

Instructions for Use

Tesla^{MF}^{M3}

MRI Patient Monitoring System



CE 0123



MIPM Mammendorfer Institut für Physik und Medizin GmbH, herein after called MIPM.

Printed in Germany.

Subject to change without prior notice. For further information contact MIPM.

It is possible that some features or functions described in this user manual are not available on your device. Please contact MIPM or your local partner for further information.

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MIPM assume no responsibility for damages, which can result from using the monitor.
The monitor is intended for use by qualified medical personnel only.

Before using the monitor, read all the manuals that are provided with your device carefully. Patient monitoring equipment, however sophisticated, should never be used as a substitute for the human care, attention, and critical judgment that only trained health care professionals can provide.



NOTE: A note presents information that helps you operate the equipment or connected devices.



CAUTION: A caution provides information or instructions that must be followed to ensure proper operation and performance of the equipment.



WARNING: A warning contains important information regarding possible danger to you or the patient that is present during normal operation of the equipment.



The indicator refers to a possible action that can be performed by the user.

Tesla^{M3} operating system software from version: v4

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1. Overview

1.1. Intended Use

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

The *Tesla^{M3}* is capable for continuous monitoring of Electrocardiogram (ECG), Pulse Oximetry (SpO₂), Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Temperature, Respiration, Capnography (etCO₂), Oxygen and Anesthetic Agents.

The *Tesla^{M3}* is intended for use by health care professionals.

The *Tesla^{M3}* is intended for use in adult, pediatric and neonatal populations

Excluded operating environment:

The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive or flammable environment.

Contraindications:

There are no known contraindications to the use of the device.

Prescription:

In the USA, federal law restricts this device to be sale by or on the order of a physician.

Clinical benefits of MRI patient monitoring

Vital signs monitoring of patients under anesthesia / sedation is mandatory and increases safety.

Tesla^{M3} enables users to observe various vital signs:

- Electrocardiogram (ECG)
- Pulse Oximetry (SpO₂)
- Non-Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP)
- Temperature
- Respiration
- Capnography (etCO₂)
- Oxygen and Anesthetic Agents

Using the *Tesla^{M3}* enables users to examine intensive care patients, infants and claustrophobic patients in the MRI.

1.2. General Safety Information

Read all operating instructions carefully before using the monitor. Specific warnings and Cautions are found throughout the User Manual where they apply.



The *Tesla^{M3}* must only be used by qualified and trained medical staff.

In order to be trained, please contact MIPM or an authorized representative.



The *Tesla^{M3}* is intended for use in the same room as magnetic resonance equipment (MRI).

Use only batteries that are approved by MIPM (contact your local representative). The use of non-approved batteries may damage the device.



NOTE: Lithium batteries have to be disposed according to the local regulations. In order to prevent the danger of explosion or fire batteries should never be burned! MIPM is only responsible for the safety of this device if:



- a) maintenance, repairs, and modifications are carried out by authorized personnel,
- b) if components are replaced with MIPM approved spare parts only
- c) the devices are used in accordance with MIPM Operating Instructions. A full technical description is available upon request from your local MIPM representative.

The transport position for the *Tesla^{M3}* should be with the monitor ahead.

1.3. Preliminary remarks for use



DANGER OF ELECTRIC SHOCK

- Do not immerse the patient monitor in liquid. This may lead to electrocution.
- Do not open the patient monitor.
- Maintenance and repair of this unit must be performed by qualified and authorized personnel only. Repairs should not be made by persons not having knowledge and experience in the repair and security of this patient monitor.
- The product only fulfils the requirement written in the Documentation only if the installation, handling as well as all maintenance, repair and service works are in accordance with the instructions in this manual.
- MIPM recommends to perform a function test and electrical safety test every 12 month. A technical control including calibration should be performed at least every 24 month. Please refer to your national regulatory requirements.
- A functional check should always be performed before using the monitor.
- A damaged device may not be used! Missing parts or parts that are: broken, worn out or contaminated have to be replaced. If a repair of the monitor is necessary please contact your technical service, your local dealer or MIPM directly.
- This device, its components or accessories may only be repaired or changed after MIPMs written approval.
- The user is solely responsible for malfunctions that arise due to faulty handling or maintenance as well as inadequate repair works or changes to the device performed by unauthorized personnel.



Caution:

- To ensure patient safety, interference free performance of the *Tesla^{M3}* as well as interference free MR images do only use original MIPM accessories that have been especially developed for the use in the MRI environment. Other cables and accessories may negatively affect also EMC performance.
- Do not place the devices in direct vicinity to the magnetic centre of the scanner.
- **The *Tesla^{M3}* has to be positioned outside the magnetic field strength of 20 mT (200G)**
- The fiber optic part of the SpO₂ Sensor consists of synthetic material and glass fibres. There is no danger of heating or attraction to the MRI scanner. Metal pigments in the colours used in the sensors may change the magnetic field homogeneity in the examination area. Place the sensor outside of the examination area
- Do not open the sensors! Opening the sensors without proper training and qualification destroys the RF shielding.
- Reusable accessories with patient contact may be cleaned with regular disinfection lotion or spray and dried with a soft tissue.

Safety information, Warnings and general remarks



- **WARNING! DANGER OF EXPLOSION!** Do not operate the monitor in presence of flammable anesthetic mixtures with air, oxygen, or nitrous oxide.
- Do not use the monitor near devices with microwave or other high frequency emissions that may interfere with the monitors operation. Excluded is the use in MRI-environment.
- Check parameter alarm limits before using the monitor
- The *Tesla^{M3}* is intended only as an adjunct in patient assessment. It must be used in conjunction with assessment of clinical signs and symptoms.
- The use of the *Tesla^{M3}* is restricted to one patient at a time.
- If an alarm condition (other than the exceptions listed herein) occurs while the audible alarm mute function is engaged, only the visual alarm indications are displayed.
- Do not silence an audible alarm, engage the audible alarm mute function, or decrease the audible alarm volume if patient safety could be compromised.
- Blocking the speaker may result in an inaudible alarm tone.
- Do not place the *Tesla^{M3}* in any position that might cause it, or any device connected to it, to fall on the patient or operator. Do not lift or carry the *Tesla^{M3}* by the power supply cable.
- Do only use MIPM accessories. Connect only items that have been specified in this manual as part of the *Tesla^{M3}* system or specified as being compatible with the *Tesla^{M3}* system.
- All parts of the Equipment are not serviced or maintained while in use with the patient.
- Do not touch simultaneously the monitor, monitor parts and a patient.
- Do not position the equipment to make it difficult to operate the disconnection device from supply mains via unplugging the appliance coupler or mains plug.
- In general for all parameters: The drop below the minimum amplitude or minimum value of patient physiological signal leads to inaccurate measurements. The measurement ranges derived from that are shown in Section 11, Technical Specification.



U.S. Federal and Canadian laws restrict this device to sale by or on the order of a licensed medical practitioner (Rx only)!



WARNING: In case of malfunction, do not continue the operation. Remove all applied parts from the patient and take the device out of operation.



NOTE: In case of a serious incident please contact MIPM or your local distributor, a service technician or a competent authority of the member state in which the user or the patient are established to report the incident.



Do not place the *Tesla^{M3}* on electrical equipment that may disturb the *Tesla^{M3}* from working properly.

- Do not expose the *Tesla^{M3}* to extreme moisture, such as direct exposure to rain. Extreme moisture can cause the *Tesla^{M3}* to fail or perform inaccurately.
- Do not place containers holding liquids on or near the *Tesla^{M3}*. Liquids spilled on the *Tesla^{M3}* may cause it to perform inaccurately.
- In the event the *Tesla^{M3}* is damaged and cannot be repaired, dispose of the *Tesla^{M3}* through an approved hazardous materials disposal facility in accordance with local regulations, or return it to MIPM or an authorized distributor. The internal battery contains Lithium, which is hazardous waste.

The *Tesla^{M3}* may be operated during defibrillation but the parameter values may be biased for a short period.

***Tesla^{M3}* Power sources**

The monitor can be operated with battery power or connected to line power inside the MRI room.



To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.



- Connect the *Tesla^{M3}* monitor only to a three-wire, grounded, hospital grade receptacle. The three-conductor plug must be inserted into a properly installed three-wire receptacle. If a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code.
- Do not under any circumstances remove the grounding conductor from the power plug.
- Do not use extension cords, adapters or multiple socket-outlets of any type. Otherwise the safety and function of the device can be disrupted. The power cord and plug must be intact and undamaged.
- If there is any doubt about the integrity of the protective earth conductor arrangement, operate the *Tesla^{M3}* on internal battery power until the AC power supply protective conductor is fully functional.

For questions please contact your local distributor or the manufacturer:

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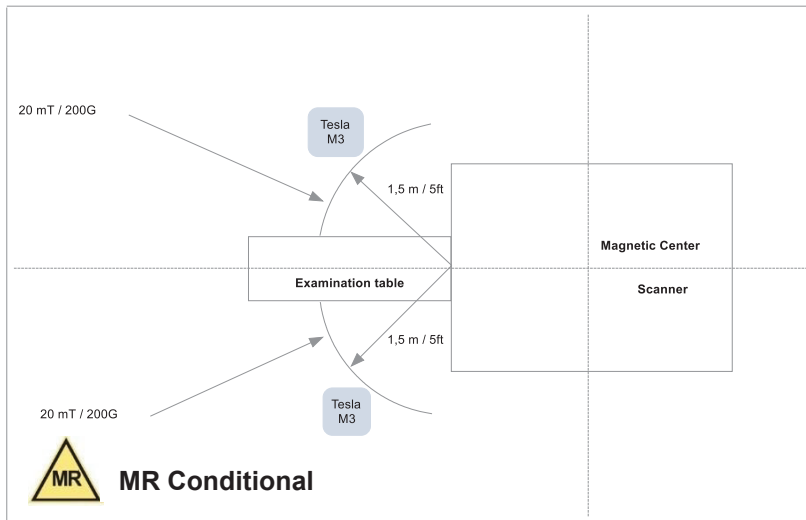
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1.4. Placement in the MRI Room



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.

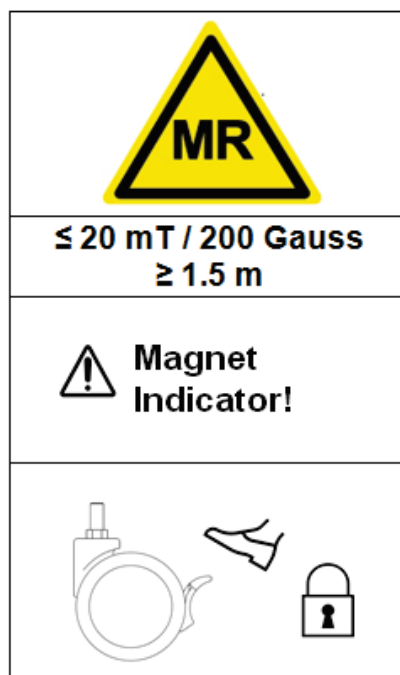


Observe the Signals of the Magnetic Field Indicator (see chapter 1.5 “Magnet Indicator”).



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

Symbol	Description
	MR conditional (The device does not cause any hazard in a specified MR Environment) Magnetic Field: maximum 20 mT / 200 Gauss Distance to MR Scanner: minimum 1.5m
	Caution! Observe the Magnet Indicator. Obligation for the user to consult the Instructions for use for important warnings and precautions
	Lock the brakes of the four castors



1.5. Magnetic Field Indicator



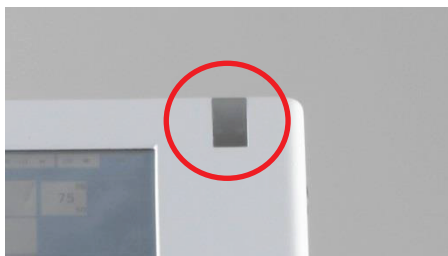
The Magnetic Field Indicator must be switched on during each application of the monitor. The activation status can be recognized by signals of the *Magnetic Field Indicator* (see Signaling of *Magnetic Field Indicator* at the bottom of the page). If you have to switch on the *Magnetic Field Indicator*, use the *Magnetic Field Indicator's* switch at the bottom of the display enclosure (picture below).



The *Magnetic Field Indicator* is an integrated self-sustaining system for continuously measuring the magnetic field density. The magnetic field detection also works if the *Tesla^{M3}* is turned off. Any violation of preset alarm limits will be recorded and can be sorted out by qualified personnel. The *Magnetic Field Indicator* is a tool to position the *Tesla^{M3}* inside the MRI room as close to the scanner as possible while ensuring safety for patients, personnel and the monitor itself. The *Magnetic Field Indicator* is battery powered and backed up by a separate power supply.

Magnetic Field Indicator is equipped with an alarm system for:

- Violation of the magnetic field strength limit
- System malfunction
- Critical battery level



The Signaling of the *Magnetic Field Indicator* takes place in the upper right corner of the display. The status is indicated with 3 colors.

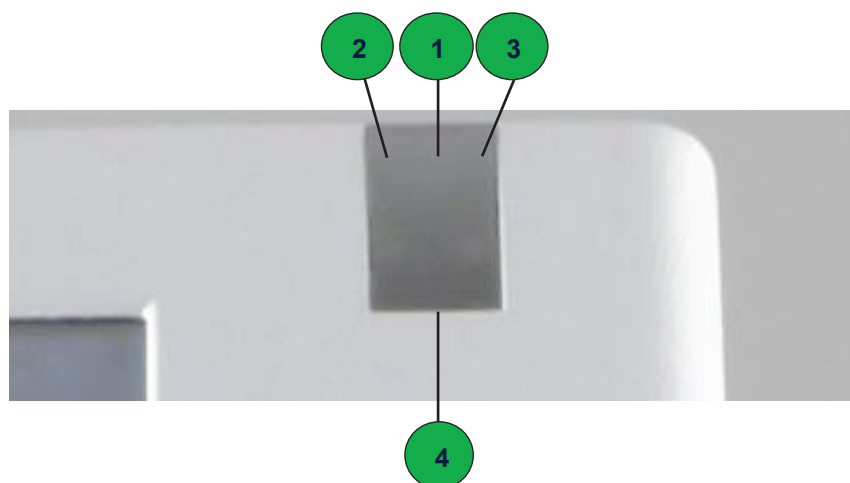
How to use *Magnetic Field Indicator*:

Slowly move the *Tesla^{M3}* towards the MRI scanner. As long as you are in the secure magnetic field area the LED flashes green. When reaching the limit for the operation of the *Tesla^{M3}* the LED flashes Yellow and an alarm sound appears.

Do not go any closer to the magnet from this point! Pull back the monitor until the LED of the *Magnetic Field Indicator* flashes green again.

If the critical limit for the operation of the *Tesla^{M3}* is exceeded a red LED is flashing and a continuous alarm sound appears. Remove the *Tesla^{M3}* from that position immediately and make sure to place the monitor in a safe position (Before using the monitor again a functional test should be conducted). Once you have placed the monitor use the breaks to fix the unit.

MIPM recommends marking the position for the *Tesla^{M3}* with a line, or a square on the floor.



Signal Nr.	Color <i>Magnetic Field Indicator</i>	Positioning	Priority	Display	Instruction
1	Green	Normal operation; Magnetic field < 20 mT	Low	LED flashes each 2 seconds.	The monitor is located outside the critical magnetic field area. (20 mT / 200G) Safe operation is ensured.
2	Yellow	Caution! Magnetic field 20 – 40 mT	Medium	Yellow LED flashes each 1.5 second and speaker sounds an audible signal.	You have reached the limit of the critical magnetic field strength. Remove the <i>Tesla^{M3}</i> from the MRI scanner until the green LED flashes again.
3	Red	Warning! Magnetic field > 40 mT	High	LED flashes each 500 ms and speaker sounds an audible signal. (Event is stored in the internal memory)	The <i>Tesla^{M3}</i> is located inside the critical magnetic field strength. Safe and reliable operation of the monitor cannot be guaranteed. Remove the monitor from the MRI scanner. The red alarm has been saved in the memory of the <i>Magnetic Field Indicator</i> . Please contact technical service or MIPM. Before using the monitor again a functional test should be conducted.
4	Red	System Error (e.g. Watchdog failure / Measurement failure / Power supply error)	High	LED flashes each 500 ms and speaker sound an audible signal.	Function has to be checked by technical service.

1.6. Reducing EMI

To reduce possible problems caused by electromagnetic interference, we recommend the following:



Warning! Use of accessories and cables other than those recommended by MIPM, could result in increased electromagnetic emissions and / or decreased electromagnetic immunity of the *Tesla^{M3}* system and result in improper operation.

- Use only MIPM-approved accessories (See chapter 8 “Accessories and applied parts”).
 - Ensure that other products used in areas where patient monitoring and/or life-support are used comply with legal emissions standards. If the products are used inside the MRI room, make sure that the products are labeled MRI conditional or MRI safe.
 - Try to maximize the distance between *Tesla^{M3}* and other WiFi electro medical devices.
 - Strictly limit exposure and access to portable radio-frequency sources (e.g., cellular phones and radio transmitters). Be aware that portable phones may periodically transmit even when in standby mode.
 - Maintain good cable management. Do not route cables over electrical equipment. Do not intertwine cables.
 - Ensure all electrical maintenance is performed by qualified personnel.
 - The medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.
- RF communications equipment can affect the *Tesla^{M3}*.



The data is transmitted via WLAN between master and remote monitor. Channel 2 (2417 MHz; 100 mW) is set.

The data is transmitted via MiWi between master monitor and both sensors (wireless ECG Sensor and wireless Pulse Oximetry Sensor). There are sixteen channel frequencies in the 2.4 GHz band:

Channel Number	Frequency
11	2.405 GHz
12	2.410 GHz
13	2.415 GHz
14	2.420 GHz
15	2.425 GHz
16	2.430 GHz
17	2.435 GHz
18	2.440 GHz
19	2.445 GHz
20	2.450 GHz
21	2.455 GHz
22	2.460 GHz
23	2.465 GHz
24	2.470 GHz
25	2.475 GHz
26	2.480 GHz

The transmitter is a direct conversion architecture with a 2.9 dBm maximum output (typical) and 36 dB power control range.

1.7. Electrical Safety

1.7.1. Electrostatic discharge (ESD) information

Warning:



- Electronic components and semiconductors can be destroyed by electrostatic discharge (ESD). In particular, MOS components can be damaged from direct or indirect discharges. Damage caused by ESD is sometimes not immediately identifiable and malfunctions can even occur after a longer period of operation.
- Exceeding and / or repeating the test level attained in guidance & manufacturer's declaration on EMC may permanently damage the device and / or cause serious malfunctions as loss of communication and system reboot.

Caution:



- Connector panel symbol
- All panel connector and communication ports are sensitive to electrostatic discharges; it is necessary to take precautions before touching connectors (pins or shield), connecting or disconnecting the associated cables.
- Touching communication ports without taking ESD precautions may result in potential fatal error and ESD protection failure.
- Points (e.g. screws) and surfaces that are only accessible for maintenance also require precautions.
- Points (e.g. battery contacts for battery replacement) and surfaces that are accessible only by intervention service users also require precautions.

1.7.2. Electromagnetic compatibility and interference GUIDANCE

Electromagnetic Compatibility

The MRI (MRI conditional) Patient Monitor *Tesla^{M3}* is evaluated to the applicable general, collateral and particular requirements (standards) for safety and essential performance of Medical Electrical Equipment (IEC 60601-x).

Medical Equipment Performance Criteria - unacceptable operating conditions / responses are:

- Component failures;
- Changes in programmable parameters;
- Reset to factory defaults (manufacturer's presets);
- Change of operating mode (adult, children, neonatal, last settings);
- False alarms;
- Cessation or interruption of any intended operation, even if accompanied by an alarm;
- Initiation of any unintended operation, even if accompanied by an alarm;
- Error of a displayed numerical value sufficiently large to affect diagnosis or treatment;

The *Tesla^{M3}* is designed for professional healthcare facility environment according to Figure 3 of IEC 60601-1-2:2014. For some test cases were selected the higher test levels of home healthcare environment.

Tesla^{M3} is classified as a Class B device according to CISPR 11 emitted radiation and should not be used outside the hospital environment. If used outside the hospital environment, this equipment might not offer adequate protection to radio-frequency communication services. The user might be required to take mitigation measures, such as relocating or re-orienting the equipment.

If *Tesla^{M3}* is placed near devices such as HF surgical equipment, X-ray equipment, cell phones, DECT phones or wireless access points, portable RFID reader, large scale RFID reader and RFID Tags, it is

essential to observe a minimum distance between the *Tesla^{M3}* and this equipment (refer to chapter – Recommended separation distances between portable and mobile RF communication equipment and *Tesla^{M3}*).

If *Tesla^{M3}* causes harmful interference or if it is itself disrupted, the user is encouraged to try to correct the interference by one of the following actions:



- Reorient or relocate the *Tesla^{M3}* or patient or disruptive equipment.
- Change the routing of cables.
- Separate power cables from the communication cables / signals.
- Connect *Tesla^{M3}* mains plug on protected / backed-up / filtered supply or directly on UPS circuit (uninterruptible power supply).
- Be careful with ground / earth loops formed by communication cables and / or power circuits: use class II powered systems or insulated bridges to break loops.
- Maintain earth potential at the same level between *Tesla^{M3}* circuit and the circuit of the remote equipment.
- Increase the separation between the *Tesla^{M3}* and patient or disruptive equipment.
- Connect the *Tesla^{M3}* into an outlet on a circuit different from that to which the patient or disruptive equipment is connected.
- In any case, whatever the context, the user should conduct interoperability testing in a real situation to find the right setup and good location.
- The *Tesla^{M3}* shall not be used adjacent to or stacked directly with other devices. If an operation of the *Tesla^{M3}* stacked directly with or used adjacent to other devices is required, the *Tesla^{M3}* should be observed to verify its proper operation used in this arrangement.
- The *Tesla^{M3}* may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

1.7.3.Guidance and manufacturer's declaration - Electromagnetic Emissions

Table 1



The *Tesla^{M3}* system is intended to be used in the electromagnetic environment specified below.

The customer or the user of the *Tesla^{M3}* system should ensure that it is used in such an environment.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
<i>Tesla^{M3}</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Tesla^{M3}</i> should assure that it is used in such an environment.		
Emission measurements	Agreement	Electromagnetic Environment - Guidelines
RF emissions according CISPR 11	Group 1	<i>Tesla^{M3}</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely to cause any interference in nearby electronic equipment. The <i>Tesla^{M3}</i> is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
RF emissions according CISPR 11	Class B	
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations Flicker emissions IEC61000-3-3	complies	


1.7.4.Guidance and manufacturer's declaration - Electromagnetic Immunity Table 2

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
<i>Tesla^{M3}</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Tesla^{M3}</i> should assure that it is used in such an environment.			
Immunity	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment Guidelines IEC 60601-1-2:2007 / IEC 60601-1-2:2014
Electrostatic discharge (ESD) according IEC 61000-4-2	+/-8 kV contact discharge +/-15 kV air discharge	+/-8 kV contact discharge +/-15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients (Burst) according IEC 61000-4-4	+/-2 kV for power lines +/-1 kV for input- and output lines	+/-2 kV for power lines +/-1 kV for input- and output lines	The quality of supply voltage should be that of a typical store or hospital environment.
Surge on AC power port according IEC 61000-4-5	+/-1 kV line to line +/-2 kV line to earth	+/-1 kV line to line +/-2 kV line to earth	The quality of supply voltage should be that of a typical store or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according IEC 61000-4-11	<5% U_T (>95% reduction of U_T) for 0.5 periods 40% U_T (60% reduction of U_T) for 5 periods 70% U_T (30% reduction of U_T) for 25 periods <5% U_T (>95% reduction of U_T) for 5s	<5% U_T (>95% reduction of U_T) for 0.5 periods 40% U_T (60% reduction of U_T) for 5 periods 70% U_T (30% reduction of U_T) for 25 periods <5% U_T (>95% reduction of U_T) for 5s	In accordance to IEC 60601-1-2:2007 The quality of supply voltage should be that of a typical store or hospital environment. If the user of the <i>Tesla^{M3}</i> requires continued operation also at disruptions in energy supply, it is recommended to power the <i>Tesla^{M3}</i> from an uninterruptible power supply or a battery.
Voltage dips according IEC 61000-4-11	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 (50/60Hz) cycles Single phase: at 0°	0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T ; 1 cycle and 70 % U_T ; 25/30 (50/60Hz) cycles Single phase: at 0°	In accordance to IEC 60601-1-2:2014
Voltage interruptions according IEC 61000-4-11	0 % U_T ; 250/300 cycle	0 % U_T ; 250/300 cycle	In accordance to IEC 60601-1-2:2014
Magnetic fields 50 Hz and 60 Hz according IEC 61000-4-8	30 A/m	30 A/m	
NOTE: U_T is AC mains voltage prior to application of the test level			

1.7.5.Guidance and manufacturer's declaration - Electromagnetic Immunity Table 3

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity			
<i>Tesla^{M3}</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Tesla^{M3}</i> should assure that it is used in such an environment.			
Immunity	IEC 60601-1-2 Test level	Compliance level	Electromagnetic Environment Guidelines
Conducted HF-Interferences according IEC 61000-4-6	3V / 6V 150 kHz to 80 MHz	3V (6V in ISM bands)	<p>In accordance to IEC 60601-1-2:2007:</p> <p>Portable and mobile RF communications equipment including cables should not be used closer to the <i>Tesla^{M3}</i>, than the recommended separation distance calculated from the equation appropriate for the transmission frequency.</p> <p>Recommended separation distance</p> <p>$d=1.2\sqrt{P}$</p> <p>$d=1.2\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>Where <i>P</i> is the power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters is less than the compliance level^b in each frequency according to a study site^a.</p> <p>In vicinity of equipment that have the following symbols, interferences are possible.</p> <div></div>
Radiated HF-Interferences according IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies			
NOTE 2: These guidelines may not occur in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflex reactions of buildings, objects and people.			
^a Field strengths from fixed transmitters, for example Base units of cordless telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To determine the electromagnetic surroundings due to fixed RF transmitters, an electromagnetic site survey is recommended. If the measured field strength in the location of the <i>Tesla^{M3}</i> exceeds the compliance level above, the <i>Tesla^{M3}</i> must be observed to verify normal operation at each application. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or relocating the <i>Tesla^{M3}</i> .			
^b Over the frequency range from 150 kHz to 80 MHz, the field strengths is less than 3 V/m.			

1.7.6. Recommended separation distances between portable and mobile RF communication equipment and *Tesla^{M3}*, Table 4



Warning:

- The *Tesla^{M3}* is intended to be used in an electromagnetic environment in which radiated RF disturbances are controlled.
- *Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Tesla^{M3}, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.*
- The device should not be used next to other equipment. If adjacent use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment in accordance to IEC 60601-1-2:2014:

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5 500						
5 785						

Table 4 in accordance to IEC 60601-1-2:2007:

Recommended separation distances between portable and mobile RF communications equipment and the <i>Tesla</i> ^{M3}			
The <i>Tesla</i> ^{M3} is intended for use in an electromagnetic environment where radiated RF interference are controlled. The customer or the user of the <i>Tesla</i> ^{M3} can help to prevent electromagnetic interferences by keeping minimum distances between portable and mobile RF communications equipment (transmitters) and the <i>Tesla</i> ^{M3} as recommended below, according to the maximum output power of the communications equipment.			
Power of transmitter W	Separation distance according to frequency transmitter*		
	m		
	150 kHz to 80 MHz d=1.2√P	80 MHz to 800 MHz d=1.2√P	800 MHz to 2.5 GHz d=2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
*in accordance to IEC 60601-1-2:2007			
For transmitters whose performance is not specified in the above table, the distance can be determined using the equation of the corresponding column, where P is the power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: To calculate the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.5 GHz an additional factor of 10/3 was used to reduce the likelihood that a mobile / portable communication device unintentionally introduced into the patient's field leads to a interference.			
NOTE 2: These guidelines may not occur in all situations. The propagation of electromagnetic waves is influenced by absorptions and reflex reactions of buildings, objects and people.			

1.7.7. Electrical Safety



Caution: The *Tesla*^{M3} including all connected devices may only be used in a clinical environment fulfilling all regulatory requirements for electric installations.

The equipotentiality connection makes the connected equipment potential equal (ref. IEC60601-1).



Symbol for equipotentiality connection:



Warning! The *Tesla*^{M3} is not approved for use inside rooms under explosion risk. If the unit is operated near inflammable anesthetic agents there is a risk of explosion.

If the *Tesla*^{M3} is disconnected from main power the light of the charging indicator in the On/Off switch disappears. The monitor automatically switches to battery power.

1.8. Connecting external devices

The *Tesla^{M3}* is equipped with interfaces to connect the following peripheral devices.

Interface	Type	Comment
USB Printer	printer must support PCL5	MIPM recommends to use the suggested printer.
USB pen drive	Transcend 4GB	MIPM recommends to use the suggested USB pen drive.
Ethernet Hospital Network PDMS	On request Individual adaption	Only available with remote screen. Network adaptation has to be performed by Network service provider.
RS232 Hospital network PDMS	On request Individual adaptation	Only available with remote screen. Network adaptation has to be performed by Network service provider.
RS232 optical data interface	On request Individual adaptation	Optical connection for Anesthesia View.

Settings for peripheral devices can be changed in the Service Menu.



Do only use devices approved by MIPM. MIPM cannot guarantee complete functionality if other devices are utilized.



Only certified devices according IEC 60950 can be connected.



Changing network and connectivity settings is reserved to personnel authorized by MIPM.



**The USB interface is intended to be used after the patient monitoring for e.g. transferring the trend data to external devices or printing them.
Do not use the USB or connect any devices to USB interface of *Tesla^{M3}* during the patient monitoring or in MRI room.**

For more details ask your local distributor or MIPM.

1.9. Safety, Inspections, Maintenance



WARNING: Because of the danger of electric shock, never remove the cover of any device while in operation or connected to a power outlet.

In the interest of patient safety, regular equipment inspection and maintenance is required. Once a year (every 12 month), check all cables, device, and accessories for damage, ground resistance, chassis and patient leakage currents, and all alarm functions. Also, ensure that all safety labels are legible. Maintain a record of these safety checks. For additional information, refer to the Service Manual.

The NIBP measurement system has to be calibrated every 2 years (24 month).

A function test must be performed before each application of this device. Do not utilize this device if known damage exists. Missing, broken, worn or soiled parts must be replaced before application. In the event that repair or part replacement is necessary, please contact your local distributor, or MIPM.

This device, its components, and optional accessories may only be repaired or changed by authorized and qualified service personnel. The user of this device is solely responsible for any failure of the device to perform properly due to unauthorized and incorrect maintenance, incomplete repair, or damage and changes made by unauthorized personnel.

Leakage current will increase when connecting multiple medical devices to a patient. Ensure the electrical shock classification for each device is suitable for the intended application. MIPM recommends that safety and functional checks be performed on the monitor *at least* once each year. The non-invasive blood pressure circuits of the monitor should be calibrated at least every two years. These checks should be performed by authorized personnel.

When main or battery power is not available, the monitor stores patient data and settings in an internal battery backed-up SRAM.

The life span of the integrated battery depends on the number of charging cycles. After approximately 2 years you should expect a loss in battery capacity. This is typical for batteries and is considered as regular wear out. In order to ensure maximum battery capacity MIPM recommends replacing the batteries in the device and its sensors (ECG and SpO₂) after 3 years of use.



CAUTION: To preserve the life of the internal battery, always leave the monitor connected to main power when not in use. If the monitor is stored unconnected from line power, the capacity of the internal battery will be drained in approximately three years.

1.10. Safety during HF surgery and defibrillation

The monitor is protected against discharges from defibrillators, as well as against 50- and 60-Hertz power line interference.



The ECG recovery time after defibrillation is 1.5 seconds.
Only patient-related accessories including, electrodes as specified by the manufacturer shall be used to guarantee defibrillator protection.



WARNING: The monitor is not protected against high-frequency interference from diathermy equipment.



The *Tesla^{M3}* is not compliant with HF surgical equipment.

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

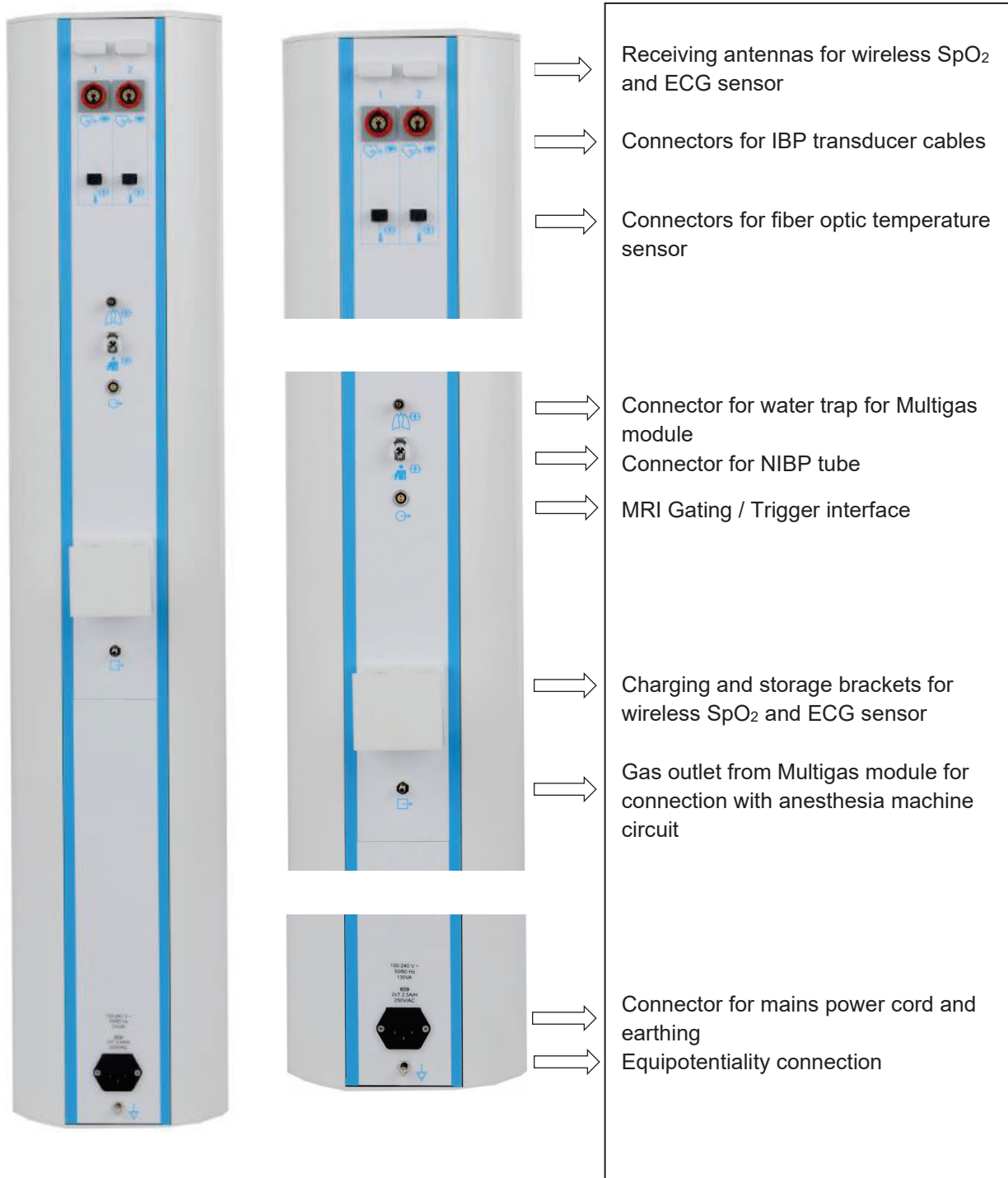
Tesla^{M3} is equipped with a 15" color touch display. The optional wireless remote monitor offers complete functionality in the MRI control room.

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.

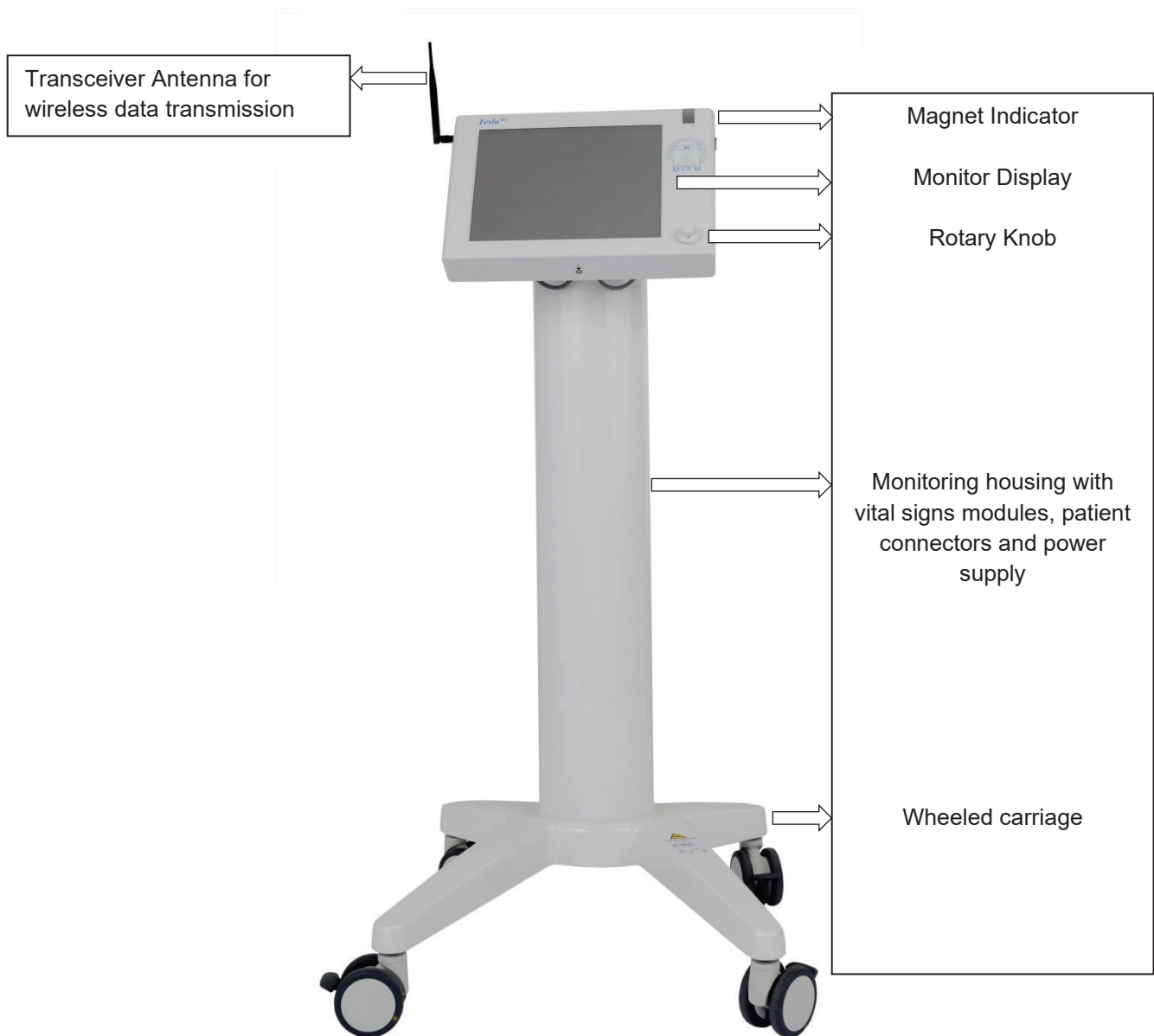
1.12. Front and Back of the device

1.12.1. Back of the device










1.12.2. Front of the device








1.13. Symbol Description

1.13.1. Symbols in Graphical User Interface (GUI)






Status bar

Symbol	Definition
Remote 	Connection status Remote Monitor
Master 	Connection status Master Monitor
ECG 	Connection and Battery status ECG sensor
SpO2 	Connection and Battery status SpO2 sensor
CIU 	Battery level main unit
DEMO MODE	Description field for text messages




















Menu bar

Symbol	Definition
	Patient mode
	Main screen
	Option Menu
	Patient data menu
	Trend menu



Patient Mode

Symbol	Definition
	Adult mode
	Pediatric mode
	Neonatal mode
	Individual configuration
	Turn off <i>Tesla^{M3}</i>







Main screen

Symbol	Definition
	Duration NIBP interval
	Start/Stop manual NIBP measurement
	Alarm Silence within 120 seconds
	Alarm Reset
	Adjust alarm function
	Auto Alarm
	Switching between large and small figures for parameter values
	Standby
	Volume
	Alarm function of the monitor is deactivated
	Single parameter alarm deactivated
	+ / - Icon
	ECG sensor connection alarm
	SpO ₂ sensor connection alarm
	ECG Lead Off alarm
	SpO ₂ finger not in sensor alarm
	“Back” / „Next“ Icon – to browse between menus
	Enter
	Status of alarm silence (within 120 sec.)

Option Menu












Symbol	Definition
<input type="radio"/> Format: 12 h <input checked="" type="radio"/> Format: 24 h	Select time format 12/24h
	Save changes
	„Ping“ Icon for connectivity check

Trend Menu






















Symbol	Definition
	Graphical trend memory
	Tabular trend memory
	Event memory
	Delete trend memory
	Send data to printer
	Send data to USB storage device








1.13.2. Symbols on the Device

Rear Panel

Symbol	Definition
	Protection against leakage current; Defibrillation-proof type CF applied part
	Protection against leakage current; Defibrillation-proof type BF applied part
	Invasive blood pressure (IBP1 and IBP2) Protection against leakage current; Defibrillation-proof type CF applied part
	Body Temperature (Temp. 1 and Temp. 2) Protection against leakage current; Defibrillation-proof type BF
	Respiration Protection against leakage current; Defibrillation-proof type BF
	Non-invasive blood pressure (NIBP) Protection against leakage current; Defibrillation-proof type BF
	MRI Gating / Trigger interface
	Gas outlet
	Equipotentiality connection
	Electrical fuses
	Alternating Current (AC)






Device and Device Packaging

Symbol	Definition
	Obligation for the user to refer to the Instructions for Use (Instruction Manual / User Manual / Booklet)
	Caution! Obligation for the user to consult the Instructions for use for important warnings and precautions
	MR conditional: (The device does not cause any hazard in a specified MR Environment)
	Lock the brakes of the four castors
	MR unsafe: (The device causes hazards in the MR Environment)
	Product reference / part number
	Product serial number
IPX1	Index of protection against vertically falling liquid drops
	Part included in a recovery / recycling process
	CE Marking
	Date of manufacture
	Manufacturer
	Medical Device
FCC – ID	Identification Number of RF-Module for USA
IC	Certification Number of RF-Module for Canada
	NCC logo with Certification Number for Taiwan
M	Mass including its safe working load in kg
	Battery status: Battery condition indicator (LED) by operation Battery charger indicator (LED) by charging
	Status of the RF-Signal from wireless Sensor to MRI Patient Monitor. (Red LED turns on in case of an Error/No wireless connection)
	Alternating Current (AC)
Rx only	Caution: Federal Law in the United States restricts the device to sale by, or on the order of a physician.
	RF equipment with non-ionizing radiation
	“ON”/“OFF” (push-push)
	Unique Device Identifier- Indicates a carrier that contains Unique Device Identifier information
	GS-1 DataMatrix Barcode
	SGS Safety Certification for US and Canada (NRTL)

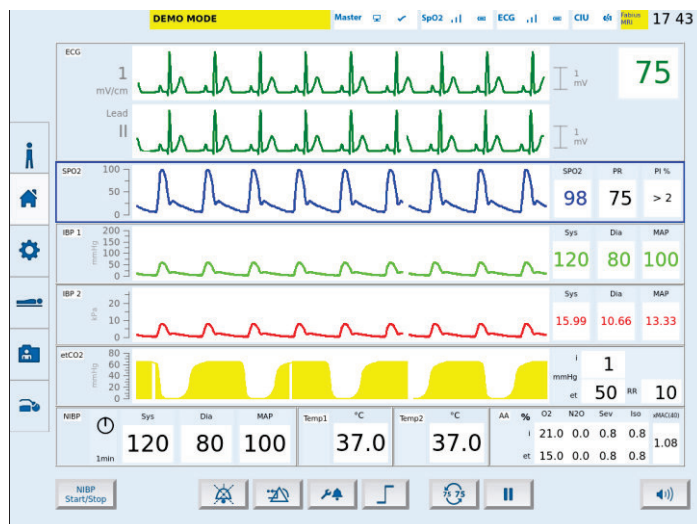
Symbol	Definition
	Keep dry
	Fragile, handle with care
	This way up (to indicate the correct upright position)
	Atmospheric pressure limitation
	Temperature limit
	Humidity limitation
	Quantity

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



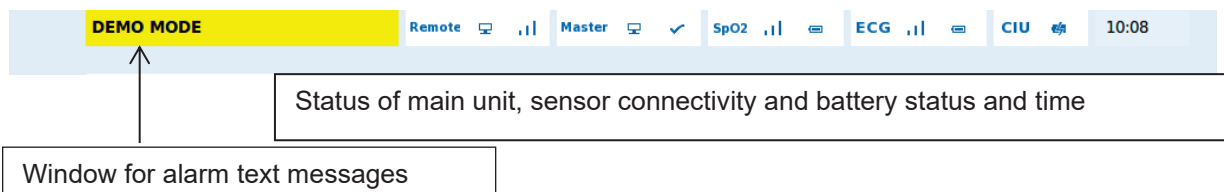
All vital signs are displayed in the main screen.

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



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.

1.17. Documentation *Tesla^{M3}*

Documentation Set

The *Tesla^{M3}* documentation set consists of documents for the clinician, the biomedical technician and the department head or purchaser of the *Tesla^{M3}* monitor, and accessories.

This *Tesla^{M3}* instruction manual contains important safety and operating information for the clinician.

Statement of Expectations to the Reader

This instruction manual was written for the clinician. Although this manual may describe some monitoring techniques, *MIPM Mammendorfer Institut für Physik und Medizin* expects you to be a trained clinician who knows how to take and interpret a patient's vital signs during Magnetic Resonance Imaging. The *Tesla^{M3}* has been designed as a quality monitor; however, inherent limitations require that good clinical judgment always prevail.

Disclaimers

MIPM Mammendorfer Institut für Physik und Medizin cautions the reader of this manual:

- This manual and product specifications may, wholly or partially, be subject to change without notice. Some features described in this manual may not be available on your model.
- All rights are reserved: No one is permitted to reproduce or duplicate, in any form, the whole or part of this manual without *MIPM Mammendorfer Institut für Physik und Medizin*'s permission.
- *MIPM Mammendorfer Institut für Physik und Medizin* assumes no responsibility for any damage that may occur due to accidents while using this system.

2. Preparations for use

2.1. General remarks







Warning: Before monitoring pediatrics or neonates, please keep in mind:

- Choose the correct size of finger adapter for SpO₂ monitoring
- Choose the correct size of NIBP cuff for the patients size
- Change the patient mode to pediatric or neonatal



Caution: Do only use accessories delivered and approved by MIPM. Accessories that are not approved by MIPM may lead to incorrect monitoring values or malfunctioning of the monitor.

2.2. Initial Inspection



1. Unpack and inspect the monitor *Tesla^{M3}* and the wireless pulse oximetry sensor for external damage. Verify that all connectors and fasteners are securely in place.
2. Inspect the wireless pulse oximetry sensor for breaking points or visible damages. Remove the transport plugs from the wireless sensors.
3. Connect the *Tesla^{M3}* to main power. Insert the wireless sensors in the charging set and see if the battery is charged. The battery LED on sensor is flashing. (To see how the sensor is placed in the charging set (see chapter 5.3 “Handling of the Wireless sensors”)
4. Check the silicon finger adapters for visible damage
5. Switch on the *Tesla^{M3}* using the main switch at the right side of the display.
6. Select a patient mode by pressing on one of the icons on the patient mode screen. The main screen is displayed. (If the sensors are in the charging bracket you will see the sensor connection alarm).
7. If the *Tesla^{M3}* is connected to main power you will see the “Battery is charged” symbol in the status bar. ()
8. Unplug the *Tesla^{M3}* and check if the “Battery” symbol appears. ()
9. Remove the SpO₂ sensor from the charging bracket. The sensor automatically turns on and performs a self-test. If a technical problem in the sensor is detected the red malfunction LED flashes. If the self-test is passed the sensor will automatically connect to the main unit and the sensor connection alarm disappears. The sensor status symbol is displayed in the status bar. ()
10. Remove the ECG sensor from the charging bracket. The sensor automatically turns on and performs a self-test. If a technical problem in the sensor is detected the red malfunction LED flashes. If the self-test is passed the sensor will automatically connect to the main unit and the sensor connection alarm disappears. The sensor status symbol is displayed in the status bar. ()

2.3. Default settings



The software language of the *Tesla*^{M3} will be English at delivery. If you want to select another language please see the Language section below.

System Time and Date




Before using the *Tesla*^{M3} please check if the system time and date are correct. To change the time and date follow the steps below:

1. Switch on the *Tesla*^{M3}.
2. Select the Options menu on the menu bar ()
3. Press the Date / Time icon.
4. Set date and time (hour: minute; day: month: year) (See chapter 3 “Monitor configuration” for further instructions)
5. Press the Back icon () to leave the date / time menu.

Language settings:

1. Switch on the *Tesla*^{M3}.
2. Select the Options menu on the menu bar ()
3. Select the Service menu (password protected!)
4. Press the language icon.
5. Select the desired language
6. Press the Back icon () to leave the language menu.

Audio Setup

1. Switch on the *Tesla*^{M3}
2. Select the main screen in the menu bar. ()
3. Press the Volume Icon in the lower right corner of the display (
Select the volume for alarm and pulse tone sound by pressing the desired volume level bar.
(See chapter 3 “Monitor configuration” for further instructions)
4. Press the Back icon () to leave the volume menu.

2.4. Assembly and positioning of the *Tesla*^{M3}

The *Tesla*^{M3} will be delivered ready for use. The monitor will be mounted on a mobile carrier.

Connect all sensors and tubes to the *Tesla*^{M3} (See chapter 3.7 “Connecting patient sensors to the *Tesla*^{M3}” for further instructions)

You can place the *Tesla*^{M3} inside the MRI cabin. Please follow the instruction in section 1 – Placement in the MRI room.

3. Monitor configuration

3.1. Initial setup



Caution: Before using the *Tesla^{M3}* on patients make sure that the battery is charged.

Read the general safety remarks in Section 1 of this user manual.

3.2. Battery power and Main power

3.2.1. Main unit

Mains supply operation

The *Tesla^{M3}* can be connected to the mains supply of the hospital. Whenever the monitor is connected to main power the batteries are charged. In the event of a power blackout the monitor automatically switches to battery supply. Monitoring values and settings are maintained.

1. Connect the power cable with the power socket on the back side of the monitor.
2. Connect the power cable to the wall socket of the hospital power supply. The LED inside the main switch is illuminated in blue.
3. If the monitor is turned on you will see the “Battery is charged” symbol in the status bar.

The power supply of the monitor is integrated to the shielding. A separate power supply device is not necessary.



Warning: If the wall socket or the grounding appears to be defective do not use the monitor on mains power.

Battery power operation

The *Tesla^{M3}* is powered by a battery if the monitor is not connected to the mains power. In the event the main power symbol disappears and main power LED switches off. The integrated Lithium polymer battery last for approximately 6.5 hours – 390 minutes.



Caution: Batteries may only be changed, or replaced by MIPM or authorized service personnel.

3.2.2.Charging the battery

The battery is automatically charged whenever the *Tesla^{M3}* is connected to the mains power supply. If the battery is depleted charge at least for 3 hours to charge the battery completely.

To avoid the discharging the batteries connect the *Tesla^{M3}* to the mains and place the ECG- and SpO₂ Sensors in the charging brackets during storing after use.

3.2.3.Wireless sensors

Tesla^{M3} is equipped with a wireless ECG and SpO₂ sensor. Both sensors may only be operated on battery power. The batteries are charged whenever the sensor is placed in the corresponding charging bracket. (See chapter 5.3 “Handling the wireless sensors” for further details).

To avoid the discharging the batteries connect the *Tesla^{M3}* to the mains and place the ECG- and SpO₂ Sensors in the charging brackets during storing after use.

3.2.4.Remote Screen

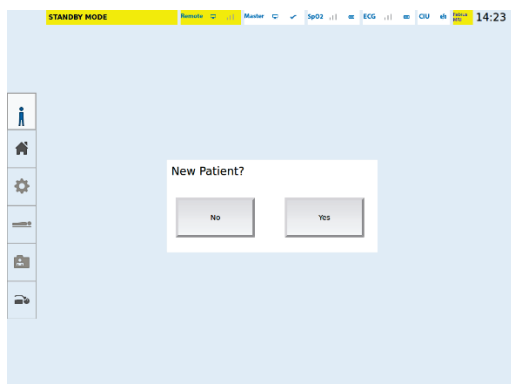
The remote screen is not equipped with a battery and has to be used on mains power.

3.3. Switching on the monitor



Switch on the *Tesla^{M3}* using the main switch at the upper right side of the display.

The *Tesla^{M3}* boot screen appears and a self-test is performed.



After a successful test the “New Patient” inquiry appears.

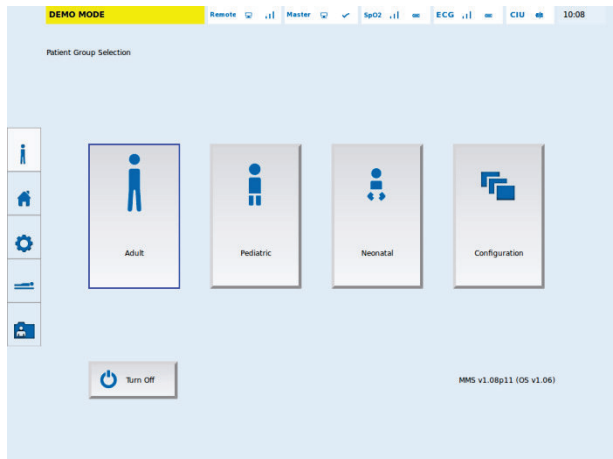
If you admit a new patient the trend memory will be erased.

If you select “No” the trend memory is maintained.

3.4. Selecting the patient mode

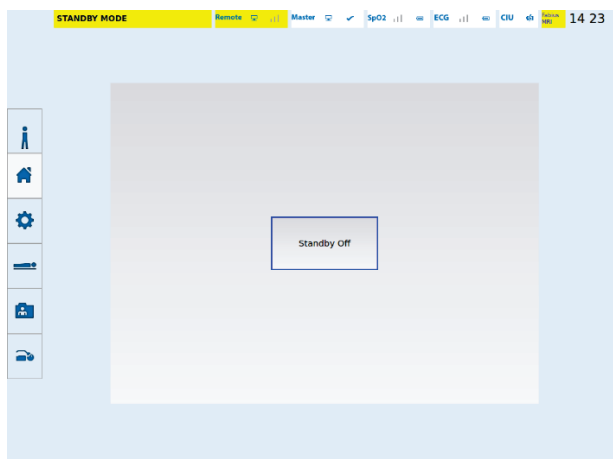
With the *Tesla^{M3}* you can monitor adult, pediatric and neonatal patients. The monitor offers 3 different patient modes which can be selected in the patient mode screen.

Press the corresponding icon to activate a patient mode. The monitor automatically switches to main screen with the specific setting of the selected patient mode.



If a patient mode has been selected it will be displayed on the tab in the menu bar.

The settings of the respective patient modes are preset according to established regulations and guidelines.



Touch the “Standby Off” button for starting from the standby mode.

3.4.1. Free patient mode

You can configure an individual patient mode with customized (alarm) settings. See chapter 4.1 “Patient Mode” for further details.

3.5. Main screen configuration

The layout of the main screen depends on the configuration of your monitor.

Every integrated vital parameter can be displayed on the main screen at the same time in wave form and/or numerical values.

3.5.1.Available parameters

Item (Name)	REF number	Parameter (Description)
MRI patient monitor <i>Tesla^{M3}</i>	1800001	Basic configuration <ul style="list-style-type: none"> • ECG • Pulse oximetry • Non-invasive blood pressure
Option <i>Tesla^{M3}</i> 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 <i>Tesla^{M3}</i> Variant: Multigas	5400038	Anesthetic Agents (Auto Detection), optional (i/et CO ₂ , O ₂ , N ₂ O, ISO, DES, HAL, ENF, SEV)
Option Gas module <i>Tesla^{M3}</i> Variant: Capnography	5400038	i/et CO ₂ , RR
Option Temperature 1	5800001	Body temperature, optional
Option Temperature 2	5800002	Body temperature, optional
Option Gating <i>Tesla^{M3}</i>	5450014	Gating / Trigger interface, optional
Option Anesthesia View	5000002	Optical interface for Anesthesia View

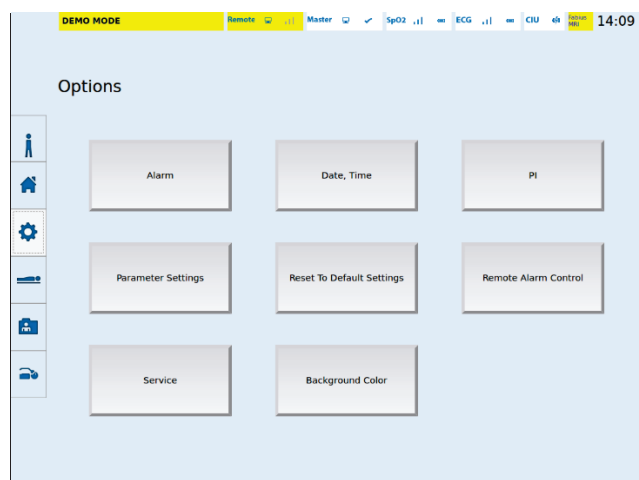
* Mandatory for Hospital network connection

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.

3.5.3.Language

The *Tesla^{M3}* is programmed with a selection of languages. Upon delivery the monitor is set to English language. If you want to change the selected language follow the steps below.



Open the Options menu by pressing the

Options tab  on the menu bar.


Select Service icon (password protected!).

Select the Language icon or

next page icon  to see more languages.

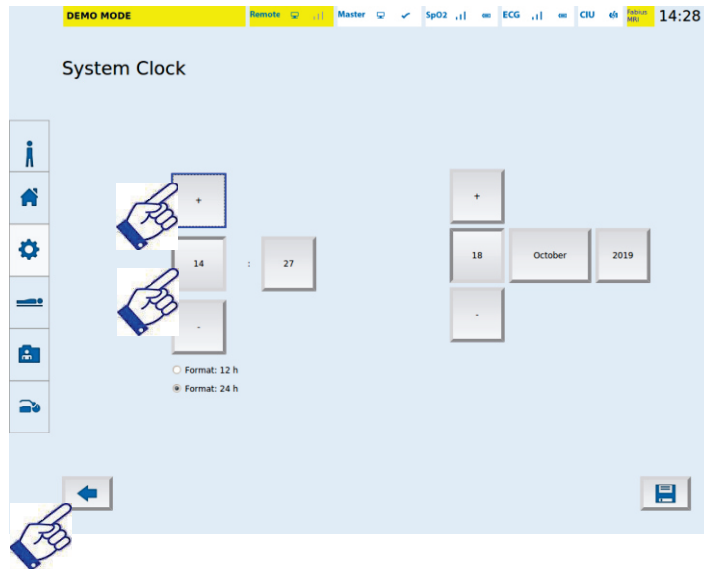
Select the desired language by pressing the respective icon


The system language is changed and applied immediately.


To leave the language menu press the Back icon 

3.5.4.Date and Time

In the Date and Time menu you can change the time format (12/24), time and date. Upon delivery the *Tesla^{M3}* will be set to CET. In order to change that, follow the steps below



To leave the Date / time menu press the back icon 

Open the date and time menu by pressing the Options tab  on the menu bar.

Press the Date / Time icon.

You can change hour : minutes , day, month and year individually.

Press the respective icon.

Pressing the +/- icon once changes the value by 1. Keeping the icon pressed changes the values faster.

The time format (12/24) can be changed by pressing the desired Format in the respective column.

Save the changes by pressing the

Save Icon 

3.5.5. Alarm function

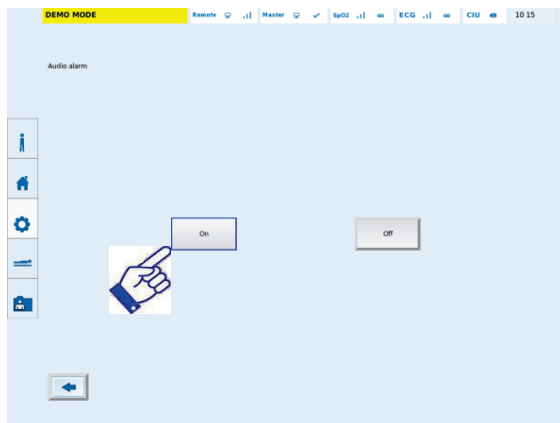
It is possible to deactivate the alarm function of the monitor. However some alarms may still be displayed in the status bar or main screen.



MIPM strongly recommends to leave the alarm function enabled! Alarms indicate critical conditions of the patient and the system. Thus alarms help to increase the awareness of the medical personnel and by that increase patients safety. Do not suppress an alarm or disable the alarm function if the safety of the patient is compromised!



The only exception is the Bradycardia alarm in the adult mode. It is possible to silence the visual and audio output of this alarm as it does not harm the patient safety. This will only stay active until the *Tesla^{M3}* is shut down or the patient is released.



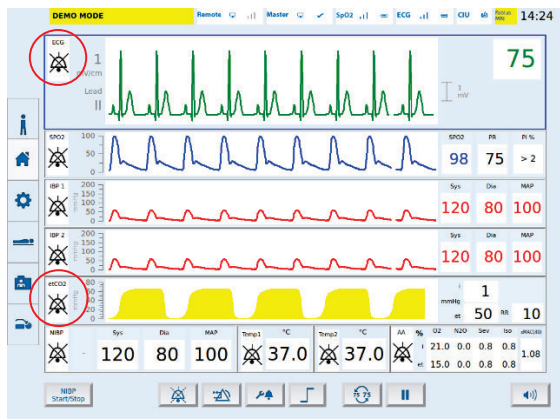
Open the Options menu by pressing the

Options tab  on the menu bar.


Select the Alarm icon.

Press On, or Off.

The Alarm function is password protected.



If the alarm function is deactivated you will see the Alarm Off sign in front of every single parameter.

To leave the Alarm menu press the back icon 

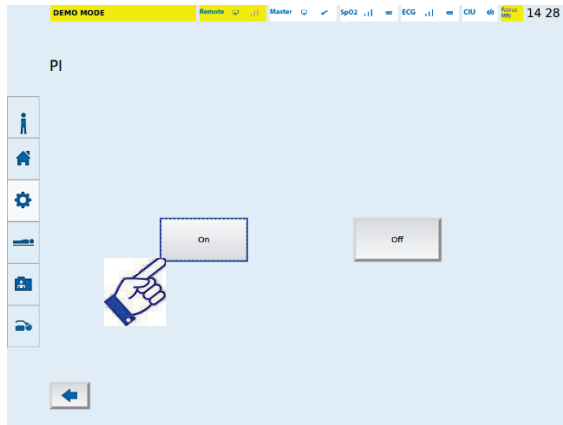



After a new start of the monitor the alarm function will be activated again.

3.5.6.Perfusion Index (PI)

The *Tesla^{M3}* calculates the perfusion index (PI) during SpO₂ monitoring. The value of the PI is displayed in the main screen in the SpO₂ parameter field when the function is activated.


You can deactivate / activate the Perfusion index manually at any time.



Open the Options menu by pressing the Options tab  on the menu bar.

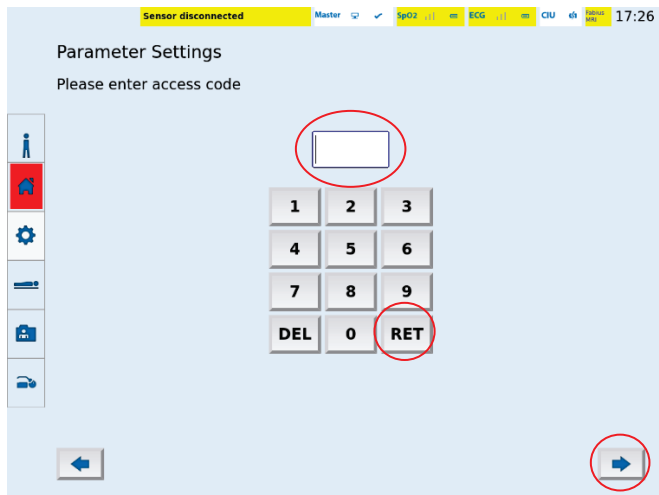
Select the Perfusion Index icon.

Press On, or Off.

To leave the PI menu press the back icon .

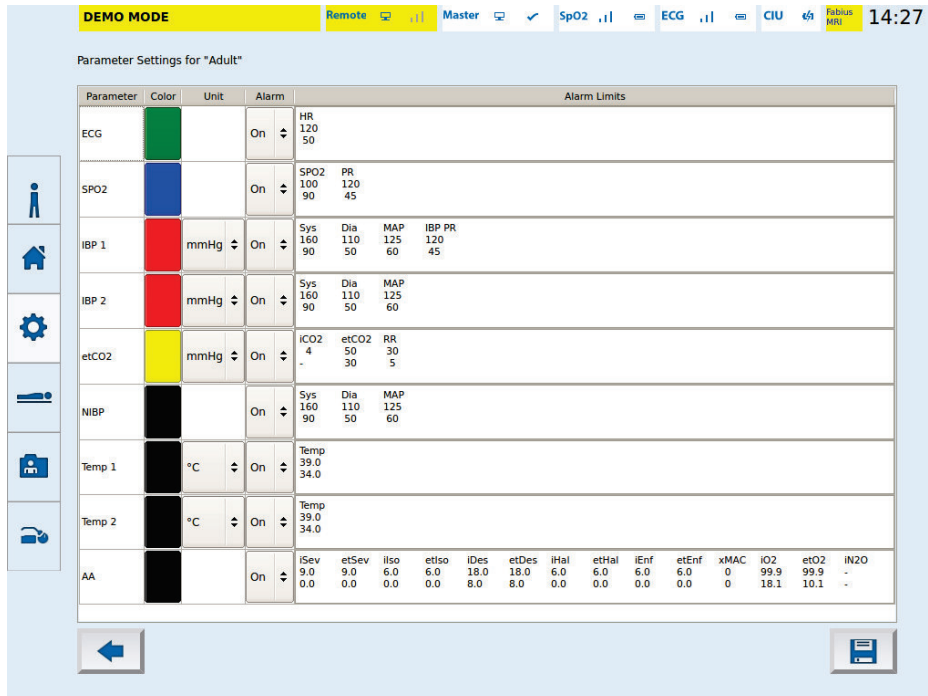
3.5.7. Parameter settings

The graphical user interface of the *Tesla^{M3}* can be customized according to your specific preferences. You can change the display and measurement unit of the parameters in the Parameter settings menu. This menu affects a sensitive area of the monitoring system. The Parameter settings menu is password protected.



Insert the code using the numeric key pad
and press RET
and then press forward icon.

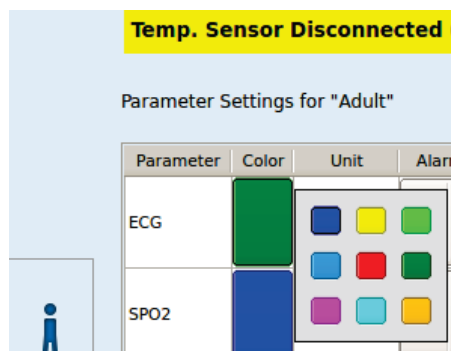
If the password input was correct the next icon becomes available. Press the next icon to enter the Parameter settings menu.



In this menu you can change the color of the parameter in the main screen, change the measurement unit for invasive blood pressure and CO₂ measurement. You may also deactivate alarms of single parameters and save the settings for the patient mode you currently use.

Changing the colors

Press the color field next to the parameter you want to change and select the color in the drop-down list.



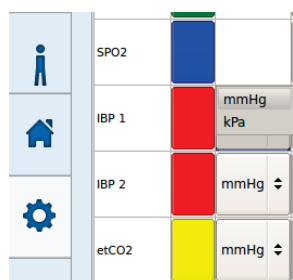
You can assign one color to several parameters.

MIPM recommends choosing only one parameter per color. This increases awareness of the different parameters.

Changing the measurement unit

You can change the measurement unit of the IBP as well as etCO₂.

Press the drop-down list field next to the parameter you wish to change. A drop-down list with the possible options opens. Select the desired measurement unit.

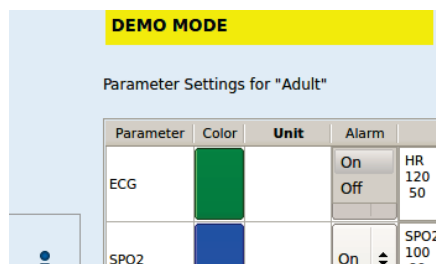


The following measurement units are available:

IBP	etCO ₂	Temperature
mmHg (default)	mmHg	°C
kPa	kPa	°F
	Vol % (default)	

Changing the alarm status

To enable/ disable the alarm status of a single parameter **permanently**, press the drop-down list field in the right column for the respective parameter. Select On, or Off in order to activate / deactivate a single parameter alarm.



This step may be repeated for every single parameter.



If an alarm status is changed to “Off” in the parameter settings menu and the changes are saved for the respective patient mode that alarm status will be disabled permanently! Even after a new start of the monitor the status will be “Off”.



MIPM strongly recommends to leave the alarm function enabled! Alarms indicate critical conditions of the patient and the system. Thus alarms help to increase the awareness of the medical personnel and by that increase patients safety. Do not suppress an alarm or disable the alarm function if the safety of the patient is compromised!

Setting the alarm limits

You can set customized alarm limits for each available patient mode. The Alarm limits column in the Parameter settings menu shows the alarm limits that are currently set. If you want to customize the alarm limits press the box where the alarm limits are shown in the display.

The alarm limits menu opens. Change the respective alarm limit according to your preferences and close the alarm limit menu by pressing the back icon. (See chapter 5.5.7. "Alarm silence and the adjust alarm function")

Repeat that procedure for every alarm limit that you want to change.

Parameter	Color	Unit	Alarm	Alarm Limits
ECG	Green		On	HR 120/50
SPO2	Blue		On	SPO2 100/90 PR 120/45
IBP 1	Red	mmHg	On	S 11/9 MAP 125/60 IBP PR 120/45
IBP 2	Red	mmHg	On	S 11/90 MAP 125/60
etCO2	Yellow	mmHg	On	etCO2 4/30 RR 30/5
NIBP	Black		On	Sys 160/90 Dia 110/50 MAP 125/60
Temp 1	Black	°C	On	Temp 39.0/34.0
Temp 2	Black	°C	On	Temp 39.0/34.0
AA	Black		On	iSev 9.0/0.0 etSev 9.0/0.0 liso 6.0/0.0 etiso 6.0/0.0 iDes 18.0/8.0 etDes 18.0/8.0 iHal 6.0/0.0 etHal 6.0/0.0 iEnf 6.0/0.0 etEnf 6.0/0.0 xMAC 0/0 iO2 99.9/18.1 etO2 99.9/10.1 IN2O -

Saving the parameter settings

If you have finished all parameter settings you have to save the new Setup to activate it for the respective patient mode.

Press the Save icon  and accept.

The changes in the parameter settings are only valid for the patient mode you had selected. If you want to customize settings of another patient mode go to the Patient Mode screen and select another patient mode and repeat the steps described above.

- The changed setting will only be applied if they are saved before the parameter settings menu is left. If you leave parameter settings without saving the changes will be discarded.

3.5.8.Service Menu

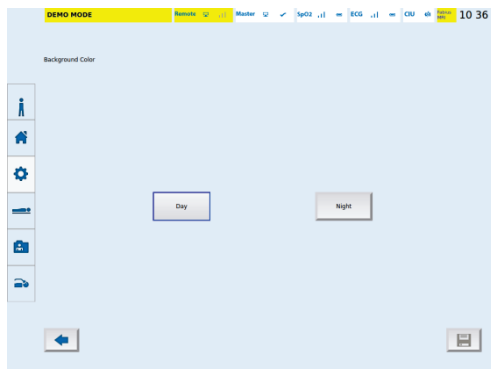
The Service menu is exclusively reserved for personnel authorized by MIPM. Settings in the Service menu affect sensitive areas of the systems core functions and may only be changed by trained personnel.

The Service menu is password protected.

For any information about the service menu contact MIPM or your local service partner.

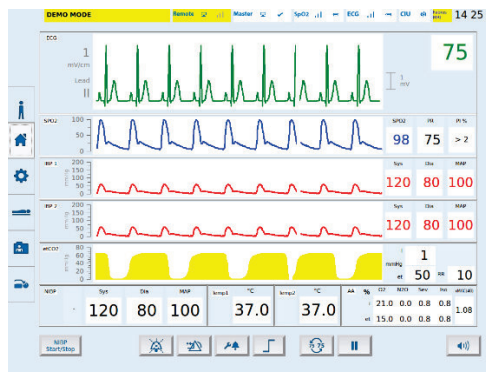
3.5.9.Background Color

The graphical user interface of the *Tesla^{M3}* can be customized according to environmental brightness. It can be switched between Day- and Night mode. (Password protected!)

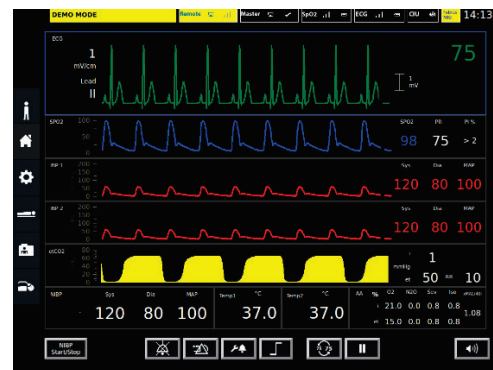


Press Day -> bright Background

Press Night -> dark Background




Main screen Day-mode

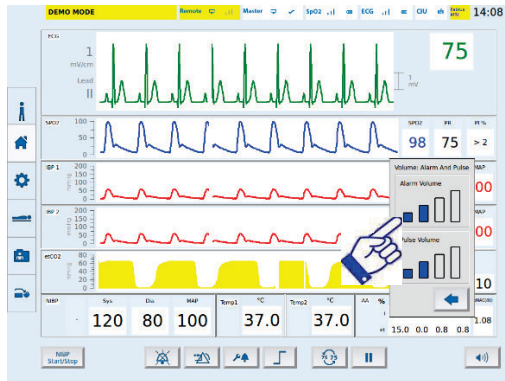


Main screen Night-mode

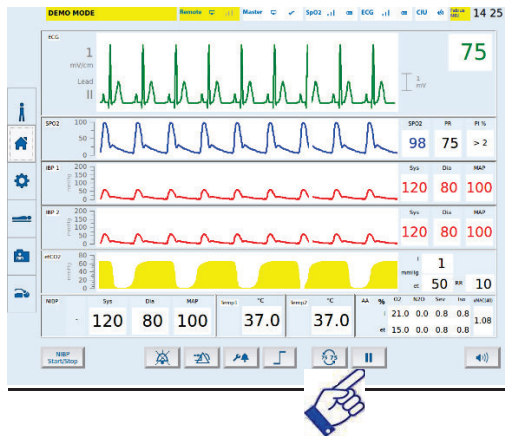
3.6. Monitor volume and Standby mode

The Volume for the alarm and pulse tone can be adjusted in 4 levels.

Open the Volume menu by pressing the volume icon () on the main screen



Select the desired volume level for pulse, or alarm tone by pressing the respective bar in the volume window.



Press Standby to set the monitor in standby mode.

Press the Standby off icon on the main screen to leave standby mode.

During standby mode the alarm function and the trend memory are deactivated.

3.7. Connecting Patient Sensors to the *Tesla*^{M3}

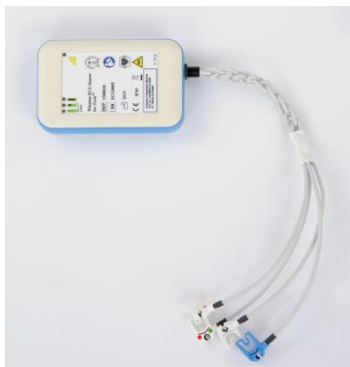
All connectors for sensors are to be found on the back side of the unit.




For more detailed picture see chapter 1.12.1 “Back of the device”

ECG, as well as SpO₂ sensor have a wireless connection to the monitor.

3.7.1. The ECG sensor



The ECG sensor is automatically connected to the monitor as soon as the sensor is removed from the charging bracket at the backside of the monitor. As long as the connection is not established you will


see the ECG sensor connection alarm on the main screen . The ECG sensor icon will not be displayed in the status bar.

If the connection is established the ECG status icon is displayed in the status bar and the ECG sensor connection alarm is turned off.

3.7.2. The SpO₂ sensor



The SpO₂ sensor is automatically connected to the monitor as soon as the sensor is removed from the charging bracket at the backside of the monitor. As long as the connection is not established you will

see the SpO₂ sensor connection alarm on the main screen . The SpO₂ sensor icon will not be displayed in the status bar.

If the connection is established the SpO₂ status icon is displayed in the status bar and the SpO₂ sensor connection alarm is turned off.

3.7.3. NIBP tubes and cuffs



The quality of the NIBP measurements corresponds with the signal quality received by the monitor. Thus it is important to use the correct cuff size for the respective patient. The size is clearly marked on the cuff. Measure the circumference of the limb.

Do only use NIBP accessories that have been approved by MIPM. (see chapter 8.3 “NIBP-Accessories”)

Connect the NIBP tube to the *Tesla^{M3}* at the connector shown in the picture. Press down the lock of the connector and plug in the tube. The lock automatically latches when the tube reaches the correct position.

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



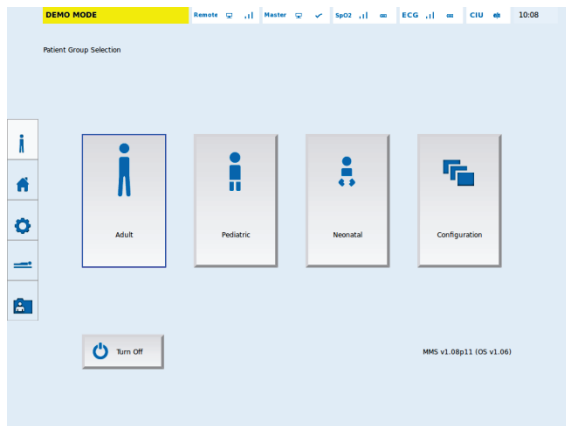
Temperature sensor for surface (axilla / armpit) temperature measurement



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.

4. Patient Admission/Release

4.1. Patient Mode



The selected patient mode will be displayed in the patient mode tab in the menu bar.



The choice of the correct patient mode is subject to the evaluation of the clinical practitioner. The patient mode should always be adapted to the respective patient.

If the patient mode is changed the following happens:

- All active alarms and alarm messages are deleted
- NIBP readings will be aborted
- Scaling of the parameter curves changes to default settings for the new patient mode



If the monitor is set to neonatal patient mode please keep in mind: The sample rate of the Multigas module is approximately 200 ml/min.

4.1.1. Adult mode



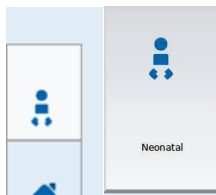
To activate the adult patient mode select the patient mode screen and press the adult icon. The default settings for alarm limits and wave form scale are active. (See chapter 2.3 “Default settings”) The monitor switches to main screen; the adult icon is shown in the menu bar.

4.1.2. Pediatric mode



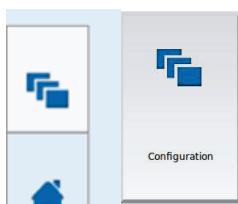
To activate the pediatric patient mode, select the patient mode screen and press the pediatric icon. The default settings for alarm limits and wave form scale are active. (See chapter 2.3 “Default settings”) The monitor switches to main screen; the pediatric icon is shown in the menu bar.

4.1.3. Neonatal mode



To activate the neonatal patient mode, select the patient mode screen and press the neonatal icon. The default settings for alarm limits and wave form scale are active. (See chapter 2.3 “Default settings”) The monitor switches to main screen; the neonatal icon is shown in the menu bar.

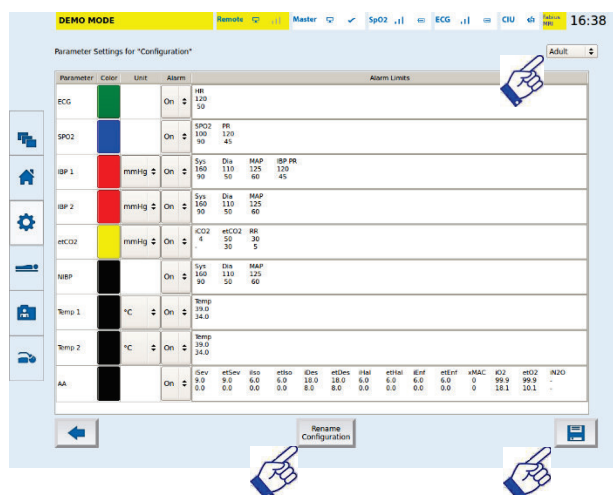
4.1.4. Custom patient mode



Tesla^{M3} offers an alternative patient mode that can be customized according to your specific demand.

To activate the free patient mode, select the patient mode screen and press the free configuration icon.

Select the alarm limits, parameter colors, alarm status and measurement units. You can now save the settings and rename the patient mode in the parameter settings. (See chapter 3.5.7 “Parameter settings”)



In the parameter settings menu, you can assign a basic patient mode to the free configuration. Press the drop-down list in the upper right corner of the display and select the patient type

Before saving the settings you can rename the configuration by pressing the icon on the bottom of the main screen. Type in the new name for the patient mode using the keyboard interface and save the changes.

To finish the parameter settings press the Save Icon in the lower right corner of the display.

4.2. Patient admission

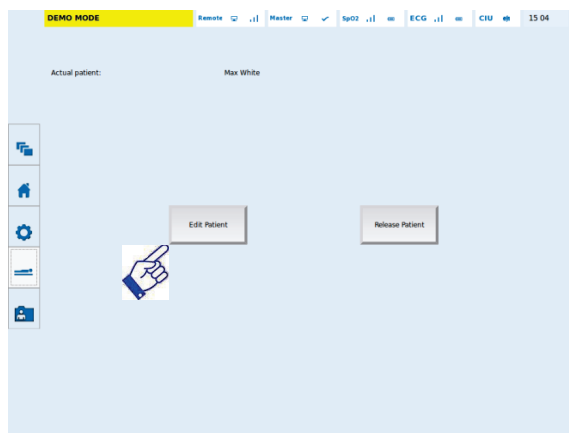
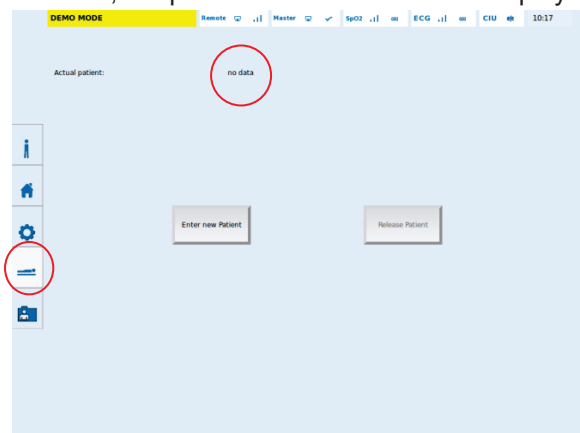
Whenever the *Tesla^{M3}* is switched on the monitor asks if there is a new patient. This ensures that the data from previous patients is deleted before a new patient is monitored.

If you want to monitor a new patient select "Yes"; all previous patient information, and trends are deleted.

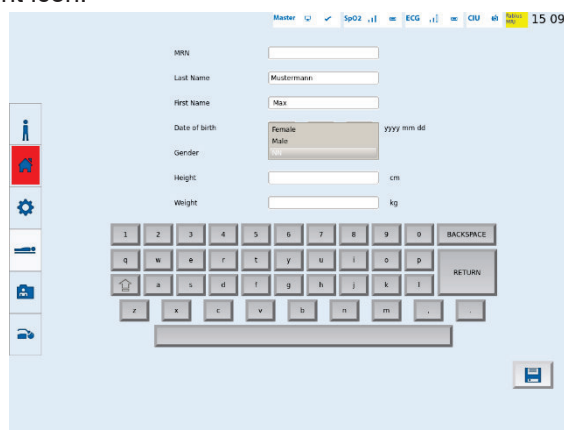
You can always change patient data at any time during the examination.

4.2.1. Enter patient data

All patient information can be entered in the patient data screen. Press the Patient data tab in the menu bar; the patient data screen will be displayed.



If the memory already contains patient data the name of the patient will be displayed on the screen. To enter new patient data press the Enter new patient icon.



Type the patient data using the display keyboard. Select the respective box by pressing on it. You can either put it data independently via the keyboard or by drop-down list. Any input has to be confirmed with "Return" before the next box can be selected.

The following data may be stored:

Medical Record Number	First name	Last name	---
Date of birth	Gender	Height	Weight

Save the patient date by pressing the disc icon .

The patient information will be used for all trend records until the patient is released, or a new patient is admitted.

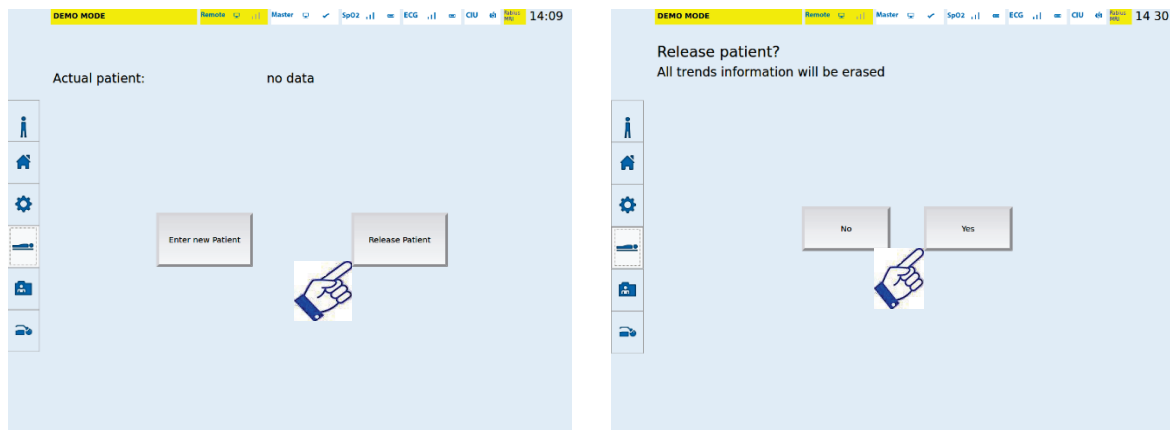
4.2.2. Utilization of patient data

If a patient is registered at the monitor all vital signs measurements are assigned to that patient. The trend data (tabular, event) can be copied to an external data storage medium (USB) or printed. Trend data is transmitted in the .csv file format. Each data string carries the complete patient information that has been stored in the monitor.

The trend data in .csv format can be changed to any other file format.

- If the *Tesla^{M3}* is connected to a hospital network all patient and trend data will be transferred to the local area network.

4.3. Patient release



After a patient release all patient data including trend memory will be erased. The monitor resets all values to the default settings of the selected patient mode.

Previously deactivated audible parameter alarms will not be re-activated by this. To activate the audible parameter alarms please follow the Alarm reset function (see chapter 5.5.6)

To release a patient chose the patient data screen and press the Release patient icon.

Confirm patient release.

4.4. Connecting *Tesla^{M3}* to a hospital network (PDMS)

The customization of the data protocol in order to align the *Tesla^{M3}* data with the hospital network cannot be performed by MIPM. The actual implementation of the monitor to the hospital network has to be done by the network administrator or the provider of the hospital network.

Tesla^{M3} provides the monitoring data (.xml File).

The transmission of monitoring data via Ethernet happens by creation of a XML file with equivalent content as data transmitted via RS232. The transmission of data to the PDMS server is based on Secure Copy – scp with Secure Shell – SSH authentication.

In order to connect the *Tesla^{M3}* to the hospital network, the monitor as well as the PDMS server have to be configured. The patterns of the configuration are not part of this user manual. (To get the PDMS manual please contact your local distributor or MIPM.)

5. Routine Use

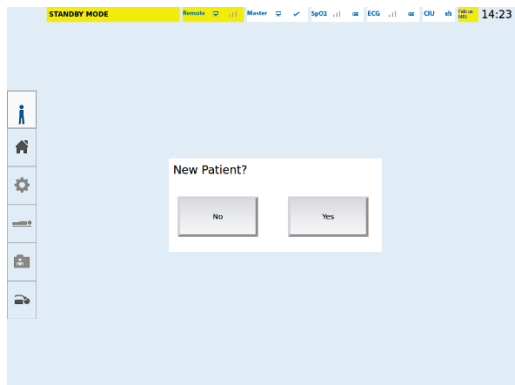
5.1. Switching on/off the monitor

Switch on the *Tesla*^{M3} using the main switch on the right side of the display.



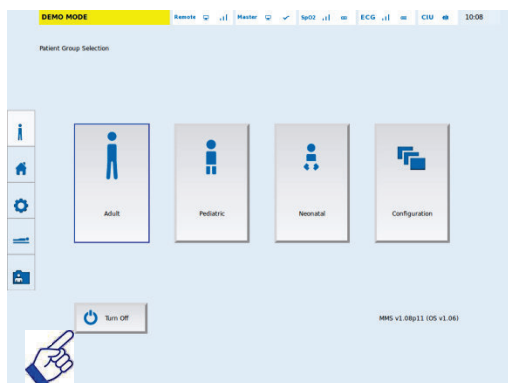
The system boots and performs a self-test. The function of every module is checked and verified. During the self-test you will see the booth screen showing the installed software version.

After the boot process is completed the monitor switches to the new patient query.



If you admit a new patient the old trend memory will be erased.
If you select “No” the trend memory is maintained.

Switch off the *Tesla*^{M3} using the “Turn off” button on the touchscreen.

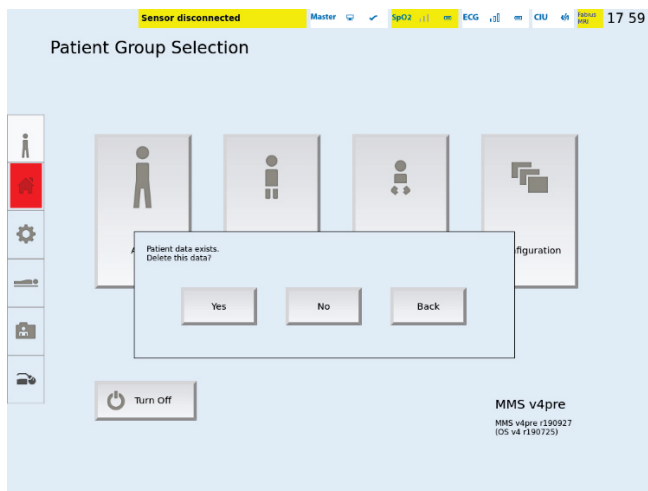


Hold the button until the turn off procedure.



Note: Ensure that the *Tesla*^{M3} is switched off once every day. It is switched off by pressing the “Turn off” button on the touchscreen as described above.

Delete patient data query before the system turn off.



Before the system turn off, a prompt appears asking whether the existing patient data should be deleted.

If this is confirmed with Yes, all data is deleted, and the system turn off.

If you confirm with No, the data is retained, and the system turn off.

If you cancel with Back, the device does not turn off and you return to the patient group selection.

Soft reset:

Switch off the *Tesla^{M3}* using the main switch on the right side of the display in case of need. The main switch button must be pressed for approx. 3 seconds. The system will completely shut down and needs to be turned on according to the switch on procedure.



Only use the "soft reset" procedure if necessary (e.g. software has hung up, monitor cannot be operated). Otherwise, switch off the system using the normal turn off procedure via the "turn off" button on the touchscreen.

5.2. Switching on/off the Remote Monitor



The operating controls of the main unit and the remote screen are identical. (See above)

The remote monitor may be positioned at any place in the MRI control room.
The unit offers complete functionality of the *Tesla^{M3}* in the MRI control room.

In addition to the 2 USB interfaces the remote monitor is equipped with an Ethernet as well as RS 232 interface. You may connect the *Tesla^{M3}* to hospital network via the remote monitor.



The remote monitor is not shielded against RF emissions. Do not place the remote monitor inside the MRI cabin.



Note: If the remote screen is turned on while the main unit is not operating a Master-Remote alarm will be displayed. The monitor does not receive any values.



Note: Ensure that the *Tesla^{M3}* Remote Monitor is switched off once every day. It is switched off in the same way as with the *Tesla^{M3}* main unit.

5.3. Handling the wireless sensors

The *Tesla^{M3}* is equipped with two wireless sensors. Both sensors have an integrated battery and battery charger. You may charge the sensor batteries in the charging brackets on the back side of the monitor. Please insert the sensors to the charging brackets as described below.

Insert the sensor with the cable pointing downwards into the charging bracket. Make sure that the cable meets the outlet off the charging bracket.



When the sensor is placed in the charging bracket it will be deactivated and automatically charged. The sensor connection alarm icon will be displayed in the main screen and the sensor status field in the status bar will be marked yellow. The charging process is indicated by the 3 sensors overhead LEDs flashing one after the other.

For a complete recharge of the sensor battery charge the sensor for at least 6 hours. Make sure that the sensor batteries are always fully charged before using the *Tesla^{M3}*.

5.3.1.The ECG sensor



The ECG cables are made of carbon fibers. This reduces the risk of cable heating to a minimum. Placement of the ECG electrodes will be described in the chapter ECG electrodes and skin preparation.

The battery of the ECG sensor lasts for at least 8 hours if it was charged completely. You may check the battery status of the sensor on the 3 LEDs directly at the sensor or in the sensor status field in the status bar.



If the battery status is low a status message will be generated in the status bar. Charge the sensor immediately. Insert the sensor in the charging bracket as described above.

To activate the ECG sensor remove it from the charging bracket. The sensor is activated automatically, performs a self-test and establishes the connection with the *Tesla^{M3}*. The ECG sensor connection alarm disappears and the ECG sensor status field in the status bar is displayed.



NOTE: When using the ECG sensor, ensure that the enclosure of the sensor is not contacting the patient's bare skin e.g. by placing a tissue underneath or by placing it near the patient.

5.3.2. The SpO₂ sensor



The SpO₂ cable is made of optic fibers. This eliminates the risk of cable heating. How to fix the sensor to the patient will be described in the chapter SpO₂ monitoring.

The battery of the SpO₂ sensor lasts for at least 8 hours if it was charged completely. You may check the battery status of the sensor on the 3 LEDs directly at the sensor or in the sensor status field in the status bar.



If the battery status is low a status message will be generated in the status bar. Charge the sensor immediately. Insert the sensor in the charging bracket as described above.

To activate the SpO₂ sensor remove it from the charging bracket. The sensor is activated automatically, performs a self-test and establishes the connection with the *Tesla^{M3}*.

The SpO₂ sensor connection alarm disappears and the SpO₂ sensor status field in the status bar is displayed.

The light source of the sensor are red and infrared LEDs. The red LED has a dominant wavelength of 645 nm, a peak wavelength of 660 +/- 20 nm and a Luminous intensity of 1300 mcd. The infrared LED has a peak wavelength of min. 890 nm and max. 910 +/- 20 nm. The radiant intensity of the infrared LED is 40 mW/sr.

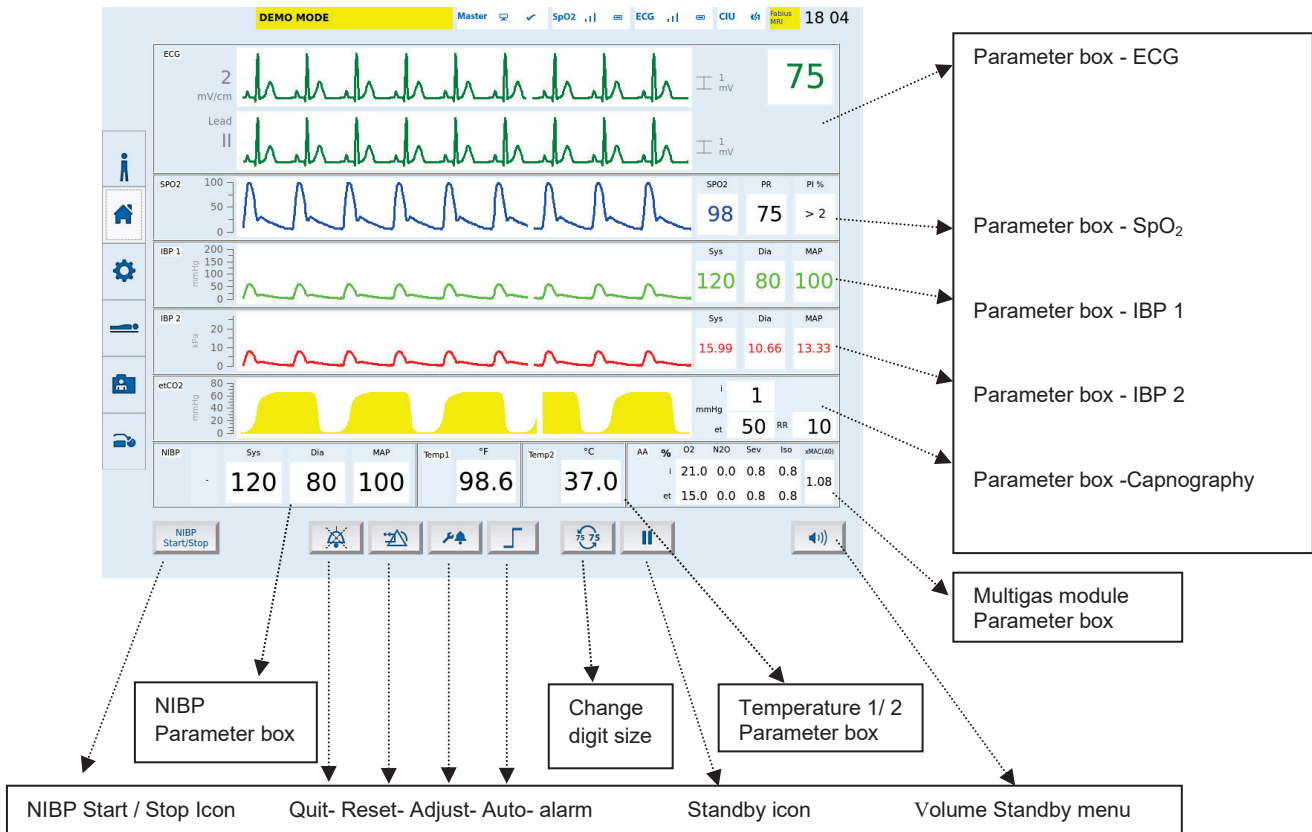


This information about the wavelength range can be especially useful to clinicians (e.g. in photodynamic therapy)



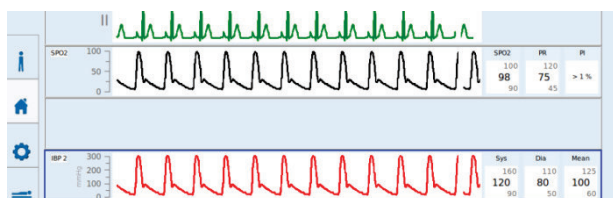
NOTE: When using the Pulse Oximetry sensor, ensure that the enclosure of the sensor is not contacting the patient's bare skin e.g. by placing it near the patient.

5.4. The main screen



➤ The parameter boxes are fixed on the main screen. If the Tesla^{M3} is not equipped with a parameter the respective parameter box remains empty.

E.g. Configuration: ECG, SpO₂, NIBP, 1x IBP, 1x Temperature, Multigas module

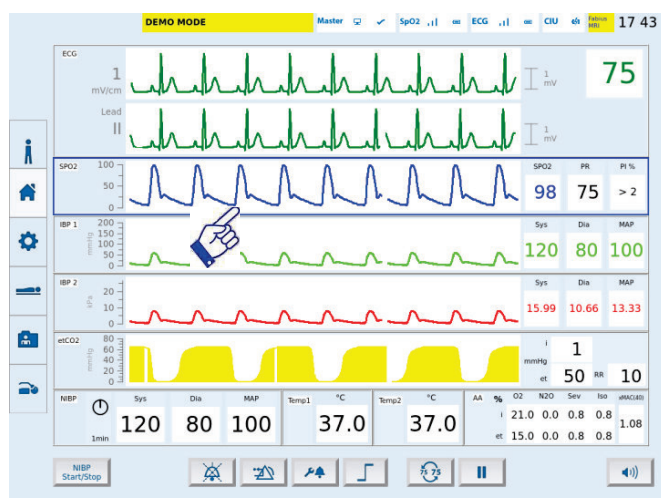


The parameter box for IBP1 remains empty and cannot be programmed by the user.

ECG cascade may be activated or deactivated at any time during the examination.

From the main screen you can change any relevant setting. All parameter menus (e.g. Alarm limits, scaling, ECG leads) may be selected in the main screen.

Via the function icons at the bottom of the main screen you can manually start and stop a NIBP measurement, suppress an alarm, set the monitor volume and put the monitor into Standby mode. You will find information about the status of the monitor and its components, as well as alarm messages in the status bar above the main screen.



Each parameter box can be activated via the touch screen. By pressing on one of the parameter boxes the corresponding parameter menu will be opened.

Please see the corresponding chapter for more details about the settings in the parameter menus.

Using the function bar on the left side of the screen you can change to any other screen at any time. Colors or units of the parameters can be changed as described in Chapter 3 – Parameter settings. All vital signs will be shown directly in the main screen as soon as the respective sensor is connected to the patient.

5.5. Alarms

The *Tes/a^{M3}* is equipped with different alarm mechanisms (System/Technical alarms, Parameter alarms). All alarms will be displayed in the main screen either in the status bar or directly in the parameter boxes. Every alarm has an assigned priority (see chapter 5.5.4 "Alarm priorities"). In case of multiple alarms, messages rotate in an interval of 5 seconds. A table with alarms is created in the background like the following.

Alarms are sorted by 1. priority and 2. time of occurrence

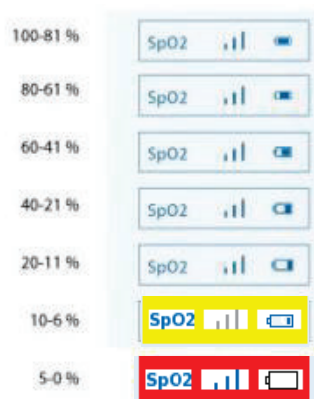
Sorted by priority and time of occurrence	Alarms	Comment
1	ASY	High - first occurred
2	IBP Malfunction	High - last occurred
3	Occlusion	Medium
4	Temp. Sensor Disconnected	Low



The Loudness of audible alarms of high priority is up to 60 and medium/low priority up to 50 dB. The alarm signal sound pressure level should be adjusted depending on ambient noise.

5.5.1. Battery alarms

The monitor as well as ECG and SpO₂ sensor may be used in battery operation. The battery life for the monitor is approximately 6.5 hours – 390 minutes (tested with standard configuration). Battery life of the sensors is at least 8 hours – 480 minutes.



The charge condition of the battery will be displayed as shown left.

If the charging condition reaches $\leq 10\%$ of the capacity an alarm is generated.

- The battery symbol of the affected component appears yellow
- You will see a yellow message in the status bar
- A single alarm tone sounds

If the charge condition reaches $\leq 5\%$ of the capacity the general battery alarm is replaced by a critical battery alarm.

- The battery symbol of the affected component flashes red
- You will see a red message in the status bar
- A repeated alarm tone sounds.



If a battery alarm occurs, please connect the *Tesla^{M3}* to mains power immediately. When the first battery alarm ($\leq 10\%$) is shown the remaining battery life is approximately 30 minutes. If the *Tesla^{M3}* is not connected to the mains power after the second battery alarm the system will shut down after a few minutes.

5.5.2. System Alarms

The following system related / technical alarms may occur:

Alarm	Description	Action
Demo Mode	The monitor displays simulated patient data.	-----
Master - Remote Disconnection (Only with Remote Option)	The connection between main monitor and remote screen in the control room is interrupted. No patient data is shown on the remote screen.	Contact Service / MIPM.
Connection to hospital network interrupted (only if connected to hospital network)	The connection between <i>Tesla^{M3}</i> and the hospital network is interrupted. No patient data is transferred to the hospital network.	Contact Network administrator / Service.
Battery Alarm - Monitor	The battery of the <i>Tesla^{M3}</i> has reached a critical charge condition.	Connect <i>Tesla^{M3}</i> to mains power.
Battery Alarm – Sensor	The battery of the SpO ₂ and/or ECG sensor has reached a critical charge condition.	Put the sensor in the charging bracket of the back side of <i>Tesla^{M3}</i> and charge for at least 6 hours.
SpO ₂ / ECG Sensor Connection alarm	The SpO ₂ and/or ECG sensor connection to the monitor has failed.	Make sure that the sensor batteries are fully charged. In case that the batteries are charged contact Service / MIPM.

5.5.3.Parameter Alarms

The following parameter related alarm may occur:

Alarm	Description
Violation of an alarm limit	One or more of the vital signs have violated the upper or lower alarm limit of a parameter. The respective parameter box flashes red and an acoustic alarm sounds.
ASY	The monitor recognized a cardiac arrest. The ECG box flashes red and ASY is displayed in the ECG box.
BRADY	The monitor recognized a Bradycardia (Heart rate < 60). BRADY is displayed in the ECG box. No alarm tone will sound.
TACHY	The monitor recognized a Tachycardia (Heart rate >150) TACHY is displayed in the ECG box. If the Tachycardia corresponds with a violation of an alarm limit the ECG box flashes red.
ECG Lead Off	One or more of the ECG electrodes are not properly connected to the patient or the ECG sensor. It may also happen that the skin resistance is too high (see chapter 5.5.3 "Parameter Alarms").
SpO ₂ – Finger not in sensor	The SpO ₂ sensor is not properly connected to the patient's finger.

Alarms Overview

Module / Parameter	Alarm Cause	Priority	Message Displayed in Status Bar	Behaviour	Message Location
CIB	CIB Malfunction	High	System Malfunction	Status message	Status bar
Master / CIB	Connection Lost	High	No communication with CIB	Status message	Status bar (Master monitor)
Master / Remote	Demo Mode	Low	Demo mode - simulated data	Status message	Status bar
Master / Remote	Service Mode	Low	Master in service mode	Status message	Status bar
Master / Remote	Connection Lost	Low	No communication with master	Status message	Status bar (Remote monitor)
PDMS / Network	No patient data	Low	No data transmission - Patient data missing	Status message	Status bar
SpO ₂ Battery	Charge Condition 10%	Low	SpO ₂ Battery < 10 %	Status message	Status bar
SpO ₂ Battery	Charge Condition 5%	High	SpO ₂ battery < 5 %	Status message	Status bar
ECG Battery	Charge Condition 10%	Low	ECG battery < 10%	Status message	Status bar
ECG Battery	Charge Condition 5%	High	ECG battery < 5 %	Status message	Status bar
System Battery	Charge Condition 10%	Low	System battery < 10 %	Status message	Status bar
System Battery	Charge Condition 5%	High	Low battery - shutdown in a few minutes	Status message	Status bar
NIBP	Selftest Error	High	NIBP System Malfunction	Status message	Status bar
NIBP	System Error in measuring unit	High	NIBP System Malfunction	Status message	Status bar
NIBP	Leakage during leakage test	Low	NIBP Leakage	Status message	Status bar
NIBP	Cuff fitted to loosely or not connected	Low	Check NIBP Cuff placement	Status message	Status bar
NIBP	Leakage during operation	Medium	NIBP Leakage	Status message	Status bar
NIBP	faulty slow loss of pressure	Medium	NIBP Occlusion - Check tubing	Status message	Status bar
NIBP	pulse not recognizable - cuff incorrectly fitted	Medium	Check NIBP Cuff placement	Status message	Status bar
NIBP	measurement range exceeded	Medium	NIBP reading out of range	Status message	Status bar
NIBP	Movement artifacts	Low	NIBP Movement Artifacts	Status message	Status bar
NIBP	excess pressure	Medium	Excess Pressure	Status message	Status bar
NIBP	Pulse signal saturated	Medium	Check NIBP Cuff placement	Status message	Status bar
NIBP	Violation of upper DIA Alarm Limit	High	N/A	DIA value flashes	NIBP field
NIBP	Violation of lower DIA Alarm Limit	High	N/A	DIA value flashes	NIBP field
NIBP	Violation of upper SYS Alarm Limit	High	N/A	SYS value flashes	NIBP field
NIBP	Violation of lower SYS Alarm Limit	High	N/A	SYS value flashes	NIBP field
NIBP	Violation of upper MAP Alarm Limit	High	N/A	MAP value flashes	NIBP field
NIBP	Violation of lower MAP Alarm Limit	High	N/A	MAP value flashes	NIBP field
SpO ₂	Selftest Error - no data	High	SpO ₂ System Malfunction	Status message	Status bar
SpO ₂	Sensor disconnected	Low	Symbol	Status message	SpO ₂ waveform
SpO ₂	Finger not in Probe	Low	Symbol	Status message	SpO ₂ waveform
SpO ₂	Low Perfusion	Low	PI value and background color changes	Status message	SpO ₂ field
SpO ₂	Violation of upper SpO ₂ Limit	High	N/A	SpO ₂ Value flashes	SpO ₂ field
SpO ₂	Violation of lower SpO ₂ Limit	High	N/A	SpO ₂ Value flashes	SpO ₂ field
SpO ₂	Violation of upper Pulse Limit	High	N/A	Pulse Value flashes	SpO ₂ field

Module / Parameter	Alarm Cause	Priority	Message Displayed in Status Bar	Behaviour	Message Location
SpO ₂	Violation of lower Pulse Limit	High	N/A	Pulse Value flashes	SpO ₂ field
ECG	Selftest Error - no data	High	ECG Malfunction	Status message	Status bar
ECG	Sensor disconnected	Low	Symbol	Status message	ECG waveform
ECG	Lead Off	Low	Lead off	Status message	ECG waveform
ECG	Resistance to high	Low	High Resistance	Status message	Status bar
ECG	Violation of upper Heart Rate Limit	High	N/A	HR Value flashes	ECG field
ECG	Violation of lower Heart Rate Limit	High	N/A	HR Value flashes	ECG field
ECG	Asystolia	High	N/A	Message: "ASY" - same colour as ECG waveform/value located beside value	ECG field
ECG	Bradycardia	Low	N/A	Message: "Brady" - same colour as ECG waveform/value located beside value	ECG field
ECG	Tachycardia	High	N/A	Message: "Tachy" - same colour as ECG waveform/value located beside value	ECG field
IBP	Selftest Error - no data	High	IBP Malfunction	Status message	Status bar
IBP	Module not calibrated	High	IBP Module not calibrated	Status message	Status bar
IBP	Zeroing in Process	Low	Zeroing in Process	Status message	Status bar
IBP	Zeroing failed	Medium	Zeroing failed. check 3-way stopcock	Status message	Status bar
IBP	Value out of range	High	Value out of range	Status message	Status bar
IBP	No waveform found	High	No waveform detected	Status message	Status bar
IBP	Violation of upper DIA Alarm Limit	High	N/A	DIA value flashes	IBP field
IBP	Violation of lower DIA Alarm Limit	High	N/A	DIA value flashes	IBP field
IBP	Violation of upper SYS Alarm Limit	High	N/A	SYS value flashes	IBP field
IBP	Violation of lower SYS Alarm Limit	High	N/A	SYS value flashes	IBP field
IBP	Violation of upper MAP Alarm Limit	High	N/A	MAP value flashes	IBP field
IBP	Violation of lower MAP Alarm Limit	High	N/A	MAP value flashes	IBP field
IBP	Cable failure	Medium	Cable fail	Status message	Status bar
IBP	Violation of upper PR Alarm Limit	High	N/A	If ECG deactivated PR value flashes	ECG field
IBP	Violation of lower PR Alarm Limit	High	N/A	If ECG deactivated PR value flashes	ECG field
Gasmodule	Violation of upper iCO ₂ Limit	High	N/A	iCO ₂ values flashes	CO ₂ field
Gasmodule	Violation of lower iCO ₂ Limit	High	N/A	iCO ₂ values flashes	CO ₂ field
Gasmodule	Violation of upper etCO ₂ Limit	High	N/A	etCO ₂ value flashes	CO ₂ field
Gasmodule	Violation of lower etCO ₂ Limit	High	N/A	etCO ₂ value flashes	CO ₂ field
Gasmodule	Violation of upper Respiration Rate Limit	High	N/A	RR value flashes	CO ₂ field
Gasmodule	Violation of lower Respiration Rate Limit	High	N/A	RR value flashes	CO ₂ field
Gasmodule	Selftest Error - no data	High	Gas Module Malfunction	Status message	Status bar
Gasmodule	No flow detected	Medium	No Flow	Status message	Status bar
Gasmodule	Flow is too low	Medium	Low Flow	Status message	Status bar
Gasmodule	Flow is too high	Medium	High Flow	Status message	Status bar
Gasmodule	Violation of upper iAA Limit	High	N/A	iAA Value flashes	AA Field
Gasmodule	Violation of lower iAA Limit	High	N/A	iAA Value flashes	AA Field

Module / Parameter	Alarm Cause	Priority	Message Displayed in Status Bar	Behaviour	Message Location
Gasmodule	Violation of upper etAA Limit	High	N/A	etAA value flashes	AA Field
Gasmodule	Violation of lower etAA Limit	High	N/A	etAA value flashes	AA Field
Gasmodule	Violation of upper iO ₂ Limit	High	N/A	iO ₂ values flashes	AA Field
Gasmodule	Violation of lower iO ₂ Limit	High	N/A	iO ₂ values flashes	AA Field
Gasmodule	Violation of upper etO ₂ Limit	High	N/A	etO ₂ value flashes	AA Field
Gasmodule	Violation of lower etO ₂ Limit	High	N/A	etO ₂ value flashes	AA Field
Gasmodule	Violation of upper Respiration Rate Limit	High	N/A	RR value flashes	AA Field
Gasmodule	Violation of lower Respiration Rate Limit	High	N/A	RR value flashes	AA Field
Gasmodule	Component failure	High	Gas Module Malfunction	Status message	Status bar
Gasmodule	Multigas warm up	Low	Multigas warm up	Status message	Status bar
Gasmodule	Multigas zero in 1 minute	Low	Multigas zero in 1 minute	Status message	Status bar
Gasmodule	Multigas zero in progress	Low	Multigas zero in progress	Status message	Status bar
Gasmodule	Watertrap full / error	Low	Check Watertrap	Status message	Status bar
Gasmodule	MAC < 3 and more than one AA detected	Low	MAC < 3 and more than one AA detected	Status message	Status bar
Gasmodule	MAC > 3 and more than one AA detected	Low	MAC > 3 and more than one AA detected	Status message	Status bar
Gasmodule	Measured values outside ISO accuracy	Low	Multigas accuracy unknown	Status message	Status bar
Temperature	Selftest Error - no data	High	Temperature Malfunction	Status message	Status bar
Temperature	Sensor disconnected (channel 1)	Low	Temp. Sensor Disconnected (channel 1)	Status message	Status bar
Temperature	Sensor disconnected (channel 2)	Low	Temp. Sensor Disconnected (channel 2)	Status message	Status bar
Temperature	Violation of upper Temperature Limit	High	N/A	Temperature value flashes	Temperature field
Temperature	Violation of lower Temperature Limit	High	N/A	Temperature value flashes	Temperature field

Alarm volume

High Priority: 71dB
Low Priority: 60,5dB

Alarm delays

There is a delay for the alarm "No communication with master". The delay time from the onset of the alarm condition to the point of representation and the maximum remote alarm signal generation delay are 2 seconds.

5.5.4. Alarm priorities



The priority setting of alarms does not take into account if the alarm is parameter related or system related. Only the potential danger for the patient or personnel matters for the evaluation of an alarm priority.

Alarm priorities:

Red: Life threatening alarm – High priority

The monitor recognizes a life threatening alarm condition (e.g. violation of an alarm limit)

A life threatening alarm has the following properties:

- The parameter box flashes red
- A repeated acoustic alarm sounds
- The alarm remains active until manually suppressed by the user or the cause of the alarm ends.

Yellow: Dangerous Alarm – Medium Priority

The monitor recognizes a dangerous alarm condition (e.g. occlusion in sample lines)

A dangerous alarm shows a significant disturbance of the monitors functionality and has the following properties:

- The symbol in the parameter box or the status bar flashes yellow
- An acoustic alarm sounds
- The alarm remains active until the cause for the alarm ends.
- The alarm is put in the background if a life threatening alarm occurs

Yellow: Information – Low priority

The monitor informs about certain conditions of the system, a system component or a technical problem.

An information alarm has the following properties:

- The symbol in the parameter box or the status bar appears yellow
- A single alarm tone sounds
- The alarm is put in the background if a dangerous or life threatening alarm occurs
- The alarm remains active until the cause for the alarm ends

5.5.5. Activate and deactivate the alarm function

It is possible to completely deactivate the alarm function for audible alarms.



MIPM strongly recommends to leave the alarm function enabled! Alarms indicate critical conditions of the patient and the system. Thus alarms help to increase the awareness of the medical personnel and by that increase patients safety.

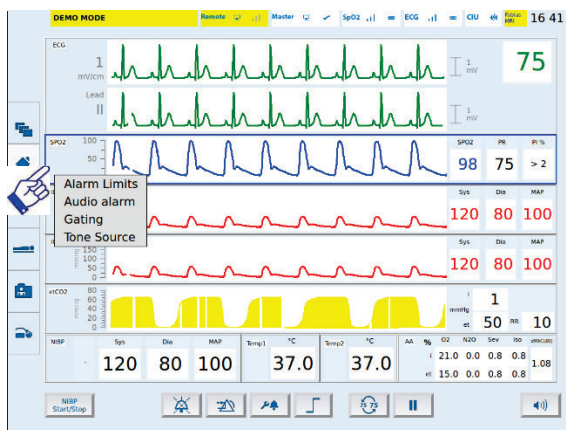
Do not suppress an alarm or disable the alarm function if the safety of the patient is compromised!

For more details see chapter 3.5.5 “Alarm function”

5.5.6. Activate and deactivate single parameter alarms

It is possible to deactivate the audible single parameter alarms.

You will find the “Alarm status” sub menu in every parameter menu. You can deactivate the audible alarm function of each parameter in that sub menu. After the audible alarms are disabled the flashing symbol “Bell cancel” as a reminder signal will appear. The flashing frequency is 1 Hz.

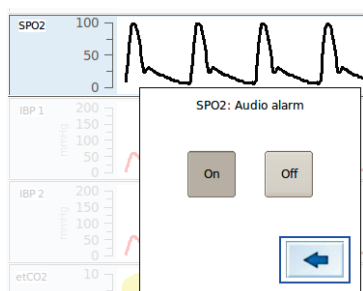


E.g. SpO₂ Parameter box

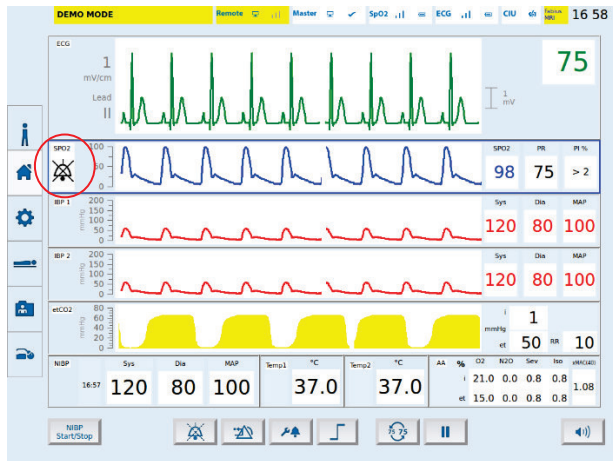
Press the parameter box of the parameter you want to change in the main screen.

The respective parameter menu opens.

Press the Alarm status bar.



Select the desired alarm status by pressing On or Off.



If the alarm function of a single parameter is deactivated you will see the Alarm function disabled icon left to the respective parameter box.

E.g. SpO₂


5.5.7. Alarm silence and the adjust alarm function

If an alarm occurs the monitor offer two possibilities.

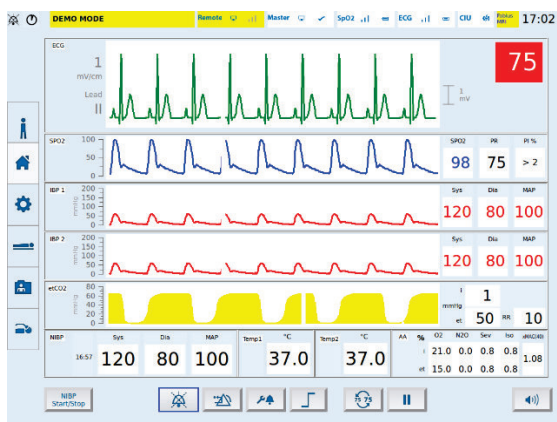
1. Activate Alarm silence within 120 seconds (Only the acoustic alarm is suppressed, the parameter box keeps flashing red)
2. Adjust the alarm limit using the adjust alarm function

Alarm silence:

If a parameter or system alarm occurs, you can suppress the alarm for 2 minutes by pressing the

Alarm silence icon () at the bottom of the main screen.

After the audible alarms are disabled the flashing symbol “Bell cancel” as a reminder signal will appear. The flashing frequency is 1 Hz.




During Alarm silence the alarm silence icon and a countdown will be displayed in the upper left corner of the main screen.



If the cause for the alarm is not eliminated within the 120 seconds the alarm tone sets in again.

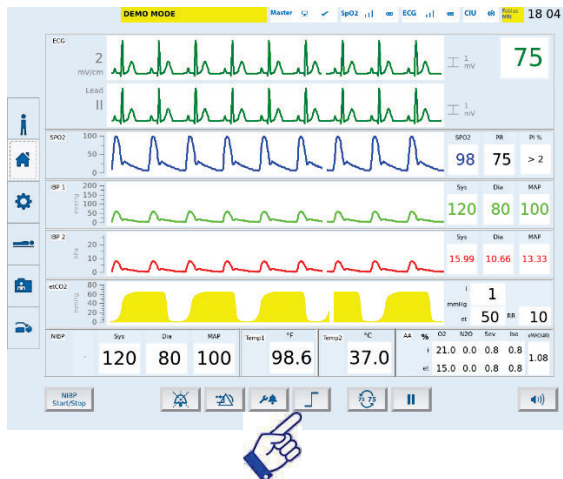
You can end the alarm silence manually by pressing the alarm silence icon at the bottom of the main screen or by pressing the symbol in the upper left corner of the display.

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.

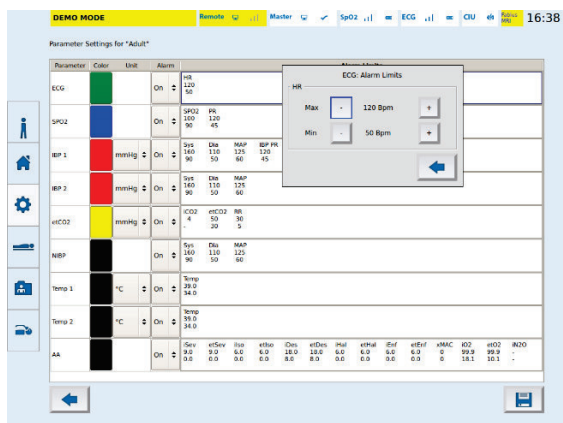
Adjust alarm:

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.

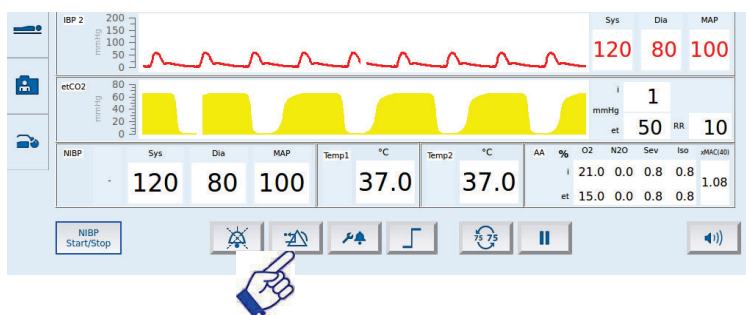
By pressing the adjust alarm icon you are immediately directed to the corresponding alarm limit menu that caused the alarm.



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.

5.6.1. Remarks ECG during MRI examination

During an MRI examination the ECG is exposed to strong interferences caused by the gradient system of the MRI scanner. *Tesla^{M3}* is equipped with a digital artifact filter. The filter enables an applicable ECG also during the scanning sequences. However the filter cannot eliminate all artifacts imposed by the scanner which leads to small deviances in the ECG reading from time to time.

Special attention needs to be paid to the placement of the ECG electrodes and the preparation of the patient's skin!



Do only use MRI compatible ECG electrodes! You can get details from the manufacturer of the electrodes. The MRI compatible ECG electrodes recommended by MIPM can be found in the accessories list in this user manual.



Due to the environment in the MRI room the ECG of this monitor is susceptible to artifacts. Thus, an advanced cardiac diagnostic cannot be performed with the *Tesla^{M3}*. If a patient is at risk of specific cardiac illnesses an appropriate diagnostic should be performed before or after the MRI scan.



The ECG cable is a conductive cable and should never be placed in loops. Loops in conductive cables may cause induction of current and heating of the cable.



0.125 mV is the minimum amplitude patients ECG signal required for the measurement. The drop below this value can lead to inaccurate measurements.



Due to electronic components in the enclosure of the ECG sensor the homogeneity of the magnetic field could be disturbed. Interference on the images could be the consequence. Please place the enclosure of the sensor out of the examination area with the spacing of at least 40 cm. Ensure that the enclosure of the sensor is not contacting the patient's bare skin e.g. by placing a tissue underneath or by placing it near the patient.



The device is not able to ensure adequate ST-segment reproduction.



The *Tesla^{M3}* is not intended to be used for patients with a pacemaker.

A pacemaker can result in inaccurate ECG readings, as the digital artifact filter may remove pacemaker pulses from the ECG waveform as they are similar to interferences from the gradient system.

The *Tesla^{M3}* does not influence the function and performance of the pacemaker and therefore poses no risk to the patient. Monitoring of other vital parameters is still possible.

Consider the general safety instructions for patients with pacemaker in the MR environment.



The enclosure of the ECG Sensor is not intended to have a direct contact with the bare skin of a patient.



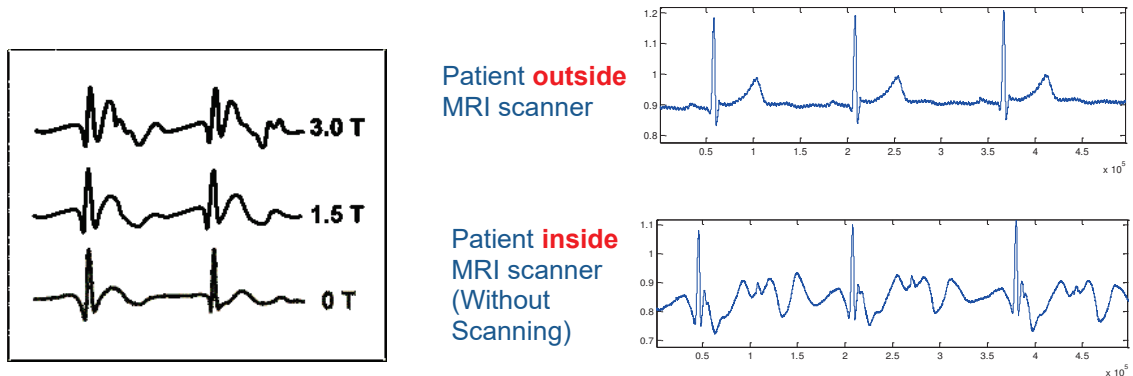
Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth.

ECG in the MRI is different from ECG in the nonmagnetic environment!

The ECG during MRI scans is susceptible to two major influences.

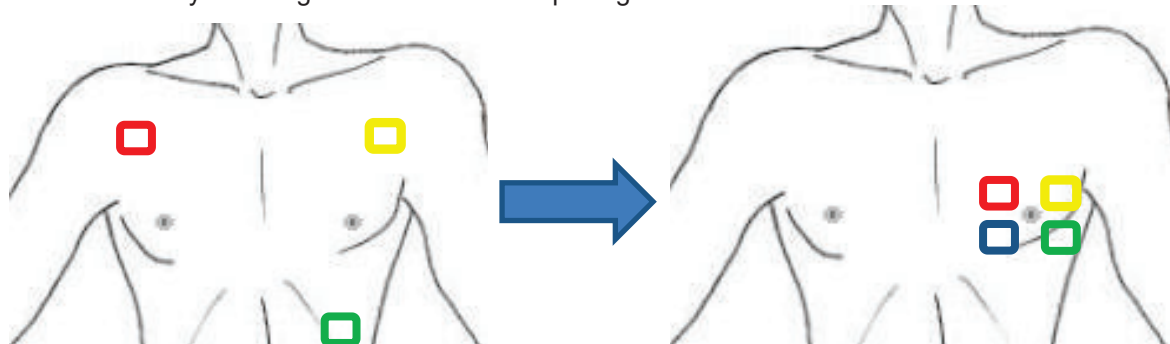
1. Static magnetic field

The magnetic field affects the shape of the ECG curve, especially the T-Wave



This effect depends on the magnetic field strength as well as electrode positioning. The magnetic effect increases with field strength and the distance between the ECG electrodes. The magnetic effect is always there independent of the actual scanning.

Since the strength of the magnetic field cannot be changed the magnetic effect on the ECG can only be minimized by reducing the inter electrode spacing.

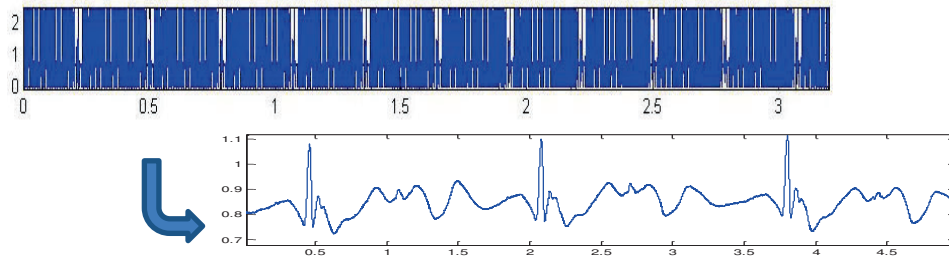


For description of ECG placing and skin preparation please see the chapter 5.6.2 "ECG electrodes and skin preparation".

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.

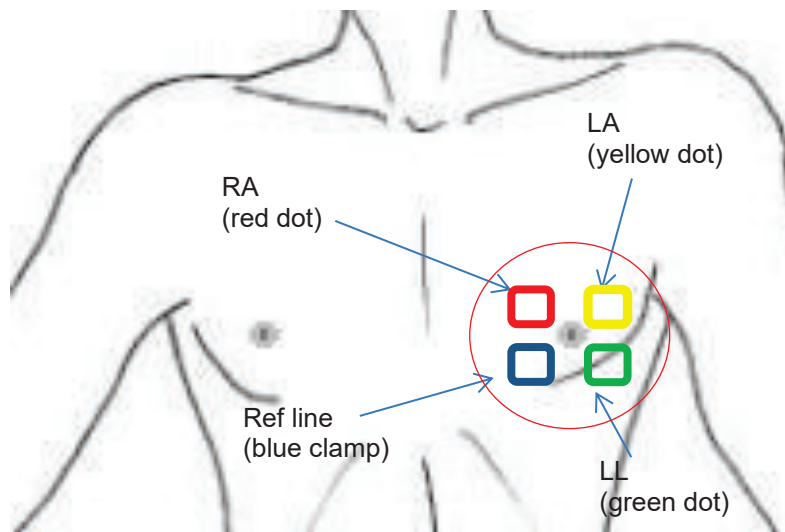
- Very hairy patients have to be shaved at the chest.

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)



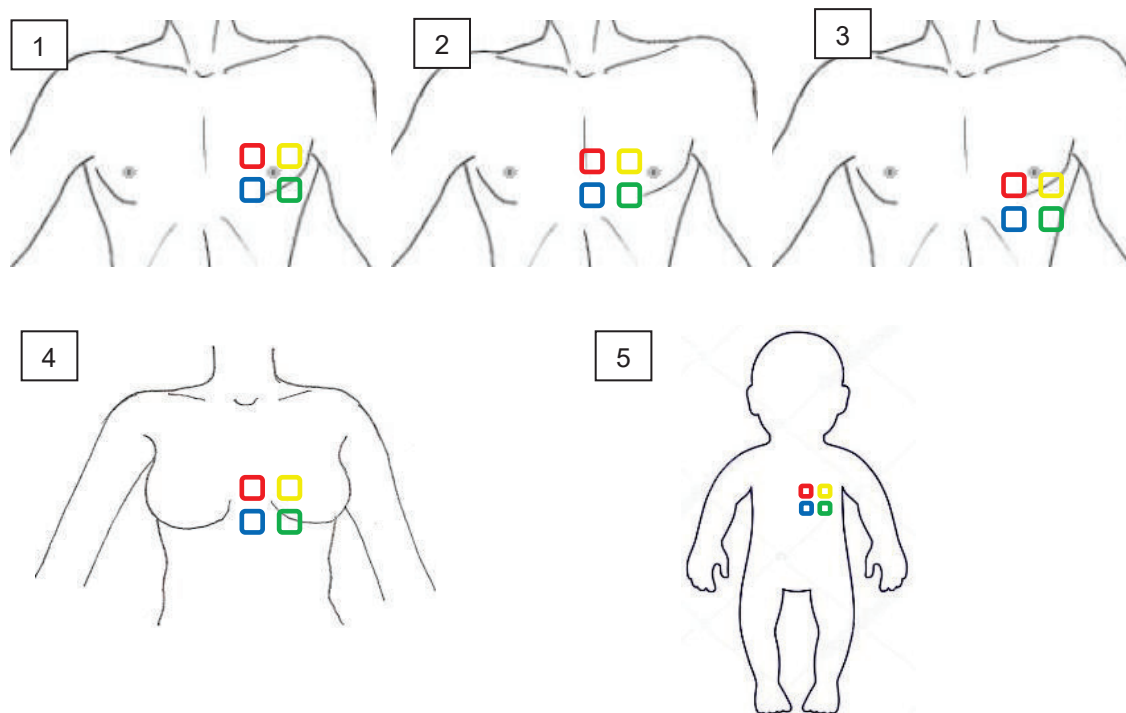
Rub the NUPREP gel in the skin gently using a paper towel.

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

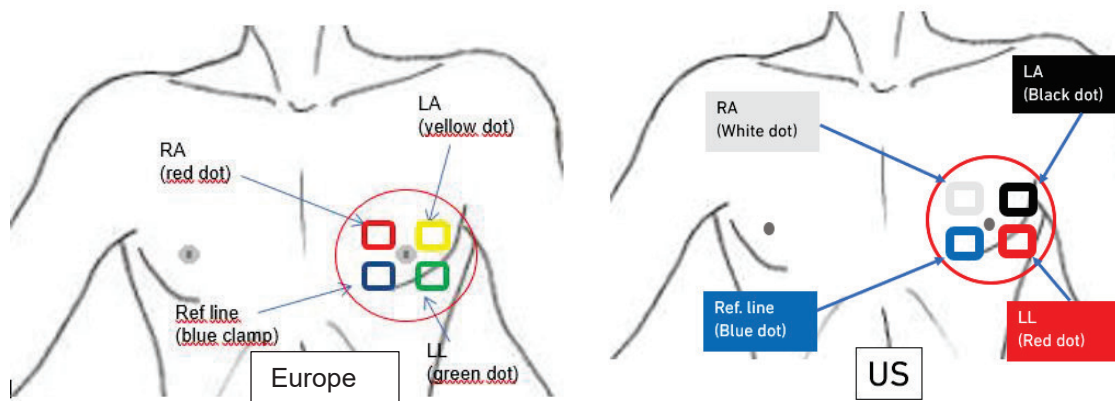
Remove remaining gel from the skin and place the ECG pads as shown in the picture.

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:



Connect snap connectors to the electrodes.



Europe: Red – RA, Yellow – LA, Green – LL, Blue – Reference electrode

US: White – RA, Black – LA, Red – LL, Blue – Reference electrode

If there are strong interferences/artefacts on the ECG curve another ECG lead or increasing/decreasing the amplitude of the ECG curve, see chapter 5.6.5 for choosing the ECG lead.

The distance between each electrode should be always 7 cm (2.75 inch) or smaller.

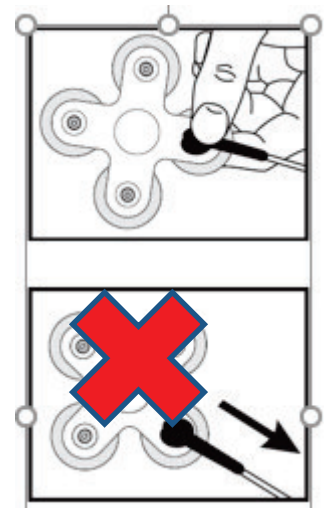
To ensure optimal impedance, the skin should be prepared before the ECG electrodes are placed. Use the NUPREP gel or another abrasive ECG gel.

Disposal:

- Dispose of as hospital contaminated waste, in accordance with regulations in force.
- Recycle package.

Caution:

- Due to high adhesion strength of the adhesive material, this product is not suitable for use on patients with fragile skin. Not suitable for use on newborn or premature infants.
- Plastic cover should be immediately disposed of in the assigned waste bin for disposal after removal of electrodes.
- Gentle retrieval of electrodes from the pouch to be ensured, to prevent any injury through a cut with the plastic cover.
- For use only on intact, clean skin (do not use on open wounds, lesions, infected or inflamed areas).
- The product is not for internal use. In case of accidental ingestion of the electrode consult a physician immediately.
- For single use only. Use on other patients can cause cross infection. Do not soak, rinse, or sterilize this device, as these procedures may leave harmful residues or cause malfunction of the device. The design and materials used are not compatible with conventional cleaning and sterilization procedures.
- Careless removal of electrode may cause damage to the skin. Should the electrode be difficult to remove, use water to dissolve the adhesive.
- Do not use if the gel is dry or discoloured.
- US: Rx only



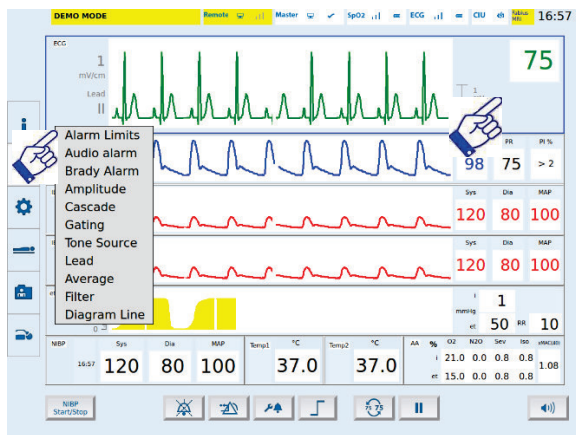
Precaution:

- Do not use the electrodes if the pouch is found damaged.
- In the event of use over extended period, check for secure adhesion and absence of skin reaction on a daily basis.
- During surgical procedures electrodes should be placed as far as possible from the electro-surgical area to minimize unwanted RF current flow.
- It is important to be aware that the MR Conditional marking applies only to the electrodes and not to any monitors, cables or lead wires, which may be attached to the electrode. Place the electrodes and electrode lead wires according to local safety guidelines for recording ECG in an MRI environment. The MR Conditional electrode shall only be used with lead wires compliant with use in an MRI environment.

Storage:

- Store in original packaging protected from weather and within the indicated temperatures.

5.6.3.The ECG menu



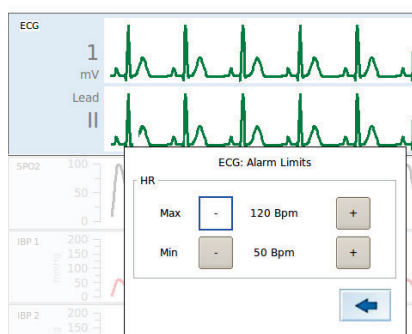
All relevant settings concerning the ECG may be changed in the ECG menu.

To open the ECG menu press the touch screen inside the ECG parameter box.

➤ An averaging function can be applied to the ECG Heart rate for a more stable output.

5.6.4.Setting the alarm limits

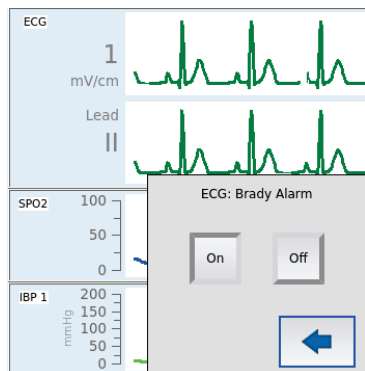
Press the alarm limits bar in the ECG menu.



In the sub menu „Alarm limits“ you can change the upper and lower heart rate limit by pressing the +/- icons. Pressing the icon once changes the value by 1 bpm. Holding the icon changes the values faster.

To exit the Alarm limits menu press the back icon.

5.6.5. Activating and Deactivating of Bradycardia alarm



Activate or deactivate the Bradycardia alarm for the investigation



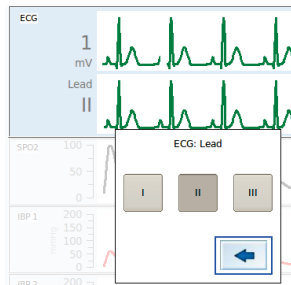
The alarm is activated automatically after restarting the system.



The alarm may only be muted by qualified personnel and only if the patient is monitored directly by a physician.

5.6.6. Choosing the ECG lead

Press the Lead bar in the ECG menu.



Select the favored lead by pressing the respective icon in the sub menu.

To exit the ECG lead menu press the back icon.

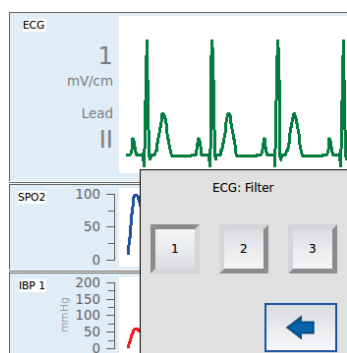
Color code of the ECG cable connectors: the connectors of the ECG lead are marked with the international accepted color code.

Europe: Red – RA, Yellow – LA, Green – LL, Blue – Reference electrode

USA: White – RA, Black – LA, Red – LL, Blue – Reference electrode

If the configuration as shown in the picture above is selected (White – RA, Black – LA, Red – LL) select lead II.

5.6.7. Activating the ECG-Filter



To activate the filter press on

the ECG window in the main screen.

In the menu you can select the three filter options.

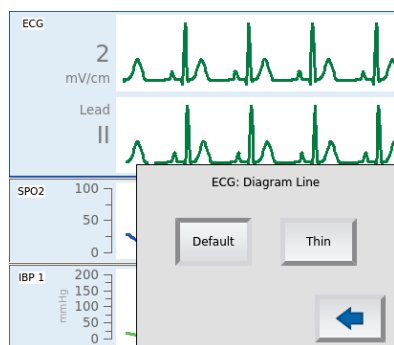
To exit the Filter sub menu press the back icon.



The ECG filter menu appears only in connection with ECG sensors starting from PV5. With older sensors a filter switching is not possible.

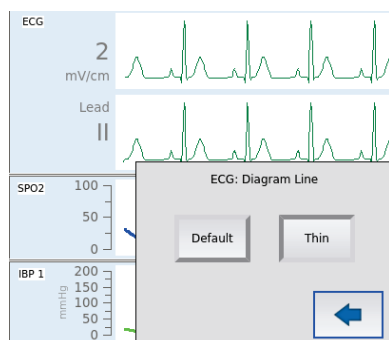
Filter#	Description
1	Standard MIPM MR-Filter (which is also available in the old sensor generation)
2	New MIPM MR-Filter (only in connection with PV5 ECG sensors)
3	Norm Filter according to IEC 60601-2-27

5.6.8. Changing the line widths of the diagram line



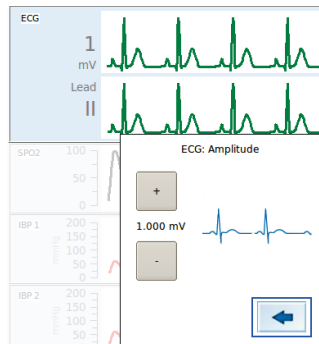
To meet the requirements of IEC 60601-2-27, the diagram line of the ECG can be switched between thin and default.

The standard diagram line is always selected as default.



5.6.9. Changing the ECG amplitude

Press the Amplitude bar in the ECG menu.



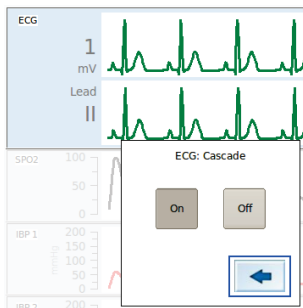
Change the amplitude of the ECG curve by pressing the +/- icons
You can select between the following scales [mV/10mm]:
0.25 – 0.5 - 1- 2 - 4mV

To exit the Amplitude sub menu press the back icon.
(setting is persistent after restart)

5.6.10. ECG Cascade mode

The ECG curve in the upper parameter box displays ECG data of approximately 10 seconds. In cascade mode the ECG is continued in the second ECG parameter box. If cascade is activated the monitor displays approximately 20 seconds of data. The ECG cascade can be turned on or off manually at any time.

Press the Cascade bar in the ECG menu.



Activate or deactivate the cascade mode by pressing the respective icon in the sub menu.

To exit the Cascade sub menu press the back icon.

5.6.11. Choosing the pulse tone source

The pulse tone may be created by the ECG or the SpO₂ readings.

Press the Tone Source bar in the ECG menu.



Press the ECG icon if the pulse ton should be generated by the ECG and the SpO₂ icon if the pulse tone should be emitted by the SpO₂ reading.

Only one tone source can be selected!

To exit the tone source sub menu press the back icon.



A pulse tone is only generated if the parameter of the selected tone source is measured.
e.g. If ECG is selected as tone source and the ECG is not connected to the patient the monitor will not generate a pulse tone.

5.6.12. Cardiac Gating function

The *Tesla^{M3}* supports ECG triggered MRI examinations. You can connect the *Tesla^{M3}* to the gating interface of the MRI scanner in order to synchronize the scanning sequences with the ECG of the monitor.

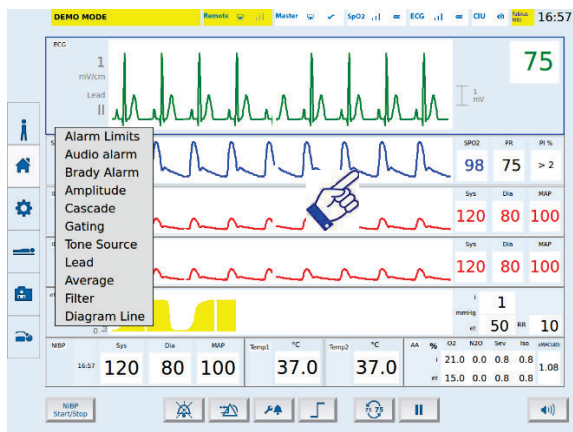
Every QRS complex (trigger point = R) creates a trigger signal which can be used to align the scanner with the patient's heartbeat. For more detailed information about the trigger signal please contact your local service partner or MIPM.

Press the Gating bar in the ECG menu.



Select the source for the trigger signal by pressing the respective icon in the sub menu. By pressing Off the gating function is deactivated.

To exit the Gating sub menu press the back icon.



To exit the ECG parameter menu press any place outside the ECG parameter box in the main screen.

5.7. SpO₂ Monitoring

SpO₂ monitoring is a non-invasive method to determine the oxygen saturation of the arterial blood as well as the pulse rate. SpO₂ is indicated as functional oxygen saturation. It has been calibrated exemplarily. A sensor (in general attached to the finger) measures the absorption of infrared light going through the tissue caused by oxyhemoglobin. The light received by the sensor is transformed in a signal which is processed by the monitor.

The *Tesla^{M3}* offers the following monitoring parameters based on SpO₂ monitoring.

- Display of the SpO₂ wave form
- Calculation of the pulse rate
- Alarm if the oxygen saturation violates a preset alarm limit
- Alarm if the pulse rate violates a preset alarm limit

➤ Alarm signal generation delay, alarm condition delay, data update period, data averaging and other signal processing effect displayed and transmitted SpO₂ and pulse rate data. A SpO₂ or a pulse rate change is displayed within 30 seconds.

➤ Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ± 2 Arms of the value measured by a co-oximeter.



SpO₂ readings strongly depend on the correct placement of the sensor and the condition of the patient. Shiver, strong movements, or inhalation of smoke may cause incorrect measurements. If SpO₂ readings seem to be incorrect check the oxygen saturation values with an alternative clinically proven method like blood gas analysis.



You may use the SpO₂ sensor on adults, pediatrics and neonates. Do only use original MIPM SpO₂ sensors. The use of any other SpO₂ sensor not approved by MIPM may lead to incorrect measurements!



Misapplication of the SpO₂ sensor with excessive pressure for prolonged periods can induce pressure injury.



Misapplication of a pulse oximeter probe with excessive pressure for prolonged periods can induce pressure injury. Check sensors periodically (recommended is at least every four hours). Move the sensor if there is any sign of skin irritation or impaired circulation.

We recommend a maximum application time of 4 hours with the wireless pulse oximetry sensor POAP2 in one place



The enclosure of the SpO₂ Sensor is not intended to have a direct contact with the bare skin of a patient.

5.7.1. Remarks SpO₂ monitoring during MRI examination

The sensor cable is made of optic fibers. Thus the sensor can be used in the MRI environment without causing artifacts or being attracted by the scanner. Please handle the sensor carefully! Do not kink or wind up the sensor cable. Do not step on the sensor cable!

If the sensor is not in use please place it in the charging bracket on the back side of the monitor.



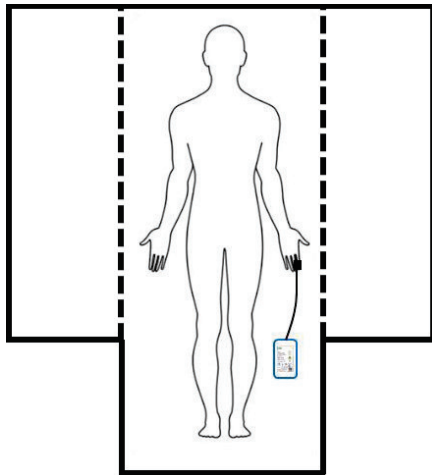
Avoid direct contact of the sensor with the inside wall of the bore. During the MRI examination the scanner produces heavy vibrations which may disturb the functioning of the SpO₂ sensor and thus lead to incorrect SpO₂ readings. Place the sensor on a cushioned surface to minimize vibrations.



Do not place the sensor under a receiver coil of the scanner. This may lead to bad connection between the sensor and the *Tesla*^{M3} and bad image quality.



Due to electronic components in the enclosure of the SpO₂ sensor the homogeneity of the magnetic field could be disturbed. Interference on the images could be the consequence. Please place the enclosure of the sensor out of the examination area with the spacing of at least 40 cm.

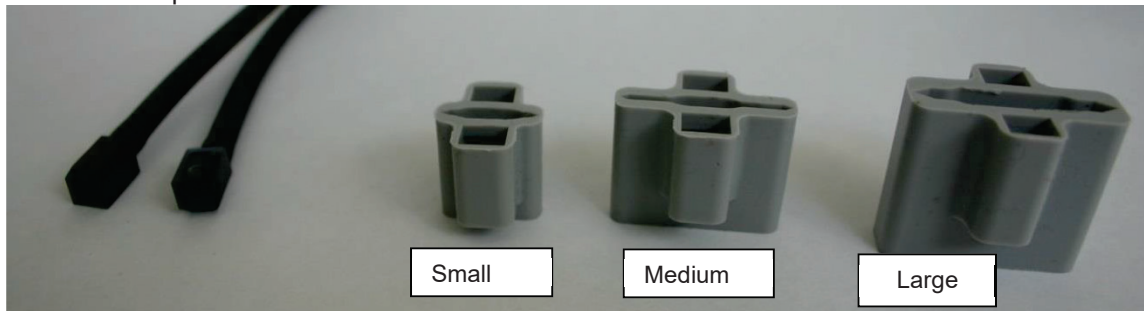


To ensure the best performance, use the following specific positioning considerations when placing the wireless Pulse Oximetry Sensor in the MR environment:

- Place the Wireless Pulse Oximetry Sensor near the patient as shown in the image
- Ensure that the enclosure of the sensor is not contacting the patient's bare skin.
- Place the Wireless Pulse Oximetry Sensor on a cushioned surface to minimize MR vibrations

5.7.2. Soft touch finger adapter – Placing the SpO₂ sensor

The SpO₂ sensor can be used for adult, pediatric and neonatal patients. In order to monitor the three patient groups 3 different sizes of the soft touch adapter (Ref: 5010012) are available and two additional adapters:



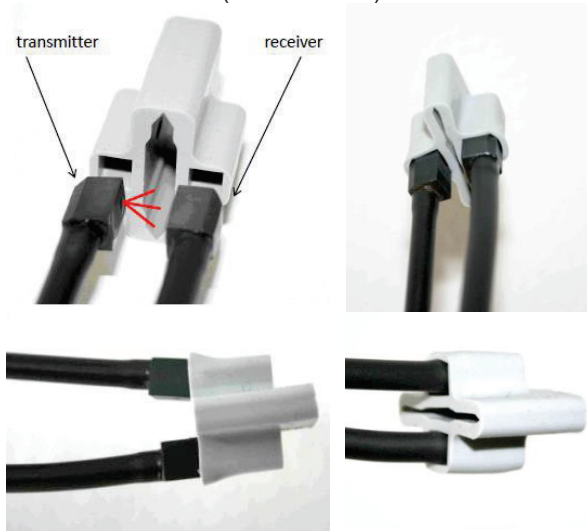
SpO₂ Clip Adapter (Ref: 5010103)



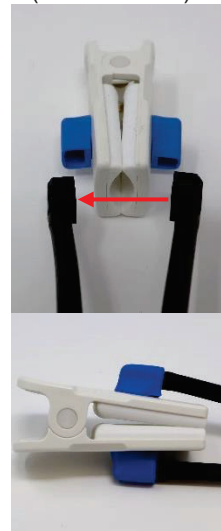
SpO₂ Adapter M-Flex (Ref: 5010049)

Change the finger adapter as shown below:

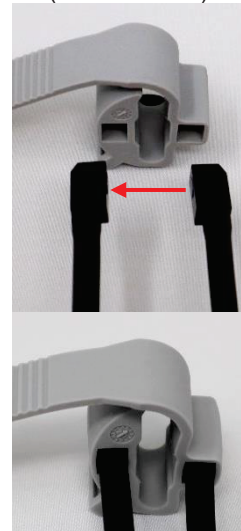
SpO₂ Adapter – Basic (Large, Medium, Small)
(Ref: 5010012)



SpO₂ Clip Adapter
(Ref: 5010103)



SpO₂ Adapter M-Flex
(Ref: 5010049)

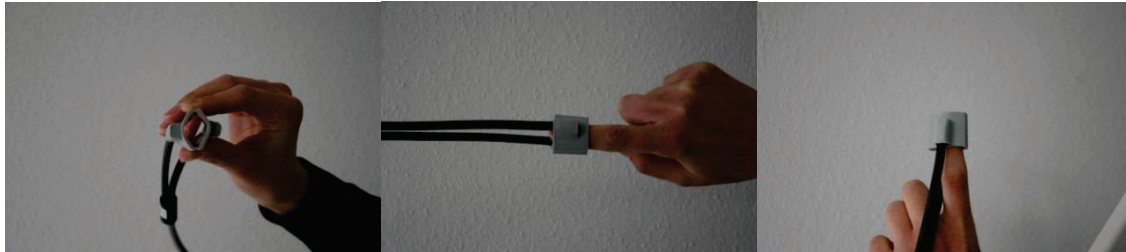


- Make sure the two LEDs (flat side of the bracket) face each other
- Insert the loose ends of the sensor to the finger adapter as shown on the picture
- Make sure to insert the sensor as far as it will go.
- To remove the adapter from the sensor, hold the back ends of the adapter and swiftly pull the adapter.

Correct placement of the SpO₂ sensor is vital for successful SpO₂ monitoring!

SpO₂ Adapter – Basic (Large, Medium, Small) (Ref: 5010012):

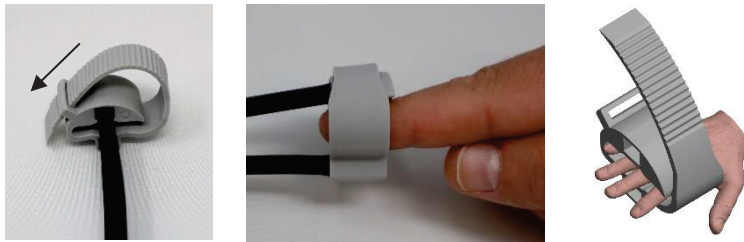
You can now insert the patient's finger from both sides of the finger adapter. Make sure that the fingernail faces the transmitter LED (see picture). The finger should not stick out of the sensor regardless from which side the finger was inserted. This way you can ensure that both, transmitter and receiver LED are in the middle of the fingernail thereby ensuring an optimal signal.



SpO₂ Clip Adapter (Ref: 5010103):



SpO₂ Adapter M-Flex (Ref: 5010049):



Successful SpO₂ monitoring:

Please observe the following advice:

- Always place the sensor on an extremity with good perfusion
- Do not place the sensor on an extremity where perfusion may be compromised, e.g. through a blood pressure cuff
- Do not fix the sensor too tight using tapes or clamps
- Do not fix the sensor to an extremity where electrical interferences may occur
- Do always read the user manual before using the SpO₂ sensor

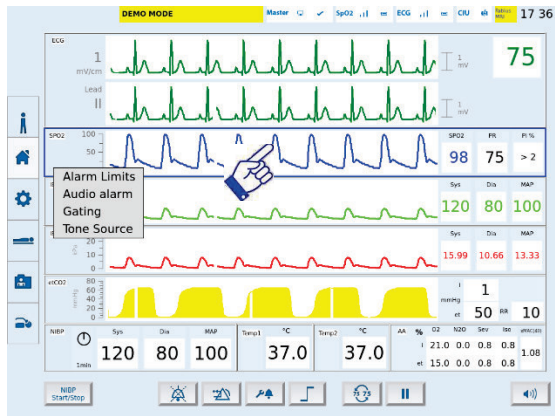


Do not open the housing of the SpO₂ sensor. This is only allowed to technical personnel authorized by MIPM. Unauthorized opening of the sensor housing leads to loss of any warranty claims and may damage the sensor!



The sensor is equipped with a rechargeable Lithium polymer battery. Do not remove the battery! Broken sensors may not be disposed in the regular waste. If a sensor has to be replaced dispose the broken sensor through an authorized person or send the sensor back to MIPM or an authorized service partner!

5.7.3.The SpO₂ menu

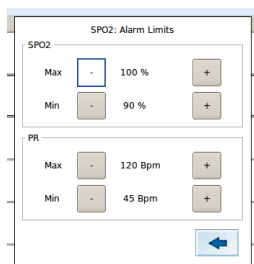


All relevant settings concerning the SpO₂ may be changed in the SpO₂ menu.

To enter the SpO₂ menu press the touch screen somewhere inside the SpO₂ parameter box.

5.7.4.Setting the alarm limits

Press the alarm limits bar in the SpO₂ 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.

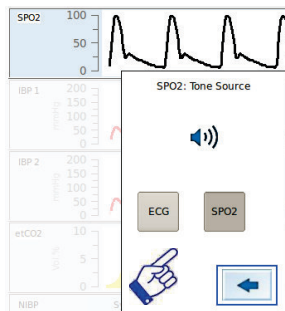
To exit the alarm limits sub menu press the back icon.

5.7.5.Changing the SpO₂ scaling

The SpO₂ module has an auto scaling function. The scaling of the SpO₂ waveform cannot be changed manually.

5.7.6.Choosing the pulse tone source

Press the tone source bar in the SpO₂ menu.



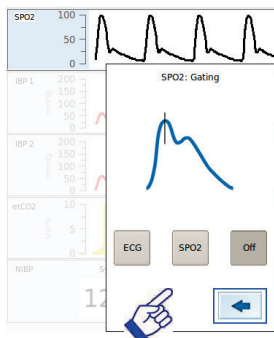
Press the ECG icon if the pulse tone should be generated by the ECG and the SpO₂ icon if the pulse tone should be emitted by the SpO₂ reading.

Only one tone source can be selected!

To exit the tone source sub menu press the back icon.

5.7.7.The SpO₂ gating function

Press the Gating bar in the SpO₂ menu.



Select the source for the trigger signal by pressing the respective icon in the sub menu. By pressing Off the gating function is deactivated.

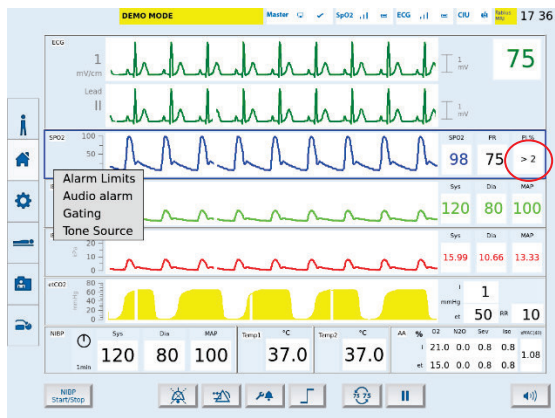
To exit the Gating sub menu press the back icon.

➤ SpO₂ gating is not supported by all MRI scanner manufacturers. Please ask MIPM or your local partner for more information.

5.7.8. Perfusion index and signal inadequacy indicator

The SpO₂ module of the *Tesla^{M3}* calculates the perfusion index. The PI gives an indication about the quality of the SpO₂ signal. PI can take values between 0.2 and 20. Any value greater than 1 guarantees reliable SpO₂ readings.

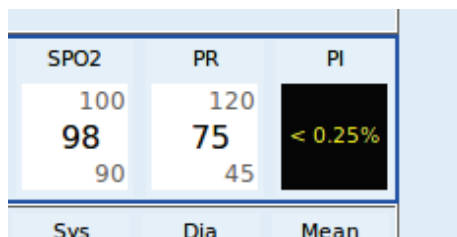
The perfusion index can be activated / deactivated in the SpO₂ menu.



If the PI is activated it will be displayed in the SpO₂ parameter box to the right of the pulse value.

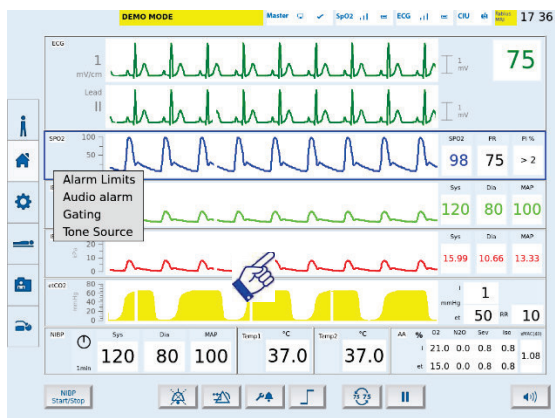
Tesla^{M3} shows the following PI values:

- < 0.25 %
- < 0.5 %
- < 1%
- > 1%
- > 2%
- > 4%
- > 8%



If PI <1 is calculated the display color changes to yellow on a black ground.

The color goes back to normal as soon as PI >1 is calculated.



To exit the SpO₂ menu press any place outside the SpO₂ parameter box on the main screen.

Signal inadequacy indicator:

The waveform of the signal is not normalized and can be used as the signal inadequacy indicator.

5.8. Noninvasive blood pressure (NIBP)



Before monitoring noninvasive blood pressure please read the NIBP safety advice (below).



**Before monitoring pediatric or neonatal patients observe the following advice:
Choose correct cuff size!
Select pediatric or neonatal patient mode. This protects children from excess cuff pressure!**



MIPM recommends NIBP calibration as a part of the regular safety check and additionally if the accuracy of the NIBP measurements is at question. NIBP calibration should only be carried out by a trained technical professional.

Tesla^{M3} receives noninvasive blood pressure values from the NIBP module and displays the values in the main screen. Blood pressure readings with this monitor are generated using the oscillometric method. The measurements comply with intra-arterial measurements within the guidelines of the Association for Advancement of Medical Instrumentation, Electronic Sphygmomanometers (AAMI/ANSI SP-10)

If a pressure value cannot be generated due to patient movements or improper cuff placement the cuff is deflated and a second attempt is carried out.

Tesla^{M3} displays the systolic, diastolic and mean NIBP values (mmHg) in the NIBP parameter box.

The quality of NIBP monitoring depends largely on the quality of the signals received by the monitor. For this reason, it is important to choose the correct cuff size for your patient. Cuff sizes are clearly marked on the cuff. Measure the circumference of your patient's limb. Use only MIPM-approved cuffs with your monitor (see the chapter 8 "Accessories").

If a malfunction is detected by the monitor or unexpected readings are obtained, the operator should observe details of alarm system. For further information refer to chapter 5.5 Alarms.

NIBP safety advice:



The cuff should be placed on the height of the heart. For any deviance of 2 cm (1 inch) above that height 1.4 mmHg should be added to the measurement value. For any deviance of 2 cm (1 inch) below that height 1.4 mmHg should be subtracted from the measurement value.

The blood pressure reading can also be affected by the measurement site, the position of the patient (standing, sitting, lying down), exercise, or the patient's physiologic condition.

The performance of the NIBP measure can be affected by extremes of temperature, humidity and altitude.



The NIBP tube should not be kinked or blocked! The cuff should not be placed on an extremity that is already used for infusions.



In some cases, rapid and prolonged measurements can result in petechia, ischemia, purpura or neuropathy. MIPM recommends that you apply the cuff appropriately and that you check the cuff site regularly when monitoring at frequent intervals or over extended periods of time. In addition, check the patient for signs of impeded blood flow in the limb. The application of the CUFF and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present, could result a temporary interference to blood flow and in injury to the patient.

The application of the CUFF on the arm on the side of a mastectomy could lead to pressurization.

For patients who have had a mastectomy or lumpectomy, do not use the involved arm(s) for NIBP if there is lymphedema.

Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb.



NIBP measurements may not be accurate with convulsive patients or patients with tremors.



NIBP is not intended for use with pregnant, including pre-eclamptic, patients.



For use only on intact skin (do not use on open wounds, lesions, infected or inflamed areas).



CAUTION: Do not allow the tube or cuff to get in contact with fluids. Check the hose and cuff frequently for signs of damage and debris. An obstruction in the hose may cause the cuff to inflate and deflate improperly and may result in inaccurate readings.



NOTES: To obtain accurate blood pressure readings, keep the limb and cuff motionless. To protect patients from extremely high cuff pressures and extended cuff inflation, the cuff deflates automatically in the following conditions:

- The cuff pressure exceeds over 300 mmHg in Adult- / Pediatric mode, or over 150 mmHg in neonatal mode.
- The measurement takes longer than 2 minutes
- A technical alarm has occurred.

5.8.1. Remarks NIBP during MRI examination

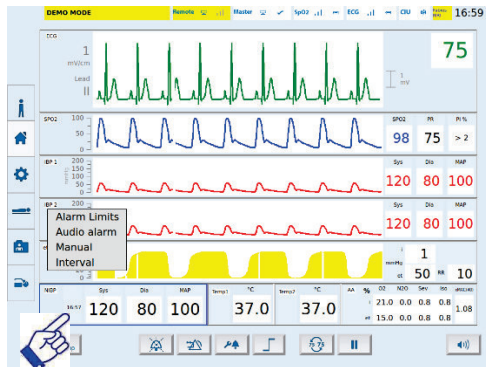


Avoid any contact between the NIBP cuff and the inside wall of the scanner tube. Heavy vibration during the scan may cause false readings or abortion of the measurement.



Make sure that the NIBP tube is not kinked through a receiver coil of the scanner. Make sure that the NIBP tube is not placed in the runner of the examination table. During the MRI examination the table of the scanner is subject to movements. This may cause damage of the NIBP tube. Replace defective NIBP tubes immediately to ensure accurate NIBP readings.

5.8.2.The NIBP menu



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

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

Parameter explanations:

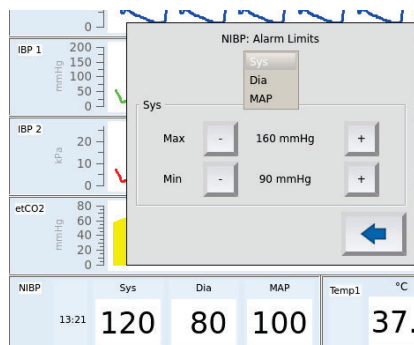
Sys: Systole → Maximum blood pressure due to heart muscle contraction

Dia: Diastole → Minimum blood pressure due to heart muscle relaxation

Map: Middle artery pressure → Average between systolic and diastolic blood pressure

5.8.3.Setting the alarm limits

Press the Alarm limit bar in the NIBP menu.



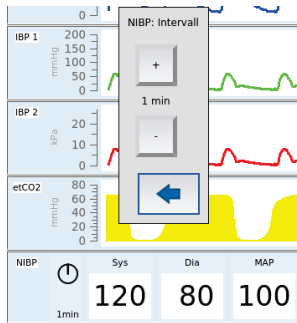
In the upper part of the menu box you will see a drop-down list. Select Sys, Dia, or Mean according to the limits you want to change.

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.

5.8.4. Setting the NIBP measurement interval

Press the Interval bar in the NIBP menu.



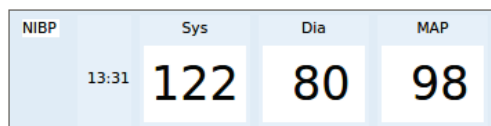
Press the +/- icons, to increase / decrease the measurement interval.

The following intervals are available: 1, 2, 3, 5, 10, 15, 30 minutes.

To exit the Interval sub menu, press the back icon.

5.8.5. Timestamp of last valid NIBP measurement

In manual measuring mode, there is a timestamp next to the NIBP "Sys" value.



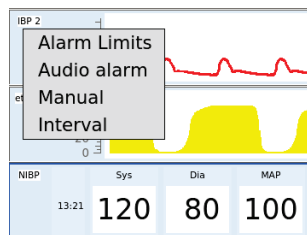
The timestamp shows the time of the last successful NIBP measurement, performed in either manual or interval mode.



The timestamp is only displayed in manual measuring mode, since there is a pie diagram indicating the time until the next measurement in interval mode.

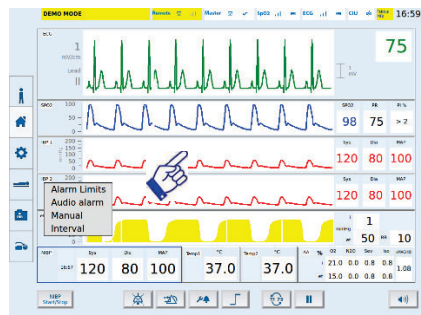
5.8.6. Automatic / Manual measurements

Press the Automatic or Manual bar in the NIBP menu



In manual measuring mode, a measurement is started by pressing the “NIBP Start/Stop” button.

For automatic measurements, a measurement interval has to be set. Press the “NIBP Start/Stop” button to begin the cycle. Each following measurement will be performed automatically after the interval you have specified.



To exit the NIBP menu press any place outside the NIBP parameter box on the main screen.

5.8.7. Operating steps

1. Ask the patient to sit or lie down. The limb should be relaxed, extended and placed on a smooth surface for support: legs uncrossed, feet flat on the floor, if seated. Back and arm should be supported.
2. Place the cuff at 2 to 5 cm above the elbow crease (or in the middle of the back of the thigh).
3. Place the Artery «. marker over the artery, pointing to hand or foot. After applying the cuff, the marker "index line" has to be located in the given zone, which is labelled "Area".
4. Wrap the deflated cuff snugly around the limb without impeding blood flow.
5. CAUTION: the patient should relax as much as possible and not talk or move upon inflation of the cuff.
6. Five min should elapse before the first reading is taken.
7. Operator should be near to monitor and patient to attend them in normal use.

5.9. Invasive blood pressure (IBP)

You can monitor arterial and venous blood pressure. *Tesla^{M3}* offers the following monitoring functions:

- Continuous display of a pressure curve
- Display of systolic, diastolic and mean blood pressure
- Display of heartrate

The monitor is equipped with up to 2 invasive blood pressure channels.

Measurements are displayed in mmHg or kPa.

5.9.1. Remarks IBP during MRI examination



Make sure that the IBP transducer is not placed closer to the MRI scanner than the *Tesla^{M3}*. Otherwise the IBP measurement will be inaccurate or lead to a malfunction. The tubing system should not be placed near the runner of the examination table. During the MRI examination the examination table is subject to movements. This may destroy the IBP pressure tubing system.

5.9.2. Use of IBP transducers

The quality of pressure monitoring depends on the quality of the signals received by the monitor. To maximize the strength of the pressure signal when it reaches the transducer, assemble the tubing system carefully following the application techniques of your hospital. Noise and motion artifact as well as air bubbles in the tubing system distort the signal and give inaccurate measurements. Consider the following:

1. Select a high pressure tubing system (soft/pliable tubing dampens and distorts the signal).
2. Select the shortest possible length of tubing to preserve signal strength and minimize motion artifact.
3. Follow your hospital procedures in assembling the tubing system.



Tubing, transducers or cables that have changes in performance as a result of ageing and environmental conditions must be considered critically. The manufacturer's instructions as replacing of affected parts must be followed.

MIPM recommends the replacing of the interface cable in the event of changes in performance as a result of ageing and environmental conditions.

You may use standard IBP transducers with the *Tesla^{M3}*. MIPM tested and approved a choice of IBP transducers. A list with approved IBP transducers can be found the accessories section. A cable that matches your standard transducer is included in the sales package.



The *Tesla^{M3}* may be operated during defibrillation but the parameter values may be biased for a short period. To ensure patient safety, interference free performance of the *Tesla^{M3}* do only use original MIPM accessories such as IBP Interface Cable and original IBP transducers are listed in the accessories section.

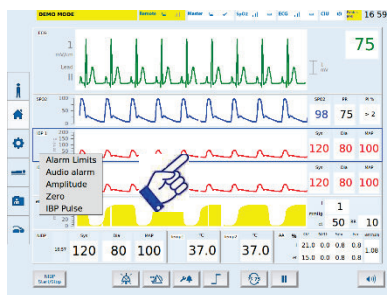
5.9.3. Connecting the IBP with the *Tesla*^{M3}

Connect the IBP connection cable with your IBP transducer. Then plug the cable with into the IBP connector at the back side of the *Tesla*^{M3}.



If the IBP connection cable or IBP transducer are damaged (short or open circuit), the technical alarm “cable fail” appears. The alarm can be cleared by replacing the damaged part and restarting the system.

5.9.4. The IBP menu

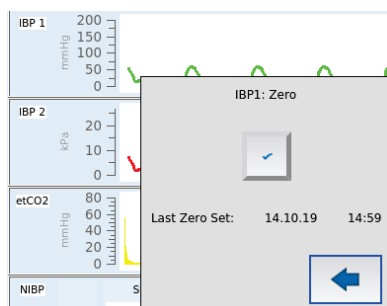


All relevant settings concerning the IBP may be changed in the IBP menu. To enter the IBP menu press the touch screen somewhere inside the IBP parameter box.

If your monitor is equipped with two IBP channels you can change the settings for each channel separately. To enter the respective IBP menu press the corresponding parameter box of the IBP channel you want to change.

5.9.5. Zeroing and calibration check

The *Tesla*^{M3} automatically records if an IBP system is connected. If an IBP transducer is recognized you are automatically directed to the zeroing sub menu.



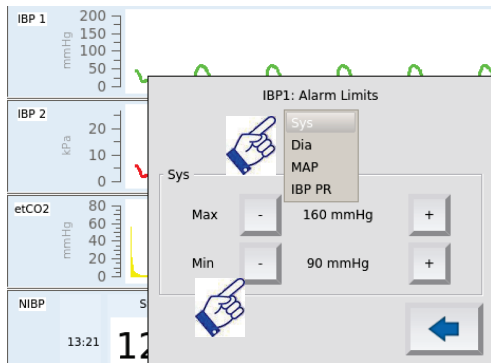
The IBP zeroing sub menu is displayed on the main screen.

- Re-align the transducer to the patient's heart level.
- Close the transducer stopcock to the patient.
- Open the venting stopcock to air (atmosphere).
- The monitor displays a flat waveform and a static IBP condition for the systolic (S) value.
- Press the checkmark to start the zeroing process

If the zeroing was successful you will see a confirmation with time stamp in the Zero sub menu. If the zeroing process hasn't been successful you will get an error message. Check your IBP tubing system and repeat the process.

5.9.6. Setting the alarm limits

Press the Alarm limit bar in the IBP menu.



In the upper part of the menu box you will see a drop-down list. Select Sys, Dia, Mean or Puls Rate according to the limits you want to change.

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.

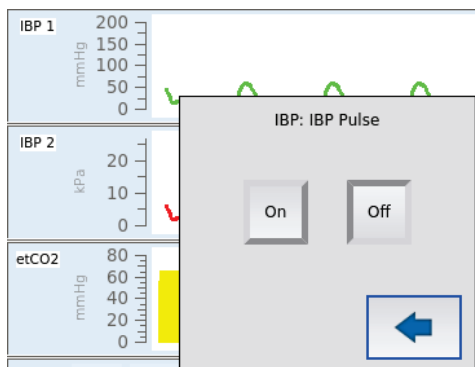
To exit the alarm limits sub menu press the back icon.



The setting of the alarm limits for IBP Pulse Rate can only be selected and changed under IBP1 Alarm limit menu

5.9.7. IBP Pulse Rate

Press the IBP Pulse bar in the IBP menu.



You can enable or disable the output of the IBP Pulse Rate.

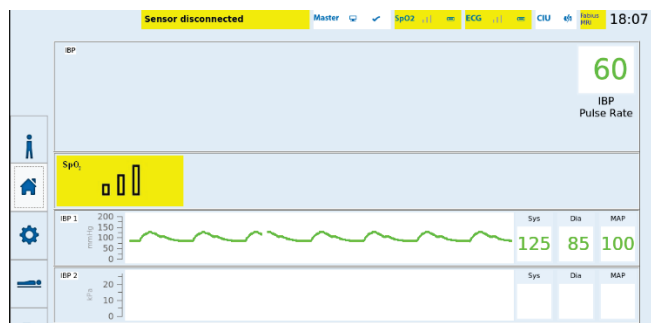


The IBP pulse rate is only output if no ECG sensor is active. As soon as an ECG sensor is active, the heart rate of the ECG is output as usual.



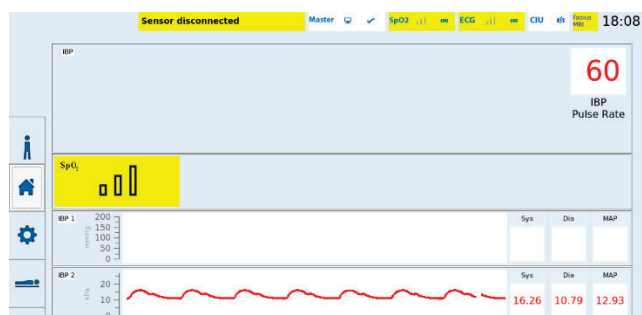
If all two IBP channels are used, only the pulse rate of one IBP channel with the better signal will be output.

The IBP pulse rate is displayed in the ECG field.



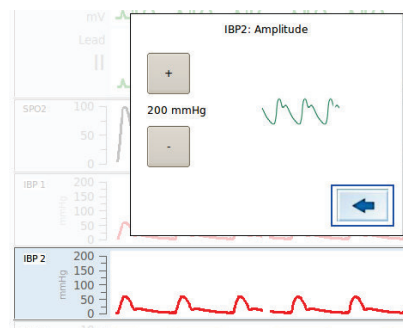
The IBP pulse rate has the same color as the IBP channel.

The ECG field is labeled IBP when the ECG sensor is disabled.



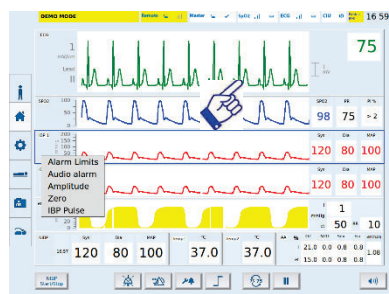
5.9.8.Changing the IBP scaling

Press the Amplitude bar in the IBP menu.



Change the amplitude of the IBP curve by pressing the +/- icons. The value of the scale depends on the measurement unit that is applied.

To exit the Amplitude sub menu press the back icon or any other place in the main screen.



To exit the IBP menu press any place outside the IBP parameter box on the main screen.

5.10. Multigas Module

The Multi Gas Module samples breathing gases from adult and pediatric patients in non-, partial- and total rebreathing systems at a sample flow rate of approximately 200 ml/min. The module measures inspiratory and expiratory gases and communicates both real-time and derived gas information to the monitor.

If the monitor is equipped with Multigas variant capnography measurement only, nothing is displayed in the fields for N₂O, anaesthetic agents (AA) and MAC value calculation.

The module is thus equipped with automatic barometer pressure compensation.



If the Multigas module is used in neonatal patient mode, please keep in mind: The sample rate of the Multigas module is 200 ml/min. This may affect your decision of the appropriate ventilation mode.

For the measurement of CO₂ and volatile anesthetics, the Multi Gas Module draws a small amount of the patient's respiratory gas through a measuring chamber. It then shines an infrared light through the chamber which the sample gas components absorb in different amounts, depending on the gas concentrations. For the measurement of O₂, the Gas module uses a paramagnetic cell that produces a physical reaction proportional to the O₂ concentration.



The displayed gas information is intended to be used by trained and authorized health care professionals only.

The multi-gas module zeroes itself once a day. The zeroing cycle lasts no longer than 20 seconds. During this time, the monitor does not update the displayed Gas parameter values on the screen and blanks the etCO₂ waveform. The message "Gas Zero in Progress" appears in the message area.

Due to the response time of the sensors and the gas sample flow rate, the stated accuracy of O₂, CO₂, N₂O and anesthetic agents is limited by the respiratory rate and by the inspiratory to expiratory ratio (I:E). For details, see the Technical Data appendix.



Do not expose the gas module to mechanical shocks as this would distort the gas measurements.



Do not use any gas supplied by oxygen-concentrators, as this will decrease the measurement accuracy.



The presence of organic cleaning solutions or gases containing Freon may adversely impact the accuracy of the Multi Gas Module.

Mechanical shocks during the measurement or the presence of other paramagnetic agents can distort measured values of oxygen concentration.

The Multi Gas Module is self-zeroing and does not need routine calibration by the clinical staff. However, a yearly check of the Gas calibration components should be performed by authorized technical personnel.



To avoid the risk of explosion, do not use flammable anesthetic agents such as ether and Cyclopropane in the presence of the Multi Gas module.



The leaks or internal venting can have effects on stated performance. E.g. when secondary air is drawn with ~0% CO₂, the displayed value can be too low. How much exactly depends on the mixing ratio, and consequently on the size of the leak.

5.10.1. Gas outlet:



If there is a gas connection to an anesthesia machine, the gas recirculation should be used in order to avoid an increased concentration of anesthetic gas in the operating room. Use the gas outlet of the module for that.



Use bacteria filter to avoid the cross-contamination and gas samples for gas recirculation from the manufacturer of the anesthesia machine. Perform the connection and its maintenance according the regulations of the manufacturer of the anesthesia machine.

Sampling of the respiratory gas from the patient breathing circuit reduces the delivered patient tidal volume. Clinicians should adjust the fresh gas supply as necessary.

5.10.2. Warm Up

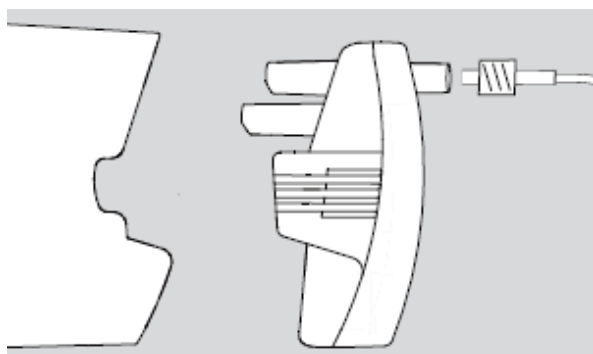
Upon start-up, the Multi Gas Module passes through an initialization and warm-up period. During this time, concentrations for certain gases may not be available and the anesthetic agent may not be identified. The Multi Gas Module achieves full accuracy after a warm-up period of about 6 minutes.



During warm-up, reported values may not be accurate. Refer to the Technical Data appendix for a detailed description of Gas accuracy.

At the end of the warm up period the Multigas module performs an automatic zero calibration. If the calibration was successful the message “Multigas Zero OK” is shown in the status bar.

5.10.3. Installing/removing the water trap



Push the water trap into its receptacle on backside of the *Tesla^{M3}* until the trap clicks into place. Make sure the water trap is empty. To remove the trap, hold it firmly on the ridged surfaces and pull it out of the receptacle. Replace the water trap according to the regulations of the manufacturer.



Warning: Do not use the Multigas module without a water trap!



Do only use water traps approved by MIPM.

For further information please see chapter 8.5 “Accessories”.

5.10.4. Connecting the sample gas lines

Connect one end of the sampling line to the water trap, and the other end to the airway T- connector. Connect one end of the exhaust tubing to the exhaust port of the monitor, and the other end to the hospital's gas scavenging system (Anesthesia machine).

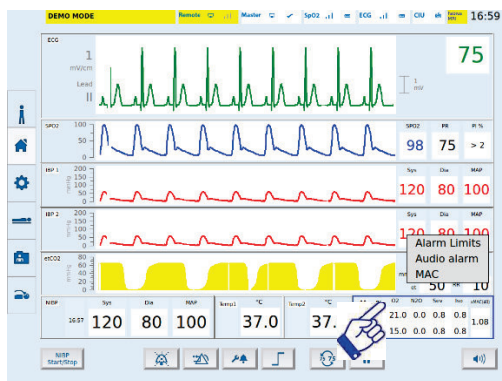


Sampling lines should be kept as short as possible (but not stretched) to minimize dead space and optimize response time. Long sampling lines degrade the performance of side stream measurements, may affect accuracy, and result in slower response times.



Always use MIPM-approved Gas sampling lines (polypropylene). Never use standard pressure sensor tubing (PVC). PVC tubing absorbs anesthetic agents, which it later releases (Degassing). The use of standard PVC tubing can result in erroneous agent concentration readings. Sampling lines and T-connectors are not reusable and must be replaced after each patient.

5.10.5. The Multigas menu

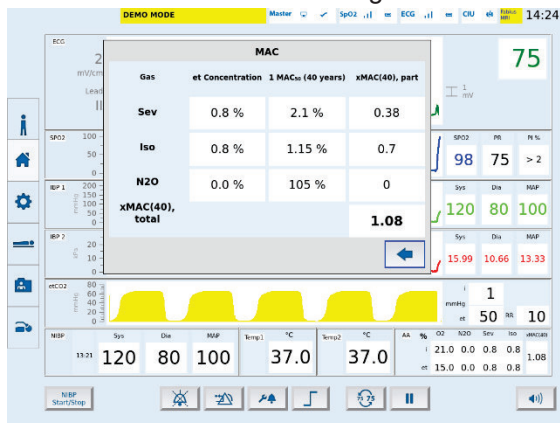


All relevant settings concerning the Multigas module can be changed in the Multigas menu.

To enter the Multigas menu press the touch screen inside the Multigas parameter box.

5.10.6. MAC Value

Press the MAC bar in the Multigas menu



In the Multigas menu is the MAC value next to the Gas values displayed.

The MAC value is helpful for monitoring the anesthesia concentration.

Pressing on the MAC-Field opens a detailed overview for all three gases.

It contains the gas name, its concentration and MAC reference.

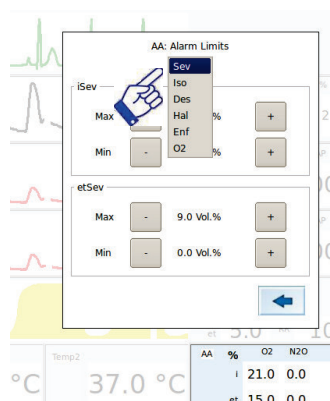
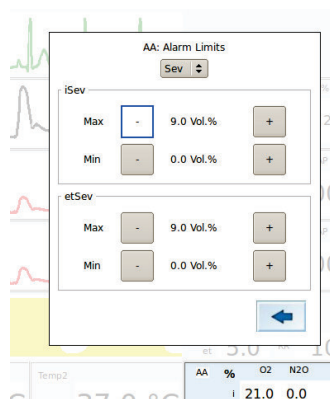
The MAC value calculation is based on the patient age and the concentration values of two anesthesia gas types and N₂O gas. (Formula for calculation in chapter 11. Technical Specifications)



MAC values are empirical, not absolute values. The MAC values correspond to those of healthy adults and cannot be applied to children. Age and other individual factors influencing the behavior of volatile agents are not considered.

5.10.7. Setting the alarm limits

Press the Alarm limit bar in the Multigas menu.



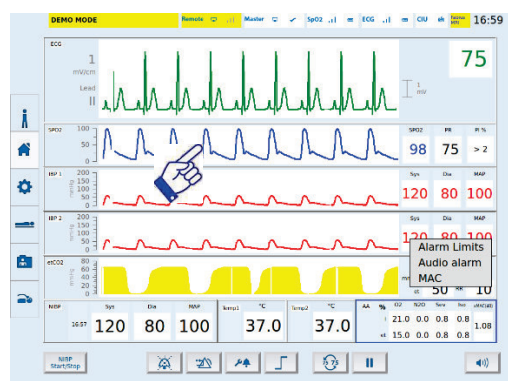
In the upper part of the alarm limits menu you will find a window with drop-down list showing all available anesthetic agents.

Press the arrow in that window to open the drop-down list. Select an anesthetic agent by pressing on the name of the agent in the drop-down list.

Now you can change the alarm limits for this specific agent. Repeat the following procedure for setting the alarm limits of other agents.

Change the respective alarm limit by pressing the +/- icons. Pressing the icons once changes the value by 0.1. Keeping the icons pressed changes the values faster.

To exit the sub menu press the back icon.



To exit the Multigas menu press any place outside the Multigas parameter box on the main screen.

5.11. Temperature measurement

The *Tesla^{M3}* determines the body temperature using fiber optic measurement. You can display up to two body temperature measurement channels (surface (axilla / armpit) and intracorporeal (rectum)). This is a direct mode clinical thermometer. The transient response ≤ 30 s.

5.11.1. Remarks Temperature Measurement during MRI examination:

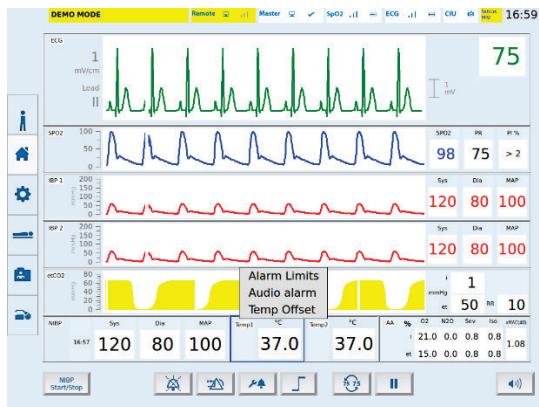


The sensor cable is made of fiber optics. Do not wind up too close or kink the sensor cable.



Make sure that the sensor cable is placed on top of the patient during the MRI examination. Do not place the sensor cable in or near the runner of the examination table as the table is subject to movements during operation. This may destroy the sensor cable. Damaged sensors have to be replaced immediately by authorized technical personnel.

5.11.2. The Temperature menu



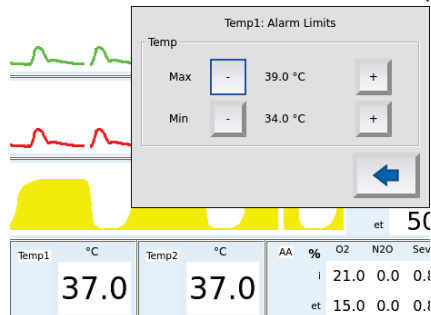
All relevant settings concerning the temperature measurement can be changed in the temperature menu.

To open the temperature menu press in the temperature parameter box on the main screen.

If your monitor is equipped with two temperature channels you can change the settings for each channel separately. To enter the respective temperature menu press the corresponding parameter box of the temperature channel you want to change.

5.11.3. Setting the alarm limits

Press the Alarm limit bar in the temperature menu.

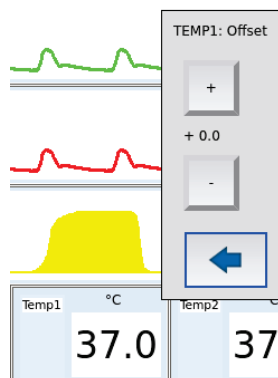


Change the respective alarm limit by pressing the +/- icons. Pressing the icons once changes the value by 1. Holding the icons changes the values faster.

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

5.11.4. Setting the Temperature Offset

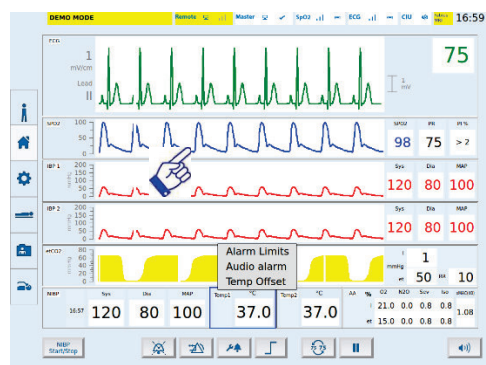
Press the Temp Offset bar in the temperature menu.



If there are fluctuations in the temperature measurement due to external influences, these can be adjusted by a correction factor.

By pressing the +/- icon you can set the correction factor in 0.1°C increments from +0.0°C to +0.5°C.

To exit the Offset sub menu, press the back icon.



To exit the temperature menu press any place outside the Temperature parameter box on the main screen.

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.

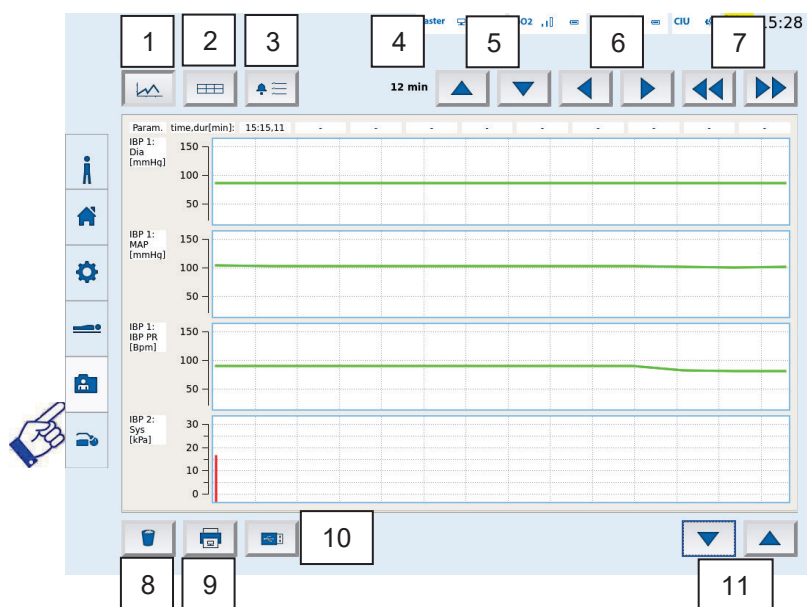


If an existing patient is released from the system or a new patient is registered, all trend memory will be deleted. The event memory cannot be deleted. The capacity of the event memory is 1000 events. If the memory is full, new events will replace old ones using FiFo (First in – First out) method.

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.

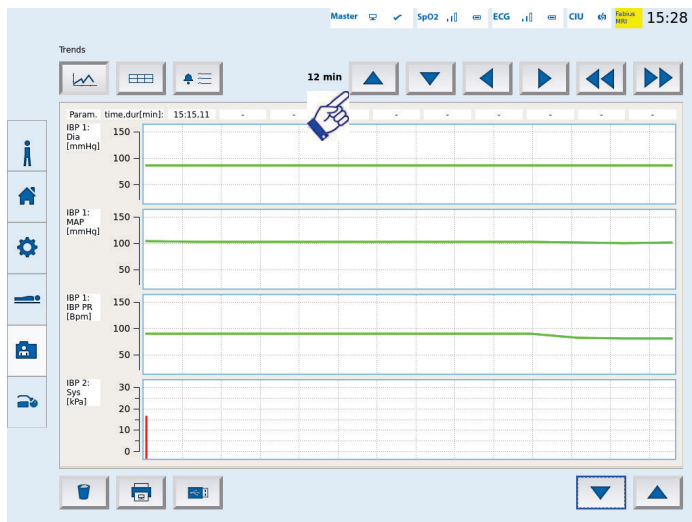


1. Icon graphical trends
2. Icon tabular trends
3. Icon Event memory
4. Time span
5. Navigation buttons for selecting the time span UP/DOWN
6. Buttons for Right / Left→ move time intervals in diagram in one-minute steps
7. Buttons for Double Left/Right→ move time intervals in diagram to next recording 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.

6.2. Graphical trends

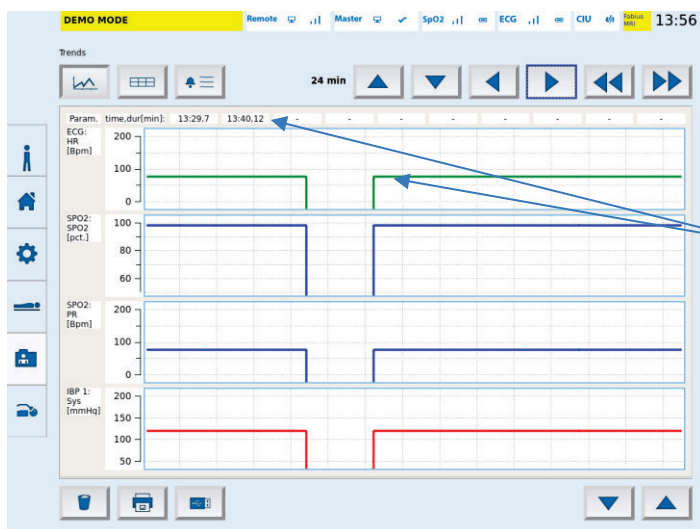


In the graphical trend screen every parameter is displayed in a separate diagram.

Press the up or down button in the bottom right corner to move through the parameters.

The time span can be set between 12 min up to 8 hours.

Select your time span by pressing on the UP/DOWN button in the upper part.



The graphic trend shows the visible time and the visible duration of the treatment in the table.

(e.g. 13:29,7 means: the grid starts at 13:29 with 7 minutes remaining duration)

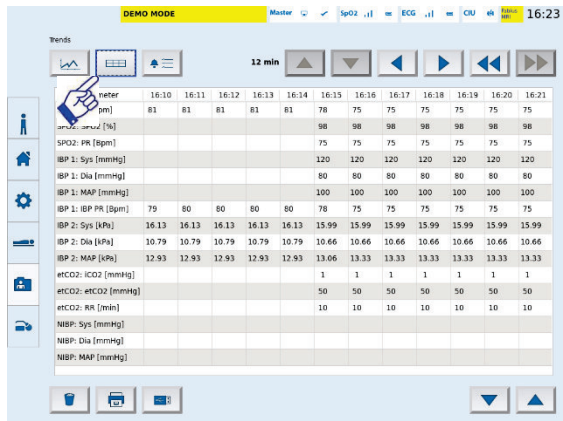
The other table columns, which are filled with "13:40", for example, indicate another investigation block.

If the examination is paused and resumed after a certain time, a new graph block is created, which is logged via another column with the time and duration of the examination.



The graphical trend is the starting point for navigation. In the graphical trend, you search for the point you want to evaluate and then jump to the tabular trend to obtain the numerical values for the selected point of time.

6.3. Trend table



To show the trend table, press the table icon in the upper part of the trend menu.

The time axis always shows 12 intervals.

e.g.

Time span = 1 hour => 12x 5-minute intervals

Time span = 2 hours => 12x 10-minute intervals

6.4. Event memory

The event memory is maintained when the alarm system is powered down or during a total loss of power. The time of powering down is not captured in the log. 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.

6.5. Printing trend data

The *Tesla^{M3}* can be connected to a printer.
(See section 1.8 “Connecting external devices”)



Warning! The printer is not MRI compatible.

Do not connect the printer to the main unit as long as it is still inside the MRI cabin.


Connect the printer to the remote screen in the control room or remove the main unit from the MRI cabin before connecting the printer!



The trend data contains processed values of all active measurements.

The trend data diagram printout is based on a separately generated and rendered report, supplying patient data and all trend diagrams in one report.

Printing trend data:

1. Connect the printer to the USB interface of the *Tesla^{M3}* (left side of the display).
2. Select the trend screen that you want to print.
3. Press the print icon .
4. The trend screen is printed out as a screen shot.

Example for printed page (Actual presentation may differ from the example):

MIPM M3 trend report

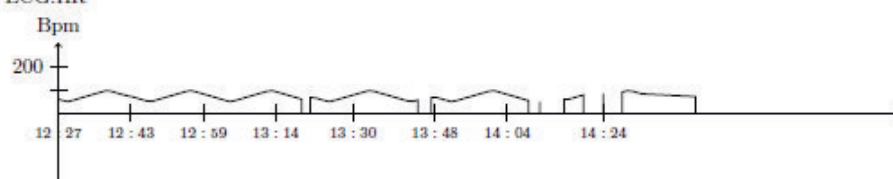
Mi. Jul 25 2018 14:43:32

Date: Mi. Jul 25 2018 14:43:32

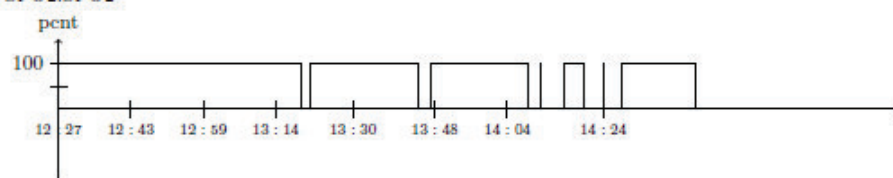
MRN:
Last Name:
First Name:
Date of birth:
Gender:
Height:
Weight:

Duration : 3 h

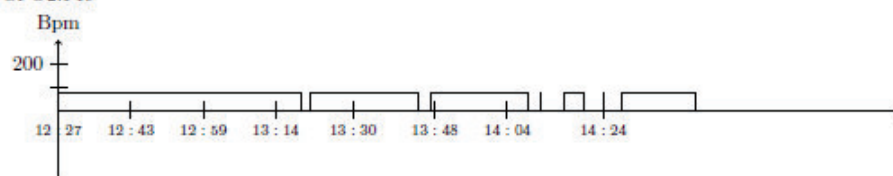
ECG:HR



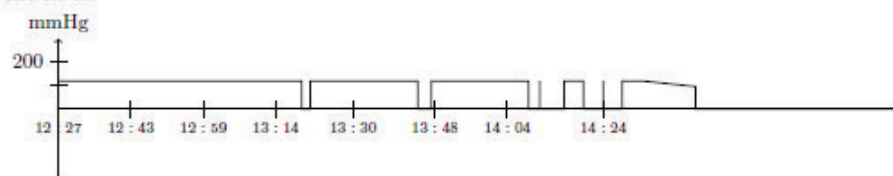
SPO2:SPO2



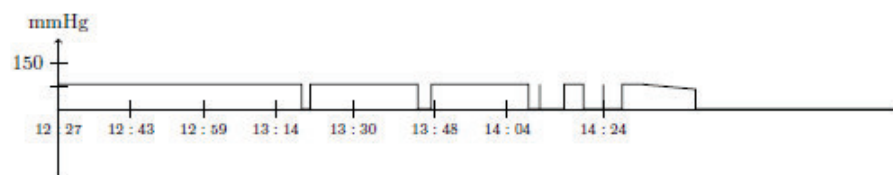
SPO2:PR



IBP1:SYS



IBP1:DIA



6.6. Data transfer to a USB storage device



Do only use storage devices that have been approved by MIPM. A list of approved devices will be shown in the section 11 “Technical specification”.

The trend data can be transferred to a digital storage device. The data is transferred to a CSV file.

Data transfer:

1. Press the USB icon
2. Connect the memory device with the USB interface of the *Tesla^{M3}* (left side of the display)
3. You can now edit the patient data before the data is transferred.
4. Press the Next icon
5. The trend data is transferred to the memory device in .csv format.

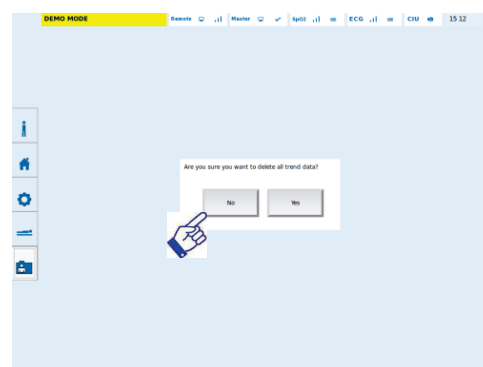
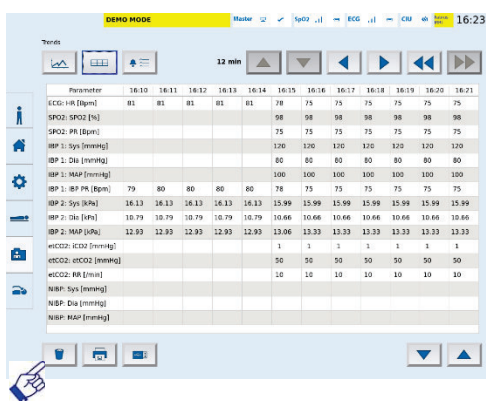


Do only connect the USB device after the USB Icon was pressed. If the USB device is connected to the *Tesla^{M3}* before the USB Transfer Menu is active the monitor will not recognize the USB device.

6.7. Deleting the trend memory

To erase the trend memory, press the Delete icon in lower part of the trend menu.

Confirm clearing.



Remember! All trend data will be erased! Restoring erased data is not possible.

7. The Service Menu



Settings and options in the service menu affect sensitive parts of the operating system and thus functioning of the patient monitor.

Access to the service menu is only granted to technical personnel authorized by MIPM.



The service menu is password secured.

8. Accessories and applied parts

8.1 ECG Accessories

Item number	Description
5300028	Wireless ECG Sensor for <i>Tesla^{M3}</i> (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 SpO₂ Accessories

Item number	Description
5010100	Wireless Pulse Oximetry Sensor for <i>Tesla^{M3}</i> (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.

9. Cleaning and disinfection

Clean the monitor and all accessories after each patient or daily according to your hospital's standard procedures. MIPM recommends the following cleaning solutions and procedures.



CAUTION: Do not use disinfectants that contain phenol as they can spot plastics. **Do not autoclave** or clean accessories with strong aromatic, chlorinated, ketone, ether, or ester solvents. Never immerse electrical connectors in liquids.

9.1 Main unit and remote screen

- Clean the monitor with gauze moistened in a soap solution.
- Dry thoroughly with a lint-free cloth.
- Disinfect the monitor with gauze moistened with diluted alcohol or an aldehyde based disinfectant.
- Dry thoroughly with a lint-free cloth.



CAUTION: The material used for the monitor housing enclosure is a surface-coated aluminium. Do not use plastic solvents, sharp tools or abrasives to clean it.



CAUTION: Do not steam autoclave, gas sterilize, or immerse the monitor in water or cleaning solutions. Do not subject the monitor to intense vacuum.

9.2 Patient connection cables and wireless sensors

- Clean the patient cables with a gauze pad moistened with a soap solution.
- Dry thoroughly with a lint-free cloth.
- To disinfect patient cables, wipe the cables with a gauze moistened with diluted alcohol or an aldehyde-based disinfectant
- Dry thoroughly with a lint-free cloth.



Do not sterilize the ECG patient cables!

9.3 NIBP cuffs

Wipe the cuff with pad moistened with a soap solution, an aldehyde based disinfectant or an alcohol / phenol solution.



The cuff may be dipped in the cleaning solution. Make sure that the solution does not flow into the pressure tubing or the cuff itself. This may affect the accurate functioning of the cuff. If cleaning solution enters the pressure tube or the cuff all warranty claims expire.

9.4 Reusable pressure measurement accessories

Observe the accompanying documentation of the accessories manufacturer.

9.5 Multigas Module



Working with used sample lines, T-connectors and water traps bears the risk of infection. Disposable items should be handled and replaced as recommended by the manufacturer. Please observe your local disposal guidelines or contact MIPM or your local affiliate.




Do never open the housing of the monitor during operation. Do not remove the water trap during operation of the module.



Do not clean the water trap! Used water traps should be replaced and disposed according to the local disposal guidelines or according the instruction of the water trap manufacturer. The water trap is not reusable.

10. Trouble shooting

Problem	Potential cause	Suggested action
<i>Tesla</i> ^{M3} monitor does not power on.	Battery is too low to operate the monitor. Battery needs replacement. Fuses need replacement.	Connect <i>Tesla</i> ^{M3} to AC power to operate. Leave connected for at least 12 hours before using the <i>Tesla</i> ^{M3} on battery. Contact MIPM or service. Contact MIPM or service.
<i>Tesla</i> ^{M3} powers on, but the patient mode screen is not displayed	Boot failure. System failure.	Press the power On/Off button for > 3 seconds. Restart the monitor. If situation occurs again contact MIPM or service.
Power cord is connected but the battery indicator is not shown 	AC power source is not active. System failure.	Check AC power source, circuit breakers, etc. Contact MIPM, or your local distributor for Service.
No response from <i>Tesla</i> ^{M3} when icons are pressed	Touch screen failure. System failure.	If monitor works normal try to use the turning knob as alternative input device. If situation recurs after restart of the monitor, contact MIPM or service.
Continuous speaker sound	System failure.	Contact MIPM or service.
ECG or SpO ₂ sensor does not connect to <i>Tesla</i> ^{M3}	Sensor battery too low. Temporary connection problem.	Check battery status LED of the sensor. Charge the sensor for at least 10 hours in the charging bracket on the back side of <i>Tesla</i> ^{M3} . Insert the sensor in the charging bracket and wait until the battery charge LEDs flash. Remove the sensor from the charging bracket to restart sensor. If situation recurs contact MIPM or service.

11. Technical specification

Environmental Conditions, Conditions for Use in MR Environment and Physical Characteristics

Environmental Conditions

Description	Specification
Operating Conditions:	
Temperature:	10°C to 40 °C
Relative Humidity:	10% to 90 % non-condensing
Ambient Pressure:	70 kPa to 106 kPa
Altitude:	max. 3000m (9842.52 feet)
Storage and Transport Conditions:	
Temperature:	-40°C to 70 °C
Relative Humidity:	10% to 90 % non-condensing
Ambient Pressure:	70 kPa to 106 kPa



CAUTION: After transport, the device should be stored at room temperature for at least one day before commissioning.

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: $\geq 1.5\text{m}$ Magnetic Field in MR Environment: $\leq 20\text{ mT} / 200\text{ Gauss}$
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: $\geq 40\text{cm}$ Magnetic Field in MR Environment: $\leq 3.0\text{ T} / 30000\text{ Gauss}$
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: $\geq 40\text{cm}$ Magnetic Field in MR Environment: $\leq 3.0\text{ T} / 30000\text{ Gauss}$
NIBP Pressure Cuffs	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: $\leq 3.0\text{ T} / 30000\text{ Gauss}$
IBP Transducer	MR Conditional (according ASTM F 2503) Not intended for use in the Magnet Bore, distance to MR Scanner: $\geq 1.5\text{m}$ Magnetic Field in MR Environment: $\leq 20\text{ mT} / 200\text{ Gauss}$
CO ₂ Nasal Line / Airway Adapter	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: $\leq 3.0\text{ T} / 30000\text{ Gauss}$
Temperature sensor (core / surface)	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: $\leq 3.0\text{ T} / 30000\text{ Gauss}$
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	± 5 BPM or ± 10 %
Response to irregular rhythm A1 A2 A3 A4	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	8 Beats
Updating rate of the display	100 msec
T-Wave rejection	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: ≤ 4 s HR change from 80 to 40 BPM: ≤ 7 s
Time to Alarm for Tachycardia:	B1-Vent Tachycardia: < 2 s B2-Vent Tachycardia: < 1 s
Min. Amplitude for ECG patient signal (Sensitivity)	≥ 0.125 mV
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 SpO₂ Accuracy in comparison with arterial blood sample references measured with a CO-Oximeter. CO-Oximeter: Blood gas analysis to determine oxyhemoglobin saturation (SaO₂) was performed on an OSM 3® multi-wavelength oximeter. (Hemoximeter, Radiometer, Copenhagen, serial 89R0243 N010).

Oxyhemoglobin Saturation (SaO₂) 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•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

Multigas

Description	Specification
Accessories and connection to MRI Patient Monitor (CIU)	Gas sample line
Parameter	end tidal and inspiratory Carbon Dioxide (etCO ₂ ; iCO ₂)*; Respiration Rate (RR)*; end tidal and inspiratory concentration of Oxygen (O ₂), Nitrous Oxide (N ₂ O), Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), Minimum Alveolar Concentration (MAC)
Units for CO ₂ *	Vol% or kPa or mmHg
Number of channels *	1 channel (Waveform and Numerics)
Sweep Speed of Waveform*	6.25 mm/s
Measurement Method*	non-dispersive infrared (NDIR) measurement of CO ₂ , N ₂ O, anesthetic agents; paramagnetic measurement of O ₂
Sampling Method *	Side Stream
Sampling Flow Rate*	200 ml/min (± 20ml/min)
Automatic detection of primary gas*	At the latest at 0.3 Vol%
Automatic detection of secondary gas*	At the latest at 0.4 Vol% With a Desflurane concentration greater than 4 Vol%, mixture detection occurs at the latest when the concentration of the second anesthetic gas rises above 10% of the Desflurane concentration
Zeroing and Calibration*	Automatic, once per day (in error-free operation); Duration < 20 s (Intake of room air due to zero procedures)
Zeroing and Zeroing duration*	Automatic, once per day (in error-free operation); Duration < 20 s
CO ₂ Range*	0.1 to 10 Vol% or 0 to 80mmHg CO ₂ in Air at 760mmHg ambient air pressure
CO ₂ Accuracy and drift*	± (0.43 Vol% + 8% rel.)
CO ₂ Rise time (10...90%) *	< 350 ms
CO ₂ time to availability ¹⁾ *	< 60 s
CO ₂ Warm-up time ²⁾ *	time to specified accuracy < 300s
N ₂ O Range	0 to 100 Vol%
N ₂ O Accuracy and drift	± (2 Vol% + 8% rel.)
N ₂ O Rise time (10...90%)	< 350 ms
N ₂ O Warm-up time ²⁾	time to specified accuracy < 300s
O ₂ Range	5 to 100 Vol%
O ₂ Accuracy and drift	± 2.5 Vol% + 2.5% rel.
O ₂ Rise time (10...90%)	< 500 ms
O ₂ Warm-up time ²⁾	time to specified accuracy < 300s
Halothane Range	0 to 8.5 Vol%
Halothane Accuracy and drift	± (0.2 Vol% + 15% rel.)
Isoflurane Range	0 to 8.5 Vol%
Isoflurane Accuracy and drift	± (0.2 Vol% + 15% rel.)

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 ₂ O); < 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	$TOTAL\ MAC = \frac{EtN_2O}{1\ MAC\ N_2O} + \frac{Et\ 1st\ Agt}{1\ MAC\ 1st\ Agt} + \frac{Et\ 2nd\ Agt}{2\ MAC\ 2nd\ Agt}$														
1 and 2 MAC Values	<table> <tr> <th>GAS</th><th>MAC Value</th></tr> <tr> <td>DES (Desflurane)</td><td>6.00 Vol. %</td></tr> <tr> <td>ENF (Enflurane)</td><td>1.70 Vol. %</td></tr> <tr> <td>HAL (Halothane)</td><td>0.77 Vol. %</td></tr> <tr> <td>ISO (Isoflurane)</td><td>1.15 Vol. %</td></tr> <tr> <td>SEV (Sevoflurane)</td><td>2.10 Vol. %</td></tr> <tr> <td>N2O (Nitrous oxide)</td><td>105 %</td></tr> </table>	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 %
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

II) Remote Monitor (CCU/R)

The optional wireless Remote Monitor is not intended to be used in the MR Environment (MR Unsafe) and has no contact to the patient.

The Remote Monitor (CCU/R) in the MR Control room has the same functionality (Graphical User Interface) as the MRI Patient Monitor (CCU/M and CIU) in the MR Environment. The Remote Monitor displays the same vital signs parameter and alarms as installed in the MRI Patient Monitor. A further feature is the possibility to connect the Remote Monitor to a PDMS-System (Patient Data Management System) via RS 232 or Ethernet.

The wireless Data Transceiver Unit (DTU) is transmitting data from MRI Patient Monitor (CCU/M) in the MR Environment to the Remote Monitor (CCU/R) in the MR Control Room and vice versa. (MRI Patient Monitor has priority by inputs from operators at the same time on MRI Patient Monitor and Remote Monitor).

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	ON/OFF-Switch (push-push) with LED Illumination of the integrated LED is on if the device is turned on
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)

Alarms

Description	Specification
Alarm Conditions	Remote Monitor / Display to MRI Patient Monitor
Indication of connection from MRI Patient Monitor to Remote Monitor	Signal Strength, Alarm by disconnection

Vital Signs Parameter

Description	Specification
ECG	Remote Monitor / Display to MRI Patient Monitor
Pulse Oximetry	Remote Monitor / Display to MRI Patient Monitor
NIBP	Remote Monitor / Display to MRI Patient Monitor
IBP	Remote Monitor / Display to MRI Patient Monitor
Multigas	Remote Monitor / Display to MRI Patient Monitor
Temperature	Remote Monitor / Display to MRI Patient Monitor

Trends

Description	Specification
Trends	same Trends as MRI Patient Monitor

Events

Description	Specification
Events	same Events as MRI Patient Monitor

Interfaces for Data Output of Trend/Event

Description	Specification
Interfaces	2x USB (same as MRI Patient Monitor)

PDMS

Description	Specification
Interfaces	RS232 or Ethernet (Selectable over service menu)
Output interval	Every 10 seconds
String format RS232	ASCII Code (.csv)
Output format Ethernet	ASCII Code (.xml)

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 /60 Hz
Power consumption	max. 70VA

Patient Modes – Default Settings of Alarm Limits

Patient Mode:	Adult		Pediatric		Neonatal		Configuration* (user configurable)	
Parameter	Upper alarm limit	Lower alarm limit	Upper alarm limit	Lower alarm limit	Upper alarm limit	Lower alarm limit	Upper alarm limit	Lower alarm limit
Heart rate	120	50	150	50	170	80	120	50
SpO ₂	100	90	100	90	100	90	100	90
Pulse rate	120	45	150	45	170	80	120	45
NIBP SYS	160	90	160	90	80	50	160	90
NIBP DIA	110	50	110	50	60	25	110	50
NIBP MAP	125	60	125	60	70	40	125	60
IBP SYS	160	90	160	90	80	50	160	90
IBP DIA	110	50	110	50	60	25	110	50
IBP MAP	125	60	125	60	70	40	125	60
IBP PR	120	45	150	45	170	80	120	45
Temperature	39	34	39	34	39	34	39	34
iCO ₂	0.5%	n/a	0.5%	n/a	0.5%	n/a	0.5%	n/a
etCO ₂	6.6 %	3.9 %	6.6%	3.9%	6.6%	3.9%	6.6 %	3.9 %
Respiration rate (RR)	30	5	80	20	80	20	30	5
iO ₂	99.9 %	18.1 %	99.9 %	18.1 %	99.9 %	18.1 %	99.9 %	18.1 %
etO ₂	99.9 %	10.1%	99.9 %	10.1%	99.9 %	10.1%	99.9 %	10.1%
iISO	6.0	0	6.0	0	6.0	0	6.0	0
etISO	6.0	0	6.0	0	6.0	0	6.0	0
iHAL	6.0	0	6.0	0	6.0	0	6.0	0
etHAL	6.0	0	6.0	0	6.0	0	6.0	0
iSEV	9.0	0	9.0	0	9.0	0	9.0	0
etSEV	9.0	0	9.0	0	9.0	0	9.0	0
iENF	6.0	0	6.0	0	6.0	0	6.0	0
etENF	6.0	0	6.0	0	6.0	0	6.0	0
iDES	18.0	8.0	18.0	8.0	18.0	8.0	18.0	8.0
etDES	18.0	8.0	18.0	8.0	18.0	8.0	18.0	8.0

* Default settings of alarm limits for user configurable mode (Configuration): Identical to default settings of Adult Mode

12. Disposal



Before disposal remove batteries from the device. Batteries and devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulation.



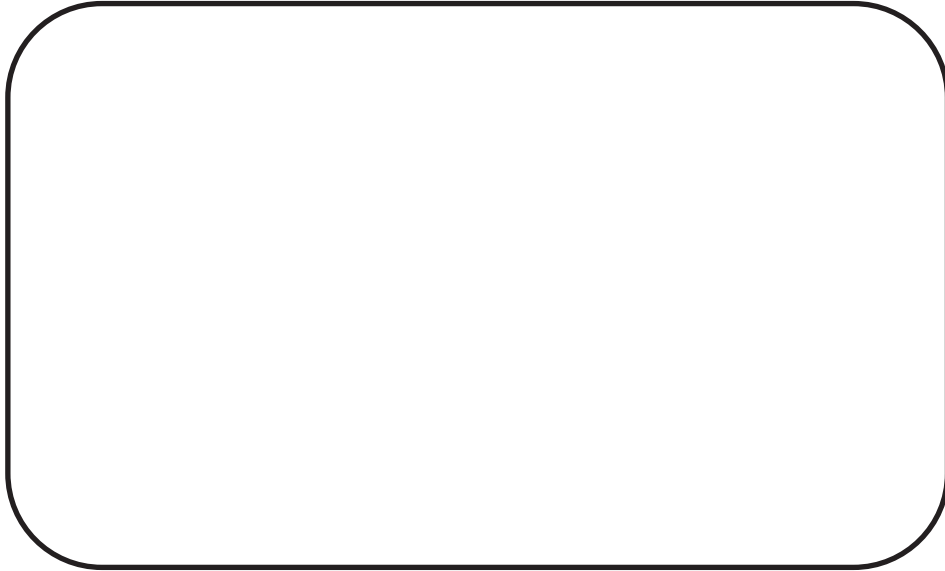
In the event the *Tesla^{M3}* is damaged and cannot be repaired, or has reached the end of the product life dispose of the *Tesla^{M3}* and all its components through an approved hazardous materials disposal facility in accordance with local regulations, or return it to MIPM or an authorized distributor. The internal battery contains Lithium, which is hazardous waste.

Lithium batteries have to be disposed according to the local regulations. In order to prevent the danger of explosion or fire batteries should never be burned!

13. Glossary

ASY	Asystole
BRDY	Bradycardia
Dia	Diastolic pressure
ECG	Electrocardiogram
hr	Hour
kPa	kilopascals
LA	Left Arm
LL	Left leg
Memory	The circuits inside the monitor that store information. Patient data and settings are stored in memory, for example
mmHg	Millimetres of mercury
mV	Milli-Volt
mT	Milli-Tesla
NIBP	Non-invasive Blood Pressure
Parameter	A monitored physiological function (e.g., heart rate).
Parameter boxes	The areas of the screen where parameter labels and values are displayed.
RA	Right arm
RL	Right leg
Sys	Systolic pressure
Tach	Ventricular Tachycardia
V	Volt

Area for company stamp or business card of the MIPM partner



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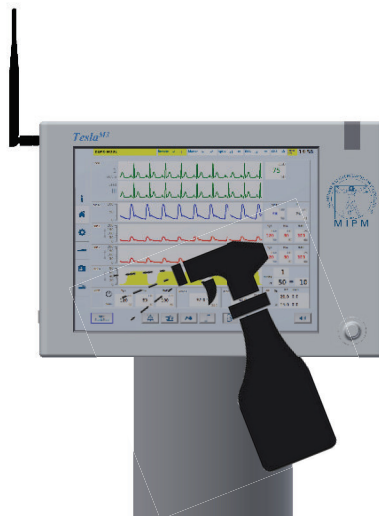
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Amendment to Instructions for Use of *Tesla^{M3}*

Chapter 9. Cleaning and disinfection

Bitte bei der Reinigung / Desinfektion keine Sprühflasche verwenden

Please do not use a spray bottle for cleaning / disinfection



Reinigen / Desinfizieren Sie den *Tesla^{M3}* mit einem Tuch

Clean / Disinfect the *Tesla^{M3}* with a wipe

