Instructions for Use

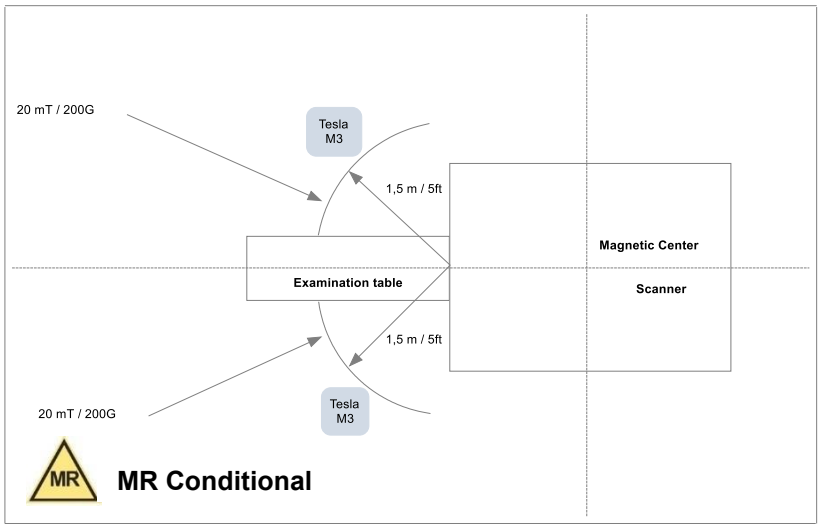
Tesla^{M3}

MRI Patient Monitoring System

CE 0123

MR

1.4. Placement in the MRI Room



The device may be operated at a maximum magnetic field strength of 20mT / 200G.
Depending on the different scanners this means a distance of approximately 1.5m / 5ft to the opening of the bore (based on actively shielded 3T scanner).
For exact positioning of the monitor please use the integrated Magnetic Field Indicator.

Fringe Field of MRI scanner	Typically values for approximately distances (A) in z-direction to opening of magnet bore		allowed position in MR Environment
	Static Magnetic fields of MRI scanner: 3.0 Tesla	Static Magnetic field of MRI scanner: 1.5 Tesla	
200 mT / 2000 Gauss	0.6 m	0.5 m	No
70 mT / 700 Gauss	0.9 m	0.8 m	No
40 mT / 400 Gauss	1.1 m	1.0 m	No
30 mT / 300 Gauss	1.2 m	1.1 m	No
20 mT / 200 Gauss	1.4 m	1.2 m	Yes
10 mT / 100 Gauss	1.7 m	1.5 m	Yes
5 mT / 50 Gauss	2.1 m	1.8 m	Yes

Do not place the *Tesla*^{M3} any closer than 1.5m / 5ft to the MRI scanner.

Observe the Signals of the Magnetic Field Indicator (see chapter 1.5 “Magnet Indicator”).

Fix the position of the Monitor due to locking the brakes of castors.

1.11. General Description

The MRI Patient monitoring system *Tesla*^{M3} ensures high quality vital signs monitoring for adult, pediatric and neonatal patients during MRI examinations.

Medical indications:

The MRI Patient Monitoring System *Tesla*^{M3} is intended for monitoring of vital signs during MRI examinations (MRI procedures) for the following patients:

- Physically or mentally unstable patients;
- Patients with compromised physiologic functions;
- Patients who are unable to communicate;
- Neonatal and pediatric patients;
- Sedated or anesthetized patients;
- Patients undergoing MR-guided interventional procedures;
- Patients who may have a reaction to an MRI contrast agent;
- Critically ill or high-risk patients.

Monitoring parameter:

- ECG and heart rate
- Pulse oximetry
- Non-invasive blood pressure
- Invasive blood pressure (2x)
- Anesthetic Agents (Auto Detection)
- Body temperature (2x)

Data management:

- Trend memory
- Event Memory
- Patient data
- Network (only with Remote Monitor)
- Printer, USB connectivity

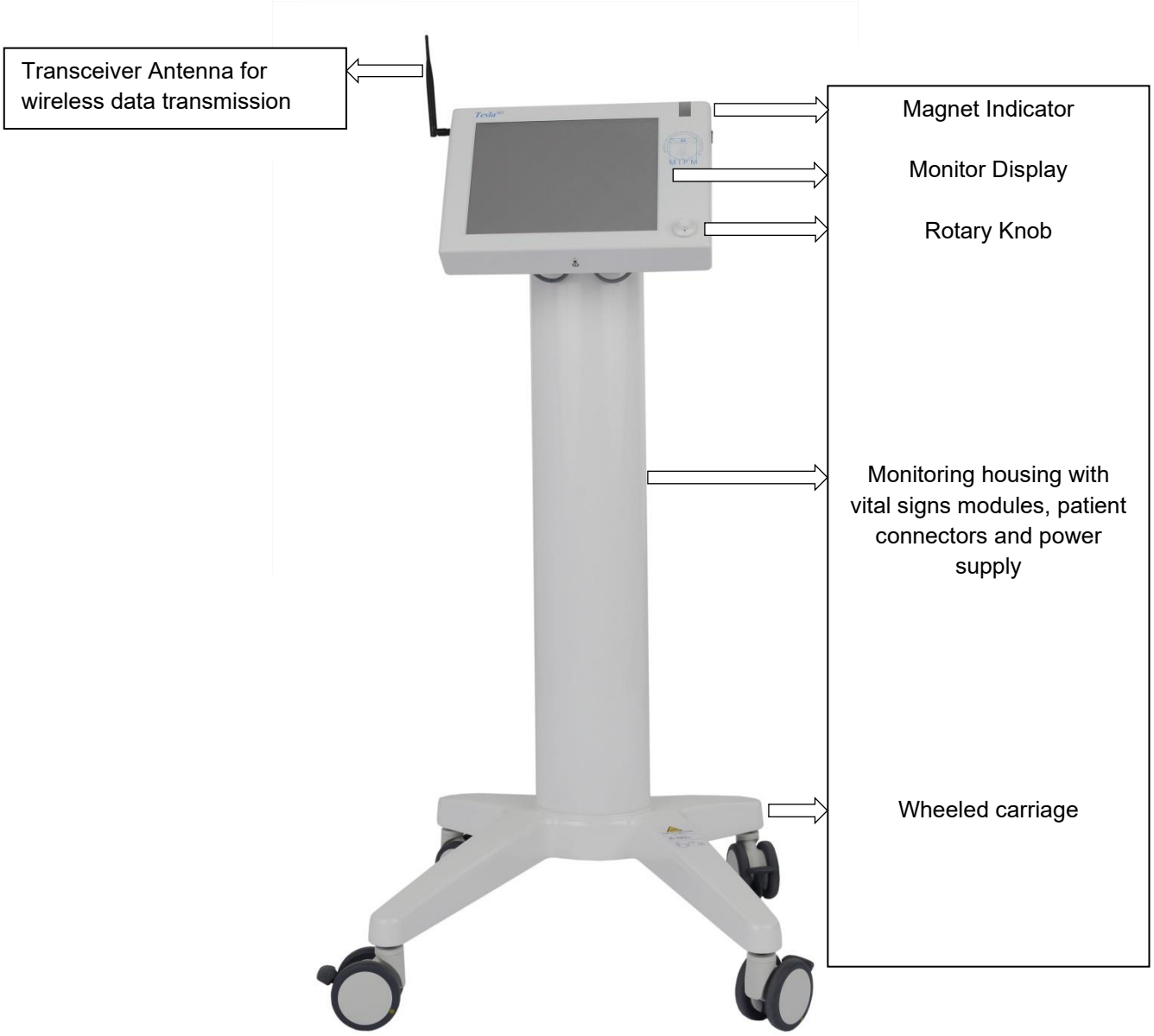
Tesla^{M3} is equipped with a 15'' color touch display. The optional wireless remote monitor offers complete functionality in the MRI control room.

The monitor is equipped with a rechargeable battery (see chapter 11."Technical Specifications" in the user manual for more details). The IEC socket enables the connection of the monitor to the hospital electricity network.

1.12. Front and Back of the device

1.12.1. Back of the device

1.12.2. Front of the device

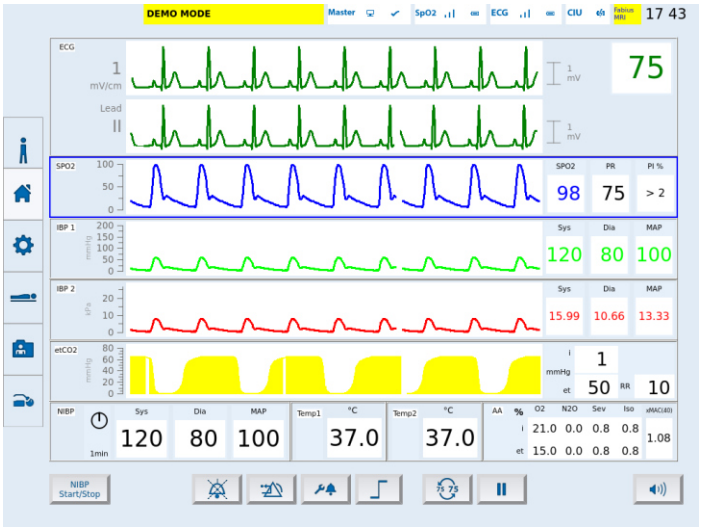


1.14. The display

1.14.1. The menu bar

Patient mode tab	Choice of patient mode and indication which patient mode is in use
Main screen tab	Display of all vital signs during regular operation
Option Menu tab	Settings
Patient data tab	Patient admission and patient release
Trend menu tab	Graphical, tabular and event memory, data export and printer

1.14.2. Main screen



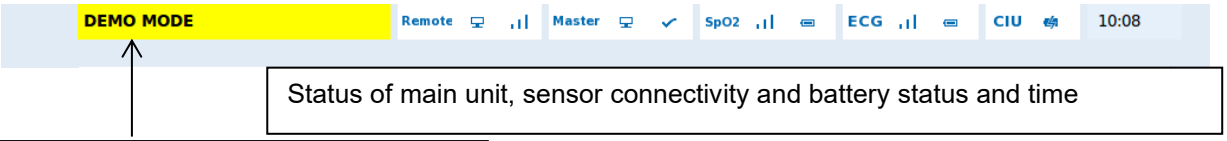
All vital signs are displayed in the main screen.

Up to 6 channels can be displayed at the same time.

In the upper part of the main screen you will find the status bar.

The function icons are at the bottom of the main screen.

1.14.3. Status bar



Status of main unit, sensor connectivity and battery status and time

Window for alarm text messages

1.15. Alarms

Tesla^{M3} signals acoustic as well as optical alarms. Here the monitor distinguishes between technical (System) alarms and parameter alarms.

Alarms are automatically prioritized according to urgency and degree of exposure for the patient. If several alarms occur simultaneously the events will be displayed on the main screen according to the respective priority.

If several alarms with equal priority occur simultaneously the respective alarm messages rotate in the text window in the status bar.

1.15.1. Technical Alarm

Technical alarms concern the basic functionality of the monitor and the different components. Technical alarms are displayed directly in the main screen (e.g. sensor connection alarm) or as a text message in the status bar (e.g. battery alarm).

1.15.2. Parameter Alarm

Parameter alarms are activated if the upper or lower alarm limit of a vital sign is violated. A parameter alarm will be displayed in the parameter box of the respective vital sign in the main screen. Parameter alarms are automatically deactivated if the reading of the respective vital sign is back to the accepted values. Users may confirm, deactivate, or adjust parameter alarms.

1.16. Touch screen and rotary knob

The *Tesla*^{M3} is equipped with two independent controls. Any setting on the monitor may be performed via Touch screen or using the rotary knob. In both cases the user has full functionality of the monitor.

In order to use the touch screen the user has to push the respective icons and menus directly on the display.

If the rotary knob is used a cursor appears on the display. This cursor can be moved to any position or menu on the display. The rotary knob may be used clockwise or anti-clockwise. The cursors direction of rotation coincides with the rotation of the rotary knob. In order to activate an icon or enter a menu, press the rotary knob.

➤ Note: If the Touch screen functionality is disabled due to malfunction of the display use the rotary knob as alternative monitor control.

3.5.1. Available parameters

Item (Name)	REF number	Parameter (Description)
MRI patient monitor *Tesla*^{M3}	1800001	Basic configuration • ECG • Pulse oximetry • Non-invasive blood pressure
Option *Tesla*^{M3} Remote Monitor	5450012	Wireless remote monitor, optional (Wireless connection to a remote screen in the MRI control room***)**
Option IBP 1	5200057	Invasive blood pressure, optional
Option IBP 2	5200058	Invasive blood pressure, optional
Option Gas module *Tesla*^{M3} Variant: Multigas	5400038	Anesthetic Agents (Auto Detection), optional (i/et CO_2, O_2, N_2O, ISO, DES, HAL, ENF, SEV)
Option Gas module *Tesla*^{M3} Variant: Capnography	5400038	i/et CO_2, RR
Option Temperature 1	5800001	Body temperature, optional
Option Temperature 2	5800002	Body temperature, optional
Option Gating *Tesla*^{M3}	5450014	Gating / Trigger interface, optional
Option Anesthesia View	5000002	Optical interface for Anesthesia View

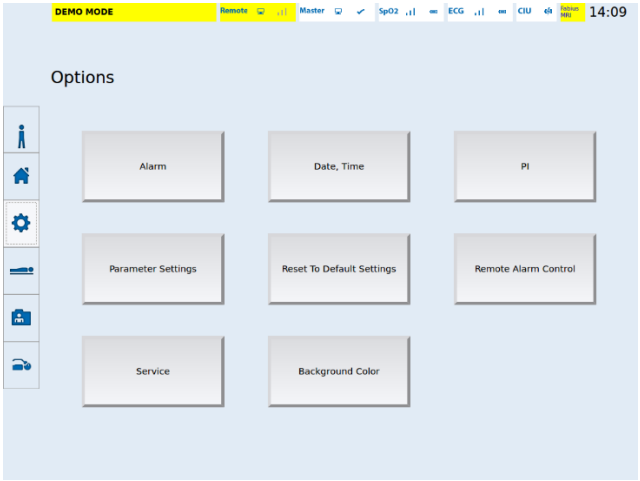
* Mandatory for Hospital network connection

All integrated parameters will be displayed on the main screen and stored in the trend memory.

The main screen is divided into parameter boxes. If a parameter is not integrated in the monitor the corresponding parameter box is empty.

Every component may be upgraded at any time. This is a hardware upgrade and has to be performed by MIPM or a service partner authorized and trained by MIPM.

3.5.2. System configuration – The Options Menu



In the options menu you can change all settings that affect the display layout and routine use of the monitor.

To open the Options menu, press the Options tab  in the menu bar.

3.7.4.IBP interface cable

You may utilize regular IBP transducers for IBP monitoring with the *Tesla*^{M3}. A list with tested and approved IBP transducers can be found in the accessories section. The shipment includes an IBP interface cable that connects your specific IBP transducer to the monitor.
The transducer type has to be specified at the initial order of the monitor.

The IBP interface cable and the connector at the *Tesla*^{M3} are color coded. The cable can only be plugged into the connector in one position with the guide bar pointing up.

3.7.5.Gas sample lines and water trap

Gas sample line for Multigas module

Water trap for Multigas module

3.7.6.The temperature sensor

Temperature sensor for intracorporeal (rectum) temperature measurement

Temperature sensor for surface (axilla / armpit) temperature measurement

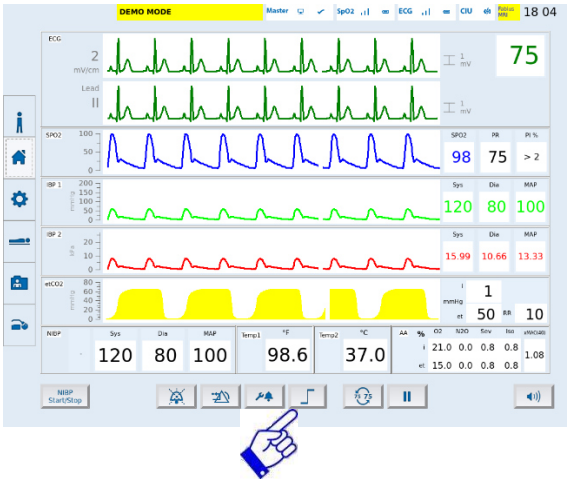
Both sensors are designed for use with monitoring system *Tesla*^{M3}. The operator is responsible for checking the compatibility of the monitoring equipment and sensor before use.
Incompatible components can result in degraded performance.

Auto alarm limits:

All alarm limits can be adjusted automatically. By press of the button  all alarms take an average of the last 15 seconds of measurement and apply alarm settings according to +/-20% of the averaged values.

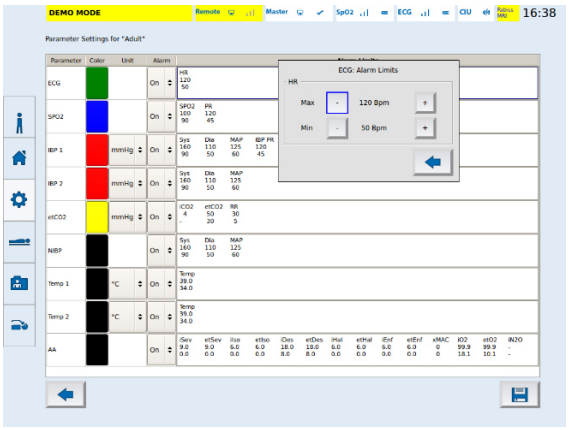
Adjust alarm:

If a parameter alarm occurs you have the possibility to change the respective alarm limit in order to eliminate the reason for the alarm.



If a parameter alarm occurs the adjust alarm icon is displayed right next to the alarm silence icon.

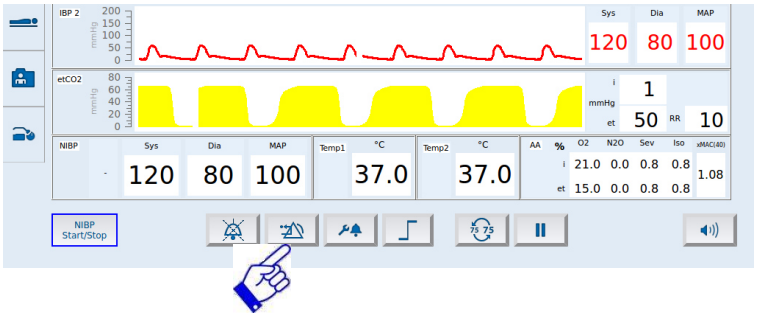
By pressing the adjust alarm icon you are immediately directed to the corresponding alarm limit menu that caused the alarm.



You can now change the respective alarm limit in order to eliminate the reason for the alarm.

After you are finished setting the alarm limit you can leave the menu by pressing any other point in the display outside the parameter menu, or by pressing the Back Icon.

There is also a reset function. Use the reset button to clear the disable status of the audible alarms (Audio off and Audio paused) and mute current alarms.



The Global Audio Alarm OFF/ON setting:
This function is restricted to responsible organization and protected via a password.

Inactivation/activation of alarm signals at remote monitor:
This function is restricted to responsible organization and protected via a password.

Warning:
A potential hazard can exist if different alarm pre-sets are used.
Please check the current alarm pre-set to ensure the pre-set is appropriate to use on each patient.

5.6. ECG and heart rate

Tesla^{M3} offers the following ECG functions:

- 3 leads ECG trace
- Digital artifact filter against impact of MRI gradients
- Display of the heart rate per minute
- Arrhythmia events: Cardiac arrest, Bradycardia, Tachycardia

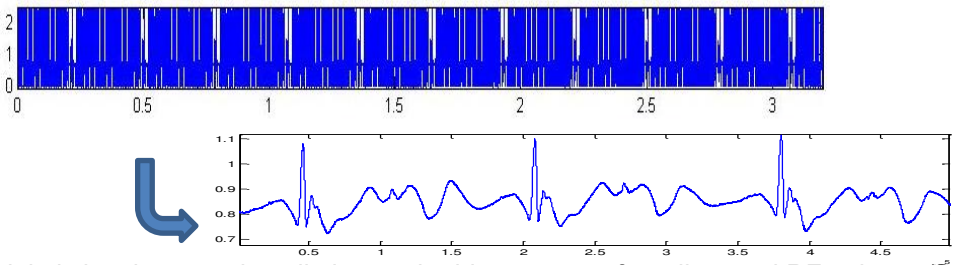
The electrodes attached to the patient measure the electrical impulses from the heart. The monitor processes, amplifies and displays the measured impulses on the main screen.

You may use a 3 lead ECG plus one reference lead. With this setup the following ECG leads are available: I, II and III. The reference lead cannot be used as an ECG lead.
The value will be displayed in the ECG parameter box.

2. Gradient Artifacts and RF Noise

During the scanning sequences the MRI scanner emits strong RF impulses. The RF noise has an impact on the ECG. In addition, gradient coils are pulsed rapidly emitting strong artifacts on the ECG curve.

Sample of unfiltered patient signal:



Digital signal processing eliminates the biggest part of gradient and RF noise artifacts.

The ECG curve is manipulated and should not be used for cardiac diagnostic analysis!

Depending on the type of scanner and the respective sequence, the ECG curve can be biased by gradient artifacts and RF noise.

MRI Scanner manufacturers as well as radiologists develop new sequences that might not be covered by the gradient filter.

In case that the ECG values are dubious use alternative parameters to evaluate the patient‘s condition.

5.6.2.ECG electrodes and skin preparation

To ensure optimal results in ECG monitoring during MRI examination MIPM recommends preparing the patient’s skin with an abrasive ECG gel. The contact between the ECG pad and the skin has a strong influence on the quality of the ECG readings.

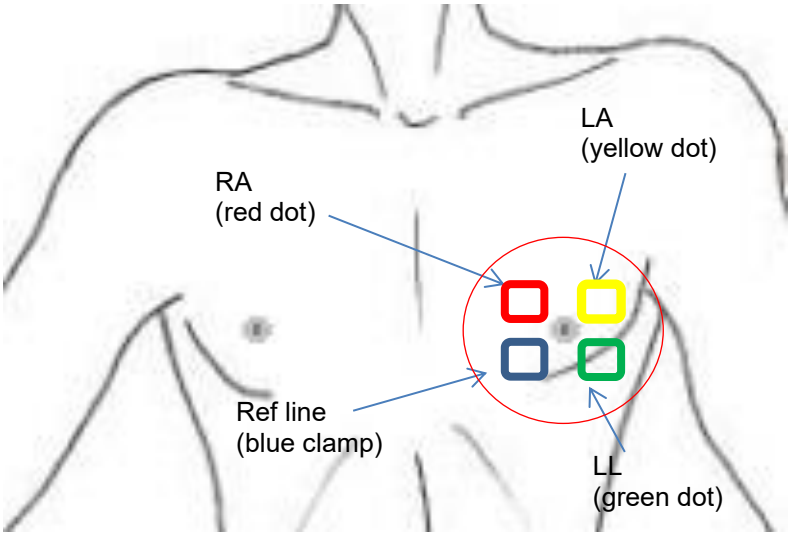
➤ Very hairy patients have to be shaved at the chest.

Skin preparation:

An essential element of the ECG Quality is the electrical resistance between the ECG pad and the skin. To ensure a minimal resistance the skin should be prepared before the ECG electrodes are placed. Please use the NUPREP gel or another abrasive ECG gel.

➤ Remove lotions or fluids from the skin before placing the ECG pads.

Try to place the ECG electrodes in standard configuration.
(left breast is in the center)



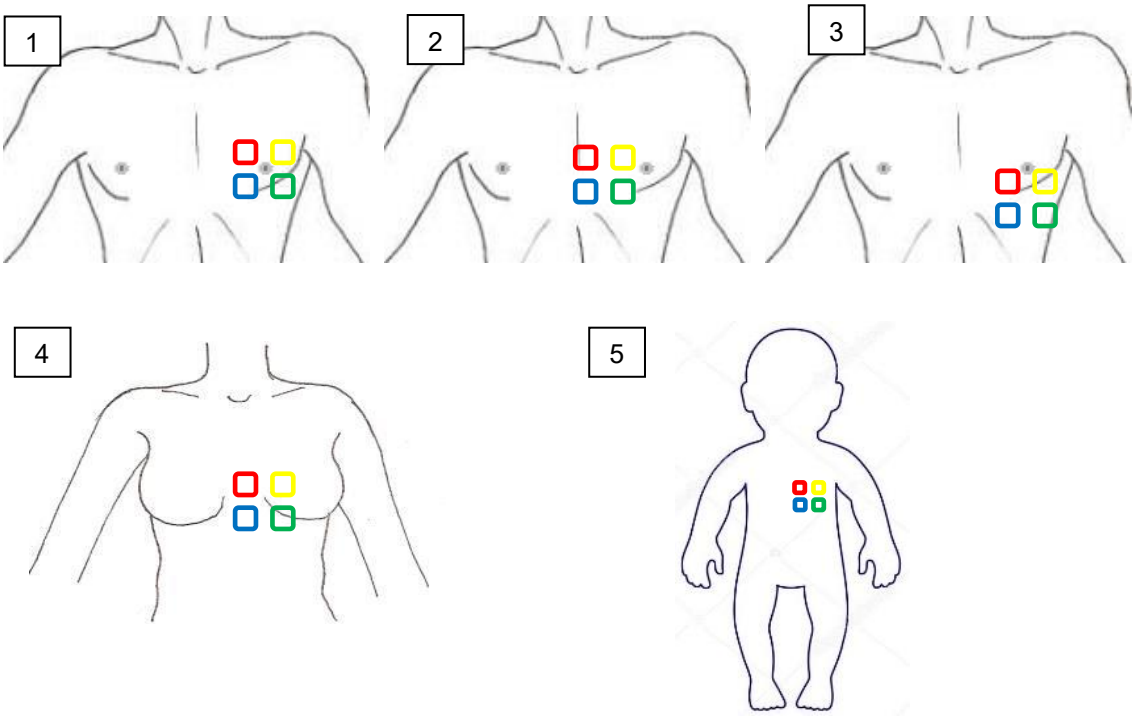
Rub the NUPREP gel in the skin gently using a paper towel.

Prepare a rather large area (red circle). This leaves you some freedom when placing the electrodes.

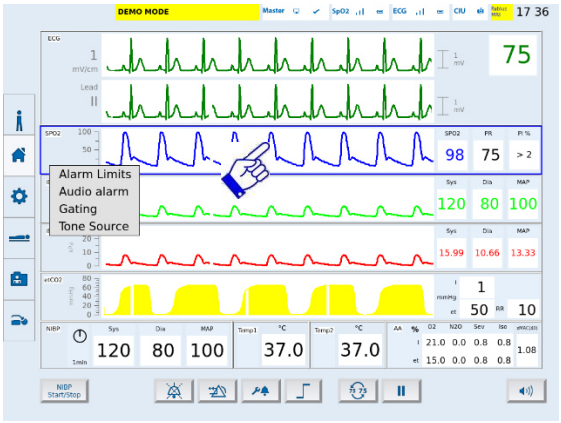
Remove remaining gel from the skin and place the ECG pads as shown in the picture.

Try to place the ECG electrodes in standard configuration.

Change configuration (1) to one of the other potential configurations (2-5), if anatomical conditions do not allow the standard configuration:



5.7.3.The SpO_2 menu

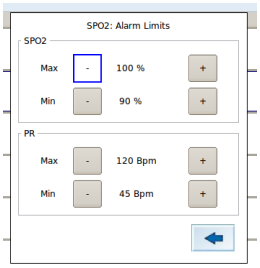


All relevant settings concerning the SpO_2 may be changed in the SpO_2 menu.

To enter the SpO_2 menu press the touch screen somewhere inside the SpO_2 parameter box.

5.7.4.Setting the alarm limits

Press the alarm limits bar in the SpO_2 menu.



Change the respective alarm limit by pressing the +/- icons. Pressing the icons once changes the value by 1. Holding the icons changes the values faster.

To exit the alarm limits sub menu press the back icon.

5.7.5.Changing the SpO_2 scaling

The SpO_2 module has an auto scaling function. The scaling of the SpO_2 waveform cannot be changed manually.

6. Trend and patient data transfer

The monitor stores trend data for 8 hours of operation. In the absence of alarm events the monitor calculates an average of the measured values and saves this value in the trend memory. Trend data may be arranged in the following ways:

- Graphical trends
- Tabular trends
- Event memory

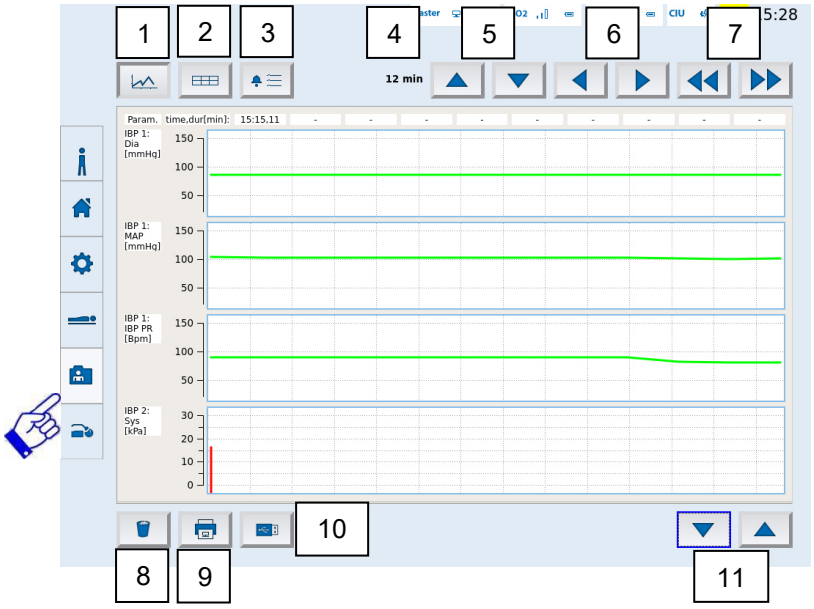
In the graphical trend screen the trend data is arranged starting at the left side of the screen. I.e. older data is shown on the left side of the screen and younger data is displayed to the right. You will see the time scale in the upper part of the diagram.

If an existing patient is released from the system or a new patient is registered, all trend memory will be deleted. The event memory cannot be deleted. The capacity of the event memory is 1000 events. If the memory is full, new events will replace old ones using FiFo (First in – First out) method.

6.1. The Trend menu

In the trend menu you can review all trend data, transfer trend data to external devices, print trends and delete the trend memory.

The trend menu can be entered by pressing the Trend tab at the bottom of the menu bar.



1. Icon graphical trends
2. Icon tabular trends
3. Icon Event memory
4. Time span
5. Navigation buttons for selecting the time span UP/DOWN
6. Buttons for Right / Left→ move time intervals in diagram in one-minute steps
7. Buttons for Double Left/Right→ move time intervals in diagram to next recording block
8. Delete memory
9. Printer menu
10. USB menu
11. UP/DOWN buttons scrolling through parameters

The control icons in the lower part of the menu will be available in all trend screens. You can always swap between the different trend screens.
You may leave the trend menu by choosing another tab on the Menu bar.

8. Accessories and applied parts

8.1 ECG Accessories

Item number	Description
5300028	Wireless ECG Sensor for *Tesla*^{M3} (Defibrillation-proof type CF applied part; multi-use)
5300025	ECG Electrodes for MRI (single-use)
5300006	NUPREP Gel
5300202	ezPad^{MRI} MRI ECG Electrode (Small) (single-use)
5300203	ezPad^{MRI} MRI ECG Electrode (Large) (single-use)
5300205	ezPad^{MRI} MRI ECG Electrode (4) (single-use)

8.2 SpO_2 Accessories

Item number	Description
5010100	Wireless Pulse Oximetry Sensor for *Tesla*^{M3} (Defibrillation-proof type BF applied part; multi-use)
5010012	SpO_2 Adapter - Basic (1x large / 1x medium / 1x small) (multi-use)
5010019	SpO_2 Adapter small (multi-use)
5010020	SpO_2 Adapter medium (multi-use)
5010021	SpO_2 Adapter large (multi-use)
5010103	SpO_2 Clip Adapter (multi-use)
5010049	SpO_2 Finger Adapter – M-Flex (multi-use)

8.3 NIBP Accessories

Item number	Description
5100044	NIBP Pressure Hose (multi-use)
5100038	NIBP Pressure cuff 9-15 cm (Defibrillation-proof type BF applied part; multi-use)
5100039	NIBP Pressure cuff 14-21.5 cm (Defibrillation-proof type BF applied part; multi-use)
5100040	NIBP Pressure cuff 20.5-28.5 cm (Defibrillation-proof type BF applied part; multi-use)
5100041	NIBP Pressure cuff 27-35 cm (Defibrillation-proof type BF applied part; multi-use)
5100042	NIBP Pressure cuff 34-44 cm (Defibrillation-proof type BF applied part; multi-use)

8.4 IBP Accessories

Item number	Description
5200031	IBP Interface Cable (multi-use)

Approved IBP transducers for use with *Tesla*^{M3} monitoring system

Item number	Cable	Manufacturer / Type
5200069	Transpac	ICU Medical
5200068	Edwards / Baxter	Edwards Lifesciences
5200059	Utah	Utah Medical
5200062	MX980	Medex 980
5200064	Medex MX960	Medex 960
5200067	BD/Ohmeda	Argon Medical
5200063	PvB 6300	PvB – Codan
5200066	PvB X-trans	PvB – Codan

8.5 Multigas Module Accessories

Item number	Description
5400017	Gas Sample Line Set (single-use)
5400036	Gas Water Trap (multi-use)

8.6 Temperature Accessories

Item number	Description
6210031	Fiber Optic Temperature Sensor Core (Defibrillation-proof type BF applied part; multi-use)
6210032	Fiber Optic Temperature Sensor Surface (Defibrillation-proof type BF applied part; multi-use)

8.7 *Tesla*^{M3} Accessories

Item number	Description
5500048	Instructions for Use (User manual) - English
5450015	Gating Cable - Siemens

Repeated use of single-use products can cause a cross-infection of the patient.

Conditions for Use in MR Environment

Description	Specification
MR Scanner	1.5 T; 3.0 T
MRI Patient Monitor (CIU and CCU/M)	MR Conditional (according ASTM F 2503) Not intended for use in the Magnet Bore, distance to MR Scanner: ≥ 1.5m Magnetic Field in MR Environment: ≤ 20 mT / 200 Gauss
Wireless ECG Sensor (ECGAP)	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Distance of enclosure of sensor to examination area: ≥ 40cm Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
Wireless Pulse Oximetry Sensor (POAP2)	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Distance of enclosure of sensor to examination area: ≥ 40cm Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
NIBP Pressure Cuffs	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
IBP Transducer	MR Conditional (according ASTM F 2503) Not intended for use in the Magnet Bore, distance to MR Scanner: ≥ 1.5m Magnetic Field in MR Environment: ≤ 20 mT / 200 Gauss
CO_2 Nasal Line / Airway Adapter	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
Temperature sensor (core / surface)	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
Remote Monitor (CCU/R)	MR Unsafe (according ASTM F 2503) Not intended for use in the MR Environment

Physical Characteristics

Description	Specification
MRI Patient Monitor:	
Height	140 cm / 55.1 inch
Width	60 cm / 23.6 inch
Depth	62 cm / 24.4 inch
Weight	36 kg / 79.3 lbs (mass including its safe working load)
Remote Monitor:	
Height	36 cm / 14.2 inch
Width	45 cm / 17.7 inch
Depth	24 cm / 9.5 inch
Weight	7.5 kg / 16.5 lbs

Wireless technology

Description	Specification
RF modules of wireless sensors	
Transfer power (E.I.R.P.)	2.9dBm
RF frequency	2.405 – 2.48 GHz
Modulation	OQPSK (Offset Quadrature Phase Shiftkeying)
Data rate	250 kbps
Protocol	MiWi P2P Wireless Protocol (IEEE 802.15.4 compliant)
Data security / Integrity	Hardware Security Engine (AES128) / Checksum
WLAN Master / Remote connection	
Transfer power (E.I.R.P.)	20dBm
RF frequency	2.417 GHz
Modulation	QAM64
Data rate	54 Mbit/s
Protocol	802.11g
Data security / Integrity	WPA2 / Checksum

I) MRI Patient Monitor (CCU/M and CIU)

Display

Description	Specification
Screen Size	15 inches; Ratio 4:3
Screen Type	Active Color LCD (Graphical Display)
Resolution	1024 x 768 pixels

User Interface

Description	Specification
ON/OFF-Switch	ON/OFF-Switch (push-push) with LED Illumination of the integrated LED is on if the device is connected AC power
User / Input device 1	Touchscreen to operate Graphical User Interface (GUI) (all functions like optical encoder)
User / Input device 2	Optical encoder to operate Graphical User Interface (GUI) (all functions like touchscreen)
Patient Modes	pre-configured (adult, pediatric, neonate); 1 user configurable

Alarms

Description	Specification
Alarm Conditions	Physiological Alarms with preset upper and lower alarm limits; Technical Alarms/Information's
Alarm Indication	Visual and Auditory Signals (depending on priority): flashing numeric, changing of color, text messages, adjustable auditory volume
Alarm silence time	Auditory Alarm Off/Paused (<120 sec.) with visual alarm indication

ECG

Description	Specification
Accessories	MRI electrodes
Sensor	Wireless ECG Sensor with high-resistant cable; MRI gradient artifact filtering
Communication with MRI Patient Monitor (CIU)	2.4 GHz wireless
Parameter	Heart Rate (HR)
Number of channels	1 channel (Waveform and Numerics)
Sweep Speed of Waveform	25 mm/s
Lead selection	I; II; III;
Heart Rate Range	30 to 300 BPM (Resolution: 1 BPM)
Heart Rate Accuracy Response to irregular rhythm A1 A2 A3 A4	± 5 BPM or ±10 % Ventricular bigeminy: 80 BPM Slow alternating ventricular bigeminy: 60 - 83 BPM Rapid alternating ventricular bigeminy: 120 BPM Bidirectional systoles: 86 - 96 BPM
Heart rate averaging Updating rate of the display T-Wave rejection	8 Beats 100 msec T-Wave rejection up to 0.80 mV with 1 mV QRS Amplitude
Response Time of Heart Rate Meter to Change in Heart Rate	HR change from 80 to 120 BPM: ≤ 4s HR change from 80 to 40 BPM: ≤ 7s
Time to Alarm for Tachycardia:	B1-Vent Tachycardia: < 2s B2-Vent Tachycardia: < 1s
Min. Amplitude for ECG patient signal (Sensitivity)	≥ 0.125mV
R-Wave Indicator	Waveform and Audible tone on each pulse
Selectable Filters	MRI Filter 1 (default) MRI Filter 2 Norm Filter
Alarm Limit Range	30 to 300 BPM
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type CF applied part
Battery operation of Wireless ECG Sensor:	
Type	Lithium-Polymer
Battery Operating Time	≥ 8 hours
Battery Charging Time	< 10 hours
Battery capacity monitoring	Indication of Battery Status / Battery Capacity on Monitor and Sensor
Lead off detection	DC Lead-Off detection

➤ Note: Measurements made with Norm Filter outside of the MR-Environment. The accuracy of the indicated heart rate may be affected by MRI gradient artifacts.

Pulse Oximetry

Description	Specification
Accessories	Large, medium and small adapters
Sensor	Wireless Pulse Oximetry Sensor with fiber optic cable (POAP2)
Communication with MRI Patient Monitor (CIU)	2.4 GHz wireless
Parameter	Oxygen Saturation (SpO_2), Pulse Rate (PR)
Number of channels	1 channel (Waveform and Numerics)
Sweep Speed of Waveform	25mm/s
Measurement Method	Red and Infrared light absorption
SpO_2 Range	0 to 100% (Resolution: 1%)
SpO_2 Accuracy	70 to 100 % ± 3% (0 to 69 % not specified)
Pulse Rate Range	30 to 240 BPM (Resolution: 1%)
Pulse Rate Accuracy	± 1 BPM or ± 1% of display
SpO_2 Alarm Limit Range	30 to 100% (Preset for lower SpO_2 = 90%)
Pulse Rate Alarm Limit Range	30 to 240 BPM
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type BF applied part
Battery operation of Wireless Pulse Oximetry Sensor:	
Type	Lithium-Polymer
Battery Operating Time	≥ 8 hours
Battery Charging Time	< 10 hours
Battery capacity monitoring	Indication of Battery Status / Battery Capacity on Monitor and Sensor

Summary of Clinical Study Report with Wireless Pulse Oximetry Sensor (POAP2):
Location: Hypoxia Research Laboratory, University of California, San Francisco
Purpose: Validation of SpO_2 Accuracy in comparison with arterial blood sample references measured with a CO-Oximeter. CO-Oximeter: Blood gas analysis to determine oxyhemoglobin saturation (SaO_2) was performed on an OSM 3® multi-wavelength oximeter. (Hemoximeter, Radiometer, Copenhagen, serial 89R0243 N010).
Oxyhemoglobin Saturation (SaO_2) range: 70 to 100%; 22 blood samples in this range of each subject.
Subjects: The study included 12 subjects (5 women and 7 men). No subject was anemic (Hemoglobin ≤ 10 $gm \bullet dl^{-1}$) and only healthy non-smoking individuals of age 21 – 49 were included in the study.
Demographics of the subjects:

Subject	Gender	Age	Skin	Ethnicity
1	Female	26	Medium	Hispanic
2	Male	30	Light-Medium	Hispanic
3	Female	24	Light	Japanese / Caucasian
4	Female	26	Dark	African American
5	Male	22	Dark	African American
6	Male	30	Dark-Medium	Asian
7	Male	31	Light-Medium	Caucasian
8	Female	26	Light-Medium	Hispanic
9	Male	26	Medium	Indian
10	Female	28	Dark	African American
11	Male	28	Light	Caucasian
12	Male	26	Light-Medium	Asian

Root mean square error (Arms) is calculated as follows:
SpO_{2i}: measured values; S_{Ri}: reference values; n: samples

$$A_{ms} = \sqrt{\frac{\sum_{i=1}^{n}(SpO_{2i} - S_{Ri})^2}{n}}$$

A_{rms} (in range of 70% to 100%) = 1.8%

NIBP

Description	Specification
Accessories and connection to MRI Patient Monitor (CIU)	NIBP-Cuffs for adults, pediatrics and neonates and extension tubing with pneumatic connector for NIBP-Cuffs
Parameter	Systolic (Sys), Diastolic (Dia) and Mean Blood Pressure (MAP)
Number of channels	1 channel (Numerics)
Measurement Method	Oscillometric
Measurement Interval	Manual or Intervals (Cycle time): 1, 2, 3, 5, 10, 15, 30 minutes
Measurement range for adults and pediatrics	SYS: 25 to 280 mmHg DIA: 10 to 220 mmHg MAP: 15 to 260 mmHg
Measurement range for neonates	SYS: 20 to 150 mmHg DIA: 5 to 110 mmHg MAP:10 to 130 mmHg
Accuracy	± 3 mmHg (static pressure)
Start Pressure	Adult and Pediatric Mode: 160 mmHg Neonate Mode: 100 mmHg
Pneumatic Overpressure Protection (Overpressure limits)	Adult and Pediatric Mode: 300 mmHg / 40 kPa Neonate Mode: 150 mmHg / 20 kPa
Alarm Limit Range	SYS: 20 to 280 mmHg DIA: 5 to 220 mmHg MAP: 10 to 260 mmHg
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type BF applied part

IBP

Description	Specification
Transducer Sensitivity	5 µV/V/mmHg
Accessories and connection to MRI Patient Monitor (CIU)	Interface cable for transducers from different manufacturers
Parameter	Systolic (Sys), Diastolic (Dia), Mean Blood Pressure (MAP) and Pulse Rate (PR)
Number of channels	1 or 2 channels (Waveform and Numerics)
Sweep Speed of Waveform	25mm/s
Measurement Method	Piezoresistive
Units	kPa or mmHg
Measurement Range	-99 to 310 mmHg
Measurement Accuracy	± 1 %, ± 1 digit over full range
Offset (Zero) Range	± 70 mmHg
Alarm Limit Range	-99 to 310mmHg
Bandwidth (Frequency response)	0 to 28 Hz (-3 dB)
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type CF applied part
Pulse Rate Range	30 to 240 BPM (Resolution: 1%)
Pulse Rate Accuracy	± 1 BPM or ± 1% of display

Description	Specification
Enflurane Range	0 to 10 Vol%
Enflurane Accuracy and drift	± (0.2 Vol% + 15% rel.)
Sevoflurane Range	0 to 10 Vol%
Sevoflurane Accuracy and drift	± (0.2 Vol% + 15% rel.)
Desflurane Range	0 to 20 Vol %
Desflurane Accuracy and drift	± (0.2 Vol% + 15% rel.)
Agents Rise time (10…90%)	< 450 ms
Agents Warm-up time [2)]	time to specified accuracy < 300s
Respiration Rate Range*	0 to 100 breaths per minute
Respiration Rate Accuracy*	0 to 60 breaths per minute ± 1 /min (> 60 breaths per minute not specified)
Total Response time *	< 1s (CO_2)*; < 30s (O_2 and N_2O); < 5s (Agents); (incl. watertrap and gas sample line)
Data sampling rate*	10 values per second
CO_2 Alarm Limit Range*	etCO_2: 0.1 to 10.0 Vol.%; 0 to 80 mmHg iCO_2: 0.1 to 10.0 Vol.%; 4 to 80 mmHg
O_2 Alarm Limit Range	iO_2: 18 to 100% etO_2: 10 to 100%
Agents Alarm Limit Range	Sevoflurane: 0 to10% Isoflurane: 0 to 8.5% Desflurane: 0 to 20% Halothane: 0 to 8.5% Enflurane: 0 to10%
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type BF applied part
Calculation of the MAC-Value	
Calculation of the Total MAC	$TOTAL\ MAC = \frac{Et N_2O}{1\ MAC\ N_2O} + \frac{Et\ 1st\ Agt}{1\ MAC\ 1st\ Agt} + \frac{Et\ 2nd\ Agt}{2\ MAC\ 2nd\ Agt}$
1 and 2 MAC Values	GAS: MAC Value DES (Desflurane): 6.00 Vol.% ENF (Enflurane): 1.70 Vol.% HAL (Halothane): 0.77 Vol.% ISO (Isoflurane): 1.15 Vol.% SEV (Sevoflurane): 2.10 Vol.% N2O (Nitrous oxide): 105 %
Et Gas Id	Is the identifier for the given end-tidal gas
Concentration	Is the current concentration of the given gas, in percent

* Note: Applicable to variant capnography

[1)] Duration from power on at 10 °C module temperature to transmission of measurements with unspecified accuracy
[2)] Duration from power on at 10 °C module temperature to transmission of measurements with specified accuracy

Temperature

Description	Specification
Accessories and connection to MRI Patient Monitor (CIU)	Fiber optic sensor (core or surface)
Parameter	Body Temperature
Measurement Method	Spectrophotometric fiber optic (direct mode clinical thermometer)
Transient Response Time	<30s
Number of channels	1 or 2 channels (Numerics)
Unit	°C / °F
Range	20 to 45 °C (68 to 113 °F)
Accuracy	± 0.3 °C (± 0.54 °F)
Alarm Limit Range	20 to 45 °C (68 to 113 °F)
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type BF applied part

Gating

Description	Specification
ECG gating	Maximum of R-Wave (Signal/Pulse according specification for MR Scanner from Siemens)
Pulse Oximetry gating	Maximum of Pulse-Wave (Signal/Pulse according specification for MR Scanner from Siemens)

Trends

Description	Specification
Graphical and Tabular Trends	All monitored parameters
Visible Area	Visible area (interval length) has to be selected by the user
Interval length	12 min, 24min, 48 min, 1 h; 2 h; 3 h; 4 h; 5 h; 6 h; 7 h; 8 h
Capacity	8 hours

Events

Description	Specification
Tabular Events	Date; Time; Patient Name; Event Name and Value (type of event)
Capacity	1000 Events (FIFO: First In - First Out)
Event Management	An event is automatically created on parameter alarms

Interfaces for Data Output of Trend/Event
(The MRI Patient Monitor has to be removed from MR Environment before performing a Data Output)

Description	Specification
Interfaces	2x USB
USB Interface for Trend	USB for pen drive or recorder/printer (selectable for the User by GUI)
USB Output format of Trend	Selectable: Screenshot or table in ASCII Code (.csv)
USB Interface for Event	USB for recorder/printer
USB Output format of Events	Screenshot
USB pen drive	USB 2.0 / FAT 32 (recommended: Transcend 4 GB)
USB recorder/printer	USB 2.0 (printer must support PCL5)

Battery Operation of MRI Patient Monitor

Description	Specification
Type	Lithium-Ion
Battery Operating Time	≥ 6 hours in basic configuration with options ECG, SpO_2, NIBP (other configurations accordingly less depending on options)
Battery Charging Time	< 6 hours
Battery capacity monitoring	Indication of Battery Status / Battery Capacity
Low Battery warning	Visual: 1st message at < 10% 2nd message at < 5% (Battery Low Alarm) Auditory: < 5% (Battery Low Alarm)

Electrical Specifications

Description	Specification
Type of protection against electric shock	Class I equipment
Classification according to the degree of protection against harmful ingress of water or particulate matter	IPX 1 (drip-proof)
Mode of operation	Continuous
Operating Voltage Range	100 to 240 VAC
Frequency	50 /60Hz
Power consumption	max. 130VA