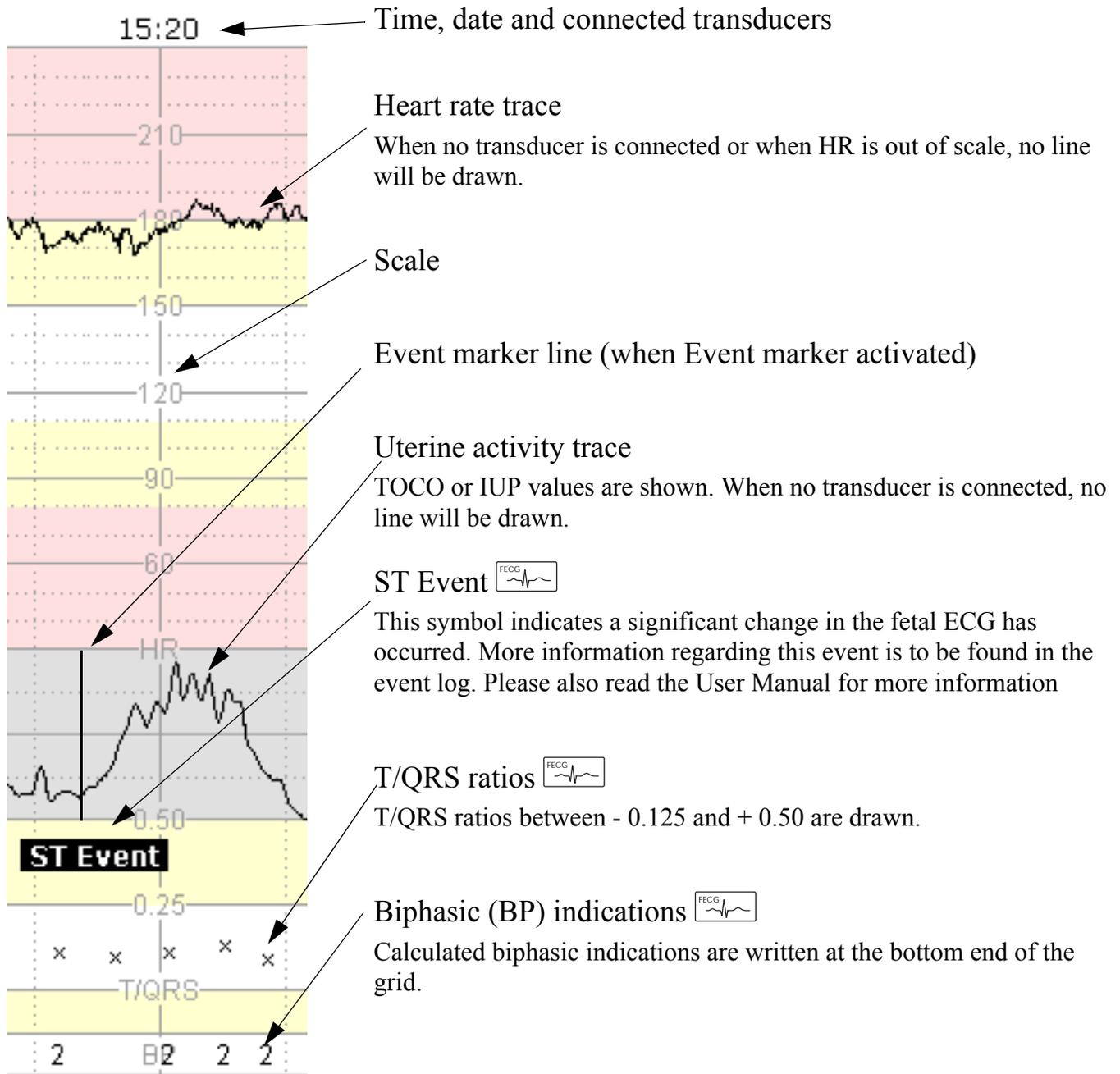
The function buttons are operated via the LCD touch screen. Tap the function button with a finger or a touchpen to activate function. Press and hold the function button to open the pop-up menu.

Maternal parameters

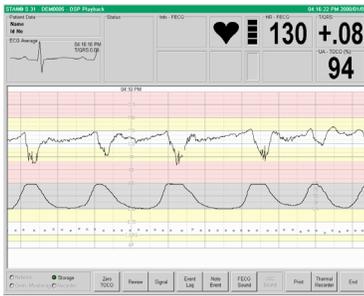
When a STAN[®] VSM 21 monitor is connected, maternal data or fetal ECG average can be chosen via the Signal pop-up menu.

Maternal Vital Signs Data			
	17:14:19		17:15:00
Temp	34.6°C	Systolic	105 mmHg
MHR	80	Diastolic	65 mmHg
MSpO2	98%	MAP	85 mmHg

Data Presentation

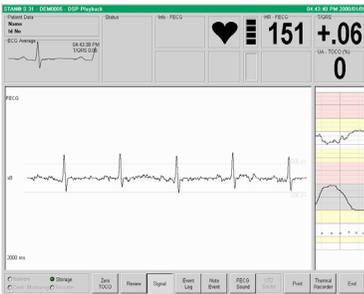


Operation Modes



Recording mode (Live EFM Window)

This is the mode normally used for monitoring. The event log can be shown in this mode.



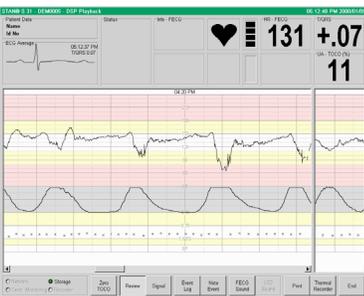
Signal mode (FECG Signal Window)

This mode is used to monitor the fetal ECG signal and is always displayed after power ON until the baseline is set and STAN® is recording with good signal quality.

In case of low or poor signal quality it may be necessary to replace the scalp or skin electrode. The current live recording is still visible in the right hand side window.

Signal

Tap the button to switch signal mode on and off.



Review mode (EFM Scroll Window)

This mode permits review of the ongoing recording. The current (live) recording is still visible to the right side.

Review

Tap the button to switch review mode on and off.

Move finger or touchpen across the scrollbar or across the recording to scroll through the recording.

Event log



The Event Log records information about various events.

The event log is always active, even when hidden. When an ST event occurs, the Event Log is automatically displayed..

Event Log

Tap the button to switch event log shown/hidden.

Note Event

Tap the button to enter an event with the keyboard. Press and hold to select a predefined event.

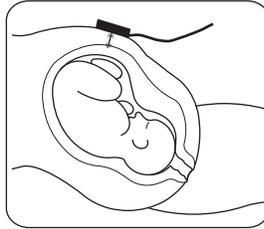


Important information might be missed when the event log is hidden.

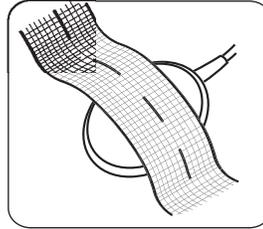
In review mode, the arrows in the event log window can be used to move up and down in the event log.

Recording of the uterine activity

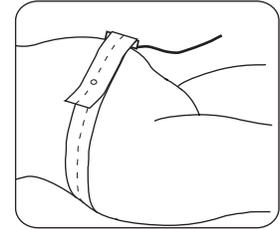
Set-up, External - TOCO



Place the sensor on the upper part of the maternal abdomen, over the fundus.



Fix the transducer in position using the elastic band, then connect to STAN[®].



Adjust the sensitivity by tightening or loosening the elastic band.

Zero TOCO

Tap the button to set the TOCO value to default value 5. Press and hold button to select sensitivity.

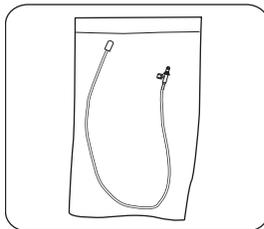
Set-up, Internal - IUP



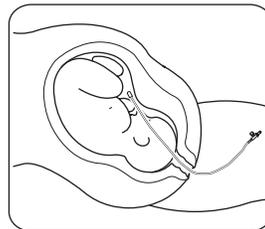
Only use recommended catheters and adapter cables. See user manual.



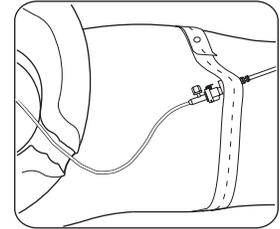
Follow the application instructions included with the catheter.



Use a sterile IUP catheter of recommended type.



Introduce the catheter.

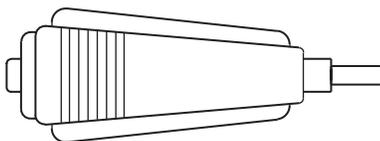


Connect the catheter and the IUP adapter cable, then connect to STAN[®].

Zero IUP

Tap the button to zero the IUP signal.

The eventmarker



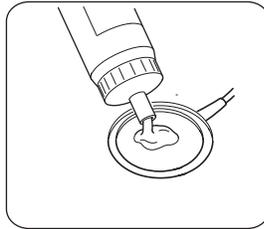
The event marker is used to indicate fetal movements or other events. Each press by the mother results in a vertical line marker in the uterine activity curve.

Recording of the fetal heart rate

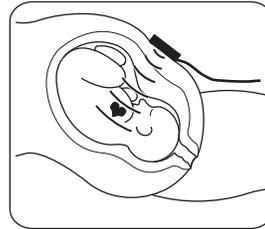
External Recording-Ultrasound



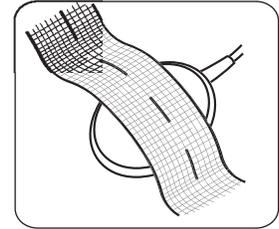
Fetal ECG cannot be recorded with ultrasound.



Always use gel for ultrasound.



Direct the US transducer towards the fetal heart.



Fix the transducer by using the elastic band then connect to STAN[®].



Reposition the transducer regularly as the fetus moves to improve signal quality.

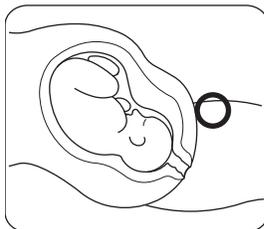
**US1
Sound**

Tap the button to switch sound on/off. Press and hold to select volume.

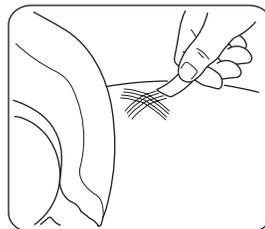
Internal Recording-Fetal ECG (FECG)



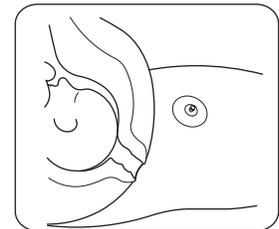
The fetal ECG is recorded.



Locate the position for the skin electrode.



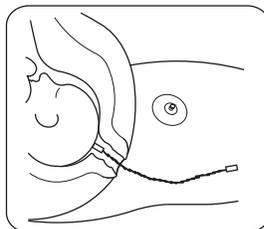
Prepare the skin properly by rubbing with sandpaper or other abrasive device thoroughly



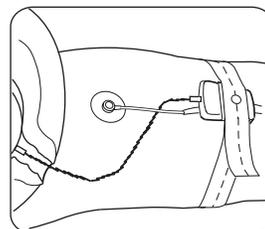
Clean the area with alcohol. Let dry. Apply the skin electrode.



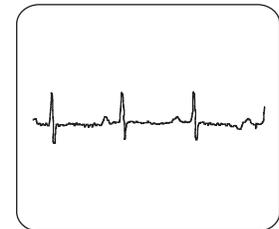
Only use approved single spiral scalp electrode.



Apply the recommended sterile scalp electrode.



Connect and strap the FECG leg plate.



Check FECG signal. Adjust electrodes if required.



Follow the application instructions included with the scalp electrode

Signal

The fetal ECG will automatically be displayed in signal mode until a stable signal has been achieved.



Please read the
STAN[®] S31 User Manual, about
FECG Signal Inspection (page 35).

Printout



Network Printer

**FECG
Sound**

Tap the button to switch FECG sound on/off. Press and hold to select volume.

Print

Tap the button to open laser printer menu.



Thermal Recorder

**Thermal
Recorder**

Tap the button to start/stop the recorder. Press and hold to select printing options.