neoventa

Service Manual
STAN S31 *fetal heart monitor*

10. Technical Specifications

Technical Specifications

Classifications

Type of protection against electric shock:	
System	Class I

Type of protection against electric shock:	
ECG Connector:	Type CF
TOCO / IUP Connector:	Type CF
US1 and US2 Connector	Type B
NIPB and SpO2 (Note, including sensors connected. Classification not applicable for Display Unit connectors. MPM only)	Type BF

Degree of protection against harmful ingress of water	
Main Unit (Display Unit and PIB, mounted on trolley)	IPX1
Toco Transducer	IPX7
US Transducers	IPX7

NOTE! The IPX7 classification only applies for cleaning of the transducers. They are not intended for underwater use.

Methods of cleaning, sterilization and disinfection: See chapter “Maintenance”.

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

Mode of operation: Continuous
However: A recording (identified with a unique case number) is always stopped and automatically restarted after 48 hours of use.

Main Unit

Display Unit and PIB mounted together

Physical Characteristics	
Dimensions (width x depth x height):	420 x 143 x 334 mm
Weight:	9 kg

Power	
Operating voltage:	100-240 V
Line frequency:	50/60 Hz
Power consumption:	90 VA max, 35 W typ.

Operation environment	
Operating temperature:	+10°C to +40°C
Relative humidity:	30% to 75% non-condensing
Atmospheric pressure range:	700 hPa to 1060 hPa

Transport and storage environment	
Transport (inside packing) or storage (without packing)	
Temperature range:	-20°C to +70°C.
Temperature range (max 16 hours):	-20°C to +70°C.
Relative humidity range:	10 % to 90 %, no condensation.
Relative humidity range (max 16 h):	10 % to 90 %, no condensation.
Atmospheric pressure range:	500 hPa to 1060 hPa.

Display	
15" 1024x768 TFT LCD Touch screen, with tilt and rotation and brightness control, displaying the following output data:	
Dual Fetal Heart Rate:	50-240 bpm (US), 30-240 bpm (FECG).
T/QRS ratio:	-0.30 to +0.90 (FECG).
Fetal ECG Average with bi phasic (BP) ST indication.	
Uterine Activity:	0-100 units (external), 0-100 mmHg (internal).

Dual heart beat and signal quality indications	
Scrolling traces (FHR: 50-210 or 30-240 bpm, T/QRS: -0.12 to +0.50, UA: 0-100, BP, time):	1, 2 or 3 cm/min, selectable range 5 to 30 minutes live data, scrollable window (up to 25 minutes) over complete recording
Event Log information:	FECG waveform data, operator notes, signal quality
Realtime FECG signal	
Maternal Pulse Oximetry ($MSpO_2$): (MPM only)	70-100%
Maternal Heart Rate from $MSpO_2$: (MPM only)	30-240 bpm
Maternal non-invasive blood pressure: (MPM only)	25-280 mmHg (pSYS.) 10-220 mmHg (pDIA) 15-260 mmHg (pMAP)
Signal and system status.	
Patient name and id	
Easy-to-use touch screen control fields, with expandable control functionality	

Audible Indications
FECG-generated heart beat beep.
US-generated heart sounds.
Configurable alarms

Digital Data Storage
Integrated flashdisk automatically storing several 100 hours of latest recorded data.
USB Connector for removable USB storage devices, or transfer of digital data to archiving systems (optional).
Connection to external network for on-line archiving using dedicated cabling and software.

Recording

The following applies when standard transducers are used.

Fetal ECG Recording	
Maximum electrode potential difference:	±0.75 VDC.
Input range:	±10 mV.
Pre-amplifier bandwidth:	0.05 to 100 Hz (-3dB).
Sensitivity FHR detection, minimum QRS ampl.	50 µV p-p
Sensitivity ECG analysis, minimum QRS ampl.	200 µV p-p

Mains frequency rejection:	>40dB
Beat-to-beat HR detection.	
HR range:	30-240 bpm.
HR accuracy:	±1 bpm (up to 180 bpm) ±2 bpm (above 180 bpm)
30-beat ECG Averages.	
ECG average T/QRS ratio range:	-0.30 to +0.90.
T/QRS accuracy:	±0.02.
Bi phasic ST segment indication:	Grade 0, 1, 2 and 3.

US Recording

Centre frequency:	1.0 MHz (US2) and 1.5 MHz (US1).
Intensity:	<20mW/cm2.
HR range:	50-240 bpm.
HR accuracy:	±2 bpm (up to 180 bpm), ±3 bpm (above 180 bpm).

Toco Recording

Max load:	500 g
Output range:	0-100 units
Sensitivity:	0.4 units/g (nominal, adjustable)
Manual output offset:	5 units
Resolution:	1 unit
Accuracy:	±20% of display
Bandwidth:	DC to 0.15 Hz (-2dB) (-40 dB at 1Hz)

IUP Recording

Range:	0-100 mmHg (0-13.33 kPa).
Resolution:	1 mmHg.
Accuracy:	±5% of display.
Bandwidth:	DC to 0.15 Hz (-2dB) (-40 dB at 0.5Hz)

Maternal Pulse Oximetry Recording (all compatible sensors according to this Service Manual)

$MSpO_2$ Range:	70-100%
$MSpO_2$ Resolution:	1%
$MSpO_2$ Accuracy:	±3.0%
MHR Range:	30-240 bpm
MHR accuracy:	±3 bpm, ±1 bpm rms

NOTE: Pulse oximeter equipment measurements are statistically distributed, therefore only about two-thirds of pulse oximeter equipment measurements can be expected to fall within +/-A_{rms} of a value measured by a CO-oximeter.

NOTE: Accuracy for conditions of motion or low perfusion is not claimed.

See also “Summary of SpO_2 accuracy claims” in the end of this chapter.

Maternal NIBP recording

Range, pSYS:	25-280 mmHg
Range, pDIA:	10-220 mmHg
Range, pMAP:	15-260 mmHg
Accuracy, mean deviation:	±5 mmHg
Accuracy, standard deviation:	<8 mmHg

Recording with wireless transducer

The following applies when input from Rimkus T800 Telemetry system is used.

Fetal Spiral Electrode Recording

Mains frequency rejection:	>40dB
Beat-to-beat HR detection.	
HR range:	30-240 bpm.
HR accuracy:	±1 bpm (up to 180 bpm) ±2 bpm (above 180 bpm)

US Recording

HR range:	50-240 bpm.
HR accuracy:	±2 bpm (up to 180 bpm), ±3 bpm (above 180 bpm).
For other information, please refer to Rimkus manual	

Toco Recording

Max load:	500 g
Output range:	0-100 units
Sensitivity:	0.4 units/g (nominal, adjustable)
Manual output offset:	5 units
Resolution:	1 unit
Accuracy:	±20% of display

Bandwidth:	DC to 0.15 Hz (-2dB) (-40 dB at 1Hz)

For other specifications, see Telemetry system documentation.

Thermal printout

Resolution:	8 dots/mm (horizontal and vertical)
Printout width:	128 mm (total) 120 mm (traces)
Offset accuracy:	±1 mm
Nominal printout speed:	1, 2 or 3 cm/min, software selectable
Printout speed accuracy:	±2%

Trolley STAN TR31

Physical Characteristics	
Dimensions (width x depth x height):	560 x 585 x 1400 mm.
Weight:	21 kg.
Input mains cable:	Removable

Power	
Nominal operating voltage:	100-240 V
Line frequency:	50/60 Hz
Max load	10 A

Trolley STAN TR21

Physical Characteristics	
Dimensions (width x depth x height):	560 x 585 x 1020 mm.
Weight:	25 kg.
Input mains cable length:	4 m.

Power	
Operating voltage:	230 V.
Line frequency:	50/60 Hz.
Max load floating outlet:	1.8 A continuously.
Max load non-floating outlet:	8 A.

Operation environment	
Operating temperature:	+10°C to +40°C.
Relative humidity:	30% to 75% non-condensing.
Atmospheric pressure range:	700 hPa to 1060 hPa.

Transport and storage environment	
Transport (inside packing) or storage (without packing)	
Temperature range:	-25°C to +65°C.
Relative humidity range:	30 % to 75 %, non-condensing.
Atmospheric pressure range:	700 hPa to 1060 hPa.

Trolley STAN TR22

Physical Characteristics	
Dimensions (width x depth x height):	560 x 585 x 1020 mm.
Weight:	20 kg.

Operation environment	
Operating temperature:	+10°C to +40°C.
Relative humidity:	30% to 75% non-condensing.
Atmospheric pressure range:	700 hPa to 1060 hPa.

Transport and storage environment	
Transport (inside packing) or storage (without packing)	
Temperature range:	-25°C to +65°C.
Relative humidity range:	30 % to 75 %, non-condensing.
Atmospheric pressure range:	700 hPa to 1060 hPa.

Trolley STAN TR23

Physical Characteristics	
Dimensions (width x depth x height):	560 x 585 x 1020 mm.
Weight:	21 kg.
Input mains cable length:	4 m.

Power	
Operating voltage:	230 V.
Line frequency:	50/60 Hz.
Max load	10 A.

Operation environment	
Operating temperature:	+10°C to +40°C.
Relative humidity:	30% to 75% non-condensing.
Atmospheric pressure range:	700 hPa to 1060 hPa.

Transport and storage environment	
Transport (inside packing) or storage (without packing)	
Temperature range:	-25°C to +65°C.
Relative humidity range:	30 % to 75 %, non-condensing.
Atmospheric pressure range:	700 hPa to 1060 hPa.

Wall-mount STAN WM31

See accompanying documentation for SBS 103 006.

Summary of evaluation of SpO2 accuracy

The evaluation was performed in accordance with guidelines in EN ISO 9919: 2005.

SpO2 accuracy was evaluated in an invasive controlled desaturation study where SpO2 readings from the equipment were compared with SaO2 values determined with a CO-oximeter, achieved from dyshemoglobin-free reference measurements. The participants of the study were all healthy

volunteers who consented to induced hypoxia and arterial blood sample as part of the testing.

The study included the sensors defined as compatible in this Service Manual, and the ChipOx® module that is integrated in the MPM in the STAN S31 Display Unit.

The characteristics of the study population were:
Gender: 6 of them were female, and 7 were male.
Age range: 20 to 35 years.
Skin range: from light to very dark.

The study objects were desaturated to five different SaO2 plateaus in the range from 70 to 100%. For every plateaus a minimum of six blood samples were taken and analyzed with a CO-oximeter.

Comparing the data from the sensors and ChipOx® module with the data from the CO-oximeter, the accuracy was defined in the range of 70% - 100% SpO2.

Source: Corscience GmbH & Co. KG (manufacturer of ChipOx module).