Instructions for Use

RAUMEDIC® MPR2 logO
REF 095254-001 and 095254-002
Firmware version
2.10.0068 HW2

Table of contents

Instructions for Use for RAUMEDIC® MPR2 logO

Battery-operated patient monitoring unit for the functions of partial oxygen pressure, invasive pressure and temperature

0 General notes

The MPR2 logO has received the mark CE 0123 in compliance with the European Directive 93/42/EEC, and meets the fundamental requirements of this directive rendered in Annex I. All manufacturing processes have been monitored by a QM system in keeping with ISO 13485.

The appliance is shielded in compliance with standard IEC 60601-1-2 and meets the limiting values in compliance with European standard EN 55011, Group 1, Class A.

The CE mark covers only those accessory parts listed in the delivery overview. These instructions for use shall be considered part of the appliance, and shall have to be kept available in the vicinity of the appliance. The exact observation of the instructions for use shall be the pre-requisite for the intended use and correct handling of the appliance as well as the safety of patient and operator dependent thereupon. These instructions for use can be supplemented by a Quick Guide, but they cannot be replaced by the said.

Patient safety, adherence to the measuring accuracy indicated and the highest possible immunity to failure shall be ensured only if original parts of the manufacturer (such as basic appliance, cables, sensors) are used.

Only those accessories shall be used which are mentioned in these instructions for use, and which have been tested along with the appliance. If foreign accessories are used nonetheless, the safe operation and safe function can no longer be guaranteed. Warranty claims shall not be accepted in case of damage caused by using foreign accessories.

The manufacturer considers himself responsible for the appliances with respect to their safety, reliability and function only, if:

- the appliance is used in conformity with these instructions for use.
- the installation, the extensions, the re-adjustments, the modifications and the repairs have been carried out by the manufacturer himself or persons authorised by the said.

1 Safety-related information

⚠ Prior to using the MPR2 logO, please attentively read the entire instructions for use and familiarise yourself with the operation of the appliance.

⚠ Prevent longer direct skin contact between patient and housing of the MPR2 logO.

⚠ In order to ensure safety, reliability and performance of the system, the following notes shall have to be observed carefully:

⚠ Changes and modifications of the unit are not permitted.

- The MPR2 logO (hereinafter referred to as MPR2 for short) may be operated by qualified staff only.
- The MPR2 may be operated only with the specified mains power adapter, see chapter 11.1 Technical data.
- Select only such wall outlet for the mains power adapter that is accessible to the user without difficulty. Do not place the mains power adapter in a way that makes it difficult to disconnect the adapter from the wall outlet.
- The mains power adapter is a part of the medical device. To completely disconnect the MPR2 from the mains, disconnect the mains power adapter from the wall outlet.
- Prior to using the MPR2, you have to be completely familiar with the operation of the system.
- The MPR2 may be used on one patient at a time only.
- No splitting into spatially separate sensors for pressure and temperature may be effected at the multi-purpose port P2/T2.
- When monitoring vital functions, a redundancy of the measuring functions is required. In this respect the pO2 channel is a special feature. A real redundancy cannot be effected in the MPR2. However, through the evaluation of the intensity of the optical receiving signal and the monitoring of the reference LED, a far-reaching monitoring has been ensured.
- When the apparatus is switched on, a signal is sounded which is intended to check the alarm sounding unit. If the signal is not sounded, the apparatus must not be used.
- If two or more apparatuses with separate mains connections are used on the same patient, the apparatus leakage current adds up which may cause a potential hazard. In this case, use shall be permitted only, if it has been secured that patient and operator are safe, and that the requirements of standard IEC 60601-1 are fulfilled.
- Every person who connects an additional unit to the signal input or signal output configures a medical system, and thus he / she shall be responsible for the fact that this system meets the requirements of standard IEC 60601-1.
- Simultaneous operation with other apparatuses connected to the patient may cause mutual influences which may have an effect on the measuring results.
- Note that in the event of different alarm pre-settings for the same or similar devices, which are used in different hospital areas (e.g. ITS or the operating suite), the interchanging of settings can cause a potential danger to patients. Therefore always check that the alarm settings are suitable for the patients concerned prior to starting monitoring. (s. chapter 4.3 Selecting the limiting alarm values)
- The unit can forward up to two pressure signals to a downstream redundant monitoring system. By means of the downstream system, it is possible to easily integrate the datalogger into a central monitoring system. In the process special attention has to be given to the fact that only approved systems from the listed accessories are connected. In case of every signal relaying, proceed as rendered in the instructions for use of the MPR2: Establish the cable connection; check the signal transmission; and set the alarm limits to the foreign system.

- Prior to using the MPR2, the correct condition of the apparatus and any accessories shall have to be checked. Check the plausibility of the readings before using the apparatus for monitoring. The apparatus and the accessories must not be damaged or soiled; otherwise the apparatus must not be used. Do not use the apparatus, if it reveals obvious signs of a wrong function; in this case forward the unit to the after-sales service of the manufacturer.
- In questions of servicing, please always get in touch with the manufacturer. The manufacturer will give you a list of authorised service partners, if and when required.
- In all fastening and erection variants, please make sure that the apparatus cannot drop or cause other hazards. Please also ensure a safe laying of the cables so that a tipping over of the arrangement is prevented.
- Do not use the apparatus in potentially explosive surroundings. The apparatus shall have to be set up at a minimum distance of 25 cm to any anaesthesia units and gas filled hoses.
- After use the accessories shall have to be cleaned, disinfected or sterilised in keeping with the instructions for use. If the accessory has been provided with separate instructions for use, the instructions rendered there shall be applicable.
- If the apparatus has been taken from colder into warmer surroundings, it may be used only when the temperature of the apparatus and of the accessories has adapted to the room temperature; there is no danger of condensation water forming or any condensation water already developed has completely dried.
- Please also observe the safety instructions in conjunction with the use of sensors and transducers which have been included to the respective sections of the instructions for use.
- No liquids or fluids shall enter the apparatus. If this should happen nonetheless, first remove the mains adapter from the port. Hand over the apparatus to the after-sales service department for inspection. Subsequently a safety-related check is necessary.
- The MPR2 has been designed in conformity with standard IEC 60601-1. It is a product of class of protection II with an internal power source and an external mains adapter, and has been allocated to class IIb (MPG).
- If sterile accessories are used, please make sure that they are marked as being sterile.
- If the apparatus is subjected to strong electro-magnetic fields, please observe that the pressure display may vary by up to 2 mmHg. For this reason, avoid using mobile phones, therapeutical microwave devices or similar units in the vicinity of the apparatus.
- The following instructions shall have to be observed for the installation of the system (with laptop and/or foreign unit – monitor):
  - Moveable multiple sockets must not lay on the floor.
  - Additional moveable multiple sockets or extension cables must not be connected up to the system.
  - Apparatuses, which are not part of the system, must not be connected.
  - The moveable multiple sockets have to be suitable for the load of the system.
  - The moveable multiple sockets which are supplied along with the system only may be used for the supply of the devices of the system.
  - Observe the instructions for the installer on how to set up the system in an ideal way. Please also read chapters 3.4, 3.5 and 3.6.

2 Description of the device

2.1 Intended purpose

2.1.1 Description

The MPR2 is used to monitor the oxygen partial pressure, to monitor up to two invasively measured physiological pressures, and to monitor of up to two temperatures of the patient (with alarm function).

2.1.2 Intended use

The MPR2 is a diagnostic unit with physiological threshold value monitoring and display of the following physiological parameters: invasive pressure (ICP, IBP, two channels), oxygen partial pressure (pO2, one channel) and temperature (T, two channels). Invasive pressure measurement, oxygen partial pressure measurement and temperature measurement are significant performance characteristics of the unit. These parameters are determined by using RAUMEDIC catheters for single-channel ICP measurement or with RAUMEDIC multi-parameter catheters for combined measurement of ICP and temperature. In addition, external transducers may also be used for the invasive pressure measurement. Optionally up to two pressure signals can be passed on through the two analogue outputs to a bed-side monitoring device with threshold monitoring.

2.1.3 Operational environment

The MPR2 is intended for use in clinical environments to be operated by specialized medical staff. The unit is used either stationary or mobile during transport in the hospital. Doctors, intensive care nurses and medical technicians shall use the unit. The unit is not intended for use outside of the hospitals, such as in helicopters or in ambulances. The MPR2 is not intended for use in domestic settings.

2.2 Indications

2.2.1 Conditions

The use of the MPR2 is indicated, when the doctor considers it necessary to measure and monitor several physiological parameters, such as invasive pressure, oxygen partial pressure and temperature.

2.2.2 Body parts or types of tissue interacting with the unit

The MPR2 has no body or tissue contact with the patient. Signals are received from sensors.

2.2.3 Frequency of use

The use of the MPR2 is indicated when the attending physician prescribes the application. The MPR2 has been designed for continuous operation.

2.2.4 Physiological purpose

The use of the MPR2 is indicated, if the intention is to obtain information for the treatment, to assess the appropriateness of the treatment, or to exclude the cause of symptoms.

2.2.5 Patient population

Please observe the information in the instructions for use of the catheter used for the application.

2.2.6 Application in connection with electrosurgical units

Devices that meet the requirements of IEC 60601-1-2:**2007** (for differentiation, see Section 10 Electromagnetic compatibility) are contraindicated for simultaneous use with electrosurgical devices. (see section 2.3 Contraindications). **Only devices** that fulfill the requirements of IEC 60601-1-2:**2014** are suitable for simultaneous use with electrosurgical units. The following notes must be observed:

- If the MPR2 is used together with an electric surgical instrument, then a measurement inaccuracy according to chapt. 10.1.1 Accuracy under the influence of electromagnetic interference phenomena can occur.
- Before using electrosurgical units, check that the test transducers used are equipped with appropriate protective measures against patient burns. If the sensors do not have suitable protective measures, they must be disconnected from the device before electrosurgical units are used.

2.3 Contraindications

The MPR2 is contra-indicated for use in MRT or MRI and must not be operated in a corresponding environment.

Devices that meet the requirements of IEC 60601-1-2:2007 (for differentiation, see Section 10 Electromagnetic compatibility) are contraindicated for simultaneous use with electrosurgical devices.

The unit is not intended for use outside of the hospitals, such as in helicopters or in ambulances. The MPR2 is not intended for use in domestic settings.

2.4 Main operating functions

The main operating functions of the MPR2 are:

- the installation of the unit, connect system components
- the installation of the device, connect system components;
- switch on the device;
- connect the catheter;
- selecting the recording mode;
- connecting to a third-party system;
- selecting the catheter zeroing;
- determining the measurement location;
- erasing the memory;
- create patient file;
- performing a simple functional pre-test of the alarm signals;
- configure alarms;
- deactivating the alarms;
- measure;
- display trend;
- set storage mode;
- monitor the temperature output value;
- perform a simple functional pre-test of the medical thermometer;
- switch off the device;
- cleaning and disinfecting

The configuration of the unit is no main operating function.

2.5 Operating elements, connections, displays

The following two pages will render an overview of the most important operating elements and displays.

The unit has been fitted with two types of keys:

1. Keys with dedicated functions and
2. Keys with context-sensitive functions

2.5.1 Keys with dedicated functions

These five keys are arranged on the left-hand bank of keys and are marked with their functions.
The key functions are described in Table 1.

2.5.2 Keys with context-sensitive functions

The unit has eight context-sensitive defined function keys (F keys). The F keys are located in the right-hand bank of keys directly next to the display. Their current functions are shown in the appertaining monitor area.

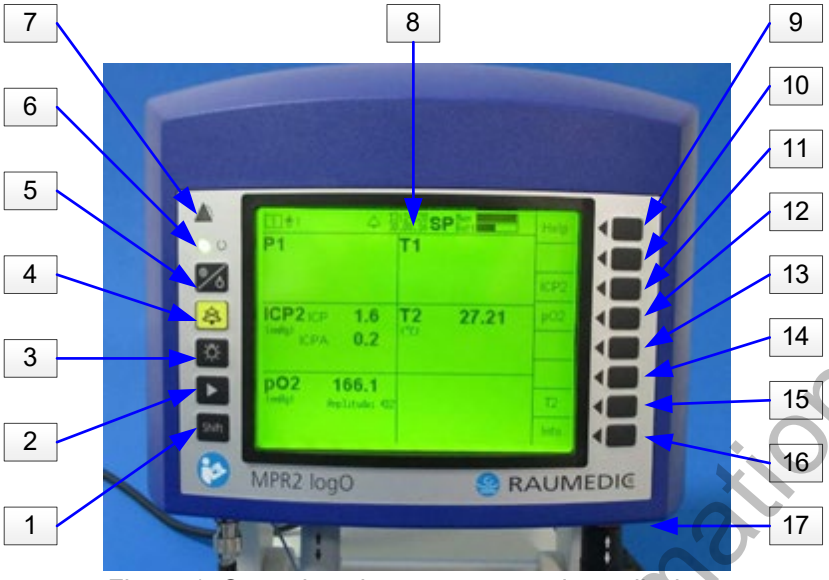


Figure 1: Operating elements, connections, displays

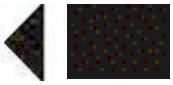
[1]		The Shift key switches this operation control key to the second level. The Shift key is a toggle key (thus it switches on and off alternately); however, the Shift status is automatically left without depression of the key after 15 seconds.
[2]		The right arrow key sets the display to the next image. When the last image is made, the first image is displayed again.
[3]		The light bulb symbol switches the background lighting on/off in battery-operated mode (toggle function). After 60 seconds the lighting is switched off automatically. During mains operation this key has no function.
[4]		The bell symbol switches the AUDIO OFF function of the active alarm conditions (in keeping with standard IEC 60601-1-8), long depression sets global AUDIO PAUSING or global AUDIO OFF).
[5]		The Symbol on/off key is used to switch the unit on and off. To switch the unit off, keep the key pressed for 2 seconds.
[6]		Power On LED (green) combined with the optical display for alarms with higher priority (red LED).
[7]		Display for alarms with high priority (flashing red LED) or average priority (flashing yellow LED).
[8]		Display
[9] to [16]		Soft keys, also referred to as F keys.
[17]		Connection field

Table 1: Keys and functions

Figure 2: Connection field

[18] not equipped

[19] pO_2: connection port for partial oxygen pressure (cf. chapter 4.4.3 Partial oxygen pressure sensor)

[20] P2/T2: multi-purpose port for invasive pressure P2 (cf. chapter 4.4.2 Transducer for invasive blood pressure IBP) and temperature T2 (cf. chapter 4.4.4 Transducer for temperature measurement)

[21] P1: multi-purpose port for invasive pressure P1 (cf. chapter 4.4.2 Transducer for invasive blood pressure IBP)

[22] Out-2: analogue output 2 (cf. chapter 4.6.1 Combine analogue outputs)

[23] Power: port for mains adapter (cf. chapter 4.1 General aspects)

[24] PC: USB interface (cf. chapter 3.6 PC interface)

[25] E: RS232 interface (cf. chapter 3.5 Interface for the extension of the apparatus)

[26] Out-1: analogue output 1 (cf. chapter 4.6.1 Combine analogue outputs)

[27] Temp-1: port for temperature probe, channel 1 (cf. chapter 4.4.4 Transducer for temperature measurement)

Figure 3: Optional stand holder [28]

Figure 4: Optional table holder [29]

2.6 Information and warning symbols

2.6.1 Information and warning symbols on the front side

The symbol below the shift key [1] has the following significance:

	The instructions for use must be read.

The triangular LED at the left-hand top has the following significance:

	Display for alarms: Flashing yellow LED, if alarm has average priority. Flashing red LED, if alarm has high priority. LED off, if no alarm.

The round LED at the left-hand top has the following significance:

	LED to signal ON / OFF and stand-by (flashing green LED for battery-pack operation and stand-by, green LED 100 per cent mains operation. Flashing red LED, if alarm has high priority.

2.6.2 Information and warning symbols on the bottom side and the type plate of the unit

The symbols on the bottom side of the apparatus at the cable connection ports [17] to [27] have the following significance:

	The patient connections [19], [20], [21], [27] are of type CF and have been classified as being defibrillation protected.
	The caution sign above the patient connections indicates that only accessory parts authorised by the manufacturer may be connected up to the RAUMEDIC MPR2 logO DATALOGGER. In this respect, please observe the instructions for use.
	Analogue outputs **Out-1** [26] and **Out-2** [22].
	The caution sign above the analogue outputs **Out-1** and **Out-2** indicates that only accessory parts authorised by the manufacturer may be connected up to the RAUMEDIC MPR2 logO DATALOGGER. In this respect, please observe the instructions for use.
	**Power** input for connection of the mains adapter.
	Caution – observe the instructions for use! The caution sign next to the **Power** port indicates that only mains adapter, art. No. 284007-002 or 284027-001 may be used (according to the type plate of the MPR2).
	Bi-directional digital input / output.
	The caution sign below port E indicates that only accessory parts authorised by the manufacturer may be connected up to RAUMEDIC MPR2 logO DATALOGGER. In this respect, please observe the instructions for use.
	Bi-directional digital USB input / output.
	The caution sign below the **PC** port indicates that only accessory parts authorised by the manufacturer may be connected up to the RAUMEDIC MPR2 logO DATALOGGER. In this respect, please observe the instructions for use.
	Please observe the disposal instructions. Do not put old units into the garbage.
	Please observe the instructions on ESD protection.
	ESD protection measures: Contact pins of plugs/sockets, which are provided with an ESD warning label, must not be touched. Connections between these plugs must not be made without using ESD protection measures. In particular, the causing of high electrostatic discharges at the labelled points must be avoided. This is supported through the use of appropriate ESD work clothing, an appropriate ESD working environment (ESD floors) and ESD packaging. It is recommended that the operator instructs all employees involved in using the device about the above mentioned ESD measures.

Table 2: Information and warning symbols

2.6.3 Remark and warning symbols on the marking plate and the packaging label off the device

The symbols on the marking plate and the packaging label have the following significance:

	Manufacturer
	Date of manufacture
	Reference number
	Serial number
	Consult instructions for use!
	Keep dry
	Keep away from sunlight
	Temperature limit during transport and storage
	Please observe the disposal instructions. Do not put old units into the garbage.
	The device meets the essential Requirements of the European Directive 93/42/EEC

2.7 Abbreviations

CD	Compact Disc
CF	Cardiac Floating
CT	Computer tomography
EMC	Electro-Magnetic Compatibility
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LP	Long Play memory mode
FOC	Fibre-Optical Cable
MPBV	German Medical Products Operator Regulations
MPG	German Act on Medical Products
MRT	Magnetic Resonance Tomography
MTK	Electrical measurement check
N.C.	Normal Condition
NFFS	Nand Flash File System
NiMH	Nickel Metal Hydride
PHB	Phiboard (optoelectronic oxygen sensor module)
S.F.C.	Single Fault Condition
SN	Serial Number
SP	Short Play memory mode
STK	Safety-related check
SW	Software

2.8 Code designations on the connection ports of the MPR2

Ext.	connection port for device extension (RS232)
Out-1	connection port for analogue output 1
Out-2	connection port for analogue output 2
PC	connection port for USB cable
Power	connection port for mains adapter
P1	connection port for pressure sensor P1
P2/T2	multi-purpose port for pressure sensor P2 / temperature sensor T2
pO2	connection port for fibre-optical partial oxygen pressure sensor
T1	connection port for temperature sensor T1

2.9 Catheter location and signal designations

ART	Arterial pressure
CPP	Cerebral Perfusion Pressure
DIA	Diastolic pressure
GP1, GP2, GP3	general pressure parameters (without specific catheter location)
IBP	Invasive Blood Pressure
ICP	Intra-Cranial Pressure
ICPA	Intra-Cranial Pressure Pulse Amplitude
MAP	Median Arterial Pressure
MD1	Median pressure D1
MD2	Median pressure D2
MD3	Median pressure D3
UL	Upper limiting value
pO2, ptiO2	Partial oxygen pressure
SYS	Systolic pressure
T1	Temperature T1
T2	Temperature T2
LL	Lower limiting value
CVP	Central venal pressure

3 Patient monitoring

Note: This chapter describes the units and their functions as well as the extension options of the MPR2. A detailed description of the operation of the MPR2 is rendered in chapter 4 Operation of the MPR2, and the technical data are listed in chapter 11.1 Technical data.

3.1 Invasive pressure measurement IBP

3.1.1 General aspects

Applied part type CF 
Type: for pressure sensors with radiometric characteristic 5 µV / V / mmHg
Number: 2
Where: Figure 2: Connection field, connection ports [20] and [21]
Application: see below

The MPR2 can be used to measure and display up to two invasive pressures. The pressure channels are type CF and have been classified as protected against defibrillation.

- Invasive procedures comprise risks for the patients. Apply aseptic techniques, and observe the instructions of the catheter manufacturer.
- Use accessories only which are listed in the overview in chapter 9 Accessories. No splitting into spatially separate sensors for pressure and temperature may be effected at the multi-purpose port P2/T2.
- Use transducers and cables only which have been protected against defibrillation. Observe the instructions of the transducer and/or catheter manufacturer.
- Disposable transducers are intended for one-time use only.

The MPR2 has two input sockets P1, P2/T2, to which up to two transducers or micro-chip precision pressure catheters can be connected. By means of the software, pressure measurement inputs can be allocated to different measuring locations.

Designation	Definition
ART	arterial pressure
CVP	central venal pressure
ICP1	intra-cranial pressure 1
ICP2	intra-cranial pressure 2
GP1	standard label - pressure 1
GP2	standard label - pressure 2
GP3	standard label - pressure 3

Table 3: Designation of the measuring location

The allocation of the measuring location of the pressure channel sets its scale, alarm source and alarm limits.

Specification of the pressure channels: cf. chapter 11 Technical parameters (Specification)
Recommended accessories: cf. chapter 9 Accessories

3.1.2 Preparation of the invasive pressure measurement

3.1.2.1 Preparation of the invasive pressure measurement with external transducer

- Prepare the monitor set in keeping with the instructions of the manufacturer. Ensure that no air is locked in the hose system.
- Connect the Datalogger transducer cable to the transducer; plug the connector with the yellow mark into port P1 or P2/T2 of the MPR2.
- Position the transducer at the height of the measuring location.
- Connect the patient catheter to the pressure hose.
- Adjust the transducer to zero.
- Use the three-way cock to open the hose to the patient.

⚠ **In conjunction with external transducers, use the "Conventional zeroing" option on the MPR2 only.**

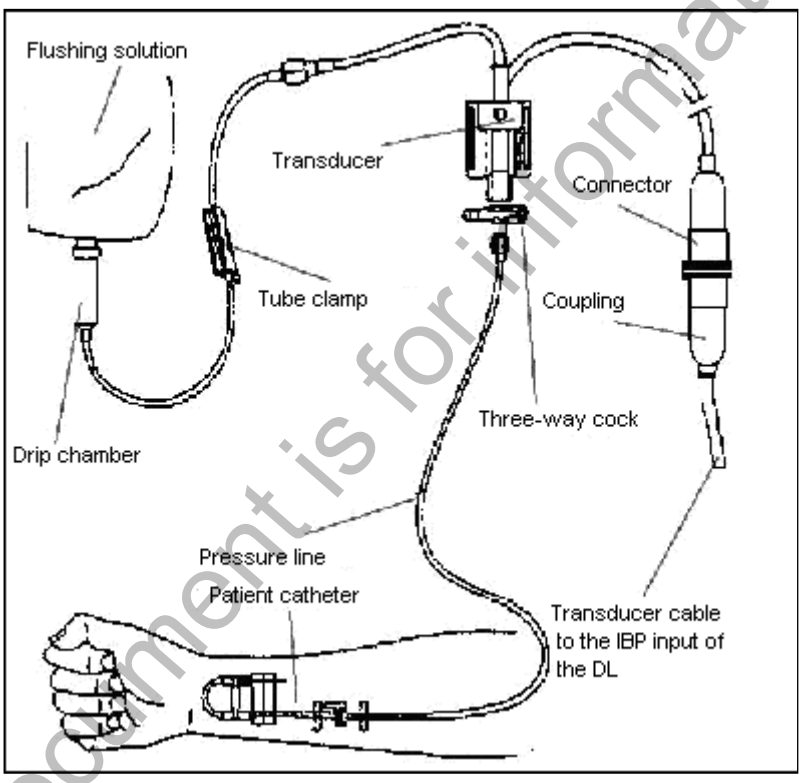


Figure 5: Pressure measurement with external transducer

3.1.2.2 Preparation of the invasive pressure measurement with micro-chip precision pressure catheter

- Please observe the instructions of the catheter manufacturer in the instructions for use for micro-chip precision pressure catheters! Prepare the micro-chip precision pressure catheter in keeping with the instructions of the catheter manufacturer.
- Connect the ICP-Temp cable or the PTO cable to the catheter; plug the connector with the yellow mark into the port P1 or P2/T2 of the MPR2.

⚠ When required, choose another measuring point.

⚠ Select the "Zeroing RAUMEDIC Catheter" zeroing option when the RAUMEDIC precision pressure catheter has been connected!

⚠ Please observe the instructions for use of the accessories, such as cable and catheter. If limitations apply in the permissible measuring range or in the protection against defibrillation, for example, the said shall have to be adhered to by all means.

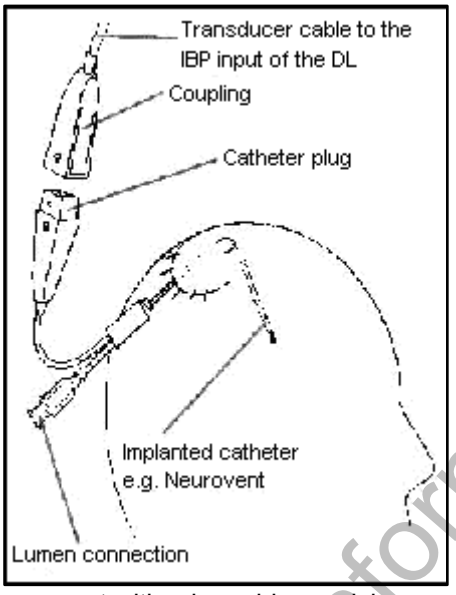
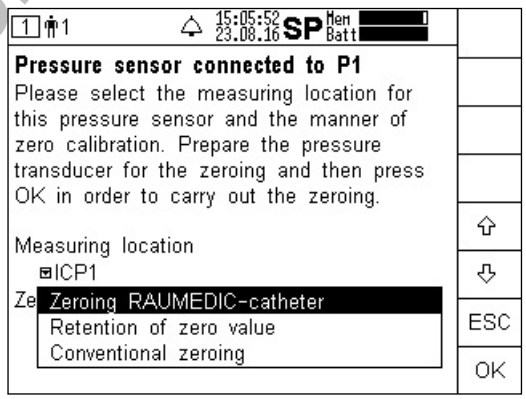


Figure 6: Measurement with micro-chip precision pressure catheter

3.1.2.3 Zero calibration

There are three options to be selected from in the Zero calibration menu of the MPR2:

- Zeroing RAUMEDIC catheter
- Retention of zero value
- Conventional zeroing



3.1.2.3.1 Zeroing RAUMEDIC catheter

During their manufacture, RAUMEDIC catheters are subjected to extensive measurements. Based on the evaluation of these measurement results, the parameters of RAUMEDIC catheters are precisely set in the works; the offset error is extremely low.

Based on this property, the Zeroing RAUMEDIC catheter option is rendered in the Zero calibration menu. In the process no relative zeroing takes place as is the case in conventional zeroing.

⚠ Use this option only, if you are well aware of the function of this process.

⚠ Use this option only in conjunction with RAUMEDIC catheters and under observation of the special instructions in the instructions for use of the catheter manufacturer.

3.1.2.3.2 Retention of zero value

In case of nursing measures it may be necessary to sever the connection of the measuring chain on the pressure catheter or on the MPR2. The pressure catheter remains in the implanted condition. A subsequent conventional zeroing of the pressure catheter in implanted condition is not possible, however. For this reason, the zero value of the first zeroing process in non-implanted condition has to be retained. This zero value saved in the MPR2 will be taken over when the pressure catheter is connected again and when the "Retention of zero value" option is selected.

⚠ Use this option only, if you are well aware of the function of this process.
⚠ Use this option only with the same pressure catheter.

3.1.2.3.3 Conventional zeroing

If conventional zeroing is carried out, the output signal of the pressure sensor is declared zero at this point in time. Frequently external transducers or pressure catheters provide an output signal deviating from zero; they produce an offset value. In case of conventional zeroing, this offset is removed for the current measurement (internal correction).

⚠ Use this option only, if you are well aware of the function of this process.
⚠ Please ensure that zero pressure pushes up at the pressure sensor prior to starting conventional zeroing.
⚠ In pressure catheters, conventional zeroing may be carried out in non-implanted condition only.

3.2 Measurement of the partial oxygen pressure

3.2.1 General aspects

Applied part	type CF
Type:	fibre-optical sensor
Number:	1
Where:	Figure 2: Connection field, connection ports [19] and [20]
Application:	see below

When a special fibre-optical catheter (NEUROVENT-PTO) made by RAUMEDIC has been fitted, the MPR2 can be used to measure and display the partial oxygen pressure. The pressure channel is CF type and has been classified as defibrillation protected.

⚠ Please observe the safety-related instructions (cf. chapter 1 Safety-related information).
⚠ Invasive procedures comprise risks for the patients. Apply aseptic techniques, and observe the instructions of the catheter manufacturer.
⚠ Use only those accessories which have been listed in the overview in chapter 9 Accessories. No splitting into spatially separate sensors for pressure and temperature may be effected at the multi-purpose port P2/T2.
⚠ Please observe the instructions of the catheter manufacturer.
⚠ Please observe the notes on the special features of optical fibres rendered in the instructions for use of the PTO catheter.
⚠ Please observe the notes on cleaning and protection of the optical plug-in connector rendered in the instructions for use of the FOC.

The fibre-optical sensor is always connected to the following two sockets: Connection of the optical signal through FOC to ST port Figure 2: Connection field, connection port [19]; the PTO cable to P2/T2 port Figure 2: Connection field, connection port [20]. Fibre-optical sensors of RAUMEDIC only may be connected. In the process, please observe that apart from the FOC the PTO cable always has to be connected. All information on the type of catheter, its usability, the measuring location and the calibration parameters have been saved to the digital memory which is read out by the MPR2 via the PTO cable. When a catheter of the NEUROVENT-PTO type is connected, for example, the digital memory will allocate the ICP2 measuring location to the invasive pressure automatically. A partial oxygen pressure measurement without the PTO cable is not possible.

Designation	Definition
pO2	ST connector for partial oxygen pressure
P2/T2	Multi-purpose connector for digital memory, invasive pressure P2 and temperature T2

Table 4: Connections for the partial oxygen pressure probe

The allocation of the measuring location of the channel sets its scale, alarm source and alarm limits.

As the partial oxygen pressure probes are multi-purpose probes as a rule, which combine partial oxygen pressure measurement, invasive pressure measurement and temperature measurement in one catheter, the notes rendered hereto shall have to be observed as well.

Specification of the pressure channels: cf. chapter 11 Technical parameters (Specification)
Recommended accessories: cf. chapter 9 Accessories

3.2.2 Preparation of the catheter

- Prepare the oxygen catheter observing the Instructions for Use of the catheter.

- Connect the FOC to the ST connector of the oxygen catheter. The connection between the ST connector of the catheter and the FOC is provided with an ST coupling. Prior to connecting the FOC, the protective caps of the connectors have to be removed, which are used to prevent a soiling of the light outlets of the FOC. These caps have to be fitted again when the FOC is not used.
  When connecting the FOC cable, please observe the instructions in chapter 6 Troubleshooting.

- Connect the PTO cable to the catheter; plug the connector with the yellow mark into port P2/T2 of the MPR2. Ensure that the markings with the 3 gold spots on the blue plug of the catheter and the cable are positioned on the same side, see 4.4.3.1 Connecting the cable to the catheter. The ICP-Temp cable is not suitable for the connection of the oxygen catheter because the catheter data saved to the catheter connector are not transferred and may lead to wrong measurement values.

⚠ During the zeroing of the pressure transducer, please observe the instructions for use of the catheter. Select the “Zeroing RAUMEDIC catheter” option only, if such a catheter has been connected, and the instructions for use explicitly prescribe this zeroing process.

⚠ The measurement of the partial oxygen pressure is a photo-optical measurement. For this reason, please avoid any soiling or mechanical damage by scratching the photo-optical connector, couplings and sockets in the signal path from the catheter and the FOC to the MPR2.

⚠ Please observe the instructions for use of the accessories, such as cable and catheter. If limitations apply in the permissible measuring range or in the protection against defibrillation, for example, the said shall have to be adhered to by all means.

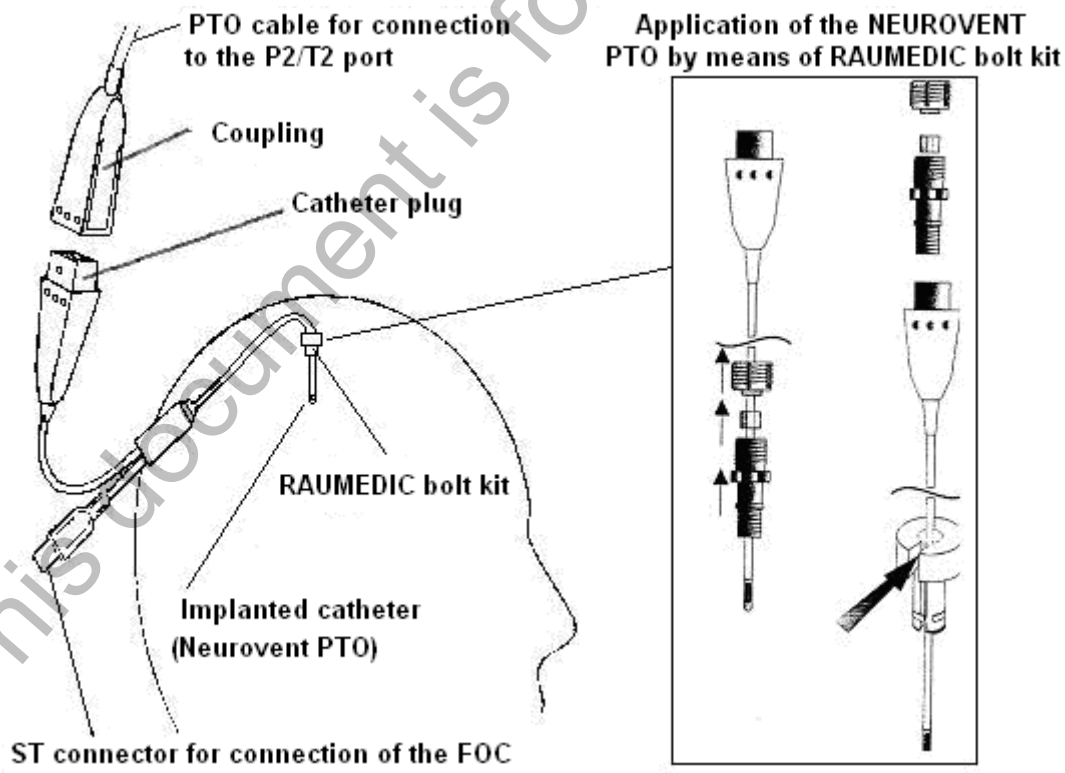


Figure 7: Measurement with NEUROVENT-PTO catheter

3.3 Measurement of the body temperature

Applied part type CF
Type: Temperature sensors with thermistor characteristic YSI400
Number: 2
Where: Figure 2: Connection field, connection ports [20] and [27]
Port [20] Multi-purpose channel P2/T2, measurement with PTO catheter and PTO cable
Port [27] ¼ inch jack plug for temperature sensors with jack
Application: see below

The MPR2 can be used to measure and display up to two temperatures. The temperature channels are type CF and have been classified as protected against defibrillation.

⚠ Please note that only the temperature sensors from the following table can be used for temperature measurement.

The following temperature sensors have been approved for MPR2:

Type	Manufacturer	Article No.
NEUROVENT-P-TEMP	RAUMEDIC	094268-001
NEUROVENT-PX-TEMP	RAUMEDIC	091431-001
NEUROVENT-TEMP	RAUMEDIC	094278-001
NEUROVENT-TEMP IFD-R	RAUMEDIC	095327-001
NEUROVENT-TEMP IFD-S	RAUMEDIC	094288-001
NEURODUR-TEMP	RAUMEDIC	094298-001
NEUROVENT-PTO	RAUMEDIC	095008-001
NEUROVENT-TO	RAUMEDIC	095908-001
NEUROVENT-PTO 2L	RAUMEDIC	095108-001
NEUROVENT-PTO 2L BOLT	RAUMEDIC	095308-001

Table 5: Temperature sensors

Specification of the temperature measurement: cf. chapter 11 Technical parameters (Specification)
Recommended accessories: cf. chapter 9 Accessories

⚠ The resolution of the temperature measurement is 0.01 °Celsius, and thus is higher than the accuracy mentioned above. The higher resolution has been provided intentionally to recognise short-time changes in temperature (without the necessity of having to ensure an absolute accuracy of 0.01 °Celsius).

3.3.1 Preparing the temperature measurement

As soon as the temperature sensor has been connected to one of the connection ports [20] or [27] and is subjected to a temperature of at least 15.0 °Celsius, the MPR2 will show the room temperature in the respective temperature channel field [7] of the display.

⚠ In this way the function of the temperature sensor can be checked prior to use.

⚠ Please observe the instructions for use of the accessories, such as cable, temperature sensor and catheter. If limitations apply in the permissible measuring range or in the protection against defibrillation, for example, the said shall have to be adhered to by all means.

Please ensure that the sensor connector is dry and free from impurities.
If the temperature displayed appears to be plausible, you can start monitoring the body temperature of the patient. It is immaterial to which temperature input the temperature sensors are connected.
After applying the sensors to the measuring point, you have to wait for 2 to 3 minutes until the sensor has taken up the temperature of the measuring point and it does not change anymore so that the exact temperature value can be read. Always wait until a constant condition has set in, at which the temperature no longer rises.
In case of a defective sensor (short circuit or cable cut) no value is displayed, instead the display **Sensor?** starts flashing.

For information on placing and handling the temperature sensors, please refer to the respective instructions for use.

3.3.2 Cleaning, disinfecting and sterilising the temperature sensor

RAUMEDIC multi-parameter catheters (precision pressure catheters with additional temperature measurement) are sterile products and are intended for single use only.

3.4 Analogue outputs

Type: resistance output, radiometric characteristics
Where: Figure 2: Connection field, connection ports [22] and [26]
Application: signal transfer

The MPR2 has two identical analogue outputs to transfer up to two invasively measured pressure signals of type ICP or pO2 to a third-party system (bed-side monitor) with alarm function.

⚠ Use approved accessories only.

⚠ Every person who connects an additional unit to the signal input or signal output configures a medical system, and thus he / she shall be responsible for the fact that this system meets the requirements of standard IEC 60601-1.

⚠ Please keep in mind that the errors in the pressure display multiply on the third-party system when analogue outputs are used. Error of the pressure sensor + error of the pressure amplifier of the MPR2 + error of the analogue output + error of the pressure amplifier of the third-party system. When using the analogue output, it is imperative that you proceed in keeping with chapter 4.6.1 Combine analogue outputs.

As from 17th March 2004 the following third-party systems shall be considered approved:

- Armeda PM 9000
- Marquette Dash 3000
- Marquette Hellige SMU 611
- Marquette Hellige EAGLE 4000
- Hewlett Packard M1166 Model 66S

Please enquire with the manufacturer for other third-party units.

Cable selection: depending on the apparatus, cf. chapter 9 Accessories

If you want to transfer the signals to another third-party system not listed here, please get in touch with the manufacturer. You will receive updated information on the cable systems available and the third-party systems approved.

3.5 Interface for the extension of the apparatus

Type: RS232
Number: 1
Where: Figure 2: Connection field, connection port [25]
Application: unit service and optional extension of the apparatus (preparation only)

Currently this interface is used only for servicing, diagnosing and maintaining the apparatus as well as for updating the software. In a later extension stage, this interface could be used to connect optional apparatus extension modules of RAUMEDIC.

⚠ **Use approved accessories only.** Never try to carry out hardware extensions yourself which are not supported by the firmware of the MPR2. Every person who connects an additional unit to the signal input or signal output configures a medical system, and thus he / she shall be responsible for the fact that this system meets the requirements of standard IEC 60601-1.

3.6 PC interface

Type: USB
Number: 1
Where: Figure 2: Connection field, connection port [24]
Application: connection of laptop

⚠ Use approved accessories only.

By means of the USB cable (RAUMEDIC article No. 283949-001), this USB interface can be used to connect a laptop, which by means of the DataView software (RAUMEDIC article No. 296900-001) is used

- for on-line display of the values measured.
- for the extended storage of the values measured on the HDU of the laptop.
- for off-line display of the values saved.
- for the administration of the patient data.
- for data export of the values measured to other data evaluation programs (e.g. MS-Excel).
- for printing out the courses measured.

⚠ Please keep in mind that the laptop has to be set up outside of the patient environment.

4 Operation of the MPR2

4.1 General aspects

4.1.1 Switching on the apparatus

⚠ **Familiarise yourself with the instructions for use prior to using the MPR2.**

⚠ **If you have already used an MPR2, please observe the differences in the behaviour of the appliance, in particular when setting the alarm limiting values. The behaviour of the appliance depends on the revision status of the firmware. Please read chapter 4.6.2 Device diagnostics.**

⚠ **The apparatus may be operated only with the battery compartment closed.**

⚠ **Listen for the short peep when the apparatus is switched on. If this peep is not sounded, the alarm system can be tested once again in the apparatus diagnosis mode. If no sound is produced in this case either, monitoring is no longer possible with this apparatus.**

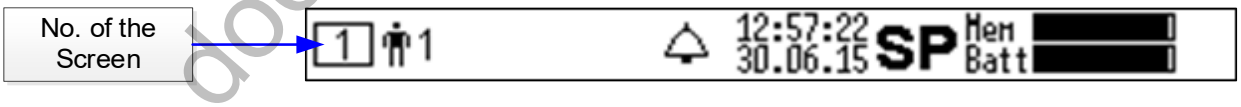
⚠ **After having switched on the apparatus, please check whether the date and time show correct values. If this is not the case, please read chapter 4.6.5 Setting date and time.**

⚠ **If in the graphics or trend screen a graph passes along the upper or lower margin (measuring range limit) of the diagram, the measured value may also be larger or smaller than shown (overmodulation). This applies in particular, if a fixed scale is used instead of automatic scaling.**

Prior to using the apparatus check the correct condition of the device and of the accessories. The apparatus and the accessories must not be damaged or soiled. Please check for the presence of loose parts by shaking or tipping the appliance, for example. If loose parts are present, the appliance must not be used. If the MPR2 is operated on battery pack, please check the charge condition of the battery pack when switching the apparatus on. The battery symbol Batt on the top right-hand side of the display can be used to read the charge condition of the battery pack. A full bar indicates a charged battery pack. Given a completely charged battery pack, the MPR2 can be operated up to two hours without a mains connection (e.g. during transport of the patient). In this case, the green power On LED starts flashing (top left-hand side on the operating panel).
If the MPR2 is to be operated by means of the mains adapter supplied, it has to be connected to the mains voltage. Now connect the red connector of the mains adapter cable with the red port of the MPR2. Please keep in mind that only one approved electrical appliance may be connected to the mains adapter.
Use key [5] to switch on the MPR2. After the apparatus has been switched on, it carries out a self test. This key is also used to switch the appliance off. In order to prevent an unintentional shut-down, the key has to be pressed for two seconds.

4.1.2 Screen selection

After the MPR2 has been switched on the start screen will appear; for the instructions to carry out the settings, please refer to chapter 4.2 Start screen.
In the start screen, the settings are made such as patient documentation, how to select the memory mode, et cetera. After the settings have been made, leave the start screen and skip to the overview screen which is marked with the 1 symbol in the information field of the display.



4.1.2.1 Information field

The following data are always displayed in the information field:

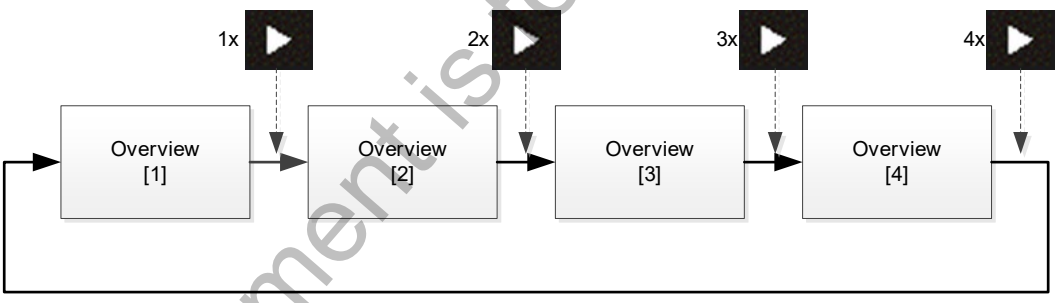
- Screen number for the data field (see below)
- Patient ID
- Time and date
- Battery charge condition (symbol)
- Available memory capacity, i.e. the free memory is symbolised, thus the same logic as in the battery charge condition shall apply: a lot = good
- Memory mode (SP or LP)
- Alarm symbol (indicates the alarm clearing when crossed out)

4.1.2.2 Navigation field

The navigation field contains the designations of the contextually defined programmable function keys (F keys). The F keys are arranged next to the display in such a way that the designation is indicated right next to the respective key when the key has been allocated to a function by the software of the MPR2.

4.1.2.3 Data field

The data field is used to display the data measured.
There are three different data displays and in addition the window for device configuration. Hereinafter, they will be referred to as screens for short. Each screen is identified by a number 1 to 4, which is displayed in the information field.
The screens have a fixed sequence; the screen forward key (also referred to as screen selector key) can be used to skip between the individual screens.
The following three symbols are available: digital display, graphics and trend.
In base condition (i.e. after the apparatus has been switched on), the start screen will always be displayed (cf. Fig. 8).
By repeated actuation of the ▶ screen forward key, you skip between the individual screens:



4.2 Start screen

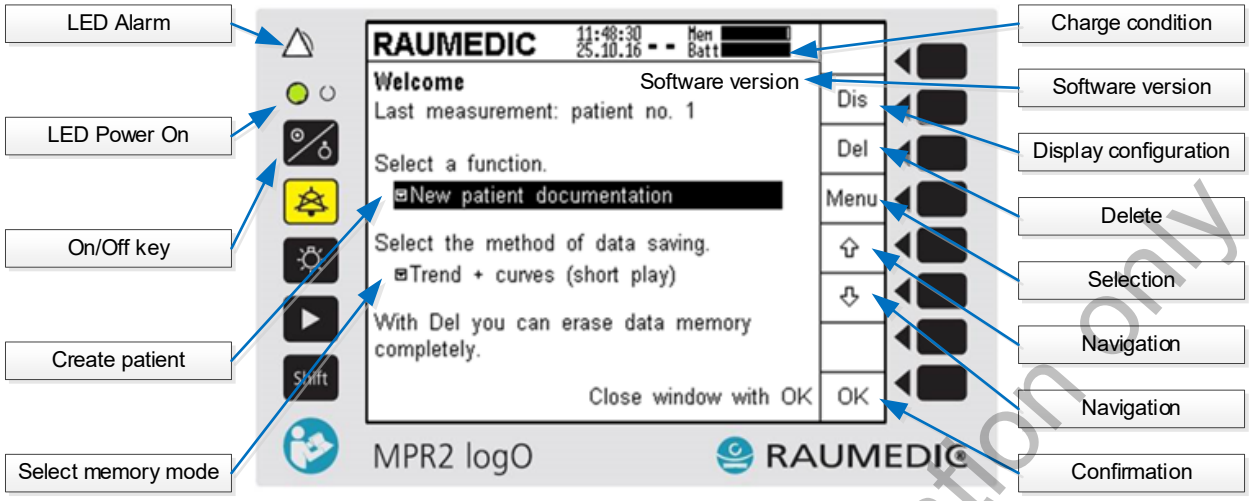


Figure 8: Start screen

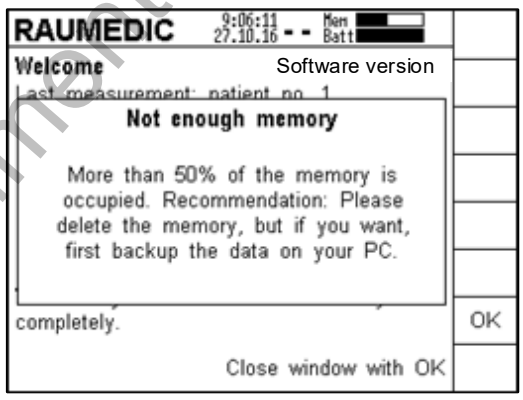
After the apparatus has been switched on you will be greeted by the **Welcome** screen. On this screen is shown the version of installed device software.

⚠ In the further description of the device, the software version shown in the graphics may differ from that installed on your device.

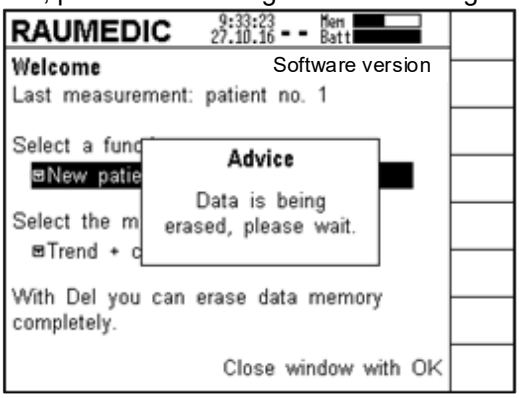
Further, you can in this view

- delete the patient data saved
- define a new patient and
- select the memory mode

If the memory is more than 50 % full, the user now receives the recommendation to delete (clear) the memory. This recommendation can be ignored, which however has the consequence that the condition "Memory full" will more than likely be reached instead.



If the memory is to be deleted now, proceed according to 4.2.2 Deleting the memory.



Deleting the memory can take a short while.

4.2.1 General notes on the key functions

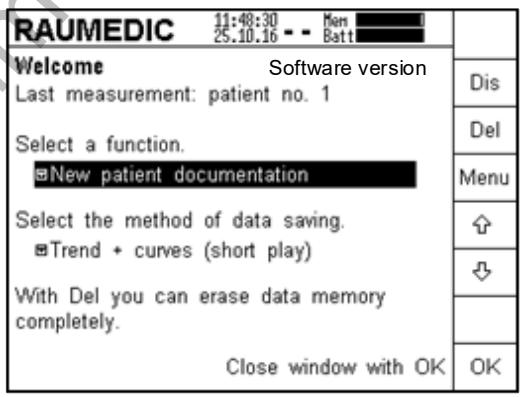
⚠ **Please observe: The functions of the keys in the left-hand row cannot be changed, and for this reason the symbol has been printed on the respective operating surface. The keys in the right-hand row are soft keys with variable functions. The function is defined by a symbol on the display of the respective key. Please observe the other key function, if the Shift key is pressed in addition.**

4.2.2 Deleting the memory

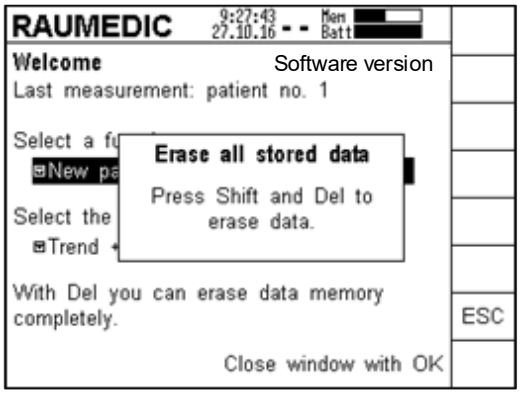
⚠ **Please observe: The memory mode set has a decisive influence on the potential recording duration. Only a fraction of the memory which is required for the recording of the curves and trends in short-play mode is required for the mere trend recording in long-play mode. However, in this case only trends will be displayed off-line on the laptop.**

⚠ **Check the memory symbol Mem [■■■■] (right-hand top in the display) to ensure that sufficient free memory is available prior to recording. A black bar indicates a free memory. If insufficient free memory is encountered during the recording process, a warning is released indicating that the eldest memory data will be overwritten when continued.**

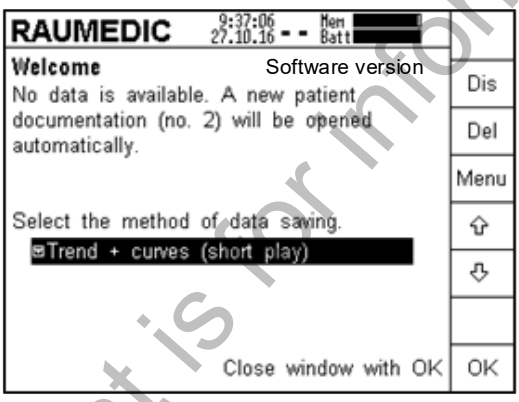
Depending on the memory display you can now decide whether all previously saved patient data are to be erased or not. You should decide in favour of erasing if you want to ensure a maximum of recording time.



After the Del key has been pressed, the memory is not deleted immediately, but a confirmation enquiry is displayed beforehand. This action prevents an erasure of the saved data by accidental actuation of the Del key.



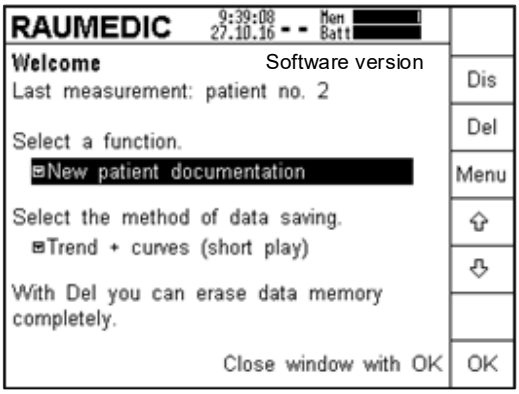
For irretrievable erasure of the data saved, press the Del delete key. The successful deletion of the data is confirmed by an acoustic signal as well as a short note on the screen. After the deletion, the memory bar is completely black.



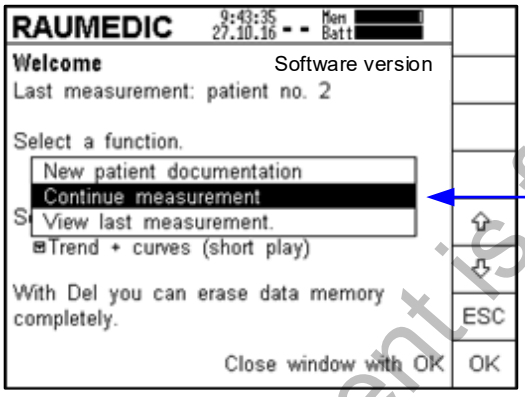
As the available data have been erased, you cannot continue with the previous patient in this case, instead a new patient documentation is opened automatically. At this point you can only select the memory mode.

4.2.3 Open a new patient documentation

The symbol ⊡ indicates that a pull-down menu has been provided. Use the arrow keys to navigate to another pull-down menu.

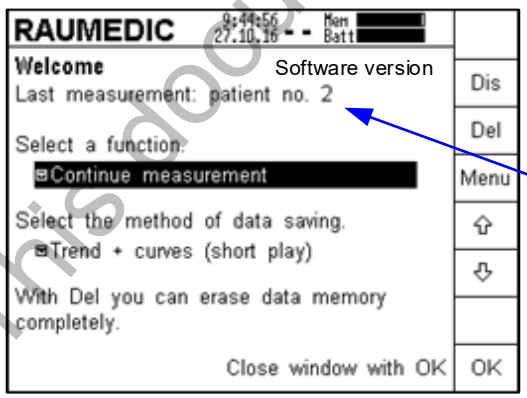


If you want to open a new patient documentation, you need not do anything and can continue with the selection of the memory mode. If you want to continue with the last patient, press the Menu key first of all. The “Continue measurement” option can only be selected, if data of a previous patient still are saved on the MPR2. If the data saved on the MPR2 have been deleted (cf. chapter 4.2.2 Deleting the memory), a new patient is set up automatically.



If the measurement is continued, this measurement will be allocated to a patient automatically when the data are downloaded to the PC. No additional query is displayed. Wrongly allocated data can not be re-sorted automatically.

Use the arrow key to navigate to the requested setting. If you want to accept the selected setting, you can now press OK. If you want to discard your selection, press the ESC key to return to the previous step.

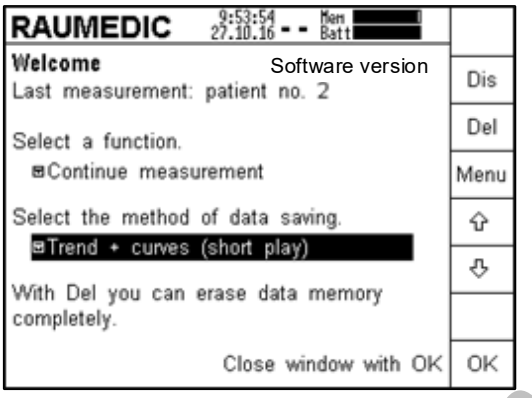


The patient IDs are counted up to 99999, subsequently the IDs are continued with 1, which however has no influence on the storage. Internally the patient IDs are counted further. The last five digits of the internal patient IDs only are displayed. An ID 0 is suppressed.

4.2.4 Selecting the memory mode

In the next step, the memory mode can be selected. This step is not obligatory.

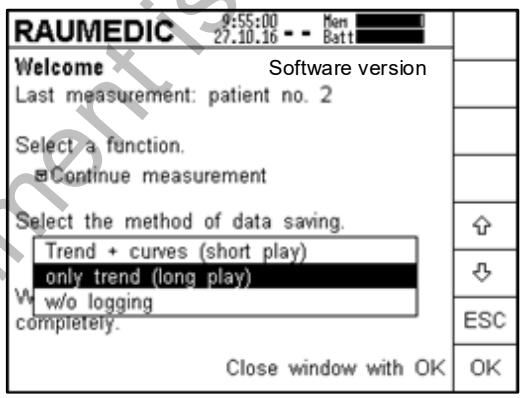
For the selection of the memory mode, use an arrow key to navigate to the next pull-down menu which can be recognised by the ▣ symbol.



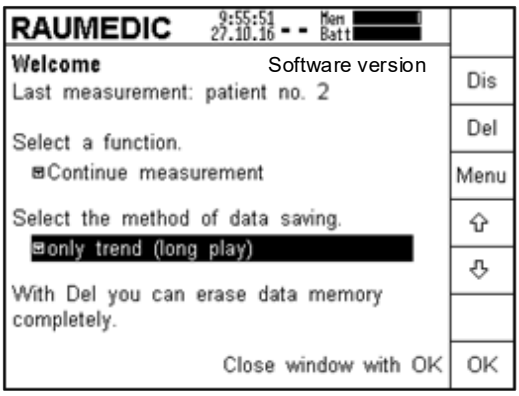
If the memory mode displayed is okay, no other selection needs to be done. If you want to continue with the displayed memory mode, press the Menu key first of all. The works settings are „Trend + curves (short play)“.
Two memory modes are available:

- Trend + curves (short play)
- only trend (long play)

If you want to set long-play mode, use the arrow key to navigate to “only trend (long play)”. If you want to accept the selected setting, you can now press OK. If you want to discard your selection, press the ESC key to return to the previous step.



If you want to accept the selected setting, you can now press OK. If you want to discard your selection, press the ESC key to return to the previous step.



If the memory mode cannot be changed, the window can be closed by pressing OK. The window can be closed only, if no pull-down menu is open any more. The memory mode selected remains saved even after the appliance has been switched off and will appear again as the basic setting when switched on again. However, the same procedure can be used to change the menu.
"Alarm limits selection" 4.3 Selecting the limiting alarm values is reached first, provided "New patient" was selected. Under "Continue measurement" this step is omitted.

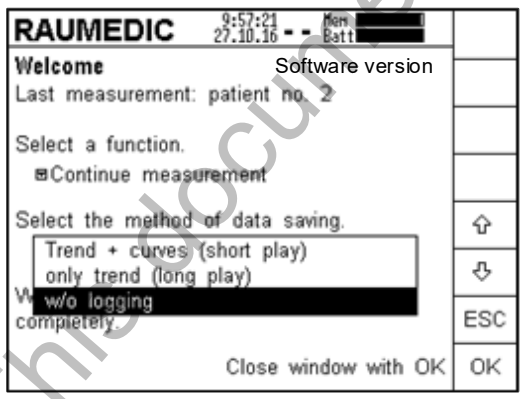
4.2.5 No storage

As an alternative to the memory modes Short play (SP) and Long play (LP), from firmware version 2.00.0053 there is an option of selected a third memory mode "No storage".
The advantage of this operating mode is that device can be used in a largely unlimited way, without a technical alarm "Memory full" being triggered.

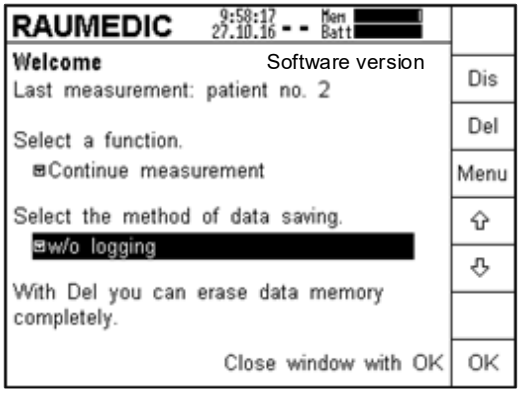
This memory mode is recommended, if:

- the user wants to carry out patient monitoring
- does not want to use the device memory function
- is not considering any subsequent data archiving or visualisation on the PC

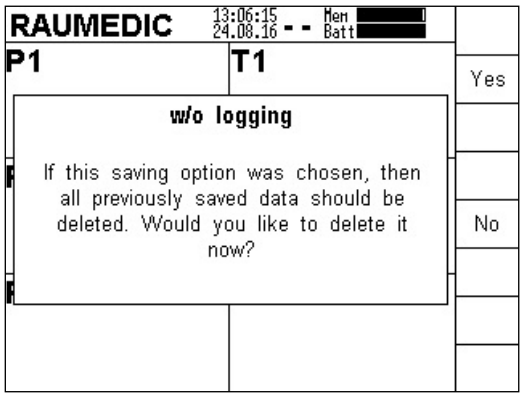
wishes to carry out measuring as quietly and smoothly as possible without unnecessary technical alarms (e.g. use at night)



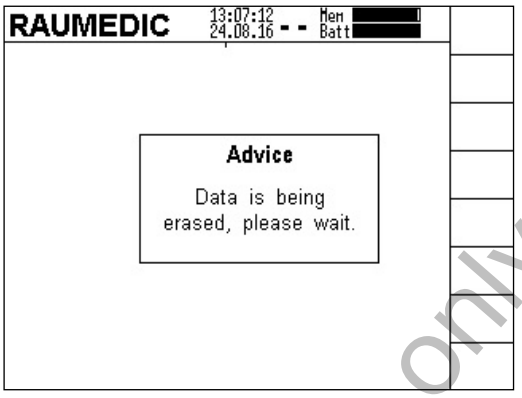
Open Data storage menu. Use the arrow keys to select the desired memory mode "No storage". Confirm with OK. The memory mode "No storing" is indicated in the status line by the symbol **- -**.



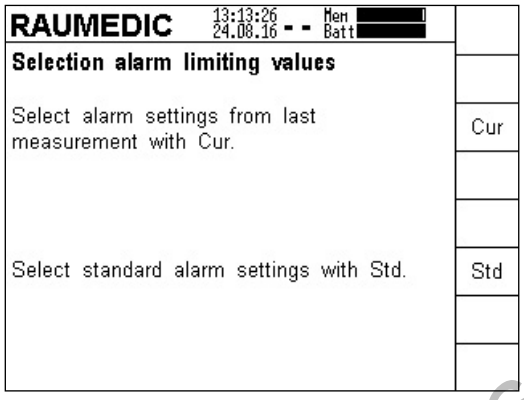
Confirm the selected Data storage with OK. If data is already stored on the device, it must be deleted.



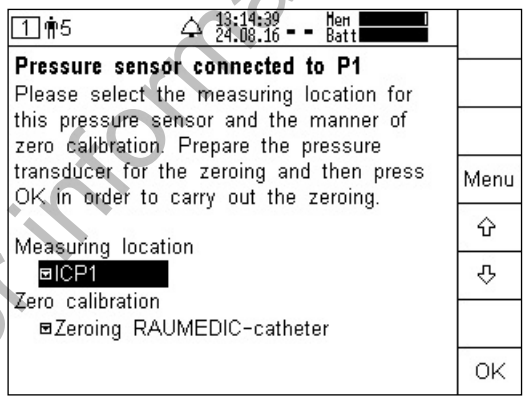
Data is stored on the device. The user has the option of backing these up before deletion (Select No). If Yes is selected, the data are irrevocably deleted.



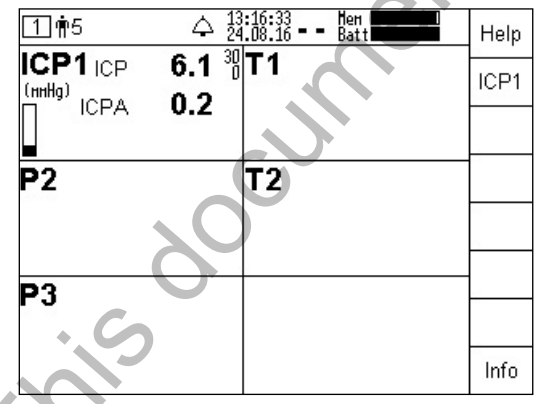
The deletion process lasts for a short period.



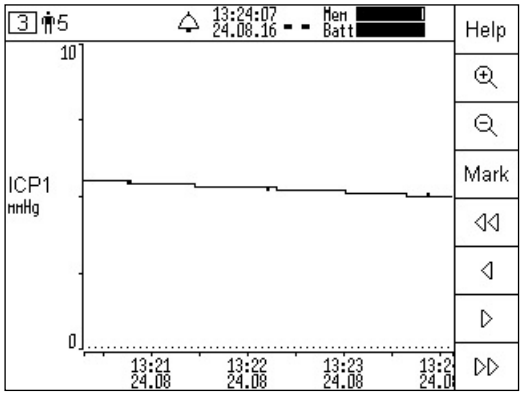
After data deletion, alarm limit selection is carried out.



Specification of the site of measurement and the possibility of zeroing, in case a pressure sensor is connected.



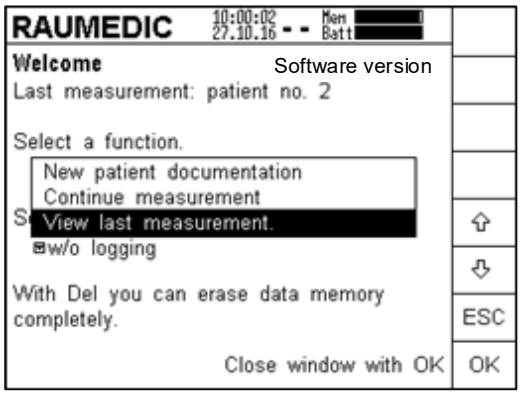
Patient monitoring. The memory mode "No storing" is indicated in the status line by the symbol - - .



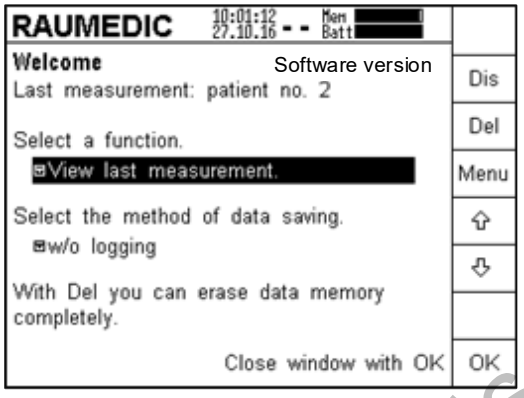
Even in memory mode “No storage“ trend display for up to 8 hours is possible. Beyond this period, older data are overwritten.

4.2.6 View last measurement

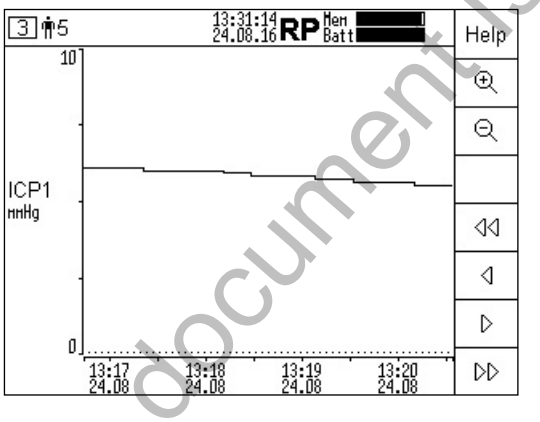
From firmware version 2.00.0053 the option now exists of viewing the trend data of the last measurement. Prerequisite for this is that data have been saved and the device memory has not already been deleted.



Open Function menu. Using the arrow keys select the function "View last measurement". Confirm with OK. This function is only available if data are stored on the device.



Confirm the selected Function with OK. This function is only available if data are stored on the device.



The trend data of the last measurement are displayed on the device. Display of measurement curves (data from SP memory mode) is not possible.

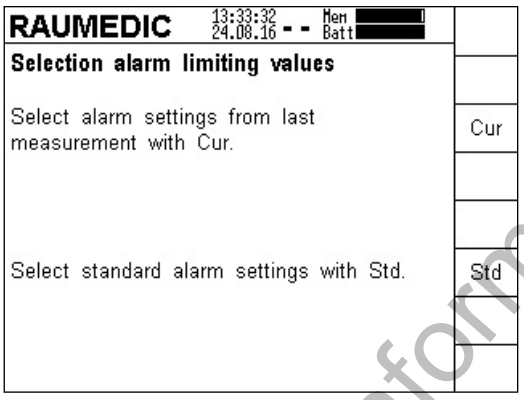
The function "View last measurement" is indicated by the reverse highlighted flashing symbol RP in the status line. In addition, the alarm LED flashes yellow in this operating mode, so that the user recognizes that the device is not in monitoring mode.

4.3 Selecting the limiting alarm values

After leaving the start screen, the screen [1] is displayed. By pressing the Cur key, the limiting alarm values of the last measurement are taken over for the current measurement.

⚠ **Select the last limiting alarm values (Cur key) with care only as the previous user could have set the limiting values to senseless values. Subsequently check the real limiting values set (which are displayed as well).**

By pressing the Std key, the limiting alarm values in the operator settings are activated. Thus, the time-consuming setting of the limiting alarm values is facilitated for repetitive monitoring tasks.



Note: After the sensors have been connected to the MPR2 and the measurement process has been started, you can change the limiting alarm values for the current measurement at any time (cf. chapter 4.4.2.2 Changing the limiting alarm value settings of invasive pressure measurement).

4.4 Connecting the transducer

The MPR2 has five input channels (cf. chapter 2.5 Operating elements, connections, displays), to which up to five units can be connected. The P2/T2 input channel has been designed as a multi-purpose channel for multi-parameter catheters.

- Please note that a splitting of this channel by cable into spatially separated units is impermissible as the measuring transducers of the multi-purpose channel are not galvanically separated. However, a single-channel pressure measurement by means of a single-channel pressure sensor can be carried out on the multi-purpose channel P2/T2 as well.

As a rule you need connection cables for the purpose. For this reason, please only use those recommended in the list of accessories. In individual cases, temperature sensors can be connected directly to the MPR2. All connections have been arranged on the bottom of the housing, and thus they are drop-proof, if the correct location is observed, cf. chapter 11.1 Technical data.
For the connection diagram, please refer to Fig. 2. All plug-in connectors have been coded mechanically and colourwise which makes wrong connections impossible. For data on the basic settings of the alarm limits, the alarm activation and the settings of the alarm limits, please refer to chapter 4.9.2 Factory settings.

⚠ Never use force ! Force will definitely cause damage. When handled correctly, the cable connectors can be plugged in and removed easily.

⚠ Transducers connected are recognised automatically by the MPR2. During the measuring action, measuring transducers can be added or removed. If and when applicable, measuring locations may be allocated to the sensors connected (applies for invasive pressure) or the limiting alarm values have to be set (applies for invasive pressure, pO2 and temperature).

4.4.1 Operating instructions – connection cable

⚠ Plug in or remove the cable always by getting hold at the connector. Never pull the cable.

⚠ Do not try to connect a connector with a different mechanical coding in a wrong port. If something works stiffly, check once again for safety reasons whether the correct allocation is attempted.

⚠ Do not try to open the connectors.

⚠ The Redel plugs (all connectors with the exception of the temperature and USB connectors) have been provided with a push-pull locking system which prevents that the plug-in connections can be removed by pulling the cable. To undo the plug-in connection, get hold of the connector in the direct vicinity of the port (at the connector part with the two arrow symbols).

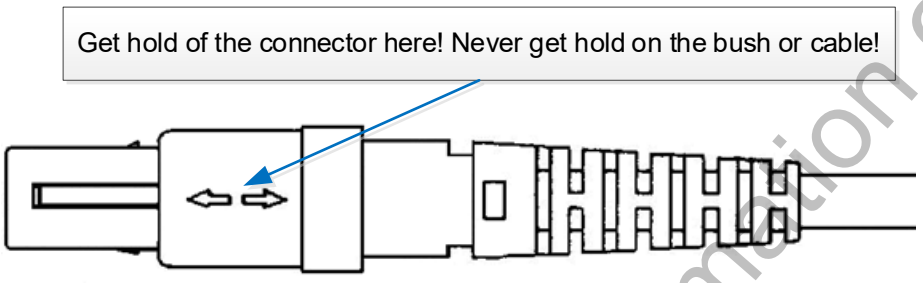


Figure 9: Cable connector

⚠ The FOC is a fibre-optical cable. Please observe notes on the FOC in the Instructions for use.

4.4.2 Transducer for invasive blood pressure IBP

⚠ **Observe chapter 3.1 Invasive pressure measurement IBP**

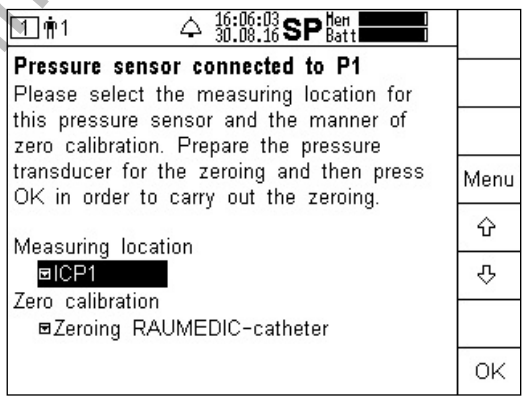
⚠ **Keep the connection cable ready prior to connecting the pressure transducer.**

⚠ **Use approved accessories only.**

⚠ **Observe the instructions for use of the accessories.**

⚠ **Observe the permissible measuring range of the transducer.**

The MPR2 has two pressure input sockets P1, P2/T2 to connect pressure sensors (external transducers or micro-chip precision pressure catheters). It is insignificant for the further measurement, to which of the two input sockets the pressure sensor is connected. The pressure sensor connected is recognised automatically. Please observe that the P2/T2 port has been designed as a multi-purpose port, which is designed for the preferred connection of a PTO catheter.



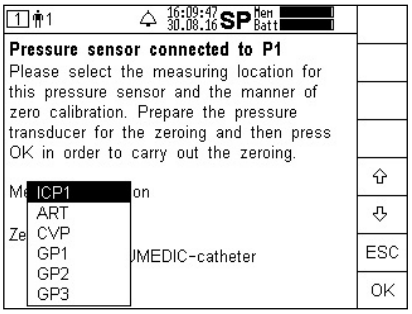
A new patient has already been created, the memory mode has been set, and the limiting alarm values have been selected. The MPR2 recognises that you have connected a pressure sensor to port P1. In this screen you can select the measuring location and the process for the zero calibration.
If you want to begin with the selection of the measuring location, press the Menu key. The pull-down menu with the overview of the measuring locations available will open. Please keep in mind that you can allocate a measuring location once only.

⚠ **If another (second) pressure sensor is connected, the measuring location allocated to P1 is not available any more in this menu. The same applies corresponding, if you want to connect a third pressure sensor.**

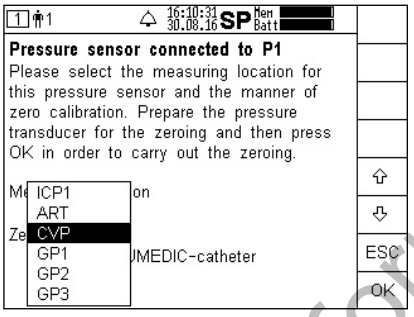
⚠ **The ICP1 measuring location is available only when the catheter has been connected up to port P1.**

⚠ **The ICP2 measuring location is available only when the catheter has been connected up to the P2/T2 port.**

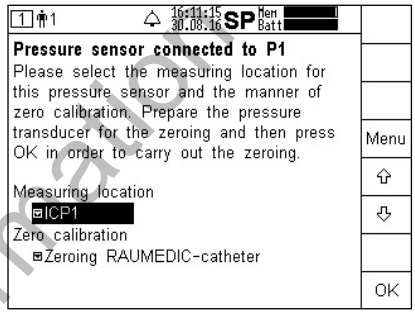
⚠ **If you have determined a measuring location, have adjusted the pressure sensor to zero and thus have started the measurement, a subsequent modification of the measuring location is not possible easily. If you want to re-define the measuring location nonetheless, remove the connector of the connecting cable for the pressure sensor on the MPR2 and reconnect.**



Press the menu key; open the selection for the measuring location.



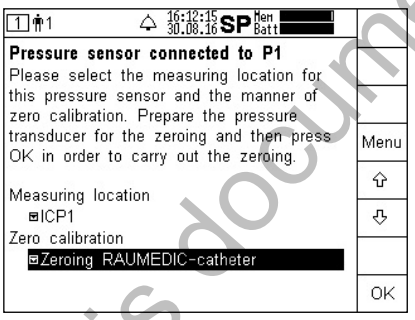
Use the arrow keys to select the requested measuring location, and then acknowledge by pressing OK.



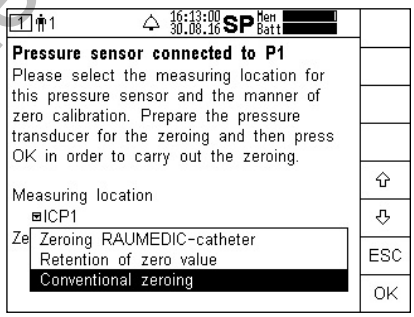
Display of the selected measuring location.

In the next step, the pressure sensor has to be zeroed. For this purpose, skip to the Zero calibration pull-down menu. Press the Menu key and select the zeroing procedure recommended for the pressure sensor. The default setting in this menu is “Zeroing RAUMEDIC catheter”. Prior to zeroing, please ensure that the pressure sensor is subjected to the pressure conditions described in the instructions for use.

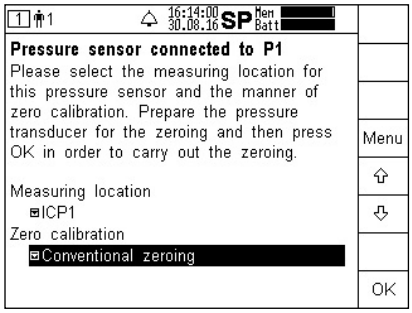
⚠ **Please observe the instructions in the instructions for use of the manufacturer of the pressure sensor. Faulty zeroing will lead to systematic measuring errors.**



Press the Menu key.



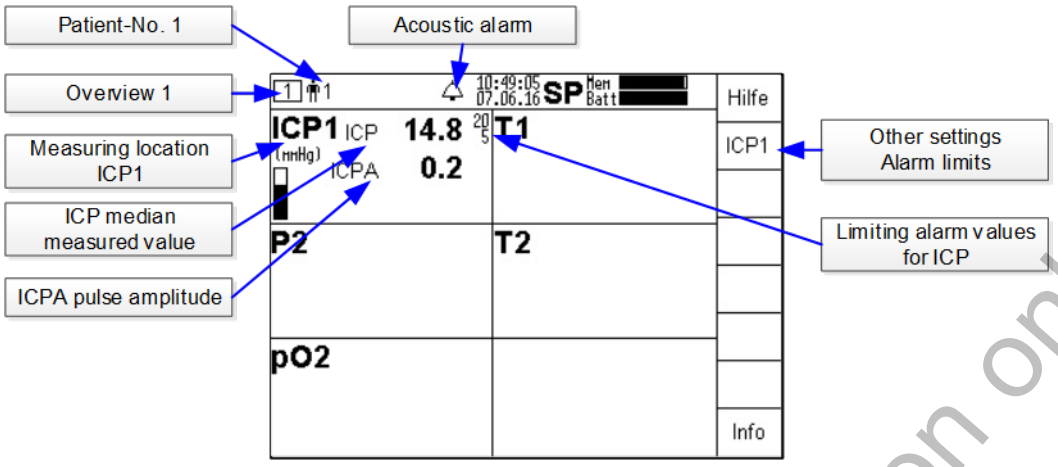
Select the zeroing procedure and acknowledge by pressing OK.



Display of the selected zeroing procedure.

Now trigger the zeroing process by pressing the OK key which will be confirmed by two short beeps. The display will automatically skip to the overview screen with the display of the measured values.

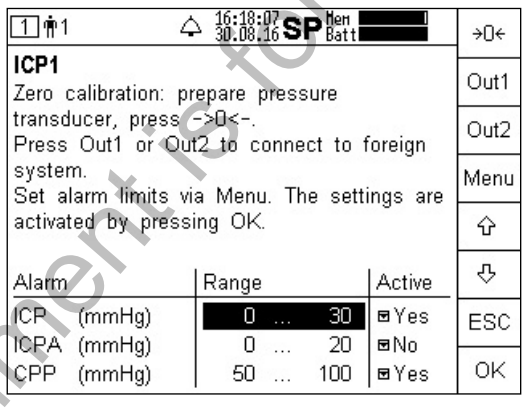
If no other sensors have been connected, the selected measuring location will be displayed.



4.4.2.1 Settings of invasive pressure measurement

⚠ **Please ensure the correct setting of the limiting alarm values. They are displayed behind the measured value, provided this function has been activated. Please make sure that you have <u>not</u> switched off the acoustic alarm permanently (= acoustic alarm permanently off).**

The right-hand column of the display holds the navigation field, in which you can use the soft keys to carry out further adjustments or to call off information or help.
Additional settings are accessed by pressing the ICP1 key. For the selection of another measuring location, this key has a different designation, such as ART. If you have connected additional pressure sensors, other soft key designations will be displayed with the defined measuring locations.



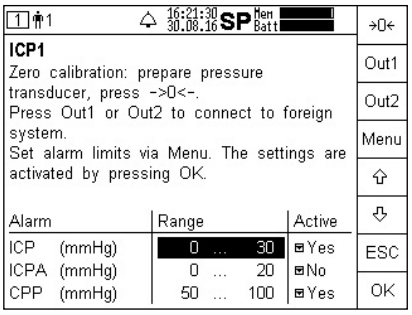
In this window, the arrow keys can be used to choose whether the pressure signal is to be switched to one of the two analogue outputs; whether you want to change the settings of the limiting alarm values; and whether the limiting value monitor of the selected parameters is to be active or not. In addition, select the measured value to be monitored.

In the measurement of the ICP, other derived values are available apart from the ICP:

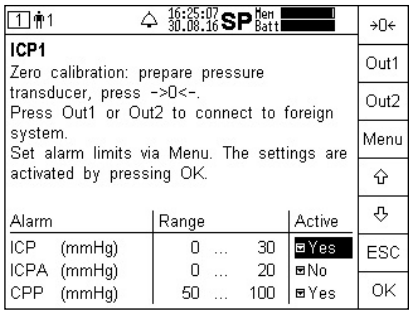
- ICP Intra-Cranial Pressure
- ICPA Pulse amplitude of the Intra-Cranial Pressure
- CPP Cerebral Perfusion Pressure (CPP = ART – ICP)

If two intra-cranial pressures (ICP1 and ICP2) are available, the CPP is calculated from ART and ICP1. If ICP1 fails (because the sensor has been removed or the sensor is defective or another hardware defect has occurred, for example) and ICP2 only is available, the CPP is calculated from ART and ICP1 automatically. In this case, a sensor alarm is activated for ICP1, but not for CPP because the limiting values for CPP calculated from ART and ICP2 are observed.
If only one intra-cranial pressure (ICP1 or ICP2) is available, the CPP is calculated from ART and ICP1 or ICP2, depending on which measuring location has been allocated.

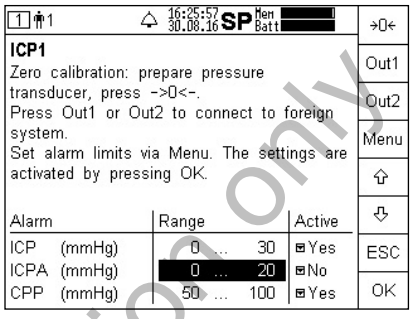
⚠ Please note that in case of a failure of ART or of one of the ICPs, no CPP can be calculated any more. In this situation no additional CPP alarm is activated in addition to the ART or ICP alarm, and the CPP is no longer displayed.



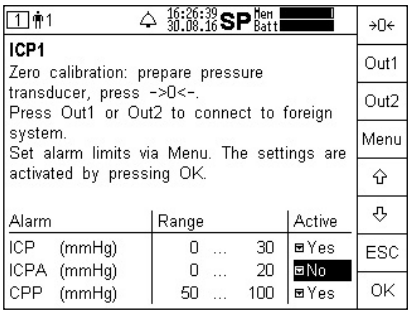
Limiting values for ICP.



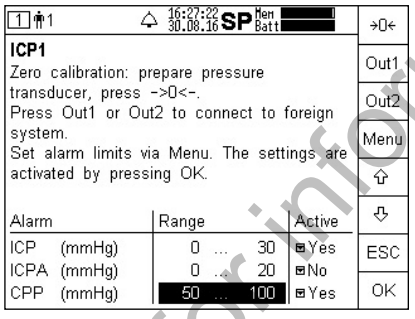
Alarm active / not active for ICP.



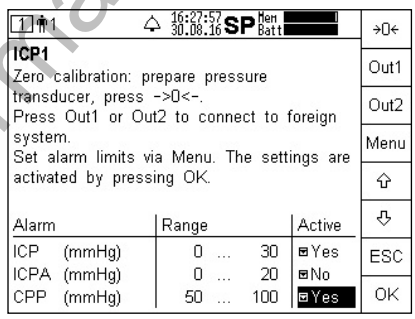
Limiting values for ICPA.



Alarm active / not active for ICPA.



Limiting values for CPP.

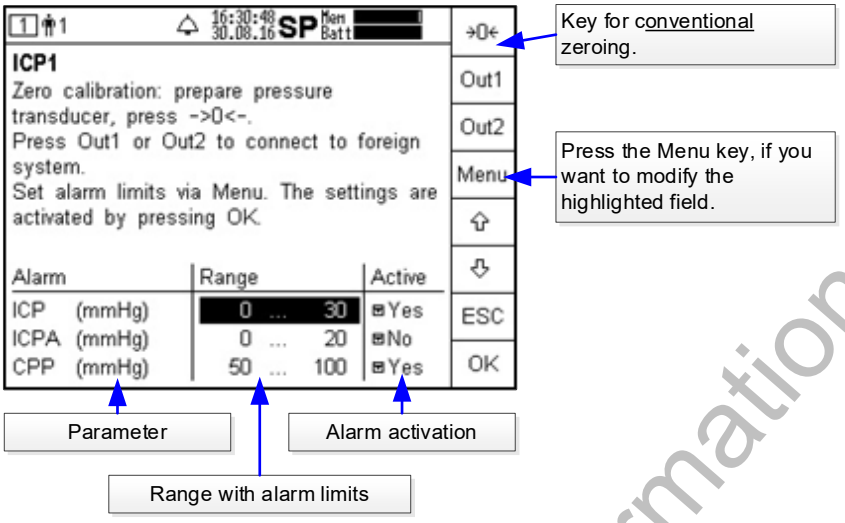


Alarm active / not active for CPP.

The settings rendered above are offered as default settings. For data on the basic settings of the alarm limits, the alarm activation and the settings of the alarm limits, please refer to chapter 4.9.2 Factory settings. In order to change the settings, use the arrow keys to navigate to the requested parameter and then press the Menu key.

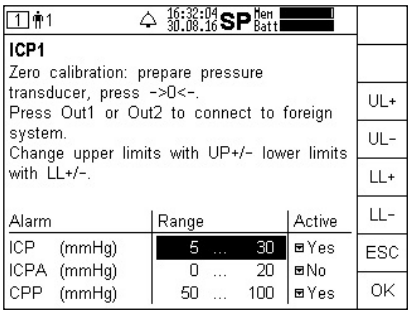
4.4.2.2 Changing the limiting alarm value settings of invasive pressure measurement

On the example of the ICP, reset the limiting values. The settings of the limiting values of the other ICPA and CPP measured values are carried out correspondingly.

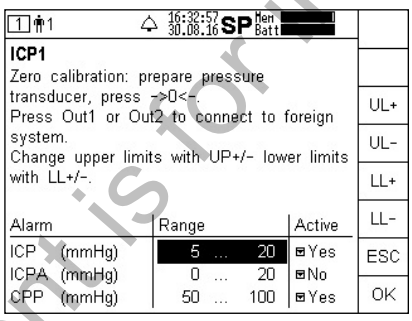


Do not set the limiting values to extreme values which could render the alarm system useless.

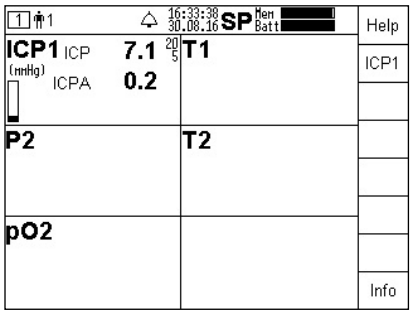
4.4.2.2.1 Changing the limiting value



Increasing the lower limiting value: Keep the LL+ key pressed until the requested value is reached.



Lowering the upper limiting value: Keep the UL- key pressed until the requested value is reached. Press OK to acknowledge the settings. Leave the window by pressing OK, if no other changes are required.

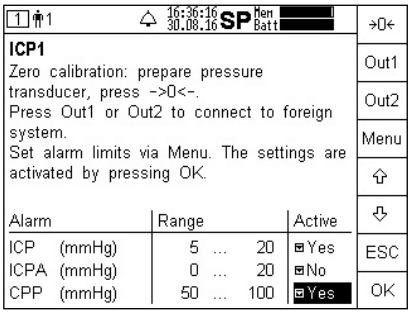


You will now access the overview of the measured values. The new limiting values will be displayed, provided Yes has been activated for the parameter Active.

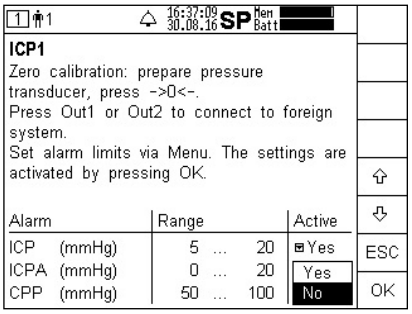
If you want to change other settings or repeat a setting, press the ICP1 key or the key of another measuring location again.

4.4.2.2.2 Activating and deactivating the alarms

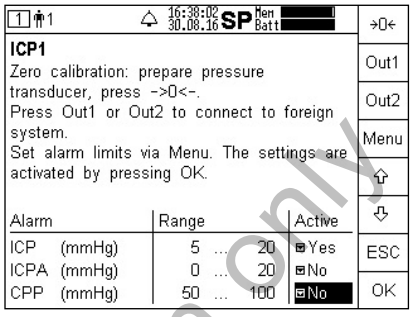
If you want to activate or deactivate an alarm, please proceed as follows:



Use the arrow keys to navigate into the table field, the settings of which you want to change. Subsequently press the Menu key.



Use the arrow keys to select the requested setting. Subsequently press the OK key.

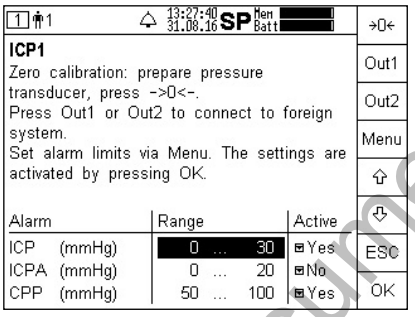


The new setting has been accepted, but it is not active yet. Press the OK key to leave the screen. Only then will all modifications be active.

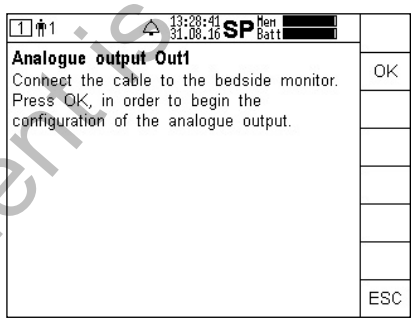
The modified settings become active only when the window is closed by pressing OK and after having returned to the overview. Press the ESC key to discard all modified settings and to return to the overview.

4.4.2.3 Combine analogue outputs

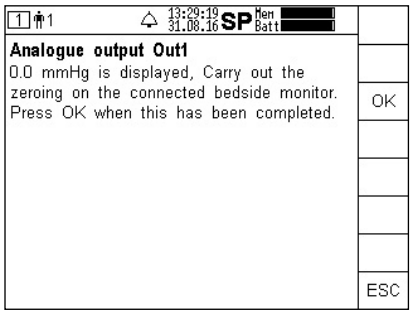
The MPR2 has two analogue outputs. The analogue outputs can be used to index two random pressure signals to a third-party system. Pressure signals could be two random pressures, but also the partial oxygen pressure. Please observe chapter 3.4 Analogue outputs. The screen displaying the settings options of the limiting values can be used to activate the connection of the analogue outputs. Another possibility is in window 4, which is described in chapter 4.6.1 Combine analogue outputs.



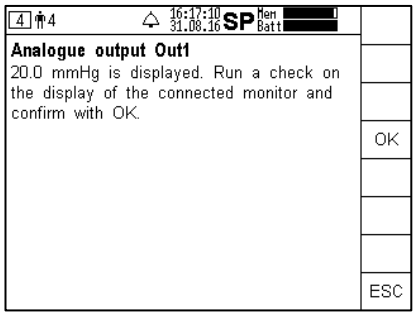
Step 1:
Select the analogue output Out1 or Out2 which you want to use to index the ICP1 pressure signal to the third-party system.



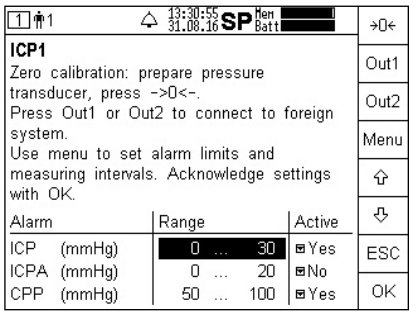
Step 2:
In the example you have selected the output Out1. Follow the instructions on the screen.



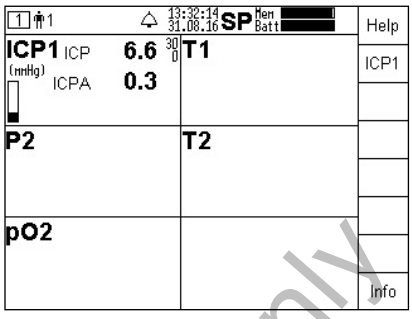
Step 3:
The cable connection between the pressure input of the third-party system and the analogue input has been established. Zero the third-party system. You have 180 seconds time to press the next button. In case of a timeout the system changes to step 1.



Step 4:
Check the display of 20 mmHg on the third-party system, and acknowledge this step. You have 180 seconds time to press the next button. In case of a timeout the system changes to step 1.



Step 5:
The ICP1 pressure signal is now switched by the analogue output Out1. Now you can carry out other settings, or you can leave the screen by pressing OK →

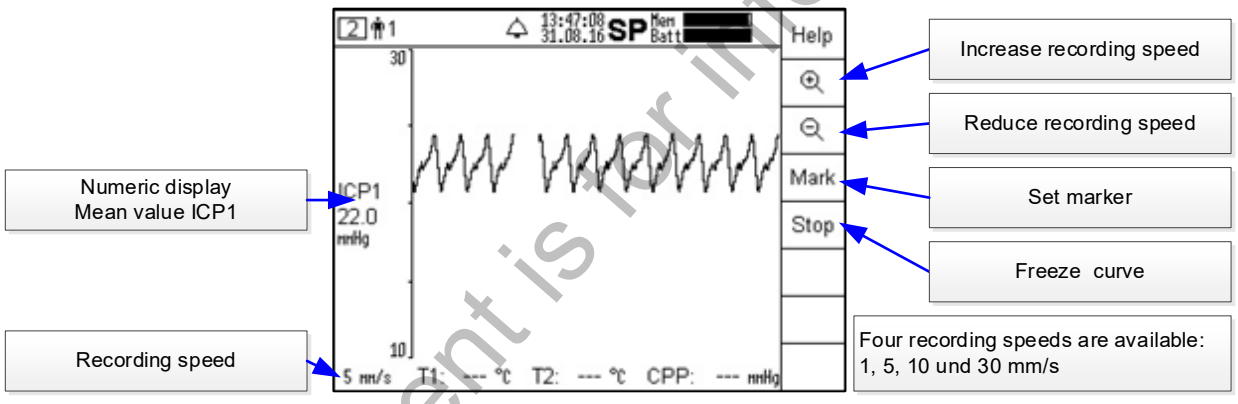


Step 6:
to return to the overview. Any potentially modified alarm settings are thus activated as well.

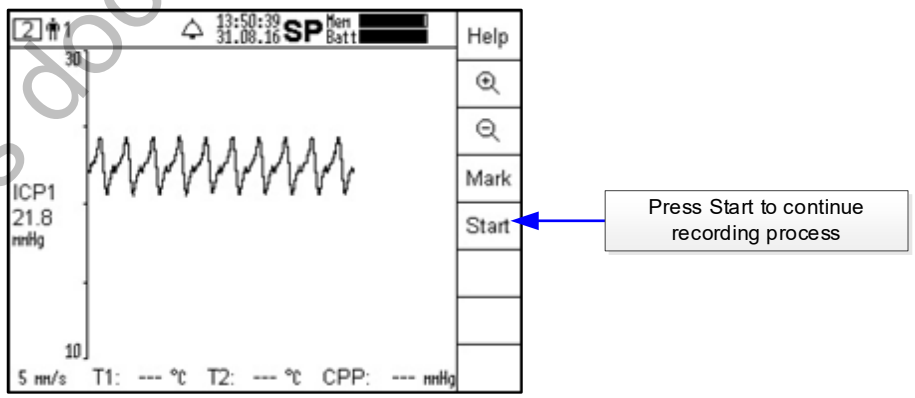
⚠ Set alarm limits to a maximum of 350 mmHg on third-party systems, if monitoring is required.

4.4.2.4 Invasive pressure measurement – Graphics

In order to skip to the graphics screen, press the key ▶. Screen [2] will be accessed.



Use the key [⊕] or [⊖] to switch over the plotting speed. 30 mm/s correspond to approx. 3 s per display width. Use the key [⊖] to reduce the plotting speed, increasing the time basis of the curve.



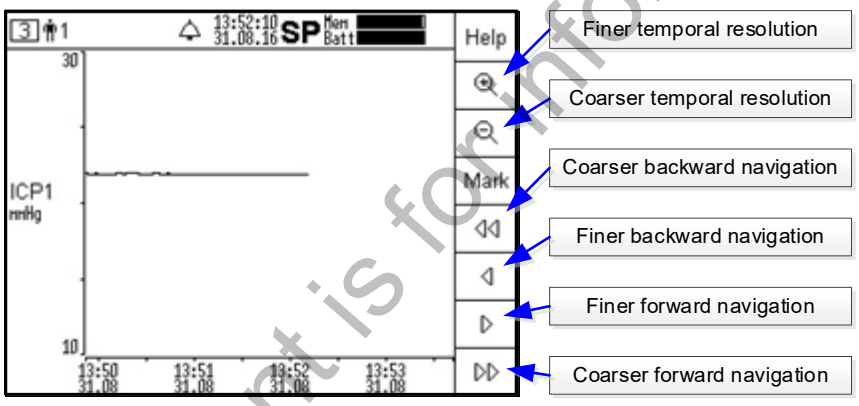
Use the [Stop] key to freeze the current curve, which is released by pressing the key [Start].

4.4.2.5 Trend

In order to skip from the graphics screen [2] to the trend screen [3], press the key ▶. The navigation field renders available keys to set the temporal resolution as well as page up and page down keys. Two different speeds are available for paging up and down. If you keep one of the navigation keys pressed for a longer period of time, the key function is carried out again through an automatic routine. Thus, you can get an overview of the entire trend fast without having to press the key several times; subsequently you can set a higher resolution for the time range of your choice. Six time ranges are available (width of the time axis in the trend graphics) which you can switch over by using the key [⊕] and [⊖]:

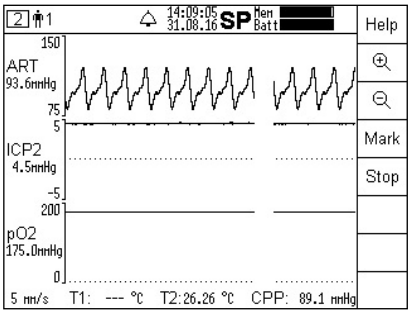
- 3 min. 50 s
- 7 min. 40 s
- 19 min. 10 s
- 38 min. 20 s
- 76 min. 40 s
- 3 h 50 min.

The somewhat odd values are produced by the number of pixels of the display range; roughly speaking a trend display of 4 min., 8 min., 20 min., 40 min., 80 min., and 4 h can be set. The trend graphics always start at the left-hand margin of the diagram. If the time basis is larger than the previous data recording time, the curve does not fill the diagram completely.

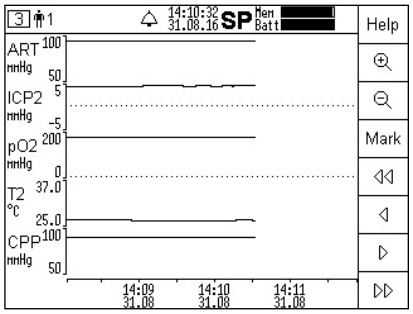


4.4.2.6 Measuring the CPP

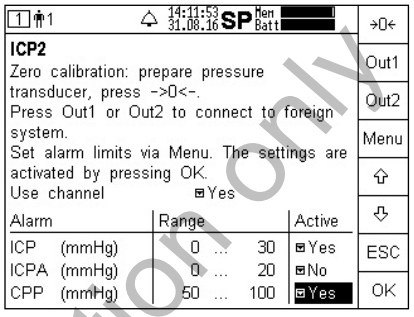
If an invasive pressure input is configured as ICP (ICP1 or ICP2) and another as ART on the MPR2, the operand CPP (Cerebral Perfusion Pressure) is calculated automatically. In screen 2 the CPP is displayed as a numerical value in the lower text line. The graphical display is rendered in the trend only. The limiting values and the alarm activation / deactivation are set when the ICP limiting values are set.



CPP displayed as a numerical value in screen 2.



CPP displayed as a curve in screen 3.



Setting the CPP alarm limits in screen 1.

4.4.3 Partial oxygen pressure sensor

Please observe chapter 3.2 Measurement of the partial oxygen pressure.

Use approved accessories only.

Please note that when RAUMEDIC PTO catheters are used for the measurement of the partial oxygen pressure (pO2), the intra-cranial pressure (ICP) and the temperature (T), the FOC, (article No. 095657-001), and the PTO cable, (article No. 095634-001), are required apart from the NEUROVENT PTO catheter, (article No. 095008-001).

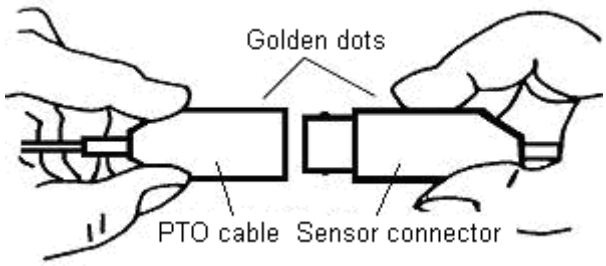
Please ensure the correct connection of the catheter connector and the cable connector (mechanical coding, colour coding).

Please observe that a wrong combination of catheter and connector with the catheter data will lead to wrong values measured.

For the connection of PTO catheters, the MPR2 has two connection ports which both have to be connected up to the PTO catheter by cables. In order to be able to measure partial oxygen pressure, it is not sufficient to connect one cable only to the catheter. Furthermore, the ICP-Temp cable, article No. 094328-001, is not suitable for the connection of the PTO catheters. Please use the PTO cable instead, cf. chapter 6.13 Reaction to fault messages and indications.

4.4.3.1 Connecting the cable to the catheter

Connection of the cable to the catheter is self-explanatory due to the design of the plug. For the PTO cable (grey cable with blue plug), ensure that when connecting the two blue plugs, the markings with the three gold spots are on the same side.



When the FOC (orange coloured cable) is connected, the moveable knurled ring on the connector also has to be turned by abt. 90 deg. clockwise until it locks into place! When undoing the connection, the moveable knurled ring on the connector first of all has to be turned anti-clockwise by abt. 90 deg. before the connector can be removed.

4.4.3.2 Connecting the cable to the MPR2

Use the following connection ports on the MPR2:

Port P2/T2 to connect the PTO cable, port [20] in Fig. 2
Port pO_2 to connect the FOC, port [19] in Fig. 2

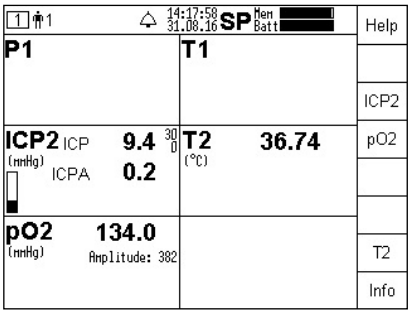
⚠ **Port P1 on the MPR2 is not intended for the connection of the PTO cable and of the PTO catheter. Exclusively use the multi-purpose port P2/T2, if you want to use the PTO cable to connect the PTO catheter to the MPR2 !**

⚠ **It is imperative that you avoid moisture or fluid getting at the electric plug-in connectors of the PTO catheter, the PTO cable and the ports P2/T2.**

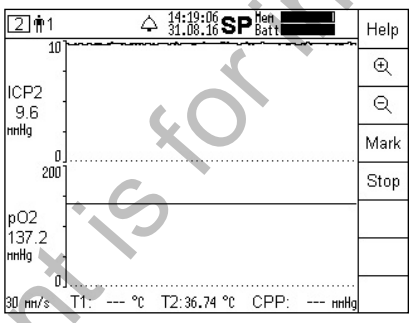
⚠ **Avoid any scratching and any soiling of the photo-optical plug-in connectors of the catheter, the FOC and the pO_2 port.**

When all cable connections between the PTO catheter and the MPR2 have been established, the MPR2 has been switched on, the sensors have been attached to the patient, the memory mode has been defined and the limiting alarm values have been selected, the measurement is started immediately when this setting mode is left. There is no query for the measuring location of the invasive pressure, neither will the catheter zeroing function be carried out (cf. chapter 3.1.2.3 Zero calibration). All necessary information has been saved to the catheter (EEPROM in the catheter connector), which is read out automatically when the MPR2 is connected. The system automatically allocates the ICP2 measuring location so that the zeroing of the RAUMEDIC catheter is correct.

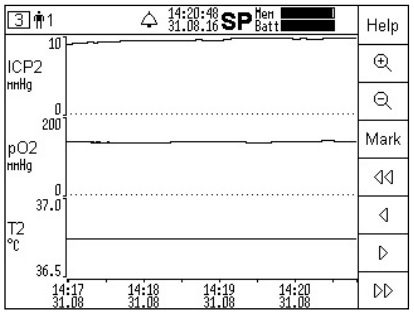
4.4.3.3 Setting the partial oxygen pressure



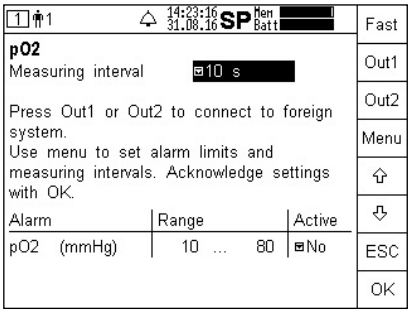
Step 1:
The pO2 is displayed in screen 1 (overview) as well as the limiting alarm values, if and when necessary, if this function has been activated. The amplitude value renders the technical information on the signal quality. If the pO2 key is pressed, other settings can be carried out.



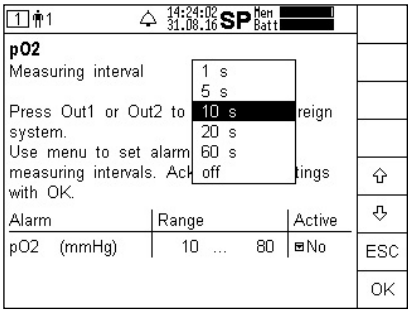
Step 2:
In screen 2 (curves) the pO2 is represented graphically. The other setting options by means of the soft keys correspond to those of the invasive pressure.



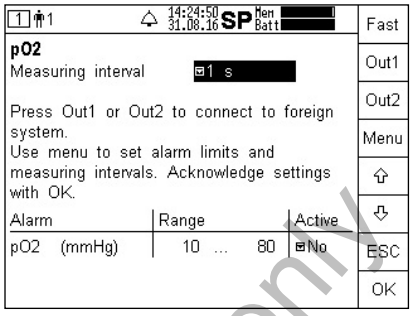
Step 3:
Screen 3 (trend) renders the pO2 as a trend. The other setting options by means of the soft keys correspond to those of the invasive pressure.



Step 4:
If the pO2 key was pressed in step 1, the setting options for alarms, signal relaying and control of the pO2 measuring intervals are accessed. The limiting alarm values are set identically with the invasive pressure; the same applies for the signal relaying to a third-party system. If the Fast key is pressed, the measuring interval of 1 sec. will be switched on for 180 sec., independent of the previous setting, and the window is closed.



Step 5:
If the Menu key is pressed in step 4, the selection of the pO2 measuring interval is accessed. The pO2 measuring interval can be set to 1 sec, 5 sec, 10 sec, 20 sec or 60 sec. In addition, the setting can be set to “off”, if and when required. The setting of the pO2 measuring intervals has a distinct influence on the achievable mobile time when the MPR2 is operated on battery pack.



Step 6:
After acknowledgement of the selected measuring interval, this is acknowledged by pressing OK. The settings will become active only after this window has been closed with the OK key, and the system has returned to the overview (screen step 1).

⚠ If screen 1 is used to call the adjustment dialogue for pO2 when a PTO catheter has been connected and an error message is active in the area of the pO2 value, than error message well appear: “An error has occurred in the O2 measuring system. Adjustments are not possible.”

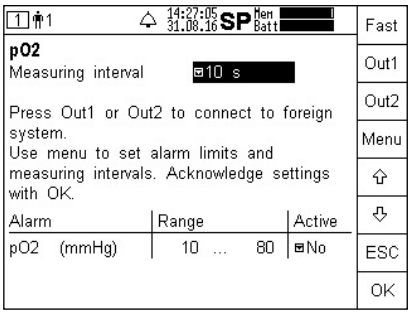
⚠ **Please observe the special features when setting the measuring interval. The measuring intervals have influence on the dynamics of the pO2 parameters to be displayed. A short measuring interval causes a higher consumption of power, thus leading to a reduced mobile time, than a longer measuring interval. Please keep in mind that the partial oxygen pressure is a parameter which changes slowly.**

4.4.3.4 Switching off individual measurement functions during pO2 measurement

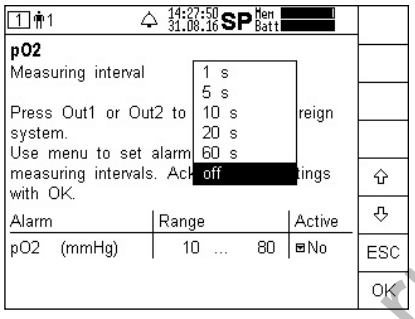
In rare cases, it can occur that one or more partial functions of a multi-parameter catheter are faulty or lost. In this case, so that it is nevertheless possible to continue measuring with the multi-parameter catheter, without alarm messages occurring constantly, the individual functions of the multi-parameter catheter can be switched off separately.

4.4.3.4.1 Switching off pO2 measurement

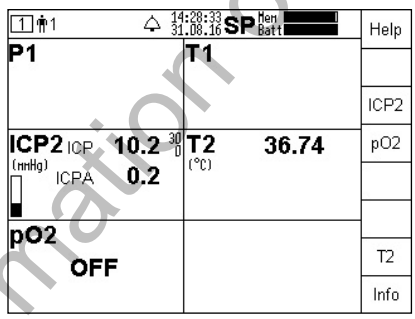
The measurement function pO2 can be switched off as a special case. This is only to be recommended if constant monitoring of the parameter pO2 is not required or not necessary and if a particularly long mobile period is to be achieved or if the pO2 measurement is subject to a technical fault.



Step 1:
Press the pO2 key in the Overview window and skip into the window to set the limiting alarm values. Subsequently press the Menu key.



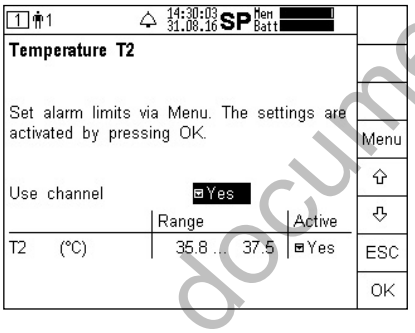
Step 2:
Select the option in the menu. Acknowledge the selection by pressing OK. The settings are accepted with the second OK.



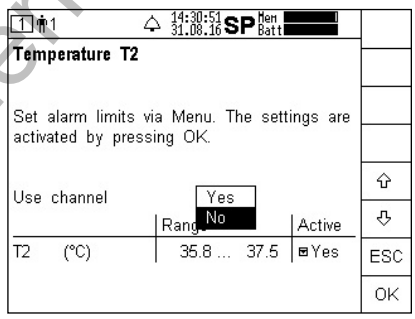
Step 3:
The Overview window indicates that the measurement of the partial oxygen pressure has been switched off.

4.4.3.4.2 Switching off temperature measurement

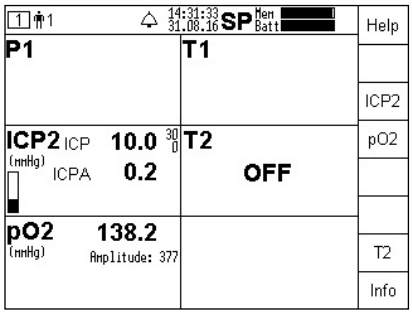
If, in conjunction with a multi-parameter catheter, a technical fault occurs in the temperature measurement T2 or temperature monitoring is not required, the measurement function T2 can be switched off separately. Note that, if the temperature measurement T2 is switched off, the accuracy of pO2 measurement will be influenced in accordance with 4.4.3.8 Technical alarms during partial oxygen pressure measurement.



In the overview window press key T2 to change to the window for setting the alarm limits and then navigate to "Use channel". Then press the menu key.



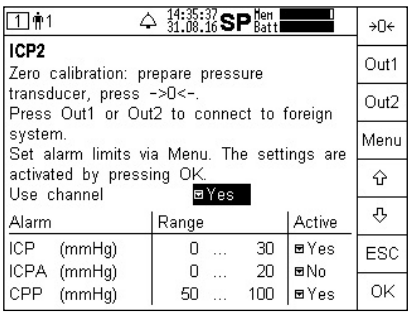
In the menu select the off option. Confirm the selection with OK. The settings are adopted when OK is pressed for the second time.



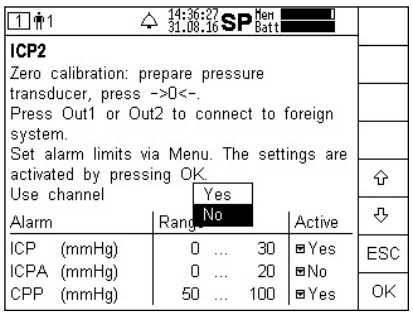
The overview window shows that the T2 temperature measurement has been switched off.

4.4.3.4.3 Switching off pressure measurement ICP2

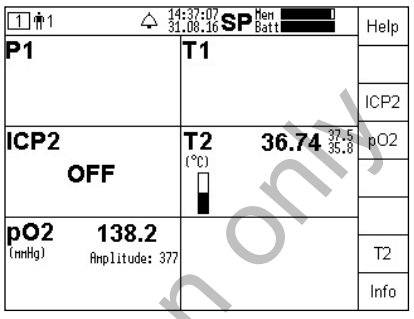
If, in conjunction with a multi-parameter catheter, a technical fault occurs in the pressure measurement ICP2 or ICP monitoring is not required, the measurement function ICP2 can be switched off separately.



In the overview window press key ICP2 to change to the window for setting the alarm limits and then navigate to "Use channel". Then press the menu key.



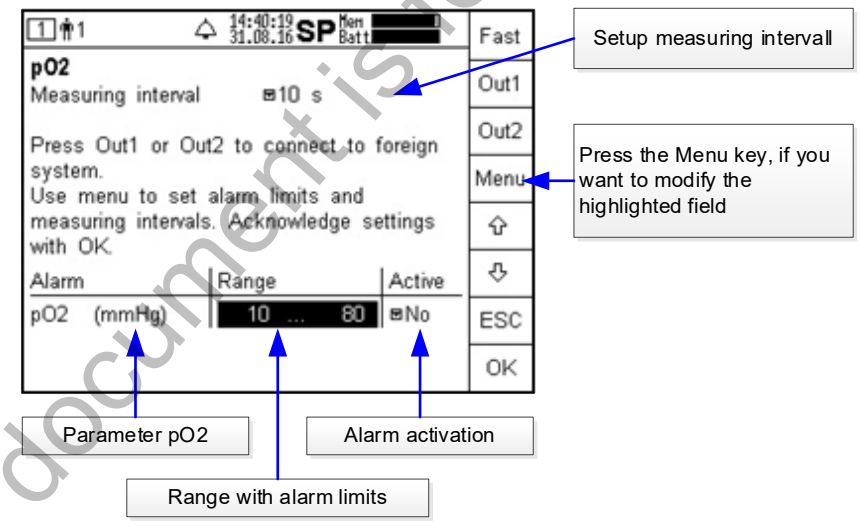
In the menu select the off option. Confirm the selection with OK. The settings are adopted when OK is pressed for the second time.



The overview window shows that the ICP2 pressure measurement has been switched off.

4.4.3.5 pO2 limiting alarm values

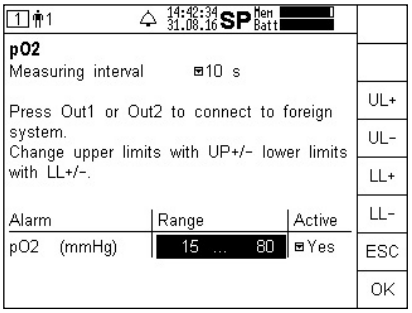
The right-hand column of the display holds the navigation field, in which you can use the soft keys to carry out further adjustments or to call off information or help.
Additional settings of the partial oxygen pressure can be accessed by pressing the pO2 key. If you have connected additional sensors, other soft key designations will be displayed with the defined measuring locations.



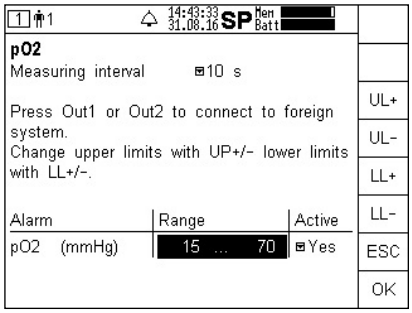
In this window you can use the arrow keys to select whether you want to set alarm limits and whether the limiting value monitor of the selected measuring value is to be active or not.

⚠ **Do not set the limiting values to extreme figures which could render the alarm system useless.**

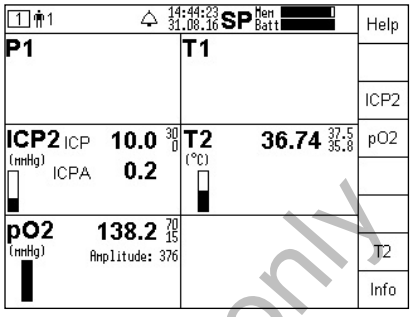
4.4.3.5.1 Setting the pO2 limiting values



Increasing the lower limiting value: Keep the LL+ key pressed until the requested value is reached.



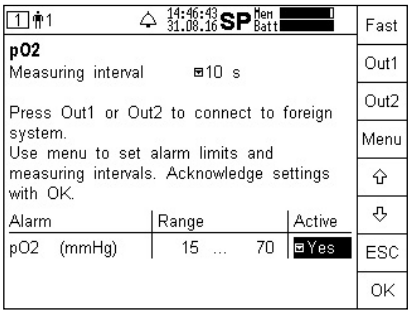
Lowering the upper limiting value: Keep the UL- key pressed until the requested value is reached. Acknowledge the settings by pressing OK. Leave the window by pressing OK, if no other changes are required. Only now will the settings be active.



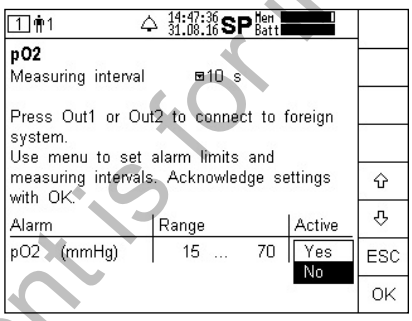
You will now access the overview of the measured values. The new limiting values will be displayed, provided Yes has been activated for the parameter Active.

4.4.3.5.2 Activating and deactivating pO2 alarms

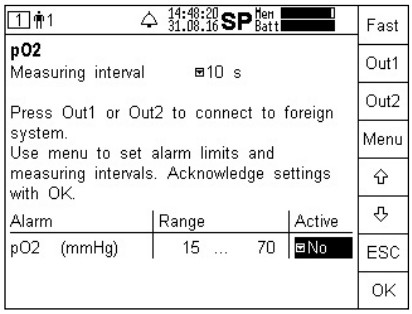
If you want to activate or deactivate an alarm, please proceed as follows:
Press the pO2 key in the Overview window.



Use the arrow keys to navigate into the table field, the settings of which you want to change. Subsequently press the Menu key.



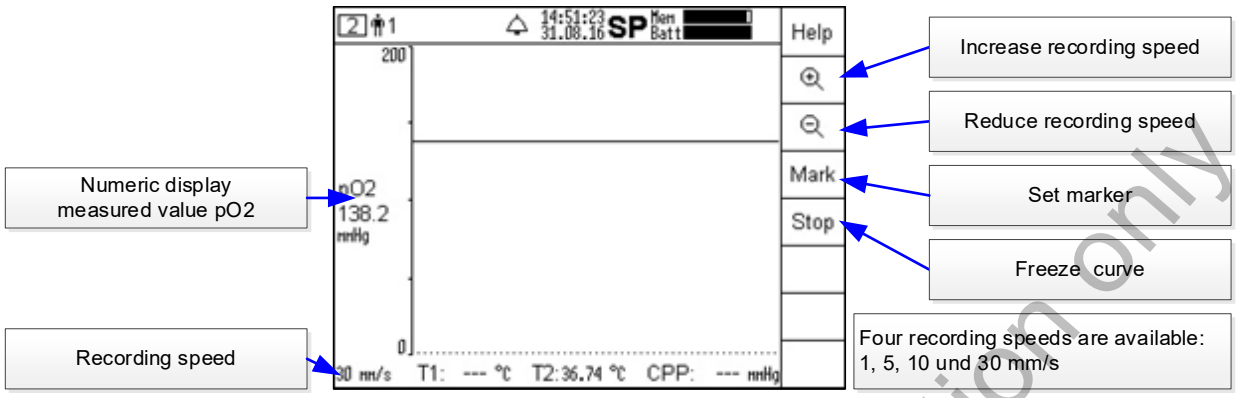
Use the arrow keys to select the requested setting. Subsequently press the OK key.



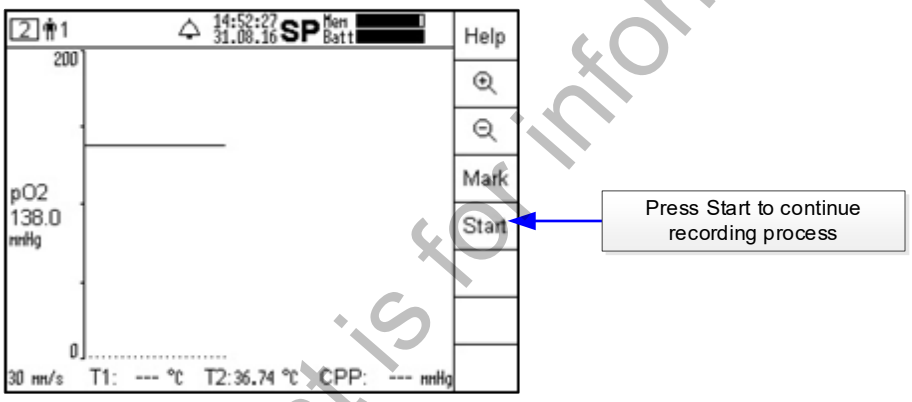
The new settings will be accepted. Press the OK key to leave the screen.

4.4.3.6 pO2 graphics

In order to skip to the graphics screen, press the key ▶. Screen [2] will be accessed.



Use the key [⊕] or [⊖] to switch over the plotting speed. 30 mm/s correspond to approx. 3 s per display width. Use the key [⊖] to reduce the plotting speed, increasing the time basis of the curve.



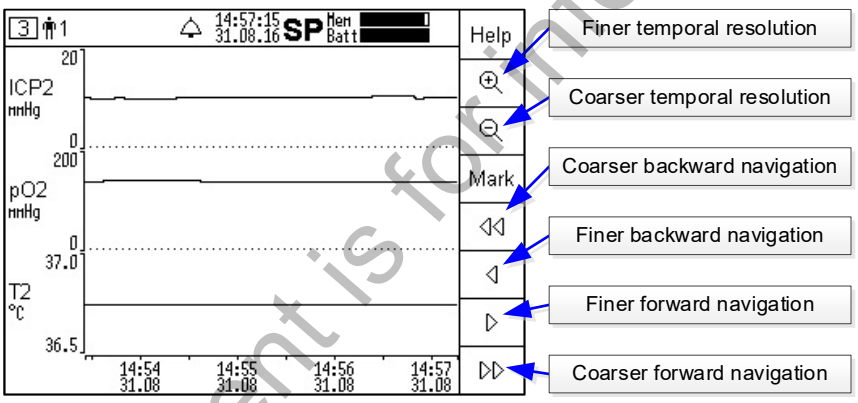
Use the [Stop] key to freeze the current curve, which is released by pressing the key [Start].

4.4.3.7 pO2 trend

In order to skip from the graphics screen [2] to the trend screen [3], press the key ▶. The navigation field renders available keys to set the temporal resolution as well as page up and page down keys. Two different speeds are available for paging up and down. If you keep one of the navigation keys pressed for a longer period of time, the key function is carried out again through an automatic routine. Thus, you can get an overview of the entire trend fast without having to press the key several times; subsequently you can set a higher resolution for the time range of your choice. Six time ranges are available (width of the time axis in the trend graphics) which you can switch over by using the key [⊕] and [⊖]:

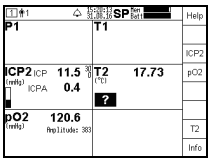
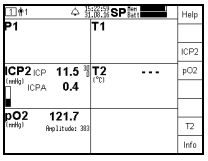
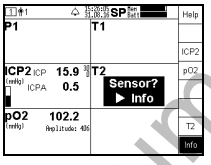
- 3 min. 50 s
- 7 min. 40 s
- 19 min. 10 s
- 38 min. 20 s
- 76 min. 40 s
- 3 h 50 min.

The somewhat odd values are produced by the number of pixels of the display range; roughly speaking a trend display of 4 min., 8 min., 20 min., 40 min., 80 min., and 4 h can be set. The trend graphics always start at the left-hand margin of the diagram. If the time basis is larger than the previous data recording time, the curve does not fill the diagram completely.



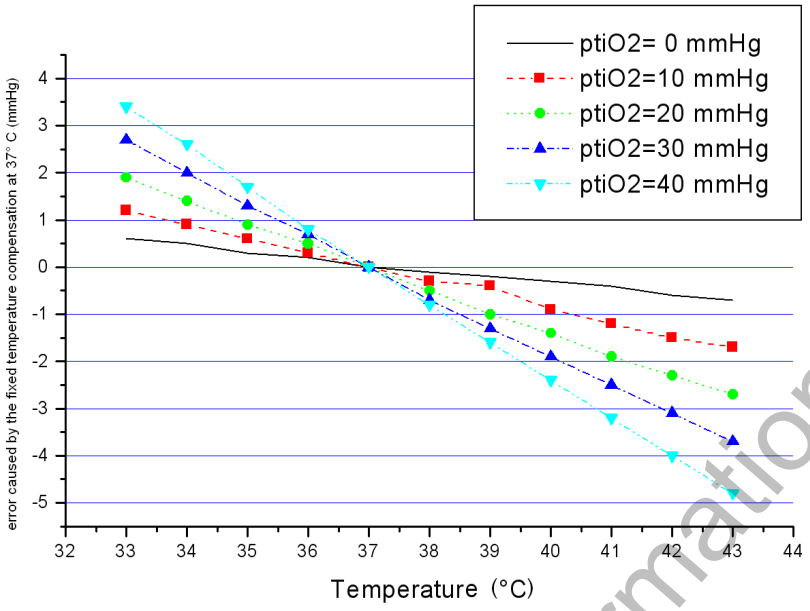
4.4.3.8 Technical alarms during partial oxygen pressure measurement

The partial oxygen pressure is a measured quantity dependent on temperature. For this reason, temperature T2 measured by means of a thermistor is not only used to obtain measured value T2, but also to compensate the temperature of the partial oxygen pressure. If the T2 temperature measurement is faulty or defective, then the oxygen partial pressure is determined at the assumed temperature 37 °Celsius. The pO2 measurement takes place in the temperature range of 32 °Celsius to 42 °Celsius; moreover an accuracy of -0.5 to +0.3 mmHg is achievable. Check the cable and catheter. *1
A technical alarm is only given for the T2 temperature measurement, not however for the pO2 measurement. The following error messages may be generated if there is a faulty or defective T2 temperature measurement:

Measuring location	Display of the parameter in window 1	Error messages after the INFO key has been pressed	Alarm
T2 in combination with pO2	Measured value? 	INFO message for T2: Internal error in temperature channel T2.	Technical alarm
T2 in combination with pO2	--- 	INFO message for T2: No INFO message	Alarm, if alarm has been activated for T2
T2 in combination with pO2	Sensor? 	INFO message for T2: There is an error in temperature channel T2. Temperature channel T2 can be switched off from the “T2” menu.	Technical alarm

*1: Please keep in mind that the error mentioned at this magnitude is an additional error (relative to the specific accuracy; please also refer to 11.1 Technical data), the way it occurs in measuring very small physiological partial oxygen pressures (close to 0 mmHg).

The additional display error caused by the fixed temperature compensation at 37 °Celsius is shown in the following diagram for various clinically relevant partial oxygen pressures.



Example: Failure of the temperature channel – a fixed temperature compensation is carried out at 37 °Celsius, patient temperature 39 °Celsius, displayed value pO2 = 20.0 mmHg. The error at this point is -1 mmHg, i.e. the measured value is 19.0 mmHg.

⚠ **If the temperature measurement T2 has failed or is defective, the measurement of pO2 continues to be possible in a temperature range of 32 °Celsius to 42 °Celsius.**

⚠ **In the measurement of very small physiological partial oxygen pressures an additional error of -0.5 mmHg to +0.3 mmHg occurs (relative to the specific accuracy, cf. 11.1 Technical data).**

4.4.4 Transducer for temperature measurement

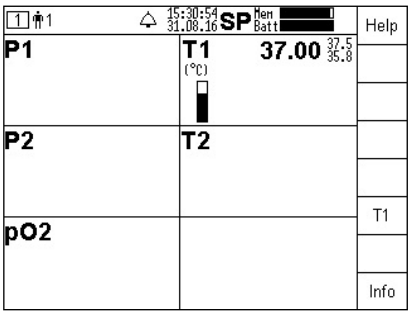
⚠ **Please observe chapter 3.3** Measurement of the body temperature**.**

⚠ **Use approved accessories only.**

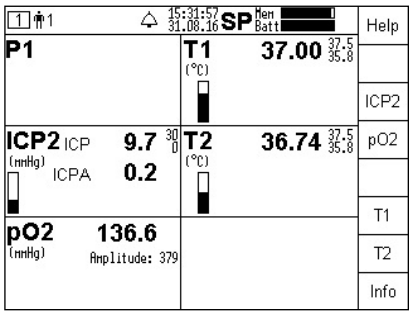
The MPR2 has two temperature input ports T1 and P2/T2 to be used to connect temperature sensors (port T1: temperature sensors made by Exacon or RAUMEDIC multi-parameter catheters with integrated temperature measurements; port P2/T2: multi-purpose port to be used for the connection of a PTO catheter). A ¼ inch jack plug can be used to connect temperature sensors to port T1. The PTO cable is required to connect a PTO catheter to the port P2/T2.
The temperature sensor connected is recognised automatically. The same applies corresponding, if you want to connect another temperature sensor. If the temperature to be measured is within a range of 15 °Celsius < T < 45 °Celsius, the temperature will be displayed in the measured value field of the overview screen [1].

⚠ **Please keep in mind that apart from the catheter, the ICP-Temp cable, (article No. 094328-001), and the ICP-Temp separator with jack plug, (article No. 094323-001), are required when the RAUMEDIC multi-parameter catheters with temperature measurement are used.**

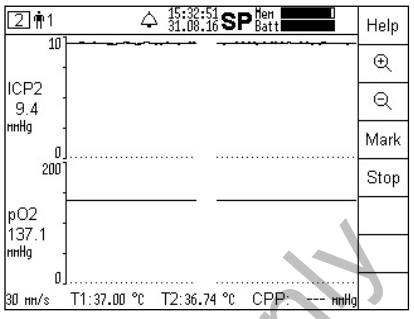
⚠ **Please observe that when RAUMEDIC PTO catheters are used for temperature measurement, the PTO cable, (article No. 095624-001), is required in addition to the NEUROVENT-PTO catheter, (article No. 095008-001).**



One temperature sensor connected to input T1.

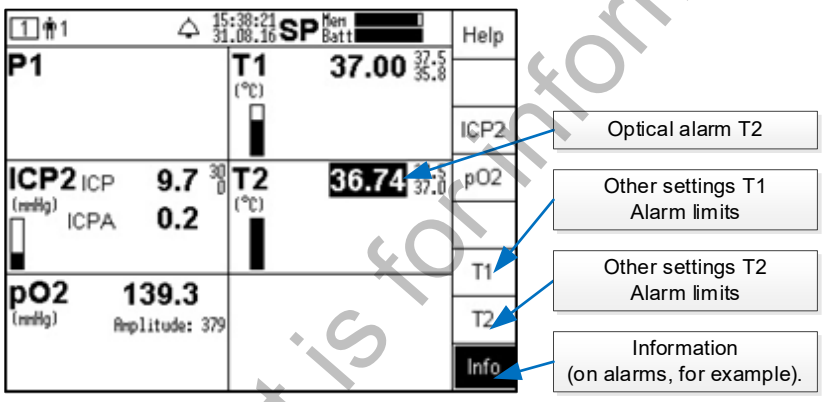


Second temperature sensor connected to input T2.



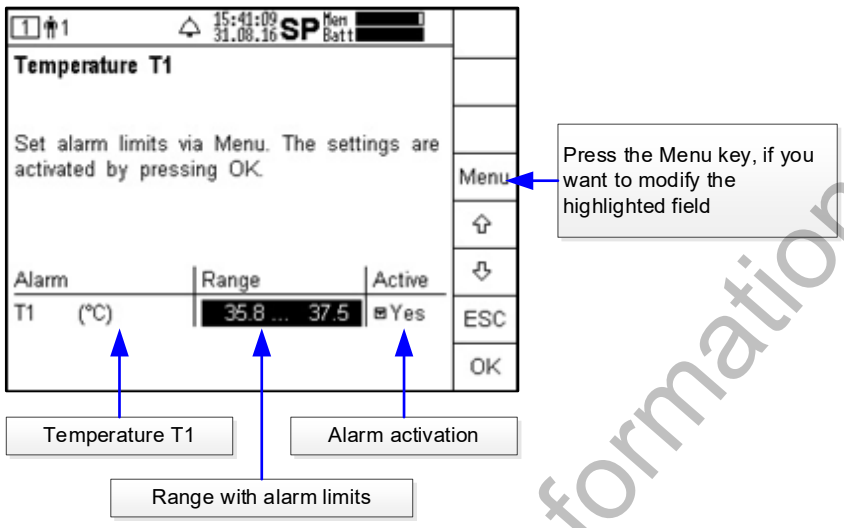
In the graphics screen, the temperatures are displayed as numerical values only.

After the temperature sensor has been connected, the display field, which has been allocated to the temperature input, will display the numerical value of the temperature measured. For the settings of the limiting alarm values the settings mode is active first which you have selected in the window Selection alarm limiting values when the unit was started. For data on the basic settings of the alarm limits, the alarm activation and the settings of the alarm limits, please refer to chapter 4.9.2 Factory settings.



4.4.4.1 Changing the temperature settings

The right-hand column of the display holds the navigation field, in which you can use the soft keys to carry out further adjustments or to call off information or help.
Additional settings of the temperature channels are accessed by pressing the keys T1 or T2. If you have connected additional sensors, other soft key designations will be displayed with the defined measuring locations.

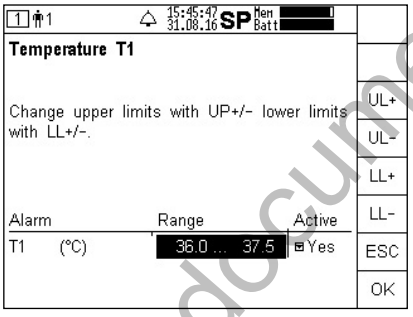


In this window you can use the arrow keys to select whether you want to set alarm limits and whether the limiting value monitor of the selected measuring value is to be active or not.

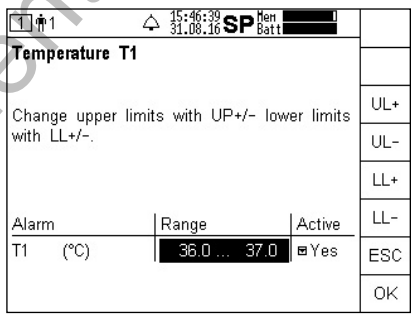
Proceed correspondingly, if you want to change the settings for temperature T2.

⚠ **Do not set the limiting values to extreme figures which could render the alarm system useless.**

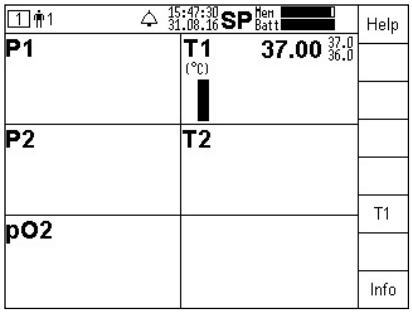
4.4.4.1.1 Setting the limiting temperature values



Increasing the lower limiting value: Keep the LL+ key pressed until the requested value is reached.



Lowering the upper limiting value: Keep the UL- key pressed until the requested value is reached. Acknowledge the settings by pressing OK. Leave the window by pressing OK, if no other changes are required.

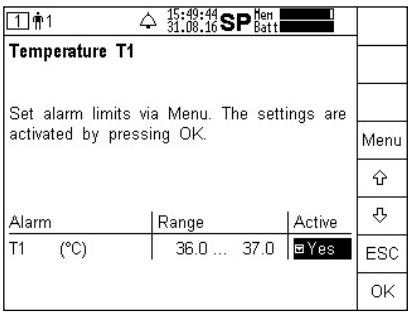


You will now access the overview of the measured values. The new limiting values will be displayed, provided Yes has been activated for the parameter Active.

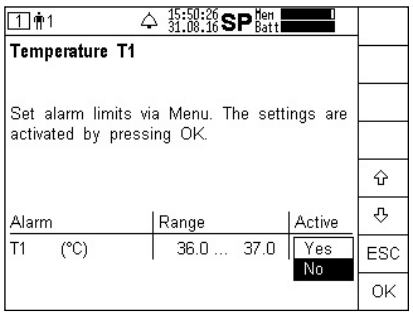
If you want to change other settings or repeat a setting, press the key T1 or T2, if another temperature sensor has been connected.

4.4.4.1.2 Activating and deactivating the temperature alarms

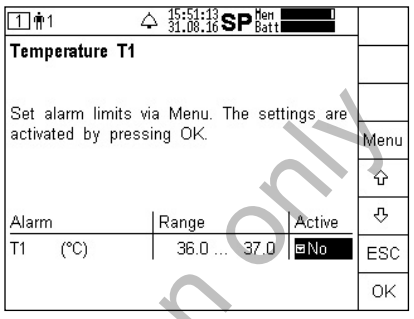
If you want to activate or deactivate an alarm, please proceed as follows:
Press the key T1 or T2, if another temperature sensor has been connected.



Use the arrow keys to navigate into the table field, the settings of which you want to change. Subsequently press the Menu key.



Use the arrow keys to select the requested setting. Subsequently press the OK key.



The new settings will be accepted. Press the OK key to leave the screen.

Description of the self-test equipment of the temperature measuring system:
Five seconds after the apparatus has been switched on or after recognition of a temperature sensor as well as after every thirty minutes, the temperature measuring system is tested. If a fault is found, a technical alarm is activated.

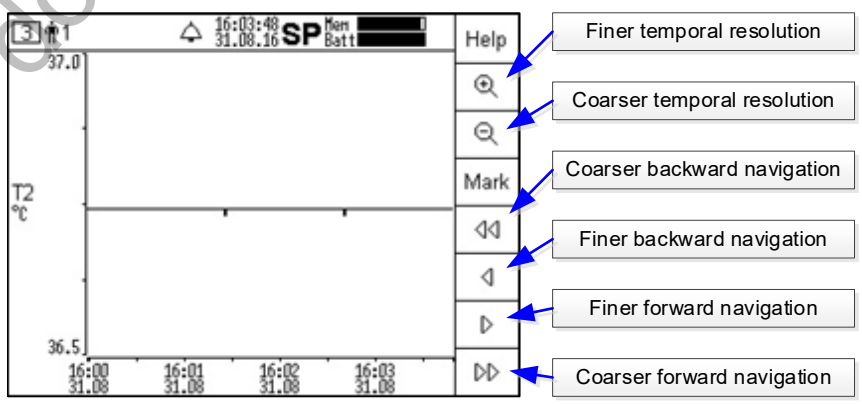
4.4.4.2 Temperature graphics

A graphical display for the temperature is not available in the graphics screen [2]. The temperature is displayed in the footer of the graphics screen in the form of a numerical value, cf. chapter 4.4.4 Transducer for temperature measurement.

4.4.4.3 Temperature trend

In order to skip from the graphics screen [2] to the trend screen [3], press the key ▶. The navigation field renders available keys to set the temporal resolution as well as page up and page down keys. Two different speeds are available for paging up and down. If you keep one of the navigation keys pressed for a longer period of time, the key function is carried out again through an automatic routine. Thus, you can get an overview of the entire trend fast without having to press the key several times; subsequently you can set a higher resolution for the time range of your choice.

Six time ranges are available (width of the time axis in the trend graphics) which you can switch over by using the key ⊕ and ⊖.

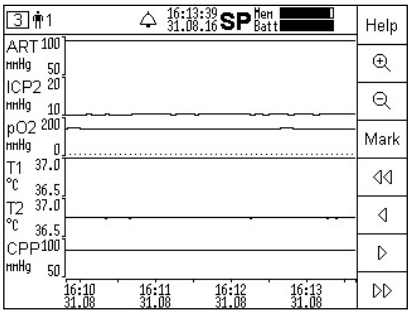


4.5 Configuring the graphics display

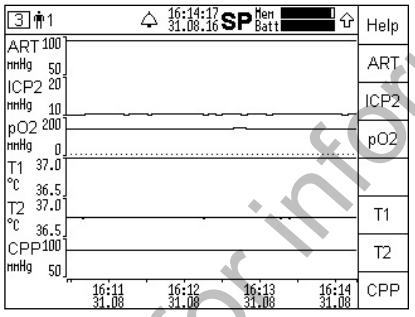
Screen [2] as well as screen [3] renders graphical displays of the measured or calculated parameters; screen [2] renders live data, and screen [3] provides the trend. If several transducers have been connected, the display area is divided up into several tracks. Thus, an overview of all connected parameters is obtained. At the same time, however, the amplitude resolution decreases with the increase in the number of tracks. Sometimes, however, it is necessary to have certain or individual parameters in a higher resolution amplitude. In screen [2] as well as in screen [3] it is possible to deselect tracks in the graphics display after having pressed the Shift key of the connected (e.g. ICP, ART) or calculated signals (CPP), which increases the resolution of the remaining tracks; in addition, tracks can be added, which decreases the resolution of the tracks.

⚠ **The key function is alternating for the deselection of the tracks. Available parameters for the function keys are displayed. The graphics track can be deselected by pressing the key, which will be added again when the key is pressed again.**

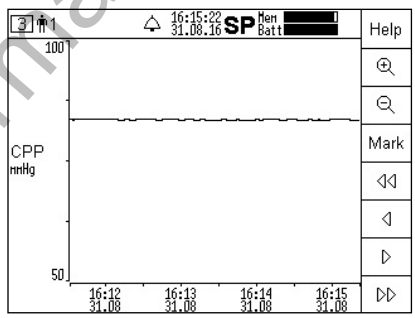
From the following example, you can see which operating steps are required to configure the graphical representation.



Step 1: Press the Shift key, and thus change the allocation of the F keys; the parameters available for the F keys are displayed.



Step 2: Select the F key parameters which you want to select or deselect as graphics tracks. For example, press the F keys ART, ICP1 and ICP2 to deselect these graphics tracks and to display the CPP at maximum resolution.



Step 3: Either you press the Shift key again to return to scroll mode (as in step 1) or it is set automatically again after a few seconds.

⚠ **Tracks can be deselected until no curve is visible any more. In this case, the display will render "Use Shift + 'channel name' to display curves". The procedure in screen 2 and 3 is identical.**

4.6 Device setup

4.6.1 Combine analogue outputs

4.6.1.1 Forwarding an individual pressure signal to Out1 or Out2

The MPR2 has two identical analogue outputs to transfer up to two invasively measured pressure signals to a third-party system (bed-side monitor) with alarm function. The software of the MPR2 provides two options to connect the analogue outputs to a third-party system. One option has already been described in chapter 4.4.2.3 Combine analogue outputs. Another option is rendered in set-up screen [4].

⚠ **Pay attention, only the pressure channels ICP1, ICP2 and pO2 can be transferred.**

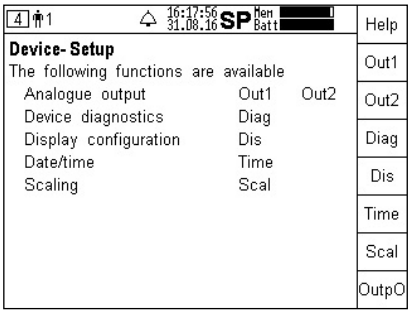
⚠ **Use approved accessories only.**

In order to be able to use the analogue outputs with a third-party system, the following operating steps have to be carried out:

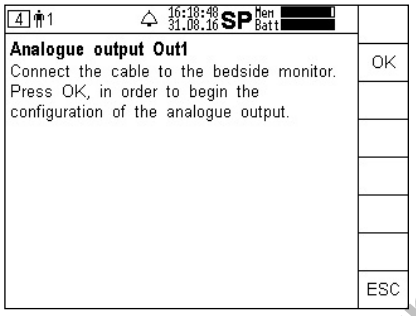
- Establish the cable connection between Out-1 or Out-2 of the MPR2 and pressure measurement input of the third-party system.

- Carry out a zero compensation of the pressure channel of the third-party system (MPR2 provides 0 mmHg).
- Check the sensitivity of the third-party system (MPR2 provides 20 mmHg).
- Select the pressure channel on the MPR2 and switch to the third-party system.
- Set the alarm limits of the third-party system to a maximum of 350 mmHg, if monitoring is required.

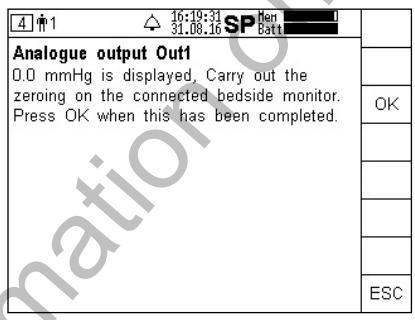
Establish the cable connection between an analogue output of the MPR2 and a pressure measurement input of the third-party system. Here it is immaterial whether you use Out-1 or Out-2 on the MPR2. Now skip to the set-up screen [4] by pressing the screen selector key ▶ several times, if and when required, and carry out the following steps 1 to 6:



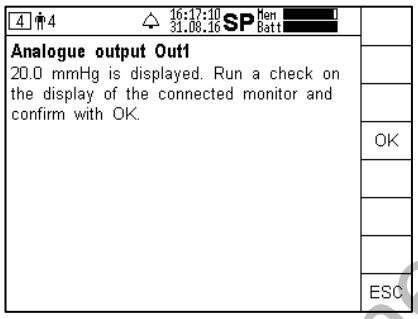
Step 1:
Access the Device setup and select the analogue output, to which the cable connection is to be established, such as Out1.



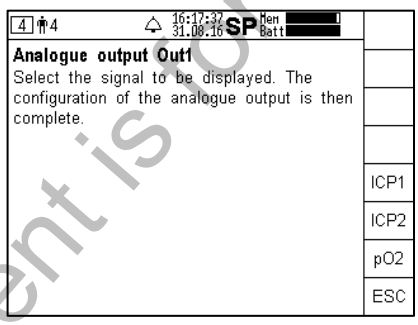
Step 2:
Establish the cable connection to the third-party system, and subsequently press the OK key.



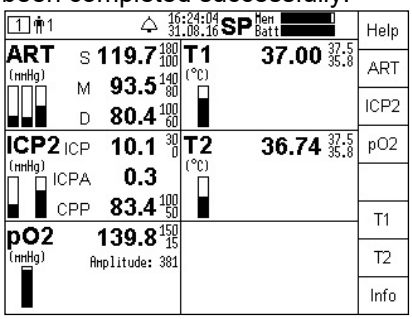
Step 3:
Carry out the zero calibration at the pressure input of the third-party system. Press the OK key when the zero calibration has been completed successfully.



Step 4:
Check whether the third-party system renders 20 mmHg ± 2 mmHg, and press the OK key.



Step 5:
The available pressure signals are displayed (soft keys). Use a key to select a signal, such as ICP2.



Step 6:
When the signal has been passed through to the MPR2 successfully, the overview screen is displayed on the MPR2, and the third-party system indicates the pressure signal passed through.

After successfully signal relaying to the third-party system set the alarm limits.

⚠ **For each one of the steps 3 to 5 you have 180 seconds to press the next button. In case of a timeout the system switches to step 1. The connection to the analogue output is not established. At least 355 mmHg are released at the analogue output of the MPR2.**

⚠ **The zeroing of the downstream monitor should be carried out when the MPR2 is at the right temperature. If this is not possible, the zeroing of the downstream monitor (screen 4, Out1 / Out2) has to be repeated at the right temperature in order to compensate the drift. The zero point of the pressure sensor is <u>not</u> lost by this action.**

⚠ **If monitoring is to be carried out using the analogue outputs, the upper alarm limit for the third-party monitor has to be set to a maximum of 350 mmHg, and the alarm has to be activated on the third-party monitor.**

⚠ **In case of non-observation, the third-party system will not release an alarm when the pressure sensor is removed from the MPR2 or is damaged. The analogue output of the MPR2 will read at least 355 mmHg, if the pressure sensor is removed from the MPR2.**

⚠ **In critical cases, two equal pressure channels shall have to be used for redundant monitoring (allocation of a pressure channel to both analogue outputs).**

⚠ **For the accuracy of the signal relaying to the third-party system, please observe: When using the analogue output, an error chain will be produced consisting of the accuracy of the pressure input, the analogue output as well as the pressure input of the third-party system. These errors sum up.**

If you want to link the analogue output Out2, please proceed as with Out1.

Specification of the temperature measurement: cf. chapter 11 Technical parameters (Specification)
Recommended accessories: cf. chapter 9 Accessories

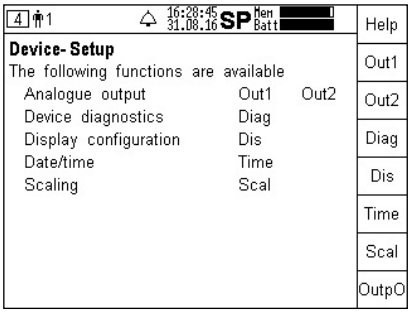
4.6.1.2 Special function OutpO

If a NEUROVENT-PTO type catheter has been connected to socket P2/T2, then the MPR2 automatically recognises the catheter type. This makes it possible to allocate the correct measurement locations to the individual functions of the catheter and shortens the dialogue until the start of measurement. The benefit of automatic catheter identification was used with the special function OutpO to implement simultaneous forwarding of the two pressure signals ICP2 and pO2 with an individual procedure.

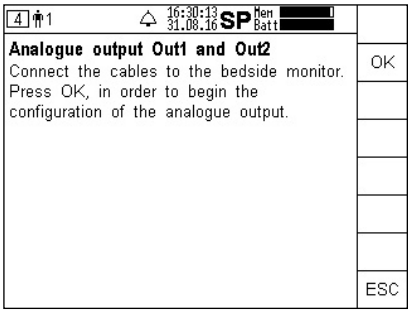
Prerequisites and special features:

A NEUROVENT-PTO type catheter has been connected to socket P2/T2. Additionally the catheter is connected with the LWL cable to the LWL socket on the MPR2.

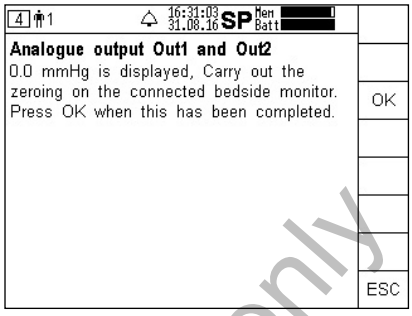
ICP2 and pO2 are forwarded in a procedure, with pO2 routed to Out1 and ICP2 to Out2. Here the control signal equals 20 mmHg.



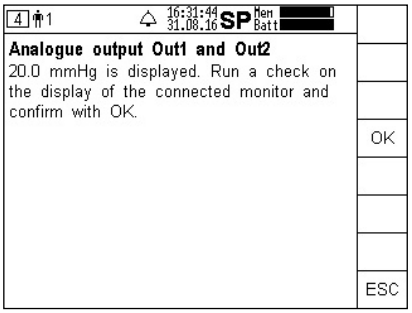
Step 1:
Call device setup and select special function OutpO



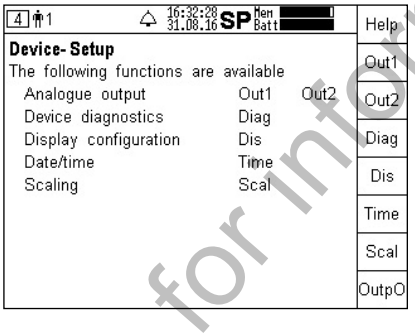
Step 2:
Make the cable connections as described and then press the OK key



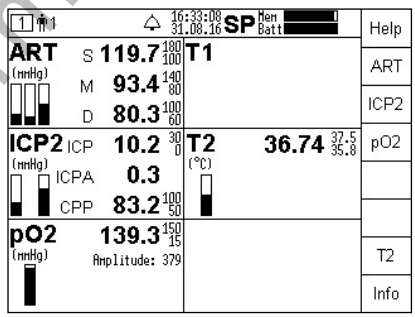
Step 3:
Carry out a null measurement at the pressure inputs of the external system. Press the OK key once the null measurement has successfully completed for both pressure inputs



Step 4:
A control signal of 20 mmHg is output on both analogue outputs. Check the displays on the external system and confirm by pressing OK.



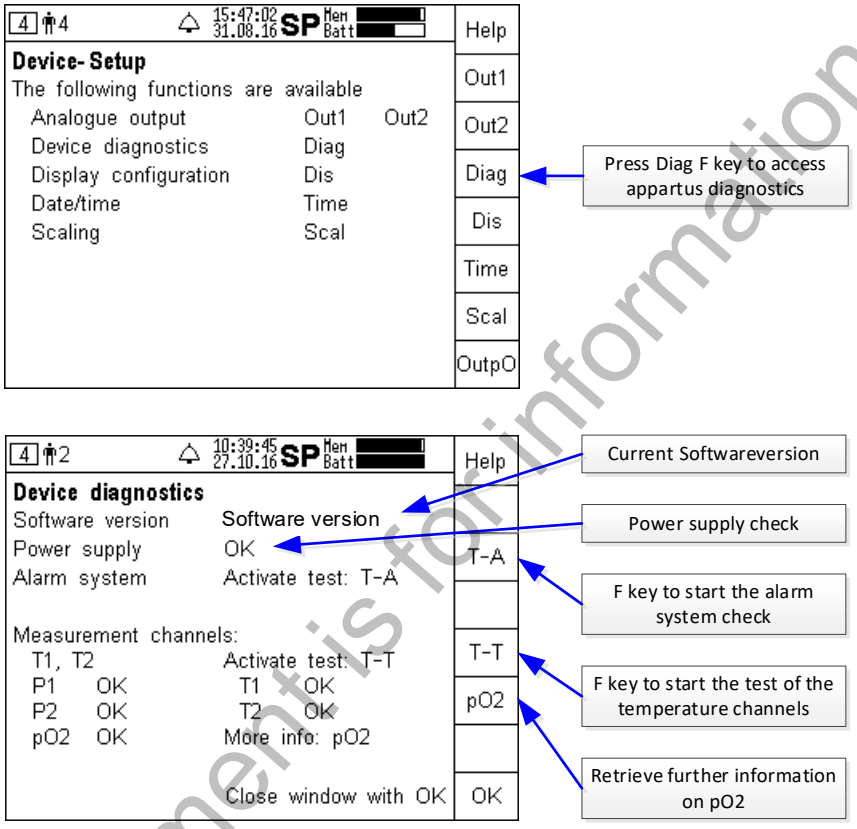
Step 5:
After the OK confirmation in step 4, enter device setup (figure 4). Exit screen 4 by pressing the next key ▶



Step 6:
pO2 is forwarded via Out1 and ICP2 via Out2.

4.6.2 Device diagnostics

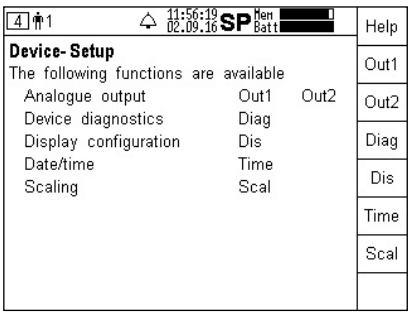
In order to diagnose the apparatus, use the Forward key to skip to the screen 4 **Device setup**. After having pressed the **Diag** F key, the **Device diagnostics** is accessed.
Here the following information is rendered:
Software version
Power supply OK
By pressing the key (F key T-A), a test run of the alarm system can be released, thus checking the acoustic and optical function of the alarm signal.
By pressing the key (F key T-T), you can run a test of the temperature channels in T1, T2. Other information on the pO2 functions can be retrieved by pressing the key (F key pO2).



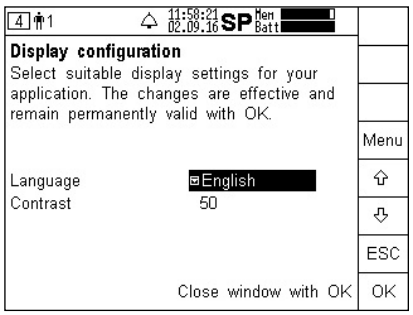
The current status of the MPR2 firmware is software version 2.10.0068 HW2.
This version of the software is intended for devices with the hardware level 2 without ECG applied part.
Devices of earlier delivery date can have a lower version of the software. With respect to the firmware, the MPR2 can be updated. Please get in touch with the manufacturer to check the availability of a new firmware version

4.6.3 Setting the LCD contrast

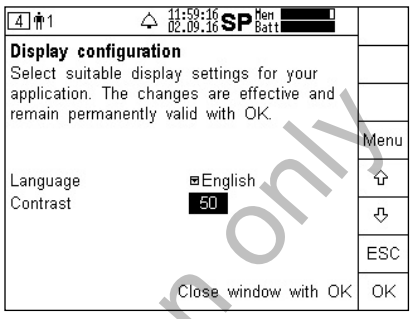
Now skip to the set-up screen by pressing the screen selector key ▶ several times, if and when required, and carry out the following steps 1 to 6:



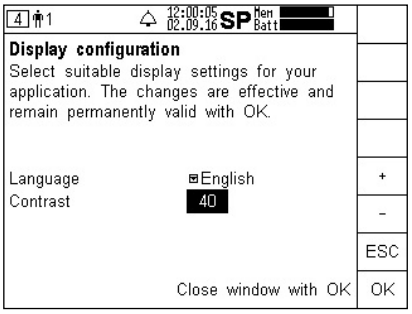
Step 1:
Call the Device setup and press the Dis key.



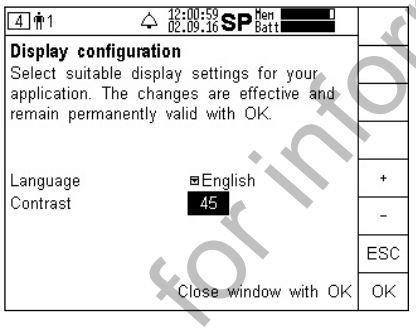
Step 2:
Use the arrow keys to access the number in Contrast.



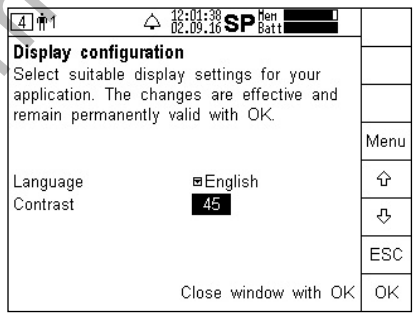
Step 3:
After having changed to Contrast, press the Menu key.



Step 4:
By pressing the + or – keys, the contrast value set can be changed. Press the ESC key to return to the previous step.



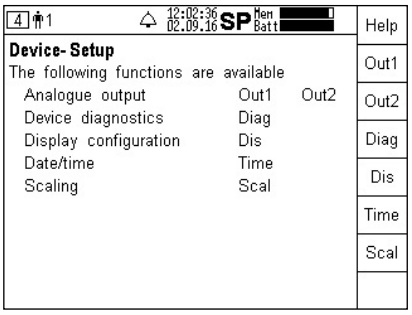
Step 5:
Set a new contrast value. (Use ESC to cancel the modification.) Accept the new value by pressing OK.



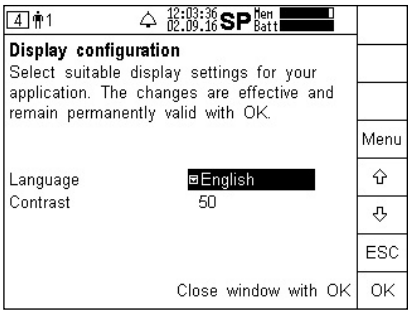
Step 6:
The new contrast value is displayed.

4.6.4 Setting the language version

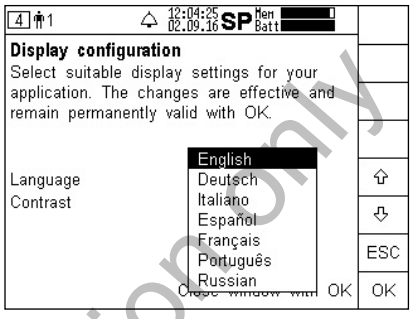
⚠ Currently the following language versions are stored: German, English, Italian, Spanish, French, Portuguese, Russian. For the availability of other language versions, please get in touch with the manufacturer.



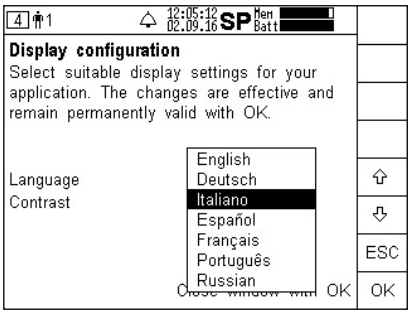
Step 1:
Call the Device setup and press the Dis key.



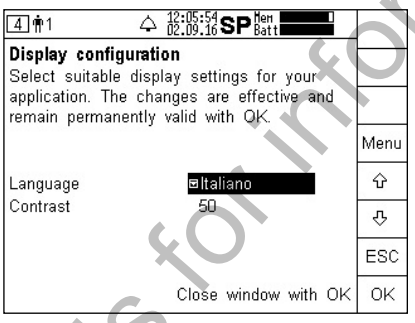
Step 2:
Press the Menu key.



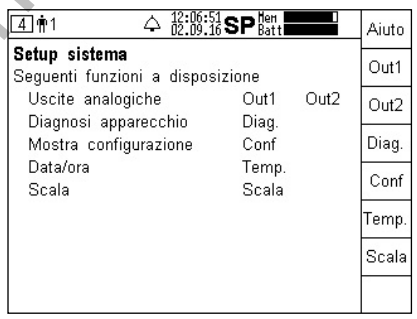
Step 3:
Use the arrow keys to change to the requested language.



Step 4:
Press the OK key.



Step 5:
Acknowledge the newly selected language by pressing OK.



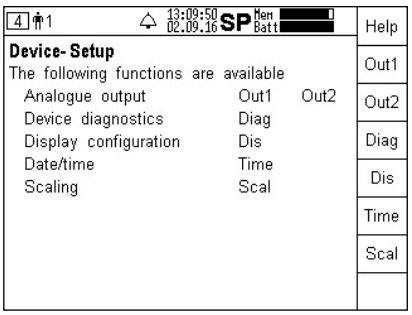
Step 6:
The new language version selected is active.

4.6.5 Setting date and time

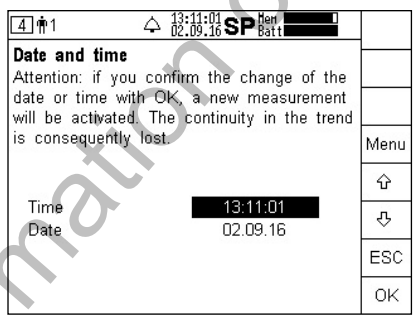
⚠ **Changing the date and time requires the automatic creation of a new measurement, which means that on saving the data on the PC two files are created, one for the time prior to the time setting and one for the time after. Thus, the data cannot be viewed continuously. On the MPR2, the trend data from the time prior to the time setting will not be displayed any more. They will remain saved, however.**

Now skip to the set-up screen by pressing the screen selector key ▶ several times, if and when required, and carry out the following steps 1 to 8:

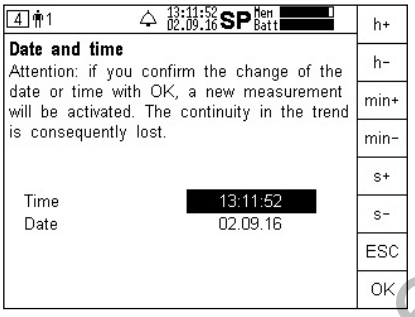
4.6.5.1 Setting the time



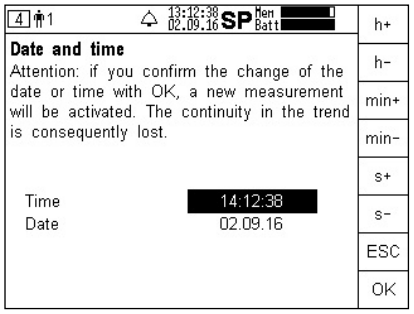
Step 1:
Call the Device setup and press the Time key.



Step 2:
Press the Menu key to set the time.

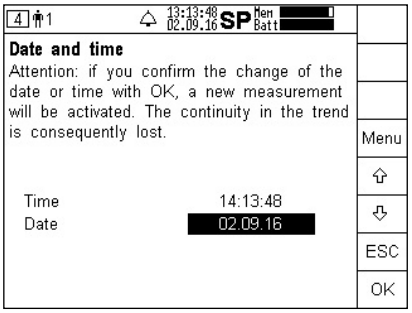


Step 3:
By pressing the + or - key the hour, minute and second can be set. Press the ESC key to return to the previous step. Complete your settings by pressing the OK key.

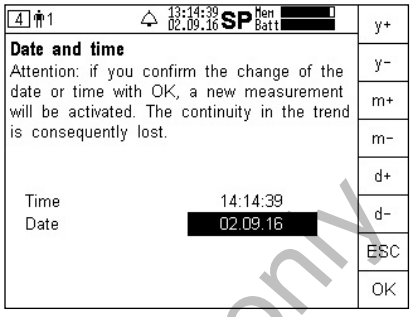


Step 4:
The modified time is displayed. The modified settings will be accepted when the windows is closed by pressing OK.

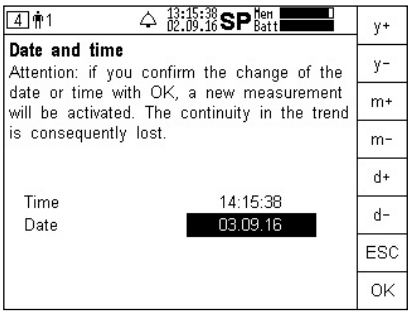
4.6.5.2 Setting the date



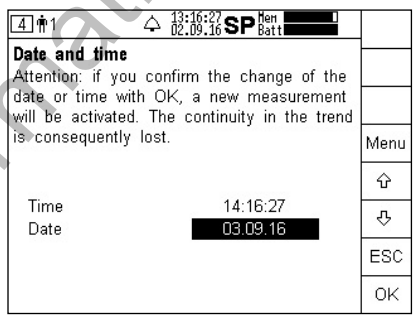
Step 5:
Use the arrow keys to navigate in the date field.



Step 6:
Press the Menu key to set the date.



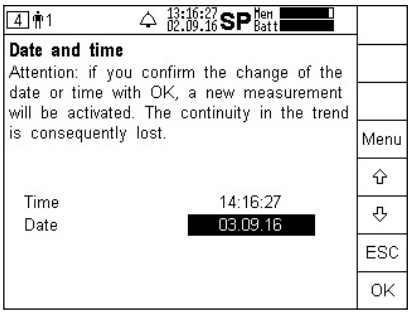
Step 7:
By pressing the + or - key the year, month and day can be set. Press the ESC key to return to the previous step. Complete your settings by pressing the OK key.



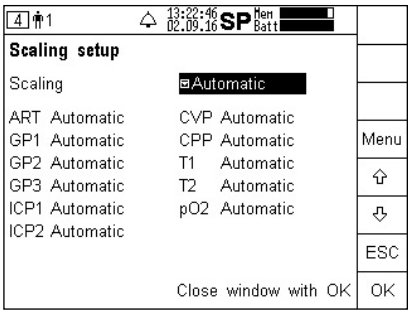
Step 8:
The modified date is displayed. The modified settings will be accepted when the windows is closed by pressing OK.

4.6.6 Modifying the scaling

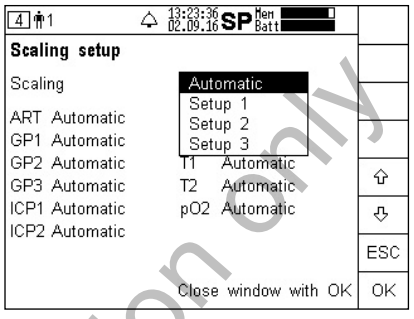
The works setting for the scaling option is “Automatic”, which means that the scaling is automatically adapted to the signal value. Alternatively one of the three following set-up settings can be chosen for the scaling:



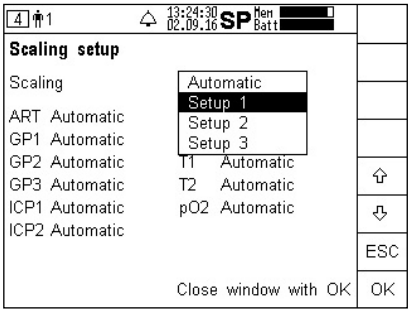
In the device setup window, press the Scal key.



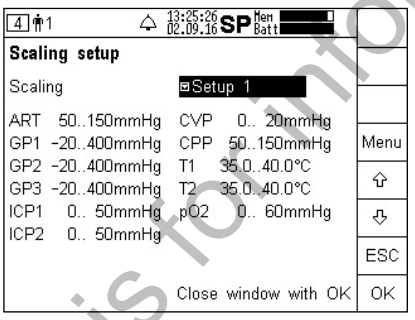
The currently set scaling is displayed. In this case, “Automatic” has been set as the works settings have not been changed yet.



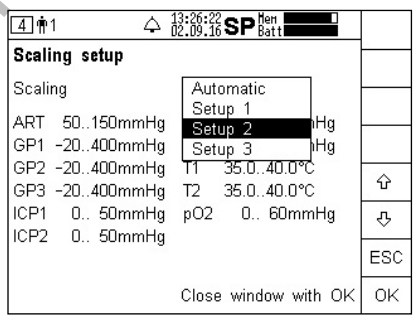
In order to change the setting, press the Menu key. The available settings will be rendered in the pull-down menu.



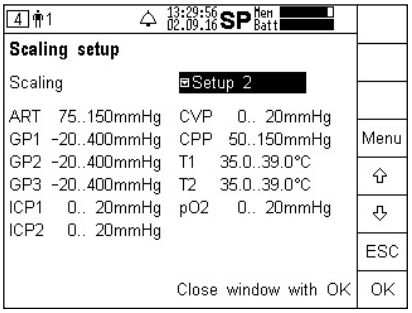
The arrow keys are used to change the requested settings, such as to Setup 1. Subsequently close the window by pressing on OK.



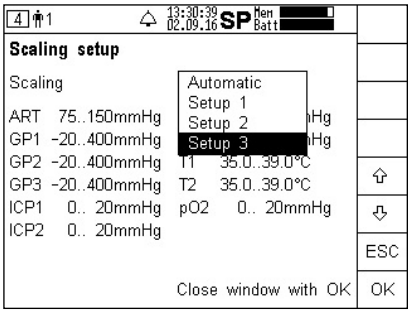
The scaling settings for Setup 1 have been accepted, but they are not active yet.



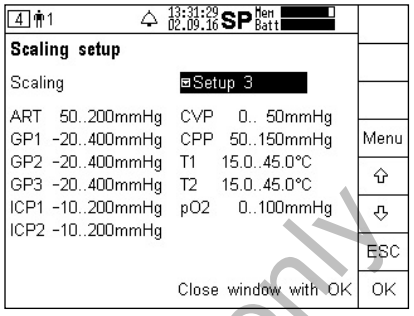
In order to change the settings, press the Menu key. The available settings will be rendered in the pull-down menu. The arrow keys are used to change the requested settings, such as Setup 2. Subsequently close the window by pressing OK.



The scaling settings for Setup 2 have been accepted, but they are not active yet.



In order to change the settings, press the Menu key. The available settings will be rendered in the pull-down menu. The arrow keys are used to change the requested settings, such as Setup 3. Subsequently close the window by pressing on OK.



The scaling settings for Setup 3 have been accepted, but they are not active yet. The settings can be cancelled by pressing on ESC. Close the window by pressing on OK to activate the settings.

4.7 Key lock

Activation:

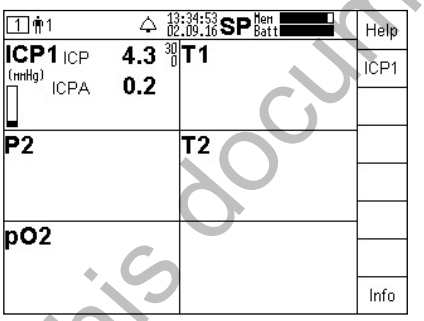
Skip into the overview screen and press the Shift + F5 key (key symbol) .
A pop-up window will render information on the active key lock “Button block active – to unblock button press F5 and hold”.
This note will disappear again after 5 seconds without having to press a key.

Function:

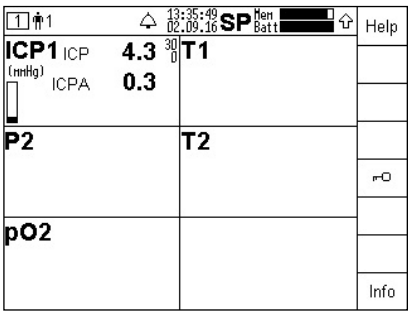
The active key lock locks all keys except the lamp and the alarm muting / reset. The background illumination in battery operation can also be switched on and off, and acoustic alarms can be muted. The alarm suppression by long key depression cannot be activated, however. If a locked key is pressed, a signal (for approx. 1 s) is sounded and the pop-up window mentioned above is displayed again (for 5 seconds).

Deactivation:

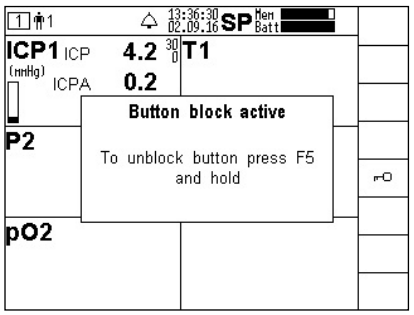
Deactivate by pressing and holding F5 .



Step 1:
Skip to the overview screen and press the Shift key.



Step 2:
Subsequently press the F5 key (key).



Step 3:
The key lock is active.

4.8 Switching on the LCD background illumination

When the MPR2 is operated by means of a mains adapter, the background lighting is switched on permanently. The ☼ key is functional only during battery operation. If the background illumination is switched on, it remains on for 60 seconds, if it is not intentionally switched off by pressing on the ☼ key again. Every key operation on the apparatus will start the 60 seconds again. In case of permanent operation, the background illumination will remain on. If the key is held continuously, the background illumination will be switched off after 60 seconds nonetheless.

Explicit switch off is possible by pressing the key again.

If a (random) alarm is activated, the background illumination is switched on, if the battery charge amounts to at least 30 minutes. If the remaining battery charge is less than 30 minutes, the illumination will not be switched on.

4.9 Alarm system

The MPR2 has been fitted with the following alarms:

- Physiological alarms (cf. chapter 4.9.1 Physiological alarms)
- Technical alarms (cf. chapter 4.9.4 Technical alarms)

Technical alarms classified into:

- Apparatus alarms (cf. chapter 4.9.4.1 Apparatus alarms)
- Sensor alarms (cf. chapter 4.9.4.2 Sensor alarms)

Alarms are classified according to their priority. The MPR2 has been fitted with alarms of high priority and alarms of medium priority.
Alarms of high priority:

- All pressure alarms with the exception of the CPP
- Severe technical alarms

Alarms of average priority:

- CPP
- Temperature
- Technical alarms with the exception of severe technical alarms
- Sensor alarms

The appliance releases optical and acoustical alarms according to the alarm priority. In order to make optical alarms more noticeable, the background illumination of the display is switched on for every alarm, even if the apparatus is operating in a power saving mode with the key lock switched on. The background lighting, however, will not be switched on any more, when a battery alarm has been released already. All alarms are non-permanent alarms, which means that the optical and acoustic signals are switched off again automatically, when the alarm condition disappears.
The only exceptions are the following apparatus alarms: alarm key error, keyboard error, memory error on NFFS (Nand Flash File System) and severe apparatus errors. These alarms are retained, even if the cause has disappeared. Alarm key error and keyboard error: So that the user can follow up the cause for the alarm.
Memory error on NFFS and severe apparatus error: Caused by system, a continuation of operation is not possible.
By viewing these info messages these alarms are deleted.

The Alarm key  has the function AUDIO OFF for the active alarm conditions. Press for longer than > 2 sec. for global AUDIO PAUSING or global AUDIO OFF.

If alarms of different priority have been released, the alarm signal with high priority is signalled (acoustically, optically). Short depression of the Alarm key  switches the acoustic signal off. The switched-off acoustic alarm is indicated in the overview screen by the symbol  alongside the parameter which caused the alarm. If the alarm conditions continue, the alarm of high priority will continue to be signalled optically (red LED flashing).

If a new alarm is added, the acoustic alarm of the corresponding priority of the new alarm is added.

The alarm key has no influence on the optical alarm signal (red LED or yellow LED and flashing display on LCD). As long as the reason for the alarm exists, the optical alarm will be signalled, and the alarm LED flashes according to the highest priority given.

As to which AUDIO OFF function (AUDIO PAUSING or global AUDIO OFF) is used, is determined by the setting in the operator settings.

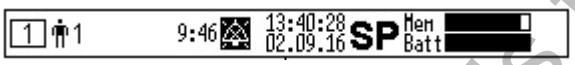
Global AUDIO OFF:

⚠ If this key Alarm is pressed for two seconds, all acoustic alarms are globally suppressed until this key is pressed again or until the MPR2 is switched off. The condition of alarm suppression is permanently indicated by a flashing symbol in the information area . In this case the system cannot produce any acoustic alarms. For this reason, the user should be handling this function very knowingly.
The operator settings (cf. Instruction for Use of Software DataView, Device setup MPR 1 - / MPR2 logO DATALOGGER) can be used to activate a reminder signal. In case of global AUDIO OFF, the reminder signal releases a beep of 0.5 sec. every 5 minutes.

AUDIO OFF can be used even when the key lock has been switched on. Global AUDIO OFF, however, is not possible when the key lock has been switched on.

Global AUDIO PAUSING:

⚠ If this key Alarm is pressed for two seconds, all acoustic alarms are suppressed for an adjustable interval or until this key is pressed again or until the MPR2 is switched off. The condition of the alarm suppression is indicated continuously in the info area by a flashing symbol (bell system crossed out by dashed lines) and by the count-down timer.



A short depression of the alarm key switches the count-down timer off; a long depression of the alarm key switches the timer on again. In this case the system cannot produce any acoustic alarms. For this reason, the user should be handling this function very knowingly.

AUDIO OFF can be used even when the key lock has been switched on. Global AUDIO PAUSING, however, is not possible when the key lock has been switched on.

A permanently pressed key Alarm does not mute any new alarms immediately. Thus, every new acoustic alarm added will also cause an audible signal which can be switched off only by pressing the alarm key again.

The following alarms are activated:

- Physiological alarms
- Technical alarms

4.9.1 Physiological alarms

Pressure alarms (for all available measuring locations including pO2, however excluding CPP) have been designed as alarms with high priority. All other alarms have been designed as alarms of medium priority. The CPP has been designed as an alarm of medium priority.

The delay of the alarm condition amounts to a maximum of 15 sec. + measuring interval. For the measurement of the partial oxygen pressure, the measuring interval, for example, can be set to a maximum of 60 sec. which results in a delay of the alarm condition of a maximum of 75 sec. (15 sec. + 60 sec.).

The apparatus monitors the following physiological alarms:

Pressure value outside of range

The alarm is activated, if the limiting value is exceeded or fallen short of for 6 seconds within an interval of 10 seconds.
The following measured values can be monitored:
- ICP: medium pressure, amplitude, CPP
- ABP: systolic and diastolic pressure, medium pressure
- GP1 – GP3: systolic and diastolic pressure, medium pressure
- CVP: medium pressure

Note: The pressure measurement input units (two input units and all available measuring locations) have been provided with a cyclic self-test. In regular intervals, a test pulse of defined value (approx. +70 mmHg) is transferred to the measuring signal of the pressure sensor, and the amplitude is then evaluated. Under the highly unlikely assumption that at the measuring location of ART (with relatively high physiological pressure values) a pressure sensor with the permissible maximum offset error of +150 mmHg and a measured pressure value MAP of > 320 mmHg and in addition a test pulse of approx. +70 mmHg meet upon each other, there is a very low probability that this would cause a technical alarm **?**.

pO2 outside of range

The alarm is activated, if the limiting value is exceeded or fallen short of for 6 seconds within an interval of 10 seconds.

Note: The amplitude of the pO2 measuring signal is monitored. The value of the amplitude is displayed on the Overview screen 1. If the amplitude drops below a value of 370, a sensor alarm “Sensor?” is released.

Temperature outside of range:
The alarm is activated, if the limiting value is exceeded or fallen short of for 6 seconds within an interval of 10 seconds.

The following shall apply for all physiological alarms:
- The adjustment range for the alarm limits comprises the entire measuring range.
- Every alarm can be activated / deactivated separately (cf. chapter digital display).
- In case of an alarm, an alarm of high (invasive pressure) or medium priority (temperature) is activated and the measured value concerned starts flashing.
- The apparatus automatically switches into the display mode (if no menu has been opened).

AUDIO OFF only switches the acoustic signal off. The value flashes until it is outside of range.

4.9.2 Factory settings

4.9.2.1 Factory settings and adjustment ranges for physiological alarms

The factory setting for the display language is English.

The table rendered below shows the factory settings for physiological alarms as well as their adjustment ranges.

Parameter	Measu-ring location		Factory settings			Adjustment range		
			Lower alarm limit	Upper alarm limit	Alarm activated	Alarm limits *1 lower	upper	Adjustment step size
Pressure	ART	SYS	100	180	Yes	-20	400	5
Pressure	ART	MAP	80	140	Yes	-20	400	5
Pressure	ART	DIA	60	100	Yes	-20	400	5
Pressure	CVP		0	20	Yes	-20	400	1
Pressure	ICP1	ICP	0	30	Yes	-20	400	1
Pressure	ICP1	ICPA	0	20	No	0	400	1
Pressure	ICP2	ICP	0	30	Yes	-20	400	1
Pressure	ICP2	ICPA	0	20	No	0	400	1
Pressure	ICP1/2	CPP	50	100	Yes	0	400	1
Pressure	GP1	SYS	100	180	Yes	-20	400	5
Pressure	GP1	MAP	80	140	Yes	-20	400	5
Pressure	GP1	DIA	60	100	Yes	-20	400	5
Pressure	GP2	SYS	100	180	Yes	-20	400	5
Pressure	GP2	MAP	80	140	Yes	-20	400	5
Pressure	GP2	DIA	60	120	Yes	-20	400	5
Pressure	GP3	SYS	100	180	Yes	-20	400	5
Pressure	GP3	MAP	80	140	Yes	-20	400	5
Pressure	GP3	DIA	60	120	Yes	-20	400	5
Oxygen	pO2		10	80	Yes	0	200	1
Tempera-ture	T1		35.8	37.5	Yes	15.0	45.0	0.1
Tempera-ture	T2		35.8	37.5	Yes	15.0	45.0	0.1

Table 6: Factory settings

*1 The alarm limits can be adjusted freely within the range given; the minimum distance between upper and lower limit has to be one step width.

4.9.2.2 Alarm signal inactivation

The global AUDIO PAUSING has been set to a duration of 10 minutes.

4.9.2.3 Scaling

In the works of the manufacturer the scaling mode has been set to “Automatic” which means that the scaling is automatically adapted to the signal value. Alternatively, one of the three following setups can be chosen for the scaling. At the point of delivery, the setups have been set according to the following table (modifications of the setup settings cf. chapter 5.9.10 Changing the operator settings).

Type of channel	Setup 1		Setup 2		Setup 3	
	Min.	Max.	Min.	Max.	Min.	Max.
ART [mmHg]	50	150	75	150	50	200
ICP1 [mmHg]	0	50	0	20	-10	100
ICP2 [mmHg]						
CVP [mmHg]	0	20	0	20	0	50
GP1 [mmHg]	-20	400	-20	400	-20	400
GP2 [mmHg]						
GP3 [mmHg]						
CPP [mmHg]	50	150	50	150	50	150
T1 [°Celsius]	35	40	35	39	15	45
T2 [°Celsius]	35	40	35	39	15	45
pO2 [mmHg]	0	60	0	20	0	100

4.9.3 Saving the alarm settings

The factory settings for the alarms (alarm limits and their alarm activation) can be changed at any time. The limiting alarm values and the alarm release settings will be retained after the apparatus has been switched off. The next measurement with the apparatus will activate the settings of the last measurement by selecting the “Cur” option in the “Selection alarm limiting values” menu item after the apparatus has been switched on (cf. chapter 4.3 Selecting the limiting alarm values).

4.9.4 Technical alarms

Technical alarms are subdivided into alarms which indicate conditions under which a correct operation of the apparatus is no longer ensured or where this fact has to be expected, respectively, and into those alarms in which measuring or saving functions can no longer be carried out at all or to a limited extent only because a sensor has been removed or due to a memory overflow, but the problem has no or could have no technical reason.
Hereinafter the first will be referred to as apparatus alarms and the latter as sensor alarms. The difference between the two is that the alarm key in case of sensor alarms also resets the optical alarm signal.

4.9.4.1 Apparatus alarms

The following apparatus alarms are distinguished:

1. Battery discharged
The alarm will be activated thirty minutes prior to automatic shut-down, which means that the alarm is activated when the calculated time remaining drops below the thirty-minute limit.

In case of an alarm, an alarm sound of medium priority is produced and the battery symbol flashes.
In case of this alarm, the AUDIO OFF function can only switch off the acoustic signal.

2. Memory full
The alarm Memory full will be activated when the available capacity remaining drops below a recording period of thirty minutes. In case of an alarm, an alarm sound of medium priority is produced and the battery symbol flashes.
In case of both alarms, the muting / reset function will switch off the acoustic signal only.
In conjunction with the info message, this alarm behaves like a sensor alarm. If the info message is viewed, the alarm is erased, but the memory filling level indicator continues to flash.

3. Internal fault (such as failure of reference measurement)
Immediately after detection the alarm is activated by a flashing question mark "?" in the display field of the measuring channel concerned. If the alarm refers to a single measuring channel, the measuring function of the other channels is still ensured.
However, if a severe error is recognised which renders a continuation of operation with the apparatus impossible, this fact is also indicated in a pop-up window and an alarm of high priority is activated. The operator can only shut down the apparatus. All other keys are blocked.

4. Oxygen module error
The alarm will be released, if at least one of the following situations is present:
- The PHB transfers an error code indicating that the self-test has failed.
- There is an error in the time behaviour of the data transmission from the PHB (time-out, extra data records transmitted).

The error is indicated by the flashing "Module?" display in the area of the digital display of the pO2 value. The measuring functions of the other channels are not affected. In case of an alarm, an alarm of medium priority will be released.

5. pO2 sensor error
In screen 4, the following further pO2 sensor catheter data are displayed under Diagnosis → pO2:
Remaining cycles
LOT
Expiry date
Remaining running time.
⚠ **In contrast with previous firmware versions prior to 2.00.0053, these values are now only displayed, but are no longer monitored or indicated by technical alarms.**

4.9.4.2 Sensor alarms

Sensor alarms are alarms of medium priority. The following alarms have been classified as sensor alarms:
(1) Pressure sensors have been removed
(2) Temperature sensor has been removed
(3) Multi-parameter sensor has been removed (this error consists of the parameters P2, T2, pO2 contained in the sensor errors which will be displayed as SENSOR? in the individual channels).
(4) Error in the memory of the multi-parameter sensors.
(5) Error measuring the pO2 value (indicated by error bits of the PHB, except error bit 6, which is not evaluated. The amplitude of the reference signal is evaluated separately).
(6) Temperature sensor in the oxygen catheter defective.

The sensor alarms are indicated by the term "Sensor?" flashing in the display field of the measuring channel concerned.
If a sensor has been removed, no value will be displayed any more as soon as the alarm has been acknowledged (with Info -> OK -> OK).
Exceptions are the sensor alarms (5) and (6). With these sensor alarms, the alarm remains active even after the info key has been pressed.

4.9.5 Summarisation

The following diagram renders clear the relationships between the cause of the alarm, the alarm signals and the AUDIO OFF for the active alarm conditions (short key depression) as well as global AUDIO OFF / global AUDIO PAUSING (long key depression).

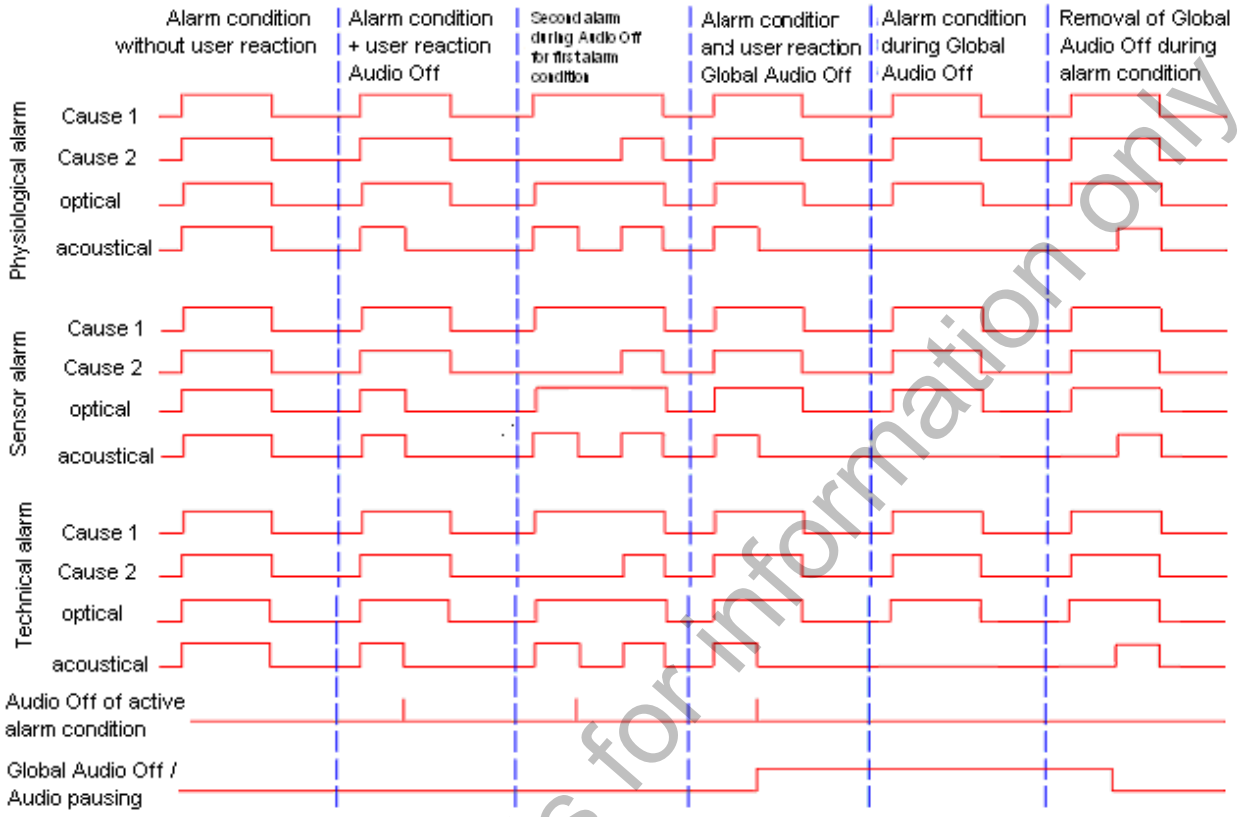


Figure 10: Alarm diagram

The following table indicates how the different alarms are acoustically and optically noticed by the operator.

Alarm condition	LED [6]*1	LED [7]*1	Display	Sound
none	green	off	normal	none*2
sensor oxygen module	off	yellow	„Sensor ?“ "Module ?"	■ ■ ■ approx. 30 sec. break
medium priority*3	off	yellow	value flashes	■■■ approx. 20 sec. break
high priority	red	red	value flashes	■■■ ■■ ■■■ ■■ approx. 6 sec. break

Table 7: Alarm conditions
*1: Cf. Table 1 in chapter 2.5 Operating elements, connections, displays
*2: Individual actions are indicated by individual short sounds.
*3: Physiological and technical alarm

4.9.6 Verifying the alarm system

The alarm system can be verified at any time. When checking the acoustic signal, please observe that you do not switch off the acoustic alarm permanently with the AUDIO OFF key. To verify the alarm system, proceed as described in chapter 4.6.2 Device diagnostics. Please observe when verifying the alarm system that alarms of high and medium priority are tested according to the table rendered above.

5 Power supply

5.1 Mains power supply

⚠ If the MPR2 is to be operated on mains power, mains adapter, which belongs to the scope of delivery, shall be used only (RAUMEDIC Art. No. 284007-002 or 284027-001, corresponding with the type plate).

⚠ The mains adapter is not protected against moisture, and thus it must not get into contact with liquids.

⚠ Please keep in mind that the mains adapter may be connected only to correctly installed and approved sockets.

5.2 Displays when operating on mains power

The Power On LED [6] is lit when the apparatus is supplied by the external mains adapter. If the apparatus has been switched on, this display is permanently lit; in addition the display illumination is switched on permanently, which cannot be switched off with the key. The Batt symbol in the upper line of the display renders information on the charge condition of the battery: A full bar indicates a charged battery pack. If the apparatus has been switched off, but the unit is connected to the mains adapter, the display flashes and signals the charge of the battery.

5.3 Battery operation

The MPR2 has been equipped with a gas-tight and rechargeable battery. In fully charged condition, the MPR2 can be supplied with power for about four hours (all channels occupied; display lighting off; PHB = 1 s; at 22 °Celsius).The data of the operating period applies for a new and fully charged battery. The frequent use of the display illumination reduces the operating period due to a larger demand of power. An aged battery caused by many charging and discharging cycles, for example, reduces the maximum operating period to be achieved as a matter of principle. The battery is charged in the MPR2 as soon as it has been connected to the external mains adapter. The battery is protected against overcharging. The MPR2 has been equipped with a deep-discharging protection system. Approximately half an hour before the apparatus is switched off automatically, an acoustic alarm is sounded.
If the apparatus is not switched off at the end of the remaining operating time or if no mains adapter is connected, the apparatus is switched off at the end of the remaining operating time. In this case, a continuous sound will be released for at least 30 seconds (typically one hour). As soon as the mains adapter is connected this warning sound will turn off. If no mains operation is possible, switch on the apparatus and off again after a few seconds. Avoid a longer period of storage in discharged condition.

⚠ **Please observe the information on the influence of storage as well as the recommendations on battery maintenance as otherwise the remaining operating period cannot be guaranteed.**

5.4 Displays when operating on battery

The Power On LED [6] flashes when the apparatus is supplied by the internal battery. If the apparatus has been switched on, this display flashes permanently; the display illumination is switched off, but can be switched on again by pressing the key. The display illumination is switched off automatically after 60 seconds. The Batt symbol in the upper line of the display renders information on the charge condition of the battery: A full bar indicates a charged battery pack. If the apparatus has been switched off and is not connected up to the mains adapter, all displays are off.

5.5 Influence of the storage conditions on the battery operation

When the MPR2 is stored, the battery pack is subject to self-discharge, which is compensated by the software as far as possible. In order to guarantee the residual operating period in battery pack operation, the battery pack has to be charged completely after storage. Depending on the storage temperature, the condition prior to storage and the ambient temperature, complete charging will take between five and twenty hours. Avoid high storage and charging temperatures in order to counter excessive aging of the battery pack. Ideal conditions may be expected after complete battery maintenance.

5.6 Battery maintenance

Every battery pack is subject to wear, which means that the real capacity decreases a bit with every charge. As this aging depends on many factors, this can be taken into consideration by the apparatus to a limited extent only. For this reason, the battery should be maintained once a year or when the operating period of the appliance decreases in battery pack operation. Disconnect the apparatus from the patient, and operate it without mains adapter until automatic shut down (apparatus will be switched off automatically; deactivate global alarm). Subsequently plug in the mains adapter, and charge the unit for 24 hours without interruption.

⚠ Please keep in mind that the charging current has to be reduced at an ambient temperature of over 35 °Celsius, and that the charging time thus increases.

If the operating period of the battery is too low after this process, we recommend to replace the battery pack. Please get in touch with the manufacturer.

5.7 Information on how to handle battery packs

We recommend having the potentially required change of battery carried out by the manufacturer. If you want to carry out the exchange yourself nonetheless, this may be done by a trained expert only. In this respect, please get in touch with the manufacturer.
Dispose the battery pack as hazardous waste. The manufacturer may also ensure the disposal. Prior to disposal, use adhesive strips or suitable other insulating material to cover the contacts so that they cannot make direct contact to other objects, which could cause fires or explosions. The use of energy sources not explicitly approved of for this apparatus may lead to damage and hazards.

6 Troubleshooting

Checking the following points should ensure that prior to the start of patient monitoring all necessary preparations have been made and that occurring typical problems can be solved during monitoring. In case of apparent or obvious incorrect operation, service must be informed insofar as the faults cannot be rectified by following the described measures.

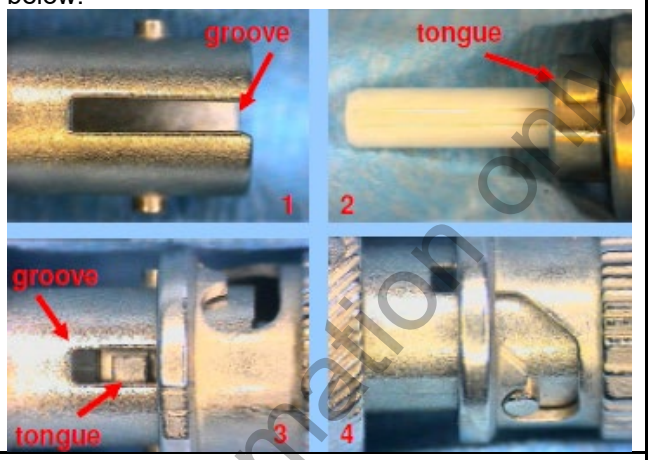
General advice

- Required equipment and accessories are available. The user is sufficiently familiar with the equipment and accessories.
- No mechanical damage such as cracks or loose parts are visible on the MPR2 or the accessories.
- All patient cables are correctly connected to the MPR2 (correct mechanical and colour coding of plug and monitor input socket).
- These Instructions for Use relate to the firmware version of the device.
- The alarm settings are suitable for new patients.
- The battery is adequately charged.
- The mains power adapter is connected and charging is taking place.
- Sufficient free storage is available. If not, then the measurement data on the device should be stored to a PC and then deleted on the MPR2.
- Operating position and ambient conditions match the specification.
- The factory setting of the display language is English.
- After a critical fault the display language is set to English.

6.1 Special advice on the measurement of partial oxygen pressure

This new MPR2 functionality has, alongside a whole series of advantages, a few possible fault sources about which you should be aware and which you should also know how rectify.

Fault	Possible cause	Rectification
No partial oxygen partial pressure measurable and no temperature T2 measurable	Wrong cable used. ICP-TEMP cable instead of cable PTO	Use cable PTO and connect it to socket P2 / T2
	Wrong socket used. Socket P1 instead socket P2 / T2	Connect the cable PTO to socket P2 / T2
	Cable PTO not properly connected to the catheter, but rotated by 180 °	Connect the cable PTO to the catheter. Gold dots on the cable connector have to be aligned the gold dots of the catheter connector

Fault	Possible cause	Rectification
No partial oxygen partial pressure measurable while temperature T2 is displayed	Cable LWL not or not properly connected	Connect Cable LWL in correct way. Follow steps below: 
	Optical fiber is broken inside catheter	Change catheter. If catheter is working properly and pO2-measurement is activated a green blinking light at the catheter tip must be visible in dark environment.
	Cable LWL is defect	Change Cable LWL. If cable is working properly and pO2-measurement is activated a green blinking light at the cable end (catheter side) must be visible in dark environment.
	ST-Connector (Connector pO2 at MPR2) is defect	Change MPR2. MPR2 with malfunction has to be send to service.
	Dirt on optical connector at the catheter	Check amplitude at MPR2. Normal value > 375. Clean optical connector at the catheter. Follow additional references.
	Dirt on optical connector at cable LWL	Check amplitude at MPR2. Normal value > 375. Clean optical connector at the catheter. Follow additional references.
	Dirt on optical connector at MPR2	Check amplitude at MPR2. Normal value > 375. Clean optical connector at the catheter. Follow additional references.
	pO2 deactivated at MPR2	Change device settings. Activate pO2 channel.

6.2 Error – Zero calibration of pressure measurement unit

The zero calibration could not be carried out. The measured pressure differs more than 150 mmHg from the expected value. The sensor is potentially defective. Please check this and repeat the zero calibration.

The pressure off-set is larger than +150 mmHg or smaller than -150 mmHg. If these limiting values are exceeded or remained under, no zero calibration can be carried out.
The zero calibration could not be carried out. The pressure has changed by more than 2 mmHg during the last five seconds. Please check this and repeat the zero calibration.

In order to carry out a safe zero calibration, the variation of the signal shall not be any larger than 2 mmHg during the zero calibration.

6.3 Internal error – pressure channel

Internal defect in pressure channel PNo. (ART, ICP ...). Remove sensor and use other channel if needs be!

The error is indicated by an acoustic signal of medium priority and a flashing question mark in the corresponding field of the overview screen. The text will appear when the Info key is pressed.
An internal test has produced an error. The measuring accuracy cannot be guaranteed anymore. The curve for this channel is still displayed, but the values are no longer taken into consideration for the trend as they are unreliable.
By removing and re-connecting the pressure sensor, the test can be initiated again; if it should fail again, subject the apparatus to an inspection.

6.4 Internal error – temperature

Internal defect in temperature channel TNo. Remove sensor and use other channel if needs be!

TNo. stands for temperature channel T1 or T2, depending on which temperature channel is concerned.

6.5 Memory full

The data memory is almost completely full. Save the data on the PC, otherwise the oldest data will soon be overwritten.

The error is indicated by an acoustic signal of medium priority and a flashing memory bar. The text rendered above will be displayed in Info. If the operator is not interested in saving the data, nothing has to be done at all, otherwise the data should be saved within the next thirty minutes.

6.6 Residual operating time – battery pack

The anticipated remaining life of the rechargeable battery is only XX minutes. Please recharge immediately!

If the apparatus is not switched off at the end of the remaining of XX min (e.q. 29 min) operating time or if no mains adapter is connected, the apparatus is switched off at the end of the remaining operating time. In this case, a continuous sound will be released for at least 30 seconds (typically one hour). As soon as the mains adapter is connected this warning sound will turn off. If no mains operation is possible, switch on the apparatus and off again after a few seconds. Avoid a longer period of storage in discharged condition.

6.7 Pressure sensor has been removed

The pressure sensor PNo. or pO2 sensor have been removed. Confirm this with OK. If you have not removed the sensor, the cause is most probably a sensor defect. Please check this and swap the sensor, if needs be!

PNo. stands for pressure channel P1 or P2, depending on which pressure channel is affected.

6.8 Temperature sensor has been removed

The temperature sensor TNo. has been removed. Confirm this with OK. If you have not removed the sensor, the cause is most probably a sensor defect. Please check this and swap the sensor, if needs be!

TNo. stands for temperature channel T1 or T2, depending on which temperature channel is concerned.

6.9 Critical error A

Error message: **Critical error**
A critical error (1) has been detected in the device settings; these will be reset to factory settings. Once you have switched the device off and on again, you can continue working. Check the settings (e.g. date, time, alarm limits).

⚠ **Follow the instructions! It is imperative that the settings of the device are checked!**

Cause: RAM error

6.10 Critical error B

Error message: Critical error
A critical error (error number) has arisen. The device will no longer work. Please switch the device off.

Error no.	Cause
2 or even 3	Error in the power supply: 3.3 V incorrect
4 or even 5	Error in the power supply: 6 V incorrect
6	Error in the system ADC. A monitoring of the device operation is not guaranteed.
7	The device-specific settings are not consistent.
9	The process for RAM monitoring is not working properly.
10	RAM error detected.
11	The process for determining the oxygen partial pressure is not working correctly.

Note: It is imperative to note down the error number before switching the device off. The most probable cause is a fault in the power supply of the device. If the error is in direct conjunction with an external event, such as the device has dropped, defibrillation of the patient, et cetera, the device has to be switched on and off again. If the error has disappeared, continue to operation of the device. If the error occurs again, switch the unit off and contact manufacturer.

6.11 Internal error – analogue output

Internal defect in chosen analogue output. Use other analogue output if needed.

Here the user cannot use the selected analogue output. A continuation of the logger operation without the use of the analogue output concerned is possible at any time. The fault can be remedied by the after-sales service department only.

6.12 Defective fuses

The MPR2 has been equipped with a safety fuse. If the fuse is defective, the MPR2 is no longer operational. The fuse is accessible when the cover to the battery-pack compartment is open.

⚠ **When the battery pack compartment is open, there is no protection against penetrating liquids!**

⚠ **The fuse may be replaced by trained staff only. If the apparatus does not operate after the first replacement, remove the fuse again and take the apparatus to the after-sales service department for repair.**

⚠ **The MPR2 must not be operated when the battery-pack compartment is open!**

⚠ **Prior to closing the battery-pack compartment, check the seal. If it is damaged, it has to be replaced by a new one.**

⚠ **When closing the battery-pack compartment, please make sure that the cable of the signal transmitter is not jammed in the sealing area.**

The fuse can be obtained from the manufacturer, if necessary. Type of fuse cf. chapter 11.1 Technical data.

6.13 Reaction to fault messages and indications

When an error occurs, the MPR2 will display a fault code after pressing the Info key, and an info message is available with recommendations for problem solution.

Fault code	Contents of messages which are displayed after pressing the Info key	Additional recommendation
Fault P01	The measured pressure P1 (ICP1) is outside of the adjusted limit values.	
	The measured pressure P2 (ICP2) is outside of the adjusted limit values.	
Fault P02	The measured temperature T1 is outside of the adjusted limit values.	
	The measured temperature T2 is outside of the adjusted limit values.	
Fault P03	The calculated CPP is outside of the adjusted limit values.	
Fault P04	The measured partial oxygen pressure is outside of the adjusted limit values.	
Fault S01	The pressure sensor P1 was removed. Confirm this with OK. If you haven´t removed the sensor, the cause is most probably a sensor defect. Please check this and replace the sensor if necessary!	
	The pressure sensor P2 was removed. Confirm this with OK. If you haven´t removed the sensor, the cause is most probably a sensor defect. Please check this and replace the sensor if necessary!	
Fault S03	The temperature sensor T1 has been removed. Confirm this with OK. If you haven´t removed the sensor, the cause is most probably a sensor defect. Please check this and replace the sensor if necessary!	
	The temperature sensor T2 has been removed. Confirm this with OK. If you haven´t removed the sensor, the cause is most probably a sensor defect. Please check this and replace the sensor if necessary!	
Fault S04	The PO2 sensor was removed. Confirm by clicking on OK. If you have not removed the sensor, the cause is most probably a sensor defect. Please check this and replace the sensor if necessary!	
Fault T01	Internal defect in pressure channel P1 (ICP1). Remove sensor and use another channel if needs be!	Get in touch with the Service Department.
	Internal defect in pressure channel P2 (ICP2). Remove sensor and use another channel if needs be!	
Fault T02	Internal defect in temperature channel T1.	Get in touch with the Service Department.
	Internal defect in temperature channel T2.	
Fault T04	A defect with the data saving has arisen, it is no longer possible to continue recording. Please switch the equipment off and then on again. Erase memory completely.	

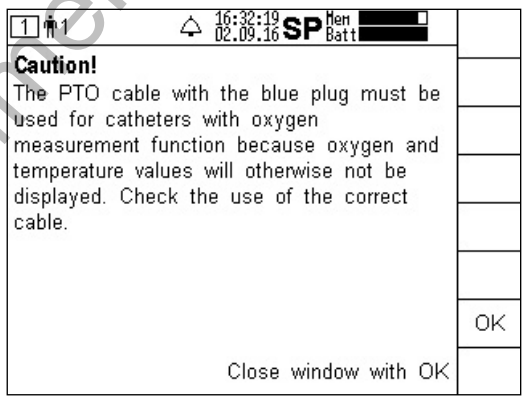
Fault code	Contents of messages which are displayed after pressing the Info key	Additional recommendation
Fault T05	The anticipated remaining life of the rechargeable battery is only xx minutes. Please recharge immediately!	
Fault T06	Pressed alarm key detected longer than 10 sec. Probably missoperation or device failure.	
Fault T07	A keyboard failure has been detected, keyboard input was not possible.	Get in touch with the Service Department.
Fault T08	There is an error in temperature channel T2. Temperature channel T2 can be switched off from the “T2” menu.	The temperature channel T2 is defective. Switch off the temperature channel to continue measuring the oxygen partial pressure. (see section 4.4.3.4.2)
Fault T09	There is an error in pressure channel ICP2. Pressure channel ICP2 can be switched off from the “ICP2” menu.	
Fault T10	An error has occurred in the O2 module or the catheter. A further measurement is not possible. Error code: x	Please note the error code, and do not use the pO2 channel. Get in touch with the Service Department.
Fault T11	The parameters for the O2 catheter connected are incorrect. A measurement is not plausible. Use another catheter.	Use another catheter
Fault T12	Internal error in the O2 channel. The accuracy of the measured value cannot be ensured anymore.	Error in the reference measurement (similar to the internal error in the pressure channel).
Fault T13	The amplitude of the measuring signal for the partial oxygen pressure is too low. The accuracy of the measured value cannot be ensured anymore. Check the catheter.	Check the (P)TO-catheter position or the catheter itself.
Fault T14	The measurement of the partial oxygen pressure is not possible. An internal error has occurred: (time out).	Get in touch with the Service Department.
Fault T15	The measurement of the partial oxygen pressure is not possible. An internal error has occurred: (time frame).	Get in touch with the Service Department.
Fault T16	The measurement of the partial oxygen pressure is not possible. An internal error has occurred: (data error).	Get in touch with the Service Department.
Fault T17	The O2 catheter connected is faulty. Another measurement is not possible. Please use another catheter. Fault code: x	
Fault T18	A fatal error has occurred in the module for the O2 measurement. The channel cannot be used anymore. Please turn to the service staff.	Get in touch with the Service Department.
Fault T19	The partial oxygen pressure cannot be measured. Check catheter for correct connection. Possibly the catheter has broken.	Catheter broken; no optical connection or dirt in the optical coupling.

Fault code	Contents of messages which are displayed after pressing the Info key	Additional recommendation
Fault T20	The temperature channel T2 is defective or the temperature T2 is outside of the measuring range. Therefore the partial oxygen pressure is determined at an assumed temperature of 37 °Celsius. The pO2 measurement is still possible at a temperature range from 32 °Celsius to 42 °Celsius and at an accuracy ranging from -0.5 mmHg to +0.3 mmHg. Please check the cable and catheter or switch off channel T2.	see section 4.4.3.8
Fault T21	The temperature channel T2 is faulty. For this reason the partial oxygen pressure is determined at the assumed temperature of 37 °Celsius. The pO2 measurement is still possible at a temperature range from 32 °Celsius to 42 °Celsius and at an accuracy ranging from -0.5 mmHg to +0.3 mmHg. Please check the cable and catheter.	
Fault T22	The partial oxygen pressure cannot be determined. An error has arisen in the communication with the oxygen module. Remove the multi-parameter sensor and reconnect. If this error occurs repeatedly, please contact the service staff.	Get in touch with the Service Department.
Fault T99	The data memory is almost completely full. Save the data on the PC, otherwise the oldest data will soon be overwritten.	

Messages on the MPR2

- Messages on the MPR2 when connecting the catheter to input P2/T2.

If a catheter is connected to the input P2/T2, the MPR2 expects a catheter with oxygen measuring function. If, however, a catheter is detected without oxygen measuring function, a “Caution! ...” note is displayed and a single reminder signal is sounded for a period of 1 s. The fault message displayed can be closed by pressing OK. The purpose of this message is to call attention of the user to a potential operating error (see 4.4.3 Partial oxygen pressure sensor).

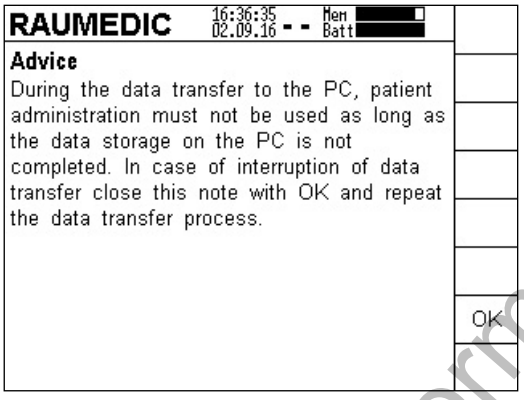


- Messages on the MPR2 when saving data to the PC

Under the following conditions

- The Datalogger has been switched on and is displayed on the start screen.
- The Datalogger is connected with the PC; the correct USB connection is displayed.
- Datalog software has been started up.
- “Save data on PC2” has been selected (download).
- Press “Start”.

the following message is displayed on the MPR2 whilst downloading data:



The user can close the message at any time by pressing ok, and can continue working, and may also start a new measurement. In case of an interruption of the data transmission, the user cannot download the data currently saved on the MPR2 because the PC does not have the information.
In this case, the process has to be repeated.

7 Cleaning and maintenance

7.1 Cleaning the MPR2

⚠ **The MPR2 cannot be sterilised.**

⚠ **Please switch the apparatus off.** Please remove all cables and lines from the apparatus before starting with cleaning and disinfecting. When removing the line, always get hold of the plug and never pull the line. The MPR2 can be cleaned with a slightly moist cloth. Please make sure that no liquid can penetrate into the housing through the openings or the connecting sockets because this would damage the apparatus or would impair its operational safety.

⚠ **When handling liquids, never hold the connecting sockets of the MPR2 up.**

⚠ Liquids on the housing have to be wiped away with a dry cloth immediately.
Use conventional hospital disinfectants, such as Lysoformin or Helipur H plus N to disinfect the MPR2. Detergents on a phenol basis are not permitted.
No liquids or fluids shall enter the apparatus. If this should happen nonetheless, switch the apparatus off and disconnect from the power mains. Remove all patient connections. Dry the apparatus on the outside. Make sure that no liquid has penetrated the housing or the plug-in connections on the bottom of the housing.
If it is probable that liquid has penetrated the apparatus or you are in doubt about the safety of the apparatus, have the apparatus checked by a service workshop. Subsequently a safety-related check is necessary.

7.2 Cleaning, disinfecting and sterilising the cables and sensors

Cables are supplied unsterile and can be re-used. Please observe the recommendations below to avoid damage or functional impairment.

7.2.1 Cleaning

- Use a moist cloth to wipe off: If and when necessary, add conventional non-alcohol soap or detergent to the warm water.
- If necessary, wipe the cable with a dry cloth.
- Clean carefully in order to prevent the rupture of internal leads by excessive bending, extension or kneading.
- Never lay or immerse cables in liquids or bring them into contact with detergents in order to prevent patient or user hazards as well as functional impairments.
- Never treat cables with oil-containing (domestic / machine oil, for example) or aggressive liquids or detergents (such as acetone).

7.2.2 Disinfection

- Clean the cables prior to disinfection, as described above.
- Use conventional hospital disinfectants Lysoformin or Helipur H plus N to wipe the units. Please observe the recommendations of the manufacturer with respect to dilution and reaction time.
- Dry the cables under low-germ conditions.
- Never lay or immerse cables in liquids or bring them into contact with detergents in order to prevent patient or user hazards as well as functional impairments.
- Do not bring contact parts into touch with disinfectants (use spray disinfectants with care as well).

7.2.3 Sterilisation

⚠ **Cables cannot be treated by autoclave and cannot be sterilised with hot air.**
Prior to using a cleaned, disinfected and sterilised cable, check it for its technically functional safety.
In order to prevent accidental re-use, destroy disposable adhesive electrodes immediately after use.

7.3 Cleaning the mains adapter

⚠ The mains adapter is not protected against moisture, and thus it must not get into contact with liquids. If and when required at all, use a dry soft cloth to clean the mains adapter.

8 Safety and measurement related checks

8.1 General aspects

⚠ **In addition, the national regulations and requirements derived from them must always be observed.**

⚠ **The following checks must be carried out at least once a year for the safe and continuousoperation of the MPR2 logO:**
- **Electrical safety test: leakage current of the device including the main power adapter and of the main power adapter separately**
- **Check of the accuracy of the pressure and temperature measurement**
- **Check of the accuracy of the analog outputs**

⚠ **The Medical Devices Operator Ordinance (German abbreviation: MPBetreibV) named below is a German regulation and is therefore not binding for other countries.**

⚠ **The Medical Devices Operator Ordinance (MPBetreibV) is the source for the operator's obligation to have a measurement check performed for medical devices that determine body temperatures (medical electronic thermometers) every two years. The MPR2 logO is a device with an electric temperature measurement function.**

⚠ **As the manufacturer, we provide you with the option of having the necessary checks carried out by RAUMEDIC.**

⚠ **These checks may only be carried out by appropriately qualified specialist personnel (suitable training, knowledge and practical experience gained "on-the-job").**

8.2 Safety-related check

⚠ **The operator must have safety checks performed for medical devices in accordance with generally recognised technical regulations. He must allow such time limits for the safety checks that corresponding defects that are to be expected on the basis of experience can be detected in good time. The safety checks include measurement functions. The manufacturer recommends a period of 12 months.**

⚠ **After each service action, a safety check must likewise be carried out.**

8.3 Measurement-related check-up

⚠ **The measurement check is to be carried out according to the legal requirements.**

⚠ **The measurement check must also be carried out if there are signs of non-adherence to the specified thresholds (see 11.1 Technical data) and if the metrological properties may have been affected by interventions or in some other way.**

The "Guideline On Metrological Check-ups of Medical Products with Measuring Functions", part 1, published by the German Federal Physical Technical Institute is recommended for orientation on scope and procedure (status: December 2016).

9 Accessories

⚠ Use accessories only, which have been approved by RAUMEDIC. Use of non-approved parts may lead to damage on the system or faulty measurements. Please refer to the following 2 tables for the order designation of the approved accessories:

Article No.	Accessory as defined in directive 93/42/EEC
092946-001	NEUROVENT-P
091580-001	NEUROVENT-PX
092956-001	NEUROVENT
091678-001	NEURVENT IFD-S
095317-001	NEUROVENT IFD-R
092976-001	NEURODUR
094268-001	NEUROVENT-P-TEMP
091431-001	NEUROVENT-PX-TEMP
094278-001	NEUROVENT-TEMP
094288-001	NEUROVENT-TEMP IFD-S
095327-001	NEUROVENT-TEMP IFD-R
094298-001	NEURODUR-TEMP
094678-001	NEUROVENT 6F
091576-001	NEUROVENT with sleeve housing
096704-001	NEUROVENT VP 16
095008-001	NEUROVENT-PTO
095908-001	NEUROVENT-TO
095108-001	NEUROVENT-PTO 2L
095308-001	NEUROVENT-PTO 2L BOLT
283957-002	Stand holder DATALOGGER (e.g. for infusion stand)
283959-002	Table Stand DATALOGGER
094858-001	Cable DATALOGGER GE/MARQUETTE, length 2.00 m
094868-002	Cable DATALOGGER Philips/HP, length 2.00 m
094878-002	Cable DATALOGGER Siemens/Draeger Infinity, length 2.00 m
094967-001	Cable DATALOGGER SpaceLabs, length 2.00 m
096006-001	Cable DATALOGGER Nihon Kohden, length 2.00 m
095017-001	Cable DATALOGGER Nihon Kohden 41xx, length 2.00 m
094908-001	Transducer Cable DATALOGGER Smiths Medical, length 2.00 m
095974-001	Transducer Cable DATALOGGER Medex MX960, length 2.00 m
096036-001	Transducer Cable DATALOGGER Edwards TRUWAVE, length 2.00 m
096046-001	Transducer Cable DATALOGGER Becton Dickinson, length 2.00 m
096664-001	Transducer Cable DATALOGGER Combitrans, length 2.00 m
094328-001	ICP-TEMP-Cable, length 2.00 m
094323-001	ICP-TEMP-Adapter, length 0.70 m
095624-001	Cable PTO, length 2.00 m
095657-001	Cable LWL, length 2.00 m
284007-002	Wide range adapter MPR1/2
284027-001	Wide range adapter MPR1/2

Table 8: Accessory as defined in directive 93/42/EEC

Article No.	**Accessory not as defined in directive 93/42/EEC**
283949-001	USB-Cable RAUMEDIC® DATALOGGER
296900-001	RAUMED DataView

Table 9: Accessory not as defined in directive 93/42/EEC

10 Electromagnetic compatibility

The MPR2 devices fulfil the EMC requirements in accordance with IEC 60601-1-2:2007, if the use of the mains adapter REF 284007-002 is specified on their type plate. If the mains adapter REF 284027-001 is used, the requirements of IEC 60601-1-2: 2007 continue to be fulfilled.

The MPR2 devices fulfil the EMC requirements according to IEC 60601-1-2:2014, if the use of the mains adapter REF 284027-001 is specified on their type plate and this is also specified is used. If the mains adapter REF 84007-002 is used differently, only the requirements of IEC 60601-1-2:2007 are fulfilled.

10.1 Manufacturer's declaration on the EMC requirements according to IEC 60601-1-2:2014

The device meets the requirements of IEC 60601-1-2:2014. The essential performance will be fulfilled.

10.1.1 Accuracy under the influence of electromagnetic interference phenomena

Essential performance under the influence of electromagnetic interference phenomena is defined as follows:

Port	Measuring point	Display parameter	Allowable variation	Additional display parameter
P1, P2*)	ICP	ICP	±2 mmHg	ICPA
		ART SAP, DAP, MAP	-40 ... 100 mmHg: ± 4 mmHg 100 … 360 mmHg: ± 4 %	---
pO2	pO2	pO2	± 5 mmHg	---
T1, T2*)	T	Temp	15 ... 25 °C: ±0.4 K 25 ... 37 °C: ±0.2 K 37 ... 39 °C: ±0.1 K 39 ... 45 °C: ±0.2 K	---
*) The catheter is placed in the water and dimmed during the tests.				

10.1.2 General information

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ Use of accessories other than those specified in chapter 9 Accessories could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ 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 MPR2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ Avoid therapeutical microwave devices or similar units in the vicinity of the device.

⚠ Interference frequencies from 810 to 930 MHz, caused by wireless communications equipment, can lead to failure of the pO2 measurement, indicated by the indication "---" or "Sensor?".

Simultaneous operation with other devices connected to the patient may cause mutual influences which may have an effect on the measuring results.

If the amplitude of the physiological signal from the patient lies below the minimum amplitude and/or the values given in section 11.1 Technical data, device use could lead to inaccurate results.

10.1.3 Electromagnetic emissions

The MPR2 is intended for use in an electromagnetic environment as specified below. The operator or the user of the MPR2 should ensure that it is operated in such an environment.

Measurement of Immunity	Immunity test level
Conducted emissionen	CISPR 11, group 1, class A
Radiated emissionen	CISPR 11, group 1, class A
Harmonic current emissions	IEC 61000-3-2, class A
Voltage changes, voltage fluctuations and flicker emissions	IEC 61000-3-3

⚠ The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

10.1.4 Electromagnetic immunity

Measurement of Immunity	Immunity test level
Electrostatic discharge immunity according IEC 61000-4-2	Contact: ±8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV
Radiated RF electromagnetic field immunity according IEC 61000-4-3	80-2700 MHz; 1 kHz AM 80%; 3 V/m at 2 Hz
Immunity to proximity fields from RF wireless communications equipment according IEC 61000-4-3	385 MHz; Pulse modulation: 18 Hz; 27 V/m 450 MHz, FM + 5Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse modulation: 217 Hz; 28 V/m 2450 MHz; Pulse modulation: 217 Hz; 28 V/m 5240, 5500, 5785 MHz; Pulse modulation: 217 Hz; 9 V/m
Electrical fast transient/burst immunity according – a. c. mains according IEC 61000-4-4	±2 kV; 100 kHz repetition frequency
Electrical fast transient/burst immunity according – I/O SIP/SOP ports according IEC 61000-4-4	±2 kV; 100 kHz repetition frequency
Surge immunity according IEC 61000-4-5	Line-to-line: ±0.5, ±1 kV
Immunity to conducted disturbances induced by RF fields – a. c. mains according IEC 61000-4-6	0,15 - 80 MHz; 1kHz AM 80%; 3 Vrms , 6 Vrms in ISM bands between 0,15 MHz and 80 MHz at 2 Hz
Immunity to conducted disturbances induced by RF fields – SIP/SOP ports according IEC 61000-4-6	0,15 - 80 MHz; 1kHz AM 80%; 3 Vrms , 6 Vrms in ISM bands between 0,15 MHz and 80 MHz at 2 Hz
Power frequency magnetic field immunity nach IEC 61000-4-8	30 A/m, 50 Hz und 60 Hz
Voltage dips, short interruptions and voltage variations immunity nach IEC 61000-4-11	0 % U_T for 0,5 cycle at 0, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 Cycle at 0° 70 % U_T for 25/30 cycles bei 0° 0 % U_T for 250/300 cycles bei 0°

10.2 Manufacturer's declaration on the EMC requirements according to IEC 60601-1-2:2007

The MPR2 devices fulfil the requirements of IEC 60601-1-2:2007.

10.2.1 General information

Special precautions in respect of electromagnetic compatibility (EMC) must be taken for medical electrical devices and the devices must be installed and operated in conformance with the EMC details contained in this instruction manual.

Portable and mobile high-frequency (HF) communication devices can impair medical electrical devices.

The transducers and cabling listed in section 9 Accessories fulfil the requirements of IEC 60601-1-2:2007 in respect of use of the MPR2.

Use of accessory parts, cables and sensors other than those listed in 9 Accessories can lead to increased emissions and/or reduced immunity of the device against such emissions.

Avoid use of the device in the direct vicinity of other devices, such as directly under, above or adjoining other devices. If such use is unavoidable, you must check, prior to the monitoring of patients, whether trouble-free operation is possible with the necessary configuration.

Interference effects may arise from other devices, even if the other devices conform to the CISPR emission requirements.

If the amplitude of the physiological signal from the patient lies below the minimum amplitude and/or the values given in section 11.1 Technical data, device use could lead to inaccurate results.

The MPR2 is intended for use in an electromagnetic environment as specified below. The operator or the user of the MPR2 should ensure that it is operated in such an environment.

10.2.2 Electromagnetic emissions

The MPR2 is intended for use in an electromagnetic environment as specified below. The customer or user of the MPR2 should ensure that it is used in such an environment.

Transient emission measurements	**Conformity**	**Electromagnetic environment - guidelines**
RF emissions as per CISPR 11	Group 1	The MPR2 uses RF energy solely for its internal operation. Therefore, its RF emissions are very low and it is unlikely that any adjoining electronic equipment will suffer interference.
RF emissions as per CISPR 11	Class B	The MPR2 is suitable for use in all facilities including those in living areas, which are directly connected to a public mains network, which also supplies buildings that are used for living purposes.
Emissions of harmonics as per IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flicker as per IEC 61000-3-3	Matches all	

10.2.3 Electromagnetic immunity

Guidelines and manufacturer declaration - electromagnetic immunity			
The MPR2 is intended for use in an electromagnetic environment as specified below. The customer or user of the MPR2 should ensure that it is used in such an environment.			
Stability check	**IEC 60601-test level**	**Conformity level**	**Electromagnetic environment - guidelines**
Discharge of static electricity (ESD) as per IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be of wood or concrete or be provided with ceramic tiles. If the floor has a synthetic covering, the air humidity should be at least 30 %.
Quick transient electrical interference/bursts as per IEC 61000-4-4	± 2 kV for mains leads ± 1 kV for input and output cables	± 2 kV for mains leads ± 1 kV for input and output cables	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Interference voltages/surges as per IEC 61000-4-5	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-earth	± 1 kV voltage outer conductor-outer conductor ± 2 kV voltage outer conductor-earth	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Voltage drops, short temporary interruptions and variations in the supply voltage as per IEC 61000-4-11	< 5 % U_T (> 95 % drop in U_T) for ½ period < 40 % U_T (> 60 % drop in U_T) for 5 periods < 70 % U_T (> 30 % drop in U_T) for 25 periods < 5 % U_T (> 95 % drop in U_T) for 5 s	< 5 % U_T (> 95 % drop in U_T) for ½ period < 40 % U_T (> 60 % drop in U_T) for 5 periods < 70 % U_T (> 30 % drop in U_T) for 25 periods < 5 % U_T (> 95 % drop in U_T) for 5 s	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment. If the user of the MPR2 requires advanced functions, even when interruptions to the power supply may occur, it is recommended that the MPR2 is fed from an uninterruptible power supply or battery. Reaction: Under this test condition, the MPR2 switches over to this in built battery.
Magnetic field at the supply frequency (50 / 60 HZ) as per IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency, should correspond to typical values, as would be expected in a typical commercial or hospital environment.
REMARK: U_T is the mains AC voltage before the application of the test level.			

In the following table P means the transmission power of the transmitter specified by the manufacturer in watts (W) and d is the recommended distance in metres (m).

Guidelines and manufacturer declaration - electromagnetic immunity

The MPR2 is intended for use in an electromagnetic environment as specified below. The customer or user of the MPR2 should ensure that it is used in such an environment.

			Portable and mobile RF communication equipment should not be used closer to any part of the device (including cabling and sensors) than the recommended safe distance, which is calculated using the relevant equation for the transmission frequency.
Conducted RF disturbance variable as per IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff} 150 kHz to 80 MHz	d = 1.17 * $P^{1/2}$
Radiated RF disturbance variable as per IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	d = 1.17 * $P^{1/2}$ for 80 MHz to 800 MHz d = 2.33 * $P^{1/2}$ for 800 MHz to 2.5 GHz d: distance in m P : transmitted power in W The field strength of stationary radio transmitters should be less than the conformity level at all frequencies, as demonstrated by an on-site[a] investigation.[b] Interference is possible in the area surrounding devices carrying the following symbol. 

At 80 MHz and 800 MHz the higher frequency range applies.

These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and people.

[a] The field strength of stationary emitters, such as mobile phone network base stations and mobile agricultural broadcasting equipment, amateur radio stations, AM and FM radio and television broadcasters cannot be accurately defined in advance. To determine the electromagnetic environment in respect of any emitters, a study of the site should be consulted. If the measured field strength at the site in which the MPR2 is used, exceeds the above conformity threshold, the MPR2 should be monitored, to demonstrate that it is functioning correctly. If unusual characteristics are observed, additional measures may be required, e.g. a changed alignment or another site of use of the MPR2.

[b] The field strength should be less than 3 V/m in the frequency range 150 kHz to 80 MHz.

Recommended safe distances between portable and mobile RF telecommunication equipment and the MPR2			
The MPR2 is intended for use in an electromagnetic environment in which RF interference is controlled. The customer or user of the MPR2 can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication equipment (emitters) and the MPR2 - dependent on the output power of the communication device as specified below.			
Emitter rated power W	Safe distance dependent on emitter frequency m		
	150 kHz to 80 MHz $d = 1.17 * P^{1/2}$	80 MHz to 800 MHz $d = 1.17 * P^{1/2}$	800 MHz to 2.5 GHz $d = 2.33 * P^{1/2}$
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.70	11.70	23.30
For emitters, whose maximum rated power is not specified in the above table, the recommended safe distance d (m), can be calculated using the equation, which is relevant for the corresponding column, where P is the maximum rated power of the emitter in watts (W) as specified by the manufacturer of the emitter. At 80 MHz and 800 MHz the higher frequency range applies. These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects and people.			

11 Technical parameters (Specification)

11.1 Technical data

Temperature

Number of channels:	2
Resolution:	0.01 °Celsius
Measuring range:	15 ... 45 °Celsius
Accuracy :	25 ... 45 °Celsius: ± 0.1 K (plus ± 0.1 K of the sensor) 15 ... 25 °Celsius: ± 0.2 K (plus ± 0.2 K of the sensor)
Scanning rate:	1 Hz
Defibrillation protection:	Yes

Invasive blood pressure

Number of channels:	2
Designation of the measuring location:	ART, CVP, ICP1, ICP2, GP1, GP2, GP3
Measuring ranges:	- 20 ... + 400 mmHg *1
Offset range:	- 150 ... + 150 mmHg *1
Resolution of the pressure values:	0.1 mmHg
Accuracy:	± 1.5 mmHg (cf. operating temperature, plus pressure sensor error)
Scanning rate:	100 Hz
Defibrillation protection:	Yes

Pressure sensor

Supply voltage:	4.46 V ± 0.1 V
Direct impedance of the sensor:	> 1 kΩ
Sensitivity of the sensor:	5 µV / V / mmHg

*1: The IBP input units (three input units and all available measuring locations) have been provided with a cyclic self-test. In regular intervals, a test pulse of defined value (approx. +70 mmHg) is transferred to the measuring signal of the pressure sensor, and the amplitude is then evaluated. Under the highly unlikely assumption that at the measuring location of ART (with relatively high physiological pressure values) a pressure sensor with the permissible maximum offset error of +150 mmHg and a measured pressure value MAP of > 320 mmHg and in addition a test pulse of approx. +70 mmHg meet upon each other, there is a very low probability that this would cause a technical alarm **?**

Partial oxygen pressure

Number of channels:	1
Designation of the location of the measurement:	pO2
Measuring ranges:	0 ... + 30 mmHg
Resolution of the pressure values:	0.1 mmHg
Measuring interval:	1 s, 5 s, 10 s, 20 s, 60 s, off
Defibrillation protection:	Yes
Oxygen sensor:	fibre-optical
Light source:	green LED
Sensitivity of the sensor:	characteristic saved in the apparatus; catheter parameters in the EEPROM in the catheter connector
Accuracy:	± 3 % of the measured value or ± 2.5 mmHg – the higher value is applicable for the partial oxygen pressure < 120 mmHg < 10 % of the measured value for the partial oxygen pressure 120 mmHg to 200 mmHg (cf. 4.4.3.8 Technical alarms during partial oxygen pressure measurement)

Analogue outputs ⚠

Number of channels:	2
Transferable input values:	invasive pressure, partial oxygen pressure
Characteristic features:	5 µV / V / mmHg
Measuring range:	- 20 ... + 360 mmHg
Resolution:	< 0.5 mmHg, typical 0.23 mmHg
Accuracy after zeroing*1:	± 1.5 mmHg at 22 °Celsius ambient temperature
Accuracy after zeroing:	± 2.0 mmHg at 10 °Celsius – 40 °Celsius ambient temperature
Recommended supply voltage:	4 – 6 V DC
Maximum supply voltage:	10 Vss
Output frequency:	100 Hz
Additional thermal drift:	max. 0.5 mmHg / K only with a software version lower than 1.06.0032 or 1.06.0032 ST (cf. 4.6.2 Device diagnostics)

*1: Zeroing of the downstream monitor

Interface for the extension of the apparatus ⚠

Type:	RS232 (V24) + power supply
Application:	unit service and optional extension of the apparatus

PC interface ⚠

Type:	USB
Application:	connection of laptop

General data

Type designation:	MPR2 logO
Mode of operation:	continuous operation
Volume of alarm:	minimum 45 dB(A) typical 60 dB(A), 1 m, in stand holder
Display:	black/white LCD 320 x 240 pixel (1/4 VGA), 74 x 97 mm
Trend display:	optional 4 min., 8 min., 20 min., 40 min., 80 min. or 4 h
Alarm limits:	to be selected by menu
Language:	German, other language versions optional
Dimensions:	approx. 200 x 69 x 150 mm (W x D x H)
Mass:	approx. 1.02 kg with battery
Fuse in battery compartment *2:	type: TR5 / No. 372 / 250V / 1.25 AT / Wickmann
Power supply:	internal battery
Type of battery:	NiMH, Panasonic HHR210AH-1Z
Operating period:	> 4 h (charged, new battery pack, all channels occupied, lighting off, PHB = 1 s, at 22 °Celsius)
Charger / mains unit:	Wide range adapter, Art. No. 284007-002 or Art. No. 284027-001 Input: 100-240 V / 50-60 Hz / 400-200 mA, Output: 12 V / 1.5 A, protection class II, IP 40
Class of protection:	- class of protection II with internal and external power supply - type CF IEC 60601-1 - Directive 93/42/EEC Class II b
IP protection class:	IP 21 in operation (sockets to the bottom, maximum inclination 20°)

*2: The fuse may be replaced by trained staff only. If the apparatus does not operate after the first replacement, remove the fuse again and take the apparatus to the after-sales service department for repair. The fuse can be obtained from the manufacturer, if necessary.

11.2 Environmental conditions

11.2.1 Operating and storage temperature

Operating temperature: + 10 °C ...+ 40 °Celsius
Storage temperature - 10 °C ...+ 40 °Celsius (for 1 month maximum 55 °C permissible)

If the apparatus has been taken from colder into warmer surroundings, it may be used only when the temperature of the apparatus and of the accessories has adapted to the room temperature; there is no danger of condensation water forming or any condensation water already developed has completely dried. A longer period of storage at over 35 °Celsius reduces the service life of the battery. As a matter of principle the apparatus should be stored with a fully charged battery. At storage temperatures of over 35 °Celsius, the battery pack has to be charged every three months; once a year at lower temperatures.

11.2.2 Humidity

The relative humidity during operation has to be between 30 and 75 %, and between 30 and 85 % (non-condensing) during storage and transport.

11.2.3 Atmospheric pressure

The atmospheric pressure during storage and transport has to be between 620 and 1050 hPa.
During operation, the permissible air pressure is 700 to 1050 hPa for devices for which the use of the mains adapter REF 284007-002 is specified. For instruments for which the use of the 284027-002 mains adapter is specified, the permissible range is 620 to 1050 hPa.

12 Environment and disposal

All components of the MPR2 inclusive of its packaging have been selected, designed and marked in such a way that the highest possible degree of environmental friendliness is achieved. The box is 100 per cent recyclable. All parts of the MPR2 have been marked and can be separated, re-used or disposed of by specialised enterprises. The mobile power supply is a NiMH type battery pack which is free from cadmium. However, it should not be disposed of in the residual waste. Defect products and/or products no longer used can be returned to the manufacturer for disposal.

13 Liability and warranty

The customer or user shall be obligated to check the suitability for the intended purpose of application, in particular by suitable functional tests. RAUMEDIC shall assume no explicit or implied warranty, guarantee or liability for the suitability for any purpose which exceeds the description of the article in these instructions of use. This shall apply also for the processing of this article and for its use for the production of other articles. The warranty terms of RAUMEDIC shall be applicable exclusively.

14 Index

15 Enclosures

Extract from the EU Declaration of Conformity

The manufacturer hereinafter mentioned

RAUMEDIC AG
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
Germany

declares under its sole responsibility that the following designated medical products

RAUMEDIC conformity group no.:	0038
Name of the conformity group:	RAUMEDIC MPR2 logO DATALOGGER
Class:	IIb

are developed, produced, tested and sold in accordance with the requirements of EC directive 93/42/EEC, Appendix I.

The EC conformity declaration process takes place according to appendix II, point 3 of EC directive 93/42/EEC.

The first declaration of EC conformance occurred on 28.10.05.

Adherence to the processes specified in directive 93/42/EEC is covered through the monitoring by the "notified body":

TÜV SÜD Product Service
Ridlerstrasse 65
80339 München
Germany

Identification No.: 0123

RAUMEDIC AG