C. System Description

1. Introduction

The STAN Fetal Hcart Monitor is a fetal heart monitoring system used during labor and delivery to measure, display and analyze the ST waveform of the fetal ECG (FECG). The STAN System combines this ST waveform analysis with standard Electronic Fetal Monitoring (EFM/CTG) to provide doctors and midwives with detailed information about the fetal hypoxic situation during labor.

The STAN System consists of a monitor, base unit, patient sensors and embedded application software. Fetal ECG and heart rate are measured continuously via a scalp electrode placed on the presenting part of the fetus and connected by a clip connector (leg plate) directly to the base unit. Uterine activity is measured either by an external transducer (TOCO) placed on the abdomen of the mother or by an intrauterine catheter connected to an adapter cable. A skin electrode is attached to the maternal thigh and connected to the base unit by the clip connector. This electrode is essential in obtaining the waveform configuration of the FECG.

Changes in the T wave and ST segment of the fetal ECG are automatically identified and analyzed by the application software. The analysis is displayed on the monitor along with an Event log identifying ST events. This information may be stored in a magneto-optical (MO) disk or communicated to external equipment via serial ports.

The system is operator controlled with a trackball and buttons. Notes can be entered from a keyboard.

2. Overview

A. System Components

The STAN® S21 Fetal Heart Monitor System consists of the following physical units:

Component	Product number	Comment
STAN® S 21 Main Unit	SBS 102 000	Release R3A
Includes: Base unit (all below monitor) Monitor Software		
Software:		
Main (SBC)	STW 102 010	Release R2G
DSP	STW 102 002	Release R4C
Kernel	LDF 102 010	Release R2B
Patient Sensors:		
STAN F 21 Clip Connector	ACC 101 000	
STAN T 21 Toco Transducer	ACC 101 0002	
STAN IUPT Adapter 1	ACC 101 004	
External Event Marker	ACC 101 006	
Accessories:		
STAN K 21 Keyboard	ACC 101 010/x	x = country specific
Power cord	CBL 102 100	
Fastening screw kit for trolley	MTP 102 031	
Network Cable	CBL 102 103/x	
Serial 1 Cable	CBL 102 104/x	
Serial 2 RS232 Cable	CBL 102 105/x	
Serial 2 RS485 Cable	CBL 102 106/x	
STAN CMS Ethernet Wall Connector	CNK 100 000	
Trolley TR 22	SBS 102 002/2	
Product Documentation		
Packing		

B. Main Unit Diagrams and Functions

The Main Unit of the STAN System is shown on the following pages. Display unit (monitor) functions are described and the modes used during a recording are illustrated and explained.

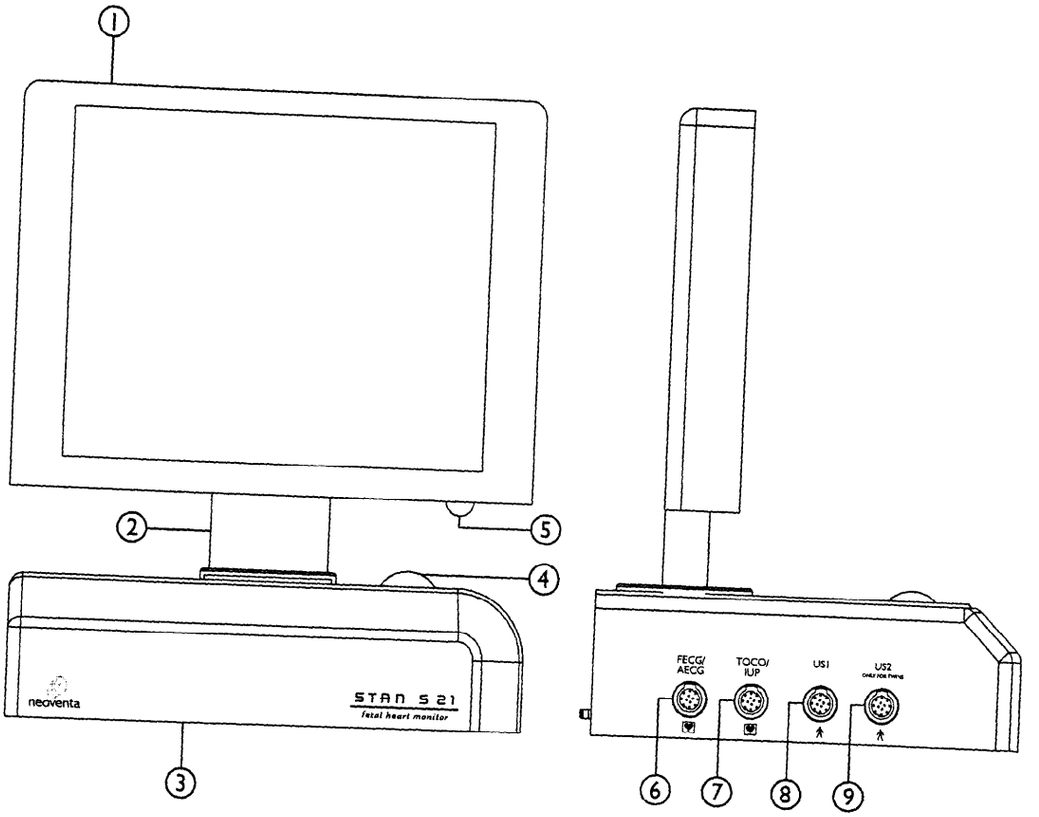


Figure II-1: Main Unit Diagram (front and side)

1. *Display unit*
   15" flat screen for data presentation

2. *Flexible mounting arm*
   Permits tilt and swivel of the display unit.

3. *Base unit*

4. *Trackball*
   For the navigation of the user interface.

5. *Brightness and contrast control*
   For the adjustment of the display unit.

6. *FECG (blue)*
   Input for scalp and skin electrode clip connector.

7. *TOCO/IUP (red)*
   Input for external uterine activity transducer or adapter cable for intrauterine pressure catheter.

8. *USI (green)*
   Not available

9. *US2 (yellow)*
   Not available

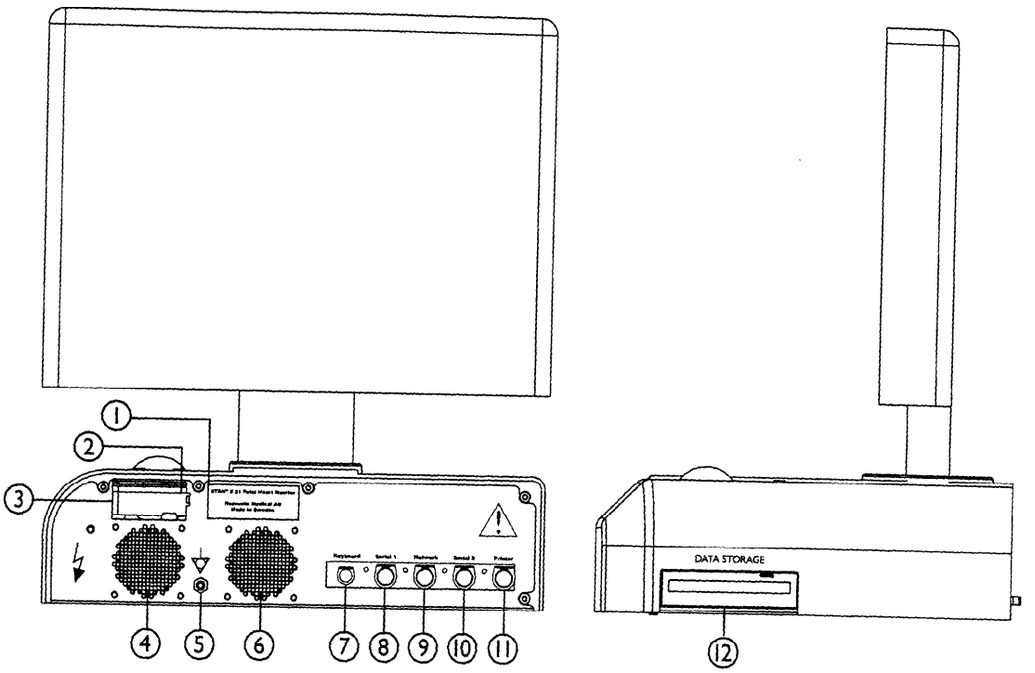


Figure II-2: Main Unit Diagram (rear and side)

1. *Product identification label*
   Shows technical data and serial number.

2. *Power input*
   For connection of 100–240 V 50/60 Hz mains cable.

3. *Power switch*
   Power switch for turning the device on and off.

4. *Exhaust outlet*
   For ventilation air. Do not cover.

5. *Earth terminal*
   For separate earth connection.

6. *Speaker*
   For audible monitoring of heartbeat and ultrasound transducers.

7. *Keyboard input*
   Use only approved keyboards.

8. *Peripheral device socket ("Serial 1")*
   Connect only approved peripheral devices.

9. *Network*
   Used for connection to Central Monitoring System and central printer.

10. *Peripheral device socket ("Serial 2")*
    Connect only approved peripheral devices.

11. *Printer socket*
    Connect only approved printers.

12. *Data storage unit*
    Used for digital storage of recordings on magneto-optical disks. Use only approved disks.

DISPLAY UNIT 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: bed number.*
   Information as to the bed to which the recording relates. This must be preset by technicians, or programmed in conjunction with connection to whatever central monitoring system is used.

3. *Header: date and time*
   This shows the current date and time, updated every second.

4. *Patient data*
   Patient data may be entered using the keyboard.

5. *Status information*
   Provides information on system status and configuration and any warnings or error messages that affect the system. This clarifies the indications in box 16.

6. *Signal info 1 (upper) and 2 (lower)*
   Signal and warning information for channels 1 and 2.

7. *Heartbeat indicator 1 (upper) and 2 (lower)*
   Indicates each detected beat (FECG) on channel 1. Channel 2 is reserved for ultrasound (US).

8. *Signal quality 1 (upper) and 2 (lower)*
   Information on signal quality based on the previous five seconds of the signal measured on channels 1 and 2 respectively

9. *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.

10. *T/QRS*
    Shows the current T/QRS ratio of the most recent ECG average, if fetal ECG is being measured.

11. *Uterine activity*
    Shows current uterine activity and indicates whether this is being measured by an external TOCO sensor or an internal IUP catheter.

12. *ECG average*
Shows the current ECG average with associated T/QRS ratio, biphasic indication and time (max. 20 seconds old) if fetal ECG is being measured.

13. *CTG window: heart rate*
Shows up to two heart rate patterns as a function of time.

14. *CTG window: uterine activity*
Shows uterine activity as a function of time.

15. *CTG window: T/QRS and BP*
Displays T/QRS ratios and biphasic ST (BP) indications as a function of time.

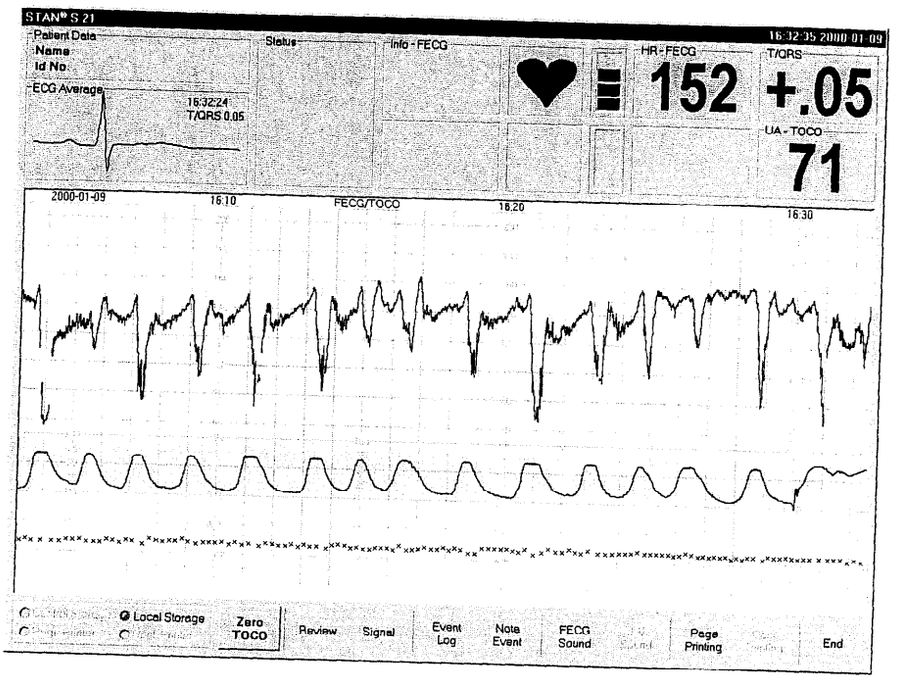
16. *Status indications*
Shows the status of certain types of externally-connected equipment:
– Functioning: green diode, normal text,
– Not installed: greyed-out diode, greyed-out text
– Error: orange diode, strikethrough text

17. *Basic menu*
Displays the 10 menu buttons corresponding to the following possible states and functions:
– Normal appearance: a button supports a function.
– Active button: select with the mouse or cursor keys.
– Button constantly depressed: shows whether a function or mode is active.
– Button function not supported (text greyed out).

The basic function of all buttons is activated by clicking the left trackball button.

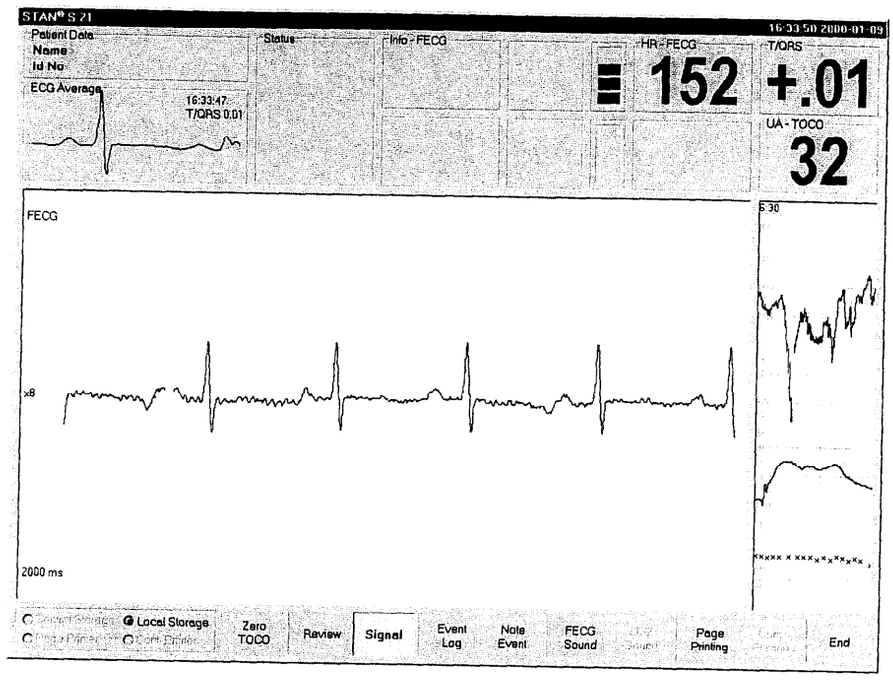
18. *Drop-down menu*
Several of the menu buttons include a drop-down menu that is activated by the right trackball button. This facilitates the finer adjustment of certain functions.

Recording Mode



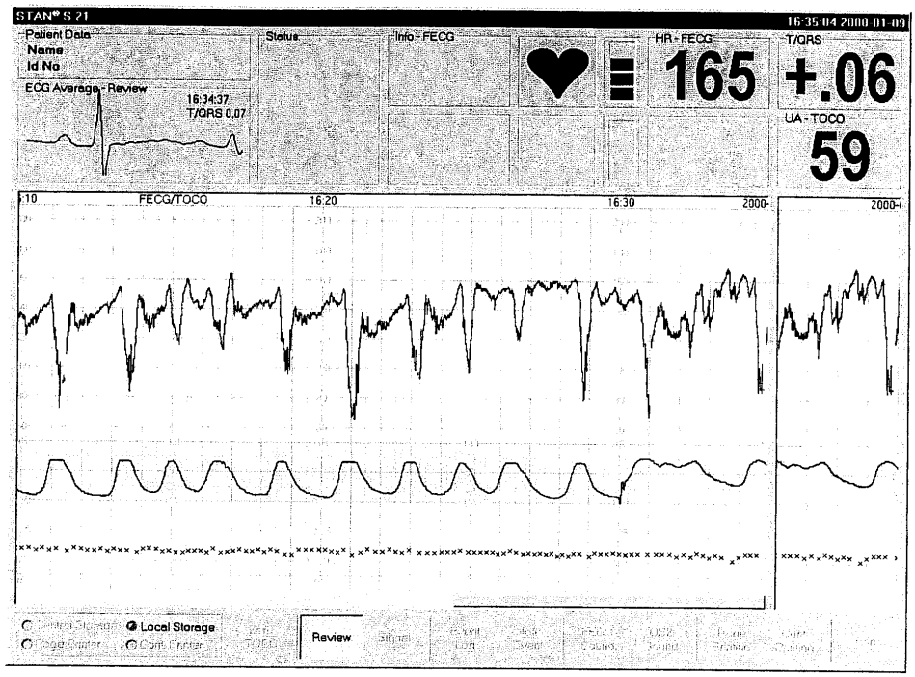
This is the mode normally used in monitoring the fetus. At a recording speed of 1 cm/min, 27 minutes of CTG and ST information will be displayed.

Signal Mode



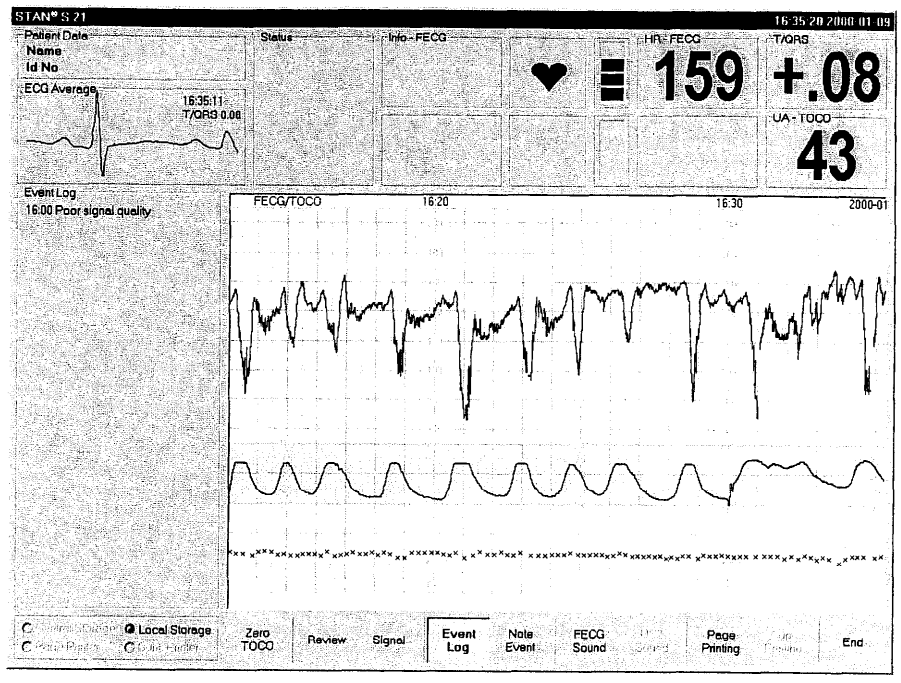
Signal mode may be used only in conjunction with internal recording by scalp electrode (FECG). When recording starts, the fetal ECG will automatically be displayed until a stable signal has been achieved, and the system will then switch to recording mode. The operator may at any time during recording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

Review Mode



This mode permits examination of the recording prior to that shown on screen in recording mode. By moving the trackball horizontally, the operator can scroll right through the recording, and if a keyboard is connected, the "Page Up" and "Page Down" keys can also be used. The last few minutes' recording always appears on the extreme right.

Event Log



The Event Log may be activated in all modes. It records information about various events.

Signal events

Two different signal events are detected:

1. Poor signal quality
   When the signal quality is inadequate, this is recorded in the Event Log.
2. Breech mode
   This is displayed when breech mode is activated.

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.
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 in terms of number, grouping and time.

The system uses strict quality criteria to detect these events, but all events must be verified manually on the basis of underlying T/QRS and biphasic check points. In brief recordings, poor signal quality conditions and during the first 20 minutes of a recording, special attention should be paid to the log and full manual data interpretation may be necessary.

User events

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