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

Conditions for Use in MR Environment

Description	Specification
MR Scanner	1.5 T; 3.0 T
MRI Patient Monitor (CIU and CCU/M)	MR Conditional (according ASTM F 2503) Not intended for use in the Magnet Bore, distance to MR Scanner: ≥ 1,5m Magnetic Field in MR Environment: ≤ 20 mT / 200 Gauss
Wireless ECG Sensor (ECGAP)	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Distance of enclosure of sensor to examination area: ≥ 40cm Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
Wireless Pulse Oximetry Sensor (POAP2)	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Distance of enclosure of sensor to examination area: ≥ 40cm Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
NIBP Pressure Cuffs	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
IBP Transducer	MR Conditional (according ASTM F 2503) Not intended for use in the Magnet Bore, distance to MR Scanner: ≥ 1,5m Magnetic Field in MR Environment: ≤ 20 mT / 200 Gauss
CO_2 Nasal Line / Airway Adapter	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
Temperature sensor (core / surface)	MR Conditional (according ASTM F 2503) Intended for Use in the Magnet Bore Magnetic Field in MR Environment: ≤ 3.0 T / 30000 Gauss
Remote Monitor (CCU/R)	MR Unsafe (according ASTM F 2503) Not intended for use in the MR Environment

Physical Characteristics

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

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	25mm/s
Lead selection	I; II; III;
Heart Rate Range	30 to 300 BPM (Resolution: 1 BPM)
Heart Rate Accuracy Response to irregular rhythm A1 A2 A3 A4 QRS amplitude of 0,15 mV and QRS duration of 10 ms and a QRS amplitude of 1 mV	± 5 BPM or ±10 % Ventricular bigeminy: 41 BPM Slow alternating ventricular bigeminy: 38-74 BPM Rapid alternating ventricular bigeminy: 96-107 BPM Bidirectional systoles: 99-107 BPM (measurements outside MR Environment; MRI gradient artifact can affect response to irregular rhythm and heart rate accuracy) The device is able to count the correct heart rate at this setting
Heart rate averaging Updating rate of the display T-Wave rejection	8 Beats 100 msec T-Wave rejection up to 0.80 mV with 1 mV QRS Amplitude
Response Time of Heart Rate Meter to Change in Heart Rate	HR change from 80 to 120 BPM: ≤ 6s HR change from 80 to 40 BPM: ≤ 14s
Time to Alarm for Tachycardia:	B1-Vent Tachycardia: <1s B2-Vent Tachycardia: <1s
Min. Amplitude for ECG patient signal (Sensitivity)	≥ 0.15mV
R-Wave Indicator	Waveform and Audible tone on each pulse
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

Pulse Oximetry

Description	Specification
Accessories	Large, medium and small adapters
Sensor	Wireless Pulse Oximetry Sensor with fiber optic cable (POAP)
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 250 BPM (Resolution: 1%)
Pulse Rate Accuracy	± 1 BPM or ± 1% of display
SpO_2 Alarm Limit Range	30 to 100% (Preset for lower SpO2 = 90%)
Pulse Rate Alarm Limit Range	30 to 250 BPM
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type BF applied part
Battery operation of Wireless Pulse Oximetry Sensor:	
Type	Lithium-Polymer
Battery Operating Time	≥ 8 hours
Battery Charging Time	< 10 hours
Battery capacity monitoring	Indication of Battery Status / Battery Capacity on Monitor and Sensor

Summary of Clinical Study Report with Wireless Pulse Oximetry Sensor (POAP2):

Location: Hypoxia Research Laboratory, University of California, San Francisco

Purpose: Validation of SpO_2 Accuracy in comparison with arterial blood sample references measured with a CO-Oximeter. CO-Oximeter: Blood gas analysis to determine oxyhemoglobin saturation (SaO_2) was performed on an OSM 3® multi-wavelength oximeter. (Hemoximeter, Radiometer, Copenhagen, serial 89R0243 N010).

Oxyhemoglobin Saturation (SaO_2) range: 70 to 100%; 22 blood samples in this range of each subject.

Subjects: The study included 12 subjects (5 women and 7 men). No subject was anemic (Hemoglobin ≤ 10 $gm \bullet dl^{-1}$) and only healthy non-smoking individuals of age 21 – 49 were included in the study.

Demographics of the subjects:

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

Root mean square error (Arms) is calculated as follows:

SpO_{2i}: measured values ; S_{Ri}: reference values ; n: samples

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

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 (Mean)
Number of channels	1 channel (Numerics)
Measurement Method	Oscillometric
Measurement Interval	Manual or Intervals (Cycle time): 1, 2, 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	± 3mmHg (static pressure)
Start Pressure	Adult and Pediatric Mode: 180 mmHg Neonate Mode: 100 mmHg
Pneumatic Overpressure Protection (Overpressure limits)	Adult and Pediatric Mode : 300mmHg / 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	5µV/V/mmHg
Accessories and connection to MRI Patient Monitor (CIU)	Interface cable for transducers from different manufacturers
Parameter	Systolic (Sys), Diastolic (Dia) and Mean Blood Pressure (MAP)
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

Capnography

Description	Specification
Accessories and connection to MRI Patient Monitor (CIU)	CO_2 nasal cannula, Airway Adapter with gas sample line
Parameter	end tidal and inspiratory Carbon Dioxide ($etCO_2$; iCO_2); Respiration Rate (RR)
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
Sampling Method	Side Stream
Sampling Flow Rate	Adult Mode: 150ml/min (+20ml / -10ml/min) Pediatric Mode: 100 ml/min (+20ml / -10ml/min) Neonate Mode: 60 ml/min (+20ml / -10ml/min)
Data sampling rate	All values: once per second; Capnogram: 50 or 25 values per second
Zeroing and Calibration	Automatic zero calibration through ambient air with CO_2 absorber. 5% calibration recommended every 24 weeks or 2000 hours of operation whatever is reached first
CO_2 Range	0.1 to 10 Vol% or 0 to 80mmHg CO_2 in Air @ 760mmHg ambient air pressure
CO_2 Accuracy and drift	± (0.43 Vol% + 8% rel.)
Respiration Rate Range	0 to 100 breaths per minute
System response time	Total system response time 400ms @ 60ml/min 10% to 90% rise time 340ms @ 60ml/min
Warm up time	15 seconds; full accuracy after 5 minutes
CO_2 Alarm Limit Range	$etCO_2$: 0.1 – 10.0 Vol.%; 0 to 80 mmHg iCO_2: 0.1 – 10.0 Vol.%; 4 to 80 mmHg
Respiration Rate Alarm Limit Range	0 to 100 breaths per minute
Degree of protection against electric shock (IEC 60601-1)	Defibrillation-proof type BF applied part

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_2O), Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES)
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_2O, 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 Zeroing duration	Automatic, once per day (in error-free operation); Duration < 20 s

Description	Specification
CO_2 Range	0.1 to 10 Vol% or 0 to 80mmHg CO_2 in Air @ 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_2O Range	0 to 100 Vol%
N_2O Accuracy and drift	± (2 Vol% + 8% rel.)
N_2O Rise time (10…90%)	< 350 ms
N_2O 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.)
Enflurane Range	0 to 10 Vol%
Enflurane Accuracy and drift	± (0.2 Vol% + 15% rel.)
Sevoflurane Range	0 to 10 Vol%
Sevoflurane Accuracy and drift	± (0.2 Vol% + 15% rel.)
Desflurane Range	0 to 20 Vol %
Desflurane Accuracy and drift	± (0.2 Vol% + 15% rel.)
Agents Rise time (10…90%)	< 450 ms
Agents Warm-up time [2)]	time to specified accuracy < 300s
Respiration Rate Range	0 to 100 breaths per minute
Respiration Rate Accuracy	0 to 60 breaths per minute ± 1 /min (> 60 breaths per minute not specified)
Total Response time	< 1s (CO_2); < 30s (O_2 and N_2O); < 5s (Agents); (incl. watertrap and gas sample line)
Data sampling rate	10 values per second
CO2 Alarm Limit Range	etCO2: 0.1 to 10.0 Vol.%; 0 to 80 mmHg iCO2: 0.1 to 10.0 Vol.%; 4 to 80 mmHg
O2 Alarm Limit Range	iO2: 18 to 100% etO2: 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

[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	<15s
Number of channels	1 or 2 channels (Numerics)
Unit	°C
Range	20 to 45 °C
Accuracy	± 0.3 °C
Alarm Limit Range	20 to 45 °C
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	1; 2; 3; 4; 5; 6; 7; 8h
Capacity	8 hours

Events

Description	Specification
Tabular Events	Date; Time; Patient Name; Event Name and Value (type of event)
Capacity	100 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 (recommended: Brother HL 20)

Battery Operation of MRI Patient Monitor

Description	Specification
Type	Lithium-Ion
Battery Operating Time	≥ 6 hours in basic configuration with options ECG, SPO2, 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

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
Capnography (CO2)	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 /60Hz
Power consumption	max. 55VA

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
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